

1 UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY

2  
3 SENJU PHARMACEUTICAL CO., LTD.,  
4 BAUSCH & LOMB, INC., BAUSCH AND  
LOMB PHARMA HOLDINGS CORP.,  
5  
6 Plaintiff, CIVIL ACTION NUMBER:  
14-667 (JBS/KMW)  
7 -vs-  
8 LUPIN LTD., LUPIN  
9 PHARMACEUTICALS, INC.,  
10 Defendants.

11 SENJU PHARMACEUTICAL CO., LTD.,  
12 BAUSCH & LOMB, INC., BAUSCH AND  
LOMB PHARMA HOLDINGS CORP.,  
13  
14 Plaintiff, CIVIL ACTION NUMBER:  
14-4149 (JBS/KMW)  
15 -vs-  
16 LUPIN LTD., LUPIN  
17 PHARMACEUTICALS, INC.,  
18 Defendants.

19 Mitchell H. Cohen United States Courthouse  
20 One John F. Gerry Plaza  
21 Camden, New Jersey 08101  
22 Monday, April 4, 2016

23 **B E F O R E:** THE HONORABLE JEROME B. SIMANDLE  
24 CHIEF JUDGE  
25 UNITED STATES DISTRICT JUDGE

26 Certified as true and correct as required by Title 28, U.S.C.,  
27 Section 1753.  
28 /s/ Lisa Marcus, CCR, CRR, /s/ Theodore Formarelli, CCR, CRR,  
29 /s/ Karen Friedlander, CCR, CRR, /s/ Robert T. Tate, CCR, CRR,  
30 /s/ Carol Farrell, CCR, CRR

United States District Court  
Camden, New Jersey

1  
2 SENJU PHARMACEUTICAL CO., LTD.,  
3 BAUSCH & LOMB, INC., BAUSCH AND  
LOMB PHARMA HOLDINGS CORP.,  
4  
5 Plaintiff, CIVIL ACTION NUMBER:  
15-335 (JBS/KMW)  
6 -vs-  
7 LUPIN LTD., LUPIN  
8 PHARMACEUTICALS, INC.,  
9 Defendants.

10 SENJU PHARMACEUTICAL CO., LTD.,  
11 BAUSCH & LOMB, INC., BAUSCH AND  
LOMB PHARMA HOLDINGS CORP.,  
12  
13 Plaintiff, CIVIL ACTION NUMBER:  
14-6893 (JBS/KMW)  
14 -vs-  
15 INNOPHARMA LICENSING, INC., et  
al.,  
16 Defendants.

17 SENJU PHARMACEUTICAL CO., LTD.,  
18 BAUSCH & LOMB, INC., BAUSCH AND  
LOMB PHARMA HOLDINGS CORP.,  
19  
20 Plaintiff, CIVIL ACTION NUMBER:  
15-3240 (JBS/KMW)  
21 -vs-  
22 INNOPHARMA LICENSING, INC.,  
23 Defendants.

United States District Court  
Camden, New Jersey

1  
2 SENJU PHARMACEUTICAL CO., LTD.,  
3 BAUSCH & LOMB, INC., BAUSCH AND  
LOMB PHARMA HOLDINGS CORP.,  
4  
5 Plaintiff, CIVIL ACTION NUMBER:  
14-5144 (JBS/KMW)  
6 -vs-  
7 LUPIN LTD., LUPIN  
8 PHARMACEUTICALS, INC.,  
9 Defendants.

10 SENJU PHARMACEUTICAL CO., LTD.,  
11 BAUSCH & LOMB, INC., BAUSCH AND  
LOMB PHARMA HOLDINGS CORP.,  
12  
13 Plaintiff, CIVIL ACTION NUMBER:  
15-335 (JBS/KMW)  
14 -vs-  
15 LUPIN LTD., LUPIN  
16 PHARMACEUTICALS, INC.,  
17 Defendants.

18 SENJU PHARMACEUTICAL CO., LTD.,  
19 BAUSCH & LOMB, INC., BAUSCH AND  
LOMB PHARMA HOLDINGS CORP.,  
20  
21 Plaintiff, CIVIL ACTION NUMBER:  
14-5144 (JBS/KMW)  
22 -vs-  
23 LUPIN LTD., LUPIN  
24 PHARMACEUTICALS, INC.,  
25 Defendants.

United States District Court  
Camden, New Jersey

1 **APPEARANCES:**  
2 PEPPER HAMILTON LLP  
BY: MELISSA A. CHUDEREWICZ, ESQUIRE  
3 301 Carnegie Center, Suite 400  
Princeton, New Jersey 08543  
4 (609) 452-0808  
chuderem@pepperlaw.com  
5 ATTORNEYS FOR PLAINTIFF  
6 FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, LLP  
BY: BRYAN C. DINER, ESQUIRE  
7 JUSTIN J. HASFORD, ESQUIRE  
CHIAKI FUJIWARA, ESQUIRE  
8 901 New York Avenue, N.W.  
Washington, D.C. 20001-4413  
9 (202) 408-4000  
bryan.diner@finnegan.com, justin.hasford@finnegan.com,  
chiaki.fujiwara@finnegan.com  
10 ATTORNEYS FOR PLAINTIFF  
11 FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, LLP  
BY: JESSICA M. LEBIS, ESQUIRE  
12 303 Peachtree Street, NE  
Atlanta, GA 30308-3263  
13 (404) 653-6400  
jessica.lebis@finnegan.com  
14 ATTORNEYS FOR PLAINTIFF  
15 PATUNAS TARANTINO LLC  
BY: MICHAEL E. PATUNAS, ESQUIRE  
16 24 Commerce Street, Suite 606  
Newark, New Jersey 07102  
17 (973) 396-8740  
mpatunas@patunaslaw.com  
18 ATTORNEYS FOR DEFENDANT LUPIN, INC.

19 GOODWIN PROCTER LLC  
BY: ELIZABETH J. HOLLAND, ESQUIRE  
20 NATASHA E. DAUGHTRY, ESQUIRE  
SARAH FINK, ESQUIRE  
21 SHAUN deLACY, ESQUIRE  
DANIEL P. MARGOLIS, ESQUIRE  
22 The New York Times Building  
620 Eighth Avenue  
New York, NY 10018  
23 (212) 813-8800  
eholland@goodwinprocter.com, ndaughtry@goodwinprocter.com,  
sfink@goodwinprocter.com, sdelay@goodwinprocter.com,  
24 dmargolis@goodwinprocter.com  
25

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Camden, New Jersey

1 ATTORNEYS FOR DEFENDANT LUPIN, LTD.  
2 GOODWIN PROCTER, LLP  
BY: EMILY L. RAPALINO, ESQUIRE  
3 53 State Street  
Boston, MA 02109  
4 (617) 570-1000  
erapalino@goodwinprocter.com  
5 ATTORNEYS FOR DEFENDANT LUPIN, LTD.  
6 ALSTON & BIRD, LLP  
BY: DEEPRO R. MUKERJEE, ESQUIRE  
7 LANCE A. SODERSTROM, ESQUIRE  
STEPHANIE ROBERTS, ESQUIRE  
8 90 Park Avenue  
New York, New York 10016  
9 (212) 210-9400  
deepro.mukerjee@alston.com, lance.soderstrom@alston.com,  
10 stephanie.roberts@alston.com  
ATTORNEYS FOR DEFENDANT INNOPHARMA LICENSING  
11  
12 ALSTON & BIRD, LLP  
BY: JITENDRA MALIK, ESQUIRE  
4721 Emperor Boulevard  
13 Suite 400  
Durham, NC 27703-8580  
14 (919) 862-2200  
jitendra.malik@alston.com  
15 ATTORNEYS FOR DEFENDANT INNOPHARMA LICENSING  
16 ALSTON & BIRD, LLP  
BY: HIDETADA JAMES ABE, ESQUIRE  
17 333 South Hope Street  
16th Floor  
18 Los Angeles, CA 90071-3004  
(213) 576-1000  
19 james.abe@alston.com  
ATTORNEYS FOR DEFENDANT LUPIN LIMITED  
20  
21 ALSTON & BIRD, LLP  
BY: JOSEPH M. JANUSZ, ESQUIRE  
Bank of America Plaza  
22 Suite 4000  
Charlotte, NC 28280-4000  
23 (704) 444-1000  
joe.janusz@alston.com  
24 ATTORNEYS FOR DEFENDANT INNOPHARMA LICENSING  
25

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Camden, New Jersey*

1 SAIBER, LLC  
BY: ARNOLD B. CALMANN, ESQUIRE  
2 One Gateway Center  
10th Floor, Suite 1000  
3 Newark, New Jersey 07102  
(973) 622-3333  
4 abc@saiber.com  
ATTORNEYS FOR DEFENDANT INNOPHARMA LICENSING  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
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1 DEPUTY CLERK: All rise.  
2 THE COURT: Good morning.  
3 Be seated.  
4 Just a moment.  
00:00 5 Welcome to everybody. We're here to commence the  
6 nonjury trial in Senju Pharmaceutical vs. Lupin and Senju  
7 Pharmaceutical vs. Innopharma, the Civil Action Numbers are  
8 14-0667, 14-4149, 14-5144, 15-335, and also 14-6893, and  
9 15-3240.  
00:01 10 Let me ask trial counsel to please enter your  
11 appearances. Here I'm just asking for the appearances of  
12 those who are likely to speak during the course of the trial.  
13 So let's begin with the plaintiffs.  
14 MR. LIPSEY: Charles Lipsey, Finnegan, Henderson, for  
00:01 15 the plaintiffs.  
16 MR. DINER: Brian Diner, your Honor, Finnegan,  
17 Henderson, for the plaintiffs.  
18 MR. HASFORD: Justin Hasford, your Honor, Finnegan,  
19 Henderson, also for the plaintiffs.  
00:01 20 MS. LEBEIS: Jessica Lebeis of Finnegan, Henderson,  
21 also for the plaintiffs.  
22 MR. SUKDUANG: Sanya Sukduang, your Honor, from  
23 Finnegan, Henderson, on behalf of plaintiffs.  
24 MS. FUJIWARA: Chiaki Fujiwara for plaintiffs Senju,  
00:02 25 et al., from Finnegan, Henderson.

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1 THE COURT: I'm sorry, can you spell your name for  
 2 me? Did you sign in?  
 3 MS. FUJIWARA: Chiaki Fujiwara.  
 4 THE COURT: Oh, yes. Thank you.  
 00:02 5 MS. CHUDEREWICZ: Melissa Chuderevicz from Pepper  
 6 Hamilton on behalf of plaintiffs.  
 7 THE COURT: Next on behalf of Lupin.  
 8 MS. HOLLAND: Good morning, your Honor.  
 9 Elizabeth Holland of Goodwin Proctor.  
 00:02 10 MR. PATUNAS: Good morning, your Honor.  
 11 Michael Patunas, Patunas Tarantino.  
 12 MS. RAPALINO: Good morning, your Honor.  
 13 Emily Rapalino of Goodwin Proctor.  
 14 MR. MARGOLIS: Good morning, your Honor.  
 00:02 15 Dan Margolis with Goodwin Proctor.  
 16 MS. DAUGHTRY: Natasha Daughtry of Goodwin Proctor.  
 17 THE COURT: And then on behalf of Innopharma.  
 18 MR. MUKERJEE: Deepto Mukerjee of Alston Bird, your  
 19 Honor.  
 00:03 20 MR. SODERSTROM. Lance Soderstrom of Alston Bird,  
 21 your Honor.  
 22 MR. MALIK: Jitendra Malik with Alston Bird, your  
 23 Honor.  
 24 MR. CALMANN: Arnold Calmann from Saiber.  
 00:03 25 THE COURT: Good morning.  

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1 All right. Are there any questions about the logistics  
 2 of trial before we begin? Did anything come up that requires  
 3 my attention that would make you more comfortable to speak to  
 4 it at this point in time?  
 00:03 5 MR. LIPSEY: Not for plaintiffs, your Honor.  
 6 MS. HOLLAND: Not for defendants, your Honor.  
 7 THE COURT: Okay. You'll recall that there were  
 8 three motions in limine in which I reserved decision and I'd  
 9 prefer not to take the time now to address them in an oral  
 00:04 10 Opinion, but I will either at the end of the day today or else  
 11 tomorrow.  
 12 And there's one motion in limine by the plaintiff,  
 13 which was actually the plaintiff's second motion in limine, it  
 14 was to preclude evidence or argument that the plaintiff's  
 00:04 15 asserted patent claims are invalid as obvious based on  
 16 plaintiff's internal documents and specifically identified  
 17 non-prior art information. This was Docket Number 161. And  
 18 I'm denying that motion. I'm denying that motion without  
 19 prejudice to raise any specific objection and I'm doing so for  
 00:05 20 reasons that will be stated in the oral Opinion.  
 21 The defendants had two motions in limine. Their first  
 22 motion in limine is to preclude evidence consistent with  
 23 admissions in the patent specifications. This was at Docket  
 24 Item 167 in the lead case. And that motion is also being  
 00:05 25 denied without prejudice. What's consistent and inconsistent  

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 Camden, New Jersey*

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1 can only be determined on an item by item basis, and there's  
 2 much in dispute about what is admitted and what's not  
 3 admitted, quote, unquote, in the patent specifications. So I  
 4 will, again, explain the reasons in an oral Opinion.  
 00:06 5 The third motion is the defendant's second motion in  
 6 limine to preclude evidence of alleged unexpected results.  
 7 This is Docket Item 169 in the lead case of 14-667. And that  
 8 motion also is going to be denied. It's being denied because  
 9 there's a very deep factual dispute about what's expected,  
 00:06 10 unexpected, the degrees of difference, and whether the  
 11 unexpected result was a change in kind, all of that needs to  
 12 be explored at trial. And, again, I'll flesh out these  
 13 reasons in on oral Opinion.  
 14 Any questions so far?  
 00:06 15 MR. LIPSEY: Not for plaintiffs, your Honor.  
 16 THE COURT: Okay. There is also an appeal from Judge  
 17 Williams' order regarding attorney/client privilege, and on  
 18 that I would like to hear oral argument, not at this time  
 19 because I know that it's unlikely you'd be prepared to do so  
 00:07 20 now. I would have the oral argument at some point tomorrow,  
 21 if you need a day to decide who's going to argue it and  
 22 collect your thoughts on that, and also to see if there's any  
 23 way it can be worked out overnight.  
 24 Would you rather have it at 9:15 or at 4:30? I'm open  
 00:07 25 to either.  

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1 MS. HOLLAND: Either one is fine with Lupin, your  
 2 Honor. Whatever is preferable to you.  
 3 MR. LIPSEY: If possible, 4:30. But, if not --  
 4 THE COURT: Okay.  
 00:08 5 MR. LIPSEY: -- whatever is convenient for the Court.  
 6 THE COURT: No, if there's a preference then for  
 7 4:30, then we'll do 4:30 tomorrow.  
 8 So 4:30 on Tuesday afternoon we will have oral argument  
 9 on the defendant's appeal from Judge Williams' determination  
 00:08 10 recognizing the attorney/client privilege.  
 11 Before we leave that topic, I don't see that the issue  
 12 of waiver is presented. In other words, there doesn't seem to  
 13 have been a dispute presented to Judge Williams about the  
 14 operation of the clawback provision that's been argued to me.  
 00:08 15 But since it wasn't presented to Judge Williams, at least not  
 16 that I can tell from the papers, there's not a question here  
 17 of whether the plaintiffs waived their privilege by producing  
 18 the unredacted document and clawing it back six months later.  
 19 And also I don't believe that there is a question about  
 00:09 20 work product protection. Work product protection for these  
 21 documents was not sought by the plaintiffs, Judge Williams  
 22 recognized it and lumped it together with attorney/client  
 23 privilege. I don't think that that's correct. If the  
 24 plaintiffs raised attorney/client protection, then you can  
 00:09 25 point that out to me in the argument tomorrow. I didn't see  

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1 it anywhere in the papers. On its face it doesn't seem that  
 2 the documents would qualify for work product protection. But  
 3 the attorney/client privilege dispute is, of course, very much  
 4 alive.

00:09 5 I hope that that focuses your arguments for tomorrow.  
 6 Do you have any questions about what I'm asking you to  
 7 address?  
 8 Okay. So are we ready to begin with opening  
 9 statements.

00:10 10 MR. LIPSEY: We're ready, your Honor.  
 11 THE COURT: Okay. Then, Mr. Lipsey, you may proceed.  
 12 MR. LIPSEY: Okay. Thank you.  
 13 May it please the Court, I have some hard copy of my  
 14 presentation, which I think the court reporter's might find  
 00:10 15 useful in the transcription, and perhaps the Court and the  
 16 Court's clerk might find useful at some point.  
 17 May I approach?  
 18 THE COURT: Yes, please.  
 19 Thank you.

00:11 20 MR. LIPSEY: How many would you all like?  
 21 MS. HOLLAND: As many as you're offering.  
 22 MR. MUKERJEE: Charles, do you have any extra copies  
 23 for Innopharma?  
 24 MR. LIPSEY: I have one.

00:11 25 MR. MUKERJEE: Thanks so much.

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1 from that abuse of the eye, and we will hear that it's  
 2 important to control that inflammation less there be some very  
 3 serious adverse consequences. There's also pain associated,  
 4 as you can imagine, with the incision and recovery.

00:13 5 And, as we all know, the eye is one of the most  
 6 sensitive organs in the body to begin with. And when it's  
 7 been surgically damaged, it's even more so. And the drugs  
 8 that are used to treat this inflammation are administered, at  
 9 least in the case of the product here, as drops directly into  
 00:13 10 the eye.  
 11 And so there are some complications and challenges in  
 12 preparing such a formulation and our evidence will focus on  
 13 these. These come largely out of the Ogawa patent, which is  
 14 the principal piece of prior art.

00:14 15 You have to have a clinically effective ingredient.  
 16 The key is to get the ingredient to penetrate the eye  
 17 to get to the tissues that need to be prevented from  
 18 inflammation.  
 19 Maintenance in the eye of clinically effective  
 00:14 20 concentration is difficult because the surface area of the eye  
 21 is quite small, the length of time the drug is actually in  
 22 contact with the surface area is quite small, and so there's a  
 23 challenge getting an adequate amount of drug into the eye.  
 24 Irritability, of course, is an issue in a surgically  
 00:14 25 compromised eye, stinging and burning principally, and most of

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1 MR. LIPSEY: May it please the Court, the case is  
 2 about the product Prolensa®, which is bromfenac ophthalmic  
 3 solution .07 percent. The approved indication is for the  
 4 treatment of postoperative inflammation and reduction of  
 00:12 5 ocular pain in patients who have undergone cataract surgery.  
 6 And the Court will be pleased to recall that while  
 7 there are many patents in issue, we have agreed with the  
 8 defendants that their right to market this product as a  
 9 generic will stand or fall with the outcome on Claim 6 and 20  
 00:12 10 of the '431 patent, which, in essence, claim formulations in  
 11 varying degrees of detail containing bromfenac sodium and  
 12 about .02 percent tyloxapol. And that's what the case will  
 13 largely be about.  
 14 THE COURT: I'm not disappointed that you narrowed  
 00:12 15 the dispute.  
 16 MR. LIPSEY: We suspected that might be the case.  
 17 Nor are we disappointed either, your Honor.  
 18 We deal here with cataract surgery. And hopefully it's  
 19 something we all don't have a lot of experience about.  
 00:12 20 We have Dr. Trattler who, unfortunately, can't be here  
 21 till next week, but he can explain to us the details. But as  
 22 you can see on the screen, what it involves, in essence, is  
 23 cutting open the eye and removing the clouded natural lens and  
 24 replacing that natural lens with an artificial one and then  
 00:13 25 allowing the patient to recuperate. And inflammation results

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1 the evidence will focus on that.  
 2 And then there are questions of the stability of the  
 3 formulation. We'll hear that making liquid formulations is a  
 4 more difficult proposition than making a solid oral dosage  
 00:15 5 form. Things happen more readily when drugs are in solution,  
 6 reactions can occur which don't normally occur when they're  
 7 dry, they can occur more quickly, the various ingredients can  
 8 interact with each other. And so life is difficult in the  
 9 liquid formulation world and even more so in the ophthalmic  
 00:15 10 formulation world.  
 11 There are two kinds of stability that we'll be talking  
 12 about. One is chemical stability and that is the active  
 13 ingredient actually getting degraded and broken down into  
 14 something that's not an active ingredient and there's several  
 00:15 15 reactions, chemical reactions by which that can occur. One  
 16 we'll be talking about is oxidation. Another is hydrolysis.  
 17 And then there's the question of the physical stability  
 18 of the formulation, and that tends to manifest itself by the  
 19 formulation having a cloudy appearance when the ingredients  
 00:16 20 actually start to separate from each other. And there will be  
 21 some testimony about that as well.  
 22 There is in the world of ophthalmic formulation a  
 23 dizzying array of ingredients that can be contained or are  
 24 available as options for inclusion. I've listed some of them  
 00:16 25 here on Slide 5 that I've extracted directly from the

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1 documentary exhibits that will be coming into evidence. And  
 2 these are categories, these are functional categories, and  
 3 within each of those categories there are a very large number  
 4 of different chemicals that are used in this regard. There  
 00:16 5 are entire books written describing each of the various  
 6 chemical options and how they differ from each other and,  
 7 indeed, they do differ from each other.  
 8 And we'll be guided through that morass by Dr. Robert  
 9 Williams who is Ph.D. in pharmaceuticals. He is the Johnson &  
 00:17 10 Johnson Centennial Chair at the University of Texas in Austin.  
 11 He has more than 400 publications. His research focus is in  
 12 development formulation and delivery of drugs. And, in  
 13 essence, what we're going to hear from Dr. Williams is that  
 14 the mantra, oh, that's routine experimentation, which most  
 00:17 15 defendants in cases like this advance and which the defendants  
 16 here have advanced, is in the case of ophthalmic formulations  
 17 is a gross oversimplification of what happens. The individual  
 18 components can interact with each other in unpredictable ways  
 19 and affect their properties in unpredictable ways, each drug  
 00:17 20 has to be considered based on its own unique properties. And,  
 21 as he will say more eloquently than I, knowing the objective  
 22 and getting there is often separated by trial and error,  
 23 failures and frustration.  
 24 Now, there are also chemistry aspects to the case.  
 00:18 25 What we have on Slide 7 here are the structure of some of the  
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1 molecules that we'll be talking about. The ones on top are  
 2 anti-inflammatory drugs and they are, more specifically, what  
 3 are called in the trade nonsteroidal anti-inflammatory drugs.  
 4 The initials N-S-A-I-D-S being amalgamated by people, and  
 00:18 5 probably by us at the trial, as NSAIDS. And when we refer to  
 6 NSAIDS, that doesn't tell us what the structure of the  
 7 molecule is, your Honor, it tells you what the therapeutic  
 8 class is and that's to distinguish them from molecules which  
 9 have been used before such as steroids. Steroids are very  
 00:18 10 powerful drugs that have a whole constellation of potentially  
 11 adverse side effects and we are not talking about steroids.  
 12 Now, we will be led through this issue by Dr. Steve  
 13 Davies who has a Ph.D. from the University of Oxford. He is  
 14 the Waynflete professor of chemistry at the University of  
 00:19 15 Oxford. He's got 550 publications. And his research include  
 16 organic and medicinal chemistry.  
 17 And the defendants were kind enough to share with us  
 18 some of their slides, and I've used one here because it  
 19 highlights I think what the difference in the proofs are going  
 00:19 20 to be, at least the difference in the focus of the proofs, and  
 21 that is defendants' arguments and evidence largely will focus  
 22 on these molecules as if they're fungible marbles or bowling  
 23 balls all with this carboxylic acid group, which is the C,  
 24 double-bond O, OH you see and which they have emphasized as  
 00:19 25 their theory of the case requires. And the fact of the matter  
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1 is our evidence will focus on the importance of structural  
 2 differences elsewhere in the molecule, all of which need to be  
 3 considered in assessing what can be expected of that molecule  
 4 and what is unpredicted from that molecule.  
 00:20 5 And one of the concepts that Dr. Davies is going to  
 6 teach us about, which is important here particularly in these  
 7 aqueous systems, is the concept of hydrogen bonding. And  
 8 this, when I tried to learn it in high school, escaped me  
 9 completely until I realized that the water molecule looks like  
 00:20 10 Mickey Mouse. It's got a big oxygen atom, it's got two little  
 11 hydrogen atoms, H<sub>2</sub>O. But the hydrogen atoms are not equally  
 12 spaced on the molecule, they're actually both on one side of  
 13 the molecule and that causes one side of this molecule where  
 14 the Mickey Mouse ears are to have a partial positive charge  
 00:20 15 and the end that has the big oxygen atom has a partial  
 16 negative charge and that allows water when it is in the liquid  
 17 form for those molecules to attract each other through  
 18 hydrogen bonding, the slightly positive hydrogen atom being  
 19 attracted to the slightly negative oxygen Mickey Mouse face.  
 00:21 20 And that's what makes water such a marvelous solvent, is those  
 21 molecules actually stick together and that explains why the  
 22 boiling point of water is as high as it is for such a small  
 23 molecule.  
 24 And those same kinds of interactions can occur between  
 00:21 25 water and organic chemicals and, indeed, between different  
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1 organic chemicals because a number of the functional groups,  
 2 which Dr. Davies is going to tell us about, have that same  
 3 property of having a partial positive charge on one end and a  
 4 partial negative charge on the other. An important one that  
 00:21 5 we'll see in a lot of these molecules is the carbonyl group,  
 6 which is in the center here. And again, the oxygen that's  
 7 hanging out in the space in the air has a partial negative,  
 8 that's where the electrons like to be, as Dr. Davies will  
 9 explain, the rest of the group has a partial positive charge.  
 00:21 10 And so when that is in an aqueous environment, the ears of  
 11 Mickey Mouse, two of them actually, can associate themselves  
 12 or become closely associated with that slightly negatively  
 13 charged oxygen.  
 14 And the same thing happens with, expect in the opposite  
 00:22 15 direction, with the molecule or functional group known as a  
 16 primary amine, which we have here on the right. And there --  
 17 now the hydrogen atoms there have a partial positive charge,  
 18 the nitrogen has a partial negative charge, and so the face of  
 19 Mickey Mouse can now associate with those positively charged  
 00:22 20 hydrogen atoms in that primary amine. And this hydrogen  
 21 bonding that goes on can increase the solvation, the  
 22 association of water solvent with these molecules, alter  
 23 substantially their solubility, it can also alter the  
 24 interaction with other excipients that may be in the drug  
 00:22 25 product, which also have slightly polar moieties.  
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1 And what Dr. Davies will teach us is that you now look  
 2 at these molecules not like fungible bowling balls with acid  
 3 groups but look at them as a whole. And he will show us that  
 4 there are indeed different numbers of different types of and  
 00:23 5 different arrangements of these molecules that are capable of  
 6 engaging in hydrogen bonding. And those are highlighted here  
 7 in red.  
 8 And you can see that for bromfenac, which is the  
 9 molecule we're interested in, as Dr. Davies will explain,  
 00:23 10 there are really more opportunities for hydrogen bonding with  
 11 that molecule than for any of the others we're likely to  
 12 discuss. And a particular feature of this molecule is that  
 13 primary amine, that NH<sub>2</sub> group that's there, which is not  
 14 shared by way of these other molecules.  
 00:23 15 While we have these up, there are two other molecules  
 16 that we'll talk about. The one on the bottom is not really an  
 17 NSAID at all but it has come into play because at one point  
 18 earlier in the case the defendants were relying on it to  
 19 suggest the invention was obvious. And then this nepafenac is  
 00:24 20 a horse of an entirely different color, you can see it doesn't  
 21 have that carboxylic acid group at all. And, in fact, that  
 22 molecule as it sits is not an active drug. In order to work,  
 23 it has to be delivered into the eye and then enzymes in the  
 24 eye actually will convert that into something that can operate  
 00:24 25 as an anti-inflammatory.

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1 And what he is particularly going to explain with  
 2 surfactants is there is a large number of them, they vary from  
 3 each other in structure and their properties are different  
 4 and, therefore, what interactions, if any, they're going to  
 00:26 5 have with complex systems with many different components is  
 6 unpredictable. And we don't really need to take Dr. Davies'  
 7 word for that because right out of the documentary evidence  
 8 that he has cited, we have the quote. And this particular  
 9 article happens to have been cited in other patent cases that  
 00:26 10 have dealt with surfactant.  
 11 "The range of available surfactants is wide, and so,  
 12 too, are the mechanisms of solubilization and the effects the  
 13 surfactants have on the solubilized material. Examples are  
 14 known of enhanced drug activity and of inactivation, of  
 00:27 15 increased stability, and instability; the interactions of the  
 16 surfactants with components of the body must also be  
 17 considered."  
 18 And the point is that's a complex and unpredictable  
 19 world, which bears directly on the issue of obviousness, which  
 00:27 20 your Honor will have to decide.  
 21 Now, these are some of the -- these are models of some  
 22 of the surfactants that we'll be talking about. And every  
 23 time we draw one of these structural formula, we put a model  
 24 on the board, it is our best effort, and scientists' best  
 25 effort, a depiction of how the structures differ. Obviously

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1 Something else we'll talk about are surfactants. And  
 2 surfactants, as the word sounds, it's kind of a made up word.  
 3 Surface active agent intends to refer, as we will hear, to  
 4 molecules that could alter the surface tension of a liquid,  
 00:24 5 particularly water in our case. And the simplest and clearest  
 6 example of a surfactant, just to get our feet wet, no pun  
 7 intended, is soap or detergent. And we have here the  
 8 simplified demonstrative exhibit. And the surfactants tend to  
 9 have one end, it is water loving, hydrophilic is the word you  
 00:25 10 may hear, and another end, it is oil loving, oleophilic or  
 11 water hating, hydrophobic, and they can associate into these  
 12 spherical, not always spherical, but these arrangements  
 13 whereby the ends that like to be in water are near the water  
 14 and other ends are all associated with each other and can hold  
 00:25 15 other molecules that are not readily soluble in water in that  
 16 area. Just add soap or detergent can hold oil droplets that  
 17 are not soluble in water, in solution in water so we can wash  
 18 them away off the dishes.  
 19 Now, my diagram here, the ends that are water loving  
 00:25 20 need not necessarily be globular, they might look like tails,  
 21 but they are nonetheless water loving. And the ends that are  
 22 oil soluble need not look like tails, they might in fact be  
 23 globules and some are in some of the molecules we'll see. But  
 24 the concept is the same and Dr. Davies will explain that to  
 00:26 25 us.

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1 the molecules are minusculely small, they're flexible, they  
 2 interact with their environment in complicated ways. But this  
 3 is the best we can do to try to depict the differences.  
 4 The one on the left is polysorbate 80, that was the  
 00:27 5 surfactant that was in the closest prior art, which we'll see  
 6 in a moment is the Ogawa patent that actually described  
 7 bromfenac eyedrop. And the surfactant, which the inventors of  
 8 the '431 patent discovered, had a whole cascade of benefits  
 9 for use in the point of 2 percent concentration, is tyloxapol.  
 00:28 10 You can see it's structurally exceedingly different and we  
 11 contend, and our evidence will show you, could not have  
 12 predicted that molecule would have positive effects in a  
 13 bromfenac formulation.  
 14 Some others that we will see are these octoxynol  
 00:28 15 molecules, which are structurally similar, at least in the  
 16 globular end, which in this case happens to be the oil loving  
 17 end, and they vary from each other simply in the length of the  
 18 tail, which is the water-loving tail. The red atoms are  
 19 oxygen atoms and the presence of the oxygen atoms in these  
 00:28 20 tails causes them to be associated easily with water, as Dr.  
 21 Davies will explain, and as you can see from the structure of  
 22 those molecules that they do not look like either polysorbate  
 23 80 or tyloxapol.  
 24 Now, there are also medical issues, as one might  
 00:29 25 imagine, with treating postsurgery inflammation in the eye.

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1 We will be guided through those by Dr. Trattler, as I've said,  
 2 who will be here next week. He has specialized in cornea and  
 3 cataract surgery since 1997, been an investigator on nearly 70  
 4 clinical trials for ophthalmic products, including bromfenac.  
 00:29 5 He conducts about 60 surgeries a month, and has actually used  
 6 many of the drugs that are both in the prior art as well as  
 7 Prolensa®, and will be here to tell us how important some of  
 8 the differences between them are. And again, part of what he  
 9 will tell us is also reflected in the prior art documentary  
 00:29 10 evidence.

11 And there are two principal medical issues that come  
 12 up, and the first is really captured here by Bowman which is  
 13 one of the references they had originally cited to us. And  
 14 Bowman points out that there are problems with these NSAID  
 00:30 15 agents, and that is, that stinging and burning sensations are  
 16 commonly experienced during the first few minutes after  
 17 topical administration on the eye. Not only are patients who  
 18 experience such stinging likely to avoid regularly taking  
 19 their medication, they also receive less benefit from each  
 00:30 20 application. Specifically, the stinging causes tearing which  
 21 washes away the drug. Having physically removed a portion of  
 22 the drug from the eye by tearing, the bioavailability of the  
 23 drug is reduced.

24 So, the stinging and burning issue, which is somewhat  
 00:30 25 downplayed, understandably, by the defendants, is an important

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1 medical issue and will be the focus of some of our testimony.  
 2 There's a second issue that arises, and it too emerges  
 3 from the prior art, and this is the Yanni publication. And in  
 4 specific reference to the family of molecules to which  
 00:30 5 bromfenac belongs, he points out that relatively high  
 6 concentrations of these drugs are often needed to achieve  
 7 corneal penetration rates sufficient to provide effective  
 8 intraocular drug concentration. Such high drug concentrations  
 9 are generally not desirable as they may provoke ocular  
 00:31 10 irritation and discomfort, particularly in the surgically  
 11 damaged eye.

12 That brings us really to the closest prior art, which  
 13 is there was an original bromfenac formulation, and it was the  
 14 subject of the Ogawa patent, which will be coming into  
 00:31 15 evidence and much discussed by both parties. And Ogawa noted  
 16 the problem right off the bat in referring to these molecules,  
 17 that these molecules are unstable in an aqueous solution with  
 18 the optimal pH range for the locally administrable therapeutic  
 19 composition.

00:31 20 Now, pH refers to the acidity or alkalinity of the  
 21 system. A pH of 7 is neutral; it's water. Numbers below 7  
 22 are acidic; numbers above 7 are alkaline. And it's an  
 23 exponential scale, which means that when you go from 7 to 8 or  
 24 from 8 to 9, that's a tenfold increase in alkalinity. So, we  
 00:32 25 have to look at those numbers quite carefully. Even when they

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1 are separated from each other by something like .5, that still  
 2 is a threefold difference in terms of the alkalinity or  
 3 acidity that you are dealing with, and we'll hear about that.

4 So, that was the problem that Ogawa acknowledged, and  
 00:32 5 specifically what he found out was that when he made up these  
 6 formulations with bromfenac and subjected them to long-term  
 7 stability tests, he found these red insoluble matter in it,  
 8 and we pointed out the sections in Ogawa where that's  
 9 mentioned. And what you will hear in the testimony is that  
 00:33 10 when there's a color change like that, that's almost always  
 11 the indication of some kind of chemical degradation, and most  
 12 particularly of an oxidative chemical reaction that results in  
 13 that color change.

14 So, what Ogawa was concerned with was a chemical  
 00:33 15 stability problem, not a physical stability problem. And we  
 16 will see, as we go through the evidence, there are some  
 17 patents that deal with chemical stability. Ogawa deals with  
 18 the problem with this red junk showing up in his formulation,  
 19 a chemical stability problem. Some of them deal with physical  
 00:33 20 stability problems where the ingredients separate from each  
 21 other and the formulation may become cloudy.

22 So, what did Ogawa do? Ogawa found out that if you  
 23 include in this formulation polyvinylpyrrolidone, which in  
 24 some of the documents is referred to as povidone, they are the  
 00:34 25 same thing, and sodium sulfite, when those coexist with

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1 bromfenac, then a change in appearance was not observed at all  
 2 and the decomposition of compound was not observed either. It  
 3 was found that the stability was remarkably enhanced. Thus,  
 4 there can be successfully obtained a stable aqueous  
 00:34 5 composition containing the compounds with his  
 6 polyvinylpyrrolidone and sulfite.

7 Now, he noted nonetheless, and herein lies the rub with  
 8 Ogawa, he noted nonetheless that the pH of the ophthalmic  
 9 composition, according to the invention, has to be selected  
 00:34 10 with due consideration paid to stability, on the one hand, and  
 11 topical eye irritativity of the active ingredient on the  
 12 other. And the question, of course, is where -- what was the  
 13 best Ogawa could do with that formulation, and we have  
 14 substantial evidence on that, and that is a formulation which  
 00:35 15 I think at this point both sides acknowledge embodies the  
 16 invention of Ogawa, was introduced into the market in Japan in  
 17 2000. It was described in a printed publication here, this  
 18 *New Drugs in Japan* in 2001, and you can see that it's got the  
 19 sodium sulfite, it has the povidone, which is  
 00:35 20 polyvinylpyrrolidone, and we can see that the best they could  
 21 do was a pH of 8 to 8.6. 8.3 is right in the middle of that  
 22 range. And the problem was that when they took that  
 23 formulation into the clinic in the clinical trials in Japan,  
 24 and this is reflected in that same document, they got stinging  
 00:35 25 and burning, which they acknowledged.

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1 And we have substantial evidence about that property of  
 2 these formulations, that same -- a formulation with those same  
 3 ingredients was introduced in the United States as Xibrom®.  
 4 You can see we now have more detailed information about the  
 00:35 5 pH. The pH was 8.3. And in the U.S. clinical trials for that  
 6 product, that was a twice-a-day drug, administered two times a  
 7 day, again, in the clinical trials, stinging and burning  
 8 emerged.  
 9 There was then introduced a once-a-day form of that  
 00:35 10 same formulation, and when that was subjected to clinical  
 11 trials, again, as we saw, that was called Bromday®, and when  
 12 that went into its own clinical trials, still there was  
 13 burning and stinging noted.  
 14 So, that then brings us to the contribution of the '431  
 00:36 15 patent which is, after all, the major focus of our attention  
 16 here today. And the Sawa '431 patent tells us in part exactly  
 17 what he's after. It is an object of the present invention to  
 18 provide an aqueous liquid preparation of bromfenac which is  
 19 stable within a pH range giving no irritation to the eyes.  
 00:37 20 And he tells us exactly what he did to get there. He has  
 21 discovered that by adding tyloxapol to bromfenac, the aqueous  
 22 solution becomes stable within a pH range giving no irritation  
 23 to the eyes.  
 24 Now, as we said before, tyloxapol is a surfactant.  
 00:37 25 When you look back at the published Bronuck® formulation, you  

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1 can see that the surfactant used there was called polysorbate  
 2 80, and our evidence will show, your Honor, there wasn't a  
 3 shred of evidence that the problem -- or there was any problem  
 4 with Ogawa's formulation arising from the surfactant that  
 00:37 5 happened to be used. And I think we've already seen that the  
 6 tyloxapol looks nothing like polysorbate 80.  
 7 And there was, in fact, a commercial product introduced  
 8 embodying the Sawa '431 invention. It is called Prolensa®.  
 9 It is the subject of this lawsuit. And there are some  
 00:38 10 important things to notice right off the bat, which is instead  
 11 of .09 percent, they were able to reduce the amount of drug to  
 12 .07 percent. Instead of a pH of 8.3, they were able to reduce  
 13 the pH to 7.8. That's that .5 difference on the logarithmic  
 14 scale which is about a factor of 3 in terms of the acidity.  
 00:38 15 And it had tyloxapol. And lo and behold, when that drug was  
 16 carried into clinical trials in the United States, there is no  
 17 reference to burning and stinging, the side effect having been  
 18 effectively eliminated.  
 19 Now, we will see also that the scientists and doctors  
 00:38 20 who conducted those clinical trials published and commented  
 21 upon the results of their studies. Defendants criticize this  
 22 work saying, oh, Bausch & Lomb sponsored the clinical trial,  
 23 but the fact remains, your Honor, these are distinguished  
 24 doctors and scientists, and all of these publications appeared  
 00:39 25 in peer-reviewed journals. This particular one from Baklayan  

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1 is in the *Clinical Ophthalmology* peer-reviewed journal, points  
 2 out the decrease in drug concentration arising from the change  
 3 in pH, noting that it led to similar, and in the case of  
 4 scleral tissue, increased penetration of ocular tissue studied  
 00:39 5 when compared to the .9 percent of pH 8.3. And that the  
 6 lowering of pH increases the unionized fraction of drug, which  
 7 can lead to enhanced corneal permeability. Additionally, the  
 8 reduction of pH to a more physiological level could reduce the  
 9 potential for discomfort and irritation.  
 00:39 10 So, that was the first problem that the prior art noted  
 11 about the discomfort and irritation, and then we will also see  
 12 that Baklayan also noted --  
 13 THE COURT: Excuse me, Mr. Lipsey, before you do  
 14 that, can you go back a slide to slide 37?  
 00:40 15 MR. LIPSEY: Certainly.  
 16 THE COURT: It mentions eye pain. Do we know that  
 17 eye pain is different from irritation and --  
 18 MR. LIPSEY: The burning and stinging.  
 19 THE COURT: -- burning?  
 00:40 20 MR. LIPSEY: The burning and stinging is a distinctly  
 21 identifiable side effect, as you can see in all the prior  
 22 trials. And my understanding is that the FDA is the arbiter  
 23 of what needs to be in as an adverse indication and what  
 24 doesn't.  
 00:40 25 THE COURT: Can a patient discern that in the test?  

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1 MR. LIPSEY: The burning and stinging?  
 2 THE COURT: I have merely burning, I don't have eye  
 3 pain, or vice versa?  
 4 MR. LIPSEY: Just from the fact that it's  
 00:40 5 differentiated throughout the other clinical trials, and since  
 6 it is specifically called out in the prior art, the burning  
 7 and stinging is a distinct feature, my assumption is yes. And  
 8 I'm sure when we get Dr. Trattler here, we can ask him that.  
 9 THE COURT: Okay. That will be helpful. Thanks.  
 00:41 10 MR. LIPSEY: So, I won't burden the record. We've  
 11 got publications from Dr. Walters in the peer-reviewed  
 12 *Ophthalmology*, making more or less the same points. Dr.  
 13 Silverstein in the peer-reviewed *Clinical Ophthalmology*, again  
 14 pointing out those benefits. Dr. Rajpal in the peer-reviewed  
 00:41 15 journal *Patient Preference and Adherence*, again pointing out  
 16 those benefits. And there is substantial evidence, which the  
 17 Court will see, laying those benefits squarely at the feet of  
 18 the use of .02 percent tyloxapol.  
 19 And what we have here on slide 43 is the original data  
 00:41 20 underlying Table 1 in the '431 patent, and the left-hand  
 21 column is the test specimen using polysorbate. The columns on  
 22 the right are various amounts of tyloxapol.  
 23 This test is being done at pH 7, which is a stringent  
 24 test of stabilizing ability at lower pH. And what you can see  
 00:42 25 is that the surfactant used in Ogawa, there was basically half  

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1 of the material was destroyed after the four week test,  
2 whereas with .02 percent tyloxapol there was almost 90 percent  
3 still remaining.

00:42 4 And interesting trend emerged from that data, which you  
5 will hear testimony about, and that is, counter-intuitively,  
6 when you graph that data out and take a look at it, you see  
7 that the stability actually goes up as the concentration of  
8 tyloxapol goes down. To the extent the defendants contend  
9 that, well, it would be obvious to use low amounts, the reason  
00:42 10 people use low amounts is because they want to find the  
11 minimum amount that's still effective. In other words,  
12 everybody assumes a lot is good. The question is how little  
13 will still be just as good as a lot, and the evidence here  
14 shows exactly the opposite trend.

00:43 15 There is also evidence that tyloxapol at .02 percent  
16 provided such a significant increase in stability over  
17 polysorbate 80 that you didn't need to use the sodium sulfite  
18 that Ogawa had said was so important. And what we have here  
19 on slide 45 is some evidence comparing the Bronuck®  
00:43 20 formulation to the formulation with .02 percent tyloxapol that  
21 does not have that sulfite. Now, this test was done at a  
22 higher pH.

00:43 23 And then we have also the evidence which is actually  
24 embodied in Table 2 of the patent where, again, .02 percent  
25 tyloxapol formulations, again has a pH of about 8.15, all had

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1 in excess of 90 percent of the drug remaining after that  
2 accelerated stability test of four weeks at 60 degrees C, and  
3 Ogawa himself points out in the patent that when you have more  
4 than 90 percent remaining, that's sufficient stability for  
00:44 5 eyedrops.

6 There are also benefits that flow from the .02 percent  
7 tyloxapol in terms of preservative efficacy that we will hear  
8 about. And this is the data actually embodied now in Table 3  
9 of the patent and also in underlying documents interpreting  
00:44 10 the results.

11 Basically, the Ogawa formulation was perfectly good for  
12 Japan. It met the preservative efficacy standards for Japan.  
13 It met the standards for the United States. In internal  
14 research, which is not part of the prior art, they studied the  
00:44 15 question, they were going to go introduce it in Europe, and it  
16 turned out it didn't meet the European Pharmacopoeia standard,  
17 which is more stringent than the U.S. or the Japanese  
18 standard.

19 There are two parts to that standard. There's a part A  
00:45 20 which I understand to be the target or goal in terms of  
21 preventing microbial growth in the solution; and there's a  
22 somewhat laxer standard B which is a, for lack of a better  
23 word, acceptable standard. And you can see that the Ogawa  
24 formulation with .15 percent polysorbate didn't meet either,  
00:45 25 whereas that formulation with .02 percent tyloxapol, even

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1 without the sulfite, passed them both. And interestingly,  
2 when you up the concentration of tyloxapol to .05 percent,  
3 while it passed the lesser standard B, it failed the more  
4 rigorous standard A.

00:45 5 So, that brings us really to the heart of our case, it  
6 being important to us for our evidence not just to snipe at  
7 whether defendants have met their burden of proof, and it is,  
8 indeed, their burden of proof on the issue of validity, but to  
9 really show the wonderful and unexpected cascade of benefits  
00:46 10 that flow from using .02 percent tyloxapol. We see that it  
11 permitted a reduction of pH from 8.3 to 7.8, which is more  
12 than a threefold difference; increased ocular penetration;  
13 reduced by 22 percent the amount of the active drug that  
14 needed to be used; effectively eliminated stinging and  
00:46 15 burning; reduction by eightfold of the surfactant load from  
16 .15 to .02; reduction of exposure of damaged ocular tissue to  
17 active drug and surfactant; improved patient compliance;  
18 increased preservative efficacy; and eliminated, if desired,  
19 the need to use the sulfite. And we will contend and our  
00:47 20 evidence will show that those are unexpected beneficial  
21 results, they are important, and that they could not have been  
22 predicted, and they highlight the unobviousness of using .02  
23 percent tyloxapol.

00:47 24 Now, the argument will be made and has been made and I  
25 expect we will hear evidence that these don't matter, that the

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1 reduction of burning and stinging isn't important. And what  
2 you will hear from Dr. Trattler is that burning and stinging  
3 matters to his patients, and since it is a compliance issue  
4 and you don't know who is going to have the compliance issue,  
00:47 5 and since there are consequences, potentially serious side  
6 effects that come from not taking the medicine, that it is  
7 important to absolutely minimize stinging and burning.

8 And there's also the objective indicator of the actions  
9 of these defendants themselves which I think speaks volumes,  
00:47 10 and that is, as we have here on slide 50, this is a report  
11 that's up on Lupin's website simply reporting a fact, and that  
12 is that the original bromfenac formulation, the Xibrom® and  
13 Bromday® formulation, is available for generic competition  
14 and, in fact, there are generics on the market. And our  
00:48 15 evidence will show that if they thought it didn't matter that  
16 those formulations were just as good, they could be on the  
17 market today with those formulations.

18 And what you will see is that's not what they want.  
19 They want to copy this formulation, and we contend that's  
00:48 20 because it's better, and they're not alone, you need look no  
21 further than the docket entrees in this court to see that  
22 there is a veritable who's who of the generic drug industry  
23 endeavoring to copy this product, and that they have, the  
24 defendants here have done so slavishly. They have copied it  
00:48 25 in every detail, even though the FDA regulations would have

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1 allowed them to make some changes, which if they could have  
 2 made and still have had the benefits, they could have avoided  
 3 this suit conceivably altogether.

4 That brings us to the claims. There are two. A couple  
 00:49 5 of features of interest. They are dependent claims and so  
 6 both parties have tried to construct them together with the  
 7 claims that they depend from into one coherent body. The  
 8 claim calls for an aqueous liquid preparation consisting  
 9 essentially of, those are magic words in patent law meaning  
 00:49 10 excluding things that alter the basic and novel  
 11 characteristics of the invention. The first component is  
 12 bromfenac sodium; the second component is tyloxapol at about  
 13 .02 percent for ophthalmic administration.

14 And interestingly here, because it will come up in some  
 00:49 15 of the evidence that we see, it excludes these quaternary  
 16 ammonium stabilizers other than BAC and benzalkonium chloride,  
 17 which is a widely used stabilizer and really is the focus of  
 18 much of the defendants' evidence. And our claims all require  
 19 that if there is such a molecule, that it be BAC.

00:50 20 The other claim, claim 20, is essentially what I guess  
 21 would be called in this business a picture claim of the  
 22 commercial formulation for Prolensa®. It has all the  
 23 important ingredients, and again specifies tyloxapol having a  
 24 concentration of about .02 percent.

00:50 25 And just so that we get oriented, taking a quick peek  
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1 at the prior art, the priority date for this patent  
 2 application is January 21, 2003, and that's the dividing line  
 3 between what's prior art and what isn't.

4 So, in the question of -- the issue here is  
 00:50 5 obviousness, and the challenge, as your Honor knows, and as we  
 6 all know, the challenge in obviousness is trying to avoid the  
 7 insidious effect of hindsight, it being almost impossible to  
 8 fully divorce yourself from knowledge of what the inventor did  
 9 in going back and reviewing the prior art, but it is important  
 00:51 10 to try to do that. But the way this case developed is the  
 11 defendants did exactly the opposite.

12 Guided by what they knew the claim to be, they  
 13 basically scoured the prior art looking for every reference  
 14 they could find mentioning tyloxapol in connection with  
 00:51 15 eyedrops, and many of them had been asserted against us in one  
 16 form or another, and as I understand it, while their opening  
 17 is relatively narrow, they have not abandoned reliance on  
 18 these, and so I will briefly take a look at them.

19 Basically, our case relies on the fact that the  
 00:51 20 totality of the prior art, not just little pieces of it which  
 21 you might pick out and look at in isolation, really do not  
 22 suggest or provide any likelihood of success or suggest you  
 23 could get the benefits we get by substituting .02 percent  
 24 tyloxapol into the formulations of Ogawa.

00:52 25 And just as a preliminary matter, their evidence will  
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1 try to create the impression that tyloxapol was commonly used  
 2 for ophthalmic NSAID solutions and was, indeed, a household  
 3 word in this field, but the fact of the matter is, I have on  
 4 slide 57 all of the ophthalmic NSAID products containing  
 00:52 5 tyloxapol that were marketed as of 2003, and the short answer  
 6 is there weren't any. They were not any.

7 Now, there were drugs. There was diclofenac, but it  
 8 used a modified castor oil. There was ketorolac; it used  
 9 something called octoxynol 9. There was bromfenac, it used  
 00:52 10 polysorbate 80.

11 And again defendants were kind enough to share with us  
 12 one of their slides, and they have suggested here that, in  
 13 fact, there were nine ophthalmic formulations using tyloxapol  
 14 that had been approved by the FDA, and that we know that none  
 00:53 15 of those was an NSAID. And so the question will be asked what  
 16 those are, and we expect the answer will be, oh, those are  
 17 steroids and, oh, those are antibiotics and, oh, those are  
 18 glaucoma drugs and not, oh, yes, those are NSAID solutions.

19 Now, something equally important from this document,  
 00:53 20 the heading here is missing for this right-hand column. That  
 21 heading says potency range, and the range of the tyloxapol  
 22 here is .05 to .1 percent, which is two-and-a-half to five  
 23 times higher than what our claims specify.

24 So, what did the prior art actually suggest, and we'll  
 00:53 25 quickly run through these. The Yanni publication acknowledges  
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1 the '225 patent here is the Ogawa patent. He says, the '225  
 2 patent compounds are difficult to formulate in stable aqueous  
 3 solutions. So what's the obvious thing to do? Yanni tells  
 4 us. He says what's needed are additional agents. And that's  
 00:54 5 exactly what he did. He went out and he chemically modified  
 6 those agents, and that was his invention. And what did he use  
 7 them with? In his lone example, he used them with polysorbate  
 8 80.

9 We have Yasueda. Yasueda does mention, but apparently  
 00:54 10 never commercialized, a formulation with tyloxapol. But in  
 11 what context, your Honor? And our evidence will bring this  
 12 out in spades. The patent itself says that pranlukast, which  
 13 is not even an NSAID, has very low water solubility, which  
 14 makes it very difficult to prepare a useful aqueous liquid  
 00:54 15 pharmaceutical composition. And that's the problem that he is  
 16 addressing here. And that problem simply does not exist with  
 17 bromfenac sodium, which is the active ingredient in the Ogawa  
 18 materials. As the *New Drugs in Japan* stated, it is freely  
 19 soluble in water. There is no solubility issue with it at  
 00:55 20 all, so it is not even a candidate for whatever solutions it  
 21 is that Yasueda happens to propose.

22 So, let's look more carefully at what you see Yasueda  
 23 actually does propose. He says, you know, you can add a whole  
 24 bunch of different excipients to my drugs, and he mentions  
 00:55 25 among them surfactants, and he says they can be nonionic,  
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1 cationic or anionic. Your Honor, that is the entire universe  
 2 of surfactants. He goes on to mention specific ones. He  
 3 mentions polysorbate 80, he mentions the modified castor oil  
 4 that we heard about. Interestingly, he mentions tyloxapol.  
 00:55 5 He does not call it an ethoxylated octylphenol, which is what  
 6 they will contend it is. He calls it a polyoxyethylene  
 7 alkylphenyl formaldehyde condensate. It is a polymer that is  
 8 made by reacting with formaldehyde. And he goes on and  
 9 mentions a whole raft of other things including among others.

00:56 10 What he actually teaches is that tyloxapol isn't as  
 11 good at solubilizing pranlukast as polysorbate 80. That's our  
 12 slide 64. You can see that polysorbate 80 actually  
 13 solubilized more of the drug than tyloxapol did. And when he  
 14 actually went to make a test drug, a test medicine, what did  
 00:56 15 he use? He used polysorbate 80.

16 Now, he does have some examples where he just says  
 17 here's a formulation, and even when he does that, he's got  
 18 tyloxapol in there at 4 percent, which is 200 times the amount  
 19 of tyloxapol in our formulation.

00:56 20 So, the bottom line is he may mention, you may have  
 21 been able to search around and find a mention of tyloxapol  
 22 with an eyedrop, but our evidence will show it doesn't suggest  
 23 making the modification that we are claiming.

24 Sallmann is another reference they found that mentions  
 00:57 25 tyloxapol. But Sallmann actually highlights the

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1 unpredictability in this art that our evidence will show. He  
 2 found that simply by changing the salt of diclofenac from  
 3 diclofenac sodium, which was the salt that had been  
 4 commercialized, to diclofenac potassium, he got dramatic  
 00:57 5 difference in properties from a change as subtle and as simple  
 6 as changing the salt. And, if anything, what that would  
 7 suggest is possibly examining bromfenac potassium instead of  
 8 bromfenac sodium. It does not suggest anything else with  
 9 respect to bromfenac.

00:57 10 And when you look, apparently because he needed it for  
 11 this potassium salt, the same way pranlukast needed it, he  
 12 proposes using a solubilizer. And among the solubilizers, he  
 13 does mention tyloxapol amongst a whole raft of others,  
 14 including vitamin E derivatives, one called TPGS that we will  
 00:58 15 see later, but the most salient point is an especially  
 16 preferred solubilizer is this Cremophor EL, a castor oil  
 17 product.

18 When he does give illustrations of formulations with  
 19 tyloxapol, he has massive amounts of cyclodextrin in there,  
 00:58 20 and you will hear evidence that cyclodextrin could be  
 21 potentially troublesome for bromfenac sodium, which would be  
 22 excluded by the "consisting essentially of" language.

23 And when he actually goes to make a medicine, what does  
 24 he make? The evidence will show what he actually makes is one  
 00:58 25 with this Cremophor in it. That's in this Example 8, and it's

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1 Example 8 that he actually does his in vivo testing with.  
 2 And then we come to what is apparently the centerpiece  
 3 of defendants' case, and that is this published application of  
 4 Fu. They call it EP 984. And Fu describes this issue that  
 00:59 5 some drugs with carboxylic acid groups can react with  
 6 benzalkonium chloride to form a complex. And what his  
 7 specific concern is, he's got this NSAID ketorolac, which we  
 8 will see when we do it, and we had on the screen before,  
 9 structurally quite different from bromfenac. And when he put  
 00:59 10 ketorolac BAC and polysorbate together, it became cloudy.

11 Now, that is a physical stability problem. And we know  
 12 what it was that Fu did to measure that. He did a test where  
 13 he mixed the ingredients up, and the solutions that remained  
 14 clear are considered stable in this procedure. And what was  
 01:00 15 in the art about the formulations of bromfenac according to  
 16 Ogawa as embodied in the Bronuck® formulation? The literature  
 17 said those formulations were clear yellow. There was not a  
 18 shred of evidence that the Ogawa formulations suffered from  
 19 this problem. Therefore, not a shred of motivation to adopt  
 01:00 20 whatever solution it is that Fu suggests to solve it.

21 And, indeed, Ogawa itself, as we saw, said that with  
 22 the use of polyvinylpyrrolidone and sodium sulfite you could  
 23 make successfully stable formulations. There are, in fact,  
 24 other examples in the literature of formulations that do not  
 01:00 25 have this problem that they characterize as universal.

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1 There's one in Bowman with diclofenac solution that was stable  
 2 with benzalkonium chloride.

3 And when we look at what Fu suggested doing, even if  
 4 you want to look at it, even though there was no apparent  
 01:01 5 reason to need to, he says he adds an ethoxylated octylphenol.  
 6 And they use this word a lot. And we'll have Dr. Davies  
 7 explain to us what it means. He gives some examples including  
 8 octoxynol 9, 12, 13, most preferably octoxynol 40.

9 And here is what those molecules look like. And  
 01:01 10 indeed, ethoxylated octylphenol, as matter of chemistry,  
 11 refers to a material that has this single head group and then  
 12 varying lengths of this oxygenated tail. Octoxynol 9 has nine  
 13 repeating units, octoxynol 40 has 40. And tyloxapol is an  
 14 entirely different animal made by the polymerization with  
 01:02 15 formaldehyde. And Dr. Davies will explain to us that  
 16 tyloxapol is not an ethoxylated octylphenol, and, your Honor,  
 17 that explains why Fu doesn't even mention it. He doesn't  
 18 mention bromfenac, he doesn't mention tyloxapol. And what we  
 19 have here is primary reliance of the defendants' evidence on a  
 01:02 20 reference that teaches a solution to a problem that the Ogawa  
 21 products didn't have, using a material that the Fu publication  
 22 does not describe.

23 And again, they have helpfully provided a slide which  
 24 actually proves too much. This is the great danger in  
 01:02 25 demonstrative exhibits, of course. This is tyloxapol, the

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1 chemical structure of it, and they have correctly noted that  
2 if all you had was this one strand here, you could call that  
3 an ethoxylated octylphenol. But when you engage in chemistry,  
4 to put these linking groups in, to join them together into  
01:03 5 this long, long chain, you have taken it out of that category,  
6 as Dr. Davies will tell us.  
7 They have also cited to us the Schott publication.  
8 This again, due to their courtesy, is one of their slides.  
9 They say that it's CMC, which I wish I remembered, critical  
01:03 10 micelle concentration, which is the concentration which forms  
11 those little balls that we saw on the original slide. They  
12 said it's 4.4 times higher than octoxynol 9.  
13 And what do they say that's good for? They say that's  
14 good in stabilizing emulsions, suspensions, ointments and  
01:03 15 foams, and none of that is bromfenac liquid solution. And the  
16 bottom line, your Honor, is that whether that change would be  
17 good, bad or indifferent in a formulation of the Ogawa type  
18 with bromfenac is entirely unpredictable, as our experts will  
19 testify.  
01:04 20 Q. Just to clean this up, Desai is -- mentions the same  
21 problem of these complexation issues, and what does he do?  
22 Again, the more obvious solution, your Honor, he says let's  
23 change the preservative. Let's put in this Polyquad® instead.  
24 And, as I noted at the outset, our claims exclude that. So  
01:04 25 we're not even in the ballpark of Desai, since all of his

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1 formulations include that.  
2 What does he say? Like a lot of these publications,  
3 he's got a laundry list of things that could be in here. You  
4 can have comfort-enhancing agents, buffers, other  
01:05 5 preservatives, tonicity agents, antioxidants, chelating  
6 agents, complexing agents, and surfactants. And he then gives  
7 a laundry list of surfactant. He's got tyloxapol in there,  
8 yes, but he's got the Cremophor that was so important in one  
9 of those other references. He's got the castor oil that was  
01:05 10 important in another. He's got the polysorbates, which was  
11 Polysorbate 80. There is nothing in there suggesting any  
12 particular benefit in using tyloxapol.  
13 And when you look at his example, what does he have?  
14 He's got no mention -- the drugs he mentions are not bromfenac  
01:05 15 and the ingredients he mentions are not tyloxapol. They are,  
16 in fact, this Vitamin E material that we saw mentioned in the  
17 Sallmann reference.  
18 And then they have the WO 13805 publication which,  
19 amongst us chickens, we've been calling the W 005 publication.  
01:06 20 It's actually directed to a new therapeutic method. Doesn't  
21 purport to be inventing really any new drugs -- well, that's  
22 not quite true. He's got a new therapeutic method, and he's  
23 got a gigantic formula of compounds that he can use for it.  
24 And that gigantic formula includes acidic materials like  
01:06 25 bromfenac. And for the compound ones, all he suggests using

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1 is Polysorbate.  
2 And he does have another material, that nepafenac  
3 molecule that we talked about at the outset, where he does  
4 suggest using tyloxapol. And, as we noted at the outset,  
01:06 5 nepafenac is a horse of a different color. It is a prodrug;  
6 it is not itself an active ingredient. It is delivered into  
7 the eye and then converted into something that is active. And  
8 when that ultimately came to market, your Honor, it came to  
9 market not as a solution, like the Ogawa materials, but as a  
01:06 10 suspension.  
11 And, getting even further afield, the defendants have  
12 found a publication that describes treating cystic fibrosis  
13 with tyloxapol, specifically, to avoid damage caused by  
14 hypochlorous acid, and what they have glommed onto is that it  
01:07 15 does that by inhibiting oxidation. The suggestion is made,  
16 well, you would have included tyloxapol in the Ogawa  
17 formulations as an antioxidant.  
18 Before you even get to that, the tyloxapol amounts that  
19 are used here, 10 milligrams per milliliter, are 50 times the  
01:07 20 concentration that we use in our invention. Well, it's a big  
21 number times. I'm being told I'm wrong. I think it's 50; he  
22 thinks it's 500. It's a lot more.  
23 And, more importantly, it kind of misses the point.  
24 Ogawa already has an antioxidant in it. That sodium sulfite  
01:07 25 that Ogawa added is an antioxidant. And so there is simply no

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1 motivation to go add tyloxapol as another.  
2 And, perhaps more importantly, the literature uniformly  
3 recognizes tyloxapol is not the recognized antioxidant in this  
4 field.  
01:08 5 We saw the Sallmann reference they rely upon. He  
6 knows about tyloxapol. He calls it a solubilizer. When he  
7 gets down to antioxidants, he mentions entirely different  
8 molecules.  
9 When we see the Yasueda publication, he knew about  
01:08 10 tyloxapol. He calls it a surfactant. When he gets down to  
11 antioxidants, he mentions entirely different molecules.  
12 And, frankly, your Honor, there is even an old, old,  
13 old publication from 1978 that suggests that, you know, this  
14 class of molecules that have these polyoxyl ethylene tails in  
01:08 15 them, which would include both Polysorbate 80 and tyloxapol,  
16 they might actually undergo reactions that might actually  
17 generate things that are oxidizers, whereby, if anything, the  
18 message is mixed on these as antioxidants. And, in any event,  
19 that teaching in 1978 certainly didn't dissuade people from  
01:09 20 using Polysorbate 80, as we saw in Ogawa, in the WO 13805  
21 publication, in Yasueda, in Yanni, and in Desai.  
22 So the bottom line, your Honor, is we feel that the  
23 evidence, in its entirety as a whole, without the aid of  
24 hindsight, simply does not suggest to a person of ordinary  
01:09 25 skill in the art to use tyloxapol in the Ogawa-type

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1 formulations; that, certainly not at .02 percent, certainly  
2 doesn't predict the cascade of benefits that flow from it.  
3 And our evidence will show that the defendants have failed to  
4 carry their burden of proof on the obviousness issue.

01:09 5 There is one more issue. They have an allegation of  
6 double patenting, obviousness-type double patenting. And this  
7 flows from the simple fact that the '431 patent being the  
8 first to issue was awarded, by statute, 604 days of patent  
9 term adjustment, under a statute that Congress passed to  
01:10 10 accommodate United States patent owners in connection with the  
11 change from the 17-year-from-issue patent term to the  
12 20-year-from-filing patent term that was needed to conform our  
13 system to the rest of the world. And that is a statutory  
14 right that Congress has granted.

01:10 15 And the evidence will show that the judge-made law of  
16 double patenting, whatever it might apply to, cannot be  
17 applied to abrogate a statutory right.

18 So, your Honor, you have been very patient. Thank  
19 you very much. We look forward to presenting our case. It  
01:10 20 will be awhile until we get to the substance since I believe  
21 the defendants will go first, after we have a presentation  
22 about the patent and the products that are at issue.

23 THE COURT: Okay. Thank you very much.

24 Is there anyone who needs a break? No?

01:10 25 All right. Then Ms. Holland.

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1 a twice -- was marketed, I should say, as a twice -- a  
2 once-a-day product, whereas Bronuck® and Xibrom® were  
3 twice-a-day products.

4 At the same time that plaintiffs put Bromday® on the  
01:13 5 market, they discontinued the Xibrom® product, and you'll hear  
6 a little bit more about this during Mr. Mukerjee's  
7 presentation, his opening, after I'm done.

8 In 2013, plaintiffs put the Prolensa® product on the  
9 market, the product that we are here to talk about at this  
01:13 10 trial. It is essentially the same formulation as what came  
11 before it as Bronuck®, as Xibrom®, as Bromday®, with the  
12 simple substitution of tyloxapol for Polysorbate 80.

13 Now, I heard Mr. Lipsey in his opening say that,  
14 well, there are the generics, you know, on the market. What  
01:13 15 are they really complaining about? But the simple fact is  
16 that when plaintiffs put Prolensa® on the market, they  
17 discontinued Bromday®. So the fact that there may be a  
18 generic to Bromday® really has no commercial meaning because  
19 there is no product on the market for it to be generic to.  
01:14 20 There is no substitution that can take place if there is no  
21 brand products on the market.

22 Let me now turn to the claims that are at issue here  
23 in this case, and, as Mr. Lipsey said, the essential parts of  
24 these claims are they're all formulation claims, and they have  
01:14 25 the active ingredient bromfenac sodium, the inactive

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1 MS. HOLLAND: Good morning, your Honor. We are going  
2 to similarly pass out binders with the opening slides.

3 THE COURT: Thank you.

4 MS. HOLLAND: Before I start, your Honor, I would like  
01:11 5 to introduce the Lupin representatives who are here in the  
6 courtroom today. First of all, Ms. Minaksi Bhatt, who is a  
7 Vice President of Intellectual Property at Lupin; and then  
8 Ms. Akanksha Kulcarni, who is in the IP Group in Lupin in  
9 Pune, India, who actually came in for the trial.

01:11 10 THE COURT: Welcome.

11 MS. HOLLAND: Your Honor, I would like to start by  
12 putting Prolensa®, the product that Mr. Lipsey talked about as  
13 an embodiment of the claims of the patent-in-suit here, in a  
14 little bit of context.

01:12 15 Bromfenac, you didn't hear about it from Mr. Lipsey,  
16 but this is actually a very old drug. It's been known for  
17 decades. Bromfenac, the active ingredient, was first used  
18 commercially in a product called Bronuck®, which was marketed  
19 in Japan in the year 2000.

01:12 20 Plaintiffs brought that Bronuck® formulation to the  
21 U.S. in 2005, marketed under the name of Xibrom®. Xibrom® is  
22 the exact same formulation as Bronuck®.

23 In 2010, plaintiffs put the Bromday® product on the  
24 market. Bromday®, again, has the same formulation as  
01:12 25 Bronuck®, same formulation as Xibrom®, but it's marketed as

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1 ingredient tyloxapol, and the inactive ingredient benzalkonium  
2 chloride. Now, this is Slide 3.

3 Slide 4, you see the Claim 20 formulation. Again, you  
4 see the active bromfenac; you see the inactives tyloxapol and  
01:14 5 benzalkonium chloride; along with additional list of  
6 excipients.

7 What I want to point out here, your Honor, when you  
8 look at these claims, what you see is that there are no  
9 limitations in these claims as to pH. Mr. Lipsey talked a lot  
01:15 10 this morning about how the pH of Prolensa® is lower than the  
11 pH of the products that had come on the market before it and  
12 how there is, I think, to quote him, a cascade flowing of  
13 benefits from that. But the simple fact is that's nowhere in  
14 the claims here.

01:15 15 So the claims, for example, cover the Prolensa®  
16 product with its pH of 7.8, but they also would cover a  
17 formulation with a pH of 8.3, which is the pH of the prior  
18 bromfenac products that had been on the market.

19 Because any benefit coming from pH, if there is any,  
01:15 20 is not commensurate with the scope of the claims, as a matter  
21 of law, it can't be considered as an unexpected result.

22 With that background, I'm now going to turn to the  
23 substantive arguments about Claim 6 and Claim 20 being obvious  
24 over the prior art.

01:16 25 I'm going to be addressing defendants' case-in-chief

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1 on invalidity, and then Mr. Mukerjee, InnoPharma's counsel, is  
 2 going to address a rebuttal's case on secondary  
 3 considerations.  
 4 Our case-in-chief is going to be presented by our  
 01:16 5 formulation expert, Professor Jayne Lawrence, and Professor  
 6 Lawrence is in the courtroom this morning, Your Honor.  
 7 THE COURT: Welcome.  
 8 MS. HOLLAND: Professor Lawrence is a Professor of  
 9 Biophysical Pharmaceutics at Kings College in London. At the  
 01:16 10 same time, she holds an appointment as chief scientist of the  
 11 Royal Pharmaceutical Society. She is a well-known expert in  
 12 formulation and drug delivery, and, importantly, collaborates  
 13 with pharmaceutical companies on ophthalmic formulations.  
 14 So, of all the experts you've heard about this morning,  
 01:17 15 your Honor, Professor Lawrence has the right experience and  
 16 the right expertise to address the issues in this case, which  
 17 are not chemistry issues. These are not chemistry patents.  
 18 These are formulation patents, and, particularly, formulation  
 19 of ophthalmic compositions.  
 01:17 20 So, as Professor Lawrence will explain, the claimed  
 21 formulations here are nearly identical, very, very close to  
 22 the prior art bromfenac formulations.  
 23 And what I have on Slide 7, on the left column, you see  
 24 the formulation of the '225 patent, Example 6. '225 patent  
 01:17 25 was referred to as Ogawa by Mr. Lipsey.

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1 And sorry about that, your Honor, but we've tended to  
 2 refer to these by numbers and plaintiffs have tended to refer  
 3 to them by names, but it's -- the '225 and Ogawa are one and  
 4 the same.  
 01:18 5 Example 6 of the Ogawa patent -- and Mr. Lipsey agreed  
 6 with this in his direct examination -- is the formulation of  
 7 the Bronuck®, Xibrom®, and Bromday® products.  
 8 On the right you see the formulation of Claim 20 of the  
 9 '431 patent, the patent-in-suit in this case. It's the  
 01:18 10 formulation of the Prolensa® product.  
 11 And as you see, the difference, the sole difference  
 12 between the two is that the prior art formulation has  
 13 Polysorbate 80 and the '431 patent has tyloxapol.  
 14 You may notice in the columns, there are some wording  
 01:18 15 differences. So, the '225 patent says borax, whereas the '431  
 16 patent says sodium tetraborate. But there is no dispute here  
 17 that those are one and the same, and that the only difference  
 18 is between Polysorbate 80 and tyloxapol.  
 19 THE COURT: So the '431 -- I'm sorry. The Prolensa®  
 01:18 20 manifestation contains sodium sulfite?  
 21 MS. HOLLAND: It does.  
 22 THE COURT: I thought that Mr. Lipsey had said it  
 23 does not.  
 24 MS. HOLLAND: He -- yes, I was confused about that as  
 01:19 25 well, your Honor. It certainly contains sodium sulfite. I

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1 believe what Mr. Lipsey said is that potentially, you could  
 2 find a formulation that doesn't, but that's not what happens  
 3 here. The claims here do have the sodium sulfite.  
 4 MR. LIPSEY: The point I made on that chart was, if  
 01:19 5 desired, you could eliminate the sulfite.  
 6 THE COURT: I see.  
 7 MR. LIPSEY: I did not mean to imply it was not  
 8 there.  
 9 MS. HOLLAND: Apparently, it either wasn't desired or  
 01:19 10 wasn't -- or plaintiffs weren't able to do it, because it is  
 11 in the Prolensa® product.  
 12 Can we put up -- Mr. Cort, can we put up one of the  
 13 demonstratives that Mr. Lipsey used this morning? It's  
 14 PDX1-4.  
 01:19 15 Your Honor, Mr. Lipsey this morning started out his  
 16 presentation by talking about all these challenges that he  
 17 called -- as he called them, in topical ophthalmic  
 18 formulation, but when you look at the list, the inventors of  
 19 the patents-in-suit in this case didn't have any of those  
 01:20 20 challenges because they had all been resolved by the prior  
 21 art, Ogawa '225 patent, and the commercial products that were  
 22 the embodiment of the inventions in that patent.  
 23 Those products -- Bronuck®, Xibrom®, Bromday® -- they  
 24 were all safe and effective ophthalmic compositions. They  
 01:20 25 were clinically effective active ingredients. They had the

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1 appropriate ocular penetration. They maintained that  
 2 penetration in the eye. To the extent there was any  
 3 irritability, stinging, burning, it was at a very, very  
 4 extremely low level. And this is something Mr. Mukerjee is  
 01:20 5 going to get into a bit later in his presentation. And  
 6 they -- and they were chemically and physically stable at the  
 7 pH of 8.3 that existed -- in which they went on the market.  
 8 Let's concentrate a little bit more then on  
 9 Polysorbate 80 and tyloxapol. As you can see on Slide 8,  
 01:21 10 these are both referred to as nonionic surfactants. A  
 11 surfactant is a surface-active agent. It's a common type of  
 12 excipient or inactive ingredient that's used in pharmaceutical  
 13 formulations. And while they can have different -- while  
 14 surfactants can have different types of functions, they can  
 01:21 15 function, and one important function is as solubilizers, and  
 16 solubilizers are, as the name sounds, agents that increase  
 17 solubility. And both Polysorbate 80 and tyloxapol were known  
 18 in the prior art as solubilizers.  
 19 When they're referred to non- -- as nonionic  
 01:22 20 surfactants, nonionic refers to them having no electrical  
 21 charge, no positive or negative charge. They are neutral  
 22 molecules.  
 23 So why are solubilizers, Polysorbate 80 or tyloxapol,  
 24 why are they used in bromfenac formulations? Well,  
 01:22 25 Dr. Lawrence is going to explain that this is based on the

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1 interaction between the active ingredient, bromfenac sodium,  
2 and the inactive ingredient, benzalkonium chloride.

3 Here on Slide 10, you see benzalkonium chloride is  
4 sometimes referred to as BAC, by shorthand. You'll hear that  
01:22 5 a lot in this trial. It's a preservative, and it's a very  
6 widely used preservative, as Mr. Lipsey acknowledged this  
7 morning, very widely used preservative in ophthalmic  
8 formulations. It prevents microbial growth.

9 And, as Mr. Lipsey said, the eye is one of the most  
01:23 10 sensitive organs in the body. You have to be very careful  
11 about microbial growth.

12 You can imagine when you have a multi-use eyedropper  
13 or container and you're taking them out, putting it in your  
14 eye, putting it back in, there is a good chance for microbial  
01:23 15 growth. So it's really important to include a strong  
16 preservative in the ophthalmic solutions, and that is why BAC  
17 is used so commonly, because it's an excellent preservative.

18 THE COURT: Maybe it doesn't matter, but in practice,  
19 are these administered with a dropper or are they administered  
01:23 20 with kind of a sealed little bottle?

21 MS. HOLLAND: These formulations are multi use. When  
22 you have the multi-use formulation, they are in a little  
23 bottle like, like Prolensa® is. Then it's with an eyedropper.  
24 There are formulations on the market that are those single-use  
01:23 25 vials. But the ones that are the eyedropper type must have a

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1 the "O" on the left-hand side of the molecule. So we refer to  
2 that as an anionic compound, anionic having the negative  
3 charge.

4 If you look now at the BAC molecule, which is the lower  
01:26 5 left-hand portion of the screen, you'll see that it is -- has  
6 the negatively charged chlorine and the positively charged  
7 nitrogen. And BAC is referred to as a cationic compound,  
8 having the positive charge.

9 And you'll see, your Honor, when the BAC and the  
01:26 10 bromfenac -- the cationic and the anionic compounds go into  
11 solution, when they go into solution, what you're left with is  
12 the bromfenac with a negative charge and the BAC with a  
13 positive charge. And, as you may remember from high school or  
14 college chemistry, the negative charge is attracted to the  
01:27 15 positive charge. What happens is they come together and form  
16 a complex, and this is the root of the problem. As you can  
17 see, they are no longer these separate molecules; they're one  
18 complex of the BAC and the bromfenac together with each other.  
19 This is an insoluble complex. In other words, it doesn't mix  
01:27 20 in with the rest of the solution.

21 And if you look on Slide 12, it kind of -- the kind of  
22 little white dots in the beaker there are meant to show these  
23 little complexes that exist in the solution, when they are --  
24 the NSAID and the BAC come together in the complexation.

01:28 25 Now, there are really two problems with this. The  
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1 preservative in them to combat any microbial growth.

2 As you heard from Mr. Lipsey, bromfenac is an NSAID,  
3 a nonsteroidal anti-inflammatory drug. It's also referred to  
4 as an acidic NSAID. The reason for that -- and if you look on  
01:24 5 Slide 11, it's clear, this is the structure of bromfenac.

6 If you look at the left-hand portion, you'll see, in  
7 green, a piece of the molecule that's known as a carboxyl  
8 group. The carboxyl group on bromfenac is what gives it its  
9 acidic name. And bromfenac is just one of a whole class of  
01:24 10 NSAIDs that are called acidic NSAIDs.

11 As you can see on Slide 11, while the structures may  
12 differ a bit from each other, the key point is that they all  
13 have that carboxyl group. That's shown in green on each of  
14 these molecules.

01:25 15 And, your Honor, sometimes you may see that in, either  
16 during testimony or in the prior art, as a COOH group. That's  
17 the same thing as a carboxyl group. And this is really the  
18 key to the issue between bromfenac and BAC when they go into  
19 solution.

01:25 20 So now on Slide 12, what I've displayed here is  
21 bromfenac. Again, the upper right-hand corner, circled in  
22 green on that molecule, you'll see a carboxyl group.

23 When bromfenac goes into solution, the positive H,  
24 hydrogen, is separated from the molecule, and it's left with a  
01:26 25 negative charge, as you can see there, next to the oxygen or

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1 first is you lose some of the effect of the active ingredient  
2 because the active ingredient that's part of the insoluble  
3 complex is not available to do its job of -- as an NSAID. You  
4 also lose some of the activity of the BAC, the preservative,  
01:28 5 because, again, it's not available to do its job as a  
6 preservative. And this was a well-known issue in the prior  
7 art as I'll show you in a moment; NSAIDs and BACs come  
8 together in solution, they form these complexes, and it  
9 affects both the efficacy and the preservative efficacy.

01:28 10 Now, what I have up on Slide 13 is an excerpt from  
11 the '431 patent itself. It's in the background art section of  
12 the '431 patent specification, which is a section of a patent  
13 that covers what's in the prior art.

14 Mr. Lipsey said a couple of things this morning  
01:29 15 relevant to this slide. First of all, he said that the '431  
16 patent -- we claim that the '431 patent was solving a problem  
17 that didn't exist. Well, as you see, your Honor, the '431  
18 patent inventors acknowledged that this problem exists in  
19 the prior -- existed in the prior art.

01:29 20 As they say right there in the patent specification,  
21 "benzalkonium chloride is a widely used preservative in  
22 ophthalmic solutions." Mr. Lipsey agreed with that this  
23 morning. Then they say, "However, benzalkonium chloride and  
24 other quaternary ammonium compounds are generally considered  
01:29 25 to be incompatible with ophthalmic compositions of drugs with

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1 acidic groups, such as nonsteroidal anti-inflammatory drugs.  
 2 And, as you see, your Honor, this is known about the  
 3 class of acidic NSAIDs in general. This was a problem that  
 4 was widely known among formulators in the art to exist between  
 01:30 5 any of the NSAIDs on this class of acidic NSAIDs and BAC.  
 6 And, just as I explained a minute ago, your Honor,  
 7 what the inventors of the patent said in their patent is that  
 8 these preservatives, in other words, BAC, lose their ability  
 9 to function as they form complexes with the charged drug  
 01:30 10 compounds.  
 11 So, contrary to what Mr. Lipsey said, the inventors  
 12 were clearly aware of this problem and clearly were concerned  
 13 about it in terms of bromfenac ophthalmic compositions.  
 14 Mr. Lipsey also said that defendants say that all  
 01:31 15 these acidic NSAIDs are fungible but that plaintiffs focus on  
 16 the differences.  
 17 Well, I submit, your Honor, it's not that defendants  
 18 say they're fungible. When you look at the prior art, they're  
 19 treated as a class. None of the prior-art references you're  
 01:31 20 going to see today make any distinction by structure of the  
 21 NSAID as to whether or not it would be expected to form a  
 22 complex with BAC.  
 23 On Slide 14, I listed just some of the references in  
 24 the prior art that make it clear that the NSAID BAC problem,  
 01:31 25 complex section problem, was well known as of 2003. And as  

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1 the activity of the active ingredient, just as I said a minute  
 2 ago.  
 3 Two problems: One is the preservative is not able to  
 4 perform its function; second problem, the active reduces its  
 01:33 5 activity because it becomes part of the complex.  
 6 The solution provided by the EP 984 reference was to  
 7 include, as you can see in the bottom portion of Slide 15, the  
 8 solution, as you can see it in Claim 1, was to include within  
 9 the formulation a stabilizing amount of nonionic ethoxylated  
 01:34 10 octylphenol surfactant.  
 11 I know you've heard that term already from Mr. Lipsey  
 12 this morning. And Mr. Lipsey actually was kind enough to put  
 13 our slide up on there to show you exactly why tyloxapol is an  
 14 ethoxylated octylphenol.  
 01:34 15 But before I get there, I want to show you one more  
 16 teaching from the EP 984 patent, which is on Slide 16.  
 17 On Slide 16, you see Example 5 of EP 984. And what  
 18 Example 5 shows is testing that was conducted comparing  
 19 Octoxynol 40, the ethoxylated octylphenol compound, with Tween  
 01:34 20 80. Tween 80 is another name for Polysorbate 80. That's not  
 21 something that's in dispute.  
 22 And what EP 984 showed was that when you used octoxynol  
 23 40, the ethoxylated octylphenol compound, and you substituted  
 24 it for Polysorbate 80, the solutions remained clear under all  
 01:35 25 the test conditions.  

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1 you see, these references, again, they're not talking about  
 2 specific NSAID compounds and saying that the problem only  
 3 applies to ketorolac or it only applies to diclofenac. These  
 4 acidic NSAIDs are being handled as a class.  
 01:31 5 Benzalkonium chloride is generally considered to be  
 6 incompatible with NSAIDs. NSAIDs tend to form insoluble  
 7 complexes with benzalkonium chloride. Acidic drugs with  
 8 carboxyl groups tend to form insoluble complexes with BAC.  
 9 Benzalkonium chloride is considered to be incompatible with  
 01:32 10 anionic drugs. As we saw earlier, your Honor, bromfenac is an  
 11 anionic drug, and they form insoluble compounds, and on and  
 12 on.  
 13 So the suggestion that the formulators or the authors  
 14 of the prior art reference in any way understood this to be  
 01:32 15 something that was specific to one or two particular NSAIDs is  
 16 simply incorrect and inconsistent with the prior art.  
 17 Now, you heard from Mr. Lipsey that one of the key  
 18 prior art references here is the EP 984 reference. And the  
 19 reason this is so key is because it provided the solution to  
 01:32 20 this NSAID BAC complexation problem.  
 21 As you can see, on Slide 15, the EP 984 reference  
 22 identified the problem here. Anti-inflammatory solutions of  
 23 NSAIDs are incompatible with BAC due to the fact that the  
 24 carboxyl group forms a complex with the BAC, rendering the  
 01:33 25 preservative less available to serve its function and reducing  

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1 When you look at the Polysorbate 80 column in the  
 2 middle, what you'll see is that the solutions were either  
 3 turbid or very turbid, meaning that these insoluble complexes  
 4 had formed into the solution and made them cloudy.  
 01:35 5 So the EP 984 reference tells the person of ordinary  
 6 skill in the art, as Professor Lawrence is going to explain,  
 7 that if you have concerns about -- with a problem of  
 8 complexation between an NSAID and BAC, substitute in an  
 9 ethoxylated octylphenol surfactant for Polysorbate 80 and you  
 01:36 10 can clear up the complexation issue.  
 11 On the subject of whether tyloxapol is an ethoxylated  
 12 octylphenol, as you can see on Slide 17, and as Professor  
 13 Lawrence is going to explain, tyloxapol has this octylphenol  
 14 portion along with the ethoxylated portion and they are simply  
 01:36 15 strung together, but they have that octylphenol portion and  
 16 the ethoxylated portion, and they would be considered, by  
 17 persons of ordinary skill in the art, by formulators, as  
 18 ethoxylated octylphenol compounds.  
 19 Professor Lawrence is going to explain that there  
 01:37 20 were only two ethoxylated octylphenol surfactants that were  
 21 approved for ophthalmic use in the FDA Inactive Ingredient  
 22 Guide as of 2003. And this is on Slide 18.  
 23 And this is absolutely critical, your Honor. If you're  
 24 a formulator, not a chemist like Dr. Davies, but somebody who  
 01:37 25 is actually working in the field of formulation, what you know  

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1 is that you want to use inactive ingredients that are already  
2 listed in the FDA's Inactive Ingredient Guide. The guide  
3 tells you which inactive ingredients have previously been used  
4 in pharmaceutical products; and it actually goes down to tell  
01:37 5 you that they are used in ophthalmic products.

6 So although Mr. Lipsey said that there were a large --  
7 that Dr. Davies, the organic chemist, is going to tell us that  
8 there were a large number of choices of surfactants,  
9 formulators know that that's simply not the case. You are  
01:38 10 going to be looking for something that was already listed in  
11 the Inactive Ingredient Guide.

12 And, as you can see here, the only two ethoxylated  
13 octylphenol surfactants that have been listed are tyloxapol  
14 and Octoxynol. Tyloxapol had been used nine times versus one  
01:38 15 time for Octoxynol.

16 So, once the formulator understands that they want to  
17 use an ethoxylated octylphenol as taught by the '984 patent,  
18 and as Dr. Lawrence will explain, there were two choices,  
19 Octoxynol 40 and tyloxapol, the prior art Schott reference  
01:38 20 actually gives a little bit more information on making -- to  
21 the formulator as when they're making their choice between  
22 these two ethoxylated octylphenols.

23 Schott says the fact that the CMC, the critical micelle  
24 concentration, is 4.4 times smaller than Octoxynol is an  
01:39 25 advantage. Why is it an advantage? Because you can use

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1 surfactants at a lower level without compromising the  
2 effectiveness. So there is a teaching there in the Schott  
3 reference that tyloxapol could potentially be used at a lower  
4 level in a formulation than octoxynol because it has 4.4 times  
01:39 5 smaller critical micelle concentration. And, again, this will  
6 be explained by Professor Lawrence.

7 THE COURT: Now, back on Slide 18 for a moment.  
8 That's your prior one, okay?

9 MS. HOLLAND: Yes.

01:39 10 THE COURT: You see the potencies or concentrations  
11 of the tyloxapol. Mr. Lipsey argued that those are  
12 two-and-a-half to five times more than the 0.02 percent that  
13 was the breakthrough. Is your witness going to be speaking to  
14 whether that distinction matters?

01:40 15 MS. HOLLAND: Yes, your Honor. And what you'll hear  
16 is that when an active -- when an inactive ingredient is  
17 listed in the inactive ingredient guide, you'll hear it  
18 referred to as the IIG. When it's listed in the IIG, it gives  
19 you the percentage that it had previously been used in other  
01:40 20 ophthalmic compositions.

21 And if you want to go higher than that percentage, it  
22 may be an issue because you'd have to perform additional  
23 toxicity, toxicological testing, to confirm the safety. But  
24 if you're going below the use that had come previously, there  
01:40 25 really isn't any issue. You don't have to perform any extra

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1 testing. And at that point it's just a matter of routine  
2 optimization for the formulator, as Dr. Lawrence is going to  
3 explain.

4 So, your Honor, what do plaintiffs say here? What  
01:41 5 did Mr. Lipsey say this morning?

6 You heard that they are going to put an organic chemist  
7 on the stand and rely on his testimony to show, basically, why  
8 the chemistry in this case, according to him, is very  
9 complicated. But the simple fact is this is not a case about  
01:41 10 chemistry. These patents are about formulations. The right  
11 expert to tell you what would be obvious to a formulator is a  
12 formulator.

13 But, as you saw in the examples for the prior art  
14 about NSAID BAC complexation, while an organic chemist may  
01:41 15 tell you there are a lot of differences in these molecules, a  
16 formulator, like Professor Lawrence -- and the formulators in  
17 the prior art acknowledge that they treat them as a class.

18 And if you look on Slide 20, perhaps there is no  
19 better evidence of that than from a treatise called  
01:42 20 Remington's, which formulators refer to as the bible of  
21 pharmaceutical science. It's the key reference that  
22 formulators rely on when they're looking to formulate a  
23 compound.

24 And this is from Remington's, the edition that was in  
01:42 25 use as of 2003. What you see is there is an entry for

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1 quaternary ammonium compounds, and benzalkonium chloride is  
2 noted as being a typical quaternary ammonium compound and by  
3 far the most common preservative used in ophthalmic  
4 preparations. Over 65 percent of these formulations are  
01:42 5 preserved with benzalkonium chloride. So, clearly, a person  
6 of ordinary skill in the art knows they want to use  
7 benzalkonium chloride. It's a very effective preservative.  
8 It's in 65 percent of ophthalmic formulations.

9 What else does the person of ordinary skill in the  
01:43 10 art know, according to Remington's?

11 Well, as you see on the second blowout for  
12 Remington's, as a cationic surface active material of high  
13 molecular weight, it is not compatible with anionic compounds.  
14 Again, as a class, it is not compatible with anionic  
01:43 15 compounds. Anionic, as we saw earlier, negatively charged  
16 compounds like bromfenac.

17 So what does that mean to the formulator? How did  
18 they deal with that issue? They want to use the BAC but they  
19 know that it's not compatible with acidic NSAIDs like  
01:43 20 bromfenac.

21 Well, what Remington says is, given the alternative,  
22 it would be preferable to modify a formulation to remove the  
23 incompatibility rather than include a compatible but less  
24 effective preservative.

01:44 25 In other words, formulator, what you should be doing,

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1 use BAC in your -- in your ophthalmic formulation. You don't  
2 want to include something less effective, but just modify the  
3 formulation to remove the incompatibility.

01:44 4 And as we saw, the '984 patent already told the  
5 formulator exactly how to do that -- using ethoxylated  
6 octylphenol compounds, problem solved.

7 Now, as I said a moment ago, this is a case about  
8 formulation science. It's not about chemistry. It's not  
9 about showing how molecules are really complicated. But to  
01:44 10 the extent that Dr. Davies is going to be discussing some of  
11 the chemistry to try to show how complicated it is, we will be  
12 presenting testimony from Dr. Clayton Heathcock. You can see  
13 his credentials on DDX-121. He's a really preeminent organic  
14 chemist in the U.S. He's the Emeritus Professor at the  
01:45 15 University of California Berkeley. He's former Dean of the  
16 College of Chemistry. He wrote one of the classic  
17 undergraduate textbooks on organic chemistry, *Introduction to*  
18 *Organic Chemistry*, and he's been the editor of many very  
19 prestigious journals in field -- *Journal of Organic Chemistry*  
01:45 20 and *Organic Syntheses*.

21 So he will be testifying to rebut some of the chemistry  
22 issues that Dr. Davies may bring up in his testimony.

23 THE COURT: I imagine a lot of tears were spilled  
24 over his organic chemistry tests by undergraduates, including  
01:45 25 my roommates who were premed.

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1 MS. HOLLAND: Well, yes, your Honor, I bet if you  
2 asked them, that would be exactly the case.

3 And one thing in particular that Dr. Heathcock is going  
4 to point out in his testimony, coming back again to this point  
01:46 5 of acidic NSAID, is that, yes, the structures may be a little  
6 different; however, the important part is that they have this  
7 carboxyl group that loses the proton, that loses the hydrogen  
8 in solution, makes it negative, and it becomes attracted to  
9 the BAC. That's the important part of the molecule for these  
01:46 10 purposes.

11 And as you can see, the flurbiprofen, the diclofenac,  
12 the ketorolac -- these are all the specific compounds that  
13 were mentioned in the references that Mr. Lipsey was talking  
14 about -- they don't have the same structure as each other.  
01:46 15 They also differ from each other. But it didn't matter  
16 because the important part of the molecule was that left-hand  
17 part, that carboxyl group. It made them all behave the same  
18 way in solution and be attracted to the BAC molecule.

19 THE COURT: Does that really make sense, though,  
01:46 20 chemically? Because the other structures are different. They  
21 have different ions that are available to -- to interact.

22 MS. HOLLAND: Yes, but what you'll hear, Your Honor,  
23 is that the specific reaction that occurs between BAC and  
24 these acidic NSAIDs is the reaction that occurs at that point  
01:47 25 at the carboxyl group. That's what was -- that's what all

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1 those prior art references are referring to, when they say  
2 acidic NSAIDs generally form complexes with BAC or it's  
3 well-known that they form complexes with BAC. That's the  
4 reaction that's being referred to. So even though they are  
01:47 5 different from each other, they all undergo the same reaction  
6 with BAC.

7 One other thing I wanted to address, Your Honor, is  
8 that one of the things Mr. Lipsey said was that the  
9 solubilities of these different acidic NSAIDs are different  
01:47 10 from each other, and that, you know, that may be the case, but  
11 we're not talking about the solubility here of the acidic  
12 NSAID. We're talking about the solubility of the complex, of  
13 the acidic NSAID attached to the BAC, and that is different  
14 from the solubility of any of these particular NSAIDs if they  
01:48 15 were just on their own in solution.

16 In terms of the percentage of tyloxapol in the '431  
17 patent formulations that Mr. Lipsey talked about this morning,  
18 this -- as Dr. Lawrence is going to explain, this is really  
19 just a matter of routine optimization for the formulator. As  
01:48 20 Your Honor pointed out earlier, there was a range of tyloxapol  
21 used in the prior products, in the IIG, that might be a  
22 starting point for the formulator, but the formulator is going  
23 to do routine optimization, test a few different  
24 concentrations, see what works.

01:48 25 The formulator, a person of ordinary skill in the art  
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1 would know that there were a known range of concentrations for  
2 ethoxylated octylphenol surfactants. As you can see on Slide  
3 24, the EP '984 reference gave a range of concentrations for  
4 its surfactant against the ethoxylated octylphenol surfactants  
01:49 5 ranging from .001 to 1. The .02 falls squarely within that  
6 range.

7 We also know that tyloxapol had been used in NSAID BAC  
8 formulations at a range of concentrations. This is from the  
9 '913 patent, it says the concentration of the solubilizer is  
01:49 10 tyloxapol in that case, is from 0.1 to 5,000 times the  
11 concentration of the actives. So again, you can use tyloxapol  
12 in a range of concentrations and that's really the bread and  
13 butter of the formulator, what they do every day at work is  
14 figure out the right concentration for these inactive  
01:50 15 ingredients in the particular formulation that they're working  
16 on.

17 And then you'll hear from Professor Lawrence that  
18 general pharmaceutical principles dictate using the lowest  
19 amount of surfactant that is compatible with a stable  
01:50 20 formulation. So in other words, if you saw that prior  
21 formulation at .05, but you think your formulation could go a  
22 bit lower than that, that's what formulators do, they figure  
23 out the proper concentration of the inactive ingredients to  
24 make a stable formulation.

01:50 25 So just to sum up on obviousness, Your Honor, this is  
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1 on Slide 28, a person of ordinary skill in the art, a  
2 formulator working on ophthalmic formulations, has the '225  
3 patent, Example 6, as a starting point. The person of  
4 ordinary skill in the art would know that that's the  
01:51 5 formulation of Bronuck, not on the market in the U.S., but a  
6 marketed product in Japan.

7 If you want to improve the physical stability of that  
8 product, the prior art says that there could be a complexation  
9 problem between the bromfenac and the BAC. EP '984 says, I  
01:51 10 can solve that problem by replacing the polysorbate 80 with  
11 the ethoxylated octylphenol surfactant. There were only two  
12 that could potentially be used at that time by formulators.  
13 There was octoxynol 40 and there was tyloxapol. The shot  
14 reference gives some preference to tyloxapol, because of the  
01:51 15 lower CMC value.

16 And then, all that would be left to do by routine  
17 optimization is to tweak the formulation until you get to the  
18 appropriate tyloxapol concentration, and that's it, Your  
19 Honor. That is the patent in this case, which is obvious in  
01:52 20 view of the prior art.

21 Now, before Mr. Mukarjee gets up, I'm just going to  
22 touch on another issue in the case which is obviousness-type  
23 double patenting. Mr. Lipsey spoke about that a bit at the  
24 end of his presentation. Obviousness-type double patenting is  
01:52 25 a judiciously-created doctrine that's meant to prevent

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1 timewise extension of a patent monopoly. It prevents  
2 patentees from patenting the same invention or obvious  
3 variance of the same invention one time after another, and by  
4 doing that, getting longer and longer patent terms for  
01:52 5 essentially the same invention.

6 And as Mr. Lipsey noted this morning, the '431 patent  
7 has a longer patent term, a couple of years longer than the  
8 other patents that had previously been at issue in this case,  
9 the '290 patent and the '131 patent. But as Professor  
01:53 10 Lawrence will explain, the '431 patent Claim 20 and Claim 6,  
11 they are essentially -- essentially obvious variants of the  
12 claims in the '131 and '290 patents, and, in fact, I didn't  
13 hear Mr. Lipsey dispute that fact this morning. He talked  
14 about the patent term adjustment, but he didn't at any point  
01:53 15 say that if the doctrine of obviousness-type double patenting  
16 applies here that the claims of the '431 wouldn't, in fact,  
17 have been obvious over the claims of the '131 and the '290  
18 patent.

19 So in sum, Professor Lawrence will explain to the Court  
01:53 20 that Claims 6 and 20 of the '431 patent are invalid, both for  
21 obviousness and for obviousness-type double patenting.

22 Mr. Mukarjee, InnoPharma's counsel, Your Honor, is now  
23 going to address some of the secondary considerations you  
24 heard about from Mr. Lipsey, unless you have any other  
01:54 25 questions.

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1 THE COURT: No, I don't at this time, Ms. Holland,  
2 thank you very much.

3 MS. HOLLAND: Thank you.

4 THE COURT: Okay. Mr. Mukarjee.

01:54 5 MR. MUKARJEE: Good morning, Your Honor. And thank  
6 you, Elizabeth.

7 Your Honor, as we had stated in the trial logistics  
8 conference about two weeks ago, I'm going to do my best to  
9 keep my comments relatively brief, and what I'd like to focus  
01:54 10 my time on is to discuss the purported secondary  
11 considerations that plaintiffs are alleging in response to or  
12 in rebuttal to the obviousness case that defendants will be  
13 putting forth at trial.

14 Now, as was just stated by my co-counsel, we believe  
01:54 15 that the evidence will show that Claims 6 and 20 of the '431  
16 patent are obvious in light of certain key references, but  
17 certainly, in light of two key pieces of prior art, namely --  
18 and here, Your Honor, I'm going to try to bridge the gap  
19 between the way plaintiffs and Lupin refer to the prior art,  
01:55 20 but they are obvious in light of the Ogawa '225 patent and the  
21 Fu EP '984 patent.

22 Now, as Ms. Holland covered in detail, among other  
23 things, Ogawa generally provides bromfenac in an ophthalmic  
24 solution. And Fu, also among other things, discloses the  
01:55 25 ethoxylated octylphenol surfactant like tyloxapol in the

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1 concentrations outlined in the claims at issue.

2 Taken together, the -- that combination, the  
3 combination of at least those two references, disclosed each  
4 and every limitation of the claims at issue.

01:55 5 Now, the strength of defendant's argument is further  
6 demonstrated by InnoPharma's successful petition to institute  
7 an interparty's review of Claims 6 and 20 of the '431 patent  
8 and for these reasons, we believe --

9 MR. LIPSEY: Excuse me, Your Honor, I'm not sure  
01:56 10 that's admissible in evidence. I think it's a non-final  
11 agency decision. I don't mean to interrupt and I apologize, I  
12 hate it when people do it to me, but just for the record, I  
13 want to lodge that.

14 THE COURT: Right. All right. The objection is  
01:56 15 noted. Has there been any word from the --

16 MR. MUKARJEE: For the PTAB? Yeah. Your Honor,  
17 thank you for asking that question. Actually, as soon as I  
18 finish up at trial here with you, my team and I are heading to  
19 the PTAB because we have our final argument on April 19th to  
01:56 20 specifically argue with respect to the validity of all of the  
21 claims of the '431 patent, obviously, then including Claims 6  
22 and 20.

23 And Mr. Lipsey, while I appreciate what you just said,  
24 you'll also recall that in our meet and confer yesterday, we  
01:57 25 both discussed that openings are not evidence, per se. So

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1 it's -- it just provides some context.  
2 But regardless, for these reasons, Your Honor, we  
3 believe the prior art will evidence that the claims at issue  
4 are invalid.  
01:57 5 Now, Your Honor, we heard from Mr. Lipsey this morning  
6 and it is apparent that among other things, plaintiffs intend  
7 to rely on purported secondary considerations to try to rebut  
8 defendant's obviousness case. Now, up until late last week,  
9 plaintiffs maintained that the so-called commercial success of  
01:57 10 Prolensa rebutted the obviousness of Claims 6 and 20. It now  
11 appears that plaintiffs will not be calling their economist,  
12 Mr. Jarosz, whose opinions were directed to this notion of  
13 purported commercial success. But be that as it may,  
14 plaintiffs continue to allege other secondary considerations,  
01:57 15 namely, industry acclaim, copying and unexpected results.  
16 Your Honor, the evidence will show that like commercial  
17 success before it, none of the secondary considerations can  
18 rebut the obviousness of Claims 6 and 20, and if I may, even  
19 though I know plaintiffs are not calling Mr. Jarosz at trial,  
01:58 20 it certainly seems as if, under the guise of at least copying  
21 an industry acclaim and certainly through the testimony of  
22 their experts, Drs. Trattler and Williams, plaintiffs are  
23 still alleging that Prolensa is a success and they are still  
24 alleging that Prolensa is an improvement over existing  
01:58 25 therapies.

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1 It is that latter point that I'd like to address first  
2 because, Your Honor, the evidence will show that Prolensa is  
3 not being prescribed because it is this improvement over  
4 existing therapies as Mr. Lipsey has alleged.  
01:58 5 In fact, defendants will show that it's not an  
6 improvement at all, rather, what really explains why Prolensa  
7 is prescribed is essentially because of two key things. One,  
8 a general familiarity with the bromfenac compound. A compound  
9 which, Your Honor, has been known for almost four decades.  
01:59 10 And the second reason is because of a campaign by  
11 plaintiffs to extend their exclusivity by making minor and in  
12 some instances no formulation changes to solutions containing  
13 bromfenac.  
14 Now, let's take a closer look at that particular point  
01:59 15 and Ms. Holland actually alluded to it as well.  
16 So, Your Honor, I've put up on the screen DDX-131 and  
17 this slide is in some ways a recap of one of the slides  
18 Ms. Holland touched on earlier, and it shows a timeline  
19 relating to a number of different bromfenac products that  
01:59 20 plaintiffs have marketed and discontinued over the past  
21 decade, and you will note the first date on the left, and  
22 again, I believe Ms. Holland mentioned this, it's -- May 2000  
23 is when plaintiffs launched their first bromfenac product,  
24 Bronuck, in Japan. Plaintiffs then launched the identical  
02:00 25 product under the name Xibrom in the United States in March of

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1 2005.  
2 Now, Xibrom, which was introduced in March 2005 was  
3 covered under the Ogawa '225 patent that Ms. Holland and  
4 Mr. Lipsey spoke about in detail and that I noted in the  
02:00 5 beginning of my opening. And that patent, the Ogawa '225  
6 patent expired in 2009.  
7 Now, why am I mentioning the expiry date? Well, up  
8 until 2009, Xibrom enjoyed patent exclusivity, and so up until  
9 that time, it was not necessarily amenable to generic  
02:01 10 competition or generic substitution.  
11 Now, obviously, it being plaintiff's own patent,  
12 plaintiffs were acutely aware that the Ogawa patent was  
13 expiring in 2009. Now Xibrom is in the market, 2009 comes,  
14 the Ogawa patent expires. Xibrom is now amenable or  
02:01 15 susceptible to generic substitution, generic competition.  
16 So what do plaintiffs do? Well, in December of 2009,  
17 plaintiffs file a supplemental NDA for Bromday, and as  
18 Ms. Holland indicated, Bromday and Xibrom, Your Honor, are  
19 identical formulations, they are the same. The only  
02:01 20 difference between Xibrom and Bromday is with respect to a  
21 change in indication. Xibrom was indicated for twice daily  
22 administration, whereas Bromday was indicated for once-a-day  
23 administration. That is it. From a formulation perspective,  
24 no difference. The only change: Twice-a-day versus  
02:02 25 once-a-day.

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1 For that change, for that change of indication, Bromday  
2 was afforded a three-year regulatory exclusivity. So they  
3 submit -- plaintiffs submit their supplemental NDA in  
4 December 2009; in October 2010, Bromday is approved.  
02:02 5 Now, keep in mind between 2009 and 2010 now, Xibrom is  
6 susceptible to generic substitution. So what do plaintiffs  
7 do? Well, not three months after Bromday is approved in  
8 February of 2011, they discontinue Xibrom. Now, why do I make  
9 mention of that? Well, by discontinuing Xibrom, what  
02:02 10 plaintiffs were effectively able to do was to stop any  
11 automatic generic substitution of that drug.  
12 Up until that point, it would have been automatically  
13 substituted for the generic, but by discontinuing, by  
14 discontinuing the reference listed drug, in this case, Xibrom,  
02:03 15 that was no longer possible. And so what plaintiffs were able  
16 to assure is really the only real bromfenac product in the  
17 market would then be Bromday, which now had this regulatory  
18 exclusivity for another three years which went out all the way  
19 to 2013. So now they've prevented generic competition on  
02:03 20 Xibrom. And now Bromday's on the market.  
21 Well, they're obviously also aware of the October 2013  
22 date. And so as that date is approaching, in June of 2012,  
23 they file the NDA for Prolensa, and Prolensa is approved in  
24 April of 2013. Now Prolensa, just like they did with respect  
02:04 25 to Xibrom, because they recognized that Bromday was soon to be

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1 susceptible to generic substitution, what plaintiffs did was  
2 once again, just four months after Prolensa gets approval,  
3 they discontinue Bromday once again. Again, ensuring that now  
4 their second follow-on product Bromday would also not be  
02:04 5 susceptible to generic substitution.

6 Now, Your Honor, neither Xibrom nor Bromday were ever  
7 discontinued for safety and efficacy reasons. They were  
8 discontinued solely for this particular purpose. They were  
9 discontinued such that plaintiff's market exclusivity could  
02:04 10 continue far longer than the 2009 expiry date of Ogawa. And  
11 that, Your Honor, is the context.

12 That, Your Honor, is the story of why Prolensa is even  
13 in the marketplace. It is not because of all these  
14 incremental benefits that Mr. Lipsey alludes to. It is not  
02:05 15 because Prolensa is a great pharmaceutical discovery or  
16 formulation. It's not because Prolensa is even an incremental  
17 advancement over the prior product. It is simply to maintain  
18 this market exclusivity for as long as possible, an  
19 exclusivity that should have ended in 2009.

02:05 20 Now, Your Honor, plaintiffs don't exactly run away from  
21 this. They openly and publicly acknowledge it. In fact,  
22 actually one thing to note, in August of 2013, Your Honor,  
23 they discontinue Bromday. In that very same month, in  
24 Valeant's quarter of -- Q2 results earnings call, both the CFO  
02:05 25 and CEO of Valeant not only acknowledged this particular

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1 plaintiff's expert, Dr. Trattler -- Dr. Trattler relies on in  
2 support of his opinion were sponsored by plaintiffs.  
3 Incidentally, Your Honor, they don't actually even give  
4 Prolensa much acclaim. What the articles actually state is  
02:07 5 that Prolensa has similar safety and efficacy profiles. It's  
6 not lauding the virtues of Prolensa. So even in articles  
7 sponsored by plaintiffs themselves, they are not lauding that  
8 this is a better or -- a better treatment than Xibrom or  
9 Bromday, or that it was an improvement over Xibrom and  
02:08 10 Bromday. They're just saying it's safe and efficacious.

11 Now, with respect to the allegation of copying, I did  
12 take note of Mr. Lipsey's slide where he had listed all of the  
13 generic filers, and I believe he stated that this in some way  
14 shows that what a great product Prolensa is.

02:08 15 Well, Your Honor, Your Honor is well aware that this is  
16 an ANDA litigation. Any evidence of copying by defendants is  
17 nothing more than defendants simply complying with FDA  
18 regulations requiring that the ANDA product be bioequivalent  
19 to the referenced drug. And in fact, Your Honor, the Federal  
02:09 20 Circuit has expressly recognized that this is not probative of  
21 nonobviousness, and I've put it up in the slide.

22 The Federal Circuit has stated evidence of copying in  
23 the ANDA convex is not probative of nonobviousness because a  
24 showing of bioequivalence is required for FDA approval. And  
02:09 25 it says *Bayer Healthcare versus Watson Pharmaceuticals*, 713 F

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1 mechanism or strategy, but they actually embrace it. Howard  
2 Bradley Schiller, the CFO of Valeant stated on the earnings  
3 call again at the exact time that Bromday was being  
4 discontinued and in the case of Bromday and Lotemax  
02:06 5 suspension, new products have already been launched to sustain  
6 these franchises. We would expect to be able to implement  
7 life cycle management programs to extend the lives of other  
8 franchises as well.

9 And J. Michael Pearson, Valeant's CEO, stated: For  
02:06 10 each of our products that are coming off patent, we are  
11 working on life cycle management products that we can  
12 introduce before the patent expires.

13 This is the real motivation for why Prolensa is in the  
14 marketplace. It is not because of any purported success or  
02:06 15 improvement over prior formulations that plaintiffs are now  
16 alleging as purported secondary considerations.

17 Now, against this backdrop, let's take a look at  
18 plaintiff's allegations that Prolensa has inured industry  
19 acclaim. Now, I know Mr. Lipsey didn't mention as part of his  
02:07 20 opening, industry acclaim, but industry acclaim is set forth  
21 in their pretrial order and industry acclaim is set forth in  
22 their expert reports.

23 The key point there, Your Honor, is that any acclaim  
24 that there is in the record comes from plaintiffs themselves.  
02:07 25 As I've highlighted on the slide, the articles that

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1 3rd 1369.  
2 Your Honor, defendants couldn't agree more. This is an  
3 ANDA litigation. Of course, there are bioequivalency  
4 requirements, and evidence of copying does nothing to rescue  
02:09 5 the claims from being obvious.

6 THE COURT: Wasn't the point somewhat different on  
7 copying, I thought, that if there's really no difference  
8 between Prolensa and its predecessor Bromday, that nothing  
9 prevents the defendants from coming out with generic Bromday  
02:09 10 and as long as it doesn't infringe Prolensa, then you're fine.

11 MR. MUKARJEE: But this is an ANDA litigation and  
12 this is a separate ANDA litigation, Your Honor. And, you  
13 know, that notion -- the fact of the matter is, that there are  
14 -- part of plaintiff's strategy was also to file scattershot  
02:10 15 patent applications, so I don't necessarily find that too  
16 compelling. But also, there is no generic substitution right  
17 now for Bromday, because they discontinued Bromday in the  
18 marketplace. So...

19 THE COURT: There wouldn't be a listed substitution,  
02:10 20 but your client's laboratory could formulate the generic  
21 version of Bromday and sell it, couldn't it?

22 MR. MUKARJEE: But there's no incentive for a generic  
23 or any other, really, pharmaceutical company to do that  
24 because the automatic substitution, Your Honor, is what's --  
02:10 25 what's really needed. That's the driving force. If, if a

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1 doctor has to write down in -- with that level of specificity,  
2 I think effectively, there would be nothing -- there would be  
3 nothing to sell. And, in fact, if you even looked at what  
4 happened to their prior predecessor product sales, like  
02:11 5 Bromday and Xibrom during the short period of time when they  
6 introduced the follow-on product, it went to nothing, it went  
7 to zero. And the same thing here would be the case, too.  
8 So there would be absolutely no incentive for my client  
9 or really any generic filer to be doing that because that  
02:11 10 automatic substitution is important.  
11 THE COURT: And so you would say it's not evidence  
12 that there's a dime's worth of difference between Bromday and  
13 Prolensa.  
14 MR. MUKARJEE: Correct, Your Honor, that is exactly  
02:11 15 right, that is exactly right.  
16 THE COURT: Even if you did generic Bromday and gave  
17 it a jazzy name?  
18 MR. MUKARJEE: Without -- without that automatic  
19 substitution, the jazzy name wouldn't do my client or any of  
02:11 20 the other generic filer clients any good.  
21 THE COURT: Why not? You could advertise it, you  
22 could have doctors go on TV and --  
23 MR. MUKARJEE: In the generic industry, Your Honor,  
24 that automatic substitution is one of the driving forces, the  
02:12 25 driving economic forces, or at least the incentive and that's  
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1 the whole point. I mean, if you really look at it, that's the  
2 whole point of even the Hatch-Waxman Act, right, it's to  
3 introduce these lower price drugs. The whole concept of the  
4 automatic substitution is really an outgrowth of that, it's an  
02:12 5 outgrowth of the fact that the doctor can write this and then  
6 you can get that.  
7 THE COURT: Doesn't that prove the point of my  
8 question? That if your argument is right, nothing prevents  
9 you from introducing that very drug today. You may not enjoy  
02:12 10 the commercial success of borrowing off of Prolensa's name.  
11 MR. MUKARJEE: Right.  
12 THE COURT: But you would have the substance  
13 available on the market at any price that you wanted to set,  
14 you know, within the market, and the patients would have the  
02:12 15 benefit of what you say is everything Prolensa has. You just  
16 wouldn't be able to borrow off the Prolensa name, you know, at  
17 that point.  
18 MR. MUKARJEE: But, but, economically, with Prolensa  
19 -- with Prolensa in the marketplace, so let's -- with Prolensa  
02:13 20 in the marketplace, as the reference-labeled drug out there,  
21 and -- and a generic coming in on a discontinued drug that's  
22 out there, even albeit with a jazzy name, I don't see how  
23 those two would even really be able to effectively be, you  
24 know, comparable certainly in the marketplace. I don't --  
02:13 25 THE COURT: Does ANDA promote comparability, or does  
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1 it promote, you know, the notion that you make a  
2 pharmaceutical breakthrough, you have protection for a limited  
3 period of time, and then it goes into the public domain in an  
4 orderly way.  
02:13 5 MR. MUKARJEE: Right. And that's the way exactly it  
6 should, actually, you know, go. But that is exactly what that  
7 slide that I was going through kind of goes to show, right?  
8 Xibrom came off patent in 2009, and they knew that, and as a  
9 result of that, they filed their supplemental NDA and had the  
02:14 10 same formulation Bromday, changed the indication and was now  
11 able to extend the exclusivity for another three years, even  
12 though it was the exact same formulation as Bromday. And the  
13 same almost can be said with Prolensa, right? They knew the  
14 2013 date was coming to an end. What did they do in 2012?  
02:14 15 They filed the NDA for Prolensa and four months after they  
16 introduced Prolensa into the marketplace, during that interim  
17 time, plaintiffs, what are they doing? Their pharmaceutical  
18 reps are all over the country promoting Prolensa in favor of  
19 Bromday, so that they can now move the Bromday position, so to  
02:14 20 speak, over to Prolensa.  
21 And once that -- once that actually occurs, they  
22 discontinue Bromday, and, therefore, now, inoculate themselves  
23 from the automatic substitution with respect to Bromday.  
24 THE COURT: No, I understand your argument.  
02:15 25 MR. LIPSEY: Excuse me, Your Honor. I've sat very  
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1 patiently listening to this. We had a dispute over what was  
2 going to be in here. This sounds very much like an allegation  
3 of either unfair competition or antitrust violation, that is  
4 unpled, that is unmeritorious and utterly irrelevant to the  
02:15 5 technical patent issues in this case, and I would like to note  
6 my objection to the entire statement to the extent it did not  
7 deal with alleged lack of meaning of our articles, as really  
8 irrelevant to the patent issues in the case, and quite  
9 detrimental to my client and we would move to strike it, Your  
10 Honor.  
11 MR. MUKARJEE: Your Honor, the prolonged conversation  
12 was an outgrowth of the colloquy between the Court and myself.  
13 The slide, the intro slide that I talked about was to also  
14 give context. Mr. Lipsey has extolled the virtues of Prolensa  
02:15 15 and that because of the improvements of Prolensa over prior  
16 formulations, that is why physicians are prescribing Prolensa.  
17 Well, the fact is that that's not correct, and just as  
18 Mr. Lipsey gave context in his view of the facts, as to the  
19 history of the development of Prolensa, defendants have, I'm  
02:16 20 sorry to say, an alternate view and a different story, and  
21 that is exactly the manner in which I presented it to you.  
22 THE COURT: All right. I'm going to consider the  
23 argument for the limited purpose for which I believe it was  
24 originally offered, which is to attempt to demonstrate that  
02:16 25 the plaintiffs have not made a dramatic change in Prolensa,  
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1 and that it allegedly is ---

2 MR. MUKARJEE: Continuing, yeah.

3 THE COURT: -- a continuing marketing strategy, and  
4 much of our discussion was in response to my question about  
02:16 5 copying, and asking you to comment on the point that  
6 Mr. Lipsey had made that if the defendants really believed in  
7 their position, why don't they just market their version of  
8 Bromday.

9 MR. MUKARJEE: Thank you, Your Honor, yes.

02:17 10 Finally, Your Honor, then moving on, finally, I'd like  
11 to address plaintiff's allegations of unexpected results.  
12 Throughout the course of this litigation, plaintiffs have  
13 contended -- throughout the course of this litigation, Your  
14 Honor, plaintiffs have contended that tyloxapol purportedly  
02:17 15 has some unexpected stabilizing effect on bromfenac, and I  
16 believe that Mr. Lipsey said that this stabilizing effect  
17 leads to a wonderful cascade of benefits.

18 But as discussed by Ms. Holland in detail, one of  
19 ordinary skill in the art would know that tyloxapol would have  
02:17 20 this stabilizing effect. And the purported benefits that were  
21 outlined in I believe your -- Mr. Lipsey's Slide 49 would  
22 naturally have flown from this effect.

23 Could we queue up Slide 49? Okay.

24 Your Honor, this was plaintiff's Slide 49 and in fact,  
02:18 25 you will see that while the slide is entitled, benefits

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1 profile, but Your Honor, the problem with that -- could we go  
2 to the next slide?

3 The problem with that, is that Prolensa's pH profile  
4 which has been given so much accolade, was actually disclosed  
02:19 5 in the prior art. So Prolensa has a target pH of 7.8 and the  
6 prior art, namely the Ogawa '225 patent actually discloses a  
7 preferred range of pH 7.5 to 8.4 and in fact, I believe  
8 Mr. Lipsey's slide, PDX-1-24 was a slide where he discussed  
9 the pH and there was a certain portion that was blown up.

02:20 10 Well, the exact line right under that blowup portion  
11 was what I have quoted here in this slide, that it discloses a  
12 preferred pH range of 7.5 to 8.5. So Prolensa's target pH  
13 of 7.8 is squarely within the actual disclosed or preferred  
14 range that the prior art Ogawa has listed.

02:20 15 So there may be, you know, exalting of the virtues of  
16 Prolensa's pH but that pH was well-known.

17 And, Your Honor, if you're looking at plaintiff's slide  
18 deck, if you go to PDX-1-24, there's a blowup, I believe, that  
19 plaintiffs highlighted, and I know that the remainder of the  
02:21 20 patent is in very, very small print, but I can tell you that  
21 literally the next line gives the preferred pH range. And if  
22 -- Elizabeth, do you have a copy of the patent?

23 THE COURT: Well, I'm sure it will be discussed.

24 MR. MUKARJEE: It's there, Your Honor, that I assure  
02:21 25 you. So in any event --

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1 flowing from the use of .02 percent tyloxapol, the evidence  
2 will show that getting to .02 percent is simply the result of  
3 routine experimentation.

4 THE COURT: Point 02.

02:18 5 MR. MUKARJEE: Point 02 percent, I'm sorry, Your  
6 Honor. And further, the vast majority of the so-called  
7 benefits listed in Slide 49 to the extent they even exist,  
8 Your Honor, would be attributable to Prolensa's pH.

9 Now, before I go into Prolensa's pH profile, I'll also  
02:18 10 just add that Mr. Lipsey here has included increased  
11 preservative efficacy as one of the wonderful cascade of  
12 benefits, and I don't believe that either claims -- either of  
13 the claims at issue have any notion of preservative efficacy.  
14 In fact, as Mr. Lipsey had noted and I think Your Honor had  
02:19 15 even noted, we narrowed the issues in this case. So any  
16 claims that dealt with preservative efficacy are no longer at  
17 issue at this trial. But be that as it may, as I said --

18 THE COURT: Aren't you saying because they are not  
19 covered by dependent Claim 6 or 20?

02:19 20 MR. MUKARJEE: They are not covered by Claim 6 or 20,  
21 Your Honor, the entire notion of preservative efficacy is not  
22 there.

23 But again, be that as it may, the vast majority of  
24 these benefits that are listed in Slide 49 is actually, if  
02:19 25 they even exist, would have been attributable to Prolensa's pH

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1 THE COURT: The print is smaller than small.

2 MR. MUKARJEE: I won't ask why it's created that  
3 small on that slide, but in any event, so whatever the virtues  
4 are with respect to Prolensa's pH and whatever benefits flow  
02:21 5 from that pH, well, that was already disclosed. The pH  
6 profile was already well-known, and further as Ms. Holland  
7 stated earlier, the asserted claims, again, much like  
8 preservative efficacy, Your Honor, the asserted Claims 6 and  
9 20 are not directed to any particular pH range.

02:21 10 And while Mr. Lipsey also spoke about Prolensa  
11 absolutely minimizing stinging and burning, although I believe  
12 in the slide, the exact verbiage was that it effectively  
13 eliminates stinging and burning. Stinging and burning had  
14 effectively been eliminated by Xibrom already, Your Honor.

02:22 15 We heard quite a bit about stinging and burning, but  
16 I've put up on the slide, Your Honor, there was a study done  
17 on Xibrom, actually, and that study showed that 1.4 percent of  
18 treated individuals may have experienced burning and stinging  
19 with Xibrom. 1.4 percent. 98.6 percent of the population  
02:22 20 experienced no burning or stinging. And any reduction by  
21 Prolensa in burning -- burning and stinging for at least, at  
22 most, I should say, that insignificant percentage of the  
23 population has no bearing on the obviousness determination.

24 THE COURT: What's the date of this source?

02:23 25 MR. MUKARJEE: Your Honor, I will get that for you

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1 because I can't read the date on the slide.  
2 Your Honor, do you mind if, just at a break, I can  
3 provide --  
4 THE COURT: Aha, you used very small print.  
02:23 5 (Laughter.)  
6 MR. MUKARJEE: Yes. Well, actually, this --  
7 THE COURT: Okay. It's --  
8 MR. MUKARJEE: I'll get it for Your Honor.  
9 But again --  
02:23 10 THE COURT: Would the date matter?  
11 MR. MUKARJEE: Would the date matter on this? No.  
12 THE COURT: Certainly it would have more weight if it  
13 was before 2003, wouldn't it?  
14 MR. MUKARJEE: But the whole notion -- ultimately,  
02:23 15 the point of the study was, well, did people complain -- you  
16 know, one of the things they looked at was with Xibrom, was  
17 there burning and stinging? There was one of plaintiff's main  
18 points, that Prolensa reduced the burning and stinging.  
19 Well -- and according to the slide, they effectively  
02:23 20 eliminated burning and stinging. But Xibrom, according to  
21 this study alone, says that only 1.4 percent of treated  
22 individuals, at most 1.4 percent of treated individuals, even  
23 experienced burning and stinging. That is effective  
24 elimination of burning and stinging.  
02:24 25 And as to your point on the date, Your Honor, I will  
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1 get you that date. But I'm not sure that the date would  
2 necessarily matter, because the study itself is just analyzing  
3 whether or not Xibrom actually resulted in burning and  
4 stinging, and that is actually one of the so-called unexpected  
02:24 5 benefits that plaintiffs purport or allege.  
6 And as Your Honor knows, secondary consideration  
7 evidence doesn't necessarily have to be prior art. So if they  
8 are alleging that, hey, Prolensa is so much better than Xibrom  
9 and it reduces this burning and stinging, with respect to  
02:24 10 secondary considerations, I can come in with evidence showing  
11 that, well, that's not exactly true. In fact, people who were  
12 treated with Xibrom were not experiencing burning and stinging  
13 anyway.  
14 And in any event, Your Honor, defendant's expert,  
02:25 15 Dr. Cykiert will testify that it is impossible to completely  
16 eliminate burning and stinging, which might be the reason why  
17 Mr. Lipsey in the opening said absolutely minimizing, instead  
18 of effectively eliminating, because as Dr. Cykiert puts it,  
19 some patients will always experience some degree of transient  
02:25 20 burning and stinging.  
21 And moreover, Your Honor, and this, to me is very  
22 probative, the record will show that plaintiffs -- while  
23 plaintiffs allege these purported benefits, they never once,  
24 not one time compared Prolensa with Xibrom. They never once  
02:25 25 compared Prolensa with Bromday in a head-to-head comparison.  
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1 You would think that if we are extolling the virtues of  
2 Prolensa, there would be some comparison, Prolensa versus  
3 Xibrom, Prolensa versus Bromday, but that never happened.  
4 Instead, what actually happened was -- any analysis that was  
02:26 5 ever done was Prolensa versus placebo and the reason that that  
6 analysis was done was to simply show that it had the same  
7 safety and efficacy, as, guess what? Xibrom and Bromday.  
8 That was it. No head-to-head comparison whatsoever, and  
9 defendant's expert, Dr. Prausnitz and Dr. Cykiert will testify  
02:26 10 to the probative value of that fact. They will testify as to  
11 what it means, also the fact that they did not put in any  
12 head-to-head comparison.  
13 Now, Dr. Cykiert will also testify that as a  
14 prescribing physician, an ophthalmic surgeon, Prolensa is no  
02:26 15 different from Xibrom or Bromday and, therefore, Your Honor,  
16 at trial, plaintiff's reliance on Drs. Trattler and Williams  
17 will be shown to be unfounded, and in fact, we believe, Your  
18 Honor, that the evidence will show that their opinions related  
19 to unexpected results are conjecture and based on anecdotal  
02:27 20 evidence.  
21 For these reasons, Your Honor, defendants submit that  
22 Claims 6 and 20 of the '431 patent are obvious in light of --  
23 at least, the Ogawa '225 patent and the Fu EP '984 patent.  
24 Moreover, the evidence will show that Claims 6 and 20  
02:27 25 are duplicative of other of plaintiff's patent claims, and  
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1 finally, Your Honor, the evidence will show that none of  
2 plaintiff's purported secondary considerations hold any weight  
3 against defendant's strong prima facie case of obviousness.  
4 Your Honor, the claims are invalid, and we look forward  
02:27 5 to presenting our evidence at this trial. Thank you.  
6 THE COURT: All right, thank you. And Mr. Lipsey.  
7 MR. LIPSEY: May I utter three sentences before we  
8 break for lunch?  
9 THE COURT: Yes, of course.  
02:27 10 MR. LIPSEY: The point I made is that the  
11 formulations of Ogawa that are set out there and that are  
12 embodied in Bronuck, had no stability problem, based on this  
13 reaction between BAC and the active ingredient. They were  
14 clear, they were acknowledged to be stable and commercially  
02:28 15 acceptable. There was no problem of the sort that they found  
16 for ketorolac in food, and, therefore, the food solution, even  
17 if you could translate it from ketorolac to bromfenac was on  
18 its face unnecessary.  
19 Second, the pH matters. The whole point of that  
02:28 20 evidence that I showed you when you tried to operate at pH 7,  
21 you couldn't get to the low pHs with the Ogawa formulations  
22 and that was what the great value of adding tyloxapol was.  
23 And lastly, just as a matter of patent law, so we don't get  
24 too far off the beam here, positive attributes that flow from  
02:29 25 the invention as claimed are perfectly relevant evidence of  
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1 unexpected results and patentability.  
 2 If you have a drug that's claimed as a chemical  
 3 compound and it cures cancer, the fact that it has that  
 4 property is perfectly acceptable evidence.  
 02:29 5 When you have a formulation that allows you to operate  
 6 at a lower pH than the prior art could get to, that's  
 7 perfectly acceptable evidence. When you have a formulation  
 8 which allows you to attain stability that was lower or better  
 9 than you -- preservative efficacy that was lower and better  
 02:29 10 than what you could with the formula -- former formulation,  
 11 perfectly acceptable evidence. And I just wouldn't want the  
 12 trial to go forward at least with the perception that there  
 13 wasn't at least an issue about whether that material was  
 14 relevant to patentability.  
 02:29 15 Thank you very much, Your Honor. The Court has been  
 16 very patient and I will not --  
 17 THE COURT: Do you agree that pH is not part of  
 18 Claims 6 and 20?  
 19 MR. LIPSEY: The formulation that is claimed in 6 and  
 02:30 20 20 can be formulated at a lower pH than the formulations that  
 21 are described in Ogawa, and that difference is a important  
 22 attribute of those formulations, which bears directly on its  
 23 patentability. Need not -- this comes up all the time, people  
 24 say, well, you've had unexpected result as it was cited in the  
 02:30 25 claims. The cases are legion. It doesn't have to be recited  
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1 in the claims, it has to flow naturally from what is in the  
 2 claim.  
 3 MS. HOLLAND: Your Honor, if I could just respond to  
 4 that for a moment.  
 02:30 5 THE COURT: Okay.  
 6 MS. HOLLAND: The way we know that that's not correct  
 7 is that there were a legion of claims in this case with  
 8 specific pH limitations that they've dropped. So it's not  
 9 like there were never any claims here with pH limitations and  
 02:30 10 so Mr. Lipsey is saying, well, it doesn't really matter.  
 11 There were actually claims here that covered the pH of  
 12 Prolensa that are no longer being asserted in this case. So  
 13 we know that there's something about the pH that's different  
 14 from the general claim. If the pH is a dependent claim, it  
 02:31 15 necessarily means that the independent claim is broader and  
 16 includes not only the pH in the dependent claims, but any pH.  
 17 MR. MUKARJEE: And that's precisely right, and that's  
 18 also the same point with preservative efficacy. There was a  
 19 whole host of claims that actually had preservative efficacy  
 02:31 20 requirements and those claims were dropped. And so Ms.  
 21 Holland is exactly right, there were actual claims at issue  
 22 here that had pH, that had a pH range and those were dropped.  
 23 But to answer your question, Your Honor, Claims 6 and  
 24 20 do not have a pH limitation.  
 02:31 25 MR. LIPSEY: The reason --  
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1 MS. HOLLAND: Your Honor, I just note --  
 2 THE COURT: Just a moment. Mr. Lipsey.  
 3 MR. LIPSEY: The reason they were dropped is because  
 4 it was unnecessary to assert those claims in order to assert  
 02:31 5 the patentability deriving from this capability. All it would  
 6 have done was require us to engage in a whole lengthy stream  
 7 of additional infringement proof that would have lengthened  
 8 this trial into something really absurd, and that's the reason  
 9 those are dropped.  
 02:32 10 And the fact that those features may have been  
 11 explicitly recited in other claims does not mean it's not an  
 12 attribute that flows naturally from what is recited in these,  
 13 and that's the standard.  
 14 THE COURT: All right. We're only at the beginning  
 02:32 15 of the trial.  
 16 (Laughter.)  
 17 THE COURT: This is something that the parties will  
 18 have ample chance to explore and to brief, and we will see  
 19 which legion of cases marches into the courtroom.  
 02:32 20 Let's take a break, then, and I think the first witness  
 21 is going to be actually for the plaintiff.  
 22 MR. LIPSEY: Yes, it will be Dr. Williams.  
 23 THE COURT: All right. So let's take a break for  
 24 15 minutes and then we will resume.  
 02:32 25 MR. MUKARJEE: Thank you, Your Honor.  
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1 THE COURT: Oh, it's 12 already? Do you want to take  
 2 a lunch break at this time instead?  
 3 MR. HASFORD: Sure.  
 4 THE COURT: Why don't we break for lunch from now  
 02:32 5 until 1:15.  
 6 (LUNCHEON RECESS; 12:05 p.m.)  
 7 (Afternoon Session)  
 8 (Open Court)  
 9 DEPUTY CLERK: All rise.  
 03:43 10 THE COURT: Be seated, please.  
 11 Good afternoon. Let's proceed.  
 12 MR. HASFORD: Good afternoon.  
 13 Yes, your Honor. Justin Hasford on behalf of  
 14 plaintiffs. May we approach to distribute binders for the  
 03:43 15 next witness?  
 16 THE COURT: Sure.  
 17 MR. HASFORD: Our next witness we'll be calling Dr.  
 18 Robert O. Williams, III.  
 19 THE COURT: Okay. Dr. Williams, please come up to  
 03:43 20 the witness stand.  
 21 (ROBERT O. WILLIAMS, III, HAVING BEEN DULY SWORN AS A WITNESS,  
 22 TESTIFIED AS FOLLOWS:)  
 23 (DIRECT EXAMINATION OF ROBERT O. WILLIAMS, III, BY MR.  
 24 HASFORD)  
 03:44 25 DEPUTY CLERK: Thank you. You can be seated, sir.  
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1 Please speak into the microphone.  
 2 THE COURT: I think you just broke your opponent's  
 3 back.  
 4 MR. HASFORD: I apologize, your Honor.  
 03:44 5 MS. HOLLAND: I'm going to assume it was  
 6 unintentional.  
 7 MR. HASFORD: I agree.  
 8 May we proceed, your Honor?  
 9 THE COURT: Yes.  
 10 BY MR. HASFORD:  
 11 Q. Good afternoon, Dr. Williams.  
 12 A. Good afternoon.  
 13 Q. Would you please state your address for the record?  
 14 A. My address is 2305A West Lake Drive, that's in Austin,  
 03:45 15 Texas.  
 16 Q. Where are you presently employed?  
 17 A. I'm employed at the University of Texas at Austin,  
 18 College of Pharmacy.  
 19 Q. What is your current position at the UT Austin, College  
 03:45 20 of Pharmacy?  
 21 A. Currently I am the Johnson & Johnson Centennial Chair of  
 22 Pharmaceuticals. I also have an appointment as the division  
 23 head of the Division of Pharmaceuticals.  
 24 Q. How long have you been a faculty member at the University  
 03:45 25 of Texas?

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1 Q. Does your curriculum vitae accurately reflect your work  
 2 experience?  
 3 A. Yes, it does.  
 4 Q. Would you please describe your educational background  
 03:46 5 following your graduation from high school?  
 6 A. Yes. So following high school, I earned a Bachelor of  
 7 Science degree in biology from Texas A & M University with  
 8 special honors. I then earned a Bachelor of Science degree in  
 9 pharmacy from the University of Texas at Austin with honors.  
 03:47 10 And then I received my Ph.D. degree from the University of  
 11 Texas at Austin.  
 12 Q. Are you a licensed pharmacist?  
 13 A. I am, yes.  
 14 Q. What is your understanding as a licensed pharmacist of  
 03:47 15 the purpose of the FDA approved package insert that  
 16 accompanies a marketed drug product?  
 17 A. My understanding as a pharmacist is the purpose of the  
 18 label is to convey directions on the approved product that  
 19 were approved by FDA.  
 03:47 20 Q. What, if any, adverse event information is included in  
 21 the FDA approved package insert that accompanies a marketed  
 22 drug product?  
 23 MS. HOLLAND: I'm going to object to this, your  
 24 Honor. As per the conversation we had at the pretrial  
 03:47 25 conference and the Order that followed, this is supposed to be

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1 A. I have been a faculty member since 1995.  
 2 Q. Would you please describe the faculty positions that you  
 3 have held at the University of Texas?  
 4 A. Yes, when I started in 1995, I was assistant professor.  
 03:45 5 And through the years I went up in rank to associate professor  
 6 with tenure and then professor went with tenure.  
 7 Q. Are you currently the division head of the Division of  
 8 Pharmaceuticals?  
 9 A. Yes, I am.  
 03:45 10 Q. In what field do you specialize?  
 11 A. I specialize in the field of pharmaceuticals of design and  
 12 development of drug delivery systems and their  
 13 characterization.  
 14 Q. Does that encompass the design, evaluation, and  
 03:46 15 formulation of drug products?  
 16 A. Yes, it does.  
 17 Q. For how long have you worked in that field?  
 18 A. Since approximately 1986.  
 19 Q. Would you please turn to PTX-165 in your binder and  
 03:46 20 identify that document?  
 21 A. I need a binder.  
 22 MR. HASFORD: Oh, I apologize.  
 23 THE WITNESS: Thank you.  
 24 So PTX-165 is a copy of my curriculum vitae.  
 25 BY MR. HASFORD:

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1 restricted to background on the patent and the products. Now  
 2 I believe we're getting to opinions on what is in the label on  
 3 adverse event.  
 4 MR. HASFORD: If I could respond, your Honor. We are  
 03:48 5 restricting it to background on the patents and the products,  
 6 necessarily the product is accompanied in its marketed form by  
 7 package insert. I'm merely asking Dr. Williams a background  
 8 question about what type of adverse event generally is  
 9 included in the FDA approved package insert.  
 03:48 10 THE COURT: All right. I understand. It's only for  
 11 background and it's just a question or two.  
 12 BY MR. HASFORD:  
 13 Q. Do you need me to repeat the question, doctor?  
 14 A. Yes.  
 03:48 15 Q. What, if any, adverse event information is included in  
 16 the FDA approved package insert that accompanies a marketed  
 17 drug product?  
 18 A. In the product label there is a section on adverse events  
 19 that were approved by FDA.  
 03:48 20 Q. You testified that you have a Ph.D. in pharmaceuticals.  
 21 What did you do after completing your Ph.D.?  
 22 A. Following completion of my Ph.D., I worked in the  
 23 pharmaceuticals industry for about nine years.  
 24 Q. At what companies in the pharmaceuticals industry did you  
 03:49 25 work?

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1 A. I worked at, first of all, at Eli Lilly & Company where I  
2 was responsible for development of liquid and solid dosage  
3 forms. I then worked at a company called Duramed  
4 Pharmaceuticals, again I was responsible for development of  
03:49 5 liquid and solid and semisolid dosage forms. And then I  
6 worked at a company called Rhone-Poulenc Rorer, which is now a  
7 part of Sanofi, and at that time I worked on development of  
8 liquids and semisolids and inhaled products, as well as solid  
9 pharmaceutical dosage forms.

03:49 10 Q. Did your work in the pharmaceutical industry include  
11 formulation work on aqueous liquid preparations?  
12 A. Yes.

13 Q. Have you founded or cofounded any pharmaceutical  
14 companies?  
03:50 15 A. Yes, I have.

16 Q. What were those?  
17 A. I cofounded a company called PharmaForm in 1996, which  
18 was a development services company that did product  
19 development and analytical development for a variety of  
03:50 20 pharmaceutical companies around the world. And then I  
21 cofounded a company called Enavail, which was a service  
22 company that specialized in particle engineering for a variety  
23 of different platform technologies.

24 Q. What courses have you taught at the University of Texas  
03:50 25 at Austin?

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1 A. So I teach several courses to the PharmD students, so  
2 these are in their first professional year. I teach a course  
3 called pharmaceuticals, which is generally a course on dosage  
4 form, design dosage form just generally. To graduate students  
03:50 5 I teach four courses, there's three graduate courses that are  
6 in -- that cover various aspects of dosage form development,  
7 characterization, and manufacturing science. And then I teach  
8 a fourth course that deals with pharmaceutical  
9 entrepreneurship.

03:51 10 Q. Have you conducted any research?  
11 A. I have, yes.

12 Q. Would you please describe your research?  
13 A. So my research generally involves the development of  
14 liquid, semisolid, and solid dosage forms, it could be  
03:51 15 administered by a variety of routes of administration.

16 Q. Has your research encompassed work on aqueous liquid  
17 preparations?  
18 A. Yes.

19 Q. Have you published any research articles?  
03:51 20 A. I have.

21 Q. Approximately how many research articles have you  
22 published?  
23 A. I have published approximately 400 peer reviewed papers,  
24 books, book chapters, abstracts during the course of my  
03:51 25 career.

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1 Q. Are your publications listed on your curriculum vitae?  
2 A. Yes, they are.

3 Q. Have you received any honors or awards in connection with  
4 your work?  
03:52 5 A. I have, yes.

6 Q. Would you please briefly describe those?  
7 A. Yes. I was elected Fellow of the American Association of  
8 Pharmaceutical Scientists. I was also elected Fellow of the  
9 American Institute of Medical and Biological Engineering. And  
03:52 10 then I received our university's highest award for teaching,  
11 which is called the Sheffield award.

12 Q. Have you served as an editor for any scientific journals?  
13 A. I have, yes.

14 Q. What journals?  
03:52 15 A. So from 2000 to 2014, I was editor and chief of a Taylor  
16 and Francis Journal called Drug Development and Industrial  
17 Pharmacy. And then beginning late 2014 to present I'm the  
18 editor and chief of a journal called AAPS PharmSciTech, it's  
19 all one word, which is the association -- it's the American  
03:53 20 Association of Pharmaceutical Scientists, it's one of their  
21 three official publications.

22 Q. Have you consulted for both innovator pharmaceutical  
23 companies and generic pharmaceutical companies?  
24 A. Yes, I have.

03:53 25 Q. Have you previously been approved by the court in this

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1 case as an expert in the field of the design, the evaluation,  
2 and formulation of drug products encompassing pharmaceutical  
3 formulation and pharmaceutical development?  
4 A. My understanding is I was, yes.

03:53 5 MR. HASFORD: Your Honor, at this time plaintiffs  
6 offer Dr. Williams as an expert in the field of the design,  
7 evaluation, and formulation of drug products encompassing  
8 pharmaceutical formulation and pharmaceutical development.

9 THE COURT: Any objection or do you wish to *voir*  
03:53 10 *dire*?  
11 MS. HOLLAND: No, your Honor.

12 THE COURT: Okay. The Court will recognize Dr.  
13 Williams as an expert in the fields in which he's offered.

14 MR. HASFORD: Thank you.

03:53 15 MR. MUKERJEE: Your Honor, may I ask one logistical  
16 question? Can we perhaps make it such that -- I don't want a  
17 situation where every time there's an objection made  
18 necessarily that Innopharma would have to stand up and say  
19 same objection or vice versa, so perhaps we could, just for  
03:54 20 simplicity, make it if one defendant makes an objection,  
21 unless otherwise noted the objection carries for both  
22 defendants. Would that work with your Honor?  
23 THE COURT: Okay. Do the plaintiffs have any  
24 objection?  
03:54 25 MR. HASFORD: We have no objection to that, your

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1 Honor.

2 THE COURT: All right. So it will be understood that

3 if an attorney for either defendant makes an objection, that

4 it will be deemed an objection by all defendants. Unless for

03:54 5 some reason you wish to distinguish yourself from their

6 objection and not assert it, in which case you'll have to rise

7 and say so.

8 MR. MUKERJEE: Correct, your Honor. And, again, my

9 apologies for interrupting.

10 BY MR. HASFORD:

11 Q. Let's now discuss the patent-in-suit. Would you please

12 turn to JTX-1 in your binder and identify that document?

13 THE COURT: Excuse me, are you offering his

14 curriculum vitae into evidence?

03:54 15 MR. HASFORD: Oh, I'll be offering all these into

16 evidence. As your Honor will recall --

17 THE COURT: That's right, at the end.

18 MR. HASFORD: -- we will offer it at the end.

19 THE WITNESS: So JTX-1 is a copy of U.S. Patent

03:55 20 8,129,431.

21 BY MR. HASFORD:

22 Q. If I refer to U.S. Patent No. 8,129,431 as the '431

23 patent, will you understand what I mean?

24 A. Yes.

03:55 25 Q. Did you review the '431 patent in connection with your

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1 opinions in this case?

2 A. Yes, I did.

3 Q. Would you now please turn to JTX-6 in your binder and

4 identify that document?

03:55 5 A. JTX-6 is a copy of the prosecution history for the '431

6 patent.

7 Q. Did you review the prosecution history of the '431 patent

8 in connection with your opinions in this case?

9 A. Yes, I did.

03:55 10 Q. Please turn back in your binder to JTX-1, which is the

11 '431 patent. What is the title of the '431 patent?

12 A. The title of the '431 patent is **Aqueous Liquid**

13 **Preparation Containing 2-amino-3-(4 bromobenzoyl)phenylacetic**

14 **acid.**

03:56 15 Q. By what other name is 2-amino-3-(4

16 bromobenzoyl)phenylacetic acid known?

17 A. That's known as bromfenac.

18 Q. Who are the named inventors of the '431 patent?

19 A. The named inventors are **Shirou Sawa and Shuhei Fujita.**

03:56 20 Q. Who is the assignee of the '431 patent?

21 A. The assignee is **Senju Pharmaceutical Company.**

22 Q. Based on your review of the '431 patent, did you develop

23 an opinion as to the qualifications of a person of ordinary

24 skill in the art would have with respect to that patent?

03:56 25 A. Yes, I did.

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1 Q. Have you prepared a demonstrative of your opinion with

2 respect to the qualifications of a person of ordinary skill in

3 the art?

4 A. I did.

03:56 5 Q. Let me direct your attention to PTD-2-1 on the screen.

6 What is your opinion regarding a person of ordinary skill in

7 the art with respect to the '431 patent?

8 A. So in my opinion a person of ordinary skill in the art

9 would have a bachelors -- at least a bachelors degree in the

03:57 10 fields of pharmaceutical chemistry, chemistry, or a related

11 discipline, with about three to five years of work experience

12 in the area or a comparable level of education and training

13 and alternatively a comparable level of overall experience in

14 designing, evaluating and/or administering pharmaceutical

03:57 15 formulations obtained by some combination of education such

16 as, for example, a degree in medicine with work experience.

17 Q. Please turn back in your binder to JTX-1, which is the

18 '431 patent. Let me direct your attention again to the paper

19 bearing Bates No. PROL followed by a sting of zeros and then

03:57 20 2, it's the face of the '431 patent. In particular let me

21 direct your attention to the left-hand column under the

22 heading Foreign Application Priority Date. Do you see that it

23 say the Japanese Patent Application No. 2003-12427 was filed

24 on January 21, 2003?

03:58 25 A. I see that, yes.

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1 Q. Were you at least a person of ordinary skill in the art

2 of the '431 patent as of January 21, 2003, according to the

3 definition that you just gave?

4 A. Yes, I was.

03:58 5 Q. On what date did the '431 patent issue?

6 A. The date of the patent is **March 6, 2012.**

7 Q. Let me direct your attention to Column 1 of the '431

8 patent, it's on the next page, and in particular to the

9 section entitled Background Art. Specifically let me direct

03:58 10 your attention to the first paragraph of that section in

11 Column 1 from Lines 24 to 47. What does the chemical

12 structure in Column 1 of the '431 patent depict?

13 A. The patent refers to the chemical structure as being

14 bromfenac.

03:59 15 Q. What type of drug is bromfenac?

16 A. The patent states in -- well, it's a nonsteroidal

17 anti-inflammatory agent it states in Line 40.

18 Q. Is nonsteroidal anti-inflammatory drug also abbreviated

19 NSAID?

03:59 20 A. Yes, it is.

21 Q. According to the paragraph in Column 1, Lines 24 to 47 of

22 the specification of the '431 patent, against what conditions

23 is bromfenac effective?

24 A. So the patent states, really starting about Line 40,

03:59 25 says, "they," and it's referring to bromfenac and salts or

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- 1 hydrates of bromfenac. It says, "they are effective against  
 2 inflammatory diseases of anterior or posterior segment of the  
 3 eye such as blepharitis, conjunctivitis, scleritis, and  
 4 postoperative inflammation in the field of ophthalmology."  
 04:00 5 Q. Let me direct your attention to the bottom of the  
 6 paragraph and in particular to Lines 44 to 45 in Column 1 of  
 7 the '431 patent. Does the '431 patent indicate whether or not  
 8 bromfenac had ever been used previously in eyedrops?  
 9 A. Yes, it does. It states that bromfenac as a "sodium salt  
 04:00 10 has been used in the form of eyedrops." And then it cites to  
 11 a 2001 New Drugs in Japan article.  
 12 Q. Would you please turn to JTX-210 in your binder and  
 13 identify that document?  
 14 A. JTX-210 is a certified translation of the article New  
 04:00 15 Drugs in Japan article.  
 16 Q. Is that the same article cited in Column 1 of the '431  
 17 patent?  
 18 A. It is, yes.  
 19 Q. Did you review JTX-210 in connection with your opinions  
 04:01 20 in this case?  
 21 A. I did, yes.  
 22 Q. Let me direct your attention to the page in JTX-210  
 23 bearing Bates Number PROL 0364735. In particular let me  
 24 direct your attention to the middle row of the box toward the  
 04:01 25 top of the page. I apologize the Bates number should be 732.

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- 1 A. They were, yes.  
 2 Q. What bromfenac products containing polysorbate 80 were  
 3 introduced into the United States market?  
 4 A. As we heard this morning, it was Xibrom® and Bromday®.  
 04:03 5 Q. Is it your understanding that the Xibrom® was introduced  
 6 in 2005?  
 7 A. It is, yes.  
 8 Q. Is it your understanding that Bromday® is was introduced  
 9 in 2010?  
 04:03 10 A. Yes.  
 11 Q. Please turn back in your binder to JTX-1, which is the  
 12 '431 patent, let me direct your attention to Column 1, Lines  
 13 48 to 53. What, if anything, does this paragraph of the '431  
 14 patent disclose about the polysorbate 80 containing eyedrop  
 04:03 15 formulations of bromfenac that we just discussed?  
 16 A. So in this passage in the '431 patent, this is referring,  
 17 it's says, "the eyedrop as mentioned above is designed to  
 18 stabilize bromfenac by means of adding a water soluble  
 19 polymer," and as an example, polyvinylpyrrolidone or polyvinyl  
 04:04 20 alcohol, "and a sulfite." And it mentions sodium sulfite or  
 21 petroleum sulfite and it reference or cites what's been  
 22 referred to this morning as the '225 Ogawa patent for that  
 23 statement.  
 24 Q. Would you please turn to JTX-147 in your binder and  
 04:04 25 identify that document?

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- 1 What product does JTX-210 disclose?  
 2 A. JTX-210 discloses here Bronuck® Ophthalmic Solution and  
 3 Bronuck®.  
 4 Q. Let me direct your attention to the box in the right hand  
 04:01 5 column of the page in JTX-210 bearing Bates No. PROL 0364732,  
 6 in particular let me direct your attention to the second row  
 7 of the box entitled Additives and specifically to additive  
 8 polysorbate 80. What is polysorbate 80?  
 9 A. Polysorbate 80 is a type of surfactant, nonionic  
 04:02 10 surfactant.  
 11 Q. What is a surfactant?  
 12 A. A surfactant is a molecule that reduces interfacial  
 13 tension between two phases, generally used as a wetting agent  
 14 or solubilizer depending on the use.  
 04:02 15 Q. Is a surfactant a compound similar to a soap?  
 16 A. Yes.  
 17 Q. Does it help things dissolve in water that might  
 18 otherwise not be soluble?  
 19 A. It could, yes.  
 04:02 20 Q. What's a nonionic surfactant?  
 21 A. A nonionic means that it's a neutral charge, it's not  
 22 positive or negative but it's neutral when dissolved.  
 23 Q. By further way of background were bromfenac products  
 24 containing polysorbate 80 ever introduced into the United  
 04:02 25 States market?

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- 1 A. JTX-147 is a copy of U.S. patent 4,910,225.  
 2 Q. Is JTX-147 the same United States Patent 4,910,225 that's  
 3 cited in Column 1, Lines 48 to 53, of the '431 patent?  
 4 A. It is, yes.  
 04:04 5 Q. Who is the first named inventor of JTX-147?  
 6 A. Ogawa is the first named inventor.  
 7 Q. If I refer to JTX-147 as the '225 patent or Ogawa patent,  
 8 will you understand what I mean?  
 9 A. Yes.  
 04:05 10 Q. Did you review the Ogawa patent in connection with your  
 11 opinions in this case?  
 12 A. I did, yes.  
 13 Q. Who are the assignees of the Ogawa patent?  
 14 A. The assignees of the Ogawa patent is Senju Pharmaceutical  
 04:05 15 and A.H. Robbins Company.  
 16 Q. Please turn back in your binder to JTX-1, which is the  
 17 '431 patent. Let me direct your attention to Column 2 of the  
 18 '431 patent and in particular to the section entitled  
 19 Disclosure of the Invention. Specifically let me direct your  
 04:05 20 attention to the first paragraph of that section in Column 2,  
 21 Lines 14 through 22. According to the specification of the  
 22 '431 patent, what was an object of the invention?  
 23 A. So it's stated here an object of the intention was an  
 24 aqueous liquid preparation that comprises bromfenac, which is  
 04:06 25 stable within a pH range giving no irritation to eyes, and

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1 when a preservative is included in that aqueous liquid  
 2 preparation such as benzalkonium chloride, the preservative  
 3 effect does not substantially deteriorate over time.  
 4 Q. You mentioned benzalkonium chloride. What is  
 04:06 5 benzalkonium chloride?  
 6 A. Benzalkonium chloride is an example of a cationic  
 7 surfactant.  
 8 Q. Is benzalkonium chloride also a type of preservative?  
 9 A. It is, yes.  
 04:06 10 Q. Is benzalkonium chloride a quaternary ammonium salt?  
 11 A. Yes.  
 12 Q. Is benzalkonium chloride commonly abbreviated BAC, BAK,  
 13 or BKC?  
 14 A. It is in the literature, yes.  
 04:06 15 Q. Let me direct your attention to Column 2, Lines 34 to 47,  
 16 of the '431 patent. According to the specification, how did  
 17 the inventors achieve the objective?  
 18 A. So, as described here, the inventors found that by adding  
 19 what they call an alkyl aryl polyether alcohol type polymer,  
 04:07 20 and the example is tyloxapol, or another type of excipient  
 21 called polyethylene glycol fatty acid ester, such as  
 22 polyethylene glycol monostearate, to that aqueous liquid  
 23 preparation containing bromfenac, that aqueous liquid solution  
 24 becomes stable within pH range giving no irritation to eyes.  
 04:07 25 And it notes that the change in bromfenac over time can be

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1 inhibited. And, furthermore, when the aqueous solution  
 2 contains a preservative, that that preservative effect is  
 3 maintained for a long period of time.  
 4 Q. You mentioned tyloxapol. What is tyloxapol?  
 04:08 5 A. Tyloxapol is an example of a nonionic surfactant.  
 6 Q. Let me direct your attention to the portion of the '431  
 7 patent from Column 4, Line 65, to Column 5, Line 15, and in  
 8 particular to the chemical structure in Column 5. What does  
 9 the chemical structure in Column 5 of the '431 patent depict?  
 04:08 10 A. The chemical structure of the patent states that it's  
 11 tyloxapol.  
 12 Q. Are tyloxapol and polysorbate 80 the same or different  
 13 nonionic surfactants?  
 14 A. They're different.  
 04:08 15 Q. Was tyloxapol used in any of the Bronuck®, Xibrom®, or  
 16 Bromday® formulations?  
 17 A. No.  
 18 Q. What nonionic surfactant was used in the Bronuck®,  
 19 Bromday®, and Xibrom® formulations?  
 04:08 20 A. That would be polysorbate 80.  
 21 Q. Let me direct your attention back to Column 2, Lines 34  
 22 through 47, of the '431 patent. At Column 2, Lines 43 through  
 23 44 of the '431 patent states that the change of the bromfenac  
 24 over time can be inhibited. What does this mean?  
 04:09 25 A. So to the person of ordinary skill in the art, when the

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1 patent states that the change in bromfenac over time can be  
 2 inhibited, it's talking about chemical degradation, so  
 3 inhibition of chemical degradation of bromfenac.  
 4 Q. Column 2, Lines 46 through 47, of the '431 patent states  
 04:09 5 that the preservative effect of said preservative can be  
 6 inhibited for a long period of time. What does this mean?  
 7 A. So what this means to a person of ordinary skill in the  
 8 art is that the deterioration, so the decrease in the  
 9 preservative effect, the preservative that's being used is  
 04:09 10 inhibited for a long period of time. So, in other words, that  
 11 aqueous liquid solution maintains its ability to be preserved.  
 12 Q. What is preservative effect or preservative efficacy?  
 13 A. So that's understood by a person of ordinary skill in the  
 14 art to refer to the ability of a liquid to not support  
 04:10 15 microbial growth over its shelf life.  
 16 Q. Let me direct your attention back to the entirety of the  
 17 paragraph at Column 2, Lines 34 for 47, of the '431 patent.  
 18 What were the inventors finding, if anything, from the use of  
 19 tyloxapol in bromfenac ophthalmic solutions?  
 04:10 20 A. Based on this, a person of ordinary skill in the art  
 21 would understand that the patentees found that when tyloxapol  
 22 is included with bromfenac in this aqueous liquid solution,  
 23 that it becomes stable within pH range, chemically stable  
 24 giving no irritation to the eyes and that it's able to  
 04:10 25 maintain its preservative effect if there's a preservative

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1 present.  
 2 Q. After the '431 patent issued, was a bromfenac product  
 3 containing tyloxapol that embodied the '431 patent introduced  
 4 into the United States market?  
 04:11 5 A. There was one, yes.  
 6 Q. What bromfenac product containing tyloxapol was  
 7 introduced into the United States market after the '431 patent  
 8 issued?  
 9 A. That's Prolensa®.  
 04:11 10 Q. Did that happen in 2013?  
 11 A. Yes.  
 12 Q. Prior to 2003, to your knowledge was tyloxapol ever used  
 13 as a stabilizer in ophthalmic solutions to increase chemical  
 14 stability?  
 04:11 15 A. Not to my knowledge, no.  
 16 Q. Prior to 2003, to your knowledge was tyloxapol ever used  
 17 as a stabilizer in ophthalmic solutions to increase  
 18 preservative efficacy?  
 19 A. Not to my knowledge, no.  
 04:11 20 Q. Prior to 2003, to your knowledge was tyloxapol ever used  
 21 in a marketed ophthalmic solution of a nonsteroidal  
 22 anti-inflammatory drug?  
 23 A. Not to my knowledge, no.  
 24 Q. Let me direct your attention to Column 6, Lines 11  
 04:11 25 through 31, of the '431 patent and in particular Lines 11 to

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1 13. What other types of excipients may be included in the  
 2 tyloxapol containing formulation of bromfenac of the '431  
 3 patent?  
 4 **A. So in that passage a person of ordinary skill in the art**  
 04:12 5 **would understand that the liquid, aqueous liquid solution**  
 6 **could also contain various additives and it mentions**  
 7 **isotonics, buffers, thickeners, stabilizers, chelating agents,**  
 8 **pH controlling agents, perfumes, and the like can be**  
 9 **appropriately added.**  
 04:12 10 **Q. The '431 patent refers to isotonic. What is isotonic?**  
 11 **A. An isotonic agent is one that's added to a liquid**  
 12 **solution to maintain the same osmotic pressure to the tissue**  
 13 **that it's being applied to or in contact with.**  
 14 **Q. Why is it important to maintain the same osmotic pressure**  
 04:12 15 **between the aqueous liquid eyedrop preparation and the fluid**  
 16 **in the eye?**  
 17 **MS. HOLLAND: Your Honor, I have an objection again.**  
 18 **I think we are veering into expert testimony here. I think**  
 19 **the question was the purpose of isotonic substance in the**  
 04:13 20 **patent.**  
 21 **MR. HASFORD: I think that's background.**  
 22 **THE COURT: I'll sustain the objection.**  
 23 **MS. HOLLAND: Thank you.**  
 24 **BY MR. HASFORD:**  
 04:13 25 **Q. What are some examples of isotonics that may be included**  
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1 '431 patent?  
 2 **A. Stabilizers include sodium sulfite as an example of**  
 3 **sulfites.**  
 4 **Q. The '431 patent also refers to chelating agents. What**  
 04:15 5 **are some examples of chelating agents that may be included in**  
 6 **the bromfenac formulations of the '431 patent?**  
 7 **A. Chelating agents include sodium edetate, sodium citrate,**  
 8 **condensed sodium, phosphate, and the like.**  
 9 **Q. The '431 patent also refers to pH controlling agents.**  
 04:15 10 **What are some of the examples of pH controlling agents that**  
 11 **may be included in the bromfenac formulations of the '431**  
 12 **patent?**  
 13 **A. PH controlling agents include hydrochloric acid, sodium**  
 14 **hydroxide, phosphoric acid, acetic acid, and the like.**  
 04:16 15 **Q. Let me direct your attention to Column 6, Line 39 through**  
 16 **41, of the '431 patent, what pH ranges are set forth for the**  
 17 **bromfenac formulations of the '431 patent?**  
 18 **A. The pH range described in Column 6 is about 6 to 9 and**  
 19 **then it says preferably 7 to 9, especially about 7.5 to 8.5.**  
 04:16 20 **Q. Let me direct your attention to Experimental Example 1 of**  
 21 **the '431 patent, which is at Column 7, Line 7, through Column**  
 22 **8, Line 2. What does Experimental Example 1 of the '431**  
 23 **patent report?**  
 24 **A. Experimental Example 1 reports a stability test for**  
 04:17 25 **bromfenac sodium and it compares different examples of the**  
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1 in the bromfenac formulations of the '431 patent?  
 2 **A. Examples for isotonics include sodium chloride, potassium**  
 3 **chloride, glycerin, mannitol, sorbitol, boric acid, glucose,**  
 4 **propylene glycol, and it says the like.**  
 04:13 5 **Q. The '431 patent also refers to buffers. What are some**  
 6 **examples of buffers that may be included in the bromfenac**  
 7 **formulations of the '431 patent?**  
 8 **A. Examples of buffer include phosphate buffer, a borate**  
 9 **buffer, citrate buffer, tartrate buffer, acetate buffer, boric**  
 04:14 10 **acid, borax, amino acids, and the like.**  
 11 **Q. The '431 patent also refers to thickness. What are some**  
 12 **examples of thickness that may be included in the bromfenac**  
 13 **formulations of the '431 patent?**  
 14 **A. Thickness listed in the '431 patent include**  
 04:14 15 **polyvinylpyrrolidone, carboxymethylcellulose, carboxypropyl**  
 16 **cellulose, hydroxymethyl cellulous, hydroxypropyl cellulose,**  
 17 **hydroxypropylmethylcellulos, polyvinyl alcohol, sodium**  
 18 **polyacrylate, and the like.**  
 19 **Q. The '431 patent refers to polyvinylpyrrolidone. Is**  
 04:14 20 **polyvinylpyrrolidone also referred to as povidone or PVP?**  
 21 **A. It is in the literature, yes.**  
 22 **Q. The '431 patent also refers to stabilizers. What is an**  
 23 **example -- actually let me direct your attention to Column 6,**  
 24 **Lines 25 through 26, of the '431 patent. What is an example**  
 04:15 25 **of stabilizers that is used in bromfenac formulations of the**  
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1 invention to a Comparison Example 1.  
 2 **Q. Is it your understanding that Experimental Example 1 of**  
 3 **the '431 patent reports the results of chemical stability**  
 4 **testing conducted on bromfenac ophthalmic solutions?**  
 04:17 5 **A. The person of ordinary skill in the art seeing the**  
 6 **results in Table 1 would understand this is chemical**  
 7 **stability.**  
 8 **Q. What storage conditions were used in Experimental Example**  
 9 **1 of the '431 patent?**  
 04:17 10 **A. The experimental conditions are stability is at 60**  
 11 **degrees C for four weeks.**  
 12 **Q. What is the significance, if anything, of the use of**  
 13 **storage condition of 60 degrees Celsius for four weeks in**  
 14 **Experimental Example 1 of the '431 patent?**  
 04:17 15 **A. A person of ordinary skill in the art --**  
 16 **MS. HOLLAND: I'm going to object again. This is**  
 17 **opinion testimony. I'll tell you, your Honor, it's in this**  
 18 **section of Dr. Williams' report that talks about unexpected**  
 19 **results. So I think it's more appropriate to have this**  
 04:18 20 **testimony when Dr. Williams gets up to testify again and it's**  
 21 **appropriate to talk about unexpected results.**  
 22 **MR. HASFORD: We're doing this as background, your**  
 23 **Honor. I think it appropriate for him to explain what the**  
 24 **'431 patent teaches on these items.**  
 04:18 25 **THE COURT: All right. I'll permit it.**  
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1 BY MR. HASFORD:  
2 Q. Shall I re-ask the question?  
3 A. No. Thank you. So, a person of ordinary skill in the  
4 art would understand, when these aqueous liquid solutions are  
04:18 5 stored at 60 degrees C for four weeks, that that is a  
6 condition of what's referred to as accelerated stability  
7 conditions.  
8 Q. At what pH are the formulations that are used in  
9 experimental example 1 of the '431 patent formulated?  
04:18 10 A. Each of the four liquids are noted at pH 7.  
11 Q. What is the significance, if anything, of the fact that  
12 the formulations that are used in experimental example 1 of  
13 the '431 patent were formulated at pH 7?  
14 A. The significance is that at pH 7 bromfenac is, as shown  
04:19 15 in the '225 Ogawa patent, bromfenac is susceptible to chemical  
16 degradation.  
17 Q. Does this better allow the relative chemical stability of  
18 the formulations to be measured?  
19 A. It does, yes.  
04:19 20 Q. Do the results in experimental example 1 relate to the  
21 '431 patent's teaching --  
22 MR. MUKERJEE: Your Honor, I have to object to that.  
23 This is now clearly going into expert testimony territory.  
24 THE COURT: I think so, and the last question was  
04:19 25 also quite leading. Describing the patent is different from  
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1 saying why are these things --  
2 MR. MUKERJEE: Significant.  
3 THE COURT: -- significant for a step forward. There  
4 will be a point in the case, of course, where the plaintiff  
04:19 5 will be able to put on that case. I'll sustain the objection.  
6 MR. MUKERJEE: Thank you, your Honor.  
7 BY MR. HASFORD:  
8 Q. Do the results in experimental example 1 relate to the  
9 '431 patent's teaching that tyloxapof chemically stabilized  
04:19 10 bromfenac in the aqueous liquid preparations of the '431  
11 patent?  
12 MR. MUKERJEE: Same objection.  
13 MR. HASFORD: I think I can ask whether they relate  
14 to that, your Honor.  
04:20 15 THE COURT: All right. I'll permit it.  
16 THE WITNESS: The results do support the combination  
17 of bromfenac sodium and tyloxapof in samples A-01, 2 and 3.  
18 BY MR. HASFORD:  
19 Q. Let's discuss these results further. First let me direct  
04:20 20 your attention to Table 1 of the '431 patent which is at  
21 column 7, lines 40 through 55. What are the components of the  
22 formulation of comparison example 1 used in experimental  
23 example 1 of the '431 patent?  
24 A. The components of comparison example 1 include bromfenac  
04:20 25 sodium, boric acid, benzalkonium chloride, polysorbate 80, and  
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1 then it's added to a final volume with sterile purified water.  
2 Q. What amounts of the components are present in the  
3 formulation of comparison example 1 of experimental example 1  
4 of the '431 patent?  
04:21 5 A. Bromfenac sodium is present at .1 grams per hundred ml.  
6 Boric acid is at 1.5 grams per hundred ml. Benzalkonium  
7 chloride is at .005 grams per hundred ml. Polysorbate 80 is  
8 at 0.15 grams per hundred ml. And then the final volume is  
9 added up to 100 mls with sterile purified water.  
04:21 10 Q. Was polysorbate 80, which is used in comparison example  
11 1, also used in the Bronuck, Xibrom® and Bromday®  
12 formulations?  
13 A. Yes.  
14 Q. What remaining percent of bromfenac was measured in the  
04:21 15 formulation of comparison example 1 in experimental example 1  
16 of the '431 patent after storage at 60 degrees Celsius for  
17 four weeks?  
18 A. The remaining rate reported as 51.3 percent.  
19 Q. What are the components of formulation A-02 in  
04:22 20 experimental example 1 of the '431 patent?  
21 A. The components of A-02 are bromfenac sodium, boric acid,  
22 benzalkonium chloride, tyloxapof, and then sterile purified  
23 water to add up to volume.  
24 Q. What amounts of the components are present in formulation  
04:22 25 A-02 of experimental example 1 of the '431 patent?  
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1 A. A-02 contains .1 grams per hundred mls of bromfenac  
2 sodium, contains boric acid at 1.5 grams per hundred ml,  
3 contains benzalkonium chloride at .005 grams per hundred ml,  
4 contains tyloxapof at 0.15 grams per hundred ml, and then the  
04:22 5 final is added up to volume with sterile purified water.  
6 Q. How does formulation A-02 differ from the formulation of  
7 comparison example 1 in experimental example 1 of the '431  
8 patent?  
9 A. The two, the comparison example 1 and formulation A-02  
04:23 10 differ in the polysorbate 80 as contained in comparison  
11 example 1 and tyloxapof as contained in formulation A-02.  
12 Q. Are all the other components the same?  
13 A. Yes.  
14 Q. What remaining percent of bromfenac was measured in  
04:23 15 formulation A-02 in experimental example 1 of the '431 patent  
16 after storage at 60 degrees Celsius for four weeks?  
17 A. The remaining rate of bromfenac sodium is 73.8 percent.  
18 Q. What are the components of formulation A-03 in  
19 experimental example 1 of the '431 patent?  
04:23 20 A. A-03 has bromfenac sodium, boric acid, benzalkonium  
21 chloride, tyloxapof and sterile purified water.  
22 Q. What amounts of the components are present in formulation  
23 A-03 of experimental example 1 of the '431 patent?  
24 A. The amounts are bromfenac sodium at .1 grams per hundred  
04:24 25 ml, boric acid at 1.5 grams per hundred ml, benzalkonium  
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- 1 chloride at .005 grams per hundred ml, tyloxapol is .02 grams  
2 per hundred ml, and then the final volume is added up with  
3 sterile purified water to 100 mls.
- 04:24 4 Q. How does formulation A-03 differ from the formulation of  
5 comparison example 1 in experimental example 1 of the '431  
6 patent?  
7 A. It differs in it contains -- A-03 contains tyloxapol  
8 whereas comparison example 1 contains polysorbate 80.  
9 Q. Are all the other formulation components the same?  
04:24 10 A. They are, yes.  
11 Q. How does formulation A-03 differ from formulation A-02 in  
12 experimental example 1 of the '431 patent?  
13 A. A-02 and A-03 are the same except for the amounts of  
14 tyloxapol; A-03 having less, .02 grams compared to 0.15 grams  
04:25 15 tyloxapol in formulation A-02.  
16 Q. What remaining percent of bromfenac was measured in  
17 formulation A-03 in experimental example 1 of the '431 patent  
18 after storage at 60 degrees Celsius for four weeks?  
19 A. The remaining percent of bromfenac is 89.6 percent.  
04:25 20 Q. How, if at all, do the results of experimental example 1  
21 of the '431 patent relate to the '431 patent's teaching that  
22 tyloxapol chemically stabilized bromfenac?  
23 A. A-02 and A-03 with the presence of tyloxapol, you have a  
24 higher bromfenac chemical amount, potency, compared to  
04:25 25 comparison example 1 with polysorbate 80.

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- 1 Q. And how did the remaining rates compare between  
2 formulation A-02 with .15 weight per volume percent tyloxapol  
3 versus formulation A-03 with 0.02 weight per volume percent  
4 tyloxapol?  
04:26 5 A. So, from Table 1 the A-03 with .02 grams per hundred ml  
6 of tyloxapol is 89.6, so it's a much greater amount of  
7 bromfenac potency compared to with the higher amount of  
8 tyloxapol.  
9 Q. Let me direct your attention to the passage beneath Table  
04:26 10 1 of the '431 patent at column 7, and in particular to the  
11 sentence beginning at line 59 beginning "As is apparent."  
12 What, if any, conclusion is drawn in the '431 patent from the  
13 data in experimental example 1?  
14 A. So, here the patent states that based on the data, the  
04:26 15 stability test that was conducted at pH 7 at 60 degrees C  
16 stored for four weeks, the bromfenac in the eyedrops was  
17 stable in the order of tyloxapol-containing, was more stable  
18 than the polyoxyl 40 stearate-containing liquid, which both of  
19 those were more stable than the polysorbate 80-containing  
04:27 20 preparation.  
21 Q. Let me direct your attention to the next sentence of the  
22 '431 patent at column 7 beginning at line 65. What, if any,  
23 further conclusion is drawn in the '431 patent from the data  
24 in experimental example 1?  
04:27 25 A. Here the patent states that with respect to the A-02 and

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- 1 A-03 from Table 1, that bromfenac made with .02 weight percent  
2 of tyloxapol is more stable with regards to the bromfenac  
3 content than the .15 weight percent tyloxapol containing A-02  
4 liquid preparation.  
04:28 5 Q. Let me now direct your attention to experimental example  
6 2 of the '431 patent, which is at column 8, lines 5 through  
7 49. What does experimental example 2 of the '431 patent  
8 report?  
9 A. So, Table 2 reports stability tests for different liquid  
04:28 10 formulations, either containing tyloxapol or containing  
11 polyoxyl 40 stearate.  
12 Q. At approximately what pH are the formulations that are  
13 used in experimental example 2 of the '431 patent formulated?  
14 A. The pH of these formulations is generally like 8.15 to  
04:28 15 8.19.  
16 Q. Do the results in experimental example 2 relate to the  
17 '431 patent's teaching that tyloxapol chemically stabilized  
18 bromfenac in the aqueous liquid preparations of the '431  
19 patent?  
04:29 20 A. Yes.  
21 Q. Let's discuss these results further. First let me direct  
22 your attention to Table 2, which is in column 8 of the '431  
23 patent. What are the components of formulation A-04 in  
24 experimental example 2 of the '431 patent?  
04:29 25 A. So, formula A-04 contains bromfenac sodium, boric acid,

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- 1 borax, benzalkonium chloride, tyloxapol, polyvinylpyrrolidone,  
2 specifically K-30 grade, sodium edetate, and then the formula  
3 can contain either sodium hydroxide -- well, could contain  
4 sodium hydroxide sufficient to adjust the pH to the 8.17, and  
04:29 5 then the final volume is made up with sterile purified water  
6 to 100 ml.  
7 Q. What amounts of the components are present in formulation  
8 A-04 of experimental example 2 of the '431 patent?  
9 A. Bromfenac sodium is present at .1 grams, boric acid at  
04:30 10 1.1 grams, borax at 1.1 grams, benzalkonium chloride at .005  
11 grams, tyloxapol at .02 grams, polyvinylpyrrolidone is at 2.0  
12 grams, sodium edetate is at .02 grams, and then the -- the  
13 sodium hydroxide could be used to adjust the pH, and then that  
14 total volume is added up to 100 mls using sterile purified  
04:30 15 water.  
16 Q. What remaining percent of bromfenac was measured in  
17 formulation A-04 in experimental example 2 of the '431 patent  
18 after storage at 60 degrees Celsius for four weeks?  
19 A. That's 92.6 percent.  
04:30 20 Q. What are the components of formulation A-05 in  
21 experimental example 2 of the '431 patent?  
22 A. Formulation A-05 contains bromfenac sodium, boric acid,  
23 borax, benzalkonium chloride, tyloxapol, polyvinylpyrrolidone,  
24 K-30, sodium edetate, may contain sodium hydroxide to adjust  
04:31 25 the pH, and then that is -- sterile water -- sorry, sterile

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- 1 purified water is used to adjust the final volume.
- 2 Q. What amounts of the components are present in formulation  
3 A-05 of experimental example 2 of the '431 patent?
- 4 A. The bromfenac sodium lists .1 gram, boric acid, 1.1 gram,  
04:31 5 borax, 1.1 gram, benzalkonium chloride, .005 gram, tyloxapol  
6 .05 gram, polyvinylpyrrolidone, 2 gram, sodium edetate, .02  
7 gram, and then it may contain sodium hydroxide to adjust the  
8 pH, and then the final volume is added up with sterile  
9 purified water to 100 mls.
- 04:32 10 Q. What remaining percent of bromfenac was measured in  
11 formulation A-05 in experimental example 2 of the '431 patent  
12 after storage at 60 degrees Celsius for four weeks?
- 13 A. 90.9 percent.
- 14 Q. What are the components of formulation A-06 in  
04:32 15 experimental example 2 of the '431 patent?
- 16 A. A-06 contains bromfenac sodium, boric acid, borax,  
17 benzalkonium chloride, tyloxapol, polyvinylpyrrolidone, sodium  
18 edetate, it may contain sodium hydroxide to adjust the pH, and  
19 sterile purified water to adjust the final volume to 100 ml.
- 04:32 20 Q. What amounts of the components are present in formulation  
21 A-06 of experimental example 2 of the '431 patent?
- 22 A. Bromfenac sodium is at 0.1 gram, boric acid at 1.1 gram,  
23 borax at 1.1 gram, benzalkonium chloride at .005 gram,  
24 tyloxapol at .03 gram, polyvinylpyrrolidone at 2 gram, sodium  
04:33 25 edetate at .02 gram, and then sodium hydroxide may be used to

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- 1 conclusion is drawn in the '431 patent from the data in  
2 experimental example 2?
- 3 A. So, what's stated here in the patent is that based on the  
4 stability data or the potency of bromfenac in Table 2, the  
04:35 5 bromfenac potency in the compositions containing tyloxapol at  
6 .02, .03, and .05 weight percent is not less than 90 percent  
7 after storage at 60 degrees C for four weeks, and it states,  
8 the patent states that this indicates that those compositions  
9 have sufficient stability for eyedrops.
- 04:35 10 Q. Let me now direct your attention to experimental example  
11 3. Actually -- yes, experimental example 3 of the '431  
12 patent. It's going to be at column 8, line 51, through column  
13 10, line 50. What does experimental example 3 of the '431  
14 patent report?
- 04:35 15 A. So, experimental example 3 takes A-04, A-05 and A-07 from  
16 experimental example 2 and performs preservative effectiveness  
17 testing on them, and that's what's reported.
- 18 Q. Do the results in experimental example 3 relate to the  
19 '431 patent's teaching that tyloxapol contributes to  
04:36 20 maintaining the preservative efficacy of the aqueous liquid  
21 preparations of the '431 patent?
- 22 A. It does, yes.
- 23 Q. Was the testing in experimental example 3 of the '431  
24 patent conducted according to European Pharmacopeia criteria?
- 04:36 25 A. Yes, according to EP criteria A and B.

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- 1 adjust the final pH, and the final volume is added up with  
2 sterile purified water.
- 3 Q. What remaining percent of bromfenac was measured in  
4 formulation A-06 in experimental example 2 of the '431 patent  
04:33 5 after storage at 60 degrees Celsius for four weeks?
- 6 A. It's 92.0 percent.
- 7 Q. How do formulations A-04, A-05 and A-06 of the '431  
8 patent differ?
- 9 A. They differ in the amount of tyloxapol that's present in  
04:34 10 each of the aqueous liquid solutions.
- 11 Q. Otherwise, are they all the same?
- 12 A. They are, yes.
- 13 Q. How, if at all, do the results of experimental example 2  
14 of the '431 patent relate to the '431 patent's teaching that  
04:34 15 tyloxapol chemically stabilized bromfenac?
- 16 A. So, it was shown by the potency value the remaining rate  
17 of bromfenac sodium when tyloxapol is used in this aqueous  
18 liquid solution, it shows that the remaining rate is at the  
19 values that it's at, in the low 90 percents.
- 04:34 20 Q. Do any of the formulations of experimental example 2 of  
21 the '431 patent use sodium sulfite?
- 22 A. No.
- 23 Q. Let me direct your attention to the passage beneath Table  
24 2 of the '431 patent at column 8, and in particular to the  
04:34 25 sentence at line 43 beginning "As is apparent." What, if any,

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- 1 Q. By way of background, is it your understanding that the  
2 European Pharmacopeia is a standard reference used in  
3 connection with drug formulation?
- 4 A. It is, yes.
- 04:36 5 Q. Generally speaking, what is the purpose of preservative  
6 efficacy testing using European Pharmacopeia criteria?
- 7 A. So, the preservative efficacy testing is a test that's  
8 done to show the ability of that liquid to maintain its  
9 ability to act as a preservative, maintain sterility.
- 04:37 10 Q. In maintaining sterility are you referring to  
11 antimicrobial stability?
- 12 A. Yes.
- 13 Q. Is there also a separate U.S. Pharmacopeia?
- 14 A. There is, yes.
- 04:37 15 Q. Do you understand that the U.S. Pharmacopeia has  
16 different preservative efficacy standards from the European  
17 Pharmacopeia?
- 18 A. Yes.
- 19 Q. Do you understand that the preservative efficacy  
04:37 20 standards of the European Pharmacopeia are more demanding than  
21 the preservative efficacy standards of the U.S. Pharmacopeia?
- 22 A. Yes.
- 23 MR. MUKERJEE: Your Honor, I'm going to object to  
24 this. I don't understand what preservative efficacy has  
04:37 25 anything to do with the trial. As we had indicated even in

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1 the opening, none of the claims require any preservative  
2 efficacy. So, even from a background perspective, I don't  
3 quite understand it.

04:37 4 MR. HASFORD: Your Honor, it's a property of the  
5 claim formulation. The Federal Circuit has repeatedly said  
6 that properties of the claim formulation are relevant.  
7 They're set forth in the background of the patent. We're  
8 merely doing background at this point.

04:38 9 MR. MUKERJEE: Even those claims that even have  
10 pharmacopeia requirements were European Pharmacopeia  
11 requirements. So, as to whether or not U.S. Pharmacopeia  
12 requirements are more stringent or less stringent, I still  
13 fail to see any relevance of that, particularly in light of  
14 the way we have streamlined this case.

04:38 15 MR. HASFORD: Your Honor, it is purely background.  
16 Their expert does not dispute that the U.S. Pharmacopeia  
17 standards are less demanding than the European Pharmacopeia  
18 standards. Again, it's just by way of background to set forth  
19 what the European Pharmacopeia is that's being testified  
04:38 20 about.

21 MR. MUKERJEE: And therein lies my problem. He's  
22 referencing expert testimony right now, and again, the whole  
23 point of this is just background information.

04:38 24 MR. HASFORD: I'm merely pointing out, your Honor,  
25 that their expert has not disputed this.

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1 Q. According to the '431 patent, what conclusions were drawn  
2 as to whether formulation A-05 satisfied the European  
3 Pharmacopeia preservative efficacy standards?

04:40 4 A. So, the patent states that A-05 was found to be  
5 compatible with EP criteria B.

6 Q. Do you understand that the European Pharmacopeia criteria  
7 A standard is more demanding than the European Pharmacopeia B  
8 standard?

9 A. Yes.

04:40 10 Q. How, if at all, do the results of experimental example 3  
11 of the '431 patent relate to the '431 patent's teaching that  
12 tyloxapol contributes to maintaining the preservative efficacy  
13 of the aqueous liquid preparations of the '431 patent?

04:40 14 A. So, the findings of the '431 patent as exemplified by the  
15 results in experimental example 3 show that over the course of  
16 this, of the samples stored at 60 degrees C for four weeks,  
17 these compositions maintain their ability to have preservative  
18 efficacy.

04:41 19 Q. Let me direct your attention to the claims of the '431  
20 patent which begin at column 11. In reviewing the '431  
21 patent, did you also consider the claims listed in columns 11  
22 to 14?

23 A. I did, yes.

04:41 24 Q. Did you gain an understanding of what is claimed,  
25 generally speaking, in the '431 patent?

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1 THE COURT: Well, if it is pointing out areas that  
2 are not in dispute, it might be helpful in framing what we are  
3 talking about in this '431 patent, so I'll permit it.

4 BY MR. HASFORD:

04:38 5 Q. Let me direct your attention to Table 3-1 and Table 3-2  
6 in experimental example 3 of the '431 patent which are in  
7 columns 9 and 10. What does Table 3-1 of the '431 patent  
8 report?

04:39 9 A. Table 3-1 reports the results of this preservative  
10 efficacy test for formulation A-04 from experimental example  
11 2.

12 Q. What does Table 3-2 of the '431 patent report?

13 A. Likewise, Table 3-2 reports the same for formulation A-05  
14 from experimental example 2.

04:39 15 Q. Let me direct your attention to column 9, lines 47 to 51  
16 of the '431 patent. According to the '431 patent, what  
17 conclusions were drawn as to whether formulation A-04  
18 satisfied the European Pharmacopeia preservative efficacy  
19 standards?

04:39 20 A. So, the '431 patent states that based on the results  
21 presented in Tables 3-1, which was A-04, that composition A-04  
22 was found to be compatible with EP criteria A.

23 Q. Do you understand that formulation A-04 also satisfied  
24 the EP criteria B standard?

04:40 25 A. Yes.

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1 A. Yes.

2 Q. What is your understanding of what is claimed, generally  
3 speaking, in the '431 patent?

04:41 4 MS. HOLLAND: Objection, your Honor. There is no  
5 such thing claimed, generally speaking. Claims define the  
6 scope of the protected invention, and we can't look at them as  
7 a general matter. And in addition, there are only two of them  
8 that are actually still in the case.

04:41 9 MR. HASFORD: I think he can provide his general  
10 understanding of what the patent sets forth, your Honor.

11 THE COURT: No, I'll sustain the objection. I think  
12 the question could be reformulated. He's giving very detailed  
13 explanations of what the patent means, and so I don't think a  
14 general one is called for.

04:41 15 MR. HASFORD: I'll go to the two patents that are  
16 currently at issue in this trial.

17 BY MR. HASFORD:

18 Q. Let me direct your attention to claim 6, and that's at  
19 column 12. Do you understand that claim 6 depends from claim  
04:42 20 4 which further depends from claim 3 which further depends  
21 from independent claim 1?

22 A. Yes.

23 Q. Have you prepared a demonstrative showing the elements of  
24 claim 6 in its independent form?

04:42 25 A. I have.

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1 Q. Let me direct your attention to PTD 2-2 on the screen.  
 2 To what is claim 6 of the '431 patent directed?  
 3 A. So, claim 6, as I have written here, in its independent  
 4 form, is directed to an aqueous liquid preparation that  
 04:42 5 consists essentially of bromfenac sodium from about .05 to  
 6 about .2 weight percent, and tyloxapol having a concentration  
 7 of about .02 weight percent, wherein said liquid preparation  
 8 is formulated for ophthalmic administration, and when a  
 9 quaternary ammonium compound is included in said liquid  
 04:43 10 preparation, the quaternary ammonium compound is benzalkonium  
 11 chloride.  
 12 Q. Let's now turn to claim 20 of the '431 patent, which is  
 13 at column 14. Do you understand that claim 20 depends from  
 14 claim 19 which further depends from independent claim 18?  
 04:43 15 A. Yes.  
 16 Q. Have you prepared a demonstrative showing the elements of  
 17 claim 20 in its independent form?  
 18 A. Yes, I have.  
 19 Q. Let me direct your attention to PTD 2-3 on the screen.  
 04:43 20 To what is claim 20 of the '431 patent directed?  
 21 A. So, claim 20, as I have shown here, and it's written in  
 22 its independent form, is an aqueous liquid preparation  
 23 consisting essentially of bromfenac sodium from about .01 to  
 24 about .5 weight percent, tyloxapol at a concentration of about  
 04:44 25 .02 weight percent, boric acid, sodium tetraborate, EDTA

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1 sodium salt, benzalkonium chloride, polyvinylpyrrolidone,  
 2 sodium sulfite, and that liquid preparation is formulated for  
 3 ophthalmic administration, and wherein benzalkonium chloride  
 4 is the only quaternary ammonium compound which is included in  
 04:44 5 that liquid solution.  
 6 Q. What is the active pharmaceutical ingredient in the  
 7 formulation of claim 20 of the '431 patent?  
 8 A. It's bromfenac sodium.  
 9 Q. Are the remaining ingredients of the formulation of claim  
 04:44 10 20 of the '431 patent also called excipients?  
 11 A. Yes.  
 12 Q. Let's now turn to plaintiff's Prolensa® product. Is  
 13 Prolensa® an embodiment of the aqueous liquid preparations of  
 14 claims 6 and 20 of the '431 patent?  
 04:45 15 A. It is, yes.  
 16 Q. Have you reviewed the FDA approved package insert for  
 17 Prolensa®?  
 18 A. Yes.  
 19 Q. Would you please turn to PTX-745 in your binder and  
 04:45 20 identify that document.  
 21 A. PTX-745 is a copy of the Prolensa® package insert from  
 22 the NDA.  
 23 Q. And when you say NDA, do you understand PTX-745 to be the  
 24 version of the package insert that the FDA approved in the new  
 04:45 25 drug application for Prolensa®?

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1 A. That's my understanding.  
 2 Q. Would you please turn to JTX-22 in your binder and  
 3 identify that document.  
 4 A. JTX-22 is a copy of the Prolensa® package insert that's  
 04:45 5 actually included with the product.  
 6 Q. Was this ultimately placed in the packaging with the  
 7 marketed Prolensa® product?  
 8 A. Yes.  
 9 Q. Do you understand that PTX-745 and JTX-22 are  
 04:46 10 substantively identical?  
 11 A. That's my understanding.  
 12 Q. Looking at JTX-22, let me direct your attention to the  
 13 indications and usage section within the full prescribing  
 14 information section on the first page of the Prolensa® package  
 04:46 15 insert. According to the Prolensa® package insert, what is  
 16 the FDA approved indication for Prolensa®?  
 17 A. It says Prolensa® .07 percent is indicated for the  
 18 treatment of postoperative inflammation and reduction of  
 19 ocular pain in patients who have undergone cataract surgery.  
 04:46 20 Q. Let me direct your attention to the dosage and  
 21 administration section within the full prescribing information  
 22 section on the first page of the Prolensa® package insert.  
 23 According to the Prolensa® package insert, how is Prolensa®  
 24 administered for ophthalmic use?  
 04:46 25 A. According to the package insert, it says one drop of

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1 Prolensa® should be applied to the affected eye once daily  
 2 beginning one day prior to cataract surgery, continued on the  
 3 day of surgery, and through the first 14 days of the  
 4 postoperative period.  
 04:47 5 Q. Let me direct your attention to the adverse reactions  
 6 section within the full prescribing information section on the  
 7 first page of the Prolensa® package insert. According to the  
 8 Prolensa® package insert, is Prolensa® associated with adverse  
 9 reactions of burning and stinging?  
 04:47 10 A. That's not listed on the package insert.  
 11 Q. Have you reviewed the formulation of Prolensa® as set  
 12 forth in the FDA approved new drug application for Prolensa®?  
 13 A. I have, yes.  
 14 Q. Would you please turn to PTX-120 in your binder and  
 04:47 15 identify that document.  
 16 A. PTX-120 is an excerpt from the NDA for Prolensa®.  
 17 Q. Let me direct your attention to the page of PTX-120  
 18 bearing Bates number PROLO002267, and in particular to Table 1  
 19 on that page. What does Table 1 in PTX-120 show?  
 04:48 20 A. Table 1 shows the composition of Prolensa®, of bromfenac  
 21 ophthalmic solution .07 percent, which is Prolensa®.  
 22 Q. What is the active pharmaceutical ingredient in  
 23 Prolensa®?  
 24 A. That is bromfenac sodium sesquihydrate.  
 04:48 25 Q. What is the amount of bromfenac sodium sesquihydrate in

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1 Prolensa®?  
 2 A. It lists .0805 grams per hundred ml.  
 3 Q. And is it your understanding that that is equivalent to  
 4 .07 weight per volume percent bromfenac free acid?  
 04:48 5 A. Yes, and that's footnoted as footnote 1 to Table 1.  
 6 Q. Does Prolensa® contain tyloxapol?  
 7 A. Yes.  
 8 Q. What is the function of tyloxapol in Prolensa®?  
 9 A. It's as a stabilizer.  
 04:48 10 Q. What amount of tyloxapol is included in Prolensa® as a  
 11 stabilizer?  
 12 A. It lists .02 grams per hundred ml, so .02 percent by  
 13 weight.  
 14 Q. Does Prolensa® contain benzalkonium chloride?  
 04:49 15 A. Yes.  
 16 Q. What is the function of benzalkonium chloride in  
 17 Prolensa®?  
 18 A. It is listed as a preservative.  
 19 Q. What amount of benzalkonium chloride is included in  
 04:49 20 Prolensa® as a preservative?  
 21 A. It is at .005 grams per hundred ml.  
 22 Q. Is benzalkonium chloride the only quaternary ammonium  
 23 compound included in Prolensa®?  
 24 A. It is, yes.  
 04:49 25 Q. What other excipients are included in Prolensa®?

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1 A. In addition to those three, it has boric acid, sodium  
 2 borate, sodium sulfite, edetate disodium, povidone, which is  
 3 also known as polyvinylpyrrolidone, sodium hydroxide, that can  
 4 be added to adjust the final pH, and then purified water to  
 04:50 5 add up to volume.  
 6 Q. What are the functions of these other excipients that are  
 7 included in Prolensa®?  
 8 A. The boric acid and sodium borate act as buffering agents.  
 9 It states sodium sulfite is a stabilizer, edetate disodium it  
 04:50 10 lists as a chelating agent, povidone it lists as a stabilizer,  
 11 and then sodium hydroxide to adjust the pH of the solution.  
 12 Q. What are the amounts of these other excipients that are  
 13 included in Prolensa®?  
 14 A. Boric acid is at 1.4 weight percent. Sodium borate is  
 04:50 15 at .74 weight percent. Sodium sulfite is at .2 weight  
 16 percent. Edetate disodium is at .02 weight percent. Povidone  
 17 is at 1 percent. And then sodium hydroxide, it can be used  
 18 just to adjust the final pH.  
 19 Q. What is the pH of Prolensa®?  
 04:51 20 A. It states here it's -- the final pH, it's made to pH 7.8.  
 21 Q. Upon review of the new drug application and the package  
 22 insert for Prolensa®, do you understand that Prolensa® is an  
 23 embodiment of the aqueous liquid preparations of Claims 6 and  
 24 20 of the '431 patent?  
 04:51 25 A. I do, yes.

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1 Q. Are you aware of any opinion to the contrary offered by  
 2 any of defendants' experts?  
 3 A. I'm not.  
 4 Q. Let's now turn to Lupin's generic bromfenac ophthalmic  
 04:51 5 solution.  
 6 Have you reviewed the proposed package insert for  
 7 Lupin's generic bromfenac ophthalmic solution?  
 8 A. I have, yes.  
 9 Q. Would you please turn to PTX-127 in your binder and  
 04:51 10 identify that document.  
 11 A. PTX-127 is a copy of the package insert for Lupin's  
 12 generic bromfenac ophthalmic solution.  
 13 Q. Please turn back to PTX-745 which is the Prolensa®  
 14 package insert.  
 04:52 15 How similar are Lupin's proposed package insert for its  
 16 generic bromfenac ophthalmic solution and the Prolensa®  
 17 package insert?  
 18 A. They're very similar.  
 19 MS. HOLLAND: Objection, Your Honor. This is not  
 04:52 20 background anymore. I believe that goes to their copying  
 21 case, if I could hazard a guess about what this is related to.  
 22 But there is certainly no reason to compare the two marketed  
 23 products. This is supposed to be a background about the  
 24 patent and a description of the product.  
 04:52 25 MR. HASFORD: It's simply a background to indicate,

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1 your Honor, that the Lupin proposed package insert is  
 2 essentially identical to the Prolensa® package insert so that  
 3 we don't have to go through, you know, the entirety, for  
 4 example, of all the formulation components.  
 04:52 5 THE COURT: I'm going to sustain the objection. I  
 6 think the purpose of this limited testimony was to explain the  
 7 patent itself, to give the plaintiffs the first opportunity to  
 8 introduce the concepts of the patent rather than to preview  
 9 the arguments that the plaintiffs are going to be making later  
 04:53 10 in the case.  
 11 MR. HASFORD: And as I understand Your Honor's ruling  
 12 in the -- from the call that the parties had with your Honor  
 13 approximately a week ago, your Honor will permit us to provide  
 14 factual information about the products, which includes Lupin's  
 04:53 15 product; is that correct?  
 16 THE COURT: The products I believe were meant to be  
 17 Prolensa®, the plaintiffs' products. What does the order say?  
 18 I don't have a copy in front of me.  
 19 MR. HASFORD: So, your Honor, this is Docket 221.  
 04:53 20 And your Honor's statement is with respect to Item 5, the  
 21 order of proof, plaintiffs will be permitted to go first and  
 22 presentations shall be limited to background testimony on the  
 23 claim subject matter of the '431 patent and the products at  
 24 issue. We understood that to mean both Prolensa® and Lupin's  
 04:54 25 generic -- Lupin's and InnoPharma's generic bromfenac

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1 ophthalmic solution. And we certainly didn't get any  
 2 objections yesterday when we disclosed these documents to  
 3 counsel for the defendants. So we believe that --  
 4 MS. HOLLAND: Your Honor --  
 04:54 5 MR. HASFORD: -- that's their understanding as well.  
 6 MS. HOLLAND: -- what this formulation is. I don't  
 7 think we have to spend another, you know, half hour of the  
 8 Court's time on this. Why don't we try to do that tonight and  
 9 we can come back with a stip tomorrow instead of having to go  
 04:54 10 through this.  
 11 MR. HASFORD: Well, your Honor --  
 12 MS. HOLLAND: There is a stip on infringement in any  
 13 event so I'm not sure --  
 14 THE COURT: It's not an infringement case, and so the  
 04:54 15 products at issue are not the defendants' products, are they?  
 16 MR. HASFORD: Well, the defendants have certainly  
 17 stipulated that those products infringe. We merely had  
 18 planned to go through that for background purposes, your  
 19 Honor.  
 04:54 20 MR. MUKERJEE: Your Honor --  
 21 THE COURT: I don't think it's necessary. I detect  
 22 that there is really no dispute about your characterization of  
 23 the defendants' products, and so the witness wouldn't have to  
 24 take the time to go through that. But this was meant to be an  
 04:55 25 introduction to the '431 patent. Perhaps I shouldn't have  
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1 used the plural form of "products."  
 2 MR. MUKERJEE: And, your Honor, in looking at  
 3 Mr. Hasford's binder, I think they intend on asking the same  
 4 type of question on InnoPharma, so to the extent that  
 04:55 5 Mr. Hasford does, I assume your sustaining of Ms. Holland's  
 6 objection applies to them also.  
 7 THE COURT: Well, do you also agree with what  
 8 Ms. Holland said, that there is no dispute that the product of  
 9 InnoPharma is identical to the Prolensa® product?  
 04:55 10 MR. MUKERJEE: I -- I agree that there is a  
 11 stipulation on infringement on file, and I also agree that the  
 12 issue of infringement is no longer an issue at trial, and so,  
 13 therefore, there really is no relevance to that. And so, just  
 14 as your Honor sustained the objection that Ms. Holland put  
 04:55 15 forth, I'm just asking that to the extent Mr. Hasford asks the  
 16 identical question again with respect to InnoPharma, that the  
 17 objection be sustained there as well.  
 18 MR. HASFORD: Your Honor, what I would do then is I  
 19 would offer Lupin's and InnoPharma's infringement stipulations  
 04:56 20 on Claims 6 and 20 of the '431 patent into evidence.  
 21 MR. MUKERJEE: Evidence with respect to what? The  
 22 stipulation speaks for itself.  
 23 MR. HASFORD: I don't believe that the stipulation  
 24 has yet been signed by your Honor, so I'm offering it in  
 04:56 25 evidence so we don't have to prove this all up.  
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1 THE COURT: I wasn't aware there is a signature space  
 2 on there for me. But it's been filed with the Court, hasn't  
 3 it, the stipulation?  
 4 MR. HASFORD: I believe it has, your Honor. And I  
 04:56 5 apologize if we forgot to include a signature space for your  
 6 Honor.  
 7 THE COURT: No, but there is no doubt now, is there,  
 8 about what the stipulation is?  
 9 MR. HASFORD: We don't believe there is, your Honor.  
 04:56 10 THE COURT: Okay. Do you agree, Mr. Mukerjee?  
 11 MR. MUKERJEE: Yes, Your Honor.  
 12 THE COURT: All right. That's like a constitutional  
 13 document. It frames the rest of the trial. I don't think it  
 14 has to be entered into evidence.  
 04:57 15 MR. HASFORD: All right. We understand.  
 16 THE COURT: If there is a dispute that comes up where  
 17 it becomes necessary for some reason, then you can offer it,  
 18 but at this point it is of record.  
 19 MR. HASFORD: Well, your Honor, then we have no  
 04:57 20 further questions at this time.  
 21 We would offer PTX-165, JTX-1, JTX-6, JTX-210,  
 22 JTX-147, PTX-745, JTX-22, and PTX-120 into evidence.  
 23 MS. HOLLAND: I don't -- your Honor, I don't believe  
 24 they were all actually used in the testimony.  
 04:57 25 MR. HASFORD: I believe that those -- those  
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1 particular ones I believe were. I didn't include the --  
 2 your -- Lupin's proposed package insert or InnoPharma's.  
 3 PTX- -- I can go through them.  
 4 THE COURT: I think you've used everything in the  
 04:57 5 book --  
 6 MR. HASFORD: Up through PTX-120, including PTX-120.  
 7 We obviously -- given your Honor's ruling on the objection, we  
 8 won't be using PTX-127 and up.  
 9 THE COURT: All right. Is there any objection to any  
 04:58 10 of those documents? And I will recite them again.  
 11 MS. HOLLAND: No objection.  
 12 MR. MUKERJEE: No, Your Honor.  
 13 THE COURT: Okay. The following then are received  
 14 into evidence: JTX-001, JTX-006, JTX-210, JTX-147, PTX-745,  
 04:58 15 JTX-22, and PTX-120.  
 16 (PLAINTIFF EXHIBITS JTX-001, JTX-006, JTX-210, JTX-147,  
 17 PTX-745, JTX-22, and PTX-120 WERE RECEIVED IN EVIDENCE.)  
 18 MR. HASFORD: And I believe PTX-165 which was  
 19 Dr. Williams' curriculum vitae, your Honor.  
 04:59 20 THE COURT: Oh, yes. The very first. PTX-165 is  
 21 also received into evidence.  
 22 (PLAINTIFF EXHIBIT PTX-165 WAS RECEIVED IN EVIDENCE.)  
 23 MR. HASFORD: Your Honor, plaintiffs also offer  
 24 PDX2-1, PDX2 -- sorry -- PTD2-1 -- is it PDX? Okay. PDX2-1,  
 04:59 25 PDX2-2, and PDX2-3 as demonstrative exhibits.  
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1 THE COURT: Well, by their nature, demonstrative  
 2 exhibits are not received into evidence and the evidence will  
 3 be his testimony. He read those exhibits and he can be  
 4 cross-examined on what he testified to. But demonstratives  
 04:59 5 are not evidence themselves.  
 6 MR. HASFORD: We would only be offering them to the  
 7 Court as demonstratives, your Honor.  
 8 THE COURT: Okay. You can retain them and if they're  
 9 helpful in your closing arguments or with some other witness,  
 05:00 10 you can use them, but they are not themselves evidence. His  
 11 testimony will be the evidence on this.  
 12 MR. HASFORD: Thank you, your Honor.  
 13 THE COURT: Is there cross-examination?  
 14 MS. HOLLAND: There is, Your Honor.  
 05:00 15 MR. HASFORD: And briefly, your Honor, we understand  
 16 that your Honor would prefer the non-bound versions of the  
 17 exhibits? We have those here.  
 18 THE COURT: Let's pause for a minute. With regard to  
 19 each witness, the parties are going to be offering packets or  
 05:00 20 bundles, and the same exhibit probably may be used with many  
 21 different witnesses. Is that same exhibit then going to  
 22 appear in each and every bundle, for instance, the '431  
 23 patent?  
 24 MS. HOLLAND: It likely will, because each witness  
 05:00 25 will need to look at the patent as part of their testimony.

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1 MS. HOLLAND: (Nods head.)  
 2 THE COURT: All right. Okay. Cross-examination.  
 3 (CROSS EXAMINATION OF ROBERT O. WILLIAMS, III BY MS. HOLLAND:)  
 4 Q. Good afternoon, Dr. Williams.  
 05:02 5 A. Hi, Ms. Holland.  
 6 MS. HOLLAND: We are going to be handing up binders  
 7 with the cross-examination exhibits.  
 8 BY MS. HOLLAND:  
 9 Q. Dr. Williams, you were asked about the disclosure of the  
 05:02 10 invention section of the '431 patent which is JTX-1. Do you  
 11 recall that?  
 12 A. Yes.  
 13 Q. And you testified that tyloxapol was inhibiting the  
 14 chemical degradation of the bromfenac formulation; is that  
 05:03 15 correct?  
 16 A. Based on the results shown in Table 2 and Table 3 of  
 17 experimental Example 1 and experimental Example 2, that was  
 18 the conclusion, yes.  
 19 Q. Well, my question was a little different.  
 05:03 20 So, you're saying that the purpose of the tyloxapol in  
 21 the formulation was to prevent chemical degradation; is that  
 22 right?  
 23 A. Well, I said that was an object of the invention.  
 24 Q. Okay. So, let's go back to that disclosure of the  
 05:03 25 invention section, and, again, it's Column 2 of JTX-1 which is

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1 THE COURT: Okay. And you've put your patents  
 2 together so I'm not going to displace that. I don't know how  
 3 many copies of the same document I need to receive, but I can  
 4 sort that out. I think that's probably the easier thing.  
 05:01 5 And so I'm okay with the binders. Everything is  
 6 included and I don't need a second set.  
 7 MR. HASFORD: All right.  
 8 THE COURT: Is there any reason why the -- you know,  
 9 the paper version of the binder version might be more useful?  
 05:01 10 MR. HASFORD: We had purely understood that the paper  
 11 version was your Honor's preference, but if your Honor is fine  
 12 with the binder version, you're certainly -- that's fine with  
 13 us.  
 14 THE COURT: Well, to me, the binder version is a  
 05:01 15 paper version.  
 16 MS. HOLLAND: Your Honor, may I suggest, it might be  
 17 easier for the Court if at the end of trial, once we know what  
 18 exhibits have actually been admitted, that we must make  
 19 binders of those for the Court so it won't be repetitious?  
 05:01 20 THE COURT: Yes, I think by the time of closing  
 21 arguments that having one set of exhibits will be helpful.  
 22 And each day, I'd encourage you to compare notes with Marnie  
 23 Maccariella as to what's actually been admitted into evidence,  
 24 make sure that our bookkeeping compares with yours. Okay?  
 05:02 25 MR. HASFORD: All right.

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1 the '431 patent. And the paragraph you pointed to starts at  
 2 Column 2, Line 34, and it goes down through Column 2, Line 49.  
 3 Are you there?  
 4 A. Yes.  
 05:04 5 Q. Okay. Now, that paragraph actually does not use the  
 6 words "chemical degradation," correct?  
 7 A. As I stated, that paragraph in Line 43 uses change of the  
 8 bromfenac over time can be inhibited, which, in my opinion,  
 9 that's understood to be chemical degradation of bromfenac.  
 05:04 10 Q. All right. But my question is a little different.  
 11 Did you see the words "chemical degradation" anywhere  
 12 in the '431 patent? Those words.  
 13 A. The words "chemical degradation," no. But that --  
 14 Q. That was my question. Thank you.  
 05:04 15 A. -- Table 1 or Table 2 is --  
 16 MR. HASFORD: Whoa. Your Honor, she's cutting him  
 17 off. He's entitled to explain his answer.  
 18 THE COURT: Well, I think it's a "yes" or "no"  
 19 question that's being asked, Doctor, is whether the words  
 05:05 20 "chemical degradation" appear anywhere in the '431 patent, to  
 21 the best of your knowledge.  
 22 THE WITNESS: Okay. Thank you. I don't see them,  
 23 no, those two words.  
 24 BY MS. HOLLAND:  
 05:05 25 Q. And, likewise, the words "chemical stability" don't

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1 appear anywhere -- anywhere in the '431 patent, correct?

2 Those words.

3 A. **I don't believe they do.**

4 Q. Now, there is another type of stability called physical

05:05 5 stability, correct?

6 A. **Yes.**

7 Q. And, in your opinion, physical stability refers to

8 whether the formulation's appearance changes over time; is

9 that right?

05:05 10 A. **That's true, yes.**

11 Q. For example, if a formulation becomes cloudy or turbid,

12 you would consider that a problem of a physical stability

13 rather than chemical stability, correct?

14 A. **Turbid. And yes, that's true.**

05:06 15 Q. Now, you also talked about the background art section of

16 the '431 patent, so I'd like to focus your attention back

17 there now. But I actually want to talk about a part of the

18 background art section that you didn't talk about in your

19 direct examination. So let me refer you to Column 1, starting

05:06 20 at Line 62, and then the paragraph goes over to Column 2, Line

21 3. Do you see that?

22 A. **Yes.**

23 Q. And do you see there that what's written in the patent is

24 that "benzalkonium chloride is a widely used preservative in

05:06 25 ophthalmic solutions"?

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1 A. **From my experience, it's a problem with physical**

2 **stability.**

3 Q. All right. Now, bromfenac is an NSAID with an acidic

4 group, right?

05:08 5 A. **Bromfenac has a carboxylic acid group.**

6 Q. Do you consider that an acidic group?

7 A. **Yes.**

8 Q. Okay. So if bromfenac forms complexes with BAC, if that

9 happened, that would be a problem of physical stability,

05:08 10 correct?

11 MR. HASFORD: Objection, Your Honor. Assumes facts

12 not in evidence. That sounds like this is getting into the

13 type of opinion testimony that Ms. Holland objected to when we

14 were doing direct exam with Dr. Williams.

05:08 15 MS. HOLLAND: May I address that, your Honor?

16 THE COURT: Yes.

17 MS. HOLLAND: Dr. Williams gave testimony that in his

18 opinion, when the patent says stability, it refers to chemical

19 stability. I'm entitled to probe whether it really refers to

05:09 20 chemical stability or not or if that's the way a person of

21 ordinary skill in the art would really understand it. It's

22 about what the patent means.

23 THE COURT: I hesitate to let you probe his

24 understanding of everything in this patent --

05:09 25 MS. HOLLAND: I'm not going to.

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1 A. **The quote, yes.**

2 Q. Okay. And then it says, "However, benzalkonium chloride

3 and other quaternary ammonium compounds are generally

4 considered to be incompatible with ophthalmic compositions of

05:07 5 drugs with acidic groups, such as nonsteroidal

6 anti-inflammatory drugs." Do you see that?

7 A. **Yes.**

8 Q. And it says, "These preservatives, referring to BAC, lose

9 their ability to function as they form complexes with the

05:07 10 charged drug compounds." Do you see that?

11 A. **Yes.**

12 Q. So that paragraph describes a phenomenon where drugs with

13 acidic groups like NSAIDs form complexes with BAC, correct?

14 A. **Well, that describes that that could happen, because it**

05:07 15 **uses the word "generally considered." So I think that would**

16 **be understood by a person of ordinary skill in the art to**

17 **mean -- or be understood that that could happen, but you have**

18 **to figure out if it's happening or not with data.**

19 Q. Okay. But the '431 patent does acknowledge that that

05:07 20 phenomenon of NSAID complexation with BAC can happen, correct?

21 A. **Well, they're quoting from this Japanese 35 -- or 2954356**

22 **patent, and I mean, that it says generally considered, so**

23 **it -- it recognizes that that could happen.**

24 Q. Now, if -- if an NSAID forms a complex with BAC, is that

05:08 25 a problem with physical stability or chemical stability?

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1 THE COURT: -- because that's what the rest of the

2 case is going to be about. If there is something that he

3 testified to on direct that you feel needs cross-examination,

4 I'll permit it.

05:09 5 MS. HOLLAND: Your Honor, what he testified to on

6 direct, and I wrote it down to make sure that I would stay

7 within the scope of the direct, was that the patent shows that

8 tyloxapol was used to combat chemical degradation. I'm

9 cross-examining him on that issue.

05:09 10 THE COURT: All right. I'll permit it.

11 BY MS. HOLLAND:

12 Q. So the question was: If bromfenac formed complexes with

13 BAC, would that be a problem of physical stability or chemical

14 stability? If that happens.

05:09 15 A. **Well, if that happens and it's -- and the complex is not**

16 **soluble, then it will precipitate, so it would be a physical**

17 **stability, from my experience.**

18 Q. Do you agree that tyloxapol is included in the claimed

19 formulations to address the problem of bromfenac forming

05:10 20 complexes with BAC?

21 A. **I mean, what I understand from the patent is that**

22 **tyloxapol is included to inhibit chemical degradation of**

23 **bromfenac, and that in that process, however it's working,**

24 **which I don't understand exactly how it works, but that the**

05:10 25 **preservative efficacy when a quaternary ammonium preservative**

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1 like benzalkonium chloride is also used, that it maintains the  
 2 preservative efficacy over some shelf life.  
 3 Q. Let me try my question again because maybe you didn't  
 4 understand it.  
 05:10 5 My question is about tyloxapol. Do you agree that  
 6 tyloxapol is included in the '431 patent to address issues of  
 7 physical stability of bromfenac formulations?  
 8 A. No.  
 9 Q. And it's your view that tyloxapol is not included to  
 05:11 10 address the problem of bromfenac forming complexes with BAC;  
 11 is that correct?  
 12 A. Say that again, please.  
 13 Q. Yes. Do you agree that tyloxapol is included in the  
 14 claimed formulations of the '431 patent to address the problem  
 05:11 15 of bromfenac forming complexes with BAC?  
 16 A. No. I don't -- I don't think it is, no.  
 17 Q. Now, you testified that -- I'm just trying to find your  
 18 quote.  
 19 You testified that tyloxapol was not used as a chemical  
 05:11 20 stabilizer as of 2003, right?  
 21 A. Yeah. There was more to the question that I answered,  
 22 but that was part of it. I think it was for NSAIDs. I can't  
 23 quite remember the question but --  
 24 Q. Well, was tyloxapol used as a chemical stabilizer as of  
 05:12 25 2003?

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1 A. It -- I'm not aware of where it was.  
 2 Q. But it was used as a physical stabilizer as of 2003,  
 3 correct?  
 4 A. Tyloxapol?  
 05:12 5 Q. Yes.  
 6 A. For suspensions or emulsions or -- I believe it was.  
 7 Q. Now, did you make any effort to determine why the  
 8 inventors actually included tyloxapol in their formulations  
 9 that are in the '431 patent?  
 05:12 10 MR. HASFORD: Objection, Your Honor. Again, this  
 11 goes beyond the background of the patent. It goes to an issue  
 12 of what was in the inventors' mind. It certainly bears  
 13 nothing on obviousness, and it's just not an issue in this  
 14 case, and it's improper for at least those reasons.  
 05:12 15 MS. HOLLAND: Your Honor, Dr. Williams gave testimony  
 16 that the tyloxapol was included for chemical degradation  
 17 purposes. I'm entitled to explore whether that's, in fact,  
 18 accurate. Just because they don't put an inventor on the  
 19 stand doesn't mean they can shield everything that the  
 05:13 20 inventors did.  
 21 MR. HASFORD: Your Honor --  
 22 MS. HOLLAND: That contradicts the expert's  
 23 testimony.  
 24 MR. HASFORD: And, your Honor, he was testifying as  
 05:13 25 to the background of what's presented in this patent. He's

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1 not testifying as to what the background was, of what may have  
 2 been in the inventor's mind, which is irrelevant in an  
 3 obviousness case in any event. The Federal Circuit has said  
 4 that over and over and over again.  
 05:13 5 THE COURT: Well, I think part of this issue has to  
 6 do with the function that this witness is serving at this  
 7 point in the trial.  
 8 As I understood the proffer by the plaintiffs and as  
 9 I understood their direct examination, the witness was to be  
 05:13 10 speaking as if he were the patent. He's explaining himself.  
 11 This is what the patent is, this is what these words mean,  
 12 this is what the references to prior art contain, and so on.  
 13 I don't believe that the witness is being asked, well, what's  
 14 his personal opinion about whether this all makes sense or  
 05:14 15 whether it's good science or whether he agrees or disagrees  
 16 with the patent. My understanding was in introducing the  
 17 patent, quote, unquote, Professor Williams' role was a limited  
 18 one, which is explaining what the patent means from the view  
 19 point of the patent.  
 05:14 20 MS. HOLLAND: That's all I'm asking, Your Honor. I  
 21 want to understand.  
 22 THE COURT: No, I think you're asking a different  
 23 question. Excuse me.  
 24 MS. HOLLAND: Yes.  
 05:14 25 THE COURT: The question that you're asking is what

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1 did the inventors have in their mind, and did he do research  
 2 on what the inventors did. Now, he did testify that he  
 3 reviewed the prosecution history. I'll permit questions about  
 4 that.  
 05:14 5 MS. HOLLAND: Your Honor, he also testified about the  
 6 function of each of the components of the formulation.  
 7 MR. HASFORD: Your Honor, that drew an objection.  
 8 When the -- when I asked about the functions in the patent of  
 9 the components, Ms. Holland jumped up and objected.  
 05:14 10 MS. HOLLAND: There was an exhibit up on the screen  
 11 that showed the function of tyloxapol and it said stabilizer.  
 12 MR. HASFORD: And that was in the new drug  
 13 application, Your Honor. That was for the commercialized  
 14 product. We wouldn't have any objection to Ms. Holland doing  
 05:14 15 cross-examination about that particular document.  
 16 The point here, she's trying to get into, as Your Honor  
 17 noted, what was in the inventors' mind, it's not relevant, and  
 18 it shouldn't be permitted here because it's additionally  
 19 beyond the scope of what he testified to on direct exam.  
 05:15 20 MS. HOLLAND: May I be permitted one more attempt at  
 21 this, Your Honor?  
 22 THE COURT: Yes, I was going to say, perhaps if the  
 23 question could be reformulated to something other than the  
 24 inventors' mind.  
 05:15 25 MS. HOLLAND: Well, let's do it this way. Let's

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1 start from --

2 THE COURT: In other words, the patent itself

3 expresses what its purpose was. What were the objects. I

4 think it mentions three of them.

05:15 5 MS. HOLLAND: So here's the issue, Your Honor. The

6 patent uses the word, "stability." Dr. Williams gets on the

7 stand and says, well, of course, it's talking about chemical

8 degradation, but I need to be able to probe whether that was

9 really the object of the invention here. If the inventors

05:15 10 think they were trying to do something else, then plaintiffs

11 don't bring the inventors to trial and then plaintiffs can say

12 whatever they want about what the object of the invention is.

13 THE COURT: Just a moment. Ms. Holland.

14 MS. HOLLAND: That permits plaintiffs to basically

05:16 15 put a witness on the stand, not show him what the inventors

16 actually said, and have him give opinions that are clearly

17 contradicted by what the inventors' own documents say. I

18 should be able to probe that.

19 THE COURT: Well, you will, throughout the trial, but

05:16 20 again, with an introductory witness, you can ask him about his

21 testimony on direct, and if some of the testimony came in

22 without objection, as to what he discerned as the purposes,

23 then I'll permit you to question him about that. But I do

24 think that overall, the scope of the direct and the cross was

05:16 25 to explain to me what the patent is saying, what brought it

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1 cross-examination as to another section of the same document.

2 BY MS. HOLLAND:

3 Q. All right. Are you open to that section, Doctor? It

4 should be in your binder.

05:18 5 A. I didn't get a binder.

6 Q. I apologize about that.

7 A. No worries. Thank you.

8 Q. Let's go to the first page of the document, please.

9 A. I'm sorry, this is --

05:18 10 Q. This is a section of the NDA for Prolensa.

11 THE COURT: What's the last document in the binder?

12 MS. HOLLAND: 125A.

13 THE WITNESS: Thank you.

14 BY MS. HOLLAND:

05:18 15 Q. And you see it's entitled pharmaceutical development.

16 Do you see that?

17 A. Yes.

18 Q. Okay. And if you go to Page 2 point -- I'm sorry, if you

19 go to Page 7 of 16, maybe that's the easiest way to look at

05:18 20 it.

21 And I want to focus your attention on the third

22 paragraph from the bottom of the page.

23 A. Okay.

24 Q. And in specific, I want you to look at the -- let's start

05:19 25 with the first sentence of that paragraph and this again is

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1 about, what it does, what it doesn't do. Okay?

2 MS. HOLLAND: All right. So let me go to a different

3 question, then.

4 BY MS. HOLLAND:

05:16 5 Q. Dr. Williams, you testified that Prolensa is an

6 embodiment of these asserted claims, correct?

7 A. Yes.

8 Q. And, in fact, you put up a section of the new drug

9 application on the screen to show what the function of each of

05:17 10 the excipients is in the claimed formulation, right?

11 A. Well, there was a page from the Prolensa NDA table that

12 one of the columns listed what the NDA stated was a function

13 of the excipients along with the amount used in Prolensa.

14 Q. And you're aware that there are other sections of the NDA

05:17 15 that give a more robust description of what the functions of

16 the different ingredients are in the Prolensa product, right?

17 A. You would have to show me. I'm --

18 Q. All right. Let's look at PTX-125A, and this is an

19 excerpt of the NDA for Prolensa, Section 2.3.2.

05:17 20 MR. HASFORD: Your Honor, I'm going to object. It's

21 beyond the scope of direct. We didn't go into this document

22 on direct. If she wants to ask about the document in the NDA

23 that we discussed on direct, we're fine with that, but this is

24 clearly beyond the scope of direct.

05:17 25 THE COURT: No, I'll permit it. It's

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1 talking about the function of tyloxapal in Prolensa, which you

2 testified is the embodiment of the claims in this case.

3 And what it says is, tyloxapal acts as a solubilizing

4 agent to prevent interaction between benzalkonium chloride and

05:19 5 bromfenac sodium.

6 Do you see that?

7 A. I do.

8 Q. Does that change your view on why tyloxapal was included

9 in the claimed formulations?

05:19 10 A. I mean, not according to my reading of the patent. I see

11 what this says, but...

12 Q. Let's go back to JTX-1. I want to go to Column 6 of the

13 '431 patent. And if you look at Line 11 through the end of

14 that paragraph, that's a paragraph you testified about on

05:20 15 direct, correct?

16 A. Yes.

17 Q. Okay. Now, you said that this paragraph talks about

18 additives that could be put into the claimed formulations,

19 right?

05:20 20 A. Yes.

21 Q. Okay. I just want to confirm that the patent

22 characterized those as conventional additives, correct?

23 A. The patent on Line 12, Column 6 says conventional various

24 additives.

05:20 25 Q. Okay. Now, you said that these could be added to the

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- 1 form -- to the formulations of the claims in suit here,  
 2 however, most of them are not actually part of those claims,  
 3 correct?  
 4 A. I'm sorry? I don't understand.  
 05:21 5 Q. Are all of the additives listed in the paragraph we've  
 6 been looking at requirements of the claims in this case?  
 7 A. Requirements of the claim? I don't believe so, no.  
 8 Q. Let's turn to Column 7 and the experimental examples that  
 9 you looked at during your direct examination.  
 05:21 10 You looked at Experimental Example 1 and you testified  
 11 that the testing there was done with a pH of 7, correct?  
 12 A. Yes.  
 13 Q. And then you looked at Example 2 and you said the pH was  
 14 done at a test -- in the testing at about 8.2, correct?  
 05:21 15 A. I didn't say that, no.  
 16 Q. Well, what is the pH?  
 17 A. I think I said it was about 8.13 to 8.19, something in  
 18 that range.  
 19 Q. Okay. The patent doesn't have any testing at a pH  
 05:22 20 of 7.8, correct?  
 21 A. Well, I mean, the -- Table 1 is at pH 7 and Table 2  
 22 ranges within the range I just said, like 8.13 to 8.19.  
 23 Q. So the answer to my question is no, there is no testing  
 24 in the patent at 7.8, is that right?  
 05:22 25 A. Not that I see.

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- 1 Q. But you believe it's going to affect the rate of  
 2 degradation, right?  
 3 A. Well, I -- probably in a positive way, if they are  
 4 included.  
 05:24 5 Q. Right. So the rate of degradation in Table 1 will be  
 6 different if the examples actually include sodium sulfite and  
 7 povidone which, of course, are in Claim 20 of the '431 patent,  
 8 right?  
 9 A. I mean, they may be.  
 05:24 10 Q. Now, let's look at Experimental Example 2.  
 11 That Table 2 does not contain any data for compositions  
 12 containing polysorbate 80, right?  
 13 A. That's true.  
 14 Q. So there's no comparison in Table 2 between compositions  
 05:25 15 with polysorbate 80 and compositions with tyloxapol, right?  
 16 A. That's true.  
 17 Q. Now, if you look at the tyloxapol compositions, you  
 18 testified on direct that they have three different amounts of  
 19 tyloxapol. The A-04 has .02, correct?  
 05:25 20 A. Yes.  
 21 Q. A-05 has .05, correct?  
 22 A. That's true.  
 23 Q. And A-06 has .03, correct?  
 24 A. Yes.  
 05:25 25 Q. And in the test, in Table 2, in the '431 patent, all of

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- 1 Q. And that's the pH of Prolensa, correct?  
 2 A. Yes.  
 3 Q. Let's go back to Table 1 then and I want you to look at  
 4 the formulation and the components in Table 1.  
 05:22 5 The formulations in Table 1 don't contain sodium  
 6 sulfite or povidone, right?  
 7 A. That's true, they don't.  
 8 Q. And I think you testified that sodium sulfite and  
 9 povidone, the patent says -- well, let me withdraw that.  
 05:22 10 You testified that the function of sodium sulfite and  
 11 povidone in Prolensa was stabilizers, correct?  
 12 A. Well, that's what the page from the NDA, that table I was  
 13 looking at, that's what it stated. And it's also in Column 6  
 14 as how the patent characterizes stabilizers -- or sorry,  
 05:23 15 characterizes sodium sulfite as stabilizers.  
 16 Q. So those stabilizers are missing from the formulations  
 17 that were tested in Experimental Example 1, right?  
 18 A. Well, polyvinyl povidone and sodium sulfite are not in  
 19 the compositions of the formulas made in Table 1.  
 05:23 20 Q. And you would expect the remaining rate percentages in  
 21 Table 1 to be different had they actually included sodium  
 22 sulfite or povidone, correct?  
 23 A. I don't know. I'd have to test it. I mean, based on  
 24 what the '225 Ogawa says with adding PVV and sodium sulfite, I  
 05:24 25 mean, Experimental Example 1 may be better.

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- 1 those formulations have greater than 90 percent remaining rate  
 2 of bromfenac after the testing, correct?  
 3 A. Those three do, yes.  
 4 Q. Okay. So formulas with any of those three amounts of  
 05:25 5 tyloxapol are stable pharmaceutical formulations, right?  
 6 A. Well, they're all -- the chemical potency of bromfenac is  
 7 all of -- it's -- A-04 is 92.6 percent, A-05 is 90.9 percent  
 8 and A-06 is 92 percent.  
 9 Q. You looked at the package insert for Prolensa. Do you  
 05:26 10 recall that?  
 11 A. Yes.  
 12 Q. That's JTX-23, I believe.  
 13 MS. HOLLAND: Can we see that, please.  
 14 THE WITNESS: I think it's -- I have JTX-22.  
 05:26 15 BY MS. HOLLAND:  
 16 Q. I think it's comparable. We can use 22. That's fine.  
 17 And I'd like to look at the adverse reaction section and  
 18 that's a section you looked at in your direct examination,  
 19 right?  
 05:27 20 A. Yes.  
 21 MR. HASFORD: I apologize. I think we might have a  
 22 binder problem here because I have JTX-23 in my binder.  
 23 MS. HOLLAND: I have it in mine as well, but  
 24 Dr. Williams said he testified about the version that's  
 05:27 25 JTX-22, so it doesn't matter to me which one we use. I think

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1 you've established that they were the same.  
2 MR. HASFORD: I think we used JTX--- let me just  
3 check my outline real quick. We used PTX-745 and JTX-22,  
4 unfortunately.  
05:27 5 MS. HOLLAND: All right. Why don't we just use  
6 JTX-22.  
7 BY MS. HOLLAND:  
8 Q. Is that the Prolensa label?  
9 A. Yes.  
05:27 10 Q. Okay. That's what we want.  
11 Let's look at the adverse reaction section and this is  
12 something you testified about on direct, correct?  
13 A. Yes.  
14 Q. Okay. And you said that there was no burning or stinging  
05:27 15 listed in the adverse reaction section, right?  
16 A. **It's not listed there, that's true.**  
17 Q. Okay. But that section only reports adverse reactions  
18 that occurred in three percent or greater of patients, right?  
19 A. **That's what it says.**  
05:28 20 Q. Okay. So it could be that up to three percent of  
21 patients in the clinical trials did experience burning and  
22 stinging, right?  
23 MR. HASFORD: Objection, Your Honor. Calls for  
24 speculation.  
05:28 25 THE COURT: I'll permit it.  
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1 THE WITNESS: I don't know.  
2 BY MS. HOLLAND:  
3 Q. Do you know what percentage of patients experience  
4 burning and stinging in the Xibrom or Bromday clinical trials?  
05:28 5 A. **The percent, I don't.**  
6 Q. Do you know if it was over or under three percent?  
7 A. **I know it's listed in there, in the comparable section in  
8 their package insert, but I don't know what percent.**  
9 Q. You don't know if it's over or under three percent, do  
05:28 10 you?  
11 A. **I do not.**  
12 Q. You talked about the pH specification of Prolensa in your  
13 direct testimony, correct?  
14 A. **Yes.**  
05:28 15 Q. And you had -- well, let's put up your demonstrative that  
16 had slides -- I'm sorry, that had Claim 6.  
17 This is your slide that you -- to show the elements of  
18 Claim 6 of the '431 patent, correct?  
19 A. **Yes.**  
05:29 20 Q. None of these elements have any requirement as to a  
21 specific pH, correct?  
22 A. **Well, I mean, it's formulated for ophthalmic  
23 administration, so I mean, there is some pH component but a  
24 specific pH range is not described in Claim 6.**  
05:29 25 Q. And 8.3 would be a pH for an ophthalmic formulation,  
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1 right? That was the pH of Bronuck and Xibrom and Bromday,  
2 right?  
3 A. **It could be.**  
4 MS. HOLLAND: Let's see Slide 20.  
5 BY MS. HOLLAND:  
6 Q. And again, can you confirm that Claim -- I'm sorry, I  
7 said Slide 20. I actually meant to say Claim 20.  
8 Can you confirm in Claim 20 similarly that there's no  
9 requirement for a specific pH for the formulation?  
05:30 10 A. **Yeah, I mean, I have the same opinion. It says  
11 formulated for ophthalmic administration. So pH is part of  
12 it. But there is no specific pH range that is a limitation in  
13 Claim 20.**  
14 Q. But again, a pH of 8.3, as in the previous bromfenac  
05:30 15 products, would be suitable for ophthalmic administration,  
16 right?  
17 A. **It could be.**  
18 Q. They were approved products, right?  
19 A. **They were approved products that had a pH of about 8.3.  
20 So that pH could be.**  
21 Q. Now, let me ask you about the preservative efficacy  
22 testimony that you gave.  
23 Do you also agree that the two asserted claims in this  
24 case have no limitations as to preservative efficacy?  
05:31 25 A. **Again, it's like a specific pH range. It says formulated  
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1 **for ophthalmic administration, so a sterility is a component  
2 of that. So preservative efficacy, but as Claim 6 or Claim 20  
3 are written, there's no specific limitation regarding  
4 preservative efficacy.**  
05:31 5 Q. And you agree that for a product marketed in the U.S., if  
6 it met the U.S. Pharmacopeia for preservative efficacy, that  
7 would be good enough to market the product, right?  
8 A. **From my experience, that's true.**  
9 MS. HOLLAND: I have nothing further, Your Honor.  
05:31 10 THE COURT: All right, thank you. Any further cross  
11 by Mr. Mukarjee?  
12 MR. MUKARJEE: No, Your Honor.  
13 THE COURT: All right. Any redirect?  
14 MR. HASFORD: Just a brief bit of redirect, Your  
05:31 15 Honor.  
16 THE COURT: All right.  
17 (REDIRECT EXAMINATION OF DR. WILLIAMS BY MR. HASFORD:)  
18 Q. Dr. Williams, would you please turn back to JTX-1 in your  
19 binder, which is the '431 patent, and take a look at  
05:32 20 Experimental Examples 1 and 2 which are on Columns 7 and 8  
21 respectively.  
22 A. **Okay.**  
23 Q. Do you remember when Ms. Holland asked you on cross  
24 whether there was a specific example in Experimental  
05:32 25 Examples 1 or 2 that disclosed pH 7.8 which is the pH of  
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1 Prolensa?  
 2 A. Yes.  
 3 Q. Okay. Turn, if you would, back to Column 2 of the  
 4 '431 patent. I apologize, Column 6 of the '431 patent.  
 05:32 5 Let me direct your attention to Column 6, Lines 39  
 6 through 41 of the '431 patent.  
 7 It states: The pH of the aqueous liquid preparation of  
 8 the present invention is adjusted to about 6 to 9, preferably  
 9 about 7 to 9, especially about 7.5 to 8.5.  
 05:33 10 Do all of those ranges encompass pH 7.8 at which  
 11 Prolensa was formulated?  
 12 A. They do, yes.  
 13 MR. HASFORD: Nothing further, Your Honor.  
 14 MS. HOLLAND: Your Honor, I would just like to put  
 05:33 15 PTX-125A into evidence.  
 16 THE COURT: Okay. Any objection?  
 17 MR. HASFORD: No objection, Your Honor.  
 18 THE COURT: Okay. Very well. PTX-125A, which is the  
 19 entire --  
 05:33 20 MS. HOLLAND: It's just the excerpt that's in the  
 21 binder. It's not the entire NDA.  
 22 THE COURT: Right. The excerpt from the NDA for  
 23 Prolensa will be received into evidence.  
 24 (DEFENDANT EXHIBIT PTX-125A WAS RECEIVED IN EVIDENCE)  
 05:33 25 THE COURT: Is this a good time for a break?  

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1 MR. HASFORD: Yes, Your Honor.  
 2 THE COURT: Okay. Let's take about a 10, 15-minute  
 3 break.  
 4 MR. LIPSEY: Your Honor, is the witness excused?  
 05:34 5 THE COURT: Yes.  
 6 MR. LIPSEY: Okay.  
 7 THE COURT: You don't have to file for a writ.  
 8 (RECESS TAKEN; 3:07 p.m.)  
 9 THE COURT: Be seated, please. All right.  
 06:02 10 You may proceed.  
 11 MS. RAPALINO: Good afternoon, Your Honor. Emily  
 12 Rapalino from Goodwin Procter on behalf of the Lupin  
 13 defendants.  
 14 The defendants call as their first witness in our case  
 06:02 15 in chief, Professor Jayne Lawrence.  
 16 THE COURT: Okay. Professor, please come to the  
 17 witness stand.  
 18 THE DEPUTY CLERK: Can you place your left hand on  
 19 the Bible and raise your right hand.  
 06:02 20 (MARGARET JAYNE LAWRENCE, having been duly sworn as a witness,  
 21 testified as follows:)  
 22 THE DEPUTY CLERK: Can you please state your name,  
 23 ma'am, and spell your first and last name, please.  
 24 THE WITNESS: Margaret Jayne Lawrence. That's  
 06:02 25 Margaret, M-A-R-G-A-R-E-T, Jayne with a Y, and Lawrence,  

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1 L-A-W-R-E-N-C-E.  
 2 THE DEPUTY CLERK: Thank you. You can be seated.  
 3 MS. RAPALINO: Your Honor, may we approach with the  
 4 witness binders?  
 06:03 5 THE COURT: Yes, of course.  
 6 THE DEPUTY CLERK: Thank you.  
 7 (VOIR DIRE EXAMINATION OF MARGARET JAYNE LAWRENCE BY MS.  
 8 RAPALINO:)  
 9 Q. Good afternoon, Professor Lawrence.  
 06:03 10 A. Good afternoon.  
 11 Q. Where do you live?  
 12 A. I live in a place called Ashford, Middlesex, which is  
 13 near London in the U.K.  
 14 Q. Are you employed?  
 06:03 15 A. Yes, I am. I have a full-time position as a full tenured  
 16 professor at King's College, London, where I'm a professor of  
 17 biophysical pharmaceuticals, and I'm also on the 50 percent  
 18 secondment at the Royal Pharmaceutical Society where I'm the  
 19 chief scientist.  
 06:04 20 Q. Are you affiliated with a particular group in connection  
 21 with your appointment at King's College, London?  
 22 A. Yes, I am. I'm head of the pharmaceutical biophysics  
 23 group.  
 24 Q. What is the pharmaceutical biophysics group?  
 06:04 25 A. It's a group of about six academics and associated  

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1 post-doctoral fellows, Ph.D. students who are concerned with  
 2 understanding drugs and drug delivery systems at the molecular  
 3 level, using a range of advanced analytical tools.  
 4 Q. You used the term, "drug delivery systems."  
 06:04 5 What does this mean?  
 6 A. Yes. This is the way in which drugs are administered to  
 7 a patient basically in the form of a medicine and this  
 8 obviously includes pharmaceutical formulation.  
 9 Q. How long have you held your position at King's College,  
 06:04 10 London?  
 11 A. Since 2002.  
 12 Q. Generally speaking, what are your academic  
 13 responsibilities as head of the biophysics group?  
 14 A. I have research, teaching and administrative  
 06:05 15 responsibilities.  
 16 Q. With respect to your research, what is the general  
 17 subject of your research?  
 18 A. It's -- it's generally on drug delivery systems which  
 19 obviously includes pharmaceutical formulation and a particular  
 06:05 20 interest of mine is increasing the solubility of poorly water  
 21 soluble drugs.  
 22 Q. What do you mean by a poorly water soluble drug?  
 23 A. This is a drug that doesn't freely dissolve in water.  
 24 Q. In terms of your teaching responsibilities at King's  
 06:05 25 College, what classes have you taught over the course of your  

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1 career?

2 A. I've taught many over the course of my career. I

3 currently teach first-year classes looking at pharmaceutical

4 formulation, in particular formulation of aqueous

06:05 5 formulations, creams, suspensions, emulsions. I also teach a

6 class on bioavailability and this is basically to do with how

7 drugs are absorbed in the body.

8 Q. What kinds of formulations do the classes that you teach

9 cover?

06:06 10 A. I cover non- -- I cover oral formulations and nonoral

11 formulations, which cover ophthalmic preparations.

12 Q. You also mentioned that in addition to your appointment

13 at King's College, London, you're also the chief scientist of

14 the Royal Pharmaceutical Society.

06:06 15 Can you describe that role?

16 A. Yes, certainly. In this role, I have an efficacy role

17 for pharmaceutical science. This may involve me talking to

18 the media, talking to other professional bodies with mutual

19 interest. Interacting with the government at a high level,

06:06 20 and also Department of Health.

21 Q. You mentioned that you talk to the media.

22 Can you give us a little bit more detail about what you

23 do in that role?

24 A. Yes, in my role at the Royal Pharmaceutical Society, I'm

06:06 25 often called upon by national TV stations, such as the BBC to

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1 can you briefly describe what surfactants are?

2 A. Yes. They're quite unique molecules in that they have a

3 part -- a part of the molecule that is soluble in water and a

4 part of the molecule that is insoluble in water and as a

06:08 5 consequence, they have a range of properties that are very

6 advantageous for pharmaceutical formulation.

7 Q. Could you give us an example of a property that's

8 advantageous for pharmaceutical formulation?

9 A. Yes. Surfactants are often used to increase the

06:08 10 solubility of poorly water soluble drugs and this is one of my

11 interests.

12 Q. Do the formulations of the '431 patent in this case

13 contain a surfactant?

14 A. Yes, they do. They contain the surfactant tyloxapol.

06:09 15 Q. You said that your Ph.D. was in the department of

16 pharmacy at Manchester University, but did your Ph.D. research

17 involve any chemistry?

18 A. Yes, it did. It involved me making a number of novel new

19 surfactants and then I characterized them using physical

06:09 20 chemical techniques.

21 Q. What did you do after you received your Ph.D.?

22 A. Well, it was actually before I received my Ph.D. At the

23 end of my second year of Ph.D., I was fortunate enough to be

24 awarded an academic position at King's College, London, and

06:09 25 I've been there ever since.

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1 give a view on matters of pharmaceutical importance.

2 Q. Could you turn in the witness binder that you have in

3 front of you to DTX-442.

4 What is DTX-442?

06:07 5 A. This is my curriculum vitae.

6 Q. Did you prepare this document?

7 A. Yes, I did.

8 Q. Does it accurately reflect your education and experience?

9 A. Yes, it does.

06:07 10 Q. Let's talk for a moment about your educational

11 background.

12 Where did you go to university?

13 A. I did my pharmacy degree at Liverpool Polytechnic in

14 Liverpool. After that, I spent a year undertaking

06:07 15 professional training to become a registered pharmacist, that

16 involved working six months in the community pharmacy or

17 retail pharmacy, as it was known there, and in the

18 pharmaceutical industry. After that, I started a Ph.D. in the

19 pharmacy department at Manchester University.

06:07 20 Q. What year did you obtain your Ph.D.?

21 A. 1985.

22 Q. What was the subject of your research for your Ph.D.?

23 A. It was concerned with synthesizing novel surfactants and

24 characterizing them using physical chemistry.

06:08 25 Q. We've heard a little bit about surfactants already, but

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1 Q. Have you followed the literature over the course of your

2 career related to pharmaceutical formulation?

3 A. Yes, I have.

4 Q. Have you had any experience working in the pharmaceutical

06:09 5 industry over the course of your career?

6 A. Yes, I have. In addition to the six months I spent while

7 I was training to be a pharmacist, I've also spent the six

8 months sabbatical working in Glaxo Group Research or GSK as

9 they are known now. I've also undertaken consultancies for

06:10 10 industry. I've undertaken research projects and I'm a member

11 of the Industrial Pharmacy Forum which is the U.K. group being

12 industrial pharmacists.

13 Q. Have you had any experience working with ophthalmic drugs

14 over the course of your career?

06:10 15 A. Yes, I have. I've -- I've undertaken consultancies for

16 pharmaceutical industry evaluating ophthalmic products.

17 Q. And can you explain, just in a general way, what kind of

18 work you did in connection with those consultancies on

19 ophthalmic products?

06:10 20 A. Yes. I was looking at the effect of the surfactants on

21 the formulation.

22 Q. Now we've heard that bromfenac, the drug at issue in this

23 case, is a nonsteroidal anti-inflammatory drug or NSAID.

24 Have you worked with any NSAID formulations over your

06:10 25 career?

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- 1 A. Yes. Well, I haven't worked with bromfenac, I've worked  
2 with a number of nonsteroidal anti-inflammatory drugs.  
3 Q. And what kind of work have you done with NSAIDS?  
4 A. I've been particularly interested in seeing how they  
06:11 5 interact, basically complex, with ingredients in the  
6 formulation.  
7 Q. Have you been active in any professional organizations  
8 over the course of your career?  
9 A. Yes, I have, lots.  
06:11 10 Q. If we look at -- back at DTX-442 in your binder, is that  
11 activity reflected at Pages 2 to 4 of your CV?  
12 A. Yes, it is.  
13 Q. Directing your attention to Pages 3 and 4, can you give  
14 us a couple of examples of professional organizations with  
06:11 15 which you've been involved?  
16 A. Certainly. I'm currently chair of the Academy of  
17 Pharmaceutical Sciences, which is a professional body in the  
18 U.K. representing pharmaceutical sciences, and I'm also chair  
19 of the Formulation of Pharmaceutical Technology Special  
06:11 20 Interest Group of the International Pharmaceutical Federation,  
21 which is a federation that promotes pharmacy and  
22 pharmaceutical sciences at a high level on the international  
23 arena.  
24 Q. Have you had any involvement with regulatory authorities  
06:12 25 over your career?

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- 1 your career?  
2 A. Yes. In addition to being a reviewer, I was on the  
3 editorial board of Journal -- Journal of Pharmaceutical  
4 Sciences, and quite a while ago, I was actually on the  
06:13 5 editorial board of Drug Development and Industrial Pharmacy.  
6 Q. Have you won any awards in connection with your work?  
7 A. Yes, I have.  
8 Q. If I could direct your attention to Page 1 of DTX-442,  
9 can you tell us about a couple of your more recent awards?  
06:14 10 A. Yes. In 2012, I was awarded an eminent fellowship of the  
11 Academy of Pharmaceutical Sciences for my leadership in  
12 pharmaceutical science, leadership and research.  
13 Q. How many such awards are given?  
14 A. It's less than 25 at the moment.  
06:14 15 Q. Can you give us another example of a recent award?  
16 A. Certainly. I was given -- awarded in 2013, a faculty  
17 fellowship from the Royal of Pharmaceutical Society, again for  
18 my leadership in research in pharmaceutical science.  
19 MS. RAPALINO: Defendants offer Professor Lawrence as  
06:14 20 an expert in pharmaceutical formulation and drug delivery.  
21 MR. HASFORD: No objection as to those two fields,  
22 Your Honor.  
23 THE COURT: Okay. Very well. The Court will  
24 recognize Professor Lawrence as an expert in those fields.  
05:34 25 MS. RAPALINO: Thank you, your Honor.

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- 1 A. Yes, I have.  
2 Q. Can you describe that involvement?  
3 A. Certainly. I was a member of the Task and Finish Group  
4 of the European Medicine Agency which is the equivalent of the  
06:12 5 FDA, and I was involved in preparing a reflection paper on  
6 micellar injectables.  
7 Q. What is a reflection paper?  
8 A. This is a paper that represents the state of the art in  
9 terms of use of -- in this case, micelles for injectable  
06:12 10 formulations and how to characterize them.  
11 Q. Have you had any other involvement with regulatory  
12 authorities?  
13 A. Yes, I have. In my role with the Pharmaceutical Society,  
14 I meet on a fairly regular basis with the MHRA, which is the  
06:12 15 English equivalent of the FDA, and we meet to discuss matters  
16 of mutual interest.  
17 Q. Have you published in your field?  
18 A. Yes, I have.  
19 Q. About how many publications do you have?  
06:13 20 A. I have over 124 papers, in addition, obviously book  
21 chapters, reviews and conference abstracts, et cetera.  
22 Q. What's the general subject matter of your publications?  
23 A. It's basically drug delivery using surfactants to  
24 increase -- improve the delivery of drugs.  
06:13 25 Q. Have you had a role in any journals over the course of

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- 1 BY MS. RAPALINO:  
2 Q. Professor Lawrence, before we talk about the substance of  
3 your opinions in this case, I'd like to talk about some of the  
4 background science that's relevant here. Have you prepared a  
06:15 5 slide that reflects the topics that you're going to cover by  
6 way of scientific background?  
7 A. Yes, I have.  
8 Q. With reference to your slide, could you briefly review  
9 the topics that you plan to cover?  
06:15 10 A. I briefly intend to cover pharmaceutical formulation of  
11 ophthalmic products.  
12 After I've done that, I'll talk about nonsteroidal  
13 anti-inflammatories or NSAIDS, in particular the NSAID  
14 bromfenac.  
06:15 15 After that, I'll have a discussion of quaternary  
16 ammonium compounds and in particular benzalkonium chloride,  
17 which I describe as BAC.  
18 And, finally, I'll finish off with the discussion about  
19 surfactants and in particular surfactant tyloxapol.  
06:15 20 Q. Very generally, beginning with the first topic that  
21 you're going to cover, what is the scientific field that's  
22 relevant to the '431 patent-in-suit?  
23 A. The scientific field that's relevant to the  
24 patents-in-suit is pharmaceutical formulation and in the  
06:16 25 particular formulation of ophthalmic products.

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1 Q. Can you describe generally what ophthalmic formulation  
 2 is?  
 3 A. Yes. Basically it's making of a medicine, it's mixing  
 4 the drug with various other inactive ingredients to make a  
 06:16 5 product that could be administered to the patient.  
 6 Q. How would a pharmaceutical formulator as of 2003 go about  
 7 making an ophthalmic solution formulation product?  
 8 A. Well, first of all, they have to have active ingredients.  
 9 And once they had an active ingredient, as they're going to be  
 06:16 10 formulating an ophthalmic product, they would actually know  
 11 there's a range of inactive ingredients to select from, these  
 12 would be well-known to the formulator and they'd be chosen  
 13 specifically to perform different types of functions.  
 14 Q. And how does the formulator go about choosing the  
 06:17 15 inactive ingredients to use in a particular formulation?  
 16 A. Well, basically literature gives guidance to this. So,  
 17 for example, there'd be textbooks such as -- or handbooks such  
 18 a Remington Pharmaceutical Excipient Handbook. There's the  
 19 FDA an active ingredient guide. And there'd also be  
 06:17 20 literature on similar products and that would be consulted as  
 21 well.  
 22 Q. And how does the formulator, generally speaking, go about  
 23 choosing the amounts of the inactive ingredient?  
 24 A. Yes, they look at the literature, consult the literature  
 06:17 25 and see what range of ingredients was actually acceptable for

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1 course, that costs a lot of money and companies aren't  
 2 interested in doing that sort of thing.  
 3 Q. Have you ever published anything discussing the  
 4 formulators' preference for previously approved ingredients?  
 06:19 5 A. Yes, I have.  
 6 Q. Can you turn in your binder, please, to JTX-45? Can you  
 7 identify for us what JTX-45 is?  
 8 A. This is a review I published in a journal called Chemical  
 9 Society Reviews in 1994 on surfactant systems they use in drug  
 06:20 10 delivery.  
 11 Q. Did you say anything in this review about the limited  
 12 number of excipients available to a formulator?  
 13 A. Yes, I did.  
 14 Q. Can you tell us what you said?  
 06:20 15 A. Yes. I basically explained what I've just explained to  
 16 you and said that there's obviously understandable reluctance  
 17 of a pharmaceutical company to actually go into full scale  
 18 toxicity tests to prove, in this case because I'm talking  
 19 about surfactants, a new surfactant was safe for drug delivery  
 06:20 20 purposes. I stated that in 1994 it was about ten million  
 21 pounds, and it's obviously going to be greater now, and, as a  
 22 consequence of this, formulators only tend to look for  
 23 ingredients that are recognized as safe.  
 24 Q. And can you point us to where in JTX-45 you see that  
 06:21 25 statement?

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1 use in the type of product that they're interested in and, in  
 2 particular, they'd consult the inactive guide of the FDA to  
 3 see what was acceptable for formulation purposes.  
 4 Q. And once they had a starting point from the literature,  
 06:18 5 what would the formulator then do to select the amount of the  
 6 inactive ingredient?  
 7 A. Once they had selected a range, what they would look at  
 8 is making preparation that contain that range of material to  
 9 effectively optimize that amount of material and they would  
 06:18 10 normally try to select the lowest concentration of that  
 11 ingredient that was appropriate to produce a stable  
 12 formulation.  
 13 Q. How many options were available to the formulator as of  
 14 2003 in terms of acceptable excipients to use in an ophthalmic  
 06:18 15 solution product?  
 16 A. Very few.  
 17 Q. Why were there very few excipients that were available?  
 18 A. When you're going to be formulating product, you don't  
 19 want to use an inactive ingredient, anything that hasn't  
 06:18 20 already obtain regulatory approval.  
 21 Q. Why is that?  
 22 A. If it hasn't obtained regulatory approval, you would have  
 23 to undertake some range of toxicity studies, which are  
 24 effectively slightly less small versions of clinical trials,  
 06:19 25 to prove that the excipient is actually safe for use. And, of

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1 A. Yes, certainly. It's on JTX-45.6 on the left-hand column  
 2 under the Choice of Surfactants.  
 3 Q. Is there other literature that discusses the limited  
 4 number of options for pharmaceutical ingredients that were  
 06:21 5 specifically available for ophthalmic formulations as of  
 6 20003?  
 7 A. Yes, there is.  
 8 Q. Can you give us an example of another piece of  
 9 literature?  
 06:21 10 A. There's a piece of literature would be Remington's, which  
 11 is a handbook for pharmaceutical formulators and is sometimes  
 12 known as the bible of formulation.  
 13 Q. Let's look in your binder at DKT-15. What is DKT-15?  
 14 A. This is an extract from the 20th edition of Remington:  
 06:22 15 The Science and Practice of Pharmacy, this is the edition from  
 16 2000, which would have been the one formulators would have  
 17 used for this present case.  
 18 Q. What does Remington say about the number of excipients  
 19 available to formulate an ophthalmic solution product?  
 06:22 20 A. Yes. On DTX-015.4 on the left-hand side of the page  
 21 under Additives it says, "The use of various additives in  
 22 ophthalmic solution is permissible; however, the choices are  
 23 very few."  
 24 Q. Would a pharmaceutical formulator as of January 2003 have  
 06:22 25 known which were the few pharmaceutical excipients that had

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- 1 been previously approved by FDA for use in ophthalmic  
2 solution?
- 3 **A. Yes. They would have done and they would have -- to**  
4 **obtain this information they would have consulted with the**  
06:22 5 **appropriate FDA inactive ingredients guide.**
- 6 **Q. Can you tell us, just generally, what is the FDA inactive**  
7 **ingredients guide?**
- 8 **A. It's a listing of all excipients that are currently**  
9 **contained in pharmaceutical formulations that have been**  
06:23 10 **approved by the FDA, it lists the type of formulation and the**  
11 **amount of excipients or the range of excipient that is used**  
12 **and also the number of formulations it's contained in.**
- 13 **Q. Can you turn in your binder to DTK-196. What is DTX-196?**
- 14 **A. This is the FDA inactive guide from 1996, 1997.**
- 06:23 15 **Q. Okay. Now, once a pharmaceutical formulator decides that**  
16 **an ingredient is appropriate for inclusion in his or her**  
17 **ophthalmic formulation, can you just explain generally how the**  
18 **formulator goes about determining the right amount of that**  
19 **excipient to use?**
- 06:24 20 **A. Yes, they would undergo a process, which I've entitled**  
21 **here as Pharmaceutical Principles. They would use the range**  
22 **of concentration of that excipient that is reported in prior**  
23 **formulations. They would then prepare the formulations using**  
24 **a range of concentrations. Test those formulations to ensure**  
06:24 25 **that they're appropriate for their use and were stable and use**

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- 1 **the lowest concentration possible to obtain a stable**  
2 **formulation.**
- 3 **Q. And is there a name for that process that formulators**  
4 **use?**
- 06:24 5 **A. Yes, it would be called routine optimization.**
- 6 **Q. And generally how does an optimization process work?**
- 7 **A. It's generally a systematic process in which the**  
8 **formulator will come up with a series of formulations**  
9 **containing different concentrations of the inactive**  
06:25 10 **ingredients, prepare the formulation and test them for the**  
11 **attributes that they're interested in.**
- 12 **Q. You mentioned earlier that the formulator is interested**  
13 **in using the lowest possible amount of the inactive ingredient**  
14 **that will be compatible with a stable formulation. Why is the**  
06:25 15 **formulator interested in the lowest possible amount of the**  
16 **inactive ingredient?**
- 17 **A. It's mainly in terms of toxicity because in every**  
18 **inactive ingredient, if used in too high concentrations, can**  
19 **exhibit some toxicity. So the formulator tries to use the**  
06:25 20 **lowest concentration that will give them a stable formulation**  
21 **to ensure the least toxicity possible.**
- 22 **Q. Okay. Let's move on to the next section of your**  
23 **background science tutorial.**
- 24 **And can you tell us, before we do that, just generally,**  
06:25 25 **the ingredients, the basic ingredients in the formulations**

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- 1 claimed in the '431 patent?
- 2 **A. The basic ingredients in the '431 patent are, for**  
3 **nonsteroidal anti-inflammatory bromfenac, the quaternary**  
4 **ammonium compound is the surfactant tyloxapol.**
- 06:26 5 **Q. Let's start with bromfenac. We heard a little bit about**  
6 **this from Professor Williams so I don't want to belabor it,**  
7 **but can you tell us generally what the class of compounds is**  
8 **that bromfenac belongs to?**
- 9 **A. Yes, certainly. Bromfenac is an example of what's known**  
06:26 10 **as a nonsteroidal anti-inflammatory drug or NSAID for short.**
- 11 **Q. And, generally speaking, what are NSAIDS used for?**
- 12 **A. NSAIDS are used to treat inflammation of various types.**
- 13 **Q. Is there anything notable about the chemical structure of**  
14 **the subclass of NSAIDS to which bromfenac belongs?**
- 06:26 15 **A. Yes. Bromfenac belongs to a subset of NSAIDS that are**  
16 **called the acidic NSAIDS because they all contain an acidic or**  
17 **carboxyl group.**
- 18 **Q. Okay. Have you prepared a demonstrative showing --**  
19 **demonstrating that carboxyl or carboxylic group?**
- 06:27 20 **A. Yes, I have.**
- 21 **Q. Can you point out DTX-210 where the carboxylic acid group**  
22 **is in bromfenac?**
- 23 **A. I have put up two examples of nonsteroidal**  
24 **anti-inflammatories, the one on the left being bromfenac, and**  
06:27 25 **in both cases the acidic group is on the left-hand side of the**

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- 1 **molecule as you look at it. It's consists of a carbon, which**  
2 **you can't see, but that's basically at the joint between the**  
3 **two solid lines and the equal sign and oxygen and an OH group,**  
4 **which consists also of oxygen and OH.**
- 06:27 5 **Q. And have you prepared a demonstrative to show what**  
6 **happens when compounds like bromfenac are put in solution at**  
7 **the pH that's relevant for ophthalmic formulations?**
- 8 **A. Yes, I have.**
- 9 **Q. Can you walk us through what happens in your**  
06:27 10 **demonstrative?**
- 11 **A. Certainly.**
- 12 **MR. HASFORD: I'll object, your Honor, to the extent**  
13 **this is going into chemistry. Dr. Lawrence is not qualified**  
14 **here as a expert in chemistry. I'll object on that basis.**
- 06:28 15 **MS. RAPALINO: Your Honor, this is squarely within**  
16 **the scope of Professor Lawrence's expert report. And at least**  
17 **her opening report Paragraph 66, she testified that her Ph.D.**  
18 **research in pharmaceutical formulation involved several**  
19 **aspects of chemistry. And she's just testifying about the**  
06:28 20 **very, very basic chemistry that's involved in ionization of**  
21 **these compounds at a pH that a formulator would be most**  
22 **concerned with when preparing an ophthalmic solution.**
- 23 **MR. HASFORD: Your Honor, she has neither been**  
24 **offered nor qualified as an expert in chemistry. They have a**  
06:28 25 **chemist of Dr. Heathcock, this information could conceivably**

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1 have been in his report. Regardless of whether it happens to  
 2 be in her report she's simply not an expert in chemistry.  
 3 That's the basis of our objection.  
 4 THE COURT: Can you perhaps ask a few clarifying or  
 06:28 5 qualifying questions to establish her expertise in this level  
 6 of chemistry?  
 7 MS. RAPALINO: Yes.  
 8 BY MS. RAPALINO:  
 9 Q. Professor Lawrence, are you familiar with the chemistry,  
 06:29 10 acid chemistry that's involved in the formulation of NSAIDS  
 11 compounds in solution?  
 12 A. Yes, I am.  
 13 Q. And have you studied that over the course of your career?  
 14 A. Yes, I have. And to formulate medicines you have to  
 06:29 15 understand basic chemistry.  
 16 Q. Thank you.  
 17 Can you then describe for us the basic chemistry that's  
 18 involved in placing an NSAID expound like bromfenac into  
 19 solution at the pH that's relevant for ophthalmic  
 06:29 20 formulations?  
 21 THE COURT: Before you answer, are you satisfied with  
 22 the foundation that's been laid?  
 23 MR. HASFORD: I think we're satisfied, your Honor, as  
 24 long as she doesn't try to go into actual organic or medicinal  
 06:29 25 chemistry opinions, which would be potentially something that  
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1 their chemist Dr. Heathcock would be doing.  
 2 MS. RAPALINO: We have no intention of doing that  
 3 because this case is about pharmaceutical formulation and  
 4 we're going to stick with the chemistry relevant for  
 06:30 5 formulation.  
 6 THE COURT: Okay.  
 7 MR. HASFORD: They've argued, your Honor, in fact  
 8 they argued in their opening statement chemistry is not an  
 9 issue in this case. It seems improper for them to try to get  
 06:30 10 that on through their formulation expert.  
 11 MS. RAPALINO: And to be fair, are --  
 12 THE COURT: Basic chemistry is relevant here and I'll  
 13 permit it. And I recognize the expert as also embracing the  
 14 field of chemistry of NSAIDS.  
 06:30 15 MS. RAPALINO: Thank you, your Honor.  
 16 BY MS. RAPALINO:  
 17 Q. Professor Lawrence, I'm just going to repeat that  
 18 question one more time.  
 19 Could you walk us through the demonstrative that  
 06:30 20 demonstrates what happens to bromfenac and other NSAIDS like  
 21 it when it's put in solution at the pH that's relevant for  
 22 ophthalmic solution products?  
 23 A. At the pH that's relevant for the products we're talking  
 24 about today, what will happen is the hydrogen ion, which is  
 06:31 25 indicated by the H and the plus, will disassociate from the  
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1 rest of the carboxylic group living in carboxylate iron, which  
 2 will be negatively charged in solution.  
 3 Q. Is there another word for the negatively charged ion?  
 4 A. Yes, there is, it's called an anion.  
 06:31 5 Q. Were NSAIDS approved for any ophthalmic indications as of  
 6 2003?  
 7 A. Yes, they were. In 2003 they were used for postoperative  
 8 inflammation, cystoid macular edema after cataract surgery and  
 9 symptoms of allergic conjunctivitis.  
 06:31 10 Q. Is there any pre-2003 literature that discusses the use  
 11 of NSAIDS in ophthalmic formulations as of that time?  
 12 A. Yes, there is.  
 13 Q. Can you turn in your binder to DTK-109, please. And once  
 14 you're there, can you identify what DTK-109 is?  
 06:32 15 A. Yes. This is a chapter from a volume called New Drugs in  
 16 Ophthalmology, and the particular chapter of interest is  
 17 edited by Allan J. Flach and it's from -- I'm trying to find  
 18 the year. I'm sorry. From 1996.  
 19 Q. What does this chapter by Allan Flach say about the NSAID  
 06:32 20 drug and indications that were approved as of 2003?  
 21 A. On DTK-109.6 at the top of the page it points out that  
 22 the flurbiprofen, suprofen, ketorolac, and diclofenac had been  
 23 approved by the FDA for ophthalmic use.  
 24 Q. Okay. We heard a little bit about this this morning so  
 06:33 25 we won't belabor this either. Was bromfenac marketed anywhere  
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1 as of 2003?  
 2 A. Yes, it was.  
 3 Q. Where was bromfenac marketed?  
 4 A. Bromfenac was marketed in Japan as of 2000.  
 06:33 5 Q. And what was the name of that product?  
 6 A. The product was called Bronuck®.  
 7 Q. Has bromfenac been marketed in the United States under  
 8 any name?  
 9 A. Yes, it has, it was marketed in 2005 as a once -- I'm  
 06:33 10 sorry, twice daily formulation known as Xibrom® and this  
 11 formulation was identical to the Bronuck® formulation.  
 12 Q. Has it been marketed in the United States under any other  
 13 name?  
 14 A. Yes, in 2010 Xibrom® replaced Bromday® and this was now a  
 06:34 15 once daily formulation.  
 16 THE COURT: Excuse me. Isn't it the other way  
 17 around, Bromday® replaced Xibrom®?  
 18 THE WITNESS: I'm sorry, did I say it wrong, your  
 19 Honor?  
 06:34 20 THE COURT: Perhaps. You could correct the record.  
 21 THE WITNESS: Thank you.  
 22 BY MS. RAPALINO:  
 23 Q. Was Bromday® marketed under any other name besides  
 24 Xibrom® in the U.S.?  
 06:34 25 A. Yes, in 2010 Bromday® replaced Xibrom® as a once daily  
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- 1 preparation.
- 2 Q. And how is bromfenac marketed in the United States now?
- 3 A. In 2013 Prolensa® replaced Bromday®, which is a slightly
- 4 different formulation than the previous formulations. This
- 06:34 5 formulation is used for postoperative inflammation and
- 6 reduction of ocular pain after cataract surgery.
- 7 Q. Okay. Now, that we've talked about bromfenac and NSAIDS,
- 8 let's move to benzalkonium chloride, the next ingredient you
- 9 said was in the claimed formulations. What is benzalkonium
- 06:35 10 chloride used for?
- 11 A. Benzalkonium chloride, or BAC, is a widely used
- 12 preservative in ophthalmic preparations.
- 13 Q. Is there anything notable about the chemical structure of
- 14 benzalkonium chloride?
- 06:35 15 A. This slide here shows the structure of benzalkonium
- 16 chloride. As can be seen on the right-hand side, there's a
- 17 long carbon chain that's indicated by the zigzags. On the
- 18 left-hand side there's a benzene ring which is a lozenge-like
- 19 structure, and in the center is a nitrogen which in solution
- 06:35 20 is positively charged.
- 21 Q. And is there another name for a positively charged
- 22 compound?
- 23 A. Yes, a cation.
- 24 Q. And just to be clear is benzalkonium chloride a single
- 06:35 25 compound?

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- 1 use of benzalkonium chloride in ophthalmic formulations?
- 2 A. On DTX-015.5, on the left-hand column under quaternary
- 3 ammonium compounds, it states that benzalkonium chloride is a
- 4 typical quaternary ammonium compound and is by far the most
- 06:37 5 common preservative used in ophthalmic preparations. And it
- 6 goes on to say it was used in over 65 percent of all
- 7 commercial ophthalmic preparations.
- 8 Q. As of 2003, were there any known disadvantages to
- 9 benzalkonium chloride?
- 06:37 10 A. Yes, there were.
- 11 Q. What were those known disadvantages?
- 12 A. One of the disadvantages, you had to be careful of the
- 13 concentration of benzalkonium chloride you use because too
- 14 high a concentration was known to be toxic to the eye, which
- 06:38 15 obviously is a bad property. And in addition, benzalkonium
- 16 chloride was known to interact with negatively charged
- 17 compounds.
- 18 Q. Does Remington's say anything about that problem, that
- 19 latter problem?
- 06:38 20 A. Yes, it does.
- 21 Q. What does Remington's say?
- 22 A. On the same page, in the same paragraph, it states that
- 23 as a cationic material of high molecular weight, in other
- 24 words, that's benzalkonium chloride, it's not compatible with
- 06:38 25 unionic compounds.

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- 1 A. No, it's a mixture of compounds. The carbon chain
- 2 length, which is shown on the right-hand side here as C12,
- 3 varies between 8 and 18.
- 4 Q. Now, why are antimicrobial preservatives like
- 06:36 5 benzalkonium chloride used in ophthalmic products at all?
- 6 A. They are particularly important when that product is a
- 7 multidose formulation because every time the patient opens the
- 8 bottle to use it, there's a chance that that formulation might
- 9 get contaminated, for example, with microbes such as fungi or
- 06:36 10 bacteria, and obviously, if that happens, there's no
- 11 preservative, they can grow, and then they can contaminate the
- 12 patient's eye when it is used next time.
- 13 Q. How common was the use of benzalkonium chloride as a
- 14 preservative in ophthalmic solution products as of 2003?
- 06:36 15 A. It was very widely used.
- 16 Q. Is there any literature that talks about how common it
- 17 was, how common benzalkonium chloride was in ophthalmic
- 18 products?
- 19 A. Yes, there is. Remington's refers to this.
- 06:36 20 Q. Okay. Can you remind us briefly, what was Remington's?
- 21 A. Certainly. Remington's is a handbook of pharmaceutical
- 22 formulation and what I referred to earlier as almost like a
- 23 bible for formulators.
- 24 Q. So, let's look back at Remington's at DTX-15 in your
- 06:37 25 binder. What does Remington's say about the prevalence of the

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- 1 Q. Did formulators as of 2003 avoid using benzalkonium
- 2 chloride because of these known problems?
- 3 A. No, they did not.
- 4 Q. Does Remington's say anything about the approach to be
- 06:38 5 taken?
- 6 A. Yes, it does. Also, in the same paragraph, obviously on
- 7 the same page, it states that given the alternative, it would
- 8 be preferable to modify a formulation to remove the
- 9 incompatibility rather than include a compatible but less
- 06:39 10 effective preservative.
- 11 Q. Okay. Let's move on now to your discussion of
- 12 surfactants and tyloxapol. Can you remind us just very
- 13 briefly what a surfactant is?
- 14 A. Yes. Surfactants are unique compounds in that they
- 06:39 15 consist of a region that likes water, in other words, it's
- 16 water soluble, and a region that dislikes water and is
- 17 water-insoluble, and as a consequence, these properties -- I'm
- 18 sorry, yes, the consequence of these properties are
- 19 particularly advantageous in pharmaceutical formulation.
- 06:39 20 Q. Let's talk specifically about tyloxapol. What is
- 21 tyloxapol?
- 22 A. First of all, tyloxapol is a nonionic surfactant. That
- 23 means when it is dissolved in solution, it's electrically
- 24 neutral, it carries no charge.
- 06:40 25 Q. And what class of nonionic surfactants does tyloxapol

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1 belong to?

2 A. Tyloxapol is an ethoxylated octylphenol surfactant.

3 Q. Can you explain what you mean by ethoxylated?

4 A. Yes, I can. If we look at the very schematic

06:40 5 representation on the slide, you can see on the right hand of

6 the slide I have marked a portion in yellow. This is the

7 ethoxylated portion of the molecule and this is the water

8 soluble part of the molecule.

9 Q. And what do you mean when you say that it is an

06:40 10 octylphenol surfactant?

11 A. An octylphenol surfactant, if we look at now the blue

12 highlighted -- I'm sorry, can I just have a drink?

13 THE COURT: Sure.

14 THE WITNESS: Sorry. Sorry. If we look at the blue

06:40 15 portion that's highlighted with the benzene ring, the lozenge

16 structure and the branch chain, that's an octylphenol region

17 of the surfactant and that's the region of surfactant that

18 doesn't dissolve in water, is water-insoluble.

19 BY MS. RAPALINO:

06:41 20 Q. Is tyloxapol a single compound?

21 A. No, it's not. It's a mixture of compounds. It consists

22 of different chain lengths of the ethoxylated portion and

23 different numbers of ethoxylate -- and oxy phenol groups in

24 the molecule.

06:41 25 Q. As of 2003, were there other surfactants within the class

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1 of ethoxylated octylphenol surfactants?

2 A. There were a large number, but there were only two that

3 were suitable for use in ophthalmic preparations.

4 Q. Why do you say there were only two that were suitable for

06:41 5 use in ophthalmic preparation?

6 A. There were only two octylphenol surfactants, octylphenol

7 ethoxylated surfactants that were actually listed in the FDA

8 Inactive Ingredient Guide.

9 Q. What were those two ethoxylated octylphenol surfactants

06:42 10 that were listed in the FDA Inactive Ingredient Guide as

11 previously approved surfactants?

12 A. For ophthalmic use, there was tyloxapol and octanol 40.

13 Q. Okay. Professor Lawrence, now that we've covered some of

14 that background science, let's turn to your opinions in this

06:42 15 case. Can you tell us briefly what issues you were asked to

16 consider with respect to claims 6 and 20 of the '431 patent?

17 A. Yes. Firstly, I was asked to consider whether claims 6

18 and 20 of the '431 patent would have been obvious to a person

19 of ordinary skill in the art as of January 2003 in view of

06:43 20 that prior art for obviousness. And for obviousness type

21 double patenting, I was asked to consider whether claims 6 and

22 20 of the '431 patent were obvious in view of claim 7 of the

23 '290 patent and claim 6 of the '131 patent.

24 Q. With respect to the first issue, the obviousness issue

06:43 25 you were asked to consider, were you asked to look at the

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1 prior art as of a particular date?

2 A. Yes, I was, and that date was January 2003.

3 Q. What type of prior art generally did you review?

4 A. I reviewed the patent literature, scientific journals,

06:43 5 and reference handbooks and textbooks.

6 Q. After forming your opinions in this case, did you review

7 any other documents besides the publicly available literature?

8 A. Yes. Only after I formed my opinion in this case, I

9 reviewed Senju's internal documents, and I reviewed these to

06:44 10 see whether or not they agreed with my opinions, which they

11 did.

12 MR. HASFORD: I'll object, your Honor, and move to

13 strike. The review of Senju's internal documents has already

14 been taken off the table by agreement of the parties. It is

06:44 15 certainly not proper to any kind of obviousness case per

16 Federal Circuit case law.

17 MS. RAPALINO: Your Honor, as Professor Lawrence just

18 testified, she did not rely on her review of any internal

19 documents in support of her obviousness opinion. She simply

06:44 20 reviewed those documents after forming her opinion to

21 determine whether or not they were consistent with her

22 opinion, and there is Federal Circuit case law directly on

23 point that supports the use of a patentee's internal documents

24 for that very purpose, just to show that it is consistent with

06:44 25 the expert's opinion about the state of the knowledge in the

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1 art as of the time that the invention was made.

2 MR. HASFORD: We disagree with that characterization,

3 your Honor. The statute itself says "patentability shall not

4 be negative by the manner in which the invention is made."

06:45 5 That's straight out of 35, U.S.C., Section 103. She shouldn't

6 be testifying about internal documents if she is not relying

7 on them in connection with an obviousness case, and she cannot

8 by statute.

9 THE COURT: Well, could it be clarified, because I

06:45 10 didn't get that from her testimony, that the witness is not

11 relying on the internal documents as a basis for her opinion?

12 MS. RAPALINO: I can clarify that with the witness.

13 THE COURT: All right.

14 BY MS. RAPALINO:

06:45 15 Q. Professor Lawrence, have you relied on the internal Senju

16 documents in support of your obviousness opinion?

17 A. No, I definitely didn't rely on those documents in

18 support of my obviousness opinion.

19 MR. HASFORD: And I'll object and move to strike the

06:45 20 last portion of that statement, your Honor. If she is not

21 relying on them as relevant to her obviousness opinion,

22 there's no need and no reason for her to testify about them

23 and they shouldn't come in.

24 MS. RAPALINO: Your Honor, again, the threshold for

06:45 25 relevance here under 402 is a liberal one, and the fact that

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1 they are not the direct support for her obviousness opinion  
 2 does not render those documents irrelevant to the issues.  
 3 They are still relevant as making more likely than not her  
 4 opinions in this case which she arrived at independently of  
 06:46 5 her review of those internal documents.  
 6 MR. HASFORD: We disagree entirely with the statement  
 7 about the liberality or alleged liberality of Federal Rule  
 8 402. The fact is they are not relevant to an obviousness  
 9 case. The statute says so, the Federal Circuit case law says  
 06:46 10 so. She has disclaimed any reliance on those in connection  
 11 with her obviousness opinion. She should not be permitted to  
 12 testify about them, your Honor.  
 13 MS. RAPALINO: If I could, there is a Federal Circuit  
 14 case again directly on point. It's the *Thomas & Betts Corp.*  
 06:46 15 *V. Litton Systems, Inc.* Case at 720 F.2d 1572. This is a Fed  
 16 Circuit 1983 case holding that a plaintiff's internal studies,  
 17 although they were not technically prior art, were proper --  
 18 can be properly used as indicators of the level of ordinary  
 19 skill in the art to which the invention pertained and were  
 06:46 20 admissible as evidence.  
 21 MR. HASFORD: And I'm not aware that that case has  
 22 been cited anywhere, your Honor, in their case law statement,  
 23 in the joint pretrial order. Even if it has, it sound like  
 24 it's a case, even if counsel's characterization of it is  
 06:47 25 correct, from well over 30 years ago and it is not consistent  

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1 exclude that evidence at trial. In fact, accepted that  
 2 evidence and just found that it was -- that that wasn't --  
 3 that that evidence wasn't sufficient, was not a sufficient  
 4 basis to support obviousness.  
 06:49 5 And, again, here we're not trying to use plaintiff's  
 6 internal documents to support our obviousness position. It's  
 7 merely to show that their internal documents are consistent  
 8 with what Professor Lawrence will present is the state -- was  
 9 the state-of-the-art as of January 2003.  
 06:49 10 With respect to the *Life Technologies v. Clontech* case,  
 11 that case is not about Rule 402 at all. It is about whether  
 12 prior art was material and should have been submitted to the  
 13 Patent Office, which is an entirely different analysis and a  
 14 different standard from Rule 402 relevance.  
 06:49 15 MR. HASFORD: And I believe I have some clarification  
 16 on the case law that defendant cited, your Honor. So, there,  
 17 the Federal circuit has at times approved the use of  
 18 unpublished internal documents only for the limited purpose of  
 19 ascertaining the level of ordinary skill in the art, and  
 06:50 20 that's the *Thomas & Betts* case that they cited, held that  
 21 internal documents were "properly used as indicators of the  
 22 level of ordinary skill in the art to which the invention  
 23 pertained."  
 24 And so for that limited purpose they were allowed, but  
 06:50 25 the defendants here are trying to take the next step, your  

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1 with the statute, if that's how she is describing it.  
 2 MS. RAPALINO: The case that -- the case --  
 3 THE COURT: Excuse me. It was cited in connection  
 4 with one of the motions in limine, and it did provide an  
 06:47 5 example consistent with what counsel has argued, that I do  
 6 recall.  
 7 MR. HASFORD: Well, your Honor, so I'm looking at  
 8 what's in the joint pretrial order here. I apologize, your  
 9 Honor. So, regardless of whether they cited it in their  
 06:47 10 motion in limine, the reality is, the statute is as I  
 11 presented it to you. There are also other Federal Circuit  
 12 cases, for example, *Life Techs v. Clontech*, 224 F.3d 1320,  
 13 1325, Federal Circuit 2000, specifically stating, "the path  
 14 that leads an inventor to the invention is expressly made  
 06:48 15 irrelevant to patentability by statute."  
 16 And then *Otsuka Pharmaceutical Company v. Sandoz*, which  
 17 is actually a case that opposing counsel, Ms. Holland, was  
 18 involved with and I was involved with, your Honor, 678 F.3d  
 19 1280, 1296, Federal Circuit 2012, essentially says the same  
 06:48 20 thing.  
 21 MS. RAPALINO: And, your Honor, if I could just  
 22 address those two cases briefly, starting with the *Otsuka*  
 23 case. In the *Otsuka* case, what the Court actually held was  
 24 that obviousness couldn't be based on the inventor's internal  
 06:48 25 path to development, but the Court did not preclude -- did not  

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1 Honor, and use internal documents to make or confirm  
 2 conclusions about the teachings of the prior art, and that is  
 3 expressly prohibited by statute. That's expressly prohibited  
 4 by the portion of the patent statute that says "patentability  
 06:50 5 shall not be negative by the manner in which the invention was  
 6 made." That's 35, U.S.C., Section 103.  
 7 And that's also confirmed by other cases, and, in fact,  
 8 there's a case out of the Fed Circuit *In re Omeprazole Patent*  
 9 *Litigation*, it's an unpublished case, but it's at 84 Fed  
 06:50 10 Appendix 76, 81, and it's Fed Circuit 2003. And it says,  
 11 "GenPharm reads too much into *Thomas & Betts* because, unlike  
 12 here, the document at issue in that case received additional  
 13 support in the form of testimony about the state-of-the-art at  
 14 the time of the publication."  
 06:51 15 In other words, they can't take the next step and try  
 16 to use these internal documents as evidence of or even as  
 17 confirmatory of their obviousness case.  
 18 MS. RAPALINO: And again, your Honor, I would submit  
 19 that we're planning to offer this evidence for precisely the  
 06:51 20 purpose that it was offered in *Thomas & Betts*. This is purely  
 21 to offer testimony that indicates the level of ordinary skill  
 22 in the art to which the invention pertained, which includes  
 23 the person of ordinary skill in the art's understanding of  
 24 what the prior art taught at that time.  
 06:51 25 THE COURT: Well, is the -- just a moment. Is the  

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1 witness offering it for that purpose? I understand *Thomas &*  
 2 *Betts* permits it where it is evidence that indicates the  
 3 ordinary skill in the art as of that time. Is that the  
 4 purpose? Because I thought a moment ago you said that the  
 06:51 5 purpose was it is confirmatory of the witness's opinions.  
 6 MS. RAPALINO: Well, I think that to the extent that  
 7 the witness's opinions, part of the obviousness analysis is an  
 8 analysis of the level of skill in the art, and based on that  
 9 level of skill in the art, the scope of the prior art and how  
 06:52 10 that art would have been understood, that the documents from  
 11 plaintiff's internal files are confirmatory of those opinions,  
 12 which go precisely to the issue of the level of skill in the  
 13 art.  
 14 THE COURT: I'm going to grant -- I'm going to  
 06:52 15 sustain the objection in part and overrule it in part. I will  
 16 permit it to be offered for a limited purpose, and the limited  
 17 purpose is as an indicator of the ordinary skill in the art  
 18 that existed at that time. I'll sustain the objection and not  
 19 receive the opinion -- I'm sorry, not receive the testimony  
 06:52 20 about internal documents to the extent that they are offered  
 21 as confirmation of this witness's opinion that she has  
 22 developed for the trial. And so in that way I think that the  
 23 *Thomas & Betts* precedent is honored and that the witness will  
 24 be permitted to testify.  
 06:53 25 MS. RAPALINO: Your Honor, if I just may quote one  

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1 more quote from the *Thomas & Betts* case. The Federal Circuit  
 2 there permitted this internal data, internal criteria as  
 3 evidence of what would have been within the knowledge of one  
 4 of ordinary skill in the art. And so thus, the criteria,  
 06:53 5 though not technically prior art, were in effect properly used  
 6 as indicators of the level of ordinary skill in the art.  
 7 So, again, that level of ordinary skill in the art  
 8 includes, includes the information regarding the knowledge of  
 9 one of ordinary skill in the art, what would have been within  
 06:53 10 the knowledge of a person of ordinary skill in the art.  
 11 MR. HASFORD: We disagree here, your Honor. What  
 12 they're trying to do is they're trying to take this very  
 13 limited exception, to the extent there really even is an  
 14 exception, and try to swallow the whole with it and  
 06:54 15 effectively backdoor this information in violation of the  
 16 statute. 35, U.S.C., Section 103 is clear on its face, and  
 17 that's the basis for our objection.  
 18 THE COURT: Well, it is an indicator of the ordinary  
 19 skill in the art. If it is offered for that purpose, then  
 06:54 20 it's admissible, is it not?  
 21 MR. HASFORD: Under *Thomas & Betts*, they accepted it  
 22 for that limited purpose, but it is certainly not available to  
 23 confirm or to support her underlying obviousness opinions.  
 24 THE COURT: That's what I ruled five minutes ago. I  
 06:54 25 sustained your objection to that extent, and I don't think  

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1 that Ms. Rapalino has argued something to the contrary. So,  
 2 I'll permit it to that limited extent.  
 3 MS. RAPALINO: Thank you, your Honor.  
 4 THE COURT: And we only have a few more minutes this  
 06:54 5 afternoon in any event.  
 6 MS. RAPALINO: Okay. We're about to launch into sort  
 7 of the details of the obviousness opinion, and if it makes  
 8 sense, we could just start with that first thing in the  
 9 morning.  
 06:54 10 MR. HASFORD: We're fine with that, your Honor.  
 11 THE COURT: Okay. Then let's conclude for today, and  
 12 the witness is excused for the day. Thank you very much.  
 13 Don't forget to come back tomorrow morning.  
 14 MS. RAPALINO: May I ask a point of clarification  
 06:55 15 regarding your Honor's practices? I understand the general  
 16 rule with the witness is so long as they are still on direct,  
 17 we can confer with the witness. Is there anything we should  
 18 know about your Honor's practice with respect to that?  
 19 THE COURT: Thanks for asking, because we should  
 06:55 20 speak now about sequestration of witnesses. I notice that it  
 21 is in the pretrial order and that all sides have agreed that  
 22 there should be sequestration of witnesses until they have  
 23 finished testifying. Is that right?  
 24 MS. RAPALINO: I think what the pretrial order says  
 06:55 25 is that there's sequestration of fact witnesses. As it turns  

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1 out, neither party has called any fact witnesses, which I  
 2 think renders that provision in the pretrial order moot.  
 3 THE COURT: Okay. So, there's no fact witnesses in  
 4 the trial even from the -- from the plaintiffs?  
 06:55 5 MR. HASFORD: We're not calling any fact witnesses,  
 6 your Honor. We're only calling experts.  
 7 THE COURT: All right. Then the sequestration would  
 8 not apply to experts. Experts can be present and enjoy the  
 9 entire trial.  
 06:56 10 And so now you asked about the rule of not conferring  
 11 during cross-examination, and that is, I think, the standard,  
 12 that when you have a witness on the stand who is under  
 13 cross-examination by your adversary, that during breaks and  
 14 even during the overnight, you're not permitted to confer with  
 06:56 15 them for the purpose of rehabilitating their testimony. Of  
 16 course, you are permitted on redirect to ask any questions  
 17 that you want, but they can't be pre-coached while your  
 18 witness is on cross. Is that a clear formulation for both  
 19 sides?  
 06:56 20 MR. HASFORD: It is for us, your Honor.  
 21 MS. RAPALINO: It is for us, your Honor. Thank you.  
 22 MR. MUKERJEE: Yes, your Honor.  
 23 THE COURT: All right. Anything else?  
 24 MR. HASFORD: Nothing from plaintiffs, your Honor.  
 06:56 25 THE COURT: Okay. Very well, then we will adjourn to  

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1 tomorrow morning at 9:30.

2 MS. RAPALINO: Thank you.

3 (Proceedings concluded at 4:29 p.m.)

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1 UNITED STATES DISTRICT COURT  
 2 FOR THE DISTRICT OF NEW JERSEY

3 \_\_\_\_\_  
 4 SENJU PHARMACEUTICAL CO., LTD.,  
 5 BAUSCH & LOMB, INC., BAUSCH AND  
 6 LOMB PHARMA HOLDINGS CORP.,  
 7 Plaintiff, CIVIL ACTION NUMBER:  
 8 14-667 (JBS/RMW)  
 9 -vs-  
 10 LUPIN LTD., LUPIN  
 11 PHARMACEUTICALS, INC.,  
 12 Defendants.

13 \_\_\_\_\_  
 14 SENJU PHARMACEUTICAL CO., LTD.,  
 15 BAUSCH & LOMB, INC., BAUSCH AND  
 16 LOMB PHARMA HOLDINGS CORP.,  
 17 Plaintiff, CIVIL ACTION NUMBER:  
 18 14-4149 (JBS/KMW)  
 19 -vs-  
 20 LUPIN LTD., LUPIN  
 21 PHARMACEUTICALS, INC.,  
 22 Defendants.

23 Mitchell H. Cohen United States Courthouse  
 24 One John F. Gerry Plaza  
 25 Camden, New Jersey 08101  
 Tuesday, April 5, 2016

BEFORE: THE HONORABLE JEROME B. SINANDLE  
 CHIEF JUDGE  
 UNITED STATES DISTRICT JUDGE

Certified as true and correct as required by Title 28,  
 U.S.C., Section 753.  
 /s/ Lisa Marcus, CCR, CRR, /s/ Karen Friedlander, CCR,  
 CRR, /s/ Robert T. Tate, CCR, CRR, /s/ Carol Farrell, CCR, CRR

United States District Court  
 Camden, NJ

1 \_\_\_\_\_  
 2 SENJU PHARMACEUTICAL CO., LTD.,  
 3 BAUSCH & LOMB, INC., BAUSCH AND  
 4 LOMB PHARMA HOLDINGS CORP.,  
 5 Plaintiff, CIVIL ACTION NUMBER:  
 6 15-335 (JBS/KMW)  
 7 -vs-  
 8 LUPIN LTD., LUPIN  
 9 PHARMACEUTICALS, INC.,  
 10 Defendants.

11 \_\_\_\_\_  
 12 SENJU PHARMACEUTICAL CO., LTD.,  
 13 BAUSCH & LOMB, INC., BAUSCH AND  
 14 LOMB PHARMA HOLDINGS CORP.,  
 15 Plaintiff, CIVIL ACTION NUMBER:  
 16 14-6893 (JBS/KMW)  
 17 -vs-  
 18 INNOPHARMA LICENSING, INC., et  
 19 al.,  
 20 Defendants.

21 \_\_\_\_\_  
 22 SENJU PHARMACEUTICAL CO., LTD.,  
 23 BAUSCH & LOMB, INC., BAUSCH AND  
 24 LOMB PHARMA HOLDINGS CORP.,  
 25 Plaintiff, CIVIL ACTION NUMBER:  
 15-3240 (JBS/KMW)  
 -vs-  
 INNOPHARMA LICENSING, INC.,  
 Defendants.

United States District Court  
 Camden, NJ

1 \_\_\_\_\_  
 2 SENJU PHARMACEUTICAL CO., LTD.,  
 3 BAUSCH & LOMB, INC., BAUSCH AND  
 4 LOMB PHARMA HOLDINGS CORP.,  
 5 Plaintiff, CIVIL ACTION NUMBER:  
 6 14-5144 (JBS/KMW)  
 7 -vs-  
 8 LUPIN LTD., LUPIN  
 9 PHARMACEUTICALS, INC.,  
 10 Defendants.

11 \_\_\_\_\_  
 12 SENJU PHARMACEUTICAL CO., LTD.,  
 13 BAUSCH & LOMB, INC., BAUSCH AND  
 14 LOMB PHARMA HOLDINGS CORP.,  
 15 Plaintiff, CIVIL ACTION NUMBER:  
 16 15-335 (JBS/KMW)  
 17 -vs-  
 18 LUPIN LTD., LUPIN  
 19 PHARMACEUTICALS, INC.,  
 20 Defendants.

21 \_\_\_\_\_  
 22 SENJU PHARMACEUTICAL CO., LTD.,  
 23 BAUSCH & LOMB, INC., BAUSCH AND  
 24 LOMB PHARMA HOLDINGS CORP.,  
 25 Plaintiff, CIVIL ACTION NUMBER:  
 14-5144 (JBS/KMW)  
 -vs-  
 LUPIN LTD., LUPIN  
 PHARMACEUTICALS, INC.,  
 Defendants.

United States District Court  
 Camden, NJ

1 APPEARANCES:  
 2 PEPPER HAMILTON LLP  
 3 BY: MELISSA A. CHUDEREWICZ, ESQUIRE  
 4 301 Carnegie Center, Suite 400  
 5 Princeton, New Jersey 08543  
 6 (609) 452-0808  
 7 chuderem@pepperlaw.com  
 8 ATTORNEYS FOR PLAINTIFF

9 FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, LLP  
 10 BY: BRYAN C. DINER, ESQUIRE  
 11 JUSTIN J. HASFORD, ESQUIRE  
 12 CHIAKI FUJIWARA, ESQUIRE  
 13 901 New York Avenue, N.W.  
 14 Washington, D.C. 20001-4413  
 15 (202) 408-4000  
 16 bryan.diner@finnegan.com, justin.hasford@finnegan.com,  
 17 chiaki.fujiwara@finnegan.com  
 18 ATTORNEYS FOR PLAINTIFF

19 FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, LLP  
 20 BY: JESSICA M. LEBEIS, ESQUIRE  
 21 303 Peachtree Street, NE  
 22 Atlanta, GA 30308-3263  
 23 (404) 653-6400  
 24 jessica.lebis@finnegan.com  
 25 ATTORNEYS FOR PLAINTIFF

26 PATUNAS TARANTINO LLC  
 27 BY: MICHAEL E. PATUNAS, ESQUIRE  
 28 24 Commerce Street, Suite 606  
 29 Newark, New Jersey 07102  
 30 (973) 396-8740  
 31 mpatunas@patunaslaw.com  
 32 ATTORNEYS FOR DEFENDANT LUPIN, INC.

United States District Court  
 Camden, NJ

259	<p>1 GOODWIN PROCTER LLC          BY: ELIZABETH J. HOLLAND, ESQUIRE          NATASHA E. DAUGHTREY, ESQUIRE          SARAH FINK, ESQUIRE          SHAUN deLACY, ESQUIRE          DANIEL P. MARGOLIS, ESQUIRE          The New York Times Building          620 Eighth Avenue          New York, NY 10018          (212) 813-8800          eholland@goodwinprocter.com,          ndaughtry@goodwinprocter.com, sfink@goodwinprocter.com,          sdelacy@goodwinprocter.com, dmargolis@goodwinprocter.com          ATTORNEYS FOR DEFENDANT LUPIN, LTD.</p> <p>9 GOODWIN PROCTER, LLP          BY: EMILY L. RAPALINO, ESQUIRE          53 State Street          Boston, MA 02109          (617) 570-1000          erapalino@goodwinprocter.com          ATTORNEYS FOR DEFENDANT LUPIN, LTD.</p> <p>13 ALSTON &amp; BIRD, LLP          BY: DEEPRO R. MUKERJEE, ESQUIRE          LANCE A. SODERSTROM, ESQUIRE          STEPHANIE ROBERTS, ESQUIRE          90 Park Avenue          New York, New York 10016          (212) 210-9400          deepr.mukerjee@alston.com, lance.soderstrom@alston.com,          stephanie.roberts@alston.com          ATTORNEYS FOR DEFENDANT INNOPHARMA LICENSING</p> <p>19 ALSTON &amp; BIRD, LLP          BY: JITENDRA MALIK, ESQUIRE          4721 Emperor Boulevard          Suite 400          Durham, NC 27703-8580          (919) 862-2200          jitendra.malik@alston.com          ATTORNEYS FOR DEFENDANT INNOPHARMA LICENSING</p> <p style="text-align: center;"><i>United States District Court          Camden, NJ</i></p>
260	<p>1 ALSTON &amp; BIRD, LLP          BY: HIDETADA JAMES ABE, ESQUIRE          333 South Hope Street          16th Floor          Los Angeles, CA 90071-3004          (213) 576-1000          james.abe@alston.com          ATTORNEYS FOR DEFENDANT LUPIN LIMITED</p> <p>6 ALSTON &amp; BIRD, LLP          BY: JOSEPH M. JANUSZ, ESQUIRE          Bank of America Plaza          Suite 4000          Charlotte, NC 28280-4000          (704) 444-1000          joe.janusz@alston.com          ATTORNEYS FOR DEFENDANT INNOPHARMA LICENSING</p> <p>11 SAIBER, LLC          BY: ARNOLD B. CALMANN, ESQUIRE          One Gateway Center          10th Floor, Suite 1000          Newark, New Jersey 07102          (973) 622-3333          abc@saiber.com          ATTORNEYS FOR DEFENDANT INNOPHARMA LICENSING</p> <p style="text-align: center;"><i>United States District Court          Camden, NJ</i></p>

261	<p style="text-align: center;"><u>I N D E X</u></p> <p>2 <u>WITNESS</u> <span style="float: right;"><u>PAGE</u></span></p> <p>3 DIRECT EXAMINATION OF PROFESSOR LAWRENCE BY MS. RAPALINO: 262</p> <p>4 CROSS-EXAMINATION OF JAYNE LAWRENCE BY MR. HASFORD 327</p> <p>5 REDIRECT EXAMINATION OF JAYNE LAWRENCE BY MR. RAPALINO 419</p> <p>6 RECROSS-EXAMINATION OF JAYNE LAWRENCE BY MR. HASFORD 428</p> <p>7 <b>STEPHEN GRAHAM DAVIES</b> 442</p> <p>8 DIRECT EXAMINATION OF STEPHEN GRAHAM DAVIES BY MR. DINER: 443</p> <p>9</p> <p style="text-align: center;"><u>E X H I B I T S</u></p> <p>10 <span style="float: right;"><u>PAGE</u></span></p> <p>12 JOINT EXHIBITS JTX-2, JTX-3, JTX-45, JTX-61, JTX-71, JTX-168, JTX-199, JTX-201, JTX-207, 326</p> <p>13 DTX-15, DTX-109, DTX-110, DTX-196, and DTX-442 WERE RECEIVED IN EVIDENCE</p> <p>14 JOINT EXHIBIT JTX-209 WAS RECEIVED IN EVIDENCE 426</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>
262	<p>1 (In open court at 9:31 a.m.)</p> <p>2 THE DEPUTY COURT CLERK: All rise.</p> <p>00:00 3 THE COURT: Be seated, please. Good morning.</p> <p>00:00 4 Good morning.</p> <p>00:00 5 THE WITNESS: Good morning.</p> <p>00:00 6 THE COURT: Are we ready to resume?</p> <p>00:00 7 MR. HASFORD: Plaintiffs are ready, your Honor.</p> <p>00:00 8 MS. RAPALINO: Yes, your Honor.</p> <p>00:00 9 THE COURT: Okay. Then go ahead.</p> <p>00:00 10 MS. RAPALINO: Thank you.</p> <p>11 (DIRECT EXAMINATION OF PROFESSOR LAWRENCE BY MS. RAPALINO:)</p> <p>00:00 12 Q. Good morning, Professor Lawrence.</p> <p>00:00 13 A. Good morning.</p> <p>00:00 14 Q. When we left off yesterday we were about to talk about</p> <p>00:00 15 your obviousness opinion. Have you applied any particular</p> <p>00:00 16 framework in determining whether the asserted claims of the</p> <p>00:00 17 '431 patent are obvious?</p> <p>00:00 18 A. Yes, I have.</p> <p>00:00 19 Q. Have you set forth that framework in a demonstrative?</p> <p>00:00 20 A. Yes, I have. It's DDX2-21. What I did was considered</p> <p>00:00 21 the qualifications of a person of ordinary skill in the art,</p> <p>00:00 22 the scope of the prior art, differences between the prior art</p> <p>00:00 23 and the claims, and determined whether the claims were obvious</p> <p>00:01 24 in view of the prior art; and in particular, whether the</p> <p>00:01 25 person of ordinary skill in the art would have been motivated</p> <p style="text-align: center;"><i>United States District Court          Camden, NJ</i></p>

00:01 1 to make and use the formulations of the asserted claims and  
 00:01 2 have had a reasonable expectation of success upon doing so.  
 00:01 3 Q. Now, you used the term "person of ordinary skill in the  
 00:01 4 art." Have you considered what the qualifications and level  
 00:01 5 of skill of the person of ordinary skill in the art would be?  
 00:01 6 A. Yes, I have.  
 00:01 7 Q. What were the qualifications of the person of ordinary  
 00:01 8 skill in the art as of 2003?  
 00:01 9 A. As of 2003, a person of ordinary skill in the art would  
 00:01 10 have had a Ph.D. in pharmaceutical science and training and  
 00:01 11 experience in the research and development of pharmaceuticals.  
 00:01 12 Q. Are you aware that Professor Williams has offered a  
 00:01 13 different opinion, a different definition for the person of  
 00:01 14 ordinary skill in the art?  
 00:01 15 A. Yes, I am.  
 00:01 16 Q. Generally speaking, can you just remind us what his  
 00:01 17 definition was?  
 00:01 18 A. Yes. That a person of ordinary skill in the art as of  
 00:02 19 January 2003 will have a bachelor's degree in pharmaceutical  
 00:02 20 chemistry, chemistry or related discipline, and about three to  
 00:02 21 five years work experience or comparable level of education  
 00:02 22 and training.  
 00:02 23 Q. Do you agree with the definition that Professor Williams  
 00:02 24 offered?  
 00:02 25 A. No, I don't. I think it's very broad and I'm rather

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00:03 1 optimization, ended up with the concentrations that are  
 00:04 2 present in the '431 patent.  
 00:04 3 Q. Okay. Let's start with claim 20 of the '431 patent.  
 00:04 4 Have you prepared a slide showing claim 20 rewritten in  
 00:04 5 independent form?  
 00:04 6 A. Yes, I have.  
 00:04 7 Q. Okay. Is that at DDX2-25?  
 00:04 8 A. Yes, it is.  
 00:04 9 Q. What does claim 20 of the '431 patent cover?  
 00:04 10 A. It's directed towards the preparation of a liquid aqueous  
 00:04 11 formulation and is intended for ophthalmic use and contains  
 00:04 12 bromfenac sodium, tyloxapol, and a range of other ingredients,  
 00:04 13 including benzalkonium chloride.  
 00:04 14 Q. And now you also mentioned that this is obvious over the  
 00:04 15 '225 patent. Could you turn in your binder to JTX-147? Are  
 00:05 16 you there?  
 00:05 17 A. I am.  
 00:05 18 Q. Is this the '225 patent you are referring to?  
 00:05 19 A. Yes, it is.  
 00:05 20 Q. What does Example 6 of the '225 patent disclose?  
 00:05 21 A. It discloses an aqueous ophthalmic preparation containing  
 00:05 22 bromfenac sodium, polysorbate, benzalkonium chloride, and the  
 00:05 23 same range of other ingredients.  
 00:05 24 Q. Now, you said it discloses bromfenac sodium. Where do  
 00:05 25 you see that in Example 6 of the '225 patent?

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00:02 1 surprised it doesn't actually list pharmaceutical science in  
 00:02 2 that list. And, for example, it would include someone with  
 00:02 3 degree of chemistry working in the agrochemical industry,  
 00:02 4 which is obviously not appropriate in a case like this.  
 00:02 5 Q. Would you agree that a pharmaceutical formulator would  
 00:02 6 consult a chemist or an organic chemist on issues of  
 00:02 7 pharmaceutical formulation?  
 00:02 8 A. It wouldn't actually dawn on me as a pharmaceutical  
 00:02 9 formulator to consult a pharmaceutical chemist, certainly on  
 00:03 10 this type of issues that we are discussing here, such as  
 00:03 11 complexation.  
 00:03 12 Q. Why wouldn't you consult an organic chemist on those  
 00:03 13 issues?  
 00:03 14 A. Because this type of information is well known by --  
 00:03 15 would have been well known by a person of ordinary skill in  
 00:03 16 the art at the time.  
 00:03 17 Q. Can you summarize what conclusions you reached concerning  
 00:03 18 the obviousness of the asserted claims?  
 00:03 19 A. Yes. It's my opinion that claims 6 and 20 of the '431  
 00:03 20 patent are obvious over the '225 patent and in view of EP 984.  
 00:03 21 Q. And can you explain in a little bit more detail the basis  
 00:03 22 for that opinion?  
 00:03 23 A. Certainly. A person of ordinary skill in the art would  
 00:03 24 have started with Example 6 of the '225 patent, and actually  
 00:03 25 replaced the polysorbate with tyloxapol and, by routine

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00:05 1 A. The long chemical name on lines 2 -- 1 and 2 of the  
 00:05 2 ingredient list is bromfenac sodium.  
 00:05 3 Q. Have you prepared a slide comparing claim 20 of the '431  
 00:05 4 patent in suit to Example 6 of the prior art '225 patent?  
 00:06 5 A. Yes, I have.  
 00:06 6 Q. Is that DTX2-27?  
 00:06 7 A. Yes, it is. On the left-hand side, I have reproduced  
 00:06 8 Example 6 of '225 patent while on the right-hand side there's  
 00:06 9 claim 20 of the '431 patent.  
 00:06 10 Q. And can you explain how the Example 6 of the '225 patent  
 00:06 11 compares to claim 20 of the '431 patent?  
 00:06 12 A. Yes. As I have just said, both are directed towards  
 00:06 13 aqueous liquid preparations for ophthalmic administration.  
 00:06 14 Q. Is that what you have highlighted here?  
 00:06 15 A. Yes. That's highlighted in yellow on the slide. Both  
 00:06 16 contain bromfenac sodium. Both contain boric acid. Both  
 00:06 17 contain borax or, as it is sometimes known, sodium  
 00:06 18 tetraborate.  
 00:06 19 Q. Are those two compounds the same?  
 00:06 20 A. They are indeed, yes. They both contain either disodium  
 00:07 21 edetate or EDTA sodium salt, which both parties have agreed  
 00:07 22 for the purposes of this case are the same thing.  
 00:07 23 Q. How else are they similar?  
 00:07 24 A. They both contain benzalkonium chloride. They both  
 00:07 25 contain polyvinylpyrrolidone, which is sometimes known as

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00:07 1 povidone, and they both contain sodium sulfite.

00:07 2 Q. How do the amounts, the amount of sodium bromfenac in

00:07 3 Example 6 of the '225 patent, how does that compare to the

00:07 4 range of concentrations for bromfenac sodium in claim 20 of

00:07 5 the '431 patent?

00:07 6 A. Yes. Example 6 of the '225 patent states sodium

00:07 7 bromfenac is present at .1 gram in a hundred ml which is .1

00:07 8 percent, and as you can see, .1 percent falls within the

00:07 9 concentration range claim for bromfenac in claim 20 of the

00:08 10 '431 patent.

00:08 11 Q. Now, before we delve more deeply into your obviousness

00:08 12 opinion, let's take a step back and talk about the scope of

00:08 13 the prior art. Did you review prior art literature that

00:08 14 reflected the scope of the art with respect to formulation of

00:08 15 ophthalmic NSAID products as of 2003?

00:08 16 A. Yes, I did.

00:08 17 Q. What type of references did you consider?

00:08 18 A. I considered the patent literature and scientific papers,

00:08 19 handbooks, textbooks from the time.

00:08 20 Q. Have you organized those references in any way for

00:08 21 purposes of your presentation today?

00:08 22 A. Yes, I have.

00:08 23 Q. Can you explain how you organized them?

00:08 24 A. Yes. This is explained on DTX-29. I've grouped the

00:08 25 prior art into three groups. Group A deals with bromfenac and

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00:11 1 teach about bromfenac sodium?

00:11 2 A. Yes. JTX-210.4, an extract of which is reproduced on the

00:11 3 slide DDX2-31, states that bromfenac sodium was the active

00:11 4 ingredient of Bronuck and was a new NSAID drug.

00:11 5 Q. Does *New Drugs in Japan* say anything about when Bronuck

00:11 6 was approved?

00:11 7 A. Yes, it does. On the same page, further down, it states

00:11 8 this was approved in Japan as of March 2000 and for use for a

00:11 9 variety of inflammation conditions of the eye.

00:11 10 Q. Does the *New Drugs in Japan* reference, JTX-210, say

00:11 11 anything about the formulation of Bronuck?

00:12 12 A. Yes, it does. It lists the ingredients of the

00:12 13 formulation of Bronuck, stating that it contains 1 milligram

00:12 14 per ml of the sodium hydrate salt, and as other ingredients

00:12 15 contain boric acid, borax, sodium sulfite, sodium edetate,

00:12 16 povidone, which is obviously polyvinylpyrrolidone, polysorbate

00:12 17 80, and benzalkonium chloride.

00:12 18 Q. Generally speaking, what would a person of ordinary skill

00:12 19 in the art understand from the *New Drugs in Japan* reference?

00:12 20 A. They would have understood that bromfenac was a new drug

00:12 21 that was useful to treat various inflammation conditions in

00:12 22 the eye, and that it was on the market in Japan being approved

00:12 23 of -- as of March 2000, and would also know the ingredients

00:12 24 the formulation contained.

00:12 25 Q. Let's move on to the next reference in your group A.

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00:08 1 the fact that its usefulness as an NSAID in ophthalmic

00:08 2 preparations was known as of January 2003. The second group,

00:09 3 which I have called group B, deals with the preservative

00:09 4 benzalkonium chloride showing that it was widely known as was

00:09 5 its compatibility with NSAIDs. And finally, group C, which

00:09 6 deals with the prior art around the use of ethoxylated

00:09 7 octylphenol surfactants and how they were used to solve the

00:09 8 complexation problem with BAC, and tyloxapol's use in

00:09 9 ophthalmic solutions at the time was known.

00:09 10 Q. Okay. Let's start with your group A references. What

00:09 11 prior art references did you put into the category of group A?

00:09 12 A. I have put in four references. They are *New Drugs in*

00:09 13 *Japan* from 2001, which is JTX-210, Hara from 2000, which is

00:09 14 DTX-110, U.S. patent number 4,910,225 from 1990, which is

00:10 15 JTX-147, and U.S. patent number 5,475,034 from 1995, which is

00:10 16 JTX-168.

00:10 17 Q. And can you remind us just at a general level what these

00:10 18 references teach?

00:10 19 A. Yes, certainly. Taken together, these references teach

00:10 20 that the usefulness of bromfenac as an NSAID in ophthalmic

00:10 21 preparations was known at the time.

00:10 22 Q. Let's talk about each of those references in turn. Could

00:10 23 you turn in your binder to JTX-210, please? What is JTX-210?

00:10 24 A. This is an extract from *New Drugs in Japan* from 2001.

00:10 25 Q. What does this *New Drugs in Japan* reference, JTX-210,

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00:13 1 Could you turn in your binder to DTX-110, please? What is

00:13 2 DTX-110?

00:13 3 A. This is an extract from a book *Clinics & Drug Therapy*

00:13 4 from 2000. Specifically, it is an evaluation of new drugs by

00:13 5 clinicians and that new drug is bromfenac sodium hydrate, and

00:13 6 it's written by Hara.

00:13 7 Q. What does the Hara reference teach about the indications

00:13 8 for bromfenac?

00:13 9 A. On DTX-110.2 on the first column, it states that

00:13 10 bromfenac sodium hydrate was developed to treat a range of

00:13 11 inflammatory conditions of the eye.

00:13 12 Q. Does the Hara reference teach anything about how

00:14 13 bromfenac compares to other NSAIDs?

00:14 14 A. Yes, it does. It specifically compares it with three

00:14 15 other NSAID drugs on the market, pranoprofen, indomethacin and

00:14 16 diclofenac sodium.

00:14 17 Q. What does the Hara reference conclude about that

00:14 18 comparison?

00:14 19 A. On DTX-110.2 -- sorry. On DTX-110.3, under the section

00:14 20 entitled Conclusion, it states that this drug, in other words,

00:14 21 bromfenac, shows superior efficacy in treating anterior eye

00:14 22 inflammation and postoperative inflammation.

00:14 23 Q. And did you say that's under the section entitled

00:14 24 Comments?

00:14 25 A. Sorry, did I -- yes, Comments.

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00:14 1 Q. Okay. Let's look now at the next reference in group A.  
 00:14 2 Could you turn in your binder to JTX-147? Are you there?  
 00:15 3 A. Yes.  
 00:15 4 Q. Okay. And can you just remind us what JTX-147 is?  
 00:15 5 A. This is U.S. patent number 4,910,225 from the 20th of  
 00:15 6 March, 1990, and this is what I've been referring to as the  
 00:15 7 '225 patent.  
 00:15 8 Q. Generally speaking, what is the '225 patent directed to?  
 00:15 9 A. It's concerned with preparing formulations for  
 00:15 10 ophthalmic -- predominantly for ophthalmic use of the  
 00:15 11 nonsteroidal antiinflammatory bromfenac.  
 00:15 12 Q. Can you remind us, is there a specific example from the  
 00:15 13 '225 patent that is particularly relevant here?  
 00:15 14 A. Yes, there is. That is on JTX-147.6 and is Example 6.  
 00:15 15 Q. Why is Example 6 particularly relevant to a person of  
 00:16 16 ordinary skill in the art?  
 00:16 17 A. As you can see on DDX2-33, the list of ingredients on  
 00:16 18 Example 6 of the '225 patent is identical to the list of  
 00:16 19 ingredients in the Bronuck formulation I showed you a few  
 00:16 20 minutes ago.  
 00:16 21 Q. Let's move on to the last reference in your group A. Can  
 00:16 22 you turn in your binder, please, to JTX-168? What is JTX-168?  
 00:16 23 A. This is U.S. patent number 5,475,034 from December the  
 00:16 24 12th, 1995, and I've been referring -- I refer to this as the  
 00:16 25 '034 patent.

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00:18 1 then this is a significant bit. It states that diclofenac was  
 00:18 2 somewhat less effective both in vitro and in vivo than the  
 00:19 3 chloro or bromo substituted 2-amino-3-benzoylbenzeneacetic  
 00:19 4 acids.  
 00:19 5 Q. And which compound in Table 1 is the bromo substituted  
 00:19 6 2-amino-3-benzoylbenzeneacetic acids?  
 00:19 7 A. That would be bromfenac.  
 00:19 8 Q. And so what would a person of ordinary skill in the art  
 00:19 9 understand from that conclusion in the patent?  
 00:19 10 A. They would understand that bromfenac demonstrated a good  
 00:19 11 level of activity, better than or comparable to diclofenac,  
 00:19 12 and think it would have been an interesting drug to look at  
 00:19 13 formulating.  
 00:19 14 Q. Are you aware that plaintiff's experts have argued that  
 00:19 15 this '034 patent showed that bromfenac was not as good as  
 00:19 16 diclofenac?  
 00:19 17 A. Yes, I am.  
 00:19 18 Q. Do you agree with that?  
 00:19 19 A. No. I think they probably misread the results in this  
 00:20 20 patent.  
 00:20 21 Q. Can you summarize for us then what the references in  
 00:20 22 group A taken together would have taught to the person of  
 00:20 23 ordinary skill in the art?  
 00:20 24 A. Firstly, that bromfenac was known to be marketed,  
 00:20 25 marketed as a commercial formulation in Japan. In addition,

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00:16 1 Q. What does the '034 patent teach about the activity of  
 00:16 2 bromfenac compared to other NSAIDs?  
 00:16 3 A. On Table 1, which is produced on JTX-168.9, there's a  
 00:17 4 table showing the results of a range of antiinflammatory  
 00:17 5 agents, some of which have been synthesized specifically for  
 00:17 6 this study. So, it compares the results in a range, in a  
 00:17 7 range of in vivo and in vitro tests.  
 00:17 8 Q. Okay. And what do -- so, can you explain just by  
 00:17 9 reference to the table what kind of data you see represented  
 00:17 10 here?  
 00:17 11 A. Yes. What you can see is in columns 4 and 5, there's  
 00:17 12 results of in vitro data, whereas in columns 6 and 7, this is  
 00:17 13 in vivo data, while column 1 lists the range of compounds that  
 00:17 14 are being tested. I've highlighted bromfenac and another well  
 00:18 15 known nonsteroidal antiinflammatory diclofenac.  
 00:18 16 Q. And what do the data for bromfenac and diclofenac teach  
 00:18 17 about the activity of bromfenac?  
 00:18 18 A. They show that bromfenac in the tests is either better  
 00:18 19 than or at least comparable to the results obtained with  
 00:18 20 diclofenac.  
 00:18 21 Q. What did the authors of the patent, the '034 patent  
 00:18 22 conclude about the activity?  
 00:18 23 A. On page JTX-168.8, under the section entitled Results at  
 00:18 24 the bottom of the first paragraph, they state similar results  
 00:18 25 were obtained with the reference compound, diclofenac. And

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00:20 1 bromfenac was known to be more effective for some indications  
 00:20 2 than other nonsteroidal antiinflammatories, that the  
 00:20 3 ingredients of the marketed formulation were known, and that  
 00:20 4 marketed formulation contained bromfenac, benzalkonium  
 00:20 5 chloride and polysorbate 80.  
 00:20 6 Q. Okay. Let's move on to the references in group B. Can  
 00:20 7 you just tell us which references you have put into the group  
 00:20 8 B category?  
 00:20 9 A. Yes, I have. They are U.S. patent number 5,558,876 from  
 00:20 10 1996, which is JTX-201, patent WO 94/15597 from 1994, which is  
 00:21 11 JTX-207, U.S. patent number 5,603,929 from 1997, which is  
 00:21 12 JTX-061, and Remington's from 2000, which is DTX-15.  
 00:21 13 Q. And just in a general way, what do the references in  
 00:21 14 group B teach to the person of ordinary skill in the art?  
 00:21 15 A. Firstly, that the preservative benzalkonium chloride was  
 00:21 16 widely used and its incompatibility between nonsteroidal  
 00:21 17 antiinflammatory drugs and benzalkonium chloride was known at  
 00:21 18 the time.  
 00:21 19 Q. Let's look at your first reference in group B. Could you  
 00:21 20 turn in your binder, please, to JTX-201? What is JTX-201?  
 00:22 21 A. This is U.S. patent number 5,558,876 from the 24th of  
 00:22 22 September, 1996.  
 00:22 23 Q. And generally what is the '876 patent directed to?  
 00:22 24 A. This is directed towards the development of an ophthalmic  
 00:22 25 formulation of acidic drugs.

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00:22 1 Q. Does the '876 patent say anything about what happens to  
 00:22 2 NSAID drugs with benzalkonium chloride in a formulation?  
 00:22 3 A. Yes. DDX2-37 reproduces an extract from JTX-201.3, which  
 00:22 4 states that the drugs tend to form insoluble complexes with  
 00:22 5 quaternary ammonium preservatives such as benzalkonium  
 00:23 6 chloride.  
 00:23 7 Q. And the drugs referred to in that statement, which drugs  
 00:23 8 is that referring to?  
 00:23 9 A. These are referring to -- I'm sorry, these are referring  
 00:23 10 to nonsteroidal antiinflammatory drugs.  
 00:23 11 Q. And so what does this reference teach the person of  
 00:23 12 ordinary skill in the art about what happens to NSAIDs and  
 00:23 13 benzalkonium chloride in solution?  
 00:23 14 A. It tells us there's an interaction between the  
 00:23 15 benzalkonium chloride and the nonsteroidal antiinflammatory  
 00:23 16 such that an insoluble complex is formed.  
 00:23 17 Q. Have you prepared a demonstrative to show how that  
 00:23 18 complexation between an NSAID and benzalkonium chloride  
 00:23 19 occurs?  
 00:23 20 A. Yes, I have.  
 00:23 21 Q. Is that at DDX2-38?  
 00:23 22 A. Yes, it is.  
 00:23 23 Q. Can you walk us through this demonstrative?  
 00:23 24 A. Certainly. On the top right-hand side we have a  
 00:24 25 nonsteroidal antiinflammatory. As I indicated yesterday, the

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00:24 1 carboxylic acid group is on the left-hand side of the molecule  
 00:24 2 and that is highlighted in green. When that's in solution,  
 00:24 3 the proton will dissociate from the rest of the molecule,  
 00:24 4 leaving a negatively charged anion in solution.  
 00:24 5 Dealing now with the benzalkonium chloride, which you  
 00:24 6 can see at the bottom just above the beaker, this has, as you  
 00:24 7 can see, a positive charge and a negative charge. In  
 00:24 8 solution, the chloride ion would dissociate from the rest of  
 00:24 9 the benzalkonium chloride leaving a positively charged  
 00:24 10 cationic molecule, both the hydrogen and chloride ions would  
 00:24 11 go into solution, and then the negatively charged anionic drug  
 00:25 12 would be attracted to the positive charge on the benzalkonium  
 00:25 13 chloride, as I've shown here, and you can see now there's a  
 00:25 14 big -- there's a complex between that NSAID and the  
 00:25 15 benzalkonium chloride. There's no charge on that. It is  
 00:25 16 effectively neutral, because the two charges have neutralized  
 00:25 17 each other, so we have a very large water-insoluble complex  
 00:25 18 resulting, which I've tried to show by the white dots in the  
 00:25 19 beaker.  
 00:25 20 Q. Okay. Let's look at the next reference in your group B  
 00:25 21 set of references. Could you turn in your binder to JTX-207?  
 00:25 22 A. Yes.  
 00:25 23 Q. What is JTX-207?  
 00:25 24 A. This is WO 94/15597, publication date 21st of July, 1984.  
 00:25 25 Q. I think you may have misspoken. Did you mean 1994?

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00:25 1 A. I'm sorry, 1994, yes.  
 00:25 2 Q. And generally speaking, what is the WO 597 reference  
 00:26 3 directed to?  
 00:26 4 A. This is a preparation of ophthalmic -- it's a preparation  
 00:26 5 of ophthalmic formulations comprising of another related  
 00:26 6 benzalkonium chloride preservative.  
 00:26 7 THE COURT: Excuse me. May I interrupt? What's the  
 00:26 8 notation WO stand for?  
 00:26 9 MS. RAPALINO: Are you asking me?  
 00:26 10 THE COURT: Well, maybe the witness.  
 00:26 11 THE WITNESS: It's the world patent, isn't it? So,  
 00:26 12 international patent.  
 00:26 13 THE COURT: I'm sorry, can you repeat that?  
 00:26 14 THE DEFENDANT: World patent.  
 00:26 15 THE COURT: Okay. Thank you.  
 00:26 16 MS. RAPALINO: An international patent application.  
 00:26 17 BY MS. RAPALINO:  
 00:26 18 Q. Does the WO 597 international patent application say  
 00:26 19 anything about preservatives generally in ophthalmic  
 00:26 20 solutions?  
 00:26 21 A. Yes, it does. On page JTX-207.3, I've highlighted an  
 00:27 22 extract on the slide, and it states that ophthalmic  
 00:27 23 formulations must be, if they're intended for a multidose  
 00:27 24 regime, be preserved with an effective antimicrobial agent.  
 00:27 25 Q. Does it say anything about benzalkonium chloride in

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00:27 1 particular in ophthalmic solutions?  
 00:27 2 A. Yes, it does. On JTX-207.4 at the top of the page, it  
 00:27 3 states that benzalkonium chloride, which is a quaternary  
 00:27 4 ammonium compound, has been widely used in ophthalmic  
 00:27 5 preparations. However, it is known to be incompatible with  
 00:27 6 anionic drugs forming insoluble compounds which can turn the  
 00:27 7 solution cloudy.  
 00:27 8 Q. Does the WO 597 patent say anything about how that  
 00:28 9 complexation with anionic drugs and benzalkonium chloride  
 00:28 10 occurs?  
 00:28 11 A. Yes, it does. On the same page, it goes on to say that  
 00:28 12 many acidic drugs carry a negative charge in solution at the  
 00:28 13 relevant pH, and that benzalkonium chloride is positively  
 00:28 14 charged, and because of this negative acidic anionic drug and  
 00:28 15 this positive cationic preservative, you get an ion pair  
 00:28 16 forming, just as I've tried to illustrate a moment ago, and  
 00:28 17 that this ion pair is insoluble and precipitates out to  
 00:29 18 solution.  
 00:29 19 Q. Let's move on to the next reference in group B. Could  
 00:29 20 you turn in your binder, please, to JTX-61? Generally  
 00:29 21 speaking -- well, first of all, what is JTX-61?  
 00:29 22 A. It's U.S. patent number 5,603,929 from the 18th of  
 00:29 23 February, 1997.  
 00:29 24 Q. Generally speaking, what does the '929 patent deal with?  
 00:29 25 A. It talks about forming ophthalmic preparations that are

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00:29 1 preserved using a polymeric quaternary ammonium compound.  
 00:29 2 Q. Does the '929 patent say anything about formulating  
 00:29 3 NSAIDs with benzalkonium chloride?  
 00:29 4 A. Yes, it does. On JTX-061.2, which I've highlighted an  
 00:30 5 extract on the first column halfway down, it states again that  
 00:30 6 benzalkonium chloride is a widely used preservative, and again  
 00:30 7 goes on to state that it's considered incompatible with acidic  
 00:30 8 drugs such as nonsteroidal antiinflammatory agents, and that  
 00:30 9 when they interact, the preservative loses its ability to  
 00:30 10 function.  
 00:30 11 Q. And why does it say it loses its ability to function?  
 00:30 12 A. Because when the complex is taken out of solution, it's  
 00:30 13 no longer available to exert its preservative properties.  
 00:30 14 Q. Okay. Let's look next at your final reference in group  
 00:30 15 B. Could you turn to DTX-15 and briefly remind us what DTX-15  
 00:30 16 is?  
 00:31 17 A. Certainly. This is the 20th edition of Remington Science  
 00:31 18 and Practice of Pharmacy, which, as I said yesterday, which is  
 00:31 19 a widely used reference book by pharmaceutical formulators.  
 00:31 20 Q. Can you remind us again just briefly what Remington's  
 00:31 21 says about benzalkonium chloride?  
 00:31 22 A. Certainly. On DTX-015.5, under quaternary ammonium  
 00:31 23 compounds, it states once again that benzalkonium chloride is  
 00:31 24 by far the most commonly used preservative in ophthalmic  
 00:31 25 preparations, and states over 65 percent of commercial

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00:31 1 ophthalmic products are preserved at that time with  
 00:31 2 benzalkonium chloride.  
 00:31 3 Q. And can you remind us, does Remington's say anything  
 00:31 4 about the problems with benzalkonium chloride?  
 00:31 5 A. Yes. It goes on to say just below that, as a cationic  
 00:32 6 surface active material of high molecular weight, in other  
 00:32 7 words, we're talking about benzalkonium chloride, it is not  
 00:32 8 compatible with anionic compounds.  
 00:32 9 Q. Does Remington's suggest that formulators avoid  
 00:32 10 benzalkonium chloride because of that complexation problem?  
 00:32 11 A. No, not at all. In the same paragraph, at the end of the  
 00:32 12 paragraph, it is stated that given the alternative, it would  
 00:32 13 be preferable to modify a formulation to remove the  
 00:32 14 incompatibility rather than include a compatible but less  
 00:32 15 effective preservative.  
 00:32 16 Q. Other than the four references you have listed on this  
 00:32 17 slide, are there any other references that show that it was  
 00:32 18 well known to the person of ordinary skill in the art as of  
 00:32 19 January 2003 that acidic drugs like NSAIDs formed insoluble  
 00:32 20 complexes with benzalkonium chloride?  
 00:33 21 A. Yes, there's lots of prior art from that time.  
 00:33 22 Q. Does the '431 patent-in-suit say anything about the  
 00:33 23 formation of complexes between NSAIDs and benzalkonium  
 00:33 24 chloride?  
 00:33 25 A. Yes, it does.

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00:33 1 Q. Could we turn then to JTX-1, which is the '431  
 00:33 2 patent-in-suit? Looking at the background art section of the  
 00:33 3 '431 patent, what does the patent-in-suit say about what was  
 00:33 4 known in the prior art about complexation between NSAIDs and  
 00:33 5 benzalkonium chloride?  
 00:33 6 A. Yes. On JTX-001.3, the bottom of the first column on the  
 00:33 7 background art, it states that benzalkonium chloride is a  
 00:33 8 widely used preservative and is considered incompatible with  
 00:33 9 acidic drugs, and in particular, or such as, nonsteroidal  
 00:34 10 antiinflammatories, and as a consequences -- as a consequence  
 00:34 11 of the interaction, what happens is the preservative becomes  
 00:34 12 less effective and loses its ability to function as a  
 00:34 13 preservative.  
 00:34 14 Q. Can you summarize for us, generally speaking, what your  
 00:34 15 group B references would have taught to the person of ordinary  
 00:34 16 skill in the art as of 2003?  
 00:34 17 A. Certainly. Taken together, the references say that  
 00:34 18 benzalkonium chloride is the most widely used preservative in  
 00:34 19 ophthalmic preparations. It was well known that benzalkonium  
 00:34 20 chloride was incompatible with anionic negatively charged  
 00:34 21 acidic drugs such as the NSAIDs, that the complexation between  
 00:34 22 benzalkonium chloride and the NSAID led to the formation of  
 00:34 23 insoluble precipitates, and that left less preservative in  
 00:35 24 solution to exert its preservative effect, and it was also  
 00:35 25 preferable to resolve the incompatibility rather than use a

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00:35 1 less effective alternative preservative to benzalkonium  
 00:35 2 chloride.  
 00:35 3 Q. Thank you. Let's move on now to your group C references,  
 00:35 4 and can you just tell us which references you have placed in  
 00:35 5 the category of group C?  
 00:35 6 A. Yes, I can. That is European patent number 0 306 984  
 00:35 7 from 1984, which I have termed the 984 patent, which is  
 00:35 8 JTX-209; a reference from Schott in 1998 from -- as a  
 00:35 9 scientific article, and it's JTX-199; and U.S. patent number  
 00:35 10 5,891,913 from 1999 which is JTX-071.  
 00:36 11 Q. Okay. Let's -- before we move to the first reference,  
 00:36 12 can you tell us just generally what the references in group C  
 00:36 13 taught to the person of ordinary skill in the art?  
 00:36 14 A. These references deal with the prior art that states that  
 00:36 15 the ethoxylated octylphenol surfactants could solve the  
 00:36 16 problem of the complexation between a nonsteroidal  
 00:36 17 antiinflammatory and BAC, and furthermore, the use of  
 00:36 18 tyloxapol in ophthalmic preparations was known.  
 00:36 19 Q. Let's go to the first reference in group C. Can you turn  
 00:36 20 in your binder, please, to JTX-209? What is JTX-209?  
 00:36 21 A. This is the European patent number 0 306 984 from the  
 00:36 22 15th of March, 1989.  
 00:37 23 Q. Generally speaking, what does the EP -- is it okay if I  
 00:37 24 call that the EP 984 patent?  
 00:37 25 A. Yes, it is.

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00:37 1 Q. Generally speaking, what does the EP 984 patent say about  
 00:37 2 the problem of NSAID benzalkonium chloride complexation?  
 00:37 3 MR. HASFORD: I'd just like to object for the record,  
 00:37 4 your Honor. I believe that JTX-209 is not actually a patent.  
 00:37 5 It looks like it is a European patent application. I just  
 00:37 6 wanted to get that on the record.  
 00:37 7 THE COURT: Is that correct?  
 00:37 8 MS. RAPALINO: It is a patent application. It is a  
 00:37 9 published patent application.  
 00:37 10 THE COURT: All right. Is the witness aware of that?  
 00:37 11 THE WITNESS: I am. My mistake. I should have said  
 00:37 12 that.  
 00:37 13 THE COURT: Okay. Very well. Let's continue.  
 00:37 14 Q. Generally speaking, what is the EP 984 patent application  
 00:37 15 directed to?  
 00:38 16 A. It's directed to forming -- or the preparation of  
 00:38 17 ophthalmic preparations that are -- that contain  
 00:38 18 negatively-charged drug, in particular, NSAIDs, that are  
 00:38 19 effectively preserved.  
 00:38 20 Q. And what does the EP 984 patent application say about  
 00:38 21 complexation TWEEN nonsteroidal anti-inflammatory drugs and  
 00:38 22 benzalkonium chloride?  
 00:38 23 A. Yes, on JTX-209.2, on the first page, near the top of the  
 00:38 24 page, it points out, when it's talking about a particular  
 00:38 25 patent, which is abbreviated as '13151 patents, that while the

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00:40 1 words, the anionic carboxylic group, and the carboxylic acid  
 00:40 2 group, and it forms a complex with the benzalkonium chloride;  
 00:41 3 and thereby renders the preservative less available to serve  
 00:41 4 its function and also, as it said before, reduces the activity  
 00:41 5 of the active ingredients.  
 00:41 6 Q. Now, generally, what is the solution given by the EP 984  
 00:41 7 patent application for this problem of NSAID benzalkonium  
 00:41 8 chloride complexation?  
 00:41 9 A. As I've shown on DDX-2-48 under the claims, it states  
 00:41 10 that the solution to this problem is that all -- a solution to  
 00:41 11 the problem is a nonionic ethoxylated octylphenol surfactant.  
 00:41 12 Q. Does the EP 984 patent application say anything about the  
 00:41 13 use of polysorbate 80 in connection with this problem?  
 00:41 14 A. Yes, it does. On Page JTX209.9, under Example 5, it  
 00:42 15 produces a table, which talks about Tween 80, which in effect  
 00:42 16 is polysorbate -- it's another name for polysorbate 80.  
 00:42 17 Q. Can you describe what you see in the table in Example 5  
 00:42 18 of the EP 984 patent application?  
 00:42 19 A. Yes, this table is reporting an experiment between an  
 00:42 20 NSAID drug, benzalkonium chloride, and nonionic surfactants,  
 00:42 21 and it's a physical stability test, and it explains how the  
 00:42 22 solution appeared after various time periods and under storage  
 00:42 23 at various temperatures.  
 00:42 24 Q. And which nonionic surfactants are being compared in this  
 00:42 25 table, in Example 5 of EP 984?

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00:38 1 formulation is efficacious, and these are formulations  
 00:38 2 containing benzalkonium chloride, an insoluble complex is  
 00:39 3 found to form between the NSAID and the BAC. And as a result,  
 00:39 4 the formulations became cloudy or turbid and did not have the  
 00:39 5 stability designed for shelf life for a commercial  
 00:39 6 formulation.  
 00:39 7 Q. Does the EP 984 patent application say anything else  
 00:39 8 about the effect of this complexation between NSAIDs and  
 00:39 9 benzalkonium chloride?  
 00:39 10 A. Yes, it does. Further down the page, again, states that  
 00:39 11 benzalkonium chloride is a widely-used preservative, and is  
 00:39 12 considered to be the preservative of choice, and that it is --  
 00:39 13 sorry. Beg your pardon. And that it is incompatible with  
 00:39 14 anionic drugs forming insoluble complexes, which cause the  
 00:39 15 solution to be cloudy and turbid.  
 00:39 16 And it goes on to say that one of the consequences of  
 00:40 17 this is that it can decrease the pharmaceutical activity of  
 00:40 18 the anionic drug, because that drug is now precipitated and is  
 00:40 19 no longer in solution to exert its activity.  
 00:40 20 Q. And does the EP 984 patent -- excuse me one minute. Does  
 00:40 21 the EP 984 patent application say anything about the effect of  
 00:40 22 this complexation on benzalkonium chloride?  
 00:40 23 A. Yes, it does. Slightly further down the page in the  
 00:40 24 section I've highlighted in yellow, it explains what the cause  
 00:40 25 of the compatibility is, which is the COOH group, in other

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00:42 1 A. I've highlighted the data for Tween 80, which as I've  
 00:43 2 explained a moment ago, is polysorbate 80, and the ethoxylated  
 00:43 3 octylphenol surfactant Octoxynol 40.  
 00:43 4 Q. What does the table demonstrate are the results of that  
 00:43 5 comparison between the use of Tween 80, or polysorbate 80 on  
 00:43 6 the one hand, and the ethoxylated octylphenol surfactant on  
 00:43 7 the other?  
 00:43 8 A. What is significant from the results shown in table -- in  
 00:43 9 Example 5 is, all the results under the two columns dealing  
 00:43 10 with Octoxynol 40 show that the solutions were clear, no  
 00:43 11 matter how long they were stored for and at what temperature,  
 00:43 12 whereas the data for polysorbate 80 or Tween 80 shows that  
 00:43 13 most of the solutions became turbid or cloudy at storage at  
 00:43 14 various temperature conditions.  
 00:43 15 Q. What does a turbid or cloudy solution suggest to the  
 00:44 16 person of ordinary skill in the art?  
 00:44 17 A. It suggests that there's a complex being formed between  
 00:44 18 the benzalkonium chloride and the nonsteroidal  
 00:44 19 anti-inflammatory drug, and that precipitates its turning the  
 00:44 20 solution cloudy.  
 00:44 21 Q. So then what would a person of skill in the art  
 00:44 22 understand about which of these nonionic surfactants is  
 00:44 23 preferable, in terms of avoiding the complexation between  
 00:44 24 NSAIDs and benzalkonium chloride?  
 00:44 25 A. From the data shown in Example 5, a person of ordinary

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00:44 1 skill in the art would have seen that Octoxynol 40, the  
 00:44 2 ethoxylated octylphenol surfactant, was superior over Tween 80  
 00:44 3 or polysorbate 80.  
 00:44 4 Q. Let's look at the next reference in group C. If you  
 00:44 5 could turn in your binder, please, to JTX199. What is JTX199?  
 00:45 6 A. This is a scientific article from the *Journal of Colloid*  
 00:45 7 *and Interface Science* in 1998, and it's authored by Hans  
 00:45 8 Schott.  
 00:45 9 Q. Generally speaking, what does this article by Schott --  
 00:45 10 what is it about?  
 00:45 11 A. It's comparing the properties of two ethoxylated  
 00:45 12 octylphenol surfactants, octoxynol 9 and tyloxapol.  
 00:45 13 Q. What does the Schott reference conclude about the  
 00:45 14 properties of tyloxapol?  
 00:45 15 A. On Page JTX199.6, at the top of the section -- in the  
 00:45 16 first paragraph of the section entitled Conclusions, it states  
 00:46 17 that from a practical point of view, the critical micelle  
 00:46 18 concentration of tyloxapol is just over four times smaller  
 00:46 19 than that of Octoxynol 9 on a weight weight basis. This is  
 00:46 20 an advantage for the pharmaceutical formulation -- advantage  
 00:46 21 for formulation.  
 00:46 22 Q. Can you explain why a lower critical micelle  
 00:46 23 concentration is an advantage?  
 00:46 24 A. Certainly. The critical micelle concentration is a  
 00:46 25 concentration of surfactants at which micelles start to form,

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00:48 1 up the page, it states a little bit about the use of the  
 00:49 2 European Pharmacopeia to look at the preservation activity of  
 00:49 3 the formulation.  
 00:49 4 Q. And what do you mean by "preservation activity of the  
 00:49 5 formulation"?  
 00:49 6 A. This is a test to assess how effective the formulation is  
 00:49 7 at -- preserving the product under challenge to various types  
 00:49 8 of antimicrobial agents.  
 00:49 9 Q. Does the '913 patent say anything about the amount of  
 00:49 10 tyloxapol that should be used in formulations of NSAIDs with  
 00:49 11 benzalkonium chloride?  
 00:49 12 A. Yes, it does. On Page -- the top of Page JTX071.4, it  
 00:49 13 states that the concentration of solubilizer, in other words,  
 00:49 14 surfactant ranges from .1 to 5,000 times the concentration of  
 00:50 15 the active ingredients.  
 00:50 16 Q. And given the amount of active ingredient or diclofenac  
 00:50 17 in Example 15 of the '913 patent, what would that translate  
 00:50 18 into in terms of a lower concentration range for tyloxapol?  
 00:50 19 A. The lowest concentration would be 0.01 weighting volume  
 00:50 20 percent of tyloxapol.  
 00:50 21 Q. Had tyloxapol ever been used in an approved ophthalmic  
 00:50 22 pharmaceutical product as of 2003?  
 00:50 23 A. Yes, it had.  
 00:50 24 Q. How would the person of ordinary skill in the art know  
 00:50 25 that?

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00:46 1 and the lower that concentration, it means you have to add  
 00:46 2 less surfactant into the formulation to form micelles.  
 00:46 3 Q. Let's look now at the last reference in your group C.  
 00:46 4 Could you turn in your binder, please, to JTX71. What is  
 00:47 5 JTX71?  
 00:47 6 A. Yes. This is U.S. Patent No. 5,891,913 from the 6th of  
 00:47 7 April, 1999.  
 00:47 8 Q. Generally speaking, what is the '913 patent directed to?  
 00:47 9 A. It's directed towards the preparation of ophthalmic and  
 00:47 10 aural compositions, but in particular, ophthalmic compositions  
 00:47 11 contained in the nonsteroidal anti-inflammatory diclofenac  
 00:47 12 potassium.  
 00:47 13 Q. Does the '913 patent say anything about tyloxapol?  
 00:47 14 A. Yes, it does. On Page JTX071.3, it states that tyloxapol  
 00:47 15 is a preferred solubilizer?  
 00:47 16 Q. Is solubilizer another name for a surfactant?  
 00:48 17 A. Yes, it is.  
 00:48 18 Q. Are there any examples in the '913 patent of the use of  
 00:48 19 tyloxapol in a formulation of a nonsteroidal anti-inflammatory  
 00:48 20 drug with benzalkonium chloride?  
 00:48 21 A. Yes, there is. Example 15 on Page JTX071.7 shows it  
 00:48 22 being used in an eye drop formulation.  
 00:48 23 Q. Does the '913 patent say anything about any aspect of the  
 00:48 24 stability of the formulations described in the '913 patent?  
 00:48 25 A. Yes, it does. On the same page, JTX071.7, just further

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00:50 1 A. To determine whether or not it had been used in  
 00:50 2 ophthalmic preparation, they would consult the FDA inactive  
 00:50 3 ingredients guide.  
 00:50 4 Q. Okay. So let's turn to the FDA inactive ingredient guide  
 00:51 5 at DTX-196. Can you explain what the FDA inactive ingredient  
 00:51 6 guide says about the use of tyloxapol?  
 00:51 7 A. Yes. Under -- on Page DTX-196, 158, there is a listing  
 00:51 8 for tyloxapol, and it states that tyloxapol at the time had  
 00:51 9 been used both in ophthalmic solutions and ophthalmic  
 00:51 10 suspensions. For solutions -- sorry. Is it five solutions,  
 00:51 11 four suspensions. It also states the range of concentrations  
 00:51 12 at which tyloxapol had been used at.  
 00:51 13 Q. Okay. Before we move on to talking about your  
 00:51 14 obviousness opinions in more detail, can you just summarize  
 00:51 15 for us, generally, what your references in group C would have  
 00:51 16 taught to the person of ordinary skill in the art?  
 00:51 17 A. They would have taught that replacing polysorbate with an  
 00:51 18 ethoxylated octylphenol surfactant removed the problem with  
 00:52 19 the complexation between the nonsteroidal anti-inflammatory in  
 00:52 20 BAC, that tyloxapol is an example of an ethoxylated  
 00:52 21 octylphenol surfactant and that it had been used in previous  
 00:52 22 products.  
 00:52 23 Furthermore, tyloxapol has a number of favorable  
 00:52 24 properties in terms of pharmaceutical formulation, and  
 00:52 25 tyloxapol had previously been used in ophthalmic formulations

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00:52 1 with an NSAID and benzalkonium chloride.

00:52 2 Q. Okay. Now that we've talked about the scope of the prior

00:52 3 art, let's talk about your specific obviousness opinion in

00:52 4 this case.

00:52 5 If we can put up again on DDX-2-57, Claim 20 of the

00:52 6 '431 patent as rewritten in independent form. What -- can you

00:52 7 remind us, what is your opinion about whether Claim 20 of the

00:52 8 '431 patent would have been obvious to a person of ordinary

00:52 9 skill in the art as of January 2003?

00:52 10 A. It's my opinion that Claim 20 of the '431 patent would

00:53 11 have been obvious to person of ordinary skill in the art, as

00:53 12 of January 2003.

00:53 13 Q. Do you have a slide summarizing the basis for your

00:53 14 opinion that Claim 20 is obvious?

00:53 15 A. Yes, I do. It's my -- opinion --

00:53 16 MR. HASFORD: And I'll just object, Your Honor. I

00:53 17 mean, it appears that she's literally reading opinions off of

00:53 18 these slides. I'm not sure that's proper in the context of

00:53 19 this witness giving obviousness opinions.

00:53 20 THE COURT: I'll permit it.

00:53 21 MS. RAPALINO: Your Honor, the slide is just there as

00:53 22 a memory aid and it's -- she has formed these opinions

00:53 23 independent of any slides that have been created, and she's

00:53 24 simply using them as a guide, and as a guide also for the

00:53 25 Court so the Court can see her opinions in writing while she

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00:55 1 '225 patent, and it would have also been aware that the

00:55 2 ingredients in Example 6 of the '225 patent are, in fact, the

00:55 3 same as those in the Bronuck formulation that was marketed in

00:55 4 Japan.

00:55 5 They would have also been aware there was this problem

00:55 6 of complexation between benzalkonium chloride and a

00:55 7 nonsteroidal anti-inflammatory, and that this could have been

00:55 8 overcome by the use of tyloxapol, and once they decided to use

00:55 9 tyloxapol would, by routine optimization, have come up with

00:55 10 the concentration of tyloxapol that's contained in examples --

00:55 11 in the '431 patent Claim 20.

00:55 12 Q. Let's start with the first part of that. That the person

00:55 13 of ordinary skill in the art would have been aware of Example

00:55 14 6 of the '225 patent as a starting point. Can you remind us

00:55 15 what '225 patent Example 6 covers?

00:55 16 A. Yes, certainly. It deals with an aqueous liquid

00:55 17 preparation intended for ophthalmic use that contained

00:56 18 bromfenac, benzalkonium chloride, polysorbate 80 and a range

00:56 19 of other ingredients.

00:56 20 Q. Why would the person of ordinary skill in the art focus

00:56 21 specifically on Example 6 of the '225 patent as the starting

00:56 22 point?

00:56 23 A. Okay. Well, they would have been aware that bromfenac

00:56 24 had showed some advantages, in terms of its use as a

00:56 25 nonsteroid anti-inflammatory over other nonsteroid

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00:53 1 -- while she expresses those opinions.

00:53 2 And I would also just -- I disagree that she's just

00:53 3 reading off of slides. She's offering her opinion, as a

00:53 4 professor often does, guided by a PowerPoint presentation.

00:53 5 But her opinions are her own.

00:53 6 THE COURT: I understand the point of the objection,

00:53 7 that the witness can't just sit here and read slides that have

00:54 8 been prepared in a way that may or may not have been her own

00:54 9 hand that created them. She can be cross-examined, certainly

00:54 10 without the benefit of slides, as to any of her testimony.

00:54 11 And it's not meant to be a memory test, but rather to fix what

00:54 12 is and what is not her opinion.

00:54 13 But I'll permit it. I mean, I don't know about anyone

00:54 14 else, but I find the material very dense. I find these slides

00:54 15 helpful, and the witness's explanation, you know, is her

00:54 16 testimony. So I'll permit it.

00:54 17 MS. RAPALINO: Thank you, Your Honor.

00:54 18 BY MS. RAPALINO:

00:54 19 Q. Professor Lawrence, can you summarize the basis for your

00:54 20 opinion that Claim 20 of the '431 patent would have been

00:54 21 obvious to a person of ordinary skill in the art as of

00:54 22 January 2003?

00:54 23 A. Yes, certainly. It's my opinion that it would have been

00:54 24 obvious to a person of ordinary skill in the art because they

00:54 25 would have been aware of formulation in the Example 6 in the

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00:56 1 anti-inflammatories, and they would have got this from the

00:56 2 Hara reference from 2000 and the 034 reference from 1995.

00:56 3 They would also be aware that Bronuck was a marketed

00:56 4 formulation in Japan as of 2000, and again, this would have

00:56 5 been from the Hara reference of 2000, and new drugs in Japan

00:56 6 from 2001, and they would have finally been aware that the

00:56 7 same ingredients were in Example 6 of '225 patent, as were in

00:57 8 the Bronuck formulation, and they would have got this from the

00:57 9 '225 patent from 1990 and new drugs in Japan from 2001.

00:57 10 Q. Can you remind us how Example 6 of the '225 patent

00:57 11 compares to Claim 20 of the '431 patent?

00:57 12 A. Yes. The next slide here compares claims -- Example 6 of

00:57 13 '225 patent which Claim 20 of the '431 patent, and as you can

00:57 14 see by what I've highlighted in blue, they are virtually

00:57 15 identical.

00:57 16 Q. What is the difference between Example 6 of the '225

00:57 17 patent and Claim 20 of the '431 patent?

00:57 18 A. Yeah, the only difference is in the type of nonionic

00:57 19 surfactant that was used in the formulation. Claim 6 of the

00:57 20 '225 preparation contained polysorbate 80, whereas Claim 20 of

00:57 21 the '431 patent contains tyloxapol.

00:57 22 Q. Other than the nonionic surfactant, how did the -- how

00:58 23 does the list of ingredients in Example 6 of '225 patent

00:58 24 compare to the list of ingredients in Claim 20 of the '431

00:58 25 patent?

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00:58 1 A. They are identical.  
 00:58 2 Q. Now, you said that it would have been obvious to a person  
 00:58 3 of ordinary skill in the art to replace the polysorbate 80 in  
 00:58 4 Example 6 with tyloxapol. But if the Bronuck formulation that  
 00:58 5 is an embodiment of Example 6 was already a sufficiently  
 00:58 6 stable product to have been marketed, why would the person of  
 00:58 7 ordinary skill in the art have had a motivation to change that  
 00:58 8 formulation?  
 00:58 9 A. There's two reasons. A pharmaceutical formulator will  
 00:58 10 always look at producing the most stable formulation. So one  
 00:58 11 of the things they would have done was to see whether they  
 00:58 12 could improve the stability, and coupled with that, there was  
 00:58 13 the knowledge that there was a problem with benzalkonium  
 00:58 14 chloride and nonsteroid anti-inflammatories, so they would  
 00:59 15 have ensured that the surfactant was suitable to overcome that  
 00:59 16 problem.  
 00:59 17 Q. Now, once the person of ordinary skill in the art decides  
 00:59 18 to replace the polysorbate 80 in Example 6 of the '225 patent,  
 00:59 19 why would the person of ordinary skill in the art have focused  
 00:59 20 on tyloxapol as the solution to that problem of complexation?  
 00:59 21 A. They would have been aware of the information contained  
 00:59 22 in patent -- in EP 984, from 1989, that ethoxylated  
 00:59 23 surfactants overcome the problem of complexation, and  
 00:59 24 obviously was being aware of the facts of the problems of  
 00:59 25 complexation in the first case. Then they would have known

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00:59 1 that tyloxapol was only one of two ethoxylated octylphenol  
 01:00 2 surfactants that had been approved for use in ophthalmic  
 01:00 3 formulations, and they would have known that from a variety of  
 01:00 4 sources, and as a consequence, they would have focused on  
 01:00 5 tyloxapol.  
 01:00 6 Q. Now, you also testified that a person of ordinary skill  
 01:00 7 in the art would have conducted routine optimization to  
 01:00 8 determine the amount of tyloxapol. Can you just remind us  
 01:00 9 what routine optimization is?  
 01:00 10 A. Yes. As I said before, a formulator will have a range of  
 01:00 11 concentrations over which they would expect to use ingredients  
 01:00 12 in the formulation. In order to find the most appropriate  
 01:00 13 formulation that contained the least amount of that  
 01:00 14 ingredient, they would go through a process where they made a  
 01:00 15 number of formulations, tested those formulations and selected  
 01:00 16 the one that had the optimal properties, again, with the least  
 01:01 17 amount of ingredient presence.  
 01:01 18 Q. Is that a process that a formulator uses on a regular  
 01:01 19 basis?  
 01:01 20 A. Yes, it is. It's routine optimization.  
 01:01 21 Q. In this situation, how would the person of ordinary skill  
 01:01 22 in the art have gone about doing that routine optimization  
 01:01 23 process?  
 01:01 24 A. Okay. A person of ordinary skill in the art would have  
 01:01 25 known that there's a range of concentrations over which to use

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01:01 1 the ethoxylated octylphenol surfactants, and they would have  
 01:01 2 known that from EP 984.  
 01:01 3 They would have also known that tyloxapol had been used  
 01:01 4 in NSAID/BAC formulations itself at a range of concentrations,  
 01:01 5 and that would have been obtainable from the '913 patent from  
 01:01 6 1999 and the FDA inactive ingredients guide, and then they  
 01:01 7 would have followed, as I've explained before, these general  
 01:02 8 pharmaceutical principles, optimized the amounts of surfactant  
 01:02 9 to obtain the formulation that contained the lowest  
 01:02 10 concentration that ensured stability.  
 01:02 11 Q. You testified that there was a known range of  
 01:02 12 concentrations for ethoxylated octylphenol surfactants in EP  
 01:02 13 984. Could you turn back to that patent application at  
 01:02 14 JTX209? What range of ethoxylated octylphenol surfactant does  
 01:02 15 the EP 984 patent application disclose?  
 01:02 16 A. Firstly, there's two tables to look at. The first table  
 01:02 17 is on JTX209.4, which lists the range of surfactant, which is  
 01:02 18 highlighted in yellow, as being from 0.001 to 1 weight in  
 01:03 19 volume percent.  
 01:03 20 Q. And then are there specific examples of specific  
 01:03 21 concentrations of ethoxylated octylphenol surfactant in EP  
 01:03 22 984?  
 01:03 23 A. Yeah, the patent then goes on to use some specific  
 01:03 24 formulations. So the table under Example 5, which I showed  
 01:03 25 you before, under Octoxynol 40, states two concentrations of

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01:03 1 0.004 and 0.02 percent.  
 01:03 2 Q. Now, when tyloxapol has been -- I'm sorry. When  
 01:03 3 polysorbate 80 has been replaced by tyloxapol in Example 6 of  
 01:03 4 the '225 patent, how does the list of ingredients in that  
 01:03 5 modified Example 6 compare to the list of ingredients in Claim  
 01:03 6 20 of the '431 patent?  
 01:04 7 A. In this case, that list of ingredients would be  
 01:04 8 identical.  
 01:04 9 Q. Have you considered whether the modified Example 6  
 01:04 10 formulation, where polysorbate 80 is replaced with tyloxapol,  
 01:04 11 would have consisted essentially of the ingredients recited in  
 01:04 12 Claim 20?  
 01:04 13 A. Yes, I have.  
 01:04 14 Q. Can you remind us, what does the phrase "consisting  
 01:04 15 essentially of" mean in this case?  
 01:04 16 A. Yes, consisting essentially of means including the listed  
 01:04 17 ingredients and, in addition, any unlisted ingredients,  
 01:04 18 assuming they don't affect -- materially affect the basic and  
 01:04 19 novel characteristics of the claimed preparation.  
 01:04 20 Q. Would the modified Example 6 formulation, where -- again,  
 01:04 21 where polysorbate 80 has been replaced with tyloxapol have  
 01:04 22 consisted essentially of the recited ingredients in Claim 20  
 01:04 23 of the '431 patent in light of that definition?  
 01:04 24 A. Yes, it would.  
 01:04 25 Q. Why do you say that?

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01:04 1 A. **Because it contains basically the same ingredients.**  
 01:05 2 Q. Okay.  
 01:05 3 A. **Exactly the same ingredients.**  
 01:05 4 Q. Thank you.  
 01:05 5 Now, you've been discussing the obviousness of Claim 20  
 01:05 6 of the '431 patent. Have you also considered the obviousness  
 01:05 7 of Claim 6 of the '431 patent that's been asserted here?  
 01:05 8 A. **Yes, I have.**  
 01:05 9 Q. And with reference to slide DDX-2-72, can you explain  
 01:05 10 what Claim 6 of the '431 patent covers when it's rewritten to  
 01:05 11 include all of its limitations?  
 01:05 12 A. **Yes. Claim 6 of the '431 patent covers an aqueous liquid**  
 01:05 13 **preparation containing bromfenac sodium and tyloxapol and when**  
 01:05 14 **a quaternary ammonium compound is present, that quaternary**  
 01:05 15 **ammonium compound is benzalkonium chloride.**  
 01:05 16 Q. And how does Claim 6 compare to Claim 20 of the '431  
 01:05 17 patent that we were just discussing?  
 01:05 18 A. **The two claims are obviously very simple -- similar.**  
 01:06 19 **Claim 6 requires only bromfenac sodium and tyloxapol to be**  
 01:06 20 **present without specifying all of the additional ingredients**  
 01:06 21 **of Claim 20, while Claim 6 also specifies a slightly narrower**  
 01:06 22 **concentration range for bromfenac sodium.**  
 01:06 23 Q. What did you conclude about whether Claim 6 of the '431  
 01:06 24 patent would have been obvious to a person of ordinary skill  
 01:06 25 in the art as of January 2003?

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01:06 1 A. **For the same reasons as I concluded for Claim -- for**  
 01:06 2 **similar reasons that I included for -- concluded for Claim 20,**  
 01:06 3 **I concluded that Claim 6 of the '431 patent would have been**  
 01:06 4 **obvious.**  
 01:06 5 Q. Can you just briefly explain those reasons?  
 01:06 6 A. **Certainly. As I've said before, a person of ordinary**  
 01:06 7 **skill in the art would have started with Example 6 of the '225**  
 01:06 8 **patent, and would have also been aware that the ingredients in**  
 01:06 9 **Claim -- Example 6 of '225 patent are identical of those in**  
 01:07 10 **the marketed formulation in Japan of Bronuck.**  
 01:07 11 **They would have been motivated to replace the**  
 01:07 12 **polysorbate with tyloxapol because of the anticipated problems**  
 01:07 13 **with complexation between the nonsteroidal anti-inflammatory**  
 01:07 14 **and benzalkonium chloride, and once they had replaced**  
 01:07 15 **tyloxapol, they would have undergone the process of routine**  
 01:07 16 **optimization to obtain the concentration of tyloxapol that is**  
 01:07 17 **present in the claims.**  
 01:07 18 Q. You testified that Claim 6 has a slightly narrower  
 01:07 19 concentration range for bromfenac sodium as compared to Claim  
 01:07 20 20. Would the narrower concentration range in Claim 6 have  
 01:07 21 rendered that claim nonobvious?  
 01:07 22 A. **No, it wouldn't, because the concentration of bromfenac**  
 01:07 23 **sodium in Example 6 of the '225 patent is included in the**  
 01:08 24 **narrower concentration range of Claim 6 of the '431 patent.**  
 01:08 25 Q. Okay. Now, you also mentioned that Claim 6 required --

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01:08 1 requires only that bromfenac sodium and tyloxapol rather than  
 01:08 2 all of the ingredients required by Claim 20 of the '431  
 01:08 3 patent, does that modified Example 6 formulation that we  
 01:08 4 talked about, where polysorbate 80 is replaced with tyloxapol,  
 01:08 5 consist essentially of bromfenac sodium and tyloxapol?  
 01:08 6 A. **Yes, it does.**  
 01:08 7 Q. Why do you say that?  
 01:08 8 A. **Because all the other added ingredients, I wouldn't**  
 01:08 9 **expect them to materially affect the basic and novel**  
 01:08 10 **characteristics of the formulation.**  
 01:08 11 Q. What do you mean by that?  
 01:08 12 A. **I wouldn't expect them to detrimentally affect the**  
 01:08 13 **stability of the preparation.**  
 01:09 14 Q. Are any of those ingredients unusual ingredients in an  
 01:09 15 ophthalmic solution product?  
 01:09 16 A. **No, they're all very standard ingredients in an**  
 01:09 17 **ophthalmic product.**  
 01:09 18 Q. Would a person of ordinary skill in the art have had a  
 01:09 19 reasonable expectation of success in making a formulation of  
 01:09 20 bromfenac, tyloxapol, and benzalkonium chloride for ophthalmic  
 01:09 21 use?  
 01:09 22 A. **It's my opinion that they would, yes.**  
 01:09 23 Q. Why would they have that reasonable expectation?  
 01:09 24 A. **Well, the person of ordinary skill in the art would be**  
 01:09 25 **aware that bromfenac sodium, tyloxapol and benzalkonium**

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01:09 1 chloride were all suitable for ophthalmic administration for  
 01:09 2 many of the reasons I've explained before, from -- with  
 01:09 3 reference to EP 984, they would understand that tyloxapol  
 01:09 4 would overcome the problem of the formation of complexes  
 01:09 5 between the nonsteroidal anti-inflammatory and benzalkonium  
 01:10 6 chloride.  
 01:10 7 Q. Now, earlier, you testified about a number of references  
 01:10 8 that you put into categories, group A, group B, group C. Did  
 01:10 9 you mean to suggest that it was necessary to combine all of  
 01:10 10 those references to support your obviousness opinion?  
 01:10 11 A. **No, I did not.**  
 01:10 12 Q. How many references did you combine to find the claims  
 01:10 13 obvious?  
 01:10 14 A. **Only two. That would be Example 6 of the '225 patent and**  
 01:10 15 **EP 984.**  
 01:10 16 Q. If you combine just those two references to support your  
 01:10 17 obviousness opinion, why did you discuss the other references?  
 01:10 18 A. **I wanted to show -- to give evidence of the body of**  
 01:10 19 **knowledge that was available to a person of ordinary skill in**  
 01:10 20 **the art at the time.**  
 01:10 21 Q. Did you discuss every reference that was available to a  
 01:10 22 person of ordinary skill in the art at the time that would  
 01:10 23 have taught those teachings from group A, B and C?  
 01:10 24 A. **No, there's a number of -- there's quite a lot more**  
 01:10 25 **references that would have supported what I've said.**

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01:11 1 Q. Okay. Now that we've talked about why Claim 6 and 20 of  
 01:11 2 the '431 patent are obvious. Let's talk about your  
 01:11 3 obviousness-type double patenting opinion.  
 01:11 4 Was there a particular framework that you used to  
 01:11 5 analyze obviousness-type double patenting?  
 01:11 6 A. Yes, there is, and this is detailed on DTX-2-77. So I  
 01:11 7 compared the claims of the patents-in-suit with other claim --  
 01:11 8 other patents. I determined whether there was any differences  
 01:11 9 between those claims, and whether there was any differences  
 01:11 10 between the claims, whether they were to be obvious to a  
 01:11 11 person of ordinary skill in the art over the prior arts.  
 01:11 12 Q. And in doing -- in applying that framework here, what was  
 01:11 13 the analysis that you did?  
 01:11 14 A. In particular, I compared Claim 60 and 20 of the '431  
 01:11 15 patent with Claim 6 of the '290 patent -- I'm sorry, Claim 7  
 01:11 16 of the '290 patent and Claim 6 of the '131 patent to determine  
 01:12 17 whether those differences would have been obvious to a person  
 01:12 18 of ordinary skill in the art.  
 01:12 19 Q. And just -- I think you may have misspoken. Which claims  
 01:12 20 of the '431 patent did you compare?  
 01:12 21 A. Claim 6 and Claim 20.  
 01:12 22 Q. Okay. Could you turn in your binder to JTX2. And was  
 01:12 23 this the '290 patent that you're referring to for that  
 01:12 24 comparison?  
 01:12 25 A. Yes, it is.

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01:13 1 intended for ophthalmic administration, that contains  
 01:14 2 bromfenac sodium, contains tyloxapol, it contains -- they both  
 01:14 3 contain boric acid, sodium tetraborate, EDTA sodium salt,  
 01:14 4 benzalkonium chloride, polyvinyl pyrrolidone, and sodium  
 01:14 5 sulfite.  
 01:14 6 Q. Are there other elements of the two claims that are  
 01:14 7 similar?  
 01:14 8 A. Yes, there are -- there are, and I've highlighted these  
 01:14 9 in green now on the slide.  
 01:14 10 Q. What's the -- can you -- can you walk us through which  
 01:14 11 elements here are similar?  
 01:14 12 A. Yes, I can. In Claim 7 of the '290 patent, it states a  
 01:14 13 stable formulation, whereas there's no such claim or statement  
 01:14 14 in Claim 20 of the '431 patent, which means that Claim 20 of  
 01:14 15 the '431 patent contained -- could be at both the stable and  
 01:14 16 unstable preparation, and as a consequence, Claim 7 of the  
 01:15 17 '290 patent is a subset of Claim 20 of the '431 patent.  
 01:15 18 Q. What other elements did you find were similar as between  
 01:15 19 Claim 7 of the '290 patent and Claim 20 of the '431 patent?  
 01:15 20 A. With respect to the concentration of bromfenac sodium,  
 01:15 21 Claim 7 of the '290 patent states the concentration of  
 01:15 22 bromfenac sodium from about 0.02 to about .1 weight in volume  
 01:15 23 percent, whereas Claim 20 of the '431 patent states a  
 01:15 24 concentration of about 0.01 to about .5 weight in volume  
 01:15 25 percent. As a consequence, Claim 70 -- 7 of the '290 patent

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01:12 1 Q. And could you also turn to JTX3 in your binder.  
 01:12 2 A. Yes.  
 01:12 3 Q. Is this the '131 patent that you referred to in doing  
 01:12 4 your comparison?  
 01:12 5 A. Yes, it is.  
 01:12 6 Q. What did you conclude about obviousness-type double  
 01:12 7 patenting?  
 01:12 8 A. It's my -- my opinion that Claims 6 and 20 of the '431  
 01:12 9 patent would have been obvious to a person of ordinary skill  
 01:12 10 over Claim 7 of the '290 patent and Claim 6 of the '131  
 01:13 11 patent.  
 01:13 12 Q. Okay. Let's start with Claim 20 of the '431 patent  
 01:13 13 compared to Claim 7 of the '290 patent. Have you prepared a  
 01:13 14 slide showing that comparison?  
 01:13 15 A. Yes, I have. It's on DDX-2-80. On the left-hand side  
 01:13 16 I've reproduced the Claim 20 of the '431 patent; on the  
 01:13 17 right-hand side, Claim 20 of the -- I'm sorry, Claim 7 of the  
 01:13 18 '290 patent.  
 01:13 19 Q. Which elements of Claim 7 of the '290 patent and Claim 20  
 01:13 20 of the '431 patent are the same?  
 01:13 21 A. I've indicated those elements of the claims that are the  
 01:13 22 same in blue on the slide now.  
 01:13 23 Q. And what are those elements?  
 01:13 24 A. Both are directed towards a stable aqueous liquid --  
 01:13 25 sorry. Both directed towards an aqueous liquid preparation

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01:15 1 is a subset of Claim 20 of the '431 patent.  
 01:15 2 Q. And what was the other limitation as between Claim 7 of  
 01:15 3 the '290 patent and Claim 20 of the '431 patent that you found  
 01:16 4 similar?  
 01:16 5 A. In Claim 7 of the '290 patent, it states that bromfenac  
 01:16 6 sodium must be the sole active ingredient, whereas there's no  
 01:16 7 such limitation in Claim 20 of the '431 patents, which means  
 01:16 8 that Claim 20 of the '431 patent can contain bromfenac sodium  
 01:16 9 alone or an additional active ingredient, and as a  
 01:16 10 consequence, Claim 7 of the '290 patent is a subset of Claim  
 01:16 11 20 of the '431 patent.  
 01:16 12 Q. Did you identify any differences between Claim 7 of the  
 01:16 13 '290 patent and Claim 20 of the '431 patent?  
 01:16 14 A. Yes, I did, just two.  
 01:16 15 Q. What was the first difference that you identified?  
 01:16 16 A. The first difference is in the concentration of tyloxapol  
 01:16 17 where Claim 7 of the '290 patent states it must be present as  
 01:17 18 an amount sufficient to stabilize bromfenac sodium, where  
 01:17 19 Claim 20 of the '431 patent states a concentration of about  
 01:17 20 .0, .002 weight in volume percent.  
 01:17 21 Q. Would the .02 weight per volume percent concentration of  
 01:17 22 tyloxapol in Claim 20 of the '431 patent have been obvious in  
 01:17 23 view of the limitation on the amount of tyloxapol specified in  
 01:17 24 Claim 7 of the '290 patent?  
 01:17 25 A. Yes, it was. A person of ordinary skill in the art

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01:17 1 preparing a formulation under Claim 7 of the '290 patent would  
 01:17 2 undergo routine optimization and then end up with a  
 01:17 3 concentration of 0.02 weight in volume percent stated in Claim  
 01:17 4 20 of the '431 patent.  
 01:17 5 Q. What was the other difference that you identified between  
 01:18 6 Claim 7 of the '290 patent and Claim 20 of the '431 patent?  
 01:18 7 A. Yes. Claim 20 of the '431 patent stated when  
 01:18 8 benzalkonium chloride is the only quaternary ammonium chloride  
 01:18 9 included in the formulation, and there was no such limitation  
 01:18 10 in Claim 7 of the '290 patent.  
 01:18 11 Q. Would it have been obvious to a person of ordinary skill  
 01:18 12 in the art to include benzalkonium chloride as the only  
 01:18 13 quaternary ammonium compound in the formulation?  
 01:18 14 A. Yes. Firstly, it's the only listed benzalkonium chloride  
 01:18 15 in the formulation and besides, it's the most commonly used  
 01:18 16 preservative.  
 01:18 17 Q. What did you mean when you said it's the only listed  
 01:18 18 benzalkonium chloride, what did you mean?  
 01:18 19 A. It's the only benzalkonium chloride, it's the only  
 01:18 20 preservative listed in Claim 7 of the '290 patent.  
 01:18 21 Q. Okay. What conclusion then did you reach regarding  
 01:19 22 whether Claim 20 of the '431 patent would be obvious in view  
 01:19 23 of Claim 7 of the '290 patent?  
 01:19 24 A. It's my opinion that the person of ordinary skill in the  
 01:19 25 art would have found that Claim 20 of the '431 patent was

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01:20 1 limitation that the formulation must be stable, whereas  
 01:20 2 there's no such limitation in Claim 6 of the '431 patent,  
 01:20 3 which, as I said before, can include a stable and unstable  
 01:21 4 preparation and, as a consequence, Claim 7 of the '290 patent  
 01:21 5 is a subset of Claim 6 of the '431 patent.  
 01:21 6 Q. What other limitations are similar between Claim 7 of the  
 01:21 7 '290 patent and Claim 6 of the '431 patent?  
 01:21 8 A. Claim 7 of the '290 patent lists extra ingredients of  
 01:21 9 boric acid, sodium tetraborate, EDTA sodium salt, benzalkonium  
 01:21 10 chloride, polyvinylpyrrolidone, and sodium sulfite where there  
 01:21 11 are no such extra ingredients listed in Claim 6 of the '431  
 01:21 12 patent, which means that Claim 6 of the '431 patent may or may  
 01:21 13 not contain these ingredients and, as a consequence, Claim 7  
 01:21 14 of the '290 patent is a subset of Claim 6 of the '431 patent.  
 01:21 15 Q. And what is the next element of Claim 7 of the '290  
 01:22 16 patent that you found similar to Claim 6 of the '431 patent?  
 01:22 17 A. Yes. Claim 7 of the '290 patent states that bromfenac  
 01:22 18 sodium is an active ingredient, whereas Claim 6 of the '431  
 01:22 19 patent has no such limitation, which means it may contain only  
 01:22 20 bromfenac sodium or there may be additional active  
 01:22 21 ingredients, which then makes Claim 7 of the '290 patent a  
 01:22 22 subset of Claim 6 of the '431 patent.  
 01:22 23 Q. And what's the final limitation between the two claims,  
 01:22 24 Claim 7 of the '290 patent and Claim 6 of the '431 patent that  
 01:22 25 you found similar?

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01:19 1 obvious in light of Claim 7 of the '290 patent.  
 01:19 2 Q. Okay. Let's move on now to a comparison of Claim 6 of  
 01:19 3 the '431 patent-in-suit to Claim 7 of the '290 patent. Did  
 01:19 4 you prepare a slide showing that comparison?  
 01:19 5 A. Yes, I did, and this is on the next slide here. On the  
 01:19 6 left-hand side again is the '431 patent, in this case Claim 6,  
 01:19 7 and on the right-hand side is Claim 7 of the '290 patent.  
 01:19 8 Q. Which elements of Claim 6 of the '431 patent are the same  
 01:19 9 as the elements of Claim 7 of the '290 patent?  
 01:19 10 A. Again, I've listed the similar elements of the claim in  
 01:20 11 blue on the slide.  
 01:20 12 Q. And can you just recite for us for the record what those  
 01:20 13 elements are?  
 01:20 14 A. Okay. Both claims are directed towards an aqueous liquid  
 01:20 15 preparation that is intended for ophthalmic use that consists  
 01:20 16 essentially of bromfenac sodium and tyloxapol.  
 01:20 17 Q. Are there other elements of the two claims that are  
 01:20 18 similar?  
 01:20 19 A. Yes, there are. And again, I have highlighted the  
 01:20 20 similar claims in green.  
 01:20 21 Q. Okay. And can you briefly summarize for us the elements  
 01:20 22 that are similar as between these two claims, and why they're  
 01:20 23 similar?  
 01:20 24 A. As before, Claim 7 has the limitation that the  
 01:20 25 formulation must be -- Claim 7 of the '290 patent has a

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01:22 1 A. Yes, Claim 6 of the '431 patent states that when a  
 01:22 2 quaternary ammonium is included, that quaternary ammonium must  
 01:22 3 be benzalkonium chloride. And, as you can see, Claim 7 of the  
 01:22 4 '290 patent explicitly lists the preservative benzalkonium  
 01:23 5 chloride making it a subset of Claim 6 of the '431 patent.  
 01:23 6 Q. Let's talk about any differences. Did you identify any  
 01:23 7 differences between Claim 7 of the '290 patent and Claim 6 of  
 01:23 8 the '431 patent?  
 01:23 9 A. Yes, I did, there were two.  
 01:23 10 Q. What was the first difference you identified?  
 01:23 11 A. Claim 7 of the '290 patent contains bromfenac sodium at a  
 01:23 12 concentration from about 0.02 to about .1 weight in volume  
 01:23 13 percent whereas Claim 6 of the '431 patent contains bromfenac  
 01:23 14 sodium at a concentration of about 0.05 to about .2 weight in  
 01:23 15 volume percent.  
 01:23 16 Q. Would the concentration range in Claim 6 of the '431  
 01:23 17 patent of .05 to about .2 weight in volume percent have been  
 01:23 18 obvious to a person of ordinary skill in the art in view of  
 01:24 19 the concentration range for bromfenac sodium specified in  
 01:24 20 Claim 7 of the '290 patent?  
 01:24 21 A. Yes, they would because they're overlapping ranges. And,  
 01:24 22 in addition, the composition of bromfenac sodium in Example 6  
 01:24 23 of the '225 patent is actually included in both of those  
 01:24 24 concentration ranges.  
 01:24 25 Q. What's the second difference you identified between Claim

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01:24 1 7 of the '290 patent and Claim 6 of the '431 patent?  
 01:24 2 A. Yes. Claim 7 of the '290 patent states that when  
 01:24 3 tyloxapol is present in an amount sufficient to stabilize the  
 01:24 4 bromfenac sodium, whereas Claim 6 of the '431 patent states  
 01:24 5 that tyloxapol is present at a concentration of about 0.02  
 01:24 6 volume percent.  
 01:24 7 Q. Would the concentration of tyloxapol of about 0.02 weight  
 01:25 8 by volume percent in Claim 6 of the '431 patent have been  
 01:25 9 obvious to a person of ordinary skill in the art in view of  
 01:25 10 the limitation on tyloxapol in Claim 7 of the '290 patent?  
 01:25 11 A. Yes, it would. A person of ordinary skill preparing a  
 01:25 12 formulation under Claim 7 of the '290 patent would by routine  
 01:25 13 optimization of the concentration range of tyloxapol end with  
 01:25 14 the concentration range stated in Claim 6 of the '431 patent.  
 01:25 15 Q. What then did you conclude about whether Claim 6 of the  
 01:25 16 '431 patent would have been obvious in view of Claim 7 of the  
 01:25 17 '290 patent?  
 01:25 18 A. It's my opinion that Claim 6 of the '431 patent would  
 01:25 19 have been obvious over Claim 7 of the '290 patent.  
 01:25 20 Q. Did you do the same analysis comparing Claim 6 and 20 of  
 01:25 21 the '431 patent to Claim 6 of the '131 patent?  
 01:25 22 A. Yes, I did.  
 01:26 23 Q. And without subjecting anyone in the courtroom to  
 01:26 24 recitation of all of the similarities and differences between  
 01:26 25 those claims, what did you conclude in light of that

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01:28 1 includes tyloxapol in place of polysorbate 80?  
 01:28 2 A. It's my opinion that there's absolutely nothing  
 01:28 3 unexpected about the improved stability and preservative  
 01:28 4 activity from use of tyloxapol.  
 01:28 5 Q. Can you explain why?  
 01:28 6 A. A person of ordinary skill in the art would have expected  
 01:28 7 tyloxapol to overcome the problem between the complexation of  
 01:28 8 BAC and benzalkonium chloride and, as a consequence, both  
 01:28 9 increase the amount of active ingredient in solution and the  
 01:28 10 amount of benzalkonium chloride in solution, and the increase  
 01:28 11 in benzalkonium chloride would result in improved preservation  
 01:28 12 of the formulation.  
 01:28 13 Q. Is there anything in the prior art that supports that  
 01:29 14 expectation that tyloxapol would have this effect on the  
 01:29 15 formulation?  
 01:29 16 A. Yes, there is.  
 01:29 17 Q. What is that?  
 01:29 18 A. If we go to EP '984, which is JTX-209, on JTX-209.2 I've  
 01:29 19 taken an extract from towards the bottom of the page which  
 01:29 20 explains that the incompatibility between benzalkonium  
 01:29 21 chloride and a nonsteroidal anti-inflammatory is due to the  
 01:29 22 presence of this acidic carboxyl group which is described here  
 01:29 23 COOH and that's -- this complexation means that benzalkonium  
 01:29 24 chloride is less effective to exert its preservative activity  
 01:30 25 by overcoming that complexation. A person of ordinary skill

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01:26 1 comparison of Claim 6 and 20 of the '431 patent to Claim 6 of  
 01:26 2 the '131 patent about whether the asserted claims of the '431  
 01:26 3 patent would have been obvious in view of Claim 6 of the '131  
 01:26 4 patent?  
 01:26 5 A. Okay. By performing a similar analysis -- and I've shown  
 01:26 6 on this slide here on DDX2-88 Claim 6 and 20 of the '431  
 01:26 7 patent and Claim 6 of the '131 patent. As I said, by  
 01:26 8 performing a similar analysis it is my opinion that Claim 6  
 01:26 9 and 20 of the '431 patent are obvious over Claim 6 of the '131  
 01:26 10 patent.  
 01:26 11 Q. And in terms of the comparison that you did between Claim  
 01:26 12 6 and 20 of the '431 patent and Claim 6 of the '131 patent,  
 01:27 13 how did that comparison compare to the analysis you did  
 01:27 14 comparing the asserted claims to Claim 7 of the '290 patent?  
 01:27 15 A. The analysis that I underwent to arrive at my conclusion  
 01:27 16 was for the Claim 6 and 20 of the '431 patent over Claim 6 of  
 01:27 17 the '131 patent was very similar to the analysis I performed  
 01:27 18 for Claim 6 of the '290 patent.  
 01:27 19 Q. Did you mean to say Claim 7 of the '290 patent?  
 01:27 20 A. Sorry. Claim 7 of the '290 patent, yes.  
 01:27 21 Q. There are a lot of patent numbers and claim numbers to  
 01:27 22 remember here.  
 01:27 23 Okay. Turning to a different topic, is there anything  
 01:27 24 unexpected about the improved stability or preservative  
 01:28 25 efficacy of a bromfenac/benzalkonium chloride formulation that

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01:30 1 in the art would have expected the formulation to exhibit  
 01:30 2 better preservative efficacy.  
 01:30 3 Q. And what does the EP '984 patent suggest about the  
 01:30 4 expectation with respect to the activity of the drug itself?  
 01:30 5 A. The same patent says that there should be an increased  
 01:30 6 activity of the drug in solution, so you would expect it, the  
 01:30 7 drug itself to be more effective as well.  
 01:30 8 Q. Is there anything unexpected about the fact that a  
 01:30 9 smaller amount of tyloxapol at .02 percent would provide  
 01:30 10 greater stability as compared to a higher amount of  
 01:30 11 polysorbate 80 at .15 percent?  
 01:30 12 A. No, there isn't.  
 01:30 13 Q. Why not?  
 01:30 14 A. Again, if we refer to EP '984, this suggested that low  
 01:31 15 levels of the ethoxylated octylphenols were effective as  
 01:31 16 overcoming the problem of complexation between BAC and the  
 01:31 17 NSAIDS and a person of ordinary still would look, as I've  
 01:31 18 explained, at reducing the concentration of tyloxapol to have  
 01:31 19 a formulation containing the least amount of tyloxapol that  
 01:31 20 was compatible with it being a stable formulation.  
 01:31 21 Q. Now, earlier you mentioned that you had reviewed some of  
 01:31 22 plaintiff's internal documents regarding the development of  
 01:31 23 the formulation that became Prolensa®.  
 01:31 24 MR. HASFORD: At this point, your Honor, we're going  
 01:31 25 to object. The defendant served revised slides on us last

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01:31 1 night after your Honor sustained our objection that in part  
 01:31 2 directed to the use of internal documents. Defendants served  
 01:31 3 revised slides on us last night, stated that they would change  
 01:31 4 these slides that they were using from the alleged internal --  
 01:32 5 or the internal documents allegedly do not support  
 01:32 6 non-obviousness or allegedly confirmed non-obviousness in that  
 01:32 7 they would change that to these documents that are relevant to  
 01:32 8 level of skill in the art. Well, that's not anywhere in any  
 01:32 9 of Dr. Lawrence's expert reports. And we lodged this  
 01:32 10 objection with defendants yesterday. We met and conferred  
 01:32 11 about it last night. Actually this morning they agreed to  
 01:32 12 withdraw that. So we ask that your Honor enforce that  
 01:32 13 agreement between the parties.

01:32 14 MS. RAPALINO: So I'm going to disagree in part with  
 01:32 15 what Mr. Hasford said. They objected to our revised slide  
 01:32 16 that we served yesterday and we agreed to withdraw the slide  
 01:32 17 and not use it for purposes of this testimony.

01:32 18 Per your Honor's ruling of yesterday, we do still  
 01:32 19 intend to present evidence from Professor Lawrence on  
 01:32 20 plaintiff's internal documents and how they reflect the level  
 01:32 21 of ordinary skill in the art. And this testimony is within  
 01:32 22 the scope of Professor Lawrence's expert report beginning at,  
 01:33 23 I believe it begins at Paragraph 733 of Professor Lawrence's  
 01:33 24 opening expert report.

01:33 25 But perhaps Mr. Hasford would agree to reserve his

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01:33 1 objection until he hears what the testimony is.

01:33 2 MR. HASFORD: No, your Honor. She doesn't have  
 01:33 3 anything in her expert reports about level of skill in the art  
 01:33 4 with respect to these documents, it's nowhere in her expert  
 01:33 5 reports.

01:33 6 THE COURT: All right. I don't believe I have a copy  
 01:33 7 of that report. Do I?

01:33 8 MS. RAPALINO: We can hand up a copy to the Court.  
 01:33 9 May I approach?

01:33 10 THE COURT: Yes, please.

01:33 11 Thank you.

01:33 12 MR. HASFORD: Do you have a copy for us?

01:34 13 MS. RAPALINO: Just give us a moment, your Honor, to  
 01:34 14 get extra copies of that opening report.

01:34 15 Mr. Hasford, you do not have a copy?

01:34 16 MR. HASFORD: I don't.

01:34 17 And, your Honor, I direct you to the heading on Page  
 01:34 18 218 above Paragraph 733, it's actually above Paragraph 731, it  
 01:34 19 says, "documents produced by plaintiffs are consistent with my  
 01:34 20 opinions regarding obviousness." Doesn't say anything about  
 01:34 21 level of skill in the art.

01:34 22 MS. RAPALINO: Your Honor, if I could just direct  
 01:35 23 your attention to the paragraphs that follow, in particular to  
 01:35 24 statements that are consistent with testimony that plaintiff's  
 01:35 25 documents are consistent with the level of skill in the art.

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01:35 1 As just one example, in Paragraph 734 she discusses an  
 01:35 2 internal document and concludes that the rapid identification  
 01:35 3 of an optimization tyloxapol --

01:35 4 MR. HASFORD: Actually, your Honor, I've got to  
 01:35 5 object to this. I object to her reading this document into  
 01:35 6 the record. These are sensitive Senju internal documents.  
 01:35 7 She's trying to make an argument to read these into the record  
 01:35 8 and I have to object to that and move to strike.

01:35 9 THE COURT: I think that there is a problem with  
 01:35 10 Paragraph 733, which attracted me to it a moment ago because  
 01:35 11 it has to do with how quickly the discovery was made, and  
 01:35 12 there's case law that says that the inventor's time line can't  
 01:35 13 be used against him to support that it was all obvious.

01:35 14 MS. RAPALINO: So that's part of Paragraph 733. But  
 01:35 15 then towards the end of that paragraph she explained how --  
 01:36 16 what was done by the inventors in this case supports the  
 01:36 17 expectation of a person of ordinary skill in the art.

01:36 18 THE COURT: I'm going to sustain the objection to  
 01:36 19 Paragraph 733 at least.

01:36 20 MS. RAPALINO: Okay.

01:36 21 THE COURT: I can cite cases, if we need to, but I  
 01:36 22 think that the parties ought to be in agreement that this is  
 01:36 23 one of the purposes that the federal circuit is pretty clear  
 01:36 24 that prior -- that the inventor's own workbooks, especially  
 01:36 25 the time line and how rapid it was that this invention came

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01:36 1 about, cannot be used to prove obviousness.

01:36 2 MS. RAPALINO: Okay. And I will limit the testimony  
 01:36 3 so we avoid anything about the time line and how rapid it was.  
 01:36 4 Again, it will just be testimony supporting what the person of  
 01:36 5 skill in the art would have known at the time, how it's  
 01:36 6 consistent with what a person of skill in the art would have  
 01:36 7 known.

01:36 8 MR. HASFORD: That's our problem, your Honor.  
 01:36 9 There's absolutely nothing in Dr. Lawrence's expert report  
 01:36 10 that states this is what the level of ordinary skill in the  
 01:37 11 art is based on plaintiff's internal documents. That's our  
 01:37 12 objection, there's nothing in any of her expert reports about  
 01:37 13 that.

01:37 14 MS. RAPALINO: If I could, this testimony will be  
 01:37 15 limited to testimony about the fact that based on the level of  
 01:37 16 skill in the art, a person of skill in the art would have  
 01:37 17 known how to conduct routine optimization. And it's just for  
 01:37 18 that limited point about the level of skill in the art  
 01:37 19 allowing for routine optimization as reflected in the  
 01:37 20 plaintiff's documents.

01:37 21 MR. HASFORD: Your Honor, counsel isn't even  
 01:37 22 responding to my objection. The objection here is that this  
 01:37 23 information is not in Dr. Lawrence's reports anywhere, it's  
 01:37 24 objectionable for that reason.

01:37 25 MS. RAPALINO: Right. I'm pointing again to

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01:37 1 Paragraph 734, the last sentence.  
 01:37 2 MR. HASFORD: That does not go, your Honor, to the  
 01:37 3 level of skill in the art. That goes to an alleged  
 01:37 4 identification, a rapid -- alleged rapid identification of  
 01:37 5 something.  
 01:37 6 THE COURT: I'll sustain the objection as to 734 for  
 01:37 7 essentially the same reasons. Now, in sustaining the  
 01:38 8 objections, I'm sustaining it with respect to the defendant's  
 01:38 9 direct case and it will depend also on what's brought up on  
 01:38 10 cross-examination. If, for instance -- well, I don't want to  
 01:38 11 give examples in the witness' presence. But there could be a  
 01:38 12 line of cross-examination that might open the door to the  
 01:38 13 witness being able to testify that such steps were so routine  
 01:38 14 they were present here, they were present in the literature, I  
 01:38 15 would permit that probably. But, otherwise, I'm seeking to  
 01:38 16 uphold the principle that the inventor's own notes can't be  
 01:38 17 used -- cannot be used to show that the invention was obvious  
 01:38 18 to a POSA just because it happened to be obvious to the  
 01:39 19 inventor, or happened to occur to the inventor, I should say.  
 01:39 20 MS. RAPALINO: Okay.  
 01:39 21 THE COURT: Very well.  
 22 BY MS. RAPALINO:  
 01:39 23 Q. Professor Lawrence, did you review the testimony of the  
 01:39 24 inventors about their development of formulations that are the  
 01:39 25 subject of the '431 patent?

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01:40 1 MR. HASFORD: It's Paragraph 13, your Honor.  
 01:40 2 The basis for our objection is Dr. Lawrence isn't here  
 01:41 3 to opine on the reasons why the inventors did or did not do  
 01:41 4 something. As your Honor will see, in Paragraph 13, this  
 01:41 5 plainly goes to the same issue, it's talking about this work  
 01:41 6 that the inventors did and characterizing it in some way.  
 01:41 7 That's our objection.  
 01:41 8 MS. RAPALINO: This is really quite different in that  
 01:41 9 here I'm asking for Professor Lawrence's experience as a  
 01:41 10 formulator and what that experience as a formulator suggests  
 01:41 11 about memory or lack of memory about a formulation process.  
 01:41 12 MR. HASFORD: That's ridiculous, your Honor. This --  
 01:41 13 again, it's just an attempt to backdoor in the information  
 01:41 14 from Mr. Sawa and Mr. Jujita, the inventors. It goes to no  
 01:41 15 issue in the case. She's not here to testify about what lack  
 01:41 16 of memory may or may not mean to a formulation scientist or  
 01:41 17 what the inventors did here. It's not relevant to the issue  
 01:41 18 in the case.  
 01:41 19 MS. RAPALINO: Plaintiffs put the testimony of the  
 01:41 20 inventors at issue in the case, they brought their inventors  
 01:41 21 for deposition but shielded them from testimony at trial.  
 01:42 22 MR. HASFORD: That's not --  
 01:42 23 THE COURT: Just a moment. You keep cutting off your  
 01:42 24 adversary.  
 01:42 25 MR. HASFORD: I apologize.

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01:39 1 MR. HASFORD: Same objection, your Honor.  
 01:39 2 THE COURT: I'll permit it.  
 01:39 3 You can answer.  
 01:39 4 THE WITNESS: Okay.  
 01:39 5 Yes, I did.  
 6 BY MS. RAPALINO:  
 01:39 7 Q. Did anything strike you about the testimony that you  
 01:39 8 reviewed about their formulation?  
 01:39 9 A. **Yes, it did. It was very striking that the inventors**  
 01:39 10 **remembered very little of the process --**  
 01:39 11 MR. HASFORD: Objection, your Honor. Not relevant to  
 01:39 12 anything in the case. Move to strike.  
 01:39 13 THE COURT: Is it in her expert report?  
 01:39 14 MR. HASFORD: I'm not sure that it is.  
 01:39 15 MS. RAPALINO: It is, your Honor. It's in her reply  
 01:39 16 expert report at Paragraph 13, and I can hand up a copy of  
 01:39 17 that.  
 01:39 18 MR. HASFORD: Your Honor, if it's in a reply expert  
 01:39 19 report, I don't think it belongs here. And it's not relevant  
 01:39 20 to any issue in the case, in any event.  
 01:40 21 MS. RAPALINO: May I approach to hand up the report?  
 01:40 22 THE COURT: Certainly.  
 01:40 23 MR. HASFORD: Do you have a copy for us?  
 01:40 24 Thanks.  
 01:40 25 THE COURT: Is there a paragraph that we should be --

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01:42 1 THE COURT: Do you realize that?  
 01:42 2 Please continue.  
 01:42 3 MS. RAPALINO: This is, again, another instance of  
 01:42 4 this pattern of shielding their internal documents, shielding  
 01:42 5 their inventors from cross-examination at trial and we feel  
 01:42 6 this testimony is in evidence through the deposition  
 01:42 7 designations. And without the benefit of the inventors here  
 01:42 8 to cross-examine them about their own testimony, we're  
 01:42 9 entitled to have an expert opine about what that testimony  
 01:42 10 means to a formulator and an expert in this field.  
 01:42 11 THE COURT: So there are excerpts of the inventors'  
 01:42 12 depositions that are going to be offered as part of the case?  
 01:42 13 MR. HASFORD: Yes.  
 01:42 14 MS. RAPALINO: Yes, your Honor, in our deposition  
 01:42 15 designations.  
 01:42 16 THE COURT: All right. And those have already been  
 01:42 17 identified?  
 01:42 18 MS. RAPALINO: They've been identified in the  
 01:42 19 pretrial order. The parties reached an agreement which I --  
 01:42 20 and I believe that it was raised with the Court in a call  
 01:42 21 prior to trial that we would submit those deposition  
 01:43 22 designations, perhaps in some reduced form, after the close of  
 01:43 23 trial so that we'd have an opportunity to cull them down  
 01:43 24 somewhat based on the testimony that came in at trial, but  
 01:43 25 they are designated in the pretrial order at the moment.

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01:43 1 THE COURT: Okay. I'll permit the expert to testify  
 01:43 2 with regard to the anticipated testimony of the inventors.  
 01:43 3 Since the parties have identified excerpts of the inventors'  
 01:43 4 depositions that are going to be used as trial testimony, the  
 01:43 5 expert is permitted to comment upon the testimony as long as  
 01:43 6 it's within the scope of her report, and that would include  
 01:43 7 this reply report and as long as it's not ruled out as  
 01:43 8 evidence under any of the rules of obviousness. In this case,  
 01:43 9 because they would be trial witnesses, albeit not live,  
 01:44 10 commenting upon their testimony, I believe, is within her  
 01:44 11 right, and due notice has been given to the plaintiffs. The  
 01:44 12 comment here has to do not with the work that they performed  
 01:44 13 but rather with their recollection of it. And it's the,  
 01:44 14 allegedly, inability to recollect as if they were testifying  
 01:44 15 at trial that, as a formulator herself, she finds striking. I  
 01:44 16 find that that's probative and that it doesn't intrude into  
 01:44 17 the forbidden area that's been staked out and so the  
 01:44 18 objection's overruled. But it itself depends upon offering  
 01:44 19 the underlying testimony that she's commenting on as if the  
 01:45 20 witnesses were present and testifying in this case.  
 01:45 21 Is there any clarification needed of the ruling?  
 01:45 22 MS. RAPALINO: No, your Honor.  
 01:45 23 MR. HASFORD: Well, our only question, your Honor, is  
 01:45 24 would this be going to level of skill in the art? Because it  
 01:45 25 clearly can't go toward the underlying obviousness issues.

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01:45 1 MS. RAPALINO: And, your Honor, if I may, as your  
 01:45 2 Honor pointed out, this is not a matter of using their  
 01:45 3 formulation process or those internal documents in support of  
 01:45 4 an obviousness position. This is a matter of a formulator  
 01:45 5 commenting on memory or lack of memory and what that suggests  
 01:45 6 about the nature of that project. And, again, I believe it  
 01:45 7 does not run afoul of the rule that plaintiffs -- the  
 01:45 8 inventors' own path to the invention not be used to support  
 01:45 9 obviousness, this is not about their path, this is about their  
 01:45 10 memory or lack thereof.  
 01:45 11 THE COURT: I'm going to admit it into evidence.  
 01:46 12 It's a nonjury case and what weight, if any, it receives will  
 01:46 13 have to be determined in the future. But I find that it is at  
 01:46 14 least relevant and probative of the issues before me that  
 01:46 15 sufficient notice has been given of it in the expert report  
 01:46 16 and that it doesn't intrude into the undue questioning of the  
 01:46 17 path that they followed.  
 01:46 18 MS. RAPALINO: Okay.  
 01:46 19 BY MS. RAPALINO:  
 01:46 20 Q. Professor Lawrence, what struck you about the testimony  
 01:46 21 of the inventors that you reviewed about their formulation  
 01:46 22 work?  
 01:46 23 A. I was particularly struck by how little the inventors  
 01:46 24 could actually remember their formulation process.  
 01:46 25 Q. Was there anything in particular that was striking about

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01:46 1 that lack of memory?  
 01:46 2 A. As a formulator myself, if I had a particular challenge  
 01:46 3 or difficult problem to overcome, I would remember that. I  
 01:46 4 tend to forget the things that are fairly routine and easy to  
 01:47 5 solve.  
 01:47 6 Q. Okay. My final question, Professor Lawrence.  
 01:47 7 Based on your review of all of the prior art, what did  
 01:47 8 you conclude about whether Claim 6 and 20 of the '431 patent  
 01:47 9 would have been obvious to a person of ordinary skill in the  
 01:47 10 art?  
 01:47 11 A. It's my opinion that Claims 6 and 20 of the '431 patent  
 01:47 12 would have been obvious to somebody of ordinary skill in the  
 01:47 13 art.  
 01:47 14 MS. RAPALINO: I pass the witness.  
 01:47 15 Thank you, Professor Lawrence.  
 01:47 16 THE COURT: Let's take a break before  
 01:47 17 cross-examination. Let's take about 15 minutes and we'll  
 01:47 18 resume at 11:30.  
 01:49 19 (Brief Recess.)  
 02:05 20 DEPUTY CLERK: All rise.  
 02:05 21 THE COURT: Be seated, please.  
 02:05 22 Okay. Cross-examination.  
 02:05 23 MS. RAPALINO: Your Honor, before we do the  
 02:05 24 cross-examination, I neglected to move into evidence the  
 02:05 25 exhibits that Professor Lawrence talked about. Could I read

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02:06 1 that?  
 02:06 2 THE COURT: Okay. Just a minute.  
 02:06 3 Okay. Have you reviewed these with opposing counsel?  
 02:06 4 Is there any objection to any of them?  
 02:06 5 MS. RAPALINO: We disclosed the exhibits prior to  
 02:06 6 Professor Lawrence's testimony and we resolved any objection  
 02:06 7 to them.  
 02:06 8 THE COURT: Okay. Very well. Then please slowly  
 02:06 9 read into the record the exhibits that you're moving.  
 02:06 10 MS. RAPALINO: JTX-2, JTX-3, JTX-45, JTX-61, JTX-71,  
 02:06 11 JTX-168, JTX-199, JTX-201, JTX-207, DTX-15, DTX-109, DTX-110,  
 02:07 12 DTX-196, and DTX-442. And I believe that yesterday three  
 02:07 13 exhibits that Professor Lawrence discussed had already been  
 02:07 14 moved into evidence, and those are JTX-1, JTX-147, and  
 02:07 15 JTX-210.  
 02:07 16 THE COURT: Okay. Any objection?  
 02:07 17 MR. HASFORD: No objection, your Honor.  
 02:07 18 THE COURT: Okay. Very well. Then each of those  
 02:07 19 will be received into evidence?  
 02:07 20 (JOINT EXHIBITS JTX-2, JTX-3, JTX-45, JTX-61, JTX-71, JTX-168,  
 02:07 21 JTX-199, JTX-201, JTX-207, DTX-15, DTX-109, DTX-110, DTX-196,  
 02:07 22 and DTX-442 WERE RECEIVED IN EVIDENCE)  
 02:07 23 THE COURT: Mr. Hasford, you may proceed.  
 02:07 24 MR. HASFORD: Thank you, your Honor.  
 02:07 25 May we approach and distribute binders?

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02:07 1 THE COURT: Yes.  
02:08 2 Let me make an offer to counsel on both sides, that if,  
02:08 3 because you have a lot of materials, it would be easier to  
02:08 4 examine from your counsel table, you can do that. You don't  
02:08 5 necessarily have to use the podium if things just don't fit.  
02:08 6 I'm sorry it's not a larger podium. But it's up to you.  
02:08 7 MR. HASFORD: Thank you, your Honor. I'll try to use  
02:08 8 the podium and see how it goes.  
9 May I proceed, your Honor?  
10 THE COURT: Yes.  
11 (CROSS-EXAMINATION OF JAYNE LAWRENCE BY MR. HASFORD:)  
02:09 12 Q. Good morning, Dr. Lawrence.  
02:09 13 A. Good morning.  
02:09 14 Q. You testified on direct exam about motivation to select  
02:09 15 and modify Example 6 of the Ogawa patent. Do you remember  
02:09 16 that?  
02:09 17 A. I do.  
02:09 18 Q. Yet in your opinion, to the extent there was even any  
02:09 19 need in the art for the claim formulations of the '431 patent,  
02:09 20 you would state that that need would have been met by the  
02:09 21 disclosures of the Ogawa patent and the Hara reference, each  
02:09 22 of which in your view purports to describe stable ophthalmic  
02:09 23 formulations. Correct?  
02:09 24 A. I'm sorry, you're going to have to slow it down. Can you  
02:09 25 repeat it, please?

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02:09 1 Q. Certainly.  
02:09 2 In your opinion, to the extent there was even any need  
02:09 3 in the art for the claimed formulations of the '431 patent,  
02:09 4 you would state that that need would have been met by the  
02:09 5 disclosures of the Ogawa patent and the Hara reference, each  
02:10 6 of which in your view purports to describe stable ophthalmic  
02:10 7 formulations, correct?  
02:10 8 A. I believe that's an extract from one of my reports, but I  
02:10 9 would like to look at the context it's put in.  
02:10 10 Q. Doctor, do you remember testifying under oath in a  
02:10 11 deposition in this case?  
02:10 12 A. Yes, I do.  
02:10 13 MR. HASFORD: Let's pull up Dr. Lawrence's deposition  
02:10 14 transcript from February 29, 2016, and let's go to Page 139,  
02:10 15 Lines 12 through 20.  
02:10 16 MS. RAPALINO: Objection, your Honor.  
02:10 17 THE COURT: Sustained. It hasn't been established  
02:10 18 that there's inconsistency. If you can get an answer from the  
02:10 19 witness that is consistent with her prior dep, then I will  
02:10 20 permit the dep to be used. And I think she asked for a copy  
02:10 21 of her materials so that she could look at it.  
02:10 22 MR. HASFORD: Certainly. I'm happy to provide those.  
02:11 23 Do we have a copy of Dr. Lawrence's opening report?  
02:11 24 THE COURT: I have an extra one.  
02:11 25 THE WITNESS: Thank you very much.

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02:11 1 THE COURT: You can borrow mine.  
02:11 2 THE WITNESS: Could you direct me to the page,  
02:11 3 please?  
4 BY MR. HASFORD:  
02:11 5 Q. Certainly. Let's go to Paragraph 727.  
02:11 6 A. And would --  
02:11 7 Q. We may have to go to the next page on the screen, it's  
02:11 8 going to be at the top of Page 217.  
02:11 9 And let me direct your attention to that first full  
02:11 10 sentence. You state: To the extent there was even any need  
02:11 11 for the claimed bromfenac ophthalmic formulations claimed in  
02:12 12 the asserted claims of the asserted patents, it is my opinion  
02:12 13 that that need would have been met by the disclosures of the  
02:12 14 '225 patent and Hara, each of which purport to describe stable  
02:12 15 ophthalmic bromfenac formulations.  
02:12 16 You wrote that in your expert report, correct?  
02:12 17 A. Yes, in the context that Senju couldn't demonstrate there  
02:12 18 had been a long felt need for the formulations.  
02:12 19 Q. You in fact wrote that sentence in your expert report,  
02:12 20 correct?  
02:12 21 A. But in a particular context.  
02:12 22 Q. Did you or did you not write that sentence in your expert  
02:12 23 report, doctor?  
02:12 24 A. I wrote the sentence in the context that Senju cannot  
02:12 25 demonstrate long felt need, yes.

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02:12 1 Q. I'll ask you once again.  
02:12 2 Did you write that exact statement in your expert  
02:12 3 report?  
02:12 4 A. I wrote -- I can see where I wrote in my report as part  
02:12 5 of a longer sentence, yes.  
02:12 6 Q. In fact it is your opinion that any need in the art for  
02:12 7 an aqueous preparation of an NSAID formulated with  
02:13 8 benzalkonium chloride for ophthalmic administration was  
02:13 9 already met by aqueous ophthalmic formulations of NSAIDS  
02:13 10 known as of January 21, 2003, correct?  
02:13 11 A. I am sorry, but I feel that's taking that out of context.  
02:13 12 Q. I'm simply asking you.  
02:13 13 It is your opinion that any need in the art for an  
02:13 14 aqueous liquid preparation of an NSAID formulated with  
02:13 15 benzalkonium chloride for ophthalmic administration was  
02:13 16 already met by aqueous ophthalmic formulations of NSAIDS known  
02:13 17 as of January 21, 2003, correct?  
02:13 18 A. Of course there's preparation been allowed at this time  
02:13 19 on to the Japanese market, so obviously had sufficient  
02:13 20 stability for that particular market.  
02:13 21 Q. You also testified on direct exam about modifying  
02:13 22 formulations to remove incompatibility issues with  
02:14 23 benzalkonium chloride. Do you remember that?  
02:14 24 A. Yes, I do.  
02:14 25 Q. Your opinions on modifying a formulation to remove any

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02:14 1 incompatibility issues with benzalkonium chloride are based on  
 02:14 2 pure hindsight, correct?  
 02:14 3 A. **No, they're not.**  
 02:14 4 Q. Take a look at your deposition transcript.  
 02:14 5 MR. HASFORD: Let's go to her deposition transcript  
 02:14 6 of February 29th at Page 125, Line 13, and let's bring it up  
 02:14 7 also on the next page as well.  
 02:14 8 BY MR. HASFORD:  
 02:14 9 Q. Okay. So starting at Line 13 -- let me know when you're  
 02:14 10 there.  
 02:14 11 A. **Sorry, I'm not --**  
 02:14 12 MS. RAPALINO: Your Honor, I'm going to object to  
 02:14 13 this as improper impeachment. What she said is not relevant  
 02:14 14 to her testimony here and it is not inconsistent with what she  
 02:14 15 just said.  
 02:14 16 MR. HASFORD: It's absolutely relevant to the  
 02:14 17 testimony, your Honor, because, as the federal circuit has  
 02:14 18 pointed out time and again, a hindsight analysis of  
 02:15 19 obviousness is entirely improper. And it's entirely  
 02:15 20 inconsistent with her testimony because I asked her this  
 02:15 21 question at her deposition and she admitted that she in fact  
 02:15 22 used hindsight.  
 02:15 23 MS. RAPALINO: That's not at all what she admitted.  
 02:15 24 And I suppose we can let the testimony be read in and it will  
 02:15 25 be clear from the testimony that she was not at all talking

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02:17 1 have formulated to use it now or are you talking with my  
 02:17 2 hindsight looking back to 2003?  
 02:17 3 And I asked a question:  
 02:17 4 QUESTION: Let's start with your hindsight looking  
 02:17 5 back to 2003.  
 02:17 6 There was another objection.  
 02:17 7 And you answered:  
 02:17 8 ANSWER: Yes.  
 02:17 9 That was your testimony, wasn't it, doctor?  
 02:17 10 A. **Well I -- okay. While I read --**  
 02:17 11 Q. Was that your testimony, doctor?  
 02:17 12 A. **While I read the word "hindsight" there, it wasn't meant**  
 02:17 13 **in the context that you've interpreted it as and that was very**  
 02:17 14 **clear from my testimony. Any opinions I've made are stated**  
 02:17 15 **with an expert -- as a person of ordinary skill in the art in**  
 02:17 16 **2003.**  
 02:17 17 Q. You never qualified your testimony in any way at your  
 02:17 18 deposition, did you, doctor?  
 02:17 19 A. **That was obviously not the appropriate word to use, but**  
 02:17 20 **that is not what's been done in this particular case as is**  
 02:17 21 **clear from my evidence.**  
 02:17 22 Q. You never qualified your testimony at your deposition,  
 02:17 23 did you, doctor?  
 02:17 24 A. **I obviously said that word, it's in the text.**  
 02:17 25 Q. You also testified on direct exam about the Ogawa '225

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02:15 1 about providing a hindsight analysis.  
 02:15 2 MR. HASFORD: Well, let's read the testimony in.  
 02:15 3 THE COURT: Well, just a moment. Looks like my Line  
 02:15 4 13 doesn't match up what's in my book. Line 13 just contains  
 02:15 5 the words "to 8.5."  
 02:15 6 MR. HASFORD: Let's see, is there -- perhaps your  
 02:15 7 Honor has a bad copy. Would you like a different one? I can  
 02:15 8 hand this up.  
 02:15 9 THE COURT: Can I hand you what I'm looking at?  
 02:15 10 MR. HASFORD: Certainly.  
 02:15 11 THE COURT: 125, Line 13. Is there a different  
 02:16 12 pagination maybe? I'm sorry, there's different dates. I  
 02:16 13 didn't realize that.  
 02:16 14 MR. HASFORD: Yes.  
 02:16 15 THE COURT: Okay. You can proceed. I'll permit it.  
 02:16 16 MR. HASFORD: Thank you, your Honor.  
 02:16 17 BY MR. HASFORD:  
 02:16 18 Q. I asked you a question:  
 02:16 19 QUESTION: Is it still your opinion that a person of  
 02:16 20 ordinary skill in the art would have found it preferable to  
 02:16 21 modify a formulation or remove any incompatibility issues with  
 02:16 22 benzalkonium chloride?  
 02:16 23 And then there was an objection.  
 02:16 24 And then you answered:  
 02:16 25 ANSWER: May I ask, are you talking in 2016 would I

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02:18 1 patent. Let's take a look at the Ogawa '225 patent, which is  
 02:18 2 JTX-147 in your binder. Let me direct your attention to  
 02:18 3 Example 6.  
 02:18 4 Are you there, doctor?  
 02:18 5 A. **Yes, I am.**  
 02:18 6 Q. The Ogawa '225 patent itself characterizes the Example 6  
 02:18 7 formulation as stable. And in your view the inclusion of  
 02:19 8 tyloxapol instead of polysorbate 80 in an identical  
 02:19 9 formulation would be expected to have no material effect on  
 02:19 10 stability, correct?  
 02:19 11 A. **Yes, in my understanding of what I understand by the word**  
 02:19 12 **"material effect on stability."**  
 02:19 13 Q. Let's -- you can put that document aside.  
 02:19 14 Let's discuss the way in which you went about preparing  
 02:19 15 your obviousness opinions in this case. The first document  
 02:19 16 you considered in connection with your opinions in this case  
 02:19 17 was the '431 patent, correct?  
 02:19 18 A. **Yes, that is correct.**  
 02:19 19 Q. You obtained the documents that you considered in  
 02:19 20 connection with your opinions in this case from defendant's  
 02:19 21 counsel, correct?  
 02:19 22 A. **As I've explained before, the initial documents were**  
 02:19 23 **provided by the counsel, yes.**  
 02:19 24 Q. In formulating your obviousness opinions you believe it  
 02:20 25 is important to know the goal you were trying to reach because

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02:20 1 you need to understand what you require from the formulation,  
 02:20 2 correct?  
 02:20 3 **A. Could you repeat that, please?**  
 02:20 4 **Q.** Certainly.  
 02:20 5 In formulating your obviousness opinions you believe it  
 02:20 6 is important to know the goal you were trying to reach because  
 02:20 7 you need to understand what you require from the formulation,  
 02:20 8 correct?  
 02:20 9 **A. I wouldn't quite put it like that but, yeah.**  
 02:20 10 **Q.** Let's take a look at your deposition transcript then,  
 02:20 11 February 29th at Page 248.  
 02:20 12 **MS. RAPALINO:** Objection, your Honor. I believe the  
 02:20 13 witness gave -- answered the question yes.  
 02:20 14 **MR. HASFORD:** I believe she said she wouldn't quite  
 02:20 15 put it like that, so I would like to show where she answered  
 02:20 16 this question at her deposition.  
 02:20 17 **THE COURT:** I'll permit it.  
 02:21 18 **BY MR. HASFORD:**  
 02:21 19 **Q.** Let's look at 248, Line 9. And I asked you:  
 02:21 20 "QUESTION: In formulating your obviousness opinions,  
 02:21 21 why do you believe it is important to know the goal you are  
 02:21 22 trying to reach?"  
 02:21 23 And then there was an objection, and you answered:  
 02:21 24 "If you're preparing a formulation, you need to  
 02:21 25 understand what you require from that formulation."

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02:22 1 testing is a very large area. The tests you performed and how  
 02:22 2 I perform them would depend upon the formulation I was looking  
 02:23 3 at and the purpose, the intended purpose."  
 02:23 4 That was your testimony, wasn't it, Doctor?  
 02:23 5 **A. The "very large area" referred to the liquids -- number  
 02:23 6 of liquid preparations.**  
 02:23 7 **Q.** That was the exact question that I asked and the exact  
 02:23 8 answer you gave, correct?  
 02:23 9 **MS. RAPALINO:** Objection, Your Honor. Improper  
 02:23 10 impeachment. This is entirely consistent with the answer the  
 02:23 11 witness just gave about the large area being the number of  
 02:23 12 preparations.  
 02:23 13 **THE COURT:** Okay. Just a moment.  
 02:23 14 Well, I don't see anything in the deposition answer  
 02:23 15 about a large number of preparations. Is it there?  
 02:23 16 **MS. RAPALINO:** I believe her answer was that it would  
 02:23 17 depend upon the formulation I was looking at and the purpose,  
 02:23 18 the intended purpose, the implication of which is that the  
 02:23 19 large area means that it depends on the number of  
 02:23 20 preparations, the large number of preparations.  
 02:23 21 **THE COURT:** I'll permit it. I think it's arguably  
 02:24 22 there, but I'll permit it.  
 02:24 23 **BY MR. HASFORD:**  
 02:24 24 **Q.** The exact question I asked you, Doctor, was:  
 02:24 25 "QUESTION: How did you conduct stability testing on

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02:21 1 And that was your testimony, wasn't it, Doctor?  
 02:21 2 **A. Yes.**  
 02:21 3 **And can you just repeat the question you asked me,  
 02:21 4 please?**  
 02:21 5 **Q.** I believe you've answered my question, actually.  
 02:21 6 Let's now discuss formulation issues. You testified on  
 02:21 7 direct exam about formulation of ophthalmic products including  
 02:21 8 stability testing. Do you remember that?  
 02:21 9 **A. Yes, I do.**  
 02:21 10 **Q.** You would characterize stability testing as a very large  
 02:21 11 area, and the tests you would perform and how you would  
 02:21 12 perform them would depend upon the formulation you were  
 02:21 13 looking at and the intended purpose, correct?  
 02:21 14 **A. My recollection of the large area is in relation to the  
 02:22 15 number of liquid preparations rather than stability.**  
 02:22 16 **Q.** Let's take a look at your deposition transcript of  
 02:22 17 September 4th, so it's going to be the first one in your  
 02:22 18 binder. And let's take a look at Page 41, and let me direct  
 02:22 19 your attention to Line 8. Tell me when you're there.  
 02:22 20 **A. I'm there.**  
 02:22 21 **Q.** I asked you:  
 02:22 22 "QUESTION: How did you conduct stability testing on  
 02:22 23 aqueous liquid preparations?"  
 02:22 24 Then there was an objection.  
 02:22 25 Then you answered: "I repeat my answer. Stability

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02:24 1 aqueous liquid preparations?"  
 02:24 2 And the exact answer you gave was:  
 02:24 3 "I repeat my answer. Stability testing is a very large  
 02:24 4 area. The tests you performed and how I perform them would  
 02:24 5 depend upon the formulation I was looking at and the purpose,  
 02:24 6 the intended purpose?"  
 02:24 7 Correct?  
 02:24 8 **A. In the context of a large number of aqueous preparations,  
 02:24 9 yes.**  
 02:24 10 **Q.** You didn't qualify your testimony in any way at your  
 02:24 11 deposition, did you?  
 02:24 12 **A. Well, it was in the context of the questions you're  
 02:24 13 asking me.**  
 02:24 14 **Q.** You didn't qualify your testimony in any way at your  
 02:24 15 deposition, did you, Doctor?  
 02:24 16 **A. Well, I thought the questions qualified it.**  
 02:24 17 **Q.** You didn't qualify your testimony in any way at your  
 02:24 18 deposition, did you?  
 02:24 19 **THE COURT:** You're being argumentative now.  
 02:24 20 **MR. HASFORD:** Okay. The point is made.  
 02:24 21 **BY MR. HASFORD:**  
 02:24 22 **Q.** In order to determine whether it is possible to  
 02:24 23 successfully formulate a drug as a medicine, it is essential  
 02:24 24 to determine the drug's basic physicochemical properties,  
 02:24 25 including its water solubility, its partitioning between oil

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02:24 1 and water, and its behavior in different pH environments,  
02:25 2 correct?  
02:25 3 A. I've stated that, yes.  
02:25 4 Q. You do not know the oil and water partition coefficient  
02:25 5 of bromfenac, correct?  
02:25 6 A. I -- I have a value for it, but that was not available,  
02:25 7 to my understanding, back in 2003.  
02:25 8 Q. Once a potential drug candidate has been identified, its  
02:25 9 fated behavior in the body have to be assessed before a  
02:25 10 decision can be made whether it is possible to develop the  
02:25 11 molecule into a safe, effective medicine, correct?  
02:25 12 A. Yes. And that would be done, as I've stated, in  
02:25 13 preformulation studies as an early stage of development rather  
02:25 14 than a stage of pharmaceutical formulation we're talking about  
02:25 15 here.  
02:25 16 Q. Let me actually direct you to your -- the middle  
02:26 17 transcript which is February 16th, and it's going to be at  
02:26 18 Line 73. Sorry. Page 73, Line 6 through 15. I apologize.  
02:26 19 Page 273, 273.  
02:26 20 THE COURT: 273?  
02:26 21 MR. HASFORD: Yes. Wait a minute. Oh, oh. Lines 3  
02:26 22 through 9, sorry. So it's going to be the February 16th  
02:26 23 transcript, Page 73 is correct, Lines 3 through 9. 73.  
02:26 24 MS. RAPALINO: Your Honor, again, I'm going to object  
02:27 25 as improper impeachment. The witness answered the question in  
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02:27 1 the affirmative when it was just asked of her, and so I don't  
02:27 2 see any inconsistency here between what was in her deposition  
02:27 3 testimony and the answer she gave here today.  
02:27 4 MR. HASFORD: Well, your Honor, I believe she tried  
02:27 5 to qualify her answer by saying that it only applied to free  
02:27 6 formulation. She certainly did not qualify that answer when  
02:27 7 she gave it in her deposition.  
02:27 8 MS. RAPALINO: And, again, there is nothing  
02:27 9 inconsistent about an affirmative answer that offers more  
02:27 10 context here to the deposition answer that was given several  
02:27 11 months ago.  
02:27 12 MR. HASFORD: I would disagree, Your Honor, if she's  
02:27 13 trying to qualify it.  
02:27 14 THE COURT: I'll permit it if the question would have  
02:27 15 embraced the answer that she gives today. If the deposition  
02:27 16 question would have embraced today's answer and what she said  
02:27 17 at her dep was materially different, then I'll permit it.  
02:27 18 MR. HASFORD: So I asked you, Doctor:  
02:27 19 "QUESTION: Once a potential drug candidate has been  
02:27 20 identified, its fate and behavior in the body have to be  
02:27 21 assessed before a decision can be made whether it is possible  
02:27 22 to develop the molecule into a safe, effective medicine,  
02:27 23 correct?"  
02:28 24 There was an objection.  
02:28 25 And you answered: "That's correct."  
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02:28 1 That was your testimony, wasn't it, Doctor?  
02:28 2 A. And I stand by it's correct in as far as it goes, but you  
02:28 3 have to put it into context.  
02:28 4 Q. You didn't qualify your testimony in any way at your  
02:28 5 deposition, did you, Doctor?  
02:28 6 A. I think we discussed that later on, in another  
02:28 7 deposition.  
02:28 8 Q. At this deposition, when I asked you that question, you  
02:28 9 gave me the exact answer, "That's correct," didn't you?  
02:28 10 A. I just agreed to that.  
02:28 11 Q. Okay. A successful drug requires a balance to be struck  
02:28 12 between potency and selectivity in its pharmacokinetic  
02:28 13 properties, correct?  
02:28 14 A. Correct.  
02:28 15 Q. In particular, the drug's physicochemical,  
02:28 16 pharmacokinetic, pharmacodynamic, and toxicological properties  
02:28 17 all have to be established, correct?  
02:28 18 A. That is correct, yes.  
02:28 19 Q. You have no understanding of the pharmacokinetic  
02:28 20 properties of any aqueous liquid preparations of bromfenac,  
02:28 21 correct?  
02:28 22 A. That is correct, yes.  
02:28 23 Q. You have no understanding of the pharmacodynamic  
02:29 24 properties of any aqueous liquid preparations of bromfenac,  
02:29 25 correct?  
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02:29 1 A. That is what I've said, yes.  
02:29 2 Q. You have no understanding of the toxicological properties  
02:29 3 of any formulation of bromfenac, correct?  
02:29 4 A. Yes, I see that.  
02:29 5 Q. Taking a drug molecule from concept through formulation,  
02:29 6 clinical trials, manufacture, and the strict regulatory  
02:29 7 process to its ultimate use as a medicine by the patient is an  
02:29 8 expensive, complex, and lengthy process with a great many  
02:29 9 hurdles at which a potential drug may fail, correct?  
02:29 10 A. Yes, I've said that previously.  
02:29 11 Q. Once a lead compound has been identified, a decision has  
02:29 12 to be made as to whether it is possible to develop the  
02:29 13 molecule into a safe, effective medicine, correct?  
02:29 14 A. Yes, that is correct.  
02:29 15 Q. To do this, the compound's physicochemical properties, as  
02:29 16 well as its fate and behavior in the body all have to be  
02:29 17 assessed, correct?  
02:30 18 A. In the context of the development process, yes.  
02:30 19 Q. Particular attention is given to the efficacy and  
02:30 20 toxicity of a lead compound, as these are the main reasons for  
02:30 21 failure of a compound to progress beyond this stage, correct?  
02:30 22 A. That is correct, yes.  
02:30 23 Q. You testified earlier that you have no understanding of  
02:30 24 the toxicological properties of any formulation of bromfenac,  
02:30 25 correct?  
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02:30 1 **A. Well, that is correct, but it is -- it doesn't follow on**  
02:30 2 **from the previous statements that you've made.**  
02:30 3 **Q. Just to be clear, you have no understanding of the**  
02:30 4 **toxicological properties of any formulation of bromfenac,**  
02:30 5 **correct?**  
02:30 6 **A. That is correct in as far as it goes, yes.**  
02:30 7 **Q. There can be considerable challenges encountered in the**  
02:30 8 **preparation of an appropriate formulation or delivery form of**  
02:30 9 **a drug, with the formulation being used for preclinical**  
02:30 10 **studies unlikely to be the formulation used in man, correct?**  
02:30 11 **A. If you're dealing with a brand new drug which is what all**  
02:31 12 **this is dealing with, yes, you are correct.**  
02:31 13 **Q. The physical and chemical properties of aqueous liquid**  
02:31 14 **preparations for ophthalmic use depend upon the drug being**  
02:31 15 **used and the drug dose, correct?**  
02:31 16 **A. That is a correct statement, yes.**  
02:31 17 **Q. Those would be factors in determining the formulation**  
02:31 18 **that would be prepared, correct?**  
02:31 19 **A. That is a correct statement as far as it goes, yes.**  
02:31 20 **Q. A formulator developing an ophthalmic solution as of 2003**  
02:31 21 **had to consider variables including efficacy, comfort to the**  
02:31 22 **patient, extent of absorption of solution into the eye, and**  
02:31 23 **shelf life, correct?**  
02:31 24 **A. As would any formulator preparing something for market,**  
02:31 25 **yes.**

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02:31 1 **Q. Efficacy of a formulation is determined by form, for**  
02:31 2 **example, free acid, free base, or salt, and the amount of the**  
02:31 3 **one or more active ingredients, and also requires a careful**  
02:31 4 **balance of excipients, correct?**  
02:31 5 **A. These statements are correct but you've got to be careful**  
02:32 6 **not to take them out of context.**  
02:32 7 **Q. For example, pH modulators such as sodium hydroxide are**  
02:32 8 **used to keep the pH as close to possible to the pH of natural**  
02:32 9 **tears, between 6.5 and 7.6, which ensures comfort and may aid**  
02:32 10 **in absorption, correct?**  
02:32 11 **A. I have made that statement, yes.**  
02:32 12 **Q. In your opinion, some of the considerable challenges**  
02:32 13 **encountered in the preparation of an appropriate ophthalmic**  
02:32 14 **formulation include the dose, dosing frequency,**  
02:32 15 **physicochemical properties of the drug, how those properties**  
02:32 16 **are affected by the likely excipients to be added to the**  
02:32 17 **formulation, the effective temperature on the formulation, the**  
02:32 18 **pH of the formulation because that may affect the stability of**  
02:32 19 **the drug, how the drug is likely to be degraded, what is the**  
02:32 20 **best formulation, and what is the best solvent to add,**  
02:32 21 **correct?**  
02:32 22 **MS. RAPALINO: Objection, compound, your Honor.**  
02:32 23 **There is a lot in that question.**  
02:32 24 **THE COURT: Well, if the witness understands the**  
02:32 25 **question and can answer it, then you may. If you would like**

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02:33 1 **it broken down into its components, then just say so.**  
02:33 2 **THE WITNESS: I would like it reread because I did**  
02:33 3 **lose what was being said.**  
02:33 4 **THE COURT: All right. Then I will sustain the**  
02:33 5 **objection as a compound question.**  
02:33 6 **MR. HASFORD: I will repeat it.**  
02:33 7 **BY MR. HASFORD:**  
02:33 8 **Q. One of the considerable formulation challenges**  
02:33 9 **encountered in the preparation of an appropriate ophthalmic**  
02:33 10 **formulation is the dose, correct?**  
02:33 11 **A. Perhaps -- yes. Perhaps you could direct me to where I**  
02:33 12 **actually wrote that in my report. It might be easier.**  
02:33 13 **Q. I will direct you to your deposition testimony, in fact.**  
02:33 14 **Take a look at your first transcript which is --**  
02:33 15 **A. Can I not see where I wrote it in the report in the**  
02:33 16 **context in which it was said? No?**  
02:33 17 **Q. You testified about it at your degradation. I'll show**  
02:33 18 **you that.**  
02:33 19 **A. Okay.**  
02:33 20 **Q. Turn in your first deposition transcript, which is the**  
02:33 21 **September 4th, 2005, transcript, and please turn to Page 271.**  
02:33 22 **And let me direct your attention to Line 9. Actually, let me**  
02:33 23 **direct your attention to Line 2. And I'm going to read you**  
02:33 24 **from Page 271, Line 2, through 272, Line 10.**  
02:34 25 **A. I believe we also discussed this in deposition in**

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02:34 1 **February 2000 -- 29th, as well.**  
02:34 2 **Q. Well, let me read you your testimony here. I said:**  
02:34 3 **"QUESTION: Take a look at the section on Page 14**  
02:34 4 **entitled 'Formulation Challenges.' In the first sentence, you**  
02:34 5 **state, 'There can be considerable challenges encountered in**  
02:34 6 **the preparation of an appropriate formulation or delivery form**  
02:34 7 **of a drug, with the formulation being used for preclinical**  
02:34 8 **studies unlikely to be the formulation used in man.'"**  
02:34 9 **And then I asked you: "What are some of the**  
02:34 10 **considerable challenges encountered in the preparation of an**  
02:34 11 **appropriate ophthalmic formulation?"**  
02:34 12 **Then there was an objection.**  
02:34 13 **I said, "You may answer."**  
02:34 14 **You said: "I believe I've already answered this**  
02:34 15 **question earlier."**  
02:34 16 **Then I asked, "Could you summarize them, please?"**  
02:34 17 **And then you testified, "There would be -- what you**  
02:34 18 **would need to understand" was -- "what you would need to**  
02:34 19 **understand, what the dose was, the dosing frequency,**  
02:34 20 **physicochemical properties of the drug, how those properties**  
02:35 21 **are affected by the likely excipients that you're going to add**  
02:35 22 **to the formulation, the effect of temperature on that**  
02:35 23 **formulation. I think pH is obviously included in there as**  
02:35 24 **well because that may be -- may affect the stability of the**  
02:35 25 **drug, how it's likely to be degraded, what's the best**

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02:35 1 formulation, what's the best solvent you're going to add."  
02:35 2 Then I asked:  
02:35 3 "QUESTION: Anything else?"  
02:35 4 You answer: "I think I've given a reasonable start."  
02:35 5 And that was your testimony, wasn't it, Doctor?  
02:35 6 **A. Well, I said that in testimony. You have to appreciate**  
02:35 7 **that they are -- although it seems like a long list, they are**  
02:35 8 **not challenges to somebody doing pharmaceutical formulation,**  
02:35 9 **particularly of a drug whose properties are known.**  
02:35 10 **Q.** You never qualified your testimony in any way at your  
02:35 11 deposition, did you, Doctor?  
02:35 12 **A. I did in a later deposition.**  
02:35 13 **Q.** In your opinion, comfort, extent of absorption, and shelf  
02:35 14 life of a formulation are controlled by the excipients,  
02:35 15 correct?  
02:35 16 **A. I have said that, yes, in the context of what I wrote.**  
02:36 17 **Q.** There are many examples of complex problems encountered  
02:36 18 in the art of the patents-in-suit, including multiple types of  
02:36 19 stability, viscosity, and avoidance of eye irritation, among  
02:36 20 other things, correct?  
02:36 21 **A. It would be helpful if you could direct me to where I**  
02:36 22 **wrote that, please.**  
02:36 23 **Q.** I'll direct you to where you testified about it. It's  
02:36 24 back to your September 4th deposition transcript.  
02:36 25 **A. Yeah.**

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02:36 1 **Q.** And if you'll turn to Page 140.  
02:36 2 **MS. RAPALINO:** Objection, your Honor. I'm just going  
02:36 3 to object to a line of questions that's simply a recitation of  
02:36 4 her deposition testimony. If there is a reason for using this  
02:36 5 for impeachment, that's another story, but this just appears  
02:36 6 to be an attempt to get her deposition testimony into the  
02:36 7 record.  
02:36 8 **MR. HASFORD:** Your Honor, she asked me to point her  
02:36 9 to where she provided this opinion.  
02:36 10 **THE COURT:** That's correct. Mr. Hasford is correct,  
02:36 11 and I'll permit it because the witness did ask to be referred.  
02:36 12 These are long questions, and they're not offered for  
02:37 13 impeachment at this point, but, rather, to refresh the  
02:37 14 witness's recollection about --  
02:37 15 **MS. RAPALINO:** Okay. I don't have a problem pointing  
02:37 16 the witness to the place in the deposition transcript. It's  
02:37 17 just the recitation of the testimony by counsel into the  
02:37 18 record that I'm objecting to. So, if it's just to orient the  
02:37 19 witness to the testimony, that's fine, and then he can ask a  
02:37 20 question, not based on the testimony itself -- not reading  
02:37 21 testimony itself.  
02:37 22 **MR. HASFORD:** Well, I'm happy, once Dr. Lawrence has  
02:37 23 reread the testimony, to ask the question again, your Honor.  
02:37 24 **THE COURT:** Well, again, it's not impermissible for  
02:37 25 counsel to read from the deposition in formulating his

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02:37 1 question. His questions are not evidence. And it's the  
02:37 2 witness's answer that's going to determine the content of the  
02:37 3 evidence. And so I'll permit it.  
02:37 4 The only thing is if there is going to be a lot of  
02:37 5 questions that have multiple factors in them, like  
02:37 6 Dr. Lawrence's answers do, they really ought to be broken down  
02:37 7 into component parts.  
02:37 8 **MR. HASFORD:** I'll try to do a better job of that,  
02:38 9 your Honor.  
02:38 10 **BY MR. HASFORD:**  
02:38 11 **Q.** So, on Page 140 of your deposition transcript, I asked  
02:38 12 you:  
02:38 13 "QUESTION: How complex are the types of problems  
02:38 14 encountered in the art of the patents-in-suit?  
02:38 15 Then there was an objection.  
02:38 16 And then you answered: "I could list some examples of  
02:38 17 formulations that are encountered."  
02:38 18 And then I asked:  
02:38 19 "QUESTION: Please do."  
02:38 20 Then you answered: "If it's a solution formulation,  
02:38 21 it's important that there are no large particulate  
02:38 22 contaminants in the formulation. If it's a suspension  
02:38 23 formulation, it's important that the particles or the  
02:38 24 suspension are small enough and not too large. That could be  
02:38 25 a problem due to poor stability of the formulation, so that's

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02:38 1 an example of a type of problem encountered."  
02:38 2 Then I asked you:  
02:38 3 "QUESTION: Are there any other examples?"  
02:38 4 You answered: "One very practical problem is getting  
02:38 5 the formulation viscous enough to stay in the eye but not too  
02:38 6 viscous to come out of the eyedrop bottle, for example."  
02:38 7 Then I asked:  
02:38 8 "QUESTION: Are there any other examples?"  
02:38 9 Then you answered: "We spoke about stability in  
02:39 10 respect to particulates, but there might be stability in the  
02:39 11 container that you choose to put the formulation in. There  
02:39 12 might be problems once you -- there is two types of stability.  
02:39 13 There's the shelf-life stability, and then there's the  
02:39 14 stability once the formulation is opened, and they may be --  
02:39 15 opened and in use, and they may be different, and that is  
02:39 16 something else that you need to consider. You need to make  
02:39 17 sure you're not introducing anything damaging that's going to  
02:39 18 irritate into the eye."  
02:39 19 Then I asked:  
02:39 20 "QUESTION: Are there any other examples?"  
02:39 21 And you answered: "I'm sure there are, but they are  
02:39 22 the ones that I can think of at the moment."  
02:39 23 That was your testimony, Doctor, wasn't it?  
02:39 24 **A. Well, that's my testimony. These problems are just bread**  
02:39 25 **and butter for a pharmaceutical formulator.**

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02:39 1 Q. When I asked you how complex are the types of problems  
 02:39 2 encountered in the art of the patents-in-suit, you provided me  
 02:39 3 a page and a half worth of testimony, correct?  
 02:39 4 A. **As I explained, these are just standard problems for a**  
 02:39 5 **pharmaceutical formulator.**  
 02:39 6 Q. You never characterized them as "standard" at your  
 02:39 7 deposition, did you, Doctor?  
 02:40 8 A. **While I don't see the word "standard" there, it looks**  
 02:40 9 **like it's a long list. What I'm just saying, you've got to**  
 02:40 10 **put it into context with the pharmaceutical formulator.**  
 02:40 11 Q. There are a large number of different possible ways to  
 02:40 12 formulate aqueous liquid preparations of NSAIDs, depending on  
 02:40 13 the dose, correct?  
 02:40 14 A. **In as far as it goes, it's correct.**  
 02:40 15 Q. There are a large number of different possible ways to  
 02:40 16 formulate aqueous liquid preparations of NSAIDs, depending on  
 02:40 17 the route of administration, correct?  
 02:40 18 A. **In as far as it goes, it's correct, yes.**  
 02:40 19 Q. There are a large number of different possible ways to  
 02:40 20 formulate aqueous liquid preparations of NSAIDs, depending on  
 02:40 21 whether you want a salt or a free acid or base, correct?  
 02:40 22 A. **In as far as it goes, yes.**  
 02:40 23 Q. As of 2003, the search was still ongoing for technologies  
 02:41 24 to overcome the solubility and permeability problems  
 02:41 25 encountered with the formulation of drugs as medicines,

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02:41 1 correct?  
 02:41 2 A. **And that is still the case today.**  
 02:41 3 Q. Let's now discuss your opinions on NSAIDs. In your own  
 02:41 4 words, quite a lot of different NSAIDs are known to exist,  
 02:41 5 correct?  
 02:41 6 A. **Yes, but as I've stated, very few of them are used as**  
 02:41 7 **medicines themselves.**  
 02:41 8 Q. Take a look, if you would, at your September 4th  
 02:41 9 deposition transcript, and let me direct your attention to  
 02:41 10 Page 157 and to Line 7.  
 02:41 11 The exact question I asked you was: "How many  
 02:41 12 different NSAIDs are known to exist?"  
 02:41 13 And the exact answer you gave was: "Quite a lot."  
 02:41 14 Correct?  
 02:42 15 A. **That is true. But that's not inconsistent with the**  
 02:42 16 **answer I've just given.**  
 02:42 17 Q. You didn't qualify your testimony at your deposition, did  
 02:42 18 you, Doctor?  
 02:42 19 A. **I'm explaining that there is a lot -- I'm quite happy to**  
 02:42 20 **say there is quite a lot of NSAIDs, but very few of them have**  
 02:42 21 **been developed into medicines, that's all.**  
 02:42 22 Q. In fact, in your own words, the range of potential drug  
 02:42 23 molecules is enormous, correct?  
 02:42 24 A. **The range of any chemical space is enormous, yes.**  
 02:42 25 Q. Different NSAIDs having different chemical structures

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02:42 1 possess different physical and chemical properties, correct?  
 02:42 2 A. **I think that's got to be a qualified statement.**  
 02:42 3 Q. Take a look, if you would, at your February 16th  
 02:42 4 transcript. And let me direct your attention to Page 85, and,  
 02:42 5 in particular, to Lines 15 through 18. Tell me when you're  
 02:43 6 there.  
 02:43 7 MS. RAPALINO: Your Honor, I would ask that further  
 02:43 8 context be provided for this question, going onto 86, Lines 3  
 02:43 9 through -- Lines 1 through 4.  
 02:43 10 MR. HASFORD: I think the exact question is Page 85,  
 02:43 11 Lines 15 through 18, your Honor.  
 02:43 12 MS. RAPALINO: Again, I'm just asking for some more  
 02:43 13 context be provided in the transcript to that question.  
 02:43 14 MR. HASFORD: If she would like me to read that  
 02:43 15 additional line into the record, I don't have any problem with  
 02:43 16 doing that.  
 02:43 17 THE COURT: Okay.  
 02:43 18 MR. HASFORD: The exact question is here so --  
 02:43 19 THE COURT: I'll permit it as completeness.  
 02:43 20 MR. HASFORD: Okay.  
 02:43 21 BY MR. HASFORD:  
 02:43 22 Q. So, Doctor, I asked you: "Different NSAIDs having  
 02:43 23 different structures possess different physical and chemical  
 02:43 24 properties, correct?"  
 02:43 25 And you answered, "Correct."

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02:43 1 Do you see that?  
 02:43 2 A. **Yes. And that's in the context of the previous**  
 02:43 3 **statement, as I said, while there is a large number of**  
 02:43 4 **potential drugs, not all of them will be developed as**  
 02:43 5 **medicines.**  
 02:43 6 Q. And then on the next page, what Ms. Rapalino asked me to  
 02:44 7 ask, to read in, is starting on Page 86, Line 1, I asked you:  
 02:44 8 "QUESTION: Diclofenac and bromfenac have different  
 02:44 9 chemical structures, correct?"  
 02:44 10 And you answered, "Yes, but they also have a lot of  
 02:44 11 similarities."  
 02:44 12 And then I asked you:  
 02:44 13 "QUESTION: Diclofenac and bromfenac, in fact, have  
 02:44 14 different chemical structures, correct?"  
 02:44 15 And then there was an objection.  
 02:44 16 And you answered, "They won't have the same name, if  
 02:44 17 they're the same chemical structure."  
 02:44 18 That was your testimony, wasn't it, Doctor?  
 02:44 19 A. **That's what's on the page, yes.**  
 02:44 20 Q. Bromfenac and indomethacin also have different chemical  
 02:44 21 structures, correct?  
 02:44 22 A. **While they're not identical, as I've explained before,**  
 02:44 23 **they have lots of similarities.**  
 02:44 24 Q. Take a look at this same deposition transcript on Page  
 02:44 25 89, and let me direct your attention to Line 6.

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02:44 1 I asked you: "Indomethacin and bromfenac have  
 02:45 2 different chemical structures, correct?"  
 02:45 3 And you answered, "They do."  
 02:45 4 That was your testimony, wasn't it, Doctor?  
 02:45 5 MS. RAPALINO: Again, I just lodge an objection as  
 02:45 6 improper impeachment. What she said was entirely consistent  
 02:45 7 with that answer in the deposition.  
 02:45 8 MR. HASFORD: She didn't say it in the qualifying  
 02:45 9 manner in which she said it here, Your Honor.  
 02:45 10 THE COURT: I'll permit it.  
 11 BY MR. HASFORD:  
 02:45 12 Q. Do you need me to ask the question again, Doctor?  
 02:45 13 A. **No, I don't.**  
 02:45 14 Q. Was that your testimony?  
 02:45 15 A. **That's what's on the page, yes.**  
 02:45 16 Q. Bromfenac and ketorolac have different chemical  
 02:45 17 structures, correct?  
 02:45 18 A. **Yes. And, as I said in that section of testimony, while**  
 02:45 19 **they are not identical structures, or else they would have the**  
 02:45 20 **same name, they have a number of similarities.**  
 02:45 21 Q. Bromfenac and suprofen have different chemical  
 02:45 22 structures, correct?  
 02:45 23 A. **Yes, but they also have similarities in their properties.**  
 02:45 24 Q. Bromfenac and flurbiprofen have different chemical  
 02:45 25 structures, correct?

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02:45 1 A. **It's the same answer as I've just given.**  
 02:45 2 Q. I'll ask it again so we're clear.  
 02:46 3 Bromfenac and flurbiprofen have different chemical  
 02:46 4 structures, correct?  
 02:46 5 A. **Yes, they do, but they have similarities in their**  
 02:46 6 **properties.**  
 02:46 7 Q. Let's now discuss your opinions on surfactants.  
 02:46 8 The number of different nonionic surfactants that are  
 02:46 9 known to exist is, in your own words, as many as you want in  
 02:46 10 your brain, correct?  
 02:46 11 A. **Theoretically, as I've said, yes, it is possible to have**  
 02:46 12 **as much and as many as you like to make.**  
 02:46 13 Q. The number of possible surfactant structures, in your  
 02:46 14 words, is absolutely huge, correct?  
 02:46 15 A. **Yes, but the reality of the numbers that actually exist**  
 02:46 16 **in practice is very small.**  
 02:46 17 Q. Take a look, if you would, at your September 4th  
 02:46 18 deposition transcript, and it's going to be at Page 309, Line  
 02:47 19 18, through 310, Line 6. And you had just asked me to repeat  
 02:47 20 the question and so I said, "Certainly." Then I asked you,  
 02:47 21 "Is it true that surfactants display diverse structures in  
 02:47 22 aqueous environments depending on their concentration, the  
 02:47 23 temperature, pH, and the presence of other species in the  
 02:47 24 system?"  
 02:47 25 Then there was an objection.

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02:47 1 And you answered: "It is vague. You have to remember  
 02:47 2 the number of surfactant structures possible is absolutely  
 02:47 3 huge. So, if you take surfactants as a whole, ionic,  
 02:47 4 cationic, anionic, zwitterionic, nonionic, that statement will  
 02:47 5 be true."  
 02:47 6 That was your testimony, wasn't it, Doctor?  
 02:48 7 MS. RAPALINO: Objection as for completeness. It's  
 02:48 8 sort of an unusual case where the deposition was really in  
 02:48 9 three parts, and if we go to the February 29th deposition,  
 02:48 10 Page 213 -- 212 to 213, and we could pull that up as well for  
 02:48 11 completeness.  
 02:48 12 MR. HASFORD: Yeah, your Honor, if all she's trying  
 02:48 13 to do here is point to a prior consistent statement, I believe  
 02:48 14 she's entitled to do that on redirect, so I don't think that's  
 02:48 15 proper at this stage.  
 02:48 16 THE COURT: That's correct. What's permitted at this  
 02:48 17 stage is to better understand the question that was asked on  
 02:48 18 September 4th.  
 02:48 19 BY MR. HASFORD:  
 02:48 20 Q. So that was your testimony, correct, Doctor?  
 02:48 21 A. **Yes. And the word "possible" is an important word in**  
 02:48 22 **that sentence.**  
 02:48 23 Q. There are a wide variety of equilibrium surfactant  
 02:48 24 structures -- let me strike that and try again.  
 02:48 25 There are a wide variety of equilibrium surfactant

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02:49 1 systems that can be used in aqueous drug formulations,  
 02:49 2 correct?  
 02:49 3 A. **Yes, but the case we're talking about is just micelles --**  
 02:49 4 **micelles.**  
 02:49 5 Q. Is it correct that there are a wide variety of  
 02:49 6 equilibrium surfactant systems that can be used in aqueous  
 02:49 7 drug formulations?  
 02:49 8 A. **I believe I said it's yes, but there is only one that's**  
 02:49 9 **of relevance here.**  
 02:49 10 Q. Take a look, if you would, at your September 4th  
 02:49 11 deposition transcript again, and let's turn to Page 291, and,  
 02:49 12 in particular, to Lines 17 through 22. I asked you:  
 02:49 13 "QUESTION: Is it fair to say that there are a wide  
 02:49 14 variety of equilibrium surfactant systems that can be used in  
 02:50 15 aqueous drug formulations?"  
 02:50 16 There was an objection.  
 02:50 17 And you answered, "Potentially there are, yes."  
 02:50 18 That was your testimony, wasn't it, Doctor?  
 02:50 19 A. **I haven't denied that.**  
 02:50 20 Q. There are a wide variety of nonequilibrium surfactant  
 02:50 21 systems that can be used in aqueous drug formulations,  
 02:50 22 correct?  
 02:50 23 A. **As a statement goes, that's correct, but irrelevant here.**  
 02:50 24 Q. Let me point you back to your deposition testimony. Page  
 02:50 25 292 in the September 4th deposition, and let me point you to

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02:50 1 Line 1.  
 02:50 2 I asked, "Take a look, if you would, at Table 3. Is it  
 02:50 3 fair to say that there are a wide variety of nonequilibrium  
 02:50 4 surfactant systems that can be used in aqueous drug  
 02:50 5 formulations?"  
 02:50 6 **A. I have agreed with that sentence.**  
 02:50 7 MR. HASFORD: May I continue, your Honor?  
 02:50 8 THE COURT: I find the witness to not offer  
 02:50 9 inconsistent testimony. She did agree. She's just saying  
 02:50 10 it's irrelevant to the issues that bring us to trial.  
 02:50 11 MR. HASFORD: Okay.  
 02:51 12 BY MR. HASFORD:  
 02:51 13 Q. There are, in your words, a plethora of stable  
 02:51 14 surfactants in water, correct?  
 02:51 15 **A. A plethora of stable surfactants in water.**  
 02:51 16 Q. There are, in your words --  
 02:51 17 **A. In what context was that said, please?**  
 02:51 18 Q. Well, let me point you to your deposition transcript, the  
 02:51 19 September 4th deposition.  
 02:51 20 **A. It doesn't sound like a very good answer.**  
 02:51 21 Q. At Page 86, and Line 1. I asked:  
 02:51 22 "QUESTION: What if they wanted to use it in a stable  
 02:51 23 aqueous liquid preparation, what characterization would they  
 02:51 24 do?"  
 02:51 25 Then there was an objection.

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02:51 1 And you answered, "There's a plethora of stable -- of  
 02:51 2 surfactants in water. So it would depend upon the aggregation  
 02:51 3 state, the formulation state."  
 02:51 4 And that was your testimony, wasn't it, Doctor?  
 02:51 5 MS. RAPALINO: Objection, Your Honor. I'm not sure  
 02:51 6 that that testimony was consistent or inconsistent. I just  
 02:52 7 don't think that there is any way to compare that testimony to  
 02:52 8 what -- the answer that the witness just gave.  
 02:52 9 MR. HASFORD: Well, I think her volunteered testimony  
 02:52 10 there was that there were a plethora of stable surfactants in  
 02:52 11 water.  
 02:52 12 MS. RAPALINO: No, I believe that's a misreading of  
 02:52 13 the transcript, your Honor.  
 02:52 14 THE COURT: Well, the witness asked in what context  
 02:52 15 was that said, and counsel directed Dr. Lawrence to her dep.  
 02:52 16 Having reread your dep, does that help you to answer  
 02:52 17 the question?  
 02:52 18 THE WITNESS: I obviously said that, but I'd actually  
 02:52 19 need to read further back because of the line of questioning  
 02:52 20 that was going on.  
 02:52 21 THE COURT: All right. I'll permit you to dial back  
 02:52 22 a few pages if you need to to refresh your recollection of the  
 02:52 23 context.  
 02:52 24 THE WITNESS: That's helpful. Thank you.  
 02:52 25 (Pause)

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02:53 1 THE WITNESS: That was a vague answer because the  
 02:53 2 line of questioning was very vague.  
 02:53 3 MR. HASFORD: Your Honor, I note that it's almost  
 02:53 4 12:30. Would this be a good time for a lunch break or would  
 02:53 5 your Honor prefer that I continue?  
 02:53 6 THE COURT: This is fine, and so let's break for  
 02:53 7 lunch and resume at 1:30, and have a pleasant lunch.  
 02:53 8 MR. HASFORD: Thank you, your Honor.  
 02:53 9 (A luncheon recess was taken at 12:25 p.m.)  
 04:05 10 (In open court at 1:37 p.m.)  
 04:05 11 THE DEPUTY COURT CLERK: All rise.  
 04:05 12 THE COURT: Be seated, please. Good afternoon. And  
 04:06 13 you may resume.  
 04:06 14 MR. HASFORD: Thank you, your Honor.  
 04:06 15 BY MR. HASFORD:  
 04:06 16 Q. Good afternoon, Dr. Lawrence.  
 04:06 17 **A. Good afternoon.**  
 04:06 18 Q. As of 2000, it was understood in the art that the drug  
 04:06 19 solubilizing capacity of most of the commonly used surfactants  
 04:06 20 was too low to be of widespread practical use, correct?  
 04:06 21 **A. I'm sorry. Can you repeat that? It's my fault.**  
 04:06 22 Q. I certainly will. As of 2000, it was understood in the  
 04:06 23 art that the drug solubilizing capacity of most of the  
 04:06 24 commonly used surfactants was too low to be of widespread  
 04:06 25 practical use, correct?

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04:06 1 **A. I noted that in a paper I wrote in 1994, yes.**  
 04:06 2 Q. Let's now discuss your opinions regarding polysorbate 80  
 04:06 3 versus tyloxapol. First, the sodium salt of bromfenac is a  
 04:06 4 water-soluble hydrophilic drug, correct?  
 04:07 5 **A. That's what I understand from the literature, yes.**  
 04:07 6 Q. Polysorbate 80 is a nonionic surfactant, correct?  
 04:07 7 **A. Yes.**  
 04:07 8 Q. Tyloxapol is a nonionic surfactant, correct?  
 04:07 9 **A. This is correct, yes.**  
 04:07 10 Q. A solution containing tyloxapol and water where water is  
 04:07 11 in the greater proportion would be considered an aqueous  
 04:07 12 surfactant system, correct?  
 04:07 13 **A. That is correct, yes.**  
 04:07 14 Q. The prior art, in fact, the prior art that you authored  
 04:07 15 in a peer-reviewed academic journal teaches that there is no  
 04:07 16 use trying to increase the solubility of a water soluble  
 04:07 17 hydrophilic drug in an aqueous-based surfactant system,  
 04:07 18 correct?  
 04:07 19 **A. Yes, I've said that, yes.**  
 04:07 20 Q. Determining how the physical and chemical properties of  
 04:07 21 tyloxapol would affect aqueous liquid preparations of NSAIDs  
 04:08 22 that contain tyloxapol would, in your words, very much require  
 04:08 23 looking on a case-by-case basis, correct?  
 04:08 24 **A. Well, there would be some general similarities, but yes,**  
 04:08 25 **you would look at the particulars on a case-by-case basis,**

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04:08 1 **yes.**  
04:08 2 Q. An understanding of the interaction between surfactants  
04:08 3 and drugs is quite complex, correct?  
04:08 4 A. **Again, you can make some generalities, but you would have**  
04:08 5 **to look on a case-by-case basis, yes.**  
04:08 6 Q. Polysorbate 80 and tyloxapol have different chemical  
04:08 7 structures, correct?  
04:08 8 A. **Yes, they have some differences, yes.**  
04:08 9 Q. Different nonionic surfactants having -- let me strike  
04:08 10 that and try again.  
04:09 11 Different nonionic surfactants have different chemical  
04:09 12 and physical properties because the structure of the  
04:09 13 surfactants can vary so the hydrophobic/hydrophilic balance  
04:09 14 can vary, correct?  
04:09 15 A. **Could you repeat that, please? Sorry.**  
04:09 16 Q. Certainly. Different nonionic surfactants have different  
04:09 17 chemical and physical properties because the structure of the  
04:09 18 surfactants can vary so the hydrophobic/hydrophilic balance  
04:09 19 can vary, correct?  
04:09 20 A. **The last bit of that sentence doesn't make sense in the**  
04:09 21 **context I think of what you are saying, but different**  
04:09 22 **surfactants may behave in different ways, that is certainly**  
04:09 23 **correct.**  
04:09 24 Q. Take a look, if you would, at your deposition transcript  
04:09 25 of September 4th, and let me direct your attention to page 76,  
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04:10 1 line 21, through page 77, line 6.  
04:10 2 I asked you, question, "Why do different nonionic  
04:10 3 surfactants have different chemical and physical properties?"  
04:10 4 Then there was an objection.  
04:10 5 And I said, you may answer.  
04:10 6 And then you answered, "Because the structure of the  
04:10 7 surfactants can vary, so the balance between the hydrophobic  
04:10 8 and the hydrophilic can vary."  
04:10 9 There was your testimony, wasn't it, Doctor?  
04:10 10 A. **I see that sentence, and that sentence as it's stated**  
04:10 11 **there is correct.**  
04:10 12 Q. In fact, different physical and chemical properties that  
04:10 13 different nonionic surfactants possess in aqueous liquid  
04:10 14 preparations depend on the structures of the surfactants,  
04:10 15 correct?  
04:10 16 A. **That is correct, yes.**  
04:10 17 Q. Let's now discuss your opinions -- actually, before I get  
04:11 18 to that, let me ask you something different. Tests would need  
04:11 19 to be conducted for a person of ordinary skill in the art to  
04:11 20 determine whether the same amount of two different nonionic  
04:11 21 surfactants having different chemical structures would be  
04:11 22 expected to have the same stabilizing effect in an aqueous  
04:11 23 liquid preparation of a nonsteroidal antiinflammatory drug,  
04:11 24 correct?  
04:11 25 A. **That is correct, because you need to understand how many**  
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04:11 1 **molecules you are adding if there are different molecular**  
04:11 2 **weights.**  
04:11 3 Q. And that is because, in your words, it would be very  
04:11 4 unexpected to have the same behavior in the same way, correct?  
04:11 5 A. **It would be very unexpected to have --**  
04:11 6 Q. In your words, it would be very unexpected to have the  
04:11 7 same behavior in the same way, correct?  
04:11 8 MS. RAPALINO: Objection. That strikes me as a very  
04:11 9 vague question.  
04:11 10 MR. HASFORD: Well, let me ask it this way.  
04:11 11 THE COURT: All right.  
04:11 12 BY MR. HASFORD:  
04:11 13 Q. In your words, it would be very unexpected for two  
04:12 14 different nonionic surfactants to have the same behavior in  
04:12 15 the same way, correct?  
04:12 16 A. **Two different nonionic surfactants, it would depend on**  
04:12 17 **the variability of the structure, how far apart they were in**  
04:12 18 **the structure obviously, sorry, in terms of the structure.**  
04:12 19 Q. Let me direct you to your second deposition transcript,  
04:12 20 which is your February 16th deposition transcript, and in  
04:12 21 particular to page 199, line 14, through 200, line 2.  
04:12 22 I asked you, question, "Tests would need to be  
04:12 23 conducted for a person of ordinary skill in the art to  
04:12 24 determine whether the same amount of two different nonionic  
04:12 25 surfactants having different chemical structures would be  
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04:12 1 expected to have the same stabilizing effect in an aqueous  
04:13 2 liquid preparation of a nonsteroidal antiinflammatory drug,  
04:13 3 correct?"  
04:13 4 And then there was an objection, and you answered, "It  
04:13 5 would be very unexpected to have the same behavior in the same  
04:13 6 way, so, yes, of course experiments would be needed."  
04:13 7 That was your testimony, wasn't it?  
04:13 8 MS. RAPALINO: Again, I'm going to lodge an objection  
04:13 9 here. There was an objection on the record to the form of the  
04:13 10 question which was quite vague and remains vague.  
04:13 11 MR. HASFORD: I believe she answered the question in  
04:13 12 her deposition with no problem, your Honor.  
04:13 13 MS. RAPALINO: She was required to answer the  
04:13 14 question at the deposition.  
04:13 15 THE COURT: You preserved your answer to form of the  
04:13 16 question at the dep. Let me reread it.  
04:13 17 I'll overrule the objection. It seems like a specific  
04:13 18 question and the witness gave a responsive answer.  
04:13 19 BY MR. HASFORD:  
04:13 20 Q. That was your testimony, wasn't it, Doctor?  
04:14 21 A. **I see that in answer to your question, yes.**  
04:14 22 Q. No tests were conducted in the Fu EP 984 reference  
04:14 23 comparing tyloxapol to octoxynol 40, correct?  
04:14 24 A. **That is correct, yes.**  
04:14 25 Q. Let's now discuss your opinions on benzalkonium chloride.  
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04:14 1 You testified on direct exam about what you called complexes  
 04:14 2 with benzalkonium chloride. Do you remember that?  
 04:14 3 A. **Yes, I do.**  
 04:14 4 Q. Yet, to your knowledge, the solubility of any complex  
 04:14 5 between bromfenac and benzalkonium chloride is not reported in  
 04:14 6 any reference, correct?  
 04:14 7 A. **I haven't seen it. It doesn't mean it obviously doesn't**  
 04:14 8 **exist.**  
 04:14 9 Q. In fact, it is your view that the benzalkonium chloride  
 04:14 10 would not materially affect the basic and novel properties of  
 04:14 11 the claimed aqueous liquid preparations of the '431 patent,  
 04:14 12 correct?  
 04:15 13 A. **That is correct, yes.**  
 04:15 14 Q. You testified on direct exam about the solubility of  
 04:15 15 complexes with benzalkonium chloride. Yet, with respect to  
 04:15 16 aqueous liquid preparations, the concepts of stability and  
 04:15 17 solubility are not synonymous at all, correct?  
 04:15 18 A. **I'm sorry. Can you repeat that question?**  
 04:15 19 Q. Certainly. I'll break it apart into two questions.  
 04:15 20 You testified on direct exam about the solubility of  
 04:15 21 what you called complexes with benzalkonium chloride. Do you  
 04:15 22 remember that?  
 04:15 23 A. **Yes, I do.**  
 04:15 24 Q. With respect to aqueous liquid preparations, the concepts  
 04:15 25 of stability and solubility are, in your words, not synonymous

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04:17 1 formulated at a specific pH of 8.3, correct?  
 04:17 2 A. **That's what the information tells me, yes.**  
 04:17 3 Q. Prolensa® was formulated at a pH of 7.8, correct?  
 04:17 4 A. **Again, that's what the literature says, yes.**  
 04:17 5 Q. When developing an aqueous ophthalmic formulation,  
 04:17 6 ideally the pH of the formulation should be 7.4, the same as  
 04:17 7 tear fluid, correct?  
 04:17 8 A. **That's the ideal to be achieved if you can, of course.**  
 04:17 9 Q. The pH of an ophthalmic formulation is important to  
 04:17 10 stability, comfort, and bioavailability, correct?  
 04:17 11 A. **That is correct, yes.**  
 04:17 12 Q. pH is measured on a logarithmic scale rather than a  
 04:17 13 linear scale, correct?  
 04:17 14 A. **That is correct, yes.**  
 04:17 15 Q. On a linear scale, Xibrom® and Bromday® are over three  
 04:18 16 times more alkaline than Prolensa®, correct?  
 04:18 17 A. **Yes, they have about the alkalinity of seawater.**  
 04:18 18 Q. Let's now discuss your opinions on the category A  
 04:18 19 references you cited referring to bromfenac. First let's turn  
 04:18 20 to the Ogawa '225 patent which is JTX-147 in your binder. Are  
 04:19 21 you there, Doctor?  
 04:19 22 A. **Yes, I am.**  
 04:19 23 Q. To be clear, you have neither stated nor suggested that  
 04:19 24 the Ogawa '225 patent teaches the formation of a complex  
 04:19 25 between bromfenac and benzalkonium chloride, correct?

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04:15 1 at all, correct?  
 04:15 2 A. **They're not synonymous, but obviously if something is a**  
 04:15 3 **complex, it then causes a physical instability.**  
 04:15 4 Q. Take a look, if you would, at your first deposition  
 04:15 5 transcript. It's going to be the September 14th transcript --  
 04:16 6 or September 4th transcript, rather. And let me direct your  
 04:16 7 attention to page 43, line 22, through page 44, line 5.  
 04:16 8 I asked you, question, "How does the concept of  
 04:16 9 stability differ from the concept of solubility with respect  
 04:16 10 to aqueous liquid preparations?"  
 04:16 11 And there was an objection.  
 04:16 12 And you answered, "They are not synonymous at all."  
 04:16 13 That was your testimony, correct?  
 04:16 14 A. **Yes, that is correct. I see that.**  
 04:16 15 Q. You testified on direct exam that benzalkonium chloride  
 04:16 16 becomes toxic to the eye at what you called high levels. Do  
 04:16 17 you remember that?  
 04:16 18 A. **Yes, I do.**  
 04:16 19 Q. You are not even aware of the level at which benzalkonium  
 04:16 20 chloride becomes toxic to the eye, correct?  
 04:16 21 A. **It's outside the concentration range recommended in**  
 04:17 22 **ophthalmic preparations.**  
 04:17 23 Q. Take a look --  
 04:17 24 A. **I don't remember the exact figure, no.**  
 04:17 25 Q. Let's now discuss pH. Xibrom® and Bromday® were

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04:19 1 A. **Beg your pardon? I have not stated that, no, but I --**  
 04:19 2 **no, I have not, but I think it probably was obvious to a**  
 04:19 3 **person of ordinary skill in the art that that might be the**  
 04:19 4 **case.**  
 04:19 5 Q. Take a look at your deposition transcript, February 29th,  
 04:19 6 the last one. Let me direct your attention to page 186, line  
 04:19 7 22, through 187, line 5.  
 04:20 8 And I asked you, question, "To be clear, you have  
 04:20 9 neither stated nor suggested that the Ogawa '225 patent  
 04:20 10 teaches the formation of a complex between bromfenac and  
 04:20 11 benzalkonium chloride, correct?"  
 04:20 12 A. **Yes, that's correct.**  
 04:20 13 Q. And you answered, "Correct, that's what I say in -- yes."  
 04:20 14 A. **I see that.**  
 04:20 15 Q. The Ogawa '225 patent identified the formulations of  
 04:20 16 Examples 6, 7 and 8.  
 04:20 17 A. **Sorry. Can I just sort out this?**  
 04:20 18 Q. Oh, of course.  
 04:20 19 A. **Sorry. I've got too many...**  
 04:20 20 Q. And if you would, go ahead and turn to Examples 6, 7 and  
 04:20 21 8 which I believe are in column 10 of the Ogawa '225 patent.  
 04:20 22 A. **Okay. I'm there now.**  
 04:20 23 Q. You are familiar with Examples 6, 7 and 8, correct?  
 04:20 24 A. **Yes, I am.**  
 04:20 25 Q. The Ogawa '225 patent identified the formulations of

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04:20 1 Examples 6, 7 and 8 as not forming red insoluble matters and  
 04:21 2 described them as stable, excellent for a long period of time,  
 04:21 3 correct?  
 04:21 4 **A. That's what it says, yes.**  
 04:21 5 **Q.** The formulations of Examples 6, 7 and 8 of the Ogawa '225  
 04:21 6 patent did not have any problems with instability or  
 04:21 7 degradation, correct?  
 04:21 8 **A. Not under the conditions of the test they were tested**  
 04:21 9 **under, no.**  
 04:21 10 **Q.** In your view, the Ogawa '225 patent solved bromfenac's  
 04:21 11 stability problem by showing that under the conditions of  
 04:21 12 Examples 6, 7 and 8, the formulations were stable, correct?  
 04:21 13 **A. It certainly showed there was no red precipitate,**  
 04:21 14 **correct.**  
 04:21 15 **Q.** Example 6 of the Ogawa '225 patent teaches the known  
 04:21 16 ability of sodium sulfite to stabilize ophthalmic  
 04:21 17 preparations, correct?  
 04:21 18 **A. Correct.**  
 04:21 19 **Q.** In fact, the Ogawa '225 patent discloses that the  
 04:21 20 stability of ophthalmic formulations containing carboxyl group  
 04:22 21 containing NSAIDs and benzalkonium chloride can be improved by  
 04:22 22 including both sodium sulfite and polyvinylpyrrolidone,  
 04:22 23 correct?  
 04:22 24 **A. It teaches that, yes.**  
 04:22 25 **Q.** Let's now turn to your opinions regarding Bronuck and the  
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04:23 1 color. The *New Drugs in Japan* reference describes the Bronuck  
 04:23 2 formulation as clear yellow, correct?  
 04:24 3 **A. That is correct.**  
 04:24 4 **Q.** The *New Drugs in Japan* reference nowhere mentions any  
 04:24 5 precipitate or cloudiness in the Bronuck formulation, correct?  
 04:24 6 **A. I believe it doesn't, no.**  
 04:24 7 **Q.** It is your position that Xibrom® is an embodiment of the  
 04:24 8 Ogawa patent, correct?  
 04:24 9 **A. That is correct, yes.**  
 04:24 10 **Q.** Is it your understanding that the Ogawa patent is listed  
 04:24 11 on the face of the Xibrom® package insert?  
 04:24 12 **A. I'm sorry. I can't answer that question.**  
 04:24 13 **MR. HASFORD:** May I hand up an exhibit, your Honor?  
 04:24 14 **THE COURT:** Yes.  
 04:24 15 **THE WITNESS:** Thank you.  
 04:25 16 **MR. HASFORD:** For the record, I have handed the  
 04:25 17 witness plaintiff's trial Exhibit PTX-749. It is a one-page  
 04:25 18 document that bears Bates number PROL0167921.  
 04:25 19 **BY MR. HASFORD:**  
 04:25 20 **Q.** Let me refresh your recollection, Doctor. Please turn or  
 04:25 21 please look at PTX-749, and specifically let me direct your  
 04:25 22 attention to the lower right-hand column where it says U.S.  
 04:25 23 patent number 4,910,225. Do you see that?  
 04:25 24 **A. Yes, I do.**  
 04:25 25 **Q.** Do you agree that the Ogawa patent is listed on the face  
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04:22 1 reference you referred to as the *New Drugs in Japan* reference.  
 04:22 2 First --  
 04:22 3 **A. Would you tell me what reference that's at, please.**  
 04:22 4 **Q.** Let me ask you a question regarding Bronuck first, if I  
 04:22 5 may. Is that okay?  
 04:22 6 **A. Yes.**  
 04:22 7 **Q.** You would agree that in order for Bronuck to be marketed  
 04:22 8 in Japan, undoubtedly the producers had to demonstrate to the  
 04:22 9 regulatory authority that the formulation had sufficient  
 04:22 10 stability, correct?  
 04:22 11 **A. To the Japanese regulator authority, of course.**  
 04:22 12 **Q.** Now, please turn to the *New Drugs in Japan* reference,  
 04:22 13 which is JTX-210 in your binder. You testified about JTX-210  
 04:23 14 on direct exam. Do you remember that?  
 04:23 15 **A. Yes, I do.**  
 04:23 16 **Q.** Let me direct your attention to the page bearing Bates  
 04:23 17 number PROL0364732, and in particular to the third line of the  
 04:23 18 top table.  
 04:23 19 **A. Yes, I see that.**  
 04:23 20 **Q.** The *New Drugs in Japan* reference describes the Bronuck  
 04:23 21 formulation, correct?  
 04:23 22 **A. Yes, it does.**  
 04:23 23 **Q.** Let me direct your attention to the table in the  
 04:23 24 right-hand column entitled Composition/Properties, and in  
 04:23 25 particular, let me direct your attention to the row that says  
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04:25 1 of the Xibrom® package insert which is PTX-749?  
 04:25 2 **A. Just one moment. I can't find the right page here.**  
 04:26 3 **Sorry.**  
 04:26 4 **Q.** I believe it is Exhibit 147.  
 04:26 5 **A. Found it, found it, sorry.**  
 04:26 6 **Q.** You found it. Do you need me to re-ask the question?  
 04:26 7 **A. No, that's fine. The number is the same, yes.**  
 04:26 8 **Q.** You may put that document aside.  
 04:26 9 **Let's now turn to the Yanni '034 patent, which is**  
 04:26 10 **JTX-168 in your binder. In particular, please turn to column**  
 04:27 11 **1 of the Yanni '034 patent and let me direct your attention to**  
 04:27 12 **line 60. Are you there, Doctor?**  
 04:27 13 **A. Yes, I am.**  
 04:27 14 **Q.** The Yanni '034 patent states that the full  
 04:27 15 antiinflammatory potential of benzoylphenylacetic acids has  
 04:27 16 not been approached due to their generally slow rate of  
 04:27 17 penetration through the cornea, correct?  
 04:27 18 **A. That is correct.**  
 04:27 19 **Q.** Bromfenac is a benzoylphenylacetic acid, correct?  
 04:27 20 **A. That is correct.**  
 04:27 21 **Q.** Let me direct your attention to the next sentence of the  
 04:27 22 Yanni '034 patent at column 1, line 63. The Yanni '034 patent  
 04:27 23 teaches that relatively high concentrations of  
 04:28 24 benzoylphenylacetic acids are often needed to achieve corneal  
 04:28 25 penetration rates sufficient to provide effective intraocular  
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04:28 1 drug concentrations, correct?  
 04:28 2 **A. That is correct.**  
 04:28 3 **Q.** Let me direct your attention to the next sentence of the  
 04:28 4 Yanni '034 patent at column 1, line 66. The Yanni '034 patent  
 04:28 5 teaches that such high drug concentrations are generally not  
 04:28 6 desirable as they may provoke ocular irritation and  
 04:28 7 discomfort, correct?  
 04:28 8 **A. I see that.**  
 04:28 9 **Q.** Let me direct your attention to column 14, lines 42  
 04:28 10 through 45 of the Yanni '034 patent. The Yanni '034 patent  
 04:28 11 states that although the in vitro potency was clearly enhanced  
 04:28 12 by halogenation of the 4-position of the benzoyl ring of the  
 04:29 13 2-amino-3-benzoylbenzeneacetic acid, there was little evidence  
 04:29 14 for such a structure related effect in vivo. Do you see that?  
 04:29 15 **A. That is correct, and the reason for my comments about**  
 04:29 16 **bromfenac.**  
 04:29 17 **Q.** Bromfenac, in fact, is halogenated with a bromine atom at  
 04:29 18 the 4-position of the benzoyl ring of  
 04:29 19 2-amino-3-benzoylbenzeneacetic acid, correct?  
 04:29 20 **A. That is correct, and there is a reason for my comments**  
 04:29 21 **earlier about it showing some benefit in the same as for**  
 04:29 22 **others.**  
 04:29 23 **Q.** Let me direct your attention to the last paragraph in  
 04:29 24 column 14 of the Yanni '034 patent. The Yanni '034 patent  
 04:29 25 states, "Conversion of the free carboxylic acid functional

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04:29 1 group of bromfenac to an ethyl ester (compound 14) also  
 04:29 2 resulted in a greater than 3 orders of magnitude decline in in  
 04:30 3 vitro cyclooxygenase inhibitory activity. However, when  
 04:30 4 tested for topical ocular antiinflammatory activity, the ethyl  
 04:30 5 ester showed significant inhibitory activity by reducing  
 04:30 6 plasma protein extravasation into the aqueous humor by 60  
 04:30 7 percent." Do you see that?  
 04:30 8 **A. I'm hesitating to answer because, although I see that**  
 04:30 9 **wording, my understanding of the table is different.**  
 04:30 10 **Q.** I'm just asking you --  
 04:30 11 **A. The results in the table are different. It shows no real**  
 04:30 12 **difference in the table.**  
 04:30 13 **Q.** I'm just asking you if you see what the Yanni patent has  
 04:31 14 disclosed in column 14 starting at that bottom paragraph  
 04:31 15 starting at approximately line 55. Do you see that?  
 04:31 16 **A. I see that statement, yes.**  
 04:31 17 **Q.** The ethyl ester of bromfenac is a different chemical  
 04:31 18 compound from bromfenac, correct?  
 04:31 19 **A. That is correct, yes.**  
 04:31 20 **Q.** You would agree that the Yanni '034 patent describes  
 04:31 21 ophthalmic formulations of bromfenac derivatives and esters,  
 04:31 22 correct?  
 04:31 23 **A. Sorry. Could you repeat that?**  
 04:31 24 **Q.** Certainly. You would agree that the Yanni '034 patent  
 04:31 25 describes ophthalmic formulations of bromfenac derivatives and

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04:31 1 esters, correct?  
 04:31 2 **A. It gives some very simple formulations, but that's not**  
 04:31 3 **what the patent is directed to.**  
 04:31 4 **Q.** Okay. Let me direct you to your deposition transcript.  
 04:31 5 This is going to be the middle one, the February 16th  
 04:31 6 deposition transcript. And in particular, let me direct your  
 04:32 7 attention to page 239, line 3, through 239, line 12.  
 04:32 8 And I asked you, question, "Well, you state in your  
 04:32 9 declaration that in 1995 Yanni described an ophthalmic  
 04:32 10 formulation of bromfenac derivatives and esters. Do you see  
 04:32 11 that?"  
 04:32 12 And you answered, "Well, I thought there was something  
 04:32 13 I read in column 16. He gave example formulations. I'm  
 04:32 14 sorry. Whether -- the statement he described an ophthalmic  
 04:32 15 formulation of bromfenac derivatives and esters, I believe is  
 04:32 16 true. He talks about under 16, column 16."  
 04:32 17 That was your testimony, wasn't it, Doctor?  
 04:33 18 **A. Yes, and I'm sorry, I thought you just said the same**  
 04:33 19 **thing, sorry.**  
 04:33 20 **Q.** The claimed formulations of the '431 patent do not use  
 04:33 21 bromfenac derivatives and esters, do they?  
 04:33 22 **A. The claim formulations of '431 patent, no, they do not.**  
 04:33 23 **Q.** In your opinion, the Yanni '034 patent teaches that to  
 04:33 24 achieve penetration, high concentrations of bromfenac might be  
 04:33 25 needed, and the Yanni '034 patent uses this as a starting

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04:33 1 point for formulation with esters and amides, correct?  
 04:33 2 **A. They use that, yes, they use that for their starting**  
 04:33 3 **point, that's correct.**  
 04:33 4 **Q.** In fact, in your opinion, the Yanni '034 patent uses  
 04:33 5 bromfenac as a jumping off point to develop other drugs such  
 04:33 6 as amfenac formulations, correct?  
 04:33 7 **A. They use it to explore the preparation of other drugs.**  
 04:33 8 **Q.** Let's take a look at Table 1 of the Yanni '034 patent  
 04:34 9 which you discussed on direct exam. In particular, let me  
 04:34 10 direct your attention to the results in Table 1 of the in vivo  
 04:34 11 aqueous humor PGE2 accumulation assay, which are disclosed in  
 04:34 12 the second to last column. Bromfenac exhibited 98 percent  
 04:34 13 inhibition while compound number 7, compound number 8, and  
 04:34 14 compound number 9 also exhibited 98 percent inhibition in this  
 04:34 15 assay, and the 4-chloro amfenac compound exhibited 99 percent  
 04:34 16 inhibition in this assay, correct?  
 04:34 17 **A. Yes, I'd say they are all effective at inhibiting the**  
 04:34 18 **enzyme.**  
 04:34 19 **Q.** Looking at Table 1 of the Yanni '034 patent, let me  
 04:34 20 direct your attention to the results of the in vivo  
 04:34 21 paracentesis protein extravasation assay, which are disclosed  
 04:35 22 in the last column. Bromfenac exhibited 62 percent  
 04:35 23 inhibition, while compound number 16 also exhibited 62 percent  
 04:35 24 inhibition, compound number 15 exhibited 64 percent  
 04:35 25 inhibition, compound number 9 exhibited 65 percent inhibition,

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04:35 1 and the 4-chloro amfenac compound exhibited 72 percent  
 04:35 2 inhibition in this assay, correct?  
 04:35 3 **A. I see that, yes.**  
 04:35 4 **Q.** The Yanni '034 patent does not teach the use of  
 04:35 5 tyloxapol, correct?  
 04:35 6 **A. No, it does not.**  
 04:35 7 **Q.** Let me now direct your attention to the Hara reference,  
 04:35 8 which is DTX-110 in your binder. In particular, let me direct  
 04:35 9 your attention to the page bearing Bates number --  
 04:35 10 **A. 110, sorry.**  
 04:35 11 **Q.** Oh, I apologize. Let me know when you're there.  
 04:35 12 **A. I've got there now.**  
 04:35 13 **Q.** Let me direct your attention to the page bearing Bates  
 04:36 14 number PROL0079164, and specifically to the first sentence of  
 04:36 15 the last paragraph of the right-hand column beginning  
 04:36 16 "diclofenac sodium." You testified on direct exam about  
 04:36 17 various comparisons involving bromfenac in the Hara reference.  
 04:36 18 Do you remember that?  
 04:36 19 **A. Yes, I do.**  
 04:36 20 **Q.** The Hara reference explains that diclofenac shows  
 04:36 21 superior antiinflammatory efficacy following cataract surgery,  
 04:36 22 correct?  
 04:36 23 **A. You stated it was -- I'm sorry, please make the statement**  
 04:36 24 **again, because I'm trying to read and listen to what you say**  
 04:36 25 **at the same time.**

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04:38 1 **Q.** When you're there, I'll ask you the question again.  
 04:38 2 **A. Okay. Thank you.**  
 04:38 3 **Q.** The Hara reference discloses Bronuck ophthalmic solution,  
 04:38 4 correct?  
 04:38 5 **A. That is correct, yes.**  
 04:38 6 **Q.** Please look back at the last page of the Hara reference  
 04:38 7 bearing Bates number PROL0079165. Let me direct your  
 04:38 8 attention to the subheading Tips in using the drug, and in  
 04:38 9 particular to the first paragraph.  
 04:38 10 **A. Yes.**  
 04:38 11 **Q.** The Hara reference describes the Bronuck formulation as a  
 04:38 12 clear yellow solution, correct?  
 04:39 13 **A. That is -- I see that, yes.**  
 04:39 14 **Q.** The Hara reference nowhere mentions any precipitate or  
 04:39 15 cloudiness in the Bronuck formulation, correct?  
 04:39 16 **A. That is correct, yes.**  
 04:39 17 **Q.** The Hara reference does not teach the use of tyloxapol,  
 04:39 18 correct?  
 04:39 19 **A. That is correct. It's looking at the evaluation of the**  
 04:39 20 **drug.**  
 04:39 21 **Q.** Okay. Let's now discuss your opinions on the category B  
 04:39 22 references you cited referring to benzalkonium chloride.  
 04:39 23 First let's turn to the Desai '929 patent which is JTX-061 in  
 04:39 24 your binder. Let me know when you're there.  
 04:39 25 **A. I've got there.**

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04:36 1 **Q.** Certainly. Take a look at that first sentence and tell  
 04:36 2 me when you're ready.  
 04:36 3 **A. Could you ask the question?**  
 04:36 4 **Q.** Certainly. The Hara reference explains that diclofenac  
 04:36 5 shows superior antiinflammatory efficacy following cataract  
 04:37 6 surgery, correct?  
 04:37 7 **A. I think it's a little bit more specific than that.**  
 04:37 8 **Q.** In what way?  
 04:37 9 **A. It suggests that it's treating anterior ocular segment**  
 04:37 10 **information following cataract surgery, that's all.**  
 04:37 11 **Q.** Let me direct your attention to the next page bearing  
 04:37 12 Bates number PROL0079165, and in particular to the top  
 04:37 13 paragraph of the right-hand column. The Hara reference warns  
 04:37 14 that based on deaths from oral administration of bromfenac  
 04:37 15 sodium, that the drug is meant to be used for less than one  
 04:37 16 month, correct?  
 04:37 17 **A. I see that, yes.**  
 04:37 18 **Q.** Please look at the previous page of the Hara reference,  
 04:37 19 again bearing Bates number PROL0079164, and let me direct your  
 04:37 20 attention to the upper portion of the left-hand column. The  
 04:38 21 Hara reference discloses Bronuck ophthalmic solution, correct?  
 04:38 22 **A. Sorry. I'm lost where you're directing me.**  
 04:38 23 **Q.** I apologize. It might be easier to look on the screen.  
 04:38 24 You can look right underneath the box.  
 04:38 25 **A. Okay.**

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04:39 1 **Q.** The only two nonsteroidal antiinflammatory drugs  
 04:39 2 exemplified in the Desai '929 patent are sodium diclofenac and  
 04:40 3 suprofen, correct?  
 04:40 4 **A. That is correct. While that's correct, it does specify**  
 04:40 5 **bromfenac in the detailed description of the invention.**  
 04:40 6 **Q.** Let's take a look at your deposition transcript, and in  
 04:40 7 particular, the February 29th, the third one. In that  
 04:40 8 transcript let's take a look at page 103, and in particular  
 04:40 9 lines 2 through 10.  
 04:40 10 I asked you, question, "What are the two nonsteroidal  
 04:40 11 antiinflammatory drugs exemplified in the Desai patent?"  
 04:40 12 You answered, "Sodium diclofenac and sodium suprofen I  
 04:40 13 think it's meant to be. It's a mistake, though, it's a  
 04:40 14 spelling mistake. My eyes --"  
 04:40 15 And then I asked you, question, "Are they sodium  
 04:40 16 diclofenac and suprofen?"  
 04:40 17 And you answered, "Yes."  
 04:41 18 That was your testimony, correct?  
 04:41 19 **A. Exemplified, yes.**  
 04:41 20 **Q.** The only nonionic surfactant exemplified in the Desai  
 04:41 21 '929 patent for which data are provided is vitamin E TPGS,  
 04:41 22 correct? Do you need me to repeat the question, Doctor?  
 04:41 23 **A. No, no. Again, my answer is the same, yes, it is the**  
 04:41 24 **only one exemplified, but it is mentioned in the detailed**  
 04:41 25 **description of the invention.**

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- 04:41 1 Q. The Desai '929 patent does not teach the use of tyloxapol  
04:41 2 in any specific example formulation, correct?  
04:41 3 A. **Not in an example formulation, no.**  
04:41 4 Q. The Desai '929 patent does not disclose any data for any  
04:41 5 formulations containing benzalkonium chloride, correct?  
04:42 6 A. **That is correct, yes.**  
04:42 7 Q. In fact, the Desai '929 patent teaches that the most  
04:42 8 preferred polymeric quaternary ammonium compound is  
04:42 9 polyquaternium 1, correct?  
04:42 10 A. **That's what the patent is directed towards, yes.**  
04:42 11 Q. You are not familiar with the chemical structure of  
04:42 12 Polyquad, such as polyquaternium 1, correct?  
04:42 13 A. **I didn't remember the precise structure, no.**  
04:42 14 Q. The Desai '929 patent discloses, in your opinion, storage  
04:42 15 stable preserved ophthalmic compositions, correct?  
04:42 16 A. **That is correct, yes.**  
04:42 17 Q. The formulations disclosed in the Desai '929 patent, in  
04:42 18 fact, did not have any stability problems, correct?  
04:42 19 A. **Sorry.**  
04:42 20 Q. The formulations disclosed in the Desai '929 patent, in  
04:42 21 fact, did not have any stability problems, correct?  
04:42 22 A. **That's my reading in the patent, yes.**  
04:43 23 Q. Claims 6 and 20 of the '431 patent specify benzalkonium  
04:43 24 chloride as the only permissible quaternary ammonium compound,  
04:43 25 correct?

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- 04:45 1 Q. The Wong reference teaches lauralkonium chloride,  
04:45 2 correct?  
04:45 3 A. **Which is a component of benzalkonium chloride, yes.**  
04:45 4 Q. The approach that the Wong reference took is different  
04:45 5 from the approach that the inventors of the '431 patent took  
04:45 6 when formulating the claimed aqueous liquid preparations of  
04:45 7 that patent, correct?  
04:45 8 A. **Yes, it is.**  
04:46 9 Q. Turn, if you would, to the Remington reference, which is  
04:46 10 DTX-015 in your binder, and actually this is a portion of the  
04:46 11 Remington reference about which you testified on direct exam,  
04:46 12 correct?  
04:46 13 A. **Just one moment, please.**  
04:46 14 Q. Certainly.  
04:46 15 A. **Yes, it is.**  
04:46 16 Q. Let me direct your attention to the page bearing Bates  
04:46 17 number DTX-015.5.  
04:46 18 A. **Yes.**  
04:46 19 Q. In particular, let me direct your attention to the last  
04:46 20 sentence of the paragraph beginning with the subheading  
04:46 21 Quaternary Ammonium Compounds. It states, "Given the  
04:46 22 alternative, it would be preferable to modify a formulation to  
04:47 23 remove the incompatibility, rather than include a compatible  
04:47 24 but less effective preservative." You testified about this  
04:47 25 sentence on direct exam. Do you remember that?

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- 04:43 1 A. **That is correct, yes.**  
04:43 2 Q. Let's now discuss the Desai '876 patent which is JTX-201  
04:43 3 in your binder.  
04:43 4 A. **Okay.**  
04:43 5 Q. Are you there?  
04:43 6 A. **Yes, I am.**  
04:43 7 Q. The Desai '876 patent does not teach the use of  
04:43 8 tyloxapol, correct?  
04:43 9 A. **That is correct, yes.**  
04:43 10 Q. The Desai '876 patent uses vitamin E or vitamin E TPGS as  
04:44 11 a surfactant, correct?  
04:44 12 A. **Yes, in combination with caffeine, yes.**  
04:44 13 Q. The formulations disclosed in the Desai '876 patent did  
04:44 14 not have any stability problems, correct?  
04:44 15 A. **That is my understanding of the patent, yes.**  
04:44 16 Q. Let's now discuss the Wong reference, which is JTX-207 in  
04:44 17 your binder. Let me know when you're there.  
04:44 18 A. **I'm there.**  
04:44 19 Q. The Wong reference teaches the use of flurbiprofen and  
04:44 20 does not teach the use of bromfenac, correct?  
04:44 21 A. **Specifically, it teaches flurbiprofen, although it's**  
04:45 22 **directed towards nonsteroidal antiinflammatories.**  
04:45 23 Q. The Wong reference does not teach the use of tyloxapol,  
04:45 24 correct?  
04:45 25 A. **No, it does not teach the use of tyloxapol.**

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- 04:47 1 A. **Yes, I do.**  
04:47 2 Q. In fact, you would agree that an aqueous liquid  
04:47 3 preparation of bromfenac could have sufficient preservative  
04:47 4 efficacy as an eyedrop without containing benzalkonium  
04:47 5 chloride if it contained a different preservative, correct?  
04:47 6 A. **I'd like to see where I said that, please.**  
04:47 7 Q. Take a look, if you would, at your first deposition  
04:47 8 transcript, the September 4th transcript, and in particular  
04:47 9 let me direct your attention to page 132, line 17, through  
04:47 10 133, Line 2.  
04:47 11 And I asked you, question, "My question is a little  
04:48 12 different. Could an aqueous liquid preparation of bromfenac  
04:48 13 have sufficient preservative efficacy as an eyedrop without  
04:48 14 containing benzalkonium chloride?"  
04:48 15 Then there was an objection.  
04:48 16 And you answered, "The simple answer, which sounds a  
04:48 17 bit facetious, is if you had a different preservative, of  
04:48 18 course."  
04:48 19 That was your testimony, wasn't it, Doctor?  
04:48 20 A. **I can't find that. Sorry.**  
04:48 21 Q. It's page 132.  
04:48 22 A. **Okay. Right. Okay.**  
04:48 23 Q. I'll ask it again. 132, line 17, tell me when you're  
04:48 24 there.  
04:49 25 So I asked you a question. My question is a little

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04:49 1 different. Could an aqueous liquid preparation of bromfenac  
 04:49 2 have sufficient preservative efficacy as an eye drop without  
 04:49 3 containing benzalkonium chloride? There was an objection, and  
 04:49 4 you answered: The simple answer, which sounds a bit  
 04:49 5 facetious, is if you had a different preservative, of course.  
 04:49 6 That was your testimony, wasn't it, Doctor?  
 04:49 7 **A. While that statement is correct, it would be an**  
 04:49 8 **un-preferred -- it wouldn't be the preferred solution to the**  
 04:49 9 **problem.**  
 04:49 10 **Q.** You never qualified your testimony at your deposition,  
 04:49 11 did you, Doctor?  
 04:49 12 **A. I wouldn't have to look back now at everything to check**  
 04:49 13 **that.**  
 04:49 14 **Q.** You don't remember qualifying your testimony?  
 04:49 15 **A. Not without reading the text.**  
 04:49 16 **Q.** Let's now discuss the category C references you cited  
 04:50 17 discussing certain surfactants. First, let's turn to the  
 04:50 18 Sallmann '913 patent, which is JTX-071 in your binder.  
 04:50 19 **A. Yes, I'm there.**  
 04:50 20 **Q.** The Sallmann '913 patent, in your opinion, does not show  
 04:50 21 any real data from anything, correct?  
 04:50 22 **A. It shows no real data from anywhere.**  
 04:50 23 **Q.** Yet you would admit that every formulator would rely on  
 04:50 24 biological data in making formulation decisions, correct?  
 04:50 25 **A. Biological data is important in deciding which particular**

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04:52 1 And you said: I believe every formulator will be aware  
 04:52 2 of certain biological data when they are formulated, yes.  
 04:52 3 That was your testimony, wasn't it, Doctor?  
 04:52 4 **A. While that statement is correct and I stand by it, I**  
 04:52 5 **think it's being taken -- I think it's being misunderstood.**  
 04:52 6 **You wouldn't formulate an un -- biological data in a**  
 04:52 7 **formulation patent.**  
 04:52 8 **Q.** You never qualified your testimony at your deposition,  
 04:52 9 did you, Doctor?  
 04:52 10 **A. I didn't believe it would be used like this.**  
 04:52 11 **Q.** You would admit that every formulator would rely on  
 04:52 12 chemical stability data in making formulation decisions,  
 04:52 13 correct?  
 04:52 14 **A. Of course. They would want a stable formulation.**  
 04:52 15 **Q.** You would admit that every formulator would rely on  
 04:52 16 physical stability data in making formulation decisions,  
 04:52 17 correct?  
 04:52 18 **A. Again, if they want a stable formulation, yes.**  
 04:53 19 **Q.** The Sallmann '913 patent does not teach the use of  
 04:53 20 bromfenac, correct?  
 04:53 21 **A. No, it's directed towards a related nonsteroidal**  
 04:53 22 **anti-inflammatory.**  
 04:53 23 **Q.** The Sallmann '913 patent discloses the superiority of  
 04:53 24 diclofenac potassium over diclofenac sodium, correct?  
 04:53 25 **A. Can you direct me to where it says that?**

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04:50 1 **drug to formulate, and once that decision is made, you would**  
 04:50 2 **not then expect a pattern of formulations of biological data.**  
 04:51 3 **Q.** Take a look, if you would, at your February 29th  
 04:51 4 deposition transcript, and in particular, Page 41, Line 6,  
 04:51 5 through 13. Are you there?  
 04:51 6 **A. Yes.**  
 04:51 7 **Q.** I asked you a question --  
 04:51 8 MS. RAPALINO: I have an objection. I'm just going  
 04:51 9 to make a completeness objection. This line of questioning  
 04:51 10 goes on through the bottom of Page 41.  
 04:51 11 MR. HASFORD: We will get to those remaining  
 04:51 12 questions.  
 04:51 13 MS. RAPALINO: I'm sorry, but I'm just asking that  
 04:51 14 they -- for completeness for this question, that he show the  
 04:51 15 rest of it, of the transcript through Page 41.  
 04:51 16 MR. HASFORD: Your Honor, if I may, I intend to ask  
 04:51 17 her about whether a formulator will rely on chemical and  
 04:51 18 physical stability data, that's what it goes to, and we will  
 04:51 19 go there if there is a need.  
 04:52 20 THE COURT: Okay. That's fine.  
 04:52 21 BY MR. HASFORD:  
 04:52 22 **Q.** I asked you a question: Have you ever relied on  
 04:52 23 biological data in making formulation decisions?  
 04:52 24 Then there was an objection, and I said: You may  
 04:52 25 answer.

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04:53 1 **Q.** Actually, let me direct you to your deposition testimony  
 04:53 2 where you testified about this. In particular, it's in your  
 04:53 3 February 16th transcript, and actually --  
 04:53 4 **A. I only want to see where it was in the patent.**  
 04:53 5 **Q.** Well, first, first, let me direct you to --  
 04:53 6 MS. RAPALINO: I'm sorry, is he withdrawing -- are  
 04:53 7 you withdrawing your previous question?  
 04:53 8 BY MR. HASFORD:  
 04:53 9 **Q.** Well, actually, let me withdraw my previous question.  
 04:53 10 I'm going to re-ask the earlier setup question.  
 04:54 11 Doctor, the Sallmann '913 patent does not teach the use  
 04:54 12 of bromfenac, correct?  
 04:54 13 **A. That is correct. It is related to nonsteroidals.**  
 04:54 14 **Q.** Okay. The Sallmann '913 patent discloses the superiority  
 04:54 15 of diclofenac potassium over diclofenac sodium, correct?  
 04:54 16 MS. RAPALINO: I'm just going to object. I think  
 04:54 17 that Professor Lawrence asked it to be pointed to that  
 04:54 18 statement in the patent in response to this question when it  
 04:54 19 was previously asked.  
 04:54 20 MR. HASFORD: Well, the statement is in her  
 04:54 21 deposition transcript. She's welcome to review as much of the  
 04:54 22 patent as she needs.  
 04:54 23 MS. RAPALINO: I don't think the question was about  
 04:54 24 the deposition transcript, it was about the '913 patent.  
 04:54 25 MR. HASFORD: The deposition testimony, I would

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04:54 1 represent to Your Honor, will support the answer that I'm  
 04:54 2 seeking from her.  
 04:54 3 THE COURT: Well, the pending question is whether the  
 04:54 4 '913 patent supports the use of -- or discloses the use of  
 04:54 5 bromfenac.  
 04:54 6 MR. HASFORD: Well, the pending question now, she  
 04:54 7 confirmed that it does not teach the use of bromfenac. The  
 04:55 8 pending question now is the Sallmann '913 patent discloses the  
 04:55 9 superiority of diclofenac potassium over diclofenac sodium,  
 04:55 10 correct?  
 04:55 11 THE COURT: All right. And so Dr Lawrence may answer  
 04:55 12 it based on the patent.  
 04:56 13 A. **There was a statement that has been demonstrated that,**  
 04:56 14 **for example, the ocular penetration of diclofenac potassium is**  
 04:56 15 **much superior in comparison to the corresponding diclofenac**  
 04:56 16 **sodium.**  
 04:56 17 Q. Let me direct your attention to the claims of the  
 04:56 18 Sallmann '913 patent. All of the claims of the Sallmann '913  
 04:57 19 patent are directed to formulations of diclofenac potassium,  
 04:57 20 correct?  
 04:57 21 A. **It states that, yes.**  
 04:57 22 Q. Potassium salts and sodium salts are different salts,  
 04:57 23 correct?  
 04:57 24 A. **They are different salts, correct.**  
 04:57 25 Q. You testified on direct exam about Example 15 of the

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04:59 1 Sallmann '913 patent. Are you there?  
 04:59 2 A. **I am there, yes.**  
 04:59 3 Q. The Sallmann '913 patent teaches the use of tyloxapol as  
 04:59 4 a solubilizer, not a stabilizer, correct?  
 04:59 5 A. **It uses the word "solubilizer," yes.**  
 04:59 6 Q. The approach that the Sallmann '913 patent took is  
 04:59 7 different from the approach that the inventors of the '431  
 05:00 8 patent took, when formulating the claimed aqueous liquid  
 05:00 9 preparations of that patent, correct?  
 05:00 10 A. **In the -- I can see they've used different excipients to**  
 05:00 11 **solve the problem, yes.**  
 05:00 12 Q. Let's now turn to the Fu EP '984 reference?  
 05:00 13 A. **Which is where, please?**  
 05:00 14 Q. We're looking for the exhibit number. I apologize. It's  
 05:00 15 JTX-209 in your binder.  
 05:00 16 A. **Okay.**  
 05:01 17 Q. In particular, let me direct your attention to Example 5,  
 05:01 18 about which you testified on direct exam. Specifically, I'd  
 05:01 19 like to direct your attention in Example 5 to the first  
 05:01 20 sentence, which begins, physical stability. Are you there?  
 05:01 21 A. **I am there, yes.**  
 05:01 22 Q. The Fu reference teaches physical stability not  
 05:01 23 overcoming chemical degradation, correct?  
 05:01 24 A. **This is -- this is dealing with physical stability, yes.**  
 05:01 25 Q. You would agree that the two different stability issues

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04:57 1 Sallmann '913 patent. Let's take a look at it. Example 15 of  
 04:57 2 the Sallmann '913 patent discloses a formulation of diclofenac  
 04:57 3 potassium, correct?  
 04:57 4 A. **That is correct, yes.**  
 04:57 5 Q. The Sallmann '913 patent provides many other examples  
 04:57 6 besides Example 15, correct?  
 04:57 7 A. **It contains a good number of examples, yes.**  
 04:58 8 Q. Let me direct your attention to Column 5, Lines 39  
 04:58 9 through 40 of the Sallmann '913 patent.  
 04:58 10 A. **Column 5?**  
 04:58 11 Q. Column 5, Lines 39 through 40, where it begins:  
 04:58 12 Preferred preservatives.  
 04:58 13 A. **Yes, I can see that.**  
 04:58 14 Q. The Sallmann '913 patent names cetrimide, benzalkonium  
 04:58 15 chloride, benzoxonium chloride, and parabens as preferred  
 04:58 16 preservatives with none being especially preferred, correct?  
 04:58 17 A. **In the section you've highlighted, I agree.**  
 04:58 18 Q. Let me direct your attention to Column 5, Lines 62  
 04:58 19 through 63 of the Sallmann '913 patent. Let me know when  
 04:59 20 you're there.  
 04:59 21 A. **Yes, go on.**  
 04:59 22 Q. The Sallmann '913 patent teaches cyclodextrin as a  
 04:59 23 stabilizer, correct?  
 04:59 24 A. **Such as, yes.**  
 04:59 25 Q. Let me direct your attention to Column 4, Line 64 of the

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05:01 1 described in the Ogawa '225 patent and the Fu EP 984 reference  
 05:01 2 are two different problems, and a person of ordinary skill in  
 05:01 3 the art would not conflate them, correct?  
 05:02 4 A. **Chemical stability is obviously different than physical**  
 05:02 5 **stability, that's correct, yes.**  
 05:02 6 Q. The Fu EP 984 reference discusses one specific example of  
 05:02 7 an NSAID, which is ketorolac tromethamine, not bromfenac,  
 05:02 8 correct?  
 05:02 9 A. **But the patent is directed towards nonsteroidal**  
 05:02 10 **anti-inflammatories, but yes, the examples only mention**  
 05:02 11 **ketorolac.**  
 05:02 12 Q. The most preferred nonionic surfactant used in the EP 984  
 05:02 13 Fu reference is Octoxynol 40, correct?  
 05:03 14 A. **I think it actually says preferred example, but they do**  
 05:03 15 **say the preferred surfactant is Octoxynol 40.**  
 05:03 16 Q. Octoxynol 40 and tyloxapol are different chemical  
 05:03 17 compounds, correct?  
 05:03 18 A. **That is correct, but they belong to the same class of**  
 05:03 19 **compounds.**  
 05:03 20 Q. Let's take a look at your deposition transcript.  
 05:03 21 February 16th, and in particular, Page 159, Line 21, through  
 05:04 22 160, Line 2. I asked you:  
 05:04 23 Question: Octoxynol 40 and tyloxapol are not  
 05:04 24 identical, correct?  
 05:04 25 And there was an objection, and you answered: They're

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05:04 1 not identical.

05:04 2 That was your testimony, wasn't it, Doctor?

05:04 3 MS. RAPALINO: Objection. Improper impeachment, and

05:04 4 her testimony is entirely consistent here.

05:04 5 THE COURT: Sustained. It's not inconsistent.

6 BY MR. HASFORD:

05:04 7 Q. Let's now turn to Example 5 again of the Fu EP 984

05:04 8 reference. Example 5 of the Fu EP 984 reference discloses six

05:04 9 ketorolac formulations, correct?

05:04 10 A. Yes, that is correct.

05:04 11 Q. The ketorolac formulations of Example 5 of the Fu EP 984

05:04 12 reference contain Octoxynol 40, polysorbate 80 or Merge 52,

05:04 13 correct?

05:04 14 A. I see that, yes.

05:04 15 Q. The Fu EP 984 reference does not disclose the pH of the

05:04 16 formulations of Example 5, correct?

05:05 17 A. Well, the Fu reference doesn't disclose the pH. All the

05:05 18 other examples are adjusted to pH 7.4 plus or minus .4. So

05:05 19 you would expect possibly.

05:05 20 Q. Well, let's take a look at your February 29th deposition

05:05 21 transcript, and in particular, Page 96, Line 6 through 14.

05:05 22 And I asked you --

05:05 23 MS. RAPALINO: Again, Your Honor, I'm just going to

05:05 24 object as improper impeachment, as with most of these, is her

05:05 25 testimony here is entirely consistent with what she said at

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05:05 1 the deposition.

05:05 2 MR. HASFORD: Well, this testimony is not entirely

05:06 3 consistent at all, Your Honor. She just testified that it

05:06 4 would be possible to tell, and at her deposition she testified

05:06 5 that it would not be possible to tell. I think the transcript

05:06 6 will show that.

05:06 7 MS. RAPALINO: I believe that's a mischaracterization

05:06 8 of her testimony here. And again, she testified that it

05:06 9 doesn't disclose the pH but all other examples are adjusted to

05:06 10 pH 7.4 plus or minus .4, so you would expect possibly.

05:06 11 MR. HASFORD: And she certainly didn't --

05:06 12 THE COURT: It's possibly inconsistent.

13 BY MR. HASFORD:

05:06 14 Q. Doctor, I asked you:

05:06 15 Question: Do the formulations of Example 5 of the FU

05:06 16 EP 984 reference have the same pH as all of the claimed

05:06 17 formulations of the patents-in-suit?

05:06 18 And there was an objection, and then you answered: It

05:06 19 is not possible to tell what the pH of the formulations are,

05:06 20 because it's not recorded in the table.

05:06 21 That was your testimony, wasn't it, Doctor?

05:06 22 MS. RAPALINO: Objection. Right now, the claims at

05:06 23 issue in the patents-in-suit have no pH limitations, and so

05:06 24 this testimony has no relevance to the claims that are at

05:07 25 issue and is not directed to the same topic that counsel is

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05:07 1 asking about here today, which are claims 6 and 20, with no pH

05:07 2 limitations.

05:07 3 MR. HASFORD: The question is still highly relevant,

05:07 4 Your Honor. As Mr. Lipsey explained in opening, the

05:07 5 compositions and their properties are one and the same

05:07 6 according to controlling Federal Circuit precedent and it goes

05:07 7 towards her opinions as to Fu.

05:07 8 THE COURT: Yeah, I'm not prepared to rule out pH as

05:07 9 being a relevant property here.

05:07 10 MS. RAPALINO: It's not so much that the pH is

05:07 11 irrelevant in this case. It's that the question that he's

05:07 12 attempting to impeach with, refers to the pH of the claims and

05:07 13 there is no claim -- there are no pH limitations in the claims

05:07 14 that Professor Lawrence is testifying about today.

05:07 15 THE COURT: Oh, okay. That's different.

05:07 16 MR. HASFORD: Notwithstanding the question itself

05:07 17 referred to the pH of the claims, Your Honor, she's -- the

05:07 18 question itself went to the pH of the formulations of Example

05:07 19 5 in Fu, and that's exactly what her testimony went to. So

05:07 20 that question would be applicable whether it specified the

05:07 21 claims of the patents-in-suit or not.

05:07 22 THE COURT: No, the question has become irrelevant,

05:07 23 the deposition question, because it's indexing it to the same

05:08 24 pH as all of the claimed formulations of the patents-in-suit,

05:08 25 and we're down to two claims with no pH limitations. So I'll

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05:08 1 sustain the objection.

05:08 2 I'm sorry, I didn't understand it the first time.

05:08 3 MR. HASFORD: Let's now turn --

05:08 4 THE COURT: I'm sorry, let me explain one thing.

05:08 5 Maybe it's obvious. I'm not saying pH has somehow become

05:08 6 irrelevant in the case. I'm just saying this particular

05:08 7 question, which refers to pH, is in the claimed formulations

05:08 8 that are in suit has become irrelevant.

05:08 9 MR. HASFORD: I understand, Your Honor, certainly.

05:08 10 THE COURT: Okay.

05:08 11 BY MR. HASFORD:

05:08 12 Q. Let's now turn to the Schott reference, which is JTX-199

05:09 13 in your binder. In particular, let me direct your attention

05:09 14 to the conclusions section on JTX-199.6 about what you

05:09 15 testified on direct exam. Specifically, let me direct your

05:09 16 attention to the first paragraph, and in particular, to the

05:09 17 first sentence, where the Schott reference states that it is

05:09 18 discussing stabilizing emulsions, suspensions, ointments and

05:09 19 foams. Do you see that?

05:09 20 A. I see that, yes.

05:09 21 Q. Emulsions, suspensions, ointments and foams are different

05:09 22 from solutions, such as the aqueous liquid preparations of the

05:09 23 '431 patent, correct?

05:09 24 A. That is correct, yes.

05:10 25 Q. The Schott reference does not teach Octoxynol 40,

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05:10 1 correct?

05:10 2 **A. It doesn't deal with Octoxynol 40, no.**

05:10 3 **Q.** And you can put the Schott reference aside.

05:10 4 I'd like to direct your attention now to DTX-196 in

05:10 5 your binder, about what you testified on direct exam. And in

05:10 6 particular, let me direct your attention to the Page

05:10 7 DTX-196.93. Let me direct your attention to the entry for

05:11 8 Octoxynol 40, ophthalmic solution. Do you see that?

05:11 9 **A. I see that, yes.**

05:11 10 **Q.** As of the date of DTX-196, only one ophthalmic solution

05:11 11 containing Octoxynol 40 had been approved by the FDA, correct?

05:11 12 **A. There was only one formulation listed in the active**

05:11 13 **ingredients list of this date, that is correct.**

05:11 14 **Q.** As of the date of DTX-196, the only ophthalmic solution

05:11 15 containing Octoxynol 40 that had been approved by the FDA was

05:11 16 Acular, correct?

05:11 17 **A. I don't have the composition of Acular in front of me, so**

05:11 18 **I can't confirm that.**

05:11 19 **Q.** Let's turn now to DTX-196.158. And let me direct your

05:12 20 attention to the entry for tyloxapol ophthalmic solution

05:12 21 toward the bottom of that page. Do you see that?

05:12 22 **A. I see that, yes.**

05:12 23 **Q.** None of the ophthalmic solution formulations containing

05:12 24 tyloxapol that are identified in DTX-196 is an ophthalmic

05:12 25 NSAID, correct?

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05:14 1 **Q.** In fact, you have relied on the 2000 edition of the

05:14 2 *Handbook of Pharmaceutical Excipients* in connection with your

05:14 3 opinions in this case, correct?

05:14 4 **A. That is correct, yes.**

05:14 5 **Q.** In 2003, a person of ordinary skill in the art would have

05:14 6 considered the *Handbook of Pharmaceutical Excipients* an

05:14 7 important reference for formulating an aqueous liquid

05:14 8 preparation, correct?

05:14 9 **A. That would have been one of the reference sources. There**

05:14 10 **are others, obviously.**

05:14 11 **Q.** In fact, in 2003, a person of ordinary skill in the art

05:14 12 definitely would have looked to the *Handbook of Pharmaceutical*

05:14 13 *Excipients* when formulating an aqueous liquid preparation,

05:14 14 correct?

05:14 15 **A. As I've said, it's definitely one of the books they would**

05:14 16 **have used, be one of them.**

05:14 17 **Q.** You, in fact, have written monographs in the *Handbook of*

05:14 18 *Pharmaceutical Excipients* on surfactants, correct?

05:14 19 **A. That is correct, yes.**

05:14 20 **Q.** The 2000 edition of the *Handbook of Pharmaceutical*

05:14 21 *Excipients* nowhere discloses tyloxapol, correct?

05:14 22 **A. That is correct, yes.**

05:14 23 **Q.** The 2000 edition of the *Handbook of Pharmaceutical*

05:14 24 *Excipients* nowhere discloses any Octoxynol, correct?

05:15 25 **A. That is correct.**

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05:12 1 **A. I don't have the information to be able to answer that**

05:12 2 **question.**

05:12 3 **Q.** Let's take a look at the right-hand column that says

05:12 4 potency range. Do you remember testifying about those entries

05:12 5 for tyloxapol ophthalmic solution on direct exam?

05:12 6 **A. I do.**

05:12 7 **Q.** The potency range for tyloxapol in the ophthalmic

05:13 8 solutions identified in DTX-196 is a potency range, not a

05:13 9 toxicity range, correct?

05:13 10 **A. It's the range of concentrations at which that excipient**

05:13 11 **is used in the formulations.**

05:13 12 **Q.** You may put that document aside.

05:13 13 You testified on direct exam that Remington's is, in

05:13 14 your words, the Bible. Do you remember that?

05:13 15 **A. For pharmaceutical formulators.**

05:13 16 **Q.** You also acknowledged that a formulator, as of 2003,

05:13 17 would have looked to a different handbook, the *Handbook of*

05:13 18 *Pharmaceutical Excipients*, correct?

05:13 19 **A. That's one of the reference sources they would have used,**

05:13 20 **correct.**

05:13 21 **Q.** You are aware, in fact, that the third edition of the

05:13 22 *Handbook of Pharmaceutical Excipients* published in 2000,

05:13 23 correct?

05:13 24 **A. I believe it will be the third edition. I don't know.**

05:14 25 **Can't remember.**

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05:15 1 **Q.** Let's discuss your opinions on obviousness-type double

05:15 2 patenting. Do you remember testifying about that on direct

05:15 3 exam?

05:15 4 **A. Yes, I do.**

05:15 5 **Q.** Let's bring up DDX-220 on the screen.

05:15 6 You testified that Claim 6 and 20 of the '431 patent

05:15 7 are, in your opinion, obvious over Claims 7 of the '290 patent

05:15 8 and Claim 6 of the '131 patent, correct?

05:15 9 **A. Yes, I did.**

05:15 10 **Q.** Let's bring up DDX-280, if we could. 8-0.

05:16 11 Claim 7 of the '290 patent and Claim 6 of the '131

05:16 12 patent both include the phrase "consisting essentially of,"

05:16 13 correct?

05:16 14 **A. That is correct.**

05:16 15 **Q.** You understand that the phrase "consisting essentially

05:16 16 of" means that Claim 7 of the '290 patent and Claim 6 of the

05:16 17 '131 patent are open to additional un-recited elements, so

05:16 18 long as they do not affect the basic and novel properties of

05:16 19 the claimed aqueous liquid preparations, correct?

05:16 20 **A. That's my understanding, yes.**

05:16 21 **Q.** You do not know, however, whether the aqueous liquid

05:16 22 preparations of Claim 7 of the '290 patent and Claim 6 of the

05:16 23 '131 patent could include other quaternary ammonium

05:16 24 preservatives besides benzalkonium chloride, correct?

05:16 25 **A. Sorry, could you slow down when you say that, please.**

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05:17 1 Q. Certainly. You do not know whether the aqueous liquid  
 05:17 2 preparations of Claim 7 of the '290 patent and Claim 6 of the  
 05:17 3 '131 patent could include other quaternary ammonium  
 05:17 4 preservatives besides benzalkonium chloride, correct?  
 05:17 5 A. I don't understand what you mean by the way you phrased  
 05:17 6 the question.  
 05:17 7 MS. RAPALINO: I'm just going to object in that it's  
 05:17 8 compound and it's a complicated question, and if he could just  
 05:17 9 break that down and perhaps direct the witness to the claims  
 05:17 10 you're referring to.  
 05:17 11 MR. HASFORD: Certainly. Yeah, I can direct the  
 05:17 12 claims.  
 05:17 13 BY MR. HASFORD:  
 05:17 14 Q. So let's look at -- let's look at Claim 7 of the '290  
 05:17 15 patent, and you see the phrase "consisting essentially of"  
 05:17 16 there. Do you see that?  
 05:17 17 A. Yes, I do.  
 05:17 18 Q. And you testified that it's your understanding that the  
 05:17 19 phrase "consisting essentially of" means that Claim 7 of the  
 05:17 20 '290 patent is open to additional un-recited elements, so long  
 05:17 21 as they do not materially affect the basic and novel  
 05:18 22 properties of the claimed aqueous liquid preparations,  
 05:18 23 correct?  
 05:18 24 A. Yes, I did.  
 05:18 25 Q. You do not know, however, whether the aqueous liquid

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05:19 1 phrase, "consisting essentially of." Do you see that?  
 05:19 2 A. I see that, yes.  
 05:19 3 Q. Could the aqueous liquid preparation of Claim 6 of the  
 05:19 4 '131 patent include other quaternary ammonium compounds  
 05:19 5 besides benzalkonium chloride?  
 05:19 6 A. It's my understanding that they could, as long as it  
 05:19 7 didn't affect -- materially affect the basic and novel  
 05:20 8 characteristics of the formulation.  
 05:20 9 Q. Thank you, Doctor.  
 05:20 10 Let's switch gears here.  
 05:20 11 MR. HASFORD: Actually, would this be a good time for  
 05:20 12 a break, Your Honor?  
 05:20 13 THE COURT: Sure. Okay. Let's take about a  
 05:20 14 10-minute break.  
 05:20 15 (RECESS TAKEN; 2:51 p.m.)  
 05:20 16 THE DEPUTY CLERK: All rise.  
 05:35 17 (OPEN COURT; 3:06 p.m.)  
 05:35 18 THE COURT: Be seated, please. Are we ready to  
 05:35 19 continue?  
 05:35 20 MR. HASFORD: Yes, Your Honor. I will be passing up  
 05:35 21 one exhibit. I want to revisit the witness's testimony with  
 05:35 22 respect to DTX-196, Your Honor. May I approach?  
 05:35 23 THE COURT: Yes.  
 05:35 24 MR. HASFORD: Thank you.  
 05:35 25 THE COURT: You're welcome.

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05:18 1 preparation of Claim 7 of the '290 patent could include other  
 05:18 2 quaternary ammonium compounds besides benzalkonium chloride  
 05:18 3 that is recited in that claim, correct?  
 05:18 4 A. I'm sorry, I really don't understand the question you're  
 05:18 5 asking me, that I don't understand or I don't know?  
 05:18 6 Q. Do you know whether --  
 05:18 7 A. I don't know -- what did you say? Sorry.  
 05:18 8 Q. Let me ask it this way.  
 05:18 9 A. Yeah.  
 05:18 10 Q. Could the aqueous liquid preparation of Claim 7 of the  
 05:18 11 '290 patent include other quaternary ammonium preservatives  
 05:18 12 besides benzalkonium chloride?  
 05:18 13 A. It is my understanding that Claim 7 of '290 patent could  
 05:18 14 do.  
 05:18 15 Q. Is that the same for Claim 131 of the -- sorry. Claim 6  
 05:18 16 of the '131 patent?  
 05:19 17 A. I'd have to see the claim.  
 05:19 18 Q. Okay. Let's take a look at the claim. Let's bring up  
 05:19 19 Claim 6 of the '131 patent. I think it's on one of her  
 05:19 20 slides.  
 05:19 21 MR. BAIRD: Can you give me a little more.  
 05:19 22 MR. HASFORD: Let's go through her slides. I don't  
 05:19 23 have it in my... It looks like DDX-2-88.  
 05:19 24 BY MR. HASFORD:  
 05:19 25 Q. Claim 6 of the '131 patent includes the transition

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05:36 1 BY MR. HASFORD:  
 05:36 2 Q. Doctor, let me direct your attention back to DTX-196 and  
 05:36 3 then I'm going to ask you a quick question regarding PTX-265.  
 05:36 4 A. I'm sorry, DTX-196?  
 05:36 5 Q. DTX-196.  
 05:36 6 A. Okay.  
 05:36 7 Q. And in particular, Page -- let me direct your attention,  
 05:36 8 Doctor, to DTX-196, and in particular, Page DTX-196.93.  
 05:37 9 Before the break, do you recall me asking you, as of  
 05:37 10 the date of DTX-196, the only ophthalmic solution containing  
 05:37 11 octoxynol that had been approved by the FDA was Acular, and  
 05:37 12 you testified that you were uncertain. Do you remember that?  
 05:37 13 A. Yes, I do.  
 05:37 14 Q. Well, for the record, I've handed you PTX-265, which is a  
 05:37 15 copy of the Acular package insert, that bears Bates numbers  
 05:37 16 PROL0332429 through PROL0332439. And in particular, let me  
 05:37 17 direct your attention to the front page and the paragraph  
 05:37 18 right above the subheading, Clinical Pharmacology.  
 05:38 19 A. Okay.  
 05:38 20 Q. Does PTX-265 refresh your recollection that Acular  
 05:38 21 contains Octoxynol 40?  
 05:38 22 A. I don't remember seeing this insert before, but  
 05:38 23 certainly, that's what this page would indicate.  
 05:38 24 Q. Do you now agree that as of the date of DTX-196, the only  
 05:38 25 ophthalmic solution containing Octoxynol 40 that had been

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05:38 1 approved by the FDA was Acular?  
 05:38 2 A. Well, that would be the assumption, based on the  
 05:38 3 information you've given me.  
 05:38 4 Q. You understand that Acular is the commercial embodiment  
 05:38 5 of the Fu EP 984 reference, correct?  
 05:38 6 A. No, I did not.  
 05:38 7 Q. The innovators of Acular sought and obtained approval of  
 05:39 8 a surfactant that had not been previously listed in DTX-196,  
 05:39 9 correct?  
 05:39 10 A. I really don't have the information to definitely say one  
 05:39 11 way or another.  
 05:39 12 Q. You may put those documents aside.  
 05:39 13 Look again at DTX-196.93, at the Octoxynol 40  
 05:39 14 ophthalmic solution line.  
 05:39 15 A. Okay.  
 05:39 16 Q. Is it fair to say that a company sought and obtained  
 05:39 17 approval of a surfactant in Octoxynol 40 that had not been  
 05:39 18 previously listed in DTX-196?  
 05:40 19 A. I would be making judgments on things I don't have enough  
 05:40 20 information to make judgments. I can agree with you, there is  
 05:40 21 only one -- apparently one compound that's listed, and you've  
 05:40 22 just shown me this, but I really don't know enough information  
 05:40 23 to necessarily put the two things together.  
 05:40 24 Q. Well, aside from the Acular package insert, let me just  
 05:40 25 direct your attention to DTX-196.93 at the number 1 that

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05:42 1 Q. You can put that document aside.  
 05:42 2 A. Okay.  
 05:42 3 THE COURT: Excuse me. May I ask for clarification?  
 05:42 4 On this DTX-196, isn't it a January 1996 document on Page  
 05:42 5 DTX-196.3?  
 05:42 6 MR. HASFORD: It looks like the date on the front  
 05:42 7 page of the document, Your Honor, says 06-09-98, and I'm just  
 05:42 8 getting that based on DTX-196.1.  
 05:42 9 THE COURT: Well, I think that's the cover letter.  
 05:42 10 MR. HASFORD: Oh, okay.  
 05:42 11 THE COURT: But the document itself on Page 3. See  
 05:42 12 where it says January, 1996?  
 05:42 13 THE WITNESS: Yes.  
 05:42 14 MR. HASFORD: Yes, I see that.  
 05:43 15 THE COURT: Would that have been the date of this  
 05:43 16 publication, then?  
 05:43 17 MR. HASFORD: I would assume, but I -- I don't know.  
 05:43 18 This is something that defendants provided.  
 05:43 19 THE COURT: And so what it says is what was going on,  
 05:43 20 in terms of approvals by January of 1996?  
 05:43 21 MR. HASFORD: That's what I understand it to be, Your  
 05:43 22 Honor.  
 05:43 23 THE COURT: All right.  
 05:43 24 MR. HASFORD: The point --  
 05:43 25 THE COURT: Is that Dr Lawrence's understanding?

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05:40 1 corresponds to Octoxynol 40 ophthalmic solution. Do you see  
 05:40 2 that?  
 05:40 3 A. Yes, I do.  
 05:40 4 Q. Is it fair to say that based on the number one in that  
 05:40 5 line, that one innovator sought and obtained FDA approval of a  
 05:40 6 surfactant that had not been previously listed in the FDA's  
 05:41 7 inactive ingredient guide?  
 05:41 8 A. I don't think I could say that on the information I have  
 05:41 9 here.  
 05:41 10 Q. Why don't you think you have enough information?  
 05:41 11 A. I don't know whether it was listed in, for example, the  
 05:41 12 U.S.P. Pharmacopoeia at the time, and it got some sort of  
 05:41 13 acceptability for that. So I'm sorry, I don't have that  
 05:41 14 information.  
 05:41 15 Q. Prior to the one approval for Octoxynol 40 that is  
 05:41 16 identified in DTX-196.93, would there have been any approvals  
 05:41 17 identified for Octoxynol 40 ophthalmic solution in the FDA's  
 05:41 18 inactive ingredient guide?  
 05:41 19 A. My hesitation to you is, I don't know when the first date  
 05:41 20 this was started. So, for example -- and the earliest  
 05:41 21 formulations from a quick scan go back to 1980 -- 1997. So it  
 05:42 22 would depend when the guide was started, to be able to answer  
 05:42 23 that.  
 05:42 24 Q. You don't know that information?  
 05:42 25 A. No, I don't know that information.

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05:43 1 THE WITNESS: That's my understanding, yes.  
 05:43 2 THE COURT: Okay. Thank you.  
 05:43 3 BY MR. HASFORD:  
 05:43 4 Q. Doctor, as of 1996, and 2003, there was one FDA-approved  
 05:43 5 ophthalmic solution containing Octoxynol 40, correct?  
 05:43 6 A. Can you confirm to me what year Acular was first on the  
 05:43 7 U.S. market?  
 05:44 8 Q. Well, let's take a look at the package insert, DTX-265  
 05:44 9 that I gave you.  
 05:44 10 MR. HASFORD: May I hand up another document, Your  
 05:44 11 Honor?  
 05:44 12 THE COURT: Yes, of course.  
 05:44 13 THE WITNESS: Thank you.  
 05:44 14 MR. HASFORD: I have two copies of this one.  
 05:44 15 THE WITNESS: Because the copyright is on 2001 for  
 05:44 16 this.  
 05:44 17 BY MR. HASFORD:  
 05:44 18 Q. Right. But let me direct your attention -- so for the  
 05:44 19 record, this is PTX-295, which bears Bates No. PROL0081123  
 05:44 20 through 27, and let me direct your attention to the entry for  
 05:45 21 Acular, which begins at PROL0081126 through 27, and then in  
 05:45 22 particular, to the middle column, on PROL0081127.  
 05:45 23 A. I'm afraid I can't read it on the copy I've been given.  
 05:45 24 Q. Our graphics assistant will highlight it on the screen  
 05:45 25 for you.

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05:45 1 THE COURT: We're all going to need eye drops soon.  
 05:45 2 (Laughter.)  
 05:45 3 MR. HASFORD: I apologize, Your Honor. Since the  
 05:45 4 print is so poor, we will just -- we will put this document  
 05:45 5 aside for now.  
 05:45 6 BY MR. HASFORD:  
 05:45 7 Q. Let's discuss your qualifications, Doctor. You testified  
 05:46 8 on direct exam about chemistry issues, yet you have never been  
 05:46 9 qualified by any court or by the U.S. Patent and Trademark  
 05:46 10 Office as an expert in chemistry, correct?  
 05:46 11 A. That is correct, yes.  
 05:46 12 Q. You are not an expert in medicinal chemistry, correct?  
 05:46 13 A. No, I'm not an expert in medicinal chemistry.  
 05:46 14 Q. You are not an expert in organic chemistry, correct?  
 05:46 15 A. No, although my laboratory routinely synthesizes novel  
 05:46 16 compounds, so I have some experience in synthetic chemistry.  
 05:46 17 Q. Take a look, if you would, at your deposition transcript,  
 05:46 18 your February 29th deposition transcript. This is going to be  
 05:46 19 Page 24, lines 15 through 20. I asked you.  
 05:47 20 Question: Have you ever held yourself out to the  
 05:47 21 public as an expert in organic chemistry?  
 05:47 22 MS. RAPALINO: Objection, Your Honor. Again, this is  
 05:47 23 improper impeachment. This is a different question that was  
 05:47 24 asked at her deposition.  
 05:47 25 MR. HASFORD: I believe she tried to say that she had  
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05:48 1 Q. You have never conducted any research on any bromfenac  
 05:48 2 product, correct?  
 05:48 3 A. That is correct, yes.  
 05:48 4 Q. You have never formulated any bromfenac product, correct?  
 05:48 5 A. That is correct, yes.  
 05:48 6 Q. You have never formulated any marketed drug product,  
 05:48 7 correct?  
 05:48 8 A. No, not a marketed drug product, no.  
 05:48 9 Q. You have never formulated any product for treating an  
 05:48 10 inflammatory disease of the eye, correct?  
 05:48 11 A. Not a marketed product.  
 05:48 12 Q. You have never formulated any product at all for treating  
 05:48 13 an inflammatory disease of the eye, correct?  
 05:48 14 A. Sorry, I've never formulated any product at all.  
 05:49 15 Q. That's my question. You have never formulated any  
 05:49 16 product at all for treating an inflammatory disease of the  
 05:49 17 eye, correct?  
 05:49 18 A. If you mean a product that got to market, no, I have not.  
 05:49 19 Q. I mean any product whether it got to market or not.  
 05:49 20 A. I've done some consultation for pharmaceutical companies.  
 05:49 21 Q. You have never formulated any product for treating an  
 05:49 22 inflammatory disease of the eye, correct?  
 05:49 23 A. I have made potential products for treating with  
 05:49 24 steroids.  
 05:49 25 Q. Let's take a look at your February 16th deposition  
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05:47 1 expertise based on this laboratory work, where she testified  
 05:47 2 at her deposition she's never held herself out as an expert in  
 05:47 3 organic chemistry, Your Honor.  
 05:47 4 MS. RAPALINO: Right. I think that the question of  
 05:47 5 whether you held yourself out to the general public as an  
 05:47 6 expert is different from whether you have expertise in a  
 05:47 7 particular area.  
 05:47 8 MR. HASFORD: I think naturally, Your Honor, if you  
 05:47 9 had expertise in that area you would hold yourself out as  
 05:47 10 such.  
 05:47 11 THE COURT: Well, I'm going to sustain the objection.  
 05:47 12 I thought the pending question was, have you ever been  
 05:47 13 qualified as an expert in organic chemistry, and her answer  
 05:47 14 was no.  
 05:47 15 BY MR. HASFORD:  
 05:47 16 Q. You are not an expert in pharmacology, correct?  
 05:47 17 A. That is correct.  
 05:47 18 Q. You are not an expert in ophthalmology, correct?  
 05:47 19 A. That is correct.  
 05:47 20 Q. You have never led any clinical testing on a  
 05:48 21 pharmaceutical product, correct?  
 05:48 22 A. That is correct, yes.  
 05:48 23 Q. You've also never designed any clinical testing on a  
 05:48 24 pharmaceutical product, correct?  
 05:48 25 A. That is correct, yes.  
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05:49 1 transcript. Let me direct your attention to Page 35, Lines 14  
 05:49 2 through 18. I asked you:  
 05:49 3 QUESTION: You have never formulated any product for  
 05:49 4 treating an inflammatory disease of the eye, correct?  
 05:50 5 There was an objection.  
 05:50 6 And you answered:  
 05:50 7 ANSWER: Correct.  
 05:50 8 That was your testimony, wasn't it, doctor?  
 05:50 9 MS. RAPALINO: Objection, your Honor. I ask for  
 05:50 10 completeness, the question and answer before that need to be  
 05:50 11 included in the record.  
 05:50 12 THE COURT: Okay. Can you read that, too, please?  
 05:50 13 MR. HASFORD: Certainly.  
 05:50 14 BY MR. HASFORD:  
 05:50 15 Q. QUESTION: You have never formulated any marketed  
 05:50 16 drug product, correct?  
 05:50 17 ANSWER: Correct.  
 05:50 18 A. I understood that question to be referring to something  
 05:50 19 not to market, which is why I asked you to clarify just now.  
 05:50 20 Q. You didn't ask me to clarify at your deposition, did you,  
 05:50 21 doctor?  
 05:50 22 A. It was straight after a marketed product so I assumed you  
 05:50 23 meant the same thing.  
 05:50 24 Q. The exact question I asked you was:  
 05:50 25 QUESTION: You have never formulated any product for  
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05:50 1 treating an inflammatory disease of the eye, correct?  
 05:50 2 And the exact answer you gave me was:  
 05:50 3 ANSWER: Correct.  
 05:50 4 Isn't that correct?  
 05:50 5 **A. A product in my opinion is something that gets -- gets to**  
 05:50 6 **market.**  
 05:50 7 **Q.** Aside from your work in this case, you have never  
 05:50 8 consulted for any party regarding any bromfenac product,  
 05:51 9 correct?  
 05:51 10 **A. That is correct, yes.**  
 05:51 11 **Q.** You never conducted any bench testing in connection with  
 05:51 12 your opinions in this case, correct?  
 05:51 13 **A. That is correct, yes.**  
 05:51 14 **Q.** You testified on direct exam about medical issues  
 05:51 15 regarding bromfenac, yet you do not practice medicine,  
 05:51 16 correct?  
 05:51 17 **A. I don't know what, other than it was used for a**  
 05:51 18 **particular medical use I mentioned.**  
 05:51 19 **Q.** You do not practice medicine, correct?  
 05:51 20 **A. No, I do not practice medicine.**  
 05:51 21 **Q.** You have never prescribed medication to a patient,  
 05:51 22 correct?  
 05:51 23 **A. No, I don't prescribe medication, I'm not a medic.**  
 05:52 24 **Q.** You have not dispensed a medication to a patient in the  
 05:52 25 last 20 years, correct?

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05:53 1 QUESTION: You have never founded or cofounded a  
 05:53 2 pharmaceutical services company, correct?  
 05:53 3 And you answered:  
 05:53 4 ANSWER: Correct.  
 05:53 5 That was your testimony, wasn't it, doctor?  
 05:53 6 **A. I see that.**  
 05:53 7 **Q.** You testified on direct exam about regulatory  
 05:53 8 requirements, yet you have never been qualified by any court  
 05:53 9 or anybody as an expert in regulatory law, correct?  
 05:53 10 **A. No, I have not been qualified.**  
 05:53 11 **Q.** You have never consulted for any party on any issue of  
 05:53 12 FDA regulatory law, correct?  
 05:53 13 **A. On FDA regulatory law? That is correct, yes.**  
 05:53 14 **Q.** You are not a named inventor on any U.S. patents or  
 05:54 15 patent applications, correct?  
 05:54 16 **A. Not on U.S. patent applications, no.**  
 05:54 17 **Q.** You only ever filed two non-U.S. patent applications,  
 05:54 18 correct?  
 05:54 19 **A. That is correct, yes.**  
 05:54 20 **Q.** You have never filed a patent application dealing with  
 05:54 21 the use of bromfenac in a pharmaceutical formulation, correct?  
 05:54 22 **A. That is correct, yes.**  
 05:54 23 **Q.** You have never filed a patent application dealing with  
 05:54 24 the use of tyloxapol in a pharmaceutical formulation, correct?  
 05:54 25 **A. That is correct, yes.**

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05:52 1 **A. That is correct, yes.**  
 05:52 2 **Q.** You have never dispensed any bromfenac product to a  
 05:52 3 patient, correct?  
 05:52 4 **A. That is correct, yes.**  
 05:52 5 **Q.** You have never founded or cofounded a pharmaceutical  
 05:52 6 services company, correct?  
 05:52 7 **A. What do you mean pharmaceutical services?**  
 05:52 8 **Q.** Do you understand my question?  
 05:52 9 **A. I would like you to define what you meant by**  
 05:52 10 **pharmaceutical services, please.**  
 05:52 11 **Q.** Well, let me go to your deposition transcript of  
 05:52 12 February 16th.  
 05:52 13 MS. RAPALINO: Objection. I don't believe that  
 05:52 14 there's a question pending at the moment.  
 05:52 15 MR. HASFORD: Well, she asked me -- she told me that  
 05:52 16 she didn't understand it, your Honor, but she understood it at  
 05:52 17 her deposition so I'd like to direct her to her testimony  
 05:53 18 there.  
 05:53 19 THE COURT: I'll permit it.  
 05:53 20 BY MR. HASFORD:  
 05:53 21 **Q.** Take a look if you would at Page 35, Lines 20 through 22,  
 05:53 22 I asked --  
 05:53 23 **A. I was just clarifying what you meant by pharmaceutical**  
 05:53 24 **services.**  
 05:53 25 **Q.** I asked you:

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05:54 1 **Q.** You have never filed a patent application dealing with  
 05:54 2 the use of benzalkonium chloride in a pharmaceutical  
 05:54 3 formulation, correct?  
 05:54 4 **A. That is correct, yes.**  
 05:54 5 **Q.** You have never filed a patent application dealing with  
 05:54 6 formulating a stable aqueous liquid preparation, correct?  
 05:54 7 **A. That is correct, yes.**  
 05:54 8 **Q.** I'd like to conclude with questions regarding your  
 05:55 9 proposed definition of a person of ordinary skill in the art.  
 05:55 10 You did not cite anything in support of your proposed  
 05:55 11 definition of a person of ordinary skill in the art of the  
 05:55 12 '431 patent, correct?  
 05:55 13 **A. That is correct, yes.**  
 05:55 14 **Q.** In proposing your definition of a person of ordinary  
 05:55 15 skill in the art, you did not consider the definitions that  
 05:55 16 any other experts have provided in other cases, did you?  
 05:55 17 **A. Not at the time; I have subsequently done so.**  
 05:55 18 **Q.** In proposing your definition of a person of ordinary  
 05:55 19 skill in the art, you did not consider the definition that any  
 05:55 20 courts have adopted in other cases, correct?  
 05:55 21 **A. Not at the time, no.**  
 05:55 22 MS. RAPALINO: I object on the ground of relevance to  
 05:55 23 what other courts in other cases about other patents, what  
 05:55 24 that has to do with the definition of the person of ordinary  
 05:55 25 skill in the art here.

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05:55 1 MR. HASFORD: I think --

05:55 2 THE COURT: Well, in terms of what she consulted with

05:55 3 I'll permit it.

05:55 4 BY MR. HASFORD:

05:55 5 Q. I will ask the question again.

05:56 6 In proposing your definition of a person of ordinary

05:56 7 skill in the art, you did not consider the definition that any

05:56 8 courts have adopted in other cases, correct?

05:56 9 A. **No, I used my knowledge at the time.**

05:56 10 MR. HASFORD: Nothing further at this point, your

05:56 11 Honor.

05:56 12 THE COURT: Okay. Thank you.

05:56 13 Redirect?

05:56 14 MS. RAPALINO: Yes, your Honor.

05:56 15 (REDIRECT EXAMINATION OF JAYNE LAWRENCE BY MR. RAPALINO:)

05:56 16 Q. Good afternoon, Professor Lawrence. Nice to see you

05:56 17 again.

05:56 18 A. **Good afternoon.**

05:56 19 Q. Do you recall in the cross-examination Mr. Hasford asked

05:56 20 you about some deposition testimony where you used the word

05:56 21 hindsight in answering a question?

05:56 22 A. **Yes, I did.**

05:56 23 Q. Can you explain what you meant by hindsight?

05:56 24 A. **What I meant was just putting myself back into that**

05:56 25 **particular period.**

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05:58 1 issue of solubilizing the sodium salt of bromfenac?

05:58 2 A. **No, it is not.**

05:58 3 Q. What is the issue that -- what is the problem to be

05:58 4 addressed by adding a surfactant in this case?

05:58 5 A. **The problem that the addition of surfactants solves is**

05:58 6 **overcoming this complexation between benzalkonium chloride and**

05:58 7 **sodium bromfenac, it doesn't need the soluble the sodium**

05:58 8 **bromfenac in that process.**

05:58 9 Q. Do you recall that you were also asked a number of

05:58 10 questions about issues that a formulator needs to consider in

05:58 11 developing a new drug product?

05:59 12 A. **Yes, I do.**

05:59 13 Q. For example, you were asked about considering the issue

05:59 14 of the efficacy of a drug. Do you remember that?

05:59 15 A. **Yes, I do.**

05:59 16 Q. Was bromfenac already a marketed product as of the

05:59 17 relevant date here, January 2003?

05:59 18 A. **Yes, it was, it was well known to be.**

05:59 19 Q. So did a formulator need to consider issues of efficacy

05:59 20 in connection with bromfenac as of that date?

05:59 21 A. **No, it didn't, that would have been done in the**

05:59 22 **preclinical, pre-formulation work.**

05:59 23 Q. Likewise, Mr. Hasford also mentioned comfort to the eye

05:59 24 as another consideration that a formulator would need to

05:59 25 consider. Given that bromfenac was already a marketed product

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05:56 1 Q. And what particular period did you put yourself back into

05:56 2 to do your obviousness analysis in this case?

05:56 3 A. **January 2003.**

05:56 4 Q. Do you recall that Mr. Hasford also asked you some

05:57 5 questions about whether substituting tyloxapol into Example 6

05:57 6 of the '225 patent would have had a material effect on

05:57 7 stability?

05:57 8 A. **Yes, I do.**

05:57 9 Q. And do you recall that you testified that it would have

05:57 10 no effect, no material effect on stability?

05:57 11 A. **Yes, I do.**

05:57 12 Q. Can you explain what you meant by a material effect?

05:57 13 A. **Yes, I meant it would have no detrimental effect on the**

05:57 14 **novel and basic properties, characteristics of the**

05:57 15 **formulation.**

05:57 16 Q. Okay. Now, Mr. Hasford also asked you some questions

05:57 17 based on one of your publications where he quoted your

05:57 18 publication as saying that there's no using a surfactant to

05:57 19 increase the solubility of an already water soluble drug. Do

05:58 20 you remember that?

05:58 21 A. **Yes, I do.**

05:58 22 Q. And then he asked you whether the sodium salt of

05:58 23 bromfenac was water soluble. Do you remember that?

05:58 24 A. **Yes, I do.**

05:58 25 Q. Is the issue that we're dealing with in this case the

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05:59 1 as of 2003, would comfort to the eye be a particular issue or

05:59 2 challenge that the formulator would need to consider?

05:59 3 A. **It wouldn't be a particular challenge, no.**

05:59 4 Q. Now, Mr. Hasford also mentioned during your cross that

05:59 5 there were other considerations -- you testified there were

06:00 6 other considerations that a formulator might consider in

06:00 7 developing a new drug product, and one of them includes

06:00 8 safety. Do you remember that?

06:00 9 A. **I do.**

06:00 10 Q. And again, in light of what was known about bromfenac in

06:00 11 2003, would safety have you been a particular issue or

06:00 12 challenge for a formulator?

06:00 13 A. **No, it would not. Many of those conditions are important**

06:00 14 **during development of a new drug, not the formulation of an**

06:00 15 **already established drug.**

06:00 16 Q. Okay. And do you recall that you testified similarly

06:00 17 that some other considerations that a formulator would

06:00 18 consider would be having sufficient viscosity to stay in the

06:00 19 eye, container stability, route of administration -- and route

06:00 20 of administration?

06:00 21 A. **Yes, I do.**

06:00 22 Q. And were any of those particular issues or challenges for

06:00 23 bromfenac given what was known as of January 2003?

06:00 24 A. **No, they were not, it would have been routine for a**

06:01 25 **formulator at that stage.**

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06:01 1 Q. Now, do you recall that Mr. Hasford pointed you to the  
 06:01 2 Ogawa '225 patent?  
 06:01 3 A. Yes, I do.  
 06:01 4 Q. And that was JTX-147. Do you remember that?  
 06:01 5 A. I don't remember the numbers.  
 06:01 6 Q. Do you recall that you offered testimony about Example 6  
 06:01 7 of the '225 patent?  
 06:01 8 A. Yes, I do.  
 06:01 9 Q. And Mr. Hasford asked you about whether there was any  
 06:01 10 report in the '225 patent of any problem of cloudiness or  
 06:01 11 complexation. Do you remember that?  
 06:01 12 A. Yes, I do.  
 06:01 13 Q. And I believe that your testimony was that there was no  
 06:02 14 report but it would have been obvious to a person of ordinary  
 06:02 15 skill in the art why there was no complexation reported. Do  
 06:02 16 you remember that?  
 06:02 17 A. Yes, I do.  
 06:02 18 Q. In light of the ingredients of Example 6 of the '225  
 06:02 19 patent, what would a person of skill in the art understand  
 06:02 20 about why there was no complexation in Example 6?  
 06:02 21 A. They would have been aware of the problems of  
 06:02 22 complexation between benzalkonium chloride and bromfenac and  
 06:02 23 realized that the surfactant polysorbate 80 was there to  
 06:02 24 overcome those problems. If it wasn't there to overcome the  
 06:02 25 problems, there would be no reason for adding that surfactant

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06:04 1 complexation. Do you remember that?  
 06:04 2 A. Yes, I do.  
 06:04 3 Q. Specifically he asked you about the '929 patent, which  
 06:04 4 uses a preservative Polyquad in place of benzalkonium  
 06:04 5 chloride. Do you remember that?  
 06:04 6 A. Yes, I do.  
 06:04 7 Q. Would a person of ordinary skill in the art have been  
 06:04 8 motivated to replace benzalkonium chloride with Polyquad to  
 06:04 9 solve the problem of complexation between an NSAID and  
 06:04 10 benzalkonium chloride?  
 06:04 11 A. No, it wouldn't have been the preferred approach, they  
 06:04 12 would have looked at modifying the formulation of benzalkonium  
 06:04 13 chloride.  
 06:04 14 Q. How would a person of ordinary skill in the art know that  
 06:04 15 was the preferred approach?  
 06:04 16 A. Can I look at the patent number?  
 06:04 17 Q. Maybe I can direct your attention to DTX-15.  
 06:05 18 A. There was two reasons why I think they wouldn't have used  
 06:05 19 the Polyquad approach, because there was far less experience  
 06:05 20 with the use of Polyquad, and coupled with the fact that  
 06:05 21 Remington suggests that it's always better to use the most  
 06:05 22 favored preservative, which is benzalkonium chloride, rather  
 06:05 23 than use a less favored preservative.  
 06:05 24 MS. RAPALINO: Can I have one moment, your Honor?  
 06:05 25 THE COURT: Yes.

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06:02 1 into the formulation.  
 06:02 2 Q. Okay. Thank you.  
 06:02 3 Now, do you also remember that Mr. Hasford pointed you  
 06:02 4 to JTX-168, which is the '034 patent?  
 06:03 5 A. Yes, I do.  
 06:03 6 Q. And specifically he pointed you to Table 1 in the '034  
 06:03 7 patent. Do you remember that?  
 06:03 8 A. Yes, I do.  
 06:03 9 Q. And he had you compare results comparing bromfenac to  
 06:03 10 various numbered compounds in that table. Do you remember  
 06:03 11 that?  
 06:03 12 A. Yes, I do.  
 06:03 13 Q. Were any of those numbers compounds in patent marketed  
 06:03 14 pharmaceutical products as of 2003?  
 06:03 15 A. No, they were not.  
 06:03 16 Q. And given the option of formulating a product that had  
 06:03 17 already been a marketed product and had gone through safety  
 06:03 18 and efficacy clinical trials as compared to starting from  
 06:03 19 scratch with a new compound that hadn't yet been approved,  
 06:03 20 what would be the preference of the pharmaceutical formulator?  
 06:03 21 A. A formulator would always go with something that already  
 06:03 22 received approval. If not, they would have to put the new  
 06:03 23 drug through very expensive clinical trials.  
 06:03 24 Q. Now, Mr. Hasford also pointed you to what he  
 06:04 25 characterized as other approaches taken to the problem of

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06:05 1 (Brief pause.)  
 06:05 2 MS. RAPALINO: Okay. I have no further questions,  
 06:05 3 your Honor.  
 06:05 4 I just want to take care of one housekeeping matter.  
 06:05 5 When I read the list of exhibits to be moved into evidence  
 06:05 6 with Professor Lawrence's testimony, I inadvertently omitted  
 06:06 7 JTX-209.  
 06:06 8 THE COURT: And which document is that?  
 06:06 9 MS. RAPALINO: It is the EP '984 patent.  
 06:06 10 THE COURT: Okay. Any objection to that being  
 06:06 11 received into evidence?  
 06:06 12 MR. HASFORD: No objection, your Honor.  
 06:06 13 THE COURT: Okay. JTX-209 is received into evidence.  
 06:06 14 (JOINT EXHIBIT JTX-209 WAS RECEIVED IN EVIDENCE)  
 06:06 15 THE COURT: Any short follow-up within the scope of  
 06:06 16 redirect?  
 06:06 17 MR. HASFORD: We've got no recross, your Honor.  
 06:06 18 We have the same housekeeping issue, we want to make  
 06:06 19 sure all the exhibits we used on cross are entered. I have  
 06:06 20 PTX-265, PTX-295, and I think there may have been another one,  
 06:06 21 PTX -- the Xibrom® package insert.  
 06:06 22 THE COURT: 749?  
 06:07 23 MS. LEBIS: It's Bates No. PROL 0167921.  
 06:07 24 THE COURT: 0167921. I don't think it was qualified.  
 06:07 25 Did the witness lay a foundation for this as something she

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06:07 1 recognizes or is there any objection?  
 06:07 2 MS. RAPALINO: There is an objection. I don't think  
 06:07 3 there was any foundation laid for this document.  
 06:07 4 MR. HASFORD: Well, I don't believe there was. So  
 06:07 5 she testified that the package insert included the same U.S.  
 06:07 6 patent number as Ogawa, so she matched that up and confirmed  
 06:07 7 in fact the Ogawa patent is listed on that package insert,  
 06:07 8 your Honor, I believe that does lay the foundation.  
 06:07 9 MS. RAPALINO: Can I just ask for clarification which  
 06:07 10 exhibit you're talking about?  
 06:07 11 THE COURT: This one page Xibrom® package insert.  
 06:07 12 MS. RAPALINO: Yeah, again, I don't think there was  
 06:07 13 any foundation laid. It was just purely a matter of her  
 06:08 14 reading whether there was a patent number on the document.  
 06:08 15 MR. HASFORD: Well, counsel didn't object at the  
 06:08 16 time, your Honor, we have argued that that objection is waived  
 06:08 17 then. I was able -- I asked the witness questions about the  
 06:08 18 document.  
 06:08 19 THE COURT: You asked her what's printed on this  
 06:08 20 piece of paper and she said what she said in terms of the  
 06:08 21 patent being listed, but I think she said that she hadn't seen  
 06:08 22 this before. So there may be another way to get it in, or  
 06:08 23 perhaps the parties can stipulate when the defense has an  
 06:08 24 opportunity to look at this, but through this witness there's  
 06:08 25 an objection to foundation. I'll give you another opportunity

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06:09 1 this. I don't think we're going to have an objection to the  
 06:09 2 exhibit, we have all just seen it for the first time during  
 06:09 3 the cross-examination, if we could have some time, we might be  
 06:09 4 able to arrive at a stipulation to enter it into evidence.  
 06:09 5 THE COURT: Okay. The reason I think that's the  
 06:09 6 better way to do it, the witness hasn't laid a foundation, she  
 06:09 7 can't say it is, she can't say it isn't, and that's  
 06:10 8 understandable.  
 06:10 9 Also, this particular document's marked confidential.  
 06:10 10 With a package insert it couldn't be confidential, could it?  
 06:10 11 MR. HASFORD: Yeah, if it's a public package insert  
 06:10 12 with that confidentiality designation, it might have been put  
 06:10 13 there inadvertently. I'm not sure.  
 06:10 14 THE COURT: The parties can track this down if it  
 06:10 15 remains in dispute.  
 06:10 16 But let me deal with the two documents that you have  
 06:10 17 moved in. You moved in PTX-265 and PTX-295.  
 06:10 18 MR. HASFORD: Correct.  
 06:10 19 THE COURT: And is there any objection to those or do  
 06:10 20 you need to consult?  
 06:10 21 MS. RAPALINO: I believe that they suffer from the  
 06:10 22 same issue. For PTX-265 I also believe that the witness  
 06:10 23 testified she hadn't seen that before. And I don't even  
 06:10 24 believe that 295, I don't think there was any testimony  
 06:10 25 elicited on PTX-295.

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06:08 1 to lay a foundation with Dr. Lawrence.  
 06:08 2 MR. HASFORD: May I, your Honor?  
 06:08 3 THE COURT: Sure. I apologize, what was the PTX  
 06:08 4 number again?  
 06:08 5 MR. HASFORD: 749.  
 06:08 6 THE COURT: Thank you.  
 06:08 7 (RE-CROSS-EXAMINATION OF JAYNE LAWRENCE BY MR. HASFORD:)  
 06:08 8 Q. Doctor, do you recognize PTX-749 as a copy of the package  
 06:08 9 insert for Xibrom®?  
 06:08 10 A. **I've never seen it until today.**  
 06:08 11 Q. Do you have any reason to believe that PTX-749 is not a  
 06:08 12 copy of the package insert for Xibrom®?  
 06:09 13 A. **I have no view either way.**  
 06:09 14 Q. You've relied on package inserts in connection with your  
 06:09 15 opinions in this case, doctor, correct?  
 06:09 16 A. **I really haven't seen this one before, that's all I can**  
 06:09 17 **say.**  
 06:09 18 Q. Again, you've relied on package inserts in connection  
 06:09 19 with your opinions in this case, correct?  
 06:09 20 A. **I would have to check, but probably.**  
 06:09 21 Q. Does PTX-749 look like the type of packaging insert you  
 06:09 22 would have relied on in connection with your opinions in this  
 06:09 23 case?  
 06:09 24 A. **I guess so. I don't know.**  
 06:09 25 MS. RAPALINO: Your Honor, maybe I can short-circuit

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06:10 1 THE COURT: That's correct. PTX-295, there is no  
 06:10 2 testimony, that was the PDR 54th addition.  
 06:10 3 MR. HASFORD: Maybe we can reach another agreement  
 06:10 4 with counsel on those because I don't believe there should be  
 06:11 5 any legitimate dispute, these are what they purport to be,  
 06:11 6 your Honor. But we're happy to take care of that on the side  
 06:11 7 with counsel.  
 06:11 8 THE COURT: Okay. Actually the Acular® one might  
 06:11 9 well be incomplete because it seems to start with Page 4.  
 06:11 10 MR. HASFORD: Oh, your Honor, I think that's how the  
 06:11 11 FDA starts their numbering with any package inserts, at least  
 06:11 12 that's what we've seen.  
 06:11 13 THE COURT: Do they charge for the first three pages?  
 06:11 14 MR. HASFORD: I hope not, your Honor.  
 06:11 15 THE COURT: Do counsel have any other questions?  
 06:11 16 Because I may have one or two questions for the witness.  
 06:11 17 MR. HASFORD: I have no recross, your Honor.  
 06:11 18 THE COURT: So for now 265 and 295 are not received  
 06:11 19 into evidence, PTX-265 and 295.  
 06:11 20 Now, throughout the trial I may ask a question here and  
 06:11 21 there, it's permitted by the Rules of Evidence. But it's also  
 06:11 22 permitted to counsel that you have a right to object and for  
 06:11 23 me to rule at sidebar on any objection before the witness  
 06:11 24 answers. So don't be reluctant to object if you feel I might  
 06:12 25 be asking a question that is not comporting with the Rules of

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06:12 1 Evidence or what's relevant in the case. And I won't be  
06:12 2 offended in the least, that's what the rules provide.  
06:12 3 My question, doctor, is about your definition of a  
06:12 4 person ordinarily skilled in the arts. Where does your  
06:12 5 definition -- well, could you repeat for me your definition of  
06:12 6 a person ordinarily skilled in the arts -- a person of  
06:12 7 ordinary skill in the art as it applies to this case?  
06:12 8 THE WITNESS: Certainly. I used, based on my  
06:12 9 experience of working with pharmaceutical companies and being  
06:12 10 aware of the people who did formulation within these  
06:12 11 companies, they were generally Ph.D.s in pharmaceutical  
06:12 12 sciences, often pharmacists, but often pharmaceutical  
06:12 13 scientists as well, and they will have a year or two -- a  
06:12 14 year -- a few years of experience, and that's how I arrived at  
06:13 15 the definition from my own experience.  
06:13 16 THE COURT: There's already been some testimony that  
06:13 17 a person with a bachelor's degree and experience could well be  
06:13 18 a POSA. Do you agree or disagree with that?  
06:13 19 THE WITNESS: I think it would have been unusual for  
06:13 20 somebody without a Ph.D. to be in that position. Although,  
06:13 21 obviously, if they had sufficient experience, that would  
06:13 22 compensate it for that. But I do have a problem with their  
06:13 23 definition of pharmaceutical chemist, chemist, I think that  
06:13 24 would have been very unusual.  
06:13 25 THE COURT: How does pharmaceutical science differ  
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06:13 1 from pharmaceutical chemistry?  
06:13 2 THE WITNESS: That's a good question. Pharmaceutical  
06:13 3 chemists tend to go and work in the medicinal chemistry side  
06:13 4 of the industry, they'd be looking at preparing new drug  
06:14 5 molecules. Pharmaceutical science, you're correct, your  
06:14 6 Honor, does include pharmaceutical chemistry, but I'm talking  
06:14 7 about pharmaceutical science related to formulation.  
06:14 8 THE COURT: And so the formulators are the  
06:14 9 pharmaceutical scientists in your view?  
06:14 10 THE WITNESS: Yes.  
06:14 11 THE COURT: Doesn't that set a very high bar for the  
06:14 12 persons who are deemed to have such skill here?  
06:14 13 THE WITNESS: I took that from my experience. And,  
06:14 14 in fact, Professor Williams had that experience when he went  
06:14 15 into working in formulation himself, he had a Ph.D.  
06:14 16 THE COURT: And he didn't work in formulation, as far  
06:14 17 as you know, before that date?  
06:14 18 THE WITNESS: He's obviously better to qualify, but  
06:14 19 that's what his CV seemed to indicate.  
06:14 20 THE COURT: All right. Are there any follow-up  
06:15 21 questions as to my questions? Beginning first with the  
06:15 22 defendant who called the witness.  
06:15 23 MS. RAPALINO: No, your Honor, no questions.  
06:15 24 THE COURT: Plaintiff?  
06:15 25 MR. HASFORD: None from plaintiff, your Honor.  
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06:15 1 THE COURT: Okay. And, Dr. Lawrence, I think we've  
06:15 2 reached the end of your testimony and you may step down.  
06:15 3 Is Dr. Lawrence excused to return or is she --  
06:15 4 MS. RAPALINO: She's going to be returning for our  
06:15 5 rebuttal case, but for now she is excused.  
06:15 6 THE COURT: So, doctor, you may step down. Thank you  
06:15 7 very much.  
06:15 8 THE WITNESS: Thank you.  
06:15 9 (Witness Excused.)  
06:15 10 THE COURT: Do you need five minutes to set up for  
06:15 11 the next witness or are you ready to go?  
06:15 12 MR. DINER: Just a couple of minutes to set up, your  
06:15 13 Honor, and we're ready to go.  
06:15 14 MR. HASFORD: Well, we would request clarification  
06:15 15 from the defendants whether they concluded their case in  
06:15 16 chief.  
06:15 17 MS. HOLLAND: Your Honor, this is the last live  
06:15 18 witness. However, as you know, there are deposition  
06:15 19 designations, those are not going to go into the record until  
06:15 20 the end of trial, so we -- you know, we can't rest at this  
06:15 21 point until all the evidence is in, I would say, but this is  
06:15 22 our last live witness.  
06:15 23 THE COURT: Okay. So all that awaits is the  
06:16 24 deposition designations?  
06:16 25 MS. HOLLAND: Correct, in our case in chief. We  
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06:16 1 expect to put on a rebuttal case.  
06:16 2 THE COURT: What I don't want to see is a couple days  
06:16 3 down the road that your real case emerges as a rebuttal case.  
06:16 4 MS. HOLLAND: No, certainly not, your Honor.  
06:16 5 Dr. Lawrence's testimony was essentially the evidence we're  
06:16 6 putting in on our obviousness and obviousness-type double  
06:16 7 patenting together with the deposition designations. The  
06:16 8 rebuttal case will go to issues of secondary considerations,  
06:16 9 which plaintiffs have the burden on, so they're going to go  
06:16 10 first on that and we will be replying to that.  
06:16 11 THE COURT: Is that the parties' understanding?  
06:16 12 MR. HASFORD: Well, this was part of our concern,  
06:16 13 your Honor, is that they would be holding back part of their  
06:16 14 case in chief and trying to put it on in their rebuttal case.  
06:16 15 If they're stipulating now before your Honor that they won't  
06:17 16 do that, then that's one thing, but that was our concern all  
06:17 17 along. I guess the question arises, since they have no  
06:17 18 further live witnesses, that a Rule 52 motion would be  
06:17 19 appropriate at this point.  
06:17 20 THE COURT: I believe it would not be because I  
06:17 21 haven't seen the deposition excerpts yet that are also part of  
06:17 22 their case. Normally a Rule 52 at the point where a party  
06:17 23 rests is fine. I think the short answer is the defendant  
06:17 24 actually is not resting yet. But also they have called their  
06:17 25 last live witness, unless somebody fits the category of  
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06:17 1 rebuttal.

06:17 2 MR. HASFORD: Respectfully, your Honor, would your

06:17 3 Honor sustain an objection to the extent they attempt to put

06:17 4 in additional evidence toward their case in chief during their

06:17 5 rebuttal case that they should have properly put in their case

06:17 6 in chief here?

06:17 7 THE COURT: I don't think I can rule *a priori*. It's

06:18 8 like any rebuttal situation, it has to be judged on its own

06:18 9 circumstances. I think there's at least two rules about

06:18 10 rebuttal, A, the same witness can't be called to give the same

06:18 11 testimony that they did before and just in a louder voice and,

06:18 12 B, that if a witness who properly is part of the party's

06:18 13 direct case could have testified but wasn't called, then the

06:18 14 reason for calling that witness has to be something that

06:18 15 happened in the opponent's case that requires rebuttal and

06:18 16 wasn't anticipated,

06:18 17 MS. HOLLAND: Your Honor, maybe I can -- I think

06:18 18 there's some veiled language here that maybe we should just

06:18 19 air out.

06:18 20 So we put Dr. Lawrence on, she's our witness on our

06:19 21 case in chief. We have Dr. Heathcock who is a chemist, his

06:19 22 report came in in rebuttal to Dr. Davies' report, so he's a

06:19 23 rebuttal witness based on the -- based on the order of the

06:19 24 expert reports that went in. And to the extent Mr. Hasford

06:19 25 was trying to preview that, I just wanted to make sure that we

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06:19 1 were clear with your Honor, that Dr. Heathcock is rebutting

06:19 2 Dr. Davies' opinions on organic chemistry.

06:19 3 MR. HASFORD: I would ask your Honor that Dr. Davies

06:19 4 served a reply report to Dr. Heathcock's rebuttal report.

06:19 5 There was some disagreement between the parties as to whether

06:19 6 that reply report was proper. Plaintiff moved to strike it

06:19 7 but then per agreement with the parties -- or defendants

06:19 8 moved, rather, to strike it. Per agreement of the parties

06:19 9 defendants withdrew that motion. So we would respectfully

06:19 10 request the opportunity to reply to anything new that they put

06:19 11 on through Dr. Heathcock or anything from the other witnesses

06:19 12 that would have been properly in their case in chief.

06:20 13 MS. HOLLAND: Your Honor, I think we -- we withdrew

06:20 14 it as part of a larger deal on withdrawing a lot of motions.

06:20 15 And the phone conference that we had pretrial, I believe I

06:20 16 asked the specific question about the order and you said

06:20 17 plaintiffs will go first and third and that defendants would

06:20 18 go second and forth, and that's what we understood the order

06:20 19 to be.

06:20 20 THE COURT: Yeah. And the fourth would be to rebut

06:20 21 new evidence that comes in --

06:20 22 MS. HOLLAND: Yes.

06:20 23 THE COURT: -- in the third stage.

06:20 24 MS. HOLLAND: Correct.

06:20 25 THE COURT: And the question we can probably resolve

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06:20 1 right now is whether Dr. Heathcock's testimony would be seen

06:20 2 by the plaintiffs as being proper rebuttal to Dr. Davies. I

06:20 3 assume Dr. Davies will testify, and then within the field of

06:20 4 organic chemistry Dr. Heathcock will say this is why we don't

06:20 5 agree with Dr. Davies.

06:20 6 MS. HOLLAND: Exactly, your Honor.

06:20 7 MR. MUKERJEE: That's exactly right.

06:20 8 MR. HASFORD: Except it's our view, your Honor, that

06:21 9 that testimony as to the organic chemistry issue should have

06:21 10 come in in defendant's case in chief, and that's exactly why

06:21 11 Dr. Davies provided the reply report to Dr. Heathcock.

06:21 12 THE COURT: Well, I can see why it hasn't. I mean,

06:21 13 the defendants don't see this as an organic chemistry case.

06:21 14 MS. HOLLAND: Correct, your Honor.

06:21 15 MR. MUKERJEE: That is correct, your Honor.

06:21 16 MS. HOLLAND: That's why he's not in our case in

06:21 17 chief. That's why Dr. Heathcock only came into the case at

06:21 18 all, to rebut Dr. Davies, that's his sole function in the

06:21 19 case.

06:21 20 MR. MUKERJEE: Right.

06:21 21 THE COURT: No, I think this makes sense. And

06:21 22 everybody is on notice what Dr. Heathcock's rebuttal testimony

06:21 23 is apt to be, since he has served the reports and they deal

06:21 24 with Dr. Davies' reports. Everybody knows Dr. Davies'

06:21 25 position with regard to what Dr. Heathcock is going to say,

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06:21 1 too, because Dr. Davies does have a reply report that has been

06:21 2 served upon the defendants. It's just that there won't be a

06:22 3 fifth stage of the case, whatever Dr. Davies wants to say,

06:22 4 including whatever he anticipates is needed to rebut

06:22 5 Dr. Heathcock, he'll have to say in this, call it stage three.

06:22 6 I think that that's fair to both sides and it won't unduly

06:22 7 prolong the trial.

06:22 8 MS. HOLLAND: We agree, your Honor.

06:22 9 MR. MUKERJEE: We agree.

06:22 10 THE COURT: Is that okay?

06:22 11 MR. HASFORD: We can see how it goes, your Honor, but

06:22 12 in principle that may work.

06:22 13 THE COURT: I'll take that as a yes.

06:22 14 Well, it's like all things at trial, no one can

06:22 15 guarantee exactly what is going to happen in the trial. If

06:22 16 the circumstances change substantially, then I'll revisit this

06:22 17 situation.

06:22 18 MR. HASFORD: Thank you.

06:22 19 THE COURT: But I think that the defendants are

06:22 20 putting their cards on the table about what they anticipate.

06:22 21 Is there any other live witness you anticipate for

06:22 22 rebuttal?

06:22 23 MS. HOLLAND: Yes, there are, your Honor. There's

06:23 24 Dr. Trat -- I'm sorry. Dr. Trattler is going to be

06:23 25 plaintiff's medical doctor witness. We're going to be

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06:23 1 rebutting that with Dr. Cykiert. As well, we have  
 06:23 2 Dr. Pranolukast, who is also addressing secondary consideration  
 06:23 3 issues.  
 06:23 4 THE COURT: And that's because on secondary  
 06:23 5 considerations, that's the plaintiffs' --  
 06:23 6 MS. HOLLAND: Burden.  
 06:23 7 THE COURT: So I think that part makes sense.  
 06:23 8 MR. HASFORD: Just to be clear, your Honor,  
 06:23 9 plaintiffs don't technically bear any burden with respect to  
 06:23 10 defendants' defenses, so it's merely their own to place  
 06:23 11 evidence on secondary considerations to further show that the  
 06:23 12 invention in fact was not obvious.  
 06:23 13 MS. HOLLAND: What I mean, your Honor, is there's  
 06:23 14 nothing to reply to until plaintiffs put on their case. We  
 06:23 15 don't have to put on any evidence on secondary considerations,  
 06:23 16 it's only in the nature of providing anything plaintiffs put  
 06:23 17 on.  
 06:23 18 MR. MUKERJEE: Correct.  
 06:23 19 THE COURT: Yes, I'm sorry, I didn't mean to suggest  
 06:23 20 the plaintiffs had the burden on that.  
 06:23 21 But there's nothing to rebut on secondary  
 06:23 22 considerations until the plaintiffs put something on, so that  
 06:23 23 makes sense to me as proper rebuttal.  
 06:10 24 MR. MUKERJEE: That's correct. And that's in  
 06:24 25 keeping, your Honor, with what you ordered for the

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06:25 1 And the plaintiff is resting its direct case, except  
 06:25 2 for the deposition excerpts which, by agreement of the  
 06:25 3 parties --  
 06:25 4 MR. HASFORD: Did you mean defendants, your Honor?  
 06:25 5 THE COURT: I'm sorry. The defendants are resting  
 06:25 6 except for the deposition excerpts.  
 06:25 7 MS. HOLLAND: Yes. And the exhibits that come in  
 06:25 8 with the deposition excerpts.  
 06:25 9 THE COURT: All right. So I think that a Rule 52  
 06:26 10 motion would be premature.  
 06:26 11 MR. HASFORD: May we reserve on it?  
 06:26 12 THE COURT: And you can -- well, you have a  
 06:26 13 placeholder.  
 06:26 14 MR. HASFORD: Thank you, your Honor.  
 06:26 15 THE COURT: You've mentioned it and I've determined  
 06:26 16 that it's premature. But, in any event, when all the evidence  
 06:26 17 is in, you can argue the motion.  
 06:26 18 MR. HASFORD: Thank you, your Honor.  
 06:26 19 THE COURT: All right. What shall we do next then,  
 06:26 20 this afternoon? Is it time for the plaintiff's witness?  
 06:26 21 MR. HASFORD: Well, the question, your Honor, is  
 06:26 22 whether, given the hour, we have the privilege issue that  
 06:26 23 needs to be resolved, whether it makes sense for Dr. Davies to  
 06:26 24 come on for just a short period of time and then have to go  
 06:26 25 back off the stand or whether it makes more sense for your

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06:24 1 presentation of proofs at trial, the last thing it says,  
 06:24 2 defendants shall present their evidence regarding lack of --  
 06:24 3 defendants shall present -- last present their evidence  
 06:24 4 regarding lack of secondary considerations.  
 06:24 5 THE COURT: And on the medical, is Dr. Cykiert a  
 06:24 6 proper rebuttal witness to Dr. Trattler?  
 06:24 7 MS. HOLLAND: Yes, Dr. Trattler is also on secondary  
 06:24 8 considerations, so it's the same issue as Dr. Prausnitz.  
 06:24 9 We'll rebutting whatever evidence comes in on secondary  
 06:24 10 considerations offered by plaintiffs in the third stage.  
 06:24 11 THE COURT: Okay. So there is actually a lot more  
 06:24 12 live testimony to go from the defendants. It's just not part  
 06:24 13 of your direct case.  
 06:24 14 MS. HOLLAND: Correct. And I don't believe these are  
 06:25 15 going to be long witnesses.  
 06:25 16 THE COURT: All right.  
 06:25 17 MR. HASFORD: But that's our concern.  
 06:25 18 THE COURT: Well, they won't be longer than 13 hours.  
 06:25 19 MS. HOLLAND: Your Honor, we are planning on keeping  
 06:25 20 to 13 hours, and we are assuming that plaintiffs are as well.  
 06:25 21 THE COURT: Okay. And, you know, by tomorrow  
 06:25 22 afternoon, we can talk more about the time and how we're  
 06:25 23 doing.  
 06:25 24 Okay. So, again, this roadmap, this blueprint makes  
 06:25 25 sense to me.

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06:26 1 Honor to adjudicate or at least hear the argument.  
 06:26 2 THE COURT: Well, why don't we get started, and then  
 06:26 3 we'll end about 4:30, and I think the argument will be short  
 06:26 4 on the privilege issue. I should say that I don't think  
 06:27 5 either side should take more than five or seven minutes in its  
 06:27 6 argument on the privilege issue.  
 06:28 7 (Pause)  
 06:29 8 THE COURT: Okay. Shall we proceed?  
 06:29 9 MR. DINER: Yes, Your Honor.  
 06:29 10 May it please the Court, Bryan Diner on behalf of the  
 06:29 11 plaintiffs.  
 06:29 12 And, your Honor, in opening our rebuttal case, we  
 06:29 13 would like to call Dr. Stephen G. Davies.  
 06:29 14 THE COURT: Dr. Davies, please come to the witness  
 06:29 15 stand.  
 06:29 16 THE DEPUTY CLERK: Sir, can you please place your  
 06:29 17 left hand on the Bible and raise your right hand.  
 06:29 18 (STEPHEN GRAHAM DAVIES, HAVING BEEN DULY SWORN/AFFIRMED,  
 06:29 19 TESTIFIED AS FOLLOWS:)  
 06:29 20 THE WITNESS: I do.  
 06:29 21 THE DEPUTY CLERK: Please state your name, sir, and  
 06:29 22 spell your first and last name for the record, please.  
 06:30 23 THE WITNESS: Stephen Graham Davies, S-T-E-P-H-E-N  
 06:30 24 D-A-V-I-E-S.  
 06:30 25 THE DEPUTY CLERK: I-E-S?

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06:30 1 THE WITNESS: That's correct.  
 06:30 2 THE DEPUTY CLERK: Thank you, sir. You can be  
 06:30 3 seated. Please speak into the microphone.  
 06:30 4 (DIRECT EXAMINATION OF STEPHEN GRAHAM DAVIES BY MR. DINER:)  
 06:30 5 Q. Good afternoon, Dr. Davies. Would you please state your  
 06:30 6 address for the record.  
 06:30 7 A. My address is 7 Apsley Road, Oxford, UK.  
 06:30 8 Q. And where are you presently employed?  
 06:30 9 A. At the University of Oxford.  
 06:30 10 Q. And what is your current position at the University of  
 06:30 11 Oxford, Dr. Davies?  
 06:30 12 A. I am the Waynflete Professor of Organic Chemistry.  
 06:30 13 Q. And how long have you been a faculty member at the  
 06:30 14 University of Oxford?  
 06:30 15 A. I joined the faculty in 1980, so 36 years.  
 06:31 16 Q. Would you please describe the faculty positions that you  
 06:31 17 have held at the University of Oxford.  
 06:31 18 A. So, I was first appointed as a University Lecturer which  
 06:31 19 is a tenure-track position, equivalent to an assistant  
 06:31 20 professorship in the U.S., I guess.  
 06:31 21 Two years later, I gained tenure on the work we had  
 06:31 22 done at that stage.  
 06:31 23 I then stayed with the title University Lecturer,  
 06:31 24 that's a peculiarity of Oxford, but I was appointed Professor  
 06:31 25 in the mid-'90s, if not a bit before then, and then was

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06:33 1 with carboxylic acids.  
 06:33 2 Q. For how long have you worked in the fields that you  
 06:33 3 mentioned previously?  
 06:33 4 A. We started since I started my independent work, and then  
 06:33 5 we built up expertise in those areas over the time, so that  
 06:33 6 would be since about 1978.  
 06:33 7 Q. Do you have a doctorate degree?  
 06:33 8 A. I do, yes.  
 06:33 9 Q. Okay. And when did you obtain that?  
 06:33 10 A. I obtained that in 1976.  
 06:33 11 Q. And how, if at all, has your work continued to the  
 06:34 12 present day? The work in the chemistry and that you do at  
 06:34 13 Oxford.  
 06:34 14 A. Well, we're still a very active group, working across the  
 06:34 15 fields I have mentioned to you. It goes on.  
 06:34 16 Q. Would you -- let me hand you your binder. Please, would  
 06:34 17 you turn to PTX-160.  
 06:34 18 A. Yes.  
 06:34 19 Q. And can you identify that document for us?  
 06:34 20 A. That is my curriculum vitae.  
 06:34 21 Q. And does your C.V. accurately reflect your educational  
 06:34 22 work experience?  
 06:34 23 A. I believe so, yes.  
 06:34 24 Q. Would you briefly describe your educational background  
 06:34 25 following your graduation from high school?

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06:31 1 appointed to the Waynflete Chair ten years ago.  
 06:31 2 Q. Is the Waynflete Chair a professorship chair?  
 06:31 3 A. It is, yes.  
 06:31 4 Q. And what is the significance of becoming the Waynflete  
 06:31 5 Professor?  
 06:31 6 A. The Waynflete Chair is the only named chair in organic  
 06:32 7 chemistry at Oxford. It's one of the oldest chairs in the UK,  
 06:32 8 if not in the world. And it's a great privilege to hold it.  
 06:32 9 Q. And what, if any, departments within Oxford do you chair?  
 06:32 10 A. So, Oxford University Chemistry Department is one of the  
 06:32 11 largest in the world, and I was chairman of the whole  
 06:32 12 department for five years up until about five or six years  
 06:32 13 ago.  
 06:32 14 Q. In what fields, Dr. Davies, do you specialize in?  
 06:32 15 A. I'm a chemist, and within that, I specialize in organic  
 06:32 16 chemistry, but in all its aspects, and then within organic  
 06:32 17 chemistry, I specialize in synthesis, stereochemistry,  
 06:32 18 medicinal chemistry.  
 06:32 19 Q. Have you ever worked with carboxylic-acid-containing  
 06:33 20 compounds as part of the work that you've done in chemistry?  
 06:33 21 A. I think throughout my career I've worked with carboxylic  
 06:33 22 acids.  
 06:33 23 Q. And have you worked with aqueous solutions of  
 06:33 24 carboxylic-containing compounds?  
 06:33 25 A. That is standard chemistry you have to do if you work

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06:34 1 A. So, I went to the University of Oxford in 1973 to study  
 06:35 2 for a B.A. in chemistry. It's a four-year course, so I  
 06:35 3 received my B.A. in 19 -- so I went in 1969. I got my B.A. in  
 06:35 4 1973, after a four-year course.  
 06:35 5 And then I stayed on for my D.Phil., which is  
 06:35 6 equivalent to a Ph.D., and I received that two years later in  
 06:35 7 1975.  
 06:35 8 I then received a competitive research fellowship that  
 06:35 9 allowed me to go and work with anybody I chose. I chose to  
 06:35 10 stay in Oxford, but moved from organic chemistry to inorganic  
 06:35 11 chemistry in order to learn applications of metals and other  
 06:35 12 inorganic compounds to organic chemistry. That was a two-year  
 06:35 13 position, so that took me to 1977, when I received -- gained  
 06:36 14 another competitive research fellowship, a N.A.T.O.  
 06:36 15 fellowship, which I took to Paris to work with Professor Sir  
 06:36 16 Derek Barton on natural product chemistry, again trying to  
 06:36 17 broaden my research experience.  
 06:36 18 And after one year there, I gave that up because I was  
 06:36 19 offered a tenure-track position in the French Scientific Civil  
 06:36 20 Service, and I held that position for two years before coming  
 06:36 21 back, being invited back to Oxford on the faculty there.  
 06:36 22 Q. What, if any, degrees did you obtain while you were in  
 06:36 23 Paris?  
 06:36 24 A. I received in 1980 a second doctoral degree from the  
 06:36 25 University of Paris.

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06:36 1 Q. And in what area of science was that?  
 06:36 2 A. It was in organic chemistry.  
 06:36 3 Q. And what did you do then after you came back from Paris?  
 06:37 4 I think you were starting to mention that.  
 06:37 5 A. So, I set up an independent research career. I started  
 06:37 6 off as a University Lecturer, and then I've moved up from a  
 06:37 7 tenure-track to a tenure position to a professorship now to  
 06:37 8 the main chair of an inorganic -- in organic chemistry.  
 06:37 9 Q. And, now, would you please briefly describe your research  
 06:37 10 work since 1980?  
 06:37 11 A. It's been in all aspects of chemistry, focussing on  
 06:37 12 organic chemistry, so we have a lot of collaborations across  
 06:37 13 other departments in the university and other parts of  
 06:37 14 chemistry. It's all to do with how to make organic compounds,  
 06:37 15 how do you control their structure and their shape, and how  
 06:38 16 those compounds can be applied to biological systems and to  
 06:38 17 the development of drugs.  
 06:38 18 Q. Do you also teach at the University of Oxford?  
 06:38 19 A. Since I think 1976, I've taught at the University of  
 06:38 20 Oxford, apart from the three years I was in Paris, but I've  
 06:38 21 been on the faculty and teaching on the faculty since 1980.  
 06:38 22 In the last ten years, my contract says I don't have to teach  
 06:38 23 anymore, but I choose to do a full teaching load.  
 06:38 24 Q. And what is it that you teach?  
 06:38 25 A. To undergraduates, in a tutorial based system, I teach

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06:38 1 the whole of organic chemistry. In terms of to the -- to --  
 06:38 2 in terms of lecture courses, I can only teach the first course  
 06:38 3 in organic chemistry that they receive at the University of  
 06:38 4 Oxford; in fact, they get their first lecture from me. And I  
 06:39 5 also teach a course on aromatic and heteroaromatic and  
 06:39 6 pharmaceutical chemistry.  
 06:39 7 Q. Do you teach about hydrogen bonding as part of your  
 06:39 8 courses that you teach at Oxford?  
 06:39 9 A. It's part of the very start of their career, so since I  
 06:39 10 give them their first course, I certainly do.  
 06:39 11 Q. And is hydrogen bonding an aspect or a type of chemistry?  
 06:39 12 A. It's chemistry, yes, absolutely. It's a fundamental part  
 06:39 13 of chemistry.  
 06:39 14 Q. Now, were you in the courtroom yesterday listening to the  
 06:39 15 defendants' opening statement?  
 06:39 16 A. I was, yes.  
 06:39 17 Q. Do you recall that the defendants gave a PowerPoint  
 06:39 18 presentation about the theory of how NSAIDs would allegedly  
 06:39 19 complex with BAC, benzalkonium chloride?  
 06:39 20 A. I saw that, yes.  
 06:39 21 Q. Could we put up -- before we get to the document I was  
 06:40 22 going to introduce, let me ask a few more questions.  
 06:40 23 I want to go back to your graduate program that you  
 06:40 24 work within and with the students at Oxford. Do you work with  
 06:40 25 graduate students at Oxford?

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06:40 1 A. I do, yes. Over the years, I've supervised more than --  
 06:40 2 well over a hundred doctoral students have come through my  
 06:40 3 group and graduated.  
 06:40 4 Q. And, Dr. Davies, have you founded or cofounded any  
 06:40 5 companies in the pharmaceutical area?  
 06:40 6 A. I have, yes. They're listed in my curriculum vitae, on  
 06:40 7 the third page of that. I've been founding companies since  
 06:40 8 1992. And there's six or seven or more different companies  
 06:41 9 that are listed there.  
 06:41 10 Q. And what do some of these companies do in terms of the  
 06:41 11 work or research that they do?  
 06:41 12 A. Well, the first company I founded was Oxford Asymmetry in  
 06:41 13 1992; it's a limited company. That was a service company to  
 06:41 14 the pharmaceutical industry. It was there to provide  
 06:41 15 synthetic methods and, in particular, ways to make  
 06:41 16 single-handed molecules to improve drugs for the  
 06:41 17 pharmaceutical industry.  
 06:41 18 And in 1995, I founded a company called Oxford  
 06:41 19 Diversity Limited, another service-type company for the  
 06:41 20 pharmaceutical and the agrochemical industries, where we made  
 06:41 21 libraries of very large numbers, up to a million single  
 06:41 22 compounds for biological evaluation by pharmaceutical  
 06:41 23 companies.  
 06:41 24 I founded in 2000 -- and so those two would be drawn  
 06:42 25 together to a company called Oxford Asymmetry International,

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06:42 1 PLC, so it's a public company. At that stage, that was in  
 06:42 2 1998, we sold it in 2000. It's still going. It's a large  
 06:42 3 contract research organization these days.  
 06:42 4 2003, I founded a company called VASTox, which is now  
 06:42 5 called Summit Corporation, which is -- started off as a novel  
 06:42 6 way to screen molecules for biological properties, drug-like  
 06:42 7 properties. Currently, it's called -- it's Summit  
 06:42 8 Corporation, which is listed on the London Exchange and on  
 06:42 9 NASDAQ, and that has -- that is a drug -- drug discovery and  
 06:42 10 development company, has two compounds going through the drug  
 06:42 11 development process. One is in Phase 2; the other one is in  
 06:42 12 Phase 3. The one in Phase 2 is for an orphan disease called  
 06:43 13 Duchenne muscular dystrophy. And the other one is a novel  
 06:43 14 completely selective antibiotic against clostridium difficile.  
 06:43 15 Most recently, I founded a company called OxStem  
 06:43 16 Limited, which is looking at regenerative medicine, how do you  
 06:43 17 develop drugs for controlling cells within the body to self  
 06:43 18 repair in disease states.  
 06:43 19 Q. What, if any, honors or awards have you received in  
 06:43 20 connection with your work?  
 06:43 21 A. As I also listed on my C.V., so there is -- over the  
 06:43 22 years, there is a significant list of awards for the work we  
 06:43 23 have been doing.  
 06:43 24 Q. Okay. There is an award on your C.V. called the Perkin  
 06:44 25 Medal. Do you see that?

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06:44 1 A. It's the Perkin Prize and Medal, yes, for organic  
 06:44 2 chemistry.  
 06:44 3 Q. What is that?  
 06:44 4 A. That's given by the Royal Society of Chemistry, London.  
 06:44 5 It's their most prestigious organic chemistry award. It's  
 06:44 6 basically a lifetime achievement award.  
 06:44 7 Q. And what, if any, scientific journals have you served as  
 06:44 8 an editor on?  
 06:44 9 A. I have been editor on a number of journals. In fact, I  
 06:44 10 founded a journal in 1990 called *Tetrahedron: Asymmetry*. I  
 06:44 11 became the editor in chief at that time, and I'm still the  
 06:44 12 editor in chief.  
 06:44 13 I'm also on the board of the *Tetrahedron* publications,  
 06:44 14 which is a set of journals of which *Tetrahedron: Asymmetry* is  
 06:44 15 one, but the others are *Tetrahedron*, *Tetrahedron Letters*,  
 06:44 16 *Bioorganic & Medicinal Chemistry*, and *Bioorganic Chemistry*  
 06:45 17 *Letters*. And I have been on the editorial board of another --  
 06:45 18 a number of others journals, as well.  
 06:45 19 Q. Would you please turn to plaintiff's trial Exhibit 632 in  
 06:45 20 your binder and identify that document?  
 06:45 21 A. That is my list of publications.  
 06:45 22 Q. And does your list of publications accurately reflect  
 06:45 23 your published research articles?  
 06:45 24 A. Well, it goes up to 568. But since the time this was  
 06:45 25 produced, I would have published four or five more papers.

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06:46 1 A. I did, yes.  
 06:46 2 Q. And if you could please turn to Columns 11 through 14 of  
 06:47 3 the '431 patent, let me know when you're there.  
 06:47 4 A. I'm there.  
 06:47 5 Q. Did you review the claims at the end in Columns 11  
 06:47 6 through 14 of the '431 patent in connection with the opinions  
 06:47 7 that you've offered in this case?  
 06:47 8 A. I reviewed the whole patent, including the claims, yes.  
 06:47 9 Q. Did you gain a general understanding, Dr. Davies, of what  
 06:47 10 is claimed in the '431 patent?  
 06:47 11 A. Yes, I did.  
 06:47 12 Q. And what is your general understanding of what is claimed  
 06:47 13 in the '431 patent?  
 06:47 14 MS. HOLLAND: Objection, Your Honor. This is the  
 06:47 15 same objection I raised earlier. I mean, to speak about  
 06:47 16 what's generally claimed is problematic. Generally disclosed  
 06:47 17 in the specification is a different question, but the claims  
 06:47 18 are very particular and you can't speak about them in  
 06:47 19 generalities.  
 06:47 20 MR. DINER: Your Honor, he can talk about what the  
 06:47 21 elements are in the claim, and I am only going to ask him as  
 06:47 22 for Claim 6, for example, can you describe generally what is  
 06:47 23 covered by Claim 6 of the '431 patent.  
 06:47 24 THE COURT: Well, it's the same problem.  
 06:47 25 By way of introduction, I'll permit it, but the

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06:45 1 MR. DINER: Your Honor, plaintiffs would like to  
 06:45 2 proffer Dr. Davies as an expert in the field of chemistry.  
 06:45 3 THE COURT: Any objection?  
 06:45 4 MS. HOLLAND: I don't have an objection to his  
 06:45 5 expertise in chemistry.  
 06:45 6 We obviously have an objection to the relevance of  
 06:45 7 his expertise to this case. I would be happy to voir dire on  
 06:45 8 that, your Honor, but I'm also happy to ask those questions  
 06:45 9 later.  
 06:45 10 THE COURT: All right. Perhaps save them for cross  
 06:46 11 and see what ground is covered on direct.  
 06:46 12 MS. HOLLAND: Okay. Yes.  
 06:46 13 THE COURT: All right. Then I'll certainly recognize  
 06:46 14 Dr. Davies as an expert in chemistry.  
 06:46 15 BY MR. DINER:  
 06:46 16 Q. Dr. Davies, let's discuss the patent-in-suit for a  
 06:46 17 moment.  
 06:46 18 Would you please turn to JTX-001 in your binder, and  
 06:46 19 identify that document.  
 06:46 20 A. This is U.S. Patent 8,129,431.  
 06:46 21 Q. And if I refer to the U.S. Patent 8,129,431 as the '431  
 06:46 22 patent, will you understand what I mean?  
 06:46 23 A. Yes.  
 06:46 24 Q. Okay. Did you review the '431 patent in connection with  
 06:46 25 your opinions in this case?

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06:48 1 claims are what the claims are.  
 06:48 2 And so what's the pending question again?  
 06:48 3 BY MR. DINER:  
 06:48 4 Q. As to Claim 6, Dr. Davies, what is your general  
 06:48 5 understanding of what that claim covers in the '431 patent?  
 06:48 6 A. Liquid aqueous preparation of bromfenac and tyloxapal for  
 06:48 7 ophthalmic use.  
 06:48 8 MS. HOLLAND: This is actually outside the scope of  
 06:48 9 his expert report, your Honor, believe it or not. Dr. Davies  
 06:48 10 really didn't look at -- didn't discuss anything about the  
 06:48 11 patents in depth. He just went right into the chemistry.  
 06:48 12 There is nothing in the expert report that talks about Claims  
 06:48 13 6 or 20.  
 06:48 14 MR. DINER: Well, your Honor, Dr. Davies was deposed  
 06:48 15 on his opinions and there was discussion in his deposition as  
 06:48 16 to the claims and what they generally cover. He offered  
 06:48 17 testimony on that. It should come as no surprise at this  
 06:48 18 point, and it's just introductory. We're going to be getting  
 06:48 19 into the chemistry in a second, your Honor.  
 06:48 20 MS. HOLLAND: Your Honor, Dr. Davies actually  
 06:48 21 testified at his deposition that he did not look at the  
 06:48 22 patents in detail. That was his question. So I'm therefore  
 06:49 23 going to continue objecting to Dr. Davies giving any kind of  
 06:49 24 detailed testimony about the patents. It's not in the report,  
 06:49 25 and at his deposition he said he did not review the patents in

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06:49 1 detail.

06:40 2 THE COURT: All right. I think I've just sustained

06:48 3 the objection. If it's not in the report and the deposition

06:49 4 didn't have detailed testimony on it, he said he had not

06:49 5 reviewed the patents to prepare his report, then I'll sustain

06:49 6 it.

06:49 7 MR. DINER: Actually, your Honor, he did say that he

06:49 8 considered the patents. He didn't review them in detail is

06:49 9 what he said at his deposition, but he did consider the

06:49 10 patents in an overall sense and has a view as to, in an

06:49 11 overall sense, what the patents are directed to.

06:49 12 MS. HOLLAND: Your Honor, again, it's not in the

06:49 13 report. He gave specific testimony at his deposition that he

06:49 14 wasn't here to talk about the patents. He doesn't know what

06:49 15 they say in detail. He's only talking about the chemistry.

06:49 16 That appears over and over in the deposition. And I'm happy

06:49 17 to hand it up and show it to you, but I don't think there will

06:49 18 be disagreement on that.

06:49 19 THE COURT: Well, his testimony is going to be about

06:49 20 the chemistry.

06:49 21 MR. DINER: That's right.

06:49 22 THE COURT: If it's necessary to ask a question or

06:49 23 two about how it relates to why we're all here, I'll permit

06:49 24 it, but --

06:49 25 MR. DINER: Okay.

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06:51 1 Q. I'd like to turn now to defendant's Exhibit DDX1-12. I

06:51 2 believe, Dr. Davies, this is also in the leaflet of your

06:51 3 binder there.

06:51 4 Now, do you recall during the opening statement that

06:51 5 you testified to earlier that you were present at, that this

06:52 6 slide was presented by defendants during their opening?

06:52 7 A. Yes, I saw it.

06:52 8 Q. And in this slide, is it reporting an alleged

06:52 9 complexation occurring as between an NSAID, which happens to

06:52 10 be bromfenac, and an ion of benzalkonium chloride in solution?

06:52 11 A. That's what it is supposed to show.

06:52 12 Q. Okay. And was it your understanding that as defendants

06:52 13 rolled this slide, because I believe it was an animated slide,

06:52 14 that when they formed the complex, they caused a precipitate

06:52 15 to develop in solution?

06:52 16 A. That's what was said.

06:52 17 Q. Dr. Davies, can you tell us if that process, if it,

06:52 18 indeed, is true, that they come together and form a complex,

06:52 19 is a matter of chemistry?

06:52 20 MS. HOLLAND: I don't -- that is not in the expert

06:52 21 report. I'm not sure I understand the question. So maybe if

06:53 22 the question were rephrased, I could --

06:53 23 MR. DINER: Well, he's talked about in his expert

06:53 24 reports about the likelihood of things precipitating in the

06:53 25 context of the complexation issue.

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06:49 1 THE COURT: In other words, it will be by way of

06:50 2 directing me to which terms and so forth he is addressing as a

06:50 3 chemist.

06:50 4 MR. DINER: Okay. Fair enough.

06:50 5 BY MR. DINER:

06:50 6 Q. Now, Dr. Davies, did you hear Dr. Lawrence testify

06:50 7 earlier about certain NSAIDs, bromfenac, diclofenac,

06:50 8 ketorolac, and flurbiprofen?

06:50 9 A. I did, yes.

06:50 10 Q. Did you hear Dr. Lawrence testify that because each of

06:50 11 bromfenac, diclofenac, ketorolac and flurbiprofen possess a

06:50 12 carboxylic acid group, that they would be expected to behave

06:50 13 similarly in solution?

06:50 14 A. I heard that, yes.

06:50 15 Q. Do each of bromfenac, ketorolac, diclofenac and

06:50 16 flurbiprofen include a carboxylic acid group?

06:50 17 A. They do as one of other groups in each of them, yes.

06:50 18 Q. And did you also hear Dr. Lawrence testify regarding the

06:51 19 preservative benzalkonium chloride?

06:51 20 A. I did, yes.

06:51 21 Q. Did you hear Dr. Lawrence testify that because each of

06:51 22 bromfenac, diclofenac, ketorolac and flurbiprofen possess a

06:51 23 carboxylic acid group, they would be expected to interact in

06:51 24 solution with benzalkonium chloride and form a complex?

06:51 25 A. I heard that, yes.

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06:53 1 THE COURT: I'll permit it. If you would like to

06:53 2 repeat the question.

06:53 3 BY MR. DINER:

06:53 4 Q. Dr. Davies, as we see in DDX1-12, the coming together of

06:53 5 the NSAID here identified as bromfenac with an ion of

06:53 6 benzalkonium chloride to form a complex, is that complexation

06:53 7 a matter of chemistry in your view?

06:53 8 A. That sort of process, if it were to happen, is chemistry.

06:53 9 That's what chemistry is, as is the solution and

06:53 10 precipitation. It's all chemistry.

06:53 11 Q. And was it your understanding that defendant's position

06:53 12 here is that the complexation is the reason or motivation for

06:54 13 how they are looking at the various pieces of prior art?

06:54 14 A. I heard that, yes.

06:54 15 Q. Okay. Now, going back to the testimony offered by Dr.

06:54 16 Lawrence, did you understand that it was her opinion that a

06:54 17 person of ordinary skill in the art would expect that

06:54 18 bromfenac to form an insoluble precipitate with benzalkonium

06:54 19 chloride in solution and precipitate out?

06:54 20 A. That's what she said.

06:54 21 Q. Do you agree with that?

06:54 22 A. I don't agree with that, no.

06:54 23 Q. Why is that?

06:54 24 A. I've not seen any evidence to suggest that would happen.

06:54 25 Q. Dr. Davies, in your opinion, when one is considering

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06:54 1 whether something like this would occur, what would the person  
 06:54 2 of ordinary skill in the art look at in terms of the molecules  
 06:55 3 that are involved in a complexation reaction like this?  
 06:55 4 A. **You would have to look at the whole molecule, whole**  
 06:55 5 **molecules or ions being involved, you have to look at all of**  
 06:55 6 **the functional groups that are in those molecules, and you**  
 06:55 7 **have to look at the effects that would keep molecules in**  
 06:55 8 **solution or cause them to precipitate.**  
 06:55 9 Q. And what else would you look at in terms of the molecules  
 06:55 10 that are in solution as to whether they would or would not  
 06:55 11 precipitate?  
 06:55 12 A. **You can't actually tell them until you do an experiment,**  
 06:55 13 **but you can compare molecules and you can look at whether they**  
 06:55 14 **are ionized, whether they form hydrogen bonds, what the**  
 06:55 15 **polarity of the various groups are, what the distribution of**  
 06:55 16 **the groups are, and what the shapes of the molecules are.**  
 06:56 17 Q. And as between the compounds, the NSAIDs that we were  
 06:56 18 mentioning before, bromfenac, diclofenac, ketorolac,  
 06:56 19 flurbiprofen, do you have an understanding of whether those  
 06:56 20 compounds are structurally similar or dissimilar?  
 06:56 21 A. **The molecules contain different functional groups,**  
 06:56 22 **different heteroatoms placed in different positions. In a**  
 06:56 23 **person of ordinary skill's view, I think that would be -- they**  
 06:56 24 **are certainly different molecules.**  
 06:56 25 Q. And so what are some of the functional properties that

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06:56 1 the differences you just testified to in structure can give  
 06:56 2 rise to?  
 06:56 3 A. **Different hydrogen bonding abilities, different**  
 06:56 4 **solubilities, different molecular weights, a whole variety of**  
 06:56 5 **different properties, physical and chemical.**  
 06:56 6 Q. You mentioned hydrogen bonding a moment ago. What in  
 06:57 7 particular is hydrogen bonding, generally speaking?  
 06:57 8 A. **It's the interaction -- it normally occurs where you can**  
 06:57 9 **put up hydrogen atom in-between two heteroatoms, which a**  
 06:57 10 **heteroatom being an oxygen or a nitrogen most commonly, and it**  
 06:57 11 **forms an additional bond that gives you stability.**  
 06:57 12 Q. Have you prepared a demonstrative to assist the Court  
 06:57 13 with your testimony in this regard?  
 06:57 14 A. **I have, yes.**  
 06:57 15 Q. Would you please describe this demonstrative in the  
 06:57 16 context of hydrogen bonding.  
 06:57 17 A. **Certainly. So, to illustrate hydrogen bonding, I picked**  
 06:57 18 **a very simple molecule, water, which is H<sub>2</sub>O, which I've drawn**  
 06:57 19 **on the top left of the screen. It has a hydrogen -- two**  
 06:57 20 **hydrogens bound to an oxygen atom.**  
 06:58 21 Q. May I interrupt you for a moment?  
 06:58 22 MR. DINER: Your Honor, may I approach the witness  
 06:58 23 and hand him a pointer?  
 06:58 24 THE COURT: Sure.  
 06:58 25 MR. DINER: I think it will assist the Court. Oh,

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06:58 1 you have one there. Okay. Thank you.  
 06:58 2 THE WITNESS: I've drawn the oxygen atom in red as a  
 06:58 3 red ball and the two hydrogens are the gray spheres. Water  
 06:58 4 has a molecular weight of 18, and at that molecular weight,  
 06:58 5 normally one might expect it to be a gas, but we all know that  
 06:58 6 water is a liquid, and the reason water is a liquid is the  
 06:58 7 water molecules are held together by what are called hydrogen  
 06:58 8 bonds, and the hydrogen -- so I've tried to illustrate that on  
 06:58 9 the bottom left here. And the hydrogen bond occurs when you  
 06:58 10 put a hydrogen, say that one, in-between that oxygen and that  
 06:58 11 oxygen, whenever a hydrogen ends up between two heteroatoms,  
 06:58 12 oxygen in this case, you get an extra bonding. This water  
 06:58 13 molecule essentially bonds to the other water molecule. That  
 06:59 14 water molecule bonds to that water molecule. So, you end up  
 06:59 15 with a chain of one molecule bonding to another, bonding to  
 06:59 16 another, bonding to another, and those bonds stabilize the  
 06:59 17 molecule, stabilize it so it is now a liquid holding those  
 06:59 18 water molecules together.  
 06:59 19 BY MR. DINER:  
 06:59 20 Q. Are those hydrogen bonds strong bonds?  
 06:59 21 A. **They are strong hydrogen bonds, yes, strong bonds.**  
 06:59 22 Q. And what is the implication of those bonds being strong  
 06:59 23 bonds?  
 06:59 24 A. **That you have to put energy in to break them and to split**  
 06:59 25 **the water molecules apart. So, for example, you have to**

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06:59 1 **put -- you have to put energy into water, liquid water, in**  
 06:59 2 **order to make it steam. That is breaking hydrogen bonds.**  
 06:59 3 Q. Please continue with your description or your  
 06:59 4 explanation.  
 06:59 5 A. **So, these types of hydrogen bonds are one of the most**  
 06:59 6 **important reasons why molecules dissolve in water. And I**  
 07:00 7 **picked two functional groups in organic chemistry to**  
 07:00 8 **illustrate that. One is a carbonyl group, which is this**  
 07:00 9 **structure on the top row in the middle. It has a carbon atom**  
 07:00 10 **bound to two other parts of the molecule, and the double bond**  
 07:00 11 **illustrated by those two vertical lines connect the carbon to**  
 07:00 12 **the oxygen atom shown in red.**  
 07:00 13 Q. Dr. Davies, may I interrupt a second? The carbonyl group  
 07:00 14 that you have drawn here, is that a basic chemical moiety?  
 07:00 15 A. **It's one of the most common chemical functional groups.**  
 07:00 16 Q. And as a chemical functional group or moiety, does that  
 07:00 17 exist on the product bromfenac?  
 07:00 18 A. **It does, yes.**  
 07:00 19 Q. Please continue.  
 07:00 20 A. **So, this is an oxygen atom. When it dissolves in water,**  
 07:00 21 **when this molecule dissolves in water, if it dissolves, it**  
 07:00 22 **dissolves because a water molecule can put a hydrogen, one of**  
 07:01 23 **these hydrogens between its own oxygen and the oxygen of the**  
 07:01 24 **carbonyl and form a hydrogen bond. Likewise, another molecule**  
 07:01 25 **of water can form a second hydrogen bond to that oxygen atom.**

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07:01 1 And those two bonds as shown in the middle structure on the  
07:01 2 bottom, those two hydrogen, strong hydrogen bonds are what's  
07:01 3 helped keep the molecule in solution.

07:01 4 Another common functional group is an amine. I've  
07:01 5 drawn a primary amine, a nitrogen bound to two hydrogens on  
07:01 6 the top right here. And this can also hydrogen bond, this  
07:01 7 type of functional group, it can hydrogen bond, but in the  
07:01 8 other way because the two hydrogens are nitrogen already.  
07:01 9 Then what happens now when it dissolves is water puts an  
07:01 10 oxygen atom in a line, oxygen, hydrogen, nitrogen on the  
07:02 11 left-hand one to form a strong hydrogen bond, so when this  
07:02 12 primary amine with the two hydrogens, a nitrogen dissolves in  
07:02 13 water, a water molecule forms a strong hydrogen bond to the  
07:02 14 hydrogen on the left by placing its oxygen in a line from  
07:02 15 between the oxygen, the hydrogen and the nitrogen. So, you  
07:02 16 have two heteroatoms, oxygen and nitrogen this time with a  
07:02 17 hydrogen in the middle.

07:02 18 It can do exactly the same on the right-hand side.  
07:02 19 Another water molecule comes up, forms a strong hydrogen bond  
07:02 20 to the hydrogen on the right. There's oxygen, hydrogen,  
07:02 21 nitrogen now. That's the hydrogen bond. And that bonding  
07:02 22 holds that type of structure, that type of functional group in  
07:02 23 water, in aqueous solution.

07:02 24 Q. Now, the primary amine functional group that you were  
07:02 25 just referring to on the right portion on the slide, is that

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07:02 1 also a chemical functional group that exists on bromfenac?  
07:03 2 A. It is indeed.  
07:03 3 Q. And so how, if at all, does this hydrogen bonding impact  
07:03 4 the solvation of an anion such as bromfenac in solution?  
07:03 5 A. Well, the more hydrogen bonds that a molecule or an ion  
07:03 6 can form, the more solvated it will be and the more soluble it  
07:03 7 will be and the less likely it will be to precipitate out of  
07:03 8 solution with anything else or, indeed, on its own.

07:03 9 MR. DINER: I think it's close to 4:30, your Honor.  
07:03 10 I think this would be a good breaking point.

07:03 11 THE COURT: It's a good time to break for the day  
07:03 12 then, and so we will adjourn the trial portion until tomorrow  
07:03 13 morning at 9:30. And why don't we take about a five-minute  
07:03 14 break, and then we will resume for the oral argument on the  
07:03 15 appeal motion. Okay?

07:04 16 (Recess at 4:35 p.m.).

07:13 17 THE DEPUTY CLERK: All rise.

07:13 18 (OPEN COURT; 4:45 p.m.)

07:13 19 THE COURT: Be seated, please. Okay. I'd like to  
07:14 20 convene oral argument upon the motion by Lupin and InnoPharma  
07:14 21 appealing from Magistrate Judge Williams, February 10th, 2016,  
07:14 22 discovery order. This is Docket Item No. 70 in the -- I think  
07:14 23 in the lead case. But it applies to all -- all cases.

07:14 24 And so this is the defendant's motion. I've read your  
07:14 25 papers, I have a few questions, and who will argue the case?

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07:14 1 MS. DAUGHTREY: Good afternoon, Your Honor, Natasha  
07:14 2 Daughtrey from Goodwin Proctor on behalf of the Lupin and  
07:15 3 defendants. And so as Your Honor stated, we are appealing  
07:15 4 Judge Magistrate Williams's order and request that the Court  
07:15 5 order the plaintiffs to produce unredacted copies of these two  
07:15 6 scientific reports or, at the very least, Your Honor, we would  
07:15 7 request that the Court review these quite short documents in  
07:15 8 camera, which is what we believe is appropriate in the  
07:15 9 circumstances such as this where the issue of privilege is  
07:15 10 contested.

07:15 11 THE COURT: And I think the document that was  
07:15 12 presented for in-camera inspection was not these reports, was  
07:15 13 it? Wasn't it just the unredacted transcript of the  
07:15 14 deposition?

07:15 15 MS. DAUGHTREY: So, Your Honor, I think at the time  
07:15 16 that we originally did this briefing, we didn't have agreement  
07:15 17 with the plaintiffs on certified English translations of  
07:15 18 Japanese documents, and so I have -- they're on our DTX list.  
07:15 19 They were in the pretrial order. I can give you the copies of  
07:15 20 the actual document, which I think will facilitate your  
07:15 21 decision here.

07:15 22 THE COURT: Well, it might. But wouldn't it have  
07:15 23 facilitated Judge Williams's decision? You're asking me to  
07:15 24 review what you presented to her and what she decided.

07:16 25 MS. DAUGHTREY: Yes, we offered, I believe on the

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07:16 1 teleconference, to send these documents to Judge Williams, and  
07:16 2 she -- at that time, she requested that the plaintiff provide  
07:16 3 the declaration from Ms. Kashida, and it might make -- that  
07:16 4 might make sense why she didn't have the documents because in  
07:16 5 her order, she just said if Ms. Kashida's declaration falls  
07:16 6 within the Bates range of the documents, you know, then I find  
07:16 7 it privileged. But she didn't have the documents in front of  
07:16 8 her, you're correct.

07:16 9 She did have the portions of the unredacted transcript,  
07:16 10 which I believe conveyed the -- some of the information that  
07:16 11 was redacted, but it did not -- she did not have the full, you  
07:16 12 know -- she did not have the full context for the documents,  
07:16 13 because at that time, we didn't have certified translations or  
07:16 14 an agreement with plaintiffs on that, and if we had been  
07:16 15 allowed to conduct full briefing in front of Judge Williams,  
07:16 16 we would have been happy to have provided it to her at that  
07:17 17 time. But we weren't and, you know, she issued her decision  
07:17 18 and so here we are.

07:17 19 THE COURT: All right. As to the transcript, are you  
07:17 20 seeking that I should inspect it in camera, the unredacted  
07:17 21 transcript of the deposition?

07:17 22 MS. DAUGHTREY: Well, yes, you can review the  
07:17 23 unredacted transcript, which I believe is part of the briefing  
07:17 24 to Magistrate Judge Williams. But it would give you context  
07:17 25 to view that in addition to the DTXs. They are on our DTX

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07:17 1 list. I have copies of them here. I can hand them up to Your  
 07:17 2 Honor. They are redacted, but viewing, I think, Mr. Sawa's  
 07:17 3 testimony about these documents, Ms. Kashida's declaration,  
 07:17 4 which I believe Your Honor already has, and the documents, it  
 07:17 5 would be an easy task for Your Honor to review them in camera  
 07:17 6 and make a decision on this.

07:17 7 THE COURT: Because the redactions in the -- in the  
 07:18 8 documents are what was read into the record of the deposition,  
 07:18 9 at least most of them, I guess?

07:18 10 MS. DAUGHTREY: I believe it's partially or all of  
 07:18 11 it, yes, that's correct.

07:18 12 THE COURT: Now I know the existence of that, but  
 07:18 13 I've not inspected it, because I didn't think it would be  
 07:18 14 appropriate in reviewing something that wasn't inspected  
 07:18 15 below. I think one of the arguments or one of the issues  
 07:18 16 today is, that you've raised is, whether it was an abuse of  
 07:18 17 discretion for the Magistrate Judge not to have inspected the  
 07:18 18 documents that you presented. So I've not inspected them.  
 07:18 19 I'm putting myself into the position that existed at that time  
 07:18 20 in determining, with the appropriate standard of review,  
 07:18 21 whether Judge Williams erred.

07:18 22 MS. DAUGHTREY: Yes, we understand. And like I said,  
 07:19 23 we requested her to review these in camera and she declined  
 07:19 24 and asked for the declaration and then issued her order  
 07:19 25 without reviewing the documents.

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07:20 1 MS. DAUGHTREY: No, and I can -- well, I think you  
 07:20 2 already have the transcript. He was asked, did you write this  
 07:20 3 document? Yes. Is that your signature? Yes. Do you  
 07:20 4 recognize it? Yes.

07:20 5 When asked about the specific contested statements, he  
 07:20 6 didn't recall why he wrote it. He was asked if he had any  
 07:20 7 reason to disagree with the statements and he said, I don't  
 07:21 8 know, and at that time, as Your Honor will recall, there was  
 07:21 9 no allegation that the information was privileged at all and  
 07:21 10 so we wouldn't have had a reason to probe whether that  
 07:21 11 information came from an attorney.

07:21 12 It was only -- I think it was close to an hour later  
 07:21 13 that the documents were clawed back, and at that point, it was  
 07:21 14 under the claim of privilege, without any explanation further.  
 07:21 15 And then I think it was six weeks later that plaintiff first  
 07:21 16 stated that the alleged privileged information came from  
 07:21 17 Ms. Kashida and she was present at the entire deposition when  
 07:21 18 all of this questioning occurred.

07:21 19 THE COURT: And so neither party really staked out  
 07:22 20 Sawa's factual testimony about whether he did or didn't confer  
 07:22 21 with the attorney?

07:22 22 MS. DAUGHTREY: No, and I mean, he couldn't recall  
 07:22 23 the specific statements, so I would -- I think that  
 07:22 24 establishes that he didn't know where the information came  
 07:22 25 from. But we were never -- we did not specifically ask him,

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07:19 1 THE COURT: Now, is that within the Judge's  
 07:19 2 discretion to obtain a sworn statement from the -- the  
 07:19 3 attorney with actual knowledge of the communication?

07:19 4 MS. DAUGHTREY: Your Honor, I think in a lot of these  
 07:19 5 cases, a declaration from an attorney or the recipient of  
 07:19 6 legal advice is used to establish the privilege. However, in  
 07:19 7 this case, the scientific reports at issue, they're not a  
 07:19 8 communication between Ms. Kashida and Mr. Sawa, they are a  
 07:19 9 report authored by Mr. Sawa. There's no evidence and I don't  
 07:19 10 think plaintiffs have made any evidence that this report was  
 07:19 11 ever forwarded to an attorney or anyone in the legal  
 07:19 12 department, and it's a scientific report, and so while Ms.  
 07:19 13 Kashida may very well be able to say that she provided certain  
 07:20 14 factual information to Mr. Sawa, she cannot -- she did not  
 07:20 15 establish in her declaration that Mr. Sawa didn't also obtain  
 07:20 16 that information from a nonlawyer or, you know, any number of  
 07:20 17 people, and unfortunately, at his deposition, Mr. Sawa was  
 07:20 18 completely unable to recall really anything about these  
 07:20 19 statements, and so given that, we really can't determine,  
 07:20 20 plaintiffs haven't demonstrated what the source, the true  
 07:20 21 source of the information is in Mr. Sawa's scientific report.  
 07:20 22 From our view of the case law, it just doesn't satisfy the  
 07:20 23 standards for privilege.

07:20 24 THE COURT: Was Sawa asked whether he communicated  
 07:20 25 with the attorney?

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07:22 1 you know, did this statement come from an attorney or  
 07:22 2 specifically Ms. Kashida or someone else. We didn't -- at the  
 07:22 3 time, we didn't think that they would be claiming privilege  
 07:22 4 over it because it had been produced and questions had been  
 07:22 5 asked about it.

07:22 6 THE COURT: Is there a reason that Judge Williams  
 07:22 7 should not have trusted the certification from Ms. Kashida?

07:22 8 MS. DAUGHTREY: So if you look at the certification  
 07:22 9 from Ms. Kashida, it -- really, there's one paragraph that's  
 07:22 10 two sentences that deals with this specific document at issue,  
 07:22 11 and she says that -- do you have a copy of it, Your Honor?  
 07:22 12 Would you like me to pass one up?

07:22 13 THE COURT: I do. It's Exhibit D to the -- to the  
 07:23 14 February 25th submission. I have it.

07:23 15 MS. DAUGHTREY: Okay. So if you see in Paragraph 4,  
 07:23 16 she says: I provided Shirou Sawa, a researcher, with certain  
 07:23 17 legal advice which was redacted from these two scientific  
 07:23 18 reports for the purposes of submitting -- and the project --  
 07:23 19 that's the project name on these scientific reports for  
 07:23 20 planning documents and summary reports.

07:23 21 Now, even if we assume that Ms. Kashida recalls from  
 07:23 22 ten years ago telling Mr. Sawa the allegedly privileged  
 07:23 23 information, that doesn't mean that the only source of the  
 07:23 24 information was from an attorney and therefore privileged.  
 07:23 25 Mr. Sawa could have learned this information from anyone, any

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07:23 1 number of people, and more importantly here, Your Honor, the  
 07:23 2 information is purely factual business information and the  
 07:23 3 case law is quite clear that even if you're getting  
 07:24 4 information from an attorney, it isn't privileged if it  
 07:24 5 relates to, you know, business strategies or commercial  
 07:24 6 aspects. And, you know, and if Your Honor would conduct an  
 07:24 7 in-camera review, I think it would be immediately apparent  
 07:24 8 that this is business as opposed to legal advice.

07:24 9 And as a further point, even assuming what Ms. Kashida  
 07:24 10 says is true and accurate, facts obtained from a third party  
 07:24 11 that you then convey to your client is not protected by the  
 07:24 12 privilege unless you're, you know, providing further legal  
 07:24 13 analysis of it.

07:24 14 And I know plaintiff in their briefing, apparently  
 07:24 15 maybe recognizing that this issue of normal attorney/client  
 07:24 16 privilege does not apply, have asserted that the common  
 07:24 17 interest privilege would apply. But as you can see from  
 07:24 18 Ms. Kashida's declaration, she doesn't say that she received  
 07:25 19 this information as part of a joint or common interest with  
 07:25 20 ISDA, an attorney at ISDA. She doesn't talk about that at all  
 07:25 21 and so -- and that's required for the common interest  
 07:25 22 privilege to apply, and furthermore the common interest  
 07:25 23 privilege does not apply if it's the conveyance of commercial  
 07:25 24 information.

07:25 25 THE COURT: Her declaration doesn't mention ISDA at  
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07:27 1 attorneys perform not only the legal functions of preparing  
 07:27 2 and prosecuting patent applications, but evaluate the business  
 07:27 3 ramifications of the company's patent position, as well. And  
 07:27 4 the Court goes on to say: The latter, it's just not  
 07:27 5 privileged. It's business ramifications.

07:27 6 It might, you know, be cloaked in the idea that has  
 07:27 7 some legal aspect to it, but it's ultimately factual business  
 07:27 8 information from a third party in this case.

07:27 9 THE COURT: All right. I don't think I have any  
 07:27 10 other questions at this time.

07:27 11 MS. DAUGHTREY: Thank you, Your Honor.

07:27 12 THE COURT: Thank you. Mr. Lipsey?

07:27 13 MR. LIPSEY: Sure, Your Honor. I mean, the fact of  
 07:27 14 the matter is that there was a procedure set forth for dealing  
 07:27 15 with this, there was plenty of time to deal with it. There  
 07:27 16 was a lot of paper exchanged. If they had wanted to put  
 07:27 17 something more before the Magistrate Judge, they could have  
 07:27 18 done that. They chose not to. And unless we are down to the  
 07:27 19 point that the Magistrate Judge must always conduct an  
 07:28 20 in-camera review, the procedure which she followed is one that  
 07:28 21 is reasonably commonly followed in the circumstances of asking  
 07:28 22 for a declaration from the legal representative involved, and  
 07:28 23 it was provided, and the statement was made that the section  
 07:28 24 that was redacted embodied legal advice that had been given to  
 07:28 25 Mr. Sawa.

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07:25 1 all, does it?

07:25 2 MS. DAUGHTREY: It does not.

07:25 3 THE COURT: And she was a Senju Pharmaceutical legal  
 07:25 4 department attorney?

07:25 5 MS. DAUGHTREY: That's correct. And the redacted  
 07:25 6 portions of the documents, and I can hand them to Your Honor,  
 07:25 7 around them, it talks about that this is related to ISDA's  
 07:25 8 stability testing or, you know, testing of a product obtained  
 07:25 9 from ISDA. The context of the document makes it clear that  
 07:25 10 this is something -- the unredacted portions of the document  
 07:25 11 make it clear that this is something related to ISDA, which is  
 07:25 12 a third party.

07:26 13 So, Your Honor, really, it boils down to, from the  
 07:26 14 defendant's point of view, Ms. Kashida possibly received  
 07:26 15 business information from a third party, told it to Mr. Sawa.  
 07:26 16 Who knows if anyone else told it to Mr. Sawa. He put it in a  
 07:26 17 scientific report and that's just not privileged. That's  
 07:26 18 factual commercial information.

07:26 19 And I think, Your Honor, particularly relevant here,  
 07:26 20 the Union Carbide case which we've cited in our briefing,  
 07:26 21 there's a sentence -- couple sentences in there, and this is  
 07:26 22 on Page 1047 of the *Union Carbide v Dow Chemical* case which is  
 07:26 23 619 F. Supp. 1036, and that's a District of Delaware case.

07:26 24 The Court said: The application of privilege in patent  
 07:26 25 litigation represents particular problems. Often patent

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07:28 1 THE COURT: Well, were the defendants really free to  
 07:28 2 send whatever they wanted to the Magistrate Judge? You've  
 07:28 3 raised objections that the defendants violated the discovery  
 07:28 4 confidentiality order by using what they did.

07:28 5 MR. LIPSEY: They could have sent the unredacted  
 07:28 6 document, which they did not do. At least, I didn't see it in  
 07:28 7 the pleadings.

07:28 8 THE COURT: The unredacted document is what you are  
 07:28 9 claiming privilege for in --

07:28 10 MR. LIPSEY: Oh, I misspoke. I misspoke. They could  
 07:28 11 have sent the redacted document. They did not is my  
 07:28 12 understanding. I think the only thing --

07:28 13 THE COURT: But they say the translation didn't exist  
 07:28 14 at that time.

07:28 15 MR. LIPSEY: I'm told they had -- they had a  
 07:28 16 translation of the deposition. We did not, is my  
 07:29 17 understanding, thus, the confusion over what was in the  
 07:29 18 document, which was then promptly clawed back.

07:29 19 THE COURT: Now, you're the party asserting the  
 07:29 20 privilege, of course. Do you agree that you have the burden  
 07:29 21 of establishing the privilege?

07:29 22 MR. LIPSEY: I think I have the burden of  
 07:29 23 establishing it within reason. I think I do not have the  
 07:29 24 burden of proving the negative and excluding all other  
 07:29 25 possible sources for the information. We have here a

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07:29 1 declaration from the involved legal professional, that the  
 07:29 2 material that's in there embodied legal advice that she had  
 07:29 3 given. The document in which it appears, while it is a  
 07:29 4 technical report, it appears in the introduction of a sort  
 07:29 5 where material relating to matters that are not specifically  
 07:29 6 scientific that are embodied in the report might well appear.  
 07:29 7 And short of standing up here and telling you what's in  
 07:30 8 the redacted portion, which, A, I can't do because we don't  
 07:30 9 want to waive the privilege and, B, as a matter of principle,  
 07:30 10 I think that what they really want you to do is they just want  
 07:30 11 you to read the document. This is not a circumstance in which  
 07:30 12 they really have a quarrel with the claim of privilege or  
 07:30 13 what's been said about it.  
 07:30 14 They had it, they saw it and they want Your Honor to  
 07:30 15 see it and they've done --  
 07:30 16 THE COURT: Well, isn't that something that should  
 07:30 17 give me pause? This is an unusual circumstance. They had the  
 07:30 18 document for six months. They prepared to examine on it.  
 07:30 19 There was no attorney/client privilege asserted at the  
 07:30 20 deposition, as far as I'm aware.  
 07:30 21 MR. LIPSEY: I think we clawed it back immediately.  
 07:30 22 THE COURT: It was clawed back based on privilege,  
 07:30 23 right?  
 07:30 24 MR. LIPSEY: Correct.  
 07:30 25 THE COURT: I don't know that it was announced that  
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07:30 1 this is attorney/client privileged information that they could  
 07:30 2 have then asked Mr. Sawa about.  
 07:31 3 It became the basis of the clawback, I believe.  
 07:31 4 MR. LIPSEY: I was not at the deposition. I  
 07:31 5 understand from my colleagues, that that was the basis on  
 07:31 6 which they clawed the document back.  
 07:31 7 MS. DAUGHTREY: Your Honor, I think -- I think  
 07:31 8 Mr. Margolis was taking the deposition. He asked Mr. Hasford  
 07:31 9 what is the basis for the privilege. Mr. Hasford said,  
 07:31 10 privilege, I'm not going to explain it anymore. So we had no  
 07:31 11 way to move forward and probe that and they had clawed the  
 07:31 12 document back at that point and asked us to immediately  
 07:31 13 destroy all copies.  
 07:31 14 So we wouldn't have been able to go through this  
 07:31 15 process and establish with Mr. Sawa, and plaintiffs could have  
 07:31 16 submitted a declaration from Mr. Sawa if there would have been  
 07:31 17 any evidence to support their claim here.  
 07:31 18 MR. LIPSEY: They already got the testimony from  
 07:31 19 Mr. Sawa that he didn't recall the event. There isn't any  
 07:31 20 testimony from Mr. Sawa. They know that.  
 07:31 21 THE COURT: So there's no support from Mr. Sawa for  
 07:31 22 the proposition that this is privileged. Is that --  
 07:31 23 MR. LIPSEY: There is no recollection of Mr. Sawa.  
 07:31 24 There is -- it is in a place in the document where a  
 07:32 25 communication from counsel in an otherwise technical document  
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07:32 1 might reasonably appear. It has been sworn by the Japanese  
 07:32 2 *bennrishi* that it, in fact, embodies legal advice that she did,  
 07:32 3 in fact, give and it -- short of having an in-camera  
 07:32 4 inspection, I don't know what more I can say about it. And  
 07:32 5 unless the Magistrate Judge was required to have conducted an  
 07:32 6 in-camera inspection, which I don't believe the law requires,  
 07:32 7 I don't think -- I guess -- let me just briefly touch on some  
 07:32 8 things that were said several times in the papers.  
 07:32 9 And that is, they say they want this because it  
 07:32 10 undermines plaintiff's contentions that the patents-in-suit  
 07:32 11 were developed to make needed improvements on its prior  
 07:33 12 formulations. The document in question is dated in 2006. The  
 07:33 13 patent application was filed fully and completely in January  
 07:33 14 of 2003. It doesn't even bare on why the work was done that's  
 07:33 15 in the patent that was done much earlier and filed much  
 07:33 16 earlier.  
 07:33 17 So I have no doubt that they want to use it. I -- I  
 07:33 18 don't believe there's been established any basis for reversing  
 07:33 19 the Magistrate Judge here. The procedure that was used is the  
 07:33 20 one that is customarily used, or at least not infrequently  
 07:33 21 used, and we would ask Your Honor to affirm the Magistrate  
 07:33 22 Judge.  
 07:33 23 THE COURT: And so, are you -- are you arguing that  
 07:33 24 the document itself is irrelevant, and that should end the --  
 07:33 25 end the inquiry? Because it comes after the formulation of  
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07:34 1 the -- after the application for the '431 patent?  
 07:34 2 MR. LIPSEY: I am arguing that in addition to the  
 07:34 3 fact that an adequate demonstration of privilege was made. In  
 07:34 4 other words, it cannot, because of its sequence in timing and  
 07:34 5 as they say, its subject matter relate to what the purpose of  
 07:34 6 the work that was embodied in the patent was.  
 07:34 7 THE COURT: And also Ms. Kashida did not come on  
 07:34 8 board until 2006, and so I assume that it's not based upon her  
 07:34 9 prior experience with the earlier application.  
 07:34 10 MR. LIPSEY: Correct, Your Honor, she --  
 07:34 11 THE COURT: Now, should I accept her conclusion or  
 07:35 12 should Judge Williams have accepted her conclusion that this  
 07:35 13 is legal advice as opposed to business chatter?  
 07:35 14 MR. LIPSEY: I believe it was within the discretion  
 07:35 15 of the trial Judge to accept that. Not trial Judge, the  
 07:35 16 Magistrate to accept that. And unless, as we say, it is to be  
 07:35 17 a matter of routine that the Magistrate Judge is required to  
 07:35 18 conduct an in-camera review, I think that we need to -- to  
 07:35 19 honor that discretion.  
 07:35 20 THE COURT: Normally, this would be a very easy call  
 07:35 21 for me, and I would tend to agree with you. There are  
 07:35 22 different ways of handling such a privilege dispute. What  
 07:35 23 gives me pause here is that the defendants actually know the  
 07:35 24 contents and they're characterizing it as business  
 07:35 25 information, and they're saying that if it had been inspected,  
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07:36 1 it would have become obvious that it was business information,  
07:36 2 that there's not some legal issue that this scientist,  
07:36 3 Mr. Sawa, is addressing. It's not authored by a lawyer, but  
07:36 4 rather, it's in his scientific report.

07:36 5 MR. LIPSEY: Your Honor, I have wrestled since you  
07:36 6 announced you wanted to discuss this, with how I can  
07:36 7 communicate to you some information about the nature of the  
07:36 8 communication without being accused of waiving the privilege,  
07:36 9 and without my own statement being offered into evidence  
07:36 10 against my client. I can't think of a way to do that, other  
07:36 11 than to say that -- that the text does reference patent  
07:36 12 matters, as the benrishi said.

07:37 13 THE COURT: Well, patents are also part of the  
07:37 14 business, aren't they? How much are we going to spend to  
07:37 15 develop, you know, further research or how much -- how much  
07:37 16 effort are we going to put into this particular product line  
07:37 17 where we have Patents A, B and C. Those are business  
07:37 18 decisions, aren't they?

07:37 19 MR. LIPSEY: I think I can fairly tell you without  
07:37 20 waiving the privilege, because I can tell you what's not in  
07:37 21 there and there's nothing about money in there. There's  
07:37 22 nothing about expense. Hypothetically, as you've given me a  
07:37 23 hypothetical, hypothetically, if a lawyer were to opine about  
07:37 24 what was covered by a patent, that would be legal advice. If  
07:37 25 the lawyer were to opine about what's covered by a pending

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07:39 1 MR. LIPSEY: I mean, if I may, Your Honor, my  
07:39 2 understanding of what happens when there's been an inadvertent  
07:40 3 production, is the proceeding is supposed to proceed as if  
07:40 4 nobody had seen it. Because frankly, using what you have  
07:40 5 learned from what you saw in order to gain access to it is  
07:40 6 improper. And some of these statements skate perilously close  
07:40 7 to the line. So I think for that reason, it should not be  
07:40 8 treated as a special situation. It should be treated as a  
07:40 9 garden-variety situation where a dispute has arisen and that  
07:40 10 the Magistrate has taken steps that the Magistrate deemed  
07:40 11 appropriate for ascertaining the applicability of the  
07:40 12 privilege, and that the Magistrate's discretion in that regard  
07:40 13 should be sustained.

07:40 14 THE COURT: I assume there's no dispute by either  
07:40 15 side that a benrishi legal advice is subject to the same  
07:41 16 protection as if she were an attorney and that the choice of  
07:41 17 law here is U.S. laws of attorney/client privilege and not  
07:41 18 Japanese law?

07:41 19 MR. LIPSEY: I believe the *East Side* case dealt with  
07:41 20 the fact that there is a privilege recognized for benrishi in  
07:41 21 Japan and that the U.S. law is that such privileges are  
07:41 22 recognized. Excuse me.

07:41 23 THE COURT: Do you agree, Ms. Daughtrey?

07:41 24 MS. DAUGHTREY: I agree, if the privilege meets all  
07:41 25 of the other requirements, for example, if it's not factual,

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07:37 1 application, that would be legal advice.  
07:37 2 These are things that patent lawyers would legitimately  
07:38 3 communicate to their -- their clients, and the fact that  
07:38 4 Mr. Sawa didn't recall where the information came from doesn't  
07:38 5 change it from being the kind of information in my  
07:38 6 hypothetical -- well, in the hypothetical, that's the sort of  
07:38 7 thing that might well be included in things like that. There  
07:38 8 are lots of explanations for this document that are benign.  
07:38 9 I'm not suggesting, and I understand Your Honor's point, you  
07:38 10 know, that sometimes, there is a, you know, a commingling of  
07:38 11 things that are clearly patent and a commingling of things  
07:38 12 that you could argue are more strategic. When they are  
07:38 13 inextricably intertwined, the privilege attaches, and all I  
07:39 14 can do by way of hypothetical is to say that there are  
07:39 15 situations of that nature where the privilege would properly  
07:39 16 apply, as described by the witness.

07:39 17 THE COURT: Well, I do feel a little left out because  
07:39 18 everybody in this courtroom but me knows what it says.

07:39 19 (Laughter.)

07:39 20 THE COURT: It's hard to decide this, imagining what  
07:39 21 it might say when your adversaries, who are honorable  
07:39 22 attorneys that said they've read it, it was in their hands for  
07:39 23 six months and they're characterizing it one way and you're  
07:39 24 characterizing it a different way, and I'm reviewing a  
07:39 25 decision of a Judge who didn't read it.

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07:41 1 business information, if it was a communication between the  
07:41 2 attorney and the client and if it wasn't just a third party's  
07:41 3 recitation of facts to a benrishi who then tells it to a  
07:41 4 scientist.

07:41 5 THE COURT: If Ms. Kashida's certification is held up  
07:41 6 to the -- to those standards, is there an element that's  
07:42 7 missing?

07:42 8 MS. DAUGHTREY: Yes. Well, you can see on their  
07:42 9 face, Your Honor, that it's not an e-mail between Ms. Kashida  
07:42 10 and Mr. Sawa, and I think when you alluded to the fact that  
07:42 11 this is an unusual situation, that's what you meant. Most of  
07:42 12 the time attorney/client privilege is claimed, it's a  
07:42 13 communication between an attorney and a client. And here,  
07:42 14 this is a scientific report that Mr. Sawa offered. There's no  
07:42 15 evidence that, you know, it was drafted by Ms. Kashida or  
07:42 16 Mr. Sawa sent it to Ms. Kashida. It's just his document and  
07:42 17 so their only claim of privilege really rests on that this  
07:42 18 redaction -- redacted information came from Ms. Kashida, and  
07:42 19 that that's the communication.

07:42 20 But in circumstances such as that, the case law has  
07:42 21 held, there's kind of a higher standard for demonstrating that  
07:42 22 it's an attorney/client communication and you have to  
07:42 23 demonstrate that the communication from the attorney to the  
07:42 24 client would not have occurred but for the need for the client  
07:42 25 to obtain legal advice. And you don't see anything in Ms.

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07:43 1 Kashida's declaration about that.

07:43 2 And I can tell you the case law that discusses that

07:43 3 issue, if you'd like, it's the *HPD v. Clorox* case, 202 FRD 410

07:43 4 414. That's a District of New Jersey case. And so, you

07:43 5 know, I think Your Honor, while an in-camera review may not

07:43 6 always be necessary, in a unique circumstance such as this

07:43 7 where there's no objective indicia -- I hate to use that word

07:43 8 in a patent case -- but there's no indicia on the face of the

07:43 9 document that it's privileged, and the parties contest it,

07:43 10 like you said, defendants characterize this as factual

07:43 11 information, plaintiffs argue Ms. Kashida's statement that it

07:43 12 is legal advice. In-camera review would be wholly appropriate

07:43 13 and very easy to resolve the dispute.

07:44 14 And in terms of the in-camera review, the matter of

07:44 15 *Grand Jury* 603 F. 2d. 469 is a Third Circuit case, 1979 -- oh,

07:44 16 I'm sorry, I misstated that, it's *United Coal v. Powell*, 839

07:44 17 F. 2d. 958 Third Circuit 1987.

07:44 18 The Court stated the proper procedure when there's a

07:44 19 dispute such as this regarding privilege is in-camera

07:44 20 inspection.

07:44 21 MR. LIPSEY: That is too slippery a slope, Your

07:44 22 Honor. The fact of the matter is, we have sworn testimony

07:44 23 that the statement embodies legal advice from a company lawyer

07:44 24 to a company employee. It is embodied in the writing of the

07:44 25 company employee which went at least to his director of

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07:44 1 applied R and D laboratory, who is also a signatory on the

07:44 2 document. The conduit theory makes quite clear that the, you

07:44 3 know, communication of legal advice from one person

07:45 4 personifying the client to another personifying the client is

07:45 5 a perfectly legitimate thing to do.

07:45 6 The Third Circuit case *In Re Teleglobe* that we cited, I

07:45 7 think makes clear that the privilege applies to any

07:45 8 communication that satisfies the following elements. It must

07:45 9 be a communication made between privileged persons in

07:45 10 confidence for the purpose of obtaining and providing legal

07:45 11 assistance for the client, and it is described as such by

07:45 12 Ms. Kashida and the idea that it is then embodied in a report

07:45 13 that goes at least to Mr. Sawa's supervisor does not cause it

07:45 14 not to be privileged. There is nothing suspicious about that

07:45 15 transaction.

07:46 16 THE COURT: I assume Mr. Sawa doesn't say in the

07:46 17 redacted information: A lawyer told me that, da-da, da-da...

07:46 18 MR. LIPSEY: I can tell you without waiving a

07:46 19 privilege that it doesn't say that. I can tell you that it is

07:46 20 the type of information that routinely comes from patent

07:46 21 lawyers.

07:46 22 MS. DAUGHTREY: And, Your Honor, information that is

07:46 23 publicly available, even if it's conveyed by an attorney would

07:46 24 not be privileged. And so even in a hypothetical situation

07:46 25 that Mr. Lipsey is referring to, if the information is

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07:46 1 otherwise publicly available, it wouldn't be privileged.

07:46 2 For example, if -- for example, if an attorney told

07:46 3 someone that a package insert, you know, document reflected

07:46 4 that that product was covered by a certain patent, well, the

07:47 5 package insert is publicly available, so you wouldn't be able

07:47 6 to shield that information by having an attorney convey those

07:47 7 facts.

07:47 8 MR. LIPSEY: If it's publicly available --

07:47 9 THE COURT: But if -- if you're aware of public

07:47 10 information that covers this same ground, why don't you just

07:47 11 use that and you can forget about penetrating the privilege?

07:47 12 MS. DAUGHTREY: So it's my understanding that their

07:47 13 claim of privilege partially relates to public information.

07:47 14 Not all of -- not all of the redacted information is public,

07:47 15 but I think their claim of privilege relates to information

07:47 16 from a third party that was publicly available, and they're

07:47 17 trying to protect their business motivations for some of their

07:47 18 research and development.

07:47 19 MR. LIPSEY: Six years after -- three years after the

07:47 20 patent was filed. The argument is, it's relevant to why the

07:47 21 invention was made. A document that's written three years

07:47 22 later cannot possibly bear on that issue.

07:48 23 MS. DAUGHTREY: Your Honor, I think you'd agree that

07:48 24 you can memorialize later motivations from previously. So --

07:48 25 and it would also be relevant to secondary considerations

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07:48 1 which can be past the priority date here.

07:48 2 THE COURT: All right. I don't want the dispute to

07:48 3 drag on throughout the trial, because if the information is

07:48 4 discoverable, this is the time to make that decision. I think

07:48 5 under the circumstances, that in order to properly determine

07:48 6 the appeal, I should make an in-camera inspection of the

07:48 7 documents, that is, of the reports with the Bates numbers,

07:49 8 which I don't have, and of the unredacted transcript, which is

07:49 9 part of the sealed record and which I can have access to.

07:49 10 The reason that I'm saying that and why I'm not

07:49 11 persuaded at the moment, that for closing the -- or refusing

07:49 12 the in-camera inspection is proper, is the following: The

07:49 13 circumstances that are known don't -- they comprise a thin

07:49 14 record. The party that seeks to protect the attorney/client

07:49 15 privilege has almost no facts that would support it, other

07:49 16 than the *benrishi* certification. Her certification doesn't

07:49 17 contain facts. It doesn't really say when she had this

07:50 18 communication, who she communicated to, and it also

07:50 19 characterizes her communication as legal advice without giving

07:50 20 a context or an explanation for why it was legal advice, other

07:50 21 than that she is the patent attorney. But I don't want to

07:50 22 sell short this certification.

07:50 23 MR. LIPSEY: May I suggest, Your Honor, if that's the

07:50 24 procedure to be followed, that maybe the appropriate thing is

07:50 25 for us to scamper over to the Magistrate Judge and let her do

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07:50 1 it, just because the consequence, if she concludes it's  
 07:50 2 privileged, as Your Honor knows as they always say in these  
 07:50 3 cases, there's no way to unring the bell, and Your Honor is  
 07:50 4 the trial Judge.  
 07:50 5 MS. DAUGHTREY: Your Honor, given the timing, where  
 07:50 6 we are right now, I think it would be quite easy, and I'm sure  
 07:50 7 Your Honor would be able to give -- firewall any information  
 07:51 8 that he sees, that the other -- even if he decides against the  
 07:51 9 defendants and that really, you know, I haven't seen any Third  
 07:51 10 Circuit law or anywhere saying that in-camera review is not  
 07:51 11 appropriate just because you're, you know, the Judge, you  
 07:51 12 know, deciding this matter at this time. I think we could  
 07:51 13 short-circuit all of this.  
 07:51 14 THE COURT: That's correct. I have to rule all the  
 07:51 15 time on what's admissible and what's not and see that evidence  
 07:51 16 even if it's not admissible.  
 07:51 17 I think because we're well into the trial that  
 07:51 18 remanding it for *in camera* inspection with the prospect of a  
 07:51 19 subsequent appeal by either side as to the result of that, we  
 07:51 20 just don't have time for it, unfortunately.  
 07:51 21 MR. LIPSEY: That's fair enough, your Honor.  
 07:51 22 THE COURT: Okay. And so why don't we make a record  
 07:51 23 of what it is that you're asking me to -- show it to  
 07:51 24 Mr. Lipsey first and make sure that he agrees that this --  
 07:52 25 MS. DAUGHTRY: Well, we don't have -- we destroyed

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07:53 1 the documents.  
 07:53 2 And the other document is DTX-031 and the Bates on that  
 07:53 3 are PROL 0075073 through PROL 0075076.  
 07:54 4 Does that sound right?  
 07:54 5 MR. LIPSEY: Those sound like the right numbers, your  
 07:54 6 Honor.  
 07:54 7 THE COURT: So I guess what I'm requesting is those  
 07:54 8 documents in unredacted form that I would receive *in camera*  
 07:54 9 and retain under seal and inspect hopefully overnight. And  
 07:54 10 then if there's a need for further argument, I'll ask you,  
 07:54 11 and, otherwise, I'll rule in due course probably tomorrow.  
 07:54 12 MS. DAUGHTRY: Thank you, your Honor.  
 07:54 13 MR. LIPSEY: Your Honor, what I do have in my hand  
 07:54 14 are the redacted copies and I have individual copies of the  
 07:54 15 two redacted pages so that the two together will constitute  
 07:54 16 the unredacted document if that facilitates your Honor's  
 07:54 17 review more promptly.  
 07:55 18 THE COURT: Okay. As long as it adds up to what I  
 07:55 19 mentioned.  
 07:55 20 MS. DAUGHTRY: Well, your Honor, I just want to make  
 07:55 21 sure I understand. So what they produced to us ultimately was  
 07:55 22 a certified translation with a redaction box over it, so we've  
 07:55 23 never seen what they're certified translation of the  
 07:55 24 unredacted information is. And I think, if I understand  
 07:55 25 Mr. Lipsey right, he'll be -- I think it would make more sense

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07:52 1 all the unredacted copies. You mean the redacted Bates  
 07:52 2 numbers?  
 07:52 3 THE COURT: Actually, I need the unredacted Bates  
 07:52 4 numbers.  
 07:52 5 MS. DAUGHTRY: We requested --  
 07:52 6 THE COURT: Are you saying I don't, because if I take  
 07:52 7 what you're giving me and review the unredacted transcript,  
 07:52 8 that I'll have the information about what's been redacted?  
 07:52 9 MS. DAUGHTRY: I think it would be easier, your  
 07:52 10 Honor, if you just take the unredacted scientific reports that  
 07:52 11 are the subject of the dispute. And plaintiffs have it. We  
 07:52 12 actually asked them to bring it a couple days ago and they  
 07:52 13 said -- they have never responded. But they could just give  
 07:52 14 that to your Honor and that would be -- I can go over the  
 07:52 15 Bates just to confirm with Mr. Lipsey these are the correct  
 07:52 16 Bates numbers because the redacted version has the same Bates  
 07:52 17 as the originals, it just has an R at the end. So --  
 07:52 18 THE COURT: All right. Is that acceptable,  
 07:53 19 Mr. Lipsey? Do you have the unredacted versions?  
 07:53 20 MR. LIPSEY: I think I do. I know what I have -- do  
 07:53 21 I have the unredacted ones?  
 07:53 22 MS. DAUGHTRY: If you'd like me to, I can read into  
 07:53 23 the record and show Mr. Lipsey the pages I'm referring to.  
 07:53 24 So this is defendant's exhibit list 32 and the Bates  
 07:53 25 numbers are PROL 0075077 through PROL 0075088, that's one of

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07:55 1 for you to review the entire document so you can have context  
 07:55 2 what's contained within it in addition to just the redacted  
 07:55 3 page. So if they have this English, you know, translation  
 07:55 4 just with the redacted box removed and if we could -- well, we  
 07:55 5 can't see it so I hope their translation is good. So that  
 07:55 6 would be fine if they gave you the entire document.  
 07:55 7 MR. LIPSEY: If I can take just a minute, I might be  
 07:55 8 able to do that.  
 07:55 9 THE COURT: Okay. Thank you, sir.  
 07:56 10 MR. LIPSEY: Okay. I assume it will be sufficient to  
 07:56 11 provide the translation without the Japanese document.  
 07:56 12 MS. DAUGHTRY: Unless your Honor speaks Japanese, I  
 07:56 13 think that's fine.  
 07:56 14 And would your Honor also like the unredacted  
 07:56 15 transcript, or can your Honor get that?  
 07:56 16 THE COURT: I have that.  
 07:56 17 MS. DAUGHTRY: Okay.  
 07:56 18 THE COURT: That's filed under seal with the Court.  
 07:56 19 MS. DAUGHTRY: Okay. Great.  
 07:57 20 MR. LIPSEY: Your Honor, I have copies of the  
 07:57 21 unredacted translation of the document PROL 0075073 through 76  
 07:57 22 and of PROL 0075077 through 88, will that suffice?  
 07:58 23 THE COURT: Okay. Very well. If you can --  
 07:58 24 MR. LIPSEY: Would you like me to mark the things  
 07:58 25 that have been redacted?

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07:58 1 THE COURT: Yeah, that's right, how else would I --  
 07:58 2 MS. DAUGHTRY: I can give you a copy of the redacted  
 07:58 3 version.  
 07:58 4 MR. LIPSEY: I have that as well. I have it as well.  
 07:58 5 THE COURT: Mr. Lipsey, I'll ask you to mark what  
 07:58 6 you're giving me, the unredacted versions, as Exhibit C-1 and  
 07:58 7 C-2 just to make a record of what I'm receiving under Court  
 07:58 8 Exhibit 1 and 2.  
 07:58 9 MR. LIPSEY: I'll just write C-1.  
 07:59 10 THE COURT: C-1 and perhaps add today's date, which  
 07:59 11 is April 5th, and mark the second one C-2.  
 07:59 12 MS. DAUGHTRY: Can you tell me which ones you're  
 07:59 13 marking as well?  
 07:59 14 MR. LIPSEY: I'm marking the one ending 073 as C-2  
 07:59 15 and the one ending 077 C-1.  
 07:59 16 MS. DAUGHTRY: Thank you.  
 07:59 17 MR. LIPSEY: And the redacted versions bear  
 07:59 18 production exhibits DTX-032 and DTX-031. And I will hand  
 07:59 19 those four copies to the Court.  
 07:59 20 THE COURT: Okay. Very good.  
 07:59 21 MR. LIPSEY: And I will be happy to answer any  
 08:00 22 questions your Honor may have as to the nature of the patent  
 08:00 23 question if and when the time comes.  
 08:00 24 THE COURT: Okay. Very well. So with that, I'll  
 08:00 25 close this hearing. I'll reserve decision on the appeal.

*United States District Court*

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08:00 1 And is there anything else for this evening?  
 08:00 2 MR. LIPSEY: Not for us, your Honor.  
 08:00 3 MS. DAUGHTRY: Not for defendants, your Honor.  
 08:00 4 THE COURT: Thank you very much. We're adjourned  
 08:00 5 until tomorrow morning at 9:30.  
 08:00 6 MR. LIPSEY: Thank you.  
 08:00 7 (Proceedings Concluded)

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1 UNITED STATES DISTRICT COURT  
2 FOR THE DISTRICT OF NEW JERSEY

3 SENJU PHARMACEUTICAL CO., LTD.,  
4 BAUSCH & LOMB, INC., BAUSCH AND  
5 LOMB PHARMA HOLDINGS CORP.,

6 Plaintiff, CIVIL ACTION NUMBER:  
7 -vs- 14-667 (JBS/KMW)

8 LUPIN LTD., LUPIN  
9 PHARMACEUTICALS, INC.,

10 Defendants.

11 SENJU PHARMACEUTICAL CO., LTD.,  
12 BAUSCH & LOMB, INC., BAUSCH AND  
13 LOMB PHARMA HOLDINGS CORP.,

14 Plaintiff, CIVIL ACTION NUMBER:  
15 -vs- 14-4145 (JBS/KMW)

16 LUPIN LTD., LUPIN  
17 PHARMACEUTICALS, INC.,

18 Defendants.

19 Mitchell H. Cohen United States Courthouse  
20 One John F. Gerry Plaza  
21 Camden, New Jersey 08101  
22 Wednesday, April 6, 2016

23 **B E F O R E:** THE HONORABLE JEROME B. SIMANDLE  
24 CHIEF JUDGE  
25 UNITED STATES DISTRICT JUDGE

26 Certified as true and correct as required by Title 28, U.S.C.,  
27 Section 753.

28 /s/ Lisa Marcus, CCR, CRR, /s/ Karen Friedlander, CCR, CRR,  
29 /s/ Robert T. Tate, CCR, CRR, /s/ Carol Farrell, CCR, CRR

United States District Court  
Camden, New Jersey

1 SENJU PHARMACEUTICAL CO., LTD.,  
2 BAUSCH & LOMB, INC., BAUSCH AND  
3 LOMB PHARMA HOLDINGS CORP.,

4 Plaintiff, CIVIL ACTION NUMBER:  
5 -vs- 14-5144 (JBS/KMW)

6 LUPIN LTD., LUPIN  
7 PHARMACEUTICALS, INC.,

8 Defendants.

9 SENJU PHARMACEUTICAL CO., LTD.,  
10 BAUSCH & LOMB, INC., BAUSCH AND  
11 LOMB PHARMA HOLDINGS CORP.,

12 Plaintiff, CIVIL ACTION NUMBER:  
13 -vs- 15-335 (JBS/KMW)

14 LUPIN LTD., LUPIN  
15 PHARMACEUTICALS, INC.,

16 Defendants.

17 SENJU PHARMACEUTICAL CO., LTD.,  
18 BAUSCH & LOMB, INC., BAUSCH AND  
19 LOMB PHARMA HOLDINGS CORP.,

20 Plaintiff, CIVIL ACTION NUMBER:  
21 -vs- 14-5144 (JBS/KMW)

22 LUPIN LTD., LUPIN  
23 PHARMACEUTICALS, INC.,

24 Defendants.

United States District Court  
Camden, New Jersey

1 SENJU PHARMACEUTICAL CO., LTD.,  
2 BAUSCH & LOMB, INC., BAUSCH AND  
3 LOMB PHARMA HOLDINGS CORP.,

4 Plaintiff, CIVIL ACTION NUMBER:  
5 -vs- 15-335 (JBS/KMW)

6 LUPIN LTD., LUPIN  
7 PHARMACEUTICALS, INC.,

8 Defendants.

9 SENJU PHARMACEUTICAL CO., LTD.,  
10 BAUSCH & LOMB, INC., BAUSCH AND  
11 LOMB PHARMA HOLDINGS CORP.,

12 Plaintiff, CIVIL ACTION NUMBER:  
13 -vs- 14-6893 (JBS/KMW)

14 INNOPHARMA LICENSING, INC., et  
15 al.,

16 Defendants.

17 SENJU PHARMACEUTICAL CO., LTD.,  
18 BAUSCH & LOMB, INC., BAUSCH AND  
19 LOMB PHARMA HOLDINGS CORP.,

20 Plaintiff, CIVIL ACTION NUMBER:  
21 -vs- 15-3240 (JBS/KMW)

22 INNOPHARMA LICENSING, INC.,

23 Defendants.

United States District Court  
Camden, New Jersey

1 **A P P E A R A N C E S:**

2 PEPPER HAMILTON LLP  
3 BY: MELISSA A. CHUDEREWICZ, ESQUIRE  
4 301 Carnegie Center, Suite 400  
5 Princeton, New Jersey 08543  
6 (609) 452-0808  
7 chuderem@pepperlaw.com  
8 ATTORNEYS FOR PLAINTIFF

9 FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, LLP  
10 BY: BRYAN C. DINER, ESQUIRE  
11 JUSTIN J. HASFORD, ESQUIRE  
12 CHIAKI FUJIWARA, ESQUIRE  
13 901 New York Avenue, N.W.  
14 Washington, D.C. 20001-4413  
15 (202) 408-4000  
16 bryan.diner@finnegan.com, justin.hasford@finnegan.com,  
17 chiaki.fujiwara@finnegan.com  
18 ATTORNEYS FOR PLAINTIFF

19 FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, LLP  
20 BY: JESSICA M. LEBIS, ESQUIRE  
21 303 Peachtree Street, NE  
22 Atlanta, GA 30308-3263  
23 (404) 653-6400  
24 jessica.lebis@finnegan.com  
25 ATTORNEYS FOR PLAINTIFF

26 PATUNAS TARANTINO LLC  
27 BY: MICHAEL E. PATUNAS, ESQUIRE  
28 24 Commerce Street, Suite 606  
29 Newark, New Jersey 07102  
30 (973) 396-8740  
31 mpatunas@patunaslaw.com  
32 ATTORNEYS FOR DEFENDANT LUPIN, INC.

United States District Court  
Camden, New Jersey

532

1 GOODWIN PROCTER, LLC  
 BY: ELIZABETH J. HOLLAND, ESQUIRE  
 2 NATASHA E. DAUGHTRY, ESQUIRE  
 SARAH FINK, ESQUIRE  
 3 SHAUN deLACY, ESQUIRE  
 DANIEL P. MARGOLIS, ESQUIRE  
 4 The New York Times Building  
 620 Eighth Avenue  
 5 New York, NY 10018  
 (212) 813-8800  
 6 eholland@goodwinprocter.com, ndaughtry@goodwinprocter.com,  
 sfink@goodwinprocter.com, sdelacy@goodwinprocter.com,  
 7 dmargolis@goodwinprocter.com  
 ATTORNEYS FOR DEFENDANT LUPIN, LTD.  
 8  
 9 GOODWIN PROCTER, LLP  
 BY: EMILY L. RAPALINO, ESQUIRE  
 53 State Street  
 10 Boston, MA 02109  
 (617) 570-1000  
 11 erapalino@goodwinprocter.com  
 ATTORNEYS FOR DEFENDANT LUPIN, LTD.  
 12  
 13 ALSTON & BIRD, LLP  
 BY: DEEPRO R. MUKERJEE, ESQUIRE  
 LANCE A. SODERSTROM, ESQUIRE  
 14 STEPHANIE ROBERTS, ESQUIRE  
 90 Park Avenue  
 15 New York, New York 10016  
 (212) 210-9400  
 16 deepr.r.mukerjee@alston.com, lance.soderstrom@alston.com,  
 stephanie.roberts@alston.com  
 17 ATTORNEYS FOR DEFENDANT INNOPHARMA LICENSING  
 18  
 19 ALSTON & BIRD, LLP  
 BY: JITENDRA MALIK, ESQUIRE  
 4721 Emperor Boulevard  
 Suite 400  
 20 Durham, NC 27703-8580  
 (919) 862-2200  
 21 jitendra.malik@alston.com  
 ATTORNEYS FOR DEFENDANT INNOPHARMA LICENSING  
 22  
 23  
 24  
 25

United States District Court  
Camden, New Jersey

533

1 ALSTON & BIRD, LLP  
 BY: HIDETADA JAMES ABE, ESQUIRE  
 2 333 South Hope Street  
 16th Floor  
 3 Los Angeles, CA 90071-3004  
 (213) 576-1000  
 4 james.abe@alston.com  
 ATTORNEYS FOR DEFENDANT LUPIN LIMITED  
 5  
 6 ALSTON & BIRD, LLP  
 BY: JOSEPH M. JANUSZ, ESQUIRE  
 7 Bank of America Plaza  
 Suite 4000  
 8 Charlotte, NC 28280-4000  
 (704) 444-1000  
 9 joe.janusz@alston.com  
 ATTORNEYS FOR DEFENDANT INNOPHARMA LICENSING  
 10  
 11 SAIBER, LLC  
 ARNOLD B. CALMANN, ESQUIRE  
 12 One Gateway Center  
 10th Floor, Suite 1000  
 13 Newark, New Jersey 07102  
 (973) 622-3333  
 14 abc@saiber.com  
 ATTORNEYS FOR DEFENDANT INNOPHARMA LICENSING  
 15  
 16  
 17  
 18  
 19  
 20  
 21  
 22  
 23  
 24  
 25

United States District Court  
Camden, New Jersey

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 8 E X H I B I T S

9 PAGE

10 PLAINTIFF EXHIBITS PTX-199, PTX-160, PTX-632, 664  
 JTX210, JTX181 JTX209, JTX043 and JTX057 WERE  
 RECEIVED IN EVIDENCE  
 11 DEFENDANT EXHIBITS JTX158 and JTX207 WERE 665  
 RECEIVED IN EVIDENCE  
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535

1 DEPUTY CLERK: All rise.  
 2 THE COURT: Be seated, please.  
 3 Okay. Good morning, everybody.  
 4 Before we resume our witness, I just wanted to at least  
 00:18 5 announce my decision with regard to the appeal from Judge  
 6 Williams' determination regarding attorney/client privilege.  
 7 And when we have time, I'll place the oral Opinion upon the  
 8 record.  
 9 But the summary is simply that I conducted the *in*  
 00:18 10 *camera* inspection of the documents. I found that the  
 11 attorney/client privilege does apply to the excerpts that had  
 12 been redacted and so the claim of attorney/client privilege is  
 13 being sustained. I find that it contains legal advice from  
 14 the benrishi which was given for purposes of legal advice upon  
 00:19 15 the patent itself, and which was being transmitted internally.  
 16 And so, therefore, it's protected as the memorialization of an  
 17 attorney/client communication rather than mere business advice  
 18 that happens to come from an attorney.  
 19 And so for these reasons I agree with the finding below  
 00:19 20 that the privilege applies but have undertaken and have the  
 21 benefit of the *in camera* review and also the additional legal  
 22 research. And I'll enter a written Order to this effect.  
 23 Are there any questions?  
 24 MR. DINER: None from plaintiffs, your Honor.  
 00:20 25 THE COURT: All right. And I thank counsel for your

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1 hard work on both sides on this issue.

2 Good morning. Are we ready to proceed?

3 MR. DINER: Yes, your Honor.

4 THE COURT: Okay.

00:20 5 MR. DINER: May it please the Court, your Honor, I

6 would like to approach the bench, I have some demonstrative

7 slides I would like to present to the witness and Court.

8 THE COURT: Yes.

9 (STEPHEN G. DAVIES, HAVING BEEN PREVIOUSLY SWORN AS A WITNESS,

10 TESTIFIED AS FOLLOWS:)

11 (DIRECT EXAMINATION OF STEPHEN G. DAVIES BY MR. DINER:)

12 Q. Good morning, Dr. Davies.

13 A. Good morning.

14 Q. Do you recall yesterday when we concluded for the day we

00:21 15 were talking hydrogen bonding?

16 A. Yes.

17 Q. Okay. I would like to transition into the impact and

18 effect of hydrogen bonding on the NSAIDS that are the subject

19 of this case. Let's start with bromfenac and diclofenac.

00:21 20 Do you have an opinion as to whether bromfenac and

21 diclofenac are structurally dissimilar?

22 A. They have a different set of functional groups that are

23 dispersed differently around the molecule and they have

24 different interactions of those functional groups, so they are

00:21 25 dissimilar molecules.

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1 Q. And have you prepared a demonstrative to assist the Court

2 in your testimony in this regard?

3 A. I have, yes.

00:22 4 Q. Will you take a look at PDX3-2 and can you please explain

5 how this demonstrative shows the structural differences

6 between bromfenac and diclofenac.

7 A. So what I've shown on this demonstrative is the chemical

8 structure in two dimensions of bromfenac on the left and

9 diclofenac on the right and I've shown the functional groups

00:22 10 as shown by the letters.

11 So bromfenac on the left has a primary amine group,

12 which is the nitrogen, the N, bonded to two hydrogens, so it's

13 the NH<sub>2</sub> group. Whereas diclofenac has a secondary amine that

14 is a nitrogen bonded to just one hydrogen.

00:22 15 Bromfenac has a 4-bromobenzoyl group, which is this

16 bromine here, that's the whole unit there, including the

17 carbonyl oxygen, is the 4-bromobenzoyl group and it's attached

18 adjacent to the NH<sub>2</sub>, whereas diclofenac has a

19 2,5-dichlorophenyl, which is this unit here, the Cl's are the

00:23 20 chlorine. The phenyl is the six membered ring with the two

21 chlorine atoms attached, and that is attached directly to the

22 NH group.

23 And as we can see, the bromfenac has the carbonyl,

24 that's a carbon with a double bump to the oxygen, a carbonyl

00:23 25 group, whereas diclofenac does not have such a group.

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1 Q. So these structural differences that you've just pointed

2 out, how would they impact the chemical or functional

3 properties of the compounds?

4 A. The chemical and functional properties of any compound

00:24 5 depends on all the functional groups, how they interact with

6 one another, how they interact in the environment in which

7 they are.

8 Q. Have you prepared a demonstrative to assist the Court in

9 this regard?

00:24 10 A. I have, yes.

11 Q. Could we go to PDX3-3?

12 A. What I've shown on this demonstrative the same structures

13 of bromfenac and diclofenac and I've highlighted by putting

14 them inside red circles the functional groups that will form

00:24 15 strong hydrogen bonds to water as a solvent. Both of the

16 compounds have a carboxylic acid at the pH we're dealing with

17 in ophthalmic preparations, these will be ionized to a

18 carboxylate anion but they'll be the same, they'll both be

19 strongly hydrogen bonded.

00:25 20 But bromfenac, in addition to that, has an NH<sub>2</sub>, as we

21 saw yesterday, that will strongly hydrogen bond to water, and

22 the carbonyl group that will also strongly hydrogen bond to

23 water. Whereas diclofenac only has one NH group, the

24 secondary amine that can hydrogen bond in addition to the

00:25 25 carboxylate to water.

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1 Q. And what is the implication of the hydrogen bonding, as

2 you've described here, to the NSAIDS solvation in an aqueous

3 formation?

00:25 4 A. Well, there're more hydrogen bonds so the molecule, the

5 more strong hydrogen bonds in particular, that any molecule or

6 anion can form to water as the solvent the stronger the

7 solvation will be and the more stable that anion will be in

8 solution.

9 Q. And what impact will it have on the solubility of that

00:25 10 product in solution?

11 A. Well, it will mean that any salts that are formed --

12 could be formed of these anions, the more solvated the anion,

13 the more soluble the salt will be, the less likely it will be

14 to precipitate.

00:26 15 Q. And does bromfenac have more hydrogen bonding sites than

16 diclofenac?

17 A. As you can see from where I placed the red balls,

18 bromfenac has more hydrogen bonds, strong hydrogen bonding

19 sites than diclofenac.

00:26 20 Q. And would one of ordinary skill in the art understand

21 that that would make bromfenac more soluble than diclofenac?

22 A. They would expect that to be the result, yes.

23 Q. And would bromfenac's better solubility impact -- or how

24 would bromfenac's better solubility impact whether bromfenac

00:26 25 would precipitate with the cation in solution and come out of

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1 solution?

2 A. If it's more -- if the anion is more solvated, then it

3 will be less likely to precipitate out of solution with any

4 cation.

00:26 5 Q. And as between bromfenac on the one hand and diclofenac

6 on the other hand, what would one of ordinary skill in the art

7 expect about whether bromfenac would precipitate out of

8 solution by interacting with the cation compared to

9 diclofenac?

00:27 10 A. They would expect the bromfenac salt -- bromfenac salts

11 to be less likely to precipitate out than diclofenac salts.

12 Q. Okay. Dr. Davies, can you turn to JTX-210 in your binder

13 and identify that document, please?

14 A. This is *New Drugs in Japan 2001*.

00:27 15 Q. Okay. Now, let me direct your attention to Page 6 of

16 JTX-210.

17 A. Okay.

18 Q. You there?

19 What's the structure that is illustrated in the

00:28 20 left-hand column on Page 6 of JTX-210?

21 A. It's the sodium salt of bromfenac as a half hydrate.

22 Q. And would you be so kind to read into the record the text

23 just below the formula for bromfenac all the way down to, but

24 before the word "packaging."

00:28 25 A. It says, "Properties: Bromfenac Sodium Hydrate is an

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1 odorless crystalline powder of yellow-orange color. It is

2 freely soluble in water, soluble in methanol, slightly soluble

3 in ethanol anhydride, and practically insoluble in

4 acetonitrile or ether."

00:28 5 Q. And would one of ordinary skill in the art in view of

6 this passage in JTX-210 understand that bromfenac was freely

7 soluble in water?

8 A. Absolutely. That's what it says so that's what it means.

9 Q. Okay. In generating PDX3-3 did you use information for

00:29 10 the summary that you presented in those slides from PTX-187,

11 PTX-180, PTX-193, PTX-321, and PTX-188?

12 A. I did, yes.

13 Q. Okay. Dr. Davies, have you had an opportunity to

14 consider the structural differences between bromfenac and

00:30 15 ketorolac?

16 A. I have, yes.

17 Q. And have you prepared a demonstrative to assist the Court

18 in your testimony in this regard?

19 A. I have, yes.

00:30 20 Q. Can we turn then to PDX3-4. And can you describe how

21 this demonstrative illustrates the differences between

22 bromfenac and ketorolac?

23 A. So again, I've drawn the structure of bromfenac in two

24 dimensions on the left-hand side and the structure of

00:30 25 ketorolac in two dimensions on the right-hand side. And I put

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1 in the functional groups. And what we see the bromfenac has a

2 primary amine group, that is this NH<sub>2</sub> group, whereas ketorolac

3 has a tertiary amine, no hydrogens on that nitrogen.

4 Bromfenac has a 4-bromobenzoyl group, which is this

00:31 5 unit here, attached to the -- adjacent to the NH<sub>2</sub>, whereas

6 ketorolac has a simple benzoyl group on the aromatic pyrrole

7 ring, which is this five membered ring here.

8 Bromfenac is an aniline, so aniline is this NH<sub>2</sub>

9 attached to the phenyl ring, six membered ring with three

00:31 10 carbon carbon double bonds, whereas ketorolac does not have

11 that grouping.

12 Q. And would one skilled in the art expect that these

13 structural differences that you just pointed out would impact

14 the functional chemical properties of bromfenac versus

00:31 15 ketorolac?

16 A. The functional properties of any molecule depends on the

17 number and distribution of the functional groups and

18 heteroatoms within the molecule.

19 Q. Have you prepared a slide -- a demonstrative to support

00:32 20 your opinion in this regard?

21 A. I have, yes.

22 Q. If we can go to PDX3-5. Can you explain how this

23 demonstrative supports your opinion?

24 A. So what I have shown, again, here is the structures of

00:32 25 bromfenac and ketorolac, ketorolac on the right. And I've

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1 highlighted the groups, the functional groups that will form

2 strong hydrogen bonds in red circles. And bromfenac, as

3 before, has the carboxylate, I've drawn it as a carboxylic

4 acid but in solution it would be the carboxylate ion, the

00:32 5 carboxylate ion, which can hydrogen bond strongly to water.

6 It has the NH<sub>2</sub> and that can strongly hydrogen bond to water.

7 It has the carbonyl oxygen that can strongly hydrogen bond to

8 water.

9 Ketorolac has the carboxylate group but only a carbonyl

00:33 10 group on the left in the red circle that can also hydrogen

11 bond to water.

12 Q. And how, if at all, do these differences in hydrogen

13 bonding sites impact how bromfenac would behave in solution

14 compared to ketorolac?

00:33 15 A. Well, the more strongly hydrogen bonding sites the

16 molecule or ion, anion has, the more soluble -- the more

17 solvated it will be in solution.

18 Q. And would bromfenac, if it was better solvated, be

19 expected to interact with an ion in solution and precipitate

00:33 20 out to a lesser extent compared to ketorolac?

21 A. Well, that's the fault of any particular atom salts, any

22 particular cations, because a bromfenac anion will be more

23 solvated, it will be more likely to stay in solution and not

24 precipitate out than the ketorolac anion.

00:34 25 Q. Okay. In preparing PDX3-5 did you use information from

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1 PTX-187, PTX-180, PTX-193, PTX-321 and PTX-188?  
 2 A. I did, yes.  
 3 Q. Dr. Davies, have you had an opportunity to consider the  
 4 structural differences as between bromfenac and flurbiprofen?  
 00:34 5 A. I have, yes.  
 6 Q. Have you prepared a demonstrative in this regard to  
 7 assist the Court with your testimony?  
 8 A. I have, yes.  
 9 Q. Okay. Let's take a look at PDX3-6, and can you explain  
 00:34 10 this demonstrative for the Court, please?  
 11 A. So again, I've drawn the structure of bromfenac in two  
 12 dimensions on the left-hand side and flurbiprofen on the  
 13 right-hand side. Bromfenac has a primary amine group, this  
 14 NH<sub>2</sub> group, whereas flurbiprofen has no amino group, no  
 00:35 15 nitrogen atom in that molecule.  
 16 Bromfenac has a 4-bromobenzoyl group attached adjacent  
 17 to the NH<sub>2</sub>. So this is this unit here. That's the 4-bromo.  
 18 The benzoyl means there's the carbonyl group attached.  
 19 Whereas flurbiprofen has a fluorine in the same position.  
 00:35 20 Bromfenac has a phenylacetic acid derivative, that's  
 21 this side chain here, whereas flurbiprofen is derived from  
 22 phenylpropionic acid and has an extra methyl group attached to  
 23 the carboxylic acid, which is this right here, that is the  
 24 propionic acid unit as shown on the right.  
 00:36 25 Bromfenac has a hydrogen distal to the acetic acid

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1 residue, that is in this position, whereas flurbiprofen has a  
 2 phenyl group, that is that phenyl group there distal to that  
 3 on there. And it is a biphenyl derivative. So there's two  
 4 phenyl groups attached to each, that's called a biphenyl  
 00:36 5 group.  
 6 Q. And would one skilled in the art expect these structural  
 7 differences would impact the functional and chemical property  
 8 of the NSAIDS that you're discussing on this demonstrative?  
 9 A. As before, the functional properties and the physical  
 00:36 10 properties of a molecule depend on the number and distribution  
 11 and type of the functional groups in any molecule or ion.  
 12 Q. And have you prepared a demonstrative in that regard to  
 13 assist the Court with your testimony?  
 14 A. I have, yes.  
 00:36 15 Q. So let's turn to PDX3-7. And can you explain how this  
 16 demonstrative illustrates the differences in hydrogen bonding  
 17 between the two molecules?  
 18 A. So again, I've drawn bromfenac in two dimensions on the  
 19 left and flurbiprofen on the right and I've highlighted again  
 00:37 20 the strong hydrogen bonding groups with red circles.  
 21 Bromfenac acid or anion, anion in the case of pH's  
 22 we're dealing with, has the carboxylate that can strongly  
 23 hydrogen bond to water, NH<sub>2</sub> group, and the carboxyl group, all  
 24 of which will strongly hydrogen bond to the water solvent.  
 00:37 25 Flurbiprofen, on the other hand, only has the

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1 carboxylic acid or the carboxylate group that can hydrogen  
 2 bond to the water solvent, has no other functional groups that  
 3 will form strong hydrogen bonds to water as a solvent.  
 4 Q. And how, if at all, do the differences in hydrogen  
 00:37 5 bonding impact how bromfenac will behave in solution compared  
 6 to flurbiprofen?  
 7 A. The more strongly hydrogen bonding sites you have, the  
 8 more solvated the carboxylate anion will be and the more  
 9 stable it will be in solution.  
 00:38 10 Q. And when you refer to being more stable in solution, what  
 11 does that mean in terms of solubility in solution?  
 12 A. It means that the water is bonding to this -- to the  
 13 bromfenac anion strongly, it will hold it in solution, it will  
 14 stop -- making it less likely for any salt to precipitate.  
 00:38 15 Flurbiprofen, for example, only has the carboxylate  
 16 that's solvated, it's going to be more likely to precipitate  
 17 from solution if you observe that effect.  
 18 Q. Okay. If the skilled person saw a precipitation in a  
 19 solution containing, for example, ketorolac, benzalkonium  
 00:38 20 chloride, and other ionic excipients, could that person draw a  
 21 conclusion what the precipitate was?  
 22 A. No, they would not be able to. So can you specify -- can  
 23 you repeat the question?  
 24 Q. Sure. If a skilled person saw a precipitation in a  
 00:39 25 solution containing, for example, the ketorolac, benzalkonium

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1 chloride, and other ionic excipients, could that person draw a  
 2 conclusion what the precipitate was?  
 3 A. No, they would not be able to draw a conclusion.  
 4 Q. Why not?  
 00:39 5 A. Because the only way you can tell what a precipitate is  
 6 made up of would be isolate that precipitate and do a chemical  
 7 analysis on that precipitate to find what the constituents  
 8 are. And if you had a solution that contains many ions, you  
 9 won't get to tell what is in the precipitate until you've gone  
 00:39 10 done a full analysis, you can't assume anything.  
 11 Q. Dr. Davies, in generating PDX3-7 did you use information  
 12 from PTX-187, PTX-180, PTX-193, PTX-321 and PTX-188?  
 13 A. I did, yes.  
 14 Q. Thank you. Now, Dr. Davies, did you hear testimony  
 00:40 15 yesterday from Dr. Lawrence about various nonionic surfactants  
 16 including polysorbate 80, tyloxapol, and octoxynol 40?  
 17 A. Yes.  
 18 Q. Are you aware that defendants here are taking the  
 19 position that the nonionic surfactants polysorbate 80 and  
 00:40 20 tyloxapol could be used interchangeably in formulation and  
 21 would be expected to behave similarly?  
 22 A. I understand that's their view, yes.  
 23 Q. Do you agree with the defendants?  
 24 A. I do not, no.  
 00:40 25 Q. And why not?

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1 A. Because those materials have very different structures  
2 and the structural properties, physical chemical properties of  
3 molecules depend on the structure and the distribution and the  
4 shape of molecules, you can't take different molecules and say  
00:41 5 you can just interchange them.

6 Q. Okay. Have you prepared a demonstrative in this regard  
7 to assist the Court in understanding your opinions?

8 A. I have, yes.

9 Q. So we now go to PDX3-8, and can you explain what this  
00:41 10 demonstrative shows?

11 A. So I've shown on the left the structure of polysorbate 80  
12 and on the right a structure of tyloxapol. The structure of  
13 tyloxapol has the unit I've shown in between the two vertical  
14 lines, brackets, has that repeated seven times. There's not  
00:42 15 room to put the whole structure on the slide but that is  
16 repeated seven times with that carbon in there. And so you  
17 can see how structurally different these molecules are.

18 Q. Can I just ask you a question? You're referring to the  
19 repeating unit identified by the small N.

00:42 20 A. That's correct.

21 Q. Do you see that?

22 The hexagonal moiety, chemical moiety there, is that a  
23 phenyl group?

24 A. That is a phenyl group, yes. The six membered ring with  
00:42 25 the three double bonds is a phenyl group.

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1 other bonds, three other lines attached to it, double bond to  
2 the top left and a vertical line to the bottom, so that's  
3 three more, that's four bonds in all. Carbon likes to form  
4 four bonds. This peak here is a carbon atom with two  
00:44 5 hydrogens on it. There's two other bonds with carbon carbon,  
6 that we've just been talking about, to the phenyl ring. And  
7 then the line to the right going down is to another carbon  
8 here, so that's two bonds. The other two are bond to  
9 hydrogen, that's CH<sub>2</sub> unit, an extra carbon, if you like, or  
00:44 10 HCH<sub>2</sub>.

11 Q. I think I may have interrupted you while you were going  
12 through your explanation on the chemical differences between  
13 them. Have you finished discussing the full demonstrative in  
14 terms of the differences?

00:44 15 A. I was in the middle.

16 Q. Okay.

17 A. So what you see on the -- while we are on tyloxapol, you  
18 can see there's this octyl chain on the bottom, which has no  
19 functional groups, no heteroatoms involved in it. And then  
00:45 20 you have this chain along the top which has an oxygen that is  
21 bound to the top carbon of the phenyl group and then a bond  
22 from the O to a point which is a CH<sub>2</sub> group, another CH<sub>2</sub> group,  
23 and then another oxygen. And that unit CH<sub>2</sub>, CH<sub>2</sub>O is in  
24 brackets because that repeats eight to ten times on each of  
00:45 25 the groups, such groups in tyloxapol.

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1 Q. What is that, just for understanding purposes --

2 THE COURT: Excuse me --

3 BY MR. DINER:

4 Q. -- what is that line that comes up?

5 THE COURT: May I interrupt?

6 I lost which small N you're referring to.

7 THE WITNESS: There's two brackets, your Honor.

8 THE COURT: Okay.

9 THE WITNESS: And then there's a small N on the right  
00:43 10 indicating that's a repeating unit. And then I've defined N  
11 underneath as N equals seven of those.

12 THE COURT: Very well. Thank you.

13 BY MR. DINER:

14 Q. Now, the question I have for you, Dr. Davies, is to the  
00:43 15 right of that phenyl group in this repeating unit we're  
16 talking about, you see how that line comes up to a peak and it  
17 comes down?

18 A. Yes.

19 Q. What is that peak? What does that peak illustrate?

00:43 20 A. That is -- whenever you see a line in organic chemistry  
21 that has no letters on it, it means that carbon atom is on  
22 each end of that line. And all of the -- carbon always has  
23 four bonds. So if you look at the left-hand end here, there's  
24 a line to the right which goes up to a carbon, that is the  
00:43 25 point of the zigzag if you like, and then there are three

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1 In polysorbate 80 you have to the right-hand side this  
2 long zigzag, which is a lot of carbon atoms bound to each  
3 other, each bond to hydrogen atoms with this carbonyl group  
4 here attached to now a chain, another chain of oxygen CH<sub>2</sub>, CH<sub>2</sub>  
00:45 5 repeat units and then to this unit here, this central part,  
6 which allows three branches to come off. Again, each of those  
7 has repeating units of oxygen carbon carbon. And so there's  
8 one chain there, another chain, a second chain bottom right,  
9 and a third chain bottom left.

00:46 10 So polysorbate 80 has a long single non-polar linear  
11 tail, which is this unit here to the right, and a  
12 triply-branched polar head group, which is this unit here,  
13 this chain, this chain, this chain.

14 Polysorbate 80 has three hydroxyls in its polar head  
00:46 15 group, one, two, and three on the end of those three branches,  
16 whereas tyloxapol has seven hydroxyls, one, this hydroxyl on  
17 the end, one on each of the seven head groups.

18 In polysorbate 80 the non-polar tail consists of a  
19 hydrocarbon chain, this unit here, whereas the many tails of  
00:47 20 tyloxapol are a combination of aromatic rings, the phenyl  
21 group, and hydrocarbon chains, this is this group at the  
22 bottom with no functional atoms attached.

23 Q. Now, does this polysorbate 80 and tyloxapol exist in  
24 three dimensions?

00:47 25 A. They do, yes.

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1 Q. And have you prepared a demonstrative to explain how they  
2 appear in three dimensions to assist the Court?

3 A. I have, yes.

00:47 4 Q. Can we go to PDX3-10? And can you explain what this  
5 demonstrative shows?

6 A. This shows three dimensional structures of polysorbate 80  
7 and tyloxapol to illustrate what I was explaining on the  
8 previous demonstrative.

00:48 9 For polysorbate 80 you see the single hydrocarbon chain  
10 in grey on the bottom. The grey colors show the CH<sub>2</sub> groups,  
11 there are no functional atoms in that part. This was the  
12 chain of the repeating, they're called methylene octy groups,  
13 CH<sub>2</sub> CH<sub>2</sub> O, that goes up to the head group of three branches,  
14 which is shown at the top. At the end of each of those  
00:48 15 branches is an oxygen atom which is bound to a hydrogen that  
16 is the hydroxy group. And all the way through these chains  
17 I've colored the oxygens in the repeat units, the ethyleneoxy  
18 repeat groups in red so it's easy to see.

00:49 19 Tyloxapol, on the other hand, has a broad based  
20 hydrocarbon unit at the bottom, again, shown in grey. And  
21 then seven of these tails that come off that have these repeat  
22 units of CH<sub>2</sub> CH<sub>2</sub> and O. And then the end of each of those, the  
23 top, is the oxygen that has a hydrogen, which is the hydroxy  
24 group, seven of them up there. So this is a very different  
00:49 25 three dimensional structure to the polysorbate 80 on the left.

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1 Tyloxapol's got a completely different shape and  
2 functionality.

00:49 3 Q. So given the differences in two dimensions and three  
4 dimension as shown, would a person of ordinary skill in the  
5 art expect that polysorbate 80 and tyloxapol would have  
6 different chemical and functional properties?

7 A. They would definitely expect them to have different  
8 chemical, physical chemical, chemical properties, yes.

00:50 9 Q. And have you prepared a demonstrative to explain your  
10 opinions in this regard to the Court?

11 A. I have, yes.

12 Q. Can you explain what this demonstrative shows.

13 I'm sorry about that. Can we please turn to PDX3-9?

14 A. I'm there, yes.

00:50 15 Q. And can you explain what PDX3-9 shows?

16 A. This compares polysorbate 80 with tyloxapol, which are  
17 the two structures we were looking at a moment ago. The  
18 molecular weight of polysorbate 80 is 1310, whereas the  
19 molecular weight of tyloxapol is 4500. The critical micelle  
00:51 20 concentration, CMC, for polysorbate 80 is .010 millimol and  
21 the corresponding CMC for tyloxapol is .018 millimol.

22 Q. Dr. Davies, does a surfactant CMC impact its ability to  
23 solubilize a compound?

00:51 24 A. It does, yes, as does its structure. Both of those will  
25 impact on whether something will be solubilized or not.

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1 Q. Let me direct your attention to PTX-181 in your binder  
2 and --

3 A. Okay.

4 Q. Before we go to PTX-181, can we return to PDX3-9.

00:51 5 And, Dr. Davies, in generating PDX3-9 did you use for  
6 information in preparing that PTX-181, PTX-190, JTX-199, and  
7 PTX-201?

8 A. I did, yes.

9 Q. Okay. Before we leave this demonstrative, could you  
00:52 10 explain a little bit what is meant by CMC?

11 A. That is the concentration of which -- above which the  
12 surfactant will produce, start to form micelles, which are  
13 aggregates of the surfactant in solution. And millimol is a  
14 thousandth of a mole, the mole being the molecular weight in a  
00:52 15 liter of water.

16 Q. Okay. And for the reasons you stated previously, one  
17 skilled in the art would expect the CMC to impact a  
18 surfactant's ability to solubilize a compound?

19 A. That's correct, yes.

00:53 20 Q. Now, let's go to PTX-181 in your binder. And would you  
21 please identify this document?

22 A. This is a book called Surfactant Systems, Their  
23 Chemistry, Pharmacology, and Biology, by Attwood and Florence  
24 from 1983.

00:53 25 Q. Okay. And have you reviewed PTX-181 in connection with

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1 your opinions in this case?

2 A. I have, yes.

3 Q. Okay. Let me draw your attention to Page 343 of PTX-181  
4 and in particular table 6.23(a).

00:53 5 A. I have it, yes.

6 Q. Thank you. What, if anything, does table 6.23(a) show  
7 about the differences in solubilizing ability between  
8 polysorbates?

9 A. Well, the table shows us the first four entries, the  
00:54 10 surfactants polysorbate 20, polysorbate 40, polysorbate 60,  
11 and polysorbate 80. And what the table is showing is how well  
12 a vitamin A palmitate is dissolved in a 20 percent aqueous  
13 solution of those surfactants and the amount that is dissolved  
14 in the right hand column under the MAC, that is the mols of  
00:55 15 vitamin per mol of surfactant. You can see very different  
16 values for those polysorbates, polysorbate 20 dissolves .15  
17 mols of vitamin per mols of surfactant, polysorbate 40  
18 dissolves .54, whereas polysorbate 60 .67, and polysorbate 80  
19 .68 per mol of surfactant.

00:55 20 Q. And so what would the person of ordinary skill in the art  
21 glean about the differences, if any, as to the solubilizing  
22 ability of the polysorbates that you just discussed?

23 A. The polysorbate compounds, surfactants have different  
24 abilities to solubilize compounds, in this case salts.

00:55 25 Q. And what does Table 6.23(a) in PTX-181 say to the skilled

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1 person about the predictability of activity among surfactants?  
2 MS. HOLLAND: Objection, your Honor. That's not in  
3 the expert report.

4 MR. DINER: I believe it is, your Honor, at  
00:56 5 Dr. Davies' responsive report at Paragraph 64 where he  
6 discusses the Attwood textbook and the differences in  
7 solubility.

8 MS. HOLLAND: There's nothing about predictability,  
9 your Honor. All it says -- I can hand it up if you want.  
00:56 10 There's nothing about whether -- this would lead to any kind  
11 of predictability or not. That's not in there. That's not in  
12 the paragraph you were just pointed to.

13 MR. DINER: The whole discussion in this part of his  
14 expert report is with regard to the interchangeability,  
00:56 15 interchangeability implicitly is about --

16 MS. HOLLAND: May I hand up the report, your Honor?

17 THE COURT: Just a moment.

18 MR. DINER: It says even when there are differences  
19 in solubilizing the ability of the polysorbate that they are  
00:56 20 different and it goes into the changeability issue, and that's  
21 what is exactly in his expert report. So this is relevant  
22 about the interchangeability and the predictability of your  
23 activity is relevant to what he's testifying to now and what  
24 is in his expert report.

00:57 25 MS. HOLLAND: Your Honor, just so I can put a fine

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1 point on this, he did testify -- I'm sorry. The expert report  
2 does contain some information about this table, but it's an  
3 entirely separate opinion to give about whether you can draw  
4 conclusions about predictability from the table, that's not in  
00:57 5 the expert report. The factual information about what's on  
6 the table, that's fine. Whether or not it tells somebody  
7 about predictability, that's not an opinion that's previously  
8 been offered.

9 MR. DINER: And, your Honor, I would disagree with  
00:57 10 that. What it says is even among polysorbates there's  
11 differences in solubilizing ability and it's in the context of  
12 the interchangeability issue that was addressed by Dr. Davies  
13 in response to Dr. Lawrence's --

14 THE COURT: Well, could the pending question be  
00:57 15 rephrased in terms of interchangeability? If he gave an  
16 opinion as to interchangeability, then I'll permit that. If  
17 he's not giving one as to predictability, then I have to  
18 sustain the objection. I may be able to infer one from the  
19 other, I don't know, I'm not a chemist.

00:58 20 MS. HOLLAND: Your Honor, just to be clear, I don't  
21 have any objection as long as the testimony is what's in the  
22 expert report, so...

23 MR. DINER: I'll rephrase the question, Your Honor.

24 THE COURT: Very well.

25 BY MR. DINER:

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1 Q. So, Dr. Davies, based on the information that is in  
2 Table 6.23A, would a person of ordinary skill in the art  
3 expect that these differences would lead to significant  
4 different functional and chemical properties with regard to  
00:58 5 the ability of the polysorbates to solubilize other compounds?

6 A. Yes, you can see that they have -- they are having a  
7 different effect in their solubilizing ability on this -- in  
8 this example.

9 Q. Now, Dr. Davies, do you have an opinion as to the  
00:59 10 structural differences between Octoxynol 9, Octoxynol 40 and  
11 tyloxapol?

12 A. I do, yes.

13 Q. And have you prepared a demonstrative in this regard to  
14 assist the Court with your opinion?

00:59 15 A. I have.

16 Q. Now, let's turn to PT -- PDX 3-11, and can you explain to  
17 the Court what this demonstrative shows?

18 A. What I've shown on this demonstrative is the structure on  
19 the left of Octoxynol 9, and the structure on the right of  
01:00 20 tyloxapol, and Octoxynol 9, I've shown nine, the nine  
21 repeating units of the ethoxy group, which is this OCH<sub>2</sub>, CH<sub>2</sub>,  
22 OCH<sub>2</sub>, CH<sub>2</sub>, et cetera, and likewise for tyloxapol. And you can  
23 see that on the left that tyloxapol -- I'm sorry, on the left,  
24 that Octoxynol 9 has a single head group with a phenyl and the  
01:01 25 octyl unit and then a long chain, one single long chain of the

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1 ethoxylated part, whereas tyloxapol has a very different  
2 structure.

3 It has seven of these groups, the phenyl and the  
4 hydrocarbon unit along the bottom as drawn. It had -- they're  
01:01 5 each connected by a CH<sub>2</sub> group which is shown by the red ball  
6 and then out of -- off of those, each of those is the tail or  
7 the ethoxylated tail. So overall, there are seven of these  
8 tails coming off. They're structurally very different  
9 compounds.

01:01 10 Q. Now, I noticed that Octoxynol 40 is not depicted on this  
11 demonstrative. Why is that?

12 A. I've not shown Octoxynol 40 on this one because it's --  
13 it's a very big molecule. If I drew Octoxynol 40 on this  
14 molecule -- on this demonstrative, you wouldn't be able to see  
01:02 15 properly either of these two. It would be -- it would draw  
16 the slide, the demonstrative.

17 Q. Now, the -- the red balls that you have indicated there,  
18 what are they highlighting in terms of what exists there in  
19 the molecules of tyloxapol?

01:02 20 A. They -- they're showing an extra carbon between each of  
21 the aryl groups, a CH<sub>2</sub> group that is linking adjacent phenyl  
22 groups. It comes from a reaction from -- with formaldehyde in  
23 order to put those in. It's a linker atom or group.

24 Q. And how do they get there again?

01:02 25 A. You have to copolymerize in a chemical reaction a

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- 1 molecule like Octoxynol 9 with formaldehyde and acid under  
2 specific conditions.
- 3 Q. And that produces what?
- 4 A. That will produce molecules like this, like tyloxapol.
- 01:03 5 Q. Would one of ordinary skill in the art consider tyloxapol  
6 to be structurally different from Octoxynol 9 and  
7 Octoxynol 40?
- 8 A. Absolutely. You will have different physical properties  
9 to Octoxynol 9.
- 01:03 10 Q. The question was actually first, would one of ordinary  
11 skill in the art consider tyloxapol to be structurally  
12 different from Octoxynol 9 and Octoxynol 40?
- 13 A. Absolutely, yes.
- 14 Q. Okay.
- 01:03 15 A. Very different. It's very different because they have  
16 completely different shapes and structures. You can see, this  
17 is a long head group with multi-tails against Octoxynol 9,  
18 which has a single head group and one tail. Octoxynol 40  
19 would be very similar -- would be similar to Octoxynol 9. Not  
01:04 20 very similar, it would be similar in the sense that it's got  
21 the same head group, but a very much longer tail.
- 22 Q. What about those methylene groups that you described  
23 before? Do they exist in Octoxynol 9 or Octoxynol 40?
- 24 A. They do not, no. They're added extra to each of the  
01:04 25 phenyl groups when you go from Octoxynol 9 to tyloxapol.

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- 1 A. Okay.
- 2 Q. And can you explain what this demonstrative shows?
- 3 A. So what I've shown on the left-hand side is Octoxynol 9,  
4 which has its single hydrophobic, greasy if you like, head  
01:06 5 group with its single chain of nine repeating units, ethylene  
6 oxy or ethoxy groups that come up here with the single OH  
7 group at the top.
- 8 Next to it, I've shown Octoxynol 40 which has the same  
9 sized head group at the bottom in gray and a very much longer  
01:07 10 single chain coming out of that head group, and then tyloxapol  
11 is on the right, that has the broad base of the head group  
12 shown in gray, and the seven tails coming out with the oxygens  
13 on them, which is the seven ethylene oxy side chains.
- 14 Q. Dr. Davies, would these structural differences that you  
01:07 15 just explained impact the functional chemical properties of  
16 Octoxynol 9, Octoxynol 40 and tyloxapol?
- 17 A. They will, indeed, yes.
- 18 Q. And how so?
- 19 A. Because the shape -- the properties depend on the shape  
01:07 20 and the distribution of the functional groups and any  
21 molecule.
- 22 Q. And have you prepared a demonstrative in support of your  
23 opinion in this regard?
- 24 A. I have, yes.
- 01:08 25 Q. And can we go to PDX 3-13? And can you explain this

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- 1 Q. And to one of ordinary skill in the art, does that  
2 constitute a contribution to the structural differences as  
3 between tyloxapol on the one hand and Octoxynol 9 and  
4 Octoxynol 40 on the other hand?
- 01:05 5 A. Absolutely, it would -- changes the structure, changes  
6 the shapes that can be adopted, changes the molecule greatly.
- 7 Q. Now, did you hear defendant's counsel state during her  
8 opening that tyloxapol is simply strung together?
- 9 A. I did, yes.
- 01:05 10 Q. Dr. Davies, is it really that simple?
- 11 A. Absolutely not. If they are simply strung together, I  
12 don't quite understand that concept in chemistry, but if they  
13 are simply strung together, the CH<sub>2</sub>s shown by balls would not  
14 be there. The electronic properties of such a conceptual  
01:05 15 molecule would be extremely -- very different to this type of  
16 molecule, the types of shapes that would be likely adopted  
17 would be very different. It's a concept you cannot apply to  
18 tyloxapol in reference to Octoxynol 9.
- 19 Q. Okay. Now, do Octoxynol 9, Octoxynol 40 and tyloxapol  
01:06 20 have three-dimensional structures?
- 21 A. They do, yes.
- 22 Q. And have you prepared a demonstrative to assist the Court  
23 in this regard with your testimony?
- 24 A. I have, yes.
- 01:06 25 Q. Could we go to PDX 3-12?

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- 1 demonstrative to the Court?
- 2 A. This compares Octoxynol 9, Octoxynol 40 and tyloxapol, in  
3 terms of the molecular weight, which is 625 for Octoxynol 9,  
4 1966 for Octoxynol 40 and 4500 for tyloxapol, and also  
01:08 5 compares a critical micelle concentration, the CMC, which for  
6 Octoxynol 9 is .24 millimolar, for Octoxynol 40 is 0.810  
7 millimolar and for tyloxapol is .018 millimolar.
- 8 Q. Okay. And what if anything would a person of ordinary  
9 skill in the art expect regarding the solubilizing abilities  
01:09 10 of Octoxynol 40, Octoxynol 9 and tyloxapol given their  
11 structural differences?
- 12 A. They would expect them to be different.
- 13 Q. And when you say -- what would you expect to be  
14 different? Or what would the person of ordinary skill in the  
01:09 15 art have expected to be different?
- 16 A. The solubilizing ability of each of those would be  
17 expected to be different from the others.
- 18 Q. Thank you. In -- in generating PDX 3-13, Dr. Davies, did  
19 you use information from PTX-190, JTX199 and PTX-201?
- 01:09 20 A. I did, yes.
- 21 Q. Now, Dr. Davies, given the structural and functional  
22 differences among NSAIDs that you explained and given the  
23 structural and functional differences among the surfactants  
24 that you explained, what could one of ordinary skill in the  
01:09 25 art reasonably expect with regard to a precipitate or whether

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1 a precipitate will form in a given system if both the NSAID  
2 and the surfactant were changed?  
3 **A. Well, if you -- as I've indicated, you can't predict what  
4 will happen --**

01:10 5 MS. HOLLAND: Your Honor, I'm sorry -- sorry to  
6 interrupt, Dr. Davies. But I was looking for that in the  
7 expert report and I didn't see it.

8 MR. DINER: I can tell you exactly where it is,  
9 Elizabeth.

01:10 10 MS. HOLLAND: Okay. Thank you.

11 MR. DINER: It's at Paragraph 57 and 58 at least of  
12 his responsive expert report. And if you also look at reply  
13 report, Paragraph 21, it's there as well.

01:10 14 MS. HOLLAND: Can I hear the question again? I  
15 apologize, but...

16 MR. DINER: No worries, no worries.

17 BY MR. DINER:

18 **Q.** Given the structural and functional differences among the  
19 NSAIDs that you explained and given the structural and  
01:10 20 functional differences among the surfactants that you've just  
21 explained, could one of ordinary skill in the art reasonably  
22 predict if a precipitate will form in a given system if both  
23 an NSAID and a surfactant were changed?

01:11 24 MS. HOLLAND: So my objection, Your Honor, is that  
25 the paragraphs we were pointed to don't say anything about

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1 accordingly no way to predict whether an individual NSAID  
2 anion will form an insoluble salt with BAC cation without  
3 experimentation. And in the bottom, it says, indeed, salt  
4 formation will depend on the interaction of all ions in  
01:13 5 solution and their solvation, including the surfactants,  
6 including those from the NSAID salt and those from separate  
7 and distinct benzalkonium chloride salts.

8 So together, what we have here is an opinion from Dr.  
9 Davies that it wouldn't -- that in any given system, you can't  
01:13 10 predict what's going to happen as between -- especially when  
11 you change one surfactant or you change the NSAID.

12 MS. HOLLAND: Your Honor, I don't have any objection  
13 to questions for each of these points separately. My problem  
14 is trying to string them together in a way that Dr. Davies  
01:13 15 never did in his own opinions in his report. That's more of  
16 an argument, and I'm sure plaintiffs will argue that later.

17 But in terms of the opinions, there are separate  
18 opinions in different places and I don't have a problem with  
19 plaintiffs asking it in that way.

01:14 20 THE COURT: Well, are you saying that the way that  
21 Dr. Davies laid it out in his two reports, that he addressed  
22 the issues separately for NSAIDs and surfactants and their  
23 predictability?

01:14 24 MR. DINER: Yes, and then in the responsive report,  
25 in Paragraph 58, he talks about in any given system, you can't

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1 surfactants and I think the question was complex in that way,  
2 it included both surfactants and NSAIDs.

01:11 3 MR. DINER: And if we go, Your Honor, to reply report  
4 at Paragraph 21, it brings it together in conjunction with  
5 Paragraphs 57 and 58 of the responsive report.

6 BY MR. DINER:

7 **Q.** It says in Paragraph 21, with regard to surfactants, a  
8 person of ordinary skill in the art would not expect all  
9 ethoxylated octylphenols to be interchangeable. With only data  
01:12 10 provided for Octoxynol 40, a person of skill in the art would  
11 not have drawn any conclusions of interchangeability for  
12 different Octoxynol -- ethoxylated octylphenols, let alone for  
13 alleging solubilizing NSAIDs, slash, BAC complexes, and  
14 then --

01:12 15 MS. HOLLAND: No, I'm sorry. I just -- that was a  
16 different -- what you just read was a different question than  
17 what you asked, so I don't have a problem if you ask that  
18 question.

01:12 19 MR. DINER: Well, no, but I'm stringing it together  
20 with what is also in Paragraphs 57 and 58.

21 MS. HOLLAND: I understand, but Dr. Davies didn't  
22 string it together in his report. That would be a new  
23 opinion, then.

24 MR. DINER: No, I don't believe so.

01:13 25 It says, in Paragraph 58, in any given system, there is

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1 just change the surfactant -- sorry, the NSAID, and expect  
2 that, you know, what may have happened in a prior system is  
3 going to carry forward into the next system, and then in  
4 Paragraph 21 of his report, he's also talking about that same  
01:14 5 concept in the context of the surfactants.

6 THE COURT: All right. Well, I think it logically  
7 follows if you can't predict for one change, you certainly  
8 can't predict for two. I'll permit it.

9 MR. DINER: Okay.

10 BY MR. DINER:

11 **Q.** Would you like the question read back?

12 **A. Yes, please.**

13 **Q.** Given the structural and functional differences among the  
14 NSAIDs and given the structural and functional differences  
01:15 15 among the surfactants, could one of ordinary skill reasonably  
16 predict if a precipitate will form in a given system if both  
17 the NSAID and the surfactant were changed?

18 **A. They would not -- a person of ordinary skill would not be  
19 able to do that, because if you change the surfactant, you  
01:15 20 can't predict. If you change the NSAIDs, you can't predict,  
21 and if you change both, you'll have no chance.**

22 **Q.** Thank you. Can we now turn to JTX147 and take a look at  
23 that in your binder, and if you could be so kind, identify  
24 that document, please.

01:16 25 **A. This is U.S. Patent 4,910,225.**

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- 1 Q. And who is the first named inventor on this patent?  
 2 A. Ogawa.  
 3 Q.  
 4 And if I refer to U.S. Patent No. 4,910,225 as the  
 01:16 5 Ogawa patent, will you understand what I mean?  
 6 A. Yes.  
 7 Q. Okay. And did you review the Ogawa patent in connection  
 8 with your opinions in this case?  
 9 A. I did, yes.  
 01:16 10 Q. And --  
 11 THE COURT: Excuse me. Can I ask you to pull the mic  
 12 a little closer? You are soft spoken, sir.  
 13 THE WITNESS: Sorry.  
 14 THE COURT: We need to pick up your voice a little  
 01:16 15 better. Thank you.  
 16 MR. DINER: Thank you, Your Honor.  
 17 BY MR. DINER:  
 18 Q. What, generally speaking, is the Ogawa patent directed  
 19 to?  
 01:16 20 A. Bromfenac ophthalmic preparations.  
 21 Q. Okay. Now, Dr. Davies, are you aware that defendants are  
 22 relying on general statements in the prior art that NSAIDs  
 23 complex with benzalkonium chloride to argue that bromfenac  
 24 would precipitate with benzalkonium chloride?  
 01:17 25 A. Yes.

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- 1 appearances of the compositions were not observed at all and  
 2 the decomposition of the compound was not -- almost observed,  
 3 the aqueous compositions being stable, excellent for a long  
 4 period of time.  
 01:19 5 Q. What would this passage in Ogawa convey to a person of  
 6 ordinary skill in the art about the stability of the  
 7 formulation of Ogawa Example 6?  
 8 A. That for a period, for a long period of time, it was  
 9 excellent.  
 01:19 10 Q. And are you also aware that defendants have taken the  
 11 position that a person of ordinary skill in the art would  
 12 expect that bromfenac and benzalkonium chloride in Example 6  
 13 of Ogawa would complex and form an insoluble salt?  
 14 A. This is showing that they do not do that, they do not  
 01:20 15 form an insoluble salt. So a person of ordinary skill would  
 16 understand that.  
 17 Q. Would understand what, I'm sorry?  
 18 A. That they do not form an insoluble salt.  
 19 Q. Thank you. Now, could we go to JTX209 in your binder and  
 01:20 20 if you can be so kind, to identify that document, please.  
 21 A. This is European Patent Application 0 306 984.  
 22 Q. And if I refer to JTX209 as the Fu patent application or  
 23 the Fu reference -- I'll strike that.  
 24 Let me -- would you tell us please first on the front  
 01:21 25 page of JTX209, who is the first named inventor?

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- 1 Q. What, if anything, does the Ogawa patent disclose that  
 2 would convey to one of ordinary skill in the art that  
 3 bromfenac complexes with benzalkonium chloride?  
 4 A. I haven't found any evidence within Ogawa to suggest that  
 01:17 5 it does.  
 6 Q. Now, let's turn to Ogawa Example 6 at Column 10.  
 7 A. I have it, yes.  
 8 Q. Okay. Can you tell us in Ogawa Example 6, the chemical  
 9 name there that begins with the word, "sodium." What is that  
 01:18 10 compound?  
 11 A. That is the sodium sulfite of bromfenac.  
 12 Q. Okay. And just for the record, could you read in the  
 13 rest of the ingredients in that formulation?  
 14 A. There's also boric acid, borax, disodium edetate,  
 01:18 15 benzalkonium chloride, polysorbate 80, polyvinyl pyrrolidone,  
 16 sodium sulfite and then sterile purified water.  
 17 Q. And what is the pH that is identified there?  
 18 A. It's pH 8.  
 19 Q. Okay. Now, let me direct your attention to Column 10,  
 01:18 20 Lines 49 to 57. And would you please read that passage into  
 21 the record.  
 22 A. The following (Table 11) are the residue and appearance  
 23 of the compositions in Examples 6 to 8 after four weeks at  
 24 60 degrees centigrade.  
 01:19 25 As shown in Table 11, it was found that changes in

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- 1 A. Roger Fu.  
 2 Q. Okay. So if I refer to JTX209 as the Fu reference or the  
 3 Fu patent application, will you understand what I mean?  
 4 A. Yes, I will.  
 01:21 5 Q. Okay. Have you considered the Fu patent in connection  
 6 with your opinions in this case?  
 7 A. I have, yes.  
 8 Q. What is the Fu patent primarily directed to?  
 9 A. Ophthalmic preparations for ketorolac.  
 01:21 10 Q. Okay. And previously, do you recall we just talked about  
 11 the structural and functional differences between Octoxynol 9,  
 12 Octoxynol 40 and tyloxapol?  
 13 A. Yes.  
 14 Q. Okay. Does the Fu patent reference disclose tyloxapol?  
 01:21 15 A. It does not, no.  
 16 Q. Please refer to Page 5, Line 21 of the Fu reference.  
 17 MR. DINER: I think it's actually further down. The  
 18 paragraph beginning with nonionic surfactants.  
 19 Can you come over a little bit so I can see the line  
 01:22 20 number?  
 21 MR. BAIRD: Yeah.  
 22 MR. DINER: So for the record, I'd like to refer the  
 23 witness to Page 5, Line 24 of the Fu patent reference. And in  
 24 particular, can you highlight the long chemical name,  
 01:24 25 octylphenoxypoly-(ethylene -- all the way through ethanol.

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1 BY MR. DINER:  
2 Q. And Dr. Davies, do you see in Line 24, which has been  
3 highlighted as octylphenoxypoly-(ethyleneoxy)ethanol?  
4 A. I see that, yes.  
01:23 5 MR. DINER: Okay. Now, can we also, on this slide,  
6 pull up PDX 3-11. Can we get them together?  
7 MR. BAIRD: One second. That's the best I could do.  
8 MR. DINER: Okay. And can you hone in on the  
9 paragraph that we were looking at where it begins nonionic  
01:23 10 surfactants? Yeah, that's good. Thank you.  
11 BY MR. DINER:  
12 Q. Can you see that roughly -- Dr. Davies, also, there's a  
13 monitor in front of you.  
14 A. Okay.  
01:24 15 Q. If you want to look more closely.  
16 A. I've got it, yes.  
17 Q. Okay. Thank you. Dr. Davies, is tyloxapol an  
18 octylphenoxypoly-(ethyleneoxy)ethanol?  
19 A. Yes.  
01:24 20 Q. How large of a class of compounds are the  
21 octylphenoxypoly-(ethyleneoxy)ethanols?  
22 A. There are huge numbers of -- a number of such compounds,  
23 so the class is enormous.  
24 Q. Okay. And what are the surfactants that are specifically  
01:24 25 disclosed in Fu?

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1 nine of them in Octoxynol 9, 12 in Octoxynol 40 -- 12, 13 in  
2 Octoxynol 13 and 40 in Octoxynol 40.  
3 Q. Okay. Does tyloxapol look like any of the specifically  
4 identified compounds in Fu?  
01:26 5 A. No. It has a completely different structure, as you can  
6 see between Octoxynol 9 and Octoxynol 40 on the top  
7 demonstrative.  
8 Q. Now, let me ask you, is Octoxynol 9 an ethoxylated  
9 octylphenol?  
01:27 10 A. Technically, no, because they're not -- octylphenol  
11 requires a hydroxy group on the phenyl ring. And this phenyl  
12 ring in Octoxynol 9 does not have a hydroxy group.  
13 Q. Okay. And is your opinion -- your opinion in that regard  
14 the same with respect to tyloxapol?  
01:27 15 A. The same applies. It's technically, it's not an  
16 octylphenol compound, because there's no OH group on any of  
17 the phenyl, seven phenyl rings in tyloxapol. However, Fu has  
18 characterized all of these compounds as ethoxylated  
19 octylphenol compounds, as his way of describing them. But  
01:28 20 technically, they're not phenols.  
21 Q. Okay. Thank you, Dr. Davies.  
22 Now, let me direct your attention to Page 2 of the Fu  
23 patent reference, and in particular, Lines 33 through 36.  
24 Are you there?  
01:28 25 A. Yes, yes.

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1 A. Fu discloses Octoxynol 9, Octoxynol 12, Octoxynol 13 and  
2 Octoxynol 40.  
3 Q. And just for the record, are you reading that from Page  
4 5, Lines 26 through 28, approximately?  
01:25 5 A. 26 to 27.  
6 THE COURT: Excuse me, Mr. Diner, can I ask you just  
7 to spell this very long term for the record, because I'm  
8 confident our court reporters won't have it in their  
9 dictionary.  
01:25 10 MR. DINER: Okay. Sure. It's  
11 O-C-T-Y-L-P-H-E-N-O-X-Y-P-O-L-Y, dash open paren,  
12 E-T-H-Y-L-E-N-E-O-X-Y, close paren, E-T-H-A-N-O-L-S.  
13 THE COURT: Thank you.  
14 MR. DINER: You're welcome. Thank you for asking.  
15 BY MR. DINER:  
16 Q. So I think the question that we left off with was what  
17 are the surfactants specified, and I believe you answered  
18 that.  
19 What did the surfactants or what do those compounds,  
01:26 20 surfactants in Fu look like?  
21 A. They -- if we look at the demonstrative at the top, they  
22 look like -- well, one of them is Octoxynol 9. The others are  
23 similar structures in the sense that they have the same head  
24 group but the tail has a different length. So the ethyleneoxy  
01:26 25 units, which are the CH2, CH2O units in the tail, there are

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1 Q. Okay. Can you read that passage into the record,  
2 beginning with the word, "however?"  
3 A. However, BAC has typically been considered to be  
4 incompatible with anionic drugs, e.g., salicylates or  
01:28 5 nitrates, et cetera, forming insoluble complexes which cause  
6 the solution to become cloudy or turbid. Such a complex  
7 between the anionic drug and benzalkonium chloride can cause a  
8 decrease in the pharmaceutical activity of the anionic drug.  
9 Q. Okay. How would a person of ordinary skill in the art  
01:29 10 interpret this statement in light of the -- as it appears in  
11 the Fu patent reference?  
12 MS. HOLLAND: Objection, Your Honor. That opinion is  
13 -- as far as I know, not in any of the expert reports.  
14 MR. DINER: That's incorrect, Your Honor. It's all  
01:29 15 over his expert report, in terms of areas in which he  
16 discusses the Fu patent reference in the general statement, as  
17 to whether or not complexation would take place.  
18 MS. HOLLAND: I'm sorry, can you point me to  
19 something?  
01:29 20 MR. DINER: Yeah, from -- if you take a look at  
21 Paragraph 12 of Dr. Davies's reply report and in particular,  
22 Footnote 3. Right. So he's addressing Dr. Heathcock's  
23 statement that -- Dr. Heathcock cites to Fu to argue that a  
24 number of poly -- a number of phenol acetic acid derivatives  
01:30 25 NSAIDs were known as of 2003 to complex with BAC and

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1 precipitate from solution.  
 2 And then he goes on to say, however, as discussed in my  
 3 opening report, however, Fu discloses formulations containing  
 4 the specific NSAID ketorolac trimethamine, non-NSAIDs  
 01:30 5 generally or bromfenac in particular with BAC, and then it  
 6 goes on to say, Fu does not establish that ketorolac and BAC  
 7 form a precipitate as Fu does not test the disclosed turbid  
 8 ketorolac formulations to determine the chemical makeup of the  
 9 precipitate.

01:30 10 So it's in the context of that statement and what is  
 11 taking place in Example 5 of Fu, to address the issue as to  
 12 whether or not the complexation actually does take place. And  
 13 his report addresses that in numerous places.

14 MS. HOLLAND: Your Honor, there's a -- the Footnote 3  
 01:31 15 that you were directed to deals with the specific question  
 16 about this patent application -- this patent and ketorolac.  
 17 This statement about BAC and how the person of ordinary skill  
 18 in the art would understand that statement, that's not in the  
 19 expert report.

01:31 20 This is a -- this, and many other patents have general  
 21 statements about the fact that NSAIDs as a class, acetic  
 22 NSAIDs don't form -- I'm sorry, will form complexes with BAC.  
 23 I think Dr. Davies's point in his report is that the one NSAID  
 24 that's typified, I would say, in this patent, is ketorolac.  
 01:31 25 So that testimony, I don't have any objection to.

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1 that the defendants are citing it for.  
 2 MR. DINER: Correct, your Honor. Thank you.  
 3 THE COURT: I'll permit it.  
 4 MR. DINER: Okay.  
 01:34 5 MS. HOLLAND: Can I just express one more thing on  
 6 this topic, your Honor?  
 7 THE COURT: Sure.  
 8 MS. HOLLAND: I'm concerned here in general because  
 9 there has been a lot that's been said and I anticipate will be  
 01:34 10 said addressing opinions about statements like this in the  
 11 prior art that are very general statements that would apply to  
 12 any NSAID.

13 There is no opinion in Dr. Davies's report  
 14 about those types of statements. There just isn't. He  
 01:34 15 addresses very, very narrow issues within these patents, and I  
 16 think that there is a lack of notice here to the extent that  
 17 it's going to be Dr. Davies, for example, versus Dr. Williams  
 18 who addresses these things. I mean, we couldn't have asked  
 19 him about these opinions at his deposition if they weren't in  
 01:34 20 his report.

21 MR. DINER: But you did actually ask him about them  
 22 in his deposition. And, in fact, it all goes to, as you  
 23 acknowledged, your Honor, the idea of whether or not these are  
 24 general statements which he was directing his testimony to in  
 01:35 25 his expert -- or his expert report to in the context of five,

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1 THE COURT: Okay. Can you repeat the pending  
 2 question, Mr. Diner.  
 3 MR. DINER: The question was: How -- so he read the  
 4 passage from the Fu patent application into the reference, and  
 01:32 5 the question was -- or into the record -- how would a person  
 6 of ordinary skill in the art interpret this statement in light  
 7 of the Fu reference?

8 THE COURT: Just a moment.  
 9 Well, was there any comment in any of Dr. Davies's  
 01:32 10 reports regarding this passage in Fu?

11 MR. DINER: It was in the context of Fu as a whole  
 12 when he was looking at Example 5 and talking about the  
 13 precipitate that formed there, and whether or not it was, in  
 14 fact, a precipitate resulting from the NSAID with benzalkonium  
 01:33 15 chloride, which is tied effectively to the statement at the  
 16 very beginning of the patent, because the patent says that  
 17 when NSAIDs come together with benzalkonium chloride, they  
 18 will precipitate, and so his -- the report was directed to why  
 19 that may not be the case.

01:33 20 THE COURT: All right. And I regard this as  
 21 necessarily included within his expressed opinion, even though  
 22 it's not -- it's not evident in so many words, but it is  
 23 something he reviewed, it's something that he opined upon, and  
 24 it's -- if I am interpreting what you're asking, an example of  
 01:33 25 why he doesn't get from the Fu patent application the concept

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1 but in the context of the whole patent is, well, do they  
 2 really form a precipitate and how do you know from looking at  
 3 the full context of the patent? So that was the whole thrust  
 4 of his expert report in trying to address this complexation  
 01:35 5 issue as raised by the defendants. And even defendants'  
 6 expert, Dr. Heathcock, recognized that in his -- in his report  
 7 back to Dr. Davies, which he responded to, and, as I  
 8 indicated, Dr. Davies was deposed for a very long time on  
 9 these exact statements in all of the references and, of  
 01:35 10 course, they -- as a result, they would have had knowledge of  
 11 that, and it's in his reports as well.

12 THE COURT: All right. No, I --  
 13 MS. HOLLAND: Your Honor, my understanding at Rule 26  
 14 is that you have to give particularized notice of the  
 01:35 15 opinions. It's not enough to say that it was the thrust of  
 16 his report, it just isn't, under the rules. And I understand  
 17 what your ruling was, your Honor, but I just wanted to make a  
 18 short record on this, because Dr. Davies is veering outside of  
 19 the opinions he gave as a chemist in this case and seems to be  
 01:36 20 addressing things that maybe a formulator would be looking at  
 21 and he wasn't --

22 MR. DINER: I would --  
 23 THE COURT: Well, the subject of precipitates is part  
 24 of his opinion. The Fu report itself is part of his opinion.  
 01:36 25 Here is a statement in the Fu report that may be general, and

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1 it I think would be a question of what weight, if any, should  
2 be given to his opinion, but I don't see it as being outside  
3 of the expression of his opinions that have been described  
4 upon the record. It's not like he's pulling Fu off some shelf  
01:36 5 somewhere and for the first time referencing it or even taking  
6 issue with its statements about the likelihood of the  
7 precipitate being formed.

8 MS. HOLLAND: I understand, Your Honor.

9 THE COURT: I haven't read all of these depositions  
01:37 10 or reports, but I don't hear you in disagreement with the fact  
11 that this is one of the major areas of Dr. Davies's opinions  
12 in this case, is whether a precipitate was known or not known  
13 to have been formed.

14 And, also, you have the opportunity to address these  
01:37 15 opinions, if they are striking you as new or as amplifications  
16 of something that you hadn't heard before, then you do have  
17 the opportunity to cross-examine him on it, and also to  
18 introduce rebuttal testimony that would, if an expert agrees  
19 with your thesis, contradict what he's testifying to.

01:37 20 MS. HOLLAND: Okay, your Honor. Thank you.

21 THE COURT: Okay.

22 BY MR. DINER:

23 Q. Okay. So, would you like the question read back?

24 A. Yes.

01:38 25 Q. How would a person of ordinary skill in the art interpret

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1 this statement from the Fu patent application?  
2 A. **It's a very general statement in the introductory part to**  
3 **the patent. It gives no experimental evidence to say that --**  
4 **to show that any precipitate will form between any particular**  
01:38 5 **NSAID and BAC. And they would look at the patent as a whole**  
6 **to see if there was any evidence within the patent to see if**  
7 **such a precipitate occurred in this case.**

8 Q. And when you reviewed the patent, did you see any  
9 evidence that a precipitate formed that was a precipitate of  
01:38 10 benzalkonium chloride and ketorolac?

11 A. **I found no evidence at all, no.**

12 Q. Now, are you aware that defendants are taking the  
13 position that the general statement that we just referred to  
14 in Fu is applicable to bromfenac formulations in Ogawa?

01:39 15 A. **I believe that's true, yes.**

16 Q. And how, if at all, does this statement that you read  
17 from Page 2 of Fu inform one skilled in the art about whether  
18 bromfenac will precipitate with benzalkonium chloride?

01:39 19 A. **It doesn't inform a person of ordinary skill at all. The**  
20 **only examples in this one are salicylates or nitrates, and**  
21 **bromfenac is neither of those.**

22 Q. Okay. Now, please take a look at Examples 2 and 3 on  
23 Page 7 and 8 of Fu.

24 A. **I'm there, yes.**

01:39 25 Q. Okay. Would one of ordinary skill in the art understand

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1 that Examples 2 and 3 are formulations that are representative  
2 of the Fu invention?

3 A. **Yes.**

4 Q. Do Examples 2 and 3 contain the same ingredients?

01:40 5 A. **They do, yes.**

6 Q. What are those ingredients?

7 A. **Ketorolac promethazine, BAC, which is benzalkonium**  
8 **chloride, Octoxynol 40, EDTA disodium, and sodium chloride.**

9 Q. Do they differ in the amount of Octoxynol 40?

01:40 10 A. **They do.**

11 Q. And what are the amounts for Octoxynol 40 in each of the  
12 examples?

13 A. **So, in Example 2, the amount of Octoxynol 40 is .02**  
14 **percent weight per volume. In Example 3, the amount of**  
01:40 15 **Octoxynol 40 is .004 percent weight per volume.**

16 Q. Thank you.

17 I would like to direct your attention now to Page 9 of  
18 Fu, and, in particular, Example 5.

19 A. **Yes.**

01:41 20 Q. Are you there?

21 A. **I'm there.**

22 Q. What is being tested in Example 5 of Fu?

23 A. **The physical stability of formulations of the present**  
24 **invention, so Fu's invention.**

01:41 25 Q. And what is the NSAID that's being used in these

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1 formulations?

2 A. **Ketorolac.**

3 Q. And what surfactants are compared in Example 5?

4 A. **Octoxynol 40, Tween 80, which is Polysorbate 80, and Myrj**  
01:41 5 **52.**

6 Q. Okay. And the Octoxynol 40 formulations, is it your  
7 understanding that those are the formulations of the Fu  
8 invention?

9 A. **That's what it says, yes.**

01:41 10 Q. And what is the amount of Octoxynol 40 used in the first  
11 identified formulation of the Fu invention?

12 A. **.004 percent.**

13 Q. Does that correspond to Fu's Example 3?

14 A. **It does, yes.**

01:42 15 Q. And what is the amount of Octoxynol 40 used in the second  
16 identified formulation of the Fu invention?

17 A. **.02.**

18 Q. Does that correspond to Fu's Example 2?

19 A. **It does, yes.**

01:42 20 Q. Would the skilled person have reasonably understood,  
21 reading this, that the Octoxynol 40 formulations in Fu,  
22 Example 5, correspond to Fu's Examples 2 and 3?

23 A. **Yes, he would, yes.**

01:42 24 Q. For comparison purposes, would the skilled person have  
25 expected that the comparative examples with Polysorbate 80 and

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1 Myrj 52 to have contained the same ingredients as Fu's  
 2 Example -- Examples 2 and 3 except for surfactants -- except  
 3 for the surfactants?  
 4 MS. HOLLAND: Your Honor, I'm going to object to  
 01:42 5 that. I don't believe this is in his report.  
 6 MR. DINER: Your Honor, his report is directed to  
 7 Example 5 on the idea of what, if anything, could be  
 8 understood from the precipitate that is disclosed in there.  
 9 And it's in that context where we're just laying foundation to  
 01:43 10 help him explain what he has already said in his expert report  
 11 which is that you don't know what that precipitate is until  
 12 you test it. And what we're doing is just going through the  
 13 foundation for the Court's benefit to understand what the  
 14 example is about, what the examples were that were compared,  
 01:43 15 such that when he comes to his testimony, it makes sense. So  
 16 it's foundation and informational for the Court, and I don't  
 17 think it's confusing or prejudicial to any of the parties.  
 18 THE COURT: Did his report mention Example 5?  
 19 MR. DINER: Yes, your Honor.  
 01:43 20 MS. HOLLAND: The report did not compare Example 5 to  
 21 Examples 2 and 3 or make any assessment of whether the same  
 22 inactive ingredients would be present for Tween 80 and Myrj  
 23 52.  
 24 MR. DINER: Your Honor, it references --  
 01:44 25 THE COURT: Well, he can be cross-examined on that.

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1 I think it's, again, within the scope of his report. I'll  
 2 permit it.  
 3 BY MR. DINER:  
 4 Q. Now, let me direct your attention to Lines 34 through 36  
 01:44 5 of Example 5.  
 6 A. 34 to 36, yes.  
 7 Q. Yes, thank you.  
 8 Would you please read that highlighted portion of the  
 9 Fu patent application into the record.  
 01:44 10 A. "The presence of turbidity suggested the inability to  
 11 solubilize a precipitate formation between ketorolac moiety  
 12 and benzalkonium chloride."  
 13 Q. What would this passage convey to one of ordinary skill  
 14 in the art?  
 01:45 15 A. That the authors don't know what the precipitate is,  
 16 because it says "suggested." They haven't done an experiment  
 17 to find out, to isolate or to analyze what the precipitate is,  
 18 so it could be something other than that; otherwise, if they  
 19 thought -- if they knew it was that, they would say it is.  
 01:45 20 Q. Okay. And what could it be other than that?  
 21 A. Well, these preparations contain --  
 22 MS. HOLLAND: Objection, your Honor. This specific  
 23 question was asked at the deposition, and Dr. Davies did not  
 24 have an answer as to what an alternative explanation could be.  
 01:45 25 MR. DINER: I disagree, your Honor. What he said in

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1 his deposition is that you could not tell exactly what it is  
 2 unless you did testing.  
 3 MS. HOLLAND: That's not --  
 4 MR. DINER: But what he said -- no, because telling  
 01:46 5 means to know exactly what it is. And what he said clearly in  
 6 his report and in his testimony, you don't know without  
 7 experimentation, and in his deposition response he said you  
 8 could not tell without testing. Obviously, it leaves open the  
 9 possibility that it's something else based on the fact that  
 01:46 10 you can't tell that it's the complex allegedly between  
 11 bromfenac -- or ketorolac and benzalkonium chloride.  
 12 THE COURT: Well, I'll sustain the objection. It's a  
 13 different question. You're asking today "what could it be"  
 14 rather than "can you tell."  
 01:46 15 BY MR. DINER:  
 16 Q. Okay. Dr. Davies, did you hear Dr. Lawrence testify  
 17 about Example 5 of Fu that a person of ordinary skill in the  
 18 art would use 0.02 weight per volume percent tyloxapol in  
 19 formulations of bromfenac based on the disclosure of a 0.02  
 01:47 20 weight percent Octoxynol 40 in Fu?  
 21 A. Yes.  
 22 Q. Do you agree with Dr. Lawrence?  
 23 A. I do not, no.  
 24 Q. And why not?  
 01:47 25 A. Because those two surfactants have -- have different

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1 structures, and you can't substitute one for another, just  
 2 like that, so you can't -- the amount you put into one  
 3 preparation has no meaning on another preparation with a  
 4 different surfactant.  
 01:47 5 Q. Dr. Davies, what, if anything, does Fu teach with regard  
 6 to bromfenac?  
 7 A. Nothing at all. Bromfenac is not -- there are no  
 8 experiments for bromfenac.  
 9 MR. DINER: Your Honor, I'm at a point where I think  
 01:48 10 it may be actually a good point for a short bio break. Would  
 11 that be okay?  
 12 THE COURT: Okay. So let's break for about ten  
 13 minutes until 11:15.  
 14 MR. DINER: Okay be, thank you.  
 01:48 15 (A recess was taken at 11:05 a.m.)  
 16 THE COURT: Okay. Be seated, please.  
 17 Before we begin, there is a matter that was brought  
 18 to my attention where the parties had written to Judge  
 19 Williams, and I wanted to see if that's still a live dispute  
 02:08 20 or not. March 25th, there was an issue raised about defendant  
 21 Lupin's designation of Ms. Kulkarni, and then there was a  
 22 response by Mr. Patunas on March 28th. Has that been  
 23 resolved?  
 24 MS. HOLLAND: I don't think it's been resolved, your  
 02:09 25 Honor, but, actually, Mrs. Kulkarni is in court and she's only

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1 had access to what's been going on in open court, so I don't  
 2 think there is an issue anymore. I think it's moot.  
 3 MR. HASFORD: So, respectfully, your Honor, from the  
 4 plaintiff's view, we don't have any problem with Ms. Kulkarni  
 02:09 5 being in open court and hearing what's here. The issue was  
 6 providing other confidential documents of plaintiffs to  
 7 Ms. Kulkarni. If plaintiffs will represent they are not going  
 8 to do that, then we have no issue.  
 9 MS. HOLLAND: Yeah, at this point, your Honor, I  
 02:09 10 think it's moot. I think it's just what -- Ms. Kulkarni is  
 11 here and this is the record now and that's all we'll be  
 12 sharing with her.  
 13 MR. HASFORD: If I may, your Honor, just so the  
 14 record is clear, will counsel for defendants stipulate that  
 02:09 15 they or represent that they will not provide any of  
 16 plaintiff's confidential documents that we have produced in  
 17 connection with this litigation that were not used in this  
 18 court proceeding to Ms. Kulkarni?  
 19 MS. HOLLAND: Yes, we can stipulate.  
 02:10 20 MR. HASFORD: Then we're fine, Your Honor.  
 21 THE COURT: Okay, fine.  
 22 And, for the record, Kulkarni is spelled  
 23 K-U-L-K-A-R-N-I.  
 24 And I'll just make note that this is moot, and Judge  
 02:10 25 Williams and I need not concern ourselves with it.

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1 patent, and, in particular, Lines 55 through 61.  
 2 A. I'm there.  
 3 Q. Okay. Would you mind reading that portion of the '444  
 4 patent into the record, please.  
 02:11 5 A. "It should be noted that BAK was found to be unexpectedly  
 6 compatible with diclofenac in the present ophthalmic  
 7 composition. While the reasons for this are not entirely  
 8 clear, and without wishing to be bound by any theory, the  
 9 presence of the divalent cation is believed to prevent the BAK  
 02:12 10 from complexing the diclofenac out of the system."  
 11 Q. How, if at all, does this portion of the '444 patent that  
 12 you just read support your opinions in this case?  
 13 A. This says they had no problem with that precipitate of  
 14 diclofenac, an NSAID, with benzalkonium chloride.  
 02:12 15 Q. Okay. And how, if at all, does this statement at Column  
 16 7, Lines 54 to 61 of the '444 patent impact how a person of  
 17 ordinary skill in the art would understand the applicability  
 18 of all NSAIDs -- of the general statement that NSAIDs and  
 19 benzalkonium chloride allegedly complex?  
 02:12 20 A. This obviously does not fall within that category. It  
 21 shows that all NSAIDs do not complex with BAK and come out of  
 22 solution.  
 23 Q. Okay. Can we please turn to your binder, JTX-057, and,  
 24 again, would you please identify this document for the record?  
 02:13 25 A. This is U.S. Patent 5,597,560.

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1 Okay. Thank you. So let's resume.  
 2 MR. DINER: Thank you, your Honor.  
 3 BY MR. DINER:  
 4 Q. Dr. Davies, before the break, do you recall we were  
 02:10 5 discussing the Fu patent reference, in particular, the Example  
 6 5 from that document?  
 7 A. Yes.  
 8 Q. To be clear, would a person of ordinary skill in the art  
 9 be able to determine what the precipitate is in Example 5 of  
 02:10 10 the Fu patent reference?  
 11 A. They would not because there is no description of that  
 12 precipitate being isolated and then analyzed.  
 13 Q. Thank you.  
 14 Now, I would like to go to JTX-043, and would you  
 02:11 15 please turn to that document in your binder and identify it  
 16 for the record, please.  
 17 A. This is U.S. Patent 6,265,444.  
 18 Q. Okay. And I'll just refer to this using defendants'  
 19 nomenclature as the '444 patent. If I do so, will you  
 02:11 20 understand what I mean?  
 21 A. I will, yes.  
 22 Q. Okay. Have you reviewed the '444 patent in connection  
 23 with your opinions in this case?  
 24 A. I have, yes.  
 02:11 25 Q. Let me direct your attention to Column 7 of the 444

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1 Q. Okay. And so I'll refer to that as the '560 patent. Is  
 2 that okay with you?  
 3 A. That's fine.  
 4 Q. Okay. Have you reviewed the '560 patent in connection  
 02:13 5 with your opinions in this case?  
 6 A. I have, yes.  
 7 Q. And now let me direct your attention to Column 6 of the  
 8 '560 patent, and, particularly, the comparative Example C  
 9 starting at Line 55, and continuing on to Column 7 through  
 02:13 10 Line 20 of the '560 patent.  
 11 A. I'm there.  
 12 Q. What is this comparative test that is -- what is the  
 13 comparative test that is being done here?  
 14 A. So, this experiment or this set of experiments is, first  
 02:14 15 of all, taking a formulation that uses -- that contains  
 16 diclofenac, Tobramycin, and benzalkonium chloride as amongst  
 17 the ingredients, and then takes some -- does some control, two  
 18 control experiments, where the formulations were paired, the  
 19 first one with sodium diclofenac as the active ingredient, so  
 02:14 20 without the tobramycin, and the second one with tobramycin and  
 21 without the diclofenac, and then looks at the stability of  
 22 those formulations. And samples from those three formulations  
 23 were stored at 4 degrees and 22 degrees, and a precipitate was  
 24 looked for.  
 02:15 25 Q. And what were the results that were reported?

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1 A. What was found was that at 41 degrees -- 41 days, sorry,  
 2 at 4 degrees Centigrade, the formulation with both diclofenac  
 3 and tobramycin developed a precipitate, while the other two  
 4 control experiments, the one with diclofenac without  
 02:15 5 tobramycin and one with tobramycin without diclofenac did not  
 6 develop precipitates.  
 7 Q. And what, if any, analysis was done here to make that  
 8 determination?  
 9 A. In this experiment, the authors of the patent did exactly  
 02:15 10 what I've been saying previously, in that they isolated the  
 11 precipitate and analyzed what was made up of the -- in the  
 12 precipitate. And they found, on analysis, the precipitate was  
 13 from diclofenac and tobramycin. So what is precipitating out  
 14 is diclofenac and tobramycin in the solid form, whereas the  
 02:16 15 solution that contained diclofenac and the benzalkonium  
 16 chloride remained clear and didn't precipitate, and the  
 17 tobramycin alone, without the diclofenac with benzalkonium  
 18 chloride, that didn't precipitate.  
 19 Q. Okay. How, if at all, does this portion of the '560  
 02:16 20 patent and this comparative experiment support your opinions  
 21 in this case?  
 22 A. It shows that even if you see a precipitate, you mustn't  
 23 make any assumptions and that the only way of knowing what is  
 24 in that precipitate is to separate it, analyze it, and find  
 02:17 25 out what the components are.

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1 Q. And, once again, did this -- did all the formulations of  
 2 the comparative example that you just discussed contain at  
 3 least diclofenac and benzalkonium chloride? Sorry. Strike  
 4 that.  
 02:17 5 Did the formulations that were tested contain  
 6 benzalkonium chloride?  
 7 A. They did, yes.  
 8 Q. Okay. What does this example from the '560 patent teach  
 9 the person of ordinary skill in the art about whether NSAIDs  
 02:17 10 and benzalkonium chloride will precipitate?  
 11 A. This shows that the NSAID diclofenac does not precipitate  
 12 with benzalkonium chloride.  
 13 Q. And, based on what we've just seen in the '560 patent, is  
 14 Dr. Lawrence's general opinion that NSAIDs form a complex and  
 02:17 15 will precipitate with benzalkonium chloride accurate?  
 16 A. I've not -- we've been through some examples where that  
 17 does not happen. I've not seen any examples where it does.  
 18 Q. Okay. Now, is benzalkonium chloride a quaternary  
 19 ammonium compound?  
 02:18 20 A. It is, yes.  
 21 Q. What does the skilled person understand about the  
 22 solubility of salts of quaternary ammonium compounds, if  
 23 anything?  
 24 A. They would understand that they are soluble.  
 02:18 25 Q. Okay.

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1 A. In water. So they are used in -- as reagents, passive  
 2 reagents in chemistry to act as water-cooled phase transfer  
 3 agents, which means they're soluble in both organic solvents  
 4 and water.  
 02:18 5 Q. Would you please turn in your binder -- (pause)  
 6 MR. DINER: Your Honor, may I ask the witness if he  
 7 has a particular document in his binder?  
 8 THE COURT: Of course.  
 9 MR. DINER: Do you have PDX-199 in your binder?  
 02:19 10 THE WITNESS: Yes.  
 11 THE COURT: PTX, right?  
 12 MR. DINER: Yeah, PTX-199. Do you have it, your  
 13 Honor?  
 14 THE COURT: Yes.  
 02:19 15 MR. DINER: Okay.  
 16 BY MR. DINER:  
 17 Q. Well, Dr. Davies, at least can you identify PTX-199,  
 18 please, for the record?  
 19 A. This is an extract from an organic textbook called  
 02:20 20 *Introduction to Organic Chemistry, Third Edition, by*  
 21 *Streitwieser and Heathcock.*  
 22 Q. Now, you mentioned Heathcock. I think it's pronounced  
 23 Heathcock. And is that the same Dr. Heathcock that is serving  
 24 as defendants' expert in this case?  
 02:20 25 A. I believe so, yes, since the first name and the initial

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1 look the same.  
 2 Q. Can I direct your attention to Page 697 of this document?  
 3 PTX-199.  
 4 A. Yes.  
 02:20 5 Q. And I'm sorry, I misspoke. It's 696. I apologize.  
 6 And will you read into the record -- well, will you  
 7 read into the record the paragraph beginning with "such  
 8 compounds" around the middle of Page 696?  
 9 A. "Such compounds which have four alkyl groups replacing  
 02:21 10 the four hydrogens of the ammonium ion are called quaternary  
 11 ammonium compounds. Since they are ionic, they are generally  
 12 water soluble and have fairly high melting points. They often  
 13 decompose at the melting point."  
 14 Q. And if you would, please, at Page 697, would you also  
 02:22 15 read the first sentence of the first full paragraph into the  
 16 record?  
 17 A. "To understand what has happened, we need to recognize  
 18 that although the quaternary ammonium compound is a salt  
 19 soluble in water, it also has a large organic group and has  
 02:22 20 solubility in organic solvents as an ion pair."  
 21 Q. Okay. And so, based on those two passages that you read  
 22 into the record, would one of ordinary skill in the art be of  
 23 the view or understanding that quaternary ammonium compounds  
 24 are water soluble?  
 02:23 25 A. They would, yes.

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1 Q. Okay. And, once again, benzalkonium chloride is a  
 2 quaternary ammonium compound?  
 3 A. **It is, yes.**  
 4 Q. Okay.  
 02:23 5 MR. DINER: Your Honor, I have no further questions.  
 6 I would like to at this time read in --  
 7 (Pause)  
 8 MR. DINER: Oh, I apologize.  
 9 BY MR. DINER:  
 02:23 10 Q. The last question, Dr. Davies.  
 11 Did you hear Dr. Williams' statement on Monday of his  
 12 view of the level of ordinary skill in the art?  
 13 A. **I did, yes.**  
 14 Q. How does that definition relate to the level of ordinary  
 02:23 15 skill that you have applied in expressing your opinions in  
 16 this case?  
 17 MS. HOLLAND: Your Honor, Dr. Davies didn't put the  
 18 level of ordinary skill in the art in his --  
 19 (Pause)  
 02:24 20 MR. DINER: It's Paragraph 11 of his responsive  
 21 report.  
 22 MS. HOLLAND: I'm sorry. Were you suggesting that it  
 23 was the same thing that Dr. Williams said?  
 24 MR. DINER: The first paragraph.  
 02:24 25 MS. HOLLAND: The first paragraph of Dr. Williams --  

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1 MR. DINER: Right. And what he has as his expert  
 2 report.  
 3 BY MR. DINER:  
 4 Q. So the question is: Does that definition relate to the  
 02:24 5 level -- I'm sorry.  
 6 How does that definition relate to the level of  
 7 ordinary skill you have applied in expressing your opinions in  
 8 this case?  
 9 A. **I believe my definition is the same as Dr. Williams'.**  
 02:24 10 Q. And have you applied that definition in connection with  
 11 opinions in this case?  
 12 A. **I have, yes.**  
 13 MR. DINER: Okay. I think that was our last question  
 14 for Dr. Davies, and so if I will -- if I may, your Honor, I  
 02:25 15 would just like move into evidence the documents that we went  
 16 through today.  
 17 THE COURT: Okay. Would you like to read that list  
 18 into the record and then I'll see if there is any objection?  
 19 Some, of course, are already in evidence.  
 02:25 20 MR. DINER: Yeah.  
 21 THE COURT: But are there new ones?  
 22 MR. DINER: There certainly are, but I don't know  
 23 which ones are the new ones and which ones are the old ones.  
 24 I think we talked yesterday that we would just bring them in  
 02:25 25 and then we'll sort it out later. Is that okay?  

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1 THE COURT: Well, if there is any dispute, I would  
 2 rather handle it now with the witness on the stand.  
 3 Ms. Holland, do you know?  
 4 MS. HOLLAND: Yeah, we have objections, your Honor.  
 02:25 5 Do you recall that there were certain demonstratives that were  
 6 shown that the witness testified about and then there was like  
 7 a general conclusory statement at the end of, you know, which  
 8 documents did you look at to put together this demonstrative.  
 9 And so to the extent that those individual documents are going  
 02:25 10 to be submitted into evidence, there was no particularized  
 11 testimony about them. We don't even know where in the  
 12 documents that the testimony came from that was -- the  
 13 information, I should say, came from that was in the slides.  
 14 And I can tell you those are PTX-187 --  
 02:26 15 THE COURT: Well, I know what you're referring to. I  
 16 think on three occasions he gave the source for his --  
 17 MS. HOLLAND: Yeah.  
 18 THE COURT: -- demonstratives, and it was kind of a  
 19 string cite of documents that are on the exhibit list.  
 02:26 20 MR. DINER: Correct.  
 21 THE COURT: All right. Are those documents being  
 22 offered at this time?  
 23 MR. DINER: I was going to, your Honor, yes.  
 24 THE COURT: Are they admissible since he merely  
 02:26 25 relied on them but didn't qualify any of them as, for  

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1 instance, learned treatises or something else that would be  
 2 admissible?  
 3 MR. DINER: They were certainly prior art, your  
 4 Honor. And I think --  
 02:26 5 THE COURT: Well, all I have is a bunch of numbers as  
 6 to those sources. Some of the sources themselves may be in  
 7 evidence. But for those that aren't, I'd have to sustain the  
 8 objection.  
 9 He's disclosed what he relied on, but that doesn't  
 02:27 10 make those sources somehow admissible without the laying of a  
 11 foundation.  
 12 MR. DINER: Okay. Can I have one second, your Honor?  
 13 (Pause)  
 14 MR. DINER: Okay, your Honor, then with regard to the  
 02:27 15 exhibits that we were just discussing from the demonstratives,  
 16 we will pass on that and we will just go and read in the other  
 17 exhibits that the witness has qualified.  
 18 THE COURT: All right. So do you want to do that  
 19 after lunch maybe? Or are you ready to do it now?  
 02:27 20 MR. DINER: I can do it right now, won't take very  
 21 long.  
 22 THE COURT: No, very well, if you're prepared to do  
 23 it.  
 24 MR. DINER: Yeah. No, I am. I'm ready.  
 02:27 25 THE COURT: Okay, fine. So read into evidence at  

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1 this time the exhibit numbers that you are seeking to have  
2 considered as evidence.  
3 MR. DINER: Okay. PTX-199, PTX-160, PTX-632,  
4 JTX-001, JTX-210, PTX-181, JTX-147, JTX-071, JTX-209, JTX-043,  
02:28 5 JTX-057.  
6 MS. HOLLAND: Your Honor, may we reserve on this  
7 right now and then just come back after lunch, after we have  
8 had a chance to look at these, and I'll let you know whether  
9 we have any objections?  
02:28 10 THE COURT: That's fine.  
11 MS. HOLLAND: Thank you.  
12 THE COURT: All right. And so those are on the  
13 table, and then we'll take care of it after lunch to see if  
14 there is any objection as to those documents.  
02:29 15 All right. Are we ready for cross-examination?  
16 MS. HOLLAND: Yes, Your Honor.  
17 THE COURT: Okay, Ms. Holland, you may proceed.  
18 (CROSS EXAMINATION OF DR. DAVIES BY MS. HOLLAND:)  
19 Q. Good morning, Dr. Davies.  
02:29 20 A. Good morning.  
21 Q. Are you aware that this case concerns pharmaceutical  
22 formulations?  
23 A. Yes.  
24 Q. And you're aware that in particular those formulations  
02:29 25 are ophthalmic formulations, right?

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1 Q. And, in fact, you have never done research on any NSAID;  
2 is that right?  
3 A. **Not that I recall. We may have done in the 560 plus**  
4 **publications, but I don't recall having done so.**  
02:30 5 Q. And how many of those 560 plus publications deal with  
6 pharmaceutical formulation?  
7 A. **I don't believe any of them do.**  
8 Q. Okay. Now, you have also never used BAC in a  
9 pharmaceutical formulation, correct?  
02:31 10 A. **We haven't worked on pharmaceutical formulations, so**  
11 **that's correct.**  
12 Q. Okay. And you don't recall -- let me withdraw that  
13 question.  
14 You don't recall working with BAC at all, correct?  
02:31 15 A. **We've worked with quaternary ammonium salts similar to**  
16 **BAC, but I don't recall working with BAC directly.**  
17 Q. You also testified about whether a person of ordinary  
18 skill in the art would understand tyloxapol and polysorbate 80  
19 to be interchangeable, right?  
02:31 20 A. **That's correct, yes.**  
21 Q. And you've never worked with tyloxapol, right?  
22 A. **I have not, no.**  
23 Q. And you've also never worked with polysorbate 80,  
24 correct?  
02:31 25 A. **Not as far as I remember.**

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1 A. **That's correct.**  
2 Q. You are not a pharmaceutical formulator; is that right?  
3 A. **I am not, no.**  
4 Q. And you've never been part of a team formulating an  
02:29 5 ophthalmic formulation, correct?  
6 A. **I have not, no.**  
7 Q. You've never been involved in selection of excipients or  
8 inactive ingredients to be used in a pharmaceutical  
9 formulation, right?  
02:29 10 A. **I've been involved in a team that's --**  
11 Q. Well, let me try again. You have never been involved in  
12 the selection of ingredients for a pharmaceutical formulation,  
13 correct?  
14 A. **Selection of ingredients, that's correct.**  
02:30 15 Q. And your opinions in this case are from the point of view  
16 of an organic chemist, right?  
17 A. **From the point of view an organic chemist, medicinal**  
18 **chemist.**  
19 Q. Okay. Now, you testified about whether bromfenac would  
02:30 20 be expected to form insoluble complexes with BAC. Do you  
21 recall that?  
22 A. **Yes.**  
23 Q. Okay. You've never done work with any -- with bromfenac,  
24 correct?  
02:30 25 A. **I have not worked with bromfenac.**

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1 Q. You also provided testimony comparing tyloxapol with  
2 octoxynol 40, right?  
3 A. **That's correct.**  
4 Q. And you have never worked with octoxynol 40 either,  
02:32 5 right?  
6 A. **I have not worked with those particular compounds. We**  
7 **work with many compounds and understand their structures.**  
8 Q. Now, you testified that ethoxylated octylphenols  
9 constitute a huge class of compounds, right?  
02:32 10 A. **That's correct.**  
11 Q. Okay. And that was based on your knowledge of organic  
12 chemistry; is that right?  
13 A. **Yes, I suppose so, yes.**  
14 Q. Now, is it correct that octoxynol 40 is an ethoxylated  
02:32 15 octylphenol compound?  
16 A. **Can you repeat the question, please?**  
17 Q. Yes. Octoxynol 40 is an ethoxylated octylphenol  
18 compound, correct?  
19 A. **Strictly, it's not, but under Fu's classification, it is.**  
02:33 20 Q. All right. Well, let's -- I think you should have a copy  
21 of your deposition transcript in your binder.  
22 MS. HOLLAND: Did we hand out the cross binders yet?  
23 Okay. Sorry. Let's get those.  
24 BY MS. HOLLAND:  
02:33 25 Q. Now, I believe you should have your deposition transcript

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1 in your binder. Did you find it, Dr. Davies?  
2 **A. Yes.**  
3 **Q.** Okay. Would you turn to page 145, please.  
4 MR. DINER: Your Honor, before we get going on this,  
02:34 5 I think that the impeachment that Ms. Holland is about to  
6 embark upon is improper. I think he's already just agreed  
7 with her in the context of Fu of what octoxynol 40 can be.  
8 MS. HOLLAND: Well, I didn't ask in the context of  
9 Fu, your Honor. That's the issue. I asked generally. So, I  
02:34 10 think it's proper impeachment once you take a look at it.  
11 THE COURT: All right. Before I see what the text of  
12 the dep says, I can't rule on whether it's inconsistent. I  
13 mean, is there an agreement that he is withdrawing certain  
14 testimony?  
02:34 15 MR. DINER: No, your Honor. I'm just thinking that  
16 he, when he answered her question about whether or not  
17 ethoxylated -- octoxynol 40 is an ethoxylated octylphenol, he  
18 said no, not strictly, but it is according to Fu and how Fu  
19 defines things. And I think what she is going to do in terms  
02:35 20 of her impeachment is just ask him what it is in terms of the  
21 octoxynol 40 that was disclosed in Fu.  
22 MS. HOLLAND: Your Honor, if I may just do the  
23 impeachment, and if there's an issue with it, so -- I'm going  
24 show everybody the -- your Honor, I'll direct you and the  
02:35 25 witness to the testimony. It's at page 145, lines 3 to 5.  

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1 THE COURT: Okay. I'll permit it.  
2 MR. DINER: If I may, your Honor, I just would ask  
3 for completeness purposes that Ms. Holland also ask the  
4 witness the questions that follow which will bring into  
02:35 5 context the Fu reference.  
6 MS. HOLLAND: I don't see anything that would make  
7 that particular Q and A complete, completer, more complete, I  
8 should say, by reading anything more in.  
9 MR. DINER: Line 6 and all that.  
02:36 10 MS. HOLLAND: That's a separate question I asked.  
11 THE COURT: I agree with Ms. Holland, that wouldn't  
12 be completeness material. It could be asked on redirect, but  
13 I don't see that it's qualifying the answer that's given on  
14 line 5 because it seems to be a different topic.  
02:36 15 BY MS. HOLLAND:  
16 **Q.** So, Dr. Davies, I'm directing you to your deposition  
17 testimony, page 145, lines 3 to 5. Were you asked at your  
18 deposition, "Octoxynol 40 is an ethoxylated octylphenol  
19 compound, right?"  
02:36 20 And did you provide the answer, "Yes"?  
21 **A. I did, yes.**  
22 **Q.** Now, you have also referred to octoxynol 40 as a  
23 polyethoxylated octylphenol surfactant, right?  
24 **A. Where do I say that?**  
02:36 25 **Q.** I'm just asking you, do you agree that octoxynol 40 can  

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1 also be referred to as a polyethoxylated octylphenol  
2 surfactant?  
3 **A. As a polyethoxylated?**  
4 **Q.** Octylphenol surfactant.  
02:37 5 **A. Under Fu's definition, yes. I'm happy to call it that.**  
6 **Q.** When you say you are happy to call it that, do you mean  
7 you agree?  
8 **A. That it's not an ethoxylated phenol. It's a -- it's  
9 where you're putting the poly. So, if you show me the  
10 reference --**  
02:37 11 **Q.** Let me direct you to your deposition testimony then at  
12 line -- page 192, please.  
13 **A. Yes.**  
14 **Q.** And I'll direct you to line 13.  
02:38 15 **A. Of 192?**  
16 **Q.** Yes. And just for now, I'm showing it to you to refresh  
17 your recollection that is it -- in your view, can octoxynol 40  
18 be referred to as a polyethoxylated octylphenol surfactant?  
19 MR. DINER: Your Honor, I'm not sure which reference  
02:38 20 she's pointing to. She's talking about column 4, starting at  
21 lines 32, and I'm not sure that we have context of where we're  
22 talking about.  
23 THE COURT: All right. Can you supply that? Is that  
24 the Fu patent?  
02:38 25 MS. HOLLAND: This is --  

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1 MR. DINER: It's a different Fu patent other than the  
2 one that we've been talking about.  
3 MS. HOLLAND: It's the '493 patent.  
4 THE COURT: Okay. Well --  
02:39 5 MS. HOLLAND: Do you want me to -- my question was  
6 just more of a definitional one.  
7 THE COURT: Maybe ask the question without reference  
8 to this aspect of the transcript, if it's not the Fu patent  
9 that he was talking about.  
02:39 10 MS. HOLLAND: Sure, your Honor.  
11 BY MS. HOLLAND:  
12 **Q.** My question is, are ethoxylated octylphenol and  
13 polyethoxylated octylphenol, do they refer to the same thing?  
14 **A. They do. If you put the phenol in the name, in terms of  
15 the name, if you put the phenol in the name strictly, it's not  
16 true, but Fu introduced to the system the easier way to call  
17 them, which is to call them the ethoxylated phenols. That's  
18 where it comes from.**  
19 **Q.** Thank you. And you agree that tyloxapol is in the family  
02:40 20 of polyethoxylated octylphenol surfactants, correct?  
21 **A. It's part of a huge family of such compounds, yes.**  
22 **Q.** Now, you said just again that ethoxylated octylphenol  
23 compounds are a huge family. Do you know whether a formulator  
24 would have considered the possible ethoxylated octylphenol  
02:40 25 compounds to be used in an ophthalmic formulation to be among  

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1 a huge family as of 2003?  
 2 A. Well, I think they could consider using anything in an  
 3 ophthalmic formulation. They would have to get it approved,  
 4 of course.  
 02:40 5 Q. How many ethoxylated octylphenol compounds were approved  
 6 for ophthalmic formulations as of 2003?  
 7 A. I haven't done that analysis.  
 8 Q. You didn't attempt to determine that before providing  
 9 your opinions in this case?  
 02:41 10 A. I don't think it was relevant to my opinions in this  
 11 case.  
 12 Q. Let me move on to something else then. You testified  
 13 that there was no evidence in the Ogawa '225 patent that  
 14 bromfenac and BAC form a precipitate. Do you recall that  
 02:41 15 testimony?  
 16 A. Yes.  
 17 Q. Example 6 of Ogawa contains polysorbate 80, correct?  
 18 A. Can you --  
 19 Q. Why don't we -- is it in the cross binder? It's JTX-147.  
 02:42 20 And we'll put it up on the screen as well, but I'm going to  
 21 refer you to Example 6, which is in JTX-147, it's in your  
 22 binder, and you can find it at column 10.  
 23 A. Yes.  
 24 Q. So, my question again was, does Example 6 of Ogawa  
 02:42 25 contain polysorbate 80?

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1 A. Well, since there are several, I believe there are  
 2 several possible functions, and one is not listed, you'd have  
 3 to ask a formulator, but I don't think -- I don't know how  
 4 they would if it's not listed.  
 02:44 5 Q. Did you attempt to find out what the function of  
 6 polysorbate 80 was in the '225 formulation?  
 7 A. I don't know how I would do that.  
 8 Q. Now, did you consider that polysorbate 80 might be  
 9 present to prevent complexation of bromfenac and BAC?  
 02:44 10 A. I don't -- I would have no way of telling. What I can  
 11 tell is that this is a stable solution, this is -- whether it  
 12 contains both bromfenac sodium and BAC and doesn't form a  
 13 precipitate.  
 14 Q. My question was a little different. Did you think about  
 02:44 15 the possible functions of polysorbate 80 in this formulation  
 16 of Example 6 in the '225?  
 17 A. What we have is -- I don't think I needed to consider  
 18 that because what we have here is an example of a stable  
 19 solution that contains both sodium bromfenac and BAC.  
 02:45 20 Q. Okay. So, is the answer to my question that you did not  
 21 consider the possible functions of polysorbate 80 in the  
 22 formulation?  
 23 A. Well, I would have looked at the list of ingredients in  
 24 general, but what I took out from it was that it contains the  
 02:45 25 two species, sodium bromfenac and BAC, and that there was no

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1 A. It's listed there, yes.  
 2 Q. Do you know what polysorbate 80 is?  
 3 A. It's -- I went through the structure earlier. It's  
 4 sorbitan with the long chain and the three groups on it, and  
 02:43 5 80 will mean there's 80 of the ethoxylated units.  
 6 Q. So, that's what it means to an organic chemist, but to a  
 7 formulator, what is the function of polysorbate 80?  
 8 A. I believe it has a number of functions.  
 9 Q. Is one of them as a solubilizer?  
 02:43 10 A. It's one of several functions it could have.  
 11 Q. Are you aware that polysorbate 80 as of 2003 had been  
 12 used as a physical stabilizer?  
 13 A. I don't recall. I'd have to look through all of that.  
 14 Q. I'm sorry. I couldn't hear you.  
 02:43 15 A. Sorry. I don't recall. But I've seen that. I'd have to  
 16 look.  
 17 Q. You didn't investigate that issue before forming your  
 18 opinions in this case?  
 19 A. I just don't recall.  
 02:43 20 Q. Do you know the function of polysorbate 80 in the '225  
 21 formulation?  
 22 A. I don't believe it's listed.  
 23 Q. Okay. Well, do you know if a formulator, when they see  
 24 polysorbate 80 in a formulation, would understand what the  
 02:44 25 function is?

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1 precipitate, it was stable. I can't tell why it's stable.  
 2 It's stable.  
 3 Q. Is one possibility for the reason it's stable is that it  
 4 contains polysorbate 80; is that a possibility?  
 02:46 5 A. Well, it's an ingredient in there. The solution as a  
 6 whole is stable. Any of the ingredients could be doing  
 7 anything.  
 8 Q. So, in your view, it is at least possible as a matter of  
 9 chemistry that polysorbate 80 is performing the function in  
 02:46 10 the '225 Example 6 of preventing complexation of bromfenac and  
 11 BAC; is that right?  
 12 A. Well, in terms of chemistry, these are systems. You have  
 13 everything in there and you can't say any one component does a  
 14 particular thing. It would be all the components together  
 02:46 15 producing the system in which material is dissolved.  
 16 Q. When you look at the list of excipients in Example 6 of  
 17 the Ogawa '225 patent, is there anything else on that list  
 18 that would prevent physical complexation other than  
 19 polysorbate 80? And if you don't know, you can just tell me  
 02:46 20 you don't know.  
 21 A. Well, I don't understand the concept of preventing  
 22 complex formation. If the ions are perfectly happy in  
 23 solution and to be staying in solution, it's not a case of  
 24 preventing complex formation. It just doesn't happen.  
 02:47 25 Q. So --

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1 THE COURT: If there's happy ions?  
2 (Laughter.)  
3 THE WITNESS: If they're happy ions to be in solution  
4 with water molecules around them, why would they form  
02:47 5 complexes?  
6 BY MS. HOLLAND:  
7 Q. All right. Let me probe that a little bit. So, we've  
8 seen several references where at least the authors of the  
9 references say that complexes form between NSAIDs and BAC. I  
02:47 10 understand you disagree with them, but you have at least seen  
11 several references where those statements are made, right?  
12 A. There are several references where they speculate that  
13 might be happening, yes.  
14 Q. And you agree that purely as a matter of chemistry, there  
02:47 15 can be a salt formed between the plus charge of the  
16 benzalkonium ion and the minus charge of the NSAID in  
17 solution, right?  
18 A. If you dissolve a salt in solution, in a solvent, you  
19 form a solution that has plus and minus charges, but again,  
02:48 20 it's a system. So, whatever the minus species, however many  
21 there are, are floating around in a lot of water molecules  
22 with a lot of equivalent number of plus species, whatever they  
23 are and whatever makeup they are, you have to look at the  
24 whole formulation to see. They don't suddenly say we're going  
02:48 25 to grab -- one is going to grab another.

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1 Q. Let me try my question again because I appreciate that  
2 chemistry lesson, but my question I believe was a little  
3 different, so let me see if I can explain it better. Do you  
4 agree as a matter of chemistry that it is potentially possible  
02:48 5 for a salt to form between benzalkonium chloride and an acetic  
6 NSAID in solution?  
7 A. In chemistry terms that doesn't have a meaning. It is  
8 already a salt. You have a salt when you have plus and minus  
9 charges. It is already a salt. If it is dissolved, you have  
02:49 10 a mixture of possibly -- it's a mixture of salts, if you want  
11 to look at it. Once you have dissolved ions into solution,  
12 they don't remember who they came in with. You end up with a  
13 mixture of minuses and a mixture of pluses floating around  
14 that come and interact occasionally and go apart again.  
02:49 15 Q. All right, well -- I'm sorry, I didn't mean to interrupt.  
16 Are you done?  
17 A. If they stay in solution, then they keep moving around.  
18 Q. All right. I'm going to try this one more time. Do you  
19 agree as matter of chemistry that a salt could form between  
02:50 20 the plus charge of a benzalkonium ion and the minus charge of  
21 an NSAID compound at pHs relevant to ophthalmic solutions?  
22 A. As soon as you dissolve the ions in solution, it is a  
23 salt form in solution.  
24 Q. I'm going to direct you to your deposition testimony,  
02:50 25 page 184, lines 3 to 13. So, at your deposition, Doctor, were

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1 you asked, "So, potentially, a salt could form between the  
2 plus charge of the benzalkonium ion and the minus charge of an  
3 NSAID compound at pHs relevant to ophthalmic solutions?"  
4 There was an objection.  
02:51 5 Your answer, "It's a theoretical possibility, but  
6 without evidence, you don't know it's going to happen."  
7 Was that the question and answer?  
8 MR. DINER: Objection. I don't think that what Ms.  
9 Holland is offering is inconsistent with how he just responded  
02:51 10 a moment ago.  
11 THE COURT: No, I'll permit it. His trial testimony  
12 doesn't offer that it may be a theoretical possibility. So,  
13 I'll permit it.  
14 THE WITNESS: I'm just looking at the context.  
02:51 15 MS. HOLLAND: There's no question and answer on the  
16 table anymore.  
17 THE COURT: No, the witness didn't answer your  
18 question.  
19 MS. HOLLAND: Oh, I'm sorry, your Honor. I thought ,  
02:51 20 there was -- that he had.  
21 THE COURT: The tail end of your question was was  
22 that the question and answer? I assume the answer is yes.  
23 THE WITNESS: Yes.  
24 THE COURT: That's what's on the paper, and you can  
02:52 25 ask the next question.

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1 MS. HOLLAND: Thank you, your Honor.  
2 BY MS. HOLLAND:  
3 Q. Now, in your testimony about Example 6 of the '225, and  
4 let's put that back up again, you said that the stability was  
02:52 5 excellent, correct?  
6 A. Well, I'm quoting from the words underneath Example 8.  
7 Q. And Example 6 of the '225 patent is at pH of 8, correct?  
8 A. That's correct.  
9 Q. Do you know whether pH has an effect on the stability of  
02:53 10 a pharmaceutical formulation?  
11 A. I'm sure it does in some cases, yes.  
12 Q. Okay. Do you know whether the stability of this  
13 particular formulation would still be excellent at a pH of 7?  
14 A. Sorry. Can you repeat that question?  
02:53 15 Q. Sure. Do you know whether the stability of Example 6 of  
16 Ogawa would still be excellent if it were at a pH of 7?  
17 A. I don't believe he does that experiment, so I can't tell.  
18 Q. You showed the Court several three dimensional structures  
19 during your direct testimony.  
02:53 20 A. Yes.  
21 Q. Do you recall that?  
22 A. Yes.  
23 MS. HOLLAND: Could we put one of those examples up  
24 on the screen? Can you tell me which PDX it is? PDX3-10.  
02:54 25 BY MS. HOLLAND:

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- 1 Q. All right. And those three dimensional structures as you  
2 testified were meant to show that the compounds look different  
3 from each other, right?  
4 A. That's correct.
- 02:54 5 Q. Now, those images, they represent structures of the  
6 molecules in the gas phase, correct?  
7 A. They are generated from a program that cannot put the  
8 solvent there, so yes.
- 02:54 9 Q. So, those are in the gas phase, but you understand that  
10 the formulations in this case are aqueous solutions, right?  
11 A. I do, yes.
- 12 Q. And your 3D images don't show what the molecules would  
13 look like in an aqueous solution, right?  
14 A. We have no way of telling what they would look like  
02:54 15 directly in solution, but a common use of these types of  
16 programs to generate 3D images, when we can get information  
17 about what they look like from the gas phase calculation to  
18 the solution, very often they are a very close correlation.
- 02:55 19 Q. You didn't mean to suggest to the Court that what you put  
20 up on the screen here are how the molecules would look like in  
21 the aqueous solutions relevant to this case, right?  
22 A. No. These things are mobile. I can't show them moving  
23 around. But you have to take one static view, and however  
24 they move around, you're not going to be able to turn  
02:55 25 polysorbate 80 on the left into the structure on the right.

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- 1 You have to take a snapshot.
- 2 Q. But these are a snapshot in the gas phase, not in an  
3 aqueous solution, right?  
4 A. The calculation is done in a gas phase, but an organic  
02:55 5 chemist's experience would be that this does translate in most  
6 cases to the aqueous or any other solvent base.
- 7 Q. I'd like to turn to your testimony on the 984, EP 984,  
8 which is JTX-209. Can you open up to that reference, please,  
9 in your binder?  
02:56 10 A. I have it. I have it.
- 11 Q. Okay. And you see that the title of this particular  
12 patent application on the first page of JTX-209 is  
13 preservative system for ophthalmic formulations. Do you see  
14 that?  
02:56 15 A. I see that, yes.
- 16 Q. So, you agree that this particular reference is directed  
17 to the field of pharmaceutical formulations, right?  
18 A. Yes.
- 19 Q. And you pointed out this sentence on page 2 of the EP 984  
02:57 20 at paragraph 40 -- I'm sorry, at line 40 on page 2.  
21 MS. HOLLAND: Can we blow that up, please?  
22 BY MS. HOLLAND:  
23 Q. And that statement here in this pharmaceutical  
24 formulation reference is that, "As in the case with other  
02:57 25 ophthalmic drugs that contain a COOH group, antiinflammatory

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- 1 solutions of NSAIDs for ocular use have proven to be  
2 incompatible with quaternary ammonium compounds such as BAC."  
3 Do you see that?  
4 A. That's what it says.
- 02:57 5 Q. Okay. Now, do you know one way or the other whether  
6 formulators as of 2003 generally considered it to be common  
7 knowledge that antiinflammatory solutions of NSAIDs with COOH  
8 groups were generally incompatible with BAC?  
9 A. I don't know how I'd know what a formulator would know.
- 02:58 10 I read this type of general statement in the introduction to a  
11 number of patents and papers, and no, it doesn't provide any  
12 evidence that it will happen in any case or any particular  
13 case.  
14 Q. Okay. So, well, let's look at the next sentence then.
- 02:58 15 "This incompatibility is due to the fact that the COOH group  
16 can form a complex with the quaternary ammonium compounds,  
17 rendering the preservative less available to serve its  
18 function, and reducing the activity of the active ingredient."  
19 Do you see that?  
02:58 20 A. Yes.
- 21 Q. And you understand that, at least in this reference, this  
22 pharmaceutical formulation reference, it is being stated as a  
23 general proposition that the incompatibility is due to the  
24 interaction between the COOH group of the NSAID with the --  
02:59 25 with BAC that renders the BAC less available to serve its

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- 1 function and reduces the activity of the NSAID. Do you see  
2 that?  
3 A. That's what it says.
- 02:59 4 Q. Okay. Now, that particular sentence doesn't say that  
5 whether or not the NSAID is going to form a complex with BAC  
6 depends in some way upon the chemical structure of the acetic  
7 NSAID, does it?  
8 A. That doesn't state that, but the chemical structure would  
9 depend on whether it would form what they term here as a  
02:59 10 complex, and it doesn't -- I don't think it says that it would  
11 have to precipitate out either. So, if it stayed in solution,  
12 you wouldn't reduce the amount of the active ingredient.
- 13 Q. All right. But just getting back to my question, my  
14 question was, does this paragraph say anything about the  
03:00 15 formation of the complex being dependent in any way on the  
16 structure of the NSAID?  
17 A. No. But a person of ordinary skill would know that  
18 forming any complex depends on the structure of the two  
19 compounds coming together or ions coming together.
- 03:00 20 Q. Okay. And it also doesn't say whether or not the ability  
21 to form a complex between an NSAID and a BAC depends -- and  
22 BAC depends upon the solubility of the NSAID, does it?  
23 A. It doesn't say that, but if they formed a complex in  
24 solution, they would -- it would be temporary and they would  
03:01 25 solvate apart and join up with something else and come back

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1 together.

2 Q. But this reference doesn't say that, does it?

3 A. **It doesn't say that, no.**

4 Q. And it doesn't mention hydrogen bonding, correct?

03:01 5 A. **Those are very basic parts of chemical knowledge that**  
6 **students learn in their first term in any chemistry course.**

7 Q. It doesn't say that whether or not the NSAID will form a  
8 complex with BAC depends upon its hydrogen bonding abilities?

9 A. **It doesn't say that.**

03:01 10 Q. Now, you said this reference is directed to ketorolac,  
11 right?

12 A. **Yes.**

13 Q. And you pointed the Court to Examples 2 and 3, correct?

14 A. **Yes.**

03:01 15 Q. Now, would you go to page 4, please. This is a part that  
16 you didn't direct the Court to, but I want to look at it  
17 anyway. Why don't we go to page 4.

18 A. **Yes.**

19 Q. There's a table on lines 30 to 40. I'm actually going to  
03:02 20 look first at line 29. It says, "In a preferred ophthalmic  
21 NSAID solution, the ingredients are combined in the following  
22 proportions." Do you see that?

23 A. **I do, yes.**

24 Q. Okay. And what is the first ingredient on that table?

03:02 25 A. **It says NSAID.**

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1 A. **Yes.**

2 Q. So, the claims of this patent are not directed  
3 specifically to ketorolac, right?

4 MR. DINER: Your Honor, I'd like to just insert an  
03:04 5 objection for the record. These are claims, and what is in a  
6 claim is not necessarily an interpretation of what is in the  
7 specification and what one of ordinary skill in the art  
8 typically looks to.

9 THE COURT: So, you're asking the question be  
03:04 10 rephrased to speak only to this claim?

11 MR. DINER: Well, I'm just saying that the -- that  
12 the claim refers to NSAID, but that is a claim, and claims are  
13 directed to lawyers whereas the specifications are directed to  
14 people of ordinary skill in the art. And it doesn't really  
03:04 15 matter what a claim says to a skilled person. It matters  
16 what's in the spec.

17 THE COURT: All right. Just a moment.

18 MR. DINER: And moreover, your Honor --

19 THE COURT: If the witness is aware of the claims of  
03:04 20 this patent, he can answer the pending question, which is,  
21 "So, the claims of the patent are not directed specifically to  
22 ketorolac?" I'll permit it.

23 THE WITNESS: Some of the claims are.

24 BY MS. HOLLAND:

03:05 25 Q. Okay. But claim 1 is general and would apply to any

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1 Q. Right. It's not particular to any particular NSAID; is  
2 that right?

3 A. **It just says NSAID.**

4 Q. And then if you look at the next table, it says another  
03:02 5 preferred ophthalmic NSAID solution, and again it's a generic  
6 NSAID, correct?

7 A. **Well, it uses the term "NSAID." It doesn't say one in**  
8 **particular or every NSAID. A person of ordinary skill would**  
9 **read the rest of the patent to see what was being referred to.**

03:02 10 Q. In these particular tables, there's no reference to the  
11 formulations being applicable to any particular NSAID,  
12 correct?

13 A. **In these general tables, it doesn't specify one or all or**  
14 **some.**

03:03 15 Q. And then if you go -- why don't we look at claim 1 on  
16 page 11.

17 MS. HOLLAND: Can we put that up on the screen?  
18 Thank you. Maybe a little larger. Is that possible? Thank  
19 you. Maybe it's me. Okay.

20 BY MS. HOLLAND:

21 Q. If you look at claim 1, it says, "An ophthalmic NSAID  
22 formulation comprising an NSAID in an effective amount for  
23 ophthalmic treatment, a quaternary ammonium preservative, a  
24 stabilizing amount of a nonionic ethoxylated octylphenol  
03:03 25 surfactant, and an aqueous vehicle." Do you see that?

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1 NSAID, correct?

2 A. **I don't know that. That's a legal conclusion I don't**  
3 **have the expertise to make.**

4 Q. And while we're on claim 1, you will see that it refers  
03:05 5 generally to nonionic ethoxylated octylphenol surfactants. Do  
6 you see that?

7 A. **Yes.**

8 Q. It doesn't name any specific nonionic ethoxylated  
9 octylphenol compound in that claim, right?

03:05 10 A. **It doesn't name any, but a person of ordinary skill would**  
11 **look at the whole patent, read the whole patent to find out**  
12 **what was being referred to.**

13 Q. Let's go to Example 5, which you discussed in your  
14 testimony.

03:06 15 A. **Okay.**

16 Q. And I believe you said that this Example 5 shows results  
17 of testing of three ketorolac-benzalkonium chloride  
18 formulations, right?

19 A. **I think it actually involves six.**

03:06 20 Q. Correct, they had different concentrations. Thank you.  
21 Thank you for that correction.

22 Okay. But there were three different surfactants that  
23 were being evaluated, right?

24 A. **That's correct.**

03:06 25 Q. And do you understand that the purpose of this experiment

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1 was to determine whether or not these three surfactants would  
 2 help in keeping the solution clear rather than turbid, right?  
 3 **A. Well, they were looking to see whether the formulations**  
 4 **that include those different surfactants stayed clear, yes.**  
 03:07 5 **Q. And more specifically, if you look at the third paragraph**  
 6 **under Example 5, it tells exactly what this experiment was**  
 7 **intended to do. It says, "Three surfactants were evaluated**  
 8 **for their ability to dissolve the ketorolac-benzalkonium**  
 9 **chloride complex and maintain a physically clear solution over**  
 03:07 10 **an extended period of time." Do you see that?**  
 11 **A. That's correct, yes.**  
 12 **Q. Do you at least agree that that was the purpose of this**  
 13 **experiment?**  
 14 **A. That's what it says, yes.**  
 03:07 15 **Q. Now, you said earlier I believe in your testimony that**  
 16 **when you looked at Example 5, it suggested -- it suggested to**  
 17 **you that the authors really didn't know what was causing this**  
 18 **turbidity in the solution. Was that your testimony?**  
 19 **A. It says the word "suggested." It doesn't say "is."**  
 03:08 20 **Q. Okay. But when you look at the paragraph I just pointed**  
 21 **to you, it says that they were "being evaluated for their**  
 22 **ability to dissolve the ketorolac-benzalkonium chloride**  
 23 **complex." Do you see that?**  
 24 **A. Yes.**  
 03:08 25 **Q. Does that indicate to you that the authors believed there**

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1 was a ketorolac-benzalkonium chloride complex?  
 2 **A. No.**  
 3 **Q. All right. And when you look at Example 5, do you agree**  
 4 **that it was the octoxynol 40 that was able to keep these**  
 03:08 5 **solutions clear?**  
 6 **A. That's what the table says.**  
 7 **Q. You also said in your direct testimony, looking at this**  
 8 **same table, you commented on Dr. Lawrence's testimony that a**  
 9 **formulator would have looked at the .02 percent octoxynol 40**  
 03:09 10 **and used that as a starting point for tyloxapol formulation.**  
 11 **Do you recall that?**  
 12 **A. No.**  
 13 **Q. You don't recall that testimony of yours about Dr.**  
 14 **Lawrence relying on the .02 percent?**  
 03:09 15 **A. I remember Dr. Lawrence saying that, yes.**  
 16 **Q. Yes. Okay. And you said that's not right because they**  
 17 **have different structures, right?**  
 18 **A. I can't remember my exact words, but I think I went on to**  
 19 **say you can't swap amounts with surfactants.**  
 03:09 20 **Q. And that's because they have different structures. That**  
 21 **was your testimony, right?**  
 22 **A. Yes.**  
 23 **Q. Okay. Now, you don't know if a formulator looking at**  
 24 **this would, in fact, use .02 percent octoxynol 40 for --**  
 03:10 25 **withdrawn.**

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1 You don't know whether a formulator would use .02  
 2 percent for a tyloxapol solution given that it had been used  
 3 at that percentage for octoxynol 40 in the 984 patent, right?  
 4 **A. Well, I can see that there would be no reason for the**  
 03:10 5 **formulator to believe that that would work, and so a**  
 6 **formulator would do the normal experimental procedures they**  
 7 **use to determine what would be, if any, the best formulation,**  
 8 **which would mean a whole set of experiments under different**  
 9 **concentrations.**  
 03:10 10 **Q. Right. I want to turn to the '560 patent, which you also**  
 11 **talked about in direct testimony, JTX-57.**  
 12 **A. I have it.**  
 13 **Q. Sorry. It's a big binder. I'm going to try to fit it up**  
 14 **here.**  
 03:11 15 **Now, the '560 patent that you testified about -- sorry**  
 16 **about that.**  
 17 **The '560 patent has an additional statement in it that**  
 18 **you didn't testify about earlier, and I'd like to take a look**  
 19 **at that. If you go to column 8.**  
 03:12 20 **A. Yes.**  
 21 **Q. And then at line 63.**  
 22 **A. 63?**  
 23 **Q. Yes, in column 8.**  
 24 **A. Yes.**  
 03:12 25 **Q. I'd like to look at that last sentence. It says, "The**

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1 discovered conditions also permit including in the formulation  
 2 quaternary ammonium compounds as preservatives, since these  
 3 same conditions also inhibit the unacceptable interaction  
 4 between diclofenac and the quaternary ammonium compounds." Do  
 03:12 5 you see that?  
 6 **A. That's what it says.**  
 7 **Q. Okay. And a quaternary ammonium compound again, BAC**  
 8 **would be an example of that, correct?**  
 9 **A. BAC would be an example of that.**  
 03:12 10 **Q. Okay. And this paragraph is telling the formulator that**  
 11 **including BAC as a preservative can be used to inhibit**  
 12 **unacceptable interaction between diclofenac -- well, I'm**  
 13 **sorry. Let me start that again.**  
 14 **This sentence is telling the formulator that there is a**  
 03:13 15 **way to inhibit the unacceptable interactions between**  
 16 **diclofenac and BAC, right?**  
 17 **A. Well, it is saying that you can include the quaternary**  
 18 **ammonium compound. That's the thing relating back to the**  
 19 **control experiment that was done where diclofenac was included**  
 03:13 20 **with the quaternary ammonium salt and they didn't see a**  
 21 **precipitate. It doesn't say that you would ever get a**  
 22 **precipitate under those conditions.**  
 23 **Q. But again, this patent acknowledges, as others that we've**  
 24 **looked at have, that there was a general understanding that**  
 03:14 25 **there was an interaction between acetic NSAIDs and BAC,**

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- 1 correct?
- 2 **A. It is making that type of statement, but for which there**
- 3 **is no experimental evidence that I've seen in the prior art.**
- 4 Q. Just to be clear, your opinions in this case are not that
- 03:14 5 these interactions don't exist or can't exist. It's that you
- 6 haven't seen experimental evidence of them existing, correct?
- 7 **A. Not in the prior art, no, I haven't, no.**
- 8 Q. Let's go to the '444 patent which is JTX-43. You also
- 9 testified about this patent on your direct examination?
- 03:15 10 **A. Which is the number?**
- 11 Q. JTX-43.
- 12 A. 43?
- 13 Q. Yes.
- 14 **A. I have it.**
- 03:15 15 Q. And you did testify about this patent as well in your
- 16 direct examination, correct?
- 17 **A. Yes.**
- 18 Q. All right. Let's look at column 2, lines 34 to 39.
- 19 Actually, I'm going to look at the sentence that starts on 36.
- 03:15 20 It says, "Conventional broad spectrum." Do you see that?
- 21 **A. I do.**
- 22 Q. And it says, "Conventional broad spectrum antimicrobial
- 23 agents like BAC tend to interact with the nonsteroidal
- 24 antiinflammatory agents over time and thereby reduce the
- 03:16 25 efficacy of the medication." Do you see that?

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- 1 **A. It is, yes.**
- 2 Q. Okay. Now, you pointed out column 7, line 55, you
- 3 pointed to a sentence that said, "It should be noted that BAC
- 4 was found to be unexpectedly compatible with diclofenac in the
- 03:17 5 present ophthalmic composition." Do you see that?
- 6 **A. Can you remind me of the line, please?**
- 7 Q. Yeah, I apologize for that. It is column 7, line, I
- 8 think it's 54. This is something you had -- or 55. It's
- 9 something you pointed to in your direct examination.
- 03:18 10 **A. Oh, yes, sorry. I have it, yes.**
- 11 Q. All right. So, again, that sentence says that, "it
- 12 should be noted that BAK was found to be unexpectedly
- 13 compatible with bromfenac in the present ophthalmic
- 14 composition." Do you see that?
- 03:18 15 **A. Yes, that's what it says here.**
- 16 Q. So does that suggest to you that it is expected that it
- 17 would be incompatible?
- 18 **A. That's one way you could interpret it. But it's another**
- 19 **one of those speculative expect or not. I haven't seen any**
- 03:18 20 **evidence that it happens.**
- 21 Q. And again, in that particular reference that you cited
- 22 earlier, there's no statements in here that say that the
- 23 interaction between BAK and the NSAID in any way depends on
- 24 structure, isn't that right?
- 03:19 25 **A. That would be in the general knowledge of either a**

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- 1 **A. It says that, but it is including the word "tend" which**
- 2 **means it may or may not.**
- 3 Q. But the authors are acknowledging that a phenomenon
- 4 exists of NSAIDs complexing with BAC, right?
- 03:16 5 **A. Well, they are making a speculative comment in the**
- 6 **introductory part of a patent for which I have not seen any**
- 7 **experimental evidence.**
- 8 Q. So, you think all the authors of these prior art
- 9 references in the area of pharmaceutical formulation, they
- 03:16 10 were all just speculating that this complexation exists?
- 11 **A. Well, since they don't seem to see any evidence that it**
- 12 **happens in their cases, it looks like speculation to me.**
- 13 Q. Okay. And again, this is a reference in the field of
- 14 pharmaceutical formulation, right?
- 03:16 15 **A. It wouldn't matter where it is.**
- 16 Q. No, but my question was different. You agree that this
- 17 is a reference in the field of pharmaceutical formulation?
- 18 **A. Right, but it's dealing with chemistry.**
- 19 Q. Is this a reference in the field of ophthalmic
- 03:17 20 formulations?
- 21 **A. Which is part of chemistry.**
- 22 Q. Do you have a problem answering my question?
- 23 **A. It is, yes.**
- 24 Q. Is this a reference in the field of ophthalmic
- 03:17 25 formulations?

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- 1 **formulator or the chemist or whoever is reading the patent.**
- 2 Q. Okay.
- 3 **A. So the person of ordinary skill in the art.**
- 4 Q. I had a bit of a different question; just answer this
- 03:19 5 question.
- 6 My question was isn't it correct that nowhere in this
- 7 patent is there any mention of the complexation issue having
- 8 anything to do with the structure of the particular NSAID.
- 9 **A. I don't believe there is, no.**
- 03:19 10 MS. HOLLAND: Your Honor, would you mind if we broke
- 11 now for lunch? It's 12:40.
- 12 THE COURT: All right. That's fine.
- 13 MS. HOLLAND: Thank you.
- 14 THE COURT: So let's break until 1:40. And remember
- 15 that this afternoon, this is the day when I have to end court
- 16 a little bit early, 3:45. Okay?
- 17 MS. HOLLAND: Yes, your Honor.
- 18 (Luncheon Recess)
- 19 DEPUTY CLERK: All rise.
- 04:32 20 THE COURT: Be seated, please.
- 21 Sorry I'm a bit late, but stuff happens during the
- 22 lunch hour in other cases and so that detained me. But we're
- 23 ready to go.
- 24 MS. HOLLAND: Thank you, your Honor.
- 04:32 25 May I begin?

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1 THE COURT: Yes.  
 2 BY MR. HOLLAND:  
 3 Q. Dr. Davies, I'd like to look at one of the demonstratives  
 4 you put up this morning, I think it's Slide 13. Yes. Thank  
 04:32 5 you.  
 6 So this slide was a comparison of octoxynol 9,  
 7 octoxynol 40, and tyloxapol, correct?  
 8 A. Yes.  
 9 Q. And you compared them in terms of molecular weight as  
 04:33 10 well as critical micelle concentration, correct?  
 11 A. That's correct.  
 12 Q. You have never personally done any experiments to assess  
 13 critical micelle concentration, right?  
 14 A. I have not, no.  
 04:33 15 Q. Okay. Now, when you look at the critical micelle  
 16 concentrations of octoxynol 9, octoxynol 40, and tyloxapol,  
 17 they differ from each other, right?  
 18 A. That's correct.  
 19 Q. And a critical micelle concentration is a property of a  
 04:33 20 surfactant, right?  
 21 A. It is, yes.  
 22 Q. Okay. And the lower the critical micelle concentration  
 23 is, the less surfactant you have to use in a particular system  
 24 in order for it to be able to solubilize in that system,  
 04:34 25 correct?

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1 right?  
 2 A. That's correct, yes.  
 3 Q. Okay. And that would be the same calculation for each of  
 4 the octoxynol 9, octoxynol 40, and tyloxapol, right?  
 04:36 5 A. Yes.  
 6 Q. Any. Now, have you done that calculation before?  
 7 A. A long time ago.  
 8 Q. Okay. So do you recall after you did that calculation,  
 9 that tyloxapol has the lowest CMC even in terms of grams per  
 04:36 10 liter?  
 11 A. I don't recall that, no.  
 12 Q. Okay. But that's a simple matter of arithmetic, right?  
 13 We would just have to multiple, as we said before, grams per  
 14 millimol times the CMC in millimol to get the grams per liter,  
 04:36 15 right?  
 16 A. That's correct, yes.  
 17 Q. Just so the record is clear, I actually have a  
 18 calculator. So why don't we do the math so that we can just  
 19 confirm that tyloxapol has the lowest CMC of those three in  
 04:37 20 terms of grams per liter as well.  
 21 A. Okay.  
 22 Q. Are you up for that?  
 23 A. Yes.  
 24 MS. HOLLAND: May I approach the witness, your Honor?  
 04:37 25 THE COURT: Yes.

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1 A. It depends on whether you're talking about molecules or  
 2 grams.  
 3 Q. So let's look. You did it in terms of moles, right?  
 4 A. That's correct.  
 04:34 5 Q. Okay. And that's what a chemist would do, right?  
 6 A. I think both are acceptable by anybody.  
 7 Q. Okay. And you've seen it -- you've seen formulation  
 8 documents look at it in terms of grams, right?  
 9 A. I have, yes.  
 04:34 10 Q. So if you look at it in terms of moles, you see that of  
 11 the three tyloxapol has the lowest critical micelle  
 12 concentration, right?  
 13 A. That's correct.  
 14 Q. It's also correct even if look at it in terms of grams,  
 04:34 15 tyloxapol has the lowest critical micelle concentration,  
 16 right?  
 17 A. I can't remember the calculation.  
 18 Q. Well, let's talk about that for a second. So in order to  
 19 figure that out, you would multiply -- so let's look at  
 04:35 20 octoxynol 90 for example. So 625 grams per mole is the same  
 21 as .625 grams per millimol, right?  
 22 A. Yes.  
 23 Q. So if you multiple the .625 grams per millimol times .24  
 24 millimol per liter that you use as the critical micelle  
 04:35 25 concentration, that gives you the CMC in grams per liter,

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1 BY MR. HOLLAND:  
 2 Q. Okay. So let's start with the octoxynol 9, I think we  
 3 had agreed that you'd multiple .625 times .24 to get the CMC  
 4 in grams per liter, right?  
 04:37 5 A. Yes.  
 6 Q. And what do you get after that calculation?  
 7 A. .15.  
 8 Q. .15?  
 9 A. Yes.  
 04:38 10 Q. And then for octoxynol 40 what do you get?  
 11 A. 1.59.  
 12 Q. Okay. Thank you.  
 13 And let's, finally, do the calculation for tyloxapol.  
 14 A. .081.  
 04:38 15 Q. Okay. So now you agree with me that of the three  
 16 nonionic surfactants that you listed on your slide, octoxynol  
 17 9, octoxynol 40, and tyloxapol, tyloxapol has the lowest CMC  
 18 both in terms of millimol and in terms of grams per liter,  
 19 correct?  
 04:38 20 A. Yes.  
 21 Q. And that is information that would have been available to  
 22 the person of ordinary skill in the art, right?  
 23 A. That's true. We just worked it out.  
 24 Q. Okay. I'd like to put something up on the screen. I  
 04:39 25 apologize, I'm not sure if these are in the plaintiff binders

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1 or not, but let's see. Thank you.

2 So what I've done here, doctor, is I've simply taken

3 the structures for flurbiprofen, ketorolac, and diclofenac

4 that were in your expert reports and just put them up on the

04:40 5 screen. You confirm those are the correct structures, right?

6 A. Yes.

7 Q. And these compounds all have different structures, right?

8 A. They do, yes.

9 Q. Okay. The thing they have in common is the COOH carboxyl

04:40 10 group, right?

11 A. They're all acids, carboxylic acids.

12 Q. They're all what we've been calling acidic NSAIDS, right?

13 A. They are acidic NSAIDS, yes.

14 Q. And these are three acidic NSAIDS that have been

04:40 15 particularly exemplified in the prior art references that

16 talked about complexation, correct?

17 A. They're the ones we've been discussing, yes.

18 Q. Now, even though these three compounds all have different

19 structures other than the carboxyl group, the COH group, they

04:41 20 all were reported as forming a complex with BAC, correct?

21 A. I don't believe any of them reported forming a complex

22 with BAC.

23 Q. I know you don't -- I know you don't think there was

24 experimental evidence, but do you recall in your direct

04:41 25 testimony talking about those three compounds being ones that

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1 A. Yes.

2 Q. They both have different structures other than the COOH

3 carboxyl group, right?

4 A. Yes.

04:42 5 Q. And both of them appear in references where there are

6 general statements about complexation between NSAIDS and BAC,

7 right?

8 A. Whether they be, yes.

9 Q. Okay. Do you recall that flurbiprofen was an Example 4

04:43 10 of EP '984, one of the references that you brought up on your

11 direct examination?

12 A. I recall that, but I don't think there was any data to do

13 with any experiment to do with it.

14 Q. Can we look at the '929 patent, JTX-61? It should be in

04:44 15 your case binder.

16 A. Oh, the cross binder.

17 Q. And I'd like to turn to Column 1.

18 THE COURT: Excuse me, I need to interrupt because my

19 monitor is not picking up the feed.

04:44 20 DEPUTY CLERK: I'm going to shut it down and bring it

21 back up.

22 (Realtime Malfunction)

23 THE COURT: We're back on board.

24 MS. HOLLAND: Thank you.

25 BY MR. HOLLAND:

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1 appeared in the prior art references that had brought up the

2 issue of complexation?

3 A. Well, the general statement was in the introductory part

4 of the papers -- of the patents.

04:41 5 Q. Okay.

6 A. But there were no -- the complexation was not seen in

7 the -- or was not evidenced in the examples of those patents.

8 Q. All right. I think I understand what you're saying. Let

9 me ask it again just to make sure.

04:42 10 What you're saying is we've looked at patents that had

11 these three different acidic NSAIDS in them, that had general

12 statements that these NSAIDS would form complexes with BAC,

13 but you saw no evidence in those patents of the complexes

14 forming, is that right?

04:42 15 A. I don't think I said would.

16 MR. DINER: It's outside the scope of his direct

17 testimony with regard to flurbiprofen.

18 MR. HOLLAND: Oh. I apologize.

19 Did you not talk about -- he did talk about it.

04:42 20 MR. DINER: Not a reference. That reference to

21 flurbiprofen, that was your question.

22 BY MR. HOLLAND:

23 Q. All right. So let's look at the ketorolac and diclofenac

24 then. That's fine. Ketorolac and diclofenac again are acidic

04:42 25 NSAIDS, right?

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1 Q. All right. So we had been looking at JTX-61, this is the

2 '929 patent. And then I believe I asked you to read Column 1

3 starting at Line 27. You see there's a paragraph that begins

4 "benzalkonium chloride is a widely used preservative in

04:49 5 ophthalmic solution?"

6 A. Yes.

7 Q. You there?

8 The next sentence says "benzalkonium chloride and other

9 quaternary ammonium compounds are generally considered to be

04:49 10 incompatible with ophthalmic composition of drugs with acidic

11 groups such as nonsteroidal anti-inflammatory drugs, NSAIDS."

12 Do you see that?

13 A. That's what it says.

14 Q. So this particular reference talks about it as a general

04:49 15 proposition that benzalkonium chloride and acidic NSAIDS are

16 considered to be incompatible. Do you see that?

17 A. It's what it says. Generally could be taken to mean not

18 always or sometimes.

19 Q. Okay. Now again, in this reference, the '929 patent,

04:50 20 there's absolutely no statement that the tendency of an acidic

21 NSAID to form a complex with BAC has anything to do with the

22 specific structure of the acidic NSAID, correct?

23 A. It doesn't say it, but it's what a person of ordinary

24 skill would understand.

04:50 25 Q. All right. Let's turn to JTX-207, this is WO 597.

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1 A. Okay.  
 2 Q. Again, this is a reference in the field of ophthalmic  
 3 compositions, correct?  
 4 A. Yes.  
 04:50 5 Q. And just to be clear, if you turn back to JTX-61 for a  
 6 moment, the one we just looked at, the '929 patent, that was  
 7 also a reference in the field of ophthalmic compositions,  
 8 correct?  
 9 A. That's what it says in the title, yes.  
 04:51 10 Q. Thank you.  
 11 So let's go back then to JTX-207. Would you turn to  
 12 Page 2 of the reference, it has JTX-207.4 on the bottom.  
 13 A. Yes.  
 14 Q. At the top of the page we again see the statement that  
 04:51 15 we've seen many times before, "benzalkonium chloride has been  
 16 widely used in ophthalmic solutions." Do you see that?  
 17 A. Yes, I see that.  
 18 Q. Okay. And then this reference says that it was  
 19 "well-known that benzalkonium chloride was incompatible with  
 04:51 20 anion drugs forming insoluble compounds which caused the  
 21 solution to turn cloudy." Do you see that?  
 22 A. It says it is considered.  
 23 Q. Bromfenac is an anion drug, correct?  
 24 A. Bromfenac is an acidic compound that forms anions when  
 04:52 25 it's in solution at a pH that we're talking about, yes.

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1 Q. Yes. But you understand that bromfenac would fall within  
 2 the meaning of anion drugs in this paragraph, right?  
 3 A. Yes.  
 4 Q. And again, there's no mention in this reference of the  
 04:52 5 tendency of the NSAID to form a complex with BAC having  
 6 anything to do with the structure of the particular NSAID,  
 7 right?  
 8 A. I wouldn't expect there to be. It's such a basic part of  
 9 chemistry.  
 04:52 10 Q. So you agree with me it's not there in the reference,  
 11 right?  
 12 A. I can't see it there.  
 13 Q. Okay. Would you turn to JTX-158, the '113 patent?  
 14 A. Okay.  
 04:53 15 Q. And this is another reference in the field of ophthalmic  
 16 formulations, right?  
 17 A. I can't see it in the title but --  
 18 Q. Let's look at Column 1 of this reference. Again, it says  
 19 at line -- let's see, 31, "benzalkonium chloride is a  
 04:53 20 quaternary ammonium compound which has been widely used in  
 21 ophthalmic solutions." Do you see that?  
 22 A. Yes.  
 23 Q. Again we see the statement that it was well-known that it  
 24 was incompatible with anion drugs. Do you see that?  
 04:54 25 A. It says it's considered incompatible.

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1 Q. It says it was well-known that it was considered  
 2 incompatible, right?  
 3 A. Yes.  
 4 Q. Okay. And this is another reference where there is no  
 04:54 5 qualification on that general statement in terms of the  
 6 specific structure of any particular NSAID, right?  
 7 A. But it's a general reference in the introductory part to  
 8 a patent. I wouldn't expect there to be a reference because  
 9 it's such a basic part of chemistry.  
 04:54 10 Q. Now, so -- all right. Now, have you heard of a reference  
 11 called Remington's?  
 12 A. Yes.  
 13 Q. Okay. That's a reference that's in the field of  
 14 pharmaceutical formulation, right?  
 04:54 15 A. Yes.  
 16 Q. And is that -- do you understand that to be a well-known  
 17 reference in the field of ophthalmic formulation?  
 18 A. I believe it is well-known, yes.  
 19 Q. All right. Can we look at DTX-15, please?  
 04:55 20 A. Sorry, 15?  
 21 Q. Yes, that should be in your cross binder.  
 22 A. Okay. I have it.  
 23 Q. Would you go to page DTX15.5, please. And you'll see  
 24 there a section of Remington's that called quaternary ammonium  
 04:55 25 compounds. Do you see that?

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1 A. Yes.  
 2 Q. And the first sentence of Remington says that "BAC is by  
 3 far the most common preservative used in ophthalmic  
 4 formulations." Do you see that?  
 04:56 5 A. Yes.  
 6 Q. And then the next sentence says that "over 65 percent of  
 7 commercial ophthalmic products are preserved with BAC." Do  
 8 you see that?  
 9 A. Yes.  
 04:56 10 Q. And then if you look two sentences later, what  
 11 Remington's tells the formulator is that "as a cationic  
 12 surface acts as material of high molecular weight, it is not  
 13 compatible with anion compounds." Do you see that? Do you  
 14 see that statement?  
 04:56 15 A. Sorry, where did you point me to?  
 16 Q. I think it's six lines down from the top of the  
 17 paragraph. It's highlighted actually if you want to look up  
 18 on the screen if that's easier.  
 19 A. That's what it says there.  
 04:56 20 Q. Okay. And Remington's makes a broad statement that the  
 21 incompatibility issue applies to anion compounds, right?  
 22 A. That's true, it does so here. But elsewhere in Remington  
 23 under benzalkonium chloride it says the incompatibility is at  
 24 certain concentrations.  
 04:57 25 Q. Okay. So why don't we look here first. Okay? So right

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1 here it says that it's incompatible with anion compounds,  
 2 right?  
 3 **A. It doesn't say under what circumstances it's**  
 4 **incompatible. It doesn't say under all circumstances.**  
 04:57 5 **Q. Does this tell -- does this section tell the formulator**  
 6 **that BAC is incompatible with anion compounds?**  
 7 **A. That's what it says, but it doesn't say under which**  
 8 **circumstances.**  
 9 **Q. All right. And this is a text that is used by**  
 04:58 10 **formulators, right?**  
 11 **A. I believe so, yes.**  
 12 **Q. Now, you looked at several references here that contained**  
 13 **what you called, I think, general statements about acidic**  
 14 **NSAIDS being incompatible with BAC, right?**  
 04:58 15 **A. Yes.**  
 16 **Q. All right. Does that indicate to you that as of 2003,**  
 17 **pharmaceutical formulators generally believed that acidic**  
 18 **NSAIDS were incompatible with BAC?**  
 19 **A. It says some were, some of the references that I've seen**  
 04:58 20 **are by the same authors or the same inventors.**  
 21 **Q. Now, a person of ordinary skill in the art in 2003,**  
 22 **they're confronted with all these references that say there's**  
 23 **a problem here or potential problem between acidic NSAIDS and**  
 24 **BACs. Is it your opinion that the person of ordinary skill in**  
 04:58 25 **the art would simply disregard the statements in those**

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1 JTX-26.  
 2 **A. Okay.**  
 3 **Q. Do you see it says -- this is a Senju document, it says**  
 4 **Study Protocol.**  
 05:00 5 **A. Where am I --**  
 6 **Q. I'm sorry, let me orient you. That's my fault. I**  
 7 **apologize.**  
 8 **The first page says Affidavit of Translation. Do you**  
 9 **see that?**  
 05:00 10 **A. Yes.**  
 11 **Q. Then if you turn over to the next page, which is 26.2,**  
 12 **you see it says Study Protocol, right?**  
 13 **A. Yes.**  
 14 **Q. And this is from the year 2000, right?**  
 05:01 15 **A. Yes.**  
 16 **Q. Okay. Now, I'd like you to -- you see the first**  
 17 **paragraph says -- let me do this.**  
 18 **The study director is Shirou Sawa. Do you see that?**  
 19 **A. I see that.**  
 05:01 20 **Can we go back to the date? This -- I don't believe**  
 21 **this would have been in the public domain at that time, this**  
 22 **looks like it's from an experimental procedure so it would be**  
 23 **from a lab notebook.**  
 24 **Q. I didn't say it was in the public domain.**  
 05:01 25 **A. Okay.**

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1 references?  
 2 **A. I think they do what any scientist would do, do an**  
 3 **experiment and find out whether their set of conditions**  
 4 **presented a problem or not.**  
 04:59 5 **Q. So in your view a person of ordinary skill in the art**  
 6 **looking to formulate bromfenac in 2003 aware of this**  
 7 **literature would at least test to see if bromfenac formed a**  
 8 **complex with BAC, right?**  
 9 **A. If they were interested in making a formulation that**  
 04:59 10 **included it, they would do an experiment, yes.**  
 11 **Q. And if they had done the experiment, they would have seen**  
 12 **that bromfenac in fact does form complexes with BAC, isn't**  
 13 **that correct?**  
 14 **A. I don't know that, no.**  
 04:59 15 **Q. Well, did you ask your attorneys if they were aware of**  
 16 **any documents that showed that bromfenac does indeed form**  
 17 **complexes with BAC?**  
 18 **A. I don't recall doing that. I may have done, I don't**  
 19 **recall.**  
 04:59 20 **Q. All right. Did you investigate that issue before you**  
 21 **came into court with your opinions today?**  
 22 **A. Well, I looked at all of the information I've been**  
 23 **presented with, which is a very large amount, and I haven't**  
 24 **seen any -- an example where such a problem is evidenced.**  
 05:00 25 **Q. All right. So let's look at -- I'd like to look at**

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1 **Q. I'm asking you -- my question had been did you see any**  
 2 **evidence that if the person of ordinary skill in the art in**  
 3 **2003 had done the experiment you said they would perform to**  
 4 **test whether there was a complex between bromfenac and BAC, if**  
 05:01 5 **they would have seen such a complex form.**  
 6 **MR. DINER: I'm not sure if there's a question**  
 7 **pending or if that was her question, your Honor, but we're**  
 8 **going to object to the line of questioning to the extent it**  
 9 **goes into whether or not someone skilled in the art would have**  
 05:02 10 **considered a document not in the public domain. And these, of**  
 11 **course, are the internal Senju documents we've been talking**  
 12 **about for the last couple days and I believe your Honor has**  
 13 **ruled that a document of this nature can only be considered as**  
 14 **part of this trial in the context of determining what the**  
 05:02 15 **level of skill is. And she's asking him about whether or not**  
 16 **this would -- is this evidence of complexation, it has nothing**  
 17 **to do with the level of skill, and it's also an internal**  
 18 **document that's not in the public domain.**  
 19 **MS. HOLLAND: Your Honor, it does have to do with the**  
 05:02 20 **level of skill. The evidence is that a person of ordinary**  
 21 **skill in the art who performed a test in 2003, according to**  
 22 **what Dr. Davies said, the question was would that person**  
 23 **indeed have found that a complex formed between bromfenac and**  
 24 **BAC. I think that's a key issue here because if they had**  
 05:02 25 **found that complex, that's the whole ball of wax, right, then**

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1 they would have known to put in the tyloxapol to deal with the  
 2 physical stability problem.  
 3 MR. DINER: And, your Honor --  
 4 MS. HOLLAND: So it's relevant to know that in 2003  
 05:03 5 if the experiment had been done, what the outcome would have  
 6 been.  
 7 MR. DINER: Your Honor --  
 8 THE COURT: Had you previously asked the question of  
 9 whether Dr. Davies is aware of any experimental evidence that  
 05:03 10 displayed such a complex --  
 11 MS. HOLLAND: Yes.  
 12 THE COURT: Displayed such a complex --  
 13 MS. HOLLAND: Yes.  
 14 THE COURT: -- or produced such a complex.  
 05:03 15 MS. HOLLAND: Yes.  
 16 THE COURT: And he had said no?  
 17 MS. HOLLAND: Right. Now I'm confronting him with  
 18 the evidence.  
 19 THE COURT: So the question is, has he seen this?  
 05:03 20 Is that right?  
 21 MS. HOLLAND: The first question is, has he seen  
 22 this, yes.  
 23 THE COURT: And was that answered?  
 24 MS. HOLLAND: I don't remember. I believe he had  
 05:03 25 seen it at his deposition, at a minimum.

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1 A. I don't know.  
 2 Q. All right. Well, let me direct your attention to JTX26.  
 3 A. Okay.  
 4 Q. And I'd like to direct your attention to -- it's four  
 05:05 5 lines up from the bottom of the objective section.  
 6 Do you see that?  
 7 A. Okay.  
 8 Q. Okay. What it says there is, bromfenac sodium forms  
 9 insoluble complexes with the addition of quaternary ammonium  
 05:05 10 salts becoming cloudy.  
 11 Do you see that?  
 12 MR. DINER: Objection, Your Honor. Again, this is  
 13 getting into this document, as a non-prior art document asking  
 14 the witness, which he's already said he hasn't seen and  
 05:05 15 doesn't know whether or not the formulator would have expected  
 16 there to be -- or as this document, would this document  
 17 establish that there was a complexation, and it's clearly not  
 18 a prior art document. It's not in the public domain.  
 19 It's the inventor's own work and as we discussed many  
 05:05 20 times yesterday, under the statute, an inventor -- the path  
 21 that the inventor takes his invention cannot negative the  
 22 invention in the context of obviousness.  
 23 MS. HOLLAND: That wasn't my question, Your Honor. I  
 24 was asking it for the very purpose that we discussed the other  
 05:06 25 day about, you know, what is the level of skill in the art.

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1 THE COURT: All right. Well, there's no objection to  
 2 that -- I mean, there's no problem with asking him whether he  
 3 has seen this document.  
 4 MR. DINER: Agreed, Your Honor, it's just -- I  
 05:03 5 thought she had asked the question of whether or not this is  
 6 going to be information that would have been considered  
 7 important to the formulator in terms of whether or not  
 8 complexation takes place, and the point is, it wouldn't have  
 9 been because it's not a prior art document and it has nothing  
 05:04 10 to do with the state of the art, as --  
 11 THE COURT: I sustain the objection on that ground.  
 12 If it's not in the public domain, it wouldn't have been  
 13 available to the formulator who is the POSA here. If it's  
 14 being asked for a different purpose, I'll permit the question  
 05:04 15 to be reframed --  
 16 MS. HOLLAND: Thank you.  
 17 THE COURT: -- and then if there's an objection, I'll  
 18 rule on it.  
 19 BY MS. HOLLAND:  
 05:04 20 Q. As a matter of level of skill in the art as of 2003, if a  
 21 formulator had tested a bromfenac/BAC solution, would they  
 22 have found that a precipitate formed?  
 23 A. I don't know. I'm sorry, would they have found if a --  
 24 Q. That a precipitate formed, a complex formed between the  
 05:04 25 two.

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1 Someone confronted with this problem in 2003, what was the  
 2 level of skill in the art about what they would have done,  
 3 procedurally, to see whether or not there was a complex.  
 4 I find it problematic that they are shielding their  
 05:06 5 experts from testifying about things that are clearly contrary  
 6 to the opinions they're giving in this case, and I'd like to  
 7 be able to explore that.  
 8 THE COURT: Well, didn't he say that there would have  
 9 been an experiment done if one were interested in looking at  
 05:06 10 that problem, that they would -- I believe his testimony five  
 11 minutes ago was --  
 12 MS. HOLLAND: Yes.  
 13 THE COURT: Yes, that's what a person of ordinary  
 14 skill in the art would do. They would do an experiment. So  
 05:06 15 this document doesn't add to that, if it just says an  
 16 experiment was done.  
 17 MS. HOLLAND: It says the -- what the outcome of the  
 18 experiment would have been.  
 19 MR. DINER: But, Your Honor, that's the whole point.  
 05:06 20 I mean, it's an internal document, it's the inventor's own  
 21 work, and she's going to use it, not for skill of the art  
 22 because now we are beyond skill of the art, she's trying to  
 23 use it to say that the experiment was done and that this  
 24 document somehow is going to substantiate that it was -- a  
 05:07 25 complex was formed. But that's -- this document is improper

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1 for that purpose.

2 He can't -- you can't use it for that because it's not

3 what the skilled formulator would have had in his or her

4 possession before the invention was made. This is something

05:07 5 that was in the public domain -- sorry, not in the public

6 domain and was the inventor's own work, and as we've been over

7 and over again, it can't be used to negative a conclusion or

8 -- or to negative the obviousness determination, and it's not

9 about level of skill any longer. It's about what would have

05:07 10 done and what would have been seen. So it has nothing to do

11 with level of skill in terms of --

12 THE COURT: I agree that there's not a level of skill

13 issue here. The witness has not said, it would be impossible

14 to do such an experiment, or no one would have thought to do

05:07 15 such an experiment. To the contrary, he said, such an

16 experiment would have been done if someone were concerned

17 about the contraindications that were being, you know,

18 mentioned in the literature.

19 As to this document though, I still don't know the

05:08 20 answer to whether Dr. Davies has reviewed it in connection

21 with formulating his opinion.

22 BY MS. HOLLAND:

23 Q. Dr. Davies, have you seen this document before?

24 MS. HOLLAND: I'm sorry, Your Honor. I banged into

25 this.

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1 THE WITNESS: I don't recall having seen this

2 document.

3 BY MS. HOLLAND:

4 Q. Do you recall testifying about it at your deposition?

05:08 5 A. I don't -- I'm looking at this document. I don't know if

6 I've seen this document.

7 MS. HOLLAND: Your Honor, I can represent to the

8 Court -- I cannot show you the transcript, but I can also

9 represent to the Court that he did review the document and

05:08 10 testified about it at his deposition.

11 THE COURT: Because you showed it to him or because

12 his attorneys had provided it as part of his preparation to

13 testify?

14 MS. HOLLAND: I believe it was because it was shown

05:08 15 to him at the deposition.

16 MR. DINER: And it's not part of his expert report,

17 Your Honor, as far as I know.

18 MS. HOLLAND: Your Honor, if I can say one more

19 thing.

05:08 20 THE COURT: Okay.

21 MS. HOLLAND: Dr. Davies sat -- testified for quite a

22 while this morning about why there would be no complex formed

23 between bromfenac and BAC as a matter of chemistry. That was

24 kind of the substance of what he said this morning. We have a

05:09 25 document in front of us that says that that's not right.

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1 Seems to me I should be able to question the witness about it.

2 THE COURT: As a matter of impeachment?

3 MS. HOLLAND: Yes.

4 THE COURT: Because you're taking the adversary's own

05:09 5 words?

6 MS. HOLLAND: Yes.

7 MR. DINER: But it's not the adversary, Your Honor,

8 and, in fact, what we're talking about here is a document that

9 is not in the public domain. The issue is whether one of

05:09 10 skill in the art before January of 2003, looking at what was

11 then available in the prior art, whether it's Desai, whether

12 it's Fu, or whether it's these other patents, would there have

13 been an expectation that those general statements would have

14 been applicable to bromfenac and whether it would have formed

05:09 15 a complex.

16 What happens internally within a company, as they're

17 marching on their way and they're doing their experiments to

18 an invention is completely irrelevant to the inquiry of

19 obviousness. The statute is clear on that, and on top of

05:09 20 that, this is not anything that Dr. Davies had in his expert

21 report, he's provided no opinions on it.

22 THE COURT: Well --

23 MS. HOLLAND: It's cross-examination.

24 THE COURT: It's cross-examination and he could be

05:10 25 asked whether this changes his opinion. If he were to be

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1 shown an example of an experiment having been done that

2 produced such a precipitate, would that change his opinion

3 that such a precipitate would not -- that there's no evidence

4 for such a precipitate being formed.

05:10 5 I don't think that that's retracing or examining the

6 inventor's steps. It's inquiring into a physical fact. If

7 one does such an experiment, what's the result? I don't see

8 that as probing.

9 MR. DINER: Well, because the issue --

05:10 10 THE COURT: Just a moment.

11 MR. DINER: Sorry.

12 THE COURT: I don't see that as probing the pathway

13 to the -- to the invention. I do see it as -- as an

14 experiment that would -- if it's believed, contradicts his own

05:11 15 opinion about a physical fact of whether, when one conducts

16 this mixing under certain conditions, there would or would not

17 be a precipitate.

18 MR. DINER: Well, can I just make a further

19 statement? The issue again that we're dealing with is

05:11 20 obviousness and, of course, that's looked at at a time prior

21 to when the invention was made, based on publicly available

22 information. What she is actually going to, Ms. Holland, is,

23 is it a fact that it's been done.

24 Well, that's really a question of inherency whether it

05:11 25 is or is not. Has nothing to do with obviousness and the law

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1 is quite clear what may be inherent is not relevant to  
 2 obviousness, because you can't predicate a position of  
 3 obviousness on what is unknown, based on the prior art, and  
 4 this is clearly not in the prior art, and there's a number of  
 05:11 5 cases on that, like, I can't think of the case off the top of  
 6 my head, but that much is clear. That -- whether it's a fact  
 7 or not is irrelevant to the issue of obviousness because  
 8 obviousness is based on and predicated on what's in the prior  
 9 art, something there or not there. If it's not known in the  
 05:12 10 prior art, then the person skilled in the art would not have  
 11 it in his or her head in order to make these assessments.  
 12 THE COURT: Prior art said that there was a  
 13 problem --  
 14 MR. DINER: Mm-hmm.  
 05:12 15 THE COURT: -- with NSAIDs forming complexes with  
 16 BAC. The witness has said that's too general of a statement,  
 17 and he's never seen experimental evidence for bromfenac  
 18 forming complexes with BAC. And he's testified as to why that  
 19 wouldn't happen. He's being confronted with evidence that it  
 05:12 20 does happen. It happens to be in -- in your client's study  
 21 protocol, but again, if it's a physical fact, why not permit  
 22 him to be questioned on it, and to see whether it changes an  
 23 important opinion that he holds in this case, that no such  
 24 complex is formed.  
 05:13 25 MR. LIPSEY: Excuse me, Your Honor. I know it's  
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1 irregular. May I be heard just briefly?  
 2 THE COURT: Yes.  
 3 MR. LIPSEY: You can see in the very first sentence  
 4 of this document, this problem arose when they went to reduce  
 05:13 5 the pH. This is exactly the path of the invention. These are  
 6 documents reflecting how the invention was made, and to allow  
 7 the information the inventor discovered and established to  
 8 then be used directly or indirectly to try to prove the  
 9 obviousness of the invention is exactly what's prohibited by  
 05:13 10 the statute, and that's why we're concerned about this.  
 11 THE COURT: Well, then, is your witness willing to  
 12 retract his testimony that he's never -- he's unaware of any  
 13 experimental evidence that such a precipitate forms?  
 14 MR. LIPSEY: I think his testimony was that there was  
 05:13 15 none in the prior art.  
 16 THE COURT: Okay. Did the questioning go beyond  
 17 prior art?  
 18 MS. HOLLAND: It did, Your Honor.  
 19 THE COURT: That's my recollection, too.  
 05:14 20 MR. LIPSEY: I think that's --  
 21 THE COURT: So which way do you want to have it? Is  
 22 he going to, you know, rest upon what he has said or is it  
 23 going to be modified? If it's not going to be modified, then  
 24 he can be impeached with experimental evidence that he's been  
 05:14 25 -- that he was made aware of for this case.  
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1 MR. LIPSEY: But if his testimony was that he had not  
 2 seen any evidence in the prior art that that happened, that's  
 3 not impeached with this document, which shows --  
 4 THE COURT: I agree.  
 5 MR. LIPSEY: Okay.  
 6 THE COURT: If his -- if the prior testimony was  
 7 whether in the prior art he saw experimental evidence of  
 8 bromfenac complex -- forming complexes with BAC, this document  
 9 does not impeach that because it's not prior art.  
 05:14 10 MR. LIPSEY: I believe that's all he testified to in  
 11 his --  
 12 THE COURT: Well, let's go back, then, and I'll ask  
 13 that a foundation be laid. It might be that my recollection  
 14 and Ms. Holland's is not correct.  
 05:15 15 MS. HOLLAND: But I think there are -- Your Honor,  
 16 there are two aspects to the impeachment here. One is the  
 17 question of, have you seen any evidence that BAC forms the  
 18 complex. The second matter of impeachment is just the general  
 19 testimony this morning that it won't happen. I mean, that's  
 05:15 20 apart from any specific evidence about whether he's seen any  
 21 experiments. I mean, he was on the stand for an hour telling  
 22 us why it wouldn't happen, and now we have a document that  
 23 says it would. So that's separate -- that's a separate  
 24 grounds of impeachment.  
 05:15 25 MR. DINER: I don't think it has --  
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1 THE COURT: Just a moment, please. A foundation has  
 2 to be laid as to whether when one goes beyond prior art and  
 3 into the realm of the chemical world, whether he's aware of  
 4 experimental evidence that such a complex forms.  
 5 BY MS. HOLLAND:  
 6 Q. Dr. Davies, are you aware of any evidence that bromfenac  
 7 forms an insoluble complex with BAC?  
 8 A. I don't believe I am.  
 9 Q. Okay. Well, let's look at JTX26, then.  
 05:16 10 MR. LIPSEY: I guess we would just like a standing  
 11 objection to the line of questioning, Your Honor.  
 12 THE COURT: Well, he's indicated that no, he's not  
 13 aware of such evidence.  
 14 MR. LIPSEY: But he's not saying his opinion was that  
 05:16 15 it never happened. His opinion -- the opinions he gave were  
 16 that there was no evidence in the prior art of that complex,  
 17 and that's all we intend to rely on his testimony for. We are  
 18 not trying to prove here an absolute negative.  
 19 MS. HOLLAND: But that's the testimony that came in.  
 05:16 20 MR. LIPSEY: I would --  
 21 MS. HOLLAND: Based on your direct examination.  
 22 MR. LIPSEY: -- you were asking him about document  
 23 after document after document, and he said, I don't see  
 24 evidence there that it happened.  
 05:17 25 MS. HOLLAND: Your Honor, my recollection is that we  
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1 heard a lot of testimony about hydrogen bonding and why  
 2 bromfenac, because of its hydrogen bonding won't form this  
 3 complex while the other stuff in the prior art does.  
 4 MR. LIPSEY: I think his testimony was that it might  
 05:17 5 not, that you couldn't tell just because one did, that another  
 6 didn't. That was the whole point of that testimony. The  
 7 molecules are different, and just because something happens  
 8 with one, you cannot, because of the differences, say it  
 9 necessarily happens with the other, and he said time and  
 05:17 10 again, when faced with documents, that I don't see any  
 11 evidence there, that it does. That was the extent of his  
 12 testimony.  
 13 THE COURT: Well, perhaps all this could be clarified  
 14 if there's an agreement by the plaintiffs that Dr. Davies is  
 05:17 15 not testifying that such a reaction, this formation of complex  
 16 with BAC does not happen or could not happen.  
 17 MR. LIPSEY: I think we are prepared to stipulate  
 18 he's not testifying that it cannot happen. What he's  
 19 testifying to is that there's no evidence in the prior art  
 05:18 20 that it did happen, and that because of chemical differences,  
 21 you couldn't predict *a priori* that it would happen from what  
 22 happened with other molecules. That was the extent of his  
 23 opinion and the extent of the testimony, as I heard it go in.  
 24 Am I correct?  
 05:18 25 MR. HASFORD: Correct.  
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1 THE COURT: So you're suggesting at least two things;  
 2 not testifying that it cannot happen and no evidence in prior  
 3 art that it did happen.  
 4 MR. LIPSEY: Correct.  
 05:18 5 THE COURT: And anything -- anything that might have  
 6 suggested that there's no evidence in the world that it  
 7 happens falls away. Is that correct?  
 8 MR. LIPSEY: There's no evidence in the prior art  
 9 that it happened.  
 05:18 10 THE COURT: Right. That is his testimony.  
 11 MR. LIPSEY: Yes.  
 12 THE COURT: But it is not his testimony that -- from  
 13 what you're saying, that it has never happened in the history  
 14 of mankind?  
 05:19 15 MR. LIPSEY: Right. Correct, that it -- that it  
 16 cannot happen is not the testimony. That it never happened  
 17 after, you know, in the course of the inventor's discovery,  
 18 he's not making that testimony.  
 19 THE COURT: Well, with that clarification, then, and  
 05:19 20 his opinion being limited to prior art and being limited to  
 21 what it is that the prior art showed to a person of ordinary  
 22 skill, then I would sustain the objection.  
 23 MS. HOLLAND: Can I ask one more question, Your  
 24 Honor, and --  
 05:19 25 THE COURT: I'm almost afraid to hear it but --  
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1 (Laughter.)  
 2 THE COURT: I have no problem with you asking a  
 3 question. This is a difficult area for --  
 4 MS. HOLLAND: Yes.  
 05:19 5 THE COURT: -- for all -- all of us, but let me ask  
 6 you the question first, and I'm asking the defendants  
 7 collectively, if this witness's expert testimony is confined  
 8 to those areas of what was shown in the prior art and also a  
 9 clarification that he's not testifying that it cannot happen,  
 05:20 10 then is that acceptable?  
 11 MS. HOLLAND: That's why -- that's why I want to ask  
 12 one more question, because I think with one more question,  
 13 that would likely be acceptable. So that the question that  
 14 I'm proposing is --  
 05:20 15 THE COURT: Go ahead.  
 16 BY MS. HOLLAND:  
 17 Q. Is it your opinion that if a person of ordinary skill in  
 18 the art had performed the experiment in 2003, that they would  
 19 not have seen complexation between BAC and bromfenac?  
 05:20 20 A. I -- you have to repeat that question to me.  
 21 Q. Is it your opinion that if a person of ordinary skill in  
 22 the art in 2003 had performed an experiment with bromfenac and  
 23 BAC to look for complexation, that they would not have seen  
 24 complexation?  
 05:21 25 A. I don't know. You have to do the experiment to find out.  
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1 MS. HOLLAND: Your Honor, I think it would be in our  
 2 view, this document goes to that question of what the person  
 3 of ordinary skill in the art in 2003 would have encountered  
 4 had they done the experiment, and that's, as you said, I don't  
 05:21 5 know if it's a matter of scientific fact, but it has to do  
 6 with the motivation of the person of ordinary skill in the art  
 7 as of 2003, which is a central issue here. If they had done  
 8 the experiment and they found that there was the complexation,  
 9 they clearly would have been motivated to do something about  
 05:22 10 it.  
 11 THE COURT: I'm going to sustain the objection that  
 12 counsel is raising to make, because of the witness's testimony  
 13 in response to your question. He does not have an opinion.  
 14 MS. HOLLAND: Okay. I think that's all I have, Your  
 05:22 15 Honor.  
 16 THE COURT: Very well. Thank you, Ms. Holland.  
 17 Redirect?  
 18 MR. DINER: No, Your Honor.  
 19 THE COURT: Okay. Just one moment. Let me see if I  
 05:22 20 have any clarifying questions.  
 21 Oh, before the witness leaves the stand, is there --  
 22 are the plaintiffs moving in the documents at this time?  
 23 MR. DINER: Oh, I believe, yes. Thank you for  
 24 reminding us, Your Honor. We talked about that and I think  
 05:23 25 defendants are fine with the documents we seek to move in.  
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1 THE COURT: Okay. And that's the list that was  
 2 previously read?  
 3 MR. DINER: Correct.  
 4 MS. HOLLAND: Yes, Your Honor.  
 05:23 5 THE COURT: Okay. Let me recite into the record what  
 6 I believe those documents are and you can correct it.  
 7 MR. DINER: Sure.  
 8 THE COURT: So the following will be received into  
 9 evidence: PTX-199, PTX-160, PTX-632, JTX001 is already in  
 05:23 10 evidence. JTX210, JTX181. Is the next one JTX147? Yes.  
 11 JTX071.  
 12 THE DEPUTY CLERK: JTX147 was already in.  
 13 THE COURT: Okay, 147 was already in. JTX071,  
 14 JTX209, JTX043 and JTX057. Is that correct?  
 05:24 15 MR. DINER: Correct.  
 16 THE COURT: Okay. So each is in evidence.  
 17 THE DEPUTY CLERK: 71 was already in.  
 18 THE COURT: Yeah, 71 was already in also. JTX71.  
 19 (PLAINTIFF EXHIBITS PTX-199, PTX-160, PTX-632, JTX210, JTX181  
 05:23 20 JTX209, JTX043 and JTX057 WERE RECEIVED IN EVIDENCE)  
 21 MS. HOLLAND: Your Honor, I believe there are a  
 22 couple of exhibits used during cross that I'd like to move in.  
 23 So it's JTX158, JTX207.  
 24 THE COURT: Any objection?  
 05:25 25 MR. DINER: Just one second, Your Honor. I'm just  
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1 MR. HASFORD: And permission, your Honor, to approach  
 2 and distribute the binders?  
 3 THE COURT: Yes. Okay. You may proceed.  
 4 MR. HASFORD: Thank you, your Honor.  
 05:45 5 (DIRECT EXAMINATION OF ROBERT O. WILLIAMS, III BY  
 6 MR. HASFORD:)  
 7 Q. Good afternoon, Dr. Williams.  
 8 A. **Good afternoon.**  
 9 Q. Did you hear Dr. Lawrence testify that the subject matter  
 05:46 10 of Claims 6 and 20 of the '431 patent allegedly would have  
 11 been obvious to a person of ordinary skill in the art over the  
 12 references she discussed?  
 13 A. **Yes.**  
 14 Q. Do you agree with Dr. Lawrence's opinions?  
 05:46 15 A. **I do not.**  
 16 Q. Let's explore the basis for your disagreement.  
 17 First, Noel, would you please put up PDX1-1 on the  
 18 screen. Oh, I apologize, 2-1.  
 19 So, for the record, this is PDX2-1 on the screen. Do  
 05:47 20 you see that, Doctor?  
 21 A. **Yes, I do.**  
 22 Q. Dr. Williams, you previously testified as to your opinion  
 23 concerning the level of education and work experience a person  
 24 of ordinary -- of a person of ordinary skill in the art of the  
 05:47 25 '431 patent. Do you remember that?  
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1 looking for 158.  
 2 THE COURT: That's the '113 patent of Lucero.  
 3 MR. DINER: We're okay with that, Your Honor.  
 4 THE COURT: Okay. So these two exhibits will be  
 05:25 5 received into evidence. JTX158 and JTX207.  
 6 (DEFENDANT EXHIBITS JTX158 and JTX207 WERE RECEIVED IN  
 7 EVIDENCE)  
 8 THE COURT: And I have no further questions and I  
 9 thank you for your testimony.  
 05:25 10 THE WITNESS: Thank you.  
 11 THE COURT: You may step down.  
 12 MR. DINER: Your Honor, could we just have a few  
 13 minutes' break to reorganize here?  
 14 THE COURT: Sure. Okay. Let's take a ten-minute  
 05:26 15 break.  
 16 (RECESS TAKEN; 2:42 p.m.)  
 17 THE COURT: You can be seated, please.  
 18 Mr. Hasford?  
 19 MR. HASFORD: Yes, your Honor. Plaintiffs call  
 05:45 20 Dr. Robert O. Williams, III.  
 21 THE COURT: Okay, Dr. Williams, please come to the  
 22 witness stand. And, Dr. Williams, I remind you that you are  
 23 still under oath and so your testimony will be given under  
 24 oath. Okay?  
 05:45 25 THE WITNESS: Yes, sir. Thank you.  
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1 A. **Yes.**  
 2 Q. Have you heard any testimony from Dr. Lawrence that has  
 3 changed your opinion in any way with respect to the level of  
 4 education and work experience of a person of ordinary skill in  
 05:47 5 the art of the '431 patent?  
 6 A. **No, I have not.**  
 7 Q. Did you hear Dr. Lawrence testify that your proposed  
 8 definition of a person of ordinary skill in the art, in her  
 9 words, excludes a pharmaceutical formulator?  
 05:47 10 A. **Yes.**  
 11 Q. Do you agree with Dr. Lawrence?  
 12 A. **I do not.**  
 13 Q. How, if at all, does your proposed definition of a person  
 14 of ordinary skill in the art of the '431 patent encompass a  
 05:48 15 pharmaceutical formulator?  
 16 A. **So, my definition, I have pharmaceutical chemistry, which**  
 17 **encompasses, in my opinion, and what I meant here, was a**  
 18 **formulator, in addition to -- I think she excluded**  
 19 **preformulation, but that's also included here as part of a**  
 05:48 20 **person of ordinary skill in the art as a formulation**  
 21 **scientist. So that's included in my definition.**  
 22 Q. How, if at all, does your use of the phrase  
 23 "pharmaceutical chemistry" within your proposed definition of  
 24 a person of ordinary skill in the art encompass a  
 05:48 25 pharmaceutical formulator?  
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1 A. Well, pharmaceutical chemistry is -- it encompasses or is  
2 encompassed by, it's really similar to pharmaceutical  
3 sciences. Some places actually grant a degree. My  
4 institution grants a degree in pharmaceutical sciences, some  
05:48 5 pharmaceutical chemistry. But my intent here is it is  
6 describing one and the same.

7 Q. Were you present in the courtroom when the Court asked  
8 Dr. Lawrence questions about the definition of a person of  
9 ordinary skill in the art?

05:49 10 A. Yeah, I was. Yes.

11 Q. Is it your opinion that a person of ordinary skill in the  
12 art of the '431 patent would need a Ph.D. degree?

13 A. Not necessarily, no.

14 Q. Why not?

05:49 15 A. Because, as I've defined it, a Bachelor's Degree with  
16 three to five years of work experience in this area, that, to  
17 me, that's a senior graduate student, so that's a Bachelor's  
18 in Science with -- towards the end of their graduate  
19 education, or it's a B.S. level pharmaceutical sciences person  
05:49 20 that gets hired into a company, undergoes training. I mean, I  
21 have hired these people and they can do this type of job.

22 They are persons of ordinary skill in the art.

23 I've also allowed for a Ph.D. When I state a  
24 comparable level of education and training, that could have a  
05:49 25 Ph.D. with maybe one year experience.

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1 art, and -- and over my 30 years of experience, I mean, it's  
2 not routine.

3 When you design a study, even with a known drug, you  
4 don't know the outcome, and so you design a study in order to  
05:51 5 try to figure out what a formulation would be and the factors  
6 that impact that formulation such as additives, so it is --  
7 it's not routine optimization at all, in my opinion.

8 Q. In your opinion, is drug formulation difficult and  
9 unpredictable?

05:52 10 A. From my experience, it is, yes.

11 Q. How, if at all, can a single modification to a  
12 pharmaceutical formulation change the properties of a  
13 formulation?

14 A. A single modification, either in the drug substance or  
05:52 15 one of the additives or a step in the manufacturing process  
16 could change the stability, either chemical or physical  
17 stability of that formulation, from my experience over the  
18 years.

19 Q. Could that potentially result in substantial changes in  
05:52 20 the properties of the formulation?

21 A. It could, yes.

22 Q. In your opinion, may individual formulation components  
23 interact with each other in unpredictable ways?

24 A. From my experience, they could, yes.

05:52 25 Q. How so?

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1 Q. And you have an alternative formulation of your level of  
2 ordinary skill in the art. Would you please explain that?

3 A. Yes. So what I meant here is -- by the alternative  
4 definition is the -- as has been discussed over the last  
05:50 5 couple of days, I mean, to me, one thing is notable, it's this  
6 development process is multi-disciplinary. And this  
7 hypothetical person of ordinary skill in the art, it's not  
8 just one background in solving a problem, as the '431 problem  
9 is solved. And so that's why I allow this alternative to also

05:50 10 be included, which is a person that is skilled in designing,  
11 evaluating and/or administering pharmaceutical formulations.

12 Q. And what is that obtained by?

13 A. That, for example, could be a degree in medicine, which  
14 would cover the clinical aspects.

05:51 15 Q. Did you hear Dr. Lawrence testify that for a person of  
16 ordinary skill in the art as of January 21st, 2003,  
17 pharmaceutical formulation development allegedly constituted  
18 routine optimization?

19 A. Yes.

05:51 20 Q. Do you agree with Dr. Lawrence?

21 A. I don't, no.

22 Q. Why do you disagree?

23 A. Because from my experience, it's the antithesis of  
24 routine optimization, even for a drug that is known by the  
05:51 25 person developing it, by the person of ordinary skill in the

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1 A. Well, so -- so, components, additives, could interact  
2 with the active drug substance or could interact with other  
3 additives in the formulation. From my experience, I have an  
4 example where -- or more than one example, but one most  
05:53 5 recently, where it was supposedly the same material as an  
6 inactive ingredient, but different vendors where it came from,  
7 and in one case, the drug degraded because of something to  
8 do -- we hadn't quite figured it out yet, but something to do  
9 with the vendor's manufacturing process for that particular  
05:53 10 additive, whereas the other additive, it's stable. So it can  
11 affect.

12 Q. Is it fair to say that these sorts of interactions may  
13 impact efficacy?

14 A. Well, if it causes drug degradation, then there is less  
05:53 15 drug, so -- and the end result could be less efficacy.

16 Q. Is it fair to say that these interactions may impact  
17 safety?

18 A. Well, if it causes a drug degradation and -- or an  
19 additive degradation that forms a degradation product in the  
05:53 20 dosage form, such that that degradation product poses a safety  
21 issue, then it could.

22 Q. Is it fair to say that these interactions may impact  
23 stability?

24 A. Definitely, they could impact stability. And one just  
05:54 25 has to design studies and figure that out as part of the

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1 formulation.

2 Q. Is fair to say that these interactions may impact

3 preservative efficacy of a formulation?

4 A. They could. If the interaction affects the -- the

05:54 5 chemical degradation of the preservative or the additive

6 somehow affects the preservative, it could affect the ability

7 of that formulation to pass a preservative efficacy test.

8 Q. How, if at all, does the selection of inactive

9 ingredients, including the amounts of those inactive

05:54 10 ingredients, involve trial and error?

11 A. Well, from my experience, when designing a formulation,

12 it -- it's -- I mean, we do it by statistical design where we

13 set up a study looking at the variables of additives and

14 processing and the active ingredient, and it -- and it is

05:55 15 trial and error. It -- in the end, it really is trial and

16 error.

17 Q. Is it fair to say that this process may also involve

18 failures and frustration?

19 A. From my experience, yes.

05:55 20 MS. HOLLAND: Your Honor, I have not objected yet,

21 these are -- all these questions are very leading.

22 MR. HASFORD: I disagree, your Honor. I think it's

23 just establishing some background here, and it's going to

24 opinions that Dr. Lawrence has offered that this is an

05:55 25 oversimplification and we're trying to fairly respond to

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1 various failures and frustrations. How, if at all, does

2 formulation of ophthalmic solutions involve trial and error,

3 failures and frustration?

4 A. So, like development of dosage forms, just generally,

05:57 5 these liquid solutions -- I mean, again, one has to design the

6 study in a very methodical way, with the additives, with the

7 processing, with the sterilization requirements on how it's

8 going to be sterilized, consider all of that in developing it.

9 So ...

05:57 10 Q. I would now like to discuss the references that

11 Dr. Lawrence has identified. But, first, let's briefly

12 discuss the '431 patent.

13 You testified previously this week about the claim

14 subject matter of the '431 patent. Do you remember that?

05:57 15 A. Yes.

16 Q. Have you heard any testimony by Dr. Lawrence that has

17 changed your opinions in any way with respect to the claim

18 subject matter of the '431 patent?

19 A. I didn't, no.

05:57 20 Q. Did you hear Dr. Lawrence testify about various

21 references in connection with the defendants' obviousness

22 arguments?

23 A. I did, yes.

24 Q. In your opinion, do any of these references, each alone

05:58 25 or in combination with the teachings of any other references

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1 those.

2 THE COURT: Well, be that as it may, refrain from

3 undue leading. All questions are to some extent leading, but

4 they cross the line where they supply the answer to the

05:55 5 witness.

6 BY MR. HASFORD:

7 Q. As of January 21st, 2003, in your opinion, did the

8 development of ophthalmic formulations in particular

9 constitute routine optimization to a person of ordinary skill

05:56 10 in the art?

11 A. They did not.

12 Q. Why not?

13 A. Because ophthalmic solution formulations, they had to be

14 sterile. There was -- in solution form, from my experience,

05:56 15 drugs, if they are going to degrade, they tend to degrade at a

16 faster rate. In solution, you have the effective pH. With

17 ophthalmic products, you have the issue of applying this

18 liquid onto the eye, so there is a patient comfort factor. So

19 it makes it, in my opinion, difficult.

05:56 20 Q. Does the residence time for the eyedrop also impact that

21 process or that consideration?

22 A. That's one of the considerations that a person of

23 ordinary skill in the art, in developing ophthalmic solution

24 formulations, would have to consider, yes.

05:56 25 Q. And earlier you testified about trial and error and

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1 Dr. Lawrence has identified during her testimony, teach the

2 claim subject matter of the '431 patent?

3 A. Not in my opinion, no.

4 Q. Let's now discuss the specific references Dr. Lawrence

05:58 5 has identified. Would you please turn to JTX-147 in your

6 binder and identify that document.

7 A. JTX [sic] is a copy of U.S. Patent 4,910,225. It's the

8 Ogawa '225 patent.

9 Q. If I refer to JTX-147 as the Ogawa '225 patent or Ogawa,

05:58 10 will you understand what I mean?

11 A. I will.

12 Q. Do you agree with how Dr. Lawrence has applied the Ogawa

13 '225 patent alone or in combination with any other reference

14 Dr. Lawrence has identified to Claims 6 and 20 of the '431

05:59 15 patent?

16 A. No, I don't.

17 Q. Let's explore the basis for your disagreement.

18 Is the Ogawa '225 patent directed to bromfenac

19 formulations?

05:59 20 A. It is, yes.

21 Q. Let me direct your attention to Column 3, Lines 7 through

22 15 of the Ogawa '225 patent.

23 A. Okay.

24 Q. Are you there?

05:59 25 A. I'm there, yes.

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1 Q. What does the passage at Column 3, Lines 7 through 15, of  
2 the Ogawa '225 patent disclose?  
3 A. So here, Ogawa discloses the fact that "the above  
4 compounds," so bromfenac compounds, "may be unstable when  
05:59 5 stored in an aqueous solution for a long period of time," and  
6 recognizes and -- by the stability and says, "and there are  
7 some problems in the stability of an aqueous solution  
8 containing the compounds. Therefore the inventors extensively  
9 investigated the stabilizing method in order to enhance the  
06:00 10 stability. As a result, unexpectedly, they have succeeded in  
11 stabilizing the solution by incorporating a water-soluble  
12 polymer and sulfite and adjusting the pH to about 6-9."  
13 Q. What specific water-soluble polymer was used in the  
14 formulations of the Ogawa '225 patent?  
06:00 15 A. That is polyvinylpyrrolidone or povidone.  
16 Q. What particular sulfite was used in the formulations of  
17 the Ogawa '225 patent?  
18 A. That's sodium sulfite.  
19 Q. How, if at all, does the passage at Column 3, Lines 7  
06:00 20 through 15, of the Ogawa '225 patent indicate to a person of  
21 ordinary skill in the art that Ogawa addressed the issue of  
22 bromfenac's stability?  
23 A. So, a person of ordinary skill in the art would  
24 understand from this passage that Ogawa solved the bromfenac  
06:01 25 stability issue by incorporating this water-soluble polymer

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1 and a sulfite and having those two in combination with a pH  
2 between about 6 to 9.  
3 Q. Let me now direct your attention to Column 10 and, in  
4 particular, Example 6 of the Ogawa '225 patent.  
06:01 5 A. Okay.  
6 Q. What is described in the formulation of Example 6 of the  
7 Ogawa '225 patent?  
8 A. So, Example 6 describes an ophthalmic solution made  
9 according to Ogawa.  
06:01 10 Q. Does the formulation of Example 6 of the Ogawa '225  
11 patent include the bromfenac sodium salt?  
12 A. Yes, it does.  
13 Q. Does the formulation of Example 6 of the Ogawa '225  
14 patent contain polyvinylpyrrolidone?  
06:02 15 A. Yes, it does.  
16 Q. Does the formulation of Example 6 of the Ogawa '225  
17 patent also contain sodium sulfite?  
18 A. It does, yes.  
19 Q. What, if any, preservative does the formulation of  
06:02 20 Example 6 of the Ogawa '225 patent include?  
21 A. The preservative is benzalkonium chloride.  
22 Q. Let me now direct your attention toward the bottom of  
23 Column 10, in particular, to Lines 50 to 57 in Column 10 of  
24 the Ogawa '225 patent.  
06:02 25 A. Okay.

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1 Q. What does the passage in Column 10, Lines 50 to 57 of the  
2 Ogawa '225 patent disclose?  
3 A. So, in this passage, Ogawa is disclosing the results from  
4 including Experimental [sic] 6, and Ogawa states that in  
06:03 5 "(Table 11) are the residue and appearance of the compositions  
6 in Examples 6-8 after 4 weeks at 60° Centigrade."  
7 And then Ogawa states that, "As shown in Table 11, it  
8 was found that changes in appearances of the compositions were  
9 not observed at all, and the decomposition of the compound was  
06:03 10 not almost observed, the aqueous compositions being stable,  
11 excellent for a long period of time."  
12 Q. I believe in your previous answer you may have said  
13 "Experimental 6." Did you mean Example 6 of the Ogawa '225  
14 patent?  
06:03 15 A. Yeah, I did not mean experimental Example 6. I meant  
16 Example 6. Sorry.  
17 Q. Thank you, Doctor.  
18 Now let's take a look at Table 11 of the Ogawa '225  
19 patent. Let me direct your attention to Column 14, starting  
06:03 20 at Line 45 where Table 11 begins.  
21 A. Okay.  
22 Q. What is reported in Table 11 of the Ogawa '225 patent  
23 with respect to Example 6 of the Ogawa '225 patent?  
24 A. So, reported here in the second column is what Ogawa  
06:04 25 calls "Appearance." And then the third column is the

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1 "Residue" or it's the amount of bromfenac that's remaining  
2 after storage at 60 degrees C. for four weeks.  
3 Q. What amount is reported?  
4 A. 100.9 percent.  
06:04 5 Q. In the context of the Ogawa '225 patent, what does the  
6 concept of stability entail?  
7 A. In my opinion, one of ordinary skill in the art would  
8 understand Ogawa to be talking about chemical stability of  
9 bromfenac.  
06:04 10 Q. What do you mean by chemical stability?  
11 A. So, chemical, by chemical stability, I mean it's the  
12 formation -- so, Ogawa is storing under conditions of 60  
13 degrees C for four weeks, and then is measuring the remaining  
14 bromfenac that is being measured chemically. And so if the  
06:04 15 number decreases, then the bromfenac molecule is not there, it  
16 is degrading into some other degradation product that is being  
17 formed, which is not bromfenac.  
18 Q. Let's go back to --  
19 THE COURT: Excuse me. May I interrupt and ask a  
06:05 20 clarifying question?  
21 MR. HASFORD: Certainly.  
22 THE COURT: The residue as reported is 100.9 percent.  
23 How is it that residue can be greater than 100 percent? Does  
24 that mean that you're getting out more than you put in?  
06:05 25 THE WITNESS: I mean, typically, it -- so, there's

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1 variation in the experimental test. They're either using --  
 2 they're using, I think, some type of chromatography is what's  
 3 normally used, and so it could vary according to what they  
 4 call their standard, gold standard, if you will, or it could  
 06:05 5 be just variation around how it's made or --  
 6 THE COURT: Like an experimental artifact?  
 7 THE WITNESS: It's not an artifact. It's usually  
 8 just a variation with the method itself. There's a few  
 9 percent variation from my experience. You have to prepare  
 06:06 10 standards, and so the standards are made, they're actually  
 11 weighed out, either by weight or by volume, and so there's --  
 12 if you're a little high on the weight, a little bit low on the  
 13 volume, when you measure the actual percent, you could be off  
 14 a little bit from 100.  
 06:06 15 THE COURT: All right. Does it cause you to be  
 16 suspicious of the result that it ends up being more than 100  
 17 percent?  
 18 THE WITNESS: It does not, no.  
 19 THE COURT: Okay. Very well.  
 06:06 20 BY MR. HASFORD:  
 21 Q. Let's turn back to Example 6 of the Ogawa '225 patent in  
 22 column 10.  
 23 A. Okay.  
 24 Q. The formulation of Example 6 of the Ogawa '225 patent  
 06:06 25 also contains polysorbate 80. Do you see that?

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1 substituting polysorbate 80 with any other nonionic surfactant  
 2 would improve bromfenac's stability?  
 3 A. I don't think a person of ordinary skill in the art would  
 4 have an expectation one way or the other what the effect would  
 06:08 5 be.  
 6 Q. Does the Ogawa '225 patent teach the formation of an  
 7 insoluble complex or precipitate between bromfenac and  
 8 benzalkonium chloride?  
 9 A. In my opinion, one of skill in the art reading this Ogawa  
 06:08 10 patent would not understand that it's talking about physical  
 11 stability or -- I mean, I saw no -- nothing that would lead me  
 12 to think that there's a complex being formed.  
 13 Q. That leads me to my next question. Would a person of  
 14 ordinary skill in the art understanding the Ogawa '225 --  
 06:09 15 would a person of ordinary skill in the art -- let me try that  
 16 again.  
 17 Would a person of ordinary skill in the art understand  
 18 the Ogawa '225 patent to ascribe any physical stability  
 19 problem for formulations containing bromfenac and benzalkonium  
 06:09 20 chloride?  
 21 A. Not in my opinion, no.  
 22 Q. Looking back at Example 6 of the Ogawa '225 patent in  
 23 column 10, would a person of ordinary skill in the art have  
 24 been motivated, as of 2003, to modify the polysorbate 80  
 06:09 25 component of the formulation of Example 6 of the Ogawa '225

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1 A. Yes.  
 2 Q. What role, if any, does the Ogawa '225 patent ascribe to  
 3 polysorbate 80 in its formulations?  
 4 A. Well, the Ogawa patent doesn't ascribe any particular  
 06:06 5 role to polysorbate 80 in the patent.  
 6 Q. For what reason, if any, would polysorbate 80 have been  
 7 included in the formulations of the Ogawa '225 patent?  
 8 A. I think a person of ordinary skill in the art seeing this  
 9 formulation would think one reason could be as a wetting  
 06:07 10 agent. It is an ophthalmic solution drop that's going to be  
 11 applied onto a hydrophobic surface of the eye. So, it helps  
 12 wet and spread the liquid over the eye, so that it will keep  
 13 it in place so the drug can be absorbed.  
 14 Q. Why, if at all, does polysorbate 80 not solubilize  
 06:07 15 bromfenac sodium in the formulations of the Ogawa '225 patent?  
 16 A. Well, it doesn't solubilize polysorbate 80 because  
 17 bromfenac is, as you've heard over the last couple of days,  
 18 bromfenac is freely water soluble. So, it's already in  
 19 solution and polysorbate 80 is not playing a role in its  
 06:08 20 solubilization.  
 21 Q. Have defendants' experts offered any opinion  
 22 contradicting that bromfenac sodium is freely water soluble?  
 23 A. I have not heard any, no.  
 24 Q. Based on the Ogawa '225 patent, would a person of  
 06:08 25 ordinary skill in the art as of 2003 have expected that

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1 patent to improve bromfenac's chemical stability?  
 2 A. Not in my opinion, they would not have been motivated to  
 3 do that.  
 4 Q. Why not?  
 06:09 5 A. Because Ogawa -- one of skill in the art reading Ogawa  
 6 would understand that Ogawa has solved the bromfenac chemical  
 7 stability problem by incorporation of a water soluble polymer  
 8 and a sulfite and controlling the pH with those two  
 9 ingredients to between 6, about 6 and 9. And so they  
 06:10 10 understand that Ogawa characterizes that composition as being  
 11 stable for a long period of time. So, I just -- I don't think  
 12 one of ordinary skill in the art would understand a motivation  
 13 would be needed to improve upon the chemical stability of  
 14 bromfenac.  
 06:10 15 Q. Does the Ogawa '225 patent teach tyloxapol?  
 16 A. No, it doesn't.  
 17 Q. Let's now discuss the Sallmann '913 patent. Would you  
 18 please turn to JTX-071 in your binder and identify that  
 19 document.  
 06:10 20 A. So, JTX-071 is a copy of U.S. patent 5,891,913 to  
 21 Sallmann.  
 22 Q. If I refer to JTX-71 as Sallmann or the Sallmann '913  
 23 patent, will you understand what I mean?  
 24 A. Yes.  
 06:11 25 Q. Did you hear Dr. Lawrence testify regarding the Sallmann

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1 '913 patent?  
 2 A. I did, yes.  
 3 Q. Do you agree with how Dr. Lawrence has applied the  
 4 Sallmann '913 patent alone or in combination with any other  
 06:11 5 reference Dr. Lawrence has identified to claims 6 and 20 of  
 6 the '431 patent?  
 7 A. No, I don't.  
 8 Q. Let's discuss the basis for your opinion. First let me  
 9 direct your attention to column 1, lines 48 to 54 of the  
 06:11 10 Sallmann '913 patent.  
 11 A. Okay.  
 12 Q. What does the passage in column 1, lines 48 to 54 of the  
 13 Sallmann '913 patent disclose?  
 14 A. So, here Sallmann is disclosing, it states, surprisingly  
 06:12 15 it was found that the potassium salt -- and then there's a  
 16 chemical name which is diclofenac potassium -- is especially  
 17 suitable to treat inflammatory ocular processes in general.  
 18 It has been demonstrated that, for example, the ocular  
 19 penetration of diclofenac potassium is much superior in  
 06:12 20 comparison to the corresponding diclofenac sodium.  
 21 Q. What does the passage in column 1, lines 48 to 54 of the  
 22 Sallmann '913 patent, indicate to a person of ordinary skill  
 23 in the art?  
 24 A. So, in my opinion, a person of ordinary skill in the art  
 06:12 25 reading this would understand that a discovery has been made

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1 for a different salt, a potassium salt of diclofenac that had  
 2 superior properties in ocular penetration over that of the  
 3 sodium salt of diclofenac.  
 4 Q. Does the Sallmann '913 patent disclose bromfenac?  
 06:13 5 A. It does not, no.  
 6 Q. Let me now direct your attention to the passage in the  
 7 Sallmann '913 patent from column 4, line 52, through column 5,  
 8 line 2.  
 9 A. Okay.  
 06:13 10 Q. Does the Sallmann '913 patent teach the use of  
 11 solubilizers in the ophthalmic compositions of diclofenac  
 12 potassium?  
 13 A. It does, yes.  
 14 Q. Let me direct your attention in particular to column 4,  
 06:13 15 lines 65 to 67. What does the passage in column 4, lines 65  
 16 to 67 of the Sallmann '913 patent disclose?  
 17 A. So, here Sallmann is talking about solubilizers, and  
 18 Sallmann says another preferred solubilizer -- sorry, the  
 19 concentration used depends especially on the concentration of  
 06:14 20 the active ingredient. The amount added -- so the amount of  
 21 solubilizer added -- is typically sufficient to solubilize the  
 22 active ingredient.  
 23 Q. Why is the solubilizer included in the Sallmann '913  
 24 patent?  
 06:14 25 A. It's included to help dissolve the diclofenac potassium.

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1 Q. Why is the solubilizer, sir, needed in the formulations  
 2 of the Sallmann '913 patent to solubilize diclofenac  
 3 potassium?  
 4 A. Because diclofenac potassium, depending on pH, will  
 06:14 5 precipitate out, and so this would keep it solubilized in  
 6 solution.  
 7 Q. Is tyloxapol disclosed as a solubilizer in the Sallmann  
 8 '913 patent?  
 9 A. It is, yes.  
 06:14 10 Q. Are the Cremophor surfactants disclosed as solubilizers  
 11 in the Sallmann '913 patent?  
 12 A. There's two Cremophor examples that are listed as  
 13 especially preferred solubilizers in Sallmann.  
 14 Q. And I believe you answered my next question. Are the  
 06:15 15 Cremophor surfactants as opposed to tyloxapol disclosed as  
 16 especially preferred in the Sallmann '913 patent?  
 17 A. Yes, that's true.  
 18 Q. Let me direct your attention to column 4, lines 58  
 19 through 64 of that previous -- right above where you just  
 06:15 20 testified of the Sallmann '913 patent.  
 21 A. Okay.  
 22 Q. Why are the Cremophor surfactants especially preferred,  
 23 according to the Sallmann '913 patent?  
 24 A. So, Sallmann states here that the Cremophor, he lists two  
 06:15 25 different types of Cremophor solubilizers, are especially

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1 preferred because they are particularly good solubilizers that  
 2 are tolerated extremely well by the eye.  
 3 Q. According to the Sallmann '913 patent, is tyloxapol an  
 4 especially preferred solubilizer?  
 06:16 5 A. No. Sallmann states that tyloxapol is preferred.  
 6 Q. Let me direct your attention now to column 5, lines 55  
 7 through 69 of the Sallmann '913 patent.  
 8 A. Okay.  
 9 Q. Does the Sallmann '913 patent separately teach the use of  
 06:16 10 stabilizers in its ophthalmic compositions of diclofenac  
 11 potassium?  
 12 A. It does, yes.  
 13 Q. What stabilizers does the Sallmann '913 patent teach?  
 14 A. So, as stabilizers -- let me find that. Yeah,  
 06:16 15 stabilizers are listed there at line 56, and Sallmann states  
 16 stabilizers such as cyclodextrin, thiourea, thiosorbitol,  
 17 sodium dioctyl sulfosuccinate or monothioglycerol vitamin E  
 18 and vitamin E derivatives, such as vitamin E Tocopherol  
 19 Polyethylene Glycol 1000 Succinate, which is also referred to  
 06:17 20 as TPGS.  
 21 Q. How, if at all, are solubilizers and stabilizers taught  
 22 as separate excipients in the Sallmann '913 patent?  
 23 A. Well, they are taught as serving different functions.  
 24 Solubilizers are taught to be present to dissolve the drug,  
 06:17 25 and the stabilizers are there as serving a function as to

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- 1 stabilize against degradation.  
 2 Q. Let me direct your attention to column 5, line 39 through  
 3 40 of the Sallmann '913 patent. Let me know when you're  
 4 ready.  
 06:18 5 A. Oh, I'm ready. Sorry.  
 6 Q. Does the Sallmann '913 patent teach the use of  
 7 preservatives?  
 8 A. Yes, it does.  
 9 Q. What preservatives does the Sallmann '913 patent teach?  
 06:18 10 A. So, Sallmann lists as preserved preservatives cetrimide,  
 11 benzalkonium chloride, benzoxonium chloride, and parabens.  
 12 Q. Does the Sallmann '913 patent include any stability data?  
 13 A. No.  
 14 Q. Let's now turn to the Fu EP 984 reference. I believe  
 06:18 15 this one is going to be in the front flap of your binder. It  
 16 is JTX-209.  
 17 A. Okay.  
 18 Q. Would you please identify JTX-209.  
 19 A. Yes. JTX-209 is -- it's a European patent application  
 06:19 20 0 306 984.  
 21 Q. If I refer to JTX-209 as Fu or the Fu EP 984 reference,  
 22 will you understand what I mean?  
 23 A. I will.  
 24 Q. Did you hear Dr. Lawrence testify regarding the Fu EP 984  
 06:19 25 reference?

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- 1 A. So, in my opinion to a person of ordinary skill in the  
 2 art, the Fu reference is concerned with physical stability.  
 3 Q. And, in fact, let's take a look at the very first  
 4 sentence at the top of Example 5 of the Fu EP 984 reference.  
 06:21 5 Does the Fu EP 984 reference in Example 5 specifically call  
 6 out physical stability?  
 7 A. Yes, Fu Example 5 states physical stability of the  
 8 formulations of the present invention is measured, and then Fu  
 9 goes into detail about how he prepared the formulations.  
 06:21 10 Q. Does the physical stability in Fu look to whether the  
 11 formulation's physical appearance, whether it's clear or  
 12 turbid, changes over time?  
 13 A. That's what it's reporting, yes.  
 14 Q. Does the Fu EP 984 reference contain any chemical  
 06:22 15 stability data?  
 16 A. Not that I saw, no.  
 17 Q. What physical stability data, if any, does the Fu EP 984  
 18 reference provide for any other NSAID compound besides  
 19 ketorolac tromethamine?  
 06:22 20 A. There's none. There's only physical stability data with  
 21 ketorolac tromethamine.  
 22 Q. What physical stability data, if any, does the Fu EP 984  
 23 reference provide for any other octoxynol compound besides  
 24 octoxynol 40?  
 06:22 25 A. It doesn't provide any.

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- 1 A. I did, yes.  
 2 Q. Do you agree with how Dr. Lawrence has applied the Fu EP  
 3 984 reference alone or in combination with any other reference  
 4 Dr. Lawrence has identified to the asserted claims of the '431  
 06:19 5 patent?  
 6 A. I don't agree with Dr. Lawrence.  
 7 Q. Generally speaking, to what nonsteroidal antiinflammatory  
 8 drug is the Fu EP 984 reference directed?  
 9 A. Fu has data on ketorolac tromethamine.  
 06:20 10 Q. Let me direct your attention to page 9 of the Fu EP 984  
 11 reference and in particular Example 5.  
 12 A. Okay.  
 13 Q. What is disclosed in Example 5 of the Fu EP 984  
 14 reference?  
 06:20 15 A. So, in Example 5 Fu discloses formulations that are made  
 16 with either octoxynol 40, Tween 80 or Myrj 52. And then Fu  
 17 stores these formulations for different periods of time and at  
 18 different temperatures and then makes an observation as to  
 19 whether there is the presence of a either physically clear  
 06:20 20 solution or a precipitant of something.  
 21 Q. Do the formulations of Example 5 of the Fu EP 984  
 22 reference contain ketorolac tromethamine?  
 23 A. Yes.  
 24 Q. In the context of the Fu EP 984 reference, what does the  
 06:21 25 concept of stability entail?

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- 1 Q. What, if anything, does the Fu EP 984 reference teach  
 2 regarding ketorolac's chemical stability?  
 3 A. There's -- Fu does not teach the chemical stability of  
 4 ketorolac.  
 06:22 5 Q. Does the Fu EP 984 reference disclose any bromfenac  
 6 formulation?  
 7 A. No, it doesn't.  
 8 Q. Does the Fu EP 984 reference disclose any formulation  
 9 containing tyloxapol?  
 06:23 10 A. No, it does not.  
 11 Q. How does the concept of stability disclosed in the Fu EP  
 12 984 reference differ from the concept of stability disclosed  
 13 in the Ogawa '225 patent?  
 14 A. So, the concept of stability in the Fu reference, one of  
 06:23 15 ordinary skill in the art would understand its physical  
 16 stability by, as I explained, it's looking for presence of  
 17 clear or turbid formulation, whereas the Ogawa reference, one  
 18 of ordinary skill in the art would understand that is  
 19 disclosing chemical stability of bromfenac.  
 06:23 20 Q. Would you please turn in your binder to JTX-157 and  
 21 identify this document.  
 22 A. JTX-157 is a copy of U.S. patent 5,110,493.  
 23 Q. Have you considered JTX-157 in connection with your  
 24 opinions in this case?  
 06:24 25 A. Yes, I have.

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1 Q. Do you understand that JTX-157 is a U.S. counterpart to  
2 the Fu EP 984 reference?

3 A. **That's my understanding, yes.**

06:24 4 Q. Did you see anything in JTX-157 that changed any of your  
5 opinions regarding the Fu EP 984 reference?

6 A. **I did not, no.**

7 Q. Let's now discuss Dr. Lawrence's obviousness opinions.

8 MR. HASFORD: I note the time, your Honor. I'm going  
9 to be going into a new area here, her overall obviousness  
06:25 10 opinions. Would your Honor like me to proceed, or is it  
11 getting about time to wrap up for the day?

12 THE COURT: Well, I guess before you get into a new  
13 area, then this might be a good time to stop.

14 MR. HASFORD: Thank you, your Honor.

06:25 15 THE COURT: Okay. Thank you. You can step down, and  
16 then we will resume on Monday morning at 9:30.

17 Just a couple of housekeeping matters. I'm going to  
18 enter an order in a couple of minutes pertaining to the  
19 discovery appeal, and I'll enter an order that pertains to the  
06:25 20 three motions in limine, and with regard to all four matters I  
21 still have to put a more extended oral opinion on the record,  
22 and, unfortunately, time is up for today, but I will attend to  
23 that when we resume on Monday.

24 Are there any questions or any logistics that need to  
06:26 25 be handled over this recess?

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1 MR. HASFORD: None from plaintiffs, your Honor.

2 MS. HOLLAND: No, your Honor.

3 MR. MUKERJEE: No, your Honor.

4 THE COURT: You're a happy kingdom?

06:26 5 MR. HASFORD: We certainly are, your Honor.

6 THE COURT: Well, that's great.

7 MR. DINER: A happy ion.

8 THE COURT: Good. All right. Then thank you,

9 everybody, and we will resume on Monday.

06:26 10 (Proceedings concluded at 3:42 p.m.)

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		<p><b>JAMES</b> [1] - 533:1</p> <p><b>james.abe@alston.com</b> [1] - 533:4</p> <p><b>January</b> [3] - 654:10, 669:16, 673:7</p> <p><b>JANUSZ</b> [1] - 533:6</p> <p><b>Japan</b> [1] - 540:14</p> <p><b>JBS/KMW</b> [6] - 528:6, 528:13, 529:4, 529:11, 529:18, 530:4, 530:11, 530:18</p> <p><b>JEROME</b> [1] - 528:20</p> <p><b>JERSEY</b> [1] - 528:1</p> <p><b>Jersey</b> [4] - 528:18, 531:3, 531:17, 533:13</p> <p><b>JESSICA</b> [1] - 531:12</p> <p><b>jessica.lebis@finnegan.com</b> [1] - 531:14</p> <p><b>JITENDRA</b> [1] - 532:18</p> <p><b>jitendra.malik@alston.com</b> [1] - 532:21</p> <p><b>job</b> [1] - 668:21</p> <p><b>joe.janusz@alston.com</b> [1] - 533:9</p> <p><b>John</b> [1] - 528:17</p> <p><b>join</b> [1] - 619:25</p> <p><b>JOSEPH</b> [1] - 533:6</p> <p><b>JTX</b> [1] - 675:7</p> <p><b>JTX-001</b> [1] - 600:4</p> <p><b>JTX-043</b> [2] - 589:14, 600:4</p> <p><b>JTX-057</b> [2] - 590:23, 600:5</p> <p><b>JTX-071</b> [3] - 600:4, 683:18, 683:20</p> <p><b>JTX-147</b> [5] - 600:4, 608:19, 608:21, 675:5, 675:9</p> <p><b>JTX-157</b> [5] - 691:20, 691:22, 691:23, 692:1, 692:4</p> <p><b>JTX-158</b> [1] - 641:13</p> <p><b>JTX-199</b> [1] - 554:6</p> <p><b>JTX-207</b> [2] - 639:25, 640:11</p> <p><b>JTX-207.4</b> [1] - 640:12</p> <p><b>JTX-209</b> [7] - 600:4, 617:8, 617:12, 688:16, 688:18, 688:19, 688:21</p> <p><b>JTX-210</b> [5] - 540:12, 540:16, 540:20, 541:6, 600:4</p> <p><b>JTX-26</b> [1] - 646:1</p> <p><b>JTX-43</b> [2] - 628:8, 628:11</p> <p><b>JTX-57</b> [1] - 626:11</p> <p><b>JTX-61</b> [3] - 638:14, 639:1, 640:5</p> <p><b>JTX-71</b> [1] - 683:22</p> <p><b>JTX001</b> [1] - 664:9</p> <p><b>JTX043</b> [3] - 534:10, 664:14, 664:20</p> <p><b>JTX057</b> [3] - 534:10, 664:14, 664:20</p>

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1 UNITED STATES DISTRICT COURT  
2 FOR THE DISTRICT OF NEW JERSEY

3  
4 SENJU PHARMACEUTICAL CO., LTD.,  
5 BAUSCH & LOMB, INC., BAUSCH AND  
6 LOMB PHARMA HOLDINGS CORP.,

7 Plaintiff, CIVIL ACTION NUMBER:  
8 -vs- 14-667 (JBS/KMW)

9 LUPIN LTD., LUPIN  
10 PHARMACEUTICALS, INC.,

11 Defendants.

12 SENJU PHARMACEUTICAL CO., LTD.,  
13 BAUSCH & LOMB, INC., BAUSCH AND  
14 LOMB PHARMA HOLDINGS CORP.,

15 Plaintiff, CIVIL ACTION NUMBER:  
16 -vs- 14-4149 (JBS/KMW)

17 LUPIN LTD., LUPIN  
18 PHARMACEUTICALS, INC.,

19 Defendants.

20 Mitchell N. Cohen United States Courthouse  
21 One John F. Gerry Plaza  
22 Camden, New Jersey 08101  
23 Monday, April 11, 2016

24 **B E F O R E:** THE HONORABLE JEROME B. SIMANDLE  
25 CHIEF JUDGE  
UNITED STATES DISTRICT JUDGE

26 Certified as true and correct as required by Title 28, U.S.C.,  
27 Section 753.  
28 /s/ Lisa Marcus, CCR, CRR, /s/ Karen Friedlander, CCR, CRR,  
29 /s/ Carol Farrell, CCR, CRR

United States District Court  
Camden, New Jersey

1 SENJU PHARMACEUTICAL CO., LTD.,  
2 BAUSCH & LOMB, INC., BAUSCH AND  
3 LOMB PHARMA HOLDINGS CORP.,

4 Plaintiff, CIVIL ACTION NUMBER:  
5 -vs- 15-335 (JBS/KMW)

6 LUPIN LTD., LUPIN  
7 PHARMACEUTICALS, INC.,

8 Defendants.

9 SENJU PHARMACEUTICAL CO., LTD.,  
10 BAUSCH & LOMB, INC., BAUSCH AND  
11 LOMB PHARMA HOLDINGS CORP.,

12 Plaintiff, CIVIL ACTION NUMBER:  
13 -vs- 14-6893 (JBS/KMW)

14 INNOPHARMA LICENSING, INC., et  
15 al.,

16 Defendants.

17 SENJU PHARMACEUTICAL CO., LTD.,  
18 BAUSCH & LOMB, INC., BAUSCH AND  
19 LOMB PHARMA HOLDINGS CORP.,

20 Plaintiff, CIVIL ACTION NUMBER:  
21 -vs- 15-3240 (JBS/KMW)

22 INNOPHARMA LICENSING, INC.,

23 Defendants.

United States District Court  
Camden, New Jersey

1 SENJU PHARMACEUTICAL CO., LTD.,  
2 BAUSCH & LOMB, INC., BAUSCH AND  
3 LOMB PHARMA HOLDINGS CORP.,

4 Plaintiff, CIVIL ACTION NUMBER:  
5 -vs- 14-5144 (JBS/KMW)

6 LUPIN LTD., LUPIN  
7 PHARMACEUTICALS, INC.,

8 Defendants.

9 SENJU PHARMACEUTICAL CO., LTD.,  
10 BAUSCH & LOMB, INC., BAUSCH AND  
11 LOMB PHARMA HOLDINGS CORP.,

12 Plaintiff, CIVIL ACTION NUMBER:  
13 -vs- 15-335 (JBS/KMW)

14 LUPIN LTD., LUPIN  
15 PHARMACEUTICALS, INC.,

16 Defendants.

17 SENJU PHARMACEUTICAL CO., LTD.,  
18 BAUSCH & LOMB, INC., BAUSCH AND  
19 LOMB PHARMA HOLDINGS CORP.,

20 Plaintiff, CIVIL ACTION NUMBER:  
21 -vs- 14-5144 (JBS/KMW)

22 LUPIN LTD., LUPIN  
23 PHARMACEUTICALS, INC.,

24 Defendants.

United States District Court  
Camden, New Jersey

1 **APPEARANCES:**

2 PEPPER HAMILTON LLP  
3 BY: MELISSA A. CHUDEREWICZ, ESQUIRE  
4 301 Carnegie Center, Suite 400  
5 Princeton, New Jersey 08543  
6 (609) 452-0808  
7 chuderem@pepperlaw.com  
8 ATTORNEYS FOR PLAINTIFF

9 FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, LLP  
10 BY: BRYAN C. DINER, ESQUIRE  
11 JUSTIN J. HASFORD, ESQUIRE  
12 CHIAKI FUJIWARA, ESQUIRE  
13 901 New York Avenue, N.W.  
14 Washington, D.C. 20001-4413  
15 (202) 408-4000  
16 bryan.diner@finnegan.com, justin.hasford@finnegan.com,  
17 chiaki.fujiwara@finnegan.com  
18 ATTORNEYS FOR PLAINTIFF

19 FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, LLP  
20 BY: JESSICA M. LEBIS, ESQUIRE  
21 303 Peachtree Street, NE  
22 Atlanta, GA 30308-3263  
23 (404) 653-6400  
24 jessica.lebis@finnegan.com  
25 ATTORNEYS FOR PLAINTIFF

1 PATUNAS TARANTINO LLC  
2 BY: MICHAEL E. PATUNAS, ESQUIRE  
3 24 Commerce Street, Suite 505  
4 Newark, New Jersey 07102  
5 (973) 396-8740  
6 mpatunas@patunaslaw.com  
7 ATTORNEYS FOR DEFENDANT LUPIN, INC.

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1 GOODWIN PROCTER LLC  
 BY: ELIZABETH J. HOLLAND, ESQUIRE  
 2 NATASHA E. DAUGHTRY, ESQUIRE  
 3 SARAH FINK, ESQUIRE  
 4 SHAUN deLACY, ESQUIRE  
 DANIEL P. MARGOLIS, ESQUIRE  
 4 The New York Times Building  
 620 Eighth Avenue  
 5 New York, NY 10018  
 (212) 813-8800  
 6 eholland@goodwinprocter.com, ndaughtry@goodwinprocter.com,  
 sfink@goodwinprocter.com, sdelacy@goodwinprocter.com,  
 7 dmargolis@goodwinprocter.com  
 ATTORNEYS FOR DEFENDANT LUPIN, LTD.  
 8  
 9 GOODWIN PROCTER, LLP  
 BY: EMILY L. RAPALINO, ESQUIRE  
 53 State Street  
 10 Boston, MA 02109  
 (617) 570-1000  
 11 erapalino@goodwinprocter.com  
 ATTORNEYS FOR DEFENDANT LUPIN, LTD.  
 12  
 13 ALSTON & BIRD, LLP  
 BY: DEEPRO R. MUKERJEE, ESQUIRE  
 LANCE A. SODERSTROM, ESQUIRE  
 14 STEPHANIE ROBERTS, ESQUIRE  
 90 Park Avenue  
 15 New York, New York 10016  
 (212) 210-9400  
 16 deepro.mukerjee@alston.com, lance.soderstrom@alston.com,  
 stephanie.roberts@alston.com  
 17 ATTORNEYS FOR DEFENDANT INNOPHARMA LICENSING  
 18  
 19 ALSTON & BIRD, LLP  
 BY: JITENDRA MALIK, ESQUIRE  
 4721 Emperor Boulevard  
 Suite 400  
 20 Durham, NC 27703-8580  
 (919) 862-2200  
 21 jitendra.malik@alston.com  
 ATTORNEYS FOR DEFENDANT INNOPHARMA LICENSING  
 22  
 23  
 24  
 25

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1  
 2 ROBERT O. WILLIAMS, 727  
 3 DIRECT EXAMINATION OF ROBERT O. WILLIAMS 727  
 BY MR. HASFORD  
 4 VOIR DIRE EXAMINATION OF DR. WILLIAMS BY 789  
 MS. HOLLAND:  
 5 CONTINUED DIRECT EXAMINATION OF DR. 792  
 WILLIAMS BY MR. HASFORD:  
 6 CROSS-EXAMINATION OF ROBERT O. WILLIAMS BY 826  
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 7 REDIRECT EXAMINATION OF ROBERT O. 919  
 WILLIAMS, III BY MR. HASFORD:  
 8 RECROSS EXAMINATION OF ROBERT O. WILLIAMS, 927  
 III BY MS. HOLLAND:  
 9 WILLIAM B. TRATTLER 931  
 DIRECT EXAMINATION OF WILLIAM B. TRATTLER 931  
 BY MS. LEBEIS:  
 10  
 11 EXHIBITS PTX-294, PTX-268, PTX-272, 929  
 PTX-326, PTX-273, PTX-324, PTX-265,  
 12 PTX-591, PTX-592, PTX-593, JTX-144,  
 PTX-474, AND JTX-18 WERE RECEIVED IN  
 EVIDENCE  
 13  
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 18  
 19  
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 23  
 24  
 25

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1 ALSTON & BIRD, LLP  
 BY: HIDETADA JAMES ABE, ESQUIRE  
 2 333 South Hope Street  
 16th Floor  
 3 Los Angeles, CA 90071-3004  
 (213) 576-1000  
 4 james.abe@alston.com  
 ATTORNEYS FOR DEFENDANT LUPIN LIMITED  
 5  
 6 ALSTON & BIRD, LLP  
 BY: JOSEPH M. JANUSZ, ESQUIRE  
 7 Bank of America Plaza  
 Suite 4000  
 8 Charlotte, NC 28280-4000  
 (704) 444-1000  
 9 joe.janusz@alston.com  
 ATTORNEYS FOR DEFENDANT INNOPHARMA LICENSING  
 10  
 11 SAIBER, LLC  
 ARNOLD B. CALMANN, ESQUIRE  
 12 One Gateway Center  
 10th Floor, Suite 1000  
 13 Newark, New Jersey 07102  
 (973) 622-3333  
 14 abc@saiber.com  
 ATTORNEYS FOR DEFENDANT INNOPHARMA LICENSING  
 15  
 16  
 17  
 18  
 19  
 20  
 21  
 22  
 23  
 24  
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1 DEPUTY CLERK: All rise.  
 2 THE COURT: Be seated, please.  
 3 Good morning, everybody. Welcome back.  
 4 Are we ready to continue?  
 00:00 5 MR. HASFORD: Yes, your Honor, we're ready to resume  
 6 with Mr. Williams.  
 7 Dr. Williams.  
 8 THE COURT: Okay. So please resume the witness  
 9 stand.  
 00:00 10 MR. HASFORD: Permission to approach and pass out the  
 11 binders, your Honor?  
 12 THE COURT: Okay.  
 13 MR. HASFORD: Thank you.  
 14 THE COURT: Good morning, Dr. Williams.  
 00:00 15 THE WITNESS: Good morning, your Honor.  
 16 MR. HASFORD: And, your Honor, the demonstratives,  
 17 there's a copy of those in the front flap of that supplemental  
 18 binder.  
 19 THE COURT: Okay.  
 00:01 20 MR. HASFORD: May we proceed?  
 21 THE COURT: Yes.  
 22 HASFORD: Thank you.  
 23 (ROBERT O. WILLIAMS, HAVING BEEN PREVIOUSLY SWORN AS A  
 24 WITNESS, TESTIFIED AS FOLLOWS:)  
 25 (DIRECT EXAMINATION OF ROBERT O. WILLIAMS BY MR. HASFORD:)

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- 1 Q. Good morning, Dr. Williams.  
 2 A. Good morning.  
 3 Q. Let's discuss Dr. Lawrence's opinions.  
 4 Did you hear Dr. Lawrence opine that the subject matter  
 00:01 5 of Claim 6 and 20 of the '431 patent would have been obvious  
 6 to a person of ordinary skill in the art over various  
 7 references about which Dr. Lawrence testified?  
 8 A. I did, yes.  
 9 Q. Do you agree with Dr. Lawrence?  
 00:01 10 A. I do not.  
 11 Q. Let's start with Claim 6 of the '431 patent.  
 12 Did you hear Dr. Lawrence opine that the subject matter  
 13 of Claim 6 of the '431 patent would have been obvious to a  
 14 person of ordinary skill in the art based on the Ogawa '225  
 00:02 15 patent, the Fu EP 984 reference?  
 16 A. I heard that, yes.  
 17 Q. Do you agree with Dr. Lawrence's opinion?  
 18 A. I do not.  
 19 Q. Have you prepared a demonstrative summarizing where you  
 00:02 20 disagree with Dr. Lawrence?  
 21 A. I have.  
 22 Q. Let's take a look at PTX-4-1. Would you please explain  
 23 the basis for your disagreement with Dr. Lawrence?  
 24 A. Yes. So I've written Claim 6 in its independent form and  
 00:02 25 compared the limitations of Claim 6 to both the Ogawa

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- 1 concentration.  
 2 Q. Just to be clear, have defendants identified any prior  
 3 art whatsoever teaching the 0.2 weight per volume tyloxapoi  
 4 element of Claim 20 of the '431 patent?  
 00:04 5 A. Not that I've seen. No.  
 6 Q. With respect to Dr. Lawrence's obvious opinions, did you  
 7 hear Dr. Lawrence testify that a person of ordinary skill in  
 8 the art allegedly would have been motivated to modify the  
 9 Ogawa '225 patent in view of the Fu EP 984 reference?  
 00:04 10 A. I did, yes.  
 11 Q. Do you agree with Dr. Lawrence?  
 12 A. I do not.  
 13 Q. Let's discuss Dr. Lawrence's opinions in more detail.  
 14 First, let's discuss bromfenac.  
 00:04 15 Has Dr. Lawrence identified any reason why a person of  
 16 ordinary skill in the art would have been motivated as of 2003  
 17 to pursue a bromfenac ophthalmic solution over other  
 18 ophthalmic NSAID solutions?  
 19 A. She has not, in my opinion.  
 00:04 20 Q. Would you please turn in the binder to JTX-168 and  
 21 identify this document.  
 22 A. So this is -- JTX-168 is a copy of U.S. Patent 5,475,034.  
 23 Q. If I refer to JTX-168 as Yanni or the Yanni '034 patent,  
 24 will you understand what I mean?  
 00:05 25 A. Yes.

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- 1 patent -- the Ogawa patent and the FU application and, as you  
 2 can see here, neither Ogawa nor Fu teach tyloxapoi as a second  
 3 component at a concentration of .2 weight percent.  
 4 Q. Just to be clear, have defendants identified any prior  
 00:02 5 art whatsoever teaching the 0.02 weight per volume percent  
 6 tyloxapoi element of Claim 6 of the '431 patent?  
 7 A. I've not seen any, no.  
 8 Q. Let's now turn to Claim 20 of the '431 patent.  
 9 Did you hear Dr. Lawrence opine that the subject matter  
 00:03 10 of Claim 20 of the '431 patent would have been obvious to a  
 11 person of ordinary skill in the art based on the Ogawa '225  
 12 patent and the Fu EP 984 reference?  
 13 A. I did, yes.  
 14 Q. Do you agree with Dr. Lawrence's opinion?  
 00:03 15 A. I do not.  
 16 Q. Have you prepared a demonstrative summarizing why you  
 17 disagree with Dr. Lawrence?  
 18 A. I have, yes.  
 19 Q. Let's take a look at PDX4-2.  
 00:03 20 Would you please explain the basis for your  
 21 disagreement with Dr. Lawrence?  
 22 A. Yes. In a similar way I've written Claim 20 in its  
 23 independent form and I've compared Ogawa and Fu to the  
 24 limitations of Claim 20 and, as noted here, neither Ogawa nor  
 00:03 25 Fu teach tyloxapoi at a concentration of .02 weight percent

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- 1 Q. Let me direct your attention to Table 1 at Columns 15 and  
 2 16 of the Yanni '034 patent.  
 3 Did you hear Dr. Lawrence cite the Yanni '034 patent  
 4 and testify that a person of ordinary skill in the art  
 00:05 5 allegedly would have selected bromfenac over other  
 6 nonsteroidal anti-inflammatory drugs, including diclofenac,  
 7 because bromfenac is allegedly more effective as an  
 8 anti-inflammatory?  
 9 A. I heard that, yes.  
 00:05 10 Q. Do you agree with Dr. Lawrence?  
 11 A. I don't, no.  
 12 Q. Why do you disagree?  
 13 A. I disagree because Dr. Lawrence focused on the in vitro  
 14 column, which is the fourth column, and didn't -- I don't  
 00:06 15 think she considered appropriately the totality of the results  
 16 in Table 1.  
 17 Q. How, if at all, does the totality of the results in  
 18 Table 1 inform your opinion?  
 19 A. Well, I think a person of ordinary skill in the art  
 00:06 20 seeing the totality of the data wouldn't draw a preference to  
 21 bromfenac over other compounds that are mentioned. That would  
 22 include the ex -- the Column 4 ex vivo, the in vivo and the  
 23 in -- both in vivo columns so, again, considering the data in  
 24 its totality.  
 00:06 25 Q. Let me direct your attention to Column or Compound 8 in

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1 Table 1 of the Yanni '034 patent.  
2 Is it your understanding that Compound 8 in Table 1 of  
3 the Yanni '034 patent is nepafenac?  
4 A. Yes.  
00:06 5 Q. Is it your understanding that nepafenac is an amide group  
6 not a free carboxylic acid group?  
7 A. That's what it shows. If you substitute the Y, the NH<sub>2</sub>,  
8 for the Y substituent in the structure that's given in  
9 Table 1, that is an amide group.  
00:07 10 Q. Let me direct your attention to Column 1, Line 60,  
11 through Column 2, Line 1, of the Yanni '034 patent.  
12 What does Column 1, Line 60 through Column 2, Line 1,  
13 of the Yanni '034 patent disclose?  
14 A. So here Yanni discloses -- he's -- Yanni is stating that  
00:07 15 although benzoylphenylacetic acids are effective in  
16 suppressing ocular inflammation, their full anti-inflammatory  
17 potential has not yet been approached due to generally slow  
18 rate of penetration through the cornea. Yanni explains that  
19 because of this, relatively high concentrations of these drugs  
00:08 20 are often needed to achieve corneal penetration rates  
21 sufficient to provide effective intraocular drug  
22 concentrations. Yanni further says, such high drug  
23 concentrations are generally not desirable as they may provoke  
24 ocular irritation and discomfort.  
00:08 25 Q. The portion of the Yanni '034 patent that you just read  
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1 references benzoylphenylacetic acid. Is bromfenac a  
2 benzoylphenylacetic acid?  
3 A. Bromfenac is an example of a benzoylphenylacetic acid.  
4 Q. How, if at all, does Column 1, Line 60, through Column 2,  
00:08 5 Line 1, of the Yanni '034 patent support your disagreement  
6 with Dr. Lawrence?  
7 A. So this passage in Yanni supports my opinion that a  
8 person of ordinary skill in the art would not draw a  
9 preference to bromfenac over other compounds disclosed in the  
00:09 10 Yanni reference.  
11 Q. Let me direct your attention to Column 2, Lines 23  
12 through 29, of the Yanni '034 patent.  
13 What does Column 2, Lines 23 through 29, of the Yanni  
14 '034 patent disclose?  
00:09 15 A. So here Yanni states that it's known that  
16 3-benzoylphenylacetic acid derivatives are useful as topically  
17 administrable anti-inflammatory compounds for treating  
18 ophthalmic inflammation disorders. Yanni describes converting  
19 the free acetic acid functional group to ester or amide  
00:09 20 enhances compound stability by slowing the rate of lactam  
21 formation, so it slows the rate of degradation.  
22 Q. How, if at all, does Column 2, Line 23 through 29, of the  
23 Yanni '034 patent support your disagreement with Dr. Lawrence?  
24 A. This passage in Yanni supports my opinion that, again, a  
00:10 25 person of ordinary skill in the art would not draw a  
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1 preference to bromfenac as I think a person of ordinary skill  
2 in the art would be more directed to these derivatives, amide  
3 or ester derivatives.  
4 Q. And you mentioned ester or amide derivatives. Is an  
00:10 5 ester or amide derivative of the benzoylphenylacetic acid a  
6 different chemical compound from bromfenac?  
7 A. Yes, it is.  
8 Q. Let me direct your attention back to Column 2 and now in  
9 particular to Lines 29 through 35 under the summary of the  
00:10 10 invention of the Yanni '034 patent.  
11 What does Column 2, Lines 29 through 34, of the Yanni  
12 '034 patent disclose?  
13 A. So here Yanni is stating about the result, and he says,  
14 among other factors the present concentration is based on the  
00:11 15 finding that certain 3-benzoylphenylacetic acid derivatives  
16 would show no significant anti-inflammatory activity in vitro  
17 are, in fact, as active or even more active than the parent  
18 3-benzoylphenylacetic acids when administered topically to the  
19 eye.  
00:11 20 Q. How, if at all, does Column 2, Lines 29 through 35, of  
21 the Yanni '034 patent support your disagreement with  
22 Dr. Lawrence?  
23 A. So this passage in Yanni supports my opinion because  
24 Dr. Lawrence relied on the column of in vitro data in Table 1  
00:11 25 and this says clearly that the in vitro data did not show  
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1 significant anti-inflammatory activity. But, according then  
2 to the ex vivo and in vivo data, Yanni says that these  
3 derivatives are as active or even more active when actually  
4 administered topically to the eye.  
00:12 5 Q. When you refer to the ex vivo and in vivo data, are you  
6 referring to those data set forth in Table 1 of the Yanni '034  
7 patent?  
8 A. I am, yes.  
9 Q. Let's switch years a bit. Would you please turn in your  
00:12 10 binder to DTX-110 and identify this document?  
11 A. DTX-110 is a paper on bromfenac sodium that's written by  
12 Hara.  
13 Q. If I refer to DTX-110 as Hara or the Hara reference, will  
14 you understand what I mean?  
00:12 15 A. Yes.  
16 Q. Let me direct your attention to page 2 of the Hara  
17 reference, which bears Bates No. PROL 0079164, and in  
18 particular the right-hand column.  
19 Did you hear Dr. Lawrence cite the Hara reference and  
00:13 20 testify that a person of ordinary skill in the art would  
21 select bromfenac over other nonsteroidal anti-inflammatory  
22 drugs, including diclofenac, because bromfenac is allegedly  
23 more effective as an anti-inflammatory?  
24 A. I did, yes.  
00:13 25 Q. Do you agree with Dr. Lawrence?  
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1 A. I do not.  
 2 Q. Let's discuss the basis for your disagreement. Let me  
 3 direct your attention to the last paragraph in the right-hand  
 4 column on the page bearing Bates No. PROL 0079164 and in  
 00:13 5 particular to the first sentence of that paragraph.  
 6 What does this sentence of the Hara reference disclose?  
 7 A. So here Hara discloses that diclofenac sodium, in  
 8 parentheses, (Diclod) is an NSAID drug that is indicated for  
 9 use in treating anterior ocular segment inflammation following  
 00:13 10 cataract surgery. And Hara states that it, meaning diclofenac  
 11 sodium, shows particular efficacy in preventing the generation  
 12 of fibrin, with superior anti-inflammatory efficacy.  
 13 Q. How, if at all, does this portion of the Hara reference  
 14 support your disagreement with Dr. Lawrence?  
 00:14 15 A. This supports my opinion that a person of ordinary skill  
 16 in the art would not have a preference to bromfenac based on  
 17 the Hara reference because Hara states that diclofenac sodium  
 18 is an approved product and that it's characterized, diclofenac  
 19 sodium is characterized as having superior anti-inflammatory  
 00:14 20 efficacy.  
 21 Q. Would you now please turn in your supplemental binder to  
 22 PTX-294 and identify that document?  
 23 A. PTX-20094 is an excerpt article from the New York Times,  
 24 it's titled New Painkiller is Withdrawn After 4 Deaths.  
 00:15 25 Q. Is it your understanding that this New York Times  
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1 A. Based on this report and the knowledge of this, yes, they  
 2 would have.  
 3 Q. Are you aware that Dr. Lawrence has contended that to the  
 4 extent there was even any need for the claimed bromfenac  
 00:16 5 ophthalmic formulations claimed in the asserted claims of the  
 6 '431 patent that need would have been met by the Ogawa '225  
 7 patent and the Hara reference?  
 8 A. I understand that.  
 9 Q. Did Dr. Lawrence identify any reason why a person of  
 00:17 10 ordinary skill in the art would focus on developing a  
 11 bromfenac commercial formulation if the Ogawa '225 patent and  
 12 the Hara reference already had met any need for a bromfenac  
 13 ophthalmic formulation?  
 14 A. Not that I heard, no.  
 00:17 15 Q. Let's now discuss benzalkonium chloride.  
 16 Do you have any opinion as to whether safety issues  
 17 existed as of 2003 for benzalkonium chloride in ophthalmic  
 18 formulations?  
 19 A. I do have one, yes.  
 00:17 20 Q. What is your understanding of the safety issues that  
 21 existed as of 2003 for benzalkonium chloride in ophthalmic  
 22 formulations?  
 23 A. As of 2003, a person of ordinary skill in the art, a  
 24 formulator, would understand that there was reports of ocular  
 00:17 25 toxicity with benzalkonium chloride use, and so that was a  
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1 article, PTX-294, involves the drug Duract?  
 2 A. Yes.  
 3 Q. Have you considered PTX-294 in connection with your  
 4 opinions in this case?  
 00:15 5 A. I have, yes.  
 6 Q. What is Duract?  
 7 A. Duract is the oral form of bromfenac.  
 8 Q. Let me direct your attention to the first page of  
 9 PTX-294, which is bears Bates No. PROL 0080502. In particular  
 00:15 10 let me direct your attention to the first sentence of the  
 11 second paragraph. What does this portion of PTX-294 disclose?  
 12 A. So here it discusses the fact that the drug Duract, which  
 13 is a painkiller manufactured by Wyeth-Ayerst, has caused a  
 14 dozen cases of serious liver failure since it went on the  
 00:16 15 market last July. It says, four patients died and eight  
 16 required liver transplants.  
 17 Q. The article refers to last July, what is date of PTX-294?  
 18 A. The date is June 23, 1998.  
 19 Q. How, if at all, does the portion of PTX-294 that you just  
 00:16 20 testified about support your opinion regarding bromfenac?  
 21 A. Well, it supports my opinion that a person of ordinary  
 22 skill in the art would not have a preference for bromfenac.  
 23 Q. In fact, based on PTX-294, is it your opinion that a  
 24 person of ordinary skill in the art would have tended to shy  
 00:16 25 away from bromfenac?  
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1 known concern as of 2003.  
 2 Q. Have you prepared a demonstrative in support of your  
 3 opinion?  
 4 A. I have.  
 00:18 5 Q. Let me direct your attention to PDX4-3 on the screen,  
 6 would you please explain the basis for your opinion?  
 7 A. Yes. So the basis of my opinion is that regarding the  
 8 benzalkonium chloride toxicity, there was the Debbasch paper,  
 9 PTX-268, where it stated BAC, which is benzalkonium chloride,  
 00:18 10 causes epithelial toxicity and inflammatory infiltration of  
 11 ocular surface structures, including growth arrest and cell  
 12 death.  
 13 The Pisella paper, which is PTX-326, states  
 14 benzalkonium chloride inhibits proliferation of trabecular  
 00:18 15 cells, and therefore inflammatory reactions may be seen in  
 16 trabeculum.  
 17 And then the Madhu paper, which is PTX-293, it states,  
 18 BAK, which is also known as benzalkonium chloride, is known to  
 19 cause ocular irritation.  
 00:19 20 So those taken together support my opinion that to a  
 21 person of ordinary skill in the art as of 2003, that there  
 22 would have been concern using benzalkonium chloride as a  
 23 preservative in ophthalmic formulation process.  
 24 Q. In your opinion, based on the safety issues, would a  
 00:19 25 person of ordinary skill in the art have been motivated as of  
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1 2003 to remove benzalkonium chloride from aqueous liquid  
 2 preparations for ophthalmic use?  
 3 A. I think they would have, yes.  
 4 Q. How, if at all, does the information on PDX4-3 support  
 00:19 5 your opinion in this regard?  
 6 A. So these are examples of literature references that a  
 7 person of ordinary skill in the art would have known about and  
 8 therefore in formulating a new ophthalmic formulation they  
 9 would have been aware of this and they would have been  
 00:20 10 motivated to try alternative preservative systems or  
 11 preservative free system.  
 12 Q. And what alternatives are identified at the bottom of  
 13 PDX4-3?  
 14 A. So at the bottom here as alternatives to benzalkonium  
 00:20 15 chloride the Debbasch article, which is PTX-268, states, it is  
 16 therefore of striking importance to become aware of the  
 17 preservative toxicity in order to develop in the near future  
 18 many more unpreserved drugs, especially for long-term use  
 19 and/or for patients with pre-existing ocular surface  
 00:20 20 disorders.  
 21 And then the Noecker paper, which is PTX-272, states,  
 22 one such product, a brimonidine compound approved by the FDA  
 23 in March 2001, has replaced benzalkonium chloride with SOC,  
 24 SOC is an alternative preservative system, in the current  
 00:21 25 formulation. A 12-month clinical comparison in patients with  

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1 we'll move them into evidence, your Honor.  
 2 THE COURT: Okay. Very well.  
 3 BY MR. HASFORD:  
 4 Q. Now, let's discuss Dr. Lawrence's opinions regarding  
 00:22 5 benzalkonium chloride and NSAIDS in solution.  
 6 Did you hear Dr. Lawrence testify that based on the  
 7 carboxylic acid moiety of some NSAIDS solutions containing  
 8 benzalkonium chloride and NSAIDS allegedly were known in the  
 9 prior art to form insoluble complexes or precipitates that  
 00:22 10 result in cloudiness or turbidity?  
 11 A. I heard that, yes.  
 12 Q. Do you agree with Dr. Lawrence?  
 13 A. I don't, no.  
 14 Q. Why not?  
 00:23 15 A. Because as Dr. Davies testified last week, that the --  
 16 it's not --  
 17 MS. HOLLAND: I have an objection, your Honor. And  
 18 I'm not 100 percent sure what Dr. Williams is going to say,  
 19 however, Dr. Williams in his expert report didn't form his own  
 00:23 20 independent opinions on this issue, he relied on the  
 21 testimony, or I should say on the expert report of Dr. Davies.  
 22 So I think it would be inappropriate for Dr. Williams to  
 23 provide opinions that are merely based on reliance on  
 24 Dr. Davies versus his own personal expertise.  
 00:23 25 MR. HASFORD: And, your Honor, I believe that  

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1 glaucoma or ocular hypertension showed that bromindione-SOC  
 2 was well tolerated and produced a significantly lower  
 3 incidence of allergic conjunctivitis than brimonidine, as well  
 4 as equivalent IOP lowering efficacy.  
 00:21 5 MR. HASFORD: Your Honor, at this point, in the  
 6 interest of time, I'm happy to, if counsel has no objection,  
 7 to have Dr. Williams confirm that he obtained the information  
 8 on PDX4-3 from the four references cited there. However, if  
 9 there's an objection from counsel, I'm happy to have  
 00:21 10 Dr. Williams identify each of those references individually.  
 11 THE COURT: Are you seeking to move them into  
 12 evidence?  
 13 MR. HASFORD: Yes, I am.  
 14 THE COURT: Any objection to the four stated  
 00:22 15 references or do you wish to *voir dire*?  
 16 MS. HOLLAND: No. I guess Mr. Hasford's point is  
 17 that he doesn't want to go into each reference individually in  
 18 the binder but rather just rely on the testimony. I'm fine  
 19 with that.  
 00:22 20 MR. HASFORD: Okay.  
 21 MS. HOLLAND: No objection.  
 22 MR. HASFORD: Thank you.  
 23 THE COURT: Okay. Are they then moved into -- or are  
 24 you going to wait?  
 00:22 25 MR. HASFORD: I will wait till the end but, yes,  

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1 Dr. Williams is entitled to, as a formulator, to rely on the  
 2 expert testimony of a chemist that there was no evidence in  
 3 the art as of January 2003 that an insoluble complex or  
 4 precipitate between bromfenac and BAC formed.  
 00:23 5 THE COURT: Well, did Dr. Williams disclose that in  
 6 his expert report?  
 7 MR. HASFORD: Yes, he did, your Honor, in his  
 8 response report, Paragraph --  
 9 MS. HOLLAND: The point is Dr. Davies was already on  
 00:24 10 the stand, he gave those opinions. Dr. Williams doesn't have  
 11 a separate opinion on those issues, that's --  
 12 THE COURT: His opinion, as I understand it, he  
 13 relies on the expertise of the chemist in addressing this  
 14 issue of NSAIDS and turbidity, is that correct?  
 00:24 15 THE WITNESS: Yes, sir.  
 16 THE COURT: So I think it's a question of weight.  
 17 MS. HOLLAND: Okay.  
 18 THE COURT: I would assume that a formulator could  
 19 rely upon a chemist, and does, and here it was disclosed in  
 00:24 20 his expert report. So even though it's not his primary area  
 21 of expertise, he can derive the chemist's opinion and use it.  
 22 So I'll permit it.  
 23 MS. HOLLAND: Okay. Your Honor.  
 24 BY MR. HASFORD:  
 00:24 25 Q. Do you need the question repeated?  

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1 A. If you don't mind. Thank you.  
 2 Q. Certainly.  
 3 Did you hear Dr. Lawrence testify that based on the  
 4 carboxylic acid moiety of some NSAIDS solutions containing  
 00:24 5 benzalkonium chloride and NSAIDS allegedly were known in the  
 6 prior art to form insoluble complexes or precipitates that  
 7 result in cloudiness or turbidity?  
 8 A. I understood that, yes.  
 9 Q. Do you agree with Dr. Lawrence?  
 00:25 10 A. I don't.  
 11 Q. Why not?  
 12 A. Because as I heard Dr. Davies testify to last week, that  
 13 one of skill in the art can't predict whether a complex is  
 14 going to form or not, it depends upon the chemical structure  
 00:25 15 of the NSAID, he explained, depends on the formulation, the  
 16 level of ingredients in the formulation, so there's factors  
 17 that go into it as I understood Dr. Davies.  
 18 Q. Did you hear Dr. Lawrence testify that the prior art  
 19 teaches that a person of ordinary skill in the art allegedly  
 00:25 20 would have limited the formation of insoluble complexes or  
 21 precipitates between benzalkonium chloride and an acidic NSAID  
 22 by the inclusion of certain nonionic surfactant?  
 23 A. I heard that, yes.  
 24 Q. Do you agree with Dr. Lawrence?  
 00:25 25 A. I do not.

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1 Q. Is it your understanding that Acular itself was approved  
 2 in 1992?  
 3 A. Yes.  
 4 Q. Let me direct your attention to, on the first page  
 00:27 5 bearing Bates No. PROL 0332429, to the second paragraph under  
 6 the chemical structure shown in the description section.  
 7 First, what nonionic surfactant is included in the  
 8 Acular formation?  
 9 A. So the nonionic surfactant is in the third line, it's  
 00:28 10 octoxynol 40.  
 11 Q. What preservative is included in the Acular formulation?  
 12 A. It states in the second line preservative is benzalkonium  
 13 chloride.  
 14 Q. To what does the PF designation in the name Acular PF  
 00:28 15 refer to?  
 16 A. PF refers to preservative free.  
 17 Q. Let me now direct your attention to the page bearing  
 18 Bates No. PROL 0332434 in the Acular PF section of the package  
 19 insert, in particular to the second paragraph under the  
 00:28 20 chemical structure shown in the description section.  
 21 Is benzalkonium chloride included in the Acular PF  
 22 formulation?  
 23 A. It's not, no.  
 24 MR. HASFORD: Noel, would you please now put up  
 00:29 25 DDX2-42 on the screen?

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1 Q. Why not?  
 2 A. Because in my opinion if such a complex did form -- was  
 3 proven to be formed, the formulation person would seek to  
 4 avoid that, they would replace the preservative, the  
 00:26 5 benzalkonium chloride, they would possibly formulate a  
 6 preservative free or potentially switch drugs to where the  
 7 drug doesn't have the chemical moiety that is causing the  
 8 complexation.  
 9 Q. Let's explore the basis for your opinion. Would you  
 00:26 10 please turn in your supplemental binder to PTX-324 and  
 11 identify that document.  
 12 A. PTX-324 is the label from Drugs at FDA for Acular  
 13 product.  
 14 Q. Let me direct your attention to the line entry for  
 00:26 15 original approval or tentative approval. When was Acular PF  
 16 approved by the FDA?  
 17 A. This states Acular Preservative Free or Acular PF was  
 18 originally approved November 3rd, 1997.  
 19 Q. Would you please now turn in the supplemental binder to  
 00:27 20 PTX-265 and identify that document.  
 21 A. PTX-265 is the label for Acular, so the approved label  
 22 for Acular.  
 23 Q. Is it your understanding that PTX-265 is also a combined  
 24 package insert for both Acular and Acular PF?  
 00:27 25 A. That's my understanding, yes.

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1 BY MR. HASFORD:  
 2 Q. Dr. Williams, did you hear Dr. Lawrence testify about the  
 3 Remington's reference using DDX2-42?  
 4 A. I did, yes.  
 00:29 5 Q. Let me direct your attention to the third call out with  
 6 the statement starting, given the alternative, did you hear  
 7 Dr. Lawrence testifying the Remington's reference allegedly  
 8 would have taught a person of ordinary skill in the art to use  
 9 a nonionic surfactant to avoid an alleged complex between an  
 00:29 10 NSAID and benzalkonium chloride?  
 11 MS. HOLLAND: Your Honor, I have an objection.  
 12 Dr. Williams doesn't talk about the Remington's reference in  
 13 his expert report.  
 14 MR. HASFORD: So, your Honor, Dr. Williams actually  
 00:29 15 was questioned about the Remington reference at two of his  
 16 depositions, one on February 25th and March 9th, so we believe  
 17 that that's a proper subject of his testimony here.  
 18 He also did submit a supplemental expert report in  
 19 which he stated he would reserve the right to rely on  
 00:29 20 statements that he made during his deposition of questions he  
 21 was asked, and he was certainly asked about the Remington's  
 22 reference. So there was, in fact, an exhibit of this portion  
 23 of the Remington's references was used at one of those  
 24 depositions.  
 00:30 25 Also, your Honor, I'd note that Remington's reference

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1 was relied upon by Dr. Lawrence in her reply expert report for  
2 the first time in the context in which Dr. Williams had no  
3 opportunity to respond because it was relied on in the reply  
4 and then she testified about it in their case in chief in this  
00:30 5 case.  
6 So we respectfully submit that Dr. Williams should have  
7 an opportunity to respond to it for all those reasons.  
8 MS. HOLLAND: I have a couple of responses to that,  
9 your Honor.  
00:30 10 First of all, to the extent it was in a reply report,  
11 Dr. Williams was fully able to testify about opinions at his  
12 deposition, he just didn't do that. When he was asked about  
13 Remington's at his deposition, he said he hadn't looked at it  
14 in forming his opinions in this case.  
00:30 15 Now, if that's the only testimony that's going to be  
16 elicited and it's consistent with his deposition, I'm fine  
17 with that. But to the extent there are new opinions now on  
18 the stand that could have been offered at the deposition in  
19 response to the questions, I have a serious objection.  
00:31 20 THE COURT: Well, he's heard the testimony of  
21 Dr. Lawrence, is he not permitted to look at the reference  
22 that she's used even for the first time and address it?  
23 MS. HOLLAND: I think he's not, your Honor, because  
24 Dr. Lawrence had it in her expert report, so to the extent he,  
00:31 25 Dr. Williams, had any comments to make about it, he had a  
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1 forum to do that but he didn't.  
2 THE COURT: Mr. Hasford said that was only in her  
3 very final report and that I guess this witness, Dr. Williams,  
4 didn't have a written report after that.  
00:31 5 MS. HOLLAND: He did, he had his deposition, your  
6 Honor, that was really my point. My point is at the  
7 deposition he already knew Dr. Lawrence's opinions about this  
8 reference and could have, when asked about the reference,  
9 given his opinions on those references. Instead he said, you  
00:32 10 know, I saw Dr. Lawrence talked about it, I didn't look at it  
11 before formulating my opinions, and he didn't offer his own  
12 opinions. He did have the opportunity to do that after the  
13 reply report.  
14 THE COURT: Okay. So Dr. Lawrence's opinion was of  
00:32 15 record before Dr. Williams was deposed.  
16 MS. HOLLAND: Yes.  
17 THE COURT: And at that time he said he had no  
18 opinion as to Remington?  
19 MS. HOLLAND: Yes.  
00:32 20 THE COURT: All right. I'll sustain the objection.  
21 BY MR. HASFORD:  
22 Q. Would you please turn to JTX-207 in your binder and  
23 identify this document.  
24 A. JTX-207 is a copy of WO 94-15597.  
00:32 25 Q. If I refer to JTX-207 as Wong or the Wong reference, will  
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1 you understand what I mean?  
2 A. Yes.  
3 Q. Have you considered the Wong reference in connection with  
4 your opinions in this case?  
00:33 5 A. I have, yes.  
6 Q. Let me direct your attention to Column 6, Line 11,  
7 through Column 7, Line 10, of the Wong reference. What does  
8 Column 6, Line 11, through Column 7, Line 10, of the Wong  
9 reference disclose?  
00:33 10 A. Here in Wong it discloses a study comparing lauralkonium  
11 chloride to benzalkonium chloride in a formulation that Wong  
12 refers to as Oculen formulations, and this contains the active  
13 ingredient sodium flurbiprofen, and Wong is describing the  
14 fact that lauralkonium chloride doesn't form a cloudy solution  
00:33 15 when studied under these conditions whereas benzalkonium  
16 chloride does form a cloudy solution.  
17 Q. Now, how, if at all, does Column 6, Line 11, through  
18 Column 7, Line 10, of the Wong reference support your opinion  
19 that the art as of 2003 talked routes for avoiding entirely  
00:34 20 the alleged complexation or precipitation problem that  
21 Dr. Lawrence has raised?  
22 A. So in my opinion a person of ordinary skill in the art  
23 considering Wong would understand that under these conditions  
24 tested, that there's an alternative to benzalkonium chloride  
00:34 25 and that is lauralkonium chloride as a preservative, that for  
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1 this drug sodium flurbiprofen did not cause a cloudy solution  
2 to be formed, so it's an alternative to try.  
3 Q. Please turn back in your binder to JTX-168, which is the  
4 Yanni '034 patent, and let me direct your attention to Column  
00:34 5 2, Lines 23 through 29. What derivatives of  
6 3-benzoylphenylacetic acids are taught in the '034 patent?  
7 A. Here Yanni states that it's ester and amide derivatives  
8 of the 3-benzoylphenylacetic acid.  
9 Q. Would an ester or amide derivative of a  
00:35 10 benzoylphenylacetic acid compound have a free carboxylic acid  
11 group?  
12 A. It would not, no.  
13 Q. Would ester or amide derivative of a benzoylphenylacetic  
14 acid compound without a free carboxylic acid group, have any  
00:35 15 alleged complexation or precipitation problem with  
16 benzalkonium chloride that Dr. Lawrence has raised?  
17 A. My understanding from Dr. Davies, it won't if that  
18 particular group is involved in the complexation.  
19 Q. How, if at all, does Column 2, Lines 23 through 29, of  
00:35 20 the Yanni '034 patent support your opinion that the art as of  
21 2003 talked routes for avoiding entirely the formulation of a  
22 potential precipitate or insoluble complex?  
23 A. So this teaches an alternative active ingredient that  
24 does not have a carboxylic acid group, namely, an amide or  
00:36 25 ester derivative that -- so one could -- one of skill in the  
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1 art will understand possibly using a derivative of these  
 2 acetic acid compounds.  
 3 Q. Based on the references we just discussed, as of 2003,  
 4 would a person of ordinary skill in the art have been able to  
 00:36 5 avoid entirely any potential precipitate of an insoluble  
 6 complex between benzalkonium chloride and an NSAID?  
 7 A. Well, to a person of ordinary skill in the art, there  
 8 would have been ways to try to avoid this complexation, as  
 9 I've discussed.  
 00:37 10 Q. Now let's discuss Dr. Lawrence's opinions regarding  
 11 reducing the alleged formation of an insoluble complex between  
 12 NSAIDs and benzalkonium chloride.  
 13 Did you hear Dr. Lawrence cite the Fu EP 984 reference  
 14 and testify that a person of ordinary skill in the art  
 00:37 15 allegedly would have substituted an ethoxylated octylphenol  
 16 compound for Polysorbate 80 in the formulation of Example 6 of  
 17 the Ogawa '225 patent?  
 18 A. Yes, I heard that.  
 19 Q. Do you agree with Dr. Lawrence?  
 00:37 20 A. No.  
 21 Q. Why not?  
 22 A. Because there's no motivation to substitute in a nonionic  
 23 surfactant into Ogawa Example 6. It's already stable. The  
 24 problem of bromfenac chemical stability has been solved by the  
 00:37 25 inclusion of polyvinylpyrrolidone and sodium sulfite in  
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1 Example 6.  
 2 Q. And you mentioned the chemical stability of the Ogawa  
 3 '225 patent's Example 6. Does the Fu EP 984 reference teach  
 4 physical stability rather than chemical stability?  
 00:38 5 A. The Fu reference is focused on physical stability.  
 6 Q. Did you hear Dr. Lawrence cite the Fu EP 984 reference  
 7 and testify that a person of ordinary skill in the art  
 8 allegedly would have substituted tyloxapal in particular for  
 9 Polysorbate 80 in the formulation of Example 6 of the Ogawa  
 00:38 10 '225 patent to create a more stable bromfenac formulation  
 11 without the formation of an insoluble complex?  
 12 A. I heard that, yes.  
 13 Q. Do you agree with Dr. Lawrence?  
 14 A. I do not.  
 00:38 15 Q. Why not?  
 16 A. Because tyloxapal is not taught in the Fu reference. Fu  
 17 teaches -- actually provides data on Octoxynol 40, which I  
 18 understand is chemically distinct from tyloxapal.  
 19 Q. Did you hear Dr. Lawrence also testify about Octoxynol 9?  
 00:38 20 A. I did.  
 21 Q. Does the Fu EP 984 reference provide any data for  
 22 Octoxynol 9?  
 23 A. It does not, no.  
 24 Q. Would you please turn in your binder to JTX-199 and  
 00:39 25 identify this document.  
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1 A. JTX-199 is the Schott reference.  
 2 Q. If I refer to JTX-199 as the Schott reference, will you  
 3 understand what I mean?  
 4 A. Yes.  
 00:39 5 Q. Let me direct your attention to Page 501 of the Schott  
 6 reference, and, in particular, to the "Conclusions" section,  
 7 and, specifically, to the first paragraph.  
 8 A. Okay.  
 9 Q. Did you hear Dr. Lawrence point to this portion of the  
 00:39 10 Schott reference and testify that tyloxapal allegedly was  
 11 considered a preferable surfactant to Octoxynol 9?  
 12 A. I did, yes.  
 13 Q. Do you agree with Dr. Lawrence?  
 14 A. No.  
 00:39 15 Q. Why not?  
 16 A. Because in the context of Schott, Schott is comparing  
 17 tyloxapal and Octoxynol 9 for, as it states here, stabilizing  
 18 emulsions, suspensions, ointments and foams, particularly at  
 19 the critical micelle concentration. And so Schott's context  
 00:40 20 is not providing chemical stability enhancement of the -- an  
 21 ophthalmic solution. It's about more physical stabilizing  
 22 these emulsions, suspensions, ointments and foams.  
 23 Q. How do the emulsions, suspensions, ointments and foams of  
 24 the Schott reference differ from solutions such as the claimed  
 00:40 25 aqueous liquid preparations of the '431 patent?  
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1 A. So, they're very different.  
 2 Emulsions are two liquids, two immiscible liquids, that  
 3 the -- there is a dispersed phase that has to be stabilized  
 4 such that the two immiscible phases do not separate on  
 00:40 5 stability.  
 6 Suspensions are known by persons of ordinary skill in  
 7 the art as being -- there is a solid particle that's being  
 8 carried in a -- a -- an external phase, and so it's not a  
 9 solution at all.  
 00:41 10 Ointments are oleaginous, typically don't contain  
 11 water, and there may be a drug dissolved or suspended in that  
 12 oleaginous base.  
 13 And then foams are -- it's air that's emulsified into  
 14 some kind of liquid phase to create a foam. So they are very  
 00:41 15 different than an aqueous solution.  
 16 Q. Let's now discuss Dr. Lawrence's opinions about nonionic  
 17 surfactants.  
 18 Did you hear Dr. Lawrence testify that a person of  
 19 ordinary skill in the art, as of 2003, would have looked only  
 00:41 20 to approved surfactants for use in ophthalmic formulations?  
 21 A. I heard that, yes.  
 22 Q. Do you agree with Dr. Lawrence?  
 23 A. I don't.  
 24 Q. Why not?  
 00:41 25 A. Because a person of ordinary skill in the art would  
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1 consider what's -- excipients or additives that are in  
2 approved products, but they wouldn't limit their choice to  
3 that.  
4 From my experience, a skilled person would seek to  
00:41 5 formulate a stable product, and if there is an ingredient, an  
6 additive that is not currently already in an approved product  
7 and it works for their product, then there is a way to -- to  
8 get that in an approved product with the FDA.  
9 Q. As of 2003, were many classes of surfactants known in the  
00:42 10 art?  
11 A. Yes.  
12 Q. And as of 2003, were large numbers of surfactants known  
13 within each of those classes?  
14 A. There was, yes.  
00:42 15 Q. Now let's discuss Dr. Lawrence's opinions regarding the  
16 specified amounts of tyloxapol, .02 weight per volume percent,  
17 in Claims 6 and 20 of the '431 patent.  
18 Did you hear Dr. Lawrence testify that it would have  
19 been obvious to use a concentration of 0.02 weight per volume  
00:42 20 percent tyloxapol?  
21 A. I did.  
22 Q. Do you agree with Dr. Lawrence?  
23 A. I do not.  
24 Q. Why not?  
00:42 25 A. Because there is nothing that I've seen that's been  
  
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1 presented by defendants that has shown .02 percent of  
2 tyloxapol that works for chemical stabilization.  
3 Q. Do any of the references cited by Dr. Lawrence teach that  
4 tyloxapol could chemically stabilize any NSAID?  
00:43 5 A. Not in my opinion, no.  
6 Q. Do any of the references cited by Dr. Lawrence teach 0.02  
7 weight per volume percent tyloxapol as claimed?  
8 A. Not in my opinion, no.  
9 Q. Please turn in your binder to the Sallmann '913 patent  
00:43 10 which is JTX-71, and let me direct your attention to Column 4,  
11 Line 65, through Column 5, Line 2.  
12 What does Column 4, Line 65, through Column 5, Line 2  
13 of the Sallmann '913 patent disclose?  
14 A. So, here Sallmann is -- again, Sallmann is about  
00:43 15 diclofenac potassium, and so in the context of diclofenac  
16 potassium, Sallmann states that the concentration used of  
17 these solubilizers, is the context here, "The concentration  
18 used depends especially on the concentration of the active  
19 ingredient. The amount added is typically sufficient to  
00:44 20 solubilize the active ingredient." Sallmann states that, "For  
21 example, the concentration of the solubilizer is from 0.1 to  
22 5000 times the concentration of the active ingredient."  
23 Q. How, if at all, does Column 4, Line 65, through Column 5,  
24 Line 2, of the Sallmann '913 patent support your disagreement  
00:44 25 with Dr. Lawrence?  
  
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1 A. So, this passage supports my opinion because this passage  
2 in Sallmann is -- is related to solubilization, so use of a  
3 solubilizer, and one of the examples is tyloxapol, and it's  
4 used to keep the diclofenac potassium dissolved in the -- in  
00:45 5 the vehicle, in the aqueous solution. It's not in the context  
6 of chemical stabilization.  
7 Q. Is the range disclosed in Column 4, Line 67, through  
8 Column 5, Line 2, of the Sallmann '913 patent specific to  
9 tyloxapol or general instead?  
00:45 10 A. That concentration is a general range for all of the  
11 listed solubilizers that are disclosed in that particular  
12 paragraph.  
13 Q. Let me direct your attention to Example 15 of the  
14 Sallmann '913 patent which is in Column 12. What does Example  
00:45 15 15 of the Sallmann '913 patent disclose?  
16 A. So, this Example 15 is a diclofenac potassium eyedrop,  
17 and it discloses two different formulations of that drug  
18 substance, and so it's specific to diclofenac potassium.  
19 Q. Did you hear Dr. Lawrence cite Example 15 of the Sallmann  
00:45 20 '913 patent and apply Example 15 to her obviousness opinions?  
21 A. Yes, I did.  
22 Q. Do you agree with Dr. Lawrence's reliance on Example 15  
23 of the Sallmann '913 patent in connection with her obviousness  
24 opinions?  
00:46 25 A. I did, yes.  
  
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1 Q. I'm sorry. Let me ask it again.  
2 Do you agree with Dr. Lawrence's reliance on Example 15  
3 of the Sallmann '913 patent in connection with her obviousness  
4 opinions?  
00:46 5 A. Sorry. I didn't hear the right question.  
6 Yes, I do not agree, no.  
7 Q. Why do you disagree with Dr. Lawrence?  
8 A. Because in the context of Sallmann, tyloxapol is used in  
9 order to solubilize diclofenac potassium, a different drug.  
00:46 10 It's not used in the context of chemical stabilization.  
11 Q. Please turn back in your binder to the Fu EP 984  
12 reference which is JTX-209, and let me direct your attention  
13 to Page 9, and, in particular, Example 5.  
14 Did you hear Dr. Lawrence point to the amount of  
00:46 15 Octoxynol 40 in Example 5 of the Fu EP 984 reference and  
16 testify that it allegedly teaches using tyloxapol at 0.02  
17 weight per volume percent, as claimed in the '431 patent?  
18 A. I heard that, yes.  
19 Q. Do you agree with Dr. Lawrence?  
00:47 20 A. I do not.  
21 Q. Why not?  
22 A. Because Octoxynol 40, it's a different entity than  
23 tyloxapol. So this teaches Octoxynol 40 at .02 percent, not  
24 tyloxapol.  
00:47 25 Q. Is it your understanding from Dr. Davies's testimony that  
  
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1 tyloxapol and Octoxynol 40 have different chemical structures  
 2 and different chemical properties?  
 3 MR. HASFORD: Objection, leading.  
 4 THE COURT: I'll permit it.  
 00:47 5 THE WITNESS: My understanding from Dr. Davies, his  
 6 testimony, is that Octoxynol 40 and tyloxapol are different  
 7 chemical structures.  
 8 BY MR. HASFORD:  
 9 Q. What drug is being tested in Example 5 of the Fu EP 984  
 00:47 10 reference?  
 11 A. **So, Fu in Example 5 is testing ketorolac tromethamine.**  
 12 Q. If the Fu EP 984 reference teaches the use of any  
 13 surfactant, what surfactant does it teach?  
 14 A. **Well, there is data actually for the surfactant Octoxynol**  
 00:48 15 **40.**  
 16 Q. And back to your previous answer regarding the drug. Is  
 17 ketorolac tromethamine a different drug than bromfenac sodium?  
 18 A. **Yes, it's a different drug.**  
 19 Q. Please turn to Page 4, Lines 8 to 18, of the Fu EP 984  
 00:48 20 reference.  
 21 Did you hear Dr. Lawrence cite Page 4, Lines 8 to 18,  
 22 of the Fu EP 984 reference and testify that it allegedly  
 23 teaches using tyloxapol at 0.02 weight per volume percent as  
 24 claimed in the '431 patent?  
 00:48 25 A. **I did.**

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1 FDA Inactive Ingredient Guide using demonstrative DDX2-55 in  
 2 connection with your obviousness positions?  
 3 A. **I did, yes.**  
 4 Q. Does DDX2-55 depict a portion of the FDA's Inactive  
 00:50 5 Ingredient Guide in DTX-196?  
 6 A. **It does, yes.**  
 7 Q. Do you agree with Dr. Lawrence's reliance on DTX-196 in  
 8 connection with her obviousness opinions?  
 9 MR. HASFORD: Objection again, your Honor. This is  
 00:50 10 another situation where Dr. Lawrence said at his deposition  
 11 that he hadn't even looked at this when he was forming his  
 12 opinions in this case.  
 13 THE COURT: You mean Dr. Williams said that?  
 14 MR. HASFORD: Did I say Dr. Lawrence? Sorry.  
 00:50 15 Dr. Williams. Thank you, your Honor.  
 16 And this is again, after all the expert reports were  
 17 in, I asked him whether he even researched what nonionic  
 18 surfactants were approved as of 2003, and he said no.  
 19 MS. HOLLAND: Well, again, your Honor, I think the  
 00:50 20 fact that they asked these questions at his deposition and the  
 21 fact that Dr. Lawrence was relying on this in her reply report  
 22 for the first time and then testifying about it in open court,  
 23 I think Dr. Williams is entitled to respond to what he heard  
 24 here in open court.  
 00:50 25 MR. HASFORD: Your Honor, what he heard in open court

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1 Q. Do you agree with Dr. Lawrence?  
 2 A. **No.**  
 3 Q. Why not?  
 4 A. **Because this is just a general table that gives wide**  
 00:48 5 **ranges for active -- active agent, for preservative, for**  
 6 **surfactant. It's not specific to any particular substance.**  
 7 **It's not specific to tyloxapol and bromfenac.**  
 8 Q. Did you hear Dr. Lawrence testify that a person of  
 9 ordinary skill in the art would have arrived at 0.02 weight  
 00:49 10 per volume percent tyloxapol through what she calls routine  
 11 optimization?  
 12 A. **I heard that, yes.**  
 13 Q. Do you agree with Dr. Lawrence?  
 14 A. **I don't.**  
 00:49 15 Q. Why not?  
 16 A. **Because there's nothing in this Fu reference that leads a**  
 17 **skilled person to think that tyloxapol is disclosed, for one,**  
 18 **or that tyloxapol would act to chemically stabilize because**  
 19 **the Fu reference is about physical stabilization. So, a**  
 00:49 20 **skilled person is not going to have a reasonable expectation**  
 21 **that tyloxapol is going to work one way or the other.**  
 22 MR. HASFORD: Noel, would you now please put up  
 23 DDX-2-55 on the screen.  
 24 BY MR. HASFORD:  
 00:49 25 Q. Dr. Williams, did you hear Dr. Lawrence testify about the

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1 is exactly what he had read in her expert report before his  
 2 deposition. When he was asked about this reference at his  
 3 deposition, he hadn't looked at it before. He hadn't looked  
 4 at it in forming his opinions. And if he had an opinion about  
 00:51 5 it, he knew what Dr. Lawrence's opinion was at the time of his  
 6 deposition, and that was the time to offer the opinion, and  
 7 it's the same exact situation that we brought up earlier.  
 8 MS. HOLLAND: Respectfully, your Honor, I mean he was  
 9 asked certain questions about it. I -- you know, I suspect  
 00:51 10 counsel would have objected, had he launched into a narrative  
 11 about everything he knows about the Inactive Ingredients  
 12 Guide. He certainly knows about --  
 13 THE COURT: But at least he would have been giving  
 14 notice that he has an opinion on this subject. Coming into  
 00:51 15 the trial, the defendants were entitled to believe that he had  
 16 no opinion on this subject. In other words, when asked about  
 17 this, he said he didn't know. And so I'll sustain the  
 18 objection for the same reasons as before.  
 19 Let me add, though, that if it's pursued on  
 00:51 20 cross-examination, then I might permit it on redirect because  
 21 on redirect, he's not required to blind himself to everything  
 22 that he's learned in the trial.  
 23 MS. HOLLAND: Thank you, your Honor.  
 24 BY MR. HASFORD:  
 00:52 25 Q. Let's now turn to secondary considerations of

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1 nonobviousness.

2 Please turn to JTX-147 in your binder, which is the

3 Ogawa '225 patent. Let me direct your attention to Example 6

4 of the Ogawa '225 patent which is at Column 10.

00:53 5 Are you aware that defendants have taken the position

6 that Example 6 of the Ogawa '225 patent is the closest prior

7 art?

8 A. Yes, I am.

9 Q. Did you hear Dr. Lawrence testify that boric acid, Borax,

00:53 10 disodium edetate, benzalkonium chloride, polyvinylpyrrolidone,

11 and sodium sulfite in the formulation of Example 6 of the

12 Ogawa '225 patent would not detrimentally affect its basic and

13 novel properties, including stability?

14 A. That's what I understood her to say.

00:53 15 Q. Let's take a look now at Table 1 of the '431 patent,

16 which is JTX-1 in your binder.

17 What are the components of Comparison Example 1 in

18 Table 1 of the '431 patent?

19 A. The components are the bromfenac sodium, boric acid,

00:54 20 benzalkonium chloride, Polysorbate 80, and purified water.

21 Q. How, if at all, do the other formulations in Experimental

22 Example 1 differ from the formulation of Comparison Example 1

23 of the '431 patent?

24 A. The other formulations differ in the type and amount of

00:54 25 surfactant, nonionic surfactant.

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1 What is described in Experimental Example 4 of the

2 Ogawa '225 patent?

3 A. So, in Experimental Example 4, Ogawa prepares a bromfenac

4 sodium formulation that contains the ingredients listed here,

00:56 5 Borax, sodium borate, sodium chloride, disodium edetate,

6 benzalkonium chloride, Polysorbate 80, and sterile purified

7 water.

8 Q. Let me now direct your attention to Columns 13 and 14,

9 and, in particular, to Table 8, which presents the results of

00:56 10 Experimental Example 4.

11 A. Okay.

12 Q. How, if at all, do the results of Table 8 of the Ogawa

13 '225 patent show that bromfenac degrades at a pH lower than 8?

14 A. So, Ogawa in Experimental Example 4 studied the solution

00:56 15 as a function of pH, four different pHs, and as shown here in

16 Table 8, it's -- he studied at pH 6, 7, 8, and 9. And after

17 three weeks' storage at 60 degrees Centigrade, the results at

18 pH 8 and 9 were roughly 98 and 99 percent respectively, but at

19 pH 7, after three weeks' storage under those conditions, the

00:57 20 remaining rate or residue percent of bromfenac sodium is only

21 54.2 percent. So this Ogawa is reporting that at pH 7 under

22 these conditions, bromfenac sodium chemically degrades.

23 Q. Please turn back to the '431 patent, and, in particular,

24 to Table 1, Experimental Example 1 in Column 7.

00:57 25 You testified earlier that the pH of the formulations

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1 Q. Otherwise, are they the same?

2 A. Yes, they are.

3 Q. What type of test results are disclosed in Table 1 of the

4 '431 patent?

00:54 5 A. The test results that are disclosed are chemical

6 stability results for bromfenac sodium, and it's given by

7 remaining rate as a percent.

8 Q. Does Comparison Example 1 in Experimental Example 1 of

9 the '431 patent reflect the closest prior art as defined by

00:54 10 defendants?

11 A. In my opinion, yes.

12 Q. Based on the Ogawa '225 patent, would a person of

13 ordinary skill in the art have expected that substituting

14 Polysorbate 80 with any other nonionic surfactant would impact

00:55 15 Bromfenac's chemical stability?

16 A. I don't believe they would have, no.

17 Q. Let me direct your attention again to Experimental

18 Example 1 of the '431 patent, and, in particular, to Table 1.

19 To what pH are the formulations of Experimental Example 1 of

00:55 20 the '431 patent adjusted?

21 A. So, the formulas that are made in Table 1 of Experimental

22 Example 1 are prepared at pH 7.

23 Q. Please turn back to JTX-147 in your binder, which is the

24 Ogawa '225 patent. Let me direct your attention to Column 8,

00:55 25 and, in particular, to Experimental Example 4.

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1 that are used in Experimental Example 1 of the '431 patent is

2 pH 7. Do you remember that?

3 A. Yes.

4 Q. What is the significance, if anything, of the fact that

00:58 5 the formulations that are used in Experimental Example 1 of

6 the '431 patent were formulated at pH 7?

7 A. To a skilled person understanding that bromfenac sodium

8 is not chemically stable, as stable at pH 7, they would

9 understand that to be a condition that may allow

00:58 10 differentiation between formulation experiments to be made at

11 a quicker -- quicker time frame.

12 Q. What storage conditions were used in Experimental Example

13 1 of the '431 patent?

14 A. The storage conditions are 60 degrees C., Centigrade, for

00:58 15 four weeks.

16 Q. What is the significance, if anything, of the use of

17 storage conditions of 60 degrees Celsius for four weeks in

18 Experimental Example 1 of the '431 patent?

19 A. So, that temperature and time would be understood by a

00:58 20 skilled person to be an accelerated stability test,

21 particularly the 60 degrees Centigrade. So, again, it allows

22 a skilled person to make a judgment, and it may be more

23 differentiating in a quicker time frame, to understand the

24 variables that are being studied.

00:59 25 Q. How, if at all, does the testing of the formulations of

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1 Experimental Example 1 of the '431 patent at pH 7 and at 60  
2 degrees Celsius for four weeks show the relative stabilization  
3 capacity of Polysorbate 80 and tyloxapol?  
4 A. So, in my opinion, a person of ordinary skill in the art,  
00:59 5 understanding the chemical degradation of bromfenac sodium at  
6 pH 7 and 60 degrees C. being accelerated temperature  
7 condition, that studying at that pH, pH 7, at 60 degrees C.  
8 for four weeks, would all allow the -- a judgment to be made  
9 in a quicker time frame, in order to differentiate between  
00:59 10 variables that are being studied and understand what the  
11 effect is on chemical stability of bromfenac sodium.  
12 Q. In your opinion, are the test conditions in Experimental  
13 Example 1 of the '431 patent considered stressed conditions?  
14 A. They are. Sometimes that's called accelerated stability  
01:00 15 conditions.  
16 Q. Do these stress conditions allow a person of ordinary  
17 skill in the art to observe the relative stabilization  
18 capacity of Polysorbate 80 and tyloxapol in Experimental  
19 Example 1 of the '431 patent?  
01:00 20 A. They do, yes.  
21 Q. In connection with your opinions in this case, have you  
22 considered summary charts of test data related to the '431  
23 patent to which defendants have stipulated?  
24 A. I have, yes.  
01:00 25 Q. Please turn to PTX-591 in your binder.  
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1 Is PTX-591 a summary chart of test data related to the  
2 '431 patent that you considered in connection with your  
3 opinions in this case?  
4 A. It is, yes.  
01:00 5 Q. Please turn now to PTX-592 in your binder.  
6 Is PTX-592 a summary chart of test data related to the  
7 '431 patent that you considered in connection with your  
8 opinions in this case?  
9 A. Yes, it is.  
01:01 10 Q. Please turn now to PTX-593 in your binder.  
11 Is PTX-593 a summary chart of test data related to the  
12 '431 patent that you considered in connection with your  
13 opinions in this case?  
14 A. Yes, it is.  
01:01 15 Q. Have you prepared a demonstrative that illustrates the  
16 unexpected chemical stabilizing effect of tyloxapol in  
17 bromfenac formulations of pH 7 using the data from PTX-591?  
18 A. I have, yes.  
19 Q. Let me direct your attention to PDX4-5 on the screen.  
01:01 20 Would you please explain what PDX4-5 illustrates?  
21 A. Yes. So what I've taken here is I've summarized the data  
22 on formulation.  
23 So there is -- across the top is the formulation code  
24 that was noted in the summary tables. A-20, A-21, A-27, A-28,  
01:02 25 and A-29.  
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1 In the second row, if there -- if it corresponds to a  
2 formula from Table 1 of Experimental Example 1 of the '431  
3 patent, I've noted that as well.  
4 And so, for example, Comparison Example 1 that's in  
01:02 5 Table 1 of the '431 patent is also called in the summary  
6 tables Formulation Code A-20. And, likewise, Formulation Code  
7 A-21 and A-27 are also referred to in Table 1 of the '431  
8 patent, and they're referred to as A-02 and A-03.  
9 And so what's reported here is, first of all, in the  
01:02 10 second column, is Comparison Example 1, Formulation Code A-20,  
11 which contains Polysorbate 80, and then in the next four  
12 columns, what's reported is then the same formulation, except  
13 tyloxapol as a nonionic surfactant, replaces Polysorbate 80  
14 and then tyloxapol is studied at four levels. And all of  
01:03 15 those -- all of these formulations are being studied when  
16 prepared at pH 7.  
17 Q. How, if at all, do the data in PTX-591 depicted on PDX4-5  
18 demonstrate that the tyloxapol containing formulations of  
19 bromfenac are superior in chemical stability as compared to  
01:03 20 the Polysorbate 80 containing formulations of bromfenac?  
21 A. So, what's shown in the column with the Formulation Code  
22 A-20 is a remaining rate or residual bromfenac of -- a percent  
23 of 51.27 percent. And then four different levels of tyloxapol  
24 are compared.  
01:04 25 First of all, there's .15 weight percent of tyloxapol  
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1 which is Formulation Code A-21. And when studied, that had a  
2 remaining rate of bromfenac sodium of 73.81 percent. So in a  
3 comparable level to Formulation Code A-20 that had .17 percent  
4 Polysorbate 80, you can see or a skilled person would  
01:04 5 understand that that change in nonionic surfactant improved  
6 the remaining rate of residual bromfenac about 44 percent,  
7 which is the difference between 51.27 percent and 73.81  
8 percent.  
9 In the next three columns, the .02 percent tyloxapol,  
01:05 10 which is Formulation Code A-27, that remaining rate was 89.64  
11 percent.  
12 And when .05 weight percent of tyloxapol is studied in  
13 Formulation Code A-28, that remaining rate is 85.96 percent.  
14 And then lastly, the .1 weight percent of tyloxapol as  
01:05 15 Formulation Code A-29, the remaining rate is 82.01 percent.  
16 And so what a skilled person would understand is that  
17 at the lowest amount of tyloxapol that was studied, the 0.02  
18 weight percent, that formulation had the highest amount of  
19 residual bromfenac.  
01:05 20 Q. How, if at all, are these superior chemical stability  
21 results of tyloxapol containing formulations of bromfenac, as  
22 shown in PTX-591 and on PDX4-5, unexpected to a person of  
23 ordinary skill in the art?  
24 A. Well, there is nothing in the literature that suggested  
01:06 25 tyloxapol would chemically stabilize a drug like bromfenac.  
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1 And this shows that the presence of tyloxapol does, in fact,  
 2 improve the chemical stability of bromfenac sodium in these  
 3 aqueous solutions.  
 4 Q. How, if at all, does the data in Formulation A-03 for the  
 01:06 5 composition containing 0.02 weight per volume percent  
 6 tyloxapol inform your opinion in this regard?  
 7 A. So in Formulation A-03, which corresponds to Formulation  
 8 Code A-27 in the summary table, again, a person of ordinary  
 9 skill in the art would not have expected tyloxapol to  
 01:06 10 chemically stabilize bromfenac sodium, would not have expected  
 11 it -- it wouldn't have known what level would have worked, if  
 12 it would have worked, and so at that low level, it seems a  
 13 surprise to me that -- or it was not known that it would have  
 14 done that.  
 01:07 15 Q. Do the results in Experimental Example 1 of the '431  
 16 patent show that Formulation A-03 containing 0.02 weight per  
 17 volume percent tyloxapol was 75 percent more stable under  
 18 these test conditions than the formulation of Comparison  
 19 Example 1?  
 01:07 20 A. It does. That's what I calculated, the difference  
 21 between the 51.27 percent and the 89.64 percent.  
 22 Q. Are you aware that Dr. Lawrence has taken the position  
 23 that the information provided in the '431 patent specification  
 24 is allegedly insufficient to make a determination of which  
 01:07 25 formulations show superior stability?

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1 A. Okay.  
 2 Q. Specifically, let me direct your attention to the last  
 3 paragraph, which spills over to the middle of the following  
 4 page. What does this portion of the prosecution history of  
 01:09 5 the '431 patent disclose?  
 6 A. So, in the "Reasons For Allowance" that are stated here,  
 7 the examiner is stating that "Applicants have found that  
 8 tyloxapol is not equivalent to Polysorbate 80 when combined  
 9 with bromfenac." And the inventor states, "The present  
 01:10 10 inventors have discovered that tyloxapol has an unexpected  
 11 property in stabilizing an aqueous solution of bromfenac in  
 12 comparison with Polysorbate 80." Then the examiner says,  
 13 "Please see the description of Experimental Example 1 and  
 14 Table 1 on Pages 14 through 16 of the specification." The  
 01:10 15 examiner states, "In the Experimental Example, the stability  
 16 of an aqueous solution of bromfenac was measured by storing  
 17 the bromfenac solution with Polysorbate 80" and then in  
 18 parentheses, "(see Comparison Example 1) and, separately, with  
 19 tyloxapol (see A-02), under conditions of pH 7 at 60 degrees  
 01:11 20 C. for four weeks."  
 21 And then the examiner reports the results of 51.3  
 22 percent of bromfenac remaining for the Polysorbate 80  
 23 solution, and in contrast, 73.8 percent of bromfenac remained  
 24 in aqueous solution with tyloxapol.  
 01:11 25 So the examiner states, "Thus the present inventors

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1 A. I understand that.  
 2 Q. Do you agree with Dr. Lawrence's opinion?  
 3 A. I don't, no.  
 4 Q. Why not?  
 01:07 5 A. Because in the patent, there is a direct comparison  
 6 between Polysorbate 80 and tyloxapol, each at .15 percent, and  
 7 you see a difference of 51.3 percent bromfenac sodium  
 8 remaining, with the Polysorbate 80 .15 percent, and one  
 9 observes in Table 1 for Formulation A-02, the remaining rate  
 01:08 10 is 73.8 percent, with .15 percent tyloxapol. So there is an  
 11 improvement.  
 12 Q. Does Table 1 of Experimental Example 1 of the  
 13 patents-in-suit show test results conducted against  
 14 Dr. Lawrence's admitted closest prior art?  
 01:08 15 A. Yes, it does.  
 16 Q. Does Table 1 of Experimental Example 1 of the '431 patent  
 17 show a direct comparison between a formulation containing  
 18 Polysorbate 80 and a formulation containing tyloxapol?  
 19 A. It does, as I've just explained.  
 01:08 20 Q. Let's now turn -- let's now turn to the prosecution  
 21 history of the 431 patent. In particular, let me direct your  
 22 attention to JTX-006A in your supplemental binder.  
 23 In PTX-6A, let me direct your attention to the  
 24 examiner's "Reasons For Allowance" of the '431 patent at the  
 01:09 25 page bearing Bates Number PROL 0000799.

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1 have found that tyloxapol has an unexpected stabilizing effect  
 2 on an aqueous solution of bromfenac in comparison to  
 3 Polysorbate 80."  
 4 Q. What did the examiner say in the next two sentences?  
 01:11 5 A. So then the examiner states that tyloxapol and  
 6 Polysorbate 80, that the inventors have found that those two  
 7 are not equivalent compounds, and the examiner states, "Such  
 8 unequivalency and such remarkable effects, could not have been  
 9 obvious to one skilled in the art from the cited references."  
 01:12 10 Q. And in the following sentence, what did the examiner  
 11 conclude?  
 12 A. So, in conclusion, the examiner states, "For the  
 13 foregoing reasons, it is respectfully submitted that the  
 14 teachings of the cited references do not suggest the claimed  
 01:12 15 bromfenac preparation as amended, nor the unexpected  
 16 properties of the preparation."  
 17 Q. How, if at all, does the prosecution history of the '431  
 18 patent support your opinion that a person of ordinary skill in  
 19 the art would not have arrived at 0.02 weight per volume  
 01:12 20 percent tyloxapol through routine optimization?  
 21 A. This supports my opinion because it wouldn't have been  
 22 known in the art, so a skilled person wouldn't have had an  
 23 expectation one way or the other if tyloxapol would have  
 24 chemically stabilized bromfenac or not in solution and at what  
 01:13 25 level.

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1 Q. Let's switch gears a bit.  
 2 Have you also prepared a demonstrative comparing the  
 3 chemical stability of tyloxapol-containing formulations of  
 4 bromfenac at a higher pH of 8.2 based on summary charts of  
 01:13 5 test data to which defendants have stipulated?  
 6 A. Yes, I have.  
 7 Q. Let me direct your attention to PDX4-6 on the screen  
 8 which cites to PTX-593. Would you please explain what PDX4-6  
 9 illustrates?  
 01:13 10 A. So, PTX-593 is a comparative table that I prepared that  
 11 has two formulations. One is Bronuck®, and it's -- the column  
 12 heading is "BF" and it says in parentheses, "(Bronuck)," and  
 13 the second column is labeled "A-01," in parentheses, "PE."  
 14 And these two formulations show that in the Bronuck®  
 01:13 15 formulation, it has the Polysorbate 80, and it has sodium  
 16 sulfite in it, which, according to Ogawa, solved the problem  
 17 of chemical stability.  
 18 And, as shown in pH 8.2, the residual amount of  
 19 bromfenac that remains, after storage at 60 degrees C. for  
 01:14 20 four weeks, is 91.45 percent.  
 21 The same formulation then that is prepared with  
 22 tyloxapol at .02 weight percent, and then not containing  
 23 Polysorbate 80 or sodium sulfite, the remaining rate is 93.61  
 24 percent when that Formulation A-01 was stored at 60 degrees C.  
 01:14 25 for four weeks.

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1 Q. How, if at all, does the pH test condition of 8.2 in the  
 2 bromfenac formulations shown on PDX4-6 differ from the pH  
 3 condition of 7 with respect to bromfenac?  
 4 A. So, a person of skill in the art would understand that  
 01:14 5 the rate of chemical degradation at pH 8.2 would be slower,  
 6 based on what Ogawa found, compared to pH 7. So it would  
 7 be -- so the conditions here would be such that the -- at  
 8 least from the pH, the drug would degrade at a slower rate.  
 9 Q. How, if at all, are the results illustrated in PDX4-6  
 01:15 10 unexpected to a person of ordinary skill in the art?  
 11 A. So, here, at A-01, that contains tyloxapol at .02 percent  
 12 and no sodium sulfite, the results were -- were -- I think a  
 13 person of ordinary skill in the art would understand those are  
 14 good results, and you didn't have to use the sodium sulfite  
 01:15 15 that Ogawa reported as solving the chemical stability problem  
 16 of bromfenac.  
 17 Q. Do the results set forth in PDX4-6 suggest the ability to  
 18 remove sodium sulfite from the formulation?  
 19 A. They do, yes.  
 01:15 20 Q. How, if at all, would it be beneficial to remove an  
 21 excipient such as sodium sulfite from an ophthalmic  
 22 formulation?  
 23 A. So, generally speaking, a skilled person in formulation,  
 24 as a formulation scientist, would understand that the least  
 01:16 25 number of excipients is more preferable. So, in other words,

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1 each excipient has to have a stated function, and if they  
 2 don't serve a function, then they should not be included. So  
 3 this would be a way to not have to include an additive.  
 4 Q. Let me direct your attention back to the Ogawa '225  
 01:16 5 patent, which is JTX-147 in your binder, and, in particular,  
 6 to Experimental Example 4 in Column 8.  
 7 Do you understand that defendants have argued that  
 8 there is allegedly no unexpected chemical stability effect of  
 9 tyloxapol because formulations of Experimental Example 4 of  
 01:16 10 the Ogawa '225 patent maintained a high level of residual  
 11 bromfenac without sodium sulfite?  
 12 A. I understand that.  
 13 Q. Do you agree with defendants?  
 14 A. I don't.  
 01:16 15 Q. Why not?  
 16 A. Because Experimental Example 4 of Ogawa at about Line 19,  
 17 20, Ogawa states, in the formula, "the change in residue rate  
 18 were not almost observed but in three weeks red insoluble  
 19 matters were observed."  
 01:17 20 And so that's stating that under the conditions that  
 21 Ogawa was measuring bromfenac chemical stability, over the  
 22 three weeks at 60 degrees C. at each of those pHs, there was a  
 23 difference, but in the end, at the three weeks, there was  
 24 still red insoluble matter found for each of those four  
 01:17 25 conditions, the four solutions tested.

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1 Q. Does that reflect chemical degradation?  
 2 A. It does, yes.  
 3 Q. Have you also prepared a demonstrative showing results  
 4 from Experimental Example 2 of the '431 patent?  
 01:17 5 A. I have, yes.  
 6 Q. Let me direct your attention to PDX4-7 on the screen,  
 7 which cites to PTX-592.  
 8 Would you please explain what PDX4-7 illustrates?  
 9 A. So, yes. So, this is a summary table, and the top row is  
 01:18 10 formulation code, so that is the reference A-0 -- to Formulas  
 11 A-01, A-02, and A-03. And those correspond to the  
 12 formulations reported in Table 2 of the '431 patent, and they  
 13 correspond to Formulas A-04, A-05, and A-06, respectively.  
 14 Q. How, if at all, are the chemical stability results in  
 01:18 15 experimental Example 2 of the '431 patent unexpected to a  
 16 person of ordinary skill in the art?  
 17 A. So, these formulations would be unexpected, because they  
 18 contain three different levels of tyloxapol and no sodium  
 19 sulfite, and based on the findings of Ogawa that solve the  
 01:18 20 chemical stability problem using sodium sulfite, in part,  
 21 these results are roughly 92.5 or 92-and-a-half percent, about  
 22 91 percent, about 92 percent. So those -- those chemical  
 23 stability results would be understood by a person of ordinary  
 24 skill in the art to be good.  
 01:19 25 Q. Were those chemical stability results in the formulations

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1 of experimental Example 2 of the '431 patent obtained without  
 2 using sodium sulfite in the formulations?  
 3 **A. Yes, and that's noted here, there's no sodium sulfite**  
 4 **used.**  
 01:19 5 **Q.** Let's now discuss your opinions regarding unexpected  
 6 results with respect to experimental Example 3 of the '431  
 7 patent.  
 8 Have you prepared a demonstrative illustrating  
 9 preservative efficacy testing data in experimental Example 3  
 01:19 10 of the '431 patent?  
 11 **A. I have, yes.**  
 12 **Q.** Let me direct your attention to PDX4-8 on the screen.  
 13 Would you please explain what PDX4-8 illustrates?  
 14 **A. Yes, PDX4-8 illustrates the preservative efficacy**  
 01:19 15 **comparison. So it's tyloxapol versus polysorbate 80. So this**  
 16 **is A-04, actually it's just tyloxapol from experimental**  
 17 **Example 3. And this shows that A-0 -- formula A-04 that was**  
 18 **described in Table 2 of the '431 patent and A-05 that's**  
 19 **described in Table 2 of the '431 patent, both with either .02**  
 01:20 20 **weight percent or .05 weight percent of tyloxapol, the lowest**  
 21 **level of tyloxapol at .02 percent passed the EP Criteria A**  
 22 **and, therefore, Criteria B, whereas the slightly higher**  
 23 **percent of tyloxapol at .05 weight percent did not pass EP**  
 24 **Criteria A, preservative efficacy, but did pass the EP**  
 01:20 25 **Criteria B.**

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1 **concentrations that were studied, so that's what enabled it.**  
 2 **Q.** Do you recall testifying last week that the Prolensa  
 3 package insert does not identify burning and stinging as  
 4 adverse reactions associated with Prolensa?  
 01:22 5 **A. Yes.**  
 6 **Q.** Before we consider Prolensa further, let's take a look at  
 7 the FDA-approved Xibrom package insert.  
 8 Would you please turn to JTX144 in your binder and  
 9 identify that document?  
 01:22 10 **A. JTX144 is a copy of Xibrom package insert.**  
 11 **Q.** Did you review the FDA-approved Xibrom package insert in  
 12 connection with your opinions in this case?  
 13 **A. I did, yes.**  
 14 **Q.** Would you please turn to PTX-749 in your supplemental  
 01:23 15 binder and identify that document.  
 16 **MS. HOLLAND:** Your Honor, we have an objection. This  
 17 is a new exhibit that was first disclosed last night.  
 18 **MR. HASFORD:** And, Your Honor, this was the exhibit  
 19 that we brought up last week with Dr Lawrence. She testified  
 01:23 20 that she hadn't seen it before. All we're getting here is to  
 21 get Dr. Williams to testify that he's reviewed this and finds  
 22 them to be essentially identical.  
 23 It's not an issue that we believe should even be in  
 24 dispute between the parties. I think Your Honor instructed us  
 01:23 25 to try to get the issue resolved by stipulation. We haven't

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1 **Q.** Do you understand that the European Pharmacopeia  
 2 Criteria A standard is more demanding than the European  
 3 Pharmacopeia Criteria B standard?  
 4 **A. Yes, I understand that.**  
 01:21 5 **Q.** Let's switch gears a bit.  
 6 Do you recall testifying earlier this week that  
 7 Prolensa is an embodiment of Claims 6 and 20 of the '431  
 8 patent?  
 9 **A. Yes.**  
 01:21 10 **Q.** How, if at all, did the unexpected stabilizing ability of  
 11 tyloxapol in the aqueous liquid preparations of bromfenac of  
 12 the '431 patent enable formulating Prolensa at pH 7.8?  
 13 **A. So, because, according to the patent, because tyloxapol**  
 14 **is able to chemically stabilize bromfenac sodium, the pH was**  
 01:21 15 **able to be lowered from pH 8.3, which is the pH of Prolensa to**  
 16 **pH 7.5. So it's a half of pH unit decrease.**  
 17 **Q.** And did you mean to say the pH of 8.3 of Bronuck or --  
 18 sorry, Bronuck, Xibrom and Bromday?  
 19 **A. Yes, I misstated that, yeah, Prolensa 7.8, yes.**  
 01:21 20 **Q.** How, if at all, did the unexpected stabilizing ability of  
 21 tyloxapol in the aqueous liquid preparations of bromfenac of  
 22 the '431 patent enable formulated Prolensa with 0.02 weight  
 23 per volume percent of tyloxapol?  
 24 **A. Well, it was found based on the data that the 0.02 weight**  
 01:22 25 **percent of tyloxapol had the best stability of the**

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1 been able to do that, so we're just going to have Dr. Williams  
 2 testify as to his understanding of it.  
 3 **THE COURT:** Okay. Ms. Holland.  
 4 **MS. HOLLAND:** This document is not in Dr. Williams's  
 01:23 5 report. To the extent that Mr. Hasford says it's the same or  
 6 similar to a document that is in his report, I'm not -- I  
 7 don't understand why that's not the document that's being used  
 8 with the witness.  
 9 I'm not sure it actually is the same or similar, and  
 01:24 10 it's not -- there's not been a disclosed opinion about it, so  
 11 to the extent that plaintiffs want to use a Xibrom package  
 12 insert, we object to using one that wasn't in Dr. Williams's  
 13 report.  
 14 **MR. HASFORD:** We're merely seeking for Dr. Williams  
 01:24 15 to testify that they appear to be essentially identical, Your  
 16 Honor.  
 17 **THE COURT:** I'm sorry, what is the "they?" Does he  
 18 have a different document that he has relied on?  
 19 **MR. HASFORD:** He's got the actual FDA-approved  
 01:24 20 version that he's relied upon in his expert report. This is  
 21 the version, as you will hear Dr. Williams testify, that was  
 22 actually included as the insert with the packaging with which  
 23 Xibrom was sold.  
 24 **MS. HOLLAND:** That's not anywhere in his report or  
 01:24 25 disclosed anywhere and --

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1 THE COURT: Well, is there disagreement about it?  
 2 MR. HASFORD: There certainly isn't from plaintiffs,  
 3 Your Honor.  
 4 MS. HOLLAND: The --  
 01:24 5 THE COURT: Well, I assume that you wouldn't  
 6 disagree --  
 7 (Laughter.)  
 8 MS. HOLLAND: The issue, Your Honor, is, is this the  
 9 right witness to talk about a package insert, A. B, it's not  
 01:25 10 the one in his report. So there's a doctor coming on the  
 11 stand, I'm understanding, Dr. Trattler, after Dr. Williams,  
 12 and I don't know if --  
 13 MR. HASFORD: Your Honor, Dr. Williams is a licensed  
 14 pharmacist so he certainly is a correct or a right witness as  
 01:25 15 Ms. Holland says, to testify about a package insert, and he  
 16 provided that background testimony, as Your Honor will recall,  
 17 as part of his background last week.  
 18 MS. HOLLAND: Your Honor, this is not essentially the  
 19 same as the one in the report. I think that's the -- real  
 01:25 20 crux of the objection. So there's a package insert on -- in  
 21 the expert report. Now this is a different package insert  
 22 that's not the same as the one in the expert report, so that's  
 23 the problem here, is that this is a new exhibit disclosed last  
 24 night that's not the same as something that was already in the  
 01:25 25 expert report.

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1 to a different Xibrom that doesn't have the information that  
 2 would be significant for a physician, we have a problem with  
 3 that.  
 4 MR. HASFORD: There's no switching going on here,  
 01:27 5 Your Honor, and respectfully, it sounds like Ms. Holland's  
 6 objection goes to weight, not to admissibility.  
 7 MS. HOLLAND: Well, it goes to admissibility because  
 8 it wasn't on the exhibit list until last night.  
 9 THE COURT: All right. I have to sustain the  
 01:27 10 objection. If there's not a reason that it was omitted from  
 11 the exhibit list or, for instance, did it just become apparent  
 12 during the trial, then it's an unlisted exhibit, and if you  
 13 have the essential equivalent, then you should use the  
 14 document previously disclosed that the defendants are familiar  
 01:27 15 with. So I will sustain the objection.  
 16 BY MR. HASFORD:  
 17 Q. Let me direct your attention back to JTX144 and in  
 18 particular, to Page 3 of the Xibrom package insert, which  
 19 bears Bates No. PROL 0080488.  
 01:28 20 Specifically, let me direct your attention to the  
 21 second paragraph of the section entitled Adverse Reactions.  
 22 Does the adverse reaction section of the FDA-approved  
 23 Xibrom package insert indicate that eye irritation, including  
 24 burning and stinging, are associated with Xibrom?  
 01:28 25 A. That's what this approved label states, yes.

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1 THE COURT: Is what's in the expert report the  
 2 proposed package insert?  
 3 MS. HOLLAND: No, it's the approved package insert.  
 4 THE COURT: It's the approved one. And what's this  
 01:26 5 one purporting to be? PTX-779?  
 6 MR. HASFORD: This one -- this one, Your Honor, is  
 7 simply the version which we contend and Dr. Williams is  
 8 prepared to testify is essentially identical. It's the actual  
 9 version that was placed in the carton, the container, the box  
 01:26 10 with the bottle of eye drops.  
 11 So it's identical in substance, because the FDA had to  
 12 approve this as well.  
 13 MS. HOLLAND: Perhaps the problem is that -- I'm not  
 14 sure what the representation is, but perhaps this is something  
 01:26 15 intended for a patient, whereas what Dr. Williams talked about  
 16 in his report was intended for a physician.  
 17 So in that respect, there are differences and could be  
 18 a material difference in the opinion.  
 19 MR. HASFORD: I don't believe there will be any  
 01:26 20 material difference in the opinion.  
 21 MS. HOLLAND: There's more information, for example,  
 22 that will be available about the Xibrom product in the version  
 23 that's in the report, and it's important information, we  
 24 believe, for the case.  
 01:27 25 So to the extent that this could be now switching out

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1 Q. Let me now direct your attention --  
 2 MS. HOLLAND: Your Honor, I have an objection to this  
 3 line of questioning. Dr. Williams is -- was put on the stand  
 4 as a formulation expert. It appears to me he's now testifying  
 01:28 5 about what adverse events are associated with the product.  
 6 That's not within his area of expertise.  
 7 MR. HASFORD: It absolutely is, Your Honor. He's a  
 8 licensed pharmacist. This is the first time Ms. Holland has  
 9 raised this objection, and this is fully disclosed in his  
 01:28 10 expert report and her -- there's no basis for the objection.  
 11 MS. HOLLAND: We raised it last night, Your Honor, in  
 12 connection with one of the demonstratives that was disclosed  
 13 to us. The issue is, regardless of whether Dr. Williams is a  
 14 pharmacist or not, I'm not saying he's not a pharmacist,  
 01:29 15 that's not what he was qualified for on the stand. He's a  
 16 formulator here at trial, and he's not qualified as a  
 17 formulator to give opinions about medical adverse events that  
 18 occur with the product.  
 19 MR. HASFORD: Your Honor, he's eminently qualified.  
 01:29 20 MS. HOLLAND: He has testified at his deposition that  
 21 he has no -- he does not have a personal opinion on those  
 22 issues. Dr. Williams said you'd have to ask the doctor about  
 23 that, about whether they actually occur.  
 24 MR. HASFORD: Your Honor, he's eminently qualified to  
 01:29 25 testify to what these package inserts show to a skilled

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1 formulator or to a pharmacist.

2 THE COURT: I'm just looking through my notes to see

3 what exactly he was qualified as an expert in for purposes of

4 this trial. I'm not finding it right off the bat.

01:30 5 Okay. He's qualified as an expert in the design,

6 evaluation and formulation of drugs, and so the issue is

7 whether -- within his field of expertise, it would include the

8 review of FDA-approved package inserts.

9 MR. HASFORD: And we --

01:31 10 THE COURT: Could you lay a foundation, please?

11 MR. HASFORD: Certainly.

12 MS. HOLLAND: Your Honor, may I have a brief voir

13 dire after that?

14 THE COURT: Yes.

01:31 15 MS. HOLLAND: Thank you.

16 BY MR. HASFORD:

17 Q. Doctor, in your general experiences, an expert in the

18 field of the design, evaluation and formulation of drug

19 products, do you review and rely upon FDA-approved package

01:31 20 inserts?

21 A. I do, yes.

22 Q. Do you understand the information contained therein?

23 A. Generally speaking, yes.

24 Q. Would that include both safety and efficacy information?

01:31 25 A. Yes.

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1 product?

2 A. No. As a formulator, I would -- formulators, persons of

3 ordinary skill in the art, look at package inserts when they

4 are looking to formulate a product to see if there's something

01:33 5 relevant with regards to -- like burning, stinging of

6 excipients. They do look at that, if there's information in a

7 similar product, they -- they would, yes.

8 Q. But in this case, the Prolensa product is not the product

9 that somebody would be looking to formulate?

01:33 10 MR. HASFORD: Objection, Your Honor. Same issue.

11 It's going beyond the scope of voir dire.

12 THE COURT: No, I'll permit it. I mean, it goes to

13 the relevance of this field of expertise.

14 THE WITNESS: So in coming up with Prolensa, one

01:33 15 would consider literature that's out there including a product

16 label of NSAID products, bromfenac -- other bromfenac products

17 that's out there.

18 BY MS. HOLLAND:

19 Q. The person of ordinary skill in the art, however, in

01:33 20 looking to formulate something, would not be looking at the

21 Prolensa label, correct? That's the product you would be

22 looking to formulate?

23 A. Well, there would -- well, there would be no Prolensa

24 label if you're looking to formulate Prolensa. But to the

01:34 25 extent there's other labels out there for other nonsteroidal

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1 Q. Would that include information on adverse events?

2 A. It would, yes. As it relates to formulations.

3 THE COURT: Okay. You may voir dire on that.

4 (VOIR DIRE EXAMINATION OF DR. WILLIAMS BY MS. HOLLAND:)

01:31 5 Q. Dr. Williams, you have no personal opinions as to whether

6 Prolensa is more or less irritating than anything that -- any

7 other prior art bromfenac formulations, correct?

8 MR. HASFORD: Objection. This doesn't go to voir

9 dire, Your Honor.

01:32 10 THE COURT: Sustained. It would be as to his

11 qualifications or his use of this sort of material as an

12 expert.

13 MS. HOLLAND: Your Honor, I think it goes to the

14 issue of whether or not Dr. Williams is qualified to provide

01:32 15 opinions in this area. The opinions are --

16 THE COURT: That's -- that's what I meant. Your voir

17 dire is limited in scope. It's limited to his expertise as to

18 one who --

19 MS. HOLLAND: Okay. Understood, Your Honor.

01:32 20 THE COURT: -- is a formulator, who says he uses

21 package inserts. That was his testimony a moment ago. And so

22 within that narrow scope, you may cross-examine him.

23 BY MS. HOLLAND:

24 Q. Dr. Williams, is it your testimony that you use patent

01:33 25 package inserts in order to figure out how to formulate a

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1 anti-inflammatory agents, other ophthalmic aqueous solutions

2 that you can -- you can learn what they, from a label, you

3 know the composition of them, maybe not quantitative, but you

4 know the qualitative composition from the label, it's in all

01:34 5 the labels, and to the extent that there is a -- like this

6 burning and stinging that could be caused from the

7 formulation, one of skill in the art definitely would look at

8 that.

9 MS. HOLLAND: Your Honor, maybe it has to do with the

01:34 10 scope of the testimony. If Dr. Williams is simply going to be

11 reading off what is on the labels, I think that that's okay.

12 I don't think there's any testimony beyond that in the expert

13 reports, and I don't know if Mr. Hasford is looking to elicit

14 anything beyond that.

01:35 15 THE COURT: Okay.

16 MR. HASFORD: The questions that we have, Your Honor,

17 will -- we will have full support for in the expert reports.

18 I can't say that we're going to limit him to simply reading

19 off the labels, but to the extent there's an objection about

01:35 20 what's in the expert report, we can deal with that --

21 THE COURT: Well, let's take these one at a time

22 then.

23 As to the pending objection, I'll overrule

24 Ms. Holland's objection, and I would find that within his

01:35 25 field of expertise, formulators whom he's defined as the POSAs

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1 for this case would be apt to look at such labels in their  
 2 design and formulation of drugs. And so I'll permit him to  
 3 testify about the label that he says a POSA would have looked  
 4 at.

01:35 5 MS. HOLLAND: Okay. Your Honor. I'll --  
 6 THE COURT: And then if there's individual questions  
 7 that are beyond the scope of his report, then that's a  
 8 different issue and I would take up any objection that you  
 9 raise at that time.

01:36 10 MS. HOLLAND: Thank you, Your Honor. It could be  
 11 beyond the scope of his report or his expertise as it pertains  
 12 to the labels, but I agree, I'll raise those as they come up.  
 13 (CONTINUED DIRECT EXAMINATION OF DR. WILLIAMS BY MR. HASFORD:)  
 14 Q. Let me now direct your attention to Page 5 of the Xibrom  
 01:36 15 package insert which bears Bates No. PROL 0080490. And in  
 16 particular, to the second paragraph under the section entitled  
 17 Description.  
 18 What is the pH of the Xibrom formulation?  
 19 A. Here, the pH of the Xibrom formulation, it's stated to be  
 01:36 20 8.3.  
 21 Q. Now, let's take a look at the FDA-approved Bromday  
 22 package insert.  
 23 Would you please turn to PTX-474 in your binder and  
 24 identify that document.  
 01:36 25 A. PTX-474 is a copy of the Bromday package insert.

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1 Bromday and Prolensa, in particular to the amount of active,  
 2 which is 0.09 percent bromfenac-free acid equivalent for  
 3 Xibrom and Bromday, and for Prolensa, it's 0.07 percent  
 4 equivalent of bromfenac-free acid.

01:38 5 I've also summarized surfactant amount and the  
 6 surfactant type. So for Xibrom and Bromday, the surfactants  
 7 polysorbate 80 in both are at 0.15 weight percent, whereas for  
 8 Prolensa, it contains tyloxapol at 0.02 weight percent.  
 9 And lastly, and as I just testified to, the pH of the  
 01:39 10 Xibrom and Bromday ophthalmic solution is 8.3 and Prolensa is  
 11 7.8.  
 12 Q. From what trial exhibits, if any, have you derived the  
 13 information summarized on PDX 4-9?  
 14 A. I derived this information from JTX144, PTX-474, JTX022.  
 01:39 15 Q. What is the degree of difference between pH 8.3 and  
 16 pH 7.8?  
 17 A. So that's a half a pH unit. So one whole pH unit is ten  
 18 times, because it's on a log scale. And so a half a pH unit  
 19 is roughly a little bit more than three times the acidity.  
 01:39 20 Q. Are you aware that defendants have taken the position  
 21 that Prolensa could have a pH as high as 8.1 based on the NDA  
 22 specification?  
 23 A. Yes, I have.  
 24 Q. Does the -- does the FDA-approved Prolensa package  
 01:40 25 insert, in fact, specify the pH of Prolensa?

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1 Q. Did you review the FDA-approved Bromday package insert at  
 2 PTX-474 in connection with your opinions in this case?  
 3 A. Yes, I did.  
 4 Q. Let me direct your attention to Page 6 of the Bromday  
 01:37 5 package insert which bears Bates No. PROL 0080495, and in  
 6 particular, to the section entitled Adverse Reactions,  
 7 followed by Clinical Trial Experience.  
 8 Does the adverse reaction section of the FDA-approved  
 9 Bromday package insert indicate that eye irritation including  
 01:37 10 burning and stinging are associated with Bromday?  
 11 A. That's what's stated here for Bromday, including burning  
 12 and stinging.  
 13 Q. Let me now direct your attention to Page 7 of the Bromday  
 14 package insert which bears Bates No. PROL 0080496, and in  
 01:37 15 particular, to the second paragraph under the section entitled  
 16 Description.  
 17 What is the pH of the Bromday formulation?  
 18 A. So the label states the pH of Bromday solution is 8.3.  
 19 Q. Have you prepared a demonstrative comparing certain  
 01:38 20 aspects of the formulations of the Xibrom, Bromday and  
 21 Prolensa products?  
 22 A. I have, yes.  
 23 Q. Let me direct your attention to PDX 4-9.  
 24 What does PDX 4-9 illustrate?  
 01:38 25 A. So here, I've summarized certain aspects of Xibrom,

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1 A. It does. It specifies it as pH 7.8.  
 2 Q. Are you aware the defendants have taken the position that  
 3 the disclosure in the Ogawa '225 patent of the pH range of 7.5  
 4 to 8.5 allegedly indicates that a commercial formulation of  
 01:40 5 bromfenac containing polysorbate 80 could have been achieved  
 6 at pH 7.8?  
 7 A. Yes.  
 8 Q. Do you agree with defendants?  
 9 A. I don't.  
 01:40 10 Q. Why not?  
 11 A. Because -- I don't agree with defendants because in the  
 12 Ogawa patent, all the data that's presented -- that's not  
 13 true.  
 14 So the examples where pH is stated, it's at pH 8.  
 01:40 15 There's one example where pH is not listed. But all the data  
 16 that -- where it states it, it's a pH 8. And Ogawa teaches  
 17 that below pH 8 that bromfenac sodium is sensitive to chemical  
 18 degradation.  
 19 Q. And does experimental Example 4 also inform your opinion  
 01:41 20 in that regard?  
 21 A. Yes, experimental Example 4, where it says at those four  
 22 pH values that were studied, after three-week storage at  
 23 60 degrees C, there was red insoluble matter, so chemical  
 24 degradation.  
 01:41 25 Q. And does the Ogawa '225 patent also teach that bromfenac

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1 degrades precipitously as the pH approaches 7?

2 A. **That's the data, yes, in Table 8 of Ogawa. It says at**

3 **pH 7, the chemical stability was decreased.**

4 Q. Would you please turn in your binder to JTX18 and

01:41 5 identify that document.

6 A. **JTX18 is the Baklayan article.**

7 Q. In what journal is JTX18 published?

8 A. **Clinical Ophthalmology.**

9 Q. Is the Journal of Clinical Ophthalmology a peer-reviewed

10 journal?

11 A. **My understanding is it is, yes.**

12 Q. In your opinion, is JTX18 a reliable authority regarding

13 the studies it describes and the conclusions to be drawn from

14 them?

01:42 15 A. **Yes.**

16 Q. Let me direct your attention to the conclusion section

17 right above introduction on the first page of JTX18.

18 What does the conclusion section of JTX18 disclose?

19 A. **So here, the Baklayan article states: Bromfenac**

01:42 20 **ophthalmic solution 0.07 percent, pH 7.8, readily penetrated**

21 **ocular tissues with levels similar to those of bromfenac**

22 **ophthalmic solution 0.09 percent pH 8.3.**

23 Q. Let me now direct your attention to the first paragraph

24 on the second page of JTX18, and in particular, to the

01:42 25 sentence beginning with, Prolensa was reformulated.

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1 What does this sentence in JTX18 disclose?

2 A. **So here, Baklayan is disclosing the fact that it states**

3 **Prolensa was reformulated from bromfenac .09 percent and then**

4 **mentions Bromday, and he states that was done to achieve**

01:43 5 **similar ocular bioavailability with a lower concentration of**

6 **active drug, thereby ensuring similar clinical efficacy to**

7 **Bromday but with reduced exposure of the**

8 **surgically-compromised ocular surface of the drug.**

9 Q. How, if at all, does this portion of JTX18 support your

01:43 10 opinion that tyloxapal's unexpected stabilizing effect led to

11 medical benefits in plaintiff's Prolensa product?

12 A. **So because tyloxapal was able to chemically stabilize**

13 **bromfenac at pH 7.8, that supports my opinion that it would**

14 **allow for this unexpected medical benefit.**

01:43 15 MS. HOLLAND: Your Honor, I'm going to object and

16 also move to strike the answer. I didn't get a chance to

17 object before Dr. Williams started speaking.

18 This now goes to medical benefits. That is clearly

19 outside -- we haven't heard any testimony about medical

01:44 20 benefits yet. There hasn't been a doctor on the stand. It's

21 clearly outside the scope of Dr. Williams's expertise to

22 comment on medical benefits. That -- I mean, that I can

23 certainly voir dire on. That's from his deposition. He

24 doesn't have opinions on medical benefits.

01:44 25 MR. HASFORD: Well, Your Honor, he has an opinion

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1 here that, as a formulator, the unexpected stabilizing effect

2 of tyloxapal led to these other benefits that are actually

3 real benefits with this product.

4 THE COURT: Can you rephrase the question?

01:44 5 MR. HASFORD: Sure.

6 THE COURT: Because if he said he has no opinion on

7 medical benefits, then I would have to sustain the objection.

8 MR. HASFORD: I can rephrase.

9 MS. HOLLAND: Your Honor, respectfully, so is the

01:44 10 last answer stricken for the moment?

11 THE COURT: Yes. The last question and answer would

12 be stricken.

13 MS. HOLLAND: Thank you.

14 THE COURT: And I agree, you didn't have adequate

01:45 15 opportunity to object before the witness -- who I'm not

16 faulting --

17 THE WITNESS: Sorry.

18 THE COURT: -- answered.

19 BY MR. HASFORD:

01:45 20 Q. How, if at all, does this portion of JTX18 support your

21 opinion that tyloxapal's unexpected stabilizing effect led to

22 additional benefits in plaintiff's Prolensa product?

23 MS. HOLLAND: That's the same objection, Your Honor.

24 The only benefits that are in anybody's expert report are the

01:45 25 medical benefits, and this witness isn't competent to testify

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1 about that.

2 MR. HASFORD: Your Honor, the goal of pharmaceutical

3 formulation is to create additional benefits.

4 THE COURT: I'll permit it. The objection is

01:45 5 overruled.

6 BY MR. HASFORD:

7 Q. Do you need me to repeat the question, Doctor?

8 A. **No. So the -- so what was found was tyloxapal was able**

9 **to chemically stabilize bromfenac sodium, such that the pH**

01:45 10 **could be lowered to pH 7.8, which is closer to the pH of**

11 **natural tears. And so by that, Baklayan is saying because of**

12 **that similar ocular bioavailability was able to be obtained.**

13 Q. Have you prepared a demonstrative illustrating these

14 unexpected additional benefits stemming from the use of

01:46 15 tyloxapal with bromfenac that we have just discussed?

16 A. **Yes.**

17 Q. Let me direct your attention to PDX10 on the screen.

18 What does PDX -- what does PDX10 illustrate?

19 A. **So PDX4-10 illustrates -- so starting from the fact that**

01:46 20 **tyloxapal was found to chemically stabilize --**

21 MS. HOLLAND: Your Honor, I'm going to interrupt with

22 an objection. So what you have on the slide here is

23 Dr. Williams apparently saying that the lower pH of Prolensa

24 is responsible for no burning or stinging.

01:46 25 Now, Dr. Williams is not a doctor and -- he has offered

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1 no opinion or no support for the fact that something about the  
 2 pH was related to burning or stinging.  
 3 MR. HASFORD: He certainly has in his expert reports,  
 4 Your Honor, and what he's doing here is he's tying together  
 01:47 5 his understanding as a formulator of the unexpected benefits  
 6 of the reduction in surfactant to .02 weight per volume  
 7 percent to these actual benefits.  
 8 THE COURT: Wasn't that part of his testimony the  
 9 first day in terms of introducing the patent?  
 01:47 10 MR. HASFORD: Well, his -- he laid some of the  
 11 background for this in the patent, Your Honor, now he's tying  
 12 it together with what he just testified about with respect to  
 13 the Baklayan article and what he just testified about with  
 14 respect to the package insert and tying this together to his  
 01:47 15 understanding as a formulator.  
 16 MS. HOLLAND: I'll just make my objection, then, Your  
 17 Honor. My objection is this is outside of the scope of  
 18 Dr. Williams's expertise. He doesn't -- he doesn't know  
 19 what's responsible for the burning or stinging in the package  
 01:47 20 insert, so that's my objection.  
 21 THE COURT: I'm going to sustain the objection. To  
 22 the extent that he's being asked for medical causation, that  
 23 does seem to be beyond his -- his opinions and expertise. To  
 24 the extent that he's being asked with what's been observed or  
 01:48 25 what is associated with, I would permit it.

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1 Is it your understanding that the companies listed on  
 2 PDX1-51 have copied the subject matter of Claims 6 and 20 of  
 3 the '431 patent?  
 4 MS. HOLLAND: Objection -- I have an objection here,  
 01:49 5 Your Honor. I don't -- again, as a formulator, I don't think  
 6 the witness is competent to testify about whether or not  
 7 someone copied. I mean, if he wants to compare labels and say  
 8 the ingredients are the same, that's one thing, but to go into  
 9 an extended discussion of why he believes subjectively someone  
 01:50 10 did or didn't, it's just inappropriate for a formulation  
 11 witness.  
 12 MR. HASFORD: He's not going into that, Your Honor,  
 13 he's simply stating his understanding having read notice  
 14 letters and having understood what these formulations are,  
 01:50 15 that these are exact copies of Prolensa.  
 16 MS. HOLLAND: So, as I said, Your Honor --  
 17 THE COURT: Ms. Holland.  
 18 MS. HOLLAND: Thank you, Your Honor. My objection, I  
 19 guess, again, Your Honor, is not to the comparison. It's to  
 01:50 20 an opinion from an expert about whether there was copying.  
 21 That doesn't seem like something that's the subject of --  
 22 should be subject of expert testimony. The documents are in  
 23 evidence. Plaintiffs can argue whatever they want in their  
 24 post-trial briefs about them, but it's certainly -- this is  
 01:50 25 not an area of Dr. Williams's expertise as to whether or not

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1 MR. HASFORD: Okay. Well, I'll rephrase the question  
 2 then, Your Honor.  
 3 THE COURT: Okay.  
 4 BY MR. HASFORD:  
 01:48 5 Q. What is your understanding of what has been observed as  
 6 you have summarized here in PDX4-10?  
 7 A. So what I've summarized here is, starting with the fact  
 8 that tyloxapol at .02 percent weight -- by weight, is able to  
 9 chemically stabilize bromfenac sodium in an ophthalmic aqueous  
 01:48 10 solution such that the pH can be lowered to pH 7.8, what I've  
 11 seen is that -- that now with that product in the Prolensa  
 12 label, burning, stinging is not recognized.  
 13 It wouldn't be recognized by a person of ordinary skill  
 14 in the art compared to the Xibrom label or the Bromday label,  
 01:48 15 and as a formulator, I recognize in the Baklayan article, that  
 16 Baklayan is talking about the fact that the pH was able to be  
 17 lowered such that a similar bioavailability was able to be  
 18 made such that the drug was able to be lowered in  
 19 concentration to provide comparable therapeutic benefits.  
 01:49 20 That's what I understand as a formulator.  
 21 Q. Let's now discuss copying by others.  
 22 In your opinion, has the claimed subject matter of  
 23 Claims 6 and 20 of the '431 patent been copied by others?  
 24 A. Yes.  
 01:49 25 Q. Let me direct your attention to PDX1-51 on the screen.

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1 someone copied.  
 2 MR. HASFORD: Perhaps I can rephrase the question,  
 3 Your Honor.  
 4 THE COURT: Okay. Please do.  
 01:50 5 BY MR. HASFORD:  
 6 Q. Is it your understanding, Dr. Williams, that Lupin,  
 7 Metrics, InnoPharma, Apotex, Paddock and Watson all have filed  
 8 an abbreviated new drug application seeking FDA approval for  
 9 generic versions of bromfenac ophthalmic solutions 0.07  
 01:51 10 percent?  
 11 A. Yes.  
 12 Q. Is it your understanding that the ingredients in Lupin's,  
 13 Metrics's, InnoPharma's, Apotex's, Paddock's and Watson's  
 14 generic bromfenac ophthalmic solutions .07 percent are the  
 01:51 15 same as the ingredients in Prolensa?  
 16 MS. HOLLAND: My objection here, Your Honor, is that  
 17 most of these companies are not defendants in this case, so I  
 18 don't see the relevance.  
 19 MR. HASFORD: They provided nonconfidential  
 01:51 20 Paragraph IV notice letters, Your Honor, and that's what he's  
 21 reviewed.  
 22 MS. HOLLAND: My objection is different. My  
 23 objection is as to relevance of what nonparties have done.  
 24 MR. HASFORD: The relevance of what nonparties have  
 01:51 25 done, Your Honor, is that they have submitted these ANDAs with

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1 exact copies of Prolensa, and I believe the case is -- well,  
 2 there's a case in New Jersey that was Rule 36 affirmed at the  
 3 fed circuit that stated that copying of the claimed  
 4 formulation is a secondary consideration of nonobviousness.  
 01:52 5 MS. HOLLAND: What I said was, you know, regardless  
 6 of what that case says, and I'm not sure what case counsel is  
 7 talking about, that can't be the case for nonparties.  
 8 MR. HASFORD: It most certainly can, Your Honor.  
 9 THE COURT: No, if there is --  
 01:52 10 MS. HOLLAND: If the question -- sorry, Your Honor.  
 11 THE COURT: Just a moment. My understanding is that  
 12 if there is copying, even by a nonparty, that that can be  
 13 evidence of secondary -- secondary considerations, and of  
 14 course, this is -- just a moment.  
 01:53 15 I know you've discussed this in -- in your final  
 16 pretrial order, I think it was, and --  
 17 MS. HOLLAND: If I may, if I may, Your Honor, the  
 18 issue is that there's nobody here on behalf of those  
 19 defendants to say yes or no to what happened, so we are kind  
 01:53 20 of being -- I guess, what's going to happen is that we're kind  
 21 of like stuck with whatever nonparties said and they're not  
 22 here to cross-examine Dr. Williams about their own, you know,  
 23 filings, so...  
 24 THE COURT: Well, if the question is limited to, are  
 01:53 25 there other companies that have produced the same formulation,  

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1 identified it with their intent to market, then I would permit  
 2 it. I believe that that is relevant to the concerns of other  
 3 considerations with regard to the obviousness inquiry.  
 4 MR. HASFORD: I'll rephrase the question that way.  
 01:54 5 BY MR. HASFORD:  
 6 Q. Is it your understanding that six different generic -- at  
 7 least six different generic drug companies have filed  
 8 Abbreviated New Drug Applications for proposed generic  
 9 bromfenac ophthalmic solution products that are exact copies  
 01:54 10 of plaintiff's Prolensa product?  
 11 A. **That's my understanding.**  
 12 Q. Is it your understanding that Lupin filed its Abbreviated  
 13 New Drug Application for bromfenac ophthalmic solution 0.07  
 14 percent just three months after Prolensa was approved?  
 01:54 15 A. **That's my understanding.**  
 16 Q. Would you please turn to JTX12 in your binder and  
 17 identify this document.  
 18 A. **So JTX12 is an HSBC report that I understand is on  
 19 Lupin's website.**  
 01:54 20 Q. Let me direct your attention to the second page bearing  
 21 Bates No. PROL 0276694 in JTX12, and in particular, to the  
 22 second paragraph of the section, Lupin recently filed  
 23 gProlensa in the right-hand column.  
 24 Specifically, let me direct your attention to the first  
 01:55 25 four lines of that paragraph.  

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1 A. **So here, Lupin is --**  
 2 Q. I apologize, Doctor, I haven't asked you a question yet.  
 3 A. **Oh, I'm sorry.**  
 4 Q. According to JTX12, were there any generic versions of  
 01:55 5 Bromday introduced into the U.S. market?  
 6 A. **Yes. It states here in the middle of this paragraph, it  
 7 says the product was approved only last year, April 2013. So  
 8 it's talking about Prolensa.**  
 9 Q. And I apologize. I think we need to be in the next  
 01:55 10 paragraph, the one that starts with the other known  
 11 formulation. Just the first four lines of that.  
 12 So I'll ask you the question again. According to  
 13 JTX12, were there any generic versions of Bromday introduced  
 14 into the U.S. market?  
 01:56 15 A. **There was, yes.**  
 16 Q. And which were those?  
 17 A. **There -- it was versions of Bromday.**  
 18 Q. And were they by Hi-Tech and Mylan?  
 19 A. **Yes.**  
 01:56 20 Q. Let's now --  
 21 MS. HOLLAND: Your Honor, this is -- I'm going to  
 22 again move to strike. This isn't in the expert report.  
 23 MR. HASFORD: Yes, Your Honor, he relied on this  
 24 document at Paragraph 389 of his opening expert report for  
 01:56 25 Lupin and he had this opinion in there.  

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1 MS. HOLLAND: He didn't provide this opinion about  
 2 the document.  
 3 MR. HASFORD: I believe it's in Paragraph 3.  
 4 MS. HOLLAND: It was a different opinion that was  
 01:56 5 provided about the document. In any event, this is a  
 6 third-party document. Be that as it may, there was no opinion  
 7 in the expert report about -- anything about generics related  
 8 to this document.  
 9 MR. HASFORD: I believe --  
 01:56 10 THE COURT: I thought this was a Lupin document.  
 11 MS. HOLLAND: No. The plaintiffs found it on the  
 12 Lupin website, apparently, but if you look at the first page,  
 13 it's a report from HSBC, I believe an analyst's report. So  
 14 this is not Lupin's opinions, this is what an analyst wrote.  
 01:57 15 MR. HASFORD: It's a document that Lupin puts on its  
 16 own website, Your Honor, and he has opinions about this  
 17 document. He's expressed those opinions at least in  
 18 Paragraph 389 of his opening expert report to Lupin, and he's  
 19 expressed these opinions.  
 01:57 20 THE COURT: Well, I don't think that a third-party  
 21 document placed on a company's website is necessarily a  
 22 statement of that company.  
 23 MR. HASFORD: No, but --  
 24 THE COURT: It's just information.  
 01:57 25 MR. HASFORD: But, Your Honor, he can rely on this  

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1 sort of document in providing his opinion and he can provide  
 2 the opinions that are -- that are consistent with this  
 3 document that, in fact, two different generic versions of  
 4 Bromday have already been introduced into the U.S. market.  
 01:57 5 MS. HOLLAND: That opinion is not in the expert  
 6 report. I'm not even sure if it's relevant to anything that's  
 7 in Dr. Williams's expert report. Commercial success is out of  
 8 the case as we know, Your Honor. I'm just not sure what this  
 9 is about, why is it up here.  
 01:57 10 MR. HASFORD: And, Your Honor, I might add --  
 11 MS. HOLLAND: What is the relevance to the case  
 12 whatsoever. I'm just -- I'm at a loss.  
 13 THE COURT: Well, let me ask that question, then.  
 14 Why would the generic, the generic efforts, directed against  
 01:58 15 -- against Bromday be relevant here?  
 16 MR. HASFORD: Well, as Your Honor --  
 17 THE COURT: I thought you were going to be asking  
 18 about generic efforts that were directed against Prolensa.  
 19 MR. HASFORD: And that's correct, we were, but as  
 01:58 20 Your Honor will recall, Mr. Mukerjee for InnoPharma argued  
 21 during opening statement that there was some reason why  
 22 allegedly the defendants here could not have gone and marketed  
 23 generic versions of Bromday. Your Honor asked that question.  
 24 This establishes that, in fact, two generic companies,  
 01:58 25 in fact, one very large one, Mylan, which is aligned with  
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1 no longer in the case, that's what this was directed to. You  
 2 see clearly -- I believe plaintiffs are trying to backdoor in  
 3 something when this opinion should not be in the case anymore  
 4 because of the commercial success dropping out.  
 02:00 5 MR. HASFORD: Your Honor, on the previous pages  
 6 you'll plainly see that this opinion was in the earlier -- two  
 7 pages before, you'll see this opinion was in connection with a  
 8 subheading entitled Copying By Others, so this opinion was not  
 9 in connection with a commercial success opinion, it was  
 02:00 10 clearly the subheading there Copying By Others.  
 11 MS. HOLLAND: Again, your Honor, if the intent here  
 12 is for Dr. Williams to give an opinion on copying, I object to  
 13 that.  
 14 MR. HASFORD: And copying --  
 02:01 15 MS. HOLLAND: That is not an appropriate subject  
 16 matter for this expert, although it could be argued, based on  
 17 the documents, I suppose, in post-trial briefing.  
 18 MR. HASFORD: And copying is mentioned in the last  
 19 paragraph of that document he was just discussing, your Honor,  
 02:01 20 which is JTX-12.  
 21 THE COURT: Is it being offered as proof of  
 22 Prolensa's significant and recognized benefits which led Lupin  
 23 and many other generics to copy plaintiff's Prolensa product?  
 24 MR. HASFORD: Despite the expected generic  
 02:01 25 competition from Bromday@.  
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1 InnoPharma in this case, in fact, marketed a generic version  
 2 of Bromday.  
 3 MS. HOLLAND: That is not an opinion that was ever  
 4 offered.  
 01:59 5 MR. HOLLAND: It is encompassed within --  
 6 THE COURT: Just a moment. We can't have three  
 7 speaking at once. Mr. Mukerjee.  
 8 MR. MUKERJEE: And an opening statement doesn't give  
 9 a door to Dr. Williams now opining on items that he never  
 01:59 10 opined on.  
 11 MR. HASFORD: I believe it's within Paragraph 389 of  
 12 his report.  
 13 THE COURT: Wait, let's take a look at that, please.  
 14 MR. HASFORD: Yes. So actually, we can -- if we can  
 01:59 15 pull up -- Noel, can we pull up Paragraph 389 of Dr.  
 16 Williams's opening report to Lupin. And it's going to be in  
 17 the -- the paragraph starts on one page and then spills over  
 18 onto the next, it will be on the second page.  
 19 So, if your Honor will note, he cites, the key phrase  
 02:00 20 here is "despite the expected generic competition from  
 21 Bromday@, PROL 0080436 to 804464," that's the exact document  
 22 we have been looking at, he has a reference to the generic  
 23 competition from Bromday@ in here.  
 24 MS. HOLLAND: Your Honor, this was in the case --  
 02:00 25 there was a commercial success allegation in the case that's  
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1 THE COURT: But the evidence is that the generics  
 2 were directed at Bromday@ not at Prolensa.  
 3 MR. HASFORD: Well, no, the evidence is that the  
 4 generics are directed at both, your Honor. They're coming in  
 02:02 5 here seeking to market FDA approved copies of Prolensa, yet  
 6 there were FDA approved copies of Bromday@ on the market,  
 7 including one by Mylan, which is aligned with Innopharma in  
 8 this case, it goes to the question that you asked Mr. Mukerjee  
 9 during opening statement.  
 02:02 10 MS. HOLLAND: Your Honor, if this testimony comes in,  
 11 defendants are going to want to put on Dr. Hoffman who was our  
 12 economics expert who can address this issue. We dropped  
 13 Dr. Hoffman from the list when we were told that there would  
 14 be no issues of commercial success or anything related to it  
 02:02 15 coming in. Dr. Hoffman actually has it his report. So, you  
 16 know, if Dr. Williams wants to put in that testimony and your  
 17 Honor rules that it's admissible, then I'll just request that  
 18 we be given the permission to put on Dr. Hoffman in response.  
 19 MR. HASFORD: And there's no basis for that, your  
 02:03 20 Honor. This is not going to an issue of commercial success,  
 21 this is going to an issue of copying. Mr. Hoffman's only  
 22 opinions in this case were responsive to a witness we're no  
 23 longer calling.  
 24 MS. HOLLAND: He substantively responds to this  
 02:03 25 allegation I'll call it at this point in time, about the, you  
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1 know, why -- directly responds to this issue how the suspected  
2 generic competition from Bromday® does or doesn't have an  
3 effect to secondary considerations. And I'm just asking that  
4 if Dr. Williams' opinion comes in, we be permitted to put in  
02:03 5 an opinion that rebuts that opinion.

6 MR. MUKERJEE: That's correct, your Honor.  
7 Mr. Hoffman goes directly into the whole notion of automatic  
8 substitution, which you'll recall from my opening statement,  
9 which Mr. Hasford keeps referring to. So if they are allowed  
02:03 10 to put on this testimony which, frankly, I still don't

11 understand how Dr. Williams is qualified to put in that  
12 testimony, then defendants have to then bring Mr. Hoffman to  
13 the stand to at least talk about what -- you know, the fact  
14 that there is generic Bromday® or could even be gleaned in  
02:04 15 some instances why that doesn't even matter in light of the  
16 way it actually works with respect to automatic substitution  
17 and other items.

18 THE COURT: But did you not argue to me in your  
19 opening that it won't be feasible to do a generic of Bromday®  
02:04 20 because it would never gain market traction, the value and the  
21 purpose of ANDA is in being the generic for the new brand, the  
22 Prolensa?

23 MR. MUKERJEE: Right. And I argued that also it  
24 undermines the very purpose of the Hatch-Waxman itself. And  
02:04 25 what Mr. Hoffman goes into in detail in his report, and I

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1 precisely for the reason that they can't -- they're not  
2 susceptible to automatic substitution, and that's what  
3 Mr. Hoffman would explain as part of his testimony. So to the  
4 extent we're getting into this area at all, which I've  
02:06 5 objected to, but to the extent we are, we just want to put in  
6 the rebuttal testimony.

7 MR. HASFORD: Your Honor, we disagree with it. The  
8 rebuttal testimony from Mr. Hoffman that they've been  
9 discussing is not responsive to Dr. Williams' testimony, this  
02:06 10 goes toward copying, this does not go toward the issues that  
11 they've stated.

12 I'll just note for the record that Mr. Mukerjee's  
13 explanation, of course, is not testimony and is not in  
14 evidence.

02:06 15 MS. HOLLAND: That's the point.

16 MR. MUKERJEE: Mr. Hasford can't have it both ways.  
17 He can't have it both ways. He can't on the one hand cite to  
18 my opening as a basis to try to bring this testimony in for  
19 Dr. Williams and then on the other hand say, well, that's not  
02:07 20 testimony, that's not evidence. I agree that opening  
21 statements are not part of evidence *per se*, there's no dispute  
22 there.

23 But to the extent that now plaintiffs are trying to  
24 bring in Dr. Williams to testify on generic Bromday®, well,  
02:07 25 yes, Ms. Holland is exactly right, then we do need to bring in

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1 think what I mentioned to your Honor during the opening, is  
2 that when plaintiff systematically discontinued the prior  
3 formulations like Xibrom® and Bromday® in favor of a new  
4 product, in this case let's say Prolensa, four months after  
02:05 5 Prolensa is introduced they discontinued Bromday®. As a  
6 result of that discontinuance, what happened was there was no  
7 ability anymore to have automatic substitution. So that  
8 generic Bromday® that might be out there in effect really has  
9 no real way of getting to the consumer because the way the  
02:05 10 generic actually goes into the consumer's hand, and the way  
11 Hatch-Waxman Act was designed itself, it needs that automatic  
12 substitution to be a driving force for getting that generic.

13 THE COURT: But apparently this witness wants to  
14 offer his observation that there's \$100 million in product  
02:05 15 revenues.

16 MR. MUKERJEE: With respect to Prolensa, \$100 million  
17 with respect to Prolensa, which, again, goes to what  
18 Ms. Holland is saying, that's a backdoor way of getting in  
19 commercial success.

02:05 20 MS. HOLLAND: Which has been dropped from the case.

21 MR. MUKERJEE: Which has been dropped from that case.

22 MS. HOLLAND: All I'm asking, your Honor, is that we  
23 have a chance to put on rebuttal testimony if this comes in.  
24 I think the rebuttal testimony would show indeed the generic  
02:06 25 versions of Bromday® have not been successful in the market

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1 Mr. Hoffman to at least say, well, generic Bromday®  
2 effectively is zero in the marketplace and that's because it's  
3 no longer amenable to automatic substitution.

4 MR. HASFORD: And, your Honor, I note that their  
02:07 5 experts are saying that Prolensa is no better than Bromday®.  
6 All we're using this document to show is generic Bromday® is  
7 out there, we're not pointing to the \$100 million statement in  
8 the document.

9 MS. HOLLAND: Then what is the relevance?

02:07 10 MR. MUKERJEE: Right.

11 MR. HASFORD: I have already explained the relevance,  
12 your Honor, that the generic Bromday® is out there. It's not  
13 that there's -- it's not the allegations that Ms. Holland and  
14 that Mr. Mukerjee are trying to make.

02:08 15 MS. HOLLAND: So the fact it's out there has to be --  
16 for that fact to be relevant there has to be some testimony of  
17 nexus between that and the sales of the product in market, I  
18 guess which is out of the case now. But the fact on its own  
19 has no relevance, the only relevance is how it relates to the

02:08 20 issue of secondary consideration. And that is exactly what  
21 Mr. Hoffman would respond to, why this statement in this  
22 document is not relevant to secondary consideration in this  
23 case because of the marketplace. And Mr. Hoffman has detailed  
24 testimony about that in his expert report. If plaintiffs  
02:08 25 don't want that testimony, then I guess they shouldn't

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1 withdraw the question.  
 2 THE COURT: Well, I'm concerned under Rule 403 that  
 3 this is going to be undue consumption of time even if in some  
 4 fashion it might be admissible. Certainly Dr. Williams is not  
 02:08 5 an expert on copying. Nor is he an expert on the markets, as  
 6 far as I know. And what he's relying on here is some sort of  
 7 an analyst's report in the trade data about the existence of  
 8 products that aren't before me in this case, the so-called  
 9 generic Bronuck®.  
 02:09 10 And so it's also not clear that this portion of  
 11 Dr. Williams' original expert report pertains to any issue  
 12 that remains in the case. It seems that it's directed more  
 13 toward the commercial success and the projection of success  
 14 that this analyst is making for a Prolensa product.  
 02:10 15 MR. HASFORD: Then we're happy to withdraw the  
 16 document, your Honor.  
 17 THE COURT: All right. And if it's questioned on  
 18 cross, again, it could be the door is open. But I'll sustain  
 19 the objection for two reasons: That it predominantly relates  
 02:10 20 to issues that are no longer in the case and, second, the  
 21 underlying source is not terribly probative and, third, it  
 22 would probably cause the defendants to rightly claim that they  
 23 should be able to put a witness on the stand to rebut it. So  
 24 I'll sustain the objection under both the scope of the  
 02:10 25 expert's testimony and also Rule 403.

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1 THE COURT: Be seated, please.  
 2 Mr. Hasford, you may proceed.  
 3 MR. HASFORD: Thank you, your Honor.  
 4 BY MR. HASFORD:  
 02:28 5 Q. Let's now turn to Dr. Lawrence's opinions regarding  
 6 obviousness-type double patenting. Would you please turn to  
 7 JTX-2 in your binder and identify this document?  
 8 A. **JTX-2 is a copy of U.S. Patent 8,669,290.**  
 9 Q. And if I refer to JTX-2 as the '290 patent, will you  
 02:29 10 understand what I mean?  
 11 A. **Yes.**  
 12 Q. Will you please turn to JTX-3 in your binder and identify  
 13 this document.  
 14 A. **JTX-3 is a copy of U.S. 8,754,131.**  
 02:29 15 Q. And I refer to JTX-3 as the '131 patent, will you  
 16 understand what I mean?  
 17 A. **I will.**  
 18 Q. Did you hear Dr. Lawrence testify that the subject matter  
 19 of Claims 6 and 20 of the '431 patent allegedly would have  
 02:29 20 been rendered obvious by Claim 7 of the '290 patent?  
 21 A. **I heard that, yes.**  
 22 Q. Do you agree with Dr. Lawrence's opinion?  
 23 A. **I don't, no.**  
 24 Q. Did you hear Dr. Lawrence testify that the subject matter  
 02:29 25 of Claims 6 and 20 of the '431 patent allegedly would have

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1 MS. HOLLAND: Can I ask, your Honor, that any  
 2 testimony about the document that's come in already be  
 3 stricken?  
 4 THE COURT: Let's see, I don't think we've heard any  
 02:11 5 testimony about this yet, have we?  
 6 MS. HOLLAND: I think we have.  
 7 MR. HASFORD: I think we just heard, your Honor, that  
 8 it's an HBSC report that was on Lupin's website, and then we  
 9 heard about the generic versions of Bromday®, and then there  
 02:11 10 was the objection.  
 11 MS. HOLLAND: Those were actually read into the  
 12 record and testified about so, your Honor, I'd ask that that  
 13 testimony be stricken, since the document is not going to be  
 14 admissible.  
 02:11 15 MR. MUKERJEE: Right.  
 16 THE COURT: All right. Consistent with my ruling, I  
 17 would have to strike the references to JTX-12, that is the  
 18 document that appeared on the Lupin website, and so that will  
 19 no longer be under consideration in the case.  
 02:11 20 Is this a good time for a break?  
 21 MR. HASFORD: Certainly, your Honor.  
 22 THE COURT: So let's take about a 15-minute break and  
 23 then we'll resume at 11:55.  
 24 (Brief Recess.)  
 02:28 25 DEPUTY CLERK: All rise.

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1 been represented obvious by Claim 6 of the '131 patent?  
 2 A. **Yes.**  
 3 Q. Do you agree with Dr. Lawrence's opinion?  
 4 A. **I don't.**  
 02:29 5 Q. Let's explore the basis for your disagreement.  
 6 Have you prepared a demonstrative comparing Claim 6 of  
 7 the '431 patent and Claim 7 of the '290 patent?  
 8 A. **Yes.**  
 9 Q. Let me direct your attention to PDX4-11 on the screen.  
 02:30 10 MR. HASFORD: And let's highlight the "consisting  
 11 essentially of" in Claim 7 of the '290 patent.  
 12 BY MR. HASFORD:  
 13 Q. Do you see that Claim 7 of the '290 patent recites the  
 14 transition phrase "consisting essentially of"?  
 15 A. **I do.**  
 16 Q. Are you aware that the Court has construed the phrase  
 17 "consisting essentially of" in the claims of the '290 patent?  
 18 A. **I'm aware of that, yes.**  
 19 Q. And what is your understanding of the Court's phrase  
 02:30 20 "consisting essentially of" in the claims of the '290 patent?  
 21 A. **My understanding is that the phrase "consisting  
 22 essentially of" means that the listed ingredients, as well as  
 23 any unlisted ingredients. Unlisted ingredients are extra  
 24 additives that can be added so long as they do not materially  
 02:30 25 affect the basic and novel property of the claimed**

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1 preparation.

2 Q. So do you see that Claim 7 of the '290 patent recites

3 benzalkonium chloride?

4 A. Yes.

02:31 5 Q. Is benzalkonium chloride a quaternary ammonium compound?

6 A. It is.

7 Q. Would a person of ordinary skill in the art understand

8 that Claim 7 of the '290 patent is also open to additional

9 quaternary ammonium compounds other than the benzalkonium

02:31 10 chloride specified in the claims?

11 A. Yes, a person of ordinary skill in the art would

12 understand that because benzalkonium chloride is listed so it

13 must be present and then the use of "consisting essentially

14 of" phrase.

02:31 15 Q. Are suitable quaternary ammonium -- strike that and let

16 me try again.

17 Are suitable quaternary ammonium compounds other than

18 benzalkonium chloride also disclosed in the art?

19 A. They are, yes.

02:31 20 Q. Would the addition of a second quaternary ammonium

21 compound to the aqueous liquid preparation of Claim 7 of the

22 '290 patent be expected to materially impact the claimed

23 composition's basic and novel properties?

24 A. Not in my opinion, no.

02:32 25 Q. Please turn back in your binder to JTX-71, which is the

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1 Q. Do you see that Claim 6 of the '131 patent also recites

2 benzalkonium chloride?

3 A. Yes.

4 Q. Would a person of ordinary skill in the art understand

02:33 5 that Claim 6 of the '131 patent is also open to additional

6 quaternary ammonium compounds other than the benzalkonium

7 chloride specified in the claim?

8 A. They would, for the same reasons I just testified to.

9 Q. Let me now direct your attention to the wherein clause at

02:34 10 the end of Claim 6 of the '431 patent.

11 MR. HASFORD: And let's actually put back the

12 previous slide PDX11 that compares Claim 6 of the '431 patent

13 to Claim 7 of the '290 patent. Let's highlight the wherein

14 clause. I apologize, highlight the bottom clause, the "where

02:34 15 a quaternary ammonium compound."

16 BY MR. HASFORD:

17 Q. Why, if at all, would a preparation of Claim 7 of the

18 '290 patent or a preparation Claim 6 of the '131 patent that

19 could include an additional quaternary ammonium compound

02:34 20 besides benzalkonium chloride fall outside the scope of Claim

21 6 of the '431 patent?

22 A. So Claim 6 where it's highlighted, it says, wherein --

23 and should say when instead of where. When a quaternary

24 ammonium compound is included in said liquid preparation, the

02:35 25 quaternary ammonium compound is benzalkonium chloride. So

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1 Sallmann '913 patent. Let me direct your attention to Column

2 5, Lines 30 through 32, of the Sallmann '913 patent. What

3 does Column 5, Lines 30 to 32, of the Sallmann '913 patent

4 disclose?

02:32 5 A. So here Sallmann discloses examples of preservatives, and

6 the first class is quaternary ammonium salts. And then

7 examples include cetrime, benzalkonium chloride, or

8 benzoxonium chloride.

9 Q. How, if at all, Column 5, Lines 30 to 32, of the Sallmann

02:32 10 '913 patent support your opinion that Claim 7 of the '290

11 patent is also open to additional quaternary ammonium

12 compounds other than the benzalkonium chloride specified in

13 the claims?

14 A. It supports my opinion because these are examples that a

02:33 15 person of ordinary skill in the art could consider as

16 additional quaternary ammonium compounds that could be added

17 without affecting the basic and novel properties of the

18 Claim 7.

19 Q. Have you prepared a demonstrative comparing Claim 6 of

02:33 20 the '431 patent and Claim 6 of the '131 patent?

21 A. Yes, I have.

22 Q. Let me direct your attention to PDX4-13 on the screen.

23 Do you see that Claim 6 of the '131 patent also recites the

24 transition phrase "consisting essentially of"?

02:33 25 A. Yes.

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1 this would be understood by a skilled person to mean that

2 there doesn't necessarily have to be a quaternary ammonium

3 compound, but when there is one, it has to be benzalkonium

4 chloride. That's a different scope of the claim compared to

02:35 5 Claim 7 of the '290 patent.

6 Q. Have you also prepared demonstrative PDX4-12 comparing

7 Claim 20 of the '431 patent and Claim 7 of the '290 patent?

8 A. I have, yes.

9 Q. Have you also prepared demonstrative PDX4-14 comparing

02:35 10 Claim 20 of the '431 patent and Claim 6 of the '131 patent?

11 A. Yes, I have.

12 Q. Let me direct your attention to the bottom clause in

13 Claim 20 of the '431 patent.

14 MR. HASFORD: If we could highlight that, please.

15 BY MR. HASFORD:

16 Q. Why, if at all, would a preparation of Claim 7 of the

17 '290 patent or a preparation of Claim 6 of the '131 patent

18 that could include an additional quaternary ammonium compound

19 besides benzalkonium chloride fall outside the scope of Claim

02:36 20 20 of the '431 patent?

21 A. So the reason is because a person of ordinary skill in

22 the art understanding Claim 20, so in the list of the aqueous

23 liquid preparation of Claim 20 of the '431 patent, it

24 specifically says benzalkonium chloride. At the end of Claim

02:36 25 20 it says benzalkonium chloride is the only quaternary

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1 ammonium compound which is included in said liquid  
 2 preparation, so in my opinion one of skill in the art would  
 3 understand that the Claim 20 of the '431 patent can only  
 4 contain the quaternary ammonium compound benzalkonium chloride  
 02:37 5 whereas Claim 6 of the '131 patent could contain other  
 6 quaternary ammonium compounds besides benzalkonium chloride.  
 7 Q. Would that opinion apply also to Claim 7 of the '290  
 8 patent?  
 9 A. It would, yes.  
 02:37 10 Q. Did you also hear Dr. Lawrence testify that the claimed  
 11 amount of tyloxapal of 0.02 weight per volume percent in  
 12 Claims 6 and 20 of the '431 patent is allegedly obvious in  
 13 light of Claim 7 of the '290 patent and Claim 6 of the '131  
 14 patent?  
 02:37 15 A. I heard that.  
 16 Q. Do you agree with Dr. Lawrence?  
 17 A. I do not.  
 18 Q. Why not?  
 19 A. Because in Claim 20 of the '431 patent, for example, that  
 02:38 20 claim specifically limits tyloxapal to having a concentration  
 21 of about .02 percent by weight, whereas Claim 6 of the '131  
 22 patent has tyloxapal in an amount sufficient to stabilize  
 23 bromfenac sodium salt. And then it says at the bottom,  
 24 wherein the concentration of tyloxapal is from about  
 02:38 25 .01 percent by weight to about .05 percent by weight. So in

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1 my opinion, one of ordinary skill in the art would understand  
 2 the scope of those claims regarding tyloxapal is different.  
 3 Q. And would your opinion regarding Claim 20 of the '431  
 4 patent with respect to Claim 6 of the '131 patent also be the  
 02:38 5 same if you applied Claim 7 of the '290 patent to Claim 20 of  
 6 the '431 patent?  
 7 A. It would be, yes.  
 8 Q. And would your opinions in this regard regarding Claim 20  
 9 of the '431 patent also apply to Claim 6 of the '431 patent?  
 02:39 10 A. Yes.  
 11 MR. HASFORD: Nothing further at this time, your  
 12 Honor. I will move the exhibits into evidence that we used  
 13 with Dr. Williams.  
 14 THE COURT: Okay. Could you read those into the  
 02:39 15 record?  
 16 MR. HASFORD: Yes. They'll be PTX-294, PTX-268,  
 17 PTX-272, PTX-326, PTX-273, PTX-324, PTX-265, PTX-591, PTX-592,  
 18 PTX-50093, JTX-144, PTX-40074, and JTX-18.  
 19 THE COURT: Is there any objection to those?  
 02:40 20 MS. HOLLAND: Your Honor, we would like to have an  
 21 opportunity to go through the list and maybe come back after  
 22 lunch and just confirm whether we have any objections.  
 23 THE COURT: Yes, you may.  
 24 MS. HOLLAND: Thank you.  
 02:40 25 THE COURT: Ready for cross-examination?

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1 MS. HOLLAND: Yes, your Honor.  
 2 THE COURT: Okay. You may proceed.  
 3 (CROSS-EXAMINATION OF ROBERT O. WILLIAMS BY MS. HOLLAND:)  
 4 Q. Good afternoon, Dr. Williams.  
 02:40 5 A. Good afternoon.  
 6 Q. Dr. Williams, you provided opinions in your direct  
 7 examination about ophthalmic drug formulations, correct?  
 8 A. Yes.  
 9 Q. Okay. And you testified in substance that formulation of  
 02:40 10 ophthalmic drugs is particularly complex, is that right?  
 11 A. The ophthalmic solutions, they are, yes.  
 12 Q. But you have only been involved in ophthalmic formulation  
 13 on two occasions in your entire career, isn't that right,  
 14 Doctor?  
 02:41 15 A. Two solutions for ophthalmic, that's true.  
 16 Q. Okay. And you didn't consult any references on  
 17 ophthalmic drug delivery in rendering your opinions in this  
 18 case, correct?  
 19 A. Well, I mean, I have -- I teach a subject on ophthalmic  
 02:41 20 solution but I didn't particularly look to -- in preparing for  
 21 this case look to -- I didn't go search for any, that's true.  
 22 Q. Okay. So it's true that you did not consult any  
 23 references in ophthalmic drug delivery in rendering your  
 24 opinions in this case?  
 02:41 25 A. I did not go consult any specifically for this case, no.

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1 Q. Okay. Thank you.  
 2 Now, you were asked on direct about some testimony that  
 3 Dr. Lawrence gave, and I'm going to quote you what the  
 4 question was. You were asked whether you agree with  
 02:42 5 Dr. Lawrence's testimony that "pharmaceutical formulation  
 6 development allegedly constituted routine optimization." Do  
 7 you recall being asked that question?  
 8 A. Generally, yes.  
 9 Q. Dr. Lawrence never testified that all pharmaceutical  
 02:42 10 formulation development was a matter of routine optimization,  
 11 did she?  
 12 A. I understood her in the context of ophthalmic  
 13 preparations that are the subject matter here, which was what  
 14 I was responding to.  
 02:42 15 Q. But she never give that testimony either, Doctor.  
 16 Didn't Dr. Lawrence testify -- well, let me withdraw  
 17 that.  
 18 Wasn't Dr. Lawrence's focus on how a formulator  
 19 determines concentration of an excipient to use in the  
 02:42 20 formulation, do you recall that that was the context of her  
 21 testimony on routine optimization?  
 22 A. I did, and that's what I disagree with.  
 23 Q. Okay. Now, Dr. Lawrence testified that a formulator  
 24 would prepare a range of concentrations of different  
 02:43 25 excipients in the formulation and test them to determine which

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1 concentration to use. Do you recall that testimony?  
 2 **A. Generally, yes.**  
 3 **Q. Okay. And you agree that that's a procedure formulators**  
 4 **use, right?**  
 02:43 5 **A. That's one in the steps of what a formulator would do to**  
 6 **try to solve whatever problem is faced -- being faced.**  
 7 **Q. And that procedure or process is generally called**  
 8 **optimization, right?**  
 9 **A. Well, I disagree it's generally called optimization. I**  
 02:43 10 **mean, there's a statistical optimization that we use where you**  
 11 **look at the variables that are being studied. But, I mean,**  
 12 **sometimes it might be called optimization. Routine is**  
 13 **definitely not part of the phrase.**  
 14 **Q. I just want to make sure we're not talking about**  
 02:43 15 **semantics here.**  
 16 **So would you agree with me that the process**  
 17 **Dr. Lawrence described is sometimes called optimization but**  
 18 **your quarrel is with the word routine?**  
 19 **A. That's probably right.**  
 02:44 20 **Q. Okay. Now, would you agree that there are some aspects**  
 21 **of formulation that are a matter of routine optimization?**  
 22 **A. Some probably would be considered routine, yes.**  
 23 **Q. And there are some aspects of formulation that you'd say**  
 24 **are routine experimentation, right?**  
 02:44 25 **A. Some would be. Towards the end of the development cycle**

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1 **Q. Okay. And what the text of the '431 patent says is that**  
 2 **the formulations can contain, for example, the minimum content**  
 3 **of about .01 percent, .02 percent, or .03 percent tyloxapol**  
 4 **and the maximum content about .05, .1 percent, .3 percent, or**  
 02:46 5 **.5 percent tyloxapol. Do you see that?**  
 6 **A. Yes.**  
 7 **Q. And the '431 patent is disclosing that that concentration**  
 8 **would fall within the claimed inventions in this case, right?**  
 9 **MR. HASFORD: Objection, mischaracterizes the**  
 02:46 10 **document, your Honor. Claims 6 and 20 plainly specify .02**  
 11 **weight by volume percent tyloxapol.**  
 12 **THE COURT: For Claims 6 and 20.**  
 13 **MS. HOLLAND: I'll ask a broader question, your**  
 14 **Honor.**  
 02:46 15 **MR. HASFORD: Well, the way she phrased it**  
 16 **mischaracterizes the document, your Honor.**  
 17 **THE COURT: Please reframe the question.**  
 18 **MS. HOLLAND: I'll reframe it, your Honor.**  
 19 **BY MS. HOLLAND:**  
 02:47 20 **Q. Doctor, does the specification indicate in the disclosure**  
 21 **of the invention that a range of tyloxapol from about**  
 22 **.01 percent through to about .5 percent would be sufficient to**  
 23 **be within the disclosure of the '431 patent?**  
 24 **A. So, I mean, generally speaking that's what this patch**  
 02:47 25 **says in the '431 patent.**

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1 **they would be.**  
 2 **Q. All right. Now, the two claims that remain in this case**  
 3 **require .02 percent tyloxapol, right?**  
 4 **A. They do, yes.**  
 02:44 5 **Q. And you testified that a formulation with .02 percent**  
 6 **tyloxapol is stable, right?**  
 7 **A. Well, according to the data in the patent tested under**  
 8 **those conditions, a formulation with .2 percent tyloxapol is**  
 9 **chemically stable, so, yes.**  
 02:45 10 **Q. It's chemically and physically stable, right?**  
 11 **A. Well, I mean, it would be physically stable because**  
 12 **nothing was reported in the patent as to any kind of**  
 13 **cloudiness or turbid.**  
 14 **Q. Now, isn't it correct that the formulations with the**  
 02:45 15 **ingredients in Claim 6 and 20 would still be stable even if a**  
 16 **higher amount of tyloxapol were used?**  
 17 **A. They might be chemically stable. They might be.**  
 18 **Q. All right. Well, let's be sure. Let's look at the '431**  
 19 **patent.**  
 02:45 20 **A. Okay.**  
 21 **Q. We put up JTX-1. Let's go to Column 5, Lines 41 to 47.**  
 22 **And do you see, Doctor, that that portion of the patent talks**  
 23 **about tyloxapol content of the inventions claimed in the**  
 24 **patent?**  
 02:46 25 **A. Yes.**

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1 **Q. So at least the specification doesn't indicate that you**  
 2 **must have .02 percent to have a stable formulation, right?**  
 3 **A. I mean, this part of the specification states that at a**  
 4 **minimum about .01 percent and then up to about .5 percent by**  
 02:48 5 **weight.**  
 6 **Q. Then if you go to Table 2 in Column 8, there are three**  
 7 **different tyloxapol concentrations listed for formulations**  
 8 **A-04, A-05 and A-06. Do you see that?**  
 9 **A. I do, yes.**  
 02:48 10 **Q. And those are .02 grams and .05 grams, and .03 grams. Do**  
 11 **you see that?**  
 12 **A. As the amount, and so it's to .02, .05, and .03 percent**  
 13 **by weight.**  
 14 **Q. And Table 2 indicates that all three of those**  
 02:48 15 **concentrations of tyloxapol led to stable formulations,**  
 16 **correct?**  
 17 **A. That's true, yes.**  
 18 **Q. Now, another part of what a skilled person does in**  
 19 **formulation development is look at the compatibility amongst**  
 02:49 20 **different components of the formulation, right?**  
 21 **A. That's true.**  
 22 **Q. Okay. And that's a standard part of the formulation**  
 23 **process?**  
 24 **A. That's probably more part of the pre-formulation process.**  
 02:49 25 **But on continuum, the excipient compatibility between**

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1 themselves or between the particular excipient and the active  
 2 drug, those are done, yes.  
 3 Q. As a standard matter in every formulation, right?  
 4 A. I mean, from my experience, they are done when one is  
 02:49 5 coming up with a formulation for a particular drug substance.  
 6 Q. Okay. So if a skilled person were going to formulate  
 7 bromfenac sodium, for example, together with BAC, they would  
 8 look to see whether there was an interaction between the two  
 9 just as a matter of standard formulation development, is that  
 02:50 10 right?  
 11 A. I think when a skilled person is studying formulations  
 12 containing bromfenac sodium, they're going to look at each of  
 13 the excipients and in combination together to see if there's  
 14 any type of chemical or physical interaction generally from my  
 02:50 15 experience.  
 16 Q. Now, you've given the opinion in this case that the goal  
 17 behind -- well, let me withdraw that.  
 18 Is it your opinion that the goal behind any  
 19 substitution or modification of Ogawa Example 6 would have  
 02:50 20 been to improve upon the formulation's stability?  
 21 A. Say that again, please?  
 22 Q. Yeah, sure.  
 23 Is it your opinion that the goal behind any  
 24 substitution or modification of Ogawa Example 6 would have  
 02:51 25 been to improve upon the formulation's stability?

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1 MR. HASFORD: Just for completeness, your Honor, can  
 2 we have the next sentence of that paragraph read in, please?  
 3 THE COURT: Yes, it may.  
 4 BY MS. HOLLAND:  
 02:52 5 Q. The next sentence reads, a person of ordinary skill in  
 6 the art would not have pursued excipients that would not be  
 7 accepted to have any effect on or would lessen the stability  
 8 benchmark set for Ogawa Example 6.  
 9 MR. HASFORD: I apologize, your Honor. We might have  
 02:53 10 to have the previous sentence to place it in proper context.  
 11 MS. HOLLAND: Your Honor, would you like me to do  
 12 that?  
 13 THE COURT: Well, the witness can read the whole  
 14 paragraph to himself.  
 02:53 15 MS. HOLLAND: Thank you.  
 16 THE WITNESS: Okay. I've read it.  
 17 BY MS. HOLLAND:  
 18 Q. Now, you testified previously that there are two types of  
 19 stability, chemical and physical, right?  
 02:53 20 A. That's true.  
 21 Q. And so potentially the goal behind any substitution or  
 22 modification of Ogawa Example 6 could be to improve either  
 23 chemical or physical stability, right, those are both  
 24 possibilities?  
 02:53 25 A. I mean, Ogawa doesn't talk about physical stability, but

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1 A. I think that's right, yes. To turn it around the other  
 2 way, which I think is what I said, there's no motivation that  
 3 I see because Ogawa Example 6 is stable in Ogawa, so I think  
 4 that's how I had answered the question.  
 02:51 5 MS. HOLLAND: Well, let me see if I can -- do we have  
 6 back Dr. Williams' expert reports for him? Thank you.  
 7 BY MS. HOLLAND:  
 8 Q. First I'll just see if I can refresh your recollection.  
 9 MS. HOLLAND: Counsel, it's in Paragraph 86 of his  
 02:51 10 responsive report.  
 11 MR. HASFORD: Actually, do you have an extra copy?  
 12 THE WITNESS: Thank you.  
 13 Paragraph 86?  
 14 MS. HOLLAND: Yes.  
 15 BY MS. HOLLAND:  
 16 Q. I'm referring to Paragraph 86.  
 17 MS. HOLLAND: And can we highlight the sentence that  
 18 begins "the goal behind," it's like four lines up from the  
 19 bottom.  
 02:52 20 THE WITNESS: Yes, I see it.  
 21 BY MS. HOLLAND:  
 22 Q. Okay. Does that refresh your recollection that you  
 23 offered an opinion that the goal behind any substitution or  
 24 modification of Ogawa Example 6 would have been to improve the  
 02:52 25 formulation's stability?

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1 if assuming you had a reason to modify it, which I'm not  
 2 saying you do, but if you did, if you were making a  
 3 substitution, you would consider stability as a whole, which  
 4 would mean chemical and physical.  
 02:54 5 Q. And just to be clear, in your opinion a change in  
 6 appearance of a formulation is a problem of physical  
 7 stability, correct?  
 8 A. If it's related to -- yeah, I think generally that's  
 9 right.  
 02:54 10 Q. All right. Let's go to the Ogawa '225 patent, JTX-147.  
 11 And I'm going to refer you back to something you talked about  
 12 in your direct testimony, it's Table 8 in Columns 13 and 14.  
 13 So let's go back there.  
 14 Do you recall talking about this in your direct  
 02:55 15 testimony?  
 16 A. I do, yes.  
 17 Q. And you talked about it, I believe, in the context of  
 18 unexpected results, is that right?  
 19 A. I believe so.  
 02:55 20 Q. Okay. Now, if you look at Table 8, you focused on the  
 21 column that says residue percent and you said that that  
 22 reflected chemical stability, right?  
 23 A. That's true, yes.  
 24 Q. Now, if you look just one column over to the left, you'll  
 02:55 25 see a column for appearance. Do you see that?

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1 A. Yes.

2 Q. And appearance, as we just heard, speaks to physical  
3 stability, right?

4 A. Well, Ogawa says there's red insoluble matter, which  
02:55 5 is -- I think to me and to a person of ordinary skill in the  
6 art that's chemical stability, so --

7 Q. Well, there's nothing in the appearance column that would  
8 take you away from the general view that you've expressed that  
9 appearance relates to physical stability, right?

02:56 10 A. Well, but if you go back to experimental Example 4, which  
11 is the basis for Table 8, Ogawa is talking about the change in  
12 residue was almost non-observed but in three weeks red  
13 insoluble matters were observed, so that red insoluble matter  
14 that's -- the degradation product apparently is not soluble so  
02:56 15 it's precipitated out.

16 Q. And so you're saying that appearance there does not refer  
17 to physical stability, is that your opinion?

18 A. Well, it starts as a chemical because he's explaining  
19 it's a red insoluble, insoluble means whatever that  
02:56 20 degradation product is, it's coming out of solution and so  
21 that is -- that then becomes a physical because it's --  
22 there's something that's not dissolved.

23 Q. So now you agree with me that the appearance column there  
24 refers to physical stability, right?

02:57 25 A. Well, it says -- yeah. I just think in the context of  
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1 Q. Yeah, exactly my point. So there is a seeming  
2 inconsistency there, correct?

3 A. Well, okay. I mean it says in the spec that -- with  
4 regards to Experimental Example 4, it describes at three weeks  
03:00 5 there is red insoluble matter, so degradation of bromfenac,  
6 but it apparently wasn't enough to attain a positive sign on  
7 the appearance column is the way I've reconciled it.

8 Q. But isn't there another explanation for this,  
9 Dr. Williams?

03:00 10 A. Okay. What --

11 Q. Isn't another possible explanation that the appearance  
12 column here, what they're looking at, is cloudiness or  
13 turbidity as in -- as you've previously testified, would be  
14 indicative of lack of physical stability.

03:00 15 A. Yeah, I mean, in the context of Ogawa, I don't think  
16 that's a possibility. I think Ogawa is talking about  
17 insoluble degradation product because it calls it this red  
18 insoluble matter." It doesn't talk about physical stability.

19 Q. And that's even though there is an inconsistency between  
03:00 20 the language in the Experimental Example 4 and Table 8, the  
21 way you've interpreted it?

22 A. I'm -- I didn't say there was an inconsistency. It's  
23 just that's the way that it's presented, it's worded in  
24 Experimental Example 4. It describes the red insoluble matter  
03:01 25 after three weeks, and then that's how it's reported in Table  
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1 Ogawa appearance is talking about the red insoluble matter, so  
2 it's the degradation product that's coming out of solution.

3 Q. All right. But let's see. Go back to Experimental  
4 Example 4. It says, in -- do you see there are two paragraphs  
02:58 5 under the actual example, and it says, "of the above four," do  
6 you see that?

7 A. Yes.

8 Q. And then it says, in the formula, "the change in residue  
9 rate were not almost observed but in three weeks red insoluble  
02:58 10 matters were observed," right?

11 A. That's what it says, yes.

12 Q. Okay. But if you look at -- and that's just -- one more  
13 time, I'm sorry -- that's going back and it's -- it refers to  
14 pH of 8, right? It says of the above four, the formula with  
02:58 15 the pH of 8 is most stable?

16 A. Yeah, the first sentence of that paragraph in column 8  
17 says, the formula at the pH of 8 is most stable.

18 Q. Okay. So let's go back to Table 8 then. If you look at  
19 a pH -- for pH of 8, there is no change in appearance, right?

02:59 20 A. Well, I mean, there's -- there's a negative dash symbol  
21 that, according to Ogawa in Table 8, change in appearance was  
22 not observed, but in the paragraph, Ogawa states that no  
23 change -- sorry -- it says in the formula, "the change in  
24 residue rate were not almost observed but in three weeks red  
02:59 25 insoluble matters were observed."  
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1 8.

2 Q. All right. Now, you testified that sodium sulfite and  
3 povidone were used in the Ogawa '225 formulations to improve  
4 chemical stability, right?

03:01 5 A. That's true, yes.

6 Q. Okay. And then -- and you said that the problem of  
7 chemical stability was solved by the use of sodium sulfite and  
8 povidone, right?

9 A. Within the pH range that Ogawa specifies.

03:01 10 Q. Okay. But, as we've already discussed in your testimony,  
11 if there were a problem with bromfenac forming a precipitate  
12 with BAC, that would be a problem of physical stability, not  
13 chemical stability, right?

14 A. Say that again, please.

03:01 15 Q. Yeah.

16 If there were a problem with bromfenac forming a  
17 precipitate with BAC in a solution, that would be a problem of  
18 physical stability, right, not chemical stability?

19 A. If that occurred, that would be a physical stability.

03:02 20 Q. And sodium sulfite and povidone wouldn't address that  
21 physical stability issue, right?

22 A. From my experience, that's probably true.

23 I'm not sure about PVP. PVP may have some effect or  
24 not. I think the sodium sulfite is there as an antioxidant  
03:02 25 for degradation. I'd have to think about the PVP.  
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1 Q. Okay. And you -- I apologize.  
 2 And in your testimony, you said that the Fu 984  
 3 reference was focused on physical stability, right?  
 4 A. True, yes.  
 03:02 5 Q. So is it fair to say that a person of ordinary skill in  
 6 the art concerned about the physical stability of a  
 7 formulation would look at the Fu reference?  
 8 A. They might, if -- if they could learn about Octoxynol 40  
 9 and its effect on the physical stability, yes.  
 03:03 10 Q. Now, I want to talk about a different ingredient used in  
 11 Example 6 of Ogawa '225 patent, and that's Polysorbate 80.  
 12 Now, one of the known functions of Polysorbate 80 is as  
 13 a physical stabilizer, right?  
 14 A. That's true, yes.  
 03:03 15 Q. Okay. And another term for physical stabilizer is  
 16 solubilizer?  
 17 A. No, I disagree with you.  
 18 Q. Does a physical stabilizer -- is it used to solubilize  
 19 things in solution?  
 03:03 20 A. Well, I'm missing something in your question. Sorry.  
 21 Q. Okay. A physical stabilizer like Polysorbate 80 is used  
 22 in connection with things that are not soluble in water,  
 23 right?  
 24 A. That's true. That's like a suspension, an emulsion,  
 03:03 25 that's true. So it's a physical stabilization of the

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1 Q. Let's explore that.  
 2 So, you agree with me that your reasoning for why  
 3 Polysorbate 80 is not used as a physical stabilizer in Ogawa  
 4 is that bromfenac sodium is already freely water soluble so  
 03:05 5 you don't need a solubilizer; is that right?  
 6 A. I'm sorry. I'm hearing solubilizer and stabilizer, and  
 7 they're different to me, and I want to make sure I get your  
 8 question.  
 9 Q. Right. So -- all right. Let me try it this way then.  
 03:05 10 You said that bromfenac sodium is freely water soluble,  
 11 right?  
 12 A. It is, yes.  
 13 Q. And you gave that as a reason for knowing that  
 14 Polysorbate 80 was not in Example 6 of Ogawa to address  
 03:06 15 solubility issues, right?  
 16 A. That's true, yes.  
 17 Q. Correct. But just to be clear here, if a complex forms  
 18 between bromfenac and BAC, its solubility would be different  
 19 from the solubility of bromfenac sodium, right?  
 03:06 20 A. I actually don't -- I don't know. It may. It depends on  
 21 the characteristics of the complex that's formed.  
 22 Q. Okay. But your opinion that bromfenac sodium is freely  
 23 water soluble would not necessarily be relevant to a complex  
 24 that forms between bromfenac and BAC, right?  
 03:06 25 A. That's true. It wouldn't.

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1 suspension or the emulsion, as example.  
 2 Q. Or an aqueous dispersion?  
 3 A. Aqueous dispersion as in suspension? That would be a  
 4 suspension.  
 03:04 5 Q. All right. Now, you, yourself, have used Polysorbate 80  
 6 as a physical stabilizer, right?  
 7 A. I have, yes.  
 8 Q. But you testified that Polysorbate 80 was not used as a  
 9 physical stabilizer in Example 6 of Ogawa, right?  
 03:04 10 A. Wait. But there's nothing to physically stabilize in  
 11 Example 6 because it's a -- it's a solution.  
 12 Q. Well, let me ask you again.  
 13 You testified that Polysorbate 80 was not used as a  
 14 physical stabilizer in Example 6 of Ogawa, right?  
 03:04 15 A. I don't recall exactly, but I would have, yes.  
 16 Q. Okay. And you said this was because bromfenac sodium is  
 17 freely water soluble, right?  
 18 A. You're asking about physical stabilization?  
 19 Q. Yes.  
 03:05 20 A. I talked about Polysorbate 80 in the context as a  
 21 solubilizer.  
 22 Bromfenac is freely water soluble, so there's no need  
 23 for a solubilizer. And there's nothing dissolved in it, so  
 24 there is also no need -- sorry. There is nothing suspended in  
 03:05 25 it, so there is also no need as a physical stabilizer.

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1 Q. Okay. So, is it at least a possibility that Polysorbate  
 2 80 is used in the '225 formulation to solubilize bromfenac-BAC  
 3 complexes?  
 4 A. I don't know. I mean, there is nothing in the '225 Ogawa  
 03:07 5 patent that would lead one of skill in the art to believe that  
 6 there is a complex formed and that's its function. It doesn't  
 7 ascribe any particular function to Polysorbate 80 in the Ogawa  
 8 patent.  
 9 Q. But you know, don't you, Dr. Williams, why Polysorbate 80  
 03:07 10 was used in Ogawa?  
 11 A. Well, I've testified one use could be as a wetting agent  
 12 because it's an ophthalmic solution.  
 13 Q. Well, didn't you review documents in the course of  
 14 forming your opinions in this case that told you exactly why  
 03:07 15 Polysorbate 80 was used in Ogawa?  
 16 MR. HASFORD: I'll object to the extent she's looking  
 17 to go into plaintiff's internal documents. I think we have  
 18 had -- we have already been down this road, your Honor.  
 19 MS. HOLLAND: Your Honor, there was extensive  
 03:07 20 testimony about unexpected results, A, which is not limited to  
 21 any piece of prior art.  
 22 In addition, the -- Ogawa is actually prior art, so  
 23 nothing in the internal documents could go to the invention in  
 24 this case. It could only go into explaining the prior art.  
 03:08 25 So, for two reasons, I think that the objections that

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1 have previously been raised are not relevant. And I think as  
 2 a matter of impeachment of this witness, I should be permitted  
 3 to ask these questions. These are documents that he actually  
 4 gave opinions on in his report. They're in his direct binder,  
 03:08 5 and I can show you that.  
 6 MR. HASFORD: Your Honor --  
 7 MS. HOLLAND: I would like to know if he -- when he  
 8 gave his opinions to the Court, why didn't he tell the Court  
 9 about what's in the documents in his direct binder that answer  
 03:08 10 this question definitively.  
 11 MR. HASFORD: Your Honor, we presented no evidence  
 12 through Dr. Williams of any of those documents that were in  
 13 his direct binder that she's referring to, and we've already  
 14 explained to your Honor that by statute, obviousness is  
 03:08 15 assessed from a hypothetical person of ordinary skill in the  
 16 art, not the inventor. Patentability shall not be negative by  
 17 the manner in which the invention was made.  
 18 To the extent she's trying to go back and reargue the  
 19 issue that your Honor has already decided, we believe that's  
 03:09 20 improper.  
 21 The Federal Circuit has made clear, time and again,  
 22 that the path that an inventor leads -- the path that leads an  
 23 inventor to the invention was expressly made irrelevant to  
 24 patentability by statute. It's the *Life Tech* Case, 224 F.3d  
 03:09 25 1320.

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1 MS. HOLLAND: In his deposition, your Honor?  
 2 THE COURT: Right.  
 3 MS. HOLLAND: I don't understand the question. I  
 4 apologize.  
 03:10 5 THE COURT: You said that he was -- that in his  
 6 expert report, that he made reliance upon the internal  
 7 documents. Was he questioned about those during his  
 8 deposition and was his testimony inconsistent with what he's  
 9 offering today?  
 03:10 10 MS. HOLLAND: His testimony -- his testimony today is  
 11 that Polysorbate 80 was not used as a physical stabilizer in  
 12 Example 6 of Ogawa, and I have documents to show otherwise,  
 13 that I'd like to impeach the witness with. I feel like it's a  
 14 straightforward married.  
 03:11 15 MR. HASFORD: To the extent these are the inventor's  
 16 own documents, your Honor, again, this does not go toward any  
 17 issue of obviousness. It does not go to the motivation that  
 18 has to be found in the prior art, and we've heard testimony on  
 19 that and there is case law to that effect, your Honor. If  
 03:11 20 she's trying to use this for that purpose, that's completely  
 21 improper.  
 22 MS. HOLLAND: It goes to unexpected results and what  
 23 exactly was meant by stability when Dr. -- when Dr. Williams  
 24 was looking through all these documents and giving testimony  
 03:11 25 about stability. Was it actually physical stability or was it

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1 There was no door opened on direct, there was no  
 2 testimony that would warrant anything to -- for your Honor to  
 3 reconsider that earlier ruling or for Ms. Holland to go into  
 4 this with Dr. Williams now on cross.  
 03:09 5 MS. HOLLAND: Your Honor, it's a completely -- if I  
 6 may, it's a completely different situation. We heard  
 7 extensive testimony this time about unexpected results based  
 8 on plaintiffs' internal testing and documents.  
 9 MR. HASFORD: No, Your Honor. We heard unexpected  
 03:09 10 results based on the patent, and we heard unexpected results  
 11 based on certain data that were stipulated to by defendants,  
 12 but there were no -- there was no testimony provided about  
 13 plaintiff's internal documents. We never showed Dr. Williams  
 14 an internal document on direct exam, we never offered one into  
 03:09 15 evidence, and we didn't provide any -- have Dr. Williams  
 16 provide any testimony on that.  
 17 MS. HOLLAND: Dr. Williams has provided testimony on  
 18 the stand inconsistent with documents that are in his direct  
 19 binder, that plaintiffs chose not to show him today but there  
 03:10 20 surely are opinions on them in his expert report, and he was  
 21 surely ready to testify about them. They are in his direct  
 22 binder.  
 23 THE COURT: Well, has he offered opinions in his  
 24 deposition that are inconsistent with what he's saying today?  
 03:10 25 MR. HASFORD: No.

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1 chemical stability?  
 2 MR. HASFORD: Your Honor --  
 3 MS. HOLLAND: I should be entitled to probe that.  
 4 He offered testimony about internal documents. He  
 03:11 5 said they showed stability. If I -- and he said that showed  
 6 chemical stability. If there are other internal documents  
 7 that show that that is not the case, I don't see why  
 8 Dr. Williams can't be impeached on them.  
 9 MR. HASFORD: Your Honor, these documents are not in  
 03:11 10 the public domain and they do not go at all to how a person of  
 11 ordinary skill in the art would have understood the disclosure  
 12 of the Ogawa '225 patent as of 2003. That's the issue for  
 13 obviousness.  
 14 MS. HOLLAND: I'm talking about unexpected results,  
 03:12 15 counsel. And as you know, Dr. Williams testified on direct  
 16 with internal data to support his unexpected results opinion.  
 17 MR. HASFORD: Your Honor, while --  
 18 THE COURT: Was that the same internal data though  
 19 that's disclosed in the patent?  
 03:12 20 MS. HOLLAND: No. No. It's internal data that was  
 21 from the IPR declaration of Dr. Sawa, who is not here today to  
 22 talk about his internal results.  
 23 MR. HASFORD: Your Honor, there were -- there were  
 24 two or three additional pieces of data that defendants  
 03:12 25 stipulated to in those documents, and they were not -- you

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1 know, those -- so the evidence of unexpected results may, in  
2 fact, come from something that is not in the prior art.  
3 However, the evidence of actual obviousness, the evidence of  
4 whether there would have been a motivation to make this  
03:12 5 claimed invention, needs to be based on what was known in the  
6 prior art, and the attempt in which Ms. Holland is trying to  
7 use this is not to go toward unexpected results but is to try  
8 to go toward a prima facie case of obviousness, and that's  
9 impermissible, your Honor.

03:13 10 MS. HOLLAND: I just said it wasn't, your Honor.  
11 And I can -- I mean Dr. Williams put up, actually  
12 from Mr. Sawa's IPR declaration, little -- I don't remember  
13 the PTX numbers, but they were charts from the declaration  
14 with Mr. Sawa's summarized internal data. Mr. Williams took  
03:13 15 that internal data, he put it into these demonstratives. He  
16 talked about residual bromfenac and that that means chemical  
17 stability, based on the internal documents. We have documents  
18 that show that that's not the case, and that these opinions  
19 that were given about chemical stability are just simply  
03:13 20 incorrect, based on the internal data.

21 THE COURT: And which demonstrative are you holding  
22 up?

23 MS. HOLLAND: Right now I'm looking at PDX4-5.  
24 And, in particular, your Honor, in Paragraph 371 of  
03:14 25 Dr. Williams' opening expert report, he says that the data and  
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1 results that he's presenting come from the specification of  
2 the patents-in-suit and Ogawa and laboratory notebooks of  
3 Mr. Shirou Sawa. That's what I want to ask about.

03:14 4 MR. HASFORD: Your Honor, they're trying to use  
5 this --

6 MS. HOLLAND: Laboratory notebooks that were used in  
7 the direct to support unexpected results.

8 MR. HASFORD: Your Honor, they're trying to back door  
9 this as a way of using it to show how a person of ordinary  
03:14 10 skill in the art would have understood Ogawa, and that's the  
11 impropriety here. It's not proper in an obviousness case, and  
12 your Honor has already ruled to that effect.

13 THE COURT: Well, when I ruled, I didn't know that he  
14 was relying upon that data, the internal data of Sawa from the  
03:14 15 IPR, and that forms the basis or seems to form a basis of his  
16 opinion.

17 I think the witness needs to be asked whether he is  
18 relying upon that data as a basis of his opinion. If he says  
19 he's not, he can be impeached with his prior testimony. If he  
03:15 20 says he is, then I'll permit the questioning on the merits.

21 MR. LIPSEY: Excuse me, your Honor, and I know it's  
22 irregular, but if I may just briefly.

23 There is a fine but important point of patent law  
24 here, and that is, everybody has said and the cases hold that  
03:15 25 the evidence of the properties of the invention and its  
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1 comparative properties and its benefits and advantages, that  
2 evidence does not have to be in the prior art. And that's  
3 basically the *Sanofi-Aventis* case that I think everybody has  
4 been talking about. Patentability may consider all of the  
03:15 5 characteristics possessed by the claimed invention whenever  
6 those characteristics become manifest.

7 And so it's quite common, as we have here, to use  
8 comparative data that was generated which itself is a prior  
9 art, and indeed often may be generated years after the patent  
03:15 10 issues, to demonstrate what the properties of the invention  
11 are, which go to the secondary considerations.

12 Reaching into things that the inventor may have known  
13 that are not in the prior art to try to prove how a person of  
14 ordinary skill in the art would have read that prior art,  
03:16 15 that's an absolutely impermissible use.

16 THE COURT: Well, if your own witness made that use  
17 of it, though, then he can be cross-examined on it. So I'm  
18 permitting the threshold question to be asked of whether he  
19 relied upon such data. If he did, then of course he can be  
03:16 20 cross-examined on it because he's relying on it in his  
21 opinions about prior art.

22 MR. LIPSEY: Agreed, as to the data and experiments.  
23 But the question that counsel wants to ask is what  
24 did the internal documents show about what the thought process  
03:16 25 was about why Polysorbate 80 was in the original formulation.  
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1 That's not part of the prior art, your Honor.

2 THE COURT: Well, let's all listen carefully to the  
3 question, if and when it's asked. I don't believe that that  
4 is the pending question. In other words, the "why" question  
03:17 5 isn't being asked.

6 I think that the question, as I understand it, is  
7 going to concern itself with whether he was aware of  
8 experimental results that contradict his -- his opinion about  
9 something that couldn't happen.

03:17 10 MS. HOLLAND: Well, let's put PTX-591 up, if you  
11 don't mind, Mr. Chase. Thank you.

12 BY MS. HOLLAND:  
13 Q. This is a document you relied on in your direct  
14 examination, correct?

03:17 15 A. Yes.

16 Q. And is your understanding that this document is from the  
17 IPR declaration of Mr. Sawa?

18 A. You know, I actually don't recall. I was thinking it was  
19 part of the prosecution history and the declaration, but I  
03:17 20 don't. Sitting here right now, I don't recall.

21 Q. Okay. Well, is part of the data here from, as you said  
22 in your expert report, laboratory notebooks of Mr. Shirou  
23 Sawa?

24 A. I don't think this is taken from the laboratory notebook.

03:18 25 Q. Does the data in this table come from, among other  
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1 sources, laboratory notebooks of Mr. Shirou Sawa?  
 2 **A. It may. Actually sitting here, I don't remember if it**  
 3 **does.**  
 4 **Q.** Okay. Well, let me see if I can refresh your  
 03:18 5 recollection.  
 6 Do we have the opening expert report? Do you have  
 7 that?  
 8 **A. I do, yes.**  
 9 MS. HOLLAND: Okay. Your Honor, do you have it as  
 03:19 10 well?  
 11 THE COURT: I don't have it in front of me. But --  
 12 MS. HOLLAND: Shall we just put it up on the screen?  
 13 THE COURT: Yes, that would be fine.  
 14 Do you recall whether that was passed up the other  
 03:19 15 day?  
 16 MS. HOLLAND: Can you say that one more time, your  
 17 Honor?  
 18 THE COURT: Okay. Here it is. Thank you.  
 19 MR. HASFORD: Can we get a copy?  
 03:19 20 MS. HOLLAND: Let's put it up on the screen. In the  
 21 meantime, it's Paragraph 371.  
 22 I'd like to look at the first sentence.  
 23 MR. HASFORD: We need a copy first actually.  
 24 MS. HOLLAND: I'm just putting it up on the screen.  
 03:20 25 MR. HASFORD: Thanks.

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1 that he's relying on.  
 2 MS. HOLLAND: I actually have one more question and I  
 3 think this will do it.  
 4 BY MS. HOLLAND:  
 03:22 5 **Q.** You gave testimony in connection with your unexpected  
 6 results testimony that the tyloxapol in -- let me withdraw  
 7 that.  
 8 You gave testimony that the tyloxapol in the  
 9 formulations you discussed was there for purposes of chemical  
 03:22 10 stability, right?  
 11 **A. In the context of the '431 patent, that's true, yes.**  
 12 **Q.** Well, now we are talking about unexpected results so I'm  
 13 asking you in every context.  
 14 Is it your testimony that the unexpected stability that  
 03:22 15 you are talking about for tyloxapol is chemical stability?  
 16 **A. Yes.**  
 17 **Q.** Okay. All right. So let's go to JTX-25.  
 18 MR. HASFORD: And --  
 19 MS. HOLLAND: I'm sorry, your Honor. I'm -- I  
 03:23 20 actually want to go to DTX- -- PTX-125A.  
 21 MR. HASFORD: Your Honor, I think we are going to  
 22 have to object to this. Your Honor --  
 23 MS. HOLLAND: This is in evidence already.  
 24 MR. HASFORD: This looks like part of the New Drug  
 03:23 25 Application, and I think your Honor's ruling was that he could

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1 MS. HOLLAND: So then, your Honor -- is everybody  
 2 ready now? Do you have it?  
 3 MR. HASFORD: Yes.  
 4 MS. HOLLAND: Okay. Now I lost my ...  
 5 BY MS. HOLLAND:  
 6 **Q.** So you see the first sentence in Paragraph 371 says the  
 7 data and results for the following table came from the  
 8 specification of the patents-in-suit, Ogawa, and laboratory  
 9 notebooks of Mr. Shirou Sawa. Do you see that?  
 03:20 10 **A. Yes.**  
 11 **Q.** Was that a true statement in your expert report?  
 12 **A. It -- yes.**  
 13 **Q.** Okay. Now, if we can go back to PTX-591.  
 14 **A. Okay.**  
 03:21 15 **Q.** That is the same table that appears in Paragraph 371,  
 16 except you have an additional column from Ogawa, right?  
 17 **A. That's -- that's true, yes.**  
 18 **Q.** Okay. So, now, have we established that what you showed  
 19 the Court here, PTX-591, was actually partially from Ogawa --  
 03:21 20 from Sawa laboratory notebooks?  
 21 **A. Yes.**  
 22 MS. HOLLAND: So, may I question, your Honor?  
 23 THE COURT: Well, it doesn't open all the notebooks  
 24 to scrutiny. It opens this particular data to scrutiny. And  
 03:21 25 so the answer is yes, you may question about the information

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1 be questioned about the data in these tables and not into any  
 2 further underlying materials.  
 3 MS. HOLLAND: I just asked a different question, Your  
 4 Honor. I asked whether the testimony about tyloxapol being --  
 03:24 5 having unexpected stability, in the context of unexpected  
 6 results, where you can go outside of the scope of the prior  
 7 art, was that about it having unexpected chemical stability.  
 8 And the witness said yes. Now I'm going to cross-examine him  
 9 on that point.  
 03:24 10 MR. HASFORD: I don't think she said anything about  
 11 the prior art in her question, your Honor.  
 12 MS. HOLLAND: You're right, I didn't. I didn't. I'm  
 13 not asking about the prior art. PTX- -- oh, I'm sorry, your  
 14 Honor. Did you rule?  
 03:24 15 THE COURT: Well, no, I didn't.  
 16 What's the pending question? Could it be read back,  
 17 please.  
 18 (The court reporter read back the following:  
 19 "QUESTION: You gave testimony in connection with  
 03:22 20 your unexpected results testimony that the tyloxapol in -- let  
 21 me withdraw that.  
 22 You gave testimony that the tyloxapol in the  
 23 formulations you discussed was there for purposes of chemical  
 24 stability, right?  
 03:22 25 "ANSWER: In the context of the '431 patent, that's

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1 true, yes.  
 2 "QUESTION: Well, now we are talking about unexpected  
 3 results so I'm asking you in every context.  
 4 "Is it your testimony that the unexpected stability  
 03:22 5 that you are talking about for tyloxapol is chemical  
 6 stability?  
 7 "ANSWER: Yes."  
 8 THE COURT: Okay, I'll permit it.  
 9 BY MS. HOLLAND:  
 03:25 10 Q. All right. Let's look at PTX-125A.  
 11 MS. HOLLAND: And this is actually already in  
 12 evidence, your Honor.  
 13 BY MS. HOLLAND:  
 14 Q. Can we -- can we go to the first page again, please.  
 03:25 15 A. **Do you know, do I have this in my notebook?**  
 16 Q. You should have it in your cross binder.  
 17 A. **Cross binder?**  
 18 Q. Do you have a cross binder?  
 19 THE COURT: I don't think that's been handed up.  
 03:25 20 MS. HOLLAND: Well, all right. That's going to delay  
 21 things for a moment. I apologize. But we're getting the  
 22 cross binders.  
 23 THE COURT: It wasn't a trick question asking what's  
 24 in a binder he hasn't received yet?  
 03:26 25 (Laughter.)

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1 there is a pharmaceutical development section. Do you see  
 2 that?  
 3 A. **Yes.**  
 4 MR. HASFORD: And, your Honor, I think this is an  
 03:27 5 appropriate time to object because if there is a  
 6 pharmaceutical development section, this is going to  
 7 pharmaceutical development of the invention. This is exactly  
 8 what we've been concerned about, that they're trying to use  
 9 this non-prior-art document, this New Drug Application that  
 03:27 10 was submitted to the FDA long after the priority date of the  
 11 patents-in-suit, as evidence toward their obviousness case.  
 12 That's impermissible, your Honor.  
 13 MS. HOLLAND: Your Honor, may I ask my question? It  
 14 will be evident that that's not where I'm going.  
 03:27 15 THE COURT: All right. You may ask the question and  
 16 then I'll hear any objection to it.  
 17 BY MS. HOLLAND:  
 18 Q. All right. Well, my first question was just do you see  
 19 that there is a -- this is a pharmaceutical development  
 03:27 20 section?  
 21 A. **I do.**  
 22 Q. Okay. Now, turn to the next page. Well, actually, turn  
 23 to Page 7 of 16.  
 24 A. **Okay.**  
 03:28 25 Q. Now, three paragraphs up from the bottom there, I'd like

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1 THE COURT: Thank you.  
 2 Let me know when your questioning comes to a good  
 3 time for a lunch break. It's about five of one.  
 4 MS. HOLLAND: Sure. I can do it after this document,  
 03:26 5 your Honor.  
 6 THE WITNESS: Oh, you know what? There's notes in  
 7 here.  
 8 MR. LIPSEY: Just answer the questions written in the  
 9 margin.  
 03:26 10 THE WITNESS: I know I don't want that.  
 11 (Laughter.)  
 12 BY MS. HOLLAND:  
 13 Q. How are we doing now, Dr. Williams?  
 14 A. **Okay. So it's DT --**  
 03:26 15 Q. Clean --  
 16 A. **Yes, it's clean.**  
 17 Q. -- copy? Okay.  
 18 A. **Okay. 125.**  
 19 Q. PTX-125A.  
 03:26 20 A. **Okay, I'm there. Thank you.**  
 21 Q. Okay. So this is -- do you see this is a section of the  
 22 New Drug Application that plaintiffs submitted to the FDA for  
 23 Prolensa®, correct?  
 24 A. **I see that, yes.**  
 03:26 25 Q. Okay. Now, in this New Drug Application for Prolensa®,

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1 to -- can you put that up on the screen, please?  
 2 So, what plaintiffs told the FDA in trying to get  
 3 approval for Prolensa® was that tyloxapol acts as a  
 4 solubilizing agent to prevent interaction between  
 03:28 5 benzalkonium --  
 6 MR. HASFORD: And I'll object at this point, your  
 7 Honor. I object, move to strike it from the record. I have  
 8 to object. I apologize, Your Honor.  
 9 This is going to the exact issue that we're concerned  
 03:28 10 about, and your Honor said that the "why" couldn't be admitted  
 11 here and shouldn't be.  
 12 He didn't testify -- he testified that tyloxapol was  
 13 added as a chemical stabilizer. This goes to, you know --  
 14 MS. HOLLAND: This goes to why that's not true.  
 03:28 15 MR. HASFORD: No, that's -- your Honor, it's -- the  
 16 basis for their obviousness case has to be what the prior art  
 17 taught as of 2003. This document is not in the prior art and  
 18 the path that led the inventor to the invention is irrelevant  
 19 by statute. This is on a New Drug Application that was filed  
 03:29 20 long after the patents-in-suit were filed.  
 21 MS. HOLLAND: Your Honor, could we go back to the  
 22 question that I asked which led to this impeachment? Because  
 23 the question was, when you looked at stability for unexpected  
 24 results and you saw that -- what you said was improved  
 03:29 25 stability for tyloxapol, was it your understanding or did you

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1 believe that tyloxapal was using -- being used to chemically  
 2 stabilize the Prolensa® or the formulations of the claims in  
 3 suit? That's a question that goes to unexpected results, to  
 4 the basis of his opinions about unexpected results. What is  
 03:29 5 this increased stability?  
 6 MR. HASFORD: Your Honor --  
 7 MS. HOLLAND: Dr. Williams says it's chemical  
 8 stability. Plaintiffs tell the FDA it's physical stability to  
 9 prevent interaction between BAC and bromfenac.  
 03:30 10 THE COURT: The paragraph you're asking about is not  
 11 about the prior art, is it?  
 12 MS. HOLLAND: I'm not asking about the prior art,  
 13 again, your Honor. I'm asking about unexpected results.  
 14 Dr. Williams testified that the Prolensa® formulation  
 03:30 15 was unexpectedly superior in terms of stability to the prior  
 16 bromfenac formulation. Necessarily, Dr. Williams has to --  
 17 well, let me not -- not saying necessarily.  
 18 Dr. Williams said that the unexpected stability of  
 19 tyloxapal in the formulation is with respect to chemical  
 03:30 20 stability. That's just a fact he said for purposes of his  
 21 unexpected results opinion.  
 22 What I'm now going into questioning Dr. Williams  
 23 about, is the -- is that actually accurate? If there is  
 24 increased stability here for purposes of unexpected results,  
 03:31 25 which has nothing to do with the prior art, is that really  

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1 internal document. It's not based on this document that was  
 2 submitted to the FDA long after the earliest priority date of  
 3 the patents-in-suit.  
 4 MS. HOLLAND: There's a pattern in this case, Your  
 03:32 5 Honor, and I've said this before, of having internal  
 6 documents, even sworn documents to the FDA, completely  
 7 inconsistent with expert testimony we hear on the stand. Then  
 8 there's an objection, I can't ask the witness about it. So  
 9 basically the witness is permitted to put in testimony that  
 03:32 10 everybody knows is not true because everybody else here except  
 11 you has the documents.  
 12 THE COURT: Well, is the ANDA considered -- or I'm  
 13 sorry, the NDA considered an internal document after the FDA  
 14 has given approval?  
 03:32 15 MS. HOLLAND: Some parts of it become public after  
 16 that.  
 17 MR. HASFORD: The -- and not before 2003, Your Honor.  
 18 And this document is marked confidential. It was produced  
 19 internally from plaintiff's files.  
 03:32 20 MS. HOLLAND: Again, Your Honor, I'm not asking this  
 21 for a matter of prior art. Whether or not the unexpected  
 22 results are truly unexpected is going to depend, at least in  
 23 part, about what's -- what is the stability that is allegedly  
 24 unexpected. Is it physical stability or chemical stability?  
 03:33 25 Because Dr. Williams testified this morning that the  

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1 chemical stability or is it physical stability? It goes to  
 2 the very heart of his unexpected results opinion.  
 3 THE COURT: And, of course, you can ask that question  
 4 of him. The objection, though, is as to your use of this  
 03:31 5 particular document.  
 6 MS. HOLLAND: Well, this particular document --  
 7 Dr. Williams says it's chemical stability. I should be able  
 8 to show him a document that says that no, actually, it's  
 9 physical stability and ask him if it changes his opinion.  
 03:31 10 This is a document -- a document that plaintiffs submitted to  
 11 the FDA.  
 12 MR. HASFORD: Your Honor --  
 13 MS. HOLLAND: They told the FDA, this is the -- we're  
 14 brought into court and we have an expert on the stand who  
 03:31 15 tells us there is all these unexpected properties based on  
 16 chemical stability. Meanwhile, plaintiffs go to the FDA and  
 17 say that the reason for the tyloxapal has nothing to do with  
 18 chemical stability. It has to do with interaction between BAC  
 19 and bromfenac.  
 03:31 20 MR. HASFORD: Your Honor, the unexpected results  
 21 about which Dr. Williams testified were unexpected results as  
 22 to chemical stability. They are trying to use this document  
 23 for purpose of showing what would have been known in the prior  
 24 art, and that's not -- I mean, so what is expected or  
 03:32 25 unexpected is based on the prior art. It's not based on this  

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1 reason tyloxapal -- the reason why it's unexpected is because  
 2 tyloxapal was not used as a chemical stabilizer in the prior  
 3 art previously, so now that it's chemically stabilizing, wow,  
 4 what an invention. In fact, it's not used for that purpose in  
 03:33 5 the formulation. It's used for the exact purpose it was used  
 6 in the prior art. Dr. Williams used it for that purpose based  
 7 on his testimony today as a physical stabilizer to solubilize  
 8 things. It's not unexpected.  
 9 THE COURT: Okay. I'm going to permit the testimony  
 03:33 10 for that limited purpose, of being that the plaintiff's own  
 11 statement to the FDA, as to the purpose for which the  
 12 substance tyloxapal was -- was being used.  
 13 MR. HASFORD: If I may, Your Honor. So the --  
 14 THE COURT: I've ruled. And the parties are free to  
 03:34 15 brief this when -- when all the evidence is in, as your  
 16 objection is preserved as to whether it can be used for even  
 17 this limited purpose. But basically, the thrust of my ruling  
 18 is that this is a statement, not in an internal document, not  
 19 in a laboratory report, but in a statement to the FDA about  
 03:34 20 the purpose of a particular constituent, additive, tyloxapal.  
 21 And the witness, it's fair to question him, because his  
 22 direct testimony touched upon this very subject, and it's fair  
 23 to ask him whether this changes his -- his views, since this  
 24 is a statement that was from the plaintiff and dignified by  
 03:35 25 being part of the NDA process. So I'll permit it.  

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1 BY MS. HOLLAND:  
 2 Q. Dr. Williams, do you see that in the NDA for Prolensa,  
 3 plaintiffs explain what the function of tyloxapal is in  
 4 Prolensa? Do you see that?  
 03:35 5 A. I do, yes.  
 6 Q. What plaintiffs say here is that tyloxapal acts as a  
 7 solubilizing agent to prevent interaction between benzalkonium  
 8 chloride and bromfenac sodium. Do you see that?  
 9 A. I do.  
 03:35 10 Q. Now, based on this statement to the FDA, do you now agree  
 11 that the purpose of tyloxapal and any stability that it gave  
 12 to the formulation was as a result of preventing interaction  
 13 between benzalkonium chloride and bromfenac sodium?  
 14 A. I don't. I've seen -- I was aware of this statement.  
 03:35 15 I've seen no data supporting it, that I'm aware of, that  
 16 actually shows where they prevented a complex. I've seen data  
 17 where the addition of tyloxapal prevents or really improves  
 18 the chemical degradation of bromfenac. So I still stand by my  
 19 opinion.  
 03:36 20 Q. And you think the statement to the FDA that was made was  
 21 -- by plaintiffs in the NDA was just wrong?  
 22 MR. HASFORD: Objection, Your Honor.  
 23 Mischaracterizes the witness's testimony. Argumentative.  
 24 THE COURT: No. He may explain.  
 03:36 25 THE WITNESS: I'm just saying, I have not seen data  
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1 result?  
 2 MS. HOLLAND: For this -- right now, the question is  
 3 on impeachment, yes.  
 4 MR. HASFORD: If it's a prior statement of  
 03:37 5 Dr. Williams that she's asking about, we have no problem with  
 6 that. If it's an internal document that she's trying to get  
 7 in and show some result that allegedly goes toward her  
 8 obviousness case, we would strongly object to that, Your  
 9 Honor.  
 03:38 10 MS. HOLLAND: Well, can I try -- can I ask some  
 11 questions and then we will see if it actually is impeachment,  
 12 as I think it is, or whether it goes to some other nefarious  
 13 purpose, as Mr. Hasford thinks? If --  
 14 THE COURT: All right, you can ask a different  
 03:38 15 question.  
 16 MS. HOLLAND: Why don't you go to JTX-25 and -- just  
 17 go to what -- your direct binder your counsel put together,  
 18 okay?  
 19 MR. HASFORD: And we're going to object to this, Your  
 03:38 20 Honor. This is an internal document. It's an internal  
 21 laboratory or research report document, and this is exactly  
 22 the problem.  
 23 THE COURT: What's the document?  
 24 MS. HOLLAND: JTX25.  
 03:38 25 MR. HASFORD: And this -- this document is not in  
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1 that proved what they're saying there. I'm not taking a stand  
 2 one way or the other whether they're right or wrong. I don't  
 3 know that. But I've not seen data that supported that fact.  
 4 I've seen data on the use of tyloxapal to chemically stabilize  
 03:36 5 bromfenac.  
 6 MS. HOLLAND: Your Honor, the witness, I believe, has  
 7 now opened the door to me showing him data that he's seen  
 8 about tyloxapal acting as a stabilizer to prevent interaction  
 9 of BAC. It's -- he said he hasn't seen the data. He's seen  
 03:37 10 the data. I'd like to be able to question him about that.  
 11 MR. HASFORD: Your Honor, I disagree. He was  
 12 responding in the context of this statement that Your Honor  
 13 allowed him to go into, that Your Honor allowed Ms. Holland to  
 14 go into, and that hasn't opened any door at all.  
 03:37 15 MS. HOLLAND: The witness testified he has not seen  
 16 data showing that tyloxapal is used as a solubilizer in  
 17 Prolensa and in the patented formulations to prevent  
 18 interaction of BAC and bromfenac. That was the testimony just  
 19 now, and I would like to impeach the witness on that point.  
 03:37 20 MR. HASFORD: Your Honor --  
 21 THE COURT: By impeachment, you mean something that  
 22 goes to his credibility?  
 23 MS. HOLLAND: Yes, showing -- yes.  
 24 MR. HASFORD: Well, Your Honor --  
 03:37 25 THE COURT: And not for the substance of the internal  
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1 evidence.  
 2 MS. HOLLAND: This directly impeaches the testimony  
 3 that was just given.  
 4 MR. HASFORD: Again, Your Honor --  
 03:38 5 THE COURT: Well, was there an objection to JTX25?  
 6 MS. HOLLAND: It's in his direct binder. There  
 7 couldn't have been an objection.  
 8 MR. HASFORD: We objected to it when they tried to  
 9 use it previously. We objected to these documents --  
 03:39 10 THE COURT: But pretrial, in the final pretrial  
 11 order, it's something that was in your direct binder, I assume  
 12 that there was no objection to JTX25 expressed in the pretrial  
 13 order?  
 14 MR. HASFORD: No, sorry. It's not something we used  
 03:39 15 directly with Dr. Williams. There would have been a relevance  
 16 objection to how they tried to use it. I mean, they're --  
 17 THE COURT: I understand that.  
 18 MR. HASFORD: Right.  
 19 THE COURT: My question is whether there was an  
 03:39 20 objection to JTX25 that you staked out in the pretrial order.  
 21 MR. HASFORD: I need to --  
 22 MS. HOLLAND: Dr. Williams relied on this document  
 23 heavily in his expert report, so I highly doubt there's an  
 24 objection.  
 03:39 25 THE COURT: Well, that doesn't mean that they're  
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1 bound to it. They could withdraw that aspect of his proposed  
 2 testimony.  
 3 MS. HOLLAND: It's still for impeachment, Your Honor.  
 4 I'm not sure -- respectfully, I'm not sure whether or not  
 03:39 5 there was an objection to the document would even matter as a  
 6 matter of impeachment.  
 7 THE COURT: Well, it would matter as to your argument  
 8 if they've waived any objection that they're now raising  
 9 because it was in their direct binder. The question is  
 03:40 10 whether they preserved an objection in the final pretrial  
 11 order. Does somebody have that document?  
 12 MR. HASFORD: Your Honor, does it make sense to take  
 13 a lunch break at this point --  
 14 MS. HOLLAND: No.  
 03:40 15 MR. HASFORD: -- so we can try to -- we can try to  
 16 look this up?  
 17 MS. HOLLAND: Your Honor, I would prefer to continue.  
 18 I just want to finish this document.  
 19 THE COURT: We had a supplemental.  
 03:40 20 MS. HOLLAND: I think there was an objection as to  
 21 the translation, which was resolved, because we were using  
 22 plaintiff's translation.  
 23 MR. HASFORD: No, no, we preserved a relevance  
 24 objection here, Your Honor. We have with the code R in here.  
 03:41 25 MS. HOLLAND: Let's see.

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1 MR. HASFORD: The objection codes are MIS, R, OSE,  
 2 and TRAN. And the R, as Your Honor will note on Page 30, is  
 3 for lacks relevance.  
 4 THE COURT: Okay. All right. So that objection was  
 03:41 5 preserved.  
 6 MR. HASFORD: Thank you, Your Honor.  
 7 MS. HOLLAND: As I said, Your Honor, this goes to --  
 8 Dr. Williams clearly read this document, and so that's what  
 9 I'm asking him about. I'm asking him about it in purposes of  
 03:41 10 impeachment, him having said he's not seen any data that  
 11 tyloxapol was used to prevent interactions between BAC and  
 12 bromfenac.  
 13 MR. HASFORD: It's not a proper source of  
 14 impeachment, Your Honor, and it's not relevant in any event.  
 03:41 15 She's trying to get this in for purposes of her obviousness  
 16 case.  
 17 THE COURT: I'll permit the question, whether he's  
 18 seen this data.  
 19 BY MS. HOLLAND:  
 03:42 20 Q. Dr. Williams, have you seen JTX25 before?  
 21 A. Yes.  
 22 Q. Okay. You've read this document, right?  
 23 A. I have, yeah.  
 24 Q. Okay. Now, let me draw your attention to Page 4 of this  
 03:42 25 document.

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1 A. Okay.  
 2 Q. Table 4 refers to a Table 1 below, right?  
 3 A. It does.  
 4 Q. Okay. And what table -- what the -- what it says --  
 03:42 5 well, let me direct -- make sure everybody is looking at the  
 6 same place. In the results and discussion section, in the  
 7 middle of the page, there's something that says surfactant  
 8 test.  
 9 THE COURT: Excuse me. I think I've lost you.  
 03:42 10 MS. HOLLAND: Sorry, Your Honor.  
 11 THE COURT: Are we on Page 4 of 125? Of JTX25?  
 12 MS. HOLLAND: We are.  
 13 THE COURT: Just a second.  
 14 THE WITNESS: JTX025.  
 03:43 15 MS. HOLLAND: I'm sorry?  
 16 THE COURT: Just a moment. Okay. I'm there.  
 17 BY MS. HOLLAND:  
 18 Q. Okay. So under surfactant test, Dr. Williams, do you see  
 19 it says: Table 1 shows the concentration of each nonionic  
 03:43 20 surfactant needed to prevent the precipitation of bromfenac  
 21 sodium in benzalkonium chloride?  
 22 Do you see that?  
 23 MR. HASFORD: And I'll object and move to strike,  
 24 Your Honor. This goes to the exact purpose that Your Honor  
 03:43 25 already ruled on that it was prohibited for.

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1 MS. HOLLAND: This is impeachment. It directly  
 2 contradicts testimony Dr. Williams gave, where he said he  
 3 never saw any data showing that tyloxapol was used to prevent  
 4 the precipitation of bromfenac sodium and benzalkonium  
 03:44 5 chloride.  
 6 THE COURT: I'll permit it for the limited purposes  
 7 of impeachment. I'm not permitting it for any other purpose  
 8 at this time.  
 9 THE WITNESS: I'm sorry, what's your question?  
 10 BY MS. HOLLAND:  
 11 Q. I'm not sure there is one.  
 12 A. Okay.  
 13 Q. So let me start again, then. You see that the first  
 14 sentence says: Table 1 shows the concentration of each  
 03:44 15 nonionic surfactant needed to prevent the precipitation of  
 16 bromfenac sodium in benzalkonium chloride.  
 17 Do you see that?  
 18 A. Yes.  
 19 Q. And the next sentence says that polysorbate 80,  
 03:44 20 tyloxapol, and another surfactant prevented the precipitation  
 21 at about .03 percent, .01 percent and .02 percent  
 22 respectively. Do you see that?  
 23 A. Yes.  
 24 Q. Okay. So, Dr. Williams, there is data that you've seen  
 03:44 25 in JTX25 that shows the ability of tyloxapol to prevent

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1 precipitation of bromfenac sodium in benzalkonium chloride.  
 2 Do you see that?  
 3 A. I see that, but these are for the polysorbate 80 and  
 4 tyloxapol solutions. This is not in the presence of the other  
 03:45 5 ingredients. That's why, in the precipitation, I'm not sure  
 6 how relevant it is, so --  
 7 Q. So you knew about this testimony when you said no  
 8 earlier?  
 9 A. Yeah, I was talking in the context of the ophthalmic  
 03:45 10 formulation. Was there -- was there information that I had  
 11 seen, where a precipitation had been shown to form where  
 12 there's all these other ions present, and I was aware of this  
 13 document, and that's -- this is -- this is not a formulation  
 14 study. This is a solution of surfactants, where -- where  
 03:45 15 bromfenac and benzalkonium chloride are being manipulated.  
 16 Q. So is it now your testimony that unless we look at the  
 17 actual formulations that are used in the prior art and in  
 18 Prolensa and compare them, that your testimony on other  
 19 formulations earlier this morning was irrelevant?  
 03:46 20 A. Well, the --  
 21 MR. HASFORD: I'll object, Your Honor. It  
 22 characterizes the witness's testimony.  
 23 THE COURT: I'll sustain it.  
 24 BY MS. HOLLAND:  
 03:46 25 Q. Earlier today, Doctor, you put some demonstratives up on  
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1 the board, and you showed the Court formulations that did not  
 2 contain PVP and sodium sulfite, right?  
 3 A. That's true.  
 4 Q. And you made -- you gave opinions about those  
 03:46 5 formulations, even though both Ogawa Example 6 and Prolensa  
 6 contained PVP and sodium sulfite, right?  
 7 A. That's true, yes.  
 8 Q. Okay. And you said you were able to do that even though  
 9 it wasn't the exact solutions that -- of Prolensa and Ogawa  
 03:46 10 Example 6, right?  
 11 A. But they had the borax, the boric acid. They had the  
 12 ingredients in there that made it a proper comparison.  
 13 Q. They didn't have all of the same ingredients, did they?  
 14 A. They had the ions that were in there. So they had --  
 03:47 15 well, and that question, I was answering with regards to  
 16 proper comparison to the closest prior art.  
 17 Q. Right. And the point is that this morning you said you  
 18 didn't need to look at the full formulations in either -- in  
 19 order to be able to make those comparisons, right?  
 03:47 20 A. One of -- I mean, you heard Dr. Davies testify last week,  
 21 what's present in the solution is going to -- could affect the  
 22 -- whether a precipitant is formed in their level, and that's  
 23 consistent with experimentally my experience, and so that's --  
 24 I mean, that's what I think.  
 03:47 25 MS. HOLLAND: All right. I think we can take a lunch  
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1 break now, Your Honor.  
 2 THE COURT: All right. Let's take an hour for lunch  
 3 and we will return at 2:15.  
 4 (LUNCHEON RECESS TAKEN; 1:18 p.m.)  
 03:33 5 THE DEPUTY CLERK: All rise.  
 6 (OPEN COURT; 2:21 p.m.)  
 7 THE COURT: Be seated, please. Good afternoon. Yes,  
 8 Mr. Mukerjee.  
 9 MR. MUKERJEE: Before we continue with the cross of  
 04:50 10 Dr. Williams, may I just address a trial logistics issue?  
 11 THE COURT: Sure.  
 12 MR. MUKERJEE: Your Honor, one of the witnesses that  
 13 defendants intend on calling is Dr. Mark Prausnitz. Dr.  
 14 Prausnitz is someone that we'll be proffering as an expert in  
 04:50 15 the area of ophthalmic drug delivery.  
 16 Now, originally -- and his opinions actually go to --  
 17 respond to or in rebuttal to Dr. Williams and Dr. Trattler's  
 18 testimony on secondary considerations, particularly on  
 19 expected results.  
 04:51 20 Now, originally, we were hoping that Dr. Prausnitz  
 21 would be testifying today, and certainly, that's what we  
 22 disclosed to plaintiffs. It does appear, though, now, given  
 23 the time of the day and where we are, that that's likely not  
 24 to happen today. Now, Dr. Prausnitz is not available,  
 04:51 25 unfortunately, due to another commitment tomorrow. He is  
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1 willing to come back for his testimony on Wednesday.  
 2 Now, I know, technically, we don't have Wednesday as a  
 3 trial day yet, Your Honor. I don't know if I'm recalling  
 4 incorrectly, but I thought that your calendar may be open on  
 04:51 5 Wednesday, if we needed to extend to that day.  
 6 THE COURT: Yeah, I've kept it open for that purpose,  
 7 if we need to extend it. This may be a reason to do that.  
 8 MR. MUKERJEE: Okay.  
 9 THE COURT: Is there any objection to Dr. Prausnitz  
 04:51 10 coming in on Wednesday?  
 11 MR. LIPSEY: No objection, Your Honor.  
 12 THE COURT: Okay.  
 13 MR. MUKERJEE: Thank you, Your Honor, I appreciate  
 14 it.  
 04:51 15 THE COURT: You're welcome.  
 16 MS. HOLLAND: May I proceed?  
 17 THE COURT: Yes, you may.  
 18 BY MS. HOLLAND:  
 19 Q. Dr. -- Dr. Williams, good afternoon.  
 04:52 20 A. Good afternoon.  
 21 Q. For your unexpected results opinions, you compared  
 22 Prolensa to Xibrom and Bromday, correct?  
 23 A. Yes.  
 24 Q. Okay. Now -- and you actually showed the Court a section  
 04:52 25 of the Xibrom NDA to support your opinion, correct, the  
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1 prescribing information?  
 2 A. **A part of it, yes.**  
 3 Q. Now, neither of those products are in the prior art,  
 4 right? I should say none of those products, Prolensa, Xibrom  
 04:52 5 and Bromday, none of them are in the prior art, right?  
 6 A. **That's my understanding.**  
 7 Q. Okay. But you still use the information about those  
 8 products to support your unexpected results position, correct?  
 9 A. **Well, with the Xibrom and Bromday, that's because they're**  
 04:53 10 **embodiments of the Ogawa patent, which is prior art. That's**  
 11 **my understanding.**  
 12 Q. But you looked, for example, at the pH of those products,  
 13 which is not a pH exactly found in Ogawa, right?  
 14 A. **So in Xibrom and Bromday, it's 8.3, and examples in the**  
 04:53 15 **Ogawa patent, I believe the ones that are stated, there are**  
 16 **actually generating data of pH 8.**  
 17 THE COURT: Excuse me. Can you pull the mic a little  
 18 closer.  
 19 THE WITNESS: Oh, I'm sorry, excuse me.  
 04:53 20 THE COURT: I can hear fine, but the folks in the  
 21 back might not.  
 22 BY MS. HOLLAND:  
 23 Q. Now, the difference between Prolensa on the one hand and  
 24 Xibrom and Bromday on the other hand, in terms of the  
 04:53 25 ingredient list, is that Prolensa has tyloxapol, and Xibrom

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1 Q. So now I'm talking about your unexpected results  
 2 opinions, okay, where you went outside of the patents, right?  
 3 You actually looked at product labeling, correct?  
 4 A. **For pH and -- yes.**  
 04:56 5 Q. Okay. And from the pH you -- you derived some opinions  
 6 about stability, correct?  
 7 A. **Well, I noted what the stability was of Xibrom and**  
 8 **Bromday.**  
 9 Q. Okay. And that -- but that was based on pH data that was  
 04:56 10 not in the prior art, right?  
 11 A. **Not in the prior art?**  
 12 Q. Yes.  
 13 A. **Well, in the Ogawa patent, the examples were noted pH was**  
 14 **at pH 8, and Ogawa also in the pH stability study that was**  
 04:56 15 **done, a pH above 8, it was more stable, and so, I mean, it**  
 16 **seemed although pH 8.3 and specifically noted in Ogawa '225 --**  
 17 Q. Can we put up the last demonstrative that was used this  
 18 morning in the direct of Dr. Williams, please? Oh, I'm sorry,  
 19 it's a couple -- before we get to the double patenting, there  
 04:57 20 was one that had the pictures of the products on it. Thanks.  
 21 Okay. So let me -- maybe I didn't focus you enough.  
 22 This is what I was talking about. Okay? So you put up a  
 23 demonstrative where you compared the actual product pHs,  
 24 right? You had the pH of Prolensa of 7.8.  
 04:57 25 A. **That's correct.**

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1 and Bromday have polysorbate 80, correct?  
 2 A. **That's true, yes.**  
 3 Q. All right. And you compared the stability of those  
 4 products, Prolensa versus Xibrom and Bromday, correct?  
 04:54 5 A. **The stability? Well, I looked to the product label to**  
 6 **get the pH of what it stated was the actual product, and then**  
 7 **I looked at stability that's in the Ogawa patent.**  
 8 Q. And as well as in Dr. Sawa's -- or Mr. Sawa's laboratory  
 9 notebook, correct?  
 04:54 10 A. **For Bronuck, that's right.**  
 11 Q. Okay. Now, we looked at the NDA for Prolensa before  
 12 lunch. Do you recall that?  
 13 A. **A portion of it, yes.**  
 14 Q. Okay. And we looked at the purpose of tyloxapol in the  
 04:55 15 Prolensa formulation. Do you recall that?  
 16 A. **Well, yeah, the part I looked at is what the -- the NDA**  
 17 **stated was the reason for tyloxapol in the formulation.**  
 18 Q. Okay. Now, in formulating your unexpected results  
 19 opinions, did you assume that polysorbate 80 had a different  
 04:55 20 function for -- in Xibrom and Bromday than tyloxapol has in  
 21 Prolensa?  
 22 A. **Well, in Ogawa, there's no role ascribed to polysorbate**  
 23 **80, so in -- and what I said is, in the '431 patent, that the**  
 24 **role of tyloxapol, in my opinion, for chemical stabilization**  
 04:56 25 **of bromfenac sodium.**

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1 Q. True?  
 2 A. **Yes.**  
 3 Q. And you had the pH of the actual product, Xibrom and  
 4 Bromday, 8.3, right?  
 04:57 5 A. **From their label, yes.**  
 6 Q. Yes. And none of that is in the prior art, right?  
 7 A. **I don't think so, no.**  
 8 Q. Okay. Now -- and as we said, the one difference between  
 9 -- in the ingredient list between the Xibrom and Bromday, on  
 04:58 10 the one hand and Prolensa on the other, is the substitution of  
 11 tyloxapol for polysorbate 80, right?  
 12 A. **That's one difference, yes.**  
 13 Q. Okay. And you said that that led to an unexpected  
 14 result, correct?  
 04:58 15 A. **That's true, yes.**  
 16 Q. And that was because you believe that the function of  
 17 polysorbate 80 and Xibrom and Bromday was different than the  
 18 function of tyloxapol in Prolensa, right?  
 19 A. **I don't think I said that about the function of**  
 04:58 20 **polysorbate 80 in Xibrom and Bromday.**  
 21 Q. Well, did you say that tyloxapol is performing a function  
 22 in Prolensa that polysorbate 80 is not performing in Xibrom  
 23 and Bromday, is that right?  
 24 A. **I don't -- I actually don't recall saying it like that.**  
 04:59 25 Q. Do you agree with that statement?

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1 A. Well, I mean, there's no role ascribed in the Ogawa  
2 patent which embodies -- which Xibrom and Bromday are an  
3 embodiment of. There's no role --

4 Q. I'm not talking about the -- oh, I'm sorry, I apologize.

04:59 5 MR. HASFORD: Your Honor.

6 THE WITNESS: There's no role ascribed to polysorbate  
7 80 in there, and so that Ogawa patent solves the chemical  
8 stability problem a different way with the water soluble  
9 polymer and the sulfite.

10 BY MS. HOLLAND:

11 Q. All right. Let me try this again. I'm not -- I want you  
12 to think broader than the Ogawa patent, okay? Because when  
13 you testified about unexpected results, you went a lot broader  
14 than the Ogawa patent. You looked at actual products on the

04:59 15 market. So my questions are not about the Ogawa patent but  
16 about the actual products on the market, okay?

17 Is it your opinion that the function of polysorbate 80  
18 in Xibrom and Bromday, the actual products on the market, is  
19 different than the function of tyloxapol in Prolensa?

05:00 20 A. I don't know what the function of polysorbate 80 is in  
21 the Bromday and Xibrom. I know from Ogawa it doesn't  
22 stabilize bromfenac sodium, but I don't -- I mean, maybe it's  
23 a wetting agent. I'm not really sure what the function is.

24 Q. Well, you knew about --

05:00 25 A. It doesn't seem like it's the same function as tyloxapol

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1 in Prolensa.

2 Q. When you were gathering up all your data about Xibrom and  
3 Bromday, did you try to figure out what the role of  
4 polysorbate 80 was in those products? You figured out what  
05:00 5 the pH was, right?

6 A. The pH is stated in the label.

7 Q. Yeah. Did you try to figure out what the function of  
8 polysorbate 80 was?

9 A. Well, like I just said, I'm not sure why it's in there.

05:00 10 It's -- I mean, in the patent, it -- polysorbate 80 does not  
11 stabilize bromfenac sodium. There's data on that.

12 Q. Okay. Now --

13 A. The role that it's playing, I'm not sure.

05:01 14 Q. I'm asking a different question, though. Did you try to  
15 investigate what the role was in the actual products? Did you  
16 try to investigate the role of polysorbate 80 in Xibrom and  
17 Bromday?

18 A. In Xibrom and -- well, not apart from my analysis of the  
19 Ogawa patent.

05:01 20 Q. Okay. Can we see DTX-479A. It should be in your binder.  
21 Well, actually, let's go to 478 first. It's in your binder.

22 Do you see this is a section from the Xibrom NDA? So  
23 this are statements that plaintiffs made to the FDA about the  
24 Xibrom product.

05:02 25 A. Okay. Let me make sure. So this is DTX-479A?

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1 Q. 478A first, please.

2 MR. HASFORD: And I'll just object and note for the  
3 record, Your Honor, this Xibrom NDA, much like the Prolensa  
4 NDA or the Bromday NDA is not prior art, it's not publicly  
05:02 5 available. To the extent counsel is attempting to use this in  
6 connection with an obviousness case, it's not proper.

7 MS. HOLLAND: I'm using it for unexpected results, as  
8 I think -- thought the lead-up to that made clear, Your Honor.

9 MR. HASFORD: And it's certainly not based on what's  
05:02 10 known in the prior art. Because that wouldn't have been known  
11 in the prior art if it was part of the confidential Xibrom NDA  
12 that was submitted to the FDA, Your Honor.

13 MS. HOLLAND: I just -- Your Honor, we heard a lot of  
14 testimony this morning about the actual Prolensa, Xibrom,  
05:02 15 Bromday products that Dr. Williams just said were not prior  
16 art. Notwithstanding that, he gave testimony about them and  
17 their properties in connection with his unexpected results  
18 opinion.

19 THE COURT: Isn't that correct?

05:02 20 MR. HASFORD: What he gave testimony based on  
21 publicly-available documents that are out there in the art,  
22 and this was not a publicly-available document. This was a  
23 submission to the FDA that was confidential and so it's not  
24 something that's properly part of an obviousness case.

05:03 25 MS. HOLLAND: That --

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1 THE COURT: Well, he can be asked his understanding  
2 of the qualities of the other products, because that's within  
3 the scope of his direct. If he didn't rely upon this NDA that  
4 was submitted with regard to -- is it Xi --

05:03 5 MS. HOLLAND: Xibrom, Your Honor.

6 THE COURT: Okay. Then he can't be asked about that.

7 MS. HOLLAND: He can?

8 THE COURT: He cannot because it would not be in the  
9 prior art.

05:03 10 MS. HOLLAND: Your Honor, nothing that was said by  
11 Dr. Williams about those products was in the prior art. I  
12 think there was a little confusion based about what Mr.  
13 Hasford said.

14 The information about Xibrom and Bromday and Prolensa,  
05:03 15 that we just saw in the slide ahead up there, none of that is  
16 in the prior art, and Dr. Williams just agreed to that.

17 Dr. Williams testified about a lot of stuff that wasn't in the  
18 prior art this morning to support unexpected results.

19 THE COURT: But you can't use the NDA that was  
05:04 20 submitted to direct his attention to something that he  
21 overlooked or whatever. You can impeach him or you can  
22 cross-examine him --

23 MS. HOLLAND: Yes, Your Honor.

24 THE COURT: -- based upon what he -- what he actually  
05:04 25 knows, what he testified to.

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1 MS. HOLLAND: All right.  
 2 BY MS. HOLLAND:  
 3 Q. Dr. Williams, I want to focus your attention to the  
 4 second full paragraph -- well, first of all, let's look at the  
 05:04 5 top of the page. It says 2.3.P.1, description and composition  
 6 of the drug product. Do you see that?  
 7 A. I do.  
 8 Q. And it says bromfenac ophthalmic solution. Do you see  
 9 that?  
 05:04 10 A. Yes.  
 11 Q. And then the second paragraph in that section says: The  
 12 drug product solution contains bromfenac sodium as the active  
 13 ingredient.  
 14 Do you see that?  
 05:04 15 A. Yes.  
 16 Q. And then it goes through a list of other -- the other  
 17 ingredients in Xibrom, and it says that polysorbate 80, as a  
 18 solubilizer.  
 19 Do you see that?  
 05:05 20 A. Yes.  
 21 Q. Okay. And do you understand that to mean that it --  
 22 polysorbate 80 is used in Xibrom to solubilize something  
 23 that's insoluble in the formulation?  
 24 MR. HASFORD: I'll object, Your Honor. This is the  
 05:05 25 issue. To the extent she is trying to use this non-prior art  
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1 document in connection with an obviousness case, it's  
 2 improper; and if it's secondary consideration, secondary  
 3 considerations are based on what would be expected or  
 4 unexpected based on the prior art. And this document is not  
 05:05 5 prior art.  
 6 MS. HOLLAND: Your Honor, there seems to be a double  
 7 standard here. We heard a lot of testimony this morning on  
 8 unexpected results, all kinds of stuff that's not in the prior  
 9 art that's in internal documents, documents that are generated  
 05:05 10 years after the prior art date of 2003, and it's just as  
 11 relevant as any other piece of non-prior art that Your Honor  
 12 has heard about this morning, to hear what the actual function  
 13 of these excipients are in Xibrom.  
 14 The unexpected results opinion is based on Dr. Williams  
 05:06 15 saying that the stability, that tyloxapol does something  
 16 different in the formulation than polysorbate 80 did. Again,  
 17 Your Honor, there's --  
 18 THE COURT: So are you asking whether he agrees with  
 19 this statement, that polysorbate 80 is a solubilizer?  
 05:06 20 MS. HOLLAND: I can ask that statement, Your Honor.  
 21 THE COURT: I'll permit that.  
 22 BY MS. HOLLAND:  
 23 Q. Do you agree with what plaintiffs told the FDA here, that  
 24 polysorbate 80 is a solubilizer?  
 05:06 25 A. I don't, no.  
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1 Q. Okay. Well, let's turn to DTX-479, then. All right.  
 2 And I'd like you to turn to Page -- it has 110 on the bottom.  
 3 It also has 18443?  
 4 MR. HASFORD: If I may, Your Honor, going back to one  
 05:07 5 of the previous questions, I'd just like to lodge an  
 6 objection. Ms. Holland said what the plaintiffs told the FDA.  
 7 This was ISTA Pharmaceuticals. This was a different  
 8 corporation, you know. It was not plaintiffs in the sense of  
 9 Senju and B and L telling this to the FDA. So I'd like to  
 05:07 10 just lodge that objection for the record, just to keep that  
 11 clear.  
 12 MS. HOLLAND: B and L acquired ISTA, Your Honor.  
 13 THE COURT: Right, I understand that. But  
 14 technically, it wasn't -- it wasn't the plaintiffs making the  
 05:07 15 statement when it was given.  
 16 MS. HOLLAND: Well, it was ISTA, which is now part of  
 17 plaintiffs.  
 18 THE COURT: Right.  
 19 MS. HOLLAND: So you could look at it either way, I  
 05:07 20 guess.  
 21 BY MS. HOLLAND:  
 22 Q. In any event, if the -- the NDA holder is telling the FDA  
 23 that polysorbate 80 is being used as a solubilizer in Xibrom,  
 24 right?  
 05:07 25 A. **That's the statement that's made there, yes.**  
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1 Q. Okay. Now, I'd like you to turn, as I said, in your --  
 2 the next exhibit in your binder, 479A.  
 3 A. Okay.  
 4 Q. Look at the top of the page. Again, the NDA holder here  
 05:08 5 is again telling the FDA that benzalkonium chloride was used  
 6 as a preservative in Xibrom. Do you see that?  
 7 A. No. Where are you?  
 8 Q. The top of the page, it's the second page of  
 9 Exhibit 479A?  
 05:08 10 A. Yes, I'm there, thanks.  
 11 Q. Okay. So let me just repeat. Do you see it says  
 12 benzalkonium chloride was used as a preservative. Do you see  
 13 that?  
 14 A. Yes.  
 05:08 15 Q. Then it says: Polysorbate 80 was added as a stabilizer  
 16 to prevent interaction with bromfenac sodium.  
 17 Do you see that?  
 18 A. Yes.  
 19 Q. Do you agree that that was the reason polysorbate 80 was  
 05:08 20 added?  
 21 A. Well, that's what they state, but again, I've not seen  
 22 any evidence that actually shows that, in fact, occurred.  
 23 Q. Let me try one more time, then. Why don't you go to Page  
 24 112 in this exhibit.  
 05:09 25 A. Okay.  
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1 Q. And this says summary from Senju. Do you see that?  
 2 A. Yes.  
 3 Q. All right. And again, this is part of the NDA. You  
 4 understand that, right?  
 05:09 5 A. Yes.  
 6 Q. So you look at the fourth paragraph down on Page 184447.  
 7 It says: As the preservative, benzalkonium chloride was used  
 8 because parabens are unstable within the pH range of the  
 9 product.  
 05:09 10 Do you see that?  
 11 A. Yes.  
 12 Q. And then it says: To prevent the action of -- and then  
 13 we have the code name for bromfenac -- with benzalkonium  
 14 chloride, polysorbate 80 was added as a solubilizer.  
 05:09 15 Do you see that?  
 16 A. Yes.  
 17 Q. Do you disagree with that statement, as well?  
 18 A. I mean, they've made that statement. Again, I've seen --  
 19 I've not seen evidence where that's, in fact, supported by  
 05:09 20 data.  
 21 Q. Well, do you think it was just conjecture on their part?  
 22 A. I haven't -- I don't know what it is. I read this  
 23 statement, but again, I haven't seen any evidence to support  
 24 it.  
 05:10 25 Q. All right. I want to -- I want to look at one of the  
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1 well, you pointed out some of the statements were made in the  
 2 '034 patent, right?  
 3 A. That if -- that's true.  
 4 Q. Okay. All right. Now, can we go back to the '034  
 05:12 5 patent, please. And I'd like to go to column 2, line 23, in  
 6 the summary of the invention, and I think that that's  
 7 something that you looked at in your direct testimony. And I  
 8 think you pointed to the second line in the summary of the  
 9 invention, and you pointed out the three benzoylphenylacetic  
 05:13 10 acid derivatives, right?  
 11 A. Well, I read from that, yes.  
 12 Q. All right. And I think you said that someone of ordinary  
 13 skill in the art would have perhaps pursued those in place of  
 14 bromfenac. Is that what you said this morning?  
 05:13 15 A. Well, I mean, it -- based on Yanni, this patent, the --  
 16 Yanni presents evidence that bromfenac wouldn't necessarily be  
 17 the preferred out of Table 1, based on what's shown about the  
 18 NSAID, about the derivatives of these compounds.  
 19 Q. And again, that was as of 1995, correct?  
 05:13 20 A. That's true.  
 21 Q. All right. So let's fast forward to 2003. None of those  
 22 three benzoylphenylacetic acid derivatives in Yanni was a  
 23 marketed NSAID at that point in time, right?  
 24 A. I -- sitting here right now, I don't know that.  
 05:14 25 Q. So at least as of 2003, bromfenac had a big lead on these  
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1 prior art documents you looked at this morning, JTX168. All  
 2 right. And JTX168 is the '034 patent, right?  
 3 A. Yes.  
 4 Q. Now, I'd like you to tell the Court when -- when did this  
 05:11 5 patent become -- when did this patent issue?  
 6 A. It says date of patent, December 12, 1995.  
 7 Q. Okay. And as of that time, bromfenac had not yet become  
 8 a marketed NSAID, correct, for ophthalmic use?  
 9 A. You know, I don't remember when Bronuck was marketed. I  
 05:11 10 can't quite remember that sitting here.  
 11 Q. Okay. Assuming Bronuck was marketed in 2000, you agree  
 12 that as of 1995, bromfenac was not yet known as a marketed  
 13 NSAID, correct?  
 14 A. If that's true, yes.  
 05:11 15 Q. All right. Now, let's -- so let's talk about what  
 16 happened in the interim between 1995 and 2003. As of 2003,  
 17 Bronuck was already on the market in Japan, right?  
 18 A. That's my understanding.  
 19 Q. Okay. So as of that time, bromfenac had gone through a  
 05:11 20 battery of clinical trials, right?  
 21 A. I would assume so, yes.  
 22 Q. Bromfenac had been shown to be a safe and effective  
 23 ophthalmic NSAID as of that time, correct?  
 24 A. I would assume that's true in Japan.  
 05:12 25 Q. Okay. But none of that was known yet in 1995 when you --  
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1 other compounds, right? It was actually a marketed drug?  
 2 A. Yeah. I just -- I don't know. I mean, the one on there,  
 3 compound 8, nepafenac, I don't know when it was -- I don't  
 4 recall when it was marketed.  
 05:14 5 Q. Now, are you aware that there are different FDA  
 6 requirements to pursue a new -- a different formulation of an  
 7 already-marketed drug versus trying to get a completely new  
 8 drug on the market?  
 9 MR. HASFORD: Objection, Your Honor. It calls for a  
 05:14 10 legal conclusion as to FDA law.  
 11 THE COURT: Just a second.  
 12 Well, I think his direct actually touched on this, but  
 13 I'll -- I'll permit him to answer this question about whether  
 14 he's aware of the different FDA requirements.  
 05:14 15 THE WITNESS: I mean, I've been involved with new  
 16 drugs and developing them for market, just in a limited sense  
 17 from the -- it's called the CMC section viewpoint. So to that  
 18 extent, I understand there's requirements.  
 19 BY MS. HOLLAND:  
 05:15 20 Q. Okay. Now, to market a completely new drug in 2003 would  
 21 have required a full battery of clinical trials, right?  
 22 A. A new -- a new chemical entity?  
 23 Q. Yes.  
 24 A. There would have -- well, ultimately, my understanding is  
 05:15 25 there would need to be a new drug application ultimately filed  
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1 covering whatever indication for that -- that new chemical  
 2 entity.  
 3 Q. Right. And there would need to be Phase 1, 2 and 3  
 4 trials as well?  
 05:15 5 A. I -- this is probably out of my area. I mean, generally,  
 6 I understand that's what's required.  
 7 Q. And is it -- are you aware, based on your time in  
 8 industry working on these things, that to get a new drug  
 9 approved takes years and years?  
 05:15 10 A. I think it varies depending on what the drug is and the  
 11 delivery system, but that's all I could say basically about  
 12 the time.  
 13 Q. And you don't know the cost to develop a new drug, do  
 14 you?  
 05:16 15 A. No.  
 16 Q. All right. All right. Now, I want to -- I want to turn  
 17 to your testimony about the use of BAC as of 2003. Do you  
 18 agree that as of 2003 ophthalmic solutions that were packaged  
 19 in multi-dose containers had to contain a preservative?  
 05:16 20 A. Yes.  
 21 Q. Okay. And that's true today as well, right?  
 22 A. That's my understanding, yes.  
 23 Q. All right. And preservative-free formulations are  
 24 limited only to ones that are single-dose unit, correct?  
 05:17 25 A. That's true.

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1 in 2003, right?  
 2 A. I've read that, yes.  
 3 Q. Now, you had a slide up with quotes that you excerpted  
 4 from several articles that you said talked about the BAC  
 5 toxicity. Do you recall that?  
 6 A. I do.  
 7 Q. All right. Let's look at slide -- I think it's PDX4-3,  
 8 but I'm not exactly sure at this point. Yes, it's PDX4-3.  
 9 Now, you told the Court that those slides -- I'm sorry,  
 05:18 10 you told the Court that those articles talk about BAC  
 11 toxicity, right?  
 12 A. They do, yes.  
 13 Q. Okay. And did you actually read all those articles?  
 14 A. I did, yeah.  
 05:19 15 Q. Okay. So you know, then, that all those references, at  
 16 least the ones that talk about testing in humans, they all  
 17 discuss toxicity associated with long-term use, right?  
 18 A. That's true.  
 19 Q. That's not on your slide, though.  
 05:19 20 A. Well, I mean, it's part of the reference that I've got it  
 21 from.  
 22 Q. Okay. And so you didn't -- you didn't want the Court to  
 23 understand from that slide that any of the toxicity issues  
 24 were associated with short-term use, did you?  
 05:19 25 MR. HASFORD: Objection, argumentative.

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1 Q. And Prolensa is a multi-dose unit, right?  
 2 A. It is.  
 3 Q. So a preservative would be required in Prolensa, right?  
 4 A. Yes.  
 05:17 5 Q. All right. You mentioned a product called Acular PF in  
 6 your direct testimony. Do you recall that?  
 7 A. Yes, I do.  
 8 Q. And you said that was a preservative-free formulation,  
 9 right?  
 05:17 10 A. Yes.  
 11 Q. And now, that was a preservative-free formulation because  
 12 it was a single-dose formulation, right?  
 13 A. It is, yes.  
 14 Q. The Acular that's not single dose contains BAC, right?  
 05:17 15 A. That's correct.  
 16 Q. Do you know what the relative cost to a patient is of a  
 17 multi-dose versus a single-dose ophthalmic product?  
 18 A. I don't.  
 19 Q. All right. You agree that BAC was used as a preservative  
 05:18 20 in ophthalmic compositions in 2003, right?  
 21 A. It was, yes.  
 22 Q. And it's still used in ophthalmic compositions today,  
 23 right?  
 24 A. It is.  
 05:18 25 Q. And, in fact, BAC was the most common preservative used

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1 THE COURT: Sustained.  
 2 BY MS. HOLLAND:  
 3 Q. All right. Let's look at that Debbasch article, PTX-268  
 4 at Page 106. Let's go to Page 106, thanks, and let's look at  
 5 the first sentence there.  
 6 It says: Long-term use of anti-glaucoma drugs has been  
 7 associated with toxic, as well as inflammatory changes of the  
 8 ocular service -- surface.  
 9 Right?  
 05:20 10 A. That's what it says.  
 11 Q. Right. And glaucoma drugs or anti-glaucoma drugs are  
 12 intended to be taken over many years, correct?  
 13 A. That's my understanding, yes.  
 14 Q. All right. Prolensa is not a drug like that, right?  
 05:20 15 A. Prolensa is not an anti-glaucoma drug.  
 16 Q. And Prolensa is also not meant to be taken every day for  
 17 years and years, right?  
 18 A. Yeah, I think it's 14 days, but Dr. Trattler can answer  
 19 that kind of question.  
 05:20 20 Q. Okay. But your understanding is that it's a 14-day dose  
 21 after surgery, right?  
 22 A. That's my understanding.  
 23 Q. Right. Let's go to Page 107 in this Debbasch reference  
 24 and -- yeah, thank you.  
 05:20 25 I want to focus your attention on the paragraph that

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1 begins: To understand the role of preservatives.  
 2 Do you see that?  
 3 A. Yes.  
 4 Q. Okay. And that says: To understand the relative role of  
 05:21 5 preservatives such as benzalkonium chloride in the toxicity of  
 6 long-term use of anti-glaucomatous drugs, we performed a  
 7 series of in vivo and in vivo -- in vitro experiments.  
 8 Do you see that?  
 9 A. Yes.  
 05:21 10 Q. Okay. And there's nothing in this article that talks  
 11 about toxicity related to 14-day use, right?  
 12 A. There's not for 14 days, no.  
 13 Q. All right. So I don't want to go through -- I can go  
 14 through all of these, but do you agree with me that none of  
 05:21 15 these articles address short-term toxicity in the range of 14  
 16 days, that you would have, for example, with a drug like --  
 17 well, let me withdraw that.  
 18 None of these references that you have on your slide  
 19 addressed short-term use of ophthalmic compositions containing  
 05:22 20 BAC; is that right?  
 21 A. Well, they -- they address BAC used as a preservative in  
 22 -- in this particular study, like it was over a long-term use  
 23 is what the focus was.  
 24 Q. All right. Well, are you willing to agree with me that  
 05:22 25 the focus of all the studies were long-term use, or should we  
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1 go through them one by one?  
 2 A. No. They were.  
 3 Q. Okay. Now, you also -- you also mentioned in your direct  
 4 testimony PTX-294, which was a 1998 reference -- well, I  
 05:22 5 shouldn't -- I'm not even going to call it a reference. It  
 6 was a 1998 article from *The New York Times*, correct?  
 7 A. Yes.  
 8 Q. And it talked about -- what you said was it talked about  
 9 an oral bromfenac product, right?  
 05:23 10 A. It does, yes.  
 11 Q. And that product was withdrawn from the market in 1998,  
 12 right?  
 13 A. That's my understanding.  
 14 Q. Okay. Just to be clear, there has never been any safety  
 05:23 15 concerns associated with -- using bromfenac as an ophthalmic  
 16 product, correct?  
 17 A. From a liver toxicity standpoint, like Duract?  
 18 Q. Yes.  
 19 A. I don't know. You would have to ask Dr. Trattler.  
 05:23 20 Q. All right.  
 21 A. I'm not aware of that.  
 22 Q. When you -- when you were putting your testimony together  
 23 here with this *New York Times* article that talked about  
 24 toxicity of oral bromfenac, did you do any research to see if  
 05:23 25 there was any -- ever any toxicity associated with ophthalmic  
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1 bromfenac?  
 2 A. I didn't. This is -- I mean, there's a passage in Hara  
 3 also that talks about the oral bromfenac, and my point was, is  
 4 if there's sufficient absorption, you know, that, you know,  
 05:23 5 that might be considered relevant to one of skill in the art.  
 6 Q. As of 2003 -- well, let me withdraw that. Is it your  
 7 opinion that as of 2003 there were formulators who were  
 8 concerned about liver toxicity in administering or developing  
 9 ophthalmic bromfenac compositions?  
 05:24 10 A. Well, as of 2003, a skilled person would have known that  
 11 oral bromfenac, taken as this was taken, did cause liver  
 12 toxicity and --  
 13 Q. Would they know also that ophthalmic --  
 14 MR. HASFORD: Your Honor, I think he had some  
 05:24 15 additional testimony.  
 16 THE COURT: Okay, you may continue.  
 17 BY MS. HOLLAND:  
 18 Q. Go ahead. I'm sorry, I didn't mean to interrupt you.  
 19 A. Thank you, thanks.  
 05:24 20 So they would have known that. So working with  
 21 bromfenac, I mean, by other routes of administration, you're  
 22 concerned possibly if it -- depending on how much is absorbed.  
 23 Q. Well, by 2003, the person of ordinary skill in the art  
 24 knew that bromfenac had passed enough safety and efficacy  
 05:25 25 clinical trials to be a marketed product, right, as an  
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1 ophthalmic?  
 2 A. In Japan, yes, that's true, yeah.  
 3 Q. Okay. So you pointed to an article in 1998 about oral  
 4 bromfenac, but as of 2003, there was no safety -- there were  
 05:25 5 no safety concerns about ophthalmic use of bromfenac, correct?  
 6 A. I'm not aware of it.  
 7 Q. Now, is it your testimony, Dr. Williams, that as of 2003,  
 8 a person of ordinary skill in the art would not have included  
 9 BAC in a formulation?  
 05:26 10 A. No, I mean, not exactly. My testimony is if there was a  
 11 known interaction problem, that a person of ordinary skill in  
 12 the art would avoid the problem and either -- what I said is  
 13 either use another preservative or a preservative free or  
 14 possibly switch the active ingredient.  
 05:26 15 Q. Well, let me ask you about from the toxicity perspective  
 16 that you had that slide with the different references that  
 17 were intended to show some toxicity of BAC.  
 18 Is it your testimony that any of -- that there was a  
 19 toxicity issue that would have precluded someone of ordinary  
 05:27 20 skill in the art from wanting to work with a BAC formulation?  
 21 A. No, my testimony is one of skill in the art would have  
 22 been aware of studies that talked about the -- when  
 23 benzalkonium chloride is applied to the ocular surface. And  
 24 so from a formulation standpoint, knowing that, then, in my  
 05:27 25 opinion, a formulator would maybe include other types of  
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1 **preservatives in their studies. But I think once -- that they**  
2 **would do the study to confirm if or if not benzalkonium**  
3 **chloride caused toxicity or not to the surface.**  
4 Q. All right. Well, you used benzalkonium chloride in  
05:27 5 products in 2003, right?  
6 **A. That's true, yes.**  
7 Q. All right. And is it also correct that you worked on  
8 some formulations for NSAIDS in 2003?  
9 **A. Yes.**  
05:28 10 Q. All right. And you have a patent on those NSAIDS  
11 formulations, right?  
12 **A. I have a -- I think the patent is more process related,**  
13 **that NSAIDS are examples of drugs that we studied that work**  
14 **under that platform.**  
05:28 15 Q. And in your patent you gave examples of suitable NSAIDS  
16 that could be used in your invention, right?  
17 **A. I would have to look at it, I may have.**  
18 MS. HOLLAND: Your Honor, this is not on the exhibit  
19 list, but I'm using it for impeachment or to refresh his  
05:28 20 recollection, he just asked to see it.  
21 THE COURT: Is it his own patent?  
22 MS. HOLLAND: Yes.  
23 THE COURT: Any objection?  
24 Mr. HASFORD: So our issue, if it's just for  
05:29 25 impeachment purposes, your Honor, it's not being moved into  
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1 evidence, that's fine.  
2 THE COURT: Okay. Very well.  
3 BY MS. HOLLAND:  
4 Q. All right. So let me --  
05:29 5 **A. I didn't get a copy, sorry.**  
6 MS. HOLLAND: Oh. We have another copy.  
7 THE COURT: Do you want to borrow mine?  
8 MS. HOLLAND: We'll get you another one. Sorry about  
9 that.  
05:29 10 THE WITNESS: Thank you.  
11 BY MS. HOLLAND:  
12 Q. So let's look at what you've just been handed. This is  
13 U.S. Patent 6,509,028, correct?  
14 **A. Yes, it is.**  
05:29 15 Q. And you're the first named inventor on this patent?  
16 **A. Yes.**  
17 Q. And the date of the patent is January 21, 2003, right?  
18 **A. Yes.**  
19 Q. And just to orient you, I'm going to ask you to look at  
05:30 20 Column 10, Line 26.  
21 **A. Okay.**  
22 Q. Do you see you have a list there of suitable nonsteroidal  
23 anti-inflammatory agents to be used in your invention?  
24 **A. Yes.**  
05:30 25 Q. Okay. And you have a pretty long list there, right?  
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1 **A. There is a long list.**  
2 Q. And you include bromfenac on that list?  
3 **A. It may be.**  
4 Q. If you look at one, two, three, four, five, six, seven --  
05:30 5 eight lines down.  
6 **A. Yes, it's there.**  
7 Q. And you include at the end of that same line diclofenac,  
8 right?  
9 **A. Yes.**  
05:30 10 Q. A couple of lines down, 15 lines down, I believe, at Line  
11 40 in Column 10 you include ketorolac, right?  
12 **A. That's true, yes.**  
13 Q. And Line 43 you include flurbiprofen, right?  
14 **A. Yes.**  
05:31 15 Q. And in your invention any of those NSAIDS could be used  
16 interchangeably, right?  
17 **A. So remember this is for nasal and buccal delivery, not**  
18 **for ophthalmic use.**  
19 Q. For nasal or --  
05:31 20 **A. But, yes, that is what our intention was, is that these**  
21 **drugs would be applicable to our platform.**  
22 Q. All right. So at least for your nasal or buccal delivery  
23 platform those drugs, bromfenac, diclofenac, ketorolac, and  
24 flurbiprofen, any of those could be used in that same  
05:31 25 platform, correct?  
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1 **A. That's what we thought.**  
2 Q. And you also used benzalkonium chloride in this patent as  
3 a preservative, right?  
4 **A. It may have been because it's a preservative used in**  
05:31 5 **nasal products.**  
6 Q. All right. Just to confirm, I'll direct your attention  
7 to Column 7, Line 60.  
8 **A. Okay.**  
9 Q. And you'll see there that the first preservative listed  
05:32 10 is benzalkonium chloride, correct?  
11 **A. Yes, it is.**  
12 Q. All right. Now, it's true, isn't it, that in this patent  
13 there's no discussion of the different chemical structures of  
14 the different NSAIDS that you say can be used in the  
05:32 15 invention, right?  
16 **A. We just presented the drugs.**  
17 Q. No discussion of the different hydrogen bonding capacity  
18 of those drugs in this patent?  
19 **A. No.**  
05:32 20 Q. You gave some testimony in your direct about the IIG,  
21 correct, the Inactive Ingredient Guide?  
22 **A. Well, I was going to testify about it but I was thinking**  
23 **it all got struck, so I actually don't recall.**  
24 Q. That was Remington that got struck.  
05:33 25 **A. Well, I did talk about IIG then.**  
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1 Q. That was spoken about as well.  
 2 So I think -- let me ask you this first. You know that  
 3 the IIG is a list of excipients contained in approved  
 4 products, right?  
 05:33 5 A. Yes.  
 6 Q. And you've used the IIG in your own work, right?  
 7 A. I do use it, yes.  
 8 Q. And you use it as a starting point in selecting  
 9 excipients, right?  
 05:33 10 A. Well, that and other references, but I do use it, yes.  
 11 Q. And you are aware, aren't you, that if you want to use an  
 12 excipient that's not listed in the IIG, you need to conduct  
 13 additional safety studies, right?  
 14 A. Yes, and that's what I testified to earlier.  
 05:34 15 Q. And it was your experience in industry that you always  
 16 used excipients listed in the IIG, right?  
 17 A. That's true. You have to have -- from my experience, you  
 18 had to have a reason to, you know, to use an excipient that is  
 19 not in an approved product for that route of administration,  
 05:34 20 it's possible but that was the easier path if it worked.  
 21 Q. Now, you talked in direct testimony about the use of  
 22 tyloxapol in prior art formulations and you mentioned that  
 23 they were suspension based formulations. Do you recall that?  
 24 A. Yes.  
 05:34 25 Q. All right. The IIG actually showed five ophthalmic  
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1 solutions that use tyloxapol, right?  
 2 A. It did, yes.  
 3 Q. I'm sorry?  
 4 A. It did, yes.  
 05:35 5 MS. HOLLAND: Let's put up PDX-4-5. It might not be  
 6 the right number anymore. Yes. Thank you.  
 7 BY MS. HOLLAND:  
 8 Q. All right. So you testified about this on direct  
 9 examination, right?  
 05:35 10 A. I did.  
 11 Q. And this was meant to show comparative stability, right?  
 12 A. Yeah, it's comparing formulations containing either  
 13 polysorbate 80 or different concentrations of tyloxapol, the  
 14 chemical stability of bromfenac.  
 05:35 15 Q. And comparison Example 1 is what you chose to use for the  
 16 stability of polysorbate 80, right?  
 17 A. Well, that's the formulation showing the stability of  
 18 bromfenac containing polysorbate 80.  
 19 Q. That formulation is nowhere in the prior art, right?  
 05:36 20 A. I think that formulation is similar to Experimental  
 21 Example 4 in Ogawa.  
 22 Q. It's not the same as Experimental Example 4, is it?  
 23 A. It's slightly different in the ingredients.  
 24 MS. HOLLAND: Now, I put a demonstrative together,  
 05:36 25 DDX-61, could we put that up?  
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1 BY MS. HOLLAND:  
 2 Q. And it should be in your binder, DDX-4 in your binder.  
 3 So what -- you can check this out. But what I've done  
 4 is taken the five formulations that you had in your  
 05:36 5 demonstrative and I added Ogawa '225 Example 6. Do you see  
 6 that?  
 7 A. Yes.  
 8 Q. And Ogawa '225 Example 6, in addition to the ingredients  
 9 in comparison Example 1, also contains polyvinylpyrrolidone  
 05:37 10 and sodium edetate and sodium sulfite, right?  
 11 A. It does, yes.  
 12 Q. Now, when Ogawa '225 Example 6 was tested at a pH of 8,  
 13 it had a stability of 100.9 percent, right?  
 14 A. Yes.  
 05:37 15 Q. And when comparison Example 1 was tested, it had a  
 16 stability of 51.27 percent, right?  
 17 A. Under the conditions of pH 7, that's what -- that's the  
 18 results, yes.  
 19 Q. But that formulation did not have polyvinylpyrrolidone or  
 05:38 20 sodium sulfite, right?  
 21 A. Comparison Example 1 does not have polyvinylpyrrolidone  
 22 nor sodium sulfite.  
 23 Q. And you had testified in your direct testimony that those  
 24 two ingredients, polyvinylpyrrolidone and sodium sulfite, were  
 05:38 25 used for stability purposes, right?  
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1 A. According to Ogawa, that's how Ogawa solved the chemical  
 2 stability problem of bromfenac sodium.  
 3 Q. You would expect a formulation that didn't have those two  
 4 ingredients to be less stable than one that did, right?  
 05:38 5 A. Well, according to Ogawa, that's true.  
 6 Q. Okay. Now, there was no example in Ogawa where the  
 7 formulation of Example 6 was tested at a pH of 7, right?  
 8 A. There's not, no.  
 9 Q. And if Ogawa Example 6 was tested at a pH of 7, you would  
 05:39 10 expect the stability to be higher than the 51.27 percent for  
 11 comparison Example 1, right?  
 12 A. I mean, that's what Ogawa states, but he doesn't have any  
 13 data so I actually don't know what it would be.  
 14 Q. But you testified, didn't you, that your opinion would be  
 05:39 15 that the stability would be somewhere in between 51.27 and  
 16 100.9, right?  
 17 A. That's probably right, yeah.  
 18 Q. And it could be somewhere in the ballpark of the  
 19 tyloxapol compositions that are on this page, right?  
 05:39 20 A. It could be, yeah.  
 21 Q. Before lunch today, we were talking about the stability  
 22 data that you had included in your direct testimony that was  
 23 based on internal laboratory notebooks of Mr. Sawa. Do you  
 24 recall that?  
 05:40 25 A. Yes.  
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1 Q. This isn't your binder but I'm going to hand up what  
 2 we've marked as JTX-33A.  
 3 MR. HASFORD: Your Honor, we are going to have to  
 4 object to it. This appears to be Mr. Sawa's laboratory  
 05:40 5 notebook. To the extent counsel, again, is attempting to use  
 6 the internal documents to show obviousness, that's improper.  
 7 We object.  
 8 MS. HOLLAND: Your Honor, earlier this morning I  
 9 believe you had made the ruling that I could question the  
 05:41 10 witness based on the underlying data that appeared in the  
 11 tables that he used in his direct testimony, that's what I'm  
 12 doing for unexpected results.  
 13 THE COURT: If it's limited to the underlying data he  
 14 actually used in the table he presented there, I'll overrule  
 05:41 15 the objection. I'll permit it.  
 16 BY MS. HOLLAND:  
 17 Q. All right. If you look at the last page, which is  
 18 JTX-33.204 -- well, you see a table there, right?  
 19 A. **On JTX-33.204?**  
 05:41 20 Q. 204.  
 21 A. **I do, yes.**  
 22 Q. And at the top of the page you see it says P2000B177. Do  
 23 you see that, top right-hand portion of the page?  
 24 A. **Yes, I do.**  
 05:41 25 Q. You understand that that was the study protocol that was  

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1 being used to generate this data?  
 2 A. **I'm -- actually sitting here right now, I'm not sure what  
 3 that number refers to.**  
 4 Q. Did you review this entire document before giving your  
 05:42 5 testimony this morning about the stability data?  
 6 A. **No, I think I have reviewed it in the past, but it's been  
 7 a while.**  
 8 MR. HASFORD: I'll also note for the record, your  
 9 Honor, it appears that this is a Japanese language document,  
 05:42 10 so to the extent there are questions on that and counsel has a  
 11 translation, that might be relevant.  
 12 MS. HOLLAND: I apologize. It's actually earlier in  
 13 the document. This is a document that was produced by  
 14 plaintiffs to us.  
 15 BY MS. HOLLAND:  
 16 Q. So now if you turn to Page 33.30, I think you'll see it  
 17 in English. And I apologize for that.  
 18 A. **Okay.**  
 19 Q. And you see this is test code P2000B177, right?  
 05:43 20 A. **That's what it says, yes.**  
 21 Q. And the tester is Shirou Sawa, right?  
 22 A. **Yes.**  
 23 Q. Now, if you look at the left-hand column, there's two  
 24 formulations that are labeled A-28 and A-29. Do you see that?  
 05:43 25 A. **Yes.**  

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1 Q. And you see that they were tested at 60 degrees C. for  
 2 four weeks. Do you see that?  
 3 A. **So A-27 and A-28?**  
 4 Q. No, A-28 and A-29.  
 05:43 5 A. **I see that.**  
 6 Q. Those were two samples you had on the stability  
 7 demonstrative this morning, right?  
 8 A. **That's true, yes.**  
 9 Q. And if you look at A-28 and A-29, it says 85.96 for A-28  
 05:44 10 as the remaining percent, and 82.01 for A-29 as remaining  
 11 percent. Do you see that?  
 12 A. **Yes.**  
 13 Q. And that's the data you had up this morning, is that  
 14 correct?  
 05:44 15 A. **That's true.**  
 16 Q. Do you know the data you used this morning came from this  
 17 test P2000B177?  
 18 A. **It appears to be, yes.**  
 19 Q. Okay. Now, in relying on this data did you review the  
 05:44 20 protocol for how the data was generated?  
 21 A. **I don't recall seeing -- I may have, I just don't  
 22 remember, sitting here right now.**  
 23 Q. Well, let's look at the beginning of the document. Page  
 24 2, do you see it says "test protocol?"  
 05:45 25 A. **Yes.**  

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1 Q. And it says for test code P2000B177. Do you see that?  
 2 A. **I do.**  
 3 Q. And that's the same test code we saw on the table of data  
 4 that you had used in compiling your stability testing results,  
 05:45 5 correct?  
 6 A. **Yes.**  
 7 Q. Okay. Does this refresh your recollection that you  
 8 reviewed the test protocol?  
 9 A. **No, not really.**  
 05:45 10 Q. Okay. So you don't know one way or the other that before  
 11 you presented the data, whether you reviewed the protocol for  
 12 how it was generated?  
 13 A. **I reviewed a lot of documents, and just sitting here  
 14 right now this doesn't look familiar.**  
 05:45 15 Q. Well, did you look at the purpose of the data, the  
 16 stabilized data that was being presented in this document  
 17 before presenting it in the Court today?  
 18 A. **Did I look at -- I'm sorry?**  
 19 Q. The purpose of this test protocol.  
 05:46 20 MR. HASFORD: I'll just note an objection for the  
 21 record, your Honor, to the extent this is again being  
 22 attempted to be used for purposes of obviousness.  
 23 THE COURT: It will be based on his next answer, so  
 24 your objection is premature.  
 05:46 25 THE WITNESS: I'm sorry, could you please repeat the  

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1 question?  
 2 BY MS. HOLLAND:  
 3 Q. Does this refresh your recollection that you reviewed the  
 4 test protocol on this document prior to giving your opinions  
 05:47 5 about the stability data that was generated pursuant to the  
 6 test protocol?  
 7 A. I would have seen it. It's been a while, I would have to  
 8 reread it again.  
 9 Q. At the time that you were reviewing the stability data in  
 05:47 10 this document, you were aware then that the stability testing  
 11 was being done because bromfenac sodium --  
 12 MR. HASFORD: Objection, your Honor. Move to strike.  
 13 This is exactly the purpose they're trying to get it in for  
 14 and it's improper. They're trying to get in obviousness. We  
 05:47 15 objected on this basis. Your Honor allowed them to use this  
 16 for the sole purpose of showing him the data, and whatever  
 17 other statements they're trying to use this for is improper.  
 18 MS. HOLLAND: Your Honor, I don't know how it could  
 19 possibly be improper to ask about the protocol of a test that  
 05:47 20 the expert used in his direct testimony.  
 21 THE COURT: You can ask about the protocol but not  
 22 the purpose. Your question goes to the purpose.  
 23 MS. HOLLAND: It goes to protocol and it goes to what  
 24 the stability testing data means.  
 05:48 25 THE COURT: The protocol in a scientific sense is  
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1 patent you testified about this morning, right?  
 2 A. Yes.  
 3 Q. And you talked about the disclosure in this reference of  
 4 tyloxapol as a solubilizer, right?  
 05:51 5 A. Yes.  
 6 Q. So let's look at that bottom of Column 4, Line 64. It  
 7 says, "another preferred solubilizer is tyloxapol," right? Do  
 8 you see that?  
 9 A. Yes.  
 05:51 10 Q. And then it says, "the concentration used depends  
 11 especially on the concentration of the active ingredient." Do  
 12 you see that?  
 13 A. Yes.  
 14 Q. Then it says, "the amount added is typically sufficient  
 05:51 15 to solubilize the active ingredient." Do you see that?  
 16 A. I do.  
 17 Q. And there's no more information there provided to a  
 18 person of ordinary skill in the art, right?  
 19 A. No more information about what?  
 05:51 20 Q. About the concentration of tyloxapol to be used in the  
 21 formulation.  
 22 A. I think the next line --  
 23 MR. HASFORD: I object, your Honor, to the extent it  
 24 mischaracterizes the document. I don't believe it discloses  
 05:52 25 an amount of tyloxapol there.  
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1 what did the scientist do that led to the results that this  
 2 witness relied on, the purpose isn't part of that, the  
 3 scientific setup. And so if you want to ask how were the  
 4 tests conducted, what were the conditions, then I'll permit it  
 05:48 5 because it reflects on the data.  
 6 But my ruling -- my permitting you to use this at all  
 7 is a very, very narrow one, it has to be exploring the data  
 8 that A-28 and A-29 experiments that the witness actually  
 9 relied on as part of his direct testimony.  
 05:48 10 MS. HOLLAND: So, your Honor, in exploring the data  
 11 the question is whether the data reflects physical or chemical  
 12 stability data. We heard testimony about the data this  
 13 morning with respect to the unexpected results opinions. It  
 14 makes a difference as to whether or not the data was generated  
 05:49 15 to show chemical stability or physical stability, that makes a  
 16 difference in terms of the unexpected results.  
 17 THE COURT: You can ask what the data showed. But,  
 18 again, the purpose, what they expected is intruding into the  
 19 area of the inventor's mind of why the inventor was doing what  
 05:49 20 he was doing.  
 21 MS. HOLLAND: Well, I'm sorry, your Honor, can I just  
 22 try one more time?  
 23 THE COURT: I've ruled. Let's move on.  
 24 BY MS. HOLLAND:  
 05:51 25 Q. Would you turn to JTX-71? This is the '931 Sallmann  
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1 THE COURT: The witness can answer if he understands  
 2 the question.  
 3 THE WITNESS: I think I do. The next sentence gives  
 4 direction on -- well, the solubilizer's concentration relative  
 05:52 5 to the active -- to the diclofenac potassium, which is what  
 6 Sallmann is about.  
 7 BY MS. HOLLAND:  
 8 Q. So it says that the -- for example, the concentration of  
 9 solubilizer is from .1 to 5000 times the concentration of the  
 05:52 10 active, right?  
 11 A. Yes.  
 12 Q. Okay. And, at least according to this patent, the person  
 13 of ordinary skill in the art is supposed to determine the  
 14 concentration to use themselves based on the concentration of  
 05:52 15 the active, right?  
 16 A. Well, the -- well, this is talking about the diclofenac  
 17 potassium because that's what Sallmann is talking about, and  
 18 this is telling a skilled person that the amount of the  
 19 solubilizer is going to depend on how much of the active is  
 05:53 20 present. So the more active, then the more solubilizer one  
 21 needs to dissolve that amount of active ingredient.  
 22 Q. And the skilled person would have performed some  
 23 experiments to determine that amount, correct?  
 24 A. Presumably they would have to. You know, given this  
 05:53 25 guidance they would have to figure that out what an  
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1 appropriate amount is under the conditions of what's in the --  
 2 other ingredients in the formulation, pH, parameters such as  
 3 those in order to come up with the amount of solubilizer.  
 4 MS. HOLLAND: Your Honor, would it appropriate to  
 05:54 5 take the afternoon break now?  
 6 THE COURT: Okay. Sure.  
 7 MS. HOLLAND: Thank you.  
 8 THE COURT: Let's about a ten-minute break and we'll  
 9 resume about 3:35.  
 05:54 10 (Brief Recess.)  
 11 DEPUTY CLERK: All rise.  
 12 THE COURT: Be seated, please.  
 13 You may proceed.  
 14 MS. HOLLAND: Thank you, your Honor.  
 15 BY MS. HOLLAND:  
 16 Q. Dr. Williams, you testified on your direct examination  
 17 about some of Dr. Davies' opinions as to chemistry issues in  
 18 this case, correct?  
 19 A. I mentioned my reliance on some of his opinions, yes.  
 06:08 20 Q. And you relied on his opinions as of the time you  
 21 submitted your expert reports in this case as well, right?  
 22 A. True, yes.  
 23 Q. At the time you submitted your expert reports, you had  
 24 never met Dr. Davies, right?  
 06:09 25 A. That's true.

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1 and the Prolensa is .5 units on the pH scale, right?  
 2 A. Yes.  
 3 Q. Okay. Now, you've said that the pH of Prolensa is 7.8.  
 4 Are you aware that there's actually a range of pH at which  
 06:10 5 Prolensa can be released?  
 6 A. Can be released?  
 7 Q. Well, let me do this in the context of the document.  
 8 Let's look at PTX-125C, and this is the section of the  
 9 Prolensa ANDA. Do you see that?  
 06:11 10 A. I do.  
 11 Q. And this section is entitled specifications. Do you see  
 12 that?  
 13 A. Yes.  
 14 Q. It says it contains the release and shelf specifications  
 06:11 15 for Prolensa, right?  
 16 A. Yes.  
 17 Q. And if you look down at the pH specification --  
 18 MS. HOLLAND: Can you highlight that? Thank you.  
 19 BY MS. HOLLAND:  
 06:11 20 Q. It says release 7.6 to 8.0. And then shelf 7.4 to 8.1.  
 21 Do you see that?  
 22 A. I do.  
 23 Q. And you've had experience with specifications before in  
 24 your time in industry, right?  
 06:11 25 A. Yes.

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1 Q. You've never spoken to him, correct?  
 2 A. That's true.  
 3 Q. And to the extent that Dr. Davies and Dr. Heathcock have  
 4 opposing views on the chemistry issues, you can't offer any  
 06:09 5 opinion on which of the two is correct, right?  
 6 A. That's true.  
 7 Q. I just want to turn briefly of your opinions on pH in  
 8 connection with unexpected results.  
 9 You testified that Prolensa has a pH of 7.8 and  
 06:09 10 Bronuck®, Xibrom®, and Bromday® have a pH of 8.3, right?  
 11 A. Yes.  
 12 Q. Now, the Ogawa Example 6 has a pH of 8, right?  
 13 A. Yes.  
 14 Q. And do you agree that the preferred pH range in the Ogawa  
 06:09 15 patent is 7.5 to 8.5?  
 16 A. That's what Ogawa states, yes.  
 17 Q. To be clear, Claim 6 and 20, the two asserted claims here  
 18 don't have any specific limitation as to pH, right?  
 19 A. They have the limitation suitable for ophthalmic  
 06:10 20 administration but there's no specific pH value or range.  
 21 Q. And you agree that pH 8.3 would be suitable for  
 22 ophthalmic administration, right?  
 23 A. Yes.  
 24 Q. Now, you testified that the pH difference between the  
 06:10 25 prior formulation, which is the Xibrom®, Bromday® formulation,

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1 Q. So you know that a release specification means that if a  
 2 batch of Prolensa has a pH anywhere between 7.6 and 8.0, it  
 3 can be released to the market, right?  
 4 A. That's true. Yes, that's my understanding.  
 06:12 5 Q. And similarly, a shelf specification means that the pH of  
 6 Prolensa can go up between -- anywhere between 7.4 and 8.1  
 7 during its shelf life and that would still be within FDA  
 8 approved product, correct?  
 9 A. That's my understanding, yes.  
 06:12 10 MS. HOLLAND: That's all I have, your Honor.  
 11 THE COURT: Okay. Thank you.  
 12 Redirect?  
 13 MR. HASFORD: We have some redirect, your Honor.  
 14 (REDIRECT EXAMINATION OF ROBERT O. WILLIAMS, III BY  
 15 MR. HASFORD:)  
 16 BY MR. HASFORD:  
 17 Q. Let's pull up PDX4-5, please.  
 18 Did you hear -- or Dr. Williams, do you recall  
 19 Ms. Holland asking you various questions about the closest  
 06:13 20 prior art in connection with PDX4-5?  
 21 A. Yes.  
 22 Q. Did you hear Dr. Lawrence testify that boric acid, Borax,  
 23 disodium edetate, benzalkonium chloride, polyvinylpyrrolidone,  
 24 and sodium sulfite in the formulation of Example 6 of the  
 06:13 25 Ogawa '225 patent would not detrimentally affect its basic and

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1 novel properties, including stability?  
 2 A. Yes, I heard her say that.  
 3 Q. And PDX4-5 includes the three formulations that were  
 4 tested in Experimental Example 1 of the '431 patent. Do you  
 06:14 5 see that?  
 6 A. Yes.  
 7 Q. What are the components of Comparison Example 1 in Table  
 8 1 in Experimental Example 1 of the '431 patent?  
 9 A. So that's the bromfenac sodium, boric acid, Borax -- I'm  
 06:14 10 sorry, there is no Borax -- benzalkonium chloride, Polysorbate  
 11 80, and then water.  
 12 Q. How, if at all, do the other formulations in Experimental  
 13 Example 1 differ from the formulation of Comparison Example 1  
 14 of the '431 patent?  
 06:14 15 A. They differ in the surfactant that's added, being  
 16 tyloxapol, and then there is different levels of tyloxapol  
 17 being studied.  
 18 Q. Does Table 1 of the '431 patent disclose chemical  
 19 stability test results?  
 06:14 20 A. Yes.  
 21 Q. Does Comparison Example 1 in Experimental Example 1 of  
 22 the '431 patent reflect the closest prior art as defined by  
 23 defendants?  
 24 A. In my opinion, yes.  
 06:15 25 Q. Do you recall that Ms. Holland asked you various  
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1 but a skilled person, if an excipient that's not in the IIG  
 2 list works in the formulation and nothing else does, then  
 3 there is a path in order -- a path to get that particular  
 4 additive in an approved product. I mean, in essence,  
 06:16 5 somebody's got to be the first.  
 6 MR. HASFORD: Noel, can you please put DDX-1-18 up on  
 7 the screen.  
 8 BY MR. HASFORD:  
 9 Q. Do you see that DDX1-18 also reflects portions of DTX-196  
 06:17 10 which the defendants have introduced into evidence as the  
 11 FDA's Inactive Ingredients Guide?  
 12 A. Yes.  
 13 Q. As of 2003, how many ophthalmic solutions containing  
 14 Octoxynol 40 had been approved by the FDA?  
 06:17 15 A. There's one listed there.  
 16 Q. Do you recall testifying earlier that Acular included  
 17 Octoxynol 40 and was approved in 1992?  
 18 A. It did, and yes, I remember testifying.  
 19 Q. As of 2003, what was the one ophthalmic solution  
 06:17 20 containing Octoxynol 40 that had been approved by the FDA?  
 21 A. That's Acular.  
 22 Q. Did the developers of Acular use a nonionic surfactant,  
 23 namely Octoxynol 40, that had not previously been listed in  
 24 the FDA Inactive Ingredient Guide?  
 06:17 25 A. They did, yes.  
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1 questions on cross exam about the FDA's Inactive Ingredients  
 2 Guide?  
 3 A. Yes.  
 4 Q. Let's put DDX2-55 up on the screen.  
 06:15 5 Does DDX2-55 depict a portion of the FDA's Inactive  
 6 Ingredient Guide in DTX-196?  
 7 A. It does, yes.  
 8 Q. Let me direct your attention to the top line for  
 9 tyloxapol-containing ophthalmic solutions. As of the date of  
 06:15 10 DTX-196, how many ophthalmic solutions containing tyloxapol  
 11 had been approved by the FDA?  
 12 A. It lists five here.  
 13 Q. As of the date of DTX-196, were any of the five  
 14 FDA-approved tyloxapol-containing ophthalmic solutions NSAID  
 06:15 15 products?  
 16 A. No.  
 17 Q. Did you hear Dr. Lawrence testify that, in her opinion, a  
 18 person of ordinary skill in the art would only have looked as  
 19 of 2003 to those excipients listed in DTX-196 when formulating  
 06:16 20 an ophthalmic NSAID solution?  
 21 A. I heard that, yes.  
 22 Q. Do you agree with Dr. Lawrence's opinion?  
 23 A. No.  
 24 Q. Why not?  
 06:16 25 A. Because, as I testified earlier to, that is one source,  
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1 Q. How, if at all, does this relate to your opinion that a  
 2 person of ordinary skill in the art as of 2003 would not have  
 3 limited the choice of surfactants for an NSAID ophthalmic  
 4 solution to only those listed in the FDA Inactive Ingredient  
 06:18 5 Guide?  
 6 A. Well, it's an -- it's an example of -- of product that's  
 7 developed with an excipient that wasn't previously listed in  
 8 the IIG, and that they apparently undertook studies to get it  
 9 approved and now it's listed.  
 06:18 10 Q. Do you remember Ms. Holland asking you questions on  
 11 cross-examination about one of your patents?  
 12 A. Yes.  
 13 Q. Does that patent deal with nasal and buccal formulations?  
 14 A. Yes, it does.  
 06:18 15 Q. Do nasal and buccal formulations differ from ophthalmic  
 16 solutions such as the aqueous liquid preparations of the '431  
 17 patent?  
 18 A. It's a different route of administration, yes.  
 19 Q. Do you remember Ms. Holland asking you questions on  
 06:18 20 cross-examination about whether the pH of Xibrom® and Bromday®  
 21 is in the prior art?  
 22 A. Yes.  
 23 Q. Is it your understanding that the pH of Bronuck® is 8 to  
 24 8.6 and that was disclosed in the prior art? And, if  
 06:19 25 necessary, we can go to the new drugs in Japan reference to  
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1 refresh your recollection.  
2 A. Okay.  
3 Q. Okay. Let's pull up the new drugs in Japan reference.  
4 Let's turn to the next page. Following page.  
06:19 5 Okay. So, take a look, if you would, at the page  
6 bearing Bates Number -- I'm sorry, Noel, go up.  
7 Let's take a look at JTX-210, at the package bearing  
8 Bates Number PROL 0364732. Let me direct your attention to  
9 the right-hand column and, in particular, the table that says  
06:20 10 "Composition/Properties." Do you see that?  
11 A. Yes.  
12 Q. Does JTX-210 disclose the pH of Bronuck® as 8 to 8.6?  
13 A. It does, yes.  
14 Q. Is it your understanding that the defendants have taken  
06:20 15 the position in this case that Bronuck®, Xibrom®, and Bromday®  
16 all have the same composition?  
17 A. That's my understanding.  
18 Q. Do you remember Ms. Holland asking you various questions  
19 on cross-examination about the unexpected results disclosed in  
06:20 20 the '431 patent?  
21 A. I do.  
22 Q. Let's take a look, if we would, at the '431 patent, and,  
23 in particular, Experimental Example 1. It's going to be  
24 JTX-1.  
06:20 25 Do you have an understanding as to whether the '431  
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1 patent discloses chemical stability results for formulations  
2 of bromfenac containing tyloxapol?  
3 A. It does -- it does.  
4 Q. Where, if at all, does the '431 patent disclose chemical  
06:21 5 stability results for formulations of bromfenac containing  
6 tyloxapol?  
7 A. So, there is a row that's titled "Remaining Rate," as --  
8 and a percent, so that's the chemical stability of bromfenac  
9 sodium that is remaining in solution, integrated as a function  
06:21 10 of the testing conditions.  
11 Q. Are those results disclosed in, among other places, Table  
12 1 in Experimental Example 1 of the '431 patent?  
13 A. They are, yes.  
14 Q. During prosecution of the '431 patent, did the patent  
06:21 15 examiner credit the unexpected chemical stability results of  
16 Experimental Example 1 in allowing '431 patent to issue?  
17 MS. HOLLAND: Your Honor, all these questions have  
18 been leading.  
19 MR. HASFORD: I'm happy to rephrase that one, your  
06:21 20 Honor.  
21 THE COURT: Okay. Please do.  
22 BY MR. HASFORD:  
23 Q. What, if anything, did the patent examiner say about the  
24 results in Experimental Example 1 of the '431 patent during  
06:22 25 prosecution?  
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1 A. As I testified to earlier, the patent examiner credited  
2 in the notice of allowance the stability results presented in  
3 Table 1 --  
4 Q. Did --  
06:22 5 A. -- of Experimental Example 1.  
6 Q. I apologize.  
7 Did the patent examiner credit them as unexpected?  
8 A. Yes, that's the word he used.  
9 Q. Regardless of whatever else tyloxapol may do in the  
06:22 10 Prolensa® formulation, do you have an opinion as to whether or  
11 not tyloxapol chemically stabilizes bromfenac?  
12 A. I do.  
13 Q. What is your opinion?  
14 A. My opinion is, based on the data I've seen, that -- is  
06:22 15 that tyloxapol does chemically stabilize bromfenac sodium in  
16 solution.  
17 Q. In your opinion, was that expected or unexpected?  
18 A. In my opinion, it was unexpected. I've not seen anything  
19 in the literature that would have suggested tyloxapol would  
06:22 20 have chemically stabilized bromfenac sodium.  
21 MR. HASFORD: Nothing further at this time, your  
22 Honor.  
23 MS. HOLLAND: Your Honor, can I follow up with just a  
24 couple of questions on one topic?  
06:23 25 THE COURT: Okay. Couple means two.  
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1 MS. HOLLAND: Now I have to select carefully.  
2 (RE-CROSS EXAMINATION OF ROBERT O. WILLIAMS, III BY  
3 MS. HOLLAND:)  
4 Q. Dr. Williams, I want to talk very briefly about your  
06:23 5 testimony that you gave on the notice of allowance. You just  
6 testified about that on redirect, correct?  
7 A. Yes.  
8 Q. Isn't it correct that the examiner who -- who you said  
9 issued the notice of allowance didn't have all the prior art  
06:23 10 that's been discussed in this case?  
11 A. I -- I'm not sure. I haven't considered that question.  
12 Q. So you don't know whether or not the Court has more prior  
13 art at its disposal than the examiner did during prosecution?  
14 A. I just haven't compared what's -- what the prior art is  
06:23 15 now compared to what the examiner had. I mean, I think on the  
16 face -- let's see -- that's JTX-2?  
17 Q. So you have --  
18 MR. HASFORD: I believe he's asking for JTX-1 --  
19 THE WITNESS: I'm sorry, the '431 patent. JTX-1?  
06:24 20 Thank you.  
21 So the examiner had -- I'm sorry?  
22 BY MS. HOLLAND:  
23 Q. You don't see the Schott reference there, for example,  
24 right?  
06:24 25 MR. HASFORD: Hold on. I think we're trying to get  
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1 the '431 patent, the face, put up, your Honor.  
 2 THE COURT: Okay.  
 3 MS. HOLLAND: I'm sorry. It's my examination. Can I  
 4 put up the exhibits I want to put up? Thank you.  
 06:24 5 THE COURT: All right. Let's proceed.  
 6 BY MS. HOLLAND:  
 7 Q. Dr. Williams, do you recall the question?  
 8 A. I don't. I'm sorry.  
 9 Q. All right. I apologize.  
 06:25 10 All right. Before offering your opinion today about  
 11 the notice of allowance, you did not check to see whether or  
 12 not the examiner had all the prior art before him that we have  
 13 before us at the trial of this case, correct?  
 14 A. I mean, I was aware that the examiner had the Ogawa '225  
 06:25 15 patent, the Yanni '034 patent, the Desai '929 patent, so, I  
 16 mean, the examiner had some of the prior art that I've been  
 17 speaking of.  
 18 Q. Okay. Some but not all, correct?  
 19 A. I -- I hesitate to say that because I hadn't actually  
 06:25 20 done the comparison.  
 21 Q. Okay, that's fine.  
 22 But you are aware that the examiner didn't have the  
 23 benefit of any expert testimony on the issues before issuing  
 24 the notice of allowance, right?  
 06:25 25 A. I -- I actually -- I don't know what -- if -- I'm not  
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1 sure the answer to that question.  
 2 Q. Okay. Nothing further. Thank you.  
 3 MR. HASFORD: Nothing further from us, your Honor.  
 4 THE COURT: Okay. I have no questions.  
 06:26 5 THE WITNESS: Thank you, sir.  
 6 THE COURT: So you may step down.  
 7 THE WITNESS: Thank you.  
 8 MR. HASFORD: I think we still have a bit of a  
 9 housekeeping matter, your Honor, in terms of getting the  
 06:26 10 exhibits moved into evidence.  
 11 THE COURT: Yes.  
 12 MR. HASFORD: I think we read the list that we had  
 13 already, and counsel was going to consider whether they had  
 14 any objections to those.  
 06:26 15 MS. HOLLAND: We don't have any objections to those,  
 16 but I would also like to move in some of the exhibits that  
 17 were used during cross-examination.  
 18 THE COURT: Okay. Just a moment. Let me return then  
 19 to the plaintiff's list and I'll read those into the record.  
 06:26 20 Okay. The following exhibits are received into  
 21 evidence: PTX-294, PTX-268, PTX-272, PTX-326, PTX-273, also  
 22 PTX-324, PTX-265, PTX-591, PTX-592, PTX-593, JTX-144, also  
 23 PTX-474, also JTX-18. They are all received into evidence.  
 24 (EXHIBITS PTX-294, PTX-268, PTX-272, PTX-326, PTX-273,  
 06:26 25 PTX-324, PTX-265, PTX-591, PTX-592, PTX-593, JTX-144, PTX-474,  
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1 AND JTX-18 WERE RECEIVED IN EVIDENCE.)  
 2 MR. HASFORD: Thank you, your Honor.  
 3 THE COURT: Okay, Ms. Holland?  
 4 MS. HOLLAND: Yes, your Honor. It's JTX-25,  
 06:27 5 DTX-479A, DTX-478.  
 6 THE COURT: Those were only for impeachment, weren't  
 7 they?  
 8 MR. HASFORD: Yes.  
 9 THE COURT: So they wouldn't come into evidence.  
 06:27 10 MS. HOLLAND: I apologize, your Honor. Why don't  
 11 I -- is it okay if I discuss this and then come back to you  
 12 rather than taking the time now? Because I agree there were  
 13 some used for impeachment.  
 14 THE COURT: All right.  
 06:28 15 MS. HOLLAND: Thank you. We will do it at the end of  
 16 the day.  
 17 MR. HASFORD: We are happy to confer with them, your  
 18 Honor, and see if we can come to an agreement.  
 19 THE COURT: All right. Okay. Are we ready for  
 06:28 20 another witness?  
 21 MR. HASFORD: We are, your Honor.  
 22 THE COURT: Now, there are some documents up here  
 23 that you may wish to retrieve.  
 24 MS. LEBEIS: Good afternoon, your Honor. Jessica  
 06:29 25 Lebeis of Finnegan, Henderson for plaintiffs.  
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1 THE COURT: Okay, Ms. Lebeis, you may proceed, and  
 2 please call your next witness.  
 3 MS. LEBEIS: Plaintiffs would now like to call  
 4 Dr. Trattler.  
 06:29 5 THE COURT: Dr. Trattler, please come to the witness  
 6 stand.  
 7 MS. LEBEIS: Your Honor, may we please pass out  
 8 binders?  
 9 THE COURT: Yes.  
 06:29 10 MS. LEBEIS: Thank you.  
 11 THE DEPUTY CLERK: Sir, place your left hand on the  
 12 Bible right there and raise your right hand.  
 13 (WILLIAM B. TRATTLER, HAVING BEEN DULY SWORN/AFFIRMED,  
 14 TESTIFIED AS FOLLOWS:)  
 06:30 15 THE WITNESS: Yes, I do.  
 16 THE DEPUTY CLERK: Can you please state your name,  
 17 sir, and I need you to spell your first and last name, please.  
 18 THE WITNESS: Sure. It's William, spelled  
 19 W-I-L-L-I-A-M, last name is Trattler, T-R-A-T-T-L-E-R.  
 06:30 20 THE DEPUTY CLERK: Thank you, sir. Please speak into  
 21 the microphone when you get in the seat, please.  
 22 THE COURT: Okay, Ms. Lebeis, you may proceed.  
 23 (DIRECT EXAMINATION OF WILLIAM B. TRATTLER BY MS. LEBEIS:)  
 24 Q. Good afternoon, Dr. Trattler.  
 06:30 25 A. Good afternoon.  
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1 Q. Would you please state your address for the record.

2 A. Sure. My address is Center for Excellence in Eye Care,

3 8940 North Kendall Drive, Number 400E, Miami, Florida, 33176.

4 Q. Where are you presently employed?

06:30 5 A. I am employed at the Center for Excellence in Eye Care.

6 Q. What is your current position at the Center for

7 Excellence in Eye Care?

8 A. I'm an ophthalmologist.

9 Q. Do you specialize in any area of ophthalmology?

06:31 10 A. Yes. I specialize in cornea, cataract, and refractive

11 surgery.

12 Q. What is refractive surgery?

13 A. Refractive surgery are procedures to help eliminate

14 people's need for glasses, whether it's glasses for distance

06:31 15 or glasses for reading.

16 Q. How long have you been an ophthalmologist at the Center

17 for Excellence in Eye Care?

18 A. Nineteen years.

19 Q. Would you please describe your responsibilities as an

06:31 20 ophthalmologist at the Center for Excellence in Eye Care?

21 A. Yes. During the week I see patients who come in for

22 consultations for typical eye problems, and they can include

23 consultations for corneal problems, they may come in for

24 cataract consultations, or for refractive surgery which is

06:31 25 like LASIK surgery, which you may have heard of, and then I

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1 School of Medicine, where I graduated from medical school.

2 I then spent one year doing my internship at Mount

3 Sinai Hospital in Miami Beach.

4 I then came here -- came to Philadelphia, to University

06:33 5 of Pennsylvania, Scheie Eye Institute, where I completed my

6 ophthalmology residency.

7 I then spent an extra year of training called a Cornea

8 Fellowship which I completed in Dallas, Texas, at the

9 University of Texas, Southwestern Medical Center.

06:33 10 Q. What did you do after completing your Cornea Fellowship?

11 A. After my training, I returned to Miami, and I joined the

12 practice at Center for Excellence in Eye Care.

13 I was also hired to be -- to work at the Veterans

14 Hospital in Miami where I trained the Bascom Palmer

06:33 15 Ophthalmology residents how to do cataract surgery and perform

16 exams.

17 Q. What, if any, academic appointments have you held?

18 A. Well, since I -- when I arrived into Miami, I started

19 teaching at Bascom Palmer and supervising residents, so I was

06:34 20 given a volunteer assistant professor of ophthalmology

21 appointment from Bascom Palmer Eye Institute, and then we also

22 teach the -- I also teach at Florida International University

23 College of Medicine, so I'm on the volunteer faculty for that

24 medical school as well.

06:34 25 Q. What, if any, teaching have you done?

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1 also perform those procedures, I perform corneal procedures,

2 lots of cataract surgery, as well, laser vision correction

3 such as LASIK.

4 Q. How much cataract surgery do you perform?

06:32 5 A. I perform approximately 60 cataract surgeries per month,

6 so a little bit over 700 per year.

7 Q. What, if any, experience have you had with drugs used to

8 treat pain and inflammation after cataract surgery?

9 A. Well, when we perform cataract surgery, you're basically

06:32 10 performing surgery, and all patients experience inflammation

11 after cataract surgery, so all cataract surgery procedures

12 are -- all patients who have cataract surgery are treated with

13 anti-inflammatory medications to control and reduce the

14 inflammation after surgery.

06:32 15 Q. Would you please turn to PTX-164 in your binder and

16 identify that document.

17 A. Yes. This is my curriculum vitae.

18 Q. Does your curriculum vitae accurately reflect your

19 educational and work experience?

06:32 20 A. Yes, it does.

21 Q. Would you please briefly describe your educational

22 background following your graduation from high school?

23 A. Of course. I went to Dartmouth College in New Hampshire

24 for my undergraduate degree and graduated with honors.

06:33 25 I then went to Miami, I went to the University of Miami

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1 A. Well, I love teaching. I started off teaching during my

2 residency. The medical students would rotate through

3 ophthalmology and I'd always volunteer to be one of the

4 instructors, and I did win two teaching awards while I was a

06:34 5 resident. And then since then, I always love teaching, both

6 supervising young doctors in training, also participating in

7 giving lectures and writing articles and things like that, but

8 just trying to help educate my colleagues.

9 Q. You mentioned that you won a teaching award. What, if

06:34 10 any, other honors or awards have you received in connection

11 with your work?

12 A. Right. Well, the C.V. is pretty much up to date, but

13 there was one recent award. I was given an award by the

14 American Academy of Ophthalmology, there is a part of it

06:35 15 called the International Society of Refractive Surgery, and I

16 was given one of the big awards for the year called the

17 Casebeer Award for my work in refractive surgery.

18 I have received the Senior Achievement Award from the

19 American Academy of Ophthalmology; a number of other awards.

06:35 20 One that may be of interest, since we're talking about

21 cataract surgery, is in 2006, I was given the Top 50 Cataract

22 and Refractive Surgery Opinion Leaders, as voted on by the

23 readers of *Cataract & Refractive Surgery Today*, and a number

24 of other awards. I have been very fortunate.

06:35 25 Q. Have you published any research articles?

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- 1 A. Yes, I have.  
 2 Q. Are your published research articles listed in your  
 3 curriculum vitae?  
 4 A. Yes, they are.  
 06:35 5 Q. Generally speaking, what types of research articles are  
 6 reflected in your list of publications in your curriculum  
 7 vitae?  
 8 A. There are articles in and around the areas of cataract  
 9 surgery, refractive surgery, and dry eye, as well as corneal  
 06:36 10 surgery.  
 11 Q. Have you conducted any clinical trials?  
 12 A. Yes, many.  
 13 Q. In how many clinical trials have you been involved?  
 14 A. I think it's been in the approximate range between 80 and  
 06:36 15 a hundred clinical trials during my career.  
 16 Q. Generally speaking, in what types of clinical trials have  
 17 you been involved?  
 18 A. I have been involved in a whole -- a wide variety of  
 19 clinical trials. I have been involved in pharmaceutical  
 06:36 20 trials for drugs to be used in and around cataract surgery, so  
 21 both NSAID studies and steroid studies in and around cataract  
 22 surgery. I have been involved in other medication studies  
 23 such -- for approvals for dry eye products. I have been  
 24 involved in -- in interocular lens technologies, both in  
 06:36 25 patients that wanted to get rid of their need for glasses for

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- 1 myopia, as well as for patients that are undergoing cataract  
 2 surgery.  
 3 Q. Are the clinical trials in which you've been involved  
 4 listed on your curriculum vitae?  
 06:37 5 A. Yes, they are.  
 6 Q. Have you conducted any clinical trials involving  
 7 bromfenac-containing products?  
 8 A. Yes, I have.  
 9 Q. Which bromfenac-containing products?  
 06:37 10 A. So, I was involved in the -- in the clinical trial for  
 11 Xibrom®, for the FDA approval for that, as well as involved in  
 12 one of the studies for -- that eventually led to the approval  
 13 of Bromday®.  
 14 Q. Have you conducted any clinical trials involving any  
 06:37 15 other NSAID-containing products?  
 16 A. Yes. I was also an investigator for ketorolac 0.45  
 17 percent, which eventually got FDA approved and is known as  
 18 Acuvail®.  
 19 Q. Do you regularly attend and present at scientific  
 06:37 20 meetings?  
 21 A. Yes, I do.  
 22 Q. Approximately how many such scientific meetings have you  
 23 attended?  
 24 A. Well, I typically speak at about 15 conferences or --  
 06:37 25 conferences a year, in the 15 range.

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- 1 Q. Have you previously been recognized by other courts as an  
 2 expert in the field of ophthalmology, including cataract,  
 3 corneal and refractive surgery?  
 4 A. Yes, I have.  
 06:38 5 MS. LEBEIS: Your Honor, plaintiffs offer  
 6 Dr. Trattler as an expert in the field of ophthalmology,  
 7 including cataract, corneal and refractive surgery, and the  
 8 drugs used in connection with cataract surgery.  
 9 THE COURT: Any objection?  
 06:38 10 MS. HOLLAND: No, your Honor.  
 11 THE COURT: All right. The Court will recognize  
 12 Dr. Trattler as an expert in those fields.  
 13 MS. LEBEIS: Thank you, your Honor.  
 14 BY MS. LEBEIS:  
 06:38 15 Q. Let's now discuss your opinions in this case.  
 16 A. Yes.  
 17 Q. Let's first discuss cataracts and cataract surgery.  
 18 First of all, what are cataracts?  
 19 A. So, cataracts are a natural aging of the lens inside your  
 06:38 20 eye, and cataracts can occur in young patients, in infants,  
 21 but typically they occur in patients aged 50 or older, and  
 22 it's just a natural aging change leading to blurring of vision  
 23 over time.  
 24 Q. Have you prepared a demonstrative to assist the Court  
 06:38 25 with your testimony?

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- 1 A. Yes, I have.  
 2 MS. HOLLAND: Is this moved in or --  
 3 MS. LEBEIS: No.  
 4 BY MS. LEBEIS:  
 06:38 5 Q. What is illustrated in the demonstrative marked as  
 6 PDX5-1?  
 7 A. All right. This is an example of a patient with a  
 8 cataracts. You can see the eyelids above and below, to give  
 9 you an orientation. The brown part of the eye is the iris and  
 06:39 10 in the white central area is the lens of this patient that's  
 11 turned white, and that is a very advanced cataract.  
 12 Q. What, if anything, are the symptoms of cataracts?  
 13 A. So, cataracts, as they develop, you slowly lose your  
 14 ability to see crisply and you get blurred vision, and it  
 06:39 15 starts to impact your ability first to -- often to drive, so  
 16 people can have difficulty seeing road signs. They can  
 17 experience glare when driving at nighttime. Patients can  
 18 report difficulty reading, working on the computer, and other  
 19 visual tasks.  
 06:39 20 Q. How common is the development of cataracts?  
 21 A. So cataracts are universal. All patients, if you live  
 22 long enough, will develop cataracts, and I guess probably by  
 23 the age 80 or so, pretty much everyone has some degree of  
 24 cataract formation in their eye.  
 06:40 25 Q. What, if anything, occurs if cataracts are left

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1 untreated?

2 A. Well, cataracts are progressive and over time, they lead

3 to worse vision over time. So, you know, patients can decide

4 at what point they want to have surgery, but eventually, it

06:40 5 leads to loss of vision and blindness.

6 Q. Why do cataracts form?

7 A. It's unknown why cataracts form. It's just a natural

8 aging change of the eye.

9 Q. How, if at all, are cataracts treated?

06:40 10 A. The only treatment for cataracts is surgery. And so at

11 some point during the development -- during a patient's

12 experience with a cataract, they'll opt to have cataract

13 surgery to basically, essentially, remove the cataract and to

14 have a new artificial lens placed inside their eye.

06:40 15 Q. How is cataract surgery performed today?

16 A. Well, minor cataract surgery today is performed basically

17 by using an ultrasound device to basically vibrate and break

18 up the cataracts, and then following that, we place a new lens

19 in the eye. We also can use laser to pretreat the cataract to

06:41 20 soften the cataract, making it a little bit easier to remove.

21 I think -- I like to think of cataract as kind of like a

22 peanut M&M, to try to make it simple. So the outer layer of

23 the cataract is called the capsule, similar to candy coating

24 of a peanut M&M. There is a -- the chocolate area is kind of

06:41 25 the cortex area that was removed near the end of the surgery.

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1 the surgery is performed and then the -- how the eye is

2 affected by the surgery, which is where Prolensa® will be

3 instilled.

4 THE COURT: Well, I'm interested in the latter part,

06:42 5 but the earlier part, I would just permit the witness to

6 quickly describe it. I am not unfamiliar with eye surgery. I

7 have not had it, but it's a subject that comes up in

8 litigation from time to time.

9 MS. LEBEIS: Well, I would add, your Honor, that the

06:43 10 video -- it's a short video. And I would -- it's not -- I

11 wouldn't describe it necessarily as graphic. It just shows

12 actually how it occurs. It shows how, as Dr. Trattler just

13 described, the capsule is removed from the eye and the

14 cataract is removed from the eye. As you know, Prolensa® is

06:43 15 used to treat inflammation.

16 THE COURT: Well, how short is it?

17 MS. LEBEIS: It's just over two minutes, between two

18 and three minutes.

19 THE COURT: Okay, I will permit it. I didn't realize

06:43 20 it was that short.

21 MS. LEBEIS: Yes. Thank you, your Honor.

22 Noel, will you please pull up the video.

23 THE WITNESS: Okay. You can see --

24 BY MS. LEBEIS:

06:43 25 Q. Dr. Trattler, would you just please explain what's being

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1 And the central part is the -- there is this dense central

2 part which we call a nucleus, which is kind of similar to the

3 peanut in a peanut M&M, but when we do cataract surgery, we

4 will work first on removing the nuclear part, and then work on

06:41 5 the cortex part, but leave the capsule in place because that's

6 where the new intraocular lens will rest after surgery.

7 Q. To assist the Court with your testimony, have you

8 prepared a demonstrative video showing how you perform

9 cataract surgery using phacoemulsification?

06:41 10 A. Yes.

11 MS. HOLLAND: Your Honor, we have an objection to

12 this video. A, we don't see the relevance of it to this case

13 in terms of the drugs that are used to treat postsurgery, and

14 it is a graphic video, so I think that the prejudice outweighs

06:42 15 the relevance in this case.

16 THE COURT: Well, what would be the relevance? I

17 didn't know that the drug was associated with anything that

18 happened before the end of surgery.

19 MS. LEBEIS: Your Honor, the video is relevant

06:42 20 because Prolensa®, as you know, is indicated for the treatment

21 of pain and inflammation following cataract surgery. It's

22 instilled before cataract surgery and then immediately

23 thereafter. But the video is relevant because it shows the

24 environment in which the drug will be instilled following

06:42 25 surgery, and it's just a visual aid to -- to illustrate how

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1 shown? And let Noel know when you're ready to start the

2 video.

3 A. So this is a patient of mine that had the laser treatment

4 of their cataracts. You see that's what the grid pattern in

06:43 5 the nucleus has already been created and is actually one of

6 the incisions, the main incision which is going to be right

7 here, has already been created with a laser, so you would just

8 open it up without using a -- a blade. But we will make a

9 tiny incision to help with the surgery so you can go ahead and

06:44 10 start the video.

11 And the first step is we're going to place an

12 anesthetic inside the eye so that during the surgery it's

13 comfortable. And then we're going to place a gel to kind of

14 keep the eye formed. You see, this is the anesthetic going in

06:44 15 and on the surface of the eye. And that's the gel that's

16 placed. And we're going to open up the incision. Right here,

17 you can see that it's just opened. And we're not going to --

18 we're not going to use a suture at the end of this surgery.

19 No sutures are needed. I will explain how that works. But we

06:44 20 basically take off the very outer layer of the candy coating

21 we talked about, the capsule. We then inject a little fluid

22 just around the nuclear -- or part of the lens, to free it up.

23 And so now this lens is -- or the central dense part has been

24 freed up. It makes it much easier to remove. And it's --

06:44 25 it's a device called ultrasound, called phaco, where we're --

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1 this little device is vibrating back and forth, and that's  
2 where there is inflammation that occurs with this procedure is  
3 because, as you can see, we're basically breaking up this lens  
4 into tiny, tiny little pieces and it's vacuumed into the  
06:45 5 little central port.

6 We can see that most of the nucleus is being removed at  
7 this point, and this is the very last piece of the nucleus  
8 being removed.

9 You can see at this point we're left with just some  
06:45 10 wisps left, and that's called the cortex, and we're going to  
11 use this little device here just vacuuming out the wisps of  
12 cortical material that's left.

13 Any cortical material that is not removed will lead to  
14 further inflammation, so it would be best to remove all the  
06:45 15 material from the eye, of the cortex and the nucleus during  
16 the procedure, although sometimes small tiny fragments,  
17 sometimes tiny amounts of the nuclear material or cortical  
18 material can be left behind. But most of it's removed with  
19 vacuum.

06:45 20 So now we're injecting the -- the gel back into the  
21 eye, and we're placing the plastic lens inside the eye. And  
22 so this is the lens, and it's going to be just positioned in  
23 the capsule, and we're going to remove the gel from the eye.  
24 And at the very end, you will see we're going to basically  
06:46 25 fill up the eye with fluid, but we do not use a suture during

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1 this procedure at all, and the incisions are all kept  
2 watertight by the internal pressure. They can be opened by  
3 just pressing on the edge or the lip of the incisions that are  
4 created, so that's why it's very important and we advise our  
06:46 5 patients not to rub their eyes during the postoperative  
6 period. But you can see no stitches are needed, and this is  
7 the end of the case, with the eye firm and the incisions are  
8 therefore closed.

9 Q. Thank you, Dr. Trattler.

06:46 10 You just mentioned that you do not --

11 THE COURT: Excuse me. May I ask a clarifying  
12 question? And, again, if there is any objection, then object.

13 Was this in realtime? Is this how quickly the  
14 procedure goes?

06:46 15 THE WITNESS: No. We -- I cut out a few little  
16 parts, like where I transition with the instruments or in  
17 showing the nuclear removal. The typical case is about eight  
18 minutes. This is about I believe two minutes and 30 seconds  
19 or so.

06:47 20 THE COURT: Okay. Thank you.

21 BY MS. LEBEIS:

22 Q. Dr. Trattler, you mentioned that you do not use sutures  
23 or stitches. How, if at all, does the incision heal?

24 A. Right. So the incision will heal over the first four --  
06:47 25 four to -- four or five days. The next day it's still very

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1 easy, if the pressure is elevated, we can actually press on  
2 the lip of one of the incisions and release some fluid if  
3 needed. So, typically, over the first few days, the incision  
4 slowly heals. But it is an open incision, which is why we  
06:47 5 instruct our patients to sleep with a shield at nighttime so  
6 they don't rub their eyes during nighttime, and also advise  
7 them to not rub their eyes because they can lead to, you know,  
8 opening of that wound which could lead to infection or other  
9 complications.

06:47 10 Q. How, if at all, does the cataract surgery which we just  
11 saw result in pain and inflammation in patients who undergo  
12 it?

13 A. Right. So, as you can see from the -- from how the  
14 surgery is performed, we make incisions in the eye, and we're  
06:48 15 using ultrasonic energy within the eye, and that leads to  
16 inflammation being generated.

17 Q. How, if at all, are pain and inflammation after cataract  
18 surgery treated?

19 A. Right. So the -- so what we typically use is we use  
06:48 20 eyedrops actually prior to surgery to pretreat the eye, and we  
21 use anti-inflammatory eyedrops, and then we continue the same  
22 anti-inflammatory drops during the postoperative period to  
23 suppress the inflammation and to treat the inflammation, and  
24 also to try to knock out the pain that's a result of the  
06:48 25 inflammation from surgery.

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1 Q. What types of anti-inflammatory drugs are used?  
2 A. There is two classes of agents that we use: We use both  
3 topical steroids and topical nonsteroidal drops.

4 Q. What types of drugs do you use?

06:48 5 A. So I use both, the combination, both of steroids and  
6 nonsteroidal drops.

7 Q. Why do you use both steroids and nonsteroidal drops?

8 A. Both steroids and nonsteroidals suppress inflammation,  
9 but they work on different parts of the inflammatory pathway  
06:49 10 and so they work synergistically. They help reduce  
11 inflammation, reduce pain, and lead to faster visual recovery  
12 by working -- by having both work together.

13 Q. And when you say nonsteroidal drops, do you mean NSAIDs?

14 A. Yes, nonsteroidal drops are -- are NSAIDs.

06:49 15 Q. Is Prolensa® indicated for the treatment of postoperative  
16 inflammation and reduction of ocular pain in patients who have  
17 undergone cataract surgery?

18 A. Yes.

19 Q. Have you prescribed Prolensa®?

06:49 20 A. Yes, I have.

21 Q. What, if anything, are the consequences of not treating  
22 pain after cataract surgery?

23 A. Well, the procedure itself will result in inflammation  
24 and therefore pain after surgery. And so if patients  
06:50 25 experience pain afterwards, they may rub their eyes, if their

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1 eyes painful. It leads to very poor postoperative experience.  
 2 Patients have very high expectations that when they have  
 3 surgery, they will have a comfortable experience and end up  
 4 with good vision, so experiencing significant pain afterwards  
 06:50 5 is a real problem.  
 6 Q. And what, if anything, are the consequences of not  
 7 treating inflammation after cataract surgery?  
 8 A. Inflammation is caused by the surgical procedure. So  
 9 what happens is we use the topical medications to reduce the  
 06:50 10 inflammation; if not, the eye will remain red, it will remain  
 11 sensitive to light, there will be blurred vision, as well if  
 12 it's not treated, it can lead to chronic problems such as  
 13 cystoid macular edema or CME.  
 14 Q. What is cystoid macular edema?  
 06:50 15 A. So cystoid macular edema is a condition of the retina.  
 16 Even though we are doing surgery in the front part of the eye,  
 17 the inflammatory, you know, mediators can get back to the  
 18 retina and cause swelling of the retina, right in the -- where  
 19 we see, and that can lead to blurred vision that can, in some  
 06:51 20 cases, be permanent.  
 21 Q. Is cystoid macular edema also abbreviated as CME?  
 22 A. Yes, it is.  
 23 Q. How, if at all, can cystoid macular edema lead to vision  
 24 loss?

06:51 25 A. Cystoid macular edema is a swelling of the retina, the

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1 central retina, and we call that area the macula, and  
 2 that's -- when we're looking at the world, we're seeing  
 3 through that region, and so if there is a swelling occurs, it  
 4 causes blurring of vision, the photoreceptors can't function  
 06:51 5 normally, and patients have loss of vision, and they can end  
 6 up either legally blind or not legal to drive. And, again,  
 7 some patients can get recovery but there are some patients  
 8 that will have permanent vision loss from CME.  
 9 Q. How, if at all, does failing to treat postoperative  
 06:51 10 inflammation increase the risk for development of CME or  
 11 cystoid macular edema?  
 12 A. It's the inflammatory mediators associated with  
 13 performing cataract surgery that result in the development of  
 14 CME. So not being aggressive at and not treating inflammation  
 06:52 15 completely leads to increased risk of developing CME  
 16 postoperatively.  
 17 Q. What patients are at risk of developing CME?  
 18 A. So, all patients undergoing contract surgery are at risk  
 19 for developing CME. There are some patients that are at  
 06:52 20 higher risk, but every single patient that has surgery are at  
 21 risk for developing CME.  
 22 Q. I would now like to turn to discuss the treatment of pain  
 23 and inflammation after cataract surgery using  
 24 bromfenac-containing ophthalmic NSAID therapies.  
 06:52 25 A. Perfect.

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1 Q. Before Prolensa®, were other bromfenac-containing  
 2 ophthalmic NSAID therapies available to treat postoperative  
 3 inflammation and ocular pain in patients who have undergone  
 4 cataract surgery?  
 06:52 5 A. Yes.  
 6 Q. Have you prepared a demonstrative to assist the Court  
 7 with your testimony?  
 8 A. Yes, I have.  
 9 Q. Would you please explain what is illustrated in the  
 06:53 10 demonstrative marked as PDX5-2?  
 11 A. So, this is basically a summary of four -- four  
 12 bromfenac-containing nonsteroidal drops used with cataract  
 13 surgery.  
 14 The top one is Bronuck®, which is available in Japan.  
 06:53 15 Then we have Xibrom® and Bromday®, which are -- are available  
 16 in the U.S. or were available in the U.S. And then, lastly,  
 17 Prolensa®, which is also available in the U.S.  
 18 Q. What, if anything, is your understanding regarding the  
 19 formulation components of Bronuck®, Xibrom®, and Bromday®?  
 06:53 20 A. It's my understanding that the components are the same in  
 21 all three products.  
 22 Q. How, if at all, are Bronuck®, Xibrom®, and Bromday®  
 23 limited by their side effects?  
 24 A. So, as you can see from this chart, all three products,  
 06:53 25 Bronuck®, Xibrom®, and Bromday®, have the postoperative side

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1 effect of causing stinging and burning and having a burning  
 2 sensation. You can see that's present in the product labels  
 3 of all three products.  
 4 Q. Is Prolensa® associated with the side effects of burning  
 06:54 5 and stinging?  
 6 A. Right. Prolensa®, per the FDA label, is not associated  
 7 with either burning or stinging.  
 8 Q. Let's discuss the basis for your opinion.  
 9 Would you please turn to PTX-277 in your binder and  
 06:54 10 identify that document?  
 11 A. Yes. So this is the -- the package insert for Bronuck®  
 12 Ophthalmic Solution, and it's translated from its Japanese  
 13 version.  
 14 Q. Did you review PTX-277 in connection with your opinions  
 06:54 15 in this case?  
 16 A. Yes, I did.  
 17 Q. Let me direct your attention to the page of PTX-277  
 18 bearing Bates Number PROL 0333505, and, in particular, to the  
 19 top of the right-hand column.  
 06:54 20 A. Okay.  
 21 Q. How, if at all, does this portion of the Bronuck® package  
 22 insert relate to your opinion that Bronuck® is limited by the  
 23 adverse events of burning and stinging?  
 24 A. You can -- this is the adverse events listed in the  
 06:55 25 product -- in the package insert, and it lists both burning

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1 sensation and stinging as adverse events that occur with the  
 2 use of this product.  
 3 Q. Would you now please turn to JTX-144 in your binder and  
 4 identify that document?  
 06:55 5 A. This is the package insert for Xibrom®.  
 6 Q. Is it the FDA-approved package insert for Xibrom®?  
 7 A. Yes, this is the FDA-approved package insert for Xibrom®.  
 8 Q. Have you reviewed the FDA-approved Xibrom® package insert  
 9 in connection with your opinions in this case?  
 06:55 10 A. Yes, I have.  
 11 Q. Have you ever treated patients with Xibrom®?  
 12 A. Yes, I have.  
 13 Q. Let me direct your attention to Page 3 of the Xibrom®  
 14 package insert which bears Bates Number PROL 0080488, and, in  
 06:56 15 particular, to the second paragraph of the section entitled  
 16 "Adverse Reactions."  
 17 How, if at all, does this portion of the Xibrom®  
 18 package insert relate to your opinion that Xibrom® is limited  
 19 by the adverse events of burning and stinging?  
 06:56 20 A. This is the adverse reactions section of the FDA-approved  
 21 package insert, and you can see that burning and stinging  
 22 occurred, was reported in -- burning and stinging was reported  
 23 in 2 to 7 percent of patients.  
 24 Q. In that same portion of the Xibrom® package insert, is  
 06:56 25 eye pain listed as a separate adverse event from eye

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1 scope of the report, or maybe Ms. Lebeis can direct me to  
 2 where in the report it is.  
 3 MS. LEBEIS: Well, certainly.  
 4 First of all, Dr. Trattler's testified -- or in his  
 06:57 5 expert Report at Paragraphs 29, 31 and 33, he separately  
 6 listed eye pain from burning and stinging as adverse events  
 7 listed on these labels. But he was also asked about the  
 8 difference between eye pain and burning and stinging at his  
 9 deposition, and I know that your Honor asked a question during  
 06:58 10 defendants' opening about -- of defendants' counsel regarding  
 11 eye pain versus burning and stinging. And so Dr. Trattler is  
 12 simply explaining eye pain and burning and stinging which were  
 13 both identified in his expert reports as adverse events for  
 14 Xibrom® and Bromday®.  
 06:58 15 THE COURT: All right. So they're separately listed  
 16 and he wishes to -- or you wish to have him explain the  
 17 difference?  
 18 MS. LEBEIS: Yes, Your Honor.  
 19 THE COURT: Okay. I will permit it.  
 20 BY MS. LEBEIS:  
 21 Q. Would you like me to repeat the question?  
 22 A. Yes, please.  
 23 Q. How do patients convey the difference between the adverse  
 24 event of eye pain and the adverse event of burning and  
 06:58 25 stinging?

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1 irritation, including burning and stinging?  
 2 A. Yes, it's listed as a separate adverse event.  
 3 Q. To an ophthalmologist, why is eye pain a separate adverse  
 4 event from eye irritation, including burning and stinging?  
 06:56 5 A. That's a great -- it's important to distinguish those two  
 6 sensations.  
 7 So, pain is if you get poked in the eye or get injured  
 8 in the eye, and you could see in surgery, we're making  
 9 incisions and that causes pain.  
 06:57 10 When we think of burning and stinging, we think of like  
 11 if you ever have a lemon and that juice hits you in the eye,  
 12 that's going to cause a burning sensation.  
 13 It's distinct, and patients can definitely tell the  
 14 difference between a burning and stinging sensation versus the  
 06:57 15 sensation of pain, which is why they're listed as separate  
 16 adverse events on the package insert.  
 17 Q. In your experience treating patients, including in  
 18 clinical trials for ophthalmic formulations, can patients  
 19 determine the difference between the adverse event of eye pain  
 06:57 20 and the adverse events of burning and stinging?  
 21 A. Without question, yes.  
 22 Q. How do patients convey the difference between the adverse  
 23 event of eye pain and the adverse events of burning and  
 24 stinging?  
 06:57 25 MS. HOLLAND: I have an objection here as outside the

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1 A. They convey by just, you know, explaining it to me, you  
 2 know, when I talk to them. So patients who have undergone  
 3 surgery and those that have eye pain will explain that their  
 4 eye, you know, feels painful, there is pain in their eye.  
 06:58 5 Again, they've had surgery, so that can be expected.  
 6 The burning and stinging is typically, you know,  
 7 related to the use of eye drops. So the eye drops can cause  
 8 the burning and stinging. We have a lot of, you know,  
 9 experience with various eye drop formulations causing burning  
 06:59 10 and stinging, because typically patients will complain that  
 11 they're -- they're experiencing a burning sensation with the  
 12 use of an eye drop.  
 13 Q. How, if at all, does the adverse event section of the  
 14 Xibrom package insert comport with what you've observed in  
 06:59 15 your practice?  
 16 A. With Xibrom, it's been very -- I agree with, you know,  
 17 the adverse events. The adverse events listed in FDA package  
 18 insert are what we expect as clinicians and all of the -- the  
 19 adverse events listed here, I've seen in patients following  
 06:59 20 cataract surgery.  
 21 Q. Let me now direct your attention to Page 5 of the Xibrom  
 22 package insert, which bears Bates No. PROL 0080490 and in  
 23 particular, to the third paragraph under the section entitled  
 24 Description.  
 07:00 25 What is the pH of Xibrom?

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1 A. This is the FDA-approved package insert, and it reports  
 2 that the pH of Xibrom is 8.3.  
 3 Q. Could you now please turn to PTX-474 in your binder and  
 4 identify that document?  
 07:00 5 A. Yes. This is the FDA-approved package insert for  
 6 Bromday.  
 7 Q. Have you reviewed the FDA-approved package insert for  
 8 Bromday in connection with your opinions in this case?  
 9 A. Yes, I have.  
 07:00 10 Q. Have you ever treated patients with Bromday?  
 11 A. Most definitely.  
 12 Q. Let me direct your attention to Page 6 of the Bromday  
 13 package insert, which bears Bates No. PROL 0080495 and in  
 14 particular, to the section entitled Adverse Reactions.  
 07:00 15 How, if at all, does this portion of the Bromday  
 16 package insert relate to your opinion that Bromday is limited  
 17 by the adverse events of burning and stinging?  
 18 A. You can see here in this FDA-approved package insert that  
 19 burning and stinging are listed as an adverse event in two to  
 07:01 20 seven percent of patients.  
 21 Q. How, if at all, does the adverse event section of the  
 22 Bromday FDA-approved package insert comport with what you have  
 23 observed in your practice?  
 24 A. All right. I have a lot of experience using Bromday in  
 07:01 25 my patients following cataract surgery and I did have patients  

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1 who report that they experience burning with the product and  
 2 we did have to switch some patients. I either stopped --  
 3 switched NSAIDs because of the experience patients were  
 4 having.  
 07:01 5 Q. In the Bromday package insert, is eye pain also listed as  
 6 a separate adverse event from eye irritation, including  
 7 burning and stinging?  
 8 A. Yes.  
 9 Q. Let me direct your attention to Page 7 of the Bromday  
 07:01 10 package insert, which bears Bates No. PROL 0080496, and in  
 11 particular, to the second paragraph under the section entitled  
 12 Description.  
 13 What is the pH of Bromday?  
 14 A. The pH of Bromday, according to the FDA-approved package  
 07:02 15 insert, is 8.3.  
 16 MS. LEBEIS: Your Honor, I'm moving on to another  
 17 document now and noting the time. Would it might be a good  
 18 time to stop for the day?  
 19 THE COURT: All right, unless you wanted to go a  
 07:02 20 little bit more. But if this is a good time, then let's stop  
 21 here.  
 22 MS. HOLLAND: All I would suggest, Your Honor, is  
 23 that we -- I feel like we are a bit behind with witnesses in  
 24 terms of timing, so, I guess, if it's -- if the Court is okay  
 07:02 25 with sitting a little longer today, it might make sense in  

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1 terms of just the overall schedule.  
 2 THE COURT: Well, why don't we go ten more minutes  
 3 and try to make up some time.  
 4 MS. LEBEIS: Certainly, sure.  
 5 BY MS. LEBEIS:  
 6 Q. Dr. Trattler, would you please turn in your binder to  
 7 JTX-023 and identify that document.  
 8 A. Yes, this is the FDA-approved package insert for  
 9 Prolensa.  
 07:03 10 Q. Have you reviewed the FDA-approved package insert for  
 11 Prolensa in connection with your opinions in this case?  
 12 A. Yes, I have.  
 13 Q. You said earlier that you've treated patients with  
 14 Prolensa, correct?  
 07:03 15 A. Yes, I have, I definitely have treated patients with  
 16 Prolensa.  
 17 Q. Let me direct your attention to the first page of the  
 18 Prolensa package insert which bears Bates No. PROL 0080219 and  
 19 in particular, to the section in the left column entitled  
 07:03 20 Indications and Usage.  
 21 According to the FDA-approved Prolensa package insert,  
 22 what is the FDA-approved indication for Prolensa?  
 23 A. So, Prolensa is a nonsteroidal anti-inflammatory drug  
 24 indicated for the treatment of postoperative inflammation and  
 07:03 25 reduction of ocular pain in patients who have undergone  

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1 cataract surgery.  
 2 Q. Let me direct your attention on the same page of the  
 3 Prolensa package insert to the section entitled Dosage and  
 4 Administration.  
 07:04 5 According to the Prolensa package insert, what is the  
 6 FDA-approved dosage and administration for Prolensa?  
 7 A. This says instill one drop into the affected eye once  
 8 daily beginning one day prior to surgery, continued on the day  
 9 of surgery and through the first 14 days postsurgery.  
 07:04 10 Q. Let me now direct your attention to Page 3 of the  
 11 Prolensa package insert, which bears Bates No. PROL 0080221,  
 12 and in particular, to the section entitled Adverse Reactions.  
 13 How, if at all, does the adverse event section of the  
 14 Prolensa package insert relate to your opinion that Prolensa  
 07:04 15 is not associated with the adverse events of burning and  
 16 stinging?  
 17 A. Yes. So this is the FDA-approved package insert for  
 18 Prolensa and it lists in here the adverse reactions that  
 19 occurred during the clinical trials, and you could see that it  
 07:05 20 does not list either burning or stinging as an adverse event  
 21 in this package insert.  
 22 Q. How, if at all, does the adverse event section of the  
 23 Prolensa package insert comport with what you have observed in  
 24 your practice?  
 07:05 25 A. It is exactly what I've seen. It's a very comfortable  

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1 drop. Patients are able to use it before and after cataract  
 2 surgery as prescribed, and they do very, very well with it and  
 3 I've had no patients report burning or stinging and I've never  
 4 had to stop a patient from continuing on with the drop.

07:05 5 Q. Let me now direct your attention to Page 4 of the  
 6 Prolensa package insert, which bears Bates No. PROL 0080222  
 7 and in particular, to the second paragraph on the page.  
 8 What is the pH of Prolensa?

07:06 9 A. According to the FDA-approved package insert, the pH of  
 10 Prolensa is 7.8.

11 Q. How, if at all, does Prolensa's pH of 7.8 as compared to  
 12 Xibrom and Bromday's pH of 8.3 contribute to the fact that  
 13 Prolensa does not cause burning and stinging?

07:06 14 A. Probably the best -- when I think of the drops that we  
 15 use for patients, you know, having a pH of the drop that's  
 16 closer to our own -- patient's own natural pH seems to be more  
 17 comfortable in general for patients, although that's not  
 18 always the case.

19 Q. What is a patient's own natural pH?

07:06 20 A. The -- the average pH for a patient, patient tear is at  
 21 7.4.

22 Q. Prior to Prolensa, was a bromfenac-containing NSAID  
 23 therapy available to treat inflammation and pain after  
 24 cataract surgery without causing burning and stinging?

07:06 25 A. No.

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1 Q. How, if at all, does burning and stinging impact patient  
 2 compliance?

3 A. Well, patients, you know, have to use eye drops both  
 4 before or after surgery. So if the drops burn and sting upon  
 07:08 5 placement, patients may decide not to take the drop, and that  
 6 can lead to, again, inability of the medication --  
 7 postoperative drops to knock out the inflammation. So poor  
 8 compliance or noncompliance can lead to worse visual outcomes  
 9 and increase risks for complication.

07:08 10 Q. Let's explore the basis for your opinion.  
 11 Would you please turn in your binder to JTX143 and  
 12 identify that document.

13 A. This is a article written by Dr. Rajesh Rajpal and it's  
 14 entitled: Bromfenac Ophthalmic Solution for the Treatment of  
 07:09 15 Postoperative Ocular Pain and Inflammation, Safety, Efficacy  
 16 and Patient Adherence.

17 Q. Have you reviewed JTX143 in connection with your opinions  
 18 in this case?

19 A. Yes, I have.

07:09 20 Q. Do you regard this article as a reliable authority on the  
 21 studies to which it refers and the conclusions to be drawn  
 22 from them?

23 A. Yes.

24 Q. Let me direct your attention to Page 928 of JTX143, and  
 07:09 25 in particular, to the right column and to the paragraph under

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1 Q. How, if at all, is the absence of burning and stinging  
 2 from Prolensa as reflected in the package insert, a benefit to  
 3 patients?

07:07 4 A. These are very critical benefit to patients. Patients  
 5 have undergone cataract surgery and we want to have a good  
 6 postoperative course and one of the keys is, we don't want our  
 7 patients rubbing their eyes and that can happen if a patient  
 8 is experiencing burning or stinging from a drop, and as well,  
 9 we want them to be compliant with their medications because we  
 07:07 10 know that inflammation needs to be knocked out by the -- by  
 11 the anti-inflammatory drops.

12 If not, a patient will get -- will have worse vision  
 13 just from blurred vision, from the inflammation not going  
 14 away, and as well, they increase their risk for developing  
 07:07 15 CME, which is a major risk with cataract surgery. So, you  
 16 know, having a drop that's comfortable is very important for  
 17 patients undergoing cataract surgery.

18 Q. How, if at all, does discontinuation of treatment with an  
 19 NSAID after cataract surgery because of adverse events like  
 07:07 20 burning and stinging impact patient outcomes?

21 A. It can be very challenging for patients, very difficult  
 22 for patients because they would have prolonged inflammation  
 23 and inflammation leads to -- you can get corneal swelling, you  
 24 get reduced vision and again, you can have an increased risk  
 07:08 25 for developing cystoid macular edema postoperatively.

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1 the heading Bromfenac Compliance and Adherence.  
 2 What do the first two sentences of this paragraph  
 3 disclose?

4 A. So, the article states that cataract surgery is typically  
 07:09 5 performed in an older population already known for poor  
 6 medication compliance in other ophthalmic disorders. Commonly  
 7 prescribed postsurgical ophthalmic medications with varying  
 8 dosing schedules can be particularly troublesome for these  
 9 patients to manage, especially if accompanied by stinging  
 07:10 10 and/or burning upon installation.

11 Q. How, if at all, does this portion of JTX143 relate to  
 12 your opinions regarding burning and stinging?

13 A. Well, this is very accurate. Patients who undergo  
 14 cataract surgery will be placed on a few drops both before and  
 07:10 15 after cataract surgery, including antibiotics and  
 16 anti-inflammation drops with different dosing regimens and,  
 17 you know, compliance can be an issue. These are older  
 18 patients and we want them to use the drops, and if a drop is  
 19 burning or stinging, they may be less likely to use that drop  
 07:10 20 and that's been shown to be -- be a risk factor for  
 21 noncompliance.

22 Q. What, if any, ophthalmic NSAID do you routinely prescribe  
 23 to treat pain and inflammation following cataract surgery?

24 A. Currently, a typical nonsteroidal drop that we will use  
 07:11 25 for our -- for my patients is Prolensa.

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1 MS. LEBEIS: Your Honor, I think we've gone another  
2 ten minutes.

3 THE COURT: This is a good time to stop then.  
4 Let's resume tomorrow morning at 9:30 a.m.

07:11 5 Is there any housekeeping that we need to attend to at  
6 this time?

7 MS. HOLLAND: No, Your Honor.

8 MS. LEBEIS: No, Your Honor.

9 THE COURT: Doctor, you may step down. I want to  
07:11 10 take a peak at where we are on time, so that if we need to use  
11 Wednesday, which we already do for one witness, we can kind of  
12 map out how to use the next two days. Okay. You can be  
13 seated and we will take a moment to do this.

14 THE DEPUTY CLERK: 10.30 for the plaintiff and 7.50  
07:12 15 for the defense.

16 MR. LIPSEY: I'm sorry, could you repeat that please.

17 THE DEPUTY CLERK: 10 hours and 30 minutes for the  
18 plaintiffs and 7 hours and 50 minutes for the defense.

19 THE COURT: Okay. And between Tuesday and Wednesday,  
07:12 20 we have -- I'll say approximately 11 hours, figure  
21 five-and-a-half each day.

22 Now, you don't have to use all your time.

23 (Laughter.)

24 THE COURT: But what would your time budget be going  
07:12 25 forward, or do you want to think about that overnight?

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1 MS. HOLLAND: Your Honor, from defendant's  
2 perspective, we're happy to keep within the 13 hours that we  
3 had been originally allotted, and...

4 THE COURT: Okay.

07:13 5 MS. LEBEIS: Your Honor, if you wouldn't mind, we  
6 would like to think about it overnight and get back to Your  
7 Honor tomorrow regarding the rest of the time allotted.

8 THE COURT: Okay. Let's do that. Now, I'm not  
9 inviting, you know, that we fill Wednesday. We do have the  
07:13 10 one witness. What was the doctor's name?

11 MR. MUKERJEE: Dr. Prausnitz, Your Honor.

12 THE COURT: How long will his testimony be Wednesday,  
13 do you know?

14 MR. MUKERJEE: I anticipate his direct will probably  
07:13 15 be within the range of about one hour or two, max, maybe one  
16 hour, 15 minutes.

17 THE COURT: Okay. Well, maybe we're more or less on  
18 schedule except for that. That would be great. Okay.

19 Then if there's nothing else, let's adjourn for  
07:14 20 tonight. Good night.

21 RESPONSE: Thank you, Your Honor.

22 (4:45 p.m.)

23

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1 UNITED STATES DISTRICT COURT  
2 FOR THE DISTRICT OF NEW JERSEY

3 SENJU PHARMACEUTICAL CO., LTD.,  
4 BAUSCH & LOMB, INC., BAUSCH AND  
5 LOMB PHARMA HOLDINGS CORP.,  
6 Plaintiff, CIVIL ACTION NUMBER:  
7 -vs- 14-667 (JBS/KMW)  
8 LUPIN LTD., LUPIN  
9 PHARMACEUTICALS, INC.,  
10 Defendants.

11 SENJU PHARMACEUTICAL CO., LTD.,  
12 BAUSCH & LOMB, INC., BAUSCH AND  
13 LOMB PHARMA HOLDINGS CORP.,  
14 Plaintiff, CIVIL ACTION NUMBER:  
15 -vs- 14-4149 (JBS/KMW)  
16 LUPIN LTD., LUPIN  
17 PHARMACEUTICALS, INC.,  
18 Defendants.

19 Mitchell H. Cohen United States Courthouse  
20 One John F. Gerry Plaza  
21 Camden, New Jersey 08101  
22 Tuesday, April 12, 2016

23 **B E F O R E:** THE HONORABLE JEROME B. SIMANDLE  
24 CHIEF JUDGE  
25 UNITED STATES DISTRICT JUDGE

26 Certified as true and correct as required by Title 28, U.S.C.,  
27 Section 753.  
28 /s/ Lisa Marcus, CCR, CRR, /s/ Karen Friedlander, CCR, CRR,  
29 /s/ Carol Farrell, CCR, CRR

United States District Court  
Camden, New Jersey

1  
2 SENJU PHARMACEUTICAL CO., LTD.,  
3 BAUSCH & LOMB, INC., BAUSCH AND  
4 LOMB PHARMA HOLDINGS CORP.,  
5 Plaintiff, CIVIL ACTION NUMBER:  
6 -vs- 15-335 (JBS/KMW)  
7 LUPIN LTD., LUPIN  
8 PHARMACEUTICALS, INC.,  
9 Defendants.

10 SENJU PHARMACEUTICAL CO., LTD.,  
11 BAUSCH & LOMB, INC., BAUSCH AND  
12 LOMB PHARMA HOLDINGS CORP.,  
13 Plaintiff, CIVIL ACTION NUMBER:  
14 -vs- 14-6893 (JBS/KMW)  
15 INNOPHARMA LICENSING, INC., et  
16 al.,  
17 Defendants.

18 SENJU PHARMACEUTICAL CO., LTD.,  
19 BAUSCH & LOMB, INC., BAUSCH AND  
20 LOMB PHARMA HOLDINGS CORP.,  
21 Plaintiff, CIVIL ACTION NUMBER:  
22 -vs- 15-3240 (JBS/KMW)  
23 INNOPHARMA LICENSING, INC.,  
24 Defendants.

United States District Court  
Camden, New Jersey

1 SENJU PHARMACEUTICAL CO., LTD.,  
2 BAUSCH & LOMB, INC., BAUSCH AND  
3 LOMB PHARMA HOLDINGS CORP.,  
4 Plaintiff, CIVIL ACTION NUMBER:  
5 -vs- 14-5144 (JBS/KMW)  
6 LUPIN LTD., LUPIN  
7 PHARMACEUTICALS, INC.,  
8 Defendants.

9 SENJU PHARMACEUTICAL CO., LTD.,  
10 BAUSCH & LOMB, INC., BAUSCH AND  
11 LOMB PHARMA HOLDINGS CORP.,  
12 Plaintiff, CIVIL ACTION NUMBER:  
13 -vs- 15-335 (JBS/KMW)  
14 LUPIN LTD., LUPIN  
15 PHARMACEUTICALS, INC.,  
16 Defendants.

17 SENJU PHARMACEUTICAL CO., LTD.,  
18 BAUSCH & LOMB, INC., BAUSCH AND  
19 LOMB PHARMA HOLDINGS CORP.,  
20 Plaintiff, CIVIL ACTION NUMBER:  
21 -vs- 14-5144 (JBS/KMW)  
22 LUPIN LTD., LUPIN  
23 PHARMACEUTICALS, INC.,  
24 Defendants.

United States District Court  
Camden, New Jersey

1 **APPEARANCES:**

2 PEPPER HAMILTON LLP  
3 BY: MELISSA A. CHUDEREWICZ, ESQUIRE  
4 301 Carnegie Center, Suite 400  
5 Princeton, New Jersey 08543  
6 (609) 452-0808  
7 chuderem@pepperlaw.com  
8 ATTORNEYS FOR PLAINTIFF

9 FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, LLP  
10 BY: BRYAN C. DINER, ESQUIRE  
11 JUSTIN J. HASFORD, ESQUIRE  
12 CHIAKI FUJIWARA, ESQUIRE  
13 901 New York Avenue, N.W.  
14 Washington, D.C. 20001-4413  
15 (202) 408-4000  
16 bryan.diner@finnegan.com, justin.hasford@finnegan.com,  
17 chiaki.fujiwara@finnegan.com  
18 ATTORNEYS FOR PLAINTIFF

19 FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, LLP  
20 BY: JESSICA M. LEBIS, ESQUIRE  
21 303 Peachtree Street, NE  
22 Atlanta, GA 30308-3263  
23 (404) 653-6400  
24 jessica.lebis@finnegan.com  
25 ATTORNEYS FOR PLAINTIFF

26 PATUNAS TARANTINO LLC  
27 BY: MICHAEL E. PATUNAS, ESQUIRE  
28 24 Commerce Street, Suite 606  
29 Newark, New Jersey 07102  
30 (973) 396-8740  
31 mpatunas@patunaslaw.com  
32 ATTORNEYS FOR DEFENDANT LUPIN, INC.

United States District Court  
Camden, New Jersey

	1007
1	GOODWIN PROCTOR LLC BY: ELIZABETH J. HOLLAND, ESQUIRE
2	NATASHA E. DAUGHTRY, ESQUIRE
3	SARAH FINK, ESQUIRE
4	SHAUN deLACY, ESQUIRE
5	DANIEL P. MARGOLIS, ESQUIRE
6	The New York Times Building 620 Eighth Avenue New York, NY 10018 (212) 813-8800
7	eholland@goodwinproctor.com, ndaughtry@goodwinproctor.com, sfink@goodwinproctor.com, sdelacy@goodwinproctor.com, dmargolis@goodwinproctor.com
8	ATTORNEYS FOR DEFENDANT LUPIN, LTD.
9	GOODWIN PROCTOR, LLP BY: EMILY L. RAPALINO, ESQUIRE
10	53 State Street Boston, MA 02109 (617) 570-1000
11	erapalino@goodwinproctor.com
12	ATTORNEYS FOR DEFENDANT LUPIN, LTD.
13	ALSTON & BIRD, LLP BY: DEEPRO R. MUKERJEE, ESQUIRE
14	LANCE A. SODERSTROM, ESQUIRE
15	STEPHANIE ROBERTS, ESQUIRE
16	90 Park Avenue New York, New York 10016 (212) 210-9400
17	deepro.mukerjee@alston.com, lance.soderstrom@alston.com, stephanie.roberts@alston.com
18	ATTORNEYS FOR DEFENDANT INNOPHARMA LICENSING
19	ALSTON & BIRD, LLP BY: JITENDRA MALIK, ESQUIRE
20	4721 Emperor Boulevard Suite 400 Durham, NC 27703-8580 (919) 862-2200
21	jitendra.malik@alston.com
22	ATTORNEYS FOR DEFENDANT INNOPHARMA LICENSING
23	
24	
25	ALSTON & BIRD, LLP <i>United States District Court Camden, New Jersey</i>

	1008
1	BY: HIDEYADA JAMES ABE, ESQUIRE
2	333 South Hope Street
3	16th Floor
4	Los Angeles, CA 90071-3004 (213) 576-1000 james.abe@alston.com
5	ATTORNEYS FOR DEFENDANT LUPIN LIMITED
6	ALSTON & BIRD, LLP BY: JOSEPH M. JANUSZ, ESQUIRE
7	Bank of America Plaza
8	Suite 4000
9	Charlotte, NC 28280-4000 (704) 444-1000 joe.janusz@alston.com
10	ATTORNEYS FOR DEFENDANT INNOPHARMA LICENSING
11	SAIBER, LLC ARNOLD B. CALMANN, ESQUIRE
12	One Gateway Center
13	10th Floor, Suite 1000
14	Newark, New Jersey 07102 (973) 622-3333 abc@saiber.com
15	ATTORNEYS FOR DEFENDANT INNOPHARMA LICENSING
16	
17	
18	
19	
20	
21	
22	
23	
24	
25	<i>United States District Court Camden, New Jersey</i>

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		1010
1	THE DEPUTY CLERK: All rise.	
2	(OPEN COURT, April 12, 2016, 9:33 a.m.)	
3	THE COURT: Good morning, be seated, please.	
4	RESPONSE: Good morning.	
00:00	THE COURT: And are we ready to resume? Okay.	
5		
6	(DR. TRATTLER, HAVING BEEN PREVIOUSLY SWORN AS A WITNESS,	
7	TESTIFIED AS FOLLOWS:)	
8	(DIRECT EXAMINATION OF DR. TRATTLER BY MS. LEBEIS)	
9	Q. Good morning, Dr. Trattler.	
00:00	A. Good morning.	
10	Q. Prior to January 21st, 2003, were ophthalmic NSAID	
11	therapies available to treat pain and inflammation after	
12	cataract surgery?	
13	A. Yes, they were.	
00:00	Q. What, if any, diclofenac product was available to treat	
14	pain and inflammation after cataract surgery prior to	
15	January 21st, 2013?	
16	A. Voltaren.	
17	Q. Have you prescribed Voltaren?	
00:00	A. I have, yes.	
18	Q. What, if any, ketorolac product was available to treat	
19	pain and inflammation after cataract surgery prior to	
20	January 21st, 2003?	
21	A. Acular, 0.5 percent.	
22	Q. Have you prescribed Acular?	
00:01		
23		
24		
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1 A. Yes, I have.

2 Q. Are diclofenac and ketorolac NSAIDs?

3 A. They both are, yes.

4 Q. How, if at all, are Acular and Voltaren limited by their

00:01 5 side effects?

6 A. So the challenge of those medications is they are -- they

7 work as nonsteroidals, but they had a lot of side effects, and

8 the main side effect they had was burning and stinging. With

9 Acular, you know, in the 40 percent range of patients, which

00:01 10 made it very difficult for some patients to use the product,

11 even though it was -- it could help them, it was difficult for

12 them to use it. And Voltaren also, about 15 percent of

13 patients had burning and stinging with instillation. So

14 again, there are some limitations for the patients.

00:01 15 Q. Let's discuss the basis for your opinion. Would you

16 please turn to JTX135 in your binder and identify that

17 document?

18 A. Yes. This is the FDA-approved package insert for

19 Voltaren.

00:02 20 Q. Did you review the FDA-approved package insert for

21 Voltaren in connection with your opinions in this case?

22 A. Yes, I did.

23 Q. Let me direct your attention to Page 6 of the Voltaren

24 package insert. And in particular, to the section entitled,

00:02 25 Adverse Reaction, in the paragraph labeled Ocular.

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1 A. Yes. This is the FDA-approved package insert for Acular,

2 0 -- which is 0.5 percent.

3 Q. Did you review the Acular package insert in connection

4 with your opinions in this case?

00:03 5 A. Yes, I did.

6 Q. Let me direct your attention to Page 7 of the Acular

7 package insert, and in particular, to the first paragraph of

8 the section entitled, Adverse Reactions. How, if at all, does

9 this portion of the Acular package insert relate to your

00:04 10 opinion?

11 A. We can see here it says: The most frequent adverse

12 events reported with the use of ketorolac tromethamine

13 ophthalmic solutions have been transient stinging and burning

14 on instillation. These events were reported by up to 40

00:04 15 percent of patients participating in clinical trials.

16 Q. How, if at all, does the adverse event section of the

17 Acular package insert comport with what you have observed in

18 your practice?

19 A. We saw this -- you know, again, we really like ketorolac

00:04 20 as a product, but, you know, the challenge was for patients,

21 they would get this burning and stinging upon instillation,

22 which really impacted their ability to use the product.

23 Q. Could you now please turn to JTX052 in your binder and

24 identify that document?

00:04 25 A. Yes, this is a document from the FDA's website and it's

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1 How, if at all, does this portion of the Voltaren

2 package insert relate to your opinion?

3 A. We can see at the very beginning, it says: Transient

4 burning and stinging were reported in approximately 15 percent

00:02 5 of the patients across studies with the use of Voltaren

6 ophthalmic.

7 Q. How, if at all, does the adverse event section of the

8 Voltaren package insert comport with what you have observed in

9 your practice?

00:02 10 A. Very similar. Again, Voltaren at the time was a very --

11 a nice, you know, an effective product at the time, but, you

12 know, patients would experience burning that could impact

13 their compliance and their ability to use their product.

14 Q. Would you please turn to JTX051 in your binder and

00:03 15 identify that document?

16 A. 051. Okay. Just make sure I get to the right one.

17 Yes, so this is from the FDA's website. Basically,

18 it's just information from the website about Voltaren.

19 Q. Did you review JTX051 in connection with your opinions in

00:03 20 this case?

21 A. Yes, I did.

22 Q. When was Voltaren approved?

23 A. It says the approval date was March 28th, 1991.

24 Q. Could you now please turn to PTX-265 in your binder and

00:03 25 identify that document?

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1 on Acular.

2 Q. Did you review JTX052 in connection with your opinions in

3 this case?

4 A. Yes, I did.

00:05 5 Q. When was Acular approved by the FDA?

6 A. On November 9th, 1992.

7 Q. I would now like to discuss in more detail Prolensa as

8 compared to the other bromfenac-containing products, Xibrom

9 and Bromday. Is it your understanding that Xibrom and Bromday

00:05 10 contain a different surfactant than Prolensa?

11 A. Yes.

12 Q. What surfactant does Prolensa contain?

13 A. Tyloxapol.

14 Q. And what surfactant do Xibrom and Bromday contain?

00:05 15 A. Polysorbate 80.

16 Q. Let's discuss the pH of these products. Were you in the

17 courtroom yesterday when Dr. Williams testified that the

18 formulation of Prolensa with tyloxapol is allowed for Prolensa

19 to be formulated at pH 7.8, as compared to the pH of 8.3 for

00:05 20 Xibrom and Bromday containing polysorbate 80?

21 A. Yes.

22 Q. How, if at all, is the lower pH of Prolensa a benefit to

23 patients?

24 A. Well, having more physiologic pH has the potential

00:05 25 benefit of being more comfortable for patients.

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1 Q. Have you had an opportunity to consider the opinions  
2 being offered by defendant's expert, Dr. Cykiert, in this  
3 case?  
4 A. Yes, I have.

00:06 5 Q. Are you aware that Dr. Cykiert has taken the position  
6 that the lower pH of Prolensa has no impact on clinical safety  
7 or efficacy or patient comfort and confers no clinical  
8 benefits over Xibrom and Bromday?  
9 A. Yes, I'm aware of his opinions.

00:06 10 Q. Do you agree with Dr. Cykiert?  
11 A. I disagree.  
12 Q. Why do you disagree with Dr. Cykiert?  
13 A. I disagree because, you know, when we use Prolensa,  
14 patients -- you know, patients who use it feel that it is a  
00:06 15 very comfortable drop, that it works well, and they don't  
16 experience the burning and stinging that they can experience  
17 with the previous generation with Xibrom or Bromday. So  
18 there's quite a difference.

00:06 19 Q. How, if at all, is the pH of Prolensa closer to the pH of  
20 natural tears?  
21 A. So the typical pH for natural tears is 7.4 and Prolensa  
22 is 7.8. So it's much closer to the physiologic pH of tears.

00:07 23 Q. Have you also had an opportunity to consider the opinions  
24 being offered by defendant's expert, Dr. Prausnitz, in this  
00:07 25 case?

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1 please turn to JTX018 in your binder and identify that  
2 document?  
3 A. Yes. This is an article by George Baklayan, is entitled,  
4 "The Ocular Distribution of C 14 Labeled Bromfenac Ophthalmic  
00:08 5 Solution 0.07 Percent in a Rabbit Model."  
6 Q. Have you reviewed JTX018 in connection with your opinions  
7 in this case?  
8 A. Yes, I have.  
9 Q. Do you regard this article as a reliable authority on the  
00:09 10 studies to which it refers and the conclusions to be drawn  
11 from them?  
12 A. Yes.  
13 Q. Let me direct your attention to Page 1718 in JTX018,  
14 which bears Bates number PROL 0080506.  
00:09 15 A. Okay. Yes.  
16 Q. And in particular to the left-hand column at -- around  
17 Line 16, to the sentence beginning with Prolensa. What does  
18 this passage in JTX018 disclose?  
19 A. It says: Prolensa was reformulated from bromfenac 0.09  
00:09 20 percent, in parenthesis, Bromday, Bausch & Lomb, close  
21 parentheses, to achieve similar ocular bioavailability with a  
22 lower concentration of active drug, thereby ensuring similar  
23 clinical efficacy to Bromday but with reduced exposure of the  
24 surgically-compromised ocular surface to the drug.

00:10 25 Q. Let me also direct your attention to Page 1722 in JTX018,

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1 A. Yes, I have.  
2 Q. Does Dr. Prausnitz share Dr. Cykiert's opinion, that  
3 lower pH has no impact on clinical safety and efficacy?  
4 A. He does not.

00:07 5 Q. What is your understanding of Dr. Prausnitz's view of pH  
6 on clinical safety and efficacy?  
7 A. It's my understanding that Dr. Prausnitz agrees that  
8 having a more physiologic pH can be, can be beneficial to  
9 comfort, and to overall efficacy of a product.

00:07 10 Q. How, if at all, does Dr. Prausnitz's opinion relate to  
11 your opinion regarding the clinical benefits of Prolensa's pH?  
12 A. They are similar.  
13 Q. Let's now discuss the amount of active ingredient. Were  
14 you in the courtroom yesterday when Dr. Williams testified  
00:08 15 that the formulation of Prolensa with tyloxapol has allowed  
16 for lowering Prolensa's bromfenac concentration to .07 percent  
17 compared to .09 percent bromfenac in Xibrom and Bromday?  
18 A. Yes.  
19 Q. How, if at all, is lowering the concentration of  
00:08 20 bromfenac a benefit to patients?  
21 A. Well, it helps because the active ingredients can have  
22 toxicity, and having a lower concentration of the active  
23 ingredients while still maintaining similar efficacy is  
24 beneficial.

00:08 25 Q. Let's explore the basis for your opinion. Would you

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1 which bears Bates number PROL 0080510. And in particular, to  
2 the right-hand column, about three lines down, to the sentence  
3 beginning with, Even, what does this sentence in JTX018  
4 disclose?  
00:10 5 A. It says: Even at a lower concentration, the bromfenac  
6 0.07 percent pH 7.8 solution exhibited similar, in the case of  
7 scleral tissue, increased penetration of ocular tissues  
8 studied, when compared with bromfenac 0.09 percent pH 8.3  
9 solution.  
00:10 10 Q. Would you also read the sentence just below that to the  
11 record?  
12 A. This is likely due to the difference in pH between the  
13 solutions; lowering the -- lowering the pH increases the  
14 unionized fraction of drugs, which can lead to enhanced  
00:11 15 corneal permeability.  
16 Q. How, if at all, do these passages in JTX018 relate to  
17 your opinions regarding Prolensa?  
18 A. All right. The key is that despite Prolensa having a  
19 lower concentration of active ingredient, it has similar  
00:11 20 penetration into the eye. So it has a clinical efficacy for  
21 patients undergoing cataract surgery.  
22 Q. Are you aware that Dr. Prausnitz has taken the position  
23 that lowering the pH from 8.3 to 7.8 could cause increased  
24 ocular penetration?  
00:11 25 A. Yes.

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1 Q. How, if at all, is Dr. Prausnitz's opinion consistent  
 2 with your opinion?  
 3 A. His opinion is consistent with my opinion and is  
 4 supported by this article and study.  
 00:11 5 Q. Let's now discuss the adverse event profiles. Are you  
 6 aware that Dr. Cykiert has taken the position that Prolensa is  
 7 clinically indistinguishable in its safety profile from Xibrom  
 8 and Bromday?  
 9 A. Yes, I'm aware of his opinion.  
 00:12 10 Q. Do you agree with Dr. Cykiert?  
 11 A. I do not.  
 12 Q. Why do you disagree?  
 13 A. I disagree because, you know, I've had the opportunity to  
 14 use both Xibrom and Bromday, and it works well, but patients  
 00:12 15 can experience burning and stinging, which can impact their  
 16 compliance. Having used Prolensa, patients find it very  
 17 comfortable. I have not had a single patient, you know,  
 18 complain to me that they've experienced burning or stinging,  
 19 and none have had to stop the use of the medication, you know,  
 00:12 20 in and around cataract surgery.  
 21 Q. Does Prolensa differ in its safety profile from Xibrom  
 22 and Bromday based on their package inserts?  
 23 A. Yes.  
 24 Q. Are you aware that Dr. Cykiert has taken the position  
 00:12 25 that burning and stinging caused by a drug product do not  
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1 A. I disagree. He's talking about a rare patient that's not  
 2 the typical patient that we'll see in our practice. I'm sure  
 3 there are patients out there like that, but even knowing that,  
 4 since -- first of all, since all patients undergoing cataract  
 00:14 5 surgery, we want them to use the medication and have a  
 6 comfortable experience, we want to use a product that is  
 7 comfortable for patients. And if there was that theoretical  
 8 rare patient having a product that was less likely to cause  
 9 burning or stinging would be beneficial versus one that  
 00:14 10 wouldn't be more likely to cause burning or stinging.  
 11 Q. How, if at all, do ophthalmologists consider burning and  
 12 stinging caused by a drug product when making prescribing  
 13 decisions?  
 14 A. We consider it because it's part of the patient  
 00:14 15 experience. With cataract surgery, they are coming to us and  
 16 they expect to have, you know, a positive experience. They  
 17 want to see better, but they also -- to see better, it  
 18 requires their use of a medication -- medications  
 19 postoperatively, and having drugs that are comfortable is just  
 00:14 20 critical to a positive experience, as well as getting good  
 21 postoperative outcomes.  
 22 Q. Are you aware that defendants are taking the position  
 23 that because there are no head-to-head clinical trial data  
 24 comparing Prolensa to Xibrom or Bromday, no comparison can be  
 00:15 25 drawn across these products regarding burning and stinging?  
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1 impact the prescribing habits of ophthalmologists?  
 2 A. I'm aware of his opinion, yes.  
 3 Q. Do you agree with Dr. Cykiert?  
 4 A. I completely disagree with his opinion.  
 00:13 5 Q. And why do you disagree?  
 6 A. Because, you know, every single patient that comes to us  
 7 for cataract surgery is expecting to get -- not only see well  
 8 but have a good postoperative experience. And if they  
 9 experience burning and stinging from the use of a medication,  
 00:13 10 it makes their experience worse. It can lead to noncompliance  
 11 and just a less happy patient.  
 12 So, you know, we have a lot of responsibility for every  
 13 single patient that comes to us for surgery, and so it's  
 14 really important that if we have an opportunity to use a  
 00:13 15 product that doesn't cause burning and stinging, that's  
 16 efficacious, it's very beneficial to patients.  
 17 Q. Are you also aware that Dr. Cykiert has taken the  
 18 position that because certain patients will always experience  
 19 burning and stinging, ophthalmologists do not consider whether  
 00:13 20 formulation causes burning and stinging when prescribing  
 21 ophthalmic NSAIDs?  
 22 A. I'm aware of his opinion, yes.  
 23 Q. Do you agree with Dr. Cykiert?  
 24 A. I disagree.  
 00:13 25 Q. Why do you disagree?  
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1 A. Yes, I'm aware.  
 2 Q. Do you agree with defendants that no comparison can be  
 3 drawn between Prolensa and Xibrom or Bromday?  
 4 A. I disagree.  
 00:15 5 Q. Why do you disagree?  
 6 A. I disagree for a few reasons. No. 1, the FDA, you know,  
 7 evaluates clinical trial results, and then develops a package,  
 8 you know, an FDA-approved package insert for us to -- for us  
 9 as clinicians to evaluate, to understand what potential  
 00:15 10 adverse events a product may cause patients, so we can advise  
 11 them.  
 12 And, you know, when you compare the different NSAID  
 13 formulations, you know, it's pretty obvious that there are  
 14 differences both in the package insert but also clinically and  
 00:15 15 how we take care of patients. So postoperatively, patients  
 16 that there -- you know, we can see the difference  
 17 postoperatively as well, you know, in how patients, you know,  
 18 feel about the different medications.  
 19 Q. If you would please turn back in your binder now to  
 00:16 20 JTX023, which is the FDA-approved package insert for Prolensa.  
 21 Let me draw your attention to Page 6, which bears Bates number  
 22 PROL 0080221, and in particular, to the first paragraph under  
 23 Adverse Reactions. What does this portion of the Prolensa  
 24 package insert disclose?  
 00:16 25 A. This -- this is in the package insert, FDA-approved  
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1 package insert, and it says: Clinical trial experience.  
2 Because clinical trials are conducted under widely varying  
3 conditions, adverse reaction rates observed in the clinical  
4 trials of drug cannot be directly compared to rates in the  
00:16 5 clinical trials of another drug and may not reflect the rates  
6 observed in clinical practice.  
7 Q. How, if at all, does this portion of the Prolensa package  
8 insert relate to your opinions regarding adverse event  
9 profiles?  
00:16 10 A. I agree with the FDA's statement here. There certainly  
11 can be -- you know, each study is performed under different --  
12 slightly different conditions and so there can be differences.  
13 But overall, the FDA package inserts, you know, gives us the  
14 information on what to expect, but also, you know, from  
00:17 15 clinical experience, I'm able to also determine how the  
16 package insert compares from one product to another.  
17 Q. And in light of this statement, how, if at all, do  
18 physicians compare the adverse event profiles of different  
19 drug products, such as Prolensa on the one hand and Xibrom or  
00:17 20 Bromday on the other hand?  
21 A. They compare in two ways. One, they'll look at the FDA  
22 package insert upon approval or if they're going to prescribe  
23 the medication, and they can see what adverse events are  
24 reported. And then if they choose to use the product, they  
00:17 25 have the clinical experience with the product and they talk to

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1 patients and can find out how well it works and what the  
2 adverse events are.  
3 Q. Now let's discuss why Prolensa is prescribed. Are you  
4 aware that Dr. Cykiert has taken the position that persistent  
00:17 5 clinically-verified cystoid macular edema is the only  
6 clinically-verified reason to prescribe ophthalmic NSAIDs like  
7 Prolensa?  
8 A. Yes, I'm aware of his opinion.  
9 Q. Do you agree with Dr. Cykiert?  
00:18 10 A. I disagree.  
11 Q. Why do you disagree?  
12 A. Well, I disagree for the fact that Prolensa is FDA  
13 approved for cataract surgery for -- for reduction in  
14 inflammation and also reduction in pain with cataract surgery.  
00:18 15 So it's -- there's no -- it's not indicated and not approved  
16 for treatment of CME. It can work. My experience is that it  
17 does work for that, but it's not approved for that, and so we  
18 use it during -- in and around cataract surgery for what it is  
19 FDA approved for, which is pain and inflammation.  
00:18 20 Q. How, if at all, does the treatment of inflammation after  
21 cataract surgery with an NSAID like Prolensa prevent the  
22 development of CME?  
23 A. All right. As you may recall from the surgical video I  
24 showed yesterday, we're doing surgery, we're, you know, making  
00:18 25 incisions in the eye, there is ultrasound energy that is used

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1 to break up the cataract, so inflammation is released. And  
2 it's really important to use anti-inflammatory medications to  
3 suppress the inflammation to help patients experience good  
4 vision postoperatively but also prevent the development of  
00:19 5 cystoid macular edema, you know, postoperatively.  
6 Q. Let's explore the basis for your opinion. Would you  
7 please turn to PTX-270 in your binder and identify that  
8 document?  
9 A. Yes. This is an article by Dr. Allan Flach, and is  
00:19 10 entitled, The Incidence, Pathogenesis and Treatment of Cystoid  
11 Macular Edema Following Cataract Surgery.  
12 Q. Have you reviewed PTX-270 in connection with your  
13 opinions in this case?  
14 A. Yes, I have.  
00:19 15 Q. Let me direct your attention to Page 568 of PTX-270, and  
16 in particular, to the second paragraph, under the heading,  
17 Pathogenesis. What does the first sentence of this paragraph  
18 disclose?  
19 A. Okay. It says that: Most investigators agree that  
00:20 20 inflammation is the major -- major etiologic factor in the  
21 development of CME following cataract surgery.  
22 Q. Going down a little bit in the paragraph, what does the  
23 fourth sentence of this paragraph in PTX-270, starting with  
24 Clinical descriptions disclose?  
00:20 25 A. It says: Clinical descriptions of patients with CME

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1 following cataract surgery suggest that inflammation is an  
2 important factor.  
3 Q. How, if at all, does this passage in PTX-270 relate to  
4 your opinion that effective treatment of inflammation  
00:20 5 following cataract surgery can avoid complications such as  
6 CME?  
7 A. Right. This article supports the finding that  
8 inflammation is the -- leads to the development of cystoid  
9 macular edema, if not treated, so being proactive in treating  
00:20 10 it -- treating inflammation in and around the time of cataract  
11 surgery will lower the incidence or risk for a patient  
12 developing CME.  
13 Q. Would you please turn to JTX146 in your binder and  
14 identify that document?  
00:21 15 A. Yes. This is an article, a peer-reviewed article by  
16 Dr. Steven Silverstein, and the article is entitled, The  
17 Efficacy of Bromfenac Ophthalmic Solution 0.07 Percent Dosed  
18 Once Daily in Achieving Zero-to-Trace Anterior Chamber Cell  
19 Severity Following Cataract Surgery.  
00:21 20 Q. Have you reviewed JTX146 in connection with your opinions  
21 in this case?  
22 A. Yes, I have.  
23 Q. Do you regard this article as a reliable authority on the  
24 study to which it refers and the conclusions to be drawn from  
00:21 25 them?

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1 A. Yes.

2 Q. Let me direct your attention to Page 966 of JTX146, and

3 in particular, to the first paragraph in the left-hand column.

4 What does the last sentence of this paragraph disclose?

00:21 5 A. The article says: The management of postoperative

6 inflammation is essential, both to ensure rapid recovery

7 following surgery, as well as to prevent or decrease the

8 potential for long-term complications, such as cystoid macular

9 edema.

00:22 10 Q. How, if at all, does this passage relate to your opinion

11 that effective treatment of inflammation can avoid

12 complications such as CME?

13 A. It is exactly how I feel when I treat my patients. Every

14 patient who is coming in for cataract surgery has an

00:22 15 expectation that they're going to see better after surgery and

16 won't experience a complication. So there's always risk with

17 surgery, so effectively suppressing inflammation in and around

18 the time of cataract surgery with anti-inflammatory

19 medications is critical to a good postoperative experience and

00:22 20 visual result, as well as preventing or reducing the risk for

21 developing CME.

22 Q. Can you now please turn to PTX-281 in your binder and

23 identify that document?

24 A. Yes. This is an article by Stephen Kim entitled, Topical

00:23 25 Nonsteroidal Anti-Inflammatory Drugs and Cataract Surgery.

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1 A. All right. So the -- this article was focused on the

2 long-term outcomes, three months or greater, not short-term.

3 Q. How, if at all, are short-term outcomes important after

4 cataract surgery?

00:24 5 A. They are critical. We are performing surgery on

6 patients. They have expectation that they're getting

7 improvement in their vision, and their vision will typically

8 start to improve after vision -- after surgery. But if two

9 weeks after surgery they've had improvement and all of a

00:24 10 sudden their vision starts to worsen, it really impacts their

11 happiness and their ability to function.

12 MS. HOLLAND: Your Honor, I have an objection to that

13 last question and answer, is outside of the scope of the

14 expert reports.

00:25 15 THE COURT: Okay. Was -- did the expert comment on

16 the Kim article and his expert report?

17 MS. LEBEIS: Yes, he did, and I can direct you to the

18 paragraphs.

19 MS. HOLLAND: I'm not -- I don't have a problem with

00:25 20 the Kim article and the rest of the testimony he's given on

21 it. It's only his explanation about the difference between

22 short-term and long-term benefits. That's a new opinion.

23 MS. LEBEIS: I believe that the expert quoted this

24 exact portion of the Kim article in his expert reports.

00:25 25 MS. HOLLAND: Would you mind just giving me a cite so

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1 Q. Have you reviewed PTX-281 in connection with your

2 opinions in this case?

3 A. Yes, I have.

4 Q. Are you aware that Dr. Cykiert has cited PTX-281 and

00:23 5 taken the position that no evidence supports the practice of

6 administering ophthalmic NSAIDs prophylactically to prevent

7 CME?

8 A. I'm aware of his opinion, yes.

9 Q. Do you agree with Dr. Cykiert's characterization of

00:23 10 PTX-281?

11 A. I disagree.

12 Q. Let's explore the basis for your disagreement. Let me

13 direct your attention to Page 2167 of PTX-281. And in

14 particular, to the left-hand column in the second paragraph

00:23 15 and the sentence starting, Although long-term.

16 What does this sentence of PTX-281 disclose?

17 A. Okay. So this says: Although long-term visual acuity

18 greater than three months after cataract surgery is an

19 important clinical measure of a therapeutic intervention, this

00:23 20 assessment was not designed to comment on the rationale and

21 potential value of NSAID therapy in preventing CME soon after

22 surgery and the patient's satisfaction and quality of life

23 improvement associated with more rapid visual rehabilitation.

24 Q. Does this portion of PTX-281 reflect long-term or

00:24 25 short-term outcomes after cataract surgery?

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1 maybe I can withdraw the objection.

2 MS. LEBEIS: Sure. Yes. It will be in the Trattler

3 reply report at paragraph 12 and paragraph 22.

4 MS. HOLLAND: It's not there exactly, but I'll let it

00:26 5 go, Your Honor, I'll withdraw the objection.

6 THE COURT: Okay. Very well, the objection is

7 withdrawn.

8 MS. LEBEIS: Thank you.

9 BY MS. LEBEIS:

00:26 10 Q. Let me now direct your attention to Page 2159 of PTX-281,

11 and in particular, to the first sentence in the section

12 entitled, Results. What does this sentence of PTX-281

13 disclose?

14 A. It states: Nonsteroidal anti-inflammatory drug therapy

00:26 15 was effective in reducing CME detected by angiography or

16 optical coherence tomography, in parentheses OCT, close

17 parentheses, and may increase the speed of visual recovery

18 after surgery when compared directly with placebo or topical

19 corticosteroid formulations with limited intraocular

00:27 20 penetration.

21 Q. And what does this portion of PTX-281 reflect?

22 A. Well, this reflects our experience, that nonsteroidals

23 are effective in reducing CME postoperatively, which is

24 exactly what this says.

00:27 25 Q. And how, if at all, is restoration of vision soon after

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1 surgery an important benefit to patients?  
2 A. I mean, it's critical. They're coming to us because they  
3 can't see. They're having difficult with their activities of  
4 daily living of seeing and functioning, and if -- and the  
00:27 5 surgery should provide them excellent postoperative vision, so  
6 if they develop a serious complication like CME that reduces  
7 their vision, it really is very impactful in a negative way to  
8 the patient overall.  
9 Q. Are you aware that defendants have taken the position  
00:28 10 that CME is a less serious complication that usually resolves  
11 without the need for treatment in most patients?  
12 A. I'm aware of that opinion.  
13 Q. Do you agree with defendants?  
14 A. I completely disagree with that opinion.  
00:28 15 Q. Okay. And why do you disagree?  
16 A. I disagree because in -- in the occasional situation when  
17 a patient does experience or develop CME, we don't just watch  
18 them and hope they get better. We actually immediately  
19 initiate therapy with various anti-inflammatory medications,  
00:28 20 because studies have shown that anti-inflammatory therapies do  
21 help improve vision in patients with CME. So we immediately  
22 initiate treatment in patients that have vision loss from CME.  
23 We don't just hope it may get better.  
24 Q. Let me direct your attention back to PTX-281, to Page  
00:29 25 2159. And in particular, to the second sentence under the  
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1 heading, Background, in the right-hand column. What does this  
2 sentence in PTX-281 disclose?  
3 A. It states: Development of CME after cataract surgery is  
4 the most common cause of visual impairment.  
00:29 5 Q. And how, if at all, does this passage in PTX-281 support  
6 your opinion that CME is a serious complication?  
7 A. Right. Again, we're performing cataract surgery and we  
8 want patients to have an excellent postoperative visual  
9 result, and the most common postoperative complication that  
00:29 10 impacts vision, as stated here, is CME. And it is preventible  
11 or -- and the risk can be reduced with treatment.  
12 Q. I'd now like to discuss the medical community's acclaim  
13 for Prolensa.  
14 What, if anything, have leaders in the field of  
00:30 15 cataract surgery publicly stated about Prolensa compared to  
16 existing therapies?  
17 A. I mean, I think that in general the experience has been  
18 very positive with the introduction of Prolensa® for patient  
19 care after cataract surgery, it's been a very positive  
00:30 20 experience for the product.  
21 Q. Let's discuss the basis for your opinion.  
22 Have you prepared demonstratives to assist the Court  
23 with your testimony?  
24 A. Yes, I have.  
00:30 25 Q. Let's pull up PDX5-3 on the screen.  
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1 What does PDX5-3 illustrate?  
2 A. This is from Dr. Thomas Walters' article on Bromfenac  
3 Ophthalmic Solution 0.07 percent Dosed Once Daily for Cataract  
4 Surgery.  
00:30 5 Q. What does Dr. Walters conclude?  
6 A. The advance formulation of bromfenac with a lower  
7 concentration of active ingredient has a similar efficacy  
8 profile as higher concentrations of bromfenac previously  
9 approved by the FDA in the United States and safety profile  
00:31 10 with consistently lower incidence rates than those seen in the  
11 placebo group.  
12 Q. If you could please turn to JTX142 in your binder.  
13 Is JTX142 the document cited on PDX5-3 we just  
14 discussed?  
00:31 15 A. Yes, it is.  
16 Q. Have you reviewed JTX142 in connection with your opinions  
17 in this case?  
18 A. Yes, I have.  
19 Q. Do you regard this article as a reliable authority on the  
00:31 20 studies to which it refers and the conclusions to be drawn  
21 from them?  
22 A. Yes.  
23 Q. Okay. Let's now pull up PDX5-4 on the screen.  
24 What does PDX5-4 illustrate?  
00:31 25 A. This is the article by Dr. Steven Silverstein entitled  
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1 **The Efficacy of Bromfenac Ophthalmic Solution 0.07 percent**  
2 **dosed once daily in achieving zero to trace anterior chamber**  
3 **cell severity following cataract surgery.**  
4 Q. What does Dr. Silverstein conclude regarding Prolensa®?  
00:32 5 A. The data show that once-daily dosing -- sorry. I just  
6 did conclusion.  
7 The bromfenac ophthalmic solution 0.07 percent dosed  
8 once-daily was clinically effective in achieving zero-to-trace  
9 anterior chamber cell severity after cataract surgery and was  
00:32 10 superior to placebo in all anterior chamber cell severity and  
11 inflammation outcome measures.  
12 Q. At the bottom of the slide how did Dr. Silverstein  
13 describe Prolensa®?  
14 A. He described as: The data show that once-daily dosing  
00:32 15 with Prolensa® provides powerful and rapid control of  
16 inflammation and pain following cataract surgery, confirming  
17 the potency of this NSAID and benefits of the new  
18 formulations, said Steven M. Silverstein, M.D., FACS, founder  
19 of Silverstein Eye Centers in Kansas City, Missouri.  
00:32 20 Prolensa® reduces the amount of medication placed on the  
21 healing eye while maintaining a high degree of efficacy and  
22 ocular comfort.  
23 Q. Please turn back to JTX146 in your binder.  
24 Is JTX146 the first document cited on PDX5-4 we just  
00:33 25 discussed?  
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1 A. Yes, it is.  
2 Q. If you could please now turn to JTX145 in your binder.  
3 Is JTX145 the second document cited on PDX5-4 we just  
4 discussed?  
00:33 5 A. Yes.  
6 Q. Have you reviewed JTX145 in connection with your opinions  
7 in this case?  
8 A. Yes, I have.  
9 Q. Now, let's pull up PDX5-5 on the screen.  
00:33 10 What does PDX5-5 illustrate?  
11 A. This is an article by Rajesh Rajpal entitled Bromfenac  
12 Ophthalmic Solution for the Treatment of Post-Operative Ocular  
13 Pain and Inflammation: Safety, Efficacy, and Patient  
14 Adherence.  
00:33 15 Q. What did Dr. Rajpal conclude regarding Prolensa@?  
16 A. He wrote: The lower concentration of bromfenac, 0.07  
17 percent, combined with once-daily dosing may help further  
18 improve patient adherence and compliance.  
19 Q. If you could please turn back to JTX143 in your binder.  
00:34 20 Is JTX143 the document cited on PDX5-5 we just  
21 discussed?  
22 A. Yes.  
23 Q. Are you aware that Dr. Cykiert has taken the position  
24 that the articles you just discussed in support of the medical  
00:34 25 community's opinion regarding Prolensa@ are entitled to little  
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1 weight because of the author's consulting or editorial  
2 arrangements with Bausch & Lomb?  
3 A. I understand his opinion.  
4 Q. Do you agree with Dr. Cykiert?  
00:34 5 A. I disagree.  
6 Q. Why do you disagree?  
7 A. Well, these articles are providing data from FDA  
8 conducted clinical trials, they're double-mass placebo  
9 controlled clinical trials and they provide the results from  
00:34 10 these clinical trials, and the information provided in these  
11 articles are very reliable.  
12 Q. In your experience in the clinical trials in which you  
13 have been involved, how, if at all, does company sponsorship  
14 of independent clinical trials influence the results reported  
00:35 15 in peer reviewed journal articles such as the ones we have  
16 discussed?  
17 A. They do not have -- clinical trials are expensive to run  
18 and the support helps the clinical trials run. But the  
19 studies, if they're mass and double-blind, we have no idea  
00:35 20 what the results will be. And once we get the results, we'll  
21 then provide the results.  
22 Q. Just to sum up, Dr. Trattler, is it your opinion that  
23 Prolensa provides meaningful benefits to the patients that you  
24 treat?  
00:36 25 A. No question, yes.  
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1 Q. Why is that?  
2 A. My patients who are coming to see me for cataract surgery  
3 have very high expectations, it's a real surgery with real  
4 risks, and so having a product like Prolensa@ that can help  
5 suppress inflammation and reduce pain after surgery is very  
6 beneficial to my patients, providing a better outcome, visual  
7 outcome and reducing the chance -- reducing the amount of  
8 inflammation.  
9 MS. LEBIS: I have no further questions, your Honor.  
00:36 10 THE COURT: Okay. Thank you very much.  
11 MS. LEBIS: I'd like to move into evidence a list of  
12 exhibits. I can list them off right now.  
13 THE COURT: Okay. Could you state the exhibit  
14 numbers?  
00:36 15 MS. LEBIS: Sure. PTX-164, PTX-277, JTX144,  
16 PTX-PTX-40074, JTX023, JTX143, JTX135, JTX051, PTX-265,  
17 JTX052, JTX018, PTX-270, JTX146, PTX-281, JTX142, and JTX145.  
18 THE COURT: Ms. Holland, do you need some time to  
19 review those?  
00:37 20 MS. HOLLAND: I do, your Honor. And, in any event, I  
21 believe we're going to have to talk about the exhibits that I  
22 moved into evidence or we have to talk about the exhibits I  
23 would like to move into evidence based on the  
24 cross-examination of Dr. Williams yesterday, so maybe we can  
00:37 25 handle all the exhibit issues at once.  
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1 THE COURT: Okay. We'll reserve on the admissibility  
2 of the list that's just been read.  
3 Do you want to take up the Dr. Williams cross exhibits  
4 at this time?  
00:38 5 MS. HOLLAND: No, I don't want to keep Dr. Trattler  
6 on the stand for that, so we can do it afterwards.  
7 THE COURT: It won't take that long.  
8 MS. HOLLAND: It might, your Honor. Unfortunately,  
9 it might be a bit of argument about it.  
00:38 10 THE COURT: Okay. We'll do that when there's no  
11 witness on the stand.  
12 MS. HOLLAND: Okay.  
13 (CROSS-EXAMINATION OF WILLIAM B. TRATTLER BY MS. HOLLAND:)  
14 Q. Good morning, Dr. Trattler.  
00:38 15 A. Good morning.  
16 Q. In your direct examination you discussed incidence rates  
17 for burning and stinging for Bronuck@, Xibrom@, Bromday@ and  
18 Prolensa@, correct?  
19 A. Yes.  
00:38 20 Q. All right. And you just agreed in your direct  
21 examination that there never have been any head-to-head  
22 clinical trials comparing Prolensa@ with Bronuck@, Xibrom@, or  
23 Bromday@, correct?  
24 A. Yes.  
00:38 25 Q. So there is no data directly comparing the incidence of  
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1 burning and stinging among those products, right?

2 **A. Well, there's no head-to-head clinical trials, but we**

3 **have our information from using the medications on patients so**

4 **we have our personal clinical experience using those products.**

00:39 5 **And we also have the information from the product, FDA product**

6 **label on the differences between the two.**

7 **Q. All right. But there is no clinical data you can point**

8 **to that shows a direct head-to-head comparison that Prolensa@**

9 **has less burning and stinging than Bronuck@, Xibrom@, or**

00:39 10 **Bromday@, right?**

11 **A. We don't have any clinical studies, but we have our**

12 **experience, which is there is a difference and it matches --**

13 **Q. You haven't --**

14 **A. -- the FDA --**

00:39 15 **Q. Okay. Go ahead. I'm sorry. I don't want to interrupt.**

16 **MS. LEBIS: Let him finish the answer.**

17 **THE WITNESS: It matches what we see on the FDA**

18 **product -- FDA approved product package insert.**

19 **BY MS. HOLLAND:**

00:39 20 **Q. Well, let's -- I'd actually like to talk about those**

21 **product inserts.**

22 **In your direct examination you presented information**

23 **from the inserts for Bronuck@, which is a Japanese product,**

24 **obviously, and Xibrom@, Bromday@, and Prolensa@, right?**

00:40 25 **A. Yes.**

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1 **Q. And there was one case of burning reported and that is an**

2 **incidence rate of .24 percent, right?**

3 **A. Yes.**

4 **Q. All right. Let's move on to Xibrom@ then. Let's go to**

00:41 5 **JTX144.**

6 **This is the Xibrom@ prescribing information that you**

7 **talked about in your direct testimony, right?**

8 **A. Yes.**

9 **Q. And let's go to Section 6.1 on Page 3 of 7, and it's PROL**

00:42 10 **0080488.**

11 **And you pointed to the adverse reaction section on that**

12 **page, right?**

13 **A. Yes.**

14 **Q. And you pointed out that there was a list of various**

00:42 15 **adverse events, including what's denoted here as eye**

16 **irritation (including burning/stinging), right?**

17 **A. Yes.**

18 **Q. And then you said that there was an adverse reaction rate**

19 **of 2 to 7 percent, right?**

00:42 20 **A. That's correct.**

21 **Q. All right. Now, you cannot tell from this package insert**

22 **what the specific incidence rate was for burning and stinging,**

23 **right?**

24 **A. That is between 2 and 7 percent.**

00:42 25 **Q. That's all you can tell from the package insert, right?**

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1 **Q. I'd like to drill down a little bit more on those numbers**

2 **that you put on the screen. Let's start with Bronuck@ and**

3 **let's go to PTX-277.**

4 **This is the exhibit you used as the package insert for**

00:40 5 **Bronuck@, correct?**

6 **A. Yes.**

7 **Q. Okay. And you pointed to the box in the upper right-hand**

8 **corner of the page that says "ocular" and then -- yeah. No,**

9 **upper right-hand corner that says "ocular" and then there's a**

00:40 10 **box that says .01 percent less than 5 percent. That's what**

11 **you pointed to in your direct examination, right?**

12 **A. Yes.**

13 **Q. All right. So I'd like to look at the beginning of the**

14 **Adverse Events section, the section right before that box that**

00:41 15 **you pointed to. And it gives a little more granular**

16 **information on the adverse events, right?**

17 **A. Yes.**

18 **Q. All right. So let's look at the particular adverse**

19 **events you've been talking about, which is burning and**

00:41 20 **stinging. Okay?**

21 **A. Yes.**

22 **Q. So in the Bronuck@ package insert it says that there were**

23 **three cases of stinging reported and that would be a rate of**

24 **.71 percent, right?**

00:41 25 **A. Yes.**

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1 **A. Yes.**

2 **Q. All right. Now, the adverse event information in the**

3 **package insert was taken from clinical trials of Xibrom@,**

4 **right?**

00:43 5 **A. Yes.**

6 **Q. And those trials were reported in a paper with the lead**

7 **author Donnenfeld, right?**

8 **A. I believe so, yes.**

9 **Q. All right. So let's look at that paper. I think I'm**

00:43 10 **going to need to hand it out, we tried not to use**

11 **cross-binders just to save some trees.**

12 **THE COURT: And some hydrocarbons to the extent**

13 **binders are made of plastic.**

14 **So you've handed DTX-210.**

00:43 15 **MS. HOLLAND: Yes, your Honor.**

16 **BY MS. HOLLAND:**

17 **Q. So let's look at DTX-210 now.**

18 **Is this the Donnenfeld paper that reports on the Phase**

19 **III clinical trials of Xibrom@?**

00:44 20 **A. Yes.**

21 **Q. Let's start out by looking at the Results section on the**

22 **first page. It's in the abstract. Do you see that?**

23 **A. Yes.**

24 **Q. And I would like to point your attention to two lines up**

00:44 25 **from the bottom with the sentence beginning eye irritation. Do**

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- 1 you see that?
- 2 A. Yes.
- 3 Q. It says, eye irritation was reported in a lower
- 4 percentage of subjects for bromfenac versus placebo, as were
- 00:44 5 burning and stinging. And then it gives the incidence rate of
- 6 burning and stinging as 1.4 percent. Do you see that?
- 7 A. Yes.
- 8 Q. Okay. Then I would like to -- now I'd like to turn your
- 9 attention to Page 1650 in the reference. I'm sorry, I gave
- 00:45 10 you the wrong page number. It's Page 1659, I'm sorry, under
- 11 the paragraph that says "Safety." Do you see that paragraph?
- 12 A. Yes.
- 13 Q. Okay. And it says Ocular Adverse Events. Do you see
- 14 that?
- 00:45 15 A. Yes.
- 16 Q. About five lines down there's a -- it says eye
- 17 irritation. Do you see that?
- 18 A. Yes.
- 19 Q. It says 2.5 percent. Do you see that?
- 00:45 20 A. I do, yes.
- 21 Q. All right. I'd like you to go a little further down in
- 22 that paragraph, there's a sentence four lines up from the
- 23 bottom that says, it's starts with the word "furthermore" and
- 24 it says, furthermore, if the burning and stinging were
- 00:45 25 separated, the proportion of the bromfenac group was

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- 1 Q. And it says in general that the adverse events were
- 2 reported in 2-7 percent of patients, right?
- 3 A. Correct.
- 4 Q. From the label itself or the package insert itself, you
- 00:47 5 can't tell what percentage of patients experienced burning and
- 6 stinging, right?
- 7 A. **From this label between 2 and 7 -- in the range of 2 to**
- 8 **7 percent was reported on the package insert.**
- 9 Q. And again, the data that's -- let me withdraw that.
- 00:48 10 I should say the statement that is here in the Adverse
- 11 Reaction section is, again, taken from clinical trial data,
- 12 right?
- 13 A. Yes.
- 14 Q. And the results of the Phase III clinical trials for
- 00:48 15 Bromday® were reported in a paper by Henderson, right?
- 16 A. I'd like to see that.
- 17 Q. Sure.
- 18 A. Yeah.
- 19 Q. DTX-215. I'm going to hand that one out as well.
- 00:48 20 Do you have that in front of you now, Doctor?
- 21 A. Yes, I do.
- 22 Q. Have you had a chance to look at it?
- 23 A. Yes.
- 24 Q. And is that indeed the results of the clinical trial for
- 00:49 25 Bromday®?

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- 1 1.4 percent. Do you see that?
- 2 A. Yes, I do.
- 3 Q. So apparently based on the Donnenfeld results, the only
- 4 reason burning and stinging were included in this Xibrom®
- 00:46 5 label is because they were included within a broader category
- 6 of eye irritation, right?
- 7 A. **Well, they're included, but there're also patients that**
- 8 **experienced burning and stinging from clinical trials and they**
- 9 **do experience it -- they can experience it potentially**
- 00:46 10 **clinically.**
- 11 Q. But it didn't meet that 2 percent threshold that we saw
- 12 on the label, right?
- 13 A. **Correct, it reports here that for this particular study**
- 14 **it was 1.4 percent.**
- 00:46 15 Q. Right. I'd like to now move on to Bromday®. Can we turn
- 16 to PTX-474. And PTX-474 was the package insert that you used
- 17 for your testimony about Bromday®, right?
- 18 A. Yes.
- 19 Q. Let's go to Page 3 of 5, it has the Bates number PROL
- 00:47 20 0080495. And under the Adverse Reaction section, we see
- 21 something very similar to the Xibrom® label, right?
- 22 A. Yes.
- 23 Q. It has burning and stinging included within the larger
- 24 category of eye irritation, right?
- 00:47 25 A. Yes.

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- 1 A. Yes.
- 2 Q. Okay. Let's go to Page 215.7. I apologize for that, I'm
- 3 sorry, I just wanted to make sure I pointed you to the right
- 4 place in the handout.
- 00:50 5 This document talks about the various adverse events
- 6 that occurred in this trial for Bromday®, correct?
- 7 A. **It includes that, yes.**
- 8 Q. And if you look at Page 215.6, right above Figure 4, four
- 9 lines above that you'll see a statement that begins "In the
- 00:50 10 clinical trials." Do you see that? It says, in the clinical
- 11 trials of Bronuck®, .09 percent dose twice-daily, it give you
- 12 the most frequent AE's there, right?
- 13 A. Yes.
- 14 Q. And then the next page says -- before I ask you that, so
- 00:51 15 that's the -- those are the adverse events that were reported
- 16 for Xibrom®, which is what we just looked at in the Donnenfeld
- 17 paper, right, .09 percent dose twice-daily?
- 18 A. Yes.
- 19 Q. So what it's saying here is that it's reporting what the
- 00:51 20 adverse events were in the clinical trial for Xibrom®. And
- 21 again, we see what we saw earlier, eye irritation, which
- 22 includes burning and stinging. Do you see that?
- 23 A. Yes.
- 24 Q. Then the next sentence says, the AE's reported with
- 00:51 25 Bronuck® .09 percent dose once-daily in these four clinical

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1 trials were comparable. Do you see that?

2 A. Yes.

3 Q. Okay. So that means the adverse events for Bromday® were

4 comparable to Xibrom®, right?

00:52 5 A. Yes.

6 Q. As we saw for Xibrom®, the percentage of burning and

7 stinging was 1.4 percent, right?

8 A. Yes.

9 Q. And again, burning and stinging was a subset eye

00:52 10 irritation on the package insert, right?

11 A. Correct. Well, it was listed as -- you know, in

12 parentheses on the package insert.

13 Q. All right. Now, let's talk about Prolensa®. And I'd

14 like to go to JTX23.

00:52 15 This is the Prolensa® prescribing information you

16 talked about in your direct examination, right?

17 A. Yes.

18 Q. Let's go to the Adverse Reaction Section 6.1 on JTX23.3.

19 And I'm going to -- I'd like to look at the second paragraph

00:52 20 where it says "the most commonly reported adverse events." Do

21 you see that?

22 A. Yes.

23 Q. This is a section of the package insert you pointed to on

24 your direct, right?

00:53 25 A. Correct.

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1 my deposition. So following my deposition I actually looked

2 at the clinical trial data to determine the exact incidence of

3 burning and stinging.

4 MS. HOLLAND: I'm going to move to strike that

00:54 5 testimony, your Honor. My -- whatever -- if it's appropriate

6 on redirect, and I'm not sure it is, to bring in a new

7 opinion. I just asked simply whether you can tell from the

8 label, the only testimony that went in on direct was what was

9 in the label. And I'd like to know, based on the label, you

00:54 10 can make those comparisons.

11 THE COURT: All right. That's the pending question.

12 So please answer that question.

13 THE WITNESS: Could you just repeat the question one

14 more time, please, so I can make sure I answer properly?

15 THE COURT: Would you like it read back?

16 MS. HOLLAND: Pardon?

17 THE COURT: Would you like it read back?

18 MS. HOLLAND: Yeah, maybe that's the best thing.

19 (Designated question is read back.)

00:55 20 THE WITNESS: Well, the FDA included burning and

21 stinging on the label in Xibrom® and Bromday® and they chose

22 not to include it in this FDA package insert, so the

23 assumption is that it's insignificant to the FDA, which is why

24 they did not include it.

25 BY MS. HOLLAND:

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1 Q. And I believe you based your opinion that Prolensa® has

2 no burning or stinging associated with it from the fact that

3 burning and stinging is not listed in this section, right?

4 A. Correct.

00:53 5 Q. And, as you can see, however, this section includes only

6 those adverse events that occurred in 3 percent or more of

7 patients, right?

8 A. Yes. This was asked of me at my deposition.

9 Q. Is the answer yes?

00:53 10 A. Yes.

11 Q. Okay. And, as we saw from Bronuck® and Xibrom®, burning

12 and stinging occurred for those products at a rate well below

13 3 percent, right?

14 A. For those products, yes.

00:53 15 Q. Okay. So Bronuck® was less than 1 percent and Xibrom®

16 was 1.94 percent, right?

17 A. Xibrom® was 1.4 percent.

18 Q. So you can't actually tell from the Prolensa® prescribing

19 information whether burning and stinging were reported for

00:54 20 that product at a similar rate for what was reported for

21 Bronuck® and Xibrom®, right?

22 A. Yes. This question was asked of me at my deposition --

23 Q. I just wanted to know the answer. Is that correct?

24 A. I would like to complete my answer.

00:54 25 So the answer was this one question was asked of me at

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1 Q. That wasn't my question, so let me try again.

2 A. All right.

3 Q. I'd like to know, looking at the Prolensa® label can you

4 tell for sure whether or not the rate of burning and stinging

00:55 5 in the Prolensa® clinical trial was any different from the

6 1.4 percent or the less than 1.4 percent we saw with Xibrom®

7 and Bronuck®?

8 A. Well, the FDA product insert says the risks of burning

9 and stinging was between 2 to 7 percent in Xibrom® and

00:56 10 Bromday® and Xibrom® -- in Bromday® package insert. So my

11 assumption would be based on the package insert, that it was 2

12 percent or higher. So you're asking a question about the

13 percents in the FDA package insert is between 2 and 7 percent

14 that it looked at -- that it mentioned in the package insert.

00:56 15 Q. Well, the package insert for Prolensa® doesn't have 2 to

16 7 percent, does it, it has 3 to 8 percent, correct?

17 A. That's correct, yes.

18 Q. So I'll ask my question again.

19 Can you tell just by comparison of the package inserts

00:56 20 whether or not there's any difference in rate of burning and

21 stinging among the products?

22 A. The package insert, you know, reports on the FDA clinical

23 trial data, so -- and the FDA makes a determination what to

24 list, so clearly it did not list burning and stinging as an

00:57 25 adverse event.

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1 Q. I don't believe that answer was responsive. Let me try  
 2 one more time.  
 3 I'm asking you whether you can tell from the label, if  
 4 you compared the labels of Bronuck® -- I'm sorry, let's stick  
 00:57 5 with the U.S. products. The labels of Xibrom® and Bromday®  
 6 versus the label of Prolensa®, can you know for sure that  
 7 Xibrom® and Bromday® had any greater level of burning and  
 8 stinging reported than was reported in the Prolensa® label?  
 9 A. **The FDA label did not mention burning and stinging, so it**  
 00:57 10 **must be less than 3 percent.**  
 11 Q. And you can't tell me whether or not from the Xibrom® and  
 12 Bromday® label the levels were less than 3 percent, can you?  
 13 A. **Well, we know it was less than 3 percent because -- true,**  
 14 **it could have been higher, it's between 2 and 7 percent, the**  
 00:58 15 **label.**  
 16 Q. So between 2 and 3 -- for example -- let me try to do  
 17 this one a different way.  
 18 The Prolensa® label has reports on 3 to 8 percent --  
 19 withdrawn.  
 00:58 20 The Prolensa® label reports on adverse events in 3 to 8  
 21 percent of patients, right?  
 22 A. **Correct.**  
 23 Q. And the Prolensa® -- I'm sorry.  
 24 And the Xibrom® and Bromday® labels report on 2 to  
 00:58 25 7 percent, right?

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1 the section of the study protocol section on Page 957.  
 2 A. **I'm sorry, what page?**  
 3 Q. 957 of the article and it's PROL 0333516.  
 4 A. **Okay.**  
 01:00 5 Q. Do you see it says, these post-hoc analyses were based on  
 6 Phase III clinical trials. Do you see that?  
 7 A. **Yes.**  
 8 Q. So what that means is that the clinical trials were not  
 9 designed to look for this particular end point, right?  
 01:00 10 A. **Which particular end point are you referring to?**  
 11 Q. The one that's described in the Silverstein paper. If  
 12 you look at the Purpose on the first -- in the abstract on the  
 13 first page.  
 14 A. **So you're asking me whether -- so the two clinical**  
 01:01 15 **trials, multicenter clinical trial were performed, the data**  
 16 **was -- the studies were completed, the data was analyzed. And**  
 17 **you're saying that -- and basically this is looking at the**  
 18 **data and presenting data from those clinical trials.**  
 19 Q. Do you know what a post-hoc analysis is as differentiated  
 01:01 20 from a forwardly designed clinical trial?  
 21 A. **Of course.**  
 22 Q. Okay. So what is that difference?  
 23 A. **So prior to initiating a clinical trial, the study**  
 24 **investigators will develop a clinical protocol with expected**  
 01:01 25 **outcome measures to analyze. Then the study's completed. So**

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1 A. **That's correct, yes.**  
 2 Q. So, for example, there could be burning and stinging with  
 3 Prolensa® in somewhere between 2 to 3 percent of patients,  
 4 right, and it wouldn't have appeared in the adverse reaction  
 00:58 5 section of the Prolensa® label?  
 6 A. **It's theoretically possible.**  
 7 Q. Thank you.  
 8 And you agree, don't you, that there can be adverse  
 9 reactions when using Prolensa® that aren't among those listed  
 00:59 10 in Section 6.1 of the Prolensa® label, right?  
 11 A. **Yes.**  
 12 Q. All right. Now, I want to discuss the Silverstein  
 13 article, JTX146, you talked about that in your direct  
 14 examination.  
 00:59 15 A. **Can you just give me the number again so I can find it?**  
 16 Q. Sure. JTX146.  
 17 This is an article you discussed in your direct  
 18 examination, right?  
 19 A. **Yes.**  
 00:59 20 Q. And did you say this was a result of an FDA clinical  
 21 trial?  
 22 A. **I said that this was basically the two Phase III**  
 23 **double-mass placebo controlled multicenter clinical trials.**  
 24 Q. That's not what this paper is. Isn't it a post-hoc  
 01:00 25 analysis of the data from those trials? I'll direct you to

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1 **that would be the prospective study. But once you have the**  
 2 **data, you can then conduct additional analysis of data to come**  
 3 **up with other findings that are present.**  
 4 Q. All right. So I guess my question, again, and I'll ask  
 01:01 5 it now with that explanation is, the study that was done and  
 6 reported in this paper was not part of the original forwardly  
 7 designed clinical trial for Prolensa®, correct?  
 8 A. **Well, the study was -- this is an FDA -- FDA clinical**  
 9 **trial and it was completed. And then this is a paper looking**  
 01:02 10 **at data from the clinical trial.**  
 11 Q. All right. Let me try to ask my question again because I  
 12 think I had a very particular question, which was, do you  
 13 agree with me that this is a post-hoc analysis and wasn't part  
 14 of the original prospectively designed clinical trial?  
 01:02 15 A. **Let me look at it. Yes, this is a study looking at**  
 16 **additional, for example, additional end points is what you're**  
 17 **asking. So after the study was completed, the investigators**  
 18 **can look at data from the study and write -- an article**  
 19 **written about the data from the study.**  
 01:03 20 Q. So you're agreeing it's a post-hoc analysis, right?  
 21 A. **Yes.**  
 22 Q. Okay. And if you turn to Page 971, the first full  
 23 paragraph on the left-hand side, it says, the clinical results  
 24 are similar to other trials evaluating higher concentrations  
 01:03 25 of bromfenac. Do you see that?

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1 A. Yes.

2 Q. And you agree with that statement as a general statement

3 about the clinical trial results presented here?

4 A. Well, obviously, there's a lot to all the different

01:03 5 clinical trials and so -- well, there's -- the results for

6 inflammation for efficacy were similar, there's obviously some

7 differences in adverse events. So this is just a general

8 statement so it's not quite accurate, but it's in general --

9 provides a general summary but there's definitely differences

01:04 10 in the clinical trial results.

11 Q. Now, I'd like to look at the disclosure section on the

12 bottom of Page 971. I think in your direct testimony you were

13 talking about trials that were sponsored by drug companies,

14 right?

01:04 15 A. Yes.

16 Q. Okay. Now, this wasn't just sponsored by Bausch & Lomb,

17 right? If you look at the disclosure section on the bottom of

18 Page 971, it says that the sponsor -- that's Bausch & Lomb,

19 right?

01:04 20 A. Yes.

21 Q. Participated in the design of the study data collection,

22 data management, data analyses, data interpretation, and

23 preparation, review, and approval of the manuscript, right?

24 A. Yes.

01:04 25 Q. Now, let me move on to your testimony about burning and

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1 stinging experienced with other NSAIDS.

2 You testified that other NSAIDS, non-bromfenac NSAIDS

3 caused burning and stinging, right?

4 A. Yes.

01:05 5 Q. The two examples you gave was Acular® and Voltaren?

6 A. Yes.

7 Q. And you said Acular® had a 40 percent rate and that

8 Voltaren had a 15 percent rate, right?

9 A. Yes.

01:05 10 Q. All right. Now, neither of those products have bromfenac

11 as the active, right?

12 A. That's correct.

13 Q. All right. And as we've seen, the rates of burning and

14 stinging with the bromfenac products were much lower than this

01:05 15 40 percent or 15 percent, right?

16 A. Right.

17 Q. So with Xibrom® we saw 1.4 percent and with Bronuck® way

18 less an 1 percent, right?

19 A. That's correct. And the key there is that we have a lot

01:05 20 of experience with non-steroidals that cause burning and

21 stinging and it really impacted our patient care and surgical

22 outcome so we're very attuned, you know, to burning and

23 stinging with nonsteroidals.

24 Q. So you don't have that issue of 40 percent and

01:06 25 15 percent, you didn't have it with Xibrom® or Bromday®,

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1 correct?

2 A. Correct.

3 Q. Let me turn now to the Flach paper, PTX-270, that you

4 cited in your direct.

01:06 5 A. Yes.

6 Q. You cited this paper when you were talking about CME's,

7 right?

8 A. Correct.

9 Q. But I'd like to look at a different part of the paper.

01:06 10 Can we go to Page 591?

11 There's a Section B on Page 591 and it says "comparison

12 of ketorolac and diclofenac, right, in reducing post-operative

13 inflammation after cataract extraction and intraocular lens

14 implanting. Do you see that?

01:06 15 A. Yes.

16 Q. And you've seen this before, right?

17 A. I have, yes.

18 Q. And so this is a study comparing ketorolac and

19 diclofenac, right, so that's comparing Acular® and Voltaren,

01:07 20 right?

21 A. Yes.

22 Q. Let's go to Page 594. 594 in the first full paragraph

23 says Results. Do you see that?

24 A. Yes.

01:07 25 Q. All right. And you see it was a trial of 120 patients.

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1 Do you see that?

2 A. Yes.

3 Q. And then if you look two paragraphs down, it says, no

4 adverse reactions were reported or observed during the study.

01:07 5 Do you see that?

6 A. Yes.

7 Q. All right. Now, I'd like you to turn to another study

8 that's reported in this paper. Let's go to Page 602.

9 And if you look at the Purpose, and you'll see the goal

01:08 10 of the study is to evaluate the effect of ketorolac in

11 patients with acute clinical CME. Do you see that?

12 A. Yes.

13 Q. All right. And ketorolac was one of the drugs you talked

14 about earlier as having a high rate of burning and stinging,

01:08 15 right?

16 A. Correct.

17 Q. So if you look under materials and methods on Page 602,

18 you'll see it was 350 patients, correct?

19 A. Correct.

01:08 20 Q. And then I'd like to look over to Page 603, there's a

21 section that says Results, right? It's in the middle of the

22 page. Do you see the Results section?

23 A. Yes.

24 Q. And you'll see the Results section goes on for a couple

01:08 25 of pages, and the part I want to ask you about is at the top

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1 of Page 605. And the first full sentence at the top of 605,  
 2 again talking about ketorolac, is both treatment regimes were  
 3 well-tolerated by the patients. There were no complaints  
 4 about burning and stinging following eyedrop instillation. Do  
 01:09 5 you see that?  
 6 A. I see that.  
 7 Q. Let me ask you about another article you talked about,  
 8 that was the Baklayan reference, JTX18, and this paper does  
 9 not report on a clinical trial, right?  
 01:09 10 A. Let me just find the page -- the section, please.  
 11 Q. Sure. Go ahead.  
 12 A. Sorry, what was the number?  
 13 Q. 18.  
 14 A. Okay. I got it.  
 01:10 15 Q. So this Baklayan paper is not a clinical trial, right?  
 16 A. Well, it's a study on -- it's a rabbit model study.  
 17 Q. So that's not a clinical trial, right?  
 18 A. It's not on humans, it's on animals.  
 19 Q. If you look at this paper, there's two authors, right?  
 01:10 20 A. Yes.  
 21 Q. And these are both Bausch & Lomb employees, right?  
 22 A. I don't know that.  
 23 Q. It says right underneath Bausch & Lomb, Irvine,  
 24 California. Do you see that?  
 01:10 25 A. It sounds like it could be, yes.

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1 surface, especially in patients who have undergone cataract  
 2 surgery, so there is a risk with toxicity.  
 3 Q. But there is no difference in adverse events related to  
 4 that between the .09 percent formulation and the .07 percent  
 01:12 5 formulation, right?  
 6 A. There can be differences in adverse events and, you know,  
 7 we don't know, is it the concentration or the pH, but there  
 8 definitely can be a difference in the adverse events.  
 9 Q. But you don't know if there is a difference in the  
 01:13 10 adverse events, right? You say there potentially could be.  
 11 A. I have seen, for example, I had a patient that was on  
 12 Prolensa® that I prescribed and got switched to the .09  
 13 percent, and that patient experienced toxicity from the .09  
 14 percent. It was the generic, but had toxicity with poor  
 01:13 15 vision and stinging of the cornea. So .09 percent can cause  
 16 toxicity which I haven't -- to a different degree than .07  
 17 percent, in my experience.  
 18 Q. You have one anecdotal experience with that happening,  
 19 correct?  
 01:13 20 A. I have a patient that, you know -- just -- it was just --  
 21 I have had other patients as well, but this is a patient that  
 22 was quite, you know, impactful to me because they had gone  
 23 through the first surgery, was seeing very well, they were set  
 24 up for their second surgery, and they got switched to the  
 01:13 25 generic without my authorization, and ended up with, on the

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1 Q. Let me help you out then. Why don't we go to the  
 2 disclosure section on Page 1723 of the article with the Bates  
 3 No. PROL 0080511.  
 4 A. Right.  
 01:11 5 Q. Okay. So in the disclosure section it says George  
 6 Baklayan, an employee of Bausch & Lomb, and Mauricio Munoz was  
 7 an employee at the time the manuscript was developed, right?  
 8 A. Yes, I agree.  
 9 Q. This was not one of those independent studies you talked  
 01:11 10 about in your testimony, right?  
 11 A. This is a study looking, right, looking at an animal  
 12 model, looking at data from two different formulations.  
 13 Q. And this was just kind of top to bottom on internal  
 14 Bausch & Lomb papers, right?  
 01:11 15 A. It appears that way, yes.  
 16 Q. You testified that lower concentration of drug in  
 17 Prolensa® places less drug in contact with the eyes, correct?  
 18 A. Yes.  
 19 Q. And you said that that's good because the active can have  
 01:12 20 toxicity, right?  
 21 A. Yes.  
 22 Q. Okay. But there is no evidence that bromfenac has any  
 23 toxicity related to it that would cause a difference between  
 24 putting .09 percent versus .07 percent in the eye, right?  
 01:12 25 A. We know that bromfenac can cause toxicity to the ocular

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1 generic .09 percent, and experienced toxicity of the cornea  
 2 and blurred vision in both eyes from the .09 percent.  
 3 I have had other patients that I found surprisingly had  
 4 been switched, without my authorization, that had been  
 01:14 5 switched and have also had toxicity, so it's not an isolated  
 6 incident.  
 7 Q. And your policy is not to prescribe generics for that  
 8 reason?  
 9 A. No, I prescribe generics all the time for various  
 01:14 10 situations. I use -- generics can be quite effective. But  
 11 there are differences in certain generic classes, and  
 12 bromfenac 0.09 percent generic has toxicity that I've seen and  
 13 many of my colleagues have reported in seeing. So it's  
 14 different from the brand name.  
 01:14 15 Q. Well, let me ask you this: There are no studies that  
 16 show that a lower concentration of bromfenac in contact with  
 17 the eye is associated with fewer adverse events, right?  
 18 A. Well, there is less burning and stinging in the study  
 19 comparing Xibrom® and Bromday® versus Prolensa®, so yes, there  
 01:14 20 is an FDA clinical trial showing there is less adverse events,  
 21 of certain types, with one versus the other.  
 22 Q. And do you attribute that to the lower concentration of  
 23 Bromfenac? I thought you had attributed that to the pH  
 24 earlier.  
 01:14 25 A. It's probably the -- it's a combination. It's the agent.

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1 I am not a formulator or a chemist so I can't tell you why,  
 2 but we definitely see a difference.  
 3 Q. Okay. Now, I want to -- I want to get to your testimony  
 4 about CME. Okay?  
 01:15 5 You testified that Prolensa® is not indicated for the  
 6 treatment or prevention of CME, right?  
 7 A. Correct.  
 8 Q. All right. Now, so I want to try to understand your  
 9 argument about the connection between Prolensa® and CME, so I  
 01:15 10 think you testified that a certain percentage of patients are  
 11 going to experience burning and stinging when they take a --  
 12 the prior Xibrom® or Bromday® formulation, correct?  
 13 A. Yes.  
 14 Q. And, as we saw, let's take Xibrom® for an example, that  
 01:15 15 was 1.4 percent burning and stinging, right?  
 16 A. Correct.  
 17 Q. All right. So what you're saying is that some fraction  
 18 of that 1.4 percent are going to stop taking their medication  
 19 because of the burning and stinging, right?  
 01:15 20 A. Correct.  
 21 Q. And then some fraction of that fraction of 1.4 percent  
 22 may develop CME, right?  
 23 A. Right. Since I do lots of surgery and, typically, many  
 24 cataract surgeons do 500 to a thousand cataract surgeries a  
 01:16 25 year, those percentage fractions are real patients and they

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1 really add up. So when a patient comes to us and they have  
 2 expectations, and they develop CME and loss of vision, it's a  
 3 horrible situation. You feel horrible as a surgeon. So it  
 4 is -- the fraction that you're calling is a real person, not a  
 01:16 5 fraction.  
 6 Q. Well, it's a fraction of the percentage, right? I'm not  
 7 downplaying anybody's problems after surgery.  
 8 I'm just saying the way you got to your opinion was by  
 9 saying a fraction of the patients who stopped taking their  
 01:16 10 medication because of burning and stinging will, in your  
 11 opinion, develop CME, right?  
 12 A. Right, that's one of the side effects of not taking the  
 13 prescribed NSAID would be -- it helps with inflammation  
 14 overall, and also one of the risks is CME.  
 01:17 15 Q. Okay. And then so we started out with 1.4 percent. We  
 16 have a fraction of those who may stop taking their medication.  
 17 We have a fraction of that fraction who may develop CME. And  
 18 then, of the people who develop CME, there is an even smaller  
 19 fraction where it doesn't resolve on its own, right?  
 01:17 20 A. I disagree with the way you're characterizing things  
 21 because -- a number of things.  
 22 First of all, per Dr. Cykiert's, you know, report, he  
 23 reports that 10 to 15 percent of patients experience CME after  
 24 cataract surgery and, depending on how you classify it, it can  
 01:17 25 be 18 to 20 percent or, you know, if you look at the Kim

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1 article, depending on the study, a good percentage of the  
 2 patients can experience CME after cataract surgery, so it's  
 3 not a super low percent.  
 4 But, more importantly, these are real patients, and  
 01:17 5 when those patients, you know, are doing well at one week and  
 6 all of a sudden at two and three weeks come back and they  
 7 can't see and they can't drive and they can't function, those  
 8 are real things that, as a clinician, as a surgeon, you do not  
 9 want to see happen in your patients.  
 01:18 10 Q. All right. Let's turn to the Kim article because you've  
 11 just mentioned it in your answer and I was going to get there  
 12 anyway.  
 13 A. Of course.  
 14 Q. Okay? This is PTX-281. Let's turn to Page 2160 of that  
 01:18 15 article. And I would like to look at the last sentence on the  
 16 left-hand column. Okay? Are you there?  
 17 A. Yep. Yes.  
 18 Q. And what Kim says, and this is the article you just  
 19 quoted, it says, "because many cases of CME are mild and  
 01:18 20 resolve spontaneously, it remains unknown whether prophylactic  
 21 NSAID treatment improves long-term visual outcomes," right?  
 22 A. Well, he says that here, but then he also writes in the  
 23 very beginning that CME is the most common cause of visual  
 24 loss after cataract surgery. So it's interesting, he's saying  
 01:18 25 two things here at once. If you go to the other section which

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1 I quoted previously, development of CME after cataract surgery  
 2 is the most common cause of visual impairment.  
 3 Q. But we don't know how common that is, right, because many  
 4 cases of CME are mild and resolve spontaneously, right?  
 01:19 5 A. It's a good percentage that, you know, they put them in  
 6 the papers.  
 7 But, again, by resolve spontaneously, they're talking  
 8 about six months or a year that some can resolve  
 9 spontaneously.  
 01:19 10 I know that if I diagnose CME and any of my colleagues  
 11 diagnose CME, we're going to treat that patient. We're not  
 12 going to let it spontaneously -- hope it improves. And then  
 13 even with treatment, some patients will not get improvement in  
 14 vision.  
 01:19 15 Q. I understand that's your opinion, Doctor. But I'm just  
 16 asking you if you agree with the statements in the Kim paper.  
 17 You cited the Kim paper.  
 18 A. Of course. And there are some definite flaws in this  
 19 paper which is without question.  
 01:19 20 Q. Okay. I want to -- let's move on to the Walters paper,  
 21 JTX142. And this is a Phase 3 clinical trial for approval of  
 22 Prolensa®, right?  
 23 A. Yes.  
 24 Q. All right. And this clinical trial compared Prolensa® to  
 01:20 25 placebo, right?

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1 A. Yes.

2 Q. It didn't compare it to any of the other bromfenac

3 formulations, right?

4 A. Correct.

01:20 5 Q. And I would like to again turn to the end of the paper,

6 it's on Page 33 of the paper, and it's PROL 0333862.

7 And you see that the Walters/Goldberg piece and Gow are

8 referred to as consultants to Bausch & Lomb; do you see that?

9 A. Okay, yes.

01:21 10 Q. Okay. And it says, again, that it was sponsored by

11 Bausch & Lomb and that Bausch & Lomb participated in the

12 design of the study, data analyses, interpretation, and

13 supervised the preparation of the manuscript and approved the

14 final version, right?

01:21 15 A. Well, if you could see just below that, if you could just

16 highlight below that, please? This is critical --

17 Q. I'm sorry. You can -- why don't you give your answer?

18 A. Well, I think it's the whole thing. You're asking about

19 a statement that's being made, but you're cutting a paragraph

01:21 20 off with a critical issue, which is that the authors had full

21 access to all study data and take responsibility for the

22 integrity of the data and the accuracy of the data analysis.

23 All authors participated in the interpretation of the study

24 findings and in the drafting --

25 THE COURT: Please slow down.

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1 there is a sentence that says, "Although all of the bromfenac

2 once-daily trials used a similar study design, direct

3 comparisons between the studies cannot be made." Do you see

4 that?

01:23 5 A. If you highlight it just because --

6 Q. Oh, yeah, of course. I'm sorry.

7 A. Perfect. I found it, yes.

8 Q. Do you see that?

9 A. Correct.

01:23 10 Q. And that's referring to direct comparisons between the

11 studies for Bromday® and Prolensa®, right?

12 A. Yes.

13 Q. And if you turn -- if you go to the next page, 31, with

14 Bates Number PROL 0333860, in the left-hand column, first full

01:24 15 paragraph that begins with the sentence, "There are

16 limitations," do you see that? And we will highlight that.

17 A. Perfect.

18 Q. And I would like to go to the second sentence in that

19 paragraph actually that begins with "The current trials."

01:24 20 A. Yes.

21 Q. It says, "The current trials," meaning the Prolensa®

22 trials, "included a smaller sample size than in other clinical

23 trials evaluating higher concentrations of bromfenac, making

24 direct comparisons difficult." Do you see that?

01:24 25 A. Yes.

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1 THE WITNESS: Oh, so sorry.

2 All authors participated in the interpretation of the

3 study findings and in the drafting of critical revision of the

4 manuscript or both.

01:22 5 So these -- this is -- while it's sponsored by Bausch

6 & Lomb, because it's clear the authors here take full

7 responsibility for the -- all of the information contained in

8 this article, all the data, all of their thoughts, and all

9 their comments.

01:22 10 BY MS. HOLLAND:

11 Q. Okay. I just wanted to make clear that when you were

12 testifying in your direct testimony that Bausch & Lomb just

13 sponsored these studies, it went a little further than that.

14 I mean, they actually approved the manuscripts, right?

01:22 15 A. They review the manuscripts and they would approve it as

16 well.

17 Q. All right. So let me point you to another place in the

18 Walters paper then that I wanted to talk about. It's on Page

19 30. It's PROL 0333859.

01:22 20 A. Okay.

21 Q. And the "Discussion" section, the right-hand side, in the

22 right column, I should say, the second paragraph starts with

23 "The results with bromfenac." Do you see that?

24 A. Yes.

01:23 25 Q. And in the middle of that paragraph, several lines down,

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1 Q. And if you look at the bottom of that column, it talks

2 about the safety profile of Prolensa®. Do you see that? The

3 last line on the left-hand column on Page 31. There is a

4 sentence that says, "This advanced formulation of bromfenac"

01:25 5 and then it says it "has a similar efficacy profile as higher

6 concentrations of bromfenac," and then when it compares safety

7 profiles, it compares it to placebo, right?

8 A. Can you just get the next sentence or --

9 Q. Sure. It's also in your book.

01:25 10 A. That is correct. That's how -- that's how that

11 particular sentence reads.

12 Q. So the safety there was compared not to another bromfenac

13 formulation but to placebo.

14 A. That's just -- I mean, obviously, we have the data of

01:25 15 the -- of the active ingredients, but this is just this

16 particular sentence is referring to the placebo.

17 Q. All right. So let's look at the Rajpal reference, 143.

18 And I want to look at the safety profile on Page 927. It's on

19 the right-hand side of the page. And what Rajpal says is

01:26 20 that, "The safety of the bromfenac molecule has remained

21 consistent throughout the various formulations," right?

22 A. Yes.

23 Q. "And adverse events have been minimal in most studies,"

24 right?

01:26 25 A. Yes.

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1 Q. Let's go back to the Baklayan paper for a minute, JTX18.  
 2 We looked at this a few minutes ago, but I want to talk  
 3 about a different part of the paper now.  
 4 I want to go to 18.2, and I want to look at the  
 01:27 5 left-hand column, the last paragraph. This is a sentence --  
 6 five lines up that begins, "The presence of a bromine." Do  
 7 you see that?  
 8 A. Yes.  
 9 Q. It says, "The presence of a bromine in the 4-prime  
 01:27 10 position, as in bromfenac, was found to improve in vitro and  
 11 in vivo potency, absorption across the cornea, and penetration  
 12 into ocular tissues." Do you see that?  
 13 A. Yes.  
 14 Q. And is that something you agree with?  
 01:27 15 A. Well, they're comparing -- this is a study -- this is  
 16 comparing to other nonsteroidals that bromfenac -- you know,  
 17 has a very good overall potency and absorption, but,  
 18 obviously, things can impact those things, but it's comparing  
 19 it to -- I believe here it's comparing it to other  
 01:28 20 nonsteroidals.  
 21 Q. And but you agree, as compared to other nonsteroidals,  
 22 bromfenac had improved in vitro and in vivo potency,  
 23 absorption across the cornea, and penetration into ocular  
 24 tissues?  
 01:28 25 A. Right. That's why the concentration is so much lower of  

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1 bromfenac versus -- like ketorolac is 0.5 percent, versus, you  
 2 know, the much lower percentage in -- of bromfenac of  
 3 Prolensa® -- of, for example, Bromday® and Xibrom®. And  
 4 Prolensa® is just, you know, orders lower in concentration  
 01:28 5 because of the way the molecule works.  
 6 Q. All right. And then you see the sources for that  
 7 statement are -- it says 13 to 15. Those are the end notes,  
 8 right?  
 9 A. Okay.  
 01:28 10 Q. So let's look at the end notes there, and I want to focus  
 11 on End Note 14.  
 12 Do you see the support for that statement is the Gianni  
 13 U.S. Patent 475,034?  
 14 A. Okay.  
 15 Q. Do you agree with that?  
 16 A. I do not know anything about this patent.  
 17 Q. Do you agree that that's the reference that's being used  
 18 to support the proposition about the superiority of bromfenac?  
 19 A. 13 to 15? I don't know the accuracy of that, but it's  
 01:29 20 obviously in the article, but I don't know the accuracy. And  
 21 I'm not familiar at all with this patent.  
 22 Q. All right.  
 23 MS. HOLLAND: I have nothing further, your Honor.  
 24 THE COURT: Okay. Thank you. Is there a redirect?  
 01:29 25 MS. LEBEIS: Your Honor, we'd need the time to take  

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1 the morning break.  
 2 THE COURT: Okay. Let's take a 15-minute break and  
 3 we will resume at 11:15.  
 4 (A recess was taken at 11:03 a.m.)  
 01:48 5 THE DEPUTY CLERK: All rise.  
 6 THE COURT: Okay. Be seated, please. You may resume  
 7 with redirect.  
 8 MS. LEBEIS: Your Honor, I have no redirect.  
 9 (EXAMINATION OF WILLIAM B. TRATTLER BY THE COURT:)  
 01:49 10 THE COURT: Okay. Just a couple of questions.  
 11 Doctor, in evaluating scientific articles, are those  
 12 that are authored by the employees of a company entitled  
 13 generally to less weight or stricter scrutiny than those that  
 14 are independently done by, say, university scientists?  
 01:49 15 THE WITNESS: Absolutely. So, in the review process,  
 16 if there is someone who works for a company, then it's much  
 17 more difficult to get that peer reviewed and published because  
 18 everyone is more suspicious that there is going to be bias  
 19 involved. So it's a more difficult process and more scrutiny  
 01:49 20 to look at it because they know it's someone who has a vested  
 21 interest in that -- whatever is being written for, about.  
 22 THE COURT: Do you serve on editorial boards  
 23 yourself?  
 24 THE WITNESS: Absolutely, yes.  
 01:50 25 THE COURT: And is that the standard you apply when  

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1 you receive the submission of a corporate-sponsored article?  
 2 THE WITNESS: Absolutely. So, you know, they have to  
 3 disclose all those pieces of information, so we have the  
 4 article and we're carefully evaluating the article to look  
 01:50 5 for, you know -- to understand, you know, what's being written  
 6 about and if there is any biasness because, you know, if one  
 7 of the authors or the authors are employees of a company.  
 8 THE COURT: What does it mean, as indicated in at  
 9 least two of these articles, that Bausch & Lomb approved the  
 01:50 10 manuscript? Does that mean that a company can disapprove and  
 11 either censor or cut off the publication?  
 12 THE WITNESS: Not that I'm aware of. I think, to me,  
 13 what that means is that the articles went through the  
 14 peer-reviewed process, and that they're acknowledging that  
 01:51 15 they have reviewed it on their own and they agree with -- or  
 16 approve -- or agree with what's being written, as well. I  
 17 don't think it's that they have -- with what's being written,  
 18 they don't have the ability to censor in any way what's being  
 19 written. It just -- I think that was a statement stating that  
 01:51 20 they reviewed what was written and what's being published and  
 21 agreed with it from a company -- or -- from a company  
 22 standpoint.  
 23 THE COURT: Well, I don't think it used the word  
 24 "agreed." I think it said "approved."  
 01:51 25 THE WITNESS: Right. So that they approved it,  

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1 that -- their company approved the -- or agreed -- for me, the  
 2 word "approved" means agreed with what was written.  
 3 Again, as you saw from the articles, these authors  
 4 had access to the data and wrote these articles and reviewed  
 01:51 5 it and it's their words and information that was used. And I  
 6 think that's just a statement that Bausch & Lomb provided  
 7 financial support and they also, you know -- that at the end  
 8 of the day, they also approved what was being written.  
 9 THE COURT: All right. I had a question about  
 01:52 10 placebos that are used in the study.  
 11 THE WITNESS: Yes.  
 12 THE COURT: I think all the studies used placebos as  
 13 a comparator.  
 14 THE WITNESS: Yes.  
 01:52 15 THE COURT: Is there a standard for what the placebo  
 16 is comprised of in an ocular solution?  
 17 THE WITNESS: Yes. It is the vehicle or everything  
 18 in the study product except for the active agents. It's the  
 19 typical vehicle that's used.  
 01:52 20 THE COURT: Would it be important to know what the pH  
 21 of the placebo is when you're comparing results between the  
 22 formulation and the placebo?  
 23 THE WITNESS: Well, I think that -- in answering the  
 24 question, we're looking at clinical data. We're looking at  
 01:52 25 the clinical results of the clinical trial, including all the  
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1 vehicle, unless the active agent also had pain-suppressing  
 2 properties, and these are nonsteroidal so they also have  
 3 pain-suppressing, you know, properties, so maybe that can help  
 4 too. But in the same ballpark is a good range, as you're  
 01:54 5 pointing out.  
 6 THE COURT: All right. I don't think I have any  
 7 other questions. Thanks.  
 8 Are there any follow-ups, first by the plaintiff?  
 9 MS. LEBEIS: Yes, Your Honor, just one follow-up  
 01:55 10 question.  
 11 (REDIRECT EXAMINATION OF WILLIAM B. TRATTLER BY MS. LEBEIS:)  
 12 Q. Dr. Trattler, once the peer-review process is completed,  
 13 is there any reason to doubt the accuracy of an article?  
 14 A. Well, I think the peer-review process is an important  
 01:55 15 part of the process, but even after it's published, there  
 16 is -- there are situations, you know, papers where other  
 17 people may disagree with the result, so it's -- so, for  
 18 example, the Kim article or things like that, they are not  
 19 always -- they are put into peer review but they are subject  
 01:55 20 to further evaluation further down the road. But the  
 21 peer-review process is very helpful because only certain  
 22 articles will actually be allowed to make it through to  
 23 that -- to that state.  
 24 MS. LEBEIS: Thank you. That's all from plaintiffs.  
 01:55 25 THE COURT: Any follow-up by the defendants?  
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1 adverse events, and there can be reasons that the placebo can  
 2 have a different adverse -- adverse event profile than the  
 3 active ingredient. And pH could be a factor. It could also  
 4 be the lack of the inactive -- lack of the active ingredients.  
 01:53 5 THE COURT: In several of the studies, the adverse  
 6 effects of burning and stinging were pretty much the same for  
 7 the bromfenac solution as for the placebo. Did you notice  
 8 that?  
 9 THE WITNESS: Yes. Sometimes the -- well, the  
 01:53 10 placebo can be higher sometimes -- I can go back and look at  
 11 the particular studies. They were all in close range but  
 12 sometimes, from what I recall from the Silverstein and from  
 13 the Walters papers, is that the adverse events in general were  
 14 higher in the placebo group versus the active ingredient --  
 01:53 15 active group.  
 16 THE COURT: There was one, which was the Donnenfeld  
 17 article, and that was looking at Xibrom®, where the placebo  
 18 was 1.75 percent burning and stinging and the solution being  
 19 studied was only 1.4 percent.  
 01:54 20 THE WITNESS: Yes.  
 21 THE COURT: Would you say that, in theory, that's  
 22 about as low as a result -- you know, the best result that you  
 23 could ever expect, if it's even better than placebo?  
 24 THE WITNESS: Right, so nonsteroidals are -- well,  
 01:54 25 yes, we would like to have the active agent be the same as the  
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1 MS. HOLLAND: No, Your Honor.  
 2 THE COURT: Okay. Then thank you very much, Doctor.  
 3 THE WITNESS: Thank you very much as well.  
 4 THE COURT: You may step down.  
 01:56 5 (The witness left the stand.)  
 6 MS. LEBEIS: Your Honor, that's our last live witness  
 7 for plaintiffs.  
 8 THE COURT: All right. And so, other than deposition  
 9 excerpts, does the plaintiff rest?  
 01:56 10 MS. LEBEIS: Other than keeping it open for the  
 11 designated deposition excerpts and also the associated  
 12 exhibits, yes.  
 13 THE COURT: Okay. Is this a good time to return to  
 14 the exhibits?  
 01:56 15 MS. HOLLAND: Your Honor, I was going to suggest that  
 16 perhaps we do it at the end of the day because some of the  
 17 witnesses I believe have timing issues, so maybe they should  
 18 get on and off the stand as quickly as we can.  
 19 THE COURT: Okay. Is that acceptable?  
 01:56 20 MS. LEBEIS: Yes, that's fine, your Honor.  
 21 THE COURT: Okay. Thank you.  
 22 MS. LEBEIS: Thank you.  
 23 All right. You may proceed.  
 24 MR. MARGOLIS: Thank you, your Honor. Defendants  
 01:57 25 call Dr. Clayton Heathcock.  
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1 THE COURT: Okay, Dr. Heathcock, please come to the  
2 witness stand.  
3 MR. MARGOLIS: Your Honor, may I have permission to  
4 approach and pass out binders?  
01:57 5 THE COURT: Yes, of course.  
6 THE DEPUTY CLERK: Sir, can you please place your  
7 left hand on the Bible and raise your right hand.  
8 (CLAYTON H. HEATHCOCK, HAVING BEEN DULY SWORN/AFFIRMED,  
9 TESTIFIED AS FOLLOWS:)  
01:57 10 THE WITNESS: I do.  
11 THE DEPUTY CLERK: Can you please state your name,  
12 sir, and I need you to spell your first and last name, please.  
13 THE WITNESS: Clayton Heathcock, C-L-A-Y-T-O-N,  
14 H-E-A-T-H-C-O-C-K.  
01:57 15 THE DEPUTY CLERK: P-H? Sorry.  
16 THE WITNESS: H-E-A-T-H-C-O-C-K.  
17 THE DEPUTY CLERK: Thank you, sir. You can be seated  
18 and please speak into the microphone.  
19 (DIRECT EXAMINATION OF CLAYTON H. HEATHCOCK BY MR. MARGOLIS:)  
01:58 20 Q. Good morning, Dr. Heathcock.  
21 A. Good morning.  
22 Q. Where do you live?  
23 A. I live in Martinez, California.  
24 Q. And are you employed?  
01:58 25 A. I'm retired.

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1 Q. And prior to retiring, what did you do?  
2 A. Well, I was a professor at the University of California.  
3 I retired several times actually. I retired as professor in  
4 2004, when my pension reached its maximum entitlement.  
01:58 5 I was a dean at the time, and there was not another  
6 person in line to take over, so I continued to be employed as  
7 a dean for another year. In 2005, I retired as dean.  
8 And at that point I was recalled by the university to  
9 be chief scientist for an interdisciplinary research institute  
01:59 10 that had just been created, and I occupied that position for  
11 three more years, and I finally went off the payroll in 2008.  
12 And now I'm Emeritus Professor, and I still occupy --  
13 have an office, and which I don't go to very often, but I  
14 operate a seminar, a regular seminar --  
01:59 15 THE COURT: Can you please pull the mic toward you.  
16 THE WITNESS: Okay. What did you not hear?  
17 A regular seminar that I created about ten years ago,  
18 and I still do that on a volunteer basis.  
19 BY MR. MARGOLIS:  
01:59 20 Q. And so now you're an Emeritus Professor at the University  
21 of California at Berkeley; is that correct?  
22 A. Yes.  
23 Q. And in what fields do you specialize?  
24 A. I'm a chemist. My specialty within the field of  
01:59 25 chemistry is organic chemistry.

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1 Q. Okay. And during your professional career, what were  
2 your responsibilities as a professor?  
3 A. Well, I taught classes. At a place like Berkeley, we  
4 have two kinds of teaching responsibility. One is classroom  
02:00 5 teaching in which we have a class of students that we meet  
6 with several times a week, and I did different kinds of  
7 courses during my 40 years as a professor. Usually, it would  
8 be undergraduate, introductory organic chemistry class.  
9 Sometimes it was advanced laboratory practice in organic  
02:00 10 chemistry for undergraduates. Other times it would be  
11 advanced chemistry course for graduate students.  
12 But the main teaching responsibility was a one-on-one  
13 mentor/apprentice relationship with students who were working,  
14 doing research and working towards a doctorate. I would have  
02:00 15 at any given time between 10 and maybe as many as 16 or 18  
16 students who worked full-time on research projects that I  
17 designed and met with them on a regular basis to evaluate and  
18 suggest new lines of research and so forth. These students  
19 would occupy laboratories and offices near my office, and we  
02:01 20 met on a regular basis over a period of about four years until  
21 they received their Ph.D.  
22 I also had regular teaching responsibilities for  
23 postdocs; these were student who already had a doctorate and  
24 had come to Berkeley to get further research experience.  
02:01 25 And so by far, the bulk of my teaching was this

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1 personal mentor/apprentice relationship with these graduate  
2 students and postdocs.  
3 Q. And over the course of your career as a professor,  
4 approximately how many doctoral students did you train?  
02:01 5 A. About 80 doctoral students, and I had about 50  
6 postdoctoral students over my career.  
7 Q. And during your active research career, what subjects did  
8 you focus on?  
9 A. My -- the main focus of my interest was synthetic organic  
02:02 10 chemistry. Synthesis is making complicated compounds from  
11 simple things that you can buy. It's the main tool, the first  
12 tool in drug discovery, and almost all of my doctoral students  
13 eventually left to take jobs in drug companies or biotech  
14 companies as medicinal chemists or process chemists.  
02:02 15 I also studied a range of other kinds of -- or had  
16 projects that ranged from other -- in other areas of organic  
17 chemistry. Medicinal chemistry is a subfield of organic  
18 chemistry. And most of my research, as a matter of fact, was  
19 funded by the National Institutes of Health, and it was  
02:02 20 research directed at synthesis of complex compounds that were  
21 already known to have some interesting biological activity and  
22 could possibly have been developed into drugs.  
23 I also had a good deal of research on creation of new  
24 synthetic methods, particularly for the control of the  
02:03 25 three-dimensional shape of molecules that were being made.

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1 Q. And, in addition to your positions as a professor,  
2 department chairman, and dean, have you held any other  
3 positions at the University of California at Berkeley?

02:03 4 A. Yes. Well, as I mentioned, after my second retirement, I  
5 was recalled as chief scientist for the -- for QB3-Berkeley,  
6 it has an interdisciplinary organization. It's part of the  
7 California Institute for Quantitative Biosciences. We call it  
8 QB3. The "QB" stands for Quantitative Biosciences. "3"  
9 stands for the fact that three of the campuses of the  
02:03 10 University of California are involved: Berkeley, San  
11 Francisco, and Santa Cruz.

12 And the purpose of QB3, when it was first established,  
13 was to bring together in a way that could result in  
14 collaborative research the quantitative scientists, mostly  
02:04 15 from Berkeley and Santa Cruz -- physicists, engineers and  
16 chemists, with the biologists and clinical practitioners at  
17 San Francisco and Berkeley to solve problems of human health  
18 that were more amenable to group efforts than to individual  
19 efforts.

02:04 20 Q. And what specifically were your responsibilities as chief  
21 scientist at QB3?

22 A. Well, I was brought on board as an experienced  
23 administrator to help get it up and running. I set up all of  
24 the core facilities at the Berkeley -- in the Berkeley branch,  
02:04 25 which was a new building, which was built about the time I

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1 took the job. And the core facilities are analytical  
2 laboratories, mass spectrometry, nuclear magnetic resonance,  
3 and things that the scientists used for analysis in their  
4 research.

02:05 5 I also established this seminar, which is a regular  
6 meeting of all of the -- of professors who are affiliated with  
7 QB3, where we meet together and people share the recent  
8 results from their laboratory. And these regular meetings  
9 have resulted in a number of productive collaborations  
02:05 10 between, for example, engineers and clinicians from -- from  
11 San Francisco even.

12 Q. Are you still involved with QB3?

13 A. Yes, I still operate the seminars on a volunteer basis.

02:05 14 Q. Would you please turn to DTX-440 in your binder and  
15 identify that exhibit?

16 A. Okay, that's my curriculum vitae.

17 Q. Okay. And did you prepare your curriculum vitae?

18 A. Yes, I did.

02:06 19 Q. And does it accurately reflect your education and  
20 experience?

21 A. Yes, it does.

22 Q. Would you briefly describe your educational background?

23 A. Yes.

02:06 24 I grew up in San Antonio, Texas, where I had my  
25 secondary education.

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1 I attended college in a small college in West Texas,  
2 Abilene Christian College, received a Bachelor of Science  
3 Degree there in Chemistry in 1958.

02:06 4 I worked for a couple of years in industry, and then  
5 entered graduate training at the University of Colorado in  
6 Boulder, received a Doctorate in Organic Chemistry from the  
7 University of Colorado in 1963.

8 And then I had one more year of study at Columbia  
9 University as a postdoctoral associate, 1963 to 1964.

02:06 10 Q. Okay. And what did you do after completing your  
11 postdoctoral studies?

12 A. I -- while I was at Columbia, I received and accepted an  
13 offer as assistant professor in the Chemistry Department at  
14 the University of California at Berkeley, and I started my  
02:07 15 work there in 1964, in the fall.

16 Q. And over the course of your career, have you followed the  
17 literature related to medicinal compounds and their structural  
18 properties?

19 A. Yes, I have.

02:07 20 Q. And approximately what percentage of your research has  
21 related to medicinal compounds?

22 A. Well, a lot of it, in the sense that my interest is in  
23 developing the methods and concepts for synthesizing  
24 complicated compounds. Mostly, my targets were natural  
02:07 25 products that had been discovered to have interesting,

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1 promising biological activity, and the bulk of my work, maybe  
2 two-thirds to three-fourths was funded by research grants from  
3 the National Institutes of Health, the Cancer Institute, the  
4 Allergies and Infectious Diseases Institute, or the Institute  
02:07 5 For General Medical Studies. So, in that -- because of that  
6 connection, I had to keep up with the, you know, potential  
7 drugs, what were needed, what was interesting, and so forth.

8 Q. Okay. Have you had any experience consulting in the  
9 pharmaceutical industry over the course of your career?

02:08 10 A. Yes. I have had three long-term consultancies. One that  
11 lasted for ten years with Merck in the '60s and '70s. I was  
12 for 11 years a member of the Abbott Laboratory Scientific  
13 Advisory Committee in the '80s, and then for -- I think nine  
14 years recently, I was a member of the Scientific Advisory  
02:08 15 Board for Flexicon Incorporated, a small drug discovery  
16 company in California.

17 Q. And can you briefly describe the nature of your  
18 consulting work?

19 A. As a consultant, I would go to the laboratory; for  
02:08 20 example, when I was a consultant at Merck, I would go to  
21 Rahway or West Point two or three times a year, spend one or  
22 two days on each visit, having meetings with the various  
23 medicinal chemists, and they would then share with me what  
24 they had accomplished since the last time we met. I would  
02:09 25 provide advice on often it was synthetic problems they were

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1 having. Sometimes I would provide suggestions on new  
 2 compounds they might make, based on structure activity  
 3 relationships that they described to me.  
 4 The consultancy with Abbott was a little different. I  
 02:09 5 was a member of a committee that consisted of eight senior  
 6 scientists. I was the chemist. The others were MDs and  
 7 various specialties. And we would meet for three days twice a  
 8 year to hear reports from the group leaders about the projects  
 9 that had been -- that they were working on at Abbott, and then  
 02:09 10 we would have a follow-up meeting with the management, CEO and  
 11 president, for example, to give kind of a report card and make  
 12 suggestions on new things they could be doing.  
 13 Q. And as a consultant, were you involved in the development  
 14 of pharmaceutical formulations?  
 02:09 15 A. No. Formulations would be something that would come  
 16 rather late in the drug discovery process. My involvement  
 17 would be in the drug discovery area. The finding of new  
 18 activities and selectivities, helping to solve pharmacokinetic  
 19 problems, bioavailability, things of that sort. The  
 02:10 20 formulation would be something that would be well downstream  
 21 from where I was involved.  
 22 Q. Have you given any talks in the pharmaceutical industry?  
 23 A. Yes. It's common for companies to invite professors like  
 24 me because they want to know what we're doing before it gets  
 02:10 25 to the -- to the journals, and they also want to develop

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1 were published in medicinal subjects.  
 2 Q. So do any of those papers relate to medicinal chemistry?  
 3 A. Well, yes, as I say, the bulk of the work was funded by  
 4 the National Institutes of Health, and so possible medicinal  
 02:12 5 uses would be mentioned in a large number of my articles.  
 6 Two, I think, were published in the *Journal of Medicinal*  
 7 *Chemistry*. A number of others were published in the *Journal*  
 8 *of Organic and the American Chemical Society journal*, but  
 9 included biological data.  
 02:13 10 Q. Have you authored any textbooks?  
 11 A. I'm coauthor of a textbook named, *The Introduction to*  
 12 *Organic Chemistry*. It was published first in the mid-1970s.  
 13 It was in print for about 30 years. It was translated into a  
 14 number of different foreign languages as well.  
 02:13 15 Q. Have you had a role on any journals during the course of  
 16 your career?  
 17 A. I served as a member of the advisory boards for a number  
 18 of journals, and I was editor-in-chief for the *Journal of*  
 19 *Organic Chemistry* for 11 years.  
 02:13 20 Q. Have you won any awards in connection with your work?  
 21 A. Yes, and they are listed on the front page of my  
 22 curriculum vitae down here at the bottom.  
 23 Q. Can you identify a few of your more significant awards?  
 24 A. Well, yes. Probably the one that means a lot to me was  
 02:13 25 my first major American Chemical Society award. That was the

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1 relationship to hire our students. And so I gave dozens of  
 2 talks at all of the major pharmaceutical companies in the  
 3 United States and many overseas.  
 4 Q. During the course of your career, have you been involved  
 02:10 5 in any professional organizations?  
 6 A. I was a member -- I've been member of the American  
 7 Chemical Society for over 50 years. I got my 50-year pin a  
 8 few years ago. I was elected in 2009 to the initial class of  
 9 American Chemical Society Fellows. I served as the -- on the  
 02:11 10 executive committee of the organic chemistry division and  
 11 chair of that organization, and I've been a long-term member  
 12 of the national academy -- of the American Association for  
 13 Arts and -- for the Advancement of Science, and I shared the  
 14 chemistry division of that organization for one year.  
 02:11 15 I also served for four years as a member of the  
 16 National Institute's of Health medicinal chemistry study  
 17 section and was chair of that organization as well.  
 18 Q. Have you published in the field of chemistry?  
 19 A. About 275 peer-reviewed and book chapters, a couple of  
 02:12 20 patents.  
 21 Q. Do any of those papers relate to organic chemistry?  
 22 A. Yeah, they're basically all related to organic chemistry,  
 23 and mostly to synthesis, some to stereochemical control.  
 24 There's a few even theoretical papers that have to do with  
 02:12 25 computational things, and a few papers -- some of the papers

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1 award for creative work in organic synthesis. I'm fond of the  
 2 Prelog medal, which was an award from the --  
 3 THE COURT: It's spelled P-R-E-L-O-G.  
 4 MR. MARGOLIS: Thank you, Your Honor.  
 5 THE WITNESS: Thank you, Your Honor.  
 6 It was awarded by the Swiss Federal Institute of  
 7 Technology. And of course, I guess my highest honor was to be  
 8 elected to the National Academy of Sciences.  
 9 MR. MARGOLIS: Defendants offer Dr. Heathcock as an  
 02:14 10 expert in chemistry.  
 11 THE COURT: Any objection?  
 12 MR. DINER: No, Your Honor.  
 13 THE COURT: All right. The Court will permit the  
 14 witness to offer opinions in the field of chemistry.  
 02:14 15 MR. MARGOLIS: Thank you, Your Honor.  
 16 BY MR. MARGOLIS:  
 17 Q. Dr. Heathcock, are you aware that Dr. Davies testified in  
 18 this case last week?  
 19 A. Yes, Yes, I am.  
 02:14 20 Q. And have you had the opportunity to review the transcript  
 21 of Dr. Davies's testimony?  
 22 A. Yes, I have.  
 23 Q. And do you understand that Dr. Davies testified that the  
 24 person of ordinary skill in the art would not have expected  
 02:15 25 bromfenac to form an insoluble complex with benzalkonium

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1 chloride?  
 2 A. Yes.  
 3 Q. And do you agree with Dr. Davies that the person of  
 4 ordinary skill in the art would not have expected bromfenac to  
 02:15 5 form an insoluble complex with benzalkonium chloride?  
 6 A. No, I don't agree with that opinion.  
 7 Q. Why not?  
 8 A. Well, it -- it seems to me that by 2003, there was a  
 9 widely-held belief in the community that formulations that  
 02:15 10 contained a particular preservative, benzalkonium chloride,  
 11 and also an NSAID that has a carboxylic acid group were  
 12 subject to forming these insoluble complexes that resulted in  
 13 cloudy or turbid mixtures.  
 14 And because bromfenac is a -- is another NSAID that has  
 02:16 15 also a carboxylic acid group, I believe that a person of  
 16 ordinary skill would have a reasonable expectation that that  
 17 problem might extend to bromfenac as well and that it would  
 18 also form soluble -- it would be likely to form soluble --  
 19 insoluble complexes that would result in turbid solutions.  
 02:16 20 Q. Have you prepared a slide showing what a carboxylic acid  
 21 group is?  
 22 A. Yes.  
 23 Q. Can we pull up DDX5-2, please. Thank you.  
 24 Can you explain what a carboxylic acid group is?  
 02:16 25 A. This drawing is just a generic representation of an  
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1 there. This one is nowhere in there, and as a general matter,  
 2 this kind of information is not in there, and so essentially,  
 3 he would be offering new opinions.  
 4 What he has in there -- well, it's actually going to be  
 02:18 5 on the next slide. But what he has in there is the potential  
 6 reaction that could take place between a carboxylic acid group  
 7 and benzalkonium chloride, but this general schematic here  
 8 where they are illustrating at a more -- at a different level  
 9 is not actually depicted in his -- in any of the schemes of  
 02:18 10 his expert report, or has not provided any opinions on that  
 11 scheme in his expert report.  
 12 MR. MARGOLIS: Your Honor, this is basic fundamental  
 13 underlying chemistry that's referred to throughout Dr.  
 14 Heathcock's report. For example, footnote 7 in paragraph 54,  
 02:19 15 he describes in the last sentence, a pH greater than 7, more  
 16 than 99.9 percent of the bromfenac and these other NSAIDs is  
 17 present in solutions in anionic form. This is explaining  
 18 visually to aid in his explanation to the Court how that  
 19 ionization occurs.  
 02:19 20 THE COURT: I'll permit it as a visual aid. It seems  
 21 to be within the scope of his testimony that's already been  
 22 put into the report, but on a more basic level. And that's a  
 23 function of a visual aid. It's not evidence, but if it helps  
 24 him to explain, I'll permit it.  
 02:19 25 MR. MARGOLIS: Thank you, Your Honor.  
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1 organic chemical structure in which a part of it in green is a  
 2 particular arrangement of atoms. There's a carbon that's  
 3 doubly bonded to an oxygen and singly bonded to an oxygen that  
 4 also has a hydrogen attached to it. That grouping is called a  
 02:17 5 carboxyl group. And that kind of compound, and I have the Ar  
 6 which is a generic part of the structure that stands for  
 7 aromatic because these NSAIDs that we will be talking about  
 8 have aromatic -- different aromatic groups attached at that  
 9 position.  
 02:17 10 They all have this kind of structure and that is called  
 11 in organic chemistry a functional group. A functional group  
 12 is a particular group of atoms that can occur in a lot of  
 13 different molecules with other structural features, but that  
 14 functional group is what determines the reaction personality  
 02:17 15 of compounds that have it. And so that's a carboxyl group.  
 16 Q. And have you prepared a slide showing the types of  
 17 reactions that carboxylic acid groups undergo?  
 18 A. We're showing one reaction that they undergo and that's  
 19 on this slide.  
 02:17 20 MR. DINER: Your Honor, at this point we would like  
 21 to lodge an objection. We spoke with defendants last night.  
 22 We have an objection as to this slide, that it's beyond the  
 23 scope of his expert report.  
 24 This depiction of this scheme here appears nowhere in  
 02:18 25 his report. He has other schemes of reactions that are in  
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1 BY MR. MARGOLIS:  
 2 Q. So just to go back, Dr. Heathcock, would you please  
 3 explain the types of reactions that carboxylic acid groups can  
 4 undergo?  
 02:19 5 A. Well, yes. Functional groups have typically associated  
 6 with them systematic reaction -- a characteristic reaction  
 7 profile. The simplest reaction of a carboxylic acid is to  
 8 simply lose the hydrogen from the OH. Now, it's shown here  
 9 with the hydrogen and the oxygen connected together by a line.  
 02:20 10 That line is a bond, and all of the lines in these drawings  
 11 that we use represent bonds, and when there's a single line,  
 12 that means there's two electrons in that bond.  
 13 And carboxylic acid has this property that the hydrogen  
 14 is not -- is easily lost, and when it's lost it can be  
 02:20 15 transferred to another oxygen, for example, to a water  
 16 molecule, that would be the solvent, and that leaves behind a  
 17 carboxylate ion, the anion. The carboxylate ion is what's  
 18 left behind when the hydrogen plus goes away. Because the  
 19 electrons that were holding the hydrogen to the oxygen both  
 02:21 20 stay with the oxygen, it has a negative charge.  
 21 When a species has a charge in chemistry, it's called  
 22 an ion. If it has a negative charge like this, it's called an  
 23 anion, and this anion comes from a carboxylic acid, so it's  
 24 called a carboxylate ion.  
 02:21 25 So this top reaction just illustrates that carboxylic  
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1 acid spontaneously lose a hydrogen ion to give a carboxylate  
2 ion. And at physiologic pH, the pH of, you know, of 7 or  
3 around 7, the vast majority of this carb -- of any carboxylic  
4 acid would be present as the carboxylate ion.

02:21 5 Q. And you've identified H<sub>2</sub>O on your slide. Does that  
6 indicate that this is a type of reaction that takes place in  
7 water?

8 A. Yes. This would be -- this would be a reaction that --  
9 in water. And this reaction, I'm showing, is actually a  
02:22 10 transfer of the H-plus from the carboxylic acid to one of the  
11 water oxygens.

12 Q. And once the carboxylate ion or the anion is formed, what  
13 types of reactions can that anion undergo in water?

14 A. Well -- sorry. If there are, in the solution, other  
02:22 15 ions, for example, a sodium ion, which is now a positively  
16 charged ion, so it's called a cation. If there are cations in  
17 solution, then it's possible for the anion and the cation to  
18 form a kind of a loose association that is sometimes referred  
19 to as an ion pair.

02:22 20 That ion pair is not bonded to -- the sodium and the  
21 oxygen in the ion pair are not bonded like the hydrogen and  
22 the oxygen are in the carboxylic acid itself. They're  
23 attracted to each other by an electrostatic attraction.  
24 Electrostatic means they just -- that a positive and a  
02:23 25 negative kind of have an attraction for each other, kind of

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1 like a boy and a girl. You know, they just kind of hang  
2 around each other, but they're not really permanently bonded.

3 It could also be thought of as like two magnets, the  
4 positive end of one magnet and the negative end of the other  
02:23 5 magnet, kind of are attracted to each other, but they're not  
6 firmly bonded by any material.

7 So that's an ion pair, and ion pairs are -- are, you  
8 know, they are very dynamic. They are separating and forming  
9 and separating and forming quite rapidly.

02:23 10 Q. And is the formation of an ion pair a reaction that any  
11 NSAID having a carboxylic acid group will undergo?

12 A. Well, any ion that -- any carboxylate ion that's in  
13 solution with cations will form ion pairs to some degree.  
14 Including NSAID carboxylate ions.

02:24 15 Q. And have you prepared a slide that shows what happens  
16 when an NSAID having a carboxylic acid group pairs with a  
17 positive ion?

18 A. Yes, that's just a more -- excuse me -- specific version  
19 of what was on this slide. At the top I'm showing again the  
02:24 20 sodium cation and the carboxylate ion coming closer together  
21 so that they form an ion pair.

22 Something like this, when sodium is involved, is  
23 generally going to be quite water soluble because the -- the  
24 charges are accessible to the water molecules that are forming  
02:24 25 the bulk of the solvent. They can easily get around there,

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1 and so this is a relatively happy situation, solvent -- a  
2 soluble ion pair.

3 Some ions are -- some cations, like this one that's  
4 shown on the bottom of the slide, have a positive charge like  
02:25 5 the sodium ion, but also there's a large organic part attached  
6 to that positive charge, and the organic part of any molecule  
7 is less happy being in water solution. It's what we call  
8 hydrophobic. These large hydrocarbon parts don't like water  
9 very much.

02:25 10 And so when this cation comes close to the carboxylate  
11 ion to form an ion pair, that is now quite a different kind of  
12 ion pair than the sodium carboxylate ion pair because the  
13 cation part has this large hydrocarbon surface. And so this  
14 would generally not be as soluble in water because of the fact  
02:25 15 that the hydrocarbon part is not really liking to be in water.

16 And that's why some of these benzalkonium carboxylates  
17 that were -- that were forming insoluble salts do separate  
18 from solution.

19 Q. And is the large cation that you've depicted on the  
02:26 20 slide, is that a benzalkonium cation?

21 A. Yeah, that's one of the benzalkonium cations.

22 Q. And you used the term "hydrophobic" to refer to the  
23 benzalkonium cation. What does hydrophobic mean?

24 A. Hydrophobic means hates water, really. Hydro is water,  
02:26 25 phobia is hates. So something that's hydrophobic does not

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1 like to be in water.

2 Q. And the bottom right structure that you've depicted as an  
3 insoluble ion pair, is that what you also refer to as an  
4 insoluble complex?

02:26 5 A. Yeah. That would be a complex. The complex is a -- sort  
6 of a general term that refers to an association of two things,  
7 two or more things.

8 Q. And what do you mean in this case when you're using the  
9 term "insoluble complex"?

02:27 10 A. Well, solubility is a gradual term. Anything can be  
11 soluble. You know, things can be soluble at one concentration  
12 but not soluble in another.

13 So if you have water like this bottle of water and I  
14 add a little bit of something and shake it up, let's say I add  
02:27 15 a little bit of sugar and shake it up, it will go clear.

16 That's because all the sugar is soluble. If I keep adding  
17 sugar, more and more and more, at some point it's not all  
18 going to go into solution, and so at that point you can say is  
19 it insoluble? Well, it's soluble at some concentrations and  
02:27 20 not soluble at other concentrations, not completely soluble at  
21 other concentrations.

22 So because of that sort of gradation, my definition for  
23 the purpose of this testimony is that when you talk about --  
24 when I talk about an insoluble ion pair, I'm talking about at  
02:28 25 the concentrations that are relevant for these ophthalmic

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1 formulations.

2 Q. And when an insoluble complex forms in such a formulation

3 in solution, what happens to that solution visually?

4 A. Well, if you -- if you add something to this bottle of

02:28 5 water that isn't sufficiently soluble, then it will look

6 cloudy. You can have little particles floating around. They

7 can be very tiny particles, it can be turbid. The particles

8 could be big enough that if you let the bottle sit, they

9 actually will settle out to the bottom of the bottle. So that

02:28 10 when something is insoluble, you will get this behavior that

11 it's turbid, cloudy, or you see actual precipitate falling to

12 the bottom.

13 Q. Are there any prior art references that indicate that an

14 insoluble complex would be expected to form between bromfenac

02:28 15 and benzalkonium chloride?

16 A. Yes, there are quite a lot of literature in 2003 that

17 indicated that -- that benzalkonium chloride was a bad actor

18 in that respect, that it was forming insoluble complexes and

19 that bromfenac could be expected to be the same way.

02:29 20 Q. And have you prepared a slide identifying some of these

21 references?

22 A. Yes. On this slide I've listed four patents and

23 applications. One at the top is international patent

24 application WO 9,415,597. That's JTX207, and I'll refer to

02:29 25 that as WO '597 application.

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1 Q. And what is an anionic drug?

2 A. Well, an anionic drug would be a drug that exists in an

3 anionic form. For example, the -- the carboxylate ions that I

4 showed in the general slide a couple of minutes ago would be

02:32 5 anionic, and the NSAIDs that contained carboxylic acid groups

6 would exist at physiological pH in those anionic forms, and

7 those would be examples of anionic drugs.

8 Q. Okay. And does WO '597 explain why anionic drugs form

9 insoluble complexes with benzalkonium chloride?

02:32 10 A. Yes. If you look at the next paragraph, the next two

11 paragraphs on this same page, at first, it says what I showed

12 you on that slide that was disputed, that at negative -- at

13 physiological pH, the acidic drug exists as an anion, that it

14 carries a negative charge, and that all acidic drugs will

02:32 15 carry a negative charge at a pH above their PKA. So that

16 means that at physiologic pHs they will be 99 point something

17 percent negative or in an anionic form.

18 And then it goes on to explain in the next paragraph

19 that because benzalkonium chloride is a positively charged

02:33 20 species, ion pairs can be formed with these negatively-charged

21 drug compounds, and this leads to an insoluble ion pair that

22 causes the drug to precipitate from solution.

23 Q. And just to be clear, is bromfenac an anionic drug?

24 A. Yeah -- well, bromfenac would be anionic at physiological

02:33 25 pH. Bromfenac is an NSAID that has a carboxylic acid group,

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1 The second one is a U.S. patent, 5,558,876. That's

2 JTX201. I'll refer to that as the '876 patent, and then

3 another U.S. patent, 5504113, that's JTX158, and I'll call

4 that the '113 patent. And then finally, a European patent

02:30 5 application, 0 306 984, that's JTX209, and I'll refer to that

6 as the EP '984 application.

7 Q. And this was Slide DDX5-5, correct?

8 A. Yeah.

9 Q. Let's take those one at a time. If you could please turn

02:30 10 to JTX207 in your binder and identify that document. 207.

11 A. Okay. That's the -- that's the '597 application, the

12 international application, published in 1994.

13 Q. And generally speaking, what's the subject matter to

14 which WO '597 is directed?

02:30 15 A. This deals with ophthalmic formulations that contain

16 acidic NSAID.

17 Q. Okay. And what, if anything, does WO '597 teach about

18 complexation?

19 A. If you look on Page 2 of this, at the top. Yeah, if you

02:31 20 look at the -- in the first paragraph on Page 2 of this

21 patent, you see that it is taught here that benzalkonium

22 chloride, which is a quaternary compound, has been widely used

23 in ophthalmic solutions, but it is considered to be

24 incompatible with anionic drugs because it forms insoluble

02:31 25 compounds that cause the solutions to turn cloudy.

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1 and it would be almost completely ionized at pH 7.

2 Q. And at the pHs of ophthalmic formulations relevant to

3 this case, would bromfenac be an anionic drug?

4 A. Yes. I think I was hearing pHs of 7 and-a-half or so in

02:33 5 testimony earlier today, so it would be, you know, 99.9

6 percent ionized under those conditions.

7 Q. And is bromfenac also considered an acidic drug?

8 A. Yes.

9 Q. So would WO '597 suggest anything to the person of

02:34 10 ordinary skill in the art about bromfenac?

11 A. Well, because this is -- this is a general teaching, and

12 bromfenac is a compound that has this -- this property, this

13 structure, it's -- it's a carboxylic acid, and I think this

14 would give a person of ordinary skill good reason to believe

02:34 15 that bromfenac will form an insoluble salt that will cause

16 cloudiness when used with benzalkonium chloride.

17 Q. And does the next slide, I believe it's DDX5-6, does that

18 explain how bromfenac could interact with benzalkonium

19 chloride to form an insoluble complex?

02:34 20 A. Yeah. This is essentially a more explicit description of

21 what I had in the general sense a few slides back. Here is

22 bromfenac in the upper left of this slide, and you can see now

23 that it's aryl is given in detail. It's a relatively complex

24 group of atoms.

02:35 25 The first part of it is an aromatic ring. But here is

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1 the acetic acid side chain, that's the carboxyl group, and  
2 it's shown here losing an associating or ionizing -- losing a  
3 hydrogen to give the bromfenac anion on the upper right, and  
4 then I've just simply shown that bromfenac anion forming an  
02:35 5 ion pair with this benzalkonium cation, and this is the same  
6 kind of ion pair I showed in a more general sense previously.  
7 And I think a person of ordinary skill would have a  
8 reasonable expectation that this ion pair is going to behave  
9 like the other BAC cation, NSAID ion pairs, and be insoluble  
02:35 10 at the relevant ophthalmic formulation concentration.  
11 Q. And again, does the H<sub>2</sub>O you've indicated on the slide  
12 suggest that this is happening in an aqueous solution?  
13 A. Yes.  
14 Q. Could you now turn to JTX158 in your binder and identify  
02:36 15 that document?  
16 A. Okay. This is the '113 patent and it was published in  
17 1996, and it also is a patent that deals with ophthalmic  
18 formulations that contain acidic -- carboxylic acid containing  
19 NSAID.  
02:36 20 Q. And what does the '113 patent teach about complexation?  
21 A. If you go to column 1, and it's in about -- okay. It's  
22 right down here at about the middle of the page, it teaches  
23 that it is well-known that benzalkonium chloride is considered  
24 to be incompatible with anionic drugs because it forms  
02:37 25 insoluble complexes that cause the solutions to be cloudy, and  
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1 it mentions that these insoluble complexes precipitate from  
2 solution. I think that's part of a -- the same thing, the  
3 same thing, that benzalkonium chloride and a negatively  
4 charged or an anionic drug, you -- it's well-known that you  
02:37 5 get cloudiness resulting from precipitate.  
6 Q. And so would a person of ordinary skill in the art have  
7 understood the teaching of the '113 patent to be applicable to  
8 bromfenac?  
9 A. Yes. Again, I think that because bromfenac is an acidic  
02:37 10 drug and it's in this same general family of NSAIDs that have  
11 a carboxylic acid functional group, a person of ordinary skill  
12 would have a reasonable expectation that it would behave the  
13 same way and result -- and be at least partially insoluble at  
14 the important -- at the important concentration.  
02:37 15 Q. Okay. Could you next turn to JTX201 in your binder,  
16 please, and identify this document?  
17 A. Okay. This is the '876 patent. It was published in  
18 1996, and as you can see, its title also deals with ophthalmic  
19 formulations that contain acidic drugs.  
02:38 20 Q. And what does the '876 patent, if anything, teach about  
21 complexation?  
22 A. Okay. Go to column 1 again, and it's right there in the  
23 first paragraph, and it teaches that acidic drugs that have  
24 carboxyl groups tend to form insoluble complexes with  
02:38 25 quaternary ammonium preservatives like benzalkonium chloride.  
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1 Q. And is bromfenac an acidic drug with a carboxyl group?  
2 A. Yes.  
3 Q. And so would a person of ordinary skill in the art have  
4 understood the teaching of the '876 patent to be applicable to  
02:38 5 bromfenac?  
6 A. Yes, I think that, generally, you would read this and  
7 understand that this is -- this is giving you, certainly,  
8 reasonable expectation that bromfenac is going to form an  
9 insoluble complex with BAC.  
02:39 10 Q. Okay. Would you please turn to JTX209 in your binder and  
11 identify this document?  
12 A. This is the European '984 application, and it was  
13 published, I think, in 1989, right about here, and it also is  
14 a patent application that deals with ophthalmic formulations  
02:39 15 that contain acidic NSAIDs.  
16 Q. And what, if anything, does EP '984 teach about  
17 complexation?  
18 A. On Page 2 of this, down toward the bottom here, it is  
19 taught that anti-inflammatory or NSAIDs that contain a  
02:39 20 carboxylic acid group -- can you make that just a little bit  
21 larger? I'm having trouble reading it just from here. I can  
22 read it from here, but then I've got to face away.  
23 The -- they -- that anti-inflammatory -- or NSAIDs that  
24 contain a carboxylic acid group are considered to have proven  
02:40 25 to be incompatible with quaternary ammonium compounds like  
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1 BAC, and this incompatibility results from the fact that the  
2 carboxylic acid group forms a complex with the quaternary  
3 ammonium compound and -- although they don't say the words  
4 "precipitate" in this passage, it renders a preservative less  
02:40 5 available, and I think a person of skill would understand  
6 they're talking about the same kind of turbidity or partial  
7 insolubility that we've been -- that we've seen in the other  
8 patents.  
9 Q. To be clear, BAC, B-A-C, refers to benzalkonium chloride;  
02:41 10 is that right?  
11 A. Yes, that's one of the acronyms for benzalkonium  
12 chloride.  
13 Q. And benzalkonium chloride is a quaternary ammonium  
14 compound; is that right?  
02:41 15 A. Yes.  
16 Q. Okay. And is bromfenac an NSAID with a carboxylic acid  
17 group?  
18 A. Yes.  
19 Q. So would a person of ordinary skill in the art have  
02:41 20 understood the teaching of EP '984 to be applicable to  
21 bromfenac?  
22 A. Yes. As far as this general teaching goes, it tells a  
23 person of skill that you have a reasonable expectation that  
24 bromfenac is also going to form -- form complexes and be  
02:41 25 subject to this incompatibility that they're talking about.  
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1 Q. So from all these references that we've looked at, what  
2 would the person of ordinary skill in the art have understood?

3 A. Well, there was a consistent pattern that's clearly the  
4 people who are writing these patents are all teaching, that  
02:41 5 there is a problem that benzalkonium chloride is not  
6 compatible with these acidic drugs because it forms complexes  
7 which are insoluble, at least insoluble enough to make the  
8 solutions be cloudy and turbid.

9 And since bromfenac is -- although -- also a member of  
02:42 10 this class of NSAIDs that contain a carboxylic acid group, I  
11 think that the overall teaching is clearly that there is a  
12 reasonable expectation that there's going to be problems with  
13 bromfenac and benzalkonium chloride and that you are likely to  
14 see -- you know, you'd expect that you're going to be seeing  
02:42 15 the same kind of partial insolubility with that as well.

16 Q. And were there any specific NSAIDs that had been shown in  
17 the prior art to form insoluble complexes with benzalkonium  
18 chloride?

19 A. Yes, there were three, and they're listed on the next  
02:42 20 slide.

21 Q. The next slide, DDX5-7?

22 A. Yes.

23 Q. And could you identify those three NSAIDs that you were  
24 discussing?

02:43 25 A. The first is a compound called flurbiprofen, and it's the  
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1 subject of WO '597 international patent application. The  
2 second is a compound called ketorolac, and it's discussed in  
3 the European patent application, the '984 -- EP '984, and then  
4 the other is diclofenac, and it's discussed in the '560  
02:43 5 patent.

6 Q. Okay. Let's start with flurbiprofen. Could you turn to  
7 JTX207 in your binder, which is WO '597?

8 A. Okay.

9 Q. And when you get there, could you let me know how WO '597  
02:43 10 shows that flurbiprofen formed an insoluble complex with  
11 benzalkonium chloride?

12 A. Yeah, if you go over to pages 8 and 9, there's a table  
13 that -- that goes over those two tables -- those two pages,  
14 Table 1, and that table lists two formulations called examples  
02:44 15 A and B. And these, if you follow down all the ingredients in  
16 those two formulations, they are identical, except at Example  
17 A formulation has benzalkonium chloride and Example B  
18 formulation has another compound, and it does not have any  
19 benzalkonium chloride.

02:44 20 Then if you look at the bottom of the table, there's a  
21 passage that explains that Example A results in a cloudy  
22 solution with precipitate, and that clearly is because of some  
23 interaction between flurbiprofen and the benzalkonium  
24 chloride, because that's the only difference between Example A  
02:44 25 and Example B.

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1 Q. So would the person of ordinary skill in the art  
2 understand from this, that flurbiprofen and benzalkonium  
3 chloride had formed an insoluble complex?

4 A. Yes.

02:45 5 Q. Okay. Could you turn to JTX209 in your binder, the EP  
6 '984, and does EP '984 show that ketorolac formed an insoluble  
7 complex with benzalkonium chloride?

8 A. Yes. If you go over to Page 209.9, there's a table,  
9 Example 5, in this patent -- in this table, is a part of  
02:45 10 Example 5. This table reports several -- there's actually six  
11 different formulations with three different surfactants.

12 The -- each of the surfactants has two concentrations  
13 of surfactant. One of the surfactants that's used is Tween  
14 80, that's another name for polysorbate 80. And you see that  
02:45 15 in that -- in both of the formulations that contain that  
16 surfactant there was turbidity. The one on the left --

17 MR. DINER: Excuse me, Your Honor, I'm sorry to  
18 interject. I would like to lodge an objection at this point  
19 in time. When he -- Dr. Heathcock spoke about or talked about  
02:46 20 the Fu reference in his report, he talked about it in the  
21 context of the general statement that he referred to at Page 2  
22 of the Fu reference. But I don't believe that in the context  
23 of his report, he got into the specific details concerning  
24 Example 5. And so I think this is outside the scope of his  
02:46 25 report. If counsel could suggest a passage elsewhere in his

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1 report.

2 MR. MARGOLIS: Yes. Your Honor, if you look at  
3 paragraph 50, last sentence, the Fu reference EP '984  
4 discloses formation of a precipitate under certain conditions  
02:46 5 and formulations containing ketorolac and BAC, citing EP '984  
6 at Page 9, lines 11 to 39, which is exactly what's up on the  
7 screen right now.

8 MR. DINER: Withdrawn, Your Honor.

9 THE COURT: All right. I'll permit it.  
02:47 10 Would you like the question repeated?

11 THE WITNESS: I think I know where we were. I was  
12 just pointing out that this table shows that in this -- in  
13 this formulations in the middle, there was turbidity, and if  
14 you go down below the table, the -- the inventors state that  
02:47 15 the presence of turbidity suggested the inability to  
16 solubilize -- the inability of this surfactant, to solubilize  
17 a precipitate formation between the ketorolac and benzalkonium  
18 chloride.

19 Q. And so, would this suggest to the person of ordinary  
02:47 20 skill in the art that an insoluble complex had formed between  
21 ketorolac and benzalkonium chloride?

22 A. Yes, that's clearly what the inventors were telling and  
23 teaching in this patent.

24 Q. Now, are you aware that Dr. Davies testified that the use  
02:48 25 of the word "suggested" in that last sentence that you

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1 discussed implies that the authors did not know what the  
2 precipitate actually was?  
3 A. Yeah, I -- I read that.  
4 Q. And do you agree with his understanding?  
02:48 5 A. Well, no. I think, if you look at the whole context of  
6 this example. I mean, can we pull back and look at the  
7 language in the -- you know, this is an -- this is an  
8 experiment that was set up. Clearly, these -- what they say  
9 about the design of the experiment was, three surfactants were  
02:48 10 evaluated for their ability to dissolve the ketorolac  
11 benzalkonium chloride complex and maintain a physically clear  
12 solution.  
13 So although they don't show any experimental data to  
14 the -- they clearly knew there was a complex between those two  
02:48 15 things, and that's why they did this experiment, to find some  
16 surfactant that would dissolve that -- that precipitate.  
17 Q. Okay. Could you turn to JTX057 in your binder, please.  
18 And identify that document?  
19 A. Okay. That's a patent -- that's a U.S. patent,  
02:49 20 5,597,560. It's a patent that was published in 1997.  
21 Q. And what is the subject matter to which the '560 patent  
22 is generally directed?  
23 A. Generally, this is another patent dealing with ophthalmic  
24 formulations and -- formulations that do contain an acidic  
02:49 25 NSAID.

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1 Q. Okay. And is the '560 patent directed to solving any  
2 particular problem?  
3 A. Yes, the particular problem that this patent was directed  
4 at was that the formulation being developed here in addition  
02:49 5 -- excuse me, in addition to containing the NSAID also  
6 contains an antibiotic.  
7 The antibiotic was a compound name tobramycin, and what  
8 the researchers were finding was that diclofenac and the  
9 tobramycin interacted with each other to form an insoluble  
02:50 10 complex, and they were looking for -- they were looking for a  
11 formulation that would dissolve that complex, that diclofenac  
12 tobramycin complex.  
13 Q. And does the '560 patent also suggest that diclofenac  
14 formed an insoluble complex with benzalkonium chloride?  
02:50 15 A. Yes. If you look on a -- yeah, there we go. It's at the  
16 bottom of -- I can't read the page number from here. It's at  
17 the bottom of Page 10. There is -- this paragraph describes  
18 that they had developed a formulation that included a  
19 relatively large concentration of surfactant and other  
02:51 20 conditions that permitted -- that solved the problem. It  
21 dissolved the tobramycin diclofenac complex, but they go on to  
22 say that these same condition also inhibit the unacceptable  
23 interaction between diclofenac and the quaternary ammonium  
24 compound.  
02:51 25 And so that would be understood by a person of ordinary

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1 skill to be referring to the same kind of undesirable  
2 insoluble complexes that were -- that were being taught by all  
3 of these patents.  
4 Q. Do you understand that Dr. Davies testified that the  
02:51 5 person of ordinary skill in the art would not have expected  
6 bromfenac to form an insoluble complex with benzalkonium  
7 chloride because it differs in some respects from these other  
8 NSAIDs?  
9 A. Yes.  
02:52 10 Q. And do you agree with Dr. Davies's opinions that  
11 bromfenac differs in some respects from flurbiprofen,  
12 diclofenac and ketorolac?  
13 A. Certainly it differs. It has different functional  
14 groups, and if it didn't have, it would be the same compound.  
02:52 15 Q. Now, do you agree with Dr. Davies's opinion that the  
16 person of ordinary skill in the art would not have expected  
17 bromfenac to form an insoluble complex with benzalkonium  
18 chloride because it differs in some respects from other  
19 NSAIDs?  
02:52 20 A. No, I don't agree with that. I don't think the  
21 differences are sufficient to give a person of ordinary skill  
22 confidence that that systematic problem would be obliterated.  
23 Q. Are there any differences among flurbiprofen, diclofenac  
24 and ketorolac?  
02:52 25 A. Yes, they -- they differ from each other, as well as each

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1 of them differing from bromfenac.  
2 Q. Could we pull up the next slide, please. DDX5-8.  
3 Does that -- can you explain using DDX5-8, what the  
4 differences are between flurbiprofen, diclofenac and  
02:53 5 ketorolac?  
6 A. Yes, on this slide, I just joined -- I've just gathered  
7 together those three carboxylic acid NSAIDs, and you can see  
8 that each of them differs from each of the other ones in  
9 significant ways. For example, flurbiprofen has two aromatic  
02:53 10 rings with a fluorene attached to one. Diclofenac has two  
11 aromatic rings, but they're attached by an amino group.  
12 Flurbiprofen doesn't even have an amino group.  
13 Diclofenac has a couple of fluorenes where -- instead of the  
14 one fluorene.  
02:53 15 So there are a lot of differences between flurbiprofen  
16 and diclofenac, also between diclofenac and ketorolac. So...  
17 Q. So why is it that despite all of these differences  
18 between flurbiprofen, diclofenac and ketorolac, all three  
19 compounds formed insoluble complexes with benzalkonium  
02:54 20 chloride?  
21 A. Well, I think it's because they all are carboxylic acids  
22 that are ionized in the carboxylate form at the pH 7. And  
23 although there are differences in the hydrophobic parts of  
24 these molecules, those differences aren't enough to overwhelm  
02:54 25 the fact that these are basically carboxylic acids, and they

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1 all have this common property of being able to associate with  
2 a cation and form -- and when the cation is a big greasy one  
3 like the benzalkonium chloride, to form an insoluble complex.

4 Q. And have you prepared a slide showing how bromfenac  
5 differs from flurbiprofen, diclofenac and ketorolac? I'm  
6 sorry. Have you prepared a slide showing how bromfenac  
7 differs from flurbiprofen, diclofenac and ketorolac?

8 A. Yes.

9 Q. And so could you explain how these compounds different?

02:55 10 A. Well, there's bromfenac, and you can see that it does  
11 differ from each of these other three compounds, but really  
12 not more than they differ from each other. It certainly has  
13 -- it has an amino group, diclofenac has an amino group. It  
14 has two benzene rings that are joined by a carbonyl.

02:55 15 Ketorolac has that. So it has some common features with each  
16 of these and it also differs. But it has over -- one  
17 overwhelmingly important common feature and that is the  
18 carboxylic acid group.

19 Q. So in view of the structural differences between  
02:55 20 bromfenac, diclofenac, ketorolac and flurbiprofen, would the  
21 person of ordinary skill in the art have expected that an  
22 insoluble complex would form between bromfenac and  
23 benzalkonium chloride, as it did with diclofenac, ketorolac  
24 and flurbiprofen?

02:55 25 A. Yes. I think you would certainly have a reasonable

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1 expectation that you would have an insolubility problem at the  
2 relevant ophthalmic concentrations.

3 Q. Now, do you understand that Dr. Davies testified that  
4 because of these differences in structure, bromfenac would be  
02:56 5 expected to be more soluble than these other NSAIDs?

6 A. Well, it is more soluble than these other three  
7 compounds, and I understand that. But that insolubility --  
8 that additional solubility is going to be moderated a lot when  
9 it's paired with this very hydrophobic benzalkonium chloride  
02:56 10 cation.

11 Q. So have you prepared a slide to explain that a little bit  
12 more?

13 A. Yeah. Next slide.

14 Q. Okay. Let's pull up 5 -- DDX5-11, please. And could you  
02:56 15 explain why it's your opinion that the difference in  
16 solubility between bromfenac and the other NSAIDs would not  
17 cause the person of ordinary skill in the art to doubt that  
18 bromfenac would form an insoluble complex with benzalkonium  
19 chloride?

02:56 20 A. Sure. What I've done here is just shown each of the  
21 three NSAIDs that were -- that were implicated with these  
22 insoluble complexes, flurbiprofen on the upper left,  
23 diclofenac on the upper right, and ketorolac on the lower  
24 left. I showed them in -- associated with the benzalkonium  
02:57 25 cation in an ion pair relationship.

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1 And the reason that these compounds -- that these  
2 complexes are all partly insoluble at the important  
3 concentration is certainly that this big hydrophobic cation is  
4 overwhelming -- each of these, each of these NSAIDs by itself  
02:57 5 would be soluble under these conditions, but when associated  
6 with this big hydrophobic cation, the complex is at least  
7 partially not soluble, and so you get a precipitate in that  
8 cloudiness.

9 And here's bromfenac and it forms the same kind of  
02:57 10 thing. And when you look at bromfenac in association with  
11 this cation, the whole complex is dominated by this big  
12 hydrophobic cation. And so even though bromfenac itself might  
13 be quite water soluble, when it's ion paired with this big  
14 greasy cation, I think a person of ordinary skill would  
02:58 15 understand that there's a high probability that it's going to  
16 be insoluble, just like the others.

17 Q. Do you understand that Dr. Davies also testified about  
18 the structural differences between tyloxapol and polysorbate  
19 80?

02:58 20 A. Yes.

21 Q. And is the interchangeability of surfactant something  
22 that is typically encountered by an organic chemist?

23 A. Well, no, it's not something that I think we would  
24 normally do in our research. It's something -- it's a  
02:58 25 formulation matter and formulation is not something that an

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1 organic chemist of my type would be normally concerned with.

2 Q. Do you have a general understanding of what a surfactant  
3 is?

4 A. Oh, yes, certainly.

02:59 5 Q. Do you have prepared a slide identifying the general  
6 properties of a surfactant?

7 A. Yes, it's shown here. This is a charming little drawing  
8 that shows a molecule that has a split personality.  
9 Surfactants or organic compounds that have a part that wants  
02:59 10 to be dissolved in water, that's called the hydrophilic part,  
11 hydrophilic means loves water, and that's often sometimes  
12 called the head group of the surfactant. And then it has  
13 another part which is hydrophobic and doesn't like to be in  
14 water, and that's sometimes called the tail group. So a  
02:59 15 surfactant is a kind of a bipolar molecule, one end of the  
16 molecule wants to be dissolved in water and the other end  
17 doesn't want to be anywhere near water. And so it's sometimes  
18 called amphiphilic, it has both hydrophilic and hydrophobic  
19 properties.

02:59 20 Q. And have you prepared a slide illustrating what happens  
21 when a surfactant is placed in water?

22 A. Yes. If you look at this slide, you see what happens.  
23 When you start dissolving or adding the amphiphilic surfactant  
24 molecule to water, because the hydrophobic tails don't want to  
03:00 25 be anywhere near water, they will tend to stick together and

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1 form a kind of a loose association so that they can benefit  
2 from being around more hydrophobic things than being away from  
3 the water.

03:00 4 And when you get enough of the surfactant around enough  
5 of the molecules around, you can form these actual closed  
6 units that are called vesicles or micelles. And what a  
7 micelle is, it's like a spherical structure, compartment where  
8 all of the hydrophobic parts of the molecules get together in  
9 the middle and that leaves the hydrophilic head groups on the  
03:01 10 outside of the ball. When the micelle -- when there are  
11 enough molecules, the micelle will form a completely spherical  
12 or somewhat spherical structure with all of the hydrophobic  
13 parts on the inside and the hydrophilic head groups on the  
14 outside. And so you can think of this like maybe a basketball  
03:01 15 filled with oil in the middle, and the outside is really water  
16 soluble.

17 And the way a micelle works to dissolve things, is if  
18 you have in solution also something like that's oily, like say  
19 butter or machine oil or, you know, one of these hydrophobic  
03:02 20 ion pairs that we've been talking about, that can get in the  
21 middle of the ball where it's oily and the hydrophobic  
22 interior of the ball can act as a good solvent and then it can  
23 solubilize that material.

03:02 24 So it would be like if you got butter on your dinner  
25 napkin and you wash it with water, you don't get the butter

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03:02 1 out. But if you add some soap to the water you wash the  
2 dinner napkin with, the soap forms these micelles and the  
3 butter molecules are happy to go in there in the oily part of  
4 the interior of the micelle and then washes away and your  
5 dinner napkin is clean.

6 The next slide shows kind of an interesting little  
7 picture that my students took once of our group. And they  
8 wanted to lie down on -- they wanted to have a group picture  
9 that wasn't standing in front of a library door and they  
03:03 10 organized this thing where they all lie down on the air intake  
11 valve with their feet pointed in and they wanted me to stand  
12 in the middle. One of my students, after I gave the intro  
13 course one day and the lecture that talked about micelles,  
14 came back to my office and said Professor Heathcock, you have  
03:03 15 a picture of a micelle on your wall and a blob of fat right in  
16 the middle.

17 So that's a cross-section of the micelle.

18 THE COURT: Excuse me, is that a good place to stop  
19 for lunch?

03:03 20 MS. HOLLAND: Your Honor, we have a timing issue with  
21 Dr. Heathcock, Dr. Heathcock has a flight that he's trying to  
22 catch. So I know it's not the Court's usual practice, but  
23 would it be okay to take a later lunch today so we can get  
24 Dr. Heathcock off the stand before lunch?

03:03 25 THE COURT: Well, Tuesday is the only day when the

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1 judges in this building meet in the building for a quick  
2 lunch. I can shorten my time at that lunch if that helps. Do  
3 you want to go about ten more minutes now and then we'll  
4 resume like 1:30? I mean, I can't solve the time problem  
03:04 5 overall because I don't know how long cross-examination is  
6 going to take.

7 MR. MARGOLIS: If it helps at all, I probably have,  
8 like, five minutes or so left.

9 THE COURT: Well, let's complete the direct then and  
03:04 10 then we'll take a shorter lunch break.

11 MR. MARGOLIS: Thank you.

12 THE COURT: I assume there's a decent amount of  
13 cross?

14 MR. DINER: Yes, your Honor.

03:04 15 THE COURT: Okay.

16 BY MR. MARGOLIS:

17 Q. Given that understanding of how micelles work, is there  
18 anything about the structural differences between tyloxapol  
19 and polysorbate 80 that would have suggested to the person of  
03:04 20 ordinary skill in the art that they could not be used  
21 interchangeably?

22 A. Actually, there was a reason to think that they could be  
23 and that tyloxapol might be even better than polysorbate, and  
24 that was in the European application, the '984.

03:05 25 MR. DINER: Your Honor, at this point I'd like to

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1 lodge an objection. Dr. Heathcock is starting to make  
2 opinions and give testimony outside the scope of his expert  
3 report. He's testified in his expert report that they're  
4 simply the substitutable, now he's starting to tell you that  
03:05 5 they're somehow better, and that wasn't in his expert report.

6 THE COURT: Well, you can impeach him with that on  
7 cross if he's made an inconsistent statement today. I'll  
8 permit it. Well, I assume that there's something in his  
9 report that would contradict what he's being asked here.

03:05 10 MR. DINER: Well, it's just outside the scope of his  
11 report. The scope of his report, the thrust of his report is  
12 that they're interchangeable, they're substitutable, now he's  
13 starting to argue that one is better than the other and that's  
14 not in his report.

03:05 15 MR. MARGOLIS: Your Honor, if I may.

16 THE COURT: Mr. Margolis.

17 MR. MARGOLIS: Paragraph 70, last sentence, indeed,  
18 the prior art EP '984 patent suggested that surfactants in the  
19 ethoxylated octylphenol class of which tyloxapol is a member  
03:06 20 are preferable to polysorbate 80 in solubilizing NSAID BAC  
21 complexes.

22 THE COURT: I'll permit it, it's within the scope.

23 MR. MARGOLIS: Thank you, your Honor.

03:06 24 BY MR. MARGOLIS:

25 Q. Dr. Heathcock, could you explain why it is that the

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1 person of ordinary skill in the art would have believed that  
 2 tyloxapal would have been better able to solubilize an NSAID  
 3 BAC complex than polysorbate 80?  
 4 A. Yeah, you just read it. It's in the EP -- it's in the EP  
 03:06 5 '984.  
 6 MR. MARGOLIS: Could we pull that up, please?  
 7 THE WITNESS: And it's on Page 5. Let's see what  
 8 number --  
 9 BY MR. MARGOLIS:  
 10 Q. JTX209.  
 11 A. That's right. I've got it here. I can see it on the  
 12 screen.  
 13 In this patent it teaches that nonionic surfactants  
 14 that are useful in these formulations were preferably these  
 03:07 15 ethoxylated octylphenol compounds of which tyloxapal would  
 16 fall in that family.  
 17 Q. Can you remind the Court what the purpose of the  
 18 invention of EP '984 was?  
 19 A. This was where they were using different surfactants to  
 03:07 20 solubilize an insoluble complex that formed between  
 21 benzalkonium chloride and ketorolac, the examples that we went  
 22 through a few moments ago.  
 23 Q. So does this suggest to the person of ordinary skill in  
 24 the art that ethoxylated octylphenol compounds would be better  
 03:07 25 able to solubilize an NSAID BAC complex than polysorbate 80?

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1 of ordinary skill in the art to expect tyloxapal to be less  
 2 effective as a solubilizer of an NSAID BAC complex?  
 3 A. Less soluble, no.  
 4 Q. And is there anything about the structural differences  
 03:09 5 between octoxynol 40 and tyloxapal that would cause the person  
 6 of ordinary skill in the art to expect tyloxapal to be more  
 7 effective as a solubilizer of an NSAID BAC complex?  
 8 MR. DINER: Your Honor, I would like to again lodge  
 9 an objection here. This is clearly outside the scope of what  
 03:10 10 he was talking about before. In his expert report, as we  
 11 established, it was with regard to polysorbate 80 --  
 12 polysorbate 80. Now he's starting to make an offer of  
 13 testimony that's not in his expert report about why tyloxapal  
 14 would be better than octoxynol 40, and that's not in his  
 03:10 15 expert report.  
 16 MR. MARGOLIS: Your Honor, he testified about this at  
 17 his deposition on Page 121, Line 17, through 122, Line 14, he  
 18 talk about how you would expect tyloxapal to be an  
 19 exceptionally good octylphenol because of the picket fence  
 03:10 20 structure he's been talking about.  
 21 MR. DINER: Your Honor, there is nothing about picket  
 22 fence or anything of that stuff in his expert report. And  
 23 there's been a bright line ruling in these proceedings so far  
 24 is that your Honor has basically taken the position if it's  
 03:10 25 not in the expert report, their witness is not allowed to

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1 A. That is what it says, yes.  
 2 Q. And is tyloxapal an ethoxylated octylphenol compound?  
 3 A. Yes, it is.  
 4 Q. And do you have a slide where you can explain why  
 03:07 5 tyloxapal is considered an ethoxylated octylphenol compound?  
 6 A. Yes. Here's the -- here's tyloxapal. And the octyl  
 7 group is this group at the bottom of the six membered ring,  
 8 it's got eight carbon, hence the octyl part. The six membered  
 9 ring with an oxygen attached to it is the phenol part, and  
 03:08 10 this phenol is functionalized by a long chain attached to the  
 11 oxygen and extending out, and that's the polyethoxyl part.  
 12 So this is a polyethoxylated octylphenol and seven of  
 13 them are already joined together by CH<sub>2</sub> bridges. It's kind of  
 14 like -- so this molecule ends up being sort of like a picket  
 03:08 15 fence with seven staves or seven children holding hands in a  
 16 line. And the reason I think that this would be viewed as a  
 17 particularly attractive member of this ethoxylated octylphenol  
 18 family is that because seven of these are covariantly bonded  
 19 together, they're already -- they have a head start on forming  
 03:09 20 a micelle.  
 21 Q. Do you understand that in the example of EP '984  
 22 octoxynol 40 and not tyloxapal was used?  
 23 A. Yes.  
 24 Q. And is there anything about the structural differences  
 03:09 25 between octoxynol 40 and tyloxapal that would cause the person

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1 testify about it. And whether it's in his deposition or not,  
 2 the fact is that we were working off of what is in fact in the  
 3 pretrial order is what is in his expert report. And we  
 4 haven't been given fair notice to be able to depose or  
 03:11 5 cross-examine him on those issues. We feel --  
 6 THE COURT: Well, did you question him, or a member  
 7 of your team, about this subject in his dep? If you brought  
 8 out the question, then his opinions wouldn't be a surprise.  
 9 If the other side brought it out, then it could be.  
 03:11 10 MR. HASFORD: I apologize, your Honor, I realize this  
 11 isn't quite standard, but I can address that because I took  
 12 his deposition.  
 13 THE COURT: Yes.  
 14 MR. HASFORD: Mr. Margolis pointed to Page 117, the  
 03:11 15 question there was:  
 16 QUESTION: Why are the CMC, which is Critical Micelle  
 17 Concentration, a unique characteristic of each surfactant?  
 18 And he launched into a page and a half answer, but  
 19 there wasn't anything about tyloxapal being superior in there.  
 03:11 20 MR. MARGOLIS: Mr. Hasford, I'm sorry, it was Page  
 21 121, Line 17. I apologize if I misspoke.  
 22 MR. HASFORD: The question on Page 121, Line 17:  
 23 QUESTION: What does it mean that tyloxapal is a  
 24 nonionic surfactant?  
 03:12 25 There was no question about whether tyloxapal would be

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1 better or worse or anything like that. The only question was:  
2 QUESTION: What does it mean that tyloxapol is an  
3 nonionic surfactant?  
4 The door was not opened to any of this, your Honor.  
03:12 5 MR. MARGOLIS: Your Honor, Dr. Heathcock proceeded to  
6 give all the information he's about to testify about. Then  
7 was asked:  
8 QUESTION: When you testified that tyloxapol is a  
9 different kind of surfactant, different from what?  
03:12 10 He continued to explain. They had ample opportunity to  
11 investigate his opinion further.  
12 MR. HASFORD: We disagree, your Honor. He's  
13 mischaracterizing the deposition testimony. There was no  
14 question that that brought out any differences or would have  
03:12 15 asked him to explain his opinion as to whether tyloxapol was  
16 superior in any way.  
17 THE COURT: All right. I'm going to sustain the  
18 objection. It doesn't appear that it's in his report or in  
19 his deposition in questioning by the plaintiffs themselves.  
03:12 20 MR. MARGOLIS: Thank you, your Honor.  
21 BY MR. MARGOLIS:  
22 Q. Dr. Heathcock, would the person of ordinary skill in the  
23 art have expected tyloxapol to stabilize bromfenac against  
24 complexation with benzalkonium chloride?  
03:13 25 A. Yes.

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1 MR. MARGOLIS: I have no further questions. If I  
2 could just move some exhibits into evidence, please?  
3 THE COURT: Okay.  
4 MR. MARGOLIS: JTX057, JTX158, JTX201, JTX207,  
03:13 5 JTX209, and DTX-440.  
6 MR. DINER: What was the last number?  
7 MR. MARGOLIS: DTX-440.  
8 THE COURT: His CV.  
9 MR. DINER: Your Honor, I don't suspect we'll have a  
03:13 10 problem, but I would like to at least consider these and we'll  
11 pick that up at the end of the day when we're preparing the  
12 evidence about each of the supplemental documents.  
13 THE COURT: All right. Well, if there's a  
14 foundational problem, it's always better, of course, to clear  
03:14 15 it up while the witness is still on the stand. But we can  
16 look at this after lunch if there is any issue.  
17 So we'll resume cross-examination, let's say, in  
18 45 minutes.  
19 MR. MARGOLIS: Thank you, your Honor.  
03:14 20 THE COURT: So at 1:30 we'll resume.  
21 (Luncheon Recess)  
22 (Open Court)  
23 DEPUTY CLERK: All rise.  
24 THE COURT: Be seated, please.  
04:04 25 Okay. Mr. Diner, you may proceed.

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1 MR. DINER: Thank you, your Honor.  
2 (CROSS-EXAMINATION OF MR. HEATHCOCK BY MR. DINER:)  
3 Q. Good afternoon, Dr. Heathcock.  
4 A. **Good afternoon.**  
04:04 5 Q. Dr. Heathcock, even though different NSAIDS have the  
6 carboxylic acid functional group, different NSAIDS  
7 nevertheless possess different physical/chemical properties,  
8 correct?  
9 A. **Yes, that's correct.**  
04:04 10 Q. And different NSAIDS have different physical/chemical  
11 properties because they have different chemical structures,  
12 correct?  
13 A. **They have different structures. Their physical structure**  
14 **will tend to be more different than their chemical properties.**  
04:04 15 Q. And different NSAIDS in terms of having different  
16 properties could have different solubilities, correct?  
17 A. **Yes.**  
18 Q. The solubility of an NSAID is going to be related to its  
19 structure, correct?  
04:05 20 A. **Yes, it will be.**  
21 Q. And so different NSAIDS having different solubilities  
22 have that different solubility because of their -- logically  
23 because of their different structures, right?  
24 A. **Yes.**  
04:05 25 MR. DINER: Okay. Now, Noel, can you bring up

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1 DDX5-10?  
2 BY MR. DINER:  
3 Q. And I believe you should have this in your binder or you  
4 can look at the screen.  
04:05 5 A. **Yes.**  
6 Q. Now, you testified on direct examination about bromfenac,  
7 flurbiprofen, diclofenac, and ketorolac. Do you recall that?  
8 A. **Yes.**  
9 Q. And each of bromfenac, diclofenac, flurbiprofen, and  
04:05 10 ketorolac have different chemical structures, correct?  
11 A. **Yes, they're all -- they have different structures or**  
12 **they would be the same.**  
13 Q. I'm sorry?  
14 A. **They have different structures or else they would be the**  
04:05 15 **same.**  
16 Q. Right.  
17 And those different structures will lead to different  
18 solubilities in aqueous systems, correct?  
19 A. **They all have different degrees of solubility.**  
04:06 20 Q. Now, we talked about, or you testified on direct  
21 examination about nonionic surfactants. Do you recall that?  
22 A. **Yes.**  
23 Q. And similarly, nonionic surfactants are going to have  
24 different chemical and physical properties because they have  
04:06 25 different structures as well, correct?

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1 A. Yes.  
 2 Q. And, generally speaking, the chemical and physical  
 3 properties of organic compounds are going to be related to  
 4 their exact structure, is that right?  
 04:06 5 A. Yes, that's right.  
 6 Q. Okay.  
 7 A. We can't group them in families, of course, but they'll  
 8 be in a family, but even within a family there will be  
 9 differences.  
 04:07 10 Q. Okay. Now, you testified on direct examination that  
 11 there would be a reasonable expectation of success that an  
 12 NSAID would complex with benzalkonium chloride and form a  
 13 precipitate. Do you recall that?  
 14 A. I don't think I said success. But I think I said there  
 04:07 15 would be a reasonable expectation that it would complex and  
 16 that such a complex would be sufficient and soluble as to form  
 17 one of these insolubility issues.  
 18 Q. So you don't believe there would be a reasonable  
 19 expectation of an NSAID successfully complexing with  
 04:07 20 benzalkonium chloride and forming an insoluble salt?  
 21 A. Well, I don't think that's a success. I mean, I think  
 22 that's a failure. If it forms the insoluble salts, that's the  
 23 only thing. I think just to be perfectly clear, I think  
 24 because of what was taught in the literature quite widely, a  
 04:08 25 person reading that literature would have a reasonable

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1 expectation that benzalkonium chloride would be likely to form  
 2 an insoluble complex with any acidic NSAID drug, that wouldn't  
 3 be a success, I think that would be a failure.  
 4 Q. Okay. So is it your opinion that all acidic NSAIDs are  
 04:08 5 going to form complexation with benzalkonium chloride, is that  
 6 right?  
 7 A. No, my opinion is that in light of the literature that  
 8 was available, a person of ordinary skill would have a  
 9 reasonable expectation that any of them would be likely to do  
 04:08 10 that.  
 11 Q. And so the flip side of that is that they, of course, may  
 12 not form a complex, that is, the NSAID with benzalkonium  
 13 chloride?  
 14 A. I didn't say it would be certain. I think it would be,  
 04:08 15 you know, a reasonable expectation that something's going to  
 16 happen does not mean you're certain that that's going to  
 17 happen.  
 18 Q. And it's also reasonably likely that it wouldn't occur,  
 19 right, that there would be no complex formed as between the  
 04:09 20 NSAID and benzalkonium chloride, is that right?  
 21 A. I wouldn't say -- I wouldn't agree with that. I would  
 22 say if you have a reasonable expectation that it's going to  
 23 happen, you don't have a reasonable expectation that it's not  
 24 going to happen.  
 04:09 25 Q. Dr. Heathcock, have you ever conducted any research on

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1 any product containing benzalkonium chloride?  
 2 A. No, I have not.  
 3 Q. And have you ever formulated a product -- a formulation  
 4 containing benzalkonium chloride?  
 04:09 5 A. No, I have not.  
 6 Q. Have you written any papers dealing with benzalkonium  
 7 chloride?  
 8 A. No.  
 9 Q. And you've never measured, have you, the solubility of  
 04:09 10 bromfenac, correct?  
 11 A. No, I looked it up, but I haven't measured it.  
 12 Q. Okay. And you never measured the solubility of any  
 13 complex or salt of bromfenac and benzalkonium chloride,  
 14 correct?  
 04:10 15 A. No.  
 16 Q. And you didn't conduct any of your own testing in  
 17 conjunction with your opinions in this case, is that correct?  
 18 A. No.  
 19 Q. Now, the formulation of an NSAID without any  
 04:10 20 preservative, would that avoid what you have called that  
 21 complexation of benzalkonium chloride and the NSAID?  
 22 A. Well, if you didn't have the benzalkonium chloride, yes,  
 23 you would not be -- it would not be possible that you would  
 24 have the complex with it.  
 04:10 25 Q. Okay. And how about a formulation of an NSAID with

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1 something like lauralkonium chloride instead of benzalkonium  
 2 chloride, would that avoid any alleged precipitation between  
 3 an NSAID and lauralkonium chloride?  
 4 A. I only can answer that in light of one case that I've  
 04:11 5 seen listed where that was done and where it was reported that  
 6 there was not turbidity. So I don't know that I could  
 7 generalize that, there was this one example certainly.  
 8 Q. But at least based on that one example, it's your opinion  
 9 that the use of lauralkonium chloride would avoid the problem  
 04:11 10 of complexation, is that correct?  
 11 A. In that case it certainly did.  
 12 Q. Okay. Thank you.  
 13 Now, Dr. Heathcock, are you familiar with the nonionic  
 14 surfactants, nonoxynol, polaxamer 1888, polyoxyethylene,  
 15 polyoxypropylene 1800, polyoxy135caster oil, or polyoxyl 40  
 16 monostearate?  
 17 A. Are those all different compounds or is that all one long  
 18 name?  
 19 Q. No, those are all nonionic surfactants.  
 04:12 20 A. I'm not familiar with those.  
 21 Q. I'd like to try to refresh your recollection on that.  
 22 MR. DINER: With the Court's permission, I'd like to  
 23 hand out up.  
 24 THE COURT: I think the problem then is in the  
 04:12 25 question. I had the impression you were reading one long

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1 name, you didn't pause between those substances.  
2 MR. DINER: Let me try it again then.  
3 BY MR. DINER:  
4 Q. So, Dr. Heathcock, so you don't know whether the use of  
04:12 5 other FDA approved surfactants such as nonoxynol or polaxamer  
6 1888 or polyoxyethylene or polyoxypropylene 1800 or  
7 polyoxy135caster oil, or polyoxyl 40 monostearate in an  
8 aqueous liquid preparation of an NSAID with BAC would avoid  
9 complex, correct?  
04:13 10 A. I don't know because I'm not sure -- I recognized one of  
11 those names when you read them slowly. And I don't think I  
12 know about its use for this particular issue.  
13 Q. Okay. So you haven't formed your opinion whether any of  
14 those nonionic surfactants that I just mentioned would avoid  
04:13 15 the alleged complex of an NSAID and benzalkonium chloride,  
16 correct?  
17 A. No, I haven't formed an opinion on that.  
18 Q. Okay. And in your opinion or your inquiry in forming  
19 your opinions was focused just on tyloxapal and whether it  
04:14 20 would avoid a complex with, as between bromfenac and  
21 benzalkonium chloride, correct?  
22 A. I'm sorry, would you restate the question?  
23 Q. Your inquiry for purposes of your opinions was focused on  
24 tyloxapal and whether it would avoid the alleged complex of  
04:14 25 bromfenac and benzalkonium chloride, is that right?  

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1 tyloxapal, it teaches the use of ethoxylated octylphenols of  
2 which tyloxapal is one but it does not mention it as an  
3 explicit example.  
4 Q. So just to be clear, it's -- tyloxapal is not mentioned  
04:16 5 in the Fu reference, correct?  
6 A. Not explicitly.  
7 Q. Okay. And the same with bromfenac, it is not mentioned  
8 specifically in the Fu reference, correct?  
9 A. Yes, that's what I said.  
04:16 10 Q. Now, I believe you testified, as Fu discloses, this broad  
11 class of ethoxylated octylphenols and that that would include  
12 tyloxapal, that's your testimony, correct?  
13 A. Yes.  
14 Q. By the time -- are you aware that the Fu patent  
04:17 15 eventually -- the Fu reference eventually issued into a  
16 European patent?  
17 A. I haven't seen that.  
18 Q. Okay.  
19 A. So I wasn't aware of it. I assumed it probably did.  
04:17 20 Q. And you also were aware by the time it was examined and  
21 issued, it was limited exclusively to octoxynol 40, is that  
22 right?  
23 A. I'm sorry.  
24 Q. By the time -- you were not also aware that by the time  
04:17 25 the Fu patent issued in Europe, it was limited exclusively and  

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1 A. That was what I was asked to give an opinion about.  
2 Q. Would you please turn in your binder to JTX209. Do you  
3 recall testifying about JTX209 on direct examination,  
4 Dr. Heathcock?  
04:15 5 A. Yes.  
6 Q. And this is the Fu EP '984 reference, correct?  
7 A. Yes.  
8 Q. The Fu reference does not teach the use of bromfenac,  
9 correct?  
04:15 10 A. No, bromfenac is not explicitly mentioned in this  
11 reference.  
12 Q. And the Fu reference does not teach specifically the use  
13 of tyloxapal, correct?  
14 A. It does not name tyloxapal. It names a generic class of  
04:15 15 surfactant to which tyloxapal belongs. Just as it names  
16 generically bromfenac as a member of the NSAID family but it  
17 does not name it explicitly.  
18 Q. But the Fu reference doesn't teach the use of tyloxapal  
19 or mention it explicitly anywhere, is that correct?  
04:16 20 A. Does not give its name explicitly.  
21 Q. Okay. And similarly with regard to bromfenac, the Fu  
22 reference does not teach or otherwise specifically name the  
23 use of bromfenac, correct?  
24 A. It teaches the use of carboxylic acid NSAIDS generally  
04:16 25 and it does not name bromfenac explicitly. Same for  

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1 directly to octoxynol 40?  
2 A. You mean the claims?  
3 Q. Yes.  
4 A. I haven't seen that patent so I'm not aware what went on  
04:17 5 in the claims. So you're saying that the claims were narrowed  
6 to name only octoxynol 40?  
7 Q. Actually it's the claims and the specification that were  
8 so narrow. Were you aware of that?  
9 A. Well, I haven't seen the patent, so I wasn't aware of  
04:18 10 these things you're asking me about.  
11 Q. I would like to refresh your recollection.  
12 MR. DINER: May I approach?  
13 MR. MARGOLIS: Your Honor, he just testified he's  
14 never seen this exhibit. How can he refresh his recollection  
04:18 15 with something he's never seen?  
16 THE COURT: Well, you can reframe the question. It  
17 wouldn't be refreshing recollecting, but you're drawing other  
18 authority to his attention.  
19 MR. DINER: Yes.  
20 BY MR. DINER:  
21 Q. So, Dr. Heathcock, I would like to draw to your attention  
22 to the issued patent that came out of the IP '984 application.  
23 THE COURT: Is there any objection?  
24 MS. HOLLAND: We don't know what it is.  
04:18 25 MR. DINER: It's going to be PTX-778.  

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1 MR. MARGOLIS: That's not even on the exhibit list,  
 2 your Honor. There's nothing inconsistent in what he's  
 3 testifying versus what is in his report. The claims of the  
 4 patent are not even an issue in this case. It's a patent that  
 04:19 5 he hasn't testified about the claims. And he's talking about  
 6 issue claims that came from the prosecution down the line way  
 7 later than anything he's looked at.  
 8 MR. DINER: Your Honor, he's testified that this  
 9 broad group of ethoxylated octylphenois encompassed tyloxapol.  
 04:19 10 What the issued version of the European patent application to  
 11 Fu will establish is that the European authorities looked at  
 12 it, examined it and actually limited it to just octoxynol 40  
 13 not just in the terms of the claims but the specification,  
 14 which is an indication of what the European authorities  
 04:19 15 thought of what this actually disclosed and support it for and  
 16 to those skilled in the art about what this invention was  
 17 about.  
 18 MR. MARGOLIS: Your Honor, what did or did not happen  
 19 in the prosecution of the European patent is not impeachment  
 04:19 20 of the witness' testimony about the subject matter of the  
 21 disclosure in the underlying specification. There could be  
 22 any number of reasons why claims could have been narrowed,  
 23 could have been on the side of the applicant, could have been  
 24 on the side of the examiner, and you can't draw any inference  
 04:20 25 just from looking at the claims.

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1 supports your opinion that the skilled person would understand  
 2 that NSAIDS would tend to form complexation with benzalkonium  
 3 chloride, correct?  
 4 A. Yes, I did.  
 04:22 5 Q. Now, you don't know if the formulations in the '876  
 6 patent have any stability problems, is that correct?  
 7 A. I don't know about the formulations in this patent, I was  
 8 quoting the background teaching in the disclosure in which the  
 9 inventors called the problem to the attention of the reader.  
 04:22 10 Q. And so in looking at the '876 patent, you did not inform  
 11 your opinions as to whether there were any formulations in  
 12 there that had a complexation issue or problem, correct?  
 13 A. No, I did not see that this particular -- the  
 14 formulations that they reported here had complexation  
 04:22 15 problems.  
 16 Q. Okay. And you don't know if the '876 patent teaches a  
 17 solution therefore to the complexation problem, correct?  
 18 A. They -- you know they don't -- their formulations don't  
 19 have this turbidity issue, and I think that's the reason they  
 04:23 20 felt he deserved a patent because they had found a way to  
 21 avoid what they described as a common problem, that's the  
 22 formation of the insoluble benzalkonium NSAID complex.  
 23 Q. And their solution to a problem that was not  
 24 substantiated, is that an approach that was different from the  
 04:23 25 approach that was taken in the '431 patent?

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1 MR. DINER: Well, it will be for impeachment  
 2 purposes, your Honor, and in fact as a document that is in the  
 3 public domain and therefore prior art, it speaks to what a  
 4 person of ordinary skill in the art would have understood  
 04:20 5 based on what was broadly disclosed from Fu in his original  
 6 application than towards what was ultimately issued in terms  
 7 of the patent, including the narrowing of its specification.  
 8 MR. MARGOLIS: So then they're offering--  
 9 THE COURT: Well, it's an unlisted document, so the  
 04:20 10 question is is it being used only for impeachment purposes?  
 11 MR. DINER: Yes, your Honor.  
 12 THE COURT: I don't know that he's given inconsistent  
 13 testimony about how the patent was issued. If he had  
 14 testified as to how the Fu patent ended up being issued and  
 04:20 15 this contradicted it, I would permit it. But I don't think  
 16 that he's gone that far in his opinion, he only talked about  
 17 the application IP '984. So I don't believe it's for  
 18 impeachment purposes and I would sustain the objection.  
 19 MR. MARGOLIS: Thank you, your Honor.  
 20 BY MR. DINER:  
 21 Q. Dr. Heathcock, could you please turn to in your binder  
 22 JTX201.  
 23 A. Okay.  
 24 Q. And with regard to JTX201, which is the Desai '876  
 04:21 25 patent, you testified on direct that this patent provides or

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1 A. I'm sorry, I didn't understand that question.  
 2 Q. Well, the approach that was taken in the Desai '876  
 3 patent, is that a different approach than was taken in the  
 4 '431 patent?  
 04:23 5 A. Yes.  
 6 Q. Okay. And, just to be clear, the '876 patent does not  
 7 teach the use of tyloxapol, is that correct?  
 8 A. That's correct, tyloxapol is not in this formulation.  
 9 Q. Now, let's go to in your binder JTX207.  
 04:24 10 A. Okay.  
 11 Q. And JTX207 is the WO '597 patent that you testified about  
 12 on direct, correct?  
 13 A. Yes.  
 14 Q. Now, I'll refer to it as WO '597 patent.  
 04:25 15 The WO '597 does not teach the use of bromfenac,  
 16 correct?  
 17 A. That's correct, bromfenac is not explicitly mentioned in  
 18 this patent.  
 19 Q. Okay. And I believe that you indicated a publication  
 04:25 20 date for the WO '597 on direct. Do you recall that?  
 21 A. Yeah, I think the publication is July 1994.  
 22 Q. And by July 1994 it was known that bromfenac could be  
 23 used in aqueous ophthalmic formulations, correct?  
 24 A. I'm just not quite sure when bromfenac was first  
 04:25 25 introduced into these formulations, but I believe it was

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1 before that time, yes.

2 Q. And despite the fact that bromfenac and bromfenac

3 formulations were known, it's not mentioned anywhere in the

4 WO '597 patent as being an NSAID that has any kind of

04:26 5 complexation problem, is that correct?

6 A. No, it's not explicitly -- it's not explicitly stated. I

7 mean, this is like the other -- the other one, a generic

8 statement that this was a common problem. And benzalkonium

9 chloride was considered incompatible because it formed these

04:26 10 complexes generally, it didn't say it formed -- it didn't say

11 in the disclosure which compounds it had formed these

12 complexes with.

13 Q. And the particular NSAID that is the focus of the WO '597

14 patent is flurbiprofen, correct?

04:27 15 A. Yes.

16 Q. And WO '597 does not teach the use of tyloxapof, correct?

17 A. That's right, they use other surfactants.

18 Q. And I believe we established earlier that the WO patent

19 teaches one skilled in the art to replace benzalkonium

04:27 20 chloride with lauralkonium chloride as a way of addressing the

21 complexation issue, is that correct?

22 A. Yes, that was their invention, they found that they did

23 not get the turbid mixtures if they used lauralkonium chloride

24 instead of benzalkonium chloride.

04:27 25 Q. And the approach that was taken in WO '597 is different

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1 from the approach in the '431 patent, is that correct?

2 A. Yes.

3 Q. Now, can you please turn to JTX158 in your binder. Are

4 you there?

04:28 5 A. Yes.

6 Q. JTX158 is what you referred to on direct examination as

7 the '113 patent, is that correct?

8 A. Yes, it is.

9 Q. And I believe when referring to the '113 patent, you

04:28 10 referred to a passage at Column 1, I believe it's Lines 31

11 through 36. Does that look about right?

12 A. Yes.

13 Q. Okay.

14 A. This was a similar generic statement that benzalkonium

04:29 15 chloride is forming these -- forming these insoluble

16 complexation with anion drugs.

17 Q. Actually, if you don't mind, if you would also at the

18 same time refer to the WO patent, which is WO '597, which is

19 JTX207. And picking up on your last statement where you said

04:29 20 it's a similar generic statement, in fact the same generic

21 statement, as you put it, appears at Page 2 of the WO '597.

22 Do you see that?

23 A. Let's see. Sorry, you want me -- you want me -- let me

24 take the page out so I can compare it.

04:29 25 So you're saying you want me to compare something from

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1 the '113 patent with something that's in this other patent?

2 Q. Right. WO '597, Page 2, top of the page, and the '113

3 patent, Column 1, Line 31.

4 A. Okay. Yeah, they're pretty much the same. That's pretty

04:30 5 much the same thing.

6 Q. And it's pretty much the same thing because both patents

7 were owned by the same company?

8 A. I was just going to say that, they're both Allergan

9 patents, so it's probably not a surprise that they used the

04:30 10 same language.

11 Q. They just perpetuated a template that they had, is that

12 correct?

13 A. I don't know.

14 MR. MARGOLIS: Objection.

04:30 15 THE WITNESS: I just know they're both Allergan

16 patents, I agree with that, and they both use that same

17 paragraph.

18 THE COURT: I'll permit the answer.

19 BY MR. DINER:

04:30 20 Q. Now, let's take a further look at the '113 patent,

21 Dr. Heathcock. The '113 patent does not teach the use of

22 bromfenac, is that right?

23 A. That's right.

24 Q. And the '113 patent does not teach the use of tyloxapof,

04:31 25 is that correct?

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1 A. Yes, that's also correct.

2 Q. And the '113 patent was issued in April 1996, is that

3 correct, from the first page of that patent?

4 A. Yes, it is.

04:31 5 Q. Okay. And by that date, at least April 1996 or even its

6 filing date of March 1994, aqueous solutions of bromfenac

7 containing benzalkonium chloride were known, correct?

8 A. Well, yes, but I think they were known in terms of these

9 other products that, yeah, we heard testimony about earlier

04:32 10 today.

11 Q. Now, I'd like to refer you -- actually, one further

12 question on that. So would you agree, Dr. Heathcock, that the

13 approach taken in the '113 patent is different from the

14 approach taken in the '431 patent?

04:32 15 A. The approach -- well, they're different patents so its

16 got to have different content. Yeah. The approach I assume

17 you mean -- what do you mean by the approach?

18 Q. Well, the '113 patent, if you take a look at it, they are

19 using an amino acid as part of their invention, correct?

04:32 20 A. Yes. They use arginine as one of their components.

21 Right.

22 Q. And so the approach of the '113 patent took was different

23 from the approach taken in the '131 patent-in-suit, is that

24 right?

04:33 25 A. Yes, because they include arginine in their composition,

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- 1 in their formulation, and I don't think -- that's not a part  
2 of the '431, the patent-in-suit.
- 3 Q. Okay. I'd like to refer your attention now to JTX057. I  
4 don't know how you referred to it before, as the Bergamini  
04:33 5 patent or '560 patent?
- 6 A. I call it the '560. I have an easier time remembering  
7 numbers than names, especially when they're names like  
8 Bergamini.
- 9 Q. Fair enough. We'll refer to it as the '560 patent.  
04:33 10 Now, the '560 patent does not teach the use of  
11 bromfenac, correct?
- 12 A. That's correct.
- 13 Q. And the '560 patent does not use tyloxapol in any of the  
14 formulations in the '560 patent, correct?
- 04:34 15 A. That's also correct.
- 16 Q. I would like to refer or direct your attention to Column  
17 8 of the '560 patent that you referred to during your direct  
18 examination.
- 19 A. Okay.
- 04:35 20 Q. And, particularly, at the bottom of that column.  
21 And I would like you to please read into the record  
22 above the sentence that you referred to, the first sentence of  
23 that paragraph that begins with, "as a result."
- 24 A. Yeah, okay. I think I summarized that but didn't read  
04:35 25 it.

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- 1 A. Sounds about right.
- 2 Q. And in all of those cases in which you've testified at  
3 deposition and in trial, you've testified on behalf of a  
4 generic pharmaceutical company, correct?
- 04:37 5 A. Yes, that's correct.
- 6 Q. Dr. Heathcock, you are not an expert in pharmaceutical  
7 formulation, correct?
- 8 A. That's right, I'm not a formulation scientist.
- 9 Q. And, in fact, you've never practiced pharmacy, either,  
04:37 10 correct?
- 11 A. That's right.
- 12 Q. And you're not an expert in ophthalmology or any field of  
13 medicine, correct?
- 14 A. That's correct.
- 04:37 15 Q. You never formulated any marketed drug product, correct?
- 16 A. That's correct.
- 17 Q. And you've never authored any papers dealing with the  
18 formulation of an aqueous liquid preparation, correct?
- 19 A. Yes, that's correct.
- 04:38 20 Q. You have never authored or edited any book chapters  
21 dealing with the formulation of aqueous liquid preparations,  
22 correct?
- 23 A. That's right.
- 24 Q. And you're not an expert in the stability testing of  
04:38 25 aqueous liquid preparations, correct?

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- 1 "As a result of these experiments, we discovered the  
2 preferred conditions (pH between 8 and 9; high concentration  
3 of solubility agent) necessary to obtain a pharmaceutically  
4 acceptable solution of diclofenac and tobramycin, thus  
04:35 5 overcoming the precipitation problems of the Fu, et al.  
6 formulations."
- 7 Q. And now, would you read the second sentence into the  
8 record for context?
- 9 A. "The discovered conditions also permit including in the  
04:35 10 formulation quaternary ammonium compounds as preservatives,  
11 since these same conditions also inhibit the unacceptable  
12 interaction between diclofenac and the quaternary ammonium  
13 compounds."
- 14 Q. So would you agree with me that the sentence that you  
04:36 15 just read into the record about discovered conditions is  
16 referring to the first sentence where it says, "we discovered  
17 the preferred conditions"?
- 18 A. Yes.
- 19 Q. And those preferred conditions are a pH between 8 and 9  
04:36 20 and a high concentration of the surface -- or the solubility  
21 agent, correct?
- 22 A. Yes.
- 23 Q. Dr. Heathcock, over the past four years, you've testified  
24 at deposition and trial in 12 separate cases besides this  
04:37 25 case, correct?

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- 1 A. That's right.
- 2 Q. You never published any paper involving NSAIDs, correct?
- 3 A. That's correct.
- 4 Q. And you never conducted any research on any product  
04:38 5 containing an NSAID, correct?
- 6 A. That's also correct.
- 7 Q. And you have never formulated a product containing an  
8 NSAID, correct?
- 9 A. Yes, that's correct.
- 04:38 10 Q. You have never conducted any research on any drug product  
11 containing any nonionic surfactant, correct?
- 12 A. No, I have not used -- I have not used surfactants in my  
13 research, ionic or nonionic.
- 14 Q. And you've never formulated any product containing a  
04:39 15 nonionic surfactant, correct?
- 16 A. That's correct.
- 17 Q. You have no understanding as to how -- how complex the  
18 types of formulation problems encountered in the  
19 patents-in-suit are, correct?
- 04:40 20 A. I'm sorry. Could you --
- 21 Q. No problem.
- 22 You have no understanding as to how complex the types  
23 of formulation problems encountered in the art of the '431  
24 patent is, correct?
- 04:40 25 A. I'm not sure I understand. You say I have no

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1 understanding about it. Of how complex they are?  
2 Q. Yeah.  
3 A. You mean -- do you mean I don't really know how  
4 complicated this is or -- I don't quite know if I'm  
04:40 5 understanding.  
6 Q. Let me try again.  
7 You have no understanding about how complex the  
8 technology is that is part of the art of the '431 patent; is  
9 that correct?  
04:40 10 A. Well, I don't hold myself out to be an expert in  
11 formulation science, and so if that's what you're asking, I  
12 don't know what -- you know, the fine points of what  
13 ingredients are compatible with each other and what -- you  
14 know, why they add these different things. So if that's what  
04:41 15 you mean by the complexity, yes, I don't have an understanding  
16 of that.  
17 Q. You also don't know how a person of ordinary skill in the  
18 art would go about formulating new aqueous liquid preparations  
19 of NSAIDs, correct?  
04:41 20 A. Again, that's -- that's not my area of expertise.  
21 Q. Okay. And you don't know how a person of ordinary skill  
22 in the art would go about characterizing the physical and  
23 chemical properties of aqueous liquid preparations of NSAIDs,  
24 correct?  
04:41 25 A. Well, no, I do know more about that. I mean, I know  
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1 about how to analyze things, and so I can certainly -- I know  
2 how to measure properties but ...  
3 Q. Well, I would like to go to your deposition transcript at  
4 Page 109, please. We will just put it up. Noel, can you put  
04:41 5 up Page 109, Lines 12 to 20.  
6 So the question that was asked at your deposition,  
7 Dr. Heathcock, was: "How would a person of ordinary skill in  
8 the art go about characterizing the physical and chemical  
9 properties of aqueous liquid preparations of NSAIDs?"  
04:42 10 There was an objection, and then you responded: It's  
11 something that I studied so -- "It's not something that I  
12 studied so I don't have -- I don't really know."  
13 A. Can I see what came after that? I'm not sure. Is that  
14 the end of my answer?  
04:42 15 Q. Yes.  
16 A. Okay. Well, you know, as I say, I don't know exactly  
17 what you would do but I -- if you say that you want me to  
18 determine the viscosity of something, I know how to do that,  
19 but I don't know what things to do.  
04:42 20 Q. And you don't know what things to do in terms of  
21 formulating NSAIDs into pharmaceutical formulations, correct?  
22 A. A person who -- who specializes in developing  
23 formulations would know what kind of tests they need to do. I  
24 wouldn't know that. If they asked me to determine the  
04:43 25 viscosity or the density or the -- you know, or the opacity, I  
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1 know how to do those things, but I'd have to be told which  
2 thing, which measurements to make.  
3 MR. DINER: Your Honor, I have no further questions.  
4 THE COURT: Is there any redirect?  
04:43 5 MR. MARGOLIS: No, your Honor.  
6 THE COURT: Okay. I don't have any questions,  
7 either, so you may step down. Thank you.  
8 (The witness left the stand.)  
9 MR. MALIK: Good afternoon, Your Honor.  
10 THE COURT: Good afternoon.  
11 MR. MALIK: Jitendra Malik, counsel for InnoPharma.  
12 MR. HASFORD: And I apologize, Your Honor. I don't  
13 mean to cut off my opponent here, Dr. Malik, but one of the  
14 court reporters asked us for a list of the chemical names that  
04:44 15 were read into the record and we have that to provide to the  
16 court reporting staff, your Honor.  
17 THE COURT: Okay. Let's take a moment.  
18 (Discussion held off the record.)  
19 MR. MALIK: Okay. Your Honor, may I proceed?  
04:44 20 THE COURT: Yes.  
21 MR. MALIK: Defendants call Dr. Robert Cykiert.  
22 THE COURT: Okay, Dr. Cykiert, please come to the  
23 witness stand.  
24 THE DEPUTY CLERK: Sir, can you please place your  
04:45 25 left hand on the Bible and raise your right hand.  
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1 (ROBERT CYKIERT, HAVING BEEN DULY SWORN/AFFIRMED, TESTIFIED AS  
2 FOLLOWS:)  
3 THE WITNESS: Yes, I do.  
4 THE DEPUTY CLERK: Can you please state your name,  
04:45 5 sir, and spell your first and last name.  
6 THE WITNESS: Sure. It's Robert Cykiert,  
7 R-O-B-E-R-T, and last name is C-Y-K-I-E-R-T.  
8 THE DEPUTY CLERK: Thank you, sir. Can you please  
9 speak into the microphone.  
04:45 10 MR. MALIK: Your Honor, may my -- can my colleague  
11 pass the binder?  
12 THE COURT: Yes.  
13 MR. MALIK: May he approach?  
14 THE COURT: Thank you.  
04:45 15 (DIRECT EXAMINATION OF ROBERT CYKIERT BY MR. MALIK:)  
16 Q. Good afternoon, Dr. Cykiert.  
17 A. Good afternoon.  
18 Q. Would you please state your full name and address for the  
19 record.  
04:46 20 A. Sure. It's Robert Cykiert, and it's 345 East 37th  
21 Street, New York, New York, 10016.  
22 Q. Can you briefly describe for the Court your educational  
23 background after high school?  
24 A. Sure. I went to Brooklyn College, which is part of the  
04:46 25 City University of New York, from 1969 to 1973, and I  
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1 graduated with a B.S. Degree in Chemistry.

2 Following that, I went to New York Medical College,  
3 which is in Westchester, New York, from 1973 to 1976 and  
4 graduated with an M.D. Degree.

04:46 5 After that, I did a year of internship in Internal  
6 Medicine at Lenox Hill Hospital in New York City, from 1976 to  
7 1977.

8 Following that, I did a three-year residency in  
9 ophthalmology at the Albert Einstein College of Medicine in  
04:47 10 Bronx, New York, from 1977 to 1980. And in my last year, I  
11 was picked as the chief resident.

12 Q. Did you have any further post-medical-school training?

13 A. Yes. After completing my three-year ophthalmology  
14 residency, I did a fellowship in Cornea and External Disease  
04:47 15 at the Wills Eye Hospital, which is nearby in Philadelphia.

16 Q. And after your medical training was complete, what did  
17 you do?

18 A. After that, I went back to New York City and went into  
19 private practice and additionally joined the faculty of the  
04:47 20 NYU Medical Center in Manhattan.

21 Q. Are you currently employed?

22 A. Yes, I am. I'm self-employed currently in my medical  
23 practice.

24 Q. Do you have a private practice?

04:48 25 A. Yes, I do.

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1 Q. And where do you currently practice?

2 A. At the address I gave, 345 East 37th Street in New York  
3 City.

4 Q. Are you an attending surgeon anywhere?

04:48 5 A. Yes. I'm an attending physician and surgeon at NYU  
6 Medical Center, also at the New York Eye and Ear Infirmary,  
7 which is part of the Mount Sinai Medical Center in Manhattan,  
8 and also the Manhattan Eye, Ear and Throat Hospital.

9 Q. How long have you had attending privileges?

04:48 10 A. Since 1981, when I finished my fellowship, so it's about  
11 35 years now.

12 Q. You also mentioned that you have a position at the New  
13 York Medical University Center; is that correct?

14 A. Yeah. NYU Medical Center, right.

04:48 15 Q. What is your current title at NYU Medical Center?

16 A. I'm a Clinical Associate Professor of Ophthalmology  
17 there.

18 Q. And how long have you been with NYU Medical Center?

19 A. Since 1981.

04:49 20 Q. Can you describe for me what you do at NYU Medical  
21 Center?

22 A. Sure. I do several things there.

23 One is I do surgery on my patients there.

04:49 24 I also teach ophthalmology residents who are in  
25 training, and I teach them about the medical and surgical

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1 aspects of ophthalmology.

2 And I also teach medical students who rotate through  
3 the various affiliated hospitals of NYU School of Medicine and  
4 Medical Center.

04:49 5 Q. Do you serve on any committees at NYU?

6 A. Yes, I do.

7 Q. Which ones?

8 A. Well, currently, I have been on the Credentials  
9 Committee. In the past, I've been on the Pharmacy and  
04:49 10 Therapeutics Committee of the NYU Medical Center.

11 Q. When were you on the Pharmacy and Therapeutics Committee?

12 A. From 1983 to 1991.

13 Q. Okay. Let's focus first on the Pharmacy and Therapeutics  
14 Committee at the NYU Medical Center. What is that?

04:50 15 A. It's a committee composed of physicians in all the  
16 specialties in medicine, and we meet regularly to review in  
17 great detail any medications that might be admitted to the  
18 formulary at the hospital.

19 For example, if there's a new drug approved by the FDA,  
04:50 20 before the hospital admits it into the hospital formulary,  
21 before doctors can use it, prescribe it, the Pharmacy and  
22 Therapeutics Committee evaluates the drug.

23 We also from time to time will reevaluate other drugs  
24 that have been approved in the past but possibly new adverse  
04:50 25 side effects may be known or there might be some issues with

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1 the drug, or perhaps newer drugs or medications have come in,  
2 and so we might decide to remove some medications from the  
3 hospital formulary from time to time.

4 Q. What was your specific role on that committee?

04:51 5 A. My specific role was to evaluate any medication that's  
6 brought forward to the committee for approval for the hospital  
7 formulary, and also for any medication that might be taken  
8 off. That includes both ophthalmic drugs as well as other  
9 systemic medications.

04:51 10 Q. Now, you also mentioned the Credentials Committee that  
11 you serve on. What is the Credentials Committee?

12 A. The Credentials Committee at NYU Medical Center basically  
13 decides whether to allow physicians on staff. Somebody may be  
14 applying to join the staff at NYU Hospital because they want  
04:51 15 to admit their patients there or they want to do surgery  
16 there. This committee, which is comprised of every specialty  
17 in medicine and surgery, goes through the doctors' credentials  
18 in great detail to make sure they have the correct  
19 qualifications and meet all the regulatory requirements to  
20 join the staff.

21 Also, on a regular basis, approximately every two  
22 years, we go through the credentials of every doctor to make  
23 sure they are fulfilling all their requirements for remaining  
24 on staff.

04:52 25 Q. And what is your role on that committee?

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1 A. My role is to evaluate every physician who has applied to  
 2 join the staff and also who has applied every couple of years  
 3 to be recredentialed.  
 4 Q. Okay. Now, you also mentioned that you still maintain a  
 04:52 5 private practice. How long have you had that practice?  
 6 A. Since 1981, so 35 years, approximately.  
 7 Q. And approximately how many patients do you see each week?  
 8 A. It varies from about 120 to 150 patients per week.  
 9 Q. And do you still perform eye surgeries?  
 04:52 10 A. Yes, I do, regularly.  
 11 Q. What kind of eye surgeries do you perform?  
 12 A. I perform a variety of surgeries, things like cataract  
 13 surgery, refractive surgery, laser vision correction, corneal  
 14 transplant surgery, LASIK, PRK, and other types of surgeries.  
 04:53 15 Q. Let's focus a little bit on cataract surgery. How many  
 16 cataract surgeries do you perform each week?  
 17 A. Currently, approximately five to six per week, on the  
 18 average.  
 19 Q. And over the course of your career, how many cataract  
 04:53 20 surgeries have you performed?  
 21 A. I've performed thousands of cataract surgeries over the  
 22 past 35 years.  
 23 Q. Dr. Cykiert, I believe you have a binder in front of you.  
 24 Would you mind turning to DTX-446?  
 04:53 25 A. Okay, I have it.

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1 website to look up information about various drugs that have  
 2 been approved or are in the process of undergoing clinical  
 3 trials.  
 4 Q. Are you active in any professional organizations?  
 04:55 5 A. Yes. I've been active in many. Currently the most  
 6 important one is the American Academy of Ophthalmology.  
 7 Q. What is the American Academy of Ophthalmology?  
 8 A. It's the largest organization or association of  
 9 ophthalmologists worldwide. They're -- about 90 percent of  
 04:55 10 all USA ophthalmologists are members, and thousands of other  
 11 doctors in other countries belong to the American Academy of  
 12 Ophthalmology.  
 13 Q. Do you recall how long you have been a member of that  
 14 academy?  
 04:56 15 A. Since 1981, when I first finished my fellowship and  
 16 started practice.  
 17 Q. Have you published any papers in the field of  
 18 ophthalmology?  
 19 A. Yes, I have.  
 04:56 20 Q. How many?  
 21 A. Approximately 37.  
 22 Q. And have you presented any lectures or presentations in  
 23 the field of ophthalmology?  
 24 A. Yes, I have.  
 04:56 25 Q. How many?

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1 Q. Dr. Cykiert, could you identify DTX-446?  
 2 A. Sure. That's my curriculum vitae, C.V., or resume.  
 3 Q. Does DTX-446 accurately reflect your education and  
 4 experience?  
 04:54 5 A. Yes, it does.  
 6 Q. Now, Dr. Cykiert, I would like to ask you a few questions  
 7 about your involvement in matters outside your professional  
 8 practice.  
 9 Over the course of your career, have you followed the  
 04:54 10 literature related to post-cataract, cataract surgery  
 11 treatments?  
 12 A. Sure, I follow the literature very carefully all the  
 13 time. I read several journals every month. I have to stay on  
 14 top of the latest developments in eye surgery and cataract  
 04:54 15 surgery and ophthalmology, especially because I teach  
 16 residents and medical students, so I have to be updated on the  
 17 latest news and the latest research and the latest articles  
 18 that come out.  
 19 Q. Let me ask you, have you participated in any clinical  
 04:54 20 trials?  
 21 A. I personally have not participated in any clinical  
 22 trials, but I have a good knowledge of how clinical trials  
 23 work. I frequently have to review the results of clinical  
 24 trials with regard to medications that I may be using or that  
 04:55 25 I come across, and I frequently go to the clinicaltrials.gov

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1 A. I've given about 150 lectures to other ophthalmologists,  
 2 doctors and residents, and also I've been interviewed on TV a  
 3 couple of dozen times on various eye, vision, and  
 4 ophthalmology-related topics.  
 04:56 5 Q. Have you won any awards or received any recognition in  
 6 connection with your work in ophthalmology?  
 7 A. Yes, I have. For four years in a row consecutively, I've  
 8 been nominated and voted for as one of the best  
 9 ophthalmologists in New York, as per New York Magazine, and  
 04:57 10 this is a peer-review nomination and voting by other  
 11 ophthalmologists, as well as other doctors of various  
 12 specialties.  
 13 MR. MALIK: Your Honor, at this time defendants offer  
 14 Dr. Cykiert as a medical expert in the field of ophthalmology  
 04:57 15 and ophthalmic surgery, including cataract surgery and  
 16 postoperative treatment regimens.  
 17 MR. LIPSEY: No objection.  
 18 THE COURT: All right. Then the Court will recognize  
 19 Dr. Cykiert as an expert in those fields.  
 04:57 20 MR. MALIK: Thank you, your Honor.  
 21 BY MR. MALIK:  
 22 Q. Dr. Cykiert, why have you been called today to testify?  
 23 A. I have been called today to basically discuss  
 24 Dr. Trattler's opinions that he's given earlier today and  
 04:57 25 yesterday.

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- 1 Q. So you were present when Dr. Trattler was on the stand  
2 yesterday and this morning?  
3 A. Yes, I was.  
4 Q. Okay. And did you form any opinions of your own  
04:58 5 regarding his testimony?  
6 A. Yes, I did.  
7 Q. Okay. Before we get into the substance of your opinions,  
8 why don't we focus a little bit on the background, the  
9 relevant background.  
04:58 10 Let's talk briefly about cataract surgery. What is a  
11 cataract?  
12 A. A cataract is a clouding of the natural lens of the eye.  
13 Each one of us has a lens that sits behind our pupil. That  
14 lens focuses the light that comes into the eye and gives us a  
04:58 15 clear image and allows us to see properly. A cataract is when  
16 this lens becomes cloudy, usually due to an aging process. If  
17 the lens is cloudy, then it can no longer focus images  
18 properly, and our vision gets blurry and distorted and hazy.  
19 Q. Dr. Cykiert, how are cataracts treated?  
04:58 20 A. When the cataract gets to a point where it significantly  
21 interferes with the patient's life or activities or  
22 functioning or work, we do surgery to remove the cataract.  
23 Q. What is the name of the surgery?  
24 A. The most common surgery that is used is  
04:59 25 phacoemulsification.

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- 1 Q. Can you briefly describe for the Court what the process  
2 of phacoemulsification involves?  
3 A. Sure. Basically, I make a small incision into the eye,  
4 usually it's about 2.4 millimeters, which is approximately a  
04:59 5 tenth of an inch. I then insert a probe into the eye called a  
6 phacoemulsification probe. What that does is by high  
7 frequency vibration, it turns the solid cataract into a  
8 liquid, and then I aspirate or vacuum out this liquid from the  
9 eye. In the process, I leave behind what's called the capsule  
04:59 10 of the cataract. I then put a small plastic lens in the eye  
11 called an intraocular lens, and I insert that into the  
12 capsule, so that now the eye has a new lens that can focus  
13 light clearly and sharply.  
14 Q. In your experience, how long does it take a patient to  
05:00 15 recover from cataract surgery?  
16 A. The recovery these days is very quick. Almost all of my  
17 patients are able to go back to their normal activities the  
18 day after surgery.  
19 Q. Do any of your patients experience pain or inflammation?  
05:00 20 A. Most patients who have cataract surgery have some mild  
21 inflammation, but with current techniques, the inflammation is  
22 usually mild.  
23 With regard to pain, only a small, very small minority  
24 of patients experience pain with the current modern techniques  
05:00 25 which you saw a video of yesterday.

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- 1 Q. How do doctors treat pain and inflammation after cataract  
2 surgery?  
3 A. The universal way that I do and all other  
4 ophthalmologists is by treating the patient with  
05:00 5 corticosteroid eyedrops after the cataract surgery.  
6 Q. What are corticosteroids?  
7 A. Corticosteroids are a class of steroid medications which  
8 basically, through several pathways, prevent and get rid of  
9 inflammation inside the eye and also eliminate pain inside the  
05:01 10 eye.  
11 Q. Are you familiar with nonsteroidal anti-inflammatory  
12 drugs?  
13 A. Yes, I am.  
14 Q. What are they?  
05:01 15 A. Nonsteroidal antiinflammatories, or NSAIDs for short, are  
16 a different type of anti-inflammatory eyedrop that also has  
17 some effects on inflammation and pain after cataract surgery.  
18 Q. Does Prolensa® contain a NSAID drug?  
19 A. Yes, Prolensa® is one of the NSAID drops.  
05:01 20 Q. And have you prescribed Prolensa®?  
21 A. Yes, I have.  
22 Q. From your experience, what do you understand to be the  
23 side effects of Prolensa®?  
24 A. Well, Prolensa® has a number of side effects. They can  
05:02 25 be things like photophobia or light sensitivity; there's

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- 1 burning, there's stinging; there's sometimes pain and  
2 inflammation in the front of the eye; there's also foreign  
3 body sensation as well.  
4 Q. Can you turn in your binder to JTX023?  
05:02 5 A. Okay, I have it.  
6 Q. What is JTX023?  
7 A. This is the package insert which is the official FDA  
8 package insert for Prolensa®.  
9 Q. Let me direct your attention to Paragraph 6.1 of JTX023.  
05:03 10 Now, you mentioned earlier that, from your experience,  
11 you see burning and stinging with your patients who are using  
12 Prolensa®. Do you recall that testimony?  
13 A. Yes, I said that.  
14 Q. Let me ask you this: Do you see burning and stinging  
05:03 15 listed as a side effect on the label for Prolensa®?  
16 A. No, I don't see it there.  
17 Q. Then let me ask you: What basis do you have for  
18 indicating that burning and stinging are side effects for  
19 Prolensa®?  
05:03 20 A. The basis is that my patients, after I prescribe  
21 Prolensa®, come back to me postoperatively, they speak with  
22 me, they tell me they're taking it and they have symptoms of  
23 burning and stinging and sometimes other side effects, so I  
24 hear it directly from my patients.  
05:03 25 Q. Now, in connection with your patients, how do they

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1 typically explain the burning and stinging manifests itself?  
 2 A. Typically, they tell me it's kind of mild and persists  
 3 for only a few seconds, in other words, it's transient, it's  
 4 usually not significant. But patients don't know whether  
 05:04 5 burning or stinging is significant or not, so they just  
 6 mention it to me and say, "Is that okay?" And I tell them,  
 7 "Sure, that's expected, don't worry about it, and it only  
 8 lasts for a brief few seconds and it's very mild."  
 9 By the way, that's very different than the example you  
 05:04 10 heard yesterday from Dr. Trattler who said that it's like  
 11 getting lemon juice in your eye. Now, for those of you who  
 12 have experienced lemon juice in your eye, which I'm sure some  
 13 of you have, you know that that's severe burning and stinging.  
 14 That will stop you in your tracks. You won't be able to  
 05:04 15 continue what you're doing. It may take you three, four, five  
 16 minutes to recover from that. That is radically different  
 17 than the burning and stinging that you get from Prolensa®  
 18 which is transient, lasts only for a few seconds. So the  
 19 lemon juice example is, I think, a highly exaggerated burning  
 05:05 20 and stinging.  
 21 Q. In your experience, is burning and stinging common to all  
 22 ophthalmic NSAIDs?  
 23 A. Yes. It's common to all of them, and, in fact, it's  
 24 common to most ophthalmic eyedrops, even non-NSAIDs.  
 05:05 25 Q. Switching gears a little bit, Dr. Cykiert, did you hear  

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1 Dr. Trattler testify regarding the role of pH in the side  
 2 effect profile for Prolensa®?  
 3 A. Yes, I did, I heard that.  
 4 Q. Do you agree with Dr. Trattler's opinions that  
 05:05 5 Prolensa®'s lower pH improves its side effect profile?  
 6 A. I disagree with that.  
 7 Q. Why do you disagree with Dr. Trattler's opinion?  
 8 A. Well, for several reasons. There's no clinical evidence  
 9 whatsoever that reducing the pH is of any benefit or value.  
 05:06 10 My patients who take Prolensa®, with the different pH, still  
 11 have burning and stinging.  
 12 Now, yes, you might expect possibly, gee, if I lower  
 13 the pH, it might be better, but clinically speaking, from a  
 14 clinical perspective, there is no benefit whatsoever that's  
 05:06 15 been demonstrated.  
 16 Q. Dr. Cykiert, do you also recall Dr. Trattler testifying  
 17 regarding CME or cystoid macular edema?  
 18 A. Yes, I do.  
 19 Q. Okay. And I'm just going to call it CME for short. Is  
 05:06 20 that fair?  
 21 A. That's a good abbreviation, right.  
 22 Q. All right. What's CME?  
 23 A. CME or cystoid macular edema is a swelling or fluid  
 24 buildup in the center of the retina called the macula, which  
 05:06 25 occurs after cataract surgery. But it's very important to  

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1 know the facts and to differentiate that there are two  
 2 different types of CME. There is something called clinical  
 3 CME, which is significant, occurs in approximately 2 to 5  
 4 percent of patients who have cataract surgery; and then  
 05:07 5 there's something called clinically insignificant or  
 6 subclinical CME, which occurs in a greater percentage, maybe  
 7 15 percent or possibly more in some studies, but this is a  
 8 very minimal swelling and a very minimal buildup of fluid in  
 9 the retina such that the patient has no symptoms from this.  
 05:07 10 The patient would not complain about blurry vision, and also,  
 11 myself, the ophthalmologist or other doctors, will not  
 12 actually see it during their examination using standard  
 13 examination techniques. So subclinical CME is not clinically  
 14 significant.  
 05:07 15 Q. Dr. Cykiert, would you please turn in your binder to  
 16 PTX-281. Let me know when you are there.  
 17 A. Yes, I have that.  
 18 Q. Is PTX-281 the document that Dr. Trattler discussed this  
 19 morning?  
 05:08 20 A. Yes, it is.  
 21 Q. Let me direct your attention to PTX-281, first page,  
 22 under "Conclusions." And can you please read for the Court  
 23 the first sentence right after "Conclusions"?  
 24 A. Sure. It's "Cystoid macular edema after cataract surgery  
 05:08 25 has a tendency to resolve spontaneously."  

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1 Q. What does that sentence mean to you?  
 2 A. That means that in most cases, the vast majority of  
 3 cases, CME resolves on its own, without any problems or  
 4 clinical difficulties.  
 05:08 5 Q. Now, when discussing this article this morning, PTX-281,  
 6 did you also hear Dr. Trattler make a distinction between  
 7 short-term and long-term recovery for CME using NSAIDs?  
 8 A. Yes, I did, I heard that.  
 9 Q. Okay. Let me direct your attention again to the first  
 05:09 10 page of PTX-281, under "Results," the first complete sentence.  
 11 Can you read that sentence into the record?  
 12 A. Sure.  
 13 "Nonsteroidal anti-inflammatory drug therapy was  
 14 effective in reducing CME detected by angiography or optical  
 05:09 15 coherence tomography, OCT, and may increase the speed of  
 16 visual recovery after surgery when compared directly with  
 17 placebo or topical corticosteroid formulations with limited  
 18 intraocular penetration."  
 19 Q. Let me ask you: Do you agree with Dr. Trattler's  
 05:10 20 characterization of this article with respect to the purported  
 21 short-term benefits for using NSAIDs for treating CMEs?  
 22 A. I disagree with Dr. Trattler.  
 23 Q. In your opinion, what does this article conclude about  
 24 any short-term benefits of using NSAIDs for treating CME?  
 05:10 25 A. So, if you're talking about short-term, yeah, maybe  

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1 NSAIDs have some value, if you're comparing them to placebo.  
 2 They may have some value if you're comparing them to a weak  
 3 steroid. They may have some value if you're talking about  
 4 subclinical CME, which I discussed before. But we don't treat  
 05:10 5 with weak steroids after cataract surgery. We treat with  
 6 potent steroid eyedrops. We never prescribe placebo for  
 7 patients. So we also, as I mentioned, don't treat subclinical  
 8 CME. So, therefore, this short-term benefit of NSAIDs is  
 9 clinically totally insignificant and irrelevant.  
 05:11 10 Q. I have no further questions at this time. Thank you.  
 11 A. Thank you.  
 12 THE COURT: Okay. Thank you. Cross-examination?  
 13 MR. LIPSEY: May it please the Court, Charlie Lipsey  
 14 for plaintiffs.  
 05:11 15 We have a binder, if we may hand it up.  
 16 THE COURT: Very well.  
 17 (CROSS EXAMINATION OF ROBERT CYKIERT BY MR. LIPSEY:)  
 18 Q. Are we all set? Okay.  
 19 Good afternoon, Dr. Cykiert.  
 05:12 20 A. Good afternoon.  
 21 Q. I would like to start by exploring a little bit your  
 22 sense of minimal, as you described it, in terms of the effect  
 23 of some of these effects.  
 24 And to lay a little foundation, could you turn, please,  
 05:13 25 in your binder to JTX51.

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1 of their own products, correct?  
 2 A. Again, they make the product. I think other people can  
 3 review the products, and there are different types of  
 4 authorities. There may be differences of opinion between what  
 05:14 5 Novartis says about their drugs and what other parties say  
 6 about their drugs. So it's -- it's a difficult answer because  
 7 it's -- the question is not precise.  
 8 Q. Do you think that the information put out by Novartis  
 9 about its own products is unreliable?  
 05:15 10 A. I didn't say that, but I don't see anywhere on this  
 11 sheet where --  
 12 MR. MALIK: Objection.  
 13 THE COURT: Just a moment, please.  
 14 MR. MALIK: Your Honor, again, objection. Outside  
 05:15 15 the scope. We are well past foundation at this point.  
 16 THE COURT: I'm going to sustain the objection. I  
 17 don't believe that he relied upon anything about Voltaren.  
 18 MR. LIPSEY: He has testified that the burning that  
 19 is seen is mild, and I'm about to show that at least Novartis  
 05:15 20 doesn't -- and minimal, and involves only a few people, that  
 21 Novartis doesn't feel the same way. It's an impeachment  
 22 point, your Honor.  
 23 MR. MALIK: Your Honor he, testified about his  
 24 experience with his patients. He didn't make any  
 05:15 25 representations about what Novartis did on the FDA or its

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1 A. That's JTX051?  
 2 Q. Yes.  
 3 A. Okay. I have it.  
 4 Q. Okay. And that's the sheet from drugs@FDA that indicates  
 05:13 5 the date of approval of Voltaren, diclofenac sodium, correct?  
 6 MR. MALIK: Objection, Your Honor, outside the scope.  
 7 MR. LIPSEY: This is foundation to get to the  
 8 question I need to ask.  
 9 THE COURT: Okay, I'll permit it as foundation.  
 05:13 10 BY MR. LIPSEY:  
 11 Q. Okay. And that product was approved in March of 1991 by  
 12 Novartis, correct?  
 13 A. It says 1991. And where does it say Novartis?  
 14 Q. Right above 1991.  
 05:13 15 A. Right.  
 16 Q. Okay. Now, it's your view that a very small percentage  
 17 of patients report mild stinging and/or burning when using  
 18 diclofenac drops, correct?  
 19 A. Right.  
 05:14 20 Q. And you would recognize Novartis as a reliable authority  
 21 on ophthalmic NSAIDs, correct?  
 22 A. They're a manufacturer of the product. Whether they're  
 23 reliable authority, it depends how you define reliable  
 24 authority.  
 05:14 25 Q. Well, reliable authority about the nature and properties

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1 label. Again, we think it's outside the scope.  
 2 THE COURT: Is this document in evidence, JTX51?  
 3 MR. LIPSEY: I believe it was offered in evidence  
 4 this morning, with Dr. Trattler.  
 05:16 5 THE COURT: If it's in evidence, then I'll permit  
 6 questioning from it.  
 7 MR. MUKERJEE: Your Honor, I do not believe it's been  
 8 entered into evidence.  
 9 THE COURT: All right. It's in the list to be  
 05:16 10 considered from this morning.  
 11 THE DEPUTY CLERK: Yes.  
 12 THE COURT: Is there any objection to this document  
 13 being received into evidence?  
 14 MR. LIPSEY: No.  
 05:16 15 MR. MALIK: No, your Honor.  
 16 THE COURT: All right. Then I'll permit limited  
 17 questioning from the document.  
 18 MR. LIPSEY: Well, let me move on to the next  
 19 exhibit.  
 05:16 20 THE COURT: No, you can't do this to me.  
 21 MR. LIPSEY: Okay.  
 22 (Laughter.)  
 23 THE COURT: No, go ahead.  
 24 MR. LIPSEY: In order to vindicate the effort, your  
 05:16 25 Honor, I'll try one more time.

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1 THE COURT: No, I'm sorry.  
2 MR. LIPSEY: No, no, no, I understand.  
3 BY MR. LIPSEY:  
4 Q. Could you take a look at JTX135, please.  
05:17 5 A. Okay, I have that.  
6 Q. Okay. And that's -- you recognize that as the Voltaren  
7 package insert, correct?  
8 A. It appears to be, that's correct.  
9 Q. Okay. And if you'll turn to the fourth page of the  
05:17 10 exhibit, under the heading "Adverse Reactions Ocular," we see  
11 there that Novartis reports that transient burning and  
12 stinging were reported in approximately 15 percent of patients  
13 across studies with the use of Voltaren Ophthalmic. Do you  
14 see that?  
05:17 15 A. Right. I see that. And you'll notice the first word in  
16 that sentence is "transient," and you'll recall that I defined  
17 "transient" previously as momentary, lasting a few seconds,  
18 and being clinically insignificant.  
19 Q. Okay. And that 15 percent there that Novartis  
05:17 20 recognizes, that's what you called a very small percentage,  
21 correct?  
22 A. That 15 percent speaks for itself. You can say that's  
23 either small or large. It's 15 percent.  
24 The main point is, is that it's transient, it's mild,  
05:18 25 it's clinically insignificant. Patients are not bothered by  
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1 it. They may mention it to me, "Doc, by the way, this drop  
2 burns and stings a little. Is that okay?" And I'll say,  
3 "Yeah, don't worry about it, that's pretty common, some people  
4 have that." It's transient, it's mild, it's clinically  
05:18 5 insignificant.  
6 Q. I'm happy to work with you, if there are things you want  
7 to say that explain your answer, that's fine. If you could  
8 try to answer my question first, I'll try to be fair and let  
9 you then explain. Okay?  
05:18 10 A. Okay.  
11 Q. You said that a very small percentage of patients report  
12 mild stinging with diclofenac, correct?  
13 A. I said that, right.  
14 Q. Okay.  
05:18 15 MR. MALIK: Your Honor, objection, outside the scope  
16 again. He never provided any testimony about diclofenac.  
17 MR. LIPSEY: He testified about all NSAIDs. He said  
18 that they -- that the effects are mild and minor and nobody  
19 cares about them, in sum or substance, is what the testimony  
05:19 20 was. And I'm simply trying to show that there is some  
21 contrary authority out there on this point.  
22 THE COURT: I'll permit it. It's impeachment  
23 evidence.  
24 BY MR. LIPSEY:  
05:19 25 Q. Okay. And by pouring a foundation, if you could take a  
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1 look at JTX52, which was also offered into evidence earlier  
2 today. That's the drugs@FDA information about the approval of  
3 Acular, right?  
4 A. Yes.  
05:19 5 Q. Okay. And it indicates that Acular contains ketorolac,  
6 was approved in November of 1992, and is marketed by Allergan,  
7 correct?  
8 A. Right.  
9 Q. Okay. Now, you have said that people on Acular reported  
05:20 10 some mild stinging and/or burning on administration, correct?  
11 A. Where do you see that?  
12 Q. Why don't we take a look at your expert report, Page 11,  
13 Paragraph 36.  
14 MR. MALIK: Your Honor, again, objection, outside the  
05:20 15 scope.  
16 MR. LIPSEY: It's exactly the same point, your Honor.  
17 THE COURT: He may be questioned on the prior  
18 statements. I'll permit it.  
19 BY MR. LIPSEY:  
05:20 20 Q. Now, four lines down, it says, "Also, similarly to  
21 Voltaren, patients using Acular -- and the preservative-free  
22 formulation Acular PF first marketed in 1997 -- reported some  
23 mild stinging and/or burning upon administration." That's  
24 what you said there.  
05:21 25 A. That's correct. Because if you look at the Acular  
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1 package insert, you'll also have that word "transient" which  
2 means mild and clinically insignificant.  
3 And, by the way, you misquoted me a few minutes ago  
4 saying that nobody cares about this stuff. I never said that.  
05:21 5 That was an exaggeration of what I said. I just want to  
6 clarify that.  
7 Q. Okay. That's important. Thank you.  
8 A. Okay.  
9 Q. Can you take a look at plaintiff's trial Exhibit 265?  
05:21 10 A. Okay, I have that.  
11 Q. Okay. This is the package insert for Acular, right?  
12 A. Yes, it is.  
13 Q. Okay. And, again, do you recognize Allergan as a  
14 reliable authority about the properties and benefits and  
05:22 15 advantages of its own drugs?  
16 A. We talked about that earlier, and I'm not prepared to say  
17 whether Allergan is a reliable authority or not. It depends  
18 on your definition. We can debate the definition endlessly.  
19 Q. Let's use your definition. Using your definition, do you  
05:22 20 regard Allergan as a reliable authority about the properties  
21 of its own drug products?  
22 A. I don't believe I've come up with a definition yet.  
23 Q. Of "reliable"?  
24 A. Yeah. I don't have a definition for that. That's not  
05:22 25 what I was asked to do. I'd have to think about what that  
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1 means and define it before I could answer your question.  
 2 THE COURT: Excuse me. May I suggest rephrasing the  
 3 question? Do ophthalmologists rely upon a publication of this  
 4 type?  
 05:22 5 MR. LIPSEY: Sure. Thank you, your Honor.  
 6 BY MR. LIPSEY:  
 7 Q. Do ophthalmologists rely upon the information provided by  
 8 Allergan about the properties of its own drug products in  
 9 making decisions in the course of their work?  
 05:23 10 A. Yes, definitely.  
 11 Q. Okay. And -- okay. Thank you.  
 12 Now, if we go to the fourth page of the exhibit, under  
 13 the heading "Adverse Reactions," it states there, "The most  
 14 frequent adverse events reported with the use of ketorolac  
 05:23 15 tromethamine ophthalmic solutions have been transient stinging  
 16 and burning on instillation. These events were reported by up  
 17 to 40 percent of patients participating in clinical trials."  
 18 Do you see where I read?  
 19 A. Yes, I see that.  
 05:23 20 Q. Okay. And that's what you had described as some mild  
 21 stinging, correct?  
 22 A. Yes. Again, the word "transient" is used there, as I  
 23 mentioned earlier, and that is -- means mild and clinically  
 24 insignificant.  
 05:24 25 Q. Okay. And just, again, by way of foundation, back on the  
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1 first page of PTX-265, the package insert, Acular had a .01 --  
 2 I'm sorry -- .5 percent ketorolac and .01 percent benzalkonium  
 3 chloride, right?  
 4 A. Yes, I see that.  
 05:24 5 Q. Okay. Now, you would agree that eliminating or reducing  
 6 ocular irritation from Acular has the potential for improving  
 7 tolerability compliance and effectiveness of treatment,  
 8 correct?  
 9 MR. MALIK: Your Honor, objection, outside the scope.  
 05:24 10 MR. LIPSEY: It's the very essence of the invention  
 11 here, your Honor.  
 12 MR. MALIK: Your Honor, Acular is not at issue in  
 13 connection with the patents-in-suit.  
 14 THE COURT: Is the question directed at Acular?  
 05:25 15 MR. LIPSEY: It is directed at Acular.  
 16 MR. MALIK: He offered no testimony regarding  
 17 preservatives. Dr. Cykiert offered no testimony on  
 18 benzalkonium chloride when he was on the stand.  
 19 MR. LIPSEY: The witness, as I understand his  
 05:25 20 testimony, has suggested that the elimination or reduction of  
 21 ocular irritation doesn't have the potential of improving  
 22 tolerability, compliance or effectiveness, and I want to  
 23 explore that.  
 24 THE COURT: Did the witness offer an opinion on  
 05:25 25 tolerability and effectiveness of the patent?  
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1 MR. MALIK: On the patent? No, Your Honor.  
 2 MR. LIPSEY: I believe the testimony was or the point  
 3 of the testimony was that there's no particular advantage to  
 4 Prolensa® because of the reduced burning and stinging, and I  
 05:26 5 would like to challenge that.  
 6 THE COURT: Right. I mean, I think all the questions  
 7 were asked in terms of burning and stinging rather than  
 8 effectiveness or compliance.  
 9 MR. LIPSEY: Well, I believe --  
 05:26 10 THE COURT: But I'll permit the pending question.  
 11 MR. LIPSEY: Thank you.  
 12 BY MR. LIPSEY:  
 13 Q. You would agree that eliminating or reducing ocular  
 14 irritation from Acular has the potential for improving  
 05:26 15 tolerability, compliance, and effectiveness of treatment,  
 16 correct?  
 17 A. The keyword there is "potential." It might have the  
 18 potential, but it's not necessarily so. There are numerous  
 19 other factors involved, so that might be one of them,  
 20 possibly. Potential.  
 21 Q. I would like to show you a document that's been marked  
 22 for identification as plaintiff's trial Exhibit 789.  
 23 MR. LIPSEY: May I approach, your Honor?  
 24 THE COURT: Yes.  
 05:27 25 THE WITNESS: Thank you.  
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1 BY MR. LIPSEY:  
 2 Q. This is U.S. Patent 8,008,338, assigned to Allergan.  
 3 MR. MALIK: Your Honor, we are going to object. This  
 4 is not on the exhibit list, nor is this for impeachment.  
 05:27 5 Dr. Cykiert is not an inventor on the patent.  
 6 MR. LIPSEY: And at least -- it is exactly  
 7 impeachment, your Honor. And if you'll allow me to proceed, I  
 8 think you'll see why.  
 9 THE COURT: All right. You would have to lay a  
 05:28 10 foundation as to whether statements in such a document are --  
 11 are deemed reliable. No, strike that.  
 12 I'll permit it, and if there's a follow-up question  
 13 that provokes an objection, then you should object.  
 14 MR. MALIK: Thank you, your Honor.  
 05:28 15 BY MR. LIPSEY:  
 16 Q. Okay. If you will turn with me to Column 1, starting at  
 17 about Line 37, near the end of that paragraph, the first  
 18 sentence is just to get our bearings.  
 19 A. Excuse me. Are we -- what page are we on?  
 05:28 20 Q. It's the page that's got the column Numbers 1 and 2.  
 21 THE COURT: It's the seventh page of the document.  
 22 THE WITNESS: Seventh? Thank you.  
 23 Okay. So I'm on the seventh page. And the columns  
 24 are 3 and 4?  
 25 BY MR. LIPSEY:  
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1 Q. 1 and 2.  
 2 A. **Oh, let me go back a page. Sorry. Okay, I have that.**  
 3 **Thanks.**  
 4 Q. Okay. And to get oriented here, starting at about Line  
 05:29 5 37, Allergan says, "The most common adverse event associated  
 6 with the use of the 0.5 percent ketorolac formulation is  
 7 ocular irritation, primarily burning and stinging on  
 8 instillation." Do you see where I've read?  
 9 A. **I see that highlighted there.**  
 05:29 10 Q. Okay. And then Allergan states, "Eliminating or reducing  
 11 ocular irritation has the potential for improving  
 12 tolerability, compliance, and effectiveness of treatment."  
 13 That was Allergan's view of that issue, correct?  
 14 MR. MALIK: Your Honor, again, I object. This is  
 05:30 15 entirely outside the scope. This is not impeachment.  
 16 MR. LIPSEY: Your Honor --  
 17 THE COURT: What is this? Is this a fact or an  
 18 opinion that's stated in this column?  
 19 MR. LIPSEY: This is Allergan commenting on the very  
 05:30 20 deficiency in their own product which our product was intended  
 21 to solve in relation to our earlier products, and commenting  
 22 that, in fact, being able to eliminate the burning does, in  
 23 fact, have the potential of improving more than simply being  
 24 happy; it has the potential to improve tolerability,  
 05:30 25 compliance and effectiveness of treatment.

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1 MR. MUKERJEE: Your Honor, forgive me for jumping in,  
 2 and I know it's unorthodox, but plaintiffs have done this too.  
 3 We do object to this. This document is not into  
 4 evidence. It was not ever cited by Dr. Cykiert. It was not  
 05:31 5 ever cited by Dr. Trattler. It was sprung right now. And  
 6 it's clearly improper impeachment. There is nothing in here  
 7 that contradicts what Dr. Cykiert said on the stand.  
 8 Dr. Cykiert's testimony was his experience with his  
 9 patients, just as Dr. Trattler testified about what his  
 05:31 10 experience allegedly was with his patients.  
 11 What Allergan thinks, what these FDA documents that  
 12 they're trying to put -- has no bearing and in no way  
 13 impeaches what Dr. Cykiert said.  
 14 If Mr. Lipsey has a document to show that one of  
 05:31 15 Dr. Cykiert's patients came in and said, "I never complained  
 16 about burning and stinging, I never thought that was an  
 17 issue," fine, that might be proper impeachment.  
 18 But this document that is not in evidence does  
 19 nothing. It's a patent. It's a patent that -- and Allergan  
 05:31 20 is putting whatever data or whatever suggestions they have in  
 21 here. It in no way impacts what Dr. Cykiert said.  
 22 And so I do object to this and this line of  
 23 questioning. We have given him a pretty wide leash here, and  
 24 yet I still don't see how any of it undermines what  
 05:32 25 Dr. Cykiert said.

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1 THE COURT: Well, it's a document that's not in  
 2 evidence. It's not been previously identified. It can be  
 3 used if it's impeachment.  
 4 MR. MUKERJEE: For impeachment. I'm sorry, your  
 05:32 5 Honor.  
 6 THE COURT: And I don't see that this particular  
 7 couple of sentences is directly impeaching to something that  
 8 the doctor testified to. Certainly, it's not his statements  
 9 or that of the party that retained him, and, secondly, I think  
 05:32 10 it's opinions that are just set forth in the patent to give a  
 11 framework.  
 12 MR. LIPSEY: With respect, Your Honor, it's opinions  
 13 from who ought to know, if anybody should, who is the  
 14 originator.  
 05:32 15 THE COURT: But they're not here to be cross-examined  
 16 and he's not testifying as to prior art. He's a clinician.  
 17 He doesn't seem to be familiar with patents, so I don't think  
 18 it's a proper zone to draw impeachment material from.  
 19 MR. MUKERJEE: Thank you.  
 05:32 20 MR. MALIK: Thank you, Your Honor.  
 21 THE COURT: And let me know whenever it's time for a  
 22 break or if you're going to --  
 23 MR. LIPSEY: No, that's fine. It would give me a  
 24 moment. My examination just got shorter, as you can imagine  
 05:33 25 and it would be a good time.

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1 THE COURT: This would be a good time?  
 2 MR. LIPSEY: Yes.  
 3 THE COURT: All right. Then let's take about a  
 4 ten-minute break. We will resume at 3:15.  
 05:33 5 (RECESS TAKEN; 3:07 p.m.)  
 6 THE DEPUTY CLERK: All rise.  
 7 (OPEN COURT; 3:21 p.m.)  
 8 THE COURT: Be seated, please.  
 9 Okay. Mr. Lipsey, you may resume.  
 05:48 10 MR. LIPSEY: Thank you.  
 11 BY MR. LIPSEY:  
 12 Q. Welcome back.  
 13 A. **Thank you.**  
 14 Q. You would agree that some patients have a very low  
 05:48 15 tolerance for putting any products in their eyes and will note  
 16 a burning and stinging sensation no matter what you prescribe  
 17 for them, correct?  
 18 A. **Right. There are some patients that have that, right.**  
 19 Q. Okay. And -- and there are some patients for whom the  
 05:48 20 stinging and burning is a genuine response to the drug  
 21 product, correct?  
 22 A. **Right. There's all different types of patients with  
 23 different reactions.**  
 24 Q. And it's difficult or impossible to predict which  
 05:48 25 patients may experience these symptoms in advance, correct?

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1 **A. Right, in advance, you can't tell.**  
 2 **Q.** Now, you gave some testimony about your experience with  
 3 Prolensa, but the fact of the matter is that you prefer to  
 4 prescribe generic .09 percent bromfenac solution over  
 05:49 5 Prolensa, correct?  
 6 **MR. MALIK:** Your Honor, objection. Outside the  
 7 scope. We never talked about his preferences.  
 8 **MR. LIPSEY:** Goes to his --  
 9 **THE COURT:** I'll permit it. He testified as to what  
 05:49 10 he prescribes.  
 11 **THE WITNESS:** I used to prescribe Prolensa a lot, but  
 12 due to patient complaints about the cost of it, it's extremely  
 13 expensive. I've switched to other products, such as Ilevro,  
 14 which is made by another company, and so I have used other  
 05:49 15 products because of complaints.  
 16 **BY MR. LIPSEY:**  
 17 **Q.** To the extent you seek to prescribe the once-daily  
 18 bromfenac-containing ophthalmic solution, you generally prefer  
 19 to prescribe generic bromfenac .09 percent solution, correct?  
 05:50 20 **A.** That's again because of an expense issue. If a patient  
 21 calls me from the pharmacy and tells me, this is incredible,  
 22 it's like a car payment, and it's a little bottle, then I will  
 23 find alternatives. And so Ilevro is a good alternative, and I  
 24 will also prescribe Acular four times a day. I will also  
 05:50 25 prescribe Voltaren four times a day, because there is a  
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1 **significant, very significant cost saving for the patient.**  
 2 **Q.** Perhaps let's take a look at your expert report, Page 16,  
 3 Paragraph 48.  
 4 **And in the second sentence there, you wrote: To the**  
 05:50 5 **extent I seek to prescribe a once-daily bromfenac-containing**  
 6 **ophthalmic solution, I generally prefer to prescribe generic**  
 7 **bromfenac 0.09 percent solution over Prolensa because, as**  
 8 **mentioned above, Prolensa is considerably more expensive for**  
 9 **the patient. That's what you wrote there.**  
 05:51 10 **A.** Can I see the rest of that?  
 11 **Q.** Help yourself.  
 12 **THE COURT:** Do you want a copy of your report?  
 13 **THE WITNESS:** That would be helpful. Thank you, Your  
 14 Honor.  
 05:51 15 **MR. LIPSEY:** It's in the notebook.  
 16 **THE WITNESS:** What tab is it?  
 17 **BY MR. LIPSEY:**  
 18 **Q.** Should be the first or second tab right in the front.  
 19 **Before we get there, and I'll give you a chance to**  
 05:51 20 **explain, but will you acknowledge that that's what you wrote**  
 21 **in your expert report?**  
 22 **A.** I wrote that, but there are other things there, so I need  
 23 some time to look at that as well, because that may be taken  
 24 out of context.  
 05:51 25 **So I'm sorry, which tab is that, so I can find it**  
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1 **quickly and not waste time?**  
 2 **THE COURT:** The very first tab.  
 3 **MR. LIPSEY:** The very first tab. PTX-743.  
 4 **THE WITNESS:** First one? And that's Page 16?  
 05:52 5 **MR. LIPSEY:** Yes.  
 6 **THE WITNESS:** Okay.  
 7 **MR. LIPSEY:** Thank you.  
 8 **THE WITNESS:** You're welcome.  
 9 **BY MR. LIPSEY:**  
 05:52 10 **Q.** And again, to get our bearings, if you turn, please, to  
 11 DTX-159 in your notebook, that is the package insert for a  
 12 generic bromfenac .09 percent solution of the sort that you  
 13 prefer to prescribe, correct?  
 14 **A.** I'm sorry, what was that number of the tab again? I'm  
 05:53 15 sorry.  
 16 **Q.** DTX-159.  
 17 **THE COURT:** Second from the back.  
 18 **THE WITNESS:** Thank you. Okay. I have that, thanks.  
 19 **BY MR. LIPSEY:**  
 05:53 20 **Q.** And that is a copy of the packaging and package insert  
 21 for a bromfenac 0.09 percent ophthalmic generic solution  
 22 specifically from Apotex Corp., correct?  
 23 **A.** I haven't seen this before, but it looks like that's what  
 24 it is, just from a quick glance at it.  
 05:54 25 **Q.** Well, the fact of the matter is, that it's cited on  
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1 Page 1 of the materials considered at the back of your expert  
 2 report, correct?  
 3 **A.** I'm not sure. I'll take your word for that.  
 4 **Q.** Okay. So you acknowledge this is a -- this DTX-159 is a  
 05:54 5 copy of the packaging and package insert for a generic .09  
 6 percent bromfenac ophthalmic solution from Apotex, correct?  
 7 **A.** It appears to be that way.  
 8 **Q.** Okay. Thank you.  
 9 **Now, the fact of the matter is that you prescribed**  
 05:55 10 **Prolensa only on rare occasions, correct?**  
 11 **A.** I used to prescribe it a lot more, as I mentioned to you,  
 12 but because of significant and frequent patient complaints  
 13 about cost, I have to find other alternatives, such as Ilevro,  
 14 such as Acular, such as Voltaren and also generic bromfenac.  
 05:55 15 **Q.** Okay. So it is true that you prescribed Prolensa on rare  
 16 occasions, correct?  
 17 **A.** That's not exactly true. I didn't state it that way.  
 18 **That's not what I said. I said I used to prescribe it a lot,**  
 19 **now I've reduced the amount of prescriptions that I'm using**  
 05:55 20 **for Prolensa because of cost. That's not the same as what you**  
 21 **said to summarize what I said.**  
 22 **Q.** Would you turn to Page 24 of your expert report,  
 23 specifically Paragraph 62.  
 24 **A.** I have that, thanks.  
 05:56 25 **Q.** And the last sentence there of that Paragraph 62, you  
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1 stated: Additionally, on the rare occasions I do prescribe  
 2 Prolensa, I do so because it contains bromfenac sodium and not  
 3 because of any other characteristics of the formulation and  
 4 because my patients cannot find an available source for  
 05:56 5 generic bromfenac .09 percent solution.  
 6 That's what you said there, correct?  
 7 A. That's what it says.  
 8 Q. Now, in connection with the preparation of your report in  
 9 this case, and at the time of your expert -- your report, you  
 05:57 10 did not conduct any testing comparing bromfenac-containing  
 11 compositions, correct?  
 12 A. I did not.  
 13 Q. Okay. Now, you have suggested that there's no relation  
 14 between pH and eye comfort.  
 05:57 15 Did I understand that correctly?  
 16 A. That's not exactly what I said.  
 17 Q. What did you say?  
 18 A. I said it earlier, I said you might expect that if the pH  
 19 is reduced, that there might be more comfort. But, in fact,  
 05:58 20 there is no clinical evidence or support or benefit or  
 21 advantage to reducing the pH and, in fact, the proof is that  
 22 my patients who use Prolensa still have burning and stinging,  
 23 so that proves it.  
 24 Q. You would agree that it is known in the scientific  
 05:58 25 literature that stinging and burning of the eye is affected by  

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1 asked if he agrees or disagrees with it.  
 2 THE WITNESS: What was that PTX number again? I'm  
 3 sorry.  
 4 BY MR. LIPSEY:  
 06:00 5 Q. 710.  
 6 A. Oh, okay. I have it, thank you.  
 7 Q. Page 16.  
 8 A. Okay. I'm there, thanks.  
 9 Q. Paragraph 41. First sentence. Dr. Prausnitz states:  
 06:00 10 Even if there were a reduction in pH, it is known in the  
 11 scientific literature that stinging and burning of the eye is  
 12 affected by pH and a more physiological pH causes less ocular  
 13 discomfort.  
 14 Do you see where I've read?  
 06:00 15 A. Yes, I see that.  
 16 Q. Do you agree or disagree with defendant's expert,  
 17 Dr. Prausnitz?  
 18 A. Well, again, it depends what scientific literature you're  
 19 referring to. I haven't reviewed all the scientific  
 06:01 20 literature that's referenced in that sentence, so I can't give  
 21 you a really good answer for that.  
 22 And again, as I explained earlier, if you look at it in  
 23 a vacuum with all other additives, excipients, ingredients,  
 24 concentrations, et cetera, if they're all identical,  
 06:01 25 absolutely identical, then perhaps maybe that might be  

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1 pH and a more physiological pH causes less ocular discomfort,  
 2 correct?  
 3 A. If taken in a vacuum, where all other ingredients of the  
 4 product are exactly identical, then perhaps that would be the  
 05:58 5 case, or one might expect that. But since there are other  
 6 parameters, such as drug concentration, surfactants, other  
 7 variables, other additives, other excipients, you can't state  
 8 that the way you said it.  
 9 Q. Do you know Dr. Mark Prausnitz?  
 05:59 10 A. What do you mean by do I know him?  
 11 Q. Do you know who he is?  
 12 A. I know who he is.  
 13 Q. He's one of the experts testifying for the defendants in  
 14 this case, correct?  
 05:59 15 A. Right.  
 16 Q. And you have a copy of his report at PTX-710 in your  
 17 notebook. Could you turn to that, please?  
 18 A. Sure.  
 19 Q. And specifically to Page 16 when you get there.  
 05:59 20 MR. MALIK: Your Honor, objection, outside the scope.  
 21 Dr. Prausnitz never came up, we never discussed his report.  
 22 This is clearly outside the scope of any opinion. The only  
 23 opinion he gave with respect to pH is his experience from a  
 24 clinician's point of view.  
 06:00 25 THE COURT: Well, he can be shown a statement and  

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1 correct.  
 2 But if there are other changes in the formulations or  
 3 solutions, then you can't categorically state that. But  
 4 again, I can't answer this accurately because I haven't looked  
 06:01 5 at the scientific literature that it refers to.  
 6 So I can read you the sentence, but that's as far as  
 7 I'll go.  
 8 Q. Well, maybe there's something we can agree on, and that  
 9 is, I gather from your answer that it's your view that there  
 06:01 10 are a lot of different factors, possibly including pH,  
 11 possibly including the ingredients, possibly including the  
 12 amount of active, the nature of the active that can affect  
 13 ocular comfort. Would you agree?  
 14 A. Yes, that, I would agree with.  
 06:02 15 Q. Okay. Now, would you turn, please, to PTX-281, which was  
 16 the Kim article.  
 17 And just to be clear about what this is, this article  
 18 is based not on a clinical trial, but on a literature review;  
 19 is that right?  
 06:02 20 A. It's a very extensive literature review done very  
 21 carefully by a panel of experts at the American Academy of  
 22 Ophthalmology.  
 23 Q. Okay. And they did run into some limitations, in terms  
 24 of their ability to draw conclusion from that literature,  
 06:02 25 correct?  

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1 **A. What specifically are you referring to?**  
 2 **Q.** Well, I'm referring specifically to the -- Page 2167, the  
 3 last sentence before the heading Future Research. The authors  
 4 acknowledge that lack of a validated and universally used  
 06:03 5 definition of CME limits accurate estimation of its incidents  
 6 and assessment of treatment benefit with cross-trial  
 7 comparisons.  
 8 Do you see where I've read?  
 9 **A. Yes, I see that.**  
 06:03 10 **Q.** So that was an acknowledged limitation that they ran into  
 11 in trying to sort this all out, right?  
 12 **A. That's a small limitation. I previously defined for you**  
 13 **the difference between clinically significant CME and**  
 14 **insignificant CME, which is known as subclinical CME.**  
 06:03 15 **Q.** Now, I think you said quite vigorously that saying that  
 16 this feeling of burning, as if acid had been in your eye was  
 17 an exaggeration, or lemon juice which is acetic acid burning  
 18 in your eye was a gross exaggeration of the burning and  
 19 stinging sensation; is that right?  
 06:04 20 **A. Yes, I didn't mention the word "acid," I said**  
 21 **specifically lemon juice, but I was referring to what Dr.**  
 22 **Trattler said, that it's like getting lemon juice in your eye,**  
 23 **and I did say that is a huge exaggeration.**  
 24 **Q.** And the reason lemon juice hurts, it's because it's a  
 06:04 25 dilute solution of acetic acid, correct?

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1 THE COURT: I'll permit that.  
 2 THE WITNESS: I'm sorry, could you ask that again?  
 3 BY MR. LIPSEY:  
 4 **Q.** Yes. You could have a report from a patient using  
 06:06 5 Bromday, the .09 percent bromfenac solution that the burning  
 6 feels like acid being put in my eyes, then goes on for several  
 7 minutes, right?  
 8 THE WITNESS: Excuse me, Your Honor, I think I'm  
 9 entitled to know where he's reading from. I don't know where  
 06:06 10 that comes from. I don't know who said that or why they said  
 11 it. I don't know.  
 12 BY MR. LIPSEY:  
 13 **Q.** I'm asking your --  
 14 **A. I don't know anything about it.**  
 06:06 15 **Q.** Let me -- backing up from the details, is that the kind  
 16 of comment that you could get from somebody who had been using  
 17 the .09 percent bromfenac in your experience?  
 18 **A. I don't recall such a comment.**  
 19 **Q.** Okay. Do you recall that in your expert report, you made  
 06:06 20 reference to WebMD?  
 21 **A. Yes, there is mention of WebMD in my expert report,**  
 22 **right.**  
 23 **Q.** Would you turn in your book to PTX -- what's been marked  
 24 for identification as PTX-791.  
 06:07 25 **A. Okay. I have that.**

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1 **A. I'm not a lemon juice expert, but I have gotten lemon**  
 2 **juice in my eye and I can tell you that it stings like hell**  
 3 **for several minutes, and usually I have to wash my eye out**  
 4 **with water and so on.**  
 06:04 5 **Q.** And you don't remember that it's acetic acid, that  
 6 doesn't ring a bell?  
 7 **A. Again, it may contain acetic acid, but it contains many**  
 8 **other ingredients and I don't want to state the wrong**  
 9 **ingredient. If you have a reference for lemon juice, I'll be**  
 06:05 10 **happy to look at it.**  
 11 **Q.** But the fact of the matter is that patients using  
 12 Bromday, which is the .09 percent ophthalmic bromfenac  
 13 solution have, in fact, characterized the sensation as the  
 14 burning feels like acid being put in my eyes, it goes on for  
 06:05 15 several minutes after instilling the drops. I have two weeks  
 16 ahead of me for the use and do not know how I'll get through  
 17 it. There have been comments like that, correct?  
 18 **A. Where are you reading from?**  
 19 MR. MALIK: Objection. It's outside the scope.  
 06:05 20 Yeah, and also what is he citing, exactly?  
 21 THE COURT: All right.  
 22 MR. LIPSEY: Right now, I'm just asking the question.  
 23 THE COURT: Whether he agrees that a patient could  
 24 have that sort of report?  
 06:05 25 MR. LIPSEY: Yes.

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1 **Q.** And you recognize that as a screen shot from WebMD?  
 2 MR. MALIK: Objection. Outside scope. And also it's  
 3 not an exhibit.  
 4 MR. LIPSEY: It's impeachment, Your Honor.  
 06:07 5 MR. MALIK: Your Honor, he's on WebMD. I mean, are  
 6 we -- every web page on WebMD at least mentioned that  
 7 material?  
 8 MR. LIPSEY: The witness cited WebMD in his expert  
 9 report, Your Honor.  
 06:08 10 MR. MALIK: Your Honor, the WebMD citing in his  
 11 expert report was to Prolensa, not Bromday.  
 12 MR. LIPSEY: What's sauce for the goose is sauce for  
 13 the gander, Your Honor.  
 14 MR. MALIK: Your Honor, that doesn't mean that  
 06:08 15 everything on WebMD --  
 16 THE COURT: I agree. Is this some anecdote that's  
 17 reported to WebMD?  
 18 MR. LIPSEY: Absolutely, Your Honor.  
 19 THE COURT: All right. I'll sustain the objection.  
 06:08 20 This could come from anywhere.  
 21 MR. LIPSEY: We have nothing further. Thank you very  
 22 much.  
 23 THE WITNESS: Thank you.  
 24 THE COURT: All right. Thank you. Any redirect?  
 06:08 25 MR. MALIK: No, Your Honor.

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1 THE COURT: Okay. I have a couple of follow-up  
2 questions and again, if there's any objection, don't hesitate  
3 to raise the objection. And if there is an objection, sir,  
4 then don't answer until I have a chance to sort it out, okay?  
06:09 5 You mentioned that in your practice, that you prescribe  
6 a number of -- of the types of drugs that contain bromfenac;  
7 is that right?  
8 THE WITNESS: Yes.  
9 THE COURT: And you said that recently, or at some  
06:09 10 point in time, you've tapered off in prescribing Prolensa and  
11 you attributed that to costs --  
12 THE WITNESS: Yes.  
13 THE COURT: -- is that right?  
14 And you also remarked that your patients have seldom --  
06:09 15 well, how often have your patients reported what you would  
16 characterize as a serious problem with burning or stinging  
17 following cataract surgery?  
18 THE WITNESS: You mean burning and stinging from the  
19 medication?  
06:09 20 THE COURT: That you would attribute to the  
21 medication.  
22 THE WITNESS: It's a small percentage. I would say  
23 it's in the range of one or two percent.  
24 THE COURT: And is that consistent, as far as you  
06:10 25 know, with the different clinical studies that have been done  
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1 that are reporting between one and two percent?  
2 THE WITNESS: Yes, it's very consistent for Prolensa  
3 and the other bromfenac NSAIDs.  
4 THE COURT: And so in the bromfenac NSAIDs, are you  
06:10 5 relying on your memory or have you kept some sort of a log or  
6 record about postoperative reactions or complaints?  
7 THE WITNESS: I don't keep a log like that because  
8 it's -- it's a small percentage and it's not a significant  
9 complaint as I mentioned. It's transient or mild, so I  
06:10 10 usually wouldn't log something like that, because it's not  
11 clinically significant.  
12 THE COURT: Would you, in hindsight, be able to  
13 detect a small improvement, for instance, from three percent  
14 complaints to one percent complaints?  
06:11 15 THE WITNESS: I don't think so. I think difference  
16 between one and three percent, without actually logging it, as  
17 you mentioned, I think would -- would not be perceptible.  
18 It's a very, very low number.  
19 THE COURT: All right. I don't have any other  
06:11 20 questions. Anything else?  
21 MR. LIPSEY: Nothing further.  
22 MR. MALIK: Your Honor, we would just like to move  
23 one exhibit into evidence. It's DTX-446, which is the CV of  
24 Dr. Cykiert.  
06:11 25 THE COURT: DTX-446. Any objection to the CV coming  
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1 into evidence?  
2 MR. LIPSEY: No, but I would like to move in DTX-159,  
3 which was the generic bromfenac package insert and packaging.  
4 THE COURT: Any objection to DTX-159?  
06:11 5 MR. MALIK: No, Your Honor.  
6 MR. LIPSEY: And I also used four documents that had  
7 previously been offered into evidence this morning, which --  
8 lest they get lost, I would --  
9 THE COURT: Well, we will return to those in a  
06:12 10 moment, okay? Okay.  
11 So DTX-446 is received into evidence and DTX-159 is  
12 received into evidence at this time.  
13 (EXHIBITS DTX-446 and DTX-159 WERE RECEIVED IN EVIDENCE)  
14 THE COURT: Are there any further questions for this  
06:12 15 witness?  
16 MR. MALIK: Not from defendants, Your Honor.  
17 MR. LIPSEY: Did you get their exhibit number  
18 correct, the information I got was that it might be wrong.  
19 THE COURT: I said DTX-446?  
06:12 20 MR. MUKERJEE: That's correct, that's correct, Your  
21 Honor.  
22 MR. MALIK: Yes, yes.  
23 MR. LIPSEY: I'm sorry, we thought it was a JTX, Your  
24 Honor.  
06:12 25 THE COURT: All right, then, thank you, sir. You may  
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1 step down.  
2 THE WITNESS: Thank you.  
3 THE COURT: Is there any other witness?  
4 MS. RAPALINO: Your Honor, Emily Rapalino again on  
06:13 5 behalf of the Lupin defendants. We're heading into the home  
6 stretch both for today and as it turns out, for the trial.  
7 Due to the way that the evidence has come in thus far and some  
8 scheduling issues, defendants do not plan to call  
9 Dr. Prausnitz tomorrow as we had originally thought, and so  
06:13 10 our next and last rebuttal witness will be Dr. Jayne Lawrence.  
11 THE COURT: All right. So the defendants, then, will  
12 not be calling Dr. Prausnitz, and your last witness is  
13 Dr. Lawrence.  
14 MS. RAPALINO: That's correct. And I have one  
06:13 15 request, if I could make that request. Professor Lawrence has  
16 a flight to catch tonight. I expect that her direct testimony  
17 won't run longer than about 20 to 30 minutes, and so if the  
18 Court has the time to sit a little bit later if necessary  
19 today, just to complete her testimony, that would be much  
06:14 20 appreciated on the part of Professor Lawrence who would very  
21 much like to get her flight back to London.  
22 THE COURT: Well, I can do that if you keep it down  
23 to about 20 minutes and that will give -- you know, between 20  
24 and 40 minutes, I would say, for cross-examination. Not  
06:14 25 knowing, you know, what you're going to cover, it's hard to  
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1 predict. But I'd have to curtail you before I curtail the  
 2 other side, since it's your witness that has the problem.  
 3 MS. RAPALINO: Understood, Your Honor. That's fine.  
 4 THE COURT: Okay. All right. So are you calling  
 06:14 5 Dr. Lawrence at this time?  
 6 MS. RAPALINO: Yes. Defendants call Professor Jayne  
 7 Lawrence.  
 8 THE COURT: So please come to the witness stand and  
 9 I'll remind you that you remain under oath.  
 06:14 10 THE WITNESS: Yes.  
 11 MS. RAPALINO: Your Honor, may we approach with some  
 12 small binders?  
 13 THE COURT: More?  
 14 MS. RAPALINO: These are very short, I promise.  
 06:14 15 THE COURT: Okay.  
 16 THE WITNESS: Thank you. Thank you.  
 17 MS. RAPALINO: May I proceed, Your Honor?  
 18 THE COURT: Yes.  
 19 (DIRECT EXAMINATION OF DR. JAYNE WILLIAMS BY MS. RAPALINO:)  
 06:15 20 Q. Welcome back, Professor Lawrence.  
 21 A. Thank you.  
 22 Q. Were you here in the courtroom for the testimony of  
 23 Dr. Davies and Dr. Williams last week and earlier this week?  
 24 A. Yes, I was.  
 06:15 25 Q. Have you been asked to render opinions in response to  
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1 MS. RAPALINO: Understood.  
 2 BY MS. RAPALINO:  
 3 Q. Now, Professor Lawrence, did you hear Dr. Davies testify  
 4 that a person of ordinary skill in the art would not have  
 06:17 5 believed the statements in Remington's and the multiple other  
 6 references because there was no experimental data or evidence  
 7 in those documents?  
 8 A. Yes, I did.  
 9 Q. As a pharmaceutical formulator, do you agree that a  
 06:17 10 person of ordinary skill in the art would disregard those  
 11 statements regarding complexation when formulating a bromfenac  
 12 product?  
 13 A. No, I do not, because there was so much in the prior art  
 14 and in the reference literature, a pharmaceutical formulator  
 06:17 15 would have done -- would have used that regarded this  
 16 complexation as a matter of fact. A person of ordinary skill  
 17 in the art would have been aware that this complexation  
 18 between benzalkonium chloride and bromfenac was likely to  
 19 occur.  
 06:18 20 Q. Did you also hear Dr. Davies testify that the structural  
 21 differences between bromfenac and other acidic NSAIDs would  
 22 lead a person of ordinary skill in the art to conclude that  
 23 complexation was unlikely to occur with bromfenac?  
 24 A. Yes, I did.  
 06:18 25 Q. Now, based on your own experience as a pharmaceutical  
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1 their testimony?  
 2 A. Yes, I have.  
 3 Q. Were you in the courtroom when Dr. Davies testified about  
 4 a number of references, prior art references that say that it  
 06:15 5 was well-known that NSAIDs and benzalkonium chloride form  
 6 complexes in solution at the relevant pH here?  
 7 A. Yes, I was.  
 8 MR. HASFORD: And if I may, Your Honor, I think I  
 9 need to lodge an objection at this point to the extent -- so  
 06:16 10 as Your Honor ruled earlier this -- this week or last week, I  
 11 believe it was, if the point of this recall of Dr. Lawrence is  
 12 simply to say what she previously said in their case in chief,  
 13 more loudly, we would object to that. I think that the proper  
 14 scope, if anything, of Dr. Lawrence's testimony here would be  
 06:16 15 a response to secondary considerations of nonobviousness at  
 16 this point.  
 17 MS. RAPALINO: Your Honor, all of Professor  
 18 Lawrence's testimony will be responsive to the testimony of  
 19 either Dr. Davies or Dr. Williams, and as far as we're  
 06:16 20 concerned, her rebuttal testimony isn't limited to issues of  
 21 secondary considerations, but is -- we are also permitted to  
 22 have Professor Lawrence rebut testimony that those experts  
 23 offered in response to our prima facie case of obviousness.  
 24 THE COURT: As long as you're not repeating  
 06:16 25 Dr. Lawrence's prior testimony, I'll permit it.  
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1 formulator working with NSAIDs, do you agree with that  
 2 testimony?  
 3 MR. HASFORD: And I'll object, Your Honor, to the  
 4 extent this goes to chemical issues about structural  
 06:18 5 differences. We have already established that Dr. Lawrence is  
 6 not an expert in chemistry.  
 7 MS. RAPALINO: I would disagree. I believe the Court  
 8 actually qualified Professor Lawrence as an expert in the  
 9 chemistry as it relates to pharmaceutical formulation.  
 06:18 10 MR. HASFORD: No, Your Honor. In fact, the Court  
 11 specifically only qualified her as to formulation issues and  
 12 we were clear on that.  
 13 THE COURT: I think Ms. Rapalino is correct that  
 14 there is a later point in the examination when her credentials  
 06:19 15 in chemistry came at issue, and I even permitted voir dire on  
 16 it and I ruled that she may give opinions regarding chemistry,  
 17 so I enlarged the scope of her recognized expertise for the  
 18 trial. So you may answer.  
 19 MS. RAPALINO: Thank you.  
 20 BY MS. RAPALINO:  
 21 Q. Professor Lawrence, do you need me to repeat the  
 22 question?  
 23 A. Yes, please.  
 24 Q. Okay. So you remember that Dr. Davies testified that the  
 06:19 25 structural differences between bromfenac and other acidic  
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1 NSAIDs would lead a person of ordinary skill in the art to  
2 conclude that complexation was unlikely to occur with  
3 bromfenac?  
4 A. Yes. I've been in pharmaceutical formulation for over 25  
06:19 5 years and a lot of that time, I've been looking at  
6 complexation and that's often complex, as being complexation  
7 of nonsteroidal anti-inflammatories, and the pharmaceutical  
8 formulator would treat a class of molecules or a group of  
9 molecules that are in the same class, such as a nonsteroidal  
06:20 10 anti-inflammatories, as one group of materials when looking at  
11 -- at formulating them in the first instance.  
12 Q. Now, does the '431 patent-in-suit say anything about the  
13 problem the inventors were trying to solve with their alleged  
14 invention here?  
06:20 15 A. Yes, it does.  
16 Q. Could you turn in your binder to JTX1, the '431 patent,  
17 and directing your attention to JTX1.3, Column 1, starting at  
18 Line 62 through Column 2, Line 11, that goes to the end of the  
19 background art section.  
06:20 20 Can you explain what the patent-in-suit and what the  
21 inventor has said here about the problem they were trying to  
22 solve?  
23 A. The inventors obviously realized there was a problem  
24 between benzalkonium chloride and acidic drugs such as the  
06:21 25 nonsteroidal anti-inflammatories and the result of which was a  
  
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1 MS. RAPALINO: Okay.  
2 BY MS. RAPALINO:  
3 Q. Let's turn now to the Ogawa '225 patent, JTX147.  
4 A. Yes.  
06:22 5 Q. Do you recall Dr. Davies offered testimony about this  
6 patent?  
7 A. Yes, I do.  
8 Q. Specifically, if we look at Column 10, Lines 49 through  
9 57, which appears just under Example 8.  
06:22 10 A. Yes, I'm there.  
11 Q. Do you recall Dr. Davies testified that the statement in  
12 the '225 patent that the formulation of Example 6 was stable,  
13 excellent for a long time, would have taught the person of  
14 ordinary skill in the art that for a long period of time, the  
06:23 15 stability was excellent and that bromfenac and benzalkonium  
16 chloride do not form an insoluble salt?  
17 A. Yes, I do.  
18 Q. Now, let's look at Example 6 again, further up in that  
19 same Column 10.  
06:23 20 Can you remind us what the ingredients were of Example  
21 6?  
22 A. Certainly. In addition to bromfenac benzalkonium  
23 chloride and polysorbate 80, the formulation contained boric  
24 acid, borax, disodium edetate, polyvinyl pyrrolidone, sodium  
06:23 25 sulfite and obviously water.  
  
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1 problem with preservative efficacy, and they assumed that  
2 somebody of ordinary skill would look to overcoming those  
3 problems.  
4 Q. Did you hear Dr. Davies testify that a person of --  
06:21 5 MR. HASFORD: Actually, I'll object, Your Honor, and  
6 move to strike the last testimony. Apparently, it's not in  
7 her reply report and that's what the scope of this testimony  
8 should be directed to at this stage.  
9 THE COURT: No, it's rebuttal. She's not cabined by  
06:21 10 her reply report. If other testimony came in during the  
11 plaintiff's case that calls for rebuttal within her area of  
12 expertise that she hasn't testified on before, I'll permit it.  
13 MS. RAPALINO: Thank you, Your Honor.  
14 BY MS. RAPALINO:  
06:21 15 Q. Did you hear Dr. Davies testify that a person of ordinary  
16 skill in the art would have tested a bromfenac-backed  
17 formulation to see whether it formed a complex?  
18 A. Yes, I did.  
19 Q. And had a person of ordinary skill in the art performed  
06:22 20 such a test, what would he or she have found?  
21 A. They would have found that the complex was formed between  
22 benzalkonium chloride --  
23 MR. HASFORD: Objection, Your Honor. This is nowhere  
24 in any of her expert reports and I move to strike.  
06:22 25 THE COURT: I'll sustain the objection.  
  
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1 Q. What would the person of person of ordinary skill in the  
2 art understand the function of polysorbate 80 to be in that  
3 formulation?  
4 A. A person of ordinary skill in the art would assume the  
06:24 5 function of polysorbate 80 in that formation was a  
6 solubilizer.  
7 Q. And what is polysorbate 80 known to be in the prior art  
8 literature?  
9 A. It's a surfactant, a commonly-used surfactant that's  
06:24 10 known to be a very effective solubilizer amongst other things.  
11 Q. Now, did you hear Dr. Williams testify regarding his view  
12 on the nomenclature relating to the terms "stabilizer" and  
13 "solubilizer" as they apply to polysorbate 80?  
14 A. Yes, I do.  
06:24 15 Q. Can you just explain how you would apply those terms to  
16 polysorbate 80 in the context of this case?  
17 A. It's my understanding that the person of ordinary skill  
18 in the art would assume that polysorbate 80 was present to  
19 disrupt the complex formed between benzalkonium chloride and  
06:24 20 bromfenac and in that way --  
21 MR. HASFORD: Object. Objection, Your Honor. This  
22 again is not in her expert reports. She's trying to testify  
23 to information outside the scope of her expert reports and we  
24 move to strike.  
06:25 25 MS. RAPALINO: Again, this testimony is squarely  
  
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1 within -- it sort of goes to the heart of her testimony and  
 2 her -- and the heart of her expert reports in this case about  
 3 the function of surfactants in these solutions to solubilize  
 4 the complex --  
 06:25 5 MR. HASFORD: It's not in her expert reports, Your  
 6 Honor.  
 7 THE COURT: Well, do you have a reference,  
 8 Ms. Rapalino?  
 9 MS. RAPALINO: Yes. If you give me one moment, I'll  
 06:25 10 get you a reference.  
 11 So as just one example, Your Honor, at Paragraph 57 of  
 12 Professor Lawrence's reply report, and I'm looking at  
 13 Footnote 8, Professor Lawrence states: I agree that these  
 14 surfactants, speaking of tyloxapol and polysorbate 80, do not  
 06:26 15 perform alike and that is why, for example, tyloxapol  
 16 interrupts the complexes between bromfenac and BAC more  
 17 effectively than polysorbate 80.  
 18 THE COURT: All right. Well, if you reframe the  
 19 question along those lines, I'll permit it.  
 20 BY MS. RAPALINO:  
 21 Q. Can you explain how, if at all, polysorbate 80 is  
 22 functioning in the formulation of Example 6 in this case?  
 23 A. Yeah. Polysorbate 80 is a very well-known nonionic  
 24 surfactant, and it's my opinion that polysorbate 80 is acting  
 06:26 25 as a solubilizer in this formulation and acting to disrupt the

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1 complex formed between benzalkonium chloride and bromfenac.  
 2 And so it's acting as a solubilizer, but in disrupting the  
 3 complex. It's also acting as a physical stabilizer in the  
 4 formulation.  
 06:27 5 Q. Could any of the other ingredients in the formulation of  
 6 Example 6 have been performing that function?  
 7 A. Absolutely not. For example, boric acid and borax are  
 8 buffers, disodium edetate is there to chelate any divalent  
 9 cations and polyvinyl pyrrolidone and sodium sulfite are  
 06:27 10 obviously there to stabilize the bromfenac.  
 11 Q. Would a person of ordinary skill in the art have been  
 12 aware of the functions of each of those excipients?  
 13 A. Yes, they are very well-established.  
 14 Q. What was the pH of the formulation of Example 6 of the  
 06:28 15 '225 patent?  
 16 A. That was pH 8.  
 17 Q. Under what conditions was the formulation of Example 6  
 18 placed to test its stability?  
 19 A. A very limited single condition of four weeks at  
 06:28 20 60 degrees C.  
 21 Q. You previously testified that a person of ordinary skill  
 22 in the art would have been motivated to replace polysorbate 80  
 23 with tyloxapol. Given the, quote, excellent stability  
 24 recorded for Example 6, under those conditions, why would a  
 06:28 25 person of ordinary skill in the art have been motivated to

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1 modify that formulation?  
 2 A. Firstly, the excellent stability refers to only one  
 3 experimental condition, obviously, 60 degrees for four weeks.  
 4 As a formulator, you would need to know stability, the  
 06:29 5 stability of the formulation at other temperatures, and by  
 6 using the Fu EP '984 reference, someone ordinarily skilled in  
 7 the art would get the stability information they needed to  
 8 look at enhancing, improving the performance of the  
 9 formulation.  
 06:29 10 Q. So given what you've just said about the Fu reference,  
 11 does the Fu reference teach the person of skill in the art  
 12 that their stability results would have been any different  
 13 under different temperature conditions?  
 14 A. Yes, it tells a person of ordinary skill in the art that  
 06:29 15 a low polysorbate 80 was sufficient to stabilize formulations  
 16 at the higher temperature of 60 degrees for four weeks. It  
 17 was not suitable for stabilizing the formulation at 40 degrees  
 18 C. room temperature for four weeks.  
 19 Q. Can you turn in your binder to JTX209, which is the Fu  
 06:30 20 '984, EP '984 reference.  
 21 Can you show us where in the EP '984 reference it  
 22 discussed those different conditions?  
 23 A. Yes, certainly. That would be JTX209.9, and that would  
 24 be Table 5, that would be the table that's included in Example  
 06:30 25 5.

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1 Q. And can you just remind us what does the table in Example  
 2 5 say about what would happen to an NSAID benzalkonium  
 3 chloride polysorbate 80 formulation under other conditions?  
 4 A. Yes, certainly. In this case polysorbate 80 is called a  
 06:30 5 tween 80. And when an NSAID, in this case ketorolac, is mixed  
 6 with benzalkonium chloride in the present salt tween 80, the  
 7 solutions were clear -- I'm sorry, the solutions were clear  
 8 after one month storage at 60 degrees C., which agrees with  
 9 the data in the '225 patent, but with turbid or very turbid,  
 06:31 10 in other words, cloudy when stored at 40 degrees C., at room  
 11 temperature for one month.  
 12 Q. What does the cloudiness or turbidity of the solutions  
 13 that were stored at the temperatures other than 60 degrees  
 14 suggest?  
 06:31 15 A. It suggests that the surfactant tween 80 was insufficient  
 16 to disrupt the complexes formed between benzalkonium chloride  
 17 and ketorolac.  
 18 Q. Given the teachings of EP '984, would a person of  
 19 ordinary skill in the art simply rely on the stability data at  
 06:32 20 60 degrees in the Ogawa '225 patent alone and conclude that  
 21 there was no problem of complexation between bromfenac and  
 22 benzalkonium chloride in a formulation with polysorbate 80?  
 23 A. No, they would not. They would use the '225 patent in  
 24 combination with EP '984 and realize that there were problems  
 06:32 25 with using polysorbate 80 at lower temperatures.

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1 Q. Could altering other conditions besides temperature  
2 affect the physical stability of the formulation?  
3 A. **Yes, they could. For example, pH is one of those. If**  
4 **you look at the pH of Example 6 in the '225 patent, that has a**  
06:32 5 **pH of 8, and a formulator may be motivated to try and**  
6 **formulate a product at a lower temperature that is closer to**  
7 **that of the pH of the tears of the eye and may have problems**  
8 **in achieving that formulation.**  
9 Q. I think you may have misspoken. Did you mean a lower pH  
06:33 10 not temperature?  
11 A. **Sorry, yes. A lower pH.**  
12 Q. Thank you.  
13 Now, were you here for Dr. Williams' testimony about  
14 the allegedly unexpected stabilizing effect of tyloxapol as  
06:33 15 compared to polysorbate 80?  
16 A. **Yes, I was.**  
17 Q. And did Dr. Williams summarize a comparison that he made  
18 of tyloxapol formulations and of polysorbate 80 formulations  
19 in a demonstrative?  
06:33 20 A. **Yes, he did.**  
21 MS. RAPALINO: Can we pull up PDX4-5?  
22 BY MS. RAPALINO:  
23 Q. Now, did you hear Dr. Williams testify with respect to  
24 PDX4-5 that the stability of the claim tyloxapol formulations  
06:34 25 represented on his demonstrative by formulation codes A-21,  
  
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1 A-27, A-28, and A-29 were unexpectedly better than the  
2 stability of comparison Example 1 in the '431 patent?  
3 A. **Yes, I did.**  
4 Q. As an initial matter, is comparison Example 1 in the '431  
06:34 5 patent prior art?  
6 A. **No, it's not.**  
7 Q. What is the closer prior art to the claimed formulations?  
8 A. **The closer prior art is Example 6 in the '225 patent.**  
9 Q. So let's go back for a moment to Example 6 of the '225  
06:34 10 patent at JTX147. And if I could direct your attention to  
11 Table 11 at Column 14 of JTX147.  
12 MS. RAPALINO: Could we pull up Column 14? Okay.  
13 BY MS. RAPALINO:  
14 Q. What was the reported stability for bromfenac sodium --  
06:35 15 the bromfenac sodium formulation of Example 6?  
16 A. **That was it was clear in appearance and had residue of**  
17 **100.9 percent, which is a bromfenac content.**  
18 MS. RAPALINO: Now, if we could pull up DDX4-2.  
19 BY MS. RAPALINO:  
06:35 20 Q. If we compare the stability of the actual closer prior  
21 art formulation of Example 6 of the '225 patent to the  
22 tyloxapol containing formulations, how does that stability  
23 compare -- how does that stability compare?  
24 A. **The stability of Example 6 is obviously better than that**  
06:35 25 **of the ones that contain tyloxapol, it's better by about 10**  
  
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1 **percent.**  
2 Q. Now, I note that the pH of Example 6 of the '225 patent  
3 is 8 and the pH of the other formulations that -- the  
4 tyloxapol formulations that Dr. Williams spoke about was 7.  
06:36 5 Did you hear Dr. Williams testify that the stability of  
6 the Ogawa '225 patent, Example 6 formulation, if formulated at  
7 pH 7, would have a stability that would be right in the range  
8 of the stability reported for the tyloxapol containing  
9 formulations?  
06:36 10 A. **Yes, I did.**  
11 Q. Does that seem reasonable to you as well?  
12 A. **It doesn't seem unreasonable.**  
13 Q. And so what does that comparison tell you about whether  
14 the claimed formulations with tyloxapol demonstrate  
06:36 15 unexpectedly superior stability over the closer prior art?  
16 A. **Okay. The formulations obviously don't demonstrate**  
17 **superior stability over the prior art.**  
18 Q. Now, turning to a slightly different topic, were you also  
19 here when Dr. Williams testified that an unexpected benefit of  
06:37 20 the claimed tyloxapol formulations was that they allowed for a  
21 stable formulation even without requiring sodium sulfite?  
22 A. **Yes, I did.**  
23 Q. And do you recall that he used DDX4-6 to show that  
24 comparison?  
06:37 25 A. **Yes, I do.**  
  
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1 Q. Now, as an initial matter, does asserted Claim 20 of the  
2 '431 patent require sodium sulfite?  
3 A. **Yes, it does.**  
4 Q. Does Claim 6 of the '431 patent permit sodium sulfite?  
06:37 5 A. **Yes, it does.**  
6 Q. Does the Prolensa product contain sodium sulfite?  
7 A. **Yes, it does.**  
8 Q. Now, did you hear Dr. Williams point to Experimental  
9 Example 4 of the Ogawa '225 patent as showing that -- in his  
06:37 10 view showing that a polysorbate 80 containing preparation  
11 would not have been stable without sodium sulfite?  
12 A. **Yes, I do.**  
13 Q. Okay. So let's turn to back to the '225 patent at  
14 JTX147.  
06:38 15 A. **I'm there.**  
16 Q. And let me direct your attention to Column 8.  
17 A. **Yes.**  
18 Q. At around Lines 3 through 14. You see Experimental  
19 Example 4?  
06:38 20 A. **Yes, I do.**  
21 Q. What stabilizer is used in Experimental Example 4?  
22 A. **Polysorbate 80.**  
23 Q. Is sodium sulfite included in that preparation?  
24 A. **No, it's not.**  
06:38 25 Q. And now if I could direct your attention just below  
  
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- 1 Experimental Example 4 in Column 8 of the '225 patent, the  
2 paragraph just below that, where are the stability data for  
3 the formulation of Experimental Example 4 reported?  
4 A. **They're shown in Table 8.**
- 06:38 5 MS. RAPALINO: So if we could look at Table 8 now,  
6 which is at Column 14, and this is Lines 23 to 32. Thank you.  
7 BY MS. RAPALINO:  
8 Q. What is the stability reported for this polysorbate 80  
9 containing formulation without sodium sulfite at pH 8?  
06:39 10 A. **After three weeks storage at 60 degrees, the formulation**  
11 **was both clear in appearance and had 8 -- sorry, had**  
12 **98 percent of residue or bromfenac sodium remaining.**  
13 Q. Have you prepared a demonstrative showing these data in  
14 comparison to the data Dr. Williams presented?  
06:39 15 A. **Yes, I have.**
- 16 MS. RAPALINO: Can we pull up DDX6-3?  
17 BY MS. RAPALINO:  
18 Q. Based on your review of these data, is the formulation of  
19 Experimental Example 4 of Ogawa stable?  
06:39 20 A. **Yes, it is.**  
21 Q. Now, do you remember that Dr. Williams pointed to the  
22 text in JTX147, the Ogawa patent, under Experimental Example 4  
23 that said that red insoluble matters formed after three weeks?  
24 A. **Yes, I do.**  
06:40 25 Q. And do you recall Dr. Williams testified that in his view

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- 1 Q. Do you agree that that was unexpected?  
2 A. **No, I don't.**  
3 Q. Can you explain why that was not unexpected?  
4 A. **Yes, certainly. That's because if you overcome the**  
06:41 5 **problem of complexation between benzalkonium chloride and**  
6 **bromfenac sodium, there'll be more benzalkonium chloride left**  
7 **in solution to exert its effect and that's obviously why it**  
8 **passed the test.**  
9 Q. Did you also hear testimony from Dr. Williams about  
06:42 10 replacing benzalkonium chloride with other preservatives or  
11 even removing benzalkonium chloride from ophthalmic solutions  
12 entirely to avoid the problem of complexation?  
13 A. **Yes, I did.**  
14 Q. And one example of that was replacing benzalkonium  
06:42 15 chloride with lauralkonium chloride, is that right?  
16 A. **Yes, that was one example.**  
17 Q. In your opinion would a person of ordinary skill in the  
18 art have taken the approach of replacing benzalkonium chloride  
19 with another preservative like lauralkonium chloride to solve  
06:42 20 the problem of complexation?  
21 A. **No, I don't believe they would, that's because a person**  
22 **of ordinary skill in the art would read all the body of**  
23 **literature, including the information in Remington's, which**  
24 **says that it is preferable to reformulate rather than replace**  
06:43 25 **benzalkonium chloride if there is a problem of complexation**

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- 1 that allegedly showed that the formulation was not stable?  
2 A. **Yes.**  
3 Q. Do you agree that means the formulation was not stable?  
4 A. **No, I don't. The formulation remained clear and it had**  
06:40 5 **over 98 percent of the drug remaining. So, as far as any red**  
6 **insoluble matter was indeed formed, if it was, that must have**  
7 **only been a small amount of the composition because --**  
8 Q. What's the maximum amount of bromfenac sodium that could  
9 have degraded to form red insoluble complexes based on the  
06:40 10 stability reported in the table?  
11 A. **The maximum amount of bromfenac sodium that could have**  
12 **formed the red precipitants is 2 percent.**  
13 Q. Now, taken together then, what does -- what do these data  
14 say about whether there is anything unexpected about tyloxapol  
06:41 15 allowing for a stable formulation without sodium sulfite?  
16 A. **There's nothing unexpected about tyloxapol forming a**  
17 **stable solution in the absence of sodium sulfite.**  
18 Q. Did you hear Dr. Williams testify that another allegedly  
19 unexpected benefit of the claimed formulations is that they  
06:41 20 have improved preservative efficacy?  
21 A. **Yes, I did.**  
22 Q. And do you recall he testified specifically that  
23 inclusion of tyloxapol allowed for the claimed formulations to  
24 pass the European pharmacopeia criteria?  
06:41 25 A. **Yes, I do.**

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- 1 **with the benzalkonium chloride.**  
2 MS. RAPALINO: Okay. Thank you, Professor Lawrence.  
3 I pass the witness.  
4 THE COURT: All right. Cross-examination?  
06:43 5 MR. HASFORD: Yes, your Honor.  
6 (CROSS-EXAMINATION OF JAYNE LAWRENCE BY MR. HASFORD:)  
7 Q. Good afternoon, Dr. Lawrence.  
8 A. **Good afternoon.**  
9 Q. You testified on direct exam about the Ogawa '225 patent.  
06:43 10 A. **Yes, I did.**  
11 Q. To be clear, you have neither stated nor suggested that  
12 the Ogawa '225 patent teaches the formulation of a complex  
13 between bromfenac and benzalkonium chloride, correct?  
14 A. **I take the section on -- if I can just turn to it if you**  
06:44 15 **allow me. Sorry. Beg your pardon. I got confused. Sorry.**  
16 **Repeat the question again.**  
17 Q. Would you like me to repeat the question?  
18 A. **Yes, repeat the question. Sorry.**  
19 Q. To be clear, you have neither stated nor suggested that  
06:44 20 the Ogawa '225 patent teaches the formulation of a complex  
21 between bromfenac and benzalkonium chloride, correct?  
22 A. **That is correct, because I had the surfactant in to**  
23 **overcome it.**  
24 Q. Let's take a look, if you would, at your deposition  
06:44 25 transcript. It's going to be the February 29th deposition

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1 transcript.  
2 A. **Okay.**  
3 Q. And let's pull up Page 186 --  
4 A. **Could I have a copy?**  
06:45 5 Q. -- line 22.  
6 Oh, certainly.  
7 MS. RAPALINO: Your Honor, while we're getting her a  
8 copy of her transcript, I'm not entirely certain what Mr.  
9 Hasford will point to, but I will note that Professor Lawrence  
06:45 10 answered the last question in the affirmative so I'm not sure  
11 what he means to impeach her with here.  
12 MR. HASFORD: I believe she qualified her answer,  
13 your Honor. And I'll point out that when she was asked this  
14 exact same question in her deposition, she answer it was an  
06:45 15 unqualified correct and yes.  
16 MS. RAPALINO: And I'll just note that she didn't  
17 qualify as much as explain why it was the case. We do see  
18 that as proper impeachment but I don't think there's any harm  
19 letting that come into the record.  
06:45 20 THE COURT: Nor do I. I'll permit it.  
21 But before we proceed, I lost my LiveNote. Can we  
22 catch it up?  
23 We're there. Thank you very much.  
24 MR. HASFORD: May I approach, your Honor?  
06:46 25 THE COURT: Yes.  

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1 correct?  
2 A. **I've said that, yes.**  
3 Q. You testified on direct exam about the Remington's  
4 reference. Do you remember that?  
06:48 5 A. **Yes, I do.**  
6 Q. The portion of the Remington reference about which you  
7 testified on direct exam does not teach the use of bromfenac,  
8 correct?  
9 A. **That is correct, yes.**  
06:48 10 Q. The portion of the Remington reference which you  
11 testified on direct exam does not teach the use of any NSAID,  
12 correct?  
13 A. **Without reading it, I believe it doesn't.**  
14 Q. The portion of the Remington reference about which you  
06:48 15 testified an direct exam does not provide any chemical  
16 stability data, correct?  
17 A. **No, I believe it doesn't.**  
18 Q. You testified an direct exam about various chemistry  
19 issues. Do you remember that?  
06:48 20 A. **Yes, I do.**  
21 Q. You have never been qualified by any court or by the U.S.  
22 Patent and Trademark Office as an expert in chemistry,  
23 correct?  
24 A. **No, I have not.**  
06:49 25 Q. You're not a expert in medicinal chemistry, correct?  

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1 THE WITNESS: Thank you very much.  
2 MR. HASFORD: You're welcome.  
3 THE WITNESS: Sorry, can I ask what page that's at --  
4 BY MR. HASFORD:  
06:46 5 Q. Certainly. It's --  
6 A. -- **it's not clear.**  
7 Q. Let me direct your attention to Page 186, Line 22, and  
8 the testimony goes to Page 187, Line 5.  
9 Are you there, doctor?  
06:47 10 A. **Yes, I am.**  
11 Q. I asked you:  
12 QUESTION: To be clear, you have neither stated nor  
13 suggested that the Ogawa '225 patent teaches the formulation  
14 of a complex between bromfenac and benzalkonium chloride,  
15 correct?  
16 And you answered:  
17 ANSWER: Correct, that's what I say. And yes.  
18 That was your testimony, wasn't it, doctor.  
19 A. **I see that, yes.**  
06:47 20 Q. You may put that aside.  
21 Now, you testified an direct exam about the concepts of  
22 solubility and stability. Do you remember that?  
23 A. **Yes, I did.**  
24 Q. With respect to aqueous liquid preparations, the concepts  
06:47 25 of stability and solubility are not synonymous at all,  

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1 A. **No, I'm not.**  
2 Q. You're not an expert in organic chemistry, correct?  
3 A. **No, I'm not.**  
4 Q. You are not a member of the American Chemical Society,  
06:49 5 correct?  
6 A. **No, I'm not.**  
7 Q. You have never punished anything in the Journal of the  
8 American Chemical Society, correct?  
9 A. **Not in JACS, no.**  
06:49 10 Q. You testified an direct exam about the Experimental  
11 Examples of '431 patent. Do you remember that?  
12 A. **Yes, I do.**  
13 Q. Let me direct your attention to Experimental Example 1  
14 and Experimental Example 2 of the '431 patent.  
06:49 15 MR. HASFORD: Noel, maybe you can pull that up on the  
16 screen.  
17 BY MR. HASFORD:  
18 Q. Feel free to go to it in your binder, doctor.  
19 Experimental Example 1 and Experimental Example 2 of  
06:50 20 the '431 patent deal with chemical stability, correct?  
21 A. **Can I just check that Tables 1 and 2 -- but you're  
22 talking -- so you're talking about -- okay. Fine. I'm with  
23 you now. So you're talking about tables?**  
24 Q. I'm talking about Experimental Example 1 and Experimental  
06:50 25 Example 2.  

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1 A. Which are in the tables, is that correct? Just let me --  
2 I want to check.  
3 Q. They include those tables, that's correct.  
4 A. Thank you.  
06:50 5 Q. I'll ask the question again just to be clear.  
6 Experimental Example 1 and Experimental Example 2 of  
7 the '431 patent deal with chemical stability, correct?  
8 A. They certainly show the rate remaining of bromfenac. But  
9 I also assume that if there had been major stability, they  
06:51 10 would have also stated that.  
11 Q. Let me direct your attention to your deposition  
12 transcript of September 4, 2015.  
13 A. Can I have a copy, please?  
14 Q. Oh, yes.  
06:51 15 A. Thank you.  
16 Q. You said --  
17 A. It's okay, I'm happy to see it on the screen.  
18 Q. You're fine with seeing it on the screen?  
19 A. I don't want to cause any trouble.  
06:51 20 Q. That's fine. Take a look then, let's go to Page 117,  
21 Line 10, through 118, Line 3. And I asked you:  
22 QUESTION: Do Experimental Example 1 and Experimental  
23 Example 2 of the patents-in-suit deal with physical or  
24 chemical stability?  
06:52 25 You answered:  
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1 ANSWER: Sorry, this Experimental -- this is on Page  
2 7, Column 7?  
3 I said:  
4 QUESTION: Correct, Column 7 and 8.  
06:52 5 You answered:  
6 ANSWER: Okay. That deals with chemical stability  
7 but only as far as it does also indicate there's some physical  
8 component to it because it's correcting for moisture  
9 vaporization from the container.  
10 And I asked:  
11 QUESTION: Aside from the correction for moisture  
12 vaporization from the container, do Experimental Example 1 and  
13 Experimental Example 2 in the patents-in-suit deal with  
14 chemical stability?  
06:52 15 And you answered:  
16 ANSWER: I guess so. Yes.  
17 That was your testimony, wasn't it, doctor.  
18 A. Yes, it is, and I don't think it's inconsistent with what  
19 I just said.  
06:52 20 MR. HASFORD: Let's pull up DDX6-2.  
21 BY MR. HASFORD:  
22 Q. You testified on direct exam about comparative stability  
23 data. Do you remember that?  
24 A. Yes.  
06:53 25 Q. You have never published a paper that mentions  
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1 comparative stability, correct?  
2 A. I don't think I've ever used the phrase comparative  
3 stability, no.  
4 Q. You testified on direct exam about the stability of the  
06:53 5 claimed formulations of the '431 patent. Do you remember  
6 that?  
7 A. Yes, I do.  
8 Q. Yet you do not understand how the aqueous liquid  
9 preparations disclose and claimed in the '431 patent regulate  
06:53 10 the dose of drug to the patient, correct?  
11 A. I didn't understand the phrase "regulate the dose," no.  
12 MR. HASFORD: Please turn to -- let's bring up  
13 DDX2-57.  
14 BY MR. HASFORD:  
06:53 15 Q. DDX2-57 shows Claim 20 of the '431 patent rewritten in  
16 independent form. Do you see that?  
17 A. Yes, I do.  
18 Q. The formulation of Claim 20 of the '431 patent specifies  
19 seven different excipients, correct?  
06:54 20 A. Yes, it does.  
21 Q. A formulator, in fact, would want to use the minimum  
22 number of excipients possible, correct?  
23 A. That's consistent with the inflammation.  
24 Q. Let's turn back to the '431 patent. Actually, let me  
06:54 25 return to your previous answer.  
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1 A formulator, in fact, would want to use the minimum  
2 number of excipients possible consistent with achieving a  
3 formulation, correct?  
4 A. Achieving the required properties of formulation.  
06:54 5 MR. HASFORD: Let's go to your deposition transcript  
6 of February 16th. Let's bring it up at Page 324, Lines 13  
7 through 19. I asked you:  
8 QUESTION: A formulator, in fact, would want try to  
9 use the minimum amount of excipients possible, correct?  
06:55 10 And there was an objection.  
11 And you said:  
12 ANSWER: The minimum number of excipients that's  
13 consistent with achieving a formulation, yes.  
14 That was your testimony, wasn't it, doctor?  
06:55 15 A. Yes. I think that's consistent with what I just said.  
16 Q. Okay. Let's turn back to the '431 patent. Let me direct  
17 your attention to Experimental Examples 1 and 2 again.  
18 Experimental Examples 1 and 2 of the '431 patent entitled  
19 Stability Test of Sodium 2-amino-3-4-bromobenzolphenylacetate  
06:55 20 disclose specific conditions under which stability may be  
21 measured, correct?  
22 A. They define the stability condition, yes.  
23 Q. Experimental Example 1 tested four formulations with  
24 identical compositions expect for variations in the type and  
06:56 25 amount of surfactant, correct?  
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1 A. **Could you repeat the question, please?**  
 2 Q. Certainly.  
 3 Experimental Example 1 of the '431 patent tested four  
 4 formulations with identical compositions except for variations  
 06:56 5 in the type and amount of surfactant, correct?  
 6 A. **I probably -- I wouldn't myself use the term "identical**  
 7 **concentrations."**  
 8 Q. Let's take a look at your deposition transcript then.  
 9 A. **Okay.**  
 06:56 10 Q. Let's go to the February -- or, sorry, the September 4,  
 11 2015, deposition transcript at Page 227, Lines 9 through 19.  
 12 I asked you:  
 13 QUESTION: Take a look now at Paragraph 63 of your  
 14 declaration on Page 18. You state, Experimental Example 1  
 06:56 15 tested four formulations with identical compositions except  
 16 for variations in the type and amount of surfactant.  
 17 Comparison Example 1 used 0.15 grams of polysorbate 80, Sample  
 18 A-02 used 0.15 grams of polyoctoxyl 40 stearate, Sample A-0 --  
 19 I believe that's meant to be A-01.  
 06:57 20 A-02 used 0.15 grams of tyloxapol, and Sample 3 used  
 21 0.02 grams of tyloxapol.  
 22 And I asked you:  
 23 QUESTION: Is that a true statement?  
 24 And you answered:  
 25 ANSWER: Yes.

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1 Q. I'm simply asking you did Experimental Example 1 test  
 2 four formulations with identical compositions expect for  
 3 variations in the type and amount of surfactant?  
 4 A. **That's not how I would put it. But if you want me to**  
 06:58 5 **answer yes because I answered yes before, I see that**  
 6 **statement.**  
 7 Q. Comparison Example 1 used 0.15 grams of polysorbate 80,  
 8 Example A-02 used 0.15 grams of tyloxapol, and Sample A-03  
 9 used 0.02 grams of tyloxapol, correct?  
 06:59 10 A. **That is a correct statement, yes.**  
 11 Q. Let me direct your attention to the discussion after  
 12 Experimental Example 1.  
 13 A. **Okay.**  
 14 Q. The discussion after Experimental Example 1 states that  
 06:59 15 the bromfenac in each eyedrop was stable in the order of  
 16 tyloxapol-containing preparation greater than polyoxyl 40,  
 17 stearate-containing preparation --  
 18 A. **Sorry. Can you just -- I just need -- exactly where are**  
 19 **you, please?**  
 07:00 20 Q. Oh, yes. I'm in the last sentence of that first  
 21 paragraph in the discussion.  
 22 A. **Okay.**  
 23 Q. Do you see it there?  
 24 A. **Yes, I do. Thank you.**  
 07:00 25 Q. Okay. I'll ask it again.

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1 That was your testimony, it wasn't, doctor?  
 2 MS. RAPALINO: Objection, your Honor. It's improper  
 3 impeachment. What the witness testified to is that she  
 4 wouldn't say identical concentrations, and this goes to a  
 06:57 5 different point.  
 6 MR. HASFORD: She said that at her deposition, your  
 7 Honor.  
 8 MS. RAPALINO: And just now at trial she said I  
 9 wouldn't say identical concentrations, which is exactly what  
 06:57 10 she said at her deposition.  
 11 MR. HASFORD: But What she said was: Experimental  
 12 Example 1 tested four formulations with identical compositions  
 13 except for variations in the type and amount of surfactant,  
 14 that was the question I asked her.  
 06:58 15 THE COURT: I think that's exactly what she testified  
 16 to on direct. I don't see this as impeaching.  
 17 MR. HASFORD: May I ask her the question then?  
 18 THE COURT: Which question?  
 19 MR. HASFORD: May I ask her did Experimental Example  
 06:58 20 1 test four formulations with identical compositions except  
 21 for variations in the type and amount of surfactant?  
 22 THE WITNESS: I don't know what I'm supposed to  
 23 answer here. I can explain there's a limitation with your  
 24 question.  
 25 BY MR. HASFORD:

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1 The discussion after Experimental Example 1 states that  
 2 the bromfenac in each eyedrop was stable in the order of  
 3 tyloxapol-containing preparation greater than polyoxyl 40  
 4 stearate-containing preparation, greater than Polysorbate  
 07:00 5 80-containing preparation." Correct?  
 6 A. **That's what it says, yes.**  
 7 Q. You would agree that when the '431 patent compared the  
 8 stability of bromfenac at pH 7.0, tyloxapol stabilized the  
 9 aqueous liquid preparation better than Polysorbate 80,  
 07:00 10 correct?  
 11 A. **The same concentration of the surfactant, that is a**  
 12 **correct statement, yes.**  
 13 Q. Experimental Example 1 also states that the composition  
 14 containing 0.02 percent by weight tyloxapol is more stable  
 07:01 15 than a concentration containing 0.15 percent weight per volume  
 16 tyloxapol, correct?  
 17 A. **Certainly, in terms of percent remaining, that's a**  
 18 **correct statement, yes.**  
 19 Q. Specifically, Experimental Example 1 compares the  
 07:01 20 stability of two different aqueous liquid preparations with  
 21 identical compositions, A-02 and A-03, where only the amount  
 22 of surfactant was varied, correct?  
 23 A. **Yes, that is correct.**  
 24 Q. You would agree that a person of ordinary skill in the  
 07:01 25 art could conduct an experiment comparing the stability of two

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1 different aqueous liquid preparations with identical  
2 compositions where only the amount of surfactant was varied,  
3 correct?

4 **A. Yes, that's correct.**

07:01 5 MR. HASFORD: May I have a moment, your Honor?

6 THE COURT: Yes.

7 BY MR. HASFORD:

8 **Q.** The '431 patent discloses stable preparations of  
9 bromfenac and tyloxapol, even without sodium sulfite, correct?

07:02 10 **A. Wait a minute.**

11 **Yes, that's correct. That's -- could I just qualify?**

12 **That's correct in the terms of the definition of stability,**

13 **yes.**

14 **Q.** You testified on direct exam about the closest prior art.

07:02 15 Do you remember that?

16 **A. Yes, I do.**

17 **Q.** You do not know whether Experimental Example 1 of the  
18 '431 patent tests against the closest prior art for comparison  
19 purposes, correct?

07:03 20 **A. Perhaps you could explain to me what you mean, "test  
21 against."**

22 **Q.** What is your understanding of testing against?

23 **A. I don't have an understanding. That's why I've asked.**

24 **Q.** Okay. Well, let me direct you to your deposition because

07:03 25 I asked you this question and you understood it there, so I'll

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1 refresh your recollection.

2 Let's go to the September 4th deposition, at Page 228,  
3 Lines 8 through 14.

4 And I asked you:

07:03 5 "QUESTION: Do you know whether Experimental Example 1  
6 tests against the closest prior art for comparison purposes?"

7 And there were some objections, and you said: "I don't  
8 have that information to hand to make that comparison." That  
9 was your testimony, wasn't it, Doctor?

07:03 10 MS. RAPALINO: I'm just going to object, your Honor.

11 We did preserve an objection that the question was vague, and  
12 I believe that the witness just testified that she felt the  
13 question was vague as well.

14 MR. HASFORD: If she felt the question was vague,

07:04 15 your Honor, she could have asked me to repeat it or rephrase

16 it at her deposition.

17 THE COURT: Well, there was an objection, and I agree

18 that the question was vague.

19 And, in any event, the response given at the dep is

07:04 20 not impeaching today.

21 MR. HASFORD: Well, if I may, Your Honor, I mean she

22 has testified extensively today about what she believes that

23 the closest prior art was for comparison purposes. And at the

24 deposition, she said she did not have that information at hand

07:04 25 to make that comparison, so I believe her testimony at the

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1 deposition does undercut the testimony she gave here to your  
2 Honor today.

3 MS. RAPALINO: And, just to put context to this, this

4 was at her deposition in the context of claim construction,

07:04 5 before she had written any of her expert reports in this case

6 and before she had fully formed all of those opinions. And

7 what she said here is that the information -- she didn't have

8 the information at hand, which I don't think is inconsistent

9 with her knowing that information sitting here today.

07:04 10 MR. HASFORD: Well, she also testified, your Honor,

11 at that deposition that she had made certain -- or she had

12 formed certain opinions prior to that time. She also

13 expressed essentially the statement substantive opinions in a

14 declaration on April 21st, 2015, before the U.S. Patent and

07:05 15 Trademark Office in the parallel IPR proceedings, and I can

16 point to deposition testimony that substantiates that in her

17 February 16th transcript.

18 MS. RAPALINO: And, again, your Honor, I would just

19 say that her testimony at her deposition was not inconsistent.

07:05 20 Her testimony was she didn't have the information at hand to

21 make that comparison, suggesting that she didn't have the

22 information in front of her at her deposition, not that she

23 was unaware of that or wouldn't be able to make that

24 comparison if presented with the right materials.

07:05 25 MR. HASFORD: Well, your Honor, I asked whether she

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1 knew, and I asked her at the beginning of the deposition that  
2 if she didn't understand a question, to please ask me to  
3 rephrase the question and I would do so.

4 THE COURT: Okay, time is running short.

07:05 5 I will permit the witness to explain her deposition

6 answer, if you care to do so. Do you see it on the screen?

7 THE WITNESS: Yes, I do.

8 I believe, without reading the context of the

9 discussion, I didn't have the understanding to be able to make

07:06 10 any comparison because I didn't understand the question.

11 BY MR. HASFORD:

12 **Q.** When I asked you do you know whether Experimental Example

13 1 tests against the closest prior art for comparison purposes,

14 you answered, I don't have that information at hand to make

07:06 15 that comparison, correct?

16 **A. Yes, I did, and I don't think that's inconsistent.**

17 **Q.** Okay. You can put that aside.

18 MR. HASFORD: And I have no further questions at this

19 time, your Honor.

07:06 20 THE COURT: All right. Any redirect?

21 MS. RAPALINO: No redirect, your Honor.

22 THE COURT: Okay. I have no questions. Professor

23 Lawrence, thank you again.

24 THE WITNESS: Thank you.

07:06 25 THE COURT: You can step down.

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1 (The witness left the stand.)

2 MS. RAPALINO: Your Honor, with that, we conclude our

3 presentation from our live witnesses, and I believe the only

4 issue that remains to be addressed is the exhibits that need

07:06 5 to be moved into evidence and the arguments with respect to

6 those exhibits.

7 THE COURT: Okay. So there was a long list of

8 exhibits at the close of the Trattler direct today, beginning

9 with PTX-164. Is that the list that we're talking about?

07:07 10 MS. HOLLAND: That's one of them, your Honor. We can

11 start there.

12 THE COURT: Okay. And are there objections to any on

13 that list?

14 MS. HOLLAND: No, your Honor.

07:07 15 THE COURT: All right. Then shall I read the

16 exhibits that are now received into evidence?

17 PTX-164, PTX-277, JTX144, PTX-474, JTX023, JTX143,

18 JTX135, JTX051, PTX-265, JTX052, JTX018, PTX-270, JTX146,

19 PTX-281, JTX142, and JTX145, all are received into evidence.

07:08 20 (EXHIBITS PTX-164, PTX-277, JTX144, PTX-474, JTX023, JTX143,

21 JTX135, JTX051, PTX-265, JTX052, JTX018, PTX-270, JTX146,

22 PTX-281, JTX142, and JTX145 WERE RECEIVED IN EVIDENCE.)

23 MS. HOLLAND: Your Honor, may I continue with two

24 exhibits that were used during the Trattler cross-examination?

07:08 25 I would like to move those into evidence. DTX-210, which was

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1 THE COURT: Any objection?

2 MR. HASFORD: We have no objection to those, Your

3 Honor.

4 THE COURT: Okay. Each of the following are received

07:11 5 into evidence: JTX57, JTX158, JTX201, JTX207, JTX209, and

6 DTX-240.

7 MS. HOLLAND: 440.

8 THE COURT: 440, pardon me. DTX-440.

9 (EXHIBITS JTX57, JTX158, JTX201, JTX207, JTX209, and DTX-440

07:11 10 WERE RECEIVED IN EVIDENCE.)

11 MS. HOLLAND: Shall we move on then to Dr. Williams'

12 cross?

13 THE COURT: Yes.

14 MS. HOLLAND: Okay. So, first, I will give you the

07:11 15 list and then we can -- I can discuss them.

16 So, the first one is PTX-125C, the next one is

17 JTX33A, DTX-478, and DTX-479A.

18 THE COURT: Okay. And are there objections?

19 MR. HASFORD: Yes, there are objections to these,

07:12 20 your Honor. I can summarize the substance of our objections.

21 THE COURT: Just a moment. Will these be in the

22 Williams' cross binder?

23 MS. HOLLAND: All except 33A, which is one I handed

24 up separately. Would you like a copy of that one, your Honor?

07:12 25 THE COURT: Well, I will ask my law clerk to retrieve

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1 the Donnenfeld article, and DTX-216, which was the Henderson

2 article.

3 THE COURT: Any objection?

4 MR. HASFORD: No objection, Your Honor.

07:09 5 THE COURT: Okay. Each of these are received into

6 evidence. DTX-210 and DTX-216.

7 (DEFENDANT EXHIBITS DTX-210 and DTX-216 WERE RECEIVED IN

8 EVIDENCE.)

9 MS. HOLLAND: So, your Honor, I think that leaves us

07:09 10 with exhibits that were introduced during the

11 cross-examination of Dr. Williams, and there are four of

12 those, and I understand there are objections to them, so I

13 will give you the list, your Honor. Maybe we can go through

14 them one by one?

07:09 15 THE COURT: Okay. Just a moment.

16 Okay. Ms. Holland?

17 MS. HOLLAND: Your Honor, I'm not -- I'm not sure if

18 you want to do this before or after, but there are also some

19 exhibits from Dr. Heathcock's direct, and I don't know if

07:10 20 those are objected to or not. Most of them are already in

21 evidence. It's JTX57, JTX158, JTX201, JTX207, JTX209, and

22 DTX-440.

23 THE COURT: That was the end of Dr. Heathcock?

24 MS. HOLLAND: That was during the direct of

07:11 25 Dr. Heathcock, yes.

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1 Dr. Williams' cross binder, please.

2 MS. HOLLAND: Your Honor, I don't know if you have a

3 copy of the trial transcript from yesterday. That may be

4 helpful in trying to figure this out. If you don't mind, I

07:13 5 can hand one up.

6 THE COURT: Okay.

7 MS. HOLLAND: This is yesterday's transcript.

8 THE COURT: All right. Why would each be admissible?

9 MS. HOLLAND: So, your Honor, 125C is a document from

07:14 10 the NDA for Prolensa®, and you may recall it contained the

11 release and shelf-life pH specifications for the product. I

12 used this in Dr. Williams' cross-examination without

13 objection. And it's proper substantive evidence as to the

14 actual pH of the Prolensa® product, which is something that

07:14 15 Dr. Williams talked about in his direct examination. It went

16 in without objection. It's clearly a party admission. It's

17 in their NDA. So I just don't see any basis for objection.

18 MR. HASFORD: Shall we address these one by one, your

19 Honor?

07:15 20 THE COURT: Yes, please.

21 MR. HASFORD: Because that's inaccurate. We made the

22 objection, we preserved the objection. Counsel has attempted

23 during Dr. Williams' cross exam to use all four of these

24 documents for impeachment purposes only.

07:15 25 I can start with PTX-125C. This is a portion of the

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1 Prolensa® NDA. She attempted to use it for impeachment on the  
 2 pH level. Your Honor actually precluded them, based on my  
 3 objection, from asking about the inventor's purpose set forth  
 4 in these documents. And --  
 07:15 5 MS. HOLLAND: Your Honor, I don't want to --  
 6 MR. HASFORD: Your Honor, may I finish?  
 7 MS. HOLLAND: Can I point you to the transcript? It  
 8 just might facilitate the discussion.  
 9 MR. HASFORD: And I'm happy to -- I was just going to  
 07:15 10 point out the transcript.  
 11 MS. HOLLAND: Go ahead. I'm sorry then. I  
 12 apologize.  
 13 MR. HASFORD: Counsel represented that these were for  
 14 impeachment purposes.  
 07:15 15 So, among other places, Page 844 and Page 847, she  
 16 stated that I think --  
 17 THE COURT: Just a moment.  
 18 MR. HASFORD: -- as a matter of impeachment of this  
 19 witness, I should be permitted to ask these questions --  
 07:15 20 THE COURT: Just a moment.  
 21 MR. HASFORD: I apologize.  
 22 MS. HOLLAND: Your Honor, the actual part where  
 23 PTX-125C is discussed is on Page 918, beginning on Line 7.  
 24 That's where the -- that's where I started talking about this  
 07:16 25 exhibit.

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1 impeachment.  
 2 871: This is impeachment.  
 3 And then, as your Honor will recall, we -- at the  
 4 end, your Honor asked, those were -- and this is Page 930 --  
 07:17 5 those were only for impeachment, weren't they? I answered  
 6 yes, and the Court acknowledged, so they wouldn't come into  
 7 evidence. And that's our objection here.  
 8 MS. HOLLAND: Your Honor, I think the problem is that  
 9 when you look at the testimony, it's not about the exhibit  
 07:17 10 we're talking about. That's the problem.  
 11 There were some exhibits that were only used for  
 12 impeachment, and I didn't put those on the list of four that I  
 13 gave you.  
 14 If you look specifically at Page 918, it's a  
 07:18 15 completely different exhibit we're talking about. It wasn't  
 16 used for impeachment because it wasn't inconsistent with  
 17 Dr. Williams' testimony. He agreed with what was in PTX-125C  
 18 that those were the specifications for the pH for Prolensa®.  
 19 There is no objection there.  
 07:18 20 I'm not -- apparently, Mr. Hasford saying that if he  
 21 objected once on the basis of one document being used for  
 22 impeachment, it applies to the entire testimony thereafter.  
 23 Clearly, that's not the case.  
 24 THE COURT: Well, is it necessary to have this  
 07:18 25 document in evidence? You have the testimony that says what

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1 MR. HASFORD: Well, your Honor --  
 2 MS. HOLLAND: And it goes through till 919, Line 9.  
 3 MR. HASFORD: This preliminary discussion on 844 and  
 4 847 applies to all these exhibits actually, and I will point  
 07:16 5 your Honor to 847 in particular.  
 6 So Page 847, Line 6: If there are other internal  
 7 documents that show this is not the case, I don't see why  
 8 Dr. Williams can't be impeached with them. And she repeated  
 9 that mantra throughout the next several pages of the  
 07:16 10 deposition transcript.  
 11 I pointed your Honor to Page 844 where she stated:  
 12 And I think as a matter of impeachment of this witness, I  
 13 should be permitted to ask these questions.  
 14 Page 859: Your Honor, can we go back to the question  
 07:16 15 that I asked which led to this -- she stated impeachment?  
 16 Page 865: That was the testimony just now, and I  
 17 would like to impeach the witness on that point.  
 18 Page 866: She stated, for this right now, the  
 19 question is on impeachment? Yes. Then she stated again, can  
 07:17 20 I ask some questions and then we'll see if it actually is  
 21 impeachment?  
 22 867: Ms. Holland states, this directly impeaches the  
 23 testimony that was just given.  
 24 Page 868: It's still for impeachment, your Honor.  
 07:17 25 869: I'm asking about it for purposes of

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1 the -- what the pH is in this formulation.  
 2 MS. HOLLAND: Your Honor, for purposes of appeal, we  
 3 should be able to have our documents in evidence. There is --  
 4 there is no reason not to put this into evidence. So --  
 07:19 5 THE COURT: Well, to avoid a fight that is probably  
 6 one that's going to require me to read about a hundred pages  
 7 of transcript and relive the glories of yesterday.  
 8 MS. HOLLAND: I apologize for that, your Honor.  
 9 I thought this was very straightforward. If you look  
 07:19 10 at PTX --  
 11 THE COURT: But didn't the witness give you the  
 12 answer that you were looking for? So why do you need the  
 13 document?  
 14 MS. HOLLAND: Your Honor, I don't -- I don't want you  
 07:19 15 to have to read a hundred pages. My only point is that to  
 16 make an evidentiary record, the best record that I can make  
 17 for my client is to have the document into evidence. I  
 18 understand what you are saying, your Honor.  
 19 There is nothing in this, for example, that says  
 07:19 20 exactly what the page is from the transcript. It says  
 21 PTX-125C.  
 22 Your Honor, if the other side is willing to stipulate  
 23 that those are the release specifications and shelf-life pH  
 24 specifications for their Prolensa® product, I agree with you,  
 07:19 25 I don't -- this is not a stipulation. If there is a

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1 stipulation like that, I agree with you, your Honor --

2 THE COURT: Well, would that solve the problem? Is

3 there any reason not to stipulate that that's -- those are the

4 release stipulations?

07:20 5 MR. HASFORD: I think we can stipulate that those are

6 the release specifications set forth in the NDA, your Honor.

7 And Dr. Williams' testimony about that is what his testimony

8 is. On only the page PROL 0003890.

9 THE COURT: Do you want to look at that page of the

07:20 10 document and see if that's the one that is -- that you were

11 asking about?

12 MS. HOLLAND: Yes, Your Honor. And, again, I

13 apologize. I just want to make sure for appeal purposes that

14 I have it.

07:20 15 THE COURT: Oh, no. And you should make the record

16 that you feel is appropriate.

17 MS. HOLLAND: And with A stipulation, I believe

18 that's fine. It's just his testimony is not -- it doesn't

19 mean I can't argue against that later. That's why I wanted

07:20 20 the stipulation.

21 All right. So I guess the stipulation would be that

22 PTX-125C, which is PROL 0003890, contains the specification

23 for plaintiff's Prolensa® product and that the pH

24 specification is for release 7.6 to 8.0, and for shelf, 7.4 to

07:21 25 8.1.

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1 MS. HOLLAND: This was part of a document that there

2 was a stipulation in this case that this document contained

3 the underlying data for Dr. Williams's exhibits. I can hand

4 up the stipulation, I hope, if we have it.

07:23 5 MR. HASFORD: No. I apologize, Your Honor. It was

6 the summary of this document that was a stipulation. The

7 document itself was not part of the stipulation. It was the

8 summary of the underlying data.

9 MS. HOLLAND: The stipulation said that this, what

07:23 10 I'm seeking to put into evidence, was the underlying data for

11 the stability chart that Dr. Williams put into evidence.

12 MR. HASFORD: Yeah. I can read the stipulation, Your

13 Honor: The parties agree that documents with Bates Nos.

14 PROL 0359933 to PROL 0359941 are admissible summaries under

07:23 15 Federal Rule of Evidence 1006. Neither plaintiffs nor

16 defendants will object to the admission into evidence of any

17 document within this Bates range other than on grounds of

18 relevance or inaccurate translation. That's Docket Item 155

19 in the 14 CV 667 Docket, that was the extent of the

07:24 20 stipulation. That stipulation did not state that JTX33A --

21 MS. HOLLAND: Can I have that, please?

22 MR. HASFORD: Certainly, certainly.

23 MS. HOLLAND: Thanks.

24 Oh, here, yeah, Mr. Hasford didn't exactly read in the

07:24 25 whole stipulation. Do we have another copy of this?

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1 THE COURT: All right. And does the plaintiff so

2 stipulate?

3 MR. HASFORD: We stipulate that that's exactly what

4 the document says, your Honor, yes.

07:21 5 THE COURT: All right. Then that stipulation is

6 received as evidence and need not be proven further. And so

7 that resolves 125C.

8 MS. HOLLAND: It does, your Honor.

9 THE COURT: All right. JTX33A I think was next?

07:22 10 MS. HOLLAND: Yes, your Honor. And just to remind

11 the Court, this was -- Dr. Williams had some testimony about

12 stability data that, if you recall, came from internal

13 documents of Mr. Sawa. There was a ruling that I could use

14 the document insofar as it was -- pertained to the underlying

07:22 15 data that was used in the demonstrative exhibit, and that's

16 what JTX33A is and what it would come in for.

17 THE COURT: Is there any objection to JTX33A?

18 MR. HASFORD: Well, yes, there's an objection to the

19 document going into evidence, Your Honor, because she used it

07:22 20 only for purposes of attempted impeachment with respect to the

21 data that she just discussed. If she's looking for a

22 stipulation as to whether one particular page depicts certain

23 data about what she questioned Dr. Williams, we would be

24 amenable to considering that. But it's the placing of the

07:22 25 entire document into evidence is what we're objecting to.

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1 MR. HASFORD: What part were you looking at because I

2 read in the entire relevant paragraph.

3 MS. HOLLAND: Well, I guess we probably have an issue

4 about relevance but...

07:24 5 MR. HASFORD: Okay. Which paragraph do you believe I

6 left out?

7 MS. HOLLAND: Yeah, I think the issue is that in

8 Paragraph 3, plaintiffs stipulated that the documents that

9 make up 33A are the underlying documents for Dr. Williams'

07:25 10 charts.

11 MR. HASFORD: No.

12 MS. HOLLAND: So I seek to put them in on that basis.

13 MR. HASFORD: No, Your Honor. Those -- the documents

14 in Paragraph 3 have entirely different Bates numbers from the

07:25 15 JTX33 document that Ms. Holland is attempting to get into

16 evidence.

17 MS. HOLLAND: Yes. Plaintiffs produced them twice

18 under different Bates numbers.

19 MR. HASFORD: I don't believe that they are the same

07:25 20 documents, Your Honor.

21 Would Your Honor like a copy of the stipulation?

22 THE COURT: Yes.

23 MS. HOLLAND: There's a stipulation not to object to

24 admission.

07:25 25 MR. HASFORD: That's -- no, Your Honor, the -- the

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1 stipulation, as far as the summary is in Paragraph 4.  
 2 MS. HOLLAND: Yeah.  
 3 MR. HASFORD: And then there's a stipulation about  
 4 various other documents in Paragraph 3, but that's not JTX33.  
 07:26 5 MS. HOLLAND: Yes, they are, and maybe we don't need  
 6 to do this today, but I can show you it's the same documents.  
 7 MR. HASFORD: Your Honor, I'd like to resolve this  
 8 today because I don't want this to turn into a round of  
 9 briefing before Your Honor to burden the Court.  
 07:26 10 MS. HOLLAND: This is your --  
 11 THE COURT: Let's take a moment and see if the same  
 12 document was produced twice. I think that's the dispute.  
 13 MR. HASFORD: And, Your Honor, we -- I would also  
 14 note in here that we've preserved a relevance objection and  
 07:26 15 the relevance objection is actually what we've made here and I  
 16 can explain that to Your Honor. As Your Honor will recall,  
 17 you precluded them --  
 18 THE COURT: Just a moment.  
 19 MR. HASFORD: I apologize.  
 07:26 20 MS. HOLLAND: It may take us a few moments to put  
 21 this together, Your Honor.  
 22 THE COURT: Okay. I agree that we should work it out  
 23 now.  
 24 MS. HOLLAND: Yeah, please. Your Honor, maybe we can  
 07:27 25 go on to the next ones then while we're having people look at  

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1 these documents for, was for attempted impeachment, not to  
 2 show any purpose of any experiments or anything like that.  
 3 And so, that's why we object to -- to placing the  
 4 entire document into evidence. And again, it goes to Your  
 07:28 5 Honor's ruling that Page 930 of the transcript yesterday,  
 6 where Your Honor asked: Those were only for impeachment,  
 7 weren't they?  
 8 We confirmed that they were, and Your Honor stated that  
 9 they wouldn't come into evidence because they were just for  
 07:28 10 impeachment.  
 11 MS. HOLLAND: Your Honor, again, we have an issue of  
 12 different places in the transcript talking about different  
 13 documents.  
 14 Let me just -- let me get the first issue off the table  
 07:28 15 about the pretrial order. The final pretrial order that was  
 16 -- the amended one that was delivered to Your Honor did have  
 17 these exhibits. Plaintiffs produced their FDA 30(b)(6)  
 18 witness after the initial pretrial order was filed with Judge  
 19 Williams, and we had permission to supplement the trial list  
 07:29 20 with documents that were connected with the 30(b)(6).  
 21 These particular ones were not marked at the deposition  
 22 but they were FDA documents that were relevant to FDA issues  
 23 raised that were part of this 30(b)(6) deposition.  
 24 Plaintiffs withheld -- well, I don't want to get into  
 07:29 25 why it happened, but the 30(b)(6) on FDA issues didn't happen  

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1 those Bates numbers.  
 2 MR. HASFORD: Maybe if you'll give us a second, Your  
 3 Honor.  
 4 Do you just want to do another stipulation like we did  
 07:27 5 on the last one, you take the portion that you used with  
 6 Dr. Williams and stipulate that that portion is what it  
 7 purports to be?  
 8 MS. HOLLAND: Well, I think we have a bigger problem  
 9 here, because we have a stipulation where you said you weren't  
 07:27 10 going to object to those documents going into evidence if we  
 11 agree to your summaries, and now you're objecting.  
 12 MR. HASFORD: We maintained a relevance objection  
 13 there in the stipulation.  
 14 MS. HOLLAND: Okay. Well, let's -- I think, Your  
 07:27 15 Honor, maybe it's better to move on then, too.  
 16 THE COURT: All right. Then we will set that aside  
 17 for a moment. The next one is DTX-478.  
 18 MR. HASFORD: And, Your Honor, I might be able to  
 19 short-circuit this, because DTX-478 and 479A, I think we can  
 07:27 20 lump them both together.  
 21 First off, these were not identified in the final  
 22 pretrial order so they are improper for that reason, No. 1 --  
 23 but at least for moving into evidence. But No. 2, as Your  
 24 Honor will recall, these were internal documents from Xibrom  
 07:28 25 NDA, the only purpose Your Honor allowed Ms. Holland to use  

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1 until after the pretrial order was entered, and we had  
 2 explicit permission to amend our exhibit list to include  
 3 documents connected with the issues in the 30(b)(6)  
 4 depositions.  
 07:29 5 MR. HASFORD: If they felt those documents were so  
 6 important, Your Honor, why didn't they use them at that  
 7 30(b)(6) deposition? That's problem No. 1. But the bigger  
 8 problem, of course, is the fact that they were used at trial  
 9 only for impeachment purposes, and they shouldn't go into --  
 07:29 10 be entered into evidence on those grounds.  
 11 MS. HOLLAND: Your Honor, so I think what happened at  
 12 trial is that there was a distinction made between internal  
 13 documents like Mr. Sawa's notebooks, et cetera, and between  
 14 plaintiff's NDA documents. And on Page 863 of the transcript,  
 07:30 15 we got into this issue about NDA documents, and basically,  
 16 Your Honor, you said you were going to permit the testimony  
 17 for that limited purpose of being plaintiff's own statement to  
 18 the FDA and then later on, you explained the ruling on Page  
 19 863, Line 17: The thrust of my ruling is that this is a  
 07:30 20 statement, not in an internal document, not in a laboratory  
 21 report, but in a statement to the FDA about the purpose of a  
 22 particular constituent, in that case it was tyloxapol. And  
 23 the witness, it's fair to question him because his direct  
 24 testimony touched upon this very subject, et cetera.  
 07:30 25 And then -- so that ruling, my understanding was that  

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1 for that purpose, the NDA was coming in as substantive  
 2 evidence on that point and not as impeachment. Other  
 3 documents I agree with Your Honor were different, and you put  
 4 them in the category of an internal document and a laboratory  
 07:31 5 report where I could only do impeachment. The FDA admissions  
 6 contained in plaintiff's NDA, I believe, were ruled on as  
 7 substantive evidence.  
 8 MR. HASFORD: It's not prior art. We also, as Your  
 9 Honor will recall, we raised the issue and this was ISTA who  
 07:31 10 filed the NDA. It was not plaintiffs. Your Honor then later  
 11 clarified on Page 913 of the transcript when Ms. Holland was  
 12 asking to use these documents to -- as to what they expected  
 13 and intruded into the inventor's area or the area of the  
 14 inventor's state of mind, Your Honor said, you could ask what  
 07:31 15 the data showed, but again, the purpose, what they expected is  
 16 intruding into the area of the inventor's mind of why the  
 17 inventor was doing what he was doing, and the Court instructed  
 18 Ms. Holland that the Court had already ruled to move on.  
 19 Again, as we go back in the transcript to Pages 844,  
 07:32 20 847, for example, Ms. Holland makes clear that the point of  
 21 using all of these documents was for alleged impeachment, and  
 22 it was not for the substance of the documents and that's how  
 23 Your Honor ruled on our objection.  
 24 MS. HOLLAND: Your Honor, Page 913 testimony that you  
 07:32 25 were just pointed to had to do with the internal documents and  

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1 as I said, there was a distinction both in my questioning and  
 2 in the admissibility of the documents between FDA admissions  
 3 and NDA documents and the internal lab notebooks, and I  
 4 believe that that ruling is clearly stated on Page 863 when  
 07:32 5 the Court made that distinction between internal laboratory  
 6 documents and FDA documents.  
 7 MR. HASFORD: And Your Honor, these are non-prior art  
 8 documents. These are documents that were transmitted under  
 9 confidentiality to the FDA. Ms. Holland was only attempting  
 07:33 10 to use them for impeachment and she made that clear on the  
 11 record time and time again, and I've already read that --  
 12 those portions of the record.  
 13 MS. HOLLAND: I never made that statement about FDA  
 14 documents. We had a whole discussion on this. Your Honor  
 07:33 15 made a ruling yesterday.  
 16 THE COURT: Well, my ruling on Page 863 permitted you  
 17 to use the documents to question the witness, and I permitted  
 18 you to use the document to see if it changed the witness's  
 19 mind or changed the witness's view, as to that particular  
 07:33 20 subject. And I did so because it wasn't just some idle  
 21 statement from the literature, but rather a statement by the  
 22 plaintiff's predecessor to the FDA.  
 23 But I didn't admit the document into evidence. I  
 24 permitted questioning that's based on the document as is done  
 07:33 25 all the time with regard to impeachment materials. So in  

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1 permitting the questioning, it doesn't lay the foundation for  
 2 the admission of the -- of the document itself. If this  
 3 actually might be an area where the parties, if the defendant  
 4 feels strongly about its admissibility, you may want to  
 07:34 5 address this in your post-trial submissions 30 days from now  
 6 about why this confidential submission to the FDA may be  
 7 admitted into evidence.  
 8 MS. HOLLAND: Just so I understand --  
 9 THE COURT: Into evidence.  
 07:34 10 MS. HOLLAND: I'm sorry, Your Honor. Just so I  
 11 understand, is the objection relevance? Because clearly, it's  
 12 a party admission that can come in.  
 13 THE COURT: Yeah, the relevance objection, I would  
 14 overrule at this point in time.  
 07:34 15 MS. HOLLAND: So what is the objection, then? I just  
 16 don't understand. What is the federal rule of evidence by  
 17 which it can't come in?  
 18 MR. HASFORD: The objection, Your Honor, it's not  
 19 prior art and they're attempting to use other portions of the  
 07:34 20 document improperly. The document was only being used -- Your  
 21 Honor allowed it to only be used for the limited purpose of  
 22 certain portions of the document. They actually attempted to  
 23 go to portions of these documents and try to reach into the  
 24 inventor's state of mind.  
 07:35 25 So it was irrelevant for that purpose but it's also --  

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1 it's not a proper document to be admitted into evidence,  
 2 because it was only being used for the limited purpose of  
 3 impeachment, and that's exactly how Your Honor ruled on Page  
 4 930 of the transcript.  
 07:35 5 THE COURT: And that was -- that was intentional.  
 6 MS. HOLLAND: It was a lot -- I'm sorry.  
 7 THE COURT: It was propounded as impeachment, I  
 8 permitted it as impeachment, and that nose inside the tent  
 9 doesn't permit the whole camel to come in. If there's things  
 07:35 10 in the record that are derived from the document, then so be  
 11 it. They are in the record and they can be used and the  
 12 witness has testified to them. That doesn't make the entire  
 13 document admissible. There's other areas of the document  
 14 where I sustained objections.  
 07:35 15 MS. HOLLAND: Not on that particular document.  
 16 THE COURT: Not on that particular one?  
 17 MS. HOLLAND: No.  
 18 THE COURT: Okay.  
 19 MS. HOLLAND: Well, Your Honor, I would -- maybe I  
 07:36 20 can suggest that we have the same sort of stipulation we had  
 21 for 125C, where the pieces that were -- actually came into the  
 22 record, we can stipulate that those were in the Xibrom NDA.  
 23 Would that be okay?  
 24 MR. HASFORD: I think we would have to look at  
 07:36 25 exactly what came into the record and how it did, Your Honor.  

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1 I apologize, but I don't think we can agree to that at this  
2 point because I'm not sure what Ms. Holland tried to read into  
3 the record and what was objected to without scouring the whole  
4 transcript, unfortunately.

07:36 5 MS. HOLLAND: And just to make clear again, Your  
6 Honor, I recognize these are not prior art, but a lot of what  
7 Dr. Williams talked about in his direct was not prior art  
8 because you don't have to be within the scope of the prior art  
9 for any secondary considerations, and we -- it seemed like  
07:36 10 Dr. Williams was pulling stuff from all over the place for his  
11 secondary considerations, labels that came later on products  
12 that weren't even around as of 2003. So to be clear, there is  
13 no prior art problem when you come to secondary  
14 considerations.

07:37 15 MR. HASFORD: And our --  
16 THE COURT: And if Dr. Williams had testified that he  
17 relied upon this document as a basis for his testimony and was  
18 -- and testified as to its contents in his direct, then that  
19 would strengthen your hand as to its admissibility, but he  
07:37 20 didn't do that.

21 MS. HOLLAND: But he based his opinions on his  
22 testimony that the stability data was -- and I think we went  
23 through this yesterday, that the stability data that he put up  
24 on the screen was chemical stability data, and that -- that's  
07:37 25 not a matter of prior art or not, it's factual. Was the data

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1 he was relying on, was that really chemical stability data or  
2 was it something else?

3 And that goes to secondary considerations and it really  
4 -- I don't think does it matter whether he used it or not.  
07:37 5 Maybe he purposely didn't use it because he didn't like what  
6 was in there. But the point is, to get to the bottom of the  
7 fact of when he put the stability up there -- data up there,  
8 was that chemical stability or physical stability?

9 The way to get to the bottom of that issue is to look  
07:38 10 at the actual fact of whether it was physical or chemical  
11 stability. Again, it's not a matter of prior art. It goes to  
12 whether there's an unexpected result here, which could turn on  
13 what the purpose of the use of the tyloxapol and polysorbate  
14 80 was in the formulations, not as a matter of prior art or  
07:38 15 obviousness, but as a factual matter, why were they in these  
16 compositions.

17 MR. LIPSEY: Your Honor --

18 MS. HOLLAND: So I believe that's an appropriate  
19 basis to put these into evidence.

07:38 20 MR. LIPSEY: Your Honor, if I may. This is the fifth  
21 time we've had this discussion. The data that was put up for  
22 unexpected results, the number was the percent drug remaining,  
23 which is a chemical stability number.

24 MS. HOLLAND: We don't agree.

07:38 25 MR. LIPSEY: Counsel has wanted to get before Your

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1 Honor information suggesting that it also played a role in  
2 physical stability, and she certainly, you know, played that  
3 out in front of Your Honor many, many times here. But the  
4 fact of the matter is, why the inventor put it in what other  
07:39 5 things it may do or may not do is within the forbidden realm.  
6 She cannot take that and say, see, it's obvious that it  
7 affects physical stability because they mentioned in their  
8 non-prior art documents, physical stability. The unexpected  
9 result was chemical stability.

07:39 10 MS. HOLLAND: With all due respect, Your Honor,  
11 Mr. Lipsey's saying that the unexpected result is chemical  
12 stability doesn't make it a fact. The fact is, there's a  
13 dispute about it, whether it was chemical or physical  
14 stability.

07:39 15 THE COURT: All right. I understand and that's why I  
16 overruled the relevance objection. But the greater objection  
17 here is that this takes us into the inventor's mind about the  
18 purpose or the why of why the inventor was doing what they  
19 were doing.

07:39 20 MS. HOLLAND: This is not -- this is about the prior  
21 art. It's not about the invention. This is about Xibrom.

22 MR. LIPSEY: It's the inventor's own work, the  
23 inventor's non-public own work, and that whole spectrum of  
24 stuff is not available for purposes of attacking the validity  
07:40 25 of the patent. She's allowed to use what's in the public

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1 domain.

2 MS. HOLLAND: I'm not sure if Mr. Lipsey is  
3 suggesting that Mr. Sawa was also the inventor of the '225  
4 patent, because that's prior art. The Xibrom NDA has nothing  
07:40 5 to do with the invention here. It's in the -- it's about the  
6 prior art.

7 MR. LIPSEY: It's only in the prior art --

8 THE COURT: Just a moment.

9 MS. HOLLAND: So that particular objection of  
07:40 10 Mr. Lipsey that he's been raising that we can't get into the  
11 inventor's own mind is completely irrelevant here because this  
12 doesn't have to do with the invention. This particular  
13 document has to do with Xibrom which is a prior art compound  
14 that -- I don't know or think the inventors in this case had  
07:40 15 anything to do with. So that needs to be taken off the table  
16 for this particular document.

17 MR. LIPSEY: It is not prior art under any section of  
18 the statute. It's not a patent, printed publication, public  
19 use, offer for sale, sale in the United States.

07:41 20 MS. HOLLAND: And I never said it was.

21 MR. LIPSEY: It's not prior art under any section of  
22 the statute and Ms. Holland knows that full well.

23 MS. HOLLAND: Neither was the internal documents on  
24 stability that Mr. -- Dr. Williams put up on the screen. That  
07:41 25 wasn't prior art either. The reason he could do it was

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1 because it went to secondary considerations, Your Honor.  
 2 MR. LIPSEY: It was --  
 3 MS. HOLLAND: And, Your Honor, respectfully, if  
 4 everything is off the table that's not prior art, that's fine,  
 07:41 5 I guess we will take back all of Dr. Williams' testimony about  
 6 stability data that wasn't in the prior art.  
 7 But to the extent he put in something that's not in the  
 8 prior art that goes to a fundamental issue in the case, I have  
 9 a document, an NDA, doesn't have anything to do with the  
 07:41 10 inventor's mindset in this case. It's Xibrom. It's not the  
 11 inventors. It's not these inventors at all.  
 12 MR. LIPSEY: The point, there's a line in the patent  
 13 law, the comparative evidence of the properties of the  
 14 invention is relevant and admissible, no matter when it shows  
 07:42 15 up. That's a very different question from what can be used to  
 16 allege the obviousness of the invention, and there, it must be  
 17 in the prior art.  
 18 She is complaining because the statute imposes upon her  
 19 the obligation to come forward with evidence of the prior art  
 07:42 20 to invalidate the patent, and the statute allows, and the case  
 21 law on it allows us to come forward with comparative evidence  
 22 of the properties of the invention, whenever it comes to pass.  
 23 MS. HOLLAND: And the comparative -- I'm sorry.  
 24 MR. LIPSEY: And that's just the law.  
 07:42 25 MS. HOLLAND: And the comparative properties of the  

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1 the witness explore exactly those points without having to  
 2 introduce the document into evidence?  
 3 MS. HOLLAND: No, Your Honor, because the key point  
 4 here is what was -- the stability data that had to do with  
 07:44 5 Ogawa Example 6 that had polysorbate 80 in it, was that or was  
 6 that not stability data that had to do with physical stability  
 7 and disruption of the interaction between BAC and bromfenac.  
 8 That, we believe, was the purpose of that stability study that  
 9 was done, and that's the comparison that should be made, not  
 07:44 10 chemical stability like Dr. Williams was saying.  
 11 And we have a document in the NDA that goes to the very  
 12 heart of that issue. Without that document -- that document  
 13 is the evidence of exactly what that formulation was and  
 14 exactly why polysorbate 80 was in there and exactly what the  
 07:44 15 stability data means when you look at formulations containing  
 16 the polysorbate 80.  
 17 THE COURT: So --  
 18 MS. HOLLAND: That's why I need the document or I  
 19 need a stipulation about what's inside the document, either  
 07:45 20 one.  
 21 MR. LIPSEY: The words "purpose" and "why" were the  
 22 important words in that sentence. And that is what cannot  
 23 come in. The fact she wants to say that number is a physical  
 24 stability number, it -- physical stability is whether it gets  
 07:45 25 cloudy, Your Honor. We talked about that. Was it clear or  

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1 prior art. That's the whole point. We have to be able to  
 2 compare the invention to the prior art outside the scope of  
 3 the prior art. We're bringing in now -- and I'm not sure if  
 4 Mr. Lipsey is doing this on purpose or not, but it's kind of  
 07:42 5 like we're two ships passing in the night.  
 6 I keep saying it's about secondary considerations and  
 7 Mr. Lipsey keeps telling you why it can't come in as prior  
 8 art. Those are -- I agree it's not prior art. I'm not  
 9 suggesting it should come in as prior art. I'm suggesting it  
 07:43 10 should come in to the live issue of the case of secondary  
 11 considerations and whether the comparisons of stability that  
 12 were made in this case by Dr. Williams were properly made,  
 13 whether they were actually chemical stability data or whether  
 14 they were physical stability data.  
 07:43 15 There's no suggestion that there -- I mean, maybe there  
 16 is a suggestion that there was some false information, but --  
 17 in the Xibrom NDA, but I'm not aware that that's what  
 18 plaintiffs are arguing.  
 19 THE COURT: All right. So the purpose that you're  
 07:43 20 seeking to admit to -- 478 and 479A into evidence is that it's  
 21 a secondary consideration and whether the comparisons of  
 22 stability of the plaintiff's witness, Dr. Williams, were  
 23 properly made?  
 24 MS. HOLLAND: Yes.  
 07:43 25 THE COURT: And didn't your examination already with  

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1 was it turbid? Chemical stability was how much of it is left,  
 2 and that's all those numbers were.  
 3 MS. HOLLAND: Well, that is a dispute. That's a very  
 4 hotly disputed issue. And again, Mr. Lipsey's saying that  
 07:45 5 that's all those numbers were doesn't make it -- that's not  
 6 evidence and it doesn't make it an undisputed fact in the  
 7 case.  
 8 THE COURT: What you're seeking to establish, then,  
 9 is, what are the characteristics of Xibrom as reflected in the  
 07:45 10 Xibrom NDA?  
 11 MS. HOLLAND: Yes.  
 12 THE COURT: All right. Can there be a stipulation as  
 13 to what those characteristics are?  
 14 MS. HOLLAND: I'm happy to take a stipulation if we  
 07:45 15 can get one.  
 16 THE COURT: Without reference to the NDA.  
 17 MR. LIPSEY: I am always happy to talk about  
 18 stipulations. That's not clear to me what it would be. As  
 19 much as Mr. Hasford wants to straighten this out, if this is a  
 07:46 20 way to do it, that's something I think we're going to have to  
 21 chat about to see what it is you propose.  
 22 MS. HOLLAND: I'm happy to come back for a conference  
 23 tomorrow morning, Your Honor, to tie up these loose knots of  
 24 the evidence, if you think that would be helpful.  
 07:46 25 MR. LIPSEY: I'm not sure we need to do that.  

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1 MR. HASFORD: I don't think --

2 MS. HOLLAND: Well, then I think we need a written --

3 I don't want to leave Camden without having gotten this taken

4 care of and I know Your Honor has time tomorrow morning

07:46 5 potentially if you want to --

6 THE COURT: Of course I do. I set all day tomorrow

7 aside.

8 Well, I think there's two realistic options rather than

9 bringing everyone back tomorrow. This is the only dangling

07:47 10 participate that I'm aware of at the moment, that either the

11 parties reach a stipulation within the next day or two, or the

12 parties will be granted leave to brief this issue of

13 admissibility of DTX-478 and DTX-479A, and there, what I'm

14 interested in, is something that I haven't had the opportunity

07:47 15 to look up myself which is how the admissibility of NDA

16 documents are treated generally in patent litigation of this

17 type, and whether it matters that it's not the NDA on the

18 invention but of a prior composition, and, therefore, entitled

19 to less protection or secrecy.

07:47 20 MR. LIPSEY: I think that's a perfectly acceptable

21 resolution from our standpoint, and probably the only

22 realistic one.

23 THE COURT: All right. And so what I'm asking you to

24 do is to see whether in the next 24 hours, you can agree to a

07:48 25 stipulation as to -- maybe a compromised version of the data

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1 that the defendant is seeking to receive into evidence.

2 If there's not a suitable stipulation forthcoming, then

3 you'll have the opportunity to brief this as part of your --

4 maybe you want to brief it sooner than 30 days from now

07:48 5 because when you are formulating your proposed findings of

6 fact and conclusions of law, you will want to know whether

7 these documents are in. They sound like, you know,

8 respectable, important documents to know whether they are in

9 or out. I'm willing to rule on them sooner if you can brief

07:48 10 it sooner.

11 MS. HOLLAND: Yeah, we would be willing to brief that

12 sooner, Your Honor. That's a good solution, I believe. So if

13 we can't reach agreement, can we brief just that one

14 evidentiary issue within a week?

07:49 15 THE COURT: Yeah. And you have the burden seeking

16 admissibility and so the defendant's brief would be due seven

17 days from now.

18 MS. HOLLAND: Okay.

19 MR. LIPSEY: Your Honor, if I may, and I know Your

07:49 20 Honor and I had a chat about this a long time ago, but we have

21 been struggling with this parallel patent office proceeding

22 that has been going on in the hearing and it is next Tuesday,

23 and I guess we would like a little bit of leeway to deal with

24 that just so that we can get that out of the way.

07:49 25 THE COURT: Well, you have a very supple team on your

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1 side. This is one limited issue.

2 MR. MURKERJEE: Your Honor, may I?

3 THE COURT: And also the defendant would have to go

4 first next week.

07:49 5 MR. LIPSEY: Fair enough.

6 THE COURT: And then the plaintiff, your brief would

7 be due, let's say seven days after that.

8 MR. LIPSEY: Okay. We can do that. I jumped the gun

9 on that. I'm sorry.

07:49 10 MR. MURKERJEE: And Your Honor, if I may just clarify,

11 plaintiff's law firm, Mr. Lipsey's law firm is not handling

12 that proceeding. It's the law firm of Crowell & Moring that's

13 representing.

14 MR. HASFORD: We are certainly handling it on behalf

07:50 15 of Senju, Your Honor. He said plaintiff's law firm. No,

16 Crowell & Moring is not representing Senju in that proceeding.

17 We are.

18 MR. MURKERJEE: That is correct, Your Honor. I

19 misspoke. I apologize.

07:50 20 MR. LIPSEY: We --

21 THE COURT: Well, look, if the briefing schedule is

22 impossible, then I'm not going to require it. If you're able

23 to do it and if you still have this dispute -- this is only if

24 you have the dispute. I guess it's an incentive to work a

07:50 25 little harder on a stipulation when you have time. On your

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1 feet, I understand that it's hard, I'm not being critical of

2 either side.

3 And so see what you can do. But that's how we will

4 leave it, and if there's a stipulation, then I would simply

07:50 5 ask Ms. Holland to reduce it to writing and send it my way and

6 it will be included as if it's part of the evidence in the

7 case.

8 MS. HOLLAND: Thank you, Your Honor.

9 THE COURT: Okay.

07:50 10 MS. HOLLAND: Then the last thing was that 33A that

11 we needed to match up the Bates numbers, but I suggest we also

12 wrap that up in the next day or so, together with the other

13 issues, and hopefully that we can come to resolution on that

14 one.

07:51 15 MR. LIPSEY: As a very last final matter on behalf of

16 the plaintiffs, we would like to thank the Court and the

17 Court's staff and particularly, the long-suffering court

18 reporters for their many courtesies that have been extended to

19 us over the last week or so, and thank you very much.

07:51 20 THE COURT: Well, that's very kind of you to say.

21 And so for 33A, we will wrap it up in the next day for

22 briefing, same thing, is that the understanding?

23 MR. HASFORD: That's our understanding, Your Honor.

24 33A, you want to wrap that into the briefing as well?

07:51 25 MS. HOLLAND: Well, I don't know if we need the

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1 briefing. If we need it.  
 2 MR. HASFORD: Oh, if we need it, sure.  
 3 THE COURT: So we will use the same procedure for  
 4 33A.  
 07:51 5 And do you have your respective excerpts from the  
 6 depositions?  
 7 MR. HASFORD: Deposition designations, Your Honor?  
 8 THE COURT: Yes, designations.  
 9 MS. HOLLAND: I think there's an issue. We still  
 07:52 10 have an issue with respect to some of plaintiff's  
 11 designations. I believe they've designated testimony from  
 12 Dr. Lawrence's deposition, and Dr. Lawrence was a live witness  
 13 and I don't think that that's appropriate.  
 14 MR. HASFORD: We can probably take care of any of  
 07:52 15 those issues with a meet and confer, Your Honor.  
 16 THE COURT: All right. I would, off the top of my  
 17 head, agree that a live witness can't be supplemented by her  
 18 deposition excerpts. You can offer a party's own deposition  
 19 against them, whether they were here live or not, but not an  
 07:52 20 expert.  
 21 MR. HASFORD: We're happy to address that with  
 22 defendants, Your Honor.  
 23 THE COURT: Okay.  
 24 MS. HOLLAND: All right. So given Your Honor's  
 07:53 25 statement just now, I assume that Mr. Hasford is going to  

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1 withdraw the Lawrence deposition designations?  
 2 MR. HASFORD: I believe we are, Your Honor, but if  
 3 you'll -- I just need to confer with my team and make sure  
 4 that there wasn't some other reason why that may have been  
 07:53 5 included. I just don't have it in front of me and I will do  
 6 that in short order, Your Honor.  
 7 THE COURT: Okay.  
 8 MS. HOLLAND: Of course, Your Honor, it goes without  
 9 saying that defendants also appreciate the Court's time and  
 07:53 10 the court reporters and courtroom staff and clerk and  
 11 everybody who's helped us out on the last few days as well.  
 12 Thank you.  
 13 THE COURT: You're welcome.  
 14 Okay. And so subject to the deposition excerpts and  
 07:53 15 subject to a determination of the admissibility of DTX-478,  
 16 479A and 33A, the parties have rested, and I'll take the  
 17 matter under advisement.  
 18 You have your briefing schedule for the next 30 days  
 19 and the simultaneous submissions, and so we will keep to that  
 07:54 20 schedule unless I hear differently from you after you confer  
 21 about them.  
 22 MS. HOLLAND: Your Honor, just to -- I just want to  
 23 make clear -- be clear on the briefing schedule. So in 30  
 24 days, there is simultaneous briefing and are there responsive  
 07:54 25 briefs after that, or is there one round?  

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1 THE COURT: Yes, there's an order that --  
 2 MS. HOLLAND: Okay.  
 3 THE COURT: -- spells it out.  
 4 MS. HOLLAND: That's fine, Your Honor, I just wanted  
 07:54 5 to make sure we were still sticking with that.  
 6 THE COURT: No, we are, unless the parties agree that  
 7 there's a different scheme. It's a trial logistics order that  
 8 was filed on March 23rd.  
 9 MR. HASFORD: From plaintiff's side, Your Honor, I  
 07:55 10 don't believe we have any requests at this point to -- for  
 11 that to be modified.  
 12 THE COURT: Okay. So it simply says in Paragraph 3:  
 13 Simultaneous submissions of proposed findings of fact and  
 14 conclusions of law shall be due no later than 30 days from the  
 07:55 15 last day of trial.  
 16 So we are talking about May the 12th.  
 17 And responses are due from both sides no later than 14  
 18 days thereafter, and it indicates that no surreplies shall be  
 19 permitted, because all good things must come to an end.  
 07:55 20 (Laughter.)  
 21 THE COURT: And then it says: Post-trial briefs  
 22 shall not exceed 40 pages and shall also be filed not later  
 23 than 30 days from the last day of trial and no responses shall  
 24 be permitted. You can respond orally when we have the  
 07:55 25 arguments.  

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1 The next paragraph says: Closing arguments will be  
 2 heard approximately 14 days after final submissions at a date  
 3 to be set by the Court.  
 4 And so that would be roughly 60 days from today. I  
 07:56 5 don't have that for you right now, to -- well, what do we have  
 6 around June 11th?  
 7 THE DEPUTY CLERK: June 11th is a Saturday.  
 8 THE COURT: Perfect.  
 9 (Discussion off the record.)  
 07:58 10 THE COURT: Okay. I'd like to set the date for  
 11 argument so that you can place it on your schedule, and I'll  
 12 move my schedule around a little to accommodate it. Friday,  
 13 June 24th would be the date at 10:00 a.m.  
 14 Does that work as far as you know?  
 07:58 15 MS. HOLLAND: Your Honor, may I consult with my  
 16 client for a moment -- he's in the gallery -- about this?  
 17 THE COURT: Yes.  
 18 MS. HOLLAND: Thank you.  
 19 (Off the record.)  
 08:00 20 MS. HOLLAND: Your Honor, the reason I wanted to  
 21 consult with my client is because he has the issue of the  
 22 30-month stay worked into this, and June 24th, I believe, is  
 23 after the expiration of the 30-month stay, which is June 19th.  
 24 So I don't know what the Court's schedule is, but to the  
 08:00 25 extent we can --  

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1 THE COURT: Well, if you want to keep this briefing  
 2 schedule and argument schedule so that all this could be  
 3 handled in the way that it is, could you confer with your  
 4 clients and see if they could agree not to launch for 30 days  
 08:00 5 after oral argument is heard?  
 6 MS. HOLLAND: That would be June --  
 7 THE COURT: That would push it to July 19th -- I'm  
 8 sorry, to July 24th.  
 9 MS. HOLLAND: I'll confer, Your Honor.  
 08:01 10 (Off the record.)  
 11 MS. HOLLAND: Your Honor, we don't have -- the  
 12 personnel in the courtroom don't have the authority to do that  
 13 but I'm told that in the next day or so, we can get back to  
 14 the Court on that.  
 08:01 15 THE COURT: All right. That's fair. And so what I'm  
 16 asking is whether the defendants, both defendants, would  
 17 voluntarily agree to not launch until at least July the 24th,  
 18 and if the answer is yes, you can agree, then it solves the  
 19 timing problem.  
 08:02 20 If not, then I'll simply advance the briefing dates and  
 21 the argument dates in a way that works for the June 19th,  
 22 30-month stay date. Is that fair?  
 23 MS. HOLLAND: Yes, Your Honor.  
 24 MR. HASFORD: I think that's fine with plaintiffs,  
 08:02 25 Your Honor. I think I would note that the 30-month stay date  
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1 is different for Lupin and for InnoPharma, so it may only be  
 2 an issue as to Lupin.  
 3 THE COURT: That's right. InnoPharma doesn't have a  
 4 30-month problem yet?  
 08:02 5 MR. MUKERJEE: We do, Your Honor, but our 30-month  
 6 stay date is considerably after the expiry of Lupin's 30-day  
 7 stay date.  
 8 MR. HASFORD: It's March 2017, Your Honor.  
 9 MR. MUKERJEE: Thank you, Mr. Hasford.  
 08:02 10 THE COURT: I would say March 2017 is not imminent.  
 11 (Laughter.)  
 12 THE COURT: And so again, in lieu of everyone coming  
 13 back tomorrow, I will just say within the next 24 hours, if  
 14 you can do so, well, please let me know whether this is an  
 08:03 15 acceptable arrangement, and if so, June 24th would be our  
 16 argument date. And if so, I would be committed to getting the  
 17 opinion out before July 24th.  
 18 MS. HOLLAND: Thank you, Your Honor. Just a couple  
 19 very small housekeeping questions that we have for the Court.  
 08:03 20 In terms of the admitted exhibits, do you want those paper  
 21 copies in binders? Would you like it on a CD or DVD? We can  
 22 do both, whatever is most helpful.  
 23 THE COURT: If you can do both, then that is most  
 24 helpful. It makes it portable but it's -- also, I'm still a  
 08:03 25 paper guy at heart.  
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1 MS. HOLLAND: Me, too.  
 2 MR. HASFORD: We can do that as well, Your Honor.  
 3 THE COURT: And so for the admitted exhibits, what  
 4 I'm asking is that I receive an ordered pair of copies of the  
 08:04 5 exhibits, you know, seriatim, plaintiff's exhibits and defense  
 6 exhibits. And who would do the joint exhibits, the party that  
 7 offered it? Or how do you want to do that?  
 8 MS. HOLLAND: We can do it that way.  
 9 MR. HASFORD: That's fine.  
 08:04 10 MS. HOLLAND: We can figure that out.  
 11 MR. HASFORD: That's fine.  
 12 MS. HOLLAND: That's pretty minuscule for us, I  
 13 believe.  
 14 And the last question was in terms of the briefing.  
 08:04 15 Would the Court like them hyperlinked; briefs with the cases  
 16 and exhibits?  
 17 (Laughter.)  
 18 THE COURT: Okay. I'm getting some coded signals.  
 19 The answer is yes.  
 08:04 20 MS. HOLLAND: Okay. Thank you.  
 21 THE COURT: Okay. Is there anything else this  
 22 afternoon while we're all together?  
 23 MR. HASFORD: Nothing from plaintiffs, Your Honor.  
 24 MR. MUKERJEE: Nothing, your Honor.  
 08:05 25 THE COURT: Okay. If you run into any roadblock,  
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1 then ask for a conference call and we will take a call and the  
 2 call can be on the record. I think it is highly unlikely that  
 3 you will have to be reassembled here before the date in June  
 4 when we have arguments.  
 08:05 5 So that concludes, then, our trial. I'd like to  
 6 compliment both the plaintiffs and the defendants. The case  
 7 has been extremely well-prepared. It's clear that you put an  
 8 awful lot of thought into your positions and into your  
 9 advocacy. It makes my job a pleasure, although the issues may  
 08:05 10 be difficult, but they were not complicated by -- by anything  
 11 less than the best professionalism, and that's what I hope for  
 12 in every case. And so, you know, I extend thanks to the  
 13 litigants and to your clients for the efforts that you have  
 14 put in so far. And so with that, let's adjourn.  
 08:06 15 RESPONSE: Thank you very much, Your Honor.  
 16 (5:39 p.m.)  
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