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IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY  
CIVIL ACTION NOS.:  
15-335 (JBS); 14-667 (JBS);  
14-4149 (JBS); 14-5144 (JBS)

-----  
SENJU PHARMACEUTICAL CO., LTD.,  
BAUSCH & LOMB INCORPORATED, and  
BAUSCH & LOMB PHARMA HOLDINGS  
CORP.

Plaintiffs,

vs.

LUPIN, LTD. AND LUPIN  
PHARMACEUTICALS, INC.,

Defendants.

-----  
SENJU PHARMACEUTICAL CO., LTD.,  
BAUSCH & LOMB INCORPORATED, and  
BAUSCH & LOMB PHARMA HOLDINGS  
CORP.,

Plaintiffs,

vs.

INNOPHARMA LICENSING, INC.,  
INNOPHARMA LICENSING, LCC,  
INNOPHARMA, INC., and  
INNOPHARMA, LLC,

Defendants.

Job No. NJ 2238413

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Transcript of deposition taken  
by and before Lisa Forlano, CCR, CRR, RMR,  
Certificate No. XI01143, at the offices of Goodwin  
Procter LLP, 620 Eighth Avenue, New York, New York  
on Wednesday, February 24, 2016, commencing at 10:05  
a.m.

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1 VIDEO OPERATOR: We're now going on the  
2 record, approximately 10:05 a.m. This is the  
3 beginning of file number one.

4 My name is Kevin Gallagher,  
5 representing Veritext New York.

6 The date today is February 24, 2016.

7 The deposition is being held at Goodwin  
8 Procter, located at 620 Eighth Avenue in New  
9 York, New York.

10 The caption of the case is Senju  
11 Pharmaceutical Company, Ltd. versus Lupin  
12 Limited and Lupin Pharmaceutical.

13 This case is filed in the US District  
14 Court for the District of New Jersey. The  
15 Case No. is 14-CV-06893-JBS-KMW. And  
16 15-CV-03240-JBS-KMW.

17 Our witness this morning is Ivan T.  
18 Hofmann.

19 At this time, the attorneys present in  
20 the room will identify themselves for the  
21 record.

22 MR. DINER: Bryan Diner with the law  
23 firm of Finnegan Hendersen, counsel for  
24 Plaintiff Senju, et al. With me is my  
25 colleague, Terrence Kim, also from Finnegan

1 Henderson.

2 MS. FINK: Sarah Fink for Goodwin &  
3 Procter, representing Lupin and the witness.

4 MR. WOOLLEY: Evan Woolley of Alston &  
5 Bird for the Innopharma Defendant.

6 VIDEO OPERATOR: Our court reporter  
7 this morning is Lisa Forlano. She also  
8 represents Veritext. She will now swear the  
9 witness and we can proceed.

10 IVAN T. HOFMANN, having been duly  
11 sworn, was examined and testified as follows:

12 BY MR. DINER:

13 Q Good morning, Mr. Hofmann.

14 A Good morning, Mr. Diner.

15 Q Would you please state your full name  
16 and address for the record?

17 A Sure. My name is Ivan T. Hofmann, and  
18 I live at 169 South Ridge Drive, Cranberry Township,  
19 Pennsylvania 16066.

20 Q And you've been deposed before; is that  
21 correct, Mr. Hofmann?

22 A I have.

23 Q A number of times?

24 A Correct.

25 Q So you're familiar with the drill?

1           A           I am.

2           Q           Okay. I'll just lay a few ground rules  
3 so we're on the same page, if that's okay with you.

4           A           That sounds good.

5           Q           So I basically just have three I'd like  
6 to talk about. One is my questions; the second is  
7 your breaks, or our breaks; and then any questions  
8 you have.

9                        So for my questions, I just -- I'll be  
10 asking questions and your job is to answer the  
11 questions and to do so truthfully and accurately.

12                       Does that sound fair?

13          A           I understand.

14          Q           Okay. With regard to breaks, we can  
15 take a break whenever you'd like. Just if I'm in  
16 the middle of a question, I would like you to finish  
17 by answering the question and then if you would like  
18 to take a break at that time, we can take a break.  
19 Is that okay?

20          A           Sounds good.

21          Q           And then with regard to any questions  
22 you may have, for example, if there is something  
23 that you don't understand in my question or you need  
24 some clarity, just ask me and I'll be happy to  
25 clarify that for you.



1 Is that okay?

2 A Yes, sir.

3 Q Okay. I guess one final point on that,  
4 if I ask a question and you answer it, I'll assume  
5 that you understood it. Is that fine?

6 A Yes.

7 Q Okay. Is there any reason that you  
8 cannot truthfully and accurately testify today?

9 A No, sir.

10 Q Okay.

11 MR. DINER: I'll mark the first  
12 exhibit.

13 (Responsive Expert Report of Ivan T.  
14 Hofmann, CPA/CFF, CLP was marked Hofmann-1 for  
15 identification.)

16 BY MR. DINER:

17 Q Okay. So the court reporter has handed  
18 you what has been marked as Hofmann Exhibit 1. Do  
19 you recognize this document, sir?

20 A Yeah. It appears to be a  
21 black-and-white version of my expert report in this  
22 matter.

23 Q Does it include your exhibits and  
24 appendices?

25 A Yes, it does.

1 Q Can you turn to the page after page 57?  
2 It's not numbered. That's the reason for my  
3 description of it.

4 A Sure.

5 Q Is that your signature at the top of  
6 the page after page 57?

7 A It is.

8 Q Okay. Mr. Hofmann, who prepared your  
9 report in this case?

10 A I did, with my team from Gleason IP.

11 Q I think after Exhibit D in Hofmann  
12 Exhibit 1, which you've identified as your expert  
13 report, it looks like your CV starts just after  
14 Exhibit D, but I don't see an identifier in terms of  
15 an appendix.

16 A In the upper right-hand corner it says  
17 appendix 1.

18 Q Very good. Thank you.

19 Is that your current CV, Mr. Hofmann?

20 A Right. So this is my current CV.  
21 Appendix 2 reflects my testimony, which is also part  
22 of the CV. And then in the fourth part of the  
23 report I've elaborated on the CV to explain some  
24 specific things that are relevant to my expertise in  
25 pharmaceutical economics.

1 Q Okay. I believe in appendix 3 you've  
2 identified some of the materials that you considered  
3 in preparing your expert report. Is that correct?

4 A Right. As of the date of my report,  
5 these were the materials that I considered.

6 Q Okay. Actually, I want to go back to  
7 your CV for a moment. I may have asked this, but is  
8 it a current -- current version of your CV?

9 A It is.

10 Q Anything more to add to it?

11 A I don't think so, as of today.

12 Q Okay. Okay. Back to appendix 3, then.  
13 So what's identified in appendix 3, which looks like  
14 it goes on for three pages of materials that you  
15 considered in preparation of your report?

16 A It's a total of four pages, but yes.

17 Q Thank you. Now, at the bottom of the  
18 first page of appendix 3 you see the section  
19 entitled, Expert Reports?

20 A Yes.

21 Q Okay. So in terms of the expert  
22 reports that you considered in preparation of your  
23 report, you identify the expert report of -- opening  
24 expert report of John Jarosz on objective indicia of  
25 non-obviousness; is that correct?

1           A           Yes, among others.

2           Q           Okay. And so you reviewed that opening  
3 report of Mr. Jarosz, correct?

4           A           I did.

5           Q           And you also reviewed the opening  
6 report of Dr. Williams on infringement and objective  
7 indicia of non-obviousness?

8           A           I did.

9           Q           And did you also review the expert  
10 report of William Trattler, M.D., on objective  
11 indicia of non-obviousness?

12          A           I did.

13          Q           Did you -- in preparation for your  
14 deposition today, did you consider any reply reports  
15 that were submitted by Dr. Williams?

16          A           I believe I have seen the Williams  
17 reply report, yes, I have.

18          Q           And have you considered the reply  
19 report of John Jarosz?

20          A           I have, yes.

21          Q           And how about the reply report of  
22 William Trattler, have you seen that?

23          A           Yes.

24          Q           Did you review the reply report of John  
25 Jarosz?

1           A           I did. I mean, for completeness.

2           There are several other expert reports I've also  
3           reviewed.

4           Q           Okay. What are they?

5           A           The expert report of Dr. Cykiert and  
6           the expert report of Dr. Prausnitz.

7           Q           And did you review the expert report of  
8           Dr. Cykiert in preparation for today's deposition?

9           A           No. No. No. Up to and leading to my  
10          issuance of my report, I had an understanding of  
11          what his opinions were with respect to certain  
12          technical issues that I relied upon in forming my  
13          report, and with the understanding that his report  
14          was going to be filed, you know, effectively  
15          simultaneously with mine. And so my intent all  
16          along was to then review it in connection with once  
17          it was finally issued, but I had an understanding of  
18          what his opinions were prior to the issuance of my  
19          report.

20          Q           And you gained that understanding from  
21          speaking with Dr. Cykiert?

22          A           From counsel.

23          Q           Through counsel?

24          A           Correct.

25          Q           Counsel told you what Dr. Cykiert's

1 opinions were?

2 A Correct.

3 Q There was another report that you  
4 mentioned that you reviewed?

5 A Dr. Prausnitz.

6 Q Dr. Prausnitz. And did you speak with  
7 Dr. Prausnitz before preparing your report?

8 A Similar process, I did not speak with  
9 him directly.

10 Q Could you explain the process?

11 A Again, I had an understanding from  
12 counsel of what Dr. Prausnitz's opinions were going  
13 to be, at least as they bore on, you know, the  
14 aspects of my report that I would care about, and  
15 had that understanding, and then fully intended to  
16 review his report, when issued, which was on the  
17 same day as my report.

18 Q Mr. Hofmann, in what areas do you  
19 consider yourself an expert?

20 A I consider myself an expert in the  
21 areas of economics, finance and accounting. I  
22 regularly am asked to consult on, broadly, areas  
23 within those spaces, and then, in particular, I have  
24 a heavy concentration in pharmaceutical economics.  
25 Probably two-thirds to three-quarters of my time is

1 spent analyzing and addressing issues in  
2 pharmaceutical economics.

3 In addition to those broad categories,  
4 an overarching area of expertise is intellectual  
5 property. I spend pretty much all of my time  
6 dealing with issues of intellectual property,  
7 primarily economic, financial and accounting issues,  
8 with respect to intellectual property. Sometimes  
9 those -- the work that I do is in a dispute setting,  
10 such as this, and then it's also regularly  
11 undertaken outside of a dispute setting as well.

12 Q Are you a patent lawyer?

13 A I'm not a patent lawyer.

14 Q Are you a named inventor on any  
15 patents?

16 A I'm not.

17 Q And not a named inventor on any pending  
18 applications, correct?

19 A No, sir.

20 Q Are you an expert in pharmaceutical  
21 marketing?

22 A I would consider myself an expert in  
23 the economic implications of pharmaceutical  
24 marketing. So while not a marketer by training,  
25 given the role of marketing in the distribution of

1 prescription pharmaceutical products, a very natural  
2 extension of the area of work that I've done and the  
3 consulting that I've done has had a heavy  
4 concentration on analyzing and considering issues  
5 with respect to pharmaceutical marketing.

6 Q Have you ever actually marketed a  
7 pharmaceutical product for a pharmaceutical company?

8 A No. My work has been as a consultant.

9 Q Have you ever worked on a marketing  
10 campaign for a pharmaceutical company?

11 A No, not directly.

12 Q Have you ever consulted for a  
13 pharmaceutical company on a marketing campaign?

14 A Well, one of the areas of work that I  
15 do is product pipeline consulting, and as part of  
16 the product pipeline consulting work that I've done  
17 I analyze markets and I analyze strategic planning  
18 with respect to, you know, budgeting, market  
19 formation, pricing, and as a part of that product  
20 pipeline consulting and consideration of market  
21 formation and strategy, certainly marketing is a  
22 piece of that. Or can be a piece of that.

23 Q Okay. Would you consider yourself an  
24 expert in commercialization of intellectual  
25 property?



1           A           I mean, I definitely consider myself an  
2 expert in analyzing issues surrounding  
3 commercialization of intellectual property, so I'm  
4 regularly asked to provide expertise and analysis  
5 and opinions with respect to licensing strategy of  
6 intellectual property. Again, like I said, market,  
7 market formation, market development of intellectual  
8 property. The actual legwork of the attorneys and  
9 the companies involved in the commercialization and  
10 getting the embodiment commercialized is not  
11 something I personally have done.

12           Q           Are you an expert in the FDA  
13 regulations regarding pharmaceutical products?

14           A           I consider myself an expert in the  
15 pharmaceutical economic implications of FDA  
16 regulations. So what I mean by that is I'm not a,  
17 per se, regulatory expert broadly, but the role of  
18 FDA regulation is so pervasive with respect to, in  
19 particular, prescription pharmaceutical products, as  
20 well as other medical foods and nutraceuticals and  
21 whatnot that I regularly analyze, consult and  
22 provide expertise with respect to the pharmaceutical  
23 economic implications of FDA regulation. But not  
24 the technical aspects, if you will.

25           Q           Do you know the applicable standards

1 for listing a pharmaceutical patent in the FDA's  
2 Orange Book?

3 A I'm familiar with those.

4 Q Do you understand the FDA's  
5 decision-making process with respect to approving  
6 drug product labeling?

7 A I mean, like I said, with the caveat  
8 that I wouldn't consider myself a technical expert  
9 of what must be proven with respect to technical  
10 aspects of the labeling, I do have familiarity and  
11 have worked regularly on issues involving product  
12 labeling, especially as they relate to  
13 pharmaceutical economics, marketing and things like  
14 that.

15 Q Okay. Are you an expert in  
16 ophthalmology?

17 A I would say I am not an ophthalmology  
18 expert from any sort of technical or medical  
19 perspective. I have done work on a number of  
20 ophthalmologic products in the course of my work in  
21 consulting in pharmaceutical economics.

22 Q Are you an expert in the field of  
23 pharmacy?

24 A Here again, with respect to the role  
25 that pharmacies play in the distribution of

1 prescription pharmaceutical products, I have a deep  
2 understanding of the role of pharmacies, along with  
3 the other actors within the distribution of  
4 prescription pharmaceutical products from a, you  
5 know, dispensing and technical perspective as far as  
6 what a pharmacist is, you know, trained to do in the  
7 decision-making process they make, no. And I do  
8 have familiarity, though, with substitution laws  
9 with respect to the role that pharmacies play in  
10 substituting generics.

11 Q You never formulated a pharmaceutical  
12 product yourself, correct?

13 A I have not.

14 Q And that would include never having  
15 formulated a bromfenac-containing composition,  
16 correct?

17 A Correct.

18 Q And that would also include never  
19 having formulated a pharmaceutical composition  
20 containing tyloxapol, correct?

21 A Correct.

22 Q Is it fair to say you've never  
23 conducted any scientific research on a bromfenac  
24 product?

25 A I have not. That's what I was

1 referring to earlier on, all of these things.  
2 That's where I rely on technical experts for those  
3 types of issues.

4 Q You're not an expert in any field of  
5 medicine, correct?

6 A No.

7 Q And have never prescribed any  
8 medication to a patient, correct?

9 A I have not.

10 Q You've never treated an inflammatory  
11 disease of an eye in a patient, have you?

12 A No, sir.

13 Q Never administered any bromfenac  
14 product to a patient, correct?

15 A No. Again, this is where I rely on the  
16 technical experts for where I've incorporated those  
17 types of issues in my report.

18 Q And you're not an expert in chemistry,  
19 either, correct?

20 A No, sir.

21 Q In connection with your opinions in  
22 this matter, did you do any laboratory testing of  
23 any pharmaceutical formulations?

24 A I did not. On something like that I  
25 would rely on technical experts.

1           Q           So you never considered or conducted  
2 any testing to assess Prolensa's ocular penetration,  
3 have you?

4           A           I did not. I relied on technical  
5 experts for those types of issues.

6           Q           Okay. We can turn to your report.  
7 If you turn to page 106 your report,  
8 paragraph 18. It's Hofmann Exhibit 1.

9           A           I'm there.

10          Q           The information provided in the table  
11 in paragraph 18, where did you obtain that  
12 information from?

13          A           You can see footnote 17, which lists  
14 the citation, which is the FDA website.

15          Q           Did you look that information up  
16 yourself?

17          A           Someone on my team did the actual  
18 looking of it up, but I reviewed all the citations  
19 in my report prior to issuance.

20          Q           Okay. Now, I'd like to turn to pages  
21 14 and 15 of your report, Hofmann Exhibit 1.

22          A           Okay.

23          Q           Now, in the sentence bridging pages 14  
24 and 15, you state that any alleged commercial  
25 success must be driven primarily by and attributable

1 to the purported merits of the claimed invention.

2 Do you see that?

3 A Yes.

4 Q Your use of the term or phrase  
5 "primarily by," does that imply that there could be  
6 other factors that could contribute to the  
7 commercial success of a product?

8 A Of course.

9 Q And what are those factors?

10 A Well, it's, I think, the question --  
11 you know, this is the definition of nexus and the  
12 question of nexus is a very facts and  
13 circumstances-based inquiry depending on the  
14 particular product at issue, the market at issue,  
15 the competitive landscape. So it varies product by  
16 product.

17 Q Are there factors, such as marketing,  
18 that could contribute to the commercial success of a  
19 product?

20 A Absolutely.

21 Q Financing?

22 A Sure.

23 Q Yeah. So these are factors outside of  
24 what you would consider the merits of the claimed  
25 invention, correct?

1           A           Yes, those are examples.

2           Q           And they could contribute to commercial  
3 success; is that your view?

4           A           Yes. And sometimes explain it.

5           Q           I'm sorry?

6           A           And sometimes explain the commercial  
7 success.

8           Q           But so long as the commercial success  
9 is driven primarily by the merits of the claimed  
10 invention, those other factors, such as marketing  
11 and financing, will not distract from or detract  
12 from the commercial success of the product, correct?

13          A           Well, that's again a very facts and  
14 circumstances-based inquiry. I think that to the  
15 extent that those examples you gave play a, you  
16 know, a diminished role, but a role that doesn't  
17 necessarily inhibit the ability to find that the  
18 patent played the primary role in the performance of  
19 a product. But you'd have to analyze the specific  
20 facts and circumstances of the case you're looking  
21 at.

22          Q           It's not your position, is it, that the  
23 proponent of commercial success has to show that no  
24 other factors besides the merits of the invention  
25 contributed to the commercial success of the

1 product?

2 A No, that's not my position.

3 MS. FINK: Mr. Hofmann, I'll just ask  
4 if you wait a second after the question to  
5 give me a chance to object.

6 THE WITNESS: Certainly.

7 MS. FINK: Thank you.

8 MR. WOOLLEY: Evan Woolley for  
9 Innopharma here, I just want to note that any  
10 objections by Lupin will be preserved to  
11 Innopharma as well so that I don't have to,  
12 you know, ditto every time. Thanks.

13 BY MR. DINER:

14 Q Mr. Hofmann, did you conduct a  
15 profitability analysis on the product Prolensa in  
16 preparation of your expert report?

17 A Right. I did an analysis and rebuttal  
18 and in response to the opening report of Mr. Jarosz  
19 that included consideration of profitability based  
20 on the information available to me.

21 Q And that was a look at profitability  
22 over a 30-month period; is that correct?

23 A Right. From launch to the date most  
24 recently available, which was about 30 months.

25 Q I believe that was about August of



1 2015. Does that sound right?

2 A August 2015? I thought I had through  
3 the third quarter of 2015. Yeah, so it would be  
4 through September 30.

5 Q September 30, 2015?

6 A Correct.

7 Q Okay. So a little over a 30-month  
8 period?

9 A Correct.

10 Q Okay. Now, I believe you noted in your  
11 report that Mr. Jarosz did not analyze the  
12 profitability for Prolensa, correct?

13 A Correct.

14 Q Did you know that Mr. Jarosz did not  
15 have the profitability data available for Prolensa?

16 MS. FINK: Objection, calls for  
17 speculation.

18 THE WITNESS: I mean, he didn't -- he  
19 didn't discuss it one way or the other. I  
20 understand from his deposition transcript,  
21 which I have since reviewed, that his position  
22 is that that information was unavailable.

23 As I explained in my report, there was  
24 information available, at least with respect  
25 to gross to net for certain periods. I find

1           it somewhat unimaginable that cost of goods  
2           sold information would be unavailable. And I  
3           guess I have to accept that, you know, the  
4           other expense components may be art tracked or  
5           available, but that didn't mean that there  
6           wasn't adequate data to look at something  
7           other than just gross sales, which is all that  
8           Jarosz's report contained.

9           BY MR. DINER:

10           Q           And the other data you're referring to,  
11           is that publicly available data that you're  
12           referring to?

13           A           Well, the particular gross-to-net  
14           information, no. There were certain periods that  
15           were included in the production that contained  
16           gross-to-net information of both Prolensa and  
17           Bromday that he didn't address in his report. And  
18           then, as I explained in my report, I did use certain  
19           publicly available information where I didn't have  
20           internal information to develop my analysis -- my  
21           analysis of profitability or lack of profitability.

22           Q           Were you aware that the company Bausch  
23           + Lomb does not track profitability for its  
24           individual products?

25                           MS. FINK: Objection, calls for

1 speculation.

2 THE WITNESS: I have been -- you know,  
3 my understanding is that, through counsel, we  
4 requested profitability information, and the  
5 position was that Bausch + Lomb doesn't, you  
6 know, track a fully-loaded product P&L, but  
7 based on the production they clearly do track  
8 gross to net, and I think are required to  
9 track gross to net. They didn't produce it at  
10 all periods. And like I said a few answers  
11 ago, I also -- I've never seen a company that  
12 doesn't track cost of goods sold. It doesn't  
13 surprise me necessarily that they don't have a  
14 fully-loaded product P&L for their expenses  
15 below that, but it certainly seemed like there  
16 was deficiencies in what was produced with  
17 respect to the actual performance of Prolensa.

18 BY MR. DINER:

19 Q So if there's no actual profitability  
20 numbers for Prolensa, as kept by the company,  
21 there's no actual data against which to judge the  
22 accuracy of your profitability analysis, correct?

23 A I totally disagree with that. I think  
24 that the purpose of my profitability analysis is a  
25 critique that the approach in the Jarosz's report is

1 to just take gross IMS sales and say that's all I  
2 have, that's the only way I'm going to look at the  
3 absolute performance of this franchise. My analysis  
4 is a qualitative analysis which includes some  
5 quantitative consideration of, okay, well, what do  
6 we know about whether gross sales is an accurate  
7 representation of the performance of this product?  
8 And what we know from some of the data produced is  
9 there are significant gross-to-net adjustments that  
10 are made that the Jarosz's report fails to consider.  
11 And I think anybody who studies pharmaceutical  
12 economics also knows that a product has cost of  
13 goods sold that are associated with it, sales and  
14 marketing costs and other costs.

15 And so, you know, the purpose of my  
16 analysis is not to quantify like lost profits in a  
17 damages case or something like that, which requires,  
18 you know, a certain level of precision. It's to  
19 support my qualitative view that, look, you know, we  
20 can't just stop the inquiry here at sales. We've  
21 gotta look at what's available with respect to other  
22 deductions that are known to occur for  
23 pharmaceutical products. It sounds like, no, there  
24 isn't an actual fully-loaded Bausch + Lomb product  
25 P&L that exist, or certainly there wasn't one in the

1 production, but I think that my profitability  
2 analysis provides a much more thorough and  
3 thoughtful consideration of the actual financial  
4 performance of Prolensa than just, you know, pulling  
5 gross IMS data, as the Jarosz report does.

6 Q It's built on a number of different  
7 assumptions from different companies and different  
8 products; is that correct?

9 A Well, I think it's best to take them  
10 one at a time. I mean, I think that it is -- again,  
11 I do this all the time, and regularly the brand  
12 company will produce product P&Ls, and I can use  
13 those actual information. Here they did produce  
14 certain actual information, and I did use the actual  
15 information, where available. Where it wasn't  
16 available I think I made reasonable determination of  
17 estimates to reflect the lack of profitability,  
18 based not only on the public filings of companies  
19 that include the sales of Prolensa, but also my, you  
20 know, many years experience in analyzing hundreds of  
21 pharmaceutical products and the types of expenses  
22 and costs that roll into the typical product P&Ls of  
23 pharmaceutical products.

24 Q Let's talk about profitability of  
25 pharmaceutical products for a moment. I believe

1 back on, I think it was paragraph 18 of your report,  
2 you had tabulated some information with regard to  
3 the patents-in-suit, correct?

4 A Yes.

5 Q And there you've indicated that one of  
6 the patents-in-suit, which I will refer to as the  
7 '431 patent is the latest expiring patent; is that  
8 right?

9 A That's my understanding.

10 Q And that patent expires in  
11 September 2025, right?

12 A Correct.

13 Q Now, pharmaceutical companies, as a  
14 general matter, invest in products for the long run;  
15 is that correct?

16 MS. FINK: Objection, calls for  
17 speculation.

18 THE WITNESS: I think that's a facts  
19 and circumstances-based inquiry. There's lots  
20 of times that pharmaceutical products have a  
21 short-term plan and there are occasions where  
22 they have a long-term view.

23 BY MR. DINER:

24 Q And there are -- strike that for now.

25 A I don't think Bromday was on the market

1 any longer than Prolensa has been on the market.

2 Q But you have no idea how long Prolensa  
3 may be on the market, correct?

4 A Well, I mean, I think that's kind of my  
5 whole point is that all we have in terms of  
6 objective evidence of its performance is what its  
7 done so far. The pharmaceutical market is very  
8 dynamic and things can happen all the time. I think  
9 Dr. Cykiert talked about the change in the AAO  
10 guidance with respect to NSAID that came out in late  
11 2015. That can materially impact the future  
12 direction of what happens with respect to a product  
13 like Prolensa. So I think when you're looking at an  
14 obviousness inquiry with respect to, you know, the  
15 commercial performance of a product you really have  
16 to look at what has happened. There's a real hazard  
17 to try and predicting, hey, this might be on another  
18 three months, five years, or ten years.

19 Q But it could be on for as long as the  
20 patent is in existence, in terms of its expiring,  
21 correct?

22 A That's theoretically possible, but, you  
23 know, I don't think that speculating on whether it's  
24 going to be provides any objective evidence of its  
25 actual commercial performance in the marketplace.

1           Q           You speculated a moment ago that based  
2 on some report from Dr. Cykiert that something else  
3 could happen, correct?

4           MS. FINK:   Objection, argumentative.

5           THE WITNESS: Well, my point is just  
6 that. Whether I'm speculating on the impact  
7 of the AAO, or you're speculating that  
8 Prolensa is going to continue to perform for  
9 another nine years, the inquiry we're faced  
10 with in commercial success is what has  
11 happened, how has the market reacted, and has  
12 the company, you know, performed well and made  
13 profits. We can't -- we can't predict the  
14 future one way or the other.

15 BY MR. DINER:

16          Q           In your experience, have you looked at  
17 drugs in the past for their -- from an economic  
18 point of view where they had low profitability in  
19 the first few years after launch, but then ramped up  
20 with profitability after that?

21          MS. FINK:   Objection, incomplete  
22 hypothetical.

23          THE WITNESS: Yeah, that's again a very  
24 facts and circumstances-based inquiry. I  
25 certainly have seen kind of the fact pattern



1           you described where out of the gates they did  
2           not perform well and later ended up performing  
3           well for a variety of reasons. I've seen ones  
4           that don't perform well out of the gates and  
5           continue to languish and I've seen others  
6           that, you know, were somewhere in between.

7 BY MR. DINER:

8           Q           So it's premature at this point to  
9           really assess whether or not based on 30 or so  
10          months of data and based on profitability, if  
11          Prolensa is, in fact, not a commercial success; is  
12          that right?

13          A           No. I disagree with that because I  
14          think that it cuts off and ignores the fact that  
15          this isn't the first formulation of a bromfenac  
16          product. So, again in the facts and circumstances  
17          in this case, to your hypotheticals where you're  
18          asking about a new drug launching and maybe not  
19          making money in early years, that's fairly common  
20          with a new molecule and some of the investment that  
21          has to be made with respect to the new molecule.  
22          Here you have a life cycle management situation  
23          where, you know, Xibrom launched in 2005, so we sit  
24          here in 2015 -- it's 2016 here, but the data I have  
25          is through 2015, the third quarter. So we have

1 about 10 years of the history of this molecule and,  
2 you know, 30-plus months of which are the Prolensa  
3 embodiment, and I think it's pretty clear, based on  
4 the data that we have available today, that  
5 represents actual performance in the market it's not  
6 a commercial success.

7 Q Let's go back to the discussion we were  
8 having a moment ago about pharmaceutical companies  
9 and their view of profitability.

10 MR. DINER: I'd like to mark the next  
11 exhibit.

12 (Deloitte 2015 Global Life Sciences  
13 Outlook - Adapting in an era of transformation  
14 PROL0339506 - PROL0339525, was marked  
15 Hofmann-2 for identification.)

16 BY MR. DINER:

17 Q You've been handed what has been marked  
18 as Hofmann Exhibit 2, bearing Bates numbers  
19 PROL0339506 through 9525.

20 Have you seen this document before,  
21 Mr. Hofmann?

22 A Yes, I have.

23 Q In what context?

24 A I think this is something that the  
25 Jarosz's report cites to.

1           Q           This looks like it's a publication put  
2 out by the Deloitte companies. Does that seem like  
3 it is that to you, Mr. Hofmann?

4           A           Yes.

5           Q           And it's entitled 2015 Global life  
6 sciences outlook, correct?

7           A           Correct.

8           Q           You used to work at Deloitte?

9           A           Yes, I did.

10          Q           Before your work on this matter had you  
11 seen this publication by Deloitte?

12          A           I may have. I don't remember one way  
13 or the other.

14          Q           Can you turn to the page that has  
15 the -- or page 7 of the document Bates number  
16 PROM0339512? And would you take a look at the  
17 right-hand column, second paragraph?

18                   MS. FINK: You should take as long as  
19 you need to read the paragraph or any  
20 surrounding material.

21 BY MR. DINER:

22          Q           Let me know when you're ready,  
23 Mr. Hofmann.

24          A           Sure.

25          Q           Is that a yes, you're ready?

1           A           No. No. I will let you know.

2                        I mean, I haven't reread the whole 20  
3 pages just now, but I've read the paragraph you've  
4 directed me to.

5           Q           Okay. Would you read that first  
6 sentence of paragraph 2 in the right-hand column  
7 into the record for me, please?

8           A           It says, The extended nature of live  
9 sciences product development mandates that the  
10 sector stakeholders adopt a long-term focus to  
11 strategic planning, portfolio management and market  
12 expansion.

13          Q           Would the statement that you just read  
14 support the proposition that we discussed earlier  
15 that in some cases pharmaceutical companies will  
16 take a long term view of profitability for their  
17 products?

18                       MS. FINK: Objection, the document  
19 speaks for itself.

20                       THE WITNESS: I mean, as a platitude  
21 sure, all companies have a long-term view.  
22 They all want to be around for a long time,  
23 but I think that, you know, as I said in my  
24 earlier answers, it's a very facts and  
25 circumstances-based inquiry. It's a

1 product-based inquiry. This long-term view,  
2 you know, could be applied to the bromfenac  
3 franchise. And certainly they've had 10 years  
4 of experience with the life cycle management  
5 strategy they've done. So, I mean, I think as  
6 a generality, I don't disagree. The companies  
7 have a long-term view. There are situations  
8 where heavy R & D investment occurs to develop  
9 a new molecule and it may take a while to  
10 recover the investment in that molecule.  
11 There are lots of situations where that fails.  
12 But I don't think that that undermines the  
13 fact that there are also lots of short-term  
14 plays, and the best -- you know, the best  
15 aspirational long-term views that are  
16 failures. So I think that, you know, I don't  
17 disagree that there's a long-term view of  
18 companies in general, but I think, you know,  
19 there's a hazard in saying that that must mean  
20 that applies across the board to every  
21 product.

22 BY MR. DINER:

23 Q You referred a moment ago to heavy R &  
24 D investments. You also referred to that in the  
25 context of molecules, I believe. Would there also

1 be R & D investments made in drug products or drug  
2 formulations?

3 MS. FINK: Objection to the extent it  
4 misstates testimony, and incomplete  
5 hypothetical.

6 THE WITNESS: I mean, I don't disagree  
7 that there is a certain amount of R & D that  
8 is necessary for any NDA to get approved. The  
9 degree of that investment varies greatly.

10 BY MR. DINER:

11 Q In the pharmaceutical industry it could  
12 take sometimes hundreds of millions of dollars to  
13 bring a single pharmaceutical product to the market,  
14 right?

15 A That's a very facts and  
16 circumstances-based inquiry. There are certainly  
17 examples that have been hundreds of millions of  
18 dollars to bring a product to market. But I don't  
19 know that that's always the case. I know that  
20 that's not always the case.

21 Q And the amount of investment is high  
22 because there's a low success rate for new products  
23 making it to the market; is that right?

24 MS. FINK: Objection, calls for  
25 speculation.

1                   THE WITNESS: I mean, I don't know if  
2                   you're referring to particular studies. It  
3                   sounds like -- you know, I've seen metrics  
4                   that talk about hundreds of millions of  
5                   dollars that account for everyone that's  
6                   successful, there's investment in many others  
7                   that isn't successful and when you look at  
8                   those altogether it amounts to hundreds of  
9                   millions of dollars. I've seen other things  
10                  where if you just look at the molecule that is  
11                  successful, it's certainly not hundreds of  
12                  millions of dollars for that one to be  
13                  successful. And then I think it's also  
14                  important to distinguish, you know, if you're  
15                  talking about the work in synthesizing, you  
16                  know, a brand-new therapeutic class, a  
17                  brand-new molecule, a biologic versus  
18                  reformulating or, you know, other changes to  
19                  existing molecules.

20 BY MR. DINER:

21                  Q           Well, whether it's a new molecule or a  
22                  formulation, there's usually a complex gauntlet that  
23                  that new product has to run before it can reach the  
24                  market; isn't that correct?

25                  A           I mean, I would -- you say "a complex

1 gauntlet." That's kind of a subjective term, but I  
2 think that there's technical aspects that I'm not an  
3 expert on that have to be gone through to develop  
4 products that are able to be approved for the FDA.  
5 There are clinical trials, et cetera. I understand  
6 all that, but that, I think, would vary by degree in  
7 pretty much every drug development process.

8 Q But that gauntlet could include at  
9 least basic R & D, and clinical trial work before a  
10 drug even makes it to the market, correct?

11 A Yeah. There are mandatory, regulatory  
12 steps that any prescription pharmaceutical product  
13 must satisfy to get FDA approval.

14 Q And with the expense and costs in  
15 trying to get that product to the market and run  
16 that gauntlet necessarily the pharmaceutical  
17 companies do take a long-term view of the  
18 profitability of their products, right?

19 MS. FINK: Objection, incomplete  
20 hypothetical, speculation.

21 THE WITNESS: I guess I'm just  
22 struggling with what you're trying to get me  
23 to agree with as far as long-term view. I can  
24 think of lots of products that have been  
25 developed and gotten FDA approval only to have



1 a life of a handful of years for a variety of  
2 reasons. Whether that's part of a long-term  
3 life cycle strategy, whether that's because  
4 the product was a failure. I think it's very  
5 much facts and circumstances based as to what  
6 it means to have a pharmaceutical company and  
7 what their strategy is with respect to  
8 development. I know there's companies like  
9 Valeant who take a view we're not going to  
10 invest much in R & D and we're going to be  
11 more opportunistic in what we do to bring  
12 products to market. There are other companies  
13 that are very heavy into R & D. So it's very  
14 company specific, product specific. I just  
15 can't, you know, give a broad, this is the way  
16 it is.

17 MR. DINER: I would like to mark the  
18 next exhibit.

19 (Deloitte document - Measuring the  
20 return from pharmaceutical innovation 2014 -  
21 turning a corner, PROL0339526 - PROL0339561,  
22 was marked Hofmann-3 for identification.

23 BY MR. DINER:

24 Q Mr. Hofmann, the court reporter has  
25 just marked Hofmann Exhibit 3. This document bears

1 Bates numbers PROL0339526 through 9561.

2 Have you seen this document before?

3 A I can't remember one way or the other  
4 right now.

5 Q Okay. This is another publication by  
6 Deloitte, right?

7 A It's -- I think this is the UK  
8 Deloitte. If you look at the very back, it's not  
9 the US Deloitte firm. I think it's the UK Deloitte  
10 firm.

11 Q Okay. That's fine. And this document  
12 is entitled, Hofmann Exhibit 3, that is, Measuring  
13 the return from pharmaceutical innovation 2014.  
14 Turning a corner?

15 Is that right?

16 A Yes.

17 Q Take a look at page 6 of the document  
18 that is marked as Hofmann Exhibit 3, left-hand  
19 column top paragraph. And take a moment, if you  
20 will, to read that to yourself.

21 MS. FINK: And take as long as you need  
22 to read that or the things surrounding it.

23 THE WITNESS: Okay, I see that.

24 BY MR. DINER:

25 Q In this passage you just read, it

1 speaks of compounds taking approximately, in some  
2 instances, 15 years to progress from discovery to  
3 launch.

4 See that?

5 MS. FINK: Objection, the document  
6 speaks for itself.

7 THE WITNESS: I think you've -- I think  
8 you've read that as it says there as a  
9 generality, but that's certainly not the  
10 experience in this case, and that's not the  
11 experience that would be across the board.

12 BY MR. DINER:

13 Q But you have seen in certain instances  
14 in the work that you've done in the past that it's  
15 not uncommon for our product or a compound to take  
16 15 years before, or after discovery before its  
17 launched, correct?

18 A I think I would say it differently. I  
19 would say it's not common for it to take 15 years.  
20 I think it's usually much less than that, but it's  
21 not unheard of that it has taken, you know, 15 years  
22 for a molecule to come to market.

23 Q The --

24 A And I think that there's also no  
25 details here on whether this is talking about a new

1 chemical entity, whether this is talking about a  
2 tweaked formulation of an existing molecule, et  
3 cetera, et cetera.

4 Q Well, against that backdrop, the  
5 article goes on to say, and this passage goes on to  
6 say that, Decisions taken by R & D leaders today are  
7 unlikely to deliver measurable results in the short  
8 term.

9 Do you see that?

10 A I think those are the words, yes.

11 Q And then it goes on and it says,  
12 Therefore, a long-term view of R & D returns is more  
13 meaningful than measuring yearly returns which can  
14 be skewed by one or two assets with particularly  
15 high or low revenue expectations.

16 Do you see that?

17 A I see those words.

18 Q Yeah. So looking at the short-term of  
19 maybe 30 months of a product isn't necessarily a  
20 sufficient time to assess whether that product is  
21 not commercially successful; is that right?

22 A .I totally disagree with you.

23 Q You disagree with what is stated in  
24 this article?

25 A I don't think that this article is

1 written with somebody addressing the question of  
2 commercial success in an obviousness inquiry with  
3 respect to the performance of Prolensa. I think, as  
4 I explained, Prolensa is the third iteration of the  
5 bromfenac molecule. We have lots of history of the  
6 performance of the franchise, and Prolensa entered  
7 the market not as a brand-new molecule, but as a  
8 tweaked formulation of a known molecule. All we  
9 have in terms of the actual performance is the  
10 30-plus months it's been on the market, combined  
11 with the life cycle management, which I think has  
12 given us plenty longitudinal data to form the  
13 opinions that I have formed.

14 Q But at this point in time you can't  
15 tell what's going to be the eventuality for the  
16 Prolensa product beyond 30 months, can you?

17 A I think that to speculate on that would  
18 be a hazard, and I think that as a result, you know,  
19 all we can do is look at the actual data which tells  
20 us that even with all the benefits that Prolensa had  
21 as being a follow-on product where the prior product  
22 was delisted and had all the benefits of the  
23 hundreds of millions of dollars of marketing of the  
24 bromfenac molecule, even with all of those benefits,  
25 in nearly three years on the market it hasn't eked

1 out a profit. And even if somehow in the future you  
2 want to speculate that it might nudge itself into  
3 profitability that's still not by any measure a  
4 commercial success.

5 Q Now, you spoke of products being  
6 delisted. Which product are you referring to?

7 A Bromday, and then Xibrom before it.

8 Q Bromday hasn't been delisted, has it?

9 A I believe it has.

10 Q There's a generic Bromday on the  
11 market, isn't there?

12 A There is, but there's no RLD.

13 Q There's no what?

14 A RLD.

15 Q But there is generic Bromday on the  
16 market; is that right?

17 A There are generic versions of bromfenac  
18 .09 on the market, without an RLD.

19 Q And Prolensa is competing with those  
20 generic Bromday products, correct?

21 A Supported by the various marketing,  
22 pricing and life cycle management strategies, yes.  
23 Those are competing available products.

24 Q And then are you aware today what the  
25 price differential is as between Prolensa and

1 generic Bromday?

2 A I think I -- my report contains some  
3 analysis on the information that we have available.  
4 I think that IMS data we have is limited to the  
5 gross data and that, you know, as I explained in my  
6 report, there is a limited differential certainly at  
7 the outset. I understand that the IMS data, that  
8 differential has grown over time, but that there's  
9 still not much of a premium, if any, on the brand  
10 product over the generic.

11 Q Well, according to the IMS data, the  
12 brand product is selling significantly higher in  
13 price than generic Bromday; isn't that right?

14 MS. FINK: Objection, the document  
15 speaks for itself.

16 THE WITNESS: I think my analysis is in  
17 my report which explains the analysis I've  
18 done.

19 BY MR. DINER:

20 Q But that doesn't answer my question.  
21 The IMS data indicates that Prolensa is selling at a  
22 much higher price than generic Bromday, correct?

23 MS. FINK: Again, objection. The IMS  
24 data speaks for itself.

25 THE WITNESS: I think it depends on the

1 period. There are some periods where the  
2 generic IMS data shows a higher price. There  
3 are some periods where the brand shows a  
4 higher price, again recognizing it's all gross  
5 data.

6 BY MR. DINER:

7 Q As we sit here today, are you aware  
8 that the IMS data indicates that the price of  
9 Prolensa is much higher than the price of generic  
10 Bromday?

11 A I don't have IMS data as of February  
12 24, 2016.

13 Q And how about as of September 2015?

14 A I would want to look at the Jarosz  
15 exhibit to weigh in on that one way or the other. I  
16 haven't committed all the data points to memory.

17 Q We'll get back to that, then.

18 Mr. Hofmann, based on your experience,  
19 the time to reach peak sales for a pharmaceutical  
20 product can take several or more years; isn't that  
21 right?

22 A I think it really varies. It's a facts  
23 and circumstances-based thing. It can, but it can  
24 also not take very long at all, particularly if it's  
25 a follow-on product as part of a life cycle



1 management situation.

2 Q Is it your experience that  
3 pharmaceutical companies will typically invest  
4 heavily in marketing following launch of a product  
5 in order to lay groundwork for the future success of  
6 that product?

7 MS. FINK: Objection, incomplete  
8 hypothetical.

9 THE WITNESS: Yeah, I think  
10 generalities are always difficult. I think  
11 you really have to look at it in each  
12 situation. I think that, as I alluded to  
13 earlier, certainly, if you have a brand-new  
14 molecule for a brand-new therapeutic class,  
15 yes. There's plenty of studies that have  
16 shown that the marketing is heavier at the  
17 outset in those situations. I think that, you  
18 know, it depends. In this situation, Prolensa  
19 benefited from many years of marketing of the  
20 bromfenac molecule well before it launched.

21 BY MR. DINER:

22 Q Have you seen, in your experience, that  
23 with pharmaceutical formulations as opposed to new  
24 molecules that there is also typically a large  
25 investment by the company following the launch of

1 the product?

2 MS. FINK: Objection, incomplete  
3 hypothetical, vague.

4 THE WITNESS: What do you mean  
5 "investment"?

6 BY MR. DINER:

7 Q Marketing investment, marketing  
8 expenditures.

9 A It depends.

10 Q Did you look at -- I'm sorry?

11 A I was going to say every product launch  
12 has its own unique attributes to it.

13 Q How about the product Ilevro, did you  
14 consider that?

15 A Sure.

16 Q Do you know what Alcon spent on its  
17 marketing expenditures to get Ilevro up and running?

18 A Right. So I don't have the data  
19 committed to memory, but I looked at it in that  
20 there was a shift in their marketing from Nevanac to  
21 Ilevro. We only have the IMS data, we don't have  
22 the actual data. I think it appears as an exhibit  
23 to Jarosz's report, which I reviewed and considered.

24 Q Okay. And Alcon also in -- after the  
25 launch of Ilevro also invested heavily in marketing

1 expenditures to get that product up and running; is  
2 that correct?

3 A As I explained in my report, they did  
4 make expenditures on the order of tens of millions  
5 of dollars. It was still half of or thereabouts of  
6 what was spent on Prolensa, but there was  
7 expenditures made.

8 Q There was significant expenditures  
9 made; is that correct?

10 A Yeah, tens of millions of dollars.

11 Q Is it also your experience that  
12 sometime after the product is launched that the  
13 marketing expenditures start to tail off?

14 A I think that again -- I've certainly  
15 seen studies of that. There are situations where  
16 that happens. I've seen more times than I can count  
17 where that doesn't always happen. It's a very, you  
18 know, product specific, market specific, strategy  
19 specific issue.

20 Q And have you also seen studies where  
21 they've indicated that after several years  
22 post-launch that the marketing expenditures decrease  
23 and the product starts to increase in sales?

24 A See, I think that's a -- it's very  
25 facts and circumstances based. And it depends on

1 the therapeutic class. It depends on the  
2 responsiveness of the prescribers to marketing. It  
3 depends on whether it's an acute condition or a  
4 chronic condition. It depends on whether additional  
5 indications have launched. It depends on, you know,  
6 so many variables that I just can't talk in these  
7 generalities and tell you this is the way it always  
8 is.

9 Q But the concept of post-launch  
10 decreasing the amount of marketing expenditures and  
11 watching as the product starts to increase in sales  
12 is not an uncommon happening; is that correct?

13 A It's certainly not unheard of. But  
14 again, there's just as frequent, or at least, you  
15 know, instances I can think of where the cessation  
16 of marketing leads to a decrease in sales. And then  
17 the brand has to reinvigorate its marketing if they  
18 want to try and sustain sales. So it's again, facts  
19 and circumstances based.

20 MR. DINER: Can we mark the next  
21 exhibit.

22 (American Marketing Association article  
23 - Early Marketing Matters: A Time-Varying  
24 Parameter Approach to Persistence Modeling,  
25 PROL0339663 - PROL0339676, was marked

1 Hofmann-4 for identification.)

2 BY MR. DINER:

3 Q Hofmann Exhibit 4 has been handed to  
4 you, and it has Bates numbers PROL0339663 through  
5 9676.

6 This document, Hofmann Exhibit 4, is  
7 entitled, Early Marketing Matters: A Time-Varying  
8 Parameter Approach to Persistent Modeling.

9 Mr. Hofmann, have you seen this --

10 MS. FINK: Objection. I believe it  
11 says "persistence modeling."

12 MR. DINER: Oh, thank you.

13 BY MR. DINER:

14 Q I'll read the title again. Early  
15 Marketing Matters: A Time-Varying Parameter  
16 Approach to Persistence Modeling.

17 As I was saying, Mr. Hofmann, have you  
18 seen this article before?

19 A I've reviewed so many articles I'm not  
20 sure one way or the other as I sit here right now.

21 Q Okay. The first named author, Ernst  
22 Osinga. Do you know that person?

23 A The name sounds familiar.

24 Q I would like to direct you to page 183  
25 of this article. The left-hand column, the last

1 paragraph in that column. It says, midway through  
2 the paragraph, For example, our empirical results  
3 suggests that drug manufacturers should use  
4 physician-oriented marketing in the periods right  
5 after an introduction of a brand because during  
6 these periods both persistent and temporary  
7 marketing effects are significant and largest in  
8 effect size. Later, manufacturers should decrease  
9 the brand's marketing expenditures because the  
10 effects become insignificant or only marginally  
11 effective.

12 Do you see that?

13 A I see the sentences you've read, yes.

14 Q Right. So have you seen in your  
15 experience, then, Mr. Hofmann, that indeed companies  
16 will decrease marketing expenditures after a certain  
17 period of time post-launch because they become less  
18 effective as time goes on?

19 MS. FINK: Objection, incomplete  
20 hypothetical.

21 And Mr. Hofmann, take all the time you  
22 need to read whatever you want to from this  
23 article.

24 THE WITNESS: I think what I tried to  
25 explain before, and I think this is perfectly

1 consistent with it, is there are situations  
2 where what you've described and what this  
3 article studies happened. I can think of  
4 plenty of other situations where persistent  
5 marketing even later in life happens. But  
6 it's very much, you know, I think something  
7 that you have to look at on a  
8 product-by-product basis.

9 BY MR. DINER:

10 Q Now, in your profitability analysis I  
11 believe the marketing expenditures that you deducted  
12 off of the gross sales constituted the largest  
13 subtraction; is that correct?

14 A That's probably right, yes. Yeah,  
15 discounts being the second largest. Yep.

16 Q So if with a product if after a couple  
17 of years post-launch the marketing expenditures  
18 decrease, but the sales of the products start to  
19 ramp up you're going to start to see a widening of  
20 the profit margin; isn't that right?

21 A I mean, as a matter of math, what  
22 you've asked in your abstract hypothetical is  
23 necessarily so without putting any numbers or actual  
24 data into context.

25 MR. DINER: I would like to mark the

1 next exhibit.

2 (Reply Expert Report of John C. Jarosz  
3 on objective indicia of non-obviousness dated  
4 2/12/16 was marked Hofmann-5 for  
5 identification.)

6 BY MR. DINER:

7 Q Mr. Hofmann, the court reporter has  
8 just handed you what has been marked as Hofmann  
9 Exhibit 5. And that is a reply expert report of  
10 John C. Jarosz on objective indicia of  
11 non-obviousness. I believe you said that you have  
12 considered this reply report of Mr. Jarosz in  
13 preparation for your deposition; is that right?

14 A That's right. I didn't have this at  
15 the time I prepared my report, but since the  
16 issuance of my report I have reviewed and considered  
17 this. But I only received it a few weeks ago.  
18 Likewise, I only received his transcript. So I'm  
19 still, you know, considering some of the points that  
20 he's made.

21 Q Okay. But you're an expert, right, in  
22 the implications of economics, finance and other  
23 economic issues concerning commercialization of  
24 pharmaceutical products, correct?

25 A I think we covered that earlier. Maybe



1 not in those exact words, but --

2 Q The concept is correct?

3 A Yeah.

4 Q So do you consider yourself  
5 sufficiently skilled to look at this document and  
6 answer questions off of it?

7 A Absolutely. My point was more a  
8 temporal one, that I -- you know, I received this  
9 and I just received the transcript. I haven't, you  
10 know, crystallized all of my opinions with respect  
11 to the response of this. I certainly have formed  
12 some opinions with respect to things in here, but I  
13 just want to, you know, as a matter of record, not  
14 make it sound like I have completely crystallized  
15 all my opinions with respect to this report, having  
16 only recently received it.

17 Q Okay. Let's go to page 12 of the  
18 report. And you'll see a graph at the top of that  
19 page. Let me know when you're there.

20 Now, is this graph entitled, Prolensa  
21 Gross Sales and Marketing Expenditures Q2 2013 to Q3  
22 2015?

23 A That's what it says.

24 Q Okay. And if I remember correctly, I  
25 think that you said that you analyzed the

1 commercially available data on Prolensa in that  
2 period of time, Q2 2013 to Q3 2015, correct?

3 A Correct.

4 Q We were talking a moment ago about  
5 marketing expenditures.

6 A Excuse me.

7 Q Are you ready?

8 A Yes, I just have a bit of a cough.

9 Q We were talking a moment ago about  
10 marketing expenditures. Do you recall that?

11 A Yes.

12 Q Okay. I would like you to take a look  
13 at this graph and the marketing expenditures which  
14 is indicated in the red line. Is that correct?

15 A Yes.

16 Q And we were saying before that at a  
17 certain point in time it's not uncommon for  
18 marketing expenditures to decrease; is that right?

19 A I think --

20 Q Post-launch.

21 A I think you were saying that. I was  
22 saying well, it really depends on the facts and  
23 circumstances.

24 Q And here's a circumstance where with  
25 regard to Prolensa around Q4 2013 into Q1 2015 we

1 start to see that the marketing expenditures fall  
2 dramatically off, correct?

3 MS. FINK: Objection to the extent it  
4 mischaracterizes the graph.

5 THE WITNESS: Yeah, that was confusing  
6 because from Q4 2013 it looks like marketing  
7 expenditures go up for quite a while and then  
8 they do appear to drop in the Q1 2015 quarter  
9 a bit later.

10 BY MR. DINER:

11 Q Oh, okay. I apologize, I misspoke.  
12 Let me restart and rephrase that question.

13 At Q4 2014 to Q4 -- to Q1 2015, there  
14 is a dropoff in marketing expenditures, correct?

15 A Quarter to quarter, according to IMS  
16 data, which is not actual data, that's what the data  
17 reflects.

18 Q Okay.

19 A Go ahead.

20 Q Okay. And then from Q1 2015 through  
21 the next two quarters, ending with Q3 2015, we start  
22 to see a downward trend -- a continued downward  
23 trend in marketing expenditures.

24 MS. FINK: Objection to the extent it  
25 mischaracterizes the graph.

1 BY MR. DINER:

2 Q Is that correct?

3 A No, it goes up in Q2 2015 and then it  
4 goes down in Q3 2015.

5 Q But as between Q1 2015 and Q2 2015  
6 there's a drop in marketing expenditures, is that  
7 right, for Prolensa?

8 A According to the data, it's slightly  
9 lower, yes.

10 Q Okay. And the marketing expenditures  
11 at Q3 2015 as compared to Q3 2013 are far less as  
12 well, correct?

13 A I mean -- go ahead.

14 MS. FINK: Same objection to the extent  
15 you mischaracterized the graph.

16 THE WITNESS: You've picked two  
17 quarters with two data points. It's  
18 \$5 million difference according to the IMS  
19 data and those data points.

20 BY MR. DINER:

21 Q Okay. Now, let's take a look at the  
22 gross sales for Prolensa starting with Q4 2014 and  
23 going through to Q3 2015.

24 You see that portion of the graph?

25 A I do.

1           Q           And do we see an upward trend in terms  
2 of the gross sales of Prolensa in that period of  
3 time, that is, Q4 2014 to Q3 2015?

4           A           With the very important caveat that  
5 these are gross sales according to IMS which don't  
6 reflect discounts and, you know, unless you have  
7 discounts reflected there, it's a hazard to assume  
8 that the slight growth in that gross sale figure  
9 necessarily translates into gross in net sales.

10          Q           But the trajectory of these numbers is  
11 that gross sales is increasing while marketing  
12 expenditures are decreasing from the period of Q4  
13 2013 to Q3 2015, correct?

14                   MS. FINK:  Objection to the extent you  
15 mischaracterized the graph.

16                   THE WITNESS:  Yeah, I just -- I can't  
17 -- I mean, we've gone through data points and  
18 for the particular quarters you've plucked  
19 out, yes, there are some data points that  
20 reflect what you say they reflect, but I think  
21 that it's important to also point out that  
22 these don't reflect the discounts, and, you  
23 know, without the discounts, if the discounts  
24 are growing that could really undermine  
25 whatever, you know, you're trying to imply

1           with respect to the gross sales figure.

2 BY MR. DINER:

3           Q       But for this period of time you don't  
4 know if the discounts are growing, do you?

5           A       Unfortunately, for whatever reason, the  
6 data for discounts in this period was not included  
7 in what Bausch + Lomb produced.

8           Q       Okay.

9           MR. DINER: Why don't we take a break  
10 for now and we'll come back in 10, 15 minutes.

11          MS. FINK: Okay.

12          VIDEO OPERATOR: We're now going off  
13 the record at approximately 11:22 a.m.

14          (Brief recess.)

15          VIDEO OPERATOR: We are now going back  
16 on the record at approximately 11:38 a.m.; the  
17 beginning of file two.

18 BY MR. DINER:

19          Q       Before the break, Mr. Hofmann, we were  
20 talking about the graph at page 12 of doctor -- of  
21 Mr. Jarosz's reply report.

22                   Do you recall that?

23          A       Yes, I do.

24          Q       And we were talking and looking at the  
25 graph from the standpoint of marketing expenditures

1 decreasing and gross sales increasing.

2 Do you recall that?

3 A I think those were some statements you  
4 made. I added some caution to what you were  
5 representing that may or may not mean.

6 Q Right. And I think just before the  
7 break we were talking about discounts and the effect  
8 of discounts on the profitability analysis. Is that  
9 correct?

10 A Yes.

11 Q Now, I recognize your point about  
12 discounts, and we'll get to that in a moment. But  
13 -- and initially unprofitability product, perhaps as  
14 you've characterized Prolensa, would become  
15 profitable as the margins increased with increasing  
16 sales and decreasing marketing expenditures; is that  
17 right?

18 MS. FINK: Objection, incomplete  
19 hypothetical.

20 THE WITNESS: I mean, in that abstract  
21 hypothetical it doesn't have particular  
22 numbers tied to it. You are also missing  
23 other variables. The most significant that  
24 comes to mind is discounts. You know, it is  
25 not unheard of at all, and it is actually

1 quite common the longer a product is on the  
2 market the more discounts increase. And so  
3 whatever purported savings you want me to, you  
4 know, assume for the future, a lot of times  
5 that's offset by increased discounts that you  
6 wouldn't have any increase in net margin.

7 BY MR. DINER:

8 Q As we look at the graph again in  
9 Mr. Jarosz's report at page 12 we see, at least from  
10 the trajectory of the blue line representing gross  
11 sales and the red line representing marketing  
12 expenditures, that the trajectory of these two lines  
13 is a widening of the gap as between gross sales and  
14 marketing expenditures, correct?

15 MS. FINK: Objection to the extent it  
16 mischaracterizes the graph.

17 THE WITNESS: I mean, subject to the  
18 fact that I object to this graph as telling us  
19 anything particularly meaningful in that it  
20 lacks discounts, and I believe there's a real  
21 hazard in trying to draw any inferences like  
22 you're trying to from the distance between the  
23 blue line and the red line in any meaningful  
24 way.

25 BY MR. DINER:



1           Q       Well, then, let's go to the issue of  
2 discounts. So in your analysis you made an  
3 assessment of discounts, correct?

4           A       I made an assessment of discounts? I  
5 took the discounts from the periods where it was  
6 available for Prolensa and Bromday and considered  
7 those in applying them to the periods for which I  
8 did not have the data.

9           Q       Okay. Within the term "discounts" does  
10 that include allowances, rebates, coupons,  
11 chargebacks and returns?

12          A       Yes.

13          Q       For ease of discussion I'll just refer  
14 to that collectively as discounts. Is that okay?

15          A       I understand.

16          Q       Now, you just mentioned a moment ago  
17 that you used certain information to calculate or  
18 estimate the amount of the discount that you applied  
19 in your profitability analysis. Am I correct in  
20 understanding that you took data obtained from  
21 Bausch + Lomb for Q2 and Q3 of 2013 to assess, or to  
22 calculate discounts to be used in your profitability  
23 analysis?

24          A       Well, I would phrase it slightly  
25 differently. It's not like I just picked those two

1       quarters but I had all the other quarters. It was,  
2       from I could tell in the production, the only two  
3       quarters where that information was produced.

4               Q       Okay. So that's all the information  
5       you had to estimate what the discounts would be for  
6       your profitability analysis?

7                       MS. FINK: Objection, mischaracterizes  
8       testimony.

9                       THE WITNESS: No. As I explained in my  
10       report, there were also discount data included  
11       in the production for Bromday that I  
12       considered in my analysis as well.

13       BY MR. DINER:

14               Q       Okay. So perhaps you can enlighten me  
15       a little bit. What was the discount information  
16       that you considered for Bromday?

17               A       Probably the easiest way to talk  
18       through it would be to go to Exhibit A of my report,  
19       which is Hofmann Exhibit 1. On the top of the  
20       spreadsheet there you see the Prolensa, the two  
21       quarters you and I were just talking about, Q2 and  
22       Q3 2013. On the bottom of the spreadsheet, within  
23       the production they included some historic Bromday  
24       discount information as well, and that's reflected  
25       on the bottom half of the spreadsheet.

1 Q And did you take from the same two  
2 quarters, Q2 and Q3 of 2013, from Bromday?

3 A I'm sorry, quantitatively I used the  
4 discounts from the top of the chart, the Prolensa  
5 discounts. What I'm saying is, in performing my  
6 analysis I considered the historic discounts of  
7 Bromday, but mathematically I did not pull them into  
8 the determination of the amount that I used in my  
9 profitability analysis.

10 Q Okay. And so you then assume that the  
11 level of reductions to gross sales, based on  
12 discounts, would be unchanged from Q3 2013 to Q2  
13 2015, correct?

14 MS. FINK: Objection to the extent it  
15 mischaracterizes the report.

16 THE WITNESS: Yes, I mean, absent the  
17 actual data, which I would be happy to use if  
18 it was available, I made, I think, a very  
19 reasonable assumption to hold it flat. In my  
20 experience, discounts frequently will increase  
21 with time, particularly rebates to formularies  
22 the longer that they're on the market.

23 BY MR. DINER:

24 Q Well, let's talk about that. With  
25 respect to coupons, for example, pharmaceutical

1 companies use them to get a consumer's attention; is  
2 that right?

3 A Coupons are used for lots of reasons.  
4 I don't quarrel that that might be a reason that  
5 coupons are used.

6 Q Are they also used to advertise a new  
7 product?

8 A I mean, they can be, but I don't -- I  
9 mean, the important thing here is you're talking  
10 about things at the outset. I mean, coupons are  
11 used frequently throughout the life cycle of  
12 products, in particular, for something like this  
13 where you have an acute use.

14 Q They're kind of marketing promotions,  
15 right, coupons?

16 A They're an incentive to get patients to  
17 use the product.

18 Q And I think we talked about earlier and  
19 established that in some instances those marketing  
20 expenditures for some products could decrease after  
21 a certain point in time post-launch, correct?

22 MS. FINK: Objection, incomplete  
23 hypothetical.

24 THE WITNESS: Theoretically, that  
25 happens in some facts and circumstances. In

1           many others they increase over time. What  
2           we're talking about here isn't marketing,  
3           we're talking about discounts. What we talked  
4           about before was marketing. These don't  
5           appear in marketing. While they are a tool to  
6           influence prescribing and fulfillment  
7           behavior, they aren't technically in the  
8           category of marketing. They're in the  
9           category of discounts.

10       BY MR. DINER:

11           Q           I think you agreed that based on the  
12           term I used that they were marketing promotions,  
13           correct?

14           A           Yeah, and I guess I just, as I thought  
15           about it more wanted to be careful with having  
16           precision in the semantics here. I don't want to  
17           confuse, you know, the geography of where they fit.  
18           They are not in the 130-some million dollars of  
19           marketing expenses that we've talked about earlier.  
20           They sit in a different place and in a different  
21           line and are an additive incentive, a form of  
22           marketing, if you will, but more so, properly  
23           categorized as a discount incentive, a pricing  
24           incentive, if you will.

25           Q           But as an incentive, and even as a

1 marketing incentive as, you called it a moment ago,  
2 the need for these kind of discounts, such as  
3 coupons, should decline as the product becomes more  
4 established and starts to take hold, correct?

5 A Totally disagree. I can think of many,  
6 many products where if anything, because of  
7 competitive pressure, because of patient resistance,  
8 because of formulary placement, because of just  
9 weakening sales, pharmaceutical companies have had  
10 to increase coupons and other discounts, and in  
11 particular formulary rebates over time. So I  
12 wholeheartedly reject that.

13 Q Well, we see in the graph on page 12 of  
14 Mr. Jarosz's reply report that actually the gross  
15 sales are starting to go on the rise and going up  
16 from Q4 2014 through Q3 2015, correct?

17 MS. FINK: Object to the extent it  
18 mischaracterizes the graph.

19 THE WITNESS: There were the couple  
20 data points that we looked at for those couple  
21 quarters, and I think I explained the hazard  
22 in trying to make inferences that you're  
23 making, that tick up in gross sales could just  
24 as well be due to increased rebates,  
25 incentives and coupons, and absent the

1 discounts in that chart that really tells us  
2 nothing.

3 BY MR. DINER:

4 Q But you mentioned before you had no  
5 data to actually know what the actual discounts were  
6 at that period of time. So they could have gone  
7 down, correct?

8 A Well, I think I do have data for the  
9 first two quarters. I do have data for the final  
10 trailing, what, six or seven quarters of Bromday,  
11 and I have my experience in having analyzed where  
12 people actually do produce gross-to-net information.  
13 They don't go down. Especially formulary rebates.  
14 Coupons can fluctuate, in terms of their use, but I  
15 don't think it's fair to say that one would expect  
16 coupons to go down as a matter of course over time.  
17 I think I've seen just as many times they go up and  
18 the degree to which they may go from a \$15 subsidy  
19 to a \$13 subsidy. It just varies.

20 Q And so because it varies, it's purely  
21 speculative to say it would go up or down?

22 A No, it's not speculative. It's -- like  
23 I said, if you're going to force me into explaining  
24 why the discounts -- let me back up. The data  
25 periods we have clearly show that it's pushing

1 40 percent. The end of life for Bromday show that  
2 it was in excess of 40 percent in some periods, on  
3 average about 35 percent. The degree of change in  
4 those discounts is, you know, it's consistent. The  
5 data points are consistent, and then when you  
6 combine that with my experience having reviewed many  
7 pharmaceutical products and the trending of  
8 discounts, and in particular, coupons and rebates  
9 over time, it's not speculation. It's a reasonable  
10 estimate for the qualitative use that the  
11 profitability analysis that I've done in support of  
12 the lack of commercial success.

13 Q Did you assess the profitability of  
14 other commercial NSAID formulations in the first two  
15 to three years post launch?

16 A I didn't. I did not. This would fall  
17 in response to, I think, Mr. Jarosz described he  
18 looks at absolute performance, he looks at relative  
19 performance. He was citing to these gross sales  
20 figures in his absolute performance, and so an  
21 absolute response would be focused on Prolensa, not  
22 other products.

23 Q So you don't know how your made-up  
24 profitability calculation compares to Ilevro, for  
25 example, over the same period of time?



1 MS. FINK: Objection, argumentative,  
2 mischaracterizes testimony.

3 THE WITNESS: Yeah, I mean, I will  
4 vigorously quarrel with your characterization  
5 of my profitability as a made-up analysis. I  
6 don't have discount data for Ilevro that I did  
7 have for certain bromfenac products, which  
8 would limit my ability to do what you're  
9 saying. The data points I do have, I know  
10 that Ilevro spent less than half, or about  
11 half, on marketing, according to IMS, and I  
12 know their sales have exceeded Prolensa, so  
13 they certainly most likely sit in a much more  
14 favorable spot than Prolensa.

15 BY MR. DINER:

16 Q But you don't know what their discounts  
17 are, do you?

18 A That's correct.

19 Q And so that conclusion that you've just  
20 drawn may not be applicable at all.

21 A I'm just trying to answer your  
22 questions.

23 Q How about that one? The conclusion you  
24 have just drawn with regard to profitability or not  
25 of Ilevro is based on incomplete information, right?

1           A           I agree. I don't have the discounts.  
2           But what I'm saying, and you spent a lot of time on  
3           this little graph from the Jarosz report, I'm  
4           saying -- and you were trying to make inferences on  
5           it, the Ilevro sales levels are much higher and  
6           their marketing is much lower. So if you want to  
7           make inferences, it would suggest that on a relative  
8           basis, based on the data we do have, as a matter of  
9           degree, recognizing you can't analyze profitability,  
10          but on the metrics we do have, Ilevro has performed  
11          much better than Prolensa.

12          Q           It doesn't mean that Prolensa is not  
13          commercially successful just because another product  
14          performs successfully in the marketplace as well,  
15          does it?

16          A           Could you read that back?

17          Q           I'll restate it.

18                      Based on your last answer with regard  
19          to Ilevro, even if it is doing better in the  
20          marketplace by some slight margin, it doesn't mean  
21          that Prolensa is not commercially successful as  
22          maybe Ilevro?

23          A           I mean, I quarrel with some embedded  
24          counterfactual assumptions in your question. You  
25          said if Ilevro is doing better by some small margin.

1 I think their sales levels on gross data are more  
2 than 20 percent higher and they've spent less than  
3 half on marketing. So that's not a minor or  
4 whatever your adjective characterizing it was  
5 difference. If your question is, is it a platitude  
6 that you can only have one commercially successful  
7 product or if there is one that is commercially  
8 successful, that's -- forecloses any others, no,  
9 it's a facts and circumstances-based inquiry,  
10 though.

11 Q And because you don't know what the  
12 discounts are from -- for outcome for Ilevro you  
13 really can't make an assessment as to its relative  
14 profitability compared to Prolensa, correct?

15 MS. FINK: Objection, asked and  
16 answered.

17 THE WITNESS: Yeah, I think I tried to  
18 explain several questions ago that what I'm  
19 doing here is critiquing the incomplete,  
20 misleading analysis in the Jarosz report on  
21 absolute performance of Prolensa. It's not a  
22 relative -- I'm not asserting anything with  
23 respect to relative performance. I'm not  
24 analyzing the commercial success of Ilevro.  
25 I'm analyzing whether the commercial

1 performance of Prolensa provides objective  
2 indicia of non-obviousness and responding to,  
3 I think, the misleading and inaccurate  
4 characterization of gross sales data for the  
5 absolute performance claims that the Jarosz  
6 report makes.

7 BY MR. DINER:

8 Q When comparing products in the relevant  
9 market, that's the only way you really can compare  
10 them is based on gross sales data, correct?

11 A I think that there are a variety of  
12 metrics, one of which is gross sales data from IMS,  
13 that can certainly give you some indications of the  
14 degree of, you know, things like market share. I  
15 would put prescriptions as a more important metric  
16 than gross sales data. So I disagree with your  
17 question that it's the only way to compare. I think  
18 that prescription data is probably the better  
19 relative way to compare. I think there's other  
20 metrics that one can compare on a relative basis,  
21 which I have done with respect to the degree of  
22 spending on marketing. And then I think there  
23 are -- I've had situations where certain companies  
24 do disclose their gross-to-net information and I am  
25 able to look at that. That just didn't happen in

1 this case with respect to what Alcon and Bausch &  
2 Lomb disclose.

3 Q When you referred a moment ago to  
4 prescription data, are you referring to unit sales?

5 A No, IMS, TRx data and NRx data.

6 Q The TRx stands for what?

7 A Prescriptions, total prescriptions.

8 Q So -- okay. And the NRx?

9 A New prescriptions.

10 Q So collectively they're the total --  
11 you don't add them?

12 A No, you don't. NRx is subsumed within  
13 TRx. So TRx is total prescriptions, and then if you  
14 want to say, well, how are we doing on getting new  
15 patients, you look at NRx's data point.

16 Q So TRx is not the same as total unit  
17 sales?

18 A No.

19 Q And IMS data, do they provide unit  
20 sales?

21 A IMS does track that. I don't think it  
22 was produced in this case. And the distinction is  
23 that a TRx is common size to a 30-day prescription  
24 or a normal course of treatment prescription. And  
25 if you think about it, depending on the therapeutic

1 class and the drug you're dealing with and the  
2 strengths and all those things, you know, TRx is a  
3 better common size way to look at things than if I'm  
4 trying to compare a twice daily medication with a  
5 once daily medication. If I look at unit sales, you  
6 know, the twice daily medication is going to look  
7 like it's two sales for every one sale. You see  
8 what I'm saying?

9 Q Yeah. Back to your profitability  
10 analysis. I think we established you didn't do one  
11 for Ilevero. Is it fair to say that you also didn't  
12 do a profitability analysis for Bromday?

13 A I did not do a separate profitability  
14 analysis of Bromday, no.

15 Q Okay. Okay. Let's go to your  
16 calculation of costs of goods sold in your  
17 profitability analysis.

18 So if I understood correctly from your  
19 report, you estimated the costs of goods sold for  
20 purposes of your profitability analysis. Using the  
21 costs of goods sold for goods at ISTA and Valeant;  
22 is that right?

23 A Yes. Said slightly differently. I  
24 analyzed the costs of goods sold for both ISTA and  
25 Valeant, and based on the prominence with which the

1 bromfenac products represent the majority of ISTA  
2 sales and the slightly lower costs of goods sold  
3 percentage that ISTA had, I thought it was  
4 reasonable to use the ISTA. So the Valeant does not  
5 quantitatively feed into what I did for costs of  
6 goods sold, but it was a qualitative consideration  
7 in settling on the ISTA percentage.

8 Q So the costs of goods sold is really  
9 based on an analysis of the ISTA costs of goods  
10 sold?

11 A That's right. With consideration of  
12 the Valeant costs of goods sold as a reasonableness  
13 check.

14 Q But the quantification measurement is  
15 based on ISTA's cost of goods sold?

16 A Yes, sir.

17 Q And for ISTA you used Q1 2010 through  
18 Q1 2012 for the costs of goods sold?

19 A That's right.

20 Q And I think you said you thought it was  
21 a reasonable because it represented a large quantity  
22 of bromfenac-containing products; is that right?

23 A Yeah. I said the majority of ISTA's  
24 sales are bromfenac-containing products.

25 Q I think in your report you say it's

1 60 percent.

2 A That's right.

3 Q So then 40 percent of company wide  
4 sales of ISTA were for non-bromfenac drugs; is that  
5 right?

6 A That's right.

7 Q And in your analysis you provide no  
8 explanation of how the cost of ISTA's non-bromfenac  
9 drugs compared with the cost of manufacturing, let's  
10 say Bromday, correct?

11 A Right. I don't have visibility to the  
12 breakout. Again, what I'm doing in developing my  
13 profitability analysis is using the best available  
14 data combined with my knowledge and experience  
15 having analyzed many, many, product P&Ls. So the  
16 fact that the majority of the sales were, in fact,  
17 bromfenac-containing products combined with where  
18 that cost of goods sold percentage falls, as far as  
19 my, you know, knowledge and experience it was a  
20 reasonable basis. But I don't disagree that I don't  
21 have visibility to the remaining 40 percent of  
22 products, costs of goods sold.

23 Q And that remaining 40 percent could  
24 have included drug products that were significantly  
25 more expensive to make than Bromday, correct?



1 MS. FINK: Objection, calls for  
2 speculation.

3 THE WITNESS: That would be, I think,  
4 very unusual. In my experience, costs of  
5 goods sold for pharmaceutical products, I  
6 think it's not really controversial that  
7 they're generally viewed as being high-gross  
8 margin, gross margin being net sales, less  
9 costs of goods sold products. Said another  
10 way, costs of goods sold percentages are  
11 usually a relatively low percentage of net  
12 sales.

13 BY MR. DINER:

14 Q But there could have been products in  
15 there that were quite difficult to manufacture and  
16 increase their costs of manufacturing them, correct?

17 A Yeah. In something like that, I would  
18 think there would be discussion in their public  
19 filings. You know, they have management discussion  
20 and analysis that talks through various line items.  
21 I didn't see any suggestion or discussion that there  
22 were any of those such issues that would skew the  
23 results in any way. And it would have to be a very  
24 significant -- it would have to be like all  
25 40 percent is some really high of costs of goods

1 sold percentage to, you know, push the needle away  
2 from 23.9 percent. And, you know, from a  
3 directional perspective, I think your concern with  
4 my analysis would be is should this percentage be  
5 lower. So you don't have a risk of the percentage  
6 being much higher. There's very little, you know,  
7 room to work with between 0 and 23.9 percent that  
8 could skew it in any meaningful way.

9 Q But you still didn't look at what those  
10 other products were in the other 40 percent to know  
11 one way or the other their cost of manufacturing or  
12 formulating or whatever the case may be, right?

13 MS. FINK: Objection, asked and  
14 answered.

15 THE WITNESS: I reject a little bit  
16 your implication that I chose not to look at  
17 them, that they were sitting here and I just  
18 ignored the file. I just don't have the  
19 disclosures, and the ISTA 10-K don't break it  
20 out by product. They list it company wide.

21 BY MR. DINER:

22 Q Now, earlier you were using the term  
23 "life cycle management."

24 Do you recall that?

25 A Yes.

1           Q           Based on your usage of the term today,  
2 and as well in the opinions in your expert report,  
3 it seems that you use, or you denigrate that term  
4 "life cycle management" or the strategy around it;  
5 is that accurate?

6                   MS. FINK:  Objection, mischaracterizes  
7 the report and prior testimony.

8                   THE WITNESS:  No, I mean, I'm not  
9 denigrating at all.  I think from an economic  
10 perspective and profit maximizing or trying to  
11 harvest value by brand companies it's an  
12 economically, you know, prudent strategy.  I  
13 can minimize my R & D.  I can migrate demand  
14 to a new product.  I can, you know, harvest  
15 more value without having to get new compound  
16 patents, things like that.  I'm not  
17 denigrating it, but where I'm talking about it  
18 in the context of an inquiry into commercial  
19 success and objective indicia of  
20 non-obviousness is just that it involves a  
21 number of extrinsic, you know, things that are  
22 extrinsic to the claims of a patent that  
23 influence the commercial performance of a  
24 product.  So it's not a denigration.  It's  
25 just -- it is a -- when you're looking in a

1 commercial success obviousness inquiry,  
2 something that someone has to pay particular  
3 attention to on the role that it played in the  
4 commercial performance of a product.

5 BY MR. DINER:

6 Q How about with respect to from the  
7 perspective of the consumer, is life cycle  
8 management or a strategy of life strategy  
9 management, does that bring benefits to the  
10 consumer?

11 MS. FINK: Objection, vague, calls for  
12 speculation.

13 THE WITNESS: Well, I mean, that's a  
14 facts and circumstances situation. I mean, I  
15 think memantine is a good example where Forest  
16 have gotten into quite a bit of trouble for  
17 trying to life cycle manage memantine or  
18 Momenta to Momenta XR, tried to eliminate  
19 memantine from the market, really to the  
20 detriment of consumers, because they wouldn't  
21 have access to cheaper generics, and the  
22 allegations are that the revised formulation  
23 doesn't provide, you know, greater clinical  
24 benefits but will cost patients much more.  
25 So, you know, I can think of situations like

1           that where it's definitely not beneficial to  
2           the consumers, and people are, you know,  
3           getting into some trouble with the Government  
4           for doing it.

5                        On the other hand, I can think of  
6           situations where improvements in a  
7           formulation, I think like Effexor to Effexor  
8           XR would be a good example, where the initial  
9           multiple daily dosing didn't do all that well,  
10          but when they came out with a once daily  
11          formulation it did quite well and that made  
12          compliance better for patients on that  
13          molecule.

14       BY MR. DINER:

15                Q           And so that was a possible outcome of a  
16          life cycle management strategy?

17                A           It's an example. But again, it's a  
18          facts and circumstances-based thing.

19                Q           Do you have any other examples from  
20          your experience in where there were positive  
21          benefits flowing to the consumer from a life cycle  
22          management strategy?

23                A           Well, I mean, I haven't really  
24          inventoried in my head all of the life cycle  
25          management situations I've seen. I think on

1 balance, you know, most of what I've seen is that  
2 there's usually a cost to the patient, and what that  
3 means is life cycle management is often undertaken  
4 to stifle the availability of generics, and so that  
5 is generally to the detriment of consumers, to  
6 payors and everybody else. What you have to balance  
7 that with is, is there any real improvement from a  
8 clinical perspective in the later generation version  
9 of the product. And I think that, you know, it's  
10 usually not so black and white that on balance it's  
11 a benefit to the consumer or a detriment to the  
12 consumer. Usually there's factors going both ways.

13 Q And so there are examples going both  
14 ways as well where a life cycle management strategy  
15 has, in fact, brought benefits to the consuming  
16 public, correct?

17 A I mean, I think that -- you know, let  
18 me make clear, too, we're talking about just in  
19 generalities, the macro-economic role of life cycle  
20 management. We're not talking about how life cycle  
21 management plays a role with respect to the issue of  
22 nexus in a commercial success inquiry, but sure,  
23 there are situations where life cycle management can  
24 benefit the patient, but the primary actor  
25 implementing them is typically the brand company to

1 harvest value and maximize profits and evergreen  
2 franchises.

3 Q Well, there's nothing improper with a  
4 company making money where the products that they're  
5 offering to the public bring benefit to the  
6 consuming public, is there?

7 A I think that as a generality I don't  
8 quarrel with that, but there are plenty of  
9 situations where the very thing you described is --  
10 it can be in dispute, whether there's really  
11 benefits to society and whether the motive was  
12 really just to stifle generic competition and  
13 harvest value over what should be expired protection  
14 for various molecules.

15 Q Well, in your experience, what would be  
16 some of the benefits flowing to the consumer from a  
17 life cycle management strategy?

18 A I just -- I don't know that I can  
19 answer that in generalities. It really depends on  
20 the product. It depends on the life cycle  
21 management situation. So, okay, if there is an  
22 injectable that I have to go get to an office where  
23 they hook me up to an IV and you can convert that to  
24 an oral dosage form that I can take at home, that's  
25 an example that would be probably good because I

1 don't -- compliance would be easier.

2 Q Any other examples?

3 A I really haven't, you know, inventoried  
4 my brain on that right now.

5 Q Okay. Maybe I can help stimulate your  
6 brain on that for a moment.

7 MR. DINER: Let's mark the next  
8 exhibit. Maybe increase the inventory.

9 (Article - Too Many Drugs? The  
10 Clinical and Economic Value of Incremental  
11 Innovations, PROL0340351 - PROL0340392, was  
12 marked Hofmann-6 for identification.)

13 BY MR. DINER:

14 Q Mr. Hofmann, you've been handed Hofmann  
15 Exhibit 6, PROL0340351 through Bates number 0392.  
16 This document is entitled, Too Many Drugs? The  
17 Clinical and Economic Value of Incremental  
18 Innovations.

19 I'll start by asking if you've seen  
20 this document before.

21 A I have.

22 Q In what context?

23 A I think it's cited in the Jarosz  
24 report. I've probably seen it before in other  
25 cases.



1 Q Okay. In the title, it refers to  
2 incremental innovations.

3 Do you see that?

4 A Yes.

5 Q Have you heard of this phrase  
6 "incremental innovations" before?

7 A I don't know that I would -- I mean,  
8 I've certainly heard the words "incremental" and  
9 "innovations." I don't know that it's a frequently  
10 used term of art.

11 Q Have you heard it in the context of  
12 life cycle management?

13 A I think that brands will sometimes  
14 argue in defense of life cycle management that  
15 they're creating incremental innovations.

16 Q If they are creating incremental  
17 innovations that bring benefits to the consumer, is  
18 that a good or bad thing?

19 MS. FINK: Objection, calls for  
20 speculation or calls -- whatever.

21 THE WITNESS: It's too abstract. I  
22 mean, there can be -- there's a lot of  
23 embedded assumptions in there. I think,  
24 theoretically, certainly like I already said  
25 there are instances where it could be, but

1           there are plenty of instances where it would  
2           not be.

3 BY MR. DINER:

4           Q       Okay. Can you take a look at the  
5           second page of this document? It says page 78 at  
6           the top and it's Bates number PROL0340352.

7                    Are you there?

8           A       Uh-huh.

9           Q       You see the paragraph beginning with,  
10          Dismissal of new agents in a class?

11          A       I do.

12          Q       Okay. I'm going to read that into the  
13          record, okay? Dismissal of new agents in a class as  
14          merely me-too drugs is predicated on the belief that  
15          these agents are essentially identical. This is a  
16          misconception. The process of incremental  
17          innovation is evolutionally, not duplicative. The  
18          new agents resulting from this process can offer  
19          advantages in terms of improved efficacy, better  
20          patient satisfaction and compliance, and in some  
21          cases greater cost effectiveness.

22                    Now, did I read that accurately?

23          A       Those are the words that there are from  
24          the 16-year-old article, and I think it's directed  
25          to agents, new agents.

1 Q Right. And by "agent," are you  
2 thinking it's referring to a molecule?

3 A Yes.

4 Q Okay. It could also be referring to  
5 drug products in general, correct?

6 A I guess potentially.

7 Q Yeah. And in the last sentence that I  
8 read, it referred to certain advantages in terms of  
9 improved efficacy.

10 Do you see that?

11 A I see that.

12 Q Yeah. So a life cycle management  
13 strategy that brought improved efficacy to the new  
14 formulation, would that be a benefit to the  
15 consuming public?

16 MS. FINK: Objection, incomplete  
17 hypothetical.

18 THE WITNESS: You know, as an abstract  
19 hypothetical I think I'd need to understand.  
20 You know, sometimes when you say improved  
21 efficacy, there can be a dispute over whether  
22 there really is improved efficacy. If you're  
23 saying in your hypothetical you want me to  
24 assume that there's a head-to-head study that  
25 shows significant improvement with respect to

1 efficacy with no increase in side effects or  
2 reduction in side effects and isn't going to  
3 cost that much more, you know, building on all  
4 those abstract assumptions, sure, that sounds  
5 like a good thing.

6 BY MR. DINER:

7 Q Do you need all those abstract  
8 assumptions for something that has an improved  
9 efficacy profile to be considered a benefit to the  
10 consuming public?

11 A I think you need the facts and  
12 circumstances of a specific situation. Because a  
13 lot of times a follow-on product will come out.  
14 There are no head-to-head studies. There's a  
15 dispute over whether there's any improved efficacy.  
16 Just because you have improved efficacy, if it's on  
17 the heels of greater side effects or, you know,  
18 other issues or negative aspects of compliance,  
19 persistency, dosage form, I mean, there's just a lot  
20 of variables that would enter into the determination  
21 of kind of the -- it's just too overly simplistic to  
22 say one variable means this is a wonderful thing for  
23 society.

24 Q How about improved efficacy that  
25 manifested itself in being able to use a lesser

1 amount of a foreign active substance?

2 MS. FINK: Objection, incomplete  
3 hypothetical.

4 THE WITNESS: There again, I think, you  
5 know, it's going to be a facts and  
6 circumstances- based thing. You said active  
7 foreign substance. So off the top of my head,  
8 if I had an oncological product with a  
9 cytotoxic agent that it, you know, does bad  
10 things to your body, as well as tries to  
11 reduce tumors and cure cancer, it's good if  
12 you can reduce the concentration of those  
13 cytotoxic concentrations and still have  
14 improved efficacy.

15 On the other hand, if the API doesn't  
16 really do anything bad for you and, you know,  
17 passes through the body without any negative  
18 implications or, you know, the tweak in the  
19 concentration is so minor that it has no real  
20 ramifications, then, no, it doesn't matter if  
21 you can do something with a reduced  
22 concentration.

23 BY MR. DINER:

24 Q Isn't it generally a good thing to  
25 reduce the amount of a foreign substance that you're

1 putting into one's body as part of a pharmaceutical

2 --

3 MS. FINK: Objection.

4 BY MR. DINER:

5 Q -- and still get the same level of a  
6 clinical efficacy with an older product that had  
7 more of the active ingredient?

8 MS. FINK: Objection, beyond the scope  
9 of his expert report, calls for speculation.

10 THE WITNESS: Yeah, I'm definitely not  
11 a formulation expert, but I have seen and read  
12 as a non-expert in this that, you know, one  
13 aspect of formulation optimization is the --  
14 you use the least amount that's still  
15 therapeutically effective.

16 BY MR. DINER:

17 Q How about improving the formulation  
18 such that you get better patient compliance, is that  
19 a benefit that -- to the consuming public in the  
20 changed formulation?

21 MS. FINK: Objection, incomplete  
22 hypothetical.

23 THE WITNESS: It would be a facts and  
24 circumstances-based thing. I've seen some  
25 situations where again, you know, and I think

1           there's some examples in what the examples in  
2           Jarosz report talks to, where missing a dose  
3           doesn't really matter for certain chronic  
4           conditions and whatnot. So improved  
5           compliance can be a meaningless, you know,  
6           thing. There are other situations like my  
7           example going from an injectable to an oral  
8           dosage form where you could see that that  
9           would improve. On the other hand, if it's  
10          a -- you know, I have terminal cancer and I  
11          have to get other injections in me, getting  
12          one more injection that is now a pill doesn't  
13          necessarily help. So it depends. On the  
14          other hand, you know, there can be situations  
15          where compliance is important and meaningful  
16          improvement and compliance can be a benefit.

17       BY MR. DINER:

18           Q           And with elderly patients such as, say,  
19           elderly patients who have had cataract surgery,  
20           would a patient compliance with a new formulation or  
21           improved patient compliance with a new formulation  
22           be a benefit to that group of consumers?

23                   MS. FINK: Objection, beyond the scope  
24           of his expert report.

25                   THE WITNESS: So I'm not a technical

1 expert. I'm not a medical doctor. I don't  
2 know that I am the right person to weigh in on  
3 that.

4 BY MR. DINER:

5 Q In paragraph 75 of your report you have  
6 indicated that going from a twice daily dose to a  
7 once daily dose is a benefit to patient compliance.  
8 Is that right?

9 A That's right.

10 Q You can put this aside. Now,  
11 mr. Hofmann, given your focus on the economic  
12 implications with regard to pharmaceutical products,  
13 have you ever heard the term "stability" in the  
14 context of your work and experience?

15 A Sure.

16 Q What's your understanding of that?

17 A I mean, stability in general is how  
18 well a pharmaceutical dosage form maintains the  
19 level of active ingredient over a period of time  
20 without degradation and what conditions by which --  
21 again, as a non-technical expert, you know, and what  
22 conditions under which the product must be stored to  
23 maintain those, and then there are stability studies  
24 that are done to figure out how long a particular  
25 dosage form maintains those aspects.



1 Q Okay. If a new drug improved the  
2 stability of the old drug formulation, would that be  
3 a benefit?

4 MS. FINK: Objection, calls for  
5 speculation.

6 THE WITNESS: Yeah, it depends. I  
7 think, you know, just to run -- since this is  
8 an abstract hypothetical like, you know, some  
9 drugs are very expensive. I've worked on  
10 oncological cases where the oncology group  
11 doesn't even keep more than a month's worth or  
12 a few weeks of inventory because the drugs are  
13 so expensive. Long term, two-year stability  
14 doesn't matter as much because they're really  
15 not maintaining much at the office. Of course  
16 there's supply chain before that, too. But,  
17 you know, a lot of oncological products don't  
18 have two-year stability. There are other  
19 situations where, you know, it would be good  
20 if you could enhance stability and/or allow  
21 storage without refrigeration or different  
22 aspects that make it easier to have a product  
23 get through the supply chain and get to the  
24 patient. There can also be meaningless  
25 improvements in stability if, you know, one

1 goes from a two-year stability to a five-year  
2 stability. That probably isn't really going  
3 to matter that much based on how much the  
4 supply chain typically maintains, depending on  
5 the facts and circumstances.

6 BY MR. DINER:

7 Q And how about drawing down on that a  
8 little bit more with regard to degradation. If a  
9 new formulation lessened the degradation of an  
10 active ingredient used in the old formulation could  
11 that be a benefit to the consumer?

12 MS. FINK: Objection, beyond the scope  
13 of his expert report, calls for speculation.

14 THE WITNESS: Yeah. Here again as a  
15 non-technical expert it would depend on the  
16 facts and circumstances. You know, if a  
17 molecule in its dosage form degrades rapidly  
18 such that it hinders efficacy and that has  
19 implications to the duration that is  
20 maintained in the supply chain, an improvement  
21 in that could be a good thing. Or, you know,  
22 I think, to some degree, all pharmaceutical  
23 products have some degradation built into  
24 them. The degree of degradation improvement  
25 would be something I would want to consider.

1           It would be a facts and circumstances-based  
2           thing.

3 BY MR. DINER:

4           Q           How about if the new formulation  
5 improved the adverse event profile of the old  
6 formulation, could that be a benefit to the  
7 consumer?

8                       MS. FINK: Objection, beyond the scope  
9 of his expert report, incomplete hypothetical,  
10 calls for speculation.

11                      THE WITNESS: I would defer to  
12 technical experts on that, and it would also  
13 depend on the particular adverse events, the  
14 severity of them, whether the decrease in one  
15 adverse event gave rise to the other adverse  
16 events that make it a wash. It really depends  
17 on the situation.

18 BY MR. DINER:

19           Q           But it could, under the right  
20 circumstances, right?

21                      MS. FINK: Same objections.

22                      THE WITNESS: I mean, I can imagine  
23 abstract hypotheticals going back to, you  
24 know, oncological agent. If you could figure  
25 out a way to reduce the negative side effects

1           that come with a chemo therapeutic agent in a  
2           way, but still have enhanced efficacy, that  
3           surface-level abstract seems like a good  
4           thing.

5 BY MR. DINER:

6           Q           And how about for ophthalmics where  
7           you're putting eye drops into sensitive eye tissue?

8           A           There again, I would defer to the  
9           technical experts. I think that, you know, there  
10          are certain side effects that, as I understand it,  
11          come with all NSAIDs. The degree of those different  
12          side effects and the real clinical implication of  
13          them I would just defer to the technical experts. I  
14          should say the real clinical information, if any.

15          Q           But there may be some indeed, correct?

16          A           I defer to the technical experts.

17                   MR. DINER: So we're actually at a good  
18          breaking point for lunch. I know it's a  
19          little bit less than an hour, but in my notes  
20          it would be a good point to break, if that  
21          works for you guys.

22                   MS. FINK: Sure. That's fine.

23                   VIDEO OPERATOR: We're now going off  
24          the record, at approximately 12:26 p.m.

25                   (Lunch recess.)

1 VIDEO OPERATOR: We are now going back  
2 on the record approximately 1:10 p.m.

3 This is the beginning of file three.

4 BY MR. DINER:

5 Q Okay. Mr. Hofmann, before the break,  
6 do you recall that we were discussing certain  
7 scenarios in which there could be benefits from a  
8 life cycle management strategy that could benefit  
9 the consumer?

10 A I think we were talking about a variety  
11 of things, many of which did not involve benefits,  
12 but yeah, some hypotheticals.

13 Q But some hypotheticals that we spoke  
14 about that could have derived from a life cycle  
15 management strategy could have brought benefits to  
16 the consumer?

17 MS. FINK: Objection to the extent it  
18 misstates testimony.

19 THE WITNESS: Yeah, it was a pretty  
20 long back and forth. I think there were a lot  
21 of abstract hypotheticals. Some of which I  
22 agreed there could theoretically be some  
23 benefits.

24 BY MR. DINER:

25 Q Okay. Can you turn to paragraph 60 of

1 your opinion -- of your expert report, please?

2 A What page or paragraph?

3 Q Paragraph 60, page 31.

4 A Okay.

5 Q Now, in paragraph 60 you have three  
6 quotes with three -- associated with three separate  
7 bullet points.

8 Do you see that?

9 A Yes.

10 Q I would like to focus on the first  
11 bullet point in the first quote. Would you do me a  
12 favor, please, and read that first quote into the  
13 record?

14 A It's like why we really like  
15 ophthalmology because they tend to be topical  
16 products that through better formulations you can  
17 generate without -- with basically the same active  
18 ingredient extend patent lives and it's really key  
19 to our strategy.

20 Q Okay. Is this a statement being made,  
21 in your view, by someone from Valeant?

22 A Yes.

23 Q Now, I see that you highlighted a  
24 portion of that quote, bolded it. The portion that  
25 is, or says, with basically the same active

1 ingredients extend patent lives.

2 Do you see that?

3 A Yeah, ingredients isn't plural, but  
4 other than that, you read it correctly.

5 Q Oh, thank you. You didn't highlight,  
6 however, in this quote the phrase "through better  
7 formulations," correct?

8 A No, I didn't.

9 Q Okay. And as we were speaking before,  
10 there could be certain better formulations that have  
11 benefits over prior formulations, correct?

12 MS. FINK: Objection, misstates prior  
13 testimony.

14 THE WITNESS: Yeah, I mean, I think,  
15 like I said, it is a multifaceted facts and  
16 circumstances situation where even if  
17 technically a better formulation exists the  
18 benefit could be so trivial that it doesn't  
19 justify the cost. But it's possible.

20 BY MR. DINER:

21 Q But then there could be better  
22 formulations that actually do bring benefits to the  
23 consumer -- consuming public, correct?

24 MS. FINK: Objection, calls for  
25 speculation, beyond the scope of his expert

1 report.

2 THE WITNESS: I thought we spent a lot  
3 of time on this already. I mean, it's  
4 theoretically possible, but there's lots of  
5 situations where that's not the case.

6 BY MR. DINER:

7 Q So as indicated in this bullet point  
8 and in the quotation that you've provided, Valeant  
9 is saying here that they want to bring better  
10 formulations to the consuming public, correct?

11 MS. FINK: Objection to the extent it  
12 misstates the quote, and the document speaks  
13 for itself.

14 THE WITNESS: I mean, it's a subjective  
15 term that this person has said what they've  
16 said. This is directed generally to  
17 ophthalmology that they believe that they can  
18 use the same active ingredient to extend  
19 patent lives. And this comes, I think, two  
20 days after they acquired Bausch + Lomb, but  
21 yeah, those are the words that they chose --  
22 this individual chose.

23 BY MR. DINER:

24 Q Right. And the better formulations  
25 could be the type of formulations that bring



1 benefits to the consuming public as part of a life  
2 cycle management strategy, right?

3 MS. FINK: Objection, calls for  
4 speculation.

5 THE WITNESS: Yeah, I mean, I don't  
6 know how fair picking three words out of this  
7 and generalizing about everything. I think  
8 this section, in this particular subsection,  
9 is just talking about the life cycle  
10 management strategy as part of their strategy.  
11 I think that there's a lot of people that  
12 question whether Valeant -- Valeant's life  
13 cycle management do result in better  
14 formulations, but certainly that's what this  
15 individual is characterizing them as in this  
16 quote.

17 BY MR. DINER:

18 Q Let's turn to paragraph 70 of your  
19 report, page 35.

20 A Okay.

21 Q Now, you state in the middle of that  
22 paragraph, I understand that no discernible  
23 differences -- strike that. I'll start again.

24 I understand that no discernible  
25 difference exists between the efficacy and safety

1 profile of Prolensa and Bromday.

2 Do you see that statement in the middle  
3 of paragraph 70?

4 A Yes.

5 Q You provide no citation for your  
6 understanding in that regard, do you?

7 A Right. That falls in the category of  
8 what I mentioned earlier, that I had an  
9 understanding of what Dr. Cykiert was planning on  
10 saying in his report, what his opinions were. And I  
11 have since, you know, gotten a copy of that report,  
12 and it's consistent. So if I had the report I would  
13 have cited to it. At the time, I didn't, so I  
14 characterized it as an understanding that I had.

15 Q And that understanding you derived  
16 indirectly from Dr. Cykiert, but directly from the  
17 attorneys for Lupin and Innopharma, correct?

18 A I think the way I described it is, I  
19 asked them for this point, is there a medical doctor  
20 that has opinions on this, and they said, yes, there  
21 is. And they explained to me what his opinions are,  
22 so yes, it was sourced directly to me from counsel,  
23 but I understood that they were Dr. Cykiert's  
24 opinions.

25 Q And did you speak with any other

1 doctors with regard to the import of your statement  
2 that we just read into the record?

3 A I did not.

4 Q In that same paragraph you make a  
5 similar statement of your understanding. I'll read  
6 it. It says, I understand that any purported  
7 reduction in side effects of stinging and burning  
8 with Prolensa is minimal or non-existent.

9 Do you see that?

10 A Yeah. That's not the entire sentence,  
11 but that's the -- that's a clause within that  
12 sentence, yes.

13 Q And once again, you were provided the  
14 basis for that understanding through counsel from  
15 Dr. Cykiert?

16 A In the manner that I expressed before,  
17 that I asked whether there was a medical doctor that  
18 had opinions on this, and I was told by counsel that  
19 Dr. Cykiert did.

20 Q Okay. And again, you didn't speak with  
21 any other doctors to inform yourself about your  
22 understanding as you've expressed it here, have you?

23 A I did not speak to any other doctors,  
24 no.

25 Q And would that be the case for any of

1 the efficacy, safety type of issues, it would have  
2 only have come from Dr. Cykiert?

3 A I relied on the understandings of the  
4 opinions of Dr. Cykiert and Dr. Prausnitz.

5 Q Okay. Were you informed, Mr. Hofmann,  
6 that Bromday and Prolensa contain different  
7 surfactants?

8 A Yes.

9 Q Were you informed, or did you know that  
10 Bromday contains polysorbate 80 as its surfactant?

11 A Yes.

12 Q I probably should ask it differently.  
13 Did you know that polysorbate 80 was  
14 the surfactant in Bromday?

15 A Yes.

16 Q Okay. Did you know that tyloxapol was  
17 the surfactant or is the surfactant in Prolensa?

18 A Yes.

19 Q Were you informed that Tyloxapol  
20 stabilizes bromfenac better than polysorbate 80?

21 MS. FINK: So I just want to -- we're,  
22 talking about information that you got through  
23 counsel. So if you fell that we're getting  
24 anyplace where you might think that there's  
25 some privileged information we could talk

1 about that off the record, if we need to.

2 THE WITNESS: Can you repeat the  
3 question, or have it read back?

4 BY MR. DINER:

5 Q Sure. Were you informed that tyloxapol  
6 stabilizes bromfenac better than polysorbate 80?

7 A That sounds like a question really for  
8 technical experts, and I would -- I would defer to  
9 them. I mean, I know there's disputes among the  
10 technical experts on what alleged benefits, if any,  
11 are provided by Tyloxapol in the formulation, but I  
12 would defer to the experts.

13 Q Okay. So you don't really have an  
14 opinion one way or the other about the stabilizing  
15 effect of Tyloxapol with regard to the active  
16 ingredient bromfenac; is that right?

17 A I certainly don't have any technical  
18 opinion. I would defer to the technical experts on  
19 that.

20 Q Is it your understanding that tyloxapol  
21 is an element of the claims of the patents-in-suit?

22 A Yes.

23 Q And that it's an element, along with  
24 bromfenac, in the claims of the patents-in-suit?

25 A Yeah. My understanding is that it's a

1 claimed formulation of the distinction, or the  
2 reason I paused there is I understand that bromfenac  
3 is not claimed as a novel molecule in the  
4 patent-in-suit but it claims a formulation that  
5 includes bromfenac and Tyloxapol.

6 Q And are you also informed that some of  
7 the claims of the patents-in-suit call for a stable  
8 aqueous pharmaceutical preparation that would  
9 comprise bromfenac and Tyloxapol?

10 A Again, as far as the scope of the patent  
11 claims and any implications thereof, I would defer  
12 to the technical experts, but I generally have that  
13 understanding.

14 Q Okay. And you generally have the  
15 understanding that tyloxapol is a claimed element  
16 and that stable is also a claimed element, correct?

17 A Again, I would defer to technical  
18 experts on the scope of the claims, but I do have  
19 that general understanding that those are aspects  
20 claimed.

21 Q Okay. Has anyone informed you that  
22 Defendant's expert provided sworn testimony that  
23 Tyloxapol stabilizes bromfenac better than  
24 polysorbate 80?

25 A I don't remember that particular

1 passage one way or the other. I don't remember that  
2 being in the reports that I reviewed.

3 Q Okay. Did you know that the pH of  
4 Prolensa is 7.8?

5 MS. FINK: Objection. To the extent  
6 that it misstates the facts about Prolensa.

7 THE WITNESS: I would again defer to  
8 the other technical experts on that. It is my  
9 understanding that the pH is around 7.8. I  
10 thought that there were specs that had a  
11 range, but again I would defer to the  
12 technical experts on that.

13 BY MR. DINER:

14 Q Do you know what the pH of natural  
15 tears is?

16 MS. FINK: Objection, beyond the scope  
17 of his expert report.

18 THE WITNESS: Off the top of my head, I  
19 didn't commit that to memory. I know I've  
20 seen it in some documents in reviewing this  
21 case, but I don't have the particular number  
22 in my head.

23 BY MR. DINER:

24 Q Mr. Hofmann, were you informed that  
25 tyloxapol's ability to stabilize bromfenac better

1 than polysorbate 80 permitted reducing the pH from  
2 8.3 in Bromday to 7.8 in Prolensa?

3 MS. FINK: Objection, assumes facts not  
4 in evidence, beyond the scope of his expert  
5 report, speculation.

6 THE WITNESS: I would defer to the  
7 technical experts on that.

8 BY MR. DINER:

9 Q So you have no opinion on that one way  
10 or another?

11 A Certainly I have no technical opinion  
12 at all.

13 Q Any other opinion?

14 A Not as you've asked it. That would be  
15 more of a technical issue.

16 Q Okay. Did you take that into account  
17 when considering your opinions in your report?

18 A I took into account the clinical and  
19 formulation opinions that I reviewed in the  
20 technical expert reports where I needed an  
21 understanding from them. I understand that there  
22 are certain things in dispute and the role of pH was  
23 something that I considered in the review of the  
24 documents and my review of nexus.

25 Q And how about your -- how about the



1 role of Tyloxapol's stabilizing ability with regard  
2 to bromfenac, did you take that into a account as  
3 part of your opinions in this matter?

4 MS. FINK: Objection, assumes facts not  
5 in evidence.

6 THE WITNESS: I guess part of where I'm  
7 getting a little hesitant on your question is  
8 I certainly considered in looking at all the  
9 materials that I saw and what motivates  
10 prescribing behavior whether the particular  
11 surfactant appeared anywhere in the materials  
12 that I saw with respect to motivating  
13 prescribing behavior. And I didn't see  
14 anything. So it was considered in that, you  
15 know, I did affirmatively look for whether  
16 those types of things seemed to play a role,  
17 and I didn't see any evidence that they did.

18 MR. DINER: I'd like to mark the next  
19 exhibit, please.

20 (Cataract Discussion Groups (CDGs),  
21 PROL0280867 - PROL0280893, was marked  
22 Hofmann-7 for identification.)

23 MR. DINER: Is this number 7?

24 MS. FINK: Yes.

25 BY MR. DINER:

1           Q           Okay. Mr. Hofmann, the court reporter  
2           has just handed you a document that is marked with  
3           Bates numbers PROL0280867 through 893. We're going  
4           to page through this document, and you may find it  
5           easier to page through I think if you bring the  
6           pages into it based on the way it's stapled. Is  
7           that helpful?

8           A           Yes, thank you.

9           Q           I figured. I was doing that the other  
10          day, so...

11                        Okay. Now, have you seen this document  
12          before?

13          A           Yes, I have.

14          Q           And you rely on it in your expert  
15          report, correct?

16          A           Yeah, it's part of the information I  
17          considered, and I think I cite to it.

18          Q           Yes, you do.

19                        Now, a moment ago we were talking about  
20          the differences in pH as between Bromday and  
21          bromfenac.

22                        Do you recall that?

23          A           Yes.

24          Q           And I also asked you a question if you  
25          knew what the pH of natural tears was.

1 Do you recall that?

2 A Yes.

3 Q Okay. I'd like for you to flip to,  
4 it's going to be, I guess it's going to be page 13.  
5 So it will have the Bates numbers at the bottom,  
6 879.

7 Let me know when you're ready.

8 A Yep.

9 Q Okay. This slide is entitled, Designed  
10 for Comfort and Convenience, right?

11 A Yes.

12 Q And this slide is discussing two  
13 products, correct?

14 A Yes.

15 Q Bromfenac and Prolensa, right?

16 A That's correct.

17 Q And -- I'm sorry to make you turn back  
18 to the beginning of this document again, but if you  
19 look, say, to page 3 in the document, is it fair to  
20 say that the slides that we are looking at in this  
21 document marked as Exhibit 7 is talking about and  
22 promoting Prolensa?

23 A I think you have to be careful. It's  
24 certainly talking about Prolensa, but this is an  
25 internal Bausch & Lomb document. I don't think that

1 there's anything on label, at least about any  
2 incremental benefit of comfort of Prolensa over any  
3 other product.

4 Q Okay. On the page that we were on,  
5 which is page 13, Bates number ending in 879 of  
6 Exhibit 7, can you read the title into the record  
7 for me, please?

8 A Designed for Comfort and Convenience.

9 Q Okay. And would you agree that what  
10 they're talking about in this slide is that Prolensa  
11 was designed for comfort and convenience?

12 MS. FINK: Objection, the document  
13 speaks for itself.

14 THE WITNESS: I mean, this is a, I  
15 think, Prolensa-focused document. But I think  
16 as far as design and formulation those are  
17 really technical issues.

18 BY MR. DINER:

19 Q Okay. Did you consider comfort as one  
20 of the benefits that may have come from the use of  
21 tyloxapol in Prolensa?

22 MS. FINK: Objection, calls for  
23 speculation.

24 THE WITNESS: I mean, this would fall  
25 in the category of where I relied on technical

1 experts. I think Dr. Cykiert addresses, you  
2 know, his opinion on whether there's any  
3 incremental benefit or comfort associated with  
4 the Prolensa formulation versus the Bromday  
5 formulation.

6 BY MR. DINER:

7 Q You criticize ice in your report  
8 Mr. Jarosz for referring to comfort, but not having  
9 mentioned that -- or not having seen anything about  
10 the product advertising its comfort, correct?

11 A Relative to any other product, that's  
12 right.

13 Q Okay. So let's go back to page 13.  
14 Bromday is indicated as having a pH of 8.3, right?

15 A According to this slide.

16 Q And the pH of natural tears is  
17 indicated to be at 7.4, right?

18 A According to this slide.

19 MS. FINK: I'll just say it doesn't say  
20 "natural tears," it says "tear fluid."

21 BY MR. DINER:

22 Q Okay, fine. Tear fluid is indicated at  
23 being at a pH of 7.4?

24 A That's what it appears here.

25 Q Now you just wiped your eye. Did you

1 get any tears fluid? Would you like to check the  
2 pH?

3 A I wouldn't know where to begin.

4 Q Okay. And Prolensa is indicated as  
5 having a pH of 7.8, correct?

6 A According to this.

7 Q And 7.8, in terms of the pH, would be  
8 closer to 7.4 than 8.3; is that correct?

9 A I mean, mathematically, sure.

10 Q Okay. And logically, if the pH of  
11 Prolensa being at 7.8 is closer to tear fluid at  
12 7.4, one would consider that to be something that  
13 would be designed to give greater comfort than  
14 Bromday at a pH of 8.3, correct?

15 MS. FINK: Objection, calls for  
16 speculation, beyond the scope of his expert  
17 report, assumes facts not in evidence.

18 THE WITNESS: Yeah. I'm not a  
19 technical expert, nor would I know enough to  
20 have an opinion on that, you know, whether  
21 this change in -- or claimed change in pH  
22 would have any meaningful impact. I did see  
23 that in Dr. Cykiert's view, you know, there  
24 really isn't any meaningful change in comfort  
25 or convenience relative to the various

1           insights he discussed.

2       BY MR. DINER:

3           Q           But you didn't consider comfort that  
4       may have been imparted by Prolensa to the eye drop  
5       as part of the aspects that would be tied to the  
6       merits of the claimed invention?

7                       MS. FINK:  Objection, mischaracterizes  
8       testimony.

9       BY MR. DINER:

10          Q           Is that correct?

11          A           I'm not sure I understood the question.

12          Q           Did you consider the aspect of comfort  
13       that this slide of the document you relied on, in  
14       referring to Prolensa, did you consider that as part  
15       of your opinions in the benefits that may have  
16       derived from what you called a life cycle management  
17       strategy?

18          A           I certainly considered this document  
19       but I didn't consider this one slide and this  
20       document alone and in a vacuum.  I looked at this  
21       document, as well as other documents, as well as the  
22       opinions of Dr. Cykiert, as well as the testimony of  
23       Miss Valerie, who explained that there is really no  
24       ability to claim any amount of comfort of Prolensa  
25       over Bromday.  And in the opinion of Dr. Cykiert,

1 there really was no difference in comfort or side  
2 effects or stinging or burning of Prolensa versus  
3 others. So I considered this, but I considered it  
4 in the context of numerous other pieces of evidence,  
5 and I think I also cite to another document that Dr.  
6 Cykiert, I think, also addresses that, you know,  
7 talks about in some ways while there may be alleged  
8 improvements on certain side effects, there are  
9 other side effects that go the other way, and on  
10 balance, you know, it kind of -- it doesn't have any  
11 meaningful difference.

12 Q So were you informed that lowering the  
13 pH of an ophthalmic formulation would increase the  
14 ocular penetration of the active ingredient?

15 A I understood that that's what the  
16 Plaintiff's experts say in their reports, and I  
17 understand that, you know, there's views on that.  
18 So it's something I was aware of.

19 Q Did you obtain any information through  
20 Dr. Prausnitz with regard to the ability of a lower  
21 pH to increase the ocular penetration of an active  
22 ingredient?

23 MS. FINK: Objection, assumes facts not  
24 in evidence.

25 THE WITNESS: I mean, I don't know that



1 I -- as we talked about before, I didn't talk  
2 directly to Mr. Prausnitz. I don't recall a  
3 specific -- that seems like more of a  
4 technical issue.

5 BY MR. DINER:

6 Q But you sourced your knowledge in some  
7 respects --

8 A Right.

9 Q -- from Dr. Prausnitz, correct?

10 A Correct.

11 Q And did the attorneys who were the  
12 in-between between you and Dr. Prausnitz initially  
13 discuss or inform you about lowering the pH of an  
14 ophthalmic formulation could increase its ocular  
15 penetration?

16 MS. FINK: Objection, assumes facts not  
17 in evidence.

18 THE WITNESS: I remember reading that.  
19 It's a technical issue. I don't remember the  
20 specifics back and forth on that, as I sit  
21 here right now.

22 BY MR. DINER:

23 Q Where do you remember reading that?

24 A I thought it was in one of the  
25 Plaintiff's experts' reports. But I read a lot of

1 stuff. It could be that I'm --

2 Q You've since signing your report  
3 reviewed Dr. Prausnitz's report?

4 A Correct.

5 Q Did you read in Dr. Prausnitz's report  
6 that he had said that?

7 A I can't remember one way or another as  
8 I sit here right now, one way or the other.

9 Q Well, I'll represent to you that Dr.  
10 Prausnitz did indeed say that lowering the pH of an  
11 ophthalmic formulation could increase the ocular  
12 penetration of the active ingredient, a formulation  
13 in this case bromfenac.

14 MS. FINK: Objection.

15 BY MR. DINER:

16 Q Would you accept that representation?

17 A Sure. I guess the implication of that  
18 representation is true, you know, where would that  
19 matter, it would be whether it has a clinical  
20 impact, and, you know, that's where I relied on Dr.  
21 Cykiert, that there really isn't any difference in  
22 the side effect profile, and then Miss Valerie's  
23 testimony that they can't really make any claims  
24 with respect to this anyhow.

25 MS. FINK: And I'm just going to lodge

1 my objection that that was misstating the  
2 expert report of Dr. Prausnitz.

3 BY MR. DINER:

4 Q I think you're aware that Bromday  
5 contains 0.09 percent bromfenac, right?

6 A I am.

7 Q And similarly you're aware that  
8 Prolensa contains 0.07 percent bromfenac, correct?

9 A Correct.

10 Q You can put that aside for now. Or I  
11 guess you're looking at Exhibit 7.

12 MR. DINER: I'll mark the next exhibit  
13 Exhibit 8, please.

14 (Clinical Ophthalmology - The ocular  
15 distribution of C-labeled bromfenac ophthalmic  
16 solution 0.07% in a rabbit model, PROL008055 -  
17 PROL0080512, was marked Hofmann-8 for  
18 identification.)

19 BY MR. DINER:

20 Q Mr. Hofmann, the court reporter just  
21 handed you what has been marked as PROL0080505  
22 through 512.

23 Have you seen this document before?

24 A I feel like I saw some reference to  
25 this, and I can't remember if I saw the actual

1 article, but I know there's reference to this in  
2 some of the technical expert reports.

3 Q Okay. Are you okay?

4 A Oh, yeah. Maybe not.

5 MS. FINK: Do you need to take a break?

6 THE WITNESS: No, I'm okay.

7 BY MR. DINER:

8 Q Okay. This document marked as Exhibit  
9 8 is entitled, The ocular distribution of  
10 carbon-14-labeled bromfenac ophthalmic 0.07% in a  
11 rabbit model.

12 I'd like to refer you, please,  
13 Mr. Hofmann, to the second page of this document,  
14 the left-hand column. And within the first full  
15 paragraph -- probably the last two or three  
16 sentences you'll see "in order to lower."

17 Do you see that there?

18 A Yes, I see that.

19 Q Okay. So it says, In order to lower  
20 the concentration, yet maintain the same degree of  
21 ocular penetration, the pH of the formulation was  
22 reduced from 8.3 (Bromday) to 7.8 (Prolensa).  
23 Bromfenac, like most NSAIDs is a weakly acidic drug.  
24 Decreasing the pH of the formulation increases the  
25 unitized fraction of the drug, which in turn

1 enhances ocular penetration.

2 Do you see that passage there?

3 A Yes.

4 MS. FINK: I'll just -- Mr. Hofmann, if  
5 you need to read more of this article to get  
6 context, you should do that.

7 BY MR. DINER:

8 Q Does this passage inform you,  
9 Mr. Hofmann, that decreasing the pH of 8.3, as it  
10 was in Bromday, to 7.8, as it is in Prolensa,  
11 enhanced or increased the ocular penetration of the  
12 active ingredient bromfenac?

13 MS. FINK: Objection, beyond the scope  
14 of his expert report, speculation.

15 THE WITNESS: That's really a technical  
16 question that isn't -- I would defer to  
17 technical experts on that.

18 BY MR. DINER:

19 Q And is it your understanding that  
20 decreasing the -- strike that.

21 Is it your understanding that  
22 decreasing the concentration of bromfenac from 0.09  
23 to 0.7 while lowering the pH effectively resulted in  
24 the same clinical efficacy for the two  
25 pharmaceutical products?

1 MS. FINK: Objection, beyond the scope  
2 of his expert report, calls for speculation.

3 THE WITNESS: That's really a technical  
4 question for someone other than me.

5 BY MR. DINER:

6 Q And did you consider that issue in  
7 rendering your opinions in this case?

8 A I considered what I saw in what Bausch  
9 + Lomb has been able to use in promoting the product  
10 and what motivates prescribing behavior. I  
11 considered the clinical implication, if any, of some  
12 of the technical claims that you're asking me about  
13 in the form of, you know, some of the -- what are  
14 the implications of this, if any. And in my review  
15 of the record, it's all -- it's all things I  
16 considered and that there were other extrinsic  
17 factors, as I explained in my report, that really  
18 explain the commercial performance of Prolensa.

19 Q But these changes that we're speaking  
20 about now in formulation, such as pH and the  
21 concentration, was it your understanding from either  
22 Dr. Prausnitz or Dr. Cykiert that they have no  
23 benefit, clinically speaking?

24 A I mean, I don't think in one sentence I  
25 can characterize the opinions of those individuals.

1 I think they explain their opinions in their  
2 reports.

3 Q And what does your understanding of  
4 what effect, if any, lowering the pH of the  
5 formulation from 8.3 in Bromday to 7.8 in Prolensa  
6 had on, for example, ocular penetration?

7 MS. FINK: Objection, beyond the scope  
8 of his expert report.

9 THE WITNESS: I mean, from a technical  
10 perspective, I don't know -- I mean, I don't  
11 have an opinion from a technical perspective.  
12 What is coming into my head is the, you know,  
13 the claims, as I understand them, in terms of  
14 what the Prolensa formulation offers is, you  
15 know, similar efficacy to Bromday, and  
16 according to Dr. Cykiert, you know, no  
17 meaningful change in the instances of the side  
18 effects, and from what I understand from  
19 Miss Valerie, no real ability to claim any  
20 implication of claimed -- increased ocular  
21 penetration or modified pH as having a benefit  
22 over the prior embodiment.

23 BY MR. DINER:

24 Q And so that was your understanding that  
25 you took into account when rendering your opinions

1 in this matter, correct?

2 A I think my opinions are explained in my  
3 lengthy report. I considered these factors as well  
4 as all the other factors. And as I explain in my  
5 report, many other factors unrelated to the claims  
6 of the patent are what explain the sales of  
7 Prolensa.

8 Q And in paragraph 70 of your report  
9 where you say, I understand that no discernible  
10 difference exist between efficacy and safety profile  
11 of Prolensa and Bromday, that is what you relied on,  
12 in part, rendering your opinions in this matter,  
13 correct?

14 A When you say, I relied on, I mean,  
15 that's me explaining that I obtained that that's the  
16 understanding or that's the opinion of technical  
17 experts on which I'm relying.

18 Q Okay. And if the technical experts are  
19 proven to be wrong, that there are differences that  
20 do impact efficacy and safety profile of Prolensa  
21 and Bromday, would that impact your opinions?

22 MS. FINK: Objection, calls for  
23 speculation, incomplete hypothetical.

24 THE WITNESS: I mean, as I understand  
25 it, that's a counter-factual hypothetical. My



1           initial reaction is there's such overwhelming  
2           evidence of extrinsic factors other than the  
3           purported claims of the patent here that  
4           explain the performance that I don't think it  
5           would change my opinions, and I don't think  
6           from what I've seen they've been able to  
7           promote any of these purported improvements  
8           that you're asking me to counter-factually  
9           assume.

10       BY MR. DINER:

11           Q           Well, we started off today's discussion  
12           with your understanding of the law concerning  
13           commercial success.

14                        Do you remember that?

15           A           Yes.

16           Q           And I quoted you from your opinion  
17           saying that that commercial success is driven  
18           primarily by and attributable to the purported  
19           merits of the claimed invention, correct? Is it  
20           your opinion that these do not constitute purported  
21           merits of the claimed invention?

22           A           When you say "these," what are these?

23           Q           Sorry. The improved ocular  
24           penetration, for example, of Prolensa compared to  
25           Bromday. Does that not constitute a merit of the

1 claimed invention?

2 A I think we're missing each other. I  
3 mean, I've assumed for the purposes of my report  
4 that Prolensa is an embodiment of the patent.  
5 Whether there are technical disputes on that, you  
6 know, I don't -- I don't quarrel with. That's not  
7 my fight.

8 Q I understand that. I'm just trying to  
9 understand the scope of your opinion. So we've  
10 established factually that Prolensa has a lower pH  
11 than Bromday, correct?

12 A I think I deferred to technical experts  
13 on that. We looked at a slide in a PowerPoint that  
14 seemed to indicate that.

15 Q And that was a slide in a PowerPoint  
16 that you relied on in your opinion?

17 A Correct.

18 Q And I represented to you that the pH  
19 could have an effect of improving ocular  
20 penetration, right?

21 A Sure.

22 MS. FINK: Objection, assumes facts not  
23 in evidence.

24 BY MR. DINER:

25 Q And I also represented to you that the

1 pH closer to natural tears would make it more  
2 comfortable as an eye drop, correct?

3 MS. FINK: Objection, assumes facts not  
4 in evidence.

5 THE WITNESS: Well, you've said that.  
6 I think that, as I explained, I deferred to  
7 technical experts and then I looked at, you  
8 know, whether there's any ability to make  
9 those claims in any of the materials, and I  
10 didn't see anything. I guess.

11 BY MR. DINER:

12 Q But my question to you is: If these  
13 benefits are tied to the merits of the claimed  
14 invention, are those something that you could or  
15 should have considered, in part, with regard to the  
16 opinions that you've rendered in this report?

17 MS. FINK: Objection, vague, calls for  
18 speculation, incomplete hypothetical.

19 THE WITNESS: I mean, I think -- I  
20 think about it in two ways. I've considered,  
21 as I've explained, the understandings I had  
22 from technical experts with respect to these  
23 issues. I've also considered what role, if  
24 any, the purported claims of the patent or  
25 aspects that are claimed had any commercial

1           implication to the commercial performance of  
2           Prolensa, and I didn't see any evidence of  
3           that. What I saw was evidence of all the  
4           different things that I explain in the report  
5           that explain the commercial performance of  
6           Prolensa, irrespective of the claimed  
7           invention.

8           BY MR. DINER:

9           Q           Now, Dr. Cykiert indicated that  
10          Prolensa and Bromday have the same clinical  
11          efficacy.

12                        Do you recall that from his opinion?

13          A           Yes.

14          Q           And I think we established that Bromday  
15          has 0.09 percent bromfenac, correct?

16          A           Correct.

17          Q           And Prolensa has 0.07 percent  
18          bromfenac, correct?

19          A           That's my understanding.

20          Q           And is it fair to say that Prolensa  
21          then has 22 percent less bromfenac in it compared  
22          with Bromday?

23          A           I haven't done the math, but just in my  
24          head it sounds like the math of .07 is 22 percent  
25          lower than .09.

1 Q Okay. And so would you agree that  
2 being able to reduce the concentration of the active  
3 ingredient by 22 percent and still getting the same  
4 clinical efficacy is a benefit that is associated  
5 with the Prolensa product?

6 MS. FINK: Objection, beyond the scope  
7 of his expert report, calls for speculation.

8 THE WITNESS: I think they we kind of  
9 talked about this in generalities earlier.  
10 First off, I would defer to technical experts.  
11 Second off, there has to be any -- as we  
12 talked about, there are situations where that  
13 could be a meaningless distinction.

14 BY MR. DINER:

15 Q Has anyone ever informed you in your  
16 work on this case so far that being able to lower  
17 the amount of active ingredient by 22 percent stems  
18 back to the stabilization benefit imparted by  
19 tyloxapol to bromfenac?

20 MS. FINK: Objection, assumes facts not  
21 in evidence.

22 THE WITNESS: That was a long question.

23 BY MR. DINER:

24 Q Has anyone informed you in this case  
25 that the reduction of 22 percent in the amount of

1 active ingredient that we see in Prolensa compared  
2 to Bromday stems back to the ability of tyloxapol to  
3 stabilize bromfenac better than polysorbate 80?

4 MS. FINK: Same objection.

5 THE WITNESS: I don't remember the  
6 specifics of what that technical issue is and  
7 where the parties are on that. I defer to the  
8 technical experts. I guess I'm looking at the  
9 commercial performance of the product, and I  
10 didn't see any implications in the commercial  
11 activity and what drove the commercial sales  
12 of Prolensa, even assuming some of these  
13 detailed technical things you're asking me  
14 about.

15 BY MR. DINER:

16 Q But these detailed technical things go  
17 to the merits of the claimed invention, correct?

18 A Which I've explained. I've assumed  
19 that this product is a commercial embodiment of.

20 Q So is your answer yes to that question?  
21 Let me repeat it. These technical details that we  
22 were just talking about go to the merits of the  
23 claimed invention in which you said is the driver  
24 for considering commercial success?

25 A For considering -- well, that is --

1 well, you have to be careful. You have to look at  
2 what is it that's driving the performance of a  
3 product. And it can be many things, one of which is  
4 the consideration of the claimed invention of the  
5 patents. And what I've done here is assumed that  
6 this is a commercial embodiment, that they have  
7 these certain claims. But what I'm looking at is,  
8 does that seem to have commercial implications or is  
9 it commercially the performance of Prolensa  
10 explained by other things. And the overwhelming  
11 evidence is it's explained by the many things I talk  
12 about within the life cycle management strategy, the  
13 pricing, the marketing and other things listed in my  
14 report.

15 Q So you primarily focus your analysis in  
16 coming up with the opinions in your report on the  
17 marketing, the pricing, what you call the life cycle  
18 management of the product as opposed to the merits  
19 of the claimed invention; is that right?

20 MS. FINK: Objection, mischaracterizes  
21 testimony.

22 THE WITNESS: That, I think,  
23 mischaracterizes. What I was objecting to and  
24 the way you asked the question, you made it  
25 sound like the primary thing you look at is

1 the claimed invention. I don't know that  
2 there's a degree of primary or secondary to  
3 anything when you come to one of these  
4 analyses. You look at, okay, what are the  
5 commercial drivers of the performance of a  
6 product. Part of that I understand the claims  
7 of the patent, part of it I try and understand  
8 what was known in the prior art versus the  
9 patent, part of it I look at marketing. I  
10 look at sales. I look at pricing. I look at  
11 discounts. I look at -- they're all things  
12 that I consider in a typical commercial  
13 success analysis. And then, as is often the  
14 case, certain ones rise as having a more  
15 significant impact on the commercial  
16 performance of a product.

17 BY MR. DINER:

18 Q So, at page 14 of your opinion in the  
19 phrase that bridges pages 14 to the top of 15, you  
20 stated that, Any alleged commercial success must be  
21 driven primarily by, and attributable to the  
22 purported merits of the claimed invention. You  
23 state that, correct?

24 A Yes.

25 Q So you just said a moment ago that your



1 analysis was more focused on what was happening in  
2 the market in terms of marketing expenditures,  
3 discounts, what you called life cycle management  
4 strategies and less on the actual technical merits  
5 of the claimed invention, correct?

6 MS. FINK: Objection, misstates prior  
7 testimony.

8 THE WITNESS: I think you're  
9 mischaracterizing my prior answers. You're  
10 mischaracterizing my report and  
11 mischaracterizing that sentence.

12 BY MR. DINER:

13 Q Well, what is your understanding of  
14 that sentence that I just read into the record?

15 A So earlier when I said it's my opinion  
16 and my analysis shows that life cycle management,  
17 marketing, pricing and discounting and other  
18 extrinsic factors are what explains a commercial  
19 performance, is the result of my analysis. Your  
20 questions suggest that I come into the analysis  
21 motivated to look at one thing versus another thing.  
22 I look at everything. And so maybe we're just  
23 having a temporal disconnect here.

24 What I'm saying is, is I came in and I  
25 said, okay, what of all of these different drivers

1 seems to be explaining the commercial performance of  
2 the product. In doing my analysis, the claims of  
3 the patented invention, particularly relative to  
4 what was done in the prior art and the prior  
5 embodiment, are down here, and life cycle management  
6 and marketing and pricing are all over here at the  
7 end of my analysis. So that consistent with the  
8 carryover piece of the sentence you are coming back  
9 to means that the performance of Prolensa does not  
10 satisfy the criteria that I explain on page 14 over  
11 to 15 because the commercial performance has not  
12 been driven primarily by, and attributable to the  
13 purported merits of the claimed invention, but is,  
14 in fact, driven by the other factors unrelated to  
15 the allegedly double features of the claimed  
16 invention.

17 Q But you really didn't consider, did  
18 you, Mr. Hofmann, the effect of stability imparted  
19 by tyloxapol on the properties of the formulations  
20 of the claimed invention, have you?

21 MS. FINK: Objection, assumes facts not  
22 in evidence, argumentative.

23 THE WITNESS: I disagree with that. I  
24 got an understanding of the scope of this  
25 patent relative to the prior patents and this

1           embodiment relative to the, you know, Prolensa  
2           versus Bromday, and in considering when I  
3           looked at all the different commercial drivers  
4           did those things seem to translate into having  
5           commercial implications, and they didn't.

6 BY MR. DINER:

7           Q           Well, when I asked you about whether  
8           you considered the stabilization imparted by  
9           tyloxapol to bromfenac you deferred and said, well,  
10          that's more of a technical question, I left that up  
11          to the technical people. Correct?

12          A           Sure. But my understanding in  
13          executing my economic and commercial analysis is  
14          informed by some of those technical claims and  
15          technical issues.

16          Q           Well, were you also informed that the  
17          amount of polysorbate 80 in Bromday is 0.15 percent?

18          A           I may have seen that, yes.

19          Q           Okay. And were you informed that the  
20          amount of tyloxapol in Prolensa is 0.02 percent?

21          A           I just don't -- I don't have the specs  
22          committed to memory, as I sit here.

23          Q           You didn't consider them, did you?

24          A           I didn't say that. I think I looked at  
25          a lot of technical reports and a lot of things.

1 You're asking me about --

2 Q Well, let me ask you some more  
3 questions about that because I think it could be  
4 interesting. The difference between 0.15 percent  
5 polysorbate 80 in Bromday and 0.02 percent in  
6 Prolensa roughly works out mathematically to  
7 tyloxapol being about one-eighth the amount compared  
8 to the amount of polysorbate 80 used in Bromday.

9 Does that sound right?

10 MS. FINK: Objection, beyond the scope  
11 of his expert report.

12 THE WITNESS: It you're going to have  
13 to run through the numbers again.

14 BY MR. DINER:

15 Q Okay. So polysorbate 80 is at 0.15  
16 percent. Polysorbate 80 is up here. Tyloxapol is  
17 at 0.02 percent.

18 A Okay.

19 Q The difference in concentration as  
20 between polysorbate 80 and tyloxapol down here is  
21 about 7 and a half, right?

22 A That's the math.

23 Q Right. And so just for round numbers,  
24 that means the tyloxapol is used at about one-eighth  
25 the amount of polysorbate 80, correct?

1 MS. FINK: Same objection.

2 THE WITNESS: Based on that math.

3 BY MR. DINER:

4 Q Mr. Hofmann, do you know what a  
5 surfactant is?

6 MS. FINK: Beyond the scope of his  
7 expert report.

8 THE WITNESS: I mean, I'm not a  
9 formulator. I've certainly seen that term and  
10 I know that surfactants play a role in  
11 formulations, particularly in ophthalmologic  
12 solutions. But I don't know --

13 BY MR. DINER:

14 Q Do you know a surfactant is actually a  
15 soap?

16 A Right.

17 MS. FINK: Same objection.

18 BY MR. DINER:

19 Q Did you ever get soap in your eye,  
20 Mr. Hofmann?

21 MS. FINK: Objection, beyond the scope  
22 of his expert report, assumes facts not in  
23 evidence.

24 THE WITNESS: So personally have I ever  
25 gotten soap in my eye?

1 BY MR. DINER:

2 Q Yeah. When you were a child, did you  
3 ever get soap in your eye?

4 A Perhaps.

5 Q Did it burn and sting?

6 A I mean --

7 MS. FINK: Objection, beyond the scope  
8 of his expert report.

9 THE WITNESS: I don't recall my  
10 childhood issues with soap in the eye, as I  
11 sit here right now.

12 BY MR. DINER:

13 Q How about an adult, did you ever get  
14 soap in your eye, Mr. Hofmann?

15 A Really, nothing comes to mind.

16 Q Would you expect that using one-eighth  
17 of the amount of a surfactant would naturally  
18 decrease the tendency of an eye drop to burn and  
19 sting?

20 MS. FINK: Objection, beyond the scope  
21 of his expert report.

22 THE WITNESS: I would defer to either  
23 formulators and technical experts on that. I  
24 just don't know enough to know at those levels  
25 and concentrations that it would have any

1 meaningful impact one way or the other.

2 BY MR. DINER:

3 Q So you didn't consider the relative  
4 concentration amounts as between Bromday and  
5 Prolensa in terms of the opinions that you've given  
6 in this matter, correct?

7 MS. FINK: Objection, mischaracterizes  
8 testimony.

9 THE WITNESS: I think you keep  
10 mischaracterizing -- I did not, and am not a  
11 technical expert. I didn't weigh in  
12 technically on some of the things you're  
13 asking me. What I got was an understanding of  
14 some of the aspects of the claimed invention  
15 and, for example, the role of tyloxapol as the  
16 surfactant. Did I consider whether that  
17 seemed to have any commercial implication in  
18 the commercial performance of the product, I  
19 definitely considered that. And based on my  
20 analysis I saw no evidence of that.

21 BY MR. DINER:

22 Q But my question was actually a little  
23 bit different, and I'll restate it. Probably make  
24 it more clear, hopefully.

25 But you didn't consider the relative

1 concentration amounts of the surfactant between  
2 Bromday and Prolensa, correct?

3 MS. FINK: Objection, mischaracterizes  
4 testimony, calls for speculation.

5 THE WITNESS: I relied on the technical  
6 experts and my understanding of the opinions  
7 of the technical experts on the issue of  
8 whether there's any meaningful impact on  
9 irritation as explained in my understanding  
10 that there is not. So which would include  
11 whether there's an implication of the  
12 concentration as you're asking the question.

13 MR. DINER: Mark the next exhibit,  
14 please.

15 (PROL0080486 - PROL0080492 was marked  
16 Hofmann-9 for identification.)

17 BY MR. DINER:

18 Q The court reporter, Mr. Hofmann, has  
19 just handed you Hofmann Exhibit --

20 MS. FINK: Nine.

21 BY MR. DINER:

22 Q -- 9, bearing Bates numbers PROL0080486  
23 through 492. Take a look at the first page of this  
24 document, Mr. Hofmann.

25 Have you seen this document before?



1 A Yes.

2 Q Okay. In what context?

3 A This case.

4 MS. FINK: One second. Do you need a  
5 break? You seem to be coughing a bit? An  
6 Advil?

7 THE WITNESS: No, I'm okay. I mean, we  
8 can go another five, ten minutes, that's fine.

9 MS. FINK: Okay, apologies.

10 THE WITNESS: When I say I've seen  
11 this, I know I've seen a Xibrom label. I  
12 don't remember if it was this exact one.

13 BY MR. DINER:

14 Q So I think earlier this morning you  
15 testified that you have some familiarity with the  
16 FDA's process for approving the labeling of drugs.

17 Do you recall that?

18 A Yes.

19 Q Okay. Now, this document, which is  
20 Hofmann Exhibit 9, from the first page, does it  
21 appear to be highlights of prescribing information  
22 for Xibrom?

23 A Yes.

24 Q Okay. If you go over to the right-hand  
25 column under adverse reactions. Are you there?

1           A           Yes.

2           Q           Do you see that one of the adverse  
3 reactions listed is eye irritation?

4           A           Yes.

5           Q           And do you see in the parenthetical  
6 next to it that eye irritation is said to include  
7 burning and stinging?

8           A           Yes.

9           Q           You may put that aside.

10                       (PROL0080493 - PROL0080497 was marked  
11 Hofmann-10 for identification.)

12 BY MR. DINER:

13           Q           Mr. Hofmann, you've just been handed by  
14 the court reporter Hofmann Exhibit 10, bearing Bates  
15 numbers PROL0080493 through 497.

16                       Have you seen this document before?

17           A           I'd say the same answer, I've seen a  
18 Bromday label.

19           Q           Okay. Does this document appear to be  
20 highlights of prescribing information for the  
21 product Bromday?

22           A           Yes.

23           Q           And over on the right-hand column, or  
24 in the right-hand column under adverse events, does  
25 it indicate as an adverse event eye irritation?

1           A           It says adverse reactions.

2           Q           Sorry. Thank you.

3           A           And eye irritation is listed among  
4 others.

5           Q           And eye irritation is said to include  
6 burning and stinging, correct?

7           A           Yes.

8           Q           Okay. When the FDA approves a label  
9 such as this, are they doing so based on clinical  
10 studies that have been provided to them?

11          A           Yes.

12          Q           Okay. And when they approve a label  
13 that identifies the adverse events, are they doing  
14 so also based on clinical studies indicating the  
15 occurrence of adverse reactions?

16                   MS. FINK: Objection, beyond the scope  
17 of his expert report.

18                   THE WITNESS: That's my understanding.

19 BY MR. DINER:

20          Q           Okay. And for Bromday, which is  
21 discussed in Hofmann Exhibit 9, and Xibrom, which is  
22 discussed in Hofmann Exhibit -- sorry, strike that.  
23 For Bromday, which is discussed in Hofmann Exhibit  
24 10, and Xibrom, which is discussed in Hofmann  
25 Exhibit 9, both of them, you testified, indicate

1 that the adverse reactions include eye irritation  
2 such as burning and stinging, right?

3 A That's what the labels read, yes.

4 Q And that would have been based on  
5 clinical studies confirming the occurrence of eye  
6 irritation for those products, correct?

7 A That's typically the case.

8 Q Okay.

9 (PROL0080219 - PROL0080224 was marked  
10 Hofmann-11 for identification.)

11 BY MR. DINER:

12 Q You've just been handed Hofmann Exhibit  
13 11, bearing Bates numbers PROL0080219 through 224.

14 And have you seen this document before,  
15 Mr. Hofmann?

16 A Yes.

17 Q What is it?

18 A It's a label for Prolensa.

19 Q Okay. And over in the right-hand  
20 column on the first page under adverse reactions, do  
21 you see anywhere in there where it indicates that  
22 Prolensa had the adverse reaction of eye irritation,  
23 including burning or stinging?

24 MS. FINK: You should read whichever  
25 parts of the document you need to.

1                   THE WITNESS: I mean, I think that the  
2                   language in this label and the 3 to 8 percent  
3                   frequency of other adverse reactions does not  
4                   include the exact same words, "eye  
5                   irritation," but I think Dr. Cykiert addresses  
6                   in his report the, I think, clinical  
7                   implication of his experience and the  
8                   experience with respect to Prolensa versus  
9                   other NSAIDs. But it does not include those  
10                  same words, but it has other adverse  
11                  reactions.

12 BY MR. DINER:

13                  Q            But it doesn't have listed here the  
14                  adverse reaction of eye irritation, including  
15                  burning or stinging, correct?

16                  MS. FINK: Objection, asked and  
17                  answered.

18                  THE WITNESS: Not those exact words. I  
19                  mean, it says eye pain and other -- other  
20                  adverse reactions, but no, not those exact two  
21                  words.

22 BY MR. DINER:

23                  Q            Well, take a look at Hofmann Exhibit  
24                  10, under adverse reactions.

25                  A            I'm there.

1           Q           Sorry. So the label as approved for  
2 Prolensa, particularly the description of adverse  
3 reactions, that also would have been -- that would  
4 also have been approved by the FDA, based on  
5 clinical studies, correct?

6           A           It appears so.

7           Q           And the fact that eye irritation and  
8 burning and stinging is not listed as an adverse  
9 reaction for Prolensa means that the clinical  
10 studies supplied by the company to the FDA supported  
11 a label that did not have a recitation of eye  
12 irritation, burning and stinging, correct?

13                   MS. FINK: Objection, beyond the scope  
14 of his expert report, calls for speculation.

15                   THE WITNESS: I think that's a very  
16 technical issue that, you know, the selection  
17 of the words for the clinical adverse  
18 reactions, I wouldn't have an opinion on one  
19 way or the other, you know, what all is  
20 factored into the FDA's decision, as well as  
21 what's advocated by the company in terms of  
22 the particular words that appear in the label.

23                   And if we're at a decent shifting point  
24 can we take a break?

25                   MR. DINER: It's fine, we can take a

1 break.

2 VIDEO OPERATOR: We're now going off  
3 the record at approximately 2:16 p.m.

4 (Brief recess.)

5 VIDEO OPERATOR: This is the beginning  
6 of file four.

7 We're going back on the record,  
8 approximately 2:31 p.m.

9 BY MR. DINER:

10 Q Okay. Mr. Hofmann, can we turn to  
11 paragraph 62 of your report? I see, unfortunately,  
12 that you have a black-and-white version. I  
13 apologize for that. I will try to muddle our way  
14 through that, if that's okay with you.

15 A I'll do my best.

16 Q Okay. So within paragraph 62 we're  
17 going to refer to the graph that is there. Can you  
18 see the line of demarcation as between what is  
19 indicated to be the Xibrom sales and then it then  
20 transitions to the Bromday sales?

21 A A lot better on yours. It's real faint  
22 up here. I can't -- I mean, I think that's it.

23 Q What is the approximate time point  
24 where the Xibrom sales cease or transition into the  
25 Bromday sales?

1           A           I mean, I know it was 2011. Do you  
2 need a month?

3           Q           No, no, that's fine. And based on the  
4 graph -- maybe you can see this one more clearly.  
5 What is the approximate time where, in just the  
6 year, where the Bromday sales appear to transition  
7 into, and then we go into and see Prolensa sales  
8 beginning?

9           A           2013.

10          Q           Okay. Now, on my copy, which is in  
11 color, and yours, unfortunately, is not, above the  
12 areas for Xibrom, but particularly Bromday and  
13 Prolensa, there's another shaded area. It appears  
14 in purple on my graph. Do you know what that is?

15          A           That's the generic bromfenac sodium  
16 products. And IMS didn't break out those that were  
17 originally launched with the Xibrom as the RLD and  
18 then those that were launched with the label more  
19 consistent with once daily Bromday.

20          Q           So those could be collectively sales of  
21 generic Xibrom and generic Bromday; is that right?

22          A           Correct.

23                   MS. FINK: I just want to put on the  
24 record here with this black-and-white version  
25 it's really very difficult to see the



1 difference between the Bromday and the  
2 bromfenac sodium. The others are difficult as  
3 well, but that demarcation line is practically  
4 invisible in the black-and-white version.

5 MR. DINER: Well, so far we've been  
6 able to muddle our way through this.

7 MS. FINK: Yes. I just wanted that of  
8 record.

9 BY MR. DINER:

10 Q So then perhaps you can help me to read  
11 and understand the significance of the sales of the  
12 collective generic bromfenac sodium products. These  
13 are prescriptions of these products, correct?

14 A Correct.

15 Q And so is this indicating that the  
16 sales of generic bromfenac sodium surpassed Bromday  
17 and Prolensa?

18 A No. It's a stacking graph, and so in  
19 your version, which is purple, and maybe we can  
20 later swap this out for a color version, the purple  
21 area is limited to that purple area. So what this  
22 means is that generic bromfenac sodium sales are a  
23 small fraction of the total sales of either Xibrom,  
24 Bromday or Prolensa.

25 Q It doesn't mean, for example, let's

1 just table directly in line with 2012 and draw a  
2 line up to the peak of the part of the graph that  
3 represents generic bromfenac sodium. Does that mean  
4 that there were, in that particular month of 2012  
5 somewhere between 200 and 250,000 prescriptions?

6 A No. That means in total bromfenac  
7 prescriptions be they Bromday or bromfenac sodium,  
8 it was 250,000 or whatever the number is, you said,  
9 comprised of, I don't know, tens of thousands being  
10 the purple in the form of generic bromfenac sodium  
11 and then over 200,000 being the red that is Bromday.  
12 And so that's why it's called a stacking graph. You  
13 basically add them together.

14 Q So this is a differential amount?

15 A No. I mean, I don't know if -- the  
16 underlying data -- we could go to Jarosz Tab 6, and  
17 you can see that it's like -- like I said, I'm  
18 making up numbers, but by an order of magnitude, you  
19 know, maybe 40,000 scripts of the generic and  
20 220,000 scripts of the brand for that period. Well,  
21 that's too high. That's too high an illustrative  
22 number. So if I go up 2012 is about 225,000  
23 scripts. So without any precision -- if we wanted  
24 precision, we would go to Jarosz Tab 6, which  
25 summarizes the underlying IMS data we're talking

1 about an order of magnitude of, you know, maybe 20  
2 to 30,000 bromfenac sodium generic sales and 170,000  
3 Bromday sales.

4 Q Okay. Okay. Now I understand. Thank  
5 you.

6 Okay. Okay. Now, in 2011 where we see  
7 a transition as between Xibrom and Bromday, was one  
8 of the benefits attributable to Bromday over Xibrom  
9 the fact that it was dosed once a day instead of  
10 twice a day?

11 MS. FINK: Objection, outside the scope  
12 of his expert report.

13 THE WITNESS: My understanding is that,  
14 you know, the formulation itself didn't  
15 change. I defer to technical experts, but my  
16 understanding is that the formulation itself  
17 didn't change. They just got it relabeled to  
18 be once daily, and that was the primary  
19 difference.

20 BY MR. DINER:

21 Q And that improved patient compliance,  
22 correct?

23 A I think that was the view that that  
24 improves patient compliance.

25 Q And the -- as a product that improves

1 patient compliance, that's a benefit to the  
2 consuming public, correct?

3 MS. FINK: Objection, calls for  
4 speculation.

5 THE WITNESS: We talked about this  
6 earlier. I mean, I think that's a -- it  
7 depends. Sometimes improved compliance is not  
8 meaningful. Sometimes it is.

9 BY MR. DINER:

10 Q And how about in the cases between  
11 Xibrom and Bromday, do you know?

12 MS. FINK: Objection, beyond the scope  
13 of his expert report.

14 THE WITNESS: I mean --

15 BY MR. DINER:

16 Q Would you like to refer to paragraph 75  
17 to see if it's within the scope of your expert  
18 report? You're certainly welcome to do that.

19 A I think where I was going is to say  
20 that in general I think that the market for these  
21 ophthalmics was moving to once daily. It started  
22 out as four times daily, moved to twice daily, and  
23 it was viewed that once daily Bromday is a benefit  
24 over multiple times daily.

25 Q Okay. Now, as we move to Bromday and

1 we look at the line as between -- in the graph as  
2 between Bromday and Prolensa, I think we said that  
3 that comes at approximately 2013, right?

4 A Correct.

5 Q Now, the differences between the  
6 Bromday and Prolensa formulation we talked about  
7 before was, in some respect, the surfactant,  
8 correct?

9 A Yes.

10 Q And that Prolensa used tyloxapol  
11 instead of polysorbate 80, correct?

12 A Correct.

13 Q And that Prolensa used approximately  
14 one-eighth the concentration of tyloxapol compared  
15 to the amount of polysorbate 80 used in bromfenac,  
16 correct?

17 A We did talk -- go ahead.

18 MS. FINK: I believe you might have  
19 misspoke. You meant compared to the  
20 concentration of polysorbate 80 in Bromday.

21 MR. DINER: I'll restate it. Thank  
22 you.

23 BY MR. DINER:

24 Q And so I believe we spoke before about  
25 how Prolensa used about one-eighth the amount of

1 tyloxapol compared to the amount of polysorbate 80  
2 used in Bromday, correct?

3 A We did talk about that.

4 Q And also that some of the other  
5 differences we mentioned between the products was  
6 that the pH in Bromday was 8.3 and it was lowered to  
7 7.8 in Prolensa, right?

8 MS. FINK: Objection, assumes facts not  
9 in evidence.

10 THE WITNESS: We looked at that  
11 document we talked about.

12 BY MR. DINER:

13 Q And that with a pH of 7.8 Prolensa was  
14 closer to the pH of natural tears at 7.4, correct?

15 A According to that slide in the  
16 PowerPoint.

17 Q And that at a pH of 7.8 the ocular  
18 penetration of Prolensa was the same or comparable  
19 to the ocular penetration of Bromday, correct?

20 MS. FINK: Objection, assumes facts not  
21 in evidence.

22 THE WITNESS: Can you read that back?

23 BY MR. DINER:

24 Q With regard to the lowering of pH from  
25 8.3 in Bromday to 7.8 in Prolensa, we spoke earlier

1 about the impact of that on ocular penetration,  
2 correct?

3 A We did.

4 Q And you remember me showing you the  
5 article which talked about how Prolensa at 7.8 got  
6 better ocular or comparable ocular penetration to  
7 Bromday at 8.3?

8 MS. FINK: Objection to the extent it  
9 mischaracterizes that document.

10 THE WITNESS: The article being the  
11 rabbit study?

12 BY MR. DINER:

13 Q Yes.

14 A Yes, those sentences you pointed me to  
15 said that.

16 Q And with the increased ocular  
17 penetration they were able to lower the active  
18 ingredient about 22 percent?

19 MS. FINK: Objection, assumes facts not  
20 in evidence.

21 BY MR. DINER:

22 Q Do you recall that?

23 A I agreed that they did lower the .09 to  
24 .07 and that works out to 22 percent.

25 Q Okay. And that that effectively will

1 put less active ingredient on compromised ocular  
2 tissue -- surgically compromised ocular tissue; is  
3 that correct?

4 MS. FINK: Objection, misstates prior  
5 testimony, beyond the scope of his expert  
6 report.

7 THE WITNESS: I mean, with all this  
8 litany of things you're going through, as I  
9 said when we went through the first time, I  
10 deferred to technical experts on all of them,  
11 but yes, there's a lower concentration which  
12 would be applied to the ocular tissue.

13 BY MR. DINER:

14 Q Now, you called these a litany of  
15 things. Plaintiffs would characterize these as  
16 benefits associated with Prolensa compared to  
17 Bromday. But with regard to your position on life  
18 cycle management tactics, if you refer to paragraph  
19 63 of your report. Take a moment if you'd like to  
20 read that.

21 A Yep. I see it.

22 Q When, as you say, Bausch & Lomb ceased  
23 manufacturing Bromday in 2013 and used the life  
24 cycle management tactic to switch to Prolensa to  
25 capture prescriptions of Bromday were there generics



1 available to doctors at that time for prescribing  
2 purposes?

3 A Was there a particular sentence you  
4 were reading or are you just summarizing?

5 Q The last part of paragraph 63.

6 A Okay. So you weren't reading it, you  
7 were just summarizing?

8 What was your question?

9 Q So at the time of the transition from  
10 Bromday to Prolensa -- let me start that over.

11 At the time that Prolensa was launched,  
12 branded Bromday was still on the market, correct?

13 A Briefly.

14 Q And also on the market was generic  
15 bromfenac sodium, correct?

16 A Labeled twice daily.

17 Q I think we also established earlier  
18 that it included some bromfenac sodium that was  
19 labeled once daily?

20 A Later.

21 Q When later?

22 A I can't remember, as I sit here right  
23 now, if it was early 2014. Like early January 2014,  
24 I think.

25 Q Mr. Hofmann, would you consider doctors

1 as part of the consumer group for ophthalmic  
2 pharmaceuticals?

3 A Sure.

4 Q And would you consider that doctors are  
5 sophisticated and informed consumers?

6 MS. FINK: Objection, calls for  
7 speculation.

8 THE WITNESS: I mean, that's a  
9 generality. I think sure as opposed to  
10 someone who's without the same level of  
11 training and education. On a relative basis.  
12 Sure.

13 BY MR. DINER:

14 Q Okay. Physicians would not prescribe a  
15 new drug product using the same active ingredient as  
16 the prior drug product if the new drug product did  
17 not deliver benefits over those offered by the prior  
18 drug product, correct?

19 MS. FINK: Objection, calls for  
20 speculation, incomplete hypothetical.

21 THE WITNESS: I mean, from the things  
22 I've seen and the role of various tactics in  
23 marketing of pharmaceutical products I think  
24 there's lots of examples where there's been  
25 questions as to whether there are incremental

1 benefits to follow-on products, and I think  
2 that, in particular, when you have a "product  
3 hopping" situation where you eliminate the  
4 prior formulation of the molecule and the only  
5 branded promoted product is the, in this case  
6 Prolensa product, I think very much so  
7 physicians will continue to prescribe a  
8 molecule that they've been familiar with  
9 that's supported by marketing and samples and  
10 coupon cards and discounts and all those  
11 things because they know the molecule has been  
12 effective.

13 BY MR. DINER:

14 Q But that same molecule existed in  
15 generic form and branded form in terms of Bromday,  
16 correct?

17 A No. Not in a traditional sense. There  
18 were not -- there was not an AB-rated bromfenac with  
19 Bromday as a reference listed drug. There was a  
20 bromfenac that had no RLD that was labeled twice  
21 daily and there wasn't, I think, a once daily  
22 bromfenac sodium until after Bromday was delisted.  
23 And so, you know, I think those are -- those are  
24 strategically removed and done in a way to minimize  
25 the prescribing of generic bromfenac sodium.

1           Q           But at the time of Prolensa's launch I  
2 think you said before there was branded Bromday out  
3 there, correct?

4           A           Correct.

5           Q           Doctors could have prescribed that  
6 since it was the same active ingredient, correct?

7           A           Well, but I think, as I explained  
8 throughout my report, both in this section and in  
9 the marketing section, you know, Prolensa -- Bausch  
10 + Lomb basically with the launch of Prolensa took a  
11 variety of steps with marketing and shifting all of  
12 the marketing support to Prolensa from Bromday,  
13 shifting the sampling to support on the products,  
14 which is, as I understand it, an important factor,  
15 did a pricing strategy to encourage changing  
16 behavior to prescribe for Prolensa and executed a  
17 strategic transition to move prescribing behavior  
18 away from Bromday to Prolensa with the aim of  
19 killing the Bromday product. Not unlike exactly  
20 what they executed from Xibrom to Bromday.

21          Q           But if doctors are sophisticated and  
22 informed consumers, why, even in light of everything  
23 you said, would they prescribe Prolensa when they  
24 could, for example, prescribe the cheaper bromfenac  
25 sodium?

1 MS. FINK: Objection, assumes facts not  
2 in evidence, calls for speculation.

3 THE WITNESS: Nobody was promoting or  
4 spreading awareness of the availability or  
5 existence of a bromfenac sodium generic.  
6 There is no mechanism by which automatic  
7 substitution of the bromfenac sodium labeled  
8 twice daily version could happen. Those are  
9 huge barriers to that being the selected  
10 molecule or the selected product.

11 I am aware, as you can see in that  
12 graph, some physicians did write the generic  
13 molecule and concentration. I think that the  
14 practical reality is the reason that they  
15 prescribe Prolensa in lieu of Bromday is all  
16 the things I just said which facilitated the  
17 transition from Bromday to Prolensa, removed  
18 any potential resistance or barrier to the  
19 movement from Bromday to Prolensa by keeping,  
20 you know, price at parity and providing  
21 samples and providing coupons and basically  
22 doing exactly what they did from Xibrom to  
23 Bromday to facilitate the product.

24 BY MR. DINER:

25 Q And it's your position that a physician

1 would still, in light of the fact that you -- let's  
2 start that.

3 It's your position that there are no  
4 differences in terms of efficacy or safety as  
5 between Bromday and Prolensa, correct?

6 A That's my understanding.

7 Q Okay. And it's your position that in  
8 spite of the fact that there are no differences  
9 between Prolensa and Bromday that physicians would  
10 still prescribe Prolensa while Bromday was  
11 available, for all the reasons you mentioned  
12 previously?

13 A Yeah. I think that that's consistent  
14 with Miss Valerie's testimony, that they weren't  
15 able to promote these purported benefits over  
16 Bromday. They had to promote to the label. So, you  
17 know, it's the other tactics that, you know, clearly  
18 it was a safe and efficacious product that the  
19 physicians had many years experience with the  
20 molecule, Bausch & Lomb did a strategic, you know,  
21 approach to remove potential resistance or barriers  
22 by facilitating pricing, coupons, discounts and  
23 other marketing support in a way that they were  
24 successfully able to migrate demand, not unlike they  
25 did from Xibrom to Bromday.

1           Q           And so your position is that they would  
2 have just bamboozled the doctors, then, to prescribe  
3 a product that, in your view, had no benefit either  
4 from a efficacy -- clinical efficacy or safety  
5 profile?

6                   MS. FINK:  Objection to the extent it  
7 mischaracterizes testimony, argumentative.

8                   THE WITNESS:  I'm not saying anybody is  
9 bamboozled, I'm saying that there's all those  
10 tactics that were used on physicians.  The  
11 other overarching tactic is to kill the prior  
12 embodiment, which, you know, basically gets  
13 rid of automatic substitution that one would  
14 typically see when generic versions of a  
15 molecule exist.  Like I said, nobody is out  
16 creating awareness to physicians that the  
17 generic bromfenac molecule is out there.  So  
18 it's not that they're bamboozled, you know.  
19 Typically what happens is they will continue  
20 to prescribe -- you know, they'll prescribe a  
21 brand and it gets substituted.  Well, that can  
22 no longer happen and so it's not a matter of  
23 bamboozling, it's a matter of product  
24 switching, product hopping to a safe, and  
25 effective product.  So it's not saying that

1           there's anything necessarily untoward from a  
2           safety and it's certainly a smart, you know,  
3           from an evergreening perspective makes some  
4           economic sense. But it isn't surprising that  
5           they were successful at doing it, much like  
6           they did from Xibrom to Bromday.

7 BY MR. DINER:

8           Q           And I think we talked about with regard  
9           from Xibrom to Bromday that it went from a twice a  
10          day dose to a once a day dose, which you said was a  
11          benefit because of patient compliance?

12          A           Well, there was no change in  
13          formulation, but yes, the label did change.

14          Q           And with regard to all the benefits,  
15          there were a litany of things, as you called them  
16          before, you dispute the fact that those are any  
17          benefits that doctors would have been aware of or  
18          even known of to consider prescribing Prolensa  
19          instead of Bromday, correct?

20          A           I think your premise is a false premise  
21          in that I necessarily agree that the reason they  
22          explained or transitioned Xibrom to Bromday is  
23          because of the once daily label. I'm not saying  
24          that. They did the same things. They killed the  
25          Xibrom product. They did the strategic pricing.



1 They did the shift in marketing. So all those  
2 things were in the tool chest, and they brought  
3 those out of the tool chest again. Based on  
4 everything I've seen, as we've talked about earlier  
5 today and throughout the day, those other technical  
6 aspects are not things that Miss Valerie said that  
7 they can promote to, the lack of awareness of the  
8 availability of a bromfenac sodium would hinder  
9 generic awareness and fulfillment, and yes, that the  
10 strategic pricing, marketing and delisting of  
11 Bromday explains the transition from Bromday to  
12 Prolensa.

13 Q Okay. So you just talked about  
14 delisting of Bromday. But we established earlier  
15 that there was overlap in the sales as between  
16 Prolensa and Bromday, correct?

17 A For a handful of months.

18 Q Right. So about four months there was  
19 overlap, correct?

20 A Right. But there was also a change in  
21 marketing strategy to, you know, basically convert  
22 all scripts, or as many scripts as they could, from  
23 Prolensa to Bromday during the four-month  
24 intervening period.

25 Q But doctors as independent informed

1 consumers can make their own choice, independent of  
2 the so-called tactics that you talked about?

3 A Right. But if the -- if the  
4 communication and part of the life cycle management  
5 strategy is that Prolensa is replacing Bromday you  
6 need to start writing Prolensa in order to get  
7 bromfenac for your patients that's going to change  
8 prescribing behavior. Hey, it's still safe and  
9 effective.

10 Q Were you aware that the price at launch  
11 for Prolensa was much higher than Bromday?

12 MS. FINK: Objection, assumes facts not  
13 in evidence.

14 THE WITNESS: I think what I've seen is  
15 that the price, based on actual data, was at  
16 parity and based on strategic documents was at  
17 parity.

18 BY MR. DINER:

19 Q So let's talk about that overlap  
20 between the Prolensa's launch and what you said was  
21 a discontinuation of Bromday. Prolensa launched in  
22 mid-April 2013, correct?

23 A Correct.

24 Q Bromday was discontinued in mid-August  
25 2013?

1 A Correct.

2 MR. DINER: I would like to mark the  
3 next exhibit, Tab 10.

4 (Ophthalmic NSAIDs Average Selling  
5 Price Per Prescription, page 2 of 2, was  
6 marked Hofmann-12 for identification.)

7 BY MR. DINER:

8 Q Okay. Mr. Hofmann, you've been handed  
9 Hofmann Exhibit 12. I'll represent to you that this  
10 document, which is identified up at the top a Tab  
11 10, Ophthalmic NSAIDs Average Selling Price Per  
12 Prescription United States is a tab that comes out  
13 of Mr. Jarosz's opening report.

14 Have you seen this document before?

15 A I have.

16 Q So back to where we were. Let's look  
17 at Tab 10. I guess you can look at page 2 of 2.  
18 It's double sided.

19 A Yep.

20 Q We'll go to 2013.

21 A Yep.

22 Q Quarter 2 is the quarter in which  
23 Prolensa was launched, right?

24 A Correct.

25 Q And there Prolensa is identified as

1 selling in quarter 2 in 2013 at approximately \$240  
2 per prescription; is that correct?

3 A Well, you have to put this in context.  
4 This is a calculation that takes gross sales data  
5 from IMS divided by TRx data from IMS, and I think  
6 there's a hazard in trying to look at it in this,  
7 you know, -- IMS data is good longitudinally, but  
8 for a particular quarter there can be noise in it.  
9 But the data does say \$238.92 on a gross basis, not  
10 reflective of any discounts, or not reflective of  
11 actual net pricing of Prolensa.

12 Q And Bromday is reported at  
13 approximately \$170 per prescription, correct?

14 A With all the caveats from my last  
15 answer, and you can see that, especially for  
16 Bromday, as it ended -- as it neared the end of its  
17 life cycles, I mean, there's periods in here where  
18 it's showing up at \$18 and \$9, according to the  
19 data. There's just noise in the data that this is  
20 not, you know, a reasonable place to look, to look  
21 at the relative pricing of Bromday and Prolensa  
22 during that four-month period. I think the strategy  
23 documents and internal correspondence regarding the  
24 plans to price at parity are reflective of the  
25 actual strategy and transition that occurred. And I

1 think it's also worth noting, too, you know, you  
2 have the generic pricing, which again is gross and  
3 doesn't have the same level of discounts nipping at  
4 the heels of Prolensa as well.

5 Q Well, it's a whole lot closer to what  
6 Bromday is than it is to Prolensa; isn't that right?

7 A They're somewhat meaningless in that  
8 they're gross sales and none of them reflect  
9 discounts.

10 Q At least as between Prolensa and  
11 Bromday the discounts would apply to both of them so  
12 it's a wash, right?

13 A Not so. Some of the tactics, as we saw  
14 in the switch in the marketing plans were, you know,  
15 they killed for Bromday, any and all marketing they  
16 switched it over to Prolensa. So things like  
17 coupons, things like sampling, things like that are  
18 not going to be the same levels as they are for  
19 Bromday as Prolensa during that transition period.

20 Q But the killing, as you call it of  
21 Bromday, it doesn't get discontinued until August of  
22 2015, right?

23 A That was the official externally, you  
24 know, announcement date. But there's other  
25 documents leading up to that in the production that

1 talk about the conversion, and the conversion being  
2 the strategy of migrating demand to Prolensa during  
3 a brief period, not unlike they did from Xibrom to  
4 Bromday.

5 Q So with a price of approximately \$240  
6 per script versus \$170 per script and the fact that,  
7 in your opinion, there is no difference in clinical  
8 efficacy or safety, that doctors, even in spite of  
9 all the lobbying that you talked about, are going to  
10 prescribe Prolensa when they can do the same thing  
11 with Bromday?

12 A I reject many premises and assumptions  
13 embedded in your question. First off, I explained  
14 why I don't think these are reflective of actual  
15 pricing, that they reflect some issues with gross  
16 sales and TRx data and IMS. There are internal  
17 documents that clearly state that the pricing is a  
18 parity between Bromday and Prolensa.

19 Additionally, this isn't a price that a  
20 physician is even aware of, whether it's this or the  
21 actual price. What a physician is aware of is what  
22 is the amount of out of pocket that my patient is  
23 going to have to pay. And that is really driven by,  
24 you know, tier placement and coupons and things like  
25 that, all of which migrated to support around

1 Prolensa. So it's not that any of these numbers  
2 that you have in Tab 10 there would be any physician  
3 that has awareness of any of these. So it's an  
4 improper suggestion to say that there's a physician  
5 sitting with his pad saying should I do Bromday  
6 which is 169 or should I do Prolensa which is 238.  
7 No physician, you know, has that information or  
8 thinks that way. What they're thinking is, you  
9 know, what will my patient's out of pocket be. And  
10 as I said, Prolensa has, you know, support through  
11 coupons and all the migration of marketing around  
12 Prolensa against Bromday.

13 Q Well, if they have none of that  
14 financial information how could they determine what  
15 that patient's out of pocket is going to be?

16 A Well, the typical way that it happens  
17 is complaints. You know, so they'll write a script,  
18 and then if nobody complains, everything seems fine,  
19 and then when they start to get feedback that could  
20 then cause them to either seek out whether there's  
21 coupon or patient assistance or migrate demand to  
22 other molecules.

23 Q There's going to be a lag time on that.  
24 They're not going to know when those complaints are  
25 going to come through and when that's going to

1 correspondence to --

2 A Right. That's what I'm trying to get  
3 through here is that the launch of Prolensa is  
4 accompanied by Bausch & Lomb reps all over the place  
5 saying guess what, we now have this Prolensa product  
6 which has the bromfenac molecule. It's as safe and  
7 efficacious as Bromday was. We're pricing it at  
8 parity, we're converting this over to Prolensa,  
9 please change your prescribing behavior. They've  
10 removed any of the implied resistance that you say  
11 should be there from a price elasticity by  
12 coordinating a strategic life cycle management  
13 campaign, the same way they did from Xibrom to  
14 Bromday.

15 Q And did doctors talk to one another  
16 about these new products that are being offered by  
17 pharmaceutical companies?

18 MS. FINK: Objection, calls for  
19 speculation.

20 THE WITNESS: I mean, I'm sure there  
21 are doctors that talk about products all the  
22 time.

23 BY MR. DINER:

24 Q Right. And are you aware of the  
25 reports authored and published by various doctors



1 talking about the benefits of Prolensa versus  
2 Bromday?

3 MS. FINK: Objection, facts not in  
4 evidence.

5 THE WITNESS: I mean, I'm aware there  
6 are some journal articles. I know there's  
7 some disputes about whether they're Bausch &  
8 Lomb funded and what weight to put on those,  
9 but I think that there are some journal  
10 articles out there on that.

11 BY MR. DINER:

12 Q Yeah. And those journal articles  
13 talked about the benefits of the new formulation,  
14 correct?

15 A I think, arguably, that is what is in  
16 some of those articles, again, funded by Bausch &  
17 Lomb, and subject to the fact that they're also  
18 doing all these other tactics and they cannot  
19 promote those purported benefits, as Ms. Valerie  
20 explained.

21 Q Well, but the doctors are not bound by  
22 what Bausch & Lomb can or cannot promote, right?

23 A Of course not. That's what I mean, is  
24 if -- your questions and where you seem to be going  
25 is you think a Bausch & Lomb rep walks in and says

1 we have new Prolensa, it's \$239, please, please,  
2 prescribe it, even though you can get cheap Bromday  
3 or cheap bromfenac. Well, that's not reality  
4 whatsoever. What the reality is that they  
5 facilitated the conversion from Bromday to Prolensa  
6 with a molecule that was known to be safe and  
7 effective and removing any potential resistance  
8 barriers by coupons and pricing parity and all the  
9 tools that were in the tool kit from when they  
10 transitioned Xibrom to Bromday.

11 Q And some of the other realities were  
12 also the published articles of doctors talking about  
13 the benefits of the new Prolensa formulation, right?

14 MS. FINK: Objection, assumes facts not  
15 in evidence.

16 BY MR. DINER:

17 Q You mentioned that a moment ago.

18 A Like I said, I am aware that there are  
19 some articles. I don't weigh in on them from a  
20 medical perspective. I know there's some question  
21 as to the objectivity of them. But that's not to  
22 say there isn't a single doctor that might have been  
23 influenced by that. I'm just saying that, in my  
24 view of everything I've seen on what commercially  
25 explains the life cycle management and transition

1 from Bromday to Prolensa, it isn't the particular  
2 formulation in Prolensa that explains, you know,  
3 what is happening here.

4 Q It's the particular benefits of the  
5 Prolensa formulations that the doctor -- of the  
6 Prolensa formulation that the doctors are seeing;  
7 isn't that correct?

8 A I totally disagree. Everything I've  
9 seen is that the commercial -- you know, what is  
10 happening commercially is a revised bromfenac  
11 formulation, a molecule that physicians are very  
12 familiar with is now available with all the same  
13 pricing incentives, samples and facilitation of  
14 converting prescriptions from Prolensa to Bromday  
15 followed by Bromday being delisted and no longer  
16 available.

17 Q And the physicians are also aware of  
18 the articles by other physicians that are talking  
19 about the benefits in the new formulation, including  
20 lower pH, greater comfort, greater ocular  
21 penetration, being able to use less active  
22 ingredient and still get the same clinical efficacy,  
23 they're aware of those articles, too, right?

24 MS. FINK: Objection, assumes facts not  
25 in evidence, calls for speculation.

1                   THE WITNESS: I don't know that that's  
2                   a fair assumption. I know that those are some  
3                   articles cited by Plaintiffs in this case.  
4                   Whether those are, you know, widely read and  
5                   understood and as far as influencing  
6                   prescribing behavior or how physicians often  
7                   rely on sales reps to explain what the  
8                   benefits are of a particular product. And so,  
9                   you know, what they are getting affirmatively  
10                  is reps from Bausch & Lomb doing the things  
11                  that they do to help convert prescriptions  
12                  from Prolensa to Bromday, which necessarily  
13                  can't include some of those alleged benefits  
14                  in those articles.

15 BY MR. DINER:

16                  Q           But you didn't consider those articles  
17                  and those alleged benefits in those articles in  
18                  rendering your opinions in this case, did you?

19                  A           Not true. I looked at the documents  
20                  that were produced and the feedback and the cataract  
21                  discussion groups and some of the, you know, what  
22                  limited documents were produced in this case on what  
23                  is driving the prescribing behavior of physicians.

24                                I looked at Dr. Cykiert's -- I  
25                  understood Dr. Cykiert's opinions with respect to

1 that, and my understanding is that what motivates  
2 the prescribing behavior has, and continues to be  
3 the, you know, efficacy, safety and familiarity with  
4 the molecule, combined with all the commercial  
5 facilitating that Bausch & Lomb did to convert  
6 demand from Bromday to Prolensa.

7 Q But you acknowledged before that  
8 doctors talk, and that doctors would have talked  
9 about the published articles of other doctors that  
10 discuss the benefits of the new Prolensa  
11 formulation, right?

12 MS. FINK: Objection, mischaracterizes  
13 prior testimony.

14 THE WITNESS: Yeah, I mean, I don't --  
15 I think that's an unfair, you know, broader  
16 characterization than what I agreed with you  
17 on. I think that what -- what we know is  
18 affirmatively happening is all the things that  
19 Bausch + Lomb is doing to get into the offices  
20 of prescribers to make them aware of this  
21 product and facilitate the conversion from  
22 Prolensa to Bromday.

23 BY MR. DINER:

24 Q And during that period of overlap of  
25 four months or so, between the launch, or after the

1 launch of Prolensa and the discontinuation of  
2 Bromday, physicians shifted approximately 70 percent  
3 of their Bromday prescriptions to Prolensa, right?

4 A I saw that metric in the -- in the  
5 Jarosz reply report. I think that according to the  
6 one, the Morgan Stanley report, that is what the  
7 data shows, and that's entirely consistent with the  
8 successful conversion strategy that was executed  
9 from the launch of Prolensa to the discontinuance of  
10 Bromday.

11 Q It's also consistent with what other  
12 doctors were saying about the benefits of the new  
13 Prolensa formulation with regard to comfort, ocular  
14 penetration, reduced active ingredient, same  
15 clinical efficacy, correct?

16 A Well, I mean, to your earlier  
17 suggestion about lag times you think there might be  
18 more of a lag to informal chatter among people over  
19 time as opposed to a coordinated, you know,  
20 strategic campaign launched by a sophisticated  
21 targeter of ophthalmologists who basically fan out  
22 and disseminate the conversion strategy and story in  
23 a molecule that people are all comfortable with.

24 Q But some of these reports by doctors  
25 that you acknowledged having seen, they were based

1 on clinical studies that would have occurred before  
2 the Prolensa product was launched, right?

3 MS. FINK: Objection, assumes facts not  
4 in evidence.

5 THE WITNESS: Yeah, I'd have to go back  
6 and look at the timing of those, but you're  
7 right, I mean, to the extent they discuss  
8 clinical trials that predated the launch,  
9 those would temporally follow there.

10 MR. DINER: I have no further  
11 questions.

12 MS. FINK: I have no redirect.

13 VIDEO OPERATOR: We are now going off  
14 the record; approximately 3:21 p.m.

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C E R T I F I C A T I O N

I, LISA FORLANO, a Certified Realtime Reporter, Certified Court Reporter and Notary Public, do hereby certify that I reported the deposition in the above-captioned matter, that the said witness was duly sworn by me; that the foregoing is a true and correct transcript of the stenographic notes of testimony taken by me in the above-captioned matter.

I further certify that I am not an attorney or counsel for any of the parties, not a relative or employee of any attorney or counsel connected with the action, nor financially interested in the action.



LISA FORLANO, CRR, CCR #XI01143

DATED: February 29, 2016



1 ATTACH TO DEPOSITION OF: Ivan T. Hoffman  
IN THE MATTER OF: Senju vs. Lupin  
2 DATE TAKEN: February 24, 2016  
3

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\_\_\_\_\_, 2016

To: Sarah Fink, Esq.

Case Name: Senju Pharmaceutical Co., Ltd v. Lupin Limited And Lupin  
Pharmaceuticals

Veritext Reference Number: 2238413

Witness: Ivan T. Hofmann                      Deposition Date: 2/24/2016

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Production Department

Encl.

Cc: All Counsel

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Federal Rules of Civil Procedure

Rule 30

(e) Review By the Witness; Changes.

(1) Review; Statement of Changes. On request by the deponent or a party before the deposition is completed, the deponent must be allowed 30 days after being notified by the officer that the transcript or recording is available in which:

(A) to review the transcript or recording; and

(B) if there are changes in form or substance, to sign a statement listing the changes and the reasons for making them.

(2) Changes Indicated in the Officer's Certificate. The officer must note in the certificate prescribed by Rule 30(f)(1) whether a review was requested and, if so, must attach any changes the deponent makes during the 30-day period.

DISCLAIMER: THE FOREGOING FEDERAL PROCEDURE RULES ARE PROVIDED FOR INFORMATIONAL PURPOSES ONLY. THE ABOVE RULES ARE CURRENT AS OF SEPTEMBER 1, 2014. PLEASE REFER TO THE APPLICABLE FEDERAL RULES OF CIVIL PROCEDURE FOR UP-TO-DATE INFORMATION.