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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 2238419

SENJU EXHIBIT 2268
Innopharma v Senju,
IPR2015-00902 & IPR2015-00903

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Transcript of deposition taken
by and before Lisa Forlano, CCR, CRR, RMR,
Certificate No. XI01143, at the offices of Alston &
Bird, LLP, 90 Park Avenue, New York, New York,
on Friday, February 26, 2016, commencing at 10:38
a.m.

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American College of Nutrition, Number 3, June 1995

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Cykiert-15 Vol. 99, No. 2, February 1997 article 143
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VIDEO OPERATOR: Good morning, we're now on the record. Please note that the microphones are sensitive and may pick up whispering and private conversations. Please turn off all cellphones or place them away from the microphones, as they can interfere with the deposition audio. Recording will continue until all parties agree to go off the record.

My name is Jim Roberts representing Veritext, with offices in Livingston, New Jersey.

Today's date is February 26, 2016.

The time is approximately 10:38 a.m. The deposition is being held at Alston & Bird, located at 90 Park Avenue, New York City, New York, and is being taken by counsel for the Plaintiff.

The caption of the case is Senju Pharmaceuticals, et al. versus Lupin, LTD., et al. The case is held in the US District Court, District of New Jersey. The name of the witness is Robert C. Cykiert.

Counsel will please state their

1 appearances for the record.

2 MR. DINER: Bryan Diner with the law
3 firm of Finnegan Henderson, representing the
4 Plaintiff, Senju, et al. With me is my
5 colleague, Terrence Kim.

6 MR. JANUSZ: Joe Janusz of Alston &
7 Bird, representing the Innopharma defendants
8 and the witness, today.

9 VIDEO OPERATOR: Our court reporter,
10 Lisa Forlano, also of Veritext, will please
11 swear in the witness.

12 ROBERT C. CYKIERT, M.D., having been
13 duly sworn, was examined and testified as
14 follows:

15 BY MR. DINER:

16 Q Good morning, sir.

17 A Good morning.

18 Q How are you today?

19 A All right. Good. How are you doing?

20 Q Fine, thank you. Can you please state
21 your full name and address for the record?

22 A Sure. Robert Cykiert, 345 East 37th
23 Street, New York, New York 10016.

24 Q Dr. Cykiert, have you been deposed
25 before?

1 A Yes, I have.

2 Q Have you been deposed in an IP case
3 before? By IP, I mean intellectual property.

4 A No, not that I recall.

5 Q Okay. I'll just go over a few ground
6 rules for today's proceeding, if that's fine with
7 you.

8 A Sure.

9 Q I kind of break them down into three
10 parts; my questions, your breaks, perhaps, or any
11 questions you have. So first with regard to my
12 questions. My job is to ask the questions, your job
13 is to answer them, and to answer them truthfully and
14 accurately.

15 Does that sound fair?

16 A Yes.

17 Q Okay. With regard to breaks, any time
18 you feel you need a break, it's fine with us, just
19 let us know. If there is a question pending,
20 however, I would just ask that you answer that
21 question and then we can take a break afterwards.

22 Is that fine?

23 A Yes.

24 Q Okay. And to the extent that you have
25 any questions of a question that I've asked or are

1 unclear about something, please let me know and I'll
2 be happy to either clarify or rephrase the question.

3 Is that okay?

4 A Yes.

5 Q And if I ask a question and you answer
6 it, I'll assume that you understood the question.

7 Is that fine?

8 A Yes.

9 Q Okay. Is there any reason why you
10 cannot testify today truthfully and accurately?

11 A No, no reason.

12 Q I'd like to mark the first exhibit.

13 (Responsive Expert Report of Robert C.
14 Cykiert, M.D., on Objective Indicia of
15 Non-Obviousness was marked Cykiert-1 for
16 identification.)

17 BY MR. DINER:

18 Q Okay. Now, Dr. Cykiert, the court
19 reporter has just handed you a document that is
20 entitled, Responsive Expert Report of Robert C.
21 Cykiert, M.D., on Objective Indicia of
22 Non-Obviousness.

23 Is what has been marked as Cykiert
24 Exhibit 1 your expert report, including any exhibits
25 or appendices that you have submitted in this case?

1 A What's the question? I'm sorry.

2 Q Is this the expert report that you have
3 submitted in this matter?

4 A Yes, it looks like it.

5 Q Okay. Can you please turn to the page
6 in your expert report after page 31.

7 A Okay.

8 Q On that page do you see the signature
9 at the top?

10 A Yes.

11 Q Is that your signature?

12 A Yes, it is.

13 Q Now, on the next page, which actually
14 doesn't have a page number, there's another
15 signature. Is that your signature as well?

16 A Yes.

17 Q Now, if you hold these two pages open
18 together, I think as you are doing presently, the
19 page after page 31 has a date of February 3 at the
20 top.

21 Do you see that?

22 A Yes.

23 Q The next page actually has a date of
24 February 1, 2016 at the top.

25 Do you see that?

1 A Yes.

2 Q Do you know why you have two signature
3 pages with two different dates.

4 A Yeah, apparently I signed it without
5 looking at the date and later I was told it was the
6 wrong date, so I had to re-sign it again with the
7 correct date.

8 Q And which one is the correct date that
9 you re-signed?

10 A I believe it was February 1.

11 Q Okay. So you signed the report on
12 February 1, but February 3 was the date indicated
13 when you signed it?

14 A Apparently it was the wrong day. I
15 believe I signed it actually on February 1, but I
16 didn't notice that it had the wrong date printed on
17 it, February 3, so I was asked to re-sign it with
18 the correct date.

19 Q Okay. Thank you.
20 Who prepared your expert report in this
21 case?

22 A I prepared it.

23 Q Did you prepare it by yourself?

24 A I prepared it with the attorneys.

25 Q Okay. Now, at the end of your report,

1 does it contain a copy of your CV?

2 A Yes, it does.

3 Q And is this CV current and accurate as
4 of today?

5 A I think it's accurate to within
6 probably about six months or so.

7 Q Okay. Is there anything that you would
8 like to add to your CV that's not presently in it?

9 A Nothing right now that I can think of.

10 Q Okay. And your curriculum vitae lists
11 your current, relevant professional experience,
12 correct?

13 A Yes.

14 Q Dr. Cykiert, in what areas do you
15 consider yourself an expert?

16 A I'm an ophthalmologist and I have
17 special expertise in what's called the anterior
18 segment of the eye, which is the front of the eye,
19 which includes things like cataract surgery, cornea,
20 external disease, any diseases, conditions, problems
21 or complications or surgeries of the front part of
22 the eye.

23 Q You're not an expert on any of these
24 conditions in the posterior part of the eye?

25 A The posterior part of the eye is

1 connected to the front of the eye, so I'm also, as
2 an ophthalmologist, an expert on all parts of the
3 eye, front to back, but I have specific fellowship
4 training in the anterior segment of the eye. So
5 many conditions that affect the front of the eye
6 also have an effect on the back of the eye, which
7 I'm an expert on as well.

8 Q Any other areas of ophthalmology that
9 you would consider yourself an expert in other than
10 what you just stated?

11 A Basically it depends how you define
12 expert. What do you mean by "expert"?

13 Q Well, do you have an expertise in any
14 other areas of ophthalmology other than what you
15 just described?

16 A I have numerous areas of expertise
17 within ophthalmology. Again, depending on how you
18 define "expert," I have special super expertise in
19 the front part of the eye, but I'm also an expert on
20 the back of the eye, the middle the eye, the sides
21 of the eye and every disease and condition of the
22 eye.

23 Q Okay. Are you an expert in the field
24 of pharmacy?

25 A That I'm not an expert in, no.

1 Q Have you ever practiced pharmacy?

2 A No, I have not.

3 Q Are you an expert in the area of
4 pharmacology?

5 A No, I'm not an expert in pharmacology.

6 Q And neither are you an expert in
7 pharmacokinetics?

8 A I am not an expert in pharmacokinetics.

9 Q Nor are you an expert in
10 pharmacodynamics, right?

11 A I'm not an expert in pharmacodynamics.
12 But I should say that I know certain things about
13 all those things that you mentioned simply because
14 part of ophthalmology is treating conditions,
15 diseases with various drugs which required me to
16 know a bit about pharmacy, pharmacokinetics and
17 pharmacodynamics.

18 Q But as you stated, you don't consider
19 yourself an expert in those areas, correct?

20 A Again, depending on how you define
21 "expert," I would say with my definition of expert,
22 I'm not an expert in those, as I previously stated.

23 Q That's fine.

24 Dr. Cykiert, have you ever conducted
25 any research on any bromfenac-containing product?

1 A No, I have not.

2 Q Have you ever conducted any research on
3 any tyloxapol-containing product?

4 A No, I haven't.

5 Q Are you an expert in chemistry, using
6 your definition of an expert?

7 A Well, I majored in chemistry in
8 college, so I do have basic fundamental knowledge of
9 chemistry, especially how it applies to the eye and
10 diseases of the eye, but I wouldn't consider myself
11 an expert in that.

12 Q Thank you. Would you consider yourself
13 an expert in chemical stability testing of aqueous
14 liquid preparations?

15 A That I'm not an expert in.

16 Q Have you ever conducted any chemical
17 stability testing on an aqueous liquid preparation?

18 A No, I haven't.

19 Q Are you an expert in patent law?

20 A No, I'm not.

21 Q Are you a named inventor on any U.S.
22 Patent?

23 A Yes, I am.

24 Q How many, approximately?

25 A One patent.

1 Q And what does it deal with?

2 A It's a patent that blocks radiation
3 from cellphones.

4 Q So not involved in ophthalmology, then?

5 A No, it's not.

6 Q Are you a named inventor on any pending
7 U.S. Patent applications?

8 A Could you repeat that?

9 Q Sure. Are you a named inventor on any
10 pending U.S. Patent applications?

11 A No.

12 Q You mentioned you have at least one
13 patent. Are you comfortable reading patent claims?

14 A What do you mean by am I comfortable?

15 Q Let me back up a minute. Do you know
16 what I mean by a patent claim?

17 A Sure.

18 Q Okay. When you read patent claims, do
19 you feel you understand them?

20 A Yes.

21 Q So, then, are you comfortable in
22 reading patent claims?

23 A I can read them, certainly.

24 Q And can you read them and understand
25 them?

1 A It depends what the patent is about.

2 Q Okay.

3 A If it's a patent in ophthalmology or
4 related to ophthalmology I feel very comfortable
5 reading it and understanding it.

6 Q Very good. Thank you.

7 Are you an expert in clinical testing?

8 A No, I'm not.

9 Q Have you ever conducted any clinical
10 testing with a pharmaceutical product?

11 A No, I don't believe I have.

12 Q And so that would include not having
13 conducted any testing, clinical testing with an
14 ophthalmic product, correct?

15 A Correct.

16 Q In connection with your opinions in
17 this matter, did you conduct any testing comparing a
18 bromfenac -- comparing bromfenac-containing
19 compositions?

20 A No, I did not.

21 Q And you understand that Prolensa is a
22 bromfenac-containing composition, correct?

23 A Yes.

24 Q And you understand that Xibrom is a
25 bromfenac-containing composition?

1 A Yes.

2 Q And you also understand that Bromday is
3 a bromfenac-containing composition, correct?

4 A Yes.

5 Q You did not conduct any comparative
6 testing between Prolensa and Bromday, correct?

7 A That's correct, I did not.

8 Q Nor did you conduct any comparative
9 testing between Prolensa and Xibrom, correct?

10 A I did not.

11 Q Were you instructed not to conduct any
12 comparative testing among bromfenac-containing
13 compositions?

14 MR. JANUSZ: I'll caution the witness
15 not to reveal the substance of any
16 communication with counsel. I think that --
17 let me just read the question.

18 MR. DINER: I'll agree that if he
19 answers it yes or no it's not a waiver of any
20 privilege.

21 MR. JANUSZ: That's fine.

22 THE WITNESS: I'm sorry, could you
23 repeat that question.

24 BY MR. DINER:

25 Q Were you instructed not to conduct any

1 comparative testing among bromfenac-containing
2 compositions?

3 A No.

4 Q Would you please turn to page 3 of
5 Cykiert Exhibit 1, which is your expert report.

6 I'd like to refer you to the bottom of
7 the prior testimony section.

8 Do you see that?

9 A Yes.

10 Q Go to the first bullet point. I think
11 it indicates cases in the last five years in which
12 you have provided expert testimony; is that correct?

13 A Yes.

14 Q The first case in the first bullet
15 point, Chery versus Malik.

16 Do you see that?

17 A Yes.

18 Q What was your role in that case?

19 A I believe that was a medical
20 malpractice case.

21 Q And what was your role?

22 A I was an expert.

23 Q And what was your role as an expert in
24 that case?

25 A I don't remember the details of that

1 case right now.

2 Q Do you remember, generally, what kind
3 of expert opinions you provided in the case as a
4 general matter?

5 A That case I don't recall.

6 Q Thank you. That was in 2015, correct?

7 A Right.

8 Q Okay. How about the next case,
9 Gallimore versus Allison. What was that case about?

10 A That's a medical malpractice case as
11 well.

12 Q And you appeared as an expert in that
13 case?

14 A I don't think I appeared in that.

15 Q You provided testimony in that case,
16 correct?

17 A Yes.

18 Q In what capacity?

19 A As a defense expert.

20 Q Did you provide testimony at trial?

21 A No, not at trial.

22 Q Did you provide deposition testimony?

23 A No.

24 Q So what kind of prior testimony did you
25 offer in this case that led you to list this in this

1 category?

2 A I don't know exactly the name, but it's
3 a court document that's submitted to the Court. It
4 might be perhaps a summary judgment document or some
5 attestation type of document. I don't recall the
6 details of it.

7 Q Such as a Declaration perhaps?

8 A Right, a Declaration, correct.

9 Q Okay. And did you say that this case
10 dealt with medical malpractice as well?

11 A Yes.

12 Q Okay. There are six more cases on your
13 list, beyond the Gallimore versus Allison case.
14 Were all of those medical malpractice cases?

15 A Yes.

16 Q And let's just go to this Cifuentes
17 versus Staciu case. Do you recall what your role
18 was in that case?

19 A Yes, that one I appeared in court.

20 Q And were you testifying in court as an
21 expert?

22 A Yes.

23 Q And what generally was the subject
24 matter of your testimony?

25 A It was a complication during cataract

1 surgery.

2 Q Okay. And which side in the litigation
3 did you represent?

4 A I represented the doctor.

5 Q So you were offering your opinions in
6 defense of a malpractice suit brought against the
7 doctor?

8 A Yes.

9 Q Dr. Cykiert, is CME an abbreviation for
10 cystoid macular edema?

11 A Yes, it is.

12 Q If I refer to cystoid macular edema
13 today as CME, will you understand what I mean?

14 A Yes.

15 Q And that will be easy for both of us, I
16 presume?

17 A Yes, that's a nice abbreviation.

18 Q Is it correct that Prolensa is approved
19 for post-operative treatment of inflammation and
20 pain after cataract surgery?

21 A Yes.

22 Q Now, Prolensa is not approved for
23 treatment of CME, correct?

24 A That's not the official approval,
25 that's correct.

1 Q It doesn't have any approval, official
2 or otherwise for CME, correct?

3 MR. JANUSZ: Objection, vague.

4 THE WITNESS: Well, approval by whom?

5 BY MR. DINER:

6 Q By the FDA.

7 A Not by the FDA, no.

8 Q Does it have approval by anyone for the
9 treatment of CME?

10 A It has approval by many doctors who use
11 it for that purpose off label, which is perfectly
12 acceptable.

13 Q Administering compounds off label is
14 acceptable?

15 A Yes.

16 Q Is that what you're saying?

17 A Right.

18 Q What is your basis for that?

19 MR. JANUSZ: Objection, calls for
20 speculation.

21 THE WITNESS: That's commonly
22 understood that certain medications have uses
23 other than the official FDA approval.

24 BY MR. DINER:

25 Q And do you often administer ophthalmics

1 off label?

2 A It depends on what you mean by "often."
3 It depends on the ophthalmic, it depends on the
4 patient's condition. It depends on numerous
5 factors.

6 Q Have you administered ophthalmics off
7 label before?

8 A Yes, I have, as have thousands of other
9 ophthalmologists every day.

10 Q Are you familiar with the ophthalmic
11 Voltaren?

12 A Yes.

13 Q Is it approved by the FDA for the
14 treatment of CME?

15 A No, it's not.

16 Q In fact, there are no ophthalmic NSAIDs
17 that are approved by the FDA for the treatment of
18 CME, correct?

19 A Correct.

20 Q And there are no ophthalmic NSAIDs
21 approved by the FDA for the prevention or
22 prophylaxis of CME, correct?

23 A Correct.

24 Q Do you draw a distinction between
25 treatment in prophylaxis with respect to CME?

1 A Yes, there is a distinction.

2 Q What is it?

3 A Well, broadly, prevention means putting
4 a patient on a drug to try to prevent a condition
5 from occurring. And treatment is the condition or
6 disease already exists and you're using a drug to
7 try to cure or treat that disease or condition.

8 Q And the explanation you just gave as
9 between prophylaxis and treatment would similarly
10 apply to the prophylaxis and treatment of CME?

11 A That's correct.

12 Q Other than for the treatment
13 post-operatively of inflammation and pain after
14 cataract surgery, Prolensa is not approved for
15 anything else, correct?

16 A I'm not aware of anything but those two
17 things you mentioned.

18 Q Now, the approved indication on the
19 Prolensa label is not limited to cases where the
20 patient is unable to receive corticosteroid
21 treatment due to allergy, correct?

22 A Could you repeat that again?

23 Q Sure. The approved indication on the
24 Prolensa label is not limited to cases where the
25 patient is unable to receive corticosteroid

1 treatment due to allergy; is that correct?

2 A That's correct.

3 Q And the approved indication on the
4 Prolensa label is not limited to cases where the
5 patient has diabetes, correct?

6 A That's correct.

7 Q Are you familiar with the term "sulfite
8 sensitivity" with regard to ophthalmics?

9 A Yes.

10 Q Are asthmatics a class of people that
11 could have sulfite sensitivity?

12 A Asthmatics can and so can anybody else.
13 Some people are allergic to sulfites.

14 Q When someone is allergic to sulfites,
15 how does that manifest itself clinically?

16 A Just like any allergy, there are
17 various manifestations. Sometimes it could just be
18 itching of the skin. Some people can get hives.
19 Some people can get respiratory problems, they have
20 difficulty breathing, and in the most severe cases
21 they can have what's called anaphylaxis, which is a
22 severe life-threatening reaction where they can't
23 breathe, their blood pressure drops, their heart may
24 even stop. So there's a broad spectrum of allergic
25 reactions that can occur with sulfite.

1 Q And in the context of ophthalmics, this
2 issue of sulfite sensitivity, was that known for
3 sometime?

4 MR. JANUSZ: I'll just object to the
5 scope. Go ahead.

6 BY MR. DINER:

7 Q You can answer.

8 A That's been known for a while. Several
9 drops contain that, and we know some patients have
10 sulfite allergies.

11 Q Was it known prior to 2003 that
12 there -- some people who were sulfite sensitive in
13 the context of taking ophthalmics, for example?

14 MR. JANUSZ: Same objection.

15 THE WITNESS: I can't tell you
16 specifically what year the sulfite allergy
17 issue came up with in ophthalmics. I'm not
18 sure why you picked 2003, but I couldn't tell
19 you exactly what year, so I can't answer that
20 accurately.

21 MR. DINER: I'd like to mark the next
22 document, please.

23 (Adverse reactions to sulfites article
24 was marked Cykiert-2 for identification.)

25 THE WITNESS: Thanks.

1 BY MR. DINER:

2 Q Now, Dr. Cykiert, the court reporter
3 has just handed you a publication to Yang, et al.,
4 and it is entitled, Adverse Reactions to Sulfites.
5 It's a couple-page document. You can take a look at
6 it and let me know when you're ready and I'll ask
7 you some questions.

8 A Do you want me to read the entire
9 document before you ask me questions?

10 Q Well, how about I ask you some
11 questions, and to the extent you need to refer to
12 the document in greater detail you should feel free
13 to do so.

14 A Okay.

15 Q Now, just a few moments ago you were
16 talking about anaphylactic shock, I believe.

17 Do you recall that?

18 A Yes.

19 Q You see in that first paragraph of this
20 article on the first page, left-hand column, it says
21 -- second sentence, In the United States more than
22 250 cases of sulfite-related adverse reactions,
23 including anaphylactic shock, asthmatic attacks,
24 urticaria and angioedema, nausea, abdominal pain and
25 diarrhea, seizures and death have been reported.

1 Do you see that passage?

2 A Yes.

3 MR. JANUSZ: Object to scope here as
4 well.

5 BY MR. DINER:

6 Q Now, in the context of what we were
7 talking before about sulfite sensitivity and some of
8 the manifestations of sulfite sensitivity, does the
9 list that I just read include some of the
10 manifestations that you were aware of for sulfite
11 sensitivity?

12 MR. JANUSZ: Same objections.

13 THE WITNESS: I mentioned earlier all
14 these things that are listed in this article
15 before I saw the article.

16 BY MR. DINER:

17 Q Okay. And at the bottom of the first
18 page it indicates that this article was published on
19 November 1, 1985; is that correct?

20 A Right.

21 Q Uh-huh. And if you look at the
22 paragraph bridging the first and second page --
23 sorry, strike that.

24 If you look at the second column of the
25 first page, you see where it identifies six

1 sulfiting agents?

2 MR. JANUSZ: Same objection.

3 THE WITNESS: What do you mean by
4 sulfiting --

5 BY MR. DINER:

6 Q Let me refer you to the second column,
7 second full paragraph on the first page. There it
8 talks about a number of different sulfites
9 identified in various products.

10 Do you see that, the different
11 sulfites?

12 A Yes.

13 Q Okay. And sodium sulfite is listed
14 there, correct?

15 MR. JANUSZ: Same objection.

16 THE WITNESS: Where is sodium sulfite
17 listed?

18 BY MR. DINER:

19 Q The fifth line down.

20 A Could you point to the paragraph? I'm
21 not sure --

22 Q Sure.

23 A That paragraph.

24 Q Yeah.

25 A Yeah. It says six sulfiting agents.

1 Q And one of the six sulfiting agents
2 includes sodium sulfite, correct?

3 MR. JANUSZ: Same objection.

4 THE WITNESS: Yes, that is listed
5 there.

6 BY MR. DINER:

7 Q And you're familiar with the ophthalmic
8 Bronuck, correct?

9 A Yes, I am.

10 Q And Bronuck contains sodium sulfite; is
11 that correct?

12 MR. JANUSZ: Same objection.

13 THE WITNESS: I'd have to see the
14 packet insert to be sure.

15 (Bronuck Ophthalmic Solution document
16 PROL0333509 - PROL0333513, was marked
17 Cykiert-3 for identification.)

18 BY MR. DINER:

19 Q Now, Dr. Cykiert, the court reporter
20 has just handed you a document marked as Cykiert
21 Exhibit 3, bearing Bates numbers PROL033509 through
22 513. Following up on my last question and your last
23 answer, I would direct you to the second page of
24 Cykiert Exhibit 3, the left-hand column at the top.
25 You see the box that identifies the composition of

1 Bronuck?

2 A Yes.

3 Q Okay. And back up a minute. Would you
4 agree that this translation appears to be the
5 package insert information concerning the ophthalmic
6 formulation known as Bronuck?

7 A Are you asking me to vouch that the
8 translation is correct?

9 Q No.

10 A Oh.

11 Q I'm asking you to let me know if you
12 agree that this appears -- that Cykiert Exhibit 3
13 appears to be the prescribing information for
14 Bronuck.

15 A Yes.

16 Q Okay. And back to the left-hand column
17 of the second page, do you see that box towards the
18 top identifying the ingredients in Bronuck?

19 A Yes.

20 Q Do you see next to additives a list of
21 additives in Bronuck?

22 A Yes.

23 Q Do you see that it -- strike that.

24 Bronuck, according to this document,
25 contains sodium sulfite, correct?

1 MR. JANUSZ: Objection, scope.

2 THE WITNESS: It says dry sodium
3 sulfite.

4 BY MR. DINER:

5 Q Okay. Can you go back to Cykiert
6 Exhibit 2, please? Now, Cykiert Exhibit 2
7 identifies that sulfites, such as sodium sulfite,
8 can be used in ophthalmics. And if it will help you
9 to answer the question I'll refer you to the bottom
10 of page 1 and the paragraph bridging the right-hand
11 column to the top of the second page of Cykiert
12 Exhibit 2.

13 MR. JANUSZ: Objection, scope.

14 THE WITNESS: Yes, I see that.

15 BY MR. DINER:

16 Q Okay. And it indicates that -- strike
17 that.

18 So this document indicates that it was
19 known in November of 1985 that adverse reactions to
20 sulfites, such as sodium sulfite, could occur in
21 ophthalmic eye drops, correct?

22 MR. JANUSZ: Objection, scope and to
23 the extent it mischaracterizes the document.

24 THE WITNESS: Yeah, I didn't read the
25 whole document, but it says in the first

1 paragraph that you mentioned that you can have
2 reactions to it, which we know, we discussed.
3 And then later it mentions that it's present
4 in eye drops. I don't know if there's a
5 discussion about the risks of eye drops, which
6 you just said, so I'd have to extensively read
7 this document and see if it says that.
8 Otherwise I'm reaching for conclusions that
9 may not be there.

10 BY MR. DINER:

11 Q Okay. But this document would
12 establish that there was knowledge of sulfur
13 sensitivity with regard to ophthalmics prior to
14 2003, correct?

15 MR. JANUSZ: Same objections.

16 THE WITNESS: No, what you just said is
17 wrong. You said sulfa sensitivity. This is
18 sulfites.

19 BY MR. DINER:

20 Q Oh, pardon me. Thank you very much.
21 So to rephrase the question, this document
22 establishes that it was known in the art prior to
23 2003 that ophthalmics containing sodium sulfite
24 could have sulfite sensitivity issues, correct?

25 MR. JANUSZ: Same objections.

1 THE WITNESS: Again, you're asking me
2 to reach a conclusion by reading two separate
3 paragraphs that are unconnected, so I think
4 that would be a far reach. If you want me to
5 read the document, I can read it and then give
6 you my interpretation of it. But --

7 BY MR. DINER:

8 Q Well, let's try it from this angle.
9 Sulfur sensitivity was something that was known in
10 the art prior to 2003, correct?

11 MR. JANUSZ: Same objections.

12 THE WITNESS: You again said sulfa, and
13 there's a difference between sulfa and
14 sulfite. Can I assume when you say "sulfa"
15 you mean sulfite?

16 BY MR. DINER:

17 Q I'll restate the question. Thank you,
18 Doctor. Sulfite sensitivity was something that was
19 known in the art prior to 2003, correct?

20 MR. JANUSZ: Same objections, asked and
21 answered.

22 THE WITNESS: This article is 1985. It
23 mentioned adverse reactions to sulfites, it's
24 in a journal that I'm not familiar with, but I
25 assume it was in a journal that people read,

1 so I assume it was known about at that time.

2 BY MR. DINER:

3 Q Thank you. You can put those aside
4 now.

5 A Thanks.

6 Q You're welcome.

7 Okay. Let's go back to Prolensa.

8 Shall we?

9 A Sure.

10 Q Okay. Back to the approved indication
11 for Prolensa. Now, the approved indication on the
12 Prolensa label is not limited to cases where the
13 patient has a diagnosis of a retinal disorder,
14 correct?

15 A Correct.

16 Q And an FDA-approved indication for a
17 drug is a clinically-verified reason for prescribing
18 that drug, correct?

19 MR. JANUSZ: Objection, vague.

20 THE WITNESS: Not necessarily. It just
21 says that's one of the uses. It doesn't mean
22 you have to use it.

23 BY MR. DINER:

24 Q My question is a little different. By
25 virtue of the fact that the drug is FDA approved,

1 that approval is based on the submission of clinical
2 studies, correct?

3 A To the FDA?

4 Q Correct.

5 A Right.

6 Q And so is it fair to say, then, that an
7 FDA-approved indication for a drug is clinically --
8 is a clinically verified reason for prescribing that
9 drug?

10 MR. JANUSZ: Objection, vague.

11 THE WITNESS: I think you're saying it
12 incorrectly.

13 BY MR. DINER:

14 Q Why is that?

15 A From what I'm understanding that you're
16 saying is that if the FDA approves a drug for
17 treating one and two, that means for disease one or
18 disease two, if you have a patient with disease one
19 and two you have to use that drug. That's my
20 understanding of what you said. That's not the
21 case. That's up to the physician to determine,
22 depending on numerous factors whether, indeed, the
23 physician should use that drug to treat that
24 condition in that patient at that time.

25 Q When the FDA approves a drug for use,

1 that approval was based on the fact that it would be
2 clinically acceptable for doctors to prescribe that
3 drug to a patient, correct?

4 A Yes.

5 Q Okay. So is the treatment of
6 post-operative inflammation and reduction of ocular
7 pain in patients who have undergone cataract surgery
8 a clinically-verified reason for prescribing
9 Prolensa?

10 MR. JANUSZ: Objection, vague.

11 THE WITNESS: It is, but there are
12 other factors that come into play to determine
13 if you should use it in a patient.

14 BY MR. DINER:

15 Q Okay. But the fact that the FDA has
16 approved Prolensa means that you could use it in a
17 patient, correct?

18 A Yes.

19 Q In a clinical setting, correct?

20 A Yes.

21 MR. JANUSZ: I'll object to vague, to
22 the last question.

23 BY MR. DINER:

24 Q Now, when cataract surgery is
25 performed, Dr. Cykiert, an incision is made in the

1 eye, correct?

2 A Yes.

3 Q And there is typically post-operative
4 inflammation associated with that surgical incision,
5 correct?

6 A Yes.

7 Q There's also post-operative pain
8 associated with that surgical incision, correct?

9 A Not always.

10 Q But typically there can be, correct?

11 A I would say in a minority of patients.

12 Q But there can be post-operative pain
13 associated with the surgical incision as part of
14 cataract surgery, correct?

15 A There can be.

16 Q Okay. Now, inflammation in a patient
17 post-cataract surgery would require medical
18 treatment, correct?

19 A Yes.

20 Q And pain in a patient after cataract
21 surgery would require medical treatment as well,
22 correct?

23 MR. JANUSZ: Objection, vague.

24 THE WITNESS: Yes.

25

1 BY MR. DINER:

2 Q Inflammation is a major factor in the
3 development of CME following cataract surgery,
4 correct?

5 A The current thinking is that that is
6 the case.

7 Q And Prolensa is indicated for treatment
8 of both operative inflammation after cataract
9 surgery, correct?

10 A Yes.

11 Q Not treating inflammation can increase
12 the chances of development of CME; is that correct?

13 MR. JANUSZ: Objection.

14 THE WITNESS: It's variable from
15 patient to patient.

16 BY MR. DINER:

17 Q But in some patients it can occur that
18 CME develops if the inflammation is not treated,
19 correct?

20 A In some patients, but not all patients.

21 Q CME can lead to blindness in some
22 cases, correct?

23 A You have to explain what you mean by
24 blindness. You have to define blindness. Blindness
25 is not a specific word or term.

1 Q Okay. It's a term of art, blindness;
2 is that correct?

3 MR. JANUSZ: Objection, vague.

4 THE WITNESS: I'm not sure what you
5 mean by a term of art.

6 BY MR. DINER:

7 Q You have an understanding of blindness,
8 correct?

9 A I do.

10 Q Okay. Let's use your definition of
11 blindness. Can CME lead to blindness?

12 A No. According to my definition. But
13 you didn't ask me what my definition is.

14 Q So tell me your definition.

15 A Blindness, from our perspective as
16 ophthalmologists, is total loss of vision in an eye.
17 CME doesn't cause that.

18 Q Okay. Could CME cause something less
19 than total blindness?

20 A Yes.

21 Q And what can it cause that would be
22 something less than total blindness?

23 A It can cause mild blurry vision or
24 moderate blurry vision.

25 Q Can it cause severe blurry vision?

1 A In rare cases it can.

2 Q And in those cases where it can cause
3 severe blurry vision, would you consider that a
4 severe complication?

5 A Yes.

6 Q Now, Dr. Cykiert, are corticosteroids
7 and NSAIDs two different types of drugs?

8 MR. JANUSZ: Object to form.

9 THE WITNESS: Yes, they are different.

10 BY MR. DINER:

11 Q And do they act by different
12 mechanisms?

13 MR. JANUSZ: Same objection.

14 THE WITNESS: Yes, they have different
15 mechanisms.

16 BY MR. DINER:

17 Q And what are the differences in their
18 mechanisms?

19 A Well, that's a complicated question and
20 answer, but, in general, the steroids inhibit
21 inflammation by inhibiting what's called the COX-2
22 pathway, whereas I think you asked NSAIDs is the
23 other one, they inhibit COX-1 and COX-2 pathways.

24 Q And so these drugs inhibiting different
25 mechanisms can have a different side effect profile,

1 correct?

2 MR. JANUSZ: Object to form.

3 THE WITNESS: Yes, they can.

4 BY MR. DINER:

5 Q Now, we spoke a moment ago about blurry
6 vision. Do you recall that discussion?

7 A Yes.

8 Q So in the context of the next few
9 questions I'm going to ask, I'm going to ask you to
10 be thinking about that concept of blurry vision as
11 we discussed before. Rehabilitation of vision in
12 the days immediately after cataract surgery is an
13 important clinical measure; is that correct?

14 MR. JANUSZ: Objection, vague.

15 THE WITNESS: It's one of the important
16 clinical measures.

17 BY MR. DINER:

18 Q Okay. What are some of the other
19 important clinical measures?

20 MR. JANUSZ: Same objection.

21 THE WITNESS: There are things like
22 preventing infection, making sure the incision
23 is healing properly, making sure the
24 intraocular lens implant is in good position,
25 making sure the anterior chamber is deep.

1 There are numerous factors. Those are some of
2 the major ones.

3 BY MR. DINER:

4 Q The time to heal -- strike that.
5 The time to obtain visual
6 rehabilitation following cataract surgery can impact
7 patient satisfaction with the surgery, correct?

8 A It varies from patient to patient
9 actually.

10 Q So can you give me some examples in
11 which it can, or visual rehabilitation can impact
12 patient satisfaction with the surgery?

13 A Sure. If you start somebody with a
14 severe cataract where they can't even see the eye
15 chart, you operate on them, and the next day they
16 can read the eye chart, to them that's an
17 incredible, remarkable improvement even though their
18 vision may not be great the next day, they think
19 it's incredible.

20 On the other hand, if you start with
21 somebody who's got only a moderate cataract with
22 mild blurring, if they don't have 20/20 vision the
23 next day they may be upset because I just had the
24 surgery, I'm not a perfect 20/20 yet. So we
25 basically educate them, let them know that the time

1 to get perfect vision is very variable from patient
2 to patient. So a lot of it has to do really with
3 patient expectations. Some people think the surgery
4 is almost magical and you have perfect vision the
5 next day. Other patients understand that with
6 surgery there may be time that it takes to get
7 better. It could be anywhere from days to weeks or
8 months. So it's a complicated question and answer
9 because there are numerous extrinsic factors, and
10 it's extremely variable from patient to patient.

11 Q With regard to both subgroups of
12 patients that you just described, when they get
13 their vision back, that impacts favorably their
14 quality of life, would you agree?

15 MR. JANUSZ: Objection, vague.

16 THE WITNESS: When they get their
17 vision back is, as he said, a very vague term.
18 What do you mean by getting your vision back?
19 It depends what your vision was. It depends
20 where you are. It depends what your needs
21 are. It depends if you're going back to work
22 the next day. It depends if you're retired.
23 It depends how old you are. It depends on the
24 vision in the other eye. I could go on for
25 another hour or two, but I don't think you

1 want me to.

2 BY MR. DINER:

3 Q How about if the person needs his
4 vision to drive, okay, with that qualification, when
5 that person gets his vision back, is that an
6 improvement in that person's quality of life?

7 A If the individual is unable to drive
8 because of poor vision and then after surgery they
9 achieve the vision that's required by law to drive
10 again, then, yes, they would be satisfied with that.

11 Q And that would be a positive effect on
12 their quality of life, correct?

13 A Yes.

14 Q Now, NSAIDs are effective in reducing
15 CME soon after surgery, correct?

16 MR. JANUSZ: Objection. Object to
17 form.

18 THE WITNESS: That's not necessarily
19 the case.

20 BY MR. DINER:

21 Q Some NSAIDs have been shown to be
22 effective in reducing CME soon after surgery,
23 correct?

24 MR. JANUSZ: Objection, vague.

25 THE WITNESS: Shown by who?

1 BY MR. DINER:

2 Q The authors of the article that you
3 cited in your expert report. The name is Kim, et
4 al.

5 A If you're referring to a specific
6 article, if I could look at it, I'd appreciate it.

7 Q Sure.

8 (Topical Nonsteroidal Anti-inflammatory
9 Drugs and Cataract Surgery Article, 2159 -
10 2168, was marked Cykiert-4 for
11 identification.)

12 BY MR. DINER:

13 Q Dr. Cykiert, the court reporter has
14 just handed you what has been marked as Cykiert
15 Exhibit 4. Cykiert Exhibit 4 is -- appears to be an
16 article from the Ophthalmic Technology Assessment or
17 from the American Academy of Ophthalmology. It is
18 entitled, Topical Nonsteroidal Anti-inflammatory
19 Drugs and Cataract Surgery. A report by the
20 American Academy of Ophthalmology.

21 Now, Dr. Cykiert, have you seen this
22 article before?

23 A Yes, I have.

24 Q And is this an article that you rely
25 on -- cite and rely on in your expert report?

1 A Yes, I did.

2 Q Okay. And so you reviewed this
3 document as part of providing your opinions in your
4 expert report, correct?

5 A Yes.

6 Q Okay. I'd like to refer you to the
7 first page of this document, Cykiert Exhibit 4, in
8 the section entitled Results.

9 Do you see that?

10 A Yes.

11 Q Can you read the very first sentence of
12 that subsection into the record, please?

13 A Sure. Non-steroidal anti-inflammatory
14 drug therapy was effective in reducing CME detected
15 by angiography or optical coherence tomography, OCT,
16 and may increase the speed of visual recovery after
17 surgery when compared directly with placebo or
18 topical corticosteroid formulations with limited
19 intraocular penetration.

20 Q So the authors of this article, Cykiert
21 Exhibit 4, concluded that NSAIDs are effective in
22 reducing CME soon after surgery when compared to
23 placebo or topical corticosteroid formulations,
24 correct?

25 MR. JANUSZ: Object to the extent it

1 mischaracterizes the document.

2 THE WITNESS: Yeah, what you just said
3 is totally wrong.

4 BY MR. DINER:

5 Q What's wrong with it?

6 A Because that's not what it says, and
7 I'll point it out to you exactly. It's effective in
8 reducing CME detected by angiography or OCT. That's
9 a very subtle testing of CME, which often is
10 clinically insignificant. So the CME detected by
11 those two tests is not necessarily significant. In
12 fact, in most cases it's not. And you missed the
13 word and "may" increase the speed. "May." It
14 doesn't say it will increase, it says may. May
15 means maybe it does, maybe it doesn't. And when
16 compared directly with placebo. Well, if you
17 compare anything to placebo it might be better
18 placebo because placebo is nothing. So maybe it's
19 better than placebo. To me that's not a big deal.
20 Or topical corticosteroid formulations with limited
21 intraocular penetration. Well, if you take a
22 corticosteroid that doesn't penetrate the eye well
23 that's almost like placebo. It doesn't have an
24 effect because you need intraocular penetration. So
25 saying that it may be better if you're testing OCT

1 or angiography means it probably isn't, and if it
2 increases the speed of visual recovery compared to
3 placebo, that doesn't mean anything, and if you're
4 comparing to it a steroid that doesn't penetrate the
5 eye, it's better than that. That doesn't mean
6 anything. So basically what they're saying here is
7 that it has no significant clinical effect. And if
8 you read their conclusion section it says that very
9 clearly.

10 Q And so you're relying on this document
11 in support of your opinions, correct?

12 A This is one of the things. This isn't
13 the sole thing, but this is an important document.
14 It's a report by the American Academy of
15 Ophthalmology, which is the leading ophthalmology
16 association in the USA and the world. And when they
17 come out with a report, it's something that is very
18 researched in a rigorous way by a panel of experts
19 in the field. So this is an extremely reliable
20 document.

21 Q And -- but they're relying on an
22 extremely insensitive method for detecting CME?

23 A No, that's not what the article says.

24 Q But that's what you said, though.

25 A No, no. You're putting words in my

1 mouth. That is not what I said. What I said, and
2 I'll say it again, is that it may be helpful if
3 you're comparing it to this test which is not
4 clinically very relevant, and it may be helpful if
5 you're comparing it to placebo, and it may be
6 helpful if you're comparing it to a weak steroid.
7 That's what they're saying.

8 Q So the clinical test that they're
9 relying on may not be clinically relevant; is that
10 correct?

11 A The OCT testing and fluorescein
12 angiography testing showing CME is often not
13 clinically relevant because it will pick up
14 extremely subtle CME that is not clinically
15 relevant. I'll give you an example. This table
16 appears pretty smooth to you, right?

17 Q Okay.

18 A Okay. The table is very smooth. If I
19 magnify the surface of this table with a hundred
20 power microscope it will look like Mount Everest or
21 the Himalayas or the Rocky Mountains, because under
22 high magnification you will see tiny bumps and
23 crevices and it will look unsmooth. However, that's
24 not relevant because this table is very smooth. You
25 can put your paper on it, you can write on it. If

1 you pass your hand on it, it's very smooth.

2 So when you do OCT testing you can pick
3 up what's called subclinical CME, which means it's
4 not relevant to the patient or doctor. If you do
5 fluorescein angiography, you can pick up subclinical
6 CME, which is not relevant to the patient or doctor.
7 What we're talking about really is clinical
8 significant CME where the patient has blurry vision
9 and the doctor can detect it. So what this
10 basically says is there's no benefit that's been
11 shown or proven for clinically significant CME.

12 Q But this very reputable journal that
13 you referred to still relied on the OCT in reaching
14 it's conclusion that non-steroidal anti-inflammatory
15 drugs may be effective in reducing CME compared to
16 placebo and topical steroids with limited
17 intraocular penetration, correct?

18 MR. JANUSZ: Object to form.

19 THE WITNESS: No, you're
20 misinterpreting the document and what it says.
21 If you read the conclusion section, which if
22 you'd like me to read in, it clearly explains
23 what they're saying. So your interpretation
24 of that is incorrect.

25 BY MR. DINER:

1 Q Now, you referred to the use of the
2 word "may" before in that sentence that we've been
3 discussing --

4 A Correct.

5 Q -- and you said that your understanding
6 is that NSAIDs may, or they may not, based on this
7 sentence, reduce CME, as determined by OCT compared
8 to a placebo or the corticosteroids that are
9 identified there; is that correct?

10 A Yeah. It says may.

11 Q Okay. And your interpretation of "may"
12 is what again in the context of this sentence?

13 A Maybe yes, maybe no. We know what may
14 means.

15 Q Okay. So in your view they're
16 equivocating, to some extent; is that correct?

17 MR. JANUSZ: Objection, calls for
18 speculation.

19 THE WITNESS: No, not at all. Again,
20 you're misinterpreting the article. If you
21 let me read the conclusion section it will
22 really verify it so we all can understand it
23 clearly.

24 BY MR. DINER:

25 Q Well, let's go to 2165 of Cykiert

1 Exhibit 4 under the conclusions. And there, the
2 left-hand column, please, Dr. Cykiert. You see it?

3 A Yes. Thanks.

4 Q There it says that NSAIDs clearly are
5 effective in reducing the incidence of angiographic
6 or OCT-based CME in hastening visual recovery in the
7 short term (less than three months) when compared
8 with placebo and topical corticosteroid formulations
9 that have poor corneal penetration, correct?

10 A Right.

11 Q It didn't use the word "may" in that
12 sentence, did it?

13 MR. JANUSZ: Objection,
14 mischaracterizes the document.

15 THE WITNESS: Why don't you read what
16 it says after the comma.

17 BY MR. DINER:

18 Q I'm just asking you.

19 A Well, you're taking a fragment of a
20 sentence to try to prove a point, which is
21 incorrect, not valid.

22 Q But what I'm asking you specifically
23 there is that's an affirmative statement using the
24 affirmative form of the verb "to be," in this case
25 the word "are" to say that they are effective under

1 these conditions, correct?

2 MR. JANUSZ: Same objection.

3 THE WITNESS: They left out the word
4 "may" here, for whatever reason, but again
5 I'll bring to your attention that in reducing
6 incidence of angiographic or OCT-based CME,
7 that's what's called subclinical CME, that's
8 me magnifying the surface of this table 100
9 power and showing you it looks like the
10 Himalayas or Rocky Mountains, when, in fact,
11 it's perfectly smooth and flat. And again,
12 they're saying compared to placebo, compared
13 to nothing, okay. Compared to a steroid
14 that's weak, okay. But it's not clinical
15 significant CME. That's what they're saying,
16 it's effective for clinically insignificant
17 CME. That's what they're saying here.

18 BY MR. DINER:

19 Q When a product is approved by the FDA
20 for marketing, it can be approved on its basis of
21 efficacy and safety versus placebo, correct?

22 A Could you repeat that?

23 Q When a product is approved by the FDA
24 for marketing, it can be approved on the basis of
25 that product's efficacy and safety versus placebo,

1 correct?

2 A That's correct.

3 Q Okay.

4 A But you're mixing two things, because
5 it's approved for pain and inflammation. This
6 article here deals with CME, which is not identical
7 to pain and inflammation. So you're making a side
8 point, but it's not valid for what we just
9 discussed.

10 Q You talked about this as being
11 subclinical CME, correct?

12 A Right.

13 Q But it's still CME, nonetheless,
14 correct?

15 MR. JANUSZ: Objection. Object to
16 form.

17 THE WITNESS: There's a difference
18 between CME, that's clinical and subclinical
19 CME. Now, to you it may seem like it's the
20 same thing, it's CME, CME. But to
21 ophthalmologists it's totally different. And
22 to patients it's totally different, because I
23 can do -- I could take 100 post-operative
24 cataract patients who have 20/20 vision, yet
25 if I do fluorescein angiography or OCT on

1 them, maybe 30 or 40 percent will have an
2 abnormality of that. So they have what's
3 called subclinical CME. But you know what,
4 those patients are thrilled because they have
5 20/20 vision. They don't know they have
6 subclinical CME, only the ophthalmologist who
7 does those tests knows it, but they're
8 clinically insignificant.

9 BY MR. DINER:

10 Q But those patients that are nonetheless
11 thrilled that their vision has improved, even though
12 they may have had subclinical CME, correct?

13 MR. JANUSZ: Objection,
14 mischaracterization.

15 THE WITNESS: I don't understand.
16 You're summarizing what I just said?

17 BY MR. DINER:

18 Q Yes.

19 A I don't know if your summary is
20 accurate. I think what I said stands for itself.

21 Q Let me ask you: You said there may be
22 patients who have subclinical CME, correct?

23 A Correct.

24 Q And they may have their subclinical CME
25 treated in a way that they are satisfied with,

1 correct?

2 MR. JANUSZ: Objection,
3 mischaracterizes prior testimony.

4 THE WITNESS: There's no reason to
5 treat subclinical CME. And so I can't answer
6 your question. Why would you treat something
7 that's subclinical?

8 BY MR. DINER:

9 Q Well, I'm just going on what you said a
10 moment ago. You said that someone with subclinical
11 CME may be thrilled to have their vision back,
12 correct?

13 MR. JANUSZ: Same objection.

14 THE WITNESS: Right.

15 BY MR. DINER:

16 Q Okay. So then that person with
17 subclinical CME who is thrilled to have their vision
18 back received the benefit from whatever treatment
19 that person received in receiving back their vision,
20 correct?

21 MR. JANUSZ: Object to form.

22 THE WITNESS: Are you implying they're
23 on an NSAID, is that what you're saying?

24 BY MR. DINER:

25 Q No, I'm just saying generally?

1 A Well, in general, people are happy to
2 get their vision back.

3 Q And if they had subclinical CME and got
4 their vision back, they would be happy, correct?

5 A That's correct.

6 Q And that would be a benefit to them,
7 correct?

8 A That's correct.

9 Q Now, Cykiert Exhibit 4 recognizes the
10 benefits, even in the short term, soon after surgery
11 in administering NSAIDs to reduce CME, correct?

12 MR. JANUSZ: Objection,
13 mischaracterization.

14 THE WITNESS: No, that's incorrect. We
15 just went over that. It's subclinical CME.
16 And if you read the paragraph it's very clear
17 after the comma. There is no Level I evidence
18 to suggest that prophylactic use of NSAIDs
19 reduces longer term, greater than three months
20 vision loss from CME after cataract surgery.
21 The body of Level II evidence supports the
22 same conclusion. The claim made by several
23 authors that use of an NSAID and
24 corticosteroid is synergistic with the
25 implication that the combined effect of each

1 drug class exceeds the additive effect of each
2 drug is not supported by the literature. This
3 clinical impression of synergy remains
4 unproven and seems unlikely, given the
5 overlapping mechanisms of the drugs.

6 That really says it all.

7 BY MR. DINER:

8 Q We'll get to that actually, but I want
9 to go back to my question, which was slightly
10 different. So I'll articulate it again. Cykiert
11 example -- excuse me, strike that.

12 Cykiert Exhibit 4 recognizes the
13 benefits, even in the short term, soon after surgery
14 in administering NSAIDs to reduce what you call
15 subclinical CME, correct?

16 MR. JANUSZ: Same objection.

17 THE WITNESS: Only if you compare it to
18 placebo, nothing, or compare it to a weak
19 steroid, which is nothing. So yes, if you
20 compare the NSAID to zero it may be a little
21 bit better, but if you compare the NSAID to a
22 true steroid that is universally used by all
23 doctors who do cataract surgery, then it's
24 probably worthless, is what this article says
25 because there is no Level I or Level II

1 evidence.

2 BY MR. DINER:

3 Q There is also no Level I or Level II
4 evidence that steroids other than the ones talked
5 about here can reduce CME, correct?

6 A That's not the case at all.

7 Q It doesn't say that in this article,
8 does it?

9 A This article doesn't deal with
10 corticosteroids. This is an article about NSAIDs,
11 as the title says. There's endless documentation
12 that steroids are beneficial for the eye, a proper
13 steroid, not a weak steroid, after cataract surgery.

14 Q Okay. Beneficial for the eye for
15 treating inflammation, correct?

16 A Yes.

17 Q Okay. But this article that you
18 characterized as coming from a very reputable
19 journal in your field of medicine doesn't support
20 the fact that steroids can be used to reduce CME,
21 correct?

22 MR. JANUSZ: Object to form.

23 THE WITNESS: This article doesn't deal
24 with that subject, so I can't comment on that.
25 The article has nothing to do about that.

1 It's dealing with NSAIDs.

2 BY MR. DINER:

3 Q Now that we've established that NSAIDs
4 can reduce subclinical CME, let's talk about
5 Prolensa. Prolensa --

6 A I'm sorry to interrupt, but you said
7 something, we've established it. We haven't
8 established that. You maybe have established it, I
9 have not.

10 Q Okay.

11 A So you have to start that question a
12 little bit differently because I haven't established
13 it.

14 Q Okay. So let's start it this way.
15 With respect to what you called subclinical CME,
16 Cykiert Exhibit 4 recognizes the benefits in
17 administering NSAIDs to reduce what you call
18 subclinical CME, correct?

19 MR. JANUSZ: Objection,
20 mischaracterization.

21 THE WITNESS: You didn't finish the
22 sentence. You're taking half the thought
23 because you're leaving out the placebo or
24 poorly penetrating topical corticosteroids.
25 So you have to be complete in the question.

1 BY MR. DINER:

2 Q I will rearticulate the question. So
3 in the context of what you call subclinical CME,
4 Cykiert Exhibit 4 recognizes the benefits in
5 administering NSAIDs to reduce subclinical CME
6 compared to placebo and corticosteroid formulations
7 with limited intraocular penetration, correct?

8 MR. JANUSZ: Same objection.

9 THE WITNESS: Yes.

10 BY MR. DINER:

11 Q And Prolensa is indicated for treating
12 inflammation post-operatively, correct?

13 A Yes.

14 Q And so Prolensa, as an NCE formulation,
15 could also reduce subclinical CME as compared to
16 placebo and corticosteroids with limited intraocular
17 penetration, correct?

18 MR. JANUSZ: Objection, vague as to

19 NCE.

20 BY MR. DINER:

21 Q NSAIDs.

22 A Oh, I'm sorry. I heard NCE, also.

23 Q My apology. I will repeat the
24 question.

25 So Prolensa could -- strike that.

1 Prolensa is indicated for use in
2 treating post-operative inflammation, correct?

3 A Yes.

4 Q And so as an NSAID-containing
5 formulation, Prolensa could be used to reduce
6 subclinical CME as compared to placebo or
7 corticosteroids with limited ocular penetration,
8 correct?

9 MR. JANUSZ: Object to form.

10 THE WITNESS: That's what it says here,
11 but that's clinically irrelevant because we
12 all universally use steroids with good
13 penetration post-operatively after cataract
14 surgery. So it's basically a clinically
15 irrelevant fact. The only exception would be
16 in the incredibly rare exception where a
17 patient may have an allergy to corticosteroid
18 drops. Then you're left with an NSAID alone.
19 So maybe that's one out of tens of thousands
20 or hundreds of thousands of patients.

21 BY MR. DINER:

22 Q Okay. Let's go to paragraph 39 of your
23 report. And you can take a moment if you'd like to
24 read that paragraph just to refresh yourself on what
25 that paragraph says.

1 A Thank you. Okay, I read it.

2 Q Now, in paragraph 39 of your report you
3 cite to what has been marked as Cykiert Exhibit 4,
4 which I referred to as the Kim article. And in your
5 report you state that -- the second sentence --
6 Ophthalmologists have "reported the impression that
7 there is a pharmacologic drug synergy from the use
8 of both an NSAID and a corticosteroid" resulting
9 from the use of an NSAID post-operatively following
10 cataract surgery to prevent the development of CME.

11 Do you see that?

12 A Yes.

13 Q Okay. Now, the drug synergy that you
14 referred to, that would result from the use of an
15 NSAID and a corticosteroid together, correct?

16 MR. JANUSZ: Objection,
17 mischaracterization.

18 THE WITNESS: That's what synergy
19 means, when you use two things together and
20 you get an effect.

21 BY MR. DINER:

22 Q So just for the record, for synergy
23 there to be present it means that the combined
24 effect of the two drugs together exceeds the
25 additive effect of each drug alone. Is that

1 reasonable?

2 A That's a definition of synergy, but
3 that's not what this paragraph says.

4 Q Well, --

5 A Well, the keyword is, reported "the
6 impression." Maybe we can bold or underline the
7 word, the impression. So what happens is doctors
8 use two drugs and they get the impression, wow, you
9 know, maybe things are better with these two drugs.
10 But basically what this article, from the American
11 Academy of Ophthalmology says is that that's just an
12 impression. There's no Level I or Level II evidence
13 to document that or to prove that. That's just an
14 impression people have. People often get
15 impressions, but there's no proof of that in this
16 case.

17 Q So effectively there is no proof of
18 synergy of the two compounds working together to
19 obtain a synergistic result, correct?

20 A Right.

21 Q And there was no evidence of synergy
22 between those two compounds in preventing CME,
23 correct?

24 A Right.

25 Q So just to say that two drugs are not

1 synergistic doesn't mean that the drugs may not
2 individually be effective in treating CME, correct?

3 MR. JANUSZ: Objection, vague, calls
4 for speculation.

5 THE WITNESS: Yeah, synergy doesn't
6 break down that way. You're kind of going
7 backwards from synergy. It doesn't work that
8 way.

9 BY MR. DINER:

10 Q What I'm saying is that when you
11 referred to drug synergy and quoting from this
12 article and that there was no synergy, it doesn't
13 mean that the individual compounds, the
14 corticosteroid and the NSAID individually didn't
15 have some effect in addressing CME, correct?

16 MR. JANUSZ: Object to form.

17 THE WITNESS: Synergy doesn't discuss
18 that at all. You're drawing conclusions that
19 can't be drawn from this. You can't say -- if
20 A and B are not synergistic that means that A
21 itself is good and B itself is good. That
22 doesn't work that way. Going backwards
23 doesn't work.

24 BY MR. DINER:

25 Q Okay. But now I understand. That

1 wasn't exactly my question. My question was: When
2 this article refers to the possible synergistic
3 effect of these two drugs, does it effectively
4 debunk that possibility that the two drugs were --
5 could be synergistic in treating CME?

6 A I just said that. It's not
7 synergistic. There's no evidence.

8 Q Okay. And -- but there is evidence, at
9 least as to the NCEs, as you testified earlier, that
10 they could be used to effectively treat what you
11 called subclinical CME as compared to placebo and
12 some specific corticosteroids, correct?

13 MR. JANUSZ: Object to form.

14 THE WITNESS: That's a long compound
15 question, and you said again NCE. I think you
16 mean NSAIDs when you say that, so I'll assume
17 you mean NSAIDs. But, again, I think we've
18 covered this. You can't go backwards from
19 synergy and say that each drug itself works
20 well. It doesn't work that way. So -- and
21 we've already discussed 15, 20 minutes of the
22 fact that the NSAIDs, there's no Level I or II
23 lefts evidence there are any benefit.

24 BY MR. DINER:

25 Q Lack of any Level I or Level II

1 evidence that there's no benefit in treating CME is
2 looking at it at a period of greater than three
3 months, correct?

4 A Let me look at the article.

5 Q And while you're doing that, I'll refer
6 you to the conclusions on the left-hand column of
7 page 2165.

8 A Yes, it refers to after three months.

9 Q Okay. And what it does, though, say in
10 that same passage in the conclusion on page 2165 is
11 that the NSAIDs are clearly are effective in
12 reducing, in your words, subclinical CME when
13 compared to placebo or corticosteroids of poor
14 corneal penetration, correct?

15 A We've gone over that, I think, many,
16 many times already.

17 Q And so your answer is yes, then?

18 A My answer is the same as it was before.
19 I've said it about half a dozen times, I think.

20 Q Okay. So I'll ask it again just to be
21 clear.

22 A Uh-huh.

23 Q In the conclusion here on page 2165 it
24 does say that NSAIDs clearly are effective in
25 reducing what you call subclinical CME when compared

1 with placebo or topical corticosteroids having poor
2 corneal penetration, correct?

3 A You left out less than three months.

4 Q Okay. So they're effective at less
5 than three months in that context, correct?

6 A They're effective -- let me summarize
7 it for you. They're effective from treating
8 non-clinically significant CME in under three months
9 when you're comparing them to zero.

10 Q And I think we established earlier that
11 someone with subclinical CME, as you called it, who
12 got their vision back would consider that to be a
13 benefit, correct?

14 MR. JANUSZ: Objection,
15 mischaracterizes.

16 THE WITNESS: Patients are not aware
17 that they have subclinical CME. It's just a
18 test that we could do. Again, this table
19 looks like the Himalayas, if you magnify it a
20 hundred times. It's not as perfectly smooth.
21 So it's basically a test used for research
22 purposes, but it's not clinically significant.

23 BY MR. DINER:

24 Q Nonetheless, that person with what you
25 call subclinical CME getting his vision back would

1 be satisfied with the return of his vision, correct?

2 MR. JANUSZ: Same objection.

3 THE WITNESS: But that would have
4 happened most likely anyway if they weren't on
5 NSAIDs, because the eye usually heals and the
6 subclinical CME is insignificant and usually
7 goes away. And on top of that, since we
8 universally use a potent steroid that
9 penetrates well it's an irrelevant fact or
10 point that you're making.

11 BY MR. DINER:

12 Q In those cases where it doesn't
13 spontaneously correct itself and that person who had
14 what you called subclinical CME and got his vision
15 back would be satisfied with the return of his
16 vision, correct?

17 A Anybody who gets their vision back is
18 satisfied, whether they have subclinical CME or not.
19 So your question is kind of vague, and I don't
20 understand what the question is.

21 Q I think you've answered it. So thank
22 you.

23 A Okay.

24 MR. DINER: Is this a good point for a
25 break?

1 MR. JANUSZ: Yeah.

2 VIDEO OPERATOR: Off the record, 12:08.

3 This is the end of disc 1 of the
4 deposition of Robert C. Cykiert.

5 (Lunch recess.)

6 VIDEO OPERATOR: Going back on the
7 record, 12:58 p.m.

8 This is the beginning of disc 2 in the
9 deposition of Robert C. Cykiert.

10 BY MR. DINER:

11 Q Welcome back from lunch, Dr. Cykiert.

12 A Thank you. Thanks.

13 Q Dr. Cykiert, you're familiar with the
14 ophthalmic Xibrom, correct?

15 A Yes, I am.

16 Q Okay. Are you also aware that the
17 prescribing label for Xibrom indicates that 2 to 7
18 percent of the patients -- strike that. Let me go
19 to a document instead.

20 (Document, PROL0080486 - PROL0080492,
21 was marked Cykiert-5 for identification.)

22 BY MR. DINER:

23 Q The court reporter has just handed you
24 Exhibit 5, bearing Bates numbers PROL0080486 through
25 492.

1 Have you seen this document before?

2 A Yes, I have.

3 Q I apologize for the small print.

4 A No problem.

5 Q Does this document appear to be
6 highlights of prescribing information for Xibrom?

7 A Yes.

8 Q Okay. Would you look at the first page
9 of Cykiert Exhibit 5, the right-hand column under
10 adverse reactions?

11 A Yes.

12 Q Does this document indicate that Xibrom
13 reported adverse reactions in 2 to 7 percent of the
14 patients, which included eye irritation?

15 A Yes.

16 Q And is burning and stinging indicated
17 in Cykiert Exhibit 5 to be a type of eye irritation?

18 A Yes.

19 Q Okay. You can put that aside.
20 And you're also familiar with the
21 product Bromday, correct?

22 A Yes.

23 Q I believe we spoke about that a little
24 bit today.

25 MR. DINER: Let me mark the next

1 exhibit.

2 (Document, PROL0080493 - PROL0080497,
3 was marked Cykiert-6.)

4 BY MR. DINER:

5 Q Now, the court reporter, Dr. Cykiert,
6 has handed you Cykiert Exhibit 6, bearing Bates
7 numbers PROL0080493 through 497.

8 Have you seen this document before?

9 A Yes, I have.

10 Q Okay. And does this document appear to
11 be highlights of prescribing information with regard
12 to Bromday?

13 A Yes.

14 Q And this first page, right column of
15 this document, does it indicate that one of the
16 adverse reactions for Bromday is eye irritation?

17 A Yes.

18 Q And does that document report that it
19 would have occurred in 2 to 7 percent of the
20 patients?

21 A Yes.

22 Q And eye irritation in this document for
23 the prescribing information highlights for
24 Prolensa -- pardon me, for Bromday also indicates
25 that it includes burning and stinging, correct?

1 A Yes.

2 Q You can put that aside.

3 Are you familiar with the product
4 Acular?

5 A Yes.

6 Q Does the product -- prescribing
7 information for the product Acular indicate that
8 40 percent of patients report burning and stinging
9 after using Acular?

10 A Do you have that document?

11 Q I'll show it to you. You can also
12 refer to, if you like, paragraph 56 of your expert
13 report.

14 (Acular information document,
15 PROL0332429 - PROL0332439, was marked
16 Cykiert-7 for identification.)

17 BY MR. DINER:

18 Q Okay. The court reporter has handed
19 you Cykiert Exhibit 7, having Bates numbers
20 PROL0332429 through 439.

21 Dr. Cykiert, have you seen this
22 document before?

23 A I have.

24 Q Does it appear to be describing
25 information for the product Acular?

1 A Yes.

2 Q Would you please turn to the fourth
3 page into Cykiert Exhibit 7, bearing Bates number
4 PROL0332432. And take a look at the bottom of the
5 page under adverse reactions.

6 A Yes.

7 Q Does this indicate that Acular has
8 adverse events that include transient stinging and
9 burning on installation?

10 A What's the page number you're on? If
11 you could give me --

12 Q The Bates number at the bottom, Dr.
13 Cykiert, is PROL0332432.

14 A Right, I have that. Which paragraph?

15 Q The first paragraph under adverse
16 events -- sorry, adverse reactions.

17 A Okay. Got it. I'm there.

18 Q Does this document, Cykiert Exhibit 7,
19 indicate that Acular reported adverse events,
20 including transient stinging and burning on
21 installation?

22 A Yes.

23 Q Okay. And did that adverse event occur
24 up to -- in up to 40 percent of the patients
25 participating in the clinical trials for Acular?

1 A Yes.

2 Q Okay. You can put that aside as well.

3 Dr. Cykiert, are you familiar with the product
4 Voltaren?

5 A Yes, I am.

6 Q You prescribe that on occasion?

7 A Yes.

8 Q Does Voltaren have adverse events that
9 include burning and stinging upon installation?

10 A Could I just see the package insert
11 again?

12 Q Sure.

13 (Voltaren Ophthalmic information
14 document, PROL0332414 - PROL0332418, was
15 marked Cykiert-8 for identification.)

16 BY MR. DINER:

17 Q Now, looking at the page numbers across
18 the top of Cykiert Exhibit 8, can you flip to page
19 6, please. There's a crosscheck, the last three
20 numbers of the Bates number at the bottom is 417.

21 A Got it.

22 Q Can you go to the subsection, adverse
23 reactions?

24 A Okay.

25 Q And beneath that, ocular, do you see

1 that?

2 A Yes.

3 Q Does this document indicate, that is,
4 Cykiert Exhibit 8, that Voltaren Exhibit exhibited
5 transient burning and stinging in approximately
6 15 percent of the patients across the clinical
7 studies submitted for Voltaren?

8 A Yes.

9 Q Okay. You may put that aside. Now,
10 Dr. Cykiert, would you agree that patients should
11 use medication as prescribed for it to be effective?

12 A Yes.

13 Q And would you agree that it is
14 important that -- that it is important for patients
15 to use the medications they have been prescribed
16 after cataract surgery as prescribed?

17 A Yes.

18 Q Now, is it your position that the
19 industry has recognized -- strike that.

20 Is it your position the industry has
21 recognized that burning and stinging -- that
22 removing burning and stinging is beneficial to
23 patients?

24 A I don't see where it states that, that
25 the industry has recognized that.

1 Q Would you agree that there is a trend
2 in the industry to reformulate NSAID treatments to
3 reduce burning and stinging?

4 MR. JANUSZ: Object to form.

5 THE WITNESS: I haven't seen that
6 trend. I don't know. Do you have any
7 documentation of that anywhere?

8 BY MR. DINER:

9 Q Yeah. Can you refer to paragraph 37 of
10 your expert report at page 12? Five lines down from
11 the top of page 12, beginning with the word
12 "Additionally."

13 A Okay.

14 Q Can you read that sentence from your
15 report into the record, please?

16 A Additionally, the trend in the industry
17 has been to reformulate ophthalmic NSAID treatments
18 to reduce or remove potential irritants and thereby
19 potentially reduce any burning and stinging.

20 Q So is the removal of -- pardon me,
21 strike that.

22 Is the reduction of burning and
23 stinging a trend that is recognized in the industry
24 for ophthalmic NSAID treatments?

25 MR. JANUSZ: Object to form.

1 THE WITNESS: It's the trend in the
2 industry. That's what this sentence says.

3 BY MR. DINER:

4 Q So on that basis, is it fair to say
5 that the industry has recognized that removing
6 burning and stinging is beneficial to patients?

7 MR. JANUSZ: Objection, vague.

8 THE WITNESS: It doesn't say anything
9 about beneficial to patients specifically. It
10 just says the trend in the industry has been
11 to reformulate to reduce potential irritants.

12 BY MR. DINER:

13 Q And it goes on to say, and potentially
14 reducing any burning and stinging, correct?

15 A Yes.

16 Q So would the reduction of burning and
17 stinging associated with ophthalmic NSAID
18 formulations be considered a benefit to patients
19 taking those formulations or taking those
20 ophthalmics?

21 MR. JANUSZ: Same objection.

22 THE WITNESS: It depends on the degree
23 of burning and stinging and other factors.
24 You'll notice in the package inserts that you
25 gave me the word "transient" is used

1 frequently. So it turns out that transient
2 burning and stinging is common for most, if
3 not all, eye drops for some individuals.

4 BY MR. DINER:

5 Q Okay. And so in the case of those
6 individuals, is it a benefit to them to reduce the
7 transient burning and stinging in the ophthalmic
8 formulations that they may take?

9 A If it's a mild burning and stinging
10 that lasts for just a few seconds, then it's
11 insignificant, patients won't even mention it. If
12 it's a significant burning and stinging that burns
13 and stings a lot and it goes on for half a minute or
14 a minute or two, then that's different, then that
15 they will complain about.

16 Q And, in your experience, have you ever
17 seen that with any patients, that they complain of
18 the burning and stinging?

19 A Yes, some patients do.

20 Q Okay. And so the removal, reduction of
21 burning and stinging associated with the ophthalmic
22 formulations that they may be treated with would be
23 a benefit to them, correct?

24 MR. JANUSZ: Object to form.

25 THE WITNESS: The ones who have

1 significant burning and stinging for a
2 prolonged period of time, those would benefit.
3 The ones who have mild transient burning or
4 stinging, really there's not much difference
5 because they don't object to it much, it
6 doesn't bother them, it doesn't prevent them
7 from using their drops. They may just mention
8 it in passing or it may come about in
9 conversation somehow with their doctor or with
10 me.

11 BY MR. DINER:

12 Q But even if they mentioned it in
13 passing, the removal of that burning and stinging
14 still would have been a benefit to those patients,
15 correct?

16 MR. JANUSZ: Same objection.

17 THE WITNESS: If somebody is not
18 complaining about something, they're just
19 mentioning it, and you remove it, then that's
20 of no benefit. If they're complaining about
21 it and you remove it, then that's a benefit.

22 BY MR. DINER:

23 Q So it's your position that only if they
24 complain of the burning and stinging that removing
25 it is a benefit?

1 A That's correct. If it's a complaint, a
2 significant complaint, you can get rid of that, and
3 that's a benefit. If they just have it, but it
4 doesn't bother them, then it doesn't really make
5 much difference.

6 Q Dr. Cykiert, is the reducing of the
7 number of daily installation of eye drops a benefit
8 to patients?

9 A It's of benefit to some patients and
10 not others, and there are other factors that come
11 into significant consideration in answering that
12 question.

13 Q Has the industry recognized, to some
14 extent, then, the benefit of reducing the number of
15 daily installations of ophthalmics as beneficial to
16 patients?

17 A I would say in general, yes, but it's
18 not an across-the-board benefit for all patients.
19 It depends on other factors. For example, expense
20 is a very significant factor. So there are some
21 patients who won't mind taking a drop three or four
22 times a day if it's one-tenth or one-twentieth the
23 cost of a drop that's only taken once a day. In
24 other words, the severe burning and stinging in
25 their wallet or pocket may be more significant than

1 the transient mild burning and stinging that they
2 get once or twice or three or four times a day.

3 Q So referring now, then, to the industry
4 trend. As you mentioned in paragraph 37 of your
5 report, is the industry's focus on removing burning
6 and stinging an indication that there are therapies
7 available on the market that don't meet the need of
8 reduced burning and stinging?

9 MR. JANUSZ: Object to form.

10 THE WITNESS: Did you say paragraph 37?

11 I'm sorry, I'm trying to find that.

12 BY MR. DINER:

13 Q Yeah. Back to where we were before in
14 paragraph 37 in your statement about the trend in
15 industry.

16 A Which part of paragraph 37 are you
17 directing me to?

18 Q So on page 12, go about five lines
19 down.

20 A Right. Yes, we already discussed that.

21 Q So is the industry's focus on trying to
22 remove burning and stinging an indication that there
23 are therapies available in the market that actually
24 don't meet the need to remove burning and stinging?

25 MR. JANUSZ: Object to form.

1 THE WITNESS: It doesn't say that there

2 --

3 BY MR. DINER:

4 Q Well, I'm asking you --

5 A -- it just says that the industry trend
6 is to reduce it.

7 Q Okay. But I'm asking you, then, beyond
8 your statement there --

9 A Right.

10 Q -- in light of that statement, does the
11 industry's focus on trying to remove burning and
12 stinging indicate that of the therapies that are
13 available, they do not meet the need to remove
14 burning and stinging?

15 MR. JANUSZ: Same objection.

16 THE WITNESS: They may be trying to
17 improve it, but that doesn't mean what's
18 currently out there is bad.

19 BY MR. DINER:

20 Q And trying to improve it and reduce the
21 burning and stinging could ultimately lead to
22 benefits for the consuming public, correct?

23 A Again, it depends on the severity and
24 duration of the burning and stinging. If the
25 burning and stinging is mild and transient, then

1 it's really of no significance because most eye
2 drops have some burning and stinging transiently
3 that's mild. If it's moderate or severe burning and
4 stinging that's for a prolonged period of time, then
5 I would say, yes, that should be improved upon by
6 the industry, where possible.

7 Q Okay. Thank you. Now, is it fair to
8 say that many cataract surgery patients are elderly?

9 A I would say that's correct.

10 Q And as people age they can sometimes
11 become forgetful, correct?

12 MR. JANUSZ: Objection, calls for
13 speculation.

14 THE WITNESS: Sometimes yes and
15 sometimes no. I have some 90-year-olds who
16 are really sharp and on the ball.

17 BY MR. DINER:

18 Q And I suspect that you have some people
19 younger than 90 that can be quite forgetful,
20 correct?

21 MR. JANUSZ: Same objection.

22 THE WITNESS: That's correct. So it's
23 extremely variable.

24 BY MR. DINER:

25 Q Now, I think you mentioned that

1 Voltaren is a medication that is prescribed four
2 times a day; is that correct?

3 A In general, it is.

4 Q Okay. According to the label it's
5 prescribed four times a day; is that right?

6 A I'd have to specifically look at that,
7 if you want me to look at it. Do you want me to?

8 Q No, I think it's in your report anyway.

9 A Yes, in general, it's used four times a
10 day, but sometimes it's used only two or three times
11 a day in some patients if what you're treating is a
12 milder case of what they have.

13 Q So let's say we're dealing with the
14 prescription of Voltaren four times a day to a
15 patient who has just had cataract surgery, okay?
16 We'll set that up as the facts that we're going to
17 be talking about.

18 A Okay.

19 Q Acceptable? And let's also say that
20 that person is elderly. Okay?

21 A Okay.

22 Q For that person having to remember to
23 take medication four times a day, could that
24 increase the likelihood that the patient could
25 forget to use the medication as prescribed?

1 MR. JANUSZ: Object to form, calls for
2 speculation.

3 THE WITNESS: Just because a patient is
4 elderly doesn't mean they're forgetful. They
5 don't necessarily go hand in hand.

6 BY MR. DINER:

7 Q And for those patients that you have
8 had that are elderly and forgetful, would having to
9 take an ophthalmic such as Voltaren four times a day
10 increase the likelihood that they could forget to
11 take the medication as prescribed?

12 MR. JANUSZ: Same objections.

13 THE WITNESS: My patients who are
14 forgetful, regardless of their age, there's
15 some young ones, some old ones and in between,
16 if they're forgetful they forget to take their
17 drops once a day or four times a day. In
18 fact, interestingly, the opposite occasionally
19 occurs because if you're supposed to take
20 something four times a day you reinforce it to
21 yourself because you're doing it frequently
22 and so you actually remember to take it two or
23 three or four times a day because it's a
24 repeated habitual thing almost. Whereas, if
25 it's once a day it kind of may slip your mind

1 overnight. So the answer is, it's extremely
2 variable, as I just gave you that example.

3 BY MR. DINER:

4 Q But it can occur that for an elderly
5 forgetful person, they could miss taking their
6 medication, if prescribed, four times a day, they
7 could miss one of those installations, correct?

8 MR. JANUSZ: Same objections.

9 THE WITNESS: It's possible. But I
10 have, for example, glaucoma patients who are
11 on one drop a day of a glaucoma eye drop and I
12 won't see them for two or three months for a
13 checkup and they come in, and I say are you
14 taking your drop and they go, what drop? And
15 it was only once a day. I go, remember, I
16 prescribed that, you have glaucoma, you're
17 supposed to take it. They go, oh, you know, I
18 forgot all about that. You're right.

19 BY MR. DINER:

20 Q Okay. Now, if that medication in our
21 scenario, elderly patient, forgetful, taking
22 medication four times a day as prescribed, for that
23 patient if that medication were to cause burning and
24 stinging could it increase the likelihood that that
25 patient may not use the medication as prescribed?

1 MR. JANUSZ: Same objections, calls for
2 speculation; if not already stated.

3 THE WITNESS: Again, it really depends
4 on the severity and duration. If it's a mild
5 burn or sting, it has really no effect, and if
6 it's a moderate or severe burning or stinging,
7 then there is an effect and they may not take
8 it and may call me. So it kind of is
9 variable. There is no one set answer to that.

10 BY MR. DINER:

11 Q Would you agree that it is impossible
12 to predict which patients will experience burning
13 and stinging?

14 A I wouldn't say it's totally impossible
15 because it depends on the patient and their history
16 and your previous experiences with them.

17 Q Is it fair to say, then, it's sometimes
18 hard to predict which patients may experience
19 burning and stinging?

20 MR. JANUSZ: Object to form.

21 THE WITNESS: Again, it's very
22 variable. I have patients who complain of
23 burning and stinging with every drop I ever
24 give them and then other patients never
25 complain about anything. So it has to do a

1 lot with tolerance of burning and stinging or
2 pain or discomfort. It has to do with the
3 patient's mental status as well. It has to do
4 a lot with patients' expectations of what eye
5 drops are supposed to feel like. There are
6 numerous factors.

7 BY MR. DINER:

8 Q And so I'll refer you to paragraph 37
9 again of your expert report, page 12, towards the
10 bottom, six lines up beginning with the sentence,
11 Because it is difficult.

12 A Okay, I see that. Thanks.

13 Q So then would you agree that it is
14 sometimes difficult or impossible to predict which
15 patients may experience burning and stinging, for
16 example?

17 A Yeah, that's what I basically just
18 said.

19 Q Okay. Would you also agree that many
20 cataract patients may have other conditions causing
21 sensitivity in their eyes?

22 A Yes.

23 Q Would dry eye be one of those?

24 A Yes, it would be.

25 Q Therefore, with such a subgroup of

1 patients would it make sense to use less irritating
2 ophthalmics as much as possible after surgery with
3 these type of patients?

4 MR. JANUSZ: Object to form.

5 THE WITNESS: It's variable. Are you
6 speaking about specifically about the dry eye
7 patients?

8 BY MR. DINER:

9 Q Yes. So let's take the dry eye
10 patient. So with a dry eye patient post-cataract
11 surgery, would it make sense to prescribe to that
12 patient an ophthalmic formulation to address
13 inflammation that is less irritating?

14 MR. JANUSZ: Object to form.

15 THE WITNESS: Again, it depends on the
16 severity of their dryness, whether it's mild
17 or severe or in between. It depends how much
18 symptoms the patient is having from their
19 dryness. For example, I have patients who
20 have severe dryness on my examination, yet
21 they have near zero symptoms. Then I have
22 patients who have very mild dry findings on my
23 exam of their eye, yet their symptoms are
24 severe, and then there is people in between.
25 So the symptoms of the dryness and my exam

1 findings of the dryness don't always correlate
2 well, and so it's difficult to predict
3 sometimes how they will respond to another eye
4 drop.

5 BY MR. DINER:

6 Q Well, let's stay with that example of
7 the person with, say, severe dry eye problems.
8 Would it make sense to administer to that person or
9 to prescribe to that person an ophthalmic NSAID that
10 had reduced irritation as one of its side effect
11 events?

12 MR. JANUSZ: Same objection.

13 THE WITNESS: What do you mean by
14 "irritation"?

15 BY MR. DINER:

16 Q Burning and stinging.

17 A The dry eye symptoms are different than
18 the burning and stinging symptoms. So they don't
19 correlate. They're two separate different things.

20 Q So someone who has dry eye, they
21 wouldn't be negatively affected by an ophthalmic
22 NSAID that was known to cause burning and stinging?

23 MR. JANUSZ: Object to form.

24 THE WITNESS: No, because burning and
25 stinging are different than dry eye. The

1 symptoms of a dry eye patient generally are
2 foreign body sensation. Whereas the symptoms
3 of burning and stinging are not foreign body
4 sensations. So they're two different things.

5 BY MR. DINER:

6 Q Now, Bromday and Prolensa, they have
7 the same active ingredient, correct?

8 A Yes, that's correct.

9 Q And that ingredient is bromfenac,
10 right?

11 A Right.

12 Q And it's your view that Bromday and
13 Prolensa have the same efficacy and safety profiles;
14 is that right?

15 A Bromday and Prolensa, yes.

16 Q Prolensa is more expensive to the
17 customers than Bromday; is that right?

18 MR. JANUSZ: Objection, foundation.

19 THE WITNESS: Well, Bromday I don't
20 believe is currently available.

21 BY MR. DINER:

22 Q Is there a generic Bromday out there
23 today?

24 A There's a generic bromfenac.

25 Q Okay. Prolensa is more expensive than

1 generic bromfenac; is that right?

2 A Yes.

3 Q By a large margin?

4 MR. JANUSZ: Same objection.

5 THE WITNESS: From what I know, from
6 what patients tell me, it's often a huge
7 difference.

8 BY MR. DINER:

9 Q A huge difference in price as between
10 Prolensa and generic bromfenac?

11 A Right.

12 Q With Prolensa being the more expensive
13 one?

14 A Yes, Prolensa being much more expensive
15 than the generic bromfenac.

16 Q And because of the price differential,
17 do you prefer to prescribe generic bromfenac over
18 Prolensa?

19 A Yes. Because it's essentially the same
20 in efficacy and safety and how it works, and if it's
21 a lot cheaper for the patient, then I think that's
22 preferable, since patients complain a lot about
23 expensive medications, and healthcare in general.

24 Q Okay. So physicians would not
25 prescribe a new drug that used the same active

1 ingredient as the prior drug if that new drug did
2 not deliver any benefits over the prior drug; is
3 that right?

4 MR. JANUSZ: Objection, foundation,
5 calls for speculation, vague.

6 THE WITNESS: That's a very broad
7 generalization, what you just said.
8 Physicians have different reasons for
9 prescribing medications.

10 BY MR. DINER:

11 Q How about for you?

12 A For me?

13 Q Yeah.

14 A If I have a generic drug that's less
15 expensive and a brand drug that's a lot more
16 expensive and they have equal efficacy and safety,
17 then I'll usually prescribe the generic, cheaper
18 brand for the patient.

19 Q Do you believe that your view, as you
20 just expressed it, is shared by other doctors?

21 A I believe my view, as I just said it,
22 is shared by the vast majority of ophthalmologists.

23 Q So then a new more expensive drug with
24 no benefits to consumers compared to the old drug is
25 probably not likely to succeed; is that right?

1 MR. JANUSZ: Objection, foundation,
2 outside the scope.

3 THE WITNESS: That's not necessarily
4 correct because there are other factors that
5 influence prescribing decisions by doctors,
6 including marketing that's done by the company
7 that makes the branded product and other
8 factors such as availability of the generic,
9 cheaper brand.

10 For example, unfortunately, sometimes
11 the generic bromfenac is not available. So
12 I'll write a prescription for it, the patient
13 goes to the drugstore and either the patient
14 or the pharmacist calls me and says they don't
15 have this generic, what do I do? So that may
16 force me to write a more expensive drug
17 because the patient has to have this drug, and
18 I have no choice, or I may go with another
19 branded drug that's essentially the same in
20 efficacy and safety made by a different
21 company, if I can get that cheaper.

22 MR. DINER: I'd like to mark the next
23 exhibit, Lisa.

24 (Prolensa information document,
25 PROL00802189 - PROL0080224, was marked

1 Cykiert-9 for identification.)

2 BY MR. DINER:

3 Q Okay. Dr. Cykiert, you've been
4 presented with Cykiert Exhibit 9, bearing Bates
5 numbers PROL0080219 through 224. Are you familiar
6 with labeling approval at the FDA level?

7 MR. JANUSZ: Objection, vague.

8 THE WITNESS: I'm familiar with it, but
9 what specifically are you referring to?

10 BY MR. DINER:

11 Q Well, when the FDA approves a label for
12 a product that's going to get market approval, does
13 it approve that label based on the clinical studies
14 that have been submitted by the applicant for that
15 product?

16 A That's my understanding of how the FDA
17 works, correct.

18 Q Okay. And when they fill out the
19 portion of the label dealing with adverse reactions,
20 that's also based on the clinical studies that have
21 been submitted by the applicant, right?

22 A That is correct.

23 Q And so Cykiert Exhibit 9 appears to be
24 the highlights of prescribing information for the
25 product Prolensa. Would you agree with that?

1 A Yes.

2 Q And you've seen this document before,
3 right?

4 A Yes, I have.

5 Q Under adverse reactions on the first
6 page, right-hand column, does it indicate burning
7 and stinging as an adverse reaction of Prolensa?

8 A It doesn't specifically say that on
9 this document.

10 Q And it doesn't indicate eye irritation
11 either for Prolensa, correct?

12 A Well, it depends how you define "eye
13 irritation." Notice that it says foreign body
14 sensation and eye pain and photophobia. And I would
15 put that under the category of eye irritation.

16 Q But there's no indication here, as
17 we've established, as to burning and stinging,
18 correct?

19 A Specifically it does not say burning
20 and stinging. Although I do know from experience
21 that patients do have burning and stinging from
22 Prolensa.

23 Q Now, this label for Prolensa was
24 approved without an indication that burning and
25 stinging is an adverse reaction to Prolensa,

1 correct?

2 MR. JANUSZ: Object to form.

3 THE WITNESS: Well, what this label
4 means is in the clinical trials that they did
5 and submitted to the FDA, burning and stinging
6 did not appear at a certain percentage of
7 patients below a certain number. So they
8 excluded it from here. But we shouldn't think
9 for a moment that this includes every possible
10 adverse reaction that can occur. Just because
11 it doesn't say that here doesn't mean it
12 doesn't occur in real life.

13 And I'll bring to your attention the
14 paragraph below that which says, to report
15 suspected adverse reactions, contact Bausch +
16 Lomb, Incorporated, at an 800 number, or the
17 FDA at an 800 number, or the FDA website,
18 which basically says that the FDA knows that
19 there can be other adverse reactions that
20 occur after a drug is approved by the FDA.
21 And it's asking doctors to report those
22 adverse reactions to the FDA so that the FDA
23 can, from time to time, amend the package
24 insert to include other adverse reactions.
25 And as you know, sometimes there are black box

1 warnings, which are more serious adverse
2 reactions, that come out after a drug is
3 approved.

4 BY MR. DINER:

5 Q Are you aware of any amendments being
6 made to the product label for Prolensa with regard
7 to adverse reactions?

8 A I'm not aware of any now, but as I
9 mentioned, that can occur at any time. There are
10 many medications that come out with subsequent
11 adverse reaction warnings, or even black box
12 warnings, which are more severe, that can come out
13 months, or even years after a drug is approved.

14 And I'll also bring to your attention
15 in Section 6.1 of this document. It says that
16 because clinical trials are conducted under widely
17 varying conditions and adverse reaction rates
18 observed in the clinical trials of a drug cannot be
19 directly compared to rates in clinical trials of
20 another drug and may not reflect the rates observed
21 in clinical practice. That last phrase, and may
22 not -- "and may not reflect the rates observed in
23 clinical practice." What they're saying there is
24 that this is not the end of it.

25 There can be things that you find in

1 your clinical practice which are not reported in a
2 package insert. And so that basically explains that
3 this is very preliminary findings based on the
4 clinical trials and a limited number of small
5 patients in the clinical trials. Later on when a
6 drug is used on thousands of patients, tens of
7 thousands of patients over years, other adverse
8 reactions can come out. And, in fact, there is
9 documentation in many places that Prolensa does have
10 burning and stinging other than what I just said.
11 There's documentation of that.

12 Q But focusing on Cykiert Exhibit 9, and
13 what's on the label, Prolensa is the only NSAID
14 approved for the treatment of post-operative
15 inflammation and reduction of ocular pain after
16 cataract surgery, which does not have burning and
17 stinging listed as an adverse event on its label,
18 correct?

19 A Currently that's the case.

20 Q Okay. You can put that aside.

21 A Thanks.

22 Q Is it advantageous when formulating
23 ophthalmics, or any pharmaceuticals, to try to use
24 the lowest effective dose of an active ingredient?

25 MR. JANUSZ: Objection, foundation.

1 THE WITNESS: In fact, there's no
2 evidence of that.

3 BY MR. DINER:

4 Q Is it preferable to use the lowest
5 effective dose of a particular active ingredient in
6 an ophthalmic, for example?

7 MR. JANUSZ: Same objection.

8 THE WITNESS: Not necessarily.

9 BY MR. DINER:

10 Q Is it beneficial to identify what the
11 lowest effective dose is for an ophthalmic?

12 A Not in all cases. It's variable. It
13 depends what the ophthalmic is and for what purposes
14 its used.

15 Q But it can be, correct?

16 A In some cases, depending on the drug
17 and what you're using it for that may be the case.
18 But that's not a general broad statement that covers
19 all ophthalmics, and specifically it doesn't cover
20 NSAID ophthalmics at all.

21 Q Is the benefit of using the lowest
22 effective dose the idea that the pharmaceutical
23 could have a minimum of side effects?

24 MR. JANUSZ: Objection, foundation.

25 THE WITNESS: Theoretically, that would

1 kind of seem like, hey, maybe that's logically
2 correct, but, in fact, that's not the case.
3 And the evidence is in all these package
4 inserts that you sent me here that I have in
5 front of me. If you look at the Prolensa
6 warnings and precautions section and then you
7 look at the Xibrom warnings and precautions
8 sections, which in both cases start with
9 Section 5.1 to about 5.6, you'll see that all
10 the serious warnings and precautions by the
11 FDA for both of these drugs are essentially
12 identical, even though Prolensa, 0.7 percent,
13 and Xibrom or Bromday are 0.9 percent. So
14 therefore, in this case, lowering the
15 percentage of the drug to 0.7 percent does not
16 make it in any way safer or better. And
17 there's no change in efficacy, either, by the
18 way.

19 BY MR. DINER:

20 Q Well, let's look at -- under Warnings
21 and Precautions -- you have Cykiert Exhibit 9 in
22 front of you for Prolensa?

23 A Yes.

24 Q All right. I have to refer to the
25 other one. I think you made a comparison allergic

1 to sulfites between Prolensa and Bromday; is that
2 right? Were you looking at Cykiert Exhibit 6 for
3 Bromday?

4 A I don't think I have Bromday. I have
5 Xibrom. Oh, wait, Bromday, I have here.

6 Q Whatever one you have, it doesn't
7 matter.

8 A Yeah, they're essentially the same.

9 Q Which one are you looking at, Xibrom or
10 Bromday?

11 A I'm looking at Bromday and Xibrom. We
12 can look at all of them. Yeah, the number 5 section
13 in all of them, it appears that it's the same number
14 section in all three drugs.

15 Q You refer to that in the context of
16 stating that lowering the amount of the active
17 ingredient may have no benefit at all; is that
18 right?

19 A Yeah, based on what you said earlier,
20 that well, if you lower the concentration of the
21 active ingredient, then isn't that better for the
22 eye or the patient, and that may initially seem
23 like, hmm, that sounds pretty logical, maybe that's
24 right. But, in fact, it isn't because you can see
25 that Section 5 for all three of these drugs is

1 essentially identical, which means that lowering the
2 dosage from -- I should say lowering the
3 concentration of the drug of the bromfenac from
4 0.9 percent to 0.7 percent makes no difference. So
5 that really is documented here very clearly.

6 Q So the first warning in precaution 5.1
7 is directed to sulfite allergic reactions, correct?

8 A That's in all three package inserts,
9 that's correct. Prolensa, Bromday and Xibrom.

10 Q And sulfite is not the active
11 ingredient, correct?

12 A That's correct. That's an inactive
13 ingredient.

14 Q Okay. You can put that aside.

15 I believe you said that you rarely
16 prescribe Prolensa; is that right?

17 A Not rarely. I used to prescribe it a
18 lot more. Recently it's rarely, and the reason I
19 have decreased my prescriptions over time is that it
20 was very expensive and I received many patient
21 complaints about it. So initially I started
22 prescribing it, but over time I've prescribed it
23 less and less because of the expense, and when I
24 used it, I found no difference in efficacy when I
25 used it, and also I found that there was no

1 difference in patient symptoms with regard to
2 burning, stinging, irritation between the drugs. So
3 I said why should I be prescribing something that is
4 very expensive and all my patients complain about,
5 or the vast majority of patients complain about,
6 when I can use equivalent generic products that are
7 much cheaper or use a competitor's branded product
8 that comes out much less expensive and has the
9 identical safety, efficacy and side effect complaint
10 profile.

11 Q You would agree that Prolensa is
12 clinically effective, correct?

13 MR. JANUSZ: Objection, vague.

14 THE WITNESS: Clinically effective for
15 what?

16 BY MR. DINER:

17 Q Treating post-operatively inflammation
18 and ocular pain after cataract surgery.

19 MR. JANUSZ: Same objection.

20 THE WITNESS: It's approved for that,
21 and when needed it can be used for that, but
22 my uses of it are for treating CME, which we
23 discussed earlier, as an off-label, acceptable
24 use for it.

25 BY MR. DINER:

1 Q And have your experiences in using
2 Prolensa to treat CME been positive?

3 A Yes, in patients who have CME, it's
4 been effective in reducing the CME, but it's
5 equivalent to generic bromfenac or Ilevro, or
6 previously when I used Bromday or Xibrom. They're
7 all basically similarly identical. And in some
8 patients where I've used either Acular generic or
9 Voltaren generic three or four times a day, those
10 are equally effective.

11 Q Now, as between Prolensa and Bromday,
12 would you agree that they are both equivalent in
13 terms of their ability to treat post-operatively
14 inflammation in ocular pain?

15 A I would say that it's approximately the
16 same, yeah, correct.

17 Q Okay.

18 MR. JANUSZ: Can I interrupt for a
19 moment. I don't think my LiveNote is working
20 here.

21 VIDEO OPERATOR: Off the record,
22 1:55 p.m.

23 (Brief recess.)

24 VIDEO OPERATOR: We're back on the
25 record, 2:03 p.m.

1 This is the beginning of disc 3 in the
2 deposition of Robert C. Cykiert.

3 BY MR. DINER:

4 Q Dr. Cykiert, before the break I believe
5 we were talking about the clinical efficacy of
6 Prolensa on the one hand and Bromday on the other.
7 And just so the record is clear, is it your view
8 that Prolensa and Bromday are equally effective?

9 A Yes.

10 Q Prolensa contains 0.7 percent of --
11 sorry, strike that. Prolensa contains 0.07 percent
12 bromfenac, correct?

13 A That's correct. Did you say 0.7?

14 Q 0.07 percent.

15 A Right. Right. .07 percent.

16 Q I'll just say it again so the record is
17 clear. So Prolensa contains 0.07 percent bromfenac,
18 correct?

19 A Right.

20 Q And Bromday contains 0.09 percent
21 bromfenac, correct?

22 A Correct. Right.

23 Q And so Prolensa achieves the same
24 clinical effect -- efficacy as Bromday at a lower
25 dose, correct?

1 MR. JANUSZ: Object to form.

2 THE WITNESS: The percentage of the
3 drug is clearly lower and they're equally
4 effective.

5 BY MR. DINER:

6 Q Okay. The pH of an ophthalmic can
7 impact the ocular comfort upon installation of the
8 drug, correct?

9 A It can in some cases, but there are
10 numerous external extrinsic factors that also
11 influence that. So it's not the pH alone.

12 Q The pH of Prolensa is indicated in
13 Cykiert example -- pardon me, Exhibit 9 to be 7.8,
14 correct?

15 A Correct.

16 Q And if you look at Cykiert Exhibit 6, I
17 believe, for Bromday, it's indicated to be 8.3; is
18 that right?

19 A Yes.

20 Q And Exhibit 5 is Xibrom prescribing
21 information, and it indicates that the pH of Xibrom
22 is 8.3 as well; is that correct?

23 A Right.

24 Q Okay. So the pH of Prolensa at 7.8 is
25 closer to the pH of natural tears than either Xibrom

1 or Bromday, correct?

2 MR. JANUSZ: Object to form,
3 foundation.

4 THE WITNESS: Not necessarily, because
5 it turns out that the pH of people's tear
6 fluid is variable. So in some cases it may be
7 closer to a person's tear fluid and in other
8 cases not. So it really depends on what the
9 individual person's pH of their tear fluid is.

10 BY MR. DINER:

11 Q I believe in footnote 2 of your expert
12 report on page 19 you indicate that the pH of tear
13 fluid can vary between 6.5 and 7.6; is that right?

14 A Right.

15 Q So Prolensa at a pH of 7.8 is closer to
16 this range of natural tear fluid, as you've provided
17 in footnote 2, than either Xibrom or Bromday at a pH
18 of 8.3; is that right?

19 A That's correct, but it's not clinically
20 significant.

21 Q But it is closer, correct?

22 A Yes, on a pure number basis I agree
23 with you. It's definitely closer, but again, it's
24 not clinically significant.

25 Q And pH is on a logarithmic scale,

1 correct?

2 A I believe it is, right.

3 Q Was that the factor of 10 for each
4 movement on the pH scale, correct?

5 A Right. But again that's not clinically
6 significant, either. As you can see above that
7 there are listed about a dozen different eye drops.
8 One of them has a pH of about 4, Ciloxan eye drop.
9 It's the first one in Table 1. And that's a drop,
10 it's antibiotic. It's commonly used and patients
11 have no symptoms from that and find it to be very
12 comfortable. And so the pH alone doesn't tell you
13 much about the tolerance or side effects from a
14 medication because there are other factors involved.

15 Q But generally, a pH that is going to be
16 closer to the range for natural tears would be
17 expected to have greater ocular comfort, correct?

18 MR. JANUSZ: Object to form.

19 THE WITNESS: No, again, that's one of
20 those logical, assumptions that turns out to
21 be not logical and there's no evidence for
22 that. If that were the case, they'd be making
23 all these other drops at a different pH. So
24 similarly before when you said, well, 0.7
25 percent -- 0.07 percent is better than

1 0.09 percent. Again, when you think about it,
2 yeah, it would seem that way, but, in fact,
3 there's no evidence of that. So the statement
4 that pH of an eye drop being closer to the pH
5 of human tear film is better, there's no
6 evidence of that. That's just kind of a
7 supposition with no basis behind it.

8 BY MR. DINER:

9 Q Those other formulations that you
10 pointed to in Table 1 of your expert report deal
11 with many different active ingredients, correct?

12 A Those are the names of the specific
13 drops and each one of those has different active
14 ingredients and also inactive ingredients and also
15 different pHs.

16 Q Okay. Thank you.

17 Now, I believe that you said that a pH
18 of an eye drop being closer to the pH of human tear,
19 that there's no evidence that that would mean it
20 would have greater ocular comfort; is that right?

21 A Right.

22 Q And that that was supposition with no
23 basis behind it; is that your opinion as well?

24 A Right. Because there are numerous
25 other factors that contribute to that. So it's not

1 the pH alone.

2 Q Did you consider the expert report of
3 Dr. Prausnitz in providing your opinions in this
4 case?

5 A I saw parts of that report.

6 Q You saw parts of it in draft form?

7 A No, in what I was given.

8 Q When you say you saw parts of it in
9 what you were given, what does that mean?

10 A I didn't see the entire report.

11 Q Well, what parts did you see?

12 A I saw sections of it, which are
13 referred to in my report.

14 Q Were those draft sections?

15 A What do you mean by "draft sections"?

16 Q Non-finalized -- was it sections of a
17 non-finalized report?

18 A No, those were just sections that I
19 were given that are in my report, that's what I saw.
20 What's in my report is what I saw.

21 Q Were you told that the sections that
22 you were viewing came from a final and signed report
23 of Dr. Prausnitz?

24 MR. JANUSZ: Objection. I'll caution
25 the witness not to reveal the substance of any

1 communication with counsel.

2 THE WITNESS: Yeah, you're asking me
3 about discussions with attorneys specifically.
4 I don't know -- I have a privileged question
5 about that.

6 BY MR. DINER:

7 Q Well, I'll withdraw the question.

8 Do you recall what sections of
9 Dr. Prausnitz's report -- do you recall what
10 sections of Dr. Prausnitz's report that you
11 reviewed?

12 A Yes, the sections that are mentioned
13 specifically in my report. That's it.

14 MR. DINER: I'll mark the next exhibit.

15 (Expert Report of Mark R. Prausnitz,
16 Ph.D., Regarding Secondary Considerations was
17 marked Cykiert-10 for identification.)

18 BY MR. DINER:

19 Q Now, Dr. Cykiert, you've just been
20 handed what has been marked as Cykiert Exhibit 10.
21 This is an expert report of Mark R. Prausnitz,
22 Ph.D., regarding secondary considerations.

23 Have you seen this document before?

24 A I don't believe I've seen this entire
25 document before.

1 Q Would you turn, please, to page 16 of
2 Cykiert Exhibit 10. And I'll direct your attention
3 to paragraph 41, please.

4 A Okay.

5 Q Would you read the first sentence from
6 paragraph 41 into the record. I'm sorry, before you
7 do that, does this -- you can take a moment and look
8 at it, if you need to, but the section that we're in
9 of the Prausnitz report begins with page 16d and
10 goes to page 17, the middle of page 17. Can you
11 just take a moment and look at this and let me know
12 if this was the portion of Prausnitz's report that
13 you've seen before?

14 A I don't recall off the top of my head
15 if I saw it before or not, so I can't tell you for
16 sure whether I did see this section or not before,
17 but I could read it, if you want me to.

18 Q No, that's fine. If you can't
19 remember, you can't remember.

20 Let's just go to paragraph 41.

21 A Okay.

22 Q Could you read the first sentence into
23 the record, please?

24 A Even if there were a reduction in pH,
25 it is known in the scientific literature that

1 stinging and burning of the eye is affected by pH,
2 and a more physiologically pH causes less ocular
3 discomfort.

4 Q Is a more physiological pH one that is
5 closer to the pH of natural tears?

6 A That's what that would mean, right.

7 Q And would you agree that Dr. Prausnitz
8 is saying that a formulation that has a pH closer to
9 natural tears would have less ocular discomfort?

10 MR. JANUSZ: Objection,
11 mischaracterization, and objection to scope.

12 THE WITNESS: Give me one second to
13 read that again. Okay. The key two words
14 here, "scientific literature." Which
15 scientific literature is he mentioning? I'm
16 not really sure.

17 BY MR. DINER:

18 Q Well, if you read the previous
19 paragraph -- why don't you take a moment to read
20 that and then I can ask you a follow-up question.

21 A Okay. Okay. I read the paragraph
22 before that. Which basically says that actually
23 it's not 7.8. It's in a range of 7.5 to 8.5, and if
24 you go with the 8.5 it's actually above 8.3. So to
25 me it would seem like in general if you average the

1 pHs they're about the same.

2 Q Well, hold on one second. The range of
3 7.5 to 8.5 is referring to what is called a claimed
4 pH range, right?

5 A That's what it says there, right.

6 Q That's not talking about the range of
7 pH for natural tears, correct?

8 A That's referring to -- let me just read
9 that again. Yeah, what he's saying there is if you
10 look at patent '431, patent claim 10, the actual pH
11 of Prolensa is not limited to 7.8. It's between 7.5
12 and 8.5. That's in the patent claim. Do we have
13 the patent? We can look that up. And then if
14 that's the case, then the pH range of Prolensa is
15 very broad and in some cases it's identical to the
16 pH of Bromday and Xibrom. So on the average I would
17 say they have the equivalent pH.

18 Q I think you're misreading the
19 paragraph.

20 A Oh.

21 Q And particularly that sentence. That
22 sentence that you are referring to is referring to
23 -- not to Prolensa, but to claims of the '431
24 patent, right?

25 A Let me ask you this, just so I'm clear,

1 is the '431 patent one of the Prolensa patents?

2 Q It's my job to ask the questions.

3 A Oh, sorry.

4 Q Let's go to paragraph 41. So then when
5 Dr. Prausnitz says that a more physiological pH
6 causes less ocular discomfort, is that also
7 supposition on the part of Dr. Prausnitz?

8 MR. JANUSZ: Objection to form.

9 THE WITNESS: Not necessarily. He's
10 referring to scientific literature, and I just
11 like to know more specifically which
12 scientific literature he's referring to for me
13 to give you a definitive answer to that
14 question.

15 BY MR. DINER:

16 Q But you don't disagree with his
17 statement, correct?

18 MR. JANUSZ: Same objection.

19 THE WITNESS: You know, I can't agree
20 or disagree because I don't have enough
21 information right now to answer that
22 accurately.

23 BY MR. DINER:

24 Q And you don't know if you relied on
25 this section of Dr. Prausnitz's expert report for

1 the opinions you've given in your expert report,
2 correct?

3 A I'm not 100 percent positive, but I can
4 tell you from experience, and from Table 1 in my
5 report, that the pH of an eye drop itself does not
6 determine how comfortable or uncomfortable it is to
7 that patient. There are numerous other external,
8 extrinsic factors that go along with the pH to
9 determine that.

10 Q And so Dr. Prausnitz hasn't taken that
11 into account when making that statement that he
12 makes in paragraph 41, correct?

13 MR. JANUSZ: Objection, foundation,
14 calls for speculation.

15 THE WITNESS: Well, I can't say that
16 for sure because I didn't read this whole
17 document right now, but again, I'm not sure if
18 he's saying if all other parameters are
19 exactly the same, then perhaps reduction of pH
20 to a physiologic level is better. But if all
21 other external factors are different, then
22 it's different. So that's basically what I
23 can't determine, without reading this entire
24 document. So that's really a question, are
25 all other factors kept at a constant and if

1 it's just reduction of pH then that may be the
2 case. But if you combine the reduction of pH
3 to approximate the tear fluid pH, but other
4 factors change, then you can't really say
5 that. So it depends on other things. Hard to
6 say for sure.

7 BY MR. DINER:

8 Q So looking at this, you don't know if
9 Dr. Prausnitz in the statement he makes there, with
10 regard to physiological pH causing less ocular
11 discomfort, is right or wrong?

12 MR. JANUSZ: Object to form.

13 THE WITNESS: I'm not saying if it's
14 right or wrong. I just don't have enough
15 information. You're asking me to take one
16 sentence out of context and tell you right or
17 wrong, and I'm saying I can't really do that
18 and give you an accurate assessment of that.

19 BY MR. DINER:

20 Q You can put that aside.

21 A Thanks.

22 Q Now, with respect to Bromday, you
23 understand that that contains the surfactant
24 polysorbate 80, correct?

25 A Right. I believe it does. I'd have to

1 check the package insert for sure, but I believe
2 that it does.

3 Q And are you aware that the amount of
4 polysorbate 80 used in Bromday is 0.15 percent?

5 A Well, let me look it up, just to be
6 100 percent certain. Give me a second.

7 Q Sure.

8 A Okay, I have the Bromday. And you're
9 asking me what the polysorbate 80 concentration is?

10 Q I'm not sure you're going to see it in
11 there, Dr. Cykiert.

12 A Oh. Well, actually it does have it.

13 Q Oh, okay.

14 A If we turn to PROL0080496, the inactive
15 ingredients include polysorbate 80 at a
16 concentration of 1.5 milligrams per ML.

17 Q Okay. And then if it's based on a
18 weight per volume percent with bromfenac being
19 present at .09, does that get the amount of
20 bromfenac -- sorry, the amount of polysorbate 80 at
21 about 0.15 weight percent per volume?

22 A I'm sorry, that question I need
23 repeated because I think there were some --

24 Q Let's do it this way. How about I
25 represent to you that the amount of polysorbate 80

1 used in Bromday is 0.15 weight percent per volume,
2 will you accept that representation?

3 A I think so, off the top of my head.

4 Q And we can proceed on that basis.

5 A Okay.

6 Q Do you know what the -- strike that.

7 And do you understand that in Prolensa
8 the surfactant used is tyloxapol?

9 A Right.

10 Q Okay. And are you aware that the
11 amount of tyloxapol is 0.02 weight percent per
12 volume?

13 A I believe that's the number, but --
14 I'll take your word for it that's the number.

15 Q Okay. So as between Bromday at 0.15
16 weight per volume percent for polysorbate 80 and
17 Prolensa with 0.02 weight per volume percent for
18 tyloxapol, that represents about a seven and a half
19 times difference, right, approximately?

20 A That's a misleading comparison because
21 they're two completely different chemical compounds
22 and substances. So comparing the percentage is
23 completely irrelevant. You have to compare apples
24 and apples. If they both had polysorbate 80 and you
25 told me that Prolensa only has this much, very

1 little, and that Bromday has a huge amount, 10 times
2 that, then I would say that's a valid comparison.
3 But when you tell me drug A has only one apple in it
4 as a preservative and drug B has 10 oranges in it,
5 isn't drug A better because I only need one apple to
6 preserve it, whereas the other one I need 10
7 oranges. That's not a valid comparison, and it's
8 not technically correct to discuss it that way, from
9 a chemistry point of view.

10 Q Now, you said that they are two
11 completely different chemical compounds and
12 substances, right?

13 A Right.

14 Q What did you mean by that?

15 A Well, Tyloxapol is not polysorbate 80.

16 Q Are they chemically dissimilar then?

17 A They are different substances,
18 different chemicals, that's correct.

19 Q Are they vastly chemically dissimilar?

20 MR. JANUSZ: Objection, vague.

21 THE WITNESS: As I mentioned in the
22 beginning, I'm not a chemistry or a
23 pharmacology expert, so I can't tell you
24 exactly what the differences are, but clearly
25 they're different because they have different

1 names. So while apples and oranges are both
2 fruits, they're very different from each
3 other. So these are both fruits, but
4 polysorbate 80 is an apple, tyloxapol is an
5 orange, or maybe even a watermelon.

6 BY MR. DINER:

7 Q And so as a result they are very
8 chemically different, right?

9 MR. JANUSZ: Objection, asked and
10 answered, vague.

11 THE WITNESS: They're different
12 chemicals, correct. Otherwise if they weren't
13 different they'd have the same name, right?

14 BY MR. DINER:

15 Q And would different chemicals, such as
16 polysorbate 80 and Tyloxapol, they have different
17 chemical -- they have different properties as a
18 result of their differences in chemical structure,
19 right?

20 MR. JANUSZ: Objection, foundation.

21 THE WITNESS: That, I wouldn't know.
22 That, you'd require a chemistry expert or a
23 pharmacology expert or an expert in inactive
24 ingredients to tell you. I can tell you
25 they're different. So that comparisons of

1 percentage or weight volume is not a valid
2 comparison. The exact differences of those
3 two compounds, I'm not an expert at,
4 unfortunately, so I can't comment in any depth
5 on that.

6 BY MR. DINER:

7 Q I believe earlier, Dr. Cykiert, you
8 testified that there's information in the public
9 that Prolensa can cause some burning and stinging;
10 is that right?

11 A Yes, I did say that.

12 MR. DINER: I'd like to mark the next
13 exhibit.

14 (WebMD document on Prolensa Ophthalmic
15 was marked Cykiert-11 for identification.)

16 BY MR. DINER:

17 Q Dr. Cykiert, the court reporter has
18 handed you what has been marked as Cykiert Exhibit
19 11, which appears to be a WebMD publication with
20 regard to Prolensa ophthalmic.

21 Have you seen this document before?

22 A I've seen this on the website.

23 Q And is this the document that you were
24 referring to which would allegedly indicate that
25 Prolensa has, on occasion, caused burning and

1 stinging?

2 MR. JANUSZ: Object to form.

3 THE WITNESS: Give me a moment to look
4 at it.

5 BY MR. DINER:

6 Q Sure. Dr. Cykiert, I'll withdraw the
7 question.

8 A Okay.

9 Q But I just have a question about WebMD.
10 Are you familiar with WebMD as a service, a
11 publication service?

12 A Yes, I am.

13 Q Is the content of WebMD regulated by
14 the FDA, do you know?

15 MR. JANUSZ: Objection, vague.

16 THE WITNESS: I doubt it, but I'm not
17 100 percent sure. I don't think the FDA
18 regulates the site in general, but if they
19 have any advertisements on the websites for
20 pharmaceuticals or drugs, then the appearance
21 and contact of those ads may be partially
22 regulated by the FDA. So the answer is kind
23 of yes and no.

24 BY MR. DINER:

25 Q Okay. With regard to the content

1 outside of advertisements, is the content of WebMD
2 peer reviewed?

3 MR. JANUSZ: Same objection.

4 THE WITNESS: I'm not sure of the
5 answer to that, if it's peer reviewed or not.
6 But the point is, this article, which by the
7 way, you gave me Anne incomplete version of,
8 because the significant portion of this
9 article would be under the side effects
10 section, which this is only the uses section
11 and excludes the side effects section,
12 mentions that there's burning and stinging as
13 a result of Prolensa. But you asked me
14 earlier is this the example. This is just one
15 of many.

16 I found about eight different websites
17 from very reputable, reliable sources that
18 Prolensa causes burning and stinging. For
19 example, the Kaiser Permanente program in
20 California, which insures hundreds of
21 thousands or maybe millions of lives has a
22 section on Prolensa where it mentions burning
23 and stinging as a side effect. Memorial Sloan
24 Kettering Cancer Center here in New York,
25 which is the top cancer center in the USA, if

1 not in the world, or maybe in the top two,
2 also has a Prolensa section where it says it
3 causes burning and stinging. The University
4 of Maryland Medical Center has a Prolensa
5 website where it says Prolensa causes burning
6 and stinging. Syracuse University medical
7 center has a website with a section on
8 Prolensa where it causes burning and stinging.
9 So -- and there are a few others I don't
10 recall off the top of my head, but that's
11 present in many websites of reliable sources.

12 BY MR. DINER:

13 Q Now, none of those organizations that
14 you just mentioned that allegedly report Prolensa as
15 having burning and stinging are cited in your expert
16 report, correct?

17 A The only one I cited was this as an
18 example.

19 Q Okay.

20 A I could have cited the other ones,
21 though.

22 Q But you didn't, correct?

23 A I did not.

24 Q Okay. Now, the WebMD, it's not -- it's
25 not a peer reviewed journal or anything, correct?

1 MR. JANUSZ: Objection, vague.

2 THE WITNESS: I think I answered
3 earlier that I'm not 100 percent sure whether
4 it's peer reviewed or not.

5 BY MR. DINER:

6 Q Okay. That's fine. Now, do you know a
7 Dr. Silverstein?

8 A Are you referring to the
9 Dr. Silverstein mentioned in Dr. Trattler's reports?

10 Q Yes.

11 A I don't know that Dr. Silverstein, no.
12 I never heard of him before reading that.

13 Q How about Dr. Thomas Walters, do you
14 know him?

15 A I don't know him, and I never heard of
16 him before reviewing these documents.

17 Q Okay.

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

20 (Bromfenac Ophthalmic Solution 0.07%
21 Dosed Once Daily for Cataract Surgery
22 document, PROL0333854 - PROL0333862, was
23 marked Cykiert-12 for identification.)

24 BY MR. DINER:

25 Q Dr. Cykiert, the court reporter has

1 handed you what has been marked as PROL0333854
2 through 862. This document is entitled, Bromfenac
3 ophthalmic solution 0.07 percent dosed once daily
4 for cataract surgery, results of two randomized
5 control trials.

6 Have you seen this document before?

7 A Yes, I have.

8 Q Okay. And I believe you just said that
9 you do not know the first named author, Dr. Thomas
10 R. Walters; is that correct?

11 A I don't know him.

12 Q Do you know any of the other authors
13 that are identified in this article?

14 A Let me take a look. No, I don't.

15 Q Are you familiar with the journal in
16 which this article appeared?

17 A Yes, this is known as ophthalmology or
18 the AAO journal, the American Academy of
19 Ophthalmology journal.

20 Q Is this a peer reviewed journal?

21 A Yes, it is.

22 Q What does it mean to be a peer-reviewed
23 journal?

24 A It means that before they publish an
25 article the article is reviewed by an editorial

1 board and the journal who are experts in the field
2 of the article and they feel that the article is
3 worthy of being published.

4 Q And do you know what kind of review
5 process the article goes through?

6 A I don't know in exact detail what the
7 editorial board does to make that decision.

8 Q And I believe you said the editorial
9 board is comprised of experts in the field; ISTA
10 correct?

11 A Generally that's what they do.

12 Q And how about for the AAO, is the
13 editorial board for the AAO comprised of experts in
14 the field of ophthalmology?

15 A Yes.

16 Q Now, have you reviewed this article as
17 part of looking at it?

18 A Yes.

19 Q And is there anything in this article,
20 in terms of its substance, that you would disagree
21 with?

22 A No, I agree with it.

23 Q Okay. The type of design for the
24 tests, you see that on the first page? Under the
25 subheading, Design?

1 A Yes.

2 Q It says two phase 3 randomized,
3 double-masked, placebo-controlled, multicenter
4 clinical trials.

5 What does that mean?

6 A That means they did trials on patients
7 that were randomized, meaning they didn't know which
8 patient got placebo and which didn't. They were
9 double masked so that the doctors didn't know who
10 was getting what, and placebo control, that means
11 some patients got nothing and some got the active
12 drug, and they were done in several centers,
13 multicenter.

14 Q Is this a proper design for a clinical
15 study?

16 MR. JANUSZ: Objection, calls for
17 speculation.

18 THE WITNESS: To my knowledge, this is
19 a proper design, but I think I mentioned
20 earlier if -- if I didn't, I'm not an expert
21 in designing clinical trials. I haven't done
22 that. So I'm not an expert in that area, and
23 if you want my opinion as a non-expert, I
24 think it's okay.

25 BY MR. DINER:

1 Q Okay. And the authors of this article,
2 Cykiert Exhibit 12, say that they take
3 responsibility for the data that is presented in
4 this article and for the analysis of that data,
5 correct?

6 A They do, but they -- the problem here
7 is in their acknowledgments on the last -- next to
8 the last page, which ends in 860. It says, The
9 authors thank Maurico Munoz, PharmD. and Karen
10 Gertz, BA, of Bausch + Lomb, Irvine, California for
11 data review and verification.

12 In general, when the company that makes
13 the product is involved in the clinical trials,
14 there's a little lightbulb that goes off in every
15 doctor's mind and makes you wonder whether this is
16 completely independent or not. And, in fact, this
17 is an ongoing controversy now in the medical journal
18 publication world as to whether companies that
19 manufacture products should be involved in any way
20 in analysis, supervision, financing, review,
21 verification of the study because it has the
22 appearance of not being valid. And you need to be
23 sure that it's totally valid, that there are no
24 biases or outside influences, and you also need to
25 have the appearance of that. And when I see that

1 the drug company that makes the product is involved
2 in the process, I question the results of this.
3 That's number one.

4 You'll notice one of the authors of
5 this is the Bromfenac Ophthalmic Solution .07 Once
6 Daily Study Group. You know, it kind of reminds me
7 of when the tobacco companies did research on
8 cigarettes and said not only weren't they unhealthy,
9 but they were actually good for you.

10 Q Well, Dr. Cykiert, AAO is a reputable
11 journal, correct?

12 A Very reputable.

13 Q And it had an editorial board to review
14 this article, correct?

15 A Correct.

16 Q And you stated before that you didn't
17 have any issue or problem with the substance of this
18 article, correct?

19 A That's correct.

20 Q And the editorial board that reviewed
21 this journal did not express the same concerns that
22 you just did with regard to appearance of
23 impropriety, did they?

24 MR. JANUSZ: Objection, calls for
25 speculation.

1 THE WITNESS: Right. I don't know what
2 they said, but I'm just telling you -- you
3 asked me what I think of it and I'm being
4 honest with you. And it says on the last
5 page, the 862 page, sponsored by Bausch +
6 Lomb, Incorporated, Irvine, California, which
7 participated in the design of the study and
8 data analyses and interpretation and
9 supervised the preparation of the manuscript
10 and approved the final version. The authors
11 had full access to all study data and take
12 responsibility for the integrity, et cetera.

13 BY MR. DINER:

14 Q Could you continue to read that,
15 please?

16 A Sure. Take responsibility for the
17 integrity of data and the accuracy of the data
18 analysis. All authors participated in the
19 interpretation of the study findings and in the
20 drafting or critical revision of the manuscript, or
21 both.

22 But what I'm telling you is when the
23 company that makes the product is so heavily
24 involved in this, I have a little lightbulb that
25 goes off that says, hmm, and so do many of my

1 colleagues. I'm just telling you what the facts
2 are.

3 Q But those are not facts as opposed to
4 just your speculation that something is done here
5 that is improper, correct?

6 MR. JANUSZ: Object to the form of the
7 question.

8 THE WITNESS: Not speculation, but I
9 would say it's a very valid opinion that's
10 held by a majority of ophthalmologists.

11 BY MR. DINER:

12 Q But you have no basis for believing
13 that anything with regard to this study and the
14 reports in this article were done in any improper
15 way, correct?

16 A I have no evidence of that whatsoever.
17 I want to state that very clearly. But I'm just
18 telling you what my reservations are about the
19 appearance of this article.

20 Q Thank you. You can put that aside.

21 MR. DINER: I'd like to mark the next
22 document, please.

23 (Volume 14 from the Journal of the
24 American College of Nutrition, Number 3, June
25 1995, was marked Cykiert-13 for

1 identification.)

2 BY MR. DINER:

3 Q Dr. Cykiert, you've just been handed
4 what has been marked as Cykiert Exhibit 13. It's an
5 article from the Journal of the American College of
6 Nutrition. And do you recall this morning we were
7 talking about the subject of sulfite sensitivity?

8 A Yes.

9 Q Okay. Is this -- Cykiert Exhibit 13
10 indicate that this is a review article entitled,
11 Sulfite Sensitivity: Significance in Human Health?

12 MR. JANUSZ: I'll object to scope.

13 THE WITNESS: Yes, that's what it says
14 as the title. I'll agree with that.

15 BY MR. DINER:

16 Q Would you turn to the page identified
17 at the bottom of this Exhibit 13, page 230.

18 A Okay. Got it.

19 Q And right-hand column of the page.

20 A Yes.

21 Q About midway down, the paragraph
22 beginning, The manifestations of sulfite
23 sensitivity.

24 You see that?

25 A Yes.

1 Q In this paragraph, if you would like to
2 take a moment to read it, please do.

3 A Okay.

4 Q But the manifestations of sulfite
5 sensitivity that are discussed here, are those
6 similar to the ones we were discussing this morning
7 with regard to sulfite sensitivity?

8 MR. JANUSZ: Object to scope.

9 THE WITNESS: Let me read it first
10 before I respond.

11 BY MR. DINER:

12 Q Sure.

13 A Okay, I read it.

14 Q And so the manifestations of sulfite
15 sensitivity that are discussed here in this
16 paragraph that I've pointed you to of Cykiert
17 Exhibit 13, are those similar to the ones that we
18 discussed this morning with regard to sulfite
19 sensitivity?

20 MR. JANUSZ: Same objections.

21 THE WITNESS: Yeah, they look pretty
22 similar to me.

23 BY MR. DINER:

24 Q Okay. And the sources of sulfites that
25 give rise to sulfite sensitivity, are they

1 identified below in that same column in Table 1?

2 MR. JANUSZ: Same objection.

3 THE WITNESS: They list several sulfate
4 salts.

5 BY MR. DINER:

6 Q And is sodium sulfite listed among
7 several of those sulfate -- sulfite salts?

8 MR. JANUSZ: Same objection.

9 THE WITNESS: It's listed there, but I
10 don't know if that's a typo where it says
11 sulfate salts because sulfate and sulfite are
12 different.

13 BY MR. DINER:

14 Q Okay. Now, on the next page of this
15 article, page 231, right-hand column, first full
16 paragraph beginning with "Finally," you see that?

17 A Yes, I see that.

18 Q And does it indicate that sulfites can
19 be added to pharmaceutical agents as antibiotics --
20 pardon me, as antioxidants?

21 MR. JANUSZ: Same objection, and to the
22 extent there's any mischaracterization of the
23 document.

24 THE WITNESS: Let me read that, please.

25

1 BY MR. DINER:

2 Q Sure.

3 A Yes, it says they're added to
4 antibiotics and antioxidants.

5 Q Okay. And they could be added in
6 pharmaceuticals, as for example, an antioxidant,
7 correct?

8 MR. JANUSZ: Same objections.

9 THE WITNESS: That's what it says.

10 BY MR. DINER:

11 Q If you refer back to page 229, what is
12 the date that this Exhibit 13 was published?

13 MR. JANUSZ: Same objection.

14 THE WITNESS: 1995.

15 BY MR. DINER:

16 Q Thank you. You can put that aside.

17 A Thanks.

18 MR. DINER: Mark the next exhibit,
19 please.

20 (Article - Adverse reactions to
21 sulfites in drugs and foods, 1077 - 1080, was
22 marked Cykiert-14 for identification.)

23 BY MR. DINER:

24 Q Okay, Dr. Cykiert, the reporter has
25 just handed you Cykiert Exhibit 14. Cykiert Exhibit

1 14 is entitled, Adverse reactions to sulfites in
2 drugs and foods.

3 Do you see in the very first paragraph
4 of this article where it identifies sulfites as
5 antioxidants used in drugs?

6 MR. JANUSZ: Objection to scope.

7 THE WITNESS: I do see that in the
8 first sentence.

9 BY MR. DINER:

10 Q Okay. And a few lines down, does it
11 refer to one of the six sulfites that are used in
12 drugs and foods as being sodium sulfite?

13 MR. JANUSZ: Same objection.

14 THE WITNESS: Yes, it says sodium
15 sulfite there.

16 BY MR. DINER:

17 Q And what is the publication date of
18 this article?

19 MR. JANUSZ: Same objection.

20 THE WITNESS: It says June 1984 at the
21 top of the page.

22 BY MR. DINER:

23 Q And if you go two pages into the
24 article, it also identifies that same date, correct,
25 June 1984?

1 MR. JANUSZ: Same objection.

2 THE WITNESS: Right.

3 MR. DINER: You can put that aside.

4 (Vol. 99, No. 2, February 1997 article
5 from the American Academy of Pediatrics,
6 "Inactive" Ingredients in Pharmaceutical
7 Products: Update (Subject Review) was marked
8 Cykiert-15 for identification.)

9 THE WITNESS: Thanks.

10 BY MR. DINER:

11 Q Okay. Dr. Cykiert, you've just been
12 handed Cykiert Exhibit 15. This is an article from
13 Pediatrics -- American Academy of Pediatrics,
14 entitled "Inactive" Ingredients in Pharmaceutical
15 Products Update. And in parens beneath the title it
16 says, Subject Review.

17 Now, I refer you to the first page of
18 this document, right-hand column. Under the
19 subheading, sulfites, do you see that, sulfiting
20 agents are used as antioxidants?

21 MR. JANUSZ: Object to scope.

22 THE WITNESS: I see that, right.

23 BY MR. DINER:

24 Q And then one of the six identified
25 sulfite antioxidants can be sodium sulfite?

1 MR. JANUSZ: Objection, scope, and
2 mischaracterization of the document.

3 THE WITNESS: I see it says that.

4 BY MR. DINER:

5 Q And then in the bottom of that same
6 paragraph it indicates that the sulfites can be used
7 in ophthalmic administration of sulfite-containing
8 drugs; is that correct?

9 MR. JANUSZ: Same objections.

10 THE WITNESS: Let me read that. That's
11 not exactly what it says, unless I
12 misunderstood your question.

13 BY MR. DINER:

14 Q Does it indicate that sulfites are used
15 in ophthalmic formulations?

16 MR. JANUSZ: Same objections.

17 THE WITNESS: It says children have had
18 serious reactions after ophthalmic
19 administration of sulfide-containing drugs.

20 BY MR. DINER:

21 Q Okay. And on the next page, does it
22 discuss what some of those reactions were?

23 MR. JANUSZ: Same objections.

24 THE WITNESS: Yes, it mentions some.

25

1 BY MR. DINER:

2 Q And does that include some of the
3 manifestations of sulfite sensitivity that we
4 discussed earlier this morning?

5 MR. JANUSZ: Same objections.

6 THE WITNESS: It appears to repeat some
7 of those.

8 BY MR. DINER:

9 Q And what is the publication date of
10 this article, Cykiert Exhibit 15?

11 A February 1997.

12 Q Thank you. You may put that aside.

13 MR. JANUSZ: Bryan, we've been going
14 for, I think, about an hour. Is this a good
15 time for a break?

16 MR. DINER: Actually, I think I'm done.
17 I have no further questions.

18 MR. JANUSZ: We have nothing further as
19 well.

20 VIDEO OPERATOR: Going off the record,
21 3:09 p.m.

22 This is the end of disc 3. and
23 completes the deposition of Robert C. Cykiert.

24

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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: March 1, 2016

1 ATTACH TO DEPOSITION OF: Robert C. Cykiert
IN THE MATTER OF: Senju vs. Innopharma

2 DATE TAKEN: February 26, 2016

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_____, 2016

To: JOSEPH M. JANUSZ, ESQUIRE

Case Name: Senju Pharmaceutical Co., Ltd v. Lupin Limited And Lupin
Pharmaceuticals

Veritext Reference Number: 2238419

Witness: Robert C. Cykiert Deposition Date: 2/26/2016

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Cc: BRYAN C. DINER, ESQUIRE
SARAH FINK, ESQ

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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.