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)

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

Plaintiffs,

vs.

LUPIN, LTD. AND LUPIN PHARMACEUTICALS, INC.,

Defendants.

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

Plaintiffs,

vs.

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

Defendants.

Job No. NJ 2238413

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

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I N D E X



E X H I B I T S

E X H I B I T S (CONTINUED)

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

My name is Kevin Gallagher, representing Veritext New York.

The date today is February 24, 2016.

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

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

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

Our witness this morning is Ivan T. Hofmann.

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

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

Henderson.

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

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

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

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

BY MR. DINER:

Q Good morning, Mr. Hofmann.

A Good morning, Mr. Diner.

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

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

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

A I have.

Q A number of times?

A Correct.

Q So you're familiar with the drill?

A I am.

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

A That sounds good.

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

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

Does that sound fair?

A I understand.

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

A Sounds good.

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

Is that okay?

A Yes, sir.

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

A Yes.

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

A No, sir.

Q Okay.

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

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

BY MR. DINER:

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

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

Q Does it include your exhibits and appendices?

A Yes, it does.

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

A Sure.

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

A It is.

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

A I did, with my team from Gleason IP.

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

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

Q Very good. Thank you.

Is that your current CV, Mr. Hofmann?

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

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

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

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

A It is.

Q Anything more to add to it?

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

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

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

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

A Yes.

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

A Yes, among others.
Q Okay. And so you reviewed that opening report of Mr. Jarosz, correct?
A I did.
Q And you also reviewed the opening report of Dr. Williams on infringement and objective indicia of non-obviousness?
A I did.
Q And did you also review the expert report of William Trattler, M.D., on objective indicia of non-obviousness?
A I did.
Q Did you -- in preparation for your deposition today, did you consider any reply reports that were submitted by Dr. Williams?
A I believe I have seen the Williams reply report, yes, I have.
Q And have you considered the reply report of John Jarosz?
A I have, yes.
Q And how about the reply report of William Trattler, have you seen that?
A Yes.
Q Did you review the reply report of John Jarosz?

A I did. I mean, for completeness. There are several other expert reports I've also reviewed.

Q Okay. What are they?

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

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

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

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

A From counsel.

Q Through counsel?

A Correct.

Q Counsel told you what Dr. Cykiert's

opinions were?

A Correct.

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

A Dr. Prausnitz.

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

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

Q Could you explain the process?

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

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

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

spent analyzing and addressing issues in pharmaceutical economics.

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

Q Are you a patent lawyer?

A I'm not a patent lawyer.

Q Are you a named inventor on any patents?

A I'm not.

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

A No, sir.

Q Are you an expert in pharmaceutical marketing?

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

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

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

A No. My work has been as a consultant.

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

A No, not directly.

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

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

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

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

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

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

Q Do you know the applicable standards

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

A I'm familiar with those.

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

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

Q Okay. Are you an expert in ophthalmology?

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

Q Are you an expert in the field of pharmacy?

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

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

Q You never formulated a pharmaceutical product yourself, correct?

A I have not.

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

A Correct.

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

A Correct.

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

A I have not. That's what I was

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

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

A No.

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

A I have not.

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

A No, sir.

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

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

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

A No, sir.

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

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

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

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

Q Okay. We can turn to your report.

If you turn to page 106 your report, paragraph 18. It's Hofmann Exhibit 1.

A I'm there.

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

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

Q Did you look that information up yourself?

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

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

A Okay.

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

to the purported merits of the claimed invention.

Do you see that?

A Yes.

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

A Of course.

Q And what are those factors?

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

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

A Absolutely.

Q Financing?

A Sure.

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

A Yes, those are examples.

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

A Yes. And sometimes explain it.

Q I'm sorry?

A And sometimes explain the commercial success.

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

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

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

product?

A No, that's not my position.

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

THE WITNESS: Certainly.

MS. FINK: Thank you.

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

BY MR. DINER:

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

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

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

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

Q I believe that was about August of

2015. Does that sound right?

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

Q September 30, 2015?

A Correct.

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

A Correct.

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

A Correct.

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

MS. FINK: Objection, calls for speculation.

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

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

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

BY MR. DINER:

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

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

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

MS. FINK: Objection, calls for

speculation.

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

BY MR. DINER:

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

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

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

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

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

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

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

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

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

A Yes.

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

A That's my understanding.

Q And that patent expires in September 2025, right?

A Correct.

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

MS. FINK: Objection, calls for speculation.

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

BY MR. DINER:

Q And there are -- strike that for now.

A I don't think Bromday was on the market

any longer than Prolensa has been on the market.

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

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

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

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

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

MS. FINK: Objection, argumentative.

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

BY MR. DINER:

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

MS. FINK: Objection, incomplete hypothetical.

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

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

BY MR. DINER:

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

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

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

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

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

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

BY MR. DINER:

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

Have you seen this document before, Mr. Hofmann?

A Yes, I have.

Q In what context?

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

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

A Yes.

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

A Correct.

Q You used to work at Deloitte?

A Yes, I did.

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

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

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

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

BY MR. DINER:

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

A Sure.

Q Is that a yes, you're ready?

A No. No. I will let you know.

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

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

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

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

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

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

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

BY MR. DINER:

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

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

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

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

BY MR. DINER:

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

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

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

MS. FINK: Objection, calls for speculation.

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

BY MR. DINER:

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

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

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

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

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

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

MS. FINK: Objection, incomplete hypothetical, speculation.

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

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

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

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

BY MR. DINER:

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

Bates numbers PROL0339526 through 9561.

Have you seen this document before?

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

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

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

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

Is that right?

A Yes.

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

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

THE WITNESS: Okay, I see that.

BY MR. DINER:

Q In this passage you just read, it

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

See that?

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

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

BY MR. DINER:

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

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

Q The --

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

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

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

Do you see that?

A I think those are the words, yes.

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

Do you see that?

A I see those words.

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

A I totally disagree with you.

Q You disagree with what is stated in this article?

A I don't think that this article is

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

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

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

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

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

A Bromday, and then Xibrom before it.

Q Bromday hasn't been delisted, has it?

A I believe it has.

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

A There is, but there's no RLD.

Q There's no what?

A RLD.

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

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

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

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

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

generic Bromday?

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

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

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

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

BY MR. DINER:

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

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

THE WITNESS: I think it depends on the

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

BY MR. DINER:

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

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

Q And how about as of September 2015?

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

Q We'll get back to that, then.

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

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

management situation.

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

MS. FINK: Objection, incomplete hypothetical.

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

BY MR. DINER:

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

the product?

MS. FINK: Objection, incomplete hypothetical, vague.

THE WITNESS: What do you mean "investment"?

BY MR. DINER:

Q Marketing investment, marketing expenditures.

A It depends.

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

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

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

A Sure.

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

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

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

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

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

Q There was significant expenditures made; is that correct?

A Yeah, tens of millions of dollars.

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

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

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

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

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

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

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

MR. DINER: Can we mark the next exhibit.

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

Hofmann-4 for identification.)

BY MR. DINER:

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

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

Mr. Hofmann, have you seen this --

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

MR. DINER: Oh, thank you.

BY MR. DINER:

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

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

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

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

A The name sounds familiar.

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

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

Do you see that?

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

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

MS. FINK: Objection, incomplete hypothetical.

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

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

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

BY MR. DINER:

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

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

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

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

MR. DINER: I would like to mark the

next exhibit.

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

BY MR. DINER:

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

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

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

A I think we covered that earlier. Maybe

not in those exact words, but --

Q The concept is correct?

A Yeah.

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

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

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

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

A That's what it says.

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

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

A Correct.

Q We were talking a moment ago about marketing expenditures.

A Excuse me.

Q Are you ready?

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

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

A Yes.

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

A Yes.

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

A I think --

Q Post-launch.

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

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

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

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

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

BY MR. DINER:

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

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

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

Q Okay.

A Go ahead.

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

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

BY MR. DINER:

Q Is that correct?

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

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

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

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

A I mean -- go ahead.

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

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

BY MR. DINER:

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

You see that portion of the graph?

A I do.

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

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

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

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

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

with respect to the gross sales figure.

BY MR. DINER:

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

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

Q Okay.

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

MS. FINK: Okay.

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

(Brief recess.)

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

BY MR. DINER:

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

Do you recall that?

A Yes, I do.

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

decreasing and gross sales increasing.

Do you recall that?

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

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

A Yes.

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

MS. FINK: Objection, incomplete hypothetical.

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

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

BY MR. DINER:

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

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

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

BY MR. DINER:

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

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

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

A Yes.

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

A I understand.

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

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

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

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

MS. FINK: Objection, mischaracterizes testimony.

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

BY MR. DINER:

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

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

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

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

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

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

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

BY MR. DINER:

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

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

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

Q Are they also used to advertise a new product?

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

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

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

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

MS. FINK: Objection, incomplete hypothetical.

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

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

BY MR. DINER:

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

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

Q But as an incentive, and even as a

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

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

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

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

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

discounts in that chart that really tells us nothing.

BY MR. DINER:

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

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

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

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

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

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

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

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

MS. FINK: Objection, argumentative, mischaracterizes testimony.

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

BY MR. DINER:

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

A That's correct.

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

A I'm just trying to answer your questions.

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

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

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

A Could you read that back?

Q I'll restate it.

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

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

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

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

MS. FINK: Objection, asked and answered.

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

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

BY MR. DINER:

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

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

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

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

A No, IMS, TRx data and NRx data.

Q The TRx stands for what?

A Prescriptions, total prescriptions.

Q So -- okay. And the NRx?

A New prescriptions.

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

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

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

A No.

Q And IMS data, do they provide unit sales?

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

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

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

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

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

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

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

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

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

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

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

A Yes, sir.

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

A That's right.

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

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

Q I think in your report you say it's

60 percent.

A That's right.

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

A That's right.

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

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

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

MS. FINK: Objection, calls for speculation.

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

BY MR. DINER:

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

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

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

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

MS. FINK: Objection, asked and answered.

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

BY MR. DINER:

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

Do you recall that?

A Yes.

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

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

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

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

BY MR. DINER:

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

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

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

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

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

BY MR. DINER:

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

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

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

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

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

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

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

harvest value and maximize profits and evergreen franchises.

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

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

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

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

don't -- compliance would be easier.

Q Any other examples?

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

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

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

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

BY MR. DINER:

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

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

A I have.

Q In what context?

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

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

Do you see that?

A Yes.

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

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

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

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

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

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

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

there are plenty of instances where it would not be.

BY MR. DINER:

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

Are you there?

A Uh-huh.

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

A I do.

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

Now, did I read that accurately?

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

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

A Yes.

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

A I guess potentially.

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

Do you see that?

A I see that.

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

MS. FINK: Objection, incomplete hypothetical.

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

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

BY MR. DINER:

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

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

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

amount of a foreign active substance?

MS. FINK: Objection, incomplete hypothetical.

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

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

BY MR. DINER:

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

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

MS. FINK: Objection.

BY MR. DINER:

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

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

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

BY MR. DINER:

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

MS. FINK: Objection, incomplete hypothetical.

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

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

BY MR. DINER:

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

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

THE WITNESS: So I'm not a technical

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

BY MR. DINER:

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

A That's right.

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

A Sure.

Q What's your understanding of that?

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

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

MS. FINK: Objection, calls for speculation.

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

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

BY MR. DINER:

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

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

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

It would be a facts and circumstances-based thing.

BY MR. DINER:

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

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

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

BY MR. DINER:

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

MS. FINK: Same objections.

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

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

BY MR. DINER:

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

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

Q But there may be some indeed, correct?

A I defer to the technical experts.

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

MS. FINK: Sure. That's fine.

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

(Lunch recess.)

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

This is the beginning of file three.

BY MR. DINER:

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

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

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

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

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

BY MR. DINER:

Q Okay. Can you turn to paragraph 60 of

your opinion -- of your expert report, please?

A What page or paragraph?

Q Paragraph 60, page 31.

A Okay.

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

Do you see that?

A Yes.

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

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

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

A Yes.

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

ingredients extend patent lives.

Do you see that?

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

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

A No, I didn't.

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

MS. FINK: Objection, misstates prior testimony.

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

BY MR. DINER:

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

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

report.

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

BY MR. DINER:

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

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

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

BY MR. DINER:

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

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

MS. FINK: Objection, calls for speculation.

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

BY MR. DINER:

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

A Okay.

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

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

profile of Prolensa and Bromday.

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

A Yes.

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

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

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

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

Q And did you speak with any other

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

A I did not.

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

Do you see that?

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

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

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

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

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

Q And would that be the case for any of

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

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

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

A Yes.

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

A Yes.

Q I probably should ask it differently.

Did you know that polysorbate 80 was the surfactant in Bromday?

A Yes.

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

A Yes.

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

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

about that off the record, if we need to.

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

BY MR. DINER:

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

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

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

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

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

A Yes.

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

A Yeah. My understanding is that it's a

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

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

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

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

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

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

A I don't remember that particular

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

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

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

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

BY MR. DINER:

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

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

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

BY MR. DINER:

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

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

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

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

BY MR. DINER:

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

A Certainly I have no technical opinion at all.

Q Any other opinion?

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

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

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

Q And how about your -- how about the

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

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

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

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

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

MR. DINER: Is this number 7?

MS. FINK: Yes.

BY MR. DINER:

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

A Yes, thank you.

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

Okay. Now, have you seen this document before?

A Yes, I have.

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

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

Q Yes, you do.

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

Do you recall that?

A Yes.

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

Do you recall that?

A Yes.

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

Let me know when you're ready.

A Yep.

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

A Yes.

Q And this slide is discussing two products, correct?

A Yes.

Q Bromfenac and Prolensa, right?

A That's correct.

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

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

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

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

A Designed for Comfort and Convenience.

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

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

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

BY MR. DINER:

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

MS. FINK: Objection, calls for speculation.

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

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

BY MR. DINER:

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

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

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

A According to this slide.

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

A According to this slide.

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

BY MR. DINER:

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

A That's what it appears here.

Q Now you just wiped your eye. Did you

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

A I wouldn't know where to begin.

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

A According to this.

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

A I mean, mathematically, sure.

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

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

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

insights he discussed.

BY MR. DINER:

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

MS. FINK: Objection, mischaracterizes testimony.

BY MR. DINER:

Q Is that correct?

A I'm not sure I understood the question.

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

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

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

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

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

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

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

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

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

BY MR. DINER:

Q But you sourced your knowledge in some respects --

A Right.

Q -- from Dr. Prausnitz, correct?

A Correct.

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

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

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

BY MR. DINER:

Q Where do you remember reading that?

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

stuff. It could be that I'm --

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

A Correct.

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

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

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

MS. FINK: Objection.

BY MR. DINER:

Q Would you accept that representation?

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

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

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

BY MR. DINER:

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

A I am.

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

A Correct.

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

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

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

BY MR. DINER:

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

Have you seen this document before?

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

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

Q Okay. Are you okay?

A Oh, yeah. Maybe not.

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

THE WITNESS: No, I'm okay.

BY MR. DINER:

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

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

Do you see that there?

A Yes, I see that.

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

enhances ocular penetration.

Do you see that passage there?

A Yes.

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

BY MR. DINER:

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

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

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

BY MR. DINER:

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

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

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

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

BY MR. DINER:

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

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

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

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

I think they explain their opinions in their reports.

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

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

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

BY MR. DINER:

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

in this matter, correct?

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

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

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

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

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

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

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

BY MR. DINER:

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

Do you remember that?

A Yes.

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

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

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

claimed invention?

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

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

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

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

A Correct.

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

A Sure.

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

BY MR. DINER:

Q And I also represented to you that the

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

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

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

BY MR. DINER:

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

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

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

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

BY MR. DINER:

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

Do you recall that from his opinion?

A Yes.

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

A Correct.

Q And Prolensa has 0.07 percent bromfenac, correct?

A That's my understanding.

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

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

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

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

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

BY MR. DINER:

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

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

THE WITNESS: That was a long question.

BY MR. DINER:

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

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

MS. FINK: Same objection.

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

BY MR. DINER:

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

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

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

A For considering -- well, that is --

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

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

MS. FINK: Objection, mischaracterizes testimony.

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

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

BY MR. DINER:

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

A Yes.

Q So you just said a moment ago that your

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

MS. FINK: Objection, misstates prior testimony.

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

BY MR. DINER:

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

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

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

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

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

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

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

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

BY MR. DINER:

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

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

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

A I may have seen that, yes.

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

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

Q You didn't consider them, did you?

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

You're asking me about --

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

Does that sound right?

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

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

BY MR. DINER:

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

A Okay.

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

A That's the math.

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

MS. FINK: Same objection.

THE WITNESS: Based on that math.

BY MR. DINER:

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

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

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

BY MR. DINER:

Q Do you know a surfactant is actually a soap?

A Right.

MS. FINK: Same objection.

BY MR. DINER:

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

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

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

BY MR. DINER:

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

A Perhaps.

Q Did it burn and sting?

A I mean --

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

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

BY MR. DINER:

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

A Really, nothing comes to mind.

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

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

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

meaningful impact one way or the other.

BY MR. DINER:

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

MS. FINK: Objection, mischaracterizes testimony.

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

BY MR. DINER:

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

But you didn't consider the relative

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

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

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

MR. DINER: Mark the next exhibit, please.

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

BY MR. DINER:

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

MS. FINK: Nine.

BY MR. DINER:

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

Have you seen this document before?

A Yes.
Q Okay. In what context?
A This case.
MS. FINK: One second. Do you need a break? You seem to be coughing a bit? An Advil?
THE WITNESS: No, I'm okay. I mean, we can go another five, ten minutes, that's fine.
MS. FINK: Okay, apologies.
THE WITNESS: When I say I've seen this, I know I've seen a Xibrom label. I don't remember if it was this exact one.
BY MR. DINER:
Q So I think earlier this morning you testified that you have some familiarity with the FDA's process for approving the labeling of drugs.
Do you recall that?
A Yes.
Q Okay. Now, this document, which is Hofmann Exhibit 9, from the first page, does it appear to be highlights of prescribing information for Xibrom?
A Yes.
Q Okay. If you go over to the right-hand column under adverse reactions. Are you there?

A Yes.

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

A Yes.

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

A Yes.

Q You may put that aside.

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

BY MR. DINER:

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

Have you seen this document before?

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

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

A Yes.

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

A It says adverse reactions.
Q Sorry. Thank you.
A And eye irritation is listed among others.
Q And eye irritation is said to include burning and stinging, correct?
A Yes.
Q Okay. When the FDA approves a label such as this, are they doing so based on clinical studies that have been provided to them?
A Yes.
Q Okay. And when they approve a label that identifies the adverse events, are they doing so also based on clinical studies indicating the occurrence of adverse reactions?
MS. FINK: Objection, beyond the scope of his expert report.
THE WITNESS: That's my understanding.
BY MR. DINER:
Q Okay. And for Bromday, which is discussed in Hofmann Exhibit 9, and Xibrom, which is discussed in Hofmann Exhibit -- sorry, strike that. For Bromday, which is discussed in Hofmann Exhibit 10, and Xibrom, which is discussed in Hofmann Exhibit 9, both of them, you testified, indicate

that the adverse reactions include eye irritation such as burning and stinging, right?

A That's what the labels read, yes.

Q And that would have been based on clinical studies confirming the occurrence of eye irritation for those products, correct?

A That's typically the case.

Q Okay.

(PROL0080219 - PROL0080224 was marked Hofmann-11 for identification.)

BY MR. DINER:

Q You've just been handed Hofmann Exhibit 11, bearing Bates numbers PROL0080219 through 224.

And have you seen this document before, Mr. Hofmann?

A Yes.

Q What is it?

A It's a label for Prolensa.

Q Okay. And over in the right-hand column on the first page under adverse reactions, do you see anywhere in there where it indicates that Prolensa had the adverse reaction of eye irritation, including burning or stinging?

MS. FINK: You should read whichever parts of the document you need to.

THE WITNESS: I mean, I think that the language in this label and the 3 to 8 percent frequency of other adverse reactions does not include the exact same words, "eye irritation," but I think Dr. Cykiert addresses in his report the, I think, clinical implication of his experience and the experience with respect to Prolensa versus other NSAIDs. But it does not include those same words, but it has other adverse reactions.

BY MR. DINER:

Q But it doesn't have listed here the adverse reaction of eye irritation, including burning or stinging, correct?

MS. FINK: Objection, asked and answered.

THE WITNESS: Not those exact words. I mean, it says eye pain and other -- other adverse reactions, but no, not those exact two words.

BY MR. DINER:

Q Well, take a look at Hofmann Exhibit 10, under adverse reactions.

A I'm there.

Q Sorry. So the label as approved for Prolensa, particularly the description of adverse reactions, that also would have been -- that would also have been approved by the FDA, based on clinical studies, correct?

A It appears so.

Q And the fact that eye irritation and burning and stinging is not listed as an adverse reaction for Prolensa means that the clinical studies supplied by the company to the FDA supported a label that did not have a recitation of eye irritation, burning and stinging, correct?

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

THE WITNESS: I think that's a very technical issue that, you know, the selection of the words for the clinical adverse reactions, I wouldn't have an opinion on one way or the other, you know, what all is factored into the FDA's decision, as well as what's advocated by the company in terms of the particular words that appear in the label.

And if we're at a decent shifting point can we take a break?

MR. DINER: It's fine, we can take a

break.

VIDEO OPERATOR: We're now going off the record at approximately 2:16 p.m.

(Brief recess.)

VIDEO OPERATOR: This is the beginning of file four.

We're going back on the record, approximately 2:31 p.m.

BY MR. DINER:

Q Okay. Mr. Hofmann, can we turn to paragraph 62 of your report? I see, unfortunately, that you have a black-and-white version. I apologize for that. I will try to muddle our way through that, if that's okay with you.

A I'll do my best.

Q Okay. So within paragraph 62 we're going to refer to the graph that is there. Can you see the line of demarcation as between what is indicated to be the Xibrom sales and then it then transitions to the Bromday sales?

A A lot better on yours. It's real faint up here. I can't -- I mean, I think that's it.

Q What is the approximate time point where the Xibrom sales cease or transition into the Bromday sales?

A I mean, I know it was 2011. Do you need a month?

Q No, no, that's fine. And based on the graph -- maybe you can see this one more clearly. What is the approximate time where, in just the year, where the Bromday sales appear to transition into, and then we go into and see Prolensa sales beginning?

A 2013.

Q Okay. Now, on my copy, which is in color, and yours, unfortunately, is not, above the areas for Xibrom, but particularly Bromday and Prolensa, there's another shaded area. It appears in purple on my graph. Do you know what that is?

A That's the generic bromfenac sodium products. And IMS didn't break out those that were originally launched with the Xibrom as the RLD and then those that were launched with the label more consistent with once daily Bromday.

Q So those could be collectively sales of generic Xibrom and generic Bromday; is that right?

A Correct.

MS. FINK: I just want to put on the record here with this black-and-white version it's really very difficult to see the

difference between the Bromday and the bromfenac sodium. The others are difficult as well, but that demarcation line is practically invisible in the black-and-white version.

MR. DINER: Well, so far we've been able to muddle our way through this.

MS. FINK: Yes. I just wanted that of record.

BY MR. DINER:

Q So then perhaps you can help me to read and understand the significance of the sales of the collective generic bromfenac sodium products. These are prescriptions of these products, correct?

A Correct.

Q And so is this indicating that the sales of generic bromfenac sodium surpassed Bromday and Prolensa?

A No. It's a stacking graph, and so in your version, which is purple, and maybe we can later swap this out for a color version, the purple area is limited to that purple area. So what this means is that generic bromfenac sodium sales are a small fraction of the total sales of either Xibrom, Bromday or Prolensa.

Q It doesn't mean, for example, let's

just table directly in line with 2012 and draw a line up to the peak of the part of the graph that represents generic bromfenac sodium. Does that mean that there were, in that particular month of 2012 somewhere between 200 and 250,000 prescriptions?

A No. That means in total bromfenac prescriptions be they Bromday or bromfenac sodium, it was 250,000 or whatever the number is, you said, comprised of, I don't know, tens of thousands being the purple in the form of generic bromfenac sodium and then over 200,000 being the red that is Bromday. And so that's why it's called a stacking graph. You basically add them together.

Q So this is a differential amount?

A No. I mean, I don't know if -- the underlying data -- we could go to Jarosz Tab 6, and you can see that it's like -- like I said, I'm making up numbers, but by an order of magnitude, you know, maybe 40,000 scripts of the generic and 220,000 scripts of the brand for that period. Well, that's too high. That's too high an illustrative number. So if I go up 2012 is about 225,000 scripts. So without any precision -- if we wanted precision, we would go to Jarosz Tab 6, which summarizes the underlying IMS data we're talking

about an order of magnitude of, you know, maybe 20 to 30,000 bromfenac sodium generic sales and 170,000 Bromday sales.

Q Okay. Okay. Now I understand. Thank you.

Okay. Okay. Now, in 2011 where we see a transition as between Xibrom and Bromday, was one of the benefits attributable to Bromday over Xibrom the fact that it was dosed once a day instead of twice a day?

MS. FINK: Objection, outside the scope of his expert report.

THE WITNESS: My understanding is that, you know, the formulation itself didn't change. I defer to technical experts, but my understanding is that the formulation itself didn't change. They just got it relabeled to be once daily, and that was the primary difference.

BY MR. DINER:

Q And that improved patient compliance, correct?

A I think that was the view that that improves patient compliance.

Q And the -- as a product that improves

patient compliance, that's a benefit to the consuming public, correct?

MS. FINK: Objection, calls for speculation.

THE WITNESS: We talked about this earlier. I mean, I think that's a -- it depends. Sometimes improved compliance is not meaningful. Sometimes it is.

BY MR. DINER:

Q And how about in the cases between Xibrom and Bromday, do you know?

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

THE WITNESS: I mean --

BY MR. DINER:

Q Would you like to refer to paragraph 75 to see if it's within the scope of your expert report? You're certainly welcome to do that.

A I think where I was going is to say that in general I think that the market for these ophthalmics was moving to once daily. It started out as four times daily, moved to twice daily, and it was viewed that once daily Bromday is a benefit over multiple times daily.

Q Okay. Now, as we move to Bromday and

we look at the line as between -- in the graph as between Bromday and Prolensa, I think we said that that comes at approximately 2013, right?

A Correct.

Q Now, the differences between the Bromday and Prolensa formulation we talked about before was, in some respect, the surfactant, correct?

A Yes.

Q And that Prolensa used tyloxapol instead of polysorbate 80, correct?

A Correct.

Q And that Prolensa used approximately one-eighth the concentration of tyloxapol compared to the amount of polysorbate 80 used in bromfenac, correct?

A We did talk -- go ahead.

MS. FINK: I believe you might have misspoke. You meant compared to the concentration of polysorbate 80 in Bromday.

MR. DINER: I'll restate it. Thank you.

BY MR. DINER:

Q And so I believe we spoke before about how Prolensa used about one-eighth the amount of

tyloxapol compared to the amount of polysorbate 80 used in Bromday, correct?

A We did talk about that.

Q And also that some of the other differences we mentioned between the products was that the pH in Bromday was 8.3 and it was lowered to 7.8 in Prolensa, right?

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

THE WITNESS: We looked at that document we talked about.

BY MR. DINER:

Q And that with a pH of 7.8 Prolensa was closer to the pH of natural tears at 7.4, correct?

A According to that slide in the PowerPoint.

Q And that at a pH of 7.8 the ocular penetration of Prolensa was the same or comparable to the ocular penetration of Bromday, correct?

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

THE WITNESS: Can you read that back?

BY MR. DINER:

Q With regard to the lowering of pH from 8.3 in Bromday to 7.8 in Prolensa, we spoke earlier

about the impact of that on ocular penetration, correct?

A We did.

Q And you remember me showing you the article which talked about how Prolensa at 7.8 got better ocular or comparable ocular penetration to Bromday at 8.3?

MS. FINK: Objection to the extent it mischaracterizes that document.

THE WITNESS: The article being the rabbit study?

BY MR. DINER:

Q Yes.

A Yes, those sentences you pointed me to said that.

Q And with the increased ocular penetration they were able to lower the active ingredient about 22 percent?

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

BY MR. DINER:

Q Do you recall that?

A I agreed that they did lower the .09 to .07 and that works out to 22 percent.

Q Okay. And that that effectively will

put less active ingredient on compromised ocular tissue -- surgically compromised ocular tissue; is that correct?

MS. FINK: Objection, misstates prior testimony, beyond the scope of his expert report.

THE WITNESS: I mean, with all this litany of things you're going through, as I said when we went through the first time, I deferred to technical experts on all of them, but yes, there's a lower concentration which would be applied to the ocular tissue.

BY MR. DINER:

Q Now, you called these a litany of things. Plaintiffs would characterize these as benefits associated with Prolensa compared to Bromday. But with regard to your position on life cycle management tactics, if you refer to paragraph 63 of your report. Take a moment if you'd like to read that.

A Yep. I see it.

Q When, as you say, Bausch & Lomb ceased manufacturing Bromday in 2013 and used the life cycle management tactic to switch to Prolensa to capture prescriptions of Bromday were there generics

available to doctors at that time for prescribing purposes?

A Was there a particular sentence you were reading or are you just summarizing?

Q The last part of paragraph 63.

A Okay. So you weren't reading it, you were just summarizing?

What was your question?

Q So at the time of the transition from Bromday to Prolensa -- let me start that over.

At the time that Prolensa was launched, branded Bromday was still on the market, correct?

A Briefly.

Q And also on the market was generic bromfenac sodium, correct?

A Labeled twice daily.

Q I think we also established earlier that it included some bromfenac sodium that was labeled once daily?

A Later.

Q When later?

A I can't remember, as I sit here right now, if it was early 2014. Like early January 2014, I think.

Q Mr. Hofmann, would you consider doctors

as part of the consumer group for ophthalmic pharmaceuticals?

A Sure.

Q And would you consider that doctors are sophisticated and informed consumers?

MS. FINK: Objection, calls for speculation.

THE WITNESS: I mean, that's a generality. I think sure as opposed to someone who's without the same level of training and education. On a relative basis. Sure.

BY MR. DINER:

Q Okay. Physicians would not prescribe a new drug product using the same active ingredient as the prior drug product if the new drug product did not deliver benefits over those offered by the prior drug product, correct?

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

THE WITNESS: I mean, from the things I've seen and the role of various tactics in marketing of pharmaceutical products I think there's lots of examples where there's been questions as to whether there are incremental

benefits to follow-on products, and I think that, in particular, when you have a "product hopping" situation where you eliminate the prior formulation of the molecule and the only branded promoted product is the, in this case Prolensa product, I think very much so physicians will continue to prescribe a molecule that they've been familiar with that's supported by marketing and samples and coupon cards and discounts and all those things because they know the molecule has been effective.

BY MR. DINER:

Q But that same molecule existed in generic form and branded form in terms of Bromday, correct?

A No. Not in a traditional sense. There were not -- there was not an AB-rated bromfenac with Bromday as a reference listed drug. There was a bromfenac that had no RLD that was labeled twice daily and there wasn't, I think, a once daily bromfenac sodium until after Bromday was delisted. And so, you know, I think those are -- those are strategically removed and done in a way to minimize the prescribing of generic bromfenac sodium.

Q But at the time of Prolensa's launch I think you said before there was branded Bromday out there, correct?

A Correct.

Q Doctors could have prescribed that since it was the same active ingredient, correct?

A Well, but I think, as I explained throughout my report, both in this section and in the marketing section, you know, Prolensa -- Bausch + Lomb basically with the launch of Prolensa took a variety of steps with marketing and shifting all of the marketing support to Prolensa from Bromday, shifting the sampling to support on the products, which is, as I understand it, an important factor, did a pricing strategy to encourage changing behavior to prescribe for Prolensa and executed a strategic transition to move prescribing behavior away from Bromday to Prolensa with the aim of killing the Bromday product. Not unlike exactly what they executed from Xibrom to Bromday.

Q But if doctors are sophisticated and informed consumers, why, even in light of everything you said, would they prescribe Prolensa when they could, for example, prescribe the cheaper bromfenac sodium?

MS. FINK: Objection, assumes facts not in evidence, calls for speculation.

THE WITNESS: Nobody was promoting or spreading awareness of the availability or existence of a bromfenac sodium generic. There is no mechanism by which automatic substitution of the bromfenac sodium labeled twice daily version could happen. Those are huge barriers to that being the selected molecule or the selected product.

I am aware, as you can see in that graph, some physicians did write the generic molecule and concentration. I think that the practical reality is the reason that they prescribe Prolensa in lieu of Bromday is all the things I just said which facilitated the transition from Bromday to Prolensa, removed any potential resistance or barrier to the movement from Bromday to Prolensa by keeping, you know, price at parity and providing samples and providing coupons and basically doing exactly what they did from Xibrom to Bromday to facilitate the product.

BY MR. DINER:

Q And it's your position that a physician

would still, in light of the fact that you -- let's start that.

It's your position that there are no differences in terms of efficacy or safety as between Bromday and Prolensa, correct?

A That's my understanding.

Q Okay. And it's your position that in spite of the fact that there are no differences between Prolensa and Bromday that physicians would still prescribe Prolensa while Bromday was available, for all the reasons you mentioned previously?

A Yeah. I think that that's consistent with Miss Valerie's testimony, that they weren't able to promote these purported benefits over Bromday. They had to promote to the label. So, you know, it's the other tactics that, you know, clearly it was a safe and efficacious product that the physicians had many years experience with the molecule, Bausch & Lomb did a strategic, you know, approach to remove potential resistance or barriers by facilitating pricing, coupons, discounts and other marketing support in a way that they were successfully able to migrate demand, not unlike they did from Xibrom to Bromday.

Q And so your position is that they would have just bamboozled the doctors, then, to prescribe a product that, in your view, had no benefit either from a efficacy -- clinical efficacy or safety profile?

MS. FINK: Objection to the extent it mischaracterizes testimony, argumentative.

THE WITNESS: I'm not saying anybody is bamboozled, I'm saying that there's all those tactics that were used on physicians. The other overarching tactic is to kill the prior embodiment, which, you know, basically gets rid of automatic substitution that one would typically see when generic versions of a molecule exist. Like I said, nobody is out creating awareness to physicians that the generic bromfenac molecule is out there. So it's not that they're bamboozled, you know. Typically what happens is they will continue to prescribe -- you know, they'll prescribe a brand and it gets substituted. Well, that can no longer happen and so it's not a matter of bamboozling, it's a matter of product switching, product hopping to a safe, and effective product. So it's not saying that

there's anything necessarily untoward from a safety and it's certainly a smart, you know, from an evergreening perspective makes some economic sense. But it isn't surprising that they were successful at doing it, much like they did from Xibrom to Bromday.

BY MR. DINER:

Q And I think we talked about with regard from Xibrom to Bromday that it went from a twice a day dose to a once a day dose, which you said was a benefit because of patient compliance?

A Well, there was no change in formulation, but yes, the label did change.

Q And with regard to all the benefits, there were a litany of things, as you called them before, you dispute the fact that those are any benefits that doctors would have been aware of or even known of to consider prescribing Prolensa instead of Bromday, correct?

A I think your premise is a false premise in that I necessarily agree that the reason they explained or transitioned Xibrom to Bromday is because of the once daily label. I'm not saying that. They did the same things. They killed the Xibrom product. They did the strategic pricing.

They did the shift in marketing. So all those things were in the tool chest, and they brought those out of the tool chest again. Based on everything I've seen, as we've talked about earlier today and throughout the day, those other technical aspects are not things that Miss Valerie said that they can promote to, the lack of awareness of the availability of a bromfenac sodium would hinder generic awareness and fulfillment, and yes, that the strategic pricing, marketing and delisting of Bromday explains the transition from Bromday to Prolensa.

Q Okay. So you just talked about delisting of Bromday. But we established earlier that there was overlap in the sales as between Prolensa and Bromday, correct?

A For a handful of months.

Q Right. So about four months there was overlap, correct?

A Right. But there was also a change in marketing strategy to, you know, basically convert all scripts, or as many scripts as they could, from Prolensa to Bromday during the four-month intervening period.

Q But doctors as independent informed

consumers can make their own choice, independent of the so-called tactics that you talked about?

A Right. But if the -- if the communication and part of the life cycle management strategy is that Prolensa is replacing Bromday you need to start writing Prolensa in order to get bromfenac for your patients that's going to change prescribing behavior. Hey, it's still safe and effective.

Q Were you aware that the price at launch for Prolensa was much higher than Bromday?

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

THE WITNESS: I think what I've seen is that the price, based on actual data, was at parity and based on strategic documents was at parity.

BY MR. DINER:

Q So let's talk about that overlap between the Prolensa's launch and what you said was a discontinuation of Bromday. Prolensa launched in mid-April 2013, correct?

A Correct.

Q Bromday was discontinued in mid-August 2013?

A Correct.

MR. DINER: I would like to mark the next exhibit, Tab 10.

(Ophthalmic NSAIDs Average Selling Price Per Prescription, page 2 of 2, was marked Hofmann-12 for identification.)

BY MR. DINER:

Q Okay. Mr. Hofmann, you've been handed Hofmann Exhibit 12. I'll represent to you that this document, which is identified up at the top a Tab 10, Ophthalmic NSAIDs Average Selling Price Per Prescription United States is a tab that comes out of Mr. Jarosz's opening report.

Have you seen this document before?

A I have.

Q So back to where we were. Let's look at Tab 10. I guess you can look at page 2 of 2. It's double sided.

A Yep.

Q We'll go to 2013.

A Yep.

Q Quarter 2 is the quarter in which Prolensa was launched, right?

A Correct.

Q And there Prolensa is identified as

selling in quarter 2 in 2013 at approximately $240 per prescription; is that correct?

A Well, you have to put this in context. This is a calculation that takes gross sales data from IMS divided by TRx data from IMS, and I think there's a hazard in trying to look at it in this, you know, -- IMS data is good longitudinally, but for a particular quarter there can be noise in it. But the data does say $238.92 on a gross basis, not reflective of any discounts, or not reflective of actual net pricing of Prolensa.

Q And Bromday is reported at approximately $170 per prescription, correct?

A With all the caveats from my last answer, and you can see that, especially for Bromday, as it ended -- as it neared the end of its life cycles, I mean, there's periods in here where it's showing up at $18 and $9, according to the data. There's just noise in the data that this is not, you know, a reasonable place to look, to look at the relative pricing of Bromday and Prolensa during that four-month period. I think the strategy documents and internal correspondence regarding the plans to price at parity are reflective of the actual strategy and transition that occurred. And I

think it's also worth noting, too, you know, you have the generic pricing, which again is gross and doesn't have the same level of discounts nipping at the heels of Prolensa as well.

Q Well, it's a whole lot closer to what Bromday is than it is to Prolensa; isn't that right?

A They're somewhat meaningless in that they're gross sales and none of them reflect discounts.

Q At least as between Prolensa and Bromday the discounts would apply to both of them so it's a wash, right?

A Not so. Some of the tactics, as we saw in the switch in the marketing plans were, you know, they killed for Bromday, any and all marketing they switched it over to Prolensa. So things like coupons, things like sampling, things like that are not going to be the same levels as they are for Bromday as Prolensa during that transition period.

Q But the killing, as you call it of Bromday, it doesn't get discontinued until August of 2015, right?

A That was the official externally, you know, announcement date. But there's other documents leading up to that in the production that

talk about the conversion, and the conversion being the strategy of migrating demand to Prolensa during a brief period, not unlike they did from Xibrom to Bromday.

Q So with a price of approximately $240 per script versus $170 per script and the fact that, in your opinion, there is no difference in clinical efficacy or safety, that doctors, even in spite of all the lobbying that you talked about, are going to prescribe Prolensa when they can do the same thing with Bromday?

A I reject many premises and assumptions embedded in your question. First off, I explained why I don't think these are reflective of actual pricing, that they reflect some issues with gross sales and TRx data and IMS. There are internal documents that clearly state that the pricing is a parity between Bromday and Prolensa.

Additionally, this isn't a price that a physician is even aware of, whether it's this or the actual price. What a physician is aware of is what is the amount of out of pocket that my patient is going to have to pay. And that is really driven by, you know, tier placement and coupons and things like that, all of which migrated to support around

Prolensa. So it's not that any of these numbers that you have in Tab 10 there would be any physician that has awareness of any of these. So it's an improper suggestion to say that there's a physician sitting with his pad saying should I do Bromday which is 169 or should I do Prolensa which is 238. No physician, you know, has that information or thinks that way. What they're thinking is, you know, what will my patient's out of pocket be. And as I said, Prolensa has, you know, support through coupons and all the migration of marketing around Prolensa against Bromday.

Q Well, if they have none of that financial information how could they determine what that patient's out of pocket is going to be?

A Well, the typical way that it happens is complaints. You know, so they'll write a script, and then if nobody complains, everything seems fine, and then when they start to get feedback that could then cause them to either seek out whether there's coupon or patient assistance or migrate demand to other molecules.

Q There's going to be a lag time on that. They're not going to know when those complaints are going to come through and when that's going to

correspondence to --

A Right. That's what I'm trying to get through here is that the launch of Prolensa is accompanied by Bausch & Lomb reps all over the place saying guess what, we now have this Prolensa product which has the bromfenac molecule. It's as safe and efficacious as Bromday was. We're pricing it at parity, we're converting this over to Prolensa, please change your prescribing behavior. They've removed any of the implied resistance that you say should be there from a price elasticity by coordinating a strategic life cycle management campaign, the same way they did from Xibrom to Bromday.

Q And did doctors talk to one another about these new products that are being offered by pharmaceutical companies?

MS. FINK: Objection, calls for speculation.

THE WITNESS: I mean, I'm sure there are doctors that talk about products all the time.

BY MR. DINER:

Q Right. And are you aware of the reports authored and published by various doctors

talking about the benefits of Prolensa versus Bromday?

MS. FINK: Objection, facts not in evidence.

THE WITNESS: I mean, I'm aware there are some journal articles. I know there's some disputes about whether they're Bausch & Lomb funded and what weight to put on those, but I think that there are some journal articles out there on that.

BY MR. DINER:

Q Yeah. And those journal articles talked about the benefits of the new formulation, correct?

A I think, arguably, that is what is in some of those articles, again, funded by Bausch & Lomb, and subject to the fact that they're also doing all these other tactics and they cannot promote those purported benefits, as Ms. Valerie explained.

Q Well, but the doctors are not bound by what Bausch & Lomb can or cannot promote, right?

A Of course not. That's what I mean, is if -- your questions and where you seem to be going is you think a Bausch & Lomb rep walks in and says

we have new Prolensa, it's $239, please, please, prescribe it, even though you can get cheap Bromday or cheap bromfenac. Well, that's not reality whatsoever. What the reality is that they facilitated the conversion from Bromday to Prolensa with a molecule that was known to be safe and effective and removing any potential resistance barriers by coupons and pricing parity and all the tools that were in the tool kit from when they transitioned Xibrom to Bromday.

Q And some of the other realities were also the published articles of doctors talking about the benefits of the new Prolensa formulation, right?

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

BY MR. DINER:

Q You mentioned that a moment ago.

A Like I said, I am aware that there are some articles. I don't weigh in on them from a medical perspective. I know there's some question as to the objectivity of them. But that's not to say there isn't a single doctor that might have been influenced by that. I'm just saying that, in my view of everything I've seen on what commercially explains the life cycle management and transition

from Bromday to Prolensa, it isn't the particular formulation in Prolensa that explains, you know, what is happening here.

Q It's the particular benefits of the Prolensa formulations that the doctor -- of the Prolensa formulation that the doctors are seeing; isn't that correct?

A I totally disagree. Everything I've seen is that the commercial -- you know, what is happening commercially is a revised bromfenac formulation, a molecule that physicians are very familiar with is now available with all the same pricing incentives, samples and facilitation of converting prescriptions from Prolensa to Bromday followed by Bromday being delisted and no longer available.

Q And the physicians are also aware of the articles by other physicians that are talking about the benefits in the new formulation, including lower pH, greater comfort, greater ocular penetration, being able to use less active ingredient and still get the same clinical efficacy, they're aware of those articles, too, right?

MS. FINK: Objection, assumes facts not in evidence, calls for speculation.

THE WITNESS: I don't know that that's a fair assumption. I know that those are some articles cited by Plaintiffs in this case. Whether those are, you know, widely read and understood and as far as influencing prescribing behavior or how physicians often rely on sales reps to explain what the benefits are of a particular product. And so, you know, what they are getting affirmatively is reps from Bausch & Lomb doing the things that they do to help convert prescriptions from Prolensa to Bromday, which necessarily can't include some of those alleged benefits in those articles.

BY MR. DINER:

Q But you didn't consider those articles and those alleged benefits in those articles in rendering your opinions in this case, did you?

A Not true. I looked at the documents that were produced and the feedback and the cataract discussion groups and some of the, you know, what limited documents were produced in this case on what is driving the prescribing behavior of physicians.

I looked at Dr. Cykiert's -- I understood Dr. Cykiert's opinions with respect to

that, and my understanding is that what motivates the prescribing behavior has, and continues to be the, you know, efficacy, safety and familiarity with the molecule, combined with all the commercial facilitating that Bausch & Lomb did to convert demand from Bromday to Prolensa.

Q But you acknowledged before that doctors talk, and that doctors would have talked about the published articles of other doctors that discuss the benefits of the new Prolensa formulation, right?

MS. FINK: Objection, mischaracterizes prior testimony.

THE WITNESS: Yeah, I mean, I don't -- I think that's an unfair, you know, broader characterization than what I agreed with you on. I think that what -- what we know is affirmatively happening is all the things that Bausch + Lomb is doing to get into the offices of prescribers to make them aware of this product and facilitate the conversion from Prolensa to Bromday.

BY MR. DINER:

Q And during that period of overlap of four months or so, between the launch, or after the

launch of Prolensa and the discontinuation of Bromday, physicians shifted approximately 70 percent of their Bromday prescriptions to Prolensa, right?

A I saw that metric in the -- in the Jarosz reply report. I think that according to the one, the Morgan Stanley report, that is what the data shows, and that's entirely consistent with the successful conversion strategy that was executed from the launch of Prolensa to the discontinuance of Bromday.

Q It's also consistent with what other doctors were saying about the benefits of the new Prolensa formulation with regard to comfort, ocular penetration, reduced active ingredient, same clinical efficacy, correct?

A Well, I mean, to your earlier suggestion about lag times you think there might be more of a lag to informal chatter among people over time as opposed to a coordinated, you know, strategic campaign launched by a sophisticated targeter of ophthalmologists who basically fan out and disseminate the conversion strategy and story in a molecule that people are all comfortable with.

Q But some of these reports by doctors that you acknowledged having seen, they were based

on clinical studies that would have occurred before the Prolensa product was launched, right?

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

THE WITNESS: Yeah, I'd have to go back and look at the timing of those, but you're right, I mean, to the extent they discuss clinical trials that predated the launch, those would temporally follow there.

MR. DINER: I have no further questions.

MS. FINK: I have no redirect.

VIDEO OPERATOR: We are now going off the record; approximately 3:21 p.m.

C E R T I F I C A T I O N

I, LISA FORLANO, a Certified Realtime Reporter, Certified Court Reporter and Notary Public, do hereby certify that I reported the deposition in the above-captioned matter, that the said witness was duly sworn by me; that the foregoing is a true and correct transcript of the stenographic notes of testimony taken by me in the above-captioned matter.

I further certify that I am not an attorney or counsel for any of the parties, not a relative or employee of any attorney or counsel connected with the action, nor financially interested in the action.

LISA FORLANO, CRR, CCR #XI01143

DATED: February 29, 2016

ATTACH TO DEPOSITION OF: Ivan T. Hoffman
IN THE MATTER OF: Senju vs. Lupin
DATE TAKEN: February 24, 2016

E R R A T A S H E E T

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_____, 2016

To: Sarah Fink, Esq.

Case Name: Senju Pharmaceutical Co., Ltd v. Lupin Limited And Lupin Pharmaceuticals

Veritext Reference Number: 2238413

Witness: Ivan T. Hofmann Deposition Date: 2/24/2016

Dear Madam:

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Sincerely,

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Cc: All Counsel

**u**

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.