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

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

Plaintiffs,

vs.

LUPIN, LTD. AND LUPIN
PHARMACEUTICALS, INC.,

Defendants.

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

Plaintiffs,

vs.

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

Defendants.

Job No. NJ 2238413

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

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I N D E X

1		
2		
3		
4	WITNESS	PAGE
5	IVAN T. HOFMANN	
6	By Mr. Diner	7
7		
8		
9		
	E X H I B I T S	
10	Hofmann-1 Responsive Expert Report of Ivan	9
	T. Hofmann, CPA/CFF, CLP	
11		
	Hofmann-2 Deloitte 2015 Global Life Sciences	34
12	Outlook - Adapting in an era of transformation	
	PROL0339506 - PROL0339525	
13		
	Hofmann-3 Deloitte document - Measuring the	41
14	return from pharmaceutical innovation 2014 - turning	
	a corner, PROL0339526 - PROL0339561	
15		
	Hofmann-4 American Marketing Association	52
16	article - Early Marketing Matters: A Time-Varying	
	Parameter Approach to Persistence Modeling,	
17	PROL0339663 - PROL0339676	
18	Hofmann-5 Reply Expert Report of John C.	56
	Jarosz on objective indicia of non-obviousness	
19	dated 2/12/16	
20	Hofmann-6 Article - Too Many Drugs? The	88
	Clinical and Economic Value of Incremental	
21	Innovations, PROL0340351 - PROL0340392	
22	Hofmann-7 Cataract Discussion Groups (CDGs),	113
	PROL0280867 - PROL0280893	
23		
	Hofmann-8 Clinical Ophthalmology - The ocular	123
24	distribution of C-labeled bromfenac ophthalmic	
	solution 0.07% in a rabbit model, PROL008055 -	
25	PROL0080512	

1
2
3
4
5
6
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14
15
16
17
18
19
20
21
22
23
24
25

E X H I B I T S (CONTINUED)

Hofmann-9	PROL0080486 - PROL0080492	144
Hofmann-10	PROL0080493 - PROL0080497	146
Hofmann-11	PROL0080219 - PROL0080224	148
Hofmann-12	Ophthalmic NSAIDS Average Selling Price Per Prescription, page 2 of 2	171

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

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

6 The date today is February 24, 2016.

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

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

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

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

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

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

1 Henderson.

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

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

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

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

12 BY MR. DINER:

13 Q Good morning, Mr. Hofmann.

14 A Good morning, Mr. Diner.

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

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

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

22 A I have.

23 Q A number of times?

24 A Correct.

25 Q So you're familiar with the drill?

1 A I am.

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

4 A That sounds good.

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

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

12 Does that sound fair?

13 A I understand.

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

20 A Sounds good.

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

1 Is that okay?

2 A Yes, sir.

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

6 A Yes.

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

9 A No, sir.

10 Q Okay.

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

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

16 BY MR. DINER:

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

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

23 Q Does it include your exhibits and
24 appendices?

25 A Yes, it does.

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

4 A Sure.

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

7 A It is.

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

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

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

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

18 Q Very good. Thank you.

19 Is that your current CV, Mr. Hofmann?

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

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

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

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

9 A It is.

10 Q Anything more to add to it?

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

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

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

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

20 A Yes.

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

1 A Yes, among others.

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

4 A I did.

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

8 A I did.

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

12 A I did.

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

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

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

20 A I have, yes.

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

23 A Yes.

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

1 A I did. I mean, for completeness.

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

4 Q Okay. What are they?

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

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

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

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

22 A From counsel.

23 Q Through counsel?

24 A Correct.

25 Q Counsel told you what Dr. Cykiert's

1 opinions were?

2 A Correct.

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

5 A Dr. Prausnitz.

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

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

10 Q Could you explain the process?

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

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

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

1 spent analyzing and addressing issues in
2 pharmaceutical economics.

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

12 Q Are you a patent lawyer?

13 A I'm not a patent lawyer.

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

16 A I'm not.

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

19 A No, sir.

20 Q Are you an expert in pharmaceutical
21 marketing?

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

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

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

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

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

11 A No, not directly.

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

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

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

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

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

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

25 Q Do you know the applicable standards

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

3 A I'm familiar with those.

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

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

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

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

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

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

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

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

13 A I have not.

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

17 A Correct.

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

21 A Correct.

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

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

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

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

6 A No.

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

9 A I have not.

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

12 A No, sir.

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

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

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

20 A No, sir.

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

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

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

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

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

9 A I'm there.

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

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

15 Q Did you look that information up
16 yourself?

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

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

22 A Okay.

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

1 to the purported merits of the claimed invention.

2 Do you see that?

3 A Yes.

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

8 A Of course.

9 Q And what are those factors?

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

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

20 A Absolutely.

21 Q Financing?

22 A Sure.

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

1 A Yes, those are examples.

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

4 A Yes. And sometimes explain it.

5 Q I'm sorry?

6 A And sometimes explain the commercial
7 success.

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

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

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

1 product?

2 A No, that's not my position.

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

6 THE WITNESS: Certainly.

7 MS. FINK: Thank you.

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

13 BY MR. DINER:

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

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

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

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

25 Q I believe that was about August of

1 2015. Does that sound right?

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

5 Q September 30, 2015?

6 A Correct.

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

9 A Correct.

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

13 A Correct.

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

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

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

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

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

9 BY MR. DINER:

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

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

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

25 MS. FINK: Objection, calls for

1 speculation.

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

18 BY MR. DINER:

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

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

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

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

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

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

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

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

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

4 A Yes.

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

9 A That's my understanding.

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

12 A Correct.

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

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

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

23 BY MR. DINER:

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

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

1 any longer than Prolensa has been on the market.

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

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

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

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

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

4 MS. FINK: Objection, argumentative.

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

15 BY MR. DINER:

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

21 MS. FINK: Objection, incomplete
22 hypothetical.

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

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

7 BY MR. DINER:

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

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

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

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

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

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

16 BY MR. DINER:

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

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

22 A Yes, I have.

23 Q In what context?

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

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

4 A Yes.

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

7 A Correct.

8 Q You used to work at Deloitte?

9 A Yes, I did.

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

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

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

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

21 BY MR. DINER:

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

24 A Sure.

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

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

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

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

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

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

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

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

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

22 BY MR. DINER:

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

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

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

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

10 BY MR. DINER:

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

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

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

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

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

20 BY MR. DINER:

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

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

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

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

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

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

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

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

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

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

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

23 BY MR. DINER:

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

1 Bates numbers PROL0339526 through 9561.

2 Have you seen this document before?

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

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

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

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

15 Is that right?

16 A Yes.

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

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

23 THE WITNESS: Okay, I see that.

24 BY MR. DINER:

25 Q In this passage you just read, it

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

4 See that?

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

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

12 BY MR. DINER:

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

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

23 Q The --

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

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

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

9 Do you see that?

10 A I think those are the words, yes.

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

16 Do you see that?

17 A I see those words.

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

22 A I totally disagree with you.

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

25 A I don't think that this article is

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

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

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

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

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

7 A Bromday, and then Xibrom before it.

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

9 A I believe it has.

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

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

13 Q There's no what?

14 A RLD.

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

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

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

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

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

1 generic Bromday?

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

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

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

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

19 BY MR. DINER:

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

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

25 THE WITNESS: I think it depends on the

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

6 BY MR. DINER:

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

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

13 Q And how about as of September 2015?

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

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

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

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

1 management situation.

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

7 MS. FINK: Objection, incomplete
8 hypothetical.

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

21 BY MR. DINER:

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

1 the product?

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

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

6 BY MR. DINER:

7 Q Marketing investment, marketing
8 expenditures.

9 A It depends.

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

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

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

15 A Sure.

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

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

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

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

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

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

10 A Yeah, tens of millions of dollars.

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

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

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

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

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

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

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

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

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

1 Hofmann-4 for identification.)

2 BY MR. DINER:

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

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

9 Mr. Hofmann, have you seen this --

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

12 MR. DINER: Oh, thank you.

13 BY MR. DINER:

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

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

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

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

23 A The name sounds familiar.

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

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

12 Do you see that?

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

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

19 MS. FINK: Objection, incomplete
20 hypothetical.

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

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

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

9 BY MR. DINER:

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

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

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

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

25 MR. DINER: I would like to mark the

1 next exhibit.

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

6 BY MR. DINER:

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

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

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

25 A I think we covered that earlier. Maybe

1 not in those exact words, but --

2 Q The concept is correct?

3 A Yeah.

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

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

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

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

23 A That's what it says.

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

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

3 A Correct.

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

6 A Excuse me.

7 Q Are you ready?

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

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

11 A Yes.

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

15 A Yes.

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

19 A I think --

20 Q Post-launch.

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

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

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

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

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

10 BY MR. DINER:

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

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

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

18 Q Okay.

19 A Go ahead.

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

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

1 BY MR. DINER:

2 Q Is that correct?

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

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

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

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

13 A I mean -- go ahead.

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

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

20 BY MR. DINER:

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

24 You see that portion of the graph?

25 A I do.

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

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

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

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

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

1 with respect to the gross sales figure.

2 BY MR. DINER:

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

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

8 Q Okay.

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

11 MS. FINK: Okay.

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

14 (Brief recess.)

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

18 BY MR. DINER:

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

22 Do you recall that?

23 A Yes, I do.

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

1 decreasing and gross sales increasing.

2 Do you recall that?

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

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

10 A Yes.

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

18 MS. FINK: Objection, incomplete
19 hypothetical.

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

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

7 BY MR. DINER:

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

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

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

25 BY MR. DINER:

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

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

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

12 A Yes.

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

15 A I understand.

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

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

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

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

7 MS. FINK: Objection, mischaracterizes
8 testimony.

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

13 BY MR. DINER:

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

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

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

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

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

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

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

23 BY MR. DINER:

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

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

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

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

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

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

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

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

22 MS. FINK: Objection, incomplete
23 hypothetical.

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

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

10 BY MR. DINER:

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

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

25 Q But as an incentive, and even as a

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

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

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

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

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

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

3 BY MR. DINER:

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

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

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

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

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

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

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

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

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

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

15 BY MR. DINER:

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

18 A That's correct.

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

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

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

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

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

16 A Could you read that back?

17 Q I'll restate it.

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

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

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

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

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

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

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

7 BY MR. DINER:

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

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

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

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

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

6 Q The TRx stands for what?

7 A Prescriptions, total prescriptions.

8 Q So -- okay. And the NRx?

9 A New prescriptions.

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

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

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

18 A No.

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

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

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

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

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

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

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

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

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

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

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

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

16 A Yes, sir.

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

19 A That's right.

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

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

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

1 60 percent.

2 A That's right.

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

6 A That's right.

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

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

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

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

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

13 BY MR. DINER:

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

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

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

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

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

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

21 BY MR. DINER:

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

24 Do you recall that?

25 A Yes.

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

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

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

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

5 BY MR. DINER:

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

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

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

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

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

14 BY MR. DINER:

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

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

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

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

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

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

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

1 harvest value and maximize profits and evergreen
2 franchises.

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

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

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

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

1 don't -- compliance would be easier.

2 Q Any other examples?

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

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

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

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

13 BY MR. DINER:

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

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

21 A I have.

22 Q In what context?

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

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

3 Do you see that?

4 A Yes.

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

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

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

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

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

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

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

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

3 BY MR. DINER:

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

7 Are you there?

8 A Uh-huh.

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

11 A I do.

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

22 Now, did I read that accurately?

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

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

3 A Yes.

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

6 A I guess potentially.

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

10 Do you see that?

11 A I see that.

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

16 MS. FINK: Objection, incomplete
17 hypothetical.

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

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

6 BY MR. DINER:

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

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

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

1 amount of a foreign active substance?

2 MS. FINK: Objection, incomplete
3 hypothetical.

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

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

23 BY MR. DINER:

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

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

2 --

3 MS. FINK: Objection.

4 BY MR. DINER:

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

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

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

16 BY MR. DINER:

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

21 MS. FINK: Objection, incomplete
22 hypothetical.

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

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

17 BY MR. DINER:

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

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

25 THE WITNESS: So I'm not a technical

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

4 BY MR. DINER:

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

9 A That's right.

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

15 A Sure.

16 Q What's your understanding of that?

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

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

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

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

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

6 BY MR. DINER:

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

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

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

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

3 BY MR. DINER:

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

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

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

18 BY MR. DINER:

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

21 MS. FINK: Same objections.

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

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

5 BY MR. DINER:

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

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

15 Q But there may be some indeed, correct?

16 A I defer to the technical experts.

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

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

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

25 (Lunch recess.)

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

3 This is the beginning of file three.

4 BY MR. DINER:

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

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

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

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

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

24 BY MR. DINER:

25 Q Okay. Can you turn to paragraph 60 of

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

2 A What page or paragraph?

3 Q Paragraph 60, page 31.

4 A Okay.

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

8 Do you see that?

9 A Yes.

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

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

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

22 A Yes.

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

1 ingredients extend patent lives.

2 Do you see that?

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

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

8 A No, I didn't.

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

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

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

20 BY MR. DINER:

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

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

1 report.

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

6 BY MR. DINER:

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

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

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

23 BY MR. DINER:

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

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

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

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

17 BY MR. DINER:

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

20 A Okay.

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

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

1 profile of Prolensa and Bromday.

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

4 A Yes.

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

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

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

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

25 Q And did you speak with any other

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

3 A I did not.

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

9 Do you see that?

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

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

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

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

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

25 Q And would that be the case for any of

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

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

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

8 A Yes.

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

11 A Yes.

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

15 A Yes.

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

18 A Yes.

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

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

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

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

4 BY MR. DINER:

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

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

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

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

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

22 A Yes.

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

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

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

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

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

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

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

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

25 A I don't remember that particular

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

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

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

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

13 BY MR. DINER:

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

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

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

23 BY MR. DINER:

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

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

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

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

8 BY MR. DINER:

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

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

13 Q Any other opinion?

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

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

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

25 Q And how about your -- how about the

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

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

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

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

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

23 MR. DINER: Is this number 7?

24 MS. FINK: Yes.

25 BY MR. DINER:

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

8 A Yes, thank you.

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

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

13 A Yes, I have.

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

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

18 Q Yes, you do.

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

22 Do you recall that?

23 A Yes.

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

1 Do you recall that?

2 A Yes.

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

7 Let me know when you're ready.

8 A Yep.

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

11 A Yes.

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

14 A Yes.

15 Q Bromfenac and Prolensa, right?

16 A That's correct.

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

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

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

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

8 A Designed for Comfort and Convenience.

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

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

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

18 BY MR. DINER:

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

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

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

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

6 BY MR. DINER:

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

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

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

15 A According to this slide.

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

18 A According to this slide.

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

21 BY MR. DINER:

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

24 A That's what it appears here.

25 Q Now you just wiped your eye. Did you

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

3 A I wouldn't know where to begin.

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

6 A According to this.

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

9 A I mean, mathematically, sure.

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

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

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

1 insights he discussed.

2 BY MR. DINER:

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

7 MS. FINK: Objection, mischaracterizes
8 testimony.

9 BY MR. DINER:

10 Q Is that correct?

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

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

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

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

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

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

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

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

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

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

5 BY MR. DINER:

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

8 A Right.

9 Q -- from Dr. Prausnitz, correct?

10 A Correct.

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

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

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

22 BY MR. DINER:

23 Q Where do you remember reading that?

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

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

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

4 A Correct.

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

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

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

14 MS. FINK: Objection.

15 BY MR. DINER:

16 Q Would you accept that representation?

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

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

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

3 BY MR. DINER:

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

6 A I am.

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

9 A Correct.

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

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

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

19 BY MR. DINER:

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

23 Have you seen this document before?

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

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

3 Q Okay. Are you okay?

4 A Oh, yeah. Maybe not.

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

6 THE WITNESS: No, I'm okay.

7 BY MR. DINER:

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

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

17 Do you see that there?

18 A Yes, I see that.

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

1 enhances ocular penetration.

2 Do you see that passage there?

3 A Yes.

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

7 BY MR. DINER:

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

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

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

18 BY MR. DINER:

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

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

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

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

5 BY MR. DINER:

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

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

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

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

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

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

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

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

23 BY MR. DINER:

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

1 in this matter, correct?

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

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

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

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

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

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

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

10 BY MR. DINER:

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

14 Do you remember that?

15 A Yes.

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

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

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

1 claimed invention?

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

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

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

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

17 A Correct.

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

21 A Sure.

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

24 BY MR. DINER:

25 Q And I also represented to you that the

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

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

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

11 BY MR. DINER:

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

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

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

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

8 BY MR. DINER:

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

12 Do you recall that from his opinion?

13 A Yes.

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

16 A Correct.

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

19 A That's my understanding.

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

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

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

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

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

14 BY MR. DINER:

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

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

22 THE WITNESS: That was a long question.

23 BY MR. DINER:

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

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

4 MS. FINK: Same objection.

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

15 BY MR. DINER:

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

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

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

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

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

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

20 MS. FINK: Objection, mischaracterizes
21 testimony.

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

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

17 BY MR. DINER:

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

24 A Yes.

25 Q So you just said a moment ago that your

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

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

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

12 BY MR. DINER:

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

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

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

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

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

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

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

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

6 BY MR. DINER:

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

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

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

18 A I may have seen that, yes.

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

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

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

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

1 You're asking me about --

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

9 Does that sound right?

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

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

14 BY MR. DINER:

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

18 A Okay.

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

22 A That's the math.

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

1 MS. FINK: Same objection.

2 THE WITNESS: Based on that math.

3 BY MR. DINER:

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

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

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

13 BY MR. DINER:

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

16 A Right.

17 MS. FINK: Same objection.

18 BY MR. DINER:

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

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

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

1 BY MR. DINER:

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

4 A Perhaps.

5 Q Did it burn and sting?

6 A I mean --

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

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

12 BY MR. DINER:

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

15 A Really, nothing comes to mind.

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

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

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

1 meaningful impact one way or the other.

2 BY MR. DINER:

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

7 MS. FINK: Objection, mischaracterizes
8 testimony.

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

21 BY MR. DINER:

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

25 But you didn't consider the relative

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

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

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

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

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

17 BY MR. DINER:

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

20 MS. FINK: Nine.

21 BY MR. DINER:

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

25 Have you seen this document before?

1 A Yes.

2 Q Okay. In what context?

3 A This case.

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

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

9 MS. FINK: Okay, apologies.

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

13 BY MR. DINER:

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

17 Do you recall that?

18 A Yes.

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

23 A Yes.

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

1 A Yes.

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

4 A Yes.

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

8 A Yes.

9 Q You may put that aside.

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

12 BY MR. DINER:

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

16 Have you seen this document before?

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

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

22 A Yes.

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

1 A It says adverse reactions.

2 Q Sorry. Thank you.

3 A And eye irritation is listed among
4 others.

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

7 A Yes.

8 Q Okay. When the FDA approves a label
9 such as this, are they doing so based on clinical
10 studies that have been provided to them?

11 A Yes.

12 Q Okay. And when they approve a label
13 that identifies the adverse events, are they doing
14 so also based on clinical studies indicating the
15 occurrence of adverse reactions?

16 MS. FINK: Objection, beyond the scope
17 of his expert report.

18 THE WITNESS: That's my understanding.

19 BY MR. DINER:

20 Q Okay. And for Bromday, which is
21 discussed in Hofmann Exhibit 9, and Xibrom, which is
22 discussed in Hofmann Exhibit -- sorry, strike that.
23 For Bromday, which is discussed in Hofmann Exhibit
24 10, and Xibrom, which is discussed in Hofmann
25 Exhibit 9, both of them, you testified, indicate

1 that the adverse reactions include eye irritation
2 such as burning and stinging, right?

3 A That's what the labels read, yes.

4 Q And that would have been based on
5 clinical studies confirming the occurrence of eye
6 irritation for those products, correct?

7 A That's typically the case.

8 Q Okay.

9 (PROL0080219 - PROL0080224 was marked
10 Hofmann-11 for identification.)

11 BY MR. DINER:

12 Q You've just been handed Hofmann Exhibit
13 11, bearing Bates numbers PROL0080219 through 224.

14 And have you seen this document before,
15 Mr. Hofmann?

16 A Yes.

17 Q What is it?

18 A It's a label for Prolensa.

19 Q Okay. And over in the right-hand
20 column on the first page under adverse reactions, do
21 you see anywhere in there where it indicates that
22 Prolensa had the adverse reaction of eye irritation,
23 including burning or stinging?

24 MS. FINK: You should read whichever
25 parts of the document you need to.

1 THE WITNESS: I mean, I think that the
2 language in this label and the 3 to 8 percent
3 frequency of other adverse reactions does not
4 include the exact same words, "eye
5 irritation," but I think Dr. Cykiert addresses
6 in his report the, I think, clinical
7 implication of his experience and the
8 experience with respect to Prolensa versus
9 other NSAIDs. But it does not include those
10 same words, but it has other adverse
11 reactions.

12 BY MR. DINER:

13 Q But it doesn't have listed here the
14 adverse reaction of eye irritation, including
15 burning or stinging, correct?

16 MS. FINK: Objection, asked and
17 answered.

18 THE WITNESS: Not those exact words. I
19 mean, it says eye pain and other -- other
20 adverse reactions, but no, not those exact two
21 words.

22 BY MR. DINER:

23 Q Well, take a look at Hofmann Exhibit
24 10, under adverse reactions.

25 A I'm there.

1 Q Sorry. So the label as approved for
2 Prolensa, particularly the description of adverse
3 reactions, that also would have been -- that would
4 also have been approved by the FDA, based on
5 clinical studies, correct?

6 A It appears so.

7 Q And the fact that eye irritation and
8 burning and stinging is not listed as an adverse
9 reaction for Prolensa means that the clinical
10 studies supplied by the company to the FDA supported
11 a label that did not have a recitation of eye
12 irritation, burning and stinging, correct?

13 MS. FINK: Objection, beyond the scope
14 of his expert report, calls for speculation.

15 THE WITNESS: I think that's a very
16 technical issue that, you know, the selection
17 of the words for the clinical adverse
18 reactions, I wouldn't have an opinion on one
19 way or the other, you know, what all is
20 factored into the FDA's decision, as well as
21 what's advocated by the company in terms of
22 the particular words that appear in the label.

23 And if we're at a decent shifting point
24 can we take a break?

25 MR. DINER: It's fine, we can take a

1 break.

2 VIDEO OPERATOR: We're now going off
3 the record at approximately 2:16 p.m.

4 (Brief recess.)

5 VIDEO OPERATOR: This is the beginning
6 of file four.

7 We're going back on the record,
8 approximately 2:31 p.m.

9 BY MR. DINER:

10 Q Okay. Mr. Hofmann, can we turn to
11 paragraph 62 of your report? I see, unfortunately,
12 that you have a black-and-white version. I
13 apologize for that. I will try to muddle our way
14 through that, if that's okay with you.

15 A I'll do my best.

16 Q Okay. So within paragraph 62 we're
17 going to refer to the graph that is there. Can you
18 see the line of demarcation as between what is
19 indicated to be the Xibrom sales and then it then
20 transitions to the Bromday sales?

21 A A lot better on yours. It's real faint
22 up here. I can't -- I mean, I think that's it.

23 Q What is the approximate time point
24 where the Xibrom sales cease or transition into the
25 Bromday sales?

1 A I mean, I know it was 2011. Do you
2 need a month?

3 Q No, no, that's fine. And based on the
4 graph -- maybe you can see this one more clearly.
5 What is the approximate time where, in just the
6 year, where the Bromday sales appear to transition
7 into, and then we go into and see Prolensa sales
8 beginning?

9 A 2013.

10 Q Okay. Now, on my copy, which is in
11 color, and yours, unfortunately, is not, above the
12 areas for Xibrom, but particularly Bromday and
13 Prolensa, there's another shaded area. It appears
14 in purple on my graph. Do you know what that is?

15 A That's the generic bromfenac sodium
16 products. And IMS didn't break out those that were
17 originally launched with the Xibrom as the RLD and
18 then those that were launched with the label more
19 consistent with once daily Bromday.

20 Q So those could be collectively sales of
21 generic Xibrom and generic Bromday; is that right?

22 A Correct.

23 MS. FINK: I just want to put on the
24 record here with this black-and-white version
25 it's really very difficult to see the

1 difference between the Bromday and the
2 bromfenac sodium. The others are difficult as
3 well, but that demarcation line is practically
4 invisible in the black-and-white version.

5 MR. DINER: Well, so far we've been
6 able to muddle our way through this.

7 MS. FINK: Yes. I just wanted that of
8 record.

9 BY MR. DINER:

10 Q So then perhaps you can help me to read
11 and understand the significance of the sales of the
12 collective generic bromfenac sodium products. These
13 are prescriptions of these products, correct?

14 A Correct.

15 Q And so is this indicating that the
16 sales of generic bromfenac sodium surpassed Bromday
17 and Prolensa?

18 A No. It's a stacking graph, and so in
19 your version, which is purple, and maybe we can
20 later swap this out for a color version, the purple
21 area is limited to that purple area. So what this
22 means is that generic bromfenac sodium sales are a
23 small fraction of the total sales of either Xibrom,
24 Bromday or Prolensa.

25 Q It doesn't mean, for example, let's

1 just table directly in line with 2012 and draw a
2 line up to the peak of the part of the graph that
3 represents generic bromfenac sodium. Does that mean
4 that there were, in that particular month of 2012
5 somewhere between 200 and 250,000 prescriptions?

6 A No. That means in total bromfenac
7 prescriptions be they Bromday or bromfenac sodium,
8 it was 250,000 or whatever the number is, you said,
9 comprised of, I don't know, tens of thousands being
10 the purple in the form of generic bromfenac sodium
11 and then over 200,000 being the red that is Bromday.
12 And so that's why it's called a stacking graph. You
13 basically add them together.

14 Q So this is a differential amount?

15 A No. I mean, I don't know if -- the
16 underlying data -- we could go to Jarosz Tab 6, and
17 you can see that it's like -- like I said, I'm
18 making up numbers, but by an order of magnitude, you
19 know, maybe 40,000 scripts of the generic and
20 220,000 scripts of the brand for that period. Well,
21 that's too high. That's too high an illustrative
22 number. So if I go up 2012 is about 225,000
23 scripts. So without any precision -- if we wanted
24 precision, we would go to Jarosz Tab 6, which
25 summarizes the underlying IMS data we're talking

1 about an order of magnitude of, you know, maybe 20
2 to 30,000 bromfenac sodium generic sales and 170,000
3 Bromday sales.

4 Q Okay. Okay. Now I understand. Thank
5 you.

6 Okay. Okay. Now, in 2011 where we see
7 a transition as between Xibrom and Bromday, was one
8 of the benefits attributable to Bromday over Xibrom
9 the fact that it was dosed once a day instead of
10 twice a day?

11 MS. FINK: Objection, outside the scope
12 of his expert report.

13 THE WITNESS: My understanding is that,
14 you know, the formulation itself didn't
15 change. I defer to technical experts, but my
16 understanding is that the formulation itself
17 didn't change. They just got it relabeled to
18 be once daily, and that was the primary
19 difference.

20 BY MR. DINER:

21 Q And that improved patient compliance,
22 correct?

23 A I think that was the view that that
24 improves patient compliance.

25 Q And the -- as a product that improves

1 patient compliance, that's a benefit to the
2 consuming public, correct?

3 MS. FINK: Objection, calls for
4 speculation.

5 THE WITNESS: We talked about this
6 earlier. I mean, I think that's a -- it
7 depends. Sometimes improved compliance is not
8 meaningful. Sometimes it is.

9 BY MR. DINER:

10 Q And how about in the cases between
11 Xibrom and Bromday, do you know?

12 MS. FINK: Objection, beyond the scope
13 of his expert report.

14 THE WITNESS: I mean --

15 BY MR. DINER:

16 Q Would you like to refer to paragraph 75
17 to see if it's within the scope of your expert
18 report? You're certainly welcome to do that.

19 A I think where I was going is to say
20 that in general I think that the market for these
21 ophthalmics was moving to once daily. It started
22 out as four times daily, moved to twice daily, and
23 it was viewed that once daily Bromday is a benefit
24 over multiple times daily.

25 Q Okay. Now, as we move to Bromday and

1 we look at the line as between -- in the graph as
2 between Bromday and Prolensa, I think we said that
3 that comes at approximately 2013, right?

4 A Correct.

5 Q Now, the differences between the
6 Bromday and Prolensa formulation we talked about
7 before was, in some respect, the surfactant,
8 correct?

9 A Yes.

10 Q And that Prolensa used tyloxapol
11 instead of polysorbate 80, correct?

12 A Correct.

13 Q And that Prolensa used approximately
14 one-eighth the concentration of tyloxapol compared
15 to the amount of polysorbate 80 used in bromfenac,
16 correct?

17 A We did talk -- go ahead.

18 MS. FINK: I believe you might have
19 misspoke. You meant compared to the
20 concentration of polysorbate 80 in Bromday.

21 MR. DINER: I'll restate it. Thank
22 you.

23 BY MR. DINER:

24 Q And so I believe we spoke before about
25 how Prolensa used about one-eighth the amount of

1 tyloxapol compared to the amount of polysorbate 80
2 used in Bromday, correct?

3 A We did talk about that.

4 Q And also that some of the other
5 differences we mentioned between the products was
6 that the pH in Bromday was 8.3 and it was lowered to
7 7.8 in Prolensa, right?

8 MS. FINK: Objection, assumes facts not
9 in evidence.

10 THE WITNESS: We looked at that
11 document we talked about.

12 BY MR. DINER:

13 Q And that with a pH of 7.8 Prolensa was
14 closer to the pH of natural tears at 7.4, correct?

15 A According to that slide in the
16 PowerPoint.

17 Q And that at a pH of 7.8 the ocular
18 penetration of Prolensa was the same or comparable
19 to the ocular penetration of Bromday, correct?

20 MS. FINK: Objection, assumes facts not
21 in evidence.

22 THE WITNESS: Can you read that back?

23 BY MR. DINER:

24 Q With regard to the lowering of pH from
25 8.3 in Bromday to 7.8 in Prolensa, we spoke earlier

1 about the impact of that on ocular penetration,
2 correct?

3 A We did.

4 Q And you remember me showing you the
5 article which talked about how Prolensa at 7.8 got
6 better ocular or comparable ocular penetration to
7 Bromday at 8.3?

8 MS. FINK: Objection to the extent it
9 mischaracterizes that document.

10 THE WITNESS: The article being the
11 rabbit study?

12 BY MR. DINER:

13 Q Yes.

14 A Yes, those sentences you pointed me to
15 said that.

16 Q And with the increased ocular
17 penetration they were able to lower the active
18 ingredient about 22 percent?

19 MS. FINK: Objection, assumes facts not
20 in evidence.

21 BY MR. DINER:

22 Q Do you recall that?

23 A I agreed that they did lower the .09 to
24 .07 and that works out to 22 percent.

25 Q Okay. And that that effectively will

1 put less active ingredient on compromised ocular
2 tissue -- surgically compromised ocular tissue; is
3 that correct?

4 MS. FINK: Objection, misstates prior
5 testimony, beyond the scope of his expert
6 report.

7 THE WITNESS: I mean, with all this
8 litany of things you're going through, as I
9 said when we went through the first time, I
10 deferred to technical experts on all of them,
11 but yes, there's a lower concentration which
12 would be applied to the ocular tissue.

13 BY MR. DINER:

14 Q Now, you called these a litany of
15 things. Plaintiffs would characterize these as
16 benefits associated with Prolensa compared to
17 Bromday. But with regard to your position on life
18 cycle management tactics, if you refer to paragraph
19 63 of your report. Take a moment if you'd like to
20 read that.

21 A Yep. I see it.

22 Q When, as you say, Bausch & Lomb ceased
23 manufacturing Bromday in 2013 and used the life
24 cycle management tactic to switch to Prolensa to
25 capture prescriptions of Bromday were there generics

1 available to doctors at that time for prescribing
2 purposes?

3 A Was there a particular sentence you
4 were reading or are you just summarizing?

5 Q The last part of paragraph 63.

6 A Okay. So you weren't reading it, you
7 were just summarizing?

8 What was your question?

9 Q So at the time of the transition from
10 Bromday to Prolensa -- let me start that over.

11 At the time that Prolensa was launched,
12 branded Bromday was still on the market, correct?

13 A Briefly.

14 Q And also on the market was generic
15 bromfenac sodium, correct?

16 A Labeled twice daily.

17 Q I think we also established earlier
18 that it included some bromfenac sodium that was
19 labeled once daily?

20 A Later.

21 Q When later?

22 A I can't remember, as I sit here right
23 now, if it was early 2014. Like early January 2014,
24 I think.

25 Q Mr. Hofmann, would you consider doctors

1 as part of the consumer group for ophthalmic
2 pharmaceuticals?

3 A Sure.

4 Q And would you consider that doctors are
5 sophisticated and informed consumers?

6 MS. FINK: Objection, calls for
7 speculation.

8 THE WITNESS: I mean, that's a
9 generality. I think sure as opposed to
10 someone who's without the same level of
11 training and education. On a relative basis.
12 Sure.

13 BY MR. DINER:

14 Q Okay. Physicians would not prescribe a
15 new drug product using the same active ingredient as
16 the prior drug product if the new drug product did
17 not deliver benefits over those offered by the prior
18 drug product, correct?

19 MS. FINK: Objection, calls for
20 speculation, incomplete hypothetical.

21 THE WITNESS: I mean, from the things
22 I've seen and the role of various tactics in
23 marketing of pharmaceutical products I think
24 there's lots of examples where there's been
25 questions as to whether there are incremental

1 benefits to follow-on products, and I think
2 that, in particular, when you have a "product
3 hopping" situation where you eliminate the
4 prior formulation of the molecule and the only
5 branded promoted product is the, in this case
6 Prolensa product, I think very much so
7 physicians will continue to prescribe a
8 molecule that they've been familiar with
9 that's supported by marketing and samples and
10 coupon cards and discounts and all those
11 things because they know the molecule has been
12 effective.

13 BY MR. DINER:

14 Q But that same molecule existed in
15 generic form and branded form in terms of Bromday,
16 correct?

17 A No. Not in a traditional sense. There
18 were not -- there was not an AB-rated bromfenac with
19 Bromday as a reference listed drug. There was a
20 bromfenac that had no RLD that was labeled twice
21 daily and there wasn't, I think, a once daily
22 bromfenac sodium until after Bromday was delisted.
23 And so, you know, I think those are -- those are
24 strategically removed and done in a way to minimize
25 the prescribing of generic bromfenac sodium.

1 Q But at the time of Prolensa's launch I
2 think you said before there was branded Bromday out
3 there, correct?

4 A Correct.

5 Q Doctors could have prescribed that
6 since it was the same active ingredient, correct?

7 A Well, but I think, as I explained
8 throughout my report, both in this section and in
9 the marketing section, you know, Prolensa -- Bausch
10 + Lomb basically with the launch of Prolensa took a
11 variety of steps with marketing and shifting all of
12 the marketing support to Prolensa from Bromday,
13 shifting the sampling to support on the products,
14 which is, as I understand it, an important factor,
15 did a pricing strategy to encourage changing
16 behavior to prescribe for Prolensa and executed a
17 strategic transition to move prescribing behavior
18 away from Bromday to Prolensa with the aim of
19 killing the Bromday product. Not unlike exactly
20 what they executed from Xibrom to Bromday.

21 Q But if doctors are sophisticated and
22 informed consumers, why, even in light of everything
23 you said, would they prescribe Prolensa when they
24 could, for example, prescribe the cheaper bromfenac
25 sodium?

1 MS. FINK: Objection, assumes facts not
2 in evidence, calls for speculation.

3 THE WITNESS: Nobody was promoting or
4 spreading awareness of the availability or
5 existence of a bromfenac sodium generic.
6 There is no mechanism by which automatic
7 substitution of the bromfenac sodium labeled
8 twice daily version could happen. Those are
9 huge barriers to that being the selected
10 molecule or the selected product.

11 I am aware, as you can see in that
12 graph, some physicians did write the generic
13 molecule and concentration. I think that the
14 practical reality is the reason that they
15 prescribe Prolensa in lieu of Bromday is all
16 the things I just said which facilitated the
17 transition from Bromday to Prolensa, removed
18 any potential resistance or barrier to the
19 movement from Bromday to Prolensa by keeping,
20 you know, price at parity and providing
21 samples and providing coupons and basically
22 doing exactly what they did from Xibrom to
23 Bromday to facilitate the product.

24 BY MR. DINER:

25 Q And it's your position that a physician

1 would still, in light of the fact that you -- let's
2 start that.

3 It's your position that there are no
4 differences in terms of efficacy or safety as
5 between Bromday and Prolensa, correct?

6 A That's my understanding.

7 Q Okay. And it's your position that in
8 spite of the fact that there are no differences
9 between Prolensa and Bromday that physicians would
10 still prescribe Prolensa while Bromday was
11 available, for all the reasons you mentioned
12 previously?

13 A Yeah. I think that that's consistent
14 with Miss Valerie's testimony, that they weren't
15 able to promote these purported benefits over
16 Bromday. They had to promote to the label. So, you
17 know, it's the other tactics that, you know, clearly
18 it was a safe and efficacious product that the
19 physicians had many years experience with the
20 molecule, Bausch & Lomb did a strategic, you know,
21 approach to remove potential resistance or barriers
22 by facilitating pricing, coupons, discounts and
23 other marketing support in a way that they were
24 successfully able to migrate demand, not unlike they
25 did from Xibrom to Bromday.

1 Q And so your position is that they would
2 have just bamboozled the doctors, then, to prescribe
3 a product that, in your view, had no benefit either
4 from a efficacy -- clinical efficacy or safety
5 profile?

6 MS. FINK: Objection to the extent it
7 mischaracterizes testimony, argumentative.

8 THE WITNESS: I'm not saying anybody is
9 bamboozled, I'm saying that there's all those
10 tactics that were used on physicians. The
11 other overarching tactic is to kill the prior
12 embodiment, which, you know, basically gets
13 rid of automatic substitution that one would
14 typically see when generic versions of a
15 molecule exist. Like I said, nobody is out
16 creating awareness to physicians that the
17 generic bromfenac molecule is out there. So
18 it's not that they're bamboozled, you know.
19 Typically what happens is they will continue
20 to prescribe -- you know, they'll prescribe a
21 brand and it gets substituted. Well, that can
22 no longer happen and so it's not a matter of
23 bamboozling, it's a matter of product
24 switching, product hopping to a safe, and
25 effective product. So it's not saying that

1 there's anything necessarily untoward from a
2 safety and it's certainly a smart, you know,
3 from an evergreening perspective makes some
4 economic sense. But it isn't surprising that
5 they were successful at doing it, much like
6 they did from Xibrom to Bromday.

7 BY MR. DINER:

8 Q And I think we talked about with regard
9 from Xibrom to Bromday that it went from a twice a
10 day dose to a once a day dose, which you said was a
11 benefit because of patient compliance?

12 A Well, there was no change in
13 formulation, but yes, the label did change.

14 Q And with regard to all the benefits,
15 there were a litany of things, as you called them
16 before, you dispute the fact that those are any
17 benefits that doctors would have been aware of or
18 even known of to consider prescribing Prolensa
19 instead of Bromday, correct?

20 A I think your premise is a false premise
21 in that I necessarily agree that the reason they
22 explained or transitioned Xibrom to Bromday is
23 because of the once daily label. I'm not saying
24 that. They did the same things. They killed the
25 Xibrom product. They did the strategic pricing.

1 They did the shift in marketing. So all those
2 things were in the tool chest, and they brought
3 those out of the tool chest again. Based on
4 everything I've seen, as we've talked about earlier
5 today and throughout the day, those other technical
6 aspects are not things that Miss Valerie said that
7 they can promote to, the lack of awareness of the
8 availability of a bromfenac sodium would hinder
9 generic awareness and fulfillment, and yes, that the
10 strategic pricing, marketing and delisting of
11 Bromday explains the transition from Bromday to
12 Prolensa.

13 Q Okay. So you just talked about
14 delisting of Bromday. But we established earlier
15 that there was overlap in the sales as between
16 Prolensa and Bromday, correct?

17 A For a handful of months.

18 Q Right. So about four months there was
19 overlap, correct?

20 A Right. But there was also a change in
21 marketing strategy to, you know, basically convert
22 all scripts, or as many scripts as they could, from
23 Prolensa to Bromday during the four-month
24 intervening period.

25 Q But doctors as independent informed

1 consumers can make their own choice, independent of
2 the so-called tactics that you talked about?

3 A Right. But if the -- if the
4 communication and part of the life cycle management
5 strategy is that Prolensa is replacing Bromday you
6 need to start writing Prolensa in order to get
7 bromfenac for your patients that's going to change
8 prescribing behavior. Hey, it's still safe and
9 effective.

10 Q Were you aware that the price at launch
11 for Prolensa was much higher than Bromday?

12 MS. FINK: Objection, assumes facts not
13 in evidence.

14 THE WITNESS: I think what I've seen is
15 that the price, based on actual data, was at
16 parity and based on strategic documents was at
17 parity.

18 BY MR. DINER:

19 Q So let's talk about that overlap
20 between the Prolensa's launch and what you said was
21 a discontinuation of Bromday. Prolensa launched in
22 mid-April 2013, correct?

23 A Correct.

24 Q Bromday was discontinued in mid-August
25 2013?

1 A Correct.

2 MR. DINER: I would like to mark the
3 next exhibit, Tab 10.

4 (Ophthalmic NSAIDs Average Selling
5 Price Per Prescription, page 2 of 2, was
6 marked Hofmann-12 for identification.)

7 BY MR. DINER:

8 Q Okay. Mr. Hofmann, you've been handed
9 Hofmann Exhibit 12. I'll represent to you that this
10 document, which is identified up at the top a Tab
11 10, Ophthalmic NSAIDs Average Selling Price Per
12 Prescription United States is a tab that comes out
13 of Mr. Jarosz's opening report.

14 Have you seen this document before?

15 A I have.

16 Q So back to where we were. Let's look
17 at Tab 10. I guess you can look at page 2 of 2.
18 It's double sided.

19 A Yep.

20 Q We'll go to 2013.

21 A Yep.

22 Q Quarter 2 is the quarter in which
23 Prolensa was launched, right?

24 A Correct.

25 Q And there Prolensa is identified as

1 selling in quarter 2 in 2013 at approximately \$240
2 per prescription; is that correct?

3 A Well, you have to put this in context.
4 This is a calculation that takes gross sales data
5 from IMS divided by TRx data from IMS, and I think
6 there's a hazard in trying to look at it in this,
7 you know, -- IMS data is good longitudinally, but
8 for a particular quarter there can be noise in it.
9 But the data does say \$238.92 on a gross basis, not
10 reflective of any discounts, or not reflective of
11 actual net pricing of Prolensa.

12 Q And Bromday is reported at
13 approximately \$170 per prescription, correct?

14 A With all the caveats from my last
15 answer, and you can see that, especially for
16 Bromday, as it ended -- as it neared the end of its
17 life cycles, I mean, there's periods in here where
18 it's showing up at \$18 and \$9, according to the
19 data. There's just noise in the data that this is
20 not, you know, a reasonable place to look, to look
21 at the relative pricing of Bromday and Prolensa
22 during that four-month period. I think the strategy
23 documents and internal correspondence regarding the
24 plans to price at parity are reflective of the
25 actual strategy and transition that occurred. And I

1 think it's also worth noting, too, you know, you
2 have the generic pricing, which again is gross and
3 doesn't have the same level of discounts nipping at
4 the heels of Prolensa as well.

5 Q Well, it's a whole lot closer to what
6 Bromday is than it is to Prolensa; isn't that right?

7 A They're somewhat meaningless in that
8 they're gross sales and none of them reflect
9 discounts.

10 Q At least as between Prolensa and
11 Bromday the discounts would apply to both of them so
12 it's a wash, right?

13 A Not so. Some of the tactics, as we saw
14 in the switch in the marketing plans were, you know,
15 they killed for Bromday, any and all marketing they
16 switched it over to Prolensa. So things like
17 coupons, things like sampling, things like that are
18 not going to be the same levels as they are for
19 Bromday as Prolensa during that transition period.

20 Q But the killing, as you call it of
21 Bromday, it doesn't get discontinued until August of
22 2015, right?

23 A That was the official externally, you
24 know, announcement date. But there's other
25 documents leading up to that in the production that

1 talk about the conversion, and the conversion being
2 the strategy of migrating demand to Prolensa during
3 a brief period, not unlike they did from Xibrom to
4 Bromday.

5 Q So with a price of approximately \$240
6 per script versus \$170 per script and the fact that,
7 in your opinion, there is no difference in clinical
8 efficacy or safety, that doctors, even in spite of
9 all the lobbying that you talked about, are going to
10 prescribe Prolensa when they can do the same thing
11 with Bromday?

12 A I reject many premises and assumptions
13 embedded in your question. First off, I explained
14 why I don't think these are reflective of actual
15 pricing, that they reflect some issues with gross
16 sales and TRx data and IMS. There are internal
17 documents that clearly state that the pricing is a
18 parity between Bromday and Prolensa.

19 Additionally, this isn't a price that a
20 physician is even aware of, whether it's this or the
21 actual price. What a physician is aware of is what
22 is the amount of out of pocket that my patient is
23 going to have to pay. And that is really driven by,
24 you know, tier placement and coupons and things like
25 that, all of which migrated to support around

1 Prolensa. So it's not that any of these numbers
2 that you have in Tab 10 there would be any physician
3 that has awareness of any of these. So it's an
4 improper suggestion to say that there's a physician
5 sitting with his pad saying should I do Bromday
6 which is 169 or should I do Prolensa which is 238.
7 No physician, you know, has that information or
8 thinks that way. What they're thinking is, you
9 know, what will my patient's out of pocket be. And
10 as I said, Prolensa has, you know, support through
11 coupons and all the migration of marketing around
12 Prolensa against Bromday.

13 Q Well, if they have none of that
14 financial information how could they determine what
15 that patient's out of pocket is going to be?

16 A Well, the typical way that it happens
17 is complaints. You know, so they'll write a script,
18 and then if nobody complains, everything seems fine,
19 and then when they start to get feedback that could
20 then cause them to either seek out whether there's
21 coupon or patient assistance or migrate demand to
22 other molecules.

23 Q There's going to be a lag time on that.
24 They're not going to know when those complaints are
25 going to come through and when that's going to

1 correspondence to --

2 A Right. That's what I'm trying to get
3 through here is that the launch of Prolensa is
4 accompanied by Bausch & Lomb reps all over the place
5 saying guess what, we now have this Prolensa product
6 which has the bromfenac molecule. It's as safe and
7 efficacious as Bromday was. We're pricing it at
8 parity, we're converting this over to Prolensa,
9 please change your prescribing behavior. They've
10 removed any of the implied resistance that you say
11 should be there from a price elasticity by
12 coordinating a strategic life cycle management
13 campaign, the same way they did from Xibrom to
14 Bromday.

15 Q And did doctors talk to one another
16 about these new products that are being offered by
17 pharmaceutical companies?

18 MS. FINK: Objection, calls for
19 speculation.

20 THE WITNESS: I mean, I'm sure there
21 are doctors that talk about products all the
22 time.

23 BY MR. DINER:

24 Q Right. And are you aware of the
25 reports authored and published by various doctors

1 talking about the benefits of Prolensa versus
2 Bromday?

3 MS. FINK: Objection, facts not in
4 evidence.

5 THE WITNESS: I mean, I'm aware there
6 are some journal articles. I know there's
7 some disputes about whether they're Bausch &
8 Lomb funded and what weight to put on those,
9 but I think that there are some journal
10 articles out there on that.

11 BY MR. DINER:

12 Q Yeah. And those journal articles
13 talked about the benefits of the new formulation,
14 correct?

15 A I think, arguably, that is what is in
16 some of those articles, again, funded by Bausch &
17 Lomb, and subject to the fact that they're also
18 doing all these other tactics and they cannot
19 promote those purported benefits, as Ms. Valerie
20 explained.

21 Q Well, but the doctors are not bound by
22 what Bausch & Lomb can or cannot promote, right?

23 A Of course not. That's what I mean, is
24 if -- your questions and where you seem to be going
25 is you think a Bausch & Lomb rep walks in and says

1 we have new Prolensa, it's \$239, please, please,
2 prescribe it, even though you can get cheap Bromday
3 or cheap bromfenac. Well, that's not reality
4 whatsoever. What the reality is that they
5 facilitated the conversion from Bromday to Prolensa
6 with a molecule that was known to be safe and
7 effective and removing any potential resistance
8 barriers by coupons and pricing parity and all the
9 tools that were in the tool kit from when they
10 transitioned Xibrom to Bromday.

11 Q And some of the other realities were
12 also the published articles of doctors talking about
13 the benefits of the new Prolensa formulation, right?

14 MS. FINK: Objection, assumes facts not
15 in evidence.

16 BY MR. DINER:

17 Q You mentioned that a moment ago.

18 A Like I said, I am aware that there are
19 some articles. I don't weigh in on them from a
20 medical perspective. I know there's some question
21 as to the objectivity of them. But that's not to
22 say there isn't a single doctor that might have been
23 influenced by that. I'm just saying that, in my
24 view of everything I've seen on what commercially
25 explains the life cycle management and transition

1 from Bromday to Prolensa, it isn't the particular
2 formulation in Prolensa that explains, you know,
3 what is happening here.

4 Q It's the particular benefits of the
5 Prolensa formulations that the doctor -- of the
6 Prolensa formulation that the doctors are seeing;
7 isn't that correct?

8 A I totally disagree. Everything I've
9 seen is that the commercial -- you know, what is
10 happening commercially is a revised bromfenac
11 formulation, a molecule that physicians are very
12 familiar with is now available with all the same
13 pricing incentives, samples and facilitation of
14 converting prescriptions from Prolensa to Bromday
15 followed by Bromday being delisted and no longer
16 available.

17 Q And the physicians are also aware of
18 the articles by other physicians that are talking
19 about the benefits in the new formulation, including
20 lower pH, greater comfort, greater ocular
21 penetration, being able to use less active
22 ingredient and still get the same clinical efficacy,
23 they're aware of those articles, too, right?

24 MS. FINK: Objection, assumes facts not
25 in evidence, calls for speculation.

1 THE WITNESS: I don't know that that's
2 a fair assumption. I know that those are some
3 articles cited by Plaintiffs in this case.
4 Whether those are, you know, widely read and
5 understood and as far as influencing
6 prescribing behavior or how physicians often
7 rely on sales reps to explain what the
8 benefits are of a particular product. And so,
9 you know, what they are getting affirmatively
10 is reps from Bausch & Lomb doing the things
11 that they do to help convert prescriptions
12 from Prolensa to Bromday, which necessarily
13 can't include some of those alleged benefits
14 in those articles.

15 BY MR. DINER:

16 Q But you didn't consider those articles
17 and those alleged benefits in those articles in
18 rendering your opinions in this case, did you?

19 A Not true. I looked at the documents
20 that were produced and the feedback and the cataract
21 discussion groups and some of the, you know, what
22 limited documents were produced in this case on what
23 is driving the prescribing behavior of physicians.

24 I looked at Dr. Cykiert's -- I
25 understood Dr. Cykiert's opinions with respect to

1 that, and my understanding is that what motivates
2 the prescribing behavior has, and continues to be
3 the, you know, efficacy, safety and familiarity with
4 the molecule, combined with all the commercial
5 facilitating that Bausch & Lomb did to convert
6 demand from Bromday to Prolensa.

7 Q But you acknowledged before that
8 doctors talk, and that doctors would have talked
9 about the published articles of other doctors that
10 discuss the benefits of the new Prolensa
11 formulation, right?

12 MS. FINK: Objection, mischaracterizes
13 prior testimony.

14 THE WITNESS: Yeah, I mean, I don't --
15 I think that's an unfair, you know, broader
16 characterization than what I agreed with you
17 on. I think that what -- what we know is
18 affirmatively happening is all the things that
19 Bausch + Lomb is doing to get into the offices
20 of prescribers to make them aware of this
21 product and facilitate the conversion from
22 Prolensa to Bromday.

23 BY MR. DINER:

24 Q And during that period of overlap of
25 four months or so, between the launch, or after the

1 launch of Prolensa and the discontinuation of
2 Bromday, physicians shifted approximately 70 percent
3 of their Bromday prescriptions to Prolensa, right?

4 A I saw that metric in the -- in the
5 Jarosz reply report. I think that according to the
6 one, the Morgan Stanley report, that is what the
7 data shows, and that's entirely consistent with the
8 successful conversion strategy that was executed
9 from the launch of Prolensa to the discontinuance of
10 Bromday.

11 Q It's also consistent with what other
12 doctors were saying about the benefits of the new
13 Prolensa formulation with regard to comfort, ocular
14 penetration, reduced active ingredient, same
15 clinical efficacy, correct?

16 A Well, I mean, to your earlier
17 suggestion about lag times you think there might be
18 more of a lag to informal chatter among people over
19 time as opposed to a coordinated, you know,
20 strategic campaign launched by a sophisticated
21 targeter of ophthalmologists who basically fan out
22 and disseminate the conversion strategy and story in
23 a molecule that people are all comfortable with.

24 Q But some of these reports by doctors
25 that you acknowledged having seen, they were based

1 on clinical studies that would have occurred before
2 the Prolensa product was launched, right?

3 MS. FINK: Objection, assumes facts not
4 in evidence.

5 THE WITNESS: Yeah, I'd have to go back
6 and look at the timing of those, but you're
7 right, I mean, to the extent they discuss
8 clinical trials that predated the launch,
9 those would temporally follow there.

10 MR. DINER: I have no further
11 questions.

12 MS. FINK: I have no redirect.

13 VIDEO OPERATOR: We are now going off
14 the record; approximately 3:21 p.m.

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C E R T I F I C A T I O N

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LISA FORLANO, CRR, CCR #XI01143

DATED: February 29, 2016

1 ATTACH TO DEPOSITION OF: Ivan T. Hoffman
IN THE MATTER OF: Senju vs. Lupin
2 DATE TAKEN: February 24, 2016
3

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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:

Enclosed please find a deposition transcript. Please have the witness review the transcript and note any changes or corrections on the included errata sheet, indicating the page, line number, change, and the reason for the change. Have the witness' signature at the bottom of the sheet notarized except in California where they are signing under penalty of perjury and forward the errata sheet back to us at the address shown above.

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Cc: All Counsel

&	123 4:23	2010 79:17	29 184:22
& 1:6,6,14,14 3:3,15 7:2,4 37:8,23 38:1,7 40:9 41:10,13 44:6 44:12 77:1 83:13 115:25 160:22 166:20 176:4 177:7 177:16,22,25 180:10 181:5	12:26 100:24 13 71:19 115:4 116:5 117:13 130 69:18 14 6:15 21:21,23 124:10 136:18,19 138:10 14-4149 1:4 14-5144 1:4 14-667 1:3	2011 152:1 155:6 2012 79:18 154:1,4 154:22 2013 57:21 58:2,25 59:6 60:11 61:13 65:21 66:22 67:2,12 152:9 157:3 160:23 170:22,25 171:20 172:1 2014 4:14 41:20 42:13 59:13 60:22 61:3 70:16 161:23 161:23 2015 4:11 25:1,2,3,5 31:11 33:24,25 34:12 35:5 48:13 57:22 58:2,25 59:8 59:13,20,21 60:3,4 60:5,5,11,23 61:3 61:13 67:13 70:16 173:22	290 185:24 186:1 2:16 151:3 2:31 151:8
0	144 5:2 146 5:3 148 5:4 15 6:16 21:21,24 43:2,16,19,21 62:10 71:18 136:19 138:11 15-335 1:3 16 90:24 16066 7:19 169 7:18 175:6 16th 3:17 17 21:13 170 172:13 174:6 170,000 155:2 171 5:5 18 21:8,11 30:1 172:18	2016 2:5 6:6 33:24 48:12 184:22 185:2 186:4 202 3:6 2025 30:11 212 3:11 213 3:18 22 132:21,24 133:3 133:17,25 159:18 159:24 220,000 154:20 2238413 1:24 186:7 224 148:13 225,000 154:22 23.9 82:2,7 238 175:6 238.92 172:9 239 178:1 24 2:5 6:6 48:12 185:2 240 172:1 174:5 250,000 154:5,8	3
0 82:7 0.02 139:20 140:5 140:17 0.07 4:24 123:8,16 124:10 132:17 0.09 123:5 125:22 132:15 0.15 139:17 140:4 140:15 0.7 125:23 03240 6:16 0392 88:15 06893 6:15 07 132:24 159:24 07039 185:25 186:2 09 46:18 132:25 159:23	183 53:24 1:10 101:2	2016 2:5 6:6 33:24 48:12 184:22 185:2 186:4 202 3:6 2025 30:11 212 3:11 213 3:18 22 132:21,24 133:3 133:17,25 159:18 159:24 220,000 154:20 2238413 1:24 186:7 224 148:13 225,000 154:22 23.9 82:2,7 238 175:6 238.92 172:9 239 178:1 24 2:5 6:6 48:12 185:2 240 172:1 174:5 250,000 154:5,8	3 4:13 11:1,12,13,18 41:22,25 42:12,18 115:19 149:2 30 24:22,24 25:4,5,7 33:9 34:2 44:19 45:10,16 77:23 30,000 155:2 31 102:3 3200 185:24 186:1 333 3:16 34 4:11 35 72:3 105:19 3:21 183:14
1	2	2016 2:5 6:6 33:24 48:12 184:22 185:2 186:4 202 3:6 2025 30:11 212 3:11 213 3:18 22 132:21,24 133:3 133:17,25 159:18 159:24 220,000 154:20 2238413 1:24 186:7 224 148:13 225,000 154:22 23.9 82:2,7 238 175:6 238.92 172:9 239 178:1 24 2:5 6:6 48:12 185:2 240 172:1 174:5 250,000 154:5,8	4
1 4:10 9:14,18 10:12 10:17 21:8,21 66:19 10 5:3 34:1 37:3 62:10 82:19 146:11 146:14 147:24 149:24 171:3,11,17 175:2 10018-1405 3:11 106 21:7 11 5:4 148:10,13 113 4:22 11:22 62:13 11:38 62:16 12 5:5 57:17 62:20 64:9 70:13 171:6,9	2 4:11 5:5,5 10:21 34:15,18 36:6 171:5 171:5,17,17,22 172:1 2/12/16 4:19 56:4 2/24/2016 186:8 20 36:2 75:2 155:1 200 154:5 200,000 154:11 20001-4413 3:5 2005 33:23	2016 2:5 6:6 33:24 48:12 184:22 185:2 186:4 202 3:6 2025 30:11 212 3:11 213 3:18 22 132:21,24 133:3 133:17,25 159:18 159:24 220,000 154:20 2238413 1:24 186:7 224 148:13 225,000 154:22 23.9 82:2,7 238 175:6 238.92 172:9 239 178:1 24 2:5 6:6 48:12 185:2 240 172:1 174:5 250,000 154:5,8	4 4:15 53:1,3,6 40 72:1,2 80:3,21,23 81:25 82:10 40,000 154:19 408-4116 3:6 41 4:13 431 30:7 492 144:23 497 146:15
		2016 2:5 6:6 33:24 48:12 184:22 185:2 186:4 202 3:6 2025 30:11 212 3:11 213 3:18 22 132:21,24 133:3 133:17,25 159:18 159:24 220,000 154:20 2238413 1:24 186:7 224 148:13 225,000 154:22 23.9 82:2,7 238 175:6 238.92 172:9 239 178:1 24 2:5 6:6 48:12 185:2 240 172:1 174:5 250,000 154:5,8	5
		2016 2:5 6:6 33:24 48:12 184:22 185:2 186:4 202 3:6 2025 30:11 212 3:11 213 3:18 22 132:21,24 133:3 133:17,25 159:18 159:24 220,000 154:20 2238413 1:24 186:7 224 148:13 225,000 154:22 23.9 82:2,7 238 175:6 238.92 172:9 239 178:1 24 2:5 6:6 48:12 185:2 240 172:1 174:5 250,000 154:5,8	5 4:18 56:4,9 60:18 512 123:22 52 4:15 56 4:18 57 10:1,6 576-1000 3:18
		2016 2:5 6:6 33:24 48:12 184:22 185:2 186:4 202 3:6 2025 30:11 212 3:11 213 3:18 22 132:21,24 133:3 133:17,25 159:18 159:24 220,000 154:20 2238413 1:24 186:7 224 148:13 225,000 154:22 23.9 82:2,7 238 175:6 238.92 172:9 239 178:1 24 2:5 6:6 48:12 185:2 240 172:1 174:5 250,000 154:5,8	6
		2016 2:5 6:6 33:24 48:12 184:22 185:2 186:4 202 3:6 2025 30:11 212 3:11 213 3:18 22 132:21,24 133:3 133:17,25 159:18 159:24 220,000 154:20 2238413 1:24 186:7 224 148:13 225,000 154:22 23.9 82:2,7 238 175:6 238.92 172:9 239 178:1 24 2:5 6:6 48:12 185:2 240 172:1 174:5 250,000 154:5,8	6 4:20 42:17 88:12 88:15 154:16,24 60 80:1 101:25 102:3,5 62 151:11,16 620 2:4 3:10 6:8

63 160:19 161:5	9676 53:5	102:25 104:18	149:3,10,14,20,24
7	973-629-1287 186:2	109:15 120:14,21	150:2,8,17
7 4:6,22 35:15	a	122:12 125:12	advertise 68:6
113:22,23 115:21	a.m. 2:6 6:2 62:13	133:2,17 134:1	advertising 117:10
116:6 123:11	62:16	159:17 160:1	advil 145:6
140:21	aao 31:9 32:7	162:15 164:6	advocated 150:21
7.4 117:17,23 118:8	ab 163:18	179:21 182:14	affirmatively
118:12 158:14	ability 23:17 73:8	activity 134:11	113:15 180:9
7.8 111:4 112:2	111:25 113:1	actor 86:24	181:18
118:5,7,11 124:22	119:24 120:20	actors 19:3	agent 91:1 93:9
125:10 127:5 158:7	127:19 131:8 134:2	actual 17:8 21:17	99:24 100:1
158:13,17,25 159:5	able 40:4 76:25	27:17,19,21 28:24	agents 90:10,13,15
7.8. 111:9	92:25 126:9 129:6	29:3,13,14,14 31:25	90:18,25,25
70 105:18 106:3	133:2,16 153:6	34:5 45:9,19 50:22	ago 27:11 32:1 34:8
128:8 182:2	159:17 166:15,24	55:23 59:16 67:17	37:23 56:17 58:4,9
75 96:5 156:16	179:21	71:5 123:25 137:4	65:16 70:1 75:18
78 90:5	absent 67:16 70:25	170:15 172:11,25	77:3 114:19 136:25
8	absolute 28:3 72:18	174:14,21	178:17
8 4:23 123:13,17	72:20,21 75:21 76:5	acute 52:3 68:13	agree 40:23 74:1
124:9 149:2	absolutely 22:20	adapting 4:12 34:13	116:9 133:1 168:21
8.3 112:2 117:14	57:7	add 11:10 77:11	agreed 69:11 101:22
118:8,14 124:22	abstract 55:22	154:13	159:23 181:16
125:9 127:5 158:6	63:20 89:21 91:18	added 63:4	ahead 59:19 60:13
158:25 159:7	92:4,7 97:8 99:23	addition 15:3 185:7	157:17
80 108:10,13,20	100:3 101:21	additional 52:4	aim 164:18
109:6 110:24 112:1	accept 26:3 122:16	additionally 174:19	al 6:24
134:3 139:17 140:5	access 84:21	additive 69:21	alcon 50:16,24 77:1
140:8,15,16,20,25	accompanied 176:4	address 7:16 26:17	allegations 84:22
157:11,15,20 158:1	account 39:5 112:16	186:14	alleged 21:24
800-227-8440 186:2	112:18 113:2	addresses 117:1	109:10 120:7
813-8800 3:11	127:25	120:6 149:5	136:20 180:13,17
879 115:6 116:5	accounting 14:21	addressing 15:1	allegedly 138:15
88 4:20	15:7	45:1	allow 97:20
893 114:3	accuracy 27:22	adequate 26:6	allowances 65:10
9	accurate 28:6 83:5	adjective 75:4	alluded 49:12
9 4:10 5:2 144:16,22	accurately 8:11 9:8	adjustments 28:9	alston 3:15 7:4
145:20 147:21,25	90:22	administered 20:13	alston.com 3:18
172:18	acidic 124:23	adopt 36:10	altogether 39:8
90071-3004 3:17	acknowledged	adult 142:13	american 4:15
901 3:5	181:7 182:25	advantages 90:19	52:22
9525 34:19	acquired 104:20	91:8	amount 38:7,21
9561 42:1	action 1:3 184:15,16	adverse 99:5,13,15	52:10 65:18 67:8
	active 93:1,6 94:7	99:15 145:25 146:2	93:1,25 94:14
	96:19 98:10 102:17	146:24,25 147:1,13	119:24 133:17,25
		147:15 148:1,20,22	139:17,20 140:7,8

<p>140:25 142:17 154:14 157:15,25 158:1 174:22 amounts 39:8 143:4 144:1 analyses 136:4 analysis 17:4 24:15 24:17 26:20,21 27:22,24 28:3,4,16 29:2 47:3,16,17 55:10 63:8 65:2,19 65:23 66:6,12 67:6 67:9 72:11 73:5 75:20 78:10,12,14 78:17,20 79:9 80:7 80:13 81:20 82:4 135:15 136:13 137:1,16,19,20 138:2,7 139:13 143:20 analyze 16:17,17 17:21 23:19 25:11 74:9 analyzed 57:25 71:11 78:24 80:15 analyzing 15:1 16:4 17:2 29:20 75:24,25 angeles 3:17 announcement 173:24 answer 8:10 9:4 47:20 57:6 73:21 74:18 87:19 134:20 146:17 172:15 answered 75:16 82:14 149:17 answering 8:17 answers 27:10 36:24 137:9 anybody 28:11 167:8 anyplace 108:24 api 93:15 apologies 145:9</p>	<p>apologize 59:11 151:13 appear 59:8 69:5 145:21 146:19 150:22 152:6 appeared 113:11 appears 9:20 50:22 117:24 150:6 152:13 appendices 9:24 appendix 10:15,17 10:21 11:1,12,13,18 applicable 17:25 73:20 applications 15:18 applied 37:2 65:18 160:12 applies 37:20 apply 173:11 applying 65:7 approach 4:16 27:25 52:24 53:8,16 166:21 approval 40:13,25 approve 147:12 approved 38:8 40:4 150:1,4 approves 147:8 approving 18:5 145:16 approximate 151:23 152:5 approximately 6:2 43:1 62:13,16 100:24 101:2 151:3 151:8 157:3,13 172:1,13 174:5 182:2 183:14 april 170:22 aqueous 110:8 area 15:4 16:2 152:13 153:21,21 areas 14:18,21,22 16:14 152:12</p>	<p>arguably 177:15 argue 89:14 argumentative 32:4 73:1 138:22 167:7 art 26:4 89:10 136:8 138:4 article 4:16,20 44:5 44:24,25 52:22 53:18,25 54:23 55:3 88:9 90:24 124:1 125:5 159:5,10 articles 53:19 177:6 177:10,12,16 178:12,19 179:18 179:23 180:3,14,16 180:17 181:9 aside 96:10 123:10 146:9 asked 11:7 14:22 17:4 55:22 75:15 82:13 106:19 107:17 112:14 114:24 135:24 139:7 149:16 asking 8:10 33:18 88:19 126:12 129:8 134:13 140:1 143:13 144:12 aspect 94:13 119:12 aspects 14:14 17:24 18:10 40:2 92:18 96:25 97:22 110:19 119:5 131:25 143:14 169:6 aspirational 37:15 asserting 75:22 assess 21:2 33:9 44:20 65:21 72:13 assessment 65:3,4 75:13 assets 44:14 assistance 175:21 associated 28:13 102:6 117:3 133:4 160:16</p>	<p>association 4:15 52:22 assume 9:4 61:7 64:4 67:10 91:24 129:9 assumed 130:3 134:18 135:5 assumes 112:3 113:4 118:17 120:23 121:16 130:22 131:3 133:20 138:21 141:22 158:8,20 159:19 165:1 170:12 178:14 179:24 183:3 assuming 134:12 assumption 67:19 180:2 assumptions 29:7 74:24 89:23 92:4,8 174:12 attach 185:1 attention 68:1 84:3 attorney 184:13,14 attorneys 3:7,12,19 6:19 17:8 106:17 121:11 attributable 21:25 129:18 136:21 138:12 155:8 attributes 50:12 august 24:25 25:2 170:24 173:21 author 53:21 authored 176:25 automatic 165:6 167:13 availability 86:4 165:4 169:8 available 24:20,24 25:15,24 26:5,11,19 28:21 29:15,16 34:4 46:23 47:3 58:1 65:6 67:18 80:13</p>
--	--	---	---

161:1 166:11 179:12,16 ave 186:1 avenue 2:4 3:5,10 6:8 185:24 average 5:5 72:3 171:4,11 aware 26:22 46:24 48:7 120:18 123:4,7 165:11 168:17 170:10 174:20,21 176:24 177:5 178:18 179:17,23 181:20 awareness 165:4 167:16 169:7,9 175:3	48:18,23 51:25 52:19 67:11 69:11 73:25 74:8,18 75:9 76:10 78:25 79:9,15 83:1 85:18 93:6 94:24 98:3 99:1 114:6 141:2 143:19 147:9,14 148:4 150:4 152:3 169:3 170:15,16 182:25 basic 40:9 basically 8:5 102:17 102:25 154:13 164:10 165:21 167:12 169:21 182:21 basis 55:8 74:8 76:20 80:20 107:14 162:11 172:9 bates 34:18 35:15 42:1 53:4 88:15 90:6 114:3 115:5 116:5 144:22 146:14 148:13 bausch 1:6,6,14,14 26:22 27:5 28:24 62:7 65:21 77:1 104:20 115:25 126:8 160:22 164:9 166:20 176:4 177:7 177:16,22,25 180:10 181:5,19 bearing 34:18 144:22 146:14 148:13 bears 41:25 beginning 6:3 62:17 90:9 101:3 115:18 151:5 152:8 behavior 69:7 113:10,13 126:10 164:16,17 170:8 176:9 180:6,23 181:2	belief 90:14 believe 11:1 12:16 24:25 25:10 29:25 37:25 46:9 53:10 55:11 56:11 64:20 104:17 157:18,24 beneficial 85:1 benefit 86:11,24 87:5 91:14 92:9 94:19 95:16,22 96:7 97:3 98:11 99:6 101:8 103:18 116:2 117:3 126:23 127:21 133:4,18 156:1,23 167:3 168:11 benefited 49:19 benefits 45:20,22,24 84:9,24 85:21 86:15 87:11,16 89:17 101:7,11,15,23 103:11,22 105:1 109:10 116:20 119:15 131:13 155:8 160:16 162:17 163:1 166:15 168:14,17 177:1,13,19 178:13 179:4,19 180:8,13 180:17 181:10 182:12 best 29:9 37:14,14 80:13 151:15 better 74:11,19,25 76:18 78:3 85:12 90:19 94:18 102:16 103:6,10,17,21 104:9,24 105:13 108:20 109:6 110:23 111:25 134:3 151:21 159:6 beyond 45:16 94:8 95:23 98:12 99:8 103:25 111:16 112:4 118:16	125:13 126:1 127:7 133:6 140:10 141:6 141:21 142:7,20 147:16 150:13 156:12 160:5 biologic 39:17 bird 3:15 7:5 bit 58:8 59:9 66:15 82:15 84:16 98:8 100:19 143:23 145:5 black 9:21 86:10 151:12 152:24 153:4 blue 64:10,23 board 37:20 43:11 body 93:10,17 94:1 bolded 102:24 book 18:2 bore 14:13 bottom 11:17 66:22 66:25 115:5 186:12 bound 177:21 brain 88:4,6 brand 29:11 39:16 39:17 45:7 47:9,12 48:3 49:13,14 52:17 54:5 83:11 86:25 154:20 167:21 brand's 54:9 branded 161:12 163:5,15 164:2 brands 89:13 break 8:15,18,18 62:9,19 63:7 82:19 100:20 101:5 124:5 145:5 150:24 151:1 152:16 breaking 100:18 breakout 80:12 breaks 8:7,7,14 bridges 136:19 bridging 21:23 brief 62:14 151:4 174:3
b			
b 4:9 5:1 back 11:6,12 30:1 34:7 42:8 48:17 62:10,15 71:24 74:16 78:9 99:23 101:1,20 109:3 115:17 117:13 121:20 133:18 134:2 138:8 151:7 158:22 171:16 183:5 186:13 backdrop 44:4 bad 89:18 93:9,16 balance 86:1,6,10 120:10 bamboozled 167:2,9 167:18 bamboozling 167:23 barrier 165:18 barriers 165:9 166:21 178:8 based 22:13 23:14 24:19 27:7 29:18 30:19 32:1,24 33:9 33:10 34:3 36:25 37:1 38:16 41:5			

briefly 161:13 bring 38:13,18 41:11 84:9 87:5 89:17 103:22 104:9 104:25 114:5 broad 15:3 41:15 broader 181:15 broadly 14:22 17:17 bromday 26:17 30:25 46:7,8,10,15 46:20 47:1,13,22 48:10 65:6 66:11,16 66:23 67:2,7 71:10 72:1 78:12,14 80:10 80:25 106:1 108:6 108:10,14 112:2 114:20 117:4,14 118:14 119:25 123:4 124:22 125:10 127:5,15 128:11,21 129:25 130:11 132:10,14 132:22 134:2 139:2 139:17 140:5,8 143:4 144:2 146:18 146:21 147:20,23 151:20,25 152:6,12 152:19,21 153:1,16 153:24 154:7,11 155:3,7,8 156:11,23 156:25 157:2,6,20 158:2,6,19,25 159:7 160:17,23,25 161:10,12 163:15 163:19,22 164:2,12 164:18,19,20 165:15,17,19,23 166:5,9,10,16,25 168:6,9,19,22 169:11,11,14,16,23 170:5,11,21,24 172:12,16,21 173:6 173:11,15,19,21 174:4,11,18 175:5 175:12 176:7,14	177:2 178:2,5,10 179:1,14,15 180:12 181:6,22 182:2,3,10 bromfenac 4:24 19:15,23 20:13 33:15 37:2 45:5,24 46:17 49:20 73:7 79:1,22,24 80:4,8 80:17 108:20 109:6 109:16,24 110:2,5,9 110:23 111:25 113:2 114:21 115:15 122:13 123:5,8,15 124:10 124:23 125:12,22 132:15,18,21 133:19 134:3 139:9 152:15 153:2,12,16 153:22 154:3,6,7,10 155:2 157:15 161:15,18 163:18 163:20,22,25 164:24 165:5,7 167:17 169:8 170:7 176:6 178:3 179:10 brought 86:15 91:13 101:15 169:2 bryan 3:4 6:22 bryan.diner 3:6 budgeting 16:18 building 3:10 92:3 built 29:6 98:23 bullet 102:7,11 104:7 burn 142:5,18 burning 107:7 120:2 146:7 147:6 148:2 148:23 149:15 150:8,12	calculate 65:17,22 calculation 72:24 78:16 172:4 california 3:17 186:13 call 110:7 135:17 173:20 called 70:1 119:16 137:3 154:12 160:14 168:15 170:2 calls 25:16 26:25 30:16 38:24 81:1 84:11 89:19,20 94:9 97:4 98:13 99:10 103:24 105:3 116:22 118:15 126:2 128:22 131:17 133:7 144:4 150:14 156:3 162:6 162:19 165:2 176:18 179:25 campaign 16:10,13 176:13 182:20 cancer 93:11 95:10 caption 6:10 captioned 184:7,11 capture 160:25 carbon 124:10 cards 163:10 care 14:14 careful 69:15 115:23 135:1 carryover 138:8 case 6:10,13,15 10:9 23:20 28:17 33:17 38:19,20 43:10 77:1 77:22 82:12 104:5 107:25 111:21 122:13 126:7 133:16,24 136:14 145:3 148:7 163:5 180:3,18,22 186:6 cases 36:15 88:25 90:21 97:10 156:10	cataract 4:22 95:19 113:20 180:20 categories 15:3 categorized 69:23 category 69:8,9 106:7 116:25 cause 175:20 caution 63:4 caveat 18:7 61:4 caveats 172:14 cc 186:25 ccr 2:2 184:19 185:23 cdgs 4:22 113:20 cease 151:24 ceased 160:22 certain 13:11 25:25 26:14,18 28:18 29:14 38:7 43:13 54:16 58:17 65:17 68:21 73:7 76:23 91:8 95:3 100:10 101:6 103:10 112:22 120:8 135:7 136:14 certainly 16:21 24:6 27:15 28:25 32:25 37:3 38:16 39:11 43:9 47:6 49:13 51:14 52:13 57:11 73:13 76:13 89:8,24 105:14 109:17 112:11 113:8 115:24 119:18 141:9 156:18 168:2 certificate 2:3 certified 184:4,5 certify 184:6,12 cessation 52:15 cetera 40:5 44:3,3 cff 4:10 9:14 chain 97:16,23 98:4 98:20 chance 24:5
	c c 3:1,4 4:18,24 56:2 56:10 123:15 184:2 184:2 185:24		

<p>change 31:9 72:3 118:21,21,24 127:17 129:5 155:15,17 168:12 168:13 169:20 170:7 176:9 185:6 185:12 186:12,12 changed 94:20 changes 39:18 126:19 186:11 changing 164:15 characterization 73:4 76:4 181:16 characterize 126:25 160:15 characterized 63:14 106:14 characterizing 75:4 105:15 chargebacks 65:11 chart 67:4 71:1 chatter 182:18 cheap 178:2,3 cheaper 84:21 164:24 check 79:13 118:1 chemical 44:1 chemistry 20:18 chemo 100:1 chest 169:2,3 child 142:2 childhood 142:10 choice 170:1 chose 82:16 104:21 104:22 chronic 52:4 95:3 circumstance 58:24 circumstances 22:13 23:14,20 30:19 32:24 33:16 36:25 38:16 41:5 48:23 51:25 52:19 58:23 68:25 75:9 84:14 85:18 92:12 93:6 94:24 98:5,16</p>	<p>99:1,20 103:16 citation 21:14 106:5 citations 21:18 cite 114:17 120:5 cited 88:23 106:13 180:3 cites 34:25 citing 72:19 civil 1:3 claim 119:24 127:19 claimed 22:1,24 23:9 110:1,3,15,16 110:20 118:21 119:6 127:20 129:19,21 130:1 131:13,25 132:6 134:17,23 135:4,19 136:1,22 137:5 138:13,15,20 143:14 claims 76:5 83:22 109:21,24 110:4,7 110:11,18 122:23 126:12 127:13 128:5 129:3 131:9 131:24 135:7 136:6 138:2 139:14 clarify 8:25 clarity 8:24 class 39:16 49:14 52:1 78:1 90:10,13 clause 107:11 clear 34:3 86:18 143:24 clearly 27:7 71:25 152:4 166:17 174:17 clinical 4:20,23 40:5 40:9 84:23 86:8 88:10,17 94:6 100:12,14 112:18 122:19 123:14 125:24 126:11 132:10 133:4 147:9 147:14 148:5 149:6</p>	<p>150:5,9,17 167:4 174:7 179:22 182:15 183:1,8 clinically 126:23 closer 118:8,11 131:1 158:14 173:5 clip 4:10 9:14 colleague 6:25 collective 153:12 collectively 65:14 77:10 152:20 color 152:11 153:20 column 35:17 36:6 42:19 53:25 54:1 124:14 145:25 146:23,24 148:20 combine 72:6 combined 45:10 80:14,17 181:4 come 43:22 62:10 92:13 100:1,11 108:2 116:20 136:3 137:20 175:25 comes 63:24 104:19 142:15 157:3 171:12 comfort 115:10 116:2,8,11,19 117:3 117:8,10 118:13,24 119:3,12,24 120:1 179:20 182:13 comfortable 131:2 182:23 coming 127:12 135:16 138:8 commencing 2:5 commercial 21:24 22:7,18 23:2,6,8,12 23:23,25 31:15,25 32:10 33:11 34:6 45:2 46:4 72:12,14 75:24,25 83:18,23 84:1,4 86:22 126:18 129:13,17 131:25 132:1,5 134:9,10,11</p>	<p>134:19,24 135:6,8 136:5,12,15,20 137:18 138:1,11 139:3,5,13 143:17 143:18 179:9 181:4 commercialization 16:24 17:3,9 56:23 commercialized 17:10 commercially 44:21 58:1 74:13,21 75:6 75:7 135:9 178:24 179:10 commit 111:19 committed 48:16 50:19 139:22 common 33:19 43:19 64:1 77:23 78:3 communication 170:4 companies 17:9 29:7,18 30:13 34:8 35:2 36:15,21 37:6 37:18 40:17 41:8,12 49:3 54:15 68:1 70:9 76:23 83:11 176:17 company 6:11 16:7 16:10,13 26:22 27:11,20 29:12 32:12 41:6,14 49:25 80:3 82:20 86:25 87:4 150:10,21 comparable 158:18 159:6 compare 76:9,17,19 76:20 78:4 compared 60:11 75:14 80:9 129:24 132:21 134:1 140:7 157:14,19 158:1 160:16 compares 72:24</p>
--	---	---	---

comparing 76:8 competing 46:19,23 competition 87:12 competitive 22:15 70:7 complains 175:18 complaints 175:17 175:24 completely 57:14 completeness 13:1 complex 39:22,25 compliance 85:12 88:1 90:20 92:18 94:18 95:5,15,16,20 95:21 96:7 155:21 155:24 156:1,7 168:11 components 26:4 composition 19:15 19:19 compound 43:15 83:15 compounds 43:1 comprise 110:9 comprised 154:9 compromised 160:1 160:2 concentration 14:24 16:4 93:12,19,22 124:20 125:22 126:21 133:2 140:19 143:4 144:1 144:12 157:14,20 160:11 165:13 concentrations 93:13 142:25 concept 52:9 57:2 concern 82:3 concerning 56:23 129:12 conclusion 73:19,23 condition 52:3,4 conditions 95:4 96:20,22	conduct 24:14 conducted 19:23 21:1 confirming 148:5 confuse 69:17 confusing 59:5 connected 184:15 connection 13:16 20:21 consider 12:14 14:19,20 15:22 16:23 17:1,14 18:8 22:24 28:10 50:14 57:4 98:25 116:19 118:12 119:3,12,14 119:19 126:6 136:12 138:17 139:23 143:3,16,25 161:25 162:4 168:18 180:16 consideration 16:20 24:19 28:5 29:3 79:6,11 135:4 considered 11:2,5 11:15,22 12:18 21:1 50:23 56:12,16 65:6 66:12,16 67:6 92:9 112:23 113:8,14 114:17 119:18 120:3,3 126:8,11,16 128:3 131:15,20,23 139:8 143:19 considering 16:4 56:19 112:17 134:24,25 139:2 consistent 55:1 72:4 72:5 106:12 138:7 152:19 166:13 182:7,11 constitute 129:20,25 constituted 55:12 consult 14:22 17:21 consultant 16:8 consulted 16:12	consulting 16:3,15 16:16,20 18:21 consumer 84:7,10 85:21 86:11,12 87:16 89:17 98:11 99:7 101:9,16 103:23 162:1 consumer's 68:1 consumers 84:20 85:2 86:5 95:22 162:5 164:22 170:1 consuming 86:15 87:6 91:15 92:10 94:19 103:23 104:10 105:1 156:2 contain 108:6 contained 26:8,15 containing 19:15,20 79:22,24 80:17 contains 47:2 108:10 123:5,8 context 34:23 37:25 55:24 83:18 88:22 89:11 96:14 120:4 125:6 145:2 172:3 continue 32:8 33:5 163:7 167:19 continued 5:1 59:22 continues 181:2 contribute 22:6,18 23:2 contributed 23:25 controversial 81:6 convenience 115:10 116:8,11 118:25 conversion 174:1,1 178:5 181:21 182:8 182:22 convert 87:23 169:21 180:11 181:5 converting 176:8 179:14 coordinated 182:19	coordinating 176:12 copy 106:11 152:10 corner 4:14 10:16 41:21 42:14 corp 1:7,15 correct 7:21,24 11:3 11:25 12:3 13:24 14:2 15:18 19:12,16 19:17,20,21 20:5,8 20:14,19 22:25 23:12 24:22 25:6,9 25:12,13 27:22 29:8 30:3,12,15 31:3,21 32:3 35:6,7 39:24 40:10 43:17 46:20 47:22 51:2,9 52:12 55:13 56:24 57:2 58:2,3,14 59:2,14 60:2,12 61:13 63:9 64:14 65:3,19 67:13 68:21 69:13 70:4,16 71:7 73:18 75:14 76:10 80:10,25 81:16 86:16 91:5 100:15 103:7,11,23 104:10 106:17 110:16 114:15 115:13,16 117:10 118:5,8,14 119:10 121:9,10 122:4 123:8,9 128:1,13 129:19 130:11,17 131:2 132:15,16,18 134:17 136:23 137:5 139:11 140:25 143:6 144:2 147:6 148:6 149:15 150:5,12 152:22 153:13,14 155:22 156:2 157:4,8,11,12 157:16 158:2,14,19 159:2 160:3 161:12 161:15 162:18 163:16 164:3,4,6 166:5 168:19
--	---	--	---

<p>169:16,19 170:22 170:23 171:1,24 172:2,13 177:14 179:7 182:15 184:9 corrections 186:11 correctly 57:24 78:18 103:4 correspondence 172:23 176:1 cost 26:1 27:12 28:12 79:15 80:8,9 80:18 82:11 84:24 86:2 90:21 92:3 103:19 costs 28:14,14 29:22 40:14 78:16,19,21 78:24 79:2,5,8,9,12 79:18 80:22 81:4,9 81:10,16,25 cough 58:8 coughing 145:5 counsel 6:23 13:22 13:23,25 14:12 27:3 106:22 107:14,18 108:23 184:13,15 186:25 count 51:16 counter 128:25 129:8 counterfactual 74:24 couple 55:16 70:19 70:20 coupon 163:10 175:21 coupons 65:10 67:25 68:3,5,10,15 70:3,10,25 71:14,16 72:8 165:21 166:22 173:17 174:24 175:11 178:8 course 18:20 22:8 71:16 77:24 97:15 177:23</p>	<p>court 1:2 6:14 7:6 9:17 41:24 56:7 114:1 123:20 144:18 146:14 184:5 185:10,24 covered 56:25 cpa 4:10 9:14 cranberry 7:18 creating 89:15,16 167:16 criteria 138:10 criticize 117:7 critique 27:25 critiquing 75:19 crr 2:2 184:19 185:23 crystallized 57:10 57:14 cure 93:11 current 10:19,20 11:8,8 cuts 33:14 cv 6:15,16 10:13,19 10:20,22,23 11:7,8 cycle 33:22 37:4 41:3 45:11 46:22 48:25 68:11 82:23 83:4 84:7,17 85:16 85:21,24 86:3,14,19 86:20,23 87:17,20 89:12,14 91:12 101:8,14 105:2,9,13 119:16 135:12,17 137:3,16 138:5 160:18,24 170:4 176:12 178:25 cycles 172:17 cykiert 13:5,8,21 31:9 32:2 106:9,16 107:15,19 108:2,4 117:1 119:22,25 120:6 122:21 126:22 127:16 132:9 149:5</p>	<p>cykiert's 13:25 106:23 118:23 180:24,25 cytotoxic 93:9,13</p> <p style="text-align: center;">d</p> <p>d 4:2 10:11,14 37:8 37:24 38:1,7 40:9 41:10,13 44:6,12 83:13 daily 78:4,5,6 85:9 85:10 96:6,7 152:19 155:18 156:21,22 156:22,23,24 161:16,19 163:21 163:21 165:8 168:23 damages 28:17 data 25:15 26:6,10 26:11 27:21 28:8 29:5 33:10,24 34:4 45:12,19 47:4,5,7 47:11,21,24 48:2,5 48:8,11,16 50:18,21 50:22 55:24 58:1 59:16,16,16 60:8,17 60:19,19 61:17,19 62:6 65:8,20 66:10 67:17 70:20 71:5,8 71:9,24 72:5 73:6,9 74:8 75:1 76:4,10 76:12,16,18 77:4,5 77:5,15,19 80:14 154:16,25 170:15 172:4,5,7,9,19,19 174:16 182:7 date 6:6 11:4 24:23 173:24 185:2,9,23 186:8 dated 4:19 56:3 184:22 day 14:17 77:23 114:10 155:9,10 168:10,10 169:5</p>	<p>days 104:20 186:16 dc 3:5 dealing 15:6 78:1 dear 186:10 decent 150:23 decision 18:5 19:7 150:20 decisions 44:6 decline 70:3 decrease 51:22 52:16 54:8,16 55:18 58:18 68:20 99:14 142:18 decreasing 52:10 61:12 63:1,16 124:24 125:9,20,22 deducted 55:11 deductions 28:22 deemed 186:17 deep 19:1 defendant 3:12,19 7:5 defendant's 110:22 defendants 1:12,21 defense 89:14 defer 99:11 100:8,13 100:16 109:8,12,18 110:11,17 111:7,11 112:6 125:16 133:10 134:7 142:22 155:15 deferred 130:12 131:6 139:9 160:10 deficiencies 27:16 definitely 17:1 85:1 94:10 143:19 definition 22:11 degradation 96:20 98:8,9,23,24 degrades 98:17 degree 38:9 40:6 71:18 72:3 74:9 76:14,21 98:22,24 100:11 124:20 136:2</p>
--	--	--	---

deletion 185:7 delisted 45:22 46:6 46:8 163:22 179:15 delisting 169:10,14 deliver 44:7 162:17 deloitte 4:11,13 34:12 35:2,8,11 41:19 42:6,8,9,9 demand 83:13 166:24 174:2 175:21 181:6 demarcation 151:18 153:3 denigrate 83:3 denigrating 83:9,17 denigration 83:24 department 186:22 depend 98:15 99:13 depending 22:13 77:25 98:4 depends 47:25 49:18 50:9 51:25 52:1,3,4,5 58:22 87:19,20 95:13 97:6 99:16 156:7 deposed 7:20 deposition 2:1 6:7 12:14 13:8 25:20 56:13 184:7 185:1 186:8,11 derived 101:14 106:15 119:16 described 33:1 55:2 72:17 87:9 106:18 description 10:3 150:2 design 116:16 designed 115:9 116:8,11 118:13 detailed 134:13,16 details 43:25 134:21 determination 29:16 67:8 92:20 determine 175:14	detract 23:11 detriment 84:20 86:5,11 develop 26:20 37:8 40:3 developed 40:25 developing 80:12 development 17:7 36:9 40:7 41:8 difference 60:18 75:5 105:25 120:1 120:11 122:21 128:10 140:4,19 153:1 155:19 174:7 differences 105:23 114:20 128:19 157:5 158:5 166:4,8 different 29:6,7,7 69:20,20 97:21 100:11 108:6 132:4 137:25 139:3 143:23 differential 46:25 47:6,8 154:14 differently 43:18 65:25 78:23 108:12 difficult 49:10 81:15 152:25 153:2 diminished 23:16 diner 3:4 4:6 6:22 6:22 7:12,14 9:11 9:16 24:13 26:9 27:18 30:23 32:15 33:7 34:10,16 35:21 37:22 38:10 39:20 41:17,23 42:24 43:12 47:19 48:6 49:21 50:6 52:20 53:2,12,13 55:9,25 56:6 59:10 60:1,20 62:2,9,18 64:7,25 66:13 67:23 69:10 71:3 73:15 76:7 81:13 82:21 84:5 85:14 88:7,13 90:3	92:6 93:23 94:4,16 95:17 96:4 98:6 99:3,18 100:5,17 101:4,24 103:20 104:6,23 105:17 109:4 111:13,23 112:8 113:18,23,25 116:18 117:6,21 119:2,9 121:5,22 122:15 123:3,12,19 124:7 125:7,18 126:5 127:23 129:10 130:24 131:11 132:8 133:14,23 134:15 136:17 137:12 139:6 140:14 141:3 141:13,18 142:1,12 143:2,21 144:13,17 144:21 145:13 146:12 147:19 148:11 149:12,22 150:25 151:9 153:5 153:9 155:20 156:9 156:15 157:21,23 158:12,23 159:12 159:21 160:13 162:13 163:13 165:24 168:7 170:18 171:2,7 176:23 177:11 178:16 180:15 181:23 183:10 direct 53:24 directed 36:4 90:24 104:16 direction 31:12 directional 82:3 directly 14:9 16:11 106:16,22 121:2 154:1 disagree 27:23 33:13 37:6,17 38:6 44:22,23 70:5 76:16 80:20 138:23 179:8	discernible 105:22 105:24 128:9 disclose 76:24 77:2 disclosures 82:19 disconnect 137:23 discontinuance 182:9 discontinuation 170:21 182:1 discontinued 170:24 173:21 discount 65:18 66:10,15,24 69:23 73:6 discounting 137:17 discounts 55:15 61:6,7,22,23,23 62:4,6 63:7,8,12,24 64:2,5,20 65:2,3,4,5 65:9,14,22 66:5 67:4,5,6,12,20 69:3 69:9 70:2,10 71:1,5 71:24 72:4,8 73:16 74:1 75:12 136:11 137:3 163:10 166:22 172:10 173:3,9,11 discovery 43:2,16 discuss 25:19 121:13 181:10 183:7 discussed 36:14 119:1 147:21,22,23 147:24 discussing 101:6 115:12 discussion 4:22 34:7 65:13 81:18,19,21 113:20 129:11 180:21 disease 20:11 dismissal 90:10,13 dispensing 19:5 dispute 15:9,11 87:10 91:21 92:15
---	--	--	---

<p>112:22 168:16 disputes 109:9 130:5 177:7 disseminate 182:22 distance 64:22 distinction 77:22 110:1 133:13 distinguish 39:14 distract 23:11 distribution 4:24 15:25 18:25 19:3 123:15 124:9 district 1:2,2 6:13 6:14 ditto 24:12 divided 172:5 doctor 62:20 96:1 106:19 107:17 178:22 179:5 doctors 107:1,21,23 161:1,25 162:4 164:5,21 167:2 168:17 169:25 174:8 176:15,21,25 177:21 178:12 179:6 181:8,8,9 182:12,24 document 4:13 9:19 34:20 35:15 36:18 41:19,25 42:2,11,17 43:5 47:14 53:6 57:5 88:16,20 90:5 104:12 114:2,4,11 115:18,19,21,25 116:12,15 119:13 119:18,20,21 120:5 123:23 124:8,13 144:24,25 145:19 146:16,19 148:14 148:25 158:11 159:9 171:10,14 documents 111:20 112:24 119:21 170:16 172:23 173:25 174:17</p>	<p>180:19,22 doing 74:19,25 75:19 77:14 80:12 85:4 114:9 138:2 147:9,13 165:22 168:5 177:18 180:10 181:19 dollars 38:12,18 39:5,9,12 45:23 51:5,10 69:18 dosage 87:24 92:19 95:8 96:18,25 98:17 dose 95:2 96:6,7 168:10,10 dosed 155:9 dosing 85:9 double 138:15 171:18 downward 59:22,22 dr 12:6,15 13:5,6,8 13:21,25 14:5,6,7 14:12 31:9 32:2 106:9,16,23 107:15 107:19 108:2,4,4 117:1 118:23 119:22,25 120:5,20 121:9,12 122:3,5,9 122:20 123:2 126:22,22 127:16 132:9 149:5 180:24 180:25 dramatically 59:2 draw 64:21 154:1 drawing 98:7 drawn 73:20,24 drill 7:25 drive 7:18 driven 21:25 23:9 129:17 136:21 138:12,14 174:23 driver 134:23 drivers 136:5 137:25 139:3 driving 135:2 180:23</p>	<p>drop 59:8 60:6 119:4 131:2 142:18 dropoff 59:14 drops 100:7 drove 134:11 drug 18:6 33:18 38:1,1 40:7,10 54:3 78:1 80:24 91:5 97:1,2 124:23,25 162:15,16,16,18 163:19 drugs 4:20 32:17 80:4,9 88:9,16 90:14 97:9,12 145:16 due 70:24 duly 7:10 184:8 dunner 3:3 duplicative 90:17 duration 98:19 dynamic 31:8</p> <hr/> <p style="text-align: center;">e</p> <hr/> <p>e 3:1,1 4:2,9 5:1 184:2 185:4,4,4 earlier 20:1 36:14 36:24 49:13 56:25 68:18 69:19 82:22 106:8 133:9 137:15 145:14 156:6 158:25 161:17 169:4,14 182:16 early 4:16 33:19 52:23 53:7,14 161:23,23 ease 65:13 easier 88:1 97:22 114:5 easiest 66:17 economic 4:20 15:7 15:23 17:15,23 32:17 56:23 83:9 86:19 88:10,17 96:11 139:13 168:4</p>	<p>economically 83:12 economics 10:25 14:21,24 15:2 18:13 18:21 28:12 56:22 education 162:11 effect 54:8 63:7 109:15 122:22 127:4 130:19 138:18 effective 54:11,18 94:15 163:12 167:25 170:9 178:7 effectively 13:14 125:23 159:25 effectiveness 90:21 effects 54:7,10 92:1 92:2,17 99:25 100:10,12 107:7 120:2,8,9 127:18 effexor 85:7,7 efficacious 166:18 176:7 efficacy 90:19 91:9 91:13,21,22 92:1,9 92:15,16,24 93:14 94:6 98:18 100:2 105:25 108:1 125:24 127:15 128:10,20 132:11 133:4 166:4 167:4,4 174:8 179:22 181:3 182:15 eighth 2:4 3:10 6:8 140:7,24 142:16 157:14,25 either 20:19 126:21 142:22 153:23 167:3 175:20 eked 45:25 elaborated 10:23 elasticity 176:11 elderly 95:18,19 element 109:21,23 110:15,16</p>
---	---	--	---

<p>eliminate 84:18 163:3</p> <p>embedded 74:23 89:23 174:13</p> <p>embodiment 17:10 34:3 127:22 130:4 134:19 135:6 138:5 139:1 167:12</p> <p>empirical 54:2</p> <p>employee 184:14</p> <p>encl 186:24</p> <p>enclosed 186:11</p> <p>encourage 164:15</p> <p>ended 33:2 172:16</p> <p>enhance 97:20</p> <p>enhanced 100:2 125:11</p> <p>enhances 125:1</p> <p>enlighten 66:14</p> <p>enter 92:20</p> <p>entered 45:6</p> <p>entire 107:10</p> <p>entirely 182:7</p> <p>entitled 11:19 35:5 42:12 53:7 57:20 88:16 115:9 124:9</p> <p>entity 44:1</p> <p>era 4:12 34:13</p> <p>ernst 53:21</p> <p>errata 185:9 186:12 186:13</p> <p>especially 18:12 71:13 172:15</p> <p>esq 186:5</p> <p>esquire 3:4,4,9,15</p> <p>essentially 90:15</p> <p>established 68:19 70:4 78:10 130:10 132:14 161:17 169:14</p> <p>estimate 65:18 66:5 72:10</p> <p>estimated 78:19</p> <p>estimates 29:17</p>	<p>et 6:24 40:5 44:2,3</p> <p>evan 3:15 7:4 24:8</p> <p>evan.woolley 3:18</p> <p>event 99:5,15 146:25</p> <p>events 99:13,16 146:24 147:13</p> <p>eventuality 45:15</p> <p>evergreen 87:1</p> <p>evergreening 168:3</p> <p>everybody 86:6</p> <p>evidence 31:6,24 112:4 113:5,17 118:17 120:4,24 121:17 129:2 130:23 131:4 132:2 132:3 133:21 135:11 138:22 141:23 143:20 158:9,21 159:20 165:2 170:13 177:4 178:15 179:25 183:4</p> <p>evolutionally 90:17</p> <p>exact 57:1 145:12 149:4,18,20</p> <p>exactly 164:19 165:22</p> <p>examined 7:11</p> <p>example 8:22 54:2 67:25 72:25 84:15 85:8,17 87:25 95:7 127:6 129:24 143:15 153:25 164:24</p> <p>examples 23:1,15 38:17 85:19 86:13 88:2 95:1,1 162:24</p> <p>exceeded 73:12</p> <p>excess 72:2</p> <p>excuse 58:6</p> <p>executed 164:16,20 182:8</p> <p>executing 139:13</p>	<p>exhibit 9:12,18 10:11,12,14 21:8,21 34:11,18 41:18,25 42:12,18 48:15 50:22 52:21 53:3,6 56:1,9 66:18,19 88:8,15 113:19 115:21 116:6 123:11,12,13 124:8 144:13,19 145:20 146:14 147:21,22 147:23,25 148:12 149:23 171:3,9</p> <p>exhibits 9:23</p> <p>exist 28:25 128:10 167:15</p> <p>existed 163:14</p> <p>existence 31:20 165:5</p> <p>existent 107:8</p> <p>existing 39:19 44:2</p> <p>exists 103:17 105:25</p> <p>expansion 36:12</p> <p>expect 71:15 142:16</p> <p>expectations 44:15</p> <p>expenditures 50:8 50:17 51:1,4,7,8,13 51:22 52:10 54:9,16 55:11,17 57:21 58:5 58:10,13,18 59:1,7 59:14,23 60:6,10 61:12 62:25 63:16 64:12,14 68:20 137:2</p> <p>expense 26:4 40:14</p> <p>expenses 27:14 29:21 69:19</p> <p>expensive 80:25 97:9,13</p> <p>experience 29:20 32:16 37:4 43:10,11 48:18 49:2,22 51:11 54:15 67:20 71:11 72:6 80:14,19 81:4 85:20 87:15 96:14</p> <p>149:7,8 166:19</p> <p>expert 4:10,18 9:13 9:21 10:12 11:3,19 11:21,23,24 12:9 13:2,5,6,7 14:19,20 15:20,22 16:24 17:2 17:12,14,17 18:8,15 18:18,22 20:4,18 24:16 40:3 56:2,9 56:21 83:2 94:9,11 94:12 95:24 96:1,21 98:13,15 99:9 102:1 103:25 110:22 111:17 112:4,20 114:14 118:16,19 123:2 124:2 125:14 126:2 127:8 133:7 140:11 141:7,22 142:8,21 143:11 147:17 150:14 155:12 156:13,17 160:5</p> <p>expertise 10:24 15:4 17:4,22</p> <p>experts 20:2,16,25 21:5 99:12 100:9,13 100:16 109:8,10,12 109:18 110:12,18 111:8,12 112:7 117:1 120:16 121:25 125:17 128:17,18 130:12 131:7,22 133:10 134:8 142:23 144:6 144:7 155:15 160:10</p> <p>expired 87:13</p> <p>expires 30:10</p> <p>expiring 30:7 31:20</p> <p>explain 10:23 14:10 23:4,6 54:25 75:18 126:18 127:1 128:4 128:6 129:4 132:4,5 138:10 180:7</p>
--	--	---

<p>explained 25:23 26:18 45:4 47:5 51:3 66:9 70:21 106:21 119:23 126:17 128:2 131:6 131:21 134:18 135:10,11 144:9 164:7 168:22 174:13 177:20</p> <p>explaining 71:23 128:15 138:1</p> <p>explains 47:17 137:18 169:11 178:25 179:2</p> <p>explanation 80:8</p> <p>expressed 107:16,22</p> <p>extend 102:18 103:1 104:18</p> <p>extended 36:8</p> <p>extension 16:2</p> <p>extent 23:15 38:3 59:3,24 60:14 61:14 64:15 67:14 70:17 101:17 104:11 111:5 159:8 167:6 183:7</p> <p>externally 173:23</p> <p>extrinsic 83:21,22 126:16 129:2 137:18</p> <p>eye 20:11 100:7,7 117:25 119:4 131:2 141:19,25 142:3,10 142:14,18 146:3,6 146:25 147:3,5 148:1,5,22 149:4,14 149:19 150:7,11</p>	<p>facilitating 166:22 181:5</p> <p>facilitation 179:13</p> <p>fact 32:25 33:11,14 37:13 64:18 80:16 80:16 86:15 138:14 150:7 155:9 166:1,8 168:16 174:6 177:17</p> <p>factor 164:14</p> <p>factored 150:20</p> <p>factors 22:6,9,17,23 23:10,24 86:12 126:17 128:3,4,5 129:2 137:18 138:14</p> <p>facts 22:12 23:13,20 30:18 32:24 33:16 36:24 38:15 41:5 48:22 51:25 52:18 58:22 68:25 75:9 84:14 85:18 92:11 93:5 94:23 98:5,16 99:1 103:15 111:6 112:3 113:4 118:17 120:23 121:16 130:22 131:3 133:20 138:21 141:22 158:8,20 159:19 165:1 170:12 177:3 178:14 179:24 183:3</p> <p>factual 128:25</p> <p>factually 129:8 130:10</p> <p>fails 28:10 37:11</p> <p>failure 41:4</p> <p>failures 37:16</p> <p>faint 151:21</p> <p>fair 8:12 19:22 71:15 78:11 105:6 115:19 132:20 180:2</p>	<p>fairly 33:19</p> <p>fall 59:1 72:16 116:24</p> <p>falls 80:18 106:7</p> <p>false 168:20</p> <p>familiar 7:25 18:3 53:23 163:8 179:12</p> <p>familiarity 18:10 19:8 145:15 181:3</p> <p>fan 182:21</p> <p>far 19:5 31:7 40:23 60:11 80:18 110:10 116:16 133:16 153:5 180:5</p> <p>farabow 3:3</p> <p>favor 102:12</p> <p>favorable 73:14</p> <p>fax 186:2</p> <p>fda 17:12,15,18,23 21:14 40:4,13,25 147:8 150:4,10</p> <p>fda's 18:1,4 145:16 150:20</p> <p>features 138:15</p> <p>february 2:5 6:6 48:11 184:22 185:2</p> <p>feed 79:5</p> <p>feedback 175:19 180:20</p> <p>feel 123:24</p> <p>fell 108:23</p> <p>field 18:22 20:4</p> <p>fight 130:7</p> <p>figure 61:8 62:1 96:24 99:24</p> <p>figured 114:9</p> <p>figures 72:20</p> <p>file 6:3 62:17 82:18 101:3 151:6</p> <p>filed 6:13 13:14</p> <p>filings 29:18 81:19</p> <p>final 9:3 71:9</p> <p>finally 13:17</p> <p>finance 14:21 56:22</p>	<p>financial 15:7 29:3 175:14</p> <p>financially 184:16</p> <p>financing 22:21 23:11</p> <p>find 23:17 25:25 114:4 186:11</p> <p>fine 9:5 42:11 100:22 117:22 145:8 150:25 152:3 175:18</p> <p>finish 8:16</p> <p>fink 3:9 7:2,2 24:3,7 25:16 26:25 30:16 32:4,21 35:18 36:18 38:3,24 40:19 42:21 43:5 47:14,23 49:7 50:2 53:10 54:19 59:3,24 60:14 61:14 62:11 63:18 64:15 66:7 67:14 68:22 70:17 73:1 75:15 81:1 82:13 83:6 84:11 89:19 91:16 93:2 94:3,8,21 95:23 97:4 98:12 99:8,21 100:22 101:17 103:12,24 104:11 105:3 108:21 111:5,16 112:3 113:4,24 116:12,22 117:19 118:15 119:7 120:23 121:16 122:14,25 124:5 125:4,13 126:1 127:7 128:22 130:22 131:3,17 133:6,20 134:4 135:20 137:6 138:21 140:10 141:1,6,17,21 142:7 142:20 143:7 144:3 144:20 145:4,9 147:16 148:24</p>
f			
<p>f 184:2</p> <p>faced 32:9</p> <p>facilitate 165:23 181:21</p> <p>facilitated 165:16 178:5</p>			

<p>149:16 150:13 152:23 153:7 155:11 156:3,12 157:18 158:8,20 159:8,19 160:4 162:6,19 165:1 167:6 170:12 176:18 177:3 178:14 179:24 181:12 183:3,12 186:5 finnegan 3:3 6:23 6:25 finnegan.com 3:6,7 firm 6:23 42:9,10 first 9:11 11:18 32:19 33:15 36:5 53:21 71:9 72:14 102:10,11,12 124:14 133:10 144:23 145:20 148:20 160:9 174:13 fit 69:17 five 31:18 98:1 145:8 flat 67:19 flip 115:3 floor 3:17 flowing 85:21 87:16 fluctuate 71:14 fluid 117:20,22 118:1,11 focus 36:10 96:11 102:10 135:15 focused 72:21 116:15 137:1 follow 45:21 48:25 92:13 163:1 183:9 followed 179:15 following 49:4,25 follows 7:11 foods 17:20 footnote 21:13</p>	<p>force 71:23 forecloses 75:8 foregoing 184:9 foreign 93:1,7,25 forest 84:15 forlano 2:2 7:7 184:4,19 185:23 form 45:12 69:21 87:24 92:19 95:8 96:18,25 98:17 126:13 154:10 163:15,15 formation 16:19,21 17:7 formed 45:13 57:11 forming 13:12 formularies 67:21 formulary 70:8,11 71:13 formulated 19:11 19:15,19 formulating 82:12 formulation 33:15 39:22 44:2 45:8 84:22 85:7,11 91:14 94:11,13,17,20 95:20,21 97:2 98:9 98:10 99:4,6 103:17 109:11 110:1,4 112:19 116:16 117:4,5 120:13 121:14 122:11,12 124:21,24 126:20 127:5,14 155:14,16 157:6 163:4 168:13 177:13 178:13 179:2,6,11,19 181:11 182:13 formulations 20:23 38:2 49:23 72:14 102:16 103:7,10,11 103:22 104:10,24 104:25 105:14 138:19 141:11 179:5</p>	<p>formulator 141:9 formulators 142:23 forth 101:20 121:20 forward 186:13 four 11:16 151:6 156:22 169:18,23 172:22 181:25 fourth 10:22 fraction 124:25 153:23 franchise 28:3 37:3 45:6 franchises 87:2 free 186:2 frequency 149:3 frequent 52:14 frequently 67:20 68:11 89:9 fulfillment 69:6 169:9 full 7:15 124:14 fully 14:15 27:6,14 28:24 funded 177:8,16 further 183:10 184:12 future 31:11 32:14 46:1 49:5 64:4</p>	<p>generalizing 105:7 generally 81:7 86:5 93:24 104:16 110:12,14 generate 102:17 generation 86:8 generic 46:10,15,17 46:20 47:1,10,13,22 48:2,9 87:12 152:15 152:21,21 153:12 153:16,22 154:3,10 154:19 155:2 161:14 163:15,25 165:5,12 167:14,17 169:9 173:2 generics 19:10 84:21 86:4 160:25 geography 69:17 getting 17:10 77:14 85:3 95:11 108:23 113:7 133:3 180:9 give 24:5 41:15 76:13 118:13 given 15:25 45:12 96:11 143:5 gleason 10:10 global 4:11 34:12 35:5 go 11:6 34:7 57:17 59:7,19 60:13 65:1 66:18 70:15 71:13 71:16,17,18,21 78:15 87:22 117:13 120:9 134:16,22 145:8,24 152:7 154:16,22,24 157:17 171:20 183:5 goes 11:14 44:5,5,11 54:18 60:3,4 98:1 going 6:1 13:14 14:12 28:2 31:24 32:8 41:9,10 45:15 50:11 55:19 60:23 62:12,15 70:15</p>
		g	
		<p>gained 13:20 gallagher 3:21 6:4 gap 64:13 garrett 3:3 gates 33:1,4 gauntlet 39:22 40:1 40:8,16 general 30:14 37:18 91:5 96:17 110:19 156:20 generalities 49:10 52:7 86:19 87:19 133:9 generality 37:6 43:9 87:7 162:9</p>	

<p>71:23 78:6 86:12,13 90:12 92:2 93:5 95:7 96:6 98:2 99:23 100:23 101:1 114:3 115:4,4 122:25 140:12 151:2,7,17 156:19 160:8 170:7 173:18 174:9,23 175:15,23 175:24,25,25 177:24 183:13 good 7:13,14 8:4,20 10:18 84:15 85:8 87:25 89:18 92:5 93:11,24 97:19 98:21 100:3,17,20 172:7 goods 26:1 27:12 28:13 78:16,19,21 78:21,24 79:2,6,8,9 79:12,15,18 80:18 80:22 81:5,9,10,25 goodwin 2:3 3:9 6:7 7:2 goodwinprocter.c... 3:12 gotta 28:21 gotten 40:25 84:16 106:11 141:25 government 85:3 graph 57:18,20 58:13 59:4,25 60:15 60:24 61:15 62:20 62:25 64:8,16,18 70:13,18 74:3 151:17 152:4,14 153:18 154:2,12 157:1 165:12 greater 84:23 90:21 92:17 118:13 179:20,20 greatly 38:9 gross 25:25 26:7,13 26:16 27:8,9 28:1,6 28:9 29:5 47:5 48:4</p>	<p>55:12 57:21 60:22 61:2,5,8,9,11 62:1 63:1 64:10,13 67:11 70:14,23 71:12 72:19 75:1 76:4,10 76:12,16,24 81:7,8 172:4,9 173:2,8 174:15 ground 8:2 groundwork 49:5 group 95:22 97:10 162:1 groups 4:22 113:20 180:21 growing 61:24 62:4 grown 47:8 growth 61:8 guess 9:3 26:3 40:21 69:14 91:6 113:6 115:4 122:17 123:11 131:10 134:8 171:17 176:5 guidance 31:10 guys 100:21</p>	<p>h h 4:9 5:1 185:4 half 51:5 66:25 73:10,11 75:3 140:21 hand 10:16 35:17 36:6 42:18 53:25 85:5 93:15 95:9,14 124:14 145:24 146:23,24 148:19 handed 9:17 34:17 53:3 56:8 88:14 114:2 123:21 144:19 146:13 148:12 171:8 handful 41:1 169:17 happen 31:8 32:3 51:17 76:25 165:8 167:22</p>	<p>happened 31:16 32:11 55:3 happening 52:12 137:1 179:3,10 181:18 happens 31:12 51:16 55:5 68:25 167:19 175:16 happy 8:24 67:17 harvest 83:11,14 87:1,13 hazard 31:16 37:19 45:18 61:7 64:21 70:21 172:6 head 85:24 91:24,24 92:14,14 93:7 111:18,22 127:12 132:24 heard 89:5,8,11 96:13 heavier 49:16 heavily 49:4 50:25 heavy 14:24 16:3 37:8,23 41:13 heels 92:17 173:4 held 6:7 help 88:5 95:13 153:10 180:11 helpful 114:7 henderson 6:23 henderson 3:3 7:1 hesitant 113:7 hey 31:17 170:8 high 38:21 44:15 81:7,25 154:21,21 higher 47:12,22 48:2,4,9 74:5 75:2 82:6 170:11 highlight 103:5 highlighted 102:23 highlights 145:21 146:20 hinder 169:8 hinders 98:18</p>	<p>historic 66:23 67:6 history 34:1 45:5 hoffman 185:1 hofmann 4:5,10,10 4:11,13,15,18,20,22 4:23 5:2,3,4,5 6:18 7:10,13,17,21 9:14 9:14,18 10:8,11,19 14:18 21:8,21 24:3 24:14 34:15,18,21 35:3,23 41:22,24,25 42:12,18 48:18 53:1 53:3,6,9,17 54:15 54:21 56:4,7,8 62:19 66:19 88:12 88:14,14 96:11 101:5 108:5 111:24 113:22 114:1 123:17,20 124:13 125:4,9 138:18 141:4,20 142:14 144:16,18,19,24 145:20 146:11,13 146:14 147:21,22 147:23,24 148:10 148:12,15 149:23 151:10 161:25 171:6,8,9 186:8 hold 67:19 70:4 holdings 1:6,14 home 87:24 hook 87:23 hope 3:16 hopefully 143:24 hopping 163:3 167:24 hour 100:19 huge 165:9 huh 90:8 hundreds 29:20 38:12,17 39:4,8,11 45:23 hypothetical 32:22 38:5 40:20 49:8 50:3 54:20 55:22</p>
--	---	--	---	---

<p>63:19,21 68:23 91:17,19,23 93:3 94:22 97:8 99:9 128:23,25 131:18 162:20 hypotheticals 33:17 99:23 101:12,13,21</p>	<p>implications 15:23 17:15,23 56:22 93:18 96:12 98:19 110:11 126:14 134:10 135:8 139:5 implied 176:10 imply 22:5 61:25 import 107:1 important 39:14 61:4,21 68:9 76:15 95:15 164:14 improper 87:3 175:4 improve 95:9 improved 90:19 91:9,13,20,22 92:8 92:15,16,24 93:14 95:4,21 97:1 99:5 129:23 155:21 156:7 improvement 86:7 91:25 95:16 98:20 98:24 improvements 85:6 97:25 120:8 129:7 improves 155:24,25 improving 94:17 130:19 ims 28:1 29:5 47:4,7 47:11,21,23 48:2,8 48:11 50:21 59:15 60:18 61:5 73:11 76:12 77:5,19,21 152:16 154:25 172:5,5,7 174:16 inaccurate 76:3 incentive 68:16 69:21,23,24,25 70:1 incentives 70:25 179:13 include 9:23 19:14 19:18 29:19 40:8 65:10 144:10 146:6 147:5 148:1 149:4,9 180:13</p>	<p>included 24:19 26:15 62:6 66:10,23 80:24 161:18 186:12 includes 28:4 110:5 including 148:23 149:14 179:19 incomplete 32:21 38:4 40:19 49:7 50:2 54:19 63:18 68:22 73:25 75:19 91:16 93:2 94:21 99:9 128:23 131:18 162:20 incorporated 1:6,14 20:16 increase 51:23 52:11 64:2,6 67:20 69:1 70:10 81:16 88:8 92:1 120:13,21 121:14 122:11 increased 63:15 64:5 70:24 125:11 127:20 159:16 increases 124:24 increasing 61:11 63:1,15 incremental 4:20 88:10,17 89:2,6,8 89:15,16 90:16 116:2 117:3 162:25 independent 169:25 170:1 indicate 130:14 146:25 147:25 indicated 30:5 51:21 58:14 96:6 104:7 117:14,17,22 118:4 132:9 151:19 indicates 47:21 48:8 148:21 indicating 147:14 153:15 186:12 indications 52:5 76:13</p>	<p>indicia 4:18 11:24 12:7,11 56:3,10 76:2 83:19 indirectly 106:16 individual 26:24 104:22 105:15 individuals 126:25 industry 38:11 inferences 64:21 70:22 74:4,7 inflammatory 20:10 influence 69:6 83:23 influenced 178:23 influencing 180:5 inform 107:21 121:13 125:8 informal 182:18 information 21:10 21:12,15 24:20 25:22,24 26:2,14,16 26:19,20 27:4 29:13 29:14,15 30:2 47:3 65:17 66:3,4,15,24 71:12 73:25 76:24 100:14 108:22,25 114:16 120:19 145:21 146:20 175:7,14 informed 108:5,9,19 109:5 110:6,21 111:24 120:12 133:15,24 139:14 139:16,19 162:5 164:22 169:25 infringement 12:6 ingredient 94:7 96:19 98:10 102:18 104:18 109:16 120:14,22 122:12 125:12 133:3,17 134:1 159:18 160:1 162:15 164:6 179:22 182:14 ingredients 103:1,3</p>
i			
<p>ice 117:7 idea 31:2 identical 90:15 identification 9:15 34:15 41:22 53:1 56:5 88:12 113:22 123:18 144:16 146:11 148:10 171:6 identified 10:12 11:2,13 171:10,25 identifier 10:14 identifies 147:13 identify 6:20 11:23 ignored 82:18 ignores 33:14 ilevero 78:11 ilevro 50:13,17,21 50:25 72:24 73:6,10 73:25 74:5,10,19,22 74:25 75:12,24 illustrative 154:21 imagine 99:22 impact 31:11 32:6 118:22 122:20 128:20,21 136:15 143:1 144:8 159:1 imparted 119:4 133:18 138:18 139:8 implementing 86:25 implication 82:16 100:12 122:17 126:11 127:20 132:1 143:17 144:11 149:7</p>			

inhibit 23:17 initial 85:8 129:1 initially 63:13 121:12 injectable 87:22 95:7 injection 95:12 injections 95:11 innopharma 1:18 1:18,19,19 3:19 7:5 24:9,11 106:17 innovation 4:14 41:20 42:13 90:17 innovations 4:21 88:11,18 89:2,6,9 89:15,17 inquiry 22:13 23:14 28:20 30:19 31:14 32:9,24 36:25 37:1 38:16 45:2 75:9 83:18 84:1 86:22 insights 119:1 insignificant 54:10 instances 43:2,13 52:15 68:19 89:25 90:1 127:17 instructions 185:5 intellectual 15:4,6,8 16:24 17:3,6,7 intended 14:15 intent 13:15 interested 184:16 interesting 140:4 internal 26:20 115:25 172:23 174:16 intervening 169:24 introduction 54:5 invention 22:1,25 23:10,24 119:6 129:19,21 130:1 131:14 132:7 134:17,23 135:4,19 136:1,22 137:5 138:3,13,16,20	143:14 inventor 15:14,17 inventoried 85:24 88:3 inventory 88:8 97:12 invest 30:14 41:10 49:3 invested 50:25 investment 33:20 37:8,10 38:9,21 39:6 49:25 50:5,7 investments 37:24 38:1 invisible 153:4 involve 101:11 involved 17:9 involves 83:20 involving 18:11 ip 10:10 irrespective 132:6 irritation 144:9 146:3,6,25 147:3,5 148:1,6,22 149:5,14 150:7,12 issuance 13:10,18 21:19 56:16 issue 22:14,14 51:19 65:1 86:21 112:15 121:4,19 126:6 134:6 144:7 150:16 issued 13:17 14:16 issues 13:12 15:1,6,7 16:4 17:2 18:11 20:3,17 21:5 56:23 81:22 92:18 108:1 116:17 131:23 139:15 142:10 174:15 ista 78:21,24 79:1,3 79:4,7,9,17 80:4 82:19 ista's 79:15,23 80:8 items 81:20	iteration 45:4 iv 87:23 ivan 4:5,10 6:17 7:10,17 9:13 185:1 186:8 <hr/> j <hr/> january 161:23 jarosz 4:18 11:24 12:3,19,25 24:18 25:11,14 29:5 48:14 56:2,10,12 72:17 74:3 75:20 76:5 88:23 95:2 117:8 154:16,24 182:5 jarosz's 26:8 27:25 28:10 34:25 50:23 62:21 64:9 70:14 171:13 jbs 1:3,3,4,4 6:15,16 jersey 1:2 6:14 185:25 186:2 job 1:24 8:10 john 4:18 11:24 12:19,24 56:2,10 journal 177:6,9,12 judge 27:21 jurat 186:16 justify 103:19 <hr/> k <hr/> k 82:19 keep 97:11 143:9 keeping 165:19 kept 27:20 kevin 3:21 6:4 key 102:18 kill 167:11 killed 168:24 173:15 killing 164:19 173:20 kim 3:4 6:25 kind 31:4 32:25 40:1 68:14 70:2 92:21 120:10 133:8	kit 178:9 kmw 6:15,16 knew 114:25 know 13:14 14:13 16:18 17:25 19:5,6 22:11 23:16 24:12 25:14 26:3 27:2,6 28:6,8,15,18,19 29:4,20 31:14,23 32:12 33:6,23 34:2 35:22 36:1,23 37:2 37:14,16,18 38:19 38:19 39:1,3,14,16 39:18 41:8,15 43:21 45:18 47:5 49:18 50:16 51:18 52:5,15 53:22 55:6 56:19 57:8,10,13,19 61:6 61:23,25 62:4 63:24 64:4 69:17 71:5 72:4,23 73:9,12,16 75:11 76:14 78:2,6 80:19 81:19 82:1,2 82:6,10 83:12,14,21 84:23,25 85:2 86:1 86:9,17 87:18 88:3 89:7,9 91:18,20 92:3,17 93:5,9,16 93:18 94:12,25 95:5 95:10,14 96:2,21 97:7,8,17,19,25 98:16,21 99:24 100:9,18 105:6 106:11 108:9,13,16 109:9 111:3,14,19 113:15 115:7 117:2 118:3,19,20,23 120:6,10,17,25 122:18,20 124:1 126:13 127:10,12 127:15,16 130:6 131:8 136:1 139:1 141:4,10,12,14 142:24,24 145:11 150:16,19 152:1,14
---	--	---	--

<p>154:9,15,19 155:1 155:14 156:11 163:11,23 164:9 165:20 166:17,17 166:20 167:12,18 167:20 168:2 169:21 172:7,20 173:1,14,24 174:24 175:7,9,10,17,24 177:6 178:20 179:2 179:9 180:1,2,4,9 180:21 181:3,15,17 182:19 knowledge 80:14,19 121:6 known 28:22 45:8 136:8 168:18 178:6 knows 28:12</p>	<p>latest 30:7 launch 24:23 32:19 43:3 49:4,25 50:11 50:25 51:22 52:9 54:17 55:17 58:20 68:21 72:15 164:1 164:10 170:10,20 176:3 181:25 182:1 182:9 183:8 launched 33:23 43:17 49:20 51:12 52:5 152:17,18 161:11 170:21 171:23 182:20 183:2 launching 33:18 law 6:22 129:12 laws 19:8 lawyer 15:12,13 lay 8:2 49:5 lcc 1:18 leaders 44:6 leading 13:9 173:25 leads 52:16 left 42:18 53:25 124:14 139:10 legal 186:1 legwork 17:8 lengthy 128:3 lessened 98:9 lesser 92:25 letter 186:17 level 28:18 67:11 94:5 96:19 100:3 162:10 173:3 levels 74:5 75:1 142:24 173:18 licensing 1:18,18 17:5 lieu 165:15 life 4:11 33:22 34:12 35:5 37:4 41:1,3 45:11 46:22 48:25 55:5 68:11 72:1 82:23 83:4 84:7,8</p>	<p>84:17 85:16,21,24 86:3,14,19,20,23 87:17,20 89:12,14 91:12 101:8,14 105:1,9,12 119:16 135:12,17 137:3,16 138:5 160:17,23 170:4 172:17 176:12 178:25 light 164:22 166:1 likewise 56:18 limit 73:8 limited 6:12 47:4,6 153:21 180:22 186:6 line 58:14 64:10,11 64:23,23 69:21 81:20 151:18 153:3 154:1,2 157:1 185:12 186:12 lines 64:12 lisa 2:2 7:7 184:4,19 185:23 list 82:20 listed 135:13 146:3 147:3 149:13 150:8 163:19 listing 18:1 lists 21:13 litany 160:8,14 168:15 little 25:7 66:15 74:3 82:6,15 98:8 100:19 113:7 143:22 live 7:18 36:8 lives 102:18 103:1 104:19 livingston 185:25 186:2 llc 1:19 llp 2:4 3:3,9,15 loaded 27:6,14 28:24 lobbying 174:9</p>	<p>located 6:8 lodge 122:25 logically 118:10 lomb 1:6,6,14,14 26:23 27:5 28:24 62:7 65:21 77:2 104:20 115:25 126:9 160:22 164:10 166:20 176:4 177:8,17,22 177:25 180:10 181:5,19 long 23:8 30:14,22 31:2,19 35:18 36:10 36:16,21,22 37:1,7 37:15,17 40:17,23 41:2 42:21 44:12 48:24 96:24 97:13 101:20 133:22 longer 31:1 64:1 67:22 167:22 179:15 longitudinal 45:12 longitudinally 172:7 look 21:15 24:21 26:6 28:2,19,21 31:16 35:16 39:7,10 42:8,17 45:19 48:14 49:11 50:10 55:7 57:5 58:12 60:21 64:8 76:25 77:15 78:3,5,6 82:9,16 90:4 113:15 115:19 135:1,25 136:4,9,10 136:10,10,11 137:21,22 144:23 149:23 157:1 171:16,17 172:6,20 172:20 183:6 looked 32:16 50:19 70:20 119:20 130:13 131:7 139:3 139:24 158:10 180:19,24</p>
1			
<p>label 116:1 145:11 146:18 147:8,12 148:18 149:2 150:1 150:11,22 152:18 166:16 168:13,23 labeled 4:24 123:15 124:10 161:16,19 163:20 165:7 labeling 18:6,10,12 145:16 labels 148:3 laboratory 20:22 lack 26:21 29:17 72:12 169:7 lacks 64:20 lag 175:23 182:17 182:18 landscape 22:15 language 149:2 languish 33:5 large 49:24 79:21 largest 54:7 55:12 55:15 late 31:10</p>			

<p>looking 21:18 23:20 31:13 44:18 62:24 83:25 113:8 115:20 123:11 134:8 135:7 looks 10:13 11:13 35:1 59:6 72:18,18 los 3:17 lost 28:16 lot 64:4 74:2 89:22 92:13,19 97:17 101:20 104:2 105:11 121:25 139:25,25 151:21 173:5 lots 30:19 37:11,13 40:24 45:5 68:3 104:4 162:24 low 32:18 38:22 44:15 81:11 lower 60:9 74:6 79:2 82:5 120:20 124:16 124:19 130:10 132:25 133:16 159:17,23 160:11 179:20 lowered 158:6 lowering 120:12 121:13 122:10 125:23 127:4 158:24 lunch 100:18,25 lupin 1:10,10 3:13 6:11,12 7:3 24:10 106:17 185:1 186:6</p>	<p>maintained 98:20 maintaining 97:15 maintains 96:18,25 98:4 majority 79:1,23 80:16 making 18:5 19:7 33:19 38:23 70:23 87:4 154:18 manage 84:17 management 33:22 36:11 37:4 45:11 46:22 49:1 81:19 82:23 83:4 84:8,9 85:16,22,25 86:3,14 86:20,21,23 87:17 87:21 89:12,14 91:12 101:8,15 105:2,10,13 119:16 135:12,18 137:3,16 138:5 160:18,24 170:4 176:12 178:25 mandates 36:9 mandatory 40:11 manifested 92:25 manner 107:16 manufacture 81:15 manufacturers 54:3 54:8 manufacturing 80:9 81:16 82:11 160:23 margin 55:20 64:6 74:20,25 81:8,8 marginally 54:10 margins 63:15 mark 9:11 34:10 41:17 52:20 55:25 88:7 113:18 123:12 144:13 171:2 marked 9:14,18 34:14,17 41:22,25 42:18 52:25 56:4,8 88:12 113:21 114:2 115:21 123:17,21</p>	<p>124:8 144:15 146:10 148:9 171:6 market 16:18,20 17:6,7,7 22:14 30:25 31:1,3,7 32:11 34:5 36:11 38:13,18,23 39:24 40:10,15 41:12 43:22 45:7,10,25 46:11,16,18 51:18 64:2 67:22 76:9,14 84:19 137:2 156:20 161:12,14 marketed 16:6 marketer 15:24 marketing 4:15,16 15:21,24,25 16:5,9 16:13,21 18:13 22:17 23:10 28:14 45:23 46:21 49:4,16 49:19 50:7,7,17,20 50:25 51:13,22 52:2 52:10,16,17,22,23 53:7,15 54:4,7,9,16 55:5,11,17 57:21 58:5,10,13,18 59:1 59:6,14,23 60:6,10 61:11 62:25 63:16 64:11,14 68:14,19 69:2,4,5,8,12,19,22 70:1 73:11 74:6 75:3 76:22 135:13 135:17 136:9 137:2 137:17 138:6 162:23 163:9 164:9 164:11,12 166:23 169:1,10,21 173:14 173:15 175:11 marketplace 31:25 74:14,20 markets 16:17 marks 185:8 material 35:20 materially 31:11</p>	<p>materials 11:2,5,14 113:9,11 131:9 math 55:21 132:23 132:24 140:22 141:2 mathematically 67:7 118:9 140:6 matter 9:22 20:22 30:14 35:10 55:21 57:13 71:16 74:8 93:20 95:3 97:14 98:3 113:3 122:19 128:1,12 143:6 167:22,23 184:7,11 185:1 matters 4:16 52:23 53:7,15 maximize 87:1 maximizing 83:10 mean 13:1 17:1,16 18:7 25:18 26:5 29:10 31:4 36:2,20 37:5,19 38:6 39:1 39:25 50:4 55:21 60:13 61:17 63:5,20 64:17 67:16 68:8,9 68:10 73:3 74:12,20 74:23 83:8 84:13,14 85:23 86:17 89:7,22 92:19 96:17 99:22 103:14 104:3,14 105:5 109:9 116:14 116:24 118:9 120:25 126:24 127:9,10 128:14,24 130:3 131:19 141:8 142:6 145:7 149:1 149:19 151:22 152:1 153:25 154:3 154:15 156:6,14 160:7 162:8,21 172:17 176:20 177:5,23 181:14 182:16 183:7</p>
m			
<p>m.d. 12:10 macro 86:19 madam 186:10 magnitude 154:18 155:1 maintain 96:23 124:20</p>			

meaningful 44:13 64:19,23 82:8 95:15 118:22,24 120:11 127:17 143:1 144:8 156:8	middle 8:16 105:21 106:2	modeling 4:16 52:24 53:8,11,16	moving 156:21
meaningless 95:5 97:24 133:13 173:7	midway 54:1	modified 127:21	mt 185:24 186:1
means 41:6 86:3 92:22 138:9 140:24 150:9 153:22 154:6	migrate 83:13 166:24 175:21	molecule 33:20,21 34:1 37:9,10 39:10 39:17,21 43:22 44:2 45:5,7,8,24 49:14 49:20 85:13 91:2 98:17 110:3 163:4,8 163:11,14 165:10 165:13 166:20 167:15,17 176:6 178:6 179:11 181:4 182:23	muddle 151:13 153:6
meant 157:19	migrated 174:25	molecules 37:25 39:19 49:24 87:14 175:22	multifaceted 103:15
measurable 44:7	migrating 174:2	moment 11:7 29:25 32:1 34:8 37:23 42:19 58:4,9 63:12 65:16 70:1 77:3 88:6 114:19 136:25 160:19 178:17	multiple 85:9 156:24
measure 46:3	migration 175:11	momenta 84:18,18	n
measurement 79:14	million 60:18 69:18 39:4,9,12 45:23 51:4,10	money 33:19 87:4	n 3:1 4:2 184:2
measuring 4:13 41:19 42:12 44:13	millions 38:12,17	month 24:22 25:7 152:2 154:4 169:23 172:22	name 6:4 7:15,17 53:23 185:10 186:6
mechanism 165:6	mind 63:24 142:15	month's 97:11	named 15:14,17 53:21
medical 17:20 18:18 96:1 106:19 107:17 178:20	mine 13:15	months 24:24 31:18 33:10 34:2 44:19 45:10,16 169:17,18 181:25	natural 16:1 111:14 114:25 117:16,20 131:1 158:14
medication 20:8 78:4,5,6	minimal 107:8	morgan 182:6	naturally 142:17
medicine 20:5	minimize 83:13 163:24	morning 6:17 7:7,13 7:14 145:14	nature 36:8
memantine 84:15,17 84:19	minor 75:3 93:19	motivated 137:21	nda 38:8
memory 48:16 50:19 111:19 139:22	minutes 62:10 145:8	motivates 113:9 126:10 181:1	neared 172:16
mentioned 14:4 65:16 71:4 106:8 117:9 158:5 166:11 178:17	mischaracterized 60:15 61:15	motivating 113:12	nearly 45:25
merely 90:14	mischaracterizes 59:4,25 64:16 66:7 67:15 70:18 73:2 83:6 119:7 135:20 135:23 143:7 144:3 159:9 167:7 181:12	move 156:25 164:17	necessarily 23:17 27:13 40:16 44:19 55:23 61:9 95:13 168:1,21 180:12
merit 129:25	misconception 90:16	moved 156:22	needed 112:20
merits 22:1,24 23:9 23:24 119:6 129:19 129:21 131:13 134:17,22 135:18 136:22 137:4 138:13	misleading 75:20 76:3	movement 165:19	needle 82:1
metric 76:15 182:4	missing 63:22 95:2 130:2		negative 92:18 93:17 99:25
metrics 39:3 74:10 76:12,20	misspoke 59:11 157:19		net 25:25 26:13,16 27:8,9 28:9 61:9 64:6 71:12 76:24 81:8,11 172:11
mid 170:22,24	misstates 38:4 101:18 103:12 104:12 111:6 137:6 160:4		nevanac 50:20

<p>new 1:2 2:4,4 3:5,10 3:11,11 6:5,8,9,14 33:18,20,21 37:9 38:22 39:16,17,21 39:23 43:25 45:7 49:13,14,23 68:6 77:9,14 83:14,15 90:10,13,18,25 91:13 95:20,21 97:1 98:9 99:4 162:15,16 176:16 177:13 178:1,13 179:19 181:10 182:12 185:25 186:2 nexus 22:11,12 86:22 112:24 nine 32:9 144:20 nipping 173:3 nj 1:24 noise 172:8,19 non 4:18 11:25 12:7 12:11 56:3,11 76:2 80:4,8 83:20 94:12 96:21 98:15 107:8 normal 77:24 nos 1:3 notarized 186:13 notary 184:5 notations 185:8 note 24:9 185:6 186:11 noted 25:10 notes 100:19 184:10 noting 173:1 novel 110:3 nrx 77:5,8,12 nrx's 77:15 nsaid 31:10 72:14 nsaids 5:5 100:11 124:23 149:9 171:4 171:11 nudge 46:2 number 6:3 7:23 18:19 29:6 35:15 83:21 88:15 90:6</p>	<p>111:21 113:23 116:5 154:8,22 186:7,12 numbered 10:2 numbers 27:20 34:18 42:1 53:4 55:23 61:10 63:22 114:3 115:5 140:13 140:23 144:22 146:15 148:13 154:18 175:1 numerous 120:4 nutraceuticals 17:20 nw 3:5</p> <hr/> <p style="text-align: center;">o</p> <p>o 184:2 185:24 object 24:5 64:18 70:17 objecting 135:23 objection 25:16 26:25 30:16 32:4,21 36:18 38:3,24 40:19 43:5 47:14,23 49:7 50:2 53:10 54:19 59:3,24 60:14 61:14 63:18 64:15 66:7 67:14 68:22 73:1 75:15 81:1 82:13 83:6 84:11 89:19 91:16 93:2 94:3,8 94:21 95:23 97:4 98:12 99:8 101:17 103:12,24 104:11 105:3 111:5,16 112:3 113:4 116:12 116:22 118:15 119:7 120:23 121:16 122:14 123:1 125:13 126:1 127:7 128:22 130:22 131:3,17 133:6,20 134:4 135:20 137:6</p>	<p>138:21 140:10 141:1,17,21 142:7 142:20 143:7 144:3 147:16 149:16 150:13 155:11 156:3,12 158:8,20 159:8,19 160:4 162:6,19 165:1 167:6 170:12 176:18 177:3 178:14 179:24 181:12 183:3 objections 24:10 99:21 objective 4:18 11:24 12:6,10 31:6,24 56:3,10 76:1 83:19 objectivity 178:21 obtain 21:11 120:19 obtained 65:20 128:15 obviousness 4:18 11:25 12:7,11 31:14 45:2 56:3,11 76:2 83:20 84:1 occasions 30:21 occur 28:22 occurred 172:25 183:1 occurrence 147:15 148:5 occurs 37:8 ocular 4:23 21:2 120:14,21 121:14 122:11 123:14 124:9,21 125:1,11 127:6,20 129:23 130:19 158:17,19 159:1,6,6,16 160:1 160:2,12 179:20 182:13 offer 90:18 offered 162:17 176:16</p>	<p>offering 87:5 offers 127:14 office 87:22 97:15 offices 2:3 181:19 official 173:23 offset 64:5 oh 53:12 59:11 103:5 124:4 okay 8:2,3,14,19 9:1 9:3,7,10,17 10:8 11:1,6,12,12,21 12:2 13:4 16:23 18:15 21:6,20,22 25:7,10 28:5 36:5 42:5,11,23 50:24 53:21 56:21 57:17 57:24 58:12 59:11 59:18,20 60:10,21 62:8,11 65:9,14 66:4,14 67:10 77:8 78:15,15 87:21 88:5 89:1 90:4,12,13 91:4 97:1 101:5,25 102:4,20 103:9 105:20 107:20 108:5,16 109:13 110:14,21 111:3 112:16 114:1,11 115:3,9 116:4,9,19 117:13,22 118:4,10 124:3,3,6,8,19 128:18 133:1 136:4 137:25 139:19 140:15,18 145:2,7,9 145:19,24 146:19 147:8,12,20 148:8 148:19 151:10,14 151:16 152:10 155:4,4,6,6 156:25 159:25 161:6 162:14 166:7 169:13 171:8 old 90:24 97:2 98:10 99:5</p>
---	--	---	---

older 94:6 once 13:16 78:5 85:10 96:7 107:13 152:19 155:9,18 156:21,23 161:19 163:21 168:10,23 oncological 93:8 97:10,17 99:24 oncology 97:10 one's 94:1 ones 33:3 136:14 opening 11:23 12:2 12:5 24:18 171:13 operator 6:1 7:6 62:12,15 100:23 101:1 151:2,5 183:13 ophthalmic 4:24 5:5 120:13 121:14 122:11 123:15 124:10 162:1 171:4 171:11 ophthalmics 100:6 156:21 ophthalmolic 141:11 ophthalmologic 18:20 ophthalmologists 182:21 ophthalmology 4:23 18:16,17 102:15 104:17 123:14 opinion 102:1 109:14,18 112:9,11 112:13 117:2 118:20 119:25 127:11 128:16 129:16,20 130:9,16 132:12 136:18 137:15 150:18 174:7 opinions 13:11,18 14:1,12 17:5 20:21 45:13 57:10,12,15	83:2 106:10,20,21 106:24 107:18 108:4 112:17,19 113:3 119:15,22 126:7,25 127:1,25 128:2,12,21 129:5 131:16 135:16 143:5 144:6 180:18 180:25 opportunistic 41:11 opposed 49:23 135:18 162:9 182:19 optimization 94:13 oral 87:24 95:7 orange 18:2 order 49:5 51:4 124:16,19 154:18 155:1 170:6 oriented 54:4 originally 152:17 osinga 53:22 outcome 75:12 85:15 outlook 4:12 34:13 35:6 outset 47:7 49:17 68:10 outside 15:11 22:23 155:11 overarching 15:4 167:11 overlap 169:15,19 170:19 181:24 overly 92:21 overwhelming 129:1 135:10	pad 175:5 page 4:4 5:5 8:3 10:1,1,6,6 11:18 21:7 35:14,15 42:17 53:24 57:17,19 62:20 64:9 70:13 90:5,5 102:2,3 105:19 114:4,5 115:4,19 116:4,5 117:13 124:13 136:18 138:10 144:23 145:20 148:20 171:5,17 185:12 186:12 pages 11:14,16 21:20,23 36:3 114:6 136:19 pain 149:19 paragraph 21:8,11 30:1 35:17,19 36:3 36:6 42:19 54:1,2 90:9 96:5 101:25 102:2,3,5 105:18,22 106:3 107:4 124:15 128:8 151:11,16 156:16 160:18 161:5 parameter 4:16 52:24 53:8,15 parenthetical 146:5 parity 165:20 170:16,17 172:24 174:18 176:8 178:8 part 10:21,22 16:15 16:19 41:2 48:25 94:1 105:1,10 113:3 113:6 114:16 119:5 119:14 128:12 131:15 136:6,7,9 154:2 161:5 162:1 170:4 particular 14:23 17:19 22:14 26:13 39:2 61:18 63:21 68:12 70:11 72:8	84:2 96:24 99:13 105:8 110:25 111:21 113:10 150:22 154:4 161:3 163:2 172:8 179:1,4 180:8 particularly 44:14 48:24 64:19 67:21 138:3 141:11 150:2 152:12 parties 134:7 184:13 parts 148:25 passage 42:25 44:5 111:1 125:2,8 passes 93:17 patent 15:12,13 18:1 23:18 30:7,7,10 31:20 83:22 102:18 103:1 104:19 110:4 110:10 128:6 129:3 130:4 131:24 136:7 136:9 138:25 patented 138:3 patents 15:15 30:3,6 83:16 109:21,24 110:7 135:5 138:25 patient 20:8,11,14 70:7 86:2,24 90:20 94:18 95:20,21 96:7 97:24 155:21,24 156:1 168:11 174:22 175:21 patient's 175:9,15 patients 68:16 77:15 84:24 85:12 95:18 95:19 170:7 pattern 32:25 paused 110:2 pay 84:2 174:23 payors 86:6 peak 48:19 154:2 penalty 186:13 pending 15:17 penetration 21:2 120:14,21 121:15
	p		
	p 3:1,1 p&l 27:6,14 28:25 p&ls 29:12,22 80:15 p.m. 100:24 101:2 151:3,8 183:14		

<p>122:12 124:21 125:1,11 127:6,21 129:24 130:20 158:18,19 159:1,6 159:17 179:21 182:14 pennsylvania 7:19 people 71:12 85:2 105:11 139:11 182:18,23 percent 72:1,2,3 75:2 80:1,3,21,23 81:25 82:2,7,10 123:5,8 132:15,17 132:21,24 133:3,17 133:25 139:17,20 140:4,5,16,17 149:2 159:18,24 182:2 percentage 79:3,7 80:18 81:11 82:1,4 82:5 percentages 81:10 perfectly 54:25 perform 32:8 33:2,4 performance 23:18 27:17 28:3,7 29:4 31:6,15,25 34:5 45:3,6,9 72:18,19 72:20 75:21,23 76:1 76:5 83:23 84:4 126:18 129:4 132:1 132:5 134:9 135:2,9 136:5,16 137:19 138:1,9,11 143:18 performed 32:12 74:10 performing 33:2 67:5 performs 74:14 period 24:22 25:8 48:1 54:17 58:2 61:2,12 62:3,6 71:6 72:25 96:19 154:20 169:24 172:22 173:19 174:3</p>	<p>181:24 periods 25:25 26:14 27:10 48:1,3 54:4,6 65:5,7 71:25 72:2 172:17 perjury 186:13 permitted 112:1 persistence 4:16 52:24 53:11,16 persistency 92:19 persistent 53:8 54:6 55:4 person 53:22 96:2 104:15 personally 17:11 141:24 perspective 18:19 19:5 82:3 83:10 84:7 86:8 127:10,11 168:3 178:20 pervasive 17:18 ph 111:3,9,14 112:1 112:22 114:20,25 117:14,16,23 118:2 118:5,7,10,14,21 120:13,21 121:13 122:10 124:21,24 125:9,23 126:20 127:4,21 130:10,18 131:1 158:6,13,14 158:17,24 179:20 pharma 1:6,14 pharmaceutical 1:5 1:13 4:14 6:11,12 10:25 14:24 15:2,20 15:23 16:1,5,7,7,10 16:13 17:13,15,19 17:22 18:1,13,21 19:1,4,11,19 20:23 28:11,23 29:21,23 29:25 30:13,20 31:7 34:8 36:15 38:11,13 40:12,16 41:6,20 42:13 48:19 49:3,23 56:24 67:25 70:9</p>	<p>72:7 81:5 94:1 96:12,18 98:22 110:8 125:25 162:23 176:17 186:6 pharmaceuticals 1:10 162:2 186:6 pharmacies 18:25 19:2,9 pharmacist 19:6 pharmacy 18:23 phrase 22:4 65:24 89:5 103:6 136:19 physician 54:4 165:25 174:20,21 175:2,4,7 physicians 162:14 163:7 165:12 166:9 166:19 167:10,16 179:11,17,18 180:6 180:23 182:2 picked 60:16 65:25 picking 105:6 piece 16:22,22 138:8 pieces 120:4 pill 95:12 pipeline 16:15,16,20 place 69:20 172:20 176:4 placement 70:8 174:24 plaintiff 6:24 plaintiff's 120:16 121:25 plaintiffs 1:8,16 3:7 160:15 180:3 plan 30:21 planning 16:17 36:11 106:9 plans 172:24 173:14 platitude 36:20 75:5 play 18:25 19:9 23:15 113:16 141:10</p>	<p>played 23:18 84:3 plays 37:14 86:21 pleasant 185:24 186:1 please 7:15 36:7 102:1,12 113:19 116:7 123:13 124:12 144:14 176:9 178:1,1 185:6 185:9 186:11,11 plenty 45:12 49:15 55:4 87:8 90:1 plucked 61:18 plural 103:3 plus 34:2 45:10 pocket 174:22 175:9 175:15 point 9:3 31:5 32:5 32:18 33:8 45:14 57:7 58:17 61:21 63:11 68:21 77:15 100:18,20 102:11 104:7 106:19 150:23 151:23 pointed 159:14 points 48:16 56:19 60:17,19 61:17,19 70:20 72:5 73:9 102:7 polysorbate 108:10 108:13,20 109:6 110:24 112:1 134:3 139:17 140:5,8,15 140:16,20,25 157:11,15,20 158:1 portfolio 36:11 portion 60:24 102:24,24 position 23:22 24:2 25:21 27:5 160:17 165:25 166:3,7 167:1 positive 85:20 possible 31:22 85:15 103:19 104:4</p>
---	--	--	--

<p>post 51:22 52:9 54:17 55:17 58:20 68:21 72:15</p> <p>potential 165:18 166:21 178:7</p> <p>potentially 91:6</p> <p>powerpoint 130:13 130:15 158:16</p> <p>practical 165:14</p> <p>practically 153:3</p> <p>prausnitz 13:6 14:5 14:6,7 108:4 120:20 121:2,9,12 122:10 123:2 126:22</p> <p>prausnitz's 14:12 122:3,5</p> <p>precision 28:18 69:16 154:23,24</p> <p>predated 183:8</p> <p>predicated 90:14</p> <p>predict 32:13</p> <p>predicting 31:17</p> <p>premature 33:8</p> <p>premise 168:20,20</p> <p>premises 174:12</p> <p>premium 47:9</p> <p>preparation 11:15 11:22 12:13 13:8 24:16 56:13 110:8</p> <p>prepared 10:8 56:15</p> <p>preparing 11:3 14:7</p> <p>prescribe 162:14 163:7 164:16,23,24 165:15 166:10 167:2,20,20 174:10 178:2</p> <p>prescribed 20:7 164:5</p> <p>prescribers 52:2 181:20</p> <p>prescribing 69:6 113:10,13 126:10 145:21 146:20 161:1 163:25 164:17 168:18</p>	<p>170:8 176:9 180:6 180:23 181:2</p> <p>prescription 5:5 16:1 17:19 19:1,4 40:12 76:18 77:4,23 77:24 171:5,12 172:2,13</p> <p>prescriptions 76:15 77:7,7,9,13 153:13 154:5,7 160:25 179:14 180:11 182:3</p> <p>present 6:19</p> <p>preserved 24:10</p> <p>pressure 70:7</p> <p>pretty 15:5 34:3 40:7 101:19</p> <p>previously 166:12</p> <p>price 5:5 46:25 47:13,22 48:2,4,8,9 165:20 170:10,15 171:5,11 172:24 174:5,19,21 176:11</p> <p>pricing 16:19 46:22 69:23 135:13,17 136:10 137:17 138:6 164:15 166:22 168:25 169:10 172:11,21 173:2 174:15,17 176:7 178:8 179:13</p> <p>primarily 15:7 21:25 22:5 23:9 129:18 135:15 136:21 138:12</p> <p>primary 23:18 86:24 135:25 136:2 155:18</p> <p>prior 13:18 21:19 45:21 83:7 103:11 103:12 127:22 136:8 137:6,9 138:4 138:4,25 160:4 162:16,17 163:4 167:11 181:13</p>	<p>privileged 108:25</p> <p>probably 14:25 55:14 66:17 76:18 87:25 88:24 98:2 108:12 124:15 143:23</p> <p>proceed 7:9</p> <p>process 14:8,10 18:5 19:7 40:7 90:16,18 145:16</p> <p>procter 2:4 3:9 6:8 7:3</p> <p>produce 27:9 29:12 29:13 71:12</p> <p>produced 27:16 28:8 62:7 66:3 77:22 180:20,22</p> <p>product 16:7,15,16 16:19 18:6,11 19:12 19:24 20:14 22:7,14 22:15,16,19 23:12 23:19 24:1,15 27:6 27:14 28:7,12,24 29:12,22 31:12,15 33:16 36:9 37:1,21 38:13,18 39:23 40:12,15 41:4,14 43:15 44:19,20 45:16,21,21 46:6 47:10,12 48:20,25 49:4,6 50:1,11,13 51:1,12,18,23 52:11 55:8,8,16 63:13 64:1 68:7,17 70:3 74:13 75:7 80:15 82:20 83:14,24 84:4 86:9 87:20 92:13 93:8 94:6 96:22 97:22 116:3 117:10 117:11 126:9 133:5 134:9,19 135:3,18 136:6,16 138:2 143:18 146:21 155:25 162:15,16 162:16,18 163:2,5,6</p>	<p>164:19 165:10,23 166:18 167:3,23,24 167:25 168:25 176:5 180:8 181:21 183:2</p> <p>production 26:15 27:7 29:1 66:2,11 66:23 173:25 186:22</p> <p>products 16:1 17:13 17:19 18:20 19:1,4 26:24 28:23 29:8,21 29:23,25 30:14,20 36:17 38:1,22 40:4 40:18,24 41:12 46:5 46:20,23 55:18 56:24 68:12,20 70:6 72:7,22 73:7 76:8 79:1,22,24 80:17,22 80:24 81:5,9,14 82:10 87:4 91:5 96:12 97:17 98:23 102:16 115:13 125:25 148:6 152:16 153:12,13 158:5 162:23 163:1 164:13 176:16,21</p> <p>profile 92:9 99:5 106:1 122:22 128:10,20 167:5</p> <p>profit 46:1 55:20 83:10</p> <p>profitability 24:15 24:19,21 25:12,15 26:21,21,23 27:4,19 27:22,24 29:1,17,24 32:18,20 33:10 34:9 36:16 40:18 46:3 55:10 63:8 65:19,22 66:6 67:9 72:11,13 72:24 73:5,24 74:9 75:14 78:9,12,13,17 78:20 80:13</p> <p>profitable 63:15</p>
--	---	--	--

profits 28:16 32:13 87:1	33:11 34:2 45:3,4,6 45:16,20 46:19,25	prom0339512 35:16	purported 22:1 64:3 107:6 129:3,7,18,20
progress 43:2	47:21 48:9 49:18	prominence 78:25	131:24 136:22
prol0080219 5:4 148:9,13	51:6 57:20 58:1,25 60:7,22 61:2 63:14	promote 129:7 166:15,16 169:7 177:19,22	138:13 166:15 177:19
prol0080224 5:4 148:9	65:6 66:20 67:4 72:21 73:12,14	promoted 163:5	purpose 27:24 28:15
prol0080486 5:2 144:15,22	74:11,12,21 75:14 75:21 76:1 106:1	promoting 115:22 126:9 165:3	purposes 78:20 130:3 161:2
prol0080492 5:2 144:15	107:8 108:6,17 111:4,6 112:2	promotions 68:14 69:12	push 82:1
prol0080493 5:3 146:10,15	115:15,22,24 116:2 116:10,15,21 117:4	properly 69:22	pushing 71:25
prol0080497 5:3 146:10	118:4,11 119:4,14 119:24 120:2 123:8	properties 138:19	put 35:1 76:15 96:10 123:10 146:9 152:23 160:1 172:3 177:8
prol0080505 123:21	124:22 125:10	property 15:5,6,8 16:25 17:3,6,8	putting 55:23 94:1 100:7
prol0080512 4:25 123:17	126:18 127:5,14 128:7,11,20 129:24	proponent 23:23	
prol008055 4:24 123:16	130:4,10 132:2,6,10 132:17,20 133:5	proposition 36:14	q
prol0280867 4:22 113:21 114:3	134:1,12 135:9 138:9 139:1,20	protection 87:13	q1 58:25 59:8,13,20 60:5 79:17,18
prol0280893 4:22 113:21	140:6 143:5 144:2 148:18,22 149:8	proven 18:9 128:19	q2 57:21 58:2 60:3,5 65:21 66:21 67:2,12
prol0339506 4:12 34:14,19	150:2,9 152:7,13 153:17,24 157:2,6	provide 17:4,22 77:19 80:7 84:23 106:5	q3 57:21 58:2 59:21 60:4,11,11,23 61:3 61:13 65:21 66:22 67:2,12 70:16
prol0339525 4:12 34:14	157:10,13,25 158:7 158:13,18,25 159:5	provided 21:10 104:8 107:13 109:11 110:22 147:10	q4 58:25 59:6,13,13 60:22 61:3,12 70:16
prol0339526 4:14 41:21 42:1	160:16,24 161:10 161:11 163:6 164:9	provides 29:2 31:24 76:1	qualitative 28:4,19 72:10 79:6
prol0339561 4:14 41:21	164:10,12,16,18,23 165:15,17,19 166:5	providing 165:20,21	quantification 79:14
prol0339663 4:17 52:25 53:4	166:9,10 168:18 169:12,16,23 170:5	prudent 83:12	quantify 28:16
prol0339676 4:17 52:25	170:6,11,21 171:23 171:25 172:11,21	public 29:18 81:18 86:16 87:5,6 91:15 92:10 94:19 103:23 104:10 105:1 156:2 184:6	quantitative 28:5
prol0340351 4:21 88:11,15	173:4,6,10,16,19 174:2,10,18 175:1,6	publication 35:1,11 42:5	quantitatively 67:3 79:5
prol0340352 90:6	175:10,12 176:3,5,8	publicly 26:11,19	quantity 79:21
prol0340392 4:21 88:11	177:1 178:1,5,13 179:1,2,5,6,14	published 176:25 178:12 181:9	quarrel 68:4 73:4 74:23 87:8 130:6
prolensa 24:15 25:12,15 26:16 27:17,20 29:4,19 31:1,2,13 32:8	180:12 181:6,10,22 182:1,3,9,13 183:2 prolensa's 21:2 164:1 170:20	pull 67:7	quarter 25:3 33:25 59:8,15,15 171:22 171:22 172:1,8
		pulling 29:4	quarters 14:25 59:21 60:17 61:18 66:1,1,3,21 67:2
		purely 71:20	
		purple 152:14 153:19,20,21 154:10	

70:21 71:9,10 question 8:16,17,23 9:4 22:10,12 24:4 45:1 47:20 59:12 74:24 75:5 76:17 105:12 109:3,7 113:7 114:24 119:11 125:16 126:4 131:12 133:22 134:20 135:24 139:10 143:22 144:12 161:8 174:13 178:20 questions 8:6,7,9,10 8:11,21 57:6 73:22 75:18 137:20 140:3 162:25 177:24 183:11 quite 59:7 64:1 81:15 84:16 85:11 quotation 104:8 quote 102:11,12,24 103:6 104:12 105:16 quoted 129:16 quotes 102:6	reaction 129:1 148:22 149:14 150:9 reactions 145:25 146:3 147:1,15 148:1,20 149:3,11 149:20,24 150:3,18 read 35:19 36:3,5,13 42:20,22,25 43:8 53:14 54:13,22 74:16 90:12,22 91:8 94:11 102:12 103:4 107:2,5 109:3 116:6 121:25 122:5 125:5 137:14 148:3,24 153:10 158:22 160:20 180:4 reading 121:18,23 161:4,6 185:5 186:17 ready 35:22,25 58:7 115:7 real 31:16 64:20 86:7 93:19 100:12 100:14 127:19 151:21 realities 178:11 reality 165:14 178:3 178:4 really 31:15 33:9 48:22 49:11 58:22 61:24 71:1 75:13 76:9 79:8 81:6,25 84:19 85:23 87:10 87:12,19 88:3 91:22 93:16 95:3 97:14 98:2 99:16 102:14 102:18 109:7,13 116:17 118:24 119:23 120:1 122:21,23 125:15 126:3,17 138:17 142:15 152:25 174:23	realtime 184:4 reason 9:7 10:2 62:5 68:4 110:2 165:14 168:21 186:12 reasonable 29:16 67:19 72:9 79:4,21 80:20 172:20 reasonableness 79:12 reasons 33:3 41:2 68:3 166:11 rebates 65:10 67:21 70:11,24 71:13 72:8 rebuttal 24:17 recall 58:10 62:22 63:2 82:24 101:6 114:22 115:1 121:2 132:12 142:9 145:17 159:22 receipt 186:16 received 56:17,18 57:8,9,16 recess 62:14 100:25 151:4 recitation 150:11 recognize 9:19 63:11 recognizing 48:4 74:9 record 6:2,21 7:16 36:7 57:13 62:13,16 90:13 100:24 101:2 102:13 107:2 109:1 116:6 126:15 137:14 151:3,7 152:24 153:8 183:14 recover 37:10 red 58:14 64:11,23 154:11 redirect 183:12 reduce 93:11,12,25 99:25 133:2 reduced 93:21 124:22 182:14	reducing 112:1 reduction 92:2 107:7 133:25 reductions 67:11 refer 30:6 65:13 124:12 151:17 156:16 160:18 reference 123:24 124:1 163:19 186:7 referred 37:23,24 77:3 91:8 referring 20:1 26:10 26:12 39:2 46:6 77:4 91:2,4 117:8 119:14 refers 89:1 reflect 29:17 61:6,20 61:20,22 173:8 174:15 reflected 61:7 66:24 reflective 172:10,10 172:24 174:14 reflects 10:21 59:17 reformulating 39:18 refrigeration 97:21 regard 8:14,21 30:2 58:25 73:24 74:18 96:12 98:8 106:6 107:1 109:15 113:1 120:20 131:15 158:24 160:17 168:8,14 182:13 regarding 17:13 172:23 regularly 14:22 15:10 17:4,21 18:11 29:11 regulation 17:18,23 regulations 17:13 17:16 regulatory 17:17 40:11 reinvigorate 52:17 reject 70:12 82:15 174:12
r			
r 3:1 37:8,23 38:1,7 40:9 41:10,13 44:6 44:12 83:13 184:2 185:4,4 rabbit 4:24 123:16 124:11 159:11 ramifications 93:20 ramp 55:19 ramped 32:19 range 111:11 rapidly 98:17 rate 38:22 rated 163:18 reach 39:23 48:19 reacted 32:11			

reabeled 155:17 relate 18:12 relative 72:18 74:7 75:13,22,23 76:19 76:20 117:11 118:25 138:3,25 139:1 143:3,25 162:11 172:21 184:14 relatively 81:11 relevant 10:24 76:8 relied 13:12 21:4 108:3 116:25 119:13 122:20 128:11,14 130:16 144:5 rely 20:2,15,25 114:14 180:7 relying 128:17 remaining 80:21,23 remember 35:12 42:3 57:24 110:25 111:1 121:18,19,23 122:7 123:25 129:14 134:5 145:12 159:4 161:22 remove 166:21 removed 163:24 165:17 176:10 removing 178:7 rendered 131:16 rendering 126:7 127:25 128:12 180:18 rep 177:25 repeat 109:2 134:21 rephrase 59:12 replacing 170:5 reply 4:18 12:14,17 12:18,21,24 56:2,9 56:12 62:21 70:14 182:5 report 4:10,18 9:13 9:21 10:9,13,23	11:3,4,15,23,23,24 12:3,6,10,17,19,21 12:24 13:5,6,7,10 13:13,13,19 14:3,7 14:14,16,17 20:17 21:6,7,19,21 24:16 24:18 25:11,23 26:8 26:17,18 27:25 28:10 29:5 30:1 32:2 34:25 47:2,6 47:17 50:23 51:3 56:2,9,12,15,16 57:15,18 62:21 64:9 66:10,18 67:15 70:14 74:3 75:20 76:6 78:19 79:25 83:2,7 88:24 94:9 95:2,24 96:5 98:13 99:9 102:1 104:1 105:19 106:10,11 106:12 111:17 112:5,17 114:15 117:7 118:17 122:2 122:3,5 123:2 125:14 126:2,17 127:8 128:3,5,8 130:3 131:16 132:4 133:7 135:14,16 137:10 140:11 141:7,22 142:8,21 147:17 149:6 150:14 151:11 155:12 156:13,18 160:6,19 164:8 171:13 182:5,6 reported 172:12 184:6 reporter 7:6 9:17 41:24 56:7 114:1 123:20 144:18 146:14 184:5,5 185:10 reporting 185:24 reports 11:19,22 12:14 13:2 111:2	112:20 120:16 121:25 124:2 127:2 139:25 176:25 182:24 represent 79:1 122:9 171:9 representation 28:7 122:16,18 represented 79:21 130:18,25 representing 6:5 7:3 63:5 64:10,11 represents 7:8 34:5 154:3 reps 176:4 180:7,10 requested 27:4 required 27:8 requires 28:17 reread 36:2 research 19:23 resistance 70:7 165:18 166:21 176:10 178:7 respect 13:11 15:8 16:5,18 17:5,18,22 18:5,9,24 19:9 25:24 27:17 28:21 31:10,12,14 33:21 41:7 45:3 57:10,12 57:15 62:1 67:25 75:23 76:21 77:1 84:6 86:21 91:25 113:12 122:24 131:22 149:8 157:7 180:25 respects 121:7 responding 76:2 response 24:18 57:11 72:17,21 responsive 4:10 9:13 responsiveness 52:2 restart 59:12 restate 74:17 143:23 157:21	result 45:18 105:13 137:19 resulted 125:23 resulting 90:18 results 44:7 54:2 81:23 return 4:14 41:20 42:13 185:10,23 returned 186:16 returns 44:12,13 65:11 revenue 44:15 review 12:9,24 13:7 13:16 14:16 112:23 112:24 126:14 186:11 reviewed 12:2,5 13:3 14:4 21:18 25:21 50:23 53:19 56:16 72:6 111:2 112:19 122:3 reviewing 111:20 revised 84:22 179:10 rid 167:13 ridge 7:18 right 10:16,20 11:4 24:17,23 25:1 30:8 30:11 33:12 35:17 36:6 38:14,23 40:18 42:4,6,15 44:21 46:16 47:13 48:21 50:18 53:20 54:4,14 55:14,20 56:13,14 56:21 58:18 60:7 63:6,17 68:2,15 73:25 78:22 79:11 79:19,22 80:2,5,6 80:11 82:12 88:4 91:1 96:2,8,9 99:19 99:20 104:24 105:2 106:7 109:16 115:10,15 117:12 117:14,17 121:8,21 122:8 123:5 130:20
--	---	--	--

<p>135:19 140:9,21,23 141:16 142:11 145:24 146:23,24 148:2,19 152:21 157:3 158:7 161:22 169:18,20 170:3 171:23 173:6,12,22 176:2,24 177:22 178:13 179:23 181:11 182:3 183:2 183:7 rise 70:15 99:15 136:14 risk 82:5 rld 46:12,14,18 152:17 163:20 rmr 2:2 185:23 role 15:25 17:17 18:24 19:2,9 23:16 23:16,18 84:3 86:19 86:21 112:22 113:1 113:16 131:23 141:10 143:15 162:22 roll 29:22 room 6:20 82:7 roughly 140:6 round 140:23 rules 8:2 run 30:14 39:23 40:15 97:7 140:13 running 50:17 51:1</p>	<p>55:12,18 57:21 60:22 61:2,5,9,11 62:1 63:1,16 64:11 64:13 67:11 70:9,15 70:23 72:19 73:12 74:5 75:1 76:4,10 76:12,16 77:4,17,20 78:5,7 79:2,24 80:4 80:16 81:8,12 128:6 134:11 136:10 151:19,20,24,25 152:6,7,20 153:11 153:16,22,23 155:2 155:3 169:15 172:4 173:8 174:16 180:7 samples 163:9 165:21 179:13 sampling 164:13 173:17 sarah 3:9 7:2 186:5 satisfaction 90:20 satisfy 40:13 138:10 savings 64:3 saw 113:9,12 123:24 123:25 126:8 132:3 143:20 173:13 182:4 saying 37:19 53:17 58:16,21,22 67:5 73:9 74:2,4 78:8 91:23 104:9 106:10 129:17 137:24 167:8,9,25 168:23 175:5 176:5 178:23 182:12 says 10:16 36:8 43:8 44:11 53:11 54:1 57:23 90:5 102:25 107:6 117:20 124:19 147:1 149:19 177:25 scenarios 101:7 sciences 4:11 34:12 35:6 36:9</p>	<p>scientific 19:23 scope 94:8 95:23 98:12 99:8 103:25 110:10,18 111:16 112:4 118:16 125:13 126:1 127:7 130:9 133:6 138:24 140:10 141:6,21 142:7,20 147:16 150:13 155:11 156:12,17 160:5 script 174:6,6 175:17 scripts 154:19,20,23 169:22,22 se 17:17 second 8:6 24:4 35:17 55:15 90:5 124:13 133:11 145:4 secondary 136:2 section 11:18 105:8 164:8,9 sector 36:10 see 10:14 11:18 21:13 22:2 42:23 43:4 44:9,16,17 51:24 54:12,13 55:19 57:18 59:1,22 60:24 61:1 64:9 66:20 70:13 78:7 81:21 89:3 90:9 91:10,11 95:8 102:8 102:23 103:2 106:2 107:9 113:13,17 118:22 124:16,17 124:18 125:2 131:10 132:2 134:1 134:10 146:2,5 148:21 151:11,18 152:4,7,25 154:17 155:6 156:17 160:21 165:11 167:14 172:15</p>	<p>seeing 179:6 seek 175:20 seen 12:16,22 27:11 32:25 33:3,5 34:20 35:11 39:3,9 42:2 43:13 49:22 51:15 51:16,20 53:9,18 54:14 71:17 85:25 86:1 88:19,24 94:11 94:24 111:20 114:11 117:9 123:23 129:6 139:18 141:9 144:25 145:10,11 146:16,17 148:14 162:22 169:4 170:14 171:14 178:24 179:9 182:25 selected 165:9,10 selection 150:16 selling 5:5 47:12,21 171:4,11 172:1 semantics 69:16 senju 1:5,13 6:10,24 185:1 186:6 sense 163:17 168:4 sensitive 100:7 sentence 21:23 36:6 91:7 107:10,12 126:24 137:11,14 138:8 161:3 sentences 54:13 124:16 159:14 separate 78:13 102:6 september 25:4,5 30:11 48:13 services 185:24 setting 15:9,11 settling 79:7 seven 71:10 severity 99:14 sfink 3:12</p>
<p>s</p>			
<p>s 3:1 4:9 5:1 185:4 safe 166:18 167:24 170:8 176:6 178:6 safety 105:25 108:1 128:10,20 166:4 167:4 168:2 174:8 181:3 sale 61:8 78:7 sales 26:7 28:1,6,13 28:20 29:19 48:19 51:23 52:11,16,18</p>			

shaded 152:13 share 76:14 sheet 185:7,9 186:12 186:13,13 shift 50:20 169:1 shifted 182:2 shifting 150:23 164:11,13 short 30:21 37:13 44:7,18 show 23:23 71:25 72:1 showing 159:4 172:18 shown 49:16 185:11 186:14 shows 48:2,3 91:25 137:16 182:7 side 92:1,2,17 99:25 100:10,12 107:7 120:1,8,9 122:22 127:17 sided 171:18 sign 185:9 signature 10:5 184:18 185:23 186:12 significance 153:11 significant 28:9 51:8 54:7 63:23 81:24 91:25 136:15 significantly 47:12 80:24 signing 122:2 186:13,17 similar 14:8 107:5 127:15 similarly 123:7 simplistic 92:21 simultaneously 13:15 sincerely 186:20 single 38:13 178:22 sir 9:2,9,19 15:19 20:12,20 79:16	sit 33:23 48:7 53:20 69:20 73:13 121:20 122:8 139:22 142:11 161:22 sitting 82:17 175:5 situation 33:22 49:1 49:12,18 84:14 87:21 92:12 99:17 103:16 163:3 situations 37:7,11 49:17 51:15 55:1,4 76:23 84:25 85:6,25 86:23 87:9 94:25 95:6,14 97:19 104:5 133:12 six 71:10 size 54:8 77:23 78:3 skew 81:22 82:8 skewed 44:14 skilled 57:5 slide 115:9,12 116:10 117:15,18 119:13,19 130:13 130:15 158:15 slides 115:20 slight 61:8 74:20 slightly 60:8 65:24 78:23 79:2 small 74:25 153:23 smart 168:2 soap 141:15,19,25 142:3,10,14 society 87:11 92:23 sodium 152:15 153:2,12,16,22 154:3,7,10 155:2 161:15,18 163:22 163:25 164:25 165:5,7 169:8 sold 26:2 27:12 28:13 78:16,19,21 78:24 79:2,6,8,10 79:12,15,18 80:18 80:22 81:5,9,10 82:1	solution 4:24 123:16 solutions 141:12 186:1 somebody 45:1 somewhat 26:1 173:7 sophisticated 162:5 164:21 182:20 sorry 23:5 50:10 67:3 115:17 129:23 147:2,22 150:1 sort 18:18 sound 8:12 25:1 57:14 135:25 140:9 sounds 8:4,20 28:23 39:3 53:23 92:4 109:7 132:24 sourced 106:22 121:6 south 3:16 7:18 spaces 14:23 speak 14:6,8 106:25 107:20,23 speaking 13:21 103:9 126:19,23 speaks 36:19 43:1,6 47:15,24 104:12 116:13 specific 10:24 23:19 41:14,14 51:18,18 51:19 92:12 121:3 specifics 121:20 134:6 specs 111:10 139:21 speculate 45:17 46:2 speculated 32:1 speculating 31:23 32:6,7 speculation 25:17 27:1 30:17 38:25 40:20 72:9 81:2 84:12 89:20 94:9 97:5 98:13 99:10 103:25 105:4 112:5 116:23 118:16	125:14 126:2 128:23 131:18 133:7 144:4 150:14 156:4 162:7,20 165:2 176:19 179:25 speculative 71:21,22 spend 15:5 spending 76:22 spent 15:1 50:16 51:6 73:10 74:2 75:2 104:2 spite 166:8 174:8 spoke 46:5 101:13 157:24 158:25 spot 73:14 spreading 165:4 spreadsheet 66:20 66:22,25 stability 96:13,17,23 97:2,13,18,20,25 98:1,2 138:18 stabilization 133:18 139:8 stabilize 111:25 134:3 stabilizes 108:20 109:6 110:23 stabilizing 109:14 113:1 stable 110:7,16 stacking 153:18 154:12 stakeholders 36:10 standards 17:25 standpoint 62:25 stands 77:6 stanley 182:6 stapled 114:6 start 51:13 55:18,19 59:1,21 88:19 105:23 161:10 166:2 170:6 175:19 started 129:11 156:21
---	--	---	---

starting 60:22 70:15 starts 10:13 51:23 52:11 70:4 state 7:15 21:24 105:21 136:23 174:17 stated 44:23 136:20 statement 36:13 102:20 106:2 107:1 107:5 statements 63:3 states 1:2 171:12 stems 133:17 134:2 stenographic 184:10 steps 40:12 164:11 stifle 86:4 87:12 stimulate 88:5 sting 142:5,19 stinging 107:7 120:2 146:7 147:6 148:2 148:23 149:15 150:8,12 stop 28:20 storage 97:21 stored 96:22 story 182:22 strategic 16:17 36:11 164:17 166:20 168:25 169:10 170:16 176:12 182:20 strategically 163:24 strategies 46:22 137:4 strategy 16:21 17:5 37:5 41:3,7 51:18 83:4,12 84:8,8 85:16,22 86:14 87:17 91:13 101:8 101:15 102:19 105:2,10,10 119:17 135:12 164:15 169:21 170:5 172:22,25 174:2 182:8,22	street 3:16 strengths 78:2 strike 30:24 105:23 125:20 147:22 struggling 40:22 studies 28:11 39:2 49:15 51:15,20 55:3 92:14 96:23 147:10 147:14 148:5 150:5 150:10 183:1 study 91:24 159:11 stuff 122:1 subject 64:17 177:17 subjective 40:1 104:14 submitted 12:15 subsection 105:8 subsidy 71:18,19 substance 93:1,7,25 substituted 167:21 substituting 19:10 substitution 19:8 165:7 167:13 subsumed 77:12 subtraction 55:13 success 21:25 22:7 22:18 23:3,7,8,12 23:23,25 32:10 33:11 34:6 38:22 45:2 46:4 49:5 72:12 75:24 83:19 84:1 86:22 129:13 129:17 134:24 136:13,20 successful 39:6,7,11 39:13 44:21 74:13 74:21 75:6,8 168:5 182:8 successfully 74:14 166:24 sufficient 44:20 sufficiently 57:5 suggest 74:7 137:20	suggestion 81:21 175:4 182:17 suggests 54:3 suit 30:3,6 109:21 109:24 110:4,7 suite 185:24 186:1 summarizes 154:25 summarizing 161:4 161:7 supplied 150:10 supply 97:16,23 98:4,20 support 28:19 36:14 72:11 164:12,13 166:23 174:25 175:10 supported 46:21 150:10 163:9 sure 7:17 10:4 22:22 35:24 36:21 50:15 53:20 86:22 92:4 96:15 100:22 109:5 118:9 119:11 122:17 130:21 139:12 162:3,9,12 176:20 surface 100:3 surfactant 108:10 108:14,17,17 113:11 141:5,14 142:17 143:16 144:1 157:7 surfactants 108:7 141:10 surgery 95:19 surgically 160:2 surpassed 153:16 surprise 27:13 surprising 168:4 surrounding 17:2 35:20 42:22 sustain 52:18 swap 153:20 swear 7:8	switch 160:24 173:14 switched 173:16 switching 167:24 sworn 7:11 110:22 184:8 synthesizing 39:15 <hr/> t <hr/> t 4:5,9,10 5:1 6:17 7:10,17 9:13 184:2 184:2 185:1,4,4 186:8 tab 154:16,24 171:3 171:10,12,17 175:2 table 21:10 154:1 tabulated 30:2 tactic 160:24 167:11 tactics 160:18 162:22 166:17 167:10 170:2 173:13 177:18 tail 51:13 take 8:15,18,18 28:1 29:9 35:16,18 36:16 37:9 38:12 40:17 41:9 42:17,19,21 43:15,19 48:20,24 54:21 58:12 60:21 62:9 67:1 70:4 87:24 90:4 112:16 113:2 124:5 144:23 149:23 150:24,25 160:19 taken 2:1 43:21 44:6 184:10 185:2 takes 172:4 talk 8:6 29:24 39:4 52:6 66:17 67:24 108:25 121:1 135:11 157:17 158:3 170:19 174:1 176:15,21 181:8 talked 31:9 68:18 69:3,19 121:1 133:9
--	--	--	--

<p>133:12 156:5 157:6 158:11 159:5 168:8 169:4,13 170:2 174:9 177:13 181:8 talking 39:15 43:25 44:1 58:4,9 62:20 62:24 63:7 66:21 68:9 69:2,3 83:17 86:18,20 101:10 105:9 108:22 114:19 115:21,24 116:10 134:22 154:25 177:1 178:12 179:18 talks 81:20 95:2 120:7 targeter 182:21 team 10:10 21:17 tear 117:20,22 118:11 tears 111:15 114:25 117:16,20 118:1 131:1 158:14 technical 13:12 17:24 18:8,9,18 19:5 20:2,16,25 21:4 40:2 95:25 96:21 98:15 99:12 100:9,13,16 109:8 109:10,17,18 110:12,17 111:8,12 112:7,11,15,20 116:17,25 118:19 121:4,19 124:2 125:15,17 126:3,12 127:9,11 128:16,18 130:5,12 131:7,22 133:10 134:6,8,13 134:16,21 137:4 139:10,11,14,15,25 142:23 143:11 144:5,7 150:16 155:15 160:10 169:5</p>	<p>technically 69:7 103:17 143:12 teleconference 3:16 tell 45:15 52:7 66:2 telling 64:18 tells 45:19 71:1 temporal 57:8 137:23 temporally 183:9 temporary 54:6 ten 31:18 145:8 tend 102:15 tendency 142:18 tens 51:4,10 154:9 term 22:4 30:21,22 36:10,16,21 37:1,7 37:13,15,17 40:1,17 40:23 41:2 44:8,12 44:18 65:9 69:12 82:22 83:1,3 89:10 96:13 97:13 104:15 141:9 terminal 95:10 terms 10:14 11:21 31:5,20 45:9 61:1 71:14 90:19 91:8 118:7 127:13 137:2 143:5 150:21 163:15 166:4 terrence 3:4 6:25 terrence.kim 3:7 testified 7:11 145:15 147:25 testify 9:8 testimony 10:21 38:4 66:8 73:2 83:7 101:18 103:13 110:22 119:8,22 122:23 135:21 137:7 143:8 144:4 160:5 166:14 167:7 181:13 184:10 185:6 testing 20:22 21:2</p>	<p>thank 10:18 11:17 24:7 53:12 103:5 114:8 147:2 155:4 157:21 thanks 24:12 theoretically 31:22 68:24 89:24 101:22 104:4 therapeutic 39:16 49:14 52:1 77:25 100:1 therapeutically 94:15 thereabouts 51:5 thereof 110:11 thing 48:23 68:9 85:18 87:9 89:18 92:5,22 93:6,24 94:24 95:6 98:21 99:2 100:4 135:25 137:21,21 174:10 things 10:24 18:13 20:1 31:8 39:9 42:22 57:12 68:10 76:14 78:2,3 83:16 83:21 93:10 101:11 112:22 113:16 126:15 132:4 134:13,16 135:3,10 135:11,13 136:11 139:4,25 143:12 160:8,15 162:21 163:11 165:16 168:15,24 169:2,6 173:16,17,17 174:24 180:10 181:18 think 10:11 11:11 22:10 23:14 27:8,23 28:11 29:1,9,10,16 30:1,18,25 31:4,8 31:13,23 33:14 34:3 34:24 36:23 37:5,12 37:16,18 39:13 40:2 40:6,24 41:4 42:7,9</p>	<p>43:7,7,18,20,24 44:10,25 45:3,11,17 45:18 47:2,4,16,25 48:22 49:9,10,12,17 50:22 51:14,24 52:15 54:24,25 55:3 55:6 56:25 57:25 58:19,21 61:20 63:3 63:6 67:18 68:18 69:11 70:5,21 71:8 71:15,17 72:17 75:1 75:17 76:3,11,17,19 76:22 77:21,25 78:10 79:20,25 81:3 81:6,18 82:3 83:9 84:15,25 85:5,7,25 86:9,17 87:7 88:23 89:13,23 90:24 91:19 92:11 93:4 94:25 97:7 98:22 100:9 101:10,20 103:14 104:19 105:7,11 106:18 108:24 114:5,17 115:23,25 116:15 116:15 117:1 120:5 120:6 123:4 126:24 127:1 128:2 129:4,5 130:2,12 131:6,19 131:20 132:14 133:8 135:22 137:8 139:24 140:3 143:9 145:14 149:1,5,6 150:15 151:22 155:23 156:6,19,20 157:2 161:17,24 162:9,23 163:1,6,21 163:23 164:2,7 165:13 166:13 168:8,20 170:14 172:5,22 173:1 174:14 177:9,15,25 181:15,17 182:5,17 thinking 91:2 175:8</p>
---	---	---	---

<p>thinks 175:8 third 25:3 33:25 45:4 thirds 14:25 thirty 186:16 thorough 29:2 thought 25:2 69:14 79:3,20 104:2 111:10 121:24 thoughtful 29:3 thousands 154:9 three 8:5 11:14 14:25 31:18 45:25 72:15 101:3 102:5,6 102:6 105:6 124:15 tick 70:23 tied 63:22 119:5 131:13 tier 174:24 time 4:16 6:19 8:18 14:25 15:5 24:12 29:10,11 31:8 36:22 44:20 45:14 47:8 48:19 52:23 53:7,15 54:17,18,21 56:15 58:2,17 61:3 62:3 67:21 68:21 69:1 70:11 71:6,16 72:9 72:25 74:2 96:19 104:3 106:13 151:23 152:5 160:9 161:1,9,11 164:1 175:23 176:22 182:19 times 3:10 7:23 30:20 51:16 64:4 71:17 92:13 156:22 156:24 182:17 timing 183:6 tissue 100:7 160:2,2 160:12 title 53:14 89:1 116:6 today 6:6 9:8 11:11 12:14 34:4 44:6</p>	<p>46:24 48:7 83:1 169:5 today's 13:8 129:11 told 13:25 107:18 toll 186:2 tool 69:5 169:2,3 178:9 tools 178:9 top 10:5 42:19 57:18 66:19 67:4 90:6 93:7 111:18 136:19 171:10 topical 102:15 total 11:16 77:7,10 77:13,16 153:23 154:6 totally 27:23 44:22 70:5 179:8 township 7:18 track 26:23 27:6,7,9 27:12 77:21 tracked 26:4 traditional 163:17 trailing 71:10 trained 19:6 training 15:24 162:11 trajectory 61:10 64:10,12 transcript 2:1 25:20 56:18 57:9 184:9 185:6,8 186:11,11 transformation 4:12 34:13 transition 151:24 152:6 155:7 161:9 164:17 165:17 169:11 172:25 173:19 178:25 transitioned 168:22 178:10 transitions 151:20 translate 139:4 translates 61:9</p>	<p>trattler 12:10,22 treated 20:10 treatment 77:24 trend 59:22,23 61:1 trending 72:7 trial 40:9 trials 40:5 183:8 tried 54:24 75:17 84:18 tries 93:10 trivial 103:18 trouble 84:16 85:3 true 122:18 180:19 184:9 truthfully 8:11 9:8 trx 77:5,6,13,13,16 77:23 78:2 172:5 174:16 try 31:17 52:18 136:7 151:13 trying 40:15,22 61:25 64:21,22 70:22 73:21 74:4 78:4 83:10 84:17 130:8 172:6 176:2 tumors 93:11 turn 10:1 21:6,7,20 35:14 101:25 105:18 115:17 124:25 151:10 turning 4:14 41:21 42:14 tweak 93:18 tweaked 44:2 45:8 twice 78:4,6 96:6 155:10 156:22 161:16 163:20 165:8 168:9 two 14:25 44:14 59:21 60:16,17 62:17 64:12 65:25 66:2,20 67:1 71:9 72:14 78:7 97:13,18 98:1 104:19 115:12 124:15 125:24</p>	<p>131:20 149:20 tyloxapol 19:20 108:16,19 109:5,11 109:15,20 110:5,9 110:15,23 116:21 133:19 134:2 138:19 139:9,20 140:7,16,20,24 143:15 157:10,14 158:1 tyloxapol's 111:25 113:1 type 104:25 108:1 types 20:3,17 21:5 29:21 113:16 typical 29:22 136:12 175:16 typically 49:3,24 86:25 98:4 148:7 167:14,19</p>
u			
<p>uh 90:8 uk 42:7,9 unavailable 25:22 26:2 unchanged 67:12 uncommon 43:15 52:12 58:17 underlying 154:16 154:25 undermine 61:24 undermines 37:12 understand 8:13,23 18:4 25:20 40:5 47:7 65:15 91:19 100:10 105:22,24 107:6 110:2 112:21 120:17 127:13,18 128:9,24 130:8,9 136:6,7 153:11 155:4 164:14 understanding 13:10,13,17,20 14:11,15 19:2 27:3</p>			

30:9 65:20 96:16 106:6,9,14,15 107:5 107:14,22 109:20 109:25 110:13,15 110:19 111:9 112:21 125:19,21 126:21 127:3,24 128:16 129:12 132:19 137:13 138:24 139:12 143:13 144:6,9 147:18 155:13,16 166:6 181:1 understandings 108:3 131:21 understood 9:5 78:18 106:23 119:11 120:15 180:5,25 undertaken 15:11 86:3 unfair 181:15 unfortunately 62:5 151:11 152:11 unheard 43:21 52:13 63:25 unimaginable 26:1 unique 50:12 unit 77:4,16,19 78:5 united 1:2 171:12 unitized 124:25 unprofitability 63:13 unrelated 128:5 138:14 untoward 168:1 unusual 81:4 upper 10:16 upward 61:1 usage 83:1 use 22:4 26:18 29:12 29:14 54:3 67:17 68:1,13,17 71:14 72:10 79:4 83:3 92:25 94:14 104:18	116:20 126:9 179:21 usually 39:22 43:20 81:11 86:2,10,12 v v 186:6 vacuum 119:20 vague 50:3 84:11 131:17 valeant 41:9 78:21 78:25 79:4,12 102:21 104:8 105:12 valeant's 105:12 valerie 119:23 127:19 169:6 177:19 valerie's 122:22 166:14 value 4:20 83:11,15 87:1,13 88:10,17 variable 92:22 variables 52:6 63:23 92:20 varies 22:15 38:9 48:22 71:19,20 variety 33:3 41:1 76:11 101:10 164:11 various 46:21 81:20 87:14 118:25 162:22 176:25 vary 40:6 varying 4:16 52:23 53:7,15 veritext 6:5 7:8 185:24 186:1,7 version 9:21 11:8 86:8 151:12 152:24 153:4,19,20 165:8 versions 46:17 167:14 versus 6:11 39:17 117:4 120:2 136:8	137:21 139:2 149:8 174:6 177:1 video 6:1 7:6 62:12 62:15 100:23 101:1 151:2,5 183:13 videographer 3:21 view 23:3 28:19 30:22 32:18 34:9 36:16,21 37:1,7,17 40:17,23 41:9 44:12 102:21 118:23 155:23 167:3 178:24 viewed 81:7 156:23 views 37:15 120:17 vigorously 73:4 visibility 80:11,21 vs 1:9,17 185:1 w w 3:15 185:24 186:1 wait 24:4 waived 186:17 walks 177:25 want 11:6 24:9 36:22 46:2 48:14 52:18 54:22 57:13 64:3 69:16 74:6 77:14 91:23 98:25 104:9 108:21 152:23 wanted 69:15 153:7 154:23 wash 99:16 173:12 washington 3:5 watching 52:11 way 25:19 28:2 32:14 35:12 41:15 42:3 48:15 52:7 53:20 64:24 66:17 76:9,17,19 78:3 81:10,23 82:8,11 99:25 100:2 106:18 109:14 111:1 112:9 114:6 120:9 122:7,8	135:24 143:1 150:19 151:13 153:6 163:24 166:23 175:8,16 176:13 ways 86:12,14 120:7 131:20 we've 28:20 61:17 69:19 130:9 153:5 169:4 weakening 70:9 weakly 124:23 website 21:14 wednesday 2:5 weeks 56:17 97:12 weigh 48:15 96:2 143:11 178:19 weight 177:8 welcome 156:18 went 160:9 168:9 whatnot 17:21 95:4 whatsoever 178:4 whichever 148:24 white 9:21 86:10 151:12 152:24 153:4 wholeheartedly 70:12 wide 80:3 82:20 widely 180:4 widening 55:19 64:13 william 12:10,22 williams 12:6,15,16 wiped 117:25 witness 4:4 6:17 7:3 7:9 24:6 25:18 27:2 30:18 32:5,23 36:20 38:6 39:1 40:21 42:23 43:7 47:16,25 49:9 50:4 54:24 59:5 60:16 61:16 63:20 64:17 66:9 67:16 68:24 70:19 73:3 75:17 81:3
---	--	---	---

82:15 83:8 84:13 89:21 91:18 93:4 94:10,23 95:25 97:6 98:14 99:11,22 101:19 103:14 104:2,14 105:5 109:2 111:7,18 112:6 113:6 116:14 116:24 118:18 120:25 121:18 124:6 125:15 126:3 127:9 128:24 131:5 131:19 133:8,22 134:5 135:22 137:8 138:23 140:12 141:2,8,24 142:9,22 143:9 144:5 145:7 145:10 147:18 149:1,18 150:15 155:13 156:5,14 158:10,22 159:10 160:7 162:8,21 165:3 167:8 170:14 176:20 177:5 180:1 181:14 183:5 184:8 186:8,11 witness' 186:12 wonderful 92:22 woolley 3:15 7:4,4 24:8,8 words 44:10,17 57:1 89:8 90:23 104:21 105:6 149:4,10,18 149:21 150:17,22 work 15:9 16:2,8,14 16:16 18:19,20 35:8 35:10 39:15 40:9 43:14 82:7 96:14 133:16 worked 16:9 18:11 97:9 works 100:21 140:6 159:24 worth 97:11 173:1	write 165:12 175:17 writing 170:6 written 45:1 wrong 128:19	york 2:4,4 3:5,10,11 3:11 6:5,9,9
	x	
	x 4:2,9 5:1 xi01143 2:3 184:19 xibrom 33:23 46:7 145:11,22 147:21 147:24 151:19,24 152:12,17,21 153:23 155:7,8 156:11 164:20 165:22 166:25 168:6,9,22,25 174:3 176:13 178:10 xr 84:18 85:8	
	y	
	yeah 9:20 22:23 25:3 32:23 40:11 44:18 49:9 51:10 55:14 57:3 59:5 61:16 69:14 73:3 75:17 78:9 79:23 81:17 91:7,12 94:10 97:6 98:14 101:12 101:19 103:3,14 104:21 105:5 107:10 109:25 114:16 118:18 124:4 142:2 166:13 177:12 181:14 183:5 year 90:24 97:13,18 98:1,1 152:6 yearly 44:13 years 29:20 31:18 31:18 32:9,19 33:19 34:1 37:3 41:1 43:2 43:16,19,21 45:25 48:20 49:19 51:21 55:17 72:15 166:19 yep 55:15 115:8 160:21 171:19,21	

Federal Rules of Civil Procedure

Rule 30

(e) Review By the Witness; Changes.

(1) Review; Statement of Changes. On request by the deponent or a party before the deposition is completed, the deponent must be allowed 30 days after being notified by the officer that the transcript or recording is available in which:

(A) to review the transcript or recording; and
(B) if there are changes in form or substance, to sign a statement listing the changes and the reasons for making them.

(2) Changes Indicated in the Officer's Certificate. The officer must note in the certificate prescribed by Rule 30(f)(1) whether a review was requested and, if so, must attach any changes the deponent makes during the 30-day period.

DISCLAIMER: THE FOREGOING FEDERAL PROCEDURE RULES ARE PROVIDED FOR INFORMATIONAL PURPOSES ONLY. THE ABOVE RULES ARE CURRENT AS OF SEPTEMBER 1, 2014. PLEASE REFER TO THE APPLICABLE FEDERAL RULES OF CIVIL PROCEDURE FOR UP-TO-DATE INFORMATION.