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U.S. PATENT AND TRADEMARK OFFICE
 PATENT TRIAL AND APPEAL BOARD
 Washington, D.C.

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 ARGENTUM PHARMACEUTICALS, :
 :
 Petitioner, :
 :
 vs. : IPR2017-00807
 :
 CIPLA LTD, :
 :
 Patent Owner. :
 -----x

Washington, D.C.

Wednesday, April 4, 2018

EXAMINATION of:

JOHN C. STAINES, JR.,
 the witness, was called for examination by counsel
 for the Patent Owner, pursuant to notice,
 commencing at 8:50 a.m., at the law offices of
 Foley & Lardner LLP, 3000 K Street, NW,
 Washington, D.C. 20007, before Dawn A. Jaques,
 CSR, CLR, and Notary Public in and for the
 District of Columbia.

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2 WITNESS: PAGE:

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1 P R O C E E D I N G S

2 Whereupon,

3 JOHN C. STAINES, JR.,

4 was called as a witness, after having been
5 first duly sworn by the Notary Public, was
6 examined and testified as follows:

7 CROSS EXAMINATION BY COUNSEL FOR THE PATENT OWNER

8 BY MR. VARUGHESE:

9 Q Good morning, Mr. Staines.

10 How are you?

11 A Good. Good morning.

12 Q Is it okay if I refer to you as
13 Mr. Staines?

14 A That's fine, yeah.

15 Q So I know you just stated your full
16 name for the record. Do you understand that
17 you're here today because you submitted a
18 declaration in an inter partes review proceeding?

19 A Yes.

20 Q Okay. And you submitted a declaration
21 on behalf of Petitioner, Argentum?

22 A Yes.

1 Q And you understand that you're under
2 oath and you're answering questions under oath,
3 correct?

4 A I understand that.

5 Q Any reason, ailment or medications,
6 anything that would preclude you from testifying
7 truthfully and accurately today to the best of
8 your ability?

9 A No.

10 Q Okay. How many times have you been
11 deposed before?

12 A Twice.

13 Q Okay. Do you remember in what type of
14 proceeding?

15 A Yes. One was a review like this, and
16 the other one was an antitrust damages case.

17 Q Okay. That review, when you say "like
18 this," it was another inter partes review?

19 A Yes.

20 Q Involving a patent?

21 A Yes.

22 Q Now, did you testify in that

1 proceeding on behalf of the Petitioner or the
2 Patent Owner?

3 A So I didn't testify per se, but I
4 submitted an affidavit and did testify at
5 deposition, and that was -- I was retained by the
6 Petitioner.

7 Q Okay, great. If I were to ask you
8 approximately how many times you've submitted
9 either a declaration like the one in this
10 proceeding or an expert report in a district court
11 case involving a pharmaceutical drug,
12 approximately how many times would that have been?

13 A It's probably indicated on my CV
14 that's attached. As I recall, there's probably
15 been -- probably been four to five.

16 Q Okay. And in those cases, do you
17 recall if you submitted your declaration or
18 reports on behalf of the patent challenger or the
19 Patent Owner?

20 A Okay, so those -- let me go back to
21 make sure not all those cases were necessarily
22 patent cases.

1 The ones that were, I can think of
2 two of them where I was retained by the challenger
3 to the patent.

4 Q So two of them?

5 A Right.

6 Q So does the drug name Trilipix®, does
7 that sound familiar?

8 A Yes, it does.

9 Q Do you recall submitting a declaration
10 or expert report in that case?

11 A No.

12 Q How about Yaz?

13 A Do I recall submitting?

14 Q Yeah.

15 A No.

16 Q Xyzal®, X-Y-Z-A-L?

17 A And the question is do I recall
18 submitting an expert report? No.

19 Q Prevacid®?

20 A And so the same question, no.

21 Q So did you do any work in conjunction
22 with those drugs for those cases?

1 MR. CHESLOCK: Object to form.

2 THE WITNESS: And so I work -- I was
3 retained to study those and research them, and in
4 that sense, do work on it.

5 BY MR. VARUGHESE:

6 Q But for all four of those drugs I just
7 mentioned, you don't recall submitting any type of
8 expert report or declaration?

9 A That's correct.

10 Q And you offered no deposition
11 testimony in connection with those drugs?

12 A That's correct.

13 Q When were you retained by Argentum for
14 this case?

15 MR. CHESLOCK: Object to the extent
16 that it calls for any privileged information, but
17 you can acknowledge when you were retained for
18 this matter by Argentum.

19 THE WITNESS: Sure. It was mid to
20 late January.

21 BY MR. VARUGHESE:

22 Q 2018?

1 A Yes, yes.

2 Q And who contacted you?

3 MR. CHESLOCK: Same objection. It's
4 fine to acknowledge who initially contacted you
5 for the engagement.

6 THE WITNESS: Okay. So contacted me
7 initially, or to say you're engaged?

8 BY MR. VARUGHESE:

9 Q Both.

10 A So initially, I'm not sure. Somebody
11 from Argentum called me.

12 And to say that I was retained, I
13 don't recall. Somebody from Foley Lardner.

14 Q And who drafted your declaration?

15 A I drafted my declaration.

16 Q Okay. And you have personnel --
17 you're an employee of Navigant? Strike that.

18 You're from Navigant Consulting; is
19 that correct?

20 A From the sense of I'm employed by
21 Navigant.

22 Q You're employed by Navigant?

1 A That's correct.

2 Q I was just clarifying. I wasn't sure
3 if you were like a shareholder or a partner or
4 anything like that. I called you an employee.

5 Did you have personnel at Navigant
6 that assisted you in drafting your declaration?

7 A I had personnel that assisted me in
8 certain aspects of preparing it, but not actually
9 drafting it. I drafted it all.

10 Q Okay. And in this proceeding, you
11 understand that the '620 patent is the patent at
12 issue?

13 A Yes.

14 Q Have you reviewed that patent?

15 A I've reviewed parts of it.

16 Q What parts?

17 A I've reviewed the claims. And other
18 than that, I've skimmed through it, and I can't
19 recall what specific parts.

20 Q Now, are you aware that the
21 '620 patent was the subject of a district court
22 trial that took place in December 2016?

1 MR. CHESLOCK: Object to form.

2 THE WITNESS: Vaguely. I saw some --
3 in the documents that are in the record of the
4 case, I saw some declarations that were from
5 another case, and so I assume that's what you're
6 talking about.

7 BY MR. VARUGHESE:

8 Q So as part of your analysis for this
9 case -- and I'm just trying to make sure I
10 understand your response to the previous question.

11 So as part of your analysis for this
12 case, you said you saw some declarations that were
13 from another case?

14 A Yes.

15 Q Do you know what declarations?

16 A No.

17 Q Were they concerning commercial
18 success?

19 A I don't recall reviewing any dealing
20 with commercial success. I saw that there were
21 declarations there; I didn't review them.

22 Q Did you review any part of the trial

1 transcripts from that case?

2 A No.

3 Q Do you recall reviewing any other
4 materials that was part of that district court
5 case from 2016?

6 A No, except to the extent they were
7 referenced in this case and got -- I want to say
8 exhibit numbers in this case.

9 Q Yeah.

10 A Some of those had exhibit numbers or
11 deposition numbers from other cases, and so those
12 I may have reviewed, but only because it was part
13 of this case.

14 Q Now, earlier you said that you had
15 reviewed portions of the '620 patent as part of
16 your analysis.

17 A I reviewed it. I mean, part of the
18 analysis? You know, I reviewed it as a layman to
19 kind of get a general understanding of what it
20 covered.

21 Q You said you reviewed the claims,
22 correct?

1 A In that sense, yes.

2 Q How did your review of the claims, if
3 at all, affect or inform your analysis for
4 purposes of your declaration?

5 MR. CHESLOCK: Object to form.

6 THE WITNESS: I need something more --
7 I mean, I don't know. You know, in a specific
8 sense, it may have. I can't recall generally how
9 it may -- did or did not inform it.

10 BY MR. VARUGHESE:

11 Q I'm going to hand you, Mr. Staines,
12 what's been previously marked as Exhibit 1140.

13 Do you recognize this document?

14 A Yes.

15 Q And you agree this is a copy of the
16 declaration of John C. Staines, Jr., in support of
17 Petitioner's Reply to Patent Owner's Response?

18 A Yes, this is the text and the -- kind
19 of my table and graph exhibits to that.

20 Q So this is the declaration that you
21 submitted in this IPR, correct?

22 A Yes. I mean, to the -- I'll just

1 caveat. To the extent that the CV isn't in here
2 and stuff, but this is the text and tables that
3 accompany that declaration.

4 Q And exhibits?

5 A And, yeah, exhibits.

6 Q Okay. Let's turn to paragraph 121 of
7 your declaration.

8 A Yes, I see that.

9 Q Now, in this paragraph you state that
10 Meda offered rebates of more than 50 percent to
11 insurers to ease reimbursement restrictions and
12 reduce patient copayment requirements, right?

13 A Yes, that's in the first sentence
14 there.

15 Q Now, did you compare Dymista®'s
16 rebates to other rebates in the industry?

17 A In some sense, yes.

18 In the sense that, first of all, I
19 cite a document that discusses rebates for other
20 drugs, brand drugs, in the industry. And then,
21 secondly, I had quite a bit of experience on my
22 own just, you know, looking at drugs and knowing

1 the extent of rebates.

2 So those two things combined, in that
3 sense, I concluded that the rebates were
4 comparatively high.

5 Q Do you talk about any of that in
6 paragraph 121?

7 A Let's see. I'm not sure if I do.

8 The exhibit numbers, it's always hard
9 to say what exhibit is cited there, but if I have
10 it in this particular paragraph, I've cited it
11 elsewhere, the Fortune document.

12 Q And anywhere in your declaration,
13 whether in paragraph 121 or elsewhere, do you
14 compare this rebate to rebates for other branded
15 drugs?

16 MR. CHESLOCK: Object to form.

17 THE WITNESS: Could you repeat that
18 again?

19 BY MR. VARUGHESE:

20 Q So anywhere in your declaration,
21 whether in paragraph 121 or elsewhere, do you
22 compare Dymista®'s rebate to rebates for other

1 branded medicines?

2 MR. CHESLOCK: Object to form.

3 THE WITNESS: So by compare -- so in a
4 couple ways. Elsewhere in the report -- and I
5 can't tell you offhand where -- I've indicated
6 that the rebates are higher than normal, and I
7 cite in support of that a particular document as
8 an example to show that it's high.

9 I also at the beginning of the report
10 indicate that my conclusions are also based on my
11 experience working in the field as a consultant,
12 and the cases that I've worked on are cited in the
13 résumé. So as a general thing up front, I've also
14 indicated that.

15 BY MR. VARUGHESE:

16 Q But can you point me to anywhere in
17 your declaration where you discuss that?

18 A It's in here. I can't. We could take
19 time to do it, but I'd have to -- I'd have to look
20 in here, find that citation.

21 Q That's fair enough. I certainly don't
22 want to waste your time or mine, but you're

1 confident you think it's in the report?

2 A Absolutely. There's a Fortune
3 document that talks about all the different
4 rebates for a number of different drugs.

5 Q Did you examine or investigate what
6 extent of Dymista®'s sales were attributable to
7 the rebate program?

8 A What do you mean by "attributable"?
9 That were generated by? That the quantities were
10 generated by the rebates?

11 Q That's one interpretation, sure.

12 A Okay. No, I don't have a precise
13 estimate of what proportion was other than it was
14 a primary driver.

15 Q Did you undertake any analysis or
16 discussion in your declaration about what portion
17 of Dymista®'s sales were due to the rebate program
18 versus the patented features?

19 MR. CHESLOCK: Object to form.

20 THE WITNESS: What I've addressed is
21 the primary drivers, and that the patented
22 features, for reasons discussed in a particular

1 section of the report, were likely not significant
2 drivers; and that the rebates, combined with the
3 copayments, combined with the high share of voice
4 in marketing, that those were primary drivers.

5 I haven't attempted, and I don't think
6 I could, attribute, you know, quantitatively what
7 proportion of the sales were due to the particular
8 factors.

9 BY MR. VARUGHESE:

10 Q Do you think any of the sales could
11 have been due to the patented features?

12 MR. CHESLOCK: Object to form.

13 THE WITNESS: And due to -- could you
14 maybe define that a little more? Well, I'll ask
15 you if you could define what you mean by "due to."

16 BY MR. VARUGHESE:

17 Q You don't understand what I mean when
18 I say do you think any of the sales could have
19 been due to the patent features?

20 A I think that's ambiguous.

21 Q What part of it?

22 A The whole thing.

1 Q I mean, I want to clarify the question
2 so you understand, so I want to know what part you
3 don't --

4 A Yeah, I just want to know what you
5 mean by "due to."

6 Q Have you ever heard of the phrase "due
7 to"?

8 A I have, but in a lot of contexts.

9 Q Do you have an understanding of what
10 "due to" means?

11 A In a given context. I need a context
12 though.

13 Q Just pick a context and give me your
14 understanding and we'll see if it matches mine.

15 A So could it be due to the patented
16 features? So, for instance, do you mean any of
17 the patented features?

18 Q Sure, yeah.

19 A Any one of them, or all of them?

20 Q Let's start with any one of them, and
21 then maybe, depending on your answer, we can do
22 them all.

1 A Yeah, I think it's possible that some
2 of the sales may have been due to that in some
3 sense, directly or indirectly.

4 Q Earlier in one of your responses you
5 used the phrase "primary driver." What is that?

6 A That the sales, incremental sales,
7 were made because of that factor, and that that
8 was the primary factor, more important than other
9 factors, to generate those sales.

10 Q Let's turn to paragraph 123 of your
11 declaration.

12 A I'm there.

13 Q In this paragraph, you discuss how
14 Meda offered a copayment card to reduce patient's
15 co-payment obligations, correct?

16 A Yes.

17 Q Did you look to see whether
18 competitors were offering similar copayment card
19 programs?

20 A No, I didn't look to see if
21 competitors were.

22 Q Do you think that would have been

1 relevant to understanding Dymista®'s copayment
2 card program?

3 A No.

4 Q Why not?

5 A I didn't see why it would.

6 Q And in your declaration, do you
7 discuss what extent the Dymista® sales were
8 attributable to the copayment card program?

9 A Again, I don't, and I don't think can,
10 estimate the precise percentage, or even general
11 percentage, other than to say it was a primary
12 driver for reasons that I've discussed at length
13 in this long report.

14 Q Did you investigate or have any
15 analysis that talks about impact of Dymista®'s
16 copayment rebate program on consumers?

17 A I'm sorry, could you repeat that
18 again?

19 Q Sure. Did you investigate or conduct
20 any analysis in your declaration that assesses the
21 impact that Dymista®'s copayment rebate program
22 had on consumers or patients?

1 A So in this sense, that I gave economic
2 reasons and cited economic articles and other
3 industry articles indicating that copayment was
4 important, a critical factor in deciding or
5 determining sales quantity; that rebates were
6 important in determining insurance coverage, which
7 in turn was very important in determining
8 quantity.

9 And then indicating that, in
10 Dymista®'s case, the copayments brought the
11 effective price down to patients to something
12 close to a generic drug, and that where the
13 rebates were accepted by insurers to give
14 favorable reimbursement status -- low copayments,
15 no prior authorization, a lot of those kind of
16 things -- that they were able to get those because
17 of the high rebates that were offered.

18 So that was my analysis.

19 Q Would you agree that this sort of
20 copayment rebate program is standard in the
21 pharmaceutical industry?

22 A In recent years, it's become more

1 prevalent. It's a very controversial practice
2 because it does -- or has been accused of trying
3 to get around the insurers' efforts to discourage
4 use of drugs that are not significant improvement
5 over other drugs.

6 There's that, and then actually it's
7 been subject to a lot of, I think antitrust suits
8 or suits that try to -- you know, that indicate
9 that it's somehow illegal or anticompetitive or
10 something, but it has become more prevalent.

11 Now, the extent to which it reduces
12 the copayment, that varies, but reducing the
13 copayment to something close to generic, I don't
14 think that that is common.

15 Q Now, is it your position that a rebate
16 program like this precludes a finding of
17 commercial success?

18 MR. CHESLOCK: Object to form.

19 THE WITNESS: So what do you mean
20 "like this"? This specific --

21 BY MR. VARUGHESE:

22 Q I'm sorry, let me be more accurate.

1 Is it your position that rebate
2 programs, such as the one that Dymista® has,
3 precludes a finding of commercial success?

4 MR. CHESLOCK: Object to form.

5 THE WITNESS: I can't say that. I
6 mean, I think this is -- you have to kind of look
7 at it in the context of the whole thing.

8 You know, this in conjunction with the
9 copayment program; that, in my opinion, the drug
10 is not all that innovative; and it's questionable
11 how much -- that there's not much that is likely
12 coming from the features of the patent.

13 All those things together would
14 indicate that, yeah, this rebate program is a
15 significant driver in sales. But in other cases,
16 I can't say that categorically.

17 BY MR. VARUGHESE:

18 Q When you say that it's your opinion
19 that you don't think this drug is innovative,
20 what's your basis for that?

21 A I have a section in here, it starts I
22 think at paragraph 109, "Dymista® Has Minimal

1 Incremental Benefit Over Concurrent Use of
2 Individual Antihistamine and Corticosteroid
3 Products," and in there I discuss the comparisons
4 that are made between Dymista® and using
5 antihistamine and corticosteroids separately or
6 concurrently, and that the evidence that it's
7 superior is not strong, I'll put it that way. I
8 use more articulate words in here.

9 Q That's fine. You're plenty
10 articulate.

11 When you say the evidence, are you
12 talking about clinical evidence?

13 A That's one of the things.

14 Q What else?

15 A Let's see. So one of the -- I'll
16 probably go through here. What's difficult is
17 that, with the exhibit numbers, I don't remember
18 what the documents are, so I'll try to remember
19 the particular documents that I'm thinking of.

20 There was a global something study
21 that discussed that there was limited evidence of
22 Dymista® being better than concurrent use of the

1 antihistamine and corticosteroids in the
2 particular of Astepro®, Astelin, and Flonase®
3 separately.

4 There was a document, I think it was
5 like a physician focus group study, that talked
6 about the physicians, ENTs and allergists, that
7 were surveyed indicated they didn't find that a
8 combination drug provided that much benefit over
9 another drug -- over the concurrent use.

10 Let's see. Let me now look in the
11 report and see what else I have on that.

12 Oh, so the other thing is that as a
13 life cycle management strategy, to get -- to
14 generate sales of a follow-on product does not
15 require significant incremental benefits, so -- so
16 I'll stop with that.

17 What else? I think that I relied on a
18 declaration by Dr. Schleimer.

19 Q "Schleimer"?

20 A "Schleimer," thank you, who also
21 indicated that the -- his opinion -- gave the
22 opinion that the Dymista® was not -- didn't

1 provide benefits over concurrent use of these
2 products.

3 And there might be a couple other
4 things I'm forgetting.

5 Q Okay. Going back to paragraph 123 and
6 your opinions concerning the rebate program, as
7 part of your analysis or work in this case, did
8 you conduct any patient surveys to assess the
9 impact of the rebate program on patients?

10 A I didn't -- no, I didn't conduct any
11 surveys. I didn't think I needed to.

12 Q Any type of study or investigation
13 into how the rebate program affected patients'
14 purchasing decisions?

15 A No. I'm sorry, could you repeat that
16 again?

17 Q Sure. Did you conduct any type of
18 study or investigation into how the rebate program
19 might have affected patients' purchasing
20 decisions?

21 A Well, so now those aren't surveys.
22 Study or investigation, I've done that, and I

1 think I mentioned that before, where I looked at
2 economic articles and, you know, economic
3 reasoning on why these things are important, so
4 that's -- I consider that study and investigation,
5 so yes.

6 Q That was specific to Dymista®, any of
7 those materials?

8 A No, not specific, no. No, that's not
9 necessary in my opinion.

10 Q Now, in your declaration you discuss
11 the impact that Meda salesforce had on Dymista®
12 sales, correct?

13 A Yes. I mean, a little more specific
14 than that, but yes.

15 Q Generally, you discuss the salesforce?

16 A Yes.

17 Q But do you recall in your declaration
18 you delineating or attributing a portion of
19 Dymista®'s sales to its salesforce?

20 A I indicated and came to the opinion
21 that it was a primary contributor to Dymista®
22 sales.

1 Q Let's say that that salesforce was cut
2 in half. What impact do you think that would have
3 on Dymista® sales?

4 MR. CHESLOCK: Object to form.

5 THE WITNESS: I think it would reduce
6 their sales.

7 BY MR. VARUGHESE:

8 Q Do you know to what extent it might?

9 A No.

10 Q Do you think if Dymista® was a bad
11 product, the salesforce would -- strike that.

12 Do you think that if Dymista® was a
13 bad product, it would still have the same sales?

14 A I need to know what a bad product is.
15 Bad product that kills people? Bad product
16 that --

17 Q That's pretty morbid.

18 A Sorry. You know, I mean, what do you
19 mean by a bad product?

20 Q Undesirable, something that patients
21 don't like.

22 A I think it depends. You know,

1 patients, from what I read in the study there
2 cited by John Jarosz, indicates that people don't
3 like using nasal sprays. They prefer oral
4 antihistamines for an antihistamine. So in some
5 sense, it already has negative aspects. So it
6 depends on to what extent, what the particular
7 negative aspects are.

8 And then, ultimately, any specific
9 thing, I'd really have to study it to really
10 understand what impact it would have.

11 Q Now, all branded products have a
12 salesforce that sells their drug, right?

13 A That's pretty much true.

14 Q So the fact that Dymista® has a
15 dedicated salesforce, that's not atypical of this
16 industry, is it?

17 A I agree with that.

18 Q So having a salesforce promoting
19 Dymista® by itself doesn't preclude a finding of
20 commercial success, correct?

21 MR. CHESLOCK: Object to form.

22 THE WITNESS: Having a salesforce. If

1 I understand that correctly, I think that's right,
2 yes.

3 BY MR. VARUGHESE:

4 Q Let's turn to paragraph 127 of your
5 declaration. I'm paraphrasing here, so feel free
6 to correct me if I'm mischaracterizing, but in
7 paragraph 127 and some of the preceding
8 paragraphs, you discuss or respond to some of the
9 opinions expressed by Mr. John Jarosz, correct?

10 A Yes.

11 Q And then that first sentence in
12 paragraph 127, and I'll just read it into the
13 record. I'm going to read it slow for the court
14 reporter.

15 "Mr. Jarosz cites certain documents,
16 including the 2015 GlobalData study, as indicating
17 Dymista®'s sales may have been constrained by the
18 lack of a large salesforce able to detail the vast
19 number of primary care physicians that prescribe
20 AR treatments," correct?

21 A Yes, that's what it says.

22 Q So I'm going to hand you a couple of

1 exhibits. The first one is CIP2149, and I'll
2 state for the record that it is the second
3 declaration of John C. Jarosz in this case. If
4 you disagree with me, just let me know.

5 MR. CHESLOCK: Do you have a copy for
6 me?

7 MR. VARUGHESE: Oh, here.

8 THE WITNESS: Yeah, this looks to be
9 Jarosz's declaration.

10 BY MR. VARUGHESE:

11 Q And then let's turn to -- I'm going to
12 hand you another one. This is CIP2074.

13 Have you seen -- just so we can stay
14 organized here, the reason why I'm handing these
15 to you, so that sentence that I just read into the
16 record, in your declaration you have a citation to
17 footnote 257, correct?

18 A 257, yes.

19 Q And then 257 is Exhibit 2149, which is
20 the Jarosz declaration, specifically at paragraphs
21 91 to 92.

22 A Yes.

1 Q Okay, let's go to paragraphs 91 and
2 92. I'm also going to hand you Exhibit CIP2074.
3 You already have it?

4 A Right here.

5 Q Okay. And then I'm going to hand you
6 CIP2064. So CIP2074 and CIP2064 are the documents
7 that John Jarosz cites in paragraphs 91 and 92 of
8 his report, which you are referring to in
9 paragraph 127 of your report, correct?

10 A Yes.

11 Q And if we go to -- let's start with
12 CIP2074. Let's go to paragraph 35.

13 A Page 35?

14 Q Page 35.

15 A Yeah, got it.

16 Q And page 35 or slide 35 -- I'm sorry,
17 page 35 is what John Jarosz was citing in his
18 report.

19 Now here, page 35 simply says that the
20 salesforce -- you know, the reach and frequency of
21 the salesforce was identified as a weakness here,
22 correct?

1 A Yes.

2 Q And it wasn't limited to any segment
3 of physicians, primary care or specialist?

4 MR. CHESLOCK: Object to form.

5 THE WITNESS: That's correct, this
6 particular document, yes.

7 BY MR. VARUGHESE:

8 Q But this is the document that -- this
9 is one of the documents that John Jarosz cites,
10 and we're going to look at the other one.

11 A That's correct.

12 Q Okay. So now if we turn to CIP2064,
13 and we're going to go to page 9, and this is what
14 John Jarosz cites in paragraphs 91 and 92, this
15 page simply says that there's a limited Meda
16 salesforce reach, and it's identified as a
17 challenge, correct?

18 A Yes. Limited, yes.

19 Q And here also, there's no discussion
20 of particular segments of prescribers, whether
21 primary care or specialist, correct?

22 A Yes, there's no discussion of that

1 here in either of these documents that he cited.

2 Q So then going back to that first
3 sentence of your declaration, paragraph 127, which
4 I read into the record, what was your basis for
5 characterizing Mr. Jarosz's opinions as being
6 limited to primary care physicians?

7 A So as I indicate there, Mr. Jarosz
8 cites the 2015 GlobalData study. That study
9 indicates that a strength of Meda is its good
10 relations with respiratory specialists, and so
11 that they have strong good marketing relationships
12 with them; but as a weakness, that they don't have
13 a salesforce that goes to PCPs. And so it's that
14 study that he cites that I'm indicating -- that is
15 the support for what I'm saying here.

16 And, again, it's important to keep in
17 mind that this is -- this is a nexus issue, so
18 that this is supporting why the sales that were
19 made were due to the salesforce.

20 The fact that a larger salesforce
21 would have gotten more sales just explains why it
22 wasn't a commercial success, but it doesn't

1 explain the nexus between the sales that were made
2 and the source of that sales, which I'm saying was
3 their higher share of voice in marketing.

4 Q So I'd like for you to maybe expand a
5 little bit on what you just said.

6 You said the fact that a larger
7 salesforce would have gotten more sales just
8 explains why it wasn't a commercial success.

9 What do you mean by that?

10 A To the extent that these documents
11 believe -- these documents, the writers of these
12 documents -- believe that a higher salesforce
13 might have generated additional sales, further
14 sales, doesn't explain a nexus to the sales that
15 actually were made.

16 And so commercial success, as I
17 understand it, is based on the actual sales that
18 were made, and so that particular issue doesn't go
19 to nexus.

20 Q Mr. Staines, I've just handed you
21 what's been marked as CIP2053.

22 A Yes.

1 Q So you agree this is the GlobalData
2 document that's cited in Mr. Jarosz's
3 paragraph 91-92 that you were discussing?

4 A Yes.

5 Q And on that page 133, which I believe
6 is a specific page that he cites, which is the
7 SWOT, S-W-O-T, analysis?

8 A Yeah, that's one of many, right. Hold
9 on a second. Oh, yes, mm-hmm.

10 Q So in one of your responses right now,
11 you said that, in your view, this 2015 GlobalData
12 study indicates that a strength of Meda is its
13 good relations with respiratory specialists, and
14 that they have strong good marketing relations
15 with them, but as a weakness, they don't have
16 salesforce that goes to PCPs.

17 But this document also doesn't
18 distinguish between primary care or respiratory
19 specialists, correct?

20 MR. CHESLOCK: Objection to form.

21 THE WITNESS: Could you point to where
22 it talks about the PCPs?

1 BY MR. VARUGHESE:

2 Q I think that's the point is that it
3 doesn't.

4 A Oh, I'm sorry, I thought you were
5 reading something about PCPs. Let me think.
6 Let's see. Yeah, that's true. I guess two things
7 on that.

8 One, I'm mistaken. There are
9 documents that -- there is at least one or two
10 documents that talk about that, and so I'm
11 mistaken in that this one only talks about the
12 respiratory specialists.

13 But by inference, if they have good
14 presence with respiratory market, that means that
15 the other market, it doesn't. So other than
16 respiratory, I think PCPs would be the only ones
17 that would be prescribing it. I mean, there
18 wouldn't be -- cardiologists wouldn't be
19 prescribing it.

20 So there's an inference here that the
21 PCPs -- if there is any weakness in marketing, in
22 salesforce, it would be for the PCPs, and I think

1 there's a pretty strong inference of that. But
2 I'm sure I've seen a document or two that have
3 indicated that they're marketing to specialists,
4 not to PCPs.

5 Q Okay, you can set that aside for now.

6 A Okay.

7 Q Let's turn to paragraph 130 of your
8 report -- your declaration.

9 A Okay.

10 Q And I'm going to try to summarize
11 paragraph 130, but feel free to correct me if you
12 think I'm mischaracterizing it.

13 In paragraph 130, you cite to three
14 documents -- CIP2079, CIP2080, and CIP2093 -- as
15 demonstrating that Meda's belief was Dymista®
16 would benefit from increased share of voice.

17 Is that a fair characterization?

18 A I think so. Can you give me the
19 footnote number that you're --

20 Q Yeah.

21 A 267?

22 Q Footnote 267, correct.

1 A Okay. Yes, I think what you said
2 there is correct.

3 Q So I'm going to hand you 2079. Let's
4 go to page 21, which is what's cited.

5 A Yes.

6 Q This document only says that Meda
7 salesforce will be realigned from azelastine
8 Astepro®, which were earlier products that Meda
9 sold, to Dymista®. It doesn't say anything about
10 share of voice, correct?

11 MR. CHESLOCK: Object to form.

12 THE WITNESS: I disagree with that.

13 In the second bullet it says, "To date, there has
14 been limited new noise in the SAR space. However,
15 two new branded entries are expected in 2013, Teva
16 and Sunovion."

17 So "limited noise" is a reference to
18 marketing, salesforce marketing. And so the
19 limited noise is an allusion to the fact that
20 there's been less marketing by other brands.
21 They're expecting these two other products to come
22 in, but those two other products turned out to be

1 pretty weak products.

2 BY MR. VARUGHESE:

3 Q Okay. I'm going to hand you 2080.

4 Turn to page 13.

5 A Okay.

6 Q So here on page 13 there's a list of
7 various products, but Dymista® is not listed here,
8 correct?

9 A That's correct.

10 Q And this document also doesn't say
11 anything about share of voice except as a comment
12 added to the slide?

13 A So, yes, it's a comment -- let me
14 think about that. I mean, so "Competitive SOV" is
15 the title of the slide -- SOV is share of voice --
16 and what they're looking at is the estimated
17 salesforce size, that they want to get information
18 on that.

19 And the purpose of this document that
20 I'm citing here is to say that Meda considered
21 share of voice to be very important for how they
22 were going to be able to sell the product, and so

1 they want to get information.

2 They have their own on
3 Astelin/Astepro® on the estimated salesforce size,
4 and they have question marks, indicating that they
5 want to get information on the salesforce size of
6 the other products so that they can assess share
7 of voice.

8 Q But in this document, does it say
9 anything about the importance of share of voice?

10 A I think it strongly implies that.

11 Q So you're inferring that from the
12 document?

13 A Yes, strong inference.

14 Q What's your basis for such a strong
15 inference?

16 A Because they want to study it.
17 They're looking at the estimated salesforce size,
18 along with the DTC spend, as something that they
19 need to study to assess the product's prospects.

20 Q Now, based on your experience in the
21 pharmaceutical industry, is this type of focus on
22 share of voice something that's atypical of

1 selling branded pharmaceutical products?

2 A No. Everybody considers -- share of
3 voice is very important, and I cite a document
4 indicating that share of voice is very important,
5 and in this case, obviously, this is no exception,
6 which is why also that other document indicated
7 that there's been less noise in the smaller share
8 of voice.

9 And I cite other documents indicating
10 that they consider -- Meda considers that a
11 competitive advantage that they're getting a
12 higher share of voice because of the loss of
13 the other -- the brand going generic and OTC.

14 Q So then how is share of voice relevant
15 to your commercial success analysis?

16 A It's in the nexus section. And
17 because share of voice is very important, and
18 because Meda -- or Dymista® is getting a very high
19 share of voice, that that indicates that it is a
20 significant contributor to the sales.

21 Q But if that's common for all branded
22 products, why would that preclude a finding of

1 commercial success?

2 A It's common to care about it. It's
3 not common to have a high share of voice,
4 especially -- I mean, they're getting close to a
5 hundred percent because there aren't many brands
6 towards the end of the period. But even early in
7 the period, they have a very high share of voice
8 for how small a product they are.

9 Q If I use the word "messaging," does
10 that have a meaning to you in this context?

11 A I'm not a marketing guy, but, I mean,
12 I have a vague understanding. It's a marketing
13 term.

14 Q What's your understanding? With the
15 caveat that it might be a vague understanding,
16 what is your understanding?

17 A Yeah, it's I guess what the -- one of
18 the things the salespeople are trying to convey to
19 the people they're selling to.

20 Q So that messaging content that
21 salesforce conveys to prescribers or consumers,
22 that would matter, right, the content of the

1 actual message?

2 MR. CHESLOCK: Object to the form.

3 THE WITNESS: Sometimes.

4 BY MR. VARUGHESE:

5 Q I mean, if I can be a little casual
6 here, and I'm not doing this to be silly, but a
7 sales rep can't just walk into a doctor's office
8 and talk about the weather, right? The content of
9 the sales pitch or the content of the messaging
10 matters in terms of driving sales, doesn't it?

11 A I can't say that categorically. It
12 may. As an example, I've referenced documents,
13 and it's been my experience too in just working
14 with pharmaceutical companies, you know, in a
15 litigation context, but also there are academic
16 studies that talk about the importance of
17 relationships, sampling, things that don't really
18 have a lot to do with the product per se.
19 Mr. Jarosz cited a document that talks about
20 persuasion versus information, those kind of
21 things.

22 So it can, but it's a continuum, and

1 the message may not be as important sometimes as
2 the relationship.

3 There may be other aspects: price,
4 copayment. I think one of the documents talk
5 about that physicians are happy that you only have
6 one copayment instead of two with Dymista®. So
7 things like that can enter in too.

8 So the messaging may or may not be
9 important. I should say messaging as I understand
10 messaging.

11 Q But the impact of the salesforce on
12 Dymista® sales, that's unknown, right?

13 MR. CHESLOCK: Object to form.

14 THE WITNESS: You know, I've indicated
15 that share of voice, and given citations and
16 reasoning that share of voice is important, and
17 that Dymista® had a very high share of voice. So
18 based on that, I conclude that salesforce was
19 important.

20 BY MR. VARUGHESE:

21 Q And, again, generally, and feel free
22 to look here, what's your basis for concluding

1 that Dymista® had a high share of voice? Compared
2 to what?

3 MR. CHESLOCK: Object to form.

4 THE WITNESS: Compared to most
5 pharmaceutical markets I've ever looked at,
6 because there are very few brands left that are
7 marketing by the time Dymista® came on the market.

8 And certainly as you go from the end
9 of 2012, basically 2013 to 2016, a large part of
10 the market had already gone generic, and more were
11 going generic, and they were going to OTC, which
12 means they're not marketing to physicians anymore.

13 And there's discussion that Meda is
14 considering that an opportunity, I think. It's in
15 one of those charts. It indicates that that's an
16 opportunity, and they're counting on that to be a
17 factor that helps their sales.

18 BY MR. VARUGHESE:

19 Q Is it fair to say that current brands
20 in the market would have the same opportunity to
21 increase their share of voice?

22 MR. CHESLOCK: Object to form.

1 THE WITNESS: Could you repeat that,
2 please?

3 BY MR. VARUGHESE:

4 Q Is it fair to say that current brands
5 in the market would have the same opportunity to
6 increase their share of voice?

7 A So the current brands in the market
8 primarily are brands that have generic
9 competitors. They have the opportunity to
10 increase their share of voice, but economically it
11 makes no sense because they would increase the
12 sales of the generics as much as -- more than
13 their own because they're automatically
14 substituted for those brands, and the vast
15 majority of sales are made to brands that have
16 generics.

17 There are two small -- well, actually,
18 I think there are one or two very small products
19 that it wouldn't make sense to have -- to increase
20 sales because they're not getting any more --
21 their sales are so small to begin with.

22 Q Let's turn to paragraph 38 of your

1 declaration.

2 A Okay.

3 Q So here you talk about how generic
4 erosion of the brand allergic rhinitis nasal spray
5 market is a primary contributor of Dymista®'s
6 increasing share of branded prescriptions?

7 A Yes.

8 Q And it appears, and we can look at it,
9 but in John Jarosz's declaration, paragraphs 22 to
10 33, it appears that you both agree on this point.

11 A Yes.

12 Q You know what, why don't we take a
13 break? We've been going for over an hour.

14 MR. CHESLOCK: Yeah, I was going to
15 say we've been going for about an hour.

16 MR. VARUGHESE: Yeah, we'll take a
17 break before I turn to that.

18 THE WITNESS: Okay.

19 (A break was taken at 9:49 a.m.)

20 (Resume at 10:01 a.m.)

21 BY MR. VARUGHESE:

22 Q Welcome back, Mr. Staines.

1 A Thank you.

2 Q So you understand that Dymista®, which
3 is the commercial embodiment -- strike that.

4 You agree that Dymista® is the
5 commercial embodiment of the '620 patent?

6 MR. CHESLOCK: Object to form.

7 THE WITNESS: If there are technical
8 things about embodiment that I don't understand,
9 I'll caveat it, but they're related, and I
10 understand that it practices features of the
11 patent.

12 BY MR. VARUGHESE:

13 Q Fair enough. Why don't I do this,
14 because I don't want to go through legalese. Let
15 me represent to you that our position is that
16 Dymista® is a commercial embodiment.

17 A Okay.

18 Q So the next line of questions, presume
19 that. Without conceding anything, just presume
20 that.

21 You understand that Dymista® is a
22 combination product of azelastine and fluticasone

1 put into a single dosage form?

2 A Yes, in general terms, yes.

3 Q Would you agree that that two-in-one
4 dosage form is more convenient than taking the two
5 separate nasal sprays separately?

6 MR. CHESLOCK: Objection to form.

7 THE WITNESS: I don't have much of an
8 opinion on that. It seems to me as a layman that
9 would be true.

10 BY MR. VARUGHESE:

11 Q And would you agree that that
12 convenience is a motivating factor for patients to
13 use Dymista®?

14 MR. CHESLOCK: Objection, outside the
15 scope.

16 THE WITNESS: Yeah, I don't know if
17 it's a -- I don't know. You know, given the
18 price, given other factors, I couldn't say that
19 for sure.

20 BY MR. VARUGHESE:

21 Q So in your analysis, you didn't
22 consider whether increased convenience is a driver

1 of sales?

2 A I've seen documents by researchers who
3 anticipated that it might be a factor. At the
4 same time, I've seen documents that indicate that
5 doctors didn't feel like it would be a significant
6 selling factor.

7 Q But for purposes of your analysis, I
8 understand you're saying that you've seen
9 documents, but your analysis, in your opinions,
10 did you consider whether convenience is a driver
11 of sales?

12 A Yeah. So I considered it in that
13 respect, that it didn't seem to be -- there was no
14 indication that it was a significant driver of
15 sales.

16 As a general matter, combination drugs
17 are considered minor improvements that don't have
18 a high value for physicians compared to efficacy
19 or safety differences. So in that regard, I
20 considered it a minor improvement, absent anything
21 that indicated it was a strong improvement.

22 Q So do you think that convenience is

1 motivating consumers to use Dymista®?

2 MR. CHESLOCK: Objection to form.

3 THE WITNESS: I can't say that it's
4 not at all, but it's not a primary factor. The
5 primary factors are the -- you know, indicate the
6 copayment, the share of voice, those kind of
7 things, get physicians to prescribe it. Those are
8 the things that are the primary drivers.

9 My opinion is that it's not -- the
10 convenience is not a primary driver.

11 BY MR. VARUGHESE:

12 Q So what's your basis for concluding
13 that you think the primary drivers are the rebates
14 and the salesforce as opposed to the convenience?
15 What factual support do you have for that?

16 MR. CHESLOCK: Object to form.

17 THE WITNESS: Well, okay. In the
18 report, I discuss how that copayment is an
19 important factor in sales, and that the copayment
20 program, copayment card that reduces the copayment
21 down to near generic levels is a significant
22 factor that increases sales.

1 The rebates are important where the
2 sales are made, where the rebates are accepted, to
3 get positioning on the insurers' formularies, good
4 positioning on the insurers' formularies, so that
5 they don't have the restrictions on reimbursement,
6 and that's a critical factor, and I have a lot of
7 citations indicating that that's a critical
8 factor.

9 And then the share of voice, as I
10 talked about. And, again, I have documents -- you
11 know, support for that. And then, obviously, as
12 we were looking at here, that in my opinion, that
13 Meda was counting on share of voice to be a
14 motivating factor.

15 So I look at those things, and I see
16 that those are important factors. And then I look
17 at the other side of the ledger, that Dymista®, as
18 a combination drug, does not have significant
19 incremental benefits for the reasons I discuss
20 there in the report, and so based on that, I
21 conclude that the primary factors are these
22 non-patent factors.

1

2

BY MR. VARUGHESE:

3

4

Q So what would you have to see to
conclude that Dymista® was a commercial success?

5

MR. CHESLOCK: Objection to form.

6

7

8

9

10

THE WITNESS: You know, that's such an
open-ended question. I'm not sure. I mean, I'd
need to see something that indicated that doctors
were finding it -- I mean, I don't know. That's
an open-ended question. I'm just not sure.

11

BY MR. VARUGHESE:

12

13

14

15

Q I guess I'm trying to understand a
little bit more about your opinions. You've
mentioned the rebate program, the salesforce, the
share of voice.

16

17

18

You know, if one of those things were
missing, then could you conclude that Dymista® was
a commercial success?

19

MR. CHESLOCK: Objection to form.

20

21

22

THE WITNESS: I'm not sure. You know,
I'd have to look at it and see -- look at it
without one of those things and see. So if

1 there's no share of voice and there's only the
2 rebates, there's no copayment card, I don't know.
3 I'd have to look at it. I don't know.

4 It could be that it is that case, but,
5 you know, that's not the facts I'm looking at
6 here.

7 BY MR. VARUGHESE:

8 Q You said earlier that the price for
9 Dymista® is near generic levels, and also that, in
10 your opinion, Dymista® has no more clinical
11 benefit than the individual ingredients
12 separately. So what do you think is driving
13 sales?

14 A High share of voice, good pricing,
15 rebates, and -- yeah, those things that I said.
16 You know, these drivers that I've mentioned,
17 that's what's driving the sales.

18 Q So why wouldn't physicians just tell
19 patients to take the generic Flonase® and
20 azelastine?

21 MR. CHESLOCK: Objection to form.

22 THE WITNESS: So they're being

1 marketed, and the high share of voice, you have
2 salespeople coming into your office and giving you
3 samples, free samples, giving you gifts, talking
4 with you, having relationships with you, talking
5 about the price is lower, the prices to your
6 patients may be lower than buying both the OTC and
7 the other drug, and giving you reasons like that.

8 I mean, I'm not entirely sure what
9 they're telling them, but it's not necessary that
10 you have an incremental benefit. I think I cite a
11 couple articles that indicate, especially with a
12 follow-on drug like this, it's a product
13 extension, or whatever we call it, that marketers
14 stop marketing the old product and market the new
15 product. And as you shift over to the new
16 product, they're basically saying, okay, instead
17 of Astepro®, or whatever I'm getting, I'm going to
18 start getting this one because that's what you
19 guys are marketing now.

20 BY MR. VARUGHESE:

21 Q So some of the things that you just
22 mentioned, the gifts, and maybe statements that

1 sales reps may make to physicians, you're just
2 talking in generalities? You don't have anything
3 in your declaration to show that Dymista® sales
4 reps are saying that, or what Dymista® sales reps,
5 what gifts they might be giving, correct?

6 MR. CHESLOCK: Objection to form.

7 THE WITNESS: That's right, I don't
8 have anything specific to Dymista®. This is just
9 kind of the general operating procedure when you
10 don't have a significant clinical benefit.

11 BY MR. VARUGHESE:

12 Q So that would be sort of the general
13 operating procedure for all pharmaceutical
14 companies selling branded products, correct?

15 A Yes.

16 Q So, I mean, under that reasoning, or
17 under your reasoning, there could never be a
18 commercial success then because these factors
19 apply to all branded drugs, correct?

20 MR. CHESLOCK: Objection to form.

21 THE WITNESS: No, because you can't
22 have incremental benefits that would get you much

1 larger sales.

2 BY MR. VARUGHESE:

3 Q So what kind of incremental benefits
4 would you need to see to conclude commercial
5 success for a drug?

6 A So in the hypothetical, I don't know.
7 Generally, efficacy benefits, safety
8 benefits, are the primary things.

9 I'm not saying compliance can never be
10 a factor, but it's much more rare that that's a
11 factor, and I've seen no indication here that it
12 is a primary factor in generating sales.

13 Q Are you aware that Dymista® has lower
14 side effects compared to the individual agents
15 alone?

16 MR. CHESLOCK: Objection to form.

17 THE WITNESS: So I understand that --
18 I've seen allusions to side effects, but not
19 necessarily safety. I'm not aware of any safety
20 differences.

21 BY MR. VARUGHESE:

22 Q What's the difference between side

1 effects and safety in your view?

2 A So the smell of the product. I
3 understand azelastine, that that can have a bad
4 smell, and certain other products have less of a
5 bad smell. So that, you know, Patanase® or
6 something didn't have the bad smell. I think I
7 read that. So that's an adverse side effect, but
8 not necessarily a safety issue.

9 Q So you mentioned safety and efficacy.
10 Do you think Dymista® is not safe or effective?

11 A I think it is because it wouldn't have
12 been FDA approved. I guess I should say, I didn't
13 specify, that it should have some superiority in
14 those aspects.

15 Q Superiority compared to what?

16 A Compared to alternative treatments.

17 Q To any alternative treatments?

18 A Yeah. If there's any alternative
19 treatment that's as good in efficacy and safety,
20 then I would say it has no incremental benefit.

21 Q You know, I'm not trying to be
22 sarcastic here. I guess I'm struggling to

1 understand your answer, because on the one hand
2 you're saying that it has to be shown to be
3 superior to alternative treatments, and then when
4 I said which alternative treatments? You said
5 alternative treatments that are as good.

6 So how can an alternative treatment be
7 as good as Dymista®, but then Dymista® still has
8 to be shown to be superior, in your view, to
9 become a commercial success?

10 A Yeah, I was kind of taking that as an
11 example of the alternative where it isn't
12 commercially -- so my point is that to be -- to
13 be a -- and I'm not saying commercial success.

14 To be a source of the commercial
15 sales -- and if the sales are commercially
16 successful, then they are -- but to be a source of
17 those sales, the drug should have superiority, for
18 instance, in safety and efficacy, and significant
19 superiority over an alternative -- the alternative
20 treatments, whatever. And if there's one
21 alternative treatment that is as good, then it's
22 no longer a source of -- or less likely not a

1 significant source of the sales.

2 Q So let's say saline nasal spray could
3 be a treatment for allergic rhinitis. Dymista® is
4 superior to a saline nasal spray.

5 Does that qualify?

6 MR. CHESLOCK: Objection, outside the
7 scope.

8 THE WITNESS: No, because there is an
9 alternative. If an alternative treatment exists
10 that gives you the same safety and efficacy as
11 Dymista®, if that's true, then I would say that
12 Dymista® has no incremental benefit.

13 BY MR. VARUGHESE:

14 Q Let's turn to paragraph 63 of your
15 declaration. So I'm looking at page 54, and I'll
16 read the sentence.

17 In characterizing the discount that
18 Dymista® offers, you say, "This 47% discount is
19 atypically large for innovative brand
20 pharmaceuticals that have no bioequivalent generic
21 competitors." Do you see that?

22 A Yes.

1 Q And then you cite the footnote 127,
2 which is Exhibit 1085. So I've handed you
3 Exhibit 1085. It's a document titled "Inside the
4 Secret World of Drug Company Rebates."

5 A Yes.

6 Q So in your view, what is a typical
7 discount, if you think Dymista®'s 47 percent is
8 atypical?

9 MR. CHESLOCK: Object to form.

10 THE WITNESS: I don't have in mind a
11 particular percentage that's typical or not
12 typical -- or that's typical.

13 I can say that when you're cutting
14 close to half the price off, that's atypical for a
15 drug that has incremental benefits.

16 BY MR. VARUGHESE:

17 Q So what if the discounts were at
18 25 percent? Would that be typical?

19 MR. CHESLOCK: Object to form.

20 THE WITNESS: You know, I'd have to --
21 I'd have to think about that. I wouldn't say
22 offhand that that's atypical, but I'd have to look

1 into it, and a lot depends -- not a lot. It
2 depends too on the drug itself that you're looking
3 at, you know, what particular position it's in.

4 Like here I'm saying for a nondrug
5 that does not have generic competitors, how
6 innovative is it? What particular class of
7 treatments is it used in? Things that I may not
8 think about. But I wouldn't necessarily consider
9 that atypical. That might be typical.

10 By the way, I should indicate, this is
11 rebates. It may also include like copayments and
12 those kind of things in here too, because this is
13 basically a gross-to-net difference, so it
14 includes rebates and other things.

15 BY MR. VARUGHESE:

16 Q Can what would qualify as a typical
17 discount in your mind vary according to product
18 segments? Like, for instance, let me give you an
19 example. Would what would be a typical discount
20 in the allergic rhinitis market be different from
21 what would be a typical discount in the
22 cholesterol market?

1 MR. CHESLOCK: Objection to form.

2 THE WITNESS: Only to the extent that
3 the economics of it are different. So, for
4 instance, how many competitors are there in the
5 market? How close are the competitors' products
6 in the market? Again, do they have generic
7 competition or not? You know, those kind of
8 economic factors.

9 BY MR. VARUGHESE:

10 Q In your declaration, or any of the
11 other supporting materials, did you identify or
12 investigate what would be deemed a typical
13 discount in the allergic rhinitis nasal spray
14 market?

15 MR. CHESLOCK: Objection to form.

16 THE WITNESS: I did not. Other than
17 to understand the economics of that market, I
18 don't have any information on what rebates those
19 other guys -- the other products charge.

20 BY MR. VARUGHESE:

21 Q I guess --

22 A Or provide.

1 Q Sure. What I'm asking is, someone
2 reading your declaration, what benchmark or frame
3 of reference do they have to understand why
4 47 percent is atypical?

5 A So I've indicated here that there are,
6 looking at a lot of drugs across a lot of
7 different classes, that the majority of those are
8 far less than 47 percent, and so based on --
9 that's one basis.

10 I also have -- I think in another
11 place I've cited a CBO study that indicates that
12 drugs that are -- that have -- are innovative, the
13 more innovative drugs provide very small discount,
14 very small rebate percentages.

15 And so as a general pharmaceutical
16 matter, that rebates of 47 percent, where you cut
17 off half the price basically, half the list price,
18 that those are comparatively large.

19 Q So looking at page 2 of 3 of
20 Exhibit 1085, the document that you cite, there's
21 a list of drugs there, but none of them are
22 allergy drugs, correct?

1 A Well, Singulair® is actually used for
2 allergies. It's also used for asthma, but a
3 significant part of its sales are for allergies,
4 and --

5 Q Again -- I'm sorry. Go ahead, finish.

6 A I would just say I'm not sure -- well,
7 there might be one other sure, but I'm not sure,
8 so I won't say.

9 Q And that's fair. So Singulair® and
10 Advair® is used for asthma, so let me just
11 identify that. But I guess there's no nasal spray
12 here, allergic rhinitis nasal spray?

13 A That's true.

14 Q And in this chart that you cite for
15 Nexium®, you see that the rebate there is at
16 61 percent, which is well higher than the
17 47 percent that you've identified for Dymista®,
18 correct?

19 A That's correct, and that's atypically
20 large. I might add too that Nexium® is considered
21 a follow-on product that has a lot -- has very few
22 incremental benefits over Prilosec®.

1 Q So this document that you relied on,
2 this is dated 2012?

3 A I'm not sure.

4 Q Right above the title there's a date
5 on there, May 10, 2012.

6 A Yes.

7 Q The 47 percent discount that you've
8 identified for Dymista®, that's from 2016 sales
9 figures, correct?

10 A I believe that's correct, yes.

11 Q So if we go to Exhibit 2a of your
12 declaration --

13 A Yes.

14 Q -- Exhibit 2a, when you look at
15 line 14, if we go to Dymista®'s sales from 2012
16 and 2013, around the time this paper published,
17 the discounts were 23 percent and 31 percent
18 respectively, correct?

19 MR. CHESLOCK: Object to the form.

20 THE WITNESS: Yeah. By the way, the
21 47 percent looks like it's 2015, not 2016, but
22 yes.

1 So the end of 2012 is 23 percent, and
2 2013, 31 percent off the list price.

3 BY MR. VARUGHESE:

4 Q Would you consider those to be typical
5 discounts?

6 A I haven't formed an opinion on that,
7 and I can't say as I sit here. I'd have to, you
8 know, study it a little more.

9 Q So you can't give me an answer to that
10 question right now?

11 A That's correct.

12 Q So let's go to paragraph 59 of your
13 declaration.

14 A Okay, I'm there.

15 Q So in paragraph 59, you talk about how
16 Dymista® ranks near the bottom of the top 200
17 drugs from 2010 gross revenue listing.

18 A Yes.

19 Q I guess one question is why is 2010
20 revenue listing even relevant if Dymista® didn't
21 hit the market until 2012?

22 A My point here is a general point to

1 indicate that that brand drugs, usually without
2 generic competition, have to generate -- sales for
3 brand drugs are generally larger comparatively
4 than in other industries. So it's kind of that
5 general point that I'm trying to make.

6 I looked at 2010 because that's the
7 last -- I think I indicate that in a footnote or
8 somewhere -- that that's the last year that this
9 list of 200 was available. So I just kind of look
10 at that as a general indicator of what in a
11 particular year snapshot, what brand drugs -- what
12 the sales of brand drugs are. And so it's just a
13 general comparator of what you might expect brand
14 drugs to make.

15 Q Would a drug, a branded drug, need to
16 be in sort of the higher end or top of the list in
17 order for it to qualify as a commercial success?

18 A No, not necessarily. My point is more
19 general than that, just that, again, brand drugs
20 typically generate large sales. So that if you
21 have \$100 million in sales, that by itself doesn't
22 tell you that those sales are significant. That's

1 my point.

2 Q Let's turn to paragraph 50 of your
3 declaration. So in paragraph 50 -- let's see
4 here. We'll come back to that. Let's actually
5 switch gears.

6 A Okay.

7 Q So you understand that Flonase®,
8 active ingredient being fluticasone, is a steroid
9 nasal spray?

10 A Yes, that's my understanding.

11 Q And some years ago, Flonase® went both
12 OTC and became a generic.

13 A It went generic first, and then more
14 recently went OTC, yes.

15 Q And OTC meaning over the counter and
16 not prescription?

17 A Yes.

18 Q And if you don't like -- I'm going to
19 use a word that you may say is ambiguous, and I'm
20 happy to use a different word, but do you agree
21 that the market tended to become more hostile to
22 branded drugs, branded prescription nasal sprays,

1 once Flonase® went OTC and went generic?

2 MR. CHESLOCK: Objection to form.

3 THE WITNESS: Yeah, I'm sorry, I'm
4 going to have to -- I don't know what you mean by
5 "hostile." Yeah, I need you to define "hostile" a
6 little more.

7 BY MR. VARUGHESE:

8 Q Sure. So, you know, branded nasal
9 sprays having to compete with Flonase®, that was
10 generic, and also now OTC, made it more
11 challenging for those branded nasal sprays to
12 maintain or continue to grow their market share?

13 MR. CHESLOCK: Objection to form.

14 BY MR. VARUGHESE:

15 Q If you disagree with that, that's fine
16 too.

17 A Not necessarily.

18 Q You don't think that the availability
19 of generic Flonase®, and also the availability of
20 Flonase® over the counter without having to go to
21 a physician, you don't think that presented a
22 challenge for branded prescription nasal sprays?

1 MR. CHESLOCK: Objection to form.

2 THE WITNESS: So what I believe is
3 that generics and over-the-counter have certain
4 advantages and disadvantages compared to brands,
5 and, you know, how they work out these advantages
6 and disadvantages is kind of an economic matter.

7 For instance, generics are cheaper,
8 and so that will make it harder on a brand if they
9 keep their price up. So more competition is going
10 to make it more difficult for a brand to get sales
11 if nobody else is competing on price.

12 On the other hand, without as much
13 marketing -- again, this share of voice idea --
14 the brands might actually do better as a result of
15 the shift over to OTC and generic.

16 BY MR. VARUGHESE:

17 Q Let's go to Exhibit 4 of your
18 declaration.

19 A Okay.

20 Q And even before we go to Exhibit 4,
21 I'd like to go to Exhibit 1, page 1 of 2.

22 A Okay.

1 Q Based on this chart that you have
2 here, I just want to establish for the record, and
3 please correct me if I'm incorrect here, that
4 several products -- Veramyst®, Dymista®, Astepro®,
5 Patanase®, Qnasl®, Omnaris®, and Zetonna® -- all
6 launched after Flonase® went generic.

7 Is that accurate?

8 A I believe that's true.

9 Q Now turning back to Exhibit 4, and if
10 we start with -- so this is a -- this is your
11 exhibit. Why don't you just briefly describe for
12 the record, what is this?

13 A This compares annual sales for the
14 brand nasal spray products that Mr. Jarosz had
15 analyzed in his exhibit, and it has the sales
16 for -- reports the sales for brand products before
17 generic entry, for those that had generic entry
18 after Dymista® -- sorry, before Dymista® came on
19 the market.

20 So, for instance, Flonase®, the sales
21 number is taken I think from 2005 or '06 before
22 generic Flonase® came on the market, with the idea

1 of giving an apples-to-apples comparison.

2 Q So my first question is, so this
3 describes peak-year sales, so --

4 A Let me amend that. I would like to
5 put peak-year sales, in many cases it is peak-year
6 sales, but I didn't have a full time series, so it
7 may be that some of these products actually made
8 more sales than I have here, but they were the
9 highest I could find.

10 Q And we don't know peak-year sales of
11 Dymista® yet, right, because the sales are
12 ongoing?

13 A We don't know. Anything's possible.
14 It sure looks like the sales quantity is leveling
15 off.

16 But I just might add too, again, for
17 purposes of commercial success, I'm looking at
18 actual sales, not what sales they may get.

19 Q Sure. And then as you mentioned, the
20 bar Flonase® there might have been 2005, whereas
21 the sales from Dymista®, or some of these other
22 products, from 2016. So we're not comparing sales

1 in a given market period?

2 MR. CHESLOCK: Objection to form.

3 THE WITNESS: What do you mean we're
4 not comparing sales in a given market period?

5 BY MR. VARUGHESE:

6 Q So, for instance, the market might
7 have resembled something in 2005, and the market
8 could look very different in 2016, isn't that
9 true?

10 A Yes, yes.

11 Q With respect to competitors.

12 A Yes, there would be -- right, there's
13 more marketing, you have to compete with other
14 brands, more marketing from other brands, things
15 like that are different back in 2005-06 than they
16 are in 2012, when there's a lot of generics now in
17 the market and there's less marketing to compete
18 with.

19 Q And now if we look at this chart,
20 starting with Veramyst®, the list of drugs there,
21 it's the same list that a few minutes ago I had
22 enumerated as products that launched after

1 Flonase® went generic.

2 A Yes, a lot of these are.

3 Q And of those products, Dymista® is
4 number two in sales, correct?

5 A Yes, I believe that's true.

6 Q And then, in fact, there are five
7 other products that have lower sales than Dymista®
8 when you look at that category.

9 A Yes.

10 Q So looking at Dymista®'s success in
11 the post Flonase® going generic era, isn't that a
12 better indicator of Dymista®'s performance in the
13 marketplace than comparing it to something in
14 2005?

15 MR. CHESLOCK: Objection to form.

16 THE WITNESS: No, I disagree with
17 that. The sales of these other products, in my
18 opinion, are also very likely -- I need to look at
19 them more closely -- are very possibly
20 commercially unsuccessful as well. And I think I
21 indicate in my report where some of the studies
22 cited extensively by Mr. Jarosz consider these

1 products all disappointments, that they fail to
2 get the sales that they anticipated getting.

3 For instance, Patanase® didn't show
4 any incremental benefit over the drugs that it was
5 compared to; and companies' drugs of the dry
6 version rather than the wet version of the
7 previous product, so they're follow-on products,
8 so I would consider these all unsuccessful.

9 And if I were an innovator looking --
10 and the patented features of Dymista® had been
11 obvious, for instance, or any of these products
12 had been obvious, I would have hoped to have made
13 more sales than any of these products made, and it
14 may be because there's a lot of generic
15 competition that wasn't anticipated when these
16 guys decided to invest in these products, and now
17 those are all sunk costs, so they get on the
18 market and they make whatever sales they can.

19 BY MR. VARUGHESE:

20 Q So you think the lower sales figures
21 for these products reflect the higher number of
22 generics in the marketplace now?

1 MR. CHESLOCK: Objection to form.

2 THE WITNESS: That may be part of it,
3 but as I indicated, the products themselves also
4 were not deemed to have significant benefits over
5 the alternatives.

6 BY MR. VARUGHESE:

7 Q So looking at this chart, which one of
8 these drugs would you say was a commercial
9 success?

10 MR. CHESLOCK: Objection to form.

11 THE WITNESS: I mean, I couldn't. I'd
12 have to look at a lot more evidence surrounding
13 them, you know, what the investment was in the
14 products, et cetera, what was expected. But, I
15 mean, to look at it, a billion dollars seems to me
16 likely to be a commercial success, but I'd still
17 have to look at it to know.

18 The lesser amounts, maybe. It's
19 possible that sometimes that a product could be --
20 I'm not saying a product that's a hundred million
21 or less is necessarily not a commercial success,
22 but in this context, what I'm looking at here for

1 Dymista®, it's my opinion that it's not.

2 BY MR. VARUGHESE:

3 Q Let's turn to paragraph 106 of your
4 declaration.

5 A Okay.

6 Q So you testified there that any
7 alleged commercial success must be driven
8 primarily by the claimed invention, correct, and
9 not by other factors unrelated to the features of
10 the claimed invention?

11 A That's my understanding.

12 Q So what's your understanding of the
13 claimed invention here?

14 MR. CHESLOCK: Objection to form.

15 THE WITNESS: I'm assuming, for
16 purposes of this report and my analysis, that
17 Dymista® is the claimed invention.

18 BY MR. VARUGHESE:

19 Q And what's your basis for that
20 statement that we just discussed?

21 A I guess one of the bases is that
22 Mr. Jarosz has assumed that it embodies --

1 Dymista® embodies the patented features.

2 Q I'm sorry, let me clarify the
3 question. Your statement in 106, or your opinion
4 in 106 that any alleged commercial success must be
5 driven primarily by the claimed invention and not
6 other factors unrelated to the claimed invention,
7 what's your basis for that opinion?

8 A I guess, first of all, instructions by
9 the attorneys -- and not just this attorney, but
10 previous cases -- that that's what they've
11 indicated I or the people I'm working with should
12 be looking for.

13 It's my layman's reading of the
14 J.T. Eaton case, and then I've looked at other
15 documents too. I think there's that Lemley
16 article that talks in those terms that indicates
17 something along those lines.

18 Q So how much of the commercial sales
19 need to be driven by the claimed invention in
20 order for that to be primary in your view?

21 MR. CHESLOCK: Objection to form.

22

1 BY MR. VARUGHESE:

2 Q Let me rephrase that actually. It's a
3 bad question.

4 In order for you to conclude that the
5 sales are driven primarily by the claimed
6 invention, how much of the sales have to be
7 attributable to the claimed invention for that to
8 be primary in your view? More than 50 percent?

9 MR. CHESLOCK: Objection to form.

10 THE WITNESS: I don't have a
11 threshold. You know, when I look at it and I look
12 at all the factors, and there might be some that
13 are gray areas that, you know, I don't know if
14 they're a commercial success or not, and that's
15 very possible. But in this case, I can see that,
16 for the reasons I've said before, that it's not a
17 close call in my opinion.

18 BY MR. VARUGHESE:

19 Q So that first sentence in
20 paragraph 106 you say, "I understand that the
21 commercial success of a product must be
22 attributable to the allegedly novel features of

1 the claimed invention to represent a secondary
2 indicium of a patent's nonobviousness," correct?

3 A Correct.

4 Q What in your view are the novel
5 features of the claimed invention here?

6 MR. CHESLOCK: Objection, outside the
7 scope, also to form.

8 THE WITNESS: So for purposes of what
9 I'm doing here, as I mentioned earlier, I'm
10 looking at does the product that practices those
11 features and the attributes of the product from
12 those features bestow an incremental benefit over
13 any alternatives that could do the same thing --
14 that couldn't do the same thing.

15 If there is an alternative that can do
16 the same thing, then I would consider that not a
17 novel feature.

18 BY MR. VARUGHESE:

19 Q Do you have an understanding,
20 Mr. Staines, of what novel features of the claims
21 of the '620 patent are?

22 MR. CHESLOCK: Objection to scope,

1 also to form.

2 THE WITNESS: Yeah, I don't have a
3 layman's understanding. Again, I've looked here
4 to look at the features of Dymista® that are
5 different than alternative treatments, and that's
6 what I've looked at.

7 I've assumed that -- I think I've
8 assumed that all the features of Dymista® are in
9 some way or form claimed in the patent, but I
10 don't have a technical knowledge really of what
11 specific things -- to the extent Dymista® has
12 things that are not claimed in the patent, I don't
13 know that.

14 BY MR. VARUGHESE:

15 Q So now your counsel, Mr. Cheslock, has
16 stated twice the objection that it's outside of
17 the scope when I asked you what the novel features
18 of the claims are.

19 Do you think that's outside the scope
20 of your declaration and understanding of the novel
21 features of the claims of the '620 patent?

22 A Yes, because "novel" has legal

1 implications that I'm just not aware of. So when
2 I say something is novel, I'm using it in a
3 layman's sense.

4 To the extent that "novel" has some
5 patent law implication here, I'm not using it in
6 that sense, and I don't have an opinion in that
7 way.

8 Q Let's turn to paragraph 108 of your
9 declaration.

10 A Okay.

11 Q So in paragraph 108, you talk about
12 how the development of an azelastine-fluticasone
13 combination formulation was blocked by previously
14 issued patents, right?

15 A I refer to the Petitioner's
16 allegations of that, yes.

17 Q Okay. By Petitioner, you mean
18 Argentum?

19 A Yes.

20 Q The Petition?

21 A Yes.

22 Q So that's what you're referring to,

1 okay. So I was going to ask you, when did you
2 first develop this opinion? Was that from having
3 read the Petition?

4 A Yeah, so I'll say that this is not my
5 opinion. I'm looking at the allegation, and then
6 concluding that if that allegation is true, then I
7 guess it's kind of obvious -- maybe it's not --
8 but Merck and Teva, or there's some case I think
9 that talks about that if you have a blocking
10 patent, that then you can't have commercial
11 success, so ...

12 Q I just -- you know, we attorneys just
13 throw around case names, and it's pretty funny to
14 hear someone from another field say Merck and Teva
15 something. So I wasn't laughing at you, I just
16 thought it was pretty humorous.

17 Do you know what a blocking patent is?

18 A You know, probably not. I mean, I
19 have a layman's understanding that it blocks you
20 from developing something that you otherwise
21 would, but, no, I don't think I really do.

22 Q Do you know or have any evidence

1 whether someone was actually blocked by these
2 patents?

3 A Yeah, I don't.

4 Q That's fine. If you know.

5 A Yeah, I don't.

6 Q Are you familiar with something called
7 the safe harbor provision, the FDA safe harbor
8 provision, as it relates to patent law?

9 A Yes.

10 Q What is that? What is your
11 understanding of that?

12 A My understanding is that a company can
13 start to develop a product without violating the
14 patent as long as it doesn't market it.

15 Q Do you know which patents are these
16 allegedly blocking patents?

17 A I talk about the Phillipps patent,
18 which applies to the fluticasone component of
19 Dymista®, and then the Hettche patent, which
20 applies to the azelastine component.

21 Q And as you sort of acknowledge
22 there -- or you may not acknowledge, but you

1 understand that those patents expired in 2004 and
2 2012 respectively?

3 A Yes.

4 Q And when was Dymista® launched?

5 A Well, it ended up being launched I
6 think September 2012. I think it was supposed to
7 be launched before then, but, yes, I think it was
8 then. It was approved May 2012 I think, yeah.

9 Q And do you have an understanding as to
10 whether Dymista® launched after these patents had
11 expired?

12 A Yes. So September 2012 is after the
13 latest patent, May 2012, and certainly after
14 May 2004, so it launched after they expired.

15 Q So these patents wouldn't have blocked
16 someone from launching alongside Dymista®,
17 correct?

18 MR. CHESLOCK: Objection to form.

19 THE WITNESS: You know, I don't have
20 an opinion on whether they actually do block or
21 not. It's possible that they could.

22 I could foresee that they would

1 inhibit or impede somebody from developing a
2 product if they're not sure when somebody is going
3 to launch or when they're going to be able to
4 launch, and that would be an impediment or
5 disincentive to develop.

6 BY MR. VARUGHESE:

7 Q If someone had wanted to develop a
8 combination azelastine-fluticasone product, and if
9 they wanted to launch in 2012, they could have
10 developed it and received approval after the
11 expiration of the Hettche patent in 2012, correct?

12 A Not an expert opinion, but logically
13 what you're saying seems reasonable, but I don't
14 know the ins and outs of patent law and how
15 exactly it would block or not block it.

16 MR. VARUGHESE: All right,
17 Mr. Cheslock, I don't have anything further.

18 MR. CHESLOCK: Okay. Let me take a
19 short break.

20 (A break was taken at 10:51 a.m.)

21 (Resume at 10:53 a.
22 m.)

1 REDIRECT EXAMINATION BY COUNSEL FOR PETITIONER

2 BY MR. CHESLOCK:

3 Q So, Mr. Staines, I'm going to hand you
4 what will now be marked, if the court reporter
5 could mark it, Exhibit --

6 MR. VARUGHESE: No, hold on.

7 Mr. Cheslock, can I just see that
8 before you mark it?

9 MR. CHESLOCK: Sure.

10 MR. VARUGHESE: So we received this
11 from Mr. Houston yesterday by email, and our
12 position is that this is not a part of the record,
13 and that if Petitioner wants to get this into the
14 record, he needs to seek leave from the Board, get
15 it in that way. We're going to object to this
16 being marked at this deposition.

17 MR. CHESLOCK: Okay. We disagree with
18 that. The changes in the errata are, you know,
19 clerical in nature, and we'll take it up after the
20 deposition I guess.

21 MR. VARUGHESE: Yeah. I mean, we
22 think that's the proper course.

1 MR. CHESLOCK: Okay. We disagree with
2 that, but we can address that after the
3 deposition.

4 MR. VARUGHESE: Okay.

5 MR. CHESLOCK: So you can keep that
6 copy. Can you mark this as --

7 MR. VARUGHESE: No, no, I'm sorry, I
8 can't allow it to be marked. So if you want to
9 get it in through the Board -- let me just
10 articulate.

11 I think if you try to mark it, we're
12 going to have to stop the deposition and call the
13 Board because we don't want to get it into the
14 record. We don't think it belongs in the record,
15 but if you think it does, the proper course is you
16 have to email the Board and see if you can get it
17 in that way.

18 We don't want to get it in through the
19 deposition. And if you try to mark it, then we're
20 going to have to call the Board to see if the
21 Board will authorize it.

22 MR. CHESLOCK: Okay. Can you give

1 me -- let's take a break, and I'll confer with my
2 colleague and see what he wants to do.

3 MR. VARUGHESE: Sure.

4 MR. CHESLOCK: Okay.

5 (A break was taken at 10:54 a.m.)

6 (Resume at 11:03 a.m.)

7 MR. CHESLOCK: Okay, so now that we're
8 back on the record, you've passed the witness to
9 us in the deposition, and so our position is you
10 can't prevent us from introducing any exhibits
11 during the deposition. So that's the first point.

12 The second point is if for whatever
13 reason you have an objection to the document
14 itself being introduced as an exhibit, then we
15 would simply have Mr. Staines go through and read
16 into the record the changes that he made after
17 doing a detailed review of his declaration, and
18 these are simply corrections that he identified as
19 he went through, and so I'm struggling to
20 understand how there could be an objection to
21 that.

22 And, of course, there's a process for

1 excluding evidence in this proceeding, and so if
2 you have some objection to either the document or
3 the errata changes, you can certainly seek to
4 exclude it at that time, which is precisely what
5 that process is for.

6 MR. VARUGHESE: So I think if the
7 Board agrees with you, Mr. Cheslock, obviously
8 we're going to have to be bound by that.

9 Our position is that in reviewing the
10 sheet -- number one, our experience is the Board
11 doesn't even like errata sheets with depositions,
12 but this, to us, resembles supplementation or
13 changing of Mr. Staines' testimony that was in his
14 declaration.

15 So if that's your position, then I
16 think we should call the Board and see what the
17 Board says. If the Board allows you to do that,
18 then that's fine, but I don't think the Board
19 will, so that's our position. We'd like to call
20 the Board before you do that.

21 MR. CHESLOCK: Okay. You know, I
22 think that given the mostly clerical nature of the

1 changes in this errata, I think calling the Board
2 isn't a requirement, but if want to do that, then
3 I guess we can use the hotline for that, but our
4 position would be that I think it's a big waste of
5 time, and there shouldn't be any impediment for
6 Mr. Staines, who prepared these errata changes, to
7 provide them in his deposition on his declaration.

8 MR. VARUGHESE: I think the Board
9 needs to look at this because we don't agree that
10 it's just merely clerical in nature.

11 For example, for a number of these
12 entries, you are adding exhibits and adding
13 citations; that's supplementing his testimony. We
14 don't think that's clerical in nature, that's
15 actually substantively changing his testimony, and
16 that's why we think the Board should be aware of
17 that. Otherwise, this would be effectively
18 supplementing his testimony after the date for it.

19 MR. CHESLOCK: Well, again, we
20 disagree with that. These are simply corrections,
21 and they're clearly a product of him preparing for
22 his deposition, identifying errors that were made

1 in the original declaration.

2 MR. VARUGHESE: Do you have a
3 conference phone?

4 MR. CHESLOCK: Yeah, we do.

5 MR. VARUGHESE: I have the numbers of
6 the Trial Division.

7 THE REPORTER: Do you want to go off
8 the record for a moment?

9 MR. VARUGHESE: Sure.

10 (Off the record at 11:06 a.m.)

11 (A call was placed to PTAB, and the
12 following is a transcription of the
13 phone call:)

14 MR. VARUGHESE: Hi, my name is Dennies
15 Varughese. We're calling from the law firm of
16 Foley & Lardner. We're in the middle of a
17 deposition, and we have an issue that arose that
18 we think needs to get some clarification from a
19 PTAB judge.

20 MR. KELLOGG: Okay, no problem amount
21 of time all. Can I get a phone number that I can
22 reach you in the deposition?

1 MR. VARUGHESE: Sure. (267) 978-4287.

2 MR. KELLOGG: Okay. Can I get the
3 case number?

4 MR. VARUGHESE: Yes. It's
5 IPR2017-00807.

6 MR. KELLOGG: 00807. Okay, let me
7 confirm that one more time. (267) 978-4287?

8 MR. VARUGHESE: Correct.

9 MR. KELLOGG: Okay. If the judges are
10 available, we will be calling you to set up a
11 call, otherwise we advise you just to continue as
12 best you're able.

13 MR. VARUGHESE: Okay. Our deposition
14 is actually completed now. We're happy to wait.
15 Do you have any sense for timing, sir?

16 MR. KELLOGG: All of the -- all of
17 the -- all of the judges are at work today. I
18 don't know what their schedules are. They usually
19 confer before they take the call. It really
20 varies. I'll tell them that you're -- the
21 deposition has been -- that you're available at
22 the moment.

1 MR. VARUGHESE: Okay, great. Thank
2 you so much.

3 MR. KELLOGG: Thank you, bye.

4 (Off the record at 11:09 a.m. to wait
5 for a return phone call.)

6 (Resume at 11:26 a.m.)

7 MR. VARUGHESE: Hello. This is
8 Dennies Varughese.

9 MR. KELLOGG: Hi, this is Andrew
10 Kellogg. I'm calling from PTAB Board.

11 MR. VARUGHESE: Hi. And I'm sorry, we
12 have a little bit of a poor connection.

13 What's your last name, Judge?

14 MR. KELLOGG: No, I'm not the judge.
15 I'm actually the person you spoke to earlier.

16 MR. VARUGHESE: Oh, okay.

17 MR. CHESLOCK: This is Andrew Kellogg.

18 MR. KELLOGG: The judges had asked --
19 wanted clarification on why you need a call now
20 that the deposition is over?

21 MR. VARUGHESE: Sure. So I'm the lead
22 counsel for Patent Owner, Cipla. We took the

1 deposition of Mr. Staines, economist expert for
2 the Petitioner, and then on redirect -- and I want
3 to let counsel for Petitioner talk -- but counsel
4 for Petitioner tried to mark an errata sheet to
5 Mr. Staines' declaration, and our position is that
6 that errata sheet actually substantively
7 supplements his declaration, and for that reason
8 is improper, and we felt that Petitioner needs to
9 seek authorization from the Board to get that into
10 the record and they can't simply mark it or read
11 it in as part of the deposition.

12 With that, I'll turn it over to
13 Mr. Cheslock.

14 MR. CHESLOCK: Hi, Andrew. This is
15 Andrew Cheslock.

16 So just to clarify it from our
17 perspective, the errata sheet is a series of
18 corrections that Mr. Staines had identified
19 through the course of his preparation for the
20 deposition, and so our position is that
21 Mr. Staines should be afforded the opportunity to
22 make those corrections.

1 And given the fact that it's my
2 portion of the deposition, it's Patent Owner's
3 burden to explain why in the interest of justice
4 these changes shouldn't come in. And other than
5 trying to rely on some of the errors in the
6 future, it's unclear why Mr. Staines shouldn't be
7 allowed to make these corrections.

8 MR. VARUGHESE: So, Andrew, this is --
9 I'm sorry, go ahead.

10 MR. KELLOGG: I'm forwarding that to
11 the panel right now. I don't know how long it
12 will take to get back to you. If you're hanging
13 out just waiting for us, we may schedule a call
14 down the line. That issue seems like something
15 that can be dealt with down the line since the
16 deposition is already over and the expert has
17 left.

18 MR. VARUGHESE: We're fine with that
19 for Patent Owner.

20 MR. CHESLOCK: We'd like to try and
21 clarify this today, if possible.

22 MR. KELLOGG: No problem.

1 MR. VARUGHESE: And I'm going to give
2 you a different phone number to call back, Andrew,
3 if that's okay.

4 MR. KELLOGG: Okay.

5 MR. VARUGHESE: (374) 722-0306.

6 MR. KELLOGG: Not a problem at all,
7 thanks.

8 MR. VARUGHESE: Thank you, appreciate
9 it.

10 (Off the record at 11:29 a.m.)

11 (Mr. Varughese left and was not
12 present the remainder of the
13 deposition.)

14 (Placing phone call to PTAB at
15 12:19 p.m.)

16 RECORDING: You have reached PTAB ...

17 (Pause in the proceedings.)

18 (Placing call again at 12:24 p.m.)

19 RECORDING: You have reached PTAB ...

20 (Pause in the proceedings.)

21 (Placing call again at 12:30 p.m.)

22 RECORDING: Sorry, Andrew Kellogg ...

1 (Pause in the proceedings.)

2 (Placing call at 1:07 p.m.)

3 MR. KELLOGG: Hello?

4 MR. CHESLOCK: Yes, hi, may I speak to
5 Andrew Kellogg, please?

6 MR. KELLOGG: Speaking.

7 MR. CHESLOCK: Oh, Andrew, hi. This
8 is Andrew Cheslock. We called earlier with
9 respect to a deposition, and we think that there
10 may have been a lack of clarity. The witness is
11 still here. It's just --

12 MR. KELLOGG: Oh, the witness is still
13 there? Let me --

14 MR. CHESLOCK: Yeah, and so we thought
15 maybe that was the issue in terms of having not
16 heard back from you, and we'd like to -- you know,
17 we're either going to do one of two things.

18 If we can get clarification from the
19 Board today, hopefully within a reasonable amount
20 of time, we can do that, otherwise my position is
21 we're just going to move forward and let Patent
22 Owner state their objection on the record.

1 MR. KELLOGG: Let me call one of the
2 judges. I don't think we understood that the
3 witness was waiting.

4 MR. CHESLOCK: Okay. And then you
5 still have the callback number, right?

6 MR. KELLOGG: Yeah, yeah.

7 MR. CHESLOCK: Okay. And do you think
8 you'd be able to get back to me relatively
9 quickly?

10 MR. KELLOGG: I'm going to flag it.

11 Let me -- I'm going to call one of the
12 panel members.

13 MR. CHESLOCK: Okay.

14 MR. KELLOGG: We will get back to you
15 as soon as we can.

16 MR. CHESLOCK: Okay. So, yeah, I'll
17 say that if we don't hear back from you by 1:30,
18 then we're just going to go forward, and that's
19 going to be our position, and Patent Owner can do
20 what it wants to do.

21 MR. KELLOGG: Okay.

22 MR. CHESLOCK: Okay?

1 MR. KELLOGG: No problem.

2 MR. CHESLOCK: All right, thank you.

3 (Off the record at 1:08 p.m.)

4 (Phone call received at 1:10 p.m.)

5 MR. CHESLOCK: Andrew?

6 MR. KELLOGG: Yes, speaking.

7 MR. CHESLOCK: Yes, hi. This is
8 Andrew.

9 MR. KELLOGG: Hi. I just wanted to
10 tell you I just talked to one of the panel
11 members. There's going to be a call at 1:30. I'm
12 going to circulate the call-in info now.

13 MR. CHESLOCK: Oh, thank you so much.

14 MR. KELLOGG: All right, no problem.
15 Bye.

16 (Off the record at 1:10 p.m.)

17 (Pause in the proceedings waiting
18 for conference call to begin.)

19 (Resume at 1:30 p.m. with call from
20 Judge Moore.)

21 MR. LaROCK: Hello. This is Adam
22 LaRock, counsel for Patent Owner.

1 MR. CHESLOCK: Hi. This is Andrew
2 Cheslock, counsel for Petitioner.

3 THE COURT: Okay. This is
4 Judge Moore. Could somebody fill me in on what's
5 going on?

6 MR. LaROCK: Sure, I'll start. This
7 is Adam LaRock.

8 So we had the deposition of
9 Petitioner's reply witness, Mr. John Staines, and
10 that was today, and last night --

11 THE COURT: Is the witness still in
12 the room?

13 MR. LaROCK: The witness is still
14 here; he's not in the room.

15 THE COURT: Okay.

16 MR. LaROCK: And last night we
17 received what's styled as an errata sheet to his
18 declaration with some changes. It's our position
19 that those changes are meaningful.

20 And during the deposition today, we
21 asked the witness a bunch of questions. The
22 witness never once directed himself or any of his

1 answers -- caveated any of his answers to needing
2 to refer to his errata sheet.

3 We concluded our portion of the
4 deposition and passed the witness, and on
5 redirect, counsel for Petitioner has tried to
6 enter into the record this errata sheet that we
7 received last night, so that's kind of where we
8 are just procedurally.

9 THE COURT: Okay.

10 MR. CHESLOCK: Your Honor, if I may,
11 I'd like to sort of give our understanding of the
12 situation.

13 So as has been mentioned, the witness
14 is still here. The exhibit or the table that's
15 being referred to here is something that
16 Mr. Staines himself created to provide some
17 corrections to his existing testimony. That
18 testimony is still ongoing, he's still here, and
19 so our position is that there isn't any reason why
20 Mr. Staines can't correct his current testimony,
21 and the table is really just a more efficient way
22 of doing that instead of having him read each and

1 every one of the changes.

2 And as far as I'm concerned, unless
3 Mr. LaRock has a different opinion, I don't
4 believe that any of the changes actually came up
5 during any of the line of questioning today, and
6 so Petitioner's position is that it makes sense
7 also for the Board to have these corrections, and
8 the most efficient way to do it is to just simply
9 mark the table that Mr. Staines himself created as
10 an exhibit and have that as part of the record,
11 and if Patent Owner cares to ask further
12 cross-examination questions with respect to any of
13 the changes, they can certainly do that, and they
14 also can deal with it in any sort of observations
15 or motion to exclude.

16 MR. LaROCK: So I just want to -- this
17 is Mr. LaRock again -- just to respond.

18 So it's our position that these
19 revisions in the errata sheet are meaningful. In
20 several instances, additional support is being
21 added to statements, and in other instances, the
22 text of the declaration itself is being changed.

1 For example, some text is being
2 narrowed from corticosteroids to now oral
3 corticosteroids, which changes the meaning of the
4 sentence. Another instance, a "not" was added
5 that was previously omitted, which obviously
6 changes the text or the meaning of the sentence as
7 well.

8 So, you know, it's our view that
9 trying to resolve these issues now is prejudicial
10 to us because we only have today to take this
11 deposition. We're already outside the deposition
12 window, and we had to get an extension of
13 Due Date 4 in order to make this deposition date
14 work, so, you know, we're kind of stuck in a bind
15 here in order to, you know, resolve these issues.

16 So that's kind of where we are.

17 THE COURT: Right, right.

18 MR. CHESLOCK: Just one minor point,
19 Your Honor.

20 THE COURT: Let's assume this document
21 did not exist, just for the purpose of discussion,
22 and there were errors in this declaration.

1 What manner -- and this would be
2 directed to the Patent Owner -- if they wished to
3 say we did make some changes, what manner do you
4 think would be appropriate for them to enter the
5 corrections, say, you know, we goofed here? Is
6 there a manner you would find appropriate?

7 MR. LaROCK: I think it would depend
8 on, from our perspective, whether that would
9 change the witness's testimony on
10 cross-examination.

11 You know, at no point in time during
12 his answering any questions did he say, you know,
13 I think I cited additional exhibits here, nor did
14 he say that he thought any of his revisions had
15 changed what the meaning of the sentence or what
16 his testimony was at that time.

17 So, you know, that's kind of --

18 MR. CHESLOCK: Well, Your Honor, this
19 is counsel for Petitioner.

20 Like I said before, and I was pretty
21 carefully tracking this, I don't believe that
22 there were any questions that directly related to

1 any of the corrections that Mr. Staines has
2 provided in the table, and Patent Owner didn't ask
3 Mr. Staines -- if he had simply asked Mr. Staines
4 if there were any corrections that he had to his
5 declaration, then he would answer that there are
6 some, and Patent Owner just avoided that question.

7 THE COURT: Right, right.

8 You know, without you all agreeing on
9 it, I'm going to have to take a look at whatever
10 this document is and make a ruling on it and get
11 the panel to look at it as well.

12 MR. HOUSTON: Your Honor, this is
13 Mike Houston for Petitioner. Could I chime in
14 here? Normally I would defer this to those
15 counsel that are at the deposition to handle it,
16 but could I offer a suggestion while you're
17 considering what to do here, which would be it
18 seems to me that this document could be allowed in
19 provisionally, even if it stands as an exhibit
20 number, and if Patent Owner really believes it
21 substantively changes the testimony, they do have
22 the motion to exclude mechanism to ask for it to

1 be excluded.

2 I just would think that would be
3 the -- your question earlier was how should this
4 be handled, and I might just suggest that, as that
5 seems to be what the mechanism kind of is for if
6 there's a dispute about whether an exhibit should
7 or shouldn't be in the record.

8 MR. LaROCK: This Mr. LaRock for
9 Patent Owner. I just want to jump in for a
10 second.

11 This isn't a situation where we can
12 resolve the issue with a motion to exclude, a
13 motion for observation on cross-examination,
14 because we have to restrategize -- given some of
15 these revisions and the additional support that's
16 been added to certain sentences, and now some of
17 the changed meaning of these sentences,
18 restrategize how we're going to take the
19 deposition, get new exhibits in here in order to
20 finish the deposition today. So even marking it
21 today provisionally, you know, it still puts us at
22 a huge prejudice.

1 THE COURT: Right. Is there a chance
2 that the cross-examination can continue till
3 tomorrow?

4 MR. LaROCK: This is Mr. LaRock for
5 Patent Owner.

6 I'm not sure. It was logistically
7 challenging in order to come to an agreement on a
8 date for this deposition, so I don't know the
9 availability of the witness after today.

10 MR. CHESLOCK: I'd have to ask him.

11 THE COURT: But there's no reason why
12 the witness can't be questioned on these proposed
13 revisions other than you feel that you haven't had
14 enough time to prepare, right?

15 MR. LaROCK: I mean, setting aside the
16 prejudice, no.

17 THE COURT: Right.

18 MR. CHESLOCK: This is Andrew for
19 Petitioner.

20 With the understanding that we sent it
21 to them -- you know, we didn't give it to them
22 this morning. I mean, they had it yesterday.

1 THE COURT: Yesterday when?

2 MR. CHESLOCK: I think around three
3 o'clock?

4 MR. HOUSTON: Let me answer that, Your
5 Honor, this is Mike Houston, because I sent it,
6 and I will just pull up my folder here just so
7 everyone is clear. I'm the one who sent it.

8 The email to Mr. LaRock attaching this
9 one-page document was sent yesterday at 2:00 p.m.
10 Central Time. I think that would probably be
11 3:00 p.m. Mr. LaRock's time.

12 THE COURT: And you were on an
13 airplane at that time.

14 MR. LaROCK: So I was actually -- I'm
15 in the D.C. office, but I'll note one thing. You
16 can't see the document, but although we received
17 it yesterday -- and I don't have the email in
18 front of me. We're using my cell phone, so I
19 can't pull up the email to confirm, but what
20 Mr. Houston said sounds about right.

21 The document itself, this errata sheet
22 that they want to mark, is actually dated for

1 February 2, which was a day earlier than we
2 received it.

3 THE COURT: February 2?

4 MR. LaROCK: Sorry, sorry, April 2.
5 Sorry, April 2.

6 MR. HOUSTON: Your Honor, all I know
7 is we forwarded it on to opposing counsel as soon
8 as we got it from the witness.

9 On the record, if Mr. LaRock wants to
10 ask the witness on cross-exam when he prepared it,
11 when he sent it to us, that's all fine. We're not
12 trying to hide anything. That's none of our
13 doing. He just sent it to us yesterday, and we
14 forwarded it along virtually immediately.

15 THE COURT: Okay. Well, you know, I
16 think I'm going to let you file it as an exhibit,
17 and I think I'm going to kick the can down the
18 road because I don't know exactly what the
19 document says, but I expect there will be a motion
20 to exclude that comes along in due course to
21 question whether or not this document should be
22 allowed, but I would recommend -- and, really,

1 absent you all rescheduling the witness for
2 another day, I would recommend that you make the
3 time, and by this I mean the person who -- I guess
4 the Petitioner, you need to let Patent Owner have
5 a sufficient time to explore these issues and take
6 the breaks they need to prepare their questions
7 for dealing with the changes that you're seeking
8 to make, and basically if there is insufficient
9 cooperation, I want a call back here.

10 MR. CHESLOCK: Okay. And just one
11 clarification, we did receive the corrections the
12 evening before, and then sent it to Patent Owner
13 after that.

14 THE COURT: Right, but, you know, the
15 day before the deposition is kind of hard.

16 MR. CHESLOCK: Yeah.

17 MR. LaROCK: Yes.

18 THE COURT: I've been in private
19 practice, I know that's hard, so I'm trying to
20 come up with a fair resolution on this for all of
21 you. Are there any questions at this point?

22 MR. CHESLOCK: Yeah, so I just want

1 clarification on what we're going to do.

2 We're going to -- we're going to I
3 guess --

4 THE COURT: What it is, it's an errata
5 to another document, right? And I think the best
6 approach would be to file it as an exhibit, it's
7 an errata to the -- well, I'm not sure what
8 document number the declaration is -- and whether
9 or not that's appropriate filing, I'm going to
10 kick that can down the road a little bit.

11 However, in exchange for letting that
12 go into the record at this time, I want the Patent
13 Owner to have an adequate chance and opportunity
14 to ask what questions they deem necessary.

15 I know it's a little difficult at this
16 time without sufficient preparation time and kind
17 of a last-minute thing, but if they don't get
18 enough time to do it, I might just strike the
19 document at the end of the day.

20 So I want to make sure that everyone
21 has a chance to do what they think is necessary,
22 and if you run into any issues about that for the

1 rest of the day, I will be standing by waiting for
2 a phone call.

3 MR. CHESLOCK: Okay. Your Honor, just
4 for clarification, does Petitioner need to just
5 question Mr. Staines on the record about the
6 document for its admissibility purposes, or are we
7 to simply allow the Patent Owner to perform his
8 cross-examination?

9 I just don't want there to be some
10 question later about the authenticity of what this
11 is.

12 THE COURT: I think he may ask
13 whatever questions he chooses to. I'm not going
14 to try to constrain him as to what he deems
15 appropriate.

16 MR. CHESLOCK: I guess my question is
17 whether or not Petitioner would be allowed to
18 simply just ask a handful of questions of the
19 witness on redirect relating to the table to
20 clarify what it is before we turn it over.

21 THE COURT: I think that would be
22 fine. Let's just stay out of areas of privilege,

1 shall we?

2 MR. CHESLOCK: Yeah.

3 MR. LaROCK: Okay.

4 THE COURT: All right.

5 Any further questions?

6 MR. LaROCK: Not from Patent Owner.

7 MR. CHESLOCK: I don't think so, not
8 from Petitioner.

9 THE COURT: All right, thank you.

10 This call is adjourned.

11 MR. LaROCK: Thank you.

12 MR. HOUSTON: Thank you, Your Honor.

13 (Off the record at 1:44 p.m.)

14 (Resume at 1:52 p.m.)

15 (Exhibit 1171 was marked
16 for identification.)

17 REDIRECT EXAMINATION BY COUNSEL FOR THE PETITIONER

18 BY MR. CHESLOCK:

19 Q Mr. Staines, I am going to hand you
20 what will be marked as Exhibit 1071 [sic].

21 MR. LaROCK: And I'm going to object
22 on the basis that this document is untimely,

1 outside the scope of the cross-examination, that
2 it is hearsay, relevance. That should be it.

3 BY MR. CHESLOCK:

4 Q Mr. Staines, do you recognize what's
5 been handed to you as Exhibit 1071 [sic]?

6 A Yes, I do.

7 Q What is Exhibit 1071 [sic]?

8 A It's a list of errata that I --
9 changes that I made to the report to correct
10 certain page numbers, exhibit numbers, that were
11 incorrectly reflected in the report, and some
12 grammatical errors that were corrected.

13 Q Okay. And I made a mistake, it should
14 be 1171, not 1071.

15 A Okay.

16 Q Is Exhibit 1171 -- let me ask you
17 this. Who created Exhibit 1171?

18 A I did.

19 Q And when did you create Exhibit 1171?

20 A I believe it was Monday, April 2nd,
21 2018.

22 Q Can you please explain the "Page"

1 column that's present in Exhibit 1171?

2 A That's the page of my declaration,
3 which is Exhibit 1040, on which the change is
4 made.

5 Q And same thing for
6 "Paragraph/Footnote," can you briefly explain
7 that?

8 A Yeah, so either the paragraph or
9 footnote number, depending on which one is
10 indicated in that column, indicates the paragraph
11 or footnote in my declaration where the change is
12 made.

13 Q And similarly for "Line"?

14 A And the line also is the same thing,
15 in my report where the change is made.

16 Q And then also for "Original"?

17 A So "Original" is an excerpt from the
18 report that is how that excerpt originally is in
19 the report.

20 Q And then same thing with "Change to"?

21 A And then the "Change to" is how I
22 correct it, and I've indicated in red what the

1 correction is.

2 So, for instance, in the first line,
3 there's an -- Exhibit 2019 should be Exhibit 2049,
4 so the "4" is in red.

5 Q And does Exhibit 1171 show all the
6 corrections that you identified in your
7 declaration?

8 A Yes, it reflects all of them.

9 MR. CHESLOCK: Okay, that's all I
10 have, Adam. If you need to take some time beyond
11 the time that you've just taken now to review your
12 notes, you can certainly do that. And if you need
13 to print anything out, we're happy to print out
14 any additional exhibits that you may need.

15 MR. LaROCK: Okay. Yeah, I'm going to
16 need to take a break and look through my notes.

17 (A break was taken at 1:56 p.m.)

18 (Resume at 2:57 p.m.)

19 RECROSS EXAMINATION BY COUNSEL FOR PATENT OWNER

20 BY MR. LaROCK:

21 Q Welcome back.

22 A Thank you.

1 Q During the break, did you talk to your
2 counsel about the substance of your testimony or
3 your expected testimony?

4 A No.

5 Q Okay. So looking at Exhibit 1171 --

6 A Yes.

7 Q -- and if you look at page -- the
8 entry for page 43, footnote 97, what was the
9 correct -- just read into the record what the
10 correction was there.

11 A So originally the passage was
12 something about corticosteroids are generally not
13 used, so that's what it said, and then I'll read
14 the change to, "above, oral corticosteroids are
15 generally not used."

16 Q Okay. Do you think the addition of
17 the word "oral" in your revised testimony is a
18 meaningful change?

19 MR. CHESLOCK: Objection to form.

20 THE WITNESS: Depends on what you mean
21 by "meaningful." I thought it was appropriate,
22 which is why I made the change.

1 BY MR. LaROCK:

2 Q And because you thought it was
3 appropriate -- and you wanted to make the change
4 because it was inaccurate without the word "oral"?

5 A Other places in the report I clearly
6 talk about that it's oral corticosteroids that
7 were not used in intranasal form, and I think
8 that's what this is talking about, so here I
9 neglected to put in "oral" in corticosteroids,
10 although this cite clearly indicates it's oral
11 corticosteroids, and I believe the text is talking
12 about oral corticosteroids.

13 Q Right. But my question is, you wanted
14 to -- well, first of all, why did you identify
15 this as a change that you wanted to make?

16 A To make it clear that it was oral
17 corticosteroids that were not generally used in
18 intranasal form, not all corticosteroids, and so
19 it would comply with what's in the text.

20 Q Mm-hmm. Because it was inaccurate
21 without that change?

22 A Inaccurate or vague, because it should

1 be oral corticosteroids, not just all. So oral is
2 a subset of that, but it was too general. It
3 should be specific to oral corticosteroids.

4 Q Okay. Now, the next entry down, so
5 it's page 43, footnote 100, what's the change that
6 you're making there?

7 A Let's see. So originally the passage
8 was oral antihistamines were often deemed
9 inadequate, which is continued on the next line.
10 The change is, "Oral antihistamines alone were
11 often deemed inadequate."

12 Q And you made that change because
13 otherwise the sentence would be inaccurate?

14 A It would be vague, because obviously
15 oral antihistamines alone are covered by oral
16 antihistamines, but I thought it would be better
17 to make it clear that it was oral antihistamines
18 alone, because they can be used in conjunction, in
19 which case my understanding is they're not deemed
20 inadequate.

21 Q And then page 100, footnote -- I guess
22 this is paragraph 121.

1 A Yes.

2 Q And then what's the change there?

3 A So originally the passage was "blocked
4 from reimbursement," and the new sentence, "It
5 does" -- something, I don't remember what it was,
6 and the new corrected version is "blocked from
7 reimbursement," new sentence, "It does not" do
8 whatever it does.

9 Q And you wanted to make that change
10 because otherwise your original testimony was
11 inaccurate?

12 A It would be misleading.

13 Q Okay. It would be accurate, but
14 misleading, or it would be --

15 A The interpretation would be -- as I
16 read the sentence, which was a long one, I could
17 interpret it a couple different ways, and so with
18 a couple -- there might have even been double
19 negatives in there as I recall, so it was
20 appropriate to say it does not, and that would
21 make it accurate.

22 Q Okay.

1 A Make it clear.

2 Q Because previously it was not accurate
3 or clear?

4 A It wasn't clear.

5 Q Okay. So for each of these changes --
6 page 43, footnote 97; page 43, footnote 100; and
7 page 100, paragraph 121 -- for each of those you
8 said that the original testimony was vague, and I
9 want to get -- well, I guess I'll take a step
10 back.

11 When you submitted this exhibit, your
12 declaration, Exhibit 1140, you reviewed it before
13 it was finally submitted, right?

14 A Yes.

15 MR. CHESLOCK: Object to form.

16 THE WITNESS: I reviewed it.

17 BY MR. LaROCK:

18 Q And you looked for typos?

19 A Yes.

20 Q And you also looked to see if there
21 was any sentences that you wanted to make sure had
22 adequate support?

1 A That had -- yeah, I wanted to make
2 sure that it had adequate support, yes.

3 Q And you otherwise reviewed the
4 declaration for clarity and to make sure that it
5 was conveying what you wanted to convey?

6 A I read it with that intent.

7 Q And now you're saying that without
8 these changes, your declaration, which was clear
9 when you submitted it, is now no longer clear?

10 MR. CHESLOCK: Objection,
11 mischaracterizes, also to form.

12 THE WITNESS: Yeah, I don't recall
13 saying it was clear. My intent was to make it
14 clear.

15 BY MR. LaROCK:

16 Q Okay. So you reviewed your
17 declaration for typos, and you reviewed it to make
18 sure you wanted to add the support that you wanted
19 to add, and I think you said you otherwise
20 reviewed it to make sure that it was clear?

21 A I reviewed it with that intent.

22 Q And it passed muster as of that time,

1 right?

2 MR. CHESLOCK: Objection to form.

3 THE WITNESS: So by pass muster, you
4 mean --

5 BY MR. LaROCK:

6 Q Well, did you make any corrections --
7 you made any corrections that you wanted to make
8 at that time, and then it was eventually filed?

9 A Well, no. By definition, I had more
10 corrections when I read it yet again.

11 Q Right, but I'm talking about right
12 when this was filed, and it's dated on the front
13 page March 6th, 2018.

14 A Mm-hmm.

15 Q So presumably either on that date or
16 the day or two before, you did a final review?

17 A Yes.

18 Q And you looked for the typos that we
19 talked about, you looked for whether you wanted to
20 add any additional support, and you looked for
21 that it was otherwise clear? That was all part of
22 your final review?

1 MR. CHESLOCK: Objection to form.

2 THE WITNESS: Okay, no. I mean, I did
3 not go over -- in my final review, go over the
4 citations again to make sure that those were
5 correct.

6 BY MR. LaROCK:

7 Q Okay. So you were the one -- I think
8 you testified much earlier on today that you were
9 the one who drafted this. Although you may have
10 gotten some assistance pulling documents or doing
11 whatever, but you were the primary drafter of this
12 document?

13 A That's correct.

14 Q And as of that time, you put together
15 the footnotes and the citations that you wanted to
16 use as you were drafting it?

17 A Yes. And I probably left some holes,
18 and then went back and did some additional
19 citations.

20 Q Okay. But at some point in time
21 before it was final, you satisfied yourself that
22 you had cited what you wanted to cite?

1 A That it was adequate.

2 Q Okay. So it wasn't totally what you
3 wanted to say? It was just adequate? Or what was
4 the thought process there?

5 A There's a degree of comprehensiveness
6 or a degree of how much you cite something, and so
7 what I cited I felt was adequate at that time.

8 Q And --

9 A Sufficient.

10 Q It was sufficient. So you were
11 drafting the declaration, you put together the
12 footnotes, you find the documents that you wanted
13 to cite, you cite them, and at some point in time
14 you satisfy yourself that you're citing a
15 sufficient amount of documents?

16 A Yes.

17 Q And you have an adequate amount of
18 support for the statements you wanted to make?

19 A Yes.

20 Q And then later you subsequently
21 reviewed this before it was -- and "this," I mean
22 Exhibit 1140 -- reviewed it for typos?

1 A Yes.

2 Q And then the other corrections you
3 wanted to make?

4 A Yes.

5 Q And then you filed it -- or then it
6 was filed?

7 A Yes.

8 Q Okay. And what I want to talk about
9 is, as of the time it was filed, this was accurate
10 and a complete collection of your thoughts and the
11 statements you wanted to make and the exhibits you
12 wanted to cite?

13 MR. CHESLOCK: Objection to form.

14 THE WITNESS: So what it was
15 represented what I believe to be an accurate and
16 sufficiently documented representation of my
17 opinions.

18 BY MR. LaROCK:

19 Q As of that time?

20 A Yeah, as of that time, yes.

21 Q And then that subsequently was not
22 right?

1 MR. CHESLOCK: Object to form.

2 THE WITNESS: No, I still believe that
3 that was sufficient to convey my opinions, and was
4 sufficiently supported.

5 BY MR. LaROCK:

6 Q Okay. So your declaration in
7 uncorrected form is still sufficient to convey
8 your opinions and was sufficiently supported, so
9 why the corrections that are shown in 1171?

10 MR. CHESLOCK: Object to form.

11 THE WITNESS: So these corrections are
12 to clarify, to correct things that aren't -- that
13 don't affect the opinions or the evidence, but to
14 make them more accurate.

15 For instance, the fact that the PTAB
16 looks like instituted the -- how would you -- how
17 do you refer to it? Instituted the Petition or
18 the IPR as of -- I indicated it was August 21st,
19 2017, because I read an opinion or a decision,
20 turned out that that was not October, but
21 August 21st. That's not important to my opinions,
22 but I wanted to get it accurate and get it right,

1 but it doesn't impact my opinions at all.

2 BY MR. LaROCK:

3 Q So do you have a rough understanding
4 of how many corrections are shown here that you
5 want to make in 1171?

6 A There look to be maybe 20 or so.

7 Q Okay. Would 34, does that ring a
8 bell?

9 A I never counted them, so I wouldn't be
10 surprised if it is.

11 Q Okay. Do you think that's a lot of
12 corrections?

13 MR. CHESLOCK: Object to form.

14 THE WITNESS: I don't -- a lot? No, I
15 don't consider -- in this context, I don't
16 consider it a lot.

17 BY MR. LaROCK:

18 Q What do you mean, this context?

19 A Where the types of corrections that
20 are being made, I don't consider it a lot, no.

21 Q Because they're -- strike that.

22 I looked at your CV. Do you publish

1 at all in your economics practice?

2 A Do I publish? No, I do not.

3 Q But you generally follow the economics
4 and financial literature, stay up to date on
5 peer-reviewed publications that may be out there
6 in your field?

7 A In certain areas within. Economics is
8 a big field, and finance is a big field. In
9 certain areas.

10 Q Fair. But you review those journals
11 and make sure -- you know, you read them, you rely
12 on them, you --

13 A Again, rely on depends on the context,
14 but I certainly read journals, yeah.

15 Q Yeah. To be informed of what's going
16 on out there for whatever purpose you are
17 reviewing these journals for?

18 A Yeah. There may be different
19 purposes, but I certainly review journals.

20 Q And if you were reading a publication
21 in, say, The Economist, and you read it and you
22 said, oh, well, that's fantastic, and in the next

1 issue they issue a series of 34 corrections, what
2 would you think about that article?

3 MR. CHESLOCK: Object to form.

4 THE WITNESS: I don't think they would
5 do that because minor corrections they wouldn't
6 make. They'd only make substantive corrections --
7 or I've certainly seen substantive corrections
8 made. So in my opinion, these corrections are not
9 important and wouldn't be made in an article in
10 The Economist, or even in American Economic
11 Review, or those kind of things.

12 So as I indicated, some of these are
13 grammar -- if I haven't indicated, I'll indicate
14 it now. Some of these are grammar issues, some of
15 these are page number issues, because hopefully
16 they -- page number issues, because my
17 understanding is the pages are renumbered for this
18 investigation, I'll call it, and I don't see the
19 page numbers before they're put on, so I
20 anticipate what the page numbers are going to be,
21 if they're numbered, with the cover page being
22 page 1, 2, 3, like that.

1 So some of these, after I went back to
2 look at them, I noticed that the cover page wasn't
3 counted as page 1, so I would have to then change
4 a page 1 to a page 2, for instance, so that's a
5 lot of these changes.

6 BY MR. LaROCK:

7 Q So if you're looking at The Economist,
8 and The Economist just issued 34 corrections to an
9 article that they previously made, is your thought
10 process -- well, what is your thought process at
11 that time about the article that was now being
12 corrected 34 times?

13 A Okay. So if an article was being
14 corrected 34 times, it must have been for
15 substantive reasons. These kind of corrections
16 would be made.

17 If there were 34 corrections, it
18 depends on what the corrections are, but that
19 would certainly raise an eyebrow as to why there
20 are these important corrections that they felt
21 they had to make in the next issue.

22 But, again, these kind of corrections

1 that I'm making here are not corrected -- I've
2 certainly seen mistakes and grammatical errors in
3 The Economist and other places that just aren't
4 corrected. So when you're counting even a date
5 that doesn't matter, that's not germane, like
6 August versus October, that's not going to be
7 corrected in The Economist because it's not
8 important to the point in the article.

9 Q Okay. So I think you testified on
10 redirect that at some point in time you were
11 preparing for this deposition, you were reviewing
12 your declaration, 1140, and you identified these
13 errors? Is that generally accurate?

14 A So I --

15 Q Just setting the table. That's kind
16 of a yes-or-no question.

17 A Well, I just want to be clear that the
18 clarifications, some are not -- some are errors in
19 the sense of August and October, but some of them
20 are clarifications. I want to say errors,
21 clarifications, grammatical corrections, yes.

22 Q Okay. And how did you -- say, for

1 example, the entry for page 4, paragraph 4, the
2 changed you've indicated is October 21 to
3 August 21 as the date that this proceeding was
4 instituted. How did you know that that was wrong?

5 A As I looked at the -- I'm trying to
6 remember. I don't remember exactly, but as I
7 looked at the document, there was an opinion from
8 the Board that pertained to this matter, and as I
9 read it -- you know, really, honestly, I don't
10 remember. I looked at the document, and somehow I
11 figured out that this wasn't exactly the Board
12 doing the institution, it was like a secondary
13 opinion or a preliminary opinion -- sorry,
14 secondary opinion right after that. So somehow I
15 figured that out when I looked at the document.

16 Q Okay. And for the entry for page 14,
17 footnote 14, the correction is --

18 A Yes.

19 Q The citation to Exhibit 1076, you
20 originally cited page 24, you now change that to
21 page 26. Is that right?

22 A Yes.

1 Q And how did you know that was wrong?

2 A I went to the document when I was
3 looking at it and realized that I hadn't counted
4 the cover page, and I think there was a title page
5 or something to that document. And so when I was
6 trying to anticipate what the page number was
7 going to be, I thought it would be 24, I guess, at
8 the time, and then when I was looking at it, I
9 realized I didn't count those two pages, so I made
10 it 26.

11 Q So when you originally were drafting
12 your declaration, 1140, you were reviewing some of
13 these documents and -- scratch that. Strike that.

14 So the next entry is page 43,
15 footnote 97, right? We talked about that
16 previously, where you're changing, in effect,
17 corticosteroids to oral corticosteroids.

18 A Yes.

19 Q And how did you know that that was
20 incorrect?

21 A I was reading the text, and then went
22 down to footnote and read that, and figured, well,

1 that's unclear. I'm only talking about the oral.

2 So I could make that -- since I'm making the other
3 change, I might as well make that clearer.

4 Q And for entry page 51, footnote 123,
5 the change, in effect, is to add citations to
6 Exhibit 1092. Do you see that?

7 A Yes, I do.

8 Q And how did you know that this
9 footnote was missing in Exhibit -- missing support
10 in 1092, and how did you know that 1092 was the
11 exhibit you wanted to cite?

12 MR. CHESLOCK: Object to form.

13 THE WITNESS: So going on memory here
14 a little bit, Exhibit 1092, as I recall, was the
15 pharmaceutical antitrust, something from the ABA,
16 and in the context of looking at other footnotes
17 where this is cited, I noticed that it also
18 pertains to whatever this particular footnote is
19 talking about, and decided since I'm doing an
20 errata anyway, I might as well go ahead and add
21 this to it to further support what was already
22 there because, as you see, there are other

1 citations there as well. But this one was another
2 one, so it's just more support for the same thing.

3 BY MR. LaROCK:

4 Q And then for entry page 90,
5 footnote 220, the change in effect there was to
6 delete citation to Exhibit 2048. And how did
7 you -- is that -- do you see that?

8 A Yes.

9 Q And how did you know that that
10 original citation was incorrect?

11 A Okay, so when I went to look at that
12 one, it turned out that citation belonged in the
13 next citation. So it was in the citation before,
14 and it belonged in the next citation.

15 So you see down below there's an
16 Exhibit 20 -- used to be 53, 2048 now -- is at
17 pages 131-132. That's where that one belonged.
18 It belonged in the next footnote.

19 Q And if you go down to entry for
20 page 99, footnote 244, the correction there is in
21 effect to change the pages being cited to
22 Exhibit 1098 -- or 89, but to also add in citation

1 to Exhibit 1069 and Exhibit 1092.

2 Do you see that?

3 A Yes.

4 Q And how did you know those,
5 Exhibit 1096 and 1092, were the ones -- or 1069
6 and 1092 were the ones that you wanted to add?

7 A Yeah. So they were, again, cited
8 elsewhere in the report, and 1092 again is that
9 ABA book, and as I was reading that, I remembered
10 that I'm making the same point in another place,
11 and this buttresses that point. So since I'm
12 doing an errata anyway, might as well throw that
13 in as further support.

14 Q So just to --

15 A Oh, by the way, this 1069 -- this is
16 dangerous because I'm starting to remember these a
17 little bit -- I think that's the CBO document,
18 which again covers a lot of the issues that I
19 cover in the report. And so as I go back and read
20 it, I notice that even though I'm citing it in
21 another section of the report, it also applies
22 here, and, again, because I'm making errata

1 anyway, I thought I would add it. But if I
2 weren't doing the August/October issue, I wouldn't
3 have done that.

4 Q So was the August/October issue the
5 first correction that you identified?

6 A I think so.

7 Q And that was --

8 A Because that's early on in the report,
9 so I started at the beginning, so ...

10 Q And at that point in time, you said,
11 ah-ha, I want to do an errata?

12 MR. CHESLOCK: Object to form.

13 THE WITNESS: Maybe. I don't
14 remember. It could have been like that. I don't
15 remember how it evolved, but it could have been,
16 oh, gees, probably should change that.

17 BY MR. LaROCK:

18 Q And so I want to go back to -- I think
19 you said you're looking at Exhibit 1069, and you
20 think that was the CBO document, and it covered a
21 lot of issues, and you noticed that you were
22 citing in some places of the report and thought it

1 also applied elsewhere, and so since you were
2 making an errata anyway, you thought you'd add it.
3 Is that --

4 A I think that's fair, yes.

5 Q So I'm trying to understand here. For
6 at least the correction that you want to make for
7 page 99, footnote 244, it wasn't that the initial
8 footnote was -- that these were missing from the
9 initial footnotes?

10 A Right.

11 Q That you just wanted to add them in
12 now because you found additional support for the
13 statements you were already making?

14 MR. CHESLOCK: Object to form.

15 THE WITNESS: I felt it gave better
16 support, more -- not better, but more support,
17 made it stronger, so I felt that it was helpful to
18 do.

19 BY MR. LaROCK:

20 Q So I'm trying to understand that.
21 During your review of your
22 declaration, you had identified the CBO report, I

1 think it was 1069, and you just thought it would
2 be helpful to add in to this footnote as well
3 given the fact you found additional support for
4 it, for whatever statement you were making?

5 A That that same source that I cited in
6 another footnote also helped to support that
7 particular point, yes.

8 Q So you weren't originally citing in an
9 earlier draft Exhibit 1069 in footnote 244 and
10 somehow it had gotten deleted, and then you wanted
11 to go back to that, realizing that there was an
12 error, you're now just finding new support for
13 that statement?

14 MR. CHESLOCK: Object to form.

15 BY MR. LaROCK:

16 Q That same statement.

17 A Right. So that -- right. In the
18 sense that it was missing, it wasn't missing
19 before. It's only that in reviewing the document
20 again that I saw that it applied elsewhere, and so
21 made that addition.

22 Q Okay. And is that also the case for

1 the entry that we previously talked about,
2 footnote -- or it's page 51, footnote 123. The
3 change there was to effectively add in a new
4 citation to 1092. Was that also a change -- first
5 of all, do you see that, that entry?

6 A Yes.

7 Q Was that also a change where 1092
8 wasn't originally cited, but now you just wanted
9 to add that information in to that footnote?

10 A Yes, again emphasizing that it was
11 cited elsewhere, but, no, it wasn't cited, even
12 originally, to whatever that citation is sourcing
13 or supporting.

14 Q Okay.

15 A Yes, that's right.

16 Q And does the same apply for the entry
17 for page 101, footnote 251?

18 A I'll have to see that document. I
19 don't remember that one.

20 Q But off the top of your head, without
21 looking at the document, you can't tell why you
22 added that citation in?

1 A I could speculate that that's why. I
2 would guess that's why, but I'm not a
3 hundred percent sure.

4 Q When you say speculate that's why,
5 what do you mean?

6 A Because I did it in those other cases,
7 I can see myself doing it here.

8 Q Okay. That this wasn't a situation
9 where somehow that Exhibit 1133 had gotten deleted
10 from that footnote, and then you wanted to go back
11 to what you had originally intended by having that
12 source now articulated in that footnote?

13 A Right, I don't believe so.

14 Q Okay. And does the same also apply to
15 the entry for page 112, footnote 279? There the
16 revision is to effectively add in citation to
17 1133, Exhibit 1133 -- 1136?

18 A Yeah. So with respect to 1136, I
19 believe that -- it would be the same answers for
20 the 1133 I just gave.

21 Q Okay. And is it also the same for
22 the -- there's two corrections to page 113,

1 footnotes 186 and 189 -- or 286 and 289.

2 A So 286? Yes, with respect to 1137 --
3 Exhibit 1137 in 286 and Exhibit 1136 in
4 footnote 289, that would be the same answer as
5 those other two.

6 Q Okay. And the same answer being that
7 they --

8 A I was --

9 Q They weren't in some earlier version
10 of 1140 that you wanted to go back to that had
11 inadvertently been deleted for some reason. You
12 just had found additional support for these?

13 A Yeah, I don't believe that those were
14 omitted. I don't believe they were.

15 Q Okay. About how long did it take you
16 to identify these corrections, identify the issues
17 that you wanted to correct, identify the
18 corrections you wanted to make, and put this chart
19 together?

20 MR. CHESLOCK: Object to form.

21 THE WITNESS: So to put the form
22 together, it took me maybe an hour or so.

1 To identify them, it's part of the
2 process of going through it, so I really don't
3 know how long that took.

4 BY MR. LaROCK:

5 Q And did that process -- how long did
6 that whole process take about?

7 A So in preparing for the deposition,
8 which included this, you know, my CV and stuff
9 like that, just kind of going through everything,
10 took probably three or four days.

11 Q And that was for the whole deposition,
12 but you don't know what portion of the three or
13 four days you spent identifying the issues you
14 wanted to correct in 1171 and the corrections you
15 wanted to make?

16 A Yeah, I have trouble distinguishing
17 going through it, understanding it, and then also
18 identifying that, boy, I should add this 1092
19 here. Since I'm going to make an errata, I should
20 add the 1092 here as well.

21 You know, I don't -- I don't know how
22 much -- you know, I'd just be speculating. I

1 don't know.

2 Q A day? Just to prepare. And by
3 "prepare," I mean identify the issues, the
4 corrections, and put together 1171.

5 A So put together 1171 took me like an
6 hour or two.

7 Q No, what I'm saying -- so my question
8 is, of the three days that you were preparing for
9 the deposition, which I think is generally what
10 you said, some portion of that was identifying
11 these issues, identifying the corrections, and
12 preparing 1171?

13 A I caught the end. I didn't hear what
14 the exact question was though.

15 Q Is that right, that understanding
16 right, that some portion of the three days --

17 A Yes.

18 Q -- was you identifying the issues that
19 you wanted to correct, you identifying the
20 corrections you wanted to make, and preparing
21 1171?

22 A Yes. Three or four days, some portion

1 of that was as you just characterized it.

2 Q But what I'm asking is, of those three
3 or four days, how much time total did it take you
4 to identify the issues, identify the corrections,
5 and put together 1171?

6 A All I -- I don't know. I can tell you
7 how long it took me to put this together after
8 going back and, you know, making mental notes of
9 where I wanted to -- I had things that, oh, maybe
10 I should make this change to August, those kind of
11 things, and I just can't distinguish. I mean, it
12 was part of the whole process. I just can't
13 distinguish. You know, I don't know how much time
14 that took.

15 MR. LaROCK: Can we go off the record
16 for a second?

17 (Off the record at 3:34 p.m.)

18 (Resume at 3:36 p.m.)

19 BY MR. LaROCK:

20 Q Now, for the two entries on page --
21 I'm looking at 1171 -- the two entries for
22 page 113, footnotes 286 and 289, you collectively

1 are adding citation to 1137 and 1136, right?

2 A Yes.

3 Q I'm going to hand you 1136.

4 A Okay.

5 Q And the citation that you have, I
6 guess it's for page 113, 289, Exhibit 1136 is to
7 page 9, right?

8 A Yes.

9 Q And I'm going to hand you what's been
10 marked as 1137. And for entry 113, footnote 286,
11 the citation that you're adding is 1137, page 4,
12 right?

13 A Yes.

14 Q And both of these documents relate to
15 the issue of branded generics in India, right?

16 A Yes, they relate to that, yeah.

17 Q What is your understanding of what a
18 branded generic is?

19 MR. CHESLOCK: Object to form.

20 THE WITNESS: I'll look in the report
21 to see exactly how I said it.

22 So I indicate that India actually is a

1 market of generic products in which large numbers
2 of suppliers offer drugs with similar or identical
3 formulations, but under different brand names;
4 i.e., branded generics. So I think that's a
5 general characterization of how I look at them.

6 BY MR. LaROCK:

7 Q How many other times before this case
8 have you looked into the issue of branded generics
9 in India?

10 A I'm not sure if I have in India
11 specifically. I'm not sure. I've looked into
12 branded generics in Third World countries a fair
13 amount. In India specifically, I'm not sure that
14 I have.

15 Q Okay.

16 A By the way, I don't want to
17 characterize India as a Third World country
18 necessarily, but where there's a large -- you
19 know, the patent system is not as developed as
20 other countries, et cetera.

21 Q So I want to go back. When I asked
22 you what a branded generic was, you read some

1 portion of your report. And correct me if I'm
2 wrong, but you were reading -- or you were at
3 least looking at your report, 1140, paragraph 137,
4 right?

5 A Yes.

6 Q And you read off a portion that the
7 domestic pharmaceutical market in India actually
8 is a market of generic products, in which a large
9 number of suppliers offer drugs with similar or
10 identical formulations under different brand
11 names, right?

12 A Yes.

13 Q For a branded -- for a product to be a
14 branded generic, does it have to be a generic of
15 another product?

16 A I think "generic" has some different
17 meanings, so it depends on the meaning of
18 "generic." For instance, "generic" in the
19 United States has a very specific, almost legal,
20 regulatory meaning, and so I don't know that that
21 pertains necessarily to India.

22 Q Okay. So when you wrote India --

1 okay, the pharmaceutical market in India actually
2 is a market of generic products, what did you mean
3 by that?

4 A That they have similar or identical
5 formulations.

6 Q So there are multiple -- so I'm just
7 trying to understand here. There are multiple
8 suppliers in India offering similar or identical
9 formulations, and that therefore they become
10 branded generics?

11 A So if I could use an example rather
12 than define it, per se, outside of this, is that
13 Mr. Jarosz's table -- Tab 5, 6, the ones that have
14 the Indian market nasal sprays, he has, for
15 instance, the molecule mometasone, which is the
16 generic of Nasonex®, and has maybe 10 or 20
17 different products, different brands, that are
18 based on the same formulation nasal spray of
19 mometasone.

20 Q And in the context of mometasone,
21 there is a branded mometasone that the innovator
22 company markets in India, right?

1 A It just started. It didn't
2 originally, but it does now.

3 Q Okay. So in your example, there were
4 just a number of products that all marketed
5 mometasone, but under different trade names, and
6 therefore that was an example of branded generic
7 collection?

8 A That's right.

9 Q Okay. What about -- one of those
10 products was the first product on the market,
11 presumably?

12 A And by "market," do you mean the
13 Indian market?

14 Q Yeah. One of those many mometasone
15 products that have different trade names, one of
16 them was first on the market?

17 A Probably.

18 MR. CHESLOCK: Objection to form.

19 THE WITNESS: Probably. There's going
20 to be -- there's probably two on the same day, but
21 I would imagine that's correct.

22

1 BY MR. LaROCK:

2 Q So if looking at that one product that
3 is a mometasone branded generic, it's first time
4 to the market, there's no other mometasone in
5 India for some period of time except for that one,
6 is that product a branded generic product --

7 MR. CHESLOCK: Object to form.

8 MR. LaROCK: -- under your definition?

9 THE WITNESS: Yeah, I would consider
10 it still a branded generic product.

11 BY MR. LaROCK:

12 Q What's your basis for that?

13 A That there's no patent protection for
14 it. Anybody can enter at any time, and probably
15 did -- to the extent it's lucrative, would have
16 entered right after that. And I think that's true
17 for Duonase. It's a very short time before a
18 second product entered with the same formulation.

19 Q So for something to be a branded
20 generic, in your opinion, it has to be patent
21 protected?

22 A I don't know that I need to define it

1 so rigorously, but some do, and I think one of
2 the -- and I won't remember where it is, but one
3 of the documents that I cite actually defines it
4 that way.

5 Q But you don't define it that way? And
6 you're looking at your declaration, paragraph 137.

7 A I don't know that I need to get that.
8 I mean, it's subsumed in this definition. It
9 could be stricter, I'm not sure, but this is
10 sufficient for the purpose that I'm using it for
11 to say that they're competition based on similar
12 identical formulations.

13 Q So what about a situation where you
14 have a molecule that's first on the market, and
15 there's no patent protection, but it's the only
16 one on the market. Is that still a branded
17 generic?

18 MR. CHESLOCK: Objection to form.

19 THE WITNESS: You know I'm going to
20 say it depends. It really depends. You know,
21 sometimes certain markets, certain countries,
22 first mover effects are important. There might be

1 exclusivity, market exclusivity, at the FDA or
2 whatever. It may be a very difficult thing to
3 make. It depends.

4 BY MR. LaROCK:

5 Q Now, if you have a pool of branded
6 generic products in India, say -- let's go back to
7 your mometasone example -- but one of those
8 products sells so much more than the other
9 products by a factor of, say, ten, would that be a
10 meaningful way of differentiating that product
11 from the other products that have the same
12 molecule so that that product can be a commercial
13 success?

14 MR. CHESLOCK: Objection to form.

15 THE WITNESS: So commercial success in
16 some sense, not for the purpose of
17 non-obviousness.

18 But certainly you can reduce your
19 price and be -- or get a first mover advantage
20 because you are the first one in the market, you
21 tie it up for those first three months, and you
22 end up getting an advantage that way.

1 Or here in India, there's discussion
2 about, you know, the reputation for quality, that
3 you don't have impurities in your product, you
4 know, those kind of things, so there could be a
5 lot of competitive reasons for companies to do
6 better than others and be successful, but not
7 because you have a patentable or an innovative
8 product that is driving the sales. And it
9 wouldn't necessarily be an indication of
10 non-obviousness of the technology.

11 BY MR. LaROCK:

12 Q So if you were the first -- if,
13 hypothetically, a product in India is the first
14 one, and it starts selling it, and then a number
15 of other generic versions of that under different
16 trade names come out, and every pharmaceutical
17 company in India makes a version of that molecule,
18 would that level of copying be relevant to
19 commercial success?

20 MR. CHESLOCK: Objection to form.

21 THE WITNESS: Again, to commercial
22 success in a general sense, but not for purposes

1 of non-obviousness, because the commercial success
2 would need to be for a particular innovator, would
3 need to apply the particular innovator, not
4 copiers of that, because that's the only way that
5 you'd be motivated to develop a product based on
6 an obvious technology, if it had been obvious.

7 But if it's not, if other companies
8 make money on it, and I don't make money on their
9 sales, then that's irrelevant to me on whether I'm
10 going to make the product or not. It has to be
11 something that I make the money.

12 BY MR. LaROCK:

13 Q Okay. So for your commercial success
14 analysis, whether someone copies your technology
15 is irrelevant to whether the product is a
16 commercial success?

17 A Yeah, for commercial success analysis,
18 for that one thing that I'm looking at here,
19 that's irrelevant.

20 Q And that's because whatever company is
21 marketing that one product, they're not going to
22 make money on copycats coming on the market?

1 A Yes.

2 Q Those sales are going to a different
3 company.

4 A So if there had been somebody else who
5 wanted to do the same thing with Dymista®, but it
6 had been obvious, then they would have done it.

7 If they're not going to make -- they
8 need to make the money in order to be motivated to
9 do it, if it had been obvious.

10 Q So for purposes of your commercial
11 success analysis, what's relevant is whether or
12 not you're going to make money on the product that
13 you're developing or developer market?

14 MR. CHESLOCK: Objection to form.

15 THE WITNESS: What matters is that the
16 sales are sufficient to have motivated me to have
17 developed the technology if it had been obvious.

18 BY MR. LaROCK:

19 Q The current sales -- so what you're
20 saying is the current sales of the product need to
21 be high enough so that if I knew of those sales at
22 the time right before I was going to develop that

1 product, I could make a decision whether or not I
2 really wanted to develop that product, given the
3 sales I'm going to make?

4 MR. CHESLOCK: Objection to form.

5 THE WITNESS: That's close. The
6 actual sales evidence. You need evidence of
7 sales, actual sales, not projected sales.

8 So looking at the sales that have
9 actually been made, if back at the time somebody
10 knew that, if those were the sales that were
11 actually realized, that would have motivated them
12 to have developed the product.

13 BY MR. LaROCK:

14 Q And say it had motivated them to
15 develop the product, then it would be a commercial
16 success?

17 MR. CHESLOCK: Objection to form.

18 THE WITNESS: Maybe. That's one
19 factor that would argue for it.

20 BY MR. LaROCK:

21 Q So although -- say your product
22 currently is only making \$50 million, but ten

1 years ago, right before you developed the product,
2 if you knew you were going to make \$50 million in
3 2016, and that was good enough for the company,
4 that would be a factor for commercial success?

5 A Yeah, I think that's fair.

6 So, for instance, that's why -- one
7 thing I looked at was the pre-launch forecast, to
8 see what they were thinking they were going to
9 make, because -- "they," I'm going now to
10 Dymista®, so I'm switching.

11 The pre-launch forecast for Dymista®
12 indicated what Meda thought they would make, and
13 that's an indication of what was motivating them
14 to develop the product, and so it would be the
15 same thing for Duonase in India.

16 Q Doesn't the commercial success
17 analysis then just boil down to whether the future
18 sale -- the future actual sales of that product
19 were good enough for that company?

20 MR. CHESLOCK: Objection to form.

21 THE WITNESS: So "good enough" meaning
22 that they cover their costs?

1 BY MR. LaROCK:

2 Q Good enough that they -- if somehow
3 they knew what their actual sales were going to
4 be, they still developed and marketed the product
5 anyway.

6 A If they knew what the sales were going
7 to be -- I have trouble distinguishing that.

8 So if you don't -- if you don't make
9 enough sales to cover the costs, then as an
10 economic matter, you wouldn't be investing in it
11 in general. There are going to be exceptions and
12 stuff, but in general, that's true.

13 So, therefore, what you think you're
14 going to make and what the sales actually are, if
15 you knew you were going to make them, and if you
16 would still do it, then you must be getting a
17 sufficient return to have done that, given the
18 risks.

19 You know, you have to take into
20 account the cost of capital and all that other
21 stuff, but taking all that into account, yeah,
22 that would be a commercial success in that case,

1 or it would argue for commercial success.

2 MR. LaROCK: Okay, no further
3 questions.

4 MR. CHESLOCK: Okay, I just have a
5 handful of clarifying questions.

6 FURTHER REDIRECT EXAMINATION

7 BY COUNSEL FOR PETITIONER

8 BY MR. CHESLOCK:

9 Q Mr. Staines, did you receive any
10 assistance from counsel in identifying any of the
11 changes that you wanted to make that are reflected
12 here in Exhibit 1171?

13 A No.

14 MR. LaROCK: Objection to form.

15 BY MR. CHESLOCK:

16 Q Are all the changes that are reflected
17 in Exhibit 1171 yours?

18 A Yes.

19 Q And did you draft Exhibit 1171?

20 A Yes, and all its detail, yes.

21 MR. CHESLOCK: I don't have anything
22 further.

1 I don't know, Adam. I mean, he's here
2 to answer questions. Do you need any more
3 exhibits or anything printed out?

4 MR. LaROCK: I mean, I --

5 MR. CHESLOCK: I just want to make
6 sure you have your opportunity to ask questions
7 about 1171.

8 MR. LaROCK: I mean, we've had one,
9 two, three, four, five new exhibits, totaling at
10 least well over a hundred pages, some of them were
11 20, 30 pages, one at least had two per page on it.

12 So, you know, given that time
13 constraint and given what I had to go through, I
14 have no further questions based on what I was able
15 to do in the time that I had.

16 MR. CHESLOCK: Okay. I just wanted to
17 make sure that we are clear that he's here to
18 answer questions, and we've been willing to assist
19 you in that. So with that, I think we're done.

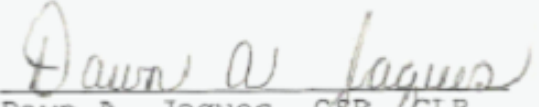
20 MR. LaROCK: Yeah.

21 (Deposition concluded at 3:56 p.m.)

22 Reading and signature were reserved.)

1 CERTIFICATE OF NOTARY PUBLIC

2 I, DAWN A. JAQUES, a Notary Public in and for
the District of Columbia, before whom the foregoing
3 deposition was taken, do hereby certify that witness
whose testimony appears in the foregoing pages was
4 duly sworn by me; that the testimony of said witness
was taken by me in shorthand at the time and place
5 mentioned in the caption hereof and thereafter
reduced to typewriting under my supervision; that
6 said deposition is a true record of the testimony
given by said witness; that I am neither counsel
7 for, related to, nor employed by any of the parties
to the action in which this deposition is taken;
8 and, further, that I am not a relative or employee
of any attorney or counsel employed by the parties
9 thereto, nor financially or otherwise interested in
the outcome of the actions.

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20

Dawn A. Jaques, CSR, CLR
Notary Public in and for
District of Columbia

21 My commission expires:

22 January 14, 2020

1 John C. Staines, Jr. c/o
2 FOLEY & LARDNER LLP
3 3000 K Street, NW, Suite 600
4 Washington, D.C. 20007-5109

5
6 Case: Argentum Pharmaceuticals LLC, v. Cipla, Ltd.
7 Date of deposition: April 4, 2018
8 Deponent: John C. Staines, Jr.

9
10 Please be advised that the transcript in the above
11 referenced matter is now complete and ready for signature.
12 The deponent may come to this office to sign the transcript,
13 a copy may be purchased for the witness to review and sign,
14 or the deponent and/or counsel may waive the option of
15 signing. Please advise us of the option selected.
16 Please forward the errata sheet and the original signed
17 signature page to counsel noticing the deposition, noting the
18 applicable time period allowed for such by the governing
19 Rules of Procedure. If you have any questions, please do
20 not hesitate to call our office at (202)-232-0646.

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6 SIGNATURE PAGE

7 Case: Argentum Pharmaceuticals LLC, v. Cipla, Ltd.
8 Witness Name: John C. Staines, Jr.
9 Deposition Date: April 4, 2018
10

11 I do hereby acknowledge that I have read
12 and examined the foregoing pages
13 of the transcript of my deposition and that:

14 (Check appropriate box):

() The same is a true, correct and
15 complete transcription of the answers given by
me to the questions therein recorded.

16 () Except for the changes noted in the
attached Errata Sheet, the same is a true,
17 correct and complete transcription of the
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6 ERRATA SHEET
7

8 Case: Argentum Pharmaceuticals LLC, v. Cipla, Ltd.
9 Witness Name: John C. Staines, Jr.
10 Deposition Date: April 4, 2018

11 Page No. Line No. Change
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22 Signature Date