

1 IN THE UNITED STATES DISTRICT COURT

2 IN AND FOR THE DISTRICT OF DELAWARE

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 4 MEDA PHARMACEUTICALS, INC.,  
 and CIPLA LTD., : CIVIL ACTION  
 :  
 5 Plaintiffs, :  
 v. :  
 6 :  
 APOTEX INC. and APOTEX CORP., :  
 7 : NO. 14-1453-LPS  
 Defendants. :  
 8 - - -

9 Wilmington, Delaware  
 10 Friday, December 16, 2016  
*Bench Trial - Volume D*

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 12 BEFORE: HONORABLE **LEONARD A. STARK**, Chief Judge

13 APPEARANCES: - - -

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 SELENA E. MOLINA, ESQ.

16 and

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

24 (REPORTER'S NOTE: The following bench trial  
25 hearing was held in open court, beginning at 8:30 a.m.)

Kaliner - direct

1 THE COURT: Good morning.

2 (The attorneys respond, "good morning.")

3 THE COURT: It's nice to say good morning  
4 instead of good evening. So is there any issue before we  
5 get Dr. Kaliner back on the stand, Mr. Varughese?

6 MR. VARUGHESE: No, Your Honor.

7 THE COURT: Mr. Klein?

8 MR. KLEIN: No, Your Honor.

9 THE COURT: Okay. All right. Doctor, why don't  
10 you come forward please.

11 ... MICHAEL KALINER, having been previously  
12 sworn as a witness, was examined and testified as follows ...

13 THE WITNESS: Good morning, sir.

14 THE COURT: Good morning, I hope you are well  
15 this morning.

16 THE WITNESS: Thank you.

17 THE COURT: I remind you that you remain under  
18 oath.

19 THE WITNESS: Thank you.

20 THE COURT: You may proceed.

21 MR. VARUGHESE: Thank you, Your Honor.

22 DIRECT EXAMINATION

23 BY MR. VARUGHESE:

24 Q. Good morning, Dr. Kaliner.

25 A. Good morning.

Kaliner - direct

1 Q. Do you have your pointer there with you?

2 A. I do.

3 Q. When we left off last night, I believe we were  
4 looking at the ARIA guidelines. Do you recall that?

5 A. I don't recall the slide, though.

6 Q. I think we have a demonstrative up which is the ARIA  
7 guidelines?

8 A. Yes.

9 Q. Okay. Can we go to the box on the bottom right,  
10 please?

11 A. Okay. Here.

12 Q. So you are familiar with the ARIA guidelines?

13 A. I am.

14 Q. You testified earlier that you followed them?

15 A. I do. Well, I followed the Dykewicz guidelines and  
16 some the ARIA guidelines.

17 Q. Thank you for that clarification. Here, the section  
18 we highlighted, it says the management of allergic rhinitis.  
19 Do you see that?

20 A. Yes.

21 Q. It starts with pharmacological management of  
22 rhinitis?

23 A. Yes.

24 Q. Now, in your experience and practice, are you aware  
25 of any nonpharmacologic management techniques for rhinitis?

Kaliner - direct

1 A. Yes, I am.

2 Q. And can you describe for the Court some of them?

3 A. Well, I think Dr. Wedner does the same thing. I use  
4 nasal saline washes. I use it with nearly every patient.  
5 And so the saline washes can be a large volume wash with  
6 something like a NeilMed sinus rinse, which is eight ounces,  
7 or just simply saline sprays. You can buy them all over the  
8 counter in any drugstore in the country. And the patients  
9 find that just wash, putting in a couple of sprays in their  
10 nostrils washes the nose, and remarkably it has a dramatic  
11 effect on the congestion and secretions, so a lot of  
12 patients just do saline sprays. We start them on medicine  
13 and saline sprays and end up using just saline spray. So  
14 it's an extremely effective, completely benign way to treat  
15 patients.

16 Q. Now, does that benefit from the saline substance  
17 itself or is it the fluid?

18 A. It's the fluid. It's just the washing. Saline is  
19 tolerable to patients, it feels good, but you can use any  
20 liquid that didn't hurt the patient and you get the same  
21 result, I think.

22 Q. Okay. Now, looking back at the ARIA guidelines, do  
23 you recall Dr. Schleimer's testimony from a few days ago  
24 where he suggested that the ARIA guidelines would have  
25 motivated a person of ordinary skill in the art to combine

Kaliner - direct

1     azelastine and fluticasone into a fixed dose formulation?

2     A.     I do.   Yes.

3     Q.     And do you agree with his position on that?

4     A.     Well, no.   Not based on the guidelines.

5     Q.     Can you explain for the Court why you disagree?

6     A.     Well, I think the guidelines are a stepwise, the  
7     guidelines are recommending a stepwise procedure with adding  
8     medications until you get relief, and then stepping down  
9     from medications once relief is achieved, and so the  
10    guidelines in no way suggest a fixed dose combination.

11    Q.     And do you think Dr. Accetta's records, from what we  
12    can tell, do you think he follows the guidelines?

13    A.     Well, Dr. Accetta is, and I said this already, and I,  
14    have been using Astelin and nasal steroids in relationship  
15    to each other in a very variable way.   In no way were they a  
16    fixed dose combination.

17    Q.     Okay.   Thank you.   Let's go back to the PDX-2.

18                 Now, Dr. Kaliner, earlier you testified in your  
19    summary that you thought that Dymista, Duonase and some of  
20    these other products in India were related to the patents.  
21    Do you recall that?

22    A.     I do.

23    Q.     Can you explain to the Court why that is your belief?

24    A.     Well, I showed on this slide, Dymista, which is the  
25    American patent, expression of the patent; Duonase, which is

Kaliner - direct

1 the Indian expression of the patent, and then there is all  
2 these other medicines; there are six listed here, I  
3 understand there are as many as 11, are all Indian copycats  
4 and the Indian system is very different.

5 So each of these products is a nasal spray. And  
6 they contain azelastine and fluticasone and in every  
7 manifestation they are the same concentration, and they are  
8 all used for the treatment of seasonal allergic rhinitis and  
9 I think that is the expression of the patent.

10 Q. In compiling this information, you relied on PTX-24,  
11 which is a Dymista package insert?

12 A. Yes.

13 Q. PTX-134, Duonase package insert?

14 A. Yes.

15 Q. And PTX-26, which are the imitator product labels?

16 A. Yes.

17 Q. You also mentioned in your earlier testimony that in  
18 your view, as of 2002, there was a need for a better  
19 treatment of allergic rhinitis. Do you recall that?

20 A. I do.

21 Q. In your opinion, does Dymista meet that need?

22 A. Yes.

23 Q. Can you explain to the Court why you believe that?

24 A. Well, Dymista, I mentioned yesterday that Ratner was  
25 a proof of concept study. And it showed that conceivably

Kaliner - direct

1 the combination of the products would work well together.

2 Now, Dymista is in a patent, this is where you  
3 actually formulated the azelastine and fluticasone into the  
4 same bottle so they got the same spray. So let me take you  
5 through this slide.

6 This is a very busy slide, Your Honor, I am  
7 sorry, I am going to take you through this step by step. It  
8 covers a lot of information and it is a very important way  
9 for all the points about Dymista.

10 So first of all, the way this experiment is  
11 done, sorry about the jargon, they took patients with  
12 allergic rhinitis and they had to have moderately severe  
13 disease. The way they had that -- this is a standard FDA  
14 requirement, this is for every patient, every drug approved  
15 for allergic rhinitis today goes through the same procedure.

16 Patients are asked to grade their symptoms,  
17 sneezing, itching, runny nose and congestion.

18 Four symptoms.

19 The severity can be zero, no symptoms, 1, 2, and  
20 3. 3 is quite incapacitating, so the patients grade  
21 themselves 0, 1, 2, 3. There are four symptoms and the  
22 scale is zero to 3, so the maximum number you could have is  
23 12 in a 12-hour period.

24 In order to get in the study, patients had to  
25 have at least eight. So they had to be two-thirds as severe



Kaliner - direct

1 as they could have been. And they had to have at least 2 on  
2 a 3-point scale for congestion. So they had to have  
3 moderate disease to get into the study at all.

4 Then the study involved giving either a placebo  
5 spray, one spray Flonase, one spray Astelin, or one spray  
6 Dymista, one spray, each of them twice a day. And over a  
7 two-week period patients were grading their symptom score on  
8 the same zero, 1, 2, 3 scale.

9 What this shows is the onset of effect. So it  
10 has a 15 to 30 minute -- actually, this is of statistical  
11 significance, that occurs in that time frame. So I already  
12 mentioned that the Astelin package insert showed that the  
13 product worked within three hours.

14 I know there has been some discussion about  
15 rapid onset of effect with Astelin or azelastine depending  
16 on the models. But this is the first time the company had  
17 actually confirmed that that data -- that the onset of  
18 effect was in 30 minutes.

19 And the FDA allowed them to put it in the  
20 package insert. So this is real data, approved by the FDA,  
21 and kind of irrefutable.

22 From the package insert, Flonase has an effect  
23 within 12 hours to several days.

24 So that's the onset.

25 Great onset.

Kaliner - direct

1           The middle data shows the improvement in symptom  
2 scores. So each of these numbers here is an improvement in  
3 symptom score. To be in the study patients had to have  
4 eight or more, and you can see that they had an improvement  
5 of five points, symptom score points. That's with Dymista.  
6 That is a huge improvement relative to anything else that's  
7 ever been shown in the American market.

8           So Flonase was minus 3.8. Astelin was minus  
9 3.25. And the combination was minus 5.31. That number is  
10 statistically significant compared to Astelin and is  
11 statistically significant compared to Flonase.

12           So it fulfills the FDA's combination rule that  
13 each component part has to contribute to the efficacy.

14           This is really phenomenal data. This is  
15 phenomenal data. You don't get data like this very often.

16           The relative potency of Dymista compared to  
17 placebo, the increment, comparing Dymista's improvement to  
18 placebo, is the largest increment of any product that has  
19 ever been marketed in the United States. This is the  
20 strongest medicine, the most effective medicine that has  
21 ever been marketed in the U.S.A. There is nothing that  
22 competes with this.

23 Q.       Just to clarify, for allergic rhinitis?

24 A.       For allergic rhinitis, I am sorry. Everything I am  
25 saying is for allergic rhinitis.

Kaliner - direct

1           As you look at this data, there is nothing ever  
2 done, approved by the FDA, that competes with this product  
3 for efficacy.

4           So then, you know, I have already shown you,  
5 combining azelastine and fluticasone in the Ratner study led  
6 to increased side effects. Dymista, amazingly, has  
7 decreased side effects with the reformulation.

8           What they have done is -- I am not a  
9 formulations expert. I am not going to really get into the  
10 formulation.

11           Whatever magic they did, in making this product,  
12 they reduced the dysgeusia from 19.7 to 4 percent, the  
13 headache two percent. The somnolence is gone. So they have  
14 less than one percent somnolence.

15           So the holy grail of medication is rapid onset,  
16 more rapid onset, better efficacy and fewer side effects.  
17 And lo and behold, Dymista fulfills the holy grail.

18           This is really an incredible medication. And,  
19 yes, you asked me the question of does this fill an unmet  
20 need in the treatment of allergic rhinitis. This is the  
21 best we have ever had.

22           I think others agree with me that this is the  
23 standard of care for treatment of allergic rhinitis in the  
24 United States after 2012.

25 Q.       By others, you mean other clinicians and

Kaliner - direct

1 practitioners treating allergic rhinitis?

2 A. Yes. I think the practice -- well, yes, other  
3 people, including the people who have reviewed the  
4 literature and the data for this product.

5 Q. Can we go to DDX-4.23.

6 Dr. Kaliner, do you recall Dr. Schleimer during  
7 his testimony discussing the Berger study from 1999?

8 A. I do.

9 Q. What was your understanding of Dr. Schleimer's  
10 opinions regarding Berger?

11 A. I think, as I heard -- this is my memory from a few  
12 days ago. I think that Dr. Schleimer said that this data --  
13 this article suggested that azelastine should be used in  
14 combination with an intranasal spray.

15 Q. Do you agree?

16 A. No, that's not what the article was. What Berger  
17 did, it's a funny study, but what Berger did was he looked  
18 at Astelin, azelastine, and compared to it a nasal steroid  
19 and an oral antihistamine. And he showed that Astelin was  
20 not as good as the nasal steroid and the oral antihistamine.

21 And his conclusions were, the whole conclusion  
22 reads, "Azelastine nasal spray can be used either in place  
23 of the oral antihistamines, in combination with an  
24 intranasal corticosteroids, or, as demonstrated in these  
25 studies, as an alternative to the combination therapy of an

Kaliner - direct

1 oral antihistamine and a nasal steroid.

2 That is what the article looked at, was the  
3 azelastine compared to the oral antihistamine and the nasal  
4 steroid with azelastine was as good and could be  
5 substituted.

6 But this article did not look at the conjunctive  
7 use of azelastine and the nasal steroid.

8 So I think that emphasizing parts of that  
9 sentence is a little misleading.

10 Q. Can we turn to DDX-4.4, please.

11 Again, during Dr. Schleimer's testimony, do you  
12 recall him referring to the Spector article from 1999?

13 A. I do.

14 Q. This is the demonstrative that he used. He said,  
15 Spector really laid it out when Dr. Schleimer was describing  
16 the optimal treatment for patients.

17 Do you recall that?

18 A. I do.

19 Q. Do you agree with him?

20 A. No, I don't.

21 Q. What is your position?

22 A. So, again, just so you understand what Spector did  
23 was he looked at the literature, looked at nasal steroids  
24 and oral antihistamines and in fact never mentioned nasal  
25 antihistamines once in the article.

Kaliner - direct

1           What he did was said the ideal product would  
2     have antihistamine activity and also anti-inflammatory  
3     activity, suggesting the ideal molecule would combine the  
4     best attributes of a nasal steroid and an oral  
5     antihistamine. In fact, that is what he says here.

6           He says the ideal pharmacologic therapy would be  
7     a drug that possessed not only H1 receptor antagonist  
8     activity but also anti-inflammatory activity.

9           So he was saying, make a better antihistamine  
10    that has anti-inflammatory activity. He never, ever said  
11    combining an antihistamine and a nasal steroid was the ideal  
12    way. He was saying make a better drug that has  
13    anti-inflammatory and H1 activity.

14           That's not a bad idea. That's why it got  
15    published. But it's not the same thing as combining these  
16    two products.

17    Q.     Can we go back to the PTX, the last slide.

18           Dr. Kaliner, you were discussing the Hampel  
19    study for the Court here?

20    A.     Yes.

21    Q.     The Hampel study, PTX-230?

22    A.     Yes.

23    Q.     Finally, based on the last hour or so of your  
24    testimony, and our discussion, is there anything as of 2002  
25    in your view to suggest that a fixed dose combination of

Kaliner - direct

1     azelastine and fluticasone is where a POSA would have come?  
2     A.     I think it's very clear. This is not just my opinion  
3     but the opinion of people who have looked at the literature,  
4     independently, at the time, and even after the time, that  
5     there was no information at 2002 that suggested in any  
6     scientifically established way that adding an oral  
7     antihistamine to a nasal corticosteroid would give you  
8     additional benefit and that at the time there was not a  
9     single study looking at nasal antihistamines combined with a  
10    nasal steroid, not a single published study that showed that  
11    combination.

12                 So my conclusion is that it is completely  
13    nonobvious that these products would be combined.

14                 MR. VARUGHESE: Your Honor, I would like to  
15    enter a few exhibits. Plaintiffs move to enter PTX-27, the  
16    Kaliner CV, PTX-1, the '620 patent, PTX-3, the '428 patent,  
17    PTX-20, the Demoly study, PTX-42, the Storms study, PTX-58,  
18    the article by Michael Blaiss, PTX-11, the Astelin label,  
19    PTX-103, the Optivar label, PTX-59, the Flonase label,  
20    PTX-98, the Data Monitor article from 2004, PTX-337, the  
21    Howarth article, PTX-36, the Nielsen 2001 article, PTX-53,  
22    the Akerlund article, PTX-330, the Ratner 2008 study,  
23    PTX-24, the Dymista label, PTX-134, the Duonase label, and  
24    PTX-230, which is the Hampel study.

25                 THE COURT: Any objection?

Kaliner - direct

1 MR. KLEIN: No objection.

2 THE COURT: Those are all admitted.

3 (Above-referenced exhibits received in  
4 evidence.)

5 MR. VARUGHESE: Thank you, Your Honor. One more  
6 item of housekeeping. I talked to the court reporter.  
7 There are a number of PDX's on Dr. Kaliner's demonstratives  
8 that overlap with defendants' DTX's. The court reporter  
9 indicated that it might be helpful if I on the record  
10 identify which ones they are.

11 THE COURT: Sure.

12 MR. VARUGHESE: He did caution me to go slow.

13 THE COURT: Go slowly, please.

14 MR. VARUGHESE: They are PTX-22 is DTX-246,  
15 Dykewicz. PTX-326 is DTX-81, ARIA. PTX-336 is DTX-40,  
16 Juniper. PTX-13 is DTX-248, Benincasa. PTX-39 is DTX-49,  
17 Simpson. PTX-333 is DTX-32, Drouin. PTX-332 is DTX-28,  
18 Brooks. PTX-331 is DTX-140, Ratner 1998. PTX-85 -- strike  
19 that one.

20 PTX-21 is DTX-31, Di Lorenzo. PTX-12 is  
21 DTX-227, Barnes.

22 That should be it.

23 Thank you, Your Honor.

24 THE COURT: Thank you very much.

25 Cross-examine.



Kaliner - cross

1 THE COURT: Cross-examination.

2 MR. KLEIN: We have a binder for the witness,  
3 Your Honor.

4 THE COURT: Yes, you may.

5 (Binders passed forward.)

6 THE COURT: You may proceed when you are ready.

7 MR. KLEIN: Thank you.

8 CROSS-EXAMINATION

9 BY MR. KLEIN:

10 Q. Good morning, Dr. Kaliner.

11 A. Good morning.

12 Q. You and I haven't met; right?

13 A. No, we haven't met.

14 Q. Just as an introduction, my name is Chuck Klein and  
15 I'll ask you a few questions on behalf of Apotex.

16 Just to be clear, you have a very close  
17 relationship with Meda, right?

18 A. I have been a consultant with Meda for a long time.

19 Q. So back in the early 2000s, you helped Meda improve  
20 its marketing for Astelin; is that right?

21 A. I did.

22 Q. And you also spent a long time helping Meda improve  
23 its marketing for Dymista; right?

24 A. Yes, sir.

25 Q. Okay. And since the early 2000s, Meda has paid you

Kaliner - cross

1 to promote its products by serving on its Speakers Bureau;  
2 right?

3 A. That's correct.

4 Q. And Meda has paid you a lot of money over the years?

5 A. I get paid for lecturing, yes.

6 Q. Let's go to DDX-7.01. Okay. And on the screen is a  
7 copy --

8 A. I'm sorry. I don't have it. Where is it?

9 THE COURT: It is in his binder as well.

10 MR. KLEIN: It's on the screen but you can look  
11 at it.

12 A. All right.

13 Q. This is a snapshot from DTX-322. And this is a  
14 propublica website, Dollars For Docs. I think we looked at  
15 something similar a couple days ago. And according to this  
16 document, you were paid \$104,000 from the period August 2013  
17 to December 2015; is that right?

18 A. That is what it says, yes. I haven't seen this  
19 number.

20 Q. Okay. And just to be clear, so this is payments  
21 going from Meda to yourself during that period; right?

22 A. Yes. And it would have been probably for lecturing  
23 and consulting, slide preparation, things like that.

24 Q. In fact, you are the third top doctor receiving  
25 payments from Meda according to this document; right?

Kaliner - cross

1 A. I'm kind of surprised I'm not the number one doctor.  
2 I could be. I can't see parts of it. I see the red box.  
3 Who is above me? I want to confront them with that.

4 Q. Meda also paid you more than \$80,000 in consulting a  
5 decade earlier for the period March 2003 to June 2004; does  
6 that sound right?

7 A. You said \$80? In one-year period?

8 Q. Well, let's go to DDX-7.02.

9 And this is a portion of the NDA for Astelin.  
10 It's DTX-316.27. So this is something that was submitted  
11 to the FDA reports. That for the period March 1st, 2003 to  
12 June 30th, 2004, you received roughly \$80,000. Does that  
13 sound about right?

14 A. It isn't that -- I have never seen these numbers  
15 before but it seems to me those are overlapping. And they  
16 are probably redundant numbers, the same time period and for  
17 the same services. So they're probably the same number.  
18 And I have to tell you that, you know --

19 Q. Sir. Sir. Sir.

20 A. -- \$80 thousand a year is not bad.

21 Q. Just answer my questions. This is cross-examination.

22 A. The answer, I see the numbers.

23 MR. VARUGHESE: Objection, Your Honor. I think  
24 Dr. Kaliner should be allowed to complete his answer.

25 THE COURT: All right. Well, that objection is

1 overruled. We will move on.

2 BY MR. KLEIN:

3 Q. Now, so just to be clear, you think that \$30 and the  
4 \$50 are overlapping numbers?

5 A. No, this number and the previous slide are probably  
6 the same numbers. I can't imagine I made more than \$40,000  
7 a year from this company.

8 Q. So you see the date is March 1st, 2003 to June 30th,  
9 2004?

10 A. Oh, no. I didn't see that. I'm sorry.

11 Q. So clearly these don't overlap?

12 A. No, I'm sorry. I thought these were 13 and 15. I  
13 misunderstood. I'm looking at the title, August 13 to  
14 December.

15 Q. Oh, I'm sorry. The title is the wrong title.

16 A. Okay. Well, that seems like a lot of money, but if  
17 it's there, I probably got it.

18 Q. So we just looked at about a two and-a-half year  
19 period. Roughly, how much money has Meda paid you over the  
20 last 15 years in total?

21 A. I don't know.

22 Q. More than \$200,000?

23 A. Probably.

24 Q. More than \$300,000?

25 A. I don't know.

Kaliner - cross

1 Q. Well, you developed quite a sense of loyalty for Meda  
2 over the years; right?

3 A. You know I consult with a number of companies.

4 Q. Okay. Well, have you developed a sense of loyalty  
5 for Meda?

6 A. I have.

7 Q. All right. And, in fact, it was a clinical director  
8 at Meda, not Meda's attorneys who first approached you to  
9 see if you could serve as an expert in this case; right?

10 A. No, that is not true.

11 Q. Okay. You remember you were deposed in this case?

12 A. Not the exact wording but I know what happened.

13 Q. No, I'm just asking. Do you remember that your  
14 deposition was taken in this case?

15 A. So, why don't you show me what I said and then we can  
16 talk about it.

17 Q. Let's -- your transcript is there but we will play a  
18 video. It is page 106, lines 10 through 21.

19 "Answer: It was the clinical director at Meda  
20 with whom I discussed opportunity to possibly deal with this  
21 case first."

22 THE COURT: I'm sorry. It started with a  
23 question.

24 MR. LOMBARDI: It started with a question.

25 "Question: How did you first get contact or who

1 first contacted you about this case?

2 "Answer: It was the clinical director at Meda  
3 with whom I discussed the opportunity to possibly deal with  
4 this case first. Actually, Bob Sheridan was probably the  
5 first person I spoke with. He's a guy at Meda.

6 "Question: He's a guy at Meda?

7 "Answer: He's a fellow, he's been with Meda 30  
8 years, 35 years. From that conversation, I dealt with the  
9 clinical director -- the project manager, not director. He  
10 may have a different title than that. And then eventually,  
11 I dealt with these guys."

12 "Question: Okay."

13 BY MR. KLEIN:

14 Q. Okay. So that was your testimony?

15 A. Yes. So what I said --

16 Q. All I asked, was that your testimony?

17 A. Yes.

18 Q. All right. And I think you testified yesterday  
19 that even before the Meda contacted you, it was Apotex who  
20 reached out to you; right?

21 A. Yes.

22 Q. And you found that Apotex was looking to invalidate  
23 the Dymista patents; right?

24 A. I think so, yeah.

25 Q. And you knew that if you were to find the Dymista

Kaliner - cross

1 patents obvious, that would hurt Meda; right?

2 A. As I said, I didn't -- I felt very uncomfortable and  
3 even unethical doing anything adverse to Meda.

4 Q. So you turned down Apotex for that reason; right?

5 A. Yes.

6 Q. And you worked too closely with Meda to do anything  
7 that would hurt them; right?

8 A. No. What I said is I have had an intimate  
9 relationship with Meda, as you see. And I did feel  
10 uncomfortable being adverse to them.

11 Q. Okay. You told Apotex you couldn't represent them  
12 because morally you couldn't. You worked with Meda too  
13 closely to do anything that would hurt them. Right?

14 A. I could not oppose them. That's right.

15 Q. So you are not disagreeing with the way I  
16 characterized?

17 A. I don't remember the exact words of the phone call a  
18 year ago, but the context is correct.

19 Q. Let's go to DDX-7.03, please. And just to be clear,  
20 this is the same as PDX-2.02.

21 Do you remember talking about this slide on  
22 direct?

23 A. Yes.

24 Q. Okay. And so your opinion is that experts in  
25 the field consistently expressed skepticism that an

1 antihistamine would add benefit to a nasal corticosteroid;  
2 right?

3 A. Yes, sir.

4 Q. And you were certainly an expert in the field of  
5 treating allergic rhinitis as of June 2002; right?

6 A. I was.

7 Q. But, sir, in May 2002, one month before the priority  
8 date in this case, didn't you tell your peers the exact  
9 opposite of what you told the Court?

10 A. Could you give more? I'm sure you are going to show  
11 me an example. Why don't we just go to it.

12 Q. Let's go to DDX-7.04.

13 This is an article from Allergy and Asthma.  
14 It's called Symposium, Ineffective Diagnosis and Treatment  
15 of Rhinitis - Can We Afford the Consequences?

16 And you see there is a date there. It says May  
17 to June of 2003. Do you see that?

18 A. I do.

19 Q. And this is actually publishing pieces from an  
20 earlier symposium. Do you understand that?

21 A. Yes.

22 Q. Okay. Let's go to DDX-7.05. And this is page 163 of  
23 the document.

24 This is your article; right?

25 A. Okay.



Kaliner - cross

1 Q. It's called Symposium Continued. Progressive  
2 Management Strategies in the Treatment of Rhinitis.  
3 Correct?

4 A. Right.

5 Q. And in the bottom, you see it says from the George  
6 Washington University School of Medicine, Washington, D.C.  
7 and the Institute for Asthma and Allergy, Chevy Chase,  
8 Wheaton, Maryland.

9 That is your institute, right?

10 A. Yes.

11 Q. And it says: Presented At the Preconference  
12 Symposium of the Eastern Allergy Conference, Key Biscayne,  
13 Florida, May 2, 2002. Right?

14 A. Yes.

15 Q. And obviously May 2, 2002, that is just a month  
16 before the priority date at issue in this case; right?

17 A. Yes.

18 Q. And this presentation was given to clinicians who  
19 treat allergic rhinitis; right?

20 A. Yes.

21 Q. Okay. And those are people who satisfy your  
22 definition of a person of ordinary skill in the art?

23 A. Yes.

24 Q. Let's look at DDX-7.07.

25 And this is page -- this is DTX-312, the same

1 document at page 6 of the document. And here, you told  
2 those skilled in the art in May 2002 that symptoms typical  
3 of allergic rhinitis; primarily sneezing, nasal itching and  
4 rhinorrhea; benefit most from an intranasal corticosteroid  
5 combined with an oral antihistamine to which a topical  
6 antihistamine can be added for additional symptomatic  
7 control. Right?

8 A. Yes.

9 Q. And let's turn to DDX-7.08.

10 This is DTX-312 at page 8. Here, this is a  
11 section called Progressive Management Algorithms; right?

12 A. Yes.

13 Q. And you are talking about the ARIA guidelines, the  
14 allergic rhinitis and its impact on asthma?

15 A. Yes.

16 Q. Okay. Here, you told those skilled in the art in  
17 March-May 2002 that the allergic rhinitis and its impact on  
18 asthma guidelines and other successful management strategies  
19 for allergic rhinitis suggested the combined use of an oral  
20 antihistamine with an intranasal corticosteroid; right?

21 A. Yes.

22 Q. And then you go on to say, residual symptoms can be  
23 treated by adding the topical antihistamine azelastine to  
24 the regimen; right?

25 A. Yes.

Kaliner - cross

1 Q. And you have actually relied heavily on the ARIA  
2 guidelines in support of your opinions; right?

3 A. No. I mean I said that, I quoted the ARIA guidelines  
4 mostly in response to your using -- your witnesses using the  
5 ARIA Guidelines. I have significant problems with the ARIA  
6 Guidelines, but in the context of what we're talking about  
7 here, I largely agree with them.

8 Q. Okay. Let's go to DTX-7.09.

9 This is a paragraph 20 from the opening report.  
10 In your opening report, did you say: I rely heavily on the  
11 Dykewicz guidelines from 1998 and the allergic rhinitis and  
12 its impact on asthma guidelines from 2001?

13 A. I just said within the context. I mean I have  
14 problems with the ARIA guidelines. I critiqued it very  
15 heavily for the American Academy of Allergy; but in the  
16 context of what we're talking about today, I do agree  
17 largely with what they say, but I like Dykewicz and that is  
18 what I use more, but that is all right.

19 Q. Okay. Let's go back to 7.08 again.

20 Now, when you talk about intranasal  
21 corticosteroids, that would obviously include fluticasone;  
22 right?

23 A. Yes. Okay.

24 Q. So you told your peers in May of 2002 that the ARIA  
25 Guidelines suggest combining intranasal steroids like

1 fluticasone with azelastine along with oral antihistamines;  
2 right?

3 A. That would have been an example of the choices, yes.

4 Q. Okay. And here you see you refer to Table III.

5 A. Okay.

6 Q. Let's look at that. DDX-7.10.

7 All right. This is the Table III that you were  
8 referring to; right?

9 A. Yes.

10 Q. And it is called Algorithms For Progressive  
11 Management Approaches; right?

12 A. Yes.

13 Q. And for allergic rhinitis, the first thing you listed  
14 was oral antihistamine plus nasal corticosteroid; right?

15 A. That's correct.

16 Q. And then the second thing you listed was oral  
17 antihistamines plus nasal corticosteroids plus nasal  
18 antihistamines for residual symptoms; right?

19 A. Yes.

20 Q. And, of course, azelastine is a nasal antihistamine;  
21 right?

22 A. Right.

23 Q. And then, the third thing you listed is the saline  
24 nasal irrigation; right?

25 A. Correct.

Kaliner - cross

1 Q. Let's go back to DDX-7.11.

2 Now, on your direct, you actually accused  
3 Dr. Schleimer of being misleading when he quoted from some  
4 of the prior art. Do you remember that?

5 A. Yes.

6 Q. During your direct you said experts in the field  
7 consistently expressed skepticism that an antihistamine  
8 would add benefit to a nasal corticosteroid. Right?

9 A. Yes.

10 Q. But at the relevant time, May 2002, you personally  
11 taught clinicians as part of a treatment algorithm that an  
12 antihistamine would add benefit to a nasal corticosteroid.  
13 Right?

14 A. Well, I note, what I say here is the way that we  
15 treat patients, and I think we went over this, not you and I  
16 but your colleague and I, in great detail at deposition,  
17 about how I treat patients. This is precisely how I treat  
18 patients.

19 I was quite frank. This is the way we do it.  
20 An oral antihistamine, if it didn't work we added a nasal  
21 steroid. If it didn't work, we added other agents. In this  
22 case we added a nasal antihistamine. By and large, patients  
23 improve.

24 Q. So just so I understand, are you telling the Court  
25 that a person of ordinary skill in the art in June 2003

Kaliner - cross

1 would have ignored what you were telling clinicians in May  
2 2002?

3 A. No, I am not saying that.

4 Q. Now, on direct, I think you testified that Flonase  
5 has an unpleasant smell. Do you remember that?

6 A. Yes.

7 Q. And that you personally didn't like to use it,  
8 something to that effect?

9 A. It was not my preferred nasal steroid.

10 Q. Are you suggesting that a skilled artisan in 2002  
11 wouldn't have looked at fluticasone as an intranasal steroid  
12 to treat allergic reliance?

13 A. No. I am responding to the fact that it would have  
14 been another choice amongst several choices.

15 Q. Are you saying that a person of ordinary skill in the  
16 art would have preferred Nasacort over Flonase? Is that  
17 what you are saying?

18 A. I did say that.

19 Q. Let's go to DTX-7.29. This is showing PTX-98 at 71.  
20 What I am looking at here is PTX-98. This is the data  
21 monitor document that you used on your direct testimony.

22 Nasacort global sales were half a billion  
23 dollars. 500 million in 2003. Right?

24 A. So we are talking about Nasacort. Right?

25 Q. Nasacort.

1 A. Yes.

2 Q. So let's go to the prior demonstrative. According to  
3 the same document, Flonase sales were twice as much. Right?

4 A. Glaxo is a great company. And they have very good  
5 sales. They know how to market very well.

6 Q. Flonase was a billion-dollar drug in 2003?

7 A. Flonase was the leading nasal steroid. I think there  
8 is no controversy about that. That's not the issue that I  
9 raised.

10 Q. Now, you also testified that azelastine had some  
11 substantial side effects. Right?

12 A. Yes.

13 Q. Let's go back to the article we looked at in  
14 DDX-7.16. And this is DTX-312 at Pages 4 and 5. Here you  
15 are talking about the second-generation oral antihistamines.  
16 I won't list them. You said that they represent a market  
17 improvement over the first generation only on their reduced  
18 effects on the central nervous system and the excerpted  
19 specification, and the long half-life. Right?

20 A. I am sorry. Are you reading from that?

21 Q. I read the part before the highlighting. Sorry.

22 A. I wasn't following you.

23 Q. You agree with the part before the highlight?

24 A. Yes.

25 Q. And then you said the benefits of the second

1 generation antihistamines have been enhanced further by the  
2 development of topical antihistamines such as azelastine.

3 Right?

4 A. Yes.

5 Q. And you explained that the intranasal delivery of  
6 azelastine increases global drug concentration and limits  
7 systemic distribution. Right?

8 A. Yes.

9 Q. And that's what you wanted as a clinician before June  
10 2002?

11 A. Yes.

12 Q. So by June 2002, a skilled artisan would have known  
13 to combine a nasal steroid with a nasal antihistamine to  
14 treat allergic rhinitis. Right?

15 A. I think you are leaving out the oral histamine as  
16 part of that combination. So I was suggesting they would  
17 have an oral histamine and a nasal steroid, and if they  
18 still had residual symptoms, adding a nasal steroid might  
19 have really benefitted.

20 Q. A skilled artisan would have known what you just said  
21 in June 2002. Right?

22 A. Yes.

23 Q. And, in fact, you had personally prescribed Flonase  
24 combined with Astelin before June 2002. Right?

25 A. I think I said that in my testimony, yes.



Kaliner - cross

1 Q. So there is no question that doctors in the field,  
2 persons of ordinary skill in the art, were prescribing  
3 Flonase with azelastine before June 2002. Right?

4 A. There were probably physicians prescribing azelastine  
5 and fluticasone at the same time. I remember, for every one  
6 nasal Astelin there were 25 Flonase prescriptions being  
7 prescribed or whatever the number is. So there had to be  
8 some recombinant administration.

9 Q. Doctors would be doing this according to the  
10 FDA-approved doses for the two drugs. Right?

11 A. You know, doctors play with doses. But that would  
12 likely be the way that people would use the medications.

13 Q. In fact, before 2002, combining a nasal steroid and  
14 an antihistamine was the best treatment available for  
15 allergic rhinitis. Right?

16 A. Oral antihistamine.

17 Q. Let's play your deposition transcript, Page 69, Line  
18 21 to Page 70, Line 19.

19 "Question: There were patients back in 2001 for  
20 whom you were giving a nasal steroid an antihistamine,  
21 correct?

22 "Answer: By antihistamine you mean oral or  
23 nasal or both?

24 "Question: Or nasal. Either one?

25 "Answer: Yes.

Kaliner - cross

1 "Question: Okay. And for those patients did  
2 you see improved efficacy over either the steroid or the  
3 antihistamine alone?

4 "Answer: Okay, in my clinical practice and at  
5 that period of time, my impression was that the combination  
6 of a nasal steroid and an antihistamine was the best  
7 treatment I can give.

8 "Question: Okay. Do you believe that it was  
9 more efficacious in terms of control of symptoms of allergic  
10 rhinitis?

11 "Answer: Yes."

12 Was that your testimony?

13 A. Yes.

14 Q. Now, can we agree now that it was obvious in June  
15 2002 to combine fluticasone with azelastine?

16 A. No, no. You are misleading what I said. I am very  
17 clear that is a hundred percent consistent with all your  
18 comments. That is not what I said.

19 Q. You are disagreeing with me. And your counsel can  
20 ask questions on redirect.

21 A. You are not representing me accurately.

22 Q. Let's go to DDX-7.17. This is DTX-154. This is an  
23 article by Cauwenberge, and that other snapshot indicates  
24 this is one of the references that you relied on in this  
25 case. Is that right?

Kaliner - cross

1 A. That's a reference to one of my articles?

2 Q. Yes. The snapshot is from your materials considered?

3 A. Okay.

4 Q. And the document is called Consensus Statement on the  
5 Treatment of Allergic Rhinitis. Right?

6 A. Yes.

7 Q. And it was published in 2000. Do you see that?

8 A. Yes.

9 Q. In the Journal of Allergy?

10 A. I do.

11 Q. It has a number of authors, I don't know if you can  
12 see that, you can see Bousquet is one of the authors?

13 A. Yes.

14 Q. And he is the lead author of the ARIA guidelines.  
15 Right?

16 A. Yes.

17 Q. And also Dr. Howarth is one of the authors. Right?

18 A. Yes.

19 Q. And he is one of the authors of the review articles  
20 that you talked about yesterday and relied on. Right?

21 A. Right.

22 Q. Let's go to DDX-7.18. And this is DTX-154 at 10.

23 This article teaches that if the patient  
24 presents with severe symptoms or if the treatment with nasal  
25 steroids in the case of moderate disease does not have an

1 adequate effect, a combination of nasal steroids and  
2 antihistamines (oral and/or topical) is recommended.

3 Right?

4 A. Yes.

5 Q. Let's go to the next page, which is DDX-7.19. This  
6 article has a flowchart. Right?

7 A. Yes. It is an algorithm.

8 Q. It is akin to a treatment algorithm. It is for  
9 seasonal allergic rhinitis. Right?

10 A. Yes.

11 Q. It says if there is a need for therapy and there is  
12 severe symptoms, you go to nasal corticosteroids plus oral  
13 or nasal antihistamines. Right?

14 A. Okay.

15 Q. And then if there is long duration, you can go to  
16 nasal corticosteroids and then if that doesn't control, you  
17 go back though that box, nasal corticosteroids plus oral or  
18 nasal antihistamines. Right?

19 A. Right.

20 Q. So the prior art here shows that nasal  
21 corticosteroids plus other nasal antihistamines should be  
22 used at least to treat some patients suffering seasonal  
23 allergic rhinitis. Right?

24 A. Yes.

25 Q. Let's turn to your definition of a person of ordinary

Kaliner - cross

1 skill in the art or POSA. DDX-7.20.

2 This was the slide you showed the Court during  
3 direct examination. Right?

4 A. Yes.

5 Q. And I believe you testified that in your view a POSA  
6 needs to have clinical acumen to be able to judge these  
7 patents. Right?

8 A. I did say that.

9 Q. You understand that Dr. Schleimer doesn't have an  
10 M.D. Right?

11 A. Yes.

12 Q. If you agreed that a POSA could be a pharmacologist,  
13 that would hurt Meda. Right?

14 A. That would hurt who?

15 Q. That would hurt Meda?

16 A. We are not talking about that. We are not talking  
17 about Meda. We are talking about POSA.

18 Q. If you had defined a person of ordinary skill in the  
19 art to include someone like Dr. Schleimer, that would tend  
20 to hurt Meda's case. Right?

21 A. The definition of a POSA is who should be judging the  
22 patents. It has nothing to do with medicine. The patents  
23 are separate.

24 I think a POSA should have an M.D., but I agreed  
25 yesterday that if we used Dr. Schleimer's definition, it

1 wouldn't change my opinion.

2 Q. Okay. Well, there is no question that Dr. Schleimer  
3 is qualified to offer an expert opinion in this case on the  
4 patents-in-suit; right?

5 A. No, I have been clear all along. Dr. Schleimer is a  
6 brilliant scientist, and I have a tremendous amount of  
7 respect for him.

8 Q. And, in fact, you have cited Dr. Schleimer in your  
9 allergic rhinitis papers; right?

10 A. I have a tremendous amount of respect for Bob and his  
11 work.

12 Q. If we go to DDX-7.21.

13 In fact, you cited Dr. Schleimer in the article  
14 that we have been talking about today; right?

15 A. The article you have been talking about today, yes.

16 Q. Okay. And you know he has published on steroids in  
17 the Middleton textbook, right?

18 A. Yes.

19 Q. And that, you refer to that as the Bible of allergic  
20 diseases; right?

21 A. It is.

22 Q. Now, just to be clear, is it your opinion that an MD  
23 is necessary to appreciate the patents in suit? Is that  
24 what you are saying?

25 A. I am saying that.

Kaliner - cross

1 Q. Now, let's go to DDX-7.23.

2 That's the wrong -- hold on. Bear with me.

3 Well, sir, you understand that neither of the  
4 inventors of the patents in suit have an MD?

5 A. I have never met or -- I have never met either of the  
6 inventors. I don't know really anything about them.

7 Q. Would it surprise you to learn neither one had an MD?

8 A. It wouldn't surprise me, no.

9 Q. Let's go to what hopefully is DDX-7.24.

10 All right. This was a document you discussed  
11 during your direct testimony, right?

12 A. That is correct.

13 Q. Okay. And I want to make sure I understand your  
14 opinion here.

15 The combination rule is a basis for FDA approval  
16 of a co-formulated product; right?

17 A. Yes.

18 Q. And so you are saying a person of ordinary skill in  
19 the art would not have been motivated to develop the claimed  
20 invention based on this FDA combination rule; is that right?

21 A. That's correct.

22 Q. Okay. On direct, you testified that a POSA would not  
23 have expected improved compliance from a co-formulation of  
24 azelastine and fluticasone; right?

25 A. Say that, the middle word there again.

Kaliner - cross

1 Q. Sure. Is it your opinion that a POSA would not  
2 have expected improved compliance from a co-formulation of  
3 fluticasone and azelastine?

4 A. What do you mean by co-formulation?

5 Q. A fixed product with the two active ingredients.

6 A. First of all, I didn't have -- so you are talking  
7 about Dymista. You are really talking about Dymista.

8 Q. Well, you can use that.

9 A. Or Duonase.

10 Q. Well, there was no Dymista in June of 2002.

11 A. That's right.

12 Q. So going back to June 2002, is it your opinion that  
13 a POSA would not have expected improved compliance if the  
14 two drugs were put together in a single formulation?

15 A. Okay. I'm sure you are going to correct me, but I  
16 don't remember talking about what you are saying. What I  
17 did say was using the two sprays conjunctively, one after  
18 the other would not lead to enhanced compliance. Because of  
19 the unpleasant side effects, they would have lower compliance.  
20 I don't recall talking about a single formulation in the  
21 same bottle in that context.

22 Q. So are you offering the opinion that a skilled  
23 artisan in June 2002 would have expected improved compliance  
24 if the two products were co-formulated?

25 A. Well, first, I have no way of knowing because the



Kaliner - cross

1 products is not there and I haven't seen any data regarding  
2 either Duonase, of which I don't know if there are any  
3 studies, but certainly Dymista. I haven't seen any  
4 compliance analysis, so I have no data to draw upon, if you  
5 are asking my opinion.

6 Q. Well, let me ask you. Improved compliance is  
7 actually the most frequently quoted reason for using fixed  
8 combination products; right?

9 A. I'm sorry. Say that again?

10 Q. Improved compliance is actually the most frequently  
11 quoted reason for using fixed combination products; is that  
12 right?

13 A. Who is the quote from?

14 Q. Well, let's go to --

15 A. It's not from me.

16 Q. Well, let's go to DDX-7.31.

17 Oh. Hold on. Sorry. 7.30.

18 This is a document from Shenfield (1986), and it  
19 is called, Fixed Drug Combinations. Which Ones Can Be  
20 Recommended. Have you seen this one before?

21 A. No, not that I remember.

22 Q. Well, here, and this is DTX-46 at pages 5 to 6. Do  
23 you see there is a Table 1, it says potential advantages of  
24 fixed drug combination, and the first one is improved  
25 compliance. Do you see that?

Kaliner - cross

1 A. I'll accept that.

2 Q. And it says, the most frequently quoted reason for  
3 using fixed combination products is improved compliance.

4 Do you agree with that?

5 A. Well, I haven't really thought about this before. I  
6 have no reason to disagree with these guys. It's not my  
7 area of expertise. I read it, and I don't disagree with it.  
8 I'm not sure that I can really go beyond that.

9 Q. All right. And just to be clear, this is DTX-48. I  
10 may have said DTX-46.

11 In fact, by 2002, a skilled artisan would have  
12 thought a nasal azelastine would act faster than nasal  
13 fluticasone; right?

14 A. Yes.

15 Q. And by 2002, skilled artisans would have been  
16 motivated to improve patient compliance by putting  
17 fluticasone and azelastine in one spray bottle; right?

18 A. Well, that is a big jump. You went from zero to 100  
19 without having any of the numbers in between. So the answer  
20 is no.

21 Q. Let me ask the question a little bit differently. It  
22 would have been obvious to a person of skill in the art to  
23 improve patient compliance by putting a steroid and an  
24 antihistamine in one spray bottle; right?

25 A. Gosh, you are using a lot of words. You used the

1 word "obvious."

2 Q. Would you like me to repeat it slowly?

3 A. Let's go through this. When you say "obvious," I  
4 am not a lawyer, but I know that I'm here to talk about  
5 nonobviousness so using the word "obvious" makes me a little  
6 worried how I'm going to respond to that because I don't  
7 want to do anything that legally puts me over some boundary.

8 So I'm a little concerned about the way you  
9 asked that question. There is a lot of hypotheses in that  
10 statement that I'm concerned about.

11 Q. Let me ask it again, and I'll ask it slowly, and then  
12 just try to give me a yes or no.

13 A. Yes, let's break it down and do it.

14 Q. Well, I'd like to ask the question but I'll do it  
15 slowly, and try to give me a yes or no.

16 It would have been obvious to a person of  
17 ordinary skill in the art to improve patient compliance by  
18 putting a steroid and an antihistamine in one bottle. Do  
19 you agree or disagree?

20 A. In hindsight, knowing what I know about Dymista, I  
21 would have loved to have had that in 2002. Of course, we  
22 didn't.

23 Putting the two sprays in one bottle, had I had  
24 data at the time, might have made sense. But I had no data  
25 at the time, and it really wasn't considered. I mean it

Kaliner - cross

1 might have been considered by some people. I don't know  
2 about that.

3 Q. Okay. Let's play your deposition, page 64, lines 13  
4 through 22.

5 "Question: So, again, the hypothetical is a  
6 person of ordinary skill in the art is prescribing two nasal  
7 sprays, a steroid and antihistamines. Do you understand?

8 "Answer: I do.

9 "Question: Okay. Would it have been obvious to  
10 a person of skill in the art at that point in time that they  
11 could improve patient compliance by putting those two in one  
12 spray bottle?

13 "Answer: I think you would have improved  
14 compliance."

15 BY MR. KLEIN:

16 Q. Was that your testimony, sir?

17 A. It was, and we had that series of hypotheticals.

18 Q. You answered the question. Thank you.

19 MR. KLEIN: And I have no further questions.

20 THE WITNESS: Okay. That's what I said.

21 MR. KLEIN: Oh. Your Honor, let me introduce --  
22 what is this? Hold on.

23 (Counsel confer.)

24 MR. KLEIN: Oh. The DTXs are 312, 316, 322,  
25 154, and 48. And then for the record, I refer to DDX, the

Kaliner - redirect

1 demonstratives, as 7.01, 2, 3, 4, 5, 7, 8, 9, 10, 11, 16,  
2 17, 18, 19, 20, 21, 28, and 29.

3 THE COURT: All right. Any objection to the  
4 admission of the substantive exhibits?

5 MR. VARUGHESE: No objection, Your Honor.

6 (Above-referenced exhibits admitted in evidence.)

7 THE COURT: And the demonstratives will be  
8 accepted as demonstratives.

9 You may have redirect, if you wish.

10 MR. VARUGHESE: Just a few follow-up questions,  
11 Dr. Kaliner.

12 REDIRECT EXAMINATION

13 BY MR. VARUGHESE:

14 Now, in responding to Mr. Klein's earlier  
15 questions you said you consulted for other pharmaceutical  
16 companies; is that correct?

17 A. Yes, I have.

18 Q. Can you identify which companies you consulted for,  
19 to the best of your memory?

20 A. It's a long list, and I can't possibly -- unless I  
21 have taken the time to prepare it, I couldn't give you a  
22 list.

23 But it includes all the major companies; and  
24 over the last probably starting around 1990 to date, I  
25 have earned somewhere between \$60 and \$200 thousand a year

1 consulting with companies, and so just, I work with many,  
2 many companies.

3 Q. And you testified that you have loyalty to Meda?

4 A. I'm sorry?

5 Q. You testified earlier that you are loyal to Meda?

6 A. I have a great deal of respect for Meda and I worked  
7 with them for a long time.

8 Q. But is that respect or loyalty the basis for any of  
9 your opinions that you provided?

10 A. It is not.

11 Q. What is the basis of your opinions?

12 A. My clinical practice, what I knew I was doing, what  
13 other people were doing, and my understanding of the world's  
14 literature.

15 Q. And is your testimony true and accurate to the best  
16 of your knowledge?

17 A. Oh, today? Yes, of course.

18 Q. You stand by your testimony?

19 A. Yes.

20 Q. Do you rely on any income from Meda for your  
21 day-to-day existence?

22 A. I am a very successful physician. And the answer is  
23 that, although this is not a small amount of income, it is  
24 certainly not my major source of income.

25 Q. Can we go to DDX-7.08, please.

1                   When presented by Mr. Klein you admitted that  
2                   you wrote this article. Right?

3                   A.           Yes.

4                   Q.           In any of the portions that he showed you, did you  
5                   see to combine azelastine and fluticasone into a fixed dose  
6                   combination?

7                   A.           No.

8                   Q.           Also, in response to Mr. Klein with respect to this  
9                   article, I believe you mentioned medication cycling. Is  
10                  that correct?

11                  A.           Cycling, that's what we were doing. That was the  
12                  whole context of this progressive approach, was to try oral  
13                  antihistamines, nasal steroids. If there were residual  
14                  symptoms you add other medications, one of which was  
15                  azelastine or a topical steroid, topical antihistamine.  
16                  That's what I said. That's entirely consistent with  
17                  everything I have said in the depositions and here.

18                  Q.           Can we go to DTX-48, Page 12 of the DTX.

19                               Highlight the bottom table.

20                               Let's go to the cover page first.

21                               Next page.

22                               Next one.

23                               Keep going.

24                               Okay. This is the article that you were just  
25                   discussing with Mr. Klein?

1 A. Yes.

2 Q. Can we go to Page 12, the bottom line of the table.

3 Can you read that?

4 A. I can.

5 Q. Can you read it for the Court, please?

6 A. "The potential disadvantages of fixed drug  
7 combinations.

8 "Fixed dosage ratio (inflexibility).

9 "Incompatible pharmacokinetics.

10 "Increased toxicity.

11 "Inappropriate combinations.

12 "Ignorance of content."

13 And "Brand names."

14 Q. What is your understanding of what is being depicted  
15 here in this article?

16 A. First of all, I have never seen this before. But the  
17 bottom line is that at least the first point was exactly  
18 what he talked about, is that once you fix the relationship  
19 between azelastine and fluticasone, then you have no  
20 flexibility to titrate the fluticasone to its lowest  
21 effective dose.

22 MR. VARUGHESE: Nothing further, Your Honor.

23 THE COURT: You may step down, Doctor. Thank  
24 you very much.

25 THE WITNESS: Thank you.



Carr - direct

1 (Witness excused.)

2 THE COURT: Plaintiffs may call their next  
3 witness.

4 MR. BARDENSTEIN: Good morning, Your Honor. I  
5 don't think we have had the pleasure of meeting. My name is  
6 Rami Bardenstein. I represent the plaintiffs Meda and  
7 Cipla. I am doing the direct examination.

8 THE COURT: Okay.

9 ... WARNER CARR, having been duly sworn as a  
10 witness, was examined and testified as follows ...

11 THE COURT: Welcome, Mr. Carr.

12 You may approach, and you may proceed.

13 DIRECT EXAMINATION

14 BY MR. BARDENSTEIN:

15 Q. Good morning, Dr. Carr. Can you state your full name  
16 for the record?

17 A. Yes. Good morning. My name is Warner Carr.

18 Q. And could you please summarize your academic  
19 background and experience for the Court?

20 A. Sure. I did my Bachelor's degree in biology at Boise  
21 State University. I moved from there to do medical school  
22 at the University of Washington in Seattle.

23 From there I did an internship and residency in  
24 internal medicine. And after that I went to Walter Reed  
25 Army Medical Center to do an allergy and clinical immunology

Carr - direct

1 fellowship.

2 Q. If you could please turn to PTX-125 in your binder  
3 and identify that for the Court?

4 A. That's my CV.

5 Q. Is it an accurate and up-to-date representation of  
6 your background and experience?

7 A. Yes.

8 Q. You mentioned a fellowship at Walter Reed. What did  
9 you do after your fellowship?

10 A. After I finished my fellowship, I stayed on as  
11 faculty there, teaching medical students, residents,  
12 fellows, and I did research at the Walter Reed Army  
13 Institute of Research.

14 Q. Did you ever leave Walter Reed, work anywhere else  
15 during that period of time?

16 A. Yes. I did a couple of details. I worked at the  
17 FDA.

18 Q. How did you come about working at the FDA?

19 A. Well, the division director at the FDA, Dr. Badrul  
20 Chowdhury was a faculty member at Walter Reed. He was one  
21 of my staff when I was in training and then we were  
22 colleagues seeing patients together, and some of the  
23 research projects that we had done at the Walter Reed Army  
24 Institute of Research, you know, we always tried to -- as a  
25 military investigator, you don't have a lot of money, so we

Carr - direct

1 would try to partner with pharma but sometimes pharma  
2 wouldn't partner with us and we would have to do stuff on  
3 our own.

4 We didn't have as much regulatory experience at  
5 that time. And I would rely on Badrul, because he was, you  
6 know, the division director over there.

7 At one point he said, You know what, Warner?  
8 Let's have you come over to the FDA and work at the FDA.

9 That's how I ended up there.

10 Q. Can you tell the Court what division of the FDA you  
11 ended up working at?

12 A. I worked at the Division of Pulmonary and Allergy  
13 Drug Products.

14 Q. Is that the same division that would approve drugs  
15 for the treatment of allergic rhinitis?

16 A. That's correct.

17 Q. How long were you at the FDA?

18 A. I was there for a year.

19 Q. What was your responsibilities there?

20 A. I served as a medical officer.

21 Q. Can you tell the Court what a medical officer at the  
22 FDA does?

23 A. Basically, what a medical officer does is, a  
24 pharmaceutical company, or a sponsor, individual  
25 investigator, whoever, will submit stuff to the FDA, the

Carr - direct

1 medical officer then will review everything. It just  
2 depends on what level in clinical development, whether it's  
3 Phase 1, Phase II, Phase III, whatever, you will review that  
4 and write a summary. And eventually these products can  
5 advance in their clinical development and ultimately they  
6 get approved or not approved.

7 Q. What did you do after you left the FDA, after a year  
8 there?

9 A. I went to Iraq.

10 Q. What did you do after that?

11 A. Well, when I got back from Iraq, I went back to  
12 Walter Reed and then once I finished up my time in the  
13 military, I went to private practice in Southern California  
14 where I am at now.

15 I am at Allergy and Asthma Associates of  
16 Southern California. We also have a very busy clinical  
17 research center, Southern California Research. And that's  
18 what I have been doing since.

19 Q. In your clinical practice, the patients that you see,  
20 do they suffer from allergic rhinitis?

21 A. Yes, amongst other things.

22 Q. And how long have you been seeing patients that  
23 suffer from allergic rhinitis?

24 A. Well, allergic rhinitis is one of the most common  
25 diseases. I graduated medical school in '96. I guess in

Carr - direct

1 some form 20 years.

2 Q. And you mentioned some research that your clinic  
3 does. Is that research on patients suffering from allergic  
4 rhinitis?

5 A. We actually have a dedicated research center, not  
6 just a clinic. It's a dedicated research center, Southern  
7 California Research. And we do research predominantly on  
8 allergic diseases, allergic rhinitis, asthma, eczema. We do  
9 other things as well.

10 Q. Are you a board certified physician?

11 A. Yes, I am board certified in internal medicine. I  
12 have recertified in internal medicine. I am board certified  
13 in allergy and clinical immunology. I have recertified in  
14 allergy and clinical immunology, and I am also a board  
15 certified clinical investigator.

16 Q. If you can go back to your CV, which is PTX-125, does  
17 it list the medical organizations you belong to?

18 A. Yes, it does.

19 Q. Does it list any editorial boards of journals that  
20 you sit on?

21 A. Yes. I have sat on various boards.

22 MR. BARDENSTEIN: Your Honor, at this time we  
23 would like to tender Dr. Carr as an expert in the treatment  
24 of allergic rhinitis and the development and conduct of  
25 clinical trials for allergic rhinitis.

Carr - direct

1 THE COURT: Any objection?

2 He is so recognized.

3 BY MR. BARDENSTEIN:

4 Q. Dr. Carr, have you been retained by the plaintiffs in  
5 this case to offer expert opinions?

6 A. Yes, I have.

7 Q. Are you prepared to do that today?

8 A. I am.

9 Q. Before we get into your opinions, were you in the  
10 courtroom when Dr. Kaliner testified about his definition of  
11 a person of ordinary skill in the art?

12 A. Yes, I was present.

13 Q. Do you use the same definition?

14 A. I do.

15 Q. Are your opinions based on what a person of ordinary  
16 skill in the art in 2002 would know and do?

17 A. Yes.

18 Q. Have you prepared some slides to help your testimony  
19 today?

20 A. Yes, I have.

21 Q. Mr. Beall, if we can bring up Dr. Carr's  
22 demonstratives.

23 Turn to the first one. If you could just tell  
24 the Court briefly what opinions you plan on testifying about  
25 today?

Carr - direct

1 A. Yes. Look, after reviewing everything in this  
2 particular case, I broke my opinions down into three things.  
3 First, that Dymista's clinical results were unexpected when  
4 they came out. It was actually quite exciting when they  
5 came out. Second, the FDA was very skeptical that Dymista  
6 even had a pathway forward that it could be approvable. And  
7 then finally, when Dymista finally came out and was on the  
8 market, there was really significant praise in my community,  
9 in the medical community for Dymista.

10 Q. I want to talk about the clinical trials, the FDA  
11 approval process for Dymista. I think we have been talking  
12 about a lot and it's been mentioned before about the  
13 combination rule. Is Dymista a combination product that  
14 would be governed by the combination rule?

15 A. Yes, it would be.

16 Q. If you could please turn to PTX-47, 110, 335, and 114  
17 in your binder, and let me know if these are the documents  
18 you are going to rely on to testify about Dymista's approval  
19 process?

20 A. Yes.

21 MR. BARDENSTEIN: Mr. Beall, if we please bring  
22 up PTX-110.

23 BY MR. BARDENSTEIN:

24 Q. And, Dr. Carr, if you could turn to that in your  
25 binder, page 2, PTX110-0002.

Carr - direct

1                   If we could highlight the introductory comment?

2                   Dr. Carr, can you tell the Court what is being  
3                   represented here on this introductory comment?

4           A.       Yes. This document is a fax. I'm actually looking  
5                   at the front of it, but this document is a fax from the FDA  
6                   back to MedPointe, the company that eventually became Meda,  
7                   and it is dealing with questions that Meda had posed to the  
8                   division specifically about satisfying the combination rule  
9                   and what would be appropriate monotherapy comparators in  
10                  order for them to be able to satisfy that combination rule.

11                  And what you are seeing here is the divisions  
12                  response. And they, they open it up with just some  
13                  introductory comments. And they say, "According to the 21  
14                  CFR 300.50, two or more drugs may be combined in a single  
15                  dosage form when each component makes a contribution to the  
16                  claimed effects."

17                  That is essentially the combination policy.

18                  And then they go on to say: "Specifically  
19                  applying that, in that division, applying the combination  
20                  rule to the Meda clinical development plan, your development  
21                  program should demonstrate the efficacy and safety."

22                  So both efficacy and safety of the fixed  
23                  combination drug and the contribution of each component to  
24                  the contribution.

25           Q.       And how did Meda go about proposing they would



Carr - direct

1     satisfy the combination rule to the FDA?

2     A.     Yeah.  So I think it's very important that it's  
3     efficacy and safety.  You have to satisfy both.  And if  
4     you have a great drug but it's not safe, there is lots of  
5     examples of drugs that never got approved because of that.  
6     So you have to meet the burden of both.

7             And the easy thing at the time was what Meda  
8     had proposed was they had formulated Dymista and they wanted  
9     to just compare it to what was commercially available to  
10    Flonase and Astelin and then placebo.

11            Just so I'm clear, what this means, efficacy,  
12    there is a strategy where the combo has to be better than  
13    placebo, than each monotherapy comparators, so the Flonase  
14    and the Astelin have to be better than placebo.

15            Then the combo has to be better than both of  
16    the monotherapies.  That is efficacy.  And then you have to  
17    gather safety information to make sure there is no safety  
18    concerns.

19            So that is what this is saying, and they had  
20    proposed using Flonase, Astelin compared to Dymista and  
21    placebo.

22            MR. BARDENSTEIN:  Mr. Beall, if we can highlight  
23    the first sentence of the next paragraph.

24    BY MR. BARDENSTEIN:

25    Q.     Dr. Carr, is this what you are referring to as

Carr - direct

1 Meda's proposal to use the commercial Flonase and Astelin?

2 A. Well, yes, this is the FDA telling Meda you propose  
3 the following monotherapy comparators, Flonase and Astelin.

4 Q. And do you know what the FDA's response to Meda's  
5 proposal was?

6 A. Yes. They basically did not agree with this. They  
7 said you cannot use it. In fact, if you read on in the next  
8 sentence there, it says: "As stated previously" -- so they  
9 had had multiple questions going back and forth -- "there  
10 are pharmaceutical differences between your combination  
11 product and your proposed monotherapy comparators which may  
12 significantly impact efficacy and safety, complicating  
13 interpretation of clinical trials."

14 So they would not accept using commercially  
15 available.

16 Q. What did the FDA make Meda do?

17 A. Well, the only difference here -- they're all the  
18 same actives, right? Fluticasone is fluticasone. The  
19 only difference is the formulation. How is fluticasone  
20 formulated?

21 And so what the FDA made the company do is  
22 make their own formulation of fluticasone, and their own  
23 formulation of azelastine, and those formulations had  
24 to be identical, exactly the same as the formulation as  
25 Dymista, and then they used, the placebo was basically

Carr - direct

1 the formulation with no active drug. So they had to make  
2 those four treatment arms to do the study.

3 Q. Do you know if these comparator products that Meda  
4 ended up formulating were ever commercialized?

5 A. No. In fact, they had to make an agreement with the  
6 FDA not to commercialize them.

7 Q. Was that the end of the FDA's concerns with Meda's  
8 approval plan for Dymista?

9 A. That was just the beginning.

10 Q. If you could turn to PTX-114 in your binder,  
11 Dr. Carr, and identify that for the Court.

12 A. So, yes, I can identify this.

13 Q. Can you tell the Court what we're looking at here?

14 A. What this is, a lot of stuff had transpired between  
15 the company and the FDA, and it finally got to the point  
16 where they had to have a face-to-face Type A meeting, and  
17 they had that meeting. And this is a fax from the FDA back  
18 to the company that includes all of the details leading up  
19 to the meeting and the actual meeting minutes.

20 Q. Let's start with the beginning of it. You said it's  
21 a Type A meeting. Can you tell the Court what a Type A  
22 meeting is?

23 A. Yes. So there are several different type of meetings  
24 that the industry can have with the FDA. Type A is when you  
25 meet with the FDA when there is a problem with your clinical

Carr - direct

1 development program.

2 Q. And I want to focus on the line that says: Received  
3 Briefing Package. Do you see that?

4 A. Yes.

5 Q. And if you could just confirm for the Court that that  
6 is what PTX-47 is?

7 A. 47?

8 Q. Yes, the briefing packet.

9 A. Yes. This is the information packet or the briefing  
10 packet that was sent by the company to the FDA, and then  
11 the FDA answered the questions that are in here. And that  
12 is basically Section 2 of this document that we're looking  
13 at right now, the 114.

14 MR. BARDENSTEIN: If we can go back to 114,  
15 Mr. Beall, and go back to page 2.

16 BY MR. BARDENSTEIN:

17 Q. I'd like to now move on to the meeting chair. Can  
18 you tell the Court who ran this meeting from the FDA?

19 A. Yes, he is the division director there. I talked  
20 about him earlier. That is Dr. Badrul Chowdhury.

21 Q. Was he is the one who brought you to the FDA from  
22 Walter Reed?

23 A. Yes. He is a very renowned allergy, immunology,  
24 clinical immunologist and the division director at the FDA  
25 in that division, yes.

Carr - direct

1 Q. Was Dr. Chaudhry a practicing physician at this time?

2 A. Yes. As I said, we saw patients together at Walter  
3 Reed. He saw clinic once a week.

4 Q. He was treating patients that suffer from allergic  
5 rhinitis?

6 A. Yes, allergic rhinitis and other diseases and  
7 teaching fellows, residents, medical students.

8 Q. And as the director of the division of pulmonary and  
9 allergic practice, he was aware of not only what was being  
10 practiced in the field but the commercially available  
11 products?

12 A. Well. As the division director, he is the signatory  
13 authority, so he signs off with they get approved or not.  
14 So, absolutely, he would be aware what is in the market.

15 Q. And if we could go to the FDA attendees section, just  
16 below.

17 Do you know anyone else on this list besides  
18 Dr. Chowdhury?

19 A. Yes. All of those people except for Ms. Bowen worked  
20 with the FDA when I worked with the FDA. So, yes, I know  
21 all those people.

22 Q. Do you know their credentials?

23 A. Yes. Well, we have already talked about  
24 Dr. Chaudhry. He is an allergist. He is a medical doctor.

25 Sally Seymour. At this point, she is the

Carr - direct

1 clinical team leader. She is a physician.

2 Joe and.

3 Jean are both Ph.Ds and they work in the pharm  
4 products division there. Joe is the team leader and Jean is  
5 the primary reviewer.

6 Q. Were you in the courtroom when Dr. Schleimer  
7 testified about his definition of a person of ordinary skill  
8 in the art?

9 A. Yes, I was.

10 Q. This group that you just described, would they fit  
11 within the definition of a person of ordinary skill in the  
12 art?

13 A. I think that group -- I mean not Ms. Bowen, I don't  
14 think she was, but I think the group that you highlighted  
15 there fits under this definition.

16 Q. And did you attend this Type A meeting?

17 A. Yes, I was present.

18 Q. If we could go to the attendees.

19 Could you tell the Court why you were present at  
20 this meeting?

21 A. Well, I had been retained by Meda as a consultant to  
22 help them. They ran into some troubles with getting their  
23 clinical development plan going forward, and they reached  
24 out to a couple of us. Phil Lieberman and I were both  
25 consultants at this meeting.

Carr - direct

1 Q. Do you recall about when you started working with  
2 Meda as a consultant on the approval process for what ended  
3 up becoming Dymista?

4 A. I don't recall the exact date. My suspicion is  
5 mid-to-late 2007, some time in 2007.

6 Q. We talked about this being a Type A meeting. Can  
7 you tell the Court what the purpose of this meeting was?

8 A. Well, as I had said, there were multiple problems.  
9 That from the time they submitted the initial new drug  
10 application, there had been multiple problems identified  
11 by the FDA and with communicating with the FDA. Meda  
12 basically couldn't find resolutions to these problems; and  
13 so we finally had to have a face-to-face meeting to see if  
14 we couldn't hash out a pathway forward for this clinical  
15 development program.

16 Realize, the FDA has guidance documents that  
17 they give to industry. And in those guidance documents,  
18 there was nothing available for a combination nasal spray  
19 because it didn't exist before. Nobody knew how to do this,  
20 and every time we would propose something, the FDA would  
21 shoot us down.

22 Q. What did Meda do in advance of this meeting?

23 A. So, they reviewed all of the documents. They looked  
24 at the major concerns that FDA had posed. And then they  
25 tried to answer each of those questions. They kind of,

Carr - direct

1     they gave a detailed -- the briefing packet that you showed  
2     earlier, that is basically giving a detailed response from  
3     Meda's perspective to the FDA. And then at the end of each  
4     one of those responses, Meda would ask the division, do you  
5     guys agree? Have we satisfied your concern? And so they  
6     submitted that briefing packet.

7     Q.     Did the FDA respond to those questions?

8     A.     Yes. The night before we were to have the meeting,  
9     we received a fax from the FDA where the FDA had responded  
10    to each one of those questions.

11           MR. BARDENSTEIN: Mr. Beall, if we could go to  
12    PTX-114, page 4.

13    BY MR. BARDENSTEIN:

14    Q.     Is this the questions? Is this a representation of  
15    the questions Meda sent to the FDA and the FDA's response?  
16    Is that what is shown in Section 2?

17    A.     Yes, Section 2 includes all of the questions. This  
18    is just the first question.

19    Q.     And, Dr. Carr, you mentioned that the meetings  
20    purpose was to resolve some issues that Meda and the FDA had  
21    had. Can you tell the Court if there were any particular  
22    questions that were posed that the meeting focused on?

23    A.     Well, I mean we had posed -- if you look through the  
24    whole of Section 2, you will see five questions. And some  
25    of them are interrelated, but I'll tell you for that hour,



Carr - direct

1     that discussion, we just couldn't get off of Question 1.  
2     I mean we just went back and forth and back and forth. And,  
3     you know, Question 1 basically, if you read it: Does the  
4     division agree that patients with moderate/severe nasal  
5     symptoms of seasonal allergic rhinitis, as defined by ARIA,  
6     is that an appropriate target population for this drug?

7             That was the question. And you see the division's  
8     response. In fact, if you go through every question you see  
9     the first thing the division says, we do not agree.

10            And then they went on even beyond the patient  
11     population and just kind of opined about all of the problems  
12     that they have, at least four different major issues that we  
13     identified just in this one response.

14     Q.     What is the first major issue you identified in the  
15     FDA's response?

16     A.     I think if you read right after, "we do not agree."  
17     It says: "We have expressed" -- so that is the FDA. "We  
18     have expressed concerns that you have not provided evidence  
19     that a population for this combination product exists."

20     Q.     What does that mean?

21     A.     That means the FDA did not believe there was a  
22     population that existed that would benefit from Dymista  
23     over, basically over its monotherapy comparators. That we  
24     couldn't even do a study.

25     Q.     And you said there is four major issues. What was

Carr - direct

1 the next major issue that you identified?

2 A. Yes. So if you go down into the next paragraph, you  
3 start where it says "demonstrating."

4 So: "Demonstrating significantly greater  
5 symptom relief with the combination product over its  
6 individual active ingredients will not be sufficient to  
7 demonstrate that both azelastine and fluticasone propionate  
8 contribute to the effectiveness of the combination."

9 Further, if you go to the next sentence:  
10 "Demonstration of greater symptom relief with the  
11 combination product over its active ingredients (for the  
12 exact same symptoms)" -- and in this case we're talking  
13 about the total nasal symptom score -- "it is likely to be  
14 due to the fact that some patients may not be responding to  
15 azelastine while responding to fluticasone and vice-versa."

16 Q. You mentioned the total nasal symptom score. I think  
17 we heard this before.

18 A. Yes.

19 Q. Is that the metric that encompasses all four  
20 symptoms?

21 A. Yes. That is basically the standard that the FDA  
22 uses as its primary endpoint to show that an allergic  
23 rhinitis medication works. You have to have benefit and a  
24 total nasal symptom score.

25 Q. What was the third major issue that Meda identified

Carr - direct

1 in the FDA response?

2 A. Well, they went on to even opine about the rationale.  
3 And they said that the rationale, based on pharmacodynamic  
4 reasoning, such as mechanism of action or onset of symptom  
5 relief, et cetera, are also not sufficient to justify the  
6 combination product.

7 So they didn't think we provided a valid  
8 rationale.

9 Q. If you could remind the Court what year this was?

10 A. This was mid-2008.

11 Q. And the FDA would have been aware what the current  
12 practice of medicine was and what current available  
13 therapies were?

14 A. Yes.

15 Q. What was the fourth major issue that Meda identified?

16 A. Well, to me, this is a safety risk that they  
17 identified. As we have discuss the multiple times, it  
18 really is the practice of medicine when doctors can titrate  
19 medicines up and down and so forth. And I think this is  
20 what they're trying to say: "As stated before, combining  
21 products eliminates flexibility with dosage titration and  
22 potentially exposes patients to unnecessary medication; and  
23 thus unnecessary risk."

24 So they just continued to shoot down the whole  
25 program there.

Carr - direct

1 Q. Do you know what the result of this whole meeting  
2 was?

3 A. Yes.

4 Q. Can you tell the Court?

5 A. So we went back and forth and back and forth and we  
6 could not get an agreement with any of these. The FDA  
7 basically said, you know, fine. We don't see a major safety  
8 concern; right? There is not going to be a body count.  
9 People aren't going to die from this drug, so you can do all  
10 the studies that you want but we're not going to recognize  
11 any of the efficacy outcomes.

12 MR. BARDENSTEIN: Mr. Beall, if you can go to  
13 PTX-114-008, the third full paragraph.

14 The last sentence, please.

15 BY MR. BARDENSTEIN:

16 Q. Dr. Carr, is this the FDA response you were just  
17 talking about?

18 A. Yes. So we were just talking about the questions a  
19 second ago.

20 This is actually the actual discussion that took  
21 place between us. And so it's in 3.0, the next section.  
22 And this is, the division stated that it would be Meda's  
23 choice on whether to pursue the study using the same  
24 endpoints to measure disease benefit, but Meda should  
25 understand the division's concerns.

Carr - direct

1 Q. And for clarity, this is the meeting minutes of the  
2 actual meeting?

3 A. Yeah. These are -- so the FDA prepares these meeting  
4 minutes and faxed them to Meda. And this is the FDA meeting  
5 minutes, yes.

6 Q. How did Meda respond to the FDA's position?

7 A. Well, I mean basically not being able to show  
8 efficacy means you are not going to get approved, and they  
9 basically said our whole program is being halted.

10 MR. BARDENSTEIN: And, Mr. Beall, if we can go  
11 to PTX-114-009. The paragraph right underneath, on the last  
12 bullet.

13 BY MR. BARDENSTEIN:

14 Q. Is this the documentation of Meda's response, the  
15 last sentence?

16 A. Yeah. So you will see, Meda verbalized their  
17 disagreement with the division's position and commented that  
18 the pathway for their proposed product for allergic rhinitis  
19 is halted. I mean they couldn't go forward at that point.

20 Q. And is that consistent with your recollection of what  
21 occurred at that meeting?

22 A. Yes, very clearly.

23 Q. What did Meda do next after telling the FDA that  
24 their view is that the FDA has halted their approval  
25 program?

Carr - direct

1 A. Well, you only have one option. I guess you have  
2 two options. The first option is you can quit, which did  
3 not happen. Or you could try to, you know, push on and the  
4 only way to override the division director is to go to his  
5 boss.

6 So they bumped it up a level and went to the  
7 office director.

8 Q. What happened next?

9 A. Well, I wasn't present at any of those meetings but  
10 I mean that Dymista is on the market now, so basically the  
11 office director met with all of the division directors and  
12 basically came back to Meda and said, okay, look. We'll let  
13 you guys do the study. We don't see any safety concern. We  
14 will accept your endpoints, changes in total nasal symptom  
15 score. However, this is a review issue.

16 So the studies were conducted.

17 Q. What does "this is a review issue" mean?

18 A. Well, as a medical officer, what you do is you  
19 review, you review stuff when it comes in. So the companies  
20 will do their safety and efficacy studies, and they'll  
21 present their view. But as an FDA reviewer, you have to be  
22 non-biased. So you take all the data in yourself, you  
23 review it yourself and you make your own conclusions. And  
24 then that is how a drug gets approved or not.

25 So basically you still have to approve this

Carr - direct

1 things works and that it is safe.

2 Q. Now, Dr. Carr, did Meda eventually run the clinical  
3 studies to prove that Dymista was safe and effective?

4 A. Yes, it's on the market.

5 Q. And we talked a little bit earlier about the  
6 comparators that Meda was forced to use the reformulated  
7 Flonase and Astelin, the commercial product. Do you recall  
8 that?

9 A. Yes. The fluticasone and the azelastine formulation  
10 comparators, we did discuss those. They are not on the  
11 market.

12 Q. Were those the studies, did Meda study Dymista  
13 compared to those as part of its approval program?

14 A. The monotherapy comparators with the same  
15 formulation?

16 Q. Yes.

17 A. Yes, that was the requirement. So the pivotal  
18 studies, okay?, the final pivotal studies that were done was  
19 the treatment arm was Dymista, fluticasone with the same  
20 formulation as Dymista, azelastine in the same formulation  
21 as Dymista, and then placebo.

22 And the placebo is basically what we call a  
23 vehicle control. So that is the formulation without any  
24 active drug.

25 Q. And you mention the term "pivotal study." Can you

Carr - direct

1 tell the Court what a pivotal study is?

2 A. Yes. So pivotal study, there are multiple stages  
3 in a clinical development program, phase 1, 2, 3. I mean,  
4 they're trying to figure out the to-be-marketed formulation  
5 or whatever.

6 The final studies that are done, the final  
7 studies that have the to-be-marketed formulation in the  
8 to-be-marketed population, that have the highest level of  
9 scientific integrity -- and what I mean by that is that they  
10 are double blind, randomized, placebo-controlled studies --  
11 those are the studies that are reviewed by the FDA and the  
12 FDA says, yes, you can do that study, and they have to do it  
13 in replicate because one study is not enough proof. You  
14 have to do it in replicate to prove that you can. Those are  
15 the pivotal safety and efficacy studies.

16 Q. How many pivotal studies did Meda for Dymista?

17 A. Meda conducted three pivotal safety and efficacy  
18 studies.

19 Q. You mentioned the term "double blind study." Can you  
20 tell the court what a double blind study is?

21 A. Yes. So a double blind study is a when a volunteer  
22 comes in and you are giving them the medication. They don't  
23 know what they're getting, and as the investigator, I don't  
24 know what they're getting. We're both blinded. It's a  
25 double blind.



Carr - direct

1 Q. And you also mentioned a "placebo control study."  
2 Can you tell the Court what that is?

3 A. Yes. We have all heard about the placebo effect. I  
4 mean you do things to patients and they can get better. We  
5 talked about earlier using nasal saline, okay? Spraying  
6 something into the nose can have benefit. You can do a  
7 sinus rinse. So there is a placebo effect.

8 You have to include a placebo as a comparator  
9 in your study because you don't know -- if you're seeing a  
10 difference, you don't know what amount of that difference  
11 is because of placebo and what amount of that difference is  
12 because of the active. So you find out what the placebo  
13 effect is and then you could remove it.

14 So when we're double blinded, patients could  
15 get placebo, patients could get active. And you know that  
16 in a clinical trial these are highly regulated, highly  
17 regulated. So patients are really looked after by the  
18 nurses and the doctors; and everybody gets better in a  
19 placebo study, it seems, placebo controlled study because  
20 they're in the study. That's the placebo effect. You have  
21 got to have that in there.

22 MR. BARDENSTEIN: Mr. Beall, if we could go back  
23 to PDX-3.2.

24 BY MR. BARDENSTEIN:

25 Q. We just talked a little bit about the FDA and Meda

Carr - direct

1 back and forth. Can you tell the Court if that relates to  
2 one of your opinions that you intend to testify about?

3 A. Well, I think that we just covered the second  
4 bullet there. The FDA was very skeptical that there was  
5 a population that existed that would benefit from this  
6 combination over either of the monotherapies. They didn't  
7 like the rationale. They didn't like that there was loss of  
8 titration. They didn't even think that they would be able  
9 to satisfy the combination rule.

10 Q. Thank you, Dr. Carr. I do want to talk a little bit  
11 more about the clinical trial results and what they did, and  
12 I would like you to turn to PTX-227 in your binder. If you  
13 could identify that for the Court?

14 A. 227?

15 Q. Yes.

16 A. Yes. 227, this is a manuscript that was published by  
17 myself and my distinguished colleagues reviewing the pivotal  
18 studies individually and then performing a meta-analysis on  
19 those three studies. And this was the publication that came  
20 from that.

21 Q. Those were the three pivotal studies for Dymista?

22 A. Yes.

23 Q. And can you tell the Court what a meta-analysis is?

24 A. Yes. A meta-analysis is when you have multiple  
25 studies and you compare them. And you get the best results

Carr - direct

1 the best results of a meta-analysis when each study is  
2 exactly the same type of study. And it's the same patient  
3 population, and you are not really then comparing apples and  
4 oranges. So you wouldn't want to do a meta-analysis, for  
5 instance, with one study that is a non-placebo controlled.  
6 I mean you could but the integrity of the data is not as  
7 valuable.

8 So this is a meta-analysis of three studies that  
9 were all conducted with the highest degree of scientific  
10 integrity. And I will point out each of these three studies  
11 were reviewed by the FDA for ten months after they were  
12 conducted. So a high level of scrutiny went into those.  
13 studies.

14 Q. I just want to focus on the last author of this Jean  
15 Bousquet. Do you know who this is?

16 A. Yes, I know Jean very well.

17 Q. Is he the same Jean Bosquet who is the author of  
18 the ARIA guidelines we have been talking about the past  
19 few days?

20 A. Yes.

21 Q. So let's turn actually to the results of your  
22 meta-analysis.

23 If you could turn to Figure 1, Mr. Beall.

24 For the record, this is PTX-227, page 0005.

25 A. Yes. Look, we jumped right to the results section.

Carr - direct

1 And this, a lot of work goes into coming into this figure,  
2 so it's a little complicated. I want to make sure that  
3 what you see here is clear.

4 So these three studies are depicted here. The  
5 studies are MP-4002; and there were 831 patients there.

6 MP-4004. There are 776 patients there.

7 MP-4006; and there are about 1,800 not quite  
8 patients there.

9 Now, remember, these studies are double-blind,  
10 randomized, placebo-controlled studies. And they're looking  
11 at the change in the total nasal symptom score from baseline  
12 at the end of two weeks treatment period.

13 I've talked to you about the placebo effect.  
14 And earlier in my paper, there is a figure or a table that  
15 shows -- that we don't have to go there but we can if you  
16 want -- that shows the placebo effect.

17 What the question is here is are the monotherapy  
18 comparators effective? And then is Dymista effective?

19 So what I have done is I have removed the  
20 placebo effect. So all I'm doing is looking at this is  
21 what I call the delta versus placebo. Okay? And it's very  
22 important, if you look at the left side, the grid there,  
23 that is the change placebo least means square change from  
24 baseline. Okay?

25 So you can present this data in multiple

Carr - direct

1 different ways. I have seen it presented in other formats  
2 and that scale is important. Okay? That scale is important.  
3 If you use raw data, for instance, the raw data would go up  
4 to -- I mean it's a total nasal symptom score, maximum score  
5 is 12 and you do that twice a day, and so that would be a  
6 maximum of 24.

7 But that is including the placebo effect. We're  
8 not talking about that here. We're talking about the delta  
9 versus placebo. So it's important that you pay attention to  
10 that scale. Okay?

11 Now, with that in mind, you see MP-2902. That  
12 is Dymista. And then you see fluticasone and azelastine.  
13 Those are the monotherapy comparators in each of these  
14 studies. So 2, 4, and 6. This is conducted over a two year  
15 time period. It's in the spring, summer, and the fall. All  
16 different pollen counts.

17 So you see reproducibly for the first time in a  
18 double-blind, randomized, placebo-controlled study, we have  
19 a drug that is on the market now that is better than a nasal  
20 steroid. We have not, in this whole presentation these last  
21 several days shown one study or a drug, head to head, is  
22 better than another nasal steroid. So I was superexcited  
23 when I saw that.

24 The other thing we have shown is that both  
25 fluticasone and azelastine is also better than placebo.

Carr - direct

1 Can I have some water, please?

2 THE COURT: Will you bring the witness some  
3 water?

4 THE WITNESS: I apologize.

5 THE COURT: No, not at all.

6 THE WITNESS: It's so arid here.

7 THE COURT: Sorry.

8 THE WITNESS: Basically, the meta-analysis is,  
9 putting all the --

10 (Witness receives water.)

11 THE WITNESS: Thank you.

12 The meta-analysis is putting all of that data  
13 together in the bottom half.

14 Q. And for clarity, can you tell the Court, what are  
15 MP-4002, 4004, and 4006, the three pivotal studies that we  
16 talked about a little bit earlier?

17 A. Right, that is accurate.

18 Q. And are the fluticasone and azelastine there, those  
19 are not the commercial Flonase and Astelin; correct?

20 A. Right. Like I said, those are the formulation  
21 comparators.

22 Q. Do you know if Meda ever actually compared Dymista to  
23 the commercial Astelin and Flonase, what would be available  
24 to a patient?

25 A. Yes, I think Dr. Kaliner presented that data.

Carr - direct

1 Q. I think we will talk a little bit about it in a  
2 moment, but I wanted to go back to your results.

3 We didn't talk about this that much. But when  
4 patients come to see you in your clinical practice, what is  
5 it that they really want?

6 A. Well, it's so funny. I mean patients have never come  
7 to me and said, hey, Dr. Carr. Can you lower my total nasal  
8 symptom score? They're coming in asking for relief. Okay?  
9 They're having problems. They are having allergy symptoms,  
10 they can't sleep at night, they can't go to school or work  
11 or whatever the issue is, and they just want relief.

12 Q. Does your paper talk anything about that point how  
13 do patients really get relief with Dymista?

14 A. Well, we do talk about how many patients get relief  
15 with Dymista, yeah. I don't think we really talk about  
16 how, the mechanisms, but we do talk about patients that get  
17 relief.

18 MR. BARDENSTEIN: Mr. Beall if, we can go to  
19 Figure 2. And, again, this is on PTX-227-0005.

20 BY MR. BARDENSTEIN:

21 Q. Can you tell the Court what we're looking at here in  
22 Figure A. Sorry, Figure 2A.

23 A. Look, when we saw the efficacy data, we were  
24 superexcited, my coauthors and myself. We were surprised  
25 that we saw this kind of robust data that was reproducible.

Carr - direct

1           So what we started doing was looking at what  
2           percentage of patients actually respond to this drug; right?  
3           Is there just a subset or what is the deal?

4           And so what this is looking at is in Panel A,  
5           it is the percentage of patients that have at least a 50  
6           percent response. So they cut the nasal symptom score in at  
7           least half. That is Panel A.

8           And you will notice if you look at the four  
9           different study drugs in this study, one of which is  
10          placebo, you will see that the only one that achieves a  
11          50 percent responder rate in half of the population is  
12          Dymista. And that is right at the end of the study.

13          These studies, they're seasonal allergic  
14          rhinitis studies. They're only two weeks long. And that  
15          is how the studies are done. That is how these drugs are  
16          approved.

17          So none of the other drugs achieve that  
18          50 percent response rate.

19          The next closest would be the fluticasone. It  
20          gets to about a 45 percent response rate. But if you can  
21          change the color of that line to like something that is  
22          easier to see and go down where that line intersects the  
23          Dymista? Yes, make that line from the top of Flonase -- go  
24          down, I'm sorry, fluticasone, all the way over to about  
25          45 percent. Okay? If you see where it intersects the



Carr - direct

1 MP-2902, draw a line straight down there to the treatment  
2 day.

3 So what you will see is that Dymista achieves  
4 the same benefit as fluticasone days earlier. Days earlier.

5 And so this is the 50 percent response rate.

6 Q. Is achieving a similar response rate days earlier  
7 clinically relevant?

8 A. Absolutely.

9 Q. How so?

10 A. Well, I mean patients don't want to wait days and  
11 days and days to get relief.

12 Look, there is a huge burden of disease. We  
13 have been talking about this burden of disease. Just to put  
14 it in perspective. If you look at the U.S. population, we've  
15 got 300-350 million people. About a third of the population  
16 has allergies. So that's about 100 million people.

17 Think about that. That is a lot of people. So  
18 if I can give them a drug that is significantly better and  
19 they're going to get better days earlier, that is affecting  
20 a lot of people. So I find that very clinically relevant in  
21 my practice.

22 Q. And Figure B, Figure 2B talks about rTNSS, less than  
23 one point for all symptom scores. Can you tell the Court  
24 what is shown in Figure B?

25 A. Yes. I find this personally, personally as a

Carr - direct

1 physician, to be the most important goal in treating my  
2 patients. And that is to achieve complete or near complete  
3 relieve of symptoms.

4 No patients want partial relief. They'll stick  
5 with it if they can get partial relief, but they want relief  
6 of their symptoms. So this is that analysis. I call it a  
7 complete or near complete resolution of symptoms, and that  
8 is where the total nasal symptom score is less than or equal  
9 to one point for all the symptom scores.

10 And what you will see is the same analysis. So  
11 the responder rate on the left side, and then on the bottom  
12 is the treatment data, and remember it is a two week study  
13 so it only goes up to 14 days. So if you do the math,  
14 right? If you look at Dymista, MP-2902 and where it comes  
15 across, if you do the math, you are going to get about one  
16 in eight patients, about one in eight patients get complete  
17 or near complete resolution of their symptoms.

18 And if you go back to that 100 million patients  
19 that are in the U.S., you are talking tens of millions of  
20 people that are getting better and they're getting better  
21 days earlier. So, to me, that is very, very impactful.

22 Q. And how does that complete or near complete symptom  
23 relief compare to the reformulated fluticasone and azelastine?

24 A. Well, we know that fluticasone and azelastine are  
25 both better than placebo, and we know that fluticasone tends

Carr - direct

1 to be more effective than azelastine.

2 So in this, you see it. Fluticasone is about.  
3 1 in 12, about 1 in 12 achieve that complete or near complete  
4 response rate.

5 But, again, if you do the same analysis, if you  
6 go from the MP-2902 where the fluticasone line intersects,  
7 MP-2902. Go down. No. If you go down to where they  
8 intersect at the treatment day. I don't know. Does this  
9 thing work?

10 Here. If you go down here? Go right here.

11 You are going to see that benefit that you got  
12 with fluticasone occurs days earlier.

13 So, again, this is a huge improvement. It's  
14 five days earlier. The average allergy season is about two  
15 weeks. 12.5 days. So that is a huge impact.

16 Now, Rami, I'm not happy with this. I want  
17 complete relief in all of my patients, but this is a huge  
18 advancement.

19 MR. BARDENSTEIN: I want to now turn to the  
20 conclusions that your study ultimately drew. If we can go  
21 to PTX-227, page 0007.

22 If we can blow up the summary.

23 BY MR. BARDENSTEIN:

24 Q. Based on all the analysis, your meta-analysis, all  
25 the results that you looked at from the three pivotal

1 studies, can you tell the Court what you and your coauthors  
2 ultimately concluded?

3 A. Well, we had a lot of conclusions, and we sat down  
4 and we discussed all of this in great detail. We actually  
5 did have face-to-face meetings and discuss this and went  
6 over e-mail before we finalized our manuscript, but I think  
7 it is summarized in that last sentence.

8 "Taken together, these results show that MP-2902  
9 can be considered the drug of choice for allergic rhinitis  
10 therapy because it offers additional benefit to patients  
11 with allergic rhinitis, in particular with moderate to  
12 severe disease."

13 Q. And I think we mentioned Jean Bousquet is a coauthor  
14 on this article?

15 A. Yes, Jean Bousquet was the senior author on the  
16 article.

17 Q. What does it mean to be an author on an article?

18 A. Well, I mean we get together, we write these  
19 manuscripts, we edit these manuscripts, and you submit them.  
20 Sometimes they get published, and sometimes they don't. But  
21 if the journal does accept them, then you have to actually  
22 sign the document that says I contributed to this. And at  
23 that point, then you confirm that you are an author and also  
24 at that point you actually give up copyright and the journal  
25 owns it.

Carr - direct

1 Q. Did Jean Bousquet agree with this conclusion?

2 A. Yes, I mean he is an author.

3 Q. And I think a moment ago we talked about that this  
4 data is comparing to noncommercial Flonase and noncommercial  
5 Astelin, and that you mentioned there was a study comparing  
6 it, comparing Dymista to the commercial product?

7 A. Yes.

8 Q. If you could turn to PTX-230 in your binder and tell  
9 me if this is the study you are referring to.

10 A. Yes, this is the Hampel article.

11 Q. And this compared Dymista to commercial Astelin and  
12 Flonase in a similar way to the Dymista pivotal studies?

13 A. Yes, it was exactly the same essentially clinical  
14 trial design. If you recall, if you recall, Meda had  
15 proposed doing this as their pivotal studies and the FDA  
16 said no.

17 But Meda went ahead and did the study, and it's  
18 exactly the same inclusion/exclusion criteria, treatment  
19 period. It's a double-blind, randomized, placebo-controlled  
20 trial. The only difference is that this is commercially  
21 available fluticasone and azelastine versus the studies  
22 that we just talked about, pivotal trials where it used a  
23 formulation comparator.

24 Q. And do you know what the authors of this study  
25 concluded?

Carr - direct

1 A. Yeah. They concluded that Dymista was significantly  
2 better than either. They came to the same conclusion I came  
3 to in the pivotal studies, using the same design but  
4 commercially available.

5 MR. BARDENSTEIN: Mr. Beall, if you could blow  
6 up the conclusion on the front.

7 BY MR. BARDENSTEIN:

8 Q. This is a conclusion you were just referring to?

9 A. Yes.

10 Q. And have you prepared a demonstrative that compares  
11 the actual results of the Hampel study with your  
12 meta-analysis to show what each of those studies conclude?

13 A. Yes. I tried my best to make that comparison.

14 MR. BARDENSTEIN: If we could turn to PDX-3.03.

15 BY MR. BARDENSTEIN:

16 Q. Can you tell the Court what we're looking at here?

17 A. Yes. So if you look on the right, you will see  
18 MP-4000, 2, 4, and 6. Okay? These are the pivotal studies.  
19 And when I presented it in my paper with my coauthors, we  
20 decided we would take out placebo, and we decided we would  
21 only show the delta versus placebo.

22 So, again, I want to point you to the scale on  
23 the left. It's exactly the same scale that was in my  
24 manuscript. If you see, it is from a zero up to a 3.5.

25 Doing it otherwise is misleading because it

Carr - direct

1 includes the placebo effect and other things. And that is  
2 not what the question is here. The question is what is the  
3 delta versus placebo. Okay? Because there is that placebo  
4 effect.

5 So to do a side-by-side comparison, you will see  
6 in those studies, MP-4000, 2, 4 and 6 that I just presented  
7 as compared to fluticasone, depending on the season and the  
8 pollen counts, et cetera, it was anywhere from a 43 to  
9 67 percent improvement in those patients.

10 If you do exactly the same thing, so you remove  
11 the placebo effect and all you are looking at is the delta  
12 versus placebo, and do exactly the same calculation that  
13 was done in my paper, you will see that it's a 90 percent  
14 improvement over commercially available Flonase, which is a  
15 generic in this case, and then the commercially available  
16 Astelin.

17 I mean if you look, it's the delta versus  
18 placebo for Astelin is just one point. That is about what  
19 you get with an antihistamine. But the delta that you get  
20 with generic Flonase is about a point and-a-half, pushing  
21 1.75 points. That is about what you get with a nasal  
22 steroid. But you will see the delta with Dymista compared  
23 to placebo is about 3.1 points, and that is a huge improvement  
24 over placebo.

25 So looking at those, that is about 196

Carr - direct

1 difference, almost 200 percent, and a 90 percent difference  
2 between the 3.11 and the 1.64.

3 Q. That is the difference when you take away what  
4 benefits a patient would get with placebo?

5 A. Correct, yeah.

6 Q. Dr. Carr, looking at this data, are there any  
7 conclusions you can draw?

8 A. Well, I'm glad Dymista got approved, because it's my  
9 first prescription drug I use now.

10 The conclusion I can draw is, when you compare  
11 Dymista to the commercially available, it's even that much  
12 better than the commercially available as compared to those  
13 that have the same formulation.

14 So the only difference between MP-4000, 2, 4 and  
15 6 and the generic Flonase, the only difference between those  
16 two is the formulation. The active ingredient is exactly  
17 the same.

18 So my conclusion is that they're -- I mean I'm  
19 not a formulator, but as a physician, my conclusion is that  
20 there is a formulation effect here. That that is the only  
21 thing that is different.

22 Q. Dr. Carr, I think you mentioned earlier that the two  
23 key considerations in any medication is not only efficacy  
24 but safety; is that correct?

25 A. Oh, it's absolutely imperative that you look at



Carr - direct

1 safety.

2 Q. I think Dr. Kaliner talked a little bit about this.

3 But can you tell the Court how Dymista compares to Flonase  
4 and Astelin in terms of safety?

5 A. Well, when you look at Dymista, I think the best  
6 thing to do is look at what the FDA said. Because they're  
7 impartial. And they're going to review this data for ten  
8 months and they're going to just list things, how they  
9 occurred, and they'll go into the label.

10 So when you look at the label for Dymista, you  
11 will see significantly less adverse events as compared to  
12 what you see with azelastine in particular.

13 MR. BARDENSTEIN: Mr. Beall, can we bring up  
14 PTX-24-006?

15 I think it had already been admitted into  
16 evidence. But for the record, it is the Dymista label.

17 BY MR. BARDENSTEIN:

18 Q. Can you tell the corticosteroid what we're looking at  
19 here?

20 A. Yes. Whenever you are looking at -- I'm going to put  
21 my nerd hat on for just a moment because I like the FDA  
22 label. Nobody else does but I do, and I read the FDA label.

23 Whenever you go to the FDA label, you can pull  
24 up Table 1 for any drug. Basically they have changed how  
25 they have done it over the years, but you can pull it up

Carr - direct

1 for any drug. And Table 1 is the adverse reactions that  
2 you are going to get that occur at greater than or equal to  
3 two percent.

4 Now, there may be adverse events that are unique  
5 to a drug that you have interest in, and they occur less  
6 than two percent. They're not going to make it into this  
7 table, but they will be in the label someplace else.

8 So if you look at this label, these are the  
9 adverse reactions that occurred in Dymista, greater than or  
10 equal to two percent, and you only see three. Three:

11 Dysgeusia. Now, the other word for dysgeusia is  
12 bitter taste.

13 Headache. And,

14 Epistaxis. The other word for epistaxis is  
15 bloody nose. Even if there is just a fleck of blood in the  
16 nose, that is epistaxis.

17 We have talked about antihistamines a lot, and  
18 antihistamines can cause sedation, and azelastine can  
19 definitely cause sedation. And that is a concern the FDA is  
20 always going to have.

21 So if you look down at the sentence below the  
22 table, it will say: "In the above clinical trials,  
23 somnolence" -- that is sedation -- "was reported in less  
24 than 1 percent."

25 So it didn't make it to the table but they list

Carr - direct

1     it there as less than 1 percent.

2                   So what you see is dysgeusia with Dymista 4  
3     percent, azelastine 5 percent. Now, remember, that is the  
4     same formulation as Dymista.

5                   And then you see the somnolence is less than  
6     1 percent.

7     Q.       And to be clear, the Astelin that you show at 5  
8     percent, that is not commercially available. That is not  
9     nasal spray, that is not Astelin.

10    A.       You are correct. If I said Astelin, I'm sorry. It's  
11    azelastine. It's the formulation comparator. This is from  
12    the studies that we conducted.

13    Q.       And do you know how this data compares to the actual  
14    Astelin safety data?

15    A.       I do. I think it is best if you just go to the  
16    label, though.

17                   MR. BARDENSTEIN: If we can go to PTX-11, page  
18    14, and blow up the top table.

19    BY THE WITNESS:

20    A.       So it would be the exact same table number, and it's  
21    done exactly the same way. So these are adverse events that  
22    occurred greater or equal than 2 percent.

23                   So the first thing you notice is there is a lot  
24    of adverse events, right? There is a whole bunch of things  
25    that were captured in there. And we can argue about how

Carr - direct

1 important some of those are.

2 But let's focus on what patients and doctors  
3 really care about with regards to azelastine, and that is  
4 the bitter taste, and the somnolence, the sedation.

5 And you will see the bitter taste is almost  
6 20 percent, and it was 4 percent with Dymista.

7 And then you will see somnolence here is  
8 11.5 percent, but with Dymista it was less than 1 percent.  
9 I think in all the studies, I think it was only six  
10 patients, six or eight patients, something like that, that  
11 complained.

12 Q. Dr. Carr, in your experience, would a reduction  
13 in side effects such as bitter taste and somnolence from  
14 20 percent to 4 percent and from 12 percent to 1 percent  
15 be an improvement over what was available at the time?

16 A. I believe it would be a huge improvement. I mean  
17 patients don't want to take a drug that they don't tolerate.  
18 They simply won't take it.

19 Q. Looking back on both of the efficacy and safety  
20 results that we discussed, would any of these results have  
21 been expected to a person of ordinary skill in the art in  
22 2002?

23 A. I don't believe it would be, no.

24 Q. And I want to just focus on something Dr. Wedner  
25 testified about. Were you in the courtroom when he was

Carr - direct

1 here?

2 A. Yes, I was.

3 MR. BARDENSTEIN: Could we bring up DTX-43, page  
4 12. And blow up the 4.1 section. And the top line on the  
5 right side.

6 BY MR. BARDENSTEIN:

7 Q. Do you recall Dr. Wedner relying on this passage for  
8 the support of onset of action for azelastine?

9 A. Yes, I do recall that discussion.

10 Q. Do you agree with him?

11 A. Absolutely not.

12 Q. Why not?

13 A. Well, this sentence is taken totally out of context.  
14 And it's contrary to what the authors actually concluded.  
15 This is noncomparative and placebo control trials. If you  
16 read the whole sentence, it says: "In one non-blinded  
17 study, 84 percent of 103 patients reported an onset of action  
18 within 30 minutes of administering the drug intranasally."

19 We know that just a simple saline nasal spray has  
20 efficacy. This is, you are not controlling for the placebo  
21 effect here. You can make no claims for the effectiveness  
22 of this drug without comparing it to placebo, and this is a  
23 non-blinded study where the patient knows what they're  
24 getting, and that just enters bias.

25 There is motivation for the investigator or the

Carr - direct

1 company. You know, there is motivation for a company to  
2 want something to work. That is why you have to do these  
3 studies blinded and randomized and placebo controlled.

4 Q. Do you know if the authors of the study ever looked  
5 at blinded, placebo-controlled studies to determine onset of  
6 action for azelastine?

7 A. Well, the authors of this review you are talking  
8 about?

9 Q. Yes.

10 A. Yes. So if you read on, in the rest of this section,  
11 they actually review five studies that are randomized,  
12 placebo-controlled studies, and that is where they make  
13 their conclusions about onset of action.

14 MR. BARDENSTEIN: If we can go actually,  
15 Mr. Beall, to DTX-43, page 4. I think it summarizes.

16 BY MR. BARDENSTEIN:

17 Q. Is this what you are talking about when you mention  
18 the author's review of the actual clinical data?

19 A. Yeah. Well, this is the summary section. It reviews  
20 each study in great detail in the manuscript, but this is a  
21 summary section. And if you go right into the middle where  
22 it says "compared." Do you see it right there?

23 "Compared with placebo, azelastine (two puffs  
24 per nostril) significantly improved baseline rhinitis  
25 symptoms as early as three hours after drug administration."

Carr - direct

1                   And this is the conclusion that the authors of  
2                   this review make. That this is the onset of action as  
3                   compared to placebos within three hours.

4           Q.       Do you know what the azelastine label indicates the  
5                   onset of action is for azelastine?

6           A.       I think it is very important we did find what onset  
7                   of action is, first off. Onset of action is when all four  
8                   symptoms, okay, the total nasal symptom score: sneezing,  
9                   runny nose, itching, congestion; when you can reproducibly  
10                  have that better than placebo, so an improvement in the  
11                  total random symptom score, that is onset of action.

12                               In the Dymista label, it's 30 minutes.

13          Q.       So for all four symptoms, the total nasal symptom  
14                   score, Dymista lists 30 minutes while the Astelin label  
15                   lists three hours, as early as three hours?

16          A.       I think it says within three hours or as early as  
17                   three hours, but, yeah, that is correct.

18          Q.       Did you hear Dr. Wedner testify about sneezing being  
19                   reduced within 15 minutes?

20          A.       I did.

21          Q.       And did you also hear him say, but the other symptoms  
22                   are reduced later?

23          A.       I recall him saying that.

24          Q.       In your experience -- or let me strike that. Is  
25                   onset of action measured by only reducing sneezing?

Carr - direct

1 A. No. It's, like I said, it's all four nasal symptom  
2 scores. He is talking about laboratory studies, by the way.  
3 These nasal challenges and stuff like that. Those aren't  
4 real live studies.

5 MR. BARDENSTEIN: If we can go to the previous  
6 page of this, DTX-043, page 3. Blow up the pharmacodynamic  
7 properties, and the paragraph underneath it as well.

8 If we look at the bottom, it says: "Azelastine  
9 significantly reduced allergy-induced sneezing within  
10 15 minutes."

11 Do you see that?

12 A. I'm sorry. Could you highlight it?

13 Q. Do you see that?

14 A. Yes. So I do see that.

15 Q. Do you recall that Dr. Wedner relied on that concept  
16 for his 15 minute onset of action?

17 A. I don't know exactly what he was relying upon, but  
18 in essence this is the data that he is referring to. These  
19 are pharmacodynamic properties. These are laboratory  
20 studies, they're not real live studies where patients go  
21 out and do their normal stuff. They come in, and like if  
22 you are allergic to grass, you come into the lab and they  
23 squirt grass into your nose and see how you do. So they're  
24 artificial. But, yeah, this is the data.

25 Q. And this is not the clinical studies where they



Carr - direct

1 actually measure patient response to the medication;  
2 correct?

3 A. Well, these are volunteers. And in these studies,  
4 they look at both normals and patients? If you go up to the  
5 very top, if you go up to the very top, sneezing caused by  
6 histamine nasal challenge was significantly reduced within  
7 one hour after initial, in patients and volunteers.

8 So that means some of these people don't have  
9 allergy, so in order to simulate stuff in a lab, they just  
10 squirt histamine in their nose. But if you have allergies,  
11 they'll squirt grass or cat or something like that.  
12 Whatever you are allergic to.

13 Q. So in looking at this article that Dr. Wedner  
14 relied on, I just want to get clear. Do you agree with  
15 his interpretation of the onset of action for azelastine  
16 being 30 minutes and maybe up to 15 minutes, as early as  
17 15 minutes?

18 A. I do not.

19 Q. Thank you. And I want to shift back to the Dymista  
20 clinical trial results. I think you mentioned that they  
21 would not have been expected, those results would not have  
22 been expected to a person of ordinary skill in the art in  
23 2002. What do you rely on to draw your conclusion that a  
24 person of ordinary skill in the art in 2002 would not have  
25 expected the Dymista clinical trial results?

Carr - direct

1 A. Look, there is a lot of hindsight. I think the best  
2 thing is to rely on what the experts in the field at that  
3 day, at that time, stated. And so I rely upon the experts  
4 and their expert conclusions at that time.

5 MR. BARDENSTEIN: If we can go to PDX-3.04,  
6 Mr. Beall.

7 BY MR. BARDENSTEIN:

8 Q. Are these the experts that you rely on?

9 A. These would be some of the experts that I would rely  
10 on, yes.

11 Q. And for the record, it is Juniper, PTX-336,  
12 Benincasa, PTX-013; Simpson, PTX-039; Ratner, PTX-331.

13 Are there any other references you relied on  
14 for your opinion that a person of ordinary skill in the art  
15 would not have expected this benefit from clinical trial  
16 results as of 2002?

17 A. Yes. I mean these are individual studies, and but  
18 there were reviews done at that time, too, comprehensive  
19 reviews of all the available data.

20 MR. BARDENSTEIN: Mr. Beall, if we can go to the  
21 next slide, please.

22 BY MR. BARDENSTEIN:

23 Q. Are these the reviews that you were talking about,  
24 the experts in the field at the time?

25 A. Yes. So these are the experts at the time, writing

Carr - direct

1 about this exact subject, and this is their conclusion.

2 Q. And for the record, it is Howarth, PTX-337, and  
3 Nielsen, PTX-338.

4 Before we move on, Dr. Carr, did you hear Dr.  
5 Schleimer testify that the closest prior art in his opinion  
6 was using Astelin and Flonase together?

7 A. I did hear him say that.

8 Q. As of June 2002, would a person of ordinary skill  
9 in the art have an understanding as to how the efficacy of  
10 the different antihistamines available compared to each  
11 other?

12 A. Yeah, they would understand how they compared.

13 Q. What would their understanding have been?

14 A. The different antihistamines were all about the same.

15 Q. And as of June 2002, would a person of ordinary skill  
16 in the art have an understanding as to how the efficacy of  
17 the different corticosteroids available compared to each  
18 other?

19 A. Yes.

20 Q. How would they have understood the efficacy of the  
21 different corticosteroids compared to each other?

22 A. Well, to my knowledge, there has never been a study  
23 to show one nasal steroid spray better than another nasal  
24 steroid spray with regard to efficacy, so they're all viewed  
25 about the same efficacy. So they're the same.

Carr - direct

1 Q. In your opinion, have you compared Dymista's  
2 clinical studies to the closest prior art?

3 A. I believe I have.

4 Q. And just to wrap up this point. Dr. Carr, were there  
5 any combination intranasal corticosteroid antihistamine  
6 nasal sprays available prior to June 7th, 2002?

7 A. Not to my knowledge.

8 Q. We've talked a lot about the FDA and the clinical  
9 studies, the results for Dymista. I want to now turn to  
10 your final opinion and talk about how the medical community  
11 has responded to Dymista.

12 Since Dymista's approval, how has it been  
13 received by the medical community?

14 A. I think very well.

15 Q. Has it received any recognition?

16 A. Yes, it's been praised in more than one format.

17 Q. If you could turn to PTX-29 in your binder and  
18 identify that for the Court.

19 A. I'm sorry. 29?

20 Q. Yes.

21 A. Is this it? Yes.

22 Q. What is this document?

23 A. What this document is -- so earlier in my testimony,  
24 we reviewed an article that I coauthored with numerous of my  
25 distinguished colleagues. And the paper was published in

Carr - direct

1 this journal, the Journal of Allergy and Clinical Immunology  
2 in this issue, and the editors of that journal have a  
3 section called The Editors' Choice. And this is the section  
4 from that journal, The Editors' Choice.

5 Q. I see two authors or editors at the top. Do you know  
6 them?

7 A. Yes. I know Donald Leung and Stan Szeffler.

8 Q. Do you know how they're viewed in the community?

9 A. These guys are premier allergy physicians. Yes,  
10 they're very, very highly esteemed.

11 Q. And the journal is the Journal of Allergy and  
12 Clinical Immunology?

13 A. Yes.

14 Q. Do you know how that is viewed in the community?

15 A. It's essentially the top allergy journal in the  
16 world.

17 Q. Do you know how materials are selected for The  
18 Editors' Choice?

19 A. I have no idea how they're selected for The Editors'  
20 Choice.

21 Q. Can you tell us how your article was selected for The  
22 Editors' Choice?

23 A. Well, I can tell you what I know happened. The  
24 coauthors and myself, we submitted the article. And it has  
25 a very high rejection rate. A lot of times, you know, if

Carr - direct

1     you submit an article, it won't get picked up in this  
2     journal. And so we received a letter of acceptance, that  
3     they had accepted it, and then we also received a letter  
4     saying that they wanted to include our article in The  
5     Editors' Choice section.

6     Q.     Looking up at the title, it says MP-2902, a major  
7     advancement in the treatment of allergic rhinitis.

8             What does this title tell about how the editors  
9     viewed Dymista?

10    A.     I think it speaks for itself. They viewed it as a  
11    major advancement in the treatment of allergic rhinitis.

12    Q.     And what were the editors' conclusions about Dymista?

13    A.     Well, they made a lot of conclusions, but I think if  
14    you just go down to the very last sentence, it says: "Given  
15    these findings, MP-2902 can be considered the drug of choice  
16    for the treatment of allergic rhinitis."

17             And I would point out that they're using the  
18    same tablets that I have been using, looking at the efficacy  
19    only compared to the delta versus placebo. So only -- that  
20    scale is only up to 3.5. That is the delta versus placebo.  
21    And these are, they're conclusions.

22    Q.     Do you know if there was ever an article in the  
23    Journal of Allergy and Clinical Immunology that said  
24    azelastine and fluticasone taken sequentially was the  
25    treatment of choice for AR?

Carr - cross

1 A. Not to my knowledge.

2 MR. BARDENSTEIN: Your Honor, at this time I  
3 would like to offer into evidence PTX-125, PTX-47, PTX-110,  
4 PTX-335, PTX-114, PTX-227, and PTX-29.

5 THE COURT: Any objection?

6 MR. WARNER: No objection.

7 THE COURT: Those are admitted.

8 (Above-referenced exhibits admitted in evidence.)

9 MR. BARDENSTEIN: I pass the witness.

10 THE COURT: Before we have cross-examination,  
11 we'll take a short recess.

12 (Brief recess taken.)

13 \* \* \*

14 (Proceedings reconvened after recess.)

15 THE COURT: All right. Cross-examination.

16 MR. WARNER: Thank you, Your Honor.

17 THE COURT: You may approach, yes.

18 (Documents passed forward.)

19 MR. WARNER: May I proceed, Your Honor?

20 THE COURT: Yes.

21 CROSS-EXAMINATION

22 BY MR. WARNER:

23 Q. Good morning, Dr. Carr.

24 A. Good morning.

25 Q. We met at your deposition a few months ago; right?

1 A. Yes. Nice to see you.

2 Q. Nice to see you again. When you testified, you  
3 talked a little bit about some of the work that you have  
4 done for Meda; right?

5 A. Yes.

6 Q. Okay. Some of the work that you have done, you  
7 mentioned that you are part of the Speakers Bureau; is that  
8 right?

9 A. I never mentioned that, but, yeah, I speak for  
10 numerous companies, one of which is Meda.

11 Q. And you have been working with Meda as part of the  
12 Speakers Bureau for about a decade; is that right?

13 A. Yes. I worked for numerous companies for that long,  
14 but I'm certain Meda is in that list, yes.

15 Q. Okay. And you, over the course of the time that you  
16 have been working with Meda on their Speakers Bureau, you  
17 would estimate that they paid you about \$75,000; is that  
18 right?

19 A. So you are telling me I have made less than  
20 Dr. Kaliner over 10 years? To be honest with you, that  
21 sounds fair.

22 Q. Okay. And apart from Speakers Bureau work, you also  
23 talked a lot about your role in the design of the clinical  
24 trials; is that right?

25 A. That is accurate, yes.



Carr - cross

1 Q. And so one of the things that you did is you were a  
2 principal investigator; yes?

3 A. I was one of numerous principal investigators, but  
4 yes, I was one of them.

5 Q. So a principal investigator is the type of person who  
6 is at a clinical trial site and is in charge of that site;  
7 is that fair?

8 A. No, not necessarily. You can be a principal  
9 investigator and not necessarily be in charge of the site.  
10 Basically, the company works with what is called a CRO, it's  
11 a contract research organization, just like a third party.  
12 That third party then goes out to 50 to 100 sites across the  
13 United States, and they negotiate with that site. So we  
14 don't necessarily negotiate directly with Meda, we negotiate  
15 with the CRO.

16 Then what you do is there is a form called a FDA  
17 form 1572, and as the principal investigator, you sign that  
18 form basically saying that you are going to be responsible  
19 for the conduct of that study at your site making sure that  
20 -- you know, you are doing experiments on human subjects, so  
21 there is a lot of regulation that goes into that. So that  
22 is what goes into being a principal investigator.

23 Q. And you have been one of those principal investigators;  
24 correct?

25 A. For numerous different studies, yes.

Carr - cross

1 Q. Numerous studies. And some studies related to  
2 Dymista; correct?

3 A. Yeah. I was the PI at my site for each of those  
4 studies, that's correct.

5 Q. And that is work that you also get paid for; yes,  
6 sir?

7 A. Well, no, I don't get paid directly for that. That  
8 is negotiated between the research center and the CRO. I  
9 mean that money that comes in has to pay for my nurses, that  
10 has to pay -- these are volunteers. So some of that money  
11 goes directly to the volunteers. They're not patients.  
12 This doesn't go through health insurance. Some of it pays  
13 for the facilities and so on and so forth. As part of the  
14 negotiation, there may be like \$50 for the doctors to see  
15 the patient, something along those lines.

16 Q. My point is that is not free work that you are doing;  
17 right, sir?

18 A. No, it is not pro-bono work.

19 Q. With respect to all of the work that you did in  
20 connection with Dymista -- and, by the way, that MP-2902 is  
21 before Dymista; right?

22 A. Yes.

23 Q. So in connection with all the work that you did in  
24 connection with that, it's a fair estimate to say you were  
25 paid about \$50,000?

Carr - cross

1 A. I'm not sure, but if you have numbers to support  
2 that, I wouldn't disagree with that.

3 Q. Okay. You wouldn't disagree an estimate about what  
4 you were paid for your work in connection with developing  
5 MP-2902 is about \$50,000; right?

6 A. Again, it would be a guess. This was a several year  
7 process, so I would not be surprised if it came into that  
8 amount. Yeah.

9 Q. Okay. So that is an estimate, and then the  
10 roughly \$75,000 for your work on the Speakers Bureau. The  
11 compensation prior to the trial here is about in the order  
12 of \$125,000; is that fair?

13 A. That sounds about right. I've made more from other  
14 companies, but Meda just didn't pay as much, I guess.

15 Q. And you talked some about your own prescribing  
16 habits; right, sir?

17 A. Yes.

18 Q. In your direct examination.

19 A. Yeah. I think we talked about my prescribing habits.

20 Q. Okay. You are a prescribing physician, yes?

21 A. Oh, yes. I have numerous patients.

22 Q. And you were talking about your background. You have  
23 been a prescribing physician in the period before June 2002;  
24 correct?

25 A. Certainly.

Carr - cross

1 Q. Okay. And at that time period before 2002, you would  
2 agree with me that there were drugs that were coadministered  
3 for the treatment of allergic rhinitis; correct?

4 A. Perhaps.

5 Q. Well, do you agree with that or not? Would  
6 physicians, including yourself, coadminister one or more  
7 drugs for the treatment of allergic rhinitis?

8 A. Well, we kind of got into this --

9 Q. Sir.

10 A. -- in our deposition.

11 THE COURT: Doctor, try to answer the question  
12 yes or no. And if you need to explain, you can add the  
13 explanation if counsel wants it.

14 A. Yes.

15 Q. So I just want to -- thank you, sir.

16 You have been sitting and watching the trial;  
17 right, sir?

18 A. Yes, I have.

19 Q. There have been some discussions about early phase  
20 and late phase in connection with allergic rhinitis; yes?

21 A. Yes, I heard about those laboratory experiments.

22 Q. Okay. And you would agree that by 2002, it was  
23 medical dogma that antihistamines predominantly treat the  
24 early phase of allergic rhinitis more effectively than  
25 steroids, wouldn't you?

Carr - cross

1 A. I'm sorry. Could you repeat the question?

2 Q. Sure. Would you agree with me that by 2002, it was  
3 medical dogma that antihistamines predominantly treat the  
4 early phase allergic rhinitis more effectively than  
5 steroids?

6 A. If you finished by saying "in a laboratory  
7 experiment," I would say yes. Those studies are in  
8 laboratory experiments, not in clinical patients. So I  
9 guess no.

10 Q. You are agreeing with me that it is medical dogma by  
11 2002 that in experiments, antihistamines predominantly treat  
12 the early phase of allergic rhinitis more effectively than  
13 steroids?

14 A. In laboratory experiments, yes.

15 Q. Okay. And you would agree with me that in similar  
16 experiments, it was medical dogma by 2002 that steroids  
17 predominantly treat the late phase reactions more  
18 effectively than antihistamines; correct?

19 A. That steroids treat the late phase better than  
20 antihistamines?

21 Q. Correct.

22 A. Correct. Yes.

23 Q. And you would also agree with me that it was known by  
24 2002 that antihistamines generally have a faster onset of  
25 action than steroids; correct?

Carr - cross

1 A. Generally speaking, yes.

2 Q. Now, Flonase, we have talked about that. That is a  
3 steroid; yes?

4 A. Correct. That is a corticosteroid.

5 Q. Okay. Astelin, the active ingredient is azelastine,  
6 that is an antihistamine; correct?

7 A. It's a mast cell stabilizing antihistamine, yes.

8 Q. Okay. And so that was all known by 2002; right?

9 A. Yeah.

10 Q. And by that point in time, you had patients that  
11 received, your own patients that received both Astelin and  
12 Flonase nasal sprays administered sequentially; correct?

13 A. For a variety of reasons, yes.

14 Q. All right. And, in fact, sir, even prior to the  
15 start of the clinical trials that you discussed that led to  
16 the approval of Dymista, wouldn't you agree with me it was  
17 widespread to coadminister azelastine with intranasal  
18 corticosteroids to patients?

19 A. I'm sorry. What was the time period that you gave?

20 Q. Prior to the start of the clinical trials that led to  
21 the approval of Dymista.

22 A. So prior to the pivotal studies that I did or prior  
23 to the Ratner study?

24 Q. Let's say prior to 2009.

25 A. Well, the Ratner study, the last Ratner study came

Carr - cross

1 out in 2008. That was a proof of concept study, and I do  
2 believe that there were more people using azelastine and  
3 fluticasone after Ratner came out in 2008. So that would  
4 be 2009.

5 Q. Let me tell you this. How about prior to April 29th,  
6 2008? Would you agree with me it was widespread in clinical  
7 practice to use azelastine in conjunction with an intranasal  
8 corticosteroid?

9 A. I don't know exactly the date in 2008 that Ratner  
10 came out. I will say before Ratner, it was not widespread.  
11 After Ratner, more people started doing it.

12 Q. And, in fact, that was an important enough fact  
13 for you to talk to FDA about when you were trying to get  
14 approval of Dymista; correct?

15 A. Which fact?

16 Q. The fact that the coadministration of azelastine with  
17 intranasal corticosteroids was widespread.

18 A. When I went to the Type A meeting, I did not bring  
19 that fact up with FDA.

20 Q. You are aware that Meda did, sir; right?

21 A. At the Type A meeting, you are saying?

22 Q. Yes.

23 A. I think in 2008, what Meda had said was that there  
24 were clinicians in the community that had given them input  
25 and that physicians wanted to see this combination. I don't

Carr - cross

1 remember the exact words that was exchanged during that  
2 meeting. Perhaps it is memorialized in our meeting minutes.

3 MR. WARNER: Yes. Let's take a look at PTX-47,  
4 please.

5 BY MR. WARNER:

6 Q. And this is the information package that you  
7 testified about; is that right?

8 A. This is PTX -- it's in my thing here?

9 Q. Its should be in both binders that you have.

10 A. I have the original one.

11 That's the cover sheet for it.

12 Q. This is the information that Meda submitted prior to  
13 the meeting; right?

14 THE WITNESS: Can I use this other binder? Is  
15 it okay for me?

16 THE COURT: You can use either one. And you can  
17 use the counter next to you, if you want.

18 THE WITNESS: Okay.

19 BY THE WITNESS:

20 A. Yes, I have it. I have it.

21 Q. And this is the document that you discussed; right?

22 A. Yes, sir.

23 MR. WARNER: And actually, Mr. Aranda, if you  
24 could just zoom out for one second.

25 BY MR. WARNER:



Carr - cross

1 Q. In all your discussions of Meda's interactions with  
2 FDA, those are confidential discussions; right?

3 A. Yes.

4 Q. And it says that right here on the face of this  
5 document; yes?

6 A. So this says that the discussions from Meda, that  
7 this meeting packet from Meda to the FDA contains  
8 confidential information.

9 Q. Okay. In the discussions between Meda and FDA, those  
10 were confidential discussions; right, sir?

11 A. Well, this is a meeting packet. There is no  
12 discussions in it.

13 Q. I am talking about, you testified about --

14 A. But when they had a discussion, it was confidential.

15 Q. Very good. So at this point in time, sir.

16 If we can go to page 1982 in this document.

17 And if you look at the Meda attendees, you are  
18 listed there; right, sir?

19 A. Yes, I am.

20 Q. As a consultant on behalf of Meda?

21 A. Yes.

22 Q. All right. And if you go to the next page, please.

23 Section 4.1 is Rationale of the Proposed  
24 Combination Product. Do you see that?

25 A. Yes, I do.

Carr - cross

1 Q. And this is Meda's effort in consultation with you  
2 to explain to FDA the rationale for allowing trials to go  
3 forward with Dymista; correct?

4 A. Yes, this delineates the rationales that the FDA  
5 rejected.

6 Q. Okay. And if you go to the next page. And I want to  
7 look at the first full paragraph.

8 What Meda, in consultation with you, told  
9 the FDA was: "Reports from many of the physicians who  
10 co-prescribe Astelin with topical nasal corticosteroids  
11 state that patients respond with substantial relief of their  
12 allergies."

13 Do you see that, sir?

14 A. Yes, I do.

15 Q. And that Meda went on to say: "In fact, among  
16 allergists, this seems to be a widespread practice, even in  
17 the absence of large, well controlled trials."

18 Do you see that?

19 A. That is --

20 Q. Do you see that, sir?

21 A. Yes, sir, I do. I see that sentence.

22 Q. And it continues. It says: "We" -- Meda, right?

23 A. They are preparing this, yes.

24 Q. "We are told about patients that took many other  
25 treatments without success, and were then well controlled

Carr - cross

1 with the combination of AZ" -- that is azelastine; right?

2 A. Yes.

3 Q. So they were "well controlled with the combination of  
4 azelastine and a topical nasal corticosteroid." Do you see  
5 that?

6 A. Yes.

7 Q. Okay. Now, it was your view, sir, that despite the  
8 practice of coadministering azelastine with intranasal  
9 corticosteroids, your testimony was there wouldn't have been  
10 any expected benefit from putting the two into one bottle;  
11 right?

12 A. Can you give me a context of what time you are  
13 talking about?

14 Q. We'll call it prior to 2002.

15 A. Yes, that is true.

16 MR. WARNER: Okay. And, in fact, can we look at  
17 PDX-3.04, please?

18 BY MR. WARNER:

19 Q. And this is the slide that you put up; right?

20 A. Correct.

21 Q. And your conclusion is: "These studies show no  
22 benefit to adding an antihistamine to an intranasal  
23 corticosteroid." Yes?

24 A. Those are the authors' conclusions, and I agreed with  
25 the authors, yes.

1 Q. And one of the authors, the first one is Juniper;  
2 right?

3 A. Yes.

4 Q. And do you know Dr. Juniper?

5 A. Not personally.

6 Q. The conclusion that she puts in this article is:  
7 "Beclomethasone plus astemizole provided no better control  
8 of rhinitis than beclomethasone alone." Correct?

9 A. That is what she wrote.

10 Q. And the conclusion you draw is there is no benefit to  
11 adding an antihistamine to a nasal corticosteroid; correct?

12 A. With regards to the total nasal symptom score, that  
13 was the context of my testimony, yes.

14 Q. So a person of ordinary skill in the art, seeing this,  
15 they wouldn't think that if they tried an antihistamine with  
16 an intranasal corticosteroid, they're going to get any  
17 difference; right? There is going to be no benefit; right?

18 A. Are you talking specifically in the setting of  
19 allergic rhinitis --

20 Q. Yes.

21 A. -- or the allergic diathesis where the people have  
22 other problems like itching and eczema?

23 Q. Well, you say there is going to be no benefit. When  
24 you are talking about no benefit, you are saying, if you  
25 read Juniper's conclusion, you are not going to get any

Carr - cross

1 benefit from combining this; right?

2 A. Well, what Juniper said is that, if I can read it:  
3 "Beclomethasone plus astemizole provided no better control  
4 of rhinitis than beclomethasone alone."

5 I think in my testimony, I said I relied on the  
6 author's conclusion and that is her conclusion.

7 Q. And you know, sir, that Dr. Juniper, she continued on  
8 studying the conjunctive use of antihistamines in intranasal  
9 corticosteroids; correct?

10 A. Yes.

11 Q. So despite these conclusions, she continued on with  
12 her work and continued studying that; right?

13 A. Yes.

14 MR. WARNER: And let's take a look at DTX-107,  
15 please.

16 BY MR. WARNER:

17 Q. And this is another article by Dr. Juniper; right?

18 A. 107? I don't have anything in my binder for DTX-107.

19 Q. Does that binder say direct examination or cross?  
20 Now you have two binders up there. It would be in your  
21 cross?

22 A. This is cross-examination of Warner Carr. I don't  
23 have anything in it.

24 THE COURT: DTX-107?

25 THE WITNESS: It's empty.

Carr - cross

1 THE COURT: I have it in mine. But I'll let you  
2 approach.

3 THE WITNESS: You may have given me yours  
4 because there are some notes. I won't look at them.

5 MR. WARNER: May I approach?

6 THE COURT: Yes, you may approach, and you may  
7 trade.

8 MR. WARNER: I apologize.

9 THE WITNESS: Do you want to switch it out with  
10 another one?

11 MR. WARNER: I'm going to give you a different  
12 binder.

13 THE WITNESS: Yes.

14 MR. WARNER: May I approach?

15 THE COURT: Yes, you may freely approach.

16 MR. WARNER: We will try this again then, sir.

17 THE WITNESS: Sorry. I just want to look at the  
18 article.

19 MR. WARNER: Sure.

20 THE WITNESS: Familiarize myself with it.

21 MR. WARNER: That's fair.

22 BY MR. WARNER:

23 Q. So, for the record, sir, you are looking at DTX-107  
24 now?

25 A. Yes, sir. That is accurate.

1 Q. All right. And this is another Juniper article; yes?

2 A. Yes. It looks like Juniper is the first author on it.

3 Q. This one is published in -- can we back out? You can  
4 see it is published in 1997, towards the bottom.

5 A. Yes.

6 Q. And that is after the Juniper article that you cited  
7 in your demonstrative exhibit; right?

8 A. Um-hmm.

9 Q. And what she is doing here -- if we can go to the  
10 objective toward the top. You can see what she is doing  
11 is the objective is to determine whether better health  
12 related quality of life is achieved by initiating treatment  
13 of seasonal rhinal conjunctivitis, or hay fever, with a  
14 nasal steroid, which is fluticasone, backed up by a  
15 non-sedating antihistamine, terfenadine, or whether it is  
16 better to start with the antihistamine and add the nasal  
17 steroid, when necessary. Right?

18 A. That appears as her stated objective, yes.

19 Q. So to summarize what she is doing is she is stating  
20 I'm going to be using an antihistamine and a nasal steroid.  
21 I want to find out if there is benefit to starting first  
22 with the antihistamine and then adding a steroid or vice  
23 versa; right?

24 A. It appears to be her experimental objective.

25 Q. So she is not considering using them alone. She is

1 solely studying the use of them together here; right?

2 A. But with a different endpoint. This isn't in  
3 rhinitis. This is looking at the health-related quality  
4 of life. That is totally a different thing.

5 Q. Is health-related quality of life irrelevant to  
6 patients?

7 A. It's not the total nasal symptom score that we have  
8 been discussing.

9 Q. Is it irrelevant to patients, sir?

10 A. No, I think quality of life is something that we look  
11 at as a secondary variable.

12 Q. And let's look at what conclusion she drew in 1997  
13 after her first article that you discussed.

14 Her conclusion is that there is little  
15 difference -- and you see the top line -- in the therapeutic  
16 benefit between the two approaches for treatment. And that is  
17 the antihistamine first and then the steroid or vice-versa;  
18 right?

19 A. Yes. I mean I would have to read the study design in  
20 great detail. It is hard for me to make conclusions without  
21 reading the study design, but she is saying there is little  
22 difference between using those two combinations. We don't  
23 know where patients get benefit. I mean they could get  
24 all the benefit from the steroid or for antihistamines,  
25 supposedly.



Carr - cross

1 Q. Okay. What she does concludes at the end, the last  
2 sentence, she said: "Regardless of the treatment, at least  
3 50 percent of the patients will need to take both types of  
4 medication in combination to control their symptoms  
5 adequately." Correct?

6 A. That is what she states.

7 Q. Now, I want to talk some about the studies that  
8 were done in support of Dymista. And just a couple of  
9 preliminary points.

10 First of all, the studies that you talked  
11 about, none of them are a comparison of Dymista to the  
12 coadministration of azelastine plus fluticasone; is that  
13 right.

14 A. I'm sorry. Say that again?

15 Q. None of the studies that you talked about compared  
16 Dymista to the coadministration of azelastine and  
17 fluticasone; is that right?

18 A. That is correct. I don't think there is a study that  
19 was ever conducted.

20 Q. And, sir, if you look at, can we have PDX-3.03,  
21 please.

22 A. 3.03.

23 Q. This was in your demonstrative exhibits.

24 A. Okay. Yes.

25 Q. This is the slide that you showed to sort of

Carr - cross

1 summarize in graphical form your discussion; right?

2 A. Well, this is a comparison of the deltas versus  
3 placebo is what this is. And it is comparing my study  
4 that was conducted with all the other investigators that we  
5 published to the Hampel study that used a similar design.  
6 It is just the delta versus placebo removed.

7 Q. Understood. And you put the 196 percent into  
8 90 percent; right?

9 A. Yeah, that is the 1.05 versus the 3.11 delta versus  
10 placebo.

11 Q. So you are not saying, sir, that Astelin isn't  
12 effective to treat allergic rhinitis, are you?

13 A. Of course not. I said effective it is effective --

14 Q. And you are not --

15 A. -- against placebo.

16 Q. You are not saying that fluticasone is not effective  
17 to treat allergic rhinitis?

18 A. Absolutely not.

19 Q. Your opinion is simply that Dymista is better at  
20 doing that?

21 A. Both statistically and clinically.

22 Q. It is a difference of degree of clinical improvement;  
23 right?

24 A. Yes. I mean when you have the same formulation it  
25 works, but when you use the Merck commercially marketed

Carr - cross

1 comparison, it is even a little bit better than the  
2 commercially available. That is all I'm saying.

3 Q. Okay. And then, sir, one of the things that you  
4 also talk about was that there is, in your view, a faster  
5 onset of action from Dymista than from either of the  
6 monotherapies; is that right?

7 A. Yes, we did discuss onset. Are you talking the exact  
8 onset or are you talking the responder rates?

9 Q. Well, what I'm talking about -- and I want to get  
10 into a discussion. What you talked about on your direct  
11 examination was you drew a distinction between clinical  
12 patients and the studies that Dr. Schleimer talked about  
13 that were done in controlled settings; right?

14 A. You mean the laboratory-based studies where they  
15 squirted histamine into the nose?

16 Q. Yes.

17 A. Yes.

18 Q. And those are relevant studies, aren't they, sir?

19 A. Oh, absolutely. You have got to take the data from  
20 the benchtop to the bedside. It's all part of the clinical  
21 development program.

22 Q. Yes. I mean that is important information, right?  
23 That you gleaned from those studies; correct?

24 A. It helps you provide a proof of concept to move  
25 forward. You don't always succeed but it is important.

Carr - cross

1 Someone has to have an idea somewhere and you explore it.

2 Q. In fact, that information was of enough importance  
3 that it is another piece of information you reported to the  
4 FDA; right?

5 A. Well, that would be included in the body of data  
6 available predominantly for safety concerns because the FDA  
7 will not use that for efficacy. They will only want it for  
8 safety. So, yes, it may have 15 minute onset for sneezing,  
9 but they want to know did anybody get bloody noses or have  
10 bad taste? It's safety.

11 Q. My point is you told the FDA about that data; right?  
12 The same type of data that Dr. Schleimer was talking about;  
13 right?

14 A. Well, I didn't personally, but that was part of the  
15 submission packet from Meda.

16 MR. WARNER: Let's take a look at that. And  
17 again this is PTX-47, please. And I want to go to, let's go  
18 to 1983, please.

19 BY MR. WARNER:

20 Q. And, again, at the bottom here, we looked at this  
21 section, sir. This is the rationale of the proposed  
22 product. Yes?

23 A. Yes. That's -- I'm sorry. You are back to the  
24 information package?

25 Q. That is correct.

Carr - cross

1 A. Yes.

2 Q. Okay.

3 A. And you're in the rationale. Okay. I'm sorry.

4 Q. Yes, I just wanted to frame us. So this is the  
5 rationale for why the FDA should allow the trials to go  
6 forward?

7 A. Well, this was, the FDA had proposed many concerns.  
8 This was Meda trying to address one of those concerns, the  
9 rationale.

10 Q. Understood. All I'm trying to say is --

11 A. Yes.

12 Q. -- this is Meda's explanation of the rationale of the  
13 proposed combination product. That is what it says; right?

14 A. Yes.

15 MR. WARNER: Okay. Now if you go to the next  
16 page. If we blow up the top paragraph, please.

17 BY MR. WARNER:

18 Q. One of the pieces of information that Meda -- and,  
19 again, you were listed as a consultant in connection with  
20 this; right?

21 A. This is a -- yes, I was a consultant, but I didn't  
22 prepare this meeting packet, if that is what you are asking.

23 Q. You were a consultant with Meda in connection with  
24 the work that they are doing. You are listed on the front  
25 page as a consultant.

Carr - cross

1 A. But I'm a consultant to attend the meeting. I didn't  
2 prepare this meeting packet, if that is what you are asking.

3 Q. I'm not suggesting you wrote the packet, but this is  
4 what Meda submitted, yes.

5 A. This is the Meda submitted to the FDA requesting the  
6 meeting, yes.

7 Q. What Meda says, if you look at the first full  
8 sentence, is they say: Azelastine provides rapid symptom  
9 relief compared to placebos as early as 15 minutes in an  
10 allergen chamber study."

11 Do you see that?

12 A. Yes.

13 Q. You don't dispute that. That is a true statement;  
14 right? Is this is something Meda told the FDA; right?

15 A. I will side with the FDA on this, and I actually  
16 disagree with this data. This is a point where Meda and I  
17 argued. They did say this, but I do not agree with it.

18 Q. Fair enough. Meda believed this statement when they  
19 told the FDA; correct?

20 A. It was in one study, and they believed it, but the  
21 FDA did not believe it and it never made it into their  
22 label.

23 Q. And Meda thought it was important enough to use this  
24 type of information to try to convince the FDA; correct?

25 A. Meda continues to use this failed information to try

Carr - cross

1 to convince the FDA, which it continued to fail, which is  
2 why they finally decided to bring two consultants in, Phil  
3 Lieberman and myself.

4 Q. There is nothing in this. You can look through the  
5 exhibits yourself. There is nothing in the document that  
6 says Dr. Carr disagrees with this sentence; right? You are  
7 listed on the cover as a consultant; right?

8 A. I am listed as a consultant on the cover sheet.

9 Q. And there is nothing in the document that says,  
10 asterisk, Dr. Carr disagrees with this?

11 A. There is nothing that says I agree with it either.

12 Q. On the onset of action. You would also agree with me  
13 that this again is an issue of the degree at which the  
14 effect happens. It happens faster than the prior art drugs;  
15 right? The onset of action?

16 A. What acts faster? Are you saying Dymista acts faster?

17 Q. It's not that the prior art drugs don't have a onset  
18 of action. It's just your view that Dymista has a faster  
19 onset of action; right?

20 A. I rely on the labels, and those are facts, and I  
21 agree with those. So the Dymista is 30 minutes, the Astelin  
22 label is within three hours. So, yes, 30 minutes is earlier  
23 than three hours.

24 Q. And with respect to the side effects, sir, you are  
25 not opining that Dymista doesn't have side effects, sir;

Carr - cross

1 correct?

2 A. Everything has a side effect.

3 Q. And your opinion is simply that Dymista in your view  
4 has fewer side effects than either Astelin or Flonase;  
5 correct?

6 A. It has fewer side effects with regard to some very  
7 significant side effects, yes.

8 Q. All right. I want to talk then about, some more  
9 about what went on at the FDA. Would you agree with me,  
10 sir, that the FDA never told you that it was skeptical  
11 that Dymista would be more efficacious than fluticasone  
12 or azelastine taken alone?

13 A. I think the context of just Question 1 is beyond  
14 skepticism. They basically said you can't do it.

15 Q. Would you agree with me, sir, that of all the people  
16 that you worked with at FDA, no one said in substance to  
17 you, we are skeptical. That if you take MP-2902 and give it  
18 to one of patients, we're skeptical it will be more  
19 efficacious than azelastine or Flonase given alone?

20 A. Rather than rephrasing what they said, I would just  
21 go based on their exact response, which they said we don't  
22 believe a population exists. To me, that is skepticism.

23 Q. Let's take a look at your deposition and see how you  
24 answered that question, sir.

25 Can I have Mr. Carr's deposition? And we'll



1 look at page 188 and 189.

2 And at line 23, at the top there, I took your  
3 deposition; right, sir?

4 A. Yes. We spent a lot of time on the skepticism thing.  
5 You tried to make me find the word "skepticism" in the  
6 document.

7 Q. And you couldn't find it; right?

8 A. It doesn't exist.

9 Q. It doesn't exist; right?

10 A. Right. You can be skeptical without saying I am  
11 skeptical.

12 Q. What I asked you, I said:

13 "Question: Did any of these people that you are  
14 referring to in any of these references or otherwise at FDA  
15 ever say in substance to you, we are skeptical that if you  
16 take MP-2902 and give it to one of your patients, we're  
17 skeptical that it will be more efficacious than azelastine  
18 or Flonase given alone?"

19 And then you answered. You said:

20 "Answer: Again, I think I've answered that  
21 question already. It's out of the purview of the conversation  
22 I would have with the FDA. They just don't have those  
23 conversations with you, and so the answer would be no."

24 Did I ask that question and did you give that  
25 answer, sir?

Carr - cross

1 A. After a very long series of back and forth, that is  
2 one small excerpt, yes.

3 Q. Okay. And you would also agree, sir, that none of the  
4 professionals with whom you interacted at FDA ever in  
5 substance expressed to your skepticism that if you were  
6 going to give MP-2902 to any one of your patients, it would  
7 be more efficacious than given azelastine and fluticasone in  
8 combination?

9 A. I think my testimony is that I feel they are very,  
10 to use your term, skeptical in substance. I think that is  
11 how you just phrased it. So they didn't use the word  
12 skepticism, but in substance, by saying they don't agree  
13 with anything we propose, that is skepticism in substance.

14 Q. Let's take a look again at your deposition. Can we  
15 look this time at page 189 over to 190? And at line 24.  
16 We'll pull it up. Go down a little more to get the answer,  
17 please.

18 And I said to you: "Did any of the  
19 professionals with whom you interacted at FDA ever in  
20 substance express to you skepticism that if you were to give  
21 MP-2902" -- and that is Dymista; right?

22 A. That is correct.

23 Q. -- "if you were to give MP-2902 to any one of your  
24 patients, it will be more efficacious than giving azelastine  
25 and Flonase in combination?

Carr - cross

1                   And you answered: "I have already answered that  
2 question?"

3                   And I said: "What's the answer?"

4                   And you said: "That is it is out of the purview  
5 of the FDA to have discussions about my individual clinical  
6 practice."

7                   Did I say ask that question and you gave that  
8 answer, sir?

9           A.       Yes.

10          Q.       All right. There were some discussions then about  
11 your view of what people outside of Meda have thought about  
12 the results of Dymista. Do you recall that?

13       A.       Yes.

14       Q.       Okay. And one of the documents that you have talked  
15 about was -- Can we have PTX-29? This is The Editors'  
16 Choice document.

17       A.       Okay.

18       Q.       And if you could put that at the top, and I want to  
19 look at the top corner.

20                   This is The Editors' Choice that you pointed  
21 out, sir; correct?

22       A.       Correct.

23       Q.       All right. And, now, you actually submitted your  
24 manuscript, of course, before this happened; right?

25       A.       Yes. Myself and my coauthors did a lot of work on

1 this manuscript, and we submitted it for acceptance to be  
2 published in the journal.

3 Q. Okay. And one of the things that these editors wrote  
4 after you submitted your journal is at the bottom, the very  
5 last sentence on the left side. It says: "Given these  
6 findings, MP-2902 can be considered the drug of choice for  
7 the treatment of AR."

8 That is what you pointed to; right, sir?

9 A. I pointed to multiple things, but that is one of the  
10 things I pointed to.

11 MR. WARNER: Now, could I have another document  
12 on the screen at the same time? I'd like to look at  
13 PTX-227, please.

14 BY MR. WARNER:

15 Q. And this, sir is the article that was in that  
16 journal; right?

17 A. Yes, sir, it was.

18 Q. And you are the lead author?

19 A. Yes, I am.

20 MR. WARNER: And I want to turn to page 9138,  
21 please. And if we could look at the upper left corner,  
22 please. The next paragraph as well.

23 BY MR. WARNER:

24 Q. Now, these are the words that you wrote; correct?

25 A. Well, as a team. Me and my coauthors came up with

Carr - redirect

1 this, but yeah.

2 Q. What you wrote at the bottom is you say: "Taken  
3 together, these results show that MP-2902 can be considered  
4 the drug of choice for AR therapy because it offers  
5 additional benefit to patients with AR, in particular with  
6 moderate to severe disease."

7 Do you see that?

8 A. Yes, I do.

9 Q. So you wrote in your article that MP-2902 can be  
10 considered the drug of choice for AR therapy and then you  
11 submitted that to the journal; right?

12 A. Yes.

13 Q. And then they wrote those same word in The Editors'  
14 Choice; right?

15 A. I was very honored that they agreed with me.

16 MR. WARNER: Nothing further, Your Honor. Thank  
17 you.

18 THE COURT: Okay. Redirect.

19 MR. BARDENSTEIN: I just have a couple of  
20 questions.

21 REDIRECT EXAMINATION

22 BY MR. BARDENSTEIN:

23 Q. Dr. Carr, do you remember when he put up your  
24 deposition and he asked you if the FDA ever expressed, I  
25 believe it's in substance expressed no skepticism if you

Carr - redirect

1     were to give MP-2902 to one of your patients, it would be  
2     more efficacious; and you said, no, it would be outside the  
3     purview of the FDA?

4     A.       Yes.

5     Q.       Were you there to talk about your clinical practice  
6     and how you use MP-2902 in your clinical practice?

7     A.       Oh, absolutely not. The FDA, that is the practice  
8     of medicine. The FDA is not going to tell or interrogate an  
9     individual physician on how they practice medicine in their  
10    own office. That is way outside of their per view.

11    Q.       In fact, MP-202 hadn't even been approved and on the  
12    market so you couldn't have used it on any of your patients?

13    A.       Exactly.

14               MR. BARDENSTEIN: I want to go back to DTX --  
15    PTX-29. If we can blow up the last sentence.

16    BY MR. BARDENSTEIN:

17    Q.       Mr. Warner was just talking to you about this?

18    A.       Yeah.

19    Q.       Did you ask the editors of this journal to include  
20    your article as an Editors' Choice?

21    A.       No.

22    Q.       Did you tell them what language to use?

23    A.       No.

24               MR. BARDENSTEIN: No further questions, Your  
25    Honor.

Carr - redirect

1 THE COURT: Thank you. You may step down.

2 Thank you, Doctor.

3 (Witness excused.)

4 MR. WARNER: Your Honor, before the next  
5 witness, can I --

6 THE COURT: One second. If you don't mind  
7 taking them, that will be helpful for the next witness.  
8 Thank you.

9 All right. Yes?

10 MR. WARNER: I just wanted to make sure I  
11 admitted two exhibits from the cross-examination. These are  
12 PTX-47 and PTX-227.

13 THE COURT: Any objection?

14 MR. BARDENSTEIN: No.

15 THE COURT: Okay. Those are admitted. Thank  
16 you.

17 (PTX-47, PTX-227 are admitted into evidence.)

18 THE COURT: Plaintiffs will call their next  
19 witness.

20 MR. KLEIN: Thank you, Your Honor. One other  
21 housekeeping matter.

22 THE COURT: Okay.

23 MR. KLEIN: I do have demonstratives from Dr.  
24 Kaliner's cross. How many do you need?

25 THE COURT: If you have two, we'll take them.

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1 MR. KLEIN: All right. Thank you.

2 MS. EVERETT: Plaintiffs call Dr. Hugh Smyth as  
3 their next witness.

4 ... HUGH DAVID CHARLES SMYTH, having been first  
5 duly sworn, was examined and testified as follows ...

6 THE COURT: Dr. Smyth, welcome.

7 THE WITNESS: Hello.

8 THE COURT: You may approach, yes.

9 (Documents passed forward.)

10 THE COURT: You may proceed whenever you are  
11 ready.

12 MS. EVERETT: Thank you.

13 DIRECT EXAMINATION

14 BY MS. EVERETT:

15 Q. Good morning, Dr. Smyth. Can you please state your  
16 full name for record?

17 A. Hugh David Charles Smyth.

18 Q. Where are you employed?

19 A. The University of Texas at Austin.

20 Q. I'm going to have you turn to your binder, Tab 1, and  
21 turn to document PTX-156.

22 A. Yes.

23 MS. EVERETT: Mr. Beall, can you bring that up  
24 please? Thank you.

25 BY MS. EVERETT:



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1 Q. Is document PTX-156 a copy of your curriculum vitae?

2 A. Yes.

3 Q. Does it accurately summarize your educational and  
4 professional experience?

5 A. It does.

6 Q. Can you walk the Court through your formal education  
7 starting with your undergraduate degree?

8 A. Sure. So I graduated with a bachelor of pharmacy in  
9 1995 from the University of Otago in New Zealand.

10 I practiced for a year as a pharmacist, then  
11 went back to the University of Otago and got my postgraduate  
12 diploma in pharmaceuticals.

13 After that, I entered the Ph.D. program, got my  
14 Ph.D. in pharmaceuticals in 2000.

15 And after that I moved to the University of  
16 North Carolina, Chapel Hill, and did a post-doctoral  
17 fellowship for a couple of years.

18 Q. Can you summarize your professional experience from  
19 your post-doctoral fellowship to present?

20 A. So after my post-doc, I became a research assistant  
21 professor at the University of North Carolina for a couple  
22 years, and then I moved to the University of New Mexico,  
23 College of Pharmacy, where I was a tenure track professor.

24 After about four years, I moved to the  
25 University of Texas at Austin. And I've been there since

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1 around 2005. I'm now currently an associate professor with  
2 tenure.

3 Q. Do you conduct research?

4 A. Yes.

5 Q. Do you have a laboratory?

6 A. I do. I have a research laboratory that has about  
7 eight graduate students, several post-docs and visiting  
8 scientists.

9 Q. Have you consulted with or performed research for  
10 industry?

11 A. Yes.

12 Q. What has been the focus of your research?

13 A. Formulation, drug delivery science, including  
14 different routes of administration, including nasal sprays,  
15 inhalation, ophthalmic inhalation.

16 Q. Have you developed nasal spray formulations before?

17 A. Yes, I have.

18 Q. When did you begin working on nasal spray  
19 formulations?

20 A. In the early 2000s, when I was a post-doc at UNC.

21 Q. Have you researched and developed nasal sprays  
22 intended for use by patients either in your consulting or  
23 your current employment?

24 A. My laboratory has had a couple projects with Industry  
25 that have been to assist them in the development of the

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1 products that would eventually lead to clinical testing of  
2 those nasal spray formulations.

3 Q. Do you publish your results from your projects with  
4 Industry?

5 A. We try to. Sometimes we don't publish those efforts  
6 because of intellectual property reasons.

7 Q. Are you involved in any professional committees  
8 related to nasal technologies?

9 A. Sure. I'm the Vice Chair of the Inhalation and Nasal  
10 Technology Focus Group for the American Association of  
11 Pharmaceutical Scientists.

12 Q. Do you serve on any editorial boards?

13 A. Several editorial boards. I'm the Editor in Chief of  
14 the Journal of Drug Development and Industrial Pharmacy.

15 Q. Have you published in the field of pharmaceuticals?

16 A. I have about 85 publications.

17 Q. And what are they directed towards?

18 A. Formulation drug delivery systems, devices.

19 Q. Have you previously testified at trial as an expert  
20 in either drug delivery or specifically nasal sprays?

21 A. Yes, once.

22 Q. Were you accepted as an expert in that case?

23 A. Yes.

24 MS. EVERETT: Your Honor, we move to offer Dr.  
25 Smyth as an expert in the field of drug formulation, drug

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1 delivery.

2 MR. LOMBARDI: No objection, Your Honor.

3 THE COURT: Okay. He is so recognized.

4 BY MS. EVERETT:

5 Q. Dr. Smyth, what were you asked to do for this case?

6 A. I was asked to provide opinions in response to I  
7 guess Apotex's contention that the patents are obvious and  
8 also provide input into some real world considerations  
9 around the validity of the patent.

10 Q. Were you in the courtroom when Dr. Donovan testified  
11 that she believed that the inventions of the patents in suit  
12 are obvious?

13 A. Yes.

14 Q. Do you agree with Dr. Donovan?

15 A. No, I don't.

16 Q. Did you prepare slides to assist with your testimony  
17 today?

18 A. I did.

19 Q. Can you summarize the opinions you will present  
20 today?

21 A. Sure. So my opinion is the invention was not  
22 obvious. And the POSA at the time would have faced  
23 significant formulation challenges and hurdles to combine an  
24 azelastine hydrochloride fixed dose nasal spray, and that  
25 they would have had no reasonable expectation of success.

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1                   In addition, it is my opinion that the Example  
2                   III of Cramer patent application is an inoperable nasal  
3                   spray. And then,

4                   Thirdly, Meda's 2006 experiments to combine  
5                   fluticasone and azelastine were a failure. And then,

6                   Lastly, Dymista, Duonase and the Indian imitator  
7                   products are embodiments of the patents.

8           Q.       Did you review and consider the patents in suit in  
9           your analysis?

10          A.       Yes.

11          Q.       Did you consider the view of a person of ordinary  
12           skill in the art?

13          A.       I did.

14          Q.       In your view, who is a person of ordinary skill for  
15           these patents?

16          A.       A person of ordinary skill has a bachelor's in  
17           pharmaceutical sciences, approximately four to five years  
18           experience as a formulator or less if they are at a higher  
19           level of formal education. And I understand a POSA would  
20           also be a clinician because the patents relate to treatment  
21           of patients.

22          Q.       Did you hear Dr. Donovan's definition of a person of  
23           ordinary skill?

24          A.       Yes.

25          Q.       Would your opinion that the patents in suit are

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1 not obvious still hold if the Court adopts Dr. Donovan's  
2 opinion?

3 A. Yes.

4 Q. In your experience, does a formulator weigh in on the  
5 selection of active ingredients in developing pharmaceutical  
6 formulations?

7 A. Yes, the formulator is the key person who talks about  
8 or understands the physicochemical properties of the drugs  
9 or the drug that is being developed or considered to be  
10 developed. They will be able to understand and relate to  
11 how formulations can be developed, the risks involved, and  
12 also the risks of different routes of administration for  
13 those particular drugs.

14 Q. How would a formulary weigh in on a particular dosage  
15 form or route of administration?

16 A. So they would, again, look at the physicochemical  
17 properties of the active ingredient that is the center of  
18 their focus, I guess, and then using their knowledge of  
19 formulation, excipients, experience and different routes of  
20 administration, be able to weigh in on the risks of  
21 developing such a product.

22 Q. In June 2002, what dosage forms would a formulator  
23 have considered for the treatment of allergic rhinitis?

24 A. So in 2002, a person of ordinary skill would look  
25 to see what was currently on the market. They would find

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1 that predominantly it was tablets for oral administration.  
2 Some oral solutions and suspensions were also available.  
3 They would also see that, as we have already heard, there  
4 were some nasal products, either nasal solutions or nasal  
5 suspensions.

6 Q. In your opinion, if a formulator, a person of  
7 ordinary skill were going to make a combination product in  
8 2002 for the treatment of allergic rhinitis, what dosage  
9 form do you think he or she would prefer?

10 A. Well, a combination product is quite complex, and so  
11 they would have chosen a dosage form that would lead to less  
12 problems, it would be less risky to develop, and there  
13 had been some combination problems developed for oral  
14 administration, tablets, so they would have chosen that.

15 Q. In June 2002, can you explain to the Court what  
16 combination forms were available?

17 A. So Allegra D, Claritin D, and Zyrtec D were all  
18 available at that time.

19 Q. And you are looking at slide PDX-4.06?

20 A. Yes.

21 Q. Dr. Smyth, what is the dosage form in the  
22 patents in suit?

23 A. It's a combination of a solution, it's active in  
24 solution, active in suspension in a nasal spray formulation.

25 Q. Why do you say it is a combination of solutions and

1 suspensions? Why is the invention not considered just a  
2 suspension?

3 A. So one of the actives in the patents in suit is in  
4 solution, and one of the actives is in suspension.

5 Q. Which part of the invention is in solution?

6 A. The azelastine hydrochloride.

7 Q. And when we say which part, you are referring to the  
8 active ingredient?

9 A. Yes.

10 Q. And which active ingredient is in suspension?

11 A. The fluticasone propionate.

12 Q. Is the fluticasone propionate in Dymista or Flonase,  
13 is any of that in solution?

14 A. An infinitesimal amount, a very, very small amount,  
15 so it is practically insoluble in water.

16 Q. What would happen to the formulation if more than an  
17 infinitesimal amount of fluticasone propionate was in  
18 solution?

19 A. So when in a suspension system -- I'll describe that  
20 in a slide in the future. But in a suspension system, you  
21 do not want significant drug to be in the solution because  
22 with fluctuations in the temperature, the solubility will  
23 change. This can lead to drug precipitating out on to  
24 particles and the particles actually growing. This is not  
25 a pharmaceutically suitable suspension.



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1 Q. Is there a scientific name or term by which this  
2 particle growth is known by?

3 A. Yes, Ostwald ripening.

4 Q. In your opinion, would a person of ordinary skill  
5 formulator have had a motivation to combine azelastine and  
6 fluticasone into a combination nasal spray in June of 2002?

7 A. No.

8 Q. If a person of ordinary skill formulator had been  
9 directed to formulate a combination azelastine and  
10 fluticasone nasal spray in 2002, would he or she have had a  
11 reasonable expectation of success?

12 A. No.

13 Q. And can you tell us why that person of ordinary skill  
14 would not have had a reasonable expectation of success or  
15 motivation to combine?

16 A. Yes. So in summary, this slide here kind of outlines  
17 those challenges that a POSA would face.

18 So, firstly --

19 Q. And just so we're clear on the record, you are on  
20 slide PDX-4.08?

21 A. That is right.

22 So the first challenge that they would face, a  
23 POSA formulator trying to develop a nasal spray, is that  
24 Astelin again is a solution, nasal spray, Flonase is a  
25 suspension, and never before had a solution suspension nasal

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1 spray formulation been developed before.

2 Secondly, developing such a formulation from  
3 those products, there would be a number of different  
4 formulation challenges such as potential incompatibilities  
5 between the ingredients and also some unknown interactions,  
6 some essentially not described combinations of the  
7 excipients and ingredients.

8 Thirdly, a POSA would have looked at the FDA  
9 labeling, and they would have found that there is dosing  
10 incompatibilities between the two products. And then,

11 Lastly, this is all layered upon, these  
12 challenges are layered upon nasal spray formulations which  
13 have a lot narrower design requirements than a tablet would  
14 have, for example.

15 Q. Let's start with the first one. Can you walk us  
16 through the challenges of combining a solution in the  
17 suspension?

18 A. Sure.

19 Q. I have slide PDX-4.09.

20 A. So as Dr. Donovan mentioned over the last few days, a  
21 solution system is one where the drugs are molecularly  
22 disbursed in a medium. So the goal, one of the goals for  
23 the formulator here is to ensure that that active ingredient  
24 is fully dissolved, and noting here that azelastine is  
25 actually a compound that is sparingly soluble.

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1           On the other hand, a suspension system is one  
2       where the drug is in particles, so it is not in its molecular  
3       form, it is in crystals. And if the goal for a formulator  
4       here is to stabilize the system but also to make sure that  
5       the fluticasone remains undissolved and insoluble for those  
6       reasons we talk about with the Ostwald ripening.

7       Q.       And specifically, again, the solubility of azelastine  
8       is sparingly soluble in water and fluticasone propionate is  
9       practically insoluble in water?

10      A.       That is correct.

11      Q.       What would happen if the azelastine was not dissolved  
12      or poorly solubilized?

13               And here, we have a slide on PDX-4.10.

14      A.       So if the drug is formulated in solution incorrectly,  
15      and during storage or temperature changes, if it comes out  
16      of solution, if it precipitates, essentially crystals will  
17      form. The drug will come out of solution, and it will make  
18      the solution nonhomogeneous. And this is pharmaceutically  
19      unacceptable because the patient doesn't get the accurate  
20      dose that is intended.

21      Q.       So when you say the patient doesn't get the accurate  
22      dose, what has happened to the active ingredient?

23      A.       So some of it has remained in the solution, but  
24      obviously some of it has come out. So it's very hard for  
25      a formulator to guarantee that a patient is going to get

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1 the accurate dose. They could be overdosed if they get a  
2 crystal in there, a particular dose that is administered  
3 or underdosed because some of the drug has come out of  
4 solution.

5 Q. Would this have been known as of June 2002?

6 A. Yes.

7 Q. And I think you started talk about this a moment ago,  
8 but what would happen if fluticasone was not sufficiently  
9 suspended?

10 A. So Dr. Donovan introduced suspensions and one of the  
11 problems that a formulator faces with suspensions is that  
12 they're essentially physically unstable. The particles  
13 want to separate out from the dispersion medium. So the  
14 formulator's goal here in terms of the physical stability is  
15 to make sure that the particles don't sediment out too fast  
16 to prevent accurate dosing of that mixture. And,

17 Most importantly, they must avoid sort of  
18 particle aggregating or caking because this causes changes  
19 to again the uniformity of the formulation and the dose that  
20 the patient is going to get.

21 Q. So rapid settling and caking is not acceptable  
22 pharmaceutically acceptable in formulation?

23 A. Yes.

24 Q. Would this have been known in 2002?

25 A. Yes.

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1 Q. Could you turn to PTX-0192 in your binder? It will  
2 be Tab 4.

3 A. Yes.

4 Q. Can you identify the document, please?

5 A. This is a textbook called Pharmaceutical Dosage  
6 Forms: Disperse Systems, By Lieberman.

7 Q. Is this textbook used in the field?

8 A. Yes, this is a comprehensive textbook on suspensions  
9 and dispersal systems.

10 Q. Can you we turn to page 5? We're at PTX-192-00005.

11 What did the authors say about rapid settling?

12 A. They say, under the desirable attributes of the  
13 suspension, in Point 1, they say that the suspended material  
14 should not settle readily at the bottom of the container.

15 Q. And what do they say about caking?

16 A. They say, further on with same point, it says must  
17 not cake.

18 Q. Now, I'm going to ask you to turn to your binder  
19 again, PTX-167. And we will discuss making suspensions and  
20 solutions.

21 Do you recognize this document?

22 A. Yes. This is one of the chapters from the  
23 pharmaceutical compounding book by Loyd Allen that Dr.  
24 Donovan relied upon.

25 Q. Did you hear her testimony yesterday that this

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1 textbook would have been able to teach a person of ordinary  
2 skill how to make a solution suspension product where one  
3 active is in solution and one active is in suspension?

4 A. Yes.

5 Q. Do you agree with her?

6 A. No.

7 Q. Why not?

8 A. If you look at this chapter, essentially it  
9 discusses solutions separately from suspensions. And the  
10 actual information that is really provided to the formulator  
11 is very, very basic with very little guidance on specifics  
12 about formulations.

13 Q. Yesterday, I believe she highlighted Step 2, dissolve  
14 in mix, as teaching a person of ordinary skill in the art to  
15 make a solution suspension. Can you explain your view on  
16 Step 2?

17 A. Step 2 is essentially saying after Step 1, which is  
18 weighing out your ingredient, you go and mix the ingredients  
19 in water. There is really no substantive guidance here on a  
20 complicated solution suspension formulation.

21 Q. Prior to this litigation, Dr. Smyth, in your research  
22 and development work, have you relied on the Allen reference  
23 for formulation guidance?

24 A. I have not.

25 Q. Why is not?

1 A. So I think this textbook is one that is used more for  
2 compounding pharmacies, compounding pharmacists. It really  
3 is a high level overview of formulations that doesn't really  
4 get into the science or the mechanisms of formulation.

5 Q. In your experience, do formulators distinguish  
6 between excipients and active ingredients?

7 A. Yes.

8 Q. How do they distinguish and why?

9 A. So as I told earlier on, an active ingredient is kind  
10 of like the centerpiece for a formulation. It is how the  
11 formulator designs the formulation. So they look at the  
12 properties of the drug, its physical properties, its  
13 chemical properties, and they select the active ingredient  
14 -- sorry -- the inactive ingredients to accommodate and  
15 support the stability and performance of that drug. They  
16 don't do it the other way around.

17 Q. So in your experience, the formulators select the  
18 active ingredients first; is that correct?

19 A. Well, they would contribute to the selection of the  
20 active ingredient, yes.

21 Q. Okay. Fair. So for clarification, in the  
22 formulation, if one were involved in the formulation  
23 process, the active would be selected first?

24 A. Yes.

25 Q. Okay. Next, I'm going to have you turn in your

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1 binder to Tab 3, PTX-189.

2 A. Yes.

3 Q. Can you identify this reference?

4 A. Yes. This is the Handbook of Pharmaceutical  
5 Excipients.

6 Q. Have you seen the reference before?

7 A. Yes. This is a common guide for formulators.

8 Q. In your experience, how do formulators use the  
9 Handbook of Pharmaceutical Excipients?

10 A. So the handbook is a list of hundreds of excipients  
11 that formulators have used before in different products, and  
12 it contains information in separate chapters about those  
13 excipients.

14 So once a formulator has sort of designed a  
15 prototype formulation or a formulation that they're working  
16 on, they use this handbook to look at those more detailed  
17 properties of the individual excipients.

18 Q. Is your understanding consistent with how you believe  
19 Apotex's experts are using the handbook?

20 A. No, I think during earlier stages of this litigation,  
21 I think how they described the use of the handbook was  
22 that this would be a guide on how to formulate. But it's  
23 really, it's more of an encyclopedia. You have to know  
24 what excipients you are going to use before you go to the  
25 handbook to find out more information about this. The



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1 handbook doesn't contain any formulations itself.

2 Q. Okay. Now, I'm going to turn us back to your slides.  
3 We're at slide 11 where you had started to discuss the  
4 specific formulation challenges.

5 You prepared a slide showing the potential  
6 incompatibility of unknown interactions that a POSA would  
7 be facing. Can you walk us through this slide?

8 A. Sure. So a POSA, beginning with Astelin and Flonase  
9 as their starting point, would look at those compositions  
10 which again would be available from the labels of those  
11 products. And they would see, as I have listed here, that  
12 only two of those ingredients were common between Astelin  
13 and Flonase: the water and the benzalkonium chloride.

14 So, initially, the POSA would realize that  
15 there is not much commonality between Astelin and Flonase.  
16 So facing this, they would know there could be potential  
17 incompatibilities or even unknown interactions between those  
18 ingredients.

19 So the first thing that they would realize is  
20 that a potential incompatibility would be azelastine and the  
21 CMC, the carboxymethylcellulose.

22 Q. And that is the first slide on your slide?

23 A. Yes.

24 Q. Do you have a slide that discloses this? I think  
25 PTX-0192, Tab 4 in your binder.

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1 A. Yes.

2 Q. First, before we get into it, can you identify the  
3 reference, please?

4 A. Yes. This is the same Lieberman book on  
5 pharmaceutical dosage forms.

6 Q. And when was this book accomplished?

7 A. I think 1996.

8 Q. Now, I think you are on page -- if we could go to  
9 page 24.

10 What does the Lieberman reference at page 24  
11 say about CMC and its compatibility with other excipients or  
12 other actives?

13 A. It talks about how carboxymethylcellulose solutions  
14 have poor tolerance for electrolytes. That di- and  
15 trivalent cations can precipitate polymer.

16 Then further down, it says, but it is  
17 incompatible with cationic drugs.

18 Q. And is azelastine hydrochloride a cationic drug?

19 A. In solution it is, yes.

20 Q. In your opinion, what would a person of ordinary  
21 skill have taken away about the interaction between CMC and  
22 azelastine hydrochloride if they were to put those two  
23 together?

24 A. They would have known that azelastine is a cationic  
25 drug, and they would have seen that carboxymethylcellulose

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1 is an anionic polymer with many negative charges. And  
2 knowing that polymer is incompatible with cationic drugs,  
3 would have been discouraged from combining those two  
4 together.

5 Q. Do you recall earlier this week when Dr. Donovan  
6 testified that the scope of the prior art said CMC is  
7 compatible with azelastine?

8 A. Yes.

9 Q. Do you agree with that?

10 A. No.

11 Q. Can you explain that further?

12 A. So the reference that she was relying on for that,  
13 that point was the Hettche patent from -- actually I can't  
14 remember the date, 92' maybe.

15 Q. Yes.

16 A. So that patent actually didn't have any examples of  
17 azelastine combined with carboxymethylcellulose.

18 It also listed carboxymethylcellulose in a  
19 larger list of polymers. So a person of ordinary skill  
20 would have to looked to a more authoritative reference such  
21 as this textbook over the Hettche reference.

22 Q. And so you understand that Lieberman was published  
23 after the Hettche reference?

24 A. Yes.

25 Q. Now, if we can go to the next point on your slide, at

1 page, back to page 11.

2 Buffer system is your next point. What is the  
3 significance about a buffer system?

4 A. So a buffer system is employed in formulations to  
5 maintain a pH within certain limits, at a certain level.  
6 And so that can be for a variety of reasons. For the  
7 stability of a drug, for solubility, among other things.

8 So if you look at the Astelin formulation,  
9 Astelin contains a buffer. This is the citric acid and  
10 diphasic sodium phosphate. So a POSA looking at that would  
11 assume that azelastine hydrochloride is very sensitive in  
12 this formulation to pH changes.

13 Q. And your next point is choice of isotonization agent?

14 A. Yes.

15 Q. Can you explain that?

16 A. So as we have heard already, these agents like sodium  
17 chloride and dextrose. So Astelin contains sodium chloride,  
18 Flonase contains dextrose. There would be no clear choice  
19 of which one to pick.

20 There could be interactions between Astelin and  
21 dextrose or sodium chloride in Flonase formulation, and it  
22 doesn't even mention glycerin which is used in the patents  
23 in suit.

24 Q. And just so we're clear for our lay people, when you  
25 talk about isotonization, is that irritation of the nasal

1 tissue?

2 A. It's like Dr. Donovan talked about. It's the number  
3 of solids that is in a particular liquid. So you don't  
4 want the number of solids between your formulation to be  
5 very different from the number of solids that is on the  
6 nasal tissues, for example, in this case.

7 Q. And what would happen if they were very different?

8 A. If they're very different, you cause irritation.  
9 You can cause water to move across the membranes, the  
10 mucosa, and that can be irritating.

11 Q. And you were, in fact, stating that the isotonization  
12 agent is different in Astelin and Flonase?

13 A. That's right, yes.

14 Q. And one point I just wanted to make, one additional  
15 point. On the buffer system, Astelin has a buffer and does  
16 Flonase have a buffer?

17 A. Flonase does not have a buffer, no.

18 Q. Okay. Now, you have listed a number of unknown  
19 interactions. Let's talk about that. First, I think you  
20 have: combining the two active ingredients.

21 A. That's right. So these unknown interactions are  
22 ones that I have characterized as these combinations of  
23 ingredients had never been reported before.

24 Q. Okay.

25 A. So azelastine and fluticasone had never been combined

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1 in a single formulation before.

2 Q. Were you in the courtroom when Apotex's expert  
3 Dr. Schleimer testified that a person of ordinary skill --  
4 the type he is opining on is an MD or researcher -- would  
5 have looked to the Advair Diskus example as a motivation to  
6 combine fluticasone with another combination?

7 A. Yes, I did hear that.

8 Q. Do you agree with that from the perspective of a  
9 formulator?

10 A. From a formulation point of view, the Advair Diskus  
11 was a dry power inhaler, so that's a very different type of  
12 formulation than a nasal spray. That would not be too  
13 informative of the formulation of a nasal spray.

14 Q. Are you aware of any studies before 2002 that would  
15 have informed a POSA formulator about combining fluticasone  
16 that would have been relevant?

17 A. There were some researchers.

18 Q. And, again, if you turn to the next tab in your  
19 binder, PTX-179.

20 A. So these are researchers from Glaxo who were  
21 developing the Advair product, and they did publish a paper  
22 on the aggregation behavior of fluticasone with another drug  
23 called salmeterol xinafoate.

24 Q. Is the formulation in PTX-179, is that solution  
25 suspension, what type of dosage form is it?

Smyth - direct

1 A. So it's a metered dose inhaler suspension system  
2 which contains propellants.

3 Q. Can you walk us through what the publication  
4 discusses?

5 A. Sure. So if you go to, actually, the conclusion is a  
6 good place to start. Yes. It says: The focus of the paper  
7 has been to gain an understanding of the interaction between  
8 salmeterol xinafoate and fluticasone propionate in single  
9 and combined formulations.

10 So there we're looking at the suspension  
11 aggregation behavior of these two actives.

12 Q. And you are on PTX-179-00010.

13 A. Yes.

14 Q. What did the researchers find in this study?

15 A. So, first of all, they found there was an interaction  
16 between the drugs in suspension during the flocculation  
17 behavior of those drugs and the other properties of those  
18 drugs, and also the properties of the medium.

19 Q. What is the significance of this finding?

20 A. Well, it would have given us, a person of ordinary  
21 skill at the time who was trying to develop a fixed dose  
22 combination product containing fluticasone an idea that  
23 there could be challenges in combining fluticasone with  
24 another drug.

25 Q. Are there any significant -- what is the significance

Smyth - direct

1 about the aggregation and the other findings?

2 A. So this would be an indication that there is  
3 unpredictable on the suspension formulation. And that  
4 this would be a potential risk in terms of formulation  
5 development success.

6 MS. EVERETT: Mr. Beall, if you can pull up page  
7 2 of that reference. PTX-179-0002.

8 BY MS. EVERETT:

9 Q. Did the authors make any statements about combination  
10 drug formulations?

11 A. Yes, they do. It's sort of at the top of this  
12 callout. It says: "Combined drug formulations are less  
13 well understood and as a result, a significant amount of  
14 fundamental scientific research work on the subject is being  
15 undertaken."

16 Q. And do they continue to discuss previous work on  
17 combined formulation?

18 A. Yes. They were very interested in understanding  
19 interactions between their two active ingredients,  
20 fluticasone and salmeterol.

21 Q. Can you explain to the Court the significance of  
22 their statements about the combination of two drugs?

23 A. Again, so it would have, from a person of ordinary  
24 skill, looking at fluticasone, combining it with another  
25 drug, they would look to this and realize that these fixed



Smyth - direct

1 dose combinations, particularly in suspension systems, are  
2 less well understood and it would be a harder task in  
3 developing such is a formulation.

4 Q. How would the person of ordinary skill use this  
5 reference or consider this reference when developing their  
6 product?

7 A. Well, it doesn't -- in terms of the combination of  
8 Astelin and Flonase, it doesn't talk about azelastine,  
9 but this would be some of the closest art in terms of  
10 fluticasone and a suspension that would helped inform them  
11 of the formulation difficulties.

12 Q. Now, we're going to come back to your list on PDX-4.11.

13 Now, the next one is fluticasone and EDTA. What  
14 was known in the art about combining fluticasone and EDTA?

15 A. Nothing was known, to my knowledge, of that  
16 combination.

17 Q. So how would that affect a POSA formulator?

18 A. It would be an unknown. They would not know if there  
19 was an interaction or potential incompatibility between  
20 those ingredients.

21 Q. What about azelastine and MCC?

22 A. MCC had been known to interact with other active  
23 compounds, but it had never been used with azelastine  
24 before. So it would be unknown.

25 Q. What about azelastine and phenylethyl alcohol?

Smyth - direct

1 A. Same thing. I couldn't find any reference showing  
2 that those had been used before the priority date.

3 Q. And what about azelastine and polysorbate 80?

4 A. Yes. Again, those two ingredients had not been  
5 combined together, to my knowledge.

6 Q. So you said you hadn't found any references that  
7 these had been combined before; is that accurate?

8 A. Yes.

9 Q. So how would a person of ordinary skill consider  
10 the unknowns interactions and the known interactions when  
11 formulating?

12 A. Well, the known interactions would obviously be a  
13 more serious concern. There would be, it would discourage  
14 them from developing those types of combinations of  
15 ingredients.

16 The unknown interactions would have formed risks  
17 in their mind of potential incompatibilities and looking  
18 at, again, looking at the Astelin and Flonase compositions,  
19 there were only two common ingredients. So there is a lot  
20 of unknowns in combining Astelin and Flonase.

21 Q. Are you saying a person of ordinary skill formulator  
22 would need a certainty of success before formulating?

23 A. No.

24 Q. Now, you mentioned dosing difficulties, I believe.  
25 Can you explain what those are?

Smyth - direct

1       A.       Yes. So at the time of the invention Astelin, the  
2       FDA approved the label, including dosing information. And  
3       so Astelin was dosed to two sprays twice a day to give a  
4       total therapeutic dose of around or exactly 1,096 micrograms.

5               Flonase, on the other hand, there is two options  
6       here: two sprays once a day or one spray twice a day. But  
7       for both of those, a maximum therapeutic daily dose of  
8       200 micrograms was shown to be safe and effective.

9               So a formulator POSA at the time would have  
10      looked at these two regimens of dosing and found it to be  
11      incompatible.

12              If you go to the next slide, these problems are  
13      illustrated here.

14              So if they were to pick the option 1. So this  
15      is the Astelin dosing label instruction; and if they had  
16      combined the formulations together in those amounts,  
17      azelastine would be delivered in its therapeutic safe and  
18      effective dose, but fluticasone would be dosed at 400, twice  
19      the known safe amount on the FDA label.

20              If you took the second option using Flonase  
21      dosing regimen, you could obviously dose Flonase or  
22      fluticasone at the therapeutically known safe and effective  
23      amount but you would be underdosing azelastine by half.

24      Q.       And you are on PDX-4.13.

25      A.       That's right.

Smyth - direct

1 Q. Would a formulator POSA consider altering the  
2 quantities of the active ingredients?

3 A. There could be one way of trying to get around these  
4 inconsistencies, yes.

5 Q. Would there be any drawbacks to a formulator doing  
6 that?

7 A. Well, for one, if they were, in option 2, for  
8 example, trying to get twice as much azelastine into the  
9 formulation per spray, they would have to increase the  
10 amount of azelastine in the formulation by double. And we  
11 have already heard by others and me that azelastine is  
12 actually sparingly soluble, so that would be a significant  
13 challenge.

14 Q. Would a POSA have been discouraged by these  
15 incompatibilities and unknown interactions?

16 A. Yes. Collectively, the dosing, the known  
17 incompatibilities, the unknown interactions result in layers  
18 of discouragement I guess for a POSA into developing a  
19 combination of an Astelin and Flonase together.

20 Q. Okay. Now, let's turn to nasal sprays. Assuming the  
21 formulator POSA forged ahead and started developing a nasal  
22 spray. What parameters would they have had to, he or she  
23 would have had to consider?

24 A. So, yes, I've got kind of a chart here that I'm going  
25 to sort of walk through.

Smyth - direct

1           But one of the first parameters and requirements  
2 of a formulation is the chemical stability. So a  
3 pharmaceutically acceptable formulation must be chemically  
4 stable.

5           The drug must not degrade or have any chemical  
6 or interactions with other components.

7           It must also be microbiological stable.

8           Free from contamination at the time.

9           It must have dose uniformity, which is  
10 essentially each time that the patient uses the system, they  
11 get the same, accurate dose. This is particularly important  
12 for nasal sprays where the dose delivered in a very small  
13 volume of potent drugs.

14           Osmolality is important -- we talked about this  
15 -- just to make sure it is not irritating to the nasal mucosa.

16           And a pH is a very important concept in  
17 formulations in particular. Nasal sprays can't be irritating  
18 to the nasal mucosa, but it also may influence other aspects  
19 of the formulation.

20           Nasal sprays obviously have to generate a spray.  
21 This is particularly important for allergic rhinitis in  
22 which the mucosa is the target tissue, so you don't want a  
23 jet. And then.

24           Lastly, the physical stability, what we talked  
25 about earlier, how the particles in a suspension system must

Smyth - direct

1 be physically stable and don't separate out.

2 Q. Are these parameters found in the patents in suit?

3 A. Yes.

4 Q. And how are these parameters found in the patents  
5 in suit?

6 A. So the limitations of the claim require that the  
7 invention of the pharmaceutical formulation is  
8 pharmaceutically acceptable, which would pertain to many of  
9 these. It also calls out certain other aspects like pH and  
10 contains preservatives which would ensure microbiological  
11 stability.

12 Q. And some of the formulations have to be suitable for  
13 nasal administration?

14 A. That is right, yes.

15 Q. How does the formulator -- so the formulator has to  
16 now consider all of these parameters, but we have heard  
17 testimony that a formulator would know how to modify pH;  
18 right?

19 A. (Nodding yes.)

20 Q. Why isn't it sufficient for a formulator that can  
21 modify pH, they can change any one parameter?

22 A. Right. So I kind of drew this diagram to kind  
23 of illustrate how you can't just take one parameter in  
24 isolation. They're all sort of connected. And if you alter  
25 one parameter in a formulation, you are going to alter other

1 parameters.

2           So for a pH, for example. If you go to the next  
3 slide. If a person of ordinary skill is developing a nasal  
4 spray formulation, and they satisfy all the requirements of  
5 these other ones except for pH, they may attempt to adjust  
6 pH, and you can adjust pH using NaOH. And that was widely  
7 known how to do that.

8           So if they create, alter the pH to fall within  
9 the acceptable range, the problem is a formulation is  
10 very complex and you may alter other aspects of that  
11 formulation. So pH may be particularly important for  
12 chemical stability or solubility of formulation. So it's  
13 not just a simple as has been talked about previously of  
14 just simply tweaking the numbers or adjusting individual  
15 parameters.

16 Q.       And do you have another example of how, say, spray  
17 quality would be affected by the other parameters?

18 A.       Sure. So if a POSA had developed a formulation and  
19 satisfied all the other parameters except for spray quality,  
20 because maybe it comes out as a jet, what they could do is  
21 look to the formulation and say, well, we want to reduce the  
22 viscosity so it sprays a nice mist.

23           But viscosity is there not just for spray  
24 quality, it's there for other reasons. So adjusting the  
25 viscosity of the formulation to improve spray quality, you

Smyth - direct

1       therefore can influence other aspects of the formulation.  
2       Reducing viscosity will increase the speed of which the  
3       particles settle out, and it will change the physical  
4       stability. That is going to change how uniform the dose  
5       is given to the patient.

6       Q.       Now, you just talked about how the particles settle  
7       out. Do the particle size affect the parameters that we see  
8       on PDX-4.24?

9       A.       Yes, particle size would be primarily related to  
10      physical stability and how fast particle sediment in a  
11      medium.

12     Q.       And there, have there been suspensions as of 2002  
13     that were both micronized and unmicronized?

14     A.       There have been suspensions that use the core  
15     suspensions that use nonmicronized but also suspensions  
16     that use micronized drugs.

17     Q.       Now, these considerations that we just discussed, are  
18     they just for commercial products?

19     A.       No, these are basic requirements of pharmaceutical  
20     formulations. These are ones that would be required for  
21     dosing to a patient, for example.

22     Q.       Are these pharmaceutical products, and nasal  
23     sprays in particular for allergic rhinitis, meant to be  
24     administered over a period of time?

25     A.       Yes. In particular for allergic rhinitis, I think



Smyth - direct

1 we've heard a lot about how long the treatments go on for  
2 and how long it takes drugs to take effect. These would be  
3 types of formulations would need to be stable over weeks.

4 Q. How does this then affect stability considerations?

5 A. So a POSA would need to look at these parameters over  
6 time.

7 Q. You have addressed a variety of formulation  
8 considerations. Would a person of ordinary skill in 2002  
9 have been aware of these considerations?

10 A. Yes, this would be common knowledge.

11 Q. In your opinion, would a POSA have been motivated or  
12 had a reasonable expectation of success in achieving a  
13 pharmaceutically acceptable azelastine and fluticasone nasal  
14 spray as of 2002?

15 A. No.

16 Q. I'm going to turn briefly to the next topic. Meda's  
17 experiments.

18 Were you in the courtroom yesterday when  
19 Dr. D'Addio testified regarding Meda's 2006 experiments?

20 A. Yes.

21 Q. Did it surprise you they failed?

22 A. No.

23 Q. Why not?

24 A. Formulation is much more complex than dropping  
25 individual drugs into existing formulations; and their

Smyth - direct

1 attempt to essentially dissolve azelastine into the Flonase  
2 vehicle, it's not surprising that they found  
3 incompatibilities or insolubility of the azelastine.

4 Q. Now I'm going to turn to the Cramer reference.

5 And just for the record, I think it was  
6 referenced, had been referenced this week as DTX-0112, or  
7 excuse me, DTX-012.

8 Dr. Smyth, have you reviewed the Cramer  
9 reference.

10 A. Yes.

11 Q. In your view, is it operable?

12 A. No.

13 Q. Why do you consider Cramer Example III to be  
14 inoperable?

15 A. There's a number of reasons why that example is  
16 not pharmaceutically acceptable or even operable at a  
17 suspension.

18 First of all, as I summarized on this slide,  
19 it's unacceptably acidic. It was unstable even after a  
20 short period of time.

21 It would give inconsistent dose delivery.

22 And in cases where the medium viscosity  
23 ingredient was used, HPMC, it was unable to produce a spray.

24 Q. And you are looking at your slide, PDX-4.29?

25 A. Yes.

Smyth - direct

1 Q. How did you arrive at your conclusion that Cramer  
2 Example III is inoperable?

3 A. I looked at the testing results of Ms. Malhotra,  
4 Dr. Govindarajan, and Dr. Herpin.

5 Q. So I think those are some new names for litigation,  
6 so I'm going to ask you to identify. Who is  
7 Dr. Govindarajan?

8 A. Dr. Govindarajan is a scientist. I think he is at  
9 the University of Iowa, and he was doing testing for the  
10 defendants in this case.

11 Q. Did you hear any reference to defendants' testing  
12 during defendants' case yesterday?

13 A. No, I don't think anyone has mentioned Dr.  
14 Govindarajan in this case.

15 Q. Who is Dr. Herpin?

16 A. Dr. Herpin is a post-doctoral fellow at the  
17 University of Texas at Austin.

18 Q. How did Dr. Herpin come to test Cramer Example III?

19 A. He followed protocols and procedures that I wrote out  
20 for the testing of Cramer Example III.

21 Q. And why did you ask Dr. Herpin specifically?

22 A. I asked him to do this testing because I know  
23 Dr. Herpin has considerable experience in developing  
24 formulations, has industry experience, and I can trust the  
25 results he gets when he does scientific experiments.

Smyth - direct

1 Q. And it's because you have worked together for a  
2 number of years?

3 A. Yes, he is a post-doctoral fellow in my lab.

4 Q. Did you tell him your opinions in this case?

5 A. No.

6 Q. Did you direct him to achieve any certain results?

7 A. No.

8 Q. Have you discussed the substance of the case with him  
9 in any way during the course of litigation?

10 A. No, I didn't.

11 Q. Okay. Did all three formulators use the same  
12 approach for testing Cramer Example III?

13 A. No, Malhotra, Govindarajan and Herpin all use slight  
14 variations on how to recreate Cramer Example III, make it  
15 operable.

16 Q. And we're looking now at PDX-4.30. What were the  
17 different approaches that Ms. Malhotra, Dr. Govindarajan,  
18 and Dr. Herpin used?

19 A. So Cramer Example III gave, this lied out some  
20 details on how to prepare this. And so there were some  
21 interpretations that had to be made by the formulators.

22 So the mixing method was one of them. It didn't  
23 really give clear instructions on how to make Example III.  
24 So there was a variety of different methods of mixing and  
25 formulating procedures that were used.

Smyth - direct

1 Cramer Example III didn't disclose what particle  
2 size of triamcinolone should be used, whether it should be  
3 micronized or unmicronized or raw. That is what you have on  
4 this table here.

5 And then Cramer didn't disclose what grade of  
6 HPMC, this thickening agent. And so both medium viscosity  
7 and low viscosity grade were used in these studies.

8 Q. And how many replications of Cramer Example III were  
9 made?

10 A. I think eight different versions of Cramer Example  
11 III were made.

12 Q. Were any of the formulators or testers who were  
13 making Cramer Example III trying to make them operable?

14 A. Yes, they were following the guidance of the patent  
15 and trying to see if they were operable.

16 Q. That includes Ms. Malhotra?

17 A. Yes.

18 Q. Did it include Dr. Herpin?

19 A. Yes.

20 Q. And Apotex's expert, Dr. Govindarajan?

21 A. Yes.

22 Q. Did any of these eight variations result in an  
23 acceptable formulation?

24 A. In my opinion, no.

25 Q. Now, let's move directly to, let's look at what we're

Smyth - direct

1 calling Dr. Govindarajan's testing of Cramer Example III.

2 Can you walk us through slide PDX-4.32?

3 A. Sure. So what I have done is sort of overlaid these  
4 basic requirements of a nasal spray formulation to what was  
5 found with Dr. Govindarajan's recreation of Example III.

6 And I must point out that Dr. Herpin's recreation of Dr.  
7 Govindarajan's Example III provides additional data from  
8 what Dr. Govindarajan's testing did not include.

9 Q. So Dr. Govindarajan, what were his tests?

10 A. So he tested, he wrote down some visual observations,  
11 and he tested osmolality. And I think later on in a  
12 deposition, he actually said he tested pH as well.

13 Q. So first his visual observations. Were they  
14 photographs, writing?

15 A. Just written observations in a lab notebook.

16 Q. Then osmolality and pH, I think you said?

17 A. Yes.

18 Q. And Dr. Herpin, what were his tests?

19 A. So, I guess Dr. Govindarajan mentioned the spray  
20 quality. Dr. Herpin, in his other formulations that he  
21 was developing, looked at pH, physical stability, took  
22 photographs, made observations, tested uniformity.

23 Q. Okay. Thank you. So can you walk us through the  
24 results of these tests?

25 And just if we can identify the documents.

Smyth - direct

1 We're looking at PDX-4.33 and the underlying exhibits are  
2 PTX-1663, and PTX-1082, and PTX-1664.

3 Go ahead, Dr. Smyth.

4 A. Right. So what was found with this Cramer III was  
5 that it was very hypertonic and that Dr. Govindarajan tested  
6 this and found it was 529 milliosmoles. Isotonic would have  
7 been more around the 300 range.

8 He also found as well as Dr. Herpin found that  
9 this example was highly acidic, around a pH of 3 or less.  
10 So this pH would be unacceptable. It's about the same  
11 acidity of vinegar, certainly not acceptable as Nasal spray.

12 They found it could be sprayed, produced a nice  
13 fine mist.

14 But if you go to the next slide.

15 It did not have sufficient physical stability or  
16 uniformity of dosing.

17 The photograph that you see in the top left-hand  
18 side is of the formulation after it has been made, after  
19 14 days. And you can see that essentially the particles  
20 have all settled down to the bottom, formed a thin layer of  
21 drug on the bottom. And when Dr. Herpin remixed this, on  
22 mixing, he noted there was large particles or agglomerates,  
23 indicating that here caking is occurring, agglomeration is  
24 occurring, changes in particle size is occurring, which  
25 would be pharmaceutically unacceptable due to poor dose

1 uniformity.

2 Q. And you mentioned on the slide before the osmolality  
3 number 529?

4 A. Yes.

5 Q. What is the significance of that?

6 A. It's hypertonic.

7 Q. Is this acceptable?

8 A. In my opinion, not for a formulation that is going to  
9 be used chronically for an allergic rhinitis.

10 Q. Why would it be unacceptable for a formulation that  
11 is going to be used chronically for allergic rhinitis?

12 A. You want your formulation to be -- if you are going  
13 to be using this everyday, you want your patients to be  
14 compliant, use it, accept it, not have irritation. You  
15 want your osmolality to be much closer to isotonicity.

16 Q. So in the art, it would have been known how to adjust  
17 any of these parameters, is that right; pH, osmolality?

18 A. That's right. Individually, pH was known how to be  
19 adjusted. Osmolality, that you can add isotonicization agents.

20 Q. And why isn't it routine optimization to just adjust  
21 pH, osmolality, and come up with a formulation?

22 A. So like I said before, you know, this diagram kind  
23 of is trying to exemplify how the different parts of a  
24 formulation are interrelated and you can't just alter them  
25 in isolation and expect success.



Smyth - direct

1           What this shows is that Cramer Example III was  
2 very, very far from being a pharmaceutically acceptable  
3 formulation. It really only achieved spray quality. It  
4 didn't achieve anything else.

5       Q.       Now, assuming a formulator POSA could have made  
6 Cramer Example III operable. Would they have been able to  
7 use that and then had a reasonable expectation of success of  
8 making an azelastine fluticasone combination nasal spray?

9       A.       So Cramer III was an example that includes  
10 triamcinolone acetonide and azelastine.

11      Q.       Just so we're clear. So the active ingredient, the  
12 steroid active ingredient in this Cramer Example III is  
13 different than the active ingredient in the patents in suit?

14      A.       That is right. So a formulator knows that they  
15 design around that active ingredient. You can't just switch  
16 out an active ingredient and expect it to work like the  
17 other one does.

18           MS. EVERETT: Now, Your Honor, I think yesterday  
19 I mentioned that there is just some confidential documents  
20 regarding Meda and plaintiff Cipla's formulations. We can  
21 probably get through these. We just won't publish the  
22 slides, we'll just do them from paper.

23           THE COURT: That's fine. I have your copy of  
24 slides. I'll look at my own copy.

25           Is there any objection to proceeding that way?

Smyth - direct

1 MR. LOMBARDI: No, Your Honor.

2 THE COURT: Fine. Thank you.

3 BY MS. EVERETT:

4 Q. So, Dr. Smyth, you have looked at the Dymista,  
5 Duonase, and Indian imitator products; is that correct?

6 A. Yes.

7 Q. And you have analyzed their compositions?

8 A. Yes.

9 Q. And come to some conclusions?

10 A. Yes.

11 Q. Looking at slide PDX-4.36.

12 A. Yes, I'm there.

13 Q. Is it your opinion that Dymista and Duonase are  
14 embodiments of the patents in suit?

15 A. Yes.

16 Q. And for Dymista and Duonase, you set forth your  
17 opinion on PDX-4.36?

18 A. Yes.

19 Q. And to arrive at your conclusions, you relied on  
20 PTX-0138, PTX-0135, PTX-0153, PTX-0141, PTX-0145 and  
21 PTX-0154?

22 A. Yes.

23 MS. EVERETT: And that was it.

24 And we can come back up.

25 BY MS. EVERETT:

Smyth - direct

1 Q. And you have also analyzed what we call the Indian  
2 imitator products?

3 A. Yes.

4 Q. And those opinions are set forth on PDX-4.37?

5 A. Yes.

6 Q. In your view, are these products embodiments of the  
7 patent in suit?

8 A. Yes.

9 Q. How did you arrive at that information?

10 A. Using information on the labels of those products  
11 as well as the testing done by a laboratory on their  
12 compositions.

13 Q. And the exhibits that you are relying on are  
14 PTX-0129, and DTX-265, or the Avomeen testing?

15 A. Yes.

16 Q. It's just listed as DTX-265?

17 A. Yes.

18 Q. And then you are relying on the label information at  
19 PTX-0026?

20 A. Yes.

21 Q. Now I'd like to turn to the Hettche reference. And  
22 if you need to, go to your binder, tab 24.

23 Were you in the courtroom when Dr. Donovan  
24 testified that the Hettche patent covers the combination  
25 product covers any product of fluticasone and azelastine?

Smyth - direct

1 A. Yes.

2 Q. Do you agree with that opinion?

3 A. No.

4 Q. Why not?

5 A. Well, if you look at the Hettche patent --

6 MR. LOMBARDI: Your Honor.

7 THE COURT: Yes.

8 MR. LOMBARDI: May I object, Your Honor?

9 I believe this is outside the scope. If counsel  
10 can point to where it is in the expert report, then I'll  
11 withdraw it, but I believe it's outside.

12 MS. EVERETT: Sure. Dr. Smyth, if we can go to  
13 the reply report, paragraph starting at paragraph 42.

14 THE COURT: Is the reply report in the binder  
15 that you passed up earlier?

16 MS. EVERETT: Yes, it's in the back in the far  
17 left.

18 MR. LOMBARDI: Your Honor, based on what I see  
19 so far, I will withdraw the objection.

20 THE COURT: Okay.

21 MR. LOMBARDI: If continues to be an objection  
22 ...

23 THE COURT: Then you will object again. Okay.  
24 You may proceed.

25 BY MS. EVERETT:

Smyth - direct

1 Q. I'll just ask the question again. In your opinion,  
2 the Hettche reference, does that cover a combination  
3 fluticasone and azelastine combination nasal spray?

4 A. No. So the Hettche patent only describes -- the  
5 only active ingredient that is described in there is  
6 azelastine and its I think pharmaceutically acceptable salt.  
7 It doesn't describe any other active ingredient. It's not  
8 really contemplated by this patent. A POSA reading this  
9 patent would know that it doesn't cover a combination like  
10 fluticasone and azelastine.

11 Q. Do you know of anyone who has been prevented or  
12 blocked from developing or marketing a combination  
13 azelastine/fluticasone product because of this patent?

14 A. No.

15 MS. EVERETT: No further questions.

16 THE COURT: All right.

17 MS. EVERETT: I have exhibits, if you don't  
18 mind, to introduce or admit: PTX-0026, PTX-0129, PTX-0156,  
19 PTX-0167, PTX-0179, PTX-0189, PTX-0192, PTX-0011, PTX-0059,  
20 PTX-1663, PTX-1082, PTX-1664, PTX-0138, PTX-0135, PTX-153,  
21 PTX-0141, PTX-0145, PTX-0154.

22 Your Honor, we move to admit these exhibits.

23 MR. LOMBARDI: No objection.

24 THE COURT: Okay. Those are all admitted.

25 (Above-referenced exhibits admitted in evidence.)

Smyth - cross

1 THE COURT: Cross-examination.

2 MR. LOMBARDI: I'm not sure we're going to need  
3 the binders, but we'll bring them up.

4 THE COURT: Can't hurt to pass them up. You may  
5 approach.

6 (Documents passed forward.)

7 CROSS-EXAMINATION

8 BY MR. LOMBARDI:

9 Q. Good afternoon, Dr. Smyth.

10 A. Good afternoon.

11 Q. My name is George Lombardi. We have not met; is that  
12 right?

13 A. That's right.

14 Q. Dr. Smyth, I wanted to ask you some questions. I'm  
15 going to start with, let's start with your PDX-4.11, one of  
16 the charts you looked at. I'm going to put it on the screen  
17 for you, Doctor. That is easier.

18 You recognize this, of course.

19 A. Yes.

20 Q. And so the record is clear, this says Potential  
21 Incompatibility and Unknown Interactions. And what you did  
22 was, in generalities, you just listed all the excipients of  
23 both azelastine and Flonase; is that correct?

24 A. That is correct, yes. On the table there.

25 Q. Yes. I'm sorry. I am just referring to the table at

1 the moment. So you listed it there, and you listed it there  
2 so that you could see what all the different excipients were  
3 that were used in those two prior art compounds; is that  
4 right?

5 A. That is right.

6 Q. And that information was easily readily available to  
7 the person of ordinary skill in the art; is that right?

8 A. Sure, that information is from the FDA labels.

9 Q. Now, did you choose to list the ingredients on this  
10 slide? Is this the format you chose or did somebody else  
11 come up with that?

12 A. Actually, that was on my account.

13 Q. Because it is normally the case that persons of  
14 skill in the art, when they do this kind of list and they  
15 are considering a new formulation combination of this type,  
16 would categorize the ingredients by the type of ingredient;  
17 correct?

18 A. That is one possible way, but actually listing the  
19 ingredients in this way shows you that the compositions, you  
20 don't necessarily need to list them by function.

21 Q. Well, you know them by their function; correct?

22 A. Mostly. Excipients can have multiple functions in a  
23 formulation.

24 Q. Let me just look at DTX-202, which I think is a  
25 document you have seen before. If we can put that up on the

Smyth - cross

1 screen. It is probably in your binder, but I'm not going to  
2 get into a lot of detail. I don't think you will need your  
3 binder to see it. But this was the internal document from  
4 Meda. Do you remember that?

5 A. Yes.

6 Q. This is the feasibility plan for the combination  
7 product. Do you remember that?

8 A. Yes.

9 Q. And there was testimony about this yesterday;  
10 correct?

11 A. I think so, yes.

12 Q. This is one of the kickoff documents for the work  
13 that was being done at Meda to explore a combination of  
14 Astelin and Flonase; is that right?

15 A. I think so. Is this the one in 2006?

16 Q. Yes, that is correct.

17 A. Yes.

18 Q. Let me just show you. Let's blow up the table at the  
19 top and see if that helps you remember.

20 Do you remember this?

21 A. Yes, I think so.

22 Q. Okay. So when the folks at Meda got ready to do this  
23 formulation, what they did was they listed Flonase, and at  
24 this time, 2006, there was a newer product called Astelin  
25 improved taste. Do you see that?



Smyth - cross

1 A. Yes.

2 Q. And on the left-hand column, they listed the type of  
3 ingredient that was involved; right?

4 A. Yes.

5 Q. Okay. And then for both Flonase and Astelin, they  
6 listed what fell within those various categories; correct?

7 A. It looks like it, yes.

8 Q. And that is actually the kind of table that  
9 Dr. Donovan used in this case; is that right?

10 A. Not exactly, no.

11 Q. Well, let's put up Dr. Donovan as table. DDX-5.22,  
12 just so you can see it. 5.22, DDX. There we go.

13 Do you recognize this as one of the charts that  
14 Dr. Donovan showed?

15 A. Yes.

16 Q. And so what she has is on the left. She has got the  
17 type of ingredient, the category of ingredient; correct?

18 A. That is by function.

19 Q. Yes, by function. Fair enough.

20 A. Yes.

21 Q. And then she has Flonase and Astelin.

22 A. Yes.

23 Q. And what is in each of the formulations; is that  
24 right?

25 A. Yes.

1 Q. And then she lists them out, and you don't have any  
2 quarrel with the way she listed those ingredients. They are  
3 the accurate ingredients from the label; isn't that right?

4 A. The ingredients are -- well, there are more  
5 ingredients there than on the label, I believe, but yes.

6 Q. There is?

7 A. No, sorry. That is the other column. Sorry. I  
8 think you are right.

9 Q. All right. Thank you. And so this would be a  
10 reasonable way for a person of skill in the art to consider  
11 a combination product, wouldn't it?

12 A. If the combination product was -- you know, if you  
13 were looking at two solutions, for example, you do that. If  
14 you were looking at two suspensions, you could do that.

15 But here what you are looking at is a suspension  
16 and a solution. So you can't actually fit them into these  
17 functional categories because, for example, the function of,  
18 you can see the thickening agents, those are very different  
19 in a solution system to that what is going on in a  
20 suspension system.

21 Q. And I'm going to -- I'm sorry. Did you finish your  
22 answer?

23 A. Well, you can continue.

24 Q. I'm going to ask you about solutions and suspensions.  
25 I promise you we'll have a chance to talk about that. But

Smyth - cross

1 let's talk about the excipients.

2 This is the way Dr. Donovan set it up; right?

3 A. Yes.

4 Q. And what you can tell is, for instance, and you  
5 pointed this out, the vehicles are the same here; correct?

6 A. That's right. It's water.

7 Q. And there is preservatives used in both; is that  
8 right?

9 A. There are preservatives in both, yes.

10 Q. There is thickening agents in both?

11 A. Well, there is a suspending agent in one and there is  
12 a thickening agent in another.

13 Q. And sometimes those terms are used interchangeably,  
14 aren't they?

15 A. Somewhat, but MCC and CMC is really more  
16 appropriately labeled as a suspending agent.

17 Q. And a tonicity adjuster is used in both; isn't that  
18 right?

19 A. That is right.

20 Q. And pH, of course, is measured in both; is that  
21 right?

22 A. It's measured, and there is also, if you noticed,  
23 there is a buffer that is kind of nested into that. That  
24 should also be listed on the left-hand side, which was  
25 listed in the other table I think you showed me.

1 Q. Okay. Now, preservatives, when we get to the  
2 preservatives, each of the preservatives that are displaying  
3 in both columns are preservatives that were known in the art  
4 at the relevant time here?

5 A. That's fair.

6 Q. And they were known to function as preservatives in  
7 the prior art?

8 A. Yes.

9 Q. And each of the preservatives that are listed there,  
10 you know the Dymista product; is that right?

11 A. I do, yes.

12 Q. And which of those preservatives are used in the  
13 Dymista product?

14 A. All three of them.

15 Q. And they function as preservatives in the Dymista  
16 product?

17 A. Yes.

18 Q. They function the way the art would predict that they  
19 function; isn't that right?

20 A. They function as preservatives, yes.

21 Q. Now, the surfactants that are used, there is a  
22 surfactant listed, polysorbate 80 with Flonase. Do you  
23 see that?

24 A. I see that.

25 Q. And you understand that that is used in Dymista; is

1     that right?

2     A.     Yes.

3     Q.     And in Dymista, polysorbate 80 functions as a  
4     surfactant; isn't that right?

5     A.     In Dymista, I mean polysorbate is a surfactant so  
6     it is functioning. That property, a surfactant functions to  
7     stabilize the suspended particles.

8     Q.     It functions as a surfactant?

9     A.     I mean, yeah, it is a surfactant.

10    Q.     But I'm talking about, just so we're clear, in  
11    Dymista, it's used as a surfactant; isn't that right?

12    A.     It's used as a surfactant.

13    Q.     Thickening agents. Do you recall which is used in  
14    Dymista?

15    A.     It's the MCC/CMC.

16    Q.     And we're going to talk a little bit more about  
17    MCC/CMC, but MCC/CMC functioned as a thickening agent in the  
18    prior art Flonase compound; is that right?

19    A.     That is a suspending agent, in my opinion.

20    Q.     And functions in the same way in Dymista; isn't that  
21    right?

22    A.     No.

23    Q.     How does it function --

24    A.     I'm sorry. In Dymista?

25    Q.     In Dymista.

Smyth - cross

1 A. In Dymista. Yes, it is a suspending agent. Yes.

2 Q. Okay. Thank you. And the tonicity adjusters, you  
3 know what the tonicity adjuster was in Dymista; is that  
4 right?

5 A. Yes, I believe it's glycerin.

6 Q. And you don't dispute that glycerin was a known  
7 tonicity adjuster at the time, at 2002, the relevant time in  
8 this case?

9 A. No, I don't dispute that.

10 Q. And you don't dispute that glycerin acts as a  
11 tonicity adjuster in Dymista?

12 A. No, I don't dispute that.

13 Q. Okay. It acts consistent with the prior art?

14 A. Sure.

15 Q. Okay. Now, you know, and you have presented no  
16 evidence -- strike the question. You started work on this  
17 case in 2016, give or take?

18 A. I can't remember.

19 Q. Okay. But it's recently, within the last year; is  
20 that fair?

21 A. Probably.

22 Q. And you have looked hard at the prior art; is that  
23 right?

24 A. I have done some prior art research, yes.

25 Q. And you have looked hard to find something that says

1     that any of those preservatives -- well, let me just make it  
2     specific. You looked hard to see if you could find  
3     something that says that phenylethyl alcohol is incompatible  
4     with azelastine hydrochloride, haven't you?

5     A.     I think I looked into that.

6     Q.     And you found nothing?

7     A.     That's right.

8     Q.     You looked hard to see if there was something  
9     incompatible, if there was an incompatibility between EDTA,  
10    disodium and fluticasone. You looked for that.

11    A.     In the prior art?

12    Q.     Yes.

13    A.     There was no evidence those were compatible or  
14    incompatible.

15    Q.     Okay. You looked hard in the prior art to see if  
16    glycerin, a tonicity adjuster, was incompatible with Flonase  
17    -- excuse me -- with fluticasone?

18    A.     I looked to see if fluticasone had been used with  
19    glycerin before and I couldn't find anything.

20    Q.     Okay. And you have looked hard to see if polysorbate  
21    80 was somehow incompatible with azelastine hydrochloride?

22    A.     I looked at that particular combination. I could  
23    never find -- I'm sorry. I could not find anyone using  
24    those two combinations together before to show that there  
25    was compatibility or incompatibility.

Smyth - cross

1 Q. Okay. Let me talk to you about CMC for a minute  
2 because you did raise something specific about CMC that you  
3 found. And CMC is the thickening or suspending agent that  
4 was used with Flonase; correct? Or MCC/CMC, I should say,  
5 in combination.

6 A. Yes.

7 Q. And MCC/CMC is a combination that is frequently used  
8 together by formulators?

9 A. Yes, under the trade name of Avicel.

10 Q. Thank you. I was going to get to that. And that was  
11 true back in 2002 and before; is that right?

12 A. Yes.

13 Q. And I think you said that CMC you said created a  
14 potential incompatibility with azelastine hydrochloride; is  
15 that right?

16 A. That is right.

17 Q. And your basis for that I believe was the Lieberman  
18 reference; is that right? Or am I getting the name wrong?  
19 Let me -- I can look at my notes but you might be able to  
20 help me.

21 A. That is what was cited in my direct, yes, Lieberman.

22 Q. So that is PTX-192. And let's go I think it is 024  
23 of that. And I hope -- I didn't have a Bates on that, I  
24 don't think. There it is.

25 Do we have that right? Is that the excerpt that



1     you looked at, Doctor?

2     A.     Yes, that's it.

3     Q.     What you were pointing out is that, it starts a  
4     little bit crooked, but that is the copying process. Maybe  
5     we can make it a littler broader so it's not so disorienting.

6             That helps a little bit.

7             Carboxymethylcellulose solutions have poor  
8     tolerance for electrolytes. And the one particularly you  
9     were talking about was cationic drugs, the incompatibility  
10    mentioned in the last line; is that right?

11    A.     That's right.

12    Q.     Now, this reference, the Lieberman reference doesn't  
13    say anything specific about, excuse me, about azelastine  
14    hydrochloride; is that right?

15    A.     No, it can't list every drug that is known to be  
16    cationic.

17    Q.     And it does not list azelastine hydrochloride; is  
18    that right?

19    A.     It doesn't list it in that sentence, no.

20    Q.     But we do know that people of skill in the art at  
21    the relevant time in this case were considering using --  
22    were talking about using CMC with azelastine hydrochloride.  
23    We know that; correct?

24    A.     Sorry. Could you refresh my recollection of that?

25    Q.     Yes. The Hettche reference specifically tells people

1 of ordinary skill in the art that you can use CMC with  
2 azelastine hydrochloride; correct?

3 A. I wouldn't necessarily call it specifically. It was  
4 listed, CMC is listed in with a number of other polymers in  
5 that reference.

6 Q. Okay.

7 A. It doesn't list the actual examples of azelastine  
8 specifically with CMC.

9 Q. Well, let's look at PTX-73, which is, this is going  
10 to be the Hettche reference, Doctor.

11 A. Okay.

12 Q. And so we'll move to the inside now that you have  
13 seen the front page.

14 And let's go to column 4, please. And it's down  
15 at the bottom, line 49. That paragraph, please.

16 And you have seen this paragraph before, it  
17 sound like, Doctor; is that right? Talking about thickening  
18 agents.

19 A. I think I have looked at this before, yes.

20 Q. So to refresh your recollection, Hettche deals with  
21 azelastine hydrochloride; is that right?

22 A. Yes, azelastine hydrochloride and its  
23 pharmaceutically acceptable salts.

24 Q. Correct. Thank you. And it's talking about, at the  
25 top, to give us the topic or the paragraph, it is talking

Smyth - cross

1 about adding thickening agents to the solutions, and the  
2 solutions refers to azelastine hydrochloride or its salts  
3 solutions; is that right?

4 A. Yes.

5 Q. And it specifically calls out carboxymethylcellulose,  
6 doesn't it? At the line 59 going over to line 60; is that  
7 right?

8 A. I see it written there, yes.

9 Q. So we at least know that at this point in time, the  
10 people who got a patent on azelastine hydrochloride were  
11 telling persons of skill in the art that you can use CMC  
12 with azelastine hydrochloride, don't we, Doctor?

13 A. I wouldn't go to that extent. I think what that  
14 tells a POSA was there was a long list of polymers here  
15 that listed in a patent that doesn't contain any examples  
16 of CMC with azelastine together, and then there is a later  
17 reference saying that CMC shouldn't be used with cationic  
18 drugs.

19 Q. And that is Lieberman?

20 A. That is right.

21 Q. So we have the timing, but I'm going to talk about  
22 the timing in just one second. But just so we're clear, at  
23 least to the people who wrote this patent, and the people  
24 who read this patent, it's not saying do not use  
25 carboxymethylcellulose with azelastine hydrochloride, is it?

1 A. It's not saying that.

2 Q. In fact, it is suggesting using it?

3 A. That is what it says.

4 Q. And then you have Lieberman which you say comes after  
5 this reference; right?

6 A. '96, I think.

7 Q. So I think your implication is that if POSA knew  
8 about Lieberman, at some point after Lieberman they wouldn't  
9 be saying use carboxymethylcellulose; right?

10 A. Well, a POSA would understand that an anionic polymer  
11 and carboxymethylcellulose in solution is going to be  
12 incompatible with cationic drugs.

13 Q. And were you here in court yesterday when Dr. D'Addio  
14 testified?

15 A. Yes.

16 Q. And did you hear him testify that up until 2006, they  
17 had no knowledge of the Cipla patent applications that  
18 turned into the patents in suit?

19 A. Yes.

20 Q. And did you hear him testify about a 2005 patent  
21 application that he, among others, had filed?

22 A. Yes.

23 Q. And did you look to see? Did you understand that  
24 patent application covered azelastine and fluticasone?

25 A. I have not looked at that patent application.

Smyth - cross

1 Q. Did you hear that in court, at least?

2 A. I --

3 MS. EVERETT: Objection.

4 THE COURT: Hold on. The objection?

5 MS. EVERETT: That is a legal conclusion on what  
6 the patent may or may not cover.

7 THE COURT: Well, it's just whether he heard it  
8 in court is the question; right?

9 MR. LOMBARDI: That's the question.

10 THE COURT: At the moment. So that objection is  
11 overruled.

12 BY THE WITNESS:

13 A. I heard there was a patent mentioned.

14 Q. And the question is did you hear it mentioned that  
15 azelastine fluticasone solutions were mentioned in the  
16 patent?

17 A. I think, yes, azelastine and steroids maybe. I'm not  
18 sure if fluticasone was called out.

19 Q. I was hoping I could shortcut, but I will show you  
20 something to make sure you are okay. Let's go to DTX-313.

21 2005 is the date you see here. That is  
22 post-Lieberman; is that right?

23 A. Yes.

24 Q. Okay. Let's go just very quickly, Doctor, to  
25 DTX-313.196, claim 101. This is an example here.

Smyth - cross

1                   This is just to show you, it says: Azelastine  
2 hydrochloride -- "pharmaceutical composition comprising  
3 azelastine hydrochloride and a steroid selected from the  
4 group consisting of ..." And you see fluticasone; correct?

5       A.       Yes.

6       Q.       All right. Now let's go to page DTX-313.0041. And  
7 actually, I'm sorry. It's the paragraph above. Thank you.

8                   And this is talking about liquid dosage forms  
9 that provide the active ingredient in suspension may  
10 comprise, in addition to the active azelastine compound,  
11 one or more of one or more suspending agents such is as  
12 microcrystalline cellulose. And if you skip over a little  
13 bit and down, it's sodium carboxymethylcellulose. Do you  
14 see that?

15      A.       Yes.

16      Q.       So post-Lieberman, the Meda folks were talking about  
17 using CMC with azelastine hydrochloride; is that correct?

18      A.       You know, I haven't looked at the patent, but it  
19 looks like that is what they were saying there.

20      Q.       More than that, they were talking about using sodium  
21 CMC with azelastine compound and fluticasone; isn't that  
22 correct?

23      A.       I don't know.

24      Q.       In this --

25      A.       I think that paragraph only relates to, in addition

1 to the active azelastine compound.

2 Q. I will let the -- we will leave the record where it  
3 is. We don't have to go further with that question. I will  
4 move on to another topic right now, Doctor. Thank you for  
5 your answers on that.

6 Now, Doctor, you said, I think one of the other  
7 things you said when you were talking about potential  
8 incompatibilities was, you said that azelastine and  
9 fluticasone was an unknown interaction, I think is your  
10 terminology. Is that right?

11 A. Yes, that's correct.

12 Q. I think you pointed to some articles, or I guess one  
13 article concerning the combination of, was it Salmeterol, if  
14 I am pronouncing that right?

15 A. Right.

16 Q. And Salmeterol, and was it azelastine or fluticasone?

17 A. It was fluticasone.

18 Q. Salmeterol and fluticasone. And you said that that  
19 supported your opinion not that there was necessarily an  
20 interaction but potentially there could have been an  
21 interaction?

22 A. Sure.

23 Q. There was a little bit more to the Salmeterol story  
24 than you had time to tell on direct. Is that right?

25 A. There was a very long story at Glaxo, it took years

1 and years to develop that.

2 Q. Let's look at PTX-179, which I think is the document  
3 that you looked at. This is the article. Do I have it  
4 right?

5 A. Yes, I think so.

6 Q. Let's go to the second page, the first column.

7 I think right up there at the top is where you  
8 were reading, I think where you said Combined drug  
9 formulations are less well understood. That's the point  
10 where you were reading. Is that right?

11 A. Yes.

12 Q. And then, if you go down, it talks about more with  
13 this combination. So if you could go down to where it  
14 begins "This phenomenon" in the same paragraph. Right there  
15 in the middle, "This phenomenon could be an advantage from a  
16 pharmaceutical point of view, i.e., the combination  
17 formulation shows a decrease in the total loss of the drugs  
18 due to deposition onto the internal surfaces of the MDI."

19 Do you see that?

20 A. Yes.

21 Q. So that's a positive associated with this combination  
22 of fluticasone and Salmeterol. Is that right?

23 A. That's the way that Glaxo was trying to paint the  
24 picture, yes.

25 Q. Well that's what they said in the art?



1 A. Yes.

2 Q. And this is the article you cited?

3 A. Sure.

4 Q. And this is just a couple lines down from the part  
5 you cited?

6 A. Yes.

7 Q. Okay. Let's go to DTX-180 -- PTX -- I apologize.  
8 This is another article on Salmeterol. I will let you look  
9 at the title. I think it was in your materials, Doctor, but  
10 I will give you a chance to look at that?

11 A. We looked at this one before.

12 Q. This is another one on Salmeterol. Is that right?

13 A. This is Salmeterol and fluticasone.

14 Q. Let's go to Page 2 of the article, and the upper  
15 right-hand paragraph, the carryover paragraph, this provides  
16 a little more of the information, right in the middle it  
17 says "A combination," do you see where I am starting?

18 A. Yes.

19 Q. "A combination inhaler of Salmeterol xinafoate and  
20 fluticasone propionate in a single MDI device has been used  
21 recently to improve the control treatment of asthma."

22 Do you see that?

23 A. Yes, actually, they are talking about the Diskus  
24 device. That is the dry powder inhaler that Dr. Schleimer  
25 was talking about.

Smyth - cross

1 Q. Again, you raised Salmeterol in your testimony?

2 A. Yes.

3 Q. And then it says, "The addition of Salmeterol to the  
4 regimen is more effective than doubling the steroid dose."

5 Do you see that?

6 A. I see that, yes.

7 Q. The suggestion here is that the activity between  
8 Salmeterol and fluticasone is positive, isn't that correct?

9 A. In this particular case, it's saying that there is an  
10 interaction that is a positive interaction. But it would  
11 not necessary lead a POSA to believe that formulating is  
12 simple and that you don't have interactions.

13 Q. But this example of fluticasone and Salmeterol is the  
14 only example you brought to court with you about potential  
15 interactions between fluticasone and azelastine?

16 A. That's right, yes.

17 Q. By the way, one thing about azelastine and  
18 fluticasone that we do know and a POSA knew in 2002 is those  
19 drugs could both be put into the human body and there was no  
20 negative interaction?

21 A. I didn't opine on that.

22 Q. You were aware that fluticasone, that Flonase,  
23 Flonase and Astelin were given conjunctively to patients.  
24 Right?

25 MS. EVERETT: Objection. This is outside the

Smyth - cross

1 scope of direct. The witness is a formulator. He is not  
2 here to talk about clinical issues.

3 MR. LOMBARDI: I can move on.

4 THE COURT: Okay. Move on.

5 BY MR. LOMBARDI:

6 Q. You also talked about suspensions and solutions.

7 Correct?

8 A. Yes.

9 Q. And you put up Slide PDX-4.09. I will put that up  
10 now again. Do you remember this one?

11 A. Yes.

12 Q. You went on to another slide, which showed further  
13 information. But are you okay if we just use this one as  
14 kind of our reference point?

15 A. Okay.

16 Q. If you need to look at the other one just, tell me.

17 You were describing here the differences between  
18 an azelastine solution system and a fluticasone suspension  
19 system. Do you remember that?

20 A. In general terms, yes.

21 Q. Now, what is important, it's very important here what  
22 the vehicle is. Correct?

23 A. Vehicles are very important.

24 Q. In this example, the vehicle is very important?

25 A. It could be. In this example, the vehicle is

1 important, yes.

2 Q. Because, for instance, I assume this is true, that  
3 there are some vehicles that you could put azelastine in and  
4 it wouldn't be soluble?

5 A. Sure, solubility is a relative term, depending on the  
6 solvent that you are talking about.

7 Q. And there is some vehicles you could put fluticasone  
8 in and it wouldn't end up to be a suspension?

9 A. That's correct.

10 Q. And so, what we know here, what persons of skill in  
11 the art knew in 2002 about azelastine and fluticasone was  
12 that they shared a vehicle in common. Is that right?

13 A. That's correct.

14 Q. It was known in 2002 that when you put azelastine in  
15 water, it was soluble. Correct?

16 A. In certain circumstances. It depended upon the pH  
17 and other ingredients that would have been in that aqueous  
18 environment.

19 Q. It was known in 2002 that azelastine dissolved to  
20 some extent in water. Isn't that true?

21 A. Yes.

22 Q. It was known in 2002 that fluticasone did not  
23 dissolve in water?

24 A. Sure. It's practically insoluble in water.

25 Q. It was reasonable to believe in 2002 that if a person

1 of skill in the art put both azelastine and fluticasone into  
2 a water vehicle, you would anticipate that azelastine would  
3 dissolve and fluticasone would not dissolve?

4 A. So to be clear, if you are just putting them in  
5 water, you would not anticipate fluticasone dissolving. It  
6 would stay insoluble. But azelastine would have some  
7 appreciable solubility in water, yes.

8 Q. So is the answer to my question that one of skill in  
9 the art in 2002 who puts azelastine and fluticasone in  
10 water, that is my question, the azelastine would dissolve,  
11 and the fluticasone would not?

12 A. In pure water. Not a formulation, yes.

13 Q. Actually, in Dymista, water is the vehicle. Is that  
14 right?

15 A. That's correct.

16 Q. And the azelastine in Dymista dissolves. Isn't that  
17 right?

18 A. To my knowledge, yes.

19 Q. And the fluticasone in that Dymista is insoluble?

20 A. Yes.

21 Q. They act the way they did in the prior art. Isn't  
22 that right?

23 A. Well, I think there is other examples of showing  
24 where azelastine does not dissolve in an aqueous environment  
25 where fluticasone is insoluble.

Smyth - cross

1 Q. Well, let me just ask you, it's consistent with the  
2 prior art that said that azelastine in water is soluble and  
3 fluticasone in water is insoluble. Isn't that correct?

4 A. Yes, but, you know, azelastine in water and  
5 fluticasone in water is not a pharmaceutical composition.  
6 But I think what you are saying is consistent.

7 Q. Okay. Let me change to another topic here, Doctor.

8 Let's go to your Slide PDX-4.21, please. You  
9 remember this one?

10 A. Yes.

11 Q. And this is the slide where you are talking about all  
12 the requirements for a formulation. Correct?

13 A. Yes, for a pharmaceutical composition, yes.

14 Q. Doctor, just one second. I am making sure I can find  
15 everything here.

16 And there were a lot of requirements that you  
17 talked about. Is that right?

18 A. Yes, they are listed here.

19 Q. And you have also reviewed the patents in this case,  
20 is that right?

21 A. Yes.

22 Q. And that's what I was looking for, Doctor. Believe  
23 it or not, I misplaced my copy of my patent. But I am sure  
24 they can pull up one of the patents in suit. One of the two  
25 patents, please.

Smyth - cross

1           You have looked at the patents, the two patents  
2           that are the subject of this lawsuit. Is that right?

3           A.       I have, yes.

4           Q.       Let's go back to your chart for a moment. We are  
5           going to toggle back and forth.

6           A lot of what you have put on this chart is not  
7           the subject of the patents. Is that right?

8           A.       No. I think the subject of the patents is a  
9           pharmaceutical nasal spray formulation which would be  
10          reflected in these requirement here.

11          Q.       Well, here, I will be more specific, chemical  
12          stability is not something that's discussed in the patents?

13          A.       A pharmaceutical formulation would require chemical  
14          stability.

15          Q.       Sir, are the words "chemical stability," is that  
16          phrase ever used in the patents?

17          A.       I didn't search for that word. But a POSA would  
18          know, looking at the patents, that chemical stability is a  
19          requirement of a pharmaceutical.

20          Q.       Does the patent provide any instruction to the person  
21          of skill in the art how to achieve chemical stability with  
22          this formulation?

23          A.       It does, through the composition that's disclosed.

24          Q.       Okay. The ingredients, the actual ingredients?

25          A.       That would be the, the POSA would look at the

1 ingredients and know that, the way that that is formulated,  
2 and it's a marketed product that provides the chemical  
3 stability for that active ingredient.

4 Q. We can go back to what the patent shows.

5 There is no claim here for a particular level of  
6 chemical stability, is there?

7 A. It would be known by a person of ordinary skill that  
8 chemical stability is a basic requirement of any dosage  
9 form.

10 Q. Is there a claim that sets forth a level of chemical  
11 stability, for instance, that is required here, sir?

12 A. Not apart from the limitation of pharmaceutical  
13 acceptability.

14 Q. Dose uniformity, is there anything in the claims that  
15 requires dose uniformity in this formulation?

16 A. That would be the same answer.

17 Q. Is there anything in this formulation that requires  
18 spray quality, a level of spray quality?

19 A. It says it should be a nasal spray and a person of  
20 ordinary skill would know what a spray looks like. It's not  
21 a jet.

22 Q. Is there anything in the claims that requires a  
23 specific level of physical stability?

24 A. Yes. It describes a suspension, actually, I am not  
25 sure there is a suspension in the claims. But physical



1 stability, if it was a suspension product, would be an  
2 innate requirement for a suspension.

3 Q. But physical stability, is that where you see how  
4 long a product can, for instance, stay on the shelf before  
5 it degrades? Or is that chemical stability?

6 A. It's a collection of all three of those, physical,  
7 chemical, and microbiological.

8 Q. So is there any requirement in the patent claims  
9 about how long, under either physical stability or chemical  
10 stability, these compounds have to stay in formulation?

11 A. Well, since --

12 Q. Is there anything in the claims?

13 A. In the claims, that talks about allergic rhinitis,  
14 there is no specific numbers, but a POSA would know that  
15 allergic rhinitis is treated for weeks.

16 Q. Doctor, you have said this is a very transitional  
17 formulation. Right?

18 A. Yes.

19 Q. The patent doesn't actually give any instruction on  
20 how to put the components together. Is that right?

21 A. I think it does give some basic level of instruction  
22 on how to mix them.

23 Q. Let's look at the patent, let's go to Column 7. We  
24 will bring that up. Doctor, at the bottom left-hand  
25 portion, let's just talk about the second paragraph there,

1 "The present invention is now illustrated by the following  
2 examples, which do not limit the scope of the invention in  
3 any way. In examples where only the ingredients of  
4 formulations according to the present invention are listed,  
5 these formulations are prepared by techniques well known in  
6 the art."

7 Do you see that?

8 A. Yes.

9 Q. So what the patent does is refer the reader to  
10 techniques that were already known in the art. Is that  
11 right?

12 A. It does, yes.

13 Q. And just so that we are clear, a lot of these  
14 examples provide nothing more than ingredients. Isn't that  
15 right?

16 A. Well, ingredients and their actual specific levels in  
17 the composition.

18 Q. Let's go to Column 8, for an example. There is one  
19 example. It just lists the ingredients. Right?

20 A. And their quantities, yes.

21 Q. And it doesn't tell you any special techniques that  
22 you have to use to make this solution suspension work.  
23 Right?

24 A. No.

25 Q. Because a person of ordinary skill in the art would

1 know how to do that. Right?

2 A. Right, and I don't think it's part of the limitations  
3 of any of the claims.

4 Q. Let's go to Example 4, just because I want to show  
5 you a little bit more of the example.

6 So this is, again, another instance where no  
7 information is provided other than the ingredients. Isn't  
8 that correct?

9 A. That's what I see on the screen, yes.

10 Q. Let me give you a little more room. I want to be  
11 fair to you. I want to make sure he can see that is the  
12 entire example that we have there. Just lower it.

13 Can you see it now?

14 A. Yes.

15 Q. We just read the part that said that if it  
16 only employs ingredients, use standard mixing  
17 techniques?

18 A. Yes.

19 Q. And so a person of skill in the art, given these  
20 ingredients at those quantities, would know exactly what to  
21 do in order to make this solution suspension. Isn't that  
22 right, Doctor?

23 A. They could try various mixing techniques before they  
24 found the one that works best.

25 Q. And they would find it, you think that's within the

1 level of skill of a person of ordinary skill in the art,  
2 don't you?

3 A. Because this disclosure describes a composition  
4 that's a working composition and there would be a finite  
5 number of ways of mixing these together.

6 Q. And there is a finite number of ways the person of  
7 skill in the art would undertake to figure out which of  
8 those ways worked and would have the level of skill to make  
9 it work, this solution suspension formulation. Isn't that  
10 right?

11 A. Yes. In the case of the Dymista patents, yes.

12 Q. Doctor, let me talk to you briefly about the Cramer  
13 testing that you talked about earlier. You obviously recall  
14 that. You know that Cramer is a patent application?

15 A. Yes.

16 Q. And you were working with Cramer exhibit -- excuse  
17 me, an example from Cramer. Example 3. Correct?

18 A. That's right.

19 Q. Can we pull that up, please, so that we have a  
20 reference point here. That is Example 3. Is that right?

21 A. Yes.

22 Q. And first of all, just so that we have a reference  
23 point here, Doctor, the testing that you -- is it fair to  
24 say you supervise testing or --

25 A. I wrote the protocols. I didn't have anything else

1 to do with it after that.

2 Q. You wrote the protocols, it was based on this  
3 example?

4 A. Yes.

5 Q. To the extent you could, because there are elements  
6 that were left out, so then you had to come up with what you  
7 thought somebody in 2002 would have done. Right?

8 A. Right. Like Dr. Govindarajan on your side did as  
9 well.

10 Q. We have a list of the components right there in the  
11 middle. Correct?

12 A. Yes.

13 Q. And so the compound, or the formulas that you did all  
14 the testing on in this case, involved two active  
15 ingredients. Is that right?

16 A. Yes.

17 Q. Azelastine hydrochloride was one of them?

18 A. Yes.

19 Q. And the other was something called triamcinolone  
20 acetone. Is that how you say that?

21 A. Exactly.

22 Q. And then it has various components. Right?

23 A. Yes.

24 Q. But that is what you were testing. Correct?

25 A. That's what was tested, yes.

Smyth - cross

1 Q. And it was not a composition that included  
2 fluticasone. Is that right?

3 A. That's correct.

4 Q. And just quickly, Doctor, if I could go to the Elmo  
5 quickly.

6 We will just move on, Judge.

7 BY MR. LOMBARDI:

8 Q. Doctor, the testing that you did -- first off, there  
9 was other testing by people associated with Cipla or Meda  
10 that was done. Is that right?

11 A. Yes, I think the inventor, Ms. Malhotra did some  
12 testing, yes.

13 Q. She was from Cipla. Is that right?

14 A. That is my belief, yes.

15 Q. Do you know what year it was that she did her  
16 testing?

17 A. I do not. I can't remember that.

18 Q. Does about 2011 sound about correct?

19 A. I actually can't remember.

20 Q. You know it was after 2002? Is that right?

21 A. Yes.

22 Q. Then the testing that you did, you wrote, I say you  
23 -- I am using you and Dr. Herpin together, I think the  
24 record is clear as to what your role was. The testing that  
25 you and Dr. Herpin did occurred after you had already filed

1 an initial report in this case. Is that right?

2 A. Yes, I think so.

3 Q. Sometime in 2016 -- 2015, sometime in that time  
4 frame?

5 A. For sure.

6 Q. And that testing was not done in 2002. Is that  
7 right?

8 A. That's right.

9 Q. And no testing in the prior art was done with respect  
10 to Example 3 in 2002 that you are aware of. Is that right?

11 A. That's right.

12 Q. There was a third person involved in the testing, and  
13 that was Dr. Govindarajan. Is that right?

14 A. Yes.

15 Q. If I am saying that correctly.

16 And he was retained by Apotex in this matter.  
17 Is that right?

18 A. That's right.

19 Q. And you saw his report and you actually commented on  
20 his testing techniques in your slides. Is that right?

21 A. Yes.

22 Q. And Dr. Govindarajan, you know, was not in this case  
23 to express an opinion on obviousness; is that right?

24 A. I presume so.

25 Q. He said in his report, he said he had no idea what

1 this case was about. Right?

2 A. I seem to remember something like that, yes.

3 Q. He was just called in and asked to do the tests. Is  
4 that right?

5 A. Yes.

6 Q. And to come to conclusions about the test, but he was  
7 never shown the patents that were in suit. That was your  
8 understanding. Right?

9 A. That's correct, yes.

10 Q. And you had seen the patents in suit?

11 A. Yes.

12 Q. And you knew what position you were taking in the  
13 case at the time the testing occurred. Is that right?

14 A. That's fair to say, yes.

15 Q. All right. So I just want to show for the record,  
16 since you characterized Dr. Govindarajan's testing, what he  
17 actually said about it. Let's go to PTX-1664. Here is his  
18 expert report.

19 Let's go to Paragraph 7, summary of work, on the  
20 second page in, just to take a look at what he was doing.  
21 It says "Apotex retained me to formulate the composition in  
22 Example III," and those numbers relate to the Cramer patent  
23 application. Is that right, Doctor?

24 A. Yes, I guess so.

25 Q. And to make the formulation, "I was directed to



Smyth - cross

1 follow any instructions or guidance included in that  
2 document. To the extent the Cramer reference did not  
3 expressly provide information I needed to formulate, I was  
4 directed to proceed as an ordinarily skilled pharmaceutical  
5 formulator would have proceeded in June 2002 after reading  
6 Cramer. Do you see that?

7 A. Yes.

8 Q. "I was directed not to take any steps or use any  
9 equipment that was not known and readily available to an  
10 ordinarily skilled pharmaceutical formulator in 2002."

11 Do you see that?

12 A. Yes.

13 Q. That is consistent with the way you tried to do the  
14 testing, as of 2002?

15 A. That's correct.

16 Q. Or the way you set up the protocol. Is that right?

17 A. Yes.

18 Q. And then it says, Cramer was the only document given  
19 to me by Apotex's counsel. Do you see that?

20 A. Yes.

21 Q. And then the next paragraph says, "I was not told  
22 what outcomes to try to obtain, or what outcome would be  
23 helpful to Apotex or their opponent in this litigation. I  
24 have not reviewed any patent asserted in this litigation."

25 Do you see that?

1 A. Yes.

2 Q. Let's go to Paragraph 13, where he starts to talk  
3 about his results. Just so it is clear, one of the things  
4 you directed Dr. Herpin to do was to perform Dr.  
5 Govindarajan's protocol, essentially. Is that right?

6 A. That's right.

7 Q. And that was what you were talking what you were  
8 talking about when you put some slides up about Dr.  
9 Govindarajan's testing today.

10 A. Yes, Dr. Govindarajan didn't provide any photographs  
11 or images or anything of the formulations or any additional  
12 testing that I could rely on. So Dr. Herpin recreated that  
13 according Dr. Govindarajan's notes disclosed in his notebook  
14 and did those additional tests.

15 Q. Here is what Dr. Govindarajan concluded,  
16 "I conclude"-- first of all, there were lab notebooks that  
17 were attached. You saw Dr. Govindarajan's lab notebooks.  
18 Right?

19 A. I did, yes.

20 Q. And he had observations in those notebooks?

21 A. He had written a few observations down.

22 Q. And his protocols?

23 A. Yes.

24 Q. "I concluded that Cramer Example III is a suspension  
25 that would be acceptable as a pharmaceutical product."

Smyth - cross

1 Do you see that?

2 A. Yes.

3 Q. "There was some settling, but no settling or  
4 sedimentation in the product that would make it  
5 pharmaceutically unacceptable."

6 That's what he wrote. Is that right?

7 A. That's what he wrote, but I disagree with that, yes.

8 Q. I understand. He was there. Is that right?

9 A. Yes.

10 Q. Paragraph 14, "I further concluded that the product  
11 could be delivered as a fine spray using a nasal spray  
12 pump."

13 Do you see that?

14 A. Yes.

15 Q. You saw the video he references in that paragraph?

16 A. Yes.

17 Q. Then he took osmolality measurements. Do you  
18 remember that?

19 A. Yes, I showed those on my slides.

20 Q. That was the report, we can look at the next page, to  
21 close it out, that is the report he submitted together with  
22 his lab notebook pages. Is that right?

23 A. Yes.

24 THE COURT: At the end of that report, I think  
25 it's a good point to stop. We will take a lunch break. We

Smyth - cross

1 will try to get started around 2:15 or thereabouts, and we  
2 will be in recess.

3 (Luncheon recess taken.)

4 THE COURT: You can have a seat, except for Mr.  
5 Lombardi.

6 MR. LOMBARDI: Your Honor, I have no further  
7 questions and just a couple of exhibits that haven't  
8 previously been discussed. PTX-1664, PTX-179, and PTX-180.

9 THE COURT: Any objection?

10 MS. EVERETT: No objection.

11 THE COURT: Those are admitted. And we will  
12 have redirect.

13 (Above-referenced exhibits received in evidence.)

14 REDIRECT EXAMINATION

15 BY MS. EVERETT:

16 Q. Doctor, I will have you turn back to where we left  
17 off, the expert report of Dr. Govindarajan, PTX-1664.

18 A. All right.

19 Q. Do you recall Mr. Lombardi was asking some questions  
20 about Dr. Govindarajan's report and pointing you to his  
21 conclusions? I would like to point you to some of the  
22 paragraphs before his conclusions, if we could go to  
23 Paragraph 9 which is on PTX-1664-00003.

24 Have you seen this part of Dr. Govindarajan's  
25 report before?

1 A. Yes, I think so.

2 Q. And can you describe what he has set forth here?

3 A. Sure. He says, if I were -- "If I were able to make  
4 a pharmaceutical formulation as described in Example 3 in  
5 Cramer, I was asked to make the following observations.

6 "Observe whether Example 3 forms a suspension,  
7 solution, or something else.

8 "If Example 3 does form a suspension, observe  
9 whether that suspension settles.

10 "If it settles, observe whether it is difficult  
11 to re-suspend.

12 "If it settles, opine on whether the settling is  
13 unacceptable for a pharmaceutical product.

14 "And B. Measure the osmolality per kilogram.

15 "C. Put the resulting composition in a nasal  
16 pump with a suitable actuator. Observe if faulty  
17 composition comes out as a spray, a jet, or something else."

18 Q. Are these tests set forth in Paragraph 9 sufficient  
19 to determine whether a composition or method of treatment is  
20 pharmaceutically acceptable?

21 A. Not alone, no.

22 MS. EVERETT: No further questions.

23 THE COURT: Thank you. You may step down.

24 Thank you very much.

25 (Witness excused.)

1 MS. EVERETT: Your Honor, we are working out  
2 some deposition designations with Apotex. You have just  
3 heard some testimony about the report of Ramprakash  
4 Govindarajan, he submitted an expert report in the  
5 litigation, and he was deposed. We are working together to  
6 isolate his deposition designations, we hope to play that  
7 later this afternoon.

8 THE COURT: Okay.

9 MS. EVERETT: In the interim, we will move to  
10 our next witness.

11 THE COURT: Mr. Lombardi.

12 MR. LOMBARDI: That is totally fine.

13 THE COURT: That is fine. If you could come --  
14 I don't know if the documents are there still there,  
15 retrieve those and call the next witness.

16 MS. EVERETT: Plaintiffs' next witness is John  
17 Jarosz.

18 But before that, my colleague, Rami Bardenstein.

19 MR. BARDENSTEIN: One quick matter. At the end  
20 of Dr. Carr's direct testimony, I forgot to ask that his  
21 demonstrative be submitted, in aid to the Court, consistent  
22 with all the other demonstratives.

23 THE COURT: That will be done. Thank you. No  
24 objection. Right? Okay. Thank you.

25 MR. LaROCK: I call John Jarosz to the stand.

Jarosz - direct

1                   ... JOHN JAROSZ, having been duly sworn as a  
2 witness, was examined and testified as follows ...

3                   THE COURT: Good afternoon, Mr. Jarosz.

4                   THE WITNESS: Good afternoon.

5                   DIRECT EXAMINATION

6 BY MR. LaROCK:

7 Q.           Please state your name for the record?

8 A.           John C. Jarosz.

9 Q.           The plaintiffs retained you as an expert in this  
10 case?

11 A.          Yes.

12 Q.          Have you prepared some demonstratives to assist you  
13 in your testimony?

14 A.          I have.

15 Q.          Did you bring your CV with you today?

16 A.          Yes.

17 Q.          I put up PDX5.00. Is that a summary of your CV?

18 A.          Yes, I have in this demonstrative summarized some of  
19 the things that are reflected in my CV. And I have shown  
20 those things that are probably of some significance in the  
21 matter today. If we can go back to that.

22               You will see, I have an undergraduate and  
23 graduate training degree in law and economics. Though I  
24 have a law degree, I have not practiced in 31 years. I am  
25 on inactive status. I have been a practicing economist for

Jarosz - direct

1 the past 31 years.

2 I actively participate in a number of  
3 professional associations that are reflected there on the  
4 screen. The one that I have been most active in of late is  
5 the Sedona Conference, which is a group of judges and  
6 academics and lawyers and economists who think about ways to  
7 improve the law, to move the law forward and adjust in a  
8 reasonable way.

9 The area that I have been most active with is  
10 any potential improvements in intellectual property law.

11 As a regular matter, I research and write and  
12 publish articles, sometimes in professional journals,  
13 sometimes in practitioner journals. You will see some of  
14 the titles there, one of the areas that I have been  
15 researching and publishing on of late is commercial success,  
16 which is relevant to my testimony here today.

17 I fairly regularly give speeches and  
18 presentations as well as teach classes. Among other places,  
19 I have taught at the Georgetown Law School, the George  
20 Washington Law School, and the Columbia Business School.

21 Finally, until fairly recently, I was the editor  
22 of a treatise on licensing with a particular focus on  
23 intellectual property licensing.

24 Q. And the court reporter has asked me to identify  
25 myself. Adam LaRock for plaintiffs.



Jarosz - direct

1 THE COURT: Thank you.

2 BY MR. LaROCK:

3 Q. So at the bottom it says PTX-1118; is that right?

4 A. That is a copy of my CV.

5 MR. LaROCK: Your Honor, we offer John Jarosz as  
6 an expert in the area of intellectual property protection.

7 THE COURT: He is so recognized.

8 BY MR. LaROCK:

9 Q. What have you been asked to opine on in this case?

10 A. I was asked to comment on the commercial success  
11 issues. Specifically, I was asked whether the patents in  
12 suit have been determined to be a commercial recess.

13 Q. Have you heard the testimony of Drs. Kaliner and Smyth?

14 A. I did.

15 Q. And that was an embodiment of whether Dymista was  
16 regarded as a patent in suit. Right?

17 A. Yes, the testimony was directed to the subject of  
18 whether Dymista was embodied in the patents in suit and I  
19 determined that it is.

20 Q. How did you determine that the patents were a  
21 commercial success?

22 A. I understood a two-part analysis. First, I sought to  
23 determine whether the product that embodies the patents,  
24 that is Dymista, has been a success in the marketplace.  
25 Then secondly, I sought to determine whether that success is

Jarosz - direct

1 due in part to the patented inventions, in other words, I  
2 did a causal nexus analysis in the second step.

3 Q. In determining whether the patents in suit were a  
4 commercial success, what information did you consider?

5 A. I considered quite a bit of information from both the  
6 discovery process and information I was able to obtain from  
7 the public domain. With regard to the marketplace success,  
8 I also looked at prescriptions and revenues and profits. I  
9 obtained that information from a third-party data source and  
10 from Meda and Cipla internal records.

11 With regard to the causal nexus analysis, I  
12 looked at marketing materials that were produced by the  
13 parties. I looked at marketing oriented materials that were  
14 put together by third parties. And I considered the  
15 testimony of the witnesses here, in particular, Drs. Kaliner  
16 and Smyth.

17 Q. And after reviewing this information, what did you  
18 conclude?

19 A. The product Dymista has been a success in the  
20 marketplace. And an important contributor to its success  
21 has been the patented inventions. As a result, the patents  
22 in suit are a commercial success.

23 Q. Now, you mentioned you looked at prescription data.  
24 After considering that data, what do you conclude?

25 A. In looking at the data, one can see that Dymista came

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1 to the market in late 2012 and immediately succeeded. It's  
2 prescriptions went up quite dramatically and are at a very  
3 impressive and high level to date. I have summarized its  
4 performance in terms of prescriptions in a demonstrative  
5 slide.

6 Q. And is PDX-5.02 the demonstrative you are referring  
7 to?

8 A. It is.

9 Q. Can you explain it to the Court, please?

10 A. Yes. You can see I have charted the prescriptions  
11 for Dymista for 2012 through 2016. 2012 is as short as  
12 it is because the product wasn't introduced into the  
13 marketplace until September, so that is only a partial  
14 year. You can see thereafter the prescriptions arose quite  
15 dramatically.

16 In 2016, I only have data through April of 2016  
17 so I annualized or extrapolated for the rest of the year.  
18 That is why you see the cross-hatched bar.

19 Q. And can you summarize for the Court the level of  
20 prescriptions from 2015 to 2016?

21 A. Yes. In both of those years, the number of  
22 prescriptions have been close to a million. So collectively,  
23 it's been close to 2 million prescriptions in the last two  
24 years.

25 Q. Where did you obtain the underlying data for your

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1 demonstrative?

2 A. From IMS. IMS is a data analytics firm that tracks  
3 and gathers information from a variety of industries, but  
4 it has a particular focus on life sciences and healthcare  
5 industries and a particular focus on pharmaceutical settings.

6 Virtually every company in a pharmaceutical  
7 business contributes data and information to IMS in one form  
8 or another, and virtually every company in a pharmaceutical  
9 business subscribes to IMS; that is, examines its reports  
10 and relies very heavily on those data. The IMS data are  
11 truly the gold standard in the pharmaceutical business.

12 Q. Is your demonstrative PDX-5.02 a fair and accurate  
13 representation of the IMS data you reviewed?

14 A. Yes, it is.

15 Q. And did you use IMS data for other charts here that  
16 you are going to present today?

17 A. I did.

18 Q. Why did you prepare this demonstrative?

19 A. Well, the IMS data are fairly voluminous. So for  
20 purposes of presentation, I summarized that information to  
21 present them those data in understandable fashion rather  
22 than just showing all of the raw data.

23 Q. And in your demonstrative, under notes and sources,  
24 it lists PTX-929. Can you identify the document for the  
25 Court?

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1 A. Yes, that is the underlying IMS data for this chart.

2 MR. LaROCK: Mr. Beall, can we put up PTX-929.

3 BY MR. LaROCK:

4 Q. Is this the data you reviewed?

5 A. That is one page of a many page document that  
6 includes the total prescription data for the Dymista and  
7 other products that I examined in this case.

8 Q. Now, let's talk about revenue. After reviewing that  
9 information, what do you conclude?

10 A. The revenue story is very similar to the prescription  
11 story. That is, immediately upon its introduction to the  
12 marketplace, Dymista performed very well in terms of  
13 dollars or revenues. It grew quite dramatically, and the  
14 revenues are at very impressive level to date. I created  
15 a demonstrative chart that summarizes the performance.

16 Q. So I put up PDX-5.03. Is that the demonstrative you  
17 are referring to?

18 A. It is.

19 Q. Can you summarize it for the Court?

20 A. Yes. It's just like the previous chart with the same  
21 explanations for 2012 and 2016. And you can see that for  
22 this year, it appears that revenues for Dymista as reported  
23 by IMS will be over \$160 million.

24 Q. And where did you obtain the data for this chart?

25 A. Again, from IMS.

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1 Q. And is the source lived again as PTX-929?

2 A. It is.

3 Q. Now, let's talk about Dymista's main competitors.

4 Can you identify those main competitors for the Court?

5 A. Branded prescription nasal sprays that are used to  
6 treat moderate-to-severe allergic rhinitis.

7 Q. And how did you determine what those competitors were?

8 A. Based on the testimony here and based on the  
9 documents that I reviewed from Meda and Cipla with regard  
10 to what it or what they perceive their competitors to be in  
11 the marketplace and based on a conversation that I had with  
12 Meda's Mr. Hostler.

13 Q. And besides branded nasal sprays, are there other  
14 treatments for allergic rhinitis in the marketplace?

15 A. There are. There are three other categories of  
16 treatments that can be thought of as broadly indirect  
17 competitors for Dymista: The first is oral treatments, the  
18 second is over-the-counter or OTC treatments, and the third  
19 is generic treatments.

20 Q. Now, you mentioned oral allergic rhinitis treatment.  
21 Do those compete directly with Dymista?

22 A. Not directly. At best, there is some indirect  
23 competition. There is not direct competitors with Dymista  
24 for at least two reasons. No. 1, oral therapies as I  
25 understand it are mainly oriented to treating mild or

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1 intermittent symptoms of allergic rhinitis. They're not  
2 oriented to the moderate-to-severe symptoms that we're  
3 talking about here today.

4 Secondly, the oral treatments don't provide  
5 immediate relief. They provide relief that takes some  
6 period before it goes into effect.

7 Q. You also mentioned over-the-counter treatments. Do  
8 those compete directly with Dymista?

9 A. They don't compete directly either, though they're  
10 out there, and they are solutions, but they're largely  
11 solutions that can be thought of as self-medication. That  
12 is, we, as patients, as sufferers of allergic rhinitis will  
13 often go to a pharmacy and look on the shelves for something  
14 that might relieve our symptoms, and sometimes we have  
15 success and sometimes we don't.

16 For those patients who don't have success with  
17 OTC treatments, then they typically go to a physician and get  
18 a prescription. So Dymista occurs, Dymista is prescribed  
19 typically after OTCs have been found to be ineffective or not  
20 effective enough.

21 Q. So in terms of prescriptions, how did Dymista perform  
22 relative to branded nasal sprays?

23 A. Relative to the branded prescription nasal sprays and  
24 all prescription nasal sprays, Dymista performed very well,  
25 and I put a chart together to show its performance.

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1 Q. Is this the demonstrative you are referring to?

2 A. Yes.

3 Q. Can you explain it to the Court?

4 A. Yes. You will see the red line represents -- I'm  
5 not sure if it is red or orange, but the brighter line, the  
6 non-blue line represents the performance of Dymista. You  
7 will see that it was introduced to the marketplace in 2012.  
8 And its first full year was in 2013. At that point, in  
9 relation to other branded prescription nasal sprays, it had  
10 about a 5 percent share. Two years later, that it increased  
11 threefold to 15 percent, and it continues to rise.

12 You will see that Dymista is far and away the  
13 second leading drug among these branded prescription nasal  
14 sprays in terms of total prescriptions. The leading, of  
15 course, is the top line which is Nasonex. That is falling  
16 and will continue to fall going forward.

17 Q. And for the record, the demonstrative is PDX-5.04.

18 By the end of the data period that you analyzed,  
19 what was the market share for Dymista?

20 A. Over 19 percent. That is for the period that I had  
21 data, through April 2016, the share was 19.3 percent.

22 Q. Now, did these shares include generic drugs?

23 A. These do not. This is just the branded prescription  
24 nasal sprays.

25 Q. And what would happen to your demonstrative if



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1 generic nasal sprays were included?

2 A. The trajectories of all these would stay the same, it's  
3 just the Y axis would change because you would superimpose  
4 on that generic drugs, and there are a substantial number of  
5 generic drugs in the marketplace.

6 But that doesn't at all change the conclusion  
7 that in relation to its direct competitors, Dymista has  
8 done very well. The direct competitors are the branded  
9 prescription nasal sprays, and so the line of both of the  
10 gross and the position of the line would be the same even  
11 if you put the generics on top.

12 Q. And if generic nasal sprays were included, would your  
13 analysis change?

14 A. No.

15 Q. Would your conclusions change?

16 A. No.

17 Q. So let's talk about revenue compared to other branded  
18 nasal sprays. How did Dymista perform?

19 A. Very well. As well, I have a chart put together that  
20 illustrates that.

21 Q. For the record, that chart is PDX-5.05.

22 Could you explain that for the Court?

23 A. Yes. This is very similar to the chart that we just  
24 saw with regard to prescriptions. In terms of revenues,  
25 you will see that in its first full year, Dymista was at

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1 about 5 percent or 6 percent of this business and grew  
2 consistently thereafter. In fact, it was the only one  
3 to grow consistently. That was true with regard to  
4 prescriptions as well.

5 You will see by 2015, the share had more than  
6 doubled, and Dymista is clearly in the second spot in this  
7 cohort, with Nasonex again occupying the first spot but not  
8 for long.

9 Q. Now, looking at both revenue and prescriptions,  
10 what conclusions can you draw about how Dymista performed  
11 relative to branded nasal sprays?

12 A. The product has performed very well. It has been  
13 quite successful in the marketplace, and it has been more  
14 successful in terms of growth than any of its competitors.  
15 So there must be something special about Dymista that allows  
16 it to differentiate it from the rest of its cohorts.

17 Q. Now, let's talk about party actions. As an  
18 economist, why are party actions relevant to the commercial  
19 success analysis?

20 A. Well, it's a concept we call reveal preferences. We  
21 economists like to put labels on things to make them seem  
22 fancier than they are. But basically what we like to do is  
23 observe behaviors and observe actions so that they reveal to  
24 us what the economic actors are motivated by, what they're  
25 preferences are. So by seeing what people or companies do,

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1 we can often draw some conclusions as to what matters to  
2 those economic actors.

3 Q. Now, is there something about Meda's actions  
4 concerning Dymista that is relevant to your analysis?

5 A. Yes. It has wanted into this business for quite some  
6 time. Dr. D'Addio talked about that. I think some of the  
7 other witnesses did as well. It wasn't able to succeed in  
8 the 2004 period and the 2005 period, but it still wanted in  
9 on this business.

10 We expect through that behavior it was sending  
11 the message that it thought it could succeed. Once it could  
12 entered this business, with a combination product, it could  
13 reap rewards associated with that entry.

14 The only way it ultimately was able to enter  
15 this business was through obtaining access to the patents  
16 in suit. So it tried and failed until it was able to obtain  
17 the patents from Cipla in 2006.

18 MR. LaROCK: And, Mr. Beall, can we put up  
19 PTX-1016.

20 BY MR. LaROCK:

21 Q. Mr. Jarosz, can you identify the document for the  
22 Court?

23 A. Yes. This was the license agreement entered into  
24 between Cipla and MedPointe. MedPointe was, of course, the  
25 predecessor to Meda, and this is the first agreement that

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1 the two entered into whereby Cipla's intellectual property  
2 was shared with Meda, allowing Meda to enter this business.

3 MR. LaROCK: Can we put up PTX-282.

4 BY MR. LaROCK:

5 Q. Can you identify what this document is?

6 A. Yes. This is the first amendment to that 2006  
7 license agreement. This was an amendment entered into in  
8 2011. There were a series of ways in which Cipla and Meda  
9 expanded and extended its relationship, and this is one way  
10 in which it did.

11 Q. And what impact did these license agreements have on  
12 your commercial success analysis?

13 A. They tell me that Meda wanted into this business and  
14 wasn't able to get into this business until it received the  
15 IP from Cipla. So by its actions, Meda was saying we think  
16 we can succeed in this business and it is a business worth  
17 succeeding in.

18 Q. Now, that was Meda's actions. Is there something  
19 about Apotex actions?

20 A. Yes, they wanted into that business -- into this  
21 business as well. They filed an ANDA. They have spent  
22 quite a number of dollars and resources to try to get into  
23 this business. A very good example is the litigation we're  
24 sitting in today.

25 They spent a lot of money to try to enter this

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1 business. That, again, sends a signal that it believes it  
2 can succeed in the business and it is worth succeeding in  
3 this business.

4 Q. Now, does Apotex already offer other generic nasal  
5 sprays for the treatment of allergic rhinitis?

6 A. They do. In fact, they offer a generic version of  
7 both azelastine and fluticasone. Yet it is said having  
8 those alone is not enough. Co-administration is not enough.  
9 We need those to be combined in an effective fashion in  
10 order to realize true success in this business.

11 So that is important reveal preference  
12 information as well. It's not alone dispositive, but it  
13 is quite important.

14 Q. Now, let's talk about the nexus requirement you  
15 talked about earlier. What analysis did you conduct?

16 A. There were two steps to my analysis here. First I  
17 sought to determine what the benefits of the patented  
18 inventions were, and then I undertook to determine the  
19 linkage between these benefits and the marketplace success  
20 of Dymista.

21 Q. And do you have an understanding what the patented  
22 benefits of Dymista are?

23 A. Yes, and I have summarized those in a demonstrative  
24 slide.

25 Q. Let me go back to the slide. So for reference, I put

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1 up PDX-5.06.

2 Can you explain what is being shown here,  
3 Mr. Jarosz?

4 A. Yes. I understand there to be three primary benefits  
5 associated with the patented technology.

6 First, I understand that the patents allow for  
7 both fast acting and sustained relief for patients who are  
8 suffering from allergic rhinitis symptoms. In other words,  
9 it works quickly and over an extended period of time. That  
10 is what the patents teach to my understanding.

11 Secondly, patents provide more complete symptom  
12 relief and less side effects than monotherapy. That is, if  
13 you used one of the active ingredients alone, that is not  
14 nearly as effective as using Dymista for both symptom relief  
15 and side effects. And,

16 Finally, I understand the patented inventions  
17 allow for a dosing in a single spray.

18 Q. Now, what was the source of your understanding for  
19 this?

20 A. It was largely from the reports and testimony of  
21 Drs. Kaliner and Smyth, and the testimony of Dr. Carr.

22 Q. And how did the benefits of the patented technology  
23 you listed here relate to Dymista's competitive position in  
24 the marketplace?

25 A. Well, these benefits almost define what Dymista is.

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1 That is, what it is is a combination of ingredients that  
2 allow for advantages for both physicians prescribing and  
3 for patients. So what the patents cover is what is the  
4 specialness of Dymista.

5 Q. And have you reviewed Meda and third-party marketing  
6 documents for your nexus analysis?

7 A. Yes, I have.

8 Q. Have you selected representative documents to discuss  
9 today?

10 A. I have, and I have summarized those in some  
11 demonstrative slides.

12 Q. So, for reference, I have put up PDX-5.07.

13 So the source listed here is PTX-397. Can you  
14 identify what that document is?

15 A. Yes. That is the GlobalData report that was  
16 published in 2015. GlobalData is a third-party vendor that  
17 gathers information about businesses; and in this case, it  
18 gathered information from physicians about Dymista. So it's  
19 a third-party report that is relying on information from  
20 third parties.

21 Q. And you selected a portion and highlighted some  
22 information. Can you discuss that for the Court?

23 A. Yes. It undertook a Dymista SWOT analysis covering  
24 2014. SWOT stands for strengths, weaknesses, opportunities,  
25 and threats. And in this slide, I have summarized some of

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1 the threats -- I'm sorry -- some of the strengths that were  
2 identified of Dymista based on GlobalData's gathering of  
3 information from physicians.

4 Q. Can you explain what is being conveyed?

5 A. Sure. There are several things that flow directly  
6 from the patented inventions, and I asked that there be  
7 highlights on the things that are of particular significance.

8 As the strength, it reads: "is a first-in-class  
9 intranasal combination of an H1 receptor antagonist and an  
10 INCS." So that is an antihistamine and intranasal  
11 corticosteroid.

12 Second, "demonstrated superior efficacy in  
13 clinical trials compared with azelastine, fluticasone, and  
14 placebo over a 14-day period when administered as a  
15 monotherapy."

16 Third, it talked about the fact that "dosing  
17 (one spray per nostril twice daily) is more convenient than  
18 when both agents are administered as a monotherapy. This is  
19 likely to increase treatment compliance, and, therefore,  
20 improve symptom relief."

21 Next, Business Strength, Dymista's characterized  
22 rapid onset of action can be effective within minutes, and  
23 produces a significant reduction in symptoms within days.

24 And finally, global data reports that trial  
25 shows improvement over INCS alone, which are currently the



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1 gold standard of AR therapy.

2 So these are precisely the things that are  
3 identified as the benefits associated with the patented  
4 invention. And these are the things that global data was  
5 learning mattered in the marketplace.

6 Q. What is INC?

7 A. Intranasal corticosteroids.

8 Q. You have selected another document to discuss today.  
9 Is that right?

10 A. Yes.

11 Q. I have put up PDX-5.08. The source is PTX-271. What  
12 is PTX-271?

13 A. That is Meda's Dymista marketing plan for 2015.

14 Q. Can you explain what's being conveyed here?

15 A. This is another SWOT analysis, this time done by the  
16 people at Meda, and the strengths that they identify are  
17 fourfold. That is the strengths associated with Dymista.

18 Superior efficacy; rapid onset of action with  
19 inflammation control with unique delivery system and fine  
20 mist spray; uniqueness of product -- the only one in the  
21 market.

22 And finally, safety profile.

23 Again, these are things that flow from the  
24 patented inventions.

25 Q. Have you selected another document to discuss today?

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1 A. Yes, I have.

2 Q. For the record, this is PDX-5.09. The source,  
3 PTX-1118. What is PTX-1118?

4 A. Meda's Dymista plan that is 2012 covering 2011 but  
5 looking forward. It is important to note that this was done  
6 before the product was even introduced to the marketplace.

7 So these were hopes and expectations as to the  
8 distinctness that the product may have and ultimately did  
9 have in the marketplace.

10 Q. And can you explain what is being conveyed here?

11 A. Yes. Meda writes, "Dymista provides rapid and more  
12 complete symptom relief - that HCPS" -- which are health  
13 care professionals -- "and patients can rely on."

14 It goes on to write, "Dymista is the first and  
15 only prescription medication to combine the effective  
16 anti-inflammatory relief of a corticosteroid coupled with  
17 the rapid multi-symptom relief of a nasal antihistamine."

18 Finally, "So that patients can have fast  
19 superior symptom control in a single spray."

20 Again, these are the advantages that flow from  
21 the patents in suit.

22 Q. Looking at the documents you have selected to discuss  
23 today, what is your conclusion about the nexus requirement?

24 A. It appears that it has been satisfied in the sense  
25 that the patented inventions identify -- the patented

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1 inventions describe the differentiating advantages of  
2 Dymista in the marketplace.

3 So the success is due in large part to the  
4 patents in suit.

5 Q. Now, let's talk about the India marketplace. What do  
6 you understand the commercial embodiments to be of the  
7 patents in suit to be in India?

8 A. Duonase and at least six copycat or imitator  
9 products.

10 Q. Do you have an understanding Duonase is marketed by  
11 Cipla?

12 A. It is.

13 Q. How did you obtain the understanding of the  
14 commercial embodiments of the patents in suit in India?

15 A. Dr. Smyth and Kaliner, both their reports and  
16 testimony. It was those individuals.

17 Q. And in relation to Dymista, when did these imitator  
18 products or copycat products, when did they launch into the  
19 market?

20 A. In relation to Duonase?

21 Q. In relation to Duonase.

22 A. The copycat or imitator products all came after  
23 Duonase. Duonase was introduced in 2004, and starting in  
24 2006 onward, imitators continued to come into the Indian  
25 market up through 2013. So they continuously came into the

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1 marketplace, but all after the introduction of Duonase.

2 Q. And how did the fact that the Duonase copycat or  
3 imitator products entered the market after Duonase affect  
4 your analysis?

5 A. Again, it revealed preference information.

6 These companies with their products are sending  
7 the message that we want into this business because this is  
8 one we can succeed in and this is one that is worth  
9 succeeding in.

10 So the fact that they want in sends a very  
11 strong message about the importance of the marketplace and  
12 importance of the patented inventions.

13 And I have charted the performance of the drugs  
14 in a demonstrative slide.

15 Q. And is PDX-5.10 the demonstrative you are referring  
16 to?

17 A. Yes, it is.

18 Q. Can you explain what's being conveyed here?

19 A. Yes. You will see Duonase is the blue bar. That  
20 product was first introduced by Cipla in 2004. And every  
21 year it's grown. That is, the units shipped of Duonase were  
22 greater each year than the year before.

23 You will see on this chart that the six copycats  
24 all came in over a several-year period following in on  
25 Duonase's success. And each one of those realized their own

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1 success with very few exceptions, each one of the copycats  
2 generated higher units shipped in a year versus the  
3 previous.

4 So they all entered, and they all grew.

5 Q. What was the source for the underlying data for this  
6 demonstrative?

7 A. That is PTX-204, which is IMS data covering India  
8 that was collected by Cipla.

9 Q. Can we put up PTX-204.

10 Is this the data you reviewed?

11 A. Yes, it is.

12 Q. Now, how did Duonase and the copycat products perform  
13 relative to other nasal sprays in the Indian market?

14 A. Collectively, from 2010 onward, they have comprised  
15 21 percent or more of that business. In other words,  
16 together, they have done very well, even individually  
17 Duonase has done very well.

18 Q. Now, similar to Dymista, let's talk about the nexus  
19 requirement as it relates to Duonase. How did the patented  
20 benefits we talked about earlier relate to Duonase's  
21 competitive position?

22 A. There seems to be a similar relationship as there was  
23 with regard to Dymista. I looked at a number of the  
24 marketing materials that were provided by Cipla, and they  
25 all showed a story that was very similar to the marketing

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1 materials shown by Meda, and that is, they revealed that the  
2 patented inventions mattered.

3 Q. And have you selected a number of marketing materials  
4 from Cipla that you can discuss today?

5 A. I did. And I think I put one in the demonstrative  
6 slide, as I recall.

7 Q. And for the record, PDX5.11 is up on the screen. The  
8 source being PTX-412. Mr. Jarosz, can you identify what  
9 PTX-412 is?

10 A. Yes, that is a Duonase marking document published by  
11 Cipla. So it's Cipla's evaluation of its business and its  
12 evaluation of Duonase.

13 Q. Can you explain for us what is being conveyed here?

14 A. Yes. In the sections that I have highlighted, it  
15 reports that Duonase provides rapid and prolonged symptom  
16 control, it also reports greater improvement in symptoms  
17 than antihistamine or corticosteroid alone.

18 So again, those flow directly from the patented  
19 invention, and those are important contributors, as  
20 acknowledged by Cipla, to the success of Duonase.

21 Q. And looking at the marketing documents from Cipla  
22 that you reviewed, what conclusions can you draw about the  
23 nexus analysis for Duonase?

24 A. There seems to be a strong nexus between the patented  
25 inventions and the success of the product and its copycat or

1 imitator products.

2 Q. Looking at Dymista and Duonase and the imitator  
3 products that we discussed, what are your overall  
4 conclusions in this case?

5 A. Those products have been a marketplace success. And  
6 the success is in large part due to the patents in suit. As  
7 a result, the patents have been a commercial success.

8 MR. LaROCK: Your Honor, I would like to offer  
9 PTX-1118, PTX-397, PTX-271, PTX-412, PTX-929, PTX-204,  
10 PTX-1016, and PTX-282 into evidence.

11 MR. WARNER: No objection, Your Honor.

12 THE COURT: Those are all admitted.

13 MR. LaROCK: As summaries of voluminous data  
14 under Federal Rule of Evidence 1006, I would also like to  
15 offer into evidence PDX-5.02, 5.03, 5.04 and 5.05.

16 THE COURT: Any objection?

17 MR. WARNER: No objection, Your Honor.

18 (Above-referenced exhibits received in  
19 evidence.)

20 MR. LaROCK: I pass the witness.

21 THE COURT: Okay. Cross-examination.

22 MR. WARNER: Thank you.

23 THE COURT: You may approach.

24 CROSS-EXAMINATION

25 BY MR. WARNER:

1 Q. Good afternoon, Mr. Jarosz.

2 A. Good afternoon.

3 Q. We haven't met. My name is Kevin Warner. I am one  
4 of the attorneys for Apotex in this matter. Nice to meet  
5 you, sir.

6 A. Nice to meet you, although I will reserve judgment  
7 until cross is over.

8 Q. We will see how it goes.

9 I want to start out by talking about why in a  
10 patent case we do an analysis of why there is commercial  
11 success.

12 You agree with me that one of the reasons we do  
13 that is because if a patented technology is successful, one  
14 can say that if it had been obvious, one would have expected  
15 economically rational sellers to have adopted the patent  
16 technology before patenting occurred. Do you agree with  
17 that?

18 A. Yes, I generally agree with that.

19 Q. Would you also agree, though, that there could be  
20 circumstances under which an economically rational potential  
21 competitor might think an invention obvious but still decide  
22 not to adopt it and sell it?

23 A. Yes.

24 Q. So you would agree that, for instance, we are talking  
25 about a pharmaceutical case, so it is possible that a



1 pharmaceutical company would consider selling a new product.  
2 If they do that, that is a decision that if they followed  
3 through on it, it's going to require a commitment of  
4 resources. Correct?

5 A. Typically, that's right.

6 Q. And the decision to commit resources to the sale of  
7 any product, including a pharmaceutical product, that's an  
8 economic and a financial choice for a company. Yes?

9 A. Yes.

10 Q. Now, parties like these pharmaceutical companies that  
11 we are talking about, they are not compelled to pursue the  
12 sale of a product even if it is obvious. Correct?

13 A. That's right.

14 Q. And if a pharmaceutical company sees an option with a  
15 higher value, they have the option to either deploy or  
16 reallocate their resources to a higher value endeavor at any  
17 time if the option exists. Correct?

18 A. That is absolutely right, and that is one of the  
19 points that I was talking about with regard to Apotex's  
20 available preferences. There is many other opportunities  
21 available to it but it wants in on this business.

22 Q. These economically reactions we are talking about, in  
23 fact, you would agree that economic theory means that they  
24 should allocate resources to activities that will generate  
25 the maximum possible return. Correct?

1 A. Yes, subject to the budget complaint of funds, should  
2 attempt to maximize their profits in order to give adequate  
3 returns to their share owners.

4 Q. Understood. I was going to get to that point.

5 When a company is making these decisions, the  
6 opportunities that it is going to have are going to be  
7 defined by which opportunities and which constraints face  
8 that company?

9 A. That's correct. Profit maximization considers both  
10 the returns and the investments required.

11 Q. Investments would be the constraints required?

12 A. Yes. In economics we use the term budget constraint.  
13 But I think we are generally saying the same thing.

14 Q. With that kind of frame of mind for why we talk about  
15 this commercial success, I want to go back to 2002 and the  
16 invention date. Okay? Are you following me?

17 A. Yes. But I am not a technical person. So I don't  
18 know exactly what the invention date is. I will follow  
19 along as well as I can.

20 Q. Fair enough. I will just ask you to assume we are in  
21 June 2002. Okay?

22 A. Fine.

23 Q. At that point in time, sir, you were aware of the  
24 fact that there was a patent that had issued that covered  
25 the Astelin azelastine product. Correct?

Jarosz - cross

1 A. I think there was a '194 patent. I have seen a  
2 reference to it. What it covers I don't know. And I don't  
3 know whether it covers any and all forms of the azelastine.

4 Q. Understood. I am talking about the '194 patent, we  
5 are on the same page there. You are not here to offer an  
6 opinion one way or another about that patent covers. Right?

7 A. No, no one wants my opinion on that.

8 Q. You agree with me, but you recall it issued in 1992?

9 A. I think I have heard that. And I think the patent  
10 might have been on the screen earlier today, and probably  
11 the issuance date was on that.

12 Q. I will put it up real quick. It is DTX-16, please.

13 There is the issuance date in 1992. Do you  
14 agree with that?

15 A. Yes.

16 Q. You have heard or do you know that it expired in May  
17 of 2011?

18 A. I think I have heard that, yes.

19 Q. So if you are a pharmaceutical company back in 2002  
20 considering making a combination azelastine and fluticasone  
21 nasal spray product, and if you do a patent search for  
22 patents related to azelastine, it is reasonable to think you  
23 could find this. Right, sir?

24 A. I can't say that it's reasonable from a technical  
25 standpoint. But this patent existed.

Jarosz - cross

1 Q. You are also aware, sir, that in 2002, by at least  
2 2002, Meda was the assignee of this patent? Do you know  
3 that, sir?

4 A. I forget when it received rights in this patent. I  
5 don't have reason to dispute your representation. But I am  
6 not -- I am not confirming it, either.

7 Q. Let's make sure we are on the same page. Can I see  
8 DTX-328, please.

9 This is, just up at the top, sir, do you see  
10 that this is -- these are a set of assignment records that  
11 are available at the United States Patent and Trademark  
12 Office? Do you see that?

13 A. Yes.

14 Q. And if you go to the second page, and the top third,  
15 please, if we could look more closely at that. The whole  
16 top third block, please.

17 Do you see up here it says, this is a conveyance  
18 assignment of assignor's interest? The assignor is Vitris  
19 GmbH and the assignor is MedPointe Healthcare?

20 Do you see that?

21 A. I am sorry. You are directing me to Assignment 3?

22 Q. Correct.

23 A. I see that.

24 Q. MedPointe Healthcare, that is one of the predecessors  
25 of Meda. Yes?

1 A. Yes.

2 Q. You are not aware of any evidence that Meda ever  
3 licensed this patent to anyone to make a combination of  
4 azelastine and fluticasone product?

5 A. Correct, I am not aware about that.

6 Q. You are not offering any opinion as to whether Meda  
7 even made it available to license. Is that right?

8 A. I don't know whether it did or not.

9 Q. Would you agree with me that that if an economically  
10 rational company thinking about making that combination of  
11 azelastine and fluticasone as a product would think that its  
12 product covered that patent and could not obtain a license  
13 on that patent, then you can't say that it would be rational  
14 to try and market that product. Is that fair?

15 A. I don't know. But the patent runs out in 2011.  
16 Moreover, I believe the FDA's safe harbor allows a company  
17 to undertake research activities so that once this patent  
18 does run out, that party could roll out a product  
19 immediately upon the end of this patent. I haven't seen  
20 that ever happen.

21 Q. I am going to talk about the expiration date issue in  
22 just a second.

23 Focusing in the 2002 time frame, the patent is  
24 alive then. Right?

25 A. I work under the assumption that it is a valid patent

1 at that point.

2 Q. And your view is that you can make this product. But  
3 my question is, if you assume that if you sold it you would  
4 infringe, then it might be a rational decision not to do  
5 that, correct?

6 A. Possibly, but it doesn't seem to have slowed down  
7 Cipla's activities.

8 Q. Do you know if Cipla had a license to the patent?

9 A. Do I know that?

10 Q. Yes.

11 A. I am not sure I know that.

12 Q. Do you know if Cipla tried to market a product in the  
13 United States?

14 A. I don't think I heard it did. But it talked to  
15 companies about the rights or ability to market products in  
16 the United States.

17 Q. Do you have any opinion about whether the United  
18 States patent covers activities and sales in India?

19 A. I don't know that it would have. If there is  
20 something made here and sold in India, it would probably  
21 cover that.

22 Q. All right. Let's talk then about, you mentioned the  
23 fact that it expires in 2011?

24 A. To the best of my knowledge.

25 Q. In your view, when it is expired, then somebody

1 doesn't have to worry about that patent. Correct?

2 A. That patent won't preclude any activity associated  
3 with the patented invention, yes.

4 Q. But you understand, sir, would you agree with me that  
5 by 2011, the application for the patents that we are  
6 currently litigating here had been filed in the Patent  
7 Office?

8 A. I don't have reason to dispute that.

9 Q. Would you agree with me, sir, that that patent  
10 actually had become published well before 2011?

11 A. That I don't know.

12 Q. Let's take a look, please at PTX-1.

13 This is the patent in suit, right, sir?

14 A. That is one of the two patents.

15 Q. You are correct. If you could back it up. Let's  
16 look at this area here, the bibliographic information.

17 Here, at Section 87 it says, PCT publication  
18 date, December 24, 2003. Do you see that?

19 A. Yes.

20 Q. Do you understand that to be the date on which the  
21 international filing of this application was published?

22 A. That makes sense to me, though I am not an expert in  
23 that.

24 Q. So that's 2003. Would you also agree with me, sir,  
25 that well before 2011, it was public knowledge that Meda was

Jarosz - cross

1 in Phase III clinical trials for a combination  
2 azelastine-fluticasone nasal spray product?

3 A. I don't know if that was public knowledge or not.

4 Q. Do you have in your binder Defendants' Exhibit 326?

5 A. Yes, I do.

6 Q. If you could take a look at that, please, sir.

7 Do you recognize the title here as Meda 2008  
8 Annual Report?

9 A. Yes, I see that.

10 Q. If you would turn to the exhibit page marked  
11 326.0027 -- before I go on, sir, the annual report, that is  
12 public information. Right?

13 A. Yes.

14 Q. And if you look in the upper right corner, actually,  
15 if we look at the top third of it, this is Meda explaining,  
16 starting in the upper left, what's going on with its Astelin  
17 portfolio. Right?

18 A. Yes. Astelin.

19 Q. Sure.

20 A. Not Dymista.

21 Q. Understood. If you look, it has three numbers.

22 There is Paragraph 1, Paragraph 2 and Paragraph 3. Right?

23 A. Yes.

24 Q. Right above those it says, Meda is pursuing a  
25 comprehensive development program for that azelastine nasal



1 spray.

2 Do you see that?

3 A. Yes.

4 Q. Then it lists the three components of that that are  
5 the subject of the annual report. Correct?

6 A. That makes sense to me, yes.

7 Q. No. 3, sir, is a combined product that contains  
8 azelastine and fluticasone, a well-established steroid, is  
9 in Phase III.

10 A. I see that, yes.

11 Q. So somebody reading the Meda annual report in 2008  
12 knows that Meda, who holds the Astelin patent, is in Phase 3  
13 trial in a combination azelastine and fluticasone nasal  
14 spray product; correct?

15 A. Yes, they are in trial. Trials are not guaranteed.

16 Q. Understood. They're working on it; right?

17 A. Correct, at that point in time.

18 Q. Now, I want to talk about some other aspects of the  
19 marketplace for nasal sprays. You talked about a few  
20 products. You talked about Dymista, and Nasonex; right?

21 A. I did, yes.

22 Q. There were some questions about over-the-counter  
23 products and some generic products as well; right?

24 A. Yes, not specific products but the concept of  
25 over-the-counter and generic.

1 Q. Understood. And so if we put ourselves back in 2002,  
2 would you agree with me, sir that if you are a competitor  
3 thinking about making a combination azelastine/fluticasone  
4 nasal spray product, you are going to launch into a market  
5 in which fluticasone is available as a nasal spray; is that  
6 right?

7 A. Yes, fluticasone was available then.

8 Q. And also at that time, azelastine was available as  
9 a nasal spray; right?

10 A. Azelastine was available, yes.

11 Q. Now, you mentioned this before. Patents don't live  
12 forever. They expire; right?

13 A. Yes.

14 Q. And so at that point in time, in 2002, the  
15 fluticasone and the azelastine were branded products, but  
16 you also know that the patents covering them were eventually  
17 going to expire; right?

18 A. Yes, and they did.

19 Q. They did. And so I think it was 2006 for  
20 fluticasone. Did I get that right?

21 A. I think that is right, yes.

22 Q. Okay. And so a competitor thinking about launching  
23 this combination azelastine/fluticasone product, if they  
24 did it in 2002, they're launching into a market that  
25 contains both fluticasone and azelastine nasal sprays sold

1 separately; right?

2 A. Separately, not combined but separately.

3 Q. Understood. You heard some testimony about the fact  
4 they are co-administered sometimes?

5 A. On occasion, they are co-administered. I don't know  
6 the rate at which they are.

7 Q. Okay. And at that same time, you know that at some  
8 point in the future, those might become generic, too; right?

9 A. It's possible.

10 Q. Well --

11 A. It depends upon whether all patent coverage expires.

12 Q. Well, it happens; right?

13 A. Oh, yes, it did happen. I'm sorry. I may have  
14 misheard your question.

15 Q. Okay. And if you fast forward then a little bit, say  
16 to 2012, that is when Dymista launched; right?

17 A. Yes, in the United States.

18 Q. In the United States. So when Dymista launched,  
19 it did launch into a market that contained both of its  
20 component parts sold as their individual nasal sprays;  
21 right?

22 A. Yes, and in spite of that, it did quite well.

23 Q. And both of them were generic; right?

24 A. I think that is right, yes.

25 Q. And you characterized the environment into which it

1 launched as a challenging one; right?

2 A. Yes.

3 Q. A highly competitive environment?

4 A. Generally, although the direct competition was much  
5 more limited than the indirect competition.

6 Q. And we'll talk about some of the competition. When  
7 we talk about generics, one of the aspects that is relevant  
8 about generic drug products is that, typically speaking,  
9 they've got a lower cost, right?, than the brand?

10 A. You mean a lower price to the patient --

11 Q. Yes.

12 A. -- or to the insurance company? Typically. That is  
13 not always the case, and there has been recent news reports  
14 on questioning that hypothesis, but generally that has been  
15 true.

16 Q. Okay. You don't have any reason to disagree that  
17 that is the case typically with fluticasone and azelastine  
18 when they went generic; correct?

19 A. Being the case meaning the generic versions were less  
20 expensive than the branded versions?

21 Q. To the patient, yes.

22 A. I think that is right. Well, certainly to the payor  
23 and probably to the patient.

24 Q. And as part of the challenging environment, you  
25 talked to us today about some slides that showed the SWOT

1 analysis; correct?

2 A. Several different SWOT analyses. One done by  
3 GlobalData and one done by Meda.

4 Q. Okay. I want to take a look at the GlobalData one  
5 first. And this is in your binder. This is PTX-397.

6 And this is the September 2015 document?

7 A. That is a question?

8 Q. The upper front page.

9 A. I believe my answer is, yes, there it is.

10 Q. All right. Very good.

11 MR. WARNER: So can we look at page 132, please,  
12 Mr. Aranda.

13 By THE WITNESS:

14 A. Should I be looking at the Bates page 133 or the  
15 document page 133?

16 Q. Actually, it's not the Bates. It's the document page  
17 133.

18 And you put up an excerpt from this page; right,  
19 sir?

20 A. I did, yes.

21 Q. And of the SWOT analysis, you showed the S part, the  
22 strength, right?

23 A. Yes, I did.

24 Q. You didn't talk about the W part, the weaknesses;  
25 right?

1 A. No, but I'm happy to now.

2 Q. We will. And you didn't talk about the T part, the  
3 threats?

4 A. Correct, but I'm happy to now.

5 Q. Let's take a look at the second section. That is the  
6 weaknesses.

7 And by the way, this is a third-party research  
8 document; right? This isn't Meda's data or anything like  
9 that?

10 A. That's right.

11 Q. And one of the first things -- well, not one of, the  
12 first thing listed in weakness -- and this is all talking  
13 about Dymista; right?

14 A. Yes, that's right.

15 Q. So it says: "Dymista is more expensive than  
16 prescribing each therapy individually."

17 That is talking about azelastine and fluticasone  
18 individually; right?

19 A. Yes.

20 Q. It's more expensive than prescribing them  
21 individually and considerably more expensive than the  
22 cheaper formulary preferred generic versions of the two  
23 individual components. Do you see that?

24 A. Yes. And I think I was calling of this out on my  
25 demonstrative slide because it is a reflection that Dymista

1 did not have a price advantage in the marketplace. In spite  
2 of that, the prescriptions and revenues have been very  
3 impressive.

4 Q. And we'll come to that. My point, though, this is  
5 all, these are things that happened, they are a result of  
6 the fact that when you launched Dymista, you are launching  
7 it into a market that you know contains fluticasone;  
8 correct?

9 A. They probably -- I'm quite sure that they did.

10 Q. And they knew that it contains azelastine; correct?

11 A. I'm quite sure that Meda knew that.

12 Q. And they knew that they either would or very possibly  
13 become generic products?

14 A. Yes.

15 Q. And that creates a highly challenging market?

16 A. Yes, it can.

17 Q. If you go down, I want to look at the fifth one that  
18 begins with "despite."

19 You also talked about, when you are doing I  
20 think your nexus analysis, you were summarizing basically  
21 the clinical benefits of the product; right?

22 A. I'm not quite sure that I would characterize that  
23 as the clinical benefits. Those are the benefits as I  
24 understand them as an economist. If you were to ask a  
25 clinical question, I would suggest that you talk to

1 Dr. Kaliner or others who are expert clinicians.

2 Q. Fair enough. And when you are talking about these  
3 things, in terms of what the drug actually does from a  
4 clinical perspective, you are relying on folks like Dr.  
5 Kaliner and Dr. Carr; right?

6 A. Yes.

7 Q. And you were in court this morning; right?

8 A. Yes.

9 Q. You heard Dr. Carr talk about some of the clinical  
10 studies that led to the approval of Dymista?

11 A. Yes.

12 Q. And he talked about how impressive the results were  
13 and he showed some slides talking about them?

14 A. Yes, and I remember he distinguished lab studies from  
15 clinical studies, and he talked about that topic at some  
16 length.

17 Q. Sure. Now, this is a third-party document; and what  
18 it says about those clinical trials in the weaknesses  
19 section for Dymista, it says: "Despite a statistically  
20 significant reduction in nasal symptoms in patients treated  
21 with Dymista compared with placebo and monotherapy, the  
22 absolute difference between the treatment arms was small,  
23 and might not be clinically relevant enough to warrant the  
24 higher price associated with the FDC drug for payers."

25 Do you see that?



1 A. Yes, I do.

2 Q. Again, that is something that if you are thinking  
3 about launching this product against fluticasone and  
4 azelastine, that might be a weakness you would recognize;  
5 is that right?

6 A. That is right. And for some purchasers, that may  
7 have mattered. The trade off may not have been sufficient  
8 to buy Dymista; but for many, the price was warranted by the  
9 clinical differences.

10 Q. You wouldn't know which is going to happen until it  
11 happens; right?

12 A. I'm not following.

13 Q. Well, to know who pays for it and who won't and how  
14 that is going to play out, you don't know that until you  
15 actually get out in the market and do it?

16 A. Yes, but they were on the market by September 2015.

17 Q. I'm talking about somebody in 2012 thinking about  
18 doing this. You know you are going to be competing against  
19 fluticasone and competing against azelastine; right?

20 A. Yes.

21 Q. And you won't know the effect of that until you are  
22 on the market and see the results; correct?

23 A. That's right.

24 Q. Okay.

25 A. You won't know with certainty until it happens, but

1 they had some confidence that this could be a success. As  
2 the result, they went forward with the project and the  
3 pricing.

4 Q. All right. I want to turn then to the actual  
5 performance in some of the market data you have showed, sir.

6 And can we take a look, please, Mr. Aranda, at  
7 PDX-5.04.

8 And this is what you put up for the Dymista  
9 performance in total prescriptions in the branded nasal  
10 spray market; right?

11 A. In the cohort of competitors that includes branded  
12 prescription nasal sprays.

13 Q. Okay. And if you listed the names of the drugs that  
14 are reflected on this chart at the bottom; and you will  
15 note, sir, that there is no fluticasone, right?

16 A. Correct, because I'm not sure that the branded  
17 prescriptions were of any significance at that point.

18 Q. Okay. And there is an Astepro, but this doesn't  
19 contain Astelin; right?

20 A. I believe that is right. It doesn't include any  
21 generics.

22 Q. It also doesn't include the brand Astelin; right?

23 A. I think that --

24 Q. I'm just looking at the key at the bottom.

25 A. Right. I think that is right, although I could go

1 back and look at my tabs, if you want me to. Do you want me  
2 to?

3 Q. All I'm asking, sir, on the key on the bottom you  
4 don't list Astelin; correct?

5 A. That is correct.

6 Q. That's all I want. Thank you.

7 And there was some discussion about whether or  
8 not or how you would characterize Dymista's competitive  
9 relationship with the generics, fluticasone and azelastine;  
10 right? You discussed that on your direct?

11 A. I'm sorry. There was some question? I'm not quite  
12 sure what you are asking.

13 Q. Well, you were trying, you sort of subcategorized  
14 the competitors of Dymista to brands, generics,  
15 prescriptions, over the counter, orals. Do you recall that?

16 A. I didn't subcategorize. I explained what the most  
17 direct competitors were of Dymista, and I explained why  
18 orals and OTCs were not direct competitors, and I explained  
19 that if you did put generics on this chart, the story  
20 wouldn't change.

21 Q. And you said if you do put generics on this chart,  
22 then the story wouldn't change?

23 A. Correct.

24 Q. So I want to take a look at -- you actually did get  
25 together the data about generics; right?

Jarosz - cross

1 A. Yes, and I summarized those in my report.

2 Q. In your report, not on this chart?

3 A. Not on this chart, because you wouldn't see much  
4 activity on this chart if you have the generic superimposed  
5 on top.

6 MR. WARNER: So I want to take a look at that  
7 data. Can we look at PTX-1189, please?

8 BY MR. WARNER:

9 Q. And --

10 A. If you will give me a moment, I will try to catch up  
11 with you.

12 Q. Yes. I apologize for moving too quickly.

13 A. Thank you very much.

14 Q. Are you there?

15 A. I am.

16 Q. Okay. So the first page is Tab 3. This is excerpted  
17 from your report; right, sir?

18 A. It appears to be, yes.

19 Q. And so this is data that shows market share for  
20 branded and generic prescriptions; right?

21 A. It shows the performance of these drugs, including  
22 both branded and generic versions for the period 2012  
23 through 2015 -- through April of 2016.

24 Q. So I want to look at just a couple things on this.

25 This one would include fluticasone propionate.

1 If we could expand that line.

2 You can probably see it better on your sheet.

3 But if you include fluticasone propionate in the total  
4 prescription category, the share from the time period  
5 2012 to 2016, in other words, the life of Dymista, is  
6 73.2 percent of the market; right?

7 A. I'm sorry. Fluticasone propionate is 73.2 percent  
8 of all these drugs during this period. If that is what you  
9 asking, I agree with you.

10 Q. Yes, great. Then you also, if you go up, we can see  
11 Nasonex. That is another one that was discussed. And the  
12 Nasonex share, you see is 12 and-a-half percent?

13 A. Yes.

14 Q. All right. And then if we look, I'm kind of doing  
15 this in rank order. So if you go down again towards the  
16 bottom, in the antihistamine history category, you can see  
17 azelastine. And that is 4.3 percent; right?

18 A. Yes. You picked the only three that are larger than  
19 Dymista on this sheet.

20 Q. Yes. There is a few others, but if we look at --

21 A. I'm sorry. That are larger than Dymista?

22 Q. There is one other that is larger than Dymista. We  
23 can look at that. That is triamcinolone. That is at the  
24 bottom of the generic steroid category, right there.

25 A. There, 1.9 percent, yes.

Jarosz - cross

1 Q. Okay. Then at the top is Dymista; right?

2 A. Correct. The very first row is Dymista.

3 Q. Yes, the very first row. And the number for  
4 Dymista -- so this is if you include the brands and the  
5 generic nasal sprays -- the number is 1.2 percent; right?

6 A. That's right. That's what I reported here.

7 Q. Okay.

8 A. For business, that includes all of those drugs, yes.

9 Q. Understood, right.

10 A. But for the direct competitors, it's a much higher  
11 share.

12 Q. So your opinion is that Dymista does not directly  
13 compete with generic fluticasone?

14 A. It doesn't compete as directly as it does with the  
15 other products that we talked about.

16 Q. Sir, do you have an opinion, does Dymista compete  
17 directly with fluticasone?

18 A. Probably on occasion but not nearly as much as it  
19 competes with the branded prescription nasal sprays.

20 MR. WARNER: Okay. Can I take a look at the  
21 Elmo, please.

22 BY MR. WARNER:

23 Q. This is the chart you put up; right?

24 A. Yes.

25 Q. So if we try to put those market shares on this

1 chart, it's a slightly different picture than what is here;  
2 right?

3 A. The growth doesn't change. I'm not exactly sure what  
4 you're saying.

5 Q. Well, so we saw the --

6 A. I'm sorry. You still have Dymista as the only  
7 branded prescription nasal spray that increases year after  
8 year after year.

9 Q. Well, let's just look at just what the numbers say.  
10 So we saw the chart of the market share over the total time  
11 period for fluticasone. Remember that was 73.2?

12 A. Yes.

13 Q. All right. So that actually goes above the top line  
14 on your chart here; right?

15 A. That's correct. That is mathematically where it  
16 goes.

17 Q. And then the next one in rank order was Nasonex;  
18 right? And that was at 12 and-a-half percent?

19 A. Yes, that is right.

20 Q. Okay. Then we looked at Astelin -- azelastine. That  
21 was 4.3 percent; correct?

22 A. That's Astelin, I think, yes.

23 Q. Let's call that A-Z. All right?

24 A. Sure.

25 Q. We looked at that, that was 1.2 percent over the time

1 period?

2 A. Right. Then if we charted the ones below that, it  
3 would be extremely crowded.

4 Q. I want to chart Dymista. But if I look at the rule  
5 you have here it says, Share of branded allergic rhinitis  
6 nasal sprays by total prescription, branded nasal sprays  
7 with a maximum share of less than 3 percent are not shown.

8 So if we follow the 1.2 percent for Dymista, it  
9 doesn't make the chart. Right, sir?

10 A. But you are changing this chart. But if you just use  
11 that as the cutoff, that is exactly right.

12 I didn't say that Dymista is the most  
13 successful product in this business. It is a very  
14 successful product.

15 Q. It doesn't make this chart, though. Right?

16 A. Based on this representation, that's right.

17 MR. WARNER: Nothing further at this time.

18 Before they begin, I will move in DTX-328,  
19 DTX-326, PTX-1189.

20 THE COURT: Any objection to those exhibits?

21 MR. LaROCK: No.

22 THE COURT: Those are admitted.

23 (Above-referenced exhibits received in evidence.)

24 REDIRECT EXAMINATION

25 BY MR. LaROCK:



1 Q. Just one question, Mr. Jarosz. Is there any  
2 threshold requirement for market share in order to find  
3 commercial success?

4 A. Not at all.

5 MR. LaROCK: No further questions.

6 THE COURT: Thank you. You may step down, Mr.  
7 Jarosz. Thank you.

8 MR. LaROCK: I have the rest of my  
9 demonstratives that I would like to be accepted as  
10 demonstratives.

11 THE COURT: They are all accepted as  
12 demonstratives.

13 MR. LaROCK: I will mark the drawing that I made  
14 as Jarosz Demonstrative 3 and pass it around to the Court at  
15 a break.

16 THE COURT: That is fine. Thank you.

17 Ms. Everett, what is next?

18 MS. EVERETT: Another housekeeping item. We  
19 offer the demonstratives we used with Dr. Smyth, which were  
20 PDX-4.01 through 4.37, as demonstratives for the Court.

21 THE COURT: They are accepted as demonstratives.

22 MS. EVERETT: We are ready to play the  
23 deposition of Dr. Ramprakash Govindarajan, which would be a  
24 total playing time of 16 minutes and 4 seconds, 11 minutes  
25 and 34 seconds to plaintiffs, 4 minutes and 18 seconds for

## Govindarajan - designations

1 defendants.

2 I believe we have the percentages. That is 27  
3 percent to defendants and 73 percent for plaintiffs.

4 THE COURT: You have copies of the transcript.  
5 Thank you.

6 You may play it when your ready.

7 (Designations of Ramprakash Govindarajan placed  
8 in evidence.)

9 "Question: Okay. So prior to your work in this  
10 litigation, had you developed an intranasal product before?

11 "Answer: I have not.

12 "Question: Okay. Are there -- did you conduct  
13 any additional tests that were not included in your lab  
14 notebook?

15 "Answer: I measured the pH of the solution, of  
16 the suspension.

17 "Question: Okay. When did you do that?

18 "Answer: I did it -- after all the suspensions  
19 were made, I measured the pH.

20 "Question: Did you measure it prior to  
21 submitting your report?

22 "Answer: I measured it after I submitted the  
23 report.

24 "Question: Do you remember which batch you  
25 measured the pH in?

## Govindarajan - designations

1           "Answer: I measured it on the final 500 ml  
2 batch that I made.

3           "Question: Do you remember the pH?

4           "Answer: The pH was 3.1.

5           "Question: Why wouldn't you -- what does it  
6 mean to be able to make the pharmaceutical formulation?

7           "Answer: So the ability to make a composition  
8 depends on the components and the process. So if you  
9 have -- there are functional ingredients that play a  
10 particular role. And the ability to have all of those  
11 ingredients put together in the right process by  
12 conventional techniques that formulators are trained on, the  
13 ability to use those tools to make a composition is the  
14 ability to make a pharmaceutical formulation.

15           "Question: So if you made a composition and it  
16 resulted in -- strike that.

17           "If you put together this formulation and it  
18 was, say, a goop, would you have said that you would have  
19 would have been able to make a pharmaceutical formulation?

20           "Answer: By the definition of formulation or  
21 pharmaceutical composition, it is still a pharmaceutical  
22 composition, yes. I would have evaluated it, and those  
23 tests would have reflected its properties.

24           "Question: Have you worked on azelastine  
25 hydrochloride before?

## Govindarajan - designations

1 "Answer: I have not.

2 "Question: You didn't have a particular  
3 tonicity target or something you had in mind for this line  
4 of product?

5 "Answer: So the product was made exactly as per  
6 the composition in Example III. So the goal was not to  
7 target a property but to make a preparation and characterize  
8 it.

9 "Question: Did you consider the uses disclosed  
10 in those references describing this grade of HPMC?

11 "Answer: That's correct, they -- so I did. And  
12 this is typically talked about for tablet coating or coating  
13 or binding properties for solid formulations. But it  
14 doesn't restrict that use to that particular formulation.  
15 It still serves the purpose in suspensions.

16 "Question: Did you consider whether there were  
17 any other HPMC grades that Shin-Etsu or any other  
18 manufacturer suggested would be suitable for a nasal  
19 prescription?

20 "Answer: I did not.

21 "Question: Did you consider what grade of HPMC  
22 is used in other nasal spray products?

23 "Answer: I did not.

24 "Question: Why not?

25 "Answer: My task here was to prepare a stable

## Govindarajan - designations

1 suspension, and I had an idea of -- well, I had to assess  
2 HPMC. And there are a wide variety of grades that are  
3 available to the formulator to choose from, and they're all  
4 pharmaceutically acceptable. So my goal was to start off  
5 with one and see what it does to the physical properties  
6 before I evaluate whether I need to refine it.

7 "Question: You noted that there were higher  
8 grades --

9 "Answer: Correct.

10 "Question: -- that were used -- strike that.  
11 You noted...

12 "Answer: So going back to your reference to  
13 their literature, Shin-Etsu literature, if I remember right,  
14 they had a table of all the grades that they sell and their  
15 target applications.

16 "But as a formulator with an understanding of  
17 what these components exactly do in the formulation, we know  
18 that you have to tailor the properties of the product to  
19 achieve the final goal. And typically, with a first  
20 approach like this, it is a best-case estimate, and then you  
21 evaluate the properties. And if required, what falls within  
22 the scope of further process refinement will involve  
23 changing grades, changing compositions.

24 "Question: I'm making sure we didn't cut  
25 anything off.

## Govindarajan - designations

1 "Okay. As we discussed earlier, you didn't  
2 conduct any chemical test to be sure of what was actually  
3 sprayed?

4 "Answer: Correct.

5 "Question: So you relied on just your visual  
6 analysis alone to determine whether the product was  
7 uniformly suspended, correct?

8 "Answer: That is correct.

9 "Question: You said that if it visually looked  
10 uniform, chances are it was uniform; was that -- is that  
11 correct?

12 "Answer: If it visually looked uniform, then  
13 there is a suggestion that there is chemical uniformity.

14 "Question: Are there limits to the human eye,  
15 what the human eye can see?

16 "Answer: Definitely, definitely, that's why I  
17 said you would have to couple that with chemical analysis.  
18 If it did not look homogeneous, we know that there was no  
19 chemical homogeneity. As we go from inhomogeneity that is  
20 visually distinguished from a more homogeneous solution, we  
21 go towards chemical homogeneity as well. But then it  
22 depends on the limits that you establish for homogeneity.  
23 Those are relative as well.

24 "Question: Is dose uniformity important in  
25 product development?

## Govindarajan - designations

1 "Answer: True. Yes.

2 "Question: Is it the most important thing in  
3 product development?

4 "Answer: It's one of the other -- one of the  
5 important things. There are other ones.

6 "Question: Did you do anything to determine the  
7 dose uniformity of the three batches that you made?

8 "Answer: I did not.

9 "Question: Do you have any opinions on the dose  
10 uniformity for the three batches?

11 "Answer: I do not, no.

12 "Question: Can a formulation that appears  
13 visually homogeneous be chemically not homogeneous?

14 "Answer: It is possible, yes.

15 "Question: Is a nasal spray that's a method of  
16 treatment that does not provide dose uniformity, is that fit  
17 for purpose?

18 "Answer: Eventually when it's developed, the  
19 process optimization stages, it would probably need to be  
20 demonstrated that it provides uniform doses.

21 "Question: So a product that's a nasal spray  
22 that's a method of treatment that does not provide dose  
23 uniformity is not fit for purpose?

24 "Answer: So it depends on how it's defined and  
25 what the limits are.

## Govindarajan - designations

1           "Question: If you -- you said that you would  
2 consider modifying the grade HPMC for subsequent tests.  
3 Which grade would you select?

4           "Answer: It is beyond the scope in the sense  
5 that I would need more data to make that decision and some  
6 thought as well.

7           "Question: What data would you need?

8           "Answer: For example, I would need to do  
9 chemical stability analysis, chemical uniformity analysis,  
10 everything else, and then come back and refine the process.  
11 And then it's a step-wise development.

12           "Question: Did you select a micronized  
13 triamcinolone?

14           "Answer: I did not intentionally select a  
15 micronized triamcinolone, but I believe what I got was  
16 micronized.

17           "Question: Did you measure the particle size?

18           "Answer: I did not.

19           "Question: Okay. You said you visually looked  
20 at the particle size?

21           "Answer: Just an evaluation to see if there  
22 were big lumps. Visually I wouldn't be able to always tell  
23 if it's micron sized. But I have a good feeling that if  
24 it's final melt were micronized, it was a fine particle  
25 grade.



## Govindarajan - designations

1           "Question: Is that how it was advertised; or is  
2           that your characterization?

3           "Answer: It's my characterization.

4           "Question: Have you ever used a magnetic  
5           stirrer before without turning on the hot plate?

6           "Answer: I have.

7           "Question: Is that a technique known by many in  
8           the art?

9           "Answer: Yeah.

10          "Question: All, would you say all persons of  
11          ordinary skill know that?

12          "Answer: There are magnetic stirrers available  
13          without the heating element in them. So basically they're  
14          designed just to stir and not to heat.

15          "Question: But if you were going to use the hot  
16          plate and stirrer, have you ever used it without turning on  
17          the heat?

18          "Answer: I have.

19          "Question: Why would you do that?

20          "Answer: Because instead of having both a  
21          separate hot plate and stirrer in the lab, if my only  
22          intention would be to mechanically mix something, I wouldn't  
23          need heat if I wasn't planning on using heat.

24          "Question: And you've set out a procedure, is  
25          that right, spanning from stamped Page 4 to stamped Page 5?

## Govindarajan - designations

1 "Answer: That's correct. That was just my  
2 thought process of how I would proceed.

3 "Question: So your first thought was to  
4 combine, you said, the ingredients that would dissolve into  
5 one phase; is that right?

6 "Answer: Correct.

7 "Question: Okay. And those ingredients were  
8 azelastine hydrochloride, sodium chloride, benzalkonium  
9 chloride?

10 "Answer: That's correct.

11 "Question: And then separately you added HPMC  
12 to that mixture?

13 "Answer: Correct.

14 "Question: And that constituted one phase?

15 "Answer: That's correct.

16 "Question: Okay.

17 "Answer: At that stage, it was everything was  
18 in solution. It was one phase.

19 "Question: And then you planned a second phase  
20 for the triamcinolone. Is that correct?

21 "Answer: Yes.

22 "Question: Adding the excipient polysorbate 80,  
23 objection glycerin, and EDTA --

24 "Answer: Correct.

25 "Question: Are you familiar with another

## Govindarajan - designations

1 product which has an active in suspension and one active in  
2 solution?

3 "Answer: I have worked on formulations like  
4 that, and I cannot disclose specifics of what molecules they  
5 were. But, yeah, there are many combination products. I  
6 cannot mention one off the top of my head. But solubilities  
7 differ, so there are ingredients that might dissolve and  
8 there are ingredients that might stay in suspension.

9 "Question: And when you say it's re-dispersed,  
10 are you saying you did not see any more solid visually in  
11 the vial?

12 "Answer: There are solid in the vial because --  
13 but now it's suspended in the entire bulk phase. There's no  
14 concentration of solid at the bottom, which does not -- so  
15 re-suspension is suspending what had separated out and  
16 settled back into the bulk phase in a visually homogeneous  
17 manner.

18 "Question: On this batch, on June 14th, how  
19 long did it stay re-suspended after you gently agitated it?

20 "Answer: I -- based on the experiments, I would  
21 say anywhere between 20 and 30 minutes, but I don't  
22 recollect having that observation on the paper here.

23 "Question: And then you begin to observe the  
24 cylinder over a period of time?

25 "Answer: That's correct.

## Govindarajan - designations

1           "Question: And at 45 minutes, the settled solid  
2 was clearly evident; is that right?

3           "Answer: That is correct.

4           "Question: Is that customary to observe  
5 preparations over time periods?

6           "Answer: Yes. If there is a need for longer  
7 term evaluation.

8           "Question: Can you point to me what the  
9 conventional mixing techniques described -- strike that.

10          "Can you show me what the conventional mixing  
11 techniques in Example I are?

12          "Answer: So Cramer defines addition order in  
13 Example 1 where certain ingredients are added one at a time,  
14 mixed, and allowed to dissolve or completely dispersed  
15 before adding the next. And then in this particular example  
16 for this particular composition, he has a slurry which is  
17 pre-mixed with azelastine and water, which is then added and  
18 then a solution of our composition with other ingredients is  
19 added. All the ingredients are combined with purified water  
20 to make up the appropriate weight. So the way Cramer  
21 defines it is sequential addition using conventional mixing  
22 techniques, which are well known in formulation development.  
23 Mixing techniques could include, you know, the stirrers I  
24 used or the homogenizer I used. They're essentially  
25 stirring and mixing equipment.

## Govindarajan - designations

1           "Question: As you said, Cramer sets forth an  
2 order in which to mix the ingredients; is that correct?

3           "Answer: In Example I, yes.

4           "Question: It suggests mixing a number of the  
5 excipients before adding the actives, either of the actives;  
6 is that correct?

7           "Answer: In this particular example, that's  
8 what has begun.

9           "Question: You didn't follow this order; is  
10 that correct?

11           "Answer: I followed sequential addition of  
12 ingredients with separate addition of actives because their  
13 properties suggested that that would be a good way of  
14 putting them together.

15           "Question: So when you say you followed  
16 sequential addition, you just meant that you added the  
17 ingredients one by one rather than adding all the  
18 ingredients at one time; is that correct?

19           "Answer: Yes.

20           "Question: But you chose to add the actives in  
21 at different times than is disclosed in Example 1; is that  
22 right?

23           "Answer: So the actives, the conventional  
24 mixing technique, and as Cramer points out, in the first  
25 paragraph under Examples, the following examples further

## Govindarajan - designations

1 describe and demonstrate embodiments within the scope of the  
2 presentation invention. The examples are given solely for  
3 the purpose of illustration and are not to be construed as  
4 limitations of the present invention as many variations  
5 thereof are possible without departing from the spirit and  
6 scope of the invention.

7 "So the way I read it is, and this is common  
8 knowledge in the art of putting things together as a  
9 pharmaceutical composition, is using appropriate methods of  
10 addition that are specific to specified compositions.

11 "So in Example 1, and as I also pointed out,  
12 there are different ways of putting them together. There  
13 are different orders. So as defined in Example 1, it is the  
14 use of sequential addition as appropriate for a composition,  
15 using appropriate mixing techniques with appropriate  
16 variations as required.

17 "And Example III says the intranasally  
18 administered pharmaceutical composition of the present  
19 invention is prepared by combining the following components  
20 using conventional mixing techniques, like used in my  
21 report, similar to that described in Example I, with  
22 variations as required by composition, or as deemed suitable  
23 by the formulator.

24 "Question: You thought it was -- strike that.

25 "You decided it was appropriate to vary the

## Govindarajan - designations

1 order of your experiments as compared to what Cramer had  
2 disclosed in Example I; is that correct?

3 "Answer: What was -- the Example I describes a  
4 very different composition, so it does not -- the order of  
5 addition of characterization of the ingredients used is --  
6 does not directly relate, except that it is a technique that  
7 is similar to what's described in Example I.

8 "Question: Do you have experience formulating  
9 steroids?

10 "Answer: I do not.

11 "Question: Did you consult the order of mixing  
12 that Cramer has disclosed before determining your order of  
13 mixing?

14 "Answer: I read through Example I, and --  
15 everything from examples down, and I did look at his  
16 sequential addition, use of conventional mixing techniques.  
17 And what changed composition, obviously, there are  
18 variations required to process a different, altogether  
19 different composition. And I used the technique that I've  
20 described in my experiments.

21 "Question: Your opinion in Paragraph 13 that  
22 Cramer Example III is a suspension that would be acceptable  
23 as a pharmaceutical product is limited to the tests you  
24 conducted in Paragraph IX; is that correct?

25 "Answer: That is correct.

1           "Question: In your opinion, is a product, a  
2 nasal spray product with pH of 3.1 fit for purpose?

3           (Designations end.)

4           THE COURT: Is that --

5           MS. EVERETT: I apologize, Your Honor. I think  
6 that was the last part.

7           THE COURT: Do you have a little more to play,  
8 is that what you are saying?

9           MS. EVERETT: No, Your Honor. I think that last  
10 question shouldn't have been there.

11          THE COURT: We will strike that last question  
12 then.

13          What is next, from the plaintiff?

14          MS. EVERETT: Plaintiffs have no more witness to  
15 call in their rebuttal case.

16          Subject to what defendants do in their reply  
17 case, we may have some witnesses.

18          THE COURT: Okay. All right. Then, back to  
19 defendants.

20          MR. WARNER: Your Honor, Apotex will next call  
21 Jeffrey Press -- I apologize, Your Honor, we are going to  
22 play some of our own videos.

23          THE COURT: Okay. Good afternoon.

24          MR. KLEIN: Your Honor, We have two videos to  
25 play by designation. The first video have of Ms. Patsy



## Jeffery - designations

1     Jeffrey, which took place on April 22, 2016. Ms. Jeffrey  
2     works for Meda, is a 30(b)(6) witness. The total time will  
3     be seven minutes and five seconds, with five minutes and 26  
4     minutes, or 76 percent, allocated to defendants, and one  
5     minute 39 seconds or 24 percent allocated to plaintiffs.

6             I have a binder of the transcript.

7             THE COURT: Thank you.

8             Okay. You may begin when you are ready.

9             (Patsy Jeffery designations placed in record.)

10            "Question: Could you please state your name for  
11     the record?

12            "Answer: I'm Patsy Jeffery.

13            "Question: And then did you have another  
14     position in the company, or did you move on to another  
15     company?

16            "Answer: I moved on to another company.

17            "Question: What company?

18            "Answer: I joined Cipla Limited.

19            "Question: What year was that?

20            "Answer: 1999.

21            "Question: What was your first role there?

22            "Answer: I was part of regulatory affairs.

23            "Question: So in 2005, what did your position  
24     become at Cipla?

25            "Answer: I -- I think it was -- at that point

## Jeffery - designations

1 in time, I was concentrating on business development and  
2 alliance.

3 "Question: And how long did you have that role?

4 "Answer: From then until today.

5 "Question: Ms. Jeffrey, before the break, we  
6 were speaking a bit about this meeting between -- among, I  
7 should say --

8 THE COURT: Are we not able to make it louder?

9 "Question: -- you, Mr. Fishman, Mr. Lulla, and  
10 Ms. Malhotra."

11 THE COURT: All right. Stop it for a second.

12 Is there, do you have another one that you want  
13 to play also? How long is that going to be?

14 MR. HAUER: Your Honor, just a minute.

15 THE COURT: The other one is a minute?

16 MR. HAUER: Yes.

17 THE COURT: All right. We'll all just be quiet.

18 Go ahead.

19 "Question: After this meeting, did MedPointe  
20 send you suggested terms for a license agreement?

21 "Answer: They sent us the terms, yes.

22 "Question: And you thought it was a little low  
23 offer because it didn't appropriately value your IP. That  
24 is what you said earlier?

25 "Answer: Yes.

## Jeffery - designations

1           "Question: Can you explain what you meant by  
2 that?

3           "Answer: So Cipla had the IP on the combination  
4 product. And besides the IP to execute the project, we  
5 definitely had to invest a lot, including our R&D or  
6 manufacturing facilities.

7           "And overall, when you in totality look at  
8 the project or the scope of the collaboration, including  
9 definitely the IP, in my opinion, it was low.

10          "Question: Did you feel that \$1 million was  
11 slightly undervaluing it, significantly undervaluing it?  
12 Can you describe the magnitude of the undervaluing?

13          "Answer: In my opinion, I think it was -- it  
14 was significantly undervaluing it.

15          "Question: Did you think \$1.5 million would be  
16 a fair price?

17          "Answer: No.

18          "Question: For the same reasons \$1 million was  
19 not a fair price?

20          "Answer: Yes.

21          "Question: I want to look at Article 3, which  
22 says, 'payments.' It's on page 7 of the agreement.

23          "With the upfront fee and the milestone fees,  
24 how much did MedPointe end up paying for the license  
25 agreement for this product?

## Jeffery - designations

1 "Or I should say, how much did they agree to pay?

2 "Answer: \$1.5 million.

3 "Question: Did you think that was a fair price?

4 "Answer: No.

5 "Question: In 2006, was the typical price for  
6 an NDA license or licenses for product that still had to go  
7 through that approval process, was it typically more than  
8 one and-a-half million?

9 "Answer: In my opinion, yes, it should have  
10 been significantly higher.

11 "Question: Should it have been more or less  
12 than \$30 million?

13 "Answer: Again, I repeat, it should have been  
14 significantly higher.

15 "Question: Did anyone else at Cipla share your  
16 concerns with the low value of this license?

17 "Answer: I cannot recollect.

18 "Question: Did Mr. Lulla share your concerns?

19 "Answer: He was of the opinion that we should  
20 go ahead with this deal mainly because he was interested in  
21 starting a business relationship with MedPointe, and also  
22 this was our first NDA deal on a nasal spray.

23 "He was an astute businessman. He would -- he  
24 would do things at very low values only to, only to initiate  
25 a very good business relationship, initiate a level of trust

## Jeffery - designations

1 and respect. And that's -- that was the kind of way in  
2 which he ran the business. And considering these factors,  
3 he was of the opinion that we should just move on.

4 "Question: Do licenses of this kind typically  
5 have royalty provisions?

6 "Answer: Yes.

7 "Question: But this one didn't in 2006; is that  
8 right?

9 "Answer: That's right.

10 "Question: Do you know why that was?

11 "Answer: Again, for the reasons that I  
12 mentioned. Mr. Lulla conceded to a new royalty payment only  
13 to forge a relationship between our companies.

14 "Question: I'm going to show you Exhibit 13.

15 "Is this an e-mail from you to Richard Rumbold  
16 at GSK dated March 17, 2008?

17 "Answer: Yes, this e-mail is dated March 2008.

18 "Question: Is this the same date as the prior  
19 e-mail to Sandoz?

20 "Answer: That's right.

21 "Question: And in this e-mail, do you -- was it  
22 your intent to offer the combination product for GSK to  
23 license if they were interested?

24 "Answer: The document talks about the  
25 combination for countries outside North America.

## Jeffery - designations

1                   "Question: Correct. And you were writing  
2 this e-mail hoping or to see if GSK might be interested in  
3 licensing the combination product in those markets?

4                   "Answer: Yes.

5                   "Question: Did anything transpire with GSK  
6 regarding licensing this product?

7                   "Answer: I cannot recollect.

8                   "Question: Did GSK ever make an offer?

9                   "Answer: No.

10                  "Question: I'd like to show you Exhibit 14.

11                  "Is this an e-mail from you to Len Holmes at  
12 AstraZeneca from the same date, March 17, 2008 as the prior  
13 e-mails?

14                  "Answer: Yes.

15                  "Question: And in this letter, was it your  
16 intent to see if AstraZeneca was interested in licensing  
17 the combination azelastine and fluticasone product in these  
18 non-U.S. markets?

19                  "Answer: Yes.

20                  "Question: Did anything ever transpire with  
21 AstraZeneca with respect to licensing this product?

22                  "Answer: No.

23                  "Question: So AstraZeneca never offered to  
24 license this product?

25                  "Answer: No."

## Hostler - designations

1 (Jeffery designations end.)

2 MR. HAUER: Your Honor, our second video is the  
3 deposition of Jeffrey Hostler who is the CFO of Cipla. This  
4 video is with all time allocated to defendants.

5 THE COURT: Okay.

6 (Jeffrey N. Hostler designations placed in record.)

7 "Question: Could you please state your name for  
8 the record?

9 "Answer: My name is Jeffrey Norman Hostler.

10 "Question: For how long were you the director  
11 of finance for MedPointe?

12 "Answer: Several years. And then I became a  
13 senior director of finance.

14 "Question: What is your current position?

15 "Answer: My current title is CFO.

16 "Question: When did you first begin in that  
17 position?

18 "Answer: 2011.

19 "Question: Let me put it this way: Is there a  
20 certain threshold for profitability under which Meda would  
21 consider pulling a drug off the market?

22 "Answer: Typically, as long as it's profitable,  
23 we would continue selling it.

24 "Question: If the product fetches any profit,  
25 whether it would be a dollar or a million dollars, would you

Press - direct

1 consider that product profitable in the sense you have been  
2 discussing?

3 "Answer: If it has a profitability that's  
4 greater than zero, by definition, that would be a profitable  
5 product.

6 (Designations end.)

7 THE COURT: Okay. What is next?

8 MR. WARNER: Your Honor, now Apotex will call  
9 Jeffrey Press.

10 THE COURT: Okay.

11 JEFFREY PRESS, having been first duly sworn, was  
12 examined and testified as follows ...

13 THE COURT: Good afternoon, Mr. Press. Welcome.

14 THE WITNESS: Good afternoon.

15 MR. WURMAN: May I approach?

16 (Binders passed forward.)

17 THE COURT: You may proceed.

18 MR. WARNER: Thank you, Your Honor.

19 DIRECT EXAMINATION

20 BY MR. WARNER:

21 Q. Good afternoon, sir. Can you please introduce  
22 yourself?

23 A. Sure. My name is Jeffrey Press.

24 Q. What do you do for a living, Mr. Press?

25 A. I am a director in the Forensic, Litigation &



Press - direct

1 Valuation Services Group at Baker Tilly in Philadelphia.

2 Q. Mr. Press, can you tell us a little bit about your  
3 involvement in this case prior to today?

4 A. Sure. I was involved from the outset of my firm's  
5 participation in this engagement. I was involved in the  
6 analysis of documents produced in this case, analysis of  
7 deposition testimony, and I assisted in drafting an expert  
8 report in this case.

9 Q. Did you file an expert report in this case, yourself?

10 A. I did not sign an expert report, no.

11 Q. So how is it you are coming here to testify or under  
12 what circumstances?

13 A. I'm sorry. My colleague Glenn Newman had signed an  
14 expert report in this case but unfortunately he experienced  
15 a serious medical issue and is not available to testify.

16 Q. Are you familiar with the subject matter of his  
17 report around the opinions in it; Mr. Newman's report, that  
18 is?

19 A. Yes, I am.

20 Q. Do you agree with those opinions?

21 A. Yes, I do.

22 Q. Do you adopt them as your own?

23 A. Yes.

24 Q. Are you prepared to testify about them today?

25 A. Yes.

Press - direct

1 Q. Have you ever testified in court before, Mr. Press?

2 A. No, I have not.

3 Q. Okay. Let's get started then. I want to -- did you  
4 bring some slides with you, sir?

5 A. Yes, I did.

6 Q. And so this is DDX, the 6 series, and let's go to  
7 DDX-6.01.

8 Can you just summarize, Mr. Press, your opinions  
9 in this case? And you are testifying on the subject matter  
10 of commercial success; is that right?

11 A. That's correct.

12 Q. So if you could summarize your opinions, please?

13 A. In my opinion, Meda has not established that Dymista  
14 is a commercial success such that if the claimed invention  
15 had been obvious, then another pharmaceutical developer  
16 would have launched the product in order to achieve that  
17 success.

18 As part of that analysis, there are reasons  
19 other than nonobviousness why a competitor may not have  
20 made an azelastine/fluticasone combination product.

21 There are reasons why Meda and Cipla may have  
22 made sales that have nothing to do with the claimed  
23 combination.

24 And the license between Meda and Cipla is not,  
25 in and of itself, indicative of commercial success.

Press - direct

1 Q. All right. Thank you, sir. We'll dig into those  
2 opinions.

3 I want to talk briefly about your background.  
4 This is DDX-6.02 with excerpts from DTX-295. Can you  
5 identify that, sir?

6 A. Yes. This is an excerpt of my CV.

7 Q. Can you tell us about your educational background?

8 A. Yes. I graduated from Franklin and Marshall College  
9 in Lancaster, Pennsylvania in 1998 with a Bachelor of Arts  
10 in Business Administration with a concentration in Accounting.

11 Q. And what have you done since then in terms of  
12 professional work, sir?

13 A. In terms of professional work. Upon my graduation, I  
14 spent four and-a-half years in the audit practice at Ernst &  
15 Young in the Washington, D.C. area.

16 And then since 2003, for almost now 14 years,  
17 I've been a member of the Forensic, Litigation & Valuation  
18 Services Group.

19 Q. Can you describe the type of work you do at Baker  
20 Tilly?

21 A. Sure. The people in the Forensic and Litigation  
22 Group in our practice, we have experience in analyzing  
23 various financial and economic and accounting data such as  
24 sales, costs, profitability, analysis of market, market  
25 dynamics and competition, and will many times apply that

Press - direct

1 information in various consulting engagements, including  
2 litigation, litigation matters such as intellectual property  
3 disputes such as this one.

4 Q. In those types of intellectual properties dispute,  
5 have you been involved in analyzing the issue of commercial  
6 success of patents or patented products?

7 A. Yes, I have been involved in commercial success  
8 analyses as well as patent damages and general consulting on  
9 patent issues.

10 MR. WARNER: Your Honor, I will proffer  
11 Mr. Press as an expert in the financial and economic  
12 analysis of commercial success.

13 THE COURT: All right. Any objection?

14 MR. VARUGHESE: No objection, Your Honor.

15 THE COURT: Okay. He is so recognized.

16 BY MR. WARNER:

17 Q. Mr. Press, can you explain your understanding of the  
18 concept of commercial success and why it is relevant from an  
19 economic and financial perspective in valuing intellectual  
20 property?

21 A. Sure. Commercial success involves an analysis and  
22 assessment of a product's marketplace, performance or  
23 success in the market to determine whether that marketplace  
24 performance rises to the level such that if an invention had  
25 been obvious, then another pharmaceutical company or another

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1 competitor would have launched the product.

2 Q. Does it always hold true if an invention is obvious,  
3 a competitor or someone in that market would make it and  
4 sell the product?

5 A. No. There may be reasons why somebody makes a  
6 decision not to launch a product.

7 Q. Did you look and see whether some of those reasons  
8 exist in the context of this case and the patents in suit?

9 A. Yes. As part of our analysis, we looked at a number  
10 of factors relevant to the commercial success.

11 Q. What are some of those factors?

12 A. We looked at the existence of what has been referred  
13 to as a blocking patent in this case is one factor.

14 Q. Let's take a look at the blocking patent. This is  
15 DDX-6.03, referring to DTX-16.

16 And before we go on, sir, can you explain the  
17 concept of what is a blocking patent?

18 A. A blocking patent would be a patent that is separate  
19 and apart from the patents in suit. However, the claims of  
20 that blocking patent can still cover aspects of the claimed  
21 invention currently at issue such that those claims may  
22 restrict the ability to launch a product.

23 Q. And is that something a rational economic actor would  
24 consider when they are deciding whether to make a product  
25 that might infringe someone else's patents?

Press - direct

1 A. Yes, I think that is a reasonable consideration one  
2 would make because there are various risks and exposure of  
3 launching a product in light of a patent.

4 Q. In your view, is there a blocking patent in this  
5 case?

6 A. Well, in this case, yes. What is relevant is the  
7 Astelin patent that launched in 1992 and was in effect  
8 through the pediatric exclusivity that ended May 1st, 2011.

9 Q. Putting aside the blocking patent, have you considered  
10 the context of the market in which Dymista plays in this case?

11 A. Yes, I also considered certain market data.

12 Q. You were in the court when Mr. Jarosz testified; is  
13 that right?

14 A. That's correct.

15 Q. We talked about, I talked about with him some of the  
16 market share data relevant to Dymista and fluticasone and  
17 azelastine. Do you recall that?

18 A. I do recall that.

19 Q. So is it relevant to your analysis that a combination  
20 azelastine/fluticasone product launched after 2002 would be  
21 in a market with fluticasone and azelastine?

22 A. Yes, I do think that is relevant.

23 Q. How is that?

24 A. Well, in launching a generic -- I'm sorry. In  
25 launching a combination fluticasone and azelastine product

Press - direct

1 such as Dymista, Dymista would be launching into a market  
2 whereby its own components, fluticasone and azelastine exist  
3 in that market. So, in essence, Dymista would compete  
4 against its own components and, therefore, Dymista would  
5 have to be able to differentiate itself and separate itself  
6 from the availability of its own components, which some of  
7 the data we see, that is available in generic form and sells  
8 at high volume.

9 Q. And have you seen evidence of whether or not Dymista  
10 has been able to differentiate itself?

11 A. Yes, I have seen evidence to suggest that there were  
12 challenges in being able to do that.

13 Q. And we are looking at DDX-6.04, referencing PTX-1117  
14 at Pages 2 to 4.

15 Can you describe this evidence, sir?

16 A. Yes. This is an excerpt from a document outlining a  
17 statement that was made by a company called Nordea Se, which  
18 is one of the investors in Meda. And from Nordea Se's  
19 perspective, they state, we argue that the cost benefit  
20 profile of Dymista versus cheap generic standard of care  
21 fluticasone is simply not good enough for a for commercial  
22 success.

23 Then they go on to talk about challenges with  
24 respect to insurance coverage and that the level of coverage  
25 would continue to hamper the use of Dymista.

Press - direct

1 Q. Can you describe the relevance of insurance coverage  
2 in this analysis?

3 A. Sure. Prescription drugs are typically placed on  
4 what is referred to as drug formularies, whereby insurance  
5 companies will place drugs on different tiers. The  
6 different tiers then correspond to how much of that drug  
7 will be paid for by the insurance company as opposed to the  
8 patient.

9 And there are various considerations that go  
10 into that tier placement on the formulary. And those  
11 include both therapeutic considerations as well as economic  
12 considerations and the availability of alternatives.

13 Q. Have you analyzed the impact of that insurance and  
14 payee/payor structure on Dymista in this case?

15 A. Well, we have seen evidence in various records that  
16 show the challenges that Dymista faced because it was not  
17 receiving favorable formulary placement.

18 Q. And were you here, I think it was the first day of  
19 trial, when Dr. Accetta testified?

20 A. Yes, I was.

21 Q. Did you hear testimony from him relevant to this  
22 subject matter?

23 A. Yes. Dr. Accetta talked about his prescribing of  
24 Dymista, with respect to insurance coverage of it.

25 Q. I put up a slide. This is DDX-6.06, which has some



Press - direct

1 of his testimony from the first day. What does he say,  
2 briefly?

3 A. Well, in general, he states that he doesn't currently  
4 prescribe Dymista because it receives poor insurance  
5 coverage. In fact, he says, Virtually none of our major  
6 carriers in Massachusetts will cover Dymista.

7 That's the substance of that.

8 Q. Okay. And so how would the ability to differentiate  
9 insurance formulary issues -- by the way, would those  
10 factors be known to a competitor thinking about entering  
11 into the nasal spray market with a combination azelastine-  
12 fluticasone product?

13 A. Yes, I believe they would.

14 Q. So how would the existence of those factors affect  
15 their analysis of whether or not it would be economically  
16 rational to launch that product?

17 A. Ultimately, you know, these factors refer to the  
18 competition that Dymista would face, as well as the ability  
19 of patients, consumers to get access to those drugs through  
20 insurance coverage.

21 So those are certainly relevant factors to an  
22 economically rational decision-maker in deciding whether or  
23 not to introduce a product.

24 Q. Have you seen evidence from Meda reflecting the  
25 existence of risks and uncertainties like this?

Press - direct

1 A. Well, I think risk and uncertainty can -- whether it  
2 is these that we have talked about or any other market type  
3 risks can manifest themselves when you look at a product's  
4 actual performance against forecasted performance,  
5 forecasted performance representing the expectations of  
6 people in the business. So looking at the actual forecasts  
7 can be a manifestation of challenges in a market.

8 Q. Have you looked at Meda's ability to meet forecasted  
9 numbers with respect to Dymista?

10 A. We looked at a number of different comparisons of  
11 Meda's actual -- actual performance against a variety of  
12 forecasts.

13 Q. And have you summarized that data on DDX-6.07?

14 A. I summarized certain of that data here. What we saw  
15 was there were a number of different versions of forecasts  
16 prepared by Meda. They were continually being revised. So  
17 I have summarized forecasts across 2013, '14 and '15, again  
18 their actual results during those time periods, against  
19 these select forecasts.

20 And as you can see here, the data reflects that  
21 actual results came in below forecasts, and we saw that  
22 occur even as Meda was revising their forecasts.

23 Q. This document refers to PTX-1123, PTX-267, PTX-1189,  
24 PTX-268, and PTX-270.

25 Sir, Mr. Jarosz also spoke about nexus. Do you

Press - direct

1 recall that?

2 A. I do.

3 Q. Can you explain the relevance of the analysis of  
4 nexus in the commercial success analysis?

5 A. Nexus looks at the issue of whether the asserted  
6 performance or the asserted success is derived from the  
7 claimed invention: Is there a direct connection or nexus to  
8 the claimed invention as opposed to other factors that are  
9 contributing to that success?

10 Q. Have you seen in this case that Dymista sales may be  
11 the result of factors other than the patented invention?

12 A. Yes. We looked at a few different factors that are  
13 relevant to the nexus issue.

14 Q. Could we take a look at DDX-6.1, referencing PTX-826  
15 and PTX-836.

16 Can you explain what you looked at, sir?

17 A. What we show here are a couple excerpts from Meda  
18 documents with respect to the marketing of Dymista. We see  
19 in the first excerpt at the top that Meda is referring to  
20 the category that Dymista is in, as being a promotionally  
21 sensitive category, promotional sensitivity referring to  
22 that, in a promotionally sensitive category are a group of  
23 products, one could expect perhaps an exponential impact or  
24 increase in sales with marketing investment, compared to  
25 non-promotionally sensitive products. So they are

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1 highlighting that promotional sensitivity in the overall  
2 category.

3 Then in the excerpt at the bottom, they  
4 highlight that Dymista growth in one week versus the prior  
5 week was driven by core team promotion after the  
6 implementation of a plan of action. Again, just  
7 highlighting their overall marketing in sales of Dymista.

8 Q. Now, Mr. Jarosz also talked a little bit, sir, about  
9 the combination azelastine-fluticasone products in India.  
10 Do you recall that?

11 A. Yes.

12 Q. One of the products he discussed was Duonase?

13 A. That's correct.

14 Q. Have you analyzed whether or not there is evidence  
15 suggesting that sales of Duonase may be due to factors other  
16 than the inventions at issue in the case?

17 A. We looked at certain factors in India as well, yes.

18 Q. DDX-6.11, which references PTX-510.

19 Can you explain some of the other factors that  
20 you saw when you reviewed the evidence?

21 A. We saw evidence that in the 2010 time frame Cipla had  
22 undertaken what they referred to as the sweet relief  
23 campaign, which introduced a sweetener in order to mask the  
24 bitter taste of Duonase. And as we see at the bottom there,  
25 the theme of the campaign, or the primary theme of the

Press - direct

1 campaign would focus on that change from bitter taste to  
2 sweetness.

3 So they were crafting a campaign around the  
4 sweetener, which it is my understanding is not something  
5 related to the claimed invention.

6 Q. And did you do an analysis of whether or not  
7 Cipla's -- that is another one of the plaintiffs. Right?  
8 Cipla?

9 A. Yes, that's correct.

10 Q. Whether or not their brand equity as opposed to  
11 aspects of the alleged inventions played a role in the sales  
12 of Duonase in India?

13 A. Yes. We also saw other documents highlighting the  
14 role of -- the importance and the role of Cipla's brand  
15 account.

16 Q. Let's take a look at -- skip to 6.13, which  
17 references DTX-113, can you explain what this evidence is?

18 A. Yes, this is a document that Cipla had prepared,  
19 where, in essence, they were highlighting the goal of  
20 leveraging off of their position in another therapeutic  
21 area.

22 Cipla manufactures drugs and sells drugs in a  
23 variety of different therapeutic areas.

24 So they had highlighted in the upper right-hand  
25 corner the goal here of translating Cipla's brand equity in

Press - direct

1 the respiratory market, its leadership in that market into  
2 allergic rhinitis therapy, where Duonase is sold.

3 Q. So is leadership in brand equity in respiratory  
4 relevant to the adversaries of allergic rhinitis drugs, like  
5 the combination product?

6 A. Again, something like brand equity would be outside  
7 of the claimed invention.

8 Q. And I am going to move on. Before I do, I want to  
9 make sure that DDX-6.13 is known to reference DTX-133.

10 One last topic, Mr. Press. Did you hear Mr.  
11 Jarosz reference the license agreement between Cipla and  
12 Meda?

13 A. I did.

14 Q. Have you formed any opinions based on your review of  
15 the data about whether or not the existence of that license  
16 is reflective of commercial success?

17 A. Yes, I did. I considered the testimony of Cipla's  
18 representatives, Patsy Jeffrey, who we just reviewed some of  
19 her deposition testimony, from her perspective as the  
20 corporate representative, the fee that Meda was paying to  
21 Cipla was low. It undervalued the intellectual property  
22 that was being licensed.

23 So we are looking at a license that at least  
24 the licensor in that case viewed as having a low royalty  
25 that wasn't paying the full value of the intellectual

Press - direct

1 property.

2 Q. So, Mr. Press, based on the analysis that Mr. Jarosz  
3 has done and the analysis that you have done, and all the  
4 factors and evidence that you have considered, are you able  
5 to call Dymista a commercial success?

6 A. I think, based on the information and evidence that's  
7 available at this time, I don't think we are able to  
8 establish it as a commercial success.

9 MR. WARNER: Your Honor, I have no further  
10 questions. Before I pass the witness, I would like to read  
11 in our exhibits. We have DTX-16, DTX-103, DTX-104, DTX-133,  
12 DTX-295, PTX-267, PTX-268, PTX-270, PTX-446, PTX-510, PTX-826,  
13 PTX-836, PTX-1117, PTX-1123, and PTX-1189.

14 THE COURT: Any objection?

15 MR. VARUGHESE: No objection, Your Honor.

16 THE COURT: Those are all admitted. Thank you  
17 very much.

18 (Above-referenced exhibits received in evidence.)

19 MR. WARNER: Thank you.

20 THE COURT: Cross-examination.

21 MR. VARUGHESE: Your Honor, one housekeeping  
22 item. I don't know that I formally asked that Dr. Kaliner's  
23 demonstrative slides be admitted in this case.

24 THE COURT: They are accepted as demonstratives.

25 MR. VARUGHESE: Thank you.

Press - cross

1 CROSS-EXAMINATION

2 BY MR. VARUGHESE:

3 Q. Good afternoon, Dr. Press.

4 A. Good afternoon.

5 Q. Nice to meet you. My name is Dennis Varughese.

6 A. Nice to meet you.

7 Q. Earlier you heard Mr. Jarosz testify that Dymista is  
8 a commercial success, correct?

9 A. That's correct.

10 Q. He relies on sales since Dymista launched in 2012 to  
11 support his opinions?

12 A. That's correct.

13 Q. And he further opines that he believes there is a  
14 nexus from those sales to the patents in suit?

15 A. That's correct.

16 Q. Can we go to DDX-601, please.

17 So this is a summary that you just described of  
18 your opinions. Obviously, you disagree with Mr. Jarosz.  
19 And one of the reasons is that you cite a blocking patent.  
20 Correct?

21 A. That's correct.

22 Q. And if I understand your position correctly, you are  
23 saying that the sales of Dymista can't be attributed to the  
24 patents in suit here because there is no nexus because the  
25 blocking patent in your view is what is driving those sales.



1 Is that accurate?

2 A. Well, I think the way I look at the blocking patent  
3 is that commercial success is asking the question with  
4 respect to obviousness and suggesting that if the patent or  
5 the claimed invention had been obvious, then somebody else  
6 would have launched the product.

7 And in my opinion the existence of that blocking  
8 patent is a factor that would or could prevent somebody from  
9 launching a product even if the patent -- if the claimed  
10 invention had been obvious.

11 Q. Respectfully, Mr. Press, I wasn't asking for your  
12 explanation. I was giving you my understanding and I wanted  
13 to know if you agreed with it. If you didn't, I thought we  
14 could discuss what parts you didn't agree with. So I would  
15 like to try that again.

16 When you cite the blocking patent, your position  
17 is that the sales of Dymista can't be attributed to the  
18 patents in suit here because in your view the blocking  
19 Hettche patent, the '194, you believe, is conferring some  
20 benefit to Dymista. So therefore, it breaks the nexus  
21 between the patents in suit and Dymista. Is that your  
22 opinion?

23 A. I don't know that I articulate it as a nexus --

24 Q. You haven't looked at nexus?

25 A. I looked at factors that are relevant to nexus, I

Press - cross

1 believe.

2 MR. WARNER: I want to make sure he gets a  
3 chance to finish his answer.

4 THE COURT: Make sure he can do that.

5 BY MR. VARUGHESE:

6 Q. In your view, does the '194 patent affect the issue  
7 of nexus here, the nexus between the sales of Dymista and  
8 the patents in suit? Have you examined that?

9 A. As to whether the claims of the '194 impact sales of  
10 Dymista?

11 Q. Let's try that. Do you think the claims of the '194  
12 or the '194 patent impact sales of Dymista?

13 A. I haven't looked at the specific claims. I know that  
14 they refer to an azelastine nasal spray. To the extent that  
15 other competitors were precluded or dissuaded from  
16 introducing an azelastine nasal spray, including a  
17 combination fluticasone/azelastine, and therefore this  
18 became a pull of sales for the Dymista product, perhaps you  
19 could articulate that as a nexus.

20 Q. Let me ask a much simpler question. Do you think the  
21 '194 -- that is the patent that you cited as the blocking  
22 patent. Correct?

23 A. That's correct.

24 Q. Do you think that '194 patent affects the sales of  
25 Dymista in any way?

Press - cross

1 A. Well, I think that, to the extent, for a period of --  
2 a number of years, at least through May of 2011, to the  
3 extent it prevented anybody else from introducing a product,  
4 then, yes, I would say it affected Dymista sales.

5 Q. And did it preclude anyone else from entering the  
6 market?

7 A. I can't pinpoint to any specific companies that it  
8 precluded. But I am also not sure that that would be  
9 publicly disclosed information.

10 Q. But you have not identified anyone that was actually  
11 blocked by that patent, right, in your testimony today?

12 A. No, I haven't identified anyone specifically.

13 Q. And you haven't identified anyone in your  
14 demonstratives who was actually blocked. Correct?

15 A. No. Again, as I said, I am not sure that that is the  
16 type of information that's typically put into the public  
17 domain.

18 Q. Let's go to DDX-6.03. The next one.

19 So this is your timeline from your  
20 demonstrative, you think, of the relevant dates. So the  
21 blocking patent or the patent, the Hettche patent that you  
22 cite as a blocking patent expired in 2011. Correct?

23 A. That's correct.

24 Q. And the sales that Mr. Jarosz is relying on didn't  
25 commence until September 2012. Correct?

Press - cross

1 A. That's correct.

2 Q. And there was a window here, a one-year window, even  
3 assuming, and we get to why I don't think you are correct,  
4 even assuming you are correct and this is a blocking patent,  
5 there was a full one-year window where anyone could have  
6 launched before Meda -- beat Meda to the punch. Right?

7 A. Well, I think, in that one-year window, I think there  
8 is other information that presumably a potential competitor  
9 would be aware of that could still dissuade them from  
10 launching a product.

11 Q. Now you are speculating?

12 A. Well, I know that there is information that is out  
13 there.

14 Q. You didn't testify to any of it?

15 A. I know it was discussed with Mr. Jarosz that the  
16 application of the patents in suit were published, I think,  
17 as far as back as 2003.

18 Q. Let's talk about this. Are you talking about this  
19 right here (indicating,) the applications that result in the  
20 '620 and the '428 patents? Is that what you are talking  
21 about?

22 A. Yes.

23 Q. Why do you think that's relevant here?

24 A. Well, to somebody who is considering launching a  
25 combination product, one would consider that there are

Press - cross

1 published patent applications for that product.

2 Q. So does that contribute to your blocking theory,  
3 those applications?

4 A. Yes. It could be a relevant factor in that 2011 to  
5 2012 time frame, and somebody's decision not to launch a  
6 product.

7 Q. So these applications could have dissuaded someone in  
8 this range, is that what you are saying?

9 A. It could be a part of a consideration of a number of  
10 factors.

11 Q. And that's a factor that you took into account in  
12 formulating your blocking theory?

13 A. To the extent that it could impact somebody's  
14 decision in that 2011-2012 time frame.

15 Q. Do you understand that these are the applications  
16 that resulted in the patents in suit that we are litigating  
17 here today?

18 A. Yes. That's my understanding.

19 Q. And the reason why Meda and Cipla have sued Apotex is  
20 because those applications resulted in patents that are  
21 supposed to block. That is the whole purpose of this  
22 litigation. Do you understand that?

23 A. Can you rephrase that question?

24 Q. You testified earlier that a blocking patent is a  
25 patent that is not at issue. Do you remember that?

Press - cross

1 A. Yes.

2 Q. And you are telling me now that you think these  
3 applications have the power to dissuade other competitors  
4 and that you factored that into your blocking analysis?

5 A. Well, we started discussing that issue with respect  
6 to why somebody may not launch a product after the  
7 expiration of what I was referring to as the blocking  
8 patent.

9 Q. And I don't want to mischaracterize his words. I'm  
10 just asking your recollection. Were you in the courtroom  
11 when counsel for both sides gave their openings?

12 A. Yes, I was.

13 Q. And do you recall Mr. Lombardi citing these  
14 applications as a factor that went to blocking?

15 A. I don't recall.

16 Q. If he said that, would you agree with him?

17 A. That it's a factor that goes to blocking?

18 Q. Yes.

19 A. I don't know all of the factors that Mr. Lombardi is  
20 considering, so I can't say one way or another.

21 Q. Okay. Are you familiar with the safe harbor  
22 provision? Strike that.

23 If I were to ask you are you familiar with the  
24 safe harbor provision of the Hatch-Waxman Act, would you  
25 know what I was talking about?

Press - cross

1 A. I heard reference to it.

2 Q. And I'm going to give you my understanding and let me  
3 know if we're on the same page.

4 A. Sure.

5 Q. Even if someone was afraid of this '194 patent, under  
6 the safe harbor provision, a company could prepare their NDA  
7 or ANDA, any drug application that needs to go to the FDA  
8 and be ready and obtain approval some time here and be ready  
9 to launch right at this date. Right?

10 A. Can you say that last part again, about the launch?

11 Q. As soon as the patent -- are you familiar with the  
12 term Paragraph III certification? Do you know what I'm  
13 saying when I say that?

14 A. Paragraph III?

15 Q. Yes.

16 A. No, I'm not.

17 Q. So accept my representation. Instead of a Paragraph  
18 IV, a generic company could file an application and file a  
19 Paragraph III certification, have tentative approval, and  
20 the day after this patent expires, they can jump on the  
21 market. Do you understand that?

22 A. I'll accept your representation of that.

23 Q. So if this patent was actually blocking someone,  
24 doesn't it stand to reason you would see evidence of that?

25 A. I think there are still other factors that come into

Press - cross

1 play, that go into that decision of whether or not to launch.

2 Q. That -- I'm sorry. I didn't mean to cut you off.

3 A. Sorry. Discussion that Meda was in Phase III trials  
4 as far back as 2008. So you know that there is at least  
5 one other product coming on to the market. And I think  
6 some of the factors we discussed before of the availability  
7 of certainly at that point generic azelastine, generic  
8 fluticasone, those in totality altogether become part of  
9 that decision of whether or not to launch a product.

10 So I don't think that it's just merely a function  
11 of the only consideration is the expiration of that patent.

12 Q. And the litany of factors you just mentioned have  
13 nothing to do with the '194 Hettche patent; right?

14 A. There are other factors, yes, that are relevant to  
15 the decision of whether or not to launch a product.

16 Q. In fact, Mr. Press, aren't you aware there is actual  
17 evidence of people not being blocked by the Hettche product  
18 regarding the azelastine formulation?

19 A. I'm not aware.

20 Q. Well, let's discuss that. You were in the courtroom  
21 when Drs. Donovan and Schleimer testified?

22 A. I believe for portions of it.

23 Q. Were you here when they discussed the Cramer  
24 reference from Proctor & Gamble?

25 A. I heard a number of references to Cramer.



Press - cross

1 Q. Do you remember if I were to say Cramer or do you  
2 want me to refresh your memory?

3 A. You can refresh my memory.

4 Q. Okay. So the way I understood it, Drs. Schleimer and  
5 Donovan believe the Cramer reference, a patent application  
6 by Proctor & Gamble, covered an azelastine/fluticasone  
7 combined nasal spray. Do you recall that?

8 A. I don't recall it.

9 Q. Okay. So allow me to give you a representation that  
10 there is such thing as a Cramer reference, and the testimony  
11 more or less was that, and you can assume that is true and I  
12 won't hold that against you.

13 A. Okay.

14 Q. If the reference did claim such a combination, isn't  
15 that evidence that Proctor & Gamble wasn't blocked? They  
16 weren't dissuaded?

17 A. I don't know -- I don't know if Proctor & Gamble  
18 actually launched a product covered by that. I'm not aware.

19 Q. And you don't know if they were blocked either?

20 A. No.

21 Q. But what we do know is they filed a patent  
22 application?

23 A. Well, I think filing an application is different  
24 than launching a product, which is what I was talking about  
25 in that intervening 11 and 12 time period.

Press - cross

1 Q. I understand. But Proctor & Gamble filed the  
2 patent application which, according to Dr. Donovan and  
3 Dr. Schleimer, supposedly claimed fluticasone/azelastine  
4 formulation. In that regard, Proctor & Gamble, the only  
5 reasonable inference is, was pursuing such a formulation;  
6 correct?

7 A. I'll accept the representation of pursuing a  
8 formulation, but, again, I think we started on this topic  
9 of discussion with respect to actually launching a product.  
10 So I'm not aware if they have actually launched a product.

11 Q. Is it your opinion that someone has to actually  
12 launch a product in order to not be blocked under this  
13 analysis?

14 A. Well, I think that is the issue that we're looking  
15 at. We're looking at the issue of whether or not somebody  
16 else would have launched a product in light of the purported  
17 marketplace performance that has been asserted as part of  
18 the commercial success analysis.

19 So, yes, I'm evaluating it from a product launch  
20 perspective.

21 MR. VARUGHESE: Your Honor, I'm cognizant of  
22 the admonition you gave me on Tuesday for cutting off the  
23 witness. I'm trying to ask the gentleman some yes-or-no  
24 questions, and he is giving lengthy answers.

25 THE COURT: It's not clear you are giving him

Press - cross

1 yes-or-no questions. So if you want to try to focus your  
2 questions, more maybe he will be able to answer them yes or  
3 no.

4 MR. VARUGHESE: That's fair.

5 BY MR. VARUGHESE:

6 Q. Are you familiar with the Segal reference that we  
7 discussed this week?

8 A. No, I'm not.

9 Q. Do you understand that the Segal reference was a  
10 patent application by Warner Lambert?

11 A. I'm not aware. I'll accept your representation of  
12 that.

13 Q. That's a fine answer. I'll represent to you,  
14 are you aware that Drs. Donovan and Schleimer have  
15 taken the position that that Segal reference covers an  
16 azelastine/fluticasone combination fluticasone combination?

17 A. I'm not aware one way or the other on that.

18 Q. And if Warner Lambert did indeed file such an  
19 application, taking my representation, it stands to reason  
20 that Warner Lambert wasn't blocked by the '194 patent  
21 because they were pursuing that formulation; correct?

22 A. Well, again, I'll come back to how we're looking at  
23 blocking in the context of how I'm evaluating the question  
24 of commercial success, and I'm approaching it from the  
25 standpoint of whether or not somebody launched a product.

Press - cross

1 So I'm not aware if Warner Lambert actually launched a  
2 product.

3 Q. Hettche is a U.S. patent; correct?

4 A. That is my understanding.

5 Q. And Hettche doesn't block anyone outside of the U.S.?

6 A. That is correct.

7 Q. Did you look to see if there were blocking patents  
8 anywhere outside the United States, like Europe?

9 A. I did not.

10 Q. So if this invention was so obvious, someone elsewhere  
11 in the world would have made it before Cipla; right?

12 A. I'm sorry. Can you say that again?

13 Q. If this invention was obvious, and you are saying  
14 that it's the Hettche patent and not the nonobviousness  
15 of the invention that kept others from inventing it before  
16 Cipla, if that is true, the invention was so obvious,  
17 someone would have made it in Europe; right?

18 A. I haven't evaluated all the reasons of why somebody  
19 would or wouldn't launch a product in Europe.

20 Q. Okay. And during your testimony, you discussed the  
21 Indian marketplace for allergic rhinitis nasal sprays;  
22 right?

23 A. I believe we talked about the sweet relief campaign  
24 and Cipla's brand recognition.

25 Q. And you understand that Cipla was a first to launch

Press - cross

1 this combination of nasal product in India?

2 A. That is my understanding.

3 Q. And that after Cipla launched it, a number of copycat  
4 generics entered into the market?

5 A. Yes, I have seen that data.

6 Q. Did you evaluate whether there was any blocking  
7 patents in India blocking any of those Indian copycats to  
8 the market before Cipla did?

9 A. I did not evaluate the Indian patent landscape.

10 Q. You testified on the safe harbor. Mr. Press, are you  
11 familiar with the Hatch-Waxman ANDA litigation, the way it  
12 works?

13 A. Generally.

14 Q. So you know if the patent is an Orange Book, when a  
15 generic company wants to file an application, they have to  
16 certify to one or more of those patents. You are familiar  
17 with that?

18 A. I'm sorry. They have to?

19 Q. Certify, file a certification. You may have heard of  
20 a Paragraph IV certification?

21 A. Yes.

22 Q. What is your understanding of a Paragraph IV  
23 certification?

24 A. Generally, we see that in the context of generic drug  
25 companies, you know, filing that Paragraph IV certification

1 claiming invalidity.

2 Q. So would you agree with me that when a generic  
3 company submits a Paragraph IV certification, that is a  
4 statement that they are going to challenge the patent either  
5 as a non-infringer and it's invalid and they want approval  
6 of their generic as soon as possible; correct?

7 A. That's my general understanding.

8 Q. And it generates litigation, and the brand company  
9 and the generic company fight it out in court; correct?

10 A. Correct.

11 Q. That would be the opposite of blocking. If a generic  
12 company was not dissuaded by that patent, did not fear that  
13 patent, they challenge the patent; correct?

14

15 A. Yes. And, again, I come back to that they have  
16 challenged it, but they haven't launched a product yet.

17 Q. So I'm going to try to ask you a yes-or-no question.  
18 Under your analysis, your blocking analysis, does a product  
19 actually have to be launched in order to not be blocked?

20 A. Yes, in the context of how I looked at this issue of  
21 whether the asserted level of marketplace success that we  
22 heard Mr. Jarosz talk about with respect to Dymista, whether  
23 that would have compelled somebody to launch a product and  
24 that brings us back to somebody to launch a product to  
25 achieve the asserted level of success.

Press - cross

1 Q. Are you aware that this '194 patent was challenged  
2 not one, not two, but six times with a Paragraph IV  
3 certification by various companies? Were you aware of that?

4 A. I was not aware.

5 Q. Were you aware the first such company to do that  
6 was actually Apotex challenged the '194 patent?

7 A. I don't know if they were the first, no.

8 Q. Do you mind turning to Tab 1 in the notebook we have  
9 given you?

10 A. (Witness complies.)

11 Q. You can go to page 17. So this is a complaint. If  
12 we can go to the page 17 before we go to the complaint.

13 You see it says MedPointe versus Apotex?

14 A. Yes.

15 Q. And MedPointe owned the '194 patent; right?

16 A. That's my understanding, yes.

17 MR. VARUGHESE: And if we can scroll down to  
18 where the patent is.

19 BY MR. VARUGHESE:

20 Q. Is that the '194 patent that you have identified as a  
21 blocking patent?

22 A. Yes.

23 Q. Okay. So this is evidence that Apotex wasn't  
24 dissuaded by this patent, challenged it with a Paragraph IV  
25 certification, and went into litigation; correct?

Press - cross

1 A. Yes. That is my understanding that they filed this  
2 litigation.

3 Q. Okay. And I have other complaints in there, and I'm  
4 happy to look through them, but I will tell you there was  
5 Sun Pharmaceuticals. Are you aware, are you familiar with  
6 them?

7 A. Yes, I'm aware.

8 Q. They challenged the '194 patent long before its  
9 expiration.

10 Are you aware of Zydis Pharmaceuticals?

11 A. I have not heard of them.

12 Q. So I'll turn to the tab. It's Tab 6.

13 Can you go to the patent, please?

14 Zydis challenged this patent. Having been  
15 presented with this, does this change your opinion on  
16 blocking at all?

17 A. Again, I don't know all the circumstances around all  
18 of these litigations and what the outcomes of them were.

19 As part of my analysis, I have considered the  
20 existence of this patent and whether this would have been a  
21 factor that an economically rational decisionmaker would  
22 have evaluated.

23 Q. Okay. Thank you. Now, going back to Cipla, you  
24 understand that even though Cipla and Meda are coplaintiffs  
25 in this litigation, they are unrelated companies; correct?



Press - cross

1 A. That is my understanding.

2 Q. And Cipla filed a patent application in the United  
3 States in 2002; correct?

4 A. Well, I'm sorry. For which patent?

5 Q. Cipla filed a patent application for the patents in  
6 suit in 2002?

7 A. Yes, that is my understanding.

8 Q. And those are patents that cover, well, at least we  
9 are asserting azelastine fluticasone?

10 A. Correct.

11 Q. Now, in your experience as an economist, you would  
12 understand when a company is doing that, they are intending  
13 to enter into the market; correct?

14 A. Presumably, yes.

15 Q. So Cipla wasn't dissuaded by the '194 patent;  
16 correct?

17 A. Cipla, from filing an application, but I think Cipla  
18 has not launched a product, again, here in the United States.

19 Q. So if we could turn to DDX-6.15.

20 Now, Mr. Press, using this slide, you testified  
21 earlier about the formulary status of Dymista?

22 A. I don't recall looking at this. I don't know if we  
23 looked at this slide. We discussed the issue.

24 Q. You don't recall looking at this slide right now  
25 during your testimony, during your direct?

Press - cross

1 A. No, I remember talking about formulary access. I  
2 just don't recall reading this slide.

3 Q. Fair enough. Fair enough. This is a slide from your  
4 demonstrative; correct?

5 A. It was prepared, yes.

6 Q. Are you familiar with the slide?

7 A. Yes.

8 Q. Okay. So if I could just draw your attention to the  
9 date. You are relying on a document dated March 31, 2014?

10 A. Correct.

11 Q. In March 2014, Dymista was about a year and-a-half  
12 old, give or take?

13 A. Give or take.

14 Q. Okay. And standing here today, Dymista is about four  
15 years, a little over four years?

16 A. Correct.

17 Q. Beyond this document, it says here, have you, in  
18 preparation for trial or formulating your opinions, did you  
19 look into the current formulary status of Dymista?

20 A. I have seen a number of different documents referring  
21 to formulary status. And I just don't recall the dates of  
22 them.

23 Q. Please turn to 6.06, DDX.

24 Do you recall this slide from your demonstrative?

25 A. Yes.

Press - cross

1 Q. This is testimony by Dr. Accetta; correct?

2 A. Correct.

3 Q. And you are relying on that testimony in formulating  
4 your opinions?

5 A. Yes.

6 Q. Okay. And are you aware Dr. Accetta was paid for his  
7 time to testify here by Apotex?

8 A. Yes.

9 Q. And that he has had a prior consulting relationship  
10 with Apotex. Are you aware of any of that relationship?

11 A. I don't recall what he said about that, if he said  
12 anything.

13 Q. Okay. Are you aware that he has testified for Apotex  
14 in other cases -- strike that. I'm sorry. He has been  
15 engaged by Apotex in other unrelated cases as an expert  
16 witness?

17 A. I am not aware. I'm not aware, one way or the other.

18 Q. Okay. Now, giving your testimony during direct exam,  
19 you didn't offer any evidence that Cipla's brand equity had  
20 any affect on sales; correct?

21 A. I testified as to it being a factor that they had  
22 that objective, but I did not measure.

23 Q. Did you provide any evidence is Cipla's sweet relief  
24 campaign had any effect Duonase's sales?

25 A. Not a quantifiable dollar amount. But we talked

Press - cross

1 about design of a campaign around it.

2 Q. And Cipla's brand equity would not assist the sales  
3 of the imitator products, correct, of Duonase?

4 A. Not directly. You know, I don't know to the extent  
5 that they are receiving any sort of tag-along effects, if  
6 you will.

7 I don't have a dollar amount associated with  
8 that.

9 Q. Now, you know, as an expert in this field, do you  
10 think knowing the most recent formatter status for Dymista  
11 would be relevant to your opinions?

12 A. It would -- I would consider it as part of my  
13 analysis.

14 Q. You don't know the most recent formatter status.  
15 Right?

16 A. No. I know based on the documents that I have  
17 reviewed that were produced in this case.

18 Q. Okay.

19 MR. VARUGHESE: I have nothing further, Your  
20 Honor.

21 THE COURT: All right. Redirect?

22 MR. WARNER: No redirect.

23 THE COURT: You may step down. Thank you very  
24 much.

25 (Witness excused.)

1           THE COURT: Before you call the next witness,  
2 why don't you give me an idea of what still lays ahead.

3           MR. KLEIN: We will call, recall Dr. Robert  
4 Schleimer. And unless I am mistaken, he is our last  
5 witness.

6           THE COURT: Okay. And the plaintiffs, have you  
7 made a determination yet as to whether you are calling  
8 anybody else?

9           MS. EVERETT: We are not calling anybody else.

10          THE COURT: Sounds like a determination.

11          Any sense as to how long this exam might be?

12          MR. KLEIN: Not very long. I would hope to be  
13 done no later than 5:30.

14          THE COURT: I think we will take a short recess  
15 and we will come back.

16          (Brief recess taken.)

17          \*       \*       \*

18          (Proceedings reconvene after recess.)

19          THE COURT: Have a seat.

20          You may call your witness.

21          MR. KLEIN: Your Honor, before we call the  
22 witness, we have one housekeeping matter. We may have  
23 not been 100 super-diligent about identifying all the  
24 demonstratives that have been used. Can we assume that  
25 if we presented it to the Court that they're in for

Schleimer - direct

1 demonstrative purposes?

2 THE COURT: Yes, you can assume that.

3 MR. KLEIN: Okay.

4 THE COURT: I have all ones you have handed me  
5 and it will be accepted as demonstratives.

6 MR. KLEIN: Thank you, Your Honor.

7 So with that, Apotex recalls Dr. Robert  
8 Schleimer.

9 THE COURT: Okay. Bring the binders up.

10 (Binders passed forward.

11 THE COURT: Welcome back, Dr. Schleimer. You  
12 remain under oath, of course.

13 THE WITNESS: Yes.

14 ... ROBERT P. SCHLEIMER, having been previously  
15 sworn, was examined and testified as follows ...

16 THE COURT: You may proceed.

17 MR. KLEIN: Thank you.

18 DIRECT EXAMINATION

19 BY MR. KLEIN:

20 Q. Welcome back, Dr. Schleimer.

21 A. Thank you.

22 Q. Are you prepared to offer rebuttal testimony on  
23 Meda's theories of secondary considerations?

24 A. I am.

25 Q. Can you briefly summarize the topics you intend to

Schleimer - direct

1 address in your testimony?

2 A. Yes, they're shown on this slide.

3 First, it's my opinion that the results from  
4 co-formulating these two known drugs for a known combination  
5 therapy were expected.

6 In my opinion, Dymista is not superior to the  
7 closest prior art; and I would maintain that the true  
8 closest prior art is the conjunctive use of the two  
9 therapies in one patient.

10 The fast onset of Dymista was also expected in  
11 my opinion.

12 And I believe there are no other secondary  
13 indicia of nonobviousness.

14 The FDA was not skeptical of Dymista's efficacy.

15 Meda's praise that was presented was not  
16 independent. And,

17 The blocking patents undercut secondary  
18 considerations.

19 Q. Let's turn to these, although I will note now I don't  
20 know if we're going to spend any time on the praise point  
21 other than what you already testified to.

22 Let's turn to the issue of unexpected results.  
23 Do you remember in your testimony from a couple of days ago,  
24 you mentioned that the PTO Examiner allowed the patents in  
25 suit in part because of a finding of unexpected superior

Schleimer - direct

1 results? Do you remember that?

2 A. Yes.

3 Q. And did the Examiner compare Dymista to the  
4 fluticasone and azelastine monotherapies?

5 A. Individually, but not in combination.

6 Q. Okay. So, in your opinion, did the Examiner compare  
7 Dymista to the closest prior art?

8 A. No. As we heard from several clinicians that have  
9 testified in this case, doctors were prescribing at the same  
10 time to the same patient intranasal fluticasone and  
11 intranasal azelastine.

12 Q. So just to be clear, was the closest prior art  
13 Flonase in combination with Astelin, is that?

14 A. Yes, conjunctively.

15 Q. Have you seen any studies, any head-to-head studies  
16 comparing the effects of Dymista to the combination  
17 therapies involving Flonase and Astelin?

18 A. No, not when the monotherapies were used  
19 conjunctively. I did not.

20 Q. Have you looked at some studies to assess whether the  
21 results of Dymista are unexpectedly superior to the results  
22 of what you have identified as the closest prior art?

23 A. There are no such studies I am aware of.

24 Q. Have you looked at any other studies, non-head-to-head  
25 studies to address that issue?



Schleimer - direct

1 A. Yes.

2 Q. Let's turn to DDX-8.04. And on the screen is the  
3 Ratner 2008 reference which is DTX-191. And, in particular,  
4 we're looking at pages I think 1 and 7.

5 Can you explain what Ratner studied in this  
6 reference?

7 A. Yes. This is one of two very similar studies from  
8 group in Texas that studied patients with Texas red cedar  
9 allergy. And in this particular study they compared the  
10 branded fluticasone, branded azelastine, and the combination  
11 of the two branded products given to patients conjunctively.

12 Q. And what did Ratner find?

13 A. Well, they found about a 40 percent superior efficacy  
14 for the conjointly given compound compared to the best of  
15 the two monotherapies.

16 Q. Now, obviously, Ratner is from 2008 so it is not  
17 prior art. But in your opinion, was Ratner assessing the  
18 results of a prior art therapy?

19 A. Yes. This would be my view of the true prior art  
20 before the priority date.

21 Q. Again, we're talking about Flonase in combination  
22 with Astelin; right?

23 A. Yes, in separate products but in the same patient.

24 Q. Now, were you here when Dr. Kaliner testified that in  
25 this study, Astelin and Flonase were given 15 to 50 minutes

1     apart?

2     A.     Yes, I was.

3     Q.     Does that affect your opinion?

4     A.     No, not really. The Astelin or azelastine was known  
5     to have a durational effect of 12 hours after administration,  
6     and the fluticasone was known to have a duration effect of  
7     24 hours or thereabouts. So it wouldn't really matter,  
8     theoretically or to me, whether five minutes separated or  
9     20 minutes or even an hour separated because both drugs  
10    remain in the tissue and they would be interacting in the  
11    same patient in the same tissue at the same time regardless  
12    of whether they were given a half hour apart or not.

13    Q.     By the way, who is the second author?

14    A.     The second author on this study is Hampel.

15    Q.     And the reason I ask is because as we go to the next  
16    demonstrative, which is DDX-8.05, are we now looking at a  
17    reference primarily authored by Hampel?

18    A.     Yes. In this paper, Hampel is the first author and  
19    all the other authors are identical to the other one. It's  
20    a couple years later, but they studied red cedar allergy.  
21    It's the same group of investigators, same allergy, probably  
22    many of the same patients, I would imagine, and both of these  
23    studies are well designed. They're slightly different, but  
24    you may recall that I testified that the Brooks and Drouin  
25    papers showed that during the early days after initiation

Schleimer - direct

1 of oral antihistamine and intranasal steroid, there was  
2 superiority of the combination over each monotherapy.

3 Well, these papers both took advantage of Brooks  
4 and Drouin in the sense that they evaluated symptoms for  
5 only 14 days, and that is the period of time where they  
6 would have known that the combination would be superior.

7 In any case, this Hampel study was slightly  
8 different because they actually used Dymista. So this is  
9 the first study to use both products in the same container  
10 and compare it to the monotherapies.

11 And as you can see on the slide, there is a  
12 38 percent improvement compared to the fluticasone alone in  
13 this study which is a similar degree of improvement as was  
14 seen in Ratner.

15 Q. And just to be clear, are we looking at DTX-229 at  
16 Pages 1 and 3?

17 A. Yes.

18 Q. Now, was the FDA approved dose of azelastine used in  
19 this study?

20 A. So in this study the combination had half the  
21 FDA-approved dose. It had the dose that was approved in the  
22 U.K. in Europe.

23 Q. All right. We are turning now to DDX-8.06. Can you  
24 describe how the findings of Hampel and Ratner compare?

25 A. Yes. This is basically summarizes what the last two

Schleimer - direct

1 slides showed, that Ratner was what I would believe was true  
2 prior art, which is the two drugs given as a combination but  
3 separately, and compared to the monotherapies.

4           Whereas Hampel was actually Dymista compared to  
5 the monotherapies. And it also had a placebo group, as Dr.  
6 Kaliner indicated.

7 Q.       These are two separate studies. They are not a  
8 head-to-head single study. Right?

9 A.       That's right. Although as I mentioned, they are  
10 very, very close to each other since it was the same  
11 patients, the same investigators, the same allergen system.

12 Q.       So what is your conclusion based on these two  
13 studies as to whether Dymista has unexpectedly superior  
14 effects compared to the prior art combination of Flonase  
15 combined with azelastine?

16 A.       Well, I have looked very carefully at the data in  
17 both of these studies. And it is my opinion that the  
18 superiority of the combination was the same, regardless of  
19 whether the combination was given conjunctively or in the  
20 same bottle.

21 Q.       Even putting aside these two studies, have you seen  
22 any evidence in this case that Dymista has the kind of  
23 results that a person of ordinary skill in the art would  
24 find unexpectedly superior to the prior art  
25 Flonase/azelastine combination therapy?

1 A. No.

2 Q. Now, as to the monotherapies, would you describe the  
3 Dymista results as superior in kind or degree when compared  
4 to the Flonase monotherapy?

5 A. Well, superior in degree. In fact, both of these  
6 studies, it's roughly additive effects of the two individual  
7 components.

8 Q. I will ask the same question with regard to azelastine.  
9 Would you describe the Dymista results as superior in kind  
10 or degree when compared to the Astelin monotherapy?

11 A. In degree.

12 Q. If we go to DDX-8.07, can you explain what you are  
13 depicting on this demonstrative?

14 A. Yes. Dr. Carr showed some highly mathematically  
15 processed data about the Hampel study, in which they took  
16 the net change from baseline and they also subtracted the  
17 placebo effect. Then he determined percentage improvement  
18 and came up with this value of 196 -- the pointer is not  
19 working great -- 196 percent.

20 I would like to point out the data before I talk  
21 about that math.

22 So these are true symptom score data. So you  
23 can see that at baseline they had a score of 18 or 19. Just  
24 to remind you, 24 is full on for all symptoms. So this is  
25 highly symptomatic. And you can see that at the end of the

1 14 days, placebo had an effect.

2 If you look at Flonase, the effect is greater  
3 than placebo. That was significant. If you look at Astelin  
4 here, the same thing, it's greater than placebo and  
5 significant. And if you look at Dymista, it's roughly  
6 additive, as you can see in this slide.

7 Now, once you have a scale where there is no  
8 zero point, by doing a subtraction and taking the net  
9 change, it's not appropriate to form ratios or determine  
10 percentages.

11 An example would be, I am going Chicago  
12 tomorrow, and if it's two degrees when I get there, is it  
13 twice as warm as if it is one degree? The answer, of  
14 course, is no, because the temperature scale starts at  
15 absolute zero Kelvin. So it is really 255, 256 and 257 that  
16 we are talking about.

17 That is not appropriate here. And what I have  
18 done in the next slide is to look again at just the raw  
19 data. This is the total nasal symptom score improvement.  
20 And you can see, there is no placebo group in the Ratner.

21 But the total improvement for azelastine was 4.8  
22 out of this total symptoms of 19. Fluticasone, 5.2. And  
23 the combination was better than either, at 7.4.

24 But if you look at the Hampel study, there is  
25 the placebo group. This is if raw value for azelastine, it

Schleimer - direct

1 is 3.2. Fluticasone was 3.8.

2 The combination was 5.3.

3 So similar degrees of improvement, whether the  
4 two agents were given separately to the same patient or in  
5 one bottle.

6 And in the box, we are just looking at the  
7 delta. That's the comparison of the combination to either  
8 fluticasone alone or azelastine alone. And you see the  
9 numbers are similar in both the Hampel and the Ratner  
10 studies.

11 Q. Now, the numbers are slightly better for the  
12 Astelin-Flonase combination. Are you saying that that  
13 combination is superior to Dymista?

14 A. You mean a conjunctive one with a Ratner?

15 Q. Correct.

16 A. I am not. I don't think it's possible to say that.  
17 Just to emphasize, to be fair, as I mentioned, the dose of  
18 azelastine in Hampel is the U.K. dose, which is half of the  
19 U.S. dose, which was the dose used in Ratner.

20 It is also not easy to compare because, as Dr.  
21 Carr mention, the excipients were slightly different in the  
22 Hampel study because they had to be identical to what was in  
23 the Dymista formulation.

24 But the active ingredients were otherwise the  
25 same.

Schleimer - direct

1 Q. Now, were you here when Drs. Kaliner and Carr  
2 compared the side effects of Dymista to those of Astelin?

3 A. I heard some discussion about that, yes.

4 Q. You mentioned earlier that the Hampel test used half  
5 of the FDA-approved dose for azelastine. Right?

6 A. That's right. As we discussed the other day, in the  
7 combination, the azelastine dose is half. As a result, the  
8 U.K. and European country approved product does not have a  
9 warning about drowsiness, but in the U.S., where the dose is  
10 twice as much, there is a warning.

11 So it's not surprising that, in the Dymista,  
12 there is a little less drowsiness because it's half the dose  
13 of the one drug that causes drowsiness.

14 Q. And in terms -- there was a Carr article from 2012  
15 that also discussed testing of Dymista. Did that use the  
16 FDA-approved dose of azelastine or half the dose, for the  
17 monotherapy?

18 A. That also used half the dose.

19 Q. Now, does Meda argue, or have they presented a theory  
20 that Dymista has an onset of action that is quicker than  
21 what would have been expected as of June 2002?

22 A. They do. And before we even start on this, one of  
23 the issues here is there is not a lot of data. Most  
24 clinical trials don't bother to look at the first ten, 20,  
25 or 30 minutes. They look at symptoms in terms of days or



Schleimer - direct

1 weeks, or months, even.

2 But they do make that claim based on a  
3 comparison of the Astelin and Dymista labels, which are  
4 negotiated documents.

5 Q. And before we get to the next slide, is there any  
6 consistency between the Astelin and the Dymista labels?

7 A. Well, as you can see by the underlining, the Astelin  
8 label just states within three hours. And the Dymista label  
9 says that the onset of action is as early as 30 minutes. So  
10 these two are not mutually exclusive. They do not in any  
11 way demonstrate a difference in rate of onset.

12 Q. Just for the record, I am referring to DTX-22 and  
13 DTX-228 on this slide.

14 Let's go to the next slide. In your opinion,  
15 were the onset results of Dymista expected or unexpected?

16 A. They are not surprising to me. They are not  
17 unexpected, because, I think parties on both sides have  
18 agreed that in antigen challenge studies, where a person, an  
19 allergic person is challenged with antigen, that sneezing  
20 can be inhibited in 15 minutes or less. And that's the  
21 McNeely article, is one that has been discussed for that.

22 The ARIA guidelines, written by experts,  
23 routinely mention that the onset of action of  
24 antihistamines, topical antihistamines, is less than 15  
25 minutes.

Schleimer - direct

1           And I brought a little bit of data that I would  
2     like to just briefly show the Court from a different model.  
3     This is done by Carl Person's lab. And they are world  
4     famous in this area.

5           If you look at the y axis, this is just a  
6     measurement of secretion in the nose.

7           These are human subjects. And if they are  
8     challenged with just saline, this zero here, there is almost  
9     no secretion as you see.

10          If they are challenged with histamine, and you  
11     can see the 40, we will just look at that, the gray bar  
12     shows a very clear secretory response.

13          If they were treated one hour before the  
14     histamine challenge, as the red arrow indicates, it  
15     completely blocked, completely blocked that secretory  
16     response.

17          That means to me, in this study, it's working  
18     within minutes. We don't know when it started. It could  
19     have been five minutes or 30 minutes. But we know it was  
20     completely inhibiting this response by 60 minutes.

21          Now, I know that Dr. Carr said these are not  
22     real-world experiments. But I would have to take issue with  
23     that view, because these are studies under controlled  
24     situations with human subjects, where the other variables  
25     can be eliminated and you are focusing only on the onset of

Schleimer - direct

1 the drug.

2 So I put a lot of stock in these challenge  
3 studies.

4 Q. Okay. Just to be clear, the last study you were  
5 referring to is the Grieff reference from 1997. Is that  
6 right?

7 A. Yes.

8 Q. And we were referring to DTX-43, PTX-326 and DTX-99.  
9 Right?

10 A. Yes.

11 Q. Okay. Does Meda have a skepticism argument that you  
12 heard?

13 A. Yes. Actually, it was interesting listening to Dr.  
14 Carr's story of the interactions with the FDA.

15 And the claim is that the FDA was skeptical as  
16 to the efficacy of this combination.

17 Q. Do you agree that FDA was expressing skepticism as to  
18 whether Dymista will be safe and effective?

19 A. I don't. I mean, they were, in my view, doing the  
20 job that I would hope they would be doing. They were  
21 raising valid issues that are a challenge to this particular  
22 program, and I would hope they raise issues that are a  
23 challenge to any program. Some of them were identifying the  
24 appropriate patient population.

25 So as we heard throughout this trial, the

Schleimer - direct

1 guidelines distinguish severe allergic rhinitis and moderate  
2 allergic rhinitis.

3 This population would have to be patients with  
4 severe allergic rhinitis.

5 That is a subset, and they have to be identified  
6 appropriately, if they expressed some concern about  
7 heterogeneity of patients. I hadn't heard of that. But as  
8 Dr. Carr explained it, he said, well, maybe some are going  
9 to be azelastine responders that don't respond to  
10 fluticasone and vice versa. That is a theoretical but valid  
11 concern.

12 And, of course, they talked about the  
13 combination rule, which is a rule that was not written for  
14 Meda. It's been around for a while.

15 So I did not find any of that evidence to be  
16 particularly persuasive.

17 At the end of the day, they may have had to call  
18 the boss in. But they were able to do their trials.

19 Q. And as a housekeeping matter, I may have referred to  
20 the wrong exhibit for DDX-8.10, I think I referred to  
21 DTX-207, and it should have been DTX-43.

22 By the way, the FDA correspondence on which Meda  
23 relied, was that public or confidential?

24 A. These documents are typically confidential  
25 discussions between a company and the FDA.

Schleimer - direct

1 Q. Skip ahead to DDX-8.13. Are you familiar with U.S.  
2 Patent No. 4,335,121, sometimes referred to as Phillipps?

3 A. That is the fluticasone patent. I am.

4 Q. Have you confirmed that this patent does, in fact,  
5 claim the fluticasone compound?

6 A. Yes, the structure is shown on the slide.

7 Q. For the record, we are looking at DTX-33 at 2, and  
8 DTX-96 at 19.

9 Were you here when Dr. Donovan testified about  
10 what has been referred to sometimes as the Astelin patent?

11 A. Yes.

12 Q. Is it your understanding that this patent covered a  
13 medicament like Dymista that contained azelastine?

14 A. It is certainly my reading of this patent, and I  
15 agree with her on the surprise when Dr. Smyth expressed an  
16 opinion otherwise, it seems obvious to me that this would  
17 cover the use of azelastine in any medicament.

18 Q. And for the record, this is DTX-16 is at 2 and 5,  
19 Column 8, Lines 1 through 6.

20 Were the Flonase and Astelin patents that we  
21 just reviewed relevant to your analysis as to secondary  
22 considerations?

23 A. Yes.

24 Q. How so?

25 A. Well, as was discussed at length in the last

Schleimer - direct

1 testimony, I would believe that patent protection of one or  
2 both of these drugs would inhibit any person of skill in the  
3 art that was in a commercial entity and considering to file  
4 a patent joining these two compounds.

5 Q. Or manufacturing a product?

6 A. Or manufacturing a product.

7 Q. Now, just so we have this information, when did the  
8 Flonase patent issue?

9 A. On June 15th, 1982.

10 Q. When did the Flonase patent expire, considering  
11 pediatric exclusivity?

12 A. May of 2004.

13 Q. And when did the Astelin patent issue?

14 A. November 17th of 1992.

15 Q. And when did that patent expire, considering  
16 pediatric exclusivity?

17 A. May 1st, 2011.

18 Q. Could the existence of these two patents explain why  
19 skilled artisans did not actually co-formulate azelastine  
20 and fluticasone before June 2002?

21 A. I would think so, yes.

22 Q. Now, there was some discussion with the last witness  
23 about the patent application for the patents in suit that  
24 became public in December 2003. Were you here for that?

25 A. Yes.

Schleimer - direct

1 Q. Would the existence of a public patent application  
2 have an effect on drug development for a co-formulated  
3 azelastine-fluticasone product?

4 A. I would think so. At the very least, it would throw  
5 down the gauntlet that Cipla was in the game and developing  
6 such product.

7 Q. And in your experience, do drug developers consider  
8 patent applications when they make their product development  
9 decisions?

10 A. Yes. I don't work at a pharmaceutical company. But  
11 I know that patent applications are exceedingly important,  
12 not only in defending one's rights, but also preventing one  
13 from developing products that are already patented.

14 Q. Now, Dr. Schleimer, you sat through the whole trial.  
15 Right?

16 A. I did.

17 Q. And in your opinion, has Meda presented any  
18 persuasive evidence of secondary considerations that  
19 overcome the evidence of obviousness that you presented a  
20 couple of days ago?

21 A. No. As we have just discussed on these various  
22 topics, I have not been persuaded by the evidence of  
23 secondary considerations.

24 MR. KLEIN: For the record, for DDX-8.95, I  
25 forgot to mention that we were referring to DTX-16, 96, and

Schleimer - cross

1 304. We will move to admit some -- some of these may have  
2 been admitted already. We have move to admit DTX-16, 43,  
3 96, 99, 191, 207, 228, 229, 296, 304, PTX-15, 29, 38, 110  
4 and 227.

5 We referenced DDX-8.00 through 8.16, although I  
6 skipped one.

7 THE COURT: Any objection?

8 MR. VARUGHESE: No objection, Your Honor.

9 THE COURT: They are admitted and the  
10 demonstratives are accepted.

11 (Above-referenced exhibits received in  
12 evidence.)

13 MR. KLEIN: Pass the witness.

14 THE COURT: Cross-examination.

15 CROSS-EXAMINATION

16 BY MR. VARUGHESE:

17 Q. Hello again, Dr. Schleimer.

18 A. Hello again. How are you, Mr. Varughese?

19 MR. VARUGHESE: Can we go to DDX-803.

20 BY MR. VARUGHESE:

21 Q. So in your demonstratives that you just presented,  
22 Dr. Schleimer, this one, you make the point that the  
23 Examiner did not compare results to the closest prior art?

24 A. Yes.

25 Q. Okay. And why is that significant that the Examiner



Schleimer - cross

1 did not compare results to the closest prior art?

2 A. Well, it's my understanding that that is one of the  
3 basic principles of the awarding of a patent is comparing  
4 the prior art and the advancement from the prior art that is  
5 made by the application.

6 MR. VARUGHESE: Let's go to 8.04.

7 BY MR. VARUGHESE:

8 Q. This is the Ratner study; correct?

9 A. Yes.

10 Q. And you testified -- and you can correct me if I'm  
11 wrong. You testified that in your view, the prior art  
12 conjunctive use with azelastine and fluticasone is the  
13 closest prior art?

14 A. Yes. That art was practiced before the priority  
15 date. Although there had never been an actual study that  
16 evaluated it, those two drugs were given in conjunction to  
17 the same patient, as we have heard repeatedly.

18 Q. But earlier, when you were responding to Mr. Klein's  
19 questions, I thought I heard you say that Ratner 2008 study  
20 was true prior art. Do you recall saying that?

21 A. I said that --

22 THE COURT: Is there an objection?

23 MR. KLEIN: The witness can correct, but I was  
24 going to object on mischaracterizing the witness.

25 THE COURT: We'll let the witness answer. Go

1 ahead.

2 THE WITNESS: Would you like to repeat the  
3 question, please?

4 Q. Sure. When you were testifying earlier and  
5 responding to one of Mr. Klein's questions, and I wrote it  
6 down, I recall hearing you characterize the Ratner 2008  
7 study as the true prior art.

8 A. Yes. In the sense that in the Ratner study, patients  
9 in the combination group were getting the branded Flonase  
10 and branded Astelin and taking them together. That was the  
11 combination group in the Ratner study.

12 Q. But my first question is the Ratner study being dated  
13 2008, you agree that that is six years after the priority  
14 date; correct?

15 A. Yes. As I just stated, that combination was  
16 practiced routinely, as all our clinician witnesses have  
17 said, prior to the priority date.

18 Q. Then I think the last time you and I spoke, we  
19 discussed the evidence that you put forth to reflect that  
20 prior use, and it was Dr. Accetta's records and then you  
21 said Dr. Wedner's oral testimony on how he prescribed those  
22 drugs; correct?

23 A. Yes. And during the trial, I heard both Drs. Carr  
24 and Kaliner state that physicians were prescribing both of  
25 those drugs to patients simultaneously with allergic rhinitis.

Schleimer - cross

1 Q. Sure. And I'm going to ask you some questions about  
2 the study design in Ratner. And I promise you I'm not  
3 trying to test your memory. I'm just trying to speed things  
4 along. If we need to go to the study to confirm, I'm happy  
5 to do that for you.

6 A. Okay.

7 Q. Now, the patients receiving conjunctive therapy in  
8 Ratner received two sprays of azelastine in the morning;  
9 correct?

10 A. Yes.

11 Q. Followed by two sprays of fluticasone in the morning?

12 A. I'm not sure if it was in that order, but they got  
13 both drugs in the morning.

14 Q. I will represent to you, I'm going to read the study  
15 design so that way we can be sure.

16 A. Okay.

17 Q. So it was azelastine nasal spray, two sprays per  
18 nostril twice daily, fluticasone -- this is DTX-191.0002.  
19 Right column, toward the bottom. And I'll read it.

20 "Patients randomized to the combination group  
21 received azelastine nasal spray two sprays per nostril twice  
22 daily in the morning and evening and fluticasone nasal spray  
23 two sprays per nostril once daily in the morning."

24 And if we go to the next page, the left column,  
25 the sentence beginning "patients." And,

Schleimer - cross

1                   "Patients were instructed to administer the  
2 morning doses of each study drug 15 to 30 minutes apart."

3                   Do you see that?

4           A.       Yes.

5           Q.       Okay. Now, in any of the testimony that you have  
6 heard here this week, or any of the evidence that you  
7 presented, do we see that regimen in the prior conjunctive  
8 use that you are referring to?

9           A.       We don't receive any information either way how  
10 patients who were prescribed both drugs might have taken  
11 them how long apart. It might have been one right after the  
12 other or they might have waited a half hour, if they found  
13 that putting them right on top of each other, the drug  
14 flowed out. I would just be speculating.

15                   So we haven't seen any information as to the  
16 precise order or time apart that they were given, but as I  
17 testified with Mr. Klein, I don't think it matters if it's  
18 an hour, a half hour, or ten minutes. I really don't think  
19 it matters because the azelastine lasts 12 hours and it  
20 doesn't go away, and the steroid lasts 24 hours and it  
21 doesn't go away.

22           Q.       But we don't know; right? We don't know what the  
23 restrictions were of how Dr. Kaliner, Dr. Carr, Dr. Wedner  
24 and Dr. Accetta's records we have, none of that testimony  
25 or the record revealed any specific regimen; correct?

1 A. Correct.

2 Q. Now, the Ratner study was a clinical trial; is that  
3 correct, Dr. Schleimer?

4 A. Yes.

5 Q. And you would agree that patients outside of the  
6 clinical trial setting often fail to adhere to intranasal  
7 steroid treatment?

8 A. They fail to adhere both within and outside the  
9 clinical trials.

10 Q. Isn't it true a clinical trial setting is much more  
11 controlled and patients are more compliant? You would agree  
12 with that?

13 A. It's a little better, but there are examples of  
14 tremendous noncompliance. For instance, when computer chips  
15 have been added to sprayers and the day before the patient  
16 is coming to visit the Doctor, it records that all the doses  
17 were sprayed in one day for two weeks worth of treatment.  
18 So I would agree that in clinical trials, compliance tend to  
19 be better, as I think Dr. Kaliner said, but it's by no means  
20 perfect.

21 Q. If there is a difference in compliance, that could  
22 mean a difference in efficacy; correct?

23 A. Sure. Compliance can influence efficacy.

24 Q. I want to turn to DDX-804 of your demonstratives.

25 A. It's the same study?

1 Q. Yes. So actually I want to turn you to, the study  
2 investigators reported a 40 percent benefit I guess of the  
3 combined treatment over fluticasone alone. Do you see that  
4 there?

5 A. Yes.

6 Q. And if we go to the next slide, you look at the  
7 Hampel study, and this is your own calculation; right? The  
8 38 percent?

9 A. Yes.

10 Q. Okay. And again, I'm happy to go to it; but do you  
11 recall in your expert report, you did calculations and the  
12 specific number that you came up with for the Hampel study  
13 was 38.3 percent?

14 A. Yeah, I think, I recall a minor adjustment to the  
15 calculations that made no meaningful change but slightly  
16 changed the numbers, but I can't recall why we made that  
17 minor adjustment.

18 Q. That is fair enough. I think I'd like to explore  
19 some of these numbers in your tape further, so I'd like to  
20 show you your calculations and let's see if the way you  
21 presented the data here is accurate. Is that okay? Can we  
22 do that?

23 A. Okay.

24 Q. Your rebuttal report, paragraph 33, footnote 1.

25 So can we go to the footnote, please? Can you

1 make it bigger?

2 Okay. So here, I think you are describing, you  
3 do a calculation to determine the benefit of the combined  
4 therapy in Ratner and Hampel over fluticasone alone. I  
5 think you conducted this calculation from Hampel to come up  
6 with the 38.3 percent number, and then this calculation from  
7 Ratner to come up with the 42.3 number. Do you see that?

8 A. Yes, I do.

9 MR. VARUGHESE: So can we go to the Elmo?

10 BY MR. VARUGHESE:

11 Q. So do you see this is an image of your demonstrative,  
12 DDX-8.08?

13 A. Yes.

14 Q. So I'm just going to put this number here. Does that  
15 make sense? I think that is, you know, the column here is --

16 A. That is not where I would write it, but those look  
17 like the right numbers.

18 Q. Okay. And I think using your formula, that is  
19 correct; right? That is how you did? You subtracted the  
20 fluticasone benefit from the combination benefit divided by  
21 fluticasone and arrived --

22 A. Times 100. Yes, I think that is right.

23 Q. Times 100. And you came up with that number.

24 A. I can't do the math in my head, but it looks about  
25 right.

1 Q. Yes.

2 A. 2.2 over 5.2.

3 Q. And then here, you did -- does that look right? And  
4 I apologize for my atrocious handwriting.

5 A. Well, all we have to do is compare it to what you  
6 just showed in my declaration report.

7 Q. Yes.

8 A. Is it slightly different or something?

9 Q. No, no. I'm not --

10 A. Okay.

11 Q. I'm not trying to trick you.

12 So I think the point --

13 A. It looks about right.

14 Q. The point you were trying to make here is that the  
15 Hampel study didn't really show any improvement over Ratner.  
16 Was that the point you were trying to make?

17 A. The point I'm making is the degree of improvement  
18 of the combination compared to the single most effective  
19 monotherapy, which would be the fluticasone, was similar.  
20 As I mentioned, you can't do an absolutely direct comparison  
21 because of the slightly different excipients and the dose  
22 difference in the azelastine, but it's a good ballpark  
23 estimate, and it shows us that the relative improvement was  
24 similar whether you used the monotherapy separately or in  
25 one model.



1 Q. But the problem here is we are not comparing apples  
2 to apples. Correct? Because Ratner doesn't have a placebo  
3 arm whereas Hampel did?

4 A. But that doesn't matter, because these improvement  
5 numbers take benefit of both placebo and active effects.  
6 So, for instance, 4.8 for azelastine includes whatever the  
7 placebo effect was in Ratner, just as 3.25 in Hampel  
8 includes the 2.2 of placebo.

9 So because there is no placebo in Ratner, we  
10 just looked at the total improvement with the combination  
11 and the monotherapies, which is the fairest way to compare  
12 these two studies that otherwise are difficult to compare  
13 since there is no placebo group in one, as you pointed out.

14 Q. Earlier in this case, you have expressed an opinion  
15 that the placebo arm is very important, and that it serves  
16 to, you know, make sure that we don't taint the studies with  
17 false positives as a result. Correct?

18 A. I don't remember being asked about the placebo  
19 effect.

20 Q. I mean, why don't we put it up. It's the Schleimer  
21 reply --

22 A. You mean in one of my written documents?

23 Q. Yes, I will show it to you, if you would like.  
24 Paragraph 34.

25 If we go to the block here. Do you see the last

1 sentence, "The fourth," meaning No. 4, the placebo control  
2 group, "The fourth serves to ensure that the data from  
3 Groups 1 to 3 are not by false positives as a result of the  
4 placebo effect"?

5 A. Yes, I think that is the purpose of placebo groups.

6 Q. Here we have one study that did have a past and one  
7 study that didn't a past?

8 A. It is true. It is an imperfect comparison. But as I  
9 said, these are the exact same investigators, two years  
10 apart with the same allergen system in the same centers,  
11 probably many of the same patients.

12 So it's not a lot of risk that the placebo  
13 effect would be fairly similar in the Ratner study.

14 But I granted you, the fact is, if I was relying  
15 just on the data I showed you, I would say, actually, the  
16 combination is better when given separately, which I refrain  
17 from doing, because of the very nature that you are raising,  
18 that there is no placebo group.

19 Q. Putting the Hampel study up, if I wanted to correct  
20 for the placebo group, I would subtract the placebo benefit,  
21 2.2, from the combination benefit and the fluticasone  
22 benefit. Right?

23 A. That's right. You can determine the delta or the net  
24 benefit compared to placebo. But once you do that, you  
25 can't make proportions anymore. That's my point.

Schleimer - cross

1 Q. I mean, you stay with the findings. But I am going  
2 -- I put down figures that does subtract placebo from those  
3 two benefit arms. And I am going to apply your formula?

4 A. You can't do that. I explained why. Is two degrees  
5 twice as warm as one degree when I go back to Chicago? No.  
6 The problem is, once you subtracted a number, it could even  
7 be you have negative numbers, you cannot make a ratio  
8 anymore. It's mathematically -- you can go ahead and do it  
9 if you want, but I am not going to buy it.

10 THE COURT: The record will show he is doing the  
11 math.

12 BY MR. VARUGHESE:

13 Q. I haven't done that kind of arithmetic in a long time  
14 to be able to memorize that.

15 I understand what you are saying. But I think  
16 that's the problem with this comparison. Right? It is  
17 comparing two different studies and you are trying to draw  
18 conclusion that the benefits are equal when I don't think  
19 it's that simple?

20 A. Well, based on the evidence, I am not sure you  
21 understand what I am saying.

22 Q. I will move on.

23 So in Slide 8.11 Dr. Schleimer, of your  
24 demonstratives, if you look at this letter from the FDA to  
25 Meda to draw your conclusion that FDA simply asked Meda to

Schleimer - cross

1 adopt a proper clinical development program to show safety  
2 and efficacy, and that you disagree with Drs. Carr and  
3 Kaliner that the FDA was skeptical as to this product.  
4 Correct?

5 A. Well, I don't know if this will help you. The FDA is  
6 paid to be skeptical. I think that, I actually take great  
7 comfort from the fact that they are providing a rigorous  
8 review in this case and in all cases. It's always been my  
9 experience that they basically tell a company everything  
10 that -- every hurdle they have to go over, every challenge  
11 they have to overcome, what their concerns are, and what  
12 problems need to be solved. That's what the FDA does.

13 Now, all of the supposed examples of skepticism  
14 that Dr. Carr presented to me were not surprising and I  
15 didn't think any of them were particularly unreasonable.

16 So that's why I view this as not evidence that  
17 the world was skeptical about this product.

18 Q. But the only evidence regarding the FDA to support  
19 your opinions on skepticism or, to be fair, you are saying  
20 the lack thereof, it is just this, in this demonstrative,  
21 you have not addressed, during your direct testimony, any of  
22 the other portions that Dr. Carr identified that in his view  
23 support a finding of skepticism. Correct?

24 A. That's correct. But I have heard him present them  
25 quite vigorously, and did not come away with the sense that

1 any of them were inappropriate.

2 Q. Let's turn to DDX-8.15.

3 A. I am getting a foreboding now after the last witness.

4 Q. Dr. Schleimer, you testified that you focused on the  
5 Cipla placebo application. Is it your testimony that that  
6 would have discouraged someone from pursuing this product?

7 A. I would think that if I was at a commercial entity  
8 and we were considering making some sort of combination like  
9 this, that once I saw that filing, even though it hadn't  
10 been approved yet, I would think that somebody is ahead of  
11 us, and we might reevaluate whether it's worth the cost of  
12 human capital and financial capital, intellectual capital,  
13 to pursue it.

14 Now, I am not a scientist. I am not an expert  
15 in business or patent law, as I am sure you know.

16 But I have visited enough companies and I have  
17 been in enough discussions in advisory boards to have seen  
18 them have conversation after conversation where they talk  
19 about other people's intellectual property position.

20 In fact, I think the whole patent law system is  
21 wonderful. It enables people to disclose discoveries so  
22 other people can work on them and in exchange for that they  
23 get protection.

24 I would want that Hettche patent to protect  
25 azelastine until 2011 if it was awarded and it's a valid

1 patent.

2 So I would think that patent and the filing,  
3 also, although it is not approved, could inhibit someone who  
4 is making a business decision about whether to pursue this.

5 Q. But do you understand that this filing doesn't relate  
6 to this? You understand that. Right? This filing, the  
7 filing of Cipla's application, not the Hettche patent?

8 A. Yes, right. I understand they are separate entities.

9 Q. And you have taken the position that this would have  
10 been obvious to a POSA. But doesn't that contradict your  
11 position that someone would have also at the same time been  
12 discouraged by looking at those applications?

13 A. No, not at all. I mean, as we discussed on  
14 Wednesday, it was obvious to Cramer and Segal and it was  
15 obvious to Lulla and Menacha. But once people start making  
16 progress and get applications in the pipeline, that changes  
17 the business decision. Not whether it is obvious or not.  
18 It changes the business decision and creates a barrier to  
19 entry.

20 To me, the Hettche patent is a much greater  
21 barrier to entry than the filing of the patent from India.  
22 But both could have a chilling effect, I would think, on  
23 prospective inventors.

24 MR. VARUGHESE: No further questions, Your  
25 Honor.

1 THE COURT: Okay. Thank you.

2 Mr. Klein?

3 MR. KLEIN: No questions, Your Honor.

4 THE COURT: Okay. Thank you.

5 Dr. Schleimer, you may step down. Thank you  
6 very much.

7 (Witness excused.)

8 THE COURT: If I am counting correctly, that is  
9 all of the evidence.

10 MR. LOMBARDI: That is all from defendants.

11 THE COURT: That is all from the plaintiffs.  
12 Correct?

13 MS. EVERETT: Yes, Your Honor.

14 MR. VARUGHESE: Your Honor, one housekeeping  
15 item. I would like to mark my demonstrative.

16 THE COURT: The one you were working up?

17 MR. VARUGHESE: Yes.

18 THE COURT: That is fine.

19 MR. VARUGHESE: May I submit it to the court  
20 reporter? You probably want copies of it as well.

21 THE COURT: Why don't you make a copy and submit  
22 it next week sometime.

23 MR. VARUGHESE: Thank you, Your Honor.

24 THE COURT: Anything else to discuss?

25 MR. LOMBARDI: Not from our side, Your Honor.

1 THE COURT: Plaintiffs?

2 MS. EVERETT: Not from our side.

3 THE COURT: Let me thank you all. I know time  
4 for the trial has been unusual and has shifted around at  
5 times. But you all made it work.

6 I am very grateful for that.

7 We will be in touch, probably next week, we will  
8 reach out to you to work out a date for the closing  
9 argument. I am thinking about the early part of March. We  
10 will see what works for both sides and for me.

11 Safe travels. Happy holidays to everybody. We  
12 will be in recess.

13 (Court proceedings adjourn at 6:00 p.m.)

14

15 I hereby certify the foregoing is a true and accurate  
16 transcript from my stenographic notes in the proceeding.

17 /s/ Brian P. Gaffigan  
18 Official Court Reporter  
19 U.S. District Court  
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