

1 UNITED STATES PATENT AND TRADEMARK OFFICE
2 BEFORE THE PATENT TRIAL AND APPEAL BOARD

3 _____)
4 ARGENTUM PHARMACEUTICALS LLC,)
5 Petitioner,) Case No.
6 v.) IPR2017-00807
7 CIPLA LIMITED,) U. S. Patent No.
8 Patent Owner.) 8,168,620
9 _____)

10

11

12

13 DEPOSITION OF DR. ALEXANDER DOMINIC D'ADDIO

14 Washington, D. C.

15 Wednesday, February 21, 2018

16

17

18

19

20

21 Reported By: Goldy Gold, RPR

22

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22

9:00 a.m.

February 21, 2018

Deposition of DR. ALEXANDER DOMINIC
A'DDIO, commencing at 9:02 a.m., Wednesday,
February 21 2018, at Sterne Kessler
Goldstein Fox, 1100 New York Avenue, NW,
Washington, D.C., 20005, before Goldy Gold, a
Registered Professional Reporter and a Notary
Public within and for the District of
Columbia.

1 A P P E A R A N C E S:

2

3 On Behalf of the PLAINTIFF:

4 ANDREW CHESLOCK, ESQUIRE

5 Foley & Lardner, LLP

6 321 North Clark Street – Suite 2800

7 Chicago, Illinois 60654

8 E-mail: acheslock@foley.com

9

10 TYLER LIU, ESQUIRE

11 In-House Counsel,

12 Argentum Pharmaceuticals

13

14

15 On Behalf of the DEFENDANT:

16 ADAM C. LaROCK, ESQUIRE

17 Sterne Kessler Goldstein Fox

18 1100 New York Avenue, NW

19 Washington, D.C. 20005

20 E-mail: alarock@skgf.com

21

22

1

I N D E X

2

Deposition of Dr. Alexander Dominic D'Addio

3

February 21, 2018

4

5

EXAMINATION BY

PAGE

6

MS. LIU

5

7

8

9

10

E X H I B I T S

11

12

D'ADDIO
EXHIBITS

13

DESCRIPTION

PAGE

14

Exhibit 1056

U. S. Patent No.
6,417,206, Antitussive
Antihistaminic
Decongestant Compositions,
July 9, 2002

41

16

17

18

19

INFORMATION TO BE FURNISHED

20

Description:

Page:

21

[None.]

22

1 WHEREUPON,

2 DR. ALEXANDER DOMINIC D'ADDIO,

3 called as a witness, having been duly sworn by a

4 Notary Public, was examined and testified as

5 follows:

6 EXAMINATION

7 BY MS. LIU:

8 Q. Good morning.

9 A. Good morning.

10 Q. Could you please state your full name
11 for the record.

12 A. Alexander Dominic D'Addio.

13 Q. Dr. D'Addio, I'm going to be handing
14 you a deposition notice for today. Have you seen
15 this document before?

16 A. I don't believe I have.

17 Q. Can you just confirm for me that that
18 is your name on the first page and that you are
19 being cross-examined today?

20 A. Yes, that is my name.

21 Q. Okay. Great.

22 Dr. D'Addio, have you ever been

1 deposed before?

2 A. I have.

3 Q. And how many times have you been
4 deposed?

5 A. I'm not sure. Maybe five or six
6 times.

7 Q. Okay, and all of those times were all
8 patent matters?

9 A. That's correct.

10 Q. Did they all relate to pharmaceutical
11 formulation technology?

12 A. Yes.

13 Q. So I take it you are familiar with the
14 general ground rules for a deposition?

15 A. Yes.

16 Q. And I just want to go over just a few
17 things with you before we get started. Is that
18 okay?

19 A. Yes.

20 Q. I'm going to ask you a series of
21 questions. If there is any question that I ask
22 that you don't understand, or you don't understand

1 something within my question, please ask me for
2 clarification. Okay?

3 A. Yes.

4 Q. If you don't understand the question,
5 I will try to restate the question and clarify it
6 for you. Is that okay?

7 A. Yes.

8 Q. If you answer a question, I'm going to
9 assume that you heard the question and you
10 understood it. Is that okay?

11 A. Yes.

12 Q. Now, during the deposition, counsel
13 for the patent owner will probably at some point
14 object to my question. When this happens, I want
15 you to be clear that unless counsel instructs you
16 not to answer the question, you are still required
17 to answer my question. Do you understand that?

18 A. Yes.

19 Q. Of course, the exception is that if
20 you believe the question I have asked requires you
21 to reveal information you believe is protected by
22 work product or attorney/client privilege.

1 Understood?

2 A. Yes.

3 Q. Also, please let me know at any time
4 if you need to take a break.

5 A. Thank you.

6 Q. Dr. D'Addio, are there any medications
7 you're taking which would prevent you from
8 answering my questions accurately and truthfully
9 today?

10 A. No.

11 Q. Are there any other issues that would
12 otherwise prevent you from answering my questions
13 accurately and truthfully today?

14 A. No.

15 Q. Great.

16 Dr. D'Addio, did you do anything to
17 prepare yourself for this deposition?

18 A. I reviewed some notes with my
19 attorney.

20 Q. Okay, and I'm assuming Mr. LaRock?

21 A. Correct.

22 Q. You met with Mr. LaRock?

1 A. Correct.

2 Q. And when did that meeting occur?

3 A. Yesterday.

4 Q. And how long, approximately, did it
5 last?

6 A. Five or six, six or seven hours.

7 Q. Dr. D'Addio, did you review any
8 documents in preparation for your deposition
9 today?

10 A. I did.

11 Q. And which documents did you review?

12 A. The documents that were associated
13 with my declaration.

14 Q. So I assume all of the exhibits in the
15 declaration, that are listed in the declaration?

16 A. Yes.

17 Q. I will now provide you, Dr. D'Addio,
18 what's been previously marked Patent Owner's
19 Exhibit 2148. It's been previously marked.

20 Do you recognize this document,
21 Dr. D'Addio?

22 A. Yes, this is the declaration that I

1 submitted.

2 Q. Dr. D'Addio, I'm sure you're aware
3 that there as a first D'Addio declaration and a
4 second D'Addio declaration, correct?

5 A. That's correct.

6 Q. And for purposes of clarity today, are
7 you comfortable if I refer to Patent Owner's
8 Exhibit 2148 as "your declaration"?

9 A. Yes.

10 Q. Are you aware of any material
11 differences between your first declaration and
12 second declaration?

13 A. There are a couple of footnotes added
14 and some clarification on documentation.

15 Q. Dr. D'Addio, let's turn to page 5 of
16 your declaration, right before paragraph 10. Let
17 me know when you're there.

18 A. I have it.

19 Q. Here you begin to discuss the product
20 journey. Do you see that?

21 A. In paragraph 10?

22 Q. Yes.

1 A. Yes.

2 Q. Now let's direct your attention to
3 paragraph 11.

4 You state in your declaration that in
5 2002, under your direction, Meda had considered
6 three lifecycle options, the first being an
7 Astelin steroid combination; the second a new
8 Astelin formulation that masked the bitter taste
9 issues associated with azelastine; and the third,
10 developing a new azelastine formulation with
11 improved taste and dosing profiles, correct? And
12 that goes onto page 6.

13 A. Yes, that does. I see it.

14 MR. LaROCK: I am just going to object
15 to the extent it mischaracterizes the
16 document, because I don't think you've read
17 every word.

18 Q. So during this time, Meda never
19 considered any other antihistamine besides
20 azelastine hydrochloride, right?

21 MR. LaROCK: Object to the form of the
22 question.

1 A. In -- in this report, we're only
2 talking about products with azelastine.

3 Q. What I'm referring to is your product
4 lifestyle strategies that your PPD group had
5 instituted. You guys never considered any other
6 antihistamine besides azelastine, correct?

7 MR. LaROCK: Object to the form of the
8 question. Outside the scope.

9 A. So in this report, we -- this report
10 reports about management, and the only thing that
11 we discussed are products using azelastine
12 hydrochloride.

13 Q. So the bitter taste issues that you
14 referenced were not considered significant enough
15 to prevent a formulation containing azelastine
16 from being accepted into the marketplace, correct?

17 A. I'm sorry --

18 MR. LaROCK: I object to the form of
19 the question. Object to the form of the
20 question, outside the scope of this
21 declaration.

22 You can answer.

1 A. I'm sorry. Repeat the question.

2 Q. So the bitter taste issues that you
3 referenced were not considered significant enough
4 to prevent a formulation containing azelastine
5 from being accepted into the marketplace, correct?

6 MR. LaROCK: Same objections.

7 A. As a matter of fact, there was a fair
8 amount of work that went into developing an
9 improved formulation for azelastine hydrochloride.
10 Trying to do the taste masking took an awful lot
11 of work, often in the laboratory and in clinical
12 studies.

13 Q. Aside from the bitter taste issues,
14 was azelastine considered the best antihistamine
15 for Meda's purposes at that time?

16 MR. LaROCK: Object to the form of the
17 question. Outside the scope of this
18 declaration.

19 A. It was a product that -- azelastine
20 hydrochloride, that we had a lot of experience
21 with.

22 Q. I don't think you answered my

1 question.

2 I just said aside from the bitter
3 taste issues, was azelastine considered the best
4 antihistamine for your consideration at this time
5 period?

6 MR. LaROCK: Again, object to the form
7 of the question. Outside the scope of this
8 declaration.

9 A. We focused on azelastine because it
10 was the one that we had the most experience with.

11 Q. So it had nothing to do with
12 azelastine's efficacy?

13 MR. LaROCK: Object to the form of the
14 question.

15 A. We knew the properties of it. We knew
16 it was an effective antihistamine.

17 Q. Okay. If you follow me on page 6 of
18 your declaration, you state that by
19 September 2002, you started analyzing the first
20 out of the three options, which was an Astelin
21 steroid combination product, correct?

22 A. Yes.

1 Q. Now, after choosing the first option,
2 the PPD group added the task, "New nasal solution
3 product, combination of azelastine hydrochloride
4 and an approved steroid," in paragraph 11. Do you
5 see that?

6 A. We added it to our weekly program and
7 priorities chart, correct.

8 Q. So at this point you were only looking
9 at FDA-approved steroids to combine with
10 azelastine, right?

11 A. We were looking at approved steroids
12 at that time.

13 Q. So FDA-approved steroids, correct?

14 A. Correct.

15 Q. Now, at this point, you had also not
16 decided on which steroid you were going to use; am
17 I correct?

18 A. We had not picked a steroid at this
19 point, no.

20 Q. Okay. Now, could you please direct
21 your attention to paragraph 13.

22 In paragraph 13, you describe one

1 aspect of why Meda's PPD group viewed combining
2 azelastine and a steroid as difficult, right?

3 A. That actually --

4 MR. LaROCK: Hold on. Object to the
5 extent it mischaracterizes the declaration.
6 You can answer.

7 A. It actually flows from the previous
8 paragraph, paragraph 12. And this was one of the
9 items that we recognized that was going to provide
10 a challenge to us in developing a formulation.

11 Q. Now, one aspect of that difficulty was
12 due to azelastine being fully dissolved in a nasal
13 spray vehicle, but that steroids are suspension
14 formulations where the steroid particles are not
15 dissolved in the nasal spray vehicle, but are
16 instead suspended in it, right?

17 A. I'm sorry. What was the question? I
18 mean, you read the sentence --

19 Q. Yes.

20 A. -- but I didn't hear a question in it.

21 Q. I'm just saying if that was true, what
22 I just read.

1 A. That's exactly what I said here in the
2 declaration.

3 Q. Yes. So steroid formulations were
4 always in suspension, correct?

5 MR. LaROCK: Object to the form of the
6 question, and outside of the scope of his
7 declaration.

8 A. So I'm not sure that that's true for
9 every steroid product. But as far as we knew for
10 nasal sprays, nasal suspensions, with steroids, I
11 believe that they are all suspensions.

12 Q. So at that time you were not aware of
13 any nasal -- nasal sprays that were -- strike
14 that.

15 So at that time you were not aware of
16 any steroid formulations that were not suspensions
17 for nasal sprays, correct?

18 MR. LaROCK: Object to the form of the
19 question. Outside the scope of his
20 declaration. Calls for speculation.

21 A. So it -- I just -- I wasn't aware of
22 any other products at that time.

1 Q. If you could now turn to paragraph 16
2 of your declaration, on page 8. Here you state
3 that because of the low probability of success and
4 the anticipated technical obstacles, this project
5 became a low priority, correct?

6 A. That's in the first sentence, based on
7 the low product of success and the challenges, it
8 became a low priority, correct.

9 Q. Then, in the same paragraph, you
10 stated that between the years of 2003 to 2006,
11 Meda began working to identify possible dual
12 chamber devices that would allow azelastine and
13 fluticasone to be stored in separate bottle
14 chambers but could also be coadministered in one
15 spray. Do you see that?

16 MR. LaROCK: Object to the extent it
17 mischaracterizes the document.

18 You can answer.

19 A. So between that -- that period, we did
20 look for possible dual chamber devices. There
21 would be, of course, two different formulations,
22 two different solutions, stored in the dual

1 chambers that would be combined in a single spray.

2 Q. When did Meda identify fluticasone as
3 a steroid of choice in a combination with
4 azelastine?

5 MR. LaROCK: Objection. Outside the
6 scope of his declaration.

7 A. I don't recall when the decision to
8 use fluticasone was made.

9 Q. Did you test -- did Meda test any
10 other steroids, besides fluticasone, in
11 combination with azelastine?

12 MR. LaROCK: Objection. Outside the
13 scope of this declaration.

14 A. When? In what period?

15 Q. In the period from late 2003 to 2006
16 and onwards, did Meda test any other steroid
17 besides fluticasone in combination with
18 azelastine?

19 MR. LaROCK: Objection. Outside of
20 scope of this declaration.

21 A. At this time we weren't looking or
22 using any azelastine or fluticasone. We were

1 looking for different devices.

2 Q. Yes, but the devices were made to
3 allow azelastine and fluticasone to be stored in
4 separate bottle chambers, as it states in
5 paragraph 16.

6 So you were looking at azelastine and
7 fluticasone in particular, correct?

8 A. Right. But your question was, were we
9 working with them. So we did not have any
10 formulations with azelastine or fluticasone. We
11 were looking for devices that could contain those
12 formulations.

13 Q. And Meda never looked at any other
14 steroid to put in that dual chamber device besides
15 fluticasone, correct?

16 MR. LaROCK: Objection. Outside the
17 scope of his declaration. Calls for
18 speculation.

19 A. Again -- again, the focus was on the
20 dual chamber device.

21 Q. Yes, the dual chamber device was
22 azelastine and fluticasone, correct?

1 A. Again, I don't remember when we
2 decided to use fluticasone in this.

3 Q. My question was very clear. It was
4 just, did you use any other steroid -- did Meda
5 look at any other steroid to put in this dual
6 chamber device, besides fluticasone?

7 MR. LaROCK: Objection. Outside the
8 scope of this declaration.

9 A. I don't recall.

10 Q. Isn't it true that fluticasone's
11 efficacy was one factor in Meda's decision to use
12 it in combination with azelastine?

13 MR. LaROCK: Objection. Outside the
14 scope of this declaration.

15 A. It -- that made -- that was a
16 determination that was probably made by our
17 medical group. I'm a formulation scientist.

18 Q. So I'm assuming Meda believed at that
19 time that the combination of azelastine and
20 fluticasone would work better than either of those
21 drugs just by themselves, right?

22 MR. LaROCK: Objection. Form, outside

1 the scope, calls for speculation.

2 A. I don't know what medical thought the
3 result would be of adding those two together, if
4 there would be a superior product or not.

5 Q. And at that time, from late 2003 to
6 2006 -- strike that.

7 So from late 2003 to early 2006, Meda
8 wasn't aware of Cipla's patent application,
9 correct?

10 MR. LaROCK: Objection. Object to the
11 form of the question.

12 A. I don't recall that, no.

13 Q. Okay. Well, let's go to paragraph 26
14 on page 12.

15 A. Yes.

16 Q. Do you see that in the first sentence
17 of paragraph 26, you say, "Shortly thereafter, in
18 May 2006, Meda discovered Cipla's published patent
19 application directed to azelastine steroid
20 formulations, U.S. 2006/0025391. Do you see that?

21 A. I do. We found that and the Duonase
22 product.

1 Q. So before May 2006, Meda was already
2 attempting to combine azelastine and fluticasone,
3 independent of Cipla's patent application,
4 correct?

5 MR. LaROCK: Objection to the form of
6 the question.

7 A. So before May 2006, we had, it stated
8 in the declaration, we had performed some
9 feasibility experience with azelastine and
10 fluticasone, correct.

11 Q. Are you aware of any information that
12 Meda might have relied upon in deciding to pursue
13 a combination formulation using azelastine and
14 fluticasone?

15 MR. LaROCK: Object to the form of the
16 question. Outside the scope.

17 A. Not to my memory. Again, it was a
18 decision that was made by our management and the
19 medical team.

20 Q. Dr. D'Addio, I am going to direct your
21 attention back to paragraph 16 on page 8. Now,
22 for this dual chamber device that Meda was working

1 on, Meda had used the -- was considering using the
2 Astelin formulation for the azelastine component
3 of the dual chamber device, correct?

4 A. I don't know that we had made a
5 decision about what that formulation would be in a
6 dual chamber device.

7 Q. So you were saying at this point in
8 time you were only looking at the devices, not any
9 formulations for either azelastine or fluticasone,
10 correct?

11 A. We were looking at the device that
12 would be able to hold two formulations separate.
13 We hadn't gotten to the point where we made
14 decisions on what formulations to use.

15 Q. So I take it you did not know --
16 strike that.

17 So I take it Meda had not decided on
18 what fluticasone formulation to use for the bottle
19 chamber device as well, correct?

20 MR. LaROCK: Object to the form of the
21 question.

22 A. Not that I recall.

1 Q. Dr. D'Addio, let's move on to the
2 small scale formulation effort that Meda embarked
3 upon, starting, I believe, in paragraph 17 of your
4 declaration.

5 Now I'd like you to look at
6 paragraph 19 of your declaration on page 9.

7 A. Yes.

8 Q. Now, this is where you outline the
9 plans that Dr. Kalidas Kale -- am I pronouncing
10 that correctly?

11 A. It's Kalidas Kale.

12 Q. I will restate the question.

13 Now, in paragraph 19, you outlined the
14 plans that Dr. Kalidas Kale drew up as part of the
15 feasibility assessment plan for an azelastine and
16 Flonase combination, correct?

17 A. Yes.

18 Q. Now, Plan A, drawn up by Dr. Kale,
19 involved an experiment to test whether azelastine
20 could be soluble in the Flonase suspension, right?

21 A. Maybe if we could go to that, I can
22 speak to it specifically.

1 Q. That is on paragraph 19, the first
2 sentence.

3 A. Right. I mean, the plan itself is in
4 my declaration as one of the attachments.

5 Q. I'm just asking a general question as
6 to what Plan A involved.

7 A. Right. And that's why I'm asking. I
8 can go down the specifics of that, if you take out
9 the plan for me.

10 Q. Well, just -- I'm asking just a basic
11 question on what Plan A generally was about. And
12 it was involving an experiment to test whether
13 azelastine could be dissoluble in the Flonase
14 suspension, correct?

15 A. After the removal of the fluticasone.

16 Q. Now, Plan B proposed to identify a
17 water-soluble steroid compatible with a azelastine
18 hydrochloride solution, correct?

19 A. Yes.

20 Q. And Plan C tested various solubility
21 enhancement technologies to increase the
22 solubility of fluticasone, correct?

1 A. That's correct.

2 Q. So only Plan A and Plan C involved
3 testing fluticasone propionate, correct?

4 MR. LaROCK: Objection. Object to the
5 form of the question.

6 You can answer.

7 A. So we know that fluticasone is not
8 water soluble, so Plan B would not have included
9 fluticasone. Plans A and C did focus on
10 fluticasone propionate.

11 Q. Now, Plan B proposed to identify a
12 water-soluble steroid compatible with an
13 azelastine hydrochloride solution, correct?

14 A. Correct.

15 Q. Does that mean that your statement
16 regarding steroids only being suspensions was
17 inaccurate, in paragraph 13 of your declaration?

18 MR. LaROCK: Object to the form of the
19 question. Object to the extent it
20 mischaracterizes the document, his testimony.

21 A. So paragraph 13, again, talked about
22 existing -- 13 -- right. So, again, for nasal

1 spray vehicles, the suspensions that we were aware
2 of are not soluble and are suspended in these
3 nasal spray suspensions. The goal here was to
4 look for other steroids that may be water-soluble.

5 Q. So Plan B proposed to identify
6 water-soluble steroids that were not available at
7 the time for a nasal spray vehicle?

8 A. We were going to do a search to see if
9 there were any available.

10 Q. Okay. Dr. D'Addio, then you moved --
11 Meda moved forward with Plan A, which was
12 determine whether azelastine could dissolve in
13 Flonase formulation without fluticasone particles,
14 correct?

15 MR. LaROCK: Object to the extent it
16 mischaracterizes his testimony.

17 A. I'm sorry. Can you repeat that?

18 (Whereupon, the referred-to question
19 was read back by the Reporter.)

20 A. That was the outline. That was what
21 Plan A, the feasibility experiment, was intended
22 to do, correct.

1 Q. Now, Mr. D'Aconti was the one
2 performing these experiments, right?

3 A. John D'Aconti in combination with
4 Dr. Kalidas.

5 Q. So if you follow me on paragraph 24,
6 on page 11.

7 A. Yes.

8 Q. Actually it's paragraphs 23 and 24.
9 You state in your declaration that Mr. D'Aconti
10 attempted the first step under Plan A and had to
11 repeat it the following day, because the sample
12 was more than the filter could withstand, and the
13 sample spilled, correct?

14 MR. LaROCK: Object to the extent it
15 mischaracterizes his testimony.

16 A. So this was the initial experiment, in
17 which they were trying to isolate the solid
18 fluticasone particles from the formulation. And
19 in ultimately trying to filter it, the sample was
20 lost, correct.

21 Q. Now, if you turn to page 12, in the
22 same paragraph, you stated that on April 26, 2006,

1 Mr. D'Aconti performed the same experiment from
2 the day before, and found that a major portion of
3 the azelastine hydrochloride had not dissolved,
4 right?

5 A. I'm sorry. You're looking at
6 paragraph 24?

7 Q. Yes, the last part of paragraph 24, on
8 page 12.

9 A. Right. But the beginning of that,
10 that's where you stated that the team prepared
11 another sample. That's correct. That's in the
12 beginning.

13 And then -- I'm sorry, then you jumped
14 down to the fact that the team had found the major
15 portion of the azelastine had not dissolved in
16 that second sample, another sample, correct.

17 Q. Isn't it true that whatever remained
18 undissolved could have been a number of things
19 besides the azelastine hydrochloride?

20 MR. LaROCK: Objection. Outside the
21 scope of his testimony. Calls for
22 speculation.

1 A. John -- John was an experienced
2 formulator. So he recognized the material that he
3 put into the vial of the azelastine hydrochloride,
4 and would likely have recognized that the shape of
5 the material and crystals would have been the same
6 the following day.

7 Q. Dr. D'Addio, I'm going to be -- I'm
8 handing you what has been previously marked as
9 Patent Owner Exhibit 2061.

10 Dr. D'Addio, do you recognize this
11 exhibit?

12 A. I do.

13 Q. What is this document?

14 A. This is a photocopy of a laboratory
15 notebook that was used by John D'Aconti in
16 recording experiments in our laboratories.

17 Q. So could you now please turn to
18 page 18 of Exhibit 2061.

19 A. I have it.

20 Q. Now, this was cited on page 12 of your
21 declaration for the proposition that a major
22 portion of the azelastine hydrochloride had not

1 dissolved, correct?

2 A. I'm sorry. You want me to go back to
3 page 12 here? And that's the page of -- at the
4 top of page 12, so this is now relating actually
5 to the experiment on page -- the notebook
6 page 117, correct.

7 Q. And you see on the bottom, I would say
8 five lines from the bottom, it said, "The
9 following morning, the sample was observed for
10 clarity/solubility, and it was found that there
11 was still a major portion of the azelastine
12 hydrochloride that had not gone into solution,"
13 correct?

14 A. That's what's stated in the notebook,
15 correct.

16 Q. Mr. D'Aconti did not run any tests to
17 determine if it was actually azelastine
18 hydrochloride that could not dissolve, correct?

19 MR. LaROCK: Object to the form of the
20 question. Outside the scope of this
21 declaration. Calls for speculation.

22 A. I do not know if any other testing was

1 performed. However, as I stated before, John did
2 observe the material that he added the day before
3 and then observed the same material the day after.
4 And that was the conclusion that he came to, that
5 the majority had not dissolved.

6 Again, John was an experienced
7 formulator and would recognize the appearance on
8 the azelastine crystal.

9 Q. Now, Mr. D'Aconti did not mention the
10 shape or characteristic of the crystals of
11 azelastine hydrochloride on page 18, correct, of
12 Exhibit 2061?

13 A. He did not record the appearance of
14 what the crystals were that he observed.

15 Q. Let's turn now to paragraph 25 of your
16 declaration.

17 A. I'm sorry, paragraph 25?

18 Q. Yes.

19 A. Yes.

20 Q. So on April 27, 2006, Mr. D'Aconti put
21 the sample through cycles of stirring and heating,
22 which is when the sample turned white, correct?

1 A. I believe that --

2 MR. LaROCK: Object to the extent it
3 mischaracterizes his testimony.

4 A. I believe that occurred through the
5 experiment.

6 Q. I'm sorry. Hold on. Are you done
7 answering my question?

8 A. I'm trying to look in the notebook for
9 the specifics of that experiment. And that was --
10 I'm sorry, I can't find it.

11 So I'm not sure that it turned white
12 automatically, but it was during these
13 experiments, through the experiments that it
14 turned white later on. Initially, it became
15 translucent, and it looked like that had dissolved
16 the crystals at that point. And then later on it
17 became a white opaque sample after standing. So
18 it did turn white, but not immediately.

19 Q. Okay. So after the stirring and the
20 heating, the sample was heated for another
21 15 minutes and then left to cool overnight,
22 correct?

1 A. So after it was translucent, then it
2 became white opaque. Then it was brought to room
3 temperature. Then it was heated again, and,
4 correct, then another 15 minutes of heating and
5 stirring, and there was no observed change in that
6 sample.

7 Q. And this was when Mr. D'Aconti found
8 that a solid had, in fact, precipitated out of the
9 sample, correct?

10 A. No, I think that was the following
11 day, the next morning, on standing.

12 Q. Yes. So after it was left overnight
13 to cool, the following morning, Mr. D'Aconti
14 observed that a solid had, in fact, precipitated
15 out of the sample, correct?

16 A. That's correct.

17 Q. Now, once again, Mr. D'Aconti did not
18 actually test to determine if the precipitant was
19 actually azelastine hydrochloride, correct?

20 MR. LaROCK: Object to the form of the
21 question. Outside the scope. Calls for
22 speculation.

1 A. John did submit -- the sample was
2 submitted for testing to evaluate the precipitate.

3 Q. And you did not follow up, Meda did
4 not follow up on that chemical analysis, correct?

5 MR. LaROCK: Object to the form of the
6 question.

7 A. I don't know if the sample was ever
8 tested. It was submitted.

9 Q. Now, I'm assuming that Mr. D'Aconti
10 had run a chemical analysis test on this solid
11 because -- strike that.

12 Dr. D'Addio, Meda never considered
13 developing a nasal drop formulation; is that
14 correct?

15 MR. LaROCK: Object to the form of the
16 question. Outside the scope.

17 Q. Let me restate it: Meda never
18 considered developing a nasal drop formulation
19 with both azelastine and fluticasone, correct?

20 MR. LaROCK: Outside the scope.

21 A. Not that I'm aware of.

22 Q. Dr. D'Addio, I'm going to hand you

1 what has been previously marked Exhibit 1001. Do
2 you recognize this patent, Dr. D'Addio?

3 A. I do.

4 Q. Dr. D'Addio, can you please turn to
5 column 11 of the '620 patent.

6 A. I have it.

7 Q. Now, if Meda had continued its
8 development efforts and eventually developed a
9 combination of azelastine and fluticasone that was
10 suitable for nasal spray administration, that
11 combination would have fallen within the scope of
12 Claim 1 of the '620 patent, correct?

13 MR. LaROCK: Object to the form of the
14 question. Outside the scope of this
15 declaration. Calls for speculation.

16 A. I don't know what the final
17 formulation would have been, so I can't say if it
18 would have fallen in the scope of this or not.

19 Q. Dr. D'Addio, Claim 1 only requires a
20 pharmaceutical formulation comprising azelastine
21 or a pharmaceutically acceptable salt thereof, and
22 a pharmaceutically acceptable ester of fluticasone

1 wherein said pharmaceutical formulation is in a
2 dosage form suitable for nasal administration.

3 It does not require a specific
4 formulation, correct?

5 MR. LaROCK: Object to the form of the
6 question. Outside the scope of his
7 declaration. Calls for legal analysis.

8 A. We never completed the development
9 program, so I can't say. What you asked me was
10 that if it proceeded, would it have formed, and I
11 don't know that, because we never completed our
12 development.

13 Q. I'm asking you a hypothetical
14 question, which is, if Meda had continued its
15 development efforts and successfully developed a
16 combination of azelastine and fluticasone that was
17 suitable for nasal spray administration, it would
18 have fallen within Claim 1 of the '620 patent,
19 correct?

20 MR. LaROCK: Objection. Outside the
21 scope of his declaration. Calls for
22 speculation.

1 A. Yeah, I don't know.

2 Q. Dr. D'Addio, you are familiar with
3 patents, correct?

4 MR. LaROCK: Object to the form of the
5 question: Outside the scope.

6 A. At some level, yes. I'm certainly not
7 an expert.

8 Q. And patents are generally important in
9 the pharmaceutical industry, right?

10 MR. LaROCK: Object to the form of the
11 question. Outside the scope.

12 A. That's my understanding.

13 Q. Do you know why they are important?

14 MR. LaROCK: Object to the form of the
15 question. Outside the scope.

16 A. The patents offer some protection
17 during the marketing of the product against
18 generic competition.

19 Q. Are patents important to Meda?

20 MR. LaROCK: Objection. Outside the
21 scope.

22 A. I believe they were.

1 Q. So if Meda was going to spend a
2 significant time developing a new product, it
3 would want its own patent rights; isn't that
4 correct?

5 A. I'm sorry. Say that again.

6 Q. If Meda was going to spend significant
7 time developing a product, it would want patent
8 rights to that product, correct?

9 MR. LaROCK: Objection. Outside the
10 scope. Calls for speculation.

11 A. I -- I believe that that would have
12 been important to the company, correct.

13 Q. To your knowledge, has Meda ever
14 developed a pharmaceutical product not covered by
15 a patent that is either owned or licensed by Meda?

16 MR. LaROCK: Object to the form of the
17 question. Outside the scope. Calls for
18 speculation.

19 A. I believe that we have.

20 Q. Do you recall what products?

21 MR. LaROCK: Objection. Outside the
22 scope. Relevance.

1 A. I believe we have a compound,
2 SOMA 250. It's a tablet containing carisoprodol
3 as an active ingredient.

4 Q. Would you agree that, when developing
5 a new product, it is Meda's general business
6 practice to pursue those products that will be
7 covered by patents?

8 MR. LaROCK: Objection. Outside the
9 scope of his declaration. Calls for
10 speculation.

11 A. I don't know that that was a rule, no.

12 Q. Dr. D'Addio, are you currently a named
13 inventor on any patents?

14 A. I am.

15 Q. How many?

16 A. Approximately seven or eight.

17 MS. LIU: Dr. D'Addio, I'm going to
18 ask the court reporter to mark this Exhibit
19 as Exhibit 1056.

20 [Whereupon, Exhibit 1056, U.S. Patent
21 No. 6,417,206, was hereby marked as for
22 identification, as of this date.]

1 BY MS. LIU:

2 Q. Dr. D'Addio, do you recognize this
3 patent?

4 MR. LaROCK: Hold on. Wait. I'm just
5 going to object to the document on relevance
6 grounds.

7 Q. You my answer the question. Do you
8 recognize this patent Dr. D'Addio?

9 A. I do.

10 Q. For clarification purposes, is it okay
11 if I refer to U.S. patent No. 6,417,206 as the
12 '206 patent?

13 A. Yes.

14 Q. This patent is entitled Antitussive
15 Antihistaminic Decongestant Composition, correct?

16 A. Correct.

17 Q. The assignee of this patent is
18 MedPointe Healthcare, Incorporated, right?

19 A. Yes.

20 Q. And you were working at MedPointe when
21 you filed this patent application and this patent
22 -- when this patent issued on July 9, 2002,

1 correct?

2 A. I was.

3 Q. Now, let's turn your attention to the
4 abstract.

5 This patent is directed to tannate
6 compositions consisting essentially of
7 carbetapentane tannate, pyrilamine tannate, and
8 phenylephrine tannate, that are effective when
9 administered orally for the symptomatic relief
10 cough associated with respiratory tract
11 conditions, such as the common cold, bronchial
12 asthma, acute and chronic bronchitis, correct?

13 A. Yes.

14 Q. Did you work on developing the
15 compositions disclosed in this patent?

16 MR. LaROCK: Object to the form of the
17 question. Outside the scope of this
18 declaration. Relevance.

19 A. I did work with Ronald Leflein on
20 developing the -- on developing the formulations.

21 Q. Approximately how long did it take to
22 develop the compositions disclosed in the '206

1 patent?

2 MR. LaROCK: Object to the form of the
3 question. Outside the scope of his
4 declaration.

5 A. I don't really recall how long it was.

6 Q. Can you give an approximate time
7 frame?

8 MR. LaROCK: Object to the form of the
9 question. Outside the scope of the
10 declaration. Calls for speculation.

11 A. It could have been a year. It could
12 have been months. I don't recall.

13 Q. Now, in the process of developing the
14 compositions of the '206 patent, can you estimate
15 how many experiments were run?

16 MR. LaROCK: Object to the form of the
17 question. Outside the scope of his
18 declaration. Relevance. Calls for
19 speculation.

20 A. I don't recall. I don't recall how
21 many there were.

22 Q. It took at least a couple of months to

1 develop the compositions disclosed in the '206
2 patent, correct?

3 MR. LaROCK: Object to the form of the
4 question. Outside the scope of his
5 declaration. Calls for speculation.

6 A. I would have said more than that.

7 Q. More than a couple of months?

8 A. I believe so. I really don't recall.

9 Q. Dr. D'Addio, do you recall any
10 failures during that experimentation to develop
11 the compositions in the '206 patent?

12 MR. LaROCK: Object to the form of the
13 question. Outside the scope of his
14 declaration. Calls for speculation.

15 A. I do not recall any failures.

16 Q. You don't recall if there were any
17 failures, or you don't think that there were any
18 failures?

19 A. I don't recall if there were any
20 failures.

21 Q. Let's look more specifically at the
22 suspension formulations in example one of the '206

1 patent. Can you please turn to Column 2. At the
2 end of Column 2, do you see Example 1?

3 A. Yes.

4 Q. And it continues to Column 3, the
5 beginning of Column 3. And at the end of the list
6 of ingredients, there's a sentence that states,
7 "Suspensions of the compositions of the present
8 invention are prepared in a conventional manner,
9 such that each 5 milliliter teaspoon contains," a
10 list of ingredients. Correct? Do you see that?

11 A. The list of active ingredients,
12 correct.

13 Q. Do you recall ever getting a
14 precipitate when developing these suspensions?

15 MR. LaROCK: Object to the form of the
16 question. Outside the scope of this
17 declaration. Relevance. Calls for
18 speculation.

19 A. I know that precipitation can occur.
20 I don't know if it re-occurred in this specific
21 formulation.

22 MS. LIU: I think we've been going an

1 hour. We can take a break.

2 (Whereupon, a short recess was taken.)

3 MS. LIU: Back on the record.

4 BY MS. LIU:

5 Q. Dr. D'Addio, did you discuss any
6 aspect of your past and future testimony with
7 counsel during the break?

8 A. I did not.

9 Q. Dr. D'Addio, do you recall Meda ever
10 developing a formulation within a couple of days?

11 MR. LaROCK: Object to the form of the
12 question. Outside the scope of his
13 declaration.

14 A. I don't recall.

15 Q. In the years you have worked at Meda,
16 what was the shortest amount of time it took to
17 develop a viable product?

18 MR. LaROCK: Object to the form of the
19 question. Outside the scope of his
20 declaration.

21 A. I guess it would depend. Probably on
22 the order of weeks to months. Typically you have

1 to perform a lot of testing on the formulation to
2 be able to decide if you've made a viable
3 formulation.

4 Q. Would it be closer to months or would
5 it be closer to weeks?

6 A. Probably months.

7 Q. Can you estimate the longest time it
8 took to develop a formulation at Meda?

9 MR. LaROCK: Object to the form of the
10 question. Outside the scope.

11 A. Probably on the order of years.

12 Q. Can you estimate the average span of
13 time it takes Meda to develop a formulation for a
14 drug product?

15 A. No, I can't.

16 Q. And why not?

17 A. Because it's such a wide range.

18 Q. Dr. D'Addio, let's turn back to your
19 declaration, to paragraph 26.

20 A. Yes.

21 Q. Now, you state that in May 2006, you
22 discovered Cipla's published patent application,

1 and that Cipla was selling a nasal spray product,
2 Duonase, correct?

3 A. Meda discovered that.

4 Q. Yes. And then you asked Mr. Balwani
5 to procure samples of Duonase from India, correct?

6 A. That's correct.

7 Q. Did you ever actually secure samples
8 of Duonase?

9 A. Mr. Balwani did procure samples of
10 Duonase.

11 Q. Did you conduct any testing -- scratch
12 that.

13 Did Meda conduct any testing on the
14 Duonase formulation received from Cipla?

15 MR. LaROCK: Object to the form of the
16 question. Outside the scope his declaration.

17 A. I believe we did. I don't recall the
18 extent of the testing that we performed on it.

19 Q. So you don't recall whether or not you
20 tested why Duonase did not present any of the
21 precipitation issues you were having over the two
22 to three days of testing you did perform -- Meda

1 did perform?

2 A. I'm sorry. Say it again.

3 Q. So Meda never -- sorry, scratch that.

4 So you don't recall whether or not

5 Meda tested why Duonase did not present any of the

6 precipitation issues that Meda was having over the

7 two to three days of testing performed?

8 MR. LaROCK: Object to the form of the

9 question. Outside the scope,

10 mischaracterizes his testimony.

11 A. I don't know how we would have tested

12 why. We probably would have tested the fact that

13 it contained the drug products, the azelastine and

14 the fluticasone.

15 Q. Did you ever find out from Cipla how

16 to formulate Duonase?

17 MR. LaROCK: Object to the form of the

18 question. Hearsay. Outside the scope.

19 A. They -- they have a process and a

20 formulation, and we became aware of that process

21 and formulation later on.

22 Q. And that process and formulation

1 testing -- strike that.

2 How did that formulation differ from
3 the pre-formulation testing that Meda had
4 performed?

5 MR. LaROCK: Objection. Outside the
6 scope.

7 A. The feasibility experiment?

8 Q. Yes.

9 A. The feasibility experiment was just a
10 lab experiment to determine if we could add
11 azelastine to the supernatant liquid of the
12 Flonase formulation.

13 Q. You state in paragraph 26 that you
14 only discovered Cipla's published application
15 after Mr. D'Aconti's testing, correct?

16 A. That's my recollection.

17 Q. So based on that, Meda realized that
18 Cipla had been first to file a patent application
19 on an azelastine and fluticasone combination,
20 correct?

21 MR. LaROCK: Objection. Outside the
22 scope.

1 A. I don't know if anybody else had filed
2 patents like that.

3 Q. Now, after seeing the published patent
4 application, did Meda ever attempt to reproduce
5 any of the combination formulations that were
6 disclosed in that application?

7 MR. LaROCK: Object to the form of the
8 question. Outside the scope of his
9 declaration.

10 A. We did work in trying to duplicate the
11 formulation in our laboratories. I don't know the
12 extent of that testing. At that point we were
13 committed to working with the Cipla formulation.

14 Q. So Meda did try to duplicate the
15 formulations in the Cipla's public, published
16 application, correct?

17 A. At some point --

18 MR. LaROCK: Object to the form of the
19 question. Mischaracterizes his testimony.
20 Outside the scope.

21 A. I think at some point after that, we
22 did try duplicating that, to duplicate the

1 formulation.

2 Q. And you do not recall any of the
3 results of those duplication efforts?

4 A. Not at this time, no.

5 Q. So those duplication efforts conducted
6 by Meda couldn't have been successful, correct?

7 MR. LaROCK: Objection. Object to the
8 form of the question. Outside the scope.

9 A. So as our program went along and we
10 became fully aware of the process that Cipla used,
11 we did actually transfer the manufacturing process
12 for what became Dymista to our Decatur facility,
13 and that we had a successful method process
14 transfer of that to our Decatur facility, so that
15 we could manufacture the Dymista product in the
16 U.S. as well as in India.

17 Q. So Meda needed Cipla's help to perform
18 the formulation beyond what was in the patent
19 application, correct?

20 MR. LaROCK: Object to the form of the
21 question. Outside the scope of his
22 declaration. Mischaracterizes his testimony.

1 A. I'm not sure what you mean by that.

2 It was the Cipla patent. It was their -- their
3 patent. Cipla manufactured the product for us,
4 and that was the initial manufacturing for Dymista
5 as well. It was all done at Cipla.

6 Q. So why did Meda try to duplicate the
7 formulation disclosed in the Cipla patent
8 application then?

9 MR. LaROCK: Object to the form of the
10 question. Mischaracterizes his testimony.
11 Outside the scope of his declaration.

12 A. So the later manufacturing was to
13 provide a second manufacturing site for the
14 product. And I believe that was through an
15 agreement with Cipla.

16 Q. No. My question was, you had stated
17 earlier that Meda had conducted some duplication
18 efforts of the Cipla's patent application.

19 My question is, why did Meda try to
20 duplicate that formulation?

21 MR. LaROCK: Object to the form of the
22 question. Outside the scope of his

1 declaration. Calls for speculation.

2 A. So what we were working on was wanting
3 to verify for ourselves what that formulation was.

4 Q. And you don't recall whether or not
5 you were able to verify?

6 A. I really don't recall the exact
7 results of that.

8 Q. But it didn't matter, because you --
9 because Meda ended up using the Cipla formulation,
10 correct?

11 A. We did end up using the Cipla
12 formulation for Dymista.

13 Q. In your declaration, you mentioned a
14 licensing arrangement between Meda and Cipla, in
15 paragraphs 27 and 28 of your declaration.

16 A. Yes.

17 Q. Why did Meda need to enter into that
18 agreement?

19 MR. LaROCK: Object to the form of the
20 question. Outside the scope of his
21 declaration. Calls for speculation.

22 A. I'm not sure why. I think obviously

1 they wanted to have the opportunity to use this
2 Cipla formulation, and I believe that's what is
3 described in the agreement.

4 Q. Dr. D'Addio, I am going to be handing
5 you what was previously marked Patent Owner
6 Exhibit 2049.

7 Dr. D'Addio, do you recognize this
8 document?

9 A. I believe this looks a little bit
10 bigger. This looks like the one that was in my
11 declaration.

12 Q. Yes, it is.

13 Doctor, can I direct your attention to
14 Section 5.6 of Exhibit 2049, on page 9. Are you
15 there?

16 A. I am, 5.6.

17 Q. Now, this section provides Meda with
18 the ability to comment and control prosecution of
19 the Cipla patent publication that Meda discovered,
20 correct?

21 MR. LaROCK: Object to the extent it
22 mischaracterizes Exhibit 2049.

1 A. So it says that they will fully
2 cooperate with each other. And what was the
3 phrase that you used?

4 Q. The ability to comment and control
5 prosecution.

6 A. I don't know that I'm aware of that.
7 This is necessary for the prosecution of the U.S.
8 patent, and continual, continuation --
9 continuation in part.

10 Q. Do you see the sentence, "Cipla shall
11 instruct its patent counsel m keep MedPointe fully
12 informed of the substance and status of the
13 prosecution of the patent applications, and shall
14 obtain MedPointe's comments and suggestions prior
15 to taking any material actions in the prosecution
16 of the patent applications."

17 Do you see that?

18 A. I do.

19 Q. So this section provides Meda with the
20 ability to, in general, comment and control
21 prosecution of the Cipla patent publication that
22 Meda discovered, correct?

1 MR. LaROCK: Objection. Outside the
2 scope of this declaration. Form. Calls for
3 a legal conclusion.

4 A. Yeah, I -- this is not my agreement.
5 That's what you read there is accurate, but I
6 don't know that I can comment on it.

7 Q. So reading Section 5.6 you would agree
8 is that Meda -- strike that.

9 You would agree, reading Section 5.6,
10 that Meda believes patent coverage over the
11 formula was important, correct?

12 MR. LaROCK: Object to the form of the
13 question. Outside the scope of his
14 declaration.

15 A. It's -- I can't say that Meda -- from
16 this, that Meda considered it important. They put
17 it in the agreement.

18 Q. Now, Dr. D'Addio, this agreement was
19 actually a product agreement and the patent
20 portion of it was only one portion of the
21 agreement, correct?

22 MR. LaROCK: Object to the form of the

1 question. Object to the extent it
2 mischaracterizes the document.

3 A. Yeah, again, I don't know. This is
4 not my agreement. This was the agreement between
5 Meda and Cipla, but I did not draft it.

6 Q. Do you see on the first page of
7 Exhibit 2049 that the title is "Azelastine
8 Combination Product Agreement"?

9 A. Yes.

10 Q. Can I direct your attention to page 26
11 out of Exhibit 2049.

12 A. Yes.

13 Q. Do you see that?

14 A. I do.

15 Q. Can you please confirm that the target
16 formulation shown on page 26 of Exhibit 2049 is
17 not provided in the '620 patent?

18 MR. LaROCK: Object to the form of the
19 question. Outside the scope of his
20 declaration. Objection to the extent it
21 mischaracterizes the Document 2049. And
22 objection to the extent it calls for a legal

1 conclusion.

2 A. So where are you looking exactly?

3 You're looking at the parameter at the top and the
4 formulation?

5 Q. Yes.

6 A. It has azelastine and fluticasone VAC
7 and phenylethyl alcohol.

8 Q. My question was, can you confirm for
9 me that the target formulation shown on top not
10 provided in the '620 patent in Exhibit 1001?

11 MR. LaROCK: Object to the form of the
12 question. Calls for a legal analysis and
13 legal conclusion. Outside the scope of his
14 testimony, form.

15 A. Yeah, I don't -- I don't know that
16 this was intended to be a word-for-word
17 duplication on what the final formulation was.

18 Q. Dr. D'Addio, I'm asking if the
19 formulation on page 26 of Exhibit 2049 is in the
20 '620 patent, which I believe I have handed to you
21 already, the '620 patent?

22 MR. LaROCK: Object to the form of the

1 question. Calls for a legal conclusion and
2 legal analysis, outside the scope of his
3 declaration. Form.

4 A. This appears to me to be just a
5 listing of the active and the preservative system
6 used in the formulation. This would not have been
7 the final formulation in Dymista.

8 Q. Can you please turn to page 5 and take
9 a look at Section 1.27.

10 A. I'm sorry, which document are you at?

11 Q. 2049. Same document.

12 A. Which page number again?

13 Q. Page 5.

14 A. Yes.

15 Q. This section refers to further
16 formulation development work that Meda and Cipla
17 would do together; is that right?

18 A. Can you point that out to me.

19 MR. LaROCK: Objection to the extent
20 it mischaracterizes the document.

21 A. Where on the page?

22 Q. Section 1.27?

1 A. Section 1.27. Chart of formulation.

2 Okay. I see that. And the question again?

3 Q. Dr. D'Addio, can you look at
4 Section 1.27 and in addition 4.1 on page 8. Let
5 me know when you're done reading it.

6 A. Yes.

7 Q. Both of those sections refer to
8 further formulation development work that Meda and
9 Cipla would do together; is that right?

10 MR. LaROCK: Object to the form of the
11 question. Objection to the extent it
12 mischaracterizes the contents of
13 Exhibit 2049.

14 A. This does is describe additional
15 formulation work that Cipla was going to do, with
16 our input.

17 Q. Did Meda and Cipla, in fact, do more
18 formulation work after this agreement was signed?

19 MR. LaROCK: Object to the form of the
20 question. Outside the scope of his
21 testimony.

22 A. I believe there was a minor

1 modification in the final formulation that became
2 Dymista.

3 Q. What was the minor modification?

4 MR. LaROCK: Object to the form of the
5 question. Outside the scope of his
6 testimony.

7 A. There was a reduction in the amount of
8 an antioxidant.

9 Q. And you don't recall what antioxidant
10 that was?

11 A. Polysorbate, I believe it was
12 polysorbate. Do you have a -- I would like to
13 refer to the formulation description. I don't
14 recall exactly what it was. Do we have that?

15 Q. No.

16 A. No formulation for Dymista?

17 Q. Actually I do. I will be handing you
18 Exhibit 2154.

19 A. Yes, the component that was modified
20 was polysorbate 80.

21 Q. Are you able to estimate for me how
22 many days of work was performed to reduce the

1 antioxidant polysorbate?

2 MR. LaROCK: Object to the form of the
3 question. Outside the scope of his
4 declaration. Calls for speculation.

5 A. I don't. I don't know how long it
6 took for us to take that modification. It was
7 more than a day or two.

8 Q. It would be less than a month, though,
9 correct?

10 MR. LaROCK: Object to the form of the
11 question. Outside the scope of his
12 declaration. Calls for speculation.

13 A. I don't know. I don't know if it was
14 more than a month.

15 Q. After getting a license from Cipla,
16 did Meda learn information from Cipla regarding
17 how to make the combination formulation of
18 azelastine and fluticasone work as a suitable
19 nasal spray?

20 MR. LaROCK: Object to the form of the
21 question. Outside the scope of his
22 declaration.

1 A. We did receive copies of their batch
2 record for the manufacture of the combination
3 product.

4 Q. Was that information learned from
5 Cipla necessary to develop a combination product
6 of azelastine and fluticasone that is suitable for
7 nasal administration?

8 MR. LaROCK: Object to the form of the
9 question. Outside the scope of his
10 declaration. Calls for speculation.

11 A. So it was Cipla's product, and it was
12 their manufacturing process.

13 Q. Meda wasn't successful in formulating
14 an azelastine and fluticasone combination product,
15 correct?

16 MR. LaROCK: Object to the form of the
17 question.

18 A. We did not -- we did not manufacture a
19 combination product. That's why we licensed the
20 Cipla product.

21 Q. So knowing what Cipla had given Meda
22 -- strike that.

1 So Meda couldn't have developed a
2 suitable combination azelastine-fluticasone
3 product without help from Cipla; is that correct?

4 MR. LaROCK: Object to the form of the
5 question.

6 A. I wouldn't say that. I mean, we
7 didn't do a full development program on it. So we
8 never -- never really got to the point where we
9 could spend a lot of time on it.

10 Q. Did Meda learn how much
11 experimentation was required to arrive at a
12 suitable nasal spray formulation for azelastine
13 and fluticasone?

14 MR. LaROCK: Object to the form of the
15 question. Hearsay. Outside the scope of his
16 declaration.

17 A. I'm not sure that I understand. Can
18 you repeat that.

19 Q. Did Meda ever learn how much
20 experimentation was required to arrive at a
21 suitable nasal spray formulation that has
22 azelastine and fluticasone?

1 MR. LaROCK: Object to the form of the
2 question. Hearsay. Outside the scope of his
3 declaration.

4 A. By who?

5 Q. Did Meda learn how much
6 experimentation was required by Cipla to arrive at
7 a suitable nasal spray formulation of azelastine
8 and fluticasone?

9 MR. LaROCK: Object to the form of the
10 question. Hearsay. Outside the scope of his
11 declaration.

12 A. I don't think we ever got details on
13 how long it took Cipla to develop that
14 formulation.

15 Q. Did Meda learn any details about the
16 experimentation that Cipla did perform to get to
17 the combination azelastine and fluticasone
18 formulation?

19 MR. LaROCK: Object to the form of the
20 question. Hearsay. Outside the scope of the
21 declaration.

22 A. We did receive a development report

1 from them that talked about their process to
2 getting to the Dymista formulation.

3 Q. Do you recall how long that process
4 took?

5 A. I do not.

6 Q. Do you recall what level of
7 experimentation Cipla had to conduct in order to
8 develop a combination azelastine-fluticasone
9 formulation?

10 MR. LaROCK: Object to the form of the
11 question. Outside the scope of the
12 declaration.

13 A. What do you mean by "level of
14 experiment"?

15 Q. I'm assuming that Cipla performed more
16 experimentation than the feasibility studies that
17 Meda had performed, correct?

18 A. I don't -- I don't know. Again, I
19 don't know how much effort they put into that
20 development of the formulation.

21 Q. I'm assuming you know that Cipla spent
22 more than the two to three days that Meda took to

1 develop its combination of the formulation,
2 correct?

3 MR. LaROCK: Object to the form of the
4 question. Outside the scope of the
5 declaration. Calls for speculation.

6 A. I would imagine so.

7 Q. So you aren't aware of what Cipla was
8 able to discover that Meda wouldn't likewise have
9 discovered had Meda simply continued on with its
10 development program?

11 MR. LaROCK: Object to the form of the
12 question. Outside the scope of this
13 declaration. Calls for speculation.

14 A. I'm going to ask you to repeat that
15 again. I'm not aware and -- and help me out with
16 the question again?

17 (Whereupon, the referred-to question
18 was read back by the Reporter.)

19 MR. LaROCK: Same objections.

20 A. Yeah, no, we didn't continue on with
21 our development programs. I can't say what the
22 difference would be.

1 Q. Now, you agree, you would agree that
2 the concept of combining azelastine and
3 fluticasone into a single product wasn't new,
4 right?

5 MR. LaROCK: Object to the form of the
6 question. Outside the scope of this
7 declaration.

8 A. I don't know that first concept came
9 in, the combination. We talked about azelastine
10 and the combination with a steroid as early as
11 2002.

12 Q. And that time frame was before seeing
13 Cipla's patent, published patent application,
14 correct?

15 A. That's correct.

16 Q. So was there anything new in Cipla's
17 final formulation that Meda had not known about?

18 MR. LaROCK: Object to the form of the
19 question. Outside the scope of this
20 declaration.

21 A. I don't know what you mean by "new."

22 Q. What was in Cipla's final formulation

1 that made it successful?

2 MR. LaROCK: Object to the form of the
3 question. Outside the scope of his
4 declaration. Calls for speculation.

5 A. The formulation itself?

6 Q. Yes.

7 A. What made it successful? I'm not
8 sure. I'm not sure what made it successful. I'm
9 still surprised that it's a -- it's a product.

10 Q. So is it your opinion that there was
11 -- scratch that.

12 So based on what you told me, is there
13 anything disclosed in Cipla's published patent
14 application that would have helped Meda develop
15 its own combination azelastine and fluticasone
16 formulation?

17 MR. LaROCK: Object to the form of the
18 question. Outside the scope of his
19 declaration. Calls for speculation.

20 A. In developing -- developing our own,
21 that would have been different than the Cipla
22 patent? I don't -- I don't know, other than

1 copying theirs. But that would have been their
2 patent.

3 Q. Let's go back to your declaration,
4 paragraph 15 of your declaration.

5 A. Yes.

6 Q. Now, you stated in your declaration
7 that FDA's combination rule was a potential
8 problem for Meda's desire to create a combination
9 product, correct?

10 MR. LaROCK: Object to the extent it
11 mischaracterizes paragraph 15.

12 A. So what we're talking about here is
13 that we recognize that we would have to --
14 according to the FDA's combination rule, we would
15 have to be able to satisfy those criteria for a
16 successful product.

17 Q. Now, why did Meda even create a
18 combination product, knowing full well that this
19 rule existed?

20 MR. LaROCK: Outside -- objection.
21 Outside the scope of his declaration calls
22 for speculation.

1 A. I'm not sure what you mean, why would
2 we do it regardless. We knew that it was going to
3 be a hurdle.

4 Q. Yes. So given that this was a
5 potential hurdle, why did Meda go through the
6 process of creating a combination product?

7 MR. LaROCK: Object to the form of the
8 question. Outside the scope of his
9 declaration. Calls for speculation.

10 A. They were still interested in a
11 combination product of azelastine and a steroid.

12 MS. LIU: I'm going to take a break
13 and see if we have any additional questions.
14 Is that okay?

15 (Whereupon, a short recess was taken.)

16 MS. LIU: Back on the record. No
17 further questions.

18 MR. LaROCK: No questions either.

19 (Deposition concluded 11:15 a.m.)

20

21

22

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22

CERTIFICATE OF DEPONENT

I hereby certify that I have read the foregoing pages of my deposition testimony in this proceeding, and with the exception of changes and/or corrections, if any, find them to be a true and correct transcription thereof.

Deponent

Date

NOTARY PUBLIC

Subscribed and sworn to before me this

_____ day of _____, 20__.

Notary Republic

My Commission Expires:_____

	ERRATA SHEET		
	PAGE --	LINE --	CORRECTION/REASON
1			
2			
3			
4			
5			
6			
7			
8			
9			
10			
11			
12			
13			
14			
15			
16			
17			
18			
19			
20			
21			
22			

	ERRATA SHEET		
	PAGE --	LINE --	CORRECTION/REASON
1			
2			
3			
4			
5			
6			
7			
8			
9			
10			
11			
12			
13			
14			
15			
16			
17			
18			
19			
20			
21			
22			

1 CERTIFICATE OF REPORTER/NOTARY PUBLIC.

2

3 I, Goldy Gold, a Notary Public of the
4 State of Maryland, do hereby certify that the
5 within-named witness personally appeared before me
6 at the time and place herein set out, and after
7 having been duly sworn by me, according to the
8 law, was examined by counsel.

9 I further certify that the examination
10 was recorded stenographically by me and this
11 transcript is a true record of the proceedings.

12 I further certify that I am not of
13 counsel to any of the parties, nor in any way
14 interested in the outcome of this action.

15 As witness my hand and notarial seal
16 this 21ST day of FEBRUARY, 2018.

17

18 _____
19 GOLDY GOLD, RPR
20 Notary Public

19

20

21 My Commission Expires: April 21, 2024

22