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

ARGENTUM PHARMACEUTICALS LLC

Petitioner

v.

CIPLA LTD.

Patent Owner

Patent No. 8,168,620

IPR2017-00807

Deposition of ROBERT P. SCHLEIMER, PH.D., at
the offices of Foley & Lardner, 321 North
Clark Street, Chicago, Illinois, before
Donna M. Kazaitis, IL-CSR, RPR, and CRR,
commencing at the hour of 10:00 a.m. on
Friday, October 20, 2017

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22

1 (Witness sworn.)

2 ROBERT P. SCHLEIMER, PH.D.,
3 having been first duly sworn, was examined and
4 testified as follows:

5 EXAMINATION

6 BY MR. VARUGHESE:

7 Q. Good morning, Dr. Schleimer.

8 A. Good morning, Mr. Varughese.

9 Q. Just for the record, my name is
10 Dennies Varughese from the law firm of Sterne
11 Kessler on behalf of patent owner here in this
12 proceeding Cipla. With me today is backup counsel
13 of record Deborah Sterling. And also joining us
14 is Joshua Miller, an associate at our firm.

15 Dr. Schleimer, we have met before.

16 A. We have.

17 Q. We've been in another proceeding,
18 which we'll get to.

19 Given our familiarity, I'm not
20 going to go over some of the preliminaries. I
21 assume that you're familiar with the deposition
22 and what we're here to do today, just the typical

1 rules.

2 One of them is I'm going to use
3 plain English words. I'm going to presume that
4 you understand the meaning of the words that I use
5 in my questions unless you tell me otherwise; is
6 that fair?

7 A. That's fair.

8 Q. Okay. Are you on any medication or do
9 you suffer from any ailment that would preclude
10 you from testifying truthfully and accurately
11 today?

12 A. No.

13 Q. So, Dr. Schleimer, I am going to hand
14 you what has been previously marked in this
15 proceeding as CIP 2018. (Document tendered to the
16 witness.)

17 A. Okay.

18 Q. Please take a moment to orient
19 yourself to that document.

20 A. Okay.

21 Q. Do you recognize this document?

22 A. Well, I recognize the front page. It

1 appears to be from the court case in Wilmington,
2 Delaware that was last December.

3 Q. And just for identification purposes,
4 I think that court case that you're referring to
5 is Meda Pharmaceuticals and Cipla Ltd., vs. Apotex
6 Inc. and Apotex Corp., Case Number 14-1453-LPS.

7 A. Yes.

8 Q. And this is a trial between Meda and
9 Apotex involving, among other things, the '620
10 Patent that is at issue in this IPR proceeding;
11 correct?

12 A. Correct.

13 Q. If you flip through that document, and
14 take as much time as you need, would you recognize
15 this document as your trial testimony from that
16 trial?

17 MR. HOUSTON: Objection, form.

18 THE WITNESS: Well, it may have my
19 testimony in it, but it appears to have many other
20 testimonies.

21 BY MR. VARUGHESE:

22 Q. If I can direct you to Page 141.

1 A. Okay.

2 Q. Do you recognize that as beginning
3 your testimony?

4 A. It appears to be when Mr. Klein said
5 "Good afternoon, Dr. Schleimer."

6 Q. Yes. And then flipping through this,
7 do you have any reason to believe that this is not
8 a transcript of your testimony from that trial,
9 recognizing that it also contains other material,
10 as you've alluded to?

11 A. Well, yeah, my brief inspection
12 suggests that it is a transcript.

13 Q. Okay. And when you testified in that
14 trial, you testified under oath; correct?

15 A. I did.

16 Q. Dr. Schleimer, I'm going to hand you
17 what's been previously marked as CIP2019 in this
18 IPR proceeding. (Document tendered to the
19 witness.)

20 A. Okay.

21 Q. Take a moment to orient yourself to
22 that document, please.

1 A. Okay. I've looked at the front page.

2 Q. Do you recognize this document?

3 A. It looks very similar to the one you
4 just handed me.

5 Q. Okay. The one I just handed you being
6 the trial transcripts from the December trial mean
7 Meda and Apotex; correct?

8 A. Yes.

9 Q. And then would you agree that this
10 document, CIP2019, is the remainder of your
11 testimony from that trial proceeding?

12 A. That would be a reasonable assumption
13 on my part. It starts on Page 157 and this one
14 ends at 156, yes.

15 Q. And the testimony that you gave that's
16 reflected in this second half of the transcript
17 was still under oath; correct?

18 A. That's correct.

19 Q. Dr. Schleimer, I'm going to hand you
20 what's been previously marked as CIP2025 in this
21 IPR proceeding. (Document tendered to the
22 witness.)

1 A. Okay.

2 Q. Take a moment to orient yourself to
3 the document, please.

4 A. These are heavy. I didn't know I was
5 going to get exercise.

6 Q. Killed a lot of trees.

7 A. Yes.

8 Q. Can you identify this document?

9 A. Well, on the front page it says it's a
10 transcript from the videotaped deposition of me at
11 Winston & Strawn.

12 Q. And who is Winston & Strawn?

13 A. Those are the attorneys that were
14 representing Apotex.

15 Q. And they were representing you for
16 purposes of that deposition? Is that fair to say?

17 A. I guess technically. You tell me.
18 I'm not a lawyer.

19 Q. Sure. So let's take a step back.

20 Looking at this document, does it
21 appear to be the transcript of your testimony from
22 a deposition that took place on September 29,

1 2016?

2 A. Yes.

3 Q. And that deposition was conducted in
4 connection with Meda Pharmaceuticals and Cipla
5 Ltd., versus Apotex Inc.; correct?

6 A. Yes.

7 Q. And this deposition would have been
8 related to the testimony that you ultimately gave
9 at trial in that case; correct?

10 A. Yes.

11 Q. And that testimony were the two
12 previous exhibits that we just discussed.

13 A. Yes.

14 Q. And Winston & Strawn, they were the
15 law firms that attended that deposition?

16 A. That's correct.

17 Q. And they worked with you to prepare
18 for that deposition?

19 A. Yes.

20 Q. And they were there representing you
21 in the sense that they lodged objections or maybe
22 other comments during that deposition on your

1 behalf?

2 A. If that's an appropriate use of the
3 word "represented," I would say yes.

4 Q. Okay.

5 A. I viewed them as representing Apotex
6 and bringing me in as an expert witness.

7 Q. Understood. You can set that aside
8 for now.

9 So, Dr. Schleimer, where are you
10 currently employed?

11 A. At Northwestern University.

12 Q. And your title there?

13 A. I'm a professor of medicine, professor
14 of microbiology immunology, professor of
15 otolaryngology, head and neck surgery, and the
16 chief of the allergy and immunology division.

17 Q. So can you briefly summarize for us
18 your post high school education and training?

19 A. Post high school. Well, I went to
20 University of California, San Diego, and majored
21 in biology. After that I attended the University
22 of California, Davis, where I received a Ph.D.

1 And then I was a post-doctoral fellow at Johns
2 Hopkins University, joined the faculty, and stayed
3 there for a total of 25 years.

4 Then in 2004 Northwestern offered
5 me the job as the chief of allergy and immunology,
6 and I left Johns Hopkins.

7 Q. So at no time did you earn a medical
8 degree or an M.D. degree, if I can call it that?

9 A. That's correct.

10 Q. So you're not a medical doctor or a
11 physician.

12 A. I am not.

13 Q. So you cannot prescribe medications
14 for patients?

15 A. That's correct.

16 Q. Have you ever been involved in drug
17 formulation work?

18 A. I'm certainly familiar with
19 formulation. I've done a limited amount of it for
20 humans. I've done more in mouse studies,
21 formulating vaccines or drugs to treat the
22 animals, as well as other species of animals

1 during my training as a Ph.D. student. But I
2 would say I'm not an expert in formulation even
3 though I understand the principles of it.

4 Q. And in the work that you did where you
5 say you were involved in formulating, did your
6 activities include selecting excipients and
7 actually developing prototypes in a laboratory
8 setting?

9 A. It wasn't terribly involved, but the
10 excipients would have included saline and a buffer
11 and things like that in which we suspended an
12 experimental drug.

13 Q. And you mentioned experimental drug.
14 Did the drug that you worked on ever make it to
15 market?

16 A. No.

17 Q. Now, focusing on nasal spray products.
18 In your opinion was it important for drugs in a
19 nasal spray product to be evenly distributed in
20 the medium?

21 MR. HOUSTON: Objection, form.

22 THE WITNESS: I'm not sure what you

1 mean by "evenly distributed."

2 BY MR. VARUGHESE:

3 Q. So when I use the phrase "evenly
4 distributed" in the drug product, you don't know
5 what I'm referring to?

6 A. I don't. It could have various
7 interpretations.

8 Q. Give me one interpretation.

9 A. Well, in the case of a suspension, the
10 drug might be a particulate or it might be in
11 droplets of oil and they could settle or they
12 could rise to the top. So some formulations have
13 to be shaken, for example, in order to distribute
14 the drug. And it's still not completely evenly
15 distributed. So I'm not sure what you mean by
16 that question.

17 Q. So you mentioned there could be
18 sedimentation -- I'm paraphrasing -- is that fair?
19 You said sometimes the suspension could settle at
20 the bottom, the drug? Is that what you said
21 earlier?

22 A. Some intranasal preparations need to

1 be shaken before administered so that it
2 distributes the drug throughout the volume of the
3 preparation so that when it's sprayed, the small
4 amount sprayed, has a representative amount of
5 drug of the totality that's in the canister.

6 Q. So when you say shaken so that it
7 distributes the drug throughout the volume of the
8 preparation, how in your view is that different
9 than evenly distributed?

10 A. Well, it's still unevenly distributed
11 if it's a suspension. Wherever there's a
12 particle, there's very high amounts of drug, and
13 wherever there's not a particle there's very low
14 amounts of drug. But the particles can be evenly
15 distributed such that in, let's say
16 100 microliters, the number of particles will be
17 roughly the same from spray to spray.

18 Q. That's helpful. Thank you.

19 So when you shake a drug product
20 that is a suspension, the particles themselves
21 will be evenly distributed, whereas the drug would
22 be concentrated around the location of the

1 particles themselves?

2 A. This is a theoretical discussion, but
3 yes, what you said can occur in some situations.

4 Q. Okay. So let's focus on the drug
5 fluticasone. Are you familiar with fluticasone?

6 A. Yes.

7 Q. Do you understand that that's one of
8 the drugs that are at issue for purposes of this
9 patent which we'll get into?

10 A. Yes.

11 Q. Do you have just a general
12 understanding of what fluticasone is in terms of
13 its class?

14 A. I do. It's an anti-inflammatory
15 steroid, sometimes called glucocorticosteriod or
16 corticosteroid.

17 Q. And you understand that fluticasone is
18 practically insoluble in water?

19 A. Yes.

20 Q. And do you know that this means that
21 fluticasone can't be used in a solution?

22 A. That question is actually not clear.

1 It can be used in a solution of acetone no
2 problem, it'll dissolve in acetone.

3 Q. So can fluticasone dissolved in
4 acetone be administered to patients?

5 A. No.

6 Q. Why not?

7 A. Well, you wouldn't administer acetone
8 to patients. So your question was can it be
9 dissolved, and my answer is it depends on the
10 solvent.

11 But let me say that I have not
12 represented myself as a formulator, and I have not
13 testified in any detail about formulations. So I
14 mean I'm happy to answer your questions, but I'm
15 not presenting myself as an expert in the
16 formulation components of this litigation.

17 Q. I appreciate that. I guess just to
18 maybe close the loop here. Setting aside acetone,
19 do you know if fluticasone can be formulated in a
20 water solution?

21 MR. HOUSTON: Objection, beyond the
22 scope.

1 THE WITNESS: By "formulated" you mean
2 in a pharmaceutically acceptable way?

3 BY MR. VARUGHESE:

4 Q. Yes.

5 A. Yes. It's used in, it's one of the
6 most popular drugs in our field and it's used in
7 Flonase in a formulation.

8 Q. Will fluticasone go into solution in
9 water?

10 A. A small amount will, but a majority of
11 it will stay out of solution.

12 Q. So you're here testifying today,
13 Dr. Schleimer, on behalf of a company called
14 Argentum; is that correct?

15 A. Yes.

16 Q. When were you first contacted by
17 Argentum or its counsel to work on this matter?

18 A. The first two weeks in January of this
19 year I believe.

20 Q. Who contacted you?

21 A. I don't recall his name. I never met
22 him in person. I'm sorry. I could find out, but

1 I don't recall his name.

2 Q. Where would you need to look to find
3 out?

4 A. I would have to go to my office and
5 look at my email.

6 Q. Was it Michael R. Houston, Mr. Houston
7 who's here present today representing you in this
8 deposition?

9 A. No.

10 Q. Was it Joseph P. Mira?

11 A. I don't believe it was either of them.

12 Q. Was it someone named James P.
13 McFarland?

14 A. I don't think so.

15 Q. Was it Tyler C. Liu of Argentum
16 Pharmaceuticals?

17 A. I spoke with him early on. He was one
18 of the -- I mean I spoke with more than one of
19 them. I was on vacation and they were calling me.
20 He was one of the early ones, but I'm not sure he
21 was the first one to call. I'm sorry.

22 Q. That's okay, that's okay.

1 When you say one of the early ones,
2 do you mean in that first two weeks in January
3 timeframe?

4 A. Yeah. When I said I spoke with more
5 than one of them, he was one of the two or three
6 people that I spoke with in that timeframe,
7 January, February.

8 Q. Had you ever spoken with Mr. Tyler Liu
9 before that conversation in January of 2017, just
10 to be precise?

11 A. No, not to my knowledge.

12 Q. Do you recall seeing him at the Apotex
13 trial, which is the trial that we discussed
14 earlier today?

15 A. I don't specifically recall that. I
16 know that there were some people at that trial
17 from other companies that had an interest. I
18 don't know which side they were interested in.

19 I know it's a little like a
20 wedding. There was a couple of them sitting on
21 the Apotex side. But I didn't have lengthy
22 conversations with them. And I don't recall that

1 Tyler Liu was there.

2 Q. That trial certainly made me think of
3 a wedding too.

4 A. Yeah.

5 Q. Were you ever contacted by Mr. Jeffrey
6 Gardner?

7 A. Can you tell me who he is? Is he with
8 Argentum also?

9 Q. So I don't want to testify on your
10 behalf. My understanding --

11 A. I don't recall the name. I may have,
12 you know. These brief interactions my brain is
13 programmed to forget quickly, unless there's a
14 reason to remember.

15 Q. Argentum in this proceeding is being
16 represented by the law firm Foley & Lardner;
17 correct?

18 A. Yes.

19 Q. And Mr. Houston is an attorney from
20 the Foley & Lardner firm.

21 A. That's correct.

22 Q. Do you recall when you first started

1 working with the Foley law firm in connection with
2 this proceeding?

3 A. It's fuzzy in my mind. I know that
4 the declaration was a collaboration that involved
5 a number of people on the attorney side.

6 As I said, we didn't have
7 face-to-face meetings, so I was dealing with, you
8 know, the electronic world, sending me documents
9 and we were sending them back and forth.

10 So I can't tell you what month. In
11 fact, I can't even recall the date of the
12 declaration. It's probably on the declaration.
13 It was sometime that spring.

14 Q. Okay. Do you have a written agreement
15 setting forth your engagement with Argentum for
16 this proceeding?

17 A. I'm not sure. I don't think I do, but
18 I may.

19 Q. Have you served as a testifying
20 witness for other companies in your career?

21 A. On a few occasions, yes.

22 Q. Is it your practice to have a written

1 engagement with those companies?

2 A. I think I have had one on occasion.

3 I've not done a lot of this, but I think there may
4 have been one once.

5 Q. What would we need to do to confirm
6 whether you have a written engagement with
7 Argentum in this case or not?

8 A. Again, I'd need to go to my office and
9 look. If I had one, it would be at my work office
10 and my secretary would have a copy of it.

11 Q. Okay. Do you recall executing a
12 written engagement with the Foley & Lardner law
13 firm in connection with this proceeding?

14 A. I do not. Again, that doesn't mean
15 there isn't one, but I do not recall having one.

16 Q. Dr. Schleimer, I'm going to hand you
17 what's been marked as Exhibit 1003 in this IPR
18 proceeding. (Document tendered to the witness.)

19 A. Thank you.

20 Q. Can you identify this document?

21 A. Yeah, on the face of it it's my
22 declaration in this litigation.

1 Q. Let's turn to Page 57 of this
2 document.

3 A. Okay.

4 Q. Is that your signature on the bottom?

5 A. Yes, it is.

6 Q. And it was signed February 2, 2017?

7 A. Yes.

8 Q. So in flipping through this, does this
9 appear to be a fair and accurate copy of the
10 declaration that was submitted in this case?

11 A. Looks to be.

12 Q. Okay. Can we turn to Paragraph 62 of
13 your declaration is. Do you mind just reading
14 Paragraph 62 into the record?

15 A. "Azelastine was the most effective
16 antihistamine on the market. As stated earlier,
17 intranasal antihistamines were known to be better
18 than oral antihistamines, since they were safer
19 and had additional anti-inflammatory effects not
20 shared by oral antihistamines. Most importantly,
21 intranasal antihistamines do not have the systemic
22 side effects that often result from utilizing oral

1 antihistamines."

2 Q. So in reading that paragraph, and I'm
3 going to paraphrase this for simplicity sake but
4 please correct me if I'm saying anything
5 incorrect, it was your opinion that at the time of
6 invention here, the '620 Patent, that a POSA would
7 have viewed intranasal antihistamines as preferred
8 over oral antihistamines; is that correct?

9 A. No, no, I would not say that. I said
10 here that it's better, it's more effective. But
11 there are issues of patient choice that play a
12 huge role in all drugs but in antihistamines as
13 well.

14 A lot of patients don't like to use
15 nasal sprays. They don't like the feel of it.
16 They don't want to do it in public. It makes them
17 uncomfortable some other way. And even though
18 intranasal drugs may be the most effective, they
19 may prefer to take an oral antihistamine.

20 Also, the oral antihistamines have
21 actions that can be beneficial outside of the
22 nose. Many of these patients have what's called

1 the allergic diathesis. They can have dermatitis,
2 they can have itching in the ears or the eyes, and
3 some of those patients will prefer to take an
4 oral, nonsedating antihistamine because it not
5 only helps them with their nasal symptoms but can
6 also help them with the itching in their skin or
7 their ears or their eyes.

8 So this statement has to do with
9 the signs and symptoms of allergic rhinitis.

10 Q. What statement are you talking about?

11 A. That azelastine was the most
12 effective.

13 So the flipside of that coin is
14 that by using them topically and locally, they
15 have many fewer systemic side effects than the
16 oral antihistamines.

17 So each patient and each physician
18 weighs the benefits of the different forms of
19 taking these different drugs and decides for
20 themselves.

21 Q. So depending on the context, some
22 physicians and patients would prefer oral

1 antihistamines, whereas in other contexts some
2 physicians and patients would prefer nasal
3 antihistamines. Is that fair to say?

4 A. Yeah, I think it's not uncommon for
5 the decision to also be made on the basis of the
6 severity of the illness.

7 So if somebody comes into a
8 doctor's office and they have very mild symptoms,
9 a little sneezing and itchiness of the nose, maybe
10 a little running of the nose but nothing too
11 bothersome, the doctor may give them an oral
12 antihistamine that's nonsedating but with
13 reasonable expectation that the symptoms would
14 improve greatly. And, as I said, many patients
15 like to take oral medicines. They can do it
16 easily. There's no bother with an intranasal
17 preparation.

18 Q. So let's go to the 2001, 2002
19 timeframe.

20 A. Okay.

21 Q. You know what a POSA is, P-O-S-A --

22 A. Yes.

1 Q. -- in the context of this case?

2 A. Person of skill in the art.

3 Q. Person of skill in the art.

4 And the declaration that you
5 submitted, both in this IPR and your expert report
6 testimony in the Apotex litigation, you were
7 offering opinions from the perspective of a POSA?

8 A. Yes.

9 Q. So if I were to ask you to go back to
10 the 2001, 2002 timeframe, would a POSA have a
11 preference as to intranasal antihistamines versus
12 oral antihistamine?

13 A. You mean as a scientist? As a person
14 who either treats patients or develops drugs for
15 allergy or both, would they have a preference?

16 Q. Let's talk about someone who treats
17 patients.

18 A. Sure. I mean that's why we pay our
19 doctors to help us with our decisions of what
20 drugs to take. Different doctors have different
21 preferences. But yeah, doctors each have their
22 own paradigm, their own regimen for treating

1 patients.

2 But then, as is true now,
3 antihistamines represented fully two thirds of the
4 total market for allergic rhinitis. So they were
5 a major weapon in the armamentarium of all
6 doctors, be they internists or allergists, who
7 were treating allergic rhinitis. Some of those
8 would be POSAs by my definition and others would
9 not.

10 So there are plenty of treating
11 physicians that are not persons of skill in the
12 art, as I have defined it. And there are plenty
13 of treating physicians who are as long as they
14 have also a scientific background and have spent a
15 few years studying drug development or formulation
16 or that sort of thing.

17 Q. So -- and I apologize if you answered
18 this part of the question there -- but let's talk
19 about the POSA, as you've defined it --

20 A. Yes.

21 Q. -- based on your definition. And if
22 it's helpful for you, we can go back to your

1 declaration and see what that is if you'd like to.

2 A. Sure. Do you have a paragraph?

3 Q. So take a look at your declaration and
4 I'll reask that question.

5 A. Paragraph 12?

6 Q. I think it's Paragraphs 11 and 12 I
7 think you've identified them.

8 So now that you've had a chance to
9 review your definition of a POSA, I'd like to ask
10 that same question. A POSA, based on your
11 definition in the 2001, 2002 timeframe, did that
12 POSA have a preference as to oral versus
13 intranasal antihistamines?

14 MR. HOUSTON: Objection, form.

15 THE WITNESS: I thought I answered
16 that.

17 Well, "preference" is a very
18 subjective word. As a patient, they may, if
19 they're a patient. As a physician, they may, if
20 they're a physician. As a scientist, they might
21 have an opinion of which are better than others.

22 I guess you could define all those

1 as a preference, but I'm not sure what you mean by
2 preference. But they would all certainly have
3 opinions. They would all have opinions of which
4 drugs were better, which are worse.

5 And it's usually not cut and dried
6 anyway. One drug is better in one aspect, another
7 drug is better in a different aspect.

8 BY MR. VARUGHESE:

9 Q. Okay. Let's go back to Page 26 of
10 your declaration. You were looking at Paragraph
11 62.

12 The header of the preceding
13 Paragraph 62, can you just read that again for the
14 record?

15 A. "Azelastine was the most effective
16 antihistamine on the market."

17 Q. What do you mean by that?

18 A. Well, "effective" means exerting
19 beneficial effect. And in the previous decade,
20 especially in the previous five or six years, the
21 mid '90s, a, I don't know if you can call it a
22 third generation, but an advanced generation of

1 antihistamines came along that had different
2 properties than their preceding drugs. Azelastine
3 was one of them. Two ended up on the market,
4 azelastine and levocabastine, but there were
5 others that exerted some of these effects orally.
6 And I'm referring to the ability of these drugs to
7 exert beneficial effects that were unrelated to
8 their ability to inhibit H1 histamine receptors.

9 So all of the antihistamines that
10 we're talking about block the H1 receptor, and
11 that mediates histamines effects from sneezing to
12 runny nose on blood vessels to mucus secretion,
13 smooth muscle constriction, there are a host of
14 effects of histamine, itching. Those are mediated
15 by the H1 receptor. So all of these
16 antihistamines can block that receptor.

17 But azelastine is the best in breed
18 of antihistamines that have other
19 anti-inflammatory beneficial effects which
20 includes inhibiting the release of mediators by
21 mast cells, which are the allergic inducing cells.

22 Leukotrienes is one class, even

1 histamine itself, they can inhibit other
2 inflammatory cells. Azelastine can inhibit the
3 expression of protein mediators that cause
4 inflammation and disease.

5 So not only was it able to block
6 the histamine H1 receptor as the other
7 antihistamines do, but it also was able to exert
8 these additional anti-inflammatory effects which
9 created a lot of excitement in the '90s and it
10 became the emergent antihistamine certainly for
11 topical use and that's what I'm referring to.

12 Q. So when you say "best in "breed, can
13 you just to the best of your knowledge right now
14 run down for me the other, you know, agents in
15 that breed? So we have azelastine...

16 A. Well, so, as I said, there were only
17 two that ended up with local administration,
18 levocabastine and azelastine. And azelastine is
19 the best of that small breed.

20 Q. Okay.

21 A. But even among other oral
22 antihistamines, there are a few that can exert

1 some of those effects, but they're vastly less
2 able to do so than azelastine.

3 Q. So in that header, header D, Page 26
4 of your declaration, where you say "Azelastine was
5 the most effective antihistamine on the market,"
6 was that in relation to the breed that you're
7 talking about?

8 A. In relation to antihistamines
9 generally and topical antihistamines specifically
10 with regard to allergic rhinitis symptoms.

11 Q. So would that statement be accurate if
12 I were to ask you is azelastine more effective
13 than cetirizine when it was on the market at that
14 time?

15 A. No, because, as I mentioned, oral
16 antihistamines can affect the allergic diathesis.
17 If you have itchy skin and itchy ears, oral
18 cetirizine may help you with those symptoms,
19 whereas azelastine is unlikely to help you with
20 your itchy skin. It might have a small effect on
21 the ears.

22 So, as I said, that's with respect

1 to the cardinal allergic rhinitis symptoms.

2 Q. So let's set aside the diathesis and
3 focus on the cardinal allergic rhinitis symptoms.

4 As of 2001, 2002, was it your
5 opinion that a POSA would consider azelastine to
6 be more effective than cetirizine?

7 MR. HOUSTON: Objection, form.
8 Objection, beyond the scope.

9 THE WITNESS: It's not a fair question
10 because, as I said, I'm talking about the local
11 symptoms, and azelastine in the nose has
12 additional effects in the nose by virtue of its
13 high local concentrations with intranasal
14 administration.

15 I'm not aware of clinical trials --
16 that doesn't mean there aren't any -- that did a
17 head-to-head comparison of azelastine to
18 cetirizine and looked at inflammatory mediators in
19 the nose. I don't think such a study exists.

20 If you were to find funding for
21 that and asked me to do the study, I would bet you
22 dinner that azelastine will be much more effective

1 than cetirizine in the local production of
2 inflammatory mediators and the suppression of
3 local inflammatory responses.

4 BY MR. VARUGHESE:

5 Q. But you haven't cited any studies or
6 articles that confirm that in your declaration;
7 right?

8 A. That's right.

9 Q. So I want to ask the same question.
10 When you say azelastine was the most effective
11 antihistamine, would you say that azelastine was
12 more effective than fexofenadine?

13 A. Well, so if it's okay with you, I
14 think that this line of questioning is taking us
15 away from the relevant area.

16 I think what's relevant in the
17 context of this litigation is the antihistamines
18 that could be administered locally in a nasal
19 formulation, and there are only two of them.

20 So you're asking me questions that
21 are not really relevant to the issue at hand, most
22 of which I don't know the answers to because it

1 hasn't been tested. So you can continue to do so
2 if you want, but I don't know if it helps --

3 Q. So --

4 A. -- the board to decide what they have
5 to decide.

6 Q. So let me just respond to that. I
7 have the utmost respect for you. I think you're a
8 preeminent expert in this field. But you and I
9 and our clients differ on what exactly the board
10 is going to find relevant.

11 A. Yes.

12 Q. The board ultimately will do that. I
13 have some questions that I want to cover with you.
14 Certainly, I'm not intending to harass or
15 embarrass you or anything like that. I just want
16 to ask you this line of questioning.

17 A. Okay.

18 Q. And the board may find it to be
19 relevant, they may not, if that's okay with you.

20 A. Okay. All right. And if it's okay
21 with you, I'll give you short answers.

22 Q. That's fine with me. Your answers are

1 your answers.

2 Getting back to this header D. I
3 just want to understand how your declaration, if
4 at all, takes into account oral antihistamines.

5 So let me ask you this: Header D, you say
6 "Azelastine was the most effective antihistamine
7 on the market."

8 Is it fair to say that that
9 statement, you were talking about among intranasal
10 antihistamines that were on the market?

11 A. That's certainly the case.

12 Q. Dr. Schleimer, the court reporter is
13 going to hand you what's going to be marked as
14 CIP2145 in this IPR proceeding.

15 (Deposition Exhibit 2145 was marked
16 for identification.)

17 BY MR. VARUGHESE:

18 Q. Take a moment to orient yourself to
19 the document, Dr. Schleimer. (Document tendered
20 to the witness.)

21 A. Yes.

22 MR. HOUSTON: Counsel, I don't know

1 how you intend to rely on this document, so I will
2 put in an objection at least as to hearsay at this
3 time pending the nature of your reliance on it.

4 MR. VARUGHESE: Mr. Houston, you can
5 lodge your objection, but the rest of what you
6 just said there is an inappropriate speaking
7 objection and I'm going to ask you to refrain from
8 doing that.

9 MR. HOUSTON: Objection, hearsay.

10 BY MR. VARUGHESE:

11 Q. Dr. Schleimer, can you identify this
12 document?

13 A. Yes.

14 Q. Please do so for the record.

15 A. This is a United States Patent Number
16 6,599,914 B2, from July 29, 2003, by Schleimer,
17 et al., on inhibition of cytokine generation.

18 Q. Okay. And when you say "Schleimer, et
19 al.," the Schleimer is Robert P. Schleimer?

20 A. That's right. That's me.

21 Q. And it's you, you're the first named
22 inventor on this patent?

1 A. I am.

2 Q. And then can you identify the other
3 two inventors?

4 A. It was John Schroeder and Bill
5 Kreutner.

6 Q. And then looking at the face of the
7 patent, you'd agree that this patent issued from
8 the application filed April 24, 2001?

9 A. Yes.

10 Q. And that's Application 09/841,506?

11 A. Yes.

12 Q. Okay. So we're going to come back to
13 the patent in a second.

14 The court reporter is going to hand
15 you what is going to be marked as CIP2146.

16 (Deposition Exhibit 2146 was marked
17 for identification.)

18 MR. HOUSTON: Objection, hearsay.
19 Objection, authentication.

20 BY MR. VARUGHESE:

21 Q. Take a moment to orient yourself to
22 the document, Dr. Schleimer. (Document tendered

1 to the witness.)

2 A. Well, I'm a little disoriented. It
3 looks like the same patent but in a different
4 form. I don't know if it's an earlier draft or
5 filed with a different agency. I'm sorry.

6 Q. Understood. Maybe I can help. If you
7 go to the first page.

8 A. The front page?

9 Q. Yes. In the top right corner, do you
10 see a stamp that says "Patent Number"?

11 A. Yes.

12 Q. And it has a number on there?

13 A. Yeah, same number.

14 Q. It's the same number as your patent.

15 A. Okay. But it differs in some way.

16 Q. Sure it does.

17 Then if you go to the little box
18 right under that stamp, the header there says
19 "U.S. Utility Patent Application."

20 A. Okay.

21 Q. Then the box under that identifies
22 yourself along with John Schroeder and William

1 Kreutner as inventors.

2 A. Yes.

3 Q. Or applicants I should say.

4 The title says "Inhibition of
5 cytokine generation." Then on top of that box
6 there's an application number. Do you see that?

7 A. In the top left corner?

8 Q. Above your name.

9 A. Above my name, yes.

10 Q. And that application number is
11 09/841,506?

12 A. Yeah.

13 Q. And that's the same application number
14 we identified on the face of your issued patent?

15 A. Yes.

16 Q. So is it fair to say that this is the
17 patent application that ultimately issued as your
18 patent?

19 MR. HOUSTON: Objection, form.

20 THE WITNESS: I don't know. I'm
21 willing to believe it, Counselor.

22

1 BY MR. VARUGHESE:

2 Q. That's fair to say. How about I do
3 this: I will represent to you so that way you
4 know.

5 A. And I accept that representation.

6 Q. I will represent to you that it is the
7 application.

8 So I'd like to turn your attention
9 to the penultimate page of the packet that I gave
10 you. The second to last page.

11 A. All right.

12 Q. And up top there it says
13 "Declaration."

14 A. Uh-huh.

15 Q. If I can draw your attention to two
16 thirds of the way down, there's a small paragraph
17 that begins with "I hereby declare."

18 A. Yes.

19 Q. Can you read that into the record.

20 A. Sure. "I hereby declare that all
21 statements made herein of my own knowledge are
22 true and that all statements made on information

1 and belief are believed to be true, and further,
2 that these statements were made with the knowledge
3 that willful false statements and the likes," I
4 don't know what that says, "and the" something "so
5 made are punishing by a fine or imprisonment or
6 both under 18 U.S.C. 1001 and that such will
7 willful false statements may jeopardize the
8 validity of the application of any patent issued
9 thereon."

10 Q. Okay. And then shortly under there is
11 your signature; correct?

12 A. Yes.

13 Q. So is it fair to say that by signing
14 there under that statement, you've acknowledged
15 that any statements made in this patent
16 application which identifies you as a lead
17 inventor were truthful and accurate to the best of
18 your knowledge at the time?

19 A. Yes.

20 Q. And that signature, you signed that on
21 April 9, 2001?

22 A. Yes, the day after my birthday.

1 Q. So let's turn back to your issued
2 patent --

3 A. Okay.

4 Q. -- Exhibit 2145. I want to turn your
5 attention to Column 2 of the patent. It's after
6 all the figures.

7 A. Okay.

8 Q. Lines 5 to 13. Can you read that
9 paragraph beginning with "The present invention
10 also provides."

11 A. Sure.

12 Q. Thank you.

13 A. "The present invention also provides a
14 method of inhibiting generation of IL-4 and IL-13
15 from human basophils in a patient exhibiting the
16 symptoms of an allergic and/or inflammatory
17 condition which comprises administering to such a
18 patient an amount of desloratadine effective to
19 inhibit the generation of IL-4 and IL-13 and to
20 concurrently treat the symptoms of such an
21 allergic and/or inflammatory conditions."

22 Q. And desloratadine is an antihistamine?

1 A. Yes.

2 Q. Did you invent desloratadine?

3 A. I did not.

4 Q. So what were you claiming as your
5 invention in this patent?

6 MR. HOUSTON: Objection, form.

7 THE WITNESS: The claim was an unknown
8 action of desloratadine in its ability to inhibit
9 the release of important cytokines from human
10 basophils, it was unexpected, although we
11 hypothesized it, and we got some funding from
12 Schering to test the idea. The drug ended up
13 inhibiting cytokines, and Schering saw fit to file
14 a patent on our behalf. And, as I recall, they
15 licensed the patent from Johns Hopkins.

16 BY MR. VARUGHESE:

17 Q. So drawing your attention a little
18 further down in that column, Line 25, can you read
19 that sentence into the record?

20 A. "The patients in need of such
21 inhibiting are those having symptoms of allergic
22 inflammatory conditions of the airway passages,

1 skin, eyes, and intestinal tract."

2 Q. Let me turn your attention to Column
3 5, Line 21.

4 A. Okay.

5 Q. Can you read the sentence beginning
6 with "The pharmaceutical compositions."

7 A. "The pharmaceutical compositions of
8 desloratadine can be adapted for any mode of
9 administration, e.g., for oral, parenteral, e.g.,
10 subcutaneous ('SC'), intramuscular ('IM'), and
11 intraperitoneal ('IP'), topical or vaginal
12 administration or by inhalation (orally or
13 intranasally). Preferably desloratadine is
14 administered orally."

15 Q. So now when you made the statement
16 around 2001, "preferably desloratadine is
17 administered orally," that was truthful?

18 A. Yeah.

19 Q. And why is that the case?

20 A. Because desloratadine was an oral
21 antihistamine and basophils are found in the
22 blood. I mean I don't remember debates we had

1 about it. And I didn't write the patent. I mean
2 John Schroeder and I wrote up the science but we
3 didn't compose the claims or write -- I mean we
4 collaborated on writing the specification.

5 Q. Did you review the application before
6 you signed the oath, the declaration?

7 A. I'm sure I did, yes. That's what I
8 do.

9 Q. And if there was something incorrect,
10 you would have flagged it upon your review?

11 A. If I disagreed with this statement, I
12 might have initiated a discussion of it. If it
13 was explained to me why Schering-Plough wanted to
14 write it that way, I probably accepted that
15 explanation. I don't find it to be objectionable.

16 Q. Turning to Column 6, Line 38, the last
17 sentence, "The use of," can you please read that?

18 A. "The use of the upper airway passage
19 decongestant, pseudoephedrine HCl, is preferred."

20 Q. And what does that mean?

21 A. I don't know. You're taking it out of
22 context.

1 Well, earlier in the paragraph it
2 states that desloratadine may be administered in
3 association with steroids, like mometasone,
4 beclomethasone, et cetera, leukotriene inhibitors,
5 other drugs including phenylephedrine and
6 pseudoephedrine and other decongestants.

7 So this is a paragraph that talked
8 about potential co-administration of desloratadine
9 in the nose with other compounds.

10 Q. And in that paragraph, of the
11 compounds that could be co-administered with
12 desloratadine, fluticasone propionate is
13 identified; correct?

14 A. Uh-huh.

15 Q. And pseudoephedrine is also
16 identified; correct?

17 A. Yes.

18 Q. But then the paragraph ends with the
19 patent saying that the use of upper airway passage
20 decongestant, pseudoephedrine, is preferred?

21 A. Yes.

22 Q. And you had no reason to find that

1 statement objectionable?

2 A. I don't know why it's there. I don't
3 know who preferred it. It wasn't me. Maybe Bill
4 Kreutner put it there for some reason. But I
5 don't find it objectionable.

6 I think they were talking about
7 among the list of decongestants, pseudoephedrine
8 is the preferred one. I had forgotten about this
9 paragraph, but in a way it anticipates, one could
10 argue.

11 Q. So you think that sentence is
12 identifying pseudoephedrine as the preferred among
13 decongestants?

14 A. No, it was a comment, just a side
15 comment.

16 Q. Let's turn to Column 12. If I could
17 draw your attention to Column 12, the paragraph
18 that says "Clinical Studies."

19 A. Yes.

20 Q. Feel free to read the whole paragraph,
21 but I want to draw your attention to the first
22 four lines, if you can read that into the record.

1 A. First four lines of "Clinical
2 Studies"?

3 Q. Correct.

4 A. "The following clinical studies are
5 designed to show that desloratadine provides
6 combined antihistaminic and anti-allergic
7 inflammatory effects to control both early and
8 late phase allergic reactions and clinical
9 symptoms on human subjects exposed to allergens or
10 exhibiting the signs and symptoms of allergic
11 and/or inflammatory diseases of the skin, eyes,
12 intestinal tract, and airway passages."

13 Q. So as of 2001, based on this
14 paragraph, people knew that desloratadine
15 exhibited an anti-inflammatory effect?

16 A. Yes. As I said, in the '90s it became
17 clear that it was possible to design
18 antihistamines that also had some
19 anti-inflammatory effects.

20 Q. Thank you, Dr. Schleimer. You can set
21 those exhibits aside.

22 A. I haven't looked at that since it was

1 written.

2 MR. VARUGHESE: Why don't we take a
3 10-minute break. We've been going for about an
4 hour.

5 (A recess was taken.)

6 BY MR. VARUGHESE:

7 Q. Dr. Schleimer, I'm going to hand you
8 what's been already marked in this proceeding as
9 Exhibit 1007. (Document tendered to the witness.)

10 Do you recognize this document?

11 A. I do. This appears to be the Hettche
12 patent on azelastine.

13 Q. And I previously handed you a copy of
14 your declaration. If we can go back to that and
15 turn to Paragraph 65.

16 A. Okay.

17 Q. You cite to actually -- strike that.
18 Let's go back.

19 So in Paragraph 65 of your
20 declaration, you cite this Hettche patent that I
21 just handed you, which is Exhibit 1007; correct?

22 A. Yes, I believe so. I didn't check

1 the -- 1007, yeah.

2 Q. And looking at Paragraph 65 of your
3 declaration, you state that Hettche teaches that
4 intranasal azelastine avoids the tiredness that
5 arises in other applications?

6 A. Yes.

7 Q. And the part of Hettche you rely on
8 is -- if you can turn to Column 1, Line 53, in
9 Hettche.

10 A. Yes.

11 Q. Now, in Hettche though this statement
12 is comparing intranasal azelastine to oral
13 azelastine; correct?

14 A. I would have to read it, but I will
15 accept that that's the case.

16 Q. You have no reason to disagree with
17 that?

18 A. No. It's a contextual thing.

19 Q. Sure. We can take a few minutes for
20 you to, you know, I hope you don't have to read
21 the whole patent, but if you want to take a look
22 at the surrounding paragraphs to confirm that.

1 A. Well, I don't see it talking about
2 oral application, but I would assume that's what
3 it's referring to because application to other
4 peripheral organs wouldn't cause that. So I'm
5 fine if we stipulate that that's what it's
6 referring to.

7 Q. Okay. And then in Paragraph 65 of
8 your declaration, you also state that nasal
9 azelastine relieves reddening and irritation of
10 the eye, and I believe you point to Column 1,
11 Lines 44 to 48 for that of Hettche.

12 A. Okay.

13 Q. But you agree that oral azelastine
14 also works on eye symptoms; doesn't it?

15 A. I don't know the answer to that. I'm
16 not aware of the clinical data on oral use of
17 azelastine, so I'm sorry.

18 Q. How about other oral antihistamines?

19 A. Is the question whether they can have
20 beneficial effects on the eye?

21 Q. Yeah, or treat ocular symptoms of
22 allergic rhinitis.

1 A. Yes, oral antihistamines, yes.

2 Q. Oral antihistamines.

3 A. Yes, it can.

4 Q. And just so the record is clear, if I
5 were to say a couple specific agents,
6 desloratadine, cetirizine, fexofenadine, would
7 these be oral antihistamines in your view that
8 would treat ocular symptoms of allergic rhinitis?

9 MR. HOUSTON: Objection, beyond the
10 scope.

11 THE WITNESS: Those are effective oral
12 antihistamines, and I would not be surprised if
13 there were data showing that they had beneficial
14 effects in the eye, but I cannot cite you the
15 references.

16 BY MR. VARUGHESE:

17 Q. Okay. So then given that fact, is it
18 fair to say that ocular efficacy isn't an
19 advantage of azelastine over other oral
20 antihistamines?

21 MR. HOUSTON: Objection, form.

22 THE WITNESS: So intranasal azelastine

1 may or may not have some beneficial effects on the
2 eyes. There's big literature on it and it
3 wouldn't surprise me if it does because there's a
4 nasal lacrimal duct and there are reflexes and it
5 could easily. So I can't say. I don't know.

6 BY MR. VARUGHESE:

7 Q. Okay. Then I believe in Paragraph 65
8 of your declaration you also note that intranasal
9 azelastine has a, quote, "barely perceptible
10 bitter taste" and here you point to Column 1, Line
11 63 through Column 2, Line 2, of Hettche. Do you
12 see that?

13 A. Yeah, they left out a letter. "It wa
14 surprisingly found in trial subjects that this
15 bitter taste was no longer in evidence."

16 Q. But, to your knowledge, azelastine is
17 the only antihistamine at the time of the relevant
18 time here 2001, 2002 that there were any concerns
19 with bitter taste with patients; correct?

20 A. I don't think that's true at all.

21 Q. What other antihistamines would you
22 say suffered from poor taste?

1 MR. HOUSTON: Objection to form.

2 Objection to beyond the scope.

3 THE WITNESS: I've tasted a few
4 myself. Diphenhydramine, dimenhydrinate. Those
5 tricyclics can taste very bad.

6 BY MR. VARUGHESE:

7 Q. So let's talk about diphenhydramine.
8 What -- and diphenhydramine is Benadryl; correct?

9 A. That's one form of it, yeah.

10 Q. Commonly refer to the trade name as
11 Benadryl?

12 A. Yes.

13 Q. Okay. Now, when you say
14 diphenhydramine has a bad taste, what dosage form
15 was that in?

16 A. I don't know. I know that other
17 antihistamines can have a bad taste. But it's not
18 an area of my interest or expertise.

19 Q. How about second generation
20 antihistamines, are you aware that they have taste
21 issues?

22 A. As I said --

1 MR. HOUSTON: Objection, form.

2 Objection, beyond the scope.

3 THE WITNESS: -- it's not an area of
4 my interest or expertise. So it wouldn't surprise
5 me if there are a number of them that have taste
6 issues. It wouldn't surprise me if there's a
7 limited number. I just don't know.

8 BY MR. VARUGHESE:

9 Q. Fair. And based on the objections
10 that we've just heard, let me ask you: Is any
11 comparison of azelastine's bitter taste to oral
12 antihistamines beyond the scope of your analysis
13 in this proceeding?

14 MR. HOUSTON: Objection, form.

15 THE WITNESS: I haven't opined about
16 it, I don't believe, about a comparison of taste
17 between azelastine and other oral antihistamines?
18 I don't recall discussing it.

19 BY MR. VARUGHESE:

20 Q. Okay. Let's turn to Paragraph 71 of
21 your declaration. So for the next few questions I
22 want to focus on Paragraphs 71 through 77 of your

1 declaration and there's a heading there for that
2 section, if you can read it into the record.

3 A. "Administration of nasal antihistamine
4 and nasal steroid to treat allergic rhinitis was
5 recommended."

6 Q. So for simplicity I'm going to
7 paraphrase, but feel free to correct me if I'm
8 incorrect. But taking these paragraphs together,
9 you're offering three reasons that a POSA might
10 have wanted to combine azelastine with fluticasone
11 into a single formulation; correct?

12 A. I don't know how many I'm offering.
13 We can go through it.

14 Q. Would you like to take a few minutes
15 to take a look?

16 A. And the question is?

17 Q. So why don't I maybe state that. I'm
18 saying that in this section you're offering, it's
19 your opinion, three reasons that a POSA would have
20 wanted to or might have wanted to combine
21 azelastine with fluticasone.

22 A. Okay.

1 Q. And then if I can identify those three
2 reasons. One is that they were used together in
3 clinical practice.

4 A. Okay.

5 Q. Two is that you say they have
6 complimentary mechanisms of action, the two drugs.

7 A. Okay.

8 Q. And three is you say that doing so
9 would improve patient compliance.

10 A. Okay.

11 Q. So now if you want to double check and
12 make sure that I'm not misstating your opinions.

13 A. Those are opinions I have given and I
14 accept that they are in this passage of
15 paragraphs.

16 Q. Okay. But in this section of your
17 declaration or elsewhere in analyzing the sort of
18 motivation to combine, you don't discuss any
19 drawbacks of a fixed dose regimen; do you?

20 A. Drawbacks of a fixed dose regimen?

21 Q. Let me be more precise. A fixed dose
22 dosage form of azelastine and fluticasone.

1 A. I'm trying to think if there's a stray
2 sentence somewhere about it.

3 Q. And this is not a memory test.

4 A. Yeah, I don't, I don't recall raising
5 that objection, although that objection has been
6 made in the case, and I have my opinions about how
7 severe an objection it is.

8 But no, I don't recall raising it
9 in the declaration. I stand to be corrected if
10 it's mentioned briefly somewhere.

11 Q. One of the motivations that you cite,
12 complimentary mechanisms?

13 A. Yes.

14 Q. You analogize this to a product called
15 Advair. Is that fair to say?

16 A. Yes, that could well be in this
17 section.

18 Q. And what is Advair?

19 A. Advair is an asthma medicine that is
20 also a combination of fluticasone propionate. And
21 in this case the second drug is a long-acting beta
22 agonist, which are drugs that dilate the airways

1 and give immediate relief of bronchospasm.

2 So, to me, it's very analogous of
3 the combination of a steroid which takes days to
4 weeks to work and works on the inflammatory
5 component with a rapidly acting drug. In the case
6 of Advair, it works on bronchial smooth muscle.
7 In the case of azelastine, it blocks the action of
8 histamine and has some other immediate effects.

9 So the analogy is that there's a
10 true complimentary between the anti-inflammatory
11 steroid which is in both cases the most important
12 and effective drug to be used in these respective
13 diseases.

14 By combining it with something that
15 works quickly, it helps with compliance during
16 those key first days or weeks where the steroid
17 effect is gradually getting better and better and
18 better. Patients can get frustrated. They can
19 think the drug is not working. It just takes
20 time.

21 And that is actually the crux of
22 the argument of obviousness between fluticasone

1 and azelastine, that fluticasone or other
2 intranasal steroids really take two weeks or three
3 weeks to reach full effect. Two weeks is probably
4 a good average. And during that time having
5 prescribed with it, either conjunctively or in the
6 same vial, as the case in point, allows for a
7 rapid effect by the azelastine blocking the
8 actions of histamine which the steroid only does
9 very slowly.

10 So the analogy here is that an
11 asthmatic has bronchospasm. If they inhaled the
12 fluticasone steroid, it's going to take a week or
13 two to improve their asthma dramatically. But
14 they're wheezing now. So by adding the
15 long-acting beta agonist, it relaxes the airways
16 immediately and improves the compliance, and in a
17 week or two the steroid is giving the patient
18 great benefit. So I think it's a very good
19 analogy with the case at question in this
20 litigation.

21 Q. So fluticasone, do you understand that
22 that's dosed once, twice daily?

1 A. Either is fine.

2 Q. Once daily or twice daily?

3 A. Either is fine. There have been forms
4 used either way.

5 Q. Okay. And then the long-acting
6 bronchodilator in Advair, is that salmeterol?

7 A. Yes.

8 Q. Do you know how salmeterol is dosed?

9 A. Well, initially I think the
10 combination was a twice-a-day preparation. I'm
11 uncertain if they have a once-a-day Advair. It's
12 possible. I'm uncertain.

13 Q. How about salmeterol by itself, do you
14 understand that salmeterol is also marketed by
15 itself?

16 A. It is. It's not a hugely popular
17 drug. And I don't know if it's once or twice a
18 day. Sorry.

19 Q. Okay. So switching gears slightly.

20 Dr. Schleimer, would you agree that
21 one way of treating allergic rhinitis is to clean
22 the nasal mucosa?

1 MR. HOUSTON: Objection, form.

2 THE WITNESS: Well, it's an
3 interesting question.

4 BY MR. VARUGHESE:

5 Q. Thank you.

6 A. "Clean the nasal mucosa is vague."
7 But I will say that the oldest treatments for
8 rhino-sinusitis and rhinitis may have been
9 invented in India, I don't know. Neti pot is a
10 device that saline rinses, because water is a
11 little irritating, it's wonderfully effective in
12 some patients with chronic sinus and nasal
13 disease.

14 I'm not sure that's what you meant
15 by the question.

16 Q. And I understand you pointed at me
17 when you said "India." I'm from Philadelphia
18 so... I'm only kidding, I'm only kidding.

19 A. So I realized I pronounced "Varughese"
20 which would be an Italian pronunciation. I don't
21 know where you're from, but...

22 Q. We'll chat about it afterward because

1 I love talking about myself.

2 So getting back to the saline rinse
3 and the Neti pot that you mentioned. Is the
4 thought from a treatment perspective that the
5 washing of the mucosa with the liquid I guess
6 creates irrigation and reduces inflammation that
7 way? If you can explain, if you know, a little
8 bit more what does the saline rinse, washing of
9 the mucosa, actually achieving?

10 MR. HOUSTON: Objection, beyond the
11 scope.

12 THE WITNESS: So during allergic
13 inflammation of the nose and sinuses, there's
14 often a secretion of mucus as well as thin nasal
15 secretions which come from serous cells.

16 There are two main kinds of
17 secretions. There's serous secretions, there's
18 mucus secretions. Mucus are the thick, tenacious
19 ones. Serous are like the running from the eye or
20 nose.

21 But the production of both of these
22 secretions accumulates in the nose and the

1 sinuses, and for some patients who are determined
2 and willing to go through the big mess and
3 trouble, nasal irrigation can have some benefits.

4 I couldn't tell you how popular it
5 is, but there are certainly companies that make
6 the rinse in containers that are purchased and
7 then thrown away. So it has adherence. There are
8 patients and doctors that use it.

9 BY MR. VARUGHESE:

10 Q. So if we look at azelastine nasal
11 spray on the one hand and fluticasone, Flonase,
12 nasal spray on the other hand, would you agree
13 that apart from the pharmacological effect of the
14 respective active ingredients, that the nasal
15 irrigation effect of the liquid from those dosage
16 forms provides an independent benefit to those
17 patients?

18 A. I would be willing to entertain that
19 notion. I'm not aware that it's been formally
20 studied. The volume of these sprays very small, I
21 mean you're talking about 1/1000 or 10000 of a
22 Neti pot.

1 So it wouldn't surprise me if it
2 had a modest effect. But I am not aware of
3 studies that have looked at that small of a spray,
4 50 microliters or 100 microliters, whatever it is.
5 It's minuscule.

6 Q. In studies that examine active nasal
7 sprays versus placebo, are you aware that there's
8 been a positive effect from placebo on these
9 patients?

10 A. Well, placebo is notoriously effective
11 in allergic disease studies, and rhinitis is one
12 of the worst. I mean even if there's no spray
13 involved, placebo pills can have a profound
14 effect.

15 I am aware of authors suggesting
16 that a nasal spray placebo may have had some
17 effects, but it wasn't formally tested or proven.
18 So I don't want to speculate that it's correct.

19 Q. At least theoretically would the
20 placebo effects of a spray from its, you know,
21 nasal irrigation properties work with irrigating
22 the nasal mucosa?

1 A. That's hard to say.

2 A colleague of mine at Johns
3 Hopkins did a study of immunotherapy where he gave
4 patients injections. Some patients got one
5 injection, some got two injections, some got three
6 injections. And he had a placebo for all of them.

7 The patients that got three
8 injections had a significantly better placebo
9 response than the ones that got one. And there's
10 almost no way to believe that it was due to
11 injection of a small amount of saline.

12 So I don't know the answer to that
13 question. As I said, the volume of those nasal
14 sprays is very small. I'm prepared to believe it
15 if there's a formal study showing it. And it
16 wouldn't shock me.

17 Q. Now, is it your opinion as part of the
18 declaration that you submitted here that reducing
19 spray volume would be one advantage of having a
20 fixed dose formulation of the two drugs as opposed
21 to separate administration?

22 A. Yeah. I think that if these drugs are

1 given conjunctively, which as you know is what I
2 maintain was the prior art, if they were given
3 simultaneously, the volume may be more prone to be
4 large enough so that some of the drug runs out of
5 the nose or back of the throat.

6 So the solution to that of course
7 is to just separate the administration of the two
8 drugs by 10 minutes or 15 minutes, and that's what
9 people have done and it works fine. There is a
10 convenience to have them in the same canister,
11 same spray bottle, and having a lower volume.

12 So yeah, I'm aware of that issue
13 and it's relevant, not overwhelmingly important to
14 the pharmacologic effects of the drugs.

15 Q. So would you say that that effect,
16 reducing spray volume, is just a modest advantage?

17 A. It's more convenient, and it has been
18 speculated it may improve compliance.

19 Modest is fair because it's not,
20 it's not necessary to achieve the beneficial
21 effects of the combination of the drugs.

22 Q. I can show you but you testified in

1 that prior proceeding that the spray volume is a
2 modest effect; right?

3 A. I'm prepared to believe that I did. I
4 just did again.

5 Q. And you stand by that?

6 A. Yes.

7 Q. Now, a few minutes ago when I asked
8 you about the dosing for fluticasone you said it
9 could be once a day or twice a day; correct?

10 A. I believe so, yes.

11 Q. Is it fair to say that dosed once a
12 day, because it has a 24-hour duration of effect,
13 is that an appropriate way to say it?

14 A. Yeah, I'm aware of studies in asthma
15 where the lung was removed, one lung was removed
16 after administration of fluticasone. These were
17 not volunteers, they were scheduled to undergo
18 surgery already. They measured the amount of drug
19 in the lung, and 24 hours later it was still there
20 in meaningful levels.

21 Q. Now, intranasal azelastine, on the
22 other hand, has only a 12-hour duration of effect?

1 A. That's a ballpark figure, and I
2 believe that's why it's administered twice a day.

3 Q. So with azelastine and fluticasone in
4 a fixed dose formulation, a POSA would have
5 understood that both drugs would have had to have
6 been dosed identically; correct?

7 MR. HOUSTON: Objection, form.

8 THE WITNESS: I don't know what you
9 mean by "dosed identically."

10 BY MR. VARUGHESE:

11 Q. That was a bad question. Let me fix
12 that.

13 A. I forgive you. I think I know what
14 you mean, but try again.

15 Q. If we were to go back to 2001, 2002
16 and a POSA considering whether to combine
17 azelastine and fluticasone into a single
18 formulation, single canister --

19 A. Yes.

20 Q. -- that POSA would understand that
21 those agents would then have to be dosed an
22 identical regimen; correct?

1 A. Meaning frequency.

2 Q. "Frequency," yes, is a better term.

3 A. Okay. Yeah, I guess the choice at the
4 time would have been to dose it once a day and
5 have the azelastine go up and down in its
6 effectiveness or use a huge dose of azelastine.
7 Or, dose it twice a day, which is fine for the
8 fluticasone, and adjust the doses appropriately.
9 And the latter choice would be I think pretty
10 obvious to a person of skill in the art.

11 Q. Now, you said earlier a few minutes
12 ago and in your declaration that the prior art was
13 prior conjunctive use; correct?

14 A. Yeah, I don't know if that's a legal,
15 if it meets legal standards, but in my opinion the
16 practice of combining these two intranasal drugs
17 long preceded the priority date.

18 And I mentioned already
19 antihistamines, fully two thirds of the market is
20 antihistamines. Well, 30 percent of the market is
21 steroids, nasal steroids. So between them they
22 occupy almost 95 percent of the whole market,

1 which means that any patient whether they are
2 started on an antihistamine or whether they're
3 started on intranasal steroid whose disease is not
4 adequately controlled, the next drug of choice to
5 add to the regimen is almost invariably the other.

6 So if they're started on an
7 antihistamine and it's not working well enough,
8 they add an intranasal steroid. If they're
9 started on an intranasal steroid, it's not working
10 well enough, they add an antihistamine, oral or
11 topical.

12 So the conjunctive use of these two
13 classes of drugs has been going on for decades,
14 and it certainly was going on then. And with the
15 availability of Astelin, which is intranasal
16 azelastine, and Flonase which is intranasal
17 fluticasone propionate, those two drugs were being
18 used together conjunctively for many years before
19 the priority date.

20 Q. So I want to just make sure, and it
21 has nothing to do with legality. I want to make
22 sure we're on the same page when we use the phrase

1 "conjunctive use."

2 A. Okay.

3 Q. By "conjunctive use" do you mean when
4 a physician co-prescribes azelastine and
5 fluticasone and tells a patient to use them
6 together?

7 A. As I am using the term, I am
8 envisioning two separate sprayers, one with each
9 drug prescribed to the same patient at the same
10 time with instructions to use both drugs.

11 Q. Okay.

12 A. Or, with instructions if one doesn't
13 help, add the other and use both.

14 Q. So let's focus on the latter one where
15 the instruction is if one doesn't work well enough
16 add the other one. Would that be what is commonly
17 referred to in clinical practice as PRN use or
18 as-needed use?

19 A. Not necessarily.

20 Q. What is PRN or as-needed use?

21 A. As-needed use is something that
22 physicians don't often advise but they can. But

1 patients often do. So, for instance, if you're
2 prescribed fluticasone for inhalation, Flonase,
3 you're supposed to take it once or twice a day,
4 whatever the recommendation is, and continuously
5 take it at that frequency. But many patients will
6 only take it when they're feeling symptomatic. So
7 that's a case where PRN is as the patient decides.

8 There's actually a very interesting
9 study that's in the collection of papers that are
10 considered in this case by Elizabeth Juniper where
11 she gave a tribute to that real world situation
12 and she recruited patients and gave them an
13 intranasal steroid and an oral antihistamine, but
14 she gave them very interesting instructions. Half
15 of them, she said, before the allergy season
16 starts, start taking this intranasal steroid and
17 keep using it and if you feel okay, just keep
18 using it through the season. On the other hand,
19 if during the season you start getting more
20 symptomatic and it's not enough, add the
21 antihistamine but keep taking the steroid. And
22 then at the end of the season, at the end of the

1 study, you know, you'll report what you used and
2 we'd like to keep track of it.

3 The other half got the oral
4 antihistamine as the first drug that they were
5 instructed to take with a regular regimen, not as
6 needed. And they were told if it's not
7 controlling symptoms when the season starts, add
8 the intranasal steroid, but keep taking both
9 drugs.

10 What she found was that over
11 50 percent of the patients ultimately ended up
12 choosing to take both the antihistamine and the
13 intranasal steroid, and the presumption is that
14 they did so because the combination controlled
15 their symptoms better than either alone.

16 So there's the reality and then
17 there's the prescription and the instructions.
18 PRN is sometimes used, but usually a physician
19 will say take this once a day as instructed.

20 Q. Would PRN use of azelastine with
21 fluticasone, in the prior art would that fall
22 under your definition of prior conjunctive use

1 that's prior art to this invention?

2 A. It's a highly theoretical question.

3 But, to me, any conjunctive use, whether drugs are
4 being used together for more than a couple weeks,
5 would qualify as conjunctive use. Because, as I
6 mentioned, we haven't talked about the underlying
7 mechanisms in the early phase and the late phase
8 but it's in the declaration.

9 It takes weeks for the steroids to
10 come to full effect, and during that period having
11 both drugs is very beneficial because the
12 azelastine, which works almost immediately, will
13 be dramatically contributing to the overall
14 benefit.

15 However, with conjunctive use, by
16 the time a couple weeks are up, or three weeks,
17 the steroid is carrying most of the or is
18 responsible for most of the beneficial effect.

19 Q. So what evidence do you cite,
20 Dr. Schleimer, for your contention that -- well,
21 let me get to that in a second.

22 Before that, the study by Elizabeth

1 Juniper, the antihistamine was not azelastine;
2 correct?

3 A. I think that's correct.

4 Q. In fact, it was terfenadine?

5 A. Yeah, I was going to say.

6 Q. God help those people.

7 A. Hopefully they weren't at risk for
8 heart disease.

9 Q. Exactly.

10 So then what is your evidence that
11 you cite for the proposition that azelastine and
12 fluticasone were used in a conjunctive use form,
13 as you've defined it?

14 A. Well, actually basically as a
15 statement by a number of opinion leaders that they
16 prescribed those two drugs to the same patient at
17 the same time before the priority date. And that
18 includes Dr. Wedner, Dr. Caliner, Dr. Carr,
19 Dr. DiDario --

20 Q. Dr. Accetta?

21 A. Accetta, those four.

22 Q. Can I get just a clarification for the

1 record?

2 A. Yes.

3 Q. Those statements that you're referring
4 to by Dr. Carr, Caliner, Wedner, and Accetta,
5 those are statements from the district court
6 trial --

7 A. Correct.

8 Q. -- in December?

9 A. Correct. And they all stated that
10 before the priority date they had prescribed those
11 two drugs to patients.

12 Q. Did you cite that testimony in your
13 declaration?

14 A. I did not.

15 Q. So then why are you relying on it
16 today in our deposition?

17 A. You're asking me questions about
18 conjunctive use of these two drugs.

19 Q. And that's my mistake. Let me
20 clarify.

21 I was asking what evidence do you
22 cite in your declaration to support the notion

1 that azelastine nasal spray and fluticasone nasal
2 spray were used in this conjunctive use fashion,
3 as you've defined it, focusing on your
4 declaration?

5 A. I don't know if I cite any. That
6 doesn't mean it wasn't happening.

7 I mean azelastine was becoming very
8 popular and Flonase was already the big steroid
9 that everyone, that the majority, was most
10 popular, most effective.

11 So, as I mentioned, 95 percent of
12 the market is those two classes of drugs, and if
13 one doesn't work you add the other. So by some
14 kind of math, which would be maybe difficult to do
15 but easy to understand, that the likelihood that
16 those two drugs were being prescribed
17 conjunctively is very high for any given patient.
18 I couldn't tell you if it's 5 percent, 10, 2, I
19 don't know.

20 Q. So you mentioned Dr. Accetta's
21 testimony from the trial. And I'll represent for
22 the record that it was Dr. Donald Accetta from

1 Boston who testified on behalf of defendant Apotex
2 in that trial.

3 A. Yes.

4 Q. And you also were an expert who
5 testified on behalf of defendant Apotex in that
6 trial.

7 A. Yes.

8 Q. At trial do you recall when we looked
9 at Dr. Accetta's patient records? Do you recall
10 in the courtroom?

11 A. I do.

12 Q. And do you recall that the great
13 majority of his patient records that were admitted
14 as evidence at trial instructed patients to do a
15 PRN dosing of azelastine with fluticasone?

16 A. I remember some discussion about PRN
17 versus continuous treatment. It was unresolvable.
18 The question, as I mentioned, is what percentage
19 of those patients were likely to have taken them
20 conjunctively for more than two weeks. And my
21 belief would be that if their disease is severe
22 enough that they need to take both drugs, it's

1 highly likely that it would have gone on for weeks
2 and months. And he said that. But I don't think
3 there was any hard data. But his proof that he
4 prescribed both drugs to the same patient was a
5 handful of charts which were selected as a sample
6 of a much larger collection of charts.

7 So I was convinced he had actually
8 tangible evidence that these two drugs were
9 prescribed to the same patients for conjunctive
10 use.

11 Q. So for clarity at trial, I think the
12 distinction was PRN conjunctive use on the one
13 hand versus what we termed fixed dosing regimen
14 where both agents were given at a fixed time
15 together on the other hand. Do you recall that?

16 A. I know that was an issue.

17 Q. Right.

18 A. And, as I said, I mean I didn't see a
19 resolution of it at the trial, and we probably
20 won't resolve it now.

21 Q. But for purposes of your analysis,
22 both the PRN use and any fixed regimen use would

1 all be prior art conjunctive use?

2 A. Okay. I've tried to say it a couple
3 times. I'll say it again.

4 The way I'm viewing conjunctive use
5 is not as a lawyer but as a pharmacologist. To
6 me, the meaningful period of conjunctive use, the
7 most important period lasts at least a week or
8 two. And if some of his patients use both drugs
9 conjunctively for that period of time, I would
10 think they would get much greater benefit than
11 either of them as a monotherapy.

12 But this is not a definition that I
13 can point to a book somewhere and someone says
14 that's the definition. That's my view from my
15 perspective of the pharmacology of these. That's
16 the key window when the additivity is most
17 evident. After that in my opinion the conjunctive
18 use, whether it's conjunctive or co-formulation,
19 the benefit of the steroid becomes much more
20 important than the added azelastine in the later
21 time periods. The benefit of the combination is
22 primarily in the first week or two before the

1 steroid has the opportunity to exert the profound
2 anti-allergic effects it causes.

3 Q. So let's focus on that two-week window
4 that you said is so important.

5 So in your view would that patient
6 be taking azelastine and fluticasone sequentially,
7 meaning immediately right after one another?

8 A. I think there were probably hundreds,
9 thousands, maybe tens of thousands of people who
10 were being prescribed both drugs at the same time,
11 and you could find almost any combination of how
12 they may have been used in the wild by patients.

13 What patients do with drugs -- I
14 mean in asthma they can be prescribed inhalers for
15 asthma, inhaled fluticasone, and maybe in a year
16 they use two canisters or three, not 12. The
17 average is a couple.

18 So I can imagine all sorts of
19 scenarios. But among them are what I'm calling
20 prior art, periods of times of weeks where they're
21 using both and that's when the additive benefit
22 would be already taken advantage of by patients

1 and doctors before the priority date.

2 Q. So when you say use at the same time,
3 you're talking, you know, administer, spray one
4 drug and then immediately you're going to spray
5 the other drug. Is that what you mean by same
6 time?

7 A. Not immediately. I think most of them
8 if they like the shirt they're wearing would
9 probably wait 10 minutes, 15 minutes in between.
10 Just so that it doesn't run back out of the nose.

11 Q. So when you say same time, one
12 definition is maybe 10 or 15 minutes apart. Is
13 that fair to say? Is that what you just said?

14 A. That would probably work. I think
15 that might have been what was done in the Meda
16 study that used them conjunctively.

17 Q. So how about if someone takes it at
18 8:00 a.m. in the morning and then takes it at 12
19 -- takes fluticasone at 8:00 a.m. in the morning,
20 takes azelastine at 12 noon, in your view would
21 that also constitute same time, quote?

22 A. It would probably take advantage of

1 the same complementarity I'm talking about. It
2 seems unlikely, but it's possible.

3 Q. I'm just trying to understand from an
4 administration standpoint, not from a
5 pharmacological effect.

6 A. Sure.

7 Q. From an administration standpoint, and
8 I laugh when you said how patients are taking it
9 in the wild, I want to know how you think they
10 were taking it in the wild.

11 So when you say "the same time,"
12 one aspect of that could be patients who take the
13 drugs 10 or 15 minutes apart.

14 I'd like to know in your view does
15 "same time" also mean when those patients take it
16 four or five hours apart or maybe even 10 hours
17 apart? Is that all, in your view, the same time?

18 A. No. I mean you know the answer to the
19 question before you asked. If they're separated
20 by 10 hours consistently, that would be less than
21 ideal. Both drugs should be there at active
22 concentrations at the same time.

1 But patients tend to use drugs like
2 this in the morning, you know, before or after
3 they brush their teeth or whatever and in the
4 evening. And my guess would be in the vast
5 majority of these cases they were separating the
6 administration by enough time so it wasn't a
7 problem. And maybe they didn't have a problem
8 with it running out, they do it immediately one on
9 top of the other.

10 Q. So a few minutes ago you mentioned a
11 Meda study where patients were taking azelastine
12 and fluticasone about 10 or 15 minutes apart.

13 A. I don't know. I think it may have
14 been.

15 Q. And I'm not going to hold you to it if
16 it's a few minutes different. But I think you're
17 referring to the Ratner 2008 study.

18 A. Yes.

19 Q. The study conducted by Ratner, et al.,
20 in 2008 where they assessed co-administration of
21 azelastine and fluticasone?

22 A. Yes.

1 Q. And it was a study that was sponsored
2 by Meda?

3 A. I believe so, yes.

4 Q. That's what you recall.

5 A. Yes.

6 Q. Okay. So looking at your declaration
7 and in terms of the papers, the support, have you
8 cited any study other than Ratner 2008 where
9 patients were taking the two agents close
10 together, let's say 10 to 15 minutes, in a fixed
11 regimen?

12 A. Well, no. As you know, there's a
13 Hamphill study that was a couple years later by
14 the very same group of investigators. The order
15 of the names was changed.

16 Q. That's not prior art.

17 A. It's not prior art. And it was
18 discussed in the trial, but it's not part of the
19 declaration. Although it's shows its head in the
20 Maus deposition. M-A-U-S.

21 Q. So for those patients who are not
22 taking azelastine and fluticasone at the same

1 time, there would be no convenience benefit to
2 putting both drugs in one bottle; correct?

3 A. No, I disagree. It would cut in half,
4 or significantly, the number of times they had to
5 stick a bottle in their nose. That's a
6 convenience for sure.

7 Q. If a doctor was -- you'd agree that
8 physicians engage in the practice of dose
9 titration? Are you familiar with that term?

10 A. Sure.

11 Q. "Titration" means, you know, titrating
12 a patient up or down in terms of a dose depending
13 on patient needs?

14 A. Yes.

15 Q. So if a patient was taking less
16 azelastine, let's say Patient A was taking less
17 azelastine than Patient B, then having both drugs
18 in a fixed dosage formulation would expose that
19 patient to more drug than necessary; true?

20 A. Well, it depends on the doses or
21 concentrations depending on how you look at it of
22 each drug in the formulation. But with both of

1 these drugs if the ratio is appropriate, you could
2 double the number of sprays with impunity. It
3 wouldn't be a big issue for side effects. You
4 definitely would give up some flexibility, I will
5 give you that. And there's a tradeoff. The
6 tradeoff is the convenience.

7 If it's impractical to increase the
8 number of sprays of a fixed combination beyond
9 what the regimen says or what's approved or if the
10 doctor doesn't want to do it or the patient
11 doesn't want to do it, you can always go back to
12 the conjunctive use of the monotherapies and
13 increase one drug and not the other if there was a
14 driving need to do that. But both of these drugs
15 are pretty safe and have a reasonable therapeutic
16 range. So there's some flexibility still. You
17 haven't given up all of it.

18 (A recess was taken.)

19 BY MR. VARUGHESE:

20 Q. Dr. Schleimer, welcome back from the
21 break.

22 A. Thank you.

1 Q. I just have a few more questions, and
2 then we should be able to wrap up here.

3 Switching gears a little bit. My
4 next few questions relate to so-called objective
5 indicia of nonobviousness or what we call
6 secondary conditions. Do you know what those are?

7 A. I have a lay knowledge of them.

8 Q. But you address them in your
9 declaration.

10 A. Yes.

11 Q. I presume that your counsel informed
12 you about some of the legal principles surrounding
13 it.

14 A. Sure.

15 Q. And so you took objective indicia and
16 secondary considerations into account for purposes
17 of your declaration?

18 A. Yes.

19 Q. If I were to say that the law is that
20 when considering the question of obviousness, one
21 must always take into account secondary
22 considerations that would tend to suggest that an

1 invention might not be obvious. Is that fair to
2 say? Is that your understanding of the law?

3 A. It is my understanding of the law.

4 Q. Okay. In your declaration here with
5 respect to the '620 Patent, you opine on two
6 secondary considerations, one being long-felt,
7 unmet need.

8 A. Yes.

9 Q. And the other being unexpected
10 results.

11 A. Yes.

12 Q. And then your analysis of long-felt
13 unmet need surrounded the declaration of
14 Dr. Sujeet Rajan. Does that ring a bell?

15 A. Yes.

16 Q. And Dr. Sujeet Rajan was a declarant
17 for Cipla during prosecution of the '620 Patent;
18 is that correct?

19 A. That sounds correct.

20 Q. And your analysis of unexpected
21 results was limited to the overall efficacy of the
22 claimed combination as compared to monotherapies.

1 A. Yes, and Dr. Maus' declaration.

2 Q. Right. So Dr. Maus' declaration from
3 prosecution, the prosecution history.

4 A. Yes.

5 Q. Now, earlier we talked about, back in
6 December 2016 you attended and testified on behalf
7 of Apotex in that trial that also involved the
8 '620 Patent; correct?

9 A. Yes.

10 Q. And in that trial you offered opinions
11 regarding several objective indicia?

12 A. Yes.

13 Q. At the trial do you remember offering
14 opinions regarding whether or not the onset of
15 Dymista, the commercial embodiment of the '620
16 Patent, was unexpected?

17 A. I remember some discussions about
18 that, yes.

19 Q. And some of the testimony that you
20 offered there at that trial, did they make their
21 way into the declaration here that you submitted
22 in the IPR?

1 A. No.

2 Q. Do you remember testifying regarding
3 industry praise as another objective indicia of
4 nonobviousness?

5 A. I think we quickly went through a
6 list, and that one was mentioned.

7 Q. But you don't discuss industry praise
8 in your declaration here?

9 A. No.

10 Q. Do you remember testifying whether
11 Dymista, again the commercial embodiment of the
12 '620 Patent, was subject to skepticism at that
13 trial?

14 A. I remember some discussion about it.
15 I remember being skeptical of the skepticism, but
16 I do remember some discussion about it.

17 Q. And by "discussion" you mean your
18 testimony?

19 A. No, other people's testimony about the
20 skepticism of the FDA, which I found unconvincing.

21 Q. But you don't address that and the
22 reasons why you find that to be unconvincing in

1 your declaration here?

2 A. That's right.

3 Q. Do you remember discussions at trial
4 that Dymista, the commercial embodiment of the
5 '620 Patent, was a commercial success and that
6 that was a reason why the patent is not obvious?

7 A. I remember some arguments about that.
8 I wouldn't say it's a failure, but I was a little
9 underwhelmed by the size of the market. But I do
10 remember discussions about the commercial success.

11 Q. And then you yourself also offered
12 some testimony that there were some blocking
13 patents that would have contributed to any success
14 of Dymista. Do you recall that?

15 A. Well, I think that topic was whether
16 some of the existing patents would have inhibited
17 other people from attempting to make the same what
18 we claimed was obvious combination.

19 Q. Why did you undertake that analysis as
20 part of your work in the district court? Why did
21 you examine whether there were blocking patents?

22 A. Well, these documents in these cases,

1 my role in them is to provide the scientific
2 answer to questions that are important. But the
3 documents, as you know, there's a great influence
4 of the attorneys involved as to what to
5 prioritize, what not to prioritize, what their
6 legal strategy, what it isn't. I won't sign it
7 unless I understand their explanation of the law
8 and why they're taking the view they have. But
9 that's the nature of these documents.

10 So, you know, I'm not making the
11 decisions of all the topics we're going to talk
12 about. I'm providing my expertise for the topics
13 that require it.

14 Q. So the discussion of blocking patents
15 also did not make their way into your declaration
16 here; correct?

17 A. That's correct.

18 Q. So why did you -- so some of these
19 other objective indicia that you either testified
20 about or were aware about from the December trial
21 of the '620 Patent, why did you leave them out of
22 your declaration here?

1 MR. HOUSTON: Objection, privileged.

2 If you can provide any reasons that
3 were not the result of discussions with counsel,
4 then you can answer. But you shouldn't reveal
5 anything that was part of your discussions with
6 counsel as to such reasons.

7 BY MR. VARUGHESE:

8 Q. So can you answer that question
9 without revealing confidential communications with
10 counsel?

11 A. They're interesting topics. I have
12 opinions. I find most of the secondary indicia of
13 nonobvious to be modest or totally unconvincing.
14 But I assume for strategic reasons they didn't fit
15 in this document.

16 There's not more I can say without
17 revealing confidential discussions I guess.

18 Q. So going back to the legal principle
19 that we started this line of questioning with
20 where you agreed that under prevailing law when
21 determining obviousness available secondary
22 considerations, or what we call objective indicia,

1 should be covered. Do you recall agreeing to that
2 as a legal principle?

3 A. I understand the principle and
4 actually appreciate it. It's been referred to as
5 a way to look back in time and ask the question in
6 a different way, and as a scientist that appeals
7 to me.

8 Q. If you felt that some of these other
9 secondary considerations were, and I'm
10 paraphrasing, minimal or of totally no value is I
11 think what you said, or the gist of it, don't you
12 think it would have been important to put in your
13 declaration?

14 A. Again, I can't talk about discussions
15 that we had or didn't have about the strategy, the
16 legal strategy.

17 Q. When you say "we," you mean with
18 counsel?

19 A. Yeah.

20 Q. So I know we touched on some of this
21 earlier, but I just want to close the loop on your
22 work with Argentum and with Apotex, Dr. Schleimer,

1 so if you'll just indulge me.

2 So you've previously worked with
3 Apotex with respect to the '620 Patent in that
4 December trial; correct?

5 A. Yes.

6 Q. Did you have a written agreement with
7 Apotex or its counsel for that work?

8 A. Didn't you ask me that? I think that
9 was asked and answered.

10 Q. I did, and I think your answer was,
11 and I just want the record to be clear, that you
12 didn't know sitting here today but you --

13 A. I don't believe I did, but I might
14 have. I do a lot of agreements in my consulting
15 work with pharmaceutical companies as a scientist,
16 and these things, you know, it's like snowflakes,
17 and my secretary takes care of them. So if it's
18 important to find out, I can look.

19 Q. Okay. And if you look or your
20 secretary looks, one way or another you can
21 confirm?

22 A. Yes. I don't think I have your email

1 though. I mean I would only do it with permission
2 of my counsel.

3 Q. Mr. Houston may have a problem with me
4 giving you my email.

5 When we were at trial in
6 Wilmington, Delaware in December, you obviously
7 had prep meetings with attorneys from Winston &
8 Strawn as part of your preparation. I don't want
9 to know what you talked about, but you had
10 meetings with them; correct?

11 A. Yes, yes.

12 Q. Was anyone from Argentum present in
13 any of those meetings during trial?

14 A. Not to my knowledge.

15 Q. Was Tyler Liu present in any of those
16 meetings?

17 A. I don't believe so.

18 Q. Was anyone from the Foley & Lardner
19 law firm present during those meetings?

20 A. I don't think so.

21 Q. Are you aware of any conversations the
22 attorneys from Foley & Lardner had with the

1 attorneys from Winston & Strawn who were Apotex's
2 counsel regarding Dymista or the '620 Patent?

3 A. No, I'm not. I know there was some
4 interaction, but I know no details.

5 Q. So how do you know there was some
6 interaction?

7 A. I think one of them -- now maybe they
8 got it through public records, but I think there
9 was some discussions about my declarations and
10 some sharing or some way to utilize it. But I
11 wasn't involved in those.

12 Q. How do you know that there was
13 discussions if you weren't involved?

14 A. Because I believe early on in January
15 during vacation that they said they could start
16 working on it and use some of the materials. But
17 I don't know what materials they're referring to.
18 I don't know if Apotex was passive or active. I
19 don't know. I'm not sure what they had access to.
20 I'm not aware that they were at the trial. They
21 might have been. I don't think I ever met Tyler
22 Liu in person.

1 Q. When you say "they," who are you
2 referring to?

3 A. The Argentum lawyers.

4 Q. Did you have to get Apotex's approval
5 before you could agree to work with Argentum on
6 this matter?

7 A. I believe that the Argentum people
8 told me they had spoken with Apotex and it was
9 okay with Apotex. I confirmed that by contacting
10 one of the people at Apotex.

11 Q. And who did you contact?

12 A. It might have been Mr. Klein, but I'm
13 not sure.

14 Q. And that's Charles Klein? I
15 understand you're not sure, when you say
16 "Mr. Klein" is that Charles Klein from --

17 A. Yes.

18 Q. -- Winston & Strawn?

19 A. He's the one I think I would have
20 naturally contacted. So I'm piecing it together
21 by what I would do if I had to do it over again.

22 Q. And you contacted him to confirm that

1 you were clear to work on this Argentum matter?

2 A. Right. I wasn't going to just take
3 their word for it.

4 Q. "They" meaning Argentum.

5 A. Argentum.

6 Q. Why did you feel the need to do that?
7 Did your agreement with Apotex give Apotex some
8 right of refusal to preclude you from working on
9 this for someone else?

10 MR. HOUSTON: Objection, form.

11 THE WITNESS: I've already told you I
12 don't -- I don't recall there even being an
13 agreement. There may be one. If there is one, I
14 couldn't tell you if there were phrases that would
15 limit my activity or otherwise, but there was
16 never any sense that they had any influence on
17 that. I just thought that it was the right thing
18 to do, make sure it's okay with everybody.

19 BY MR. VARUGHESE:

20 Q. I guess that's what I'm trying to get
21 to. And I could be wrong here. In America the
22 way I think is you're free to do whatever you want

1 to do unless you've agreed not to do it. So I'm
2 curious why you felt the need to contact Apotex's
3 counsel before you took on this matter.

4 A. Well, maybe it was just being
5 thorough. I don't know.

6 I'm by nature a fairly trusting
7 person. But when it comes to lawyers, I feel the
8 need to double check.

9 Q. I take umbrage with that.

10 A. My father was the dean of a law school
11 and my brother was a litigator, so I can love
12 lawyers, okay.

13 Q. Okay. Did Apotex or the lawyers at
14 Winston have any input in your declaration in this
15 IPR?

16 A. Not to my knowledge, other than
17 whatever happened right there in the beginning. I
18 know of no active participation in preparation of
19 documents or anything.

20 Q. Is Apotex or its counsel, Winston &
21 Strawn, paying any part of your invoices as part
22 of this IPR proceeding?

1 A. Not to my knowledge. I haven't
2 submitted any invoices yet, but I don't believe
3 so.

4 Q. And when you do submit invoices, who
5 are you planning to submit them to?

6 A. I haven't been told, but I'll probably
7 send it to Mr. Houston.

8 Q. If there is an engagement letter, is
9 it fair to say that engagement letter would
10 probably identify who you should submit invoices
11 to?

12 A. If there is one. Can I ask my
13 counselor if there's an engagement letter? No?
14 Okay.

15 Q. I'm fine with you asking.

16 So you started working with
17 Argentum and its counsel in January 2017. Is that
18 your testimony?

19 A. Yeah, I was on vacation and I was in
20 San Diego, and they called me and said Hey, you
21 know, we're interested --

22 MR. HOUSTON: Be careful about

1 revealing the substance of the conversations.

2 THE WITNESS: Okay.

3 MR. VARUGHESE: That's fair.

4 THE WITNESS: And they said we're
5 interested in retaining you as an expert.

6 BY MR. VARUGHESE:

7 Q. Sure. And I think your declaration,
8 you can confirm, was signed I think February 12th.

9 A. Yeah, it went fast.

10 Q. So is it fair to say -- February 2,
11 2017.

12 A. Whatever it was.

13 Q. Is it fair to say you started working
14 with Argentum in January?

15 A. Yeah, immediately.

16 Q. So it's October 20, 2017 now. Ten
17 months has elapsed and you still have not
18 submitted any invoices in connection with this
19 matter?

20 A. Oh. So I did -- I must have submitted
21 invoices. I did at that time, and I could look up
22 who it was submitted to. I don't recall.

1 Q. You would have those records?

2 A. Yes, I'm sure I do.

3 MR. VARUGHESE: I have nothing
4 further, Dr. Schleimer. Thank you.

5 MR. HOUSTON: We'd like to take a
6 break, and I'll confer with the witness to see if
7 we have any Redirect. We'll be right back.

8 (A recess was taken.)

9 EXAMINATION

10 BY MR. HOUSTON:

11 Q. Dr. Schleimer, could you pull out from
12 that stack of papers in front of you, the marked
13 exhibits, the one that's marked CIP2145.

14 A. Yes.

15 Q. Can you confirm that this is what you
16 discussed earlier with counsel, the '914 Patent?

17 A. Those are the last three digits of the
18 number, yeah.

19 Q. I want to ask you about one of the
20 passages that you were questioned on. It's at
21 Column 6 starting around Line 29 going to Line 40.

22 A. Yes.

1 Q. Do you recall being asked about that
2 passage?

3 A. I do.

4 Q. At the end of that passage, the final
5 sentence says "the use of the upper airway passage
6 decongestant, pseudoephedrine HCl, is preferred."
7 Do you see that?

8 A. I do.

9 Q. What would be your understanding, if
10 any, of what's meant by that sentence?

11 A. I believe that that was stating that
12 among those decongestants that were mentioned
13 which included phenylephedrine, pseudoephedrine,
14 and phenylpropanolamine, that pseudoephedrine is
15 preferred.

16 Q. So is it the case that azelastine is
17 not part of the group that's listed there?

18 A. Azelastine is not mentioned in this
19 paragraph.

20 Q. I'm sorry?

21 A. Azelastine is not mentioned in this
22 paragraph.

1 Q. Okay. Thank you. You can set that
2 aside.

3 You recall another line of
4 questioning from counsel involved either the
5 testimony you gave or the testimony you heard
6 during the district court litigation back in
7 December regarding secondary considerations?

8 A. Yes.

9 Q. If all of that same testimony were
10 introduced by the patent owner in this proceeding,
11 would it change your opinions as to the
12 obviousness of the '620 Patent?

13 MR. VARUGHESE: Objection, leading,
14 outside the scope.

15 BY MR. HOUSTON:

16 Q. You may answer.

17 A. No. At the time and now I still think
18 it's obvious.

19 Q. So even taking into account the
20 testimony you heard at the trial, that's the case?

21 MR. VARUGHESE: Objection, leading.

22 THE WITNESS: Even including the

1 secondary indicia of nonobviousness, I still
2 believe it was obvious at the time.

3 MR. HOUSTON: Okay. I have no further
4 questions.

5 MR. VARUGHESE: I have a few questions
6 on Recross.

7 FURTHER EXAMINATION

8 BY MR. VARUGHESE:

9 Q. Let's go back to your '914 Patent,
10 Dr. Schleimer.

11 A. Yes.

12 Q. I believe that is Exhibit CIP2145.

13 A. Yes.

14 Q. So I'd like to go to Column 6, Line
15 29, starting there -- we'll get to that in a
16 second.

17 So you just answered Mr. Houston's
18 question regarding part of that passage; correct?

19 A. Yes.

20 Q. And you just returned from the break?

21 A. Yes.

22 Q. Did you speak about that passage with

1 Mr. Houston?

2 A. Briefly.

3 Q. What did you discuss?

4 MR. HOUSTON: Objection, irrelevant
5 and privileged.

6 MR. VARUGHESE: How is that
7 privileged, Mr. Houston? The witness is still
8 under oath.

9 MR. HOUSTON: Unless you're going to
10 get the witness to say that I told him what to say
11 or how to testify, it is privileged and
12 irrelevant.

13 MR. VARUGHESE: And that's what I'm
14 focusing on.

15 MR. HOUSTON: Well, ask your question
16 that way. You just said what did you discuss.
17 That's a very open-ended, broad question.

18 BY MR. VARUGHESE:

19 Q. Did you discuss your testimony that
20 you just gave with Mr. Houston?

21 A. We discussed the meaning of that last
22 sentence.

1 Q. And what did you discuss?

2 A. I said the same thing that I just said
3 to you, which is, my opinion, it refers to the
4 list, the short list, of decongestants, and not
5 the entire paragraph.

6 Q. Did Mr. Houston instruct you to say
7 that?

8 A. No. That's my opinion.

9 Q. But do you understand you're changing
10 your answer now from what you said earlier this
11 morning?

12 A. I don't think that's true.

13 Q. Did Mr. Houston point to any part of
14 that passage to lead you to that conclusion?

15 A. No. That was my conclusion after
16 reading this paragraph.

17 But it's ambiguous because that
18 sentence is at the end of a whole paragraph, and
19 it could possibly be misconstrued to mean that
20 pseudoephedrine HCl is preferred among all the
21 drugs mentioned there.

22 I think it's not totally ambiguous

1 because it says "decongestant." But just to be
2 clear, that sentence "pseudoephedrine" refers only
3 to the decongestants, in my opinion. I don't
4 recall writing this paragraph.

5 Q. And it's not your opinion that you're
6 changing your answer right now from what you said
7 earlier?

8 A. No, I don't think I am.

9 Q. Okay. Now, during the other breaks
10 that we took, did you speak with Mr. Houston about
11 this deposition?

12 A. No.

13 Q. You had no conversations about your
14 testimony with Mr. Houston?

15 A. No.

16 Q. I want to look at that sentence a
17 little more closely.

18 So your testimony is, and I'm going
19 to quote the passage, "the use of the upper airway
20 passage decongestant, pseudoephedrine HCl, is
21 preferred."

22 A. Yes.

1 Q. And your testimony right now is that
2 "preferred" refers to pseudoephedrine HCl among
3 the few decongestants that are cited in that
4 paragraph above?

5 A. Yes.

6 Q. So your testimony is not that that
7 sentence is saying that the class of decongestant,
8 pseudoephedrine specifically, is preferred over
9 other classes cited in that passage?

10 A. It's not a class, it's a compound.

11 Q. Decongestant is not a class or a
12 compound?

13 A. Pseudoephedrine is a compound.

14 Q. Right. The word "decongestant" refers
15 to class; right?

16 A. Yes, that's fair.

17 Q. Okay. So point for me as a matter of
18 English, can you point to me what words in that
19 sentence seems to suggest to you that it is that
20 the word "preferred" is referring to
21 pseudoephedrine among other decongestants as
22 opposed to decongestants being preferred among the

1 other classes that are cited in that paragraph?

2 MR. HOUSTON: Objection, form.

3 THE WITNESS: That sentence doesn't
4 refer to decongestants as a class, first off. It
5 just indicates that pseudoephedrine is a
6 decongestant. So that leads to the conclusion
7 that pseudoephedrine is being singled out among
8 the other decongestants that were just mentioned
9 immediately before that sentence.

10 Having said that, if you could get
11 rid of the list of decongestants and if that
12 sentence were there, the interpretation would be
13 that it's preferred amongst everything mentioned
14 in the paragraph, which was not the intention. So
15 that's the ambiguity that I'm referring to.

16 BY MR. VARUGHESE:

17 Q. And did Mr. Houston contribute to any
18 of this testimony that you're just giving me right
19 now about this explanation?

20 A. No. I'm explaining my opinion of it
21 which was formed immediately upon reading it, but
22 I also noticed the ambiguity.

1 Q. And when did you notice it?

2 A. I noticed it immediately when I read
3 it, when you gave it to me, which I don't, as I
4 said, this was written 17 years ago, 15 years ago,
5 I don't recall. I don't read my own patents, so I
6 haven't read it since then.

7 MR. VARUGHESE: That's all I have.

8 Thank you.

9 THE WITNESS: Thank you.

10 (Said deposition was so concluded
11 at 12:56 p.m.)

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4 I, Donna M. Kazaitis, CRR, RPR, CSR

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