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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 MAUREEN D. DONOVAN, 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 9:00 a.m. on  
Tuesday, October 24, 2017.

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1 (Witness sworn.)

2 MAUREEN DONOVAN, PH.D.,  
3 having been first duly sworn, was examined and  
4 testified as follows:

5 EXAMINATION

6 BY MS. EVERETT:

7 Q. Good morning, Dr. Donovan.

8 A. Good morning.

9 Q. You may recall I took your deposition  
10 about this time last year in the Apotex case?

11 A. Yes.

12 Q. So I know that you're familiar with  
13 the rules of the deposition, but before we go  
14 forward I'm just going to remind you just some  
15 basics.

16 We obviously have a court reporter  
17 here today. She'll be taking down what we say.  
18 So I just ask that we not speak over one another.

19 A. That's fine.

20 Q. And if you don't understand a question  
21 that I ask, I would ask that you ask me to clarify  
22 it for the record; otherwise, I will assume you

1 understood.

2 A. Okay.

3 Q. Is there any reason you can't testify  
4 truthfully today?

5 A. No.

6 Q. Could you please state your full name  
7 for the record.

8 A. Maureen Donovan.

9 Q. What is your current employer?

10 A. I am employed by the University of  
11 Iowa.

12 Q. And I just mentioned I took your  
13 deposition last year and you were an expert  
14 witness in the Meda Pharmaceuticals and Cipla  
15 versus Apotex case; is that correct?

16 A. Yes, I was.

17 Q. I'm going to hand to you what's  
18 already been marked as CIP2014. (Document  
19 tendered to the witness.)

20 If you can take a moment to go  
21 through this to confirm for me that this was your  
22 deposition testimony from that case, I would

1 appreciate it.

2 A. Yes. With a quick review, it  
3 essentially looks like my deposition testimony  
4 from that case.

5 Q. Okay. Thank you. I'm just going to  
6 put that to the side.

7 Then we also met at trial for the  
8 Apotex case. Do you recall?

9 A. Yes.

10 Q. I'm going to hand to you what's been  
11 previously marked as CIP2019. (Document tendered  
12 to the witness.)

13 Can you please go through that to  
14 whatever detail you need to confirm that is your  
15 trial testimony on Wednesday, December 14th. And  
16 I know you testified for a two-day period, so I  
17 have your second day as well and we can go through  
18 that in a moment.

19 A. Okay. There's also Dr. Schleimer's  
20 testimony included in this. If that was  
21 intentional or not, I don't know.

22 Q. And I just want you to focus on the

1 part that's yours, where you begin testifying.

2 A. Okay. I see my direct testimony.

3 Q. It starts on Page 72, either you can  
4 look at Page 72 or Page 228. Is that accurate?

5 A. Yes. The only part in here is my  
6 direct testimony; correct?

7 Q. Yes.

8 A. Okay.

9 Q. This is your accurate testimony from  
10 trial last year?

11 A. You know, I'd have to read every word  
12 of it, but I'm going to accept that this is the  
13 official court recording of that testimony.

14 Q. And you have no reason to doubt that  
15 it is actually your testimony?

16 A. No, I don't.

17 Q. Thank you. You can put that one to  
18 the side.

19 I'm going to hand to you what has  
20 been previously marked as CIP2020. (Document  
21 tendered to the witness.)

22 Dr. Donovan, if you can go through



1     this and confirm to me that this is the remainder  
2     of your trial testimony, I would appreciate that.

3             A.     It appears to be the remainder of my  
4     testimony, yes.

5             Q.     And you have no reason to doubt that  
6     it's not correct.

7             A.     No.

8             Q.     Dr. Donovan, when did you become  
9     involved -- strike that.

10                    You currently have been retained by  
11     Argentum in connection with this IPR; is that  
12     accurate?

13             A.     That's correct.

14             Q.     When were you retained by Argentum?

15             A.     Sometime earlier this year.

16             Q.     When were you first contacted?

17             A.     Again, sometime earlier this year.

18             Q.     January, February?

19             A.     Probably.

20             Q.     Who contacted you?

21             A.     Somebody from Argentum, and I don't  
22     remember exactly who.

1 Q. Was it Mr. Houston?

2 A. No, it was not Mr. Houston in the  
3 initial contact.

4 Q. Was it someone from the company  
5 Argentum?

6 A. Yes, it was somebody from Argentum.

7 Q. Was it Tyler Liu?

8 A. I don't remember. That could very  
9 well be.

10 Q. Do you have an agreement with  
11 Argentum?

12 A. Yes, I do.

13 Q. Who pays your -- strike that.

14 Who do you send your invoices to  
15 for the IPR?

16 A. They are sent to Argentum.

17 Q. And who pays your invoices?

18 A. I don't know that I really recall the  
19 way the check looked, but I am going to assume  
20 that it was an Argentum check.

21 Q. Did you discuss your involvement in  
22 this IPR with Apotex or counsel for Apotex?

1           A.    I consulted with counsel for Apotex  
2 before I took on the engagement for Argentum.

3           Q.    Who did you consult?

4           A.    I talked to one of the attorneys that  
5 was involved in the case. So I talked to Kevin  
6 Warner about it.

7           Q.    Without revealing, if you're able to  
8 answer without revealing any privileged  
9 communication, did Mr. Warner in that phone  
10 call -- strike that.

11                   How many times did you talk to  
12 Mr. Warner?

13           A.    I don't remember exactly. I think it  
14 may have been two times.

15           Q.    Okay. In the first -- what was the  
16 subject of your communication in the first call?

17           A.    I called to ask whether I was in  
18 conflict if I would take on this additional case.

19           Q.    Did he respond to you on that call?

20           A.    I don't recall what he said on that  
21 call.

22           Q.    You said there may have been a second

1 communication with Mr. Warner?

2 A. I think the second communication  
3 confirmed that there wasn't a belief that I would  
4 be in conflict if I took on this case.

5 Q. Do you recall when you had those  
6 conversations with Mr. Warner?

7 A. It was before I signed my agreement  
8 with Argentum.

9 Q. Are you aware of any communications  
10 between Argentum or counsel for Argentum and  
11 Apotex or counsel for Apotex?

12 A. I have no basis to be aware of that.

13 Q. Did Mr. Warner tell you he would speak  
14 to Argentum?

15 A. I don't recall who he had intended to  
16 speak to or that he even told me.

17 Q. After Mr. Warner confirmed it would  
18 not be a conflict, who did you speak to next that  
19 was connected with Argentum?

20 A. I don't remember whether -- I must  
21 have spoken to -- I think most of my communication  
22 with Argentum was actually via email, and I think

1 I confirmed with them that I was willing to take  
2 on this matter. And shortly thereafter I started  
3 having conversations with the attorneys at Foley.

4 Q. So when you confirmed you were willing  
5 to take on the matter, did you speak with someone  
6 at Argentum or were you speaking with counsel from  
7 Foley & Lardner?

8 A. I don't recall.

9 Q. Do you recall whether these  
10 conversations happened in 2016 or 2017?

11 A. They happened in 2017.

12 Q. Did you meet Mr. Liu at the Apotex  
13 trial?

14 A. Not to my recollection.

15 Q. Have you ever met Mr. Liu?

16 A. I don't recall meeting him.

17 Q. Have you ever met anyone else at  
18 Argentum?

19 A. No, not that I recall.

20 Q. Have you ever communicated with anyone  
21 else at Argentum?

22 A. Outside of if they were copied on an

1 email.

2 Q. Did anyone from Argentum or Argentum's  
3 counsel tell you they were going to speak with  
4 someone from Apotex?

5 A. I don't recall that.

6 Q. Do you know what steps Mr. Warner took  
7 or you took to confirm it was not a conflict for  
8 you to represent Argentum in this IPR?

9 A. Again, the steps I took was to call  
10 the counsel I had worked with in representing  
11 Apotex. I don't know what steps they took to  
12 confirm that I was not in conflict.

13 Q. Do you recall how long the timeframe  
14 was between the first and second conversation?

15 A. It wasn't long, probably less than a  
16 week, but I don't remember the number of days or  
17 hours.

18 Q. Who is your agreement -- strike that.

19 You said you had an agreement that  
20 covers your representation -- strike that.

21 You said you have an agreement that  
22 covers your engagement in this IPR; is that

1 correct?

2 A. Yes.

3 Q. Who is that with?

4 A. Again, that's with Argentum.

5 Q. Is it directly with Argentum?

6 A. Yes, it is.

7 Q. Do you know who signed that agreement?

8 A. Again, I don't recall, but I think it  
9 was Mr. Liu or Dr. Liu, but I don't recall if  
10 there's other signatures or if I'm mistaken on who  
11 actually signed it.

12 Q. Do you have a copy of that agreement?

13 A. I do.

14 Q. I'm going to hand to you your  
15 declaration which is Exhibit 1004. (Document  
16 tendered to the witness.)

17 Is this your declaration,  
18 Dr. Donovan?

19 A. Yes, it is.

20 Q. Did you prepare this document?

21 A. I prepared it in collaboration with  
22 counsel, yes.

1           Q.    And you did your best to make sure it  
2    was truthful and accurate?

3           A.    Yes, I did.

4           Q.    On the last page that is your  
5    signature?

6           A.    Yes, it is.

7           Q.    And you signed it on February 2, 2017?

8           A.    Yes, I did.

9           Q.    So is it fair to say you spoke to  
10   Argentum and to Kevin Warner before February 2,  
11   2017?

12          A.    That's certainly my expectation.

13          Q.    Now that you've seen this, the date  
14   you signed, does it refresh your recollection on  
15   when you may have had the conversation with  
16   Mr. Warner?

17          A.    Not specifically, except it would have  
18   been before this.

19          Q.    Do you recall whether it was  
20   immediately after the trial in December 2016?

21          A.    It wasn't that close to after the  
22   trial, no.



1           Q.     Now, I'm going to ask you to turn to  
2     Paragraph 12 of your declaration. It is the  
3     paragraph under "Summary of Opinions."

4           A.     Okay.

5           Q.     In there the first sentence says  
6     "Based on my investigation and analysis and for  
7     the reasons set forth below, it is my opinion that  
8     Claims 1, 4 through 6, 24 through 26, and 29 of  
9     the '620 Patent would have been obvious to a  
10    person of ordinary skill in the art at the time of  
11    the alleged invention," and then you go on to cite  
12    some references; is that accurate?

13          A.     Yes.

14          Q.     What investigation and analysis did  
15    you take specifically for your declaration in the  
16    IPR?

17          A.     Again, for this declaration I was told  
18    that I should, that essentially effective --

19                 MR. HOUSTON: I'm going to caution the  
20    witness to not reveal the substance of  
21    communications with attorneys, please.

22                 THE WITNESS: Okay. That the

1 effective date of this was about 2002 and that I  
2 should evaluate or that I should understand the  
3 state of the art, what a POSA would know in 2002,  
4 and then evaluate and form my opinion about the  
5 specific claims of the '620 Patent.

6 BY MS. EVERETT:

7 Q. Did you undertake any additional  
8 investigation or analysis over and above what you  
9 had done for your expert opinion in the Apotex  
10 trial?

11 A. You know, I don't really recall what  
12 the overlap may have been. Certainly obviously  
13 there would have been overlap. There's a number  
14 of similar articles that I relied on for this.  
15 But, you know, I took on the appropriate amount of  
16 looking at previous, previous to 2002 materials,  
17 that were relevant to the claims in the '620  
18 Patent.

19 Q. Did you go back to the materials you  
20 had prepared for the Apotex case to prepare your  
21 materials for your opinion in this IPR?

22 A. I believe that most of those materials

1 are confidential. So no, I did not look at those.

2 Q. Including the opinions that you  
3 presented in open court?

4 A. I have seen those or I've seen a  
5 couple of versions of those again, but only what  
6 is available publicly or what was available as a  
7 part of this case. So I did not review anything  
8 that was submitted, anything that was used in the  
9 prior case.

10 Q. So I just want to make sure we're on  
11 the same page. When you say I've seen those and  
12 I've seen a couple versions of those, what are you  
13 referring to?

14 A. I've seen -- and I don't recall  
15 exactly which of my reports were provided to me by  
16 current counsel in this matter, but I have  
17 reviewed at least two of the reports that were  
18 filed in the previous matter as part of this  
19 matter because they were provided to me by current  
20 counsel.

21 Q. So I just want to make sure I  
22 understand. So in the Apotex IPR you submitted --

1 A. In the Apotex IPR?

2 Q. In the Apotex litigation. Excuse me.

3 A. Okay.

4 Q. In the Apotex litigation you submitted  
5 expert reports.

6 A. Yes, I remember submitting expert  
7 reports.

8 Q. You submitted I think three rounds of  
9 expert reports. And are you saying that counsel  
10 for Argentum provided you those, at least some of  
11 the expert reports you prepared in Apotex, to  
12 prepare your opinion for the Argentum IPR?

13 A. Not to prepare my opinion, no. I've  
14 seen them in preparation for this deposition, but  
15 I did not refer to those in the preparation of my  
16 declaration.

17 Q. And you were provided your expert  
18 reports by counsel for Argentum?

19 A. That's who they arrived from, yes.

20 Q. Do you know how counsel for Argentum  
21 had copies of your expert reports from the Apotex  
22 case?

1           A.    I believe in --

2                   THE WITNESS:   Is that privileged?

3                   MR. HOUSTON:   Well, if it's something  
4   that you learned, that we told you.  I think you  
5   can answer that question if you know.

6                   THE WITNESS:   Okay.  I think in  
7   conversation I learned that you had, or whomever  
8   you're representing, had filed them with the court  
9   in this IPR matter and then they were able to be  
10  provided to me.

11  BY MS. EVERETT:

12                  Q.    Did you in connection with your IPR  
13  declaration search for any additional prior art?

14                  A.    I know that I looked at some standard  
15  textbooks and I probably read some additional art  
16  or some new art that I had not been as familiar  
17  with as part of the preparation for this.

18                  Q.    And so I just want to -- one point you  
19  made earlier about some of these information being  
20  confidential.  You also testified at trial; is  
21  that correct?

22                  A.    Yes.

1 Q. And you know you testified publicly at  
2 trial?

3 A. Yes.

4 Q. And that the information that you  
5 provided or any witness provided at trial was  
6 public.

7 A. Correct.

8 Q. Are you aware of that?

9 A. Uh-huh.

10 Q. Did you refer back to your trial  
11 testimony or the testimony of anyone else in the  
12 Apotex trial in preparation for your declaration  
13 for the IPR?

14 A. No, I did not.

15 Q. A moment ago you testified that you  
16 looked at some standard textbooks and you probably  
17 read some additional art.

18 Did you search for that art or was  
19 that provided to you?

20 A. I don't recall. I think it's probably  
21 a combination.

22 Q. What type of art did you search for?

1           A.     Again, my search is, when I start, is  
2     typically in the realm of texts or treatises that  
3     were published around the time of the effective  
4     date or prior to that to understand what had been  
5     written as sort of general instructions to  
6     formulators regarding particular formulations or  
7     substances.

8                     I may have looked to become -- may  
9     have looked at physical properties of the  
10    compounds that were being described in various  
11    pieces of the art.

12           Q.     Anything else?

13           A.     That's all I can recall.

14           Q.     I'm going to have you turn to  
15    Paragraph 20 of your declaration. You can just  
16    take a moment to read that, and I have a few  
17    questions for you.

18           A.     Okay.

19           Q.     At the bottom of page -- sorry. Tell  
20    me when you're ready.

21           A.     That's fine, that's fine.

22           Q.     At the bottom of Page 7, and this

1 would be your numbers, I know there's two sets of  
2 numbers, but your numbers, there's a sentence  
3 "Nasal sprays contain a solution and/or a  
4 suspension of the active ingredient in a vehicle  
5 which may include a mixture of excipients such as  
6 preservatives, buffers, emulsifiers, solubilizing  
7 agents, viscosity modifiers, humectants, and  
8 others."

9 A. That's what it says.

10 Q. Every nasal spray does not necessarily  
11 contain each one of these excipients you listed;  
12 is that accurate?

13 A. That's accurate. Every nasal spray is  
14 probably, has some components that are listed but  
15 doesn't necessarily have all of the components  
16 that are listed.

17 Q. So a formulator would have to make a  
18 decision and a choice of what to include or what  
19 not to include?

20 A. Typically, yes.

21 Q. And they would do that because they  
22 are aiming for sort of an end product and they



1 would want a spray that achieves certain  
2 characteristics?

3 A. Well, formulators have multiple goals  
4 for why they might combine materials to prepare a  
5 formulation. So depending on what those goals are  
6 drives often times what's included in that  
7 formulation.

8 Q. Then your next sentence says "A nasal  
9 spray must be formulated so that" and then you  
10 have three characteristics and I want to take each  
11 of them one by one.

12 The first one is "the spray pump  
13 can reliably deliver the same amount of active  
14 ingredients with each actuation."

15 A. That's what it says, yes.

16 Q. And why is that important?

17 A. Because the dose that's administered  
18 is a reflection of the formulation and the device  
19 that it's contained in. And so we rely on the  
20 device to be able to reproducibly emit a  
21 particular volume so that we know that the dose  
22 being emitted is the dose that was designed in the

1 formulation to be administered.

2 Q. And the formulation itself could  
3 effect the amount of active ingredient that's  
4 delivered to each actuation; is that correct?

5 A. Can you reask that, please?

6 Q. Sure. Are there certain properties of  
7 the formulation that could affect whether  
8 the -- strike that.

9 So is it fair to say -- to give  
10 point 1 a shorthand we can call that dose  
11 uniformity?

12 A. It certainly is a component of dose  
13 uniformity, yes.

14 Q. So for dose uniformity, a moment ago  
15 you were talking about the spray, the qualities of  
16 the device. Do you recall that?

17 A. I mentioned something about the device  
18 and the formulation acting together to determine  
19 the dose, yes.

20 Q. And the formulation could potentially  
21 on its own affect whether the dose is uniform; is  
22 that accurate?

1           A.    Well, again, it's the combination of  
2   the formulation and the device that's emitting  
3   that formulation that determine the dose that's  
4   emitted.

5           Q.    Right.  So the device is because the  
6   dose is administered through the device, is  
7   that --

8           A.    Yes.

9           Q.    Okay.  But the formulation itself has  
10  to have some sort of uniformity before it is  
11  sprayed through the device; is that accurate?

12          A.    I'm not sure that that's accurate in  
13  all cases, but it depends on the device design.

14          Q.    What do you mean "it depends on the  
15  device design"?

16          A.    There are likely devices that are  
17  designed to do things with whatever is intended to  
18  be sprayed such that they have some influence on  
19  the uniformity or combination or something, but  
20  there are more technically developed devices that  
21  do a number of things that perhaps the simplistic  
22  devices that we're most familiar with as consumers

1 don't necessarily do.

2 Q. You are opining on the '620 Patent; is  
3 that correct?

4 A. For this declaration, yes, I am  
5 opining on the '620 Patent.

6 Q. And that's a formulation patent?

7 A. I don't usually participate in  
8 qualifying a patent using adjectives. That's out  
9 of my realm.

10 Q. You didn't opine on or see any claims  
11 directed to a device?

12 A. I guess I'd have to take a look at the  
13 '620 Patent to determine that.

14 Q. Actually, I'm going to have you look  
15 back to your own declaration, Page 6, where you  
16 describe the '620 Patent.

17 A. Okay.

18 Q. You can tell me when you've had a  
19 chance to review.

20 A. All right.

21 Q. Does this refresh your recollection  
22 that the '620 Patent is about a pharmaceutical

1 formulation?

2 A. Not specifically. I would still like  
3 to take a look at the '620 Patent and then have  
4 you help me understand what you mean by  
5 formulation patent.

6 Q. Do you see Paragraph 18 where you say  
7 "a pharmaceutical formulation comprising"?

8 A. Well, that's a repetition of Claim 1.  
9 But I think there are more than one claims in the  
10 '620 Patent.

11 Q. You don't talk about devices anywhere  
12 in your description of the '620 Patent; do you?

13 A. In Paragraphs 18 and 19, no.

14 Q. 16 through -- strike that.

15 A. Or 16 through 19, no.

16 Q. In your entire section in your  
17 description of the '620 Patent, you don't talk  
18 about a device; do you?

19 A. I don't point out anything specific  
20 about devices in Paragraphs 16 through 19.

21 Q. So I'd like to go back to 20 and focus  
22 on formulation, the effects of formulation.

1 A. So Paragraph 20? Page 20?

2 Q. Paragraph 20, where we were.

3 A. Okay.

4 Q. So for dose uniformity, there are a  
5 number of factors that affect whether the  
6 formulation is uniform; is that true?

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

9 THE WITNESS: Can you repeat the  
10 question, please?

11 BY MS. EVERETT:

12 Q. I'll rephrase it.

13 So in Section 1 we said for  
14 shorthand we can talk about dose uniformity.

15 A. Well, in Section 1 I think -- why  
16 don't you read back to me what I said about that  
17 last statement?

18 Q. Can you be more specific about what  
19 you would like read back?

20 A. I said something in response about  
21 dose uniformity when we were talking about point  
22 number 1 previously and I'd like to be reminded of

1     what I said.

2                     (The record was read back as  
3                     requested.)

4                     THE WITNESS: I said it was a  
5     complement of dose uniformity.

6     BY MS. EVERETT:

7                     Q. And you referred to the device and the  
8     formulation?

9                     A. Again, I need to be reminded about  
10    what the context of that conversation was 10  
11    questions ago.

12                    Q. Is it fair to say that when you are  
13    looking at Point 1, that part of that relates to  
14    the formulation itself?

15                    MR. HOUSTON: Objection, form.

16                    THE WITNESS: Well, the sentence that  
17    Point 1 is contained in says "a nasal spray must  
18    be formulated so that the spray pump can reliably  
19    deliver the same amount of active ingredients with  
20    each actuation." There is information about the  
21    spray being formulated and there is information  
22    about the pump, the spray pump.

1 BY MS. EVERETT:

2 Q. So what factors go into the nasal  
3 spray being formulated such that it can reliably  
4 deliver the same dose with each spray?

5 A. I don't recall that I was really asked  
6 to provide an opinion on formulation factors, the  
7 dose uniformity.

8 So just in keeping with that, I  
9 don't think I was asked to provide an opinion in  
10 this matter about that. But as a POSA formulator,  
11 if I were going to be concerned with dose  
12 uniformity of a nasal spray that was going to be  
13 emitted using a traditional simple spray pump  
14 device, there's a number of factors I'd consider.

15 I'd consider what the formulation  
16 was, what its components were, whether I needed  
17 the formulation to remain homogeneous during its  
18 use or during the shelf life or whether that  
19 homogeneity could be brought about shortly before  
20 spraying.

21 I'd need to know sort of what the  
22 goal of why I was formulating such a spray, what



1 the patient population was, a number of other  
2 things that would go into my determination of what  
3 the formulation would need to be able to be  
4 formulated so that the spray pump could reliable  
5 deliver the same amount of active ingredients with  
6 each actuation. So I'd even need to know perhaps  
7 which spray pump I was intending to use or what  
8 spray pumps were available to me to test.

9 Q. Thank you. I'm going to turn to the  
10 second point.

11 "The solution or mixture is shelf  
12 stable and avoids bacterial contamination."

13 A. That's what it says, yes.

14 Q. What is shelf stable?

15 A. Well, as a POSA formulator, often  
16 times the goal of a formulation, especially if  
17 you're doing product development, the goal is to  
18 have some reasonable storage lifetime of the  
19 mixture so that it can be manufactured and  
20 qualified and sent to a distributor and then  
21 provided to patients and they have some reasonable  
22 period of time over which they can use it, and all

1 of the materials in that formulation are still at  
2 the potencies that the formulation specifications  
3 state they will be and that the FDA approved them  
4 to be.

5 Same thing, bacterial  
6 contamination. These spray devices, if we're  
7 spraying them into noses, get exposed to areas of  
8 the body where there's a relatively high bacterial  
9 load, and we design formulations to minimize the  
10 ability of those bacteria to then essentially set  
11 up shop in the formulation and grow. So we  
12 minimize the amount of bacteria that can grow if  
13 there are bacteria that are potentially inoculated  
14 into the formulation upon use.

15 Q. Is it your belief that every nasal  
16 spray has to be shelf stable and avoid bacterial  
17 contamination?

18 A. That is not my belief, no.

19 Q. So when you say a nasal spray must be  
20 formulated that, 2., "the solution or mixture is  
21 shelf stable and avoids bacterial contamination,"  
22 does that only apply to certain nasal sprays?

1           A.    It applies to nasal sprays that are  
2   intended to be commercial products. But many  
3   times in my own research I may develop or begin  
4   formulation of a nasal spray that the shelf  
5   stability time is less than 24 hours and that's  
6   perfectly adequate for my goals. So I may or may  
7   not formulate that the same way as something that  
8   was intended to have a shelf life of 24 months.

9           Q.    I'd like to turn to Point 3. It says  
10  "is as comfortable as possible for the patient  
11  without compromising the therapeutic efficacy and  
12  safety of the nasal spray."

13          A.    That's what it says.

14          Q.    What does that mean?

15          A.    Well, it means, again, if patients are  
16  going to be using these formulations, that they  
17  should certainly not put the patient at an  
18  additional risk, that the patient should find them  
19  to be usable, that they won't refuse to use them  
20  because the treatment is worse than whatever  
21  you're trying to treat. And the important thing  
22  is that we retain the activity of the particular

1 therapeutic agent in the formulation so that when  
2 it's administered it works as intended.

3 Q. What factors go into whether a nasal  
4 spray is as comfortable as possible?

5 A. A lot of times those are actually  
6 human perception factors. So they can be things  
7 like temperature of the spray, they could be shape  
8 of the tip of the spray device. You know, how the  
9 spray device is actually designed and somebody  
10 holds onto it in their hand. It could be whether  
11 somebody is administering that spray to somebody  
12 else and whether that's able to be easily done.  
13 It could be how the spray feels or tastes or a  
14 number of other things that, again, are usually  
15 patient reports and we get a variety of patient  
16 reports about a variety of formulations.

17 Q. Could pH affect the comfort of nasal  
18 spray for patient?

19 A. It may affect comfort, yes.

20 Q. Would osmolality affect the comfort of  
21 the spray for a patient?

22 A. Individuals generally report a

1 mechanical stimulus when you spray something into  
2 their nostrils. So whether it's hypotonic,  
3 isotonic, or hypertonic, they report however they  
4 feel to communicate that spray went into their  
5 nose and whatever. It wasn't as comfortable as no  
6 spray in their nose at all. Something changed and  
7 they perceived that. But those reports happen for  
8 hypotonic vehicles, they happen for isotonic  
9 vehicles, they happen for hypertonic vehicles.

10 Q. Are there more incidents of patient  
11 complaints with hypertonic nasal sprays than  
12 isotonic nasal sprays?

13 A. I don't know if I'm aware of any  
14 direct evidence regarding that.

15 Q. So a moment ago you were referring to  
16 individuals generally reporting discomfort or  
17 perceived discomfort related to a spray going into  
18 their nose, whether it's hypertonic or isotonic.  
19 What reports were you referring to?

20 A. Often times when you look at the side  
21 effects of a label, there's a listing of things  
22 that people report as far as what was observed

1 during clinical trials. Frequently with nasal  
2 sprays there are reports of stinging or discomfort  
3 or, you know, it depends on what the questionnaire  
4 used as an adjective is what you get as a report.  
5 And a POSA reads those and understands that in  
6 many cases it's the result simply of a spray of  
7 any type entering the nose.

8 Q. So you're reading the side effects or  
9 the results of clinical trials as the basis of  
10 your statement?

11 A. Most of the basis of my statement is  
12 looking at the labels that describe the side  
13 effect profiles of a number of nasal spray  
14 products and noticing the similarity in patient  
15 reports regarding discomfort or whatever and then  
16 reflecting on what I know about those particular  
17 formulations. And I don't necessarily see a  
18 strong correlation to any specific attribute of  
19 the formulation that determines whether there's a  
20 report of stinging or discomfort.

21 Q. When you say you don't see a strong  
22 correlation of any specific attribute, have you

1 taken a formalized study to look at lists of  
2 attributes and then compare them to the label?

3 A. I have not.

4 Q. I'm going to go then to the last  
5 sentence of Paragraph 20. "Formulators routinely  
6 balance these objectives by employing well-known  
7 excipients having well-known functions to control  
8 solubility, settling for suspensions, pH,  
9 viscosity, osmolality, preservation, and user  
10 comfort"; is that fair?

11 A. That's what it says.

12 Q. When you say "using excipients having  
13 well-known functions to control solubility," what  
14 did you mean by that?

15 A. Well, if a formulator is intending to  
16 formulate a solution formulation, we want to be  
17 able to have a vehicle in which the concentration  
18 of the drug intended in that formulation is below  
19 its solubility limits so that it is indeed in  
20 solution.

21 If we aren't able to or if the  
22 desire is not necessarily to have a solution

1     formulation or if after some formulation  
2     investigations it's determined that we're likely  
3     not going to be able to have a vehicle where the  
4     intended dose is below its solubility limit in  
5     that composition, we may determine that  
6     formulating as a suspension is a reasonable  
7     alternative. And formulating as a suspension  
8     gives us a known amount of drug in solution and  
9     then a known remainder amount of drug that remains  
10    undissolved as solid.

11           Q.    Next you refer to that you would use  
12    excipients to control settling for suspensions.  
13    What's that?

14           A.    Well, in a suspension we certainly  
15    anticipate that there be a density difference  
16    between the solid and the vehicle. It may not  
17    always be the case but it's frequently the case.  
18    Which then means that as they sit under the forces  
19    of gravity, things will separate. And as a result  
20    we put excipients into a formulation to perhaps  
21    reduce that, slow the rate at which materials may  
22    separate or at least even if we allow them to



1     separate, that we can redisburse them prior to  
2     dosing.

3             Q.     Why do you want to prevent these  
4     things from separating?

5             A.     Well, if we return to the discussion  
6     about the interface between the spray pump and the  
7     formulation, we are intending to administer a  
8     known amount of drug per actuation. And with a  
9     traditional simple spray pump device, the  
10    formulation as it enters the spray chamber needs  
11    to be homogeneous and essentially equivalent for  
12    each spray. So we'd want to be able to reform a  
13    homogeneous suspension prior to spraying.

14            Q.     So if you had a formulation where you  
15    were not able to reform it into a homogeneous  
16    suspension and there was still settling, that  
17    would result in a lack of dose uniformity?

18            A.     Can you repeat that, please?

19            Q.     Sure. So if you had a formulation  
20    where you were not able to resuspend the  
21    suspension, so it was homogeneous, would that pose  
22    a problem with dose uniformity?

1 MR. HOUSTON: Objection, form.

2 THE WITNESS: Well, I think as a  
3 formulator, our goal is to develop a formulation  
4 that does resuspend. So we will use well-known  
5 excipients to accomplish that goal.

6 BY MS. EVERETT:

7 Q. And if you are not able to accomplish  
8 that goal, would that have problems with dose  
9 uniformity?

10 A. I don't know because, again, the  
11 actual dose uniformity of a nasal spray is a  
12 function of both the spray device and the  
13 formulation. And if for some strange reason a  
14 formulator was unable to develop a formulation  
15 that could reproduce the homogeneity necessary for  
16 a simple spray device, there is likely the  
17 opportunity to look at other devices that may be  
18 able to assist with that.

19 Q. So why did you say "if for some  
20 strange reason a formulator was unable to develop  
21 a formulation that could reproduce the homogeneity  
22 necessary for a simple spray device," what was

1 strange about that?

2 A. Well, because formulators know how to  
3 develop suspension formulations, and there are a  
4 number of excipients available to use to develop  
5 those for their particular suspension goals which  
6 frequently are being able to resuspend any settled  
7 material.

8 So given that there are a number of  
9 well-known excipients to use and methods for doing  
10 that, it's probably not the usual case that one  
11 couldn't develop a suspension that could reform  
12 into a homogeneous system that was able to be  
13 sprayed through some spray pump system.

14 Q. So in your opinion a person of  
15 ordinary skill would be able to make any  
16 suspension homogeneous and resuspendible?

17 A. I believe what I said was in the  
18 typical case there are a number of excipients,  
19 there are a number of product goals, there's a  
20 number of spray devices that one could evaluate  
21 and even outside of being a spray that, you know,  
22 formulators are trained to develop suspensions

1     that can be resuspended. I'm not saying that in  
2     every single possible case in history that a  
3     formulator has been able to do that, but in many  
4     cases formulators are able to do that.

5                     Now, they may not achieve their  
6     long-term product goals by doing that, but I do  
7     believe that there are enough well-known  
8     excipients and methodologies that could be brought  
9     to the problem that it's highly likely that a  
10    homogeneous suspension could be reformed. But  
11    there are a number of compromises probably that  
12    would have been made along the way. And upon  
13    evaluation of the likelihood of that being  
14    commercially viable or economical or whatever,  
15    they may have lost on those sides in the effort.

16            Q.    I'd like to turn back to Paragraph 20.  
17    The next one is pH.

18            A.    Oh, okay, all right. I lost my place.

19            Q.    Formulators routinely balance these  
20    objectives by employing well-known excipients  
21    having well-known functions to control, and then  
22    the next on the list is pH.

1 A. Okay.

2 Q. And that's because pH should be in a  
3 certain range for nasal sprays; is that accurate?

4 A. Well, formulators are aware of general  
5 treatises that suggest that the pH of a nasal  
6 formulation be within a particular range of units.  
7 And formulators are well aware that pH often times  
8 affects chemical stability of a formulation. So  
9 we are typically aware of and attentive to the pH  
10 of our formulations and evaluating whether that pH  
11 is both adequate for the formulation goals,  
12 because pH also affects solubility, and whether  
13 it's appropriate for users.

14 Q. A nasal spray can't be acidic, is that  
15 correct, if it's to be sprayed in the nose?

16 A. Pardon me?

17 Q. Would a nasal spray that's acidic say  
18 with a pH of 3, would that be suitable to spray in  
19 the nostrils?

20 A. It may be. Certainly there are plenty  
21 of commercial nasal sprays that are acidic  
22 available in the marketplace.

1           Q.    Are you aware of any treatments for  
2   allergic rhinitis where the nasal spray is acidic?

3           A.    I don't keep track of the specific pHs  
4   of specific products, especially by therapeutic  
5   class.  So I can't tell you sitting here whether  
6   that happens to be the case or not.

7           Q.    Would it be suitable to have a nasal  
8   spray for allergic rhinitis at a pH of 3?

9           A.    I don't know.  Maybe.  Depends on  
10   patient perception of that particular product and  
11   the product efficacy.

12          Q.    Next I'd like to turn to viscosity on  
13   your list.

14          A.    Okay.

15          Q.    Why is it important to control  
16   viscosity?

17          A.    Well, viscosity ends up being a factor  
18   that may affect a suspension and its settling  
19   rate.  So that would be one reason.

20                    There are formulation attempts to  
21   utilize the viscosity of the emitted spray as it  
22   interacts with the nasal mucosa to do something to

1 either effect the residence time or the absorption  
2 or something about the resulting effect of the  
3 formulation post administration.

4 So viscosity is addressed and often  
5 times folded into a product goal. And there are a  
6 variety of viscosities that would be appropriate  
7 for a variety of different product goals.

8 Q. So viscosity can be used, you said,  
9 one, it may factor into the suspension of the  
10 formulation I think is the first answer you said?

11 A. Yeah.

12 Q. And the second is viscosity can affect  
13 the time or the residence of the nasal spray in  
14 the mucosa?

15 A. I said there are individuals who have  
16 attempted to utilize viscosity to affect the  
17 residence time in the nasal cavity.

18 Q. Is there a distinction you're making  
19 when you say there are individuals who have  
20 attempted to do this versus the well-known  
21 properties of viscosity?

22 A. Well, those individuals have utilized

1 viscosity as an attempt when they're investigating  
2 or formulating a nasal spray to potentially change  
3 the residence time of the resulting formulation as  
4 it's administered to the nasal cavity to remain in  
5 the nasal cavity for a longer period of time  
6 and/or improve the absorption of the material or  
7 the activity of the material once it's been  
8 administered.

9 Q. And residence time in a nasal spray is  
10 one of the factors that's considered in developing  
11 a nasal spray; is that right?

12 A. Well, a POSA understands that the  
13 residence time is very short in the nasal cavity.  
14 And because of that, often times, or may consider  
15 with a particular formulation and a particular set  
16 of goals for that active, to potentially lengthen  
17 the residence time, if possible, through changes  
18 in formulation.

19 Q. When you say the residence time is  
20 very short, how short?

21 A. Well, usually the clearance half times  
22 are reported somewhere in the range of 15 to 30



1 minutes.

2 Q. And you said the goal is to extend the  
3 residence time?

4 A. A goal may be to extend the residence  
5 time if it's believed or shown that administration  
6 would be improved by extending the residence time  
7 and having the formulation present on the nasal  
8 mucosal surface longer than 15 to 30 minutes, then  
9 there may be formulation attempts to try to effect  
10 that.

11 Q. And is it one of the goals of  
12 developing a nasal spray for allergic rhinitis to  
13 improve that residence time?

14 A. It depends on the particular agents I  
15 believe that are being used and their mechanisms  
16 of action, whether extending the residence time  
17 would be something that would be necessary or not.

18 Q. Would that have been necessary to  
19 extend the residence time in 2002 for a  
20 combination of azelastine and fluticasone?

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

1 THE WITNESS: I wasn't asked to opine  
2 on that, and I would need some additional  
3 information and some time to think about that  
4 particular question and my determination what a  
5 POSA in 2002 might consider.

6 BY MS. EVERETT:

7 Q. Next I'm going to turn back to your  
8 list. Osmolality. I believe we were discussing  
9 that a moment ago.

10 Why would somebody control  
11 osmolality?

12 A. Similar to pH, there's a number of  
13 guidances that formulators will look to that  
14 suggest particular aspects or ranges or osmolality  
15 for nasal formulations. So many times a  
16 formulator will try to utilize that knowledge to  
17 control the osmolality of the final formulation  
18 that they produced.

19 Q. Is there a suggestion that osmolality  
20 for a nasal spray for allergic rhinitis should be  
21 isotonic?

22 A. I'm not sure that I've ever seen that

1 phrase specifically detailed outside of sort of a  
2 casual direction.

3 Again, formulators understand that  
4 there are osmolality ranges that various treatises  
5 suggest are appropriate for nasal formulations.  
6 And they're also aware that there potentially can  
7 be excursions from those with a specific  
8 formulation, with specific formulation goals.

9 Q. And when you say "formulators  
10 understand that there are osmolality ranges for  
11 various treatises," most of those suggest an  
12 isotonic range for seasonal allergic rhinitis; is  
13 that fair?

14 MR. HOUSTON: Objection, form.

15 THE WITNESS: I can't speak to whether  
16 most of them. Depends on what treatises they are  
17 and how many you stack up against one another, but  
18 I'm not sure most is. And based on how a  
19 formulator would either interpret or value a  
20 particular treatise, I don't think I can agree to  
21 whether it's most or not.

22 BY MS. EVERETT:

1           Q.    Are there treatises that say a nasal  
2    spray should be isotonic if it's to be -- strike  
3    that.

4                    There are treatises that say nasal  
5    sprays, particularly those for daily use like  
6    seasonal allergic rhinitis, should be isotonic?

7           A.    I can't think of one that has that  
8    many specific details in a single statement. But  
9    if you show me one, there may be one.

10          Q.    Are there treatises that say nasal  
11    sprays should be isotonic?

12          A.    As general guidelines, many of the  
13    treatises that are that simplistic are not  
14    necessarily the most valuable treatises to a  
15    formulator. But yes, there are treatises that  
16    simply state they should be isotonic.

17          Q.    I'm going to return to your list.  
18    Preservation.

19          A.    Yes.

20          Q.    And I believe we spoke about that  
21    earlier, that you needed to be shelf -- you need  
22    the spray to be shelf stable and avoid bacteria.

1 Would that summarize the importance of  
2 preservation?

3 A. Well, it does under a product goal  
4 where that product is going to be used for a  
5 period of time and is going to be exposed to a  
6 region where it is likely to be contaminated by  
7 bacteria, that all of those would be factors that  
8 would be considered by a POSA.

9 Q. And then, finally, user comfort is the  
10 last point you had.

11 A. Uh-huh.

12 Q. I think you talked about that earlier.  
13 That's all the factors going into the user's  
14 comfort, perceived or otherwise, in using the  
15 spray?

16 A. Well, I think it's user's ability,  
17 desire, risk/benefit evaluation of any particular  
18 formulation and their decision to continue to use  
19 that formulation if it would be required that  
20 continued use is important for efficacy. There's  
21 lots of user variables that would fall under user  
22 comfort.

1           Q.    Now, at the beginning of the sentence  
2    you say "formulators routinely balance these  
3    objectives."

4           A.    Yes.

5           Q.    And that's because each factor has a  
6    potential to influence another factor; is that  
7    right?

8                   MR. HOUSTON:  Objection, form.

9                   THE WITNESS:  Multi-component systems  
10   are well known to have or to need to be evaluated  
11   as multi-component systems, that materials  
12   interact with one another and you may have to  
13   balance effects or make choices regarding the  
14   inclusion of particular materials in a  
15   multi-component system.

16   BY MS. EVERETT:

17           Q.    So as you make a choice or a decision  
18   to affect one component, you will affect another  
19   component in a multi-component system?

20           A.    You may.  They may remain perfectly  
21   independent from one another and totally  
22   unaffected by having an additional material or

1     they may interact. You know, it's how materials  
2     placed in the same environment interact with one  
3     another. A formulator understands that those are  
4     possibilities and often times designs a  
5     formulation procedure to evaluate those.

6             Q. And a formulator designs a procedure  
7     to evaluate the influence of a change in one  
8     component on other components because it is a  
9     distinct possibility that in a multi-component  
10    system a change in one will affect others?

11            A. So can you ask a direct question  
12    regarding that statement?

13            Q. Sure. You said a formulator designs a  
14    procedure to evaluate -- strike that.

15                    You said a formulator often times  
16    designs a procedure to evaluate the changes in a  
17    multi-component system.

18            A. They either may do that in a  
19    prospective manner or they may have a knowledge  
20    certainly that changes in materials may affect or  
21    there may be interactions, but they may choose not  
22    to investigate them until they actually observe

1     that changes actually are apparent.

2             Q.     But a formulator would understand that  
3     a change in one component could potentially affect  
4     other components in a multi-component system.

5             A.     Yes, a formulator would be aware of  
6     those.

7             Q.     And a formulator would need to --  
8     strike that.

9                     A formulator when formulating would  
10    potentially take that into account?

11            A.     Well, I guess what do you mean by  
12    potentially take it into account? If the  
13    formulator is aware of it, there's either  
14    intentionally ignoring it or taking it into  
15    account.

16            Q.     And you would say they at most would  
17    not intentionally ignore it. They would  
18    understand that this was a challenge of a  
19    multi-component system?

20            A.     It's just a known circumstance with  
21    multi-component systems that the components may  
22    interact with one another.



1                   That may be good, that may be by  
2    design, it may be bad, it may need to be overcome,  
3    it may not need to be overcome. There's a variety  
4    of situations with multi-component systems.

5                   MS. EVERETT: I think we've been going  
6    for over an hour, so if we can take a short break.

7                   THE WITNESS: Okay.

8                   MR. HOUSTON: That would be great.

9                   (A recess was taken.)

10   BY MS. EVERETT:

11                  Q. Welcome back, Dr. Donovan.

12                  A. Thanks.

13                  Q. I am now going to turn to a different  
14    section of your report. I'm going to have you  
15    turn to Paragraph 75.

16                  A. Okay.

17                  Q. In Paragraph 75 you say, "Lastly, an  
18    osmolality of 554 milliosmols per kilogram would  
19    not have prevented acceptance as a nasal spray  
20    because hypertonic intranasal drug solutions were  
21    FDA approved and in prior use prior to 2002 in  
22    addition to the fact that daily use of hypertonic

1 solutions as nasal wash is applied directly to the  
2 nasal mucosa was well known to manage the symptoms  
3 of inflamed sinuses."

4 A. That's what it says, yes.

5 Q. So the first part is an osmolality of  
6 554 milliosmols per kilogram, you were referring  
7 there to the testing results of the Cramer  
8 reference? And if you need to look around, that's  
9 fine.

10 A. I don't see anywhere in the  
11 declaration that it actually states where that  
12 value or what it's referring to. My prior  
13 recollection is it might have something to do with  
14 Cramer.

15 Q. Okay, that's fine. I just wanted to  
16 place this in context.

17 Your opinion is that that  
18 osmolality would not have prevented use of the  
19 nasal spray because there were other FDA-approved  
20 nasal sprays prior to 2002 that were hypertonic;  
21 is that correct?

22 A. That's correct.

1           Q.    And I believe you are in there  
2   referring to the Imitrex reference?

3           A.    That's usually the first reference  
4   that I cite regarding a high osmolality nasal  
5   formulation.

6           Q.    Are you aware of any other  
7   FDA-approved intranasal drugs -- strike that.

8                   Are you aware of any other  
9   FDA-approved intranasal drug solutions that were  
10  approved prior to 2002 that are hypertonic?

11          A.    I don't know, in the same way that I  
12  don't necessarily keep track of the pHs of each  
13  individual approved formulation, I don't know that  
14  the osmolality is actually given in the label for  
15  many of the approved formulations. So I have no  
16  way of knowing whether they're hypertonic or not.

17          Q.    But you at the time you prepared your  
18  declaration did not know of another FDA-approved  
19  intranasal drug as of 2002 that was hypertonic?

20          A.    I didn't look for that information  
21  because I knew of at least one.

22          Q.    And sitting here today, you do not

1 know of any others besides Imitrex that's an  
2 FDA-approved hypertonic intranasal drug solution?

3 A. I have no basis for that knowledge.

4 Q. So no additional FDA-approved products  
5 as of 2002 that are hypertonic and were for  
6 intranasal use?

7 A. I don't know the tonicity of most of  
8 the approved products; therefore, I do not know  
9 whether any of them are hypertonic, isotonic, or  
10 hypotonic.

11 Q. So you cite the Imitrex reference, and  
12 to make it easier I have it here. This has  
13 already been premarked as Exhibit 1046. And it's  
14 the label for Imitrex. (Document tendered to the  
15 witness.)

16 A. Continue.

17 Q. Imitrex is indicated for the treatment  
18 of migraine headaches; is that accurate?

19 A. Yes. That's what the Indications and  
20 Usage section initially starts out with an  
21 explanation.

22 Q. In the dosing a person taking Imitrex

1 would only take this upon establishment of a clear  
2 migraine?

3 MR. HOUSTON: Objection, form.

4 THE WITNESS: The FDA-approved  
5 indication is for acute treatment of migraine.

6 BY MS. EVERETT:

7 Q. And I'm looking at Page 1 for the  
8 Indications and Usage. In the box Indications and  
9 Usage it says "Use only if a clear diagnosis of  
10 migraine headache has been established."

11 A. Okay.

12 Q. So a person taking Imitrex would take  
13 this only for a migraine?

14 A. I think prescribers in general  
15 understand that the FDA has approved this for use  
16 in migraine. I'm not sure that I can extrapolate  
17 that to what every individual uses it for.

18 Q. Do you have any knowledge of how else  
19 prescribers may prescribe or users may use  
20 Imitrex?

21 A. Not directly, no.

22 Q. So FDA has approved Imitrex for use in

1       migraines.

2               A.     Yes.

3               Q.     And the dosage is that a dosage --  
4       there's a first dosage if you look at dosage  
5       administration.

6               A.     Uh-huh.

7               Q.     And a second dosage should only be  
8       considered if there's a response to the first  
9       dose.

10              A.     Okay.

11              Q.     And the dosage should be separated by  
12      at least two hours.

13              A.     Yes, that's what it says.

14              Q.     And is it your understanding that --  
15      strike that.

16                     Dr. Donovan, what is your  
17      understanding of how long a user of Imitrex would  
18      take this product?

19              A.     Do you mean for a single headache? Do  
20      you mean for their lifetime? What are you asking?

21              Q.     Let's start with a single headache.  
22      How often would a user of Imitrex take this

1 product?

2 A. I'm not sure, but likely for at least  
3 the amount of times and number of doses that are  
4 approved in the FDA indication.

5 Q. Is it your understanding that a person  
6 would take Imitrex for the same amount of time a  
7 person would take a treatment for seasonal  
8 allergic rhinitis?

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

11 THE WITNESS: I don't know that I have  
12 a good basis to make any comments regarding that.

13 BY MS. EVERETT:

14 Q. Did you compare or consider that in  
15 your opinion when relying on Imitrex?

16 A. I'll go back and refer to what I said  
17 about Imitrex in my opinion.

18 Well, in my declaration I don't  
19 really say anything about the frequency or length  
20 of time that someone might continue to use  
21 Imitrex. But I have additional information about  
22 an additional use of hypertonic formulations that

1 are used.

2 Q. Okay, that's fine.

3 A. But neither of those are actually  
4 directly reflective of however long somebody might  
5 use a treatment for allergic rhinitis.

6 Q. So let's stick with the Imitrex first.

7 In your opinion for Imitrex, you  
8 did not consider the frequency or length of time a  
9 user would take Imitrex; is that accurate?

10 A. The description in my declaration is  
11 stating that there are FDA-approved formulations  
12 that are hypertonic and that hypertonicity doesn't  
13 prevent acceptance of use of a nasal spray.

14 Q. Okay. So just to be clear, you do not  
15 consider the length in time and duration of use of  
16 Imitrex, that did not factor into your opinion?

17 MR. HOUSTON: Objection, asked and  
18 answered.

19 THE WITNESS: My opinion is regarding  
20 the osmolality of a nasal spray formulation and  
21 its acceptability and my opinion is as stated,  
22 that there are FDA approved hyper-osmotic nasal



1     spray formulations that are accepted for use, an  
2     acceptable use.

3     BY MS. EVERETT:

4             Q.     So, again, just to be clear, your  
5     opinion, you looked only at the osmolality of  
6     Imitrex. You did not consider the length and  
7     duration a person would take Imitrex?

8             MR. HOUSTON:   Objection, asked and  
9     answered.

10            MS. EVERETT:   Counsel, you're making  
11    this objection but she hasn't actually answered my  
12    question.

13            MR. HOUSTON:   You're asking the same  
14    question over and over again.

15            MS. EVERETT:   Well, "Yes" or a "No"  
16    have you considered length and duration?

17            THE WITNESS:   Okay. Repeat that  
18    question because it's clouded in what did I  
19    consider and a number of other things. Ask the  
20    question that you would like me to answer.

21     BY MS. EVERETT:

22             Q.     For your opinion and for your

1 declaration, you did not consider the length and  
2 duration a person would use Imitrex?

3 MR. HOUSTON: Objection, asked and  
4 answered.

5 THE WITNESS: In my evaluation of  
6 tonicity effects of formulations and their  
7 acceptability for use as nasal formulations, my  
8 opinions are based in knowledge of residence time  
9 in the nasal mucosa, reactions of the nasal mucosa  
10 to formulations that are placed there, and I  
11 typically don't need to consider any sort of  
12 length or long-term use issues outside of a  
13 formulation that may be, you know, intended to  
14 remain at the surface of the nasal mucosa for  
15 hours and hours of time.

16 BY MS. EVERETT:

17 Q. So in 75 you also refer to a daily use  
18 of hypertonic solutions as nasal wash is applied  
19 directly to the nasal mucosa. Do you see that?

20 A. Yeah, there's discussion regarding  
21 that in the sentence that starts "In addition,  
22 daily use of hypertonic saline solutions."

1 Q. And in that I think you are referring  
2 to, if you go to Page 34 --

3 A. I'm on Page 34.

4 Q. You have, again, daily use of  
5 hypertonic saline solutions.

6 A. Yes.

7 Q. And in that you cited Exhibit 1048 and  
8 1049?

9 A. I think it's primarily 1048.

10 Q. I'm going to first hand you a copy of  
11 Exhibit 1049. (Document tendered to the witness.)

12 A. Okay.

13 Q. Now, which part -- strike that.

14 For your opinion on the daily use  
15 of hypertonic saline solution, you've cited two  
16 references, 1048 and 1049.

17 This is 1049; is that correct?

18 A. It is.

19 Q. Which part of 1049 are you relying on  
20 for your opinion?

21 A. Actually, I don't really see or recall  
22 anything in 1049. So I think I was just a bit

1 overenthusiastic during the finalization of my  
2 declaration and misnumbered some, that particular  
3 cite. So it's primary 1048 that I'm relying on  
4 for that statement.

5 Q. Okay. So you said you misnumbered  
6 1049. Should it have been something else or is  
7 this inadvertently included?

8 A. No, I think it's just inadvertently  
9 included, yes.

10 Q. Okay. I'm going to hand you 1048.  
11 (Document tendered to the witness.)

12 A. Okay.

13 Q. So this is the document you are  
14 relying on when you reference daily use of  
15 hypertonic saline solution.

16 A. Yes.

17 Q. When did you become aware of this  
18 reference?

19 A. During the course of working on my  
20 declaration for this IPR.

21 Q. Did you search and locate this  
22 reference?

1           A.    No.  I believe that the reference was  
2   identified for me to look at.

3           Q.    Were you familiar with the practice  
4   of -- strike that.

5                        So Exhibit 1048 details a study on  
6   the effects of daily hypertonic saline nasal  
7   irrigation among patients with sinusitis; is that  
8   accurate?

9           A.    By its title.

10          Q.    Were you aware of daily hypertonic  
11   saline nasal irrigation practices before you  
12   received this article?

13          A.    In general, yes, I'm aware of a number  
14   of practices with saline solutions for a number of  
15   respiratory conditions.

16          Q.    So the article identifies this as  
17   hypertonic saline?

18          A.    Uh-huh.

19          Q.    Has the osmolality been identified in  
20   this article?

21          A.    I believe the article describes the  
22   materials used, and from that you can draw some

1 conclusions about osmolality. I'm trying to find  
2 that.

3 Okay. So on Page 1050, right-hand  
4 column in the section on Intervention, it  
5 describes using a solution containing 2 percent  
6 saline buffered with baking soda or a heaping  
7 teaspoon of canning salt, a half teaspoon of  
8 baking soda and a pint of tap water. And at least  
9 knowing the amount of canning salt, being able to  
10 do a few measurements with canning salt or just  
11 believing that it's 2 percent saline with a  
12 buffer, I can at least approximate what a minimum  
13 tonicity would be for that solution.

14 Q. What is that?

15 A. What is it?

16 Q. Yes.

17 A. Based in 2 percent saline, it's  
18 probably on the order of at least 600 milliosmols.

19 Q. Did you do any tests to confirm this?

20 A. I did not, no.

21 Q. Have you performed any calculations  
22 before today on this?

1           A.    I, again, read it, approximated in my  
2    head.  I was certainly willing to believe it was  
3    hypertonic as stated in the title and didn't feel  
4    any need to actually calculate the value of  
5    tonicity since I can only calculate a likely  
6    minimum value.

7           Q.    What is nasal irrigation?

8           A.    It's an administration where a volume  
9    larger than the volume intended to remain on the  
10   nasal mucosa is placed into the nasal cavity and  
11   the intention is that a fraction of that volume  
12   will be relatively rapidly eliminated from the  
13   nasal cavity.

14          Q.    Is the purpose of the nasal irrigation  
15   actually to eliminate not only what the  
16   sinu-cleanse that goes through the nose but also  
17   debris and other mucus and other irritants in the  
18   nose?

19               MR. HOUSTON:  Objection, beyond the  
20   scope.

21               THE WITNESS:  Well, as described in  
22   this second paragraph of the article, so after

1 keywords in the abstract version, "hypertonic  
2 nasal irrigation is a therapy that flushes the  
3 nasal cavity with saline solution, facilitating a  
4 wash of the structures within." So it's washing,  
5 it's washing the structures.

6 And later in that paragraph it  
7 describes observations that it improves mucus  
8 clearance, and there's a reference for that, thins  
9 the mucus, there are references to that. And may  
10 decrease inflammation, and there's a reference to  
11 that, those statements.

12 Q. So the irrigation is a wash, as you  
13 read.

14 A. Uh-huh.

15 Q. So the solution goes through the nasal  
16 cavities. It's not intended to stay there.

17 A. Well, it certainly would be well  
18 recognized that some fraction of the solution  
19 would stay on the surface of the nasal mucosa for  
20 a period of time.

21 Q. But that's not its purpose; right?

22 A. It is what it is. Some fraction of



1     that wash will remain on the surface of the nasal  
2     mucosa.

3             Q.     Again, but that's not the purpose.  
4     I'm asking about the purpose of a wash.

5             A.     Well, the purpose of a wash, again, is  
6     to put in a large volume, relatively large volume,  
7     compared to the amount that can be retained on the  
8     surface and have that excess volume administered.

9                     There may be other situations where  
10    in a wash it's actually intentional that the  
11    residual amount that remains on the surface of the  
12    nasal cavity is there to have a continued role.

13            Q.     What is the purpose of the nasal wash  
14    in this article, 1048?

15            A.     It's facilitating a wash of the  
16    structures within and potentially having some of  
17    the additional potential efficacy effects  
18    described at the lower part of that paragraph that  
19    I read off previously.

20            Q.     Have you ever designed a solution for  
21    a nasal wash?

22            A.     No, I have not.

1           Q.    Have you ever participated in an  
2    irrigation study?

3           A.    No, I have not.

4           Q.    Irrigation, as we talked about, is a  
5    wash.

6           A.    Uh-huh.

7           Q.    You have opined on a nasal spray; is  
8    that accurate?

9           A.    I've opined on nasal formulations and  
10   formulations able to be administered to the nasal  
11   cavity, and nasal sprays are certainly one of  
12   those types of administrations.

13          Q.    And a nasal spray and an irrigation  
14   have different purposes; is that accurate?

15               MR. HOUSTON:  Objection, form.

16               THE WITNESS:  I don't know that I'd  
17   agree in all cases that that's accurate.

18   BY MS. EVERETT:

19          Q.    The delivery of the active ingredient  
20   to the nasal mucosa differs in an irrigation from  
21   a nasal spray; is that accurate?

22          A.    Again, I don't think I agree with

1     that.

2             Q.     So you think they're delivered in the  
3     same manner?

4             A.     Well, physically they're not delivered  
5     in the same manner, no.

6             Q.     So an irrigation is a wash, we  
7     discussed --

8             A.     Well, an irrigation because of its  
9     large volume washes the structures, washes over  
10    the structures, is in contact with the structures  
11    in the nasal cavity.

12            Q.     And a nasal spray is designed to  
13    deliver medication to the nasal mucosa and reside  
14    there for some period of time; is that accurate?

15            A.     That's the goal of a nasal spray.  
16    It's not always accomplished.

17            Q.     Is that accomplished in  
18    Dymista -- strike that.

19                    You're familiar with Dymista?

20            A.     Yes, I am.

21            Q.     Okay. In Dymista does the nasal spray  
22    deliver medication to the nasal mucosa which

1     resides there for a period of time?

2             A.     I'd have to look at some evidence that  
3     might be able to tell me regarding how long it  
4     resides in which regions of the nasal mucosa. But  
5     I certainly understand that the intent of Dymista  
6     is to have the formulation administered to the  
7     nasal mucosa.

8             Q.     Are you aware of how -- strike that.

9                     Are you aware of why this nasal  
10    irrigation is hypertonic?

11            A.     I'd have to reflect on that a little  
12    longer. I'm certainly aware of hypertonic saline  
13    being used, but I would need to look at some of  
14    the previous reports for what the investigators  
15    believed the advantage of hypertonicity was --

16            Q.     When you say "previous reports" --

17            A.     -- or whether there really was.

18            Q.     What are you referring to?

19            A.     Well, even as is stated early in the  
20    introduction, that it's flushing with some sort of  
21    saline solution, which was originally part of the  
22    yogic tradition, has been brought forward since

1     those times and adopted and adapted into other  
2     medical use. And I'm not familiar enough with  
3     studies regarding the tonicity and direct efficacy  
4     correlations to make a statement about those  
5     today.

6             Q.     Dr. Donovan, I'd like to turn back to  
7     your report. Go to Page 21. In here you provide  
8     an opinion on the use of EDTA, or that edetate  
9     disodium, benzalkonium chloride, and phenylethyl  
10    alcohol, using these three together.

11            A.     Oh, I'm sorry. I was on the wrong  
12    page. But now it is. Okay. So there's a section  
13    titled "Edetate disodium, benzalkonium chloride,  
14    and phenylethyl alcohol."

15            Q.     And, first, if you look at your  
16    opinion on Page 53, you refer to the Hettche  
17    reference.

18            A.     Yes.

19            Q.     As part of your basis that a person of  
20    ordinary skill would have used edetate disodium  
21    and benzalkonium chloride; is that accurate?

22            A.     Yes, that's what it says.

1           Q.    And you also later in the paragraph  
2   refer to the Flonase label for why a person of  
3   ordinary skill would have used benzalkonium  
4   chloride and phenylethyl alcohol.

5           A.    Yes.

6           Q.    And then I'd like to turn to Paragraph  
7   54.  You state that a person of ordinary skill  
8   would then consult the Handbook of Pharmaceutical  
9   Excipients on Paragraph 54?

10          A.    I said they would consider it,  
11   consider the Handbook of Pharmaceutical  
12   Excipients.

13          Q.    What's the difference between  
14   considering the handbook and consulting the  
15   handbook?

16          A.    Well, if the POSA were familiar enough  
17   with the monograph in the Handbook of  
18   Pharmaceutical Excipients, they wouldn't need to  
19   actually consult it.  But if they wanted to use  
20   that as a reference to remind themselves of some  
21   aspect of the characteristics of the material,  
22   they would consult that.

1           Q.     In which circumstances would a POSA  
2     after having selected excipients based on one set  
3     of references then go to the Handbook of  
4     Pharmaceutical Excipients for further  
5     consultation?

6           A.     When a POSA wants to be reminded of  
7     specific aspects or details of that particular  
8     material, they might use it simply to identify the  
9     brand name of one of the providers of that  
10    material, a whole number of other reasons.

11                     There's quite a bit of information  
12    in each monograph. And what a POSA would be  
13    looking for, referring to based on their likely  
14    general knowledge of the material, and what they  
15    needed to know specifically is, you know, what  
16    each POSA happens to need on any particular day or  
17    whether they felt the need to consult the handbook  
18    directly or just use the knowledge they knew was  
19    there.

20           Q.     Why did you say in Paragraph 54 that a  
21    formulator would turn from the labels to the  
22    Handbook of Pharmaceutical Excipients?

1 MR. HOUSTON: Objection, form.

2 THE WITNESS: Do I say that they would  
3 turn from the labels?

4 BY MS. EVERETT:

5 Q. You said "just as with the labels, a  
6 skilled formulator would have considered the  
7 Handbook of Pharmaceutical Excipients."

8 A. Right. And, again, the Handbook of  
9 Pharmaceutical Excipients contains more specific  
10 information on each of the excipients than the  
11 information provided in the label.

12 So if they would like to have a  
13 refresher of that specific information, if they're  
14 looking for a particular attribute of an  
15 excipient, the label is not the place to look for  
16 those details. The Handbook of Pharmaceutical  
17 Excipients is.

18 Q. So would a person of ordinary skill  
19 needed to have consulted the handbook to determine  
20 the characteristics and details of the excipient  
21 before deciding to select it?

22 A. They could if they so chose. It's



1 very dependent on the POSA's specific background  
2 and where they are in the formulation development  
3 process. I don't know that on every single  
4 formulation attempt with every single excipient  
5 that a POSA would look at the monograph and the  
6 Handbook of Pharmaceutical Excipients, but they  
7 know it's there and available and know what  
8 material it contains and when they would like to  
9 know additional specific information would not  
10 hesitate to look at the monograph and the Handbook  
11 of Pharmaceutical Excipients.

12 Q. So, Dr. Donovan, you understand for  
13 obviousness you need to assess obviousness from  
14 the point of a person of ordinary skill?

15 A. Uh-huh.

16 Q. So then in your view wouldn't the  
17 person of ordinary skill have gone to the Handbook  
18 of Pharmaceutical Excipients before selecting  
19 these, in this case these preservatives, for use  
20 in the azelastine fluticasone formulation?

21 A. Well, again, the definition or  
22 understanding I have of a legal description of a

1 person of ordinary skill in the art is someone who  
2 has all knowledge of everything in the, available  
3 prior to the effective date.

4           Mere mortals who may be one of a  
5 component of individuals who then would define  
6 that POSA likely don't have an immediate working  
7 knowledge of all things prior to the effective  
8 date. And, as a result, they choose to refresh  
9 their memories, get specific details that they  
10 have not committed to memory, from well known,  
11 understood, respected resource materials.

12           The Handbook of Pharmaceutical  
13 Excipients is exactly that. It's a monograph that  
14 describes physical properties of excipients, their  
15 safety, and potential toxicities as explained in  
16 that paragraph. And a POSA would go to that  
17 monograph, or those monographs, without hesitation  
18 if they desired that information.

19           Q. So you keep saying "without  
20 hesitation." Would they go? Not would they  
21 hesitate. Would they actively turn to the  
22 Handbook of Pharmaceutical Excipients before

1 selecting these preservatives?

2 A. A POSA with all knowledge would not  
3 need to because they have all knowledge  
4 immediately available to them.

5 An individual? I can't speak to  
6 what exact specific numerical values, names,  
7 chemical structures they have retained in their  
8 head and are accessible for use at any instant.

9 So in the legal definition of POSA,  
10 a POSA wouldn't, you know, there wouldn't be the  
11 need to refer to anything. They remember  
12 everything, they know everything, they have it all  
13 immediately available.

14 To justify what a POSA would know,  
15 we have put in selected reference resources that  
16 demonstrate that that's exactly what a POSA would  
17 know.

18 Q. The Handbook of Pharmaceutical  
19 Excipients contains a number of preservatives; is  
20 that correct?

21 A. The Handbook of Pharmaceutical  
22 Excipients contains monographs describing physical

1 properties of excipients, their safety, and  
2 potential toxicities.

3 Q. Does it contain preservatives beyond  
4 phenylethyl alcohol, benzalkonium chloride, and  
5 edetate disodium?

6 A. It contains monographs on a number of  
7 pharmaceutical excipients. So I could look at the  
8 table of contents or the index of the Handbook of  
9 Pharmaceutical Excipients, I may be able to  
10 identify other materials that may be used as  
11 preservatives.

12 Q. And when you say "may be used as  
13 preservatives," are you talking in the context of  
14 fluticasone propionate and azelastine or just  
15 generally?

16 A. I don't understand why it really  
17 matters, so I'm going to say both.

18 Q. Could any preservative that's listed  
19 in the Handbook of Pharmaceutical Excipients have  
20 been used in an azelastine hydrochloride  
21 fluticasone propionate combination?

22 MR. HOUSTON: Objection, beyond the

1 scope.

2 THE WITNESS: I haven't considered  
3 that for this declaration.

4 BY MS. EVERETT:

5 Q. Next I'd like to turn to Paragraph 56.  
6 And you identify glycerine as an obvious tonicity  
7 adjuster. Do you see that?

8 A. Yes, I did, uh-huh.

9 Q. The commercial embodiment of  
10 azelastine, Astelin, does not have glycerine; is  
11 that correct?

12 A. I guess I'd like to review that. So  
13 if you have a copy of the components of the  
14 commercial embodiment of azelastine as Astelin,  
15 I'd like to take a look and refresh my memory.

16 Q. I actually will get that for you on a  
17 break. I'm going to ask a different set of  
18 questions.

19 Why did you select glycerine?

20 A. As I said in the next sentence, that  
21 the Hettche reference discloses that glycerine is  
22 a preferable solvent and isotonization agent and

1       therefore it makes perfect sense to consider that  
2       as a tonicity adjuster.

3               Q.     And just so we're talking about the  
4       same, I'm going to hand you 1007, which is the  
5       Hettche reference. (Document tendered to the  
6       witness.)

7               A.     Okay.

8               Q.     The Hettche reference lists a number  
9       of isotonization agents; is that correct?

10              A.     Yes, it does.

11              Q.     But you've only identified glycerine.

12              A.     Well, I have brought attention to  
13       glycerine in my declaration, but a POSA  
14       understands that there's a -- I mean every  
15       material that dissolves in the aqueous solution  
16       could be considered an isotonization agent.

17              Q.     Does that mean it can be used in  
18       combination with azelastine and fluticasone?

19              A.     I'm just stating that any material  
20       that dissolves in the aqueous vehicle contributes  
21       to the tonicity of a formulation.

22              Q.     But there are certain agents that are

1 considered isotonicity adjusting agents?

2 A. There are certain agents that are  
3 commonly used as additional agents to add to  
4 adjust tonicity values, but every agent that's  
5 added into solution contributes to the tonicity.

6 Q. And Hettche discloses a number of  
7 agents that adjust tonicity values; is that  
8 correct?

9 A. Well, the paragraph I'm looking at,  
10 Column 4 starting with Line 31, simply states "in  
11 the case of dosage forms containing water it is  
12 optionally possible to use additional  
13 isotonization agents. Isotonization agents which  
14 may, for example, be used are saccharose, glucose,  
15 glycerine, sorbitol, 1 2-propylene glycol, and  
16 NaCl."

17 Q. But you did not identify or discuss  
18 any other agent besides glycerine in your report;  
19 correct?

20 A. I didn't highlight them in the report.  
21 But a POSA is well aware that there are many  
22 materials that will contribute to the tonicity.

1     There are some materials that frequently are used  
2     to adjust the tonicity and would have no  
3     difficulty selecting among materials to try in  
4     formulation optimization to use as a tonicity  
5     adjuster.

6             Q.     But you provided no reason a POSA  
7     would select glycerine over sodium chloride; is  
8     that correct?

9             A.     Well, again, I read the Hettche  
10    reference. The Hettche reference has a lot of  
11    information about azelastine and formulation of  
12    azelastine and tells me about two aspects of  
13    glycerine that I might find to be useful in a  
14    preliminary formulation, both that it can be used  
15    to adjust tonicity and that it's a preferred  
16    solvent. So it seems like a perfectly good place  
17    to start.

18            Q.     I'm going to actually hand you 1008,  
19    the PDR. (Document tendered to the witness.)

20                    If you go to Page 2, you can see  
21    the list of ingredients in Astelin nasal spray on  
22    the third column.



1 A. Okay.

2 Q. Glycerine does not appear in that  
3 list; is that correct?

4 A. No, it doesn't.

5 Q. And sodium chloride does appear in  
6 that list.

7 A. Yes, it does.

8 Q. And sodium chloride is an isotonicity  
9 adjusting agent?

10 A. As is citric acid or dibasic sodium  
11 phosphate.

12 Q. And you haven't provided a reason why  
13 a POSA would, looking at the -- strike that.

14 You haven't provided a reason a  
15 POSA would deviate from what's in the Astelin  
16 reference?

17 A. Actually, I think I did. I think  
18 there's a statement at the end of Paragraph 56  
19 that states "even though there are a number of  
20 tonicity adjusters to choose from, a skilled  
21 formulator would have considered glycerine because  
22 Hettche discloses its suitability for use with

1     azelastine formulations."

2             Q.     You provided no reason that a person  
3     of ordinary skill would deviate from what was in  
4     the commercial formulation of Astelin; is that  
5     right?

6             A.     A person of --

7             MR. HOUSTON:   Objection, asked and  
8     answered.

9             THE WITNESS:   A person of ordinary  
10    skill in the art is familiar with a number of  
11    excipients that can be utilized for a number of  
12    purposes and as they go through formulation  
13    development understand that they can select among  
14    those for a variety of reasons, whether it might  
15    be that they may serve a dual purpose in the  
16    formulation or, you know, there's many reasons why  
17    a POSA may select a particular excipient to begin  
18    with.

19            They also know that there are,  
20    again, other excipients that may actually perform  
21    the same function that they are free to select  
22    among if they determine that their original

1 selection didn't give the characteristics or is no  
2 longer available. There's a whole world of  
3 reasons why a formulator may decide to change  
4 among excipients during a formulation development  
5 process.

6 So a skilled formulator, again, as  
7 I stated, would have considered glycerine because  
8 Hettche directly discloses it and they know that  
9 they could select something else if the  
10 characteristics of glycerine in their formulation  
11 caused them to reconsider its use.

12 Q. You stated that a person of ordinary  
13 skill might consider other excipients if the ones  
14 don't perform the same function or if the original  
15 selection is no longer available; is that right?

16 A. I guess I'd like that read back  
17 exactly what I said.

18 (The record was read back as  
19 requested.)

20 THE WITNESS: I stand by that answer.  
21 Is there an additional question about that?

22 BY MS. EVERETT:

1           Q.    Yes.  I want to focus on the part of  
2    your answer where you said a formulator may change  
3    if they determine that the original selection  
4    didn't give the desired characteristics or are no  
5    longer available.

6           A.    What about that statement?

7           Q.    Are you aware whether sodium chloride  
8    gave or didn't give the desired characteristics in  
9    the azelastine fluticasone formulation?

10          A.    I don't have any recollection of or  
11   basis for knowledge of how sodium chloride may or  
12   may not have affected formulations containing  
13   azelastine.  So if you have information that a  
14   POSA would have considered in 2002, I could  
15   consider it.

16          Q.    Is sodium chloride -- strike that.

17                    To your knowledge, was sodium  
18   chloride available in 2002?

19          A.    Yes.  To my knowledge, sodium chloride  
20   as a pharmaceutical excipient was available in  
21   2002.

22          Q.    And in this case, Paragraph 56, you

1 did not have a person of ordinary skill consulting  
2 the handbook; is that accurate?

3 MR. HOUSTON: Objection, form.

4 THE WITNESS: And I think my statement  
5 in Paragraph 54 that we just finished describing  
6 describes general formulator activities regardless  
7 of which specific excipient is being considered,  
8 that a formulator would certainly consider and  
9 would be free to and would readily consider  
10 referring to the Handbook of Pharmaceutical  
11 Excipients as they are using any excipient or  
12 considering its use in a formulation that they are  
13 developing.

14 BY MS. EVERETT:

15 Q. But you didn't list the handbook in  
16 Paragraph 56 in your discussion of glycerine?

17 A. There's not a specific citation to the  
18 Handbook of Pharmaceutical Excipients in Paragraph  
19 56. But, again, a POSA formulator at any time  
20 dealing with any excipient would feel free to and  
21 would readily access the handbook for information  
22 about that excipient.

1           Q.    And there are other isotonicity  
2   adjusting agents in the handbook; is that correct?

3           A.    As I stated before, any material that  
4   dissolves in solution contributes to the tonicity  
5   of that solution.

6           Q.    So can any material that dissolves in  
7   solution that contributes to the tonicity be used  
8   as a tonicity adjusting agent in the azelastine  
9   fluticasone combination?

10          A.    It automatically changes the tonicity  
11   value. So it is by its own dissolution behavior  
12   adjusting the tonicity.

13          Q.    Could someone have -- but there are  
14   certain -- Dr. Donovan, we just talked about it.  
15   There are certain excipients that are used  
16   specifically for the purpose of adjusting  
17   tonicity; is that correct?

18          A.    There are materials that are commonly  
19   added that are there or that are materials that  
20   get added to additionally adjust the tonicity  
21   value. But, again, every single material that  
22   goes into solution in the vehicle contributes to

1 adjusting the tonicity.

2 Q. The Handbook of Pharmaceutical  
3 Excipients lists materials that are commonly used  
4 to adjust the tonicity.

5 A. Are you suggesting it has a list of  
6 materials with a title that says "Materials  
7 commonly used to adjust tonicity"?

8 Q. No. There's sections -- strike that.  
9 The Handbook of Pharmaceutical  
10 Excipients lists a range of excipients.

11 A. The Handbook of Pharmaceutical  
12 Excipients contains monographs that describe the  
13 properties of materials that are frequently used  
14 as excipients in pharmaceutical products.

15 Q. And some of those excipients that are  
16 contained in the handbook, the handbook describes  
17 their tonicity adjusting properties; is that  
18 accurate?

19 A. Maybe. You know, I'd like to take a  
20 look at the monographs and see exactly what those  
21 monographs say about their tonicity adjusting  
22 properties.

1           Q.    So you'd need to look at the handbook  
2   to --

3           A.    Well, you're asking me whether the  
4   handbook says something specific.  So I'd like to  
5   be able to refer to the handbook to make sure it  
6   says the specific thing you are indicating it  
7   says.

8           Q.    So would a person of ordinary skill  
9   turn to the handbook to look to determine  
10   glycerine's tonicity adjusting properties?

11          A.    I guess I'd like to refer to the  
12   monograph from the handbook regarding glycerine to  
13   see what it says about its tonicity adjusting  
14   capabilities to answer that question.

15          Q.    So you're not able to answer whether a  
16   person of ordinary skill would have turned to the  
17   handbook to select glycerine for its tonicity  
18   adjusting properties?

19          A.    Again, a person of ordinary skill in  
20   the art, the theoretical person, knows all of  
21   this.

22                   I, as an expert formulator, know to



1 tell in a declaration which monograph series,  
2 which references demonstrate what a POSA would  
3 know at the time. So I need to refer to those  
4 monographs I've identified to make sure that that  
5 is indeed a monograph or wherever for a specific  
6 piece of information that the POSA would already  
7 know whether it's there or whether it happens to  
8 be in a different source that also I have  
9 considered.

10 Q. You said a different source that  
11 you've also considered. What other source are you  
12 referring to?

13 A. There's information that is found in  
14 many sources. For example, if we look later in  
15 Hettche, same column actually, Column 4, Line 47  
16 and 48, Hettche starts to describe a composition  
17 that is also I think being described in Column 6  
18 as Example 1, where Hettche specifically includes  
19 the amount of glycerine added to that. And that  
20 amount of glycerine is in some ways contributing  
21 to the tonicity of that formulation.

22 A POSA could use even that

1 knowledge and that indication and that amount to  
2 help guide them in the selection of glycerine and  
3 in starting amounts of glycerine to utilize to  
4 adjust tonicity if they were using a similar or  
5 near similar approach in a formulation development  
6 scheme.

7 Q. So in addition to Hettche, were you  
8 referring to any other reference when you  
9 referenced these different sources?

10 A. Again, I looked at all of the sources  
11 that are indicated here. I suspect there's  
12 information in the Handbook of Pharmaceutical  
13 Excipients about glycerine and tonicity values  
14 that are achieved in glycerine water mixtures, but  
15 I cannot say that with absolute assuredness unless  
16 I'm able to look at the glycerine monograph from  
17 the Handbook of Pharmaceutical Excipients at this  
18 time.

19 Q. Did you look at it before you signed  
20 your declaration?

21 A. Yes, I did.

22 Q. But you didn't cite it in the

1 paragraph on glycerine?

2 A. Again, I didn't feel I needed to.  
3 Hettche describes glycerine. It describes it as a  
4 material that was both suitable for use with  
5 azelastine, that it was a preferred solvent, that  
6 it's a known agent to effect isotonicity.

7 I could have cited a number of  
8 references that describe that. But the Handbook  
9 of Pharmaceutical Excipients was in my list of  
10 things I considered as references. And, like I  
11 said, I would like to have the opportunity to  
12 refer to that just to make sure that my  
13 recollection is accurate. But I would anticipate  
14 that the Handbook of Pharmaceutical Excipients  
15 contains information about glycerine and  
16 concentrations of glycerine that achieve  
17 particular tonicity values.

18 Q. Next I'm going to have you turn to  
19 Paragraph 57, microcrystalline cellulose and  
20 sodium carboxymethyl cellulose?

21 MR. HOUSTON: Before you start that,  
22 Counsel, we've been going for a little over an

1 hour now. Would it be a good time for a break.

2 MS. EVERETT: Okay.

3 (A recess was taken.)

4 BY MS. EVERETT:

5 Q. Before we had the break, Dr. Donovan,  
6 I believe we were on Paragraph 57,  
7 microcrystalline cellulose and sodium  
8 carboxymethyl cellulose?

9 A. Uh-huh.

10 Q. And here you opined that a person of  
11 ordinary skill would look to combine these two  
12 references, and you suggested that they would look  
13 at the Flonase label, 1010, Paragraph 58?

14 A. What two preferences are you  
15 suggesting I suggest people combine?

16 Q. Strike that. I apologize. That's not  
17 what I meant.

18 You were suggesting that a person  
19 of ordinary skill would select microcrystalline  
20 cellulose and sodium carboxymethyl cellulose based  
21 on --

22 A. Paragraph 57 says they'd be motivated

1 to use MCC and CMC in combination or in the  
2 combination of fluticasone propionate azelastine  
3 in a nasal formulation, yes.

4 Q. And in Paragraph 58 you explain that  
5 the basis of that is the Flonase label.

6 A. Yes.

7 Q. Did you consult Hettche to determine  
8 whether there was -- strike that.

9 Microcrystalline cellulose and  
10 sodium carboxymethyl cellulose serve as a  
11 suspending agent in the azelastine fluticasone  
12 propionate combination; is that accurate?

13 A. That's probably one of the roles it  
14 serves, yes.

15 Q. Did you consult the Hettche reference  
16 to determine whether there would be a suspending  
17 agent a person of ordinary skill would have  
18 selected from that reference?

19 A. My recollection is Hettche describes  
20 agents as thickening agents and identifies at  
21 least carboxymethyl cellulose directly as a  
22 thickening agent, and a POSA would understand that

1 frequently thickening agents also act as  
2 suspending agents.

3 Q. Was there anything else that they  
4 would have consulted in Hettche to determine  
5 whether to select microcrystalline cellulose and  
6 sodium carboxymethyl cellulose?

7 MR. HOUSTON: Objection, form.

8 THE WITNESS: Is there something  
9 specific you want me to comment on the Hettche  
10 reference --

11 BY MS. EVERETT:

12 Q. Sure. I think you have it in front of  
13 you?

14 A. Yes.

15 Q. Terrific. Column 4, Line 51:  
16 "Moreover, it is possible to add thickening agents  
17 to the solution to prevent the solution from  
18 flowing out of the nose too quickly."

19 Then it goes on and it gives some  
20 examples, and in that it includes something like  
21 hydroxypropyl methyl cellulose, which I think goes  
22 by the shorthand HPMC.

1           A.    Yes.

2           Q.    You didn't explain why a person of  
3 ordinary skill wouldn't pick HPMC?

4           A.    Well, a person of ordinary skill is  
5 free to consider HPMC or carboxymethyl cellulose  
6 or other materials that fit the description above  
7 from the Hettche reference.

8                   I merely described in Paragraph 57  
9 and 58, especially using the Flonase label, that a  
10 person of ordinary skill would be motivated to use  
11 the same suspending agent that was present in  
12 Flonase because it has already been demonstrated  
13 to be an adequate suspending agent for fluticasone  
14 propionate.

15          Q.    And if you have in front of you the  
16 Astelin label, which is 1008, and in that you can  
17 see on the second page, third column, that Astelin  
18 uses hydroxypropyl methyl cellulose.

19          A.    It does, but Astelin is a solution  
20 dosage form and it is not using hydroxypropyl  
21 methyl cellulose as a suspending agent. It's  
22 using it as a thickening agent. And that's fine.

1 Hettche describes those materials as thickening  
2 agents.

3 Hydroxypropyl methyl cellulose  
4 would certainly be something that a POSA could  
5 consider in a formulation. But I, as a POSA  
6 formulator, when I was approaching formulating a  
7 material as a suspension, having information about  
8 a formulation already prepared of that material in  
9 suspension would at least start with the  
10 suspending agents that are present in the already  
11 formed or described suspension, or at least that  
12 would in many cases be my approach.

13 Q. And would a person of ordinary skill  
14 then have needed a reason to deviate from using  
15 the agent that is in the already formulated  
16 Flonase or Astelin?

17 A. Well, again, formulation is a process.  
18 That if, beginning with a combination of  
19 excipients or even beginning with the excipients  
20 one at a time, if those particular materials  
21 aren't meeting the formulation goals or they don't  
22 look like they're likely to meet the formulation



1 goals, POSAs select other excipients to use in  
2 their place to achieve the final compromised  
3 product that they're, you know, that they're  
4 intending to develop.

5 Q. Is it true that in other formulations  
6 HPMC has been used as a suspending agent?

7 A. Can you be more specific?

8 Q. Are you aware of any formulations  
9 where HPMC has been used as a suspending agent?

10 A. I haven't looked at other, the world  
11 of formulations containing HPMC and whether any of  
12 them contain HPMC. I strongly suspect it has, but  
13 I'd need to be able to do that search. I wasn't  
14 asked to do that and I don't have that specific  
15 piece of information at hand. But I think there's  
16 probably examples even in the materials that I  
17 considered, but I'd need to go back and look.

18 Q. Okay. Dr. Donovan, you never  
19 formulated azelastine for a nasal spray; is that  
20 correct?

21 A. I have not worked directly with  
22 azelastine to formulate it as a nasal spray, no.

1           Q.    Have you worked -- and you haven't  
2   worked with formulating fluticasone propionate in  
3   a nasal spray?

4           A.    I have not intentionally worked with  
5   fluticasone propionate to formulate as a nasal  
6   spray.

7           Q.    And when you say "intentionally," was  
8   there a different context?

9           A.    No.

10          Q.    And you are a formulator by trade?

11          A.    Yes, I am.

12          Q.    And so you don't treat patients?

13          A.    No, I don't.

14          Q.    Now I'm going to take you back to the  
15   Apotex litigation. And you recall there was a  
16   Cramer reference that was the subject of much  
17   discussion during that.

18          A.    I do recall that. And I also have the  
19   Cramer reference as a citation that I considered  
20   in my declaration. And if we're going to talk  
21   about Cramer, I would like to actually have a copy  
22   of Cramer in front of me, please.

1           Q.    I'm not going to talk to you about the  
2 details of Cramer. I'm just going to bring you  
3 back.

4                   Do you recall that both sides  
5 actually formulated versions of the examples  
6 disclosed in Cramer?

7           A.    I recall that there were details about  
8 formulations during the trial and that there were  
9 descriptions of compositions that were directed  
10 sort of by Cramer 3 during the trial, yes.

11           Q.    Okay. So do you recall reviewing some  
12 tests of Cramer 3 that were performed by your  
13 colleague, Dr. Govindarajan during the litigation?

14           A.    What I reviewed and didn't review I  
15 believe is privileged. But I think there are  
16 comments regarding how I saw information regarding  
17 what Dr. Govindarajan reported that are probably  
18 in the court transcript, and I'd be happy to talk  
19 about those comments.

20           Q.    And do you recall it was also the  
21 subject of your deposition?

22           A.    Yes.

1           Q.    And you opined on it in your expert  
2    reports?

3           A.    I believe I referred to those tests in  
4    my expert reports at times, yes.

5           Q.    But you chose not to discuss  
6    Dr. Govindarajan's tests in your IPR declaration?

7           A.    In the IPR declaration, as explained  
8    to me, this is a declaration regarding what a POSA  
9    would know at the time of or the effective time of  
10   the '620 Patent or patent application, and there  
11   is nothing about the Govindarajan report that  
12   would have been available to a POSA at that time.

13          Q.    You understand Dr. Govindarajan  
14    actually created or what he thought he created  
15    Example 3 of Cramer?

16          A.    You know, I don't exactly remember the  
17    specifics of what Dr. Govindarajan was told to do  
18    and what Dr. Govindarajan interpreted he was told  
19    to do. So I'd need to be reminded of that in  
20    order to agree to what you just said.

21          Q.    I'm going to hand to you what's been  
22    marked CIP2030, the expert report of Ramprakash

1 Govindarajan. (Document tendered to the witness.)

2 MR. HOUSTON: Counsel, is there a  
3 question pending?

4 MS. EVERETT: I think Dr. Donovan is  
5 refamiliarizing herself with Dr. Govindarajan's  
6 report. As soon as she is ready, I do have some  
7 questions.

8 MR. HOUSTON: Thank you.

9 THE WITNESS: What I am doing is  
10 reviewing the summary of work because we were  
11 discussing what Dr. Govindarajan did or was told  
12 to do. So I'll read that section, and then if we  
13 move on to other sections I may stop and read  
14 whatever sections are pertinent to that also.

15 MS. EVERETT: That's fair.

16 THE WITNESS: Okay. So I've read  
17 Section 2.

18 BY MS. EVERETT:

19 Q. And Dr. Govindarajan was instructed to  
20 recreate Cramer Example 3 as a person of ordinary  
21 skill.

22 A. I'd say that's a reasonable

1 generalized description of what he was instructed  
2 to do as described in Paragraph 7.

3 Q. And you were aware of his report  
4 obviously at the time you signed your declaration  
5 for the IPR; correct?

6 A. Yes, I was aware of the previous  
7 litigation, and I was aware that this report was  
8 part of that previous litigation.

9 Q. And you chose not to rely on that in  
10 this case?

11 A. Again, well, yeah, I work under the  
12 assumption that everything from previous cases is  
13 confidential. So I don't share my knowledge  
14 regarding things that I was privy to in a previous  
15 case in future cases.

16 When given that information and  
17 it's not confidential, then I am free to use it.  
18 Anything about the previous litigation was not  
19 necessarily part of information I brought to this,  
20 the declaration I've written. It's about a  
21 different matter. It's a different case. And  
22 information that was available to a POSA in 2002

1 is the information that I used to form my opinions  
2 regarding the '620 Patent.

3 Q. And just to be clear, when you say  
4 it's a different case, it's the same patent;  
5 correct? The '620 Patent was at issue in the  
6 Apotex trial.

7 A. I actually need to be refreshed on  
8 exactly which claims of which patents were part of  
9 the Apotex trial. There were multiple patents and  
10 I don't have any recollection of which ones were  
11 being disputed.

12 Q. So you have no recollection of -- I'll  
13 represent to you the '620 was part of the Apotex  
14 trial.

15 A. Okay. All of the claims? Some of the  
16 claims? I don't have any recollection on the  
17 specific claims that were at issue.

18 Q. Who decided not to include  
19 Dr. Govindarajan's testing in your declaration?

20 MR. HOUSTON: Objection, calls for  
21 privileged information.

22 MS. EVERETT: It's who. I'm not

1     saying why.

2                   MR. HOUSTON: But you said who decided  
3     and then you followed it with a long description  
4     of what the decision was about. That's clearly  
5     trying to get at privileged information.

6                   MS. EVERETT: Who decided not to  
7     include Dr. Govindarajan's testing in the  
8     declaration, that's not a long description.

9                   MR. HOUSTON: Objection, privileged.  
10    I instruct the witness not to answer.

11                  THE WITNESS: I've been instructed not  
12    to answer. I will not answer that question.

13                  MS. EVERETT: Counsel, I disagree.  
14    That is not privileged. If we were exchanging,  
15    say, privilege logs, you would have to identify  
16    the attorney giving the advice, the subject matter  
17    is Dr. Govindarajan's testing. Clearly your  
18    instruction is beyond the scope.

19                  MR. HOUSTON: Communications with an  
20    expert witness are not logged. That is an  
21    incorrect assessment of what would be logged on a  
22    privilege log.



1                   You're getting at who decided what  
2     about the decision making that went into this IPR  
3     petition. That is asking for privileged  
4     information.

5                   If the witness can add anything to  
6     this discussion that the witness is sure was not  
7     the result of communications with an attorney,  
8     then she is free to answer.

9                   MS. EVERETT: My point is not that  
10    expert communication is logged. My point is if  
11    you are going to make a claim of privilege, there  
12    is a basic threshold you need to make. And my  
13    question gets to the basic threshold of what is  
14    privileged: Who made that call.

15                  There is no way that the identity  
16    of the person deciding whether or not to include  
17    it is somehow under the veil of privileged and  
18    can't be discussed. It's a threshold issue.

19                  MR. HOUSTON: Counsel, I would  
20    respectfully disagree for the reason that if, for  
21    example, hypothetically the witness were to say  
22    Oh, the attorneys decided that, now you have

1 elicited from the witness a specific decision that  
2 was made by the attorneys regarding the content of  
3 an expert report.

4 That is clearly privileged/work  
5 product information. And, by the corollary, if  
6 you elicit from the witness that it wasn't an  
7 attorney, by the same token now you have  
8 identified what the attorneys didn't tell the  
9 witness.

10 MS. EVERETT: That's not privileged,  
11 Counsel. The privilege is why.

12 MR. HOUSTON: I respectfully disagree.

13 MS. EVERETT: The privilege is why and  
14 the basis of your decision, not who.

15 MR. HOUSTON: It's work product.

16 MS. EVERETT: Not who.

17 MR. HOUSTON: It's work product.

18 You've heard my objection. I further object that  
19 it's irrelevant.

20 BY MS. EVERETT:

21 Q. During the course of the Apotex  
22 litigation, Dr. Donovan, you opined on some

1 testing that plaintiffs put forward. Do you  
2 recall that?

3 A. I recall forming an opinion. If you  
4 could direct me to where in my expert reports  
5 those opinions are, I'd like to refer or I'd like  
6 to refresh my memory about them.

7 Q. Do you recall opining on testing from  
8 math that was performed by Matthew Herpin?

9 A. In general I recall having commentary  
10 about the testing that Dr. Herpin conducted in  
11 some form of a report, but I'd need to refresh my  
12 memory regarding that.

13 Q. Handing to you what's been marked as  
14 CIP2016. And you have a table of contents in your  
15 report. (Document tendered to the witness.)

16 A. Uh-huh.

17 Okay. So I've reviewed my report  
18 starting on Page 18, Section E that starts with  
19 descriptions about Dr. Herpin's study. And  
20 essentially my report is a commentary on  
21 Dr. Smithe's opinions regarding the Govindarajan  
22 report and regarding the testing done by

1 Dr. Herpin.

2 Q. And so you recall that Dr. Herpin  
3 tried to recreate Cramer Example 3; is that fair?

4 A. I recall that Dr. Herpin conducted  
5 some formulation or prepared some compositions and  
6 tested them and that those compositions had some  
7 relationship to the materials described in Example  
8 3 of Cramer.

9 But, you know, if I had Cramer's  
10 Example 3 and if I had all of the compositions  
11 that Dr. Herpin actually prepared, I could make a  
12 more definitive description of the relationships  
13 between those.

14 Q. So you don't recall what you were  
15 opining on here without further documents?

16 A. It's been a really long time since I  
17 thought about the various things that happened  
18 with Cramer 3. So I just don't have an immediate  
19 knowledge of all of the specifics of that  
20 activity.

21 Q. So I'm going to direct you to  
22 Paragraph 41 where it says Dr. Smithe opined that

1 EP0780127, Example 3 of Cramer, which discloses a  
2 combined aqueous suspension of an antihistamine  
3 and a steroid as inoperable. Dr. Smithe bases his  
4 opinion primarily on testing done by Dr. Matthew  
5 Herpin, a former graduate student of his, in his  
6 Dr. Herpin attempts to formulate Cramer's example  
7 using a variety of methods.

8 A. Yeah, that's exactly what it says.  
9 And that's why I said, I recall that Dr. Herpin  
10 formulated some compositions. I don't exactly  
11 remember the relationship of those compositions to  
12 Example 3 of Cramer or the specifics of Example 3  
13 of Cramer that were available for Dr. Herpin to  
14 use. And I would like to review those before I  
15 make further comments about the specific  
16 activities of Dr. Herpin.

17 Q. You wrote what's in Paragraph 41, this  
18 is your report?

19 A. It is.

20 Q. And so you were aware of Dr. Herpin's  
21 testing, whatever it may be, as of the date you  
22 signed your declaration in the IPR?

1           A.    I personally was aware of Dr. Herpin's  
2    work when I signed my declaration in the IPR. Yet  
3    my approach in signing the declaration of the IPR  
4    is I took on the visage of a POSA in 2002 and  
5    utilized the information that was available in  
6    2002 to form my opinions.

7           Q.    So that the reason you say you do not  
8    rely or reference Dr. Herpin's tests was because  
9    they were conducted after 2002, is that your  
10   opinion -- sorry. Is that the basis for not  
11   including that?

12          A.    Well, that's certainly part of it.  
13   But I was aware of Dr. Herpin's testing as part of  
14   a previous litigation.

15                   I no longer have access to those  
16   documents. I don't know who does have access to  
17   those. I don't have the expertise to know what is  
18   in the public domain and what is not. And so I  
19   was not privy, I was not even able to discuss  
20   Dr. Herpin's work with anybody besides myself in  
21   anything regarding the IPR for the '620 which  
22   requires an evaluation of what a POSA would know

1 in 2002 to draw their opinions.

2 Q. You are aware, again, that the Apotex  
3 trial occurred in a public courtroom?

4 A. Yes.

5 Q. And anyone in the public was able to  
6 attend?

7 A. Yes, except I think there was -- I  
8 don't remember whether -- I know of situations  
9 where the courtroom can be closed to the public.  
10 I don't recall any of those circumstances in the  
11 particular Apotex litigation.

12 Q. Now, I'd like to turn to other  
13 azelastine fluticasone formulations. You're aware  
14 that in India there are a number of azelastine  
15 fluticasone combinations on the market?

16 A. Only in the most general sense.

17 Q. Were you -- do you recall that these  
18 -- strike that.

19 Do you recall, we'll just call them  
20 copycats, if that's okay.

21 A. Okay.

22 Q. These copycats were presented at

1 trial?

2 A. I don't recall that they were  
3 discussed in my testimony. But if they were, you  
4 can point out where in the trial documents that  
5 that is.

6 And other individuals' testimonies?  
7 I wasn't present for all testimony, so I can't  
8 speak to everything that was presented at trial.

9 Q. Do you recall being made aware of  
10 copycats while you were giving your expert opinion  
11 during the litigation, pretrial?

12 A. I do recall being made aware that  
13 there were copycats in India, yes, in preparation  
14 for trial.

15 Q. And you were aware of them at the time  
16 you signed your declaration for the IPR?

17 A. My awareness was that there are other  
18 formulations of these drugs in other places of the  
19 world. I don't remember anything distinctly about  
20 any of them.

21 So their relevance to this IPR,  
22 when they came into the commercial marketplace,



1     whether they were patented in India, a whole bunch  
2     of other things, I don't have any specific  
3     awareness of any of them outside of there are some  
4     compositions that contain antihistamines and  
5     corticosteroids in other places of the world.

6             Q.     Are you familiar with the term  
7     "copying" as a consideration for -- strike that.

8                     Are you familiar with secondary  
9     considerations?

10            A.     I am certainly familiar with the  
11     terms. I need to be reminded of their meaning in  
12     most of the time when it becomes an important  
13     phrase in an expert report or a deposition or  
14     anything else.

15            Q.     And are you aware there are a number  
16     of factors called "secondary considerations" that  
17     must be consulted to determine whether an  
18     invention is obvious?

19            A.     I think I even spoke to that a bit in  
20     my declaration.

21            Q.     I think maybe if you go to Paragraph  
22     11.

1           A.    So as stated in Paragraph 11, yes, I  
2   do understand that in considering obviousness of  
3   an invention, one should also consider whether  
4   there are any secondary considerations that  
5   support the nonobviousness of the invention. But  
6   I offer no opinion on secondary considerations in  
7   my declaration.

8           Q.    Are you aware of copying as one of the  
9   secondary considerations?

10          A.    I really don't know because I can't  
11   recall whether that's actually been used as a  
12   term.

13                   When secondary considerations have  
14   been described to me, I kind of think it has, but  
15   I will -- if what you mean by copying -- well,  
16   yes, what we've already described as copying, I  
17   think I've been instructed that that's part of  
18   secondary considerations.

19          Q.    And so you were aware of the copycats  
20   at the time you signed your declaration?

21          A.    Again, I was aware of other  
22   formulations other places in the world that were

1 of similar composition. But I have no specific  
2 recollection of whether they were copies or  
3 whether they were, you know, had similar actives  
4 or not or concentrations. I just don't have any  
5 recollection enough to have me state that there  
6 absolutely were copies.

7 Q. And do you recall during the  
8 litigation Meda put forward some of its own  
9 development tests regarding some initial  
10 development on azelastine and fluticasone?

11 A. I can't say as I actually specifically  
12 remember that. Again, I wasn't present for the  
13 full trial, so I don't recall whether that may  
14 have been described during a portion of the trial  
15 I was not in attendance.

16 Q. Do you recall that testimony or those  
17 lab notebooks opining that during the course of  
18 the litigation and when you gave your expert  
19 opinion?

20 A. I recall seeing documents that were  
21 obtained I believe during some phase of discovery  
22 that were from Meda that described some of the

1 work that they had conducted at a relevant  
2 timeframe on potentially relevant materials. I  
3 understand that what I saw were confidential  
4 documents.

5 Q. And do you understand that those Meda  
6 trials were describes in open court?

7 A. Again, like I said, I was not present  
8 for the entire trial. So I don't necessarily  
9 actually recall being present when that was  
10 described. I may have been and I just don't  
11 recall it.

12 Q. You did not address Meda's tests in  
13 your declaration; fair?

14 A. In my declaration for the '620 IPR?

15 Q. Yes.

16 A. As I said before, my ability to see  
17 Meda's testing was part of expert discovery -- or  
18 it was some part of discovery in a different  
19 litigation. It was confidential. I don't have  
20 the opportunity to bring that information forward  
21 into any other litigation or evaluation or discuss  
22 that with anybody else outside of counsel who

1 provided it to me.

2 Q. Again, you are aware that it was  
3 discussed in court --

4 A. You're telling me it was discussed in  
5 court. I have said I'm not sure I was present  
6 when it was discussed in court. So I'm not sure I  
7 actually have an awareness it was discussed in  
8 court.

9 If it was discussed in court, it  
10 would have been part of the transcript and others  
11 would have the ability to see that information and  
12 to discuss it with me and I would be free to  
13 discuss the portions and things that are part of  
14 my knowledge that are relevant to the material  
15 that was discussed in court.

16 But until that's pointed out to me,  
17 I can't discuss information that was provided to  
18 me as confidential information in a different  
19 litigation.

20 Q. Were you present during the testimony  
21 of Alex Dadio?

22 A. What day did Alex Dadio testify?

1           Q.    I believe he testified right after you  
2   on Thursday, the 15th.

3           A.    I'm trying to remember which day I  
4   left.

5           Q.    It's Exhibit CIP2020.

6           A.    I suspect I was still in the courtroom  
7   for his testimony. I'm going to have to go back  
8   and read it because I don't have any direct  
9   recollection of what his testimony was about.

10          Q.    Are you able to recall whether you  
11   were in the courtroom?

12          A.    I think I was in the courtroom for  
13   this, yes.

14          Q.    Okay, great. I'm going to have you  
15   turn back to your declaration, Paragraph 68.

16          A.    Okay.

17          Q.    And here you are opining on a  
18   declaration submitted by Ms. Geena Malhotra.

19          A.    Uh-huh.

20          Q.    And there she's tried to replicate  
21   Example 3 of Cramer?

22          A.    I believe that's how she described it.

1 If you have her declaration, I would enjoy the  
2 opportunity to review it.

3 Q. This is the entire prosecution history  
4 which has been marked as 1002. I'll just note  
5 you've referenced Pages 284 through 287.  
6 (Document tendered to the witness.)

7 A. I've asked for this before. I would  
8 like a copy of Cramer so I can compare what is in  
9 this declaration to Cramer Example 3 as described  
10 in the declaration of Ms. Malhotra.

11 Q. And I'm actually not going to ask you  
12 questions about details of the experiment. I'm  
13 interested in your opinion.

14 Why did you opine on Ms. Malhotra's  
15 declaration?

16 MR. HOUSTON: Objection to the extent  
17 it calls for attorney-client privilege as to the  
18 reasons why.

19 Please don't reveal the content of  
20 attorney communications. If you can answer the  
21 question otherwise, you may do so. Objection,  
22 relevance.

1                   THE WITNESS: I don't really think I  
2     can answer the question about why I opined on this  
3     in the previous litigation, yet I can answer  
4     questions that being familiar with these documents  
5     and sitting here today and reviewing these  
6     documents I'm happy to answer questions about the  
7     information in the document.

8     BY MS. EVERETT:

9                   Q.     Sure. I didn't mean the previous  
10    Apotex litigation. My questions now are directed  
11    to this IPR.

12                  A.     Okay.

13                  Q.     Was Ms. Malhotra's test results and  
14    declarations available to a person of ordinary  
15    skill as of 2002?

16                  A.     It's my understanding that as part of  
17    the patent prosecution, that that in some manner  
18    is publicly available. But it's beyond me to know  
19    how to actually request the actual patent  
20    prosecution documents.

21                  Q.     I'm going to have you turn to Page  
22    287. It is a page with Ms. Malhotra's signature.



1 A. Okay.

2 Q. And it appears she signed August 12,  
3 2011. Do you see that?

4 A. Uh-huh.

5 Q. So it's fair to say Ms. Malhotra's  
6 declaration would not have been available to a  
7 person of ordinary skill in 2002?

8 A. Yes, that's true.

9 MS. EVERETT: Could we take just a  
10 quick break.

11 (A recess was taken.)

12 BY MS. EVERETT:

13 Q. Welcome back.

14 A. Thanks.

15 Q. I'm going to turn you back to your  
16 declaration, Page 2 and 3, where you list the  
17 documents you considered.

18 A. Okay.

19 Q. In addition to the documents that are  
20 listed in the table that spans Pages 2 and 3, and  
21 those are your numbers 2 and 3, are there any  
22 other documents you consulted to prepare your

1 declaration for this IPR?

2 A. Well, again, I used my general  
3 knowledge as a formulator very familiar with nasal  
4 formulations. And so there are, you know, it's  
5 just that knowledge is based in a lot of  
6 documents, none of which were specifically  
7 referred to in this report but certainly knowledge  
8 that came in as a result of my knowledge base.

9 Q. In connection with your preparation  
10 for your deposition today, in addition to the  
11 documents listed on Pages 2 and 3, what documents  
12 did you consult for your preparation for your  
13 deposition today?

14 A. I, again, was provided the court  
15 transcripts from the Apotex litigation for my  
16 testimony and a couple of expert reports of mine  
17 that were introduced as part of this IPR and I  
18 believe a couple of other expert reports that were  
19 also introduced as part of this IPR.

20 Q. Do you recall which other expert  
21 reports you reviewed in addition to your own?

22 A. I was provided Smithe's, one of Dr.

1 Smithe's reports; I think I was provided part of  
2 Dr. Herpin's but I don't recall that it had all of  
3 his testing details, but I was provided them very  
4 recently and didn't use them certainly in the  
5 preparation of this report but just used them  
6 briefly in preparation for today.

7 Q. Was there any other documents that you  
8 consulted besides what's listed in 2 and 3, your  
9 court transcripts, your own expert reports,  
10 Dr. Smithe's report and Dr. Herpin's report in  
11 preparation for your deposition today?

12 A. Nothing that I can recall right now.

13 Q. Have you consulted any other documents  
14 in connection with any other issue for the IPR,  
15 not just your declaration or your deposition, but  
16 in any way for this IPR?

17 A. Not that I can recall.

18 Q. We've had a couple breaks today.  
19 During the breaks have you spoken to counsel about  
20 the substance of your testimony?

21 A. No, I have not.

22 MS. EVERETT: Okay. I have no further

1 questions.

2 MR. HOUSTON: We'll take a short  
3 break. I want to consult with the witness to see  
4 if we have any Redirect.

5 (A recess was taken.)

6 EXAMINATION

7 BY MR. HOUSTON:

8 Q. Dr. Donovan, do you still have your  
9 declaration in front of you, Exhibit 1004?

10 A. It's right here on top.

11 Q. Could I ask you to turn to nearly the  
12 last page of that, Page 34, if you're looking at  
13 the big numbers there.

14 A. Uh-huh.

15 Q. Which is the second part of Paragraph  
16 75 that continues from the previous page.

17 A. Okay.

18 Q. Do you see a cite there in the third  
19 line from the bottom that says EX.1048,1049?

20 A. Yes.

21 Q. Do you recall that counsel in your  
22 Cross Examination asked you about the relevance of

1 Exhibit 1049 to this section of your testimony?

2 A. Yes.

3 Q. In your stack of papers there, could  
4 you also pull out Exhibit 1048, please.

5 A. Okay.

6 Q. Do you see that the front page number  
7 on Exhibit 1048, if we're looking at the journal  
8 article page numbers, is 1049?

9 A. I see that.

10 Q. Does that clarify for you whether or  
11 not you intend to cite Exhibits 1048 and 1049 in  
12 this Paragraph 75 of your declaration?

13 A. It does. And in that citation I am  
14 intending to describe Page 1049 of Exhibit 1048.

15 Q. Thank you.

16 Again, in your declaration could I  
17 ask you to turn to Paragraph 12. Do you see in  
18 Paragraph 12 you provide a summary of your opinion  
19 regarding the challenged claims there and whether  
20 or not they were obvious to one of ordinary skill  
21 in the art in view of the various references that  
22 you list there?

1           A.    Yes.

2           Q.    Do you recall during today's Cross  
3   Examination testimony that counsel has raised on a  
4   number of different occasions the testimony and  
5   evidence that was involved in the related  
6   litigation involving the '620 Patent, among  
7   others?

8           A.    Yes, I recall that.

9           Q.    At the time you signed your  
10   declaration, were you aware of any information  
11   from that trial or that proceeding in general,  
12   whether it was confidential or not, were you aware  
13   of any information from that proceeding that would  
14   change the opinions that you're expressing here in  
15   your declaration in this proceeding?

16          A.    No.   My recollection of all of those  
17   materials, confidential or not, would not change  
18   my opinion as written in Paragraph 12.

19          Q.    So you recall that counsel went  
20   through with you in at least some level of detail,  
21   maybe not the full detail, but some level of  
22   detail discussed with you Dr. Herpin's testing,

1 for example?

2 A. Yes.

3 Q. From the prior proceeding.

4 If you had been able to bring the  
5 details of that testing into this proceeding,  
6 would it have changed your opinion that you  
7 express here in Paragraph 12 and then further on  
8 in your declaration?

9 A. No. I recall that there were  
10 questions regarding the testing that Mr. Herpin  
11 conducted, and any of that testing does not change  
12 my opinion expressed in Paragraph 12 that the  
13 claims were obvious.

14 Q. I'd like to ask the same question  
15 about another topic that counsel asked you about  
16 from trial which was these alleged copycats that  
17 were being introduced in India.

18 Is there anything about those  
19 alleged copycats in India that if it had been  
20 brought into this proceeding it would change the  
21 opinions that you've expressed in your  
22 declaration?

1           A.    No.   Again, I don't have very many or  
2   intentionally don't have opinions on secondary  
3   considerations included and even knowledge of  
4   those copycats.

5                   My recollection even at the trial  
6   is that it's not a straight forward interpretation  
7   of the copycats to be able to make a determination  
8   about what I've been told are secondary  
9   considerations, at least in my own understanding.

10          Q.    And then I think the last topic that  
11   was raised by counsel had to do with a company  
12   called Meda's development testing.   And, again,  
13   that was something that was apparently discussed  
14   or raised during trial.   It was not raised  
15   expressly in your declaration.

16                   If it had been raised in your  
17   declaration, would that change your opinions that  
18   you've expressed?

19          A.    No.   Again, even at trial I expressed  
20   issues with the testing and the conclusions that  
21   were drawn from that, and none of that information  
22   affects my opinion on the claims in the '620



1 matter being obvious.

2 MR. HOUSTON: Okay. Counsel, I have  
3 no further questions.

4 MS. EVERETT: We don't have any other  
5 questions either.

6 (Said deposition was so concluded  
7 at 1:09 p.m.)

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1 STATE OF ILLINOIS )

2 ) SS:

3 COUNTY OF C O O K )

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

5 No. 084-003145, do hereby certify:

6 That the foregoing deposition of MAUREEN D.  
7 DONOVAN, PH.D., was taken before me at the time  
8 and place therein set forth, at which time the  
9 witness was put under oath by me;

10 That the testimony of the witness and all  
11 objections made at the time of the examination  
12 were recorded stenographically by me, were  
thereafter transcribed under my direction and  
13 supervision and that the foregoing is a true  
record of same.

14 I further certify that I am neither counsel  
for nor related to any party to said action, nor  
15 in any way interested in the outcome thereof.

IN WITNESS WHEREOF, I have subscribed my name  
16 this 31st day of October, 2017.

17

18

19

20

21

22



DONNA M. KAZAITIS, IL-CSR, RPR, CRR  
Registered Professional Reporter  
Certified Realtime Reporter

1 Maureen D. Donovan c/o  
FOLEY & LARDNER LLP

2 321 North Clark Street  
Suite 2800

2 Chicago, Illinois 60654-5313

3

4 Case: Argentum Pharmaceuticals LLC v. Cipla Ltd.

Date of deposition: October 24, 2017

5 Deponent: Maureen D. Donovan

6

7 Please be advised that the transcript in the above  
8 referenced matter is now complete and ready for signature.  
9 The deponent may come to this office to sign the transcript,  
10 a copy may be purchased for the witness to review and sign,  
11 or the deponent and/or counsel may waive the option of  
12 signing. Please advise us of the option selected.  
13 Please forward the errata sheet and the original signed  
14 signature page to counsel noticing the deposition, noting the  
15 applicable time period allowed for such by the governing  
16 Rules of Procedure. If you have any questions, please do  
17 not hesitate to call our office at (202)-232-0646.

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19

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4 SIGNATURE PAGE  
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5 Witness Name: Maureen D. Donovan  
Deposition Date: October 24, 2017

6  
7 I do hereby acknowledge that I have read  
and examined the foregoing pages  
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6 ERRATA SHEET

7

8 Case: Argentum Pharmaceuticals LLC v. Cipla Ltd.

9 Witness Name: Maureen D. Donovan

10 Deposition Date: October 24, 2017

11 Page No. Line No. Change

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