

UNITED STATES PATENT AND TRADEMARK OFFICE

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MYLAN PHARMACEUTICALS, INC.,
CELLTRION, INC., and
APOTEX, INC.,

Petitioners,

vs.

CASE NO.

IPR2021-00881

REGENERON PHARMACEUTICALS, INC.,

Patent No.

9,254,338 B2

Patent Owner.

-----/

VIDEO-RECORDED DEPOSITION OF DIANA V. DO, M.D.
PALO ALTO, CALIFORNIA
THURSDAY, APRIL 21, 2022

Reported by:

Anrae Wimberley, CSR No. 7778

Job No. 5149529

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Patent No.

9,254,338 B2

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_____ /

Transcript of video-recorded deposition
of DIANA V. DO, M.D., taken at Arnold & Porter LLP
located at 3000 El Camino Real, Suite 500, Five Palo
Alto Square, Palo Alto, California 94306, beginning
at 9:10 a.m. and ending at 5:10 p.m. on THURSDAY,
APRIL 21, 2022, before Anrae Wimberley, Certified
Shorthand Reporter No. 7778.

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7 behalf of Petitioner Mylan Pharmaceuticals
8 (TELEPHONIC APPEARANCE)

9
10 KEIGO PAINTER, VIDEOGRAPHER
11 VERITEXT LEGAL SOLUTIONS

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I N D E X

EXAMINATION BY: PAGE
MR. SALMEN 9, 133

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E X H I B I T S

EXHIBIT	DESCRIPTION	PAGE
Exhibit 1	Petitioner's Notice of Deposition of Diana V. Do, M.D.; No Bates numbers, 3 pages	9
Exhibit 2	Regeneron press release dated 11/22/19; No Bates numbers, 2 pages	56
Exhibit 3	Scientific American article dated 10/6/08; No Bates numbers, 4 pages	57
Exhibit 4	Claim 1 recreated document; No Bates numbers, 1 page	147

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EXHIBIT	PREVIOUSLY MARKED	
EXHIBIT	DESCRIPTION	PAGE
Exhibit 1001	U.S. Patent No. 9,254,338; No Bates numbers, 14 pages	53
Exhibit 1024	Application for Extension of Patent Term re '758 patent; No Bates numbers, 198 pages	51
Exhibit 1035	Lalwani article; No Bates numbers, 17 pages	180
Exhibit 1074	Ciulla/Rosenfeld article; No Bates numbers, 8 pages	177
Exhibit 2002	Curriculum Vitae; No Bates numbers; 40 pages	198
Exhibit 2051	Declaration of Diana V. Do, M.D.; No Bates numbers, 67 pages	12
Exhibit 2093	Margolis article; No Bates numbers, 4 pages	190
Exhibit 2122	Study of ranibizumab first posted 1/17/13; No Bates numbers, 12 pages	206
Exhibit 2123	Study of ranibizumab first posted 1/17/13; No Bates numbers, 12 pages	207
Exhibit 2185	EYLEA prescribing information; No Bates numbers, 15 pages	23

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QUESTIONS WITNESS INSTRUCTED NOT TO ANSWER:
(None.)

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1 THURSDAY, APRIL 21, 2022;

2 PALO ALTO, CALIFORNIA;

3 9:10 A.M.

4 - - -

5 THE VIDEOGRAPHER: Good morning.

09:10:25

6 We're going on the record at 9:10 a.m. on
7 April 23rd [sic], 2022.

8 Please note that the microphones are
9 sensitive and may pick up whispering, private
10 conversations and cellular interference. Please
11 turn off all cell phones or place them away from the
12 microphones, as they can interfere with the
13 deposition audio.

09:10:37

14 Audio and video recording will continue to
15 take place unless all parties agree to go off the
16 record.

09:10:46

17 This is Media Unit 1 of the video-recorded
18 deposition of Dr. Diana Do taken by the counsel for
19 petitioner in the matter of Mylan Pharmaceuticals,
20 Inc., et al., versus Regeneron Pharmaceuticals, Inc.
21 filed in the United States Patent and Trademark
22 Office. Case No. IPR2021-00880 [sic].

09:10:56

23 This deposition is being held at Arnold &
24 Porter LLP located at 3000 El Camino Real, Suite
25 500, Five Palo Alto Square, Palo Alto, California

09:11:17

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1 94306.

09:11:20

2 My name is Keigo Painter from the firm
3 Veritext. I'm the videographer. The court reporter
4 is Anrae Wimberley from the firm Veritext.

5 I'm not related to any party in this
6 action, nor am I financially interested in the
7 outcome.

09:11:28

8 Counsel and everyone present in the room
9 and everyone attending remotely will now state their
10 appearances and affiliations for the record.

09:11:37

11 If there are any objections to the
12 proceeding, please state them at the time of your
13 appearance, beginning with the noticing attorney.

14 MR. SALMEN: Heinz Salmen of RMMS on behalf of
15 Petitioner Mylan.

09:11:48

16 MR. BEALL: Scott Beall, RMMS, on behalf of
17 petitioner.

18 MR. SALMEN: With us on the phone is Vinny Lee
19 of -- in-house counsel at Viatris on behalf of
20 Petitioner Mylan.

09:12:02

21 MS. FISHMAN: Deborah Fishman of Arnold &
22 Porter on behalf of patent owner and representing
23 the witness. With me today are in-house counsel
24 from Regeneron, Dr. Petra Scamborova and Eileen Woo.

25 And then one correction to the record.

09:12:17

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1 This deposition is being taken in IPR2021-00881.

09:12:20

2 THE VIDEOGRAPHER: Okay.

3 Will the court reporter please swear in
4 the witness.

5 DIANA V. DO, M.D.,

09:12:36

6 sworn in personally as a witness by the Certified
7 Shorthand Reporter, testified as follows:

8 EXAMINATION

9 BY MR. SALMEN:

10 Q. Good morning, Dr. Do.

09:12:51

11 A. Good morning.

12 Q. I'm going to hand you what's been marked
13 Do Exhibit No. 1.

14 MR. SALMEN: Actually, can I keep one of them?

15 MS. FISHMAN: Of course.

09:13:03

16 (Deposition Exhibit 0001 was marked.)

17 BY MR. SALMEN:

18 Q. Dr. Do, is it your understanding that you
19 are being deposed today pursuant to this notice and
20 agreement of the parties in the IPR
21 Proceeding 2021-00881?

09:13:12

22 A. Yes, it is.

23 Q. You understand that there is a second
24 proceeding as well; correct?

25 A. Which proceeding is that you're referring

09:13:23

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1 to?

09:13:28

2 Q. This proceeding on the face of Do
3 Exhibit 1 pertains to Patent No. 9,254,338; is that
4 correct?

5 A. Yes, it does.

09:13:37

6 Q. Are you familiar with the '069 patent?

7 A. I am familiar with it.

8 Q. You've reviewed the '069 patent?

9 A. I have not reviewed it recently, but I am
10 familiar in general with it.

09:13:56

11 Q. Did you review the prosecution history for
12 the '069 patent?

13 A. No, I did not review that.

14 Q. Did you review Dr. Albini's declaration
15 with respect to the '069 patent?

09:14:07

16 A. I read briefly Dr. Albini's deposition.

17 Q. Okay. So my question was with regard to
18 Dr. Albini's declaration for the '069 patent.

19 Did you review that?

20 A. Yes, I did review that.

09:14:24

21 Q. Did you review Dr. Albini's deposition
22 transcript?

23 A. No. I believe I only reviewed his
24 declaration.

25 Q. Okay. Did you review Regeneron's patent

09:14:36

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1 owner response with respect to the '069 patent?

09:14:39

2 A. No, I did not.

3 Q. So as far as you know, your testimony
4 today is only being applied in support of the '338
5 patent proceedings that's Case No. IPR 2021-00881?

09:14:52

6 A. Yes, that is correct.

7 Q. Do you understand that your declaration --
8 and I'm going -- strike that.

9 I'm going to refer to the current
10 proceeding as "the '338 patent proceeding."

09:15:09

11 Do you understand what I'm referring to
12 then?

13 A. Yes, I do.

14 Q. Okay. You understand that your
15 declaration for the '338 patent is your direct
16 examination in this proceeding?

09:15:17

17 A. Yes, I do.

18 Q. And do you understand that the questions
19 I'm asking you today constitute your
20 cross-examination in that proceeding?

09:15:29

21 A. Yes, I do.

22 Q. Have you ever been cross-examined?

23 A. No, I have not.

24 Q. Have you ever been deposed before?

25 A. Yes, I have.

09:15:42

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1 Q. When was your last deposition?

09:15:44

2 A. In thinking back, it may have been a year
3 ago.

4 Q. Okay. Dr. Do, I'm going to hand you a
5 couple of documents that have been previously
6 marked.

09:16:02

7 First, your declaration in the '338 patent
8 proceeding. That's Exhibit 2051.

9 MR. SALMEN: I have a copy for you, Counsel.

10 MS. FISHMAN: Thank you.

09:16:20

11 MR. SALMEN: And there are extra copies.

12 (Deposition Exhibit 2051 was previously
13 marked.)

14 BY MR. SALMEN:

15 Q. So, Dr. Do, I'm also going to hand you a
16 binder that I've prepared that has, just for
17 convenience, several of the exhibits that you cite.

09:16:27

18 (Telephonic interruption.)

19 MR. SALMEN: Sorry for the interruption.

20 BY MR. SALMEN:

09:16:46

21 Q. This binder has several of the exhibits
22 that you cite in there. And I'm giving this to you.
23 All of the exhibits have been previously marked, so
24 to the extent we address them, I'll call out the
25 exhibit numbers.

09:16:57

1 MR. SALMEN: There's one for you, Counsel.

09:16:58

2 MS. FISHMAN: Thank you.

3 BY MR. SALMEN:

4 Q. Dr. Do, you consider Lucentis to be an
5 effective treatment for angiogenic eye disorders;
6 correct?

09:17:24

7 A. May I ask which time frame are you
8 referring to?

9 Q. Prior to January 2011.

10 A. Yes, as I stated in my declaration,
11 Lucentis was the standard of care prior --

09:17:35

12 Q. So referring to your declaration in
13 paragraph 17.

14 MS. FISHMAN: Counsel, please let the witness
15 finish her answer when you're questioning her.
16 Thank you.

09:17:53

17 BY MR. SALMEN:

18 Q. In paragraph 17 of your declaration, you
19 state, "The claimed method of treating must achieve
20 a high level of efficacy, one that is non-inferior
21 to the existing standard of care at the time the
22 '338 patent was filed."

09:18:04

23 Do you see that?

24 A. No. Where are you?

25 Q. Paragraph 17.

09:18:18

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1 A. Okay. Thank you.

09:18:19

2 Yes, I see paragraph 17.

3 Q. The standard of care you're referring to
4 there includes Lucentis; correct?

5 A. Yes. In my declaration, I stated that at
6 the time, prior to 2011, Lucentis was the standard
7 of care.

09:18:30

8 Q. Dr. Do, this is a cross-examination. I'm
9 going to ask my questions. To the extent you can
10 answer them yes or no, I ask that you answer them
11 yes or no. I don't need further clarifications.
12 Okay?

09:18:46

13 A. (Nods head affirmatively.)

14 Q. So prior to January 2011, you considered
15 Lucentis to be a highly effective treatment for
16 angiogenic eye disorders; correct?

09:18:58

17 A. As stated in my declaration, prior to
18 2011, Lucentis was the standard of care.

19 Q. Okay. Lucentis was approved in 2006;
20 correct?

09:19:14

21 A. Yes, that is correct.

22 Q. Are you familiar with the VIEW 1/VIEW 2
23 trials?

24 A. Yes, I'm familiar with those two clinical
25 trials.

09:19:28

1 Q. And at the time of the VIEW 1/VIEW 2 09:19:28
2 trials, you agree that the standard of care was,
3 quote, moved beyond observation and monitoring or
4 destructive therapies such as laser and PDT;
5 correct? 09:19:44

6 MS. FISHMAN: Where are you reading from?
7 Objection. Where are you reading from?

8 BY MR. SALMEN:

9 Q. Can you answer the question?

10 A. Can you repeat the question. 09:19:54

11 Q. At the time of the VIEW 1/VIEW 2 trials,
12 you defined the standard of care as having, quote,
13 moved beyond observation and monitoring or
14 destructive therapies such as laser and PDT;
15 correct? 09:20:09

16 A. After Lucentis was approved, then the
17 standard of care had changed. And Lucentis, because
18 it was effective at improving vision or maintaining
19 vision, had become the new standard of care.

20 Q. So the answer to my question is "yes"; 09:20:28
21 right?

22 MS. FISHMAN: Objection; mischaracterizes
23 testimony.

24 But you can answer his question.

25 THE WITNESS: The standard of care had evolved 09:20:38

1 because Lucentis was effective at improving vision
2 or maintaining vision.

09:20:43

3 BY MR. SALMEN:

4 Q. Lucentis was highly effective; correct?

5 That is the standard of care?

09:20:53

6 A. Lucentis was very effective and it was the
7 standard of care, highly effective.

8 Q. I'll direct your attention to paragraph 65
9 of your declaration. The header for this section
10 before paragraph 65 is "Lucentis Approval and the
11 New Standard of Care."

09:21:20

12 Do you see that?

13 A. Yes, I see that.

14 Q. The standard of care that you are
15 referring to is the administration of Lucentis or
16 Avastin; is that correct?

09:21:31

17 A. As stated in my declaration, at that time
18 point, prior to 2011, Lucentis or off-label Avastin
19 had become the standard of care because they could
20 improve vision or maintain vision.

09:21:56

21 Q. Okay. And in this paragraph, you
22 specifically refer to "wet AMD" and that Lucentis or
23 Avastin off label were the standard of care for that
24 particular angiogenic eye disorder; correct?

25 A. In paragraph 65, I mentioned wet AMD as

09:22:15

1 the reference here.

09:22:24

2 Q. And if we turn to paragraph 54 of your
3 declaration, you referred to many other angiogenic
4 eye disorders, including wet AMD; correct?

5 A. Correct.

09:22:47

6 Q. So Lucentis, or off-label Avastin, were
7 the standard of care for wet AMD as well as many
8 other angiogenic eye disorders as of January 2011;
9 correct?

10 A. As of January 2011, Lucentis was FDA
11 approved for both wet AMD and retinal vein
12 occlusion. Simultaneously at that time, off-label
13 Avastin was used in the ophthalmology community to
14 treat other angiogenic eye disorders.

09:23:02

15 Q. So you agree that Lucentis was also the
16 standard of care for other angiogenic eye disorders
17 at that time, prior to January 2011; correct?

09:23:40

18 A. As I stated, Lucentis was FDA approved for
19 wet AMD and retinal vein occlusion by January of
20 2011 and was the standard of care for those two
21 indications because of its FDA approval.

09:24:05

22 However, off-label Avastin had also
23 emerged as a standard of care option because it was
24 highly efficacious in both -- in many of these
25 angiogenic eye disorders.

09:24:27

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1 Q. So is it your testimony that Lucentis was
2 not used off label prior to January 2011 to treat
3 angiogenic eye disorders other than AMD and RVO?

09:24:28

4 A. I did not provide an opinion on that in my
5 declaration. But in my experience as an
6 ophthalmologist, at that time, Lucentis was only FDA
7 approved for wet AMD and retinal vein occlusion.

09:24:46

8 Q. That's not my question, Dr. Do. You can
9 answer my question.

10 MS. FISHMAN: Objection; argumentative.

09:25:03

11 BY MR. SALMEN:

12 Q. Was Lucentis used off label prior to
13 January 2011 to treat angiogenic eye disorders other
14 than AMD and RVO, the indications that it was
15 approved for?

09:25:15

16 MS. FISHMAN: Again objection; argumentative.

17 But you can answer.

18 THE WITNESS: I did not offer an opinion on
19 that specific question in my declaration. But in my
20 experience, because it was not yet approved in other
21 angiogenic eye disorders, Lucentis was only
22 available to investigators in clinical trials at
23 that time if the indications were not wet AMD or
24 retinal vein occlusion.

09:25:29

25 BY MR. SALMEN:

09:25:49

1 Q. So prior to January 2007 -- strike that.

09:25:49

2 Prior to January 2011, Avastin was being
3 used off label to treat angiogenic eye disorders;
4 correct?

5 A. That is correct.

09:25:59

6 Q. And Lucentis was available to licensed
7 ophthalmologists prior to January 2011; correct?

8 A. At that time period, as I stated, Lucentis
9 was FDA approved for the treatment of wet AMD or
10 retinal vein occlusion, and it was available for
11 those indications.

09:26:21

12 Q. Were you treating patients prior to
13 January 2011 that were suffering from angiogenic eye
14 disorders other than AMD and RVO?

15 A. In my declaration, I did not provide an
16 opinion on my clinical practice at that time.

09:26:36

17 Q. I'm not asking for an opinion. I'm asking
18 for factual information regarding your practice.
19 I'll say it again.

20 Prior to January 2011, were you treating
21 patients suffering from angiogenic eye disorders
22 other than AMD and RVO?

09:26:49

23 MS. FISHMAN: Objection; argumentative.

24 You can answer.

25 THE WITNESS: In my experience as an

09:27:03

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ophthalmologist, at that time period, before 2011, I
was treating patients with angiogenic eye disorders.

09:27:05

BY MR. SALMEN:

Q. Okay. And did you treat those patients
suffering from angiogenic eye disorders other than
AMD and RVO prior to January 2011 with Lucentis?

09:27:15

A. Prior to 2011 for many of these
indications in clinic, I was using off-label
Avastin. However, I was also an investigator on
many Genentech-sponsored clinical trials where I
used Lucentis in the setting of a clinical trial.

09:27:40

Q. And that was off-label Lucentis that you
were using; correct?

MS. FISHMAN: Objection; lacks foundation and
mischaracterizes testimony.

09:27:54

You can answer.

THE WITNESS: At that time period, for
indications other than wet AMD or retinal vein
occlusion, I was only using Lucentis as a clinical
investigator using an IRB protocol to test Lucentis
in different angiogenic eye disorders.

09:28:12

BY MR. SALMEN:

Q. Okay. How about in your current practice?
So prior to today, in the years between January 2011
and today, do you use Lucentis off label to treat

09:28:30

1 angiogenic eye disorders other than the ones that
2 are approved indications in the Lucentis label?

09:28:35

3 A. In my clinical practice, I use Lucentis in
4 patients where Lucentis is FDA approved for their
5 specific eye condition.

09:28:59

6 Q. So is the answer then you do not use
7 Lucentis off label in your current practice?

8 A. Can you give me more clarification on your
9 question.

10 Q. I'm referring back to my original
11 question.

09:29:21

12 In your current practice, post
13 January 2011 up until today, do you use Lucentis off
14 label to treat angiogenic eye disorders other than
15 in accordance with the approved indications in the
16 label?

09:29:38

17 A. Post 2011, I do not use Lucentis off
18 label.

19 Q. So you understand that "off label" refers
20 to using Lucentis for angiogenic eye disorders that
21 are not approved in the label; correct?

09:29:51

22 A. Correct.

23 Q. And you understand that using Lucentis
24 "off label" also refers to administering Lucentis in
25 a regimen that is not in the approved indication of

09:30:08

1 the Lucentis label; correct?

09:30:12

2 MS. FISHMAN: Objection; lacks foundation.

3 You can answer.

4 THE WITNESS: Currently I do not use Lucentis
5 off label.

09:30:25

6 BY MR. SALMEN:

7 Q. Is that how you're answering my question
8 regarding the regimen?

9 A. Can you repeat your question on the
10 regimen.

09:30:35

11 Q. What indications currently are Lucentis
12 approved for?

13 A. Which time frame are you referring to?

14 Q. Currently.

15 A. Currently, Lucentis is FDA approved for
16 the treatment of wet age-related macular
17 degeneration, diabetic macular edema, retinal vein
18 occlusion, diabetic retinopathy, myopic choroidal
19 neovascularization.

09:31:07

20 Q. What is the approved dosing regimen in the
21 current Lucentis label for age-related macular
22 degeneration?

09:31:30

23 A. Do you have a copy of the label?

24 Q. Can you tell me -- you're a licensed
25 ophthalmologist.

09:31:45

1 In your experience -- in your current 09:31:45
2 practice, do you have an understanding of what the
3 approved dosing regimen is for age-related macular
4 degeneration in the Lucentis label?

5 MS. FISHMAN: Objection; argumentative. This 09:31:56
6 isn't a memory test and the witness has asked for a
7 copy of the document.

8 BY MR. SALMEN:

9 Q. Can you answer the question?

10 A. In my recollection, Lucentis is FDA 09:32:08
11 approved for the treatment of wet age-related
12 macular degeneration as often as every four weeks.

13 Q. So monthly dosing; correct?

14 A. Monthly dosing can be employed, yes.

15 Q. Is it approved for other dosing regimens? 09:32:26

16 A. I believe in the label, it may suggest
17 other dosing regimens, but I don't recall at this
18 time. I would have to see the label.

19 Q. I'm going to hand you what's previously
20 been marked Exhibit 2185. 09:32:56

21 (Deposition Exhibit 2185 was previously
22 marked.)

23 BY MR. SALMEN:

24 Q. This is a 2011 version of the Lucentis
25 label. 09:33:09

1 A. What I have in front of me is a copy of
2 the EYLEA label.

09:33:09

3 Q. Oh. Yeah, you do. Okay. You can set
4 that aside for now.

5 What was the FDA-approved dosing regimen
6 for treating angiogenic eye disorders with Avastin
7 prior to 2011?

09:33:33

8 MS. FISHMAN: Objection; lacks foundation.

9 THE WITNESS: Can you repeat your question.

10 BY MR. SALMEN:

09:33:47

11 Q. What was the FDA-approved dosing regimen
12 for treating angiogenic eye disorders with Avastin
13 prior to January 2011?

14 MS. FISHMAN: Objection; lacks foundation.

15 You can answer.

09:33:58

16 THE WITNESS: Avastin for use in angiogenic eye
17 disorders was off label.

18 BY MR. SALMEN:

19 Q. There was no dosing regimen for Avastin
20 that was approved by FDA to treat wet AMD, for
21 example; correct?

09:34:09

22 A. That is correct.

23 Q. So in other words, all uses of Avastin to
24 treat wet AMD were off-label dosing regimens;
25 correct?

09:34:26

1 A. That is correct.

09:34:28

2 Q. So skilled ophthalmologists like yourself
3 prior to January 2011 were able to administer
4 Avastin to treat angiogenic eye disorders like wet
5 AMD even though there was no FDA-approved dosing
6 regimen; is that correct?

09:34:44

7 A. That is correct.

8 Q. Prior to January 2011, were skilled
9 ophthalmologists like yourself able to use Lucentis
10 off label to treat angiogenic eye disorders?

09:35:04

11 A. I believe I answered that question
12 already.

13 Q. You answered it with respect to your own
14 practice. I'm asking for the general community of
15 skilled ophthalmologists.

09:35:18

16 A. In my declaration, I did not provide an
17 opinion on that. However, in my experience as an
18 ophthalmologist, I do not recall ophthalmologists
19 using Lucentis off label outside of its FDA-approved
20 conditions.

09:35:43

21 Q. So with respect to Avastin, still today
22 licensed ophthalmologists like yourself still
23 administer Avastin to treat angiogenic eye disorders
24 off label; correct?

25 A. Yes, ophthalmologists and retinal

09:36:04

1 specialists currently still use Avastin off label to
2 treat angiogenic eye disorders.

09:36:10

3 Q. So is it your testimony that prior to
4 January 2011, Lucentis was never used off label to
5 treat angiogenic eye disorders like wet AMD?

09:36:25

6 MS. FISHMAN: Objection; mischaracterizes
7 testimony.

8 You can answer.

9 THE WITNESS: As I stated before, prior to
10 2011, I don't recall ophthalmologists or retinal
11 specialists using Lucentis off label.

09:36:36

12 BY MR. SALMEN:

13 Q. Now, in your declaration, you extensively
14 refer to the standard of care prior to January 2011;
15 is that correct?

09:36:54

16 A. Yes, I do.

17 Q. Does your standard of care as of
18 January 2011 include administering Lucentis off
19 label to treat wet AMD and other angiogenic eye
20 disorders?

09:37:10

21 MS. FISHMAN: Objection; lacks foundation and
22 vague.

23 THE WITNESS: Can you repeat the question.

24 BY MR. SALMEN:

25 Q. Sure.

09:37:17

1 Does your standard of care, which you
2 referred to in your declaration, as of January 2011
3 include administering Lucentis off label to treat
4 wet AMD and many other angiogenic eye disorders?

09:37:18

5 MS. FISHMAN: Objection; lacks foundation.

09:37:35

6 THE WITNESS: As I stated in my declaration,
7 prior to 2011, Lucentis had become the standard of
8 care for its FDA-approved label of wet age-related
9 macular degeneration or retinal --

10 BY MR. SALMEN:

09:37:55

11 Q. That's not what you say in your
12 declaration, Dr. Do. You say the standard of care
13 was Lucentis or off-label Avastin. There's no
14 mention of Lucentis with respect to its approved
15 indication.

09:38:05

16 Can you show me where you say that in your
17 declaration?

18 MS. FISHMAN: Objection; argumentative. And
19 you're cutting off the witness. Let the witness --

20 BY MR. SALMEN:

09:38:13

21 Q. Can you show me where you --

22 MS. FISHMAN: Let the -- Heinz, now you're
23 cutting me off. I'm still making my objection. Let
24 the witness --

25 MR. SALMEN: Your objections are improper and

09:38:18

1 outside --

09:38:19

2 MS. FISHMAN: Let the witness finish answering
3 her question. Let the witness finish answering her
4 question.

5 BY MR. SALMEN:

09:38:25

6 Q. Did you finish answering the question?

7 A. Can you repeat the question?

8 Q. No.

9 MS. FISHMAN: Could you please read back the
10 question, the last question.

09:38:33

11 MR. SALMEN: I'll withdraw the last question.

12 BY MR. SALMEN:

13 Q. Can you show me in your declaration where
14 you refer to the standard of care being Lucentis
15 with respect to the approved indications in the
16 Lucentis label?

09:38:46

17 (Witness reviews document.)

18 A. In my declaration, in paragraph 54, I
19 wrote that "The standard of care for treating wet
20 AMD and many other angiogenic eye disorders improved
21 drastically in the years leading up to the '338
22 patent filing date driven in large part by the
23 testing and approval of Lucentis."

09:39:46

24 Q. What testing are you referring to in that
25 paragraph?

09:40:04

1 A. In that paragraph, I'm referring to the
2 clinical trials that led up to the approval of
3 Lucentis in wet age-related macular degeneration.

09:40:08

4 Q. So you agree then that the clinical trial
5 testing data prior to FDA approval can influence
6 ophthalmologists like yourself in their
7 administration of angiogenic -- strike that.

09:40:28

8 You agree that clinical trial testing data
9 prior to FDA approval can influence licensed
10 ophthalmologists like yourself in the treatment of
11 angiogenic eye disorders; correct?

09:40:48

12 MS. FISHMAN: Objection; incomplete
13 hypothetical.

14 You can answer.

15 THE WITNESS: In my experience as an
16 ophthalmologist, clinical trials, particularly the
17 pivotal Phase 3 trials, can provide evidence on the
18 efficacy and safety of a particular drug.

09:41:03

19 BY MR. SALMEN:

20 Q. Let's look at paragraph 20 and 21 of your
21 declaration.

09:41:35

22 Are you there?

23 A. Yes, I am.

24 Q. Okay. In paragraph 20, you state, "I have
25 been informed that patent claim terms are construed

09:42:02

1 from the vantage point of a skilled artisan to which
2 the invention relates at the time of the invention
3 (or as of the effective filing date of the patent
4 application). The skilled artisan I understand is
5 presumed to be familiar with what was known in the
6 art at the time."

09:42:06

7 Is that the standard you applied in
8 forming the opinions you provide in the '338
9 declaration?

10 A. Yes, it is.

09:42:40

11 Q. And the effective filing date that you
12 applied was January 13th, 2011 for the '338 patent
13 in forming your opinions; is that correct?

14 A. May I see a copy of the filing date of the
15 patent?

09:43:05

16 Q. Sure.

17 You actually reference it in paragraph 30
18 of your declaration. And if you need the '338
19 patent, it's Tab No. 1 in your binder.

20 A. Yes, I see that date.

09:43:22

21 Q. That's the date that you applied in
22 forming your opinions?

23 A. Yes, it is.

24 Q. You also provide a definition for a person
25 of ordinary skill in the art of the '338 patent; is

09:43:36

1 that correct?

09:43:39

2 A. Yes, I did.

3 Q. Paragraph 28 of your declaration; right?

4 A. Yes, it is.

5 Q. Sitting here today, do you still agree
6 with that definition?

09:43:48

7 A. I agree with my definition.

8 Q. Don't want to make any changes to that
9 definition today?

10 A. That is correct.

09:43:59

11 Q. Okay. In paragraph 20 -- sorry to jump
12 around so much.

13 But paragraph 20, under "Legal Framework,"
14 you state that "The patent claim terms are construed
15 from the vantage point of a skilled artisan to which
16 the invention relates at the time of the invention";
17 correct?

09:44:14

18 A. That is correct.

19 Q. And you use the term "skilled artisan"
20 synonymous with "a person of ordinary skill in the
21 art"; correct?

09:44:28

22 A. Yes.

23 Q. Now, in forming your opinions that you set
24 forth in your declaration, you applied the
25 perspective of that person of ordinary skill in the

09:44:39

1 art or skilled artisan; is that correct?

09:44:43

2 A. That is correct.

3 Q. So you construed the claim terms of the
4 '338 claims from the vantage point of your skilled
5 artisan at the time of the effective filing date of
6 the '338 patent; right?

09:44:57

7 A. That is correct.

8 Q. You also reviewed all of the prior art
9 references that you cite in your declaration from
10 that same vantage point, the skilled artisan as you
11 define them in your declaration; right?

09:45:15

12 A. That is correct.

13 Q. What are the education and training
14 qualifications for an ophthalmologist under your
15 definition of skilled artisan?

09:45:33

16 A. As I mentioned in my declaration, I
17 believe the skilled artisan was the ophthalmologist
18 who would have firsthand experience of diagnosing
19 and treating angiogenic eye disorders to which the
20 patent is plainly directed.

09:46:02

21 Q. How much experience? Years? Patients?
22 Can you quantify the amount of experience that is
23 required for a skilled artisan to qualify as an
24 ophthalmologist under your definition?

25 A. In my definition, I did not specify the

09:46:28

1 years in practice that were necessary. I merely
2 stated it had to be an ophthalmologist who was
3 diagnosing and treating angiogenic eye disorders.

09:46:32

4 Q. But a licensed ophthalmologist; correct?

5 That's also in your definition?

09:46:48

6 MS. FISHMAN: Objection; mischaracterizes.

7 MR. SALMEN: Doesn't mischaracterize.

8 BY MR. SALMEN:

9 Q. It's in your definition; right?

10 Paragraph 28. You can read it to yourself if you
11 need to.

09:46:57

12 (Witness reads document.)

13 A. In my declaration, I state that "In the
14 event that Mylan argues that the skilled artisan
15 need not be a licensed physician (ophthalmologist),
16 whatever other qualifications they must possess, I
17 disagree because only an ophthalmologist would have
18 firsthand experience of diagnosing and treating
19 angiogenic eye disorders to which the patent is
20 plainly directed."

09:47:15

09:47:34

21 Q. So you agree that your definition requires
22 that the ophthalmologist who's a skilled artisan be
23 a licensed ophthalmologist because if it doesn't,
24 you disagree with that definition; right?

25 MS. FISHMAN: Objection. The document speaks

09:47:48

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Mylan Exhibit 1109
Mylan v. Regeneron, IPR2021-00881
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Celltrion Exhibit - 1016
Celltrion, Inc. v. Regeneron Pharmaceuticals, Inc.

1 for itself, misstates her --

09:47:50

2 MR. SALMEN: The document is her direct
3 examination testimony. It's a completely
4 inappropriate objection. Knock it off.

5 MS. FISHMAN: You are --

09:47:59

6 BY MR. SALMEN:

7 Q. Do you want to answer the question?

8 MS. FISHMAN: You are both being argumentative,
9 rude and you are misreading her declaration. So why
10 don't you knock it off. Would you like to put the
11 question to her again, Heinz?

09:48:04

12 BY MR. SALMEN:

13 Q. Is it your opinion that the skilled
14 artisan, under your definition, must be a licensed
15 ophthalmologist?

09:48:17

16 A. I believe what I said in my declaration is
17 the correct definition of a skilled artisan.

18 Q. How many years of practice as an
19 ophthalmologist is needed to qualify as a skilled
20 artisan under your definition?

09:48:39

21 A. In my declaration, I did not provide an
22 opinion on the years necessary in practice to be an
23 ophthalmologist. I stated that the ophthalmologist,
24 as a skilled artisan, would need to have firsthand
25 experience diagnosing and treating angiogenic eye

09:49:04

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Mylan Exhibit 1109
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Celltrion Exhibit - 1016
Celltrion, Inc. v. Regeneron Pharmaceuticals, Inc.

1 disorders.

09:49:07

2 Q. How many patients? Can you quantify how
3 many patients are required under your definition?

4 MS. FISHMAN: Objection; lacks foundation.

5 THE WITNESS: Can you repeat the question.

09:49:27

6 BY MR. SALMEN:

7 Q. Can you quantify how many patients are
8 required to qualify as a skilled artisan under your
9 definition?

10 MS. FISHMAN: Same objection.

09:49:35

11 But you can answer.

12 THE WITNESS: I did not quantify how many
13 patients are necessary for this skilled artisan,
14 otherwise known as the ophthalmologist. But an
15 ophthalmologist who was a skilled artisan would need
16 to have firsthand experience in diagnosing and
17 treating angiogenic eye disorders.

09:49:58

18 BY MR. SALMEN:

19 Q. Okay. And a person who just graduated
20 medical school would not have firsthand experience
21 diagnosing and treating angiogenic eye disorders; is
22 that correct?

23 A. In my declaration, I did not provide an
24 opinion on people who just graduated medical school.
25 However, in my experience, an ophthalmologist, in

09:50:44

1 addition to graduating medical school, has to 09:50:48
2 complete an ophthalmology residency training program
3 to become an ophthalmologist.

4 Q. Okay. So just having a medical degree is
5 not enough to qualify as a skilled artisan under 09:51:03
6 your definition; can we agree to that?

7 A. I agree that it has to be an
8 ophthalmologist who's familiar with treating and
9 diagnosing angiogenic eye disorders.

10 Q. So any person without firsthand experience 09:51:18
11 of diagnosing and treating angiogenic eye disorders
12 would not qualify as a person of ordinary skill in
13 the art of the '338 patent under your definition; is
14 that right?

15 A. As I stated, the skilled artisan is one 09:51:38
16 who has firsthand experience in diagnosing and
17 treating angiogenic eye disorders --

18 Q. So are you --

19 A. -- to which the patent is plainly
20 directed. 09:51:53

21 Q. Are you agreeing with my question?

22 A. I agree with what I wrote in my
23 declaration.

24 Q. Any person without firsthand experience of
25 diagnosing and treating angiogenic eye disorders 09:52:07

1 would not qualify as a person of ordinary skill in
2 the art of the '338 patent under your definition;
3 right?

09:52:11

4 A. As I stated in my declaration, the person
5 of ordinary skill in the art, in relation to this
6 patent, would be an ophthalmologist who would have
7 firsthand experience diagnosing and treating
8 angiogenic eye disorders.

09:52:28

9 Q. Okay. I understand that's your opinion.

10 I want to know if a person without that
11 experience can still qualify as a person of ordinary
12 skill in the art under your definition.

09:52:40

13 A. In relation to this patent, the person of
14 ordinary skill in the art would need to be an
15 ophthalmologist who had firsthand experience
16 diagnosing and treating angiogenic eye disorders.

09:53:04

17 Q. Do you consider yourself a person of
18 ordinary skill in the art of the '338 patent?

19 A. Yes, I do.

20 Q. Prior to your involvement in this case for
21 Regeneron, you were aware of the clinical trials
22 that were conducted for EYLEA before it was approved
23 by FDA; right?

09:53:33

24 A. Which clinical trials are you referring
25 to?

09:53:48

1 Q. All of them. You were aware of them.

09:53:48

2 A. Can you specify what "all of them" means?

3 Q. Sure.

4 The VIEW 1/VIEW 2 trials, you were aware
5 of those prior to EYLEA's approval by FDA; correct?

09:54:03

6 A. Yes, I was.

7 Q. And you were aware of the CLEAR-IT 1 and
8 CLEAR-IT 2 trials prior to January 2011; correct?

9 A. Yes, I was.

10 Q. And prior to January 2011, did you know
11 what drug was being tested in the CLEAR-IT 1 and
12 CLEAR-IT 2 trials?

09:54:21

13 A. Yes, I was.

14 Q. What drug was that?

15 A. Do you have a copy of the manuscripts?

09:54:39

16 Q. No.

17 Do you know what drug was being tested in
18 the CLEAR-IT 1 and CLEAR-IT 2 trials prior to
19 January 2011?

20 A. I recall it was VEGF-Trap.

09:54:54

21 Q. Did you use ClinicalTrials.gov prior to
22 January 2011?

23 (Reporter seeks clarification.)

24 Q. I'll restate it.

25 Did you use ClinicalTrials.gov prior to

09:55:17

1 January 2011 to monitor CLEAR-IT 1 and CLEAR-IT 2

09:55:20

2 trials?

3 A. I didn't provide an opinion on that in my
4 clarification.

5 Q. I'm not asking for an opinion, Dr. Do.
6 I'm asking for factual information regarding your
7 practice prior to January 2011. So I'll say it
8 again.

09:55:32

9 Did you use ClinicalTrials.gov prior to
10 January 2011 to monitor the CLEAR-IT 1 and
11 CLEAR-IT 2 trials?

09:55:46

12 MS. FISHMAN: Objection; lacks foundation.

13 You can answer.

14 THE WITNESS: I may have used
15 ClinicalTrials.gov. But that was a long time ago
16 and I would have to refresh my memory.

09:55:58

17 BY MR. SALMEN:

18 Q. In your current clinical practice, do you
19 monitor clinical trials on ClinicalTrials.gov?

20 MS. FISHMAN: Objection; vague, lacks
21 foundation.

09:56:16

22 You can answer.

23 THE WITNESS: In my current clinical practice,
24 I sometimes monitor trials on ClinicalTrials.gov.

25 BY MR. SALMEN:

09:56:35

1 Q. And did you monitor clinical trials like 09:56:36
2 CLEAR-IT 1 and CLEAR-IT 2 in your practice prior to
3 January 2011?

4 A. As I stated, that was a long time ago. I
5 don't recall. I'd have to look at prior records. 09:56:51

6 Q. You understand that CLEAR-IT 1 and
7 CLEAR-IT 2 were Phase 2 trials; right?

8 MS. FISHMAN: Objection; lacks foundation.

9 THE WITNESS: If you have a copy of those
10 manuscripts, that will help refresh my memory. 09:57:11

11 MR. SALMEN: Let me strike that. I misspoke.

12 BY MR. SALMEN:

13 Q. You're aware that CLEAR-IT 2 was a Phase 2
14 clinical trial for VEGF-Trap; is that correct?

15 A. Do you have a copy of the publication? 09:57:29

16 Q. No.

17 Do you recall that?

18 A. I would need a copy of the manuscript to
19 refresh my memory.

20 Q. Sitting here today, you can't recall 09:57:42
21 whether or not CLEAR-IT 2 was a Phase 2 clinical
22 trial for VEGF-Trap?

23 A. Again, I would like to have a copy of the
24 manuscript to refresh my memory.

25 Q. Dr. Do, are you a molecular biologist? 09:58:23

1 A. I am a physician, ophthalmologist.

09:58:30

2 Q. So you are not an expert in molecular
3 biology?

4 A. I have an understanding of molecular
5 biology as a physician.

09:58:43

6 Q. That wasn't my question.
7 You are not an expert in molecular
8 biology; correct?

9 A. What is your definition of an expert in
10 molecular biology?

09:58:59

11 Q. Do you consider yourself an expert in
12 molecular biology?

13 A. In my declaration, I did not offer an
14 opinion on whether or not I was an expert in
15 molecular biology.

09:59:12

16 Q. Have you ever consulted as an expert in
17 molecular biology?

18 A. I have not consulted as an expert in
19 molecular biology.

20 Q. You mentioned that you'd been deposed
21 recently.

09:59:32

22 In that case, were you testifying as an
23 expert in molecular biology?

24 A. I was not testifying as an expert in
25 molecular biology in the prior case.

09:59:49

1 Q. In your declaration, you state that you
2 have published over 140 peer-reviewed publications.

10:00:04

3 Of those 140, how many of them would you
4 describe as having a focus on molecular biology of a
5 protein therapeutic?

10:00:24

6 A. Do you have a copy of my CV?

7 Q. It's in your binder.

8 I'll strike the question. You don't need
9 to.

10 You've been practicing as a licensed
11 ophthalmologist since 2000; is that correct?

10:00:47

12 MS. FISHMAN: Objection; lacks foundation.

13 You can answer.

14 BY MR. SALMEN:

15 Q. I'm sorry if I got it wrong.

10:00:56

16 A. I completed my residency in ophthalmology
17 training in 2003.

18 Q. So you've been practicing as a licensed
19 ophthalmologist since 2003?

20 MS. FISHMAN: Same objection.

10:01:16

21 You can answer.

22 THE WITNESS: Subsequently, I also completed a
23 retinal fellowship from 2003 to 2005. And then I
24 joined the faculty at Johns Hopkins University
25 School of Medicine in 2005.

10:01:30

1 BY MR. SALMEN:

10:01:33

2 Q. So when did you start practicing as a
3 licensed ophthalmologist?

4 MS. FISHMAN: Same objection.

5 You can answer.

10:01:38

6 THE WITNESS: I started practicing in 2003.

7 BY MR. SALMEN:

8 Q. 2003. Okay.

9 And in -- strike that.

10 In your practice as a licensed
11 ophthalmologist, have you ever sequenced a
12 therapeutic protein?

10:01:49

13 A. In my clinical practice, I have not
14 sequenced a therapeutic protein.

15 Q. As a licensed ophthalmologist, have you
16 ever analyzed the glycosylation pattern of a
17 therapeutic protein?

10:02:07

18 A. In my clinical practice, I don't recall
19 doing that.

20 Q. So as part of the treatment of your
21 patients suffering from angiogenic eye disorders, do
22 you routinely ask about glycosylation patterns of
23 the therapeutic proteins you are administering?

10:02:28

24 A. In my experience, I typically do not ask
25 about those topics.

10:02:49

1 Q. Okay. I asked this before, but I'll state
2 it again just for context.

10:02:50

3 In your declaration, you do state that
4 it's your opinion that the '338 patent claimed
5 method of treating must achieve a high level of
6 efficacy; is that correct?

10:03:04

7 A. I agree that it must achieve a high level
8 of efficacy in terms of vision gains or maintenance
9 of vision.

10 Q. It's in paragraph 17 of your declaration
11 if you need it for context.

10:03:21

12 But my question is, as a licensed
13 ophthalmologist who administers EYLEA, can you tell
14 me how many sialic acid residues are necessary to
15 achieve the high level of efficacy that you argue is
16 required by the '338 patent claims?

10:03:39

17 A. Can you repeat your question.

18 Q. Sure.

19 As a licensed ophthalmologist who
20 administers EYLEA, can you tell me how many sialic
21 acid residues are necessary to achieve the high
22 level of efficacy you argue is required by the '338
23 patent claims?

10:03:54

24 MS. FISHMAN: Objection; lacks foundation and
25 incomplete hypothetical.

10:04:10

1 You can answer.

10:04:11

2 THE WITNESS: I don't recall how many are
3 necessary.

4 BY MR. SALMEN:

5 Q. As a licensed ophthalmologist, are you
6 familiar with how the degree of glycosylation among
7 VEGF-Trap-Eye glycoforms can affect the potency and
8 durability of the molecule?

10:04:25

9 A. I don't know.

10 Q. Before you administer VEGF-Trap-Eye to
11 your patients, do you determine the level of sialic
12 acid residues on the molecule in that specific batch
13 that you're using?

10:04:44

14 MS. FISHMAN: Objection; incomplete
15 hypothetical, lacks foundation.

10:05:04

16 You can answer.

17 THE WITNESS: Can you repeat the question.

18 BY MR. SALMEN:

19 Q. Sure.

20 Before you administer VEGF-Trap-Eye to
21 your patients suffering from an angiogenic eye
22 disorder, do you determine the level of sialic acid
23 residues per molecule in that specific batch?

10:05:09

24 A. I do not determine the level of the acid.

25 Q. Have you ever synthesized a receptor-based

10:05:38

chimeric molecule?

10:05:41

A. I've not personally synthesized that peptide.

Q. Have you ever sensitized a receptor-based molecule with multimerization components?

10:05:52

A. I have not synthesized that either.

Q. Do you consider yourself qualified to give a definition of a receptor-based chimeric molecule with multimerization components?

MS. FISHMAN: Objection; incomplete hypothetical, lacks foundation.

10:06:11

You can answer.

THE WITNESS: Can you repeat the question.

BY MR. SALMEN:

Q. Sure.

10:06:20

Do you consider yourself qualified to provide a definition for a receptor-based chimeric molecule with multimerization components?

MS. FISHMAN: Same objection. Vague.

You can answer.

10:06:39

THE WITNESS: Can you show me which molecule you're referring to?

BY MR. SALMEN:

Q. I can show you the language of the claims.

A. Sure.

10:06:52

1 Q. Sure.

10:06:53

2 Turn to Claim 1 of the '338 patent.

3 A. I see Claim 1.

4 Q. The third wherein clause.

5 Do you see where it states, "wherein the

10:07:19

6 VEGF antagonist is a VEGF receptor-based chimeric
7 molecule comprising," and then the third component
8 is "a multimerization component"?

9 Do you see that?

10 A. I see that wording.

10:07:34

11 Q. So my question is, do you consider
12 yourself qualified to provide a definition for a
13 receptor-based chimeric molecule comprising
14 multimerization components?

15 MS. FISHMAN: Objection; lacks foundation,
16 incomplete hypothetical.

10:07:49

17 You can answer.

18 THE WITNESS: As I stated, I haven't personally
19 synthesized any receptor-based chimeric molecule.

20 BY MR. SALMEN:

10:08:17

21 Q. You do offer an opinion that EYLEA meets
22 the sequence elements of Claim 1; isn't that
23 correct?

24 It's paragraph 102 of your declaration, if
25 you need it for context.

10:08:31

1 Did you conduct the side-by-side 10:09:01
2 comparison of the amino acid sequence set forth in
3 Claim 1 against the amino acid sequence for the
4 VEGF-Trap-Eye that is used in EYLEA?

5 MS. FISHMAN: Objection; vague. 10:09:14

6 THE WITNESS: Can you repeat the question.

7 BY MR. SALMEN:

8 Q. Sure.

9 Did you conduct a side-by-side comparison
10 of the amino acid sequence set forth in Claim 1 10:09:21
11 against the amino acid sequence for the
12 VEGF-Trap-Eye that is used in EYLEA?

13 A. I did not perform a side-by-side
14 comparison of the amino acid sequence.

15 Q. Your opinion in paragraph 102 is based 10:09:39
16 entirely on the information contained in
17 Exhibit 1024; right?

18 MS. FISHMAN: Objection; lacks foundation,
19 document speaks for itself.

20 You can answer. 10:09:49

21 MR. SALMEN: It's an inappropriate objection,
22 Counsel. This is her testimony.

23 MS. FISHMAN: It's an inappropriate question,
24 Counsel.

25 But you can answer. 10:09:57

1 THE WITNESS: Can you show me Exhibit 1024.

10:09:58

2 BY MR. SALMEN:

3 Q. That's not my question, Dr. Do. I'm
4 asking you about the opinion that you set forth in
5 Exhibit 1024.

10:10:08

6 And my question is, your opinion in
7 paragraph 102 is based entirely on the information
8 contained in Exhibit 1024; is that correct?

9 A. As I stated in my declaration,
10 "Exhibit 1024 explains that EYLEA includes a
11 multimerization component also discussed in
12 Example 20 of the '758 patent, with an amino acid
13 sequence disclosed in Figures 24A to 24C."

10:10:30

14 Q. You did not conduct any independent
15 investigation to confirm the accuracy of that
16 information from Exhibit 1024 that you just quoted,
17 did you?

10:10:53

18 MS. FISHMAN: Objection; vague.

19 You can answer.

20 THE WITNESS: I don't recall conducting an
21 independent investigation.

10:11:17

22 BY MR. SALMEN:

23 Q. In paragraph 102, the only document that
24 you cite is Exhibit 1024; is that correct?

25 A. In that paragraph 102, I do cite

10:11:42

1 Exhibit 1024.

10:11:44

2 Q. That's the only document that you cite in
3 Exhibit 102; is that correct?

4 MS. FISHMAN: Objection; lacks foundation,
5 vague question. Look at your question, Counsel.

10:11:58

6 THE WITNESS: I also mention --

7 MR. SALMEN: I'll restate the question. Maybe
8 I misspoke.

9 BY MR. SALMEN:

10 Q. Exhibit 1024 is the only document that you
11 cite in paragraph 102 of your declaration; is that
12 correct?

10:12:14

13 A. In paragraph 102, I mention Exhibit 1024
14 and the '758 patent.

15 Q. To be clear, Exhibit 1024 is the file
16 history of U.S. Patent No. 7,374,758, the
17 December 22nd, 2011 patent term extension
18 application that's in your Footnote 20; is that
19 correct?

10:12:54

20 MS. FISHMAN: Objection; misstated the
21 document, you mischaracterized the document. The
22 document is what it is.

10:13:15

23 BY MR. SALMEN:

24 Q. Dr. Do, I'm going to hand you what's been
25 marked --

10:13:46

MR. SALMEN: Do you have a copy of it in your binder?

MS. FISHMAN: It is in the binder.

(Deposition Exhibit 1024 was previously marked.)

BY MR. SALMEN:

Q. Exhibit 1024 is in your binder?

A. Yes, it is.

Q. Do you recognize Exhibit 1024 as the December 22nd, 2011 patent term extension application as it appears in the file history of U.S. Patent No. 7,374,758?

A. Yes, I recognize this.

MS. FISHMAN: Counsel, when you're at a convenient stopping point, we've been going just over an hour.

MR. SALMEN: I'll need another five, ten minutes.

BY MR. SALMEN:

Q. Is that okay?

A. Sure.

MS. FISHMAN: He means for this segment.

MR. SALMEN: Yeah, not for the day.

THE WITNESS: I was about to make plans for the afternoon.

1 BY MR. SALMEN:

10:14:48

2 Q. Prior to preparing your declaration in
3 this proceeding, did you know what an application
4 for extension of a patent term was?

5 A. No, I did not.

10:15:02

6 Q. Do you understand that Regeneron was
7 petitioning the Patent Office to extend the term of
8 the '758 patent beyond its statutory expiration for
9 this application?

10 MS. FISHMAN: Objection; calls for a legal
11 conclusion.

10:15:20

12 But you can answer.

13 THE WITNESS: I do now.

14 BY MR. SALMEN:

15 Q. You agree that Regeneron was not an
16 unbiased party in the application that you relied on
17 to form your opinion regarding whether EYLEA meets
18 the sequence element of Claim 1 of the '338 patent;
19 is that correct?

10:15:30

20 MS. FISHMAN: Objection; lacks foundation.

10:15:47

21 THE WITNESS: Can you repeat the question.

22 BY MR. SALMEN:

23 Q. Sure.

24 Regeneron was not an unbiased party in
25 this patent term extension application that you

10:15:57

1 relied on to form your opinion regarding whether

10:16:01

2 EYLEA meets the sequence element of Claim 1 of the

3 '338 patent; correct?

4 MS. FISHMAN: Lacks foundation, calls for

5 speculation.

10:16:11

6 You can answer.

7 THE WITNESS: I don't understand your question.

8 BY MR. SALMEN:

9 Q. What part of it do you not understand?

10 A. I guess the entirety.

10:16:19

11 Q. Okay. You understand that Regeneron
12 submitted this application to extend the term of the
13 '758 patent beyond its statutory expiration.

14 You agreed to that; correct?

15 A. I agree.

10:16:35

16 Q. You already testified that you consider
17 yourself a person of ordinary skill in the art,
18 under your definition, for the '338 patent; correct?

19 A. That is correct.

20 Q. Can you turn to the '338 patent, the cover
21 page. It's Exhibit 1001.

10:16:56

22 (Deposition Exhibit 1001 was previously
23 marked.)

24 BY MR. SALMEN:

25 Q. Are you there?

10:17:08

1 A. Yes, I am. 10:17:08

2 Q. Who is the named inventor of the '338
3 patent?

4 A. Yancopoulos.

5 Q. George D. Yancopoulos; is that correct? 10:17:16

6 A. Correct.

7 Q. There's only one inventor; right?

8 A. That is what is listed.

9 Q. Have you ever met George Yancopoulos?

10 A. No, I have not. 10:17:28

11 Q. You didn't talk to him before submitting
12 your declaration?

13 A. No, I did not.

14 Q. Do you know whether George Yancopoulos was
15 an ophthalmologist with experience in treating 10:17:39
16 angiogenic eye disorders prior to January 2011?

17 A. I don't know that information.

18 Q. You didn't inquire to your attorneys to
19 answer that question?

20 MS. FISHMAN: Objection. 10:17:54

21 To the extent this calls for privileged
22 communication, I instruct you not to answer.

23 BY MR. SALMEN:

24 Q. Did you ask whether George Yancopoulos was
25 a licensed physician as of January 2011? 10:18:04

1 MS. FISHMAN: You can answer, but I caution the
2 witness not to get into any privileged
3 communications.

10:18:10

4 BY MR. SALMEN:

5 Q. Did you ask that question?

10:18:16

6 A. Again, this might be privileged
7 information and I can't answer that.

8 Q. She just said you can answer it.

9 Did you ask whether George Yancopoulos was
10 a licensed physician as of January 2011?

10:18:31

11 A. I did not ask.

12 Q. So do you know whether George Yancopoulos
13 was a practicing physician as of January 2011?

14 A. I don't recall.

15 Q. Did you ever know whether George
16 Yancopoulos was a practicing physician as of
17 January 2011?

10:18:55

18 A. In my declaration, I did not provide an
19 opinion on George Yancopoulos, and I don't know that
20 information.

10:19:12

21 Q. Well, you answered "I don't recall," and
22 that suggests that you did know at it some point.

23 But the answer is, no, you do not know
24 whether George Yancopoulos was a practicing
25 physician as of January 2011; correct?

10:19:25

1 A. I do not know if George Yancopoulos was a
2 practicing physician.

10:19:28

3 Q. And you do not know whether George
4 Yancopoulos had ever treated an angiogenic eye
5 disorder in a patient prior to January 2011; right?

10:19:36

6 A. I do not know if George Yancopoulos has
7 treated patients with angiogenic eye disorders.

8 Q. So sitting here today, you cannot say
9 whether the sole named inventor of the '338 patent
10 is a person of ordinary skill in the art, applying
11 your definition; correct?

10:19:55

12 A. I don't know if George Yancopoulos is a
13 practicing ophthalmologist.

14 Q. Okay.

15 MR. SALMEN: Can I get 2.

10:20:27

16 MS. FISHMAN: Are you about to start with a new
17 exhibit?

18 MR. SALMEN: I'm just ending this line of
19 questioning. If it's okay to go five more minutes,
20 we can take a break after this. It's all related to
21 this.

10:20:44

22 MS. FISHMAN: It's up to you.

23 (Deposition Exhibit 0002 was marked.)

24 BY MR. SALMEN:

25 Q. I'm going to hand you what's been marked

10:20:50

1 Do Exhibit 2.

10:20:53

2 (Deposition Exhibit 0003 was marked.)

3 BY MR. SALMEN:

4 Q. And I'm going to hand you what's been
5 marked Do Exhibit 3.

10:21:19

6 In Do Exhibit 2, this is a Regeneron press
7 release dated November 22nd, 2019.

8 Do you see the section heading there that
9 states "Biography and Career Accomplishments"?

10 A. Yes, I do.

10:21:46

11 Q. And about halfway down in that first
12 paragraph, there's a statement that reads, quote,
13 "Yancopoulos then received his M.D. from Columbia
14 University's College of Physicians and Surgeons and
15 his Ph.D in biochemistry and molecular biophysics
16 from Columbia University's Graduate School of Arts
17 and Sciences where he was chosen to represent his
18 doctoral class as commencement speaker. He launched
19 his career as an academic scientist with
20 Frederick W. Alt at Columbia publishing sentinel
21 papers in molecular immunology."

10:22:04

10:22:25

22 Do you see that?

23 A. I see that sentence.

24 Q. The next sentence states, "In 1989,
25 Yancopoulos left academia to join Leonard Schleifer,

10:22:39

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1 M.D., Ph.D., as co-founder, president and chief
2 executive officer of Regeneron."

10:22:46

3 Do you see that?

4 A. I see that sentence.

5 Q. Now, if we look at Do Exhibit 3, page 2 of
6 4, about two-thirds of the way down, there's a
7 paragraph that starts "Yancopoulos earned an M.D.
8 and Ph.D. at Columbia University in biochemistry and
9 molecular biophysics, finishing in 1987. He then
10 accepted a junior faculty position studying the

10:22:56

11 immune system. Shortly thereafter, he won an
12 eight-year grant worth well over \$1 million in
13 today's money from Lucille P. Markey Charitable
14 Trust, a foundation that's specialized in promoting
15 young biomedical researchers."

10:23:38

10:23:57

16 Do you see that?

17 A. I see that sentence.

18 Q. Okay. So according to these publications,
19 George Yancopoulos graduated Columbia University in
20 1987; correct?

10:24:11

21 MS. FISHMAN: Objection. The document speaks
22 for itself, calls for speculation.

23 You can answer.

24 THE WITNESS: According to this sentence in the
25 document of Exhibit 3, it states, "Yancopoulos

10:24:30

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1 earned an M.D. and Ph.D. at Columbia University in
2 biochemistry and molecular biophysics, finishing in
3 1987."

10:24:36

4 BY MR. SALMEN:

5 Q. And according to these documents, after
6 graduating in 1987, Yancopoulos launched his career
7 as an academic scientist with Frederick W. Alt at
8 Columbia; is that correct?

10:24:47

9 MS. FISHMAN: Objection; document speaks for
10 itself.

10:25:01

11 THE WITNESS: According to Exhibit 2, the
12 sentence does state that fact.

13 BY MR. SALMEN:

14 Q. And then in 1989, Yancopoulos left
15 academia to join Regeneron; is that correct?

10:25:17

16 MS. FISHMAN: Are you asking the witness if she
17 knows or if the document says it?

18 MR. SALMEN: I'll rephrase it.

19 BY MR. SALMEN:

20 Q. According to these documents, in 1989,
21 Yancopoulos left academia to join Regeneron;
22 correct?

10:25:25

23 MS. FISHMAN: Objection; document speaks for
24 itself.

25 You can answer.

10:25:32

1 THE WITNESS: According to the document,
2 Exhibit 2, the sentence states that "In 1989,
3 Yancopoulos left academia to join Leonard Schleifer
4 at" -- et cetera.

10:25:33

5 BY MR. SALMEN:

10:25:47

6 Q. According to the documents, Yancopoulos
7 was never a licensed ophthalmologist with firsthand
8 experience of diagnosing and treating angiogenic eye
9 disorders; right?

10 MS. FISHMAN: Objection; lacks foundation,
11 calls for speculation and documents speak for
12 themselves.

10:25:58

13 You can answer.

14 THE WITNESS: These documents only mention his
15 graduation from Columbia Medical School and his work
16 with Frederick Alt. I don't know any additional
17 information about the question you ask.

10:26:14

18 BY MR. SALMEN:

19 Q. And you never inquired whether Yancopoulos
20 was a licensed ophthalmologist with firsthand
21 experience of diagnosing and treating angiogenic eye
22 disorders; right?

10:26:32

23 A. Can you repeat the question.

24 Q. You never inquired whether George
25 Yancopoulos was a licensed ophthalmologist with

10:26:49

1 firsthand experience of diagnosing and treating

10:26:52

2 angiogenic eye disorders; right?

3 A. I never inquired about that topic.

4 MR. SALMEN: Okay. We can take a break.

5 THE VIDEOGRAPHER: We're going off the record.

10:27:03

6 The time is 10:27.

7 (Recess taken.)

8 THE VIDEOGRAPHER: We're back on the record.

9 The time is 10:43.

10 MR. SALMEN: Counsel, we're going to ask on the

10:43:36

11 record for a copy of George Yancopoulos' CV, if we

12 can get that produced immediately.

13 MS. FISHMAN: Why don't you put your request in

14 writing and I'll take it under advisement.

15 MR. SALMEN: Okay.

10:43:52

16 BY MR. SALMEN:

17 Q. Dr. Do, let's look back at your

18 declaration, paragraph 87, please.

19 In paragraph 87, you state, "It is my

20 opinion that 'tertiary doses' mean doses

10:44:14

21 administered after the initial and secondary doses,

22 that maintain the efficacy gain achieved after the

23 initial and secondary doses."

24 Do you see that?

25 A. Yes, I see that sentence.

10:44:32

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1 Q. Sitting here today, this is how you define
2 the claim term "tertiary dose" in the context of the
3 '338 patent; correct?

10:44:34

4 A. Yes, that's correct.

5 Q. You're not going to make any changes to
6 this definition; correct?

10:44:47

7 A. I'm not making any changes.

8 Q. And this is the definition that you
9 applied in forming your opinions regarding the '338
10 patent claims; correct?

10:44:58

11 A. That is correct.

12 Q. You understand that Dr. Albini presented a
13 definition for the claim term "tertiary dose"?

14 A. Yes, I am aware of that.

15 Q. And you disagree with Dr. Albini's
16 proposed definition for the claim term "tertiary
17 dose" as it appears in the '338 patent claims; is
18 that correct?

10:45:18

19 A. Can you remind me of what Dr. Albini
20 stated in his deposition?

10:45:35

21 Q. I'll direct your attention to -- that's an
22 interesting question, Dr. Do.

23 You do not cite Dr. Albini's deposition
24 transcript anywhere in your declaration, do you?

25 A. Which statement are you referring to?

10:46:13

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1 Q. I'm referring to the entire document, your
2 declaration.

10:46:14

3 You asked me for where does Dr. Albini
4 testify about "tertiary dose" in his deposition.

5 You do not cite his deposition transcript
6 anywhere in your declaration, do you?

10:46:26

7 A. In my declaration, I do refer -- for
8 example, in paragraph 89, I state, "Dr. Albini
9 states that a skilled artisan would understand the
10 term 'tertiary doses' as used in the claims of the
11 '338 patent."

10:47:02

12 Q. But I want to make sure we're clear on
13 what we're talking about here.

14 You reviewed Dr. Albini's declaration in
15 this proceeding, a written document that he
16 prepared; correct?

10:47:16

17 A. I believe I did, but I would need the
18 document to refresh my memory.

19 Q. You cite to it here, Exhibit -- what you
20 read, Exhibit 1002, "Albini declaration."

10:47:32

21 That's the document you reviewed; correct?

22 A. Yes, I cite that in paragraph 88.

23 Q. Okay. You understand that Dr. Albini was
24 deposed in this proceeding; correct?

25 A. Correct.

10:47:51

1 Q. And I asked you earlier whether or not you 10:47:53
2 reviewed the transcript of that deposition.

3 Do you recall that?

4 A. I do recall.

5 Q. So did you review the deposition 10:48:02
6 transcript from Dr. Albini's deposition?

7 A. I reviewed his declaration.

8 Q. So you did not review the deposition
9 transcript.

10 A. Correct. 10:48:17

11 Q. So in paragraph 89 is where you state,
12 "Dr. Albini states that a skilled artisan would
13 understand the term 'tertiary dose' as used in the
14 claims of the '338 patent based solely on the
15 following passage from the '338 patent 10:48:40
16 specification."

17 Do you see that?

18 A. I see that sentence.

19 Q. And then you provide the passage, which is
20 Column 3, lines 31 to 45, of the '338 patent; 10:48:50
21 correct?

22 A. That is correct.

23 Q. And you disagree with how Dr. Albini
24 defines the claim term "tertiary dose"; correct?

25 (Witness reviews document.) 10:49:43

1 A. I stated in my declaration that "I
2 understand that 'tertiary doses' require that the
3 efficacy gain achieved from the initial and
4 secondary doses are maintained after the initial and
5 secondary doses."

10:49:46

10:49:59

6 Q. So you disagree with Dr. Albini's
7 definition; correct?

8 A. Can you remind me of Dr. Albini's
9 definition?

10 Q. It's stated right in the part of the
11 specification that you reference in your
12 declaration. "The tertiary doses are the doses
13 which are administered after the secondary doses."

10:50:15

14 A. Which paragraph are you referring to?

15 Q. Dr. Do, I'm referring to your declaration,
16 paragraph 89. You provide an insert there, which is
17 a callout from Column 3, lines 31 to 45, of the '338
18 patent specification.

10:50:33

19 Are you there?

20 A. Yes, I am.

10:50:53

21 Q. In the middle of that section, it states,
22 "The 'tertiary doses' are the doses which are
23 administered after the secondary doses."

24 Do you see that?

25 A. Yes.

10:51:05

1 Q. Do you agree with that definition for the
2 claimed term "tertiary doses"?

10:51:06

3 A. As I stated in my declaration, I believe
4 the tertiary dose requires that it maintains the
5 efficacy achieved from the initial and secondary
6 doses.

10:51:26

7 Q. And your definition is set forth in 87,
8 paragraph. And that is not the same as what I just
9 read from the patent specification; correct?

10 A. In my declaration, "It is my opinion that
11 the 'tertiary dose(s)' means 'dose(s)' administered
12 after the initial and secondary doses, that
13 maintain(s) the efficacy gain achieved after the
14 initial and secondary doses."

10:51:45

15 Q. Okay. This paragraph from Column 3 of the
16 '338 patent specification refers to the terms
17 "initial dose" and "secondary doses"; is that
18 correct?

10:52:08

19 A. The paragraph uses the terms "initial
20 dose" and "secondary doses."

10:52:27

21 Q. And you see that the paragraph provides a
22 definition for the claim term "initial dose";
23 correct?

24 MS. FISHMAN: Objection; calls for a legal
25 conclusion.

10:52:41

1 But you can answer.

10:52:42

2 THE WITNESS: The document states, "The
3 'initial dose' is the dose which is administered at
4 the beginning of the treatment regimen."

5 BY MR. SALMEN:

10:52:53

6 Q. Okay. You agree with that definition for
7 the claim term "initial dose"?

8 MS. FISHMAN: Objection; outside the scope.

9 But you can answer.

10 THE WITNESS: In my declaration, I did not
11 provide an opinion on the definition of the initial
12 dose. However, in my --

10:53:07

13 BY MR. SALMEN:

14 Q. Can I address that? Because you actually
15 do comment on "initial dose" in paragraph 92 of your
16 declaration.

10:53:21

17 You state, "I agree with Dr. Albini that
18 the passage at Column 3, lines 31 to 45 (quoted
19 above) informs the temporal sequence of initial
20 dose, second dose and tertiary dose."

10:53:38

21 MS. FISHMAN: Is there a question, Counsel?

22 BY MR. SALMEN:

23 Q. Do you see that?

24 A. I see that statement.

25 Q. Sitting here today, do you disagree with

10:53:51

1 how the term "initial dose" is used in the '338

10:53:54

2 patent specification?

3 A. As I stated in my declaration, I did not
4 provide a definition or opinion on the definition of
5 an initial dose. Where you referenced paragraph 92,
6 I simply stated that it informs the temporal
7 sequence of initial dose, secondary dose and
8 tertiary dose.

10:54:12

9 Q. But you use the terms "initial dose" and
10 "secondary dose" in your definition of "tertiary
11 dose"; correct? In paragraph 87.

10:54:33

12 A. In paragraph 87 in my declaration, I state
13 that "It is my opinion that the 'tertiary dose(s)'
14 means 'dose(s)', administered after the initial and
15 secondary doses, that maintain(s) the efficacy gain
16 achieved after the initial and secondary doses."

10:55:00

17 Q. So you use the term "initial" and
18 "secondary doses" in your definition of "tertiary
19 dose"; correct?

20 A. I do use the terms "initial" and
21 "secondary doses" in relation to maintaining the
22 efficacy gains achieved after those initial and
23 secondary doses in relation to the tertiary dose.

10:55:15

24 Q. Sitting here today, do you agree that the
25 initial dose in the method of treating covered by

10:55:38

1 the '338 patent claims is the dose which is
2 administered at the beginning of the treatment
3 regimen, also referred to as the baseline dose?

10:55:45

4 A. In my experience, in relation to this '338
5 patent, the initial dose is the dose which is
6 administered at the beginning of the treatment
7 regimen that begins to provide efficacy for the
8 method of treatment.

10:56:10

9 Q. Where do you state that opinion in your
10 declaration?

10:56:40

11 MS. FISHMAN: Objection; lacks foundation.

12 But you can answer.

13 THE WITNESS: In my declaration, in
14 paragraph 87, I state that "It is my opinion that
15 the 'tertiary dose(s)' means 'dose(s)', administered
16 after the initial and secondary doses, that
17 maintain(s) the efficacy gain achieved after the
18 initial and secondary doses."

10:56:56

19 BY MR. SALMEN:

20 Q. Where do you provide the definition of
21 "initial dose" that you just gave me?

10:57:12

22 MS. FISHMAN: Objection; mischaracterizes
23 testimony and lacks foundation.

24 But you can answer.

25 MR. SALMEN: I'll strike the question.

10:57:30

1 BY MR. SALMEN:

10:57:31

2 Q. Let me address your attorney's objection.

3 Are you providing a definition for the
4 claim term "initial dose" sitting here today?

5 A. Again, in my declaration, I did not
6 provide a definition on "initial dose."

10:57:41

7 Q. And sitting here today, you're not
8 providing a definition for the claim term "secondary
9 dose"; correct?

10 A. Again, in my declaration, I did not
11 provide an opinion on the definition of "secondary
12 dose."

10:57:53

13 Q. Let's look where this appears in the '338
14 patent specification, Column 3.

15 I'm going to direct your attention to the
16 paragraph directly under -- beginning at lines -- at
17 line 46.

10:58:34

18 Do you see that?

19 A. What are the words of the paragraph you're
20 referring to?

10:58:54

21 Q. The paragraph begins "In one exemplary
22 embodiment of the present invention."

23 Do you see that?

24 A. Yes, I see that.

25 Q. And about halfway down that paragraph, the

10:59:02

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1 inventor states, "The phrase 'the immediately
2 preceding dose', as used herein means, in a sequence
3 of multiple administrations, the dose of VEGF
4 antagonist which is administered to a patient prior
5 to the administration of the very next dose in the 10:59:23
6 sequence with no intervening doses."

7 Do you see that?

8 A. I see that statement.

9 Q. Do you recognize the term "immediately
10 preceding dose" as a term that appears in the claims 10:59:39
11 of the '338 patent?

12 A. Can you repeat the question.

13 Q. Do you recognize the term "immediately
14 preceding dose" as a term that appears in the claims
15 of the '338 patent? 11:00:15

16 A. I don't recall that exact wording that was
17 used in the claims.

18 Q. Let's look at Claim 1, first wherein
19 clause, "wherein each secondary dose is administered
20 2 to 4 weeks after the immediately preceding dose." 11:00:42

21 Do you see that?

22 A. I see that phrase.

23 Q. Do you recognize the term "immediately
24 preceding dose" as a term that appears in the claims
25 of the '338 patent? 11:00:58

1 A. I see those three words, yes.

11:01:02

2 Q. It is a claim term of the '338 patent
3 claims; right?

4 MS. FISHMAN: Objection; calls for a legal
5 conclusion.

11:01:12

6 But you can answer.

7 THE WITNESS: I see the words "immediately
8 preceding dose."

9 BY MR. SALMEN:

10 Q. Sitting here today, you're not proposing
11 your own definition for the claim term "immediately
12 preceding dose"; correct?

11:01:18

13 A. In my declaration, I did not provide an
14 opinion or definition on "immediately preceding
15 dose."

11:01:34

16 Q. But you recognize in Column 3, beginning
17 at line 51, the inventor presented a definition for
18 the claim term "immediately preceding dose";
19 correct?

20 MS. FISHMAN: Objection; calls for a legal
21 conclusion.

11:01:48

22 But you can answer.

23 THE WITNESS: I see in that paragraph the words
24 "immediately preceding dose."

25 BY MR. SALMEN:

11:01:58

1 Q. It's more than that, though; right?

11:01:58

2 It says, "The phrase 'immediately
3 preceding dose', as used herein, means, in a
4 sequence of multiple administrations, the dose of
5 VEGF antagonist which is administered to a patient
6 prior to the administration of the very next dose in
7 the sequence, with no intervening doses"; correct?

11:02:14

8 A. I see that sentence.

9 Q. Okay. That's the definition that the
10 inventor provides for the claim term "immediately
11 preceding dose"; correct?

11:02:27

12 MS. FISHMAN: Objection; calls for a legal
13 conclusion.

14 You can answer.

15 THE WITNESS: I see that sentence written
16 there.

11:02:37

17 BY MR. SALMEN:

18 Q. That's the definition that the inventor is
19 providing for that claim term; correct?

20 MS. FISHMAN: Objection; asked and answered,
21 calls for a legal conclusion.

11:02:46

22 BY MR. SALMEN:

23 Q. If you disagree, it's fine.

24 But my question is, is that the definition
25 that the inventor is providing for the claim term

11:02:57

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1 "immediately preceding dose"?

11:03:02

2 MS. FISHMAN: Same objections.

3 You can answer.

4 THE WITNESS: As I read it, the sentence

5 states, "The phrase 'the immediately preceding

11:03:09

6 dose', as used herein, means, in a sequence of

7 multiple administrations, the dose of VEGF

8 antagonist which is administered to a patient prior

9 to the administration of the very next dose in the

10 sequence, with no intervening doses."

11:03:28

11 BY MR. SALMEN:

12 Q. Okay. Dr. Do, I asked you earlier if you

13 construed the claim terms of the '338 patent from

14 the vantage point of your skilled artisan at the

15 time of the effective filing date of the '338

11:04:01

16 patent.

17 Do you recall that?

18 A. Yes, I recall that.

19 Q. And your answer was, "Yes."

20 Do you recall that?

11:04:09

21 A. Yes, I recall that.

22 Q. So you construed these claims from the

23 vantage point of the skilled artisan, as you have

24 defined her; correct?

25 A. Yes, I have.

11:04:25

1 Q. Now, with respect to Claim 1, how did you
2 construe the claim term "immediately preceding
3 dose"?

11:04:26

4 MS. FISHMAN: Objection; asked and answered.

5 But you can answer.

11:04:40

6 THE WITNESS: Can you repeat the question.

7 BY MR. SALMEN:

8 Q. How did you construe the claim term
9 "immediately preceding dose"?

10 A. Which line sentence are you referring to?

11:05:14

11 Q. Claim 1.

12 (Witness reviews document.)

13 Q. Let me ask a different question, Dr. Do.

14 Did you apply the definition that appears
15 in Column 3, lines 51 to 56, for the claim term
16 "immediately preceding dose" in your construction of
17 the -- of Claim 1 for the '338 patent?

11:05:52

18 MS. FISHMAN: Objection; lacks foundation,
19 vague.

20 THE WITNESS: Can you rephrase the question. I
21 don't understand.

11:06:14

22 BY MR. SALMEN:

23 Q. Sure.

24 The term "immediately preceding dose"
25 appears in Claim 1; correct?

11:06:19

1 A. Correct.

11:06:21

2 Q. And you've already testified that you are
3 not proposing your own definition for the claim term
4 "immediately preceding dose"; is that correct?

5 A. Correct.

11:06:37

6 Q. Okay. Now, my question is, did you apply
7 the definition that George Yancopoulos presents in
8 Column 3, lines 51 to 56, with regard to the
9 "immediately preceding dose" as that claim term
10 appears in Claim 1?

11:06:59

11 MS. FISHMAN: Objection; calls for a legal
12 conclusion, lacks foundation and incomplete
13 question.

14 You can answer.

15 THE WITNESS: In my declaration, I did not
16 provide an opinion on the definition of "immediately
17 preceding dose." However, as an ophthalmologist and
18 thinking as a skilled artisan, I would say that, in
19 the context of the '338 patent, "It is my opinion
20 that a 'tertiary dose' means doses administered
21 after the initial and secondary doses and it
22 maintains the efficacy gain achieved after the
23 initial and secondary doses."

11:07:10

11:07:38

24 MR. SALMEN: Okay. I'm going to move to strike
25 that as nonresponsive.

11:07:55

1 BY MR. SALMEN:

11:07:58

2 Q. Dr. Do, that does not answer my question.
3 I was not asking you about the "tertiary dose"
4 definition.

5 There is a claim term "immediately
6 preceding dose"; correct?

11:08:07

7 A. Correct.

8 Q. And the inventors of the '338 patent
9 address the term "immediately preceding dose" in
10 lines 51 to 56 of the '338 patent specification;
11 correct?

11:08:21

12 A. I see that.

13 Q. And you agreed earlier today that you
14 construed the claim terms of the '338 patent from
15 the vantage point of your skilled artisan at the
16 time of the effective filing date of the '338
17 patent; correct?

11:08:35

18 MS. FISHMAN: Objection; misstates testimony.

19 MR. SALMEN: It doesn't.

20 THE WITNESS: Can you repeat the question.

11:08:48

21 BY MR. SALMEN:

22 Q. Yes.

23 Earlier today you confirmed that you
24 construed the claim terms of the '338 patent from
25 the vantage point of your skilled artisan at the

11:08:55

1 time of the effective filing date of the '338

11:08:58

2 patent; correct?

3 MS. FISHMAN: Same objection.

4 You can answer.

5 THE WITNESS: I am viewing this in the eyes of

11:09:07

6 a skilled artisan.

7 BY MR. SALMEN:

8 Q. Okay. So how did you construe the claim

9 term "immediately preceding dose" as it appears in

10 Claim 1 of the '338 patent?

11:09:24

11 MS. FISHMAN: Objection; lacks foundation,

12 beyond the scope and asked and answered.

13 THE WITNESS: I think I already answered that

14 question.

15 BY MR. SALMEN:

11:09:36

16 Q. No, you didn't.

17 Let me ask a new question.

18 You're not proposing a definition for the

19 claim term "immediately preceding dose"; correct?

20 A. As I stated in my declaration, I did not

11:09:57

21 provide an opinion on the definition of "immediately

22 preceding dose."

23 Q. Let's look at Column 3, lines 19 to 30.

24 Beginning at line 20, the sentence reads

25 "The methods of the invention comprise sequentially

11:10:33

1 administering to a patient multiple doses of a VEGF
2 antagonist."

11:10:37

3 Do you see that?

4 A. I see that sentence.

5 Q. You recognize the term "sequentially
6 administering" as a claim term of the '338 patent
7 claims; correct?

11:10:47

8 A. I do see those words.

9 Q. Specification goes on to state, "As used
10 herein, 'sequentially administering' means that each
11 dose of VEGF antagonist is administered to the
12 patient at a different point in time, e.g., on
13 different days separated by predetermined -- a
14 predetermined interval (e.g., hours, days, weeks or
15 months)."

11:11:00

11:11:22

16 Do you see that?

17 A. I see those words.

18 Q. Sitting here today, you are not proposing
19 a definition for the claim term "sequentially
20 administering"; correct?

11:11:33

21 A. In my declaration, I did not provide an
22 opinion on the definition.

23 Q. You did form an opinion regarding the
24 meaning and scope of the method of treating that's
25 covered by the '338 patent claims; correct?

11:11:52

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1 A. That is correct.

11:11:54

2 Q. And in forming that opinion, did you apply
3 this definition for the claim term "sequentially
4 administering" that appears in the specification at
5 Column 3, lines 22 to 26?

11:12:09

6 MS. FISHMAN: Objection; lacks foundation, also
7 calls for a legal conclusion.

8 But you can answer.

9 THE WITNESS: Can you repeat the question.

10 BY MR. SALMEN:

11:12:28

11 Q. You agreed that you formed an opinion
12 regarding the meaning and scope of the method of
13 treating that's covered by the '338 patent claims;
14 correct?

15 A. Can you rephrase the question. I don't
16 understand it.

11:12:43

17 MR. SALMEN: No.

18 Can you read the question and answer
19 beginning at line 5.

20 (Record read by reporter as follows:

11:13:02

21 "Question: You did form an opinion
22 regarding the meaning and scope of the
23 method of treating that's covered by the
24 '338 patent claims; correct?

25 "Answer: That is correct.

11:11:53

1 "Question: And in forming that opinion,
2 did you apply this definition for the
3 claim term 'sequentially administering'
4 that appears in the specification at
5 Column 3, lines 22 to 26?.")

11:11:57

11:12:09

6 MS. FISHMAN: Same objection.

7 You can answer.

8 THE WITNESS: In my declaration, I did state
9 that "The POSA would consider the clinical method of
10 treatment as one that achieves a high level of
11 efficacy that is non-inferior to the standard of
12 care at the time of the patent filing."

11:14:17

13 BY MR. SALMEN:

14 Q. What paragraph are you reading from from
15 your declaration?

11:14:30

16 A. Paragraph 84, page 32.

17 MR. SALMEN: I'm going to again move to have
18 that testimony stricken as being nonresponsive.

19 BY MR. SALMEN:

20 Q. Dr. Do, my question was specific to the
21 claim term "sequentially administering."

11:14:42

22 You recognize the term "sequentially
23 administering" as a claim term that appears in the
24 '338 patent claims; correct?

25 A. That is correct.

11:14:59

1 Q. And you formed an opinion regarding the
2 meaning and scope of the method of treating that is
3 covered by Claim 1 of the '338 patent; correct?

11:15:03

4 A. Can you repeat the question.

5 Q. It's the same question that I asked
6 before.

11:15:22

7 You formed an opinion regarding the
8 meaning and scope of the method of treating that is
9 covered by Claim 1 of the '338 patent; correct?

10 A. That is correct.

11:15:33

11 Q. In forming that opinion, did you apply the
12 definition for the claim term "sequentially
13 administering" that appears in Column 3, lines 22 to
14 26?

15 MS. FISHMAN: Objection; calls for a legal
16 conclusion, lacks foundation.

11:15:52

17 You can answer.

18 THE WITNESS: In my experience, the claim deals
19 with initial, secondary and tertiary doses, which
20 are given sequentially to maintain a high level of
21 efficacy.

11:16:12

22 BY MR. SALMEN:

23 Q. You do not provide your own definition of
24 the claim term "sequentially administering" in
25 forming your opinions regarding the scope and

11:16:28

1 meaning of the method of treating that's covered by

11:16:30

2 Claim 1; correct?

3 A. I did not provide my own definition. I

4 simply understood it in the eyes of a POSA.

5 Q. And your understanding in the eyes of a

11:16:59

6 POSA regarding the claim term "sequentially

7 administering," is that the same or different as the

8 definition that's provided in Column 3 at lines 22

9 to 26?

10 A. In my experience and thinking as a POSA,

11:17:21

11 the sequentially administered initial, secondary and

12 tertiary doses at the time of the patent filing

13 would, in the eyes of the POSA, require a high level

14 of efficacy in this context.

15 Q. Okay. So the claim term here,

11:17:48

16 "sequentially administering," as George Yancopoulos

17 defined it in Column 3, lines 22 to 26, make no

18 mention of efficacy; correct?

19 MS. FISHMAN: Objection; document speaks for

20 itself and calls for a legal conclusion.

11:18:07

21 You can answer.

22 THE WITNESS: Can you remind me which lines --

23 BY MR. SALMEN:

24 Q. Column 3, lines 22 to 26.

25 (Witness reviews document.)

11:18:34

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1 A. I agree that the word "efficacy" is not
2 explicitly written in this line. However, the POSA,
3 in the context of the patent and the standard of
4 care, would understand that sequentially
5 administered doses, referring to initial, secondary
6 and tertiary doses, would at that time require a
7 high level of efficacy.

11:18:36

8 Q. Okay. So let me recap.

9 Sequentially administering doses, in your
10 opinion, require a high level of efficacy; is that
11 correct?

11:19:16

12 MS. FISHMAN: Objection; misstates testimony
13 and outside the scope.

14 You can answer.

15 THE WITNESS: As I stated in my declaration, in
16 the context of this patent, the doses, particularly
17 the tertiary dose and the initial and secondary
18 doses, require a high level of efficacy.

11:19:28

19 BY MR. SALMEN:

20 Q. Okay. So the initial dose requires a high
21 level of efficacy, as that claim term is used in the
22 '338 patent claims?

11:19:50

23 MS. FISHMAN: Objection; beyond the scope.

24 You can answer.

25 MR. SALMEN: It's not beyond the scope,

11:20:01

1 Counsel. This all goes down to -- it's fundamental
2 to her opinions. I'll ask it again.

11:20:03

3 BY MR. SALMEN:

4 Q. The initial dose, in your opinion,
5 requires a high level of efficacy as that claim term
6 is used in the '338 patent claims?

11:20:11

7 MS. FISHMAN: Same objection.

8 But you can answer.

9 THE WITNESS: Although I did not provide an
10 opinion -- an opinion on initial dose in my
11 declaration, in my experience in the context of this
12 patent claim filing in the time period and taking
13 into account the standard of care in 2011, the
14 tertiary dose would require to maintain a high level
15 of efficacy. In addition, the initial and secondary
16 doses should also provide a high level of efficacy.

11:20:29

11:20:56

17 BY MR. SALMEN:

18 Q. Okay. So it's your opinion that the
19 initial dose requires a high level of efficacy;
20 correct?

11:21:11

21 MS. FISHMAN: Misstates her testimony.

22 But you can answer.

23 Let me clarify my objection. Beyond the
24 scope.

25 You can answer.

11:21:22

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1 THE WITNESS: In my experience, at that time
2 period, the standard of care was requiring a high
3 level of efficacy and therefore initial and
4 secondary and tertiary doses should also have a high
5 level of efficacy.

11:21:23

11:21:43

6 BY MR. SALMEN:

7 Q. So all of the doses listed in the '338
8 patent claims, the initial dose, the secondary dose
9 and the tertiary dose, in your opinion, require a
10 high level of efficacy; correct?

11:21:58

11 MS. FISHMAN: Again outside the scope.

12 But you can answer.

13 THE WITNESS: In my declaration, I provide an
14 opinion specifically on the tertiary dose. But in
15 my experience, as you're asking, one would also
16 expect the initial and secondary doses to provide a
17 high level of efficacy.

11:22:19

18 BY MR. SALMEN:

19 Q. Let me ask a question regarding your
20 counsel's objection.

11:22:33

21 Do you believe that whether initial dose
22 and secondary dose require efficacy is outside the
23 scope of your opinions in your declaration?

24 MS. FISHMAN: Objection; calls for a legal
25 conclusion.

11:22:48

1 But you can answer.

11:22:49

2 THE WITNESS: Again, in my declaration, I
3 specifically provide an opinion on tertiary doses.

4 BY MR. SALMEN:

5 Q. And in that definition, in your opinion,
6 of "tertiary dose," you include the initial and
7 secondary doses; correct? You make reference to
8 those?

11:22:59

9 A. In paragraph 87 in my declaration, I state
10 that "It is my opinion that the 'tertiary dose(s)'
11 means 'dose(s)', administered after the initial and
12 secondary doses, that maintain(s) the efficacy gain
13 achieved after the initial and secondary doses."

11:23:13

14 Q. You read that perfectly.

15 A. Thank you.

11:23:32

16 Q. The initial dose that you use in your
17 definition of "tertiary dose," does that require
18 highly effective treatment?

19 A. Based on what I stated in paragraph 87,
20 the initial and secondary doses would require
21 efficacy.

11:23:52

22 Q. Okay. And you don't provide that opinion
23 anywhere in your declaration, though; is that
24 correct?

25 A. I stated what I wrote here.

11:24:06

1 Q. Let's look at the term "efficacy."

11:24:09

2 Now, you reviewed all the claims of the
3 '338 patent prior to coming to the deposition today;
4 correct?

5 A. Correct.

11:24:34

6 Q. Do you agree that the term "efficacy" does
7 not expressly appear in any of those claims?

8 A. Which lines are you referring to?

9 Q. All of them. We can start at Claim 1 of
10 the '338 patent.

11:24:59

11 Does the word "efficacy" appear anywhere
12 expressly in Claim 1?

13 A. Although the word "efficacy" is not
14 literally written in Claim 1, at this time period of
15 2011, a method for treating an angiogenic eye
16 disorder does require a high level of efficacy
17 because the standard of care had changed and
18 required treating angiogenic eye disorders with
19 medicines that provided a high level of efficacy in
20 regards to visual acuity gained or maintenance.

11:25:21

11:25:47

21 Q. Does the patent itself describe the
22 standard of care that you just stated prior to
23 January 2011?

24 A. Let me review the patent.

25 Q. I'll withdraw the question. Let me ask

11:26:16

1 you a different question.

11:26:20

2 Would you be surprised that the phrase
3 "standard of care" appears nowhere in the '338
4 patent?

5 A. I could be surprised.

11:26:36

6 Q. Okay. Let's look at your paragraph 69 of
7 your declaration.

8 In paragraph 69, you refer to "treatment
9 population and efficacy" as it appears in the '338
10 patent specification at Column 7, line 15.

11:27:09

11 Do you see that?

12 A. I see that sentence.

13 Q. If we look at that section of the patent,
14 Exhibit 1001, Column 7, starting at line 15 -- and
15 you specifically quote and cite Column 7, lines 24
16 to 26, I believe.

11:27:33

17 Do you see that?

18 A. Yes, I see that.

19 Q. You state, "The passage refers to methods
20 for treating angiogenic eye disorders such as AMD,
21 CRVO and DME"; correct?

11:27:48

22 A. Yes, that is correct.

23 Q. Now, the passage in the patent reads, "In
24 the context of methods for treating angiogenic eye
25 disorders such as AMD, CRVO and DME, 'efficacy'

11:28:08

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1 means that, from the initiation of treatment, the
2 patient exhibits a loss of 15 or fewer letters on
3 the Early Treatment Diabetic Retinopathy Study
4 (ETDRS) visual acuity chart"; is that correct?

11:28:15

5 A. That is what that sentence states.

11:28:34

6 Q. The next sentence reads, "In certain
7 embodiments, 'efficacy' means a gain of one or more
8 (e.g., 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11 or more)
9 letters on the ETDRS chart from the time of
10 initiation of treatment."

11:28:58

11 Do you see that?

12 A. I see that sentence.

13 Q. You agree that the inventor of the '338
14 patent is providing a definition for the term
15 "efficacy" here?

11:29:10

16 MS. FISHMAN: Objection; lacks foundation.
17 Pardon me. Calls for a legal conclusion.

18 You can answer.

19 THE WITNESS: Can you repeat the question.

20 BY MR. SALMEN:

11:29:22

21 Q. You agree that the inventor of the '338
22 patent is providing a definition for the term
23 "efficacy" here?

24 MS. FISHMAN: Objection; lacks foundation and
25 calls for a legal conclusion.

11:29:35

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1 You can answer.

11:29:37

2 THE WITNESS: At the time of the patent filing,
3 the POSA would understand that "efficacy" in the
4 treatment of angiogenic eye disorders referred to a
5 gain or maintenance of visual acuity after treatment
6 of certain medicine.

11:29:51

7 BY MR. SALMEN:

8 Q. That was not my question, Dr. Do.

9 MR. SALMEN: I'm going to again move to have it
10 stricken as nonresponsive.

11:30:02

11 BY MR. SALMEN:

12 Q. My question was, referring to the section
13 of the '338 patent which you cite in your
14 declaration, lines 15 to 32 of Column 7, do you
15 agree that the inventor is providing a definition
16 for the term "efficacy" here?

11:30:20

17 A. In that paragraph, the skilled artisan
18 reviewing those words would understand that those
19 lines refer to clinical trial endpoints, such as the
20 loss of 15 or fewer ETDRS letters.

11:30:47

21 Q. So do you disagree with my question that
22 this is where the inventor provides a definition for
23 the term -- the claim term "efficacy"?

24 MS. FISHMAN: Objection; vague.

25 THE WITNESS: In my experience, I interpret

11:31:10

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1 this statement as referring to clinical trial

11:31:14

2 endpoints. And I believe the person of ordinary
3 skill in the art would also interpret it the same
4 way.

5 BY MR. SALMEN:

11:31:29

6 Q. Okay. So, again, in your definition of
7 "tertiary dose," which you provide as "doses
8 administered after the initial and secondary doses
9 that maintain the efficacy gain achieved after the
10 initial and secondary doses," are you using the
11 inventor's definition of "efficacy" as it's set
12 forth in Column 7, lines 15 to 32?

11:31:48

13 MS. FISHMAN: Objection; lacks foundation.

14 You can answer.

15 THE WITNESS: In my declaration, when I talk
16 about tertiary doses maintaining the high level of
17 efficacy achieved after the initial and secondary
18 doses, I'm referring to "efficacy" as how the POSA
19 would understand it at that time period, which is
20 gain of vision or maintenance of vision.

11:32:15

11:32:34

21 BY MR. SALMEN:

22 Q. So the answer to my question is, no, you
23 are not using the definition of "efficacy" as it
24 appears in Column 7, lines 15 to 32, in your
25 construction of the claim term "tertiary dose" where

11:32:51

1 you use "efficacy"?

11:32:55

2 MS. FISHMAN: Objection; mischaracterizes the
3 patent, calls for a legal conclusion, lacks
4 foundation.

5 But you can answer.

11:33:01

6 THE WITNESS: In my opinion, I am looking at
7 this through the eyes of a POSA and understanding
8 that "efficacy" would mean at that time something
9 that is non-inferior to the standard of care. And
10 the standard of care at that time required a high
11 level of efficacy in terms of gaining vision or
12 maintaining vision.

11:33:28

13 BY MR. SALMEN:

14 Q. Are you suggesting that George Yancopoulos
15 didn't know what the standard of care was as of
16 January 2011?

11:33:43

17 MS. FISHMAN: Objection; misstates testimony
18 and calls for speculation.

19 You can answer.

20 THE WITNESS: In my declaration, I did not give
21 an opinion on what George Yancopoulos knew.

11:33:52

22 BY MR. SALMEN:

23 Q. Because he states, at Column 7, beginning
24 at line 24, that "In the context of methods of
25 treating angiogenic eye disorders such as AMD, CRVO

11:34:10

1 and DME, 'efficacy' means that, from the initiation
2 of treatment, the patient exhibits a loss of 15 or
3 fewer letters on the ETDRS visual acuity chart";
4 right?

11:34:15

5 MS. FISHMAN: Objection; document speaks for
6 itself, incomplete.

11:34:30

7 You can answer.

8 BY MR. SALMEN:

9 Q. That's what it says?

10 A. I see what is written there.

11:34:35

11 Q. But your definition of "efficacy" as you
12 apply it in -- with respect to "tertiary doses"
13 further requires a gain of visual acuity; is that
14 right?

15 A. A skilled artisan at that time would
16 understand that "efficacy" required a high level of
17 either vision gain or maintenance of vision based on
18 the standard of care at that time.

11:34:52

19 Q. You see here, in Column 7, George
20 Yancopoulos refers to "In certain embodiments,
21 'efficacy' means a gain of one or more letters on
22 the ETDRS chart from the time of initiation of
23 treatment."

11:35:30

24 Do you see that?

25 A. I see those words.

11:35:45

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1 Q. So you understand that your definition for
2 the term "tertiary dose" then is only applicable to
3 those certain embodiments that he is referring to in
4 Column 7, lines 29 to 32, of the '338 patent?

11:35:47

5 MS. FISHMAN: Objection; lacks foundation,
6 calls for a legal conclusion.

11:36:07

7 THE WITNESS: I mention that the POSA would
8 understand that the lines 25 through 32 in Column 7
9 refer to clinical trial endpoints.

10 BY MR. SALMEN:

11:36:33

11 Q. Is it your opinion then that clinical
12 trial methods of treating are not covered by the
13 claims of the '338 patent?

14 MS. FISHMAN: Objection; vague, lacks
15 foundation.

11:36:45

16 THE WITNESS: I don't understand that question.
17 Can you rephrase that.

18 BY MR. SALMEN:

19 Q. I'm having trouble understanding your
20 testimony.

11:36:52

21 MS. FISHMAN: Is there a question?

22 BY MR. SALMEN:

23 Q. Are clinical trials -- here. Let's look
24 at Example 4 of the '338 patent.

25 That reports the Phase 3 clinical trial

11:37:09

1 results; correct?

11:37:12

2 A. That is correct.

3 Q. And if we look at Table 1, one of the arms
4 of this clinical trial was VEGF-Trap 2 milligrams
5 every eight weeks, otherwise known as "2Q8" dosing.

11:37:36

6 Do you see that?

7 A. I see Table 1.

8 Q. Okay. This reports the clinical trial
9 endpoints for that -- for all of the arms of this
10 particular trial; right?

11:38:11

11 MS. FISHMAN: Objection; vague.

12 (Witness reviews document.)

13 THE WITNESS: Table 1 lists certain outcomes of
14 the clinical trials.

15 BY MR. SALMEN:

11:38:37

16 Q. All right. Let's come back to that.

17 I want to go back to Column 3, lines 31 to
18 45. This is where the inventor discusses the terms
19 "initial dose," "secondary doses" and "tertiary
20 doses."

11:39:18

21 Do you see that?

22 A. Yes, I see that.

23 Q. And, again, it's your opinion that in
24 order for a dose to qualify as a tertiary dose, it
25 must maintain the efficacy gain achieved after the

11:39:30

1 initial and secondary doses; is that correct?

11:39:34

2 A. That is correct.

3 Q. In that paragraph where the inventor is

4 describing the terms "initial dose," "secondary

5 doses" and "tertiary doses," the '338 patent

11:39:52

6 specification provides no parameters to a person of

7 ordinary skill in the art to understand what the

8 efficacy gains of the initial dose is; do you agree

9 with that?

10 A. Can you repeat the question.

11:40:13

11 Q. Sure.

12 It's your opinion that the tertiary dose

13 must maintain the efficacy gained after the initial

14 dose; is that right?

15 MS. FISHMAN: Objection; misstates her

11:40:36

16 testimony.

17 THE WITNESS: Let me --

18 BY MR. SALMEN:

19 Q. Paragraph 87.

20 A. Thank you.

11:40:46

21 In my declaration, I state that "It is my

22 opinion that the 'tertiary dose(s)' means 'dose(s)',

23 administered after the initial and secondary doses,

24 that maintain(s) the efficacy gain achieved after

25 the initial and secondary doses."

11:41:04

1 Q. Okay. So that suggests that there are
2 efficacy gains after the initial dose; correct?

11:41:06

3 A. It states that there are efficacy gains
4 achieved after the initial and secondary doses.

5 Q. Okay. The '338 patent specification
6 describes the terms "initial dose," "secondary dose"
7 and "tertiary dose" in Column 3.

11:41:21

8 Nowhere in that section does it inform a
9 person of ordinary skill in the art what -- how to
10 identify the efficacy gains of the initial and
11 secondary doses, does it?

11:41:45

12 A. The word "efficacy" is not explicitly
13 written in that paragraph, but the skilled artisan
14 would understand, in the context of the standard of
15 care at that time, that method of treatment using
16 initial, secondary and tertiary doses would require
17 a high level of efficacy based on the standard of
18 care.

11:42:09

19 Q. Okay. Let's look at Example 4 again.
20 Column 9, about two-thirds of the way down, there's
21 a reference to the "Study Design."

11:42:30

22 Do you see that?

23 A. Which line?

24 Q. Column 9, beginning around line 45.

25 A. Yes, I see that.

11:42:47

1 Q. That describes the various arms of the 11:42:48
2 clinical trial; right?

3 A. Yes.

4 Q. And I believe what's described here as Arm
5 No. 3 was, quote, "2 milligrams VEGF-Trap 11:43:00
6 administered every 4 weeks to week 8 and then every
7 8 weeks (with sham injection at the interim 4-week
8 visits when study drug was not administered (2Q8)
9 [sic]."

10 Do you see that? 11:43:25

11 A. I see those words.

12 Q. Do you consider the 2Q8 arm of Example 4
13 to be a method of treating within the scope of
14 Claim 1 of the '338 patent?

15 MS. FISHMAN: Objection; vague as to time. 11:43:46

16 BY MR. SALMEN:

17 Q. Prior to January 2011, when this trial was
18 conducted.

19 MS. FISHMAN: Objection; calls for a legal
20 conclusion. 11:43:56

21 But you can answer.

22 THE WITNESS: Can you repeat the question.

23 BY MR. SALMEN:

24 Q. Sure.

25 Can I refer to this as "the 2Q8 arm" for 11:44:00

1 shorthand?

11:44:03

2 A. Yes.

3 Q. You'll understand what I'm referring to?

4 A. Yes.

5 Q. Okay. Do you consider the 2Q8 arm of the
6 Phase 3 clinical trial that's described in Example 4
7 as a "method for treating" within the scope of Claim
8 1 of the '338 patent?

11:44:07

9 MS. FISHMAN: Same objections.

10 THE WITNESS: And which time period are you
11 referring to?

11:44:28

12 BY MR. SALMEN:

13 Q. Any time period.

14 A. You mean 2022, 2000 --

15 Q. Would your answer be different for
16 different time periods?

11:44:39

17 A. I think it depends on what the standard of
18 care was at that time.

19 Q. I'm referring to the specific Example 4 as
20 it's written in the '338 patent. Okay. So we'll
21 start with January 2011. Okay?

11:44:53

22 A. Okay.

23 Q. So as of January 2011, do you consider the
24 2Q8 arm of the Phase 3 clinical trial that's set
25 forth in Example 4 to be a method of treating within

11:45:14

1 the scope of Claim 1 of the '338 patent?

11:45:20

2 A. I'm not sure I understand your question
3 because it's quite long. But speaking as an
4 ophthalmologist, prior to 2011, the standard of care
5 for angiogenic eye disorders was either Lucentis or
6 Avastin -- off-label Avastin. And those medicines
7 needed to be administered nearly every four weeks to
8 be highly efficacious.

9 Q. Okay. Let's look at the 2Q8 arm as it's
10 described here in the study design.

11:46:12

11 Again, "2 milligrams VEGF-Trap
12 administered every 4 weeks to week 8 and then every
13 8 weeks (with sham injection at the interim 4-week
14 visits when study drug was not administered (2Q8)
15 [sic]."

11:46:33

16 Do you see that?

17 A. I see that.

18 Q. And if we look at Table 1, the right-hand
19 column, you see the "2Q8"; correct?

20 A. Yes, I see that.

11:46:45

21 Q. So you agree that the right-hand column of
22 Table 1 is referring to the same arm that I just
23 read in the study design; right?

24 A. Yes.

25 Q. Okay. Now, with respect to Claim 1 of the

11:46:58

1 '338 patent, it requires "a method for treating an
2 angiogenic eye disorder in a patient."

11:47:03

3 A. Yes.

4 Q. So did the 2Q8 arm of Example 4 provide a
5 "method for treating an angiogenic eye disorder in a
6 patient"?

11:47:19

7 MS. FISHMAN: Objection; vague as to time.

8 THE WITNESS: Are you referring to -- which
9 time period again?

10 BY MR. SALMEN:

11:47:36

11 Q. When this trial was conducted.

12 A. So prior to the approval of EYLEA?

13 Q. When was this trial conducted?

14 A. Do you have the manuscript so I could look
15 at what time it was conducted? I don't recall the
16 exact dates.

11:47:53

17 Q. Well, the data is all here.

18 So prior to January 2011, was the 2Q8 arm
19 that's set forth in Example 4 of the '338 patent "a
20 method for treating an angiogenic eye disorder in a
21 patient," as that phrase is used in Claim 1?

11:48:15

22 MS. FISHMAN: Objection; calls for a legal
23 conclusion and vague as to time.

24 You can answer.

25 THE WITNESS: In my experience as an

11:48:31

ophthalmologist, prior to January 2011, in clinical practice, the standard of care was using either Lucentis or off-label Avastin for the treatment of angiogenic eye disorders. And those medicines,

Lucentis or Avastin, needed to be administered close to every four weeks to be efficacious.

BY MR. SALMEN:

Q. Um-hum.

A. Therefore, ophthalmologists were not using Lucentis or Avastin 2Q8 weeks.

Q. This is VEGF-Trap-Eye that I'm referring to in the 2Q8 arm; right?

A. Yes.

Q. Okay. So the 2Q8 arm of Example 4 which administered VEGF-Trap --

A. Um-hum.

Q. -- at an eight-week dosing regimen after three initial doses --

Right?

A. Yes.

Q. -- is that a method of treating an angiogenic eye disorder in a patient as set forth in Claim 1?

MS. FISHMAN: Objection; vague as to time.

THE WITNESS: In my experience, in the clinical

11:48:34

11:48:53

11:49:09

11:49:23

11:49:35

11:49:53

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1 trials of VIEW 1 and VIEW 2, they were evaluating
2 VEGF-Trap using the 2 milligrams every eight weeks
3 as a dosing regimen in the clinical trials.

11:49:55

4 BY MR. SALMEN:

5 Q. Is the answer then, yes, the 2Q8 arm of
6 Example 4 is a method of treating an angiogenic eye
7 disorder in a patient as set forth in Claim 1?

11:50:13

8 MS. FISHMAN: Objection; lacks foundation,
9 misstates witness' testimony and it's still vague as
10 to time.

11:50:30

11 THE WITNESS: Prior to January 2011, the
12 clinical trials -- one of the arms in the VIEW 1 and
13 VIEW 2 studies involved using VEGF-Trap 2 milligrams
14 given every eight weeks after a certain number of
15 initial, secondary and tertiary doses.

11:51:00

16 BY MR. SALMEN:

17 Q. So the -- strike that.

18 The 2Q8 arm of Example 4 included initial
19 doses; right -- or an initial dose; right?

20 A. Yes.

11:51:22

21 Q. It's in the study design.

22 A. Yes, that's correct.

23 Q. Okay. And the 2Q8 arm of Example 4
24 included secondary doses; is that correct?

25 A. Yes.

11:51:39

1 Q. And the 2Q8 arm of Example 4 in the '338 11:51:40
2 patent included tertiary doses; is that correct?

3 A. The sentence states that the "2 milligram
4 VEGF-Trap administered every 4 weeks to week 8 and
5 then every 8 weeks (with sham injections at the 11:52:11
6 interim 4-week visits [sic]."

7 Q. So my question was, the 2Q8 arm of
8 Example 4 in the '338 patent included tertiary
9 doses; is that correct?

10 A. I believe that the 2Q8-week dosing, as 11:52:46
11 described in this study design, do have tertiary
12 doses.

13 Q. How did you determine that? Let me
14 rephrase it.

15 How did you determine that the 2Q8 dosing 11:53:05
16 arm in Example 4 of the '338 patent includes
17 tertiary doses?

18 A. In looking at the study results and the
19 study design, I understood that the initial,
20 secondary and tertiary doses resulted in the high 11:53:42
21 level of efficacy in terms of vision improvement or
22 maintenance of vision. And, thus, I understood that
23 in this clinical trial, Phase 3 clinical trial, they
24 were evaluating --

25 Q. Okay. 11:54:10

1 A. -- this drug. 11:54:10

2 Q. So you were motioning towards Table 1 of
3 Example 4.

4 That reports 52-week results; right?

5 A. I believe it does. 11:54:21

6 Q. And only results at 52 weeks; is that
7 correct?

8 A. I would have to look at the manuscript to
9 refresh my memory.

10 Q. I'm referring to Table 1 of the '338 11:54:34
11 patent. The first row of results is "Maintenance of
12 vision (percent patients losing less than 15
13 letters) at week 52 versus baseline."

14 Do you see that?

15 A. I see that. 11:54:56

16 Q. Okay. Table 1 does not provide any data
17 at, for example, Week 8; is that correct?

18 A. I do not see the Week 8 data in Table 1.

19 Q. Okay. And it doesn't provide any data for
20 maintenance of vision at Week 4; is that correct? 11:55:29
21 In Table 1.

22 A. I do not see data on Week 4 in Table 1.

23 Q. There's nothing in Table 1 that reports
24 the efficacy gains that may have been achieved after
25 the initial and secondary doses of the 2Q8 dosing 11:55:55

1 arm; isn't that correct?

11:56:02

2 MS. FISHMAN: Objection; lacks foundation,
3 document speaks for itself.

4 You can answer.

5 THE WITNESS: In Table 1, it only reports the
6 52-week results.

11:56:14

7 BY MR. SALMEN:

8 Q. Yeah.

9 Doesn't report any results of the efficacy
10 gains that may have been achieved after the initial
11 or secondary doses; right?

11:56:26

12 MS. FISHMAN: Objection; lacks foundation.

13 You can answer.

14 THE WITNESS: Table 1 did not include the
15 efficacy gains seen in, let's say, Week 4 or 8, but
16 the POSA at that time would take all the data that
17 was available and understand, based on the standard
18 of care, that a high level of efficacy was needed in
19 the initial, secondary and tertiary doses.

11:56:44

20 BY MR. SALMEN:

11:57:13

21 Q. All that information that you're referring
22 to about the high level of efficacy that was needed
23 after the initial and secondary doses would come
24 from documents outside of this '338 patent; correct?

25 MS. FISHMAN: Objection; lacks foundation and

11:57:30

1 document speaks for itself.

11:57:32

2 You can answer.

3 THE WITNESS: Table 1 also includes mean

4 improvements in visual acuity at Week 52,

5 demonstrating that the study arms -- all the study

11:57:57

6 arms were efficacious in improving vision.

7 BY MR. SALMEN:

8 Q. At Week 52; right?

9 A. At Week 52.

10 But the POSA would understand, based on

11:58:11

11 the scientific literature to date, that the vision

12 improvements seen at Week 52 also started before

13 Week 52.

14 Q. How can you say that based on the data

15 that's presented in Table 1?

11:58:42

16 (Witness reviews document.)

17 A. I think Table 1 does not include that

18 data. It only reports the data at Week 52.

19 Q. And the entirety of Example 4 does not

20 provide any data regarding any visual acuity gains

11:59:29

21 that may have been achieved after the initial and

22 secondary doses; isn't that right?

23 MS. FISHMAN: Objection; lacks foundation,

24 document speaks for itself.

25 You can answer.

11:59:48

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1 BY MR. SALMEN:

11:59:48

2 Q. Do you agree that the document would speak
3 for itself with regard to whether any data was
4 presented regarding actual efficacy gains after the
5 initial and secondary doses?

12:00:02

6 A. The Table 1 is just a summary of the
7 primary endpoint at Week 52. It does not provide
8 the entire data from the clinical trial.

9 MS. FISHMAN: When you're at a good stopping
10 point, we've been going well over an hour, we need
11 to take a break.

12:00:31

12 BY MR. SALMEN:

13 Q. Can I ask a few more questions, Dr. Do,
14 before we take a break? It's on the same line.

15 MS. FISHMAN: I count we've been going almost
16 an hour 20, just so you know.

12:01:06

17 THE WITNESS: Yeah, maybe we should take a
18 break now.

19 MR. SALMEN: Okay.

20 THE VIDEOGRAPHER: We're going off the record.
21 The time is 12:01.

12:01:16

22 (Recess taken.)

23 THE VIDEOGRAPHER: We're back on the record.
24 The time is 12:12.

25 BY MR. SALMEN:

12:12:12

1 Q. Dr. Do, let's look back at Example 4 where
2 we left off, please. And for context, let's start
3 at the study design, again in Column 9, beginning at
4 line 45.

12:12:12

5 Direct your attention back to what's
6 labeled here as the third arm, the 2Q8 arm, of the
7 Phase 3 clinical trial for VEGF-Trap that's
8 described in Example 4.

12:12:29

9 A. Yes.

10 Q. You agree that 2 mgs of VEGF-Trap under
11 the 2Q8 arm were administered at baseline; correct?

12:12:48

12 A. According to this paragraph, that was the
13 dosing regimen being evaluated.

14 Q. So the first dose would be the initial
15 dose in that 2Q8 arm; correct?

12:13:24

16 A. Yes.

17 Q. And then there were secondary doses that
18 were administered through Week 8.

19 Do you agree with that?

20 MS. FISHMAN: Objection; calls for a legal
21 conclusion.

12:13:38

22 You can answer.

23 THE WITNESS: It appears from the document that
24 in that study arm, 2 milligrams VEGF-Trap
25 administered every four weeks to Week 8 and then

12:13:53

1 every eight weeks.

12:13:59

2 BY MR. SALMEN:

3 Q. So there were secondary doses administered
4 at every four weeks in the 2Q8 arm through Week 8.

5 Do you agree with that?

12:14:16

6 MS. FISHMAN: Objection; calls for a legal
7 conclusion.

8 You can answer.

9 THE WITNESS: It appears that in that study
10 arm, 2 milligrams VEGF-Trap was administered every
11 four weeks to Week 8 and then every eight weeks,
12 yes.

12:14:27

13 BY MR. SALMEN:

14 Q. Okay. So through Week 8, you agree that
15 there was an initial dose and at least two secondary
16 doses; correct?

12:14:40

17 MS. FISHMAN: Objection; calls for a legal
18 conclusion.

19 You can answer.

20 THE WITNESS: I believe there was initial dose,
21 secondary dose and tertiary doses.

12:14:57

22 BY MR. SALMEN:

23 Q. And the tertiary doses you refer to in the
24 2Q8 arm of Example 4, those are the eight-week doses
25 that are described there in Column 9, lines 50 to

12:15:12

1 53; correct?

12:15:19

2 MS. FISHMAN: Objection; calls for a legal
3 conclusion.

4 You can answer.

5 THE WITNESS: I agree that in this clinical
6 trial, this dosing regimen was being evaluated.

12:15:28

7 BY MR. SALMEN:

8 Q. And there are eight-week doses in this 2Q8
9 arm; correct?

10 A. Correct.

12:15:40

11 Q. Now, directing your attention again to
12 Table 1 -- let me first ask this question: There
13 were multiple eight-week doses in the 2Q8 arm of
14 Example 4 in the '338 patent; correct?

15 A. Yes, I believe they were given every eight
16 weeks.

12:16:13

17 Q. Can we agree that the first eight-week
18 dose was given at Week 16 of the study for the 2Q8
19 arm? Is that right?

20 A. I think that is correct.

12:16:39

21 Q. So now looking at Example 4 and the data
22 presented in Table 1, you cannot tell me if the
23 first eight-week dose under the 2Q8 arm maintained
24 the efficacy gains that may have been achieved after
25 the initial and secondary doses; is that correct?

12:16:58

MS. FISHMAN: Objection; lacks foundation.

12:17:13

You can answer.

THE WITNESS: Table 1 lists only the 52-week outcomes. But the POSA would understand, based on the data to date, scientific presentations, that the standard of care in the context of this patent would require a medicine being tested to have a highly effective result after the initial, secondary and tertiary doses.

12:17:37

BY MR. SALMEN:

12:18:09

Q. The second eight-week dose under the 2Q8 arm, that would have occurred in Week 24 of the study; is that correct?

A. That is correct.

Q. Looking at Example 4 and the data presented in Table 1, you cannot tell me if the second eight-week dose under the 2Q8 arm maintained the efficacy gains that may have been achieved after the initial and secondary doses; is that correct?

12:18:33

MS. FISHMAN: Objection; lacks foundation.

12:18:55

You can answer.

THE WITNESS: Can you repeat the question.

BY MR. SALMEN:

Q. Looking at Example 4 and the data presented in Table 1, you cannot tell me if the

12:19:19

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1 second eight-week dose under the 2Q8 arm maintained
2 the efficacy that may have been achieved after the
3 initial and secondary doses; correct?

12:19:25

4 MS. FISHMAN: Same objection.

5 You can answer.

12:19:38

6 THE WITNESS: In Table 1, it lists both
7 maintenance of vision at Week 52 and also mean
8 improvement in vision at Week 52 compared to
9 baseline. And both of those columns show highly
10 efficacious results in the study arms.

12:20:14

11 The POSA would look at this data in the
12 context of all other publicly available data and
13 inform a decision that this medicine would need to
14 be highly efficacious after the initial, secondary
15 and tertiary doses in the context of standard of
16 care in relation to the patent at this time.

12:20:54

17 BY MR. SALMEN:

18 Q. Again -- this time let's look at Example 4
19 and the data presented in Table 1.

20 The last eight-week dose would have
21 occurred at Week 52; correct?

12:21:26

22 That's not correct. I'll strike that. My
23 math was off.

24 Week 48.

25 A. Yes.

12:21:53

1 Q. The last eight-week dose under the 2Q8 12:21:54
2 regimen in Example 4 would have occurred around
3 Week 48; is that correct?

4 A. That is correct.

5 Q. So looking at the data available in the 12:22:05
6 '338 patent, Example 4, including Table 1, you
7 cannot tell me whether that last eight-week dose
8 actually maintained the efficacy that was achieved
9 in the initial and secondary doses; is that correct?

10 MS. FISHMAN: Objection; lacks foundation. 12:22:29

11 You can answer.

12 THE WITNESS: In my declaration, I did not
13 offer an opinion on that specific topic you are
14 discussing.

15 BY MR. SALMEN: 12:22:39

16 Q. I don't agree with that, Dr. Do.

17 Your definition of "tertiary dose" is that
18 each tertiary dose maintains the efficacy gained in
19 the initial and secondary dose; correct?

20 MS. FISHMAN: I'm going to object that you cut 12:22:55
21 the witness off on her answer. I'm not sure she was
22 done. And also you're just arguing with the
23 witness. Do you want to read --

24 BY MR. SALMEN:

25 Q. Do you offer that opinion about "tertiary 12:23:06

1 dose"?

12:23:08

2 A. Can you restate what you had just
3 mentioned.

4 Q. You offered an opinion that a tertiary
5 dose must maintain the efficacy gains achieved in
6 the initial and secondary doses; correct?

12:23:14

7 A. That is correct.

8 Q. Okay. And the last eight-week dose in
9 Example 4 is a tertiary dose; correct?

10 A. That is correct.

12:23:28

11 Q. Okay. So applying your definition, that
12 last eight-week dose in the 2Q8 arm of Example 4
13 must maintain the efficacy gains achieved in the
14 initial and secondary doses; is that your opinion?

15 A. As I stated in my declaration, my opinion
16 is that "the 'tertiary dose' means doses
17 administered after the initial and secondary doses
18 and that the tertiary dose maintains the efficacy
19 achieved after the initial and secondary doses."

12:23:49

20 Q. But none of the data in Example 4 of the
21 '338 patent, including Table 1, actually demonstrate
22 that the last eight-week dose, which you just agreed
23 is a tertiary dose, maintains the efficacy that was
24 achieved in the those initial and secondary doses;
25 correct?

12:24:05

12:24:28

MS. FISHMAN: Objection; lacks foundation.

12:24:29

You can answer.

THE WITNESS: Table 1 merely lists the endpoint at Week 52. However, the POSA, in his or her experience, would understand, based on the standard of care in relation to this patent, that visual acuity gains after administration of a VEGF blocker usually occur over time and occur after the initial, secondary and tertiary doses.

12:24:52

BY MR. SALMEN:

12:25:26

Q. Do those visual acuity gains occur throughout the entire 52-week period of the Example 4 Phase 3 clinical trial for the 2Q8 arm?

MS. FISHMAN: Objection; lacks foundation and calls for speculation.

12:25:41

You can answer.

THE WITNESS: Do you have the manuscript from the VIEW 1 and VIEW 2 studies we can refer to?

BY MR. SALMEN:

Q. I want to know the answer to that question based on the information that's provided in the '338 patent, Example 4.

12:25:49

Can you answer that question based on what's provided there?

A. I would need to see the manuscript to give

12:26:04

1 you a complete answer.

12:26:08

2 Q. So you cannot answer my question just
3 based on the information that's provided in
4 Example 4, including Table 1?

5 A. I would say that Table 1 shows that the
6 dosing of VEGF-Trap in this clinical trial appears
7 to be highly efficacious compared to Lucentis, which
8 was the standard of care at that time for wet AMD.

12:26:20

9 Q. I'm referring to the last eight-week dose
10 of the 2Q8 arm in Example 4. Okay.

12:26:55

11 You cannot tell me whether that eight-week
12 dose qualifies as a tertiary dose, applying your
13 definition for that term; right?

14 MS. FISHMAN: Objection --

15 BY MR. SALMEN:

12:27:13

16 Q. Based on the information that's available
17 in the patent.

18 MS. FISHMAN: Objection; lacks foundation,
19 misstates testimony.

20 You can answer.

12:27:20

21 THE WITNESS: In my experience as an
22 ophthalmologist, the visual acuity gains or
23 maintenance seen at Week 52 suggest that the
24 VEGF-Trap 2 milligrams given every eight weeks
25 appears to be highly efficacious given the visual

12:27:53

1 acuity results are non-inferior to Lucentis, which
2 was the standard of care at that time.

12:28:01

3 BY MR. SALMEN:

4 Q. Let's turn to your declaration. I'm going
5 to focus on your paragraph 93.

12:28:14

6 Are you there?

7 A. Yes, I am.

8 Q. You provide a hypothetical patient in your
9 paragraph 93. I'll read it for the record.

10 "If a patient achieved a letter gain after
11 the initial and secondary doses and then declined
12 after the tertiary dose(s) began, but nonetheless
13 exhibited a loss of fewer than 15 letters during the
14 tertiary dosing, I would not consider this level of
15 efficacy to be sufficient for the dosing regimen
16 claimed in the '338 patent."

12:28:37

17 Do you still agree with that opinion?

18 A. I agree.

19 Q. Not making any changes to it; correct?

20 A. Not making any changes.

12:29:23

21 Q. This hypothetical patient of yours is
22 receiving the VEGF antagonist that is set forth in
23 the '338 patent claims; right?

24 A. I didn't state which VEGF antagonist it
25 was receiving.

12:29:43

1 Q. Okay. I'm reading this within the context
2 of the entire paragraph.

12:29:52

3 And you are specifically referring to the
4 level of efficacy sufficient for the dosing regimen
5 claimed in the '338 patent; right?

12:30:10

6 A. I state in paragraph 93 that "As I read
7 the claims of the '338 patent, in view of the
8 specification, this level of efficacy would not be
9 sufficient for the dosing regimens claimed in the
10 '338 patent."

12:30:36

11 Q. "For example," and then you provide your
12 hypothetical; correct?

13 A. I state that I disagree that efficacy only
14 requires that the patient exhibit a loss of 15 or
15 fewer letters on the ETDRS visual acuity chart.

12:30:58

16 Q. Is there a reason why you don't want to
17 apply this hypothetical to the VEGF antagonist
18 that's set forth in Claim 1 of the '338 patent?

19 MS. FISHMAN: Objection; lacking foundation.

20 MR. SALMEN: Strike that.

12:31:22

21 BY MR. SALMEN:

22 Q. Just to be clear, the hypothetical patient
23 of yours in paragraph 93 is receiving the VEGF
24 antagonist that is set forth in the '338 patent
25 claims; is that correct?

12:31:33

1 MS. FISHMAN: Are you asking her to assume 12:31:34
2 that?

3 MR. SALMEN: It's her hypothetical.

4 THE WITNESS: It was merely a hypothetical, but
5 I was not suggesting it was receiving a particular 12:31:40
6 VEGF antagonist.

7 BY MR. SALMEN:

8 Q. You state, "I would not consider this
9 level of efficacy to be sufficient for the dosing
10 regimen claimed in the '338 patent"; right? 12:31:58

11 A. I further state that "I understand
12 'tertiary dose(s)' to require that the efficacy gain
13 achieved from the initial and secondary doses are
14 maintained after the initial and secondary doses."

15 Q. So to be -- your paragraph 93 hypothetical 12:32:24
16 patient received an initial dose followed by one or
17 more secondary doses followed by one or more
18 tertiary doses; correct?

19 A. I mentioned that in this hypothetical
20 example. 12:32:40

21 Q. But it is your opinion that this
22 hypothetical patient did not receive the dosing
23 regimen of the '338 patent; is that correct?

24 MS. FISHMAN: Objection; misstates testimony.

25 THE WITNESS: In this hypothetical patient, I 12:33:01

1 merely stated that they received initial and

12:33:03

2 secondary doses and then declined after the tertiary

3 doses began.

4 BY MR. SALMEN:

5 Q. What VEGF antagonist were you envisioning

12:33:21

6 in presenting this hypothetical?

7 MS. FISHMAN: Objection; lacks foundation.

8 You can answer.

9 THE WITNESS: I did not specify which VEGF

10 antagonist this hypothetical patient was receiving.

12:33:37

11 I was just merely stating that, in this hypothetical

12 scenario, a patient could receive some medicine and

13 after the initial and secondary doses, they began to

14 decline after receiving tertiary doses.

15 BY MR. SALMEN:

12:34:00

16 Q. So in this hypothetical, at least one

17 option would have been the VEGF-Trap-Eye that's set

18 forth in the '338 patent claims; right?

19 A. If they were in a clinical trial at that

20 time.

12:34:17

21 Q. Okay. So let's assume that -- in your

22 hypothetical in paragraph 93, let's assume that your

23 hypothetical patient was receiving the VEGF-Trap-Eye

24 in a clinical trial. Okay? Can we assume that?

25 A. In this hypothetical case, I wasn't

12:34:41

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1 suggesting the patient was in a clinical trial.

12:34:45

2 Q. You just told me that that was an option.

3 A. If I had used the hypothetical case that

4 they were in a clinical trial. But in this case, I

5 did not specify they were in a clinical trial.

12:34:56

6 Q. Okay. Let's look at Example 4. Keep this

7 open and look at Example 4. And then Column 10,

8 lines 18 to 19. It says, "Approximately 1200

9 subjects were enrolled, with a target enrollment of

10 300 subjects per treatment arm."

11 Do you see that?

12 A. I see that.

13 Q. Now, if we take that information and look

14 at Table 1, and again focusing on the right-hand

15 column for the VEGF-Trap 2 milligrams every eight

12:35:49

16 weeks, or the 2Q8 arm, you understand that

17 approximately 300 patients were in that column -- in

18 that arm; correct?

19 A. Correct.

20 Q. And we looked at this earlier, but the

12:36:08

21 first row of data presented there, the "Maintenance

22 of vision (percent patients losing less than 15

23 letters) at 52 weeks -- at Week 52 versus baseline."

24 Do you see that?

25 A. Yes, I do see that.

12:36:29

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1 Q. So you'd agree that not every single 12:36:33
2 patient in the 2Q8 arm of the Example 4 clinical
3 trial experienced a loss of less than 15 letters at
4 52 weeks versus baseline; correct?

5 A. I agree with that. 12:36:49

6 Q. That's because over 4 percent of the
7 patients in that arm lost more than 15 letters; is
8 that correct?

9 A. I agree with that.

10 Q. So now if we apply your conclusion in the 12:37:05
11 paragraph 93 hypothetical, that 4 percent of
12 patients in the 2Q8 arm of Example 4 did not receive
13 a dosing regimen that falls within the scope of the
14 '338 patent claims; right?

15 MS. FISHMAN: Objection; calls for a legal 12:37:33
16 conclusion.

17 But you can answer.

18 THE WITNESS: Can you rephrase the question.

19 BY MR. SALMEN:

20 Q. I can't. I'll state it again. 12:37:39

21 A. Yes.

22 Q. So applying the conclusion that you drew
23 in your paragraph 93 hypothetical. Okay?

24 A. Um-hum.

25 Q. The 4 percent of patients in the 2Q8 arm 12:37:52

1 of Example 4 did not receive a method of treating
2 that falls within the scope of the '338 patent
3 claims; is that correct?

12:37:58

4 A. I don't understand the legal term you're
5 using.

12:38:20

6 Q. Which legal term?

7 A. The ones that you just used.

8 Q. I wasn't suggesting any legal terms.

9 So in paragraph 93, you set forth a
10 hypothetical of a patient that exhibited a loss of
11 fewer than 15 letters during the tertiary dosing.
12 And you state that you would not consider that
13 patient -- strike that.

12:38:37

14 In paragraph 93 of your hypothetical, you
15 state, "if a patient achieved a letter gain after
16 the initial and secondary doses and then declined
17 after the tertiary dose(s) began, but nonetheless
18 exhibited a loss of fewer than 15 letters during the
19 tertiary dosing, I would not consider this level of
20 efficacy to be sufficient for the dosing regimen
21 claimed in the '338 patent."

12:39:04

12:39:23

22 Do you see that?

23 A. I see the statement I wrote.

24 Q. And the reason for your conclusion that
25 this dosing regimen would not have the level of

12:39:38

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1 efficacy of the method of treating in the '338

12:39:42

2 patent is because, in your hypothetical patient, you

3 didn't see those visual acuity gains that you are

4 requiring for that method of treatment; correct?

5 A. In my experience as an ophthalmologist,

12:40:00

6 there are some specific patients who have very

7 challenging angiogenic eye disorders, such as wet

8 age-related macular degeneration. And a few of

9 those patients do not demonstrate the vision gains

10 that the majority of the population achieves.

12:40:29

11 Q. And for those patients, applying your

12 hypothetical in paragraph 93, you would not consider

13 the level of efficacy that they experienced to be

14 sufficient for the dosing regimen claimed in the

15 '338 patent; correct?

12:40:51

16 MS. FISHMAN: Objection; vague.

17 You can answer.

18 THE WITNESS: In my experience, there are a

19 minority of patients who may not gain vision or

20 maintain vision with certain medicines, but that

12:41:13

21 doesn't mean that that medicine might not be highly

22 efficacious in the vast majority of other patients.

23 BY MR. SALMEN:

24 Q. And the 4 percent of patients in the 2Q8

25 arm that did not have a maintenance of vision of

12:41:34

1 losing less than 15 letters at Week 52, those

12:41:43

2 patients would be in that minority that you're

3 describing?

4 A. Those patients, that 4 percent who did not

5 maintain vision at Week 52, I would have to review

12:42:00

6 the manuscript and see why they lost or did not

7 maintain the vision.

8 Q. Would you consider those patients as not

9 receiving the level of efficacy that was sufficient

10 for the dosing regimen of the '338 patent claims?

12:42:20

11 A. Again, I would have to review their

12 specific cases to understand why they did not have

13 the maintenance of vision.

14 Q. That information is not available in the

15 '338 patent; correct?

12:42:56

16 A. I don't see that information in Column 13,

17 but it may be available in published manuscripts. I

18 don't recall.

19 Q. So sitting here today, you cannot tell me

20 whether the 4 percent, roughly, of the patients that

12:43:20

21 did not achieve the maintenance-of-vision endpoint

22 in the 2Q8 arm received a level of efficacy that's

23 required in the dosing regimen claimed in the '338

24 patent; is that right?

25 MS. FISHMAN: Objection; misstates testimony.

12:43:44

1 But you can answer.

12:43:46

2 THE WITNESS: In looking at this Table 1, I can
3 see that the clinical trial's results at Week 52
4 showed that the vast majority of patients did
5 maintain vision or have an improvement in vision and
6 a small minority did not.

12:44:11

7 BY MR. SALMEN:

8 Q. And that small minority received the same
9 sequence of doses as the majority of patients;
10 correct?

12:44:27

11 A. Again, I would have to read and review the
12 manuscript to understand those individual cases that
13 did not have the maintenance or improvement in
14 vision to understand if they missed visits or if
15 they had some other complications.

12:44:51

16 Q. Is that your experience in clinical
17 trials, that if a patient missed a visit, they would
18 still be included in the final data?

19 A. I did not offer an opinion on that in my
20 declaration, but as an experienced ophthalmologist
21 who has participated in clinical trials, patients
22 who have missed visits are included in the final
23 data.

12:45:08

24 Q. Let's look at paragraph 101 of your
25 declaration, please.

12:45:38

1 Are you there? 12:45:50

2 A. Yes, I am.

3 Q. In paragraph 101 of your declaration, you
4 state your opinion that the EYLEA prescribing
5 information satisfies the tertiary dose element of 12:46:01
6 Claim 1 to the '338 patent; is that correct?

7 A. I state that "The dosing and
8 administration for each of the wet AMD, DME and DR
9 includes tertiary dosing where each tertiary dose is
10 administered 'once every 8 weeks' after the 12:46:23
11 immediately preceding dose."

12 Q. And is it those eight-week doses, that you
13 just quoted, what you refer to as the "tertiary
14 doses" of the EYLEA prescribing information?

15 A. Yes, I state that "where each tertiary 12:46:49
16 dose is administered 'once every 8 weeks'."

17 Q. And in paragraph 101, you do not explain
18 how, in your opinion, the EYLEA prescribing
19 information confirms that those eight-week doses
20 actually maintained the efficacy gains achieved by 12:47:08
21 the initial and secondary doses of those regimens;
22 is that correct?

23 MS. FISHMAN: Objection; document speaks for
24 itself.

25 You can answer. 12:47:24

1 THE WITNESS: I mention earlier in my 12:47:26
2 declaration that tertiary dose maintains the high
3 level of efficacy achieved after the initial and
4 secondary doses.

5 BY MR. SALMEN: 12:47:38

6 Q. Okay. But in your opinion here set forth
7 in paragraph 101, you are describing how, in your
8 view, the eight-week doses in that dosing regimen in
9 the EYLEA label qualify as "tertiary doses," as you
10 define that claim term; correct? 12:48:02

11 A. I state that "tertiary dose is
12 administered 'once every 8 weeks'."

13 Q. Correct.

14 You don't say anything in here about how
15 the eight-week doses that are recommended under the 12:48:20
16 EYLEA regimen actually maintain the initial and
17 secondary doses or the efficacy that was achieved in
18 those initial and secondary doses; is that correct?

19 MS. FISHMAN: Objection; document speaks for
20 itself. 12:48:35

21 You can answer.

22 THE WITNESS: I mention in paragraph 87 that
23 "It is my opinion that the 'tertiary dose(s)' means
24 dose(s), administered after the initial and
25 secondary doses, that maintain(s) the efficacy gain 12:48:49

1 achieved after each -- the initial and secondary
2 doses."

12:48:54

3 BY MR. SALMEN:

4 Q. But to reach your conclusion in
5 paragraph 101, you're only relying on the temporal
6 sequence of the eight-week dose that's in the EYLEA
7 label; right?

12:49:01

8 MS. FISHMAN: Objection; lacks foundation.

9 You can answer.

10 THE WITNESS: When I refer to "tertiary doses,"
11 I'm referring to tertiary doses that maintain the
12 high level of efficacy achieved after the initial
13 and secondary doses.

12:49:22

14 MR. SALMEN: How do we want to handle lunch?

15 Because I'm moving on to a completely new section.

12:49:53

16 MS. FISHMAN: We could take a break now if you
17 want -- whatever you want, but I thought we would go
18 until like 1:00 or something. But if you wanted to
19 break earlier or --

20 MR. SALMEN: I mean, I'm happy to continue, but
21 it may take more than 15 minutes.

12:50:06

22 MS. FISHMAN: Do you think it will take more
23 than 30 minutes?

24 MR. SALMEN: No. No.

25 MS. FISHMAN: Well, do you want to keep going

12:50:15

1 then?

12:50:16

2 (Discussion off the record.)

3 THE VIDEOGRAPHER: We're going off the record.

4 The time is 12:50.

5 (Lunch recess was taken at 12:50 p.m.)

6 (Nothing omitted or deleted. See next
7 page.)

1 AFTERNOON SESSION

1:52 P.M.

2 - - -

3 THE VIDEOGRAPHER: We're back on the record.

4 The time is 1:52.

5 EXAMINATION RESUMED

13:52:26

6 BY MR. SALMEN:

7 Q. Dr. Do, let's turn back to your
8 declaration, please. I want to focus on
9 paragraphs 22 to 26 for a moment.

10 Dr. Do, in paragraphs 22 to 26, you set
11 forth some of your legal standards that you applied
12 in forming your opinions; is that correct?

13:52:50

13 A. Yes, that is correct.

14 Q. Now, looking specifically at paragraph 23,
15 you state, "I have been informed that absent an
16 explicit statement to the contrary by the patent
17 applicant, a patent claim term should have its
18 ordinary and customary meaning and not be limited to
19 a specific example that may appear in the patent
20 specification as referring to a preferred
21 embodiment."

13:53:07

22 Do you see that?

23 A. Yes, I see that.

24 Q. Did you apply that legal standard in
25 forming your opinions that are set forth in your

13:53:26

13:53:37

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1 declaration?

13:53:40

2 A. Yes, I did.

3 Q. And specifically with regard to the
4 "method of treating" claim term, did you apply that
5 standard in forming your opinion regarding the
6 understanding of that term as it appears in the '338
7 patent claims?

13:53:54

8 A. Yes, I did.

9 Q. Looking at paragraph 24 of your legal
10 framework section, you state, "I have been informed
11 that where a term has no ordinary and customary
12 meaning to those of ordinary skill in the prior art,
13 one looks to the specification in the patent."

13:54:08

14 Do you see that?

15 A. Yes, I see that.

13:54:25

16 Q. You applied that legal standard from
17 paragraph 24 of your declaration in forming your
18 opinions in this proceeding; correct?

19 A. Yes, I have.

20 Q. And specifically with regard to the
21 "method of treating" claim term, you applied that
22 legal standard that appears in paragraph 24 of your
23 declaration in forming your opinion regarding the
24 construction of that term; correct?

13:54:42

25 A. Can you rephrase the question.

13:54:59

1 Q. Yeah.

13:55:06

2 I'm just asking if you applied the legal
3 standard that you set forth in paragraph 24 in
4 forming your opinion regarding the construction of
5 the "method of treating" claim term that appears in
6 the '338 patent claims.

13:55:19

7 A. I do.

8 Q. Okay. Now, if we turn to paragraph 44 of
9 your declaration. And this section begins at
10 paragraph 43, titled "A Method for Treating an
11 Angiogenic Eye Disorder in a Patient."

13:55:42

12 Do you see that?

13 A. Yes.

14 Q. And the heading for this entire section
15 appears on the previous page under "Claim
16 Construction."

13:55:54

17 Do you see that?

18 A. Yes.

19 Q. Okay. So now in paragraph 44 of your
20 declaration, Exhibit 2051, you state, "a skilled
21 artisan would understand the language 'a method for
22 treating an angiogenic eye disorder in a patient' in
23 the context of the '338 patent to require actually
24 treating a patient's angiogenic eye condition."

13:56:06

25 Do you see that?

13:56:31

1 A. Which paragraph are you referring to?

13:56:32

2 Q. 44.

3 A. 44.

4 (Witness reviews document.)

5 A. And you're talking about the last

13:56:43

6 sentence, "a skilled artisan would understand the

7 language 'a method for treating an angiogenic eye

8 disorder in a patient' in the context of the '338

9 patent to require actually treating a patient's

10 angiogenic eye condition."

13:57:01

11 Yes, I wrote that.

12 Q. You still agree with that statement;

13 correct?

14 A. Yes.

15 Q. And in that statement in paragraph 44, you

13:57:09

16 emphasize that a skilled artisan would understand

17 this claim term "in the context of the '338 patent";

18 correct?

19 A. Yes.

20 Q. And do you emphasize the context of the

13:57:24

21 '338 patent here because you are not applying the

22 ordinary and customary meaning this claim term has

23 outside the context of the '338 patent?

24 MS. FISHMAN: Objection; lacks foundation.

25 You can answer.

13:57:39

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1 THE WITNESS: Can you repeat the question.

13:57:42

2 BY MR. SALMEN:

3 Q. Sure.

4 I'll first direct you to your legal
5 standard on paragraph 24, so you have the context of
6 my question in mind.

13:57:46

7 In there you state, "I have been informed
8 that where a term has no ordinary and customary
9 meaning to those of ordinary skill in the prior art,
10 one looks to the specification of the patent."

13:58:06

11 Okay?

12 A. Yes.

13 Q. So with that context in mind, did you
14 identify an ordinary and customary meaning for the
15 claim term "a method for treating an angiogenic eye
16 disorder in a patient"?

13:58:19

17 A. In interpreting this "method for treating
18 an angiogenic eye disorder in a patient," the
19 skilled artisan would in the context -- look at the
20 standard of care in the context of the '338 patent
21 and understand that "a method for treating an
22 angiogenic eye disorder" required using something
23 that was highly efficacious.

13:58:45

24 Q. Okay. So my question is trying to
25 differentiate between an ordinary and customary

13:59:12

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1 meaning within the context of the '338 patent, as
2 you state in your declaration, versus an ordinary
3 and customary meaning outside the context of the
4 '338 patent.

13:59:16

5 So did you identify an ordinary and
6 customary meaning of the claim term "a method for
7 treating an angiogenic eye disorder in a patient"
8 outside the context of the '338 patent?

13:59:31

9 MS. FISHMAN: Objection; vague.

10 You can answer.

13:59:46

11 THE WITNESS: I believe the POSA would
12 understand that "a method for treating an angiogenic
13 eye disorder in a patient" in the context of the
14 '338 patent to be a therapy that is -- requires
15 efficacy.

14:00:14

16 BY MR. SALMEN:

17 Q. And that definition is within the context
18 of the '338 patent; correct?

19 MS. FISHMAN: Objection; misstates testimony.

20 You can answer.

14:00:26

21 THE WITNESS: "A method for treating an
22 angiogenic disorder -- eye disorder" requires not
23 only intent to treat, but also that the treatment be
24 effective based on the POSA's understanding of the
25 standard of care at the time in the context of the

14:00:49

1 '338 patent.

14:00:52

2 BY MR. SALMEN:

3 Q. Okay.

4 MS. FISHMAN: Can I interrupt. I'm sorry to do
5 this. My LiveNote stopped working. Is yours
6 working?

14:00:57

7 MR. SALMEN: No, it stopped working.

8 MS. FISHMAN: Can we go off the record.

9 THE VIDEOGRAPHER: We're going off the record.

10 The time is 2:01.

14:01:08

11 (Recess taken.)

12 THE VIDEOGRAPHER: We're back on the record.

13 The time is 2:17.

14 BY MR. SALMEN:

15 Q. Okay. Dr. Do, I'm going to go back a
16 little bit since we had that interruption.

14:17:12

17 Looking back at your legal framework
18 section in your declaration, paragraph 24.

19 A. Yes.

20 Q. You state, "I have been informed that
21 where a term has no ordinary and customary meaning
22 to those of ordinary skill in the prior art, one
23 looks to the specification in the patent."

14:17:37

24 Okay?

25 A. Yes.

14:17:51

1 Q. Now, with that legal framework in mind, 14:17:53
2 did you provide an ordinary and customary meaning of
3 the claim term "method for treating an angiogenic
4 eye disorder in a patient"?

5 (Witness reviews document.) 14:18:37

6 MS. FISHMAN: Objection; vague.

7 Sorry. Go ahead.

8 THE WITNESS: In the patent as of January 13th,
9 2011, the POSA would consider the claimed method of
10 treatment as one that achieves a high level of 14:19:01
11 efficacy and that is non-inferior to the standard of
12 care at the time of the patent filing.

13 MR. SALMEN: Okay. I'm going to again move to
14 strike that answer as not responsive to my question.

15 BY MR. SALMEN: 14:19:18

16 Q. The legal framework that you --

17 A. Yes.

18 Q. -- you applied in paragraph 24 states,
19 "where a term has no ordinary and customary meaning
20 to those of ordinary skill in the prior art, one 14:19:33
21 looks to the patent -- one looks to the
22 specification in the patent"; correct?

23 A. Um-hum, yes.

24 Q. So I'm just trying to gain an
25 understanding of how you came to your construction 14:19:47

1 for the claim term "method of treating."

14:19:52

2 Did you provide or identify an ordinary
3 and customary meaning for that term to persons of
4 ordinary skill in the art?

5 A. I don't know if I understand your
6 question, but at that time of the patent filing, I
7 believe the person of ordinary skill of the art
8 would understand -- excuse me -- would understand
9 that the term "method of treatment" ordinarily
10 referred to at that time something that was
11 efficacious in treating angiogenic eye disorders.

14:20:11

14:20:38

12 Q. Okay. But that's not the ordinary --

13 A. Excuse me.

14 Q. Are you okay?

15 A. Yes, just sneezed.

14:20:52

16 Q. The definition that you just provided is
17 not the ordinary and customary meaning of the claim
18 term "a method for treating an angiogenic eye
19 disorder in a patient"; is that correct?

20 MS. FISHMAN: Objection; misstates testimony.

14:21:07

21 You can answer.

22 THE WITNESS: I believe at that time of the
23 patent filing, that the POSA would understand that
24 the ordinary term for "method of treatment" --
25 "method of treating an angiogenic eye disorder"

14:21:29

1 would require using something that was highly

14:21:35

2 efficacious.

3 BY MR. SALMEN:

4 Q. Let me ask it this way: In order to

5 develop an understanding for the meaning of the

14:21:55

6 claim term "method of treating an angiogenic eye

7 disorder in a patient," did you have to look to the

8 specification of the '338 patent to develop that

9 understanding?

10 A. I think an ophthalmologist would develop

14:22:20

11 an understanding of what the meaning of "method of

12 treating" would be by looking at the standard of

13 care at that time in the context of the patent.

14 Q. Okay. And that's what you did.

15 You developed that understanding in the

14:22:36

16 context of the '338 patent; correct?

17 A. And what was the standard of care at that

18 time.

19 Q. And the standard of care is not discussed

20 in the '338 patent; is that correct?

14:22:48

21 MS. FISHMAN: Objection; lacks foundation.

22 THE WITNESS: I believe the '338 patent does

23 mention ranibizumab, Lucentis, and how it was FDA

24 approved for angiogenic eye disorders such as AMD

25 and CRVO in the first column of the patent.

14:23:18

1 BY MR. SALMEN:

14:23:22

2 Q. Okay. Let me ask this a different way.

3 What is your actual definition for the
4 claim term "a method for treating an angiogenic eye
5 disorder in a patient" as that term appears in the
6 '338 patent claims?

14:23:32

7 A. Let me look back at my declaration because
8 I believe I put that definition there.

9 As I stated in my declaration, "It is my
10 opinion that the claims of the recited 'method for
11 treating' require not only an intent to treat, but
12 also that the treatment be effective."

14:24:21

13 Q. Where are you reading from?

14 A. Paragraph 46 in my declaration.

15 Q. Let's look at paragraph 84, which is on
16 page 32. This paragraph has a heading "Conclusion."

14:24:49

17 Do you see that?

18 A. Yes.

19 Q. And this is the final paragraph in the
20 section of your declaration that starts at
21 paragraph 43, "A method for treating an angiogenic
22 eye disorder in a patient"; correct?

14:25:11

23 A. I see paragraph 84.

24 Q. Okay. This is the last paragraph in that
25 section of your declaration that begins at

14:25:50

1 paragraph 43; right?

14:25:53

2 It's a very long section --

3 A. Okay. Yes.

4 Q. Very long section discussing your opinions
5 regarding the claim construction for "a method for
6 treating an angiogenic eye disorder in a patient";
7 right?

14:26:03

8 A. Yes.

9 Q. Now, there you state, "It is therefore my
10 opinion that, as of January 13, 2011, the POSA would
11 consider the claimed method of treatment as one that
12 achieves a high level of efficacy that is
13 non-inferior to the standard of care at the time of
14 patent filing. This may vary somewhat depending on
15 the particular angiogenic eye disorder."

14:26:20

16 Do you see that?

17 A. I see that.

18 Q. Sitting here today, you agree with that
19 statement; correct?

20 A. Yes, I agree with my statement.

14:26:52

21 Q. Is that -- is that statement consistent
22 with how you would construe the claim term "a method
23 for treating an angiogenic eye disorder in a
24 patient"?

25 A. Yes, it is.

14:27:06

1 Q. And I'm asking this, Dr. Do, because I 14:27:08
2 don't believe you provide a definition anywhere else
3 in these 40-some paragraphs for "a method of
4 treating an angiogenic eye disorder."

5 Do you disagree with that? 14:27:23

6 MS. FISHMAN: Objection; lacks foundation.

7 You can answer.

8 THE WITNESS: Can you repeat the question.

9 BY MR. SALMEN:

10 Q. I'm trying to find an actual definition 14:27:35
11 that I can plug into the claim.

12 Other than what you state here in
13 paragraph 84, do you provide a definition for the
14 claim term "a method for treating an angiogenic eye
15 disorder in a patient"? 14:27:49

16 A. In my declaration, I state that "the POSA
17 would [understand that] the claimed method of
18 treatment as one that achieves a high level of
19 efficacy that is non-inferior to the standard of
20 care at the time of the patent filing." 14:28:16

21 Q. And you just read from paragraph 84;
22 right?

23 A. I did read from paragraph 84.

24 Q. So let me try it this way: Earlier today
25 we looked at your definition for "tertiary dose." 14:28:34

1 Do you recall that? 14:28:38

2 A. Yes, I do.

3 Q. And if you want to look at it for
4 reference, it's in paragraph 87.

5 Do you see that? 14:28:44

6 A. Yes.

7 Q. You state, "It is my opinion that
8 'tertiary [dose]' means," and then you provide your
9 definition; right?

10 A. Yes, I state that "'tertiary [dose]' means 14:28:56
11 '[dose]' administered after the initial and
12 secondary doses, that maintain(s) the efficacy gain
13 achieved after the initial and secondary doses."

14 Q. And you would agree that I could take that
15 language of your definition and plug it into the 14:29:13
16 claims in place of the word "tertiary dose"; right?

17 A. It is my opinion that the POSA would
18 understand that "tertiary dose" means what I stated
19 in 87.

20 Q. So can I take that meaning that you 14:29:31
21 present in paragraph 87 and plug it into the claims
22 of the '338 patent where the term "tertiary dose"
23 appears?

24 A. If it makes grammatical sense.

25 Q. All right. So actually did do that. 14:29:49

(Deposition Exhibit 0004 was marked.)

14:30:24

BY MR. SALMEN:

Q. All right. Dr. Do, I'm going to hand you what I've marked as Do Deposition Exhibit 4.

So, Dr. Do, you'll see that I've recreated Claim 1 of the '338 patent in Do Deposition Exhibit 4. And in place of the term "tertiary dose," I've inserted the definition that you provide in paragraph 87, and that's highlighted in yellow.

14:30:48

Do you see that?

14:31:13

A. Yes, I see that.

Q. Okay. And to your point earlier, do you agree that the highlighted language there makes grammatical sense -- the yellow highlighted language makes grammatical sense when it's inserted into the claims here?

14:31:29

(Witness reads documents.)

A. I see that you replaced the word "tertiary doses" with the wording "doses, administered after the initial and secondary doses, that maintains -- that maintain the efficacy gained after the initial and secondary doses." I see that part.

14:32:27

Q. So my question was, do you agree that it makes grammatical sense to insert the language that you provide in paragraph 87 of your declaration into

14:32:54

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1 the claims in place of the term "tertiary dose"?

14:32:59

2 A. I think it encompasses the spirit of the
3 meaning, yes.

4 Q. So you'll also see I have some green
5 highlighted language in this recreation of Claim 1.

14:33:17

6 Do you see that?

7 A. Yes, I do.

8 Q. And there I've highlighted the claim term
9 "method for treating an angiogenic eye disorder in a
10 patient."

14:33:30

11 Do you see that?

12 A. Yes.

13 Q. And that's followed by additional language
14 highlighted in green that reflects what you state in
15 paragraph 84 of your declaration, "that achieves a
16 high level of efficacy that is non-inferior to the
17 standard of care for that particular angiogenic eye
18 disorder at the time of patent filing."

14:33:42

19 Do you see that?

20 A. I see that.

14:34:00

21 Q. Does the green highlighted language
22 reflect your opinion of how a skilled artisan or a
23 POSA, as you've referred to, would understand the
24 "method of treating" claim term in the context of
25 the '338 patent?

14:34:15

1 A. I did state in my declaration that "the
2 POSA would consider the claimed method of treatment
3 as one that achieves a high level of efficacy that
4 is non-inferior to the standard of care at the time
5 of patent filing."

14:34:19

14:34:32

6 Q. Okay. Does Do Deposition Exhibit No. 4
7 adequately reflect how you understand a POSA would
8 interpret the claimed "method of treating"?

9 A. I think it encompasses what a POSA would
10 understand at the time of the patent filing.

14:35:01

11 Q. Okay. Now, you use the phrase "standard
12 of care" in your definition for the "method of
13 treating" claim term; correct?

14 A. I do refer to the "standard of care,"
15 which requires a high level of efficacy.

14:35:30

16 Q. And we've incorporated that "standard of
17 care" into the claim language now that's highlighted
18 in green; correct?

19 A. I see the word "standard of care."

20 Q. Okay. And just to be clear -- strike
21 that.

14:35:45

22 In paragraph 47 of your declaration, you
23 also referred to "the existing standard of care"; is
24 that correct?

25 A. Yes, I do refer to "the existing standard

14:36:11

1 of care."

14:36:18

2 Q. Okay. Now, "the existing standard of
3 care" is not described in the '338 patent
4 specification anywhere, is it?

5 MS. FISHMAN: Objection; lacks foundation.

14:36:30

6 You can answer.

7 THE WITNESS: I don't recall the words
8 "standard of care" was used in the '338 patent, but
9 the patent does mention ranibizumab and its FDA
10 approval for macular degeneration and CRVO.

14:36:58

11 BY MR. SALMEN:

12 Q. Where are you reading from in the patent
13 specification?

14 A. Column 1. In the background section,
15 second-to-last paragraph.

14:37:20

16 It states, "FDA-approved treatments of
17 angiogenic eye disorders such as AMD and CRVO
18 include the administration of an anti-VEGF antibody
19 called ranibizumab on a monthly basis by
20 intravitreal injection."

14:37:42

21 Q. Is that how you are defining the "standard
22 of care" with respect to the "method of treatment"
23 as you construe that claim term in the '338 patent
24 Claim 1?

25 MS. FISHMAN: Objection; misstates testimony.

14:38:01

1 But you can answer.

14:38:03

2 THE WITNESS: In my declaration, I stated that
3 the standard of care at the time of the patent
4 filing included both Lucentis and off-label Avastin.

5 BY MR. SALMEN:

14:38:15

6 Q. But it's Lucentis monthly that's set forth
7 in the '338 patent specification at Column 1, lines
8 49 to 52; correct?

9 A. That line 52 states, "ranibizumab on a
10 monthly basis by intravitreal injection."

14:38:37

11 Q. So with respect to Lucentis, is that the
12 dosing regimen that represents the standard of care,
13 in your opinion?

14 A. Although I did not provide in my
15 declaration the specific dosing regimen of Lucentis
16 as defined by the standard of care, the most
17 effective dose of Lucentis was monthly
18 administration.

14:38:56

19 Q. Okay. So are you including other dosing
20 regimens for Lucentis in your definition of the
21 standard of care as of January 2011?

14:39:17

22 A. No. As of January 2011, the
23 every-four-week administration of Lucentis provided
24 the high efficacy seen in the clinical trials.

25 Q. You're not aware of any dosing regimen

14:39:41

1 prior to January 2011 that provided similar efficacy
2 as Lucentis monthly?

14:39:45

3 MS. FISHMAN: Objection; vague.

4 THE WITNESS: Are you referring to clinical
5 trial results of the VIEW 1 and VIEW 2 studies?

14:40:08

6 BY MR. SALMEN:

7 Q. No. No. No.

8 Prior to January 2011, were you aware of
9 any Lucentis dosing regimens that provided similar
10 results as Lucentis monthly dosing?

14:40:26

11 A. I don't recall any other dosing regimens
12 of Lucentis that were as efficacious as
13 every-four-week administration of Lucentis.

14 Q. Okay. Did you review the results of the
15 PrONTO study in forming your opinions that you set
16 forth in your declaration?

14:41:17

17 A. I did not in my declaration provide an
18 opinion on the PrONTO study, but I'm aware of it.
19 If you have the manuscript, I would be happy to
20 review it.

14:41:37

21 Q. I want to focus on the claim term
22 "angiogenic eye disorder" that appears in Claim 1 of
23 the '338 patent and in your construction of the
24 claim term "method for treating an angiogenic eye
25 disorder in a patient" that's highlighted in green

14:42:35

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1 in Do Deposition Exhibit 4. Okay?

14:42:40

2 Now, do you agree that the '338 patent
3 claims are not limited to treating -- let me
4 rephrase that.

5 Do you agree that Claim 1 of the '338
6 patent is not limited to treating neovascular or wet
7 AMD?

14:42:56

8 A. I agree that Claim 1 encompasses
9 angiogenic eye disorders.

10 Q. And that would be more than just
11 neovascular or wet AMD; correct?

14:43:15

12 A. Yes, it would include more than just
13 neovascular AMD.

14 Q. So, for example, we can take a look at
15 Claim 6 of the '338 patent.

14:43:31

16 A. Um-hum.

17 Q. And that refers to "The method of Claim 1,
18 wherein the angiogenic eye disorder is selected from
19 the group consisting of."

20 Do you see that?

14:43:45

21 A. Yes, I do see that.

22 Q. And there's a list of angiogenic eye
23 disorders; correct?

24 A. Yes, there is a list.

25 Q. And you understand that the list of

14:43:54

1 angiogenic eye disorders provided in Claim 1 are a 14:43:57
2 subset of the angiogenic eye disorders that are -- I
3 misspoke. I'm sorry. Strike that.

4 You understand that the list of angiogenic
5 eye disorders provided in Claim 6 are a subset of 14:44:11
6 the angiogenic eye disorders covered by Claim 1;
7 correct?

8 A. Yes, I understand that.

9 Q. Okay. They have to be a subset, otherwise
10 the two claims would have the same scope; right? 14:44:26

11 MS. FISHMAN: Objection; calls for a legal
12 conclusion.

13 But you can answer.

14 THE WITNESS: It appears to be a list of
15 angiogenic eye disorders. 14:44:37

16 BY MR. SALMEN:

17 Q. So you agree then that there are other
18 angiogenic eye disorders that are not listed in
19 Claim 6 that fall within the scope of Claim 1's
20 method of treatment; correct? 14:44:53

21 A. I agree that there are other angiogenic
22 eye disorders that are not listed here.

23 Q. Not listed here in Claim 6 that would fall
24 within the scope of Claim 1; is that correct?

25 A. It is possible. 14:45:09

1 Q. Okay. Well, let's take a look at the 14:45:12
2 patent specification at Column 5.

3 And what looks like line 11 of Column 5,
4 there's a header that says, "Angiogenic Eye
5 Disorders." 14:45:35

6 Do you see that?

7 A. Yes, I see that.

8 Q. And the paragraph begins, "The methods of
9 the present invention can be used to treat any
10 angiogenic eye disorder." 14:45:50

11 Do you see that?

12 A. I see that.

13 Q. It goes on to state, "The expression
14 'angiogenic eye disorder', as used herein, means any
15 disease of the eye which is caused by or associated 14:46:02
16 with the growth or proliferation of blood vessels or
17 by blood vessel leakage."

18 Do you see that?

19 A. Yes, I see that sentence.

20 Q. So, again, the term "angiogenic eye 14:46:25
21 disorder" in that paragraph -- in that sentence I
22 just read is in quotation marks; right?

23 A. Yes.

24 Q. And you agree that George Yancopoulos is
25 expressly defining that term, "angiogenic eye 14:46:39

1 disorder," as "any disease of the eye which is 14:46:42
2 caused by or associated with the growth or
3 proliferation of blood vessels or by blood vessel
4 leakage"; correct?

5 MS. FISHMAN: Objection; calls for a legal 14:46:56
6 conclusion.

7 You can answer.

8 THE WITNESS: I agree that that sentence
9 states, "The expression 'angiogenic eye disorder',
10 as used herein, means any disease of the eye which 14:47:05
11 is caused by or associated with the growth or
12 proliferation of blood vessels or by blood vessel
13 leakage."

14 BY MR. SALMEN:

15 Q. Do you agree with that definition of the 14:47:19
16 term "angiogenic eye disorder"?

17 A. Although I did not specifically give an
18 opinion on the exact definition of "angiogenic eye
19 disorders" in my declaration, I think that is
20 reasonable. 14:47:43

21 Q. No disagreement with that definition of
22 the claim term "angiogenic eye disorder"?

23 MS. FISHMAN: Again, objection; calls for a
24 legal conclusion.

25 But you can answer. 14:47:54

1 THE WITNESS: I agree that this statement is 14:47:57
2 logical.

3 BY MR. SALMEN:

4 Q. Let me ask it this way: Did you apply
5 this definition of "angiogenic eye disorder" in 14:48:06
6 forming your opinions about the meaning and scope of
7 the "method of treatment" that's covered by the
8 claims of the '338 patent?

9 A. Yes, I considered this.

10 Q. You see here that the next sentence 14:48:30
11 provides "Non-limiting examples of angiogenic eye
12 disorders that are treatable using the methods of
13 the present invention include," and then it's
14 followed by a rather lengthy list of disorders.

15 Do you see that? 14:48:50

16 A. I see that sentence.

17 Q. Okay. I counted them. There are 19
18 angiogenic eye disorders that are listed there.

19 Do you see that?

20 A. Yes, I see that list. 14:49:00

21 Q. Okay. Turning back to Claim 1, do you
22 agree that every one of the 19 disorders that are
23 listed here fall within the scope of the "angiogenic
24 eye disorders" that are covered by the "method of
25 treating" in Claim 1 of the '338 patent? 14:49:19

1 MS. FISHMAN: Objection; calls for a legal
2 conclusion.

14:49:25

3 You can answer.

4 (Witness reviews document.)

5 THE WITNESS: The Claim 1, I understand it
6 discusses "a method for treating an angiogenic eye
7 disorder in a patient." That's my understanding.

14:49:43

8 BY MR. SALMEN:

9 Q. Okay. And is it your understanding that
10 the non-limiting list of examples of angiogenic eye
11 disorders that's provided in Column 5, lines 16 to
12 29, all fall within the scope of that language that
13 you just read from Claim 1?

14:50:04

14 MS. FISHMAN: Objection; calls for a legal
15 conclusion.

14:50:25

16 You can answer.

17 THE WITNESS: In that list in the Column 5,
18 there are angiogenic eye disorders that should be
19 included in this "method for treating" which
20 requires a high level of efficacy.

14:50:52

21 BY MR. SALMEN:

22 Q. Are there angiogenic eye disorders that
23 are listed in Column 5, lines 16 to 29, that should
24 not be included in the "method of treating" under
25 Claim 1?

14:51:12

1 A. In my declaration, I did not provide an 14:51:23
2 opinion on all of these angiogenic eye disorders. I
3 specifically gave an opinion on wet age-related
4 macular degeneration. More specifically I mentioned
5 diabetic macular edema and retinal vein occlusion. 14:51:47
6 I would have to look at the literature more
7 carefully on this extensive list to provide a more
8 accurate answer.

9 Q. And you did not look at the literature
10 more carefully against this extensive list in 14:52:05
11 formulating your opinion regarding "a method of
12 treating an angiogenic eye disorder" as that term is
13 used in Claim 1 of the '338 patent?

14 A. In my declaration, I provided an opinion.

15 (Conference operator interruption.) 14:52:28

16 A. In my declaration, I provided an opinion
17 on how the "method of treatment" should provide a
18 high level of efficacy that is non-inferior to the
19 standard of care. I did not directly provide an
20 opinion on some of the angiogenic eye disorders 14:53:06
21 listed here that I do not have clinical trial
22 information on.

23 Q. So sitting here today, is it your opinion
24 that the existing standard of care as of
25 January 2011 was exactly the same for every one of 14:53:25

1 these 19 angiogenic eye disorders?

14:53:30

2 A. The standard of care is the best available
3 medical treatment for that particular condition.

4 This list includes many angiogenic eye disorders.

5 And I would have to review the medical literature on

14:53:54

6 some of these more less-common angiogenic eye
7 disorders to refresh my memory on what the current
8 standard of care at 2011 was for some of those
9 conditions.

10 Q. Did you refresh your recollection, as you
11 just testified, prior to forming your opinions
12 regarding the "method of treating" that's covered by
13 Claim 1 of the '338 patent?

14:54:19

14 A. In my experience, I understood the
15 standard of care prior to January of 2011 to be use
16 of Lucentis or off-label Avastin for many of the
17 angiogenic eye disorders, including wet age-related
18 macular degeneration, diabetic macular edema,
19 retinal vein occlusion and so forth.

14:54:42

20 Q. Okay. But you did not determine what the
21 standard of care was for the entire list of
22 angiogenic eye disorders that appears in Claim 5,
23 lines 16 to 29; is that correct?

14:55:09

24 A. I don't recall. But I would have to
25 review. Because some of those disorders mentioned

14:55:34

1 on this list, such as corneal neovascularization, 14:55:38
2 have not been in clinical trials. So I would have
3 to review the literature.

4 Q. Okay. In paragraph 84 of your
5 declaration, in the second sentence, you state, 14:56:02
6 "This may vary somewhat depending on the particular
7 angiogenic eye disorder."

8 Do you see that?

9 A. Yes, I see that.

10 Q. And you're referring to -- you're 14:56:21
11 referring to the standard of care at the time of
12 patent filing as what may vary somewhat depending on
13 the particular angiogenic eye disorder; is that
14 correct?

15 A. That is correct. 14:56:38

16 Q. And you agree with that statement, sitting
17 here today; correct?

18 A. As I stated, "The POSA would consider the
19 claimed method of treatment as one that achieves a
20 high level of efficacy that is non-inferior to the 14:56:51
21 standard of care at the time of patent filing. This
22 may vary somewhat depending on the particular
23 angiogenic eye disorder."

24 Q. Okay. And looking back at our Do
25 Deposition Exhibit No. 4, where we have the green 14:57:10

1 highlighted language inserted in Claim 1, the
2 standard of care for that particular angiogenic eye
3 disorder at the time of filing, that language is
4 what may vary somewhat depending on the particular
5 angiogenic eye disorder that this method of
6 treatment is being used for; correct?

14:57:13

7 A. It refers to the high level of efficacy
8 that is non-inferior to the standard of care.

9 Q. And the standard of care is specific to
10 the angiogenic eye disorder that is being treated
11 under this claimed method of treatment; right?

14:57:36

12 A. Yes, that would be true.

13 Q. And there's potentially a different
14 definition of "standard of care" for every single
15 one of these 19 angiogenic eye disorders; right?

14:57:53

16 A. That is possible.

17 Q. Do ophthalmologists like yourself still
18 use laser and photodynamic therapies to treat
19 angiogenic eye disorders?

14:58:06

20 A. What time period are you referring to?

14:58:32

21 Q. Currently.

22 A. Currently -- are you referring to -- which
23 type of laser?

24 Q. What types of lasers are there?

25 A. Types of laser procedures would include

14:58:56

1 focal laser photocoagulation or panretinal laser

14:59:00

2 photocoagulation.

3 Q. So back to my question.

4 Do ophthalmologists like yourself still

5 use lasers and photodynamic therapies to treat

14:59:28

6 angiogenic eye disorders?

7 A. In my declaration, I did not give an

8 opinion on what -- or whether ophthalmologists

9 currently are using laser for angiogenic eye

10 disorders, but in my experience, the standard of

14:59:50

11 care for many angiogenic eye disorders is the use of

12 intravitreal VEGF inhibitors and, therefore, laser

13 is not an effective method of treatment.

14 Q. Okay. So is it your opinion that laser

15 and photodynamic therapies are below the standard of

15:00:20

16 care in treating angiogenic eye disorders?

17 MS. FISHMAN: Objection; vague as to time.

18 THE WITNESS: Which time period are you

19 referring to?

20 BY MR. SALMEN:

15:00:38

21 Q. Start with currently.

22 A. In my experience as an ophthalmologist,

23 currently, in the year 2022, focal laser

24 photocoagulation and photodynamic therapy are not

25 part of the standard of care for treating angiogenic

15:00:56

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1 eye disorders.

15:01:00

2 Q. In your experience as an ophthalmologist
3 in January 2011, were focal photocoagulation laser
4 and photodynamic therapies parts of the standard of
5 care for treating angiogenic eye disorders?

15:01:21

6 A. In my experience as an ophthalmologist,
7 prior to January of 2011, intravitreal VEGF
8 inhibitors, such as Lucentis or off-label Avastin,
9 had become the standard of care in treating
10 angiogenic eye disorders because they provided a
11 high level of efficacy in terms of vision gain or
12 maintenance of vision.

15:01:54

13 Q. Are you applying that same opinion to all
14 19 of the angiogenic eye disorders that are listed
15 in Column 5, lines 16 to 29?

15:02:14

16 A. As I stated earlier, the standard of care
17 may vary depending on the particular angiogenic eye
18 disorder at a certain time period.

19 Q. So I don't think I got an answer to
20 whether or not, currently, ophthalmologists like
21 yourselves are still using the laser and
22 photodynamic therapies to treat angiogenic eye
23 disorders.

15:02:54

24 A. In my experience, I am not using focal
25 laser photocoagulation or photodynamic therapy laser

15:03:12

1 for the treatment of angiogenic eye disorders

15:03:17

2 because those are not effective options for

3 angiogenic eye disorders.

4 Q. Are you aware of any of your colleagues

5 that are licensed ophthalmologists that are still

15:03:30

6 using those treatments?

7 A. Currently, in 2022, the standard of care

8 for many of these angiogenic eye disorders is the

9 use of intravitreal VEGF inhibitors. And,

10 therefore, I believe the vast majority of

15:03:55

11 ophthalmologists are following this new standard of

12 care.

13 Q. So you referred to "the vast majority."

14 Does that mean the answer to my previous

15 question was, yes, some of your colleagues that are

15:04:19

16 licensed ophthalmologists are still using those

17 treatments for angiogenic eye disorders?

18 MS. FISHMAN: Objection; lacks foundation.

19 You can answer.

20 THE WITNESS: I don't think ophthalmologists in

15:04:33

21 today's medical world are using focal laser

22 photocoagulation or photodynamic therapy for most of

23 these angiogenic eye disorders. But I can't rule

24 out the possibility that a very small minority may

25 be.

15:05:01

1 BY MR. SALMEN:

15:05:01

2 Q. Is it your opinion then that that small
3 minority that may still be using laser and
4 photodynamic therapies are treating their patients
5 unethically?

15:05:12

6 MS. FISHMAN: Objection; misstates testimony.

7 But you can answer.

8 THE WITNESS: In my declaration, I do not
9 provide an opinion on how ophthalmologists in 2022
10 may or may not be using focal laser photocoagulation
11 or photodynamic therapy.

15:05:30

12 BY MR. SALMEN:

13 Q. What about Lucentis off-label dosing
14 regimens? Are you aware of any colleagues that are
15 licensed ophthalmologists that administer Lucentis
16 in an off-label dosing regimen to treat angiogenic
17 eye disorders?

15:05:55

18 MS. FISHMAN: Objection; vague, lacks
19 foundation.

20 You can answer.

15:06:05

21 THE WITNESS: What are you referring to as "an
22 off-label dosing regimen"?

23 BY MR. SALMEN:

24 Q. What do you consider a dosing regimen that
25 is a recommended approved indication in the Lucentis

15:06:19

1 label?

15:06:24

2 A. Do you have a copy of the current Lucentis

3 label?

4 Q. Did you cite one in your expert

5 declaration?

15:06:33

6 (Witness reviews document.)

7 A. It would be helpful to have the actual

8 label here to reference.

9 Q. Let me ask you a different question.

10 Could we turn to example 5 of the '338 patent.

15:07:17

11 (Conference operator interruption.)

12 Q. Dr. Do, you reviewed Example 5 of the '338

13 patent in forming your opinions regarding the scope

14 and meaning of the "method of treating" that's

15 covered by the '338 patent; correct?

15:07:55

16 A. Yes, I have.

17 Q. And Example 5 provides the results for a

18 Phase 2 clinical trial of VEGF-Trap-Eye in subjects

19 with diabetic macular edema, or DME; correct?

20 A. That is correct.

15:08:15

21 Q. Starting at line 64 of Column 13 here, you

22 see that one of the VEGF-Trap arms of the trial

23 included a dosing regimen of three initial doses at

24 baseline in Weeks 4 and 8 followed by

25 every-eight-week dosing through Week 52; is that

15:08:38

1 correct?

15:08:42

2 A. Yes, I see that sentence.

3 Q. Okay. So you would agree that the regimen
4 for this arm of the Phase 2 clinical trial comprises
5 an initial dose followed by two secondary doses
6 followed by a series of eight-week doses through
7 Week 52; is that correct?

15:08:55

8 A. Yes, that is what is written.

9 Q. Do you agree that this regimen falls
10 within the scope of Claim 1 of the '338 patent?

15:09:13

11 MS. FISHMAN: Objection; calls for a legal
12 conclusion and vague as to time.

13 THE WITNESS: In Example 5, this is a Phase 2
14 clinical trial in diabetic macular edema. And it
15 appears that they are evaluating different dosing
16 regimens.

15:09:37

17 BY MR. SALMEN:

18 Q. My question was, the regimen that we just
19 described, the 2Q8 arm of the Phase 2 clinical
20 trial, do you agree that that regimen falls within
21 the scope of the Claim 1 "method of treating" for
22 the '338 patent?

15:10:00

23 MS. FISHMAN: Objection; vague as to time.

24 THE WITNESS: Example 5 is a Phase 2 clinical
25 trial, whereas the Example 4, which we discussed,

15:10:23

1 was the Phase 3 clinical trial. So there are

15:10:29

2 differences between Phase 2 and Phase 3 clinical
3 trials.

4 MR. SALMEN: Okay. I'm going to again move to
5 strike that answer as not being responsive to my
6 question.

15:10:42

7 BY MR. SALMEN:

8 Q. My question was, do you agree that the 2Q8
9 regimen that's described in Example 5 of the '338
10 patent falls within the scope of Claim 1 of the '338
11 patent?

15:10:57

12 MS. FISHMAN: Same objection.

13 THE WITNESS: In Example 5, the Phase 2
14 clinical trial of VEGF-Trap in subjects with
15 diabetic macular edema, the study is evaluating the
16 dosing regimen of 2 milligrams of VEGF-Trap given
17 every eight weeks after initial and secondary doses.

15:11:22

18 BY MR. SALMEN:

19 Q. Is the data in Example 5 not sufficient,
20 in your opinion, to qualify that 2Q8 dosing regimen
21 as "a method for treating an angiogenic eye disorder
22 in a patient that achieves a high level of efficacy
23 that is non-inferior to the standard of care for
24 that particular angiogenic eye disorder at the time
25 of the '338 patent filing"?

15:11:50

15:12:14

1 A. In my declaration, I did not specifically
2 provide an opinion on Example 5. As an
3 ophthalmologist, in my experience, Phase 2 clinical
4 trials do not always predict results of Phase 3
5 clinical trials. That's why pivotal Phase 3
6 clinical trials are necessary to determine the
7 efficacy and safety of a new medicine.

15:12:23

8 Q. There are no Phase 3 clinical trial data
9 for the use of VEGF-Trap in subjects with diabetic
10 macular edema in the '338 patent; correct?

15:12:46

11 A. I believe at the time of the filing of the
12 patent, the Phase 3 clinical trials were under way
13 and the results were not yet known.

14 Q. Okay. So the answer to my question is,
15 yes, there are no Phase 3 clinical trial data for
16 the use of VEGF-Trap-Eye in subjects with diabetic
17 macular edema in the '338 patent; correct?

15:13:14

18 A. In this patent, the Example 5 lists the
19 Phase 2 data.

20 Q. And it's your opinion that the Phase 2
21 clinical trial data of VEGF-Trap in subjects with
22 diabetic macular edema is not sufficient to support
23 or confirm the "method for treating an angiogenic
24 eye disorder in a patient achieves a high level of
25 efficacy that is non-inferior to the existing

15:13:40

15:14:06

15:14:30

1 standard of care"; right?

15:14:34

2 A. I believe the Phase 2 clinical trial,
3 which I did not provide an opinion on in my
4 declaration, provides a positive signal. But
5 Phase 3 clinical trials are always necessary to
6 confirm.

15:15:00

7 Q. So I still want an answer to my question,
8 Dr. Do.

9 Is it your opinion that Example 5, the 2Q8
10 dosing regimen that's described, is "a method of
11 treating" that falls within the scope of Claim 1 of
12 the '338 patent?

15:15:25

13 MS. FISHMAN: Objection; lacks foundation and
14 asked and answered.

15 But you can answer.

15:15:39

16 THE WITNESS: Can you repeat the question.

17 BY MR. SALMEN:

18 Q. Yeah. And it hasn't been answered.

19 Is it your opinion that Example 5, the 2Q8
20 dosing regimen described in that example, is "a
21 method of treating" that falls within the scope of
22 Claim 1 of the '338 patent?

15:15:52

23 A. I believe the Example 5, which was a
24 Phase 2 clinical trial, provided a very positive
25 signal that VEGF-Trap given every eight weeks after

15:16:16

1 initial and secondary doses was highly efficacious
2 in improving visual acuity, as stated in the table
3 at Week 24 and 52.

15:16:25

4 Q. Okay. Does Example 5 provide a positive
5 signal that VEGF-Trap was non-inferior to the
6 existing standard of care?

15:16:50

7 MS. FISHMAN: Objection; vague and incomplete.

8 THE WITNESS: As I mentioned, I did not provide
9 an opinion on this Example 5 in my declaration.

10 Looking back as an ophthalmologist at the time
11 period January 2011, the standard of care at that
12 time for diabetic macular edema was off-label
13 Avastin.

15:17:19

14 BY MR. SALMEN:

15 Q. The control arm -- the control group for
16 the Phase 2 clinical trial in Example 5 received
17 macular laser therapy.

15:17:38

18 Do you see that?

19 A. I see that.

20 Q. That was below the standard of care at the
21 time, as of January 2011, when this patent
22 application was filed; right?

15:17:54

23 A. I agree that at the time this patent was
24 filed, laser photocoagulation was no longer the
25 standard of care for diabetic macular edema.

15:18:17

1 Q. Lucentis was approved in 2006; right?

15:18:20

2 MS. FISHMAN: Objection; lacks foundation.

3 THE WITNESS: Lucentis was approved for

4 neovascular AMD in 2006.

5 BY MR. SALMEN:

15:18:28

6 Q. And Lucentis was available to licensed

7 ophthalmologists to treat diabetic macular edema off

8 label if they chose to do so; correct?

9 MS. FISHMAN: Objection; lacks foundation.

10 But you can answer.

15:18:41

11 THE WITNESS: At that time, prior to

12 January 2011, I do not recall ophthalmologists using

13 Lucentis off label for the treatment of diabetic

14 macular edema prior to its FDA approval.

15 As I stated, in January of 2011, the

15:19:01

16 standard of care for diabetic macular edema had

17 evolved to the use of off-label Avastin because that

18 could provide high efficacy.

19 BY MR. SALMEN:

20 Q. Let's look at Example 6. That appears in

15:19:19

21 Column 14 of the '338 patent.

22 Example 6 refers to "A Randomized,

23 Multicenter, Double-Masked Trial in Treatment Naive

24 Patients with Macular Edema Secondary to CRVO."

25 Do you see that?

15:20:14

1 A. I see that.

15:20:15

2 Q. Macular edema is an angiogenic eye
3 disorder; correct?

4 A. Macular edema, secondary to CRVO, yes, is
5 an angiogenic eye disorder.

15:20:29

6 Q. If we look at Column 5 of the '338 patent,
7 macular edema following CRVO is listed as an
8 angiogenic eye disorder that is treatable using the
9 method of treatment claimed in the '338 patent;
10 correct?

15:20:48

11 A. Yes, it lists macular edema and vein
12 occlusion.

13 Q. Here in Example 6, you see the control arm
14 in the clinical trial involves 73 patients that
15 received six monthly sham injections; is that
16 correct?

15:21:09

17 A. Yes, I see that wording.

18 Q. I'm stating the obvious here, Dr. Do.

19 Sham injections were not the standard of
20 care for treating macular edema following CRVO as of
21 January 2011; is that correct?

15:21:23

22 A. As of January 2011, the standard of care
23 for treating macular edema to CRVO had evolved to
24 off-label Avastin or the recently FDA-approved
25 Lucentis.

15:21:52

1 Q. So sham injections were not the standard 15:21:53
2 of care as of January 2011; correct?

3 A. I did not provide an opinion on the
4 specific study design or sham injections that you're
5 referring to in my declaration. However, in my 15:22:11
6 experience as an ophthalmologist, these clinical
7 trials of VEGF-Trap in central retinal vein
8 occlusion were initiated before the FDA approval of
9 Lucentis. And, therefore, sham injections were used
10 as a study arm. 15:22:44

11 Q. So is it your opinion that sham injections
12 were the standard of care at the time that this
13 Example 6 trial was conducted?

14 MS. FISHMAN: Objection; misstates testimony
15 and lacks foundation. 15:23:00

16 You can answer.

17 Also beyond the scope.

18 You can answer.

19 THE WITNESS: As I stated before, the standard
20 of care by January 2011 for the treatment of macular 15:23:11
21 edema due to retinal vein occlusion was the use of
22 off-label Avastin or the recently approved, as of
23 2010, Lucentis.

24 BY MR. SALMEN:

25 Q. You also stated that, at the time of this 15:23:29

1 trial, Lucentis had not been approved; is that

15:23:36

2 correct?

3 A. That is what I stated.

4 Q. So prior to the approval of Lucentis, when

5 you testified that this trial was conducted, were

15:23:47

6 sham injections the standard of care?

7 A. In my declaration, I did not provide an
8 opinion on this specific trial design and whether or
9 not sham injections should have been considered.

10 However, as an ophthalmologist with many

15:24:14

11 years of experience, I can say that clinical trial

12 designs include what the treatment options were at

13 the time of the initiation of the trial. And

14 because, at the time of initiation of that clinical

15 trial, Lucentis was not FDA approved, observation or

15:24:38

16 sham injections was an option, albeit not a very

17 effective one, for retinal vein occlusion.

18 MS. FISHMAN: Do you want to take a break?

19 Heinz, are you at a good stopping point?

20 MR. SALMEN: Yeah, I think so. Why don't we

15:25:34

21 take a short break.

22 THE VIDEOGRAPHER: We're going off the record.

23 The time is 3:25.

24 (Recess taken.)

25 THE VIDEOGRAPHER: We're back on the record.

15:32:32

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1 The time is 3:32.

15:32:33

2 BY MR. SALMEN:

3 Q. Dr. Do, let's look at paragraph 67 of your
4 declaration, please. It's on page 25 of 67 in
5 Exhibit 2051.

15:32:48

6 Are you there?

7 A. Yes, I am.

8 Q. Okay. In this paragraph, you refer to a
9 couple of references, "Ciulla and Rosenfeld," in
10 2009. It's actually one reference, Exhibit 1074.

15:33:03

11 A. Yes, I see that exhibit.

12 Q. Am I pronouncing that name correctly?

13 A. That's correct, Ciulla.

14 Q. And you state in your declaration that all
15 documents and references that you cite are ones that
16 you've reviewed; is that correct?

15:33:40

17 A. That is correct.

18 Q. So you reviewed Ciulla in forming your
19 opinions?

20 A. That is correct.

15:33:52

21 (Deposition Exhibit 1074 was previously
22 marked.)

23 BY MR. SALMEN:

24 Q. Okay. Look at page 4 of the Ciulla
25 reference. It's Exhibit page 4, so the bottom

15:34:00

1 right-hand corner, page 4.

15:34:06

2 Top left-hand corner, do you see that
3 paragraph along the left-hand column that describes
4 the PrONTO study?

5 A. Yes, I see that sentence.

15:34:29

6 Q. You stated earlier today that you're
7 familiar with the PrONTO study; is that correct?

8 A. Yes, I am familiar with that study.

9 Q. Do you agree that the PrONTO study
10 required 24 dilated office visits in the first year
11 with injections on an as-needed basis?

15:34:57

12 MS. FISHMAN: Objection; beyond the scope.

13 But you can answer.

14 THE WITNESS: I would like to see the
15 manuscript of the PrONTO study to provide a more
16 accurate answer for you.

15:35:17

17 BY MR. SALMEN:

18 Q. The PrONTO study was completed before
19 January 2011; is that correct?

20 MS. FISHMAN: Same objection.

15:35:33

21 THE WITNESS: Again, I would like to see the
22 actual manuscript to provide the most accurate
23 answer.

24 BY MR. SALMEN:

25 Q. Dr. Do, this Ciulla reference,

15:35:49

1 Exhibit 1074, on the front page, you'll see that it
2 says published in 2009; correct?

15:35:52

3 A. That is correct.

4 Q. And on page 4, which we were looking at,
5 it provides the two-year, or 24-month, results of
6 the PRONTO study; correct?

15:36:04

7 A. In the Ciulla paper, it does make a
8 reference to "at 24 months" in the PRONTO study.

9 Q. So you agree then that the PRONTO study
10 was completed before January 2011; is that correct?

15:36:33

11 MS. FISHMAN: Objection; document speaks for
12 itself.

13 You can answer.

14 THE WITNESS: It appears to be that way.

15 BY MR. SALMEN:

15:36:46

16 Q. In 2009, when Ciulla published, you would
17 agree that Lucentis was the standard of care for
18 treating angiogenic eye disorders; is that correct?

19 MS. FISHMAN: Objection; misstates testimony.

20 But you can answer.

15:37:15

21 MR. SALMEN: Let me rephrase the question.

22 BY MR. SALMEN:

23 Q. In 2009, when Ciulla published, you would
24 agree that Lucentis or off-label Avastin was the
25 standard of care for treating angiogenic eye

15:37:28

1 disorders; is that correct?

15:37:29

2 A. As I stated earlier, at the time period of
3 2009, Lucentis was FDA approved for the treatment of
4 wet age-related macular degeneration and had become
5 one of the standard of care options for that
6 condition as well as off-label Avastin.

15:37:50

7 Q. Dr. Do, I'm going to hand you what was
8 previously marked as Mylan Exhibit 1035 in
9 IPR 2021-00881. This is a paper by Lalwani.

10 (Deposition Exhibit 1035 was previously
11 marked.)

15:38:58

12 BY MR. SALMEN:

13 Q. Dr. Do, have you seen Exhibit 1035 in
14 preparing your declaration?

15 A. I don't recall if I've seen this exact
16 exhibit.

15:39:30

17 Q. You reviewed Dr. Albin's declaration;
18 correct?

19 A. I did review his declaration.

20 Q. And during Dr. Albin's deposition, he was
21 asked a number of questions about the information
22 regarding the PRONTO study that's published in
23 Exhibit 1035.

15:39:45

24 Are you aware of that?

25 MS. FISHMAN: Objection; lacks foundation and

15:40:02

1 calls for speculation.

15:40:04

2 You can answer.

3 THE WITNESS: I did not review his deposition.

4 BY MR. SALMEN:

5 Q. Okay. Do you agree that Exhibit 1035
6 provides the Year 2 results of the PRONTO study?

15:40:10

7 A. It appears that from the title, "A
8 Variable-Dosing Regimen with Intravitreal
9 Ranibizumab for Neovascular Age-related Macular
10 Degeneration: Year 2 of the PRONTO Study," that it
11 may provide that information.

15:40:44

12 Q. Direct your attention to page 3 of this
13 exhibit.

14 On the left-hand side column, the first
15 full paragraph reads, "Eligible patients underwent
16 VA testing and ophthalmoscopic examination at
17 baseline, days 14, 30, 45 and 60, and then monthly
18 thereafter. Fundus photography and OCT imaging were
19 performed at baseline and on days 1, 2, 4, 7, 14 and
20 30 after the first two injections and then monthly
21 thereafter. FA was performed at baseline, months 1,
22 2 and 3, and then every three months thereafter.

15:41:06

23 All ophthalmic photographers and the single OCT
24 technician involved in the study were previously
25 certified and participated in FDA-approved clinical

15:41:36

15:41:58

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1 trials at the Bascom Palmer Eye Institute."

15:42:01

2 Do you see that?

3 A. I see that paragraph.

4 Q. And then the first sentence of the next
5 paragraph states, "Intravitreal injections of
6 ranibizumab were administered to all patients at
7 baseline, month 1 and month 2."

15:42:09

8 Do you see that?

9 A. I see that.

10 Q. Now, Dr. Do, are you aware that Regeneron
11 has taken the position that the PrONTO study
12 required 24 dilated office visits in the first year
13 with injections on an as-needed basis?

15:42:24

14 A. I think that sounds reasonable.

15 Q. Is that your understanding of the PrONTO
16 study, that it required 24 dilated office visits in
17 the first year with injections on an as-needed
18 basis?

15:42:53

19 MS. FISHMAN: Objection; beyond the scope.

20 But you can answer.

15:43:08

21 THE WITNESS: Could you repeat the question.

22 BY MR. SALMEN:

23 Q. Is it your understanding from the PrONTO
24 study that it required 24 dilated office visits in
25 the first year with injections on an as-needed

15:43:19

1 basis?

15:43:22

2 A. I believe from the study design, what is
3 written here, that patients were seen at Days 1, 2,
4 4, 7, 14, 30, 45, 60 and then monthly thereafter.

5 And there were, based on this document, certain
6 criteria for reinjections.

15:44:04

7 Q. Okay. The dosing regimen that was being
8 tested only allowed for injections on a monthly
9 basis; is that correct?

10 MS. FISHMAN: Objection; document speaks for
11 itself.

15:44:28

12 You can answer if you know.

13 THE WITNESS: Although I didn't specifically
14 provide an opinion on this Year 2 PrONTO study
15 document in my declaration, in looking at this
16 manuscript and the method statement, it writes that
17 "During the first year, retreatment with ranibizumab
18 was performed at each monthly visit if any criterion
19 was fulfilled, such as an increase in OCT-CRT of at
20 least 100 microns or a loss of five letters or
21 more."

15:44:53

15:45:22

22 BY MR. SALMEN:

23 Q. So you agree then that the PrONTO dosing
24 regimen did not allow for dosing more frequent than
25 monthly injections? Would you agree with that?

15:45:37

1 MS. FISHMAN: Objection; document speaks for 15:45:39
2 itself, outside the scope.

3 But you can answer.

4 THE WITNESS: As I stated, what the document
5 writes is that retreatment with ranibizumab was 15:45:50
6 performed at each monthly visit if any criterion was
7 fulfilled.

8 BY MR. SALMEN:

9 Q. So all of those extra visits in the
10 initial 60 days were needed to evaluate the 15:46:19
11 performance of the drug within the dosing regimen
12 that was being tested during the actual PrONTO
13 clinical trial; would you agree with that?

14 MS. FISHMAN: Objection; lacks foundation.

15 But you can answer. 15:46:41

16 (Witness reviews document.)

17 THE WITNESS: The manuscript states that the
18 protocol for the PrONTO study required patients to
19 come back at these certain time points.

20 BY MR. SALMEN: 15:47:17

21 Q. In your experience, Dr. Do, is it uncommon
22 during a clinical trial to have the patients come in
23 for extra visits even though the patient is not
24 receiving an injection with a therapeutic amount of
25 the drug being tested? 15:47:35

1 A. In my declaration, I do not provide an
2 opinion on a specific topic of clinical trial
3 design. However, my experience as an
4 ophthalmologist in a clinical trial, additional
5 visits are sometimes included in the study design
6 for safety or other reasons --

15:47:38

7 Q. Okay.

8 A. -- depending on the trial.

9 Q. So with respect to the VIEW 1/VIEW 2
10 trials for VEGF-Trap, you understand that those
11 incorporated monthly visits and sham injections for
12 the patients in the 2Q8 arm of that trial; correct?

15:48:13

13 A. Yes, I understand that study design.

14 Q. Yeah, and I think -- in paragraph 75 of
15 your declaration, you state, "2 milligrams VEGF-Trap
16 every 4 weeks to Week 8 and then every 8 weeks (2Q8)
17 (to maintain masking, sham injections were given at
18 the interim 4-week visits after Week 8)"; is that
19 correct?

15:48:35

20 A. That is correct.

15:48:59

21 Q. And I think you're quoting directly from
22 the patent, Example 4, Column 9, beginning at
23 line 55; is that correct?

24 A. Which patent are you referring to?

25 Q. The '338 patent, Exhibit 1001, Column 9,

15:49:19

1 line 58.

15:49:24

2 (Witness reviews document.)

3 Q. Is that correct?

4 A. The wording is similar.

5 Q. So to maintain masking during the VIEW

15:50:00

6 trials, the patients in the 2Q8 arm actually had the
7 same number of office visits as the patients in the
8 Lucentis monthly arm; is that correct?

9 A. In the VIEW studies, patients who were

10 randomized to 2 milligrams VEGF-Trap every four

15:50:28

11 weeks and then to every eight weeks were required to
12 come back monthly to maintain masking with sham
13 injections.

14 Q. And they were -- they were evaluated

15 during those monthly visits -- let me strike that

15:50:49

16 and say it more clearly.

17 The patients in the 2Q8 arm were evaluated

18 at each of those monthly visits; is that correct?

19 A. I would have to review the exact

20 manuscript to refresh my memory if they were

15:51:11

21 evaluated at each of those monthly sham visits.

22 Q. They did have to at least come into the

23 office for each of those monthly visits; correct?

24 A. Yes, those patients had to come to the

25 office.

15:51:31

1 Q. And the patients in the VEGF-Trap 2Q8 arm
2 of the VIEW trials were injected at each of the
3 monthly visits; correct?

15:51:31

4 MS. FISHMAN: Objection.

5 THE WITNESS: In regards to the 2 milligrams
6 every eight weeks, "sham injections" do not mean
7 actual injections. They mean pretend injections.
8 Sham is otherwise known as a fake injection. So in
9 my experience as an ophthalmologist in clinical
10 trials, a sham injection is a pretend injection to
11 preserve masking in the clinical trial.

15:51:52

15:52:20

12 BY MR. SALMEN:

13 Q. So to be clear, the patients in the 2Q8
14 arm came in every single month and received either
15 an injection of EYLEA or a sham injection; is that
16 correct?

15:52:40

17 A. In the patients randomized to the
18 2 milligram every-eight-week arm in the VIEW trials,
19 there were designated time periods where those
20 participants would come in and, based on the
21 schedule, either receive a sham/fake injection or
22 injection of VEGF-Trap.

15:53:01

23 Q. After the VIEW trials were published and
24 EYLEA was approved, you didn't require your patients
25 to come in on a monthly basis and receive either a

15:53:29

1 sham injection or an injection of EYLEA, did you?

15:53:34

2 A. After VEGF-Trap was approved, then
3 patients could be placed on an every-eight-week
4 dosing schedule. And I did not treat patients with
5 sham or have them come in for a sham treatment.

15:53:55

6 Q. So after the VIEW trials were published
7 and EYLEA was approved, licensed ophthalmologists
8 like yourself were able to eliminate those sham
9 injections from the dosing regimen that was used in
10 the 2Q8 arm of the VIEW trials; is that correct?

15:54:15

11 MS. FISHMAN: Objection; lacks foundation.

12 But you can answer.

13 THE WITNESS: After EYLEA was approved for wet
14 age-related macular degeneration, no ophthalmologist
15 was performing sham injections.

15:54:33

16 BY MR. SALMEN:

17 Q. So even though the regimen applied during
18 the clinical trials required monthly visits and
19 bimonthly sham injections, licensed ophthalmologists
20 like yourself did not have to follow that rigorous
21 protocol in your actual practice; is that correct?

15:54:50

22 MS. FISHMAN: Objection; lacks foundation,
23 mischaracterizes the document.

24 You can answer.

25 THE WITNESS: The document you're referring to,

15:55:07

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1 the VIEW 1 and VIEW 2 clinical trials, required the
2 sham injection because of the design of the clinical
3 trial and what the FDA required to keep the patients
4 masked or blinded to whatever treatment they were
5 receiving. Once EYLEA is FDA approved, in clinical
6 practice, no ophthalmologist would be offering sham
7 injections.

15:55:10

15:55:34

8 BY MR. SALMEN:

9 Q. So no ophthalmologist adopted the
10 bimonthly sham injection visit that was used in the
11 VIEW clinical trials; is that correct?

15:56:00

12 A. After EYLEA was FDA approved,
13 ophthalmologists, based on the data from the VIEW 1
14 and VIEW 2 trials, could use EYLEA with the initial,
15 secondary and tertiary doses, with the tertiary
16 doses being given every eight weeks apart while
17 still providing the high level of efficacy.

15:56:33

18 Q. Those sham injection visits were just part
19 of the clinical trial design for the VIEW trials;
20 right?

15:56:58

21 A. Sham injection visits are part of clinical
22 trial designs, not part of clinical practice.

23 Q. So after the PRONTO clinical trial was
24 completed, did ophthalmologists like yourself adopt
25 the rigorous testing that was required, the 24

15:57:23

1 dilated visits for treating patients with

15:57:28

2 ranibizumab?

3 A. In my declaration, I did not provide an

4 opinion on what ophthalmologists did in regards to

5 the PrONTO study design. However, in my experience

15:57:47

6 as an ophthalmologist, I did not adopt the multitude

7 of visits that were employed in the PrONTO study.

8 Q. So licensed ophthalmologists like yourself

9 did not interpret the PrONTO results as actually

10 requiring 24 dilated office visits for your patients

15:58:22

11 to treat angiogenic eye disorder with ranibizumab;

12 correct?

13 MS. FISHMAN: Objection; beyond the scope and

14 calls for speculation.

15 But you can answer.

15:58:34

16 THE WITNESS: I did not offer an opinion on

17 what ophthalmologists did after reading the PrONTO

18 study. I don't recall and don't know if they

19 followed the protocol written in the PrONTO study.

20 MR. SALMEN: I'm going to hand you what was

15:59:05

21 previously marked as Exhibit 2093.

22 (Deposition Exhibit 2093 was previously

23 marked.)

24 BY MR. SALMEN:

25 Q. Exhibit 2093 is a reference authored by

15:59:14

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1 Ron Margolis, M.D. and K. Bailey Freund, M.D.

15:59:30

2 Dr. Do, do you know what Dr. Ron Margolis
3 is?

4 A. I am not familiar with him.

5 Q. Do you know Dr. David Brown?

15:59:52

6 A. I do know Dr. David Brown.

7 Q. Are you aware that Dr. Brown submitted a
8 declaration in this proceeding?

9 A. I am aware he submitted a declaration.

10 Q. Did you review his declaration?

16:00:07

11 A. I did not review his declaration.

12 Q. I'll represent to you that Dr. Brown
13 relies on Exhibit 2093 in his declaration. He cites
14 to it.

15 If you look at page 3 of this exhibit.

16:00:24

16 A. Um-hum.

17 Q. The bottom full paragraph states, "The
18 PRONTO trial demonstrated visual outcome data
19 similar to the MARINA and ANCHOR trials of
20 ranibizumab while reducing the total number of
21 injections by 50 percent."

16:00:45

22 Do you dispute that conclusion that
23 Dr. Margolis had here in his paper?

24 MS. FISHMAN: Objection; beyond the scope,
25 document speaks for itself.

16:01:00

1 You can answer.

16:01:03

2 THE WITNESS: I did not provide an opinion on
3 the Margolis paper in my declaration. However, I do
4 not completely agree with the statement "The PrONTO
5 trial demonstrated visual acuity outcome data
6 similar to the MARINA and ANCHOR trials of
7 ranibizumab."

16:01:24

8 BY MR. SALMEN:

9 Q. Why do you not completely agree with that
10 statement?

16:01:36

11 A. I did not discuss the intricacies of the
12 PrONTO study in my declaration. However, as an
13 ophthalmologist with experience, I would say that
14 the PrONTO study is an open-label, single-center
15 uncontrolled clinical trial. Whereas the MARINA and
16 ANCHOR trials of Lucentis were randomized,
17 controlled Phase 3 clinical trials. And one cannot
18 directly compare the PrONTO study results with the
19 MARINA/ANCHOR trial results.

16:02:05

20 Q. So you do disagree with Dr. Margolis here
21 then. Because he does compare the PrONTO results
22 with the MARINA and ANCHOR results.

16:02:29

23 A. Yes, I guess I disagree with him.

24 Q. So the next sentence states, "It is
25 potentially significant that most clinical practices

16:02:47

1 deviate from the rigorous testing of visual acuity 16:02:50
2 with the Early Treatment Diabetic Retinopathy Study
3 chart as was used in the PrONTO study. Clinicians
4 have taken the PrONTO results a step further and are
5 commonly implementing a 'treat and extend' 16:03:11
6 strategy."

7 Do you see that?

8 A. I see those sentences.

9 Q. Do you disagree with those sentences as
10 well? 16:03:21

11 MS. FISHMAN: Objection; document speaks for
12 itself.

13 You can answer.

14 THE WITNESS: I --

15 BY MR. SALMEN: 16:03:35

16 Q. Sorry. I was going to make it easier.
17 Let me break it down.

18 The first sentence, "Most clinical
19 practices deviate from the rigorous testing of the
20 visual acuity with the ETDRS study chart as used in 16:03:46
21 the PrONTO study."

22 Do you agree or disagree with that
23 statement?

24 A. As I mention in my declaration, I did not
25 provide an opinion on the details of the PrONTO 16:04:03

1 study. However, as an ophthalmologist, in clinical
2 practice, we typically use the Snellen visual acuity
3 chart and not the early treatment in diabetic
4 retinopathy study chart to test visual acuity.

16:04:07

5 Q. Okay. Post PrONTO trial, did you require
6 your patients that you were administering Lucentis
7 to to treat their angiogenic eye disorder -- did you
8 make them come in for 24 dilated visits in the first
9 year?

16:04:28

10 A. Post Lucentis approval for wet age-related
11 macular degeneration, most patients were coming in
12 monthly if they were on Lucentis.

16:04:55

13 Q. And for the -- most patients that you were
14 just referring to that were receiving Lucentis, did
15 you inject every one of them on a monthly basis in
16 accordance with the label for Lucentis?

16:05:21

17 A. At the time period, prior to January 2011
18 and after 2006, when Lucentis was FDA approved, I
19 recall, yes, the vast majority of patients I was
20 treating with Lucentis did require monthly treatment
21 to become efficacious.

16:05:52

22 Q. You say they "did require monthly
23 treatment."

24 Is that based on evaluations that were
25 conducted at each of the monthly visits?

16:06:04

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1 A. Again, I did not provide an opinion on my
2 clinical practice details and testing of patients.
3 In my experience as an ophthalmologist, when
4 patients came in, I did evaluate them with the
5 clinical examination and with eye imaging before
6 administering Lucentis.

16:06:13

7 Q. And did you come to a conclusion as to
8 whether or not each of your patients needed an
9 additional injection of Lucentis?

10 A. In my clinical practice, I do carefully
11 assess each patient. And the majority of them did
12 need monthly administration of Lucentis to achieve
13 highly efficacious outcomes.

16:07:00

14 Q. The minority of the patients in your -- in
15 your clinical practice that did not need Lucentis on
16 a monthly basis, did you nonetheless inject them
17 with Lucentis every month?

16:07:24

18 A. In my declaration, I did not provide an
19 opinion on all the patients I treated with Lucentis.
20 As an ophthalmologist, I can speak to the fact that
21 many of these elderly patients with wet AMD had
22 health issues and sometimes missed their monthly
23 visit and therefore I could not inject them monthly.
24 And then I had to reassess them at their next
25 available appointment, which likely required another

16:07:48

16:08:13

1 administration of Lucentis because they missed their
2 prior visit.

16:08:21

3 Q. So after the approval of Lucentis, in your
4 clinical practice, did you commonly implement a
5 treat-and-extend strategy?

16:08:33

6 MS. FISHMAN: Objection; misstates testimony,
7 lacks foundation.

8 You can answer.

9 THE WITNESS: In my declaration, I did not
10 provide an opinion on treat-and-extend regimens. In
11 looking back at my practice, I can recall that
12 Lucentis was most efficacious in my hands when
13 treated monthly.

16:08:47

14 BY MR. SALMEN:

15 Q. You're familiar with the term
16 "treat-and-extend strategy"; right?

16:09:10

17 A. Yes, I am familiar with the term
18 treat-and-extend.

19 Q. Can you tell me what that means to you?

20 A. "Treat-and-extend regimen" means that a
21 patient comes in for a visit, receives a treatment
22 of an intravitreal VEGF inhibitor, then returns
23 again in one month for another assessment and
24 treatment. If at that next visit, the patient is
25 still active with their angiogenic eye disorder,

16:09:23

16:09:58

1 they get a treatment and come back the following
2 month.

16:10:05

3 If at some point, the disease is inactive
4 or stable, then the ophthalmologist may try to
5 extend the next visit, usually by two-week
6 intervals. But at each visit, a treatment is given
7 and an assessment is performed.

16:10:22

8 Q. In your description of a treat-and-extend
9 strategy, if the Lucentis patient is not given the
10 second monthly dose that you were referring to and
11 their treatment is extended two weeks, would that be
12 an off-label use of Lucentis at that point?

16:10:48

13 MS. FISHMAN: Objection; beyond the scope.

14 But you can answer.

15 THE WITNESS: I would need to see the specific
16 label of Lucentis to refresh my memory of what was
17 included in the label.

16:11:08

18 BY MR. SALMEN:

19 Q. Okay. Let me ask you this with regard to
20 Dr. Margolis' paper: He states, "Clinicians have
21 taken the PRONTO results a step further and are
22 commonly implementing a treat-and-extend strategy.
23 In this regimen, the time interval between
24 examinations and intravitreal injections is
25 gradually increased by one- to two-week increments

16:11:23

16:11:44

1 as long as there are no signs of re-exudation,
2 either clinically or on OCT."

16:11:48

3 Do you see that?

4 A. I see that sentence.

5 Q. Do you agree with Dr. Margolis'
6 description of a treat-and-extend strategy?

16:11:59

7 MS. FISHMAN: Objection; document speaks for
8 itself.

9 But you can answer.

10 THE WITNESS: What Dr. Margolis states in this
11 paragraph is a potential treat-and-extend regimen.

16:12:14

12 BY MR. SALMEN:

13 Q. And do you agree with Dr. Margolis that
14 clinicians, as of the time of this publication,
15 which was 2010, have taken the PrONTO results a step
16 further and are commonly implementing a
17 treat-and-extend strategy?

16:12:29

18 A. I didn't provide an opinion on
19 treat-and-extend and the prevalence of that in my
20 declaration. And I don't recall if it was commonly
21 employed or not.

16:13:08

22 Q. Dr. Do, let's look at your CV that was
23 marked previously as Exhibit 2002.

24 (Deposition Exhibit 2002 was previously
25 marked.)

16:15:21

1 BY MR. SALMEN:

16:15:21

2 Q. Is this a current copy of your CV?

3 A. Yes, it is.

4 Q. Can you tell me how many cases you've

5 served as an expert witness in the last 10 years?

16:15:54

6 A. Probably about five.

7 Q. And of those five cases that you've served

8 as an expert witness in the last 10 years, how many

9 of them were for Regeneron?

10 A. This is the first one.

16:16:18

11 Q. Okay. In page 21 of your CV, you have a

12 list there for "Current Research Support" under

13 "Grants and Clinical Trials."

14 Do you see that?

15 A. Yes, I see that.

16:16:51

16 Q. And it's stated here that you are

17 principal investigator on a project for Regeneron,

18 No. 5?

19 A. Yes, I see that.

20 Q. And is that project still ongoing?

16:17:13

21 A. Yes, that clinical trial is still ongoing.

22 Q. Are you being compensated by Regeneron for

23 that clinical trial?

24 A. I am not being compensated for that

25 clinical trial, but Stanford University is receiving

16:17:32

1 research funding.

16:17:36

2 Q. How much funding is Stanford University
3 receiving for your role as a principal investigator
4 on that clinical trial for Regeneron?

5 A. I don't recall the exact figure at this
6 time.

16:17:52

7 Q. Can you approximate how much money
8 Stanford is receiving?

9 A. I couldn't provide an approximate at this
10 time.

16:18:08

11 Q. Do you have access to that information?

12 A. I could get that information from Stanford
13 administrators.

14 MR. SALMEN: Counsel, we're going to ask that
15 that information be produced regarding the amount of
16 compensation that Stanford University is receiving
17 for Dr. Do's role as a principal investigator in the
18 ongoing clinical trial for Regeneron that's listed
19 on page 21 of her CV.

16:18:31

20 MS. FISHMAN: You can put the request in
21 writing and we'll take it under consideration.

16:18:51

22 MR. SALMEN: Without an agreement that that's
23 going to be produced, we're going to have to keep
24 this deposition open.

25 MS. FISHMAN: You have no basis to keep the

16:19:04

1 deposition open.

16:19:06

2 MR. SALMEN: I sure do.

3 MS. FISHMAN: You can ask the witness if she
4 has personal knowledge about it, but it's beyond the
5 scope of her declaration. It's beyond the --

16:19:14

6 MR. SALMEN: It goes to the credibility of her
7 testimony. It's not beyond the scope.

8 BY MR. SALMEN:

9 Q. You've been a principal or a
10 co-investigator on at least three other projects for
11 Regeneron; is that correct?

16:19:21

12 A. I have been a clinical investigator on
13 trials sponsored by Regeneron and Genentech and
14 Santen and other industry sponsors.

15 Q. Specific to the three other clinical
16 trials that you list in your CV where you are a
17 principal or co-investigator for Regeneron, were you
18 or Stanford University compensated for those -- your
19 role in those clinical trials?

16:19:42

20 A. In those clinical trials in the past, most
21 of them occurred when I was a faculty member at
22 Johns Hopkins University School of Medicine. And at
23 that period, the research funding for clinical
24 trials would go to the Johns Hopkins University
25 School of Medicine.

16:20:09

16:20:31

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1 Q. And how much funding went to Johns Hopkins 16:20:32
2 for your role as an investigator in those trials?

3 A. I don't recall. We'd have to ask Johns
4 Hopkins University School of Medicine because they
5 received the research funding. 16:20:48

6 Q. And you can access that information, if
7 needed?

8 A. I don't know if I can since I'm no longer
9 at Johns Hopkins University School of Medicine.

10 MR. SALMEN: Why don't we take a break. 16:21:18

11 MS. FISHMAN: Before we go off the record, I'm
12 just going to make a statement.

13 The witness is available for you to depose
14 today. She's here. You can depose her. You can
15 use your seven hours. If you don't use your seven 16:21:29
16 hours today, you're forfeiting them.

17 There's no basis to hold this witness'
18 deposition open on a meritless claim of bias for
19 money that she testified was received by a third
20 party. So do what you like, but she's here today. 16:21:43

21 And I cannot -- not only can I not assure you, you
22 will have to take it to the board if you want her
23 produced another day.

24 BY MR. SALMEN:

25 Q. Are you currently employed by Stanford? 16:21:56

1 A. Yes, I'm a full-time employee of Stanford.

16:21:58

2 Q. Are you -- do you receive a salary from

3 Stanford for your full-time employment?

4 A. Yes, I do receive a salary from Stanford

5 University as a full-time employee.

16:22:12

6 MR. SALMEN: We can take a break, please.

7 MS. FISHMAN: Sure.

8 THE VIDEOGRAPHER: We're going off the record.

9 The time is 4:22.

10 (Recess taken.)

16:22:37

11 THE VIDEOGRAPHER: We're back on the record.

12 The time is 4:57.

13 BY MR. SALMEN:

14 Q. Dr. Do, referring back to what's been

15 marked Do Exhibit 4, the demonstrative that has

16:57:14

16 Claim 1 on it.

17 Are you there?

18 A. Yes, I am.

19 Q. The reference to "standard of care" in the

20 highlighted green text.

16:57:30

21 Do you see that?

22 A. Yes, I see that.

23 Q. Do you include Lucentis off-label dosing

24 regimens in the "standard of care," as that term

25 appears in the Claim 1 of the '338 patent, under

16:57:47

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1 your construction?

16:57:52

2 A. What do you mean by "Lucentis off-label
3 dosing regimens"?

4 Q. Do you include off-label Avastin in the
5 standard of care for the "method of treating" in
6 Claim 1 of the '338 patent as that term is used
7 under your definition?

16:58:13

8 A. When I refer to "standard of care" at the
9 time of the patent filing, I have included off-label
10 Avastin as "a method for treating angiogenic eye
11 disorders" at that time based on the standard of
12 care.

16:58:37

13 Q. Are you including Lucentis monthly dosing
14 as part of the standard of care for treating
15 "angiogenic eye disorders," as that term is used in
16 Claim 1 of the '338 patent?

16:58:59

17 A. The standard of care at January of 2011
18 did include monthly dosing of Lucentis for wet
19 age-related macular degeneration.

20 Q. Did the standard of care as of
21 January 2011 include monthly dosing of Lucentis to
22 treat any other angiogenic eye disorders?

16:59:30

23 A. At the time of January 2011, Lucentis was
24 also FDA approved for the treatment of retinal vein
25 occlusion. And in those clinical trials, monthly

16:59:58

1 dosing was used and provided high levels of
2 efficacy.

17:00:03

3 Q. As of January 2011, the time of the patent
4 filing, do you include any Lucentis off-label dosing
5 regimens, other than the two you just described,
6 within the "standard of care," as that term is used
7 under your construction in Claim 1 of the '338
8 patent?

17:00:23

9 MS. FISHMAN: Objection; vague.

10 You can answer.

17:00:35

11 THE WITNESS: What are you referring to when
12 you mention "off-label dosing regimens" of Lucentis?

13 BY MR. SALMEN:

14 Q. Okay. If we look at the '338 patent where
15 the term "angiogenic eye disorder" is described in
16 Column 5.

17:00:59

17 A. Um-hum.

18 Q. As of January 2011, was there an approved
19 dosing regimen for the treatment of macular edema
20 following central retinal vein occlusion in the
21 Lucentis label?

17:01:40

22 A. In January 2011, I believe Lucentis was
23 FDA approved for macular edema associated with
24 central retinal vein occlusion.

25 Q. As of January 2011, was there an

17:02:02

1 FDA-approved indication in the Lucentis label for
2 the treatment of choroidal neovascularization?

17:02:06

3 A. In my declaration, I did not give an
4 opinion specifically on when Lucentis was approved
5 for choroidal neovascularization. I don't recall
6 the exact date it was FDA approved for myopic
7 choroidal neovascularization.

17:02:45

8 Q. Could we look at paragraph 71 of your
9 declaration, please. In paragraph 71, you state,
10 "After Lucentis was approved, anti-VEGF studies,
11 including some of the examples reported in the '338
12 patent, began using clinical trial endpoints that
13 measured visual acuity gains as primary outcome
14 measures."

17:03:29

15 Do you see that?

17:03:47

16 A. I see that sentence.

17 Q. You're following that sentence with three
18 bullet points; is that correct?

19 A. I do see three bullet points.

20 Q. And in Bullet Point 1, you cite
21 Exhibit 2122 and Exhibit 20 -- sorry -- and
22 Exhibit 2123 as support.

17:04:01

23 Do you see that?

24 A. Yes, I see those exhibits.

25 (Deposition Exhibit 2122 was previously

17:04:19

1 marked.)

17:04:19

2 BY MR. SALMEN:

3 Q. Exhibit 2122 should be in your binder.

4 Are you there?

5 A. Yes. I am at that exhibit.

17:04:40

6 Q. And you see near the bottom of page 1 of
7 Exhibit 2122, it says, "Results first posted
8 January 17, 2013."

9 Do you see that?

10 A. Yes, I see that phrase.

17:04:58

11 (Deposition Exhibit 2123 was previously
12 marked.)

13 BY MR. SALMEN:

14 Q. If we turn to Exhibit 2123, the front page
15 of that exhibit, same position. On the first page,
16 it says, "Results first posted January 17, 2013."

17:05:07

17 Do you see that as well?

18 A. Yes, I see that.

19 Q. You agree that the results of
20 Exhibits -- strike that.

17:05:33

21 You agree that the results of the trials
22 described in Exhibits 2122 and 2123 were first
23 posted after the patent filing for the '338 patent
24 in January 2011; correct?

25 MS. FISHMAN: Objection; documents speaks for

17:05:57

1 themselves.

17:05:59

2 But you can answer.

3 THE WITNESS: The Exhibit 2122 and Exhibit 2123
4 state that the results of those clinical trials were
5 first posted January 17, 2013.

17:06:19

6 BY MR. SALMEN:

7 Q. So the results of those trials that are
8 described in Exhibits 2122 and 2123 were not
9 available to a skilled artisan as of January 2011;
10 correct?

17:06:39

11 MS. FISHMAN: Objection; document speaks for
12 itself.

13 You can answer.

14 THE WITNESS: According to these documents, the
15 results were first posted in January 17th, 2013.

17:06:47

16 BY MR. SALMEN:

17 Q. So those results were not available to a
18 skilled artisan in January 2011; right?

19 A. As I stated, according to these documents,
20 the results were first posted January 17th, 2013.

17:07:09

21 Q. Dr. Do, did you have any conversations
22 with your attorneys regarding the substance of your
23 testimony today during any of the breaks?

24 A. No, I did not.

25 MR. SALMEN: Okay. Pending any re-cross, I

17:07:27

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1 don't have any further questions.

17:07:34

2 THE WITNESS: Thank you.

3 MS. FISHMAN: No questions for this witness.

4 MR. SALMEN: If I can just make one last

5 statement for the record to respond to your

17:07:43

6 statement, Counsel, regarding keeping the deposition
7 open.

8 I simply made two requests for production
9 of information that is pertinent to the credibility
10 of this witness' testimony. All I'm asking for is a
11 commitment to producing that information. It was
12 George Yancopoulos' CV and information regarding
13 compensation that Stanford is receiving for her
14 pending -- still-pending clinical trial.

15 So we ask that that information be
16 produced. And without a commitment to produce that
17 information, we can't close the deposition.

17:08:20

18 MS. FISHMAN: Well, we disagree with your
19 position. You can put your requests in writing.
20 You don't have a basis under any rule that I'm aware
21 of before the board to keep her deposition open.

17:08:33

22 Our position is -- I'm not sure how much
23 time you have remaining, but you're welcome to use
24 that time today. If you don't use that time today,
25 you're forfeiting it and we're not agreeing to make

17:08:46

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1 her available for further deposition.

17:08:50

2 So I understand your position and I hope
3 you understand mine.

4 MR. SALMEN: Are you not agreeing to produce
5 the information that we requested?

17:08:56

6 MS. FISHMAN: I will consider it. And if you
7 put it in writing and you cite some rule to me, I'm
8 happy to consider it. But I'm unaware of a basis in
9 which you're entitled to that discovery in this
10 proceeding. Actually, with that, let me actually --
11 I will ask you a further question.

17:09:09

12 MR. SALMEN: You've already --

13 MS. FISHMAN: I will ask you a further
14 question. It's relevant to your request.

15 MR. SALMEN: I don't think you're permitted to
16 do that. You've already said that you had no
17 questions.

17:09:22

18 MS. FISHMAN: You told me you were done with
19 the deposition. Now you're suggesting you're
20 holding it open. Which is it? Are you closing the
21 deposition or are you holding it open?

17:09:31

22 I'm telling you I don't agree that the
23 deposition is open, but if you're telling me that
24 you believe that you have a right to hold the
25 deposition open for something that's relevant to

17:09:44

1 Dr. Do's testimony, I'm going to elicit testimony
2 from her.

17:09:44

3 MR. SALMEN: Accepting your representation that
4 you have no redirect, I'll close the deposition.

5 MS. FISHMAN: Okay. No further questions.

17:10:23

6 THE VIDEOGRAPHER: We're off the record at
7 5:10 p.m. and this concludes today's testimony given
8 by Dr. Diana Do. Total number of media units used
9 was seven and will be retained by Veritext.

10 (Whereupon, the proceedings were concluded
11 at 5:10 p.m.)

17:10:41

12 ---o0o---

1 I declare under penalty of perjury
2 under the laws that the foregoing is
3 true and correct.
4

5 Executed on _____, 20____,
6 at _____, _____.

7
8
9
10
11 _____
12 DIANA V. DO, M.D.
13
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25

1 I, the undersigned, a Certified Shorthand
2 Reporter of the State of California, do hereby
3 certify:

4 That the foregoing proceedings were taken
5 before me at the time and place herein set forth;
6 that any witnesses in the foregoing proceedings,
7 prior to testifying, were administered an oath; that
8 a record of the proceedings was made by me using
9 machine shorthand which was thereafter transcribed
10 under my direction; that the foregoing transcript is
11 a true record of the testimony given.

12 Further, that if the foregoing pertains to
13 the original transcript of a deposition in a Federal
14 Case, before completion of the proceedings, review
15 of the transcript () was (X) was not requested.

16 I further certify that I am neither
17 financially interested in the action nor a relative
18 or employee of any attorney of any party to this
19 action.

20 IN WITNESS WHEREOF, I have this date
21 subscribed my name.

22 Dated: April 22, 2022

23
24 

25 ANRAE WIMBERLEY, CSR No. 7778

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