

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

MYLAN PHARMACEUTICALS, *
INC., CELLTRION, INC., *
AND APOTEX, INC., * CASE IPR2021-00880
*
PETITIONERS, * PATENT 9,669,069 B2
*
VS. *
* CASE IPR2021-00881
*
REGENERON *
PHARMACEUTICALS, INC., * PATENT 9,254,338 B2
*
PATENT OWNER. *

ORAL AND VIDEOTAPED DEPOSITION OF
DAVID M. BROWN, M.D.
APRIL 26, 2022

ORAL AND VIDEOTAPED DEPOSITION OF DAVID M.
BROWN, M.D., produced as a witness at the instance
of the PETITIONERS, and duly sworn, was taken in
the above-styled and numbered cause on APRIL 26,
2022, from 9:07 A.M. to 3:03 P.M., before AMY
PRIGMORE, CSR, in and for the State of Texas,
reported by stenographic means, at the offices of
Arnold & Porter Kaye Scholer LLP, 700 Louisiana St,
Suite 4000, Houston, Texas, pursuant to the Federal
Rules of Civil Procedure and the provisions stated
on the record or attached hereto.

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Mylan Exhibit 1022
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A P P E A R A N C E S

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P R O C E E D I N G S

* * *

THE VIDEOGRAPHER: Good morning. We are going on the record at 9:07 a.m., on April 26th, 2022. This is Media Unit No. 1 of the video recorded deposition of Dr. Brown, taken by counsel for the Petitioner, in the matter of Mylan Pharmaceuticals versus Regeneron Pharmaceuticals, filed in the Patent Trial and Appeal Board, Case No. IPR 2021-00881.

This deposition is being held at Arnold & Porter Kaye Scholer, LLP, located at 700 Louisiana Street, Suite 4000, Houston, Texas.

My name is Jonathan Curran. I'm with the firm Veritext. I'm the videographer. The court reporter is Amy Prigmore, from the firm Veritext.

Now, if everybody present, counsel, could state their appearances, starting with my left.

MR. SALMEN: Heinz Salmen, of RMMS, in Chicago, on behalf of Mylan, Petitioner.

Joining me in -- in person here is Scott Beall, also of RMMS, on behalf of the Petitioner. And on the conference line, Vinny Lee

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1 of Regeneron, on behalf of Petitioner, Mylan.

2 MS. FISHMAN: Good morning. Deborah
3 Fishman, of Arnold & Porter, on behalf of patent
4 owner, Regeneron, and on behalf of the witness.

5 With me today is Jeremy Cobb, also
6 of Arnold & Porter, on behalf the Regeneron, patent
7 owner. And with us present in the room today,
8 James Evans and Eileen Woo, both in-house counsel
9 of Regeneron.

10 And one clarification on the
11 caption, our understanding is that this deposition
12 is taking place in both IPR 2021-00881, as well as
13 2021-00880, for both proceedings.

14 THE VIDEOGRAPHER: And may the court
15 reporter now swear in the witness.

16 DAVID M. BROWN, M.D.,
17 having been first duly sworn, testified as follows:

18 EXAMINATION

19 BY MR. SALMEN:

20 Q. Good morning, Dr. Brown.

21 A. Good morning.

22 Q. In front of you, I -- I placed a few
23 documents. First is what's been previously marked
24 Exhibit 2050. That's the stapled paper there.

25 Do you see it?

1 A. Yes, sir.

2 Q. Do you recognize this as a copy of your
3 expert declaration --

4 A. Absolutely.

5 Q. -- in the -- okay.

6 And if you could please turn to the last
7 page there, and confirm that that's your signature?

8 A. It is.

9 Q. Okay. I've also provided you with a couple
10 binders. I'm not going to go through them now, but
11 those include, I believe, the majority, if not all
12 of the exhibits that you cite in your declaration.
13 So to the extent you need any of them, you're -- go
14 ahead and look at those.

15 A. Perfect.

16 Q. Now I'm going to hand you what I've marked
17 as Brown Exhibit 1.

18 (Exhibit 1 is marked.)

19 Q. (BY MR. SALMEN) And Brown Exhibit 2.

20 (Exhibit 2 is marked.)

21 Q. (BY MR. SALMEN) Brown Exhibit 1 is
22 Petitioner's Notice of Deposition of David M.
23 Brown, M.D. And Brown Exhibit 2 is Petitioner's
24 Notice of Deposition of David Brown, M.D.

25 Dr. Brown, is it your understanding that

1 you're being deposed today pursuant to these
2 notices?

3 A. Yes, sir.

4 Q. And you understand that there are two
5 proceedings pending before the United States Patent
6 and Trademark Office?

7 A. That's what I've been told.

8 Q. The first proceeding is IPR 2021-00881,
9 pertaining to what I'll refer to as the
10 '338 patent.

11 Is that okay?

12 A. Correct.

13 Q. And the second proceeding is IPR 2021-00880,
14 pertaining to what I'll refer to as the
15 '069 patent.

16 Is that okay?

17 A. Sure.

18 Q. And, Dr. Brown, you understand that the
19 declaration that you prepared for these
20 proceedings, Exhibit 2050, represents your direct
21 examination in these proceedings?

22 A. Correct.

23 Q. And do you understand that the questions
24 I'll be asking you today represent your
25 cross-examination testimony?

1 A. Correct.

2 Q. You ever been cross-examined?

3 A. For a med mal, as defense, so...

4 Q. Okay. Did that appear in an in-court
5 cross-examination proceeding?

6 A. It was all video.

7 Q. Okay. All right. Dr. Brown, let's look at
8 your declaration.

9 I'm going to start at paragraph 12.

10 A. Paragraph 12.

11 Q. This is in the section that you titled, A
12 Person of Ordinary Skill in the Art.

13 Do you see that?

14 A. Yes, sir.

15 Q. And here, you state that you, quote: Have
16 been asked to consider the level of ordinary skill
17 in the art, as it relates to the earliest effective
18 filing date of the '338 patent and '069 patent.

19 Do you see that?

20 A. Yes.

21 Q. Now, for context, I'd like to look at your
22 legal standards section, beginning at paragraph 16,
23 on the next page.

24 And this section is the -- from paragraph 16
25 to paragraph 25.

1 Is that correct?

2 A. That's correct.

3 Q. And these are the legal standards that you
4 applied in forming your opinions, that are set
5 forth in your declaration, Exhibit 2050.

6 Is that correct?

7 A. Yes, with help of counsel.

8 Q. You applied the legal standards, though --

9 A. I did --

10 Q. -- in forming your opinion --

11 A. -- they helped me define the legal
12 standards. I went to med -- medical school, not
13 law school.

14 Q. I understand that.

15 And just for the sake of the court reporter,
16 Dr. Brown, if we can try not to talk over each
17 other. Okay. So, I -- I just ask you to allow me
18 to finish my question, and then give your counsel
19 an opportunity to object, if she needs to, and then
20 answer it.

21 Is that okay?

22 A. It's okay.

23 Q. Thank you.

24 Now, turning back to your paragraph 12, in
25 your declaration. You state, at the last sentence,

1 quote: I have been informed and understand that
2 the earliest filing date of the '338 patent and
3 '069 patent is January 13th, 2011.

4 Do you see that?

5 A. I do.

6 Q. And is that the date that you applied in
7 forming your opinions that are set forth in your
8 declaration?

9 A. It is.

10 Q. Now, the rest of your section titled, The
11 Person of Ordinary Skill in the Art, you do not
12 provide your own definition for a person of
13 ordinary skill in the art.

14 Is that correct?

15 A. That is correct.

16 Q. Instead, in paragraph 14 of your
17 declaration, you provide your understanding of
18 Regeneron's and Dr. Do's definition for a person of
19 ordinary skill in the art.

20 Is that correct?

21 A. That is correct.

22 Q. Then, in paragraph 13, you replicate the
23 Petitioner's definition for a person of ordinary
24 skill in the art.

25 Is that correct?

1 A. That is correct.

2 Q. Okay. Do you agree that these are two
3 different definitions for the person of ordinary
4 skill in the art, in the '338 and '069 patents?

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

7 You can answer.

8 A. Yeah, I to law school, not medical school.
9 I'll defer to counsel.

10 Q. (BY MR. SALMEN) I'm asking you to answer
11 the question.

12 Do you believe that these are different
13 definitions for the person of ordinary skill in the
14 art?

15 A. They're different wording; one's expanded.
16 So, yes, they are different wording.

17 Q. Okay. I'm going to hand you what's been
18 marked previously as Exhibit 2051.

19 (Voices en sotto.)

20 Q. (BY MR. SALMEN) Dr. Brown, do you recognize
21 Exhibit 2051?

22 A. I do.

23 Q. This is the declaration of Dr. Do.
24 Is that correct?

25 A. That's correct.

1 Q. Okay. Let's look at her paragraph 28.
2 Dr. Do states that, quote: In the event Mylan
3 argues that the skilled artisan need not be a
4 licensed physician (ophthalmologist), close quote,
5 she disagrees.

6 Do you see that?

7 A. I see that.

8 Q. Do you agree with Dr. Do's opinion in
9 paragraph 28 of her declaration?

10 A. I didn't offer an opinion in my declaration.

11 Q. Do you agree with Dr. Do's opinion that is
12 set forth in paragraph 28, of her declaration?

13 A. I concur with her opinion.

14 Q. Okay. Now, let's look back at your
15 paragraph 13, where you recite Mylan's definition.

16 You see that Mylan's definition does not
17 require that the skilled artisan be a licensed
18 ophthalmologist.

19 Is that correct?

20 A. That is correct.

21 Q. Okay. Now, I want you to turn to the
22 section in Dr. Do's declaration that she titles,
23 Legal Framework, beginning around paragraph 19.

24 And before I proceed on -- on this point,
25 Dr. Brown, you did review Dr. Do's declaration.

1 A. I did.

2 Q. Okay. Paragraph 20, Dr. Do states, quote:
3 I have been informed that the patent claims are
4 construed from the -- excuse me.

5 I'm going to strike that and restart.

6 Dr. Do states, in paragraph 20 of her
7 declaration, quote: I have been informed that
8 patent claim terms are construed from the vantage
9 point of a skilled artisan to which the invention
10 relates at the time of the invention (or as of the
11 effective filing dates of the patent application.)

12 The skilled artisan, I understand, is
13 presumed to be familiar with what was known in the
14 art at the time.

15 Do you see that?

16 A. I see that.

17 Q. Does that paragraph reflect your
18 understanding, as well, for how patent claims are
19 termed to be construed?

20 MS. FISHMAN: Objection; lacks
21 foundation.

22 You can answer.

23 A. I'm -- I'm not a patent attorney, but that
24 is my -- I concur with that.

25 Q. (BY MR. SALMEN) Okay. So your -- your

1 attorney just objected for my question lacking
2 foundation.

3 Is it true that you do not offer any of your
4 own opinions regarding claim construction for
5 the -- the terms of the '338 patent?

6 A. So, we discuss that in my declaration.

7 Q. Okay. Why don't we turn to paragraph 97 of
8 your declaration.

9 Is this the section of your declaration that
10 you were referring to?

11 A. One of them.

12 Q. This is the section titled, Claim
13 Construction.

14 A. Correct.

15 Q. And it's -- and encompasses paragraphs 97 to
16 103.

17 Is that correct?

18 A. That is correct.

19 Q. Okay. Paragraph 97, you state, quote: I
20 understand that the parties dispute the meaning of
21 the term, quote, a method for treating an
22 angiogenic eye disorder in a patient, close quote.

23 Do you see that?

24 A. I see that.

25 Q. And in the next paragraph, 98, you state,

1 quote: I have been informed that the Board has
2 preliminarily found that the phrase, a method for
3 treating an angiogenic eye disorder in a patient,
4 is limiting.

5 And it goes on from there.

6 Do you see that?

7 A. I do.

8 Q. Paragraph 99, you state: I understand that
9 Dr. Do has offered the opinion that the claim term
10 method for treating, in Claims 1 and 14 of the
11 '338 patent, requires highly effective treatment
12 that was non-inferior to the standard of care by
13 the time the patent was filed in 2011.

14 Do you see that?

15 A. I do.

16 Q. And in paragraph 100, you state: I have
17 reviewed Dr. Do's declaration and agree with her
18 conclusion that method of treating requires an
19 effective treatment, and further, that by 2011, the
20 POSA would have understood an effective treatment
21 that was one that was at least non-inferior to the
22 standard of care; i.e., Lucentis.

23 Do you see that?

24 A. I do.

25 Q. Now, Dr. Brown, you did not offer your own

1 opinion regarding the claim construction for the
2 '338 patent claim term, a method for treating an
3 angiogenic eye disorder in a patient, correct?

4 A. Correct.

5 Q. The next section, the heading 2,
6 paragraphs 102 and 103, you similarly did not offer
7 your own opinion regarding the proper claim
8 construction for the '338 patent claim term,
9 tertiary dose.

10 Is that correct?

11 A. That's correct.

12 Q. I believe you have, in your first binder,
13 Exhibit 1001, the '338 patent.

14 A. I do.

15 Q. Let's take a look at that.

16 MS. FISHMAN: Are you done with
17 Exhibit 2051?

18 MR. SALMEN: He's going to need that
19 the whole time.

20 MS. FISHMAN: The Do declaration?

21 MR. SALMEN: Oh, you said 51. I'm
22 sorry.

23 MS. FISHMAN: Yeah.

24 MR. SALMEN: Done with it for now.

25 MS. FISHMAN: Okay.

1 Q. (BY MR. SALMEN) All right. Dr. Brown, you
2 have the '338 patent in front of you?

3 A. Yes, sir.

4 Q. Exhibit 1001?

5 A. I do.

6 Q. All right. Let's look at Example 4, that
7 begins column 9.

8 You reviewed this example in forming the
9 opinions you set forth in your declaration,
10 correct?

11 A. I did.

12 Q. Okay. And you understand the data that's
13 presented in Table 1 of Example 4, and that starts
14 on column 13.

15 Is that correct?

16 MS. FISHMAN: Objection; vague.

17 MR. SALMEN: That's not a proper
18 objection, Counsel.

19 A. I understand Table 1.

20 Q. (BY MR. SALMEN) Okay. All right.

21 Dr. Brown, do you -- let's -- I'm going to
22 focus your attention on what appears in Table 1.
23 The -- the right-hand column is labeled VEGF-T 2
24 milligrams every eight weeks, 2Q8.

25 Do you see this?

1 A. I see that, yeah.

2 Q. And I'm going to refer to this as the 2Q8
3 arm of this trial.

4 Is that okay?

5 A. Perfect.

6 Q. All right. Now, do you agree that the 2Q8
7 arm of the clinical trial, summarized by Example 4,
8 represents a method of treating within the scope of
9 the '338 patent claims?

10 MS. FISHMAN: Objection; vague as to
11 time.

12 A. Repeat your question. I'm sorry.

13 Q. (BY MR. SALMEN) Let me ask a follow-up
14 question.

15 Your attorney objection -- objected that my
16 question was vague as to time.

17 When I asked the question, did you have a
18 particular time frame in mind to answer it?

19 A. No. I just didn't quite understand your
20 question. Can you repeat it?

21 Q. Sure. I will repeat it.

22 For context, why don't we take a quick look
23 at the claims. We haven't been there yet. Okay?

24 Claim 1 starts on the last page, in
25 column 1.

1 A. On the last page. So column 23?

2 Q. Yes. I'm sorry. I -- I misspoke, and said
3 column 1. You're correct. It's column 23.

4 So I'm referring to this claim in my last
5 question. And I'll restate it. Okay?

6 A. Okay.

7 Q. Do you agree that the 2Q8 arm of the
8 clinical trial, summarized by Example 4, represents
9 a method of treating within the scope of the '338
10 patent claims?

11 MS. FISHMAN: Objection; calls for a
12 legal conclusion, and vague as to time.

13 A. So column 4 in that table gives the
14 percentage of those who lost less than 15 letters,
15 which was the primary end point on the FDA clinical
16 trial, VIEW 1, VIEW 2.

17 It does not encompass the totalitary of
18 the -- total -- all of the VIEW studies, and what
19 it means to a clinician.

20 Q. (BY MR. SALMEN) What does, capture the
21 total of the VIEW studies --

22 A. Sure.

23 Q. -- that would be relevant to a clinician?

24 MS. FISHMAN: Objection; beyond the
25 scope.

1 You can answer.

2 A. So when one designs a clinical trial, you
3 have two objectives. Your first objective is to
4 try to get a drug approved.

5 The objective to clinicians, though, is to
6 determine is something safe, is it effective, and
7 will it help the patient.

8 Q. (BY MR. SALMEN) Let me restate my earlier
9 question, because again, your counsel objected as
10 to it being vague, with respect to time.

11 Would your answer to my question change, if
12 I applied different dates?

13 A. I'm not sure it would. I'd have to look at
14 the dates you give me.

15 Q. Okay. So, here, how about as of
16 January 2011, the date that you applied in forming
17 your opinion regarding the '338 patent, does the
18 2Q8 arm of the clinical trial, summarized by
19 Example 4, represent a method of treating, within
20 the scope of the '338 patent claims?

21 MS. FISHMAN: Objection; calls for
22 legal conclusion.

23 But you can answer.

24 A. Yeah, I'm not -- I'm not a lawyer. And I
25 would draw you to my declaration, where, again, in

1 paragraph 100 that you read to me, I believe that
2 an effective method of treatment is one that is at
3 least non-inferior to the standard of care,
4 Lucentis.

5 Q. (BY MR. SALMEN) Okay. Here, I'm going to
6 show you what's been marked previously as Do
7 Deposition Exhibit 4.

8 Have you seen this before?

9 A. If it's part of the Do declaration, yes.

10 Q. This is not part of the Do declaration.
11 This was marked as an exhibit at her deposition
12 last week.

13 A. I haven't seen it then. I didn't see her
14 deposition.

15 Q. Okay. So go ahead and read the language in
16 the green highlight.

17 MR. SALMEN: And for the record,
18 this is a recreation of Claim 1 for the '338
19 patent, with Dr. Do's claim constructions inserted
20 in the green and yellow highlights.

21 MS. FISHMAN: Are you marking this
22 as an exhibit --

23 MR. SALMEN: No.

24 MS. FISHMAN: -- to his deposition?

25 MR. SALMEN: No.

1 MS. FISHMAN: But you're showing it
2 to him?

3 MR. SALMEN: Yeah.

4 MS. FISHMAN: Okay. I object. I
5 would say let's mark this as the next exhibit in
6 this deposition. I believe it's Exhibit 3.

7 And for the record, this is a
8 demonstrative prepared by Petitioner's counsel that
9 was shown to Dr. Do in her deposition and is now
10 being shown to Dr. Brown.

11 Q. (BY MR. SALMEN) Did you review the green
12 language in there?

13 A. Still reviewing it.

14 Q. Okay.

15 A. I read the green.

16 Q. Okay. With that language in mind, can you
17 answer my question, as of January 13th, 2011, the
18 date that you applied in forming your opinions,
19 does the 2Q8 arm of the clinical trial, summarized
20 by Example 4, represent a method of treating,
21 within the scope of the '338 patent claims?

22 MS. FISHMAN: Objection; beyond the
23 scope, and calls for a legal conclusion.

24 A. I say it doesn't. It -- you know, when I
25 just see loss of 95 percent -- we have a lot of

1 trials that did that, Macugen included, that
2 weren't effective treatments, and weren't inferior
3 to the standard of care, in my opinion.

4 Q. (BY MR. SALMEN) Okay. We'll go ahead and
5 mark that now.

6 MS. FISHMAN: I already did.

7 MR. SALMEN: Shoot. Here it is.
8 Can I have that copy back?

9 I'm going to mark this Brown
10 Exhibit 3. And that Brown Exhibit 3 is a printout
11 of Do Deposition Exhibit 4.

12 (Exhibit 3 is marked.)

13 Q. (BY MR. SALMEN) And let me ask you another
14 question similar to the last one, but I'm going to
15 give you another date, because I don't want --

16 A. Okay.

17 Q. -- to raise another vague as to time
18 objection. Okay? Okay?

19 A. Okay.

20 Q. So, as of December 2012, after the Heier
21 2012 publication came out, does the 2Q8 arm of the
22 clinical trial, summarized by Example 4, represent
23 a method of treating, within the scope of the '338
24 patent claims?

25 MS. FISHMAN: Objection; beyond the

1 scope of this witness's declaration, and calls for
2 a legal conclusion.

3 You can answer.

4 A. I don't think the percentage of less than 15
5 letter gainers allows me to determine whether it's
6 a method of treatment, according to my
7 declaration --

8 Q. (BY MR. SALMEN) Okay.

9 A. -- definition.

10 Q. Let's turn back to your declaration. And
11 I'm going to direct your attention to the section
12 beginning at paragraph 75.

13 This section, you title, VIEW 1 and VIEW 2.

14 Is that correct?

15 A. That's correct.

16 Q. And this section spans from paragraph 75,
17 through -- it looks like paragraph 85.

18 A. Correct.

19 Q. And that's between pages 35 and 43.

20 Is that correct?

21 A. Correct.

22 Q. Now, in paragraph 75 to 82, you provide a
23 summary of the VIEW clinical trials, based on the
24 Heier 2012 publication.

25 Is that correct?

1 A. That's correct.

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

4 MR. SALMEN: It's his direct
5 examination testimony, Counsel. It's a completely
6 improper objection. This is cross-examination. I
7 can ask him the questions.

8 MS. FISHMAN: You can ask your
9 question, and I can lodge my objections, which I
10 just did. The document speaks for itself.

11 MR. SALMEN: The document does not
12 speak for itself. It's his direct examination
13 testimony.

14 MS. FISHMAN: Correct. But you're
15 asking him a question that lacks foundation, based
16 on the fact that he's quoting more than just the
17 Heier 2012 publication in his declaration.

18 Q. (BY MR. SALMEN) Okay. Let's go through the
19 paragraphs. Okay.

20 Paragraph 75, do you cite anything other
21 than Exhibit 1018, Heier '12, in paragraph 75?

22 A. In paragraph 75, I do not.

23 Q. Okay. Paragraph 76, do you cite to anything
24 other than Exhibit 1018, Heier 2012?

25 A. I do not.

1 Q. Okay. In paragraph 76, you do cite another
2 document, other than Heier 2012.

3 Is that correct?

4 A. That's incorrect. It's paragraph 77.

5 Q. Oops. Well, thank you for that correction.

6 In paragraph 77, you cite to Exhibit 2097,
7 and then you provide a footnote for what that
8 document is, correct?

9 A. I take your word for it on the number of the
10 exhibit. So, yeah.

11 Q. So, it -- it -- you have it in -- in your
12 declaration, under about the third line --

13 A. 2097. There you go.

14 Q. Gotcha.

15 A. Yeah, perfect.

16 Q. And that is, according to your footnote, the
17 FDA non-inferiority clinical trials to establish
18 effectiveness guidance for industry.

19 Do you see that?

20 A. That's correct.

21 Q. That document doesn't prep -- doesn't
22 provide any data from the VIEW 1 trials, does it?

23 A. Does not.

24 Q. That document also doesn't provide any data
25 from the VIEW 2 clinical trials, right?

1 A. It does not. But when you design a trial
2 that's non-inferiority, you have to play by the
3 house rules. So you look at what the agency
4 suggests, and you design your trial based on that.

5 Q. Certainly.

6 A. So I designed the VIEW trials.

7 Q. Certainly. I -- my question was specific to
8 the data for the VIEW 1 and VIEW 2 trials.

9 None of that data appears in Exhibit 2097,
10 right?

11 A. None of that data.

12 Q. Okay. So moving on to Exhibit 2078, the
13 only document you cite there, again, is exhibit --
14 sorry. I think I may have misspoke, though. Let
15 me strike that.

16 Turning to paragraph 78 of your declaration.
17 The only document you cite in that paragraph is,
18 again, Exhibit 2097, the FDA guidance, right?

19 A. Correct.

20 Q. Paragraph 79, nothing's cited, paragraph 79,
21 right?

22 MS. FISHMAN: Objection; lacks
23 foundation.

24 Q. (BY MR. SALMEN) Oh, I stand corrected.
25 I'll withdraw the question.

1 You cite to Exhibit 2098, in paragraph 79.

2 Do you see that, at the top of page 38?

3 A. That is correct.

4 Q. And you provide a footnote. That document
5 is CDER Statistical Review of Application
6 No. 125387, November 18th, 2011.

7 Do you see that?

8 A. That's correct.

9 Q. All right. Now, is it your opinion that the
10 Heier 2012 publication is important to confirming
11 the efficacy of the Eylea 2Q8 arm dosing regimen
12 from the VIEW 1 and VIEW 2 trials?

13 MS. FISHMAN: Objection; beyond the
14 scope.

15 You can answer.

16 A. So, the Heier 2008 paper certainly provides
17 the data we found in the VIEW trial, demonstrating
18 both the safety and the efficacy, and its
19 non-inferiority, and not just to three line losers,
20 but to visual acuity gains, which is what our
21 patients care about.

22 MS. FISHMAN: Can I just interject?

23 MR. SALMEN: Yeah.

24 MS. FISHMAN: You said Heier 2008.
25 Did you mean Heier 2012?

1 MR. SALMEN: I was going to make the
2 same clarification.

3 MS. FISHMAN: Okay.

4 Q. (BY MR. SALMEN) In your -- in your
5 answer --

6 A. Sure.

7 Q. -- you -- I think you may have misspoke.
8 You said Heier 2008.

9 A. No problem.

10 Q. Were you referring to Heier 2012?

11 A. Yeah, yes.

12 Q. Okay. And Heier 2012, I believe, is in your
13 binder. And...

14 A. It's 1018.

15 Q. That's correct.

16 Now, I'm going to direct you to a couple
17 paragraphs in your declaration for some context for
18 my questions here.

19 And so, first, let's look at paragraph 109
20 of your declaration. And the header here,
21 subheader A, reads, quote: The POSA would not have
22 had a reasonable expectation of success that the
23 claimed Q8 dosing regimen would be effective until
24 after rever -- Regeneron's VIEW trials.

25 A. I see that.

1 Q. Okay. That's your opinion with regard to
2 what's in the header above, Ground 6, the
3 challenged claims, in your opinion, are not obvious
4 based on Dixon.

5 Is that correct?

6 A. That's correct.

7 Q. Okay. Now, again for context, let's turn
8 back to paragraph 83 of your declaration.

9 A. I'm there.

10 Q. Okay. You state there, in the first line,
11 quote: The 52-week results from VIEW 1 and VIEW 2
12 are also set forth in the '338 patent at Example 4,
13 Exhibit 1001, at 9:10-13:48.

14 Do you see that?

15 A. I do.

16 Q. Now, in that citation, you're referring to
17 the entirety of Example 4, in the '338 patent.

18 Do you agree with that?

19 A. I agree with that.

20 Q. Okay. Now, I want to direct your attention
21 to the patent itself. And within the section that
22 you cite, let's look at column 12, line 65.

23 The results that are reported in Example 4
24 only begin at this line, at the bottom of
25 column 12, at line 65.

1 Is that correct?

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

4 You can answer.

5 A. Looks like it.

6 Q. (BY MR. SALMEN) Okay. So when you were
7 re -- referring to the 52-week results from the
8 VIEW 1/VIEW 2 trial, that are also set forth in the
9 '338 patent, you were just referring to the section
10 that begins at column 12, line 65, correct?

11 A. I would disagree.

12 Q. Why?

13 A. Any clinical trial, you have to look at the
14 inclusion criteria, the studies that were examined.
15 And all of those are in columns 10, 11, 12,
16 et cetera.

17 Q. Okay. The results of the clinical trial
18 start at column 12, though, right?

19 A. The results of -- yes.

20 Q. Okay. And just -- we'll -- we'll get into
21 more detail of this, but comparing the data that
22 appear in Heier 2012, Exhibit 1018, versus the
23 results that appear in the Example 4 of the '338
24 patent, Heier provides extensive more data.

25 Do you agree with that?

1 MS. FISHMAN: Objection; documents
2 speak for themselves, beyond the scope.

3 You can answer.

4 A. Yeah. Yes. The patent essentially says,
5 Victory over Europe, and then the Heier paper tells
6 you how it was won.

7 Q. (BY MR. SALMEN) Okay. I -- I can't accept
8 analogies. And can you be more specific?

9 A. Yes. The patent gives the summary of the
10 15-letter losers and gainers and the summary of the
11 mean improvement in vision at 52 weeks. But does
12 not give all of the data that's in Heier.

13 Q. Now, let's -- I want to do a bit of a
14 side-by-side comparison. So keep the -- the patent
15 open there, but you're also -- I guess you don't
16 have --

17 A. I can flip.

18 Q. Let me...

19 MR. SALMEN: Do we have Heier by
20 itself anywhere, or the patent by itself?

21 (Voices en sotto.)

22 Q. (BY MR. SALMEN) Okay. Well, unfortunately,
23 I don't have a -- a loose leaf copy of them.

24 A. I can flip.

25 Q. So I'm going to have to ask you to flip back

1 and forth.

2 So, in Heier, Exhibit 1018, I'm going to
3 direct your attention Table 2, which appears on
4 exhibit pages 6 and 7.

5 Do you see, it's spread across the top
6 there?

7 A. Yes, sir.

8 Q. Okay. On the -- the left-hand side, page 6,
9 are the VIEW 1 results, correct?

10 A. Correct.

11 Q. And on the right-hand side, page 7, of
12 Table 2, those are the VIEW 2 results, correct?

13 A. Correct.

14 Q. Now, I'm going to flip -- keep your finger
15 on that. And here, if you -- if you want to -- if
16 you want to mark it, I can give you a Post-It there
17 to mark that page.

18 A. All right.

19 Q. I'm going to flip you back to the patent, at
20 column 10. And about a third of the way down,
21 beginning at line -- it appears to be 18, there's a
22 statement there that says, quote: Approximately
23 1200 subjects were enrolled, with the target
24 enrollment of 300 subjects per treatment arm.

25 Do you see that?

1 A. I'm sorry. We're in the patent?

2 Q. Yeah. In the patent, column 10.

3 A. Okay. I was on 13.

4 Q. Oh, sorry.

5 A. There you go.

6 Q. I may have -- I -- I probably misspoke.

7 A. No worries.

8 Q. Column 10, line 18.

9 A. Yeah, I see it.

10 Q. Okay. I'm going to read it again for the
11 record. Quote: Approximately 1200 subjects were
12 enrolled, with a target enrollment of 300 subjects
13 per treatment arm.

14 Is that correct?

15 MS. FISHMAN: Objection; document
16 speaks for itself.

17 You can answer.

18 A. That's correct.

19 Q. (BY MR. SALMEN) Okay. Now, what we don't
20 see in the patent are the exact number of patients
21 per treatment arm.

22 Is that correct?

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

25 You can answer.

1 A. That is correct.

2 Q. (BY MR. SALMEN) Okay. In Heier, however,
3 if we look at Table 2, across the top, the first
4 row, we see the exact number of patients in each of
5 the VIEW 1 and VIEW 2 clinical trial arms, correct?

6 MS. FISHMAN: Same objection.

7 You can answer.

8 A. That is correct.

9 Q. (BY MR. SALMEN) Okay. Now, looking more
10 specifically at some of the data that appears in
11 Heier Table 2, Exhibit 1018, I'm going to start
12 at about halfway down.

13 You see a row there that reads, quote:
14 Change in CNV area.

15 Do you see that?

16 A. I do.

17 Q. Okay. What does CNV refer to?

18 A. Choroidal neovascular membrane. Choroidal
19 neovascular. It's a -- in clinical trials,
20 especially back then, there were reading centers
21 that had trained graders that graded specific
22 metrics. One of them was the area of the new blood
23 vessel growth, CNV area.

24 Q. Sure. Thank you.

25 Right below the change in Z -- strike that.

1 Right below the -- the row, change in CNV
2 area, you see another entry for change in total
3 NEI.

4 Do you see that?

5 A. I do.

6 Q. What's -- what's the NE -- EI refer to?

7 A. That's the National Eye Institute.

8 So there is a visual function category, a
9 visual function test, that is called the NEI
10 VFQ-25. It's a 25-question score on how it affects
11 your activities of daily living.

12 Q. And below that one, there is that's labeled,
13 an exploratory end point change in retinal
14 thickness.

15 Do you see that?

16 A. I do.

17 Q. And it provides -- the Table 2 provides data
18 for this exploratory end point change in retinal
19 thickness, for each one of the dosing arms in the
20 VIEW 1 and VIEW 2 clinical trials, right?

21 A. That is correct.

22 Q. And you agree that none of that data appears
23 in Example 4 of the '338 patent, right?

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

1 A. Yeah, pretty sure it doesn't. Let me look.
2 That is correct.

3 Q. (BY MR. SALMEN) Dr. Brown, is a decrease in
4 retinal thickness, would you describe that as --
5 let me strike that question and say it more
6 clearly.

7 Would you describe a decrease in retinal
8 thickness as a visual acuity gain?

9 MS. FISHMAN: Objection; lacks
10 foundation, outside the scope.

11 You can answer.

12 A. So, macular degeneration is a problem where
13 the back wall of the eye wears out too soon.

14 The biggest blinding complication is when
15 new blood vessels go through the back, like weeds
16 go through the cracks in concrete. Those weeds
17 elevate the RPE, and leak and bleed, all increasing
18 the retinal thickness.

19 Analogous to a cancer or any other disease,
20 you've got to alleviate those symptoms before you
21 can expect visual acuity gains.

22 So a -- a clinical trial that does not
23 improve the mean retinal thickness is unlikely to
24 affect visual acuity gains, but they're not
25 directly correlated.

1 Q. (BY MR. SALMEN) Okay. Let me it -- asking
2 it this way. Do the change in retinal -- sorry.
3 Strike that.

4 Do the change in central retinal thickness
5 data that's provided in Table 2 of Heier
6 demonstrate an efficacy gain?

7 MS. FISHMAN: Objection; calls for a
8 legal conclusion, vague, and outside the scope.

9 You can answer.

10 A. So, as a clinician, and who's been doing
11 this research for 25 years, and treating patients,
12 if we don't see a visual acuity -- say it's an
13 early trial, and we do not see a anatomic
14 improvement, a change in clinical thickness, with a
15 small number of patients, even if they got a visual
16 acuity gain, I think most of us would be skeptical.

17 In other words, we expect form follows
18 function. We expect the totality of the data to
19 show that it works anatomically and that the
20 patient saw better, and that -- that then they
21 could assume their activities of daily living on a
22 better function.

23 Q. (BY MR. SALMEN) Okay. Now, I -- I'm going
24 to look at little more closely at the data that's
25 in Table 1 of the '338 patent.

1 A. I'll take another one of your stickies, if
2 you have one.

3 Q. Oh, yeah. Here, have the whole pack.

4 A. Thanks. Got it.

5 Q. Okay. So, for context, again, we already
6 looked at the section of the patent that explains
7 that approximately 300 patients were in each arm of
8 the clinical trial, correct?

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

11 A. Correct.

12 Q. (BY MR. SALMEN) Let's look at the
13 specification again, to make sure we're not
14 misstating the document.

15 Column 10, line 18, quote: Approximately
16 1200 subjects were enrolled, with a target
17 enrollment of 300 subjects per treatment arm.

18 Do you see that?

19 A. I do.

20 Q. Okay. So approximately 300 patients were in
21 each arm of the clinical trial, correct?

22 A. That's correct.

23 Q. Now, and again, I'm going to focus your
24 attention on the 2Q8 arm of Table 1, the data for
25 that dosing arm. And I'm looking at the first row

1 of data, that is referred to as, quote, main --
2 maintenance of vision.

3 Do you see that?

4 A. I do.

5 Q. And that first set of data, quote,
6 maintenance of vision, is measured as a percentage
7 of patients losing less than 15 letters at week 52,
8 versus baseline.

9 Is that correct?

10 A. That is correct.

11 Q. Now, the data there represent the -- the
12 percentage of patients that achieved that primary
13 end point in this study.

14 Is that correct?

15 A. That is correct.

16 Q. Okay. Now, underneath there, there's
17 another row of data that reads, quote: Mean
18 improvement in vision.

19 Do you see that?

20 A. I do.

21 Q. Okay. That's also at 52 weeks, correct?

22 A. That is correct.

23 Q. And the data in that row, the mean
24 improvement in vision at 52 weeks, is reported in
25 letters gained.

1 Is that correct?

2 A. That is correct.

3 Q. Now, based on the information that's
4 available in Example 4 of the '338 patent, in its
5 entirety, what percentage of 2Q8 patients
6 experienced visual acuity improvements by 15 or
7 more letters?

8 MS. FISHMAN: Objection --

9 A. That data is not here.

10 MS. FISHMAN: The document speaks --
11 yeah.

12 Q. (BY MR. SALMEN) That data is in Heier 2012,
13 though, right?

14 A. Correct.

15 Q. Okay.

16 MS. FISHMAN: You need to give me
17 time to put in objections.

18 Q. (BY MR. SALMEN) Let's look at the data that
19 I just referred to, as it appears in Heier 2012.
20 Table 2, Exhibit 1018.

21 I'll call it about halfway down the table.
22 There's a -- a row reading, quote: Proportion
23 gaining greater than or equal to 15 ETDRS letters,
24 percent. And then, (N).

25 Do you see that?

1 A. I do.

2 Q. Okay. So Heier 2012 Table 2 provides exact
3 data for the proportion of patients in each of the
4 VIEW 1 and VIEW 2 dosing arms -- strike that.

5 Let me -- I misspoke there.

6 Heier 2012 Table 2 provides exact data for
7 the proportion of patients in each arm gaining 15
8 or more letters.

9 Is that correct?

10 A. That is correct.

11 Q. And it's reported as a percentage and as the
12 exact number of patients, in each column.

13 Is that correct?

14 A. That is correct.

15 Q. Now, real quick, I want to look at the --
16 the three rows of data, the first three rows of
17 data, in Table 2.

18 MS. FISHMAN: Objection --

19 Q. (BY MR. SALMEN) The first --

20 MS. FISHMAN: Objection; vague.

21 Which Table 2 are you talking about?

22 Q. (BY MR. SALMEN) Let me start over

23 Dr. Brown.

24 I'm in Heier 2012, Exhibit 1018, Table 2.

25 Are you with me?

1 A. Yes, sir.

2 Q. Okay. Let's look at the third row of data.

3 That one is titled, Secondary End Points.

4 Do you see that?

5 A. Yes, sir.

6 Q. Okay. Quote: Change in ETDRS BCVA (mean
7 plus or minus SD).

8 Do you see that?

9 A. Yes, sir.

10 Q. What does SD refer to?

11 A. Standard deviation.

12 Q. Okay. And what does change in ETDRS BCVA
13 refer to?

14 A. BCVA is best corrected visual acuity. In
15 these clinical trials, there is mask refractionists
16 who perform a standardized 20- to 30-minute
17 refraction on each patient, using a specialized eye
18 chart that was initially used for the early
19 treatment for diabetic retinopathy study. That's
20 what ETDRS is.

21 Q. Okay. I'm going to ask you to do a little
22 side-by-side comparison, again, looking at that row
23 in Table 2 of Heier 2012, Exhibit 1018.

24 On the one hand, and then on the other,
25 Table 1, the second row of data that we were

1 looking at earlier, the mean improvement in vision
2 at 52 weeks. Okay?

3 A. Got it.

4 Q. Do those two correspond to the same data?

5 A. Yeah, I'm making sure they didn't mess it
6 up. I looked --

7 Q. So let --

8 MS. FISHMAN: I --

9 Q. (BY MR. SALMEN) Yeah, why don't we go
10 through them one at time, okay, just to make sure
11 they didn't mess it up. All right?

12 MS. FISHMAN: Objection; the
13 documents -- objection; documents speak for
14 themselves. Go ahead.

15 Q. (BY MR. SALMEN) Okay. Column 1, on
16 Table 2, Heier, reads, 8.1 plus or minus 15.3.

17 Do you see that?

18 A. Correct.

19 Q. Column 1, in Table 1 of the '338 patent,
20 reads 8.1.

21 Do you see that?

22 A. Yeah, they eliminate the error -- the
23 standard deviation. But, yes, correct.

24 Q. They do not include the standard deviation?

25 A. Correct.

1 Q. Okay. And maybe to short-circuit that, for
2 none of the data in this row --

3 A. Sure.

4 Q. -- Table 1, '338 patent, do they provide the
5 standard deviations.

6 Is that correct?

7 MS. FISHMAN: Objection; document
8 speaks for itself.

9 A. That's correct.

10 Q. (BY MR. SALMEN) Okay. Now, row 2, in
11 Table 2 of Heier, VIEW 1, that refers to the 2Q4
12 dosing arm, and the change in ETDRS is 10.9 plus or
13 minus 13.8, correct?

14 A. Correct.

15 Q. And the 2Q4 arm in the patent, Table 1, is
16 actually column 3.

17 Is that correct?

18 A. Correct.

19 Q. And the number there is also 10.9, right?

20 A. Correct.

21 Q. No standard deviation, again?

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

24 A. That's correct.

25 Q. (BY MR. SALMEN) All right. Go through the

1 last two. Column 3, Table 2, VIEW 1 trial, in
2 Heier 2012, change in ETDRS for the 0.5 Q4 arm is
3 6.9 plus or minus 13.4, correct?

4 A. Correct.

5 Q. Column 2 in Table 1 of the patent is 6.5, no
6 standard deviation, right?

7 A. Correct.

8 Q. Last column of Table 2, Heier 2012,
9 referring to the 2Q8 arm, change in ETDRS is 7.9
10 plus or minus 15.

11 A. Correct.

12 Q. Do you see that?

13 A. Yes, sir.

14 Q. And in Table 1 of the patent, column 4, the
15 change in -- the mean improvement in vision is 7.9,
16 no standard deviation, right?

17 A. Correct.

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

20 Q. (BY MR. SALMEN) Okay. So, did they get it
21 right, with respect to --

22 A. They did.

23 Q. Okay.

24 MS. FISHMAN: You got to let me put
25 in objections.

1 THE WITNESS: Okay.

2 MS. FISHMAN: You're -- you're going
3 too fast.

4 Q. (BY MR. SALMEN) Dr. Brown, is it your
5 opinion that as of January 2011, Lucentis or
6 Avastin, off label, was the standard of care of
7 treating angiogenic eye disorders?

8 A. Yes, it was.

9 Q. Let's turn to your declaration,
10 paragraphs 34 and 37.

11 MS. FISHMAN: If you're starting a
12 new line of questioning, we've been going about an
13 hour --

14 MR. SALMEN: I'm actually not. This
15 is all tied to the -- the data in the table that we
16 were looking at.

17 Q. (BY MR. SALMEN) Are you at paragraph 34?

18 A. Yes, sir.

19 Q. You could read any portion of that, if you
20 want. But I'm going to direct your attention to
21 the last sentence of paragraph 34.

22 You state, quote: Impressively, visual
23 acuity improved by 15 or more letters in
24 24.8 percent of the 0.3-milligram group, and
25 33.8 percent of the 0.5-milligram group.

1 MS. FISHMAN: Hold on. I object.

2 This has nothing to do with the table we were just
3 looking at. Objection.

4 MR. SALMEN: This -- that is a
5 completely improper objection.

6 MS. FISHMAN: We -- we've been going
7 for about an hour. I asked for a break. You told
8 me this was related to your last line of questions.
9 This is not about the patent.

10 MR. SALMEN: It is.

11 MS. FISHMAN: Okay. Well, why don't
12 you re-formulate your question again.

13 Q. (BY MR. SALMEN) Can you answer? Do you see
14 that line -- that sentence in your declaration,
15 paragraph 34?

16 A. I see that sentence.

17 Q. Okay. And this paragraph is referring to
18 the one-year results of the MARINA trial, correct?

19 A. That is correct.

20 Q. Okay. And you -- again, for the one-year
21 results of the MARINA trial, you state, quote:
22 Impressively, visual acuity improved by 15 or more
23 letters in 24.8 percent of the 0.3-milligram group,
24 and 33.8 percent of the 0.5-milligram group.

25 Do you see that?

1 A. I do.

2 Q. Okay. Paragraph 37. Here, you're referring
3 to the ANCHOR trial, correct?

4 A. Correct.

5 Q. And for the one-year results of the ANCHOR
6 trial, you state, in the last sentence, quote:
7 Impressively, visual acuity improved by 15 or more
8 letters, in 35.7 percent of the 0.3-milligram
9 group, and 40.3 percent of the 0.5-milligram group,
10 at month 12.

11 Do you see that?

12 A. I see it.

13 Q. Okay. The ANCHOR data was published in
14 2009.

15 Is that correct?

16 MS. FISHMAN: Objection; the
17 document speaks for itself.

18 A. I published the ANCHOR data in 2006.

19 Q. (BY MR. SALMEN) 2006. Okay. Thank you for
20 that correction.

21 A. During the term.

22 MS. FISHMAN: Okay. We've been
23 going for more than an hour. It seems like you've
24 moved on to another topic. I'd like to take a
25 break.

1 THE WITNESS: Yeah, I might need to
2 hit the washroom here in a bit.

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

5 THE VIDEOGRAPHER: We are off the
6 record at 10:10 a.m.

7 (Break.)

8 THE VIDEOGRAPHER: And we're back on
9 the record at 10:23 a.m. This is Media Unit No. 2.

10 Q. (BY MR. SALMEN) Dr. Brown, we were
11 discussing paragraphs 34 and 37 in your
12 declaration, before the break. So I'm going to
13 direct your attention back to those, please.

14 A. I'm there.

15 Q. Okay. And let's see. So, you had
16 mentioned, before the break, that you had published
17 the ANCHOR -- the one-year results in 2006.

18 Is that correct?

19 A. Correct.

20 Q. And the two-year results of ANCHOR were
21 published in January of 2009.

22 Is that correct?

23 A. I can't believe it was that far back, but I
24 guess it is.

25 Q. I can --

1 A. No, no. It is. I just can't believe it
2 took us that long to get it published.

3 Q. So, the publication, it -- you -- that you
4 cite is Exhibit 2085, and it should be in your
5 binder.

6 This is a paper that you're the lead author
7 on, titled, quote: Ranibizumab versus -- I'm going
8 to stop right there. I -- I still don't know how
9 to pronounce that word.

10 Maybe you can help me.

11 A. Verteporfin.

12 Q. Okay. So, this is Exhibit 2085, an article
13 that you're the first named author on.

14 Is that correct?

15 A. That is correct.

16 Q. And this is the document that you cite in
17 paragraph 37 for the two-years results of ANCHOR,
18 in January 2009, right?

19 A. Correct.

20 Q. Now, I want to direct your attention to
21 Table 3 of this document. It appears on exhibit
22 page 4, of 14, top left-hand corner.

23 The table is, quote: Key Visual Acuity
24 Outcomes Relative to Baseline in the Study Eye At
25 Month 12 and Month 24.

1 Do you see that?

2 A. I do.

3 Q. About halfway down on this table, there is a
4 row that reads, quote: Gained greater than or
5 equal to 15 letters, N percent.

6 Do you see that?

7 A. I do.

8 Q. Now, I'm going to focus your attention on
9 the -- the right-hand column, the ranibizumab,
10 0.5 milligrams. Okay.

11 A. Yep.

12 Q. And you'll see that the data -- the month 12
13 data for the number of patients that gained greater
14 than or equal to 15 letters is 56, correct?

15 A. So 56 patients, 40.3 percent.

16 Q. Okay. That was my --

17 A. I'm sorry.

18 Q. -- that was my second question. But --

19 A. No. It's 56 -- it's 56 -- the parentheses
20 is the percent.

21 Q. Yes.

22 A. So 40.3 percent or 56 of the 140 patients.

23 Q. Okay. And at month 24, the number of
24 patients that gained greater than or equal to 15
25 letters was 57 out of 140, or 41 percent.

1 Is that correct?

2 A. That is correct.

3 Q. Now, would you agree that these data from
4 ANCHOR, demonstrating over 40 percent of patients
5 experiencing a visual acuity gain of 15 or more
6 letters, represent a meaningful, real-world
7 difference for patients at the time of this study?

8 MS. FISHMAN: Objection; beyond the
9 scope.

10 You can answer.

11 A. Yes, it does.

12 Q. (BY MR. SALMEN) Okay. And by January 2011,
13 a person of ordinary skill in the art of the '338
14 patent would have been aware of the visual acuity
15 improvements by 15 or more letters demonstrated in
16 the ANCHOR trial.

17 Is that correct?

18 A. That is correct.

19 Q. Okay.

20 A. It was presented all over the place.

21 Q. Yep.

22 Now, I believe you had an Exhibit 1035 in
23 your binder there. That's Lalwani.

24 You're familiar with this document, correct?

25 A. Correct.

1 Q. So, I'll direct your attention to the
2 left-hand column of page -- exhibit page 1 of Mylan
3 Exhibit 1035, under the bullet that reads, results.

4 Do you see that?

5 A. I do.

6 Q. Okay. Quote: 40 patients were enrolled,
7 and 37 completed the two-year study. At month 24,
8 the mean visual acuity, VA, improved by 11.1
9 letters (P less than .001) and the OCT-CRT
10 decreased by 212 micrometers (P less than .001).

11 Do you see that?

12 A. I do.

13 Q. You with me? Okay.

14 The next sentence reads, quote: VA improved
15 by 15 letters or more in 43 percent of patients.

16 Do you see that?

17 A. I do.

18 Q. Lalwani published in 2010, correct?

19 MS. FISHMAN: Objection; document
20 speaks for itself. Calls for --

21 A. Looks like 2009. July 2009, I think, was
22 the journal publication.

23 Q. (BY MR. SALMEN) Okay. My mistake. So
24 Lalwani was published in July 2009.

25 Is that correct?

1 MS. FISHMAN: Objection; calls for
2 speculation, and document speaks for itself.

3 A. It's what the footer of the AJO says down
4 there, so...

5 Q. (BY MR. SALMEN) Okay. Can we agree that
6 Lalwani, Exhibit 1035, was published before
7 January 2011?

8 MS. FISHMAN: Same objection.

9 A. The time is before 2011, sure.

10 Q. (BY MR. SALMEN) Okay. So by January of
11 2011, a person of ordinary skill in the art of the
12 '338 patent would have been aware of the visual
13 acuity improvements by 15 or more letters,
14 demonstrated in the PrONTO trial, correct?

15 MS. FISHMAN: Objection; lacks
16 foundation. The document speaks for itself.

17 You can answer.

18 A. So I discuss in my declaration the PrONTO
19 trial at length and --

20 Q. (BY MR. SALMEN) Yeah. I'm just asking
21 if --

22 A. Yeah. I --

23 MS. FISHMAN: You --

24 Q. (BY MR. SALMEN) -- a person of skill in the
25 art, in the '338 patent, would have been aware of

1 the visual acuity improvements by 15 or more
2 letters that we just read, that were demonstrated
3 in the PrONTO trial.

4 Can you agree with that?

5 MS. FISHMAN: You just cut off the
6 witness. Okay. Hold on. You cut off the witness
7 when he was giving his answer. So why don't you
8 put the question to him, and let him finish his
9 answer.

10 A. So, the person skilled in the art would have
11 been aware of the PrONTO study, which I discussed
12 at length in my declaration, and would have had a
13 hard time interpreting it, based on there was no
14 comparator arm. It's on -- it's non-randomized.

15 If you look at what you just showed me, the
16 ANCHOR paper, which I published, that 30 percent --
17 higher than 30 percent, three-line gainers,
18 compared to only 6 percent in the PDT arm.
19 Ordinary clinicians require a -- a comparator arm,
20 or you don't know what to make of a set visual
21 acuity gain.

22 MR. SALMEN: Okay. I'll move to
23 strike that answer as being nonresponsive to my
24 question.

25 Q. (BY MR. SALMEN) My question was, by

1 January 2011, a person of ordinary skill in the art
2 would have been aware of the visual acuity
3 improvements by 15 or more letters, demonstrated in
4 the PrONTO trial, as published in Exhibit 1035,
5 Lalwani, correct?

6 MS. FISHMAN: Object -- objection;
7 lacks foundation, document speaks for itself, asked
8 and answered.

9 You can answer.

10 A. So the person skilled in the art would be
11 aware of that visual acuity gain, and that it was
12 an open-label, single -- single-center
13 non-randomized study.

14 Q. (BY MR. SALMEN) Okay. Now, referring back
15 to the '338 patent, Example 4. The data providing
16 the percentage of patients experiencing a visual
17 acuity improvement of 15 or more letters in the
18 VIEW trial do not appear anywhere in Example 4 of
19 the '338 patent.

20 Is that correct?

21 MS. FISHMAN: Objection; document
22 speaks for itself.

23 You can answer.

24 A. That is correct.

25 Q. (BY MR. SALMEN) And as far as you're aware,

1 those data were not published prior to Heier 2012,
2 correct?

3 MS. FISHMAN: Objection; lacks
4 foundation.

5 You can answer.

6 A. They were probably published in abstract
7 form, from when they were presented at the Academy
8 of Ophthalmology. And -- and the data was
9 certainly available in Regeneron press releases.

10 Q. (BY MR. SALMEN) The -- the data regarding
11 the improvement of 15 or more letters in the VIEW
12 trials, that's the data you're referring to, that
13 would have been available prior to Heier 2012?

14 MS. FISHMAN: Objection; beyond the
15 scope, lacks foundation, calls for speculation.

16 You can answer.

17 A. Yeah. So 15-letter gainers were certainly
18 presented at national conferences. Whether it was
19 published, I don't know.

20 Q. (BY MR. SALMEN) Okay.

21 MR. SALMEN: Amy, I'm going to need
22 Exhibit 5, please.

23 Q. (BY MR. SALMEN) Dr. Brown, let me direct
24 your attention to paragraph 71 of your declaration,
25 please.

1 71 is the second paragraph in the section
2 that you titled, Clinical Testing and Approval of
3 Eylea.

4 Is that correct? Previous page.

5 A. Correct.

6 Q. Okay. And in paragraph 71, the first
7 statement, you say, quote: In each of these
8 clinical trials, Regeneron required its clinical
9 investigators to sign a confidentiality agreement
10 and clinical trial agreement that limited
11 disclosure of information regarding its
12 investigational drug, VEGF Trap-Eye.

13 Do you see that?

14 A. I see that.

15 Q. Okay. So -- and you participated in the --
16 the VIEW trials, correct, as an investigator?

17 A. That is correct. I was the top enrolling
18 physician in the world.

19 Q. Okay. And you signed that confidentiality
20 agreement, right?

21 MS. FISHMAN: Objection; lacks
22 foundation.

23 A. I -- for that particular study, my partner
24 did, but our institution signed it, yes.

25 Q. (BY MR. SALMEN) Okay. Well, let's look at

1 Exhibit 2096 and ex -- well, let's start with --
2 yeah, let's start with Exhibit 2096. It should be
3 in one of your binders.

4 Is this the confidentiality agreement that
5 you were referring to in paragraph 71 of your
6 declaration?

7 A. That's correct.

8 Q. The last page of this document, there's
9 this -- the last two pages, there's a series of
10 signatures.

11 Are you there?

12 A. Last two pages of this.

13 Correct.

14 Q. And none of those signatures are yours,
15 correct?

16 A. That's correct.

17 Q. Did you provide this document, in these
18 proceedings?

19 A. So, all of our documents in clinical trials
20 have to be kept for 15 to 20 years, as per the FDA.
21 The majority of the documents go off-site, to Iron
22 Mountain.

23 I remember them requesting it and asking for
24 Iron Mountain, but I'm actually not sure whether I
25 provided this document, or whether Genentech

1 found it -- I mean, whether Regeneron found their
2 copy.

3 Q. Okay.

4 A. We keep a copy in a -- in a regulatory
5 binder. For a study that's, you know, 15 years
6 out, some of those were -- when you send things to
7 Iron Mountain, you can really categorize it well,
8 and be able to find it, or you can get 8 million
9 boxes when it shows up.

10 So I honestly don't know.

11 Q. So sitting here today, you don't know
12 exactly where this version of the document --

13 A. I -- I don't know. I know that I was the
14 principal investigator of the trial. I know that,
15 looking at the date, it was mid July. So I'm sure
16 I was on holiday. And that's why my associate
17 partner signed it.

18 Q. Okay. Let's look at Exhibit 2128. You also
19 cite this at the very end of paragraph 71. This is
20 titled, Investigator's Agreement.

21 Do you see that?

22 Do you see that?

23 A. I see it.

24 Q. Okay. And it looks like each one of these
25 pages has a signature on there.

1 Do you see that?

2 A. Correct.

3 Q. None of those are your signature.

4 Is that correct?

5 A. All the signatures are my partner, and other
6 principal investigator, Matt Benz. He was co...

7 Q. Did you provide this version of
8 Exhibit 2128, in these proceedings?

9 A. I have to -- have to go to my last answer.
10 It was either us, or it was Regeneron. They have a
11 copy. We have a copy. Ours would have come from
12 Iron Mountain. And I ask all my -- I remember
13 asking my clinical staff to scrounge through all
14 the boxes and look, because they asked for it.

15 And I don't know if we were successful or
16 they were successful. But this is our document
17 from my institution.

18 Q. Okay. But sitting here today, you don't
19 know where this version came from?

20 A. I don't.

21 Q. Okay.

22 MR. SALMEN: Well, I want to mark a
23 couple new exhibits.

24 Q. (BY MR. SALMEN) I'll hand you what I've
25 marked as Brown Exhibit 4.

1 (Exhibit 4 is marked.)

2 Q. (BY MR. SALMEN) And does that one say 4 on
3 it -- okay.

4 I'm going to hand you what I've marked as
5 Brown Exhibit 5.

6 (Exhibit 5 is marked.)

7 Q. (BY MR. SALMEN) Brown Exhibit 4 is a trial
8 record of NCT 00509795, from ClinicalTrials.gov.

9 Do you see that?

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

12 You can answer.

13 A. I see it.

14 Q. (BY MR. SALMEN) Okay. Now, I want to
15 direct your attention to the first page there, that
16 big red bar across the middle.

17 Do you see that?

18 A. I see it.

19 Q. Okay. It says, quote: Results first
20 posted, April 16th, 2012.

21 Do you see that?

22 A. It doesn't say results first posted. It
23 says first posted.

24 Q. Okay. Well, so directly below that line.

25 A. Results first posted, April 16th.

1 Q. Okay. Let me -- let me just make sure the
2 record is clear here.

3 In -- in the middle of the red bar, the
4 third line down says, quote: Results first posted,
5 April 16th, 2012.

6 Do you see that?

7 A. I do.

8 Q. Okay. Now, let's look at the list of
9 publications, which appears on the second-to-last
10 page, page 8 of 9.

11 Sorry. Just for context, Dr. Brown, I just
12 want to make sure that you under -- you recognize
13 what that document is. But I'm going to refer to
14 this as the NCT 795. You understand that this --
15 and agree, that this is the ClinicalTrials.gov
16 record for the VIEW 1 trial?

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

20 You can answer.

21 A. Yeah, this is the printout of the
22 ClinicalTrials.gov. Yeah.

23 Q. (BY MR. SALMEN) Okay. For the VIEW 1
24 trial?

25 A. For VIEW 1, correct.

1 Q. Okay. And the publications there, the first
2 one is by an author, Li, L-I.

3 Do you see that?

4 A. I do.

5 Q. And the date -- the year for that
6 publication appears to be 2020.

7 Do you see that?

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

10 A. I see that.

11 Q. (BY MR. SALMEN) And the next publication,
12 the year appears to be 2020.

13 Do you see that?

14 MS. FISHMAN: Same objection.

15 A. I do.

16 Q. (BY MR. SALMEN) And the next publication,
17 the year appears to be 2014.

18 Do you see that?

19 MS. FISHMAN: Same objection.

20 A. I do.

21 Q. (BY MR. SALMEN) So, based on the
22 information that's available from
23 ClinicalTrials.gov for NCT 795, do you have any
24 reason to believe that the results of the VIEW --
25 VIEW 1 trial were posted prior to April 16th, 2012?

1 A. On ClinicalTrials.gov, evidently not.

2 Q. Okay. So let's look at Exhibit 5, Brown
3 Deposition Exhibit 5.

4 A. One more time.

5 Q. Brown Deposition 5.

6 A. 5, yeah.

7 Q. This is the ClinicalTrials.gov printout for
8 VIEW 2 NCT 377.

9 Do you see that?

10 A. I do.

11 Q. And here, again, in the red bar for this
12 exhibit, the results were first posted in
13 January 23, 2012.

14 Do you see that?

15 MS. FISHMAN: Objection; document
16 speaks for itself.

17 You can answer.

18 A. I see where it says that.

19 Q. (BY MR. SALMEN) Okay. And if we look at
20 the publications of results, which appears on page
21 7 of 9 -- are you there?

22 A. I am.

23 Q. You see the first publication there is
24 Heier.

25 A. Correct.

1 Q. And that's the same Heier reference that
2 we've marked in these proceedings as Exhibit 1018,
3 correct?

4 A. So what's -- what's marked here is the
5 E-publication, which went before the print
6 publication. And it -- it really doesn't matter
7 whether it's -- whether that was the E-pub, or that
8 we can figure that out. So if...

9 Q. Well, it wouldn't have been published any
10 later than -- well, let me strike that.

11 It wouldn't have been published any earlier
12 than the date that's listed here, December 2012,
13 for Heier, correct?

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

16 But you can answer.

17 A. So if you read the ClinicalTrials.gov, and
18 this is interesting, because I -- we don't use
19 ClinicalTrials.gov that much in looking at the
20 literature. The first -- the publication results
21 is what the sponsor, or the authors, put in.

22 And so here, they reference Heier and Ursula
23 Schmidt-Erfurth's paper. They should have done
24 that for both.

25 And then the next column, automatically

1 indexed is where, I guess, the computer, with
2 artificial intelligence or something, looks for
3 data that's -- that's relevant.

4 If you -- to answer your question, though,
5 the ClinicalTrials.gov actually gives the
6 E-publication date of October 17th, 2012.

7 Q. (BY MR. SALMEN) Okay.

8 A. And then it came out in print, I guess, in
9 the November journal, several months later.

10 Q. Okay. Dr. Brown, did you review the
11 prosecution history for the '338 patent, in forming
12 your opinions?

13 A. I'm sorry. I'm not a lawyer. What do you
14 mean by prosecution history?

15 Q. Okay. So the prosecution history is, in
16 this case, a rather large document that records the
17 communications between the patent applicant and the
18 patent office, before the patent issued.

19 Do you recall reviewing that document?

20 A. I don't recall re -- reviewing it.

21 Q. Okay. Let's take a look at it. All right.

22 I only have one copy of this one. It's
23 Exhibit 1017 -- already been marked as
24 Exhibit 1017, in the 881 proceedings for the '338
25 patent. And I'm just asking for identification

1 here.

2 So you can go ahead and look at that, with
3 your counsel, and tell me if you recognize that
4 document.

5 (Voices en sotto.)

6 A. I'm pretty sure I didn't review it. If so,
7 I've -- I've -- I've forgotten it, so...

8 Q. (BY MR. SALMEN) Okay. So just to make
9 things easier on you, I -- I printed out a small
10 excerpt of that document.

11 So I'm going to hand you that.

12 MS. FISHMAN: Counsel, do you have
13 copies of the excerpt?

14 MR. SALMEN: This one -- the
15 excerpt, I have copies of. I'm sorry. The giant,
16 full one, I do not have.

17 A. The environment thanks you.

18 Q. (BY MR. SALMEN) The -- this is an excerpt
19 of Mylan Exhibit 1017. And you'll see, I've
20 duplicated page 1, which corresponds to that, and
21 then pages 283 through 292.

22 MS. FISHMAN: Can you put a new
23 exhibit number on that and -- and give me a copy of
24 it, just so we have a -- a control version.

25 MR. SALMEN: Sure. I'll mark it as

1 Brown Exhibit 6.

2 (Exhibit 6 is marked.)

3 MS. FISHMAN: And you're
4 representing that this is a subselection of
5 exhibit --

6 MR. SALMEN: I am representing that
7 this is an excerpt.

8 MS. FISHMAN: Okay. Just for the
9 record, I believe counsel has represented that
10 Exhibit 6 is a subselection, or an excerpt, of
11 Mylan Exhibit 1017.

12 MR. SALMEN: That's correct.

13 Q. (BY MR. SALMEN) So you looked through the
14 full document, and compared it to what's been
15 marked as Brown deposition Exhibit 6?

16 A. I looked at each page, yes.

17 Q. Okay. So it looks the same, at least. But
18 I'll represent to you that it is an excerpt of the
19 pages that are printed at -- in the bottom
20 right-hand corner.

21 So, page 283 through page 292 of
22 Exhibit 1017 is referred to as an amendment, under
23 37 CFR Section 1.111.

24 MS. FISHMAN: This is --

25 Q. (BY MR. SALMEN) Do you see that?

1 MS. FISHMAN: Okay. So this --
2 sorry. I'm going to -- this is super confusing.

3 Can you just use this as Exhibit 6,
4 because it's Exhibit 6 you're using with the
5 document, and say what page of Exhibit 6 you're on?

6 MR. SALMEN: Sure.

7 MS. FISHMAN: If you don't mind
8 restating your question, because you asked your
9 question to Exhibit 1017, and that's not in the
10 record and it's not before the witness right now.

11 Thank you.

12 Q. (BY MR. SALMEN) So, Dr. Brown, referring
13 you to what's been marked as Brown Deposition
14 Exhibit 6.

15 A. Can you just give me all the reference, sort
16 of what this is?

17 Q. Yes, this --

18 A. Again, I'm not a lawyer.

19 Q. I'm trying to.

20 A. I have no clue what this is.

21 Q. Okay. So I'm going to direct your attention
22 to what begins on the second page of Brown
23 Exhibit 6. And this document is marked pages 283
24 through 292.

25 (The witness peruses the document.)

1 Q. (BY MR. SALMEN) Are you with me?

2 A. Yes, sir.

3 Q. Okay. So, my first question is, have you
4 seen this amendment under 37 CFR Section 1.111
5 before?

6 A. If so, I don't recollect.

7 Q. Okay. I'll direct your attention to the
8 last page, which is marked page 292.

9 Are you there?

10 A. So, the last page, getting there. One more
11 time? Last page, the signed page?

12 Q. I'm -- I'm just going to refer to the
13 exhibit pages --

14 A. Okay.

15 Q. -- at the bottom right-hand corner.

16 A. That's fine.

17 Q. It says page 292.

18 A. Okay.

19 Q. Okay. And you see that this is dated
20 September 11th, 2015?

21 MS. FISHMAN: Objection; document
22 speaks for itself.

23 A. I see that.

24 Q. (BY MR. SALMEN) Okay. Now, I'll direct
25 your attention to a portion of this document where

1 the Heier paper is discussed. And that is on
2 exhibit page 289.

3 (Voice interruption.)

4 MR. SALMEN: For anyone that's on
5 the conference call, will you please mute your
6 phones? Thank you.

7 Q. (BY MR. SALMEN) The first full paragraph,
8 it states, quote: The attached Heier, et al, paper
9 published in December of 2012, and as such, is not
10 prior art with respect to the present application
11 filed on January 11th, 2012, and claiming priority
12 to November 21st, 2011.

13 Do you see that?

14 A. I do.

15 Q. Okay. So, were you aware that Heier 2012
16 was submitted to the patent office as not being
17 prior art to the '338 patent application?

18 MS. FISHMAN: Objection; calls for a
19 legal conclusion, but you can answer.

20 A. Yeah, it's not in my declaration. And I'm
21 not an expert on what's...

22 Q. (BY MR. SALMEN) Okay. So you were not
23 aware of the information that's provided in this
24 document, Brown Deposition Exhibit 6.

25 Is that correct?

1 MS. FISHMAN: Objection; misstates
2 testimony, lacks foundation.

3 A. I was aware we published it after the
4 patent. It took us a long time to get it
5 published.

6 Q. (BY MR. SALMEN) Okay. And by it, you're
7 referring to the data from the -- the VIEW 1/VIEW 2
8 trials?

9 A. I'll referring to the manuscript that's
10 ended up in Ophthalmology.

11 Q. Can you explain that in more detail?
12 Manuscript of what?

13 A. So the primary manuscript of the VIEW 1 and
14 2 studies were published in Ophthalmology, after --
15 well, after a while, after the data was presented
16 and was on the podium, and was approved, actually.
17 So...

18 Q. Is that something other than the Heier --
19 what we've discussed as the Heier 2012 document,
20 Exhibit 1018?

21 A. So that's the only -- that's the primary
22 document that describes the data.

23 Q. Okay. So, when you're referring to the
24 manuscript, are you referring to Heier 2012,
25 Exhibit 1018?

1 A. That is correct.

2 Q. Okay. All right. You can set that aside.

3 Now, I want to direct your attention to
4 paragraph 87 of your declaration. Okay?

5 A. I'm at paragraph 87.

6 Q. Okay. I'm -- you know what, that was not --
7 I want to give you proper context here. Not -- not
8 that paragraph. So, paragraph 102, actually.

9 Here, you state, quote: I also understand
10 that Dr. Do has offered the opinion that the
11 claimed term, tertiary dose, means doses
12 administered after the initial and secondary doses
13 that maintain the efficacy gained -- the efficacy
14 gain achieved after the initial and secondary
15 doses.

16 Do you see that?

17 A. I see that.

18 Q. Okay. Now, in paragraph 80 of your
19 declaration, you include a figure from Heier, and I
20 want to ask you about that figure.

21 Figure 3 from Heier 2012, Exhibit 1018.

22 A. I'm there.

23 Q. Okay. And if you need the actual Heier
24 reference, again, it's Exhibit 2018. And this is
25 Figure 3 from that document that you excerpt into

1 your declaration.

2 MS. FISHMAN: And just for the
3 record, it's Exhibit 1018.

4 Q. (BY MR. SALMEN) Okay.

5 A. Correct.

6 Q. Now, you can look at either version. But
7 looking at Figure 3 from Heier 2012, you agree that
8 this provides ETDRS letters data from the VIEW 1,
9 and VIEW 2 trials, correct?

10 A. Provides the mean change, yes, correct.

11 Q. Okay. And just by way of example, I'm going
12 to focus on the VIEW 1 graph, at the top of
13 Figure 3.

14 You see, there's a 2Q8 arm that's depicted
15 there?

16 A. I do, with the little triangles.

17 Q. It looks like the little triangles. Okay.
18 And it says 7.9 2Q8.

19 Do you see that?

20 A. Correct.

21 Q. Okay. Now, you -- you understand that the
22 patients in the VIEW 1 trial, irrespective of what
23 arm -- dosing arm they were in, were evaluated
24 every single month.

25 Is that correct?

1 A. That is correct.

2 Q. Okay. And -- but in the -- in the 2Q8 arm,
3 they were injected only every eight weeks after the
4 first three initial doses.

5 Is that correct?

6 MS. FISHMAN: Objection; lacks
7 foundation.

8 You can answer.

9 A. Yeah, I designed the trial. That's correct.

10 Q. (BY MR. SALMEN) Okay. So, for the VIEW 1,
11 doses were administered at weeks 0, 4, 8, 16, 24,
12 32, 40, and 48.

13 Is that correct?

14 A. In the 2Q8 arm, that is correct.

15 Q. Okay. And you agree that these data in
16 Figure 3, with respect to the 2Q8 arm, demonstrate
17 efficacy gains that were achieved over the 52-week
18 dosing regimen, right?

19 MS. FISHMAN: Objection; vague.

20 You can answer.

21 A. So they demonstrate the mean visual acuity
22 gains, which, in clinical practice, and in clinical
23 trials, is perhaps the most important thing. But
24 certainly, you got to look at safety, you have to
25 look at if you gain this and you had a bunch of

1 patients lose vision, and despite that, overcome it
2 with the mean change.

3 You have to look at the totalitary of -- the
4 totality of the data -- it's a hard word for me
5 today -- before you can make a total judgment of
6 what you think of the drug.

7 Q. (BY MR. SALMEN) Okay. Okay. So, let me
8 ask you a more targeted question. If -- if we just
9 look at the dose that was administered in week 16
10 for the 2Q8 arm, can you tell me -- so let me
11 scratch that.

12 You would describe the week -- week 16 dose
13 as an 8-week dose? Can I refer to it as that?

14 MS. FISHMAN: Objection; lacks
15 foundation.

16 A. It's the first Q8 dose.

17 Q. (BY MR. SALMEN) Okay. The first Q8 dose.

18 A. Yeah.

19 Q. Okay.

20 A. Following the monthly load.

21 Q. Okay. And the monthly load are the doses
22 that were administered in weeks 0, 4, and 8.

23 Is that correct?

24 A. That is correct.

25 Q. Okay. So looking at the information

1 available in Figure 3, for VIEW 1, you can tell me
2 that the first 2Q8 dose at week 16 maintained the
3 efficacy that was achieved during the 0, 4, and 8
4 week doses, correct?

5 MS. FISHMAN: Objection; vague.

6 But you can answer.

7 A. Macular degeneration patients, and even in a
8 clinical trial, have some fluctuation.

9 Grandma sometimes has a good day. Grandma
10 sometimes doesn't sleep. There is a slight -- ever
11 so slight dip in that. And what you don't know is
12 that just randomly, was the mean just a little riff
13 that day, or did some of these patients potentially
14 require monthly dosing.

15 Q. (BY MR. SALMEN) Okay. But based on the
16 information that's here in Figure 3, you can
17 compare the week 16 dose, with the weeks 0, 4, and
18 8 dose.

19 Is that correct?

20 A. You really have to compare it to the
21 comparators. And all I can say is, is that the
22 graph is continuing the same fashion. I'm happy
23 with that. The patients are happy with that. But
24 I don't know that at a -- any single -- let me step
25 back.

1 I do a lot of work with the FDA. The FDA
2 doesn't let you have one extended dose, and give
3 you approval based on that. They prefer you to
4 have five -- at least three, but five of that
5 extended dosing interval.

6 Q. Okay. Let me ask it this way. Let's --
7 let's look at Figure 3, doses 0, 4, and 8.

8 Are you with me?

9 A. Yes, sir.

10 Q. Would you agree that efficacy gains were
11 achieved during that loading period?

12 MS. FISHMAN: Objection; vague.

13 You can answer.

14 A. So, efficacy encompasses a lot of things,
15 vision being the most important to me. And sure, I
16 love the way that curves look.

17 Q. (BY MR. SALMEN) Okay. And then, in -- if
18 we compare that curve from weeks 0, 4, and 8, to
19 the week 16 dose, for the 2Q8 arm, would you
20 conclude that the week 16 dose maintained the
21 efficacy gains that were achieved in weeks 0, 4,
22 and 8?

23 MS. FISHMAN: Objection; vague.

24 You can answer.

25 A. So when you design a clinical trial, you

1 have to design set end points that the FDA has to
2 agree to.

3 And so, at this time, the FDA required
4 52-week data, with a non-inferiority margin of 4.5
5 letters, as they went against Lucentis. The FDA
6 would not allow you to just pick a 16 or 20, or
7 somewhere that wasn't a pre-specified end point, in
8 its determination of efficacy.

9 The vision gains are good, though, and
10 you're maintaining them. So...

11 Q. (BY MR. SALMEN) Okay. And you can come to
12 that conclusion, based on the information that's
13 provided in Figure 3.

14 Is that correct, with respect to the week 16
15 dose?

16 A. As respect to the mean visual acuity, yes.

17 Q. Okay. Let's try the same question for the
18 week 40 dose, in Figure 3 of Heier 2012.

19 Are you with me? I'll ask the question.
20 Okay?

21 A. Okay.

22 Q. All right. Would you agree that the week 40
23 dose, based on the information that's available
24 here in Figure 3 of Heier 2012, Exhibit 1018,
25 demonstrates that the week 40 dose maintained the

1 efficacy gained during the 0, 4, and 8 week doses?

2 MS. FISHMAN: Objection; vague.

3 Q. (BY MR. SALMEN) Of the 2Q8 arm?

4 MS. FISHMAN: Pardon me.

5 Objection; vague.

6 You can answer.

7 A. Yeah, what I would say is that it
8 demonstrates that with repetitive Q8 week dosing,
9 after a dose at 0, 4, and 8, you're certainly
10 maintaining a visual acuity within the error bars
11 required by the FDA.

12 Q. (BY MR. SALMEN) Okay. Can -- can we turn
13 to the '338 patent real quick, Example 4?

14 A. And one more time, what was that column?

15 Q. It begins on column 9 and extends through
16 column 13.

17 Are you there?

18 A. I'm here. Thank you.

19 Q. Okay. And the month-to-month ETDRS data,
20 that we just looked at in Figure 3 of Heier 2012,
21 Exhibit 1018, do not appear anywhere in Example 4
22 of the '338 patent, correct?

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

25 You can answer.

1 A. That is correct.

2 Q. (BY MR. SALMEN) So looking at Example 4 of
3 the '338 patent, you cannot tell me whether the
4 week 16 dose in the 2Q8 arm maintain the efficacy
5 gains that were achieved after the 0, 4, and 8 week
6 doses, correct?

7 MS. FISHMAN: Objection; beyond the
8 scope.

9 A. So what I would say is that what the -- the
10 data in Table 1, not necessarily the maintenance of
11 vision, because it sort of got antiquated pretty
12 quickly.

13 But the visual acuity mean letter gains in
14 study 1, study 2, in the bottom of that table, give
15 me some confidence that the -- that -- that the
16 totality of the doses, the three loading doses, 0,
17 4, 8, and then the Q8 led to a good outcome at the
18 end of a year.

19 Q. (BY MR. SALMEN) At the end of a year, at 52
20 weeks --

21 A. The primary end point, 52 weeks.

22 Q. Okay. And the -- the Table 1 data only
23 provide the 52-week mean improvement in vision that
24 you were just referring to, correct?

25 A. Correct.

1 Q. There's nothing in Table 1 regarding what
2 the mean improvement in -- in vision was at
3 week 16, correct?

4 MS. FISHMAN: Objection; asked and
5 answered, document speaks for itself.

6 But you can answer.

7 A. Yeah, so it doesn't. I mean, in my clinical
8 experience, macular degeneration is typically not a
9 disease where you can give an adequate treatment,
10 and then lose a bunch of vision and then gain it
11 all back, and lose a bunch of vision and gain it
12 all back.

13 So, I've never seen, in any of our agents,
14 where if you had a mean visual acuity with -- that
15 was that good, at your 52-week endpoint, you were
16 tanking in between.

17 So it just gives me evidence that the three
18 doses in Q8 led to a 52-week end point that not
19 only got it clinically approved, but had a
20 favorable gain at that primary end point.

21 MR. SALMEN: Well, maybe this is a
22 sign that it's a good time to break. This is about
23 to die. The realtime battery is dead.

24 THE REPORTER: Okay.

25 MR. SALMEN: And it hasn't been

1 following for a while.

2 MS. FISHMAN: Before we go off the
3 record -- I think it's -- it's a connection problem
4 because mine is still working.

5 Before we go off the record, I just
6 wanted to announce that it sounds as though
7 Regeneron in-house counsel, Petra Scamborova,
8 joined audio and dialed in, during this segment of
9 the deposition, so that the record reflects that.

10 But if you want to go off the record
11 to fix the --

12 MR. SALMEN: You know what, I'm at
13 a -- going to change gears, so...

14 MS. FISHMAN: Okay.

15 THE WITNESS: The coffee is cold. I
16 appreciate it.

17 MS. FISHMAN: Okay.

18 THE VIDEOGRAPHER: We're off the
19 record at 11:17 a.m.

20 (Break.)

21 THE VIDEOGRAPHER: We're back on the
22 record at 11:43 a.m. This is Media Unit No. 3.

23 Q. (BY MR. SALMEN) Dr. Brown, let's turn back
24 to the '338 patent, please, Exhibit 1001.

25 A. I'm here.

1 Q. I'll direct your attention to column 13,
2 Example 5.

3 Are you there?

4 A. I'm here.

5 Q. Okay. You reviewed Example 5 in forming
6 your opinions regarding the '338 patent claims,
7 correct?

8 MS. FISHMAN: Objection; lacks
9 foundation.

10 But you can answer.

11 A. I did, but my declaration doesn't address
12 DME, so...

13 Q. (BY MR. SALMEN) Okay. So, did you consider
14 this Example 5 when you formed your opinions,
15 regarding the '338 patent claims?

16 MS. FISHMAN: Objection; vague.

17 A. So, I -- I think I was instructed to do it
18 as of 2011. And I designed the -- these -- just
19 the Vivid trials. So I certainly know them very
20 well, but I don't think I offered an opinion, based
21 on them in my declaration.

22 Q. (BY MR. SALMEN) But you do offer opinions
23 about the '338 patent claims, right?

24 A. I -- I certainly do, as it's --

25 Q. Okay.

1 A. -- one of the angiogenic eye diseases
2 listed.

3 Q. Sure. Let's be more specific. Let's take a
4 look at Claim 6, for example, on the last page of
5 the '338 patent, column 23.

6 A. I'm there.

7 Q. Okay. And you see diabetic macular edema,
8 or DME, is listed as an angiogenic eye disorder in
9 that claim, right?

10 A. I believe Claim 6 is CRVO, and Claim 5 is
11 diabetic macular edema.

12 Q. Are we looking at the -- oh, I'm sorry.
13 Okay. Let -- let's start over. I'm looking at the
14 claims on the last page.

15 A. Oh, I'm sorry. I was looking at --

16 Q. I may have misspoke there.

17 A. No worries.

18 Q. Last page of the patent, all the way to the
19 last page.

20 A. So which line are we?

21 Q. Column 23. So, up at the -- so, look at --
22 look up at the top of the page.

23 A. Yeah.

24 Q. I'm looking at the column numbers.

25 A. I got it.

1 Q. Yeah. There you go.

2 A. There we go.

3 Q. Column 23.

4 A. Yeah.

5 Q. You understand -- let's start at line 1. It
6 says: What is claimed?

7 Do you see that?

8 A. Yes, sir.

9 Q. And you understand that what appears here in
10 bold print, numbers 1 through 26, represent the
11 claims of the '338 patent, right?

12 A. Correct.

13 Q. Okay. So, directing your attention to
14 Claim No. 6, on the left-hand column, 23, about
15 halfway down the page.

16 Do you see it?

17 A. Yes, sir.

18 Q. Okay. You see the diabetic macular edema is
19 listed there as an angiogenic eye disorder,
20 correct?

21 A. Correct.

22 Q. Okay. So DME is called out, specifically,
23 in the claims of the '338 patent, right?

24 A. Correct.

25 MS. FISHMAN: Objection; document

1 speaks for itself.

2 You can answer.

3 Q. (BY MR. SALMEN) Now, let's take a look at
4 Exhibit 5 -- I'm sorry, not Exhibit 5, Example 5,
5 column 13.

6 This is -- Example 5 refers to a Phase II
7 clinical trial of VEGF Trap in subjects with
8 diabetic macular edema, DME, right?

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

11 You can answer.

12 A. So one more time. We're in column 23, bold
13 part 5, right? Or we switched somewhere?

14 Q. (BY MR. SALMEN) Yeah, sorry. We're --
15 we're switching now back to Example 5, and that's
16 in column 13.

17 A. Okay.

18 Q. I want to talk about the actual clinical
19 trial that's summarized there.

20 A. Got it. Example 5, not bullet 5. I'm
21 there.

22 Q. All right. Example 5 provides the results
23 for the Phase II clinical trial of VEGF Trap-Eye in
24 subjects with DME, correct?

25 MS. FISHMAN: Objection; document

1 speaks for itself.

2 You can answer.

3 A. That is correct.

4 Q. (BY MR. SALMEN) Okay. And if we -- if we
5 start at line 64 of column 13, in Example 5, you
6 see that one of the VEGF Trap arms of this trial
7 included a dosing regimen of three initial doses at
8 baseline, week 4, and week 8, followed by every
9 eight-week dosing through week 52, right?

10 MS. FISHMAN: Same objection.

11 You can answer.

12 A. I -- I see that.

13 Q. (BY MR. SALMEN) Okay. So, let's -- just to
14 clarify, this regimen comprises an initial dose,
15 followed by two secondary doses, followed by a
16 series of eight-week doses through week 52,
17 correct?

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

20 You can answer.

21 A. I agree with that.

22 Q. (BY MR. SALMEN) Okay. Well, do you agree
23 that this regimen falls within the scope of Claim 1
24 of the '338 patent?

25 MS. FISHMAN: Objection; vague as to

1 time. Calls for a legal conclusion.

2 A. Yeah --

3 MS. FISHMAN: Outside the scope.

4 You can answer.

5 A. Yeah, I'm not sure I'm qualified to
6 determine whether something meets a legal claim,
7 so...

8 Q. (BY MR. SALMEN) Okay. So, you did not come
9 to that conclusion, in forming your opinions,
10 whether or not Example 5, the 2Q8 arm in that
11 dosing regimen, falls within the scope of any of
12 the '338 patent claims?

13 MS. FISHMAN: Objection; beyond the
14 scope.

15 A. Yeah, I don't make -- I don't make a opinion
16 based on this in my declaration. As I said before,
17 I don't talk about anything in DME.

18 Q. (BY MR. SALMEN) Okay. So, are you aware
19 that Regeneron represented to the Patent and
20 Trademark Office that Example 5 does fall within
21 the scope of the '338 patent claims?

22 MS. FISHMAN: Objection; beyond the
23 scope.

24 You can answer.

25 A. Yeah, like I said, I didn't mention diabetic

1 macular edema, in my -- in my declaration. And
2 so -- in a cross, I don't know how it's pertinent,
3 but I didn't -- I never -- I didn't do that.

4 Q. (BY MR. SALMEN) Okay. Let's -- let's look
5 at Brown Deposition Exhibit 6. Yeah, that one.

6 A. That guy.

7 Q. I'll direct your attention to what is
8 page 290, in the bottom right-hand corner of this
9 exhibit.

10 You see, in the first full paragraph, it
11 says: Within the discussion section of the Heier,
12 et al, paper.

13 Do you see that?

14 A. I do.

15 Q. Okay. And then the next full paragraph
16 states, quote: Similar --

17 A. Hold on one second. I'm -- we've got
18 three -- we've got several Heier, et al, papers
19 registered -- referenced here. This is the AMD --
20 this is the VIEW Heier paper.

21 Q. I'll -- I'll try to confirm that with you,
22 in this document. Okay. So let's -- let's flip
23 ahead to the previous page, what's marked page 289
24 of this exhibit.

25 Okay. You see in the --

1 A. Yeah.

2 Q. -- first full paragraph on this page, it
3 states, quote: The attached Heier, et al, paper
4 published in December of 2012, and as such, it is
5 not prior art with respect to the present
6 application.

7 Do you see that?

8 A. I do.

9 Q. Okay. Does that clarify for you, which
10 Heier, et al --

11 A. Sure.

12 Q. -- paper we're referring to?

13 A. Correct.

14 Q. Does that clarify it for you?

15 A. Yes, sir.

16 Q. Okay. And we're referring to the Heier, et
17 al -- I'm sorry, the Heier 2012 that we've been
18 discussing today, Exhibit 1018, correct?

19 MS. FISHMAN: Objection; document
20 speaks for itself.

21 A. That's correct, 1018.

22 Q. (BY MR. SALMEN) Okay.

23 A. Yeah.

24 Q. Now, going back to page 290 of Brown
25 Deposition Exhibit 6, I'm going to take you to the

1 second full paragraph there. Quote: Similar
2 remarkable results are shown in Example 5 of the
3 present application, which illustrates an
4 administration regimen encompassed by Claims 1
5 and 21, i.e., three initial doses of VEGF Trap
6 administered once every four weeks, followed by
7 additional doses administered once every eight
8 weeks, for the effective treatment of diabetic
9 macular edema.

10 Do you see that?

11 MS. FISHMAN: Objection; document
12 speaks for itself.

13 You can answer.

14 A. I see that.

15 Q. (BY MR. SALMEN) Okay. So you agree here
16 that Regeneron represented to the patent office
17 that Example 5 fell within the scope of Claim 1 of
18 the '338 patent, correct?

19 MS. FISHMAN: Objection; beyond the
20 scope, calls for speculation, calls for a legal
21 conclusion.

22 You can answer.

23 A. It seems that way. I'm not a lawyer, but it
24 sure seems that way.

25 I know that Table 2, Phase II trials, that's

1 not in a patient's -- nor enough length of
2 follow-up for the FDA to approve an indication,
3 but...

4 Q. (BY MR. SALMEN) For the FDA to approve an
5 indication.

6 A. Correct.

7 Q. Was that correct?

8 A. Correct.

9 Q. Okay. Does that have anything to do with
10 whether or not the patent office could grant a
11 patent?

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

14 A. Again, my daughter went to NYU and UT Law,
15 but I didn't. So I don't know.

16 Q. (BY MR. SALMEN) Okay. Are you aware
17 whether or not FDA approvability is required for a
18 method of treatment, like the '338 patent claims?

19 MS. FISHMAN: Objection; calls for a
20 legal conclusion, beyond the scope of his
21 declaration.

22 A. I'm pretty sure it doesn't, but again, I'm
23 not a lawyer.

24 Q. (BY MR. SALMEN) Okay. So, we agree that
25 there are no Phase III data in Example 5 of the

1 '338 patent, right?

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

4 A. I -- correct.

5 Q. (BY MR. SALMEN) And I think you do comment
6 about Phase II data in your declaration. For
7 example, if we look at paragraph -- beginning of
8 paragraph 114, regarding the CLEAR-IT 2 trial?

9 A. Definitely.

10 Q. Okay. And with respect to the CLEAR-IT 2
11 data, as you set forth in these paragraphs, it is
12 your opinion that Phase II data are not sufficient
13 to provide a reasonable expectation of success for
14 the method of treating under the '338 patent
15 claims, right?

16 A. Not this Phase II study, no.

17 Q. Also not the Phase II study that appears in
18 Example 5.

19 Isn't that right?

20 MS. FISHMAN: Objection; beyond the
21 scope of his declaration, calls for speculation.

22 A. I don't make the opinion in my declaration.

23 MS. FISHMAN: Hold on. Let me
24 finish my objection.

25 It was beyond the scope, calls for

1 speculation, and a legal conclusion.

2 You can go ahead and answer.

3 Q. (BY MR. SALMEN) Regeneron did consider the
4 Phase II data that was presented in Example 5 to be
5 sufficient to support the method of treating in the
6 claims, right? That's what they said?

7 MS. FISHMAN: Objection; calls for
8 speculation, and beyond the scope.

9 You can answer.

10 A. Yeah, I don't think I can speculate. What
11 Regeneron claimed was part of their claims, and
12 something that's not in my declaration.

13 Q. (BY MR. SALMEN) You read it in the -- in
14 the document, Deposition Exhibit 6, right? That's
15 what Regeneron said.

16 MS. FISHMAN: Objection; asked and
17 answered, and argumentative.

18 Q. (BY MR. SALMEN) Well, let's look at it
19 again.

20 Brown Deposition Exhibit 6, page 290, the
21 second full paragraph, quote: Similar remarkable
22 results are shown in Example 5 of the present
23 application, which illustrates an administration
24 regimen encompassed by Claims 1 and 21.

25 Do you see that?

1 MS. FISHMAN: Objection; document
2 speaks for itself.

3 You can answer.

4 MR. SALMEN: I just asked him if he
5 saw it.

6 A. I see it.

7 Q. (BY MR. SALMEN) Okay. Let's look at
8 Claim 1, which appears on page 284 of Brown
9 Exhibit 6.

10 A. Where are we at? Sorry.

11 Q. Page 284, in the bottom right-hand corner.

12 A. 284.

13 (Voices en sotto.)

14 Q. (BY MR. SALMEN) Are you there, page 284,
15 Brown Exhibit 6?

16 A. I'm at page 284.

17 Q. Okay. You see that's Claim 1.

18 Do you see that?

19 MS. FISHMAN: Objection; document
20 speaks for itself.

21 A. So, what number are we here?

22 Q. (BY MR. SALMEN) Claim No. 1.

23 A. All right. Current amended, is that what it
24 says?

25 Q. Yeah.

1 MS. FISHMAN: What is your question,
2 Counsel?

3 MR. SALMEN: Did you see that, which
4 you objected to --

5 MS. FISHMAN: Well, I objected
6 because you're --

7 MR. SALMEN: -- and said the
8 document is speaking for itself.

9 MS. FISHMAN: Well, you're
10 representing that this is Claim 1. Are you asking
11 the witness to do a word-by-word comparison to
12 issued Claim 1, in a document he's never seen
13 before?

14 MR. SALMEN: Is that your
15 representation, he's never seen this document?

16 MS. FISHMAN: He testified --

17 MR. SALMEN: I'll accept that --
18 I'll accept that representation.

19 MS. FISHMAN: He testified he's
20 never -- it's not my representation. It's the
21 witness's testimony.

22 MR. SALMEN: Great. Thank you.

23 Q. (BY MR. SALMEN) You can put that down.

24 (Voices en sotto.)

25 Q. (BY MR. SALMEN) Dr. Brown, you reviewed

1 Regeneron's patent owner response in this
2 proceeding, right?

3 A. Which one was that? What's the --

4 Q. It's the...

5 (Voices en sotto.)

6 THE REPORTER: It should be 7.

7 Q. (BY MR. SALMEN) All right. Dr. Brown, I'm
8 going to hand you what's been marked Brown
9 Exhibit 7.

10 (Exhibit 7 is marked.)

11 Q. (BY MR. SALMEN) Do you recognize Brown
12 Exhibit 7?

13 A. I do. I reviewed it.

14 Q. Okay. I'm just going to point you to a
15 couple of passages here to give you some context --

16 A. Okay.

17 Q. -- for my question. Okay.

18 So -- okay. Sorry about that. Let's look
19 at the top of page 16, please.

20 Are you there?

21 A. Yes, sir.

22 Q. Here, Regeneron states, quote: The
23 prosecution history confirms that the claimed
24 method -- sorry. Strike that.

25 Quote: The prosecution history confirms

1 that the claimed treatment methods must achieve a
2 high level of efficacy.

3 Do you see that?

4 A. I do.

5 Q. Next sentence, quote: During prosecution,
6 Regeneron relied on Heier 2012, Exhibit 1018, to
7 overcome a double patenting rejection.

8 Do you see that?

9 A. I do.

10 Q. Okay. Now, do you understand that this is
11 the prosecution history, referring to the
12 prosecution history that I showed you earlier, that
13 very large document?

14 MS. FISHMAN: Objection; calls for
15 speculation.

16 A. The wording says it's the prosecution
17 history confirms.

18 Q. (BY MR. SALMEN) Okay.

19 A. And it's from Regeneron, so I --

20 Q. You didn't -- you didn't --

21 A. -- would assume that, yeah.

22 Q. Okay. And you didn't review that document?

23 A. I didn't review the prosecution history, no.

24 Q. Okay. Okay. Let's turn back to your
25 declaration, on the patent owner responses side.

1 Let's look at paragraph 117. All right.
2 Let's -- do you still have the Do deposition
3 exhibit, with the green and yellow highlight on
4 there?

5 A. The Do declaration?

6 Q. No. It's the one-page deposition exhibit.

7 A. What exhibit number was it?

8 Q. It's Do Deposition Exhibit 4. I think we
9 marked it as --

10 A. Okay. Here. So, I have 4. Then 5 is the
11 clinical trials. Oh, here we go.

12 Q. It's Brown --

13 A. Exhibit 3.

14 Q. Okay. So Brown Exhibit 3?

15 A. Yeah.

16 Q. Okay. Now, directing your attention back to
17 Example 5 that we talked about, the Phase II
18 clinical trial data.

19 A. In the patent?

20 Q. Yep.

21 So you -- you see that in Brown Exhibit 3,
22 the green highlighted language, Dr. Do refers to a
23 high level of efficacy, in the method of treating
24 language.

25 Do you see that?

1 A. That's correct.

2 Q. Okay.

3 A. I see that.

4 Q. Well, in your opinion, do the Phase II data
5 of Example 5 sufficiently demonstrate the high
6 level of efficacy that's required under the method
7 of treating, under Claim 1 of the '338 patent?

8 MS. FISHMAN: Objection; beyond the
9 scope, and calls for a legal conclusion.

10 A. So, what I can say is that the Phase II data
11 was very positive. It demonstrates visual acuity
12 change mean change of 8-5 to 11-4, depending on the
13 arms.

14 You know, the problem at that point in time
15 was the Lucentis DME trials had data about the time
16 of this patent, and so, the FDA would no longer let
17 you go against laser.

18 I think they started their trial right
19 before approval of Lucentis. So, although we knew
20 the data, this data seems good, but the numbers are
21 too small to -- to feel conclusively that this is
22 as good of a treatment as the other anti-VEGF's for
23 DME.

24 Q. (BY MR. SALMEN) So, am I understanding that
25 answer, that -- correctly, that Lucentis would have

1 been considered the standard of care for treating
2 DME at the time of this Example 5 data?

3 MS. FISHMAN: Objection; misstates
4 testimony, and also --

5 A. At exactly what time?

6 MS. FISHMAN: Hold. Hold on.

7 And beyond the scope.

8 Go ahead.

9 Q. (BY MR. SALMEN) Whatever time frame you
10 were referring to in your answer. You had
11 mentioned that at the time that this trial was
12 started, in Example 5, there was Lucentis data
13 available to FDA.

14 Did I understand that correctly?

15 MS. FISHMAN: Objection; misstates
16 testimony.

17 You can...

18 A. Yeah, I don't know the exact times. You'll
19 have to tell me. I'm just saying that in this
20 example, they're comparing to laser. And
21 certainly, in modern times, you would never compare
22 to laser.

23 You know, in the scope of 2011, or whenever
24 it is, I'm not exactly sure what exactly data was
25 out there. You'd have to interpret it based on the

1 data that was there at the time.

2 Q. (BY MR. SALMEN) And under the '338 patent
3 claims, you would have to interpret it to the
4 existing -- against the existing standard of care
5 for that particular angiogenic eye disorder
6 treatment, right?

7 MS. FISHMAN: Objection; beyond the
8 scope.

9 You can answer.

10 A. Yeah, for the -- for the -- I didn't address
11 this in my declaration. I design a bunch of
12 clinical trials, and it is very encouraging that
13 the Phase II data is this strong. Phase II, you
14 can go against anything that's ethical. The FDA
15 doesn't consider it for registration.

16 Q. (BY MR. SALMEN) Okay. Let's shift gears a
17 little bit. I want to look at paragraph 26 of your
18 expert declaration.

19 You have a section here titled, State of the
20 Art.

21 Do you see that?

22 A. I do.

23 Q. And the subheading is, The Prior Art
24 Treatment of Angiogenic Eye Disorders with
25 Anti-VEGF Therapies.

1 Do you see that?

2 A. I see it.

3 Q. Okay. In paragraph 26, you provide a
4 description of angiogenic eye disorders.

5 Is that correct?

6 A. That is correct.

7 Q. Okay. And you understand that the '338
8 patent also provides a description of angiogenic
9 eye disorders?

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

12 You can answer.

13 A. So we can go back and look at it.

14 Q. (BY MR. SALMEN) Sure. Column 5. Beginning
15 at what looks like a line 11, there's a header,
16 quote, Angiogenic Eye Disorders.

17 Do you see that?

18 A. Yes. And I agree, it also describes it.

19 Q. Okay. So, let me just follow up on -- on
20 that.

21 You said you agree. Are you agreeing with
22 the description of angiogenic eye disorders that's
23 provided in the '338 patent, at column 5, beginning
24 at line 11?

25 MS. FISHMAN: Objection; misstates

1 testimony.

2 You can answer.

3 A. It's semantics, but I probably wouldn't
4 agree that proliferative vitreoretinopathy is an
5 angiogenic eye disease.

6 Q. (BY MR. SALMEN) Okay. Can you give me the
7 line number that that one appears on, please?

8 A. 25.

9 Q. Okay.

10 A. I guess -- so it's a wound healing response,
11 when we do retinal surgery that some people get
12 scar tissue.

13 And so, that scar tissue is typically
14 fibroblastic proliferation of cells. Sure, it may
15 get vascularized, so I guess that's where they're
16 coming from. But it's not a primary angiogenic
17 response. It's a wound healing scar tissue
18 response, so...

19 Q. Okay. So, with the exception of
20 proliferative vitreoretinopathy, PVR, do you agree
21 with the rest of the description, as provided here
22 in column 5 for angiogenic eye disorders?

23 A. Yeah, it's pretty conclusive.

24 Q. Okay.

25 A. Inclusive.

1 Q. And is that description in column 5
2 consistent with the description that you provide in
3 column 26 of your declaration?

4 A. So my description in column 26 is the
5 predominant angiogenic eye diseases that deal with
6 my part of the eye, which is macular degeneration.

7 Q. Okay.

8 A. The maculae, maculae degeneration, diabetic
9 macular edema, the -- the section of the eyeball
10 I'm an expert in.

11 Q. Okay. Now, I want to ask you a couple
12 questions about your declaration. Let's look at
13 paragraph 40, for example. You refer to the
14 standard of care, in this paragraph, after
15 June 2006, when Lucentis received FDA approval.

16 Do you see that?

17 A. I see it.

18 Q. Okay. After June 2006, was Lucentis, or
19 off-label Avastin, as you state here, the standard
20 of care for wet AMD?

21 A. Yes, it was.

22 Q. Now, as of January 2011, was Lucentis, or
23 off-label Avastin, the standard of care for
24 wet AMD?

25 A. Yes, it still was. There was no other

1 agents.

2 Q. So after Lucentis was approved in 2006, and
3 before January 2011, what was the standard of care
4 for diabetic macular edema?

5 MS. FISHMAN: Objection; beyond the
6 scope.

7 You can answer.

8 A. Yes. The standard of care for diabetic
9 macular edema really depended on what access the
10 patients had. I run the biggest clinical trial
11 center in the world. So I would put those patients
12 in an anti-VEGF trial, so that they would have the
13 opportunity to get that agent.

14 Only other way to get anti-VEGF agents was
15 off-label Avastin, which I agree is the standard of
16 care, if you could get it. Some patients couldn't
17 afford it because it wasn't -- it wasn't covered by
18 their insurance.

19 There was still some focal laser, because if
20 your only suit is at the cleaners, you wear what
21 you got. And that's the best thing we had up until
22 the point where we had anti-VEGF agents.

23 Q. (BY MR. SALMEN) Okay. So, just to try to
24 unpack that.

25 So, one option for your patients with

1 diabetic macular edema, during that time frame,
2 2006 to January 2007, would have been putting them
3 into a VEGF -- anti-VEGF clinical trial?

4 Is that correct?

5 MS. FISHMAN: Objection; beyond the
6 scope.

7 You can answer.

8 A. Maybe I misunderstood your question. I
9 thought you said before 2011.

10 Q. (BY MR. SALMEN) I misspoke. I'm sorry.
11 Let me -- let me strike that question, and I'll --
12 I'll restate it.

13 One option for your patients, during that
14 time frame, after 2006, before -- but before
15 January 2011, you would have put them into a
16 anti-VEGF clinical trial, for the treatment of
17 their diabetic macular edema?

18 A. I would have given risk and benefits, and
19 recommended they consider that trial, because
20 that's the best -- that's the best option they had
21 for gaining vision.

22 Q. Okay. And during that same time period,
23 after 2006, when Lucentis was approved, but before
24 January 2011, another option for your patients
25 would have been off-label Lucentis, to treat them

1 for their diabetic macular edema?

2 MS. FISHMAN: Objection; beyond the
3 scope.

4 You can answer.

5 A. It would be an option. But at \$1800 a dose,
6 very few patients could afford that. A more
7 realistic -- a more realistic option was off-label
8 Avastin.

9 Q. (BY MR. SALMEN) Okay. So, what about after
10 Eylea was approved -- strike that.

11 So Lucentis was approved for treating
12 diabetic macular edema in 2012, right?

13 A. I'm pretty sure that's correct.

14 Q. Okay. So after the approval of Lucentis to
15 treat diabetic macular edema, would the standard of
16 care have been Lucentis to treat that?

17 MS. FISHMAN: Objection; beyond the
18 scope.

19 A. In my clinic, yes.

20 Q. (BY MR. SALMEN) And would that -- in your
21 clinic, would you have applied a fixed monthly
22 dosing regimen of Lucentis to treat diabetic
23 macular edema, in 2012, after Lucentis was
24 approved?

25 A. Yes.

1 MS. FISHMAN: Objection; beyond --
2 objection; beyond the scope.

3 You can answer.

4 A. Yes, I would.

5 Q. (BY MR. SALMEN) I want to -- all right.
6 Dr. Brown, I'm going to hand you what I've
7 marked --

8 THE REPORTER: 8, it should be 8.

9 MR. SALMEN: Okay.

10 MS. FISHMAN: What's Exhibit 7? Oh,
11 yeah. That's true. Patent owner response. That's
12 right. Yeah, okay.

13 Q. (BY MR. SALMEN) All right. Dr. Brown, I'm
14 going to hand you what I've marked as Brown
15 Exhibit 8.

16 (Exhibit 8 is marked.)

17 MS. FISHMAN: Thank you.

18 Q. (BY MR. SALMEN) Dr. Brown, do you recognize
19 this document, Brown Exhibit 8?

20 A. Memory is fuzzy, but I do recognize it.

21 Q. Okay. So, if we look at the second page,
22 page 222, you'll see at the very top, it states,
23 quote: Ophthalmology Volume 120, No. 1,
24 January 2013.

25 A. Correct.

1 Q. Do you see that?

2 Okay. So now back to the first page, in the
3 center, there's a letter to the editor, titled,
4 quote: Ranibizumab for Diabetic Macular Edema.

5 Do you see that?

6 A. I do.

7 Q. Okay. And this letter to the editor was
8 written by Rahul Mayor and his colleagues?

9 Do you see that?

10 A. I do.

11 Q. All right. And the first line, he states --
12 well, I shouldn't -- I don't -- Dr. Mayor states,
13 quote: We read with interest the recent study,
14 quote, Ranibizumab for Diabetic Macular Edema,
15 Results from Phase -- from 2 Phase III Randomized
16 Trials: RISE and RIDE, close quote, by Nguyen, et
17 al.

18 Do you see that?

19 A. I do.

20 Q. And then we see the reference that they're
21 referring to as Nguyen, in Footnote 1.

22 Do you see that?

23 A. That's correct.

24 Q. Okay. Now, on the second page here -- or it
25 actually starts at the bottom of the first page, I

1 should say, is the author reply, right?

2 A. Correct.

3 Q. And are you the author of this author reply?

4 A. I am.

5 Q. Okay. It shows your name on page 2, David
6 M. Brown, M.D.

7 That's you, right? Correct?

8 A. Correct.

9 Q. Okay. Now, I just want to direct your
10 attention, again, to the bottom -- the -- the last
11 line of the -- the first full paragraph, there.

12 It states, quote: Thus, we are quite
13 confident that the control groups in RIDE and RISE
14 have provided a fully appropriate comparison group
15 to understand and illustrate the beneficial effects
16 of ranibizumab, relative to standard of care
17 treatment (macular laser photocoagulation for DME).

18 Do you see that?

19 A. I do.

20 Q. Okay. So, you agree that until Lucentis was
21 approved for DME, in 2012, macular laser
22 photocoagulation was the standard of care treatment
23 for DME, right?

24 MS. FISHMAN: Objection; misstates
25 document, lacks foundation, and mischaracterizes

1 testimony. Also beyond the scope.

2 But you can answer.

3 A. So, the ETDRS laser protocols, which were in
4 the '90s, demonstrated that patients with diabetic
5 macular edema close to the fovea, or involving the
6 fovea, the center of the vision, had less vision
7 loss with focal laser than those with observation.

8 In those trials, very few percent of
9 patients gained vision. But it was the best thing
10 we had.

11 So, from the mid '90s, till anti-VEGF
12 therapy was there, if you met this criteria of the
13 National Eye Institute studies that I was part of,
14 you were offered focal laser photocoagulation.

15 If you read my letter to the editor, their
16 complaint was that we didn't offer focal laser
17 immediately in the trial, and that was because of
18 FDA concerns of masking. If you have a laser, you
19 get this bright flash of light, and there's no way
20 to fake that.

21 So, that's why a three-month delay was given
22 before laser was instituted, but diabetic patients
23 have years of non-compliance to a diabetic regimen
24 before they get DME, and often years before they
25 got out.

1 So, the fact they had 18 months, or 21
2 months, of potential laser, we felt, gave them
3 adequate treatment to say that they were treated
4 adequately per the ETDRS controller.

5 Q. (BY MR. SALMEN) Okay. So, with respect to
6 the -- the RISE and RIDE clinical trials that is
7 the subject of the letter to the editor, you agree,
8 then, that the patients received the standard of
9 care treatment, i.e., macular laser
10 photocoagulation for the treatment of DME, in the
11 control arm of those studies?

12 MS. FISHMAN: Objection; misstates
13 testimony, beyond the scope, asked and answered.

14 A. So, as we talked about before, if you could
15 get anti-VEGF therapy, I would not consider focal
16 laser standard of care.

17 Q. (BY MR. SALMEN) You --

18 A. If you couldn't, focal laser is the best you
19 can get. And in a clinical trial, you can't get
20 both.

21 Q. Okay. So, in the RISE and RIDE clinical
22 trial, the patients in the control groups received
23 macular laser photocoagulation for their DME,
24 correct?

25 A. That is correct.

1 Q. And you refer to that treatment for DME, the
2 macular laser photocoagulation, as the standard of
3 care treatment, as of the time of that RISE and
4 RIDE clinical trial?

5 MS. FISHMAN: Objection --
6 objection; misstates document, misstates testimony,
7 beyond the scope.

8 A. So, as -- as we talked about before, in any
9 clinical trial, you've got to look at the inclusion
10 and exclusion criteria; you've got to look at the
11 patient population. RISE/RIDE excluded anybody who
12 had had previous anti-VEGF therapy.

13 You know, it -- it also -- it -- it
14 precluded you from giving any anti-VEGF therapy.
15 So that was the best comparator arm we could give,
16 and exactly was standard of care from '95 until,
17 you know, probably 2005, when Avastin became
18 available.

19 Q. (BY MR. SALMEN) But Avastin would have been
20 available off label, and would not have been
21 available in this clinical study -- study in the
22 control arm, right?

23 A. Correct.

24 Q. Okay. So the existing standard of care, as
25 far as on-label treatment, would have been the

1 macular laser photocoagulation --

2 MS. FISHMAN: Objection --

3 Q. (BY MR. SALMEN) -- for DME, right?

4 MS. FISHMAN: Pardon. Objection;
5 beyond the scope. Beyond the scope, misstates
6 testimony, asked and answered.

7 You can answer.

8 A. Yes.

9 Q. (BY MR. SALMEN) Okay. So, Nguyen was
10 published in 2012, according to Footnote 1, on
11 page 221 of Brown Exhibit 8, right?

12 A. Correct.

13 It's pronounced win, like you win a ball
14 game. So...

15 Q. Oh, okay.

16 A. Half -- half the town is Vietnamese here,
17 and there's a million Nguyens.

18 Q. Okay.

19 A. So letting you know.

20 Q. For some reason, I've always thought that
21 was pronounced Nguyen, but I -- I (unintelligible).

22 A. I just pronounce it the way they tell me to.

23 Q. Yeah.

24 A. You don't ask a South Texan usually for
25 pronunciation, but...

1 Q. Okay. Let me try to put this in perspective
2 of the '338 patent for a second. Okay?

3 Prior to January 2011, the date that you
4 applied in forming your opinions on the '338
5 patent, the standard of care treatment for DME was
6 macular laser photocoagulation, correct?

7 MS. FISHMAN: Objection; misstates
8 testimony, beyond the scope, and asked and
9 answered.

10 You can answer.

11 A. So retina specialists, in particular, often
12 go off label, and hear about a therapy and go for
13 it.

14 Prior to 2011, there were a lot of doctors
15 giving intravitreal triamcinolone, which is a
16 steroid in the eye. The DRCR study did a -- did a
17 study and showed that it was actually better to not
18 give the steroid, than to give it.

19 Likewise, if they had availability of
20 Avastin, and the patients could afford it, a lot of
21 retina specialists in this country gave Avastin,
22 once it became available, and before.

23 It was covered by some insurances, not many.
24 But the standard of care, in most clinics, would
25 have been either steroids, or Avastin, or focal

1 laser photocoagulation. Of those, not only -- in
2 retrospect, now that we have studies to show it
3 works, the anti-VEGF would have been their best
4 option, so...

5 Q. (BY MR. SALMEN) Okay. So let me see if I
6 can sum that up for you.

7 So, as of January 13th, 2011, when the '338
8 patent application was filed, in your opinion, the
9 standard of care treatment for DME could have
10 varied, in any one of the different types of
11 treatments that you just provided?

12 MS. FISHMAN: Objection; beyond the
13 scope of his declaration, misstates testimony.

14 You can answer.

15 A. Yeah, so, I mean, I -- I'm -- you know, if
16 you're talking to a pointy-headed clinical
17 trialists in a tertiary care setting, you know, I
18 would have had access to RISE/RIDE or to the
19 Phase II DME, or other anti-VEGF trials to offer
20 them.

21 Outside of the -- the clinical trialist
22 center, you really were limited to laser, Avastin,
23 or steroids. And different retina physicians did
24 different things. And I certainly can't testify
25 what -- what the prevalence it was, et cetera.

1 Q. (BY MR. SALMEN) Okay. Well, what about
2 after -- let me strike that.

3 So...

4 (Voices en sotto.)

5 Q. (BY MR. SALMEN) Do you have Exhibit 2214 in
6 your binder there?

7 A. I don't think so.

8 Q. Okay.

9 A. I think I go to 2128.

10 Q. I think -- I think I got -- got a loose leaf
11 version of it here.

12 Okay. I don't need the -- okay. So this
13 was previously marked Exhibit 2214.

14 And you -- you'll see here that this is the
15 Lucentis label that was revised in August 2012,
16 correct?

17 A. Correct.

18 Q. So, when you agreed with me earlier that
19 Lucentis was approved for the treatment of DME, in
20 2012, this would have been the approved revised
21 label reflecting that, correct?

22 A. This confirms that, yes.

23 Q. Okay. So, now, I want to ask my earlier
24 question, but give you a different time frame.

25 So, after January 2011, when the '338 patent

1 was filed, but before the approval of Lucentis for
2 the treatment of DME, do you agree that the
3 standard of care treatment for DME would have been
4 the variety of approaches that you described in
5 your last answer?

6 MS. FISHMAN: Objection; beyond the
7 scope of his declaration, lacks foundation,
8 misstates testimony.

9 You can answer.

10 A. Yeah, with the addition of, if you did have
11 lots of money, you could probably buy off-label
12 Lucentis.

13 Q. (BY MR. SALMEN) Okay. Let me ask you one
14 last question here.

15 After Lucentis was approved for the
16 treatment of DME, in August 2012, as reflected in
17 exhibit -- Exhibit 2214, was the standard of care
18 for treating DM -- DME, Lucentis on a fixed monthly
19 dosing regimen?

20 MS. FISHMAN: Objection; beyond the
21 scope.

22 A. After this approval, this 8-2012, the
23 standard of care, in my clinic, would be Lucentis
24 monthly.

25 Q. (BY MR. SALMEN) For the treatment of DME,

1 right?

2 A. For the treatment of DME.

3 Q. Okay. Let's look back at your declaration,
4 paragraph 26, where you provide your description of
5 angiogenic eye disorders.

6 A. I'm here.

7 Q. Sitting here today, can you tell me what the
8 standard of care was for every single one of those
9 angiogenic eye disorders, as of January 13th, 2011?

10 MS. FISHMAN: Objection; beyond the
11 scope.

12 A. I -- the treatment, in my clinic, would have
13 been, again, to try to get you in a randomized
14 clinical trial, especially for retinal vein
15 occlusion, or diabetic -- diabetic retinopathy, we
16 didn't have clinical trials for yet. We did have
17 them for diabetic macular edema and retinal vein
18 occlusion.

19 Outside of that, the standard of care for
20 most of those, the others, if you couldn't get in
21 the trial, would have been Avastin.

22 Q. (BY MR. SALMEN) Off-label Avastin?

23 A. Off-label Avastin.

24 Q. What about off-label Lucentis, as of prior
25 to January 2011?

1 MS. FISHMAN: Objection; beyond the
2 scope.

3 You can answer.

4 A. So, one more time, this is before 2011? Oh,
5 yeah, yeah, you could --

6 Q. (BY MR. SALMEN) Yeah.

7 A. If you could afford it. You know,
8 literally, it's a handful of patients will pay
9 \$2,000 a shot, when there's a -- when Avastin is
10 available.

11 So, certainly, the standard of care was to
12 offer Lucentis, but very few people ponied up,
13 could afford it.

14 Q. Okay. Included in your list of angiogenic
15 eye disorders is wet AMD, though, right?

16 A. Yeah. So standard of care for that would
17 be, treatment of -- treatment with Lucentis,
18 monthly, sure.

19 Q. What about --

20 A. That was covered by insurance, sure.

21 Q. What about less-than-monthly dosing? Would
22 that have been included in this -- strike that.

23 Would less-frequent-than-monthly dosing
24 Lucentis have been included in your standard of
25 care for wet AMD, as -- prior to January 2011?

1 MS. FISHMAN: Objection; beyond the
2 scope, vague.

3 You can answer.

4 A. In this country, insurers are happy if you
5 go less than monthly, because it saves them lots of
6 money.

7 Patients with wet AMD are old. They often
8 have problems getting rides. A lot of patients got
9 suboptimal therapy because they didn't have access
10 to rides.

11 So often you treated patients less than
12 monthly, with Lucentis, with wet AMD.

13 MR. SALMEN: Okay. I think I'm
14 ready to break for lunch. How are you feeling?
15 Otherwise, I'm -- I've got a section that's going
16 to take much longer. It's 12:45. You said you
17 wanted to break at 1:00.

18 MS. FISHMAN: Around 1:00. How long
19 do you have, do you think, in your next section?

20 MR. SALMEN: 45 minutes.

21 THE WITNESS: I'm good.

22 MS. FISHMAN: Okay. You want a
23 break, or you want to keep going?

24 THE WITNESS: I -- totally up to
25 y'all.

1 MS. FISHMAN: Why don't we break?
2 That's fine.

3 THE WITNESS: All right. I could
4 use a restroom, though.

5 THE VIDEOGRAPHER: And we're off the
6 record at 12:44 p.m.

7 (Break.)

8 THE VIDEOGRAPHER: And we are back
9 on the record at 1:43 p.m. This is Media Unit
10 No. 4.

11 Q. (BY MR. SALMEN) Dr. Brown, I'm going to
12 hand you a document that I've marked as Brown
13 Exhibit No. 9.

14 (Exhibit 9 is marked.)

15 Q. (BY MR. SALMEN) Dr. Brown, do you recognize
16 this document that I've marked as Brown Exhibit
17 No. 9?

18 A. I don't think I've seen this before, but I'm
19 familiar with local coverage determinations.

20 Q. Okay. You haven't seen this particular
21 document, but you're familiar with the local
22 coverage determination regarding vascular
23 endothelial growth factor inhibitors for the
24 treatment of ophthalmological diseases (L36962)?

25 MS. FISHMAN: Objection; beyond the

1 scope.

2 A. Yeah, it's not part of my declaration. I'm
3 on the -- you know, we have different Medicare
4 contractor --

5 Q. (BY MR. SALMEN) Okay.

6 A. -- here. And so I'm not -- I haven't looked
7 at any of the first codes, but --

8 Q. All right. Let's --

9 A. -- I understand.

10 Q. Let's look at your declaration.

11 A. Sure.

12 Q. Paragraph 85.

13 Are you there?

14 A. I am.

15 Q. Okay. In paragraph 85, you begin your
16 opinion, stating, quote: It is worth noting that a
17 retrospective analysis of VIEW, published in 2016,
18 showed that for a subpopulation of patients with
19 early persistent fluid, about 20 percent of the
20 subjects --

21 (Interruption.)

22 Q. (BY MR. SALMEN) -- about 20 percent of the
23 subjects in the VIEW trials, 8-week dosing, was
24 significantly less effective than monthly dosing.

25 Do you see that?

1 A. I do.

2 Q. And then -- excuse me.

3 MR. SALMEN: For those on the call,
4 can you please mute your phone?

5 Q. (BY MR. SALMEN) And then the last sentence
6 of that paragraph, you state, quote: Consequently,
7 in 2016, Eylea's label was amended to specify that,
8 quote, some patients may need every four-week
9 monthly dosing after the first 12 weeks, 3 months,
10 close quote.

11 Do you see that?

12 A. I see it, yeah.

13 Q. Okay. Now, does this document that we
14 marked as Brown Exhibit No. 9, relate to the change
15 in that Eylea label?

16 MS. FISHMAN: Objection; calls for
17 speculation.

18 A. I've never seen it before. I'd certainly
19 have to read it.

20 Q. (BY MR. SALMEN) Okay. Well, let's -- let's
21 start at page No. 5 of 19. If you look at the
22 bottom row, you'll see the page numbers.

23 You see the header, Limitations, on that
24 page?

25 A. I do.

1 Q. And it reads, quote: The following are
2 considered not reasonable and necessary, therefore,
3 may be denied.

4 Do you see that?

5 A. I do.

6 Q. What's your understanding of that -- that
7 statement, in this section of the L36962 document?

8 MS. FISHMAN: Objection; document
9 speaks for itself. You're asking him to comment on
10 a document he hasn't read and provide an
11 understanding. It's beyond the scope. I just
12 object to this whole line of questioning.

13 A. I --

14 MS. FISHMAN: Objection; lacks
15 foundation that he has an understanding.

16 MR. SALMEN: He actually did testify
17 already that he does have an understanding,
18 although he hasn't seen this particular document.

19 MS. FISHMAN: Objection; misstates
20 testimony.

21 A. Let me just read these five things, and then
22 we can talk about it. I -- it's outside of scope
23 of my declaration.

24 By way of reference, I'm on the CAC,
25 Clinical Advisory Committee, for Novitas, which is

1 our Medicare contractor.

2 So, yes, I do know what LCDs are, local
3 coverage determinations. And Novitas did not have
4 an LCD that covered this, as far as I know.
5 Although, that would have been ten years ago,
6 so maybe my memory is not clear.

7 But let me read their -- what they're
8 limiting.

9 (The witness peruses the document.)

10 A. I have read them.

11 Q. (BY MR. SALMEN) You've read what --

12 A. Happy to answer questions about it. I mean,
13 you want me to summarize this? Is that what you
14 want?

15 MS. FISHMAN: Wait for a question.

16 Q. (BY MR. SALMEN) I want to direct your
17 attention to No. 4, under the header, Limitations.
18 Okay? Can we start there?

19 A. I'm there.

20 Q. Okay. Quote: Frequency is considered
21 excessive when services are performed more
22 frequently than listed in the package insert, or
23 generally accepted by peers, and the reason for
24 additional services is not justified by
25 documentation. Dose and frequency should be in

1 accordance with the FDA label, or recognized
2 compendia for off-label uses.

3 When services are performed in excess of
4 established parameters, they may be subject to
5 review for medical necessity.

6 Do you see that?

7 A. I do.

8 Q. So I'm going to -- since you mentioned
9 Novitas, I'm going to hand you what I've marked as
10 Brown Exhibit No. 10.

11 MR. SALMEN: Sorry.

12 (Exhibit 10 is marked.)

13 Q. (BY MR. SALMEN) And Brown Exhibit No. 10 is
14 a two-page document, with the title, quote, ASRS
15 Fights Novitas Decision to Interpret Eylea Usage
16 More Frequently Than Q8 as Off-Label.

17 Do you see that?

18 A. I do.

19 Q. Do you recognize this document that's been
20 marked Brown Exhibit 9 [sic]?

21 A. This is a printout of a Web blast, so I
22 remember the situation, yes.

23 Q. And I -- I think -- I think -- is this one
24 Exhibit 9 or Exhibit 10 on yours?

25 A. 10.

1 Q. 10. Sorry. I misspoke.

2 A. No worries.

3 Q. You're quoted in this document, correct?

4 MS. FISHMAN: Objection; document
5 speaks for itself.

6 You can answer.

7 A. It says I discussed the issue. It doesn't
8 really quote me.

9 Q. (BY MR. SALMEN) Okay.

10 A. Yeah.

11 Q. So, do you have a recollection of what the
12 issue was that's addressed in this Brown
13 Exhibit 10?

14 A. I do.

15 Q. Okay. What was it? What was the issue
16 here?

17 A. Again, outside my declaration, but I, at the
18 time, was the head of practice management for the
19 ASRS. ASRS is 3,000 retina specialists in the
20 United States. We advocate for their patients and
21 for causes.

22 The -- Eylea was approved, we agreed, end
23 of -- in 2011, 2012-ish. And the label mentions
24 the data for monthly dosing and for Q8 week dosing.
25 And until that point, until 2016, there was never

1 any indication from Medicare, or CMS, that they
2 considered anything less than Q8 dosing
3 inappropriate.

4 In 2016, they audited some charts of a
5 clinician, and said, you used it more than Q8, give
6 us our money back.

7 I, as representative of the ASRS, talked
8 with Wiley Chambers, who I know well, a physician,
9 ophthalmologist, who runs the Ophthalmic Division
10 of the FDA, who had reviewed our data.

11 And he said it was absolutely not the
12 intention of the label to restrict its use. And he
13 said, but we're happy to clarify the label, so that
14 pointy-headed Medicare people will allow you to use
15 it the way we think the label is -- is okay to use.

16 Q. Okay. And then, after that communication
17 that you had with Wiley Chambers at the FDA, is
18 that when Regeneron initiated its efforts to change
19 the label for Eylea?

20 A. Simultaneous.

21 Q. Okay. In the first paragraph of this
22 document, and I think you already commented on
23 this, but I'm going to read it into the record. It
24 states, quote -- this is the second sentence: This
25 interpretation came to our attention as a result of

1 a Medicare utilization audit in which Novitas
2 indicated that it is seeking recoupment of
3 reimbursement for Eylea doses that it deems
4 off-label, under this definition.

5 Do you see that?

6 A. I see that.

7 Q. Does that reflect the concern that the
8 medical community had with regard to this issue?

9 MS. FISHMAN: Objection; vague and
10 confusing.

11 Q. (BY MR. SALMEN) Was the concern in the
12 medical community, that Novitas, and other
13 providers, were going to seek reimbursement for
14 dosing Eylea more frequently than Q8?

15 MS. FISHMAN: Objection; vague and
16 confusing.

17 You can answer, if you understand.

18 A. That was -- that was certainly the concern
19 of the ASRS members.

20 Q. (BY MR. SALMEN) Okay. I'm going to hand
21 you what I've marked as Brown Exhibit 11.

22 (Exhibit 11 is marked.)

23 Q. (BY MR. SALMEN) Brown Exhibit 11 is a
24 four-page document. First line of page 1 reads:
25 L36962, Medicare Part A, B, local coverage

1 determination, LCD, comment summary.

2 Dr. Brown, have you ever seen Brown
3 Exhibit 11?

4 A. No, I have not.

5 Q. Okay. Are you familiar with the comments
6 that were provided, as -- in response to the
7 Medicare Part A, B, local coverage determination?

8 MS. FISHMAN: Objection, asked and
9 answered.

10 A. If I do, I don't recollect, so...

11 Q. (BY MR. SALMEN) Did you, yourself, submit
12 any comments for L36962, local coverage
13 determination?

14 A. If I did, I don't recollect.

15 Q. Okay. Well, why don't we look at a couple
16 of these comments, specifically, and see if they
17 refresh your recollection.

18 You see that the comment period here is
19 between September 29, 2016, and November 14th,
20 2016 --

21 MS. FISHMAN: Objection; document --

22 Q. (BY MR. SALMEN) -- in the middle of the
23 document?

24 MS. FISHMAN: Document speaks for
25 itself.

1 You can answer.

2 A. I see that.

3 Q. (BY MR. SALMEN) Okay. All right. Let's
4 take a look at comment No. 1.

5 Are you there?

6 A. Comment No. 1.

7 Q. Okay. I'm going to start at line 2:
8 Long-term results often suffer in some patients, if
9 the treatment interval is stretched out too far,
10 and it sometimes is necessary to treat every four
11 weeks. Allow it to be based on clinical evidence
12 supported by optical coherence tomography, OCT, or
13 angiogram.

14 Do you see that?

15 A. I do.

16 Q. Did you submit this comment?

17 A. I did not submit that comment.

18 Q. Okay. Let's look at comment No. 2. A
19 comment was received suggesting the potential for
20 under-treating patients due to fear of
21 non-reimbursement for Eylea. The recent American
22 Society of Retina Specialists, ASRS, meeting and
23 many journal articles show that real-life patient
24 vision gain maintenance two to five years after
25 diagnosis does not mirror clinical trials, and the

1 single consistent reason is undertreatment. Treat
2 and extend with close monitoring has the best
3 success rate in maintaining vision.

4 Did you submit comment No. 2?

5 A. I did not.

6 Q. Do you know who may have submitted comment
7 No. 2?

8 A. I don't.

9 Q. Why don't you look at comment No. 3, and you
10 can read that to yourself?

11 (The witness peruses the document.)

12 Q. (BY MR. SALMEN) Did you submit comment
13 No. 3?

14 A. No. I don't think the ASRS did, either. I
15 mean, that is not something that is consistent with
16 what the retina community would have commented. I
17 don't know who submitted that. I was thinking the
18 ASRS submitted the other two, but, boy, not three.

19 Q. Okay.

20 A. Who knows?

21 Q. Well, just one more. Comment No. 4, you can
22 read that to yourself, and let me know when you're
23 done.

24 (The witness peruses the document.)

25 A. I've read it.

1 Q. (BY MR. SALMEN) Okay. Did you or ASRS
2 submit comment No. 4?

3 MS. FISHMAN: Objection; calls for
4 speculation.

5 You can answer.

6 A. I didn't submit it. And I -- if the ASRS
7 submitted it, they submitted it in error, because
8 it's against what the majority of retina
9 specialists believe is clinically appropriate.

10 Q. (BY MR. SALMEN) Okay. You can put that
11 away.

12 Dr. Brown, let me direct your attention back
13 to your declaration, please, and we'll look at
14 paragraph 46.

15 And you can read paragraph 46 to yourself,
16 to provide context for my question.

17 Let me know when you're done.

18 (The witness peruses the document.)

19 A. I've read it.

20 Q. (BY MR. SALMEN) Okay. Dr. Brown, is it
21 your opinion that in the time frame after Lucentis
22 was approved, in 2006, and before Eylea was
23 approved in 2011, that licensed ophthalmologists
24 did not explore less frequent dosing in their
25 clinical practice?

1 MS. FISHMAN: Objection; beyond the
2 scope. It misstates testimony.

3 You can answer.

4 A. So it's certainly not in my declaration. In
5 my declaration, you'll see that along the time of
6 approval, and shortly thereafter, Genentech, and
7 others, instituted studies to try to figure out if
8 you could dose less frequently.

9 Q. (BY MR. SALMEN) Okay. I was specifically
10 asking about within clinical practice, during that
11 time frame, 2006 to 2011, were ophthalmologists
12 implementing less frequent dosing of Lucentis, to
13 treat angiogenic eye disorders.

14 MS. FISHMAN: Objection; beyond the
15 scope, and calls for speculation.

16 You can answer.

17 A. I'd have to speculate what other people were
18 doing. So...

19 Q. (BY MR. SALMEN) Okay. But you can testify
20 as to what you were doing, in your clinical
21 practice, right?

22 A. Sure.

23 Q. Okay. Let's look at your binder,
24 Exhibit 2103.

25 A. 2103. I'm there.

1 Q. Okay. 21 -- Exhibit 2103 is a document
2 titled, Ongoing Treatment for Patients with
3 Neovascular AMD, titled -- dated October 1st, 2007.

4 Do you see that?

5 A. I do.

6 Q. Okay. And you see, you can -- have you seen
7 this document before?

8 A. I saw it back in 2007, so...

9 Q. Okay. It -- it's cited in your declaration.
10 Did you not review this --

11 A. I did review it, yeah.

12 Q. -- in preparing your declaration?

13 A. I did.

14 Q. Okay. So, are you the Dr. Brown that's
15 referred to here, periodically?

16 A. That's me.

17 Q. Okay. Let's look at page 2 of this
18 document.

19 The header of the -- the second topic here,
20 is, quote: Keeping the Macula Free of Fluid.

21 Do you see that?

22 A. I do.

23 Q. And near the bottom of the first Dr. Brown
24 quote, you stated: For patients with good initial
25 visual acuity, or in whom we are dealing with the

1 primary eye, I treat and extend from the start. I
2 give three monthly injections, and see them in
3 eight weeks.

4 If fluid is absent at that visit, I give
5 another injection, and see them in ten weeks.

6 Do you see that?

7 A. I do.

8 Q. So, in 2007, when this document was
9 published, you, yourself, in your clinical
10 practice, implemented a treat and extend approach
11 to your patients, correct?

12 A. So, treat and extend is a misnomer. Treat
13 and extend is you treat and extend to find a fixed
14 dosing interval.

15 In 2007, when Lucentis was approved, you
16 only dried out a small percentage of patients. And
17 in those, you extended the dosing to see if you
18 could go longer. 20 percent of patients never
19 really need another dose, if you look at studies
20 that were published later, CAT, Harbor, et cetera.

21 So the thought was, if you could decrease
22 the number of visits and treat those patients
23 appropriately by keeping them dry, we did what was
24 the beginnings of treat and extend. Was it common
25 that patients were dry and could go? Not that

1 common, but it happened.

2 Q. In 2007, when Exhibit 2103 was published,
3 treat and extend, that language, was not a
4 recommended dosing regimen for any indication in
5 the Lucentis label, right?

6 A. Correct.

7 Q. So your treat and extend regimen that you
8 comment on in Exhibit 2103, at page 2, was an
9 off-label use of Lucentis, right?

10 MS. FISHMAN: Objection; beyond the
11 scope. It also lacks foundation.

12 You can answer.

13 A. So, in this country, insurers really only
14 care if you treat more frequently than the label.
15 They love it if you treat less frequently, because
16 it saves them money.

17 So, in this country, the label is not,
18 per se, enforced unless you go over it, like,
19 you -- examples you gave in the previous local
20 coverage determinations.

21 Q. (BY MR. SALMEN) So, in 2007, when
22 Exhibit 2103 was published, at least with respect
23 to the patients that exhibited, quote, good visual
24 acuity, your standard of care in treating them was
25 Lucentis off-label treat and extend, correct?

1 MS. FISHMAN: Objection; lacks
2 foundation, misstates testimony.

3 You can answer.

4 A. The label states, for Lucentis, that you can
5 give it monthly. It also states, because we
6 submitted the peer data, that you can give it three
7 doses, and quarterly, although that leads to vision
8 loss. Anything in between there, insurance
9 companies would pay for, and they normally wouldn't
10 pay for off-label medicines.

11 Q. (BY MR. SALMEN) All right. Dr. Brown, I'm
12 handing you what I've marked as Brown Exhibit 12.

13 (Exhibit 12 is marked.)

14 Q. (BY MR. SALMEN) Brown Exhibit 12 is a
15 September 2017 document titled, Treatment Paradigms
16 in AMD Management, Assessing Consistent Long-Term
17 Dosing. It lists W. Lloyd Clark, M.D., as
18 moderator; David Brown, M.D., FACS; David
19 Eichenbaum, M.D.; and Peter K. Kaiser, M.D.

20 Dr. Brown, do you recognize what I've marked
21 as Brown Exhibit No. 12?

22 A. More recent than a lot of the papers, so I
23 vaguely remember.

24 Q. Okay. I'm going to direct your attention to
25 a couple statements in here that you make.

1 What's listed as page number 4 of this
2 document, you see your name, halfway down, on the
3 left-hand column, correct?

4 A. Correct.

5 Q. And the text following is from you, correct?

6 A. That's me.

7 Q. Okay. Right-hand column, quote: The
8 problem is patients want the least amount of
9 treatments possible, and every two months is still
10 too frequent for many patients. That is why, in my
11 practice, and I think most of the country, we use
12 treat and extend.

13 We treat until dry. We extend until the
14 patient has evidence of active exudation, and then
15 we back off and treat at interval that avoids
16 recurrent leakage.

17 Did I read that correctly?

18 A. You did.

19 Q. Okay. Sitting here today, do you still
20 agree with that statement that you made back in
21 September 2017?

22 MS. FISHMAN: Vague as to time.
23 Objection; vague as to time.

24 A. I agree. I also agree with what Peter
25 Kaiser says on the next page. There's no question,

1 fixed monthly, or every other month in the case of
2 aflibercept injections, is the gold standard and
3 often is the best -- offers the best visual
4 outcomes.

5 MR. SALMEN: Okay. You can strike
6 that last part as nonresponsive to my question.

7 Q. (BY MR. SALMEN) In 2017, when this was
8 published, again, treat and extend, that language,
9 was not a recommended dosing regimen for any of the
10 indications in Lucentis, right?

11 MS. FISHMAN: Objection; outside the
12 scope, misstates testimony, and calls for a legal
13 conclusion.

14 You can answer.

15 A. So, it's out -- outside of my declaration.
16 I can say that treat and extend, as it's called,
17 has increased in popularity. And over time, if you
18 looked at preference trends of retina surgeons,
19 more and more physicians.

20 So, it would be more than -- it's probably
21 50 percent of the retina surgeons in the country,
22 at that time, would say that they treat and
23 extended.

24 But again, it's a misnomer. They're not
25 continuously extending. They're finding a fixed

1 dosing interval.

2 And in my experience, the average patient
3 with Eylea, the treatment I gave is three doses and
4 then Q8, is where you find.

5 Q. (BY MR. SALMEN) Okay. Well, in -- in the
6 last document we looked at, Exhibit 2103, that same
7 comment, you stated, quote: I give three monthly
8 injections and see them in eight weeks.

9 If fluid is absent at that visit, I give
10 them another injection, and see them in ten weeks.

11 Is that correct?

12 MS. FISHMAN: Objection; document
13 speaks for itself.

14 Q. (BY MR. SALMEN) That was your statement?

15 A. That's my statement. And the majority of
16 the time, there's fluid at ten weeks, and you back
17 off to eight, and you stay there.

18 Q. So, then, if -- if you see fluid at ten
19 weeks, you back it back down to eight weeks?

20 A. Correct.

21 Q. Okay. And then, if you see them at eight
22 weeks, do you try to extend them back out to ten?

23 A. So you don't --

24 MS. FISHMAN: Objection; incomplete
25 hypothetical, beyond the scope.

1 You can answer.

2 A. So treat and extend is the philosophy where
3 you're trying to have the least amount of recurrent
4 disease. My analogy is I try. And once I learn --
5 once I touch a hot stove, I learn not to touch a
6 hot stove.

7 If a patient can't go to ten weeks, they
8 often can't go to ten weeks, so you don't keep
9 testing it. You stay at fixed dosing intervals, at
10 the level which they do not get recurrent retinal
11 disease.

12 Q. (BY MR. SALMEN) Okay. So between these two
13 documents, 2007, which is Exhibit 2103, and 2017,
14 Exhibit 2012, the standard of care in your clinical
15 practice was treat and extend?

16 MS. FISHMAN: Objection; lacks
17 foundation.

18 You can answer.

19 A. Standard of care in our clinical practice
20 changed as different drugs got approved.

21 We did try to treat and extend to eight
22 weeks, with Lucentis, in 2007. But it was
23 exceedingly rare that patients could do that,
24 and -- and stay at that interval, with the
25 exception of the patients whose exuded disease

1 became quiescent very shortly.

2 Q. (BY MR. SALMEN) So, let's say -- let me
3 give you a -- a time frame, prior to January 2011.
4 So, after Lucentis was approved in 2006, prior to
5 January 2011. Okay? And I'll ask my question.

6 A. Sure.

7 Q. You okay with that time frame?

8 During that time frame, your clinical
9 practice implemented a treat and extend approach
10 for your patients, correct?

11 MS. FISHMAN: Objection; lacks
12 foundation.

13 But you can answer.

14 A. So, it's certainly not in my declaration.
15 But our clinical practice, as was stated in the
16 2007 paper, was to give three monthly doses, and
17 then assess how the patient is doing.

18 Q. (BY MR. SALMEN) Okay. So, let's -- I want
19 to focus on those -- those three monthly doses.

20 So the -- the three monthly doses, did they
21 occur on day zero, week 4, and week 8?

22 A. Usually, unless a holiday got in the way.

23 Q. Okay. So, can we --

24 A. Yes.

25 Q. Can we assume that those were the dates?

1 Okay. Now, can we -- can I refer to day
2 zero as baseline?

3 A. Sure.

4 Q. Okay. Now, you evaluated, in -- in that --
5 your patients at baseline, day zero, correct,
6 before you implemented your treat and extend
7 strategy?

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

10 But you can answer.

11 A. So, when I evaluate a patient, in a retina
12 clinic, in 2007, almost every patient got a
13 fluorescein angiogram, almost every patient --
14 every patient got a CT. You're looking for, is
15 this macular degeneration; is there other
16 components that make you think this is a masquerade
17 syndrome, or something that's not macular
18 degeneration.

19 And then I don't commit to a treatment
20 strategy right away. I said, you would have gone
21 blind. We now have treatments that don't sound
22 good. They're shots in the eyes. But we're going
23 to give you shots in the eyes once a month, for
24 three months, assess how you do, and then figure
25 out what to do from there.

1 Q. (BY MR. SALMEN) Okay. So, at that baseline
2 visit, do you also do fundus photography testing?

3 A. As part of a fluorescein, generally, there's
4 a fundus photography. The coding bundles it. And
5 if you've done a good clinical exam, the fundus
6 photography doesn't add much.

7 But generally, it's done, just because
8 they're at the -- they're at the photographer at
9 the same time.

10 Q. Okay. So then, on -- on Day 2, do you do
11 all of that testing again, back in -- in that time
12 frame, between 2007 and 2011?

13 MS. FISHMAN: Objection; vague.

14 A. I can certainly tell you what our current
15 clinical practice is, and it hasn't changed. When
16 you come in, and it's usually -- it's semantics.
17 But usually you can't get treated the same day,
18 because you have to get insurance approvals and
19 such.

20 Q. (BY MR. SALMEN) Okay.

21 A. So, generally, it's sometimes you can get
22 treated right away. Usually it's three to seven
23 days before you're treated.

24 At that point, patients come in. They're
25 scared to death. They're worried about this needle

1 in the eye. They've never had that experience.

2 You tell them what can happen, good and bad.
3 You could begin to see some improvements in your
4 vision. You have a chance of endophthalmitis,
5 which is an infection in the eye.

6 Q. Uh-huh.

7 A. Which is -- currently, our rates are 1 per
8 7,000. At that time, they were probably 1 in
9 3,000. Our techniques are a little better.

10 But you warn them what the signs and
11 symptoms of those are. They are pain, decreased
12 vision, irritation.

13 They're so scared, they usually don't hear a
14 word you say. So, we typically bring them back one
15 week later, one, to look for inflammation and
16 trouble. We do an OCT at that visit, to see if
17 there's an initial response. And then we admonish
18 them the same warnings.

19 Because this time, they're not as worried
20 about the shot. They've already had one. They're
21 not going to get one.

22 Q. Uh-huh.

23 A. You tell them again about endophthalmitis.
24 After that, you don't -- we don't do that one-week
25 safety check, except that one time after the

1 initial baseline shot, as you put it.

2 Q. Okay. So the baseline shot occurs at week
3 zero. You bring them back on Day 7? I'm sorry --

4 A. Roughly day 7, yeah.

5 Q. I -- I misspoke there.

6 The baseline shot occurs at day zero, and
7 you bring them back roughly around Day 7 --

8 A. Correct.

9 Q. -- for the safety check?

10 A. Correct.

11 Q. Okay. Do you bring them back on Day 14, and
12 run those same tests, the fluorescein angiography,
13 and the OCT?

14 A. No.

15 Q. Do you bring them back on Day 30, and do --
16 run all of the tests, the fluorescein angio --
17 angiography, and the OCT?

18 A. It's usually Day 28, but it could be Day 30.
19 It depends on the clinic, right. And typically,
20 you never -- you do not repeat the fluorescein
21 angiogram, at least in your practice.

22 Q. Okay.

23 A. You repeat a visual acuity. You repeat an
24 OCT.

25 Q. Okay. What about Day 31, do you bring them

1 back in again --

2 A. We don't.

3 Q. -- and run all the tests?

4 A. We don't.

5 Q. Day 32, do you bring them back in again and
6 run all the tests?

7 A. We do not.

8 Q. Day 34, do you bring them back in again and
9 run all the tests?

10 A. We do not.

11 Q. Day 37, do you bring them back in and run
12 all the tests?

13 A. You'd probably be caught for Medicare abuse
14 of services, but we don't. We -- We see them
15 monthly after that.

16 Q. Okay. What about Day 44, do you bring them
17 back in on Day 44, and run all those tests?

18 A. We don't. We do not.

19 Q. Okay. And that applies to your clinical
20 practice today, as well as during that time frame
21 that we started this line of questioning in,
22 between 2006 and 2011, right?

23 A. That is correct.

24 Q. Okay. Got it. I put the sticker where it
25 doesn't block anything.

1 All right. I'm going to hand you what I've
2 marked as Brown Exhibit 13.

3 (Exhibit 13 is marked.)

4 MS. FISHMAN: Can I have a copy?

5 MR. SALMEN: Yeah.

6 MS. FISHMAN: You sound unsure as to
7 whether --

8 MR. SALMEN: No. You can have a
9 copy -- you can have a copy. I don't -- I don't
10 need it. Just let -- let me orient myself real
11 quick with this one --

12 MS. FISHMAN: Oh, do you not have a
13 copy of the --

14 MR. SALMEN: No. I've got it here.

15 MS. FISHMAN: Before you ask him
16 questions about it --

17 MR. SALMEN: Can I just lay my
18 foundation, and then I'll give you this copy?

19 MS. FISHMAN: Or I just wanted to
20 look over what he -- he has, before you start
21 questioning him. Hold on one second.

22 If you wanted to have an extra --

23 MR. SALMEN: I -- I found my copy.

24 MS. FISHMAN: Oh, you did. Okay. I
25 was going to say if you wanted to have an extra

1 copy made, we could always take a break. Okay.

2 MR. SALMEN: Here you go.

3 Q. (BY MR. SALMEN) What number did we mark
4 this, Dr. Brown?

5 A. Lucky 13.

6 Q. All right. Lucky No. 13. Brown Exhibit 13
7 is a document titled, quote: Randomized Trial of
8 Treat and Extend Versus Monthly Dosing for
9 Neovascular Age-Related Macular Degeneration.

10 Do you recognize this publication,
11 Dr. Brown?

12 A. I do.

13 Q. And is that you listed as one of the authors
14 of this publication?

15 A. That's me.

16 Q. Now, for context, I want to keep that in
17 hand, but I want to direct you back to
18 Exhibit 2103, that 2007 discussion.

19 MS. FISHMAN: I'm sorry.

20 Q. (BY MR. SALMEN) And actually, I'm sorry. I
21 directed you to the wrong document.

22 It's the 2017 Treatment Paradigms, Brown
23 Exhibit 12. This (indicating).

24 MS. FISHMAN: Are we still using
25 Exhibit 13?

1 MR. SALMEN: Yes.

2 MS. FISHMAN: Okay. But we're not
3 using 2103?

4 MR. SALMEN: No. So Brown
5 Exhibit 12.

6 Q. (BY MR. SALMEN) Yep. And that same
7 statement that I read you earlier, the bottom right
8 of page 4, where you stated, quote: That is why,
9 in my practice, and I think most of the country, we
10 use treat and extend.

11 Do you see that?

12 A. I do.

13 Q. And now, I -- I want you to direct -- I want
14 to direct your attention to Exhibit 13, the Wykoff
15 paper that you're coauthor on, the second page,
16 which is labeled page 315.

17 You'll see there, top left-hand corner,
18 treat and extend -- sorry. Scratch that.

19 Quote: A treat and extend approach attempts
20 to realize the benefits of both approaches.

21 Monthly injections are given until signs of
22 exudation resolve. At which point, the interval
23 between treatments is individualized, with the goal
24 of maintaining an exudation-free macula, and
25 avoiding multiple disease recurrences, while

1 minimizing total treatment burden through fewer
2 treatments, in addition to fewer clinical visits,
3 and diagnostics.

4 Do you see that?

5 A. I do.

6 Q. The next statement is, quote: The 2016
7 American Society of Retinal Specialists Preferences
8 and Trends Survey reveal that 70.1 percent of the
9 retina specialists in the United States use
10 primarily a treat and extend management strategy
11 for neovascular AMD.

12 Do you see that?

13 A. I do.

14 Q. You'd agree that this statement here from
15 your coauthored paper confirms that most of the
16 country utilizes a treat and extend approach in
17 their clinical practice, right?

18 MS. FISHMAN: Objection; vague as to
19 time, and the document speaks for itself.

20 A. By the 2016 time period, correct.

21 Q. (BY MR. SALMEN) Okay. Looking back in
22 Exhibit 12, the other document, Treatment
23 Paradigms, Dr. Brown.

24 A. Hold on a second. Let me just spend a
25 little more time with this document --

1 Q. Sure.

2 A. -- since it's the first I've seen it in a
3 while.

4 (The witness peruses the document.)

5 Q. (BY MR. SALMEN) All right. Can we look at
6 Exhibit 12 now?

7 A. Beg your pardon?

8 Q. Can we look at Exhibit 12, the other
9 document, Treatment Paradigms?

10 A. Yeah, I'm just refreshing my memory on this
11 document.

12 (The witness peruses the document.)

13 A. Okay.

14 Q. (BY MR. SALMEN) Let's look at page 3 of the
15 Treatment Paradigms document. It's marked as Brown
16 Exhibit 12. Left-hand column, David Brown, M.D.,
17 FACS.

18 Do you see that?

19 A. Which column are we in? Which page?

20 Q. Page 3.

21 A. Page 3. Okay.

22 Q. Left-hand side.

23 A. Yep.

24 Q. That's you, correct, David -- David Brown,
25 in --

1 A. Right there (indicating).

2 Q. I'll state it. On the left-hand column,
3 there's a paragraph that starts, David Brown, M.D.,
4 FACAS, that's referring to you, correct?

5 A. That's correct.

6 Q. The statement reads: David Brown has a
7 financial agreement or affiliation during the past
8 year with the following commercial interests, in
9 the form of consultant, advisory board, speakers
10 bureau.

11 And then it lists a series of corporations.
12 Do you see that?

13 A. I do.

14 Q. The list there is, quote: Alcon; Allergan,
15 PLC; Bayer Pharmaceuticals, Genentech, Inc.;
16 Novartis, AG; Regeneron Pharmaceuticals, Inc.; and
17 ThromboGenics NV.

18 Is that correct?

19 A. That is correct.

20 Q. Okay. For how long, prior to this 2017
21 publication, did you have that financial agreement
22 or affiliation with Regeneron?

23 A. Best of my recollection, I started
24 consulting for Regeneron, 2006, maybe.

25 Q. Okay. And this refers to a financial

1 agreement, or affiliation, your relationship with
2 Regeneron.

3 A. Sure.

4 Q. Can you describe which one it is, or both?

5 A. Sure. Yeah, I've never been an employee of
6 Regeneron. I've received, or my institution has
7 received, payments for either me consulting,
8 helping them design trials, or clinical trial work,
9 where we're doing the VIEW study, where we're doing
10 the Vista Vivid. And that's on a per patient,
11 per -- you know, a budget, where what you do, you
12 have -- you get paid what you work.

13 Q. Okay.

14 A. Only recently have I begun to work with them
15 for the legal consulting, as it pertains to this
16 matter.

17 Q. Okay. So I just want to -- you said it
18 dates back to 2006.

19 Am I remembering that correctly?

20 A. Roughly. Shortly after Lucentis was
21 approved, Regeneron started looking at the
22 potential of doing eye work.

23 And I remember consulting with them before
24 they had an eye product.

25 Q. Okay. So, with that starting date in mind,

1 through September 2017, the date of this document,
2 did that financial agreement extend the entire
3 duration of that time period?

4 A. It did. I -- I worked for Regeneron, or had
5 trials with Regeneron, through that whole period.
6 Yes.

7 Q. Okay. And have -- have you been
8 compensated, you or your institution been
9 compensated, by Regeneron, throughout that entire
10 time frame, 2006 to 2017?

11 A. Yes. Me, personally, for the consulting;
12 the institution, for the trial work.

13 Q. Okay. So, now, first, you, personally, how
14 much money has this financial agreement with
15 Regeneron paid you, from 2006 to 2017?

16 A. Actually, no idea. You know, the most I've
17 ever probably been paid for consulting is -- I'm
18 totally guessing, less than 25,000 a year. Most
19 years, it was way less than that, so...

20 Q. Okay. So 25,000 a year over ten years?

21 A. It probably hasn't averaged that. I mean --

22 MS. FISHMAN: Ob -- yeah.

23 Objection; calls for speculation, incomplete
24 hypothetical.

25 But you can answer.

1 Q. (BY MR. SALMEN) Do you have access to your
2 financial information regarding how much
3 compensation you, personally, have received from
4 Regeneron, pursuant to this financial agreement,
5 between 2006 and 2017?

6 A. I probably have the last few years. I maybe
7 could scrounge up before.

8 Q. What about from -- excluding the legal
9 consulting work that you're here for today.

10 A. Right.

11 Q. What about from 2000 -- September 2017, to
12 today, how much money have you been paid by
13 Regeneron as compensation pursuant to this
14 financial agreement?

15 A. I -- certainly speculating, probably 10,000
16 to 20,000 a year, at the most. Helping design --
17 they have a high dose trial. There's been some
18 other clinical trials I've helped design.

19 Certainly, it's de minimus, compared to my
20 other compensation.

21 Q. Okay. Now, you mentioned your institution
22 is also compensated by Regeneron, pursuant to this
23 financial agreement.

24 Is that correct?

25 A. That is correct.

1 Q. Okay. So, in that first time frame, from
2 2006 to 2017, how much has your institution been
3 compensated for your financial agreement with
4 Regeneron?

5 A. Again, totally speculating. As we were the
6 worldwide leading recruiters for VIEW, Vista,
7 Vivid, we were not worldwide recruiters for the
8 Copernicus Galileo study.

9 MS. FISHMAN: I'll caution the
10 witness not to speculate, but if you know, you can
11 answer.

12 A. I don't. It's hundreds of thousands of
13 dollars, or more.

14 Q. (BY MR. SALMEN) Per year, or throughout the
15 entire time frame?

16 A. Some years, it's per year.

17 Q. Okay. What about after 2017, how much
18 compensation has your institution received from
19 Regeneron, pursuant to your financial agreement
20 with them?

21 A. Not very much, because they really haven't
22 had many trials until the high dose. It was sort
23 of in a hiatus between their approved and their
24 current trials looking at high-dose aflibercept.

25 Q. Okay. How much money?

1 MS. FISHMAN: Same admonition. If
2 you know, you can testify.

3 A. I'd have to totally speculate.

4 Q. (BY MS. FISHMAN) I'm asking you to
5 speculate.

6 A. 2017 --

7 MS. FISHMAN: Objection.

8 A. -- through 2020, I can't even remember if we
9 did any Regeneron trials.

10 MS. FISHMAN: Objection; calls for
11 speculation.

12 A. So, I have the biggest trial center in the
13 world. And we have -- I have colleagues that do
14 tumor trials. I have colleagues that do Uveitis
15 trials. There may or may not have been a tumor
16 trial where they used this for radiation
17 retinopathy.

18 And macular degeneration, I -- I do not
19 think we've had a Regeneron trial of any
20 substance -- in other words, more than a hundred
21 thousand a year -- until last year, when they
22 started the high-dose trials.

23 In those trials, you're paid by the patient,
24 by what you do. And so, if it's an involved
25 clinical protocol, the budgets can be 20, 30,000 a

1 patient. So, five patients will get you there, but
2 you do all the work to get there. So...

3 MR. SALMEN: Okay. Why don't we
4 take a break?

5 THE VIDEOGRAPHER: We're off the
6 record at 2:41 p.m.

7 (Break.)

8 THE VIDEOGRAPHER: And we are back
9 on the record at 2:59 p.m. This is Media Unit
10 No. 5.

11 Q. (BY MR. SALMEN) Dr. Brown, referring back
12 to the line of questioning we had before the break.

13 Do you have access to your institution's
14 financial information, regarding the compensation
15 that the institution received from Regeneron, with
16 respect to the financial agreement that you have
17 with them?

18 MS. FISHMAN: Objection; vague as to
19 time.

20 You can answer.

21 A. I -- we do. I don't know how far back.

22 Q. (BY MR. SALMEN) Okay. Would it go back to
23 2006, when --

24 A. I doubt it.

25 Q. -- the financial --

1 A. I doubt it. The IRS --

2 MS. FISHMAN: You have to let him
3 finish his question.

4 A. Go ahead.

5 Q. (BY MR. SALMEN) Do you have financial
6 information dating back to 2006, regarding the
7 compensation that your institution received from
8 Regeneron?

9 A. I personally don't. It may be in the -- it
10 may be in the budgets that are in Iron Mountain.
11 There may be a way to find that.

12 Q. Okay. During the last break, did you
13 discuss your declaration or any of your
14 cross-examination testimony today with any of the
15 Regeneron attorneys here?

16 A. No.

17 MR. SALMEN: Okay. I have no
18 further questions. Pursuant -- or pending any
19 redirect from your counsel, I have no further
20 questions.

21 MS. FISHMAN: I have just a couple
22 questions. Let me find it.

23 EXAMINATION

24 BY MS. FISHMAN:

25 Q. Earlier, during his cross-examination of

1 you, Dr. Brown, Mr. Salmen --

2 MS. FISHMAN: Am I pronouncing that
3 correctly?

4 MR. SALMEN: Sure. Close. Salmen.

5 MS. FISHMAN: Salmen.

6 Q. (BY MS. FISHMAN) Mr. Salmen was asking you
7 about an exhibit marked 2103, a Retinal Physician
8 article. Could you please turn to that?

9 At -- and in particular --

10 MR. SALMEN: If you could give me a
11 second to get there, please.

12 MS. FISHMAN: Absolutely. Let me
13 know when you're ready.

14 MR. SALMEN: Okay.

15 Q. (BY MS. FISHMAN) Okay. And I'd like to
16 direct your attention to page 2 of 7 on
17 Exhibit 2103.

18 And under the heading, Keeping the Macula
19 Free of Fluid, he pointed you to a quote that: For
20 patients with good initial visual acuity or in whom
21 we are dealing with the primary eye, I treat and
22 extend from the start. I give three monthly
23 injections and see them in eight weeks.

24 Do you see that statement there?

25 A. I do.

1 Q. Was that with Lucentis?

2 MR. SALMEN: Objection; leading.

3 Q. (BY MS. FISHMAN) What -- what agent were
4 you giving? How -- okay.

5 MR. SALMEN: Sure. Objection. It's
6 still leading.

7 A. It --

8 MR. SALMEN: But you can answer the
9 question.

10 A. At -- at that point, it was either Lucentis
11 or Avastin.

12 Q. (BY MS. FISHMAN) Okay.

13 A. The two available options.

14 Q. And did that work in treating your patients?

15 MR. SALMEN: Objection; leading.

16 A. So, for Avastin, and with Eylea --

17 Q. (BY MS. FISHMAN) Right.

18 A. -- you'd have a certain number of patients
19 that three shots and you're done. And then, that's
20 sort of the purpose of that technique back then.

21 You --

22 Q. Okay.

23 A. -- learn pretty early that you were wrong
24 all -- most all the time with Avastin, and nearly
25 all the time with Lucentis. They couldn't go eight

1 weeks.

2 Most of them needed every four to five week
3 dosing to maintain a dry retina.

4 Q. And I just have a question, because I -- I
5 know it's late in the day, and I think we're all
6 tired.

7 In response to my first question, I had
8 asked you, did that work in treating your patients,
9 and you answered, so for Avastin and with Eylea.

10 A. I -- I misspoke. With Avastin or Lucentis.
11 Eylea wasn't available then.

12 Q. Okay.

13 MS. FISHMAN: No further questions
14 at this time.

15 MR. SALMEN: I have nothing further.
16 Thank you, Dr. Brown.

17 THE WITNESS: Thank you.

18 Elias has less hair now, by the way.

19 MR. SALMEN: Oh.

20 THE VIDEOGRAPHER: Let me take us
21 off the record.

22 We're off the record at 3:03 p.m.
23 This concludes today's testimony given by
24 Dr. Brown. The total number of media units used
25 was five, and will be -- will be retained by

Veritext.

(The deposition concluded at
P.M.)

-- SIGNATURE REQUIRED --

1 COUNTY OF HARRIS

2 STATE OF TEXAS

3
4 REPORTER'S CERTIFICATE

5
6 I, AMY PRIGMORE, Certified Shorthand
7 Reporter in and for the State of Texas, hereby
8 certify that this transcript is a true record of
9 the testimony given by the witness named herein,
10 after said witness was duly sworn by me.

11 I further certify that the deposition transcript
12 was submitted on _____, _____ to
13 the witness or to the attorney for the witness for
14 examination, signature, and return to me by

15 _____.

16 I further certify the amount of time used
17 by each party at the deposition is as follows:

18 Heinz J. Salmen - (04h07m)

Deborah Fishman - (00h03m)

19
20 I further certify that I am neither
21 attorney nor counsel for, related to, nor employed
22 by any of the parties to the action in which this
23 testimony was taken. Further, I am not a relative
24 or employee of any attorney of record in this
25 cause, nor do I have a financial interest in the

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1 action.

2 SUBSCRIBED AND SWORN TO by the undersigned
3 on this the 27th day of April, 2022.

4
5 

6 AMY PRIGMORE, Texas, CSR 3929

Expiration Date: 4/30/2023

7 Firm Registration: 571

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April 27, 2022

To: Deborah Fishman

Case Name: Mylan Pharmaceuticals, Inc., et al. v. Regeneron
Pharmaceuticals, Inc.

Veritext Reference Number: 5149542

Witness: David M. Brown, M.D. Deposition Date: 4/26/2022

Dear Sir/Madam:

Enclosed please find a deposition transcript. Please have the witness review the transcript and note any changes or corrections on the included errata sheet, indicating the page, line number, change, and the reason for the change. Have the witness' signature notarized and forward the completed page(s) back to us at the Production address shown

above, or email to production-midwest@veritext.com.

If the errata is not returned within thirty days of your receipt of this letter, the reading and signing will be deemed waived.

Sincerely,

Production Department

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DEPOSITION REVIEW
CERTIFICATION OF WITNESS

ASSIGNMENT REFERENCE NO: 5149542

CASE NAME: Mylan Pharmaceuticals, Inc., et al. v. Regeneron Pharmaceuticals, Inc.

DATE OF DEPOSITION: 4/26/2022

WITNESS' NAME: David M. Brown, M.D.

In accordance with the Rules of Civil Procedure, I have read the entire transcript of my testimony or it has been read to me.

I have made no changes to the testimony as transcribed by the court reporter.

Date David M. Brown, M.D.

Sworn to and subscribed before me, a Notary Public in and for the State and County, the referenced witness did personally appear and acknowledge that:

They have read the transcript;
They signed the foregoing Sworn Statement; and
Their execution of this Statement is of their free act and deed.

I have affixed my name and official seal

this _____ day of _____, 20____.

Notary Public

Commission Expiration Date

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DATE OF DEPOSITION: 4/26/2022

WITNESS' NAME: David M. Brown, M.D.

In accordance with the Rules of Civil Procedure, I have read the entire transcript of my testimony or it has been read to me.

I have listed my changes on the attached Errata Sheet, listing page and line numbers as well as the reason(s) for the change(s).

I request that these changes be entered as part of the record of my testimony.

I have executed the Errata Sheet, as well as this Certificate, and request and authorize that both be appended to the transcript of my testimony and be incorporated therein.

Date

David M. Brown, M.D.

Sworn to and subscribed before me, a Notary Public in and for the State and County, the referenced witness did personally appear and acknowledge that:

They have read the transcript;

They have listed all of their corrections in the appended Errata Sheet;

They signed the foregoing Sworn Statement; and

Their execution of this Statement is of their free act and deed.

I have affixed my name and official seal this _____ day of _____, 20____.

Notary Public

Commission Expiration Date

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ERRATA SHEET
VERITEXT LEGAL SOLUTIONS MIDWEST
ASSIGNMENT NO: 5149542

PAGE/LINE(S) /	CHANGE	/REASON
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Date David M. Brown, M.D.
SUBSCRIBED AND SWORN TO BEFORE ME THIS _____
DAY OF _____, 20_____.

Notary Public

Commission Expiration Date

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Federal Rules of Civil Procedure

Rule 30

(e) Review By the Witness; Changes.

(1) Review; Statement of Changes. On request by the deponent or a party before the deposition is completed, the deponent must be allowed 30 days after being notified by the officer that the transcript or recording is available in which:

(A) to review the transcript or recording; and

(B) if there are changes in form or substance, to sign a statement listing the changes and the reasons for making them.

(2) Changes Indicated in the Officer's Certificate. The officer must note in the certificate prescribed by Rule 30(f)(1) whether a review was requested and, if so, must attach any changes the deponent makes during the 30-day period.

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