UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

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SAMSUNG BIOEPIS CO., LTD.,	)	
Petitioner,	)	
vs.	)	No. IPR2023-00442
REGENERON PHARMACEUTICALS, INC.,	)	
Patent Owner.	)	

_____)

VIDEOTAPED DEPOSITION OF DIANA V. DO, M.D.

Palo Alto, California

Friday, December 8, 2023

Volume I

Reported by:

CATHERINE A. NOLASCO, RMR, CRR, B.S.

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PAGES 1 - 239

Veritext Legal Solutions
Calendar-CA@veritext.com 866-299-5127

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SAMSUNG BIOEPIS CO., LTD.,)
Petitioner,)
vs.) No. IPR2023-00442
REGENERON PHARMACEUTICALS, INC.,)
Patent Owner.)

Videotaped deposition of DIANA V. DO, M.D., Volume I, taken on behalf of Petitioner, with the Witness appearing at ARNOLD & PORTER KAYE SCHOLER, LLP, 3000 El Camino Real, Five Palo Alto Square, Suite 500, Palo Alto, California, beginning at 8:53 a.m. and ending at 4:32 p.m., on Friday, December 8, 2023, before CATHERINE A. NOLASCO, Certified Shorthand Reporter No. 8239.

APPEARANCES:

For Petitioner:
QUINN, EMANUEL, URQUHART & SULLIVAN, LLP
BY: MATTHEW A. TRAUPMAN
ELLIOT CHOI
Attorneys at Law
51 Madison Avenue, 22nd Floor
New York, New York 10010
(212) 849-7322 (Mr. Traupman)
(212) 849-7546 (Mr. Choi)
matthewtraupman@quinnemanuel.com
elliotchoi@quinnemanuel.com

For Patent Owner:
ARNOLD & PORTER KAYE SCHOLER LLP
BY: ABIGAIL STRUTHERS
Attorney at Law
250 West 55th Street
New York, New York 10019-9710
(212) 836-7915
abigail.struthers@arnoldporter.com

BY: DAVID DENUYL (appearing remotely)
Attorney at Law
3000 El Camino Real
Five Palo Alto Square, Suite 500
Palo Alto, California 94306-3807
(650) 319-4551
david.denuyl@arnoldporter.com

ALSO PRESENT:
EILEEN WOO, in-house counsel, Regeneron Pharmaceuticals, Inc.

SHAWNA V. HYNES, Videographer, Veritext

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Exhibit 2 "APPENDIX 2: Eligibility Criteria"; 34 pages 145

PREVIOUSLY MARKED EXHIBITS

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Exhibit 2056 "DECLARATION OF DIANA V. DO, M.D."; 111 pages 10
Exhibit 1001 "United States Patent, Yancopoulos, Patent No.: US 10,130,681 B2, Date of Patent: *Nov. 20, 2018"; 15 pages 105

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Exhibit 2119 "BLA 125387/S-051, Page 4, HIGHLIGHTS OF PRESCRIBING INFORMATION"; 26 pages 108
Exhibit 1016 "Intravitreal Aflibercept (VEGF Trap-Eye) in Wet Age-related Macular Degeneration"; 12 pages 144
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Palo Alto, California; Friday, December 8, 2023
8:53 a.m.

THE VIDEOGRAPHER: Good morning. We are going on the record at 8:53 a.m. on December 8th, 2023. 08:53:37

Please note that the microphones are sensitive and may pick up whispering and private conversations.

Please mute your phones at this time. 08:53:52

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

This is Media Unit 1 of the video-recorded deposition of Dr. Diana V. Do, taken by counsel for Petitioner in the matter of Samsung Bioepis, CO., LTD. versus Regeneron Pharmaceuticals, Inc., filed in the Patent Trial and Appeal Board, Case No. IPR2023-00442. 08:54:05

The location of the deposition is 3000 El Camino Real, Suite 500, Five Palo Alto Square, Palo Alto, California 94306. 08:54:31

My name is Shawna Hynes, representing Veritext Legal Solutions, and I am the videographer.

The court reporter is Catherine Nolasco, 08:54:50

from the firm Veritext Legal Solutions. 08:54:54

I am not related to any party in this action, nor am I financially interested in the outcome.

If there are any objections to proceeding, 08:55:08 please state them at the time of your appearance.

Counsel and all present, including remotely, will now state their appearances and affiliations for the record, beginning with the noticing attorney. 08:55:18

MR. TRAUPMAN: Good morning. My name is Matt Traupman, from Quinn Emanuel. With me is my colleague, Elliot Choi, also from Quinn Emanuel. We represent the petitioner, Samsung Bioepis.

MS. STRUTHERS: And this is Abigail 08:55:32 Struthers, from the law firm of Arnold & Porter. With me remotely is my colleague, David Denuyl, also from Arnold & Porter. And here with me in person is Eileen Woo, from Regeneron. We represent the witness and Regeneron Pharmaceuticals. 08:55:46

THE VIDEOGRAPHER: Thank you.

Will the court reporter please swear in the witness, and then counsel may proceed.

DIANA V. DO, M.D.,

having been administered an oath, was examined and 08:56:07

testified as follows: 08:56:07

EXAMINATION

BY MR. TRAUPMAN:

Q Good morning.

A Good morning. 08:56:10

Q Can you please state your name for the record.

A I'm Dr. Diana Do.

Q Can you please give us your business address? 08:56:16

A I work at Stanford University at the Byers Eye Institute, which is the department of ophthalmology, at 2452 Watson Court in Palo Alto, California.

Q And you're here today as an expert on behalf of Regeneron, correct? 08:56:28

A Yes, I am.

Q Thank you.

So I'm pretty sure you've been deposed a few times before, so I'm guessing you're familiar with the process, but just to briefly go over a few reminders, because I've done this a bunch of times myself, and I always like to try to make -- give myself a reminder, in addition to the witness. 08:56:38

So first and foremost, as you can see, 08:56:54

we're being -- everything we say is being both videotaped and taken by the court reporter, and so it's really important we both try to have a clear record here today, which means I need to do my best to let you finish your answers before I ask my -- my -- any follow-up question, and I ask you to, similarly, extend the courtesy to me, to let me finish my answer -- or excuse me -- finish my question before you begin your answer. 08:56:56 08:57:07

Okay? 08:57:20

A Yes.

Q And if there is -- any of my questions are unclear or you need additional clarification, please let me know, and I'll do my best. Okay?

A Yes. 08:57:33

Q And is there any reason, sitting here today, that you can't testify truthfully and accurately?

A I will testify truthfully and accurately.

Q Right. 08:57:43

There's -- but there's no -- there's no reason why -- you know, there's no -- you're not on any medications or there's no -- you're not experiencing any health issues or anything like that that would impair your ability to give your best 08:57:52

testimony here today, correct? 08:57:54
A I have no impairment.
Q Great.
And you understand that this testimony is all being given -- being given under oath as if you 08:58:02 were testifying in a court or administrative proceeding?
A Yes, I do.
MR. TRAUPMAN: Can we mark the -- yeah. So I'm handing -- hand it to you. It doesn't need 08:58:25 to be marked. I was just going to hand it across.
Does the court reporter need --
THE VIDEOGRAPHER: Oh, it doesn't need to be. Sorry.
(Exhibit 2056 was introduced.) 08:58:35
BY MR. TRAUPMAN:
Q So I'm giving what's already been marked before as Exhibit 256, which is the -- your declaration in this proceeding, correct?
A Yes, that is correct. 08:58:53
Q And I take it you've seen this document before, correct?
A Yes, I have.
Q Did you prepare this document?
A Yes. 08:59:05

Q Did you have any help preparing this 08:59:07 document?
A Yes. I had assistance from counsel.
Q Great.
Have you had a chance to review this 08:59:14 document?
I think it -- this document was signed, just to remind yourself, on October 11th of 2023.
Do you recall that?
A Yes, I do. 08:59:24
Q Did you have a chance to review your declaration in preparing for your deposition here today?
A Yes, I did.
Q Great. 08:59:29
And did you notice any errors or anything you'd like to correct in your -- your declaration as you reviewed it in preparation for your deposition here today?
A I did not have any corrections. 08:59:40
Q Okay. I'll ask you, then, if -- as we go through various parts of your declaration here today, if you notice anything that needs to be -- that's incorrect or that needs to be clarified, please let me know, okay? 08:59:53

A (Witness nods head.) 08:59:58
Yes.
Q And that gives me one more reminder for the procedure.
Because we're being -- because we're being 09:00:03 videotaped and -- and transcribed, it's important for you to answer everything orally, with a "yes" or "no," rather than a head nod. I know that's oftentimes a way we can communicate, but just do your best to articulate an audible answer, please. 09:00:18
A Yes, I will.
Q Okay. So I'd like to just start with your -- some of your background and professional experience here today.
I understand, based on your declaration, 09:00:37 that you were a practicing ophthalmologist at the Wilmer Eye Institute in Baltimore from 2005 through 2010.
Is that correct?
A Yes, that is correct. 09:00:51
Q And what were your responsibilities at Wilmer Eye Institute from 2005 to 2010?
A During the period of 2005 to 2010, I was a -- an assistant professor of ophthalmology and then an associate professor of ophthalmology in the 09:01:16

department of ophthalmology at the Johns Hopkins 09:01:20 University. I practiced retina surgery. I took care of patients. I also taught medical students, ophthalmology residents, and retina fellows at the Wilmer Eye Institute. 09:01:39
Q So I think you mentioned just now part of your responsibilities from '05 to 2010 were clinical, seeing patients.
Is that correct?
A Yes, I had an active clinical and surgical 09:01:49 practice.
Q Okay. And is it correct to say that your patients you were seeing generally had some -- the patients you were seeing clinically were -- were in need or had some condition related to their retina? 09:02:07 That's why you were seeing them; is that correct?
A Yes. I am a retina specialist and surgeon, and all the patients I saw generally had a disorder in their retina.
Q Right. 09:02:26
And that -- among the disorders that you treated among those patients in, again, 2005 to 2010 were wet AMD patients; is that correct?
A Yes, I also took care of patients with wet age-related macular degeneration. 09:02:42

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Q Yeah. And you gave the full clinical name, age-related macular degeneration.
Can we refer to that as "AMD" as we go forward today?
A Yes, we can.
Q Great.
Were you performing intravitreal injections on patients in the 2005 to 2010 time frame?
A Yes, I was performing intravitreal injections.
Q What substances were you injecting into patients intravitreally in the 2005 to 2010 time frame?
A During that time frame of 2005 to 2010, the most common intravitreal agents I was employing in my practice included Lucentis and off-label Avastin.
Q Were you injecting Macugen intravitreally in the 2005 to 2010 time frame?
A In the earlier part of -- let me look at the exact date.
In the early part of 2005, at that time, Macugen was the first anti-VEGF agent approved for the treatment of wet age-related macular

degeneration. Initially some physicians, including myself, used Macugen because there were no other alternatives. However, once Lucentis gained FDA approval, I no longer used Macugen and switched exclusively to Lucentis or off-label Avastin.
Q Understood.
So just -- I know you were looking for dates. I can represent to you that Lucentis was approved for AMD in June of 2006.
A Yes.
Q Does -- does that sound right to you?
A Yes.
Q And so I take it, prior to June of 2006, you were administering Macugen to your AMD patients, correct?
A Prior to Lucentis approval, I had used Macugen in some patients.
Q Right.
Do you recall when the first time you performed an intravitreal injection was?
A I don't recall the exact date. I'd have to look back at my records --
Q Sure.
A -- to determine the exact date for you.
Q Was it -- was it during your residency?

A There are different reasons to perform intravitreal injections, and I'd have to look back to give an accurate date.
Q Okay. Well, let me ask: Did you -- a different question.
Did you receive training at any point as to how to perform an intravitreal injection?
A Yes, during ophthalmology residency and retina fellowship, we do receive training on how to perform intravitreal injections.
Q Okay. And can you describe what -- what you were -- how you were trained to perform an intravitreal injection during your residency?
A During this -- in my declaration, I didn't go into the details of performing an intravitreal injection or the training I received, and so I would like to review that before answering this question.
Q I'm just asking if, sitting here today, you could describe for me the training you received on -- as to how to perform an intravitreal injection.
Can -- can you do that?
MS. STRUTHERS: Objection to form. Asked and answered.
THE WITNESS: In order to give you the

most accurate answer, I would need to review my prior records, give you exact dates, in order to provide you with the most accurate answer.
BY MR. TRAUPMAN:
Q Yeah. My question doesn't call for dates, Doctor. I just want to understand what the steps you were trained -- what steps you were trained to perform when conducting an intravitreal injection.
Can you -- can you do that, sitting here today?
A As I stated, I didn't go into the details of my training regarding intravitreal injections; and in order to accurately answer your question, I'd have to review my records to provide you with that --
Q What --
A -- complete answer.
Q What records would you review to provide a complete answer?
A Again, as I reiterated earlier, I did not go into the details of my ophthalmology training specific to intravitreal injections; and, therefore, in order to give you the best and complete answer, I'd like to have time to look back in my training logs, other records I've kept, to --

Q Okay. So you say -- 09:11:07
A -- give you an answer.
Q -- you say your training log.
You have -- you retain training logs from your residency that you'd want to review to answer 09:11:15 my question?
A I did not discuss my training, experience regarding the nuances of intravitreal injection training in my deposition; and, therefore, I don't feel comfortable giving you an answer without 09:11:40 looking back at my prior records.
Q Right.
And so other than training logs, what other prior records would you need to review in order to be able to be comfortable to answer my 09:11:55 question?
A I did not discuss the techniques or the training I underwent regarding intravitreal injections; therefore, in order to give you the most accurate answer, I'd want to review the data that I 09:12:24 had at that time in order to provide you with the best answer.
Q Right.
And what data are you referring to?
MS. STRUTHERS: Objection. Asked and 09:12:41

answered. 09:12:42
THE WITNESS: As I mentioned, I did not go into those details in my deposition; and, therefore, I don't feel comfortable discussing that topic regarding my training in intravitreal injections at 09:13:10 this time point.
BY MR. TRAUPMAN:
Q Well, if you could turn to page 2 of your declaration, there's a subsection two, that begins at the top of the page, about -- entitled 09:13:34 Qualifications and Experience, correct?
A Yes. I see that.
Q And that section goes on for several pages, 'til the bottom of page 7.
Do you see that? 09:13:51
A Yes.
Q All right.
A I see that.
Q And so on these pages, pages 2 to 7, specifically paragraphs 3 to 13 of your -- of your 09:13:57 declaration, you set forth your qualifications and experience, correct?
A Yes.
Q And you understand that's -- that's the qualifications and experience that make you 09:14:11

qualified to be an expert witness on behalf of 09:14:13 Regeneron in this matter, correct?
MS. STRUTHERS: Objection to form.
THE WITNESS: This document lists my qualifications and experience. 09:14:27
MR. TRAUPMAN: Right.
Q And -- and you, in this declaration, are purporting to hold yourself out as a qualified expert, able to test- -- able to offer expert opinions on behalf of Regeneron, correct? 09:14:41
A That is correct.
Q Right.
And part of the reason why you believe you're qualified -- qualified to offer expert opinions on behalf of Regeneron is based on your 09:14:50 qualifications and experience that you set forth in pages 2 to 7 of your declaration, correct?
A Pages 2 to 7 do list my qualifications and experience.
Q Right. 09:15:06
And, for instance, you talk about some of the qualifications and experience that you specifically mention -- I'm quoting from the bottom of page 2 -- was that, from 2000 to 2003, you completed your residency in ophthalmology at the 09:15:18

Wilmer Eye Institute at Johns Hopkins University 09:15:20 School of Medicine, correct?
A That is correct.
Q And then you had -- I take it you received training in ophthalmology during your residency from 09:15:30 2000 and 2003, correct?
A That is correct.
Q Did -- did you learn how -- did you receive training on how to perform an intravitreal injection while you were a residents at -- resident 09:15:39 at the Wilmer Eye Institute from 2000 to 2003, Doctor?
MS. STRUTHERS: Objection. Counsel, I think you might have misread the dates.
MR. TRAUPMAN: Oh. I'm reading here. 09:15:52
Q It says (as read): "From 2000 to 2003, I completed my residency at -- in ophthalmology at the Wilmer Eye Institute."
Is that correct?
A That is correct. 09:16:02
Q Okay. I don't know --
MS. STRUTHERS: Apologies. Sorry.
BY MR. TRAUPMAN:
Q And did you -- again, between 2000 and 2003, when you were a resident, did you receive 09:16:12

training on how to perform an intravitreal injection?
A Yes, I did.
Q Okay. And then you remained at Wilmer Eye Institute for a retina fellowship in surgical and medical retina from 2003 to 2005, correct?
A That is correct.
Q Did you also receive training on how to perform an intravitreal injection during your retina fellowship? 09:16:32
A Yes, I did.
Q But you're not able to provide any details about the training you received either as a resident or a retina fellow in how to perform an intravitreal injection; is that correct? 09:16:49
MS. STRUTHERS: Objection. Asked and answered.
THE WITNESS: I did receive extensive training in performing intravitreal injections during my residency and retina fellowship. 09:17:04
MR. TRAUPMAN: Okay.
Q And could you describe what that training was?
A To provide you with the most accurate answer, I'd like to review what was taught in the 09:17:29

textbooks at that time; and that's why I didn't go into greater detail, because I wanted to be accurate, and I had not discussed those specific details in my declaration. 09:17:39
Q Okay. Let me ask you: In -- let's just talk about the entire -- your -- your -- both your residency and your retina fellowship together, hopefully in the interest of time. 09:18:00
Were you trained that, prior to performing an intravitreal injection, you should check the patient's vision and intraocular pressure? 09:18:20
A Can you ask the question again?
Q Yes.
When you received the training in how to perform an intravitreal injection, while either a resident or retina fellow at the Wilmer Eye Institute, were you trained that prior to performing an intravitreal injection, you should check a patient's vision and intraocular pressure? 09:18:40
A In my clinical practice and in my training, we evaluate patients before performing any procedure. 09:19:01
Q Including intravitreal injections?
A Yes, before performing an injection too.
Q And let me ask, then, a follow-up 09:19:28

question, because -- when you were performing intravitreal injections of Lucentis in the 2005 to 2010 time frame, prior to giving the injection of Lucentis, did you check the patient's vision and measure their intraocular pressure? 09:19:31 09:19:47
A Again, in my clinical practice, we would evaluate patients before any intravitreal injection, and part of the evaluation would include assessing vision, evaluating the eye and other parameters.
Q But, again, in the 2005 to 2010 time frame, when you were conducting intravitreal injections of Lucentis, did you measure a patient's intraocular pressure prior to performing the intravitreal injection? 09:20:26
A I would have to look back at all my records to accurately answer that question, and I didn't cover that in my declaration, so I couldn't answer completely, that question, right now. 09:20:49
Q Okay. Well, I believe you've testified elsewhere that you current- -- your current practice is to measure a patient's intraocular pressure prior to performing an intravitreal injection; is that correct? 09:21:05
A And which time period are you referring to? 09:21:20

Q I'm talking about the present. 09:21:20
A Yes, I did mention that currently I evaluate the patient. Part of the evaluation may include checking vision and other parameters.
Q Oh, let me make sure we're -- we're in alignment. 09:21:41
When you -- when was the last time you conducted an intravitreal injection of a VEGF agent, Doctor?
A I performed an intravitreal injection last week. 09:21:55
Q Last week.
Just one?
A There were several --
Q Okay. 09:22:06
A -- injections.
Q What did you -- what molecule did you inject intravitreally last week?
A Again, I'd have to look back at my records to answer that question, since I didn't go into detail about that in my declaration. 09:22:22
Q You don't -- you don't recall what molecule you administered intravitreally last week?
A Again, I'd have to look at my records, but I -- there are several agents that are available 09:22:38

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now. 09:22:40
Q What -- what agents do you -- what VEGF agents do you currently inject as part of your clinical practice?
A Again, in my declaration, I didn't go into great detail about my current clinical practice; and in order to answer that accurately, I'd have to look back at all my records. 09:22:54
Q So you can't, sitting here today, name me what VEGF agents you currently administer in your clinical practice? 09:23:09
MS. STRUTHERS: Objection. Argumentative.
THE WITNESS: In my clinical practice, the most common intravitreal injection agents that we use for angiogenic eye disease include EYLEA, Lucentis, off-label Avastin. 09:23:31
BY MR. TRAUPMAN:
Q Do you currently administer any biosimilars of Lucentis -- ranibizumab biosimilars that aren't branded Lucentis? 09:24:06
A I currently do not.
Q Okay. So in the intravitreal injection that you -- injections that you performed last week, did you measure the patient's intraocular pressure prior to performing the intravitreal injection? 09:24:25

A Again, I'd have to look back at the records to give you the most accurate answer, but as I stated, we evaluate the patient before giving an injection or doing a procedure. 09:24:32
Q And does that evaluation include measuring a patient's intraocular pressure? 09:24:54
A Often, when we evaluate the patient, we measure many parameters, one of which is intraocular pressure.
Q Okay. So back to the -- back to your time as a assistant professor from 2005 to 2010 at the Wilmer Eye Institute, when you -- when you performed an evaluation of a patient prior to performing intravitreal objection -- injection, did you, at that time frame, measure the patient's intraocular pressure? 09:25:23 09:25:44
A In order to answer that completely, I would have to look back at my records to give you the most accurate answer, as I did not specifically go into that detail in my declaration. 09:26:06
Q Okay. So you can't say, one way or the other, whether or not you did or did not perform -- measure a patient's intra- -- intraocular pressure prior to performing intravitreal injection when you were a professor at the Wilmer Eye Institute from 09:26:19

2005 to 2010; is that correct? 09:26:23
A As I stated, we evaluated the patient before any intravitreal injection, and that evaluation included examination of the eye, checking the vision, and likely also evaluating the pressure, but in order to answer that more -- most accurately, I'd have to look back at all the records. 09:26:41
Q Okay. So, again, focusing on the '05 to 2010 time frame, did you -- when you were performing the assessment of a patient prior to performing an intravitreal injection, did you also assess the patient's medical records? 09:27:07
A During that time period, when I evaluated the patient, I'm synthesizing all the data that's available. 09:27:36
Q Right.
And that data includes the patient's medical records, correct?
A Yes, that data -- data could include prior records. 09:27:48
Q Right.
And that data would also include information you learned from a patient interview, correct?
A Yes, we would take a history from the 09:27:56

patient and talk to the patient. 09:27:59
Q Right.
And you -- what -- what information would you be seeking to learn when you take a patient history? 09:28:08
A When taking a patient's history, we would discuss their symptoms and ask about any prior eye history, conditions.
Q Okay. So, again -- then, again, focusing on the 2005 to 2010 time frame, when you were an assistant professor at the Wilmer Eye Institute, prior to giving an intravitreal injection of Lucentis to a patient, did you dilate the patient's eyes and perform an examination using a slit lamp? 09:28:47
A In evaluating a patient, I would use the slit lamp to look carefully at the eye and also perform a dilated exam. 09:29:19
Q The slit lamp allows you to see into the back of the eye; is that correct?
A Yes, the slit lamp is helpful in visualizing the structures in the back of the eye. 09:29:40
Q You'd agree with me that the slit lamp is a common tool used by ophthalmologists when conducting an examination?
A Yes, I agree. 09:30:06

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Q So one other -- one other analytical technique that I saw in your declaration was OCT, which -- correct me if I'm wrong -- stands for optical coherence tomography. 09:30:13

Did I get that right? 09:30:27

A Yes, that is correct.

Q Again, I'm a big fan of acronyms, so I can keep a clear record.

Can you explain for us what OCT is?

A OCT is an imaging technique to evaluate the retina. 09:30:42

Q Okay. How long has OCT been in use; do you know?

A I would have to look back at records to know the specific dates OCT was put into use, so I couldn't answer that accurately right now. 09:31:02

Q Was OCT in use when you became a ophthalmology resident in 2000?

A Again, I'd have to look back at records to know the exact date that OCT was, you know, available for use. 09:31:22

Q My question -- my follow-up question was a little bit different.

I'm talking about: When you became a ophthalmology resident in 2000, was OCT in use when 09:31:35

you -- at that time? 09:31:40

A Again, that was over 23 years ago; and to answer that question accurately, I'd have to look back at when OCT was available at Johns Hopkins Hospital. 09:32:01

Q Okay. Were you trained on performing OCT when you were a retina fellow from '03 to '05?

A OCT was utilized at that time period, and I was familiar with OCT imaging during that period.

Q Did you perform any OCTs yourself when you were a retina fellow from '03 to '05? 09:32:41

A Again, I'd have to look back at the records, since that was, you know, over 15 years ago, to answer that accurately.

Q So you can't, sitting here today, tell us whether or not you performed OCT procedures while you were a retina fellow from '03 to '05? 09:33:05

A OCT imaging is performed typically by an ophthalmic photographer, and the majority of time the OCT image is obtained by the photographer but interpreted by the ophthalmologist. 09:33:31

So I would have to look back at my records to determine when I physically performed the OCT myself.

Q I see. Thank you for that clarification. 09:33:47

Were you interpreting OCT images when you were a retina fellow from 2003 to 2005? 09:33:52

A Yes, I was trained to interpret OCT images.

Q So, again, now, let's go to the time period from '05 to 2010, your time as an assistant professor at Wilmer. 09:34:16

Did you -- prior to -- strike that. Let me just ask a better question.

From the 2005 to 2010 time frame, when you were performing intravitreal injections of Lucentis, did you look at the results of an OCT image prior to performing the intravitreal injection? 09:34:33

A Yes.

Q Okay. So we've been talking now, for a little bit of time, about the examination you perform prior to -- let me strike that. 09:35:12

We've been talking a little bit here about the examination you did perform, from '05 to 2010, prior to conducting an intravitreal injection of Lucentis. 09:35:25

What was the purpose of that -- of that examination?

MS. STRUTHERS: Objection. Vague.

THE WITNESS: Could you ask the question again? 09:35:39

MR. TRAUPMAN: Yeah. 09:35:40

Q What -- why is it necessary to conduct an examination of the patient, including looking at her eye, taking a patient's history, reviewing medical records -- why is all -- why were all those steps necessary prior to performing an intravitreal injection of Lucentis in the '05 to 2010 time frame? 09:35:48

A Before performing an injection, I would evaluate the patient in order to determine the diagnosis and to make sure that the treatment that I was recommending would be appropriate, and to evaluate the eye to determine if there were any other active conditions in the eye. 09:36:16

Q Why would it be important to determine whether or not there were any other active conditions in the eye prior to performing an intravitreal injection of Lucentis in the 2005 to 2010 time frame? 09:36:44

A It was important to evaluate the eye to determine if there were other diagnosis [sic] occurring in the eye at that time. 09:37:05

Q But why is it important to know whether or not there are other diagnosis [sic] in the eye prior to performing intravitreal injection of Lucentis in 09:37:27

the 2005 to 2010 time frame? 09:37:30
A Could you repeat the question?
Q Why is it important to know whether or not there are other diagnoses in the eye prior to performing an intravitreal injection of Lucentis in 09:37:58 the 2005 to 2010 time frame?
A It would be important to evaluate the eye to determine the correct diagnosis and to determine if any other conditions might be present that needed treatment. 09:38:34
Q Did -- when you were performing intravitreal injections of Lucentis in the 2005 to 2010 time frame, did you ever discuss with your patients any risks associated with those injections?
A Yes. Before -- before performing any 09:39:15 procedure, we would discuss benefits and risk.
Q What -- what were some of the risks of performing intravitreal injection of Lucentis in the '05 to 2010 time frame that you would have told your patients about? 09:39:36
A The risks associated with intravitreal injections include bleeding, retinal tear, infection, decreased vision, among other things.
Q So is it fair to say that the intravitreal injections have at least the potential for some 09:40:26

serious side effects? 09:40:29
A That is correct.
Q And so in the 2005 to 2010 time frame, as a practicing physician, it would have been important for you to have informed your patients about those 09:40:45 serious side effects, correct?
A That is correct.
Q So one of the side effects you mentioned of an intravitreal injection is infection.
Did I get that right? 09:41:06
A That is correct.
Q Can you explain why an intravitreal injection has the risk of infection associated with it?
A Any invasive procedure, including 09:41:26 intravitreal injection, could pose the risk of infection because of -- bacteria could enter the eye through the incision that's made.
Q Right.
And so just to understand your 09:41:53 terminology, when you say an "invasive procedure" in the context of -- of ophthalmology, you're talking about some sort of incision or -- or some other method of entering the intraocular space; is that correct? 09:42:10

A Yes, that is correct. 09:42:11
Q And would -- did you receive training, either as a resident or retina fellow, that any invasive procedure of the eye carries with it the risk of infection? 09:42:44
A Yes, that is a risk.
Q Right.
And so the training you received at Wilmer Eye Institute would have included performing an assessment of the patient prior to any invasive 09:43:01 procedure of the eye; is that correct?
A Yes, that is correct.
Q And, again, the training you received at Wilmer, either as a resident or a retina fellow, was that if there were signs -- if the assessment showed 09:43:22 signs of infection or inflammation, that -- that those signs needed to be assessed prior to performing an invasive procedure of the eye, correct?
MS. STRUTHERS: Objection to form. 09:43:40
THE WITNESS: Could you repeat the question?
MR. TRAUPMAN: Sure.
Q Were you trained, as either a resident or a retina fellow, that if the results of your patient 09:43:47

assessment prior to performing an invasive procedure 09:43:52 showed the presence of infection or inflammation, that the patient needed to be further assessed prior to moving forwards with the invasive procedure, correct? 09:44:10
MS. STRUTHERS: Objection to form.
THE WITNESS: Could you specify what you're talking about when you mention "infection or inflammation"?
BY MR. TRAUPMAN: 09:44:24
Q Well, in either -- let's start with an infection of the eye, so intraocular infection.
If you observe intraocular infection prior to an invasive procedure, that's something you would need to consider and evaluate as to whether or not 09:44:41 it made sense to move forward with the invasive procedure. That was among the training you received at Wilmer as a resident and retina fellow, correct?
MS. STRUTHERS: Objection. Mischaracterizes testimony. Objection to form. 09:44:51
THE WITNESS: Could you repeat the question?
MR. TRAUPMAN: Sure.
Q I'm talking about the training you received at Wilmer, from 2000 to 2005, as a -- as a 09:45:00

resident and later a retina fellow. 09:45:04
If you -- and you -- I believe you testified that you were trained to perform a patient evaluation before any invasive procedure, correct?
A Yes. 09:45:16
Q Okay. So in -- based on the training that you received, if the patient evaluation showed a intraocular infection, the training that you were -- you were then trained that you needed to perform additional evaluations of the patient and take 09:45:37 additional steps to make sure that it would be safe to perform an invasive procedure in the presence of a intraocular affection -- infection observed, correct?
MS. STRUTHERS: Objection. 09:45:51
Mischaracterizes the testimony. Objection to form.
THE WITNESS: Could you rephrase the question again?
MR. TRAUPMAN: Sure.
Q Based on the training that you received at 09:46:04 Wilmer, would you perform an invasive procedure in a patient with an active intraocular infection?
MS. STRUTHERS: Again, objection to form.
THE WITNESS: Would you repeat the question? 09:46:27

MR. TRAUPMAN: Sure. 09:46:28
Q Based on the training that you received at Wilmer, from 2000 to 2005, would you perform an invasive procedure of the eye in a patient with an active intraocular infection? 09:46:38
MS. STRUTHERS: Same objection, but you can answer.
THE WITNESS: I would have to evaluate the patient to assess if there truly was an intraocular infection before, you know, proceeding with anything 09:46:58 else.
BY MR. TRAUPMAN:
Q How would you assess if there, to use your words, truly was an intraocular infection?
A I would examine the patient with slit lamp 09:47:13 biomicroscopy, a dilated fundus exam to see the peripheral retina, to look at, you know, all structures of the eye.
Q Right.
And then, when you were looking at those 09:47:28 structures, you would be looking for any abnormalities; is that correct?
A Yes, that is correct.
Q And among the abnormalities you would be looking for would be inflammation, correct? 09:47:34

MS. STRUTHERS: Objection to form. 09:47:36
THE WITNESS: What type of inflammation are you referring to?
BY MR. TRAUPMAN:
Q Well, for instance, you would be looking 09:47:47 for uveitis, correct?
MS. STRUTHERS: Objection to form.
THE WITNESS: In evaluating a patient, I would look at the entire eye and look for signs of infection. 09:48:08
MR. TRAUPMAN: Right.
Q And one of the signs of infection is inflammation, correct?
MS. STRUTHERS: Objection.
THE WITNESS: Many common ocular 09:48:23 infections do not always have intraocular inflammation.
MR. TRAUPMAN: Right.
Q You would agree that one of the signs of intraocular infection is inflammation, correct? 09:48:34
MS. STRUTHERS: Objection to form.
THE WITNESS: Can you repeat the question?
MR. TRAUPMAN: Yes.
Q You would agree that one of the signs of intraocular infection is inflammation, correct? 09:48:48

MS. STRUTHERS: Same objection. 09:49:00
THE WITNESS: Again, when the patient has an intraocular infection, depending on the presentation of the patient and the timing, sometimes inflammation may or may not be obvious or 09:49:33 present in all cases.
MR. TRAUPMAN: Okay. So let -- let me maybe take a step back.
Q A little while ago -- and I'm reading from the transcript here -- you said -- and I'm quoting 09:49:54 you -- "In evaluating a patient, I would look at the entire eye and look for signs of infection."
Do you recall giving that testimony about three minutes ago?
A Yes. 09:50:03
Q Okay. Can you tell us, please, what are the signs of infection that you would be looking for when evaluating a patient?
A In assessing a patient for infection, I would look at all structures of the eye, perform 09:50:29 slit lamp biomicroscopy, dilated fundus exam, look for redness in the eye, hemorrhage in the retina, other abnormalities.
Q What causes redness in the eye?
A And can you specify what structures you're 09:51:15

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talking about? 09:51:17
Q Well, you just said -- I'm just really picking up on your answer.
You said you would look for redness in the eye. 09:51:25
That's -- you remember giving that testimony?
A Yes, I do.
Q Okay. So I'm referring to your statement that you would look for redness in the eye, and I'm 09:51:32 asking you: What causes that redness in the eye that you're looking for?
MS. STRUTHERS: Objection. Asked and answered.
THE WITNESS: Redness can be caused by 09:51:50 infection.
BY MR. TRAUPMAN:
Q Would you agree with me that redness is a sign of inflammation?
MS. STRUTHERS: Objection to form. 09:52:07
THE WITNESS: What type of inflammation are you referring to?
BY MR. TRAUPMAN:
Q Inflammation of the eye.
MS. STRUTHERS: Objection to form. 09:52:24

THE WITNESS: In order to answer the 09:52:51 question, we'd have to evaluate the entire patient to determine what the redness is due to.
BY MR. TRAUPMAN:
Q You would agree that inflammation could 09:52:58 cause redness in the eye, correct?
MS. STRUTHERS: Again, objection to form.
THE WITNESS: What type of inflammation are you referring to?
BY MR. TRAUPMAN: 09:53:14
Q Ocular information -- inflammation.
MS. STRUTHERS: Same objection.
THE WITNESS: One would have to evaluate the patient and examine the patient to determine what the redness was due to. 09:53:33
BY MR. TRAUPMAN:
Q And how would you perform that evaluation to determine what the redness was due to?
A I would carefully examine the eye with the slit lamp biomicroscopy and also dilate the eye to 09:53:54 look more carefully at the retina.
Q So all -- it's visual examination to determine the cause of a redness; is that right?
A In conjunction with discussing with the patient his or her symptoms and the course of the 09:54:20

symptoms. 09:54:24
Q Do you ever -- in determining whether or not a patient has an intraocular infection, do you ever take culture samples?
MS. STRUTHERS: Objection to form, but you 09:55:03 can answer.
THE WITNESS: Could you ask the question again?
MR. TRAUPMAN: Right.
Q When -- when trying -- when performing 09:55:07 your assessment -- and let me -- let me be -- give a little more specificity.
When you're assessing a patient, in the 2005 to 2010 time frame, prior to performing an intravitreal injection of Lucentis, did you ever 09:55:20 take a culture of -- you know, swab the patient's eyes and take a culture of any discharge from the patient's eye to determine whether or not the patient had an infection?
MS. STRUTHERS: Objection to form. 09:55:39
THE WITNESS: Could you ask the question again?
MR. TRAUPMAN: Sure.
Q Again, you talked about a patient of -- how you would evaluate a patient prior to performing 09:55:48

an intravitreal injection. Do -- in the 2005 to 09:55:50 2010 time frame.
Do you recall talking about that?
A Yes.
Q Okay. And as part of that evaluation, did 09:55:58 you ever try to take a culture to assess whether or not the patient has a infection?
A Again, I'd have to look back at my records to accurately answer, you know, that question.
Q Okay. So you -- but do you recall ever 09:56:24 taking a culture of a patient's eye prior to performing an intravitreal injection of Lucentis from the '05 to 2010 time frame?
A Again, that was, you know, over 13 years ago. I'd have to look back at my records to 09:56:41 accurately answer that question.
MR. TRAUPMAN: Okay. Okay. Why don't we -- why don't we take a short break, and we'll pick up with a new topic after the break.
THE VIDEOGRAPHER: This marks the end of 09:57:17 Media No. 1. Off the record. The time is 9:57.
(Recess.)
THE VIDEOGRAPHER: This marks the beginning of Media No. 2 in the deposition of Dr. Diana Do. Back on the record. The time is 10:07:40

10:07. 10:07:43
MR. TRAUPMAN: Welcome back, Dr. Do.
I'd like to switch topics a bit, if we could, and I'd like to talk with you about your definition of a "person of ordinary skill in the 10:07:52 art." It's on -- begins -- your opinions begin on pa- -- paragraph 35, page 12, of your declaration, if you'd like to refer to that for my questions.
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THE WITNESS: Oh, page 12 -- 10:08:16
MR. TRAUPMAN: -- para- --
THE WITNESS: -- paragraph 35.
MR. TRAUPMAN: -- paragraph 35.
THE WITNESS: Yes.
MR. TRAUPMAN: Great. 10:08:24
Q So paragraph 35, you're quoting Dr. Chaum's definition of a "person of skill in the art."
Do you see that?
A I see those words. 10:08:34
Q Right.
And then, in paragraph 36, you offer some of your views regarding a person of skill in the art.
Do you see that? 10:08:42

A Yes, I see that. 10:08:42
Q And so focusing on paragraph 36 -- I'm skipping to the second sentence -- you state (as read): "In the event that Samsung argues that the skilled artisan need not be a licensed 10:08:58 physician," parenthetical, "(ophthalmologist)," whether other qual- -- "whatever other qualification they must possess, I disagree because only an ophthalmologist would have the firsthand experience of diagnosing and treating angiogenic eye disorders 10:09:14 to which the patent is plainly directed."
Do you see that?
A Yes, I see that.
Q Okay. So I just want to make sure I understand. 10:09:25
So it is your opinion that a person of skill in the art must be an ophthalmologist; is that correct?
A In my view, the skilled artisan is an ophthalmologist with experience in treating 10:09:39 angiogenic eye disorders, including through the use of VEGF antagonists.
Q Right.
And so my understanding of the rest of paragraph 36 is that if the person is not an 10:09:53

ophthalmologist, he or she cannot be a person of 10:09:55 skill in the art; is that right?
A As I stated, in my view, the skilled artisan is an ophthalmologist with experience in treating angiogenic eye disorders. 10:10:10
Q And in your view, can a person who is not an ophthalmologist be a person of skill in the art for the '681 patent?
A In my view, the skilled artisan is an ophthalmologist with experience in treating 10:10:31 angiogenic eye disorders.
Q Okay. And why -- why does the skilled person have to be an ophthalmologist, in your view?
A In my view, only an ophthalmologist would have the firsthand experience with diagnosing and 10:10:51 treating angiogenic eye disorders to which the patent is plainly directed.
Q So I understand you just read from the part of paragraph 36.
You don't have any further explanation as 10:11:05 to why you believe the person of skill in the art must be an ophthalmologist?
A I believe the skilled artisan is an ophthalmologist because he or she has experience in treating angiogenic eye disorders, including through 10:11:24

the use of VEGF antagonists, and the ophthalmologist 10:11:27 would have the firsthand experience of diagnosing and treating angiogenic eye disorders to which this patent is directed.
Q Do you -- can someone who is not an 10:11:46 ophthalmologist be able to learn and understand diagnosing and treating angiogenic eye disorders?
MS. STRUTHERS: Objection. Calls for speculation.
THE WITNESS: Could you repeat the 10:12:05 question?
MR. TRAUPMAN: Yeah.
Q Can -- someone who is not an ophthalmologist, could that person gain knowledge regarding diagnosing and treating angiogenic eye 10:12:13 disorders?
MS. STRUTHERS: Same objection.
THE WITNESS: In my view, the skilled artisan is an ophthalmologist who has experience in treating angiogenic eye disorders. 10:12:36
BY MR. TRAUPMAN:
Q What information did you consider when forming your opinion as to the definition of a "person of" -- "of skill in the art"?
A Could you repeat the question? 10:12:51

Q Sure.
What information did you consider when forming your opinion as to the definition of a "person of skill in the art"? 10:12:52
A When forming my view of the skilled artisan, I looked at what the patent was directed at, which was treating angiogenic eye disorders, and I believe that only an ophthalmologist would have the firsthand experience of diagnosing and treating angiogenic eye disorders. 10:13:08 10:13:46
Q Right.
And so is having firsthand experience diagnosing and treating angio- -- angiogenic eye disorders necessary to understanding the subject matter to which the '681 patent is directed? 10:14:00
A In my view, the skilled artisan is the -- an ophthalmologist who has experience in treating angiogenic eye disorders.
Q Yeah, that really wasn't my question, though, so let me try to ask it, and just if you can --
Is having firsthand experience diagnosing and treating angiogenic eye disorders necessary in order to understand the subject matter to which the '681 patent is directed? 10:14:23 10:14:38

A Could you repeat the question again? 10:14:51
Q Sure.
Is having firsthand experience diagnosing and treating angiogenic eye disorders necessary in order to understand the subject matter to which the '681 patent is directed? 10:15:02
A In my view, the skilled artisan is the ophthalmologist who has experience in treating angiogenic eye disorders, including through the use of VEGF antagonists, and only the ophthalmologist would be able to have the firsthand experience of diagnosing and treating angiogenic eye disorders, and that is what the patent is directed at. 10:15:37
Q Right.
I understand that you basically just reread paragraph 36, but my question is a little bit different. I'm focusing, though, on the firsthand experience diagnosing and treating angiogenic eye disorders. 10:15:55
Is it your opinion that having that firsthand experience of diagnosing and treating angiogenic eye disorders is necessary in order to understand the subject matter to which the '681 patent is directed? 10:16:09
MS. STRUTHERS: Objection. Calls for a legal conclusion and calls for speculation. 10:16:24 10:16:26
THE WITNESS: Again, I -- I don't understand your question, so I don't know that I could answer it accurately.
BY MR. TRAUPMAN: 10:16:39
Q So you, sitting here today, can't say, one way or another, whether or not you have to have firsthand experience diagnosing and treating angiogenic eye disorders in order to understand the subject matter to which the '681 patent is directed? 10:16:51
MS. STRUTHERS: Objection. Mischaracterizes the testimony, but you can answer.
THE WITNESS: I believe the skilled artisan is the ophthalmologist who has experience in treating angiogenic eye disorders, and the patent is directed, you know, towards treating angiogenic eye disorders, and only the skilled artisan, who is the ophthalmologist, would be able to have experience in that arena. 10:17:09
BY MR. TRAUPMAN: 10:17:33
Q So we've talked -- used the term a lot already today, but I want to make sure we have agreement as to what it means.
Throughout paragraph 36, you refer to "angiogenic eye disorders." 10:17:45

Can you tell us what you understand that term to mean? 10:17:47
A Angiogenic eye disorders are conditions in which there is abnormality of blood vessels that can lead to leakage and abnormal growth of blood vessels. 10:18:13
Q All right. And you would agree that wet AMD is an angiogenic eye disorder, correct?
A Yes, I agree.
Q Would you agree that DME, diabetic macular edema, is an angiogenic eye disorder? 10:18:29
A Yes, I agree.
Q Would you agree that macular edema following retinal vein occlusion is an angiogenic eye disorder? 10:18:50
A Yes, I agree.
Q All right. We can maybe switch topics again, please. Let's go to paragraph 74 of your declaration, which is page 28.
Are you there, Dr. Do? 10:19:31
A Yes, I am.
Q Great.
All right. And so at the bottom of page 28, you have a section -- or a subsection header stating that effective treatment must be on par with 10:19:48

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the existing standard of care.
Do you see that?
A Yes, I see that.
Q You know, you can feel free to refer to the paragraphs that follow, but, broadly speaking, this is part of your claim construction opinions regarding what is required by the claims.
You understand that, correct?
A Yes.
Q And in your opinion, in order to practice the claims, one would need to have an efficacy that is on par with the existing standard of care; is that correct?
A Yes.
Q Great.
And can you -- would you just tell us, what do you mean when you say "on par"?
A When I use the word "on par," I'm referring to something that is similar to some other comparison I'm doing at that time.
Q Okay. And how would a person of skill in the art assess whether or not one treatment is similar to another treatment?
A And what time period are you referring to?
Q Well, I want to -- you understand this is

claim construction.
Do you understand what time period you're offering opinions of claim construction on?
A Yes.
Q Okay. What time period is that?
A During the Lucentis time period, are you referring to?
Q No. Let me maybe orient you.
If you go back to page 22, you have a larger section heading of Roman numeral VIII, "CLAIM CONSTRUCTION."
Do you see that?
A Oh, yes.
Q Right.
And you understand -- again, it's your declaration. You can feel free to review it, but I'm asking all questions within this "CLAIM CONSTRUCTION" section heading, Doctor. And you state in section -- in paragraph 61 that you were providing these opinions as of January 13th, 2011.
Do you see that?
A Yes, I do.
Q Okay. So when I'm asking you about claim construction, I'm assuming you're offering these opinions from the January of 2011 time frame --

A Yes.
Q -- okay?
A That is correct.
Q Okay. Great.
So back to my question: In the January 2011 time frame, how would a person of skill in the art determine whether or not one treatment is similar to another?
A Yes. The person of ordinary skill in the art at that time period would be familiar with Lucentis and the phase 3 clinical data that was available and understand the benefits associated with using Lucentis in angiogenic eye disorders.
Lucentis had become the standard of care in treating angiogenic eye disorders at that time period.
Q Well, let me -- let me explore. You said "angiogenic eye disorders."
As of January 2011, I think we all agree that Lucentis had received FDA approval to treat wet AMD, correct?
A Yes.
Q Had Lucentis received FDA approval as of January 2011 to treat DME?
A No, it had not yet been approved for DME

at that time.
Q Oh, okay.
And how about for macular edema following retinal vein occlusion; had Lucentis been approved for that indication by January 2011?
A Yes, Lucentis was already FDA approved for retinal vein occlusion macular edema.
Q Okay. Do you know when Lucentis was approved for RVO?
A I would have to look back to see the specific date.
Q Okay. So in January 2011, what was the standard of care for diabetic macular edema?
A In January of 2011, the standard of care was using off-label Avastin for diabetic macular edema because Lucentis was not yet FDA approved.
Q Okay. And what were the -- strike that.
What was the efficacy of off-label use of Avastin to treat diabetic macular edema that would have been known to a person of skill in the art in January of 2011?
MS. STRUTHERS: Objection to form.
THE WITNESS: Can you repeat the question?
MR. TRAUPMAN: Sure. Let me ask a different question.

Q So if -- if a person -- in January 2011, if a person of skill in the art is trying to assess whether or not a new dosing regimen is on par, to use your words, with the standard of care for diabetic macular edema, where would that person of skill in the art look to find what the standard of care for diabetic macular edema was in January of 2011? 10:26:31 10:26:47

MS. STRUTHERS: Objection to form.

THE WITNESS: Could you repeat the question? 10:27:00

MR. TRAUPMAN: Sure.

Q Where would a person of skill in the art look to see what the efficacy of off-label use of Avastin to treat diabetic macular edema was in -- as of January of 2011? 10:27:21

A The skilled artisan would look to publications in the scientific literature and also presentations at continuing medical education congresses to understand what the evidence was for off-label Avastin use. 10:27:49

Q Sitting here today, can you identify any publications or presentations at continuing medical education conferences showing the efficacy of off-label Avastin use in diabetic macular edema on 10:28:15

or before January of 2011? 10:28:19

A I would have to look back at the literature at that time point to give you an accurate answer to that question.

Q Okay. So you -- on page 31, paragraph 81, you summarize the results of the MARINA study. 10:29:24

Do you see that?

A I see those words.

Q Right.

And -- correct me if I'm wrong -- the -- and -- let me just take a step back, and I'll withdraw that prior question. 10:30:07

MARINA studied Lucentis in wet AMD patients, correct?

A That is correct. 10:30:19

Q It was one of -- one of the pivotal studies that led to FDA approval of Lucentis for wet AMD; is that correct?

A That is correct.

Q And you would agree that MARINA was informative of the standard of care for wet AMD as of January 2011, correct? 10:30:30

A Yes. The results showed Lucentis was beneficial, and it changed the standard of care.

Q Right. 10:30:53

And the increase -- MARINA showed the mean increase in visual acuity for MARINA was plus 6.5 letters in one dosing group, the .3 milligram group, and 7.2 letters in the .5 milligram group, correct? 10:30:57

A That is correct. 10:31:18

Q All right. And the comparator, which was a sham arm result, had a 10.4-letter decrease, correct?

A Yes, that was one of the results.

Q Right. 10:31:29

So -- and I believe you -- again, using your word "on par," which you said would also mean similar, is a treatment in January of 2011 for wet AMD that resulted in a 5-letter increase.

Is that similar to 6.5- or a 7.2-letter increase? 10:31:48

MS. STRUTHERS: Objection. Calls for speculation. Incomplete hypothetical.

THE WITNESS: Could you repeat the question? 10:32:00

MR. TRAUPMAN: Yeah.

Q You said -- your claim construction is that it has -- the method -- to practice the claimed methods, the efficacy needs to be on par with the standard of care, right? 10:32:07

A Yes. 10:32:12

Q Thank you.

And the standard of care is -- as reported in MARINA and as you just agreed to, is an increase in letters -- and we're talking about BVCA [sic] measurement, correct? 10:32:22

A That was part of the research study.

Q Right.

But the -- you're -- the specific data that you're reporting in paragraph 81 of plus 6.5 and plus 7.2 letters is BV- -- CVA, best corrected visual acuity, correct? 10:32:35

A Yes, that is correct.

Q And so my question for you is -- I'm just trying to understand how you delineate your claim construction. 10:32:54

If I practice a method, in January of 2011, that results in an increase in BCVA of plus 5 letters, is that on par with the results of MARINA?

MS. STRUTHERS: Objection. Calls for speculation. Incomplete hypothetical. 10:33:16

THE WITNESS: What study are you referring to?

BY MR. TRAUPMAN:

Q I'm not referring to any study. I'm 10:33:22

trying to understand how one would determine whether or not a -- a method is on par with the standard of care.

That's your opinion, right?

A Yes. 10:33:35

Q Okay. So how would I go about -- if I get a result -- I follow the MARINA trial protocol, just with a different agent, different -- different molecule, and my result is plus 5 letters, instead of plus 6.5 or 7.2 letters, in your opinion, is that result on par with the standard of care as of January 2011? 10:33:50

MS. STRUTHERS: Same objections.

THE WITNESS: The skilled artisan would look at the totality of the scientific evidence, looking at phase 3 clinical trials, to understand if a treatment was similar to the standard of care at that time. 10:34:10

BY MR. TRAUPMAN:

Q So the skilled artisan would need to look at phase 3 clinical trial results to understand whether or not a particular treatment was similar to the standard of care? 10:34:42

MS. STRUTHERS: Objection.

Mischaracterizes the testimony. 10:34:55

THE WITNESS: I said that the skilled artisan would look at the totality of the evidence, which could include phase 3 clinical trials. 10:35:00

BY MR. TRAUPMAN:

Q Would you be able to term -- determine whether or not a treatment is similar to the standard of care without phase 3 clinical trials? 10:35:11

A The skilled artisan would have to look at all the evidence that was available in order to determine if a new medication was beneficial and similar to the existing standard of care. 10:35:36

Q I'm sorry. I forgot, when we were talking about angiogenic eye disorders, one other condition: Diabetic retinopathy.

Is that an angiogenic eye disorder? 10:36:08

A Yes, it is.

Q What was the standard of care for diabetic retinopathy in January 2011?

A In 2011, diabetic retinopathy would need to be evaluated to determine the severity of that condition to determine what the standard of care would be. 10:36:34

Q I see.

So the stand- -- in January of 2011, the standard for diabetic retinopathy would have depended on how severe the condition was? 10:36:56

MS. STRUTHERS: Objection.

Mischaracterizes the testimony.

THE WITNESS: Could you ask the question again? 10:37:10

MR. TRAUPMAN: Yeah.

Q In Jan- -- in January of 2011, the standard of care for diabetic retinopathy --

A Retinopathy.

Q -- retinopathy -- thank you -- would have depended on how severe the condition was? 10:37:29

A The ophthalmologist would evaluate a patient with diabetic retinopathy to determine the severity of the condition. The severity of the diabetic retinopathy would affect any treatment recommendations. 10:37:55

Q And so is it correct, the severity of the diabetic retinopathy -- I'm never going to get it right -- would have affected the standard of care, correct? 10:38:17

MS. STRUTHERS: Same objection.

THE WITNESS: Evaluation is necessary to determine the severity of diabetic retinopathy.

MR. TRAUPMAN: Right.

Q And depending on the severity of the 10:38:55

diabetic -- strike that. 10:39:00

The severity of the diabetic retinopathy affects what the treatment is at -- or did at least affect the treatment as of January 2011, correct?

A Diabetic retinopathy can have different severity, and the ophthalmologist would need to evaluate the patient to determine, you know, the level of diabetic retinopathy in that individual patient. 10:39:32

Q Right. 10:39:56

And the level of severity of diabetic retinopathy in the patient affects the -- the treatment for that particular patient, correct?

A Was there a question?

Q Yes. 10:40:29

I said: The level of severity of diabetic retinopathy in the patient affects the treatment for that particular patient, correct?

A The ophthalmologist would need to evaluate a patient with diabetic retinopathy to determine the severity; and based on that, you know, the ophthalmologist would recommend the next steps. 10:40:46

Q Are there different levels or grades of diabetic retinopathy -- retinopathy?

A In my declaration, I did not go into the 10:41:26

specific details of the grading of diabetic retinopathy.
Q Okay. But I'm asking you, as a expert ophthalmologist, if there are different levels of gradation of diabetic retinopathy. 10:41:42
A There are different grades of diabetic retinopathy.
Q Okay. What are they?
A Again, I did not go into details about the grading of diabetic retinopathy in my declaration; 10:42:09 and in order to give you the most accurate answer, I'd have to take a closer look at that topic to provide you with the most up-to-date answer for you.
Q Do you treat patients with diabetic retinopathy in the clinic currently? 10:42:47
A And what levels of diabetic retinopathy are you referring to?
Q Do you treat patients -- you state in your declaration you spend -- strike that.
In your declaration, you state currently 10:43:08 you spend about two days a week in the clinic --
A Yes, I do.
Q -- is that correct?
A That is correct.
Q High- -- high-volume practice, correct? 10:43:14

A I see a lot of patients. 10:43:17
Q Right.
Twenty patients a day?
A More than 20 patients.
Q More than 20 patients a day. 10:43:25
More than 30 patients a day?
A Sometimes more than 30 patients.
Q So in those two days that you're pra- -- doing clinical practice, 50 patients a week, at least, correct? 10:43:40
A That's correct.
Q Okay. Do those -- among those 50 or more patients that you, on average, see a week, are those -- included in those patients, are they patients who have diabetic retinopathy? 10:43:52
A I do examine patients with diabetic retinopathy.
Q And do you need to -- do you assess the -- the level of their diabetic retinopathy when you see patients in the clinic? 10:44:07
A Yes. When I see a patient with diabetic eye disease, I carefully examine their eyes and assess their disease.
Q Right.
And you note that diagnosis -- diagnosis 10:44:21

in patient notes -- a patient chart, correct? 10:44:24
A Yes. I evaluate patients with diabetic eye disease in my clinical practice.
Q I'm talking specifically about diabetic retinopathy, okay? That's my question specific to 10:44:40 not diabetic eye disease but diabetic retinopathy.
Are you with me Dr. Do?
A Yes.
Diabetic eye disease is diabetic retinopathy. 10:44:52
Q Okay. Thank you.
So diabetic macular edema is not diabetic eye disease?
A Diabetic macular edema is diabetic eye disease. It's just a specific diagnosis within the 10:45:05 realm of diabetic eye disease.
Q Right.
And a different diagnosis is -- diagnosis is diabetic retinopathy, correct?
A Diabetic retinopathy, yes, is diabetic eye 10:45:15 disease.
Q Well, I want to make sure we are saying the same thing.
Diabetic eye disease includes both diabetic macular edema and diabetic retinopathy, 10:45:27

correct? 10:45:31
A Yes.
Q Right.
So not -- not every diabetic eye disease is a diabetic retinopathy; is that correct? 10:45:35
A Diabetic eye disease is diabetic retinopathy.
Q So your belief is diabetic retinopathy and diabetic eye disease are synonymous?
MS. STRUTHERS: Objection. Beyond the 10:46:06 scope.
THE WITNESS: I didn't -- not go into the nuances of the nomenclature regarding diabetic retinopathy or diabetic eye disease, and so I don't feel comfortable going into depth about the 10:46:24 nomenclature at this time.
BY MR. TRAUPMAN:
Q All right. Well, I was using -- I was asking you about diabetic retinopathy, and you kept on saying "diabetic eye disease," and so I wasn't 10:46:37 trying to introduce a "diabetic eye disease" nomenclature into this. I'm focusing on diabetic retinopathy, which is in your declaration, okay? So I'm asking about diabetic retinopathy.
When -- and when you diagnose patients, 10:46:55

Samsung Bioepis Exhibit 1070
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you note that -- you note the level of -- of -- of 10:46:58
their diabetic retinopathy in their patient chart,
in your clinical practice today, correct, Dr. Do?
A In my clinical practice today, yes, I
document all the findings I discover on clinical 10:47:14
examination --
Q Right.
A -- in the chart.
Q And among those findings is the level of
the diabetic retinopathy, correct? 10:47:22
A If a patient had diabetic retinopathy, I
would document the severity of it.
Q Right. Okay.
And when you're conducting those patient
exams, do you go consult medical textbooks and other 10:47:39
outside sources in order to assess the level of
diabetic retinopathy in your high-volume practice,
when you're seeing 25 or more patients a day?
MS. STRUTHERS: Objection. Argumentative.
You can answer. 10:47:51
THE WITNESS: In my clinical practice
today, I have vast experience taking care of
patients, and I can diagnose them in the clinic
using the findings I see on clinical examination and
ancillary imaging that I might order. 10:48:16

MR. TRAUPMAN: Okay. Great. 10:48:20
Q So based on your vast experience di- --
diagnosing patients with diabetic retinopathy, can
you please explain for us today what the different
levels of diabetic retinopathy are? 10:48:28
MS. STRUTHERS: Objection. Beyond the
scope.
THE WITNESS: I'd be happy to explain it
on a different date, when I have more time to review
that data, but today I didn't include it in my 10:48:53
declaration.
BY MR. TRAUPMAN:
Q So you're not going to answer and tell me
what the different levels of diabetic retinopathy
are? 10:49:08
Is -- am -- I just want to understand your
testimony.
MS. STRUTHERS: Objection. Argumentative.
Mischaracterizes the testimony.
THE WITNESS: Could you repeat the 10:49:19
question?
BY MR. TRAUPMAN:
Q I just want you to tell me what the
different levels of diabetic retinopathy are.
MS. STRUTHERS: Objection. Asked and 10:49:26

answered. 10:49:27
THE WITNESS: As I stated, I did not go
into the details of the different stages of diabetic
retinopathy in my declaration; and, therefore,
although I'd be happy to discuss it at a different 10:49:53
time, right now, in order to give you the most
accurate answer, I couldn't do that at this time
without looking at more data for you.
MR. TRAUPMAN: Great.
Q What -- what was the standard of care for 10:50:12
diabetic retinopathy in January of 2011, Dr. Do?
A In 2011, the standard of care for diabetic
retinopathy depended on the severity of the disease.
Q All right. How about for severe diabetic
retinopathy; what was the standard of care for 10:50:52
severe diabetic retinopathy in January of 2011?
A In January of 2011 -- are you discussing
diabetic retinopathy without diabetic macular edema?
Q Yes.
A In 2011, there were not yet any approved 10:51:46
anti-VEGF, you know, agents for diabetic retinopathy
at that time; and, therefore, many patients who had
severe nonproliferative diabetic retinopathy were
either observed, because there was no other therapy,
or, in some cases, laser photocoagulation was used. 10:52:25

In other instances, off-label Avastin was used. 10:52:45
Q What's the standard of care today for
patients with severe nonproliferative diabetic
retinopathy?
MS. STRUTHERS: Objection. Beyond the 10:53:50
scope.
THE WITNESS: In my declaration, I did not
discuss the current standard of care of severe
nonproliferative diabetic retinopathy; therefore, I
couldn't accurately answer that question without 10:54:10
having more time to evaluate all the data on that
topic.
MR. TRAUPMAN: I just want to understand
your testimony.
Q Without having more time to consider other 10:54:25
data, you, sitting here today, can't tell me what
the standard of care today is for a patient with
severe nonproliferative diabetic retinopathy; is
that your testimony?
MS. STRUTHERS: Objection. 10:54:39
Mischaracterizes the testimony.
THE WITNESS: I did not discuss the
standard of care today for severe nonproliferative
diabetic retinopathy; therefore, in order to give
you the most accurate answer, I would need more time 10:55:05

to evaluate the data to provide you with the most accurate answer. 10:55:11

BY MR. TRAUPMAN:

Q Well, I find that fairly incredible for someone who has a high-volume practice of retina patients, but I also want to challenge your assertion that you didn't talk about the standard of care today for patients with diabetic retinopathy, because, on paragraph 170 of your report, you talk about the fact that EYLEA is approved for diabetic retinopathy, and then you go on to talk about how you use EYLEA to treat your patients today and talk about the steps you perform when practicing -- allegedly practicing the patent. 10:55:27 10:55:41

So do you use EYLEA to treat diabetic retinopathy today -- 10:55:55

MS. STRUTHERS: Objection.

BY MR. TRAUPMAN:

Q -- Dr. Do?

MS. STRUTHERS: Objection. Argumentative. 10:56:01

If you want to repeat your question.

THE WITNESS: Can you repeat where you --

MR. TRAUPMAN: Yeah.

THE WITNESS: -- are referring?

MR. TRAUPMAN: 170. 10:56:08

THE WITNESS: Paragraph 1- -- 10:56:09

MR. TRAUPMAN: Yes.

THE WITNESS: -- 70?

I see paragraph 170.

MR. TRAUPMAN: Right. 10:56:39

Q And -- and then -- and then, if you go on, you -- in your paragraph 198, just as a for-instance -- are you there?

A Yes, I see that.

Q "Physicians, including myself, treat patients experiencing" a number of things, including DR -- that's diabetic retinopathy, right? 10:56:56

That's true today, right, Dr. Do?

A Yes, that is correct.

Q And I'm not imagining things. 10:57:07

That's in your declaration, right?

MS. STRUTHERS: Objection. Argumentative.

You can answer.

THE WITNESS: Yes, I stated that.

BY MR. TRAUPMAN: 10:57:15

Q Okay. So is your treatment of patients today using EYLEA for diabetic retinopathy in accordance with the standard of care -- the current standard of care?

A Yes, today EYLEA is approved for diabetic retinopathy and is part of the standard of care. 10:57:33 10:57:40

Q All right. Let's move on.

You have para- -- page 44, paragraph 107. The bottom -- the last sentence in that paragraph, you say (as read): "In my opinion the Challenged Claims are not so limited, instead relate to both clinical studies and clinical practice."

Do you see that? 10:58:28

A Which paragraph?

Q One -- 107. 10:58:39

A Okay.

Q I just read the last sentence.

A Okay.

Q Do you see that?

A Yes. 10:58:52

Q Okay. Great.

So -- so just to understand you, so it's your opinion -- correct me if I'm wrong -- that the challenged claims at issue in this proceeding relate to both clinical studies and clinical practice, correct? 10:59:11

A As I stated in my opinion, the challenged claims relate both to clinical studies and clinical practice.

Q Great. 10:59:26

And when you say "clinical practice," what are you referring to there? 10:59:27

A I'm referring to taking care of patients in the clinic outside of clinical trials.

Q So any -- any administration to a patient outside the context of the clinical study would be clinical practice? 10:59:51

A Yes.

Q And I take it your opinion is that someone would -- strike that. 11:00:07

Your opinion is that a practicing ophthalmologist would still follow the claimed methods that are at issue here -- the claims are all methods -- in clinical practice, correct?

A Yes, the ophthalmologist sees patients in clinical practice. 11:00:26

Q Right.

And the ophthalmologist will, in your opinion, apply the exclusion criteria that are set forth in the challenged claims in clinical practice, correct? 11:00:38

A Yes.

Q What's the purpose of applying those exclusion criteria -- the three that are recited in the challenged claims -- in clinical practice? 11:00:54

A Could you repeat the question? 11:01:07
Q Sure.
What's the purpose of applying the three claimed exclusion criteria in clinical practice?
A The purpose of applying the exclusion 11:01:37 criteria in clinical practice would be to practice the claim and to treat patients according to the claimed method.
Q Do the -- does practicing the claim, including practicing the three exclusion criteria, 11:02:03 in clinical practice offer any benefits to the patient?
A What benefits are you referring to?
Q I'm asking a wide-open question to see if you can identify any benefits to the patient that 11:02:23 result from some -- an ophthalmologist practicing the claimed methods, including the claimed exclusion criteria, in clinical practice.
MS. STRUTHERS: Objection to form. Vague.
THE WITNESS: Can you be more specific in 11:02:45 your question?
BY MR. TRAUPMAN:
Q Can you identify any clinical benefits that result from someone practicing -- strike that.
Can you identify any clinical benefits 11:03:03

that result from an ophthalmologist, in clinical 11:03:04 practice, practicing the claimed methods, including specifically applying the three exclusion criteria?
MS. STRUTHERS: Same objection.
THE WITNESS: What benefits are you 11:03:27 specifically referring to?
BY MR. TRAUPMAN:
Q I'm asking if you -- you, as an expert on behalf of Regeneron, can identify any benefits.
A In order to identify benefits to the 11:03:38 individual patient, the ophthalmologist would have to evaluate the patient, perform the examination, look at ancillary imaging studies to determine the benefit for that individual patient.
Q Of practicing the claimed methods? 11:03:59
A Yes, of -- in treatment, they would need to assess the patient to evaluate the benefit.
Q All right. Let's go a little bit forward, to paragraph 124. And just looking at that first sentence of paragraph 124, you describe the purpose 11:04:34 of the claimed exclusion criteria in the clinical trial context.
Do you see that?
MS. STRUTHERS: Objection.
Mischaracterizes the testimony. 11:04:47

THE WITNESS: Could you repeat your 11:04:49 question?
MR. TRAUPMAN: Yeah.
Q Again -- and I'm really not trying to mischaracterize your testimony or the document, but 11:04:55 my understanding is -- just reading the first sentence, is you're providing an explanation as to what the purpose of the claimed exclusion criteria are in the clinical trial context.
Is that correct? 11:05:11
A In paragraph 124, I state that, by 2011, the POSA would have been familiar with the concept of exclusion criteria and with their purpose in the clinical trial context.
Q Right. 11:05:31
In fact, if you look at the very top of the next page, the subheading is "The purpose of exclusion criteria in clinical trials," right?
A Yes.
Q So it's fair to say this entire subsection 11:05:39 is talking about the purpose of exclusion criteria in the clinical trial context, correct?
A Yes, this section deals with that topic.
Q Right.
You formed opinions in this proceeding 11:05:57

about the purpose of -- of exclusion criteria in the 11:05:58 clinical trial context, correct?
A I discuss the purpose of exclusion criteria in clinical trials in this section.
Q Right. 11:06:12
Did you form opinions in this proceeding about the purpose of exclusion criteria in the clinical practice context?
A Could you repeat your question?
Q Yes. 11:06:54
Did you form opinions in this proceeding about the purpose of the claimed exclusion criteria in the clinical practice context?
A In my declaration, I state that, "Given the knowledge that a key purpose of exclusion 11:07:44 criteria was to avoid safety issues, and the understanding that" the "study protocols were not proven until tested, the POSA looking to prior studies for the purpose of designing or selecting exclusion criteria for use in the claimed methods 11:08:02 would have looked to exclusion criteria from studies that had published, positive safety results, ideally using the same anti-VEGF agent, in a similar condition and patient population. This is because such data would be more informative as to the 11:08:21

appropriateness of the referenced exclusion criteria in the population that the POSA intended to treat. The POSA would therefore look to studies that had treated subjects with the same condition as the claimed methods." 11:08:39

Q Okay. You just read the entirety of the paragraph 126, correct?

A I read the words that I made in my declaration, yes.

Q Right. 11:08:58

And from -- from paragraph 126, correct?

A Yes, that is correct.

Q Right.

Does that paragraph apply to clinical practice? 11:09:07

A Sorry. Could you repeat the question?

Q Does paragraph 126 of your declaration apply to clinical practice?

A In my declaration, I discuss that the POSA would look to prior studies for the purpose of 11:12:11 designing or selecting exclusion criteria for use in the claimed methods and would have looked to exclusion criteria from studies that had been published with positive safety results, ideally using the same anti-VEGF agents in similar 11:12:33

conditions and patient population, and the POSA would use this information to help guide their treatment in clinical practice. 11:12:37

Q So the answer I -- am I understanding that you -- your opinion is that -- strike that. 11:13:05

Am I correct in understanding that paragraph 126 of your declaration does apply to clinical practice?

A Could you ask that again?

Q Right. 11:13:29

Is it your opinion that paragraph 126 is meant to apply to clinical practice and not just clinical trials?

A As I mentioned in my declaration, the exclusion criteria would be applied in both clinical trials and in clinical practice, if we're practicing the claimed method. 11:14:01

Q Right.

Let me just -- I understand that.

But you're talking about the purpose, here in 126, of exclusion criteria is to avoid safety issues, and you go on from there. I just read the first part of it. I'm not trying to crop quote; I'm just directing you. 11:14:26

Is the purpose of the exclusion -- the 11:14:40

claimed exclusion criteria to avoid safety issues in clinical practice? 11:14:41

A A key purpose of the exclusion criteria was to identify and exclude individuals with preexisting conditions that could increase the risk of adverse events or confounding study results. 11:15:00

Q Confounding study results, that's something that's specific to clinical trials, though, right?

A Yes, confounding study results refers to clinical trials. 11:15:15

Q Right.

So I'm focusing on the applicability of the exclusion criteria in clinical practice, not clinical trials. 11:15:25

Would you agree that the key purpose of the exclusion criteria was to avoid safety issues in clinical practice?

MS. STRUTHERS: Objection. Mischaracterizing the document. 11:15:36

THE WITNESS: I mention in my declaration that the POSA would have recognized the concept of exclusion criteria and their purpose in clinical trials and the POSA would have understood that a key purpose of exclusion criteria was to identify and 11:16:08

exclude individuals with preexisting conditions that could increase the risk of adverse events and safety. 11:16:11

BY MR. TRAUPMAN:

Q Is that purpose limited to clinical trials or is that also applicable to clinical practice, what you just said? 11:16:21

A The exclusion criteria would be applied in both clinical trials and clinical practice, if one were to practice the claimed methods. 11:16:55

Q That doesn't really answer my question, though.

Would you agree, "yes" or "no," Doctor, that the key purpose of the claimed exclusion criteria was to identify and exclude individuals with preexisting conditions that could increase the risk of adverse events in clinical practice? 11:17:05

MS. STRUTHERS: Objection to form.

THE WITNESS: Could you rephrase the question? 11:17:18

BY MR. TRAUPMAN:

Q Would you agree, Dr. Do, that a key purpose of the claimed exclusion criteria is to identify and exclude individuals with preexisting conditions that could increase the risk of adverse 11:17:30

events in clinical practice? 11:17:34
MS. STRUTHERS: Objection to form.
THE WITNESS: In order to evaluate patients in clinical practice, one would have to examine the patient to determine if they met any 11:18:01
exclusion criteria, and so the ophthalmologist -- the POSA would have to see the patient, look under the slit lamp, perform a dilated fundus exam to determine if that patient met any exclusion criteria. 11:18:29
BY MR. TRAUPMAN:
Q Are you done with your answer?
A Yes.
MR. TRAUPMAN: I move to strike it as nonresponsive. 11:18:35
I'm going to ask my question again.
Q Dr. Do, would you agree that a key purpose of the claimed exclusion criteria is to identify and exclude individuals with preexisting conditions that could increase the risk of adverse events in 11:18:47
clinical practice?
MS. STRUTHERS: Again, objection to form.
THE WITNESS: In clinical practice, in order to determine if a patient met any exclusion criteria, one would have to examine them carefully 11:19:07

using slit lamp biomicroscopy, dilated fundus exam, 11:19:14
to see if they had any exclusion criteria.
BY MR. TRAUPMAN:
Q Doctor, very respectfully, that doesn't answer my question, okay? 11:19:27
My question isn't how you determine and identify if -- someone with or without the exclusion criteria in clinical practice. My question is directed to the purpose of the exclusion criteria in clinical practice. 11:19:40
Do you understand the distinction between those two concepts?
MS. STRUTHERS: Objection. Argumentative.
THE WITNESS: Perhaps you could rephrase your question, then. 11:19:47
MR. TRAUPMAN: Yeah.
Q I want to understand -- do you understand there's a difference between how you determine whether a patient has exclusion criteria and what the purpose of the exclusion criteria are? 11:19:54
Do you understand that those are two different concepts, ma'am?
MS. STRUTHERS: Same objection.
THE WITNESS: The ophthalmologist would need to examine the patient and actively evaluate 11:20:13

them to determine if they met any of the exclusion 11:20:16
criteria.
MR. TRAUPMAN: I don't disagree with that one bit, but that's not the subject of my question, very respectfully. 11:20:26
I'm asking what the purpose of applying the exclusion criteria are in clinical practice.
Let me just ask a broad question.
Q What is the purpose of utilizing the claimed exclusion criteria in clinical practice? 11:20:39
MS. STRUTHERS: Objection to form. Compound.
THE WITNESS: Could you repeat the question again?
BY MR. TRAUPMAN: 11:20:58
Q What is the purpose of utilizing the claimed exclusion criteria in clinical practice?
A In my declaration, I discuss the purpose of exclusion criteria in clinical trials; and I further discuss that, in clinical practice, the POSA 11:23:15
and I would have to evaluate the patient and actively examine them to determine if they had any active issues in their eyes that would change my treatment recommendation for that patient, if they met any of the exclusion criteria. 11:24:11

Q Can you point to me anywhere in your 11:24:17
declaration where you discuss the purpose of utilizing the claimed exclusion criteria in clinical practice?
A On page 83, paragraph 184, I discuss, in 11:24:53
clinical practice, how I assess the patient at each visit before administering the intravitreal injection.
Q You're still flipping through pages. I want to make sure I'm not cutting you off. 11:25:54
Are you done with your answer, or do you have more to add?
A I'm done.
Q Thank you.
So paragraph -- you identified paragraph 11:26:09
184 as identifying the purpose of the exclusion criteria in clinical practice, correct?
A I stated that -- in paragraph 184, I discuss what I do in clinical practice to actively evaluate a patient to determine if they have any 11:26:40
signs of other active conditions in the eye that would fit exclusion criteria for that patient.
Q Right.
And you'd agree with me that the steps you're describing in paragraph 184 describe the 11:27:03

standard of care for administrating -- administering intravitreal injections, correct?

MS. STRUTHERS: Objection. Mischaracterizes the document.

THE WITNESS: In paragraph 184, I describe what I do in clinical practice when I treat a patient with EYLEA. I assess the patient before administering the individual injection and carefully examine the eye to make sure that there are no other active issues that would make me pause and not perform the injection.

MR. TRAUPMAN: Right.

Q And -- but you're not just describing the steps you take. You're describing the steps that, in your opinion, most retinal specialists take, correct?

A Based on my experience working with and speaking with other retina specialists, I believe most retina specialists practice the way I practice as well.

Q Right.

And one of the things you're -- one of the reasons why you're performing this evaluation that you describe in paragraph 184 is to make sure there won't -- there's not any increased risks or any

concerns about performing the intravitreal injection, correct?

A In evaluating the patient before the intravitreal injection, I'm assessing multiple factors, including the diagnosis of the patient's condition and to look for any other active conditions that could be occurring in the eye that would affect the patient's, you know, safety.

Q Right.

Because other active conditions in the eye may increase the risks associated with an intravitreal injection, correct?

A In certain conditions, the risks could be increased with intravitreal injections if a patient has another active issue in the eye.

Q Right.

So, for instance, as we talked about earlier today, one of the risks, even in the best of circumstances, of an intravitreal injection is infection, correct?

A Yes, in intravitreal injection, a risk could be infection.

Q Right.

And so if the patient can have other conditions, but -- based on your examination that

increased the risk of infection associated with intravitreal injections, correct?

A Would you rephrase the question?

Q Sure.

So one of the reasons why you perform your pre-injection examination that you describe in paragraph 14- -- 184 is because the patient could have certain conditions that increase the risk of infection associated with the -- the administration of an intravitreal injection, correct?

A Before performing an injection, I evaluate the patient, assess for any other conditions in the eye; and if there are no other active conditions, then I would, you know, proceed with the intravitreal injection of the anti-VEGF agent.

Q Right.

And, conversely, if there are active conditions, you need to make further evaluation to determine whether or not it's appropriate to proceed with the intravitreal injection; that's what you describe in paragraph 184, correct?

A That is correct.

Q And because -- and that -- the reason why you perform that evaluation and then make an assessment based on that evaluation is because there

are conditions that can increase the risk associated with the intravitreal injection, correct?

A I would need to actively evaluate and examine the patient to determine any conditions in the eye at that time that could pose a safety risk.

Q Right.

And, in fact, you talk about how the fact that sometimes -- not often -- but sometimes you make the assessment that there is a safety risk associated with the intravitreal injection, and you don't proceed with the -- with the injection, correct?

A In my declaration, I did discuss that there are rare cases where I will withhold the injection because of other issues that I've identified on the examination.

Q Right.

And some of those issues are safety issues, right?

A There could be different issues that could affect it, and one of them could be safety, yes.

MR. TRAUPMAN: Why don't we take a break.

THE VIDEOGRAPHER: This marks the end of Media No. 2. Off the record. The time is 11:33.

(Recess.)

THE VIDEOGRAPHER: This marks the beginning of Media No. 3 in the deposition of Dr. Diana Do. We're back on the record. The time is 11:45. 11:45:38

MR. TRAUPMAN: Welcome back, Dr. Do. 11:45:50

I just want to kind of pick up a few -- a few topics that we had before we took our break.

Q As we -- we saw, it's -- well, let me -- let me ask: Is -- do you -- well, let me just with -- start all over. I'm sorry. I need to get back in my flow. 11:46:11

When you're conducting a clinical trial, are you achieving efficacy on par with the existing standard of care?

MS. STRUTHERS: Objection to form. 11:46:24

THE WITNESS: Which clinical trial are you referring to?

BY MR. TRAUPMAN:

Q Any clinical trial. A clinical trial of a study to continue -- to conduct the study of the efficacy of a molecule. 11:46:36

Are you -- are you going to achieve efficacy on par with the existing standard of care?

MS. STRUTHERS: Objection to form.

THE WITNESS: Which phase of a clinical 11:46:53

trial are you referring to? 11:46:56

MR. TRAUPMAN: Phase 3.

THE WITNESS: And can you repeat your question with that in mind?

MR. TRAUPMAN: Right. 11:47:04

Q Are you going -- if you're conducting a clinical trial, phase 3, are you going to achieve an efficacy that's on par with the existing standard of care?

MS. STRUTHERS: Objection to form. 11:47:15

Incomplete hypothetical.

THE WITNESS: Again, I did not discuss, you know, designing hypothetical clinical trials in my declaration, and I wouldn't want to provide an inaccurate answer, so I'd need, you know, more details, more time to think it over. 11:47:40

BY MR. TRAUPMAN:

Q Well, I guess I'm just trying to explore the opinions that are in your declaration, which is to -- correct me if I'm wrong, but it's your opinion that in order to practice the claimed methods, you need to achieve an efficacy that's on par with the existing standard of care, correct? 11:47:50

A Can you point to me which part of my declaration you're referring to? 11:48:07

Q I'd be happy to. We looked at this already earlier today, page 28 -- oh, my colleague is saying maybe a summary paragraph. 11:48:09

So 7 -- paragraph 17, you state (as read): "It is also my opinion, for at least the reasons set forth below, that the claimed," quote, "'method for treating'" closed quote, "must achieve efficacy that is on par with the existing standard of care at the time the '681 patent was filed." 11:48:32

Do you see that? 11:48:48

A Yes, I see those words.

Q That's your opinion, right?

A That is my opinion regarding the topic that we are discussing in this declaration.

Q Right. 11:49:00

And the -- the claimed method for treating, those are the -- that's recited in the claims that you're offering opinions on here, correct, Doctor?

A The claimed method for treating in this paragraph 17 must achieve efficacy that is on par with the existing standard of care at the time the '681 patent was filed. 11:49:12

Q Right.

So, in other words, to practice the 11:49:28

claimed methods, you must achieve efficacy that is on par with the existing standard of care at the time the '681 patent was filed, correct? 11:49:30

A I wrote that it is my opinion, for at least the reasons set forth in my declaration, that the claimed method for treating must achieve efficacy that is on par with the existing standard of care at the time the '681 patent was filed. 11:49:49

Q Correct. I understand.

So, in other words, in order to practice the claimed methods, you must achieve efficacy that is on par with the existing standard of care at the time the '681 patent was filed, right, Doctor? 11:50:04

MS. STRUTHERS: Objection. Asked and answered. 11:50:20

THE WITNESS: I stated that it was my opinion that the claimed method for treating must achieve efficacy that is on par with the existing standard of care at the time the '681 patent was filed. 11:50:39

MR. TRAUPMAN: Right. Okay.

Q So can you -- is a person -- is running a phase 3 clinical trial -- does the claimed -- does that achieve the claimed method of treating such that -- let me strike that. 11:50:52

Would you be practicing the claimed method for treating, specifically achieving the efficacy that is on par with the existing standard of care at the time the '681 patent was filed, when you're conducting a phase 3 clinical trial? 11:50:54 11:51:05

MS. STRUTHERS: Objection. Incomplete hypothetical. Calls for speculation.

THE WITNESS: Could you rephrase the question?

MR. TRAUPMAN: No, I can't. I'm going to ask it again, though. 11:51:17

Q Are -- are you practicing the claimed method for treating -- specifically, are you achieving -- in your -- in your opinion, achieving efficacy that is on par with the existing standard of care at the time the '681 patent was filed when you're conducting a phase 3 clinical trial? 11:51:31

MS. STRUTHERS: Same objection. Calls for speculation.

THE WITNESS: Again, I couldn't answer that question because you're asking about a hypothetical phase 3 clinical trial, and I don't know what data you're referring to. 11:51:45

BY MR. TRAUPMAN:

Q So does any phase 3 clinical trial achieve 11:51:56

efficacy that is on par with the existing standard of care at the time the '681 patent was filed, if you're conducting a phase 3 clinical trial? 11:52:04

MS. STRUTHERS: Objection to form.

THE WITNESS: What phase 3 clinical trial are you referring to? 11:52:15

MR. TRAUPMAN: I'm not referring to any specific phase 3 clinical trial.

Q You would agree with me that the purpose of the phase 3 clinical trial is to test the efficacy of a molecule, right? 11:52:23

A That's one of the goals, yes --

Q Right.

A -- of a phase 3 clinical trial.

Q Right. 11:52:31

And you don't know whether or not the -- what the results of the phase 3 clinical trial are going to be until after it's completed and the data is analyzed, correct?

A That is correct. 11:52:49

Q Okay. So you would have no way, when conducting a phase 3 clinical trial, of knowing whether or not you are achieving efficacy that is on par with the existing standard of care until after the phase 3 clinical trial is complete and the data is analyzed, correct? 11:53:02

A Can you repeat the question? 11:53:04

Q Yeah.

You would have no way of knowing, when conducting a phase 3 clinical trial, whether or not you were achieving efficacy that is on par with the existing standard of care at the time the '681 patent was filed until after the phase 3 clinical trial is over and the data has been analyzed, correct? 11:53:15 11:53:28

MS. STRUTHERS: Objection to form.

THE WITNESS: Could you ask the question again?

MR. TRAUPMAN: Sure.

Q You would have no way of knowing, when conducting a phase 3 clinical trial, whether or not you were achieving efficacy that is on par with the existing standard of care at the time the '681 patent was filed 'til after the phase 3 clinical trial is over and the data has been analyzed, correct? 11:53:40 11:53:52

A What phase 3 clinical trial are you referring to?

Q Just any phase -- I'm not asking about a fact that's a historical fact. 11:54:04

I'm asking about how phase 3 clinical trials are designed, because you've said this patent applies to phase 3 clinical trials. Remember we talked about -- or strike that. 11:54:08

You shared your opinions that you believe that the patent applies to clinical trials, correct? 11:54:20

MS. STRUTHERS: Objection. Mischaracterizes the testimony.

BY MR. TRAUPMAN:

Q You don't recall that, Dr. Do? 11:54:28

A Can you point to me the area you're talking about?

Q Right.

For instance, on page 53, para- -- footnote 38, you say, "While the Challenged Claims are not limited to the clinical trial context, it is my opinion that this background knowledge would inform a POSA regarding exclusion criteria for the claimed methods." 11:54:46

A I see that footnote. 11:55:00

Q Right.

And again, at paragraph 106 -- excuse me -- 105, you talk about how the challenged claims relate to both clinical studies and clinical practice. We read that as well earlier today. 11:55:16

Do you recall that? 11:55:21
A Which sentence are you referring to?
Q I'm referring to the last sentence in paragraph 107.
A The last -- 11:55:48
Q Sentence.
A -- sentence in paragraph --
Q "The Challenged Claims...instead relate to both clinical studies and clinical practice."
Do you see that? 11:55:56
Paragraph 107.
A Under the heading "Exclusion Criteria"?
Q Yes, Doctor. The last sentence in paragraph 107 (as read): "The Challenged Claims...relate to both clinical studies and" 11:56:14
clinical trial -- "clinical practice."
Do you see that?
A I see those words.
Q That's your opinion, right, Doctor?
A In paragraph 107, I'm discussing 11:56:44
Dr. Chaum's declaration and how Dr. Chaum offered no opinion on whether the term "exclusion criteria" is limit- -- limited to the clinical study context.
Q Right.
And you're -- and you say: "In my opinion 11:57:08

the Challenged Claims are not so limited, and 11:57:10
instead relate to both clinical studies and clinical practice." Right?
A In my declaration, I wrote that, "In my opinion the Challenged Claims are not so limited, 11:57:25
and instead relate to both clinical studies and clinical practice."
Q Great.
So the challenged claims relate to both clinical studies and clinical practices, you just 11:57:39
said, right?
A I wrote that, in my opinion, the challenged claims relate to both clinical studies and clinical practice.
Q Right. 11:57:55
And clinical studies would certainly include phase 3 clinical studies, right?
A They include the phase 3 clinical studies of EYLEA.
Q Well, the claims are -- relate -- 11:58:11
A Yeah.
Q -- to a method of treating angiogenic eye disorders --
A Yes.
Q -- right? 11:58:19

And they're not limited to just the 11:58:20
phase 3 clinical trials of EYLEA. You -- as you say, they relate to both clinical studies and clinical practice generally, right?
A Could you repeat the question? 11:58:44
Q Sure.
When you say, in your paragraph 107 of your declaration, that the challenged claims relate to both clinical studies and clinical practice, did the clinical studies that challenged claims relate 11:59:00
to include phase 3 clinical studies, Doctor?
A The claims I'm discussing relate to the '681 patent.
Q Right.
Those are the challenged claims? 11:59:20
A Yes.
Q Capital C, capital C, "Challenged Claims"?
A Yes.
Q It's the -- it's the -- all of the claims of the '681 patent, right? 11:59:26
A Yes.
Q You defined that earlier in your declaration, but you -- I don't need to show that to you because you just agreed with me and that's correct. 11:59:36

But I see you now looking. You can go 11:59:36
look.
Challenged claims are -- in the very first paragraph, it's 1, 3 to 11, 13 to 14, 16 to 24, and 26 of the '681 patent, those claims. 11:59:50
Do you need a copy of the '681 patent? Would you like to see the claims?
A Sure.
MR. TRAUPMAN: Sure.
(Exhibit 1001 was introduced.) 12:00:04
MR. TRAUPMAN: Sorry.
MS. STRUTHERS: Thank you.
MR. TRAUPMAN: It's a much bigger stretch.
Okay. I've marked -- well, I haven't marked. I've put in front of you what's been 12:00:15
previously marked as Exhibit 1013 [sic] in this proceeding. It's a copy of U.S. Patent No. 10,130,681.
Q Do you have that in front of you, Doctor?
A Yes, I do. 12:00:27
Q All right. So, again, if you need to see the claims -- the challenged claims, you can -- you can now refer to them.
As we just saw, the challenged claims are -- many of them, and the two challenged -- 12:00:38

independent claims -- perhaps we can focus our efforts on the independent claims -- are claims 1 and 14. 12:00:42

So back to paragraph 107, Doctor. You say that the challenged claims relate to both clinical studies and clinical practice, right? 12:00:53

A I state that the challenged claims relate to both clinical studies and clinical practice.

Q Right.

And within the -- within the words "clinical studies" that you're referring to, that -- they -- they relate to, among other things, phase 3 clinical studies, right? 12:01:16

A I'm sorry. Repeat the question, please.

Q Within the words "clinical studies," as you used it in paragraph 107, you're referring to the claims relating to, among other things, phase 3 clinical studies, right? 12:01:55

A Those clinical trials refer to the VIEW 1 and VIEW 2 studies, phase -- which are phase 3 clinical trials too, yes. 12:02:17

Q So when you -- when you used the words "clinical studies" in the last sentence of paragraph of 107, you're referring specifically to VIEW 1 and VIEW 2? 12:02:32

A What was your question? 12:02:56

Q Yes.

When you used the words "clinical studies" in the last sentence of paragraph 107 of your declaration, were you referring specifically to the VIEW 1 and VIEW 2 studies? 12:03:04

A Part of the clinical studies include VIEW 1 and VIEW 2.

Q Okay. Are there any other clinical studies you're referring to when you use the words "clinical studies" in the last sentence of paragraph 107 other than VIEW 1 and VIEW 2? 12:03:23

A I'm referring to the VIEW 1 and VIEW 2 studies.

Q Okay. All right. I'd like to go back -- sorry. We're going to switch topics, just to give you the directional header. I'm going to go back to paragraph 184 of your report, which we were discussing before the break. It's page 83. It looks like you're there. 12:04:17 12:05:38

So I guess maybe to orient ourselves a little bit, this is in the larger section of your declaration where you state both the EYLEA label and physicians administration of EYLEA practice the challenged claims. 12:06:03

You recall drafting that section of your declaration, right? 12:06:04

A Yes.

Q Okay. Good.

And for many of the claimed -- many of the claimed steps of these methods, you refer to the EYLEA label to show why following the label practices the claimed methods, right? 12:06:10

You can see --

A Yes. 12:06:35

Q -- it's Exhibit 2119, and I'll give you a copy of that document just so you can have it.

(Exhibit 2119 was introduced.)

MR. TRAUPMAN: So I've marked -- or presented to you what has been previously marked as Exhibit 2119. It's a copy of the EYLEA label, and it's referenced in, for instance, paragraph 170 of your report. 12:06:46

Q Do you see that?

A I'm sorry. Which paragraph? 12:07:02

Q 170, but it's in many of the -- many of the paragraphs, starting at 170.

And you're familiar with the EYLEA label, right?

A Yes. 12:07:17

Q Right. 12:07:18

But then getting to paragraph -- back to -- sorry to keep jumping around. Just trying to orient ourselves -- back to paragraph 184, that's where you talk about limitation 1.e, relating to the exclusion criteria, correct? 12:07:31

A Correct.

Q And -- and feel free to review. Paragraph 184 is a long one. It spans over a page.

But you would agree with me that you don't cite the EYLEA label at all in paragraph 184, right? 12:07:49

A What was your question about 184?

Q Yeah, the EYLEA label, Exhibit 2119, is not cited anywhere in paragraph 184 of your declaration, correct? 12:08:52

A Are you referring to citing footnotes or...?

Q There's one footnote. It's footnote 62. I'll include that in my question.

There's no citation to the EYLEA label in paragraph 184, including footnote 62, of your declaration, right, Doctor? 12:09:07

MS. STRUTHERS: Bless you.

THE WITNESS: Paragraph 184, which I wrote, is under the -- that the heading that both 12:09:38

the EYLEA label and the physicians' administration of EYLEA practice the challenged claims.

MR. TRAUPMAN: Understood.

Q But, again, in the text of paragraph 184, including footnote 62, there's no citation to the EYLEA label, correct? 12:09:42 12:09:57

A I agree that in 184 I do not put a specific footnote regarding the EYLEA label.

Q Not only in a footnote; you don't have any citation -- there's no mention of the EYLEA label anywhere in paragraph 184, right, Doctor? 12:10:46

A I put in my declaration the reference to the EYLEA label at the beginning of the section 10 on page 77. And in this section, I discuss that "BOTH THE EYLEA LABEL AND THE PHYSICIAN'S ADMINISTRATION OF EYLEA PRACTICE THE CHALLENGED CLAIMS." Paragraph 184 is under that section header. 12:11:18

Q Right.

Let me just -- let's orient -- let's orient ourselves. Limitation 1.e states: "wherein" the "exclusion criteria for the patient include all of: (1) active intraocular inflammation; (2) active ocular or periocular infection; (3) any ocular or periocular infection within the last 2 weeks prior to treatment." 12:11:35 12:12:00

Correct?

A Yes, I see those words.

Q Right.

That's what you've defined as limitation 1.e, correct? 12:12:03 12:12:09

A Yes.

Q Right.

And you have a subsection 6 in your declaration for limitation 1.e. 12:12:19

Do you see that?

A Yes.

Q And that subsection -- it's two pages long, but it's all one paragraph, paragraph 184, correct? 12:12:30

A Yes.

Q Okay. And you would agree with me, Doctor, that you don't, in paragraph 184, refer to or reference the EYLEA label in that paragraph of your declaration, correct? 12:12:44

MS. STRUTHERS: Objection. Asked and answered. The document speaks for itself.

THE WITNESS: I stated that -- in section 184, I discuss how I evaluate a patient in clinical practice by examining them, actively looking in their eye, and determining if there are any other active conditions at that time that would affect whether or not I administer the intravitreal anti-VEGF agent. 12:13:12 12:13:16

BY MR. TRAUPMAN:

Q In paragraph 184, can you point to me where you cite the EYLEA label? 12:13:42

MS. STRUTHERS: Objection. The document speaks for itself.

THE WITNESS: In this part of my declaration, I discuss how I actively evaluate the patient to look for any active inflammation or active infection at the time of the evaluation that would change my recommendation for an intravitreal injection of EYLEA at that time point and that practices the claim of actively evaluating the patients for any of the exclusion criteria. 12:14:26 12:14:59

BY MR. TRAUPMAN:

Q Doctor, my question was if you can point to me where in paragraph 184 you cite to or refer to the EYLEA label in that paragraph of your declaration. 12:15:25

Can you point to me where that -- where that occurs?

A I see that I did not include a footnote in that paragraph concerning the EYLEA label, but this paragraph discusses the active evaluation that is performed by myself or a skilled artisan in evaluating a patient at the time of a possible intravitreal injection to determine if they -- if that patient had any of the exclusion criteria that were mentioned in the claim. 12:15:45 12:15:50 12:16:21

Q Okay. You have the EYLEA label in front of you there, right, Exhibit 2119?

A Yes. 12:16:42

Q Can you point to me where the EYLEA label instructs physicians not to inject into a patient with any ocular or periocular infection within the last two weeks prior to treatment?

MS. STRUTHERS: Objection. Beyond the scope. 12:16:58

THE WITNESS: Could you repeat the question?

MR. TRAUPMAN: Yes.

Q Where in the EYLEA label that's in front of you as Exhibit 2119 does it instruct a healthcare practitioner not to perform an injection in a patient with an ocular or periocular infection in the last two weeks prior to treatment? 12:17:02

MS. STRUTHERS: Objection. Beyond the 12:17:20

scope.
THE WITNESS: In my declaration, I did not specifically discuss the EYLEA label in regards to that; and, therefore, in order to accurately answer that question, I'd have to carefully read over the label and prepare, you know, an accurate answer to -- to provide you with a correct answer.
BY MR. TRAUPMAN:
Q Did you carefully review the EYLEA label before signing your declaration in October? 12:17:21 12:17:40 12:17:57
A I did review the label.
Q Carefully?
MS. STRUTHERS: Objection. Argumentative.
You can answer.
THE WITNESS: I did review the label, yes. 12:18:13
BY MR. TRAUPMAN:
Q Carefully, though? Did you carefully review it?
You said you'd have to carefully review the label before you could answer my question. 12:18:19
I'm wondering if you carefully reviewed the label before you signed your declaration in October of this year.
A Yes, I did review the label.
Q Did you review it carefully, though? 12:18:30

MS. STRUTHERS: Objection. Argumentative. 12:18:32
THE WITNESS: I reviewed it very thoroughly.
MR. TRAUPMAN: Okay.
Q So in paragraph 184 -- the one we've been talking about here for a little while -- I'm at the bottom of the page 84 of your declaration. The last line of that -- of that page states: "It is rare that patients present with active" -- 12:18:53
Are you there? I'm sorry. 12:19:19
A Yes, I see it.
Q Let me start over.
"It is rare that patients present with active ocular or periocular infection, active intraocular inflammation, or history of prior ocular or periocular infection within the last two weeks. Such issues arise only in less than 2 percent of the cases." 12:19:29
Do you see that?
A Yes, I see those words. 12:19:41
Q Okay. So those are -- in that sentence, those are the three claimed exclusion criteria, correct?
A Yes, they are.
Q Right. 12:19:50

And in your experience, a patient presents with one of the three exclusion criteria in less than 2 percent of the cases, correct? 12:19:50
A I stated that it is rare that patients present with active ocular or periocular infection, active intraocular inflammation, or a history of prior ocular or periocular infection within the last two weeks. 12:20:08
Q Right.
And then you go and say: "Such issues arise in only less than 2 percent of the cases." 12:20:21
Right?
A Yes, I stated that.
Q Right.
That statement is based on your personal experience; is that right? 12:20:30
A Yes, that's based on my clinical practice.
Q Right.
Your high-volume clinical practice that you've been doing now for almost 20 years, right? 12:20:38
Sorry to make you feel old.
A Yes, I've been in clinical practice for a while now.
Q Since 2005, right?
A Yes. 12:20:52

Q Okay. So that's 18 years, then, right? 12:20:53
A Yes.
Q Okay. Did you always have a high-volume clinical practice, Doctor?
A When I first began my academic career, I can recall it probably was not as busy as it is now. 12:21:07
Q Okay. All right. So two perc- -- less than 2 percent of the cases present with one of the three exclusion criteria.
And then you go on -- I'm just reading now from the declaration: "When this does happen, I determine whether to administer the intravitreal injection of the VEGF antagonist or whether to wait and treat the condition, if needed." 12:21:32
Did I get that right? 12:21:47
A Yes, I see those words.
Q And that's what -- that's what you actually do in practice.
You're accurately describing your clinical practice here, correct? 12:21:54
A Yes.
Q Okay. And then in -- you go on to say: "In certain of these cases (less than 1%) I do determine to withhold the injection, i.e., exclude the patient from treatment, at least temporarily." 12:22:09

Right? 12:22:12
A Yes, I see those words.
Q Right.
And I just want to understand the math here. I think it's apparent, but I just want to 12:22:16 make sure.
You're talking about 1 percent of all of the patient population, not 1 percent of the less than 2 percent that present with the exclusion criteria; is that correct? 12:22:26
A Correct.
Q Right.
In other words -- so in other words, in less than 1 percent of the total patient population that you would consider administering intravitreal 12:22:39 injection to, you withhold the injection on the basis of the exclusion criteria; is that correct?
A Yes, in my declaration, I state that, you know, after actively assessing the patient and examining them, if they have an active infection or 12:22:58 inflammation at that time, I have to determine whether or not to administer the anti-VEGF agent. And in less than 1 percent of the total patients I see do I withhold the injection.
Q Thank you. 12:23:25

My only point is: It could be 1 percent 12:23:26 of the whole or 1 percent of the already limited 2 percent.
A Yes.
Q And I was just trying to clarify: It's 1 12:23:33 percent of the whole, not 1 percent of 2 percent?
A Yes.
Q Okay. Great.
Okay. So -- and I want to understand -- so obviously there's a subset of patients that have 12:23:47 one or more of the exclusion criteria, where you then make a clinical decision to move forward with the intravitreal injection; is that right?
A Could you repeat the question?
Q I mean, I think it flows from the math. 12:24:03
You say 2 percent of the patients have -- less than 2 percent have one of the three exclusion criteria, right?
A Yes.
Q But yet only less than 1 percent have the 12:24:12 injection withheld, correct?
A Yes.
Q So I think the logic dictates that there is some subset of the patient population that has one or more of the exclusion criteria, yet 12:24:26

nonetheless gets the intravitreal injection as 12:24:30 scheduled.
Is that correct?
A That is correct.
Q Can you explain how you make the 12:24:39 determination clinically to move forward with an intravitreal injection even if the patient has one or more of the claimed exclusion criteria?
A Again, I didn't go into that detail in my declaration, but I would have to actively, you know, 12:25:03 evaluate the patient, examine them, look at additional retinal imaging to determine whether or not to give an anti-VEGF injection, and looking at the totality of the evidence in front of me, I would have to make a determination. 12:25:31
Q Are there any guidelines that help inform the determination, looking at the totality of the evidence?
A Which guidelines are you referring to?
Q I'm asking. I don't know if there are 12:25:51 any.
You know, I'm asking -- I'm asking how you, as a practicing clinician -- how you go about making a determination to move forward with a intravitreal injection, not withstanding the fact 12:26:04

that a patient has one or more of the claimed 12:26:06 exclusion criteria.
And so my question is: Are there guidelines that you consult for that determination?
A I didn't discuss in my declaration, you 12:26:28 know, specific details of guidelines; and so in order to answer that question, I'd have to look at resources to give a more accurate answer for you.
Q I'm trying to understand the basis for your -- your statement in your declaration that 12:26:52 there's times where you move forward with an intravitreal injection, notwithstanding the fact that you've identified one or more exclusion criteria in the patient; and you're saying, beyond the words that are in your declaration, you -- you 12:27:06 can offer no additional details.
Is that your testimony, Doctor?
MS. STRUTHERS: Objection. Mischaracterizes the testimony.
THE WITNESS: I'd have to look back at my 12:27:16 clinical practice and records to refresh my memory on those specific cases, and that's why I couldn't give you an answer at this time, because I'd like to give you an accurate answer. And to do so, I'd have to review those records more closely. 12:27:32

BY MR. TRAUPMAN: 12:27:38
Q How did you come up with the 2 percent number?
Did you review records to come up with the 2 percent number that's in paragraph 184 of your -- 12:27:42
your report?
A Yes. In order to come up with that estimate, I reviewed my clinical practice records to estimate that number.
Q And I take it, then, you also reviewed 12:28:12
your clinical practice records to estimate the 1 percent number that's the subset of the 2 percent; is that correct?
A In order to determine that, I did review my clinical records to come up with that estimate. 12:28:29
Q So if you -- if you go to paragraph 15 of your declaration, please, Doctor, here you have your -- you say (as read): "In forming my opinions, I reviewed at least the following materials" -- and you list the materials. 12:29:47
A I see that paragraph.
Q Right.
And you didn't identify any clinical practice records in paragraph 15, correct?
A I do not see those exact words. 12:30:14

Q Did you make the clinical trial records 12:30:16
that you reviewed in preparing your opinions in paragraph 184 an exhibit to these proceedings?
A No, I did not.
Q Okay. We can go back to paragraph 184, 12:30:50
please.
So I believe -- by the way, just -- would you agree with me that exclusion criteria are mandatory?
A Yes, exclusion criteria are mandatory. 12:31:21
Q Okay. And you would agree with me that, in your practice, the three claimed exclusion criteria, you don't -- you view them as mandatory, correct?
MS. STRUTHERS: Objection. 12:31:36
Mischaracterizes the testimony.
THE WITNESS: I do view them as mandatory.
BY MR. TRAUPMAN:
Q But yet you -- and -- but yet you don't follow them on at least some occasions, correct? 12:31:45
MS. STRUTHERS: Objection to form.
THE WITNESS: I do feel that the exclusion criteria are mandatory, and in those rare cases that I did not follow those exclusion criteria, I was not practicing the claimed method. 12:32:08

BY MR. TRAUPMAN: 12:32:10
Q In those rare cases, are the exclusion criteria not mandatory?
MS. STRUTHERS: Objection to form.
THE WITNESS: The exclusion criteria are 12:32:25
mandatory. In those rare cases where I did not follow exclusion criteria, I did not follow the claimed method.
BY MR. TRAUPMAN:
Q Well, let's talk about the -- let's talk 12:32:51
about the -- what you state here in paragraph 184.
So you talk about -- you say, again, back to that last sentence on page 184 [sic]: "It is rare that patients present with active ocular or periocular
infection, active intraocular inflammation, or 12:33:14
history of prior ocular or periocular infection within the last two weeks."
Right?
A Yes, I see those sentences.
Q "Such issues arise only in less than 2% 12:33:28
of" the "cases."
So those are the three claimed exclusion criteria, right?
A Yes. I'm speaking about my clinical
experience. 12:33:37

Q Right. 12:33:37
But the -- you quote verbatim the three claimed exclusion criteria --
A Yes.
Q -- in the sentence that I just read, 12:33:41
right?
A Yes.
Q Right.
And then you say: "When this does happen,
I determine whether to administer the intravitreal 12:33:46
injection of the VEGF antagonist, or whether to wait, and treat the condition." Correct?
A Yes, that's what I wrote.
Q Right.
And so that -- that's a step you take 12:33:57
every time one of the exclusion criteria -- you identify one of -- one or more of the three claimed exclusion criteria, correct?
MS. STRUTHERS: Objection.
Mischaracterizes the testimony. 12:34:08
THE WITNESS: Could you repeat the question?
MR. TRAUPMAN: Right.
Q Every time you identify that a patient has
one or more of the three exclusion criteria, you -- 12:34:13

the next step you do is determine whether to 12:34:16
administer the intravitreal injection of the VEGF antagonist or whether to wait and treat the condition, if needed, correct?
A I stated that when I identify one of the 12:34:31
exclusion criteria, I then, you know, evaluate the patient further and determine whether to administer the intravitreal VEGF antagonist.
Q And, in your opinion, that reflects
exclusion criteria -- that practice that you just 12:34:54
described reflects exclusion criteria that are mandatory?
MS. STRUTHERS: Objection to form.
THE WITNESS: In my declaration, I stated
that exclusion criteria are mandatory. 12:35:09
MR. TRAUPMAN: Right.
Q And I'm asking you whether or not the
practice that you described here, that we -- in these few sentences of paragraph 184, reflect
mandatory exclusion criteria. 12:35:20
MS. STRUTHERS: Objection to form.
THE WITNESS: In my declaration, I stated
that the exclusion criteria are mandatory; and in order to assess a patient for those, we'd have to
actively evaluate the patient, examine them, look at 12:35:42

all the evidence to determine if the eye had any of 12:35:46
the exclusion criteria.
BY MR. TRAUPMAN:
Q And that's what you, in fact, say you do
in clinical practice, right? 12:35:56
A I mention that, in clinical practice, I
evaluate the patient, examine them, and look for any signs of active inflammation or active infection, and evaluate the entire eye, yes.
Q Right. Right. 12:36:22
You perform an evaluation to determine
whether or not the patient present with active ocular or periocular infection, active intraocular inflammation, or history of prior ocular or
periocular infection within the last two weeks, 12:36:37
right?
A I stated in my declaration that I need to
actively evaluate and assess the patient to determine if any of these conditions are present.
Q Right. 12:36:55
And -- but that's what you actually do in
your clinical practice, correct?
A I do so in my clinical practice.
Q Do you do that every time you perform a
intravitreal injection? 12:37:03

A I evaluate the patient every time I 12:37:07
perform an intravitreal injection.
Q Do you -- every time you perform an
intravitreal injection, do you determine whether or not the patient has any of the three claimed 12:37:17
exclusion criteria?
A I actively evaluate the patient before I
perform an intravitreal injection to look for any of these exclusion criteria that would affect my
recommendation of an injection. 12:37:41
Q Right.
My question is: Do you do that for every
single intravitreal injection you perform?
MS. STRUTHERS: Objection. Asked and
answered. 12:37:48
THE WITNESS: As I stated, before
injections, I evaluate the patient and assess and look at any imaging or any other ancillary tests to look for any signs of active infection or active
intraocular inflammation or history of prior ocular 12:38:14
or periocular infection within the past two weeks.
BY MR. TRAUPMAN:
Q Is there any time when you're treating a
patient in the clinic where you don't make that
determination? 12:38:27

MS. STRUTHERS: Objection to form. 12:38:28
THE WITNESS: Could you answer [sic] that question?
MR. TRAUPMAN: I don't -- unfortunately,
I -- 12:38:34
THE WITNESS: Oh, could you -- I mean, can
you ask that question again? Excuse me. Can you ask that question again?
MR. TRAUPMAN: I'd love to answer all
these questions. 12:38:42
Sure.
Q Is there ever a time in your clinical
practice where you don't make a determination as to whether or not the patient has an active intraocular
inflammation, an active ocular or periocular 12:38:53
infection, or any ocular or periocular infection within the past two weeks prior to treatment?
A I can't recall that -- I didn't do those
steps. I'd have to review all the charts to accurately answer that question. 12:39:16
Q Okay. And then, your clinical practice
is, then, when you identify one of those -- one or more of those three conditions, you make a
determination whether to move forward with the
intravitreal injection or withhold it, correct? 12:39:33

A If I identified one of those criteria, I would have to further assess the patient and determine, you know, what the next steps would be. 12:39:41

Q Right.

And one potential is that the patient still gets the intravitreal injection. 12:39:53

That's you what you state in paragraph 184, correct?

A Yes, that's one possibility.

Q And one possibility is the patient obviously has the injection withheld for some period of time, correct? 12:40:01

A Yes, that's another possibility.

Q In a clinical trial, though, that has exclusion criteria, there wouldn't be an option to continue with the intravitreal injection if one of the three exclusion criteria were met; you would have to stop as soon as you identify a patient with one or more exclusion criteria, correct? 12:40:15

MS. STRUTHERS: Objection. Incomplete hypothetical. 12:40:30

THE WITNESS: Could you repeat the question?

MR. TRAUPMAN: Yeah.

Q So let -- let's assume that you're doing a 12:40:34

clinical trial with these three exclusion criteria. 12:40:38

Are you with me?

A Yes.

Q And you identify a patient with one of the three exclusion criteria, okay? 12:40:47

You with me?

A Yes.

Q In the situation of the clinical trial, you wouldn't have the option of making a further determination as to whether or not you can move forward with the injection, correct? 12:40:57

A I stated in my declaration that exclusion criteria are mandatory; and, therefore, in a clinical trial setting, if a patient met an exclusion criteria, they would be excluded. 12:41:21

Q Right.

You could not move forward with the administration of the intravitreal injection and be in compliance with the clinical trial protocols, correct? 12:41:33

A That is correct.

Q Now, in your clinical practice, do you consider any other factors, other than the three claimed exclusion criteria, to determine whether or not to withhold an intravitreal injection from a 12:42:03

patient? 12:42:06

A Would you repeat the question?

Q Yeah.

Do you consider any other factors, other than the three claimed exclusion criteria, in your practice to determine whether or not it might be inappropriate to move forward with an intravitreal injection? 12:42:17

A What other factors are you thinking of?

Q I'm not trying -- I'm asking you -- or you're the expert who treats -- treats these patients in a high-volume practice, so I was hoping you could give me some elucidation of that fact, Doctor. 12:42:34

I'm wondering whether or not, other than the three specific exclusion criteria, there's any other factors you consider, when you're in the examination room with a patient, to determine whether or not you should move forward with an intravitreal injection. 12:42:48

A I always, you know, assess the patient; make sure, you know, especially, you know, the first time I see the patient, that they actually have an angiogenic eye disorder; and make sure they can give informed consent. And if they do not have any 12:43:06 12:43:24

exclusion criteria and if my assessment does not show any other reasons for their vision loss, most likely I would proceed with an injection. 12:43:33

Q Right.

Well, let me ask: I mean, high intraocular pressure, would that be a potential reason to withhold an intravitreal injection? 12:43:56

A Intraocular pressure is one assessment that would be performed during the evaluation of a patient, and there could be a possibility that high eye pressure would be something to be evaluated to determine if or -- 12:44:27

Q Right.

A -- what was going on in the patient's eye.

Q Right. 12:44:49

And you would agree with me that a patient can have high intraocular pressure and not have any of the three claimed exclusion criteria, correct?

It's possible to have a high intraocular pressure and not have any of the three claimed exclusion criteria, correct? 12:45:10

A A patient could have high eye pressure, yes.

Q And not have any of the three exclusion criteria, correct? 12:45:24

A I'd have to assess the patient to determine what he or she has. 12:45:27

Q Right.

But it's possible -- for instance, glaucoma -- to have high eye intraocular -- intraocular pressure and not have any of the three claimed exclusion criteria, correct? 12:45:34

A Again, I would have to evaluate the patient to determine what was occurring in the eye.

Q Right. Right. 12:45:53

A glaucoma is characterized by, among other things, high intraocular pressure, correct?

A Again, I did not discuss glaucoma specifically in my declaration, and so I wouldn't want to answer glaucoma questions right now. 12:46:13

Q Do you really not -- are you going to sit here and testify that you're an ophthalmologist who has been practicing for 18 years and you don't know that glaucoma is characterized by, among other things, intraocular -- high intraocular pressure? 12:46:27

Are you going to --

MS. STRUTHERS: Objection. Argumentative.

BY MR. TRAUPMAN:

Q Are you going to look into that camera and give that testimony? 12:46:34

I -- I -- 12:46:34

MS. STRUTHERS: Counsel, please stop badgering.

MR. TRAUPMAN: I welcome you to do that, Doctor. 12:46:38

MS. STRUTHERS: Objection. Argumentative.

Do you have a question?

MR. TRAUPMAN: Yes.

Q Is glaucoma characterized by high intraocular pressure, Doctor? 12:46:46

A I would be happy to answer that question, but there are different forms of glaucoma; and in order to give you the most accurate explanation, I would need to take time, prepare a detailed, careful response. 12:47:07

And at this time, since I didn't opine on that in my declaration, I don't feel comfortable explaining all of glaucoma to you at this time.

Q I'm not asking you to explain all of glaucoma with me, just whether or not you want to agree -- whether or not you'd agree that high intraocular pressure is a common symptom of glaucoma. 12:47:17

A In my declaration, I did not discuss glaucoma and high intraocular pressure; and, 12:47:39

therefore, I wouldn't want to delve into that topic without proper preparation. 12:47:47

Q Well, see, here's -- here's why I'm trying to get back to your declaration, because you did testify -- you did testify in your declaration, in paragraph 184, that you measure a patient's intraocular pressure, and I assume you don't do that -- strike that. 12:48:01

I assume you measure a patient's intraocular pressure before administering an intravitreal injection for a reason, right? 12:48:12

A Yes, I did mention that, as a part of my assessment of the patient, I check the pressure, evaluate the patient.

Q Right. 12:48:27

And that's because if the pressure is not within a clinically appropriate range, it might be cause to withhold the intravitreal injection, correct?

A In my declaration, in -- on page 84, I mention that intraocular pressures are assessed. I also mentioned that the patient's eyes are dilated and the images of the patient's retinas are captured on imaging. 12:48:49

I did not discuss glaucoma in my 12:49:05

declaration and -- 12:49:09

Q I didn't mean to get sidetracked by glaucoma, but you seem to be resisting a -- what I would, you know, think would be a pretty noncontroversial point, that a patient can have high intraocular pressure and not have an active -- and not have an active intraocular inflammation, an active ocular or periocular infection, or any ocular or peri- -- periocular infection within the last two weeks prior to treatment, and I just want to know whether or not you agree with that or not. 12:49:18 12:49:39

MS. STRUTHERS: Objection to form.

THE WITNESS: Could you repeat the question?

MR. TRAUPMAN: Yes. 12:49:46

Q Could a patient have high intraocular pressure and not have any of the three claimed exclusion criteria, which I'm not going to reread to you for -- in the interest of time?

A I stated that high eye pressure could be a possibility. 12:49:59

Q Of what?

A In any patient.

Q Right.

And a patient who doesn't have any of the 12:50:08

three exclusion criteria could still have high eye pressure, correct? 12:50:10

A I would have to evaluate the patient to determine if they had any of the exclusion criteria.

Q Right. 12:50:24

But you could evaluate the patient, first take his or her intraocular pressure, realize that it's high, conduct a further evaluation, and also under- -- come to the conclusion that he or she does not have any of the three exclusion criteria, 12:50:37 correct?

A Again, in order to answer the question, I'd have to, you know, evaluate the patient and determine, you know, what is causing the high eye pressure. 12:50:53

Q Okay. Is it -- in your high-volume clinical practice, have you ever seen a patient with high intraocular pressure who doesn't have any of the three claimed exclusion criteria?

A I would have to review my medical records to give you the proper answer to that question -- 12:51:12

Q Right.

A -- and so I can't answer that right now.

Q Right.

Those are the same records you reviewed to 12:51:19

come up with the 1 and 2 percent numbers, right? 12:51:20

MS. STRUTHERS: Objection.

BY MR. TRAUPMAN:

Q Right?

A (Witness nods head.) 12:51:26

Q You have to answer audibly.

A Yes, but I was reviewing it for a different purpose.

Q Understood.

MS. STRUTHERS: We've been going for about an hour. 12:51:43

MR. TRAUPMAN: Yep.

MS. STRUTHERS: So whenever --

MR. TRAUPMAN: I'm al- -- yep. I'm almost done. 12:51:47

MS. STRUTHERS: Okay.

BY MR. TRAUPMAN:

Q So would you -- would you agree with me that there are other exclusion criteria that you apply when assessing to move forward with an intravitreal injection of a VEGF agent other than the three claimed exclusion criteria? 12:51:51

MS. STRUTHERS: Objection to form.

THE WITNESS: What was the question?

MR. TRAUPMAN: Yes. 12:52:03

Q Are -- when you're con- -- paragraph 184, our favorite paragraph, when you're conducting that -- that examination that you describe in paragraph 184, are there any other exclusion criteria that you apply when determining to -- 12:52:04 12:52:16 whether or not to move forward with an intravitreal injection other than the three that are claimed by the challenged claims?

MS. STRUTHERS: Same objection.

THE WITNESS: As I stated, I'm evaluating the patient, evaluating the entire eye on examination and looking for any of these exclusion criteria that might change my recommendation for a treatment. 12:52:31

MR. TRAUPMAN: Right. 12:52:51

Q And when you say "these exclusion criteria," it's more than just the three recited in the claims?

MS. STRUTHERS: Objection. Mischaracterizes the testimony. 12:52:59

THE WITNESS: I stated, when I'm evaluating the patient, I am looking for any signs of inflammation or infection. I'm also reviewing, you know, any imaging studies, any past medical records to look for any of the three exclusion 12:53:32

criteria. 12:53:41

MR. TRAUPMAN: Right.

Q Do -- my question, though, is: When you're performing the evaluation you describe in paragraph 184, do you apply only the three recited exclusion criteria, or are there other exclusion criteria that you apply when performing the evaluation described in paragraph 184 before moving forward with an intravitreal injection of a VEGF agent? 12:53:49 12:54:05

MS. STRUTHERS: Objection to form.

THE WITNESS: I'm looking at the entire eye and looking for other causes of vision loss that could be the culprit for the patient's symptoms.

MR. TRAUPMAN: That's not really my question. 12:54:36

Q Do you apply any exclusion criteria, other than the three recited in claim 1 of the '681 patent, when performing the evaluation you describe in paragraph 184 of your declaration? 12:54:44

MS. STRUTHERS: Objection to form. Asked and answered.

THE WITNESS: I do assess the entire eye. I look for any other conditions that could be contributing to the patient's symptoms, while also 12:55:04

evaluating for any of the exclusion criteria. 12:55:09
BY MR. TRAUPMAN:
Q All right. So if you go to para- -- take the patent. It's right over there. Go to column 11. And right around line 35 -- you understand this 12:55:24 is a column -- this column 11 describes a series of exclusion criteria, Doctor? You're familiar with that, right?
A Yes.
Q And No. 17 is (as read): "Uncontrolled 12:55:48 glaucoma (defined as intraocular pressure greater than or equal to 25 millimeters of mercury despite treatment with anti-glaucoma medication) in the study eye."
If -- in your clinical practice, if a 12:56:03 patient presents with uncontrolled glaucoma -- and I'm not going to read the rest of it -- will you move forward with the intravitreal injection?
A Again, I would have to assess the whole patient and determine, you know, what was causing 12:56:19 that abnormal finding.
Q So if -- uncontrolled glaucoma may be a reason for you to withhold an intravitreal injection in your clinical trial practice [sic], Doctor?
A Again, I would have to assess the patient 12:56:52

and look at all the -- the data to come up with a 12:56:54 determination.
Q But it's certainly something you would consider?
A As part of my assessment, I would take 12:57:05 that into account.
MR. TRAUPMAN: Why don't we take a break.
THE VIDEOGRAPHER: This marks the end of Media No. 3. Off the record. The time is 12:57.
(Lunch Recess.) 12:57:17
THE VIDEOGRAPHER: This marks the beginning of Media No. 4 in the deposition of Dr. Diana Do.
Back on the record. The time is 1:33.
MR. TRAUPMAN: Welcome back, Dr. Do. 13:33:59
Q Are you -- Dr. Do, are you familiar with the VIEW 1 and VIEW 2 clinical trials?
A Yes, I am familiar with those trials.
Q How are you familiar with those?
A I've read the manuscript. 13:34:22
Q You weren't personally involved in those trials, correct?
A No, I wasn't personally involved.
Q Got it.
Are you familiar with the exclusion 13:34:33

criteria that were used in the VIEW 1 and VIEW 2 13:34:34 trials?
A I would love to see the manuscript to be refreshed on all those exclusion criteria.
Q Sure. I'd be happy to -- I'd be happy to 13:34:47 do that for you.
MR. CHOI: I have three copies. Well, that's one copy. Another copy.
MR. TRAUPMAN: All right. Let's -- okay. I -- I see. I see. These are -- let's do this kind 13:35:11 of in order. So we have to do a little bit of archeology here.
So let's start with this. This is -- this is what's been previously marked as 1016.
(Exhibit 1016 was introduced.) 13:35:26
MR. TRAUPMAN: This is the publication of the VIEW trial, but you can confirm that. I believe you've seen that before.
THE WITNESS: Yes, this is "Intravitreal Aflibercept (VEGF Trap-Eye) in Wet Age-related 13:35:36 Macular Degeneration" manuscript.
MR. TRAUPMAN: All right. And then I'm going to mark as Do 1 and 2 to Appendix 1 and 2 to that publication.
That's for you, Counsel. 13:35:58

MS. STRUTHERS: Thank you. 13:36:00
MR. TRAUPMAN: And I need -- do I have a copy here?
MS. STRUTHERS: I think I'm -- I think I'm missing the top paper. 13:36:04
MR. TRAUPMAN: Did I not hand you this one?
MS. STRUTHERS: Thank you.
(Exhibit 1 was marked for identification by the court reporter.) 13:36:24
THE WITNESS: Thank you.
(Exhibit 2 was marked for identification by the court reporter.)
THE WITNESS: Thank you.
BY MR. TRAUPMAN: 13:36:26
Q So, again, you see -- Do 1 and 2 are Appendix 1 and 2 to the VIEW -- VIEW trial manuscript.
Do you see that, Dr. Do?
A Yes. 13:36:55
Q And that looks familiar to you, right?
A Yes.
Q And the second -- in particular, the second appendix lists the exclusion criteria.
Do you see that? 13:37:08

A Yes. 13:37:10
Q And among the exclusion criteria that are listed are the three that are claimed by the challenged claims, correct?
A Which page are you referring to? 13:37:21
Q The exclusion criteria start at the -- roughly the middle of page 1, and I believe they continue through page 4, but you can correct me if you disagree.
A Yes, I see those exclusion criteria. 13:37:34
Q And you've seen these exclusion criteria before today, correct, the VIEW 1 and VIEW 2 exclusion criteria, correct?
A Yes.
Q And, in fact, the exclusion criteria that 13:37:46 are reflected in Appendix 2, which is Do Exhibit 2, are the same exclusion criteria that are listed in the '681 patent, starting at the bottom of column 10, line 58, and continuing through to column 12, line 24, correct? 13:38:08
A I think that is correct.
Q Thank you.
And as -- do you know, by the way, who came up with the exclusion criteria for the VIEW 1 and VIEW 2 trial? 13:39:17

A I do not know. 13:39:21
Q You don't know what methodology was used to come up with the exclusion criteria for the VIEW 1 and VIEW 2 trial?
A I wasn't a part of the study design 13:39:31 committee, and so I could not answer that -- that question accurately.
Q Right.
And in forming your opinions in this proceeding, you also didn't try to investigate how 13:39:43 the exclusion criteria for the VIEW 1 and VIEW 2 trials were developed, correct?
A In my declaration, I did not investigate who wrote the exclusion criteria, and I could not provide an accurate answer to that question at this 13:40:07 time.
Q Right.
And my question isn't limited just to the who, but it's also the how and the why of the exclusion criteria. 13:40:20
You don't know what materials were considered when coming up with this list of exclusion criteria, what exclusion criteria might have been considered and rejected, what the -- or -- strike that. Let me just -- 13:40:32

You don't know what process was followed 13:40:35 to come up with the exclusion criteria reflected in Do Exhibit 2; is that correct?
A In my declaration, I did not expand on why exclusion criteria were selected for this clinical 13:40:54 trial, so I couldn't answer that question accurately right now.
Q Right.
But as you do note in your declaration, the comparator for -- for this trial was Lucentis? 13:41:05
A Yes.
Q And by the time this clinical trial -- the VIEW 1 and VIEW 2 trials started, the MARINA and ANCHOR studies had been published, correct?
A Yes, that is correct. 13:41:24
Q So you would agree that prior to the start of the VIEW 1 and VIEW 2 trials, the exclusion criteria for the ANCHOR and MARINA studies were available to the study group that developed the VIEW 1 and VIEW 2, correct? 13:41:45
A The manuscript for the Lucentis phase 3 clinical trials were published and publicly available.
Q Prior to the start of VIEW 1 and VIEW 2, correct? 13:42:01

A Yes. 13:42:01
Q All right. So if you go to your declaration, paragraph 132, you summarize some of the exclusion criteria for ANCHOR and MARINA in that paragraph, correct? 13:42:43
A In that paragraph, I discuss some of the exclusion criteria of ANCHOR and MARINA clinical trials.
Q Right.
And I guess -- sorry. One other thing I 13:42:58 guess I should have just made sure we have agreement on is -- is: In the VIEW 1 and 2 exclusion criteria -- that's Do 2 -- each of the three claimed exclusion criteria are included in -- for VIEW 1 and VIEW 2, right? 13:43:16
I'll specifically call your attention to the first three bullets on the top of page 3.
A Yes, I see those sentences.
Q Right.
And they are verbatim the same as the 13:43:40 three exclusion criteria that are in the challenged claims, correct?
MS. STRUTHERS: Objection.
Mischaracterizes the document.
THE WITNESS: What was your question? 13:44:04

MR. TRAUPMAN: Sure. Let's maybe take it one step at a time.
Q Let's go to the claim. You have the patent in front of you; I don't. Give me one second. Here we go. 13:44:12
So if you have Do Exhibit 2 in front of you, on page 3, and the patent -- and let's just go maybe exclusion criteria by exclusion criteria.
So the patent says -- the first exclusion criteria is: "Active intraocular inflammation." 13:44:29
Do you see that?
A Yes. In the patent?
Q Right.
And the VIEW 1 and 2 exclusion criteria state: "An active intraocular inflammation in either eye." 13:44:40
Right?
A Yes, I see those words.
Q Right.
So you would agree that that is the same exclusion criteria in both the claim and the VIEW 1 and VIEW 2 trial, correct? 13:44:47
A I agree that those are similar.
Q The only thing that's different is the words "in either eye" in the clinical trial that's 13:45:03

not repeated in the claim, right? 13:45:07
A Yes.
Q And the second exclusion criteria in the claim is: "Active ocular or periocular infection"; and in the VIEW 1 and 2 trials, the exclusion was: 13:45:18
"Active ocular or periocular infection in either eye."
Right?
A Yes.
Q Right. 13:45:28
And save for the words "in either eye," those two exclusion criteria are the same, correct?
A Yes.
Q Okay. And in -- the third exclusion criteria in the claim is: "Any ocular or periocular infection within the last 2 weeks prior to treatment." 13:45:48
Correct?
A Yes.
Q And the VIEW 1 and 2 -- VIEW 1 and VIEW 2 states: "Any ocular or periocular infection within the last 2 weeks prior to screening in either eye." 13:45:55
Correct?
A Correct.
Q So what's your -- what's your 13:46:10

understanding what "prior to screening in either eye" refers to? 13:46:15
A I think "prior to screening" refers to the screening visit to see if the patient could be eligible for the clinical trial. 13:46:34
Q I see.
And so you -- do you think -- is that different than "prior to -- any ocular or periocular infection within the last 2 weeks prior to treatment"? 13:46:47
MS. STRUTHERS: Objection. Beyond the scope. Calls for speculation.
THE WITNESS: I could not answer that question right now because I was not, you know, involved in making these criteria or choosing these words; and, therefore, I don't have enough information to accurately answer that question. 13:47:11
BY MR. TRAUPMAN:
Q So you're unable, sitting here today, to offer opinions as to whether or not the third claimed exclusion criteria in the claim, which is: "Any ocular or periocular infection within the last 2 weeks prior to treatment," is different from the exclusion criteria in the VIEW 1 and VIEW 2 trials, which is: "Any ocular or periocular infection 13:47:35 13:47:52

within the last 2 weeks prior to screening in either eye;" is that correct? 13:47:53
MS. STRUTHERS: Objection. Mischaracterizes testimony.
THE WITNESS: Could you repeat the question? 13:48:02
MR. TRAUPMAN: Yeah.
Q You're unable, sitting here today, to offer opinions as to whether or not the third exclusion criteria in the patent, which I won't reread right now, is different from the exclusion criteria in Do Exhibit 2, which states -- says: "Any ocular or periocular infection within the last 2 weeks prior to screening in either eye"? 13:48:10
A I only mentioned that I do not know why they chose the word "prior to screening," but this was written for the clinical trial, Exhibit 2 Do. And I mentioned I was not involved in choosing the words for the exclusion criteria. 13:48:29
Q Right. 13:49:04
So you're not able to offer opinions on those words because you weren't involved in choosing them, correct?
MS. STRUTHERS: Objection. Mischaracterizes the testimony. 13:49:13

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THE WITNESS: I stated that I do not know 13:49:17
if the authors who wrote the exclusion criteria
intended to use the word "screening" to be similar
to "treatment" because I did not select the words
myself. 13:49:53
MR. TRAUPMAN: Got it.
Q All right. So back to paragraph 132 of
your declaration, please. I hope we're done with
Do 2.
Okay. And so you state in 132: "Notably, 13:50:21
the exclusion criteria of ANCHOR and MARINA differ
from those of the Challenged Claims in material
respects and, most relevant here, do not require
exclusion of subjects having had prior, as opposed
to active, ocular or periocular infection, let alone 13:50:37
exclusion of subjects having any ocular or
periocular infection within the specific two-week
time period specified in criteria 3."
Do you see that?
A I see that sentence. 13:50:53
Q Okay. So -- and, again, we've looked at
the comparison of the challenged claims exclusion
criteria and the VIEW 1 and VIEW 2 exclusion
criteria.
So you would agree with me, though, that 13:51:05

the VIEW 1 and VIEW 2 exclusion criteria differ from 13:51:07
the ANCHOR and MARINA exclusion criteria, correct?
A Yes, there are differences in the
exclusion criteria between these clinical trials.
Q Right. 13:51:23
So even though ANCHOR and MARINA were
published and available prior to the VIEW 1 and
VIEW 2 trials, the authors of VIEW 1 and VIEW 2
chose different exclusion criteria than the ones
used in ANCHOR and MARINA, correct? 13:51:36
A There are differences in the exclusion
criteria between ANCHOR and MARINA, and that -- and
those exclusion criteria are in VIEW 1 and VIEW 2.
Q And you don't -- you're not able, sitting
here today, to offer any opinions as to why the 13:52:03
exclusion criteria used for VIEW 1 and VIEW 2 differ
from those used in ANCHOR and MARINA?
A I was not part of the committee that
selected these exclusion criteria; and, therefore, I
could not answer that question without more 13:52:22
knowledge from the committee.
Q Okay. And you also don't know whether or
not the VIEW 1 and VIEW 2 committee considered the
exclusion criteria for ANCHOR and MARINA when they
developed the exclusion criteria for VIEW 1 and 13:52:39

VIEW 2, correct? 13:52:43
A I could not answer your question since I
was not part of the committee who derived these
exclusion criteria.
Q Right. 13:52:59
But it is your opinion that a person of
skill in the art, in January of 2011, would have
looked to the exclusion criteria for VIEW 1 or -- or
excuse me -- for ANCHOR and MARINA when designing a
clinical trial; is that correct? 13:53:12
A Can you point to me where I wrote that?
Q Sure. Paragraph 130.
What are you looking at? 132?
A Which sentence are you referring to?
Q Yeah. The first one. 13:53:44
You say: "In my opinion, if the POSA were
to look to the exclusion criteria of clinical trials
using different anti-VEGF agents in designing or
selecting exclusion criteria for the claimed methods
for treating patients, the POSA would consider 13:53:55
MARINA and ANCHOR to be much more reliable sources
for exclusion criteria than Samsung's MACTEL and
CATT references."
Correct?
A I see that sentence. 13:54:07

Q Right. 13:54:08
And so, again, your opinion is a POSA
would look to MARINA and ANCHOR when designing a
clinical trial, correct?
MS. STRUTHERS: Objection. The document 13:54:19
speaks for itself.
THE WITNESS: In my declaration, in
paragraph 130, I was discussing that (as read): "In
my opinion, if the POSA were to look at -- to look
to the exclusion criteria of clinical trials using 13:54:39
different anti-VEGF agents in designing or selecting
exclusion criteria for the claimed methods for
treating patients, the POSA would consider MARINA
and ANCHOR to be much more reliable sources for
exclusion criteria than Samsung's MACTEL and CATT 13:54:59
references."
I further explain in my declaration why
MacTel and CATT references would not be reliable
sources for the POSA.
BY MR. TRAUPMAN: 13:55:22
Q Well, let me ask you, just your opinion:
Would a person of skill in the art in January of
2011 have looked to the MARINA and ANCHOR studies
when designing or selecting exclusion criteria for
the claimed methods? 13:55:38

A Could you repeat your question again? 13:55:51
Q Yes. I'd be happy to.
Would a person of skill in the art in
January of 2011 have looked to the MARINA and ANCHOR
studies when designing or selecting exclusion 13:56:01
criteria for the claimed methods?
A In my declaration, I stated that "If the
POSA were to look to the exclusion criteria of
clinical trials using different anti-VEGF agents in
designing or selecting exclusion criteria for the 13:56:26
claimed methods for treating patients, the POSA
would consider MARINA and ANCHOR to be much more
reliable sources for exclusion criteria than
Samsung's MACTEL and CATT references" because ANCHOR
and MARINA were robust phase 3 clinical trials that 13:56:45
had published, positive safety results prior to
2010.
Q So -- thank you. I see that you've just
read paragraph 130 of your declaration, but that
really wasn't my question. 13:57:02
My question is a little bit different, and
it follows from what is written in paragraph 130,
but I can read just as -- along with you as well,
but my question is not just to have you read back
what's in your declaration. 13:57:14

My question, Doctor, is: Would a person 13:57:16
of skill in the art, in January of 2011, have looked
to the MARINA and ANCHOR studies when designing or
selecting exclusion criteria for the claimed
methods? 13:57:25
MS. STRUTHERS: Objection. Asked and
answered.
THE WITNESS: I answered your question by
correctly pointing to my declaration in which I
explained: "If the POSA were to look to the 13:57:44
exclusion criteria of clinical trials using
different anti-VEGF agents in designing or selecting
exclusion criteria for the claimed methods for
treating patients, the POSA would consider MARINA
and ANCHOR to be much more reliable sources for 13:58:00
exclusion criteria than Samsung's MACTEL and CATT
references."
MR. TRAUPMAN: Okay. Again, I'll just
note for the record all you did was read verbatim
paragraph 130, which I will move to strike as 13:58:15
nonresponsive because it doesn't answer my question.
But let me ask a different question.
Q Would a POSA look to -- when -- when
looking to administer VEGF agents to treat
angiogenic eye disorders, would a POSA look to 13:58:34

exclusion criteria of clinical trials using 13:58:39
different VEGF agents in designing or selecting
exclusion criteria?
A Could you repeat the question?
Q Sure. 13:59:02
If a POSA -- and you understand -- I say
"POSA," but person of skill in the art.
You understand that, right?
A Yes.
Q Okay. Just making sure -- 13:59:11
A An ophthalmologist.
Q In your definition.
Would a POSA who wants to administer VEGF
agents to treat angiogenic eye disorders -- would
that POSA look to exclusion criteria of clinical 13:59:29
trials using different VEGF agents in designing or
selecting exclusion criteria?
MS. STRUTHERS: Objection to form.
Incomplete hypothetical.
THE WITNESS: Could you repeat your 14:00:05
question one more time?
MR. TRAUPMAN: Sure.
Q Would a POSA who wants to administer VEGF
agents to treat angio- -- angiogenic eye
disorders -- would -- would they look to exclusion 14:00:16

criteria of clinical trials using different VEGF 14:00:20
agents in designing or selecting exclusion criteria?
MS. STRUTHERS: Same objections.
THE WITNESS: I wrote in my declaration
that the POSA who is looking at prior studies, such 14:00:47
as MARINA and ANCHOR, because they were robust
phase 3 clinical trials that had published, safety
data -- and the POSA would have looked to exclusion
criteria from these studies because such data would
be more informative as to the appropriateness of the 14:01:22
referenced exclusion criteria in the population that
the POSA intended to treat, page 55.
BY MR. TRAUPMAN:
Q Do you know whether or not the people who
designed the VIEW 1 and VIEW 2 trials were persons 14:02:39
of skill in the art?
A I do not know who designed the VIEW 1 and
VIEW 2 clinical trials; and, therefore, I couldn't
accurately answer your question at this time.
Q Okay. Well, let's look at -- look at the 14:03:02
authors of -- on -- on the publication of the
VIEW -- VIEW 1 and VIEW 2 trials.
Do you know any of those authors?
A I do know several of the authors.
Q Who do you know? 14:03:21

A I know Jeffrey Heier, David Brown, Victor Chong, Jean-Francois Korobelnik, Peter Kaiser, Quan Dong Nguyen, Allen Ho, Robert Vitti. I could name a few other ones: Ursula Schmidt-Erfurth, Alyson Berliner. 14:03:57

Q It's pretty good. You know a good number of those folks.

Let's talk -- let's start with Dr. Heier. I think he's the first-named author, and you mentioned you know him. 14:04:20

Would he have fit your definition of "person of skill in the art" in 2011?

A Dr. Heier is an ophthalmologist who treats patients with angiogenic eye disorders.

Q He's -- and I misspoke. I said "2001." I meant to say "2011," but I assumed your answer wouldn't be any different -- difference in ten years, correct? 14:04:38

A In 2011, he was an ophthalmologist treating patients with angiogenic eye disorders. 14:04:55

Q Right.

And I assume the same is true of Drs. Brown and Chong, correct?

A Yes.

Q Actually, all of the people you identified 14:05:12

that you know are MDs, correct? 14:05:15

A Yes.

Q Are they all ophthalmologists?

A I don't know if all of them are ophthalmologists. 14:05:29

Q Okay. But you can -- you know many of the people listed as authors in Exhibit 1016 are ophthalmologists, correct?

A Yes, many of them are ophthalmologists.

Q And you would have expected them to have been aware of the ANCHOR and MARINA studies, correct? 14:05:49

A Since Lucentis was already FDA approved, yes, I would expect them to be familiar with Lucentis. 14:06:11

Q Right.

And, again, Lucentis was the comparator for this clinical trial, of which they're authoring the paper describing the results, correct?

A Yes. 14:06:19

Q So you would expect them to be familiar with the ANCHOR and MARINA studies, correct?

A Yes.

Q And Lucentis -- just to confirm, Lucentis, when it was approved by the FDA, changed the 14:06:42

standard of care for the treatment of wet -- age-related macular de- -- age-related macular degeneration, correct? 14:06:46

A Yes, that is correct.

Q Would you agree with me that when Lucentis got FDA approval, it was a big deal in the field of retina care? 14:06:59

A Yes, Lucentis became the new standard of care in the treatment of angiogenic eye disorders after its approval. 14:07:27

Q All right. And yet the people who chose -- who designed the exclusion criteria for VIEW 1 and VIEW 2 chose not to follow the exclusion criteria of ANCHOR and MARINA, correct?

A Could you repeat your question? 14:08:05

Q Right.

The authors who designed the exclusion criteria for the VIEW 1 -- strike that.

The investigators who designed the exclusion criteria for the VIEW 1 and VIEW 2 clinical trials chose not to follow the exclusion criteria from ANCHOR and MARINA, correct? 14:08:17

A Again, I don't think I could answer that question completely because I do not know what the investigators were thinking at the time of the 14:08:55

planning of the clinical trial. 14:09:00

Q But you know what the exclusion criteria are for the VIEW 1 and VIEW 2 trials, right?

A Yes.

Q And as you note in paragraph 132 of your report, they're different from the exclusion criteria for ANCHOR and MARINA, correct? 14:09:11

A There are differences in the exclusion criteria.

Q Right. 14:09:27

And one of the one -- one of the differences you -- one of the -- one of the differences you call out between -- that the ANCHOR and MARINA didn't have was excluding patients who had prior ocular or periocular infection, correct? 14:09:43

A I stated in paragraph 132 that the exclusion criteria of ANCHOR and MARINA differed from those of the challenged claims and did not require exclusion of subjects having had prior, as opposed to active, ocular or periocular infection, let alone exclusion of subjects having had any ocular or periocular infection within the specific two-week period specified in criterion 3. 14:10:12

Q Right.

And, again, we've already been through 14:10:29

this, but the challenged claim exclusion criteria are reflected in the VIEW 1 and VIEW 2 exclusion criteria, correct?

A Yes.

Q Okay. So let's go forward in your declaration, if we could, Doctor, to -- well, we can start on 61 -- page 61. We're going to end up on 62.

You there?

A Yes.

Q Okay. We're at the bottom of the page. There's a subsection where you start talking about MacTel and CATT.

Let me ask you: Before you were involved in this proceeding, were you familiar with the CATT study?

A Yes, I was.

Q Okay. How did you, if you recall, become familiar with the CATT study?

A What time period were you referring to?

Q I'm wondering when you first became aware of the CATT study.

A I would have to look back at the specific date of when the CATT study started enrolling patients, but I was aware that a clinical trial was

being planned to evaluate Lucentis and off-label Avastin.

Q Right.

CATT was a clinical study that tried -- that did a direct comparison between Lucentis and Avastin, understanding that the Avastin was an off-label use, correct?

A Yes.

Q And that's because off-label use of Avastin to treat angiogenic eye disorders was fairly common practice, correct?

A That is correct.

Q Is it still common practice today?

A Off-label Avastin is still used in clinical practice today.

Q And I think you said you, yourself, use Avastin off-label in clinical practice from time to time, correct?

A Yes, that is correct.

Q Did the CATT study have an impact on clinical practice when it was -- once it was published?

A Yes, once it was published -- and that was after, you know, 2011 -- it did have an impact.

Q What was the impact?

A I'd have to look back to give you a thorough and complete answer to that question, but it compared Lucentis and off-label Avastin, and it showed that off-label Avastin was effective when dosed in a similar fashion to Lucentis.

Q Okay. And prior to your work on this proceeding, were you familiar with the MacTel study?

A Yes, I was.

Q How did you become familiar with Mac- -- MacTel study, again, prior to your work on this proceeding?

A I'll correct. I wasn't familiar with this particular study, but I was familiar with macular telangiectasia, the condition.

Q I see. So you were familiar with the disease.

It's a retinal disease; is that right?

A Yes, macular telangiectasia is a retinal disease.

Q But you weren't familiar with the MacTel clinical trial; is that correct?

A Correct. I was not familiar with this specific MacTel clinical trial.

Q Understood. Thank you.

I'm sorry. Give it to me one more time.

MacTel is macular tel- --

A Telangiectasia.

Q Tel- -- I'm going to write this down -- telangiectasia?

A Telangiectasia.

Q Telangiectasia. I'll do my best.

A That's why it's abbreviated MacTel.

Q The problem is, if I say "Mactel," we're talking about a paper and a disease.

A Yes.

Q So I've got to try to distinguish between the two of them so we don't lose both lose our minds here today.

Do you treat patients in your high-volume clinical practice who have macular telangiectasia?

A Currently there's no current effective treatment for macular telangiectasia, and so we don't treat patients with macular telangiectasia.

Q You may diagnose a patient with macular telangiectasia, but there's no treatment options; is that a correct statement?

A Correct. For the diagnosis of macular telangiectasia, there's no effective treatment.

If a patient with macular telangiectasia develops another condition, then we would obviously

treat that additional condition. 14:16:42
Q Got it.
Okay. So if we go to the next page of your declaration, page 62, please.
And you repeat a summary table from the 14:16:55 petition here at the top of the page, correct?
A Correct.
Q And that, then, is, in turn, quoting both the MacTel study and the CATT study on the right-hand column, correct? 14:17:29
A Yes.
Q And because I know you're going to mention it, I acknowledge that you have -- there was a typo that you noted in the footnote at the bottom of the page. So I thank you for calling that to our 14:17:37 attention, but -- so I just want to, you know, understand the words -- some of the words that are written here on the page because I think they have some technical meanings.
So looking on the right-hand column, the 14:17:50 MacTel study references: "Current acute ocular or periocular infection."
Do you see that?
A Yes.
Q Okay. And you agree -- I mean, you 14:18:12

confirm that's what the MacTel study says? 14:18:13
I'm just trying to move things along without showing you --
A Yes --
Q -- the exhibit yet. 14:18:18
A -- that's what the sentence says.
Q Okay. So I just want to try to understand: What -- what is your understanding of an acute ocular or periocular infection?
A Could you repeat the question? 14:18:58
Q Yeah.
What is your understanding of what an acute ocular or periocular infection is?
A On page 66, paragraph 149, I provide a definition of "acute," and I state that acute is 14:19:37 having a sudden onset, sharp rise in short course, such as an acute disease. And this was based on the Merriam-Webster's Medical Desk Dictionary.
Q Thank you, but I wasn't asking about the word "acute." I was asking about a series of words 14:20:07 that are "acute ocular or periocular infection."
As an expert ophthalmologist, can you tell us what that means?
A Could you repeat the question?
Q Yes. 14:20:31

What does "acute ocular or periocular 14:20:32 infection" mean?
A An "acute ocular or periocular infection" means a infection on the ocular surface or around the eye that has a sudden onset in a short course. 14:21:10
Q Okay. What length of time is a short course?
A In my declaration, I did not specifically discuss the definition of the length of a acute infection or the course of it specifically, and so I 14:22:04 would have to think over that more carefully to provide you with the most accurate answer.
Q I understand.
So sitting here today, you can't tell me what length of time is "a short course," as you used 14:22:31 that term, when defining "acute ocular or periocular infection"; is that correct?
MS. STRUTHERS: Objection.
Mischaracterizes the testimony.
THE WITNESS: I did not go into the 14:23:00 specific details regarding the definition of the length of an acute infection in my declaration; and in order to provide you with a comprehensive answer, I would need more time to -- to evaluate the topic to provide you with that answer. 14:23:32

BY MR. TRAUPMAN: 14:23:35
Q Okay. And what does it mean to have "sudden onset"?
Again, this term that you used.
A The term "sudden onset" confers a sense of 14:24:08 rapid onset of some occurrence.
Q Okay. So I guess we could keep on using different adjectives.
What length of time is either sudden or rapid when used in the context of acute ocular or 14:24:31 periocular infection?
A There are different types of infections; and in order to answer your question accurately, I would need more time and -- to review all the possible infections and give you a more thorough 14:24:58 answer to your question.
Q Okay. So that's not something you investigated prior to your declaration; is that correct?
A Could you repeat the question? 14:25:22
Q Right.
The length of time, as either sudden or rapid, when used in the context of acute ocular or periocular infection, that's not something you formed an opinion on prior to signing your 14:25:32

declaration on October 11th of this year, correct? 14:25:34
MS. STRUTHERS: Objection.
Mischaracterizes the testimony.
THE WITNESS: In my declaration, I discuss the exclusion criteria in the claimed methods, but I 14:25:50
did not delve into the definitions of the -- the exact time course of an acute infection; therefore, I couldn't answer that question completely right now without adequate time and preparation to provide you with an answer. 14:26:25
BY MR. TRAUPMAN:
Q All right. So we've been talking about the MacTel study, and I've been asking about the words "acute ocular or periocular infection."
Now let's add the last word in that quote, 14:26:43
which is "current."
What is a "current acute ocular or periocular infection"?
A A current infection would be an infection that one would diagnose at the time the physician 14:27:01
was evaluating the patient.
Q Right.
So at the time of the evaluation, the patient has some sort of microbe infecting the eye or area surrounding the eye; is that correct? 14:27:23

A Could you repeat the question? 14:27:34
Q Yeah.
So a current acute ocular or periocular infection is that the patient, at the time of the examination, has some sort of microbes that's 14:27:39
infectious -- infectious microbes in their eye or in the area around the eye, correct?
MS. STRUTHERS: Objection.
Mischaracterizes the testimony.
THE WITNESS: I said a current infection 14:27:55
is an infection that is occurring at the time of the diagnosis.
BY MR. TRAUPMAN:
Q Okay. How would you diagnose whether or not a patient has a current acute ocular or 14:28:25
periocular infection?
A In order to diagnose an infection, an ophthalmologist would have to examine the patient, look with a slit lamp biomicroscopy, do a guided fundus exam, evaluate all the evidence that is there 14:28:47
to come up with a diagnosis.
Q Would that include a patient history?
A Taking a patient history is also a part of the assessment.
Q And that would lead the ophthalmologist to 14:29:06

determine whether or not the patient has a current 14:29:10
acute ocular or periocular infection, correct?
A The ophthalmologist would have to evaluate the patient, examine the patient, look at all the
evidence in order to come up with a diagnosis of an 14:29:29
acute infection.
Q I just want to make it clear: I asked about a current --
A Okay.
Q -- acute infection. I just want to make 14:29:37
sure your answer is not any different.
To diagnose a current acute infection, an ophthalmologist would have to conduct an exam, a patient history, look in the slit lamp, do what
other kind of imaging, all the things that you 14:29:52
described -- that that's what they would have to do to determine if a patient has a current acute ocular or periocular infection, correct?
A That is correct.
Can you remind me the page you're 14:30:09
referring to again?
Q I'm on 62.
A Okay. Thank you.
Q How would an ophthalmologist determine when an infection -- an acute ocular or periocular 14:30:18

infection ends, such that it's no longer current? 14:30:23
A The ophthalmologist would need to examine the patient and do a thorough evaluation to determine if infection was resolved or if it was ongoing. 14:30:49
Q How could an examination of the patient determine whether or not an infection is resolved?
A If the exam is normal and there are no signs of infection, then the infection may be resolved. 14:31:19
Q So a visual examination would allow an ophthalmologist to determine that an acute ocular or periocular infection has resolved?
A Yes, an examination of the eye could help in that determination. 14:31:40
Q Well, what else -- you said "could help."
What else would an ophthalmologist consider, other than the examination, to determine whether or not an acute ocular or periocular infection had resolved? 14:31:52
A I think the basis would be the examination, but depending on where the ocular or periocular infection was located, additional ocular imaging may be used to help the ophthalmologist.
Q Okay. Let me -- let me just -- does 14:32:38

the -- does the -- any ongoing treatment for the ocular or periocular infection factor into whether or not the ophthalmologist concludes that the infection has resolved? 14:32:41

A What treatment are you referring to? 14:33:06

Q Well, I'd assume acute ocular or periocular infections, particularly bacterial ones, are oftentimes treated with antibiotics, are they not?

A In some cases, yes, they are treated with antibiotics. 14:33:17

Q Right.

Would the -- would the fact that a patient is still taking antibiotic treatment in an eye factor into the determination as to whether or not a patient has a current acute ocular or periocular infection? 14:33:30

A The ophthalmologist would have to examine the patient and evaluate them in order to make that diagnosis and assessment. 14:33:48

Q Would -- would part of that evaluation be considering whether or not the patient was on antibiotics, for instance?

A Understanding the medical history and the current medications is helpful. 14:34:06

Q Okay. I mean, let's maybe try and see if we can put a little more precision on this. 14:34:11

Would you agree that conjunctivitis is an acute ocular or periocular infection?

MS. STRUTHERS: Objection to form. 14:34:28

THE WITNESS: Can you repeat the question?

BY MR. TRAUPMAN:

Q Would you agree that conjunctivitis is an acute ocular or periocular infection?

A What type of conjunctivitis are you referring to? 14:34:42

Q Bacterial.

A And could you rephrase the question with that now?

Q Yes. 14:34:52

Would you agree that bacterial conjunctivitis is -- is an acute ocular or periocular infection?

MS. STRUTHERS: Objection to form.

THE WITNESS: Could you repeat the question? 14:35:09

MR. TRAUPMAN: Yes.

Q Would you agree that bacterial conjunctivitis is an acute ocular or periocular infection? 14:35:19

MS. STRUTHERS: Same objection. 14:35:19

THE WITNESS: Again, I did not, in my declaration, provide an opinion on bacterial conjunctivitis; and since there are multiple, you know, bacteria that could be involved, I would have to think this question over to give you a more complete answer. 14:35:50

BY MR. TRAUPMAN:

Q So I just want to understand your testimony. 14:36:03

You're -- sitting here today, you're unable to tell me, one way or the other, whether or not bacterial conjunctivitis is an acute ocular or periocular infection?

MS. STRUTHERS: Objection. 14:36:16

Mischaracterizes the testimony.

THE WITNESS: Although conjunctivitis could be acute ocular infection, I would need to do further analysis to answer your question completely, to describe and give you more details on the different presentations of bacterial conjunctivitis. 14:36:58

BY MR. TRAUPMAN:

Q I'm not asking for details on the different presentations of bacterial conjunctivitis, Doctor. 14:37:18

I'm simply asking whether or not the exclusion criteria in MacTel, which you say you considered and reviewed, which is a chronic acute -- excuse me -- current acute ocular or periocular infection -- does bacterial conjunctivitis fit within that description, "yes" or "no," Doctor? 14:37:18 14:37:32

MS. STRUTHERS: Objection. Argumentative. Asked and answered.

THE WITNESS: I think I already answered that question. 14:37:46

MR. TRAUPMAN: You didn't, respectfully, Doctor.

Q And I'm not going to pull any punches. I will present this testimony to the judges, who can evaluate your credibility. 14:37:56

I think conjunctivitis is a pretty common eye disease. Am I right -- I know that to be the case.

So I just want you to know, as an expert ophthalmologist, Doctor, whether or not you can say, one way or the other, whether or not current -- excuse me. Strike that. Let me start over. 14:38:06

I want you to say, one way or the other, Doctor, whether bacterial conjunctivitis is a current acute ocular or periocular infection, "yes" 14:38:20

or "no." 14:38:22
MS. STRUTHERS: Objection. Asked and answered. Argumentative.
THE WITNESS: As I stated, there are different presentations of bacterial conjunctivitis. 14:38:36
It could present as current acute ocular conjunctivitis.
And if you would like more information, I would have to have more time to research all the different presentations of bacterial conjunctivitis. 14:39:06
MR. TRAUPMAN: Let me ask -- sorry. I put the word "current" in, and I didn't mean to, so let me ask my question again.
Q Is bacterial conjunctivitis an acute ocular or periocular infection, Doctor? 14:39:17
MS. STRUTHERS: Objection. Asked and answered.
THE WITNESS: As I mentioned, bacterial conjunctivitis can present as acute ocular infection. 14:39:40
BY MR. TRAUPMAN:
Q Okay. Can you tell me: Does -- can bacterial conjunctivitis present as something other than acute ocular or periocular infection?
A As I stated, bacteria can cause 14:40:06

conjunctivitis, and there are different bacteria 14:40:10
that can be pathogens.
I did not describe all the forms of bacterial conjunctivitis in my declaration; and, therefore, I wouldn't be able to answer your 14:40:30
question completely without more time and preparation.
Q In forming your opinions in your declaration, did you consider the definition of "acute ocular or periocular infection"? 14:40:45
A I did consider the definitions, as I wrote in my declaration, in regards to page 66, paragraph 149, and the Merriam-Webster's Medical Desk Dictionary definition of "acute."
Q Okay. So you considered the definition of 14:41:23
"acute" in paragraph 149, correct?
A Yes.
Can I ask -- is there an extra shade? The sun is right in my eye.
MR. TRAUPMAN: Well, you know what? Okay, 14:41:37
why don't we just take a break. We've been going a little over an hour. We can get the shade taken care of.
THE VIDEOGRAPHER: This marks the end of Media No. 4. Off the record. The time is 2:41. 14:41:46

(Recess.) 14:41:49
THE VIDEOGRAPHER: This marks the beginning of Media No. 5 in the deposition of Dr. Diana Do. We're back on the record. The time is 2:53. 14:53:44
MR. TRAUPMAN: Welcome back, Dr. Do. The sun's not in your eyes anymore.
Q Before we took our break, we were on page 62 of your declaration. Okay. You're there now. Great. 14:53:59
Can you identify even one condition that fits within the definition of "acute ocular or periocular infection"?
A There are different conditions that can cause, you know, infections. One would have to 14:54:34
evaluate the patient to assess, you know, what the diagnosis is.
Q Can you name one condition of the eye that fits within the definition of "acute ocular or periocular infection," Doctor? 14:54:47
MS. STRUTHERS: Objection. Asked and answered.
THE WITNESS: There are many different conditions related to either bacterial or viral infections of the eye that could, at some times, 14:55:12

present acutely, such as viral conjunctivitis. 14:55:21
BY MR. TRAUPMAN:
Q Okay. So viral conjunctivitis can present as an acute ocular or periocular infection, correct?
A At times, viral conjunctivitis can present 14:55:46
as an acute ocular infection.
Q Okay. Are there times when viral conjunctivitis doesn't present as an acute ocular or periocular infection?
A I would have to do a little bit more 14:56:28
research to answer that question accurately. So at this time, I -- I couldn't give you a clear answer.
Q Okay. And is it fair to say the symptoms of viral conjunctivitis would be a pussy discharge?
A Again, in my declaration, I did not go 14:57:09
over the symptoms or presentation of viral conjunctivitis.
Q Right. I understand.
But you're also a trained ophthalmologist, right? 14:57:25
A Yes, I am.
Q Right.
You certainly have learned about viral conjunctivitis, right?
A Yes, I have learned about it. 14:57:31

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Q Right, right. 14:57:33
In your present- -- and viral conjunctivitis would present as watery, scratchy eyes, correct? Well, let me withdraw the question.
Would you agree that viral conjunctivitis 14:57:45 would present with some or all of the following symptoms: watery, scratchy eyes; mucusy discharge; inflammation of the conjunctiva?
A In order to diagnose viral conjunctivitis, an ophthalmologist would have to do a thorough 14:58:09 examination of the eye to detect any abnormalities.
And as I mentioned in my declaration, I did not go over the specifics of the findings related to viral conjunctivitis, because viral conjunctivitis can present in a variety of ways. 14:58:40
In order to give you the most accurate answer, I would need more time to carefully synthesize everything to give you the best and most accurate answer.
Q Okay. How would an ophthalmologist 14:59:01 determine whether or not viral conjunctivitis has resolved, such that it is no longer current -- a current acute ocular or periocular infection?
A A careful eye examination would inform the ophthalmologist about whether or not active viral 14:59:27

conjunctivitis was present or not. 14:59:35
Q Okay. And does that careful eye examination include a patient history?
A The assessment of the patient would include both examination and taking a history from 14:59:53 the patient.
Q All right. So let me ask: If a patient -- taking the pa- -- if the examination that you conduct as -- of a patient doesn't show any symptoms of viral conjunctivitis, but the patient 15:00:16 said, "I had these symptoms yesterday," is that -- is that going to be a case of current acute ocular or periocular infection or is that -- or is that then resolved?
A Could you repeat the question? 15:00:43
Q Sure.
Let's maybe develop this.
The patient -- you diagnose the patient with viral conjunctivitis because he or she has symptoms that you conclude is viral conjunctivitis. 15:00:53
Okay? You with me?
A Perhaps.
Q Okay. And you see the patient, just for a follow-up exam, five days later, okay?
You with me still? 15:01:11

A Trying to be. 15:01:14
Q Right.
The patient -- in conducting the follow-up exam five days later, all of the symptoms of the viral conjunctivitis have resolved. You don't see 15:01:22 any symptoms through your examination of the patient, but the patient tells you that he or she had -- still had symptoms the day before, so four days after the initial vision -- visit.
Based on that -- that description, does -- 15:01:40 does the patient still have a current acute ocular or periocular infection?
A I think it's challenging to follow this hypothetical case; and, as an ophthalmologist, we would want to, you know, evaluate the patient and 15:02:06 look carefully that day to assess for any acute infection.
Q Does a patient -- well, does a patient who's -- would you -- when -- I'm trying to understand when you can say -- how you could make a 15:02:31 determination whether a acute ocular or periocular infection is no longer current.
So, again, if a patient doesn't present with any symptoms in an exam but tells you they were experiencing symptoms the day before the exam, does 15:02:46

that patient have a current acute ocular or 15:02:49 periocular infection, Doctor?
MS. STRUTHERS: Asked and answered.
THE WITNESS: An ophthalmologist would have to evaluate the patient at the time of the 15:03:44 patient's presentation to determine if an active infection was present.
If the exam was normal, then there would be no active ocular infection at that visit.
BY MR. TRAUPMAN: 15:04:09
Q Even if the patient said they had symptoms of an infection the day before the visit?
A The ophthalmologist would have to synthesize all the data; but if the exam was completely normal, there would be no sign of an 15:04:31 ocular infection that was active at that time.
Q Okay. Can you tell us what your understanding of a chronic ocular or periocular infection is?
A In my declaration, I stated that the POSA 15:05:28 would understand that the terms "chronic" and "acute" are not synonymous. I refer to Merriam-Webster's Medical Desk Dictionary, for example, that defines "chronic" as: "marked by long duration, by frequent recurrence over a long 15:05:46

time, and often by slowly progressing seriousness." 15:05:51
Q Right.
You just read to me a paragraph in your report, right?
A Yes. 15:06:06
Q That's number -- what number paragraph is that?
A Paragraph 149.
Q 149. Right.
That -- the words "ocular" or "periocular" 15:06:17 don't appear in paragraph 149, do they, Doctor?
A I do not see those words specifically in that paragraph.
Q So, again, my question was: What's the meaning of the term "chronic ocular or periocular 15:06:38 infection"? Can you give that to us here today, please?
A In my declaration, I mention that the POSA would understand the terms "chronic" and "acute" when discussing, like, infection and that a chronic 15:07:07 infection would refer to something that was marked by long duration, by frequent recurrence over a long time.
Q You just read from paragraph 149 again, right? 15:07:30

A Yes. 15:07:31
Q That's the same paragraph that you just admitted that doesn't have the words "ocular" or "periocular" in it, right?
MS. STRUTHERS: Objection. Argumentative. 15:07:38
THE WITNESS: I recognize that the exact words "ocular" and "periocular" are not specifically in that paragraph, but I was referring to how the POSA would understand the terms "chronic" and "acute" when discussing chronic and acute conditions 15:08:05 such as an infection.
MR. TRAUPMAN: Great. I understand.
Q But my question was: What's the meaning of the term "chronic ocular or periocular infection"? Can you give it to us here, please, 15:08:22 Doctor?
MS. STRUTHERS: Asked and answered.
THE WITNESS: I stated that the POSA would understand that a chronic ocular or periocular infection would be one that was marked by long 15:08:38 duration, by frequent recurrence over a long time, and often by slowly progressing seriousness.
BY MR. TRAUPMAN:
Q Okay. In the context of an ocular or periocular infection, what is a "long duration," as 15:08:56

you used that term? 15:09:00
A In my declaration, I did not go into the specific details of the time length for a chronic ocular or periocular infection because there are different pathogens that can cause ocular or 15:09:27 periocular infections, and the duration is variable depending on the pathogen.
Q What does it mean to have a history within the past 30 days of a chronic ocular or periocular infection? 15:09:49
A Having a history means having a prior diagnosis of a chronic ocular or periocular infection within the past 30 days.
Q So is that -- I just want to understand.
So you're saying if you have a diagnosis 15:10:29 within the last 30 days of a chronic ocular or periocular infection, you have a history of chronic ocular or periocular infection?
A I think having a history of a prior ocular or periocular infection suggests that the patient 15:11:01 was evaluated and diagnosed with that condition at that prior time.
Q And "that prior time" here is within the last 30 days; is that correct?
A If you are referring to that sentence on 15:11:23

page 62, which uses the word "past 30 days" in the 15:11:27 MacTel study, then --
Q Right.
A -- you would be discussing that sentence.
Q That's my whole -- all of my questions 15:11:45 have been about that --
A Yes.
Q -- sentence. I hope that's been clear.
I'm asking: What does it mean to have a history within the la- -- past 30 days of a chronic 15:11:53 ocular or periocular infection? And that's what I'm asking about.
Now, I believe you said, if you have a diagnosis within the last 30 days, that would be a history within 30 days of a chronic periocular -- 15:12:05 ocular or periocular infection, but please correct me if I'm wrong, if I'm misunderstanding your testimony, Doctor.
A I stated that having a diagnosis would fall into the category of having a history within 15:12:25 the past 30 days of a chronic ocular or periocular infection.
Q Would you agree that chronic ocular or periocular infections can have periodic flare-ups?
A Yes, it's possible that chronic infections 15:12:42

could have recurrences. 15:12:55
Q When you say "recurrence," what do you --
what do you mean by "recurrence"?
A "Recurrence" would be, in the terms of a
chronic ocular or periocular infection, a period 15:13:17
where the disease becomes more active.
Q Okay. And would the period when the
chronic disease becomes more active -- would that be
a history within the past 30 days of a chronic
ocular or periocular infection, in your opinion? 15:13:43
MS. STRUTHERS: Objection to form.
THE WITNESS: Could you repeat the
question?
MR. TRAUPMAN: Yeah.
Q I believe you just said -- and please, 15:13:55
again, correct me if I'm wrong -- that you said a
chronic ocular or periocular infection can have
periods when the disease is more active.
Did I get that right?
A Yes, it could have recurrence of the 15:14:09
disease.
Q Right.
So, I mean, for instance, we can just take
what I hope we all agree, because it's right here
written down in -- on the page, an example of a 15:14:20

chronic ocular or periocular infection is herpes 15:14:23
zoster, correct?
A Yes.
Q And that's the virus that causes shingles;
same virus, right? 15:14:36
A Yes.
Q And so it's chronic because once you get
herpes zoster, you have it for the rest of your
life, correct?
A Yes. 15:14:47
Q But there are times when the herpes zoster
condition is dormant, correct?
A Yes.
Q And then there are times when the herpes
zoster condition is, I think, to use your word 15:15:07
"recurrent" or "active," correct?
A Yes, it could recur.
Q And by "recur," you mean become active,
correct?
A And when it recurs, the patient can have 15:15:27
more symptoms. There can be signs of, you know,
infection in the eye.
Q Right.
Because, as you said, once you have the
herpes zoster virus, you have it for the rest of 15:15:44

your life, right? 15:15:48
A In the case of herpes, that is true.
Q Right.
And so would you understand the MacTel
exclusion criteria, that's here on page 62, to 15:16:00
exclude every patient that has herpes zoster?
A Could you repeat the question?
Q Yes.
Does the exclusion criteria that you
quoted from the MacTel study, that's here on page 15:16:33
62, have every patient that has herpes zoster?
A In the MacTel exclusion criteria, it
specifically lists excluding any history of ocular
herpes zoster. So those patients would be excluded
from that MacTel clinical trial. 15:17:06
Q Okay. So even if the patient has -- has
no symptoms from the herpes zoster virus for more
than 30 days before the examination, your
understanding of the MacTel exclusion criteria is
that it would still exclude the patient because the 15:17:33
patient has been shown to have ocular herpes zoster?
A For the MacTel study, it lists that, in
the exclusion criteria, any history of ocular herpes
zoster would be excluded.
Q Okay. So let's -- in paragraph 152, you 15:18:13

give a second example -- many other examples of 15:18:29
chronic -- pathogens that cause chronic ocular or
periocular infection.
Do you see that?
A Yes, I see that. 15:18:47
Q Again, another example you list is
Epstein-Barr virus, correct?
A Yes.
Q Right.
And, again, that's another condition that, 15:19:02
once you get the Epstein-Barr virus, you have that
virus for the rest of your life, correct?
A Yes.
Q So same question that I had before.
Does the MacTel study, in your opinion, 15:19:18
exclude every patient who has been diagnosed with
Epstein-Barr virus?
MS. STRUTHERS: Objection. Form.
THE WITNESS: Could you repeat the
question? 15:19:48
MR. TRAUPMAN: Yes.
Q Does the MacTel study exclude every
patient who's been diagnosed with the Epstein-Barr
virus?
MS. STRUTHERS: Also beyond the scope. 15:20:13

THE WITNESS: Could you repeat the question?
MR. TRAUPMAN: Yes.
Q Does the MacTel -- I'm looking at -- you can look at the MacTel exclusion criteria on 62, but I'm also -- on 152, you specifically list MacTel exclusion criteria; and in that same paragraph, you mention the Epstein-Barr virus.
So I'm trying to understand whether, in your opinion, the MacTel exclusion criteria excludes every patient who's been diagnosed with Epstein-Barr virus.
MS. STRUTHERS: Objection. Beyond the scope.
THE WITNESS: I would have to take a look at all the exclusion criteria in the MacTel study in order to answer your question regarding Epstein-Barr virus.
BY MR. TRAUPMAN:
Q I'm talking about this exclusion criteria.
Does the exclusion criteria in MacTel, that reads "history within the past 30 days of a chronic ocular or periocular infection" -- does that exclude all patients who have been diagnosed with Epstein-Barr virus?

MS. STRUTHERS: Again, objection. Beyond the scope.
THE WITNESS: Again, I don't think I could answer your question at this time because I did not go into the details of the entire clinical course of Epstein-Barr virus; and to provide, you know, an accurate answer, I would need time to do more research and gather more information about that topic.
MR. TRAUPMAN: Understood.
Q So what -- I'm just trying to understand what it means to have a part of the MacTel exclusion criteria that says "history within the past 30 days."
What does -- what do the -- what do -- what does it mean to have a history within the past 30 days and a chronic ocular or periocular infection, Doctor?
A Again, I did not write these exclusion criteria for the MacTel study, and so I do not know what the authors were completely thinking about in regards to the meaning, but from the way it's written, it says: "A history within the past 30 days of a chronic ocular or periocular infection, including any history of ocular herpes zoster."

Q Okay. So how would you assess whether a patient has had a history within the past 30 days of a chronic ocular or periocular infection?
A Assessing a patient would involve examining the patient, taking a history, looking at any prior medical records, synthesizing all that data to come up with a diagnosis.
Q Right. But I guess I'm not asking you about a diagnosis.
How would you determine whether or not a patient did or did not meet the MacTel exclusion criteria that states: "History within the past 30 days of a chronic ocular or periocular infection, including any history of ocular herpes zoster"?
MS. STRUTHERS: Asked and answered.
THE WITNESS: The ophthalmologist would have to evaluate the patient, look carefully at the examination to see if there was any active infection. Part of the assessment would include taking a history, looking at prior medical records. And all of that data would be important to determine what condition the patient has.
BY MR. TRAUPMAN:
Q To determine whether or not a patient satisfied the MacTel exclusion criteria of history

within past 30 days of a chronic ocular or periocular infection, including any history of ocular herpes zoster, would the ophthalmologist conduct an examination of the eye?
A Part of the assessment would involve evaluating the eye, taking a medical history, and then synthesizing all of that data together.
Q Right.
And it would involve an examination using the slit lamp?
A Yes.
Q It would involve an examination following dilation to see the back of the eye, correct?
A Yes.
Q And it would involve an examination of taking the intraocular pressure, correct?
A Part of the evaluation would include assessment of intraocular pressure.
Q Okay. And so then the CATT study, right here on page 62 as well, has an exclusion criteria of: "Active or recent (within four weeks) intraocular inflammation (grade trace or above)" -- I'm going to read the correct version that you note in the footnote.
Do you see that?

A Yes. 15:26:52
Q How would an ophthalmologist assess whether a patient has had a recent, within the last four weeks, intraocular inflammation?
A An ophthalmologist would need to perform 15:27:16 an evaluation of the patient using the slit lamp biomicroscopy, dilated fundus exam, other imaging, if necessary, to look for signs of intraocular inflammation inside the eye.
Q Would that exam inform the ophthalmologist 15:27:41 whether or not the patient's had inflammation -- intraocular inflammation within the last four weeks?
A The exam would be helpful in identifying active intraocular inflammation at the time of the exam, and with the assistance of any prior medical 15:28:07 records and patient history, additional time course of the disease could be elicited.
Q Right.
And for instance, the CATT study, four weeks was the space between the -- the doses of the 15:28:36 administration of the VEGF agent, correct?
A Within the CATT study, one of the treatment intervals was four weeks.
Q Yeah. One of the arms was four. The other one was 12, right? 15:29:00

A Was as-needed treatment. 15:29:02
Q Okay. So I just want to understand. If a patient presents with an active ongoing infection, based upon an examination, you'd agree with me that that patient has had an ocular or periocular 15:29:45 infection within the last two weeks, correct?
MS. STRUTHERS: Objection to form.
THE WITNESS: Could you repeat the question?
MR. TRAUPMAN: Sure. 15:29:55
Q If a patient comes to your office; you have examined them; based upon your evaluation, both the clinical evaluation of the eye, the prior review of the medical records, the interview with the patient, anything else you want to do to conclude 15:30:10 that the patient has a current ocular or periocular infection -- you understand?
A No. Could you repeat the question again?
Q You've diagnosed a patient -- you've -- you've -- you've examined a patient and concluded 15:30:32 that the patient I just examined has a ocular or a periocular infection.
That's happened in your career before, right, Doctor?
A Yes. 15:30:42

Q Okay. In that situation, has a patient 15:30:43 had a ocular or periocular infection within the last two weeks?
MS. STRUTHERS: Objection to form.
THE WITNESS: If I diagnose a patient with 15:31:04 an active ocular or periocular infection that day, I know that they have an active infection at this time, but it may be challenging to determine when it started.
MR. TRAUPMAN: Right. 15:31:32
Q But if you make a determination that a patient has an active ocular or periocular infection at the day of the examination, you would agree that that is within the last two weeks of the day of the examination, correct? 15:31:43
MS. STRUTHERS: Objection. Form.
THE WITNESS: No, I don't agree because I would only know that the patient has an active ocular or periocular infection at that time, that day. 15:32:05
BY MR. TRAUPMAN:
Q Okay. Well, let's -- let's -- so you've said you've diagnosed a patient with an active ocular or periocular infection; that's happened before in your high-volume career over the last 18 15:32:17

years, right, Doctor? 15:32:20
A Yes.
Q Okay. And have you ever then told the patient to come back in two or three days for a follow-up visit based on that diagnosis? 15:32:28
A Yes, that has happened in the past.
Q That's happened in the past, great.
And when that patient comes back in two or three days and is still presenting with symptoms of the infection -- has that ever happened? 15:32:42
A Yes, that may happen.
Q Right.
So on that -- the day of that second exam, the follow-up exam, can you say that the patient has had a ocular or periocular infection within the last 15:32:54 two weeks?
MS. STRUTHERS: Objection. Incomplete hypothetical.
THE WITNESS: Again, I stated if I examine a patient that day and I diagnose an ocular or 15:33:09 periocular infection that day, I can say that the patient has an active ocular or periocular infection that day.
MR. TRAUPMAN: Right.
Q But I gave a little bit more context to my 15:33:29

hypothetical, where the patient that has a follow-up visit three days later and you continue to see symptoms and -- and diagnose that the infection still has not resolved. And in that situation, where you've seen a patient for the second time -- so you've seen a patient once on Monday and once on Thursday. On Thursday, can you say, then, based upon your two exams, that the patient has had an ocular or periocular infection within the last two weeks? 15:33:33 15:33:43 15:34:04

MS. STRUTHERS: Asked and answered. Same objection.

THE WITNESS: As I stated earlier, if I diagnose a patient on this day with an ocular or a periocular infection, that patient has an active ocular or periocular infection that day. 15:34:20

BY MR. TRAUPMAN:

Q Right, but if you know he -- if you know the patient also had an infection three days earlier, based upon your examination, right, can you say that the patient has had an ocular or periocular infection within the last two weeks? 15:34:33

MS. STRUTHERS: Asked and answered.

THE WITNESS: Again, I stated that if I were to diagnose a patient on this particular day 15:34:57

with an ocular or periocular infection, that patient would have an active ocular or active periocular infection this day. 15:34:59

MR. TRAUPMAN: Right.

Q And if they had that -- also had that infection three days earlier, would they have had an infection within the last two weeks? 15:35:12

MS. STRUTHERS: Asked and answered.

THE WITNESS: Again, if I diagnosed them with an infection that day that affects the ocular or periocular surface, I would diagnose that as an active periocular or active ocular infection. That would not be a history. That would be an active infection. 15:35:42

MR. TRAUPMAN: Yeah, there was no -- my question didn't say anything about a history. 15:36:05

Q My question just said: Did that patient -- again, you had examined a patient on Monday. You diagnosed the patient with an active ocular or periocular infection. The patient comes back on Thursday. You make the same diagnosis. 15:36:19

Does that patient have -- would you be able to say that patient had an ocular or periocular infection within the last two weeks?

MS. STRUTHERS: Asked and answered about 15:36:35

four times now. 15:36:36

THE WITNESS: I reiterate that if I diagnose a patient with ocular or periocular infection, at this particular visit, I would say that patient has an active ocular or periocular infection that visit. 15:37:06

MR. TRAUPMAN: Right.

Q But my question was whether the patient has had an ocular or periocular infection within the last two weeks. 15:37:32

MS. STRUTHERS: Asked and answered.

THE WITNESS: And my reply would be: That patient has an active ocular or periocular infection today.

MR. TRAUPMAN: Right. 15:37:44

Q And is a patient who has an active ocular or periocular infection today a patient who has had an ocular or periocular infection within the last two weeks?

MS. STRUTHERS: Objection to form. 15:37:54

THE WITNESS: My reply would be the same; that the patient has an ocular or periocular infection that is active today.

MR. TRAUPMAN: Right. I understand.

Q If -- I'm happy to use your terminology, 15:38:10

but I want to understand: Does a patient who has an active or periocular infection [sic] today -- does that patient fit within the words "a ocular or periocular infection within the last two weeks," "yes" or "no"? 15:38:11 15:38:25

MS. STRUTHERS: Matt, she's answered about six times now.

MR. TRAUPMAN: She hasn't.

MS. STRUTHERS: She has.

MR. TRAUPMAN: She's refused to answer, and I'm happy to keep going because I think this is going to be informative of her credibility, but I haven't gotten an answer to my question. 15:38:29

MS. STRUTHERS: Asked and answered.

You can answer again. 15:38:42

THE WITNESS: I believe I have answered it, because if I were to diagnose an ocular or periocular infection that day, I would classify it as being active that day.

MR. TRAUPMAN: Right. 15:39:14

Q And my question is: Is your viewing that -- is: If you clari- -- characterize or classify infection as being active that day, is that -- can that also fit within the definition of an infection within the last two weeks, or do you 15:39:32

view those two concepts as mutually exclusive? 15:39:35
A Could you repeat that last part?
Q Right.
So I'm happy to use your words, Doctor.
You say, "I classify that as a -- as a 15:39:51
active infection that day."
I'm willing to accept that, but I'm
separately going to ask you whether or not you could
also, at the same time, call that an -- an ocular or
periocular infection within the last two weeks. 15:40:06
MS. STRUTHERS: Asked and answered.
THE WITNESS: I think, in my
understanding, I would diagnose that as an ocular or
periocular infection that day because of the
clinical findings I would have seen that day to help 15:40:40
me make that diagnosis.
MR. TRAUPMAN: Yeah, I guess I'm just
really just asking you -- I'm still -- I'm trying to
get an answer.
Q Would you -- could you also call that an 15:41:02
ocular or periocular infection within the last two
weeks?
MS. STRUTHERS: Asked and answered.
THE WITNESS: Given the knowledge I have
of that particular case, I would say it's an active 15:41:40

infection. 15:41:46
BY MR. TRAUPMAN:
Q So is it, no, you wouldn't call it an
ocular or periocular infection within the last two
weeks? You wouldn't call it that? 15:41:51
A I would call it an active ocular or active
periocular infection.
Q Would you not call it an ocular or
periocular infection within the last two weeks?
A I would simply call it an active infection 15:42:05
or a periocular infection because that's what I saw
that day.
Q Would a patient that you see that day and
you diagnose with an active infection -- would that
patient fit within a description of an ocular or 15:42:22
periocular infection within the last two weeks? Put
that patient in that -- would you be able to
describe that patient using those words or not?
MS. STRUTHERS: Asked and answered.
THE WITNESS: I would describe that 15:42:36
patient as having an active ocular or periocular
infection that day.
BY MR. TRAUPMAN:
Q That, very respectfully, doesn't answer my
question, though. 15:42:46

Would you also -- would you be able to 15:42:48
describe that patient that you just diagnosed with
an active ocular or periocular infection as falling
within the category of an ocular or periocular
infection within the last two weeks? 15:42:58
MS. STRUTHERS: Asked and answered.
THE WITNESS: And I think I have been
clear by stating that I would classify that patient
as having an active ocular or periocular infection
that day because that is what I diagnose that day. 15:43:17
BY MR. TRAUPMAN:
Q But that's not answering my question. I'm
asking about a different classification, a
characterization of the patient as having an ocular
or periocular infection within the last two weeks. 15:43:34
Do you understand what those words mean?
MS. STRUTHERS: Objection. Argumentative.
BY MR. TRAUPMAN:
Q Do you understand what the words "any
ocular or periocular infection within the last two 15:43:44
weeks" mean as a person of skill in the art?
A Yes, I do.
Q What do they mean?
A Any periocular or oracular infection
within the past two weeks. 15:43:59

Q Okay. And does a patient who you examine 15:44:01
today and you conclude that they have an active --
to use your words, active ocular or periocular
infection, does that patient fall within the group
of patients who have any ocular or periocular 15:44:15
infection within the last two weeks?
MS. STRUTHERS: Asked and answered.
THE WITNESS: I stated that if a patient
were to have, on examination today, active infection
or active -- or have an infection on the ocular 15:44:34
surface or in the periocular region, I would
classify them as having an active ocular or active
periocular infection. That would be their
classification.
MR. TRAUPMAN: Right. 15:44:51
Q And is that classification mutually
exclusive with patients -- with patients who have
had any ocular or periocular infection within the
last two weeks?
MS. STRUTHERS: Asked and answered. 15:45:03
THE WITNESS: As I mentioned, in that
clinical case, that patient who has an infection at
this time point of examination would have an active
ocular or periocular infection, and that is
different than having a history. 15:45:51

MR. TRAUPMAN: Okay. Let me just -- let me just maybe ask a slightly different question.
Q Category one, group one of patients are those with active ocular or intraocular infections, okay? 15:46:10
A Yes.
Q Category two are patients with any ocular or periocular infection within the last two weeks, okay?
Are categories one and two mutually exclusive in your opinion? 15:46:23
MS. STRUTHERS: Asked and answered.
THE WITNESS: I stated that a person who presents with an infection in the ocular or periocular region today has an active ocular or active periocular infection, and that is different from an ocular or periocular infection within the past two weeks. 15:46:44
MR. TRAUPMAN: I'm just going to note this for the record regarding the refusal to answer. 15:47:22
MS. STRUTHERS: Counsel, I'd object to that characterization. The witness has answered your question many times.
MR. TRAUPMAN: Yeah, I would just -- we're going to move on. I'm not going to engage on that, 15:47:33

but I just don't agree. 15:47:36
Q I saw you look at the patent just a second ago, Dr. Do.
MS. STRUTHERS: I'm sorry. My realtime just stopped working. 15:47:48
THE REPORTER: It's slow.
MS. STRUTHERS: Sorry, Matt. Go ahead.
BY MR. TRAUPMAN:
Q You would agree with me that exclusion criteria 3 doesn't say anything about the -- any ocular or periocular infection being resolved, correct? 15:48:11
A Which page are you referring to?
Q I -- the one right in front of you, the claim 1. You can read the third exclusion criteria. 15:48:21
I assume you're familiar with that criteria, aren't you, Dr. Do?
A Yes, the exclusion criteria?
Q Yeah, number 3.
A Yes. 15:48:37
Q Right. It doesn't say anything about the ocular or periocular infection being resolved, does it?
MS. STRUTHERS: Objection. The document speaks for itself. 15:48:44

THE WITNESS: I do not see the actual word "resolved." 15:48:46
BY MR. TRAUPMAN:
Q In exclusion criteria 3, right?
A Yes, I do not see that exact word in exclusion criteria. 15:48:55
Q Right.
Do you see any words to the effect that the ocular or periocular infection is resolved in exclusion criteria 3? 15:49:10
MS. STRUTHERS: Objection to form.
THE WITNESS: Can you repeat the question?
MR. TRAUPMAN: Yes.
Q Is there any -- you say you don't see the exact word "resolved." I agree it's not there. 15:49:16
Do you see any -- any words to the same effect, that the ocular or periocular infection must be resolved in the context of exclusion criteria number 3 in claim 1 of the '681 patent, Doctor?
MS. STRUTHERS: Objection to form. 15:49:31
THE WITNESS: Could you repeat the question?
BY MR. TRAUPMAN:
Q Do -- do you see any words to the effect that the ocular or periocular infection must be 15:49:42

resolved in the context of exclusion criteria No. 3 in claim 1 of the '681 patent? 15:49:44
A I do not see a specific word such as "resolved" in this exclusion criteria or claim, but the POSA would not read this passage in isolation and would take into account the entirety of the document. 15:50:06
Q So what -- what else would the POSA take into account when reading exclusion criteria 3?
A As I wrote in my declaration, the POSA would understand, based on the plain language of the challenged claims, that excluding active ocular or periocular infection is not the same as excluding any ocular or periocular infection within the last two weeks prior to the treatment, particularly when these two conditions are listed as separate and distinct exclusion criteria. 15:51:00
Q Are you done?
A Yes.
Q Okay. Great. 15:51:48
So you just read a portion of paragraph 121 of your expert report; is that right?
A Yes.
Q Okay. So your -- your basis for informing your understanding of what you allege to be the 15:52:00

plain meaning of exclusion criteria No. 3 is simply reading it in conjunction with exclusion criteria No. 2 --

MS. STRUTHERS: Object- --

BY MR. TRAUPMAN: 15:52:13

Q -- is that right?

MS. STRUTHERS: Objection. Mischaracterizes the testimony.

THE WITNESS: I tried to explain that exclusion criteria 2 and exclusion criteria 3 are separate and distinct. 15:52:28

MR. TRAUPMAN: Right.

Q Is there any overlap between exclusion criteria 2 and exclusion criteria 3?

A It's my opinion that the POSA would understand that they are separate and distinct. 15:52:53

Q Right.

And my under- -- and what I'm trying to understand is, when you say "separate and distinct," does that allow for any overlap between exclusion criteria 2 and 3 or not? 15:53:03

A As I mentioned, they are separate and distinct, so there would not be overlap to suggest that they were alike.

Q Right. 15:53:28

So if a patient -- a patient who -- there is -- it's not possible for a patient to fall within the exclusion criteria 2 and exclusion criteria 3; is that correct? 15:53:29

A Exclusion criteria 2 refers to an active ocular or periocular infection; whereas exclusion criteria 3 refers to any ocular or periocular infection within the last two weeks prior to the treatment, and I believe that the criterion 2 and 3 have different and distinct meanings to the POSA. 15:53:52

Q Right.

And my question is: Can a patient fit within the definition of -- I'm sorry -- the exclusion criteria 2 and 3? 15:54:20

MS. STRUTHERS: Asked and answered. 15:54:33

THE WITNESS: And my reply is that criterion 2 and 3 are different and, therefore, there is not overlap.

MR. TRAUPMAN: All right. We've been going an hour. Why don't we take a break. 15:55:06

THE VIDEOGRAPHER: This marks the end of Media No. 5. Off the record. The time is 3:55.

(Recess.)

THE VIDEOGRAPHER: This marks the beginning of Media No. 6 in the deposition of 16:05:07

Dr. Diana Do. We're back on the record. The time is 4:05. 16:05:09

MR. TRAUPMAN: Welcome back, Dr. Do. I'd like to switch topics one more time. We're in the home stretch here. 16:05:19

Q If you turn to page 17, paragraph 51 of your declaration, please. And, actually, just to maybe orient yourself, go one paragraph earlier, paragraph 50. Here you're talking about the Dixon prior art reference. 16:05:44

A Yes.

Q Right?

A I see that reference.

Q And as you state, Dixon describes the VIEW 1/2 study design, correct? 16:05:50

A Yes.

Q And then in paragraph 51, you note that Dixon does not disclose an exclusion criteria for the treatment of wet AMD or any angiogenic eye disorder with intravitreal injection of anti-VEGF agents. 16:06:09

Do you see that?

A Yes, I see that sentence.

Q Would a person of ordinary skill in the art who read Dixon have understood that the VIEW 1/2 16:06:20

trial that's described in Dixon had exclusion criteria associated with it? 16:06:24

A Do you have the Dixon reference?

MR. TRAUPMAN: Sure do. Here you go.

(Exhibit 1006 was introduced.) 16:06:44

THE WITNESS: Thank you.

MS. STRUTHERS: Thank you.

MR. TRAUPMAN: I put before the witness what's been marked previously as Exhibit 1006. It's the Dixon reference. 16:06:51

Q So, again, my question, Dr. Do, is: Would a POSA skilled in the art [sic] who reads Dixon sees the study design for VIEW 1 -- 1/2 but sees that no information is provided about exclusion criteria -- would the person of skill in the art have understood that, even though not given in Dixon, there were exclusion criteria associated with the VIEW 1/2 study? 16:07:08

A In my declaration, I stated that the Dixon published article does not disclose the exclusion criteria for the VIEW 1 or VIEW 2 clinical trials of wet age-related macular degeneration. 16:07:39

And what was your question related to that?

Q My question wasn't related to anything 16:08:09

what you answered. So let's try again, and -- and I'm asking whether or not a person of skill in the art who reads the Dixon reference would understand that, even though not given in the Dixon reference itself, that the VIEW 1/2 clinical trials had exclusion criteria associated with them. 16:08:11 16:08:24

A In my declaration, I did not discuss whether or not the POSA would know these exclusion criteria if they were not reported, and so I couldn't answer that question because those exclusion criteria were not reported in the Dixon study. 16:09:10

Q Right. My question is a little different.

I'm not trying to ask whether or not the person of skill in the art would have known what the specific exclusion criteria are that -- all those ones listed in Appendix 2 that we looked at earlier today. 16:09:21

I'm just wondering whether or not a person of skill in the art who reads Dixon, hears about a phase 3 clinical trial with aflibercept, the VIEW 1/2 study design -- would that person of skill in the art know that there are some exclusion criteria that were being applied for that phase 3 clinical trial, even if that person of skill in the 16:09:32 16:09:44

art doesn't know what the precise exclusion criteria were? 16:09:48

A The POSA would have understood that clinical trials have inclusion and exclusion criteria, but they would not know what they were for the VIEW 1 and VIEW 2 studies. 16:10:25

Q Got it.

All right. If we can go on to paragraph 66 of your declaration, and here you're talking about the different doses of aflibercept, correct? 16:11:14

A Yes.

Q Right.

And so I'm just trying to, hopefully in the interest of time, move things along.

At the bottom of -- third or so of the page here, page 24, you state (as read): "Specifically by 2011, the POSA would have understood, quote, initial and, quote, secondary doses to correspond to loading doses and, quote, tertiary doses to correspond to maintenance doses." 16:11:34 16:11:51

Do you see that?

A Yes, I see that sentence.

Q Okay. What -- what do you mean by "loading doses"?

A In this context, "loading doses" was 16:12:17

referring to the initial and secondary doses of the anti-VEGF agent. 16:12:27

Q Right.

Why do you -- why, in the administration of anti-VEGF agent, do you have loading doses and maintenance doses? 16:12:43

A I stated in my declaration that the purpose and the expected effect of loading doses was to achieve visual acuity gains and retina drying.

Q Okay. Let me just try to understand -- so -- and then you go on to say: "The goal of the maintenance doses was to maintain the efficacy achieved with loading doses once dosing became less frequent," correct? 16:13:09

A Yes. 16:13:27

Q So I understand from that sentence the --you -- you achieve the efficacy improvements through the loading doses and then maintain that efficacy improvement through the maintenance doses; is that correct? 16:13:41

A I did state that, you know, the purpose of the loading doses was to achieve visual acuity gains and retina drying and the goal of the maintenance doses was to maintain the efficacy achieved with the loading doses once dosing became less frequent. 16:14:05

Q Right. 16:14:07

And when you were referring to "the efficacy achieved with the loading doses," that's referring back to visual acuity gains and retina drying, correct? 16:14:15

A Those are some of the parameters, yes.

Q Well, let me just ask maybe a broader question.

When you say "maintain the efficacy achieved with the loading doses," what are you referring to in that sentence? 16:14:37

A We are referring to, you know, in -- retina drying; reducing any swelling in the retina; improving vision, if possible; you know, controlling the disease. 16:15:07

Q In your experience, does the maintenance -- do the maintenance doses continue to generate efficacy improvements?

MS. STRUTHERS: Objection to form.

THE WITNESS: Can you repeat the question? 16:15:28

MR. TRAUPMAN: Right.

Q Do maintenance doses -- do -- do maintenance doses continue to achieve additional efficacy beyond what's achieved through the loading doses? 16:15:39

MS. STRUTHERS: Objection. Vague. 16:15:45
THE WITNESS: Could you rephrase the question? I don't understand it.
BY MR. TRAUPMAN:
Q What don't you understand? 16:15:53
A Perhaps you could re-ask the question again?
Q Sure.
Can -- do the loading doses -- strike that. 16:16:08
Can the loading doses cause additional efficacy improvements beyond what's achieved through the loading doses?
MS. STRUTHERS: Objection to form.
You might want to check your question, 16:16:22 Counsel.
THE WITNESS: Could you repeat the question?
MR. TRAUPMAN: Oh. Thank you. Yes, I appreciate that. Let me withdraw the question 16:16:46 because it was poorly worded.
Q Can the maintenance doses cause additional efficacy improvements beyond what's achieved through the loading doses?
MS. STRUTHERS: I'll object as an 16:17:06

incom- -- excuse me -- incomplete hypothetical, but 16:17:07 you can answer.
THE WITNESS: I mentioned in my declaration that treating requires efficacy and that -- that treatment still has a therapeutic 16:17:32 effect -- a beneficial therapeutic effect for that patient. The maintenance doses still have a beneficial effect.
BY MR. TRAUPMAN:
Q Do the maintenance doses cause additional 16:18:24 visual acuity gains beyond what's seen in the loading doses?
MS. STRUTHERS: Objection. Incomplete hypothetical.
THE WITNESS: Are you talking about in the 16:18:39 VIEW 1/VIEW 2 studies? Are you -- which --
MR. TRAUPMAN: Well, this -- this --
THE WITNESS: -- scenario are you referring to?
BY MR. TRAUPMAN: 16:18:50
Q This paragraph is talking about the claimed invention, correct?
A Yes.
Q So that's what I'm talking about.
A Yes. 16:18:55

Q I'm just trying to understand what you 16:18:56 wrote here at the bottom of paragraph 66.
A In that paragraph, I wrote that, you know, the purpose and the expected effect of loading doses was to achieve visual acuity gains and retina drying 16:19:15 and the goal of the maintenance doses was to maintain the efficacy achieved with loading doses once the dosing became less frequent.
Q Okay. You're --
A The doses still require a beneficial 16:19:32 therapeutic effect.
Q You reference "retina drying" in that sentence.
What does that refer to?
A When I state "retina drying," I refer to 16:19:50 reducing any edema or swelling in the macula region.
The macula being the center of the retina.
Q Right.
And the swelling of the macula is caused by excess blood vessel growth; is that correct? 16:20:16
A In wet age-related macular degeneration, abnormal blood vessel growth, known as choroidal neovascularization, causes swelling within the macula.
Q Right. 16:20:38

And so the retina drying you're referring 16:20:39 to is reversing or stopping the excess blood vessel growth in the macula; is that correct?
A Yes, part of retinal drying involves stopping the blood vessel -- abnormal blood vessel 16:21:01 growth in wet age-related macular degeneration.
Q Right.
You said part of retinal drying involves stopping that excess blood vessel growth.
We're all talking about wet AMD here -- 16:21:16
A Yes.
Q -- just to be clear.
Is there any -- what -- what other aspects of retinal drying are involved, other than stopping the excess blood vessel growth, again, in the 16:21:27 context of wet AMD?
A In the context of wet AMD, in addition to stopping the growth of choroidal neovascularization, one goal is to stop leakage of those abnormal blood vessels. 16:21:52
Q Okay. And so -- and it's then -- so the purpose of the loading doses is to stop the ab- -- the abnormal blood vessel growth and the leakage of those blood vessels in a wet AMD patient; is that correct? 16:22:19

A It's -- the purpose of the loading doses is to provide, you know, a beneficial therapeutic effect, which could result in drying of the retina and could lead to, you know, visual acuity gains. 16:22:26

Q Right. 16:22:53

Well, let's maybe -- the beneficial therapeutic effect is -- is visual acuity gains, correct?

A That's one of the beneficial effects.

Q What are the other beneficial therapeutic effects achieved by the loading doses? 16:23:09

A Other beneficial effects would be decreasing swelling within the macula. It could also be decreasing hemorrhage or bleeding in the macula. 16:23:27

Q Okay. And so the goal of the loading doses is to reduce or eliminate the swelling in the macula, the bleeding in the macula, and the leaking blood vessels, and the excess blood vessel growth, correct? 16:23:50

A Yes, those are all reasonable goals.

Q Right.

And so then, once those goals have been achieved, the maintenance doses prevent relapse; is that correct? 16:24:05

A The maintenance doses still provide beneficial therapeutic effect in stopping leakage, reducing blood vessel growth, while offering fewer injections over time. 16:24:13

Q And I take it, fewer injections over time, all else being equal, is a good thing; is that right? 16:24:40

A Yes. In this particular disease of wet age-related macular degeneration, the standard of care in 2000 -- prior to 2011 was monthly Lucentis, and developing something novel that could be beneficial but dosed less frequently could be very beneficial. 16:25:04

Q I guess I'm just trying to understand: Why is less frequent dosing beneficial? 16:25:32

A It would only be beneficial if it provided a therapeutic benefit.

Q Okay. And you're -- you've said many times that the loading -- the intent or the purpose of the loading doses is to continue to provide therapeutic benefit, but why, while still providing a therapeutic benefit, are less -- is less frequent dosing beneficial? 16:25:51

A Again, I didn't go into the details of, you know, all the benefits of less frequent dosing 16:26:09

in my declaration; and so to give you, you know, a complete answer, I would have to have more time to prepare it. 16:26:14

Q Okay. So you're saying -- go ahead.

A Yeah. But, in general, one aspect would be easier for patients to not have to come back so frequently. 16:26:30

Q And you'd also agree that less frequent dosing while still maintaining a therapeutic benefit could -- would decrease the risks of side effects from the intravitreal injection, correct? 16:27:00

MS. STRUTHERS: Objection to form.

THE WITNESS: Could you re- -- rephrase the question again?

MR. TRAUPMAN: Sure. 16:27:22

Q One of the benefits of less frequent dosing is less chance of a side effect occurring from the intravitreal injection, correct?

A Again, I would have to look at what intravitreal injection you're talking about, evaluate the safety data to answer your question completely. 16:27:47

Q Okay. One -- one other point, just on the therapeutic benefits of the loading doses, one additional effect of those loading doses is to 16:28:07

reduce the central retinal thickness, correct? 16:28:10

A The loading doses can help reduce swelling within the macula, and the central retinal thickness is a measurement that could be done.

Q Of -- the central retinal thickness is -- measures how much swelling there is of the macula; is that correct? 16:28:34

A Yes.

THE VIDEOGRAPHER: Doctor, can I ask you to move that way a little bit? 16:28:50

THE WITNESS: Oh, sorry.

THE VIDEOGRAPHER: The computer is in the way. Thank you. Her computer. Thank you.

MR. TRAUPMAN: Okay. At this time, I don't have any further questions for Dr. Do, although I am going to note -- and we'll have to take this up -- she testified that she relied on certain data in forming her opinions on the 1 and 2 percent of her patients that she treats that has not been produced in this proceeding, and we certainly would have expected, considering she said it was part of the bases of her opinions, that they would have been provided to us. 16:29:01 16:29:19

So I'm just noting that, and we'll have to -- we plan to follow up next week regarding that, 16:29:33

but I don't believe that was proper, to not have 16:29:36
produced the materials that -- all of the materials
that she relied upon.
MS. STRUTHERS: And I would just state for
the record that I would disagree that individual 16:29:46
patient medical records should typically be produced
in a PTAB proceeding, but if you'd like to follow
up, that's, of course, your prerogative.
MR. TRAUPMAN: Right.
Well, I could understand the sensitivities 16:29:57
of that -- of that data, but I also don't think it's
proper for her to form her opinions based on that
data and not have -- give us access to it, so...
MS. STRUTHERS: We can agree to disagree,
but I'll note it for the record. 16:30:15
MR. TRAUPMAN: Yeah. So we're going to be
holding the deposition open --
MS. STRUTHERS: No. I do not agree with
holding the deposition open.
MR. TRAUPMAN: -- pending resolution. 16:30:24
Well, I --
MS. STRUTHERS: I do not agree with
holding the deposition open, so that's -- that's not
up for debate. If you would like to follow up in
writing requesting additional discovery, you may do 16:30:30

topics. And, again, it's the full bases for her 16:31:33
opinions that are reflected which she said she --
she relied upon patient records in forming. So I
think that's -- I don't --
Look, you can disagree with me, but I 16:31:45
think it's pretty -- pretty standard practice that
an expert should produce, before her deposition, all
the materials relied upon in forming the opinions of
the declaration of which the deposition is the
subject, it being, you know, the subject matter. 16:32:01
So, again, I'm not asking for your
agreement. I -- you know, we can take this up
otherwise, but I do think proper procedure has not
been followed here.
MS. STRUTHERS: And I disagree, and I also 16:32:15
disagree with keeping this deposition open. I
believe this deposition is closed. If you'd like to
ask for a follow-up deposition, then that's, again,
your prerogative.
MR. TRAUPMAN: Okay. Well, I appreciate 16:32:24
it.
I appreciate everyone's time today, and
have a great weekend, everybody.
MS. STRUTHERS: All right. I have no
questions for the witness. Thank you. 16:32:31

that, but we are not going to hold the deposition 16:30:32
open.
MR. TRAUPMAN: Well, I'm just -- again,
you know, you can say it's not up for debate. I
don't agree that it's not up for debate, and we can 16:30:38
deal with it -- we -- just -- we're going to ask for
additional discovery; and if we get the additional
discovery, one of the things we're going to ask for
is a follow-up deposition so that we can depose
Dr. Do on the, you know, full bases of her opinion. 16:30:52
So I'm not expecting you to agree with me.
We can agree to disagree with me, but I'm just
noting that that's our position, and I don't believe
this deposition is properly concluded because we
haven't been properly provided with all of the 16:31:05
materials that she relied upon in forming her
opinions in her declaration.
MS. STRUTHERS: And to be clear, Counsel,
the topic that you would want to redepose her on is
simply the percentage of patients in which she has 16:31:17
withheld an injection?
MR. TRAUPMAN: No, it's -- it's the bases
of the opinions primarily in paragraph 184 of her
report about what -- instances when she does or does
not follow the exclusion criteria and other related 16:31:29

THE VIDEOGRAPHER: We are off the record 16:32:34
at 4:32 p.m., and this concludes today's testimony
given by Dr. Diana V. Do. The total number of media
used was six, and it will be retained by Veritext
Legal Solutions. 16:32:44
(TIME NOTED: 4:32 p.m.)

I, DIANA V. DO, M.D., do hereby declare under penalty of perjury that I have read the foregoing transcript; that I have made any corrections as appear noted, in ink, initialed by me, or attached hereto; that my testimony as contained herein, as corrected, is true and correct.

EXECUTED this _____ day of _____, 2023, at _____, _____.

(City) (State)

_____

DIANA V. DO, M.D.

VOLUME I

I, the undersigned, a Certified Shorthand Reporter of the State of California, do hereby certify:

That the foregoing proceedings were taken before me at the time and place herein set forth; that any witnesses in the foregoing proceedings, prior to testifying, were administered an oath; that a record of the proceedings was made by me using machine shorthand which was thereafter transcribed under my direction; that the foregoing is a true record of the testimony given.

Further, that if the foregoing pertains to the original transcript of a deposition in a Federal Case, before completion of the proceedings, review of the transcript [X] was [ ] was not requested.

I further certify that I am neither financially interested in the action nor a relative or employee of any attorney or any party to this action.

IN WITNESS WHEREOF, I have this date subscribed my name this 11th day of December, 2023.

Catherine A. Nolasco

Catherine A. Nolasco, RMR, CRR, B.S.

CSR No. 8239

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Errata

Deposition of Diana V. Do, MD

December 8, 2023

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Diana Do

Diana V. Do, MD