

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

MYLAN PHARMACEUTICALS, INC.,)
and CELLTRION, INC.,)
) No. IPR2022-01225
vs.) Patent 10,130,681 B2
)
REGENERON PHARMACEUTICALS)
-----)
MYLAN PHARMACEUTICALS, INC.,)
and CELLTRION, INC.,)
) No. IPR2022-01226
vs.) Patent 10,888,601 B2
)
REGENERON PHARMACEUTICALS)

The videotaped deposition of DIANA DO, MD,
called by the Petitioners for examination, taken
before Valerie Calabria, CSR, RPR, taken via Zoom
videoconference on June 2, 2023, at 10:58 a.m.

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Page 2 1 APPEARANCES: (via videoconference) 2 RAKOCZY MOLINO MAZZOCHI SIWIK LLP BY: MR THOMAS H EHRICH 3 6 West Hubbard Street, Suite 500 Chicago, Illinois 60654 4 312 527 2157 tehrich@rmmslegal.com 5 6 appeared on behalf of the Petitioners; 7 ARNOLD & PORTER KAYE SCHOLER LLP BY: MS ABIGAIL STRUTHERS 250 West 55th Street 8 New York, New York 10019 212 836 8000 9 abigail.struthers@arnoldporter.com ARNOLD & PORTER KAYE SCHOLER LLP BY: MS VICTORIA L REINES 11 601 Massachusetts Ave, NW Washington, D C 20001 12 202 942 6861 victoria.reines@arnoldporter.com 13 14 appeared on behalf of the Respondent 15 ALSO PRESENT: 16 Laura Switalski, videographer Alejandro Hernandez, RMMS 17 18 ***** 19 20 21 22 23 24 25 Reported By: Valerie M Calabria, CSR, RPR	Page 4 1 THE VIDEOGRAPHER: Good morning. We're now on 2 the record at 10:59 a.m. Today's date is June 2nd 3 of 2023. 4 This is the video-recorded deposition 5 of Diana Do, MD, in the case of Mylan 6 Pharmaceuticals, Incorporated, et al., versus 7 Regeneron Pharmaceuticals, United States Patent and 8 Trademark Office Number IPR2022-01225 along with 9 Mylan Pharmaceuticals, Incorporated, et al., versus 10 Regeneron Pharmaceuticals, Number IPR2022-01226. 11 My name is Laura, the videographer. 12 Today's court reporter is Valerie, both 13 representing Veritext. 14 Will the attorneys present please 15 introduce themselves, who they represent, and will 16 the court reporter please swear in the doctor. 17 MR. EHRICH: Thomas Ehrich of RMMS, LLP, for 18 petitioner, and with me today is Alejandro 19 Hernandez, also of RMMS. 20 MS. STRUTHERS: Abigail Struthers of Arnold & 21 Porter for patent owner and also for the witness. 22 With me today is my colleague 23 Victoria Reines, also from Arnold & Porter. And as 24 previously stated, we may have our client join us 25 later, but we will state so on the record if and
Page 3 1 INDEX 2 WITNESS EXAMINATION 3 DIANA DO, MD 4 BY MR. EHRICH 6 5 6 DEPOSITION EXHIBITS 7 NUMBER/DESCRIPTION IDENTIFIED 8 Do Deposition Exhibit 9 Exhibit 1 Notice of deposition 7 10 Exhibit 2 Notice of deposition 8 11 Exhibit 3 4/1/23 declaration 9 12 Exhibit 4 10/11/22 declaration 10 13 Exhibit 5 2022 deposition transcript 40 14 15 16 17 18 19 20 21 22 23 24 25	Page 5 1 when that happens. 2 (Witness duly sworn.) 3 MS. STRUTHERS: Tom, before you get going, one 4 housekeeping point, which is I have clean copies of 5 Dr. Do's declaration that I would like to hand her 6 so she has some separate from binders, if that's 7 permissible. 8 MR. EHRICH: Perfectly fine. Thanks. 9 Also the -- another housekeeping 10 point. Paper copies should have been provided in 11 binders. We can go off the record if you want to 12 open those now or we could do it on the record, 13 whatever you prefer. 14 MS. STRUTHERS: We have the box right here, so 15 it should take us two seconds to open it. 16 MR. EHRICH: Okay. That'll be fine. Go 17 ahead, please. 18 THE WITNESS: I have to ask my counsel just to 19 fix the Zoom. It has this box here. 20 MR. EHRICH: While she's opening the boxes, 21 I'd like to say good morning, Dr. Do. 22 THE WITNESS: Good morning. 23 MS. STRUTHERS: Okay. The boxes are open. 24 MR. EHRICH: Okay. There should be, 25 hopefully, two different binders. Copies of each

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Page 6 1 one should be labeled "Declarations" on the front, 2 one should be labeled "Exhibits." 3 Okay. So if you're all set. All 4 right. 5 DIANA DO, MD, 6 called as a witness herein, having been first duly 7 sworn, was examined and testified as follows: 8 EXAMINATION 9 BY MR. EHRICH: 10 Q. So, Dr. Do, could you please state your 11 full name for the record. 12 A. My name is Diana Do. 13 Q. And I know you've been deposed before, 14 but I just want to go over a couple of points. One 15 is that your attorney today will be objecting to 16 some of my questions, and that's just part of the 17 process. But even when your attorney objects, you 18 still have to answer the question to the best of 19 your ability unless your attorney specifically 20 instructs you not to answer the question. Okay? 21 A. Yes. 22 Q. And the only other thing is that we'll 23 be taking breaks from time to time, but if you need 24 a break at any point, please just let me know. And 25 the only thing I would ask is that if there's a	Page 8 1 A. Yes. Yes. 2 Q. Okay. And so you recognize that your -- 3 I just want to make sure. Do you recognize you're 4 being deposed today for the patent that ends in 5 '601, 10,888,601, and that the case is IPR that 6 ends in 1226? 7 A. Yes, that is correct. 8 Q. Okay. Okay. And then, similarly, if 9 you please turn to Paper 55, which should be very 10 similar, I just want to verify. Do you recognize 11 that you're also -- and, sorry, Paper 55 let's 12 introduce as Do Exhibit 2. 13 (Do Deposition Exhibit 2 was 14 marked for identification.) 15 BY MR. EHRICH: 16 Q. And do you recognize you're also being 17 deposed for the patents that's 10,130,681, case 18 ending in 1225? 19 A. Yes. It says "Petitioner's Notice of 20 Deposition." 21 Q. Yep. Okay. And so you recognize that 22 the deposition is for both of these two IPR cases 23 and both of these two patents? 24 A. Yes. 25 Q. Okay. Great.
Page 7 1 question pending, please just answer the question, 2 and otherwise that's totally fine. Okay? 3 A. Yes. 4 Q. Okay. So I'd like to put in front of 5 you, Dr. Do -- if you could please take the binder 6 that's labeled "Declarations," and there should be 7 some tabs in there. And toward -- and toward the 8 end of that binder, there should be two tabs, one 9 labeled "Paper 54" and one labeled "Paper 55." 10 Do you see those? 11 A. Yes, I do. 12 Q. Could you please turn to the tab labeled 13 "Paper 54." 14 MR. EHRICH: And for the record, we'll just 15 introduce that as Do Exhibit 1. 16 (Do Deposition Exhibit 1 was 17 marked for identification.) 18 BY MR. EHRICH: 19 Q. And, Dr. Do, do you recognize this 20 document? 21 A. The Paper 54 states my declaration for 22 the '601 patent. 23 Q. It should be -- it should say 24 "Petitioner's Notice of Deposition" on the front 25 page.	Page 9 1 And just for ease going forward, I'm 2 going to refer to the patents as the '681 patent 3 and the '601 patent or the '601 patent. Okay? 4 A. Yes. 5 Q. Okay. And then I'd also like you to 6 please turn to, in the same binder, the tab marked 7 Exhibit 2056 (1225). 8 A. Could you repeat the number? 9 Q. Sure. Exhibit 2056 (1225). 10 A. Yes. 11 Q. Okay. And do you recognize this 12 document, Dr. Do? 13 A. The first page states it's the 14 declaration of myself related to U.S. Patent 15 Number 10,130,681, IPR Number 2022-01225. 16 Q. Okay. And you can flip through it if 17 you'd like, but I just want to verify. Is this the 18 declaration that you submitted on the '681 patent? 19 A. Yes, it appears to be so. 20 MR. EHRICH: And, sorry, for the record, let's 21 call this Do Exhibit 3. 22 (Do Deposition Exhibit 3 was 23 marked for identification.) 24 MR. EHRICH: And so then the next tab -- the 25 tab right after it, Exhibit 2056 (1226). And we'll

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Page 10 1 call this -- let's please introduce this as Do 2 Exhibit 4. 3 (Do Deposition Exhibit 4 was 4 marked for identification.) 5 BY MR. EHRICH: 6 Q. And same question, Dr. Do. 7 Do you recognize -- do you recognize 8 this document? 9 A. It states this is the declaration that I 10 gave for U.S. Patent Number 10,688,601, 11 IPR2022-01226. I recognize this. 12 Q. Okay. Thank you. 13 Okay. So, Dr. Do, thank you for all 14 that. If you could please just turn one tab back, 15 then, to your declaration for the '681 patent, Do 16 Exhibit 3, and it's the tab that ends in 1225. 17 Are you there? 18 A. Yes, I am. 19 MS. STRUTHERS: Counsel, for clarity of the 20 record, this is the declaration submitted on 21 April 1st, 2023, Exhibit 2056, correct? 22 MR. EHRICH: Yeah, that is correct, yep, 23 Exhibit 2056, Exhibit 3, yeah, that's right. 24 BY MR. EHRICH: 25 Q. And, actually, that's a good point.	Page 12 1 please turn to page 12 of that declaration, 2 specifically paragraph 39. 3 Are you there? 4 A. Yes, I am. 5 Q. So my question is about the meaning of 6 the preamble term "method for treating an 7 angiogenic eye disorder in a patient." 8 And you see here in paragraph 39, you 9 write that it means that "the claimed dosing 10 regimen achieves and maintains a high level of 11 efficacy, i.e., comparable to that seen with 12 Lucentis and Avastin, and that it is effective for 13 the patient in need of treatment," right? 14 A. Yes, I see that. 15 Q. Okay. So here you define a method for 16 treating angiogenic eye disorder in a patient as a 17 dosing regimen that achieves and maintains a high 18 level of efficacy that's comparable to that seen 19 with Lucentis and Avastin, right? 20 That is -- that is what's written. 21 I'm just making sure that you -- do you stand by 22 this -- the definition? 23 A. As I stated in this declaration, I 24 understand the preamble "method for treating an 25 angiogenic eye disorder in a patient" to mean that
Page 11 1 Could you please turn to what's -- we'll introduce 2 it as what is marked as Exhibit 2001 in that same 3 binder. So let's introduce that as Exhibit 2001. 4 A. Yes. I see that. 5 Q. And same question, Dr. Do. Do you -- do 6 you recognize this document? 7 A. It's my declaration regarding Patent 8 Number 10,130,681, IPR 2022-01225. And this was 9 the one that was signed October 11th, 2022. 10 Q. Okay. Great. 11 Okay. And going forward, Dr. Do, so 12 I do plan to ask questions related primarily to 13 Exhibit 2001 and your -- your declaration that's 14 Exhibit 2001 and your other declaration that is 15 Exhibit 3, the one that ends in 1225. And so if 16 you have clean copies in front of you, it's easier 17 to do that than flip through the binder, that's 18 fine. If you want to take them out of the binder 19 so it's easier for you to access them, that's fine. 20 Just letting you know. Whatever is most convenient 21 for you. 22 Okay. So with that in mind, my 23 first -- my next question is I'd like you to please 24 go -- stay with Exhibit 2001. That's your 25 October 2022 declaration. And I'd like you to	Page 13 1 the claimed dosing regimen achieves and maintains a 2 high level of efficacy, which at that time is 3 comparable as seen in Lucentis and Avastin and that 4 it is effective for the patients in need of 5 treatment. 6 Q. Okay. So maybe keeping -- keeping a 7 finger or keeping a tab on that paragraph of that 8 declaration, I'd like you to now, then, please turn 9 to your 1225 declaration. And if you please go to 10 paragraph 98 on page 37. 11 And just let me know when you're 12 there, please. 13 A. I see that text now. 14 Q. So in paragraph 98 of your 15 1225 declaration, you write that the POSA would 16 consider the claimed method as one that achieves a 17 high level of efficacy that is noninferior to the 18 standard of care at the time of patent filing in a 19 given patient, right? 20 A. I see that text. 21 Q. Okay. So my question is about some of 22 the words in these two definitions are a little 23 different, and I'm trying to figure out how to 24 reconcile that, I guess. I under -- it looks like 25 they both -- both paragraph 39 of Exhibit 2001 and

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Page 14 1 paragraph 98 of your 1225 declaration -- say that 2 the claimed dosing regimen should be defined as one 3 that achieves a high level of efficacy. 4 And so I guess the first question is 5 in paragraph 39 of Exhibit 2001, you write that it 6 achieves and maintains a high level of efficacy, 7 and in paragraph 98 of your 1225 declaration, you 8 write that the claimed regimen achieves a high 9 level of efficacy. And I'm just wondering is 10 "achieving a high level of efficacy" different than 11 "achieving and maintaining a high level of 12 efficacy"? In other words, do these two phrases 13 mean different things in these two paragraphs? 14 MS. STRUTHERS: Objection to form. 15 You can answer. 16 THE WITNESS: Can you repeat the question? 17 BY MR. EHRICH: 18 Q. Sure. In paragraph 39 of Exhibit 2001, 19 you write that the claimed dosing regimen achieves 20 and maintains a high level of efficacy, and in 21 paragraph 98 of your 1225 declaration, you write 22 that the claimed dosing regimen achieves a high 23 level of efficacy. And I'm just wondering is 24 achieving a high level of efficacy something 25 different than achieving and maintaining a high	Page 16 1 maintaining a high level of efficacy? 2 A. In paragraph 98 of the declaration, the 3 POSA would understand that the claimed method for 4 treating as one that achieves a high level of 5 efficacy and that does also require maintaining 6 that level of efficacy, and at that time the 7 standard of care was either monthly Lucentis or 8 Avastin. And the POSA would understand that the 9 level of efficacy should be on par with those 10 agents. 11 Q. Okay. Okay. Thank you. 12 So they would understand that 13 achieving a high level of efficacy means achieving 14 and maintaining? Is that -- I just want to make 15 sure I understand what you're -- what you just 16 said. 17 A. Yes, that is what I said. 18 Q. Okay. Thank you. 19 And I think you actually anticipated 20 my next question because you just stated in 21 paragraph 98 of your 1225 declaration, the high 22 level of efficacy is in comparison to the standard 23 of care at the time of patent filing, and in 24 paragraph 39 of Exhibit 2001, the high level of 25 efficacy is comparable to Lucentis and Avastin.
Page 15 1 level of efficacy. 2 A. As I stated in my declaration -- 3 Q. I apologize for interrupting, but which 4 declaration? 5 A. In -- let's go to Exhibit 2001. 6 Q. Okay. 7 A. The POSA at that time would understand 8 that the method of treating an angiogenic eye 9 disorder in a patient means that the claimed dosage 10 regimen achieved and maintained a high level of 11 efficacy that is comparable to that seen with 12 Lucentis and Avastin, which were the standard of 13 care at that time period. 14 And that is similar to what is 15 written in Exhibit 2056 (1225), which I stated the 16 POSA would consider the claimed method for treating 17 as one that achieves a high level of efficacy that 18 is on par to the standard of care at that time, 19 which was Lucentis and Avastin. 20 Q. Right. But -- so in paragraph 98, then, 21 in your 1225 declaration, where you write that the 22 POSA would consider the claimed method for treating 23 as one that achieves a high level of efficacy, do 24 you mean something different than achieving and 25 maintaining or do you mean achieving and	Page 17 1 And so -- and I think you said this, but I just 2 want to make sure that I'm not misquoting you. 3 Are you saying, then, that in 4 paragraph 98 of your 1225 declaration, the standard 5 of care at the time of patent filing is Lucentis 6 and Avastin? 7 MS. STRUTHERS: Objection to form. 8 THE WITNESS: Can you repeat the question? 9 BY MR. EHRICH: 10 Q. Sure. In -- sure. And we'll take it 11 reverse. In paragraph 98 of your 1225 declaration, 12 you compare the high level of efficacy to the 13 standard of care at the time of patent filing, 14 right? 15 A. I see the text. 16 Q. And in paragraph 39 of Exhibit 2001, you 17 compare the high level of efficacy to Lucentis and 18 Avastin, correct? 19 A. I see that text. 20 Q. Okay. And so do -- does the standard of 21 care at the time of patent filing mean the same 22 thing as Lucentis and Avastin? 23 MS. STRUTHERS: Objection to form. 24 THE WITNESS: In my declaration, Exhibit 2001, 25 I stated that the POSA would understand that the

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Page 18 1 method for treating an angiogenic eye disorder in a 2 patient to mean that the claimed dosing regimen 3 achieves and maintains a high level of efficacy 4 that is comparable to the standard of care at the 5 time of the patent filing, which was monthly 6 Lucentis or Avastin. And that -- and that is -- is 7 effective for the patients in lieu of treatment. 8 BY MR. EHRICH: 9 Q. And you just said -- and another 10 question I was going to ask you. You just 11 specified comparable to monthly Lucentis and 12 Avastin, and the term "monthly" is not in this 13 paragraph 39 of Exhibit 2001. But by saying 14 Lucentis and Avastin, do you mean to say monthly 15 Lucentis and Avastin, then? 16 MS. STRUTHERS: Objection to form. 17 THE WITNESS: Can you repeat the question? 18 BY MR. EHRICH: 19 Q. Sure. So you had recently said -- so 20 you just said that, in paragraph 39 of 21 Exhibit 2001, the standard of care at the time of 22 the patent filing was monthly Lucentis and Avastin. 23 And the term "monthly" does not appear in 24 paragraph 39 of Exhibit 2001. So I just want to 25 make sure that I'm understanding that when you say	Page 20 1 Avastin. 2 Q. Okay. Thank you. 3 And then my next question, again 4 comparing these two paragraphs, paragraph 98 of 5 your 1225 declaration with paragraph 39 of 6 Exhibit 2001, the -- in paragraph 98 of your 7 1225 declaration, you write that the level of 8 efficacy is noninferior to the standard of care, 9 and in paragraph 39 of Exhibit 2001, you write that 10 the level of efficacy is comparable to the standard 11 of care. And I'm wondering do the terms 12 "noninferior" and "comparable," do they have 13 different meanings or the same meaning as you're -- 14 as you are using them in these two paragraphs? 15 A. In those two paragraphs, when I use the 16 term "noninferior to the standard of care" in 17 paragraph 98 of Exhibit 2056 (1225), I'm conveying 18 the same meaning as the text "comparable to that 19 seen with Lucentis and Avastin" in Exhibit 2001. 20 Q. Okay. Thank you. 21 So if we can please, then, stay with 22 your 1225 declaration, paragraph 98, can you tell 23 me what "noninferior" means, then, because 24 "noninferior" just doesn't seem like a word a 25 layperson would use very often. Like, I might
Page 19 1 comparable to that seen by Lucentis and Avastin in 2 paragraph 39, you mean comparable to that seen with 3 monthly Lucentis and monthly Avastin. 4 A. In my declaration, I mention that the 5 claimed dosing regimen achieves and maintains a 6 high level of efficacy comparable to what was the 7 standard of care at the time of the patent filing. 8 And the standard of care to achieve the 9 effectiveness for the patient at that time was 10 monthly Lucentis or Avastin. 11 Q. Okay. So then if we can please turn 12 back, then, to paragraph 98 of your 13 1225 declaration. In your previous answer you just 14 said that the standard of care at the time of the 15 patent filing was monthly Lucentis or Avastin. 16 And so my question is is that the 17 same meaning of standard of care that you're using 18 in paragraph 98 of your 1225 declaration? 19 A. In the Exhibit 2056 (1225), it stated 20 that the POSA would consider the claimed method of 21 treating as one that achieves a high level of 22 efficacy that is noninferior to the standard of 23 care at the time of the patent filing in a given 24 patient. And at that time period of January 2011, 25 the standard of care was monthly Lucentis or	Page 21 1 say -- a layperson might say apples and oranges are 2 comparable, but I don't know that they would say 3 that apples are noninferior to oranges. 4 So can you -- can you please tell me 5 what do you mean by "noninferior" or are you -- or 6 are you using it as synonymous with the common 7 English language usage of "comparable"? 8 MS. STRUTHERS: Objection to form, vague. 9 THE WITNESS: Can you repeat the question? 10 BY MR. EHRICH: 11 Q. Sure. The term "noninferior" -- well, 12 actually, I'd like to talk about the term 13 "noninferior" in 98 of your -- so I'm staying with 14 the 1225 declaration -- the term "noninferior" in 15 paragraph 98. And maybe to make things more clear, 16 I'm wondering if there's a relationship between 17 your use of the term "noninferior" in paragraph 98 18 with your discussion of noninferiority on page 36 19 of that same 1225 declaration. 20 If you'd like to turn, please, to 21 starting maybe at the bottom of page 35 and going 22 into page 36, you'll see you're discussing -- 23 you're discussing Eylea's noninferiority Phase 3 24 wAMD trials. 25 MS. STRUTHERS: Is there a question pending?

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Page 22 1 BY MR. EHRICH: 2 Q. Yeah. Please just take -- look at the 3 paragraph and just let me know when you're ready, 4 Dr. Do. 5 A. Yes, I see that text you're referring 6 to. 7 Q. Okay. So my question is are you using 8 the term "noninferior" in paragraph 98 to mean 9 noninferior the way you're using the term in -- on 10 page 36? 11 A. In regards to paragraph 98, the POSA 12 would understand that when I use the word "the 13 claimed method for treating as one that achieves a 14 high level of efficacy that is noninferior to the 15 standard of care at the time of the patent filing 16 in a given patient," that word "noninferior" in 17 this context means on par with comparable to the 18 standard of care at that time, which was Lucentis 19 or Avastin. 20 In the text you're referring to in 21 paragraph 96 regarding the Phase 3 Eylea wet AMD 22 trials, the term "noninferiority" in that context 23 is different because it's talking about a clinical 24 trial endpoint. 25 Q. Okay. Dr. Do, at the top of page 36,	Page 24 1 data presented in the clinical trials that VEGF 2 Trap-Eye or Eylea administered on a Q8 dosing 3 schedule achieved and maintained a high level of 4 efficacy that was noninferior to ranibizumab. 5 BY MR. EHRICH: 6 Q. And you're -- it looks like you're 7 reading the last sentence in paragraph 96 of your 8 declaration; is that right? 9 A. Yes, that's correct. 10 Q. So the term "noninferior" in that 11 sentence that you just read, do you mean 12 established as noninferior in a clinical study or 13 do you mean noninferior as in comparable? 14 A. In paragraph 96, I was discussing the 15 clinical trial of Phase 3 ranibizumab, and the term 16 "noninferiority" in this paragraph was referring to 17 the clinical trial's endpoint. 18 Q. Okay. And, again, am I correct that 19 noninferior as established in clinical trial 20 endpoints, that's a -- that's a statistical test; 21 is that -- is that right? 22 And if you like, for reference, I'm 23 looking at that same paragraph 96, the parentheses 24 about a third of the way down page 36, you quote 25 the '681 patent at Column 13, lines 31 to 34, as
Page 23 1 you refer to Phase 3 ranibizumab trials, right? 2 A. I see that text. 3 Q. Just to make -- just for ease of 4 pronunciation, do you mind if I use the term 5 "Lucentis" for ranibizumab or would you rather I 6 use "ranibizumab"? 7 A. Either term is fine with me. 8 Q. Okay. Thank you. 9 So is it fair to say, based on what 10 you've written in paragraph 96 of your declaration, 11 pages 35 to 36, that Eylea -- that the claimed 12 dosing regimen using Eylea is noninferior to 13 monthly Lucentis? 14 MS. STRUTHERS: Objection to form. 15 THE WITNESS: Can you repeat the question? 16 BY MR. EHRICH: 17 Q. Sure. Actually, I'll broaden it. Since 18 this declaration is setting forth your opinions as 19 an expert and as an ophthalmologist, is it your 20 opinion that the claimed dosing regimen using Eylea 21 is noninferior to monthly Lucentis for the 22 treatment of AMD? 23 MS. STRUTHERS: Same objection. 24 THE WITNESS: In my declaration, I noted that 25 the POSA would have concluded from the totality of	Page 25 1 statistically noninferior. 2 And so my question -- when you say 3 noninferior in this paragraph, you mean 4 statistically noninferior as established in the 5 clinical trial; is that -- is that correct? 6 MS. STRUTHERS: Objection to form. 7 THE WITNESS: Can you repeat the question? 8 BY MR. EHRICH: 9 Q. Sure. You said that -- again, the last 10 sentence of paragraph 96, you say that -- you use 11 the term "noninferior," and I believe you said that 12 you're -- that in this context of this 13 paragraph 96, you're using the term "noninferior" 14 as a clinical trial endpoint. And I just wanted to 15 confirm, based on your quote from the '681 patent, 16 that noninferior as a clinical trial endpoint is a 17 statistical test; is that correct? 18 MS. STRUTHERS: Objection to form. 19 THE WITNESS: In paragraph 96, when I discuss 20 Eylea's Phase 3 wet AMD trials, I note that 21 noninferiority was established by matching or 22 exceeding ranibizumab success at achieving this 23 endpoint, and statistically noninferior was based 24 on the noninferiority margin of 10 percent using 25 confidence interval approach. In that context,

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Page 26 1 we're talking about noninferiority as a clinical 2 trial endpoint. 3 BY MR. EHRICH: 4 Q. Okay. And -- but is it fair to say not 5 just the clinical trial endpoint but having about 6 95 percent of the patients meeting that endpoint; 7 is that -- is that correct? 8 MS. STRUTHERS: Objection to form. 9 THE WITNESS: Which line are you referring to? 10 BY MR. EHRICH: 11 Q. Well, go toward the top of page 36, the 12 first complete sentence, you write, "Noninferiority 13 was established by matching or exceeding 14 ranibizumab's success at achieving this endpoint 15 for about 95 percent of the patients treated 16 according to the protocol." Right? 17 A. I see that text. 18 Q. Okay. So noninferiority isn't a single 19 patient meeting -- achieving endpoint but 20 95 percent of the patients in the clinical trial 21 meeting endpoints; is that fair to say? 22 MS. STRUTHERS: Objection to form. 23 THE WITNESS: Can you repeat the question? 24 BY MR. EHRICH: 25 Q. Sure. You write that "Noninferiority	Page 28 1 ranibizumab's success at achieving this endpoint 2 for about 95 percent of the patients treated 3 according to the protocol in that clinical trial. 4 BY MR. EHRICH: 5 Q. Okay. Well, I guess -- and, then, let's 6 look -- so there's the sentence that you read and 7 there's the parenthetical quote from the '681 8 patent, and then you see the sentence that begins 9 with "efficacy," and then still on paragraph 96, 10 page 36? 11 A. Yes. 12 Q. So you write the "Efficacy, based on 13 this particular measure, is not achieved merely by 14 having a single patient satisfying the 'loss of 15 15 or fewer letters' endpoint, but instead by 16 having about 95 percent or more of all patients 17 meeting this endpoint." Right? 18 A. I see that text. 19 Q. And so efficacy here is -- means 20 statistically noninferior, right? 21 MS. STRUTHERS: Objection; mischaracterizes 22 the testimony, the document speaks for itself. 23 THE WITNESS: Do you have a question? 24 BY MR. EHRICH: 25 Q. My question is what does efficacy mean?
Page 27 1 was established by matching or exceeding 2 ranibizumab's success and achieving this endpoint 3 for about 95 percent of the patients treated 4 according to the protocol." Right? 5 You did not -- 6 A. Yes, I see that text. 7 Q. Okay. You did not write noninferiority 8 was established by matching or exceeding 9 ranibizumab's success at achieving this endpoint 10 for one of the patients treated according to the 11 protocol. Right? This is something that does not 12 appear. That is not the sentence, correct? 13 My question is, in the context of 14 paragraph 96 where you're talking about Eylea's 15 noninferiority Phase 3 wet AMD trials as set forth 16 in Example 4 of the '681 patent, the noninferiority 17 is established by having 95 percent of the patients 18 meet the clinical endpoint, not -- and is not 19 established by having a single patient meet the 20 clinical endpoint; is that correct? 21 MS. STRUTHERS: Objection to form. 22 THE WITNESS: In paragraph 96, a POSA would 23 understand that in the context of Eylea's Phase 3 24 wet AMD trials, noninferiority was established in 25 the clinical trials by matching or exceeding	Page 29 1 MS. STRUTHERS: Objection to form. 2 BY MR. EHRICH: 3 Q. What does the word "efficacy" in this -- 4 in this sentence mean? 5 A. In paragraph 96, I am discussing the 6 Phase 3 clinical trials of Eylea and wet AMD. I 7 noted that noninferiority was established in these 8 clinical trials by matching or exceeding 9 ranibizumab's success at achieving this endpoint 10 for about 95 percent of the patients treated 11 according to the protocol. 12 And in the context of the clinical 13 trial, efficacy based on this particular measure is 14 not achieved merely by a single patient satisfying 15 the "loss of 15 or fewer letters" endpoint, but 16 instead by having about 95 percent or more of all 17 patients meeting this endpoint. 18 Q. Right. And so what -- you say "based on 19 this particular measure" in that sentence you just 20 read. What is -- what is "this particular 21 measure"? 22 A. This paragraph is discussing the 23 noninferiority clinical trial's outcome of the 24 Phase 3 Eylea studies in wet AMD, and we're talking 25 about the clinical trial endpoint of

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Page 30 1 noninferiority. 2 Q. Okay. Thank you. 3 Now, if you please turn the page of 4 the same 1225 declaration to paragraph 98 on 5 page 37, a couple of the words in paragraph 98 are 6 the same as text on the page as a couple of the 7 words in paragraph 96, and my question is whether 8 you're using those words in paragraph 98 the same 9 way you're using those words in paragraph 96. 10 Let's start with "efficacy." So you 11 had just -- you had just been talking about what 12 you mean by the term "efficacy" in paragraph 96, 13 and so now I'm asking -- now the question is what 14 do you mean by the term "efficacy" in paragraph 98? 15 MS. STRUTHERS: Objection to form. 16 THE WITNESS: Can you repeat the question? 17 BY MR. EHRICH: 18 Q. Sure. In paragraph 96, you talk about 19 "efficacy, based on this particular measure," and 20 in paragraph 98 you also use the term "efficacy." 21 In paragraph 98, do you also mean efficacy based on 22 this particular measure or are you using some other 23 meaning for the word "efficacy"? 24 MS. STRUTHERS: Objection to form. 25 THE WITNESS: In paragraph 98, I state that	Page 32 1 according to the protocol," would that be 2 sufficient data for a POSA to conclude that the 3 claimed method of treating -- that the method of 4 treating is comparable to the standard of care? 5 MS. STRUTHERS: Objection; vague, 6 mischaracterizes the testimony. 7 THE WITNESS: Can you repeat the question? 8 BY MR. EHRICH: 9 Q. Sure. So you had said that -- just a 10 second. I just want to make sure that I'm quoting 11 you correctly here. You said "The POSA would look 12 at the totality of the data, analyze it, and come 13 up with a conclusion" in order to determine whether 14 or not a method of treating is comparable to the 15 standard of care. And I'm trying to get at what 16 kind of data is the POSA -- does the POSA need to 17 reach this conclusion. For example, you write in 18 paragraph 96 that "Noninferiority was established 19 by matching or exceeding ranibizumab's success at 20 achieving this endpoint for about 95 percent of the 21 patients treated according to the protocol." 22 Is it fair to say that this would be 23 part of the totality of the data that the POSA 24 would consider in concluding that a method of 25 treating is comparable to the standard of care?
Page 31 1 the POSA would consider the claimed method for 2 treating as one that achieves a high level of 3 efficacy that is noninferior to the standard of 4 care at the time of the patent filing in a given 5 patient. 6 The POSA would understand that the 7 standard of care at that time to treat angiogenic 8 eye disorders was either Lucentis or Avastin. And 9 in paragraph 98, the term "noninferior to the 10 standard of care," the POSA would understand that 11 referring to a level of efficacy that is comparable 12 to the standard of care at the time of the patent 13 filing, in that paragraph. 14 BY MR. EHRICH: 15 Q. Okay. How does a POSA determine whether 16 or not a method of treating is comparable to the 17 standard of care? 18 A. The POSA would look at the totality of 19 the data, analyze it, and come up with a 20 conclusion. 21 Q. Okay. So at the top of page 36, 22 paragraph 96, when you write that "Noninferiority 23 was established by matching or exceeding 24 ranibizumab's success at achieving this endpoint 25 for about 95 percent of the patients treated	Page 33 1 MS. STRUTHERS: I'm sorry, Tom. Are you on 2 paragraph 96? 3 MR. EHRICH: Mm-hmm. 4 MS. STRUTHERS: Thank you. 5 THE WITNESS: I recall that we discussed that 6 paragraph 96, much of this discusses the Phase 3 7 wet AMD clinical trials of Eylea, and I wrote that 8 noninferiority in much of this paragraph refers to 9 a clinical trial endpoint. 10 BY MR. EHRICH: 11 Q. Yes. 12 A. And that noninferiority was established 13 by matching or exceeding ranibizumab's success at 14 achieving this clinical trial endpoint for about 15 95 percent of the patients treated according to the 16 protocol. 17 Moreover, although this was the 18 primary endpoint as explained, patients also 19 achieved an average gain of seven or more letters 20 in the clinical trial of Eylea and ranibizumab. 21 And the POSA would have concluded from the totality 22 of the data that the VEGF Trap-Eye administered on 23 a Q8 dosing schedule achieved and maintained a high 24 level of efficacy. 25 Q. And maintained and achieved a high level

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Page 34 1 of efficacy, you write, that was noninferior to 2 ranibizumab. But would your -- would it also be 3 your opinion that it -- that it would show that it 4 achieved and maintained a high level of efficacy 5 that was comparable to ranibizumab? 6 MS. STRUTHERS: Objection; vague. 7 THE WITNESS: Can you repeat the question? 8 BY MR. EHRICH: 9 Q. Sure. You told me that in paragraph 98 10 you're using the term "noninferior" to mean 11 comparable, and so I'm wondering if we can 12 substitute the word "comparable" for "noninferior" 13 in the last sentence of paragraph 96. 14 A. In paragraph 98, when I write "The POSA 15 would consider the claimed method for treating as 16 one that achieves a high level of efficacy that is 17 noninferior to the standard of care at the time of 18 patent filing in a given patient," the standard of 19 care that we're referring to was Lucentis or 20 Avastin for the treatment of angiogenic eye 21 disorders. 22 And in paragraph 98, when I use the 23 term "noninferior," I mean the POSA would 24 understand that would be similar to saying 25 comparable, on par, with the standard of care.	Page 36 1 what the POSA would conclude in understanding all 2 of this evidence that's present. 3 Q. Okay. You said "all of this evidence 4 that's present," and my question is what 5 specifically do you mean by "this evidence"? 6 A. The POSA would have knowledge of the 7 Eylea clinical trial, the prior ranibizumab 8 clinical trials, and using their knowledge to come 9 up with the conclusion that the claimed method for 10 treating is one that achieved a high level of 11 efficacy that is noninferior or on par with the 12 standard of care at the time of the patent filing 13 in a given patient, and the standard of care at the 14 time of the patent filing was Lucentis or Avastin. 15 Q. Just so I can understand what you're 16 referring to. In your last answer, you said the 17 POSA would have knowledge of the Eylea clinical 18 trial. And by "the Eylea clinical trial," are you 19 referring to the Phase 3 trials that you discussed 20 in paragraph 96 of your declaration? 21 A. Yes, I'm referring to the Eylea Phase 3 22 wet AMD trial. 23 Q. Okay. Thank you for clarifying. 24 And then you also reference -- you 25 also said that the POSA would have knowledge of the
Page 35 1 Q. Okay. But you -- but you said that a 2 POSA would look at the totality of the data and 3 reach a conclusion that a method of treating is 4 comparable to the standard of care. And that term 5 "totality of the data" you also use in the last 6 sentence of paragraph 96. 7 So is this an example of the skilled 8 artisan looking at the totality of the data and 9 concluding that a method of treating is comparable 10 to the standard of care? 11 MS. STRUTHERS: Objection to form. 12 THE WITNESS: Could you repeat your question? 13 BY MR. EHRICH: 14 Q. Sure. You said earlier that with regard 15 to paragraph 98, the POSA would look at the 16 totality of the data in reaching a conclusion that 17 a method of treating is comparable to the standard 18 of care. The last sentence of paragraph 96 also 19 discusses the skilled artisan or the POSA reaching 20 a conclusion from the totality of the data, right? 21 A. I think what I stated earlier, which was 22 that the POSA would consider the claimed method for 23 treating as one that would achieve a high level of 24 efficacy that is comparable to the standard of care 25 at the time of patent filing in a given patient, is	Page 37 1 prior ranibizumab clinical trials. 2 Can I ask what you mean by "the prior 3 ranibizumab clinical trials"? My understanding is 4 that there are quite a few of them. 5 A. The Phase 3 ranibizumab clinical trials 6 I'm referring to would be Anchor and Marina, which 7 were the ranibizumab Phase 3 clinical trials in 8 wet AMD. 9 Q. Okay. Thank you for clarifying. 10 MS. STRUTHERS: I think we've been going for 11 about an hour. Would it be a good time for a 12 break? 13 MR. EHRICH: That's fine. 14 Do you want to do the standard 15 ten minutes? 16 MS. STRUTHERS: Works for me. 17 MR. EHRICH: Okay. 18 THE VIDEOGRAPHER: Off the record at 12:06. 19 (Short recess.) 20 THE VIDEOGRAPHER: We're now back on the 21 record at 12:18. 22 Please continue. 23 MR. EHRICH: Welcome back, Dr. Do. 24 THE WITNESS: Thank you. 25

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Page 38 1 BY MR. EHRICH: 2 Q. I would like to, I believe, compare -- 3 so, Dr. Do, I believe since we went off the record 4 you've been handed a third binder; is that correct? 5 And it should say "IPR2021-00881" on the front? 6 A. Yes, it does. 7 Q. Okay. And you can look at -- I'd like 8 you to look at -- well, first of all, the first 9 question is -- and you don't need to recognize, but 10 do you recognize the case 2021-00881? And, if not, 11 feel free to maybe flip to the first tab in that 12 binder labeled Exhibit 2051 to refresh your memory. 13 MS. STRUTHERS: Counsel, I note for the record 14 that the cover sheet is a little confusing because 15 it's got a caption from the West Virginia District 16 Court litigation on it, as well. 17 MR. EHRICH: Oh, I apologize. That is a 18 clerical error. 19 THE WITNESS: In Exhibit 2051, I recognize my 20 declaration regarding U.S. Patent Number 9,254,338. 21 BY MR. EHRICH: 22 Q. Okay. And do you recognize that the 23 '338 patent is related to both the '681 and '601 24 patents that we've been discussing today? 25 A. And which lines of the patent are you	Page 40 1 related U.S. Patent Number 9,254,338. 2 Q. Okay. And, Dr. Do, do -- so as you note 3 in your declaration, you previously submitted a 4 declaration on the '338 patent. 5 Do you recall that you were also 6 previously deposed regarding your declaration on 7 the '338 patent? 8 A. Yes, I think I recall that. 9 Q. Okay. So I'd like you to please go back 10 to the third binder, the binder that just arrived, 11 and there should be a tab in there that's labeled 12 "2022 transcript." 13 A. Yes, I see that. 14 Q. Okay. Thank you. 15 MR. EHRICH: And let's please introduce this 16 as Do Exhibit 5. 17 (Do Deposition Exhibit 5 was 18 marked for identification.) 19 BY MR. EHRICH: 20 Q. I'm going to represent to you that this 21 is a transcript of your deposition on the 22 '338 patent, as it states on the front page, but 23 feel free to flip through it, if you'd like, just 24 to confirm that. 25 A. Yes.
Page 39 1 referring to? 2 Q. Okay. Let me -- let me come at that 3 another way. Just a second, please. 4 Let's go back, please, to -- let's go 5 back, please, to the binder -- the declarations 6 binder, and let's go back, please, to your 1225 7 declaration, Exhibit 2056 (1225). 8 Are you there? 9 A. Yes. 10 Q. And I'd like you to please turn to 11 paragraph 4 on page 2 of that declaration. And I 12 just want to establish do you understand that you 13 had -- or do you agree that you have previously 14 submitted a declaration in another IPR regarding 15 Patent Number 9,254,338? Well, first that 16 question. Do you understand that you submitted a 17 declaration regarding that patent? 18 A. Yes. I see the text in line 4. 19 Q. Okay. And you see that you -- in line 4 20 you characterize the Patent 9,254,338 as related, 21 presumably, to the '681 patent; is that fair to 22 say? 23 A. I see the text in line 4 in which I 24 state my qualifications and experience are detailed 25 in my declaration in a proceeding regarding the	Page 41 1 Q. Okay. So staying with the 2022 2 transcript, please, can you please turn to -- well, 3 you provide an answer previously that starts at the 4 top -- towards the top of page 93. If you could 5 please turn to pages 92 and 93. 6 And do you see that in your answer on 7 page 93, lines 6 through 9, you stated that the 8 POSA would understand "that 'efficacy' would mean 9 at that time something that is noninferior to the 10 standard of care"? 11 A. I see those text. 12 Q. Okay. And so do you recall, are you 13 using the term "noninferior" the same way you're 14 using it in paragraph 98 of your 1225 declaration 15 or the way you're using the term "noninferior" in 16 paragraph 96 of your 1225 declaration? 17 A. Could you repeat the question? 18 Q. Sure. You used the term "noninferior" 19 here in line 9 of the 2022 transcript. You also 20 used the term "noninferior" in paragraph 98 of your 21 1225 declaration. And you used the term 22 "noninferior" in the last sentence of paragraph 96 23 of your 1225 declaration. 24 Are you using the term "noninferior" 25 in the transcript to mean what you mean in

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Page 42 1 paragraph 98 of your declaration or to mean what 2 you mean in paragraph 96 of your declaration? 3 MS. STRUTHERS: Objection; foundation, the 4 document speaks for itself. 5 THE WITNESS: Could you repeat the question? 6 BY MR. EHRICH: 7 Q. Sure. You used the term "noninferior" 8 in paragraph 96 of your declaration. You also used 9 the term "noninferior" in paragraph 98 of your 10 declaration. And here I'm referring to, in both 11 cases, your 1225 declaration. 12 Are either of those uses of the term 13 "noninferior" the same as your use of the term 14 "noninferior" in line 9 of the 2022 transcript? 15 A. In Exhibit 2056 (1225), paragraph 98, 16 the POSA would consider the claimed method for 17 treating as one that achieves a high level of 18 efficacy that is noninferior to the standard of 19 care at the time of patent filing in a given 20 patient. 21 In paragraph 98, the POSA would 22 understand the word "noninferior" in that sentence 23 to mean on par or comparable to the standard of 24 care at that time, which was Lucentis or Avastin. 25 Q. And is that how you're using the term	Page 44 1 A. Yes. I'm on page 160. 2 Q. Okay. And just for your reference, 3 Dr. Do, the question looks like it begins on the 4 bottom of page 159, but my question is regarding 5 your answer at the top of page 160 starting line 2 6 where you say, "The standard of care is the best 7 available medical treatment for that particular 8 condition." And I believe several times today 9 you've said that the standard of care at the time 10 of the patent filing would have been monthly 11 Lucentis or Avastin; is that right? 12 A. Yes, that's what I said. 13 Q. Okay. And so my question is just is 14 that what you mean, then, here in lines 2 and 3 on 15 page 160 of the transcript is the -- at the time of 16 the patent filing was the best available medical 17 for angiogenic eye disorders monthly Lucentis or 18 Avastin? 19 A. In the 2022 transcript, line 2, I think 20 the standard of care is the best available medical 21 treatment for that particular condition. 22 Q. Okay. Yes. Okay. Well, so if we -- 23 would the standard of care -- at the time of patent 24 filing in January 2011, would the best available 25 medical treatment for angiogenic eye disorders have
Page 43 1 "noninferior" in line 9 of the 2022 transcript? 2 MS. STRUTHERS: For clarity, we're talking 3 about page 93 at line 9; is that correct? 4 MR. EHRICH: Yeah, that's right. Page 93, 5 line 9, of the 2022 transcript. And thank you for 6 clarifying, Counsel. 7 THE WITNESS: In the transcript taken in 2022, 8 I stated that through the eyes of a POSA and 9 understanding that efficacy would mean at the time 10 of the patent filing something that is noninferior 11 to the standard of care, and the standard of care 12 at that time required a high level of efficacy in 13 terms of gaining vision or maintaining vision. 14 The POSA would understand that the 15 term "noninferior" in line 9 would mean on par, 16 comparable, to the standard of care at that time, 17 and, of course, the standard of care at that time 18 was either Lucentis or Avastin. 19 BY MR. EHRICH: 20 Q. Okay. Thank you for clarifying, Dr. Do. 21 And, actually, your answer, I think, 22 kind of anticipated my next question. But also 23 relating to this transcript, if you can flip 24 forward to page 160 of the 2022 transcript. And 25 just let me know when you're there, please.	Page 45 1 been monthly treatment with Lucentis or Avastin? 2 A. At the time of the patent filing in 3 2011, the best available medical treatment for 4 angiogenic eye disorders was VEGF inhibitors such 5 as Lucentis or Avastin. 6 Q. Okay. Can you please tell me what other 7 VEGF inhibitors were available in January 2011 8 besides Lucentis and Avastin? 9 A. In 2011 the VEGF inhibitors that were 10 available were Lucentis, Avastin, and also Macugen, 11 although that was not used frequently at that time. 12 Q. Okay. Would Macugen have been the best 13 available medical treatment for angiogenic eye 14 disorders in January 2011? 15 A. At the time of 2011, the POSA would not 16 think Macugen was the best available treatment at 17 that time for angiogenic eye disorders. 18 Q. Okay. So if we take out Macugen, are we 19 left with monthly Lucentis or Avastin as the best 20 available medical treatments for angiogenic eye 21 disorders as of January 2011? 22 A. As of January 2011, the POSA would 23 consider the best available medical treatment for 24 angiogenic eye disorders would be Lucentis or 25 Avastin.

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Page 46 1 Q. Okay. Thank you for clarifying, Dr. Do. 2 I'd like you to please set aside that 3 third binder, and I'd like to have you -- ask you 4 to please go back to the declarations binder. And 5 if you could please turn back to Exhibit 2001, 6 which, as you may recall, is your October 2022 7 declaration. And, specifically, I'd like you to 8 please turn to paragraph 39, which I believe is on 9 page 12. And just please let me know when you're 10 there. 11 Okay. Do you see paragraph 39? 12 A. Yes. 13 Q. You know what, I apologize. I would 14 like you to then, since you're already there, 15 though, go back to page 11, paragraph 38, same 16 declaration, Exhibit 2001. 17 Do you see the second sentence to 18 paragraph 38 of Exhibit 2001 says "Once VEGF Trap 19 was shown to be highly effective in wet AMD, 20 ophthalmologists would have expected it to also be 21 highly effective for other angiogenic eye 22 disorders." 23 My question is what do you mean by 24 the term "highly effective"? 25 A. In paragraph 38 of Exhibit 2001, I state	Page 48 1 established by a single patient in paragraph 98 -- 2 or paragraph 96 of your 1225 declaration, but it 3 sounded to me like you just said that efficacy is 4 established in a single patient in paragraph 38 of 5 Exhibit 2001. 6 And so if you could just please 7 explain to me how is it that efficacy is not 8 established by a single patient in one context and 9 is relevant to a single patient in the other 10 context. 11 MS. STRUTHERS: Objection to form, 12 mischaracterizes the testimony. 13 THE WITNESS: Could you repeat the question? 14 BY MR. EHRICH: 15 Q. Sure. In reference to paragraph 38 of 16 Exhibit 2001, you said that "the POSA would 17 understand the method of treatment for the 18 individual patient would be on par with what is 19 seen in the standard of care at the time." But 20 then -- 21 A. Can you show me where that text is 22 again? 23 Q. I'm actually reading back your answer 24 from the transcript. 25 I had said -- I had asked, what do
Page 47 1 that "By 2011, the role of VEGF in angiogenic eye 2 diseases and the mechanism of action of anti-VEGF 3 agents was generally well-understood in the art. 4 Once VEGF Trap was shown to be highly effective in 5 wet AMD, ophthalmologists would have expected it to 6 also be highly effective for other angiogenic eye 7 disorders." 8 And the term "highly effective" in 9 that sentence refers to the POSA understanding that 10 the claimed method of treatment for an individual 11 patient would be on par with what is seen in the 12 standard of care at that time, which was Lucentis 13 or Avastin. 14 Q. Okay. I'm a little confused now because 15 you just said that the method of treatment for the 16 individual patient would be on par with the 17 standard of care at the time, which is Lucentis or 18 Avastin. But then if we go back to your 1225 19 declaration, paragraph 96, page 36, you write that 20 "Efficacy, based on this particular measure, is not 21 achieved merely by a single patient satisfying the 22 'loss of 15 or fewer letters' endpoint, but instead 23 by having about 95 percent or more of all patients 24 meeting this endpoint." 25 So I'm confused that efficacy is not	Page 49 1 you mean by the term "highly effective" in 2 paragraph 38 of Exhibit 2001, and you had said that 3 the sentence refers to the POSA understanding the 4 method of treatment for the individual patient 5 would be on par with what is seen in the standard 6 of care at the time. 7 But in paragraph 96 of your 1225 8 declaration you had said that "Efficacy, based on 9 this particular measure, is not achieved merely by 10 a single patient satisfying the 'loss of 15 or 11 fewer letters' endpoint." 12 MS. STRUTHERS: Is there a question pending? 13 BY MR. EHRICH: 14 Q. How does a POSA understand that a method 15 of treatment is on par with the standard of care 16 for an individual patient, as you state with 17 respect to paragraph 38 of Exhibit 2001, if 18 efficacy is not achieved merely by a single patient 19 satisfying a "loss of 15 or fewer letters" 20 endpoint, as you state in paragraph 96 of your 1225 21 declaration? 22 MS. STRUTHERS: Objection to form, 23 mischaracterizes the testimony. 24 THE WITNESS: In my declaration of 25 Example 2056 (1225), paragraph 98, it's my opinion

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Page 50 1 that as of January 13th, 2011, the POSA would 2 consider the claimed method for treating as one 3 that achieves a high level of efficacy that is 4 noninferior or comparable to the standard of care 5 at the time of patent filing in a given patient. 6 At the time of the patent filing, the 7 standard of care was Lucentis or Avastin. 8 In paragraph 96 of Exhibit 2056 9 (1225), the line "efficacy, based on this 10 particular measure, is not achieved merely by a 11 single patient satisfying the 'loss of 15 or fewer 12 letters' endpoint but instead by having 95 percent 13 or more of all patients meeting this endpoint" 14 refers to the clinical trial endpoint of 15 noninferiority. And that was a statistical 16 endpoint we're referring to. 17 BY MR. EHRICH: 18 Q. Yes. And you just explained how you 19 used the term "efficacy" in paragraphs 96 and 98 of 20 your 1225 declaration, and now I'm asking how are 21 you using the term "highly effective" in 22 paragraph 38 of Exhibit 2001? 23 MS. STRUTHERS: Objection; vague. 24 THE WITNESS: Can you repeat the question? 25	Page 52 1 mean something else? 2 A. In Exhibit 2001, paragraph 98, the POSA 3 would understand the term, you know, "highly 4 effective in wet AMD" would represent that the 5 claimed dosing regimen achieves and maintains a 6 high level of efficacy and is comparable to that 7 seen with Lucentis and Avastin. 8 Q. Okay. Thank you for clarifying. 9 Now, that same sentence that you just 10 read from, you also say that ophthalmologists would 11 have expected it to also be highly effective for 12 other angiogenic eye disorders, right? 13 A. I see the text. 14 Q. And what do you mean by "highly 15 effective for other angiogenic eye disorders"? 16 A. In paragraph 38 of Exhibit 2001, the 17 POSA would understand that in the context of the 18 word "ophthalmologist would have expected to also 19 be highly effective for other angiogenic eye 20 disorders" to mean that it would behave similar to 21 the standard of care which was Lucentis or Avastin 22 at that time. 23 Q. Okay. What do you mean by "similar to 24 the standard of care"? Does that mean the same as 25 comparable to the standard of care, or does that
Page 51 1 BY MR. EHRICH: 2 Q. Sure. What do you mean by the term 3 "highly effective" in paragraph 38 of Exhibit 2001? 4 A. In Exhibit 2001, when I mention highly 5 effective, you can see in line 39 I state that 6 "Viewed in light of the patent and the 7 state-of-the-art in 2011, I understand the preamble 8 method for treating an angiogenic eye disorder in a 9 patient to mean that the claimed dosing regimen 10 achieves and maintains a high level of efficacy, 11 that is, comparable to that seen with Lucentis and 12 Avastin, that is effective for the patient in need 13 of treatment." 14 Q. Okay. So just to make sure I'm 15 understanding what you're saying, Dr. Do, are you 16 saying that the term "highly effective" in 17 paragraph 38 has the same meaning as "effective" in 18 paragraph 39? 19 MS. STRUTHERS: Objection; mischaracterizes 20 the testimony. 21 THE WITNESS: Could you repeat the question? 22 BY MR. EHRICH: 23 Q. Sure. Are you saying that the term 24 "highly effective" in paragraph 38 has the same 25 meaning as "effective" in paragraph 39, or does it	Page 53 1 mean something else? 2 A. Could you repeat the question? 3 Q. Sure. What do you mean by "similar to 4 the standard of care"? Do you mean comparable to 5 the standard of care, or do you mean something 6 else? 7 A. Recall that in paragraph 39 of 8 Exhibit 2001 states that, you know, the -- the 9 method of treating -- for treatment -- treating an 10 angiogenic eye disorder in a patient to mean that 11 the claimed dosing regimen achieves and maintains a 12 high level of efficacy that is comparable to that 13 seen with Lucentis and Avastin and is effective for 14 that patient in need of treatment. 15 Q. Okay. And by "comparable to that seen 16 with Lucentis and Avastin," you're referring in 17 that sentence to angiogenic eye disorders 18 generally, not just to wet AMD specifically, right? 19 A. Which line are you referring to? 20 Q. I'm referring to paragraph 39 of 21 Exhibit 2001. 22 A. I believe that in line 39 of 23 Exhibit 2001, we're discussing wet AMD in this 24 particular line in reference to the patent '681 and 25 the preamble "method for treating an angiogenic eye

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Page 54 1 disorder in a patient" to mean that the claimed 2 dosing regimen achieves and maintains a high level 3 of efficacy is comparable to that seen with 4 Lucentis and Avastin and is effective for the 5 patient in need of treatment. 6 Q. Okay. So you just said that you believe 7 that -- you said line 39. I assume you meant 8 paragraph 39 of Exhibit 2001; is that right? 9 A. Yes. And it's paragraph 39. 10 Q. Okay. Thank you. 11 And so you said that in paragraph 39 12 of Exhibit 2001 you're discussing wet AMD, but then 13 what would "method for treating an angiogenic eye 14 disorder in a patient" mean for angiogenic eye 15 disorders other than wet AMD? 16 A. And which lines are you referring to? 17 Q. Well, I'm looking at paragraph 39 of 18 Exhibit 2001, and you say that you -- and you talk 19 about your understanding of the meaning of the 20 preamble "method for treating an angiogenic eye 21 disorder in a patient." But then in your last 22 answer, you said that that was discussing wet AMD. 23 And so my question is what about other angiogenic 24 eye disorders besides wet AMD? 25 MS. STRUTHERS: Objection to form,	Page 56 1 paragraph 39 was referring to wet AMD specifically. 2 And so my question is would a POSA 3 have understood VEGF Trap to be comparable to 4 Lucentis for angiogenic eye disorders generally or 5 only for wet AMD specifically? 6 MS. STRUTHERS: Objection to form, 7 mischaracterizes the testimony. 8 THE WITNESS: Can you repeat the question? 9 BY MR. EHRICH: 10 Q. Sure. Would a POSA have understood VEGF 11 Trap to be comparable to Lucentis in the treatment 12 of angiogenic eye disorders generally or only 13 comparable to Lucentis for the treatment of wet AMD 14 specifically? 15 MS. STRUTHERS: Objection to form, vague as to 16 time. 17 BY MR. EHRICH: 18 Q. Just to clarify and respond to counsel's 19 objections, I'm referring to January 2011. 20 A. In January of 2011, the Eylea Phase 3 21 clinical trials of wet AMD had concluded and we had 22 the data on the trial results. Based on the 23 wet AMD trials of Eylea, the POSA would consider 24 the claimed method for treating as one that 25 achieves a high level of efficacy that is
Page 55 1 mischaracterizes the testimony. 2 THE WITNESS: As I stated in paragraph 38 of 3 my Exhibit 2001, "By 2011, the role of anti-VEGF in 4 angiogenic eye diseases and the mechanism of action 5 of anti-VEGF agents was generally well-understood 6 in the art. Once VEGF Trap was shown to be highly 7 effective in the wet AMD, ophthalmologists would 8 have expected it to also be highly effective for 9 other angiogenic eye disorders. In particular, wet 10 AMD is one of the more challenging retinal vascular 11 diseases to treat, so once it was demonstrated that 12 VEGF Trap resulted in vision gains for wet AMD 13 patients, similar to the vision gains shown for 14 Lucentis, the POSA would have expected VEGF Trap to 15 be similarly efficacious to Lucentis in treating 16 other angiogenic eye disorders." 17 BY MR. EHRICH: 18 Q. So in view of that answer, in 19 paragraph 39, would it apply to angiogenic eye 20 disorders generally or just to wet AMD? I am a 21 little confused because I may be misunderstanding, 22 but it sounded to me that you said that in 23 paragraph 38, the POSA would expect VEGF Trap to be 24 comparable to Lucentis for angiogenic eye disorders 25 generally, but you had earlier said that	Page 57 1 comparable to the standard of care at the time of 2 the patent filing in a given patient. 3 Q. Right, Dr. Do. And in your answer, you 4 just said, "Based on the wet AMD trials of Eylea, 5 the POSA would consider the claimed method for 6 treating as one that achieves a high level of 7 efficacy that is comparable to the standard of care 8 at the time of the patent filing in a given 9 patient." 10 And do you mean comparable to the 11 standard of care for wet AMD specifically or 12 comparable to the standard of care for angiogenic 13 eye disorders generally? 14 MS. STRUTHERS: Objection to form, 15 mischaracterizes the testimony. 16 THE WITNESS: As I stated in paragraph 38 of 17 Exhibit 2001, the POSA would have expected VEGF 18 Trap to be similarly efficacious to Lucentis in 19 treating other angiogenic eye disorders given the 20 results seen in the Phase 3 Eylea wet AMD clinical 21 trials. 22 BY MR. EHRICH: 23 Q. Okay. And by "similarly efficacious" in 24 paragraph 38, does that mean the same thing as 25 "comparable" in paragraph 39?

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Page 58 1 MS. STRUTHERS: Objection to form. 2 THE WITNESS: Can you repeat the question? 3 BY MR. EHRICH: 4 Q. Sure. Does the phrase "similarly 5 efficacious" in paragraph 38 mean the same thing as 6 "comparable" in paragraph 39? 7 MS. STRUTHERS: Same objection. 8 THE WITNESS: As stated in paragraph 38 of 9 Exhibit 2001, "By 2011, the role of VEGF in 10 angiogenic eye disease and the mechanism of action 11 of anti-VEGF agent was generally well-understood in 12 the art. Once VEGF Trap was shown to be highly 13 effective in wet AMD, ophthalmologists would have 14 expected it to also be highly effective for other 15 angio eye diseases. In particular, wet AMD is one 16 of the more challenging retinal vascular diseases 17 to treat. So once it was demonstrated that VEGF 18 Trap resulted in vision gains for wet AMD patients, 19 similar to the vision gains shown for Lucentis, the 20 POSA would have expected VEGF Trap to be similarly 21 efficacious to Lucentis in treating other 22 angiogenic eye disorders. Accordingly, viewed in 23 light of the patent and the state-of-the-art in 24 2011, I understand the 'preamble method for 25 treating an angiogenic eye disorder in a patient'	Page 60 1 according to the claimed method of treating? In 2 other words, are you referring to VEGF Trap just as 3 the molecule, the active ingredient, or do you mean 4 VEGF Trap as the molecule administered according to 5 the claimed method of treating? 6 MS. STRUTHERS: Objection to form, 7 mischaracterizes the testimony. 8 THE WITNESS: Could you repeat the question? 9 BY MR. EHRICH: 10 Q. Sure. You say there's -- you write -- 11 do you see that the second sentence of paragraph 38 12 of Exhibit 2001 begins "Once VEGF Trap was shown to 13 be highly effective in wet AMD," right? 14 A. I see those texts. 15 Q. Okay. And by the term "VEGF Trap" in 16 that sentence, do you mean just the molecule VEGF 17 Trap or do you mean the molecule VEGF Trap 18 administered according to the Q8 dosing regimen of 19 the VIEW trials? 20 MS. STRUTHERS: Objection to form, lack of 21 foundation, beyond the scope. 22 THE WITNESS: Can you repeat the question? 23 BY MR. EHRICH: 24 Q. Sure. It seems to me that you're saying 25 that once VEGF Trap is shown to be highly effective
Page 59 1 to mean that the claimed dosing regimen achieves 2 and maintains a high level of efficacy that is 3 comparable to that seen with Lucentis and Avastin, 4 and that it is effective for the patient in need of 5 treatment." 6 BY MR. EHRICH: 7 Q. And by the term "angiogenic eye 8 disorder" in paragraph 39, then, are you meaning to 9 refer to angiogenic eye disorders generally or are 10 you using the term "angiogenic eye disorder" to 11 refer specifically to wet AMD? 12 A. In paragraph 39, method for treating an 13 angiogenic eye disorder means in general an 14 angiogenic eye disorder. 15 Q. Okay. Thank you. 16 I do have another question about your 17 terminology, Dr. Do, in paragraph 38 of 18 Exhibit 2001. 19 You see the second sentence says 20 "Once VEGF Trap was shown to be highly effective in 21 wet AMD." Now, I will tell you, Dr. Do, that just 22 reading the plain language, it looks to me that 23 you're referring to VEGF Trap as the substance, as 24 the medicine itself. And is that what you mean 25 here, or do you mean VEGF Trap administered	Page 61 1 in wet AMD, you're saying that the active 2 ingredient, VEGF Trap, had been shown to be highly 3 effective in wet AMD; is that right? 4 MS. STRUTHERS: Objection; form. 5 THE WITNESS: Recall that in paragraph 39 of 6 Exhibit 2001 I state that the "method for treating 7 an angiogenic eye disorder in a patient" to mean 8 that the claimed dosing regimen achieves and 9 maintains a high level of efficacy that is 10 comparable to that seen with Lucentis and Avastin 11 and that it is effective for the patient in need of 12 treatment. 13 BY MR. EHRICH: 14 Q. Yes. And I see that that's what you say 15 in paragraph 39. And so do you mean, then, that 16 the term "VEGF Trap" in paragraph 38 means VEGF 17 Trap administered according to the claimed dosing 18 regimen? 19 A. I think the POSA would not take the word 20 "VEGF Trap" in line -- in paragraph 38, the second 21 sentence, out of context without understanding the 22 whole patent, and the POSA would understand that 23 the "method for treating an angiogenic eye disorder 24 in a patient" to mean that the claimed dosing 25 regimen achieves and maintains a high level of

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Page 62 1 efficacy that is comparable to that seen with 2 Lucentis and Avastin and that it is effective for 3 the patient in need of the treatment. 4 MR. EHRICH: Okay. Thank you. 5 MS. STRUTHERS: Would it be good time for a 6 break, Tom? It's been an hour again. 7 MR. EHRICH: Yeah, that would be fine. 8 Would 15 minutes be okay with you 9 guys, or we could make it shorter or longer if you 10 prefer. 11 MS. STRUTHERS: 15 is fine, if that's what 12 you'd like. 13 MR. EHRICH: All right. 14 THE VIDEOGRAPHER: Off the record at 1:16. 15 (Short recess.) 16 THE VIDEOGRAPHER: We're now back on the 17 record at 1:33. 18 Please continue. 19 MR. EHRICH: Welcome back, Dr. Do. 20 THE WITNESS: Thank you. Welcome back. 21 BY MR. EHRICH: 22 Q. So, Dr. Do, I think -- I would like to 23 switch back, please, to your 1225 declaration, and 24 I'd like you to please turn to page -- I suppose 25 page 30, I want to ask you about -- and	Page 64 1 assess the therapeutic effectiveness of a method 2 for treating subjects with an anti-VEGF agent." 3 Did you have a question about that? 4 Q. Yes. My -- I'm reading your -- the 5 phrase "these clinical trial results" to be the 6 clinical trial results you're discussing in 7 paragraph 86, and I was just wondering if that's 8 correct, if you could please just confirm that. 9 A. In Exhibit 2056 (1225), in paragraph 86, 10 I state that "In addition to the clinical trial 11 endpoints mentioned in Column 7, the '681 patent's 12 specification discloses the use of a number of 13 different clinical trial endpoints to measure the 14 results of VEGF Trap-Eye in different angiogenic 15 eye disorders (Example 2 primary endpoint of 16 reduction of retinal thickness after 12 weeks; 17 secondary endpoint of mean change in visual 18 acuity), (Example 4 is primary endpoint prevention 19 of vision loss of greater than or equal to 20 15 letters on the ETDRS chart at 52 weeks; 21 secondary endpoints were, A, change in letter score 22 on the ETDRS chart at 52 weeks, B, gain of 15 or 23 more letters on the ETDRS chart at 52 weeks, C, 24 change in total NEI VFQ-25 score at 52 weeks)," and 25 so forth.
Page 63 1 specifically on paragraph 87, page 31. I want to 2 ask you about the first sentence of paragraph 87 of 3 your declaration, Dr. Do. And so if you want to 4 take a minute to look at -- it looks like it refers 5 back to paragraph 86. So if you want to just take 6 a minute to review paragraph 86, feel free to do so 7 and please just let me know when you're ready. 8 A. I want to clarify. Are you referring to 9 Exhibit 2056? 10 Q. Yeah, I -- I -- yeah, I am, yes. 11 2056 (1225) which, for the record, we previously 12 marked as Exhibit 3, but, yes, that one. 13 And, again, just let me know once 14 you're ready, please. 15 A. Yes, I see the paragraph that you 16 mentioned. 17 Q. Okay. So, Dr. Do, I understand the 18 first sentence of paragraph 87 where you say "The 19 skilled artisan would have been able to evaluate 20 these clinical trial results" to refer back to the 21 clinical trials summarized in the '681 patent that 22 you discuss in paragraph 86; is that correct? 23 A. In Exhibit 2056 (1225), paragraph 87 24 starts with "The skilled artisan would have been 25 able to evaluate these clinical trial results to	Page 65 1 Those are all different clinical 2 trial results needed to assess the therapeutic 3 effectiveness of a method for treating subjects 4 with anti-VEGF agent. 5 Q. Okay. So again looking at paragraph 86 6 of your 1225 declaration, toward the bottom of that 7 paragraph, about midway through page 31, you say 8 that in one of the trials, "Regeneron used mean 9 change in visual acuity from baseline (Phase II DME 10 study, Example 5)." 11 Do you see that? 12 A. I see that text. 13 Q. Is that one of the clinical trials that 14 a skilled artisan would have been able to evaluate 15 to assess the therapeutic effectiveness of a method 16 for treating subjects with an anti-VEGF agent? 17 MS. STRUTHERS: Objection to form. 18 THE WITNESS: Could you repeat the question? 19 BY MR. EHRICH: 20 Q. Sure. And we can go -- certainly go to 21 the patent itself if you'd like, Dr. Do, but for 22 now I'll just state it as you have written it in 23 paragraph 86. Example 5 concerns a Phase II DME 24 study, right? 25 And my question is would the results

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Page 66 1 of that Phase II DME study be something the skilled 2 artisan would have been able to evaluate to assess 3 the therapeutic effectiveness of a method for 4 treating subjects with an anti-VEGF agent? 5 A. Do you have the manuscript of that 6 Phase II DME study? 7 Q. I -- well, we have the -- we certainly 8 have the Example 5 in the patent. If you give me 9 just a minute, I'll pull up which -- so I think, 10 Dr. Do, if you could please go to the binder marked 11 "Exhibits," and you see the last tab is -- should 12 be labeled Klibanov Exhibit 13? 13 A. Yes, I see that tab. 14 Q. Okay. If you could just go there, 15 please. 16 MR. EHRICH: And for the record, we'll just 17 keep that designation. We'll introduce this as 18 Klibanov Exhibit 13. 19 BY MR. EHRICH: 20 Q. And, Dr. Do, if you can just confirm 21 that this does appear to be the '681 patent, 22 correct? 23 A. Yes, the Exhibit 13, Klibanov, first 24 page is the United States patent, Patent 25 Number 10,130,681.	Page 68 1 the -- appears to set forth the results of this -- 2 of that clinical trial? 3 A. Table 2 does appear to present some of 4 the visual acuity results. 5 Q. Okay. Now, I'm sorry to ask you to flip 6 between documents, Dr. Do, but if you could look 7 at -- keep Table 2 but then also please go back to 8 paragraph 86 and 87 of your 1225 declaration. 9 And can we agree that Table 2 appears 10 to set -- Table 2 of the '681 patent appears to set 11 forth clinical trial results for the Phase II DME 12 study in Example 5 that you reference in 13 paragraph 86 of your 1225 declaration? 14 A. In paragraph 86 of Exhibit 2056 (1225), 15 I did mention "For clinical trials of VEGF Trap-Eye 16 that were not designed as noninferiority studies, 17 Regeneron used mean change in visual acuity from 18 baseline (the Phase II DME study, Example 5) and 19 proportion of patients who gained 15 or more 20 letters in best corrective visual acuity at 21 month 24 (Phase 3 study in CRVO Example 6) as 22 primary endpoint measures." 23 Q. Right. And does Table 2 in the '681 24 patent provide the results of that Phase II DME 25 study, Example 5?
Page 67 1 Q. Okay. And recall that my question was 2 about Example 5, and if you want -- Example 5 looks 3 like it runs from the bottom of Column 13 to the 4 top of -- or about halfway down Column 14 of 5 Klibanov Example 13, the '681 patent. So please 6 feel free to turn there. 7 A. Can you repeat what column it was? 8 Q. Sure. It starts on the bottom of 9 Column 13. 10 A. Okay. I see that Example 5. 11 Q. Okay. And am I correct that Table 2 12 sets forth the clinical trial results that are 13 associated with Example 5? 14 A. Example 5 has a Table 2 that has some 15 data in it regarding visual acuity changes at 16 Week 24 and 52. 17 Q. Right. And it appears to me that the 18 results in Table 2 are from the Phase II clinical 19 trial of VEGFT in subjects with diabetic macular 20 edema. 21 Do you agree? 22 A. Example 5 appears to discuss the 23 Phase II clinical trial of VEGFT in subjects with 24 diabetic macular edema. 25 Q. And do you agree that Table 2 sets forth	Page 69 1 MS. STRUTHERS: Objection; asked and answered. 2 THE WITNESS: I think I already answered that 3 question. 4 BY MR. EHRICH: 5 Q. Does Table 2 provide clinical trial 6 results that a skilled artisan would have been able 7 to use to assess the therapeutic effectiveness of a 8 method for treating subjects with an anti-VEGF 9 agent? 10 MS. STRUTHERS: Objection to form. 11 THE WITNESS: Can you repeat the question? 12 BY MR. EHRICH: 13 Q. Sure. Would a skilled artisan have been 14 able to evaluate the data in Table 2 in Column 14 15 of the '681 patent to assess the therapeutic 16 effectiveness of a method for treating subjects 17 with an anti-VEGF agent? 18 MS. STRUTHERS: Objection; incomplete 19 hypothetical. 20 THE WITNESS: Could you repeat the question 21 again? 22 BY MR. EHRICH: 23 Q. Sure. Should I rephrase it? Would that 24 help? 25 A. Either way is good.

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Page 70 1 Q. I'll try to rephrase again. In 2 paragraph 86 of your 1225 declaration, you refer to 3 a Phase II DME study in Example 5 of the '681 4 patent. 5 Would a skilled artisan have been 6 able to evaluate the results of the Phase II DME 7 study set forth in Example 5 of the '681 patent to 8 assess the therapeutic effectiveness of a method 9 for treating subjects with an anti-VEGF agent? 10 MS. STRUTHERS: I'm going to have to object to 11 the form again. 12 THE WITNESS: I guess I don't understand your 13 question. 14 BY MR. EHRICH: 15 Q. Okay. Let's -- let's look at 16 paragraph -- the first sentence, please, of 17 paragraph 87 of your 1225 declaration. 18 I believe you stated that the 19 clinical trial results you refer to in the first 20 sentence of paragraph 87 are results of clinical 21 trials you discuss in paragraph 86; is that fair? 22 A. In paragraph 87 of Exhibit 2056 (1225), 23 I state that "The skilled artisan would have been 24 able to evaluate these clinical trial results to 25 assess the therapeutic effectiveness of a method	Page 72 1 the filing." 2 Paragraph 86 of Example 2056 is a 3 list of various clinical trial endpoints used in 4 different studies. 5 Q. Okay. Then -- what -- can I ask, then, 6 what specific clinical trial results do you mean by 7 "these clinical trial results" in the first 8 sentence of paragraph 87 of your 1225 declaration? 9 A. In paragraph 87 of Exhibit 2056 (1225), 10 the skilled artisan would evaluate clinical trials, 11 specifically Phase 3 clinical trials, and look at 12 the totality of the data to evaluate the 13 therapeutic effectiveness of a method for treating 14 subjects with an anti-VEGF agent. 15 Q. Okay. So, Dr. Do, I am not aware of any 16 Phase 3 clinical trials examining VEGF Trap in the 17 treatment of DME that had published by 18 January 2011. 19 Are you aware of any Phase 3 clinical 20 trials of VEGF Trap that had published by 21 January 2011? 22 MS. STRUTHERS: Objection to form. 23 Check your question, Counsel, sorry. 24 MR. EHRICH: Okay. Thank you. You're right. 25 I'll rephrase.
Page 71 1 for treating subjects with an anti-VEGF agent." 2 Q. Right. And as I had asked earlier -- 3 when I'd asked you earlier what you meant by "the 4 clinical trial results," you had read paragraph 86. 5 And so -- and please let me know if I'm 6 misunderstanding you, but I thought that you were 7 confirming that the clinical trials you discuss in 8 paragraph 86 are the ones that you're referring to 9 in the first sentence of paragraph 87. 10 A. In paragraph 87 of Exhibit 2056 (1225), 11 I state that "The skilled artisan would have been 12 able to evaluate these clinical trial results to 13 assess the therapeutic effectiveness of a method 14 for treating subjects with an anti-VEGF agent. 15 However, as discussed above, because the standard 16 of care for treating angiogenic eye disorders had 17 evolved from observation and monitoring or 18 destructive therapies to ranibizumab or off-label 19 bevacizumab, the skilled artisan would not have 20 assumed that simply meeting a clinical trial 21 endpoint, standing alone, would mean that an 22 anti-VEGF agent would effectively treat angiogenic 23 eye disorders as of 2011. Instead, the skilled 24 artisan would compare the clinical trial results 25 for the prevailing standard of care at the time of	Page 73 1 MS. STRUTHERS: Thank you. 2 BY MR. EHRICH: 3 Q. Are you aware, Dr. Do, of any results of 4 Phase 3 clinical trials examining the treatment of 5 diabetic macular edema with VEGF Trap that had 6 published by January 2011? 7 A. As of January 2011, I do not recall any 8 Phase 3 clinical trials that had been published 9 about VEGF Trap-Eye in diabetic macular edema yet. 10 Q. Okay. Then on what basis would a 11 skilled artisan conclude that VEGF Trap-Eye 12 administered according to the claimed method was 13 comparable to monthly administration of Lucentis in 14 the treatment of diabetic macular edema on or 15 before January 2011? 16 A. Could you repeat the question? 17 Q. Sure. In January 2011, on what basis 18 would a skilled artisan conclude that 19 administration of VEGF Trap-Eye according to the 20 claimed method of treatment was comparable to 21 monthly administration of Lucentis? 22 A. As we laid out earlier in Example 5 of 23 Patent '681, there is data from a Phase II clinical 24 trial of VEGFT in subjects with diabetic macular 25 edema. That was the available data at the time of

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Page 74 1 the patent filing because the Phase 3 data was not 2 yet available at the time. 3 Q. Understood. 4 So then, given that the Phase 3 data 5 were not available at the time of the patent 6 filing, on what basis at that time would a skilled 7 artisan have concluded that administration of VEGF 8 Trap-Eye according to the claimed method was 9 comparable to monthly administration of Lucentis in 10 the treatment of diabetic macular edema? 11 A. As I mentioned earlier, the skilled 12 artisan would have concluded from the totality of 13 the data that the claimed method for treating was 14 one that achieves a high level of efficacy that is 15 noninferior to the standard of care at the time of 16 the patent filing in a given patient. 17 And what that means is the claimed 18 method of treating achieved a high level of 19 efficacy that is comparable to the standard of care 20 at that time, and the standard of care at that time 21 was Lucentis or Avastin. 22 We mentioned that the POSA would 23 understand that the standard of care of treatment 24 applied across angiogenic eye diseases. 25 Q. Okay, Dr. Do. Can you please explain to	Page 76 1 understand some of these references a little bit 2 better. Do we agree that Example 4 of the '681 3 patent -- and it begins on Column 9. Do we agree 4 that that describes the Phase 3 VIEW 1 and VIEW 2 5 clinical trials? 6 A. Example 4 is the Phase 3 clinical trials 7 of the efficacy, safety, and tolerability of 8 repeated doses of intravitreal VEGFT in subjects 9 with neovascular age-related macular degeneration. 10 And in Section A of that Example 4, 11 it mentions the two parallel Phase 3 clinical 12 trials, which would be VIEW 1 and VIEW 2. 13 Q. Okay. Thank you. 14 So can you please turn to Column 13 15 of the '681 patent, then. And it looks like the 16 results summary of the VIEW 1, VIEW 2 clinical 17 trials are -- start on line 10 of Column 13. 18 Do you agree? 19 A. Line 10, Section C states results 20 summary (52 week data). 21 Is that what you're referring to? 22 Q. Yes. Okay. So on Column 13, then, you 23 see that it says, lines 10 and 11, "The primary 24 endpoint, prevention of moderate or severe vision 25 loss, was met for all three VEGFT groups in the
Page 75 1 me, though, in your previous answer what you mean 2 by the term "the totality of the data"? 3 A. Would you repeat your question? 4 Q. Sure. In your last answer, you said the 5 skilled artisan would have concluded from the 6 totality of the data that the claimed method for 7 treating was noninferior to the standard of care at 8 the time of the patent filing in a given patient. 9 My question is what do you mean by 10 the term "the totality of the data"? 11 A. The POSA would not look at one piece of 12 data out of context, but would analyze everything 13 regarding the patent as a whole. And when looking 14 at everything as a whole, the POSA would consider 15 the claimed method for treating as one that 16 achieves a high level of efficacy that is 17 comparable to the standard of care at the time of 18 the patent filing in a given patient. 19 Of course, that's January 2011; the 20 standard of care was Lucentis and Avastin for the 21 treatment of angiogenic eye disorders. 22 Q. Okay, Dr. Do, let's please turn to -- 23 let's -- please stay with the '681 patent which is 24 Klibanov Exhibit 13. 25 So, Dr. Do, maybe you can help me	Page 77 1 study"? 2 A. Yes. 3 Q. And it looks like the numbers behind 4 that statement are set forth in Table 1 right 5 below, right, correct, going from about line 16 to 6 35 of Column 13? 7 MS. STRUTHERS: Objection; the document speaks 8 for itself. 9 THE WITNESS: I see Table 1. 10 BY MR. EHRICH: 11 Q. Okay. And then you also see line 36 it 12 says that in Study 1 patients receiving VEGFT 13 2 milligrams monthly -- actually, apologize. 14 Strike that second question. 15 I think my first question is just are 16 the results set forth in Table 1 of the '681 patent 17 sufficient for a POSA to conclude that the 2Q8 18 dosing regimen is comparable to Lucentis? 19 MS. STRUTHERS: Objection; beyond the scope. 20 THE WITNESS: What was your question? 21 BY MR. EHRICH: 22 Q. Well, earlier you talked about how the 23 POSA would consider the totality of the data in 24 assessing VEGF Trap-Eye for treatment of angiogenic 25 eye disorders, but we were talking about angiogenic

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Page 78 1 eye disorders other than wet AMD. 2 And so my question is would the data 3 in Table 1 on Column 13 of the '681 patent be 4 sufficient for a POSA to conclude that the 2Q8 5 VEGFT dosing regimen is comparable to monthly 6 Lucentis in the treatment of wet AMD? 7 MS. STRUTHERS: Objection; beyond the scope. 8 THE WITNESS: Exhibit 13, Klibanov Exhibit -- 9 Column 13 discusses the Phase 3 Eylea trials in wet 10 AMD, and the primary endpoint was the prevention of 11 moderate or severe vision loss. We mentioned 12 earlier that the primary endpoint was 13 noninferiority because it was a statistical 14 endpoint for this clinical trial. 15 BY MR. EHRICH: 16 Q. Right. And if you'd like, it might be 17 easier, Dr. Do, if you -- if you could just keep 18 Column 13 of the '681 patent in front of you and 19 then also look at paragraph 96 on page 36 of your 20 1225 declaration. 21 A. I see that section. 22 Q. So do you see towards the top of page 36 23 you cite this Column 13 of the '681 patent to 24 point -- to state that "Noninferiority was 25 established by matching or exceeding ranibizumab's	Page 80 1 paragraph 96, sort of toward the bottom, you say 2 that "although this was the primary endpoint, as 3 explained above, patients also achieved an average 4 gain of seven or more letters." Right? 5 So are you there in paragraph 96? 6 A. Yes, I see that text. 7 Q. Okay. And then you say, "The skilled 8 artisan would have concluded from the totality of 9 the data presented in Example 4 that VEGF Trap-Eye 10 administered on a Q8 dosing schedule achieved and 11 maintained a high level of efficacy that was 12 noninferior to ranibizumab." Right? 13 A. Yes, I see that text. 14 Q. Okay. So by "the totality of the data," 15 are you referring to both the primary and secondary 16 endpoints reported in Example 4? 17 A. As I stated earlier in paragraph 96 of 18 Exhibit 2056 (1225), noninferiority was a clinical 19 trial endpoint where it was established in the 20 clinical trial by matching or exceeding 21 ranibizumab's success in achieving this endpoint 22 for about 95 percent of the patients treated 23 according to the protocol. 24 Then in paragraph 97 of Example 2056 25 (1225), I further state that the skilled artisan
Page 79 1 success at achieving this endpoint for about 2 95 percent of the patients treated according to the 3 protocol," right? 4 A. I see that text. 5 Q. Okay. And I understand that that's 6 specifically referring to statistical 7 noninferiority. I understand that, for example, in 8 paragraph 98 of your 1225 declaration, you use the 9 term "noninferiority" to mean comparable. 10 And so my question is, is that 11 statistical noninferiority sufficient for a POSA to 12 conclude that the 2Q8 dosing arm is comparable to 13 monthly ranibizumab? 14 MS. STRUTHERS: Objection to form. 15 THE WITNESS: In my declaration, line -- or 16 paragraph 98 of Exhibit 2056 (1225), I state that 17 the POSA would consider the claimed method for 18 treating as one that achieves a high level of 19 efficacy that is noninferior, which means 20 comparable in this case in context, to the standard 21 of care at the time of the patent filing in a given 22 patient. The standard of care as of January 2011 23 was Lucentis or Avastin. 24 BY MR. EHRICH: 25 Q. Right. And then going back to	Page 81 1 would understand that the level of efficacy 2 achieved by the claimed invention is noninferior to 3 the existing standard of care. 4 And in this context, "noninferior" 5 means comparable to the existing standard of care 6 for the average patient. It's far more than the 7 mere loss of 15 or fewer letters. 8 Q. Right. But I'm just coming back to that 9 term "the totality of data presented in Example 4," 10 towards the end of paragraph 96 of your 11 1225 declaration. 12 And I'm just -- well, as a threshold 13 question, are you referring to both the percentage 14 of patients meeting the primary and secondary 15 endpoints? 16 A. In paragraph 96 of Exhibit 2056 (1225), 17 I state that, moreover, although noninferiority was 18 the primary endpoint, "patients also achieved an 19 average gain of seven or more letters. The skilled 20 artisan would have concluded from the totality of 21 the data presented in Example 4 that VEGF Trap-Eye, 22 administered on a Q8 dosing schedule, achieved and 23 maintained a high level of efficacy that was 24 noninferior to ranibizumab." 25 And in this context, "noninferior" in

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Page 82 1 this sentence meant, you know, on par, comparable, 2 to ranibizumab. 3 Q. Okay, Dr. Do. I just want to make sure 4 I'm understanding. As you just read toward the 5 bottom of paragraph 96, "Although this was the 6 primary endpoint, as explained above, patients also 7 achieved an average gain of seven or more letters." 8 Right? 9 And I just wanted to make sure, are 10 you referring to in Table 1, Column 13 of the '681 11 patent, I guess the bottom part of the table around 12 line 28 or so where it says that the 2Q8 arm had a 13 mean improvement in vision at 52 weeks of 7.9? I 14 just want to understand where you're getting 15 this -- the seven or more number from. 16 A. Can you repeat that? 17 Q. Sure. You say in paragraph 96 that 18 patients also achieved an average gain of seven or 19 more letters, right? 20 A. Yes. 21 Q. Okay. And I would just like -- it seems 22 to me that you're getting that number from Table 1, 23 Column 13 of the '681 patent around line 28 or so 24 where it indicates that the 2Q8 arm had a mean 25 improvement of 7.9 letters. And I would just like	Page 84 1 the mean improvement data to reach that conclusion? 2 MS. STRUTHERS: Objection to form. 3 THE WITNESS: In my declaration, paragraph 97 4 of Exhibit 2056 (1225), I state that "Nor would a 5 skilled artisan accept any treatment that merely 6 prevented a given patient from losing 15 or fewer 7 letters as even approaching the standard of care at 8 the time of filing." "Instead, the skilled artisan 9 would understand that the level of efficacy 10 achieved by the claimed invention is 11 noninferior" -- or comparable in this context -- 12 "to the existing standard of care which for the 13 average patient is far more than the mere loss of 14 15 or fewer letters." 15 And then I go on in paragraph 98 to 16 say that the POSA would consider the claimed method 17 for treating as one that achieves a high level of 18 efficacy that is noninferior, or in this context 19 comparable, to the standard of care at the time of 20 patent filing in a given patient. 21 Of course, the standard of care as of 22 January of 2011 was Lucentis or Avastin. 23 MS. STRUTHERS: Tom, do you have a sense of 24 when you're going to want to break for lunch? 25 MR. EHRICH: Oh. I think just this -- just
Page 83 1 for you to, you know, please confirm that or let me 2 know where you are -- where you're getting the 3 number from. 4 A. Yes, I see Table 1 and read line 28 5 where the mean improvement in vision at 52 weeks 6 versus baseline is written, and there is an average 7 gain of about 7 to 8 letters. 8 Q. Okay. Is that where you're getting the 9 seven or more letters in paragraph 96, then, of 10 your 1225 declaration? 11 A. Yes. I believe I'm referring to the 12 VIEW 1, VIEW 2 clinical trials. I believe so. 13 Q. So staying with Table 1, Column 13 of 14 the '681 patent, the table shows really two 15 different sets of results, right? It shows 16 percentage of subjects who maintained vision and it 17 also shows mean improvement of vision. 18 Do you agree? 19 A. I see those texts. 20 Q. Okay. And again coming back to that 21 phrase "totality of the data" in paragraph 96 of 22 your 1225 declaration, would just the maintenance 23 of vision data be enough for a skilled artisan to 24 conclude that the 2Q8 arm is comparable to 25 Lucentis, or would the skilled artisan also need	Page 85 1 this line of questioning, Abby, and then it will be 2 fine with me. 3 MS. STRUTHERS: All right. 4 BY MR. EHRICH: 5 Q. So, Dr. Do, you said, though, that the 6 POSA reaches those conclusions based on -- in 7 paragraph 96 of your declaration you state the POSA 8 reaches those conclusions based on the totality of 9 the data presented in Example 4. And Example 4 is 10 presenting both data on maintenance of vision and 11 data on mean improvement of vision. 12 And I'm wondering would only the 13 maintenance of vision data have been enough for the 14 POSA to reach that conclusion or does the POSA also 15 need to have the mean improvement in vision to 16 reach that conclusion? 17 MS. STRUTHERS: Objection to form. 18 THE WITNESS: Could you repeat the question? 19 BY MR. EHRICH: 20 Q. Sure. In paragraph 96, you say that the 21 POSA reaches the conclusions that you just read in 22 paragraphs 97 and 98 based on the totality of the 23 data presented in Example 4. And the data 24 presented in Example 4 include both maintenance of 25 vision and mean improvement of vision.

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Page 86 1 So would the POSA have reached the 2 same conclusion had they only been presented with 3 maintenance of vision data, or would the POSA also 4 need the mean improvement in vision data in order 5 to reach that conclusion? 6 MS. STRUTHERS: Objection; mischaracterizes 7 the document. 8 THE WITNESS: I state in my declaration of 9 Example 2056 (1225) that -- in paragraph 97 "A 10 skilled artisan would not have read in that case 11 the sentence in Column 7 of the patent upon which 12 Dr. Albini relies in isolation from the remainder 13 of the specification and knowledge of the 14 state-of-the-art at that time. Nor would a skilled 15 artisan accept any treatment that merely prevented 16 a patient from losing 15 or fewer letters as even 17 approaching the standard of care at the time of 18 filing." 19 I recall the standard of care at that 20 time was Lucentis or Avastin because they improved 21 vision in these angiogenic eye disorders. 22 And I conclude that the POSA would 23 consider the claimed method for treating as one 24 that achieved a high level of efficacy that is 25 noninferior to the standard of care at the time of	Page 88 1 right? 2 A. Yes, I was referring to paragraph 97 and 3 98. 4 MR. EHRICH: Okay. Thank you. 5 If you want, I'm fine breaking for 6 lunch now. Just how much time are you thinking? 7 MS. STRUTHERS: I guess that depends on how 8 much you want and, you know, what the day is 9 looking like. So what do you think makes sense? 10 MR. EHRICH: I mean, I would say half-hour, 11 45 minutes, but I don't know -- but I don't know -- 12 since I'm not there, I don't know what your 13 logistics situation is and how much time you need. 14 So I'm happy to be flexible either way. 15 MS. STRUTHERS: Half-hour. 16 THE WITNESS: Half-hour is good. 17 MR. EHRICH: All right that's fine. 18 THE VIDEOGRAPHER: Off the record at 2:38. 19 (Lunch recess taken from 20 2:38 p.m. to 3:11 p.m.) 21 22 23 24 25
Page 87 1 the patent filing in a given patient. And in that 2 concluding sentence, the standard of care at the 3 time of the filing is Lucentis or Avastin, and they 4 were generally associated with vision improvement 5 across angiogenic eye disorders. 6 BY MR. EHRICH: 7 Q. Okay. So as you write in paragraph 96, 8 part of what the POSA would have considered in 9 reaching their conclusion would have been the 10 average gain of seven or more letters; is that what 11 you're saying? 12 A. As I wrote in Example 2056 (1225), the 13 POSA would look at the totality of the data 14 presented, which includes seeing that patients also 15 gained on average seven or more letters, and the 16 POSA would look at everything together to 17 understand that the claimed method for treating as 18 one that achieves a high level of efficacy that is 19 noninferior to the standard of care at the time of 20 the patent filing in a given patient. In that 21 sentence, "noninferior" means comparable to the 22 standard of care, which was Lucentis or Avastin. 23 Q. Okay. Sorry, Dr. Do. You seem to have 24 lost me for a second. You're referring to 25 paragraph 97 of your 1225 declaration; is that	Page 89 1 AFTERNOON SESSION 2 THE VIDEOGRAPHER: We're now back on the 3 record at 3:11 p.m. 4 Please continue. 5 MR. EHRICH: Welcome back, Dr. Do. 6 THE WITNESS: Thank you. Welcome back. 7 EXAMINATION (resumed) 8 BY MR. EHRICH: 9 Q. Okay. I'd like to stay, please, with 10 your 1225 declaration, but flip back a few pages to 11 paragraph 64, which is on pages 19 and 20, and 12 I'm -- go ahead and review that paragraph, if you'd 13 like, Dr. Do. Let me know when you're ready. 14 Just to preview for you, I'm -- my 15 questions are mostly going to center around the 16 last part of that paragraph. 17 A. Yes, I see that paragraph, 64. 18 Q. Okay. Dr. Do, it's my understanding 19 that the specification, meaning the words and the 20 tables and, you know, the data in the '338 patent 21 that you're talking about in paragraph 64, are the 22 same as the words and the tables and the data and 23 the figures in the '681 patent that you're 24 discussing in this declaration. 25 And with that in mind, I would

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Page 90 1 just -- my understanding from paragraph 64, Dr. Do, 2 is that the second-to-last sentence of that 3 paragraph is your opinion that applies to both the 4 '338 patent and the '681 patent. And I would just 5 like for you to please confirm that. 6 MS. STRUTHERS: Objection to form, 7 mischaracterizes the testimony. 8 THE WITNESS: Could you repeat your question? 9 BY MR. EHRICH: 10 Q. Sure. Let me rephrase it, in fact. 11 Do you see the second-to-last 12 sentence of paragraph 64 in your declaration, your 13 1225 declaration, you write -- or you say it is 14 further your opinion that those nonresponding 15 patients would not be treated according to the 16 claimed method. 17 And my question is is this your 18 opinion for both the '338 patent and the 19 '681 patent? 20 A. Paragraph 64 of Exhibit 2056 (1225) is 21 dealing with the '681 patent as evidenced in the 22 cover sheet and I think in paragraph 64. "As I 23 previously testified, a skilled artisan reading 24 this passage in the context of the overall 25 disclosure and what was known at the time about the	Page 92 1 method. This opinion is based on my reading of the 2 specification as a whole." 3 Q. And does that opinion also apply, 4 Dr. Do, to the claimed method of the '681 patent? 5 A. In paragraph 65 of Exhibit 2056 (1225), 6 I state that the '681 patent's specification makes 7 clear, repeatedly, that the present invention 8 relates to therapeutic treatment of an angiogenic 9 eye disorder in a patient. 10 And in paragraph 67 of the 11 Exhibit 2056 (1225), I further state that "It is 12 therefore my opinion that the recited method for 13 treating not only requires an intent to treat but 14 must actually treat." 15 Q. Okay. And what do you mean by "must 16 actually treat"? 17 A. When I refer to "actually treat," we can 18 look at my declaration, Exhibit 2001. This is the 19 declaration I signed October 11, 2022. In 20 paragraph 39, page 12, I state that "Accordingly, 21 viewed in light of the patent and the 22 state-of-the-art in 2011, I understand the preamble 23 'method for treating an angiogenic eye disorder in 24 a patient' to mean that the claimed dosing regimen 25 achieves and maintains a high level of efficacy
Page 91 1 standard of care treatments would not have 2 understood the patentee's invention to include 3 ineffective methods of treating. Instead, I 4 observed that the passages quoted by the board from 5 Column 6 of related U.S. Patent Number 9,254,338 6 are consistent with the fact that an amount which 7 is therapeutically effective is effective in most 8 cases even if some patients do not respond. In 9 other words, when administered across a population 10 of patients, an amount that is therapeutically 11 effective amount in most patients would not be 12 therapeutically effective in other nonresponding 13 patients. 14 "This aligns with the data reported 15 in the specification showing that while 96 percent 16 of the subjects receiving VEGFT achieved the 17 primary endpoint, which is prevention of moderate 18 or severe vision loss as defined above, the 19 remaining 4 percent did not achieve this endpoint. 20 "I agree with the board's finding 21 that for such nonresponding patients, the 22 administered amount would not be considered a 23 therapeutically effective amount. It is further my 24 opinion, however, that the nonresponding patients 25 would not be treated according to the claimed	Page 93 1 comparable to that seen with Lucentis and Avastin 2 and that it is effective for the patient in need of 3 treatment." 4 Q. Okay. Let's maybe -- right. But -- 5 okay. So you're saying that -- so for the method 6 of treating, actually treating, you're referring 7 back to paragraph 39 of Exhibit 2001; is that 8 right? 9 A. As I stated in paragraph 39 of 10 Exhibit 2001 in this declaration regarding 11 Patent '681, "The 'method for treating an 12 angiogenic eye disorder in a patient' means that 13 the claimed dosing regimen achieves and maintains a 14 high level of efficacy comparable to that seen with 15 Lucentis and Avastin and that it is effective for 16 the patient in need of treatment." 17 Q. Okay. And what do you mean here by -- 18 let me come at this another way, then. What do you 19 mean here by "is effective for the patient in need 20 of treatment"? 21 A. In Exhibit 2001, I state in paragraph 35 22 that by the year 2011, ophthalmologists would have 23 been able to assess whether a patient with an 24 angiogenic eye disorder was responding to a 25 particular drug or dosing regimen and, in fact, did

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Page 94 1 so in normal clinical practice. There were several 2 parameters ophthalmologists used and still 3 currently use to assess patients' response to an 4 anti-VEGF agent for patients being treated for 5 angiogenic eye disorders. 6 As of 2011, the POSA would have 7 expected to see initial visual acuity gains and 8 drying of the retina when administering Lucentis or 9 Avastin. At this time, treating ophthalmologists 10 would measure visual acuity using a Snellen eye 11 chart or early treatment diabetic retinopathy 12 study, perform retinal imaging using optical 13 coherence tomography to visualize fluid on the 14 retina, and perform a critical exam at each patient 15 visit to assess whether a patient is responding to 16 a particular drug. Thus, ophthalmologists could 17 and can ascertain whether a particular drug and 18 dosing regimen is effective for a given patient. 19 Q. Okay. I understand that you say that an 20 ophthalmologist -- that ophthalmologists could and 21 can ascertain whether a particular drug and dosing 22 regimen is effective, but I'm asking what -- are 23 there any metrics that would separate effective 24 from ineffective. Maybe -- let's try -- let's look 25 at some examples maybe.	Page 96 1 [REDACTED] 2 [REDACTED] 3 [REDACTED] 4 Q. Okay. So, Dr. Do, please, then, look at 5 paragraph 33, which is on page 9 of your 1225 6 declaration, and you see that that -- you see that 7 that paragraph sets forth Claim 1 of the '681 8 patent, right? 9 A. Yes, I see the text in Example 2056 -- 10 Exhibit 2056 (1225), page 9, paragraph 33. 11 Q. Okay. And you just said that it's your 12 opinion that the [REDACTED] 13 [REDACTED] 14 [REDACTED] 15 [REDACTED] 16 [REDACTED] 17 Can you point out to me, please, in 18 Claim 1 which of the steps are not being carried 19 out for the patients -- for that [REDACTED] 20 [REDACTED] 21 [REDACTED] 22 A. I didn't understand the question. Could 23 you repeat it? 24 Q. Sure. Can you please point out to me 25 which part of Claim 1, which is set forth in
Page 95 1 Could you please turn, Dr. Do, to 2 page 48 of your 1225 declaration. And 3 paragraph 115. 4 Are you there? 5 A. Yes. I see paragraph 116. 6 Q. Okay. Do you see there's a sentence 7 perhaps two-thirds of the way down the page. "[REDACTED] 8 [REDACTED] 9 [REDACTED]" Right? 10 A. Yes, I see that sentence. 11 Q. Okay. So did -- were those [REDACTED] 12 of patients in 2Q8 arm treated according to the 13 claimed method? 14 A. Recall that in my declaration, 15 Exhibit 2001, paragraph 39, I stated that the 16 method for treating an angiogenic eye disorder in a 17 patient, regarding the preamble, meant that the 18 claimed dosing regimen achieved and maintained a 19 high level of efficacy that is comparable to that 20 seen with Lucentis and Avastin and that it is 21 effective for the patient in need of treatment. 22 Therefore, paragraph 116 in Exhibit 2056 (1225), 23 the [REDACTED] 24 [REDACTED] 25 [REDACTED]	Page 97 1 paragraph 33 of your 1225 declaration, is not 2 carried out for the [REDACTED] 3 [REDACTED] 4 [REDACTED] 5 [REDACTED] 6 MS. STRUTHERS: Objection; calls for a legal 7 conclusion. 8 You can answer. 9 THE WITNESS: As I stated in paragraph 39 of 10 Exhibit 2001, which also referred to on '681 in 11 paragraph 39, I stated that "In light of the patent 12 and the state-of-the-art in 2011, I understand the 13 preamble 'method for treating an angiogenic eye 14 disorder in a patient' to mean that the claimed 15 dosing regimen achieves and maintains a high level 16 of efficacy comparable to that seen with Lucentis 17 and Avastin and that it is effective for the 18 patient in need of treatment. 19 Using that understanding of the 20 preamble, we stated the [REDACTED] 21 [REDACTED] 22 [REDACTED] 23 [REDACTED] 24 [REDACTED] 25 [REDACTED]

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Page 98 1 BY MR. EHRICH: 2 Q. Okay, Dr. Do. Please turn your referral 3 back to paragraph 39 of Exhibit 2001. 4 Are you saying that the phrase "a 5 method for treating an angiogenic eye disorder in a 6 patient" is not being carried out for those 7 [REDACTED] 8 A. As I state in paragraph 39, "Viewed in 9 light of the patent and the state-of-the-art in 10 2011, a POSA would understand that the preamble 11 'method for treating an angiogenic eye disorder in 12 a patient' to mean that the claimed dosing regimen 13 achieved and maintained a high level of efficacy 14 comparable to that seen with Lucentis and Avastin 15 and that it is effective for the patient in need of 16 treatment. 17 Q. Right, Dr. Do. I understand that that's 18 what paragraph 39 of Exhibit 2001 says, but my 19 question is which part of Claim 1 is not being 20 carried out as far as [REDACTED] 21 [REDACTED]? 22 MS. STRUTHERS: Objection; asked and answered. 23 You can still answer. 24 THE WITNESS: Yes. I think I already answered 25 that question.	Page 100 1 Therefore, in paragraph 116 of Exhibit 2056 (1225), 2 the [REDACTED] 3 [REDACTED] 4 [REDACTED] 5 [REDACTED] 6 [REDACTED] 7 [REDACTED] 8 BY MR. EHRICH: 9 Q. Okay. Actually, I think you sort of 10 anticipated one of my next questions. So -- so 11 you're -- actually, let me make sure I understand 12 your answer. 13 Okay. You said that the patients, 14 [REDACTED] 15 [REDACTED] 16 [REDACTED] 17 [REDACTED] 18 Dr. Do, are you -- you're familiar 19 with the Heier 2012 reference? 20 A. Do you have a copy of that reference? 21 Q. I do. And I believe -- I think you cite 22 it, for example, in -- as Exhibit 1018 in, for 23 example, paragraph 116 of your 1225 declaration. 24 And there should be a copy as -- which was entered 25 into the record as Brown Exhibit 4, which should be
Page 99 1 BY MR. EHRICH: 2 Q. Okay. With reference to paragraph 39 of 3 Exhibit 2001? 4 A. Yes. 5 Q. And, Dr. Do, quick question. I'm sorry 6 for making you flip around so much, but back to 7 paragraph 116 on page 48 of your 1225 declaration. 8 A. Could you repeat the page? 9 Q. Sure. Page 48 of your 1225 declaration, 10 paragraph 116. 11 A. I see paragraph 116 now. 12 Q. Okay. And back to that sentence that 13 begins with "The study results show that the 14 [REDACTED] 15 [REDACTED] 16 [REDACTED] 17 [REDACTED] 18 MS. STRUTHERS: Objection to form. 19 THE WITNESS: Recall that in Exhibit 2001, 20 paragraph 39, I stated that the claimed method for 21 treating an angiogenic eye disorder in a patient to 22 mean that the claimed dosing regimen achieved and 23 maintained a high level of efficacy comparable to 24 that seen with Lucentis and Avastin and that it is 25 effective for a patient in need of a treatment.	Page 101 1 the first tab of the exhibits binder. 2 A. You're talking about Brown Exhibit 6? 3 Q. Brown Exhibit 4, the very first tab. 4 A. Oh, Brown Exhibit 4. 5 Q. Yes. 6 A. Yes. 7 Q. Can you confirm that is the Heier 2012 8 reference and you are familiar with it? 9 A. Brown Exhibit 4 is intravitreal 10 aflibercept VEGF Trap-Eye in wet age-related 11 macular degeneration. 12 Q. Are you familiar with that reference? 13 A. Yes. The VIEW 1 and VIEW 2 studies. 14 Q. Okay. Could you please turn to page 7 15 of Brown Exhibit 4 -- page 7 as -- in the far lower 16 right corner of the page. 17 A. Yes, I'm on page 7. 18 Q. And do you see it looks like there's 19 a -- I apologize. Let's go back a page to page 6, 20 please. And you see it's -- there's a heading at 21 the top of page 6, Table 2? 22 A. Yes, I see Table 2. 23 Q. Okay. And -- no, I'm sorry. Let's go 24 to page 7, Outcomes at Week 52 for the VIEW 2 25 trial. Page 7. It looks there in Outcomes at Week

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Page 102 1 52, that for the 2Q8 arm, 95.6 of the patients met 2 the primary endpoint, right? 3 A. I see that text. 4 Q. Okay. Would the remaining 4.4 percent 5 have been treated according to the claimed method? 6 MS. STRUTHERS: Objection; beyond the scope, 7 the document speaks for itself. 8 THE WITNESS: Could you repeat the question? 9 BY MR. EHRICH: 10 Q. Sure. 95.6 percent of the patients in 11 the Outcomes At Week 52 table met the primary 12 endpoint, agreed? 13 A. I see that text. 14 Q. Would the remaining 4.4 percent have 15 been treated according to the claimed method? 16 MS. STRUTHERS: Objection; beyond the scope. 17 THE WITNESS: As we said before, the primary 18 endpoint in the VIEW 1 and VIEW 2 clinical trials 19 was noninferiority compared to Lucentis, and that 20 was a statistical endpoint. And the table you're 21 referring to talks about this clinical trial 22 endpoint. 23 BY MR. EHRICH: 24 Q. Right. But earlier you had said that 25 [REDACTED]	Page 104 1 Do you see that the last sentence of 2 paragraph 97 says that "The skilled artisan would 3 understand that the level of efficacy achieved by 4 the claimed invention is noninferior to the 5 existing standard of care which for the average 6 patient is far more than mere loss of 15 or fewer 7 letters." Right? 8 A. I see that sentence. 9 Q. Okay. So -- now, you had also said in 10 paragraph 116 of the same declaration that the 11 [REDACTED] 12 [REDACTED] 13 [REDACTED] 14 So my question is what if the patient 15 loses 15 letters? Are they being treated according 16 to the claimed method? 17 MS. STRUTHERS: Objection; incomplete 18 hypothetical. 19 THE WITNESS: Could you repeat the question? 20 BY MR. EHRICH: 21 Q. Sure. And if you want, it might be 22 easier to go to -- why don't we go back to the 23 exhibits -- Klibanov Exhibit 13, which is the '681 24 patent. Okay. And Column 13, please, Table 1. 25 You see that Table 1 sets forth the
Page 103 1 [REDACTED] 2 [REDACTED]. And my question is just 3 looking at the data in the Outcomes At Week 52 4 table, were the patients who did not meet the 5 primary endpoint treated according to the claimed 6 method? 7 A. As I stated in paragraph 39 of 8 Exhibit 2001 which discusses the Patent '681, the 9 method for treating an angiogenic eye disorder in a 10 patient means that the claimed dosing regimen 11 achieved and maintained a high level of efficacy 12 comparable to that seen with Lucentis and Avastin 13 and that it's effective for the patient in need of 14 treatment. 15 The POSA would not look at this 16 clinical trial endpoint out of context to 17 understand if the claimed dosing regimen was being 18 practiced. And as I said before, the [REDACTED] 19 [REDACTED] 20 [REDACTED] 21 [REDACTED] 22 [REDACTED] 23 [REDACTED] 24 Q. Okay. Well, let's just go back to your 25 1225 declaration, paragraph 97.	Page 105 1 mean improvement in vision in letters at 52 weeks, 2 right? I believe earlier -- sorry? 3 A. I see that text. 4 Q. Okay. So does a patient who does not -- 5 does a patient who does not gain any letters -- is 6 a patient who has not gained any letters being 7 treated according to the claimed method? 8 MS. STRUTHERS: Objection; incomplete 9 hypothetical. 10 THE WITNESS: Could you repeat the question? 11 BY MR. EHRICH: 12 Q. Sure. Well, let's start with if a 13 patient -- did -- would a patient who gained seven 14 letters be treated according to the claimed 15 method -- have been treated according to the 16 claimed method? 17 MS. STRUTHERS: Objection; incomplete 18 hypothetical. 19 THE WITNESS: In my declaration, Example 2056 20 (1225), page 37, paragraph 98, "The POSA would 21 consider the claimed method for treating as one 22 that achieves a high level of efficacy that is 23 noninferior," which in this context means 24 comparable, "to the standard of care at the time of 25 the patent filing in a given patient,"

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Page 106 1 understanding that the standard of care was 2 Lucentis or Avastin. 3 Therefore, in any of these clinical 4 scenarios, one would have to examine the patient, 5 look at all the medical evidence to understand if 6 the patient was having a result that was a high 7 level of efficacy that was comparable to what we 8 would expect from the current standard of care. 9 BY MR. EHRICH: 10 Q. Okay. Well, if as you say in -- as you 11 say in paragraph 116 of your 1225 declaration, 12 [REDACTED] 13 [REDACTED] So what I'm really 14 trying to get at is at what point, at what 15 cutoff -- what's the cutoff for patients being 16 treated according to the claimed method? 17 [REDACTED] 18 [REDACTED] If they lose 14 letters or 10 19 letters or if they lose zero letters, at what point 20 is the patient being treated according to the 21 claimed method? 22 MS. STRUTHERS: Objection; misstates 23 testimony, incomplete hypothetical. 24 THE WITNESS: Could you repeat the question?	Page 108 1 one that achieves a high level of efficacy that is 2 noninferior, or comparable in this context, to the 3 standard of care at the time of the patent filing 4 in a given patient. And, of course, the standard 5 of care at that time was Lucentis or Avastin. 6 BY MR. EHRICH: 7 Q. Right. And for an individual patient, 8 how are you supposed to determine whether the 9 claimed method has achieved a level of efficacy 10 that is noninferior to Lucentis or Avastin at the 11 time of the filing of the patent? 12 A. In my declaration, Exhibit 2001, which 13 is regarding Patent '681, paragraph 35, page 10, I 14 state that "In 2011, ophthalmologists would have 15 been able to assess whether a patient with an 16 angiogenic eye disorder was responding to a 17 particular drug or dosing regimen and, in fact, did 18 so in normal clinical practice. There were several 19 parameters ophthalmologists used (and still 20 currently use) to assess patient response to an 21 anti-VEGF agent for a patient being treated for 22 angiogenic eye disorders. 23 "As of 2011, the POSA would have 24 expected to see initial visual acuity gains and 25 drying of the retina when administering Lucentis or
Page 107 1 BY MR. EHRICH: 2 Q. Sure. I -- you said earlier that the 3 [REDACTED] 4 [REDACTED] 5 [REDACTED] The question is at what point, 6 what is the cut off, how does one assess whether a 7 patient has been treated according to the claimed 8 method? 9 MS. STRUTHERS: Objection; incomplete 10 hypothetical. 11 THE WITNESS: In Exhibit 2056 (1225), my 12 declaration, paragraph 97, I state that "Nor would 13 a skilled artisan accept any treatment that merely 14 prevented a given patient from losing 15 or fewer 15 letters as even approaching the standard of care at 16 the time of the patent filing. Instead, the 17 skilled artisan would understand that the level of 18 efficacy achieved by the claimed invention is 19 noninferior," which in this sentence, the context 20 would mean comparable to the existing standard of 21 care for the average patient is far more than the 22 mere loss of 15 or fewer letters. 23 Therefore, in paragraph 98, the POSA 24 would consider the claimed method for treating as	Page 109 1 Avastin. By this time, treating ophthalmologists 2 would measure visual acuity, perform retinal 3 imaging using optical coherence tomography to 4 visualize fluid in the retina, and perform a 5 critical exam at each patient visit to assess 6 whether a patient is responding to a particular 7 drug. Thus, ophthalmologists could and can 8 ascertain whether a particular drug and dosing 9 regimen is effective for a given patient. 10 Q. Right. And I understand that you just 11 read how an ophthalmologist assesses whether giving 12 dosing regimen is effective for a given patient. 13 But in your paragraph 97 of your 1225 declaration, 14 you say that that assessment would mean -- well, 15 would mean far more than the mere loss of 15 or 16 fewer letters. 17 And my question is what would you 18 need to see -- not how would you assess it, but 19 what would you need to see in a specific patient to 20 determine that the method of treatment is 21 comparable to monthly Lucentis or Avastin? 22 MS. STRUTHERS: Objection; incomplete 23 hypothetical. 24 THE WITNESS: In my declaration of 25 Exhibit 2001, paragraph 35, I describe how

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Page 110 1 ophthalmologists would assess whether a patient 2 with an angiogenic eye disorder was responding to a 3 particular drug or dosing regimen. And because the 4 standard of care at that time was Lucentis or 5 Avastin, I further mention that the POSA would have 6 expected to see initial visual acuity gains or 7 drying of the retina. Therefore, assessing whether 8 or not the patient was responding to the claimed 9 method of treatment would involve examining the 10 patient, looking at the patient's response, doing 11 retinal imaging, checking vision, doing all of 12 those things in combination. 13 BY MR. EHRICH: 14 Q. Okay. And in that same paragraph 35 of 15 Exhibit 2001, what do you mean by initial visual 16 acuity gains? 17 A. In paragraph 35 of Exhibit 2001, I 18 mention that as of 2011, the POSA would have 19 expected to see initial visual acuity gains and 20 drying of the retina when administering Lucentis or 21 Avastin, which means patients who are being treated 22 with Lucentis or Avastin were likely to have 23 improvement in their vision. 24 Q. Would the -- would the POSA have 25 expected these initial visual acuity gains to be	Page 112 1 is effective for the patient in need of treatment." 2 Q. So would a patient have to show initial 3 visual acuity gains that were maintained in order 4 for their treatment to be considered comparable to 5 that of Lucentis or Avastin? 6 MS. STRUTHERS: Objection; incomplete 7 hypothetical. I'm sorry. 8 You can answer. 9 THE WITNESS: In paragraph 39 of Exhibit 2001, 10 the POSA would understand that the "method for 11 treating an angiogenic eye disorder in a patient" 12 to mean that the claimed dosing regimen achieves 13 and maintains a high level of efficacy comparable 14 to that seen with Lucentis and Avastin and that it 15 is effective for the patient in need of treatment. 16 BY MR. EHRICH: 17 Q. I understand what that -- what that 18 says, but again, I'm still coming back to what does 19 "effective" mean? If the patient does not see 20 initial visual acuity gains, is the method of 21 treatment not comparable to Lucentis or Avastin? 22 MS. STRUTHERS: Objection; incomplete 23 hypothetical. 24 THE WITNESS: I mentioned that the 25 ophthalmologists and the POSA in paragraph 35 of
Page 111 1 maintained for, for example, 52 weeks? 2 MS. STRUTHERS: Objection; incomplete 3 hypothetical. 4 BY MR. EHRICH: 5 Q. I'm trying to get at what you mean by 6 "initial." Do you mean initial and maintained or 7 initial and they go away? I'm just not 8 understanding what "initial" means for initial 9 visual acuity gains. 10 A. I think in paragraph 35 of Exhibit 2001 11 I describe what the POSA would have expected to see 12 when administering Lucentis or Avastin. The 13 standard of care was Lucentis or Avastin at that 14 time, which resulted in initial visual acuity gains 15 that were maintained over time, because we know 16 from the data from the Marina/Anchor trials that 17 the visual acuity gains were maintained. And 18 that's consistent with my statement in paragraph 39 19 of Exhibit 2001 which states "Accordingly, viewed 20 in light of the patent and the state-of-the-art in 21 2011, I understand the preamble 'method for 22 treating an angiogenic eye disorder in a patient' 23 to mean that the claimed dosing regimen achieves 24 and maintains a high level of efficacy comparable 25 to that seen with Lucentis and Avastin and that it	Page 113 1 Exhibit 2001 is able to assess whether a patient 2 with an angiogenic eye disorder responds to a 3 particular drug or dosing regimen, and we would 4 need to perform a complete examination, evaluate 5 the patient's eye, look at imaging studies, look at 6 all these parameters to assess whether or not the 7 patient was responding. 8 BY MR. EHRICH: 9 Q. And if a patient is responding, then is 10 the treatment considered comparable to Lucentis or 11 Avastin? 12 MS. STRUTHERS: Objection; mischaracterizes 13 the testimony. 14 THE WITNESS: For the claimed dosing regimen, 15 the POSA would expect to see that the method for 16 treating this angiogenic eye disorder in patients 17 achieves and maintains a high level of efficacy 18 comparable to that seen with the experience with 19 Lucentis and Avastin and that it's effective for 20 patients who need that treatment. 21 BY MR. EHRICH: 22 Q. Right. But what would -- when you say 23 that it has to be comparable to Lucentis or 24 Avastin, are you saying that the POSA would 25 administer VEGF Trap for a period of time and then

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Page 114 1 administer Lucentis or Avastin for a period of time 2 and see which one works better? 3 A. No, I'm not saying that. 4 Q. Okay. Then how would a POSA determine 5 for an individual patient that a method of 6 treatment with VEGF Trap is comparable to monthly 7 administration of Lucentis or Avastin? 8 A. As we discussed, and we can see that in 9 paragraph 34, by 2011, Lucentis and off-label 10 Avastin were widely used for the treatment of 11 angiogenic eye disorders. This is paragraph 34, 12 Exhibit 2001. The pivotal Phase 3 ranibizumab 13 trials, Anchor and Marina, that formed the basis 14 for Lucentis's approval, established for the 15 retinal community the potential effectiveness of 16 anti-VEGF therapy. Results from the Phase 3 17 Lucentis Anchor and Marina trials demonstrated that 18 patients with wet AMD had a mean improvement in 19 vision after one year of treatment, and those 20 efficacy outcomes were maintained through the 21 second year. 22 By 2011, it was well-established in 23 the retinal community that standard of care for 24 treating angiogenic eye disorders had moved beyond 25 merely slowing vision loss to frequent intravitreal	Page 116 1 And the POSA, to assess this response 2 with efficacy, they would need to examine the 3 patient -- look at the retina, look at the imaging, 4 visual acuity, all those -- to assess the response 5 in an individual patient. 6 BY MR. EHRICH: 7 Q. Okay. So, Dr. Do, are you able to 8 articulate any criteria by which a POSA could 9 determine if an individual patient is receiving a 10 method of treatment comparable to that of monthly 11 Lucentis or Avastin? 12 MS. STRUTHERS: Objection; argumentative, 13 asked and answered. 14 THE WITNESS: I thought I did answer that 15 question, because I explained, demonstrated by 16 paragraph 35 in Exhibit 2001, that the POSA would 17 be familiar with these assessments, these 18 examinations -- analyzing the retina, the vision, 19 the OCT imaging for patients with angiogenic eye 20 disorders -- and they would be able to evaluate, 21 through analysis of these assessments, whether or 22 not the patient was having a response to a 23 particular medicine. 24 And given that the POSA would have 25 had prior knowledge and experience with Lucentis
Page 115 1 injections of ranibizumab or off-label Avastin 2 which could improve patients' vision and maintain 3 those gains (if administered frequently enough) 4 over the course of treatment. 5 Given the availability and efficacy 6 of Lucentis and Avastin, it is my opinion that by 7 January of 2011, ophthalmologists would not have 8 considered a dosing regimen that only slowed vision 9 loss and could not, on average, produce visual 10 acuity gains to be the treatment of an angiogenic 11 eye disorder. 12 Q. So for a given patient, would their 13 vision have to be improved and maintained over the 14 course of treatment in order for the treatment to 15 be considered comparable to monthly treatment with 16 Lucentis or Avastin? 17 MS. STRUTHERS: Objection; incomplete 18 hypothetical. 19 THE WITNESS: I think the POSA would 20 understand that the method for treating an 21 angiogenic eye disorder in a patient to mean that 22 the claimed dosing regimen achieved and maintained 23 a high level of efficacy comparable to that seen 24 with Lucentis and Avastin and that it's effective 25 for that patient.	Page 117 1 and Avastin, because they were the standard of care 2 at that time, the POSA could ascertain whether a 3 particular drug and dosing regimen was effective 4 for a given patient. 5 BY MR. EHRICH: 6 Q. Okay. Dr. Do, let's maybe go back, 7 please, to Brown Exhibit 4. Again, the first tab 8 in the exhibits binder. And, again, I'd like to 9 please turn to Exhibit 7, and that's the one that 10 has the table that's headed "Outcomes At Week 52" 11 for the VIEW 2 Trial. Just for reference. 12 A. Yes, I see that. Page 7. 13 Q. Okay. And, Dr. Do, since you're at the 14 commission, I just want to make sure that I'm 15 reading this table correctly. 16 Was the primary endpoint of the 17 VIEW 2 trial the proportion of subjects maintaining 18 vision or defined as losing less than 15 ETDRS 19 letters? 20 A. Yes. The primary endpoint was based on 21 the noninferiority study design. 22 Q. Okay. Would it be possible to phrase 23 "comparable to treatment with monthly Lucentis" as 24 a primary endpoint for a single patient? 25 MS. STRUTHERS: Objection to form.

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Page 118 1 THE WITNESS: What are you referring to? 2 BY MR. EHRICH: 3 Q. Well, let's -- are you -- we're still on 4 the Outcomes At 52 Week VIEW 2 table, right? 5 A. Yes. 6 Q. The primary endpoint is proportion 7 losing less than 15 ETDRS letters, right? 8 A. Yes. 9 Q. Okay. And in the 2Q8 arm, for example, 10 95.6 percent, or 258 out of 270 patients, met the 11 primary endpoint, right? 12 A. Yes. 13 Q. Okay. So an individual patient, for 14 example, one of those 258 patients, could be said 15 to have met the primary endpoint by losing fewer 16 than 15 ETDRS letters, right? 17 MS. STRUTHERS: Objection to form. 18 THE WITNESS: This table lists the primary 19 endpoint, and so the 95.6 percent of patients in 20 the 2Q8 arm met the primary endpoint, which was a 21 statistical one for noninferiority in regards to 22 losing 15 or fewer letters on visual acuity at 23 Week 52. 24 BY MR. EHRICH: 25 Q. Okay. Am I correct in interpreting that	Page 120 1 be treatment of an angiogenic eye disorder. 2 Therefore, meeting the primary endpoint alone, 3 which was the loss of 15 letters or fewer at 4 Week 52, was not enough to pass as the claimed 5 dosing regimen which is achieving and maintaining a 6 high level of efficacy. 7 BY MR. EHRICH: 8 Q. Okay. What else would the POSA need to 9 see to conclude that they had been practicing the 10 claimed dosing regimen on a patient? 11 MS. STRUTHERS: Objection; incomplete 12 hypothetical, asked and answered. 13 THE WITNESS: Recall that I answered that 14 question when I referred to my declaration in 15 Exhibit 2001, paragraph 35, where it describes 16 ophthalmologists by 2011 were very familiar with 17 assessing patients with angiogenic eye disorders, 18 and ophthalmologists would have been able to assess 19 whether a patient with an angiogenic eye disorder 20 was responding to a particular drug or dosing 21 regimen. 22 The POSA would be familiar with 23 examining the retina, looking at retinal imaging 24 using OCT, and they would have been familiar with 25 how an eye responds to Lucentis or Avastin given
Page 119 1 this table, then, Dr. Do, to be saying 258 out of 2 270 patients, so 258 patients lost fewer than 3 15 ETDRS letters -- I'm sorry, 258 patients in the 4 2Q8 arm lost fewer than 15 ETDRS letters, right? 5 A. According to this table, looking at the 6 primary endpoint of the VIEW 1 and 2 clinical 7 trials, 95.6 percent, or 258 patients in the VIEW 2 8 study met the primary endpoint. 9 Q. Okay. Were those 258 patients treated 10 according to the claimed method? 11 MS. STRUTHERS: Objection; incomplete 12 hypothetical. 13 THE WITNESS: As I mentioned earlier, in 14 Exhibit 2001, paragraph 39, "The POSA would 15 understand the preamble 'method for treating an 16 angiogenic eye disorder in a patient' to mean that 17 the claimed dosing regimen achieved and maintained 18 a high level of efficacy comparable to as seen with 19 Lucentis and Avastin and that it is effective for 20 the patient in need of treatment." 21 Furthermore, I mention in 22 paragraph 34 that -- of Exhibit 2001, by January of 23 2011, ophthalmologists would not have considered a 24 dosing regimen that only slows vision loss and 25 could not on average produce visual acuity gains to	Page 121 1 that those agents were the standard of care. 2 I conclude with paragraph 35 stating 3 that "Thus, ophthalmologists could and can 4 ascertain whether a particular drug and dosing 5 regimen is effective for a given patient." 6 BY MR. EHRICH: 7 Q. Dr. Do, would you please turn to page 46 8 of your 1225 declaration, looking at paragraph 113 9 and 114. And just let me know when you're ready, 10 please. 11 A. Could you repeat the page and the 12 paragraph. 13 Q. Sure. Page 46 of your 1225 declaration, 14 and I'm interested in paragraphs 113 and 114 that 15 go from page 46 to page 47. 16 A. I see those paragraphs. 17 Q. Okay. And you see in paragraph 114 you 18 say that "Administration of VEGF Trap-Eye under the 19 dosing regimen disclosed in the '681 patent did not 20 necessarily result in a high level of efficacy for 21 20 percent of patients," right? 22 A. I see that text. 23 Q. And it looks like that conclusion is 24 based on your analysis of a retro -- based on your 25 summary of a retrospective analysis by Jaffe,

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Page 122 1 et al. Am I saying that right? 2 A. You're saying it correctly. Jaffe, yes. 3 Q. Okay. And is that fair to say that your 4 conclusion is based on the Jaffe article? 5 A. In Exhibit 2056 (1225), paragraph 113, I 6 do cite a retrospective analysis of the VIEW 1 and 7 VIEW 2 studies by Jaffe and colleagues showing that 8 a group of patients with early persistent fluid 9 after the initial three injections of Eylea, which 10 was present in approximately 20 percent of eyes 11 initially treated with intravitreal aflibercept 12 injection, there was a higher proportion of dry 13 retinas, a greater visual acuity improvement, and a 14 smaller proportion with visual acuity loss in eyes 15 treated with 2 milligrams every four weeks compared 16 with eyes treated with Lucentis every four weeks or 17 aflibercept every eight weeks at Week 52. 18 Q. And it looks like in your declaration, 19 Dr. Do, you're citing to Exhibit 2121, which is, I 20 believe, Jaffe at page 6, right? 21 A. Can you restate those -- 22 Q. Sure. I'm just looking at your 23 declaration, Dr. Do, at page 47, the top of 24 page 47, the sentence that you just read ends with 25 a cite to Exhibit 2121, which according to the	Page 124 1 you cite -- 2 (Audio disruption.) 3 (Short recess.) 4 THE VIDEOGRAPHER: We're now back on the 5 record at 4:40 p.m. 6 Please continue. 7 MR. EHRICH: Welcome back, Dr. Do. 8 THE WITNESS: Thank you. Welcome back. 9 BY MR. EHRICH: 10 Q. As you may recall, when we left off, we 11 were looking at the Jaffe reference Exhibit 2121, 12 page 6. 13 A. Yes. 14 Q. And my question is which of the subjects 15 did not achieve a high level of efficacy? 16 MS. STRUTHERS: Objection; document speaks for 17 itself. 18 THE WITNESS: In my declaration, Exhibit 2056 19 (1225), page 46, paragraph 112, I discuss that the 20 recited dosing regimen will not necessarily achieve 21 the high level of efficacy that is required by the 22 challenged claim. 23 In paragraph 113, I reference Jaffe's 24 manuscript, which is a retrospective analysis of 25 VIEW 1 and VIEW 2 studies, and they determined in
Page 123 1 footnote I believe is the Jaffe reference and 2 specifically the Jaffe reference at page 6, 3 correct? 4 A. I see what is written there. 5 Q. So could you please turn, then, to the 6 exhibits binder, and we'll introduce it as it's 7 already been marked, Exhibit 2121. And just let me 8 know when you're there, please. 9 A. Yes, I found that article. 10 Q. Okay. So -- and can you confirm, then, 11 please, that this is the Jaffe reference that 12 you're discussing in paragraph 113 of your 13 declaration? 14 A. Exhibit 2121 is the Jaffe reference. 15 Q. Okay. And could you please turn to 16 page 6. 17 A. Yes, I see that. 18 Q. Can you please show me on page 6 which 19 of the study subjects whose results are shown here 20 did not achieve a high level of efficacy? 21 MS. STRUTHERS: Objection to form, the 22 document speaks for itself. 23 THE WITNESS: Could you repeat the question? 24 BY MR. EHRICH: 25 Q. Sure. So, again, in your declaration	Page 125 1 their retrospective analysis that approximately 2 20 percent of eyes initially treated with 3 aflibercept did better when they were treated every 4 four weeks compared to eyes that were treated every 5 eight weeks, because in this group of patients, 6 they had early persistent fluid after the initial 7 three injections. And, thus, we concluded in 8 paragraph 114 that the administration of VEGF 9 Trap-Eye under the dosing regimen disclosed in the 10 '681 patent did not necessarily result in a 11 high-level efficacy for 20 percent of these 12 patients that were mentioned in the Jaffe 13 manuscript. 14 BY MR. EHRICH: 15 Q. Right. And as we discussed, you base 16 this on the cite to the Jaffe manuscript at page 6, 17 and so I would just like for you to please walk me 18 through which of the subjects on page -- detailed 19 on page 6 of the Jaffe manuscript achieved a high 20 level of efficacy and which ones did not. 21 MS. STRUTHERS: Objection; asked and answered. 22 THE WITNESS: In reference to the Jaffe 23 manuscript, I did not conclude in my declaration an 24 analysis of who achieved the high level of 25 efficacy, so I can't comment on that at this time

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Page 126 1 without further analysis and time. 2 BY MR. EHRICH: 3 Q. Okay. Dr. Do, could you please turn to 4 page -- bottom of page 57, top of page 58 of your 5 1225 declaration, specifically paragraph 137. And 6 just let me know when you're there, please. 7 A. I see paragraph 137. 8 Q. Okay. You say that if an infection like 9 conjunctivitis is still symptomatic and/or 10 contagious, you would consider it to be an active 11 infection and not a prior infection as required by 12 Criterion 3, right? 13 A. In my declaration, Exhibit 2056 (1225), 14 paragraph 137, I state that "If an infection like 15 conjunctivitis is still symptomatic and/or 16 contagious, I would consider it to be an active 17 ocular or periocular infection and not a prior 18 infection as required by Criterion 3." 19 Q. And, Dr. Do, is that sentence still true 20 if phrased as negative? For -- would you -- does 21 this mean that a prior infection as required by 22 Criterion 3 is not symptomatic or contagious? 23 MS. STRUTHERS: Objection to form, beyond the 24 scope. 25 THE WITNESS: I don't understand that	Page 128 1 me if in paragraph 158 you describe an activity 2 that identifies patients with a prior infection as 3 required by Criterion 3? 4 A. In my declaration, Exhibit 2056 (1225), 5 paragraph 158, I state that an assessment is 6 performed at each visit before administering the 7 intravitreal injection. As part of this 8 assessment, the patient's vision, intraocular 9 pressure, dilated exam, evaluation of the retina, 10 the retinal imaging is performed. All of these 11 active steps need to be performed to evaluate for 12 any ocular or periocular infection. 13 Q. But I -- and I understand and -- but 14 would those steps identify a prior infection as 15 required by Criterion 3? 16 A. In my declaration at paragraph 158 in 17 this section, part of assessing the patient is also 18 discussing their medical history and asking them 19 questions, and that would help identify prior 20 infections. 21 In addition, we would actively 22 examine the patient, evaluate everything that we 23 have at that in-person visit to determine if there 24 were any ocular or periocular infections. 25 Q. Okay. So I understood you to say that a
Page 127 1 negative. For me, it makes more sense how I 2 phrased it, which is paragraph 137, "If an 3 infection like conjunctivitis is still symptomatic 4 and/or contagious, I would consider it to be an 5 active ocular or periocular infection and not a 6 prior infection as required by Criterion 3." 7 BY MR. EHRICH: 8 Q. Okay. Well, let's go forward a little 9 bit, then, to -- could we talk about paragraph 158, 10 then, please. And it goes from page 66 to page 67 11 of your 1225 declaration, and just let me know when 12 you're ready, please, Dr. Do. 13 A. I see paragraph 158. I have it in front 14 of me. 15 Q. Okay. Dr. Do, do you describe -- first 16 of all, we agree that paragraph 158 is generally 17 the description of your clinical practice, right? 18 The first words are literally "In clinical practice 19 when I" -- meaning you -- "treat a patient." 20 Right? Agreed? 21 A. In Exhibit 2056 (1225), paragraph 158, I 22 describe my clinical practice, which I also state 23 is in line with what other retina specialists or 24 ophthalmologists would practice, as well. 25 Q. Is there anything -- can you please tell	Page 129 1 patient interview would help identify a prior 2 infection. Am I understanding that correctly? 3 A. In my declaration, in paragraph 158, I 4 describe all of the active assessments that are 5 necessary to determine whether or not active or 6 even prior infections may have been present, and it 7 involves interviewing the patient, examining the 8 patient, looking at retinal imaging. All these 9 things which any ophthalmologist would do. 10 Q. Okay. And can you please specify which 11 of those assessments would identify a prior 12 infection as opposed to an active infection? 13 MS. STRUTHERS: Objection; asked and answered. 14 THE WITNESS: I think I answered that question 15 already. 16 BY MR. EHRICH: 17 Q. Okay. You say you -- so does this 18 mean -- well, in your last answer, you said 19 that you describe all of the active assessments 20 that are necessary to determine whether or not 21 active or even prior infections may have been 22 present. 23 Does this mean that all of the 24 assessments that you describe in paragraph 158 25 would be able to determine whether there had been a

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Page 130 1 prior infection? 2 A. Every ophthalmologist is trained to do 3 assessments, to ask medical questions, and doing 4 these actions would help the ophthalmologist 5 identify ocular or periocular infections or even 6 possibly, you know, interview the patient, evaluate 7 the patient, identify prior infection. It depends 8 on each clinical scenario, so we'd have to evaluate 9 each patient and thoroughly look at all the 10 evidence at that time to come up with an 11 assessment. 12 Q. Okay. In your last answer, you just 13 said that doing these actions would help the 14 ophthalmologist identify ocular or periocular 15 infections, and then you say "interview the 16 patient, evaluate the patient, identify prior 17 infection." 18 And so setting aside active 19 infections for the moment, which of those 20 assessments identify prior infections? 21 MS. STRUTHERS: Objection; asked and answered. 22 You're allowed to answer again. 23 THE WITNESS: Okay. As I stated in 24 paragraph 158 of my declaration, Exhibit 2056 25 (1225), as part of this assessment, I also review	Page 132 1 in combination, the ophthalmologist should be able 2 to identify intraocular or ocular or periocular 3 infection. 4 Q. Sure. And again staying at the top of 5 page 39 of your 1225 declaration, you say that 6 these techniques -- slit-lamp biomicroscopy, 7 indirect ophthalmoscopy, ocular imaging via optical 8 coherence tomography, and/or fluorescein 9 angiography -- would allow a physician to screen 10 for ocular or periocular infection as well as most 11 intraocular inflammation. But I don't see a 12 reference at the top of page 39 to prior infection. 13 And so I'm wondering, do these 14 techniques also allow a clinician to screen for 15 prior infection? 16 MS. STRUTHERS: Objection; asked and answered. 17 THE WITNESS: You're referring to 18 paragraph 102 in page 39 of Exhibit 2056 (1225); is 19 that correct? 20 MS. STRUTHERS: I'm sorry. I thought you were 21 still on 158. Am I wrong? 22 BY MR. EHRICH: 23 Q. Top of -- reading the techniques, yes, 24 that's right, the top of page 39, yes. That's 25 paragraph 101, actually, I think.
Page 131 1 the patient's medical records and interview the 2 patient, determine if the patient has had any 3 issues with his or her eyes since the last 4 appointment. And doing all of this, in combination 5 with the active assessment of examining the 6 patient's eye when they're dilated and looking at 7 the images of the retina, it would help me identify 8 ocular or periocular infection or a history of 9 prior ocular or periocular infections. 10 BY MR. EHRICH: 11 Q. Okay. So would slit-lamp biomicroscopy 12 identify a prior infection that had no symptoms? 13 A. In order to answer that question, we'd 14 have to look at the entire patient, evaluate not 15 only the slit-lamp but the medical history, any 16 other ocular imaging to make an accurate diagnosis. 17 Q. Okay. And what about dilated 18 examination of the retina using indirect 19 ophthalmoscopy? And I'm at the top of page 39 of 20 your declaration, Dr. Do, if you want to follow 21 along and tell me how to pronounce those. 22 A. As I mentioned, during our assessment, 23 we dilate the pupils, image the retina, perform a 24 clinical examination using a slit lamp and indirect 25 ophthalmoscope. And using all of these assessments	Page 133 1 MS. STRUTHERS: Thank you. 2 THE WITNESS: What was your question regarding 3 this paragraph? 4 BY MR. EHRICH: 5 Q. Well, my question is that -- starting at 6 the bottom of page 38, there's a sentence that 7 begins with "Assessments for infection and/or 8 inflammation," and then it lists the techniques -- 9 or lists the assessments and ends with that this 10 would have allowed the clinician to screen for 11 intraocular or periocular infection as well as most 12 intraocular inflammation. 13 And my question is that -- would this 14 also allow the clinician to screen for prior 15 infection? And, again, I'm just asking because I 16 don't see a reference to prior infection at the top 17 of page 39. 18 A. In my declaration, paragraph 101 of 19 Exhibit 2056 (1225), I discuss assessing the 20 patient to evaluate for exclusion criteria. And I 21 state in the first sentence of paragraph 101, "By 22 2011, the POSA would understand that to apply the 23 exclusion criteria recited in the claims, a 24 clinician would first need to assess a patient for 25 the recited conditions. And specifically, the POSA

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Page 134 1 would have understood that practicing the methods 2 of Claims 1 and 14 requires ruling out active 3 ocular inflammation, active ocular or periocular 4 inflammation in a patient, and any ocular or 5 periocular infection within the last two weeks 6 prior to treatment." 7 I then describe different 8 assessments. I didn't say this was the exhaustive 9 list of all assessments. And the POSA would 10 understand that assessing the patient would also 11 involve talking to the patient, taking a medical 12 history, doing all the standard things an 13 ophthalmologist would do to look for active or 14 prior infection. 15 Q. Okay. Thank you for clarifying. 16 Can we -- let's go back to page 67 of 17 your 1225 declaration. 18 Do you see toward the bottom of 19 page 67 you say in other cases you may proceed with 20 the intravitreal injection despite the presence of 21 one of these conditions but that in those cases 22 you're not performing the claimed method? 23 A. I see that sentence. 24 Q. In your practice, Dr. Do, do you ever 25 withhold an injection if a patient presents with a	Page 136 1 the intravitreal injection of the VEGF antagonist, 2 right? 3 A. Which line are you referring to? 4 Q. I'm looking essentially at the sentence 5 about halfway down where it says "When this does 6 happen." 7 A. I see that sentence. 8 Q. And so you make the determination as to 9 whether to administer the injection is what you're 10 saying, right? 11 A. In my declaration, I state that after I 12 do all these active assessments -- examining a 13 patient, looking at the imaging, reviewing the 14 medical history, talking to the patient -- using 15 all that information, then I make a determination. 16 Q. Right. And if you determine to proceed 17 with the injection -- again, looking at the bottom 18 of page 67 -- you say that you are not performing 19 the claimed method, right? 20 MS. STRUTHERS: Objection; mischaracterizes 21 the testimony. 22 THE WITNESS: Could you repeat the question? 23 BY MR. EHRICH: 24 Q. Sure. Again, just as -- as you write, 25 you say that you may proceed with the intravitreal
Page 135 1 prior infection but not an active infection? 2 A. I would have to evaluate the entire 3 patient -- look at the medical history, look at 4 retinal imaging -- in order to answer that type of 5 question in that clinical scenario. 6 Q. Okay. Just sitting here, can you recall 7 ever withholding an injection from a patient who 8 had a prior infection but not an active infection? 9 A. I don't know if I could recall right 10 now. I'd have to, you know, review my medical 11 charts and spend hours looking through the records 12 to answer that accurately. 13 Q. Okay. Do you see that, again, towards 14 the bottom of page 67, again, you state that you -- 15 in other cases, you may proceed with the 16 intravitreal injection despite the presence of one 17 of these conditions, but that in those cases, 18 you're not practicing the claimed method, right? 19 A. I see that sentence. 20 Q. Okay. So -- and a ways up, maybe 21 halfway or so down that page 67, Dr. Do, it looks 22 like when you come across one of these cases, such 23 as a patient with an active ocular or periocular 24 infection or an active intraocular inflammation, 25 you say that you determine whether to administer	Page 137 1 injection despite the presence of one of these 2 conditions but that in those cases you're not 3 performing the claimed method, correct? 4 A. In my declaration, Exhibit 2056 (1225), 5 paragraph 158, I state that in other cases I may 6 proceed with the intravitreal injection despite the 7 presence of one or more of these conditions. The 8 "conditions" refers to an active ocular 9 inflammation or active ocular or periocular 10 infection or active ocular or periocular 11 infection within the last two weeks prior to 12 treatment. If the patient has any of these 13 exclusion criteria and I inject them, then I am not 14 performing the claimed method. 15 Q. Okay. Right. Now, you see just above 16 that, Dr. Do, you say that in certain of these 17 cases, less than 1 percent, you do determine to 18 withhold the injection, that is, to exclude the 19 patient from treatment, at least temporarily? 20 A. I see that sentence. 21 Q. Okay. Couple questions about that 22 sentence. One is if you do determine to withhold 23 the injection, are you performing the claimed 24 method? 25 MS. STRUTHERS: Objection; calls for a legal

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Page 138 1 conclusion. 2 THE WITNESS: Recall that I stated in my 3 declaration, Exhibit 2001, paragraph 39, that in 4 view of -- in light of the patent and 5 state-of-the-art in 2011, the POSA would understand 6 that the method of treating an angiogenic eye 7 disorder in a patient to mean that the claimed 8 dosing regimen achieves and maintains a high level 9 of efficacy as comparable to that seen with 10 Lucentis and Avastin and that it is effective for 11 the patient in need of treatment. 12 BY MR. EHRICH: 13 Q. Dr. Do, I -- maybe -- let me try to 14 rephrase the question, make it a little more 15 specific. When you write -- when you say that you 16 may proceed with the intravitreal injection despite 17 the presence of one of these conditions but that in 18 those cases you're not performing the claimed 19 method, are you saying that you're not performing 20 the claimed method because you're not applying the 21 exclusion criteria? 22 A. According to the claimed method for 23 treating an angiogenic eye disorder in a patient, 24 the claimed dosing regimen has to achieve and 25 maintain a high level of efficacy comparable to	Page 140 1 or the other stuff. I'm just asking if you do 2 withhold the injection, are you following at least 3 the exclusion criteria of the claims? 4 MS. STRUTHERS: Objection to form. 5 THE WITNESS: As I mentioned earlier, in the 6 claim, there were exclusion criteria. 7 BY MR. EHRICH: 8 Q. Agreed. 9 A. And if you were practicing the claim, 10 any patient who has any one of these exclusion 11 criteria could not be included or could not receive 12 an injection of aflibercept. 13 Q. Okay. Well, so -- and you can flip 14 back, if you'd like to, Dr. Do, but I think on 15 page 43 of your declaration, there's a heading 2 16 and paragraph 106. And heading 2 says "The 17 Exclusion Criteria Are Mandatory," and 18 paragraph 106 begins with "The POSA would further 19 understand that exclusion criteria, including the 20 exclusion criteria of Claims 1 and 14, are not 21 optional." 22 A. I see that sentence. 23 Q. And so I guess my question is if you are 24 determining whether to administer the intravitreal 25 injection of the VEGF antagonist to a patient who
Page 139 1 that standard of care and the patient could not 2 have any of these exclusion criteria. 3 Q. Okay. And so in paragraph 158, when you 4 say that you're not performing the claimed method, 5 can you tell me what part of the claimed method are 6 you not performing? 7 MS. STRUTHERS: Objection to form. 8 THE WITNESS: In paragraph 158, we're 9 discussing the assessment that is performed to 10 evaluate whether or not a patient has active ocular 11 infection, inflammation, or any ocular or 12 periocular infection within the last two weeks 13 prior to treatment, these are exclusion criteria. 14 BY MR. EHRICH: 15 Q. Okay. 16 A. And I state that if I proceed with the 17 intravitreal injection despite the patient having 18 one or more of these exclusion criteria, then I am 19 not performing the claimed method because I'm 20 including someone who was initially excluded from 21 the claimed method. 22 Q. Okay. So if you do determine to 23 withhold the injection from such a patient, are you 24 following at least the exclusion criteria of the 25 claims? And I'm not trying to ask about efficacy	Page 141 1 presents with an active or recent ocular or 2 periocular infection or an active intraocular 3 inflammation, then how are such exclusion criteria 4 mandatory? 5 MS. STRUTHERS: Objection to form, 6 mischaracterizes the testimony. 7 THE WITNESS: Could you repeat the question? 8 BY MR. EHRICH: 9 Q. Well, it kind of goes back to my 10 previous question, which is if you make a 11 determination not to administer an injection to a 12 patient presenting with one of the exclusion 13 criteria, then are you performing -- are you 14 applying those exclusion criteria? 15 MS. STRUTHERS: Objection to form. 16 THE WITNESS: In my declaration, paragraph 106 17 of Exhibit 2056 (1225), I state that exclusion 18 criteria are mandatory and "the POSA would further 19 understand that exclusion criteria, including 20 exclusion criteria in Claims 1 and 14, are not 21 optional. To practice the claimed methods of 22 treating wherein the excluded criteria for the 23 patient includes all of, number one, active 24 intraocular inflammation; number two, active ocular 25 or periocular infection; and, number three, any

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Page 142 1 ocular or periocular infection within the last two 2 weeks prior to treatment, patients must be assessed 3 and treated only if clear of the excluded 4 conditions." 5 BY MR. EHRICH: 6 Q. Sure. And on page 67 of your 7 declaration, you say that you -- that when a 8 patient presents with one of the claimed exclusion 9 criteria, you determine whether to administer the 10 intravitreal injection of the VEGF antagonist, 11 right? 12 A. Can you repeat that question? 13 Q. Sure. On page 67 of your declaration, 14 you say that you determine whether to administer 15 the intravitreal injection of the VEGF antagonist 16 to a patient who presents with one of the claimed 17 exclusion criteria. 18 A. I see that text. 19 Q. Okay. So whether to administer the 20 intravitreal injection of the VEGF antagonist is at 21 your discretion as the treating physician, correct? 22 MS. STRUTHERS: Objection; mischaracterizes 23 the testimony. 24 THE WITNESS: Recall that in my declaration, 25 so Exhibit 2056 (1225), paragraph 106, the header	Page 144 1 discretion as the treating physician? 2 MS. STRUTHERS: Objection to form, 3 mischaracterizes the document. 4 THE WITNESS: Again, if we're practicing the 5 claimed method, the exclusion criteria are 6 mandatory, and as I stated in paragraph 106 of 7 Exhibit 2056 (1225), the POSA would further 8 understand that exclusion criteria, including the 9 exclusion criteria of Claims 1 and 14, are not 10 optional, and to practice the claimed methods of 11 treating when the exclusion criteria for the 12 patient include all of active intraocular 13 inflammation or active ocular or periocular 14 infection or any ocular or periocular infection 15 within the last two weeks prior to treatment, 16 patients must be assessed and treated only if clear 17 of the excluded condition. 18 BY MR. EHRICH: 19 Q. So let's stay, then, on paragraph 106. 20 You say that to practice the claimed methods, 21 patient must be assessed and treated only if clear 22 of the excluded conditions. So if you determine to 23 withhold an injection from a patient presenting 24 with one of these excluded conditions, then are you 25 practicing the claimed methods as you've described
Page 143 1 right above it, I state that exclusion criteria are 2 mandatory and they are not optional. 3 So in paragraph 106, I state that the 4 POSA would further understand that exclusion of 5 criteria, including exclusion criteria of Claims 1 6 and 14, are not optional, that these are not 7 discretionary, they're mandatory. 8 BY MR. EHRICH: 9 Q. Sure. And then in paragraph 110 of your 10 declaration on page 45, you contrast mandatory 11 exclusion criteria with contraindications that are 12 recommendations left to the discretion of the 13 treating physician, right? 14 A. In paragraph 110 of my declaration, 15 Exhibit 2056 (1225), I state that the POSA would 16 understand that exclusion criteria are more 17 stringent than contraindications on a drug label. 18 Q. Okay. So in your description of your 19 practice on page 67 of your declaration, when you 20 determine whether to administer the intravitreal 21 injection of the VEGF antagonist to a patient who 22 presents with one of the claimed exclusion 23 criteria, are you treating the exclusion criteria 24 as mandatory exclusion criteria, or are you 25 treating them as contraindications left to your	Page 145 1 them in paragraph 106? 2 MS. STRUTHERS: Objection; form, calls for a 3 legal conclusion. 4 THE WITNESS: Are you saying -- you're saying 5 if the patient has one of the exclusion criteria, 6 then they would be excluded if you were practicing 7 the claimed method because exclusion criteria are 8 mandatory and they're not optional. 9 BY MR. EHRICH: 10 Q. I missed, kind of, my question, I guess. 11 If the exclusion criteria are 12 mandatory, then are they still mandatory if you 13 determined to follow them -- or to apply them? 14 MS. STRUTHERS: Objection to form. 15 THE WITNESS: Could you repeat the question? 16 BY MR. EHRICH: 17 Q. Sure. If you determined to follow -- to 18 exclude patients with these conditions, then is it 19 mandatory that they be excluded? 20 MS. STRUTHERS: Objection to form. 21 THE WITNESS: As I stated in my declaration of 22 Exhibit 2056 (1225), paragraph 106, the exclusion 23 criteria are mandatory and the POSA would 24 understand that exclusion criteria are not 25 optional. To practice the claimed methods of

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Page 146 1 treating wherein the exclusion criteria for the 2 patient include all of the following -- the active 3 intraocular inflammation, active ocular or 4 periocular infection, any ocular or periocular 5 infection within the last two weeks prior to 6 treatment -- the patient needs to be assessed to 7 determine whether any of these are present. If any 8 of them are present, they would be excluded because 9 that's mandatory. And they would only be treated 10 if they were cleared of any of the exclusion 11 criteria. 12 BY MR. EHRICH: 13 Q. Okay. And in paragraph 109 on the next 14 page, page 44 of your 1225 declaration, you see 15 that you write that -- toward the bottom of that 16 page, "Only patients not meeting the exclusion 17 criteria are eligible for treatment"? 18 A. I see the text. 19 Q. Okay. So in a clinical study, if a 20 patient presents with one of -- one or more of the 21 exclusion criteria, it looks like what you're 22 saying here in paragraph 109 is that the patient 23 would not be eligible to participate in the study; 24 is that correct? 25 MS. STRUTHERS: Objection; mischaracterizes	Page 148 1 hypothetical. 2 THE WITNESS: Could you repeat that question? 3 BY MR. EHRICH: 4 Q. Sure. I guess I'm just trying to figure 5 out how exclusion criteria apply to a clinical 6 practice. 7 So in paragraph 108, you say that the 8 Eylea MR further confirms that subjects meeting the 9 VIEW exclusion criteria were actually excluded from 10 treatments, which I think means that they were not 11 allowed to participate in the VIEW study at all. 12 So my question is then, in the 13 clinical practice, does this mean that a patient 14 who presents, let's say initially with one of 15 the -- one or more of the claimed criteria, does 16 this mean that that patient will not ever be 17 treated? 18 MS. STRUTHERS: Objection to form, incomplete 19 hypothetical. 20 THE WITNESS: In my declaration, paragraph 109 21 of Exhibit 2056 (1225), I think that the clinician 22 seeking to apply exclusion criteria in clinical 23 practice would likewise understand that patients 24 must actually be assessed for the excluded 25 conditions and treated only if clear of them in
Page 147 1 the document. 2 THE WITNESS: Can you repeat your question? 3 BY MR. EHRICH: 4 Q. Sure. Well, maybe it would be easier to 5 go to page 44 at the top of paragraph 108 of your 6 1225 declaration. 7 You write -- you say that "The Eylea 8 MR further confirms that subjects meeting the VIEW 9 exclusion criteria were actually excluded from 10 treatment," right? 11 A. I see that text. 12 Q. Okay. So -- then in paragraph 109, just 13 below that, the first sentence says, "A clinician 14 seeking to apply the exclusion criteria in clinical 15 practice would likewise understand that patients 16 must actually be assessed for the excluded 17 conditions and treated only if clear of them," 18 right? 19 A. I see that text. 20 Q. So if a clinician is treating a patient 21 and then after they start treating the patient the 22 patient presents with one of the exclusion 23 criteria, does the physician exclude the patient 24 from treatment forever? 25 MS. STRUTHERS: Objection to form, incomplete	Page 149 1 order to practice a method that includes exclusion 2 criteria. 3 BY MR. EHRICH: 4 Q. Right. But it seems that -- so it seems 5 that in paragraph 108. If a patient -- if a 6 subject presents with one or more of the exclusion 7 criteria, they just don't get to participate in the 8 VIEW study, period, ever. Agreed? 9 A. I think in the context of a clinical 10 trial, if a patient has one or more of the 11 exclusion criteria, they would not be included in 12 clinical trial. 13 Q. Okay. So then in paragraph 109, you 14 discuss a clinician seeking to apply the exclusion 15 criteria in the context of a clinical practice, 16 right? 17 A. Mm-hmm. 18 Q. And so my question is how do we apply 19 that? Does that mean that in the context of a 20 clinical practice, the clinician never treats the 21 patient who initially presents with one of the 22 exclusion criteria? 23 MS. STRUTHERS: Objection to form, incomplete 24 hypothetical. 25 THE WITNESS: In paragraph 109 on my

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Page 150 1 declaration, Exhibit 2056 (1225), I discuss that a 2 clinician seeking to apply exclusion criteria in 3 clinical practice would likewise understand that 4 patients must actually be assessed for the excluded 5 condition and treated only if clear of them in 6 order to practice a method that includes exclusion 7 criteria. 8 BY MR. EHRICH: 9 Q. Right. Right, Dr. Do. And I see that 10 paragraph 109 of your declaration says that, but it 11 doesn't -- paragraph 109 does not follow up with 12 does the patient get another chance. 13 MS. STRUTHERS: Is there a question pending? 14 BY MR. EHRICH: 15 Q. In -- for a clinician seeking to apply 16 exclusion criteria in clinical practice, if a 17 patient presents with one or more of the excluded 18 conditions, does that patient get another chance to 19 come back later? 20 MS. STRUTHERS: Objection; incomplete 21 hypothetical. 22 THE WITNESS: I state in my declaration, 23 paragraph 110 on Exhibit 2056 (1225), that, in the 24 last sentence, "However, such physician would not 25 be practicing a method for treating wherein	Page 152 1 exclusion criteria for the patient include all of, 2 number one, active intraocular inflammation; number 3 two, active ocular or periocular infection; number 4 three, any ocular or periocular infection within 5 the last two weeks prior to treatment, patient must 6 be assessed and treated only if clear of that 7 excluded condition. 8 BY MR. EHRICH: 9 Q. So, Dr. Do, could we maybe go back to 10 your description of your practice on page 67 of 11 your 1225 declaration. 12 And a little bit toward the bottom 13 you say that in certain of these cases, less than 14 1 percent, you do determine to withhold the 15 injection, that is, to exclude the patient from 16 treatment, at least temporarily, right? 17 A. I see that sentence. 18 Q. Okay. So if you temporarily exclude the 19 patient from treatment, do you start over with the 20 loading doses, or do you continue where you had 21 left off? 22 MS. STRUTHERS: Objection; incomplete 23 hypothetical, beyond the scope. 24 THE WITNESS: For any of the clinical 25 scenarios, I would have to examine the patient,
Page 151 1 exclusion criteria for the patient included active 2 intraocular inflammation because he or she would be 3 administering intravitreal injection to the patient 4 notwithstanding that the patient had an active 5 intraocular inflammation." 6 So they wouldn't be practicing the 7 claimed method if they were including patients who 8 met exclusion criteria. 9 BY MR. EHRICH: 10 Q. Right. And by "who met," do you mean 11 who ever met? 12 MS. STRUTHERS: Objection; incomplete 13 hypothetical, calls for a legal conclusion, and 14 beyond the scope. 15 BY MR. EHRICH: 16 Q. Sorry, same question. Do you mean -- 17 "by met," do you mean who ever met those criteria? 18 MS. STRUTHERS: Again, objection; incomplete 19 hypothetical, beyond the scope. 20 THE WITNESS: In my declaration, I didn't 21 discuss patients who ever met in the past the 22 exclusion criteria. I mentioned in my declaration, 23 paragraph 106, that the POSA would understand that 24 exclusion criteria are not optional and to practice 25 the claimed methods of treating wherein the	Page 153 1 look at the medical record, evaluate the retinal 2 imaging, look at all the clinical data to determine 3 when I would want to treat the patient. 4 BY MR. EHRICH: 5 Q. Sure. And my question wasn't so much 6 when you determined when to start treating the 7 patient again. My question is if you do treat the 8 patient again, do you pick up where you had left 9 off with, for example, the every-eight-week dosing, 10 or do you start over with the monthly loading 11 doses? 12 MS. STRUTHERS: Objection; incomplete 13 hypothetical, beyond the scope. 14 THE WITNESS: In my declaration, I didn't give 15 an opinion on restarting intravitreal injection on 16 patients who had prior treatment. So at this time 17 I don't think I could answer that question. 18 BY MR. EHRICH: 19 Q. Okay. Well, sitting here now, can you 20 recall or think of any examples where you've 21 started over with loading doses after a patient had 22 presented with, for example, an intraocular 23 inflammation or infection? 24 MS. STRUTHERS: Objection; beyond the scope. 25 THE WITNESS: I couldn't answer that question

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Page 154 1 right now because I'd have to look through the 2 medical chart, review all of the patient records to 3 understand, identify these patients. 4 BY MR. EHRICH: 5 Q. Okay. Dr. Do, could we please turn to 6 page 64 of your 1225 declaration, paragraph -- 7 well, paragraph 155 that begins on the bottom of 63 8 and goes to the top of page 64. 9 My question is about the last 10 sentence of that paragraph, the last sentence of 11 paragraph 155. You write that in some cases in 12 clinical practices, for appropriate RVO patients, 13 physicians will use eight-week or longer dosing 14 intervals, right? 15 A. I see that text. 16 Q. And I don't see a, for example, 17 literature citation there. So I was just wondering 18 how are you aware of this? 19 A. In regards to that sentence in 20 paragraph 155, I don't recall exactly. I'd have to 21 look back at my records to give an appropriate 22 answer. 23 Q. Okay. Okay, Dr. Do. Well, we've just 24 been talking about, recall, page 66 and 67 where 25 you talk about your practice, and I note that,	Page 156 1 clinical practice, for appropriate RVO patients, 2 physicians will use eight-week or longer dosing 3 intervals." 4 BY MR. EHRICH: 5 Q. So in clinical practice, for appropriate 6 RVO patients, would clinicians use eight-week or 7 longer dosing intervals when treating with 8 Lucentis? 9 MS. STRUTHERS: Objection; incomplete 10 hypothetical, beyond the scope. 11 THE WITNESS: In my declaration, I did not 12 give an opinion on dosing intervals of Lucentis in 13 retinal vein occlusion, so I couldn't answer that 14 question today. 15 BY MR. EHRICH: 16 Q. Okay. So just to clarify, then, Dr. Do, 17 so as an ophthalmologist, you don't have personal 18 knowledge of physicians treating RVO patients with 19 Lucentis at eight-week or longer dosing intervals; 20 is that correct? 21 MS. STRUTHERS: Objection; mischaracterizes 22 the testimony. 23 THE WITNESS: In my declaration, I did not 24 give an opinion on dosing of Lucentis in retinal 25 vein occlusion; therefore, I couldn't give a -- an
Page 155 1 turning back to those pages, you're speaking in 2 first person, and I see that at the last sentence 3 of paragraph 155, you're speaking in third person. 4 And so my question is since you used 5 the term "physicians" instead of referring to 6 yourself, would you include yourself among the 7 physicians that will use eight-week or longer 8 dosing intervals, for appropriate RVO patients? 9 A. Again, to accurately answer that 10 question, I'd have to look back at my records of 11 the patients I've taken care of, but it's not 12 unreasonable that some patients have been given -- 13 have received Eylea with that retinal vein 14 occlusion off the eight-week dosing interval. 15 Q. Can you tell me in that sentence what 16 you mean by the term "appropriate RVO patients," 17 what the word "appropriate" means to a person of 18 skill in the art, in this sentence? 19 MS. STRUTHERS: Objection; calls for a legal 20 conclusion, beyond the scope. 21 THE WITNESS: In my declaration, on 22 paragraph 155, I state that "While the Eylea 23 label's recommended dosing regimen for macular 24 edema following retinal vein occlusion is one 25 intravitreal injection once every four weeks, in	Page 157 1 appropriate discussion about that topic at this 2 time. 3 BY MR. EHRICH: 4 Q. Okay. Sorry. Can you tell me, then, 5 what you would need to be able to give an 6 appropriate discussion about that topic? 7 MS. STRUTHERS: Objection; beyond the scope, 8 incomplete hypothetical. 9 THE WITNESS: In my declaration, I do provide 10 an opinion on dosing of Lucentis in retinal vein 11 occlusion and clinical practice of that. So I 12 couldn't give a fair answer to that question 13 without reviewing the medical literature, looking 14 at charts, doing all that necessary background 15 work. 16 BY MR. EHRICH: 17 Q. Okay. Well, so then what about for wet 18 AMD, would physicians ever treat wet AMD with 19 Lucentis using eight-week or longer dosing 20 intervals? 21 MS. STRUTHERS: Objection; beyond the scope, 22 incomplete hypothetical. 23 THE WITNESS: In my declaration, I mentioned 24 for Lucentis Phase 3 minimized clinical trials, 25 Anchor and Marina, which evaluated monthly dosing

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Page 158 1 of Lucentis for the treatment of wet AMD. And as 2 of January of 2011, the standard of care for 3 angiogenic eye disorders was Lucentis or Avastin. 4 And certainly the evidence from the Phase 3 5 clinical trials of Lucentis demonstrated that 6 monthly administration of Lucentis was effective in 7 wet AMD. 8 BY MR. EHRICH: 9 Q. Sure. Understood that Anchor and Marina 10 demonstrated that monthly administration of 11 Lucentis was effective in the treatment of wet AMD. 12 But in at least some cases was the administration 13 of Lucentis at eight-week or longer intervals 14 effective in the treatment of wet AMD? 15 MS. STRUTHERS: Objection; beyond the scope. 16 THE WITNESS: In my declaration, I did not 17 give an opinion on other dosing regimens of 18 Lucentis, so I couldn't provide an appropriate 19 discussion on that topic today at this time. 20 BY MR. EHRICH: 21 Q. Okay. Well, let's turn, please, then, 22 to the binder marked "Exhibits," and we'll just 23 introduce it as it's been marked, Exhibit 2103, 24 please. 25 And for reference, do you see at the	Page 160 1 MS. STRUTHERS: Objection; beyond the scope, 2 the document speaks for itself. 3 THE WITNESS: In my declaration, I did not 4 provide an opinion on Dr. Brown's statement or this 5 reference, Exhibit 2103, and so I don't feel 6 comfortable answering these questions because I did 7 not review this topic and provide an opinion on it. 8 BY MR. EHRICH: 9 Q. Understood, Dr. Do. 10 And I'm not asking for your opinion. 11 I'm just asking if this is consistent with your 12 memory as to how ophthalmologists administered -- 13 or treated neovascular AMD in 2007. 14 MS. STRUTHERS: Objection; beyond the scope. 15 THE WITNESS: As I stated in my declaration, 16 the standard of care at 2011 was the use of 17 Lucentis or Avastin for the treatment of angiogenic 18 eye diseases, and certainly for wet age-related 19 macular degeneration, the Phase 3 clinical trials 20 of Lucentis demonstrated that monthly 21 administration of Lucentis provided -- 22 (Reporter clarification.) 23 THE WITNESS: I stated that monthly 24 administration of Lucentis in those Phase 3 25 clinical trials demonstrated efficacy.
Page 159 1 top of the first page that this article is titled 2 "Ongoing Treatment for Patients With Neovascular 3 AMD"? 4 A. Yes, I see that text. 5 Q. Dr. Do, my understanding is that an 6 ophthalmologist uses the term "neovascular AMD" to 7 refer to wet AMD. Is that -- am I correct in that? 8 A. Yes, that is correct. 9 Q. Okay. Thank you. 10 So turning towards the bottom of 11 page 2, please. Do you see that there's a 12 statement attributed to Dr. Brown that begins "For 13 patients with good initial visual acuity"? 14 A. I see that section. 15 Q. Okay. And so Dr. Brown says that for 16 patients with visual acuity or in whom we're 17 dealing with the primary eye, he treats and extends 18 from the start. He gives three monthly injections 19 and sees them in eight weeks. And if the fluid is 20 absent at that visit, he gives another injection 21 and sees them in ten weeks. 22 And my question is is this consistent 23 with your knowledge as a practicing ophthalmologist 24 as to how ophthalmologists would have treated 25 neovascular AMD in 2007?	Page 161 1 MS. STRUTHERS: Would it be a good time for a 2 break? 3 MR. EHRICH: Sure. That's fine. Five 4 minutes? 5 MS. STRUTHERS: Sure. That's fine. 6 Laura, before -- oh, after we go off 7 the record, I have a question for you. 8 THE VIDEOGRAPHER: Off the record at 6:03. 9 (Short recess.) 10 THE VIDEOGRAPHER: We're now back on the 11 record at 6:08 p.m. 12 Please continue. 13 MS. STRUTHERS: Thank you. Just two 14 housekeeping items. One is that I'd like to 15 designate this transcript confidential under the 16 protective order in this case. 17 And the second is just for clarity of 18 the record, I wanted to note that the exhibit, 19 Exhibit 2103 that's been discussed today, is an 20 exhibit to proceeding IPR2021-00881, again, just 21 for clarity of the record. 22 MR. EHRICH: Thank you, Counsel. 23 Welcome back Dr. Do. 24 THE WITNESS: Thank you. Welcome back. 25

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Page 162 1 BY MR. EHRICH: 2 Q. So turning back to your 1225 3 declaration, I'd like you to please turn to 4 page 70, paragraph 166, and I just have a couple of 5 questions about how the categories apply in this 6 first sentence. 7 You say that physicians, including 8 yourself, have treated wet AMD, DME, DR, and RVO by 9 administering five bimonthly doses following the 10 loading doses, right? 11 A. I see the text in line 166. 12 Q. My question is does the "including 13 yourself" apply to all of the listed indications in 14 that sentence? 15 A. Yes, I am including myself in that 16 sentence, as I stated. 17 Q. Okay. So you've treated all of wet AMD, 18 DME, DR, and RVO by administering at least five 19 bimonthly doses following the loading doses? 20 A. In my declaration, in paragraph 166, I 21 do mention that physicians, including myself, have 22 treated angiogenic eye diseases by administering at 23 least five bimonthly, approximately every eight 24 week, doses following the loading doses. 25 Particularly for wet AMD and DME, which are chronic	Page 164 1 And the question is does this apply 2 to all of wet AMD, DME, DR, and RVO? 3 MS. STRUTHERS: Objection; mischaracterizes 4 the document. 5 THE WITNESS: In my declaration, in 6 paragraph 159, I am referring to the header of 7 Claim B -- Claim 3, the method of Claim 1 when only 8 two secondary doses are administered to the 9 patient, and state the Eylea USPI for wet AMD, DME, 10 and DR set forth in the Eylea USPI satisfies this 11 requirement. 12 The Eylea USPI for wet AMD recommends 13 a 2 milligram dose of Eylea administered by 14 intravitreal injection every four weeks -- that 15 would be monthly -- for the first 12 weeks -- that 16 would be three months. Thus, the Eylea USPI 17 provides for three monthly loading doses, an 18 initial dose followed by two secondary doses. 19 BY MR. EHRICH: 20 Q. Okay. And, Dr. Do, you referenced the 21 Eylea USPI Exhibit 2119 in that paragraph you 22 described, right? 23 A. Yes. 24 Q. So let's go to the exhibits binder and 25 turn to -- we'll introduce it as its marked, as
Page 163 1 conditions, patients are typically treated for more 2 than a year. 3 Q. Right. So you're saying that physicians 4 have treated all of wet AMD, DME, DR, and RVO by 5 administering at least five bimonthly doses 6 following the loading doses, right? 7 A. I would say that in my declaration, in 8 paragraph 166, physicians, including myself, have 9 treated wet AMD, DME, DR, and RVO by administering 10 at least five bimonthly doses following the loading 11 doses. 12 Q. Right. I understand that that's what it 13 says, but I -- but there's also the word "and" in 14 there when -- for the conditions. It's "wet AMD, 15 DME, DR, and RVO." So does that mean that you have 16 treated wet AMD, DME, DR, and RVO by administering 17 at least five bimonthly doses following the loading 18 doses? 19 A. Yes. 20 Q. Okay. Thank you. 21 I'd also like for you to please turn 22 just back a couple pages to page 68, paragraph 160. 23 So a similar question. You write -- you say that 24 in your experience and to your knowledge, patients 25 are at times administered only three loading doses.	Page 165 1 Exhibit 2119. 2 Just let me know when you're there, 3 please. 4 A. Yes, I have that Exhibit 2119. 5 Q. Okay. And do you see at the top of the 6 second column it says "Diabetic macular edema (DME) 7 and diabetic retinopathy (DR) in patients with 8 diabetic macular edema"? 9 A. Yes. 10 Q. And do you see that the first bullet 11 says that the recommended dose for Eylea is 12 2 milligrams administered by intravitreal injection 13 every four weeks for the first five injections? 14 A. I see that text. 15 Q. And -- so -- I guess, can you please 16 explain to me how that is recommending only two 17 secondary doses? 18 MS. STRUTHERS: Objection; mischaracterizes 19 the testimony. 20 THE WITNESS: Could you repeat the question? 21 BY MR. EHRICH: 22 Q. Sure. Just referring back to 23 paragraph 159 of your 1225 declaration, you say 24 that the Eylea USPI for wet AMD, DME, and DR set 25 forth in the Eylea USPI satisfies this requirement,

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Page 166 1 and "this requirement" being when only two 2 secondary doses are administered to the patient. 3 And so I -- don't see a cite for -- in your 4 declaration for DME and DR. 5 And so looking at the Eylea USPI, I 6 was just -- would like -- was wondering if you can 7 explain to me how -- how it satisfies the 8 requirement for only two loading doses -- sorry, 9 only two secondary doses. 10 A. As I mentioned in paragraph 161 in my 11 declaration, Exhibit 2056 (1225), the Eylea USPI 12 for wet AMD, DME, and DR set forth in the Eylea 13 USPI satisfies this requirement, and the Eylea USPI 14 recommend that each secondary dose is administered 15 four weeks after the immediately preceding dose. 16 Q. Right. You see that paragraph 161 that 17 you just read applies to what you have under the 18 heading Claim 3.b, and I'm asking about 19 paragraph 159, which you have under the heading 20 Claim 3.a. 21 A. Mm-hmm. Yes. In my declaration under 22 Claim 3.a, I state that the Eylea USPI for wet AMD, 23 DME, and DR set forth in the Eylea USPI satisfies 24 this requirement. 25 The Eylea USPI for wet AMD recommends	Page 168 1 although Eylea may be dosed as frequently as 2 2 milligrams every four weeks, additional efficacy 3 was not demonstrated in most patients when Eylea 4 was dosed every four weeks compared to every eight 5 weeks. 6 BY MR. EHRICH: 7 Q. Okay. And how many secondary doses does 8 the Eylea USPI recommend for DME and DR? 9 A. As I stated in my declaration in 10 Section 161, the secondary dose is administered 11 four weeks after the immediately preceding dose and 12 the Eylea USPI recommends that each secondary dose 13 is administered four weeks after the immediately 14 preceding dose, and it satisfies the requirement. 15 Q. For paragraph 161, right, but, again, I 16 was asking about paragraph 159. 17 A. And as I state in my declaration, in 18 paragraph 159, the Eylea USPI for wet AMD, DME, and 19 DR set forth in the Eylea USPI satisfies this 20 requirement. 21 The Eylea USPI for wet AMD recommends 22 a 2 milligram dose of Eylea administered by 23 intravitreal injection every four weeks for the 24 first 12 weeks. That's -- the Eylea USPI provides 25 for three monthly loading doses, an initial dose
Page 167 1 a 2 milligram dose of Eylea administered by 2 intravitreal injection every four weeks for the 3 first 12 weeks, but the Eylea USPI provides for 4 three monthly loading doses, an initial dose 5 followed by two secondary doses. 6 Q. Okay. And does the Eylea USPI also 7 recommend an initial dose followed by two secondary 8 doses for DME and DR? 9 A. Can you repeat the question? 10 Q. Sure. Does the Eylea USPI recommend an 11 initial dose followed by only two secondary doses 12 for DME and DR? 13 MS. STRUTHERS: For clarity, Counsel, you're 14 still referring to Exhibit 2119? 15 MR. EHRICH: I am. Yeah, that's right. 16 THE WITNESS: Well, in that section of 17 Exhibit 2119 under the heading "Diabetic Macular 18 Edema and Diabetic Retinopathy in Patients With 19 Diabetic Macular Edema," we note that the 20 recommended dose for Eylea is 2 milligrams 21 administered by intravitreal injection every four 22 weeks for the first five injections followed by 23 2 milligrams via intravitreal injection once every 24 eight weeks. 25 Further noted in the second bullet,	Page 169 1 followed by two secondary doses. 2 Q. Right. Understood. 3 But the first sentence of 4 paragraph 159 says that it satisfies the 5 requirement for wet AMD, DME, and DR, and then in 6 paragraph 159, you provide an example specifically 7 for wet AMD. 8 And so my question is can you also 9 provide a similar example for DME and DR? 10 MS. STRUTHERS: Objection; mischaracterizes 11 the testimony, mischaracterizes the document. 12 THE WITNESS: I thought I answered the 13 question, but do you have a different question? 14 BY MR. EHRICH: 15 Q. Okay. Looking at Exhibit 2119, at the 16 top of the second column, do you see it says that 17 the recommended dose -- under -- for DME and DR, it 18 says the recommended dose is 2 milligrams 19 administered by intravitreal injection every four 20 weeks for the first five injections, right? 21 A. I see that text. 22 Q. Okay. Is an intravitreal injection 23 every four weeks for the first five injections a 24 recommended dose wherein only two secondary doses 25 are administered to the patient, as you state in

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Page 170 1 paragraph 159 of your declaration? 2 MS. STRUTHERS: Objection; mischaracterizes 3 the testimony and mischaracterizes the document. 4 THE WITNESS: Again, in my declaration, 5 paragraph 159, I state that the Eylea USPI for wet 6 AMD, DME, and DR set forth in the Eylea USPI 7 satisfies this requirement of the method of 8 Claim 1. 9 I further state that the Eylea USPI 10 for wet AMD recommends a 2 milligram dose of Eylea 11 administered by intravitreal injection every four 12 weeks for the first 12 weeks, that the Eylea USPI 13 provides for three monthly loading doses, an 14 initial dose followed by two secondary doses. 15 In paragraph 160 in my declaration, I 16 also state that in my experience and to my 17 knowledge, patients are at times administered only 18 three loading doses, an initial dose of Eylea 19 followed by two secondary doses. 20 BY MR. EHRICH: 21 Q. Okay. But can you tell me whether the 22 Eylea USPI recommends only two secondary doses for 23 the treatment of DME and DR? 24 MS. STRUTHERS: Objection; asked and answered, 25 the document speaks for itself.	Page 172 1 doses. 2 BY MR. EHRICH: 3 Q. So do you in your practice administer an 4 initial dose of Eylea followed by only two 5 secondary doses to patients presenting with DME, 6 DR, or RVO? 7 MS. STRUTHERS: Objection to form, incomplete 8 hypothetical. 9 THE WITNESS: To answer that question, I'd 10 have to examine the patient, look at their response 11 to the Eylea injection, evaluate the retinal 12 imaging and the OCT to determine the administration 13 of IVF. 14 BY MR. EHRICH: 15 Q. Okay. Dr. Do, could you please go back 16 to the declarations binder. And I'd like this time 17 to go to Exhibit 2056 (1226). And we previously 18 introduced this. I believe this is Exhibit 4. 19 A. Can you repeat those numbers? 20 Q. Sure. Exhibit -- in the declarations 21 binder, Exhibit 2056 (1226). And I'd specifically 22 like you to please turn to page 41. And just let 23 me know when you're there, please. 24 A. I see that page. 25 Q. I'd like to focus on paragraph 107.
Page 171 1 THE WITNESS: I think we already discussed 2 this topic. 3 MS. STRUTHERS: You can answer again. 4 THE WITNESS: The -- Exhibit 2119, under the 5 diabetic macular edema and diabetic retinopathy in 6 patients with diabetic macular edema, states the 7 recommended dose for Eylea is 2 milligrams 8 administered by intravitreal injection every four 9 weeks for the first five injections followed by 10 2 milligrams via intravitreal injection once every 11 eight weeks. 12 The second bullet is "Although Eylea 13 may be dosed as frequently as 2 milligrams every 14 four weeks, additional efficacy was not 15 demonstrated in most patients when Eylea was dosed 16 every four weeks compared to every eight weeks." 17 And then I stated in my declaration, 18 paragraph 159 of Exhibit 2056 (1225), that the 19 US -- the Eylea USPI provides for three monthly 20 loading doses, an initial dose followed by two 21 secondary doses. 22 And I further state in paragraph 160, 23 to my experience and to my knowledge patients are 24 at times administered only three loading doses, an 25 initial dose of Eylea followed by two secondary	Page 173 1 Do you see it says that it's your 2 opinion that the claimed 2Q8 dosing regimen will 3 not necessarily result in a gain of at least 4 15 letters of BCVA in age-related macular 5 degeneration patients? 6 A. I see that text. 7 Q. Okay. What do you mean by "not 8 necessarily"? 9 A. In my declaration, I discuss that the 10 recited dosing regimen by Eylea will not 11 necessarily achieve the visual acuity gains 12 required by the dependent claim limitation. 13 And in paragraph 107, it is my 14 opinion that the claimed 2 milligrams given every 15 eight weeks dosing regimen will not necessarily 16 result in a gain of at least 15 letters of best 17 corrected visual acuity in age-related macular 18 degeneration patients as required by Claim 5 and 6. 19 Q. Okay. But if you administer the claimed 20 dosing regimen to a thousand patients, would any of 21 them achieve a gain of at least 15 letters of BCVA 22 in age-related macular degeneration? 23 MS. STRUTHERS: Objection; incomplete 24 hypothetical. 25 THE WITNESS: In my declaration, Exhibit 2056

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Page 174 1 (1226), paragraph 110, I state that data reported 2 in the '601 patent also show that, on average, VIEW 3 subjects did not achieve a gain of at least 15 4 letters of best corrected visual acuity. 5 Example 4 shows that subjects in the 6 2-milligram-every-eight-week dosing arm of the 7 VIEW 1 and 2 studies who were treated with the 8 claimed dosing regimen had a mean gain in best 9 corrected visual acuity of 7.9 letters and 8.9 10 letters respectively. 11 Thus, administering the dosing 12 regimen of Claims 5 and 6 to a patient will not 13 necessarily result in the patient achieving a gain 14 of at least 15 letters as is required by those 15 claims. 16 BY MR. EHRICH: 17 Q. Okay. But in the VIEW studies, did any 18 of the patients achieve 15 letters gain? 19 A. In my declaration, in paragraph 109, I 20 state I have reviewed the VIEW data reported in 21 Heier's manuscript in 2012, and while these data 22 show that certain patients in VIEW achieved gains 23 of at least 15 letters of best corrected visual 24 acuity, most VIEW patients did not achieve gains of 25 this magnitude. In particular, Heier reports that	Page 176 1 A. Yes, I have opened that Exhibit 5. 2 Q. And do you recognize this as the Dixon 3 reference? 4 A. Yes, it is the Dixon reference. 5 Q. Okay. I have a question about in the 6 abstract on the first page of this reference. You 7 see about halfway down the abstract it says "One 8 promising new drug is aflibercept (VEGF Trap-Eye), 9 a fusion protein that blocks all isoforms of VEGF-A 10 and placental growth factors-1 and 2." 11 And my question is do you understand 12 that sentence to be referring to a specific 13 molecule or to a class of molecules? 14 MS. STRUTHERS: Objection; beyond the scope, 15 the document speaks for itself. 16 THE WITNESS: Could you repeat the question? 17 BY MR. EHRICH: 18 Q. Sure. And maybe come at -- we can come 19 at it another way. You -- in paragraph, for 20 example, 43 of your 1225 declaration, you say that 21 Dixon does not disclose whether treatment would be 22 effective, and in paragraph 44, you say that Dixon 23 does not disclose the exclusion criteria. 24 And so my question is -- and I see 25 that you don't write whether Dixon discloses, for
Page 175 1 the majority of subjects in the VIEW study, 2 69.4 percent of patients in VIEW 1 and 68.6 percent 3 of patients in VIEW 2, did not gain at least 15 4 letters of best corrected visual acuity." 5 Q. Oh, I'm sorry, go ahead. I did not mean 6 to cut you off. 7 A. Consequently, the data reported in Heier 8 show that the claimed visual acuity gains do not 9 necessarily or naturally result from administering 10 the claimed dosing regimen to a given patient. 11 Q. Okay. Thank you, Dr. Do. 12 I think -- let's -- I'd like to turn 13 back, please, to your 1225 declaration and 14 specifically page 12. And just let me know when 15 you're there, please. 16 A. I see page 12 now. 17 Q. Okay. And it looks like on page 12, in 18 general, you're discussing what the Dixon 19 reference, Example 1006, describes and also what it 20 does not disclose; is that fair? 21 A. Yes. 22 Q. Okay. Could you please turn back to the 23 exhibits binder to the tab marked "Klibanov 24 Exhibit 5" toward the end. And just let me know 25 when you're there, please.	Page 177 1 example, the third wherein clause at Claim 1 which 2 recites the amino acid sequence of the aflibercept 3 molecule. 4 And so my question is is that 5 omission because, in your opinion, the Dixon does 6 disclose that -- the aflibercept molecule? 7 MS. STRUTHERS: Objection; beyond the scope. 8 Objection to form. 9 THE WITNESS: In my declaration I did not 10 provide an opinion on the amino acid sequence of 11 aflibercept, and so I couldn't answer that 12 question. 13 BY MR. EHRICH: 14 Q. Let's look at your 1225 declaration, 15 page 64, paragraph 156 and paragraph 157. 16 It looks like you say that Eylea, as 17 administered by physicians, does satisfy this claim 18 element, "this claim element" being the amino acid 19 sequence of the aflibercept molecule, right? 20 MS. STRUTHERS: Objection; the document speaks 21 for itself. 22 THE WITNESS: What was your question? 23 BY MR. EHRICH: 24 Q. Well, my question is, since you do 25 provide an opinion as to whether the Eylea USPI and

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Page 178 1 a practicing physician satisfy that claim element, 2 can you tell me whether the Dixon reference 3 meets -- also meets that claim element? 4 MS. STRUTHERS: Objection; beyond the scope. 5 THE WITNESS: In my declaration I state 6 that -- in paragraph 156, I have reviewed the 7 Exhibit 1024 in this proceeding, and I am informed 8 Exhibit 1024 is an Application for Extension of 9 Patent Term under 35 USC, and the application 10 references Eylea. Based on my review of 11 Exhibit 1024, I understand that Eylea is a 12 recombinant fusion protein consisting of VEGF 13 receptor component having Ig domains consisting of 14 an Ig domain 2 of human Flt1 and Ig domain 3 of 15 human Flk1, and so forth. 16 BY MR. EHRICH: 17 Q. And do you understand that the active 18 ingredient for Eylea is known as aflibercept and is 19 also known as VEGF Trap-Eye? 20 MS. STRUTHERS: Objection; beyond the scope, 21 vague as to time. 22 BY MR. EHRICH: 23 Q. To address Counsel's objections, do you 24 understand that sitting here today in the year 25 2023?	Page 180 1 document speaks for itself. 2 THE WITNESS: What time period are you 3 referring to? 4 BY MR. EHRICH: 5 Q. Right now. 2023. 6 A. In 2023, I would consider Eylea and 7 aflibercept to be different names of the VEGF 8 inhibitor. 9 Q. Okay. And by "the VEGF inhibitor," are 10 you referring to a specific molecule or to a class 11 of molecules? 12 MS. STRUTHERS: Objection; beyond the scope. 13 THE WITNESS: In 2023, I would consider Eylea 14 and aflibercept to be different names for Eylea. 15 BY MR. EHRICH: 16 Q. Okay. So now let's please turn back to 17 Klivanov Exhibit 5, which is the Dixon reference, 18 and the sentence in the -- midway down the 19 abstract. 20 "One promising new drug is 21 aflibercept (VEGF Trap-Eye)." 22 Can you tell me how would a POSA 23 in -- prior to January 2011, have read the phrase 24 "aflibercept (VEGF Trap-Eye)"? 25 MS. STRUTHERS: Objection; beyond the scope,
Page 179 1 A. And what is the question about today's 2 time period? 3 Q. The question is -- you know what, 4 let's -- let's go to -- back to Exhibit 2119, which 5 you recall is the Eylea USPI. 6 A. Okay. 7 Q. Do you see toward the top of the 8 left-hand column it says "Eylea (aflibercept)"? 9 A. I see that text. 10 Q. What does that text mean to you? In 11 other words, what is the relationship between the 12 word "Eylea" and the word "aflibercept"? 13 MS. STRUTHERS: Objection; the document speaks 14 for itself. 15 THE WITNESS: I see in this document "Eylea," 16 and then next to it in parentheses "aflibercept," 17 then the word "injection." 18 BY MR. EHRICH: 19 Q. Okay. What is aflibercept? 20 MS. STRUTHERS: Objection; beyond the scope. 21 BY MR. EHRICH: 22 Q. As a practicing ophthalmologist, are you 23 able to look at this phrase "Eylea (aflibercept)" 24 and tell me what aflibercept is? 25 MS. STRUTHERS: Objection; beyond the scope,	Page 181 1 document speaks for itself. 2 THE WITNESS: In my declaration, I did not 3 provide an opinion on what the POSA would consider 4 regarding the nomenclature aflibercept or VEGF 5 Trap-Eye. And so at this time I wouldn't be 6 comfortable answering that question. 7 BY MR. EHRICH: 8 Q. Okay. How would you have read 9 "aflibercept (VEGF Trap-Eye)" in the year 2009? 10 MS. STRUTHERS: Objection; beyond the scope. 11 THE WITNESS: Again, I did not provide an 12 opinion on the different names VEGF Trap-Eye or 13 aflibercept at that time period. And so I don't 14 feel comfortable discussing that today. 15 BY MR. EHRICH: 16 Q. So you're unable to tell me how an 17 ophthalmologist in 2009 would have read that 18 phrase, just to clarify? 19 MS. STRUTHERS: Objection; mischaracterizes 20 the testimony, beyond the scope. 21 THE WITNESS: Since I did not provide an 22 opinion on the names aflibercept or VEGF Trap-Eye 23 in my declaration, I don't feel comfortable 24 providing a clear answer on that topic at this 25 time.

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Page 182 1 BY MR. EHRICH: 2 Q. Okay. If you could please continue in 3 Klivanov Exhibit 5 to page 3. You'll see midway 4 down the right -- left-hand column, there's a 5 heading "2.3, Chemistry." And just let me know 6 when you're there, please. 7 A. Yes. I see that text. 8 Q. Okay. Thank you. 9 And the same question. Would a POSA 10 have read the first sentence under Section 2.3 as 11 referring to a specific molecule or to a general 12 class of molecules? 13 MS. STRUTHERS: Objection; beyond the scope. 14 THE WITNESS: I did not provide an opinion on 15 the chemistry of VEGF Trap-Eye and aflibercept, the 16 oncology product noted here in this reference. And 17 so I don't feel comfortable discussing that topic 18 today. 19 BY MR. EHRICH: 20 Q. Okay. I understand that's not in your 21 declaration, Dr. Do, but the question is -- so are 22 you saying that you're unable to answer either way 23 at this point? 24 MS. STRUTHERS: Objection; mischaracterizes 25 the testimony and beyond the scope.	Page 184 1 aflibercept; therefore, I don't feel comfortable 2 answering questions regarding systemic 3 activities -- activity. 4 BY MR. EHRICH: 5 Q. Okay. Well, are you able to tell me, 6 sitting here, in general, then, would negligible 7 systemic activity be a desirable or undesirable 8 attribute for a VEGF antagonist intended for the 9 treatment of angiogenic eye disorders? 10 MS. STRUTHERS: Objection; beyond the scope. 11 THE WITNESS: Because I had not provided an 12 opinion on systemic activity of aflibercept, I 13 couldn't answer that question at this time. 14 BY MR. EHRICH: 15 Q. Could you please stay in the exhibits 16 binder and turn to -- and we'll introduce it as 17 such -- 2090. 18 Are you there? 19 A. Yes, I see that. 20 Q. Okay. Thank you. 21 And, Dr. Do, this appears to be a 22 scientific journal article that you are listed as 23 first author on; is that correct? 24 A. Yes, that's correct. 25 Q. And then my question is the -- on the
Page 183 1 THE WITNESS: Since I didn't provide an 2 opinion on that specific section regarding the 3 chemistry of VEGF Trap-Eye and aflibercept, the 4 oncology product, I wouldn't feel comfortable 5 opining on that topic, having not had any 6 background reading or knowledge of it at this time. 7 BY MR. EHRICH: 8 Q. Okay. Maybe let's move to a little bit 9 more of a clinical question, then. 10 That same column, Dr. Do, do you see 11 the next section is 2.4, Pharmacodynamics? 12 A. I see that section. 13 Q. Okay. And do you see that it -- that 14 section ends with saying that VEGF Trap-Eye would 15 be predicted to give negligible systemic activity 16 as it will be rapidly bound to VEGF and 17 inactivated? 18 A. I see that text. 19 Q. Okay. Would a -- would an 20 ophthalmologist in 2009 have thought negligible 21 systemic activity to be a desirable attribute or an 22 undesirable attribute for VEGF Trap-Eye? 23 MS. STRUTHERS: Objection; beyond the scope. 24 THE WITNESS: In my declaration, I did not 25 provide an opinion on systemic activity of	Page 185 1 first page, the right-hand column. The second full 2 paragraph, do you see it begins with "VEGF Trap is 3 a 115 kilodalton recombinant fusion protein"? 4 A. Yes, I see that text. 5 Q. Okay. And in that passage, are you 6 referring to VEGF Trap as a single molecule or as 7 to a heterogeneous class of molecules? 8 MS. STRUTHERS: Objection; beyond the scope, 9 document speaks for itself. 10 THE WITNESS: Again, in my declaration, I did 11 not give opinion on the individual molecule versus 12 a class of molecule. So what I wrote here is 13 simply VEGF Trap is a 115 kilodalton recombinant 14 fusion protein consisting of the VEGF binding 15 protein -- VEGF binding domain of human VEGF 16 receptors 1 and 2 fused to the FC domain human IgG. 17 BY MR. EHRICH: 18 Q. Okay. Well, I will say that just 19 because, in English, it looks like you're using the 20 singular form, "a 115 kilodalton recombinant fusion 21 protein," it appears you're referring to a single, 22 a unique molecule. 23 And my question is just is that an 24 accurate reading of the sentence? 25 MS. STRUTHERS: Object to form.

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Page 186 1 BY MR. EHRICH: 2 Q. I understand it's not in your 3 declaration. I'm just asking what this sentence 4 means in this paper for which you are listed as the 5 first author? 6 MS. STRUTHERS: Object to form, beyond the 7 scope, asked and answered. 8 THE WITNESS: As I stated, I did not provide 9 an opinion on the topic of a class of agents versus 10 a single molecule, and so I don't feel comfortable 11 answering questions related to that topic because I 12 did not provide opinion on that. 13 BY MR. EHRICH: 14 Q. Okay. Can you -- can you please turn to 15 page 2 of Exhibit 2090. This is your 2009 paper. 16 Do you see in the left-hand column 17 there's -- under the heading -- there's the heading 18 "Study Population"? 19 A. Yes, I see that. 20 Q. Okay. And do you see about two-thirds 21 down that paragraph, there's a sentence that begins 22 with "Eyes were also excluded if there was an 23 ocular abnormality other than DMO"? 24 A. I see that text. 25 Q. And it looks like the example is ocular	Page 188 1 paragraph that the results of this study strongly 2 support additional testing of VEGF Trap-Eye 3 patients with DMO in which repeated injections are 4 given at an interval of every six weeks or longer. 5 A. I see that text. 6 Q. So I just want to confirm. Two of four 7 patients showing persistent effects at six weeks 8 strongly supports additional testing in which the 9 interval -- the injection interval would be every 10 six weeks or longer. 11 Am I understanding this last page of 12 this article correctly? 13 MS. STRUTHERS: Objection; beyond the scope, 14 document speaks for itself. 15 THE WITNESS: In my declaration I did not 16 provide an opinion on this document, and I don't 17 feel comfortable at this time discussing the 18 results of the document as I haven't prepared 19 myself in reading it and analyzing all the data. 20 MR. EHRICH: Okay. Could we please take ten 21 minutes? 22 MS. STRUTHERS: That's fine. Sure. Thank 23 you. 24 MR. EHRICH: Okay. 25 THE VIDEOGRAPHER: Off the record at 7:03.
Page 187 1 abnormalities are vein occlusion, age-related 2 macular degeneration, Irvine-Gass syndrome, 3 uveitis, and some other ones, right? 4 A. I see that text. 5 Q. Okay. Can you tell me why were these 6 excluded? 7 MS. STRUTHERS: Objection; beyond the scope. 8 THE WITNESS: In my declaration I did not 9 provide an opinion on this particular manuscript, 10 and I don't feel comfortable recalling or 11 explaining these exclusion criteria at this time 12 without going back and looking at additional data 13 about this study. 14 BY MR. EHRICH: 15 Q. Okay. Can you please turn to page 6 of 16 the same Exhibit 2090. 17 And it looks in the left-hand column 18 that you write -- you wrote that two of the four 19 patients who were examined at six-week -- at the 20 six-week endpoint showed a persistent 21 antipermeability effect. 22 Do you see that kind of midway down 23 the left-hand column? 24 A. Yes, I see that text. 25 Q. Okay. And then you write in the final	Page 189 1 (Short recess.) 2 THE VIDEOGRAPHER: We are now back on the 3 record at 7:13. 4 Please continue. 5 MR. EHRICH: Welcome back again, Dr. Do. 6 THE WITNESS: Thank you. Great to be back. 7 MR. EHRICH: Good for you. 8 BY MR. EHRICH: 9 Q. Please turn to your 1225 declaration, 10 specifically paragraph 125, which is at the top of 11 page 53. And just let me know when you're there, 12 please. 13 A. I see that paragraph. 14 Q. Okay. Do you see in that paragraph you 15 state that the Lucentis trials did not include the 16 third exclusion criterion of the '681 claims? 17 A. I see that sentence. 18 Q. Had the Lucentis trials included that 19 third exclusion criterion, would the results of the 20 trials have been different? 21 MS. STRUTHERS: Objection; incomplete 22 hypothetical, beyond the scope. 23 THE WITNESS: As I stated in my declaration, 24 in paragraph 125 of Exhibit 2056 (1225), "I have 25 compared the exclusion criteria from the

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Page 190 1 Marina/Anchor trials with the exclusion criteria 2 from VIEW and, while there is some overlap between 3 exclusion criterion used in Marina and those used 4 in VIEW, they are not identical. As is 5 particularly relevant here, the Lucentis trials did 6 not include the third exclusion criterion of the 7 '681 claim, which are ocular or periocular 8 infection within the last two weeks prior to 9 treatment. So consequently, Rosenfeld 2006 does 10 not disclose Criterion 3." 11 BY MR. EHRICH: 12 Q. Okay. Can you tell me what -- what's 13 the rationale for adding Criterion 3 as an 14 exclusion criterion as someone who has participated 15 in a great many clinical trials of products, 16 including, I believe, both Lucentis and Eylea, 17 right? 18 MS. STRUTHERS: Objection to form. 19 THE WITNESS: What's the question? 20 BY MR. EHRICH: 21 Q. The question is what is the rationale 22 for including that third exclusion criterion? 23 What's the rationale for adding it? 24 MS. STRUTHERS: Objection; calls for 25 speculation, incomplete hypothetical.	Page 192 1 BY MR. EHRICH: 2 Q. Okay. Well, then I'm curious as to what 3 you mean, then, when you say "As is particularly 4 relevant here, the Lucentis trials did not include 5 the third exclusion criterion." 6 What do you mean, then, when you say 7 it is particularly relevant that they don't include 8 that? 9 A. I think in my declaration, 10 paragraph 125, I use the term "as is particularly 11 relevant here" because I merely wanted to point out 12 that the Lucentis trials did not include the third 13 exclusion criterion of the '681 claim. 14 Q. And can you comment on the relevance of 15 exclusion criterion -- the third exclusion 16 criterion beyond that? Beyond the fact that it 17 exists? 18 MS. STRUTHERS: Objection to form. 19 THE WITNESS: I think I, frankly, answered 20 that question when I explained I did not provide an 21 opinion on why the VIEW 1 and VIEW 2 trials were 22 designed to specifically include that third 23 exclusion criterion and, therefore, I wouldn't feel 24 comfortable providing an accurate answer regarding 25 that part of the clinical trial design at this
Page 191 1 THE WITNESS: In my declaration I did not 2 provide an opinion on why the people who designed 3 the VIEW clinical trials decided on the third 4 exclusion criteria, so I couldn't provide an 5 accurate answer or discuss that properly with you 6 today. 7 BY MR. EHRICH: 8 Q. Okay. Do you have an opinion, then, as 9 to whether including people with -- subjects with 10 ocular or periocular infection within the last two 11 weeks prior to treatment would affect the results 12 of either the Lucentis or the Eylea Phase 3 trials? 13 MS. STRUTHERS: Objection; incomplete 14 hypothetical, beyond the scope. 15 THE WITNESS: In my declaration, I didn't 16 discuss or provide an opinion on whether or not 17 including or removing that third exclusion 18 criterion in the VIEW trials or adding them in the 19 Marina or Anchor trials, how that would affect the 20 trial result. And because I did not provide an 21 opinion on that, I wouldn't feel comfortable 22 answering that question accurately without knowing 23 more data about how the criterion would affect the 24 population. 25	Page 193 1 time. 2 MR. EHRICH: Okay. Thanks you for your time, 3 Dr. Do. No further questions. 4 THE WITNESS: Thank you. 5 MS. STRUTHERS: I have no questions for this 6 witness. 7 THE VIDEOGRAPHER: Off the record at 7:20 p.m. 8 FURTHER DEPONENT SAITH NAUGHT 9 (Proceedings concluded at 10 7:20 p m.) 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25

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Page 194 1 STATE OF ILLINOIS)) SS: 2 COUNTY OF COOK) 3 I, Valerie M. Calabria, CSR, RPR, do hereby certify that DIANA DO, MD, was duly sworn by me to 4 testify the whole truth, and that the foregoing deposition was recorded stenographically by me and 5 was reduced to computerized transcript under my direction, and that the said deposition constitutes 6 a true record of the testimony given by said witness 7 I further certify that the reading and 8 signing of the deposition was not waived, and that the deposition was submitted to Ms. Abigail 9 Struthers, respondent's counsel, for signature 10 I further certify that I am not a relative or employee or attorney or counsel of any of the 11 parties, or a relative or employee of such attorney or counsel, or financially interested directly or 12 indirectly in this action 13 IN WITNESS WHEREOF, I have hereunto set my hand this 7th day of June, A.D. 2023 14  15 Valerie M. Calabria, CSR, RPR 16 Illinois CSR License 084-003928 17 18 19 20 21 22 23 24 25	Page 196 1 DEPOSITION REVIEW CERTIFICATION OF WITNESS 2 ASSIGNMENT REFERENCE NO: 5905476 3 CASE NAME: Mylan Pharmaceuticals, Inc. Et Al v. Regeneron Pharmaceuticals, Inc. Et Al DATE OF DEPOSITION: 6/2/2023 4 WITNESS' NAME: Diana Do, MD 5 In accordance with the Rules of Civil Procedure, I have read the entire transcript of 6 my testimony or it has been read to me 7 I have made no changes to the testimony as transcribed by the court reporter 8 9 Date <u>Diana Do, MD</u> 10 Sworn to and subscribed before me, a Notary Public in and for the State and County, 11 the referenced witness did personally appear and acknowledge that: 12 They have read the transcript; 13 They signed the foregoing Sworn Statement; and 14 Their execution of this Statement is of their free act and deed 15 I have affixed my name and official seal 16 this <u> </u> day of <u> </u>, 20<u> </u> 17 18 Notary Public 19 Commission Expiration Date <u> </u> 20 21 22 23 24 25
Page 195 1 Veritext Legal Solutions 1100 Superior Ave 2 Suite 1820 Cleveland, Ohio 44114 3 Phone: 216-523-1313 4 June 7, 2023 5 To: Abigail Struthers, Esq. 6 Case Name: Mylan Pharmaceuticals, Inc. Et Al. v. Regeneron 7 Pharmaceuticals, Inc. Et Al. 8 Veritext Reference Number: 5905476 9 Witness: Diana Do, MD Deposition Date: 6/2/2023 10 Dear Sir/Madam: 11 12 Enclosed please find a deposition transcript. Please have the witness 13 review the transcript and note any changes or corrections on the 14 included errata sheet, indicating the page, line number, change, and 15 the reason for the change. Have the witness' signature notarized and 16 forward the completed page(s) back to us at the Production address shown 17 above, or email to production-midwest@veritext.com. 18 19 If the errata is not returned within thirty days of your receipt of 20 this letter, the reading and signing will be deemed waived. 21 Sincerely, 22 Production Department 23 24 25 NO NOTARY REQUIRED IN CA	Page 197 1 DEPOSITION REVIEW CERTIFICATION OF WITNESS 2 ASSIGNMENT REFERENCE NO: 5905476 3 CASE NAME: Mylan Pharmaceuticals, Inc. Et Al v. Regeneron Pharmaceuticals, Inc. Et Al DATE OF DEPOSITION: 6/2/2023 4 WITNESS' NAME: Diana Do, MD 5 In accordance with the Rules of Civil Procedure, I have read the entire transcript of 6 my testimony or it has been read to me 7 I have listed my changes on the attached Errata Sheet, listing page and line numbers as 8 well as the reason(s) for the change(s) 9 I request that these changes be entered as part of the record of my testimony 10 I have executed the Errata Sheet, as well 11 as this Certificate, and request and authorize that both be appended to the transcript of my testimony and be incorporated therein 12 13 Date <u>Diana Do, MD</u> 14 Sworn to and subscribed before me, a Notary Public in and for the State and County, 15 the referenced witness did personally appear and acknowledge that: 16 They have read the transcript; 17 They have listed all of their corrections in the appended Errata Sheet; 18 They signed the foregoing Sworn Statement; and 19 Their execution of this Statement is of 20 their free act and deed 21 I have affixed my name and official seal 22 this <u> </u> day of <u> </u>, 20<u> </u> 23 24 Notary Public 25 Commission Expiration Date <u> </u>

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1	ERRATA SHEET
2	VERITEXT LEGAL SOLUTIONS MIDWEST
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20	Date Diana Do , MD
21	SUBSCRIBED AND SWORN TO BEFORE ME THIS
22	DAY OF , 20 .
23	Notary Public
24	
25	Commission Expiration Date

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Federal Rules of Civil Procedure

Rule 30

(e) Review By the Witness; Changes.

(1) Review; Statement of Changes. On request by the deponent or a party before the deposition is completed, the deponent must be allowed 30 days after being notified by the officer that the transcript or recording is available in which:

(A) to review the transcript or recording; and

(B) if there are changes in form or substance, to sign a statement listing the changes and the reasons for making them.

(2) Changes Indicated in the Officer's Certificate. The officer must note in the certificate prescribed by Rule 30(f)(1) whether a review was requested and, if so, must attach any changes the deponent makes during the 30-day period.

DISCLAIMER: THE FOREGOING FEDERAL PROCEDURE RULES ARE PROVIDED FOR INFORMATIONAL PURPOSES ONLY.

THE ABOVE RULES ARE CURRENT AS OF APRIL 1, 2019. PLEASE REFER TO THE APPLICABLE FEDERAL RULES OF CIVIL PROCEDURE FOR UP-TO-DATE INFORMATION.

VERITEXT LEGAL SOLUTIONS
COMPANY CERTIFICATE AND DISCLOSURE STATEMENT

Veritext Legal Solutions represents that the foregoing transcript is a true, correct and complete transcript of the colloquies, questions and answers as submitted by the court reporter. Veritext Legal Solutions further represents that the attached exhibits, if any, are true, correct and complete documents as submitted by the court reporter and/or attorneys in relation to this deposition and that the documents were processed in accordance with our litigation support and production standards.

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