

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

MYLAN PHARMACEUTICALS,)
INC. and CELLTRION, INC.)
)
vs.) CASE NO. IPR2022-01225
) Patent 10,130,681 B2
REGENERON PHARMACEUTICALS)

MYLAN PHARMACEUTICALS,)
INC. and CELLTRION, INC.)
)
vs.) CASE NO. IPR2022-01226
) Patent 10,888,601 B2
REGENERON PHARMACEUTICALS)

ORAL VIDEOTAPED DEPOSITION

DAVID BROWN, M.D.

May 17, 2023

ORAL VIDEOTAPED DEPOSITION OF DAVID BROWN, M.D.,
produced as a witness at the instance of the
Petitioner and duly sworn, was taken in the
above-styled and numbered cause on the 17th day of
May, 2023, from 8:44 a.m. to 1:31 p.m., before Shauna
Foreman, Certified Shorthand Reporter in and for the
State of Texas, reported by computerized stenotype
machine at the offices of Arnold & Porter, 700
Louisiana Street, Suite 4000, Houston, Texas,

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Page 2 1 pursuant to the Federal Rules of Civil Procedure and 2 the provisions stated on the record or attached 3 hereto. 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25	Page 4 1 INDEX 2 PAGE 3 DAVID BROWN, M.D. 4 Examination by Mr. Ehrich 5 5 6 EXHIBITS 7 8 NO. DESCRIPTION PAGE 9 Exhibit 1 Expert Declaration of David M. Brown, M.D. 7 10 Exhibit 2 Article - VEGF Trap-Eye for the Treatment of Neovascular Age-Related Macular Degeneration 8 11 12 Exhibit 3 Curriculum Vitae 27 13 Exhibit 4 Article - Intravitreal Aflibercept (VEGF Trap-Eye) in Wet Age-Related Macular Degeneration 33 14 15 Exhibit 5 '681 Patent 42 16 Exhibit 6 '601 Patent 42 17 Exhibit 7 Article - Ranibizumab for Neovascular Age-Related Macular Degeneration 53 18 19 Exhibit 8 Article - Ranibizumab Versus Verteporfin for Neovascular Age-Related Macular Degeneration 54 20 21 Exhibit 9 BLA Application Number 125156 Approved Labeling 67 22 23 Exhibit 10 Slide Presentation 102 24 Exhibit 12 Expert Declaration of Dr. Thomas A. Albini 74 25
Page 3 1 APPEARANCES 2 3 FOR PETITIONER: 4 THOMAS H. EHRICH, Ph.D., ESQ. 5 RMMS 6 Six West Hubbard Street 7 Chicago, Illinois 60654 8 E-mail: tehrich@rmmslegal.com 9 FOR RESPONDENT: 10 ABIGAIL STRUTHERS, ESQ. 11 DAVID DENUYL, ESQ. 12 ARNOLD & PORTER 13 290 West 55th Street 14 New York, New York 10019 15 E-mail: abigail.struthers@arnoldporter.com 16 17 ALSO PRESENT: 18 Lauren Huston, Videographer 19 Eileen Woo 20 21 22 23 24 25	Page 5 1 VIDEOGRAPHER: The date is May 17th, 2 2023. We are on the record at 8:44 a.m. We're here 3 for the deposition of David Brown, M.D. 4 At this time, will counsel please 5 state their appearances and the witness be sworn? 6 MR. EHRICH: Thomas Ehrich of RMMS for 7 petitioner. 8 MS. STRUTHERS: Abigail Struthers of 9 Arnold & Porter for the witness and Regeneron. With 10 me via phone is my colleague, David Denuyl, also with 11 Arnold & Porter. And with me here in person is 12 Eileen Woo of Regeneron. 13 DAVID BROWN, M.D., 14 having been first duly sworn, testified as follows: 15 EXAMINATION 16 Q. (BY MR. EHRICH) Good morning, Dr. Brown. 17 A. Good morning. 18 Q. Could you please state your full name for 19 the record? 20 A. Yep. David Mark Brown. 21 Q. I know you've been deposed before, but I 22 would like to start by just going over a couple 23 ground rules. 24 As you can see, the deposition is 25 being transcribed. Please remember that

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Page 6 1 transcriptionists cannot understand a head nod or a 2 shake, so please answer all questions verbally. 3 If any of my questions today are 4 unclear to you, please just let me know and I'll 5 repeat or I'll try to clarify. 6 As we're going along, if you later on 7 happen to think of something more to say about an 8 earlier question, please just let me know and we'll 9 certainly go back and talk about it some more. 10 And your attorney will be objecting to 11 some of my questions in order to preserve the record. 12 This is part of the process, but you still need to 13 answer all of my questions to the best of your 14 ability unless the attorney specifically advises you 15 not to. 16 Do you understand? 17 A. I do. 18 Q. All right. We'll be taking breaks from 19 time to time, but if you would like a break at any 20 point, please just let me know. This is not an 21 endurance contest. The only thing I ask is that if 22 there's a question pending, please answer the 23 question before we go on break. 24 A. Sure. 25 (Exhibit 1 marked)	Page 8 1 Dr. Brown, turn in your declaration to Page 3, 2 Section 4 describing a person of ordinary skill in 3 the art. 4 Are you there? 5 A. I'm here. 6 Q. Okay. And do you see at the start of 7 Paragraph 9 you state you've been asked to consider 8 the level of ordinary skill in the art in forming 9 your opinions in this declaration? 10 A. Yes, sir. 11 Q. Okay. And so, with that in mind, then, I 12 would like to hand you what's been marked Brown 13 Exhibit 2. 14 (Exhibit 2 marked) 15 Q. (BY MR. EHRICH) This appears to be a 16 scientific journal article. 17 Do you recognize this article, 18 Dr. Brown? 19 A. I do. 20 Q. Okay. And is it okay with you if I refer 21 to this as the Dixon reference? 22 A. Perfect. 23 Q. Okay. I'm correct that you reviewed this 24 article in connection with preparing your 25 declaration, correct?
Page 7 1 Q. (BY MR. EHRICH) Dr. Brown, I would like to 2 hand you what's been marked as Brown Exhibit 1. 3 And do you recognize this as a copy of 4 the declaration you prepared? 5 A. I do. 6 Q. And, Dr. Brown, you understand that this 7 deposition is in connection with two different IPRs, 8 right, one ending in 1225 and one ending in 1226? 9 A. That is correct. 10 Q. Okay. And it appeared to me that the 11 declaration that you prepared was the same for both 12 IPRs. 13 Could you just confirm that or, if 14 not, are you aware of any difference? 15 A. There -- one declaration for both, but we 16 mention each individual patent as it pertains. 17 Q. In each of them? So the point being, 18 though, we could go from one copy of -- 19 A. Yeah, there's -- 20 (Simultaneous cross-talk.) 21 Q. (BY MR. EHRICH) -- that there's -- the 22 material is all in one copy of the declaration? 23 A. That is correct. 24 Q. Okay. Thank you. 25 Okay. If you could please, then,	Page 9 1 A. That is correct. 2 Q. Okay. So I just have a couple of initial 3 questions. If you could please look at the first 4 page at the abstract, do you see it starts off with 5 Background and then later it says Objective and 6 Methods, et cetera? 7 A. I do. 8 Q. Okay. And could you please look at the -- 9 the last sentence before the word "objective"? It 10 begins with "one promising new drug." 11 A. I see it. 12 Q. Okay. And you can either read the sentence 13 to yourself or read it aloud, but can you tell me in 14 your own words how would a person of skill in the art 15 in 2011 have interpreted that sentence? 16 MS. STRUTHERS: Objection. Beyond the 17 scope. 18 Q. (BY MR. EHRICH) I can be more specific, if 19 you'd like. 20 A. Sure. 21 Q. Do you see it says, "One promising new drug 22 is aflibercept," and then in parentheses it says VEGF 23 Trap-Eye in parentheses? 24 A. I see that. 25 Q. Would a person of skill in the art in 2011,

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Page 10 1 and specifically under Regeneron's definition of a 2 person of skill in the art -- for example, an 3 ophthalmologist -- have understood the terms 4 aflibercept and VEGF Trap-Eye in this sentence to be 5 referring to the same molecule? 6 MS. STRUTHERS: Objection. Beyond the 7 scope. 8 A. Yeah. I understand the objective today is 9 to go over my declaration, and I don't believe I 10 dealt with that in my declaration. So -- I can look 11 through it and see if I did, but I don't remember 12 that. 13 Q. (BY MR. EHRICH) I don't believe you did 14 either. 15 Given that you reviewed this reference 16 from the standpoint of a person of skill in the art, 17 I was just asking what this sentence means to a 18 person of skill in the art. 19 MS. STRUTHERS: I'll offer the same 20 objection that it's beyond the scope. 21 A. Again, I didn't go through it in my 22 declaration. There's speculation on what a person of 23 skill in the art would think about different 24 molecular structures. 25 Q. (BY MR. EHRICH) Okay. Can you tell me how	Page 12 1 relationship to the rest of that first sentence? 2 A. Sure. There it refers to an abbreviation 3 for age-related macular degeneration, and we do this 4 in scientific literature so that you don't have to -- 5 you can then use the word AMD and you don't have to 6 type out "age-related macular degeneration" and 7 interfere with the word count. 8 Q. Okay. And staying on that page, do you see 9 it has an introduction section below the abstract? 10 A. I do. I'm there. 11 Q. Sorry. Go ahead. 12 A. I'm there. 13 Q. Thank you. 14 About two-thirds, maybe a little bit 15 more of the way down, do you see a sentence that 16 begins "with treatment outcomes improved"? 17 A. I see the sentence, yes. 18 Q. Okay. So similar question. Do you see it 19 says -- it has the phrase "photodynamic therapy 20 (PTDN)"? 21 A. I see that. 22 Q. Can you tell me what PTD refers to, what 23 the parenthetical refers to in relation to the rest 24 of the sentence? 25 A. Again, PTD is an abbreviation shortening
Page 11 1 you read that sentence? 2 MS. STRUTHERS: Objection. Beyond the 3 scope. I would ask you not to speculate, Doctor. 4 A. You know, it's a review article in a 5 journal I've never heard of until the patent 6 applications, written by a medical student in 7 Colorado, Naresh Mandava. He was probably at the 8 meeting where the data was presented, but I -- you 9 know, I haven't spent time thinking about what that 10 sentence means to me. I guess we can take the time 11 and I can do it, but I spent a lot of careful time on 12 each part of this declaration, and I feel I should do 13 the same thing for anything outside of the 14 declaration. 15 Q. (BY MR. EHRICH) Okay. Okay. Well, let's 16 stay with the Dixon reference for just a minute, 17 please, then. 18 Could we then -- maybe on that same 19 page, do you see that the abstract begins with the 20 word "background"? 21 A. Background? I see that. 22 Q. And you see that the sentence following 23 begins with "age-related macular degeneration (AMD)"? 24 A. I see that. 25 Q. Can you tell me what AMD means in	Page 13 1 for photodynamic therapy. So then in the next 2 sentence, you can say, "While more efficacious than 3 previous treatment, patients receiving PTD" -- you 4 can use that shortened phrase of it as opposed to 5 writing out photodynamic therapy and increasing the 6 word count. 7 Q. And do you see the same sentence -- so the 8 one before also has -- it says "that utilized a 9 photo-sensitizing dye" and then (verteporfin). I'm 10 not sure if I'm pronouncing that correctly. 11 A. Yeah. Verteporfin. I see that. 12 Q. Can you tell me what verteporfin refers to, 13 given that it's in parentheses in relation to the 14 rest of the sentence? 15 A. Verteporfin was the drug produced by QLT 16 that was used as a previous treatment for age-related 17 macular degeneration prior to 2005. 18 Q. And is verteporfin -- so is verteporfin a 19 photo-sensitizing dye, then? 20 MS. STRUTHERS: Objection. The 21 document speaks for itself. 22 A. So verteporfin is one of probably thousands 23 of photo-sensitizing dyes. 24 Q. (BY MR. EHRICH) Okay. So the phrase 25 "verteporfin" is specifying which photo-sensitizing

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Page 14 1 dye it is? 2 MS. STRUTHERS: Objection. The 3 document speaks for itself. 4 A. That's what the document states. 5 Q. (BY MR. EHRICH) That's what the document 6 states? So that's extraordinarily plain to you? 7 MS. STRUTHERS: Objection. 8 Mischaracterizes the testimony. Again, the document 9 speaks for itself. 10 A. I wouldn't say extraordinarily. I wouldn't 11 say that. If you go to 1575, you see Regeneron 12 Pharmaceuticals (Tarrytown). It doesn't mean that 13 Tarrytown is Regeneron Pharmaceuticals. 14 Q. Uh-huh. 15 A. So parentheses can mean different things 16 after different words. 17 Q. Dr. Brown, do you have an understanding of 18 the terms "drug substance" and "drug product"? 19 MS. STRUTHERS: Objection. Beyond the 20 scope. 21 A. I've been involved in the development of 22 drugs, so I have dealt with the terms "drug 23 substance" and "product," but I haven't gone into 24 that in this declaration or as it regards these 25 molecules.	Page 16 1 Trap-Eye and aflibercept (the oncology product)" to 2 refer to the same molecule? 3 MS. STRUTHERS: Objection. Document 4 speaks for itself. Beyond the scope. 5 A. I can read it, sure. 6 Q. (BY MR. EHRICH) Sorry. That wasn't my 7 question. 8 My question was: Do you have an 9 understanding as an ophthalmologist as to whether in 10 that sentence VEGF and aflibercept, the oncology 11 product, are referring to the same molecule? 12 MS. STRUTHERS: Objection. Beyond the 13 scope. Document speaks for itself. 14 A. Prior to medical school, everybody has to 15 take organic chemistry and physical chemistry and 16 certainly have some of that in medical school, but 17 very little after. 18 The differences in molecular 19 structure, I'm certainly not an expert. So I can 20 read what it says, but I don't know that that means 21 much to me. 22 Q. (BY MR. EHRICH) Okay. Could you please 23 stay with the Dixon reference and then turn to 24 Page 1577? 25 A. I'm here.
Page 15 1 Q. (BY MR. EHRICH) Sure. I understand. My 2 question, though, was: Do you have an understanding 3 as to what those terms mean? 4 MS. STRUTHERS: Objection. Asked and 5 answered. Beyond the scope. 6 A. Again, as it regards drug development, most 7 of my experience has been in non-biologic drug 8 development in terms of the -- using those terms. 9 In terms of biologic drug development, 10 I understand it's way more complicated and not 11 something I'm an expert in. 12 Q. (BY MR. EHRICH) Okay. So similar 13 question -- or another question, I guess, staying 14 with the Dixon reference, please. 15 Will you please turn to Page 1575? Do 16 you see on the left-hand column there's a section 17 headed 2.3, Chemistry? 18 A. I do. 19 Q. Okay. And then in either -- feel free to 20 read aloud or read to yourself just the first 21 sentence of that paragraph. 22 A. I've read it. 23 Q. Thank you. 24 Reading the sentence as an 25 ophthalmologist, do you understand the clause "VEGF	Page 17 1 Q. Thank you. 2 And I would like you to please look 3 at -- toward the end, the bottom of the right-hand 4 column. 5 A. Towards the bottom of the right-hand 6 column. 7 Q. Yes, that last -- that last paragraph that 8 crosses from 1577 to 1578. 9 A. Okay. 10 Q. So do you see the second sentence of that 11 paragraph reads, "The multi-factorial nature of DME 12 including non-VEGF mediated causes such as pericyte 13 and endothelial cell damage and tractional 14 mechanisms, has made treatment of this condition 15 difficult using current modalities"? 16 MS. STRUTHERS: Objection. Document 17 speaks for itself. 18 A. I see that. 19 Q. (BY MR. EHRICH) Okay. Can you tell me 20 what DME stands for in this context? 21 A. Sure. I'm sure it's spelled out early in 22 the manuscript, but it's diabetic macular edema. 23 Q. Diabetic macular edema? 24 A. Yes, sir. 25 Q. Would you mind just briefly telling me in

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Page 18 1 your own words for a lay person, what is diabetic 2 macular edema? 3 A. Diabetes hurts small blood vessels all over 4 the body. The retinal vascular vessels are 5 particularly prone to be the first manifestation of 6 end-stage diabetic retinopathy. Normally the vessels 7 have tight junctions and don't have leakage into the 8 retina; but when they do, it causes swelling in the 9 retina, which the medical term is diabetic macular 10 edema. 11 Q. Okay. Thank you. 12 Can you please tell me, then, what 13 does this phrase, then, "the multi-factorial nature 14 of DME" refer to here? 15 MS. STRUTHERS: Objection. Document 16 speaks for itself. 17 A. Just means there's a bunch of factors 18 involved in diabetic macular edema. 19 Q. (BY MR. EHRICH) Could you please expand on 20 that a little bit? What do you mean by "factors," or 21 maybe give some examples of factors? 22 A. Sure. Diabetes affects small blood vessels 23 all over the body. If you kill off blood vessels, 24 different people have different amounts of capillary 25 perfusion. In other words, different damage to the	Page 20 1 assuming it's not found in the literature. 2 Q. Okay. So in the context of ophthalmology, 3 would it have been correct in 2006, just to your 4 memory? 5 A. That's correct. 6 Q. Okay. And can you just explain, please, 7 what it means by "exudative AMD"? 8 A. Sure. Fancy word for leakage. In other 9 words, if you have vessels that leak fluid, they 10 exude fluid or exudate it. It's synonymous. 11 Q. Okay. So you had already explained what 12 the term -- the multi-factorial edema is in that 13 second sentence. And that same sentence ends by 14 saying that it's made treatment of this condition, by 15 which it's referring to DME, difficult using current 16 modalities, right? 17 MS. STRUTHERS: Objection. Document 18 speaks for itself. 19 A. That's correct. 20 Q. (BY MR. EHRICH) Okay. And so, Dr. Brown, 21 given that Dixon published in 2006, would this -- 22 would you generally have agreed with this statement 23 in 2006? 24 MS. STRUTHERS: Objection. 25 Mischaracterizes the document. I think you have the
Page 19 1 capillary structures. 2 Diabetics -- people with diabetic 3 retinopathy, by nature of it, have been non-compliant 4 with a medical regimen for 10 to 15 years, they get 5 into trouble. In other words, they didn't take care 6 their of their blood sugars, their AIC is out of 7 control, most of them have hypertension, many of them 8 have some kind of renal disease. Many are obese. 9 That's why they got diabetes in the first place. And 10 so, they could have sleep apnea. Unlike an animal 11 experiment where all the little white mice are the 12 same, in humans, every diabetic is different. 13 Q. Dr. Brown, you understand if I use the 14 phrase ADM, I'm referring to age-related macular 15 degeneration, right? 16 A. Yes. 17 Q. So this paragraph that we're looking at 18 right now begins with "Anti-VEGF agents are currently 19 only approved for the treatment of exudative AMD," 20 right? 21 A. That's what it says. It's probably 22 incorrect because anti-VEGF agents were approved for 23 different cancers at that point. 24 Q. Okay. 25 A. Regardless of the fact, I guess it's	Page 21 1 date wrong, Counsel. 2 Q. (BY MR. EHRICH) I apologize. 2009. 3 And so, the question, but would you 4 have agreed with the statement as of 2009? 5 MS. STRUTHERS: Objection. Document 6 speaks for itself. 7 A. In 2009 certainly RISE/RIDE, the study 8 which I was first authored on, was probably fully 9 recruited. It might have had some preliminary data. 10 I don't know exactly when we presented RISE/RIDE the 11 first time. You can check my CV. 12 Q. (BY MR. EHRICH) Sorry, Doctor, but I'm not 13 understanding how that relates to my question, 14 though, which is just: Would treatment of DME have 15 been considered difficult in 2009? And maybe just 16 specify outside of a clinical study setting. 17 MS. STRUTHERS: Objection. Vague. 18 A. Treatment of DME is still difficult even 19 with great drugs we have. So I agree. 20 Q. (BY MR. EHRICH) Okay. So in the context 21 of our conversation today, would you be -- you 22 understand that if I use the term wAMD, I'm referring 23 to age-related macular degeneration? 24 A. It's not a commonly-used abbreviation, but 25 sure. I understand it.

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Page 22 1 Q. Okay. 2 A. Usually it's neovascular AMD. NAMD is a 3 much more common scientific. Certainly the lay press 4 calls it more wet. 5 Q. Okay. 6 A. Related to that exudation or leakage we 7 alluded to. 8 Q. Okay. And I don't think I caught it. You 9 said that you would -- in ophthalmology circles, what 10 term would you use? 11 A. We call it neovascular AMD. 12 Q. Neovascular. 13 A. So dry vascular degeneration, wet macular 14 degeneration, it's typically referred to as 15 neovascular AMD -- 16 Q. Okay. 17 A. Because it deals with new blood vessels, 18 neovascular. I don't know if they use wAMD in this 19 article or not, but we typically don't use it in 20 publications. In the last 20 years anyway. 21 Q. So my question is: In -- well, prior to 22 2011, would treatments for neovascular AMD and DME 23 have been the same? 24 A. Certainly by 2011 anti-VEGFs, namely 25 ranibizumab and off-label bevacizumab were used quite	Page 24 1 for neovascular AMD would have been ranibizumab and 2 off-label bevacizumab, and the standard of care 3 for -- at the time for DME also would have been 4 ranibizumab or off-label bevacizumab? I just want to 5 make sure I'm following what you're saying. 6 A. In 2011, that's correct. 7 Q. Okay. 8 A. Macugen was also approved, but was -- 9 pegaptinib, which is much less efficacious and really 10 lost what very little traction it had once 11 ranibizumab was approved. 12 Q. Now, given, as you said, ranibizumab and 13 bevacizumab are different molecules, correct? 14 A. That's my understanding, yes. 15 Q. Okay. So does that mean that the dose 16 would have been different between those two molecules 17 for neovascular AMD? 18 MS. STRUTHERS: Objection. Beyond the 19 scope. 20 A. I certainly don't go into my declaration 21 exactly how we treat and what doses of different 22 agents. The rate-limiting factors -- the eyeball is 23 relatively small, and you can't inject different 24 volumes without raising the pressure, et cetera. So 25 most intravitreal formulations prior to 2011 had the
Page 23 1 frequently for diabetic macular edema. The drugs 2 were approved at different times because the FDA 3 requires shorter trials for AMD, and it was thought 4 to potentially be an easier market. 5 So the original trials were in wet 6 AMD, and then the subsequent trials were in diabetic 7 macular edema. Certainly the standard of care in 8 2011 was anti-VEGF therapy for both of those 9 disorders, at least in my clinic -- 10 Q. Okay. 11 A. -- by 2011. 12 Q. And just to clarify, by "anti-VEGF 13 therapies," in this context you mean it would have 14 been the same -- at least the same active ingredient 15 for both of those conditions? Am I understanding 16 correctly? 17 A. That's different. I mean, the only 18 approved therapy was ranibizumab from Genentech 19 Roche. At the time, there was also off-label 20 bevacizumab/Avastin, which was used off label. So 21 they are totally different molecules, to my 22 understanding. 23 Q. Okay. And again, just to make sure I'm 24 following, you're saying that -- is it correct that 25 you're saying that prior to 2011, standard of care	Page 25 1 same volume but different amounts of drug within that 2 volume. 3 Q. (BY MR. EHRICH) Okay. What about the 4 dosing schedule between ranibizumab and bevacizumab? 5 A. Sure. I apologize. In science, we have to 6 use the stupid generic terms. And so, I'm used to 7 doing it. I apologize. Continuing medical education 8 rules and whatnot. 9 So, you know, the -- the dosing is 10 always a compromise in a patient population that is 11 either elderly like macular degeneration or 12 non-compliant like diabetic macular edema. 13 The only -- the gold standard studies 14 that showed that these drugs were so efficacious and 15 changed the standard of care were MARINA and ANCHOR 16 for age-related macular degeneration, which were 17 monthly trials. I was first author of ANCHOR in the 18 New England Journal, second author on MARINA, so 19 intimately involved with those. And then the same 20 for diabetic macular edema, RISE/RIDE, which was 21 monthly ranibizumab. That's given us the gold 22 standard curves of improve vision and maintain vision 23 that exist to this day. That's essentially what we 24 strive for, is that level of efficacy. That was the 25 gold standard standard of care in 2011.

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Page 26 1 Q. Okay. That dosing -- and by -- you mean 2 gold standard meaning that that dose of monthly 3 dosing schedule was the gold standard care as of 4 2011? 5 A. Certainly the best results we've ever had 6 in a clinical trial with the best safety to risk 7 ratio. 8 Q. And I know that just now you were talking 9 about in the context of neovascular AMD. 10 So my question, then, is: What would 11 have been the gold standard dosing schedule for DME 12 prior to 2011? 13 A. I really need to -- I apologize. Even 14 though I'm first author of the RISE/RIDE papers, we 15 can either show me my CV and I can look at the dates, 16 or you can show me RISE/RIDE. 17 By that time, they certainly would 18 have been presented at different Retina meetings, and 19 I think the gold standard in 2011 would have been 20 monthly ranibizumab for DME. 21 I could -- by 2011, that's almost 22 certainly the case, but happy to look at the papers 23 and look at the exact dates for you. 24 (Exhibit 3 marked) 25 Q. (BY MR. EHRICH) Okay. Here, Dr. Brown.	Page 28 1 another anti-VEGF trial or given off-label 2 bevacizumab, and that would have been my standard of 3 care as opposed to focal laser photocoagulation, 4 which has gone the way of the buffalos since we've 5 figured out these drugs work so well. 6 So you're right at the cusp of where 7 the POSA would have definitely considered anti-VEGF 8 therapy for the standard of care for DME. 9 Q. (BY MR. EHRICH) Okay. Thank you. 10 Dr. Brown, I think we can set your CV aside. I would 11 like to go back to your declaration, but I would also 12 like you to please keep the Dixon reference handy 13 because we might come back to it later. 14 A. Yep. 15 Q. So in your declaration, I would like you to 16 please turn to the claim construction of the '681 17 patent, and that looks like it begins on Page 46. 18 A. I'm there. 19 Q. Okay. Thank you. I would like to focus 20 your attention, please, on Paragraph 95. 21 The last part, do you see it says the 22 POSA -- I assume we agree here that POSA here refers 23 to person of ordinary skill of the art? 24 A. I see that. 25 Q. -- "would have understood an effective
Page 27 1 I'm handing you what's been marked Brown Deposition 2 Exhibit 3. 3 I believe this is a copy of your CV; 4 is that correct? 5 A. Perfect. 6 Q. And I just hand it to you if that helps 7 with my previous question -- 8 A. Sure, it does. Thank you. (Witness 9 reviews the document.) So when in 2011 are we 10 talking about? 11 Q. How about before 2011? How about up until 12 the end of 2010 or before January 2011? 13 A. So it looks like I presented the 24-month 14 late-breaking results of RISE/RIDE in May the 3rd of 15 2011 at ARVO. 16 (Reporter clarification.) 17 A. So I guess it's tricky when you have a lead 18 investigator in a trial that is randomized to sham 19 injection where you can tell something is really 20 working in two-thirds of the patients and not working 21 in a third of the patients. We also had data from 22 Phase 2 that showed that these drugs really made a 23 difference. 24 So in my clinic, you were likely to 25 get enrolled in a ranibizumab trial or potentially	Page 29 1 treatment was one that was at least non-inferior to 2 the standard of care, i.e., Lucentis." So my 3 question is about the phrasing. 4 Why would an effective treatment have 5 been at least non-inferior to the standard of care? 6 It seems -- to a lay audience, for example, why not 7 just say the effective treatment would be, for 8 example, at least as good as the standard of care? 9 So my question is: Why the term 10 "non-inferior"? 11 MS. STRUTHERS: Objection. Document 12 speaks for itself. 13 A. In scientific studies, statistically we 14 design studies as either non-inferior studies or 15 inferior studies. Non-inferior, your -- your 16 phrasing "at least as good as" is the same as 17 non-inferior to a lay audience. 18 Statistically, non-inferior gives you 19 a little -- you have to have a larger sample size to 20 prove -- if you run a horse race a bunch of times, 21 sometimes the long-shot wins. And so, you have to 22 have larger studies to prove that just by chance -- 23 the long-shot didn't win by chance. 24 So non-inferior studies are designed 25 with larger sample sizes and non-inferiority margins

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Page 30 1 to give you confidence that the results of your trial 2 didn't happen by sheer luck. 3 So we use the phrase "at least 4 non-inferior to standard of care" just as I do here 5 because I think the totalitarian of the patent means 6 that the -- a method of treatment would have to be 7 effective. And to me, it has to be at least as good 8 as or non-inferior to that MARINA/ANCHOR curve you 9 saw and then replicated in the RISE/RIDE studies, 10 which in May 2011 I guess I presented, with improve 11 visual acuity and maintain vision gains. That would 12 be the 2011 standard of care. 13 Q. (BY MR. EHRICH) I just want to paraphrase 14 to make sure I'm understanding you. 15 You're saying that "non-inferior" 16 means something that has been statistically 17 demonstrated to be non-inferior in a study? 18 MS. STRUTHERS: Objection. 19 Mischaracterizes the testimony. 20 Q. (BY MR. EHRICH) As in, for example, 21 MARINA/ANCHOR or RISE/RIDE? 22 A. The standard of care for each individual 23 patient is the best care you can give that patient at 24 the time. Depending on insurance status, 25 socioeconomic status, et cetera, all patient --	Page 32 1 in the context of a clinical study like 2 MARINA/ANCHOR? 3 A. Sure. So it can mean -- the principal 4 investigator is typically, according to the FDA, the 5 single site. We were the largest site in the world. 6 I had lots of patients in MARINA and ANCHOR. 7 You can also serve as -- it's a 8 different term, but you can be the investigator that 9 presents -- certifies the documents for the FDA. For 10 MARINA/ANCHOR, I was not. That was a Genentech 11 ophthalmologist. But I was the lead author of the 12 primary manuscript ANCHOR and the second author of 13 the primary manuscript for MARINA in the New England 14 Journal and then the primary author of the two-year 15 paper for ANCHOR in Ophthalmology, which means that I 16 wrote the paper, helped design -- helped design the 17 study, vouch for the results to the editors, looked 18 at all the side effects, looked at -- to make sure 19 that we were not just spewing out what the 20 manufacturer wanted us to say. 21 Q. Thank you for the explanation. 22 Dr. Brown, you've just been handed 23 what's been marked Brown Exhibit 4. This is a -- 24 appears to be a cite to a general publication. First 25 author is Jeffrey Heier.
Page 31 1 whether the patient has compliance issues, 2 co-morbidities. They may not be able to get monthly 3 ranibizumab therapy, but that's the best vision and 4 risk/benefit ratio we've ever shown. So you want to 5 try to emulate that as close as you can. 6 Again, I -- the way I said it was 7 exactly the way I came to the conclusion after 8 reviewing the claim constructions and Diana Do's 9 treatise. I agree with her conclusion that method of 10 treatments recited in the challenge claim of the '681 11 patent requires an effective treatment and, further, 12 that by 2011, the POSA would have understood an 13 effective treatment was one that was at least 14 non-inferior to the standard of care, which is those 15 RISE/RIDE, MARINA/ANCHOR gold curves. 16 I mean, I'm a little biased -- I'm one 17 of the lead authors -- but it was pretty impressive 18 that we were able to make those gains with -- and 19 help patients, which is the goal. 20 Q. Actually, as long as you're talking about, 21 for example, MARINA/ANCHOR, I believe you see 22 yourself as the principal investigator to those 23 studies in your declaration. 24 And assuming that that's correct, can 25 you please tell me what a principal investigator is	Page 33 1 (Exhibit 4 marked) 2 A. Heier. 3 Q. (BY MR. EHRICH) Heier? 4 A. He's a good friend. You can call him 5 whatever you want, but -- 6 Q. Looks like it published in 2012. Thank you 7 for correcting me. 8 A. No problem. 9 Q. And looks like you are second author on 10 this paper, as well. Is that -- 11 A. That's correct. 12 Q. So it's fair to say that you recognize this 13 paper, Dr. Brown? 14 A. I do. 15 Q. And we can refer to your declaration if 16 you'd like to, but I believe, just generally, this is 17 a paper that you discuss at several points in your 18 declaration. 19 Is that fair to say? 20 A. That's correct. 21 Q. Okay. Thank you. 22 And so, Dr. Brown, I would like you to 23 please turn to -- and I can use either system, 24 whichever is easier to you. We can say, for example, 25 Page 2540 on the lower left-hand side or Page 4 on

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Page 34 1 the middle right, whichever you prefer. 2 A. I've got 2540. 3 Q. Okay. 4 A. I'm there. 5 Q. Okay. Thank you. 6 And see the heading End Points and 7 Statistical Analysis -- Analyses on the left-hand 8 column? 9 A. I do. 10 Q. Okay. And I would like you to go maybe 11 about halfway down that paragraph in that column. Do 12 you see the sentence that begins "A non-inferiority 13 margin of 10 percent in the individual studies was 14 chosen to preserve approximately two-thirds of the 15 ranibizumab effect for prevention of moderate vision 16 loss"? 17 A. I do. 18 Q. Okay. Do you have an understanding as one 19 of the authors of this paper what this term "a 20 non-inferiority margin of 10 percent of individual 21 studies" means? 22 A. (Witness reviews the document.) In all of 23 these studies, we have really smart, really superior 24 statisticians. When you go to the FDA with your 25 clinical trial design, they also have really smart,	Page 36 1 Q. Okay. 2 A. So it shows you that you need to be within 3 5 percent of what the results were if you repeated 4 the study a hundred times. Less than five would be 5 out of pure chance. 6 Q. And so, if you could please turn to the 7 next page, 2541, you see the heading in the 8 right-hand column Primary End Point Analysis? 9 A. I do. 10 Q. Okay. And do you see the second sentence 11 there reads, "All aflibercept groups achieved 12 statistical non-inferiority compared with monthly 13 ranibizumab," right? 14 A. I see that. 15 Q. Okay. So when you and Dr. Heier were 16 preparing this paper, then, are you indicating that 17 aflibercept met that 10 percent non-inferiority 18 confidence interval but not the 5 percent clinical 19 equivalence confidence interval? 20 MS. STRUTHERS: Objection. Document 21 speaks for itself. 22 A. One more time repeat your question. 23 Q. (BY MR. EHRICH) Sure. This phrase "All 24 aflibercept groups achieved statistical 25 non-inferiority," does that indicate that the
Page 35 1 really experienced statisticians. The discussions 2 between the teams of statisticians are often like a 3 different language. 4 Q. Okay. 5 A. So I certainly understand the rationale for 6 the two confidence intervals, et cetera, but don't 7 know that I can cogently explain them to you. 8 Q. Okay. And just to make sure I understand 9 what you're referring to by "two confidence 10 intervals," are you referring to a 10 percent 11 confidence interval for non-inferiority versus a 12 5 percent confidence interval for clinical 13 equivalence? 14 A. Correct. 15 Q. Okay. 16 A. Dr. Chambers, Wiley Chambers who is the 17 head of the ophthalmic FDA, is a particularly astute 18 statistician, and this is what he mandates for a 19 trial where you're going against ranibizumab and -- 20 in a trial. 21 So like I said, I don't know that I 22 can cogently explain it to you, but basically you 23 have a 5 percent chance of being one side, 5 percent 24 chance of being on the other, so it's a 10 percent. 25 It's sort of a straddle of where it could be.	Page 37 1 aflibercept groups achieved the 10 percent 2 non-inferiority confidence interval but not the 3 5 percent clinical equivalence confidence interval? 4 A. I don't read it that way. I read, if you 5 continue the paragraph, "All the aflibercept regimens 6 also met the pre-specified 7 percent non-inferiority 7 margin and the pre-specified integrated analysis, 8 combining the two VIEW studies" -- capital V-I-E-W -- 9 "as well as the 35 percent margin for clinical 10 equivalence compared with ranibizumab in the 11 individual VIEW studies." 12 MS. STRUTHERS: Is there a question 13 pending, Counsel? 14 Q. (BY MR. EHRICH) I'm just making sure that 15 that was the full answer. 16 A. I beg your pardon? 17 Q. Oh, that's the full answer? 18 A. That's the full answer. 19 Q. Okay. All right. So are you saying, then, 20 that all aflibercept groups achieved statistical 21 clinical equivalence compared with monthly 22 ranibizumab? 23 MS. STRUTHERS: Objection. Document 24 speaks for itself. 25 A. The 2Q8 arm and the 2Q4 arm -- well, let me

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Page 38 1 look at this. Sorry. 2 Q. (BY MR. EHRICH) Uh-huh. 3 A. So if you go to the abstract, I think it 4 summarizes it well. "All aflibercept groups were 5 non-inferior and clinically equivalent to monthly 6 ranibizumab for the primary." 7 Q. Okay. But then given there are these two 8 terms, non-inferior and clinical equivalent, used in 9 Heier 2012, right, I'm just curious why, for example, 10 in Paragraph 95 of your declaration you state that an 11 effective treatment is at least non-inferior to the 12 standard of care as opposed to clinically equivalent 13 to the standard of care. And just for reference, 14 Paragraph 95 is on Page 46. 15 A. Yeah, I'm there. I would have been 16 comfortable using either term. 17 Q. Okay. Thank you. 18 So then -- and again, just to make 19 sure because there are some times when it seems like 20 you used a slightly different term. 21 So if you could maybe look at 22 Paragraph 107, which is the top of Page 51, you see 23 the second sentence says, "The POSA would have 24 understood that the effective treatment at the time 25 of the invention was treatment on par with Lucentis,	Page 40 1 exclusion criteria. 2 A. I see that. 3 Q. Okay. Now, just a little bit earlier we 4 were talking about that you agree with Dr. Do's claim 5 construction, and I didn't see anything about claim 6 construction in these three exclusion criteria in 7 your declaration, and I would just like you to please 8 either confirm that that's the case or let me know if 9 I missed something. 10 A. I don't comment on it in my declaration. 11 Q. Okay. And just to formalize it, is it fair 12 to say that you're not offering an opinion as to the 13 claim construction of those exclusion criteria? 14 A. I'm not. 15 Q. Okay. And looking forward in your 16 declaration, you talk about Claim 14 of the '681 17 patent. Just confirming that it's the same with 18 regards to all the claims of the '681 patent. 19 Is that fair to say? 20 A. Repeat the question. I'm sorry. 21 Q. Oh, just that you're not offering a claim 22 construction as to the exclusion criteria that appear 23 in any of the challenge claims. 24 A. That's correct. 25 Q. Okay. Thanks.
Page 39 1 which ways the standard of care at the time." 2 The phrase "on par with," based on 3 your previous answer, that could mean either 4 non-inferior to or clinically equivalent to? 5 MS. STRUTHERS: Objection to form. 6 Mischaracterizes his testimony. 7 A. I think the underlying point is that in 8 2011, effective therapy was as good as you could give 9 the patient, which tries to get as close to the gold 10 standard ANCHOR/MARINA curves, which was monthly 11 ranibizumab. 12 Q. (BY MR. EHRICH) Okay. And that's what you 13 mean by "on par with" in Paragraph 107? 14 A. Yes. 15 Q. So, Dr. Brown, I would like you to please 16 turn to Paragraph 88 in your declaration. And I 17 believe that's on Page 44. Just for reference, you 18 see that you're setting forth Claim 1 of the '681 19 patent there? 20 A. That's correct. 21 Q. Okay. And you see that this Claim 1 of the 22 '681 patent, at the -- toward the end under the last 23 "wherein," there are three Roman Numerals setting 24 forth three exclusion criteria? I apologize. I 25 meant three Arabic numerals setting forth three	Page 41 1 MS. STRUTHERS: We've been going a 2 little over an hour now. Would it be a good time for 3 a break? 4 MR. EHRICH: One more question, and 5 then that would be totally fine. 6 Q. (BY MR. EHRICH) If you could just quickly 7 turn, please, to Page 1 of your declaration, 8 Dr. Brown. Paragraph 1. 9 A. Okay. 10 Q. Toward the end, it says that you've been 11 asked to comment on the state of the art as of the 12 earliest filing date and respond to the opinion and 13 views of Dr. Albini, right? 14 A. That's correct. 15 Q. And kind of a similar question. Do -- 16 is -- is there a place in your declaration where 17 you're responding specifically with regard to those 18 exclusion criteria or commenting on the state of the 19 art as to the exclusion criteria? Again, I didn't 20 see one. I just want to make sure I'm not missing 21 something. 22 A. I guess I use the abbreviation wet AMD, 23 wAMD. I actually used it. 24 Q. It's okay. We'll understand the terms are 25 synonymous.

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Page 42 1 A. You're correct. I didn't comment on it. 2 Q. Okay. Thanks. It's time for a break. 3 VIDEOGRAPHER: Off the record at 4 9:58 a.m. 5 (Recess from 9:58 a.m. to 10:08 a.m.) 6 VIDEOGRAPHER: On the record at 7 10:08 a.m. 8 (Exhibit 5 marked) 9 Q. (BY MR. EHRICH) Welcome back, Dr. Brown. 10 So again, I would like you to please 11 keep your declaration in front of you, and then have 12 the Dixon and Heier 2012 references handy. 13 A. Got them. 14 Q. And then I'm also going to hand you what 15 has been marked Brown Exhibit 5. This is the '681 16 patent that your declaration refers to? 17 A. That's correct. 18 Q. While we're at it, I'll also hand you 19 Exhibit 6. Exhibit 6 is the '601 patent. 20 A. Okay. 21 (Exhibit 6 marked) 22 Q. (BY MR. EHRICH) Just for easy reference, 23 Dr. Brown, I'm going to primarily refer to the '681. 24 A. Okay. 25 Q. Okay. And so, looking at the '681 patent,	Page 44 1 Lucentis. Agreed? 2 A. That is correct. 3 Q. So my question, Dr. Brown, then, is: What 4 is it in this patent, the '681 patent, that informs 5 the POSA that aflibercept is non-inferior to Lucentis 6 for the treatment of DME? 7 MS. STRUTHERS: Objection. Beyond the 8 scope. Calls for a legal conclusion. 9 A. I'm not a lawyer. 10 Q. (BY MR. EHRICH) Sure. 11 A. Paid a lot of law school tuition, by the 12 way. 13 Q. But if you go back to Paragraph 95 of your 14 declaration -- 15 A. Paragraph 95 of the declaration? 16 Q. Yes. Just let me know when you're there, 17 please. 18 A. I'm there. 19 Q. Okay. In Paragraph 95, you write that "A 20 POSA would have understood an effective treatment to 21 be at least non-inferior to the standard of care, 22 i.e., Lucentis," right? 23 A. That's what I state. 24 Q. Right. And so, if it's your opinion that 25 an effective treatment is at least non-inferior to
Page 43 1 please correct me if I'm wrong, but I think Example 2 4, which begins in Column 9 of the '681 patent, 3 summarizes the VIEW 1, VIEW 2 non-inferiority 4 clinical trials. 5 Do you agree? 6 A. Let me look. 7 Q. Sure. 8 A. Yeah, that's the VIEW 1 and 2 trials. 9 Q. Okay. Thank you. Actually, I want you to 10 go just a little bit past that, please, to Example 5 11 of the patent. 12 A. Okay. 13 Q. And if you could please keep it open to 14 that section, but then also look at Page 15 of your 15 declaration, Paragraph 39. 16 A. Okay. 17 Q. Okay. So as you say in Paragraph 39 of 18 your declaration, Example 5 is a study that pertains 19 to DME, and it's not a non-inferiority trial. 20 Agreed? 21 A. That's correct. 22 Q. Okay. And looking at -- back on the patent 23 and looking toward the top of Column 14, it looks 24 like this DME trial described in Example 5 has a 25 control that is macular laser therapy as opposed to	Page 45 1 the standard of care, i.e., Lucentis, my question is: 2 How do you reach that opinion with regard to the 3 treatment of DME? 4 MS. STRUTHERS: Objection. 5 Mischaracterizes the testimony. 6 A. So in my declaration, I'm informed that a 7 person of ordinary skill in the art is presumed to 8 have access to and be aware of all the prior art at 9 the time of the invention. And so, the POSA 10 certainly would have more relevant art known at the 11 time of -- at the time of making that determination 12 than just the Phase 2 DME trial reported in the '681 13 patent. 14 Q. (BY MR. EHRICH) Just to clarify, 15 Dr. Brown, by "at the time" are you referring to the 16 January 2011 priority date of the '681 patent? 17 A. Correct. 18 Q. Okay. And sitting here today, can you 19 think of any additional prior art the POSA would have 20 been aware of that would have allowed them to reach 21 this determination -- "this determination" being that 22 aflibercept is at least non-inferior to Lucentis for 23 the treatment of DME? 24 MS. STRUTHERS: Objection. 25 Mischaracterizes the testimony and beyond the scope.

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Page 46 1 A. I'm not sure they would have known that 2 aflibercept was non-inferior. We hadn't completed 3 the VIVID trials. But the POSA would have known that 4 method of treatment required an effective treatment 5 equal to the standard of care, which was Lucentis, at 6 least in my clinic, and off-label bevacizumab in many 7 clinics around the United States. 8 Q. (BY MR. EHRICH) And I think, Dr. Brown, if 9 you still have your CV handy -- 10 A. I do. 11 Q. -- is the VISTA trial what you're referring 12 to toward the bottom of Page 6 of your CV? I just 13 want to make sure that I'm understanding the trial 14 that you're referring to. 15 A. Which one? 16 Q. It looks like it's toward the bottom of 17 Page 6, and the first author of the publication is 18 J.P. Ehlers. 19 A. I'm on Page 6. J.P. Ehlers. I'm a little 20 confused. So it's a 2019 article? 21 Q. Yeah. You're just talking about the 22 VISTA/VIVID trials. I was wondering if there was a 23 reference to those trials in your CV. 24 A. Yeah, a better reference would be the 25 primary paper, which is back in the weeds here.	Page 48 1 press -- 2 Q. (BY MR. EHRICH) Uh-huh. 3 A. -- on anti-VEGF therapy for DME. 4 Q. Okay. I think we established earlier 5 RISE/RIDE -- I think you presented it in May 2011. 6 Does that sound right? 7 A. Yeah. There probably would have been a 8 press release prior to that. 9 Q. Okay. 10 A. If it was potentially materially relevant, 11 but I don't know. 12 Q. Okay. And please correct me if I'm wrong, 13 but do I remember correctly you said that RISE/RIDE 14 was -- 15 A. Ranibizumab for DME. 16 Q. But monthly administration; is that right? 17 A. Correct. 18 Q. Okay. Thanks. So feel free to look at the 19 patent if you want to, but can we agree that the 20 challenge claims specify tertiary doses administered 21 at least every eight weeks? 22 A. Where are we? In the patent or the -- 23 my -- 24 Q. Well, your declaration. You could go to -- 25 if that's easier -- maybe Page 44 of your
Page 47 1 Yeah, the first would be primary author Corbalenic in 2 2014. 3 Q. Okay. 4 A. I was a corresponding author of that, which 5 was the one-year VISTA/VIVID. And then the two-year 6 VISTA/VIVID would have been Brown, D.M. from 2015, 7 both published in Ophthalmology. 8 Q. Okay. 9 A. The USC paper was an anatomic paper looking 10 at automated -- almost artificial intelligence 11 reading of the scans of the VISTA/VIVID. So the 12 primary papers are these two. 13 Q. Okay. And I would just like to clarify, 14 please. 15 When you -- when you're referring to 16 other information that a POSA would be aware of with 17 regard to the treatment of DME, are there any 18 references that were published prior to 2011 that 19 come to mind? 20 MS. STRUTHERS: Objection. Asked and 21 answered. Beyond the scope. 22 A. Well, RISE/RIDE wasn't presented until that 23 year. Certainly the Phase 2 DME data for ranibizumab 24 would have been presented and probably published -- I 25 don't know -- as well as multiple articles in the lay	Page 49 1 declaration. 44 to 45 is the '681 patent. 2 A. Okay. 3 Q. And then Pages 47 and 48 are the '601 4 patent. I just want to make sure we agree that all 5 these claims, it talks about a tertiary dose 6 administered eight weeks. 7 A. Yep. 8 Q. Okay. So were there articles that would 9 have informed a POSA that aflibercept administered 10 every eight weeks was non-inferior to ranibizumab 11 administered monthly for the treatment of DME? 12 MS. STRUTHERS: Objection. Beyond the 13 scope. 14 A. Prior to 2011, I can't think of any. 15 Q. (BY MR. EHRICH) Okay. I would like to 16 stay with your declaration, please, Dr. Brown. I 17 would like you to turn, please, to Paragraph 76 of 18 your declaration. 19 A. Okay. 20 Q. Paragraph -- just in general, we can agree 21 that Paragraph 76 is talking about the results of the 22 VIEW trials? 23 A. Yeah, Paragraph 76 is summarizing one of 24 our primary secondary end points, which is maintain 25 visual acuity from baseline compared to monthly

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Page 50 1 ranibizumab. 2 Q. Okay. Thanks. 3 So -- now, I see that you -- just to 4 clarify, just to make sure we're on the same page, at 5 the top of Paragraph 76, you have a quote from the 6 Heier 2012 reference, right? 7 A. That is correct. 8 Q. Okay. And we can agree that the Heier 2012 9 reference also discusses those same VIEW 1 and VIEW 2 10 trials. Agreed? 11 A. That's the primary manuscript, yes. 12 Q. Okay. So sticking with your declaration, 13 Dr. Brown, at the top of Paragraph 76, you state that 14 the 2Q8 VEGF Trap-Eye group, quote, "achieves 15 statistical non-inferiority compared with monthly 16 ranibizumab," right? 17 A. That's what it says. 18 Q. Okay. And so, my question is: How -- 19 would it be possible for an individual receiving 2Q8 20 VEGF Trap-Eye treatment to achieve statistical 21 non-inferiority compared with monthly ranibizumab? 22 MS. STRUTHERS: Objection. Vague. 23 Incomplete hypothetical. 24 A. Statistically, no. 25 Q. (BY MR. EHRICH) Okay. If we could stay	Page 52 1 A. That's correct. It's a hundred percent. 2 The remainder didn't meet it. 3 Q. Okay. So in the VIEW 1/VIEW 2 trials for 4 that 4 to 5 percent who did not meet the primary end 5 point, would VEGF Trap-Eye for neovascular AMD be 6 non-inferior to ranibizumab? 7 MS. STRUTHERS: Objection. 8 Mischaracterizes the document. Incomplete 9 hypothetical. 10 A. Statistically, non-inferiority deals with 11 cohort. In other words, taking the good with the 12 bad. And so, I'm not a statistician, but everyone in 13 the cohort met non-inferiority. The bad ones would 14 have been compared to the bad ones in ranibizumab, 15 and you really have to look at each individual 16 patient to figure out why they didn't gain -- did 17 they get cataract? Did they have concomitant dry 18 macular degeneration? Did we catch the disease too 19 late, et cetera -- to figure out on an individual 20 basis we had some losers. 21 Q. (BY MR. EHRICH) Okay. All right. Thank 22 you. I'm going to hand you another document. Just a 23 minute, please. 24 (Exhibit 7 marked) 25 Q. (BY MR. EHRICH) Okay. Dr. Brown, I'm
Page 51 1 with your declaration, please, and turn to the next 2 page, Page 39, Paragraph 77. It looks like this 3 paragraph also is in reference generally to the VIEW 4 1/VIEW 2 trials, correct? 5 A. Correct. 6 Q. Okay. So, now, I see that you say that 7 94.4 percent of the patients who received active 8 control, which is 0.5 milligrams ranibizumab Q4, met 9 the primary end point, right? 10 A. That's correct. That's what the study 11 showed. 12 Q. Okay. And then you see the next sentence 13 states that in the VIEW trials, VIEWS 1 and 2 14 respectively, 95.1 percent of patients and 15 95.6 percent of patients dosed aflibercept or VEGF 16 Trap-Eye 2Q8 met the same end point, right? 17 A. Yeah. Respectively, 95.1 and 95.6 percent 18 of patients dosed 2Q8 met the same end point. 19 Q. Now, understanding or probably agreeing 20 that these are very high percentages, this means 21 presumably that somewhere between -- in each of VIEW 22 1 and VIEW 2, somewhere between 4 or 5 percent of 23 patients did not meet the primary end point. 24 Is that -- am I referring that 25 correctly from your statement here?	Page 53 1 handing you what's been marked Brown Exhibit 7. This 2 appears to be a New England Journal of Medicine 3 article by Phillip Rosenfeld, with you as the second 4 author; is that correct? 5 A. That's correct. 6 Q. So I assume, Dr. Brown, that you recognize 7 this document? 8 A. I do. 9 Q. And can you tell me just in your own words 10 what it is? 11 A. Sure. Prior to 2002 or three when we began 12 to investigate anti-VEGF agents, namely ranibizumab, 13 macular degeneration was a blinding disorder where 14 every patient -- not every patient. Some people got 15 lucky, but 99 percent or so lost central vision where 16 they couldn't recognize faces or get a driver's 17 license or read. 18 Injecting intravitreal ranibizumab was 19 very promising in Phase 2. We did two large trials. 20 The previous standard of care was photodynamic 21 therapy, verteporfin -- a hard drug to spell -- for a 22 particular kind of new blood vessels that were 23 aggressive and grew fast called classic. 24 So we ran two parallel trials, one 25 comparing verteporfin to ranibizumab and those type

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Page 54 1 of lesions, called the ANCHOR study, which I was the 2 first author of, and it was the sister study to the 3 MARINA study, which was all the rest of the lesions, 4 the ones that weren't, quote, classic. Because there 5 was no treatment for this, the MARINA study was 6 compared to sham injection. 7 The New England Journal paper here by 8 Rosenfeld, et al, is the primary results of that 9 Phase 3 study that immediately preceded its sister 10 study, the ANCHOR study, which I was the first author 11 on. 12 Q. Okay. And just to complete the collection, 13 then, I'll hand you what's been marked Brown 14 Exhibit 8. 15 So I believe you said that Brown 16 Exhibit 7 was the MARINA study? 17 A. Correct. 18 (Exhibit 8 marked) 19 Q. (BY MR. EHRICH) And so, do you recognize, 20 then, Brown Exhibit 8 as the ANCHOR study that -- 21 A. Very well. 22 Q. Okay. Actually, Dr. Brown, if it's easier 23 for you, let's set aside Brown Exhibit 7 for now, the 24 MARINA study, and we'll focus on Brown Exhibit 8, the 25 ANCHOR study.	Page 56 1 Q. Okay. 2 A. When you have a study design, you have to 3 present it to the FDA. They give guidance back 4 before you start the study. You submit the study 5 design to clinicaltrials.gov, PubMed, and the study 6 designs are partially designed on what was the 7 standard of care before and what you go against. 8 Q. Uh-huh. 9 A. In other words, in ANCHOR, we went against 10 verteporfin PDT. And when you go against a trial 11 that has a prior standard of care, you often 12 replicate the indices that got it approved. The 13 agency has -- the agency -- FDA -- the Food and Drug 14 Administration agency -- and I talk about it in my 15 declaration on VIEW, but it's the same. We can go 16 there. 17 Q. Back to your declaration? Sure. Please 18 let me know what page. 19 A. We can go to Paragraph 73, 74. "A 20 non-inferiority study is used when it would not be 21 ethical to use a placebo, and it seeks to show the 22 amount of margin by which the test drug is inferior. 23 In designing a non-inferiority study, the FDA 24 estimates this margin based on past performance of 25 the active control."
Page 55 1 A. Okay. 2 Q. So I have a couple of questions about the 3 study design, and that looks like it's on Page 1433 4 toward the top of the right-hand column. 5 A. Okay. 6 Q. I would just like you to please walk me 7 through some of the process that you talk about here. 8 First of all, to lay some foundation, 9 I understand that you're the primary -- you're the 10 main author, first author on this paper? 11 A. That's correct. 12 Q. And so, you had a role in -- did you have a 13 role in the study design? 14 A. Yes. I had some role in the study design. 15 Typically there would be a steering committee. These 16 studies sort of had an ad hoc steering committee, 17 which included ophthalmologists from Genentech and 18 statisticians, as well as clinicians, such as Jeff 19 Heier, Phil Rosenfeld. Same cast of characters you 20 see in a few. 21 Q. I'm gathering from that you're saying that 22 this is the group that would have come up with the 23 study design, or am I misunderstanding your answer? 24 A. No, it's certainly the group that would 25 guide the study design.	Page 57 1 In the VIEW study, the active control 2 was Lucentis, and the active control in ANCHOR was 3 verteporfin in its pivotal trials. TAP was -- 4 T-A-P-- was the name of that trial. 5 So the agency applies constancy 6 assumption. In other words, they want you to have 7 reasonably similar study populations and the same 8 dose that was used in the prior approval study for 9 the comparator and similar characteristics. 10 So that's why we had to do two 11 separate studies in getting ranibizumab approved that 12 are different because there was no treatment for the 13 population that had lesions like MARINA, but there 14 was an approved treatment for the classic lesions 15 that are tested in ANCHOR versus verteporfin. 16 Q. Okay. Okay. So that's why you needed two 17 studies. It wasn't just so that both you and 18 Dr. Rosenfeld could get first-author papers? 19 A. That might have been part of it, but no. 20 Q. So staying with -- staying with the ANCHOR 21 paper, please -- and if it's okay with you, I'm going 22 to refer to it as the ANCHOR paper. 23 A. Yeah. 24 Q. So staying in that same section -- 25 MS. STRUTHERS: Sorry. Which section?

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Page 58 1 Q. (BY MR. EHRICH) We're in Methods, which is 2 on Page 1433 toward the -- in the right-hand column. 3 Just from memory sitting here, 4 Dr. Brown, can you tell me a little bit about the 5 process of obtaining approval from institution review 6 boards or ethics committees at all clinical centers? 7 A. Sure. There's a -- in human subjects, 8 there always hasn't been a great history of 9 protection of human subjects. And -- and through 10 time, we've evolved ways to make sure that when we 11 enroll a patient in a trial that somebody else is 12 looking out for them, not just the manufacturer who 13 makes the great drug, Dr. Rosenfeld and I that could 14 publish the paper, and that's an institutional review 15 board which is composed of typically other experts 16 that aren't involved in the trial -- typically 17 statisticians, oftentimes ethicists, rabbis, priests, 18 et cetera, looking out for the interests. 19 That has to approve both that the 20 study tenets themselves are ethical -- in other words, 21 we're not doing something that would harm a patient 22 just in the name of science -- and that the informed 23 consent process adequately informs them of what 24 risks, potential benefits, potential time 25 implications that would be entailed if they agree to	Page 60 1 subjects. So there's the IRB, there's the DSM, and 2 then there's the investigators themselves. 3 Q. Okay. So multiple safeguards? 4 A. We hope. We hope that works, right? The 5 goal is to first do no harm. So you want to try 6 to -- I tell patients when I enroll them, "My first 7 job is to treat you as good as I can and make sure 8 that if I have a better treatment that I don't let 9 you be in a study and that we pull you out of the 10 study." And then my second job is to make sure the 11 science is okay, right, and make sure that we perform 12 the experiment such that we can both publish it but 13 also figure out if it works or not, and that's what's 14 beneficial to the manufacturer because then they can 15 make an expensive drug. So -- 16 Q. Okay. Thank you for explaining. 17 And then -- so do you see the last 18 sentence of the same paragraph says, "screening 19 lasted as long as 28 days"? 20 A. Study design -- 21 Q. Uh-huh. 22 A. "No patients excluded. Screening lasted as 23 along as 28 days," yeah. 24 Q. Okay. Can you tell me, what does 25 "screening" mean in this context?
Page 59 1 be part of our experimental trial. 2 Q. Okay. 3 A. So the informed consent process is 4 incredibly rigorous, and we take it very seriously 5 because you really want patients to know what they 6 are getting into. 7 Q. Uh-huh. 8 A. And that process is guided by the 9 investigators in the trial. 10 Q. Uh-huh. 11 A. But also the IRB -- or the institutional 12 review board -- that's hopefully also looking out for 13 that patient population. That subject population, I 14 should say. 15 Q. Looking out for the interests of the 16 patient population? 17 A. Right. 18 Q. Okay. 19 A. Their role is also to monitor the study 20 along and, if side effects get reported to, say, it's 21 expected or should this study be shut down or, you 22 know, can the study continue? And they are supposed 23 to be independent of -- there's also a data and 24 safety monitoring committee that has another role in 25 the same thing, looking after for the safety of those	Page 61 1 MS. STRUTHERS: Objection. Beyond the 2 scope. 3 A. Certainly I've spent a lot of my life 4 designing clinical trials, going to the FDA, 5 publishing clinical trials, and certainly don't go 6 into the declaration of how the sausage is made or 7 how we design clinical trials and decide different 8 things. And I'm not going to rehash little parts of 9 each one, but I will answer your question. 10 Screening is -- from the beginning 11 from when you sign an informed consent to the time 12 which you are randomized, given a potential dose, 13 that is the screening period. Currently -- the 14 reason screening could be 28 days then is we didn't 15 have another treatment. Now with what macular 16 regeneration -- it's probably unethical to withhold 17 treatment more than about seven days. So now our 18 screening is much tighter because you have -- you 19 really can't withhold a treatment that you know to be 20 efficacious for that long period of time, in my 21 opinion, in 2023, which you could when we started 22 this trial in 2003-ish. 23 Q. (BY MR. EHRICH) Okay. And I think you're 24 kind of anticipating my next question, which is just 25 the way the sentence is phrased, "screening lasting

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Page 62 1 as long as 28 days." 2 A. It doesn't have to. It could be shorter. 3 MS. STRUTHERS: Let him finish the 4 question. 5 Q. (BY MR. EHRICH) Is -- is it meant to 6 convey that it was a relatively long screening 7 process just by the phrase "lasted as long as 28 8 days"? 9 MS. STRUTHERS: Objection. Beyond the 10 scope. The document speaks for itself. 11 A. I wouldn't say that. You try and make it 12 as rapid as you can. 13 Q. (BY MR. EHRICH) Okay. Okay. I think -- 14 so I do have, then, another question, if you could 15 please -- stay right there, please, on the same page. 16 You see the very next paragraph begins 17 "for inclusion in the study"? Just let me know when 18 you're there, please. 19 A. I see it. 20 Q. Okay. And just looking at the last 21 sentence of that paragraph that says, "No patients 22 were excluded because of pre-existing cardiovascular, 23 cerebrovascular, or peripheral vascular 24 conditions" -- just noting that you specify that in 25 the paper, I'm wondering is that noteworthy for some	Page 64 1 Q. Okay. And could we maybe turn then back, 2 please, to the Heier 2012 reference? 3 A. Okay. 4 Q. And please turn to Page 2540. Do you see 5 the heading Participants? 6 A. I'm sorry? 7 Q. Do you see the heading at the top 8 Participants? 9 A. I do. 10 Q. Okay. So I guess my question here: Do you 11 see it says that the inclusion/exclusion criteria 12 were designed to maintain constancy with the pivotal 13 trials? 14 A. Correct. 15 Q. I think you've already explained why that's 16 so, but then I guess my question is more 17 process-related. 18 Would you just copy and paste the same 19 criteria from the pivotal trial? 20 MS. STRUTHERS: Objection. Beyond the 21 scope. 22 A. From a practical standpoint, it's generally 23 separate companies, so they don't have the Word 24 document to go from. You often choose similar to 25 make sure the population is the same, right?
Page 63 1 reason? And I believe the same phrase comes up in 2 the description of the MARINA publication, too, if 3 I'm not mistaken. 4 MS. STRUTHERS: Objection. Beyond the 5 scope. Document speaks for itself. 6 A. Certainly we don't go into it in my 7 declaration. 8 Q. (BY MR. EHRICH) No, I understand. But 9 given that you wrote the ANCHOR study, I was just 10 curious as to why that was a noteworthy phrase to put 11 into the -- into the paper. 12 MS. STRUTHERS: Objection. Asked and 13 answered. Beyond the scope. 14 A. Class agents -- anti-VEGF agents in cancer 15 chemotherapy and others are associated with 16 cardiovascular issues. The concern in testing the 17 first in human anti-VEGF, even with small doses in 18 the eyes, could it affect the -- the cardiovascular 19 status -- heart attack, hypertension, et cetera, in 20 the subjects. 21 Q. (BY MR. EHRICH) Okay. 22 A. So it was -- certainly looked at all those 23 components when we began testing anti-VEGF agents, 24 including up until the new ones we're looking at 25 today.	Page 65 1 Q. (BY MR. EHRICH) Okay. 2 A. Visual acuity, age, that kind of thing. 3 Q. So is it fair to say, then, that as a 4 clinic investigator, you would want the populations 5 to be as statistically similar as possible? 6 MS. STRUTHERS: Objection. Beyond the 7 scope. 8 A. Again, like I said, we could have 70 hours 9 of deposition on clinical trial design. Part of it 10 is a living process where as time goes on, therapies 11 are out in the population where it's harder to 12 recruit for a trial because there's effective 13 therapies out there. 14 So we certainly modify our criteria to 15 reflect the times. Like, for example, the trial in 16 2023 now, we typically go much better visual acuity 17 because we find patients much earlier in the disease 18 process. 19 So you can't always exactly have every 20 criteria the same and they are generally not the 21 same, but there's a compromise between trying to have 22 a trial that you can recruit and not the take forever 23 because you can't find that population anymore while 24 still comparing it as close as you can to that prior 25 population.

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Page 66 1 Q. (BY MR. EHRICH) Okay. Thank you. 2 MS. STRUTHERS: When you're done with 3 this line of questioning, would that be a good time 4 for a break? 5 MR. EHRICH: Actually, this is a good 6 time. 7 VIDEOGRAPHER: Off the record at 8 11:03 a.m. 9 (Recess from 11:03 a.m. to 11:16 a.m.) 10 VIDEOGRAPHER: On the record at 11 11:16 a.m. 12 Q. (BY MR. EHRICH) Welcome back, Dr. Brown. 13 So I would like to turn now in your 14 declaration again, please, to Paragraph 53. 15 A. Paragraph 53? 16 Q. Yes, Paragraph 53. It starts on page -- or 17 it looks like it's Page 23. 18 A. Yep. 19 Q. Okay. And here you're discussing -- you 20 see at the bottom you're referring to -- looks like 21 the 2006 Lucentis label, correct? 22 A. That's correct. 23 Q. Okay. 24 (Exhibit 9 marked) 25 Q. (BY MR. EHRICH) I'm handing you what's	Page 68 1 of the 5.1, whatever it is. 2 Q. Sure. It's Page 2 of 8 in the exhibit, I 3 believe. 4 A. Page 2 of 8? 5 Q. What would be the first page of the label, 6 essentially. 7 A. Got it. 8 Q. So I just want to confirm. The language 9 you're referring to in Paragraph 53 of your 10 declaration is that third bullet point in the 11 left-hand column that starts with "although less 12 effective"? 13 A. That is correct. 14 Q. Okay. And just to make sure -- I'm trying 15 to get to the crux of your disagreement with 16 Dr. Albini. 17 Your opinion as stated in your 18 declaration, Dr. Brown, is that this language in this 19 third bullet does not suggest less frequent dosing? 20 Or if there's a better way to phrase it, please, you 21 know, go ahead and say so. 22 MS. STRUTHERS: Yeah. Objection. 23 Document speaks for itself. 24 A. Repeat the question. I'm sorry. 25 Q. (BY MR. EHRICH) Sure. I just want to make
Page 67 1 been marked Brown Exhibit 9, and I think that this is 2 the reference you're citing in Paragraph 53 of your 3 declaration. 4 Can you let me know if that's correct? 5 A. That is correct. 6 Q. Okay. And if we go to -- let's see. Now, 7 turning back to Paragraph 53 of your declaration, you 8 state here that in his declaration, Dr. Albini says 9 that the language in the 2006 Lucentis label, quote, 10 "suggested a regimen of less frequent dosing 11 following four-monthly intravitreal injections," 12 right? 13 A. That's what it says. 14 Q. Okay. And then the next sentence in 15 Paragraph 53 states that you disagree with 16 Dr. Albini, right? 17 A. That's what it says. 18 Q. Okay. So I would like to turn, please, 19 to -- I would like to please turn to the Lucentis 20 label, then, on Page 2 that you cite. And it looks 21 as though you're referring to -- the language you're 22 referring to in Paragraph 53 of your declaration is 23 in the third bullet point on the left-hand column; is 24 that right? 25 A. What page -- I'm sorry. Give me the number	Page 69 1 sure I'm clear that your disagreement is that to you, 2 as an ophthalmologist, the language of this third 3 bullet point in the left-hand column does not suggest 4 less frequent dosing following four monthly 5 intravitreal injections, emphasis on the word 6 "suggest"? 7 MS. STRUTHERS: Objection. 8 Mischaracterizes the testimony. Document speaks for 9 itself. 10 A. After we presented and published MARINA and 11 ANCHOR, what we expect for our patients, which is the 12 best possible treatment, is to gain vision and to 13 maintain it at the curves you see in MARINA and 14 ANCHOR. 15 The PIER study was to see could 16 patients get by with less frequent dosing, and it was 17 a miserable failure. The gains we gained at three 18 months were virtually eliminated by the end of 12 19 months. 20 Q. (BY MR. EHRICH) Uh-huh. I want to make 21 sure I'm understanding the nuances of your answer. 22 You're saying that taking the 23 knowledge from the PIER study into this language here 24 in the Lucentis label, your conclusion is that this 25 is not optimal treatment.

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Page 70 1 Is that a fair characterization? 2 MS. STRUTHERS: Objection. 3 Mischaracterizes the testimony. The documents speak 4 for themselves. 5 A. As I state in Paragraph 54, "It is my 6 understanding the FDA would present a comprehensive 7 look at the clinical data submitted when issuing 8 approval guidelines, and indeed the clinical study 9 section of the Lucentis label plainly shows the 10 drastic disparity between the study results from 11 ANCHOR and MARINA and those of PIER. Figure 1 shows 12 that the Lucentis 0.5-milligram arm in MARINA had a 13 mean change in visual acuity of plus 6.6 letters at 14 24 months, and the Lucentis 0.5-milligram arm in 15 ANCHOR had a plus 11.3 letters mean change at 24 16 months, while Figure 2 shows the Lucentis 17 0.5-milligram arm in PIER had a mean change of 18 negative 0.2 letters at 12 months. The import of 19 these figures would be clear to the POSA. The fixed 20 quarterly dosing regimen appear carries a high risk 21 for permanent vision loss." 22 Q. (BY MR. EHRICH) So it's safe to say you 23 stand by the opinions expressed in that paragraph? 24 A. I do, and the subsequent paragraph. "In my 25 opinion, FDA's review and consideration of the PIER	Page 72 1 optimum retinal treatment. 2 Q. Uh-huh. So for such patients, would their 3 ophthalmologist scale back on the frequency of 4 injections, or would they cease the therapy 5 altogether? 6 MS. STRUTHERS: Objection. Calls for 7 speculation and incomplete hypothetical. 8 A. You would have to look at each case 9 individually. You have to look at their clinical 10 exam, their OCT, their fluorescein. Are they 11 undergoing cancer chemotherapy at MD Anderson next 12 door to my clinic? Do they have other things going 13 on? You try to give them and recommend the best 14 possible therapy. You never recommend therapy where 15 you know that they are going to lose vision, although 16 it's up to them whether they can comply to that. 17 Q. (BY MR. EHRICH) So are there at least some 18 cases in which the ophthalmologist would reduce the 19 frequency of ranibizumab dosing to something less 20 than monthly in circumstances where monthly dosing is 21 infeasible for a given patient? 22 MS. STRUTHERS: Again. Incomplete 23 hypothetical. 24 A. Again, every patient is different. You 25 have to look at the patient and recommend what you
Page 71 1 results and this language in the label would not 2 suggest to the person of ordinary skill that 3 quarterly maintenance dosing is an effective or 4 acceptable option for a treatment regimen for a 5 patient with an angiogenic eye disorder such as wet 6 AMD. Indeed, I'm not aware of any doctor who, after 7 the results of the PIER were published, would have 8 treated a patient with wet AMD on a Q12 maintenance 9 dosing regimen of ranibizumab or would view such a 10 dosing regimen as acceptable treatment for an 11 angiogenic eye disorder." 12 Q. And I noticed in Paragraph 55 that you just 13 read, you used the word "acceptable" twice, as to 14 less frequent dosing being an acceptable option or 15 such a dosing regimen as being an acceptable 16 treatment, right? 17 A. That's correct. 18 Q. Okay. And I believe earlier today you said 19 that outside of the clinical study context, sometimes 20 there could be insurance issues or co-morbidity 21 issues or other circumstances for a given patient 22 that make monthly injections infeasible. 23 Am I remembering that correctly? 24 A. It's correct that patients are variable and 25 often have other conditions that interfere with their	Page 73 1 can recommend. And if they can do it, great. If 2 they can't, you deal with what they have. 3 Q. (BY MR. EHRICH) So if a patient were to 4 miss two of their monthly injections, would the 5 ophthalmologist just stop treatment at that point? 6 MS. STRUTHERS: Objection. Incomplete 7 hypothetical. 8 A. So you have to give the best treatment you 9 can possibly give. The treatment -- the best 10 treatment you can possibly give would not be to stop 11 injections. The treatment would be to restart. "See 12 if you can try to come in, Ms. Jones." 13 Q. (BY MR. EHRICH) Okay. All right. I 14 noticed -- so I'm looking at, for example, 15 Paragraph 53 of your declaration, Paragraph 59 of 16 your declaration, and just seeing that it cites 17 Dr. Albini's declaration in places. Agreed? 18 A. One more time. 53 and 59 do what? 19 Q. Cite to Dr. Albini's declaration. 20 A. That's correct. 21 Q. All right. So -- I would like to hand you 22 what's been marked as Brown Exhibit 12, which is 23 Dr. Albini's declaration for the '681 patent. 24 A. I have it. 25 (Exhibit 12 marked)

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Page 74 1 Q. (BY MR. EHRICH) Okay. Thanks. So I would 2 like specifically to turn in Dr. Albini's declaration 3 to Page 33, Paragraph 77. 4 MS. STRUTHERS: I'm sorry. Which 5 paragraph? 6 Q. (BY MR. EHRICH) I apologize. Page 33, 7 Paragraph 72. It goes from Page 33 to Page 34. Are 8 you there? 9 A. Yeah. 10 Q. So I would like to focus on the second 11 sentence of Paragraph 72 where Dr. Albini says, "As a 12 result, the frequency of injections was the subject 13 of investigation for those of ordinary skill in the 14 art at the time, as well as in the patient community, 15 and the trend in the mid to late 2000s already was 16 moving away from monthly dosing." 17 And if you would like to refer back to 18 your own declaration, Dr. Brown, again, you cite this 19 paragraph, for example, in Paragraphs 53, 59, 56 of 20 your declaration, and I would like to try to focus in 21 on what parts of this paragraph you disagree with. 22 So in Dr. Albini's declaration, 23 Paragraph 72, he says that the frequency of 24 injections in the mid to late 2000s was the subject 25 of investigation for those of ordinary skill in the	Page 76 1 Q. Okay. Do you see a little bit further down 2 in Paragraph 72 of Dr. Albini's declaration he refers 3 to trials that occurred after the ANCHOR/MARINA 4 monthly dosing trials that he characterizes as 5 exploring ways to reduce injection frequency and he 6 refers specifically to, for example, SUSTAIN, EXCITE, 7 PrONTO, SAILOR, PIER? 8 Do you see that section? 9 A. I do. 10 Q. Okay. Do you see that those trials were 11 exploring ways to reduce injection frequency, setting 12 aside for the moment whether or not they did so 13 successfully? 14 A. I do. 15 Q. Okay. Okay. I would like to go back, 16 then, to your declaration, please, Dr. Brown, to 17 Paragraph 65. And it looks like Paragraph 65 -- I 18 see that you quote Heier 2012, and then -- but I 19 would like to focus, please, on the last sentence of 20 that paragraph where you're also quoting, again, 21 Heier 2012. 22 "Despite these efforts, before 2011, 23 studies showed fixed quarterly or as-needed dosing 24 regimens without requiring monthly monitoring visits 25 were not effective at maintaining vision."
Page 75 1 art. 2 Is that -- do you disagree with that 3 statement, that it was the subject of investigation? 4 MS. STRUTHERS: Objection. Document 5 speaks for itself. 6 A. I reiterate I disagree with Dr. Albini and 7 note it doesn't address the label's explicit caution 8 that a less effective regimen than fixed monthly will 9 lead to loss of visual acuity benefit, quote, 10 unquote. 11 Q. (BY MR. EHRICH) Okay. So -- but I don't 12 think that addresses -- do you disagree that the 13 frequency of injections was the subject of 14 investigation for those of ordinary skill in the art 15 in the mid to late 2000s? 16 A. I guess I don't understand what Dr. Albini 17 means here, subject of investigation. If it's me, I 18 would design an investigator's sponsor trial and test 19 it. Most POSAs don't do that, so I haven't seen 20 that. 21 Q. Okay. 22 A. Does he mean that they were going to design 23 a trial and run it and put an NDA to the FDA and run 24 a trial? I don't know exactly what that means. He 25 doesn't spell it out for me. That's what I would do.	Page 77 1 Do you see that quote? 2 A. I do. 3 Q. I'm curious about that clause in the quote, 4 "without requiring monthly monitoring visits." 5 So I guess my question is: Why is 6 that clause there? In other words, how would 7 required monthly monitoring visits affect fixed 8 quarterly or PRN dosing regimens? 9 MS. STRUTHERS: Objection. The 10 document speaks for itself. 11 A. Yeah. Just like it says, "Despite these 12 efforts, before 2011 studies showed fixed quarterly 13 or as-needed (pro re nata PRN) dosing regimens 14 without requiring monthly monitoring visits were not 15 effective at maintaining vision." 16 This alludes to the fact that many of 17 the pro re nata studies required a patient to come 18 every month with treatment as needed, given whichever 19 parameters they wanted. 20 These patients are elderly, have a 21 tough time getting in. If their daughter has to 22 takeoff work, is a teacher, they have to get a 23 substitute, whether they get a shot or not. It's 24 still an onerous burden to the patient and their 25 caregivers to have a therapy that requires monthly or

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Page 78 1 even more than monthly visits to the doctor. 2 Q. (BY MR. EHRICH) Uh-huh. But does that 3 mean, then, that PRN dosing regimens that did require 4 monthly monitoring visits were effective at 5 maintaining vision? I'm asking if, given the way the 6 sentence is written that you quote in Paragraph 65, 7 if that indicates that the opposite would be true? 8 MS. STRUTHERS: Objection to form. 9 A. Repeat your question one more time. 10 Q. (BY MR. EHRICH) The sentence of Heier 2012 11 you quote in Paragraph 65 -- 12 A. Yep. 13 Q. -- states that without requiring monthly 14 monitoring visits, PRN dosing regimens were not 15 effective at maintaining vision, right? 16 A. There have been multiple PRN studies. 17 Some, as you mentioned, were quarterly PRN. Some 18 were monthly PRNs. Even after 2011, no PRN therapy 19 has ever been able to maintain the steady, consistent 20 maintenance of vision as monthly dosing as seen in 21 ANCHOR and MARINA monthly ranibizumab. 22 Q. Okay. Thank you. 23 Okay. Dr. Brown, I would like you to 24 please have your declaration and Dr. Albini's 25 declaration side by side.	Page 80 1 monthly loading doses followed by as-needed dosing 2 thereafter based on OCT and visual acuity assessment 3 or two, engage in what has been termed treat and 4 extend. 5 Do you see that? 6 A. I do. 7 Q. And I understand that you set forth your 8 opinion in, for example, Paragraph 55 that a Q12 9 maintenance dosing regimen of ranibizumab would be -- 10 would not be an acceptable treatment, and -- but then 11 turning to Paragraph 73 of Dr. Albini's declaration, 12 my question is: Does his characterization of the 13 typical practice in 2010, 2011 -- is his assessment 14 something that you would agree with as a practicing 15 ophthalmologist yourself? 16 MS. STRUTHERS: Objection to form. 17 A. Repeat the question one more time. 18 Q. (BY MR. EHRICH) Sure. Dr. Albini writes 19 that the typical practice was to treat with two or 20 three monthly loading doses followed by as-needed 21 dosing or treat and extend, essentially. 22 And my question is: Do you agree that 23 by 2010 to 2011 that would have been the typical 24 practice? 25 A. So 2010, 2011, the gold standard of
Page 79 1 A. I have them both. 2 Q. I would like to compare a couple paragraphs 3 where you're both providing your opinions on what 4 kind of dosing regimen a person would opt for. 5 In your declaration, I believe it's -- 6 I would like to focus, please, on Paragraph 55. 7 A. 55? 8 Q. Yes, 55, which is at the bottom of Page 24. 9 And for Dr. Albini's declaration, I would like you to 10 please turn to Paragraph 73, which is at the bottom 11 of Page 34 of his declaration. 12 Let me know when you're there in both 13 declarations, please. Are you there? 14 A. I'm there. 15 Q. Okay. Now, in your declaration in 16 Paragraph 55, you write that you're not aware of any 17 retina doctor who, after the results of PIER were 18 published, would treat any AMD patient on a Q12 19 maintenance dosing regimen of aflibercept. 20 By Q12, you mean quarterly? 21 A. Q12 weeks, correct. 22 Q. Okay. Every 12 weeks. Sure. Now, in 23 Paragraph 73 of his declaration on the bottom of Page 24 34, managers Dr. Albini writes that the typical 25 practice was either, one, treat with two or three	Page 81 1 treatment was to give the patients as much chance of 2 gaining vision as possible, and the bar was set up at 3 MARINA and ANCHOR where patients gained vision and 4 maintained that vision with monthly ranibizumab 5 dosing. 6 Life gets in the way. Physicians 7 think their waiting room is too busy. 8 Doctor/patients want to try to get by with less. And 9 so, it's a compromise. You treat each patient 10 individually. 11 I told patients in 2011 that the best 12 treatment would be for you to get a shot in your eye 13 every month, and I felt that was the best standard of 14 care. Did patients want that? No. Do patients, you 15 know, like getting their teeth cleaned? No. But 16 things are often in the best interest of the patient 17 that can't be done. 18 Sure there's all kinds of dosing 19 intervals tested, even trials examining these 20 techniques even following 2011. Nothing has shown 21 maintenance of vision and a safety to benefit ratio 22 equivalent to monthly ranibizumab as seen in MARINA 23 and ANCHOR. 24 Q. Okay. Okay. Thank you, Dr. Brown. 25 All right. Dr. Brown, I would like to

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Page 82 1 stay with your declaration, please. You can set 2 aside Dr. Albini's declaration for now. Thank you. 3 Turning back to your declaration, 4 Paragraph 75, please. Paragraph 75 is on Page 37. 5 A. I'm there. 6 Q. Okay. Thanks. 7 So I'm looking at the last sentence in 8 your declaration of Paragraph 75 that begins with 9 "based on my clinical trial experience," and -- 10 A. I'm sorry. The last sentence of -- 11 Q. Of Paragraph 75. 12 A. Okay. 13 Q. You write that "If Regeneron had an 14 expectation that an eight-week maintenance dosing 15 schedule would be successful, it would have had a 16 strong incentive to eliminate the four-week VEGF 17 dosing arms," right? 18 A. That's what I write, correct. 19 Q. Okay. So I would like to ask about the 20 inverse of that statement. If Regeneron didn't think 21 the eight-week dosing regimen would be successful, 22 then why would it go through the additional time and 23 expense to have an eight-week dosing arm in the VIEW 24 1/VIEW 2 trials in the first place? 25 MS. STRUTHERS: Objection. Calls for	Page 84 1 don't, then you're only competing on price. And 2 Dixon refers to that, right? Dixon refers to the 3 fact that they didn't know if it was going to work, 4 and if it does then -- if it doesn't work, then they 5 are competing on price than if it isn't. 6 And so, it's kind of like if you know 7 your horse is going to win, you don't put two horses 8 in the race. If you think your horse is definitely 9 going to lose, he's lame, you don't put him in the 10 race. I think they the horse might win, but they 11 weren't sure, so they put him in the race. And 12 that's the 2Q8. 13 We had every indication that it looked 14 like it definitely lasted four weeks. So monthly 15 versus monthly, I think was a safe bet for Regeneron. 16 But if they knew for sure that Q28 -- it takes longer 17 to enroll in trial and costs way more to have more 18 arms. If they knew for sure it was going to work -- 19 and I didn't know for sure it was going to work -- 20 then they would have eliminated the monthly arms for 21 expense. They had very little money. They had to 22 sell the European rights to the drug just to finance 23 the trial to Bayer. 24 Q. (BY MR. EHRICH) I just want to make sure 25 I'm understanding what you're saying.
Page 83 1 speculation. Incomplete hypothetical. 2 A. So one more time, your question is -- 3 repeat. Sorry. 4 Q. (BY MR. EHRICH) Sure. You write that if 5 Regeneron had an expectation that an eight-week 6 dosing maintenance would be successful, then it would 7 not have gone through the time and expense of 8 including four-week dosing arms in the VIEW 1/VIEW 2 9 trial. 10 And my question is: If Regeneron had 11 an expectation that the eight-week maintenance dosing 12 would not be successful, then why go through the time 13 and expense of including eight-week maintenance 14 dosing in the first place? 15 MS. STRUTHERS: Objection. Form. 16 A. Ranibizumab is an incredibly successful 17 drug, like changed the standard of care. Incredibly 18 successful both financially and to patients. 19 Regeneron has a competitor. They are, 20 with their science, hoping it's a better horse in the 21 horse race. Maybe stronger, maybe last longer. 22 Don't know until you run the horse race. 23 If you test a longer dosing interval 24 and you win, then you have a competitive advantage 25 both in the clinic and the financial world. If you	Page 85 1 You're saying that there was an 2 expectation that the two Q4 arms would work. In your 3 answer just now -- we can go to the declaration if 4 that's easier. 5 In your answer just now, you said 6 there was an expectation that the 2Q4 arms would work 7 and, therefore, Regeneron included those because that 8 trial would lead to approval. 9 Am I understanding correctly? 10 MS. STRUTHERS: Objection. 11 Mischaracterizes the testimony. Go ahead. 12 A. Right. Sorry. Jumped in too soon. 13 If you put all your eggs in one basket 14 and went for the 2-milligram every eight weeks, which 15 the guys that helped design the trial -- Jeff Heier 16 and myself -- said, "Boy, based on CLEAR-IT, I'm not 17 sure it's going to work" and you lost, you had no 18 drug. 19 If you included an additional arm at 20 an additional expense and additional time in running 21 the trial, it's your failsafe. You at least have a 22 competitive drug that you can compete with Genentech 23 on price with. 24 You don't know other things. Like 25 when we run a bigger trial, we don't know in a bigger

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Page 86 1 population, are we going to have a higher side effect 2 profile? Are we going to have -- you know, are we 3 going to have reasons why their drug's better because 4 of safety? 5 You have to have both the safety and 6 the efficacy for both getting a drug approved and 7 getting the market to accept it and say, "This is the 8 best thing for you, Ms. Jones." 9 Q. (BY MR. EHRICH) Okay. Well, I would like 10 to come back to CLEAR-IT in a little bit, but for 11 now -- and I don't believe this is addressed directly 12 in your declaration, but there were -- can you say 13 then -- again, given that each arm is more time and 14 expense for Regeneron, right, why would they have 15 both of these two Q4 arms and why would they have 16 both a 2-milligram and a 0.5-milligram dose? 17 MS. STRUTHERS: Objection. Beyond the 18 scope. 19 A. Again, I'm not going to go into clinical 20 trial design, but the FDA likes a dose response 21 curve. They like seeing two different doses of the 22 drug tested. Specifically, Wiley Chambers in our 23 agency always asks for a dose response curve. 24 Q. (BY MR. EHRICH) Okay. Thank you. 25 So then, Dr. Brown, if we could skip	Page 88 1 speaks for itself. 2 A. Glen Jeffries' paper certainly helped us 3 understand better the populations treated with wet 4 AMD in the VIEW trial. So I would say it helped us 5 medically and scientifically. 6 Q. (BY MR. EHRICH) Okay. Okay. But are 7 you -- just sitting here, are you able to otherwise 8 relate those retrospective analyses to the scope of 9 your declaration which is set forth in Paragraph 1? 10 MS. STRUTHERS: Objection to form. 11 Document speaks for itself. 12 A. Paragraph 1 of the whole get-go? 13 Q. (BY MR. EHRICH) Paragraph 1 of your 14 declaration, yes. 15 A. I'm not an attorney. 16 Q. Okay. 17 A. But it seems to me if you knew for sure 18 that the 2Q8 would work, it would work in everyone. 19 And this demonstrates that there was a group that 20 needed more frequent dosing. 21 Q. Okay. Okay. I believe, Dr. Brown, you 22 mentioned the CLEAR-IT 2 trials a little bit earlier, 23 and I would like to turn to those now. It looks like 24 you talk about those starting at Paragraph 122 of 25 your declaration. And Paragraph 122 -- well, in
Page 87 1 forward a few pages. Could you please turn to 2 Page 42 of your declaration? I'm looking at 3 Paragraph 81. See Paragraph 81 begins with "It is 4 worth noting"? 5 The question is: Why is it worth 6 noting? 7 MS. STRUTHERS: Objection to form. 8 Document speaks for itself. 9 Q. (BY MR. EHRICH) And more specifically, 10 even if, for example, it's scientifically or 11 medically interesting, how does this relate to the 12 overall opinions set forth in this declaration? 13 A. I'm sorry. Give me the question one more 14 time. 15 Q. Sure. Paragraph 81 of your declaration 16 begins with "It is worth noting," and then it goes 17 into the results of retrospective analyses, right? 18 A. Yeah. 19 Q. Okay. So my question is -- let's break 20 down the question. 21 First of all, is it worth noting 22 because it's medically or scientifically interesting, 23 or is it worth noting because it relates to the 24 opinions that you've set forth in this declaration? 25 MS. STRUTHERS: Objection. Document	Page 89 1 general, the CLEAR-IT 2 you start talking about it in 2 Paragraph 119 on Page 57, just to orient you. 3 A. I give you a preview on Page 34, and then 4 we go back to it multiple times, both in Page 57 and 5 then sort of the expanded dance version on Page 67. 6 So yes. 7 Q. Okay. So turning to, looks like -- well, 8 Paragraph 121, for example, of your declaration at 9 the top of Page 59, you write that the therapeutic 10 effect of VEGF Trap-Eye on the CLEAR-IT 2 trial had 11 begun to wear off between Week 4 and Week 8, right? 12 A. I'm sorry. Where are we? 13 Q. Paragraph 121. 14 A. Sorry. 15 Q. No problem. It's on Page 59. 16 A. Yeah, correct. 17 Q. And specifically in Paragraph 121 in 18 referencing the slide reproduced on Page 60, you 19 write that there -- the CLEAR-IT 2 data showed a 20 re-accumulation of fluid between Weeks 4 and 8, 21 right? 22 A. That's correct. 23 Q. Okay. And then in Paragraph 122, you 24 essentially summarize this by saying that those data 25 would strongly suggest that VEGF Trap-Eye would not

23 (Pages 86 - 89)

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Page 90 1 be effective on eight-week dosing intervals, right? 2 MS. STRUTHERS: Objection. 3 Mischaracterizes the testimony. Document speaks for 4 itself. 5 A. I state "The POSA would have understood 6 that fluid re-accumulation between Week 4 and Week 8 7 on center retinal thickness strongly suggests that 8 VEGF Trap-Eye would not be effective on an eight-week 9 dosing interval." That's what I state. I agree with 10 that. 11 Q. (BY MR. EHRICH) Okay. And you stated 12 previously today, I believe, that neovascular AMD can 13 be irreversible, right, the damage caused by it, if 14 not properly treated? You can refer to Paragraph 23 15 of your declaration, if you would like. 16 A. No, I agree with that. 17 Q. So I guess my question, then, is with 18 reference to some of our earlier discussion about 19 clinical trial protocols, how does a study arm that 20 you're pretty sure is not going to work and that will 21 result in irreversible damage to the patient's vision 22 get approved by institutional review boards and 23 ethics committees for the VIEW 1 -- during the 24 process of putting together the VIEW 1 and 2 trials? 25 MS. STRUTHERS: Objection.	Page 92 1 the scope. 2 A. Ethics committees or institutional review 3 boards have experts in retina for a retina trial that 4 would have known about this data and would have been 5 aware of it. 6 Q. (BY MR. EHRICH) Okay. Okay. And -- 7 A. Rabbis and priests probably wouldn't, but 8 the retina guys probably would. 9 Q. Okay. And, Dr. Brown, if you still have 10 the Dixon reference handy -- 11 A. Which one? 12 Q. The Dixon reference. 13 A. I've got the Dixon reference right here. 14 Q. And I think that you at least obliquely say 15 this in your declaration. I just want to make sure 16 I'm clear on it. Just for reference, Dixon looks 17 like it talks about CLEAR-IT 2 starting on Page 1576. 18 A. Yep. 19 Q. Okay. I just want to confirm that the 20 fluid re-accumulation between Weeks 4 and Weeks 8 in 21 CLEAR-IT 2 that you talk about in, for example, in 22 Paragraphs 120 -- 121 and 122, I just want to be sure 23 I'm clear that those -- those data -- those results 24 aren't -- they don't appear in the Dixon reference; 25 is that correct?
Page 91 1 Mischaracterizes the testimony. The document speaks 2 for itself. 3 A. When you design a trial, you base a lot of 4 your Phase 3 design on your Phase 2 design. When we 5 designed VIEW, we didn't have the PRN dosing phase. 6 We only had that fixed dosing phase. And you see 7 that in the arms that didn't get a dose at Week 4, 8 there's some beginnings of recurrence of fluid. 9 The concept was that if you dosed 10 those patients with three loading doses, you might do 11 better than that, get a higher concentration. And 12 then if you continually re-dosed at eight, you might 13 be okay on average in a population. 14 Certainly the data and safety 15 monitoring committee would have monitored the 16 patients and, if they were going down the tubes, 17 could discuss stopping the trial. Fortunately, that 18 didn't happen. 19 Q. So when you and Dr. Heier were developing 20 the VIEW 1/VIEW 2 protocols, are the -- are data from 21 the slides reproduced in around Paragraph 120 to 125 22 of your declaration -- are those among the data that 23 would have gone to the ethics committees and 24 institutional review boards? 25 MS. STRUTHERS: Objection. Outside	Page 93 1 A. They do not. 2 Q. You can set that aside for now, please. I 3 would like to go back to your declaration, though, 4 page -- top of Page 57, Paragraph 126. Feel free to 5 refer to earlier paragraphs, as well. 6 A. Sorry. Page 57 -- 7 Q. Yeah, sure. Top of Page 57, Paragraph 126. 8 A. Wait a minute. I think I goofed up here. 9 MS. STRUTHERS: I'm not seeing the 10 paragraph either. 11 Q. (BY MR. EHRICH) Page 57, Paragraph 126. 12 A. In my declaration? 126, I have on Page 63. 13 Q. Page 63. I'm sorry about that. Thank you 14 for correcting me. Paragraph 126 on Page 63. 15 Okay. In Paragraph 126, you're 16 recalling discussions, apparently, with Jeff Heier 17 about the results of the CLEAR-IT 2 trial. 18 Is that a fair summary? 19 A. That's correct. 20 Q. Okay. And you write that the two of you 21 had great deal of skepticism about the prospects for 22 the eight-week fixed dose regimen and that you viewed 23 it as a long-shot, right? 24 MS. STRUTHERS: Objection. 25 Mischaracterizes the testimony.

24 (Pages 90 - 93)

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Page 94 1 A. So Jeff and I have a long history of 2 clinical trials, and we failed in many of them before 3 MARINA ANCHOR. So maybe we're just skeptics at 4 heart, but we thought that it would be a tough race 5 to go against ranibizumab monthly. And those changes 6 in the mean CRT, as I state, had us skeptical that it 7 would be non-inferior to Lucentis if given eight 8 weeks compared to Lucentis on a four-week dosing 9 regimen. 10 Q. (BY MR. EHRICH) Okay. Okay. And so, 11 Dr. Brown, you still have the Heier 2012 reference? 12 A. I do. 13 Q. So I would like to take a look at how you 14 talk about the CLEAR-IT 2 trial here. And 15 specifically, I would like you to please turn to 16 Page 2539 of Heier. 17 A. 25 -- I'm sorry. 18 Q. Sure. 2539. It's otherwise page -- 19 A. 2539. I've got it. 2539. Okay. 20 Q. So kind of about halfway down the first -- 21 the paragraph that begins in the left-hand column on 22 that page, you see where it starts "Intravitreal 23 aflibercept subject doses of 0.5 milligrams to 24 2 milligrams"? 25 A. Yep.	Page 96 1 Q. (BY MR. EHRICH) Okay. Same with the Heier 2 2012 reference, that same paragraph. You see there's 3 a sentence that begins at the bottom starting "The 4 greater affinity could translate into a higher 5 efficacy or, as predicted by mathematical model, it 6 shows substantially longer duration of action in the 7 eye." 8 And my question is -- again, this is a 9 paper that you and Dr. Heier wrote. Is this 10 something that was influencing the VIEW 1/VIEW 2 11 study design, this prediction of a mathematical 12 model? 13 MS. STRUTHERS: Objection. Document 14 speaks for itself. 15 A. Dr. Heier and I both worked for a lot of 16 different manufacturers and pharmaceutical companies, 17 and binding affinity is interesting in that it's how 18 tight a drug binds to a molecule and releases. If 19 you have higher binding affinity, you should have 20 more effect than if you don't. 21 That being said, binding affinity 22 assays are dependent on a lot of things like the 23 temperature, the PH, and every company reports their 24 binding affinity at whatever temperature and whatever 25 PH makes their drug look the best.
Page 95 1 Q. Okay. Now, it says here that those doses 2 provided the most robust outcomes in the CLEAR-IT 2 3 study. And so, this is a paper that you and 4 Dr. Heier wrote looking back on the CLEAR-IT 2 study, 5 and I'm just having trouble reconciling that with 6 this great skepticism expressed in Paragraph 126 of 7 your report. 8 So I guess I'm asking specifically: 9 Do you -- do you stand by these statements in here, 10 Heier 2012, saying that the intravitreal aflibercept 11 doses of 0.5 milligrams and 2 milligrams provided the 12 most robust outcomes in the CLEAR-IT 2 study? 13 MS. STRUTHERS: Objection. Document 14 speaks for itself. 15 A. Again, we have the benefit of hindsight 16 knowing that our Phase 3 trial worked. That being 17 said, if we go back to the same figure on the bottom 18 of 121, you see that the only two doses in the fixed 19 dosing regimen that kept improving the anatomy were 20 the 2-milligram and the half milligram given monthly. 21 And so, perhaps we should have said -- 22 added the word "monthly" into the introduction to the 23 VIEW paper, but that's the doses that showed us the 24 best efficacy in the fixed dosing, which was the 25 primary end point.	Page 97 1 So I would say that I think both Jeff 2 and I have a high degree of skepticism on anything we 3 hear on that kind of thing until we see how it's 4 going to work in a trial. 5 Sure, we would love -- a drug with a 6 higher binding affinity should work better, but I -- 7 if you test one molecule at the temperature that the 8 manufacturer's is, it may not perform as well. At a 9 different temperature, the other one could be better 10 or different. 11 So binding affinities, pre-clinical 12 assays are all important, but we really don't -- we 13 really don't trust something until we see it in 14 humans in a large trial. 15 Q. (BY MR. EHRICH) Okay. So I just want to 16 be clear, to back up just a little bit. 17 I thought you were saying that -- and 18 I'm on that same paragraph of Heier 2012 talking 19 about the intravitreal aflibercept doses of 0.5 20 milligrams and 2 milligrams. 21 It sounds to me that you're just 22 saying that that statement applies to monthly dosing, 23 but you would not -- but that statement does not 24 apply to PRN dosing? 25 MS. STRUTHERS: Objection.

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Page 98 1 Q. (BY MR. EHRICH) Or did I misunderstand 2 what you were saying? Again, just looking at how in 3 Heier 2012 you and Dr. Heier characterize the 4 CLEAR-IT 2 outcomes as robust. 5 I'm just wondering if that's referring 6 to the dose or the dose and the dosing regimen? 7 MS. STRUTHERS: Objection. 8 Mischaracterizes the testimony. The document speaks 9 for itself. 10 A. In a clinical trial where I write the 11 manuscript, we certainly try to teach, express, 12 explain what we did. It's difficult when you know 13 the results to go back to how you designed the trial 14 and temper it with those same times as if you were 15 designing the trial. 16 I don't know that we would have chosen 17 a half milligram arm for the VIEW trial if the agency 18 didn't require a dose response curve. 19 Q. (BY MR. EHRICH) Okay. But you still would 20 have kept the 2Q8 arm? 21 MS. STRUTHERS: Objection. 22 Mischaracterizes the testimony. 23 A. My opinion -- 24 MS. STRUTHERS: I'm sorry. Incomplete 25 hypothetical.	Page 100 1 was. 2 Q. Dixon published in 1990, correct? 3 A. Correct, but the slides I'm showing you are 4 2008. So -- 5 Q. But -- sorry. Don't mean to interrupt. 6 MS. STRUTHERS: Let him finish his 7 question. Go ahead. 8 Q. (BY MR. EHRICH) The slides on CLEAR-IT 2. 9 Is that what you're talking about? I'm sorry. I was 10 just trying to establish that Dixon published before 11 the VIEW results were in. 12 A. That's correct. 13 Q. So Page 177, the right-hand column, the 14 second full paragraph -- 15 MS. STRUTHERS: So you mean -- 16 Q. (BY MR. EHRICH) 1577, Page 1577, the 17 right-hand column, second full -- full paragraph. 18 "Data from the Phase 2 study with VEGF Trap-Eye were 19 positive." 20 That's what Dixon writes, and I'm 21 curious as to whether you agree with Dixon's 22 assessment. 23 A. I agree with Dixon's assessment. We 24 improved the anatomy in a lot of patients, and we 25 didn't blow up eyeballs.
Page 99 1 A. Sure. You know, I -- certainly Regeneron 2 didn't come to me and say, "We're running out of 3 money, Dave," but if you want to have a successful 4 drug, you need a competitive advantage. If you run a 5 trial -- like a similar trial and you do the exact 6 same drug and the exact same dosing, really the only 7 competitive advantage you have is pricing or 8 marketing or better safety or something of the above. 9 If you can actually meet an unmet 10 need, like the way to be able to treat a patient with 11 less frequent dosing and less frequent visits to the 12 doctor, then you had a potentially blockbuster drug. 13 And so, it was worth taking the risk it took to put 14 that horse in the horse race. 15 Q. (BY MR. EHRICH) Okay. You can set aside 16 Heier 2012 for now. I would like to -- kind of the 17 same topic, but turn back to Dixon, please, and 18 specifically Dixon Page 1577. 19 So bearing in mind we agree, right, 20 that Dixon published before the -- any results of the 21 VIEW 1/VIEW 2 trials were public, right? 22 A. Dixon would have published after the 23 presentations at the Retina Society and the senior 24 author, Naresh Mandava, was a member of the Retina 25 Society. I don't know if he was there, but I bet he	Page 101 1 I also agree with his second sentence, 2 "Its adoption into clinical practice will depend on 3 the efficacy of at four- and eight-week intervals. 4 If effective at four-week intervals only, VEGF 5 Trap-Eye will be adopted in the clinical process if 6 it offers a competitive price advantage over 7 ranibizumab. If effective at eight-week intervals, 8 VEGF Trap-Eye offers the opportunity to significantly 9 reduce treatment burden on patients and physicians 10 and would probably find wide acceptance." So I agree 11 with that. 12 Q. Okay. Thank you. 13 MS. STRUTHERS: What time were you 14 thinking for lunch? 15 MR. EHRICH: I think any time would be 16 fine with me. Regardless, this is a decent stopping 17 point. 18 MS. STRUTHERS: How do you feel? 19 THE WITNESS: It's totally up to you. 20 MS. STRUTHERS: Let's take a break for 21 lunch. 22 VIDEOGRAPHER: Off the record at 23 12:29 p.m. 24 (Recess from 12:29 p.m. to 1:04 p.m.) 25 VIDEOGRAPHER: On the record at

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Page 102 1 1:04 p.m. 2 Q. (BY MR. EHRICH) Welcome back, Dr. Brown. 3 A. I have Exhibit 10. 4 Q. I'll hand you what's been marked as 5 Exhibit 10. 6 Do you recognize Exhibit 10 as a black 7 and white version of the slide presentation that you 8 reference at around, for example, Paragraphs 120 to 9 123 of your declaration? 10 (Exhibit 10 marked) 11 A. I do. 12 Q. (BY MR. EHRICH) Okay. Could you please 13 turn to Page 14 of this presentation? 14 A. Okay. 15 Q. And I believe the heading is Distribution 16 of Injections over PRN Phase. 17 A. I see that. 18 Q. Okay. So am I correct that this shows 19 that -- this bar chart shows the percentage of 20 patients who received a given number of injections 21 during the one-year PRN phase of the CLEAR-IT 2 22 trial? 23 MS. STRUTHERS: Objection. Document 24 speaks for itself. 25 A. That's what it shows.	Page 104 1 Week 12, and then the PRN phase is Week 12 to Week 2 52. So whatever that is, 40 weeks. 3 Q. Okay. Okay. And 95 percent of the 4 patients received four or fewer injections during 5 that 40 weeks? 6 A. That's correct, with the caveat of the 7 retreatment criteria that we're specifying on 8 Slide 11. 9 Q. Okay. Does that mean that patients who met 10 those criteria on Slide 11 would not be reflected in 11 this bar chart on Slide 14 as having received more 12 injections? 13 MS. STRUTHERS: Objection. 14 Mischaracterizes the testimony. 15 THE WITNESS: One more time. 16 MS. STRUTHERS: I said objection. 17 Mischaracterizes the testimony. 18 A. So when you design a Phase 2 trial or any 19 trial, you can't just let your investigators go rogue 20 and treat whoever they want or else different 21 investigators could treat different ones differently. 22 So you have criteria that says you can treat if you 23 meet this, and the retreatment criteria in Slide 11 24 should have specified who got these injections. 25 Investigators don't always get it right; but this is
Page 103 1 Q. (BY MR. EHRICH) Okay. And do you see how 2 there's a 5 with a bracket going out for the Bars for 3 5, 6, 7, 8, and 9? 4 A. I do. 5 Q. So that means presumably that 5 percent of 6 patient total had five or more injections during the 7 PRN phase; is that correct? 8 A. Of all five cohorts combined, yes. 9 Q. Okay. And so, then, therefore, 10 mathematically 95 percent of the cohorts combined had 11 four or fewer injections during the PRN phase? 12 A. That's correct. 13 Q. Okay. And just to be clear, then, that 14 would be four injections or fewer over the course of 15 a year? 16 MS. STRUTHERS: Objection. 17 Mischaracterizes the document. 18 A. So that's in addition to the -- what they 19 got in the fixed phase for the year, right? 20 Q. (BY MR. EHRICH) I understand. So 21 during -- this would be during the second year; is 22 that correct? 23 A. It's not even a full year, though. 24 Q. Okay. 25 A. It's nine months after, right? You go to	Page 105 1 a pretty seasoned group, so I imagine it was pretty 2 close. 3 Q. (BY MR. EHRICH) Okay. So -- I just want 4 to make sure I'm understanding. 5 You're saying that Slide 11 is showing 6 who would have gotten more injections in the PRN 7 phase? 8 A. I'm saying that in clinical practice we 9 would certainly treat more stringently than we 10 designed this trial in 20 whatever it was. 2006 or 11 whatever. 12 Q. Okay. 13 A. Right? We realized that fluid is bad for 14 you, and you need more stringent retreatment 15 criteria. And so, when you look at a PRN phase of a 16 trial with retreatment criteria, you have to temper 17 the number based on -- like if you treated any fluid 18 at all, you would have a lot more injections than if 19 you wait a hundred microns, for example. 20 Q. Okay. So again, just make sure I'm 21 understanding you. 22 Since PRN assumes some degree of 23 assessment on the part of the clinician -- is that a 24 fair thing to say? 25 A. Correct.

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Page 106 1 Q. Okay. And -- 2 A. Well, let me step back. Some trials, you 3 have a reading system or an IVRS system where you 4 punch in data. Like the vision is this, the fluid is 5 this, and then it spits out the protocol, "You do 6 this." 7 We have other trials where the 8 investigator is supposed to look for these things and 9 do his best to maintain that. I don't honestly 10 remember which one this was, but -- 11 Q. Okay. But this is the assessment by which 12 someone on the PRN treatment regimen would receive -- 13 A. A dose. 14 Q. -- a dose? 15 Okay. So then -- so then this 16 assessment on -- these assessment criteria on 17 Slide 11, then, basically forms the basis, then, of 18 the numbers on Slide 14 in terms of those show the 19 percentage of patients who were -- received however 20 many more doses? 21 MS. STRUTHERS: Objection. 22 Mischaracterizes the testimony. 23 A. So it just gives the criteria with which 24 the investigator is allowed or suggested to give the 25 treatment.	Page 108 1 chart on Slide 14? 2 A. Slide on 14, correct. 3 Q. Okay. Okay. So if we compare the data 4 in -- so Slide 14 includes dropouts, as you just 5 said? 6 A. Correct. 7 Q. Okay. If you go forward a few pages to 8 Slide 19, which is Visual Acuity at Week 52 -- 9 A. Okay. I'm there. 10 Q. Okay. So presumably that does not include 11 the dropouts, then? 12 A. It would because at the bottom it says 13 LOCF. 14 Q. Okay. 15 A. Which means last observation carried 16 forward, which means if they started the study and 17 they dropped out immediately, they would be a zero 18 letter gain because they only have one point. In 19 other words, you take that zero, you go all the way 20 to 52. 21 Q. It carries forward? 22 A. That's what LOCF is. That's every patient, 23 including the people that dropped out. To be fair, 24 they could have dropped out because they were doing 25 poorly or they could have dropped out because they
Page 107 1 Q. (BY MR. EHRICH) Okay. 2 A. Some of these criteria are overlapping, and 3 some of them are subjective. So we don't know from 4 this presentation nor the CLEAR-IT manuscript what 5 caused people to re-dose, et cetera. 6 Q. Okay. But whatever caused the re-dosing is 7 reflected -- 8 A. Correct. 9 Q. The data are in Slide 14; is that right? 10 A. That is correct. That is the number of 11 doses given between Week 12 and Week 40. This 12 includes every patient, so it includes patients that 13 dropped out of the trials. So some of those patients 14 might have only been in the trial a couple months. 15 Some of them lasted all the way to week 52. 16 Q. Okay. 17 A. If you go to Page 8, it shows you that 18 approximately 15.7 percent didn't complete Week 52. 19 So about 1 out of 8, you don't know when they dropped 20 out -- when they dropped out, you know, Week 1 or 21 Week 50. They didn't make it to Week 52. 22 So this encompasses all the doses 23 given, including those that made it to Week 52 and 24 those that did not. 25 Q. And just to clarify, by "this" you mean the	Page 109 1 moved to Florida. Who knows? 2 Q. Okay. Okay. All right. So at least, 3 then, the understanding -- so both Slide 14 and 4 Slide 19 encompass the patient -- 5 A. All the patients randomized. 6 Q. Okay. Got it. Got it. Okay. Dr. Brown, 7 I think you can set that slide presentation aside, 8 then. 9 So I would like to turn to -- back to 10 the Dixon reference, please, to Page 1575. 11 A. One more time. 12 Q. I would like to turn, please, to the Dixon 13 reference, Page 1575. 14 A. Dixon reference, 1575. Okay. 15 Q. Okay. So I would like to focus your 16 attention, please, on the top of the right-hand 17 column on that page, and this is under the heading 18 Pharmacokinetics and Metabolism. 19 A. One more time. 1575. Okay. 20 Pharmacokinetics and Metabolism, yeah. 21 Q. You see that's on the top of the right-hand 22 column? 23 A. Okay. 24 Q. So Dixon writes, "You see that the 25 half-life of human intravitreal doses" -- and I

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Page 110 1 believe we're referring to aflibercept -- "is 2 unknown." 3 Do you see that about halfway down 4 that paragraph? 5 A. Okay. Yeah. 6 Q. And then immediately after that, Dixon 7 writes that "Intravitreal primate doses of 8 ranibizumab have a half-life of about three days," 9 right? 10 A. Okay. 11 Q. Was it known in the art at this time as to 12 how the half-life of an intravitreal dose of 13 aflibercept would compare to the half-life of an 14 intravitreal dose of ranibizumab? 15 MS. STRUTHERS: Objection. Beyond the 16 scope, and objection to form. 17 Q. (BY MR. EHRICH) And if you would like to 18 reference -- I'm asking in reference to the statement 19 that you and Dr. Heier made regarding mathematical 20 models on Page 2539 of the Heier 2012 reference. 21 A. Refresh my memory on the question one more 22 time. 23 Q. Sure. Just looking at the Dixon 24 reference -- well, actually, yeah, just looking at 25 the Dixon reference, Dixon writes that the half-life	Page 112 1 just a couple minutes. We'll be back in five. 2 VIDEOGRAPHER: Off the record at 3 1:21 p.m. 4 (Recess from 1:21 p.m. to 1:31 p.m.) 5 VIDEOGRAPHER: On the record at 6 1:31 p.m. 7 MS. STRUTHERS: All right. Thank you, 8 Dr. Brown. I have no questions for you. 9 THE WITNESS: Thanks. 10 VIDEOGRAPHER: Okay. We're off the 11 record at 1:31 p.m. That concludes this deposition. 12 (Whereupon the deposition was adjourned.) 13 14 15 16 17 18 19 20 21 22 23 24 25
Page 111 1 of an intravitreal dose of aflibercept is unknown, 2 but they do list the half-life of an intravitreal 3 dose of ranibizumab in primates. 4 And given that you and Dr. Heier make 5 a reference to models predicting the duration of 6 aflibercept, I was just wondering if it was known in 7 the art at the time how the half-life of an 8 intravitreal dose of aflibercept would compare to the 9 half-life of an intravitreal dose of ranibizumab. 10 MS. STRUTHERS: Objection. 11 Mischaracterizes the documents. Beyond the scope. 12 A. I don't reference it in my declaration, and 13 I'm not even sure we know that answer in 2023, to be 14 honest. 15 Q. (BY MR. EHRICH) Okay. And with regard to 16 serum half-life, do we know in 2023? 17 MS. STRUTHERS: Objection. Beyond the 18 scope. 19 A. Certainly -- certainly not -- not published 20 data or -- 21 Q. (BY MR. EHRICH) Okay. I have no more 22 questions. Thank you very much for your time, 23 Dr. Brown. 24 A. Thank you. 25 MS. STRUTHERS: If you can give me	Page 113 1 UNITED STATES PATENT AND TRADEMARK OFFICE 2 BEFORE THE PATENT TRIAL AND APPEAL BOARD 3 4 MYLAN PHARMACEUTICALS,) 5 INC. and CELLTRION, INC.) 6) 7 vs.) CASE NO. IPR2022-01225 8) Patent 10,130,681 B2 9 REGENERON PHARMACEUTICALS) 10 ----- 11 MYLAN PHARMACEUTICALS,) 12 INC. and CELLTRION, INC.) 13) 14 vs.) CASE NO. IPR2022-01226 15) Patent 10,888,601 B2 16 REGENERON PHARMACEUTICALS) 17 18 REPORTER'S CERTIFICATE 19 ORAL VIDEOTAPED DEPOSITION OF DAVID BROWN, M.D. 20 May 17, 2023 21 I, Shauna Foreman, Certified Shorthand Reporter 22 in and for the State of Texas, hereby certify to the 23 following: 24 That the witness, David Brown, M.D., was duly 25 sworn by the officer and that the transcript of the oral deposition is a true record of the testimony given by the witness; That the original deposition was delivered to Thomas Ehrich. That a copy of this certificate was served on all parties and/or the witness shown herein on _____.

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Page 114 1 I further certify that pursuant to FRCP Rule 2 30(f)(1), the signature of the deponent: 3 ___x___ was requested by the deponent or a party 4 before the completion of the deposition and that the 5 signature is to be before any notary public and returned 6 within 30 days (or _____ days, per agreement of counsel) 7 from date of receipt of the transcript. If returned, the 8 attached Changes and Signature page contains any changes 9 and the reasons therefor; 10 _____ was not requested by the deponent or a 11 party before the completion of the deposition; 12 I further certify that I am neither counsel for, 13 related to, nor employed by any parties or attorneys 14 in the action in which this testimony is taken, and 15 further that I am not financially or otherwise interested 16 in the outcome of this action. 17 Certified to by me on this the 18th day 18 of May, 2023. 19 20 21 <i>Shauna Foreman</i> Shauna Foreman, CSR Texas CSR 3786 22 Expiration: 10/31/2023 Veritext Legal Solutions 23 300 Throckmorton Street Suite 1600 24 Fort Worth, Texas 76102 Tel. (817)336-3042 25 Firm No. 571	Page 116 1 DEPOSITION REVIEW CERTIFICATION OF WITNESS 2 3 ASSIGNMENT REFERENCE NO: 5905374 CASE NAME: Mylan Pharmaceuticals, Inc., et al. v. Regeneron Pharmaceuticals, Inc., et al. DATE OF DEPOSITION: 5/17/2023 4 WITNESS' NAME: David Brown, M.D. 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 David Brown, M.D. 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 13 They have read the transcript; They signed the foregoing Sworn Statement; and 14 Their execution of this Statement is of their free act and deed. 15 16 I have affixed my name and official seal this _____ day of _____, 20 _____. 17 18 _____ Notary Public 19 _____ Commission Expiration Date 20 21 22 23 24 25
Page 115 1 Veritext Legal Solutions 1100 Superior Ave 2 Suite 1820 Cleveland, Ohio 44114 3 Phone: 216-523-1313 4 May 18, 2023 5 To: ABIGAIL STRUTHERS 6 Case Name: Mylan Pharmaceuticals, Inc., et al. v. Regeneron 7 Pharmaceuticals, Inc., et al. Veritext Reference Number: 5905374 8 Witness: David Brown, M.D. Deposition Date: 5/17/2023 9 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 22 Sincerely, 23 24 Production Department 25 NO NOTARY REQUIRED IN CA	Page 117 1 DEPOSITION REVIEW CERTIFICATION OF WITNESS 2 3 ASSIGNMENT REFERENCE NO: 5905374 CASE NAME: Mylan Pharmaceuticals, Inc., et al. v. Regeneron Pharmaceuticals, Inc., et al. DATE OF DEPOSITION: 5/17/2023 4 WITNESS' NAME: David Brown, M.D. 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 11 I have executed the Errata Sheet, as well as this Certificate, and request and authorize 12 that both be appended to the transcript of my testimony and be incorporated therein. 13 14 _____ Date David Brown, M.D. 15 16 Sworn to and subscribed before me, a Notary Public in and for the State and County, 17 the referenced witness did personally appear and acknowledge that: 18 They have read the transcript; They have listed all of their corrections in the appended Errata Sheet; 19 They signed the foregoing Sworn Statement; and 20 Their execution of this Statement is of their free act and deed. 21 I have affixed my name and official seal 22 this _____ day of _____, 20 _____. 23 24 _____ Notary Public 25 _____ Commission Expiration Date

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Mylan Exhibit 1110

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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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