

1 UNITED STATES PATENT AND TRADEMARK OFFICE
2 BEFORE THE PATENT TRIAL AND APPEAL BOARD
3

4 SAMSUNG BIOEPIS CO., LTD.,)
) CASE IPR2023-00739
5 Petitioner,) U.S. Patent No.
) 10,888,601
6 v.)
) CASE IPR2023-00884
7 REGENERON PHARMACEUTICALS,) U.S. Patent No.
 INC.,) 11,253,572
8)
 Patent Owner.)
9 _____)

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11
12 REMOTE VIDEOTAPED DEPOSITION OF
13 DAVID M. BROWN, M.D.
14 APRIL 3, 2024
15 9:02 a.m. CDT
16
17

18 Witness Appearing From:
19 Houston, Texas
20
21
22
23
24

25 Conducted Remotely Via Videoconference

Page 1

1 A. Yeah, I'm David Brown. 2 Q. And is it okay if I refer to you as 3 Dr. Brown today? 4 A. No problem. 5 Q. Excellent. I did want to make just one 6 comment. I know the videographer identified the IPR 7 884, which is the '572 patent, and just want to 8 confirm that today's deposition also involves the 9 IPR related to the '601 patent that's IPR2023-739. 10 Is that your understanding as well, Dr. Brown? 11 A. I thought it was related to the -- 12 MR. COBB: Dr. Brown, I'll represent that 13 that's correct. 14 A. Got it. 15 Q. Great. Thank you very much. I appreciate 16 that. Just wanted to make sure we were all on the 17 same page. 18 Dr. Brown, is there anything restricting 19 you from providing complete and truthful testimony 20 today? 21 A. No, sir. 22 Q. And are you taking any medication that 23 would impede your ability to provide complete and 24 truthful testimony? 25 A. No, sir. Page 6	1 aside from those erratas that were in the 2 transcripts? 3 A. No, sir. 4 Q. And anything that you are aware of that 5 might have changed with respect to your opinions 6 since those depositions? 7 A. I don't quite understand that. What's the 8 question? 9 Q. You gave those depositions and you 10 reviewed those transcripts. And my question is 11 just, in your mind, if there's anything that you 12 recall that is different from what you testified in 13 those depositions. 14 A. Not that I recall. 15 Q. And Dr. Brown, have you ever testified at 16 trial? 17 A. Live trial, no. 18 Q. What did you do to prepare for today's 19 deposition? 20 A. I reviewed my declaration and the cited 21 references within. 22 Q. Okay. And you said you reviewed your 23 declaration. Did you review both declarations, the 24 one for the '572 patent and the one for the '601 25 patent? Page 8
1 Q. Dr. Brown, you've been deposed before, 2 correct? 3 A. That is correct. 4 Q. Do you recall how many times? 5 A. I think three for this particular matter 6 and a time or two for some medical malpractice 7 cases. 8 Q. Okay. And you said three times. I know 9 you were deposed back in December, is that right, on 10 the '681 patent? 11 A. Correct. 12 Q. And then there were a couple other 13 depositions that you recall? 14 A. Yeah, they were for the Mylan dispute with 15 Regeneron. 16 Q. And after those depositions, did you have 17 an opportunity to review your deposition 18 transcripts? 19 A. Yes, I reviewed deposition transcript for 20 errors shortly thereafter and haven't looked at them 21 since. 22 Q. Okay. And did you submit erratas for 23 those transcripts? 24 A. I did. 25 Q. And are you aware of any other mistakes Page 7	1 A. Yes, I did. 2 Q. All right. And I've marked those as 3 exhibits in the Exhibit Share. I assume you have 4 hard copies. For the record, the exhibit -- I'm 5 sorry. The declaration for the '572 patent is 6 Exhibit 2066 from the 884 IPR proceeding, and the 7 declaration for the '601 patent is Exhibit 2035 from 8 the 739 IPR proceeding. And again, just want to 9 confirm. Do you have hard copies of the 10 declarations in front of you? 11 A. I do. 12 Q. All right. And so just back to the prep 13 for a moment. I think you said you reviewed those 14 declarations and the documents cited within the 15 declarations? Is that correct? 16 A. That is correct. 17 Q. All right. And did you review any other 18 documents besides those? 19 A. I don't think so. 20 Q. I think you testified earlier that you did 21 not review any of your deposition transcripts in 22 preparation for today's deposition? 23 A. No, sir. I haven't reviewed those since 24 they were current, December and then probably six 25 months before that for the Mylan stuff. Page 9

1 Q. All right. Last review was when you 2 checked for errors and submitted your erratas? 3 A. That's correct. 4 Q. All right. And did you speak to anyone in 5 preparation for today's deposition? 6 A. Only -- 7 MR. COBB: Dr. Brown, I'll just counsel 8 you, you can answer the question but don't reveal 9 the substance of any conversations you've had in the 10 presence or with counsel. 11 A. Yeah, just counsel. 12 Q. Okay. And did you meet with counsel in 13 preparation for today's deposition? 14 A. I did. 15 Q. And when was that? 16 A. Yesterday. 17 Q. Who did you meet with? 18 A. Jeremy Cobb and Rebecca Weires with MOFO. 19 Q. And did you meet in person? 20 A. We did. 21 Q. And was that in Arnold & Porter's Houston 22 office? 23 A. 40th floor, 700 Louisiana, yes, sir. 24 Q. Got it. And other than Mr. Cobb and 25 Ms. -- did Ms. Weires -- is it Weires? Page 10	1 Exhibit 2066. And I think you said you have a copy 2 in front of you. 3 A. I do. 4 Q. Excellent. Just generally, is it your 5 understanding that the '572 declaration and the '601 6 declaration are virtually identical with the 7 exception of some paragraphs concerning your work on 8 the DA VINCI trial? 9 A. That is correct. 10 Q. All right. I'm asking that just -- I'm 11 hoping that I can reduce some time for today's 12 deposition. And apologize for -- apologize for the 13 long explanation, but rather than go through each 14 individually, if there are portions that are 15 identical, I think it would be more efficient if I 16 went through it together, so to speak. Just want to 17 make sure that's okay with you. 18 A. That makes sense to me. 19 Q. All right. Great. 20 Let's start -- and I'm just going to be 21 very candid with you, Dr. Brown. I'm just going to 22 walk through the deposition. I may introduce some 23 exhibits, but the idea is just to get your views as 24 they're set forth in the declaration. 25 So I'm going to start with Exhibit 2066 Page 12
1 A. I think it's Weires, but I don't know. 2 Q. Okay. Did they both participate in 3 person? 4 A. They did. 5 Q. All right. And was anyone else present 6 besides yourself and those two individuals? 7 A. There was another Arnold & Porter attorney 8 on video for part of it. And I'm sorry. Counsel 9 can give her name if you want it. 10 Q. It's okay if you don't recall. We can get 11 that -- 12 A. I don't recall. 13 Q. -- off the record. Yeah. 14 And how long did you meet for? 15 A. I met yesterday probably seven hours. 16 Day before, couple hours. 17 Q. All right. So Monday for a couple of 18 hours and Tuesday for seven hours? Is that correct? 19 A. Seven, eight hours, yeah. We had lunch, 20 so -- 21 Q. All right. And Monday, was that also an 22 in-person meeting? 23 A. That was. 24 Q. All right. So I'd like to start with your 25 '572 IPR declaration. And as I said, I think that's Page 11	1 and I'm going to start with paragraph 1. And I 2 think that's on page 3, so just let me know when 3 you're there. 4 A. Okay. So it's the page numbers, the 5 pagination from the bottom, page 3? 6 Q. Exactly, yeah. I think it's page 2 of the 7 document, page 3 of the exhibit. But if easiest, 8 I'll just use the one at the bottom right. 9 A. No problem. 10 Q. And in paragraph 1, you indicate that 11 you've been retained by Regeneron as a technical 12 expert. Is that correct? 13 A. That is correct. 14 Q. And in this declaration and the '601 15 declaration, are you offering expert opinions? 16 A. I am. 17 Q. And are you also offering a factual 18 declaration? 19 A. Yes, sir. 20 Q. And the reason I'm asking is that in 21 previous declarations, you may recall that you 22 offered specific opinions on things that were 23 related to legal matters. Are you aware of that? 24 A. I'm not an attorney, but I certainly 25 answered the questions as best I could. Page 13

1 Q. Okay. And I appreciate that. I was 2 actually just talking about your declaration. For 3 example, do you recall that you submitted a 4 declaration with respect to the '681 patent and the 5 IPR associated with that? 6 A. I do, but I haven't reviewed that in many 7 months. 8 Q. All right. But did you draft that 9 declaration for that particular patent? 10 A. With counsel's help, I did. 11 Q. All right. Is that the same for the '572 12 and the '601 declarations? 13 A. The ones we're going over today, that is 14 correct. 15 Q. All right. Now, back to the '681 16 declaration. And happy to introduce that as an 17 exhibit if it's helpful. I did just have some 18 general questions. 19 Do you recall that that declaration was 20 structured somewhat differently than the ones we're 21 looking at today, the '572 and the '601? 22 A. I know it was longer. That's all I 23 remember. 24 Q. All right. Do you recall that you 25 included specific opinions on something called Page 14	1 concerning reasonable expectation of success, 2 correct? 3 MR. COBB: Objection. Document speaks for 4 itself. 5 A. That's correct. 6 Q. All right. And you also do not -- in 7 those declarations, the '572 and '601 declarations, 8 you do not provide any opinions concerning secondary 9 considerations of nonobviousness, correct? 10 A. Again correct. 11 Q. All right. And in the '572 and '601 12 declarations, you do not set forth your view of the 13 state of the art concerning any prior art, correct? 14 A. Certainly a majority of the declaration 15 deals with ANCHOR and MARINA which defined the state 16 of the art at that time, but no specific topics 17 defining state of the art in the legal term. 18 Q. Okay. And was -- for the '572 19 declaration, was there a reason that you did not 20 provide any opinions on reasonable expectation of 21 success? 22 MR. COBB: Objection, privileged. 23 Do not answer the question. 24 You're not entitled to conversations with 25 counsel and related to the content or selections of Page 16
1 reasonable expectation of success? 2 A. I remember that in generalities, yes. 3 Q. Okay. And do you recall that you also 4 offered specific opinions on something called 5 secondary considerations of nonobviousness? 6 A. I remember that title as well, yes, sir. 7 Q. All right. And do you also recall that 8 you set forth your view of the state of the art with 9 respect to certain prior art? 10 MR. COBB: Form. 11 A. The question is -- repeat the question 12 again. I'm sorry. 13 Q. Sure. Do you also recall that in that 14 '681 declaration, you set forth your view of the 15 state of the art concerning certain prior art? 16 MR. COBB: Objection, vague. 17 A. I remember there's sections entitled 18 similar to that. But again, it's been six months or 19 so. 20 Q. All right. I think you said that in prep 21 for today's deposition, you looked at this '572 22 declaration yesterday. Is that right? 23 A. That is correct. 24 Q. All right. In the '572 declaration and 25 the '601 declaration, you don't include any opinions Page 15	1 his declaration. 2 Q. All right. Let me ask it this way, 3 Dr. Brown. Outside of communications with counsel, 4 was there any reason that you decided not to include 5 opinions concerning reasonable expectation of 6 success? 7 A. Repeat the question? 8 Q. Sure. Outside of any of your 9 communications with counsel, was there any reason 10 that you decided not to include opinions concerning 11 reasonable expectation of success for the '572 12 patent? 13 A. When I do a project, I look at the work 14 that needs to be done and I do that work. I don't 15 go outside that work. I was told to review MARINA, 16 ANCHOR, PIER, and my role in the DA VINCI trial. 17 Q. Okay. So you were not asked to provide 18 opinions concerning -- 19 MR. COBB: Objection, privileged. 20 Do not answer the question. 21 MR. ERWINE: Counsel -- 22 MR. COBB: Conversations -- 23 MR. ERWINE: -- please let me -- I'm 24 sorry, Counsel. Please let me finish the question. 25 MR. COBB: -- what you were asked to do. Page 17

1 MR. ERWINE: I understand. You can make 2 your objection. You can instruct him not to answer, 3 but I'm entitled to ask my question before you step 4 over my question. Please let me finish the 5 question. 6 Q. And I'll ask the opinion -- question again 7 as part of what you were asked to do with respect to 8 this particular declaration, Dr. Brown. 9 Were you not asked to provide any opinions 10 on reasonable expectations of success? 11 MR. COBB: Objection, privileged. 12 Do not answer the question. 13 Q. And with respect to the '572 patent, were 14 you not asked to provide any opinions concerning 15 secondary considerations of nonobviousness? 16 MR. COBB: Objection, privileged. 17 Do not answer the question. 18 Q. And with respect to -- I think -- let me 19 go back to your previous answer. 20 So I think you had testified you were told 21 to review MARINA, ANCHOR, PIER in your -- and your 22 role in the DA VINCI trial. Is that correct? 23 A. That's what I said. 24 Q. All right. And were you -- let me ask it 25 this way. Did you look at any prior art that was Page 18	1 Q. I think you stated in your declaration, 2 which I think you repeated in your testimony, that 3 the Shams reference focuses on the protocol for 4 Genentech's PIER trial? Is that right? 5 A. That is correct. 6 Q. And how do you know that it focuses on the 7 protocol for Genentech's PIER trial? 8 MR. COBB: Objection. 9 Dr. Brown, I'll just counsel you do not 10 disclose conversations that you've had with counsel, 11 but you're certainly permitted to answer his 12 question. 13 A. Yeah, the PIER trial was a unique trial 14 where Genentech and investigators were testing 15 ranibizumab, three doses followed by quarterly 16 doses, compared to a sham injection. And it's 17 different than sham. Naveed Shams is his name, and 18 sham injection is when we don't do an injection but 19 try to simulate one. 20 And the material of the Shams patent is 21 very similar if not exact to the PIER trial. 22 Q. And let me -- let me make this hopefully 23 easier for you, Dr. Brown. I'll mark as an exhibit 24 or I'll introduce as an exhibit the Shams reference. 25 It's Exhibit -- it's Exhibit 1017 from the '572 IPR. Page 20
1 cited by Samsung Bioepis in the IPR petition 2 concerning the '572 patent? 3 A. I don't recollect. You can give me 4 specific examples. I might be able to remember 5 which prior art. 6 Q. Okay. Sure. Anytime I step over or talk 7 over you, I apologize. I don't mean to. So forgive 8 me if I do that. Kind of did that there, so I'm 9 sorry. 10 In paragraph 3, you -- of your 11 declaration, you reference a piece of art that's 12 entitled "Shams." Do you see that? 13 A. I do. 14 Q. And do you have an understanding of the 15 Shams reference? 16 A. The Shams reference is a Genentech patent 17 filed in 2004. Focuses on the protocol for 18 Genentech's PIER trial. I was principal 19 investigator on PIER. So I was -- I opined on 20 aspects of PIER that color the POSA's understanding 21 of the Shams reference. I'm not an attorney and 22 don't expect to be able to explain much of the Shams 23 patent itself. 24 Q. You did review the Shams patent? 25 A. I did. Page 19	1 And -- 2 MR. COBB: I'm going to hand Dr. Brown 3 what's been marked as 1017 from -- there you go. 4 Q. All right. And sounds like you have a -- 5 A. I have it, yeah. 6 Q. -- hard copy? Great. And so, again, this 7 is -- bear with me here for one second -- 8 Exhibit 1017. This is a PCT application, and looks 9 like the title is "Method For Treating Intraocular 10 Neovascular Diseases." 11 And I think, again, Dr. Brown, you 12 mentioned that this reference focuses on the 13 protocol for Genentech's PIER trial. Is there 14 somewhere in the document that it says that? 15 A. Well, on page 31 of the patent, page 32 on 16 the bottom, it describes pretty well what we did in 17 PIER. In the study two treatment groups received 18 multiple intravitreal doses of VEGF antagonists, 19 0.3-milligram to 0.5, compared to sham, with each 20 dose administered every month for three doses 21 followed by dosing every three months, months 5, 8, 22 11, 14, 17, 20, 23. 23 And then it -- the treatment with 30-gauge 24 needle and the sham injection and the preinjection 25 procedures and the drape are all consistent with the Page 21

6 (Pages 18 - 21)

1 way the PIER trial was performed. It never mentions 2 PIER that I can find, but you've got a search 3 function, so it's probably not there if you don't 4 think it is. I don't think it is. 5 Q. Okay. And you mentioned that the 6 inventor's last name was Shams, and I think on the 7 first page of the document it identifies the 8 inventor as Naveed Shams. Do you know Mr. Shams or 9 Dr. Shams? 10 A. Yeah, I know Dr. Shams. He's a -- he was 11 a -- a physician employed by Genentech as a -- I 12 don't know their exact titles but essentially ran 13 the -- ran the PIER trial. 14 Q. Okay. And did you work with him at all on 15 the PIER trial? 16 A. I did. 17 Q. And can you describe the work that you did 18 with him on the PIER trial? 19 A. My predominant work on the PIER trial was 20 as an investigator to recruit patients, give 21 informed consent, follow the protocol, look for side 22 effects. And then as the trial went along, at the 23 end of the trial, to help Genentech analyze the data 24 from the one-year outcomes and then present that 25 data to a scientific meeting. Page 22	1 He's been -- not been with Genentech for a long 2 time. 3 Q. And did you speak to Dr. Shams at all in 4 connection with your preparation of this declaration 5 or the '601 declaration? 6 A. Not in the -- not a bit, no, sir. 7 Q. I think you testified and you state in 8 paragraph 3 of your declaration that you've been 9 asked to opine on aspects of PIER that could color a 10 POSA's understanding of the Shams reference. 11 Do you see that, Dr. Brown? 12 A. I see that. 13 Q. And what do you mean by that statement? 14 Can you provide any more color? 15 A. Because I was heavily involved in 16 ANCHOR/MARINA, first author of ANCHOR, second author 17 of MARINA, and was a large recruiter and the 18 presenter for PIER and second author for PIER, my 19 experience on the disappointment that those patients 20 or subjects had and my disappointment that we 21 weren't giving them everything that was potentially 22 available with these therapeutic agents is -- in my 23 mind, would help an understanding of the importance 24 of the PIER trial and its ramifications. 25 Q. Let me see if I can break that down a Page 24
1 Q. And as part of your work, did you 2 communicate directly with Dr. Shams? 3 A. Was 20 years ago, but yes, I did 4 communicate. I'm sure it was some phone calls, some 5 emails, but -- 6 Q. Any in-person meetings? 7 A. Yeah, there would have been investigator 8 meetings, and there would have been -- I remember -- 9 I recall a live meeting in San Francisco when I 10 received the -- went over the data with Genentech to 11 help prepare the presentation. 12 Q. And that was a live meeting with 13 Dr. Shams? 14 A. Almost positive he was there. It would 15 have been a large team of Genentech scientists. And 16 again -- or, you know, Genentech clinician 17 scientists. And that was 20 years ago. I would 18 be -- that he was there, but I couldn't be confident 19 with 20 years of memory. 20 Q. Do you recall the last time you spoke to 21 Dr. Shams? 22 A. I saw Dr. Shams at a ophthalmology retina 23 meeting in the last year somewhere, I think 24 New Orleans, Academy of Ophthalmology. He is -- 25 works with, I think, a gene therapy company now. Page 23	1 little bit. First of all, you used the word "POSA." 2 And can you tell -- tell us what POSA stands for? 3 A. So in the declaration, I say, "I was a 4 principal investigator on PIER, and so I've been 5 asked to opine on the aspects of PIER that would 6 color a POSA's understanding of the Shams 7 reference." 8 POSA is a legal term, a person of ordinary 9 skill in the art. 10 Q. Okay. And what is your understanding of a 11 person of ordinary skill in the art? 12 A. A POSA is a legal term, and it's an 13 imaginary thing where somebody has infinite 14 knowledge of every publication that could possibly 15 have been written about the subject matter and, with 16 that foundation of knowledge, has at least the 17 knowledge or ability to practice, in my phrase 18 practice retina; in other words, know when to treat 19 patients or how to treat patients. 20 Q. And that would be your understanding of 21 the level of ordinary skill in the art with respect 22 to the '572 patent? 23 MR. COBB: Object to form. 24 A. What's the question exactly? 25 Q. I had asked you about your understanding Page 25

1 of a POSA generally, and what I was trying to 2 understand was your understanding of what is the -- 3 what's considered to be the level of ordinary skill 4 in the art for the '572 patent. 5 MR. COBB: Objection, form. 6 A. Yeah, I think I defined that as best I 7 can. Again, I'm not a lawyer. I can only -- my 8 main purpose of this declaration is to give my 9 experiences in PIER, and then -- and that's what 10 I've done. 11 Q. Thank you, Dr. Brown. I appreciate that. 12 That's what I was trying to get at earlier. I 13 understand that part of your declaration is directed 14 to the facts as you understand them from the PIER 15 trial. Is that correct? 16 A. That is correct. 17 Q. And in terms of expert opinions, as best 18 as I can tell from your declaration, it looks as if 19 the opinion you'd be offering is how aspects of PIER 20 could color a POSA's understanding of the Shams 21 reference. Is that fair? 22 A. That's what I state in paragraph 3, "asked 23 to opine on the aspects of PIER that could color a 24 POSA's understanding of the Shams reference." 25 Q. Okay. And just to confirm, I think you Page 26	1 be factual on the ANCHOR/MARINA/PIER and my role in 2 the DA VINCI trial. 3 Q. That's super helpful, Dr. Brown. That's 4 what I was trying to figure out was the distinction 5 between facts and if you set forth any expert 6 opinions. And so that was the kind of basis for my 7 previous question, so I appreciate that. 8 And with respect to that Shams prior art 9 reference, other than the sentence, a couple of 10 sentences in paragraph 3, you don't discuss the 11 Shams reference anywhere else in your declaration. 12 Is that right? 13 MR. COBB: Objection. Document speaks for 14 itself. 15 Q. I'm not trying to trick you or anything, 16 Dr. Brown. I just -- I didn't see "Shams" mentioned 17 anywhere else, and I just wanted to confirm it was 18 your understanding that you didn't offer any other 19 opinions concerning the Shams reference. 20 A. Yeah, it's my -- it's -- I don't think I 21 offer any opinions on any of the patents. I mainly 22 offered opinions or fact on MARINA, PIER, ANCHOR, 23 and my role in the DA VINCI trial. 24 Q. Okay. That's helpful. Thank you, 25 Dr. Brown. Page 28
1 said -- this is with respect to a POSA's -- or, 2 sorry, the level of ordinary skill for the '572. I 3 think you said that a POSA would have the knowledge 4 or ability to practice retina; in other words, know 5 when to treat patients or how to treat patients. 6 Is that a fair assessment of your 7 understanding of the level of ordinary skill in the 8 art for the '572 patent? 9 MR. COBB: Objection. Asked and answered. 10 Form. 11 A. Yeah, that's my understanding. Again, 12 it's a legal term. I haven't been to law school, 13 so -- 14 Q. And is that your understanding of the -- 15 of level of skill in the art for the '601 patent as 16 well? 17 A. They would be the same. 18 Q. Okay. And did you consider that level of 19 ordinary skill in the art in forming whatever 20 opinions you set forth in this declaration? 21 MR. COBB: Objection, form. 22 A. This declaration is predominantly factual. 23 It's just what happened. How that would color a 24 POSA's understanding, I would hope that the facts 25 would help a POSA, but that's as far as I did is to Page 27	1 If I can direct your attention to the next 2 paragraph in your declaration, paragraph 4. 3 A. I see it. 4 Q. And you mention the DA VINCI trial? Is 5 that right? 6 A. DA VINCI? Named after Leonardo da Vinci, 7 I think. 8 Q. All right. And in that paragraph, you say 9 that you've been asked to explain your and 10 Dr. Major's role, roles in preparing the abstract, 11 the 2010 ARVO abstract? Is that right? 12 A. That's correct. 13 Q. So again, with respect to the DA VINCI 14 trial, your declaration is setting forth certain 15 facts associated with that trial and you're not 16 offering any expert opinions? 17 A. I'm certainly an expert on the material 18 and I've offered facts which are -- opinions versus 19 facts, maybe that's a legal term. I don't quite 20 understand the question. 21 Q. Let me ask it this way, Dr. Brown. 22 Are you offering an opinion concerning how 23 aspects of the DA VINCI trial could color a POSA's 24 understanding of the ARVO abstract? 25 A. Repeat the question one more time. I Page 29

1 think I'm -- 2 Q. Sure. Are you offering an opinion 3 concerning -- sorry. Let me repeat that. Let me 4 rephrase. 5 Are you offering an opinion concerning how 6 aspects of the DA VINCI trial could color a POSA's 7 understanding of the ARVO abstract? 8 MR. COBB: Objection. Document speaks for 9 itself. Form. 10 A. So the majority of the declaration on the 11 DA VINCI is just how -- my role in the DA VINCI 12 trial and not necessarily in the results or 13 implications of the DA VINCI trial. 14 Q. All right. And I think you testified 15 earlier that you were -- you were offering an 16 opinion about the POSA's understanding of the Shams 17 reference based on your knowledge of the PIER trial. 18 And I'm just trying to understand if you're offering 19 any opinions of a POSA's understanding of the ARVO 20 abstract based on your work in the DA VINCI trial. 21 A. Yeah, the Shams reference, the PIER parts 22 of this declaration are what would color a POSA's 23 understanding of the Shams reference. The 2010 ARVO 24 abstract had top-line results of DA VINCI. 25 I was a clinical investigator. I was Page 30	1 personnel at each site and is the ultimate 2 responsibility of determining that causality if they 3 disagree with the other clinical investigators. 4 Q. And going back to PIER for just a second. 5 So the PIER trial, you were both the principal 6 investigator and the clinical -- and a clinical 7 investigator? 8 A. Correct. 9 Q. But in the DA VINCI trial, you were just a 10 clinical investigator and not the principal 11 investigator. Is that right? 12 A. That's correct. 13 Q. And do you recall who was the principal 14 investigator for the DA VINCI trial? 15 A. Yeah, my site, it was Dr. Matthew Benz. 16 Q. And how do you spell his last name? 17 A. B-E-N-Z. 18 Q. And do you know where he's located? 19 A. I beg your pardon? 20 Q. Do you know where he's physically located, 21 where he maintains his practice? 22 A. Yeah, he's my partner in practice in 23 Houston, Texas. 24 Q. Got it. So this is someone you've worked 25 with for many years? Page 32
1 asked to explain why -- myself and the other 2 clinical investigator's role in DA VINCI and my role 3 and Dr. Major's role in preparing the abstract. 4 There is portions of the abstract that give data 5 excerpted in my declaration on page 21, but I really 6 don't opine on the ramifications or meaning of the 7 DA VINCI trial at all. 8 Q. All right. And with respect to the 9 DA VINCI trial, I think you said that you were a 10 clinical investigator? Is that right? 11 A. That's correct. 12 Q. And you were also a clinical investigator 13 in the PIER study as well, correct? 14 A. That's correct. 15 Q. And is there a difference between a 16 clinical investigator and the principal 17 investigator? 18 A. The principal investigator is a clinical 19 investigator and typically does the same thing as 20 clinical investigators in terms of recruiting 21 patients, offering informed consent, examining 22 patients, looking for adverse events, and 23 determining causality. The principal investigator 24 is responsible for the actions of all the 25 investigators, sub-investigators, and all the trial Page 31	1 A. Yes, sir. Hired him probably 15 years 2 ago. 3 Q. And did you -- 4 (Overtalk) 5 A. -- hired him before this trial, before 6 this abstract, so yes. 7 Q. And did you speak to Dr. Benz at all in 8 preparation for either the '572 or the '601 9 declaration? 10 A. He was at my daughter's wedding, but we 11 did not discuss any legal -- these patents at all or 12 the trial, or I don't think he knows I'm doing this, 13 so -- 14 Q. Okay. And in paragraph 4, you also 15 mention Dr. James Major. Was he also a clinical 16 investigator in that trial? 17 A. He was. 18 Q. All right. And did you speak to Dr. Major 19 at all in preparing this declaration, the '572 20 declaration or the '601 declaration? 21 A. I did. 22 Q. And when did you speak to him? 23 A. Would have been several months ago. It 24 would have been, you know, in preparation for this 25 abstract on -- Page 33

1 Q. Sorry. Are you finished? 2 A. I am. Several months to go in preparation 3 for this abstract, so -- 4 Q. And just to be clear, when you said 5 "preparation for this abstract," do you mean 6 the declaration? 7 A. I'm sorry. The declaration. Yeah, yeah, 8 yeah. I'm sorry. 9 Q. Okay. Got it. 10 A. Yeah. 11 Q. And did you speak to him in person or by 12 some other means of communication? 13 A. A telephone call. 14 Q. And what did you guys talk about? 15 MR. COBB: Dr. Brown, to the extent that 16 counsel was present for any of this conversation, 17 don't disclose any substance, but you may answer his 18 question (indiscernible). 19 A. Yeah, I was -- this is an abstract from 15 20 years ago. I was seeing if he had a copy of the 21 abstract because I had a hard time finding it. 22 Q. And did you ask him any questions about 23 your or his role in the DA VINCI trial? 24 A. Yeah, I asked him, Do you remember when I 25 had you present this abstract at ARVO? And he goes, Page 34	1 Phase III trial, we were going to have 2 data and it was just really a particular obtuse rule 3 of the -- of the committee, the subject committee, 4 that all those abstracts were rejected. So ARVO 5 also has a late-breaking session and they don't want 6 people to present twice. So they have a rule that 7 if you haven't present- -- if you're not presenting, 8 you can submit a late-breaker. 9 Because Regeneron wanted to submit 10 DA VINCI as a late-breaker and because they knew 11 that my abstract was rejected, we thought I would be 12 eligible to present. When the actual rules were 13 like printed or published, it says you can't submit 14 an abstract if you've previously submitted an 15 abstract. And so really didn't know was I eligible 16 or not. I submitted an abstract, but it was 17 rejected. 18 So rather than risk submitting an abstract 19 and having a foot fault where the committee says, 20 oh, you previously submitted an abstract, I asked 21 James Major, who was also going to ARVO and has a 22 house in Florida, and it was in ARVO, would he 23 consider presenting this abstract and me write it 24 with him. So that's how the circuitous way why I 25 was on the DA VINCI abstract. Page 36
1 Yeah, that was a long time ago. And then we sort of 2 sorted out how it came about that he was the 3 presenter of this abstract. 4 Q. And how did it come about? 5 A. ARVO is the Association for Research and 6 Vision in Ophthalmology. It's the biggest 7 scientific meeting, peer scientific meeting in 8 visual sciences. I've been part of ARVO and 9 presented for, gosh, longer than I like to admit, 10 probably 30 years, and had presented both basic 11 science and clinical data. That year, in 2010, I 12 submitted an abstract for the VIEW trial, which 13 would have been the results of a big phase III 14 Regeneron Aflibercept trial. 15 The program committee at that year had 16 instituted a policy where promise abstracts were not 17 accepted. A promise abstract's one where you say 18 you're going to present data but you don't actually 19 have the data in hand. That makes a lot of sense 20 for a basic science. I'm going to test, you know, 21 whatever, the pH of some chemical in 800 rats and 22 the results are 7.2 pH. And the reason they have a 23 non-promise abstract is because in basic science you 24 can promise something, but if the experiment doesn't 25 work out, there's no data. Page 35	1 The more -- you know, we were a pretty 2 small role in DA VINCI. We had recruited some, but 3 we certainly weren't part -- a bigger part of 4 DA VINCI. But Regeneron was just looking for who 5 could present this abstract that's a member of ARVO, 6 has scientific credibility, you know, is a decent 7 presenter, and that's how I got asked and then 8 that's how James Major ended up presenting the 9 abstract. 10 Q. And was Regeneron itself restricted from 11 submitting the abstract on its own behalf? 12 A. That's a good question. I don't know at 13 that time. You know, currently, most of our 14 societies, Mac Society, Retina Society, American 15 Academy of Ophthalmology, you cannot submit if 16 you're an employee of a pharmaceutical company. 17 So I don't know if ARVO had that in two 18 thousand -- whatever this is, 2010, but generally 19 it's not deemed credible if somebody's got a lot of 20 stock in a company and a lot of vested interest and 21 they're the one presenting the scientific paper. 22 Q. Was there a reason that you asked 23 Dr. Major to submit the abstract instead of 24 Dr. Benz? 25 A. Only because I knew he was going to Page 37

1 Florida. I knew he was attending. You know, he was 2 planning on attending that meeting. And to drag 3 somebody to a meeting for an abstract they're just 4 not in love with ... 5 It's a very scientific meeting. It's not 6 a, you know, junket, play-on-the-beach kind of 7 meeting. So it's not one that people go to for -- I 8 mean, I go to for pleasure because I love the 9 science, but it's not one that people think of as a 10 pleasure kind of meeting. 11 Q. Dr. Benz did not attend that meeting? 12 A. I don't remember. I don't think so or I 13 would have asked him. 14 Q. Got it. Okay. 15 A. Or he had already presented another 16 abstract. To be honest, I don't -- you know, if he 17 was on another abstract, then he also wouldn't be 18 eligible, but -- 19 Q. The only reason I asked was because I 20 think you had testified that he was the principal 21 investigator, so I was just trying to understand why 22 he wouldn't have been the first choice. 23 A. They both would have been excellent 24 choices, but I -- for whatever reason, Major was 25 available and I picked Major. Page 38	1 MR. COBB: Objection, form. 2 A. Yeah, they were prepared in parallel. 3 Q. And in terms of your work for Regeneron on 4 these IPR petitions, do you have a sense for how 5 many hours you've worked? 6 A. Not really. It's been, you know, over a 7 couple years, so -- 8 Q. Starting in about 2022? Is that right? 9 A. You know, the initial Mylan -- it's been 10 years. I mean, it may be longer than 2022. 11 Q. The work that you've done on the IPRs has 12 been IPR petitions that have been brought by Mylan 13 and Samsung Bioepis? 14 A. Correct. 15 Q. And other than that work, have you done 16 any other work for Regeneron? 17 A. Yes. I've done -- majority of what I do 18 for Regeneron has been clinical -- clinical trial 19 consultant. 20 Q. And when you say clinical trial 21 consulting, does that include work as an actual 22 investigator, or is that separate from your work as 23 an investigator? 24 A. Yeah, that's separate. I was -- for 25 example, I was on the VIEW steering committee. I Page 40
1 Q. Okay. Let me turn you to paragraph 6 of 2 your declaration. And that's page 4 on the bottom 3 right. And I just want to make sure you're there. 4 A. I'm here, yeah. I see it. 5 Q. Okay. Great. Sorry. In the first 6 sentence, you say you're being paid at your usual 7 hourly rate for your work on this matter. 8 What is your usual hourly rate? 9 A. Yeah, for industry consulting and legal 10 matters, it's a thousand dollars an hour. 11 Q. Okay. And do you know how many hours you 12 have worked on this particular matter? 13 A. I -- I don't. You know, less than -- you 14 know, as part of the preparation for this 15 declaration, totally guessing, five or six hours at 16 the most probably. And then the prep, which we 17 discussed, yesterday and Monday, so -- 18 Q. Okay. So in terms of drafting the 19 declaration, it would have been about five to six 20 hours? 21 A. We can certainly -- I can certainly find 22 that out, but I'm -- I'm assuming it didn't take 23 much longer than that, my role in it. 24 Q. All right. And that time is for both the 25 '572 and the '601 declarations? Page 39	1 was on the VISTA/VIVID steering committee for their 2 diabetes trial. I have -- on their 8-milligram 3 development steering committee. Those are 4 steering -- scientific steering committees of retina 5 experts who advise them or help them run clinical 6 trials. 7 The investigator work is separate. 8 That's -- that's contract work with Retina 9 Consultants of Texas where you're paid, you know, 10 based on a budget on exactly what's done, so -- 11 Q. I see. So as an investigator, that would 12 not be -- the pay would not pay your usual hourly 13 rate? 14 A. No, my -- you know, I don't know how it 15 pertains to this, but my group splits income evenly. 16 So we're Communists. So our surgical work, our 17 clinical work, our research work all gets put in one 18 big pot and we split it. So it would be really hard 19 to delineate how much each one is. I do a lot of 20 principal investigator work that my partners don't 21 do. I don't get paid extra for that, but I like to 22 do it, so -- 23 Q. But your work for Regeneron, either in 24 connection with the IPRs or I think you mentioned 25 the steering committees, that would just go to you Page 41

1 and would not be shared with your partners? 2 A. That is correct. 3 Q. Okay. And so the work that you mentioned 4 for the various Regeneron steering committees, that 5 work would have been at your usual hourly rate? 6 A. Probably. You know, within a range. In 7 other words, the average rate for most of my peers 8 was around 800 for a while and now it's crept up to 9 more like a thousand. Regeneron may be up to 1,200 10 for the clinical work now. It's based on fair 11 market value around the country and that kind of 12 thing. 13 Q. And do you know, ballpark, how many hours 14 per year you were working on this consulting for 15 Regeneron separate from the work on the IPRs? 16 A. Probably average 10 to 20 hours a year, 17 some years more if we're designing a big trial, some 18 years not so much if they're in between trials, 19 so -- 20 Q. And as part of that role, the steering 21 committee, is that actually designing trials? 22 A. It can. Usually the trials are baked by 23 the time you get a steering committee. In other 24 words, usually the trial is already in its 25 formulation and it's -- you know, there may be some Page 42	1 patients, it makes the trial not very scientifically 2 valid. If we can call investigators, figuring out 3 what are the pressure points or what are the 4 difficulties patients are having, work with the 5 sponsor to say, hey, is there any way to get, you 6 know, a little more travel money or whatever it is 7 to help retain patients. 8 The role of the steering committee is also 9 to help look at the data afterwards and to present 10 that data. And steering committee is usually a 11 bunch of key opinion leaders, so they've got a nice, 12 you know, a nice pool of talent to which to present 13 at scientific meetings to demonstrate what the study 14 did or did not show. 15 Q. And are you allowed to be both an 16 investigator and a member of the steering committee 17 for a particular trial? 18 A. Yeah, almost all are. 19 Q. Okay. And with respect to the PIER trial, 20 was there a steering committee? 21 A. There was not a -- best of my 22 recollection, there was not a steering committee for 23 the PIER trial. Steering committees were more of 24 a -- more of a Regeneron function back then. 25 Genentech Roche has steering committees now, but Page 44
1 nuances like do we change something here or there, 2 but it's usually -- it's usually pretty set by the 3 time a steering committee's set. 4 Q. Okay. And who typically is responsible 5 for setting the clinical trial? Is it the entity 6 that's sponsoring it? 7 A. Yeah, absolutely. They're the ones having 8 to figure out can they afford this, what's the size 9 of the trial, how long is it going to take them. 10 They have big clinical teams to help develop the 11 clinical trial protocol. And part of that's 12 scientific and part of that's business decisions 13 on -- on, you know, how they're going to get this 14 funded, who are they going to get for the contract 15 research organization, who are they going to get for 16 the reading center, all that stuff. 17 Q. So what exactly is the role of the 18 steering committee? 19 A. Steering committee role is to -- the main 20 role that we've created through the years is to 21 figure out how you can support clinical 22 investigators around the country doing this trial 23 and patient recruitment and retention. 24 In other words, we can have a great trial 25 and recruit it well, but if we lose half the Page 43	1 there wasn't necessarily an ANCHOR or MARINA 2 steering committee or a PIER steering committee. 3 Q. Was there a steering committee for the 4 DA VINCI trial? 5 A. No idea. I -- I wasn't on it. 6 Q. Okay. And you don't know even if one 7 existed? 8 A. So a phase II trial typically wouldn't 9 have a steering committee. They're a much shorter 10 trial. Phase III trials are lots of patients, long 11 years of recruitment. There's a lot more reason to 12 have physician involvement in recruitment and 13 retention than a phase II trial. 14 Q. Got it. And just to confirm, the DA VINCI 15 trial was a phase II trial? 16 A. DA VINCI trial was a phase II trial. 17 MR. ERWINE: Okay. Great. Dr. Brown, 18 we've been going for a little over an hour. Is now 19 an okay time to take a break? 20 THE WITNESS: Good for me. 21 MR. ERWINE: Great. 22 THE VIDEOGRAPHER: Okay. Time is 23 10:11 a.m. We are off the record. 24 (Recess from 10:11 to 10:23) 25 THE VIDEOGRAPHER: Time is 10:23 a.m. Page 45

1 We are on the record. 2 BY MR. ERWINE: 3 Q. All right. Welcome back, Dr. Brown. 4 Back to your '572 declaration, and I 5 wanted to ask you just a few questions about 6 paragraph 11 which starts on page 5. 7 A. Okay. 8 Q. And in that paragraph, you reference some 9 work on safety and efficacy of the use of 10 antivasular endothelial growth factor agents, or I 11 think what you approximate as -- or characterize as 12 anti-VEGF agents? Is that right? 13 A. Yeah, anti-VEGF. 14 Q. And anti-VEGF agents, are those things 15 like ranibizumab? 16 A. Ranibizumab. 17 Q. Apologies for my butchering of that 18 pronunciation. So that's one example of a VEGF 19 agent? 20 A. Yeah, ranibizumab, which was the trade 21 name Lucentis, and now there's biosimilar versions, 22 but it's ranibizumab, yeah. 23 Q. Okay. And is Aflibercept also an 24 anti-VEGF agent? 25 A. Yes, it is. Page 46	1 changes are in an eye, very few eye doctors in the 2 United States or around the world use it to treat 3 diabetic retinopathy other than for diabetic macular 4 edema. 5 Q. Okay. Now, Dr. Brown, turning to 6 paragraph 12 of your declaration, and that's on page 7 6 of the '572 declaration. 8 A. Yeah, I'm there. 9 Q. Okay. And there you list a number of 10 phase III clinical trials that you worked on. 11 Is that right? 12 A. That's correct. 13 Q. And I know we'll talk more about ANCHOR, 14 MARINA, and PIER, but you also reference the RISE 15 and RIDE trials? Is that right? 16 A. That's correct. 17 Q. And the VIEW1 trial? 18 A. That's correct. 19 Q. And the PANORAMA trial? 20 A. That's correct. 21 Q. Is it fair to say that other than your 22 listing of those trials in paragraph 12 that you 23 don't reference those trials anywhere else in your 24 declaration? 25 And again, I'm not trying to -- this isn't Page 48
1 Q. And that's Regeneron's product? 2 A. That is Regeneron's product, and I think 3 the petitioner also has Aflibercept. 4 Q. Got it. And Regeneron's trade name for 5 Aflibercept is Eylea? 6 A. That's correct. 7 Q. And some of the -- you reference some 8 angiogenetic -- again, I think I mispronounced it -- 9 angiogenic eye disorders in paragraph 11, wAMD, DME, 10 DR. Do you see that? 11 A. I do. 12 Q. And those are disorders that one would use 13 these anti-VEGF agents to treat? 14 A. Yeah. The -- the big diseases for 15 anti-VEGF agents to treat are wet macular 16 degeneration, diabetic macular edema, and edema from 17 retinal vein occlusion. 18 Q. What about DR, diabetic retinopathy? 19 A. So diabetic retinopathy, the pathogenesis 20 of diabetic retinopathy certainly involves VEGF. So 21 it makes sense that anti-VEGF agents would alter the 22 course of diabetic retinopathy. 23 Currently, despite studies showing 24 efficacy in improving diabetic retinopathy scores, 25 which is a photographic grading of how much diabetic Page 47	1 meant to be like a memory contest. I'm just trying 2 to understand if, you know, the declaration is 3 primarily directed to ANCHOR, MARINA, and PIER and 4 not RISE and RIDE, VIEW1 and PANORAMA. 5 A. Yeah, predominantly directed at ANCHOR, 6 MARINA, PIER, and the discussions on the abstract 7 regarding DA VINCI, yeah. 8 Q. Okay. And I think you say that for all of 9 these trials, they're all phase III trials? 10 Is that right? 11 A. That's correct. 12 Q. And for the PIER trial, you identify it as 13 a phase IIIb trial. Is that right? 14 A. Correct. 15 Q. Is there a distinction between a phase III 16 trial and a phase IIIb trial? 17 A. There is. The exact nuanced definition I 18 probably couldn't give you. Phase III trials are 19 for registration, to get a drug approved. IIIb was 20 an additional phase III to see if ranibizumab could 21 be treated quarterly after three monthly doses. An 22 alternative dosing -- basically an alternative 23 dosing regimen. 24 Q. And so when it references -- for the PIER 25 trial and it references IIIb, is that in connection Page 49

1 with the phase III trials for ANCHOR and MARINA? 2 A. The -- IIb is how it's described in 3 clinicaltrials.gov and in its applications to the 4 FDA. I can't tell you what the exact nuances are 5 between a phase III and a phase IIb. 6 Q. Let me ask it this way. Was there -- was 7 there a Genentech PIER trial that was just a phase 8 III trial? 9 A. No, Genentech -- there was only one PIER 10 trial, and it was classified as a phase IIb. 11 Q. Okay. And do you know, is the IIb 12 notation, was that referring back to the phase III 13 trials for ANCHOR and MARINA? 14 A. I don't know. 15 Q. Okay. Let's go to the next paragraph, 16 paragraph 13. And this is under your "Materials 17 Considered" section on page 7 of the declaration. 18 Do you see that? 19 A. I do. 20 Q. And within the "Materials Considered," you 21 reference the declaration of Dr. Edward Chaum. 22 Do you see that? 23 A. I do. 24 Q. And did you review Dr. Chaum's declaration 25 in preparation for today's deposition? Page 50	1 Q. What do you mean by "large scale" when you 2 describe those trials? 3 A. MARINA randomized 716 patients. And 4 ANCHOR randomized 4- or 500 patients, but let me 5 look it up. It's in here. 423 patients. So those 6 are very large, well-controlled trials testing the 7 effects of ranibizumab, a anti-VEGF antibody 8 fragment, against the standard of care or the way 9 people treated those diseases before. 10 And wet macular degeneration previously 11 was a blinding condition where everybody, 99 percent 12 or 98 percent, went blind centrally with no 13 effective treatments. There were some marginally 14 effective treatments for a particular subtype of wet 15 macular degeneration called classic choroidal 16 neovascular membrane, which was verteporfin PDT 17 developed by Novartis, actually by QLT and Novartis. 18 And this -- when we tested the anti-VEGF 19 for macular degeneration, we tested that population 20 against PDT, and that was the ANCHOR trial, directly 21 head to head. People got either one of two doses of 22 ranibizumab versus PDT. The other patients with 23 macular degeneration that didn't have that -- 24 specific characteristics that had a treatable agent 25 were compared to sham because that's -- there was no Page 52
1 A. I read it prior to -- as part of 2 developing this declaration, but I haven't read it 3 in several months. 4 Q. And in your declaration, you offer -- 5 A. Haven't looked at -- 6 Q. Sorry. 7 A. I haven't looked at it in several months. 8 I did it just in preparation for the -- preparation 9 of this -- this declaration and the sister 10 declaration on the '601 patent. 11 Q. And Dr. Brown, do you -- in your 12 declaration for '572 or '601, do you offer any 13 responsive opinions to opinions set forth by 14 Dr. Chaum in his declaration? 15 MR. COBB: Objection. Document speaks for 16 itself. Form. 17 A. I don't think so. 18 Q. All right. Let me direct you to paragraph 19 15 of your declaration. And this is -- it starts on 20 page 7 and rolls into page 8. 21 A. I'm there. 22 Q. And -- great. And so in this paragraph 23 you're referring to the MARINA and ANCHOR trials? 24 Is that correct? 25 A. That's correct. Page 51	1 treatment for it. 2 So we ran two very large studies to test 3 the efficaciousness of this anti-VEGF antibody 4 fragment in wet macular degeneration. 5 Q. And these angiogenic eye disorders, are 6 they all related to diabetes? 7 MR. COBB: Objection, form, vague. 8 A. Angiogenic eye diseases are not 9 necessarily just diabetes. Age-related macular 10 degeneration is the first one we tested. And while 11 diabetes is prevalent in an older population as is 12 macular degeneration, there's no direct correlation. 13 Q. How about for diabetic macular edema? 14 A. Diabetic macular edema is a specific 15 condition where chronic hyperglycemia causes damage 16 to the microvasculature all over the body, including 17 the eye, and that can lead to swelling or edema in 18 the central retina which is diabetic macular edema. 19 So you are correct. Diabetic macular 20 edema is a direct responsibil- -- is a direct 21 consequence of not controlling diabetes mellitus. 22 Q. And does that -- is there a distinction 23 between type 1 and type 2 diabetes? 24 MR. COBB: Objection, vague. 25 A. So there's certainly a distinction between Page 53

1 type 1 and type 2 diabetes and the potential 2 pathogenesis of how it comes about. But both type 1 3 and type 2 diabetes can develop diabetic macular 4 edema with inadequate control of their glycosylated 5 hemoglobin over time. 6 Q. I see. And with the wet age-related 7 macular degeneration, I think you said that there's 8 no direct causal relationship between diabetes and 9 that particular disorder? 10 A. That is correct. 11 Q. But is it fair to say that individuals 12 that have that disorder, many of them also have 13 diabetes? 14 MR. COBB: Objection, scope. 15 A. So age-related macular degeneration is 16 part genetics, but a lot of it's aging. And since 17 diabetics don't live as long, there's actually not 18 that many patients that have both diabetic eye 19 disease and macular degeneration at the same time. 20 They're sort of two populations. 21 Q. Back to the term "large scale." 22 I think you said that MARINA had 716 23 patients and ANCHOR had 423. Is there some dividing 24 line between when a clinical trial is considered 25 large scale versus not large scale? Page 54	1 A. Yeah, I was principal investigator in my 2 site in Texas which enrolled patients in both ANCHOR 3 and MARINA. 4 Q. And is there only one principal 5 investigator for these trials? 6 A. Sometimes there's a principal investigator 7 over the entire trial and -- but most of the time 8 you're a principal investigator in your own site. 9 Because a principal investigator has to have direct 10 oversight over the training and study personnel 11 of -- from refraction to data acquisition, it's -- 12 really, you couldn't be a principal investigator and 13 take responsibility for the personal action of every 14 person in the trial. It just couldn't be done. 15 So each individual trial site has a 16 principal investigator. I served as the principal 17 investigator in my Houston site for both ANCHOR and 18 MARINA. 19 Q. And do you know how many other principal 20 investigators there were for ANCHOR and MARINA? 21 A. So we -- you can look at the manuscript. 22 It would be however many sites they have. In other 23 words, if it says we enrolled 716 patients in 80 24 sites, there would be 80 principal investigators. 25 We can pull the paper if you want. Page 56
1 A. Not defined, no. 2 Q. In your mind as a physician, what would 3 you consider to be something other than large scale? 4 A. Never really thought of it that way, but, 5 you know, typically phase Is are very small. Phase 6 IIs are medium-sized. There are some larger phase 7 IIs. But most phase IIIs have to be large scale to 8 meet the FDA's criteria for adequately controlled 9 randomized clinical trials. 10 Q. For a phase III trial, does the FDA 11 require a minimum number of participants? 12 MR. COBB: Objection, scope. 13 A. There are a million FDA trials from 14 vitamins to, you know, internal medicine drugs to 15 ophthalmology. The FDA makes you do a statistical 16 analysis and, based on that, will have sample sizes 17 that have to meet criteria. But to my knowledge, 18 there's no defined number of patients that have to 19 be in a trial. Up until very recently the agency 20 might have provided guidance on macular 21 degeneration, but that was in the last two or three 22 years. 23 Q. Okay. And just to confirm, for both 24 MARINA and ANCHOR you were the principal 25 investigator? Page 55	1 Q. Okay. And is that -- does that also apply 2 to the PIER trial as well? 3 A. That would be the same. 4 Q. Okay. And jumping ahead a little bit, but 5 you were also the principal investigator for your 6 site for the PIER trial? 7 A. That is correct. 8 Q. And were you the principal investigator 9 for the full duration of the phase IIb PIER trial? 10 A. I was. 11 Q. And there -- just to confirm, there would 12 have been principal investigators at all the other 13 sites for the PIER trial? 14 A. Correct. 15 Q. And do you know ballpark how many sites 16 there were for the PIER III -- PIER IIb trial? 17 MR. COBB: Objection, form. 18 A. Yeah, I'd be -- I'd be guessing. We can 19 pull the paper. 30 or 40 probably, maybe 50, 60. 20 Who knows? 21 Q. In paragraph -- sorry. Moving to 22 paragraph 16. And this -- 16 is primarily directed 23 to the MARINA trial, correct? 24 A. That's correct. 25 Q. Oh, and I forgot to ask you. Just for the Page 57

1 record, what does it mean for a trial to be 2 randomized? 3 A. Randomization means that you pick a cohort 4 of patients with similar entry criteria, and then 5 you have certain groups of patients that are treated 6 differently. And MARINA patients got either 7 0.3-milligram ranibizumab or 0.5-milligram 8 ranibizumab or sham injections. 9 So the 716 patients that went into the 10 trial were then randomized typically by a computer 11 algorithmic system where you divide it into three 12 groups, and based on luck of the draw, you get 13 assigned to one of the groups with which that 14 clinical trial protocol is given to you throughout 15 the course of the study. 16 Q. And the particular patients wouldn't know 17 which of the three options they would actually 18 receive? 19 A. So, patients shouldn't know, and the 20 investigator doesn't know as well. In other words, 21 in all of these randomized trials, there are two 22 investigators that see the patient at every visit. 23 One's called masked, and that's because they don't 24 know what the patient's getting. And one is 25 unmasked because they actually have to administer Page 58	1 most of us don't feel that's ethical. 2 So a sham injection is a injection of a 3 numbing medicine around the eye, which both groups 4 get. So they do get the numbing medicine. But then 5 one group actually gets an injection with a needle 6 into the eye with an active agent. The other one, 7 the unmasked investigator fakes it. He puts a 8 syringe with no needle, presses on the eye, and 9 pretty effective at patients thinking they got 10 something done to them. So -- 11 Q. I see. Thank you for that. I appreciate 12 that. 13 Last sentence of paragraph 16, you say, 14 "The primary endpoint of the study was the 15 proportion of subjects losing fewer than 15 letters 16 from baseline visual acuity at 12 months." 17 What does it mean to lose fewer than 15 18 letters from baseline visual acuity? 19 A. So prior to these -- this amazing, really, 20 paradigm shift in the treatment of macular 21 degeneration, everyone went blind. And so the prior 22 attempts at treatment involved either laser photo 23 coagulation; in other words, frying the center of 24 the vision to limit the size of your eventual blind 25 spot, and it's hard to prove that that's good for Page 60
1 the protocol treatment. 2 Q. Okay. And for MARINA, were you masked or 3 unmasked? 4 A. MARINA, I was unmasked. Principal 5 invest- -- I mean, I'm sorry, I was masked. I 6 apologize. Principal investigators are almost 7 always the masked investigator, and that is because 8 if you have a side effect, you don't want to be 9 biased, "Could this be from this experimental drug 10 or not." In other words, there's a heart attack and 11 I know that the patient got a sham. Could it be 12 related to the sham? I doubt it, unless they're 13 afraid of the needle coming at them. 14 However, if I don't know what they have, I 15 may say that, yes, it could be related to the 16 procedure. And if there's no heart attack 17 associated with the therapy, then by randomization, 18 you should have an equal number of heart attacks in 19 your sham group as your control group. 20 Q. And in terms of sham injections, are those 21 actual physical injections? 22 A. So yes and no. You know, the -- our 23 injections involve putting a needle all the way into 24 the center of your eye. And that, by definition, 25 has a risk of infecting the center of your eye. So Page 59	1 someone to make them worse and to -- but to have a 2 smaller, you know, a blind spot the size of, say, a 3 basketball instead of a blind spot the size of a 4 beach ball. 5 So in those studies, the only way they 6 could really figure out if it was effective was to 7 see what percentage of patients didn't lose 15 8 letters, which is three lines of visual acuity. In 9 other words, you've seen an eye chart at your 10 doctor. If you begin the eye chart, you know, at 11 one line and you lost all that line and then you 12 lost all the line above it, the bigger line, and 13 then you lost all the line above that, then you lost 14 three lines. 15 So believe it or not, an effective therapy 16 then was seen as those who got a letter or two right 17 on that third line. That is how verteporfin PDT was 18 approved with that low bar. And as the comparator 19 for ANCHOR was that low bar, that was the comparator 20 for both ANCHOR and MARINA since they were parallel 21 trials. 22 Q. Got it. And just to understand more 23 baseline, baseline visual acuity, that's the 24 reference point at the beginning versus where they 25 are at 12 months? Page 61

1 A. Yes. So in a macular degeneration or any 2 kind of retina trial, we do a very -- the doctor 3 doesn't. The doctor couldn't do it if you made him 4 probably, but we have refractionists that do a -- 5 you go to the eye doctor and they say, "What's 6 better, this or this." And you do that a couple of 7 times and they hand you your glasses, right, or give 8 you a prescription. 9 There is a specific 30-minute refraction 10 where they do very -- the exact same things to every 11 patient to see if they can get the absolute, squeeze 12 the best possible visual acuity out of the eyeball 13 for the visual acuity measurement. 14 When we do it the first time at baseline, 15 that's the baseline visual acuity. They then go 16 along, and typically every month in ANCHOR and 17 MARINA, they get that same 30-minute refraction to 18 see did they gain any vision or lose vision in that 19 month and then the next month and then the next 20 month. 21 So if you go from baseline to 12 months, 22 you're counting how much vision they gained or lost 23 between the start of the trial when you haven't done 24 your experiment to them and then the end of the 25 trial. Page 62	1 right? 2 A. That's correct. 3 Q. All right. Do you know, was there a 4 specific reason attributed to why those patients 5 either did not maintain or lost vision? 6 A. No specific common denominator. Our 7 thought is that most of those patients came in 8 really too late to help them. In other words, the 9 brain is really good at ignoring one-eye troubles. 10 So a lot of times you or your grandma or whatever 11 doesn't really realize that she has trouble until 12 she kind of gets one eye covered and she goes, Oh, 13 my God, I can't see in that eye. 14 If you come in when the eye is too far 15 gone, our treatments don't help. And so that's -- 16 my personal opinion is that the majority of those we 17 could have done better if we would have caught them 18 in time, but -- 19 Q. Okay. And then in terms of the mean 20 increases that you reference in the last sentence of 21 paragraph 17, an improvement of 6.5 letters for the 22 .3-milligram and improvement of 7.2 letters for the 23 .5-milligram? Is that right? 24 A. That's correct. 25 Q. And then the sham injections, there was a Page 64
1 Q. I understand. And again, if I'm going 2 astray, I apologize, but is that -- is that test, 3 that 30-minute test, when I go to the eye doctor 4 they put in some drops and then I take the test, is 5 that the same kind of thing? 6 A. So it's -- it would be a expanded dance 7 version that's very scientifically precise. And 8 for -- your eye doctor may give you the drops and do 9 it. These are all done before any drops are given. 10 In other words, these are all done when 11 the patient comes in and -- because the drops could 12 affect that, depending on how long they take to work 13 and such. Your doctor is trying to not have you 14 wait in the office four hours, probably, like our 15 research patients. 16 Q. Got it. Okay. Let me turn you to the 17 next paragraph, paragraph 17. And again, this 18 appears to be more facts concerning MARINA. In the 19 first sentence, you state that nearly 95 percent of 20 the subjects treated maintained or improved vision 21 in 12 months. Do you see that? 22 A. I do. 23 Q. So there is some small percentage, a 24 little more than 5 percent, that either did not 25 maintain or lost vision at 12 months? Is that Page 63	1 decrease of 10.5 letters. But that would still be 2 within -- that would still be fewer than the 15 3 letters that was the endpoint of the study, right? 4 MR. COBB: Objection, form. 5 A. So the average patient in the sham 6 injection in MARINA did not have 15 letters of loss. 7 However, they were -- they were -- they had lost the 8 line that they read and then they lost the whole 9 next line and they lost a half letter in that third 10 line. So they were certainly not happy patients 11 compared to the ones that read the letter they came 12 in with, the line, and then a whole 'nother line, 13 which is five letters, and then a few letters on 14 that next line. 15 So there was a massive difference between 16 patients randomized to the active control -- the 17 active agent, ranibizumab, than those in the sham 18 one. 19 Q. Okay. Now, in paragraph 19 you transition 20 to the ANCHOR trial. And I'll direct your attention 21 to paragraph 19 on page 9, but it looks like ANCHOR 22 and MARINA essentially overlapped for most of the 23 trials? Is that fair? 24 MR. COBB: Objection, vague. 25 A. You mean in time frame? Page 65

1 Q. Yes. 2 A. Yes. So we were recruiting two groups of 3 patients. Patients come in with macular 4 degeneration, and prior to -- prior to this, they 5 were classified based on a dye test we injected into 6 a vein. And macular degeneration, wet macular 7 degeneration is a problem where new blood vessels 8 grow through the back wall like weeds go through the 9 cracks in concrete. If those new blood vessels grow 10 underneath the retinal pigment epithelium, which is 11 the supporting layer of the retina, but not through 12 it, it doesn't show up very well in the dye tests. 13 We call that occult choroidal neovascular membrane 14 because you know it's there like a ghost but you 15 can't exactly see it specifically. Photodynamic 16 therapy was not shown to be effective in those 17 patients. 18 So MARINA, we don't subject them to 19 photodynamic therapy since it didn't work. They 20 went against sham. If those weeds or new blood 21 vessels grow through the retinal pigment epithelium 22 underneath the retina, it shows up much more 23 specifically on a fluorescein angiogram. 24 So it's called classic. Those are ones 25 that PDT had a modest effect on. And so ethically, Page 66	1 0.3-milligram arm, and 10.7 was in the 0.5-milligram 2 arm. And the 0.5-milligram is what went on to FDA 3 approval and indication for wet AMD. 4 Q. And the patients that only received the 5 PDT, they saw a decline in 9.8 letters? 6 A. That's correct. 7 Q. All right. So then it looks like in your 8 declaration we transition to -- and I'm moving to 9 section B on page 11. This is PIER and other trials 10 testing less frequent ranibizumab. Sorry. 11 A. Ranibizumab. 12 Q. Ranibizumab. I'll get it. 13 A. I've been saying it for 20 years, so I 14 don't fault you for having trouble saying it. 15 Q. I appreciate that. 16 So in paragraph 22, you reference, looks 17 like, five other trials, SUSTAIN, EXCITE, PrONTO, 18 SAILOR, and PIER, correct? 19 A. That's correct. 20 Q. And just to be clear, I think that other 21 than paragraph 22, you don't in your declaration 22 provide any more details about SUSTAIN, EXCITE, 23 PrONTO, or SAILOR. Is that fair? 24 A. That's correct. 25 Q. Okay. And is there a reason that you Page 68
1 that population we had to give the best thing we 2 had, which is PDT, and then randomized with the 3 ranibizumab arms .3 and .5 against that. It turns 4 out classic membranes are much more aggressive. 5 Patients lose vision faster in natural history. And 6 so they do react differently. 7 And it took longer to recruit the classic 8 membranes. It took longer to recruit ANCHOR to 9 finish it and get results than it did MARINA, but 10 they started within a month or two of each other. 11 It just took longer to recruit that classic 12 component patient population. 13 Q. And you used the acronym "PDT." Is that 14 photodynamic verteporfin therapy? 15 A. Yeah, I apologize. Photodynamic -- PDT 16 stands for photodynamic therapy. PDT, the agent 17 used is verteporfin, or was back then. We don't use 18 it much anymore. 19 Q. Got it. And in terms of the results of 20 ANCHOR, which I think you set forth in paragraph 20, 21 it looks like the improvement there was either 8.1 22 letters or 10.7 letters? And I'm assuming 8.1 is 23 for -- or maybe -- I apologize. Is there -- was 24 there just one dosage of -- 25 A. No, there were two doses. 8.1 was in the Page 67	1 chose not to provide any factual information about 2 those particular trials? 3 A. They -- for the most part, they showed -- 4 you know, SUSTAIN was sort of the European version 5 of PIER. EXCITE was a version where you got PRN 6 instead of -- you know, instead of every three 7 months, and SAILOR was the same thing in the U.S. 8 Neither one of them showed a significant 9 change from PIER, so -- 10 Q. So you compare the results of those and 11 chose -- and -- 12 A. That's one reason. The other reason was 13 the European trials I obviously didn't participate 14 in. Right? SAILOR I was a participant in, but it 15 was a trial that ended up losing a lot of patients 16 because the drug became available and so it kind of 17 made the trial superfluous. Right? 18 And so the only trial that I participated 19 to any extent in was SAILOR, and it really wasn't 20 that great of a trial. PIER was the significant 21 trial that showed us ranibizumab was not effective 22 when given three doses and then quarterly. 23 Q. Okay. And so in terms of firsthand 24 information, you would have had firsthand 25 information about SAILOR and PIER but not SUSTAIN, Page 69

1 EXCITE, and PrONTO? 2 A. Correct. 3 Q. And did those SUSTAIN, EXCITE, PrONTO, and 4 SAILOR, were those also quarterly treatments after 5 some initial set of treatments, or was their dosage 6 different? 7 A. SUSTAIN, EXCITE, SAILOR were quarterly 8 after a load. PrONTO was a small 9 investigator-sponsored trial by Phil Rosenfeld in 10 Miami without a control arm where patients were seen 11 up to every week and given PRN dosing. So that was 12 a very small, unique trial that wasn't a 13 registration or a -- it wasn't a registration trial 14 or a randomized control trial. 15 Q. And PRN, that stands for pro re nata? 16 A. Yeah. Means you wait until you see any 17 evidence of disease and then you treat. "As needed" 18 is another way of saying it. 19 Q. And in paragraph 22, you indicate that 20 the -- you state that, "Each of these prior art 21 studies with Lucentis demonstrated inferior results 22 to the fixed monthly dosing regimen of ANCHOR and 23 MARINA." 24 What do you mean by "inferior results"? 25 A. In ANCHOR and MARINA, patients who were Page 70	1 back then, but now PubMed, you put a study group in 2 and if your son is a med student and he's listed as 3 the study group, he would list in PubMed. And so it 4 gives recognition to people doing work. 5 Q. I see. And with respect to paragraph 23, 6 I think you state that, "The PIER study" -- I'm just 7 going over the last sentence -- "The PIER study 8 revealed that fixed quarterly intravitreal 9 injections of ranibizumab over an extended treatment 10 period was not an effective method of treatment." 11 Is that right? 12 A. That is correct. 13 Q. Okay. Do you agree that the PIER dosing 14 of three monthly doses followed by quarterly dosing 15 provided significant visual acuity benefit to 16 patients? 17 A. So as the PIER trial was randomized to 18 sham treatment, which is in modern paradigm 19 catastrophic because you lose all your vision, it 20 provided a statistically significant change in 21 visual acuity compared to that sham arm. 22 However, compared to MARINA/ANCHOR where 23 you gain vision and maintain it, the loss of 24 those -- of that hard-fought vision gain was 25 heart-wrenching to me as an investigator. When I Page 72
1 randomized to ranibizumab gained vision literally in 2 the first month, continued to gain, and then 3 stabilized that vision with continued monthly 4 therapy. In all the trials doing less than monthly 5 dosing, three doses in Q12, they got the same 6 benefit from the first three doses, as you might 7 imagine, but then lost those gains over time to 12 8 months, which was the endpoints of SUSTAIN and 9 EXCITE. SAILOR kind of got extended because it was 10 an extension trial. 11 Q. Okay. And then in paragraph 23 we kind of 12 get into the nuts and the bolts of the PIER study. 13 And I think you said that the dosage there for the 14 PIER study was three monthly doses followed by fixed 15 quarterly? 16 A. That's correct. 17 Q. And what was -- you referenced the PIER 18 study group. What was the PIER study group? 19 A. Yeah, PIER study group would just be all 20 the investigators, clinical investigators, 21 sub-investigators that were part of the PIER group. 22 We started doing that to really allow investigators 23 that worked on the trial but weren't necessarily an 24 author to get recognition. 25 In other words, I don't know if it was Page 71	1 saw that data the first time, I felt like I'd been 2 hit in the gut because I felt like I had not treated 3 those patients the way I thought I had. 4 When you play golf, you remember the shots 5 and down the fairway. You don't remember the ones 6 you lose in the woods. It's a randomized trial when 7 you really see how an average population does. And 8 while technically we met the primary endpoint of 9 being better than sham, because of ANCHOR and MARINA 10 we knew what we could get, and this was not that 11 effective visual acuity gain with maintenance that 12 we now come to expect from an anti-angiogenic eye 13 treatment. 14 Q. Okay. And now, you mentioned that with 15 the sham treatments that it was catastrophic because 16 you lost all vision. But in the ANCHOR trial -- I'm 17 sorry. In the MARINA trial, the sham patients lost 18 9.8 letters? I'm sorry. Let me rephrase that. 19 In the -- in the MARINA trial, the -- 20 let's see -- the sham patients lost -- I'm just 21 looking for the number. 22 A. 10.5 letters. 23 Q. 10.5 letters. So that isn't going blind, 24 right? 25 A. Legal blindness is 2200 visual acuity in Page 73

1 your best-seeing eye as it pertains to most states 2 in the United States and for Social Security. You 3 know, these trials involve only one eye. So if 4 their other eye is already blind and they get to 5 2200, sure, they're legally blind. 6 Some subsequent papers reported rates of 7 legal blindness. And certainly way more patients in 8 the sham arm went legally blind compared to the 9 control arms, but they're not listed in the primary 10 manuscripts for ANCHOR or MARINA. 11 Q. I see. And so it is fair to say that in 12 the PIER trial that the treatment was an effective 13 method in comparison to the sham injections? 14 MR. COBB: Objection. Asked and answered. 15 Form. 16 A. Because we compared it to no treatment at 17 all, there was a statistical benefit from 18 undertreatment with ranibizumab as we demonstrated 19 in the PIER trial three doses and quarterly. 20 However, if you looked at page 14, 21 paragraph 28, we instituted -- actually before that, 22 we instituted two protocol amendments because we 23 felt they were ethically imperative. One, once the 24 12-month data from ANCHOR and MARINA showed that we 25 have an effective therapy, we stopped treating Page 74	1 it provided significant visual acuity benefit to 2 patients? 3 MR. COBB: Objection. Mischaracterizes 4 his testimony. 5 A. So would I rather get one or two doses of 6 an effective therapy or none? I'd rather get one or 7 two. The PIER dosing demonstrated, compared to a 8 sham arm where they got no treatment at all, a 9 visual acuity difference with those to about month 10 12. We stopped the quarterly dosing once we knew 11 that it was that ineffective. So we really don't 12 know how bad it would have been if we would have 13 continued to underdose those patients over time. 14 Would they have reached the low level of 15 the sham arm? I don't know. We'd have to run that 16 trial that way, and that's not ethically to do. But 17 the investigators and the study sponsor felt it was 18 so important that they change the trial, and that is 19 very hard for a sponsor to do. 20 Q. Once they made those protocol amendments, 21 did every patient in the study that was part of the 22 sham portion change? 23 A. So when you start to recruit a study, it 24 takes awhile before you reach the end of 25 recruitment. You don't get the one-year data till Page 76
1 patients with sham and we started giving them 2 .5-milligram ranibizumab. That's in paragraph 27. 3 That's called a crossover amendment. 4 But I direct you to paragraph 28, and it 5 is a direct result of the review of the 12-month 6 PIER data and the disappointing lack of efficacy in 7 subjects in the treatment arms. The study was 8 amended to provide all patients remaining in the 9 study to roll over to 0.5-milligram ranibizumab 10 monthly for the remainder of the study. 11 The second year was functionally designed 12 to give confirmation of the fixed quarterly dosing's 13 efficacy. And given the disappointing lack of 14 efficacy, the study sponsor initiated this rollover 15 basically at the -- at the push of the 16 investigators, such as myself and others, because it 17 just wasn't ethically correct to continue to 18 undertreat them. 19 Q. And back to a statement you made. I think 20 you said that the PIER dosing of the three monthly 21 doses followed by quarterly dosing provided 22 statistically significant visual acuity benefit to 23 patients. And I just want to understand that. 24 So does it have to be statistically 25 significant, or is it your position that it was -- Page 75	1 that last patient finishes the one year. By that 2 point, many of the initial patients are quite a ways 3 through the second year. And some patients might 4 have even been -- some patients were even finished 5 before that opportunity. 6 So there's quite a few patients that did 7 not have an opportunity to roll over because they'd 8 already finished the two years. Once those 9 amendments come through, the investigators present 10 to the patients, "Do you want to do this?" And I 11 can't imagine any patient turning it down, but I 12 don't know that answer. 13 Q. Okay. Dr. Brown, did you consider the 14 PIER trial to be a failure? 15 A. I did. 16 Q. And is it fair to classify it as a 17 miserable failure? 18 MR. COBB: Objection, form. 19 A. I don't like to lose. Failures are 20 failures. 21 Q. Okay. I'm just trying to understand if 22 you agree with the statement that the PIER trial was 23 a miserable failure. 24 MR. COBB: Objection. Asked and answered. 25 Form. Page 77

1 A. I personally felt miserable that I 2 enrolled patients into a trial with a drug that I 3 thought was going to give them sustained visual 4 gains, but it turns out our underdosing schedule 5 caused them to not be able to maintain and lose 6 those gains. 7 Q. So I'll ask you one more time. 8 Did you -- setting aside about how you 9 felt, very specifically, did you consider the PIER 10 study to be a miserable failure? 11 MR. COBB: Objection. Asked and answered. 12 A. Yeah, I don't know that I really thought 13 of that miserable failure versus failure. It was a 14 failure. 15 Q. All right. So in your -- one of your past 16 depositions, and I'm happy to give you the 17 transcript if you don't recall it, but you stated, 18 "The PIER study was to -- was to see could patients 19 get by with less frequent dosing, and it was a 20 miserable failure." 21 Do you recall giving that testimony? 22 A. I don't recall giving it specifically, but 23 I don't have a problem with that statement. 24 Q. Let's have you look at another exhibit. 25 This is Exhibit -- it's Exhibit 1021. And 1021 is Page 78	1 publication October 5th, 2007? Is that right? 2 A. That's correct. 3 Q. And did you draft this publication? 4 A. I participated in the review of the 5 manuscript but did not draft the manuscript. 6 Q. And do you know who did draft the 7 manuscript? 8 A. Yeah, with -- you know, the first author, 9 Carl Regillo, would have been the primary drafter 10 along with the Genentech authors listed. 11 Q. And who is Carl Regillo? 12 A. Carl Regillo is a clinical professor of 13 ophthalmology at Wills Eye Institute in Philadelphia 14 and a scientific researcher and colleague I've been 15 working with for 25, 30 years. 16 Q. What was his involvement in the PIER 17 trial? 18 A. Carl was another principal investigator in 19 the PIER trial. 20 Q. And he was a principal investigator at his 21 particular site? 22 A. Correct. 23 Q. And would that have been in Philadelphia? 24 A. Correct. 25 Q. Okay. And I think you said that -- so he Page 80
1 the exhibit number from the '572 IPR. And I've 2 added it to the -- to the Exhibit Share, but maybe 3 you have it also. 4 And this is -- the document is entitled, 5 "Randomized, Double-Masked, Sham-Controlled Trial of 6 Ranibizumab for Neovascular Age-related Macular 7 Degeneration: PIER Study Year 1." 8 Do you have a copy of that or do you see 9 it, Dr. Brown? 10 A. I do. I have a copy. Yeah, I have a 11 copy. 12 Q. Okay. Great. And do you recognize this 13 document? 14 A. I do. 15 Q. Okay. And you're one of the authors of 16 this document? 17 A. Yeah, I'm the second named author. 18 Q. All right. And do you know the other 19 authors? 20 A. I do. 21 Q. And one of them is that inventor on the 22 Shams prior reference, Dr. Naveed Shams? 23 A. Naveed Shams, correct. 24 Q. Got it. Okay. And this was -- this 25 particular publication, it was accepted for Page 79	1 would have drafted the manuscript? 2 A. I only know what I do when I draft 3 manuscripts. If I'm the first author or 4 corresponding author, I play a major role in the 5 drafting of all the wording. Some -- some use 6 industry writers to help start the process and then 7 guide it. Carl's a pretty -- he's like me. I bet 8 he took a responsible role as lead author. 9 Q. And did you speak to Dr. Regillo in 10 preparation for the '572 IPR declaration? 11 A. I've certainly seen him at local meetings 12 in the last six months, but we haven't talked about 13 this at all. I don't know that he knows I'm even 14 doing it, yeah. 15 Q. Okay. Got it. And this was a -- this 16 particular publication, this was a document you 17 reviewed yesterday in preparation for today's 18 deposition? 19 A. Yeah, I looked at it yesterday. 20 Q. Got it. And on the -- on the front page 21 of the document, page 1, on the left column you see 22 there's a "Conclusions" sentence? 23 A. I do. 24 Q. And that sentence states, "Ranibizumab 25 administered monthly for three months and then Page 81

1 quarterly provided significant VA benefit to 2 patients with AMD-related subfoveal CNV and was well 3 tolerated. The incidence of serious ocular or 4 non-ocular adverse events was low." 5 Did I read that correctly? 6 A. I see that. Yeah, you did. 7 Q. Okay. And do you agree with that -- that 8 conclusion? 9 MR. COBB: Objection. Document speaks for 10 itself. Form. 11 A. So if you look at Figure 1 best explains 12 it. Figure 1 demonstrates that patients who got 13 ranibizumab gained right at five letters. But by -- 14 they were going down by month 4. Got additional 15 dosing at month 5, but were still going down at 16 month 6, 7. Additional dosing at month 8, we're 17 going down, 9, 10. Got a dose at 11, and one month 18 later .2 letters, a bit above or what they were than 19 the month before but nowhere near those gains. 20 And so if you compare that to the sham 21 arm, they lost 16 letters. Would I rather lose a 22 little bit of a letter or letter and a half, or 23 would I rather lose 16 letters? Sure, I'd rather 24 lose a letter or so. However, if you go to the 25 final conclusion paragraph, I say, "Observations Page 82	1 correct. 2 Q. Okay. So there are some patients that the 3 quarterly dosing was effective, correct? 4 MR. COBB: Objection, form. 5 A. You'd have to look at each individual 6 patient. 7 Q. Okay. And then if we look at that same 8 page, which is page 247 of the publication, page 9 9 in the lower right, about the middle of the column 10 on the right, it says, "Considered together, we 11 conclude that although this regimen provided 12 clinically meaningful and statistically significant 13 benefit to patients, the outcomes were not as strong 14 as those observed with monthly dosing of 15 ranibizumab, suggesting that some patients may 16 require dosing on a more frequent schedule such as 17 that used in the MARINA and ANCHOR studies." 18 Hopefully I read that correctly? 19 A. Yeah, I'm just looking for it again. 20 (Reading sotto voce) Yeah. 21 Q. And do you agree with that sentence? 22 A. I agree that it's clinically meaningful 23 over not treating patients at all. So -- which 24 is -- there are patients that may not have access or 25 be able to be treated with our best regimens and Page 84
1 from" -- I'll read the whole conclusion. 2 "In conclusion, ranibizumab monthly 3 provided visual acuity benefit to patients and was 4 well tolerated. However, observations from MARINA 5 and ANCHOR trials suggest the PIER regimen of every 6 three months after three quarterly doses provides 7 less benefit." 8 My goal is to provide the best treatment 9 and the best benefit, and this treatment did not 10 provide that. 11 Q. And apologies. Where were you reading 12 from? 13 A. Yeah, that's the last -- I'm sorry. That 14 is the last paragraph of the "Discussion," page 9 in 15 your pagination or page 247 in, I guess, the 16 pagination of the paper. It's the last paragraph. 17 Q. I see. 18 A. And then the graph I showed you would be 19 on your pagination 5, Figure 1. 20 Q. Okay. And that last paragraph -- I think 21 you read the first two sentences of the last 22 paragraph. The third sentence says, "Monthly dosing 23 may be necessary in some patients to achieve maximal 24 treatment benefit from ranibizumab." 25 A. Yeah, it's the last sentence of that, Page 83	1 best drugs. As a physician, we give them the best 2 we have. It's certainly better than no treatment at 3 all, but it pales in comparison to what's possible 4 as we demonstrated in MARINA and ANCHOR. 5 Q. And if we go to the Figure 1 that you 6 referenced, which is on page 243 or page 5, there at 7 the -- at the 12-month point, the figure indicates a 8 16.1-letter difference between sham and I believe 9 the .3-milligram dosage? Is that correct? 10 A. I -- it's kind of small, but I think it's 11 against .5, but -- 12 Q. Okay. And the 14.7-letter difference is 13 between .3 and sham? 14 A. Correct. 15 Q. Okay. So -- let's see. So with the 16 .5 milligrams after a year of the three treatments 17 plus quarterly, those patients, the mean loss was 18 just .2 letters, correct? 19 MR. COBB: Objection. Document speaks for 20 itself. 21 A. I'm sorry. Repeat the question one more 22 time. I was -- 23 Q. Yeah, yeah. So I think it's for the 24 .5 milligrams at the end of 12 months, the number 25 that we see in Figure 1 for visual acuity loss is Page 85

1 .2 letters? Is that right? 2 A. Compared to when they came in at baseline, 3 they gained approximately five letters with the 4 three doses, lost all that, and had lost actually a 5 smidge less than baseline on average by week -- by 6 month 12. 7 Q. Okay. So comparison from baseline at the 8 beginning to treatment at the end of 12 months was 9 they had lost .2 letters, .2 -- 0.2 letters? 10 A. I see that in the graph. 11 Q. Okay. And for the 0.3 milligrams from the 12 beginning of the study to 12 months, those patients 13 had lost 1.6 letters? 14 A. Correct. 15 Q. Okay. And then I think the sham patients, 16 those patients at one year had lost 16.3 letters? 17 A. That's correct. 18 Q. Okay. And at -- let me -- may have a few 19 more questions about that exhibit, so maybe keep 20 that handy. 21 A. Yeah, to answer your question from 22 earlier, I just -- this is fascinating. If you look 23 at Figure 2, you see that in the last -- the bottom 24 sort of bar graph, you had 5 percent of patients in 25 the .3 arm that were legally blind in that eye on Page 86	1 THE VIDEOGRAPHER: The time is 11:54 a.m. 2 We are on the record. 3 BY MR. ERWINE: 4 Q. All right. Welcome back, Dr. Brown. 5 I wanted to stay within your '572 6 declaration, and if we can move to paragraph 24 7 which is on page 12 of the declaration. 8 A. Correct. 9 Q. And in this particular paragraph, I think 10 you're talking about some of your expectations after 11 MARINA and ANCHOR. And in the last sentence, you 12 said that, "I thought it would be feasible to find a 13 longer dosing interval that would maintain at least 14 some of the initial vision gains, and I thought the 15 PIER dosing schedule was likely to work for this 16 purpose." 17 So first of all, do you know who was 18 responsible for the PIER dosing schedule, for coming 19 up with it? 20 A. I don't. I'm assuming Genentech. 21 Q. And that dosing schedule was the three 22 monthly injections followed by quarterly injections? 23 A. Correct. 24 Q. Do you know if other longing -- I'm sorry. 25 Do you know if other longer dosing Page 88
1 presentation and 16.4 at baseline and the .5, and at 2 the end of the study you had more patients legally 3 blind than when you started. It went from 5 percent 4 to 23.3 and 16.4 to 24.6. 5 I don't know the specific numbers for 6 ANCHOR and MARINA, but we had less patients legally 7 blind in the treatment arms at the end than we did 8 at the beginning. So in my mind, that's a failure. 9 Q. Okay. So let me take you to -- back to 10 your declaration. 11 MR. COBB: Counsel, if you're done with 12 that document, it's been over an hour. 15 minutes? 13 Do you want to do a quick break? 14 MR. ERWINE: I'm happy to take a break. 15 I'm actually -- I think I'll have some more 16 questions, but it's a -- it's fine to take a break 17 now if you'd like. 18 MR. COBB: Yeah, I'll take a short one. 19 THE WITNESS: Thanks a lot. 20 MR. ERWINE: Okay. 21 THE WITNESS: Your body will appreciate 22 that. 23 THE VIDEOGRAPHER: Time is 11:34 a.m. We 24 are off the record. 25 (Recess from 11:34 to 11:54) Page 87	1 intervals were considered other than quarterly? 2 MR. COBB: Objection, form. 3 A. I don't know. 4 Q. All right. Do you know if anyone else 5 suggested other longer dosing intervals other than 6 quarterly? 7 A. Not that I know of. 8 Q. Did you? 9 A. I did not. 10 Q. And paragraph 25 I think goes back to the 11 result of the PIER trial. And there -- consistent 12 with I think what we talked about with Figure 1, by 13 month 12 the 0.3-milligram study arm saw a minus 14 1.6-letter difference from baseline visual acuity 15 and the 0.5-milligram study arm saw a 0.2-letter 16 difference from baseline. You referenced Figure 1. 17 Is that consistent with what we talked 18 about earlier, Dr. Brown? 19 A. That's correct. That's numbers from 20 Figure 1. 21 Q. And understanding that those are, I 22 believe, the mean numbers, is it your understanding 23 that some patients did experience gains or that the 24 visual acuity remained the same at that 12-month 25 point? Page 89

1 MR. COBB: Objection, form. 2 A. So we don't list individual patients, but 3 sure, a mean is -- there's patients that do really 4 well and patients that do really poorly, and the 5 mean is the, just like it sounds, the average visual 6 acuity gain or loss from baseline. 7 Q. Okay. And then in paragraph 26, this is 8 on page 13 of your declaration, you introduce 9 something called optical coherence tomography or 10 OCT? Is that right? 11 A. That's correct. 12 Q. What is OCT? 13 A. Optical coherence tomography is an amazing 14 breakthrough in imaging that happened almost 15 simultaneously with the anti-VEGF trials. And it's 16 where a beam of light is used with an oscillating -- 17 kind of like your television, you don't need to know 18 exactly how it works to watch TV, but it allows very 19 precise imaging of layers within the retina that we 20 can't see with our naked eye or looking at it. 21 In other words, it's almost like a CT scan 22 without any radiation or -- and acquired in several 23 seconds. So OCT allowed us to really see changes in 24 the retina and revolutionized our treatment of 25 retina almost as much as these anti-VEGF drugs. It Page 90	1 frequent dosing or do they have a problem that I 2 didn't recognize. 3 Q. And do you agree that OCT is the best tool 4 for tailoring treatment for a patient? 5 MR. COBB: Objection. Asked and answered. 6 A. OCT is a great tool. I'd hate to live 7 without it. 8 Q. Are you uncomfortable with the statement 9 that it's the best treatment or best tool to help 10 patients tailor treatment? 11 A. You know, I hesitate to say that our 12 clinical exams aren't super important because they 13 sure are. You know, we can see hemorrhage on a 14 clinical exam where we can't see on an OCT. You 15 know, it's like picking your favorite kid. I don't 16 know that I could say that OCT is my absolute 17 favorite. It's certainly the one that's used the 18 most frequently and probably the workhorse of our 19 clinic. 20 Visual acuity is certainly what patients 21 care about, and that's what the -- the FDA doesn't 22 approve anything on OCT. They only approve based on 23 visual acuity gains or losses. So the Food and Drug 24 Administration has not -- does not feel that it's 25 the best. Page 92
1 really changed the way we can see what's going on 2 and monitor activity. 3 Q. Got it. And OCT was something that was 4 used in the PIER study? 5 A. So you asked earlier how many sites were 6 in PIER, and I'm not exactly sure, but only about a 7 third of the sites had OCT. It was that early in 8 technology. So about a third of the patients had 9 OCT imaging and data, and the best of my 10 recollection, two-thirds did not just because it 11 wasn't -- it wasn't available at those sites. 12 Q. Okay. OCT is something that you consider 13 to be the best tool to help patients tailor 14 treatment. Is that right? 15 MR. COBB: Objection, form. 16 A. I would say it's the most clinically 17 available and useful tool. There are a lot of other 18 things. The clinical exam is still important. The 19 visual acuity is still important. How the patient's 20 doing's still important, you know, is grandma still 21 able to see her TV and recognize her grandkids. 22 So all of that's useful, but the OCT is 23 what's used probably the most day-to-day in clinical 24 patients by retina docs to say, is -- you know, is 25 the patient need more frequent dosing or less Page 91	1 Q. All right. And in paragraph 26 of your 2 declaration, you reference some of the OCT data from 3 Exhibit 1021. Is that right? 4 A. Correct. 5 Q. Okay. And that's -- if we go back to that 6 exhibit, Exhibit 1021, that's Figure 4? 7 A. That's Figure 4, yes. 8 Q. Yeah. And in the -- there's two different 9 charts in Figure 4? Is that right? 10 A. That's correct. 11 Q. And the top chart is the mean change in 12 foveal center point retinal thickness? Is that 13 right? 14 A. Correct. 15 Q. The bottom chart is the mean change in 16 central subfield retinal thickness? Is that right? 17 A. That's correct. 18 Q. In your declaration you only reference the 19 top chart, right? 20 A. That's correct. 21 Q. Okay. Is there a reason you didn't 22 reference the bottom chart in your declaration? 23 A. Not necessarily. 24 Q. Okay. And in the bottom chart, first with 25 respect to the 0.3 milligrams, at the -- at the Page 93

1 one-month point there was a change in the central 2 subfield retinal thickness. It dropped to negative 3 60? Is that right? 4 MR. COBB: Objection. Document speaks for 5 itself. Form. 6 A. So we're looking at the bottom graph here, 7 the .3 and the .5-milligram ranibizumab that 8 dropped, yes, 60 microns or so, yeah. 9 Q. Okay. And then it looks like at month 2 10 it dropped to about, I don't know, about 75? Is 11 that -- 12 A. I'll give you that, yeah. 13 Q. Okay. And then at month 3, it dropped to 14 looks like about 80? 15 A. Yeah. 16 Q. And then for the 3 milligrams at month 5, 17 it -- that would have been at two months. It was 18 back closer to about 75? 19 A. Yeah, and that's because there wasn't a 20 data recording at month 4. Right? You don't -- you 21 don't have -- you only have the data at the -- there 22 was not OCTs done at the -- at every month. Like, 23 the data -- the data points are the only data points 24 we had. In other words, OCT wasn't either read or 25 wasn't done at 4, 6, 7, 9 -- 9, 10 -- 9 or 10. Page 94	1 after your first loading dose, yeah. 2 Q. So for purposes of OCT, you would have 3 felt pretty good about the treatment at that point, 4 right? 5 MR. COBB: Objection, form. 6 A. Yes, so let's describe what we're looking 7 at and then -- center point thickness is the very 8 center point in an OCT, and that's where your visual 9 acuity is. Center subfield is an area of -- it's a 10 circle with a -- basically a millimeter circle of 11 the entire center. 12 With macular degeneration, wet macular 13 degeneration, if you have a lesion that's right in 14 the center like a bull's eye, the center point 15 thickness correlates pretty good with the center 16 subfield thickness. 17 If, however, you have a lesion that's 18 eccentric, like most of them, it's off to the side, 19 you can have a ton of swelling that's affecting the 20 center, but it -- the center subfield's not that 21 high because three quadrants are relatively normal. 22 So that's what I attribute the difference 23 along with a very small sample size. You only have 24 20 patients. It's kind of weird if you look at this 25 that we only have -- it must have been two different Page 96
1 Right? So -- 2 Q. Okay. And if we look at the 3 .5 milligrams, so at .3 it was -- it was at around 4 80, reduction to I'll call it negative 80. Is that 5 fair? 6 A. What -- where are we at? Three months? 7 Yeah. 8 Q. Yeah, three months. 9 A. Yeah. 10 Q. And then it looks like it even -- at five 11 months, for the .5 milligrams, it looks like it's 12 even a little lower, maybe around 81 or 82, negative 13 81 or 82? Is that right? 14 A. Looks a little lower, yeah. 15 Q. Okay. So that would have been at the 16 three-month point after the injection at month 2, 17 right? 18 A. Yeah, that would have been one month after 19 your third loading dose. 20 Q. Three months after the third loading dose, 21 right? 22 A. I'm sorry. Are we talking about month 5 23 now? 24 Q. Yeah, month 5. 25 A. Yeah. So five months, you're three months Page 95	1 types of OCT because why we have 41 patients in the 2 .5 arm in the top graph and only 20 in the bottom 3 graph means that, you know, it's only about half the 4 sample size. 5 So I'm just trying to imagine why those 6 numbers are different. Maybe the reading center 7 couldn't read 20 of them or -- this is -- anyway, 8 you're correct that 20 patients on .5 have a little 9 bit lower subfield thickness. But I would take -- I 10 would feel a lot better looking at the center point 11 thickness in 41 patients than the center subfield 12 which is a less accurate measurement of the center 13 point problems with visual acuity in age-related 14 macular degeneration. 15 Q. Interestingly, if we look at the center 16 point, we do the comparison at month 8 versus month 17 12, there's a decrease from about minus 90 to about 18 minus 120. Is that fair? 19 A. Yeah, you -- one of the -- wouldn't call 20 it gamesmanship, but one of the things you do when 21 you design a clinical trial, if you're trying to get 22 your best outcome at month 12, you give a dose the 23 month before. So in PIER, they all got a dose at 24 month 11. And so that really helps you a month 25 later compared to looking at something three months Page 97

1 before. 2 And so since there wasn't an OCT at month 3 11, which we probably should have done, you don't 4 really know what the benefit of that one dose was. 5 So, sure, on average, after given that dose at 11, 6 it helped, but I would have loved to have seen it at 7 10 or 11, but we don't have that data. 8 Q. Okay. Yeah, because it sure looks pretty 9 good at month 12 with respect to the OCT data in 10 both charts for purposes of continuing this 11 quarterly treatment, right? 12 MR. COBB: Objection, form. 13 A. The effects of the dose at month 11 give 14 you that. I would tell you from doing other trials 15 that if the -- if you took a dose -- you know, if 16 you got more points in there, you would see more of 17 a seesaw where it's going up and down with some 18 benefit from each shot anatomically. 19 The longer you allow disease activity and 20 edema in the retina, the less likely you are to be 21 able to resurrect visual acuity. So chronic 22 undertreatment over time, you lose potential for 23 vision gain, and that's exactly what we show in 24 Figure 1 where on average they lost all the gains 25 and were heading in the wrong direction. Page 98	1 These are major protocol amendments where 2 we changed the course of the randomization or the 3 eventual outcome. And there were only two major 4 protocol amendments. The crossover, which once we 5 found out that ANCHOR and MARINA worked, it wasn't 6 ethical to give sham anymore. And then the 7 rollover, once we figured out that underdosing with 8 three doses and then quarterly didn't work, it 9 wasn't ethical to continue to treat patients in that 10 manner. That was called the rollover amendment. 11 Q. All right. And so the second protocol 12 amendment, the one you reference in paragraph 28, 13 that's -- that was called a rollover amendment? 14 A. That was called a rollover amendment, 15 correct. 16 Q. Okay. All right. And so the first 17 amendment, did that have a name or was that just 18 the -- just a name? 19 A. Yeah, it was called the crossover 20 amendment. So you crossed over sham to active 21 therapy. 22 Q. Okay. And that crossover, that was a 23 change for the sham patients to instead receive 24 .5 milligrams of ranibizumab quarterly? 25 A. Correct. Page 100
1 Q. Okay. But to repeat for Figure 1, we're 2 seeing only a letter loss of .2 for the 3 .5 milligrams at 12 months, right? 4 A. You're seeing loss of all their mean 5 visual acuity gain. And in Figure 2, you're seeing 6 that more patients were legally blind at the end of 7 12 months than were at the beginning of 12 months, 8 which is certainly not our goal in our fight against 9 blindness. 10 Q. Okay. Now, in paragraph 27 of your 11 declaration, you -- this is where you start talking 12 about the two key protocol amendments to the PIER 13 study, right? 14 A. That's correct. 15 Q. Were there other protocol amendments 16 besides the two that you described in paragraphs 27 17 and 28? 18 A. Not that I recall. There are typically 19 protocol amendments all along. For example, they'll 20 change the reimbursement for travel per mile from 21 something to another, and that requires a different 22 informed consent. You know, there are often little 23 tweaks to the protocol throughout -- throughout a 24 trial design. How many protocol amendments there 25 were in PIER, I don't know. Page 99	1 Q. That was in February 2006. 2 A. February 2006, correct. 3 Q. So at that time was the expectation that 4 quarterly was effective as opposed to monthly? 5 A. We didn't know the results. We hadn't ran 6 the trial yet, so -- 7 Q. So in February you didn't have -- 8 February 2006 you didn't have the results? 9 A. No. 10 Q. Then why did you implement the crossover 11 amendment? 12 A. We had the results of MARINA and ANCHOR 13 demonstrating that sham therapy was -- sham therapy 14 was not efficacious and not ethical. You didn't 15 have the results of the one-year data from PIER 16 until all the patients finished one year after 17 recruitment. That's when the data was looked at and 18 said this quarterly dosing isn't working, we need to 19 put everybody on monthly. That's the rollover 20 amendment. 21 So you did -- the new data, you had 22 insti- -- you know, which initiated the crossover 23 amendment was the MARINA/ANCHOR data. 24 Q. Okay. But the MARINA/ANCHOR trials were 25 monthly, correct? Page 101

1 A. Correct. 2 Q. But the crossover amendment was changing 3 from sham to quarterly, correct? 4 A. That's correct. 5 Q. Okay. And when did you get the one-year 6 results from the PIER trial? 7 A. The one-year results from the PIER 8 trial -- and let me just -- let me just iterate one 9 thing. In terms of the -- the reason quarterly was 10 given to the sham arm is that if you would have gone 11 to monthly therapy in that arm, you would have 12 unmasked the trial. In other words, those patients 13 were coming in and they were getting -- no patients 14 were getting testing and injection or fake injection 15 except at months 5, 8, and 11. 16 So if you would have started treating them 17 at month 6, month 7, month 8, then there would have 18 been unmasking, and so the whole trial would have 19 been -- it was thought that that would impair the 20 scientific validity of the trial. It kept them on 21 their dosing schedule. They just went from sham 22 injection to real injection. 23 We got the results of the PIER trial. The 24 first results were presented by me, as it states, in 25 I think it was June 1st or June 2nd, 2006. And that Page 102	1 have the SEC, you know, raise eyebrows. 2 So that -- the data would have been 3 between ARVO, which is always the first week of May, 4 and this meeting which was the first week of June. 5 So that's when we found out for sure what the data 6 was. It then took, you know, a month or so, by 7 August 21st, to get new informed consents, present 8 to the IRB, and institute the rollover amendment. 9 Q. I see. And is there any -- any indication 10 in any of the documents you cited about the exact 11 date you received the results from the first year? 12 A. No, only the exact time it was presented 13 for the first time, which was at that Retinal 14 Physician Symposium. 15 Q. Okay. So we know it was some point -- 16 A. And that was me presenting -- that was me 17 presenting the data. That was my personal 18 presentation of the data. 19 Q. I see. And apologize for interrupting 20 you. 21 So we know you got the data at some point 22 before May 31st. We just don't know how much 23 earlier before May 31st that was. 24 MR. COBB: Objection. Asked and answered. 25 A. Like I said, would have been between ARVO Page 104
1 data literally was hot off the presses. That was -- 2 from Genentech I got that data probably a week or 3 two before that. And that's the reason it was 4 presented at this relatively obscure meeting instead 5 of ARVO, which would have been the first week of 6 May, because we didn't have the data then. 7 Q. And apologies. Where do you indicate that 8 you got that data? Is that somewhere else in your 9 declaration? 10 A. It's not. It just says I received 11 the first -- page -- paragraph 25, page 11, "As one 12 of the lead investigators on the PIER trial, I 13 received the first readout of the one-year data from 14 the study in early 2006." And that -- it was -- 15 actually should say mid-2006, I guess, if you want 16 to be specifically correct. "And I was the first to 17 present the data at the Retinal Physician Symposium 18 May 31st to June 30th" (sic). 19 I'm just telling you, when you are a -- 20 either a scientist or a company, you present as soon 21 as you can at a big meeting because it's material or 22 relevant to the stock price. Right? You either 23 issue a press release or you try to present as best 24 you can because you don't want somebody who has 25 access to the data to start trading the stock and Page 103	1 and that date. I don't recollect exactly when it 2 was between then, but sometime in that three- or 3 four-week period of time is when the statistical 4 analysis and data was available that I looked over 5 and helped make the presentation for that June 1st 6 through June 2nd presentation. 7 Q. And so I think you said that when the -- 8 you did the rollover amendment that you stayed with 9 quarterly because if you had treated them monthly, 10 then that would have been unmasking and that would 11 impair the scientific validity of the whole trial. 12 Is that right? 13 MR. COBB: Objection, form. 14 A. So Genentech is the one that did that, but 15 I would -- my opinion based on trial design is 16 that's why that decision was made, to keep patients 17 on the same masking schedule. 18 Q. Okay. But the second protocol amendment, 19 they didn't care about that when they changed it to 20 monthly? 21 A. It was a dead trial at that point. 22 Q. And what do you mean by "dead trial"? 23 A. It was a trial where it had failed its -- 24 it had failed -- we can -- the second year PIER 25 trial was functionally designed to be confirmatory Page 105

1 of fixed quarterly dosing efficacy. And given the 2 disappointing lack of efficacy observed in the PIER 3 quarterly treatment regimen, the study sponsor 4 initiated rollover at this point to mitigate against 5 future vision losses, which would be expected on 6 continued quarterly dosing. 7 Q. And with the second protocol amendment, 8 was that a change that -- I understand that the sham 9 patients changed with the second protocol amendment 10 or were given the option to change. Were the 11 quarterly patients also given the option to change? 12 A. Yeah. So the -- in the first amendment, 13 the sham patients went to quarterly dosing. In the 14 second amendment, every arm went to monthly because 15 we didn't feel it was effective or ethical to 16 continue to dose patients quarterly in either arm. 17 So all of them rolled to monthly therapy. 18 Q. And when you say "arm," what do you mean 19 by "arm"? 20 A. So we talked about randomization earlier. 21 If you get randomized to one of three groups, we -- 22 they're scientifically called a cohort because 23 they're a cohort of subjects that get the same 24 treatment. But we also call it an arm of the -- of 25 the design which got that treatment. So that cohort Page 106	1 dosing." Nobody wants that. Or, "I want to stick 2 to a dosing regimen that's less effective." 3 And did anybody do that? I doubt it, but 4 I don't know. Not at my site. 5 Q. So at your site, what if you had a patient 6 who did not suffer visual acuity losses with 7 quarterly? Would you still have recommended they go 8 to monthly? 9 A. Absolutely. 10 Q. Even though it would have been more 11 injections versus less, correct? 12 A. You know, we saw from the first-year data 13 that the average patient or on average patients 14 didn't do well with quarterly. If somebody was 15 doing well with quarterly, how do I know they 16 wouldn't have done better with monthly? 17 Like, you know, you don't know -- an 18 individual patient, you can't -- you can't tell how 19 they would have done, and you have to stick with the 20 best scientific evidence of, "I'm going to recommend 21 monthly therapy. It looks like you've done well, 22 Mrs. Jones, but, you know, on average, people didn't 23 and maybe you'll do better if I give it to you more 24 frequently." 25 Q. But isn't one of the goals of treatment to Page 108
1 is in that arm of the treatment. So I apologize for 2 using those synonymously. 3 Q. No worries. Thank you for that 4 explanation. 5 And with the rollover amendment or the 6 second protocol amendment, was this an option to 7 patients or did they have to change? 8 A. Yeah. So in a clinical trial, a patient 9 is voluntary. And when you have a protocol 10 amendment that changes the way a trial happens, you 11 present that as a new informed consent. And I don't 12 exactly remember my exact conversations, but I can 13 tell you what I would have done is I would have met 14 with each individual patient and I would have said, 15 you know, you've been in this trial and you've 16 really helped out. Turns out you were in a group 17 that we think now you would do better with more 18 frequent dosing. I would recommend you sign this 19 new informed consent and we start giving you new 20 dosing. 21 And in my experience, the great majority 22 will say, "Yes, let's do that," or they say, "Forget 23 it. I'm out of the trial, Doc. I tried." Right? 24 So it's very unusual to have any patients like this 25 that would have said, "I want to stick to sham Page 107	1 give less injections rather than more? 2 MR. COBB: Objection, scope. 3 A. So anytime in medicine when you offer a 4 treatment, you look at risk-benefit ratio. In other 5 words, what's the risk of me giving a treatment 6 versus benefit. It turns out that the risk-benefit 7 ratio from these intravitreal injections of 8 ranibizumab are incredibly in favor of the benefit 9 versus the risk. The chance of hurting someone is 10 literally the risk of endophthalmitis or infection 11 from the needle in the eye, about one in 4,000 to 12 one in 7,000. The chance of helping somebody is 13 really, really good. 14 And so while, yes, the more injections you 15 have, the higher risk you have of these rare 16 complications, it's not guidance to decrease 17 injections at the expense of efficacy. 18 Q. Got it. And I think you said at your site 19 you're not aware of any patients who were quarterly 20 that didn't transition to monthly? Is that right? 21 A. Yeah, we would not -- I would not have 22 recommended that. I would have said, Look, you need 23 to go to monthly. Unfortunately, like we discussed 24 before, it's a relatively small number of patients. 25 Like, the majority of them unfortunately had Page 109

1 finished the trial and had two years of quarterly 2 dosing, and those didn't do well, on average. 3 Q. Okay. But if we were to look at the OCT 4 data that we looked at in Figure 4, that suggests 5 they were doing just fine, right? 6 MR. COBB: Objection. Mischaracterizes 7 his testimony. Form. 8 A. Mean thickness or mean center point 9 thickness is a number. You really don't know if 10 they have disease activity unless you look at the 11 individual scans, and that's what I do on every 12 patient at every visit. I never look at these 13 numbers. Right? I tell residents, fellows, the 14 numbers are there to help make you want to commit 15 malpractice to not look at the actual scans. 16 So just looking at a mean thickness 17 doesn't mean that they don't have fluid and they 18 don't need more active treatment. So, no, I 19 disagree that that number in itself says they're 20 doing fine. 21 Q. But isn't the best tool to help tailor 22 treatment OCT? 23 MR. COBB: Objection. Asked and answered. 24 A. An OCT qualitative analysis, which is 25 where you look at the scans and look for subretinal Page 110	1 put it in a publication that goes free to virtually 2 every ophthalmologist in the world to try to sell 3 ads. Not in the world, in the United States, people 4 who would actually buy the products that they 5 advertise in Ocular Surgery News. 6 Q. All right. And this -- this came out 7 September 1st, 2006? Is that right? 8 A. What it says, yes. 9 Q. All right. And this -- so that would have 10 been after the rollover amendment, the second 11 protocol amendment, correct? 12 A. That would have been almost immediately 13 after the protocol amendment. In other words, 14 August 21st, 2006, is when it was launched out. In 15 all likelihood, the interview for this would not 16 have been in real time. It would have been before 17 the protocol amendment. But it doesn't matter. 18 Go ahead. 19 Q. All right. And this is a document that -- 20 that you cite in your declaration, correct? And the 21 place that I think it said it is in paragraph 32, if 22 you want to check, on page 16. 23 A. 2087, that's correct. 24 Q. Yeah. And in that -- I think you quote 25 from this article, right? You say, "As a result, my Page 112
1 fluid, intraretinal fluid, sub-RPE fluid is what we 2 do in clinic. We do not look at the automated 3 segmentation numbers as is shown in this graph. 4 Q. All right. Let me take you to another 5 exhibit, Dr. Brown. This is Exhibit 2087, 2087. 6 And I'll mark it. And I'm -- I suspect you probably 7 have a hard copy of it. 8 MR. COBB: You said 2087, correct? 9 MR. ERWINE: Yeah. 10 A. I think I have it. "PIER data suggest a 11 need"? Is that it? 12 Q. That is. Just -- I'm not sure why these 13 are -- for some reason these are not seem to be 14 transferring over, but I'll try it anyway with this 15 one, introduce it. All right. Should be added to 16 the Exhibit Share. 17 And so, Dr. Brown, do you recognize this 18 document? 19 A. I do. 20 Q. And what is it? 21 A. This is -- pretty sure it came in Ocular 22 Surgery News, which is a trade publication where 23 after meetings or once data's known, a reporter 24 calls you, and I guess it was Daniele Cruz, it says, 25 for more information. And then they summarize and Page 111	1 conclusion from the PIER study results was that 'we 2 cannot just mandatorily treat on a quarterly basis 3 and maintain the visual gains seen with the first 4 three monthly injections." 5 Is that right? 6 A. That is correct. 7 Q. Okay. And so in this particular article, 8 publication, if you turn to page 2. And do you see 9 where there's a subheading, "An Effective Tool"? 10 A. Correct. 11 Q. And do you see that -- I think you're 12 quoted. You say, "You can't just do mandatory 13 quarterly injections. We are going to have to 14 follow the patients, I think, every four to six 15 weeks by OCT, optical coherence tomography, and if 16 there is evidence of fluid, then reinject." 17 Did I quote you correctly there? 18 A. I see that, yeah. 19 Q. Okay. So that -- you're not saying we 20 have to go to monthly there. You're saying, "We're 21 going to have to follow the patients" -- and just to 22 quote, "We're going to have to follow the patients, 23 I think, every four to six weeks by OCT, and if 24 there is evidence of fluid, then reinject." 25 That's what you state, right? Page 113

1 MR. COBB: Objection. Document speaks for 2 itself. Form. 3 A. That's what it says. 4 Q. All right. And then you say, "The best 5 tool to help tailor treatment is OCT," right? 6 A. That's correct. 7 Q. That's your statement, correct? 8 A. I -- it's here in print. I see it. 9 Q. Okay. And in the "Patient Response" 10 section, do you see that? 11 A. Yeah. But before we go on, look at this 12 right below that. So we talk about an OCT, "a 13 high-resolution optical biopsy can demonstrate the 14 presence of subretinal fluid, intraretinal fluid, or 15 sub-RPE fluid indicating active CNV damage." 16 And I reiterate what I told you earlier. 17 Amazingly, 20 years later I use the macular 18 thickness map on -- which has six high-resolution 19 cross-sectional views. I look at every scan just 20 like a radiologist looks at every image. The 21 automated foveal thickness measurements, which you 22 address in the manuscript, figure whatever it was, 23 Figure -- Figure 4, are actually almost always 24 inaccurate in wet AMD. 25 Just as a cardiologist doesn't rely on EKG Page 114	1 A. Yeah, let me put that in context. At that 2 point in time, ranibizumab was not approved. My 3 experience and treatment were based on patients that 4 were in MARINA and ANCHOR who had had at this point 5 three to five years of anti-VEGF therapy. A third 6 of those had had sham or PDT treatment and basically 7 their eyes were scarred down. Two-thirds of those 8 had had really intensive treatment for two to four 9 years and then the PIER study. 10 In other words, I had no experience 11 treating any patients in the real world that came in 12 brand-new. And we really thought if we treated 13 patients with that many shots, people really 14 wouldn't need many more shots. And it wasn't until 15 we got access to these drugs outside of clinical 16 trials that we realized most patients, 80 percent of 17 patients need ongoing therapy for a long, long time, 18 including their whole life. So here I'm very 19 optimistic that we'd need less, and in retrospect I 20 was probably over -- overly optimistic. 21 Q. And that was at the same time that -- or I 22 should say after this rollover amendment was 23 implemented by Regeneron (sic), right? 24 MR. COBB: Objection. Mischaracterizes 25 the document and the company. Page 116
1 automatic diagnosis, I rely more on my 2 interpretation of the individual images than the 3 retinal thickness measurements generated by the 4 machine. And that is the best tool to help tailor 5 treatments is the actual qualitative examination of 6 every image. 7 Q. Okay. And again, at this time you said 8 that your recommendation to every patient in the 9 PIER study after the rollover amendment was that 10 they go from quarterly to monthly, correct? 11 A. Correct. 12 Q. But in this article under "Patient 13 Response," you said that, "In practice, outside the 14 clinical trial setting, patients with AMD who are 15 candidates for Lucentis will likely be given three 16 monthly injections and then be monitored regularly 17 with OCT after the three-month treatment." Right? 18 MR. COBB: Objection. Document speaks for 19 itself. Form. 20 A. Yes, that's what I said. 21 Q. And you even go on to state that -- 22 further down you say -- it says, "Dr. Brown 23 estimated that the average patient might need six or 24 seven treatments in the first year and hopefully 25 fewer treatments in subsequent years." Right? Page 115	1 A. Yeah, like I said, this interview is 2 probably contemporaneous with that rollover 3 amendment. I mean, if it -- this is a print 4 journal. In other words, it came out like from 5 printing presses and stuff and got mailed. And so 6 for one dated September 1st, it probably was before 7 August. But it's semantics. It's about the same 8 time. 9 Q. Okay. 10 MR. COBB: Counsel, I'll just state for 11 the record, I think you misspoke. This PIER is not 12 a Regeneron trial. 13 MR. ERWINE: I'm sorry? 14 MR. COBB: I believe you mis- -- I'm just 15 going to clarify the record because I believe you 16 misspoke. The PIER study, ANCHOR, and MARINA are 17 Genentech trials, not Regeneron. 18 MR. ERWINE: Apologies. Thank you for 19 that clarification, Counsel. And if I said 20 Regeneron, I apologize. 21 Q. And in paragraph 29, Dr. Brown -- 22 A. Paragraph 29 of the declaration? Yes, 23 sir. 24 Q. Yeah, the declaration. You see that? Are 25 you there? Page 117

1 A. I do. 2 Q. And there you reference an article. It's 3 Exhibit 2051, Abraham, 2010. Do you see that? 4 A. I do. 5 Q. And if you have -- if you have a print -- 6 have a copy of that, take a look. I'll -- 7 A. He's pulling it for me. 8 Q. Great. 9 A. He's an incredibly organized guy. He's 10 got this box with all these file folders. 11 Q. Yeah, I'm super impressed. We could use 12 people like that in my firm. 13 A. No, I mean, he's -- he's more -- all 14 right. I see the article. Yeah. 15 Q. Okay. Great. And I've tried to introduce 16 it on Exhibit Share. There must be some flaw in the 17 system because I'm not sure it's coming up. 18 But in any event, do you recognize this 19 document? 20 A. I do. 21 Q. All right. And what is it? 22 A. This is the two-year study results of PIER 23 with Prema Abraham, a retina physician from 24 South Dakota, being the first author, and a 25 statistician, Huibin Yue, from Genentech. Second Page 118	1 Q. Just at the bottom of 316, it says, 2 "Subsequently, after careful review of the 12-month 3 PIER data, the protocol was amended again on 4 August 21st, 2006, to provide all patients remaining 5 in the study the opportunity to roll over to receive 6 0.5 milligrams ranibizumab monthly for the remainder 7 of the two-year study. No patients were unmasked to 8 their original treatment assignment as a result of 9 the crossover and rollover amendments." 10 So I guess I -- my understanding from what 11 you had testified earlier was that there was 12 unmasking as a result of the rollover amendment. 13 Is that not true? 14 A. No, so the rollover amendment, you unmask 15 if you do something different to one patient at a 16 visit versus another. Okay? So when you went and 17 did the crossover visits, you still had -- you still 18 had patients get a procedure, whether that be a sham 19 procedure or an injection procedure, and then they 20 rolled over to where all of them were getting 21 procedures. So you still had that. And then you 22 had two visits where we didn't do that, and then we 23 did a visit where we did that. 24 Once you went to the -- and you'll see in 25 Figure 1, it's a pretty good kind of little -- shows Page 120
1 author, Laura Wilson, is a physician at Genentech 2 who was, kind of like Naveed Shams, a medical 3 director that did ophthalmology. 4 Q. All right. And do you know Dr. Abraham? 5 A. I do. 6 Q. And was she a clinical practitioner for 7 the PIER trial? 8 A. Yes. She would have been a principal 9 investigator for her site, and I think it's 10 Rapid City, South Dakota. I've never been there, 11 but -- 12 Q. Okay. And did you speak to her in 13 connection with this declaration or the '601 14 declaration? 15 A. No. I haven't seen Prema in several 16 years, so -- 17 Q. I have some more questions about that but 18 maybe just set that aside for now. 19 A. Okay. 20 Q. Let me just -- give me one second. So 21 one que- -- actually, I did have a question about 22 this document. And if I could turn your attention, 23 it's pages 2 and 3 of the document, pages 316 and 24 317 of the article. 25 A. Yeah. Page 119	1 you crossover, rollover, all that stuff. So once 2 you got to rollover amendment, every patient got 3 that procedure every month. 4 So unmasking would mean you knew what you 5 got before, right? In other words, the sham -- the 6 previous shams, you would tell them your previous 7 shams. And your other injection patients, you say, 8 "You were lucky you got the drug but unlucky we 9 didn't give it to you enough," but then we gave it 10 to everybody monthly. So that didn't officially 11 unmask the study. 12 In other words, everybody got something 13 monthly, and so that didn't change whether you were 14 sham injection or whether you were active injection 15 initially. 16 Q. Got it. By the way, in the exhibits that 17 we've looked at concerning the PIER1 study, none of 18 those exhibits refer to the PIER trial as a failure, 19 correct? 20 MR. COBB: Objection, form, vague. 21 A. Conclusion of the PIER paper by Carl 22 Regillo, just point you to the last "Conclusion" 23 sentence, next to last. "Observations from MARINA 24 and ANCHOR suggest that PIER regimen of dosing every 25 three months provided less benefit in VA on average Page 121

1 than monthly dosing," so -- 2 Q. I'm sorry. That was the Exhibit -- 3 A. 1021. 4 Q. 1021? What page are you on? 5 A. 1021, basically repeat of testimony from 6 page 247, page 9 of your pagination, last paragraph. 7 Right? Sort of the conclusion. It is the 8 conclusion. "In conclusion," it starts. 9 Q. Okay. And that word doesn't -- or that 10 paragraph doesn't use the word "failure," right? 11 MR. COBB: Objection. Document speaks for 12 itself. 13 A. That's correct. 14 Q. And it says at the end, "Monthly dosing 15 may be necessary in some patients to achieve maximal 16 treatment benefit from ranibizumab." 17 A. That's what it says. 18 Q. Okay. I think we were talking about 19 paragraph 29. And then in paragraph 32, let's jump 20 to paragraph 32. And let me know when you're there. 21 A. I'm there. 22 Q. Okay. And the first sentence talks about 23 that exhibit which was the September 1 press release 24 that we talked about. And then in paragraph -- I'm 25 sorry. Same paragraph -- Page 122	1 Q. And what is it? 2 A. This is a article out of a group in 3 New York that we do a lot of -- you know, that's 4 similar to our group in terms of does a lot of 5 research, published in the journal Retina in 2009. 6 Q. Okay. And the lead author is -- 7 A. First author is a Jonathan Levine. I 8 don't know him. It's either a med student or 9 fellow. Rick Spaide, Mike Cooney, Bailey Freund are 10 all colleagues and friends, so -- the senior authors 11 are -- yeah, it's a very good, respected retina 12 group in New York that does a lot of research like 13 we do. 14 Q. Okay. And you mentioned that other than 15 Dr. Levine that I think you know the other authors? 16 Is that right? 17 A. I don't know Inna Marcus either. That was 18 probably another resident or fellow. Sorenson, sort 19 of know. I know the other three very well. They're 20 both very active in academic retina circles. 21 Q. Okay. That's Dr. Spaide, Dr. Cooney, and 22 Dr. -- 23 A. Yeah. 24 Q. -- Freund? 25 A. Dr. Freund, yeah, correct. Page 124
1 A. Just a correction. It wasn't a press 2 release. It was a lay -- lay publication article 3 based on a -- probably a telephone interview. 4 Q. Got it. And then in -- sticking with 5 paragraph 32, there is also a reference to an 6 Exhibit 2085. Do you see that, Levine 2009? Looks 7 like Daniele Cruz was the author? 8 A. Daniele Cruz. Yeah, I see that. She's an 9 author. Why does it say Levine? I'm not sure those 10 are the same. 11 Q. Yeah. 12 A. Daniele Cruz is the -- is the lay press 13 thing we saw from Ocular Surgery News. I think 14 Levine is separate. You can pull it up. 15 Q. Got it. Yeah, let's do that. And -- 16 THE WITNESS: Get 2085 for me? 17 Q. I think that was my mistake. I think I 18 referenced it and it is -- Daniele Cruz is the 2087. 19 But 2085 is the one that I wanted to look at. 20 A. Perfect. We're pulling it up. I got it. 21 Q. Great, great. And I'll mark that, see if 22 it works. Okay. I think you have a hard copy of 23 that document. And Dr. Brown, do you recognize this 24 document? 25 A. I do. Page 123	1 Q. And fair to say that you didn't speak to 2 any of those three individuals in connection with 3 preparation of this declaration? 4 A. Spoke to Bailey yesterday about another 5 project we're doing, but we haven't talked about 6 this at all, no. 7 Q. Okay. And in terms of this particular 8 article, you rely on this article in your 9 declaration to set forth views that were shared 10 across the retina community at the time, correct? 11 A. Yeah, you saw in paragraph 32 I say, "My 12 expressed concerns with fixed quarterly injections 13 were shared across the retinal community. Levine 14 demonstrated that monthly intravitreal ranibizumab 15 dosing significantly" -- I'm sorry. 16 "A recent analysis of ANCHOR, MARINA, and 17 PIER demonstrated that monthly intravitreal 18 ranibizumab dosing significantly reduced the 19 frequency of macular hemorrhages compared with sham 20 controls or photodynamic therapy regardless of 21 lesion type." 22 Q. Okay. And -- 23 A. So what I'm -- 24 Q. And again -- sorry. 25 A. What I'm showing in Levine is just the Page 125

1 risk of hemorrhaging without adequate control of the 2 disease process. 3 Q. And let me direct your attention to -- 4 there's a paragraph I wanted to look at on -- it 5 starts on page 4 of the document, the lower right 4. 6 It's actually 1077 on the top right and rolls into 7 the next page, 1078 or page 5 of the document on the 8 bottom. 9 A. Okay. I'm sorry. What page? 10- -- 10 Q. 1077. 11 A. Seventy -- 12 Q. That's on the top, and on the bottom it's 13 page 4 of the exhibit. 14 A. Okay. There we go. Page 4 and 10- -- I 15 got it. Sorry about that. 16 Q. Okay. And do you see the last -- the 17 beginning -- it's really the last two lines of page 18 4 where it starts "A recent analysis"? 19 A. Okay. Yeah. 20 Q. And it says, "A recent analysis of the 21 ANCHOR, MARINA, and PIER data demonstrated that 22 monthly intravitreal ranibizumab dosing 23 significantly reduced the frequency of macular 24 hemorrhages compared with the sham controls or 25 photodynamic therapy-treated patients regardless of Page 126	1 further down, the next paragraph on page 5 or 1078 2 near the bottom, they state, "For some patients a 3 monthly examination schedule, similar to the PrONTO 4 strategy, may be sufficient to detect early 5 recurrence and to allow for timely treatment as 6 needed with fewer treatments than a monthly 7 regimen." Correct? 8 MR. COBB: Objection. Document speaks for 9 itself. Form. 10 A. That's what it says. 11 Q. Okay. So some patients, based on this 12 PIER study, the "something less than monthly" is an 13 effective dosing regimen, right? 14 MR. COBB: Objection, scope. 15 A. So I'm aware that "effective therapy" has 16 specific legal meanings in this proceedings, which I 17 don't know if I'm qualified to address. But I do 18 know that an effective therapy in my hands is one 19 where I get the most maximal gain of visual acuity I 20 can and maintain those gains. 21 So were there patients in PrONTO that 22 gained as much as they can? You'll never know 23 because you didn't ever treat any of them by adding 24 more doses monthly until way late in the game. 25 Q. So let me ask you if you agree with this Page 128
1 lesion type. The effect was lost when patients were 2 switched from monthly to quarterly dosing in the 3 PIER Study." 4 Do you see that? 5 A. Yeah. 6 Q. And I don't think you included this quote 7 in your paragraph 32, but the last sentence of that 8 paragraph states, "Reducing the frequency of 9 injections should therefore be done with caution." 10 A. I -- yes, I see that. 11 Q. And do you agree with that -- that last 12 sentence? 13 A. Absolutely. 14 Q. Okay. So for some agents -- 15 A. Just to give you a little color, so the 16 quote is in this paper and it's out of the same 17 group. If you look at the reference, it's an ARVO 18 presentation -- no, Retina Society presentation by 19 Irene Barbazetto. She is in that same group with 20 Dr. Spaide and Dr. Cooney and Dr. Freund. So that's 21 why they quote that as if they know it, because 22 they're part of that same -- that same -- that 23 presentation by Irene was what they quote in this 24 paper. 25 Q. Okay. And in this paper a little bit Page 127	1 statement from that article that you rely on. On 2 page 1079, it's -- and this is the next to last 3 par- -- or the paragraph before the "Key Words" 4 section. It says, "As the PrONTO study has 5 demonstrated, an as-needed treatment regimen based 6 on the clinical status of the individual patient can 7 be an effective strategy with fewer patients -- 8 fewer treatments than a monthly dosing regimen." 9 Do you see that? 10 A. I see that. 11 Q. Do you agree with that statement? 12 A. You know, I think at the time that this 13 paper was written, the authors believed that. The 14 PIER -- the PrONTO study, which I said was a small, 15 non-randomized, very intensive trial by Phil 16 Rosenfeld, another colleague of ours, actually 17 realized that the PRN was increasing 18 sight-threatening hemorrhages and changed the 19 protocol to where -- you know, to modify for that. 20 So, you know, I think as we learn more and 21 more from treating with new agents, we perhaps -- we 22 often learn more. And while at the time this paper 23 came out I think a lot of us thought that you might 24 be able to do a really tight PRN, I have been on the 25 podium and in publications, such as the ones you've Page 129

1 referenced, calling PRN "progressive retinal 2 neglect," because I think over time, allowing fluid 3 to recur and allowing disease activity can recur can 4 really harm the patient. 5 So I don't do any PRN therapy routinely, 6 and most retinal physicians in the U.S. have steered 7 away from that over the last decade or so. 8 Q. It's interesting you mention that about 9 Dr. Rosenfeld. Let's take a look at another exhibit 10 and another one that I think you cite in your 11 declaration. This is Exhibit 2050. 12 MR. COBB: Richard, we're at an hour and 13 ten and we're after 1:00, so maybe this is a good 14 time for lunch before you change -- 15 MR. ERWINE: Yeah, let me -- let me just 16 finish this exhibit and then we can take a break. 17 MR. COBB: Like ten minutes? 18 MR. ERWINE: Won't take long. 19 MR. COBB: Is that what we're talking? 20 Are we talking like ten minutes or 30 minutes? I 21 hate this game where we're one more exhibit and then 22 we question forever. So if it's like ten minutes, 23 that's fine. 24 MR. ERWINE: Yeah, I don't foresee it 25 being more than -- certainly no more than ten Page 130	1 THE WITNESS: They're not showing up. 2 THE VIDEOGRAPHER: Ms. Shelton, did we 3 drop out? 4 THE REPORTER: He's gone, yes. 5 THE VIDEOGRAPHER: Okay. Let's go off the 6 record. I'm sorry. Time is 1:06 p.m. We're off 7 the record. 8 (Off record from 1:06 to 1:08) 9 THE VIDEOGRAPHER: Time is 1:08 p.m. 10 We're on the record. 11 BY MR. ERWINE: 12 Q. And Dr. Brown, we were talking about 13 Exhibit 2050, and I think the question was I asked 14 you if this was dated September of 2006. 15 A. Yeah, it's dated September 1, 2006. It 16 would have been a review issue of Retinal Physician 17 which sponsored the symposium I gave the PIER 18 results at. But the majority of all this data, and 19 it says at the beginning, "Many of the country's 20 leading retina specialists ... from May 31st to 21 June 3rd," and then, "The following are condensed 22 recaps of key presentations." 23 So I don't know if there were any 24 secondary interviews after that. I think it's just 25 they looked at the tapes and created some summaries, Page 132
1 minutes. 2 MR. COBB: All right. What number? 3 MR. ERWINE: It's 2050. 4 A. I've got it. 5 Q. Great. And do you recognize this 6 document, Dr. Brown? 7 A. I do. 8 Q. What is it? 9 A. This is a review of the talks that were at 10 the Retinal Physician Symposium where incidentally I 11 first presented the PIER data. 12 Q. All right. And this was -- this looks 13 like this is also dated September -- 14 (Mr. Erwine's Zoom disconnected) 15 A. Yeah, it would have been. I mean, that -- 16 this is a review article from the talks that were 17 given in that May 31st to June symposium. Whether 18 there were additional interviews afterwards, there 19 probably weren't. I think they maybe did this from 20 the -- from those talks. But yes, it probably came 21 out several months later because they had to print 22 it and mail it to everybody's house and stuff. 23 THE VIDEOGRAPHER: Dr. Brown, I'm sorry to 24 interrupt, folks. It looks like we lost counsel. 25 Hang on one second. Page 131	1 but -- but yeah, the date of the issue would be 2 September 1st. Again, it's an article -- it's a 3 journal that gets sent to a lot of retina doctors. 4 And so it was probably printed, you know, August or 5 so. But it's all from data from that symposium 6 May 31st to June 3rd. 7 Q. Okay. Great. And if I can direct your 8 attention to page 4 of the article and in particular 9 the section that talks about the PrONTO study. 10 A. Yeah. 11 Q. And you see the -- that's -- Dr. Rosenthal 12 that's referenced there, that's the same 13 Dr. Rosenfeld that you mentioned in your -- 14 A. Yeah. 15 Q. -- testimony earlier? 16 A. Yeah, that's Philip Rosenfeld. He was the 17 first author of MARINA and I was second author, and 18 we traded on the ANCHOR. I was first author, he was 19 second author. So, yes, same guy. 20 Q. Okay. Got it. And it looks like OCT was 21 one of the primary tools that was used for 22 measurement in the PrONTO study? 23 MR. COBB: Objection, scope. 24 A. Yeah. It says, you know, in the 25 paragraph, "Dr. Rosenfeld reasoned that vision loss Page 133

1 was gradual as the fluid accumulated and that 2 optical coherence tomography was reliable in 3 detecting the fluid before it became symptomatic. 4 Initially, all patients received three monthly 5 injections. They received additional injections 6 only if the OCT needed a need for treatment." 7 Q. And that's need for retreatment, right? 8 A. That's correct. 9 Q. Okay. And then towards the end of that, 10 it says, "Using these criteria, the mean number of 11 injections per patient in year 1 of a two-year, 12 40-patient study was 5.5, though at least one 13 patient received 13 injections." And it said, 14 "Clearly, the need for reinjection is unpredictable 15 and varies from individual to individual." 16 A. I see -- 17 Q. Is that consist- -- is that consistent 18 with your understanding of the PrONTO study? 19 MR. COBB: Objection, form. 20 A. The PrONTO study was a very unique study. 21 It was non-randomized. In other words, every 22 patient got treatment. It was a very particular 23 group that got examined more than every month. They 24 got examined something like 17 or 20 times in the 25 first year. Page 134	1 A. That's what it says. 2 MR. ERWINE: All right. So why don't we 3 take our lunch break and we'll go off the record and 4 talk about time. 5 THE VIDEOGRAPHER: Okay. Time is 6 1:13 p.m. We are off the record. 7 (Recess from 1:13 to 1:59) 8 THE VIDEOGRAPHER: The time is 1:59 p.m. 9 We are on the record. 10 BY MR. ERWINE: 11 Q. All right. Welcome back, Dr. Brown. 12 A. Yes, sir. 13 Q. If you could, I'm going to go back to your 14 '572 declaration which is Exhibit 2066. 15 A. Yeah, I'm there. 16 Q. And continuing where we left off, I'm 17 going to go to paragraph 34 on page 17. 18 A. Okay. 19 Q. And in paragraph 34, you provide some 20 information about the FDA's labeling of Lucentis. 21 Is that correct? 22 A. That's correct. 23 Q. And one of the things that you reference 24 is the -- what the label itself says, which is, 25 "although less effective treatment may be reduced to Page 136
1 The protocol changed over time. 2 Originally they had to have a certain amount of 3 fluid and then they had to have any fluid and then 4 they changed it after hemorrhaging. So this is one 5 of the -- you know, this is after -- this was 6 presented year 1 of the two-year study. 7 And then at year -- by year 2 there was 8 certainly a lot of -- lot of feeling amongst retina 9 investigators, including Phil, that PRN therapy 10 wasn't enough to prevent severe vision loss in some 11 patients. And as best I know, he doesn't do PRN 12 therapy now. 13 Q. Got it. And in the -- in this -- this 14 particular exhibit, couple pages earlier, there's -- 15 it looks like there's some -- a reference to you, is 16 that right, on page 2 of the document? 17 A. Page 2 of the document. Yeah. Like I 18 said, this is where I first presented the one-year 19 data from PIER. 20 Q. Okay. And this states at the end of that 21 discussion, "The PIER data have led Genentech to 22 recommend that patients receive either monthly 23 injections of ranibizumab or have -- or have their 24 retreatment schedules determined through 25 individualized testing." Is that right? Page 135	1 one injection every three months after the first 2 four injections if monthly injections are not 3 feasible." 4 Is that part of what's in the label? 5 A. That's correct. 6 Q. Okay. So fair to say that the FDA label 7 did not restrict quarterly injections, correct? 8 A. That's correct. 9 Q. And is that -- is it fair to say that 10 based on that, it's fair that quarterly injections 11 work with some patients but perhaps not others? 12 MR. COBB: Objection, form. 13 A. I don't think that's what the label means. 14 There's labeled indications for Macugen, which is a 15 drug we don't use because it's ineffective, and a 16 label for PDT which basically became irrelevant 17 after the ANCHOR trial. Just because a drug has a 18 label, an indication, doesn't mean that the 19 treatment's efficacious. 20 Q. Okay. Is it your understanding that -- 21 that at the time that the Lucentis drug could be 22 used on a quarterly basis for some patients? 23 MR. COBB: Objection, form. 24 A. Once a drug becomes available from the 25 FDA, you can use it any way you want, including Page 137

1 inefficiently and underdosed. So, yes, it can be 2 used. 3 Q. Okay. Had a question for you about 4 something you had included in your '681 declaration 5 in the same context as this paragraph 34 but you 6 didn't include here. 7 And what you -- the sentence you included 8 stated the following. It said, "Indeed, I am not 9 aware of any retina doctor who, after the results of 10 PIER were published, would treat a wAMD patient on a 11 Q12 maintenance dosing regimen of ranibizumab or 12 would view such a dosing regimen as acceptable 13 treatment for an angiogenic eye disorder." 14 Do you recall that language from your '681 15 declaration? 16 A. Vaguely. It's been six months or so. 17 Q. All right. 18 A. I agree with the statement though. I 19 don't think anyone would -- I don't agree -- I don't 20 think anyone, after seeing the PIER data, walked out 21 of the room or heard the data and said, "This is a 22 great way to treat patients; this is my new 23 paradigm." 24 Q. I understand that. I guess the question 25 is, are you aware of any retina doctor who actually Page 138	1 statement today that you're not aware of any retina 2 doctor who, after the results of PIER were 3 published, would treat a wAMD patient on a Q12 4 maintenance dosing regimen of ranibizumab or would 5 use such a dosing regimen as acceptable treatment 6 for an angiogenic eye disorder? 7 A. You know, after PIER was presented and 8 became publicly available, I don't think anyone who 9 cared about their patients said, "This is how I'm 10 going to start treating you, Mrs. Jones. I'm going 11 to give you three doses and then go quarterly, 12 because, you know, we get a little vision and we 13 lose most of it, but it's way better than not 14 treating you, and you only have to come in four 15 times the second year instead of 12," or whatever. 16 So we don't -- the data does not support 17 treating a population based on quarterly dosing 18 after three doses. 19 Q. Yeah, I wasn't asking about the 20 population. I was just asking about any specific 21 individual, because that's what the statement says. 22 A. So a statement in a declaration six months 23 ago that we're not being deposed on today? That's 24 what we're talking about? 25 Q. Yeah. Page 140
1 treated a patient with the quarterly dosing regimen? 2 MR. COBB: Objection, form. 3 A. So human patients are very variable. Some 4 need incredibly intensive therapy. Some get lucky 5 and don't need much therapy. Everything's based on 6 individual patients and their individual 7 circumstances, how often, is it a big challenge to 8 come in, do they have -- do they have one eye and 9 they're living alone. All these factors sort of go 10 into our thought process on how aggressively to 11 treat their disease. I personally am very 12 aggressive and prefer the best visual acuity gains I 13 can get and maintenance of those gains. 14 Q. All right. Well, thank you. I appreciate 15 that. And again, I was just trying to understand if 16 there was a reason that you took out this statement 17 and if in fact you were aware of a retina doctor who 18 had treated a wAMD patient on a quarterly dosing 19 regimen, because you had included this language in 20 an earlier declaration in the same context as what's 21 in paragraph 34, but it doesn't appear in the '572 22 or '601 declarations. 23 MR. COBB: Objection, form. 24 A. There was no reason I left that out, no. 25 Q. And so do you -- do you stand by the Page 139	1 A. I think you misconstrue what I'm saying 2 there. I'm not saying that any -- if you look at -- 3 if you look at pure PRN treatment trials, there's a 4 portion of the population that three doses and 5 they're done, like literally. They are the luckiest 6 people in the world. They get three doses of an 7 effective anti-VEGF and they don't seem to need more 8 treatment. 9 So, sure, there are patients that three 10 doses and you don't have to treat very often. If 11 you don't ever have to be treated, you can be 12 treated at three months or six months or 12 months 13 or none, you don't need it. So certainly there's a 14 bell curve of a population on average in a treatment 15 population that's a small number, 15 percent or so. 16 Vast majority of the patients need consistent and 17 frequent anti-VEGF therapy to maintain their 18 disease. 19 Q. Well, I'll tell you what. Let's make this 20 simple. I have marked as an exhibit the -- your 21 declaration from the '681 patent. I believe that 22 counsel should have a copy. It's also in the 23 Exhibit Share, Exhibit 2055 from the 442 IPR. Let 24 me know if you are able to take a look at a copy of 25 that. Page 141

1 A. He's pulling it up. 2 Q. Okay. Thank you, Dr. Brown. 3 MR. COBB: Are you talking about 4 Exhibit -- give me the number again. I'm sorry. 5 MR. ERWINE: Yeah, no problem. It's 2055 6 is the exhibit from the 2023-442 IPR petition. 7 MR. COBB: IPR2023-00442, Expert 8 Declaration of Dr. David Brown? Is that right? 9 MR. ERWINE: That's right. 10 MR. COBB: Okay. I'm just going to note 11 for the record you guys have already taken his 12 deposition on this declaration. He's not prepared 13 to testify as to the contents. Go ahead and pose 14 your question. 15 Q. All right. Do you have a -- do you have a 16 copy, Dr. Brown? 17 A. I do, yeah. 18 Q. Okay. And I would turn your attention 19 to -- it's paragraph 60 which is -- it rolls onto -- 20 the sentence I read you was from page 26. 21 A. Yes. 22 Q. All right. And the sentence, I'll read 23 it. "Indeed, I am not aware of any retina doctor 24 who, after the results of PIER were published, would 25 treat a wAMD patient on a Q12 maintenance dosing Page 142	1 treated less than monthly who do fine. It's a -- 2 it's a -- it's a bell curve. 3 Q. All right. Thank you, Dr. Brown. 4 And that was paragraph 34. Let's go to 5 the next section of your declaration. This is 6 the -- what is Section 5, the DA VINCI trial, 2010 7 ARVO abstract. Do you see that? It's -- 8 A. I do. I'm there. 9 Q. Yeah. Okay. Great. 10 And in paragraph 35, you provide some 11 insight into the DA VINCI trial, correct? 12 A. Yeah, I state, "Patients were enrolled 13 between December 2008 and June of 2009. Primary 14 endpoint was best-corrected visual acuity at 24 15 weeks." 16 Yeah, that's -- that's sort of -- that 17 was -- that's -- it's a DME trial with 18 best-corrected visual acuity at 24 weeks with, I 19 believe, four different dosing arms compared to 20 focal laser. 21 Q. Thank you, Dr. Brown. First of all, what 22 is a phase II trial? 23 A. I'm sorry? 24 Q. What is a phase II trial -- 25 A. Sure. Page 144
1 regimen of ranibizumab or would view such a dosing 2 regimen as acceptable treatment for an angiogenic 3 eye disorder." 4 And I think you see that statement in 5 paragraph 60? 6 A. I see that. 7 Q. All right. And that statement doesn't 8 appear in your '572 or '601 declarations, correct? 9 MR. COBB: Objection. Asked and answered. 10 A. That's correct. 11 Q. And my question is, do you agree with that 12 statement? 13 A. I certainly agree with that statement as a 14 general population. I know of no physician who 15 a priori treats three doses and then quarterly, 16 because we showed in PIER it didn't work and 17 compared to ANCHOR, MARINA, and previous treatments 18 that are more effective given on effective dosing 19 regimens. 20 Q. That's fine with respect to the 21 population. I'm just curious if you're aware of any 22 retina doctor who's -- who's used that particular 23 dosing regimen. 24 A. So an individual patient, again, based on 25 OCT, visual acuity, there are patients that get Page 143	1 Q. -- which I believe you said DA VINCI trial 2 was. 3 A. Right. A phase I trial, just to put it in 4 reference, is a very small trial of typically five 5 to ten patients per dose, just to see if a drug is 6 reasonably safe, or not -- you know, there's no 7 dose-limiting side effects and can you dose-escalate 8 to a point to where the pharmacology people and 9 others think that there should be a benefit. It's 10 usually too small to really show if a drug works 11 unless it's something that nothing works and it 12 works. Right? 13 But phase II is typically a larger trial. 14 So that first trial's normally 30 to 50 patients. 15 Can be smaller. Can be as small as 15. Phase II 16 trials, generally more 50 to a couple hundred 17 patients. There are some -- some exceptions. Some 18 people run great big phase IIs. 19 But you run a phase II to sort of see 20 what -- what dose regimens or what -- how should you 21 design your phase III. You do it to be informative 22 of how to run a phase III. In other words, do we 23 think the drug will last this long or that long and 24 does it work in this indication enough to put the 25 money forth for a very large, expensive phase III Page 145

1 trial. So -- 2 Q. And what was the name of the phase III 3 trial that followed the DA VINCI trial? 4 A. The phase III trial for VEGF Trap-Eye and 5 diabetes would be two parallel trials, VISTA and 6 VIVID. 7 Q. VISTA and VIVID. Okay. And did you work 8 on those? 9 A. I did. 10 Q. What was your role on VISTA? 11 A. Role on VISTA was I would have been on the 12 steering committee of the VISTA/VIVID, you know, 13 trials. VISTA was predominantly in the U.S. VIVID 14 was predominantly in Europe. And I was a principal 15 investigator in VISTA at the Houston site, and then 16 I was co-lead author of -- I guess I was second -- 17 corresponding author on the first manuscript one 18 year, VISTA/VIVID, together with my friend 19 Jean-Francois Korobelnik who had the European 20 section and then first author of the second year. 21 We flip-flopped. 22 Q. Got it. And for the phase III, you were 23 the -- for VISTA, you were the principal 24 investigator in Houston? 25 A. I was the principal investigator in Page 146	1 attaches to it and doesn't let go. So it does the 2 same thing as an anti-VEGF antibody but does it in a 3 different mechanism. 4 Q. And is that Aflibercept? Are they the 5 same thing? 6 MR. COBB: Objection, scope. 7 A. Yeah. So the Aflibercept, they started 8 calling it Aflibercept quite a bit later. And 9 whether there were actual changes in our initial 10 VEGF Trap-Eye and what became Aflibercept, I don't 11 know. 12 Q. So VEGF Trap-Eye was some precursor to 13 Aflibercept? 14 MR. COBB: Objection, scope. 15 Mischaracterizes his testimony. Form. 16 A. It could be a precursor. It could be the 17 same molecule. In other words, whenever I -- I do 18 clinical trial work. I don't do the development of 19 the actual drugs themselves. And so often the drug 20 changes throughout the trial for a couple reasons. 21 One, it may be more stable. Sometimes they change 22 it to make it where they can manufacture it in large 23 quantities because if it starts looking like it's 24 working, you want to make sure that you can scale up 25 once you get to production. Page 148
1 Houston, correct. 2 Q. And I apologize if I asked you this 3 already, Dr. Brown, but who was the principal 4 investigator in Houston for the DA VINCI phase II 5 trial? 6 A. Yeah, pretty sure it was Matt Benz, 7 Matthew Benz. 8 Q. Thank you. Like I said, I think I may 9 have asked you that. I apologize for the 10 repetition. 11 A. No, that's okay. 12 Q. And the DA VINCI trial was for VEGF 13 Trap-Eye. What is VEGF Trap-Eye? 14 MR. COBB: Objection, form. 15 A. VEGF Trap-Eye was what the drug or agent 16 or experimental drug that was used or that's what it 17 was called in the DA VINCI trial and then the 18 beginnings of the VIEW trial and VISTA/VIVID, I 19 think. So it's a drug manufactured by Regeneron, 20 developed. It's a fusion protein of two different 21 VEGF receptors that's human -- human components that 22 ends up combining with VEGF. 23 So it's not an anti-VEGF antibody like 24 ranibizumab. It's actually a fusion protein 25 receptor. So it's a dummy receptor. So the VEGF Page 147	1 The VEGF trap, my -- I mean, that idea 2 might have been thought to be too commercial. 3 Right? You got a molecule that's trapping VEGF. 4 And that's sort of why it was named that way from 5 Regeneron. But once you got closer to 6 commercialization, they had to have a generic term 7 that ended up being Aflibercept. And whether that's 8 the same drug or not, I really don't know, the exact 9 same, you know, test agent that we got. So -- 10 Q. In paragraph 35, Dr. Brown, you state that 11 the primary endpoint was change in best-corrected 12 visual acuity at 24 weeks. 13 What did you mean by "primary endpoint"? 14 A. Yeah. So when you have a trial, you pick 15 what you -- what you pick as your primary endpoint, 16 which is for a phase III trial what the FDA agrees 17 that if you meet a certain success rate on that, you 18 get approval, you know, based on everything else, 19 side effects and that kind of thing. 20 In a phase II trial -- and then you have a 21 bunch of secondary endpoints. In a phase II trial, 22 it really doesn't matter what your primary endpoint 23 is. You do multiple endpoints, but you generally 24 pick a primary endpoint that you know is a 25 acceptable phase III primary endpoint because you Page 149

1 want to keep -- change as little as possible going 2 from phase II to phase III, because if your phase II 3 shows you something and you change it a lot, then 4 you could -- you know, you wouldn't be in -- you 5 could -- you could make mistakes and you could -- it 6 could not be effective because you changed too many 7 things. 8 Q. And the primary endpoint for DA VINCI 9 trial was -- it was 24 weeks? Is that right? 10 A. That's correct. 11 Q. And what did you mean by "best-corrected 12 visual acuity"? 13 A. So in the testimony earlier today, I 14 talked about when you go to your doctor, they go, 15 "This or this," "This or this," and, you know, a 16 minute or so later they give you your prescription 17 and that's it. And that's corrected visual acuity 18 is a very rigorous, precise mechanism of going -- of 19 trying different lenses in a set pattern with every 20 patient to make sure that you're getting the exact 21 same visual acuity measurement or the best possible 22 correction you can get it every time. 23 It's something that's never done 24 clinically. It's only done in clinical trials, best 25 I know. Part of it is the average patient wouldn't Page 150	1 subjects? 2 A. That's correct. 3 Q. Is that right? 4 A. That's correct. 5 Q. How did you go about -- how did you go 6 about recruiting subjects? 7 A. So as a busy retinal clinician, 8 particularly in South Texas, we have a very large 9 portion of the population that has diabetes and 10 diabetic macular edema. When a patient comes in 11 with diabetic macular edema, and between 2008 and 12 2009, I see them and I say we've been treating 13 people with focal laser for years and it doesn't 14 improve vision, it merely slows down vision loss. 15 There's some very promising shots in the 16 eyes that we're using in macular degeneration that 17 very likely may improve your vision, but the only 18 way to do that is to be in a clinical trial. And in 19 a clinical trial, you may get access to these drugs. 20 Again, they're shots in the eyes, and that scares 21 probably half of them off right away. But ones 22 especially that will listen to the potential 23 benefits, that maybe I can make you better and keep 24 you driving and keep your job, you go through the 25 risk and benefits of being in a trial. And for this Page 152
1 put up with it, but it's a very rigorous way of 2 testing visual acuity. And they're tested on 3 individual eye charts from -- that were part of the 4 diabetic studies years ago, the ETDRS. They're made 5 by one specific company and you have to buy the 6 exact light bulbs that light them up and it's very 7 precise. 8 Q. Got it. And in paragraph 35, you also 9 mention Bayer. What was Bayer's role in the 10 DA VINCI trial? 11 MR. COBB: Objection, scope. 12 A. I actually don't know how much input Bayer 13 had on the DA VINCI trial. I know that Regeneron 14 partnered with Bayer to get more funding. They 15 didn't have the funding to run the phase III AMD 16 trials. And I think as part of that, it was a 17 collaboration across all the VEGF Trap-Eye trials. 18 Whether Bayer had input on the design or 19 not, I don't know. It certainly helped with the 20 funding. 21 Q. Okay. Dr. Brown, turning to paragraph 36 22 of your declaration. And here I think you give some 23 of the -- some of the information about the DA VINCI 24 trial. I think you said that you and other clinical 25 investigators were responsible for recruiting Page 151	1 trial, one of the risks is you got a one out of five 2 chance of just getting that laser that I told you 3 wasn't very effective. 4 The other risk is this is a drug that 5 really hasn't been given much. You know, there's a 6 chance it won't work. You know, there's another 7 drug coming out, but right now it's \$2,000 a dose 8 from macular degeneration and, you know, I doubt you 9 can afford that. But there's a chance this drug's 10 just as good or will be effective, and you want to 11 think about being in a trial? 12 You tell them how many times they have to 13 come and how often and that unlike my usual retina 14 visit, which is probably two or three times longer 15 than your eye doctor's visit, it's an hour and a 16 half, two hours, just because we're always running 17 behind. Clinical trial visits are longer. They 18 have to do this big refraction, more testing. 19 And then after all of that, some patients 20 say, yeah, I'm interested in that, let's -- why 21 don't you sign me up. And then you test their 22 visual acuity, and it might be too good or too bad 23 to get in a trial after an informed consent which 24 they sign and -- and then there's lab work and they 25 may get kicked out for lab work, their diabetes is a Page 153

1 blood sugar that's too high to get in the trial and 2 other different things. 3 And then if they pass that, then they're 4 randomized to one of those five doses like we talked 5 about before and they enter a clinical trial based 6 on the protocol that's set up. 7 Q. Okay. And what was the clinical trial 8 protocol for DA VINCI? 9 MR. COBB: Objection, scope. 10 A. The trial protocol of DA VINCI, just from 11 40,000 feet, is essentially summarized in my draft 12 abstract paragraphs on page 21 of the declaration. 13 It's -- it's five different cohorts or arms, and 14 there's four different doses and dose intervals of 15 VEGF Trap-Eye that were tested: 0.5 milligrams 16 every four weeks, 2 milligrams every four weeks, 17 2 milligrams every eight weeks, or 2 milligrams PRN. 18 And that was compared to focal laser which was based 19 on some studies we'd done with the National Eye 20 Institute in the 1990s. 21 Q. And in paragraph 36, you reference or 22 state that DA VINCI was a double-masked trial. 23 Does that mean that what you say after 24 that, that each side had both masked and unmasked 25 clinical investigators, is that the definition of Page 154	1 A. I -- 2 MR. COBB: Objection, vague. 3 A. Yeah, I know I didn't. I don't know about 4 other investigators. I was not that involved with 5 DA VINCI clinical trials. 6 Q. Okay. And let me ask it this way. 7 Did you have any input whatsoever into the 8 dosing regimen for DA VINCI? 9 A. None -- none whatsoever. 10 Q. And are you aware of any other clinical 11 investigators who had input -- 12 A. I -- 13 Q. -- into the dosing regimen? 14 A. I don't. I mean, we participated in this 15 trial, but I was not -- to be fair, I was 16 essentially the lead investigator of RISE/RIDE, 17 Genentech's competitor diabetes trials, and was 18 publishing and presenting those trials. 19 And this is a competitor's diabetes drug, 20 and I -- it's one of the reasons Dr. Benz was the 21 principal investigator. I not only had enough food 22 on my plate with all the diabetes trials for 23 Genentech, it made sense to have a different 24 principal investigator for a -- sort of an upstart 25 company with another diabetes drug. Page 156
1 double-masked? 2 A. That's correct. 3 Q. Okay. In paragraph 37 of your 4 declaration, you say that you did not play a role in 5 developing the DA VINCI clinical trial protocol. 6 Is that right? 7 A. That's correct. 8 Q. And you follow that neither you, to your 9 knowledge, or to your knowledge the other clinical 10 investigators chose to test VEGF Trap-Eye and DME. 11 Is that right? 12 A. Yeah, that would have been a Regeneron -- 13 a Regeneron decision. 14 Q. Okay. And also that neither you nor the 15 other clinical investigators chose the dosing 16 regimen? Is that right? 17 A. That's correct. There was a protocol and 18 we stuck to it. 19 Q. Or the visual acuity endpoints? You guys 20 didn't chose -- choose those? 21 A. Correct. That was a Regeneron call. 22 Q. So is it fair to say that you -- neither 23 you nor any of the clinical investigators had any 24 input whatsoever into the choice of testing VEGF 25 Trap-Eye? Page 155	1 Q. And again, apologize if I asked you this 2 question in -- previous in the deposition, but did 3 you speak to Dr. Benz at all in preparation for this 4 declaration? 5 A. I did not. 6 Q. Okay. And I think you said that Regeneron 7 developed the DA VINCI clinical trial protocol? 8 A. I -- truthfully, I wasn't part of it. But 9 based on historical practices from industry, the 10 industry company would have developed this protocol 11 and then presented it to probably some 12 investigators. 13 Again, I wasn't a big part of the -- this 14 company or this trial until really quite a bit 15 later, until, you know, until this -- I was on the 16 DA VINCI trial, and yes, I'm on the one-year 17 manuscript, but I wasn't there at the beginning 18 parts of who actually -- who actually designed the 19 trial. I would bet that that was Regeneron. 20 Q. Okay. But sounds like you don't know. 21 A. I don't know. Correct. 22 Q. All right. And do you know who chose the 23 dosing regimens for the VEGF Trap-Eye arms? 24 A. I don't know. I can only -- you know, I 25 can only speculate that it was the Regeneron medical Page 157

1 team. 2 Q. Okay. But at this stage, you don't know? 3 A. I don't know. 4 Q. But you do know that you had no input 5 whatsoever into the dosing regimens? 6 A. I know I had no input whatsoever, correct. 7 Q. And do you know who chose the visual 8 acuity endpoints for the DA VINCI trial? 9 A. Again, it would have been the Regeneron 10 medical term -- team. That's not a, you know, 11 shocking thing to choose because it's basically our 12 endpoint for RISE/RIDE and you knew that eventually 13 you might have to go against it. Right? 14 So 24 weeks is an endpoint really to just 15 see where the drug is. In other words, the FDA 16 wouldn't give you a 24-week endpoint. That was 17 their endpoint because they really wanted to see can 18 this drug work in diabetes, you know, with different 19 dosing regimens. 20 Q. So it sounds like for that particular 21 concept, the visual acuity endpoint, you're pretty 22 sure that was Regeneron? 23 A. Yeah. I mean, it could have been -- yes, 24 that should have been Regeneron, probably with input 25 from other doctors, but it wouldn't have been me. Page 158	1 the first draft of the abstract because they're the 2 ones that actually have the data. And I -- I make 3 some comments and corrections and shorten it to fit 4 the term. 5 And then we get the actual ARVO rules. 6 Maybe they were out already and maybe -- you know, 7 this is sort of before the time when you had online 8 access to everything. And it turns out the wording 9 said you can only submit a late-breaking abstract if 10 you had not previously submitted an abstract. 11 And I technically had submitted an 12 abstract but been rejected. So I said, I'm not sure 13 I should do it. What I don't want to do is get you 14 guys rejected because I'm, you know, technically 15 not -- I technically did submit an abstract. 16 And so at this point, I've already 17 modified the abstract, it's all ready to go, but 18 they need an author probably within a week or so. 19 James Major is from south Florida. The meeting's in 20 Florida. I know he's going to the meeting anyway, 21 and I ask James, Hey, can you mind presenting an 22 abstract at ARVO? Are you presenting anything else? 23 And he would have said, No, I'd be happy to. He's a 24 former professor. He's a great speaker. And then 25 we put him on the abstract and he gave the talk. Page 160
1 Q. Just going down a few paragraphs, 2 Dr. Brown. Paragraph 45, I know you had given us 3 some insight into the ARVO late-breaking abstracts, 4 and I think you talk about that in paragraph 45? 5 A. Correct. 6 Q. And again, apologies if I asked you this 7 already. You referenced that you reached out to 8 Dr. Major about submitting the abstract? Is that 9 right? 10 A. Yes. So the initial -- let me just go 11 over what I said earlier. So I had submitted an 12 abstract which should have been one of the biggest 13 papers at ARVO, but it was rejected due to they 14 decided they wanted only papers that had actual data 15 in the abstract, which we didn't have because we 16 hadn't completed the trial. We would have done by 17 the time ARVO was presented. 18 So Regeneron knew that I didn't have a 19 presentation at ARVO, and they wanted to -- they got 20 this data and they said, We want to present it at 21 ARVO. Are you available? We know that your other 22 abstract, you know, was not accepted. And I go, I 23 think I'm available, sure. 24 So they send me a draft of the abstract. 25 As is the custom, the pharmaceutical company does Page 159	1 So the reason I didn't ask Benz, I have no 2 idea. He probably wasn't going to ARVO. He was a 3 pretty new employee of mine at the time. He came 4 from Baylor, and which is another institution in 5 town. But Matt Benz would have been a great choice 6 and would have done a great job. And he was a 7 principal investigator, so it would have been fine. 8 But that's how it came about that James 9 Major and I are on an abstract even though we were 10 sort of only tangentially involved with the 11 beginnings of the study. What that means, I guess, 12 is that everybody else that was really involved in 13 this study had already submitted an abstract for 14 ARVO and they were off the table. 15 Q. I see. And I think you said that in 16 preparation of your declaration you spoke to 17 Dr. Majors about what he recalled from this time 18 period? 19 A. I did. I was trying to find the abstract 20 itself. And since my computer system's changed and 21 my email system's changed, it was a bit of a 22 treasure hunt, but we found the emails to kind of 23 sort out what had happened 14 years earlier and 24 refresh our memory. 25 Because I literally would not have had Page 161

1 this much recollection of the event if we wouldn't 2 have found those old emails and our old -- it's -- 3 they're all put into -- they're all referenced here, 4 but they're -- you know, the actual dialogue between 5 Alyson Berliner, who was the physician 6 ophthalmologist at Regeneron that was responsible 7 for drafting this abstract and myself and then the 8 story about, Oh, my gosh, I better not do it because 9 I actually submitted an abstract, maybe that's a -- 10 you know, maybe that's wrong. We found all that in 11 email which helped refresh all this recollection. 12 Q. I see. And just, Dr. Brown, segueing back 13 just a moment to the PIER trial. At the time that 14 you were working on PIER, that was a trial that was 15 for Genentech, right? 16 A. That's correct. 17 Q. At that time did you speak to anyone at 18 Regeneron about the PIER results? 19 A. I didn't know anybody at Regeneron at that 20 time. 21 Q. Was there any point in time up till now, 22 other than your communications with counsel, of 23 course, that you spoke to someone at Regeneron about 24 the PIER results? 25 A. Not -- not that I recollect. Basically Page 162	1 exactly the same comments if you asked me the 2 questions in the '601. 3 Q. That was exactly what I was getting at. 4 So I didn't want to waste your time by asking you 5 the same questions. 6 A. I thought you were talking about the six 7 months ago. Oh, my God, I don't know if I said the 8 same thing word for word. I doubt it, but -- 9 MR. COBB: You don't get to stay on the 10 record four more hours. 11 MR. ERWINE: Well, thank you very much, 12 Dr. Brown. I have no further questions. 13 THE WITNESS: Thank you very much. 14 MR. COBB: And I too, Dr. Brown, have no 15 questions, so thank you for your time today and we 16 can go off the record. 17 THE VIDEOGRAPHER: Okay. Ms. Shelton, do 18 you have anything for the record? 19 THE REPORTER: I can get it when we go 20 off. Thank you. 21 THE VIDEOGRAPHER: Okay. If there's 22 nothing further, this concludes today's deposition. 23 Time is 2:41 p.m. We are off the record. 24 (Off the video record) 25 MR. COBB: On the transcript, can I get a Page 164
1 PIER would have been a study two or three years 2 before Regeneron had an eye molecule. Right? And 3 there's no real reason we would have talked about 4 it, so -- that I can imagine. 5 Q. Okay. So Dr. Brown, I raised this before, 6 but I have what would essentially be the same 7 questions about the '601 declaration. Is it fair to 8 say that your answers for the identical paragraphs 9 from '601 would match up with what I asked you for 10 the '572 patent? 11 A. I -- I guess we'd need to look at them. 12 I'm a very truthful guy and a fifth generation 13 cattle producer. We try to tell the truth. But I 14 guess I better look at it before I tell you that I 15 said the same thing six months ago as I said now. 16 Q. No, sorry. I'm actually talking about the 17 two that are -- that are the subject of today's 18 deposition. 19 A. No, no, no, they're the same, yeah. 20 They're the same. They're -- the -- I apologize. 21 I thought you meant the one from six months ago. 22 Q. Yeah. 23 A. The '601 and the '572, best I can tell, 24 are synonymous word for word until you get to the 25 parts about DA VINCI. So, yeah, I would have Page 163	1 rough? And then maybe like two days, is that what 2 everybody's ordering? 3 THE REPORTER: I have a one-day 4 turnaround, so tomorrow by end of business for the 5 final. But would you like a rough as well and then 6 same turnaround on your copy? 7 MR. COBB: Sure, yeah. 8 9 (Deposition concluded at 2:41 p.m. CDT) 10 -oOo- 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 Page 165

1 CHANGES AND SIGNATURE 2 WITNESS NAME: DATE OF DEPOSITION: 3 DAVID M. BROWN, M.D. APRIL 3, 2024 4 PAGE LINE CHANGE REASON 5 _____ 6 _____ 7 _____ 8 _____ 9 _____ 10 _____ 11 _____ 12 _____ 13 _____ 14 _____ 15 _____ 16 _____ 17 _____ 18 _____ 19 _____ 20 _____ 21 _____ 22 _____ 23 _____ 24 _____ 25 _____ Page 166	1 REPORTER'S CERTIFICATE 2 3 I, KAREN L. SHELTON, Texas CSR No. 7050, 4 RDR, CRR, do hereby certify; 5 That DAVID M. BROWN, M.D., the witness 6 whose deposition is hereinbefore set forth, was duly 7 sworn by me and that this transcript is a true 8 record of the testimony given by the witness; 9 I further certify that I am neither 10 counsel for, related to, nor employed by any of the 11 parties or attorneys in the action in which this 12 proceeding was taken. Further, I am not a relative 13 or employee of any attorney of record in this cause, 14 nor am I financially or otherwise interested in the 15 outcome of the action. 16 17 Certified to by me on this the 4th day of 18 April, 2024. 19 20 <i>Karen L. Shelton</i> 21 Karen L. Shelton, CSR, RDR, CRR 22 TX CSR 7050 Exp: 10/31/25 23 Veritext Legal Solutions 24 Firm No. 571 25 300 Throckmorton Street Suite 1600 Fort Worth, Texas 76102 (817) 336-3042 (800) 336-400 Page 168
1 I, DAVID M. BROWN, M.D., have read the 2 foregoing deposition and hereby affix by signature 3 that same is true and correct, except as noted 4 above. 5 6 _____ 7 DAVID M. BROWN, M.D. 8 9 STATE OF _____) 10 COUNTY OF _____) 11 Before me, _____, on this 12 day personally appeared DAVID M. BROWN, M.D., known 13 to me (or proved to me under oath or through 14 _____) (description of identity card or 15 other document) to be the person whose name is 16 subscribed to the foregoing instrument and 17 acknowledged to me that they executed the same for 18 the purposes and consideration therein expressed. 19 Given under my hand and seal of office 20 this _____ day of _____, 2024. 21 22 _____ 23 NOTARY PUBLIC IN AND FOR 24 THE STATE OF _____ 25 My Commission Expires: _____ Page 167	

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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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