

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

3 SAMSUNG BIOEPIS CO, LTD.,

4 Petitioner,

5 vs.

6 REGENERON PHARMACEUTICALS, INC.,

7 Patent Owner.

8 Case IPR2023-008844

9 U.S. Patent No. 11,253,572

10 VIDEO-RECORDED

11 DEPOSITION OF: MICHAEL STEWART, MD

12 DATE: May 30, 2024

13 TIME: COMMENCED: 8:49 a.m.

14 CONCLUDED: 2:03 p.m.

15 TAKEN BY: Petitioner

16 PLACE: Hampton Inn Jacksonville/Ponte Vedra
Beach

17 1220 Marsh Landing Parkway
Jacksonville Beach, Florida 32250

18 REPORTED BY: Mae Fisher, RMR, CRR

1 Do you solemnly swear or affirm that the 2 testimony you are about to give in this cause will be 3 the truth, the whole truth, and nothing but the truth? 4 THE WITNESS: I do. 08:50:48 5 MICHAEL STEWART, MD, 08:50:48 6 a witness herein, having been first duly sworn, was 7 examined, and testified as follows: 08:50:49 8 DIRECT EXAMINATION 08:50:49 9 BY MR. NIMROD: 08:50:49 10 Q. Good morning, Dr. Stewart. 08:50:50 11 A. Good morning, Mr. Nimrod. 08:50:51 12 MR. NIMROD: I'd like to mark as Stewart 08:50:55 13 Exhibit 1 a copy of the 572 patent. 08:50:56 14 (Exhibit No. 1 was marked for identification.) 08:51:08 15 MR. NIMROD: I'd also like to mark as Stewart 08:51:22 16 Exhibit 2 a copy of Dr. Stewart's declaration. 08:51:23 17 (Exhibit No. 2 was marked for identification.) 08:51:34 18 BY MR. NIMROD: 08:51:34 19 Q. Here you go. 08:51:36 20 A. Thank you. 08:51:37 21 MR. BRAUSA: Thank you. 08:51:37 22 BY MR. NIMROD: 23 Q. Dr. Stewart, if you could turn in your 08:51:42 24 declaration to paragraph 65, please -- 64. 08:51:44 25 A. Okay. 08:51:56 Page 6	1 in the dependent claim only two secondary doses are 08:53:24 2 administered to the patient. 08:53:28 3 Do you see that? 08:53:29 4 A. Yes, I do. 08:53:29 5 Q. So what is the predetermined fixed dosing regimen 08:53:31 6 required by claim 27? 08:53:35 7 MR. BRAUSA: Objection; form. 08:53:39 8 THE WITNESS: So since 27 depends on 26, my 08:53:41 9 understanding is that this is a method of treating 08:53:48 10 age-related macular degeneration and the patient need 08:53:53 11 thereof, comprising sequential administration of a 08:53:56 12 single dose of 2 milligrams of Aflibercept. 08:54:00 13 And then 27 says: Wherein, only two secondary 08:54:03 14 doses are administered to the patient and then 08:54:07 15 followed by one or more tertiary doses of 2 milligrams 08:54:14 16 of Aflibercept. 08:54:19 17 And then you have the qualifier: And those 08:54:20 18 doses, the tertiary doses, are given at eight weeks 08:54:24 19 intervals. Each secondary dose is four weeks 08:54:27 20 following immediate preceding dose. 08:54:30 21 And then you have a qualifier for a visual 08:54:32 22 result at the end. 08:54:35 23 BY MR. NIMROD: 08:54:36 24 Q. Okay. So for claim 27, the fixed regimen 08:54:36 25 requires three initial doses that are a month apart and 08:54:42 Page 8
1 Q. You state in paragraph 64: It is my opinion 08:51:56 2 based on the claims and specification of the 572 patent 08:52:00 3 that a POSA would understand that challenged claims, 08:52:04 4 specifically claim 15 and thereby claim 25, be limited 08:52:08 5 to a predetermined fixed dosing schedules. 08:52:14 6 Do you see that? 08:52:16 7 A. Yes, I do. 08:52:17 8 Q. And then on paragraph 74, you state -- seems more 08:52:18 9 broadly, in the last sentence of paragraph 74. Are you 08:52:26 10 with me? 08:52:29 11 A. I see it. 08:52:30 12 Q. It says: In my opinion -- it is my opinion that 08:52:30 13 a POSA would see this as further evidence that the 572 08:52:33 14 patent claims are drawn to predetermined fixed interval 08:52:37 15 dosing regimens. 08:52:41 16 Do you see that? 08:52:42 17 A. I see it. 08:52:42 18 Q. Is it your opinion that all the claims of the 572 08:52:43 19 patent are directed to predetermined fixed interval 08:52:47 20 dosing regimens? 08:52:52 21 A. Yes, it is, it's my opinion. 08:52:56 22 Q. So if we could turn to Exhibit 1, which is the 08:52:58 23 patent, the 572 patent. And go to claim 27, claims near 08:53:02 24 the end. You're already there. Good. 08:53:13 25 Claim 27 depends from claim 26. And it requires 08:53:16 Page 7	1 then followed by dosing every eight weeks till the end 08:54:44 2 of treatment; is that right? 08:54:48 3 MR. BRAUSA: Objection; form. 08:54:50 4 THE WITNESS: So 27 when combined with 26 08:54:51 5 requires three initial doses, a primary, two 08:54:56 6 secondaries, and then followed by tertiary doses at 08:54:59 7 eight-week intervals. 08:55:03 8 BY MR. NIMROD: 08:55:04 9 Q. And to be within the scope of claim 27, I think 08:55:05 10 we talked about this last time, it's your opinion that 08:55:13 11 if by happenstance or by treatment by PRN, a physician 08:55:16 12 does not have a predetermined regimen but simply through 08:55:21 13 observation of the patient decides on an ongoing basis 08:55:26 14 to do first dose, two secondary doses and then have 08:55:30 15 eight-week dosing after that, that would not fall within 08:55:35 16 the scope of the claims; is that right? 08:55:37 17 MR. BRAUSA: Objection; form. 08:55:39 18 THE WITNESS: Would you repeat the question, 08:55:40 19 please? You combined a couple of different factors 08:55:43 20 there. 08:55:46 21 BY MR. NIMROD: 08:55:46 22 Q. Right. So if a physician does not have a 08:55:47 23 predetermined dosing regimen, does that mean that the 08:55:48 24 treatment does not fall within the scope of claim 27? 08:55:52 25 MR. BRAUSA: Objection; form. 08:55:56 Page 9

1 THE WITNESS: So my opinion, 27 requires a 08:55:57	1 follows 26, my answer is no, in advance, you cannot 08:59:16
2 predetermined dosing regimen. 08:56:03	2 predict the outcome of a given patient. 08:59:20
3 BY MR. NIMROD: 08:56:08	3 Q. So does that mean that for claim 27, where you 08:59:24
4 Q. If you could then turn to page 30 and 31 and just 08:56:08	4 have a predetermined fixed schedule, that is not based 08:59:28
5 read paragraph 65 to yourself, please -- I'm sorry -- of 08:56:12	5 on patient outcomes, as you're going along with the 08:59:34
6 your declaration. 08:56:16	6 treatment, one would simply measure the outcome at 08:59:37
7 A. Okay. Paragraph 65? 08:56:17	7 52 weeks to see if a patient achieved the required gain 08:59:42
8 Q. Yes, please. 08:56:21	8 or not; is that right? 08:59:47
9 A. Okay. 08:57:17	9 MR. BRAUSA: Objection; form. 08:59:48
10 Q. All right. On page 31, you -- sorry, go back to 08:57:18	10 THE WITNESS: In order to meet -- in order to 08:59:51
11 30. You say: Fixed regimens are those where doses are 08:57:23	11 meet claim 26, then you would measure the outcome at 08:59:56
12 administered on a predetermined schedule regardless of 08:57:28	12 week 52 to see if the claim were followed. In 09:00:02
13 observed outcomes at any given visit. 08:57:31	13 clinical practice, obviously that's not something you 09:00:06
14 Do you see that? 08:57:33	14 would consider. 09:00:09
15 A. Yes, I see that. 08:57:34	15 BY MR. NIMROD: 09:00:11
16 Q. Okay. And then you go on and say that fixed 08:57:36	16 Q. You wouldn't consider whether or not -- what the 09:00:11
17 regimens include monthly doses, as well as regimens 08:57:39	17 outcome was at 52 weeks in particular? Is that what you 09:00:13
18 involving a set number of loading doses all by dosing at 08:57:42	18 mean? 09:00:16
19 longer fixed interval as described in the EYLEA label. 08:57:46	19 A. You wouldn't -- 09:00:17
20 Do you see that as well? 08:57:50	20 MR. BRAUSA: Objection; form. 09:00:17
21 A. Yes, I do. 08:57:51	21 THE WITNESS: You would not compare it to the 09:00:17
22 Q. And then you go on the next sentence and you say 08:57:52	22 claim. 09:00:22
23 that: Sometimes adherence to the predetermined 08:57:55	23 BY MR. NIMROD:
24 schedules in perfect regimens are still considered fixed 08:58:00	24 Q. You would not compare it to -- how do you 09:00:24
25 when the intended dosing interval is based on a schedule 08:58:01	25 pronounce that again -- Ranibizumab? 09:00:28
Page 10	Page 12
1 rather than patient outcomes. 08:58:05	1 A. Ranibizumab. 09:00:30
2 Do you see that? 08:58:06	2 Q. Got it. Okay. So in actual clinical practice, 09:00:31
3 A. Yes, I do. 08:58:07	3 you would not compare your patient's results to what the 09:00:36
4 Q. What do you mean by rather than patient outcomes? 08:58:09	4 patient would have achieved with Ranibizumab -- 09:00:40
5 MR. BRAUSA: Objection; form. 08:58:13	5 MR. BRAUSA: Objection. 09:00:43
6 THE WITNESS: By that, we mean that we adhere 08:58:14	6 BY MR. NIMROD: 09:00:43
7 to the predetermined schedule and whether the patient 08:58:19	7 Q. -- for an individual patient? 09:00:44
8 has significant success, marginal success, we stick to 08:58:23	8 MR. BRAUSA: Objection; form. 09:00:45
9 the schedule, regardless of that and we do not use 08:58:30	9 THE WITNESS: So in clinical practice, we have 09:00:46
10 patient-determined data at the visit to modify the 08:58:34	10 no way to know what that patient would have achieved 09:00:50
11 dosing. 08:58:38	11 had they received Ranibizumab instead of Aflibercept. 09:00:54
12 BY MR. NIMROD: 08:58:40	12 BY MR. NIMROD:
13 Q. So then does that mean that if -- strike that. 08:58:41	13 Q. So for claim 26, how would a physician know 09:01:01
14 When you -- strike that again. 08:58:45	14 whether or not the -- let me strike that again. 09:01:09
15 If a physician decides to use a predetermined 08:58:49	15 How would a -- for claim 26, how would a skilled 09:01:14
16 dosing regimen, as called for by claim 27 in the 572 08:58:51	16 artisan know whether they were practicing claim 26 and 09:01:18
17 patent, does the physician know -- can the physician 08:58:55	17 specifically know whether or not they had achieved a 09:01:24
18 predict in advance whether an individual patient will 08:59:00	18 gain in visual acuity as compared to Ranibizumab? 09:01:26
19 have a specific outcome? 08:59:02	19 MR. BRAUSA: Objection; form. 09:01:32
20 MR. BRAUSA: Objection; form. 08:59:05	20 THE WITNESS: Well, if you look at the writing 09:01:33
21 THE WITNESS: You're speaking of treating with 08:59:07	21 of 26, and you are concerned about meeting the claim, 09:01:38
22 Aflibercept? 08:59:10	22 then you would compare it to the comparator, which is 09:01:43
23 BY MR. NIMROD: 08:59:10	23 Ranibizumab, if you were worried about meeting the 09:01:47
24 Q. Yes, I am. 08:59:10	24 claim. 09:01:51
25 A. And according to claim 27, which, of course, 08:59:11	25 BY MR. NIMROD: 09:01:52
Page 11	Page 13

1 Q. But the claim 26 and, therefore, claim 27 refer 09:01:52 2 to treating a patient. Do you see that? 09:01:58 3 A. Yes. 09:02:00 4 Q. So for a patient, how would you determine, as a 09:02:00 5 skilled artisan, whether you were practicing the 09:02:04 6 method -- let me start over again, okay? 09:02:08 7 All right. So let's say a physician decides to 09:02:10 8 practice the dosing regimen that's required by claim 27, 09:02:15 9 which is an initial dose, two secondary doses and then 09:02:20 10 one month apart, and then tertiary doses that are eight 09:02:24 11 weeks apart, do you follow me? 09:02:28 12 A. Yes. 09:02:31 13 Q. Okay. So a skilled person is then treating a 09:02:31 14 patient following that regimen, that's required by claim 09:02:35 15 27, how does the skilled person know whether the patient 09:02:39 16 that they're treating meets the limitation -- limitation 09:02:44 17 of wherein is as effective in achieving a gain in visual 09:02:49 18 acuity as monthly administration of 0.5 milligrams of 09:02:53 19 Ranibizumab by intravitreal injection in human subjects 09:02:58 20 with age-related macular degeneration at 52 weeks 09:03:03 21 following the initial dose? 09:03:09 22 MR. BRAUSA: Objection; form. 09:03:11 23 THE WITNESS: So let me answer that two ways. 09:03:12 24 So one, the physician would not know what might have 09:03:19 25 happened if Ranibizumab had been used instead of 09:03:22 Page 14	1 BY MR. NIMROD: 09:05:14 2 Q. So in order to meet the method of claim 27, the 09:05:14 3 patient would have to achieve at least 8.1 in terms of 09:05:17 4 improved visual acuity? 09:05:23 5 MR. BRAUSA: Objection. 09:05:25 6 BY MR. NIMROD: 09:05:25 7 Q. Is that right? 09:05:26 8 MR. BRAUSA: Objection; form. 09:05:26 9 THE WITNESS: So treated, according to 26 and 09:05:28 10 27, with Aflibercept, patient would -- at 52 weeks, 09:05:30 11 would have to meet eight letters. We don't measure at 09:05:35 12 point 1. 09:05:41 13 BY MR. NIMROD: 09:05:43 14 Q. You also said in your answer, you get the results 09:05:44 15 that you get. What -- let me start over again. 09:05:53 16 In your answer, you said you get the results that 09:05:57 17 you get at 52 weeks. What did you mean by that? 09:05:59 18 A. Sort of a colloquial way of saying it. You treat 09:06:03 19 according to your regimen. And the results you end up 09:06:08 20 with are what you end -- are what you have for that 09:06:11 21 patient. You have no way of comparing to a different 09:06:14 22 regimen that could have been used or a different drug 09:06:19 23 that could have been used. 09:06:21 24 Q. And when you say you get what you get, if you're 09:06:24 25 practicing the method of claim 27, that means that you 09:06:26 Page 16
1 Aflibercept. So you get the results that you get. 09:03:27 2 Secondly, if you're looking to know, does it 09:03:33 3 meet the claim, then you look at the data -- you look 09:03:35 4 at the monthly -- the expected visual acuity results 09:03:42 5 at 52 weeks with monthly Ranibizumab. 09:03:46 6 BY MR. NIMROD: 7 Q. And what is the expected visual acuity results at 09:03:50 8 52 weeks for monthly Ranibizumab? 09:03:56 9 A. So my understanding is that comes from the 09:03:59 10 specifications. And that comes -- and that comes from 09:04:03 11 table 1 in the specifications. And in table 1, there 09:04:09 12 are two numbers. Column 15. 09:04:16 13 Q. I'm there. Yeah. 09:04:22 14 A. Yeah. So 8.1 and 9.4. Those are derived from 09:04:24 15 two parallel similarly structured studies. 09:04:28 16 Q. So is it your opinion that in order for a method 09:04:31 17 to fall within the scope of claim 27, there has to be a 09:04:38 18 mean improvement in visual acuity of 8.1 or 9.4? 09:04:44 19 MR. BRAUSA: Objection; form. 09:04:51 20 THE WITNESS: So if treating with Aflibercept 09:04:51 21 according to the specifications in 26 and 27, then my 09:04:55 22 understanding is it has to meet those numbers. Now, 09:04:59 23 we can argue is it 8.1, is it 9.4, but that's the 09:05:03 24 comparator for Ranibizumab that's specified in the 09:05:09 25 claim. 09:05:13 Page 15	1 don't have a way of predicting whether or not you're 09:06:29 2 going to be above or below the baseline for Ranibizumab 09:06:31 3 of eight letter gains; is that right? 09:06:34 4 A. So you're saying -- 09:06:36 5 MR. BRAUSA: Objection; form. 09:06:39 6 THE WITNESS: That if you treat according to 09:06:43 7 the specifications in claims 26 and 27, that there's 09:06:44 8 no way in advance to know if your 52-week visual 09:06:47 9 acuity result is going to be above or below the 09:06:52 10 comparator, which is Ranibizumab result. 09:06:54 11 BY MR. NIMROD: 09:06:58 12 Q. And you agree with that? 09:06:58 13 A. As I stated it, yeah. Well, as I stated it, yes. 09:07:00 14 Q. You stated it better. Let me just repeat that, 09:07:05 15 then. 09:07:12 16 A. Okay. 17 Q. It's your opinion that if you treat according to 09:07:12 18 the dosing regimen of claims 27, I'll say, there's no 09:07:16 19 way to know in advance if you're going to meet the 09:07:18 20 52-week visual acuity result that is going to be above 09:07:22 21 or below the comparator, which is Ranibizumab; is that 09:07:27 22 right? 09:07:30 23 A. Treating with Aflibercept, yes. That's correct. 09:07:30 24 Q. And when I say claim 27, that -- of course, that 09:07:34 25 always requires Aflibercept, just -- 09:07:38 Page 17

1 A. I know. I understand. Because it's included in 09:07:40 2 26. 09:07:43 3 Q. Right. Okay. And so if you're practicing the 09:07:43 4 method of claim 27, there's no discretion with respect 09:07:49 5 to practicing that claim as to modifying the dosing 09:07:56 6 regimens in terms of the number of secondary doses and 09:08:00 7 the spacing between the weeks of administration; is that 09:08:04 8 right? 09:08:09 9 MR. BRAUSA: Objection; form. 09:08:09 10 THE WITNESS: If you're practicing according to 09:08:11 11 the claim, then the dose is fixed, and you don't 09:08:14 12 modify or you don't change from the fixed dosing. 09:08:18 13 BY MR. NIMROD: 14 Q. Thank you. All right. So now, let's turn to 09:08:22 15 claim 1 of the 572 patent. Claim 1 is a method of 09:08:26 16 treating an angiogenic eye disorder in a patient in need 09:08:42 17 thereof. 09:08:46 18 Do you see that? 09:08:47 19 A. I do. 09:08:47 20 Q. And it requires a sequential administration of an 09:08:48 21 IV injection of a single dose of 2 mg of Aflibercept; is 09:08:56 22 that right? 09:09:02 23 A. Intravitreal and intravenous, yes. 09:09:03 24 Q. Oh, intravitreal, thank you. 09:09:05 25 And then it says: Followed by one or more 09:09:07 Page 18	1 BY MR. NIMROD: 2 Q. So if a skilled person is practicing claim 1, is 09:10:29 3 the regimen fixed in advance such that there's no 09:10:33 4 discretion as to how many secondary and how many 09:10:38 5 tertiary doses are administered? 09:10:42 6 MR. BRAUSA: Objection; form. 09:10:46 7 THE WITNESS: So the predetermination is the 09:10:47 8 number of doses given. If there is no 09:10:52 9 predetermination or if the treatment regimen is 09:10:55 10 changed because of an observation of the patient, then 09:11:00 11 the physician is now practicing an individualized and 09:11:05 12 not a predetermined fixed regimen. 09:11:09 13 BY MR. NIMROD: 14 Q. So could you describe how a physician would 09:11:13 15 practice claim 1, be within the scope that it's not PRN? 09:11:15 16 MR. BRAUSA: Objection. 09:11:21 17 BY MR. NIMROD: 09:11:21 18 Q. Give me an example. 09:11:22 19 MR. BRAUSA: Objection; form. 09:11:22 20 THE WITNESS: So I'm -- by you're -- you're 09:11:23 21 saying is, is not PRN, so I'm interpreting that as how 09:11:29 22 would a physician practice that as a fixed regimen. 09:11:34 23 So the fixed regimen, an example, would be a physician 09:11:38 24 would say, I'm going to start by giving a primary 09:11:43 25 dose, I'm going to then give two secondary doses, and 09:11:46 Page 20
1 secondary doses and one or more tertiary doses. 09:09:10 2 Do you see that? 09:09:13 3 A. Yes, I do. 09:09:13 4 Q. Okay. And then it goes on and says that each 09:09:14 5 secondary dose is administered approximately four weeks 09:09:19 6 apart and that each tertiary is administered 09:09:21 7 approximately every eight weeks apart. Is that right? 09:09:24 8 A. Yes. 09:09:28 9 Q. Now, in what sense is claim 1 a predetermined 09:09:28 10 dosing regimen -- or let me strike that. 09:09:34 11 In what sense is claim 1 a predetermined fixed 09:09:38 12 dosing regimen? 09:09:42 13 MR. BRAUSA: Objection; form. 09:09:43 14 THE WITNESS: The claim -- claim 1 says you're 09:09:49 15 going to give your primary dose, then you're going to 09:09:51 16 give a number of secondary doses and then followed by 09:09:53 17 tertiary doses at set intervals. 09:09:57 18 BY MR. NIMROD: 19 Q. But if a skilled artisan is practicing claim 1, 09:10:01 20 how is the number of secondary doses predetermined and 09:10:11 21 fixed, if at all? 09:10:15 22 MR. BRAUSA: Objection; form. 09:10:18 23 THE WITNESS: So my read of claim 1 is that 09:10:19 24 this number of secondary doses is predetermined, and 09:10:23 25 therefore, is fixed. 09:10:27 Page 19	1 then I'm going to switch after that to tertiary doses, 09:11:50 2 which we're going to continue. 09:11:55 3 BY MR. NIMROD: 4 Q. Okay. And once the physician has made that 09:11:59 5 decision, then the regimen is fixed in the sense that it 09:12:02 6 was for claim 27 going forward with no discretion based 09:12:06 7 on the patient outcomes along the way; is that right? 09:12:12 8 MR. BRAUSA: Objection; form. 09:12:15 9 THE WITNESS: The -- if you meet the number of 09:12:16 10 doses, you eventually get to the point where you might 09:12:22 11 elect to stop therapy or reassess. But as long as you 09:12:29 12 meet the number of doses here and in a predetermined 09:12:34 13 fashion, then that's the fixed regimen. 09:12:38 14 THE VIDEOGRAPHER: Excuse me, can we go off the 09:12:42 15 record? 09:12:45 16 MR. NIMROD: Sure. 09:12:46 17 THE VIDEOGRAPHER: Stand by. We are going off 09:12:46 18 the record at 9:12. 09:12:48 19 (A brief recess was taken.) 09:12:50 20 THE VIDEOGRAPHER: We are back on the record at 09:14:45 21 9:14. 09:14:56 22 BY MR. NIMROD: 09:14:57 23 Q. So if we turn now to -- on claims 24 and 25. 09:15:01 24 A. Yes. 09:15:08 25 Q. Claim 24 depends from claim 15 and says: Wherein 09:15:08 Page 21

1 only two secondary doses are administered to the 09:15:12	1 patient will meet the gain required by claim 2 in 09:18:05
2 patient. 09:15:18	2 advance -- know that in advance of start of the 09:18:09
3 Do you see that? 09:15:18	3 treatment? 09:18:11
4 A. Yes. 09:15:19	4 MR. BRAUSA: Objection; form. 09:18:12
5 Q. And then claim 25 says: Wherein, four secondary 09:15:19	5 THE WITNESS: No. He would not know in advance 09:18:12
6 doses are administered to the patient. 09:15:23	6 if the visual acuity requirement were going to be met. 09:18:16
7 Do you see that? 09:15:25	7 BY MR. NIMROD:
8 A. Yes. 09:15:25	8 Q. So the physician would simply measure at week 52 09:18:20
9 Q. Are those methods fixed in the sense that -- in 09:15:26	9 whether there was a gain and whether the gain was a gain 09:18:24
10 the same sense that claim 27 is, with the difference 09:15:32	10 in the BCVA; is that right? 09:18:29
11 being that claim 15 -- 25 requires four secondary doses 09:15:36	11 MR. BRAUSA: Objection; form. 09:18:32
12 but otherwise is fixed in the same type of way? 09:15:39	12 THE WITNESS: No. The claim 1 talks about a 09:18:33
13 MR. BRAUSA: Objection; form. 09:15:42	13 visual acuity gain within 52 weeks and so he would 09:18:37
14 THE WITNESS: So those doses follow from 15 09:15:43	14 measure periodically along the way. Typically we'd 09:18:42
15 and, again, this is predetermined dosing with 09:15:48	15 measure it every visit. Could be measured monthly but 09:18:45
16 Aflibercept, so a single dose and then followed by 09:15:53	16 he would measure on a regular basis and look at each 09:18:48
17 exactly two secondary doses to meet claim 24 or four 09:15:59	17 of those results up through week 52. 09:18:51
18 secondary doses to meet claim 25 and then regarding 09:16:04	18 BY MR. NIMROD: 09:18:55
19 whichever predetermined decision the physician made, 09:16:12	19 Q. Is the gain in visual acuity required by claim 1 09:18:55
20 he would then follow with the tertiary doses. 09:16:15	20 the same as the BCVA gain or is that different -- a 09:19:00
21 BY MR. NIMROD: 09:16:19	21 different measurement? 09:19:05
22 Q. Okay. So it would be fixed then in the same 09:16:20	22 MR. BRAUSA: Objection; form. 09:19:07
23 sense that claim 27 was fixed, that there would be no 09:16:23	23 THE WITNESS: So the gain in visual acuity in 09:19:09
24 discretion as to how you change the -- to change the 09:16:26	24 claim 1, my interpretation is that is a gain relative 09:19:14
25 dosing, timing, throughout the treatment? 09:16:29	25 to baseline, not relative to the Ranibizumab 09:19:19
Page 22	Page 24
1 MR. BRAUSA: Objection; form. 09:16:33	1 comparator. 09:19:24
2 THE WITNESS: So predetermined, fixed and the 09:16:33	2 BY MR. NIMROD: 09:19:24
3 physician would not exercise discretion. 09:16:41	3 Q. Okay. But what -- strike that. 09:19:25
4 BY MR. NIMROD: 09:16:45	4 You have a claim 2, there's a BCVA score, when 09:19:28
5 Q. Okay. Could you look at claim 2, please. Just 09:16:46	5 you're looking at claim 1, is -- are you looking for a 09:19:35
6 read that to yourself. 09:16:52	6 BCVA gain when it says: Wherein, the patient achieves a 09:19:38
7 A. Okay. 09:16:59	7 gain in visual acuity within 52 weeks following the 09:19:42
8 Q. So claim 2 relates to achieving a gain in BCVA 09:17:00	8 initial dose? 09:19:44
9 according to ETDRS letter score. 09:17:06	9 A. So claim 1 says a gain in visual acuity. Claim 2 09:19:48
10 Do you see that? 09:17:10	10 tells us that you measure the visual acuity by an ETDRS 09:19:53
11 A. Yes. 09:17:14	11 letter score. 09:19:59
12 Q. And is it your understanding that the -- that 09:17:15	12 Q. For claim 1, is there some other way of measuring 09:20:00
13 that's referring to -- well, strike that. 09:17:18	13 visual acuity to see if there's a gain, other than the 09:20:02
14 Again, would you have -- would a physician that 09:17:21	14 ETDRS letter score? 09:20:06
15 is practicing the dosing regimen of claim 1 with 09:17:27	15 A. So the ETDRS is a specific chart that's used. 09:20:09
16 Aflibercept know whether or not an individual patient 09:17:30	16 There are other charts that can be used as well. 09:20:14
17 will meet the gain required by claim 2 in advance at the 09:17:33	17 Q. What are some of the other charts? 09:20:20
18 start of the treatment? 09:17:40	18 A. The Snellen chart, they're commonly used. 09:20:23
19 MR. BRAUSA: Objection; form. 09:17:45	19 Q. Do the results from the Snellen chart correlate 09:20:29
20 THE WITNESS: So -- repeat the question, 09:17:48	20 well with the ETDRS letter score? 09:20:34
21 please. 09:17:52	21 MR. BRAUSA: Objection; form. 09:20:37
22 BY MR. NIMROD:	22 THE WITNESS: They correlate closely but not 09:20:40
23 Q. Would a physician that is practicing the dosing 09:17:54	23 exactly. 09:20:44
24 regimen of claim 2, which depends on claim 1, with 09:17:56	24 BY MR. NIMROD:
25 Aflibercept, know in advance whether an individual 09:18:02	25 Q. All right. Could you turn to claim 30 on the 09:20:51
Page 23	Page 25

1 next page of the 572 patent. 09:20:56	1 Q. I meant to say -- 09:23:49
2 Claim 30 depends from claim 29 and states: 09:21:04	2 A. No. That's not correct. 29 says: The clause 09:23:51
3 Wherein, maintenance of visual acuity means loss of less 09:21:07	3 for vision is as effective as maintaining visual acuity 09:23:56
4 than 15 letters, BCVA, as measured by the ETDRS letter 09:21:10	4 as monthly administration of 0.5-milligram Ranibizumab 09:24:00
5 score. 09:21:19	5 at 52 weeks. 09:24:05
6 Do you see that? 09:21:19	6 Q. What's the difference? 09:24:18
7 A. Yes. 09:21:20	7 A. 26 says: As effective as achieving a gain in 09:24:19
8 Q. And does a physician know, if they're 09:21:20	8 vision as monthly Ranibizumab at 52 weeks. 09:24:24
9 practicing -- strike that. 09:21:29	9 Q. Okay. So thank you for pointing that out. 09:24:29
10 Why don't you look at claim 29 so we have the 09:21:30	10 So what is the standard, then, go through the 09:24:33
11 context here since it's dependent from it. 09:21:34	11 same exercise, skilled artisan is treating a patient, 09:24:35
12 Are you there? 09:21:35	12 according to the regimen of claim 29, with Aflibercept, 09:24:40
13 A. I'm reading. 09:21:36	13 and wants to know whether or not they are practicing the 09:24:44
14 Okay. 09:21:59	14 method of claim 29, what standard they use, since they 09:24:48
15 Q. Okay. So claim 29, like claim 26, has a: 09:22:00	15 can't redose the same patient in some hypothetical 09:24:51
16 Wherein, the method is effective -- is as effective in 09:22:04	16 world? 09:24:56
17 maintaining visual acuity as monthly administration of 09:22:08	17 MR. BRAUSA: Objection; form. 09:24:57
18 0.5 milligrams of Ranibizumab by intravitreal injection 09:22:13	18 THE WITNESS: I -- by standard, do you mean, is 09:24:58
19 in human subjects with age-related macular degeneration 09:22:17	19 the visual acuity result meeting the claim? Is that 09:25:02
20 at 52 weeks following the initial dose. 09:22:21	20 what you're asking me by standard? 09:25:06
21 Do you see that? 09:22:23	21 BY MR. NIMROD: 09:25:07
22 A. Yes. 09:22:24	22 Q. Yes. 09:25:07
23 Q. And the claim 30 has that limitation regarding 09:22:24	23 A. Yes. So stated there, as effective as 09:25:07
24 loss of less than 15 letters in the ETDRS letter score. 09:22:37	24 maintaining visual acuity and then claim 30 tells us the 09:25:12
25 Do you see that? 09:22:42	25 definition of maintenance, which is a less than 15 09:25:17
Page 26	Page 28
1 A. Yes. 09:22:43	1 letter loss. 09:25:20
2 Q. So if a POSA or the skilled person meets the 09:22:44	2 Q. So claim 29, if you just look at that. 09:25:22
3 limitation of the wherein clause in claim 29, won't they 09:22:51	3 A. Yes. 09:25:28
4 always meet the wherein -- the limitation of claim 30 09:22:55	4 Q. Is if a skilled person practices the regimen 09:25:29
5 because you told me that the limitation at the bottom of 09:22:59	5 called for by claim 29. 09:25:33
6 claim 26 and therefore, 29, requires at least an 09:23:03	6 A. Yes. 09:25:35
7 eight-letter gain; is that right? 09:23:07	7 Q. And the patient does not have a loss of more than 09:25:35
8 MR. BRAUSA: Objection; form. 09:23:10	8 15 letters, then the physician is practicing the method 09:25:45
9 THE WITNESS: Repeat the question, please. I 09:23:11	9 of claim 29; is that right? 09:25:51
10 think there are two questions in there. 09:23:15	10 MR. BRAUSA: Objection; form. 09:25:53
11 BY MR. NIMROD:	11 THE WITNESS: So assuming he's practicing the 09:25:54
12 Q. Okay. Just to go back, I believe you told me 09:23:16	12 treatment, the injections, per the schedule up above 09:25:58
13 that the wherein clause at the bottom of 26 require a 09:23:19	13 and his -- he is -- one second -- and then the patient 09:26:01
14 gain in visual acuity of at least eight letter scores. 09:23:23	14 has a less than 15-letter vision loss, then he is 09:26:16
15 Is that right? 09:23:30	15 practicing the claim. 09:26:22
16 A. Yes. 09:23:31	16 BY MR. NIMROD: 09:26:24
17 Q. Okay. And so claim 29, likewise, requires a 09:23:32	17 Q. And I was asking about claim 29. You understand 09:26:24
18 visual acuity gain in letter score of at least eight. 09:23:37	18 that, right? 09:26:26
19 Correct? 09:23:41	19 A. Yes. 09:26:27
20 MR. BRAUSA: Objection; form. 09:23:42	20 Q. Just to be clear. 09:26:27
21 THE WITNESS: I'm sorry. 29 requires that? Is 09:23:44	21 A. Yes. Yes. 09:26:28
22 that what you're asking me? 09:23:46	22 Q. Okay. So it's your opinion that the wherein 09:26:28
23 BY MR. NIMROD: 09:23:47	23 clause at the bottom of claim 29, which requires the 09:26:31
24 Q. Did I say that? 09:23:47	24 comparison to Ranibizumab, has the same standard or is 09:26:38
25 A. That's what you said, yes. 09:23:48	25 the same standard as the wherein clause of claim 30. Is 09:26:41
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1 that right? 09:26:48	1 MR. BRAUSA: Objection; form. 09:29:41
2 MR. BRAUSA: Objection; form. 09:26:49	2 THE WITNESS: So yes. That would also fall 09:29:41
3 THE WITNESS: So maintaining visual acuity at 09:26:51	3 within the scope of 29. 09:29:45
4 the time, and to this day, on macular degeneration 09:26:56	4 BY MR. NIMROD:
5 patients, is defined as a less than 15-letter vision 09:26:59	5 Q. And just as another example, if I only -- if the 09:29:46
6 loss. That's been standard. 09:27:05	6 physician only gave two secondary doses, that likewise 09:29:48
7 BY MR. NIMROD: 09:27:05	7 would fall within the scope of claim 29, assuming it was 09:29:52
8 Q. So the answer to my question is yes? 09:27:06	8 fixed and predetermined at the start? 09:29:55
9 A. Is yes. 09:27:07	9 A. So assuming -- 09:29:57
10 Q. Thanks. 09:27:08	10 MR. BRAUSA: Objection; form. 09:29:57
11 Turning, again, to claim 29, does the 09:27:09	11 THE WITNESS: So assuming it's two secondary 09:29:58
12 specification provide guidance as to how many secondary 09:27:38	12 doses, given four weeks apart after the primary, and 09:30:01
13 doses should be administered to an individual patient? 09:27:45	13 then followed by tertiary doses, one or more tertiary, 09:30:05
14 A. The guidance here is one or more secondary doses. 09:27:52	14 at eight-week intervals, and then meeting the visual 09:30:09
15 Q. That's the only guidance? 09:27:57	15 specifications, then that would meet the claim. 09:30:14
16 MR. BRAUSA: Objection; form. 09:27:58	16 BY MR. NIMROD: 09:30:17
17 BY MR. NIMROD: 09:27:59	17 Q. Okay. So my three examples had two secondary 09:30:17
18 Q. I meant -- let me start over again. 09:27:59	18 doses, I think 8 and 11. So my question is, does a 09:30:21
19 Does the patent specification provide guidance as 09:28:01	19 specification teach a skilled person, specification of 09:30:28
20 to how many secondary doses should be administered to 09:28:05	20 the 572 patent, not just the claim, how to select the 09:30:31
21 a -- actually, let me strike that and start over again. 09:28:10	21 number of secondary doses to give to an individual 09:30:34
22 All right? 09:28:13	22 patient? 09:30:37
23 So claim 29, if I look at that, it says that 09:28:13	23 MR. BRAUSA: Objection; form. 09:30:38
24 there is some number of secondary doses and it simply 09:28:17	24 THE WITNESS: So that's a broad question. Are 09:30:39
25 says one or more, as you just said. Right? 09:28:21	25 you asking the entire patent, the specifications of 09:30:44
Page 30	Page 32
1 A. That's correct. 09:28:24	1 the patent, does that teach the patient -- teach the 09:30:49
2 Q. And then it says: One or more tertiary doses. 09:28:25	2 physician -- 09:30:53
3 Right? 09:28:28	3 BY MR. NIMROD: 09:30:53
4 A. Yes, it says that. 09:28:29	4 Q. Yeah, how many -- 09:30:54
5 Q. So if a physician decided to give one initial 09:28:30	5 A. -- or are you asking for 29 specifically? 09:30:54
6 dose, 11 secondary doses, followed by tertiary doses, at 09:28:36	6 Q. No, the specification. Does it teach the 09:30:57
7 eight weeks apart, that physician would be practicing 09:28:43	7 physician how to select the number of secondary doses? 09:31:01
8 claim 29 assuming that the effectiveness was achieved; 09:28:46	8 If you don't know right now, that's fine. 09:31:04
9 is that right? 09:28:52	9 A. Yeah.
10 MR. BRAUSA: Objection; form. 09:28:52	10 Q. If you'd have to read the whole spec, I don't 09:31:05
11 THE WITNESS: So given the scheduling that 09:28:54	11 want to wait for that. 09:31:08
12 we've talked about, assuming that is predetermined, 09:28:58	12 A. Okay. 09:31:08
13 and assuming when we say effectiveness, we're meeting 09:29:02	13 Q. Do you have -- I'll strike it.
14 the final clause with respect to maintaining visual 09:29:05	14 Do you have a current opinion as to whether or 09:31:09
15 acuity, then yes. That would be meeting the claim. 09:29:07	15 not the specification of the 572 patent provides any 09:31:10
16 BY MR. NIMROD:	16 guidance to a skilled person as to how to select the 09:31:13
17 Q. So then my question would be -- let me ask 09:29:12	17 number of secondary doses to administer to an individual 09:31:16
18 another one. 09:29:14	18 patient in a predetermined fashion? 09:31:20
19 If a physician decided, predetermined, to give a 09:29:15	19 MR. BRAUSA: Objection; form. 09:31:23
20 single initial dose of Aflibercept as required in claim 09:29:20	20 THE WITNESS: So I'm not completely familiar 09:31:24
21 29 and then gave eight secondary doses four weeks apart, 09:29:23	21 with what the specifications say off the top of my 09:31:30
22 followed by the tertiary doses, and they achieved -- the 09:29:29	22 head. But other than, we would look to probably 09:31:32
23 patient achieved the visual acuity requirement, that 09:29:33	23 change, based on disease. And then past that, it does 09:31:40
24 method would fall within the scope of claim 29 as well, 09:29:36	24 not tell us that -- strike that. 09:31:44
25 right? 09:29:39	25 So I'm not aware of anything in the 09:31:49
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1 specifications to guide the physician as to how many 09:31:58 2 secondary doses to give. 09:32:01 3 BY MR. NIMROD: 4 Q. So a question, in your -- in one's individual 09:32:04 5 practice, how does one determine the number of secondary 09:32:10 6 doses to give a patient if the patient is going to be on 09:32:14 7 a fixed predetermined dosing schedule? 09:32:17 8 MR. BRAUSA: Objection; form. 09:32:20 9 THE WITNESS: So in our practice now, we would 09:32:24 10 base predetermined dosing regimens with Aflibercept, 09:32:30 11 based upon phase 3 trials, which prespecify the dosing 09:32:35 12 regimens. 09:32:42 13 BY MR. NIMROD: 09:32:42 14 Q. Okay. So for AMD, what would be the number of 09:32:43 15 secondary doses, according to the clinical trial, phase 09:32:47 16 3 trials? 09:32:51 17 A. That would be two secondary doses. 09:32:51 18 Q. And then for DME, what would it be? 09:32:54 19 MR. BRAUSA: Objection; form. 09:32:59 20 THE WITNESS: For DME, from the secondary 09:32:59 21 trial, from the phase 3 trials, on a predetermined 09:33:03 22 regimen, we would give four secondary doses. 09:33:09 23 BY MR. NIMROD: 24 Q. Does the 572 patent, in your view, provide any 09:33:14 25 guidance as to -- I'll strike that. You've answered 09:33:24 Page 34	1 Q. So if I were to follow the method of -- strike 09:35:12 2 that. I think that's fine. 09:35:17 3 MR. NIMROD: I'd like to mark as Stewart 09:35:18 4 Exhibit 3 a copy of Exhibit 1039 in the record, which is 09:35:44 5 an article by Jeffrey Heier, H-E-I-E-R, and it looks 09:35:55 6 like it was published in 2011. 09:36:02 7 (Exhibit No. 3 was marked for identification.) 09:36:07 8 THE WITNESS: Okay. 09:36:07 9 BY MR. NIMROD: 09:36:22 10 Q. Dr. Stewart, have you seen this article in the 09:36:22 11 past? 09:36:24 12 A. I have. 09:36:24 13 Q. When do you recall reading this article? 09:36:26 14 A. Probably years ago. 09:36:35 15 Q. Probably when it was published, about then? 09:36:36 16 A. Probably. 09:36:39 17 Q. Would you turn to -- strike that. 09:36:40 18 You understand that the Trap-Eye is a reference 09:36:46 19 to Aflibercept in this article? 09:36:50 20 MR. BRAUSA: Objection. 09:36:53 21 THE WITNESS: It's vascular endothelial growth 09:36:53 22 factor, Trap-Eye is -- is a reference to Aflibercept. 09:36:59 23 BY MR. NIMROD: 09:37:01 24 Q. And you understand that this article is providing 09:37:09 25 the one-year results of the CLEAR-IT, that's CLEAR 09:37:12 Page 36
1 that already. 09:33:31 2 Would you agree that the -- that for the method 09:33:31 3 of claim 29, if given to a patient population, the 09:33:48 4 regimen of the practice, it would be inherent in the 09:33:54 5 results that at least some patients would meet the 09:34:00 6 effectiveness of the visual acuity required by claim 29? 09:34:02 7 MR. BRAUSA: Objection; form. 09:34:10 8 THE WITNESS: You would have to take 29 and you 09:34:12 9 would have to be sure that the patients were treated 09:34:18 10 adequately for one year, meaning a sufficient number 09:34:23 11 of secondary and/or tertiary doses to extend out 09:34:26 12 through one year before you could make a determination 09:34:30 13 on whether or not you're going to meet the visual 09:34:36 14 acuity requirement. 09:34:40 15 BY MR. NIMROD: 16 Q. So just -- you wouldn't know? 09:34:41 17 A. What I'm saying is, you would have to make sure 09:34:43 18 you're adequately treating the patient for an extended 09:34:47 19 period of time. The reason for that is that the visual 09:34:49 20 acuity result here ends at 52 weeks. So if you were to 09:34:53 21 treat a patient with one primary, one secondary, one 09:34:59 22 tertiary, that might not be sufficient to give you the 09:35:01 23 52-week result you're looking for. 09:35:08 24 Q. Under just three doses? 09:35:09 25 A. That's correct. 09:35:12 Page 35	1 Hyphen I-T 2, phase 2 study for Aflibercept; is that 09:37:19 2 right? 09:37:24 3 A. Yes. 09:37:24 4 Q. Are you familiar with the dosing regimen of 09:37:26 5 the -- dosing regimens of the 2-milligram arms for the 09:37:35 6 CLEAR-IT 2, phase 2 clinical trial? 09:37:41 7 A. Let me read it again to refresh my memory. 09:37:43 8 Q. If you could turn to page 5, which is 1102 in the 09:37:48 9 article, and there is a chart that refers to some 09:37:54 10 designations such as 2Q12 and 2Q4, if that helps. 09:38:03 11 A. I see that. 09:38:25 12 Q. Okay. 09:38:27 13 A. Okay. 09:38:28 14 Q. All right. So what is the arm of 2Q12 mean? 09:38:28 15 MR. BRAUSA: Objection; form. 09:38:33 16 THE WITNESS: So you have to go into the 09:38:33 17 methods section to actually see what that means. And 09:38:37 18 in the methods section -- I'm sorry, did you say 2Q12, 09:38:41 19 is that what you're asking? 09:38:46 20 BY MR. NIMROD: 09:38:48 21 Q. Yes, and I'm going to ask about 2Q4 next if you 09:38:48 22 want to just tell me about both. 09:38:51 23 A. All right. So let me start off with 2Q4 since 09:38:53 24 it's in that order. So 2Q4 is 2 milligrams of 09:38:58 25 Aflibercept dosed at four-week intervals, a total of 09:39:03 Page 37

1 four injections. And then after that, patients were 09:39:08 2 dosed PRN through the course of one year. 09:39:15 3 2Q12 means that they were dosed at baseline. 09:39:21 4 They had a second dose 12 weeks later and then were 09:39:26 5 treated PRN through one year. 09:39:30 6 Q. All right. If we could go, then, to that chart I 09:39:36 7 mentioned. 09:39:38 8 A. Okay. I'm sorry. Are you -- is it Figure 5, is 09:39:39 9 that -- 09:39:43 10 Q. Figure 5. Yes, please. 09:39:43 11 So for the 2Q4, those are the light gray boxes 09:39:49 12 that go along and at the end have a 9.0 next to them; is 09:40:00 13 that right? 09:40:07 14 A. Yes. I see that. 09:40:07 15 Q. And that means that at the end of 52 weeks, the 09:40:08 16 patients who are on the 2Q4 arm on average achieved a 09:40:12 17 letter gain, according to the ETDRS letter score, of 09:40:18 18 nine letters; is that right? 09:40:23 19 A. That's the mean, yes. 09:40:24 20 Q. And for the 2Q12, the mean letter gain for the 09:40:27 21 arm of 2Q12 was 5.2; is that right? 09:40:36 22 A. At 52 weeks, that's the mean gain. Yes. 09:40:42 23 Q. And that's for a group where the first regimen is 09:40:45 24 given and then the second one is given 12 weeks later? 09:40:50 25 MR. BRAUSA: Objection; form. 09:40:55 Page 38	1 In contrast, are you talking to the 2Q4 arm in 09:42:25 2 the CLEAR-IT -- 09:42:31 3 BY MR. NIMROD: 09:42:33 4 Q. No. 09:42:33 5 A. -- or what are you talking -- which arms are you 09:42:33 6 talking about in CLEAR-IT? 09:42:35 7 Q. Well, it would be both. So based on the 09:42:37 8 teachings -- 09:42:38 9 A. Okay. 10 Q. -- of the results of a nine-letter gain of 2Q4 09:42:38 11 and a 5.2 mean gain for 2Q12, would you agree that a 09:42:43 12 POSA looking at those results from the CLEAR-IT 2 09:42:48 13 one-year study, would expect, based on those results, 09:42:53 14 that following the regimen of claim 29 would, in fact, 09:42:57 15 achieve the effectiveness that's required by that claim? 09:43:00 16 MR. BRAUSA: Objection; form. 09:43:06 17 THE WITNESS: So for several reasons I would 09:43:07 18 say no, a POSA could not expect that. One is the 09:43:10 19 regimens themselves are going to be vastly different. 09:43:14 20 Predetermined in 29 without specifying within the 09:43:18 21 claim the number of injections through one year, but 09:43:22 22 predetermined, whereas in the CLEAR-IT 2, it is 09:43:26 23 basically a PRN regimen after either four loading 09:43:32 24 doses monthly or two loading doses separated by 09:43:35 25 12 weeks followed by PRN. So CLEAR-IT 2 is basically 09:43:39 Page 40
1 THE WITNESS: That's for the cohort where the 09:40:55 2 first dose of 2 milligrams was given at baseline and 09:40:59 3 then the second dose was given 12 weeks later. 09:41:02 4 BY MR. NIMROD: 09:41:06 5 Q. So could you leave that open in front of you and 09:41:06 6 just turn back to the patent for a moment. 09:41:10 7 A. Okay. 09:41:12 8 Q. And go to claim 29, please. 09:41:12 9 A. Okay. 09:41:23 10 Q. So based on the teachings in -- sorry. Strike 09:41:24 11 that. 09:41:30 12 Based on the results of the CLEAR-IT 2, phase 2 09:41:30 13 clinical results at one year, would you agree that a 09:41:35 14 POSA reading that would find it to be -- or would 09:41:39 15 expect, I should say, that treating a patient in 09:41:46 16 accordance with the regimen of claim 29 would achieve 09:41:48 17 the visual acuity required by that claim which is the 09:41:53 18 comparison to the Ranibizumab at 52 weeks? 09:41:57 19 MR. BRAUSA: Objection; form. 09:42:01 20 THE WITNESS: These are very different 09:42:02 21 treatment protocols. Claim 29 requires single, 09:42:06 22 followed by at least one secondary dose four weeks 09:42:12 23 later and then one or more secondary doses and then 09:42:16 24 tertiary doses given eight weeks later on a 09:42:19 25 predetermined schedule. 09:42:23 Page 39	1 an individualized therapy regimen, whereas the claim 09:43:44 2 is fixed dosing regimen. 09:43:49 3 Secondly, the effectiveness in claim 29 talks 09:43:53 4 about -- it talks about maintenance of visual acuity, 09:43:58 5 which is a less than 15-letter loss. 09:44:04 6 Now, from the data in Figure 5, we don't know 09:44:07 7 the data for every patient. There might have been a 09:44:13 8 patient in a year that lost 15 letters. We don't know 09:44:15 9 that. All we know is the mean. 09:44:20 10 So for those reasons, I can't say that -- I 09:44:22 11 can't say that this teaches, according to 29, that 09:44:25 12 that would work. 09:44:29 13 BY MR. NIMROD: 09:44:30 14 Q. But by the same token, you don't know when you 09:44:31 15 start the method of claim 29 whether any individual 09:44:34 16 patient is going to meet it. You told me that a couple 09:44:36 17 times, right? You never know that, you just have to 09:44:39 18 measure it at week 52, right? 09:44:42 19 A. That's correct. We never know. 09:44:44 20 Q. Okay. And let's talk about the patient 09:44:46 21 populations, then, because you don't know with claim 29 09:44:51 22 what's taught in the 572 patent, and you're saying you 09:44:54 23 don't know for individual patients with respect to what 09:44:58 24 happened with the CLEAR-IT 2 study, right? 09:45:01 25 MR. BRAUSA: Objection. 09:45:03 Page 41

1 BY MR. NIMROD: 09:45:04	1 decided to practice claim 29 by giving one initial dose, 09:47:50
2 Q. You don't know for individuals; you've just got 09:45:04	2 11 secondary doses four weeks apart, followed by 09:47:55
3 the mean? 09:45:07	3 eight-week dosing for tertiary doses, would you agree 09:48:01
4 MR. BRAUSA: Objection; form. 09:45:08	4 that based on the teachings of the CLEAR-IT 2 study, a 09:48:05
5 THE WITNESS: So from the CLEAR-IT 2, depending 09:45:09	5 skilled person would expect that a significant portion 09:48:08
6 on which dosing regimens you do, but following the 09:45:11	6 of the patient population would achieve the acuity 09:48:12
7 dosing regimens as pointed out in the CLEAR-IT 2, 09:45:14	7 limitation of claim 29? 09:48:16
8 which are individualized dosing regimens, we know what 09:45:17	8 MR. BRAUSA: Objection; form. 09:48:18
9 the means were. We don't know individual patient 09:45:21	9 BY MR. NIMROD: 09:48:20
10 data. 09:45:24	10 Q. Just to be clear, that means you're giving 09:48:21
11 BY MR. NIMROD:	11 monthly dosing for the full year. 09:48:22
12 Q. Okay. So based on the results of the CLEAR-IT 2 09:45:25	12 A. For one year. I understand. 09:48:24
13 study, for example, shown at Figure 5, would you agree 09:45:29	13 MR. BRAUSA: Same objection. 09:48:25
14 that based on the teachings of those results, a POSA 09:45:35	14 THE WITNESS: So I don't know we've established 09:48:27
15 would expect that a significant portion of a patient 09:45:39	15 expectation. I think there is a hope, and based on 09:48:30
16 population being treated according to the method of 09:45:43	16 significant treatment numbers, that there's a chance 09:48:35
17 claim 29, would achieve the acuity limitation of claim 09:45:47	17 that the patient will achieve that 9.0 letters that we 09:48:43
18 29, and that is a loss of less than 15 letters? 09:45:54	18 get there. But I don't think we have the data to say 09:48:46
19 MR. BRAUSA: Objection; form. 09:46:02	19 that we can expect that. 09:48:49
20 THE WITNESS: No. Once again, claim 29 doesn't 09:46:02	20 BY MR. NIMROD:
21 actually require, according to the way it's written, 09:46:10	21 Q. Okay. So I think I need to ask you again about 09:48:51
22 it doesn't require treatment through the course of one 09:46:14	22 patient populations. Because that came up in our last 09:48:54
23 year. And so if he's following 29, the physician on a 09:46:16	23 deposition, and it's come up today. 09:48:57
24 predetermined basis could stop in advance. 29 doesn't 09:46:21	24 A. Okay. 09:48:59
25 require one year's worth of treatment. So you can't 09:46:26	25 Q. So looking at Figure 5 in the Heier reference, 09:49:00
Page 42	Page 44
1 extrapolate. 09:46:29	1 which is the result of the one-year CLEAR-IT 2 study, we 09:49:04
2 BY MR. NIMROD: 09:46:29	2 see that the mean for 2Q4, which is four doses by week 09:49:07
3 Q. Would you expect that if a skilled person 09:46:30	3 12, a month apart, and then PRN, the average or mean, 09:49:15
4 practiced claim 29 by doing an initial dose, one 09:46:35	4 sorry, letter gain is 9.0, right? 09:49:19
5 secondary dose and one tertiary dose, that the patient 09:46:39	5 A. Yes. 09:49:21
6 would achieve the acuity limitation of claim 29? 09:46:42	6 Q. And so my question for claim 29 was, if a skilled 09:49:23
7 MR. BRAUSA: Objection; form. 09:46:49	7 person decided to dose a patient population with a 09:49:27
8 THE WITNESS: I'm sorry, repeat the question. 09:46:49	8 regimen predetermined to be a single initial dose, 11 09:49:33
9 BY MR. NIMROD: 09:46:52	9 secondary doses one month apart, and then tertiary doses 09:49:37
10 Q. I said if a physician decided to do a 09:46:52	10 eight weeks apart, you would agree that a skilled person 09:49:41
11 predetermined regimen that was simply one single initial 09:46:57	11 would expect, based on the nine-letter gain for 2Q4, as 09:49:46
12 dose, one secondary dose and one tertiary dose and no 09:47:02	12 provided by the CLEAR-IT 2 study, that a significant 09:49:51
13 other doses to week 52, would you expect that a patient 09:47:06	13 portion of the patient population would, in fact, 09:49:54
14 would meet the acuity limitation of claim 29? 09:47:10	14 achieve the visual acuity limitation of claim 29? 09:49:57
15 MR. BRAUSA: Objection; form. 09:47:14	15 MR. BRAUSA: Objection; form. 09:50:02
16 THE WITNESS: I don't know because there's a 09:47:16	16 THE WITNESS: We don't have the data to say 09:50:03
17 lot of time between the final dose and week 52. And 09:47:19	17 what would happen at the end of one year. I think the 09:50:06
18 we know that under treatment, over time with macular 09:47:24	18 physician would have reasonable grounds to hope that, 09:50:11
19 degeneration tends to cause vision loss. And I don't 09:47:31	19 indeed, they would meet the specifications but I don't 09:50:17
20 know what to expect at the end of one year. 09:47:35	20 think there can be an expectation. 09:50:22
21 BY MR. NIMROD:	21 BY MR. NIMROD: 09:50:23
22 Q. And that's even based on the teachings of the 572 09:47:37	22 Q. I'm not asking you about whether an individual 09:50:23
23 patent, right? 09:47:40	23 patient would achieve it. Do you understand that? 09:50:25
24 A. Correct. 09:47:41	24 A. Okay. 09:50:27
25 Q. Okay. All right. So let's say a physician 09:47:47	25 Q. You follow me? 09:50:28
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1 A. Okay. I gotcha. 09:50:28 2 Q. You know, of course, that the -- for 2Q4, none of 09:50:30 3 the patients achieved more than monthly dosing in the 09:50:35 4 CLEAR-IT 2 study, right? 09:50:40 5 MR. BRAUSA: Objection; form. 09:50:42 6 THE WITNESS: I'm sorry, repeat that again. 09:50:43 7 BY MR. NIMROD: 09:50:45 8 Q. So for the CLEAR-IT 2 study -- 09:50:46 9 A. Yes. 09:50:47 10 Q. -- the patients who were in the 2Q4 arm did not 09:50:47 11 get monthly dosing of Aflibercept. Do you understand 09:50:51 12 that? 09:50:56 13 MR. BRAUSA: Objection; form. 09:50:56 14 THE WITNESS: Past the first four doses, unless 09:50:57 15 the PRN arms required it, I understand. 09:51:00 16 BY MR. NIMROD: 17 Q. Okay. So if we understand that 2Q4 did not 09:51:02 18 provide even monthly dosing of Aflibercept, and a 09:51:07 19 significant portion of that arm achieved nine-letter 09:51:10 20 gain, right, do you agree? 09:51:15 21 MR. BRAUSA: Objection; form. 09:51:19 22 BY MR. NIMROD: 09:51:20 23 Q. Well, if the mean -- 09:51:20 24 A. The mean was nine letters. 09:51:21 25 Q. Let me ask you this -- 09:51:23 Page 46	1 2 study of one-year results for the 2Q4 arm where you 09:52:12 2 have four monthly doses by week 12, then you have PRN. 09:52:17 3 Would you agree that a significant portion of that 09:52:21 4 patient population achieved more than five-letter gains? 09:52:23 5 MR. BRAUSA: Objection; form. 09:52:28 6 BY MR. NIMROD: 09:52:29 7 Q. A significant portion. I didn't ask whether it's 09:52:29 8 50 percent or not. 09:52:32 9 MR. BRAUSA: Objection; form. 09:52:33 10 THE WITNESS: I -- I don't know if you and I 09:52:34 11 have the same definition of significant. If you give 09:52:37 12 me your definition of significant, then we can do 09:52:39 13 this. 09:52:41 14 BY MR. NIMROD: 09:52:41 15 Q. You can give me your definition. What does 09:52:42 16 significant mean to you? 09:52:44 17 A. Okay. So if more than -- more than a third. 09:52:44 18 Q. Okay. I'll go with that. 09:52:49 19 A. Okay. 09:52:50 20 Q. Would you agree that more than a third of the 09:52:51 21 patients in the 2Q arm achieved a gain of more than five 09:52:53 22 letters? 09:52:57 23 A. We don't have the data but I think that's likely. 09:52:57 24 Q. Okay. And would you agree that a POSA looking at 09:53:00 25 this data, where there's a nine-letter mean gain, would 09:53:04 Page 48
1 A. Yeah. The mean was nine letters. We don't have 09:51:24 2 it broken apart. 09:51:27 3 Q. Okay. If the mean is nine letters, you would 09:51:27 4 agree that the arm of 2Q4 of CLEAR-IT 2, a significant 09:51:31 5 portion of the patient population achieved nine letters 09:51:35 6 or more; is that right? 09:51:38 7 MR. BRAUSA: Objection; form. 09:51:39 8 THE WITNESS: I don't have a number as to what 09:51:41 9 it was. 09:51:43 10 BY MR. NIMROD: 11 Q. What does a mean mean? 09:51:45 12 A. Yeah, a mean means -- a mean means the 09:51:48 13 mathematical average, so, you know, could it be 09:51:51 14 50 percent? Possibly. 09:51:52 15 Q. All I asked was a significant portion and you 09:51:53 16 won't give me that? 09:51:55 17 A. A significant portion. Okay. Well -- 09:51:57 18 Q. Will you give me that? 09:51:58 19 MR. BRAUSA: Objection. Asked and answered. 09:51:59 20 MR. NIMROD: I'll ask it again. 21 MR. BRAUSA: Now badgering the witness. 09:57:23 22 BY MR. NIMROD: 09:52:04 23 Q. I'll ask it again. 09:52:06 24 A. Okay. 09:52:06 25 Q. Okay. So you have a disclosure from the CLEAR-IT 09:52:06 Page 47	1 assume that there is a significant portion of a patient 09:53:07 2 population, or would understand that that had achieved a 09:53:11 3 nine-letter gain in order to have a nine-letter mean? 09:53:15 4 MR. BRAUSA: Objection; form. 09:53:18 5 THE WITNESS: Again, we can debate significant 09:53:20 6 but, yes, quite a few patients would have exceeded 09:53:23 7 nine letters. 09:53:26 8 BY MR. NIMROD: 9 Q. Okay. So then if the 2Q4 arm didn't give the 09:53:27 10 patients 12 monthly doses, then wouldn't you agree that 09:53:31 11 a POSA who decided to practice claim 29 with one single 09:53:37 12 initial dose followed by 11 monthly doses and thereafter 09:53:41 13 tertiary doses, would expect, based on the CLEAR-IT 2 09:53:49 14 studies, that a significant portion of the patient 09:53:51 15 population would obtain the acuity limitation of claim 09:53:54 16 29? 09:54:00 17 MR. BRAUSA: Objection; form. 09:54:01 18 BY MR. NIMROD: 09:54:02 19 Q. Which only requires no more than a loss of 15 09:54:02 20 letters? 09:54:04 21 MR. BRAUSA: Objection; form. 09:54:06 22 THE WITNESS: So the trouble is, we don't know 09:54:09 23 what happens with one-year worth of therapy. We know 09:54:11 24 what happens with four weeks' worth of therapy in a 09:54:15 25 PRN, which is a smaller number. We don't know what 09:54:17 Page 49

1 happens with one year, we don't know if that becomes 09:54:20 2 toxic. That's why phase 3 trials are done. 09:54:22 3 BY MR. NIMROD: 09:54:25 4 Q. I didn't ask you that. I said -- 09:54:25 5 A. I understand. 09:54:26 6 Q. I said based on the fact that you have -- you 09:54:27 7 have 12-month data from CLEAR-IT 2, don't you? 09:54:29 8 A. We have -- but we don't have 12-month data for a 09:54:31 9 cohort of patients without monthly therapy. And -- 09:54:34 10 Q. No, we have 12-month data. Hold on. We have for 09:54:35 11 a cohort that got less than monthly therapy, right? 09:54:37 12 A. Right. 09:54:41 13 Q. And so you won't agree to me as a matter of 09:54:42 14 teachings that a POSA that saw that there was a cohort 09:54:45 15 that got 2Q12 where they got less than -- sorry. Let me 09:54:47 16 start over again. 09:54:53 17 You would not agree with me, then, that a cohort 09:54:54 18 that was a 2Q4 that got less than monthly dosing and at 09:54:57 19 week 52 achieved nine-letter gain on average, you would 09:55:01 20 not agree with me, then, that a POSA looking at that 09:55:03 21 data would say, gosh, I expect that a significant 09:55:06 22 portion of a population giving -- given one initial dose 09:55:11 23 followed by 11 secondary doses at one month followed by 09:55:15 24 eight weeks would achieve at 52 weeks, that's at the end 09:55:19 25 of the 12 months, where they get monthly, a significant 09:55:23 Page 50	1 2 studies for 2Q4 would be that a significant portion of 09:56:39 2 the patient population practicing claim 29, just based 09:56:43 3 on the knowledge of the CLEAR-IT 2 study, where you had 09:56:47 4 one initial dose and 11 secondary doses and then 09:56:50 5 followed by tertiary doses at eight weeks, would assume 09:56:54 6 that a significant portion of the patient population 09:56:57 7 would not have toxicity and would, in fact, achieve the 09:57:00 8 acuity limitation of claim 29? 09:57:03 9 MR. BRAUSA: Objection; form. 09:57:06 10 THE WITNESS: I'm sorry. Repeat the question 09:57:08 11 because I -- 09:57:09 12 BY MR. NIMROD: 09:57:10 13 Q. I said -- 09:57:10 14 A. Yes. 09:57:11 15 Q. -- so you're looking at the results of the 09:57:11 16 CLEAR-IT 2 study -- 09:57:13 17 A. Yes. 09:57:14 18 Q. -- which show the gains at the end of 52 weeks -- 09:57:14 19 A. Yes. 09:57:17 20 Q. -- for 2Q4 and 2Q12. And then you, the POSA, 09:57:17 21 decide to practice a regimen as in claim 29, where you 09:57:22 22 have one initial dose at 2 mg, then you have 11 09:57:27 23 secondary doses four weeks apart, and then you have 09:57:31 24 eight weeks apart for tertiary doses; would you agree 09:57:33 25 that a POSA would expect that a significant portion of 09:57:36 Page 52
1 portion would get -- would meet the limitation of claim 09:55:27 2 29, which is no more than a loss of 15. You won't agree 09:55:31 3 with that? 09:55:35 4 MR. BRAUSA: Objection; form. 09:55:38 5 THE WITNESS: I would say that a POSA looking 09:55:38 6 at this would say, I want to look at 12-month data. 09:55:42 7 BY MR. NIMROD: 09:55:45 8 Q. Got that. 09:55:46 9 A. Well, I want to look at monthly for 12 months. 09:55:46 10 Until you do the trials, you just can't get the 09:55:52 11 expectation. And I want to know what the numbers are 09:55:56 12 with 12-month data. 09:56:00 13 Now, would I look at this data and say, that's a 09:56:01 14 good result? I would. I would say it's worth doing a 09:56:05 15 monthly trial for 12 months. But I don't have an 09:56:11 16 expectation. I have a hope. 09:56:14 17 Q. And your reason for saying that is that even 09:56:19 18 though I'm giving more monthly doses, the reason is 09:56:22 19 because you're worried that it might be toxic to the 09:56:25 20 eye? 09:56:28 21 A. There's always that possibility until you 09:56:28 22 actually do it. 09:56:31 23 Q. Okay. And you're saying also -- I am going to 09:56:32 24 ask you this. Would you agree with me that the 09:56:35 25 reasonable expectation of a POSA looking at the CLEAR-IT 09:56:36 Page 51	1 the patient population getting that regimen would 09:57:41 2 achieve the acuity limitation of claim 29 without this 09:57:44 3 toxicity that you are worried about? 09:57:49 4 MR. BRAUSA: Objection. 09:57:51 5 BY MR. NIMROD: 09:57:51 6 Q. That a significant portion would, not everybody? 09:57:52 7 MR. BRAUSA: Objection; form. 09:57:54 8 THE WITNESS: Once again, until you do 12 -- 09:57:55 9 until you do 12 monthly injections, until you have 09:57:58 10 that data, you don't -- you don't have an expectation. 09:58:01 11 BY MR. NIMROD: 12 Q. You're saying you don't have expectation for the 09:58:05 13 patient population that a significant portion will not 09:58:07 14 have the toxicity; is that what you're saying? 09:58:09 15 A. You can project and you can say, I think there's 09:58:12 16 a good likelihood. I think it's worth doing a phase 3 09:58:14 17 trial. But I don't have an expectation yet until I have 09:58:18 18 data. 09:58:21 19 Q. For any portion of the patient population? 09:58:21 20 A. Well, once again, you don't know. I mean, I -- 09:58:24 21 that's what phase 3 trials are all about is you don't 09:58:27 22 know. You've got to look at results and you look at 09:58:29 23 toxicity. You don't know yet. 09:58:33 24 Q. Okay. And so setting aside the toxicity, do you 09:58:35 25 have any reason to give an opinion that based on the 09:58:38 Page 53

1 CLEAR-IT 2 results for the 2Q4 that the monthly dosing 09:58:41 2 regimen that I have mentioned for claim 29 for the first 09:58:46 3 year would not have a significant portion of the patient 09:58:48 4 population meeting the acuity limitation of claim 29? 09:58:52 5 MR. BRAUSA: Objection; form. 09:58:55 6 THE WITNESS: I think that the data coming out 09:58:58 7 of CLEAR-IT 2 says to me, this is good-looking data 09:59:01 8 and it is reasonable to create a phase 3 trial based 09:59:07 9 on monthly therapy. But I have not yet put together 09:59:11 10 an expectation. I simply think this is -- I hope this 09:59:14 11 is going to work and I think it's worth trying. 09:59:17 12 BY MR. NIMROD: 09:59:19 13 Q. A lot of hope? 09:59:19 14 A. A lot of hope. That's what phase 3 trials are 09:59:22 15 all about. 09:59:27 16 Q. I don't think you answered my question, though. 09:59:27 17 I didn't ask you about phase 3. 09:59:28 18 A. Okay. Well, that's as close as I can get. 09:59:30 19 Q. Well, we -- I didn't ask you about phase 3. You 09:59:32 20 understand that? 21 A. I understand. 22 Q. So let me start over. 23 A. Okay. 24 Q. If you set aside your -- your toxicity issue. 09:59:33 25 A. Yes. 09:59:35 Page 54	1 BY MR. NIMROD: 2 Q. Okay. So explain to me why it is that you're 10:00:37 3 giving an opinion now that when I see a 2Q4 where the 10:00:40 4 patients are getting less than 12 monthly doses, and 10:00:45 5 then I decide to increase the doses, that setting aside 10:00:49 6 toxicity, that I would expect that a -- that I wouldn't 10:00:53 7 expect a significant portion of the patient population 10:00:57 8 would achieve the gain of nine letters or more? 10:01:00 9 MR. BRAUSA: Objection. Mischaracterizes. 10:01:04 10 THE WITNESS: We simply haven't done a study to 10:01:05 11 show that. 10:01:08 12 BY MR. NIMROD: 13 Q. I understand that. I said expect. Do you 10:01:09 14 understand I'm saying the word expect? 10:01:11 15 A. No, I understand you're saying expect. 10:01:12 16 Q. At your last deposition, you were perfectly 10:01:13 17 understandable -- you understood what expect meant, 10:01:16 18 right? 10:01:18 19 A. So, again, I think there's good reason to hope 10:01:18 20 that this is going to happen. But I can't say that he 10:01:22 21 can expect it to happen. 10:01:29 22 Q. So your testimony before the board is that given 10:01:31 23 the data that the 2Q4 arms shows that the mean result 10:01:35 24 for patients is a nine-letter gain getting less than 12 10:01:40 25 monthly doses, that a POSA would not expect that giving 10:01:44 Page 56
1 Q. Just set it aside. 09:59:36 2 A. Yes. 09:59:36 3 Q. Assume for me -- you're an expert, I can ask you 09:59:37 4 to make assumptions; you understand that? 09:59:39 5 A. Yes. 09:59:40 6 Q. Okay. So my assumption is, I want you to set 09:59:41 7 aside a POSA says I'm not worried about toxicity. Okay? 09:59:48 8 A. Okay. 09:59:46 9 Q. So that POSA who looks at the CLEAR-IT 2 results 09:59:50 10 at 52 weeks and sees that a significant portion of the 09:59:54 11 patient population for the 2Q4 achieved a nine-letter 09:59:57 12 gain -- 10:00:01 13 A. Yes. 14 Q. -- and then decided to practice for a patient 10:00:01 15 population, the regimen of claim 29, which would have a 10:00:03 16 single initial dose of 2 mg followed by 11 secondary 10:00:07 17 doses four weeks apart, followed by tertiary doses, 10:00:12 18 would expect that a significant portion of the patient 10:00:16 19 population would achieve a nine-letter gain or more? 10:00:20 20 MR. BRAUSA: Objection; form. 10:00:24 21 THE WITNESS: Ray, I don't know how to answer 10:00:26 22 any differently than I have already. I think that he 10:00:27 23 would look and say there's a good chance; I don't have 10:00:29 24 data to support that yet; and that may happen but I 10:00:32 25 can't be sure. 10:00:36 Page 55	1 another patient population 12 monthly doses of the 2 mg 10:01:48 2 of Aflibercept, that a significant portion would not get 10:01:52 3 at least nine-letter gains. That's your testimony? 10:01:55 4 MR. BRAUSA: Objection. Asked -- 10:01:58 5 BY MR. NIMROD: 10:01:59 6 Q. Setting aside toxicity as I asked you to do. 10:01:59 7 MR. BRAUSA: Objection. Asked and answered now 10:02:03 8 several times. 10:02:04 9 THE WITNESS: Again, I have to stand by what I 10:02:05 10 said. Good reason for hope. I can't set an 10:02:07 11 expectation yet. 10:02:09 12 MR. NIMROD: Do you want to take a break now? 10:02:10 13 MR. BRAUSA: Sure. 10:02:11 14 THE VIDEOGRAPHER: We are going off the record 10:02:14 15 at 10:02. 10:02:15 16 (A brief recess was taken.) 10:02:17 17 THE VIDEOGRAPHER: We are back on the record at 10:18:02 18 10:18. 10:18:22 19 BY MR. NIMROD: 10:18:24 20 Q. Dr. Stewart, could you look back at Exhibit 3? I 10:18:28 21 think you're in it right now. 10:18:33 22 A. The CLEAR-IT 2? 10:18:34 23 Q. Yes, please. So if we could turn to -- well, let 10:18:35 24 me ask you a question. 10:18:38 25 A. Yes. 10:18:39 Page 57

1 Q. Would you agree that mathematical models 10:18:39 2 predicted that based on the affinity and estimated 10:18:47 3 intravitreal half-life in humans, Aflibercept would 10:18:53 4 maintain biological activity for 10 to 12 weeks, whereas 10:18:57 5 Ranibizumab would maintain such activity for 30 days? 10:19:01 6 MR. BRAUSA: Objection; form. 10:19:04 7 BY MR. NIMROD: 10:19:04 8 Q. I'm just asking, would you agree with that? 10:19:04 9 A. So that sounds like my article. 10:19:06 10 Q. So you would agree with me? 10:19:08 11 A. So that's the number we came up with. And that 10:19:11 12 was based on a lot of assumptions. And it was not as 10:19:14 13 accurate as we would have wanted because of the inputs. 10:19:20 14 But that's what we came up with in terms of our final 10:19:23 15 analysis that obviously had to be then, you know, 10:19:26 16 correlated with outcomes from clinical trials. 10:19:29 17 Q. Okay. Your article is reference 3 on page 8, 10:19:33 18 which is the Stewart article: Predicted Biological 10:19:42 19 Activity of Intravitreal VEGF Trap. 10:19:47 20 Correct? 10:19:52 21 A. Correct. 10:19:52 22 Q. And that's an 2008 article; is that right? 10:19:53 23 A. Yes. 10:19:56 24 Q. And VEGF Trap, again that's Aflibercept, right? 10:19:56 25 A. That's correct. 10:19:59 Page 58	1 column, about one-third of the way down, in the first 10:21:17 2 full paragraph near the end. 10:21:19 3 A. Yes. 10:21:21 4 Q. It says, quote: Based on its binding affinity an 10:21:22 5 estimated intravitreal half-life in humans, a 10:21:26 6 mathematical model has predicted that after intravitreal 10:21:28 7 injection, VEGF Trap-Eye would maintain biological 10:21:33 8 activity for 10 to 12 weeks, whereas Ranibizumab would 10:21:37 9 maintain such activity for 30 days, supporting the 10:21:40 10 concept of less frequent dosing with VEGF Trap-Eye. 10:21:44 11 Do you see that? 10:21:49 12 A. I see it. 10:21:49 13 Q. And the citation again is to your article, yes? 10:21:50 14 A. Yes, it is. 10:21:52 15 Q. Okay. Now, in the next paragraph, it states: By 10:21:52 16 the end of the fixed dosing phase at week 12, VEGF 10:21:57 17 Trap-Eye showed significant improvement in visual acuity 10:22:02 18 from baseline and this efficacy was maintained at week 10:22:08 19 52. 10:22:11 20 Do you see that? 10:22:11 21 A. I do. 10:22:11 22 Q. And the next sentence says that: However, 10:22:12 23 patients randomized to monthly injections during the 10:22:14 24 fixed dosing regimen had a trend toward improved visual 10:22:18 25 outcomes at 52 weeks, compared to those randomized to 10:22:22 Page 60
1 Q. Okay. And at the time, in 2008, you predicted 10:20:00 2 based on a mathematical model, that given the binding 10:20:06 3 affinity and estimated intravitreal half-life in humans, 10:20:10 4 Aflibercept would maintain biological activity for 10 to 10:20:15 5 12 weeks; is that right? That's what you predicted at 10:20:21 6 the time? 10:20:23 7 A. That's what we predicted from the model, yes. 10:20:23 8 Q. And you published that to the world, correct? 10:20:25 9 A. Correct. 10:20:27 10 Q. Okay. And you also stated that Ranibizumab would 10:20:29 11 maintain such activity for only 30 days in comparison, 10:20:33 12 right? 10:20:36 13 MR. BRAUSA: Objection; form. 10:20:37 14 THE WITNESS: That's correct. 10:20:37 15 BY MR. NIMROD: 16 Q. And you also predicted in 2008 that the longer 10:20:39 17 half-life and binding activity of Aflibercept, as 10:20:43 18 compared to Ranibizumab, would support the concept of 10:20:49 19 less frequent dosing with VEGF Trap-Eye in your 2008 10:20:52 20 article, correct? 10:20:58 21 MR. BRAUSA: Objection; form. 10:20:59 22 THE WITNESS: Correct. 10:20:59 23 BY MR. NIMROD: 24 Q. Okay. Now, if you could turn to page 7 of 10:21:02 25 Exhibit 3, please. And on page 7, in the right-hand 10:21:04 Page 59	1 quarterly injections. 10:22:25 2 Do you see that as well? 10:22:26 3 A. I do. 10:22:28 4 Q. Okay. And the quarterly injections would be a 10:22:28 5 reference to 2Q12 of the CLEAR-IT 2 study, which just 10:22:30 6 had one quarterly injection and then if there's PRN; is 10:22:36 7 that right? 10:22:39 8 A. The baseline and then quarterly and then PRN, 10:22:40 9 yes -- 10:22:43 10 Q. Okay. 11 A. -- correct. 10:22:43 12 Q. And then it says: This difference was apparent 10:22:43 13 at 12 weeks and was maintained through the 40-week PRN 10:22:46 14 phase, despite the fact that all patients were treated 10:22:49 15 as often as necessary during the PRN phase. 10:22:53 16 Right? 10:22:55 17 A. Yes. 10:22:56 18 Q. Okay. All right. In the next paragraph, there's 10:22:56 19 a reference to ongoing phase 3 studies for VEGF 10:23:03 20 Trap-Eye. Do you see that? 10:23:08 21 A. I do. 10:23:08 22 Q. And they say that they were evaluating VEGF 10:23:09 23 Trap-Eye, Aflibercept, at doses of .5 and 2 milligrams 10:23:13 24 every four weeks and 2 milligrams of Aflibercept every 10:23:21 25 eight weeks after three initial monthly doses compared 10:23:25 Page 61

1 to Ranibizumab at .5 milligrams every four weeks. 10:23:30 2 Do you see that? 10:23:33 3 A. I do. 10:23:34 4 Q. Okay. And it says that the quote: The rationale 10:23:34 5 for the 2 milligrams Q84 -- Q8-week -- what is a 2 mg Q8 10:23:37 6 WK mean in this instance? 10:23:48 7 A. So 2 milligrams is the size of the dose. And Q8 10:23:49 8 weeks means every eight weeks, it's the dosing interval. 10:23:54 9 Q. But that's after three monthly doses; is that 10:23:58 10 right? 10:24:01 11 A. In this case, yes. 10:24:01 12 Q. Okay. And so it says: The rationale for the 10:24:03 13 arm, that is the 2 milligrams to Q8-week dose was based 10:24:07 14 on an observation from the fixed dosing phase of 10:24:13 15 CLEAR-IT 2. At eight weeks, the improvement in BCVA 10:24:16 16 after a single 2-milligram dose was similar to that 10:24:20 17 obtained with the 2-milligram dose monthly to eight 10:24:24 18 weeks and that the effect in visual acuity gain for the 10:24:28 19 single dose groups began to wane by week 12. 10:24:32 20 Do you see that? 10:24:35 21 A. I do. 10:24:36 22 Q. Okay. So the rationale, then, for going to three 10:24:37 23 initial doses, three monthly doses, followed by Q8 10:24:43 24 dosing, the eight-week dosing, was from the results of 10:24:47 25 the CLEAR-IT 2 study; is that right? 10:24:50 Page 62	1 You see that? 10:26:14 2 A. Yes, I do. 10:26:14 3 Q. And then there's a reference to the PIER study 10:26:16 4 which you reference in your expert report as well? 10:26:18 5 A. Yes. 10:26:20 6 Q. Okay. All right. And it says in there that, in 10:26:23 7 the next sentence: In the PIER study, patients 10:26:26 8 initially received monthly injections of Ranibizumab for 10:26:29 9 three months, followed by quarterly injections. 10:26:33 10 You see that? 10:26:35 11 A. I do. 10:26:36 12 Q. Okay. And it states that: Although patient 10:26:36 13 visual acuities actually improved at three months, 10:26:40 14 during the quarterly dosing segment, visual acuity 10:26:44 15 returned to baseline. 10:26:46 16 And would that be at the end of the 12 months, 10:26:50 17 when it says: Returned to baseline? 10:26:53 18 A. That's my understanding of the clear results, was 10:26:58 19 by one year after 52 weeks, that the results were very 10:27:01 20 close to baseline. 10:27:05 21 Q. But this is the -- you said PIER, right? 10:27:06 22 A. PIER, yes. 10:27:07 23 Q. Okay. So baseline would be what? 10:27:07 24 A. Well, it's the visual acuity that was measured 10:27:09 25 right before the patient entered the trial. 10:27:13 Page 64
1 MR. BRAUSA: Objection; form. 10:24:53 2 THE WITNESS: Certainly, it's stated here. 10:24:54 3 There may have been other considerations. But this is 10:24:56 4 consistent with that. Yes. 10:24:58 5 MR. NIMROD: Okay. All right. Let me mark, 10:24:59 6 then, as Exhibit 4 a copy of Exhibit 1009 in this 10:25:06 7 proceeding. 10:25:13 8 (Exhibit No. 4 was marked for identification.) 10:25:13 9 BY MR. NIMROD: 10:25:25 10 Q. Do you recognize Exhibit 4 as the Dixon article? 10:25:26 11 A. I do. 10:25:29 12 Q. Okay. And Dixon discloses results from the 10:25:29 13 MARINA and ANCHOR -- strike that. 10:25:38 14 Dixon discloses results from -- well, it mentions 10:25:42 15 the MARINA and ANCHOR trials, correct? 10:25:46 16 A. Yes, it does. 10:25:48 17 Q. Okay. So if we turn to page 2 there is, on the 10:25:49 18 right-hand column, it talks about the MARINA and ANCHOR 10:25:56 19 trials examine the efficacy of Ranibizumab when 10:25:59 20 administered monthly. 10:26:02 21 You see that? 10:26:03 22 A. Yes. 10:26:03 23 Q. And it says that the time and financial burden of 10:26:04 24 monthly injections has led to the initiation of studies 10:26:07 25 to examine the efficacy of alternative dosing schedules. 10:26:09 Page 63	1 Q. So then for the Ranibizumab study where, for 10:27:15 2 PIER, where you have three initial monthly injections, 10:27:19 3 which I guess is one initial and two secondaries; is 10:27:23 4 that right? 10:27:25 5 A. Yes. Okay. 10:27:25 6 Q. So for the PIER study where you have three 10:27:29 7 initial injections one month apart, followed by 10:27:32 8 quarterly injections, the patients at least achieved, as 10:27:34 9 a mean, a loss of less than 15 letters by the ETDRS 10:27:42 10 letter score. 10:27:52 11 A. Yes. Patients that were treated, yes. 10:27:54 12 Q. Okay. So would you agree with me, then, that 10:27:56 13 based on that data, a POSA would expect that 10:27:59 14 Aflibercept, if it were dosed in the same manner, that 10:28:04 15 is, three initial monthly injections, followed by 10:28:08 16 quarterly injections, at week 52 would likewise obtain a 10:28:11 17 acuity score of less than 15 letters lost? 10:28:19 18 MR. BRAUSA: Objection; form. 10:28:24 19 BY MR. NIMROD: 10:28:29 20 Q. Do you understand my question? 10:28:29 21 A. I think I do. Repeat it, but I believe I 10:28:30 22 understand it. 10:28:34 23 Q. So a POSA is looking at the PIER study and saying 10:28:34 24 I see that for the patients that received three monthly 10:28:37 25 doses of Ranibizumab and then quarterly doses of 10:28:39 Page 65

1 Ranibizumab, that they basically returned to the 10:28:43	1 Q. -- first full paragraph. 10:31:42
2 baseline, which means that the mean had no loss in 10:28:49	2 A. First paragraph, I see it. 10:31:43
3 letter score, they returned to a zero, in effect, right? 10:28:54	3 Q. You see it? Yes? 10:31:46
4 A. Minus one letter, yes. 10:28:57	4 A. Yes. 10:31:46
5 Q. Okay. So would you agree, then, that a POSA 10:28:58	5 Q. Would you agree that as of 2009, the Aflibercept 10:31:47
6 looking at those results would then expect that if one 10:29:01	6 was the most promising anti-VEGF investigational drug 10:31:49
7 dosed, instead, Aflibercept, three monthly injections, 10:29:07	7 that was in a phase 3 clinical trial? 10:31:55
8 2 mg, followed by quarterly injections, that they would 10:29:12	8 A. In my opinion, it was, yes. 10:31:57
9 also achieve at least no loss -- would achieve at least 10:29:14	9 Q. Okay. 10:32:08
10 an acuity score loss of less than 15 letters as a mean? 10:29:21	10 MR. NIMROD: Okay. And then let me mark as 10:32:09
11 MR. BRAUSA: Objection; form. 10:29:25	11 Exhibit 5, Exhibit 2047 from this proceeding. And 10:32:12
12 THE WITNESS: I think that a POSA would look at 10:29:26	12 then mark as Exhibit 6 the patent owner's preliminary 10:32:25
13 that and think that if I dosed the patient the same 10:29:30	13 response in this IPR proceeding. 10:32:30
14 way in PIER, that the mean is likely to be 10:29:34	14 (Exhibit Nos. 5 and 6 were marked for 10:32:34
15 significantly better than 15-letter loss. 10:29:40	15 identification.) 10:32:43
16 BY MR. NIMROD:	16 BY MR. NIMROD: 10:32:43
17 Q. Dosed it with Aflibercept? 10:29:46	17 Q. We're just going to look at Exhibit 6 very 10:32:53
18 A. With Aflibercept. 10:29:46	18 briefly. 10:32:55
19 Q. Okay. Okay. Let's go on in Exhibit -- what is 10:29:50	19 A. Okay. 10:32:55
20 this -- 4. If you turn to page 4. Okay. On page 4, we 10:29:54	20 Q. You'll notice that the -- on Exhibit 5 is 10:32:57
21 have a summary of the -- or a discussion of the phase 2 10:30:11	21 Exhibit 2047 at the very bottom. You can see Exhibit 5 10:33:02
22 CLEAR-IT 2 trials that we were discussing earlier, 10:30:17	22 here. 10:33:05
23 right? 10:30:20	23 A. Oh, I see, yes. 10:33:06
24 A. Yes. 10:30:20	24 Q. Yeah. So I just want you to turn to -- the 10:33:08
25 Q. Okay. And at the end of that section, the 10:30:22	25 patent owner in this proceeding, as you know, is the 10:33:10
Page 66	Page 68
1 conclusion that's on the right-hand column near the top 10:30:24	1 other side. Correct, Regeneron? 10:33:14
2 of the page was, quote: Patients in the three quarterly 10:30:28	2 A. Regeneron, yes. 10:33:16
3 dosing groups also showed mean improvements in BCVA in 10:30:32	3 Q. Okay. So this is -- Exhibit 6 is their paper. 10:33:17
4 retinal thickness. However, they were not generally -- 10:30:37	4 A. Yes. 10:33:20
5 they were generally not as profound as the monthly 10:30:40	5 Q. Okay. And in their paper, if you turn to 10:33:20
6 injection group. 10:30:42	6 romanette vi -- or vii, excuse me. 10:33:25
7 Do you see that? 10:30:43	7 A. Yes. 10:33:27
8 A. I do. 10:30:45	8 Q. You'll see that one of the exhibits that they 10:33:28
9 Q. And so for the CLEAR-IT 2 study, where there was 10:30:45	9 submitted was Exhibit 2147, which is entitled VEGF 10:33:30
10 the three quarterly dosing groups -- strike that. 10:30:52	10 Trap-Eye in wet AMD, CLEAR-IT 2 summary of one-year key 10:33:37
11 Let me move on. I asked you that already. 10:30:55	11 results presented at the 2008 Retina Society meeting, 10:33:42
12 Actually, let me ask you this: Would you agree, then, 10:31:03	12 Scottsdale, Arizona. 10:33:48
13 based on the -- no, I'm going to strike that and move 10:31:06	13 A. I'm sorry.
14 on. 10:31:12	14 Q. It's right here. 10:33:50
15 Let's go to page 5, please. On page 5, there's a 10:31:13	15 A. I'm struggling to find it but, yes. 10:33:50
16 section called expert opinion. Do you see that? 10:31:19	16 Q. It's romanette vii. 10:33:54
17 A. I see that. 10:31:24	17 A. Thank you. Okay. Got it. And -- 10:33:56
18 Q. Okay. And in the right-hand column, it states 10:31:24	18 Q. Do you want to take a look, 2047 is about halfway 10:33:56
19 that: VEGF Trap-Eye, which is Aflibercept, represents 10:31:27	19 down. 10:33:59
20 the most promising anti-VEGF investigational drug that 10:31:31	20 A. Thank you. I see it. 10:33:59
21 is currently in a phase 3 trial. 10:31:36	21 Q. You see the title? 10:33:59
22 Do you see that? 10:31:38	22 A. Um-hmm. 10:34:00
23 A. I'm not seeing it. 10:31:39	23 Q. Okay. By the way, were you at the meeting in 10:34:01
24 Q. It's at the top of the right-hand column -- 10:31:40	24 2008 in Scottsdale, Arizona? 10:34:03
25 A. Oh, I see, yes.	25 A. I remember being in a meeting in Scottsdale 10:34:05
Page 67	Page 69

1 around that time. I might have been. I can't recall 10:34:08 2 for sure. 10:34:12 3 Q. Okay. Okay. So now if we turn, then -- you can 10:34:12 4 set that aside. I don't think I'll be going back to it. 10:34:16 5 A. Okay. 10:34:18 6 Q. If we can turn then to this 2008 presentation, 10:34:19 7 which is Exhibit 5 here and that's Exhibit 2047 in the 10:34:24 8 IPR proceeding. 10:34:33 9 A. Yes. 10:34:34 10 Q. I needed a stapler. 10:34:35 11 All right. If you could please turn to the 10:34:58 12 second page that's entitled CLEAR-IT 2 Rationale. 10:35:05 13 A. Okay. 10:35:10 14 Q. Do you see that there is a first bullet that 10:35:10 15 says: Anti-VEGF therapy has dramatically changed the 10:35:17 16 treatment paradigm for wet AMD. 10:35:26 17 Do you see that? 10:35:29 18 A. Yes. 10:35:29 19 Q. Okay. And it states that: Improvement in visual 10:35:30 20 acuity is now an achievable goal of treatment. 10:35:31 21 Do you see that as well? 10:35:34 22 A. Yes, I do. 10:35:35 23 Q. What does that mean in your understanding as to 10:35:36 24 improvement of visual acuity is now an achievable goal 10:35:39 25 as compared to what? 10:35:41 Page 70	1 page, the header or the title is the VEGF Trap-Eye and 10:37:04 2 the Wet AMD CLEAR-IT 2 -- 10:37:10 3 A. Yes. 4 Q. Summary of One-Year Key Results. 10:37:13 5 You see that? 10:37:14 6 A. I see. 10:37:15 7 Q. And those are the same results, the one-year 10:37:15 8 results that were discussed in Heier Exhibit 3, and 10:37:18 9 also, Dixon, Exhibit 4, correct? 10:37:22 10 MR. BRAUSA: Objection; form. 10:37:25 11 THE WITNESS: I'm sorry. Start that again, 10:37:27 12 please. 10:37:33 13 BY MR. NIMROD: 14 Q. You go to the title page. 10:37:34 15 A. Oh, yes. Okay. Thank you. 10:37:35 16 Q. It references to a -- 10:37:36 17 A. Thank you. 10:37:37 18 Q. My mistake. 10:37:38 19 A. Okay. 10:37:39 20 Q. Its reference to one-year -- 10:37:40 21 A. Yes. 10:37:41 22 Q. -- key results of CLEAR-IT 2. Do you see that? 10:37:42 23 A. Yeah. 10:37:44 24 Q. And there's the Heier article we're looking at 10:37:45 25 was also referencing the one-year results of the 10:37:50 Page 72
1 MR. BRAUSA: Objection; form. 10:35:42 2 THE WITNESS: So generally when we read this we 10:35:47 3 say improvement is an achievable goal and if you ask 10:35:49 4 the question of compared to what, it's prior 10:35:52 5 therapies. 10:35:55 6 BY MR. NIMROD: 10:35:55 7 Q. Like laser? 10:35:55 8 A. Laser or photodynamic therapy. Those were the 10:35:56 9 two available to us at that time. 10:35:59 10 Q. Okay. The next bullet says: A potential 10:36:08 11 limitation of anti-VEGF therapy is the unpredictable 10:36:10 12 durability of vision gain initially achieved with 10:36:16 13 monthly dosing when the treatment interval is prolonged. 10:36:18 14 You see that? 10:36:23 15 A. Yes. 10:36:24 16 Q. What does that mean to your understanding as to 10:36:24 17 unpredictable durability? 10:36:27 18 A. It's unpredictable durability of vision gain, 10:36:30 19 meaning once you have switched from your initial phase, 10:36:34 20 which this is usually referring to monthly therapy, and 10:36:38 21 you've tried to extend the interval between injections, 10:36:42 22 that it's unpredictable as it cannot be predicted if a 10:36:47 23 patient's vision gain achieved during the monthly 10:36:52 24 therapy is going to continue with the extended interval. 10:36:56 25 Q. And just to be clear, if we go back to the title 10:37:02 Page 71	1 CLEAR-IT 2. That's Exhibit 3. Correct? 10:37:53 2 A. That's correct. 10:37:54 3 Q. Okay. And then Dixon was also discussing those 10:37:56 4 same results, that is, the one-year key results of the 10:37:59 5 CLEAR-IT 2 study, correct? 10:38:03 6 MR. BRAUSA: Objection; form. 10:38:04 7 THE WITNESS: Dixon, of course, talks about 10:38:05 8 lots of things but, yes, that was in there. 10:38:07 9 BY MR. NIMROD: 10:38:08 10 Q. That was one of them? We looked -- 10:38:09 11 A. Okay. Yes. Okay. 10:38:11 12 Q. Great. You, as part of your opinions given here, 10:38:13 13 you were reviewing Dixon's disclosures of the results 10:38:17 14 from the phase 2 clinical CLEAR-IT 2, correct, in your 10:38:23 15 expert report? 10:38:29 16 A. Correct. 10:38:30 17 Q. Okay. So going back to the second page of 10:38:35 18 Exhibit 5, the third bullet on that page states that: 10:38:37 19 VEGF Trap-Eye, Aflibercept, is a novel anti-VEGF therapy 10:38:48 20 with a high binding affinity for VEGF-A and placental 10:38:52 21 growth factor, PlGF. 10:39:00 22 Do you see that? 23 A. PlGF. 10:39:02 24 MR. BRAUSA: Objection; form. 10:39:02 25 BY MR. NIMROD: 10:39:05 Page 73

1 Q. Did I not say it right? 2 MR. BRAUSA: You added the word Aflibercept. 3 BY MR. NIMROD: 4 Q. Oh. You understand that the word VEGF Trap-Eye 10:39:05 5 is a reference to Aflibercept, correct? 10:39:08 6 MR. BRAUSA: Objection; form. 10:39:10 7 THE WITNESS: I do. 10:39:12 8 BY MR. NIMROD: 10:39:12 9 Q. Okay. So the third bullet is saying that 10:39:14 10 Aflibercept is a novel anti-VEGF therapy with high 10:39:15 11 binding affinity for VEGF-A and placental growth factor, 10:39:20 12 PG -- PIGF; is that correct? 10:39:25 13 MR. BRAUSA: Objection; form. 10:39:27 14 THE WITNESS: PLGF. It says VEGF Trap-Eye but 10:39:28 15 I understand it to mean Aflibercept, and otherwise, 10:39:33 16 yes. 10:39:34 17 BY MR. NIMROD: 18 Q. Oh, it's PL. 10:39:38 19 A. PL. 10:39:39 20 Q. Oh, for -- thank you. Got it. It's pla. 10:39:40 21 MR. BRAUSA: It's not a piacenta. 10:39:45 22 BY MR. NIMROD: 10:39:49 23 Q. All right. Then it says: CLEAR-IT 2 is designed 10:39:50 24 to assess response at 12 weeks to a range of doses 10:39:52 25 administered monthly and quarterly and also durability 10:39:56 Page 74	1 MR. NIMROD: Somehow when it got copied last 10:41:06 2 night, apparently -- 10:41:08 3 THE WITNESS: The colors went away. 10:41:08 4 MR. NIMROD: -- the colors went away for that. 10:41:11 5 MR. BRAUSA: Okay. Got it. Again, no 10:41:11 6 objection provided that that is, in fact, an accurate 10:41:12 7 representation of -- 10:41:15 8 MR. NIMROD: I believe it is. 9 MR. BRAUSA: -- what we see on the exhibit. 09:57:23 10 MR. NIMROD: I don't think I would be capable 10:41:17 11 of anything else on that particular one. 10:41:19 12 BY MR. NIMROD: 10:41:21 13 Q. Okay. Good. All right. So what is the 2 mg 10:41:22 14 Q212 weeks is a reference where we talked about before 10:41:26 15 where you give one initial dose, then you give a second 10:41:29 16 dose 12 weeks later and then you do PRN; is that right? 10:41:31 17 A. That's correct. 10:41:34 18 Q. Out to 52 weeks? 10:41:35 19 A. That's correct. 10:41:37 20 Q. And then the 2 mg Q4 weeks is four doses four 10:41:38 21 weeks apart, followed by PRN; is that right? 10:41:45 22 A. Yes. That's correct. 10:41:49 23 Q. Okay. Hopefully this copy's a little better. 10:41:57 24 Okay. If we could turn to the next page. All 10:41:57 25 right. What is shown on this page here? 10:41:59 Page 76
1 of response with PRN as-needed dosing out to one year. 10:39:59 2 Do you see that? 10:40:03 3 A. I do. 10:40:03 4 Q. And you were familiar with these results in 2008, 10:40:04 5 correct? 10:40:08 6 A. I don't remember if it was 2008 or subsequent to 10:40:10 7 that. I think it probably was. 10:40:14 8 Q. Okay. And then if we look on the next page 3, 10:40:18 9 there's a reference to the various arms that are being 10:40:25 10 studied; is that right? 10:40:30 11 A. Which are difficult to read. But yes. 10:40:31 12 Q. Okay. Yes, they are. 10:40:36 13 A. But yes. Okay. 10:40:37 14 Q. There's not much here. I can show you, if you 10:40:41 15 want a better photocopy. 10:40:42 16 A. I can interpolate. Thank you. Yeah. 10:40:45 17 I mean, this should be a 4-milligram quarterly -- 10:40:49 18 oh, 2 milligrams, Q4, and that's the 4-milligram 10:40:51 19 quarterly. Okay. I'm fine. 10:40:55 20 MR. BRAUSA: I'm going to lodge an objection. 10:40:57 21 I don't know what you just showed him. 10:40:58 22 MR. NIMROD: I just showed him a better 10:41:00 23 photograph of the same page. 10:41:02 24 THE WITNESS: Yeah, better photograph of the 10:41:03 25 same page. 10:41:05 Page 75	1 A. So this is entitled The Study Schedule and this 10:42:17 2 then tells us for each of the five treatment cohorts 10:42:22 3 when the first injections are given through week 12. 10:42:28 4 Q. Okay. And so the two that are 2 milligrams have 10:42:33 5 the Q12, which is at one initial and then one at 12 and 10:42:43 6 then one at week zero, the initial dose, week 4, week 8 10:42:47 7 and week 12, right? 10:42:52 8 A. That's correct. 10:42:54 9 Q. Okay. Let's turn to the next page. What is this 10:42:55 10 page showing? 10:43:05 11 A. Oh, I assume we're talking about this page here. 10:43:09 12 Q. Yes. 13 A. Is that correct? 10:43:12 14 Q. Yes. It's page 5 of Exhibit 2047 which is our 10:43:12 15 Exhibit 5 in this proceeding -- this deposition. 10:43:19 16 A. Thank you. 10:43:19 17 So this a duplication of the previous but on the 10:43:20 18 right-hand side, it enumerates the number of mandatory 10:43:27 19 doses through week 12 of each treatment arm. 10:43:30 20 Q. What does it mean by mandatory doses? 10:43:36 21 A. Meaning they were predetermined. The protocol 10:43:38 22 said this is when you get the doses. 10:43:42 23 Q. Okay. So the phrase mandatory, I can think of as 10:43:44 24 being the same as predetermined? 10:43:48 25 A. Yes. 10:43:49 Page 77

1 Q. Fixed? Right? 10:43:50	1 Q. Okay. And the third bullet says that: The 10:45:59
2 A. Predetermined. Yes. 10:43:52	2 groups dosed at baseline in week 12 showed improved 10:46:01
3 Q. Okay. But not fixed? 10:43:55	3 visual acuity and retinal thickness. 10:46:05
4 A. Well, this is not a fixed dosing schedule because 10:43:55	4 Do you see that? 10:46:08
5 we go to PRN afterwards. 10:43:58	5 A. I do. 10:46:08
6 Q. Right. Just for the first 12 weeks, the regimen 10:44:00	6 Q. Okay. What does it mean that they showed 10:46:09
7 is fixed and mandatory but after that, it's PRN and 10:44:03	7 improved visual acuity and retinal thickness for the 10:46:11
8 therefore, individualized? 10:44:06	8 dosing that had one baseline treatment and then another 10:46:15
9 MR. BRAUSA: Objection; form. 10:44:09	9 one at week 12? 10:46:19
10 BY MR. NIMROD: 10:44:09	10 MR. BRAUSA: Objection; form. 10:46:21
11 Q. Would you not refer to this as a fixed dosing 10:44:10	11 THE WITNESS: So what this says is that at week 10:46:22
12 regimen? 10:44:13	12 12, 12 weeks after baseline, the patients showed 10:46:28
13 MR. BRAUSA: Objection; form. 10:44:14	13 better visual acuity compared to baseline and improved 10:46:36
14 THE WITNESS: I wouldn't refer to this as a 10:44:14	14 retinal thickness, which means decreased swelling of 10:46:41
15 fixed dosing regimen. These are the initial doses of 10:44:16	15 the retina as measured on OCT. 10:46:43
16 a PRN study. 10:44:19	16 BY MR. NIMROD: 10:46:47
17 BY MR. NIMROD: 10:44:20	17 Q. Okay. And is that the result at the end of the 10:46:49
18 Q. Okay. But you would agree that it's a fixed 10:44:21	18 52 weeks? 10:46:53
19 dosing phase as in the title on the top? 10:44:24	19 A. No. This is just the 12-week data, or report on 10:46:55
20 A. Yes. 10:44:26	20 12 weeks. 10:47:01
21 Q. Okay. Just not an overall regimen? 10:44:27	21 Q. Okay. The bullet -- the next round bullet, it 10:47:04
22 A. Correct. 10:44:28	22 says: Maintained effect on visual acuity with a single 10:47:09
23 Q. Let's turn to page 9. So in 2008, Regeneron 10:44:36	23 dose to eight weeks. 10:47:13
24 published these conclusions, that at 12 weeks, the VEGF 10:44:49	24 What do you understand that to mean? 10:47:14
25 Trap-Eye, which is Aflibercept, had significantly 10:44:58	25 A. What I understand that to mean is that the visual 10:47:15
Page 78	Page 80
1 improved mean visual acuity. 10:45:02	1 acuity that was achieved at week 4 was roughly the same 10:47:24
2 Do you see that? 10:45:05	2 as that at week 8, maintenance through eight weeks after 10:47:28
3 A. This is reported at 2007 Retina Society. 10:45:05	3 a single dose. 10:47:32
4 Q. Oh, okay. But then it was re, I guess, reported 10:45:11	4 Q. Meaning that the regimen where you get an initial 10:47:32
5 in 2008 in Scottsdale -- 10:45:14	5 dose and then a quarterly dose, meaning you don't get a 10:47:40
6 A. I --	6 dose at weeks 4, week 8, maintained the effect up till 10:47:46
7 Q. -- because that's what the title of this -- 10:45:15	7 week 8 but not week 12; is that right? 10:47:52
8 A. Right. I assume there was something different 10:45:16	8 MR. BRAUSA: Objection; form. 10:47:54
9 about this but don't know what they reported 10:45:19	9 THE WITNESS: So I think you have the groups 10:47:56
10 differently. 10:45:21	10 correct. It was the 0.5-milligram and the 2-milligram 10:47:59
11 Q. Okay. So, but in 2007, actually, the report of 10:45:21	11 who got initial dose and then a dose at week 12. And 10:48:03
12 the primary end points were given at the Retina Society 10:45:25	12 the way I interpret this is that they were followed at 10:48:08
13 for the CLEAR-IT 2 study? 10:45:29	13 week 4, visual acuity was measured. Then at week -- 10:48:10
14 MR. BRAUSA: Objection; form. 10:45:32	14 no dose. Visual acuity was then remeasured at week 8. 10:48:14
15 THE WITNESS: I would have to look at the 10:45:32	15 And that the effect -- effectively, the visual acuity 10:48:18
16 primary end point first to be sure. They certainly 10:45:35	16 at week 8 was similar to that at week 4. 10:48:26
17 reported -- I mean, they referenced it. I'm assuming 10:45:39	17 BY MR. NIMROD: 10:48:28
18 they reported it because they talked about significant 10:45:46	18 Q. Okay. And then also states there was -- it was 10:48:29
19 mean vision at 12 weeks. 10:45:49	19 generally well tolerated with no drug-related serious 10:48:31
20 BY MR. NIMROD:	20 adverse effects. Strike that. 10:48:35
21 Q. Well, at least they reported this, again, by 10:45:50	21 I see you're looking in Exhibit 3 now? 10:48:38
22 2008, these -- 10:45:54	22 A. I'm looking back at CLEAR-IT, yes. 10:48:42
23 A. Yes. 10:45:54	23 Q. That's fine. 10:48:44
24 Q. -- conclusions, correct? 10:45:54	24 A. Yes. 10:48:45
25 A. 2008, yes. They did as well. 10:45:55	25 Q. And were you looking at Figure 5? 10:48:45
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1 A. Yes, I was. 10:48:47 2 Q. Okay. Does -- well, I think we're going to get 10:48:49 3 to the same chart on the next -- 10:48:51 4 A. Okay. 10:48:53 5 Q. Or soon anyway. 10:48:54 6 A. Okay. 7 Q. Because it's in Exhibit -- 10:48:57 8 A. Okay. 9 Q. -- 5 also. 10:48:59 10 All right. The last bullet, then, we can go to 10:48:59 11 that chart, was on page 9, that is, of Exhibit 5 is: 10:49:01 12 Was generally well tolerated with no drug-related 10:49:05 13 serious adverse effects. 10:49:08 14 What does that mean, drug-related serious adverse 10:49:09 15 effects? 10:49:13 16 A. There's a long list of drug-related adverse 10:49:13 17 events, and apparently none of them were found in these 10:49:16 18 patients. 10:49:18 19 Q. And would that include toxicity? Would toxicity 10:49:18 20 be a drug-related serious adverse effect -- event, 10:49:24 21 excuse me? 10:49:30 22 A. So toxicity itself is not, not by word. There 10:49:30 23 are other ways of looking at toxicity. But that would 10:49:33 24 not be a word that we used as an adverse event. 10:49:36 25 Q. Okay. So when someone -- what's the result of 10:49:39 Page 82	1 Q. Okay. Do you recall that you had that concern in 10:50:51 2 2008? 10:50:53 3 A. Yes. I've had that concern about every drug. 10:50:53 4 Q. For every drug, so nothing different there? 10:50:56 5 A. No. 10:50:58 6 Q. Did you have that same concern with Ranibizumab 10:50:59 7 in 2008, that monthly dosing would potentially cause a 10:51:00 8 toxicity adverse event? 10:51:03 9 A. By 2008, there was minimum concern about that 10:51:07 10 with Ranibizumab because we had good phase 3 trials with 10:51:13 11 monthly therapy. 10:51:18 12 Q. Okay. All right. Let's turn to page 17 of 10:51:19 13 Exhibit 5, which is Exhibit 2047 in the proceeding. And 10:51:24 14 I think this is the same chart that appears in Heier 10:51:33 15 Exhibit 3, Figure 5 of that. Is that correct? 10:51:39 16 A. I'm looking at both and it certainly looks the 10:51:43 17 same. 10:51:46 18 Q. And to be specific, It's exhibit -- Figure 5B of 10:51:46 19 Heier, right? 10:51:51 20 A. 5B. Correct. 10:51:51 21 Q. Okay. So then looking at the page 17, and we 10:51:53 22 have just saw on the page 9 that the statement was that 10:51:59 23 maintain effect on visual acuity with a single dose to 10:52:06 24 eight weeks in that bullet. 10:52:08 25 Looking at the figure on page 17 of Exhibit 5, 10:52:12 Page 84
1 toxicity? Because you had mentioned earlier that there 10:49:43 2 would be a concern about toxicity. 10:49:46 3 A. Vitreous inflammation, retinal vasculitis, RPE 10:49:47 4 damage. Those would be things that would be included. 10:49:57 5 Q. And those would be -- if there were toxicity and 10:49:57 6 those things happened, those things would be adverse 10:49:59 7 events; is that right? 10:50:01 8 A. Yes. 10:50:02 9 Q. And that's what you were referring to earlier 10:50:05 10 when you said that you wouldn't know if you gave 12 10:50:07 11 monthly doses of Aflibercept as of, let's say, 2008, 10:50:10 12 whether or not there would be toxicity because it might 10:50:14 13 be too much? 10:50:16 14 MR. BRAUSA: Objection; form. 10:50:18 15 THE WITNESS: That's what I said previously was 10:50:19 16 my concern, yes. 10:50:23 17 BY MR. NIMROD: 10:50:24 18 Q. Right. And in 2008, when you were like in the 10:50:24 19 field here, which you were, obviously, did you have 10:50:26 20 concerns that monthly dosing of Aflibercept would cause 10:50:30 21 toxicity, if you did 12 doses for, you know, one month 10:50:34 22 each? 10:50:38 23 A. We always have concerns with every drug. This 10:50:40 24 one was no different than any other and safety is always 10:50:44 25 a primary concern. 10:50:49 Page 83	1 what line or what -- which points show that effect 10:52:17 2 that's mentioned on slide 9? 10:52:24 3 MR. BRAUSA: Objection; form. 10:52:28 4 THE WITNESS: So you're referring to slide 9 in 10:52:30 5 the statement of maintained visual acuity -- 10:52:32 6 BY MR. NIMROD: 10:52:35 7 Q. Right. 10:52:36 8 A. -- with a single dose at -- to eight weeks. 10:52:36 9 Q. Right. 10 A. So if you look at page 17, it is -- you've got 10:52:40 11 five different graph lines. And it is the one with the 10:52:44 12 triangle, as well as the one with the X. 10:52:50 13 Q. Looking at the one with the -- is it the X that's 10:52:55 14 the 2Q12? 10:53:02 15 MR. BRAUSA: Objection. 10:53:04 16 BY MR. NIMROD: 10:53:04 17 Q. No, what is that? 10:53:05 18 A. It's 4Q12. The X is 4Q12. 10:53:07 19 Q. Okay. And what's -- the other one's a 10:53:14 20 triangle -- excuse me -- 10:53:16 21 A. The triangle is -- 10:53:19 22 Q. Where is the 2Q12? 10:53:19 23 A. There is no 2Q12 here. 10:53:21 24 Q. Doesn't it show it on yours? It's right here. 10:53:25 25 Does yours not -- yeah, it's here. Figure 7, page 17. 10:53:32 Page 85

1 A. Yes. I'm sorry. I'm sorry. 10:53:37	1 Q. Okay. And the 2Q4 got about a seven-letter 10:56:16
2 Q. There's a 2Q12. 10:53:38	2 score; is that right? 10:56:22
3 A. Right. They're the 3Q12 dosing arms, yes. 10:53:40	3 A. Yes. A letter less than that but close, yes. 10:56:26
4 Q. What is the -- where should I be looking for the 10:53:44	4 Q. About what? 10:56:30
5 2Q12 figure on page 17 of Exhibit 2047? 10:53:52	5 A. I would characterize that as 6.6, somewhere in 10:56:30
6 A. The purple diamond. 10:53:57	6 there. 10:56:34
7 Q. Purple diamond. Okay. And so referring to the 10:53:58	7 Q. Okay. So would you say that based on the data 10:56:34
8 purple diamonds, what data shows that the -- there was a 10:54:03	8 for 2Q4, versus 2Q12, they performed similarly with 10:56:38
9 maintenance of effect on visual acuity with a single 10:54:11	9 respect to letter scores for weeks 4 and 8? 10:56:45
10 dose to 8 weeks? 10:54:14	10 A. Yes. I would characterize it that way. 10:56:49
11 MR. BRAUSA: Objection; form. 10:54:16	11 Q. Okay. All right. And would you agree, then, 10:56:53
12 THE WITNESS: So if we look at for the 2Q arm 10:54:20	12 that the -- that looking at this data published in 2008, 10:56:57
13 and look at the visual acuity, first of all, at four 10:54:22	13 that would provide a rationale for a dosing regimen 10:57:03
14 weeks, it's approximately six letters. 10:54:26	14 which had 2 milligrams for the first three doses four 10:57:08
15 BY MR. NIMROD:	15 weeks apart, and then a Q8-week dosing regimen for the 10:57:14
16 Q. Okay. 10:54:28	16 tertiary doses? 10:57:19
17 A. And then we look at eight weeks, once again, it's 10:54:29	17 MR. BRAUSA: Objection; form. 10:57:20
18 approximately six letters. Hence, the characterization 10:54:31	18 THE WITNESS: I would look to this and say 10:57:21
19 of maintenance. 10:54:36	19 after a single dose, that the effect at eight weeks 10:57:25
20 Q. Okay. And then what happens at week 12 with 10:54:38	20 appeared to be about as good as four weeks and that 10:57:28
21 respect to -- strike that. 10:54:43	21 that was worth investigating at phase 3 trial. 10:57:33
22 Is it your understanding that when Regeneron said 10:54:43	22 BY MR. NIMROD: 10:57:35
23 in 2008 that it would maintain effect with a single dose 10:54:48	23 Q. Phase 3 trial? 10:57:36
24 to eight weeks, that it did not maintain it at week 12? 10:54:51	24 A. Yes. 10:57:36
25 MR. BRAUSA: Objection; form. 10:54:56	25 Q. Because this was phase 2, right? 10:57:37
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1 THE WITNESS: Well, they didn't say -- they 10:54:58	1 A. This was phase 2 -- this was phase 1. 10:57:40
2 didn't characterize it that way. 10:55:01	2 Q. This is CLEAR-IT 2? 10:57:45
3 BY MR. NIMROD: 10:55:02	3 A. I'm sorry. Phase 2. My mistake. I'm sorry. My 10:57:46
4 Q. How would you understand it? Well, let me ask 10:55:03	4 mistake. This is phase 2, so I would say it's worth 10:57:51
5 you the question. 10:55:05	5 investigating at phase 3 trial. 10:57:53
6 A. Okay. 10:55:05	6 Q. But would you agree that this data here in 10:57:55
7 Q. In your view, did the 2Q12 regimen maintain the 10:55:05	7 figure -- the figure on page 17 of Exhibit 2047 provided 10:57:59
8 effectiveness up to week 12? 10:55:14	8 the rationale for the 2 mg, three initial doses one 10:58:03
9 A. So when I look at week 12, I see a good 10:55:17	9 month apart, followed by tertiary doses that were eight 10:58:08
10 improvement but there is a trend line that goes down, 10:55:21	10 weeks apart? 10:58:11
11 and it accelerates slightly after eight weeks. 10:55:26	11 MR. BRAUSA: Objection; form. 10:58:14
12 Q. Okay. So your -- in your opinion, the 2Q12 10:55:30	12 THE WITNESS: I think this is one piece of data 10:58:16
13 treatment, which is a single dose, initial dose followed 10:55:38	13 with that. I don't know what the discussions were 10:58:18
14 by a second dose at week 12, showed a good improvement 10:55:42	14 behind the scenes and what other data they would have 10:58:21
15 through week 12, but then there was a trend line down; 10:55:47	15 looked at. For example, drying of the retina, other 10:58:24
16 is that right? 10:55:52	16 things could have been there as well. 10:58:28
17 A. So there was a good improvement through week 12. 10:55:52	17 BY MR. NIMROD: 10:58:29
18 The trend line had already started to move down by that 10:55:56	18 Q. Okay. If you look at the Heier Exhibit 3, it's 10:58:29
19 time. 10:55:58	19 going back to that. If you look at Exhibit 3, the title 10:58:37
20 Q. Okay. All right. So if we look at six weeks -- 10:55:59	20 page, there's a reference to a person like George 10:58:45
21 excuse me. Strike that. 10:56:04	21 Yanco -- how do you pronounce that? 10:58:52
22 If we look at the eight weeks, you said that the 10:56:04	22 A. Yancopoulos. 10:58:53
23 2Q12, which is just a single dose at month zero, got 10:56:09	23 Q. Yancopoulos. 10:58:55
24 about a six-letter score, right? 10:56:12	24 A. Yancopoulos. 10:58:58
25 A. Yes. 10:56:16	25 Q. Yancopoulos. Yancopoulos. You understand that 10:58:58
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1 he was the top guy at Regeneron in this -- science guy? 10:59:00 2 MR. BRAUSA: Objection; form. 10:59:06 3 THE WITNESS: He is a senior officer. He's not 10:59:06 4 the CEO, nor do I believe he was at the time. 10:59:13 5 BY MR. NIMROD: 10:59:15 6 Q. But you understand Regeneron approved this 10:59:15 7 article, correct? 10:59:17 8 A. George has a high position at Regeneron. I -- 10:59:18 9 yes. 10:59:22 10 Q. Okay. So if we go to the page that we looked at 10:59:22 11 before, page 7 of Exhibit 1039, which is our Exhibit 3 10:59:25 12 in the deposition, let me know when you're there. Page 10:59:33 13 7. 10:59:36 14 A. Page 7. Yes. Go ahead. 10:59:37 15 Q. Right-hand column. 10:59:38 16 A. Um-hmm. 10:59:40 17 Q. Near the bottom, it says, quote: The rationale 10:59:40 18 for the 2 mg Q8-week dose was based on an observation 10:59:44 19 from the fixed dosing phase of CLEAR-IT 2: -- 10:59:49 20 A. Yes. 21 Q. -- at eight weeks the improvement in BCVA after a 10:59:57 22 single 2-milligram dose was similar to that obtained 10:59:59 23 with a 2-milligram dose monthly to eight weeks and the 11:00:02 24 effect to the visual acuity gain for the single dose 11:00:06 25 groups began to wane by week 12. 11:00:09 Page 90	1 apart, that you would reasonably expect that a 11:01:46 2 significant portion of the patient population would gain 11:01:49 3 letters in the visual acuity score? 11:01:53 4 MR. BRAUSA: Objection; form. 11:01:56 5 THE WITNESS: I don't believe you can 11:01:57 6 extrapolate out beyond where we see here because there 11:02:00 7 was no Q8 arm. There was data to suggest that in a 11:02:03 8 very small number of patients, the vision was stable 11:02:10 9 between four and eight weeks. But to extrapolate that 11:02:13 10 as an extension arm through the course of 52 weeks 11:02:15 11 after a loading phase, I don't think you can get a 11:02:21 12 reasonable expectation from that. You have data that 11:02:23 13 is suggestive, but you don't have an expectation from 11:02:26 14 it. 11:02:29 15 BY MR. NIMROD: 16 Q. Okay. So if I do three initial dose -- let's 11:02:30 17 say, you know, one initial dose and three secondary 11:02:38 18 doses, that would be like the Q -- 2Q4 arm, right? 11:02:40 19 A. That would be the start. Yes. 11:02:47 20 Q. Okay. And if I looked at this data on slide 17, 11:02:48 21 I would see a nice jump by week 4, stability at week 8 11:02:51 22 and another jump at week 12, right? 11:02:55 23 A. Between 12 and 16 -- 8 to 12 and 12 to 16, yes. 11:02:57 24 Q. Okay. 11:03:03 25 A. For the 2Q4 arm, there are improvements of visual 11:03:03 Page 92
1 Do you see that? 11:00:11 2 A. I see that. 11:00:12 3 Q. So according to Regeneron, the rationale for the 11:00:12 4 2 milligram with three initial doses monthly, followed 11:00:14 5 by tertiary doses of eight weeks apart came from the 11:00:18 6 observation we see on slide 17 of Exhibit 2047, correct? 11:00:23 7 A. Certainly the way I read it, yes. 11:00:29 8 Q. Okay. Would you agree with me that based on the 11:00:31 9 results shown in Exhibit 2047, slide 17, that it would 11:00:44 10 have been obvious to somebody that you could do monthly 11:00:51 11 dosing of 2 milligrams of Aflibercept for an initial and 11:00:57 12 two secondary doses followed by Q8 dosing and get 11:01:02 13 improved visual acuity for the patient population as a 11:01:07 14 whole? 11:01:11 15 MR. BRAUSA: Objection; form. 11:01:12 16 THE WITNESS: No. I don't think it's obvious. 11:01:12 17 I think the data is compelling enough to do a phase 3 11:01:16 18 trial. But I don't think it's obvious what your 11:01:22 19 result is going to be. 11:01:25 20 BY MR. NIMROD: 21 Q. Okay. Would you agree with me that the 11:01:26 22 reasonable expectation of a skilled artisan in 2008 11:01:28 23 based on the data shown in slide 17 of Exhibit 2047 11:01:32 24 would be that if they dosed with three monthly doses to 11:01:36 25 start, followed by Q8 tertiary doses, that's eight weeks 11:01:41 Page 91	1 acuity at the 12- and 16-week time points. 11:03:07 2 Q. Okay. And then that is between 0 and 12 -- 11:03:09 3 that's a fixed dosing that's monthly for the 2Q4, 11:03:12 4 correct? 11:03:15 5 MR. BRAUSA: Objection; form. 11:03:16 6 THE WITNESS: The 2Q4 includes injections at 11:03:17 7 every four-week interval from zero through 12 weeks, 11:03:25 8 yes. 11:03:28 9 BY MR. NIMROD: 11:03:28 10 Q. So that's the fixed dosing phase? 11:03:28 11 A. Phase. 11:03:30 12 Q. Right. Okay. And then after that, it was PRN, 11:03:31 13 right? 11:03:33 14 A. That's correct. 11:03:34 15 Q. Okay. And you're saying, though, that the -- you 11:03:35 16 couldn't draw any conclusions as to whether or not a 11:03:40 17 POSA looking at this data would expect that if I did 11:03:44 18 monthly dosing through week 12 and then I did eight-week 11:03:46 19 dosing through week 52 that I would get a significant 11:03:50 20 portion of my patient population getting improvement in 11:03:53 21 letter score by week -- at week 52; is that right? 11:03:57 22 MR. BRAUSA: Objection; form. 11:04:01 23 THE WITNESS: The problem again becomes you 11:04:01 24 don't know what happens after week 12. We have the 11:04:05 25 PRN arm. That, we have. But you don't have an 11:04:09 Page 93

1 expectation as to what the 2Q8 arm is going to do. 11:04:13 2 And up until this time, nobody had ever shown that 11:04:18 3 injections with intervals past Q4 weeks on a regular 11:04:23 4 basis had ever maintained vision. 11:04:28 5 BY MR. NIMROD: 6 Q. Okay. So the 2Q4 mean letter score was nine, 11:04:29 7 correct? 11:04:35 8 A. At week 52, yes. 11:04:35 9 Q. At week 52. Okay. Do you know how many PRN 11:04:37 10 injections were given as a mean during that period? 11:04:43 11 A. I don't. But I could find it in CLEAR-IT 2. 11:04:51 12 Q. Okay. Why don't we look in slide 12, 11:04:54 13 Exhibit 2047. 11:04:58 14 A. Okay. We're good. 11:04:59 15 Q. Which is our Depo Exhibit 3. 11:05:00 16 So we have retreatment outcome, number of 11:05:05 17 injections over PRN phase. 11:05:08 18 MR. BRAUSA: Sorry, just -- I think you said 11:05:10 19 Exhibit 3. You want to stay in Exhibit 5, right? 11:05:11 20 MR. NIMROD: I do. Thank you for clarifying 11:05:14 21 that. 11:05:15 22 MR. BRAUSA: Okay. 11:05:15 23 MR. NIMROD: I do that a lot. 11:05:18 24 BY MR. NIMROD: 25 Q. Okay. We have retreatment outcome and it says 11:05:23 Page 94	1 is that right? 11:06:47 2 A. The mean number was 1.55. Yes. 11:06:47 3 Q. And then the median would mean that half of the 11:06:50 4 people -- half of the patients received, I guess, one or 11:06:53 5 more and half received one or less? Is that what it 11:06:57 6 means? 11:07:00 7 A. We don't know where the numbers fell here. So 11:07:00 8 I -- again, I know what median means. But we don't know 11:07:06 9 here where it fell on this. 11:07:10 10 Q. Okay. They indicated one, whatever that means. 11:07:13 11 A. Yeah. 11:07:16 12 Q. Okay. Then it has the word range. Zero to four. 11:07:17 13 What do you understand that to mean? 11:07:21 14 A. So most injections on any given patient and least 11:07:22 15 injections on any given patient. So the least 11:07:27 16 injections on any given patient was four. The most 11:07:31 17 injection on any given patient -- I'm sorry, least was 11:07:35 18 zero and the most was four. 11:07:38 19 Q. Okay. That means that the -- some patients 11:07:43 20 received no injections in the PRN phase, right? 11:07:45 21 A. Well, it means that at least one but we don't 11:07:47 22 know how many. 11:07:51 23 Q. Well, it says range, zero to four. 11:07:51 24 A. At least one patient received no injections. 11:07:54 25 Q. Oh, right, right. 11:07:56 Page 96
1 number of injections over PRN phase and there is a -- 11:05:27 2 first column that says VEGF Trap-Eye, which is 11:05:32 3 Aflibercept, right? 11:05:36 4 A. Yes. 11:05:36 5 Q. And then it tells you the different arms and the 11:05:36 6 milligrams of Aflibercept in each arm, right? 11:05:40 7 A. Yes. 11:05:42 8 Q. Okay. And then next it has a mean and then a 11:05:43 9 median and a range. What do you understand mean to 11:05:48 10 indicate in the figure -- slide 12? 11:05:51 11 A. So for each arm, it is the numerical average, 11:05:56 12 pull it up, divide by the number of injections for each 11:06:03 13 arm given after week 12. 11:06:06 14 Q. Okay. 15 A. That's the PRN phase. 11:06:11 16 Q. Okay. So that means that -- okay. 11:06:12 17 What's the difference there between mean and 11:06:15 18 median? 11:06:17 19 A. Median is simply you have half of your patients 11:06:17 20 had more, half had less. But when you're dealing with 11:06:21 21 integers, it doesn't always work out exactly half and 11:06:26 22 half but that's the mid number. 11:06:30 23 Q. Okay. Then that would indicate that for the 11:06:31 24 2-milligram Q4 arm, the average number of PRN injections 11:06:35 25 between -- or after week 12 up through week 52 was 1.55; 11:06:41 Page 95	1 A. But we don't know how many of them did. 11:07:57 2 Q. Gotcha. And then some patients, one or more 11:08:00 3 received one? 11:08:02 4 A. We don't know that. 11:08:03 5 Q. Okay. 11:08:05 6 A. The median doesn't tell us how it fits in the 11:08:06 7 middle. 11:08:09 8 Q. Okay. 11:08:09 9 A. It only tells us the end points. 11:08:10 10 Q. The maximum number of injections that anyone got 11:08:11 11 in the arm during the PRN phase, which is 40 weeks, was 11:08:16 12 four, correct? 11:08:19 13 A. In the 2Q4 arm, the most was four. 11:08:20 14 Q. Okay. And that would come out if you averaged it 11:08:22 15 to about ten weeks apart; is that right? 11:08:24 16 MR. BRAUSA: Objection; form. 11:08:27 17 THE WITNESS: If -- on that patient, again, you 11:08:27 18 don't know exactly when they were given but if you 11:08:34 19 take an overall average, it's about -- that actually 11:08:38 20 is probably a little less because it would not include 11:08:47 21 week 52 data. 11:08:50 22 BY MR. NIMROD: 11:08:51 23 Q. Okay. So it'd be more like eight weeks apart? 11:08:51 24 MR. BRAUSA: Objection; form. 11:08:53 25 THE WITNESS: I don't know the number. Would 11:08:53 Page 97

1 be probably less than ten. 11:08:55 2 BY MR. NIMROD: 11:08:56 3 Q. Less than ten. Okay. 11:08:56 4 So the maximum number of injections during the 11:08:57 5 PRN phase for the patients in the 2Q4 arm was likely 11:09:01 6 less than ten? Sorry. I did that wrong, didn't I? Let 11:09:08 7 me start over again. 11:09:15 8 A. Okay. 11:09:16 9 Q. So for the maximum number of injections during 11:09:16 10 the PRN phase for the patients in the 2Q4 arm was 11:09:20 11 probably less than ten weeks apart on average? Is that 11:09:28 12 right? 11:09:34 13 A. If you -- 11:09:34 14 MR. BRAUSA: Objection; form. 11:09:35 15 THE WITNESS: The -- if you do the math and 11:09:35 16 spread it out over that time frame, it's probably less 11:09:41 17 than ten weeks apart. 11:09:44 18 BY MR. NIMROD: 11:09:46 19 Q. Okay. 20 A. Correct. 21 Q. And then for the other patients that were 11:09:46 22 either -- if there were any at zero, that would be no 11:09:49 23 injections at one, two or three, then it would be more 11:09:52 24 than ten weeks apart on average, right? 11:09:56 25 MR. BRAUSA: Objection; form. 11:09:59 Page 98	1 Q. 44? 11:11:17 2 A. 44. 11:11:18 3 Q. And 52? 11:11:19 4 A. Well, 52 doesn't count. 11:11:20 5 Q. Because you're measuring it at that week and the 11:11:22 6 injection, if you gave it that day, is not going to 11:11:24 7 impact your score? 11:11:26 8 A. Right. 11:11:26 9 Q. Because you would take the score before you 11:11:27 10 inject and wouldn't have the impact anyway? 11:11:29 11 A. Right. 11:11:32 12 Q. Okay. So it would be four. And so given that 11:11:32 13 there were no adverse effects for any of the arms, 11:11:37 14 including 2-mg Q4, would you agree that a POSA looking 11:11:41 15 at the data on slide 12 in 17 of Exhibit 2047, would 11:11:45 16 conclude that there were no toxicity issues if you gave 11:11:54 17 four monthly doses followed by four further injections 11:11:59 18 between weeks 12, after week 12, through before week 52? 11:12:03 19 MR. BRAUSA: Objection; form. 11:12:10 20 THE WITNESS: I'm sorry, repeat the question, 11:12:10 21 please. 11:12:13 22 BY MR. NIMROD: 11:12:13 23 Q. Okay. Given the results that are reported, both 11:12:13 24 on slide 12 and 17 of Exhibit 2047, would you agree that 11:12:16 25 a POSA would conclude that since there were no adverse 11:12:23 Page 100
1 THE WITNESS: We don't know when they were 11:09:59 2 given but that would be an average. 11:10:02 3 BY MR. NIMROD: 4 Q. All right. So based on this data that we see 11:10:06 5 here for the 2Q4 arm, that was published in 2008, would 11:10:09 6 you agree that a POSA -- well, let me strike that. 11:10:14 7 How many injections would be given between weeks 11:10:17 8 12 and 52 if one were practicing a fixed dosing regimen 11:10:20 9 with an initial dose and then three monthly doses 11:10:27 10 followed by tertiary doses that are eight weeks apart, 11:10:32 11 how many tertiary doses would there be between -- after 11:10:36 12 week 12 through week 52? 11:10:40 13 MR. BRAUSA: Objection; form. 11:10:42 14 THE WITNESS: So you're looking at if after 11:10:44 15 four monthly doses, the patients then received Q8-week 11:10:47 16 injections through week 52. You're asking how many 11:10:53 17 injections would that be in that Q8-week phase if you 11:10:57 18 were to structure it. I count four. 11:11:02 19 BY MR. NIMROD: 20 Q. So it would be at week 20? 11:11:12 21 A. 20. 11:11:14 22 Q. 28? 11:11:15 23 A. 28. 11:11:15 24 Q. 36? 11:11:16 25 A. 36. 11:11:16 Page 99	1 events reported, then it would be safe at least to give 11:12:27 2 four initial monthly doses of 2 mg of Aflibercept 11:12:31 3 followed by four injections of 2 mg in the period after 11:12:36 4 12 weeks but before 52 weeks? 11:12:43 5 MR. BRAUSA: Objection; form. 11:12:45 6 THE WITNESS: We don't know how many patients 11:12:46 7 received four injections in the PRN phase. But I 11:12:49 8 think the conclusion would be that's encouraging, the 11:12:53 9 fact that no -- well, let me also say one thing. I 11:12:57 10 don't think we've shown that there were no -- there 11:13:00 11 were no adverse events in the PRN phase. 11:13:03 12 BY MR. NIMROD: 13 Q. Well -- 11:13:07 14 A. Did I miss something? 11:13:07 15 Q. I thought we had a slide that said there were no 11:13:09 16 adverse effects. 11:13:12 17 A. I think we found that through week 12 but did I 11:13:13 18 miss it and it was week 52? 11:13:17 19 Q. Well, the study is the -- of a study that goes 11:13:20 20 through 52 weeks, correct? 11:13:23 21 A. Correct. 11:13:24 22 Q. And when they report they were generally well 11:13:27 23 tolerated -- this is on slide 9 -- with no drug-related 11:13:29 24 serious adverse events, do you not read that to mean 11:13:33 25 through week 52 since that was the study? 11:13:37 Page 101

1 MR. BRAUSA: Objection; form. 11:13:39 2 BY MR. NIMROD: (Indicating) 11:13:40 3 Q. I mean, did they stop looking to see their 11:13:40 4 adverse events? 11:13:43 5 A. This is slide 9. 11:13:43 6 Q. Yes. 11:13:45 7 A. Yes. And you're saying was generally well 11:13:45 8 tolerated with no drug-related serious adverse events. 11:13:48 9 That's the report through 12 weeks. 11:13:52 10 Q. So you're saying they did not find the same thing 11:13:53 11 through week 52? 11:13:56 12 A. I'm saying I don't know. I'm saying this is -- 11:13:57 13 they reported through week 12. I don't know what they 11:14:01 14 found through the maintenance -- through the PRN phase. 11:14:04 15 Q. Okay. Let's assume, since you're an expert, I'm 11:14:06 16 going to ask you to assume this -- that Regeneron 11:14:08 17 reported that there was no drug-related serious adverse 11:14:11 18 events through the end of the 52 weeks. If that were, 11:14:19 19 in fact, what was reported, would you agree, then, that 11:14:22 20 a POSA looking at the data on slides 12 and 17 would 11:14:25 21 conclude that if you gave four monthly doses of 2 mg, 11:14:29 22 followed by four doses eight weeks apart, after week 12 11:14:32 23 through before week 52, would believe that that would be 11:14:39 24 well tolerated with no adverse events? 11:14:43 25 MR. BRAUSA: Objection; form. 11:14:48 Page 102	1 A. All groups combined, correct. 11:15:57 2 Q. Okay. Is there data for adverse events for Q24? 11:15:59 3 A. I would have to go into the paper to look. This 11:16:04 4 table does not tell us that. 11:16:08 5 Q. And do you consider any of those events there in 11:16:09 6 Table 6 to be serious adverse events? 11:16:13 7 A. Before I answer that, above that, it says that 11:16:16 8 the number of patients with systemic adverse events was 11:16:21 9 similar among treatment groups. So -- okay. Now your 11:16:24 10 question is, are any of these serious adverse events? 11:16:30 11 Yeah. A couple of them, yes, a couple of them are. 11:16:34 12 Q. Which ones? 11:16:37 13 A. Detachment of the retinal pigment epithelium. 11:16:38 14 (Court reporter clarification.) 15 THE WITNESS: Sorry. Detachment of retinal 11:16:55 16 pigment epithelium, retinal edema, subretinal 11:16:55 17 fibrosis, retinal hemorrhage. 11:16:59 18 BY MR. NIMROD: 19 Q. Okay. So those are happening with the fixed 11:17:10 20 dosing phase, followed by PRN in this CLEAR-IT 2 study, 11:17:14 21 those events? 11:17:19 22 A. Yes. 11:17:20 23 Q. And those events were not so serious that the 11:17:20 24 study, the phase 3 study did not proceed, correct? In 11:17:24 25 other words, those adverse events were acceptable to 11:17:28 Page 104
1 THE WITNESS: Rather than assuming that, I'd 11:14:49 2 rather go back to this paper. And if you look at 11:14:56 3 Table 6, it does talk about -- 11:14:59 4 BY MR. NIMROD: 11:15:02 5 Q. Wait. Let me go -- 11:15:02 6 A. Go ahead. 7 Q. When you say this paper you mean -- 11:15:04 8 A. I'm sorry. The CLEAR-IT. Exhibit 3. 11:15:05 9 Q. Do you mean Exhibit 2039? 11:15:06 10 A. Exhibit 3. 11:15:09 11 Q. So that's Exhibit 1039 and preceding exhibit, 11:15:10 12 deposition Exhibit 3? 11:15:13 13 A. Yes. 1039. 11:15:14 14 Q. Where are you at now? 11:15:16 15 A. Page 1103, Table 6. 11:15:17 16 Q. Okay. Go ahead. 11:15:24 17 A. So if you look at that, that gives us ocular 11:15:24 18 adverse events in the study eye over the course of the 11:15:31 19 entire trial. And you see that there are some adverse 11:15:35 20 events. 11:15:42 21 Q. With -- 11:15:43 22 A. So I don't think you can assume that there were 11:15:43 23 no adverse events. 11:15:45 24 Q. So there's adverse events for the combination of 11:15:46 25 all the groups combined? 11:15:51 Page 103	1 proceed to a phase 3 study, were they not? 11:17:30 2 MR. BRAUSA: Objection; form. 11:17:33 3 THE WITNESS: I would assume so. They went 11:17:33 4 through phase 3. 11:17:38 5 BY MR. NIMROD: 11:17:39 6 Q. So then I guess if I ask the question a different 11:17:39 7 way, given the data on slides 12 and 17 of 11:17:41 8 Exhibit 2047 -- 11:17:51 9 MR. BRAUSA: Just to be clear, that's 11:17:51 10 Exhibit 5? 11:17:53 11 BY MR. NIMROD: 11:17:54 12 Q. Which is Exhibit 5 in the deposition. I'll start 11:17:54 13 that over again. 11:17:56 14 Given the data on deposition Exhibit 5, which is 11:17:56 15 the Exhibit 2047 in the IPR proceeding -- 11:18:00 16 A. Yes. 11:18:06 17 Q. -- looking at slides 12 and 17, would a POSA 11:18:07 18 conclude that a 2-milligram dosing regimen for four 11:18:11 19 monthly doses followed by eight-week dosing between 11:18:19 20 weeks 12 and 52, which would be four, would not have 11:18:22 21 serious adverse effects that would preclude one from 11:18:27 22 going forward with a phase 3 clinical trial? 11:18:31 23 MR. BRAUSA: Objection; form. 11:18:34 24 THE WITNESS: Repeat the question, please. 11:18:37 25 BY MR. NIMROD: 11:18:39 Page 105

1 Q. Okay. Looking at slides 12 and 17, of depo 11:18:39 2 Exhibit 5, which is also IPR preceding Exhibit 2047, 11:18:44 3 would a POSA conclude that based on the data in those 11:18:52 4 slides that a 2-milligram dose for five months followed 11:18:54 5 by 2-milligram doses of Aflibercept every eight weeks 11:18:59 6 would be tolerated enough that you could proceed with a 11:19:03 7 phase 3 clinical study? 11:19:11 8 MR. BRAUSA: Objection; form. 11:19:13 9 BY MR. NIMROD: 11:19:13 10 Q. Which, in fact, is what they did? 11:19:14 11 A. Right. 11:19:16 12 MR. BRAUSA: Same objection. 11:19:17 13 THE WITNESS: But, no, you can't -- you 11:19:18 14 couldn't make the conclusion based on the way you 11:19:20 15 asked the question. Two things, one is, it was four 11:19:23 16 monthly dosing at the beginning, not five. Secondly, 11:19:28 17 it was a PRN arm -- excuse me -- not a 2Q8 arm. And 11:19:31 18 certainly the -- excuse me -- the number of 11:19:39 19 injections, the medium number of injections during the 11:19:43 20 PRN phase was much less than what you would expect 11:19:47 21 with a 2Q8 phase. So you can't make that 11:19:49 22 extrapolation. 11:19:53 23 BY MR. NIMROD: 24 Q. So then how did Regeneron justify going into 11:19:53 25 phase 3 with a different regimen than phase 2 that 11:19:57 Page 106	1 BY MR. NIMROD: 11:21:09 2 Q. Right. And so before you go into the big patient 11:21:09 3 population in phase 3, you want to make sure it's safe 11:21:13 4 what you're going to give them in phase 3, right? 11:21:16 5 A. You want to make sure there are no safety 11:21:18 6 signals, correct. 11:21:21 7 Q. Right. And so you look at the results -- by the 11:21:22 8 way, is phase 1 or 2 safety versus one or the other, or 11:21:24 9 are they both safety, which one looks at safety? 11:21:28 10 MR. BRAUSA: Objection; form. 11:21:31 11 THE WITNESS: Safety -- safety is usually the 11:21:32 12 primary end point of a phase 1. 11:21:37 13 BY MR. NIMROD: 11:21:42 14 Q. Okay. And what is the primary end point of phase 11:21:42 15 2, efficacy? 11:21:45 16 A. Dose exploration with efficacy. 11:21:47 17 Q. Okay. So in order to proceed on phase 3, with 11:21:48 18 the arms that you're proposing, you have to have data 11:21:53 19 showing that the expectation is that they'll be a safe 11:21:56 20 dose for the patient population and efficacious, 11:22:00 21 correct? 11:22:03 22 MR. BRAUSA: Objection; form. 11:22:03 23 THE WITNESS: You have to show that there's 11:22:04 24 good safety data out of your phase 2, which suggests 11:22:07 25 minimal tolerable risk to patients. 11:22:12 Page 108
1 required, I believe, monthly dosing, was it, in phase 3; 11:20:01 2 what were the different arms for 2 milligrams? 11:20:06 3 MR. BRAUSA: Objection; form. 11:20:09 4 THE WITNESS: So you're talking about phase 3, 11:20:09 5 macular degeneration, AMD. 11:20:12 6 BY MR. NIMROD: 11:20:13 7 Q. Yes, I am. 11:20:13 8 A. Yes. One was the doses were monthly 2-milligram, 11:20:13 9 2-milligram Q4 weeks times three, afterwards, two -- 11:20:19 10 afterwards, Q8 weeks. 11:20:26 11 Q. Just to clarify, when you say -- 11:20:27 12 A. I'm sorry. 11:20:29 13 Q. The one that has eight weeks, is it an initial 11:20:30 14 and two or is it initial and three? 11:20:32 15 A. Initial and two. 11:20:34 16 Q. Okay. Go ahead. 11:20:35 17 A. Okay. Yeah. Then 0.5 milligrams, Q4, and 11:20:36 18 Ranibizumab, Q4. 11:20:44 19 Q. Okay. So I assume that when the FDA authorizes a 11:20:45 20 phase 3 clinical or Regeneron proposes one, they have to 11:20:53 21 believe that there's safety in a phase 3, because don't 11:20:55 22 the other trials, like phase 1 or 2, go into safety? 11:21:00 23 MR. BRAUSA: Objection; form. 11:21:05 24 THE WITNESS: The other trials look at safety 11:21:07 25 in small numbers. 11:21:08 Page 107	1 BY MR. NIMROD: 2 Q. Okay. So you have to show -- in order to go to 11:22:15 3 the phase 3, you have to show that there's an 11:22:17 4 expectation of safety based on your phase 1 and phase 2 11:22:20 5 data, correct? 11:22:24 6 A. You have to show -- 11:22:27 7 MR. BRAUSA: Objection; form. 11:22:27 8 THE WITNESS: You have to show that there are 11:22:27 9 no safety signals out of your phase 1 and phase 2. 11:22:29 10 BY MR. NIMROD: 11:22:34 11 Q. Okay. Would you agree with me that means you 11:22:34 12 have to show there's an expectation of safety, not just 11:22:35 13 a mere hope? 11:22:37 14 MR. BRAUSA: Objection; form. 11:22:38 15 THE WITNESS: You want data to back it up. 11:22:38 16 BY MR. NIMROD: 11:22:41 17 Q. Right. So -- 11:22:41 18 A. But I don't know that you can have an expectation 11:22:42 19 of it. 11:22:44 20 Q. So you're telling me that you can't even agree 11:22:44 21 with me that when you go to phase 3 of a study, that you 11:22:46 22 have to have an expectation of safety based on your 11:22:52 23 phase 1 and phase 2 clinical studies? 11:22:56 24 MR. BRAUSA: Objection. 11:22:58 25 BY MR. NIMROD: 11:22:58 Page 109

1 Q. You don't agree with that? 11:22:58	1 FDA to accept the phase 3 arm that was monthly dosing at 11:24:56
2 MR. BRAUSA: Objection; form, asked and 11:23:00	2 2 milligrams, there had to be an expectation that it was 11:25:05
3 answered. 11:23:02	3 probable that that would be a safe dosage for patients 11:25:09
4 BY MR. NIMROD: 11:23:02	4 in the phase 3 study? 11:25:13
5 Q. Just expectation. Not guarantee, not certainty. 11:23:02	5 MR. BRAUSA: Objection; form. 11:25:15
6 Expectation. 11:23:04	6 THE WITNESS: So would you restate the 11:25:16
7 MR. BRAUSA: Same objection to all of the 11:23:05	7 question, please? 11:25:19
8 questions. 11:23:07	8 BY MR. NIMROD: 11:25:19
9 THE WITNESS: You have to be able to project 11:23:09	9 Q. I said in order for Regeneron to propose and the 11:25:19
10 forward that your safety data is acceptable. And both 11:23:12	10 FDA to accept a phase 3 arm that was monthly dosing of 11:25:22
11 internally, as well as to the FDA. 11:23:18	11 Aflibercept at 2 milligrams, there had to be an 11:25:26
12 BY MR. NIMROD: 11:23:20	12 expectation that it was probable that it would be a safe 11:25:39
13 Q. Which means that you would have to have an 11:23:20	13 dosage regimen for patients in the phase 3 study; is 11:25:33
14 expectation that you're going to have safety in your 11:23:21	14 that right? 11:25:38
15 phase 3 studies, right? 11:23:25	15 MR. BRAUSA: Objection; form. 11:25:41
16 MR. BRAUSA: Objection; form. 11:23:26	16 THE WITNESS: No, I think a better way to 11:25:41
17 THE WITNESS: I don't know that we can get to 11:23:26	17 characterize it would be that to proceed with a phase 11:25:43
18 the point of expectation. We can get to the point of 11:23:28	18 3, there had to be, based on the phase 2 data, 11:25:45
19 history provides us with good data. There's the hope 11:23:32	19 probability that you're not going to have a severe 11:25:48
20 that we're going to go forward and meet that again. 11:23:35	20 number of adverse events. 11:25:50
21 But I don't know that we have an expectation. Not 11:23:38	21 BY MR. NIMROD: 11:25:53
22 without data being achieved -- being actually 11:23:41	22 Q. Okay. So the probability in order to proceed in 11:25:53
23 acquired. Data at the phase 3 level being acquired. 11:23:45	23 the phase 3 study, if we take out the word expect, would 11:25:56
24 BY MR. NIMROD: 11:23:47	24 be -- let me start over again. 11:26:00
25 Q. So you can't really use the word expectation 11:23:48	25 For the phase 3 study to proceed, and for 11:26:02
Page 110	Page 112
1 today in this deposition, I assume? 11:23:51	1 Regeneron to propose it and the FDA to accept it, there 11:26:05
2 MR. BRAUSA: Objection; mischaracterizing. 11:23:54	2 had to be data showing that it was probable that there 11:26:08
3 THE WITNESS: Well, I'm not about to use it 11:23:55	3 wouldn't be any adverse events for whatever the arm was? 11:26:11
4 with respect to the question you asked. 11:23:57	4 MR. BRAUSA: Objection; form. 11:26:14
5 BY MR. NIMROD: 11:23:57	5 BY MR. NIMROD: 11:26:16
6 Q. What would be your criteria for an expectation of 11:23:59	6 Q. Any significant adverse events, I guess you'd 11:26:16
7 safety, as opposed to a hope? 11:24:03	7 say? 11:26:18
8 A. My criteria would be that I'm treating according 11:24:06	8 A. No. I don't think that's correct. The -- you 11:26:18
9 to an established protocol and I'm probably going to get 11:24:16	9 can never show or predict you're not going to have any 11:26:22
10 the results already established previously from that 11:24:17	10 adverse events. 11:26:28
11 protocol in a full study. 11:24:21	11 Q. Oh, right. Let me read your answer back. I 11:26:28
12 Q. Okay. 11:24:23	12 misspoke. 11:26:30
13 A. That's not been established here. 11:24:24	13 A. All right. Then -- go ahead. 11:26:31
14 Q. Okay. So you're saying that -- how about this 11:24:25	14 Q. You said: I think a better way to characterize 11:26:32
15 question, would you say that in order to have a phase 3 11:24:29	15 it would be that to proceed with the phase 3, there had 11:26:34
16 study, it has to be probable that the regimen you're 11:24:33	16 to be, based on the phase 2 data, probability that 11:26:37
17 giving is going to be safe? 11:24:39	17 you're not going to have a severe number of adverse 11:26:40
18 MR. BRAUSA: Objection; form. 11:24:40	18 events. 11:26:43
19 BY MR. NIMROD: 11:24:40	19 A. Correct. So I didn't say zero. 11:26:44
20 Q. Would you give me that? 11:24:41	20 Q. Right. I misspoke. I didn't intend to. 11:26:46
21 MR. BRAUSA: Same objection. 11:24:43	21 All right. So then what data in the phase 1 or 11:26:48
22 THE WITNESS: Yeah. I would give you that. 11:24:43	22 phase 2 study of Aflibercept at 2 milligrams gave 11:26:55
23 Probable. 11:24:49	23 Regeneron, the FDA, the ability to believe that there 11:27:01
24 BY MR. NIMROD: 11:24:49	24 was a probability that monthly dosing of Aflibercept was 11:27:05
25 Q. Okay. And in order for Regeneron to propose and 11:24:50	25 not going to have a severe number of adverse events? 11:27:09
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1 MR. BRAUSA: Objection; form. 11:27:12 2 THE WITNESS: So I don't know what the -- that 11:27:13 3 the discussions were within -- internally Regeneron or 11:27:18 4 with the FDA. But as I look at the data, I think it's 11:27:22 5 that there were no serious drug-related adverse events 11:27:28 6 at week 12. I think that's the data that speaks the 11:27:32 7 loudest. 11:27:35 8 BY MR. NIMROD: 9 Q. Okay. And why does the -- explain to me how is 11:27:36 10 the data at week 12 informative -- let me start over 11:27:42 11 again. 11:27:47 12 The data you're referring to at week 12 would be 11:27:47 13 the CLEAR-IT 2 and, also, phase 1 studies of monthly 11:27:50 14 dosing at weeks zero, 4, 8, and 12? Is that right? 11:27:54 15 MR. BRAUSA: Objection; form. 11:27:59 16 THE WITNESS: There was safety data from the 11:28:00 17 phase 1 but no monthly dosing. For phase 2, the 2Q4 11:28:04 18 arm would be the CLEAR-IT 2, the 2Q4 arm had monthly 11:28:11 19 dosing times four. So through 12 weeks. And that 11:28:15 20 probably would have been the most important data. 11:28:20 21 BY MR. NIMROD: 11:28:24 22 Q. Most important data for -- 11:28:24 23 A. I'm sorry. To show that there were no serious 11:28:27 24 adverse events through week 12 in patients, particularly 11:28:29 25 those that were receiving monthly injections. 11:28:33 Page 114	1 was available or would come into play there so I don't 11:30:05 2 know. 11:30:09 3 BY MR. NIMROD: 11:30:09 4 Q. Could you explain to me why would the 12-week 11:30:09 5 data for the 2Q4 in the phase 2 CLEAR-IT 2 study be 11:30:15 6 informative as to potential adverse events for ongoing 11:30:21 7 12-month monthly doses of 2 mg of Aflibercept? 11:30:30 8 A. It represents the cohort that had the most drug 11:30:34 9 injected. And then a time frame over which adverse 11:30:41 10 events could appear. 11:30:47 11 Q. Do adverse events normally appear within the 11:30:49 12 first couple injections if a patient's going to have a 11:30:52 13 problem, the adverse events? 11:30:55 14 MR. BRAUSA: Objection; form. 11:30:58 15 THE WITNESS: So with anti-VEGF therapy, I 11:30:58 16 don't have data on the top of my head to know if 11:31:06 17 it's -- usually it's at the beginning, but I can't 11:31:09 18 give you data to -- in terms of numbers. 11:31:14 19 BY MR. NIMROD: 11:31:17 20 Q. Okay. Would that -- was that known in 2008, that 11:31:17 21 adverse events would usually be at the beginning of 11:31:21 22 anti-VEGF-Trap treatment? 11:31:29 23 MR. BRAUSA: Objection; form. 11:31:30 24 THE WITNESS: That, I can't recall. I don't 11:31:30 25 know if it was available at that time. 11:31:32 Page 116
1 Q. Okay. So the phase 1 study did not have monthly 11:28:36 2 in any of the arms; is that right? 11:28:41 3 A. No. 11:28:42 4 Q. What I said was correct, it did not? 11:28:43 5 A. It did not. Sorry. 11:28:46 6 Q. My fault. 11:28:47 7 Okay. So then in your view, the data that speaks 11:28:48 8 the loudest as to the probable safety for monthly dosing 11:28:52 9 of Aflibercept 2 mg for 12 -- excuse me -- for 12 months 11:29:00 10 was the 12-week data of the 2Q4 arm in the CLEAR-IT 2 11:29:05 11 phase 2 study; is that right? 11:29:11 12 A. You confused me there by talking about 12 months, 11:29:12 13 throwing in there. So repeat the question, please. 11:29:16 14 Q. Yeah. I'll say it again. Let me go back. 11:29:18 15 Okay. The data that speaks the loudest as to the 11:29:21 16 probable safety for the 12 months monthly dosing of 11:29:24 17 Aflibercept in the phase 3 study, 2 mg, was the data for 11:29:31 18 12 weeks in the 2Q4 arm in the CLEAR-IT 2 phase 2 study; 11:29:36 19 is that right? 11:29:41 20 A. Yes. I believe that to be the case. 11:29:41 21 Q. Okay. Was there other data that contributed to 11:29:44 22 that conclusion, that the 12 months of monthly dosing of 11:29:49 23 Aflibercept would be acceptable in terms of safety? 11:29:54 24 MR. BRAUSA: Objection; form. 11:29:59 25 THE WITNESS: I'm not aware of what other data 11:30:02 Page 115	1 MR. NIMROD: Okay. All right. 11:31:39 2 MR. BRAUSA: And Ray, when you get -- I'm 11:31:39 3 sorry, I didn't mean to interrupt -- when we get to a 11:31:41 4 stopping point, if we can take a break. 11:31:45 5 MR. NIMROD: Now's fine. 11:31:46 6 MR. BRAUSA: Okay. 09:57:23 7 THE VIDEOGRAPHER: Stand by. We are going off 11:31:49 8 the record at 11:31. 11:31:51 9 (A brief recess was taken.) 11:31:52 10 THE VIDEOGRAPHER: We are back on the record at 11:46:51 11 11:47. 11:47:01 12 BY MR. NIMROD: 11:47:03 13 Q. Dr. Stewart, we were talking about the criteria 11:47:07 14 for, you know, safety to go to a phase 3 trial and we 11:47:11 15 also discussed that one of the purposes of the phase 2 11:47:15 16 trial, I think you mentioned, was dosing -- it was 11:47:20 17 dosing regimen and efficacy? 11:47:25 18 A. Yes. 11:47:27 19 Q. Okay. Is it dosing or dosing regimen and 11:47:28 20 efficacy? Is that the same thing? 11:47:32 21 A. Oh, so dosing and dosing regimen. 11:47:33 22 Q. Okay. So is it the case, then, in order to 11:47:36 23 propose and have accepted an arm for your phase 3 trial, 11:47:41 24 in addition to having a probability of safety, that you 11:47:46 25 have to have a probability of efficacy for the dose and 11:47:49 Page 117

1 dosing regimen that you're proposing for an arm? 11:47:55	1 29 percent is not simply a roll of the dice in each 11:50:43
2 MR. BRAUSA: Objection; form. 11:47:58	2 case, I assume. If you roll a ten-sided dice, if you 11:50:48
3 THE WITNESS: Would you repeat the question, 11:47:59	3 get a one, two, or three, you're good; if you roll a 11:50:52
4 please? 11:48:02	4 four out of ten, you're out of luck. It's not quite 11:50:58
5 BY MR. NIMROD: 11:48:02	5 that simple, is it? 11:51:01
6 Q. In order to have -- to propose and have an arm 11:48:03	6 MR. BRAUSA: Objection. Characterization of a 11:51:02
7 accepted for your phase 3 trial, other than maybe 11:48:09	7 ten-sided dice. 11:51:04
8 control, you have to have a probability of efficacy for 11:48:14	8 THE WITNESS: Pretty much everybody going into 11:51:05
9 the dose and dosing regimen that you're proposing for 11:48:19	9 phase 3 thinks that they have the next big thing. And 11:51:08
10 the arm? 11:48:22	10 when you look at the history of macular degeneration, 11:51:10
11 MR. BRAUSA: Objection; form. 11:48:23	11 it's littered with drugs that were extreme to 11:51:13
12 THE WITNESS: When you're doing a new drug, 11:48:25	12 promising, great drugs, and failed miserably. 11:51:16
13 which is essentially what this is. And Aflibercept 11:48:30	13 BY MR. NIMROD:
14 moving into phase 3, and this worked for any of the 11:48:33	14 Q. Okay.
15 indications. Did you have an indication in mind? Are 11:48:40	15 A. So you can't predict. 11:51:20
16 we talking about macular degeneration? 11:48:42	16 Q. Right. All right. So let's go back to Exhibit 5 11:51:22
17 BY MR. NIMROD: 11:48:44	17 of the deposition which is Exhibit 2047 in the IPR and 11:51:25
18 Q. Yeah. AMD. 11:48:44	18 go to slide 19, please. 11:51:32
19 A. Yeah. For AMD, then what you're going to need to 11:48:45	19 A. Okay. 11:51:33
20 do in the phase 3 is have a control that is FDA 11:48:48	20 Q. What do you understand slide 19 is showing? 11:51:46
21 approved. And so what you have to -- what you have to 11:48:54	21 A. So -- there's a lot in slide 19. It really is 11:51:51
22 imagine is that your drug with your dose and your 11:48:58	22 three different slides, if you will, all at the same 11:51:58
23 regimen and your safety profile is going to be 11:49:02	23 time. All of them are pertaining to a visual outcome. 11:52:01
24 comparable, currently it's not inferior, to the control 11:49:07	24 On the left, you have each of the five treatment arms. 11:52:09
25 that you put it up against. 11:49:11	25 On the left-hand side, you have the percentage or the 11:52:12
Page 118	Page 120
1 Q. Okay. You used the word imagine. Does that mean 11:49:12	1 proportion of patients in each treatment arm that lost 11:52:17
2 that you have data to show it's probable? 11:49:15	2 fewer than 15 letters. In the center, you have the 11:52:21
3 A. No. You have data to say that you -- you have 11:49:18	3 proportion of patients in each treatment arm that had 11:52:25
4 data accrued from your phase 1 and phase 2 to think that 11:49:22	4 zero -- zero change in visual acuity or a positive gain 11:52:30
5 if I put together this dosing and this protocol with 11:49:26	5 in visual acuity and then on the right side, you have a 11:52:34
6 this safety, that I think I'm going to get a result 11:49:30	6 proportion of patients in each treatment arm that gained 11:52:37
7 that's going to be comparable to the control. 11:49:33	7 15 or more letters of visual acuity and this was at week 11:52:40
8 Q. All right. When you say, I think I'm going to 11:49:36	8 52. 11:52:44
9 get a result, is that probable, more likely than not? 11:49:39	9 Q. Okay. All right. So then if I'm looking at the 11:52:45
10 A. I think that if you're ending up with a -- 11:49:43	10 first set of bars, that's for less than 15 letters lost, 11:52:48
11 when -- let me back up for a second. 11:49:50	11 right? 11:52:55
12 I think in the minds of the people doing the 11:49:52	12 A. That's correct. Less than 15 letters lost. 11:52:57
13 studies, that's what they're thinking. But the reality 11:49:55	13 Q. Okay. So for the patients that were in the arm 11:53:00
14 is, only about 25 to 30 percent of drugs going to phase 11:50:00	14 that was four monthly doses, followed by PRN with a mean 11:53:02
15 3 trials actually end up meeting their end points. So 11:50:05	15 number of injections during the PRN of 1.55, 100 percent 11:53:11
16 the probability is they won't meet their end points. 11:50:09	16 of the patients had the acuity score of a loss of less 11:53:16
17 The thought in the minds of the people designing the 11:50:13	17 than 15 letters; is that right? 11:53:23
18 studies is that we think we have a good chance. So, you 11:50:15	18 A. So based on your mean, I assume you mean the 2Q4 11:53:26
19 know, is it probable? It's -- it's probable enough that 11:50:19	19 arm? 11:53:29
20 we're willing to put up the effort and the money. 11:50:24	20 Q. Yes. Did I not say 2Q4? 11:53:29
21 Q. Okay. 11:50:28	21 A. You didn't say that.
22 A. Knowing that your odds are not very good. 11:50:28	22 Q. Let me start -- I've got to start over again. 11:53:33
23 Q. I take it the odds, though, would vary from drug 11:50:32	23 A. So just, as you say that, this is what we're 11:53:35
24 to drug in a sense, because you might have more robust 11:50:36	24 seeing. And I think it is -- 11:53:37
25 data in phase 1 and 2 for one drug than another, so the 11:50:40	25 Q. Okay. I'm going to give you a better one, then. 11:53:40
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1 A. Okay. 11:53:42 2 Q. I don't think there's anything on here. 11:53:42 3 A. We can verify left to right from the bottom 11:53:44 4 across -- 11:53:47 5 Q. I can give this to you? 6 A. -- then that would make sense. 11:53:47 7 Q. I'll just give you the better color version. I'm 11:53:48 8 not sure why this printer didn't do as well, but it 9 didn't. 11:53:53 10 MR. BRAUSA: Just to confirm, Ray, do you have 11:53:53 11 a Bates numbered version of that? Because this 11:53:54 12 appears to be a copy of what was produced. Do you 11:53:58 13 have -- okay. So it is a copy. That's fine. 11:54:01 14 MR. NIMROD: I think it's an exhibit you 11:54:04 15 produced, as I'm told, but -- 11:54:05 16 MR. BRAUSA: I just wanted to make sure that as 11:54:08 17 produced -- 11:54:09 18 MR. NIMROD: Yeah. 19 MR. BRAUSA: -- it's the same as that. 09:57:23 20 MR. NIMROD: Yeah. It looks like this except 11:54:10 21 for there are some red circles on this that my 11:54:11 22 colleagues gave me for simplicity. But this is what 11:54:13 23 the original looked like. 11:54:16 24 THE WITNESS: Thank you. 11:54:17 25 MR. NIMROD: I'll hand that to the witness. 11:54:17 Page 122	1 Q. Okay. 2 A. Were zero or gained letters. 11:55:27 3 Q. And for the 2Q12 arm, which would be one initial 11:55:29 4 injection, a second injection after 12 weeks, followed 11:55:33 5 by a mean number of injections over the PRN period of 11:55:40 6 2.48, what percentage of the patients achieved an acuity 11:55:45 7 score of less than 15 letters lost? 11:55:52 8 A. And for that 2Q12 arm, 90 percent of them lost 11:55:56 9 fewer than 15 letters. 11:56:00 10 Q. Okay. Would you agree, then, that given that 11:56:01 11 data, a POSA looking at the data in exhibit depo 11:56:04 12 Exhibit 5, Exhibit 2047, would conclude that it was 11:56:13 13 probable that dosing four monthly doses at one month 11:56:16 14 each, followed by eight-week dosing as tertiary dosing 11:56:26 15 would meet the limitation of claim 29, which is simply 11:56:32 16 that it is as effective as .5 milligrams of Ranibizumab, 11:56:35 17 which you told me means that it's less than a 15-letter 11:56:42 18 loss? 11:56:45 19 MR. BRAUSA: Objection; form. 11:56:46 20 THE WITNESS: So I think what a POSA could say 11:56:46 21 is that four monthly doses, one plus three, followed 11:56:50 22 by PRN through the course of one year, has a very high 11:56:55 23 likelihood of losing fewer than 15 letters. I think 11:56:59 24 what a POSA would take from this is moving to Q8 weeks 11:57:03 25 is the stretch and that's the part we don't know. 11:57:08 Page 124
1 THE WITNESS: Yeah. And for simplicity's sake, 11:54:20 2 it's the bottom left to right across. 11:54:23 3 BY MR. NIMROD: 11:54:26 4 Q. Yeah. 11:54:26 5 A. Okay. 11:54:28 6 Q. Let's go over that again. So the copy we have in 11:54:28 7 front of us, the rest of us is not so good but the one 11:54:30 8 that you've got -- 11:54:33 9 A. Okay. 11:54:34 10 Q. -- has the bars shown -- 11:54:34 11 A. Thank you. 12 Q. -- more accurately than simply all purple, except 11:54:36 13 for one. 11:54:40 14 So for the less than 15 letters lost, the 11:54:41 15 patients who were in the 2Q4 arm, meaning they got four 11:54:43 16 initial monthly doses and then a mean of 1.55 doses in 11:54:49 17 the PRN period up to week 52, 100 percent of them 11:54:56 18 achieved the acuity score of less than 15 letters lost; 11:55:00 19 is that right? 11:55:05 20 A. That's correct. 11:55:05 21 Q. Okay. Then for those same patients, what 11:55:07 22 percentage of them achieved -- this is the 2Q4 arm with 11:55:11 23 the PRN that I mentioned -- of zero or greater letter 11:55:15 24 gain? 11:55:20 25 A. And for the 2Q4, that was 81 percent of those. 11:55:21 Page 123	1 BY MR. NIMROD: 2 Q. Stretch in terms of safety or efficacy? 11:57:12 3 A. Efficacy. We're talking efficacy now because 11:57:14 4 you're talking -- because you're talking letters lost. 11:57:16 5 Q. Right. 11:57:20 6 A. Yeah. And because when you do a PRN, you treat 11:57:20 7 patients when they need to. When you do a Q8, you may 11:57:25 8 overtreat a lot of patients. You may undertreat a bunch 11:57:30 9 of patients. And you don't know which is which. 11:57:32 10 Q. Well, you could be undertreating patients if you 11:57:35 11 look at the patient population because nobody got more 11:57:41 12 than five in the -- excuse me -- nobody got more than 11:57:43 13 five in the 2Q4 regimen; in fact, the highest was four. 11:57:46 14 A. Um-hmm. 11:57:51 15 MR. BRAUSA: Objection; form. 11:57:51 16 BY MR. NIMROD: 11:57:51 17 Q. And 100 percent of the people got the -- less 11:57:51 18 than 15 letters lost. 11:57:57 19 A. So the numbers -- the numbers are comparable. 11:57:59 20 But you don't know when the doses were done. And it's 11:58:05 21 when the doses were done could be a clinical feature -- 11:58:07 22 critical feature because if you're giving a Q8, then 11:58:11 23 you're giving it at eight weekly intervals. If you're 11:58:14 24 giving it PRN, those that got four, they might have had 11:58:18 25 one, two, three, four right at the beginning, we don't 11:58:23 Page 125

1 know that. 2 Q. Okay. 3 A. So you can't extrapolate -- 11:58:25 4 Q. And you wouldn't extrapolate anything on that? 11:58:26 5 A. I wouldn't hazard a guess. 11:58:28 6 Q. You wouldn't? 11:58:30 7 A. No. 11:58:30 8 Q. Okay. And you wouldn't even say that it's 11:58:31 9 probable that if I did -- I saw the data on the 2Q4, 11:58:34 10 four monthly doses followed by an average or mean of 11:58:40 11 1.55 PRN injections through week 52, that it was 11:58:44 12 probable that four monthly doses of 2 mg of Aflibercept 11:58:49 13 followed by eight-week dosing through week 52 was 11:58:54 14 probable to have a significant portion of the patient 11:59:00 15 population meet the less than 15 letters lost criteria. 11:59:02 16 Is that right? 11:59:06 17 A. I think it's -- I think it's very encouraging. 11:59:07 18 That would be a regimen that I think is worth 11:59:11 19 investigating. And I think that there's a good chance 11:59:17 20 that you would not end up with that vision loss, that 11:59:21 21 degree of vision loss, but we don't know that until you 11:59:25 22 do it. 11:59:29 23 Q. I just said probable. I didn't say no. I've 11:59:29 24 been saying that because you gave me the word probable. 11:59:33 25 A. I gave you the word probable. I understand. 11:59:33 Page 126	1 data doesn't give it to you. 12:00:45 2 BY MR. NIMROD: 12:00:47 3 Q. Okay. So when you say good chance, you don't 12:00:47 4 mean more likely than not? Because that's another 12:00:49 5 phrase. Probable, I think it was more likely than not, 12:00:50 6 that's what you understood? 12:00:53 7 A. Yeah, I can't say. I can't say. 12:00:54 8 Q. You can't say whether or not the good chance in 12:00:57 9 this case would be probable in the sense of more likely 12:01:00 10 than not that a significant portion of the patient 12:01:06 11 population you would expect to have meet the criteria of 12:01:07 12 less than 15 letters lost if you did four monthly 2 mg 12:01:11 13 of Aflibercept followed by eight-week dosing of 2 12:01:16 14 milligrams through week 52? 12:01:21 15 MR. BRAUSA: Objection; form. 12:01:22 16 THE WITNESS: So if you use the probability as 12:01:22 17 more likely than not, then I think yes, that is 12:01:26 18 probably the case. 12:01:29 19 BY MR. NIMROD: 20 Q. Okay. So you would agree, then, it's -- a POSA 12:01:31 21 would conclude, based on the data from the CLEAR-IT 2 12:01:34 22 study shown in Exhibit 2047 for the 2Q4 arm, that it was 12:01:38 23 more likely than not that four monthly doses of 2 mg of 12:01:44 24 Aflibercept followed by eight-week dosing would meet the 12:01:50 25 15 letters lost criteria for a significant portion of 12:01:55 Page 128
1 Q. So I'm trying to -- I'll ask it again. 11:59:34 2 A. I understand. 3 Q. Because you know how you're saying encouraging, 11:59:35 4 we don't know that. So certainty, I'm not asking for, 11:59:37 5 and you understand that. 11:59:41 6 A. Okay. 11:59:41 7 Q. Okay. And my word is probable, which you gave 11:59:41 8 me. 11:59:43 9 A. I gave you. 11:59:44 10 Q. Okay. Would you agree that if a POSA saw the 2Q4 11:59:44 11 data from Exhibit 2047, deposition Exhibit 5, which has 11:59:49 12 four monthly doses followed by an average of 1.55 PRN 11:59:55 13 injections through week 52, that the POSA would conclude 12:00:01 14 is probable that four monthly doses of 2 milligrams of 12:00:07 15 Aflibercept followed by eight-week dosing through week 12:00:10 16 52 was probable to have a significant portion of the 12:00:13 17 patient population meet the less than 15 letters lost 12:00:16 18 criteria; is that right? 12:00:20 19 MR. BRAUSA: Objection; form. 12:00:20 20 THE WITNESS: So I think when you get into the 12:00:21 21 2Q8 phase, you have good reason to believe that 12:00:28 22 patients are not going to lose a lot of vision. But I 12:00:32 23 don't think you can project what the probability would 12:00:38 24 be. You just -- because you don't have the 12:00:39 25 comparator. That, you don't have. And the phase 2 12:00:42 Page 127	1 the patient population; is that right? 12:01:58 2 MR. BRAUSA: Objection; form. 12:02:00 3 THE WITNESS: Repeat the question, please. 12:02:01 4 BY MR. NIMROD: 12:02:03 5 Q. Okay. You would agree that a POSA would 12:02:05 6 conclude, based on the data from the CLEAR-IT 2 study 12:02:06 7 shown in Exhibit 2047 for the 2Q4 arm, that it was more 12:02:10 8 likely than not that four monthly doses of 2 milligrams 12:02:17 9 of Aflibercept followed by eight-week dosing at 2 12:02:21 10 milligrams would result in a significant portion of the 12:02:26 11 patient population meeting the five letters lost 12:02:28 12 criteria; is that right? 12:02:31 13 MR. BRAUSA: Objection; form. 12:02:32 14 THE WITNESS: I think the -- you have a couple 12:02:34 15 of what ifs in there. One is the more likely than not 12:02:37 16 and the other is significant. 12:02:44 17 BY MR. NIMROD: 12:02:45 18 Q. Well, we already talked about significant. 12:02:45 19 That's a third. That was your word. 12:02:47 20 A. Yeah. I would put those two together and say 12:02:52 21 yes. 12:02:54 22 Q. Okay. Would you agree that a POSA looking at the 12:02:59 23 data for the CLEAR-IT 2 study in Exhibit 2047 for the 12:03:01 24 2Q4 arm would conclude that it was more likely than not 12:03:05 25 that four monthly doses of 2 mg of Aflibercept followed 12:03:11 Page 129

1 by eight-week dosing of 2 mg of Aflibercept through week 12:03:16 2 52 would result in a significant portion of the patient 12:03:19 3 population meeting the criteria of zero or more letters 12:03:24 4 gained as shown in the middle column here? 12:03:29 5 MR. BRAUSA: Objection; form. 12:03:33 6 THE WITNESS: So under that regimen, now the 12:03:33 7 bar is higher. And now I can't say. 12:03:37 8 BY MR. NIMROD: 9 Q. Okay. So even -- what percent met the 2Q4, was 12:03:41 10 it 81 percent? You have the color copy. 12:03:45 11 A. Oh, I'm sorry. 2Q4 PRN is 81 percent. 12:03:47 12 Q. Okay. So you can't say whether or not your 12:03:51 13 expectation would be -- oh, by the way, so the 12:03:54 14 hypothetical I'm giving is that there's more injections 12:03:57 15 overall being given in the 52 weeks than the 2Q4 arm 12:04:00 16 gave, correct? 12:04:04 17 A. The hypothetical that you gave me of four 12:04:05 18 followed by Q8 would give more injections than was given 12:04:09 19 in the 2Q4 followed by PRN in the CLEAR-IT 2. 12:04:15 20 Q. Right. And so even though that would be the 12:04:18 21 case, you can't agree with me that a POSA would conclude 12:04:21 22 that it was more likely than not that the four monthly 12:04:24 23 doses of 2 mg of Aflibercept followed by eight-week 12:04:27 24 dosing of the 2 mg would result in a significant portion 12:04:34 25 of the patient population obtaining a letter gain of 12:04:37 Page 130	1 15-letter gain, what percentage of that patient 12:05:52 2 population that had the 2Q12 arm -- in the 2Q12 arm 12:05:55 3 achieved a greater than 15 letter gain? 12:06:03 4 A. So for those treated with 2Q12 and then, of 12:06:08 5 course, PRN, at 52 weeks, 29 percent of them had a 15 or 12:06:12 6 more letter gain. 12:06:16 7 Q. Okay. And what percentage of the 2Q4 patient 12:06:17 8 population achieved the greater than 15-letter gain for 12:06:21 9 the CLEAR-IT 2 study as shown in Exhibit 2047? 12:06:24 10 A. And again, the 2Q4 is four doses monthly followed 12:06:30 11 by PRN through week 52, there was 29 percent was zero 12:06:33 12 letter -- or 15 or more letters. 12:06:38 13 Q. So that means that both the 2Q4 and the 2Q12 arms 12:06:40 14 had 29 percent of the patients achieve a greater than 15 12:06:47 15 letter gain at week 52; is that right? 12:06:53 16 A. Under this regimen, yes. 12:06:55 17 Q. Okay. And on average, the persons in the 2Q12 12:07:02 18 regimen received 4.48 doses or injections and the 12:07:07 19 persons in the 2Q4 arm were given an average of 5.55; is 12:07:16 20 that right? 12:07:26 21 A. If you could remind me what page that's on, 12:07:26 22 please? 12:07:31 23 Q. That's on Exhibit 12 -- slide 12 in -- 12:07:31 24 A. Thank you. So repeat the question, please. 12:07:34 25 Q. I said on average, the persons in the 2Q12 12:07:40 Page 132
1 zero or more; is that right? 12:04:40 2 MR. BRAUSA: Objection; form. 12:04:44 3 THE WITNESS: That's correct. At this point I 12:04:45 4 can't because your bar is higher. 12:04:48 5 BY MR. NIMROD: 12:04:49 6 Q. Okay. And then let's look at the last set of 12:04:50 7 bars. It says greater than 15-letter gain -- 12:04:58 8 A. Um-hmm. 9 Q. -- on the right. What does that indicate? 12:05:00 10 A. Well, the proportion of patients in each of the 12:05:01 11 treatment arms that gained 15 or more letters at week 12:05:04 12 52. 12:05:08 13 Q. So then -- by the way, I don't know if I asked 12:05:08 14 you this. What was the result for zero or more letter 12:05:11 15 gains for the 2Q12 arm? 12:05:16 16 A. That was 71 percent. 12:05:18 17 Q. Okay. 12:05:20 18 A. Zero or more. 12:05:20 19 Q. So the 71 percent of the patients who were given 12:05:22 20 initial dose, a second dose at week 12 and then a mean 12:05:27 21 of 2.48 between -- after week 12 and before week 52, 12:05:32 22 71 percent of them did the zero or better letter gain, 12:05:42 23 right? 12:05:46 24 A. That's correct. 12:05:47 25 Q. Okay. And then if you look at the greater than 12:05:48 Page 131	1 regimen received 4.48 injections at 2 mg and the 12:07:47 2 person -- with the 52 weeks, and the persons in the 2Q4 12:07:56 3 arm were given an average of 5.55 injections over the 12:08:00 4 52 weeks. Is that right? 12:08:05 5 A. That's correct. 12:08:06 6 Q. And as -- again, if we do, instead, a POSA would 12:08:09 7 think of doing a 2 -- four monthly injections at 2 mg, 12:08:13 8 followed by eight-week dosing, how many milligrams would 12:08:18 9 that be -- I'm sorry, how many injections would that be? 12:08:20 10 You said it was at ten? 12:08:22 11 A. We said -- 12:08:23 12 Q. Or nine? 12:08:24 13 A. -- eight total. 12:08:26 14 Q. So it would be four, because it's monthly? 12:08:27 15 A. Right. 12:08:30 16 Q. And then it would be four more, eight? 12:08:31 17 A. Eight. 12:08:32 18 Q. Okay. Got it. All right. So with that in mind, 12:08:32 19 would you agree that a POSA looking at the data in 12:08:35 20 Exhibit 2047, which is our depo Exhibit 5, would 12:08:39 21 conclude that it was likely that about 29 percent or 12:08:42 22 more of patients that were to be given a -- four monthly 12:08:49 23 doses of 2 mg of Aflibercept followed by eight-week 12:08:55 24 dosing through week 52 would get a 15-letter or more 12:08:58 25 gain at the end -- at the 52-week mark? 12:09:03 Page 133

1 MR. BRAUSA: Objection; form. 12:09:08 2 THE WITNESS: Again, the time of the injections 12:09:08 3 may well matter. And in what we see in CLEAR-IT 2 was 12:09:11 4 these were given when they were needed. When they're 12:09:17 5 given 2Q8, we don't know if they're given when they're 12:09:20 6 needed. And when we look at our only other major 12:09:23 7 comparators, for example, the PIER trial, when 12:09:28 8 extended dosing resulted in vision loss. So the POSA 12:09:31 9 doesn't have the data to say that this is likely to 12:09:35 10 give you that 29 percent. 12:09:38 11 BY MR. NIMROD: 12 Q. Okay. But don't we have that data? I thought 12:09:40 13 that the reason that eight weeks was chosen is because 12:09:42 14 the data showed that when you give an injection of 2 mg, 12:09:46 15 it maintains the gain for eight weeks. 12:09:50 16 A. Only at one -- only one data point. 12:09:52 17 Q. Well, that was the data point that justified the 12:09:54 18 two -- the four monthly injections followed by 12:09:57 19 eight-week dosing, right? 12:09:59 20 A. Right. 12:10:00 21 MR. BRAUSA: Objection; form. 12:10:01 22 THE WITNESS: So what they said was it 12:10:06 23 justifies further examination. And I don't remember 12:10:08 24 the words. 12:10:09 25 BY MR. NIMROD: 12:10:10 Page 134	1 said, three different treatment cohorts, compared to 12:11:26 2 Ranibizumab. 12:11:30 3 BY MR. NIMROD: 4 Q. Right. 12:11:30 5 A. And the FDA was not going to be making a decision 12:11:30 6 simply based on one cohort -- 12:11:34 7 Q. No, I mean, the decision -- 8 A. -- like the 2Q8. 12:11:36 9 Q. -- to proceed with a phase 3 study. 12:11:36 10 A. Yes. 12:11:41 11 Q. The phase 3 study was embarked on based on the 12:11:42 12 data from the phase 2 study which had 31 patients per 12:11:46 13 cohort, right? 12:11:51 14 MR. BRAUSA: Objection; form. 12:11:51 15 THE WITNESS: That was the -- that was -- the 12:11:51 16 primary number of patients was from phase 2. So yes, 12:11:52 17 31 per cohort. 12:11:56 18 BY MR. NIMROD: 19 Q. And Regeneron's rationale for going to four 12:11:57 20 monthly doses followed by eight-week dosing was based on 12:12:03 21 a cohort of 31 patients in phase 2, correct? 12:12:08 22 MR. BRAUSA: Objection; form. 12:12:11 23 THE WITNESS: So Regeneron didn't do that. 12:12:12 24 That was not the structure of the phase 3. 12:12:16 25 BY MR. NIMROD: Page 136
1 Q. Said the rationale. 12:10:11 2 A. The rationale. 12:10:11 3 Q. Right. 12:10:13 4 A. So the rationale to go into phase 3, but that's 12:10:14 5 not the same as saying that we think there's going to be 12:10:17 6 a 29 percent of patients getting 15 letters or greater. 12:10:20 7 That's a different -- that's a different stand. 12:10:24 8 Q. No, I guess what my point was -- is that if you 12:10:25 9 had data that showed that when you give an injection at 12:10:29 10 2 mg, it maintains the gain for eight weeks, then you 12:10:32 11 would certainly expect that giving the monthly doses up 12:10:36 12 to week 12 followed by eight-week dosing is going to 12:10:40 13 maintain the gain that you've had, right? 12:10:44 14 MR. BRAUSA: Objection; form. 12:10:47 15 THE WITNESS: So that was in, I believe, 31 12:10:47 16 patients. And I don't think you can draw an 12:10:51 17 expectation from 31 patients. You can say that this 12:10:54 18 is a reasonable set of data based on a very small 12:10:58 19 cohort that is worth examining in a phase 3. But 31 12:11:01 20 patients does not provide an expectation for you. 12:11:06 21 BY MR. NIMROD: 12:11:09 22 Q. Even though the FDA and Regeneron based their 12:11:09 23 phase 3 studies on the 31 patients; is that right? 12:11:14 24 MR. BRAUSA: Objection; form. 12:11:18 25 THE WITNESS: So the phase 3 included, as I 12:11:19 Page 135	1 Q. Well, I guess I must have misspoke because I'm 12:12:19 2 referring to the statement in Exhibit 3 that says that 12:12:22 3 the rationale for the 2-milligram Q8-week dose, that, 12:12:26 4 again, is that's four monthly injections followed by 12:12:33 5 eight-week dosing, right? 12:12:36 6 A. No. 12:12:37 7 Q. What is that, then? 12:12:38 8 A. Phase 3 was three monthly doses -- 12:12:39 9 Q. Okay. 10 A. -- followed by Q8. 12:12:42 11 Q. Okay. I apologize. Okay. So the rationale for 12:12:43 12 having three monthly doses followed by eight-week dosing 12:12:46 13 was based on the fixed dosing phase of the CLEAR-IT 2 12:12:51 14 and it says at eight weeks, the improvement in the BCVA 12:12:57 15 after a single 2-milligram dose was similar to that 12:13:01 16 obtained with 2-milligram dose monthly to eight weeks. 12:13:05 17 Do you see that? Or do you understand that? 12:13:08 18 Yeah. 12:13:10 19 A. Yes. 12:13:10 20 Q. Those cohorts that are being referred to there 12:13:11 21 are about 31 patients each, correct? 12:13:13 22 A. That's correct. 12:13:15 23 Q. And so Regeneron drew conclusions on what they 12:13:16 24 thought would be an appropriate phase 3 arm based on 12:13:19 25 cohorts of 31 patients, right? 12:13:23 Page 137

1 MR. BRAUSA: Objection; form. 12:13:24 2 THE WITNESS: Unless there was other data that 12:13:24 3 I'm not aware of, that's correct. 12:13:27 4 BY MR. NIMROD: 12:13:28 5 Q. Well, they say right here, this is what it was 12:13:29 6 based on? 12:13:31 7 A. Right. That's what I'm saying. I believe that's 12:13:31 8 correct. 12:13:33 9 Q. Okay. But again, just to be clear, would you 12:13:33 10 agree with me that at least one patient, you'd -- let me 12:13:45 11 start over again. 12:13:49 12 Based on the data in Exhibit 2047, which is from 12:13:50 13 the CLEAR-IT 2 study, including the data on slides 12, 12:13:55 14 17 and 19, that you would expect that if you had a 12:14:01 15 cohort of patients being given four initial monthly 12:14:06 16 doses followed by eight-week dosing, that at least one 12:14:11 17 patient in a cohort would get a greater than 15-letter 12:14:15 18 gain? 12:14:19 19 MR. BRAUSA: Objection; form. 12:14:20 20 BY MR. NIMROD: 12:14:22 21 Q. That would be the expectation or I would say more 12:14:22 22 likely than not? 12:14:25 23 A. You're projecting out too far. We've not had 12:14:25 24 extended dosing that prior to this time had ever been 12:14:28 25 shown to work. And so I don't think you can make that 12:14:32 Page 138	1 MR. NIMROD: All right. All right. I'm going 12:16:44 2 to mark as Exhibit 7 a copy of IPR Exhibit 1052. 12:16:45 3 (Exhibit No. 7 was marked for identification.) 12:16:50 4 BY MR. NIMROD: 12:16:52 5 Q. Do you recognize this article as a publication 12:17:25 6 related to the Ranibizumab ANCHOR study? 12:17:28 7 A. This is the Marina study. 12:17:32 8 Q. Oh, Marina. Okay. 12:17:34 9 All right. What's the difference between the 12:17:36 10 Marina and the ANCHOR study for Ranibizumab? 12:17:43 11 MR. BRAUSA: Objection; form. 12:17:48 12 THE WITNESS: So both the Marina and ANCHOR 12:17:48 13 were studies of neovascular age-related macular 12:17:53 14 degeneration treated with Ranibizumab. The difference 12:18:02 15 was in the Marina study, the lesions were 12:18:05 16 characterized by fluorescein angiography. They're 12:18:09 17 characterized as what we call occult. 12:18:14 18 In the ANCHOR study, they were characterized as 12:18:18 19 classic. And so in the ANCHOR, photodynamic therapy 12:18:21 20 was the comparator. In Marina, observation was -- or 12:18:26 21 sham injections were the comparator. 12:18:30 22 BY MR. NIMROD: 12:18:32 23 Q. Which one came first? 12:18:33 24 A. They came at the same time. 12:18:34 25 Q. Okay. All right. In the 2009 time frame, was it 12:18:36 Page 140
1 conclusion. 12:14:35 2 Q. Okay. So you have a cohort of patients that are 12:14:35 3 all getting eight doses over 52 weeks. 12:14:37 4 A. Yes. 12:14:40 5 Q. And you're saying that you couldn't even conclude 12:14:41 6 from this data that it's more likely than not that one 12:14:43 7 patient in a cohort of let's say 30 would get at least a 12:14:45 8 15-letter gain? 12:14:48 9 A. I can't conclude that. 12:14:48 10 Q. Okay. Would you agree that -- oh, no, we already 12:14:51 11 went over that. Never mind. That's good. Let me go 12:15:25 12 back here. 13 Could you look at claim 1 of the 572 in 12:15:39 14 Exhibit 1, please. 12:15:44 15 A. I'm sorry, claim 1? 12:15:48 16 Q. Yes. 12:15:50 17 A. Okay. 12:15:50 18 Q. Okay. Do you have an opinion as to whether or 12:15:55 19 not claim 1 requires an intent to treat the recited 12:15:59 20 diseases -- disease, in claim 1? If you have an opinion 12:16:08 21 one way or another is all I'm asking. 12:16:13 22 A. It's a method of treatment. So I think once you 12:16:16 23 start down that road, you're intending to treat the 12:16:20 24 patient. 12:16:23 25 Q. Okay. Page 139	1 believed that Aflibercept was superior to Ranibizumab in 12:18:45 2 terms of its efficaciousness, the binding affinity and, 12:18:53 3 also, half-life? 12:18:56 4 MR. BRAUSA: Objection; form. 12:18:58 5 THE WITNESS: So we had data to show it had a 12:18:58 6 stronger binding affinity. We also had some data to 12:19:03 7 show longer half-life. But when you say efficacious, 12:19:06 8 then you're talking about clinical efficacy. And we 12:19:10 9 did not have data on that. 12:19:12 10 BY MR. NIMROD: 11 Q. Okay. All right. Okay. Could you look to the 12:19:16 12 first page, the results section for Exhibit 7. 12:19:23 13 A. Is that page 1421? 12:19:28 14 Q. 1419. The first page. 12:19:30 15 A. Oh, there. 12:19:34 16 Q. Cover page. 12:19:34 17 A. Sorry. 12:19:37 18 Q. It's in the summary, the abstract. 12:19:40 19 A. Yes. 12:19:42 20 Q. Okay. All right. In the results, there's not -- 12:19:42 21 they mention there's 716 patients and that they are 12:19:46 22 looking at 12 months; is that right? 12:19:50 23 A. Correct. 12:19:53 24 Q. All right. And then the fourth line down, it 12:19:55 25 says: Visual acuity improved by 15 or more letters in 12:19:57 Page 141

1 24.8 percent of the .3-milligram group and 33.8 percent 12:20:03	1 me. That I didn't have a copy of before. 12:23:07
2 of the 0.5-milligram group as compared with 5 percent of 12:20:07	2 (Exhibit No. 8 was marked for identification.) 12:23:09
3 the sham injection group. 12:20:14	3 THE WITNESS: Okay. 12:23:10
4 Do you see that? 12:20:15	4 BY MR. NIMROD: 12:23:10
5 A. Yes. 12:20:16	5 Q. So just to have it in the record. 12:23:11
6 Q. Now, when it says 5 percent of the sham 12:20:17	6 A. Okay. 12:23:12
7 injection, what does that mean? 12:20:20	7 MR. BRAUSA: Just as an FYI, Ray, I'm told 12:23:14
8 A. In the Marina study, the sham injection were 12:20:21	8 lunch is here. 12:23:17
9 patients who had a fake injection, no active treatment. 12:20:27	9 MR. NIMROD: Okay.
10 Q. Okay. And 5 percent of those patients 12:20:40	10 MR. BRAUSA: There's no hurry, but just -- 09:57:23
11 nevertheless achieved a gain of 15 letters or more? 12:20:35	11 MR. NIMROD: We'll take a break soon. 12:23:19
12 A. That's correct. 12:20:40	12 I don't have a stapler. I guess I could have 12:23:21
13 Q. Okay. And from that data, can you conclude, 12:20:43	13 asked the front desk. 12:23:23
14 then, that it would be more likely than not that if you 12:20:46	14 BY MR. NIMROD:
15 gave a patient three or four monthly doses of 2 mg of 12:20:49	15 Q. All right. Okay. Exhibit 8 is an article by 12:23:27
16 Aflibercept followed by eight-week dosing, that you 12:20:54	16 Dr. Stewart and Dr. Rosenfeld, I assume, doctor? 12:23:34
17 would get some portion of the patients, whether it's 12:20:57	17 A. Correct. 12:23:38
18 one, two, three, or four, that would get a gain of 12:21:00	18 Q. That is entitled Predicted biological activity of 12:23:39
19 15-plus letters given that sham injection can give you 12:21:07	19 intravitreal VEGF-Trap, and it looks like it was 12:23:46
20 that result? 12:21:11	20 published in 2007. Is that right? Oh, no. 2008. 12:23:49
21 MR. BRAUSA: Objection; form. 12:21:12	21 Excuse me. 12:23:52
22 THE WITNESS: So I've seen patients who lose 12:21:13	22 A. 2008, yes. 12:23:52
23 significant vision immediately after treatment with 12:21:20	23 Q. And is this the article that we referred to 12:23:54
24 all of our drugs, including Aflibercept, and so though 12:21:23	24 earlier in connection with Exhibit 3, the Heier article 12:23:58
25 I think there's a good chance that somebody would gain 12:21:29	25 that was cited as reference 30? 12:24:03
Page 142	Page 144
1 15 letters, the sham, though, is not the same as an 12:21:32	1 A. Yes. That's the one. 12:24:05
2 active treatment. They're different. And until you 12:21:35	2 Q. Okay. If you wanted to break for lunch, we can 12:24:07
3 prove the active treatment as on a regimen that you've 12:21:39	3 do that now. I was just going to run through some stuff 12:24:16
4 never tried, is going to give you those results you 12:21:43	4 in here. I'm fine either way. If you're hungry. 12:24:18
5 can't predict. 12:21:47	5 MR. BRAUSA: What would you prefer? 12:24:25
6 BY MR. NIMROD:	6 THE WITNESS: 12:24. If we're going to do it, 12:24:26
7 Q. So the sham is not giving any treating active 12:21:52	7 this would probably be a good time. 12:24:36
8 drug, right? 12:21:57	8 MR. NIMROD: Okay. That's fine. 12:24:37
9 A. That's correct. 12:21:57	9 THE VIDEOGRAPHER: We're going off the record 12:24:37
10 Q. Okay. So my question, I guess, was, if no active 12:21:59	10 at 12:24. 12:24:38
11 drug results in the gain of 15-plus letters for the sham 12:22:03	11 (Luncheon recess was taken.) 12:24:41
12 injections, then wouldn't you expect that it's more 12:22:13	12 THE VIDEOGRAPHER: We are back on the record at 12:57:02
13 likely than not that at least one patient in an arm that 12:22:16	13 12:57. 12:57:33
14 had the dosing I mentioned, which is, you know, four 12:22:19	14 BY MR. NIMROD: 12:57:36
15 monthly doses of 2 mg of Aflibercept followed by 12:22:22	15 Q. Okay. We were looking at your article, which is 12:57:36
16 eight-week dosing that at least one patient would get 12:22:27	16 Exhibit 8. 12:57:38
17 the gain of a 15-plus letters that it would be more 12:22:30	17 A. Um-hmm. 12:57:39
18 likely than not that that would happen? 12:22:34	18 Q. And the aim of the article was to compare the 12:57:39
19 MR. BRAUSA: Objection; form. 12:22:34	19 intravitreal binding activity of VEGF-Trap with that of 12:57:44
20 THE WITNESS: I think it would be more likely 12:22:35	20 Ranibizumab against vascular endothelial growth factor 12:57:51
21 than not that that would happen to at least one 12:22:39	21 using a time-dependent dose-dependent mathematical 12:57:56
22 patient. 12:22:40	22 model. 12:57:59
23 MR. NIMROD: Okay. All right. Okay. Let me 12:22:53	23 Can you explain what you were doing in this 12:57:59
24 go to -- I'm going to mark as Exhibit 8 a copy of your 12:22:53	24 study? 12:58:02
25 article that we referred to later -- earlier. Excuse 12:23:04	25 A. So this was, as you said, a mathematical model 12:58:02
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1 based on any inputs to the mathematical modeling were 12:58:10 2 intravitreal half-lives and binding affinity and the 12:58:17 3 comparator to -- was to Ranibizumab, which clinically 12:58:20 4 was about 30 days durability. And so we would then make 12:58:24 5 comparisons of different doses of the VEGF-Trap with 12:58:31 6 Ranibizumab and see how long it would effectively bind 12:58:34 7 VEGF at the same level as Ranibizumab did. 12:58:39 8 Q. Where did you get the data that showed that 12:58:44 9 Ranibizumab was good for 30 days? 12:58:47 10 A. So we took that -- we took that from the 12:58:50 11 literature saying it's monthly dosed. 12:58:54 12 Q. Okay. 13 A. And use that as a comparator. 12:58:58 14 Q. Okay. And then how did you get the data for the 12:59:00 15 Aflibercept for your model? 12:59:03 16 A. Various places in the literature. People who 12:59:04 17 have done studies on intravitreal half-lives, binding 12:59:07 18 affinity various papers. 12:59:12 19 Q. Okay. So papers that were -- you got the data 12:59:14 20 for Aflibercept based on papers that came before your 12:59:17 21 article in 2008 regarding the binding affinity for 12:59:19 22 Aflibercept? 12:59:25 23 A. Binding affinity. 12:59:25 24 Q. Anything else? 12:59:27 25 A. Intravitreal half-life. 12:59:27 Page 146	1 Is that a reference to efficacy? 13:00:38 2 A. So we entitled this biological activity, binding 13:00:40 3 capacity would have been a better title. 13:00:46 4 Q. Okay. But did you mean by predicted biological 13:00:47 5 activity? 13:00:52 6 A. So it really meant predicted binding of VEGF over 13:00:52 7 time and until we got to a point where it was comparable 13:00:56 8 to Ranibizumab in 30 days. 13:01:02 9 Q. Okay. Okay. And -- but based on your modeling 13:01:04 10 of the predicted biological activity, then you drew 13:01:07 11 conclusions regarding the dosing possibilities for 13:01:12 12 Aflibercept as compared to Ranibizumab, right? 13:01:19 13 MR. BRAUSA: Objection; form. 13:01:21 14 THE WITNESS: We used doses that were being 13:01:24 15 looked at for Aflibercept and those were inputs. 13:01:25 16 BY MR. NIMROD: 13:01:28 17 Q. But you drew conclusions based on your 13:01:29 18 mathematical modeling relating to binding affinity and 13:01:30 19 half-life, you drew conclusions based on -- using that 13:01:35 20 data to predict the efficacy in terms of dosing 13:01:38 21 regimens, right? 13:01:45 22 MR. BRAUSA: Objection; form. 13:01:46 23 THE WITNESS: Well, we really didn't -- we 13:01:46 24 really didn't predict efficacy. We predicted binding 13:01:49 25 over time and when -- when would we get to the point 13:01:54 Page 148
1 Q. Okay. 2 A. And then we had comparable numbers for 12:59:29 3 Ranibizumab. 12:59:33 4 Q. Okay. And so your study was based on the data 12:59:34 5 for intravitreal half-life and binding affinity and not, 12:59:37 6 for example, efficacy? 12:59:42 7 A. Correct. 12:59:43 8 Q. Okay. Got it. And what was the reason for 12:59:46 9 studying the intravitreal half-life and binding 12:59:48 10 affinity? 12:59:52 11 A. Do you mean the reason for the model or the 12:59:54 12 reason for those things? 12:59:59 13 Q. Well, why did you do the study based on 13:00:01 14 intravitreal half-life and binding affinity, as opposed 13:00:04 15 to some other data? 13:00:05 16 A. Because my belief at the time was those would be 13:00:07 17 the strongest predictors or determinants of binding -- 13:00:10 18 of binding capacity inside the eye and biological 13:00:16 19 activity, those would be the strongest determinants of 13:00:19 20 that. 13:00:22 21 Q. When you say binding capacity inside the eye, 13:00:22 22 what do you mean? 13:00:26 23 A. Is the ability to bind VEGF in total over time. 13:00:26 24 Q. Okay. And you also said an indicator or 13:00:33 25 determinant of biological activity. 13:00:36 Page 147	1 where the binding, total binding capacity of 13:01:59 2 Aflibercept at its various doses would equal that of 13:02:05 3 Ranibizumab at 30 days. 13:02:07 4 BY MR. NIMROD: 13:02:09 5 Q. Okay. And then -- but that mathematical model 13:02:09 6 based on half-life and binding affinity or binding time 13:02:13 7 would give you a theoretical -- a greater theoretical 13:02:18 8 duration of biological activity in the eye, right? 13:02:25 9 A. That's correct. 13:02:27 10 Q. Okay. All right. So then if we go to the second 13:02:28 11 page under discussion. 13:02:32 12 A. Um-hmm. 13 Q. It states in the top: At ten weeks after 13:02:33 14 injection, the intraocular biological activity of 13:02:42 15 VEGF-Trap is theoretically comparable to the activity of 13:02:46 16 Ranibizumab at 30 days. 13:02:49 17 Do you see that? 13:02:50 18 A. Yes. 13:02:50 19 Q. And biological activity would be the activity in 13:02:50 20 the eye, the theoretical prediction, right? 13:02:53 21 A. It's the theoretical prediction of the binding at 13:02:57 22 that time. 13:03:00 23 Q. Well, it says biological activity. 13:03:01 24 A. Well, yeah. Again, I think that was an imprecise 13:03:02 25 use of words. It's really binding capacity. It's the 13:03:05 Page 149

1 ability to bind to VEGF over time. It's not the same as 13:03:08 2 clinical efficacy. That's totally different. 13:03:14 3 Q. Well, not totally different completely because 13:03:15 4 you drew conclusions about the possibility of less 13:03:17 5 frequent dosing based on your numbers, right? 13:03:20 6 A. And that's what we said, is that perhaps this can 13:03:21 7 lead to less frequent dosing. 13:03:25 8 Q. Okay. Your paper supported the idea that based 13:03:28 9 on your mathematical modeling for bonding affinity and 10 half-life, that less frequent dosing with Aflibercept 13:03:33 11 was a possibility as compared to Ranibizumab, right? 13:03:35 12 A. Correct. 13:03:38 13 Q. Okay. All right. So you say in the discussion 13:03:43 14 section, second sentence: This prolonged biological 13:03:47 15 activity could be explained by the higher VEGF binding 13:03:50 16 affinity of VEGF-Trap and its presumed longer 13:03:54 17 intravitreal half-life when compared with Ranibizumab, 13:03:58 18 right? 13:04:00 19 A. Correct. 13:04:01 20 Q. And you say: If this theoretical model is 13:04:01 21 correct, then the advantages of Aflibercept will include 13:04:04 22 less frequent drug administration resulting in fewer 13:04:08 23 physician appointments and ancillary tests, lower 13:04:11 24 overall costs, less cumulative risks from intravitreal 13:04:15 25 injections and the potential for improved patient 13:04:18 Page 150	1 think it is data that's worth exploring and it's worth 13:05:31 2 exploring in some sort of extended manner. 13:05:36 3 BY MR. NIMROD: 13:05:37 4 Q. Right. I didn't say there would be one. I said 13:05:38 5 would you agree -- I probably spoke too fast. 13:05:41 6 A. Okay. 13:05:43 7 Q. Let me start over, okay? 13:05:44 8 A. Okay. 13:05:45 9 Q. Would you agree with me that this data in your 13:05:46 10 conclusions -- and your conclusions -- excuse me -- 13:05:49 11 reported to the public in 2008 would at least be a data 13:05:52 12 point that a POSA could consider when deciding whether 13:05:55 13 or not there was a reasonable expectation of success of 13:05:59 14 using longer dosing intervals; that is, longer than 13:06:01 15 30 days for Aflibercept? 13:06:05 16 MR. BRAUSA: Objection; form. 13:06:07 17 THE WITNESS: So again, it's a stepping off 13:06:07 18 point for looking at extended dosing. But to 13:06:13 19 extrapolate from that and suggest that there is better 13:06:15 20 efficacy or longer durability, that requires clinical 13:06:19 21 studies and I don't think we can extrapolate 13:06:25 22 completely. It's a good starting point but it's not 13:06:27 23 something that one can rely on. 13:06:30 24 BY MR. NIMROD: 25 Q. Not even as a data point for considering the idea 13:06:32 Page 152
1 compliance. 13:04:21 2 Do you see that? 13:04:21 3 A. I do. 13:04:21 4 Q. Would you agree with me that a skilled artisan 13:04:22 5 reading this paper would have a strong motivation to use 13:04:27 6 Aflibercept with dosing regimens that exceeded four 13:04:34 7 weeks? 13:04:37 8 MR. BRAUSA: Objection; form. 13:04:41 9 THE WITNESS: So I think a POSA reading this 13:04:42 10 would take from this the message that Aflibercept 13:04:46 11 might be effective at a longer interval than 13:04:50 12 Ranibizumab. 13:04:54 13 BY MR. NIMROD: 14 Q. Okay. And Ranibizumab, to be clear, that was 13:04:55 15 every 30 days or once a month? 13:04:59 16 A. That was the standard. 13:05:00 17 Q. Okay. And so would you also agree with me that 13:05:01 18 this data in your conclusions reported to the public in 13:05:03 19 2008 would at least be a data point that a POSA could 13:05:08 20 consider when deciding whether or not there was a 13:05:13 21 reasonable expectation of success at using longer dosing 13:05:16 22 intervals, longer than 30 days for Aflibercept? 13:05:20 23 MR. BRAUSA: Objection; form. 13:05:23 24 THE WITNESS: So I don't think there's a 13:05:24 25 reasonable expectation of success in here. But I do 13:05:29 Page 151	1 of like I haven't exercised, to determine whether it's 13:06:34 2 an expectation of success, your article wouldn't even be 13:06:38 3 a data point to consider when going through that 13:06:41 4 exercise? 13:06:44 5 MR. BRAUSA: Objection; form. 13:06:45 6 THE WITNESS: One can consider this and say, 13:06:48 7 maybe this has a longer duration of action and maybe 13:06:49 8 we should try extended durability. 13:06:52 9 MR. NIMROD: All right. Let me mark as -- I 13:06:56 10 believe it's Exhibit 9 a copy of an article that is 13:06:58 11 Exhibit 1049 in the IPR proceeding. 13:07:11 12 (Exhibit No. 9 was marked for identification.) 13:07:14 13 THE WITNESS: Thank you. 13:07:15 14 BY MR. NIMROD: 15 Q. Do you -- I'll wait until you're cleaned up 13:07:39 16 there. 13:07:41 17 A. Okay. Great. Thank you. 13:07:41 18 Q. All right. You're with me? 13:07:42 19 A. Yes. 13:07:43 20 Q. Okay. Exhibit 9 is an article entitled: 13:07:44 21 Ranibizumab versus Verteporfin Photodynamic Therapy for 13:07:51 22 Neovascular Age-Related Macular Degeneration: Two-year 13:08:00 23 results of the ANCHOR study, close quote. 13:08:01 24 Do you see that? 13:08:02 25 A. Yes. 13:08:05 Page 153

1 Q. And you are familiar with this article? 13:08:05 2 A. Yes. 13:08:07 3 Q. Okay. The ANCHOR study was on Ranibizumab, 13:08:08 4 right? 13:08:15 5 A. That's correct. 13:08:15 6 Q. Okay. Here we go here. If we look in the -- on 13:08:26 7 the first page, the summary of the results, I guess this 13:08:28 8 would be, it refers to the idea that there was 423 13:08:33 9 patients; is that correct? 13:08:35 10 A. In total, yes. 13:08:37 11 Q. And there was 140 in each of the two Ranibizumab 13:08:38 12 arms; is that right? 13:08:42 13 A. Correct. 13:08:42 14 Q. Okay. It says the majority, that is greater than 13:08:43 15 77 percent in each Ranibizumab arm was statistically -- 13:08:48 16 sorry -- completed the two-year study. 13:08:52 17 You see that? 13:08:56 18 A. Yes. 13:08:57 19 Q. Okay. Is that pretty common that not all or in 13:08:57 20 this case, three-quarters of the persons who started 13:09:01 21 completed the study or is that usual in some way, it's 13:09:04 22 not -- 13:09:08 23 A. No. 13:09:09 24 MR. BRAUSA: Objection; form. 13:09:09 25 THE WITNESS: There's always a dropoff over 13:09:10 Page 154	1 know from what we've read so far but that hasn't been 13:10:41 2 defined yet -- 13:10:44 3 Q. Okay. 4 A. -- in the article. 13:10:44 5 Q. Okay. Got it. 13:10:45 6 All right. So if we go on, it says: And 13:10:47 7 clinically -- 13:10:51 8 PDT, is that a laser treatment? What is PDT? 13:10:51 9 A. PDT is a combination of an intravenous dye 13:10:54 10 infusion, followed by a very low intensity laser. 13:10:58 11 Q. Okay. All right. The sentence goes on and says: 13:11:01 12 And clinically meaningful: 89.9 to 90.0 percent of the 13:11:05 13 Ranibizumab patients had lost less than 15 letters from 13:11:12 14 baseline, versus 65.7 percent of PDT patients. 13:11:15 15 See that? 13:11:20 16 A. Yes. 13:11:20 17 Q. Okay. And then 34 to 41 percent had gained 13:11:21 18 greater than 15 letters -- 15 or -- 15 or more letters, 13:11:28 19 versus 6.3 for PDT. 13:11:31 20 See that? 13:11:34 21 A. Yes. 13:11:34 22 Q. And on average, the VA -- I guess that's visual 13:11:35 23 acuity? 13:11:39 24 A. Yes. 13:11:39 25 Q. -- was improved from a baseline -- from the 13:11:40 Page 156
1 time. 13:09:12 2 BY MR. NIMROD: 3 Q. Okay. 4 A. And that number dropoff increases with time. 13:09:13 5 Q. Okay. All right. It says: Consistent with the 13:09:17 6 result at month 12, at month 24, the VA benefit from 13:09:20 7 Ranibizumab was statistically significant. And then it 13:09:26 8 says: (P less than 0.0001 versus PTD). 13:09:30 9 What is the reference to (P less than that amount 13:09:39 10 versus PDT)? 13:09:43 11 A. It -- I believe it's the data that follows. 13:09:47 12 Q. Is P -- 13:09:54 13 A. So P is the probability. The probability of the 13:09:55 14 arms receiving Ranibizumab, versus the arm with -- that 13:09:58 15 was treated with PDT. And then what the intravitreal 13:10:06 16 acuity benefit is, we don't know yet because that's to 17 follow. 13:10:17 18 (Reporter request for clarification.) 13:10:17 19 THE WITNESS: I'm sorry. Where were you? 13:10:17 20 THE COURT REPORTER: The last sentence. 13:10:24 21 BY MR. NIMROD: 13:10:26 22 Q. Something about what the benefit was but you 13:10:26 23 don't know. I think you said something like that but I 13:10:27 24 can't -- I'm not quoting you, of course. 13:10:29 25 A. No, it's that the visual acuity benefit, we don't 13:10:31 Page 155	1 baseline by 8.1 to 10.7 letters, versus a mean decline 13:11:43 2 of 9.8 letters in the PDT group. 13:11:51 3 You see that? 13:11:55 4 A. Yes. 13:11:55 5 Q. So if we consider the number of patients that had 13:11:56 6 a gain of 15 letters or more using Ranibizumab -- strike 13:12:06 7 that. 13:12:10 8 These are monthly injections of Ranibizumab at 13:12:10 9 either .3 or .5 milligrams; is that right? 13:12:14 10 A. That's correct. 13:12:17 11 Q. Okay. And so that means that 34 to 41 percent of 13:12:18 12 the Ranibizumab patients who receive monthly injections 13:12:23 13 had a gain of 15 or more letters, right? 13:12:28 14 A. That's correct. 13:12:30 15 Q. Okay. And that's at month 24? 13:12:32 16 MR. BRAUSA: Objection; form. 13:12:37 17 THE WITNESS: I can't tell from this. I think 13:12:37 18 that's month 24. 13:12:48 19 BY MR. NIMROD: 20 Q. Okay. 21 A. Can't be sure the way it's written. 13:12:50 22 Q. Why don't we go to the end of the table -- 13:12:52 23 A. Oh, I'm sorry, I take it back. I take it back. 13:12:55 24 It is month 24. 13:12:57 25 Q. Okay. 13:12:59 Page 157

1 A. Yes. 13:12:59 2 Q. So if a POSA were looking at this data and seeing 13:13:00 3 that Ranibizumab monthly at .3 or .5, either one, 13:13:03 4 milligrams, for 24 months resulted in 34 to 41 percent 13:13:12 5 of the patients having a gain of 15-plus letters, would 13:13:19 6 that POSA then believe it was reasonably likely, that 13:13:22 7 is, more probable than not that if the POSA dosed 13:13:28 8 Aflibercept at 2 milligrams for three monthly injections 13:13:33 9 followed by eight-week injections through 52 weeks, that 13:13:37 10 a significant portion of the patients would gain at 13:13:44 11 least 15 letters? 13:13:47 12 MR. BRAUSA: Objection; form. 13:13:50 13 THE WITNESS: The treatment groups here are 13:13:51 14 completely different or at least significantly 13:13:57 15 different. The treatment groups here in ANCHOR are 13:13:59 16 what are called classic neovascularization, whereas 13:14:02 17 once we got to Aflibercept trials, it was all versions 13:14:10 18 of macular degeneration. And so you're treating a 13:14:12 19 little bit apples and oranges when you're trying to 13:14:14 20 compare, and therefore, it's harder to compare the 13:14:16 21 results directly. 13:14:19 22 BY MR. NIMROD: 23 Q. Okay. Well, maybe it's hard -- my question is, 13:14:22 24 given the fact that 34 to 41 percent of the arms in this 13:14:26 25 Ranibizumab study at .3 and .5 milligrams monthly had 13:14:32 Page 158	1 determination. 13:16:03 2 Q. Okay. But we do have the, by 2008, we have both 13:16:05 3 your predicted biological activity showing that you 13:16:11 4 expected or predicted, I should say, biological activity 13:16:16 5 of perhaps up to ten weeks for Aflibercept and we also 13:16:19 6 have the CLEAR-IT 2 results that show that a dosing of 2 13:16:22 7 milligrams lasted -- its effect lasted for eight weeks. 13:16:29 8 So with that in mind, looking at what happens for 13:16:32 9 Ranibizumab -- 13:16:36 10 A. Ranibizumab. 13:16:37 11 Q. -- Ranibizumab, wouldn't a POSA be able to 13:16:38 12 conclude that, you know, given the superiority in the 13:16:42 13 binding, as you've shown, and the superiority in the 13:16:45 14 half-life, that you would expect that at least a 13:16:48 15 significant portion of the patient population getting 13:16:50 16 three monthly doses of Aflibercept followed by 13:16:55 17 eight-week interval dosing through 52 weeks would get a 13:16:57 18 15-plus letter gain? 13:17:02 19 MR. BRAUSA: Objection; form. 13:17:04 20 THE WITNESS: That's why we do the phase 3 13:17:04 21 trials, is to try to determine that. And until you 13:17:07 22 have the phase 3 trials, you don't have a reasonable 13:17:11 23 expectation. You have data that supports doing the 13:17:12 24 trials. We have plenty of other drugs that have gone 13:17:16 25 through phase 2 and looked really good and they got to 13:17:21 Page 160
1 that 15-plus letter gain, would a POSA conclude that it 13:14:38 2 was more likely than not that a significant portion of 13:14:42 3 patients to be treated with 2 milligrams of Aflibercept 13:14:45 4 for three months followed by eight-week intervals of 13:14:48 5 treatment of 2 milligrams would result in a 15-plus 13:14:52 6 letter gain for that significant portion at 52 weeks? 13:14:57 7 MR. BRAUSA: Objection; form. 13:15:01 8 THE WITNESS: So these are excellent results. 13:15:04 9 But we're changing drugs. We're changing protocols -- 13:15:06 10 regimens. And we've -- once you're at that point of 13:15:10 11 thinking, can I do extended therapy, there's not been 13:15:15 12 any data to show that extending beyond four weeks is 13:15:20 13 going to result in maintenance of visual acuity 13:15:24 14 because the only extended data we had prior to when 13:15:28 15 Aflibercept was eligible for that, resulted in loss of 13:15:32 16 vision. That was a PIER trial. 13:15:35 17 BY MR. NIMROD: 18 Q. I was talking about Aflibercept, not -- 13:15:39 19 A. I understand. But I'm just saying when you're 13:15:41 20 making comparisons, you have to keep in mind that the 13:15:43 21 drugs are different and that the regimens are different 13:15:45 22 and so you've got to try to make as close a comparison 13:15:49 23 as possible. And this is monthly therapy. And 13:15:53 24 Aflibercept is monthly and then Q8 weeks, which we don't 13:15:56 25 have any data on at this point to make that 13:16:00 Page 159	1 phase 3 and they failed spectacularly. 13:17:24 2 And as I said earlier on, 25 percent to 13:17:27 3 30 percent of patients -- only 25 percent to 13:17:30 4 35 percent of drugs will actually pass phase 3. So 13:17:34 5 you can't make that leap of faith when you've never 13:17:36 6 tested the Q8-week arm. 13:17:39 7 BY MR. NIMROD: 13:17:41 8 Q. And when you say they fail, or only 25 to 13:17:41 9 35 percent pass, that means that the patient population 13:17:48 10 as a whole meets whatever the, you know, end point is, 13:17:50 11 right? 13:17:53 12 MR. BRAUSA: Objection; form. 13:17:54 13 THE WITNESS: Well, failure for all of these 13:17:55 14 drugs has always meant a visual end point. And it 13:17:59 15 differs as we've gone over time. But what it means is 13:18:06 16 a drug has failed, means it's failed to meet its 13:18:12 17 primary end point. 13:18:15 18 BY MR. NIMROD: 13:18:15 19 Q. Which is an end point that's based on a mean or 13:18:16 20 median for an arm of a patient population, not 13:18:19 21 individual results; is that correct? 13:18:22 22 MR. BRAUSA: Objection; form. 13:18:24 23 THE WITNESS: So it's not necessarily mean or 13:18:24 24 median, although we've gravitated in that direction. 13:18:27 25 But it is the population cohort of patients that are 13:18:31 Page 161

1 treated and -- yes, it is the cohort of patient 13:18:34 2 population who are treated, not individual patients. 13:18:39 3 BY MR. NIMROD: 13:18:40 4 Q. Okay. And you don't have any percentages to give 13:18:41 5 us as to for phase 3 trials, how many of them are ones 13:18:43 6 where no one in the cohort of interest would meet the, 13:18:47 7 you know, efficaciousness that you were looking for, 13:18:53 8 that any individual patient, it's simply the statistics 13:18:58 9 you're citing is for the patient population as a whole, 13:19:00 10 right? 13:19:02 11 MR. BRAUSA: Objection; form. 13:19:02 12 THE WITNESS: So that's what the end points are 13:19:03 13 based on is the population as a whole, not the 13:19:07 14 individuals. And I don't have those numbers to give 13:19:11 15 you. 13:19:13 16 BY MR. NIMROD: 13:19:13 17 Q. Okay. So then if I asked you a slightly 13:19:13 18 different question I've kind of gone to a couple times 13:19:16 19 today -- maybe we'll have some agreement -- if a POSA 13:19:20 20 looked at the data from this ANCHOR study -- and let's 13:19:22 21 say also the Marina study, and saw that there was a 13:19:28 22 significant portion -- by that I mean, you know, 20 to 13:19:36 23 41 percent -- of the patients in those randomization of 13:19:39 24 arms got a 15-plus letter gain, then would that POSA 13:19:43 25 conclude that it was more likely than not that at least 13:19:49 Page 162	1 Well, just for the record, Exhibit 10 is 13:21:21 2 Exhibit 1021 in the IPR proceeding. I'm not sure if I 13:21:24 3 have another copy of that, Adam. 13:21:30 4 MR. BRAUSA: If you can stand by, I think we 13:21:32 5 can pull it up. 13:21:34 6 MR. NIMROD: Okay. 13:21:36 7 MR. BRAUSA: We're just navigating through. I 13:22:06 8 think we've got it. 13:22:09 9 MR. NIMROD: Any luck? 13:22:23 10 MR. BRAUSA: We got it. I got it. Go ahead. 13:22:24 11 BY MR. NIMROD: 13:22:25 12 Q. Okay. So Exhibit 10 is an article entitled: 13:22:25 13 Randomized, Double-Masked, Sham-Controlled Trial of 13:22:29 14 Ranibizumab for Neovascular Age-Related Macular 13:22:34 15 Degeneration: PIER 1 Study, Year 1 -- PIER Study, Year 13:22:40 16 1. Excuse me. 13:22:42 17 Do you see that? 13:22:46 18 A. I do. 13:22:46 19 Q. And so this is the PIER study that you refer to 13:22:47 20 your expert report? 13:22:49 21 A. Yes, it is. 13:22:50 22 Q. Okay. What were the regimens of Ranibizumab -- 13:22:51 23 well, first of all, in this study are there three arms? 13:23:09 24 A. Yes. 13:23:13 25 Q. Okay. One is a sham injection, meaning there's 13:23:14 Page 164
1 one patient in a cohort being given three monthly doses 13:19:51 2 of 2 milligrams of Aflibercept followed by eight-week 13:19:56 3 interval dosing of 2 milligrams, at least one patient, 13:20:00 4 it's more likely than not would get the 15-plus letter 13:20:03 5 gain? 13:20:06 6 MR. BRAUSA: Objection; form. 13:20:08 7 THE WITNESS: I think it's difficult to 13:20:08 8 predict. We certainly can't do numbers. It's a high 13:20:14 9 bar. Would more likely than not that one patient 13:20:17 10 would, yes. I think it would. 13:20:20 11 MR. NIMROD: Okay. All right. Let me go now 13:20:25 12 to the PIER study, the PIER study. I'm going to mark 13:20:27 13 as I think it's -- are we on 10? 13:20:34 14 THE COURT REPORTER: Yes. 13:20:49 15 (Exhibit No. 10 was marked for identification.) 13:20:51 16 MR. NIMROD: Oops. That's my copy. 13:20:58 17 THE WITNESS: I'm sorry? 13:20:59 18 MR. NIMROD: I just marked my copy. 13:21:00 19 MR. BRAUSA: We'll take the one with the 13:21:02 20 circles on it, if you want. 13:21:03 21 MR. NIMROD: Doesn't really give much away, 13:21:06 22 other than I have a lot of scribbles. 13:21:08 23 THE WITNESS: I'll take it. 13:21:11 24 MR. NIMROD: Exhibit 10 -- where is it? Must 13:21:13 25 be another one somewhere. 13:21:14 Page 163	1 no active; is that right? 13:23:16 2 A. That's correct. 13:23:18 3 Q. Okay. And then the next is Ranibizumab at 13:23:18 4 .3 milligrams? 13:23:22 5 A. Correct. 13:23:23 6 Q. And how is that dosed? 13:23:24 7 A. So that is dosed monthly times three and then 13:23:25 8 quarterly until the end of one year. 13:23:31 9 Q. Okay. And then when you say monthly times three, 13:23:36 10 that's zero, one and two months? 13:23:38 11 A. Correct. 13:23:40 12 Q. Okay. And then how was the arm that says 13:23:40 13 .5 milligrams dosed? 13:23:44 14 A. The same as the .3 milligrams. 13:23:45 15 Q. Okay. All right. And if you could turn to -- 13:23:49 16 one second. I lost my spot here. 13:24:10 17 Is there a data in here that you're aware of -- 13:24:16 18 but I will look through it also -- but data in here 13:24:19 19 somewhere that talks about patient populations that 13:24:23 20 achieve 15-plus letter gain? Oh, there it is. Okay. 13:24:25 21 If we go to page 244, which is exhibit page 6 in the 13:24:41 22 left-hand column under Table 2. 13:24:49 23 A. Okay. 13:24:53 24 Q. Third line, fourth line says: However, the three 13:24:53 25 treatment groups did not differ significantly in the 13:24:57 Page 165

1 proportions gaining at least 15 letters, 9.5 in the sham 13:25:00 2 group, 11.7 in the .3-milligram group, and then 13:25:03 3 13.1 percent in the .5-milligram group. 13:25:09 4 A. I'm sorry. I'm just not there yet. 13:25:12 5 Q. Right here. 13:25:14 6 A. Oh, thank you. Okay. Starting with however? 13:25:16 7 Q. Yes. 13:25:19 8 A. Yes. 13:25:19 9 Q. Do you want to read that to yourself? 13:25:20 10 A. Okay. Yes. 13:25:21 11 Q. So you have 10 percent -- well, 9.5 percent of 13:25:28 12 the patients achieving 15-plus letter gains with the 13:25:37 13 sham injections, right? 13:25:44 14 A. Yes. 13:25:46 15 Q. And that's after 12 months, right, or at 13:25:46 16 12 months? 13:25:50 17 A. At 12 months. 13:25:51 18 Q. Right. So in the last study or one of the last 13:25:52 19 ones -- prior ones we looked at we saw 5 percent of the 13:25:57 20 sham group achieved gains of at least 15 letters, at 13:26:00 21 52 weeks, right? 13:26:03 22 A. Yes. 13:26:04 23 Q. Okay. And do you know why it would be that 13:26:05 24 participants who received the sham injection with no 13:26:12 25 active would be able to achieve 15 -- at least 15 letter 13:26:15 Page 166	1 active treatment groups for effective regimens do better 13:27:29 2 than sham treatment. But we don't know the mechanism of 13:27:35 3 why and we don't know what contribution is spontaneous, 13:27:41 4 versus what's drug induced. We just know the outcome. 13:27:44 5 Q. Okay. All right. If we also look at the data in 13:27:57 6 this, for example, the -- strike that. 13:28:03 7 You've characterized this as a failure PIER 13:28:07 8 study; is that your view? 13:28:14 9 A. Yes, I believe I used that word. 13:28:16 10 Q. And the reason was why? 13:28:17 11 A. Because at 12 months, you ended up on average 13:28:19 12 treating patients, lost vision. And when you compare to 13:28:23 13 what was available at the time, which was Ranibizumab, 13:28:28 14 when patients on average gained significant letters, 13:28:33 15 then this is a failure. 13:28:40 16 Q. And then where would be the data in here that 13:28:40 17 shows that they lost, on average, letters? What are the 13:28:43 18 numbers that we have? 13:28:48 19 A. If you look at the front page. 13:28:49 20 Q. Okay. 13:28:52 21 A. And the very first sentence under results. 13:28:53 22 Q. Yes. 13:28:57 23 A. Mean changes from baseline, visual acuity at 12 13:28:57 24 months were minus 16.3, that's the sham group, minus 1.6 13:29:01 25 letters, that's the 0.3-milligram and minus 13:29:06 Page 168
1 gains at the 12-month point? 13:26:21 2 MR. BRAUSA: Objection; form. 13:26:24 3 THE WITNESS: We know that for patients with 13:26:24 4 neovascular MB there's significant interpatient 13:26:28 5 variability. Some do surprisingly well, most do not. 13:26:34 6 So -- and we can't predict who does which. 13:26:38 7 BY MR. NIMROD: 13:26:44 8 Q. When you say some do surprisingly well, that 13:26:45 9 means that some will regain letters just based on 13:26:47 10 whatever the natural process is, as opposed to an active 13:26:50 11 ingredient? 13:26:53 12 A. For patients in sham groups, yes. 13:26:54 13 Q. Would that also be true for patients in the 13:26:57 14 active ingredient groups? 13:27:03 15 MR. BRAUSA: Objection; form. 13:27:06 16 BY MR. NIMROD: 13:27:06 17 Q. You have two arms where there's active 13:27:07 18 ingredient. 13:27:09 19 A. Right. 13:27:09 20 Q. I said -- so would you also expect then that 13:27:09 21 persons who were in those groups could have, you know, 13:27:14 22 natural processes going on that will cause a recovery of 13:27:16 23 letters, as opposed to simply the active ingredient? 13:27:19 24 A. I think you're asking a biological question that 13:27:23 25 nobody knows the answer to. I mean, we know that the 13:27:27 Page 167	1 0.2 milligrams, that's the 0.5-milligram. 13:29:09 2 Q. Okay. So the groups that were given the 13:29:14 3 Ranibizumab with three monthly injections followed by 13:29:19 4 quarterly injections did better statistically, 13:29:24 5 significantly better than the sham group? 13:29:29 6 A. When measured with visual acuity, from baseline 13:29:32 7 to 12 months, yes, they did. 13:29:35 8 Q. Okay. And those groups would meet the limitation 13:29:36 9 of claim 29 and claim 30 of the 572 patent which simply 13:29:41 10 require that you have a loss of less than 15 letters, 13:29:48 11 right? 13:29:51 12 MR. BRAUSA: Objection; form. 13:29:52 13 THE WITNESS: I'm not sure how to apply that. 13:29:52 14 That's the Aflibercept claim and you're talking 13:29:56 15 about -- 13:29:59 16 BY MR. NIMROD: 13:29:59 17 Q. Well, if you -- let's just look at -- 13:30:00 18 A. Maybe clarify, please. 13:30:02 19 Q. Sorry. Let's look at the 572 patent, go to claim 13:30:04 20 30. 13:30:07 21 A. Yes. Okay. Go ahead. 13:30:08 22 Q. So claim 30 of the 572 patent says: The method 13:30:16 23 of claim 29 wherein the maintenance of visual acuity 13:30:20 24 means loss of less than 15 letters in the ETDRS letter 13:30:24 25 score. 13:30:30 Page 169

1 Right? 13:30:30	1 directed to Aflibercept compound -- 13:32:24
2 A. Yes. 13:30:31	2 A. Okay.
3 Q. And both of the Ranibizumab trials in the PIER 13:30:31	3 Q. -- I'm just going to ask you, would you agree 13:32:25
4 study that had three monthly doses followed by quarterly 13:30:36	4 that the PIER 1 groups that have Ranibizumab were 13:32:26
5 dosing met that standard of acuity test, right? 13:30:41	5 successful in maintenance of the visual acuity score of 13:32:30
6 MR. BRAUSA: Objection; form. 13:30:46	6 loss less than 15 letters under the ETDRS letter score? 13:32:34
7 THE WITNESS: Well, I'm puzzled by this. This 13:30:46	7 A. I'm looking for the data here. I'm not yet able 13:32:41
8 depends on claim 29. 29 has a treatment regimen. 13:30:51	8 to find it. 13:32:45
9 It's talking about Aflibercept. So the way you're 13:30:58	9 Q. I thought you pointed me to the first page. 13:32:46
10 phrasing the question, I'm not quite sure I understand 13:31:01	10 A. Yes. But that's the average visual acuity. 13:32:48
11 what you're asking. 13:31:03	11 That's not the percentage of patients who lost 15 13:32:50
12 BY MR. NIMROD:	12 letters or more. And claim 30, the verbiage of claim 30 13:32:54
13 Q. I'm asking you, looking at claim 30, I'm just 13:31:04	13 is the percentage of patients who lost 15 letters or 13:33:00
14 asking about the acuity test. Claim 30's acuity test 13:31:08	14 more. 13:33:03
15 is, quote, where maintenance of visual acuity means loss 13:31:12	15 Q. The percentage? 13:33:03
16 of less than 15 letters BCVA as measured by using the 13:31:15	16 A. Well, that's what it means. Maintenance of 13:33:04
17 ETDRS letter score. 13:31:20	17 vision that's defined -- we define it in clinical 13:33:06
18 Do you see that? 13:31:22	18 practice as the percentage of patients who lost 15 13:33:08
19 A. No, I see what you're saying -- 13:31:23	19 letters or more. 13:33:11
20 Q. I'm just asking you about -- 13:31:24	20 Q. I thought that you took me to a table in here 13:33:12
21 A. Right. 13:31:26	21 that just had average letters. Is it Table 2, wasn't 13:33:16
22 Q. -- the test. That's it. 13:31:26	22 it? It wasn't patient by patient. 13:33:22
23 A. Okay. 13:31:27	23 A. That wasn't -- I don't believe that was claim 30 13:33:27
24 Q. I'm not asking about whether it meets claim 29. 13:31:27	24 that we did that. 13:33:32
25 A. Okay. So -- 13:31:30	25 Q. Well, any claim. 13:33:33
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1 Q. We'll separate those. 13:31:31	1 A. Well, but they're all different. But the claims 13:33:34
2 A. If we take that verbiage -- 13:31:32	2 are different in terms of what their visual requirements 13:33:36
3 Q. Right.	3 are. 13:33:39
4 A. -- pull it out of the claim. 13:31:34	4 Q. You're saying that given that the average loss -- 13:33:39
5 Q. Yeah. 13:31:34	5 A. Yes.
6 A. Okay. So -- 13:31:36	6 Q. -- of the two arms were in the PIER 1 -- the PIER 13:33:44
7 Q. Let me ask the question. 13:31:37	7 studies were -- what were the numbers again? 13:33:48
8 A. Yes. 13:31:38	8 A. That's what I'm looking for.
9 Q. Is it not true that both of the Ranibizumab arms 13:31:38	9 Q. Negative 1.6 and negative .2. 13:33:54
10 that were tested in the PIER study met the -- met a 13:31:41	10 A. Yes. 13:33:58
11 maintenance -- strike that. 13:31:47	11 Q. That you can't conclude that those results would 13:33:59
12 Is it not true that both of the arms, Ranibizumab 13:31:49	12 show success in a criteria where you require maintenance 13:34:04
13 in the PIER study, succeeded in achieving a maintenance 13:31:53	13 of visual acuity, loss of less than 15 ETDRS letters? 13:34:09
14 of a visual acuity score of loss of less than 15 letters 13:31:58	14 A. I can say I'd love to see the calculations. What 13:34:14
15 using the ETDRS letter score? 13:32:03	15 I think the calculations would show is that there is a 13:34:17
16 MR. BRAUSA: Outside the context of claim 30. 13:32:07	16 likely significant difference. Meaning -- 13:34:22
17 MR. NIMROD: It's the same thing. It's 13:32:09	17 Q. In what? 13:34:24
18 outside -- 13:32:14	18 A. In maintenance of visual acuity. That the 13:34:25
19 MR. BRAUSA: Objection; form. 13:32:14	19 Ranibizumab arms maintain visual acuity better than 13:34:30
20 MR. NIMROD: -- the concept of Aflibercept. 13:32:15	20 sham. I think that's likely based on these numbers. 13:34:34
21 Yes. Yes. 13:32:19	21 Q. I'm not asking that. 13:34:35
22 MR. BRAUSA: Objection; form. 13:32:19	22 A. Then I don't understand. 13:34:36
23 BY MR. NIMROD: 13:32:20	23 Q. I'm just asking you whether -- it says there's a 13:34:37
24 Q. Actually, that will be fine. I'll say that. 13:32:20	24 measurement here, right? 13:34:40
25 Outside the context of claim 30, which is 13:32:21	25 A. Right. 13:34:41
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1 Q. What you told me before was what this test 13:34:41	1 Q. -- on average -- 13:36:32
2 required is that you start off with some determination 13:34:44	2 A. Yes. 13:36:33
3 as to somebody's score. 13:34:46	3 Q. -- the patients -- and I think there were -- how 13:36:33
4 A. Yes. 13:34:48	4 many were there? -- 61 patients, on average, they lost 13:36:36
5 Q. And then -- and for the whole population, and 13:34:49	5 .2 letters, correct? 13:36:42
6 then you, at the very end you look to see what their 13:34:52	6 A. That's correct. 13:36:45
7 score is. That's what they did here, right? Maybe it's 13:34:54	7 Q. Okay. So on average, will you not agree that the 13:36:45
8 getting later in the day or I'm missing something. 13:34:58	8 .5-milligram arm in the PIER study that had three 13:36:50
9 Could be. 13:35:02	9 monthly doses followed by quarterly doses met a criteria 13:36:53
10 A. Okay. So -- so I think -- let me try to clarify 13:35:02	10 which required a loss of less than 15 ETDRS letters? 13:37:00
11 and see if this makes sense. When we talked about claim 13:35:11	11 MR. BRAUSA: Objection; form. 13:37:03
12 9 and then subsequently claim 30, we were talking about 13:35:15	12 THE WITNESS: I -- okay. Let me make another 13:37:04
13 a patient. When we're talking about -- if you're taking 13:35:18	13 statement, see if this answers your question. Okay. 13:37:07
14 claim 30 and just taking the verbiage out -- 13:35:24	14 The average patient in a treatment arm met the 13:37:13
15 Q. That's what we did. 13:35:27	15 criteria of losing less than 15 letters. Is that -- 13:37:18
16 A. -- the way we usually look at that is based on 13:35:28	16 BY MR. NIMROD: 13:37:23
17 percent proportions. So the way I'm interpreting this 13:35:34	17 Q. Yes. 13:37:23
18 is, did the proportion of patients losing 15 letters in 13:35:37	18 A. Is that the kind of answer you're looking for? 13:37:23
19 the sham group differ significantly from the 13:35:42	19 Q. Yes. That's what I've been asking. 13:37:25
20 proportions -- 13:35:46	20 A. Well, I'm sorry. But I -- we're missing -- you 13:37:27
21 Q. No. 13:35:46	21 and I were thinking different ways about a patient, 13:37:29
22 A. But I can't tell you individual patients. 13:35:47	22 versus percentages proportions. That's all. 13:37:32
23 Q. I'm not talking about sham groups. I'm just 13:35:49	23 Q. Okay. And you would agree, I guess, if the -- if 13:37:34
24 talking about the patient population -- just look at one 13:35:51	24 the mean is .2 letters, wouldn't they be very likely 13:37:37
25 arm, the .5-milligram Ranibizumab arm. Okay? 13:35:53	25 that most of the patients didn't lose more than 15? 13:37:43
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1 A. Right. So -- 13:35:57	1 MR. BRAUSA: Objection; form. 13:37:49
2 Q. Okay. So on average, what would happen is all of 13:35:57	2 THE WITNESS: I'd love to see the individual 13:37:50
3 those patients would have been scored -- 13:36:00	3 data. But I think it's likely that most did not. 13:37:52
4 A. Yes. 13:36:01	4 BY MR. NIMROD:
5 Q. -- on day zero? 13:36:01	5 Q. Okay. All right. So if you have this data for 13:38:01
6 A. Yes. 13:36:02	6 Ranibizumab showing that it could achieve using 13:38:04
7 Q. And then they were all scored on week 52, right? 13:36:03	7 quarterly dosing, followed -- let me start over. 13:38:08
8 A. Right. 13:36:08	8 You have the data from the PIER study showing 13:38:15
9 Q. And to determine whether they lost more or less 13:36:09	9 that after three monthly injections of .5 Ranibizumab, 13:38:17
10 than 15 letters, you simply take the score at the 13:36:12	10 followed by quarterly dosing of Ranibizumab, and you -- 13:38:20
11 beginning versus score at the end, or am I missing 13:36:16	11 that group as a whole achieves a loss of .2 letters, 13:38:26
12 something? 13:36:18	12 would you agree that a POSA looking at that data would 13:38:32
13 A. Okay. So -- 13:36:19	13 believe that it was more likely than not that treatment 13:38:34
14 Q. Is that wrong? 13:36:19	14 with 2 milligrams of Aflibercept for three months 13:38:38
15 A. Well, if you're asking me for individual 13:36:19	15 followed by eight weeks of dosing of 2 milligrams would 13:38:42
16 patients -- 13:36:21	16 likely lead to the result of a significant portion of 13:38:47
17 Q. No, I'm just asking how each -- yeah, each 13:36:21	17 patients meeting the criteria of less than 15 letters 13:38:50
18 patient is just scored that way, right? 13:36:22	18 lost at 52 weeks? 13:38:55
19 A. Each patient is scored that way and -- 13:36:24	19 MR. BRAUSA: Objection; form. 13:38:59
20 Q. And then at the end, you average them all 13:36:26	20 THE WITNESS: So I would say I can't answer 13:38:59
21 together to get an average for that arm, right? 13:36:28	21 that. The -- clearly, quarterly dosing with 13:39:02
22 A. Right. 13:36:28	22 Ranibizumab is not very effective. 13:39:11
23 Q. Okay. And so if we look at the .5-milligram 13:36:29	23 BY MR. NIMROD:
24 arm -- 13:36:31	24 Q. Well, it's as effective as what claim 30 13:39:14
25 A. Yes. 13:36:32	25 requires. 13:39:16
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1 MR. BRAUSA: Object -- objection to form. 13:39:18	1 Q. Okay. And that in contrast, if the POSA was 13:42:20
2 BY MR. NIMROD: 13:39:20	2 thinking about a regimen that had four monthly doses, 13:42:23
3 Q. Is that right? 13:39:20	3 followed by eight-week intervals, there would be a total 13:42:29
4 A. In my world it's not very effective. 13:39:20	4 of eight injections, right? 13:42:32
5 Q. But it's as effective as claim 30 requires? 13:39:23	5 A. (Nods head.) 13:42:34
6 MR. BRAUSA: Objection; form. 13:39:25	6 Q. Yes? 13:42:35
7 THE WITNESS: I -- for an individual patient, 13:39:25	7 A. Yes. 13:42:36
8 the majority of individual patients, yes. 13:39:28	8 Q. Okay. And so my question was, and I guess the 13:42:36
9 BY MR. NIMROD:	9 gist of it was, well, then wouldn't a POSA conclude that 13:42:39
10 Q. Okay.	10 getting eight injections in that regimen would give as 13:42:42
11 A. So Q12-week therapy is not very effective. Is 13:39:31	11 good as or better results than the 2Q4, the 2Q12 of the 13:42:46
12 Q8-week with Aflibercept going to be effective or is it 13:39:41	12 CLEAR-IT 2? And I think you disagreed with me. 13:42:53
13 six weeks or is it five weeks or is it seven weeks is 13:39:46	13 A. I did. 13:42:55
14 the magic number? And we don't have the data to show 13:39:49	14 Q. Or do -- do you disagree with me? 13:42:56
15 that. 13:39:51	15 A. Right, I disagree with you. 13:42:58
16 Q. Okay. Let's go back to Exhibit 2047, which is 13:40:02	16 Q. And I thought the reason was because you said, 13:43:00
17 our deposition Exhibit 5. I believe you may have some 13:40:09	17 well, it's possible that it has to do with timing, that 13:43:03
18 of those little pictures. Do you still have those in 13:40:25	18 maybe the timing was done earlier than the eight weeks 13:43:05
19 case we have visual issues? 13:40:27	19 would have been; is that right? 13:43:08
20 A. Yeah, this one here? Yes. 13:40:29	20 A. I don't remember the exact testimony but, yes, 13:43:09
21 Q. Yeah. Okay. Just in case. I don't know if we 13:40:32	21 that's the gist of what I said. 13:43:12
22 need that. But I was asking you questions about, before 13:40:33	22 Q. And is there some other factor that would play 13:43:13
23 the last -- the lunch break, I was asking you questions 13:40:36	23 into whether a POSA would expect or, you know, predict 13:43:16
24 about, well, if you look at -- what is this -- yeah. If 13:40:38	24 that the two four monthly doses followed by four 13:43:19
25 you look at slide 13, there is the retreatment outcome 13:40:46	25 eight-week doses would not perform as well or better 13:43:28
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1 for the 2Q4 and the 2Q12. And I also noted that that 13:40:55	1 than the 2Q4 or the 2Q12 of the CLEAR-IT 2 study? 13:43:30
2 meant that the mean number of injections for the 2Q4 was 13:41:02	2 A. So timing, I think, is the big thing. We don't 13:43:34
3 4.5 -- 5.55 and the mean number of the 2Q12 was 4.48, 13:41:10	3 have the knowledge that if timing is a significant 13:43:37
4 right? 13:41:16	4 factor or not. The other thing is, this is based on a 13:43:42
5 A. Yes. 13:41:16	5 phase 2 study of 31 patients. And if you go to phase 3 13:43:45
6 Q. And then I asked you, well, wouldn't you agree, 13:41:17	6 and you now have 300 patients, you can get very 13:43:49
7 then, looking at this data from 2008 that a POSA would 13:41:21	7 different results based on different cohorts and 13:43:53
8 conclude that giving four monthly injections of 2 13:41:24	8 variation, especially when you're having small cohorts 13:43:55
9 milligrams followed by another four injections at 13:41:30	9 in your phase 2. So that can be another factor. 13:43:58
10 eight-week intervals would likely achieve results that 13:41:33	10 Q. Now, of course, the claims here require a 13:44:02
11 were as good or better than the 2Q4 results? 13:41:38	11 patient. You understand that, claims of the 572 patent? 13:44:05
12 And I think you said that you couldn't say that 13:41:43	12 A. Yes, they do. 13:44:08
13 it would be as good because of the timing of the 1.55 on 13:41:46	13 Q. They're directed to a patient? 13:44:09
14 average made a difference? 13:41:52	14 A. To a patient. 13:44:10
15 MR. BRAUSA: Objection; form. 13:41:54	15 Q. Okay. Can you turn to slide 13, please. 13:44:10
16 THE WITNESS: I think you repeated 2Q4. Were 13:41:54	16 A. Yes. 13:44:15
17 you intending to do 2Q12? 13:41:57	17 Q. Okay. So slide 13 -- are you there already? 13:44:15
18 BY MR. NIMROD: 13:42:00	18 A. 13? 13:44:21
19 Q. No. What I'm saying is if you -- I asked you a 13:42:00	19 Q. Okay. 13. Okay. For slide 13, it says the mean 13:44:22
20 question about a POSA looking at this data. 13:42:04	20 number of days to first injection over PRN phase. 13:44:26
21 A. Yes. 13:42:06	21 Do you see that? 13:44:29
22 Q. And the POSA sees that for the 2Q4 and the 2Q12, 13:42:06	22 A. I do. 13:44:29
23 there's a total of somewhere between 4.55 -- 4.48 and 13:42:11	23 Q. Okay. So for the 2Q4, the mean number of days to 13:44:30
24 5.55 total injections in those two cohorts, right? 13:42:16	24 the first injection over the PRN phase was 160 days. Do 13:44:36
25 A. Right. 13:42:19	25 you see that? 13:44:41
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1 A. 100 -- I'm sorry. Mean number of first injection 13:44:41 2 over PRN phase. Yes. 13:44:46 3 Q. Okay. Do you understand that to be 160 days, by 13:44:47 4 the way, from the time zero or from time 12 weeks? 13:44:50 5 A. I would -- I would read that as from 12 weeks. 13:44:53 6 Q. Okay. So, in fact, the average number -- or the 13:44:58 7 average timing, I should say, for the fifth injection on 13:45:06 8 the 2Q4 patients was actually five months, five and a 13:45:12 9 third months from the 12 injection; is that right? 13:45:16 10 A. Yes. 13:45:20 11 Q. Okay. So actually it's much longer on average 13:45:21 12 than you would be doing with eight-week intervals after 13:45:25 13 the fourth week, right? 13:45:28 14 A. Yes, it is. 13:45:29 15 Q. Okay. 13:45:31 16 A. On the average, yes. 13:45:32 17 Q. So wouldn't that then tell you a POSA looking now 13:45:33 18 at slide 13, which I did not add to the mix before, now 13:45:36 19 I've got it mixed in there. 13:45:40 20 A. Okay. 13:45:41 21 Q. So a POSA looks at that data and says, all right, 13:45:42 22 2Q4, there's a total of 5.55 injections, 2Q12, 4.48, the 13:45:45 23 2Q4 is monthly for the first four doses and on average, 13:45:55 24 the next dose is not given until 160 days after 12, so I 13:45:59 25 can be pretty confident that if I do four monthly doses 13:46:03 Page 182	1 BY MR. NIMROD: 13:47:23 2 Q. Just one patient. 13:47:24 3 MR. BRAUSA: Same objection. 13:47:25 4 THE WITNESS: I don't know the -- so 50 -- I 13:47:26 5 don't know variability, the standard deviation. I 13:47:31 6 think there is a good chance, but I can't say that 13:47:34 7 there is a high likelihood. I think there's a good 13:47:40 8 chance. 13:47:42 9 BY MR. NIMROD: 10 Q. Okay. I think I messed up there, too, because I 13:47:43 11 didn't use my phrase more likely than not or probable. 13:47:45 12 A. More likely than not. 13:47:48 13 Q. I'm going to try it again. 13:47:49 14 A. Yeah, okay. All right. 13:47:50 15 Q. So would you agree that a POSA looking at the 13:47:51 16 data from 2047 with the CLEAR-IT 2, one-year results 13:47:54 17 from phase 2, including the mean number of days to the 13:47:59 18 first injection of the -- after the PRN phase starts, 13:48:02 19 for the 2Q4 and 2Q12 cohorts would conclude that it's 13:48:07 20 more likely than not if they dosed Aflibercept 2 mg for 13:48:12 21 four monthly doses followed by eight-week injections, 13:48:17 22 intervals, 2 mg, that at least one patient, it is more 13:48:22 23 likely than not, would get results of a 15-plus letter 13:48:26 24 gain? 13:48:29 25 MR. BRAUSA: Objection; form. 13:48:29 Page 184
1 followed by eight-week dosing through week 52, I'm going 13:46:09 2 to get results that are at least as good as if better 13:46:13 3 than in terms of efficacy, visual acuity than either the 13:46:18 4 2Q4 or the 2Q12. And I said at least as good as if not 13:46:21 5 better, so equal is okay too. Would you agree with me 13:46:26 6 that? 13:46:30 7 MR. BRAUSA: Objection; form. 13:46:30 8 THE WITNESS: So I would disagree because once 13:46:31 9 again, you need to get into phase 3 trial and phase 3 13:46:32 10 is a whole different game. What I would say is a POSA 13:46:35 11 would look at that and say that's very encouraging 13:46:38 12 data. 13:46:41 13 BY MR. NIMROD: 14 Q. Okay. 15 A. And that should be investigated in phase 3. 13:46:41 16 Q. Okay. Now go to the one patient question again. 13:46:44 17 Would you agree that a POSA looking at the data from 13:46:47 18 2047, including the data on the mean number of days to 13:46:49 19 the first injection over the PRN phase for the 2Q4 and 13:46:54 20 2Q12, would conclude that if I dosed at four monthly 13:46:58 21 injections followed by four eight-week injections up to 13:47:05 22 week 52 of Aflibercept 2 mg, that at least one patient 13:47:10 23 would get the results of a 15-plus letter gain in the VA 13:47:14 24 score? 13:47:22 25 MR. BRAUSA: Objection; form. 13:47:23 Page 183	1 THE WITNESS: Based on the dosing that you've 13:48:30 2 said, the four times and then 2Q8, given the results 13:48:34 3 we see in the PRN arm, I think it's more likely than 13:48:41 4 not you get one patient. 13:48:44 5 MR. NIMROD: All right. Okay. Can I get like 13:48:55 6 five minutes to go through my notes? 13:48:55 7 MR. BRAUSA: Sure. 13:48:58 8 MR. NIMROD: Maybe call... 13:48:58 9 THE VIDEOGRAPHER: Stand by. We're going off 13:49:01 10 the record at 1:49. 13:49:02 11 (A brief recess was taken.) 13:49:04 12 THE VIDEOGRAPHER: We are back on the record at 14:01:38 13 2:01. 14:01:53 14 BY MR. NIMROD: 14:01:55 15 Q. Dr. Stewart, on Exhibit 2047, we saw that 14:01:56 16 29 percent of the patients in the 2Q4 and 2Q12 arms for 14:02:02 17 the CLEAR-IT 2 phase 2 study achieved a 15 or more 14:02:07 18 letter gain. That was on slide 19. 14:02:14 19 A. Yes. 14:02:17 20 Q. Okay. My question is, do you know, in terms of 14:02:17 21 the phase 3, which had the arm that was -- was it three 14:02:20 22 monthly doses followed by eight-week dosing? 14:02:26 23 A. Correct. 14:02:30 24 Q. Okay. Do you know what percentage of the 14:02:30 25 patients or ballpark achieved a 15-plus letter gain? 14:02:32 Page 185

1 Was it about the same or do you know? 14:02:38 2 A. So without looking at the data, I can't give you 14:02:39 3 an exact number. I know it was approximately 29 to 14:02:42 4 30 percent. 14:02:46 5 MR. NIMROD: Okay. I have no more questions. 14:02:48 6 MR. BRAUSA: Signature. We're off the record. 14:02:50 7 THE WITNESS: Great. Thank you. 14:02:54 8 THE VIDEOGRAPHER: For the record, does anyone 14:02:54 9 want to order the video? 14:02:57 10 MR. BRAUSA: Can we go off the record, please? 14:02:58 11 THE VIDEOGRAPHER: I have to get that on the 14:03:01 12 record. 14:03:02 13 MR. NIMROD: Well, I don't know, so I'll have 14:03:02 14 to get back to you. 14:03:04 15 MR. BRAUSA: Same. 14:03:04 16 MR. NIMROD: I'm not in charge of that. 14:03:05 17 THE VIDEOGRAPHER: Stand by. We are going off 14:03:07 18 the record at 2:03. 14:03:08 19 THE COURT REPORTER: Is a rough or expedite 14:03:49 20 needed? 14:04:24 21 MR. BRAUSA: We'll take a rough. 14:04:28 22 MR. NIMROD: Yeah, we'll take a rough. 14:04:29 23 (The deposition was concluded at 2:03 p.m.) 24 25 Page 186	1 TRANSCRIPT CERTIFICATE 2 STATE OF FLORIDA) 3 COUNTY OF ORANGE) 4 5 I, MAE FISHER, Registered Merit Reporter, 6 Certified Realtime Reporter and Notary Public, State of 7 Florida, certify that I was authorized to and did 8 stenographically report the deposition of Michael 9 Stewart, MD; that a review of the transcript was 10 requested; and the foregoing transcript, pages 5 through 11 186, is a true record of my stenographic notes. 12 I FURTHER CERTIFY that I am not a relative, 13 employee, attorney, or counsel of any of the parties, 14 nor am I a relative or employee of any of the parties' 15 attorney or counsel connected with the action, nor am I 16 financially interested in the action. 17 18 DATED this 3rd day of June, 2024, at Orlando, 19 Orange County, Florida. 20 21 22 23 24 25  MAE FISHER, Notary Public State of Florida Page 188
1 CERTIFICATE OF OATH 2 3 STATE OF FLORIDA) 4 COUNTY OF ORANGE) 5 I, MAE FISHER, Registered Merit Reporter, 6 Certified Realtime Reporter and Notary Public, State of 7 Florida, certify that MICHAEL STEWART, MD personally 8 appeared before me on May 30, 2024, and was duly 9 sworn/affirmed. 10 11 WITNESS my hand and official seal this 3rd day of 12 June, 2024. 13 14 15 16  MAE FISHER, RMR, CKR Notary Public - State of Florida Commission HH 443649 Expires: January 8, 2028 17 18 19 20 Personally known _____ 21 OR Produced Identification X _____ 22 Type of Identification Produced Driver's license 23 24 25 Page 187	1 Adam Brausa, Esquire June 3, 2024 2 Abrausa@mofo.com 3 4 RE: Samsung Bioepis Co. Ltd. v. Regeneron 5 Pharmaceuticals, Inc. 6 Deposition of: Michael Stewart, MD 7 Date: 5/30/24 8 Job No. 6728352 9 10 The above-referenced transcript is available for 11 review. 12 The witness should read the testimony to verify its 13 accuracy. If there are any changes, the witness should 14 note those with the reason on the attached Errata Sheet. 15 The witness should, please, date and sign the Errata 16 Sheet and email to the deposing attorney as well as to 17 Veritext at Transcripts-fl@veritext.com and copies will 18 be emailed to all ordering parties. 19 It is suggested that the completed errata be 20 returned 30 days from receipt of testimony, as 21 considered reasonable under Federal rules*, however, 22 there is no Florida statute to this regard. 23 If the witness fails to do so, the transcript may be 24 used as if signed. 25 Yours, Veritext Legal Solutions *Federal Civil Procedure Rule 30(e)/Florida Civil Procedure Rule 1.310(e). Cc: Raymond Nimrod, Esquire Page 189

1 RE: Samsung Bioepis Co. Ltd. v. Regeneron Pharmaceuticals, Inc. 2 Deposition of: Michael Stewart, MD Date: 5/30/24 3 4 E R R A T A S H E E T 5 PAGE____ LINE____ CHANGE_____ 6 _____ 7 REASON_____ 8 PAGE____ LINE____ CHANGE_____ 9 _____ 10 REASON_____ 11 PAGE____ LINE____ CHANGE_____ 12 _____ 13 REASON_____ 14 PAGE____ LINE____ CHANGE_____ 15 _____ 16 REASON_____ 17 PAGE____ LINE____ CHANGE_____ 18 _____ 19 REASON_____ 20 21 Under penalties of perjury, I declare that I have read the foregoing document and that the facts 22 stated in it are true. 23 24 _____ Michael Stewart, MD DATE 25 cc: Raymond Nimrod, Esquire Page 190	

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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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