

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

4 SAMSUNG BIOEPIS CO., LTD.,

5 Petitioner,

Patent No.

10,888,601

6 vs.

7 REGENERON PHARMACEUTICALS, INC.,

Inter Partes

8 Patent Owner.

Review No.

IPR2023-00739

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Hampton Inn Ponte Vedra
1220 Marsh Landing Parkway
Jacksonville Beach, FL 32250
March 29, 2024
8:17 a.m. - 12:56 p.m.

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18 VIDEOTAPED DEPOSITION OF MICHAEL W. STEWART, M.D.

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Taken on behalf of the Petitioner before
Alice J. Teslicko, Registered Professional Reporter,
Registered Merit Reporter, and Notary Public in and
for the State of Florida at Large, pursuant to a
Notice of Taking Deposition in the above cause.

Page 1

1 APPEARANCES:	1 PETITIONER'S EXHIBITS
2 QUINN EMANUEL URQUHART & SULLIVAN, LLP	2 EXHIBIT DESCRIPTION PAGE
3 BY: RAYMOND N. NIMROD, ESQ.	3
4 51 Madison Avenue, 22nd Floor	4 Exhibit 1 Declaration of Michael W. 7
5 New York, NY 10010	5 Stewart, M.D.
6 (212) 849-7000	6 Exhibit 2 U.S. Patent No. 10,888,601 7
7 raynimrod@quinnemanuel.com	7 Exhibit 3 Eylea DME Market Assessment 34
8 Attorneys for the Petitioner	8 Q3 2017
9 MORRISON & FOERSTER, LLP	9 Exhibit 4 Decision granting 84
10 BY: ADAM R. BRAUSA, ESQ.	10 institution of U.S. Patent
11 425 Market Street	11 10,888,601
12 San Francisco, CA 94105	12 Exhibit 5 Final written decision 109
13 (415) 268-6053	13 regarding IRP2022-01226
14 abrausa@mofo.com	14
15 Attorneys for the Patent Owner	15
16 Also Present: Eileen Woo - Regeneron (Via Zoom)	16
17 Cameron Hodges - Videographer	17
18 ---	18
19	19
20	20
21	21
22	22
23	23
24	24
25	25
Page 2	Page 4
1 INDEX	1 THE VIDEOGRAPHER: Good morning. We are now 08:17:31
2 WITNESS PAGE	2 on the record at 8:17 a.m. This is March 29th,
3	3 2024. Please note that this deposition is being
4 MICHAEL STEWART, M.D.	4 conducted in person and virtually. Quality of
5 Direct Examination by Mr. Nimrod 6	5 recording depends on the quality of camera and 08:17:42
6 Certificate of Oath 157	6 internet connection of participants. What is
7 Errata Sheet 160	7 seen from the witness and heard on screen is what
8	8 will be recorded. Audio and video recording will
9	9 continue to take place unless all parties agree
10	10 to go off the record. 08:17:55
11	11 This begins media unit one of the deposition
12	12 of Michael Stewart, taken in the matter of
13	13 Samsung Bioepis Co. Ltd., et al. vs. Regeneron
14	14 Pharmaceuticals, Incorporated. This deposition
15	15 is happening in person at the Hampton Inn 08:18:09
16	16 Jacksonville in Ponte Vedra and online via Zoom.
17	17 My name is Cameron Hodges. I'm the
18	18 videographer. The court reporter is Alice
19	19 Teslicko. We represent Veritext.
20	20 Will counsel please introduce themselves, 08:18:27
21	21 after which would the court reporter please swear
22	22 in the witness. Thank you.
23	23 MR. NIMROD: Ray Nimrod from Quinn Emanuel
24	24 on behalf of petitioner Samsung Bioepis.
25	25 MR. BRAUSA: Adam Brausa from Morrison & 08:18:33
Page 3	Page 5

1 Foerster on behalf of patent owner Regeneron. 08:18:35 2 I'm joined by Eileen Woo remotely from Regeneron, 3 and I'm also here on behalf of the witness. 4 Thereupon: 5 MICHAEL STEWART, M.D. 08:18:44 6 was called as a witness and having been first duly 7 sworn, was examined and testified as follows: 8 THE WITNESS: I do. 9 THE COURT REPORTER: Thank you. 10 DIRECT EXAMINATION 08:18:55 11 BY MR. NIMROD: 12 Q Would you state your name for the record, 13 please? 14 A My name is Michael W. Stewart. 15 Q Dr. Stewart, have you been deposed before? 08:19:01 16 A I have. 17 Q About how many times? 18 A Three or four. 19 Q Okay. In patent cases? 20 A No. 08:19:07 21 Q In what type cases? 22 A They were medical malpractice cases. 23 Q So this is your first patent case? 24 A Correct. 25 Q I'm going to mark as Stewart Exhibit 1 a 08:19:16 Page 6	1 MR. BRAUSA: Just so we're clear, are we 08:20:52 2 going with the middle page number or the bottom 3 right-hand corner page number? 4 MR. NIMROD: Oh, yes, that's a good point. 5 Let's go to the middle one, because that's the 08:21:01 6 page of his expert report. 7 MR. BRAUSA: Sounds good. 8 BY MR. NIMROD: 9 Q Okay. On page three there's a Roman II, 10 "Summary of Opinions." Do you see that? 08:21:10 11 A Yes. 12 Q And the first bullet says: "The plain and 13 ordinary meaning of the challenged claims requires a 14 predetermined dosing regimen." 15 Do you see that? 08:21:22 16 A Yes. 17 Q And that would be your opinion with respect 18 to Claims 10, 18, and 26, correct? 19 A Correct. 20 Q All right. Is there a particular phrase 08:21:29 21 within Claim 10 that you're interpreting to determine 22 that this requires a predetermined dosing regimen? 23 MR. BRAUSA: Objection, form. 24 A So it's not a particular phrase as much as 25 it is the writing of the entire claim. Because it 08:21:50 Page 8
1 copy of your declaration from this IPR proceeding. 08:19:18 2 A Thank you. 3 Q I'd also like to mark as Stewart Exhibit 2 a 4 copy of the patent, the 601 patent. 5 A Thank you. 08:19:50 6 (Whereupon document/items were marked for 7 identification as Petitioner's Exhibits 1 and 2.) 8 BY MR. NIMROD: 9 Q Dr. Stewart, you recognize Exhibit 1 as your 10 declaration? 08:20:04 11 A I do. 12 Q And you provided opinions regarding the 601 13 patent, which is Exhibit 2? 14 A Correct. 15 Q Okay. Can you turn in Exhibit 2 to the 08:20:12 16 claim section, which starts at column 22, which is 17 page 20. 18 A Okay. 19 Q You provided opinions regarding claim 10; is 20 that correct? 08:20:29 21 A That's correct. 22 Q And also claims 18 and 26? 23 A Correct. 24 Q If you could go to your declaration, please, 25 to page three. 08:20:44 Page 7	1 states "comprising intravitreal administration to said 08:21:53 2 patient in an effective amount, which is 2 milligrams, 3 approximately every four weeks" -- so the first five 4 weeks -- "followed by 2 milligrams approximately every 5 eight weeks or once every two months," which to me 08:22:07 6 means predetermined, a predetermined schedule, 7 predetermined intervals. 8 Q Can you turn to the page in Exhibit 2, 9 page 17 in the bottom corner. In Column 16 -- 10 A Yes. 08:22:41 11 Q -- there's a reference to -- strike that. 12 There's an example seven that has a list of 13 dosing regimens, correct? 14 A A list of possible dosing regimens, yes. 15 Q And these are dosing regimens for which 08:22:54 16 there's no data provided as to any test results from 17 patients, correct? 18 MR. BRAUSA: Objection, form. 19 A There's no data provided within the example. 20 Q Is there any data provided elsewhere with 08:23:06 21 respect to the dosing regimens in example seven? 22 A Under example five, there is some data which 23 comes out of the phase two trial, some of which is -- 24 well, let me catch myself, please. 25 So although we have data elsewhere, I don't 08:23:36 Page 9

1 see where that data is the same as what would be 08:23:39 2 listed in example seven, dosing regimens. So that's 3 correct, that data does not apply. So there's no data 4 that I can tell that is associated with example seven. 5 Q When you say example seven, you mean the 08:23:56 6 dosing regimens of example seven, there's no data 7 provided for those regimens? 8 A Not that I can tell. 9 Q By "data", we mean test results on patients, 10 yes? 08:24:06 11 A Correct. 12 Q All right. So if we turn to Column 16, the 13 second one at about line seven refers to VEGFT, 14 2 milligrams, administered by intravitreal injection 15 once every four weeks for the first 16 weeks. 08:24:25 16 So is that a reference to five initial 17 doses? 18 A It is, yes -- let me count them up, but I 19 believe the answer is yes. 20 16, yes, five doses. 08:24:42 21 Q We do that the same way. 22 Okay, and then it says followed by 23 2 milligrams once every eight weeks, correct? 24 A Followed by 2 milligrams -- number seven, 25 yes, 2 milligrams intravitreally once every eight 08:24:55 Page 10	1 patent as to whether these dosing regimens set forth 08:26:11 2 in example seven would be appropriate for DME? 3 MR. BRAUSA: Objection, form. 4 A Can you repeat the question, please? 5 Q Sure. Do you know, is there any teaching in 08:26:21 6 the 601 patent that any of the dosing regimens in 7 example seven would be appropriate for DME? 8 MR. BRAUSA: Objection, form. 9 A So the patent gives you the same regimen as 10 the one you pointed me to in terms of the frequency of 08:26:40 11 the injections, as well as the follow-ups. So that 12 those two are the same. 13 Q Okay. Does the patent teach that the 14 regimen set forth in Column 16, lines seven to ten, is 15 appropriate for DME treatment? 08:26:55 16 MR. BRAUSA: Objection, form. 17 A Well, the patent describes a method for DME 18 treatment. I'm not quite sure what you're meaning by 19 "teaching" that. 20 Q Where does the patent teach that the dosing 08:27:09 21 regimen set forth in example seven at Column 16, lines 22 seven to ten, is appropriate for DME? 23 MR. BRAUSA: Objection, form. 24 A So if we look at number 10, then we find 25 that the patent is a method for treating diabetic 08:27:29 Page 12
1 weeks. 08:25:07 2 Q Now, the dosing regimen that I just directed 3 you to in Column 16, lines seven to ten, does not 4 state whether it's for DME or any other indication, 5 correct? 08:25:17 6 A That's correct. 7 Q And the dosing regimens that are set forth 8 in example seven are intended to be for what types of 9 medications, as you understand it? 10 MR. BRAUSA: Objection, form. 08:25:34 11 A Well, it is not stated what indication it's 12 for. 13 Q So, in your opinion, would all these dosing 14 regimens that are set forth in example seven be 15 suitable for DME treatment? 08:25:43 16 MR. BRAUSA: Objection, form, scope. 17 A There are a lot of them there and I would 18 have to go through each individually to determine if 19 all of them were appropriate for DME. 20 Q Well, you studied the patent, right? 08:25:59 21 A I have. 22 Q And you directed -- I think in your expert 23 report you referred to example seven, correct? 24 A Correct. 25 Q Do you know if there's any teaching in the 08:26:09 Page 11	1 macular edema, five monthly injections followed by 08:27:34 2 injections every eight weeks, which is the same 3 regimen as was listed in example seven. 4 Q Is there any other teaching in the patent 5 other than -- strike that. Let me start over. 08:27:51 6 When you said example 10, did you mean 7 Claim 10? 8 A I'm sorry, Claim 10. Thank you. 9 Q So in your view, Claim 10 teaches that the 10 regimen of example seven in Column 16, lines seven to 08:28:02 11 ten, is appropriate for DME; is that right? 12 A Again, I'm hung up on your term of 13 "teaching." It certainly lists this as a method for 14 treating, and example seven -- line seven also talks 15 about a possible dosing regimen. So they're saying 08:28:28 16 the same thing. 17 I'm hung up on the "teaching" of this. 18 Q Other than Claim 10, is there any teaching 19 in the 601 patent that the dosing regimen in 20 Column 16, line seven to ten, would be appropriate for 08:28:46 21 the treatment of DME? 22 MR. BRAUSA: Objection, form. 23 A Repeat the question, please. 24 Q Other than Claim 10, is there any teaching 25 in the 601 patent that the dosing regimen set forth in 08:29:03 Page 13

1 example seven, Column 16, lines seven to ten, would be 08:29:07 2 appropriate for treatment of DME? 3 MR. BRAUSA: Objection, form. 4 A I'm not aware of anything else in the patent 5 that speaks to the treatment with this regimen for 08:29:21 6 DME. 7 Q And the same would be true for DR; is that 8 correct? 9 A "The same" meaning -- 10 Q The same as if there's no teaching in the 08:29:34 11 patent that the regimen of example seven, Column 16, 12 line seven to ten, would be appropriate for treatment 13 of DR? 14 MR. BRAUSA: Objection, form. 15 A Well, I would say that Claim 18 gives us the 08:29:57 16 similar regimen, and so the answer would be the same. 17 Q Got it, thank you. 18 By the way, what is -- just so it's for the 19 record, when I say "DME", what does that refer to? 20 A Diabetic macular edema. 08:30:16 21 Q And I'm just going to say "DME" throughout 22 the deposition. 23 A Very good. 24 Q And then just for the record, what is "DR"? 25 A Diabetic retinopathy. 08:30:23 Page 14	1 that would be within the scope of Claim 10? 08:32:08 2 MR. BRAUSA: Objection, form, calls for a 3 legal conclusion. 4 A Certainly on its face the schedule -- the 5 predetermined schedule in 16 is the same as the 08:32:23 6 predetermined schedule in line 10 -- or in Claim 10. 7 Q So does that mean that your opinion is that 8 the dosing regimen of Claim 16, lines seven to ten, if 9 practiced by a physician, would fall within the scope 10 of Claim 10? 08:32:46 11 MR. BRAUSA: Counsel, I think you referred 12 to Claim 16. 13 MR. NIMROD: Oh, I'm sorry. Thank you. 14 BY MR. NIMROD: 15 Q Start over again. 08:32:56 16 A Go ahead. 17 Q Is it your opinion that if a physician 18 practiced the dosing regimen in Column 16, lines seven 19 to ten, that would fall within the scope of Claim 10 20 if it was for the treatment of DME? 08:33:05 21 MR. BRAUSA: Objection, form, outside the 22 scope. 23 A Yes, I would think it was within that scope. 24 Q It would necessarily be within the scope? 25 A Yes, I would think it would be. 08:33:28 Page 16
1 Q And then Claim 26 refers to DR in a patient 08:30:25 2 with DME. How should I refer to that? 3 A That was fine. 4 Q What is the difference between DR and DME? 5 A So DR is changes to the retina. So DR is 08:30:41 6 commonly believed to be a vasculopathy of the retina 7 where you see microvascular changes related to 8 diabetes, and it can occur anywhere in the retina, be 9 it the posterior pole, which is where DME exists, or 10 it can be the more peripheral parts of the retina. 08:31:04 11 DME is only confined to the macula; hence 12 the name diabetic macular edema, and specifically it 13 is swelling of the retina in the back center of the 14 eye, the macula. 15 DME may or may not have associated-- I'm 08:31:24 16 sorry, DR may or may not have associated DME. The two 17 can coexist, but they do not necessarily coexist. 18 Q So DME occurs in the central region of the 19 eye, in short terms? 20 A The macula, which is the central region of 08:31:44 21 the retina. 22 Q So let's go back to Column 16 of the 601 23 patent. 24 In Column 16 at lines seven to ten, the 25 dosing regimen I referred you to, is that something 08:32:05 Page 15	1 Q Now, there is another dosing regimen right 08:33:29 2 below the one that we looked at that has five monthly 3 doses, starting at line 11, right? 4 A Yes, I see that. 5 Q So at line 11 through 16 in Column 16 of the 08:33:38 6 patent, the dosing regimen has five initial doses on a 7 monthly basis and then speaks to dosing on a less 8 frequent basis. Do you see that? 9 A Yes. 10 Q Under what circumstances would a physician 08:33:57 11 or other qualified medical professional decide to do 12 dosing on a less frequent basis? 13 MR. BRAUSA: Objection, form. 14 A So there are different treatment strategies 15 that we employ. There are fixed dosing regimens, and 08:34:10 16 the fixed dosing is what we see in lines seven through 17 ten, where it is predetermined an initial number of 18 injections, followed by a predetermined frequency of 19 injections to follow, and that's set up and 20 established right from the beginning and the physician 08:34:30 21 follows it regularly. 22 In your second example, beginning at line 11 23 and going through 16, that's what we call an 24 individualized reactive schedule, where at some point 25 during the treatment the physician is making elective 08:34:53 Page 17

1 assessments of the patient and either treating or not 08:34:58 2 treating based on the way the patient looks. 3 Some people prefer the first example, which 4 is the predetermined regimen. Some people prefer the 5 second, which is more individualized or as needed or 08:35:13 6 prn, and it's individual preference. 7 Q So Column 16 at lines 15 to 16 refers to 8 assessment by a physician or other qualified medical 9 professional to start doing dosing on a less frequent 10 basis. 08:35:37 11 What are the circumstances that would lead a 12 physician to dose on a less frequent basis than 13 monthly after five initial monthly doses? 14 MR. BRAUSA: Objection, form. 15 A So there are lots of circumstances here to 08:35:50 16 discuss and I don't even think I can go through all of 17 them. But there have to be assessments that are done, 18 and in this case it's after the five monthly doses. 19 Assessments usually include visual acuity, 20 both in terms of absolute visual acuity and change 08:36:07 21 from baseline; the swelling or thickness of the 22 retina, which is usually done with our OCT 23 laser-guided machines; the satisfaction of the 24 patient, where are they in terms of the treatment, are 25 they happy or not happy; is this stable, meaning have 08:36:29 Page 18	1 suggests one versus the other or guides a physician to 08:37:54 2 one versus the other. 3 Q So there's no criteria in the 601 patent as 4 to when one would apply a predetermined dosing regimen 5 versus an individualized regimen; is that correct? 08:38:11 6 A That's my understanding, yes. 7 Q So let's go back to Column 16, lines 11 8 to 16, which is one where there's five initial monthly 9 doses and then there is a less frequent dosing, okay. 10 A Yes. 08:38:27 11 Q Now, if a physician using -- strike that. 12 If a physician followed the dosing regimen 13 set forth in Column 16, lines 11 through 16, and gave 14 five initial monthly doses followed by dosing every 15 eight weeks, would that fall within the scope of 08:38:50 16 Claim 10, if it was for the treatment of DME? 17 MR. BRAUSA: Objection, form, calls for a 18 legal conclusion. 19 A It is a different strategy and the reason 20 there's a different strategy is in Claim 10, that's a 08:39:06 21 predetermined regimen. So the physician is not 22 required or even advised to go ahead and make 23 assessments as time goes by. He simply follows the 24 instruction. 25 In our example under Column 16, there's an 08:39:21 Page 20
1 you got progressive improvement over the course of 08:36:33 2 five injections or have you reached a plateau after 3 two or three. 4 So there are lots of different factors that 5 come into play and then are used repeatedly down the 08:36:42 6 road to assess is the patient stable, are they 7 worsening, and if worsening based on any of the 8 factors, including the ones I mentioned, that would 9 probably suggest to the physician another injection is 10 needed. 08:37:00 11 Q What is the criteria that a physician would 12 apply to determine whether or not to use a 13 predetermined dosing regimen versus an individualized 14 regimen? 15 MR. BRAUSA: Objection, form. 08:37:14 16 A Again, much of that is an individual 17 preference for the physician. There's lots of data to 18 support either one of those and it's a matter of 19 individual preference, the patient's desire, and some 20 combination of the two as to which regimen is reached. 08:37:33 21 Q Does the 601 patent teach under what 22 circumstances a physician should use a predetermined 23 dosing regimen versus an individualized regimen? 24 MR. BRAUSA: Objection, form. 25 A I'm not aware of anything in the patent that 08:37:52 Page 19	1 assessment that's done at each month or perhaps at 08:39:24 2 every eight weeks here and then based on the 3 assessment, the patient either gets or does not get an 4 injection. But it's the assessment that drives the 5 injection, not the predetermination. 08:39:38 6 Q You had said Column 16, just to be clear? 7 A Yes. 8 Q Let me ask another question. 9 The regimen in Column 16, lines 11 through 10 16, if a professional physician followed that regimen 08:39:51 11 and gave five monthly doses followed by dosing every 12 eight weeks for treatment of DME, that would not fall 13 within the scope of Claim 10, in your opinion? 14 A In my opinion, that's correct. 15 Q Similarly, if a physician -- oh, strike 08:40:10 16 that. 17 Please read the dosing regimen in Column 16, 18 lines 17 to 22, just to yourself, please. 19 A Okay. 20 Q The dosing regimen in Column 16, lines 17 08:40:39 21 to 22, refers to a dosing regimen where there is an 22 injection every -- let me start that over. 23 The dosing regimen in Column 16, lines 17 24 to 22, includes five initial doses every four weeks 25 followed by prn, correct? 08:41:06 Page 21

1 A Correct. 08:41:09 2 Q And what is "prn", as you understand it? 3 A So it's short for "pro re nata," which means 4 as needed. 5 Q So the dosing regimen in Column 16, lines 17 08:41:17 6 to 22, would be what you refer to as an individualized 7 regimen, correct? 8 A Yes, it would. 9 Q Similarly, the one right above it in 10 Column 16, line 11 to 16, would be an individualized 08:41:28 11 dosing regimen; is that correct? 12 A Correct. 13 Q Now, if a physician practiced the dosing 14 regimen of Column 16, lines 17 to 22, and gave five 15 initial doses four weeks apart and then went to prn 08:41:44 16 and decided to do dosing every eight weeks thereafter, 17 let's say for two years, to treat DME, would that fall 18 within the scope of Claim 10? 19 MR. BRAUSA: Objection, form. 20 A Well, I don't agree with your question, 08:42:04 21 because he would not agree to do every eight weeks, 22 because the prn applies that it is individually based 23 and it's -- it's individually assessed at each visit. 24 So he would not make that decision up front. 25 He would make the decision at every visit, to treat or 08:42:23 Page 22	1 MR. NIMROD: I appreciate that, actually. 08:43:57 2 (Discussion off the record.) 3 BY MR. NIMROD: 4 Q You ready? 5 A Go ahead. 08:44:15 6 Q So it is your opinion that if a physician 7 followed the dosing regimen in Column 16, lines 17 to 8 22, and gave five initial doses every four weeks and 9 then following prn for the next year and a half gave 10 doses every eight weeks for the treatment of DME, that 08:44:33 11 would not fall within the scope of Claim 10, correct? 12 MR. BRAUSA: Objection, form. 13 A Correct, I agree. 14 Q The dosing regimens in example seven -- let 15 me start over. There appear to be 20 dosing regimens 08:45:12 16 set forth in example seven; is that right? 17 A I would have to count them. 18 Q Please do. 19 A Please do? Okay, I count 20. 20 Q Thank you. And there are some dosing 08:45:35 21 regimens set forth in example seven where there are 22 three initial monthly doses; is that right? 23 A That's correct, which leads me back to an 24 earlier question of yours. If I remember the 25 question, it is do any of the regimens in example 08:45:53 Page 24
1 not to treat. 08:42:26 2 Q That's helpful. Let me reframe the question 3 then. If a physician decided to practice the regimen 4 of Claim 16, line 17 to 22, and gave five initial 5 doses every four weeks and then following prn for the 08:42:42 6 next, let's say, year and a half gave dosing every 7 eight weeks for treatment of DME, would that fall 8 within the scope of Claim 10? 9 MR. BRAUSA: Objection, form. 10 A For the same reason that I answered 11 08:43:00 11 through 16, as the assessments are made, the 12 injections are given based on assessment. 13 That differs from the claim, which is 14 predetermined, and the injections are five followed by 15 every eight weeks regardless of the response of the 08:43:16 16 patient. 17 So I would say no, it does not. 18 Q Okay. So your opinion is that if a 19 physician followed the dosing regimen of Claim 16, 20 lines 17 to 22, gave five initial doses every four 08:43:28 21 weeks and then followed by prn eight-week dosing, that 22 would not fall within the scope of Claim 10, if it was 23 for the treatment of DME? 24 MR. BRAUSA: Objection. You said Claim 16. 25 I know you meant that. 08:43:57 Page 23	1 seven -- are any of them supported by data in the 08:45:57 2 patent application. I believe that was one of your 3 original questions. 4 Q That's correct. 5 A So the regimens that talk about once every 08:46:07 6 four weeks for the first eight weeks are three loading 7 doses, followed by 2 milligrams once every eight 8 weeks. That is something that we see on page 16, 9 Column 14, Table 2. 10 Q You said page 16? 08:46:43 11 A Yeah, page 16. 12 Q And then what? 13 A Column 14. 14 Q Oh, Table 2? 15 A Table 2. 08:46:50 16 Q All right. So there is data for which 17 dosing regimen of example seven? 18 A So the example seven, the first one, 19 2 milligrams intravitreally every four weeks. When 20 you look at Table 2, that is the third example, laser. 08:47:12 21 Then 0.5-milligram monthly and 2 milligram monthly. 22 That is 2 milligrams monthly. 23 The next one on example seven is one 24 injection every four weeks for the first eight weeks, 25 followed by 2 milligrams every eight weeks. That is 08:47:33 Page 25

1 the fourth one on Table 2. And then the fourth one 08:47:36 2 under example seven is the same as the fifth one on 3 Table 2. 4 Q Okay, thank you. 5 Is there any data for any of the dosing 08:48:02 6 regimens, other than the three that you just mentioned 7 in example seven? 8 MR. BRAUSA: Objection, form. 9 A You're speaking of data within the patent? 10 Q Yes. 08:48:20 11 A And you're speaking, of course, of VEGF-Trap 12 or aflibercept? 13 Q That's correct. 14 While you're looking, all of the regimens 15 set forth in the 601 patent are for aflibercept, as 08:48:34 16 you understand it, correct? 17 A That's right, yes. 18 The one, two, three -- the third one down 19 under example seven is -- though by different wording, 20 is essentially a prn protocol as well. So the third 08:48:53 21 and fourth are both prn that follow the same regimens. 22 Q Okay. The next one, two, three regimens 23 speak to an injection once every four weeks for the 24 first 12 weeks. Which would be four initial loading 25 doses; is that right? 08:49:17 Page 26	1 20 weeks. Do you see that? 08:50:36 2 A Uh-huh, correct. 3 Q And there's no data -- that would be six 4 initial loading doses, correct? 5 A That would be correct. 08:50:45 6 Q And there's no data in the patent with 7 respect to dosing regimens where there is six initial 8 loading doses, correct? 9 MR. BRAUSA: Objection, form. 10 A None that I'm aware of. 08:50:59 11 Q And then the rest of the regimens in example 12 seven speak to -- well, strike that. 13 The next six dosing regimens in Column 16, 14 lines 38 to 67, refer to injections once every four 15 weeks for the first 24 weeks or once every four weeks 08:51:20 16 for the first 28 weeks; is that right? 17 MR. BRAUSA: Objection, form. 18 A That is correct. 19 Q And that would be seven or eight initial 20 monthly loading doses; is that right? 08:51:37 21 A Correct. 22 Q And there's no data in the patent with 23 respect to any regimens where there is six or seven -- 24 excuse me, seven or eight -- yeah, seven or eight 25 initial monthly loading doses, correct? 08:51:55 Page 28
1 A That would be correct. 08:49:18 2 Q Is there any data in the patent for those 3 regimens? 4 MR. BRAUSA: Objection, form. 5 A I'm not aware of any data in the patent that 08:49:25 6 has four monthly injections at the beginning. 7 Q And the next ones, of the ones we looked at, 8 which are an injection every four weeks for the first 9 16 weeks, would be five initial loading doses, 10 correct? 08:49:43 11 A I'm sorry, say that again. 12 Q Going to Column 16, the next four are all 13 ones where there's an injection every four weeks for 14 the first 16 weeks, which would be five initial 15 loading doses, right? 08:49:55 16 A Starting at line seven, yes. 17 Q And for those regimens, with five initial 18 loading doses, there's no data in the patent, correct? 19 MR. BRAUSA: Objection, form. 20 A I'm not aware of any data in the patent that 08:50:06 21 talks about the results from five monthly injections 22 at the beginning. 23 Q All right. So then the next dosing regimens 24 in example seven and Column 16 at lines 23 to 38 speak 25 to injections once every four weeks for the first 08:50:33 Page 27	1 MR. BRAUSA: Objection, form. 08:51:58 2 A None that I'm aware of. 3 Q Does that patent teach anywhere that the 4 dosing regimen of Column 16, lines seven to ten, where 5 there are five initial monthly doses followed by 08:52:12 6 injections once every eight weeks, is superior to any 7 of the other regimens? 8 MR. BRAUSA: Objection, form, scope. 9 A I'm not aware of anything in the patent that 10 says that's a superior regimen to anything else. 08:52:33 11 Q Does that patent teach anywhere that the 12 dosing regimen in Column 16, lines seven to ten, would 13 provide any unexpected results? 14 MR. BRAUSA: Objection, form, scope, and 15 calls for a legal conclusion. 08:52:48 16 A We don't have data from the beginning to 17 know what results we would get. So in a sense, 18 anything that comes out of that when we subsequently 19 do the trial, you have a degree of expectation but you 20 never know for sure. So is it unexpected, sure, 08:53:10 21 because you're predicting. 22 Q So going back to Claim 10, is there any data 23 in the patent that would suggest that the method of 24 Claim 10 would provide superior results compared to 25 other methods taught in the 601 patent? 08:53:37 Page 29

1 MR. BRAUSA: Objection, form, scope. 08:53:40 2 A Not that I'm aware of. 3 Q Is the same true with respect to Claims 18 4 and 26? 5 MR. BRAUSA: Same objection. 08:53:49 6 A Once again, not that I'm aware of. 7 Q Is there anything that would suggest that 8 the method of Claims 10, 18, or 26 would provide any 9 unexpected results? 10 MR. BRAUSA: Objection, form, scope. 08:54:03 11 A Once again, without testing you're never 12 sure of what the results are going to be. So I would 13 have to say by definition, they're unexpected. You 14 can make a guess at it, but you can't have an 15 expectation. 08:54:18 16 Q But the patent then doesn't teach one way or 17 the other whether you're going to get good or bad 18 results for the Claims 10, 18, and 26, correct? 19 MR. BRAUSA: Objection, form, scope. 20 A So if you look at the claims, no. But if 08:54:30 21 you look at the rest of the patents, then at least 22 there's data in there to suggest that this regimen 23 would make sense. 24 Q This regimen being the one of Claims 10, 18, 25 and 26, where you start with five monthly doses and 08:54:46 Page 30	1 Q The fourth one down that you're referring 08:56:30 2 to -- 3 A Yes. 4 Q -- is a reference to three initial monthly 5 doses, that's for the first eight weeks, and then it's 08:56:38 6 followed by dosing every eight weeks? 7 A That is correct. 8 Q So what you were referring to as 9 providing -- strike that. 10 Are you saying that the data in Table 2, 08:56:53 11 providing for three initial monthly doses followed by 12 dosing every eight weeks, would support some 13 conclusion with respect to whether the regimen of 14 Claim 10 would make sense? 15 MR. BRAUSA: Objection, form. 08:57:09 16 A Yeah, I would -- I'm not sure about your 17 wording. I would say that the data out of Table 2 18 supports the idea of pursuing a regimen like that in 19 Claim 10 in a prospective study. It's worth pursuing. 20 Q In sticking with the 601 patent again, 08:58:01 21 example seven includes these 20 dosing regimens, 22 including the one that is for Claim 10, and then what 23 follows is a discussion of variations in Column 17. 24 Do you see that? It's in line nine. 25 A I'm sorry -- 08:58:31 Page 32
1 then you go to eight-week dosing? 08:54:53 2 A Well, we'll say certainly for 10, because 3 that's where we're dealing with DME and that's where 4 we have the most data for comparison sake. 5 Q So what data in the 601 patent would suggest 08:55:02 6 that -- okay, you said that I think for at least 7 Claim 10, there's data in the patent to suggest that 8 the regimen in Claim 10 would make sense? 9 A Yes. 10 Q What is the data in the 601 patent that 08:55:33 11 would suggest that the regimen of Claim 10, where 12 there's five initial monthly doses followed by 13 eight-week dosing, would make sense? 14 A So the data listed in Table 2. 15 Q What is the data in Table 2? 08:55:58 16 A I'm referring to the fourth one down, 17 VEGF-Trap, 2 milligrams every eight weeks. 18 Q VEGF-Trap every eight weeks -- strike that. 19 The entry says VEGF-2 -- 20 A Let me qualify that, because that's actually 08:56:20 21 not a complete "right". The table is incomplete the 22 way it's written. 23 Q Let me just -- I was going to try and 24 clarify that. 25 A Okay, yeah. 08:56:30 Page 31	1 Q Column 17. 08:58:33 2 A Column 17, yeah. Line nine, okay, yeah. 3 Q Now, you've studied the patent, as you said, 4 right? 5 A Uh-huh. 08:58:40 6 Q Yes? 7 A Yes. 8 Q And it starts off in Column 17, line nine: 9 "Variations on the above-described dosing 10 regimens would be appreciated by persons more skilled 08:58:51 11 in the art and are also within the scope of the 12 present invention." Do you see that? 13 A I see that. 14 Q And the "above-described dosing regimens" 15 would refer to the dosing regimens that are listed in 08:59:06 16 example seven, correct? 17 A I would take that as being 18 "above-described", yes. 19 Q And then it goes on and says in Column 17, 20 line 11: 08:59:21 21 "For example, the amount of VEGFT and/or 22 volume of formulation administered to a patient may be 23 varied based on patient characteristics, severity of 24 disease, and other diagnostic assessments by a 25 physician or other qualified medical professional." 08:59:42 Page 33

1 Do you see that? 08:59:45 2 A I see that. 3 Q Does that suggest that the regimen in 4 Column 16, lines seven to ten, can be varied? 5 MR. BRAUSA: Objection, form. 08:59:56 6 A Well, it says that you can vary any of the 7 ones that are there, is what my understanding is. 8 Q Including the one in Column 16, lines seven 9 to ten? 10 A You already have those as other options. 09:00:07 11 They're there, so yes. 12 Q Let me mark as Stewart Exhibit 3 a document 13 that is Exhibit 2156. 14 (Whereupon a document/item was marked for 15 identification as Petitioner's Exhibit 3.) 09:00:53 16 A Thank you. 17 Q Dr. Stewart, have you ever seen -- well, 18 take a moment just to flip through the document. 19 A Thank you. 20 Q Thank you. My question is whether you've 09:01:11 21 seen the document before. 22 A No. 23 Q I thought you might have figured that out. 24 A I've not seen this before. 25 Q Okay. So a question for you -- 09:05:02 Page 34	1 A That's correct. 09:06:39 2 Q So there's codes that are in color to the 3 left of that. Do you see that? 4 A Yes. 5 Q Just so DME -- strike that. 09:06:47 6 What do you understand "centrally involved 7 DME" to mean? 8 A So DME is swelling of the retina in the 9 macula. Centrally involving means the swelling 10 extends to the very center of the macula. 09:07:01 11 Q And that's true for all DME, as you stated 12 earlier, right? It's centrally involved? 13 A Well, it's involving the macula, yes, 14 correct. 15 Q Which means it's centrally involved? 09:07:12 16 A Not necessarily, because the macula is an 17 area. So any swelling within the macula is DME. When 18 that swelling extends to the center, then it's 19 center-involving DME. 20 Q Okay, got it. And are most patients 09:07:26 21 centrally involved or are most not centrally involved, 22 or do you know? 23 MR. BRAUSA: Objection, form. 24 A Most at the time they are diagnosed are not 25 centrally involved. 09:07:39 Page 36
1 A Go ahead. 09:05:04 2 Q Have you ever been the subject of a survey 3 that folks at Regeneron were doing for Eylea? 4 A I have not. 5 Q So let's turn, if we could, to page 22 of 09:05:15 6 the document, please. Actually, sorry, the title of 7 this document, if we go back to page one, is the "DME 8 Market Assessment Q3 2017"? 9 A Correct. 10 Q By Q3 2017, had the dosing regimen for DME 09:05:35 11 of five initial doses, followed by eight-week 12 dosing -- five initial monthly doses, followed by 13 eight-week dosing, been approved in part of the label? 14 MR. BRAUSA: Objection, form. 15 A For aflibercept, yes. 09:05:56 16 Q So then if we go to page 22, there's a chart 17 on the left side that is entitled "Centrally Involved 18 DME Anti-VEGF Treated Eyes." Do you see that? 19 A Yes. 20 Q Below that it says "Percent Receiving Dosing 09:06:20 21 Schedule." Do you see that? 22 A Yes. 23 Q And for Eylea, there's -- strike that. 24 The Eylea patients or product is in the 25 third bar; is that right? 09:06:35 Page 35	1 Q So for the centrally involved DME there is a 09:07:41 2 gray bar that says "monthly dosing throughout." 3 Do you see that? 4 A Yes. 5 Q "Monthly dosing throughout" would not fall 09:07:48 6 within the scope of Claim 10, correct? 7 A That's correct. 8 Q Then the next bar -- by the way, that's 9 eight percent, correct? 10 A Correct. 09:07:59 11 Q Okay. Now, the next bar is 59 percent for 12 Eylea, right? 13 A Yes. 14 Q And that's -- 15 A You're talking about the light blue going 09:08:06 16 down? 17 Q Light blue, correct. And that light blue is 18 monthly until dryness attained, then T&E. 19 Do you see that? 20 A Yes. 09:08:15 21 Q Great. What does it mean "until dryness 22 attained"? 23 MR. BRAUSA: Objection, form. 24 Just a standing objection to the use of this 25 document. He testified he hasn't seen it and 09:08:22 Page 37

1 you're asking him to interpret charts. 09:08:24 2 A So until dryness is attained, which means 3 you have no obvious pockets of intra or subretinal 4 fluid. And generally, if you have a retina that is 5 thin -- and it varies by definition -- below 300 or 09:08:39 6 325 microns is usually accepted as dryness, consistent 7 with dryness. 8 Q And what is the relevance of dryness to 9 treatment of a patient with DME? 10 A The dryness suggests that you're not going 09:09:00 11 to get any further anatomic improvement by injecting 12 frequently, and so at that point it can be considered 13 to inject less frequently. 14 Q Okay. You at least once or twice in this 15 deposition, maybe more, you used the phrase "loading 09:09:21 16 dose." 17 A Yes. 18 Q What does it mean to be a loading dose? 19 A So to me, loading dose is a series of 20 injections, and it varies from disease to disease. It 09:09:29 21 may even vary from patient to patient. But it's a 22 series of injections at the beginning to get the 23 disease under control. 24 Q Is the criteria for the number of loading 25 doses if it's individualized to wait for dryness to be 09:09:47 Page 38	1 A The green going down, yes. 09:11:22 2 Q And that says "monthly until dryness 3 attained, then prn," right? 4 A Correct. 5 Q And a treatment regimen of monthly until 09:11:30 6 dryness attained then prn is individualized and 7 therefore does not fall within the scope of Claim 10, 8 in your view, correct? 9 MR. BRAUSA: Objection, form. 10 A Correct. 09:11:42 11 Q And that would be true whether or not the 12 physician used five monthly loading doses and then by 13 prn went to eight -- every eight weeks by examining 14 the patient every eight weeks; is that right? 15 MR. BRAUSA: Objection, form. 09:11:57 16 A Restate the question, please, for clarity. 17 Q I'm going to strike that. You've already 18 given the answer anyway. 19 A Okay. 20 Q The next one is -- oh, the one that says -- 09:12:06 21 sorry, let me strike that. 22 There is now a color that's sort of an 23 orange-ish color that is four percent for Eylea. 24 Do you see that? 25 A Yes, I see that. 09:12:18 Page 40
1 attained? 09:09:51 2 MR. BRAUSA: Objection, form. 3 A There are several criteria. That would be 4 one of them. 5 Q What are the other ones? 09:09:57 6 A Visual acuity of 20/20, stability of vision, 7 or stability of fluid where further injections -- 8 further frequent injections are thought not to have 9 further improvement. 10 Q Once you decide that there is -- dryness is 09:10:14 11 attained -- well, strike that. Let me stick with the 12 chart. 13 It says "then T&E." Does the phrase "T&E" 14 have any meaning to you? 15 A "T&E" means treat and extend. 09:10:28 16 Q So 59 percent of the physicians were using 17 monthly until dryness attained, then T&E, correct? 18 MR. BRAUSA: Objection, scope. 19 A In this survey it lists 59 percent. 20 Q And the method of using monthly until 09:11:01 21 dryness attained, then T&E for DME treatment, would 22 not fall within the scope of Claim 10, correct? 23 A That is correct. 24 Q Then the next entry in the green bar for 25 Eylea is 24 percent, correct? 09:11:20 Page 39	1 Q And then it says "immediate prn without 09:12:19 2 initial monthly dosing." Do you see that? 3 A Yes. 4 Q And that would be, again, not within the 5 scope of Claim 10 for the treatment of DME, right? 09:12:27 6 MR. BRAUSA: Objection, form. 7 A That would be correct. 8 Q Then the next says "immediate treatment 9 extended without monthly dosing." That's like a dark 10 blue, right? 09:12:39 11 A Yes. 12 Q And that's three percent? 13 A Correct. 14 Q And that again is not within the scope of 15 Claim 10, in your view, correct? 09:12:44 16 MR. BRAUSA: Objection, form. 17 A That's correct. 18 Q And then there's another, I guess little 19 darker gray bar, which has no number on it. 20 Do you see that? 09:12:55 21 A Yeah, I see that. 22 Q And it says "other schedule," right? 23 A It says "other schedule." 24 Q And you don't know what "other schedule" 25 would be, I assume; is that right? 09:13:04 Page 41

1 A Correct. 09:13:06 2 MR. BRAUSA: I'll just object to a 3 mischaracterization of the document. There's a 4 dark gray at eight percent and a light gray shown 5 on the bottom in Eylea. I think you mixed those 09:13:13 6 up. 7 BY MR. NIMROD: 8 Q Dr. Stewart, did you provide any opinion 9 or -- strike that. Let me start over again. 10 Do you provide any data in your expert 09:13:44 11 report of any physicians that practice the method of 12 Claim 10; that actually practice it? 13 MR. BRAUSA: Objection, form. 14 A Did I provide data? 15 Q Yes. Well, let me give you some context. 09:13:57 16 Here we have a survey that Regeneron conducted or has 17 conducted -- 18 A Yes. 19 Q -- that asked physicians how do you 20 actually treat your patients for DME, right? 09:14:08 21 A Correct. 22 Q And none of these responses include a 23 statement that says a predetermined dosing regimen 24 according to five initial doses and then going to 25 monthly doses and then going to every eight weeks on a 09:14:25 Page 42	1 Is that set forth in your expert report 09:15:26 2 anywhere? 3 MR. BRAUSA: Objection, form. 4 A No. 5 Q So you've given no opinion in your expert 09:15:35 6 report that any physician has ever followed Claim 10, 7 correct? 8 MR. BRAUSA: Objection, form, outside the 9 scope. 10 A Right, I don't recall anything in the report 09:15:42 11 that says that. 12 Q So could you go to your expert report at 13 Stewart Exhibit 1, please. And if you'd go to 14 page 92, please. 15 There's a section that's Roman XIV entitled 09:16:20 16 "Commercial Success." Do you see that? 17 A Yes. 18 Q You state in paragraph 178, "I understand 19 that when considering obviousness, the commercial 20 success of a patent can be an indicator that the 09:16:45 21 claims are less obvious." 22 Do you see that? 23 A Yes. 24 Q And then you go on in the same paragraph and 25 say, "I understand that in order for commercial 09:16:55 Page 44
1 predetermined basis, right? 09:14:28 2 MR. BRAUSA: Objection, form, scope, and 3 mischaracterizes the document. 4 BY MR. NIMROD: 5 Q There's no entry for that, is there? 09:14:33 6 A Well, we don't know what "other schedule" 7 means. But beyond "other schedule," I don't see an 8 entry for that. 9 Q And you don't know what "other schedule" 10 means anyway. You told me that, right? 09:14:46 11 A Correct. 12 Q So here we have some data for what some 13 doctors are doing for centrally involved DME, right? 14 A Correct. 15 Q So my question was, did you provide any data 09:14:55 16 in your expert report as to any physicians that 17 practice Claim 10 in accordance with the way you 18 interpret it, which is a predetermined regimen? 19 Did you provide any data in your expert 20 report? 09:15:12 21 MR. BRAUSA: Objection, form. 22 A No, I did not. 23 Q Did you provide any opinion as to the number 24 of physicians -- or any physicians that practice 25 Claim 10, as you interpret it? 09:15:23 Page 43	1 success to be considered, there must be a nexus 09:16:59 2 between the claims and the product such that the value 3 of the product is derived from the patent it 4 features." 5 Do you see that? 09:17:12 6 A Yes. 7 Q Then you say, "It is my opinion that Eylea 8 embodies the claims of the 601 patent and that the 9 claim features have contributed to the commercial 10 success of Eylea." 09:17:23 11 Do you see that? 12 A Yes. 13 Q Before we go on, you also provided no data 14 or opinion as to any physicians that actually practice 15 the methods of Claims 18 and 26 as you interpret them, 09:17:33 16 to require a predetermined dosing regimen, correct? 17 A That's correct. 18 Q Okay. Now, going back to paragraph 178 of 19 your expert report, you say, "It is my opinion that 20 Eylea embodies the claims of the 601 patent." 09:17:52 21 Do you see that? 22 A Yes. 23 Q What do you mean that -- strike that. 24 Eylea is a product, right? 25 A Correct. 09:18:02 Page 45

1 Q And as we've seen in Stewart Exhibit 3, 09:18:04 2 Eylea can be used in many different ways, right? 3 Well, strike that. It's not many different 4 ways, is it. 5 So as we saw in Stewart Exhibit 3, Eylea can 09:18:20 6 be used to treat centrally involved DME following 7 monthly dosing throughout. It can be used monthly 8 until dryness and T&E and then monthly dryness until 9 prn, etc., right? 10 A I don't like the "etc.", but okay. The ones 09:18:39 11 you've stated, yes. 12 Q It also could include immediate prn and 13 immediate treat and extend, right? 14 A It can. 15 Q So when you said "Eylea embodies the claims 09:18:53 16 of the 601 patent," you would agree that Eylea, as 17 you're saying, would embody treatment outside the 18 claims. For example, the ones I just read, right? 19 A It would include those things as well. 20 The important thing here is that the claims, 09:19:14 21 which was followed up by the clinical data, showed 22 that Eylea had an extended duration of action, which 23 was something that had never been seen before, and the 24 five loading doses followed by the Q8 weeks was the 25 first time we saw that, and for nearly 10 years was 09:19:32 Page 46	1 the 601 patent? 09:20:47 2 A Right. 3 Q Eylea is a product, not a method, right? 4 A Well, the patent is for a method. 5 Q Right. So you're saying Eylea embodies a 09:20:55 6 method? 7 A I think we're getting to a legal question 8 that I'm not sure I -- 9 Q I just want to understand your opinion. 10 You say, "It is my opinion that Eylea" -- 09:21:05 11 which is a product -- "embodies the claims of the 601 12 patent," which are method claims, right? 13 A Well, Eylea as used as -- with the claim, 14 gives an excellent result. To me that's what that 15 means. 09:21:22 16 Q But you're not aware of any physician -- 17 strike that. 18 You gave no opinion that any physician 19 actually practices that method, right? 20 MR. BRAUSA: Objection, form. 09:21:28 21 A In the declaration I did not. 22 Q In paragraph 186, if you go there, and in 23 Section D, "Commercial Success of Eylea," you state: 24 "Eylea has achieved widespread commercial 25 success due to its impressive medical efficacy and 09:21:57 Page 48
1 the only time we had something that worked well with 09:19:36 2 extended dosing more than monthly. 3 Physicians grabbed that and physicians said 4 we have a drug that lasts longer. We're going to 5 decide how to use it. 09:19:50 6 But that was the message that came out of 7 the claims, supported by the clinical data, was the 8 extended duration. 9 Q The clinical data is what was done from 10 these clinical studies you're referring to, right -- 09:20:02 11 A Correct. 12 Q -- to get approval? 13 A Correct. 14 Q And just to be clear, when I asked you the 15 questions about whether any physicians actually 09:20:09 16 practiced Claims 10, 18, and 26, I was referring to 17 other than the clinical studies. 18 You understood that? 19 A Yes. No, yes, I understand. 20 Q But just to be clear, those other methods of 09:20:28 21 treatment for DME that I mentioned, prn, T&E, they 22 also embody -- Eylea also embodies those methods, 23 correct? 24 A I'm not sure I understand the question. 25 Q Well, you say Eylea embodies the claims of 09:20:43 Page 47	1 ability to treat patients on a less frequent, easier 09:22:01 2 to follow dosing -- less frequent, easier to follow 3 dosing regimens." 4 Do you see that? 5 A Yes. 09:22:12 6 Q That widespread success does not necessarily 7 mean anything with respect to Claim 10, correct? 8 MR. BRAUSA: Objection, form. 9 A Once again, Claim 10 and the data that 10 supports Claim 10 told physicians that this is a 09:22:25 11 product that has impressive durability, better than 12 we've seen with any other product so far. 13 So that concept is what physicians then 14 took, and some of them -- many of them -- changed 15 that. But they included the durability concept 09:22:42 16 because that's what drew them to the product. 17 Q The durability concept you're referring to 18 can be applied using the methods that are outside of 19 Claim 10, including the ones that we mentioned 20 before -- monthly until dryness attained and then T&E, 09:23:01 21 monthly until dryness attained and then prn, immediate 22 prn and immediate T&E, right? 23 A So all of those regimens work with good 24 durability. 25 Q So the answer is yes? 09:23:22 Page 49

1 MR. BRAUSA: Objection, form. 09:23:23 2 Q That's fine. Withdraw that. 3 A Okay. 4 MR. NIMROD: Take a break now? 5 MR. BRAUSA: Yeah. 09:23:37 6 THE VIDEOGRAPHER: We are off the record at 7 9:23 a.m. 8 (Whereupon a recess was taken from 9:23 a.m. 9 to 9:38 a.m.) 10 THE VIDEOGRAPHER: This begins media unit 09:38:45 11 two. We are back on the record at 9:38 a.m. 12 BY MR. NIMROD: 13 Q Could you turn to pages three to four again 14 of Stewart Exhibit 1, which is your expert 15 declaration. 09:38:58 16 A Okay. 17 Q So on page three, first bullet, you state 18 that: "The plain and ordinary meaning of the 19 challenged claims requires a predetermined dosing 20 regimen," right? 09:39:13 21 A Correct. 22 Q And then your second bullet says: "The 23 plain and ordinary meaning of the challenged claims 24 required both one, an intent to treat a specific 25 angiogenic disorder; and two, treating the angiogenic 09:39:24 Page 50	1 bullet says: "The dosing regimen in the challenged 09:40:39 2 claims of the 601 patent is not obvious over the 2009 3 press release, either alone or in combination with 4 Shams." 5 Do you see that? 09:40:53 6 A Yes. 7 Q Your second bullet is: "The dosing regimen 8 is not obvious over the 2009 press release, in view of 9 element 2010." 10 Do you see that? 09:41:02 11 A Yes. 12 Q Are all of your obviousness opinions based 13 on your interpretation of the challenged claims as 14 requiring a predetermined dosing regimen? 15 A Yes. 09:41:13 16 Q And are all of your obviousness opinions 17 regarding the 601 patent based on your interpretation 18 that the plain and ordinary meaning of the claims 19 requires both an intent to treat a specific angiogenic 20 disorder and treating the angiogenic disorder with a 09:41:29 21 level of efficacy comparable to monthly Lucentis or 22 Avastin? 23 A Yes. 24 Q On page three, again, the second bullet 25 talks about a level of efficacy comparable to monthly 09:41:55 Page 52
1 disorder with a level of efficacy comparable to 09:39:28 2 monthly Lucentis or Avastin." 3 How do you pronounce that? 4 A Avastin. 5 Q Avastin, excuse me. 09:39:39 6 Then your next bullet -- actually, the 7 bottom bullet we've already kind of talked about. It 8 says on page four, last bullet above Roman III: 9 "Eylea embodies the claims of the 601 patent 10 such that there is a nexus between the 601 patent and 09:39:54 11 the commercial success of Eylea." 12 Do you see that? 13 A Yes. 14 Q When you say a "nexus between the patent," 15 are you referring to the asserted claims or you're 09:40:06 16 referring to the patent in general? 17 A I'm referring to the claims. 18 Q Claims 10, 18, and 26? 19 A Correct. 20 Q When you gave an opinion regarding the nexus 09:40:18 21 and commercial success, were you applying your claim 22 construction regarding the plain and ordinary meaning 23 of the challenged claims? 24 A Yes. 25 Q Okay. Going back to page four, the first 09:40:36 Page 51	1 Lucentis or Avastin. 09:42:00 2 How do you pronounce that again? 3 A Avastin, Avastin. 4 Q I'll know that by trial. 5 What is the level of efficacy required to be 09:42:18 6 comparable to monthly Lucentis or Avastin? 7 A So it's the data that existed at the time 8 that was in the literature that was accrued with 9 trials that did monthly Avastin and Lucentis. 10 Q But what is the data? What's the level of 09:42:43 11 efficacy? 12 A Oh, the level of efficacy? 13 Q Yeah. 14 A Is roughly eight letters of visual acuity 15 improvement. 09:42:52 16 Q So you're saying that to fall within the 17 scope of the challenged claims, a patient would need 18 to -- strike that. 19 You're saying that in order to practice the 20 method of Claims 10, 18, and 26, a patient would need 09:43:01 21 to achieve roughly eight levels of visual acuity 22 improvement to fall within the scope of the claims? 23 MR. BRAUSA: Objection, form, scope. 24 A It would be the eight letters of visual 25 acuity improvement, roughly, and that would define the 09:43:26 Page 53

1 effective amount as in the claims. 09:43:30 2 Q So if a patient did not obtain roughly eight 3 levels of visual acuity improvement after receiving 4 the doses specified for DME treatment in Claim 10, 5 that patient would not be practicing the method of 09:43:51 6 Claim 10? 7 MR. BRAUSA: Objection, form and outside the 8 scope. 9 BY MR. NIMROD: 10 Q I think I should rephrase it anyway. 09:44:00 11 If a physician treated a patient using the 12 dosing regimen in Claim 10 for treatment of DME, but 13 the patient did not achieve eight levels of 14 improvement in visual acuity, then that treatment 15 would not follow within the scope of Claim 10; is that 09:44:18 16 right? 17 MR. BRAUSA: Objection, form. 18 A So we're looking at averages and because 19 there is wide variability amongst the way patients 20 respond. Some patients get eight letters, some 09:44:31 21 patients get zero, some get 20, and that's true of all 22 of the anti-VEGF drugs for the treatment of DME. So 23 when we say effective, we're meaning on average, 24 patients need this in order for this to work. 25 Q So when you say -- strike that. 09:44:54 Page 54	1 letters, on average, correct. 09:46:00 2 Q Thank you. When you say "on average," what 3 do you mean by that? 4 A So on average is usually simply a mean of 5 all of the -- a mean of all of the patients in the 09:46:11 6 study. When you look at their delta, the number of 7 letters improved, average them together, that's your 8 average. It's the mean. 9 Q So if I were a physician and I treated, 10 let's say 50 patients, using the regimen set forth in 09:46:28 11 Claim 10 for DME and my average improvement in visual 12 acuity for my patients was, let's say four letters, 13 would I be practicing the method of Claim 10? 14 MR. BRAUSA: Objection, form, and outside 15 the scope. 09:46:50 16 A Well, you're practicing the method outlined, 17 which is the five injections followed by the Q8 weeks, 18 but you're going to get variability. It's going to 19 happen in all practices. It's going to happen amongst 20 all patients. 09:47:08 21 Q But you said "the plain and ordinary meaning 22 of the claim requires both an intent to treat a 23 specific disorder and treating the disorder with a 24 level of efficacy comparable to monthly Lucentis or 25 Avastin," right? 09:47:27 Page 56
1 Could you just give me a little bit more of 09:44:57 2 an explanation about the eight levels of visual 3 acuity? 4 A Eight letters. 5 Q Letters? 09:45:05 6 A Letters. 7 Q Okay, so eight letters of visual acuity -- 8 A Visual acuity improvement. 9 Q So your view is that -- I think I've been 10 saying it wrong. Your view is that the level of 09:45:12 11 efficacy required for Claims 10, 18, and 26 is that on 12 average, there's an improvement of about eight letters 13 of visual acuity? 14 A So certainly not for 18, for Claim 18. 15 Q Okay. 09:45:31 16 A That's a different story. 17 Q Let's stick with Claim 10 then. 18 A Let's stick with Claim 10, okay. 19 Q I'll rephrase it. 20 So your opinion is for Claim 10, the level 09:45:38 21 of efficacy required is about eight letters of 22 improvement in visual acuity, on average, for the 23 patient population? 24 A On average. That the drug with the treated 25 regimen needs to produce an improvement about eight 09:45:57 Page 55	1 A But it doesn't require that for every 09:47:28 2 physician treating every group of patients. It means 3 that in studies across data, that you need to have 4 that average. Otherwise it's not going to be 5 effective. It's not going to meet the efficacy 09:47:40 6 standard. 7 Q So if I came to you as an expert -- which 8 you are, right -- you've been submitted as an expert? 9 A Yes. 10 Q I come to you and say, Dr. Stewart, I just 09:47:52 11 want to know if I fall within the scope of Claim 10. 12 I've treated 200 patients for DME and I have used a 13 regimen that is five initial monthly loading doses, 14 followed by eight-week dosing on a predetermined basis 15 for all my patients, and none of my patients have 09:48:12 16 gotten eight letters. They've all gotten four. 17 Just follow my hypothetical. Is what I'm 18 doing within the scope of Claim 10? 19 MR. BRAUSA: Objection, form. 20 A So there are too many variables that aren't 09:48:26 21 taken into account. Because within Claim 10, this is 22 data that's going to be accrued from phase three 23 trials, and we know that phase three trials are going 24 to give you different results than what's done in 25 private practice, in anybody's practice. In general, 09:48:49 Page 57

1 private practices may not get the same level of visual 09:48:50 2 acuity as the clinical trials. 3 So there are a lot of differences in private 4 practice, in anybody's clinical practice, in terms of 5 the way the patients are treated and in terms of the 09:49:04 6 way the patients are analyzed, their visual acuities, 7 that are different from what's done in the trials. 8 So this the trial-based data. 9 Q So I take it then your opinion is that if 10 I'm a physician practicing the regimen set forth in 09:49:17 11 Claim 10, which is five initial loading doses on a 12 monthly basis, followed by eight-week dosing on a 13 predetermined basis for treatment of DME, I'm 14 practicing the method of Claim 10 regardless of 15 whatever improvement my individual patient gets; is 09:49:37 16 that right? 17 MR. BRAUSA: Objection, form, 18 mischaracterizes the testimony. 19 A So you're practicing the regimen put forth 20 in Claim 10, which we ultimately know to be a very 09:49:46 21 good regimen to give you results that have yet to be 22 beaten by any other regimen, and your results may not 23 be exactly the same for any number of reasons. 24 Q But you'd still fall within the scope of 25 Claim 10, because the overall clinical study showed 09:50:04 Page 58	1 patent, so Claim 10 is set forth in Column 22. We 09:51:38 2 talked about that, right? 3 A Yes. 4 Q Then we go down to Claim 13 -- actually, 5 let's go to Claim 15. 09:52:01 6 It says: "The method of Claim 10, wherein 7 the patient gains at least 15 letters of best 8 corrected visual acuity BCVA score." 9 Do you see that? 10 A I see that. 09:52:19 11 Q When you were talking about letters of 12 improvement, were you referring to a BCVA score? 13 A Yes. 14 Q So is Claim 10 related to what an individual 15 patient obtains once the method of Claim 10 has been 09:52:38 16 practiced for DME treatment, or is that directed to 17 the average population? 18 MR. BRAUSA: Objection, form. 19 A Claim 10 is directed -- in my mind, Claim 10 20 is directed to the average population. 09:52:53 21 Q So then if you turn now to Claim 13, it 22 states: "The method of Claim 10 where the patient 23 loses less than 15 letters of BCVA score." 24 Do you see that? 25 A I see that. 09:53:11 Page 60
1 that on average, people following the regimen of 09:50:07 2 Claim 10 for DME get about eight letters of 3 improvement or better, right? 4 MR. BRAUSA: Objection, form. 5 A Yes. 09:50:17 6 Q So if we could go to -- let me start the 7 question over again. You ready? 8 A Go ahead. 9 Q In your view, Claim 10 does not require any 10 particular level of efficacy for an individual 09:50:47 11 patient; is that fair to say? 12 MR. BRAUSA: Objection, form, 13 mischaracterizes the testimony. 14 A There's tremendous variability in individual 15 patients and there's no way we would expect any 09:51:02 16 patient to get eight letters. It would be by chance. 17 Q So then it is your opinion that Claim 10 18 does not require that an individual patient receive 19 eight letters of improvement; is that correct? 20 MR. BRAUSA: Objection, form. 09:51:20 21 A So that's correct. 22 Q So I think I know the answer to the next 23 questions I have for you, but I'm going to go to them 24 anyway. 25 So if you go to Stewart Exhibit 2, the 601 09:51:34 Page 59	1 Q In your opinion, would Claim 13 likewise be 09:53:13 2 a reference to the entire average patient population, 3 as opposed to individual patients? 4 MR. BRAUSA: Objection, form, outside the 5 scope. 09:53:23 6 A We talk about loss of letters like this both 7 in terms of individual patients and in terms of 8 populations of patients. So it could be construed 9 either way. 10 Q What's your opinion on it? 09:53:35 11 MR. BRAUSA: Objection, form, outside the 12 scope. 13 A In my opinion, it's population. 14 Q So how is it that your opinion for Claim 10 15 is that the patient population as a whole has to 09:53:55 16 achieve a level of efficacy of eight letters or 17 better, but Claim 13 allows the patient population to 18 simply lose less than 15 letters? 19 How is that consistent? 20 MR. BRAUSA: Objection, form, and outside 09:54:13 21 the scope. 22 A Well, gaining eight is losing less than 15. 23 That's the same thing, or at least the two overlap. 24 Q Okay. But Claim 13 would then be broader 25 than Claim 10, because it would include patients who 09:54:29 Page 61

1 gain 10 or more and also include patients that lost 09:54:32 2 15, lost 10, etc. -- patient populations, correct? 3 MR. BRAUSA: Objection, form, scope. 4 A Say that again, please. 5 Q I said, Claim 13 would be broader than 09:54:44 6 Claim 10, because Claim 13 would include patient 7 populations that achieve 10 letters or better of 8 improvement and also include patient populations that 9 lost 10 letters of improvement, for example? 10 MR. BRAUSA: Objection, form, scope. 09:55:03 11 A I don't see lost 10 anywhere here. 12 Q Well, it says loses less than 15. 13 A Loses less than 15. 14 Q So a patient population that loses 10 would 15 lose less than 15, right? 09:55:18 16 A Yes, correct. 17 Q You said they overlap. I was just trying to 18 put an example on it. 19 A Yes. 20 Q Okay. So Claim 13 is broader than Claim 10 09:55:23 21 in the sense that Claim 13 would include patient 22 populations that gained eight letters or more and also 23 include patients where they lost, let's say, 10 24 letters, correct? 25 A They would, yes, some would. Not 09:55:43 Page 62	1 sure I have your opinion. 09:57:05 2 A Yes, thank you. 3 Okay, I'm sorry, repeat the question. 4 Q In your opinion, what is the -- strike that. 5 Page three of your expert report mentions, 09:57:25 6 you know, "the plain and ordinary meaning of the 7 challenged claims requiring some level of efficacy," 8 and so my question is for Claim 18, which is a method 9 for treating DR, what is the level of efficacy, in 10 your opinion, that is required for Claim 18? 09:57:43 11 A So the level of efficacy is improvement in 12 the diabetic retinopathy severity score. That's not a 13 visual acuity improvement. 14 Q What is a DR severity score? 15 A DRSS. 09:58:05 16 Q So a diabetic retinopathy severity score is 17 also referred to as DRSS? 18 A Correct. 19 Q What is DRSS? What is it measuring? 20 A It is measuring the amount of pathology -- 09:58:19 21 the hemorrhages, aneurysms, things like that, diabetic 22 changes in the peripheral retina -- and the more of 23 them that are there, the more severe the disease, and 24 there's a scoring scale that is used to numerically 25 take what you see in the picture and put it on paper 09:58:39 Page 64
1 populations, but individuals, some individuals. 09:55:44 2 Well, a proportion of patients, that's how 3 we would define them. A proportion of patients losing 4 10 letters or less than 10 letters, yes. 5 Q So in that sense Claim 13 is broader than 09:55:57 6 Claim 10, right? 7 A Yes. 8 MR. BRAUSA: Objection, form. 9 BY MR. NIMROD: 10 Q Now, you had said that the standard for the 09:56:07 11 level of efficacy required for Claim 18 was different, 12 perhaps, than Claim 10. 13 What, in your opinion, is the level of 14 efficacy required for Claim 18? 15 And that's in column 23, by the way, 09:56:23 16 Claim 18. 17 A Right. So there is no established change in 18 vision that's appropriate, because the endpoints for 19 treating diabetic retinopathy are improvement in the 20 severity score of the retinopathy while maintaining 09:56:46 21 vision. 22 Q I don't follow that. You said there's no 23 established change in vision? 24 A I'm sorry, I misread that. I apologize. 25 Q Why don't you read Claim 18. I want to make 09:57:03 Page 63	1 as a number, a severity score. 09:58:42 2 Q Is the severity score something that is like 3 generated by a computer? You feed an image into it? 4 A It's images based on photography and then it 5 has to be done -- graded by hand, by a person. 09:58:55 6 Q And are the standards such that two 7 physicians looking at the same photos would come up 8 with the same number? 9 A Generally, you'll get very close. 10 Q And what are some of the like examples of -- 09:59:08 11 strike that. 12 So what is the severity score, the DRSS, 13 that would be required, in your view, as to the level 14 of efficacy required for Claim 18? 15 A So you're looking at at least two levels of 09:59:24 16 improvement in about one-third of patients. 17 Q What about the other two-thirds? 18 A Then they might not get two levels of 19 improvement. 20 Q Might they get no improvement? 09:59:48 21 A They might. 22 Q Might they get worse? 23 A They might. Small numbers, but they might. 24 Q Well, two-thirds? 25 A Two-thirds will be less than two levels of 09:59:56 Page 65

1 improvement. But many of those will have improvement 09:59:58 2 but not two levels. 3 Q So two-thirds of the patient population 4 would have either one level of improvement or no 5 improvement or perhaps a slight worsening? 10:00:09 6 A Correct. 7 Q And that's if you treated them with a 8 regimen set forth in Claim 18 for DR? 9 A Yes. 10 Q So then in order to fall within the scope of 10:00:21 11 the claims, what is the level of improvement that I 12 would need to obtain for my patient population in 13 order to know that I'm infringing or falling within 14 the scope of Claim 18 for treating DR? 15 MR. BRAUSA: Objection, form, and outside 10:00:38 16 the scope, calls for a legal conclusion. 17 A Well, your expectation is a third of your 18 patients would improve by two levels if you treat 19 according to the regimen. That would be your 20 expectation. 10:00:48 21 On an individual patient, it's going to 22 vary. Some are going to be two, some are going to be 23 three, some are going to be zero. It has to be a 24 population. 25 Q But then the whole -- all the patients 10:00:58 Page 66	1 MR. BRAUSA: Objection, form, outside the 10:02:28 2 scope. 3 A So the primary goal of 18 is improvement in 4 DRSS. A secondary goal is stability of vision, 5 meaning zero change in BCVA. 10:02:40 6 Q So going back to your opinion on page three 7 regarding the plain and ordinary meaning requiring 8 some level of efficacy as it applies to Claim 18, does 9 that require something for DRSS and BCVA? 10 A No, the DRSS is the primary score, so that's 10:03:03 11 the one that's taken. The expectation is roughly 12 stable visual acuity. 13 Q But not required for the level of efficacy, 14 in your opinion, for Claim 18; is that right? 15 A That's correct. 10:03:18 16 Q So turning now to Claim 26, why don't you 17 read that to yourself. It's a method of treating DR 18 in a patient with DME. Read the whole claim, please. 19 You've read it? 20 A I've read it. 10:04:02 21 Q Going back again to your opinion regarding 22 the "plain and ordinary meaning of the challenged 23 claims requiring some level of efficacy," what is the 24 required level of efficacy for Claim 26? 25 A So 26, what trumps everything here is the 10:04:22 Page 68
1 within the population, no matter what their number is, 10:01:00 2 as long as one-third of them achieve two or better 3 would mean that the method of treating all those 4 patients fell within the scope of Claim 18, right? 5 MR. BRAUSA: Objection, form, and outside 10:01:12 6 the scope. 7 A Yes. Assuming the regimen were followed, 8 yes. 9 Q For treatment of DR? 10 A For treatment of DR. 10:01:24 11 Q There is a reference in Claim 20 to a BCVA 12 according to an early treatment diabetic retinopathy 13 study, ETDRS score. 14 What is an ETDRS score? 15 A So EDTRS is originally derived from a study 10:01:46 16 back in the '80s and it's come commonly to mean the 17 eye chart itself and the size of the letters, the 18 number of letters. That's the ETDRS eye chart. 19 So the best correct acuity score is taken 20 from the way that patient performs on the ETDRS eye 10:02:10 21 chart. 22 Q But the best visual acuity score is not the 23 relevant score for determining whether or not a 24 patient population falls within Claim 18, because that 25 has to do with DRSS; is that right? 10:02:25 Page 67	1 DME and so that's what you're treating. The majority 10:04:25 2 of us don't treat DR by itself. We treat DME. So a 3 POSA is going to look at that and say yeah, you can 4 treat the DR, but what I'm really interested in is 5 treating the DME. 10:04:41 6 So then it comes back to a level of efficacy 7 similar to what we talked about in Claim 10, which is 8 similar to Avastin and Lucentis. That's the 9 expectation we're looking for. 10 Q So the level of efficacy required for 10:04:53 11 Claim 26 is the same as for Claim 10? 12 A Correct. 13 Q Now, you said that the majority of 14 physicians, I guess you mean, don't treat DR. What do 15 you mean by that? 10:05:08 16 A So there's intent to treat. You treat DME. 17 We all agree on that, because DME was 18 central-involving. It either has affected or is going 19 to affect central acuity. It usually has affected and 20 we want to get that back. 10:05:24 21 So DME is a vision-threatening and 22 vision-compromising condition. DR by itself is not a 23 vision-threatening condition. Patients don't lose 24 vision from DR. So as a result, many of us don't 25 treat DR. 10:05:43 Page 69

1 Because when you look at the studies over 10:05:44 2 time, the visual acuities at the end, whether you've 3 treated them or not for DR, are roughly the same as 4 the treatment in the treatment group as the 5 nontreatment group. So we look at that and say we're 10:05:55 6 not sure that treating just for the DR improvement is 7 worth the regimen. 8 Q In your practice, if a patient only has DR 9 with no centrally-involved DME, do you treat the 10 patient? 10:06:12 11 A So we can parse this out. If it's not 12 central-involving DME, then it's a matter of is it 13 center-threatening DME, meaning outside the center, 14 and in that case I would certainly treat them probably 15 with laser. It's one of the few indications for 10:06:29 16 laser. I would not treat the DR in that patient, not 17 specifically with injections, no. 18 Q If you have patients that do not have 19 centrally-involved DME, do you treat with a VEGF 20 molecule or do you just use laser treatment for that? 10:06:45 21 MR. BRAUSA: Objection, form. 22 A So if a patient has non-center-involving 23 DME, then it can be a combination of either. I would 24 use laser more frequently than I would use anti-VEGF. 25 Q Can you turn to page 27 of your expert 10:07:37 Page 70	1 visual acuity improvement by six months. Some 10:08:58 2 patients will have a little bit of continued 3 improvement through one year. 4 So six months for the majority of 5 improvement, a little more for a year. 10:09:06 6 Q So to be within the scope of the claim, 7 which you say requires a level of efficacy for 8 Claim 10 of eight letters or better, at what point in 9 time would I, you know, as a person trying to see if 10 I'm within the claim scope look to see if I've 10:09:22 11 achieved those eight letters? 12 MR. BRAUSA: Objection, form, outside the 13 scope. 14 A So most patients -- most studies will use 15 one year as the primary endpoint. So if we're talking 10:09:32 16 about efficacy, the best data exists at the one-year 17 mark, one year. 18 Q So would a skilled person, POSA -- 19 you understand "POSA" is a person of ordinary skill in 20 the art? 10:09:52 21 A Yes. 22 Q Would a POSA reading the 601 patent 23 understand that the required level of efficacy for 24 Claim 10 is to be determined at the one-year point? 25 A I mean, assuming what we assume about a 10:10:01 Page 72
1 declaration, Stewart Exhibit 1, please. 10:07:39 2 Oh, before we do that, I did have another 3 question. Let's go back to your patent -- not your 4 patent, "the" patent. 5 A Okay. 10:07:57 6 Q Let's go to Claim 10 again. I've got a 7 couple more questions about this improvement in -- 8 what's that phrase again -- a level of efficacy that 9 you are saying is required for Claim 10. 10 At what point in time is the level of 10:08:17 11 efficacy required to be obtained? 12 A So -- 13 Q And just to frame that a little, I'm sorry, 14 there's five initial doses every four weeks? 15 A Yes, yes. 10:08:29 16 Q And then there's eight-week dosing. 17 With that in mind, what is the point in time 18 that one -- or a patient population needs to achieve 19 the level of efficacy of eight letters or better in 20 order to be within the scope of the claim? 10:08:42 21 What's a relevant time period? 22 A So it's certainly not specified, other than 23 it is to be effective. 24 Now, the way the patient populations behave 25 is that most of them achieve the majority of their 10:08:54 Page 71	1 POSA, I believe so, yes. 10:10:03 2 Q Now, let's go to page 20 again of your 3 expert declaration. Would you read paragraph 35 to 4 yourself, please. It goes over to the next page as 5 well. Let me know when you're done. 10:10:18 6 Okay. In paragraph 35 of your expert 7 declaration you have a statement that is about halfway 8 down. It says, "Compare this to Figure 2 of the 9 MARINA study, showing no mean change in visual 10 acuity." 10:11:40 11 Do you see that sentence? 12 A I see the sentence, yes. 13 Q Then you say -- as part of that sentence you 14 say, "It is clear why" -- hold on one second. Let me 15 start over. 10:11:55 16 You say, "It is clear why the PIER trial was 17 regarded as 'highly disappointing' and a failure by 18 the investigators." Citing Exhibit 2035 at 19 paragraph 22. 20 Do you see that? 10:12:12 21 A Yes. 22 Q Do you recall, what is Exhibit 2035 at 23 paragraph 22? 24 A Could I have 2035? 25 Q You don't recall what it was? 10:12:20 Page 73

1 A I don't recall what that was. I think that 10:12:22 2 might have been the PIER trial, but I don't recall by 3 number. 4 Q I think it is a declaration that was 5 submitted in these proceedings in let's say the 2023, 10:12:30 6 2024 timeframe. 7 A Okay. 8 Q So I'm going to ask a different question, 9 because the record shows what that is. 10 A Okay. 10:12:40 11 Q Are you aware of any contemporaneous 12 documents from the timeframe using the -- the 13 timeframe as to when this study was being done and 14 being considered, where it was described as being 15 "highly disappointing" or a failure? 10:12:53 16 A You're saying have I seen documents with 17 those words regarding the study? 18 Q Yes. 19 A I don't recall seeing those words in 20 documents, no. 10:13:03 21 Q So nothing from the contemporaneous time. 22 If I represent to you that this Exhibit 2035 is from 23 the 2023-'24 timeframe -- 24 A Okay. 25 Q So I'm asking you, are you aware of any 10:13:15 Page 74	1 Q Yes. 10:14:39 2 A Yes, the majority of anti-VEGF treatments 3 for diabetic patients is for the diagnosis of DME. 4 Q Centrally-involved DME? 5 A Centrally-involved DME. 10:14:50 6 Q Is that right? 7 A Yes. 8 Q Could you go to page 25, please. 9 Page 25 of your report has Claim 10 10 reproduced. Do you see that? 10:15:03 11 A I do. 12 Q And it says, "It's a method for treating DME 13 in a patient in need thereof," right? 14 A Yes. 15 Q Then it says, "comprising intravitreally, 10:15:12 16 administering to said patient an effective amount of 17 aflibercept." Do you see that? 18 A Yes. 19 Q Then the claim goes on and says, "which is." 20 Do you see that? 10:15:29 21 A Uh-huh. 22 Q Yes? 23 A Yes. 24 Q Is it your understanding that the words 25 "which is" would refer to the effective amount? 10:15:37 Page 76
1 documents other than whatever that is, that use the 10:13:18 2 phase that the study was "highly disappointing"? 3 A I'm not aware of documents that did it, but 4 clearly amongst those of us who treat patients, we all 5 knew and were saying very disappointing. 10:13:29 6 Q Nothing in writing, though? 7 A Not that I recall. 8 Q And anything in writing where the 9 investigator said that the PIER trial was a failure? 10 MR. BRAUSA: Objection, form. 10:13:41 11 A I would have to go back and look at PIER 12 itself to see if "failure" was used, but I don't 13 remember from the document if that was included. 14 Q And sitting here today, you're not aware of 15 any documents that describe the PIER trial as a 10:13:53 16 failure, other than what you cite as Exhibit 2035 in 17 paragraph 22; is that right? 18 A I'm not aware of documents that state that. 19 Q Based on what you said earlier about when 20 you would treat DR or not and DME or not, is it fair 10:14:16 21 to say that the majority of treatments using Eylea, 22 for example, is for -- with respect to DME and DR -- 23 is for centrally-involved DME? 24 A For diabetic patients, is that what you're 25 referring to? 10:14:38 Page 75	1 MR. BRAUSA: Objection, form. 10:15:41 2 A So my understanding is it's both the dose 3 and result. It's the dose that produces the result. 4 Q So the claim is stating that the effective 5 amount of aflibercept is in fact the dose that's set 10:15:49 6 forth there, 2 milligrams approximately every four 7 weeks for the first five injections, followed by 8 2 milligrams approximately once every eight weeks or 9 once every two months, correct? 10 MR. BRAUSA: Objection, form, 10:16:06 11 mischaracterizes the claim. 12 A So yes. 13 Q And I think you told me earlier that your 14 opinion as to what is required for a level of efficacy 15 is defined by the clinical trials? 10:16:22 16 A Correct. 17 Q Which means that anytime someone 18 practices -- a physician practices the method of 19 Claim 10 on a patient with DME in need of treatment 20 and they follow the regimen of 2 milligrams 10:16:40 21 approximately every four weeks for the first five 22 injections, followed by 2 milligrams approximately 23 once every eight weeks or once every two months, that 24 would be within the scope of the claims as an 25 effective amount per se because of the clinical trials 10:16:56 Page 77

1 that were done before, right? 10:17:00 2 MR. BRAUSA: Objection, form, outside the 3 scope. 4 A So if they use that dosing regimen, then 5 that follows the effective amount of drug that's used 10:17:08 6 that ultimately produced the results in the trials. 7 Q So you agree with me? 8 A I agree with you. 9 Q Can you go to page 30, please. 10 Page 30 is a section Roman X entitled "Claim 10:17:45 11 Construction." Do you see that? 12 A Yes. 13 Q And then you have a header A that's entitled 14 "Every four weeks for the first five injections, 15 followed by every eight weeks." 10:17:58 16 That refers to a predetermined dosing 17 regimen, right? 18 A Yes. 19 Q For a predetermined dosing regimen, if a 20 physician decides from the start, prior to the first 10:18:11 21 injection, I'm going to follow the method of Claim 10 22 and then at some point when a patient comes in they 23 have some kind of condition -- an inflammation, 24 something, that would suggest -- strike that. Let me 25 ask the question again. 10:18:31 Page 78	1 predetermined dosing regimen in accordance with 10:19:54 2 Claim 10 for treatment of DME and then based on an 3 examination of the eye determined that I needed to do 4 more frequent dosing for a particular patient, would 5 that treatment fall within the scope of Claim 10 10:20:08 6 because I decided on a predetermined basis to do it, 7 although I had to deviate, or would it fall outside 8 the scope of Claim 10? 9 MR. BRAUSA: Objection, form, outside the 10 scope. 10:20:23 11 A So we always have, if you will, failure 12 protocols where poor results mandate a change in 13 therapy. That's built into every different drug 14 that's being used. 15 So would it be following the protocol? 10:20:38 16 Well, you change the protocol because you have a 17 patient who failed or you change what you're doing. 18 Q Yeah, I'm not asking if you would follow the 19 protocol. Because my question assumed you were not, 20 right? 10:20:50 21 A Okay. 22 Q So my question is -- you're an expert here. 23 If I tell you that I have a patient that I've done a 24 predetermined dosing regimen decision and I, let's 25 say, give them three monthly doses and then upon 10:21:03 Page 80
1 You're the doctor. Are there circumstances 10:18:33 2 where a person, a physician would say, "I'm going to 3 follow the method of Claim 10 in a predetermined basis 4 and then deviate from that based on some specific 5 patient condition where they arrive for one of their 10:18:47 6 injections"? 7 A Yes, there are. 8 Q What are those circumstances? 9 A So you wait for a result and on average, a 10 15-letter loss is something we would look at as a poor 10:18:59 11 result. Very infrequent, but occasionally happens. 12 We would probably switch therapy. 13 Hemorrhage of the eye, might need to do surgery. 14 Infection, you treat the infection. 15 Q When you say you might need to change the 10:19:19 16 therapy, you mean in terms of changing the dosing 17 regimen for, for example, Eylea or do you mean to 18 another drug or do you mean like giving it more 19 frequently? 20 A It could be. So there are several options. 10:19:30 21 One is give more frequently. Secondly is change the 22 drug either to another anti-VEGF or to a steroid, or 23 even possibly do surgery. All of those become 24 options -- or laser. 25 Q If I'm a physician who has decided to use a 10:19:52 Page 79	1 examination I decide that I'm going to do a dose 10:21:07 2 sooner than that or a dose later than that just based 3 on the results I'm seeing, would that fall within the 4 scope of Claim 10 because I've deviated from what the 5 predetermined dosing regimen was, or is it still 10:21:23 6 within the scope of it because that's what you decided 7 at the beginning? 8 A Well, the -- 9 MR. BRAUSA: Objection, form. 10 You got to give me a little time, 10:21:31 11 Dr. Stewart. 12 THE WITNESS: Thank you. 13 So for the example you're giving me, no, 14 that would not be within the scope. But it's 15 also not something that we would generally do 10:21:37 16 either. 17 BY MR. NIMROD: 18 Q If a patient came in and it's a patient who 19 had a predetermined -- strike that. 20 If a patient comes in and has 10:21:44 21 inflammation -- you mentioned that -- what does that 22 mean and how does that impact treatment? 23 What's inflammation? Let's do one question 24 at a time. 25 A So inflammation is white cells in the eye. 10:21:55 Page 81

1 Basically, it's a reaction to the body's immune 10:21:59 2 system, presumably to the drug itself, or it could be 3 to other conditions. But the drug has to be included 4 in the realm of possibilities as to what's causing the 5 body's immune system to react, and that is an adverse 10:22:14 6 reaction. 7 Q So if a patient has inflammation, what does 8 one do in that situation? 9 MR. BRAUSA: Objection, form. 10 A So depends on the severity. Usually you use 10:22:30 11 steroids. It can be topical steroids, drops. It can 12 be steroids given around the eye. It can be oral 13 steroids, but any of those. 14 As long as the physician believes this is 15 not an infection but rather is a sterile inflammation, 10:22:48 16 which really was the assumption here, then you're 17 going to treat it with steroids. 18 Q What's an infection versus inflammation? 19 A So infection is some agent, the drug or 20 something else, reacting with the body's immune 10:23:07 21 system, causing white cells in the absence of 22 microorganisms. 23 Infection is microorganisms and then the 24 body reacts to that, causing inflammation. But a 25 sterile inflammation is in the absence of 10:23:25 Page 82	1 give the next injection of Eylea, let's say. 10:24:42 2 Would that fall within the scope of Claim 10 3 because I'd done a predetermined decision or would it 4 not fall within it because I deviated from it? 5 MR. BRAUSA: Objection, form, outside the 10:24:58 6 scope. 7 A So you have to take care of the patient and 8 taking care of the patient means treating the 9 infection, inflammation, probably stopping the 10 injections. And so you would be then stopping the 10:25:11 11 scope of what the claim says, because you've got to 12 take care of the individual rare patient that it 13 happens. 14 Q So for the patient I would be outside the 15 scope of Claim 10? 10:25:23 16 A At that point, yes. 17 Q Let me mark as Stewart Exhibit 4 a copy of 18 the decision granting institution for the 601 patent 19 in this IRP proceeding. 20 (Whereupon a document/item was marked for 10:26:55 21 identification as Petitioner's Exhibit 4.) 22 A Thank you. 23 Q You recall you reviewed this decision as 24 part of your -- it's one of the documents you studied 25 in connection with your expert declaration? 10:27:13 Page 84
1 microorganisms. 10:23:28 2 Q Do patients from time to time come in with 3 infections when they're coming in for their treatment? 4 Let's say somebody is on a predetermined 5 dosing regimen with five initial doses monthly and 10:23:36 6 then eight weeks -- every eight weeks thereafter and 7 the patient shows up with an infection. How does that 8 impact treatment, if at all? 9 A So yes. Does it happen, absolutely. It's 10 unusual. I don't know if rare is the right word, but 10:23:52 11 unusual, and at that point we treat the infection, 12 which usually means antibiotics into the eye. Some 13 physicians would do surgery, and at that point we'd 14 probably put further injections on hold until we treat 15 the infection and get rid of the inflammation 10:24:10 16 associated with the infection. 17 Q So I think I know the answer to this. 18 If I have a patient -- I'm a doctor and I've 19 decided to use the regimen in Claim 10 to treat DRE 20 and then on the third visit -- start over again. I 10:24:26 21 got to look there. 22 Start over again. So I'm a physician. I've 23 decided to on a predetermined basis practice the 24 regimen of Claim 10 to treat DME, and my patient shows 25 up for the fourth visit with an infection and I don't 10:24:37 Page 83	1 A I think I did. This is going back a long 10:27:24 2 way. It doesn't jump to mind. 3 Q Let's go to page seven. I'll just refresh 4 your recollection. 5 A Okay. 10:27:34 6 Q Page seven of your -- sorry, of your 7 declaration, Stewart Exhibit 1. 8 A Uh-huh. 9 Q Page seven -- actually, go to page six. It 10 says "Materials Considered". 10:27:47 11 A Yeah. 12 Q And then on the next page, letter C is the 13 board's decision granting institution. 14 A Yes. 15 Q So the board's decision, Stewart Exhibit 4, 10:27:59 16 is a document you reviewed in connection with forming 17 your opinions in this case, yes? 18 A Yes. 19 Q Can you go to page 39 of Stewart Exhibit 4, 20 please. On page 39, the patent office, the PTAB, 10:29:19 21 states: 22 "Finally, patent owner argues that the 23 challenged claims are directed to fixed dosing 24 throughout, with a transition from monthly to 25 eight-week dosing after five fixed monthly loading 10:29:40 Page 85

1 doses." 10:29:44 2 Do you see that? 3 A Yes. 4 Q And it states: "Patent owner asserts that a 5 fixed approach is advantageous because it provides for 10:29:51 6 a predetermined schedule regardless of whether 7 re-accumulated fluid has been detected, while 8 assessment-based approaches take a fundamentally 9 different approach by making injections conditional on 10 patient characteristics." 10:30:07 11 Do you see that? 12 A Yes. 13 Q In your opinion, is it more advantageous to 14 use an individualized approach than a predetermined 15 approach? 10:30:18 16 MR. BRAUSA: Objection, form. 17 A It depends on what your objectives are. So 18 if your objectives are to maximize vision, get best 19 possible visual acuity results, then the literature 20 shows that predetermined regimens are superior. 10:30:31 21 If your objective is to treat the patient 22 very effectively, minimize the number of doses, 23 minimize the number of visits, the cost, etc., then 24 individualized therapy is generally better. So 25 depends on the objectives. 10:30:52 Page 86	1 that was a phase three trial that produced an 10:32:25 2 effective result that was comparable to monthly 3 therapy with injection intervals greater than every 4 four weeks. 5 Q Okay, but the idea of using a fixed extended 10:32:38 6 dosing regimen was not something new with the 601 7 patent, right, just that idea? 8 MR. BRAUSA: Objection, form. 9 A So the idea was not new. The idea of five 10 monthly injections followed by Q8-week therapy, that 10:32:54 11 was new. 12 Q New for aflibercept or new for other 13 compounds? 14 MR. BRAUSA: Objection, form. 15 A So that particular one was new for all 10:33:07 16 compounds. 17 Q And you mentioned that the majority of the 18 time you're treating for DME you use an individualized 19 approach. Why is that? 20 A Again, depending on objectives, and when 10:33:18 21 discussing with patients we usually say we can get 22 results that are fairly similar to protocolized or 23 predetermined therapies but I can treat you fewer 24 times with fewer visits. 25 Q And is that a benefit to patients, to have 10:33:36 Page 88
1 Q And you provided no opinion in your report 10:30:53 2 as to the percentage of physicians that use for their 3 patients a fixed approach versus an individualized 4 approach in your expert report, have you? 5 A No, I have not. 10:31:10 6 Q And for your own treatment, do you use a 7 predetermined approach or a fixed approach for DME? 8 MR. BRAUSA: Objection, form. 9 A For most of my patients I use an 10 individualized approach. 10:31:21 11 Q In the next sentence it says: 12 "Patent owner asserts that the 601 patent's 13 achievement of the first fixed extended dosing regimen 14 was a departure from prior assessment-based 15 approaches, rather than an obvious variant to them." 10:31:47 16 Do you see that? 17 A I see that. 18 Q Do you agree that the 601 patent was the 19 first fixed extended dosing regimen or were there 20 other anti-VEGF compounds that were used on a fixed 10:31:59 21 extended dosing regimen? 22 MR. BRAUSA: Objection, form. 23 A Well, we know there were others. PIER, for 24 example, was an extended treatment-based program. But 25 PIER also was not a success. So this is the first one 10:32:18 Page 87	1 fewer treatments at fewer visits? 10:33:41 2 A I think most patients would agree with that, 3 yes. 4 Q In your report you say that for some of 5 these patients it's difficult for them to even drive 10:33:47 6 to the visit. So it would seem that would be a pretty 7 good benefit, right? 8 A Correct. 9 Q Okay. The PTAB goes on in Exhibit 4, 10 Stewart 4, it states that -- at the bottom of page 39 10:34:08 11 it says: 12 "The language of the challenged claims 13 nowhere requires that the doses required therein are 14 fixed or determined." 15 Do you see that? 10:34:25 16 A I see that. 17 Q You, of course, would agree the words 18 "fixed" or "determined" are not set forth in 19 Claims 10, 18, and 26, right? 20 A Correct. 10:34:32 21 Q Then it says: "Further, the disclosure of 22 the specification of the 601 patent expressly 23 undermined the patent owner's argument that the doses 24 of the VEGF antagonist, aflibercept, are fixed and 25 invariable." 10:34:46 Page 89

1 Do you see that? 10:34:47 2 A I see that. 3 Q And you disagree with that, I take it? 4 A I would disagree with that. 5 Q Okay. The PTAB then on page 40 goes to a 10:34:53 6 portion of the 601 patent at Column 4, lines 13 to 19. 7 Do you see that? 8 A You're referring to this, a third of the way 9 down? 10 Q Yes. Could you read that paragraph to 10:35:14 11 yourself, just the quote right above where you pointed 12 with your finger. 13 A Above where I quoted? 14 Q Yeah. 15 A Okay. 10:35:38 16 Q So would you agree that the portion cited by 17 the PTAB at Column 4, lines 13 to 19, would suggest 18 that the methods of the invention would include 19 individualized treatments? 20 MR. BRAUSA: Objection, form. 10:35:53 21 A I'm puzzled by this, because I don't see 22 where the 601 patent teaches this. 23 Q Teaches what? 24 Just to set the stage a little, you agree 25 that this paragraph appears in the 601 patent, yes? 10:36:13 Page 90	1 paragraph from Column 4, lines 13 and 19, of the 601 10:37:11 2 patent would support the notion that the methods of 3 the invention of the 601 patent would include 4 individualized treatments? 5 MR. BRAUSA: Objection, form. 10:37:29 6 A Well, so the body of the patent describes 7 that. The claims of the patent do not. The claims of 8 the patent do not describe individualized treatments. 9 Q So you would agree then that the 10 specification of the 601 patent would -- or describes 10:37:53 11 inventions where there's both individualized and fixed 12 treatments? Is that your idea? 13 MR. BRAUSA: Objection, form. 14 Q Let me restate that. That was a little 15 awkward. 10:38:09 16 A Okay. 17 Q Do you agree that the specification of the 18 601 patent teaches that the methods of the invention 19 for treatment, let's say, of DME would include 20 individualized treatment methods? 10:38:21 21 A Again, that's mentioned as possibilities in 22 the body of the patent. But when it comes to the 23 claims of the patent, no, individualized therapy is 24 not included. 25 Q So I just want to -- focusing on the 10:38:34 Page 92
1 A Yes. 10:36:15 2 Q So you understand this is a quote from the 3 patent? 4 A Yes, I'm sorry. 5 Q I can take you to where it is, just to make 10:36:19 6 sure of the context. 7 A Okay, okay. 8 Q So if you go to Exhibit 2, Column 4, that is 9 page 11, and then go to lines 13 and 19 -- right about 10 there -- 10:36:35 11 A Uh-huh. 12 Q That's the paragraph that the PTAB is 13 quoting. 14 A I'm sorry, give me the numbers again, 15 please. 10:36:41 16 Q Column 4. It's page 11 -- 17 A Okay, thank you. 18 Q -- and then Column 4, it's lines 13 and 19. 19 So it's on the right-hand side, Column 4. 20 A Yeah. 10:36:54 21 Q If you want to just read that over to 22 yourself and just confirm that's the same as the quote 23 in the PTAB decision. 24 A Okay, yeah. 25 Q Would you agree that the quote -- or the 10:37:11 Page 91	1 specification, the body of the patent, when you say 10:38:36 2 "body", you mean specification? 3 A Yeah. Is this a specification as far as 4 you're referring to? 5 Q Yes. 10:38:45 6 A Just so we're on the same page, okay. 7 Thank you. 8 Q So basically everything before the claims? 9 A All right. 10 Q So would you agree that the specification of 10:38:52 11 the 601 patent teaches that the methods of the 12 invention for treatment, for example, of DME would 13 include individualized treatments? 14 A It says they may comprise administering, 15 yes, and that would include individualized. 10:39:07 16 Q Then the PTAB goes down further on page 40 17 and states -- you're back to that now? 18 A Yes. 19 Q It says -- between the two block quotes it 20 says: 10:39:25 21 "Furthermore, the specification expressly 22 contemplates that a physician of ordinary skill in the 23 art might contemplate altering the amount of second or 24 tertiary doses." 25 Do you see that? 10:39:36 Page 93

1 A Yes. 10:39:37 2 Q Just so we have the nomenclature, what is a 3 secondary dose and -- what's a secondary dose? 4 A I hate the terms secondary and tertiary. We 5 don't use those. The second is the number of monthly 10:39:51 6 injections given after the first injection. 7 Q So just to frame it for the claims, whether 8 or not -- the spec has it, so -- 9 A I hear you. 10 Q There's an initial injection, for example, 10:40:05 11 in Claim 10? 12 A Yes. 13 Q And then there would be four secondary 14 injections that are given on a monthly basis, right? 15 A Yes. 10:40:14 16 Q So therefore you have five loading doses 17 because it's zero, one, two, three, four, right? 18 A Well, okay. It's five doses, one plus four. 19 Q Right. And then the tertiary doses would be 20 what? 10:40:28 21 A The tertiary doses are what then follows 22 after the initial loading sequence, primary plus 23 secondary, are completed. Then you get into tertiary 24 doses. 25 So, for example, in Claim 10 the tertiary 10:40:41 Page 94	1 A I would never use primary, secondary, 10:42:03 2 tertiary, when talking about monthly therapy. I would 3 simply say this is a monthly therapy regimen. 4 Q Okay, got it. So now let's go back to 5 page 40 then and the PTAB says: 10:42:15 6 "Furthermore, the specification expressly 7 contemplates that a physician of ordinary skill in the 8 art might contemplate altering the amount of secondary 9 or tertiary doses." 10 Do you see that? 10:42:29 11 A Yes. 12 Q And then they have a block quote and that 13 quote is -- well, why don't you read the block quote 14 to yourself. 15 A Okay. 10:42:39 16 Q So it's quoting from the 601 patent. You 17 understand that? 18 A Uh-huh. 19 Q Yes? 20 A Yes. 10:43:04 21 Q And it says that: "The administration might 22 be varied based on patient characteristics, severity 23 of disease, or other diagnostic assessments by a 24 physician or other qualified medical professional." 25 Do you see that? 10:43:20 Page 96
1 doses are the ones that begin at eight-week intervals. 10:40:43 2 Q So if you're following just a monthly dosing 3 regimen for Eylea for treatment of centrally-involved 4 DME, there's an initial dose, correct? 5 A Yes. 10:41:02 6 Q And then -- well, strike that. 7 You mentioned earlier the loading doses were 8 to get to what kind of endpoint? 9 MR. BRAUSA: Objection, form. 10 A So loading doses are to get basically to 10:41:16 11 disease control. 12 Q And then in the nomenclature that we see in 13 this part of the patent, the initial and secondary 14 doses would be the doses to get to the level of 15 disease control? 10:41:33 16 A You would hope and assume that you're at 17 that point. But yes, the primary plus secondary are 18 going to be your loading doses to disease control. 19 Q And if I'm doing monthly dosing of Eylea for 20 DME, are there things that we call tertiary doses 10:41:48 21 because you've achieved disease control after some 22 number of monthly doses, or are they all called 23 secondary doses? 24 MR. BRAUSA: Objection, form, outside the 25 scope. 10:42:02 Page 95	1 A I mean, I've lost it after the word 10:43:23 2 "diagnostic." 3 Q If you just go to the next page -- there. 4 A Okay, got it. 5 Yeah, okay. Footnotes, okay. Thank you. 10:43:33 6 Q Why don't you read that, just to make sure 7 you read the last part of the sentence on page 41. 8 A Okay. 9 Q So would you agree that the statement that 10 is set forth by the PTAB on the pages bridging 40 and 10:43:44 11 41 of their decision it would be applicable to the 12 method of Claim 10, 18, and 26? 13 MR. BRAUSA: Objection, form. 14 A No, because you would use fixed doses at 15 fixed intervals at fixed numbers. So you would not 10:44:05 16 employ those strategies. 17 Q Okay. But you told me earlier that if you 18 had a patient come in and there was inflammation, 19 infection, or maybe something else, you would vary the 20 dosing regimen, wouldn't you? 10:44:20 21 A Yes. For those few patients that are poor 22 responders or other things, then yes. 23 Q So doesn't that mean that the dosing regimen 24 of Claim 10 can be varied? 25 MR. BRAUSA: Objection, form, 10:44:35 Page 97

1 mischaracterizes the testimony. 10:44:36 2 A So as soon as you vary the dosing regimen of 3 10, you're no longer working under 10. You're 4 adapting to the patient. 5 Q Well, it's fair to say then that every 10:44:49 6 predetermined dosing regimen leaves open the 7 possibility that you might have to vary it based on 8 what you see with respect to the patient? 9 MR. BRAUSA: Objection, form, 10 mischaracterizes the testimony. 10:45:02 11 A So you always have to be willing to change 12 therapies if you have an unusual adverse event, and 13 they're really talking about adverse events or 14 failures that are always in patient populations, and 15 you have to be willing to change if that happens. 10:45:20 16 Q Which would include things like infection 17 and inflammation? 18 A Correct. 19 Q So your understanding of a predetermined 20 dosing regimen would always leave open the possibility 10:45:29 21 that the physician might have to vary from that 22 predetermined dosing regimen based on what happens 23 with the patient, for example, with infections and 24 inflammation, correct? 25 MR. BRAUSA: Objection, form. 10:45:46 Page 98	1 actually in the reference? Is that what you are 10:46:59 2 referring to? 3 Q The reference being the 601 patent, yes. 4 A No, I understand that. But I think I'm hung 5 up on "fixed," because to me fixed means 10:47:07 6 predetermined, and it might be monthly forever. It 7 might be five doses followed by every eight weeks, it 8 might be three doses followed by every eight weeks. 9 All of those are fixed. 10 Q Were you aware that the patent specification 10:47:23 11 uses the word "fixed" in connection with one or more 12 regimens? 13 A I don't remember having seen it. But sure, 14 it wouldn't surprise me. 15 Q So let's go to example two, Column 8, 10:47:33 16 lines 39 to 42. 17 A I'm sorry, 38 to 32? 18 Q Column 8. It's page 13 of Exhibit 2. 19 A Yep. 20 Q And they refer to lines 39 to 42. So that's 10:47:56 21 under example two. Do you see that? 22 A Yeah, I'm getting to it right now. 23 Q The header, for example, two is circled, 24 lines 29 to 32. 25 A Yep. 10:48:15 Page 100
1 A Correct. 10:45:46 2 Q Would you agree that -- going to page 41 of 3 the PTAB decision, it states at the top of the page 4 after the block quote ends, so like line three: 5 "In fact, the only reference to fixed doses 10:46:03 6 is in example two of the specification, which 7 describes a clinical study in which patients were 8 dosed at a fixed interval for the first 12 weeks," and 9 then it goes on. 10 Do you see that? 10:46:21 11 A I see that. 12 Q Do you agree that the only reference to 13 fixed doses in the specification is in example two? 14 MR. BRAUSA: Objection, form. 15 A No, there were references to fixed doses in 10:46:31 16 example seven. 17 Q Let me try it again. Do you see that the 18 PTAB had put the word "fixed" in quotes? 19 A I see that. 20 Q So I guess I'll frame the question better. 10:46:43 21 Would you agree that the only reference 22 using the word "fixed" in connection with dosing 23 regimens is in example two of the specification of the 24 601 patent? 25 A Are you saying that the word "fixed" was 10:46:56 Page 99	1 Q You see that. Okay, so example two at 10:48:16 2 lines -- 3 A Why am I missing the word "fixed"? 4 Q Here it is, okay. So line 40 -- or 39 5 says -- 10:48:37 6 A Oh, fixed interval, thank you. Got it. 7 Q So when you rendered your opinions, you were 8 not aware of the fact that the patent references a 9 "fixed interval" in example two? 10 MR. BRAUSA: Objection, form, 10:48:52 11 mischaracterizes the testimony. 12 A Well, I looked at multiple intervals, 13 multiple regimens, in the specifications that in my 14 mind were fixed. Now, did I remember that this was 15 the only place the word "fixed" was used? No, I did 10:49:01 16 not. 17 Q Did you know that at the time you rendered 18 your opinions? 19 MR. BRAUSA: Objection, form. 20 A Did I know it was the only place that the 10:49:07 21 word "fixed" was used? 22 Q Do you know that the word "fixed" appeared 23 with respect to the description of the dosing regimen 24 in Exhibit 2? 25 A I don't recall offhand. We use it 10:49:18 Page 101

1 frequently, but we don't have to use it when we 10:49:19 2 describe these regimens. So I don't remember if I 3 thought about that. 4 Q So if you turn to Claim 10, if the patentee 5 had wanted to make -- let me start over. 10:49:34 6 If you turn to page 10, if the patentee had 7 wanted to make reference to this being a fixed dosing 8 regimen, they simply could have put that language in 9 the claims, correct? 10 MR. BRAUSA: Objection, calls for 10:49:53 11 speculation. 12 A So they could have added the word "fixed", 13 but in my mind I would just as easily interpret this 14 as fixed intervals, because the intervals are set. So 15 I look at this -- without the word "fixed" it's 10:50:06 16 predetermined and I could use the word "fixed" as an 17 adjective to describe this, yes. 18 Q How would you use the word "fixed" in 19 Claim 10 if you wanted to make it clear that this was 20 a fixed interval as opposed to one that allowed 10:50:17 21 variability? 22 MR. BRAUSA: Objection, form, and lacks 23 foundation. 24 A It already to me is predetermined, so I 25 don't need to add the word "fixed" because it becomes 10:50:26 Page 102	1 I'm sorry, would you tell me the question 10:52:10 2 again, please? 3 Q I said, would you agree that the dosing 4 regimen in example two is not the dosing regimen in 5 Claims 10, 18, or 26? 10:52:18 6 A Well, it's not only the dosing regimen but 7 it's for a different disease as well. 8 Q So it's not the dosing regimen of five 9 initial doses, right? 10 A Followed by every eight weeks. That is 10:52:31 11 correct, it's not that. 12 Q And it's also not for the treatment of DR or 13 DME, right? 14 A And that's correct. 15 MR. BRAUSA: Counsel, if you're switching 10:52:47 16 gears, do you want to take a break? 17 MR. NIMROD: Sure, that's fine. 18 THE VIDEOGRAPHER: We're off the record at 19 10:52 a.m. 20 (Whereupon a recess was taken from 10:52:54 21 10:52 a.m. to 11:08 a.m.) 22 THE VIDEOGRAPHER: This begins media unit 23 three. We are back on the record at 11:08 a.m. 24 BY MR. NIMROD: 25 Q We talked earlier about your own practice 11:08:24 Page 104
1 redundant. 10:50:29 2 Q So in your view, the fact that the 3 specification only refers to -- strike that. 4 So in your view, the fact that the 5 specification refers to a study "where patients were 10:50:43 6 dosed at a fixed interval" plays no role in your 7 interpretation of Claim 10 with respect to it being 8 predetermined only? 9 MR. BRAUSA: Objection, form. 10 A As long as the intervals are unvarying, and 10:51:03 11 now you can have it as monthly as fixed or fixed for 12 the first and then a different fixed, meaning a 13 different interval for the second. Then it's the same 14 thing. 15 Whether you use fixed or not, it's 10:51:15 16 predetermined. Fixed interval dosing is 17 predetermined. 18 Q Can you go back to the -- actually, let's 19 finish up this part of the expert report. 20 You would agree that the example two in the 10:51:30 21 601 patent specification is not the dosing regimen in 22 the challenged Claims 10, 18, and 26, right? 23 A Let me get back to example two. That was 24 the variability, I believe. But let me look back 25 first. 10:51:51 Page 103	1 with respect to DME. By the way, does your practice 11:08:26 2 focus on DME or is it all types of macular 3 degeneration? 4 A So it's all types of retinal diseases, of 5 which macular degeneration and DME are the most 11:08:37 6 prevalent. 7 Q In your practice for DME you said the 8 majority of the time you do individualized methods, 9 regimens, right? 10 A For patients with DME, yes. 11:08:50 11 Q And about what percentage do you use, if 12 any, with the fixed regimen or predetermined for DME 13 patients? 14 A Probably less than 10 percent. 15 Q Would you agree that's a fair estimate for 11:09:10 16 most physicians or you just don't know? 17 A I don't know. I know the majority of 18 physicians use individualized therapy, but beyond that 19 I couldn't tell you percentages. 20 Q All right. Going back to page 41 of the 11:09:22 21 board's decision, the PTAB's decision in Exhibit 4, 22 which I think you have open, there is a statement 23 about halfway down with a paragraph that begins 24 "claims are interpreted in light of." 25 Do you see that paragraph? 11:09:42 Page 105

1 A Yes. 11:09:43 2 Q Could you read that paragraph to yourself. 3 Finished? 4 A Sure. 5 Q Okay. The patent office says: 11:10:18 6 "Moreover, patent owner adduces no evidence 7 that providing the first five doses at the prescribed 8 interval provided a surprising or even superior result 9 that would have been unexpected by those of ordinary 10 skill in the art." 11:10:32 11 Do you see that? 12 A I see that. 13 Q Do you agree with that statement? 14 MR. BRAUSA: Objection, form. 15 A Well, you never know what results you're 11:10:41 16 going to get until you've actually done them. So you 17 have hope and you have thoughts, but you're always 18 a little bit surprised when you get the results back. 19 So I would disagree with that statement. 20 Q How about if I asked you this. Would you 11:10:56 21 agree that there's no evidence that providing the 22 first five doses at the prescribed interval provides a 23 superior result? 24 MR. BRAUSA: Objection, form. 25 A Well, I don't think we can determine 11:11:09 Page 106	1 that's following in this case three monthly loading 11:12:31 2 doses. That's the data I'm referring to. 3 Q And the data then being the mean change in 4 acuity? 5 A Correct. 11:12:38 6 Q Okay, that's fine. Thank you. 7 Just for the record, the mean change in 8 acuity at week 24 is 8.5; is that right? 9 A That's correct. 10 Q And when you came up with -- when you gave 11:12:56 11 me the opinion about you would expect -- strike that. 12 You gave me the opinion that with respect to 13 Claim 10 -- wrong one -- that the level of efficacy 14 required for the scope of Claim 10 was about ten or 15 better letters of improvement -- sorry, eight or 11:13:23 16 better letters of improvement, right? 17 A Comparable to Avastin and Lucentis. And 18 when you asked me for a number, I gave eight. 19 Q And I thought you told me that that was at 20 52 weeks? 11:13:40 21 A 52 is the most commonly cited endpoint. But 22 we had the discussion where most of that improvement 23 occurs within six months and then you tend to get a 24 leveling, with only a small amount of improvement 25 within six months and a year. 11:13:55 Page 108
1 superior results. What we can say is that ultimately, 11:11:12 2 the five doses followed by a Q8 gave a result that was 3 very similar to monthly fixed therapy and certainly 4 gave a superior result to laser. 5 Now, it depends on what other we're 11:11:25 6 comparing to. But laser was our most comparator and 7 that it was superior. 8 Q Monthly dosed fixed therapy was also 9 superior to laser, right? 10 A Correct. 11:11:42 11 Q Earlier in the deposition I asked you about 12 Table 2 or you took me to Table 2. Can you go back to 13 that in Exhibit 2, which is the 601 patent, Column 14. 14 A Yes. 15 Q Page 16, there's a Table 2? 11:11:57 16 A Yes. 17 Q You had said that the data out of Table 2 18 supports the idea of pursuing a regimen like that in 19 Claim 10 in a prospective study. It's worth pursuing. 20 I just read your testimony, okay. 11:12:14 21 A Yes. 22 Q What data in Table 2 were you referring to? 23 A Referring to the fourth line down, if you 24 will, or fourth result down, which is VEGF-Trap 25 2 milligrams every eight weeks, as we said before, 11:12:27 Page 107	1 Q So then the data that would support the idea 11:13:57 2 of pursuing a regimen like Claim 10 would be the 3 improvement in initial dosing of 8.5, for example? 4 MR. BRAUSA: Objection, form. 5 A It's the data shown here, yes, of 8.5 11:14:09 6 letters in this study, which is called the DA VINCI. 7 Q Let me mark as Exhibit 5, Stewart Exhibit 5, 8 a copy of the final written decision in IPR2022-01226, 9 which is also directed to the 601 patent. 10 (Whereupon a document/item was marked for 11:15:31 11 identification as Petitioner's Exhibit 5.) 12 A Thank you. 13 Q Before we get to that, you were involved in 14 the clinical study for Eylea; is that right? 15 A I was involved in a couple of clinical 11:15:53 16 studies for Eylea. 17 Q Which ones? 18 A The VIEW trials and GALILEO. 19 Q And the VIEW trial was directed to what 20 indication? 11:16:04 21 A Neovascular age-related macular 22 degeneration. 23 Q And what about the GALILEO trial? 24 A And that was macular edema due to central 25 retinal vein occlusion. 11:16:17 Page 109

1 Q Have you seen the document that I've shown 11:16:30 2 you, Stewart Exhibit 5? 3 A I don't recall having seen it before. 4 Q Were you aware that there was a separate IPR 5 directed to other claims in the 601 patent? 11:16:45 6 A I recall this existing, yes. 7 Q Would you go to page 42, please. I'm sorry, 8 page 43, wrong one. 9 It states on page 43, this is the PTAB: 10 "We also addressed in the 881 decision 11:17:39 11 whether the claims required, as patent owner argued, 12 any degree of efficacy." 13 Do you see that? 14 A I see that. 15 Q And in your opinion, the claims of the 601 11:17:51 16 patent that you have studied require some level of 17 efficacy? 18 A Yes. 19 Q Okay. And they require a level of efficacy 20 for the patient population as a whole in a clinical 11:18:00 21 study but do not require a level of efficacy for any 22 individual patient, right? 23 MR. BRAUSA: Objection, form. 24 A They don't require the same efficacy. 25 Q Well, they don't require any, you told me, 11:18:13 Page 110	1 of improvements that are better than we see in 11:19:28 2 clinical practice. That's a common observation. 3 So as a whole, yes. 4 Now, when it comes to individual patients 5 within that population, there are some that we will 11:19:40 6 define as failures, and we went through several of 7 those -- poor visual acuity results, loss of vision, 8 infection, inflammation -- and those are patients that 9 then need to be treated differently outside of the 10 claim. 11:19:57 11 Q Okay. But if a patient, an individual 12 patient is treated for DME following a regimen set 13 forth in Claim 10 and gets, hypothetically, a 14 four-letter gain after 52 weeks, is that treatment 15 within the scope of Claim 10 for that individual 11:20:11 16 patient? 17 MR. BRAUSA: Objection, form, and outside 18 the scope. 19 A It could very well be, because again, it 20 varies from patient to patient. 11:20:23 21 For example, if the patient comes in with a 22 vision of 20/25, then four letters gets them to 20/20, 23 they're not going to get more than four letters. 24 That's a success. 25 But on average, I'm treating patients who 11:20:32 Page 112
1 because you told me that patients could have -- an 11:18:15 2 individual patient could have zero letter gain -- 3 A Yes. 4 Q -- by following the regimen of Claim 10 and 5 still be within the scope of it because the broader 11:18:28 6 patient population got the eight; isn't that right? 7 MR. BRAUSA: Objection, form. 8 BY MR. NIMROD: 9 Q I didn't say that very well. 10 I thought you told me before -- 11:18:37 11 A Yes. 12 Q -- that it didn't matter if an individual 13 patient didn't get the gain of eight to be within the 14 scope of the claims, so long as the patient population 15 as a whole did achieve a gain of eight letters or 11:18:50 16 better following the regimen described in Claim 10? 17 MR. BRAUSA: Objection, form, 18 mischaracterizes the testimony. 19 A So let me state again, it is that the 20 patient population as a whole doesn't have to get the 11:19:09 21 same average level of visual acuity. In fact, most of 22 the time we don't expect them to because of the 23 changes -- the differences between clinical practice 24 versus clinical trials. 25 Clinical trials generally give you numbers 11:19:24 Page 111	1 have average vision of 20/50. So when you pool all 11:20:35 2 those together, then I'm getting numbers that on 3 average are going to be better than some of the 4 individuals, especially those that are up against the 5 ceiling, where there are only so many letters you can 11:20:46 6 gain. 7 Q So if I am a physician treating a patient 8 according to the regimen of Claim 10 for DME and that 9 patient after 52 weeks gets a four-letter gain, is 10 that a method that is inside or outside the scope of 11:21:02 11 the claims for that individual patient? 12 MR. BRAUSA: Objection, form. 13 A So for that patient that may very well be 14 effective, because that's as good as the patient gets. 15 Q So is that within the claim or not within 11:21:15 16 the claim? That's what I'm asking. Is it treatment 17 within the scope of the claim? 18 A For that patient, yes, that's within the 19 scope of the claim. 20 Q I thought you said that. 11:21:25 21 So if I have a patient that has 20/50 22 vision, that's worse than what you described in your 23 other example, right? 24 A Right. 25 Q So now I'm a physician, I'm treating a 11:21:35 Page 113

1 patient with 20/50 vision who's got centrally-involved 11:21:37 2 DME. I treat the patient for a year to get a 3 four-letter gain. Would that treatment for that 4 individual patient fall within the scope of Claim 10? 5 MR. BRAUSA: Objection, form, and outside 11:21:52 6 the scope. 7 A So now I'm going to assess why has the 8 patient gotten only four letters and that may be as 9 much as they get. If they've had a good anatomic 10 result and they can't get any better by any different 11:22:05 11 method of treatment, then I would say yes, that fits 12 within. 13 Because I'm also going to have other 14 patients that are going to get at 20/50, probably 12 15 letters, and I'm going to get that average that I'm 11:22:17 16 looking for. 17 Q The average of eight or better? 18 A Or better. Although, again, with clinical 19 practice it's generally going to be less. The average 20 is going to be less. 11:22:27 21 Q For a clinical practice, the average gain 22 for a patient population is generally lower than the 23 gain in the clinical trials? 24 A Correct. 25 Q Do you know why that is? 11:22:43 Page 114	1 On page 43 at the bottom half of the page, 11:24:15 2 the PTAB is quoting from another decision saying: 3 "We find instructive the specification's 4 discussion which is identical to the 601 patent" -- 5 that's the patent at issue here. You understand that? 11:24:29 6 A Yes. 7 Q -- "regarding the 'amount of VEGF antagonist 8 administered.' In that discussion the specification 9 explains" -- you see that? 10 A Yes. 11:24:42 11 Q And then there's a block quote that says: 12 "The amount of VEGF antagonist administered 13 to the patient in each dose is in most cases a 14 therapeutically effective amount." 15 Do you see that? 11:24:54 16 A Yes. 17 Q And it says: "As used herein, the phrase 18 'therapeutically affected' amount means a dose of a 19 VEGF antagonist that results in a detectable 20 improvement in one or more symptoms or indicia of 11:25:06 21 angiogenic eye disorder or a dose of VEGF antagonist 22 that inhibits, prevents, lessens or delays the 23 progression of an angiogenic eye disorder." 24 Do you see that? 25 A Yes. 11:25:22 Page 116
1 MR. BRAUSA: Objection, form. 11:22:44 2 A There have been lots of explanations for 3 that, including compliance, the method of checking 4 visual acuity, the absence of doing refractions at the 5 time of clinical practice, pushing patients to the 11:22:58 6 limit, standardized rooms. All of that which affect 7 visual acuity have been proposed as explaining why the 8 results in clinical practice is inferior to trials. 9 Q All right. So just getting back to that 10 patient, I think that had the 20/50 vision, you said 11:23:17 11 that might be the best they can get, right? 12 A Yes. 13 Q So let's say I have a patient and -- I'm a 14 physician and the patient has 20/50 vision and I treat 15 the patient according to the regimen of Claim 10 for 11:23:32 16 DME, and after a year the patient gets a four-letter 17 gain and I determine that's the best the patient's 18 going to get and I'm satisfied. Was that treatment 19 within the scope of Claim 10? 20 MR. BRAUSA: Objection, form, and outside 11:23:46 21 the scope. 22 A Yes. 23 Q If you would go to page 43 of this decision 24 in the IPR ending in 01226, which is Stewart 25 Exhibit 5. 11:24:12 Page 115	1 Q And they say, going on -- now, that's a 11:25:22 2 quote from the 601 specification. You understand 3 that? 4 A Yes. 5 Q And that's the specification you studied? 11:25:26 6 A Yes. 7 Q And then at the bottom the board goes on and 8 says: "That description" -- this is their own 9 characterization, not the spec -- "along with the 10 absence of the phrase 'therapeutically effective' in 11:25:39 11 the claims signals for us the inventor's intention not 12 to limit claims to" -- and it goes on. 13 So let me ask you a question about the block 14 quote then. If "therapeutically effective amount" 15 includes, the last portion quoted by the PTAB, a dose 11:25:55 16 of VEGF antagonist that delays progression of an 17 angiogenic eye disorder, isn't that inconsistent with 18 your opinion that an effective amount requires an 19 improvement? 20 MR. BRAUSA: Objection, form, and outside 11:26:13 21 the scope. 22 A So there are lots of other issues, primary 23 and secondary results. The primary is, on average, 24 getting an improvement in vision that is comparable to 25 what already exists in the literature. 11:26:24 Page 117

1 Secondary results are prevention of -- hold 11:26:26 2 on one second. I don't even know where this came 3 from. I need to find this. 4 Q I'll get the -- 5 A Yeah, I need to find this, to put it in 11:26:51 6 context. 7 Q So if you go back to Stewart 2, go to 8 Column 6. Let me know when you're there and I'll 9 direct you to the lines. 10 Bottom of Column 6, it's the last paragraph 11:27:01 11 on that page, starting on line 58, if you want to read 12 that to yourself. 13 A Thank you. 14 Q It also -- I guess it carries over a bit to 15 Column 7. But that looks to be a lot of doses or -- 11:27:11 16 yeah, amounts. 17 A I'm sorry, again, bottom of Column 6? 18 Q So read Column 6. 19 A Yes. 20 Q It starts, "The amount of VEGF antagonist 11:27:22 21 administered to the patient in each dose is in most 22 cases a therapeutically effective amount." 23 Do you see that sentence? 24 A I see that. 25 Q And that's a sentence that was quoted by the 11:27:33 Page 118	1 the scope. 11:28:24 2 A I mean, again, I would agree they're the 3 same thing. 4 Q Okay, good. So then since the patent is 5 teaching that the therapeutically effective amount can 11:28:32 6 include doses that inhibit, prevent, lessen or delay 7 the progression of an angiogenic eye disorder, doesn't 8 that mean -- or isn't that inconsistent with your view 9 that the claims require an efficacy where there's an 10 improvement of eight letters? 11:28:52 11 MR. BRAUSA: Objection, form. 12 A So the average improvement of eight letters 13 is specific to Claim 10. This, when it talks about 14 prevention, lessens, or delays the progression of an 15 angiogenic eye disorder, is really very suggestive of 11:29:11 16 DR, not DME. Because that's the reason why we give 17 injections in DR, if we give them, is to one, get 18 improvement and two, prevent progression of DR. 19 So I don't look at this as being contrary to 20 608 -- I'm sorry, to Claim 10, rather -- because I 11:29:32 21 don't think this is referring to DME. I think this is 22 referring to DR. 23 Q So when you see the phrase "or delays the 24 progression of an angiogenic eye disorder," you 25 believe that to be limited to DR? 11:29:52 Page 120
1 PTAB? 11:27:35 2 A Yeah. 3 Q And then it goes on: "As used herein, the 4 phrase 'therapeutically effective amount' means a 5 dose" -- and it goes on with the phrase that -- the 11:27:42 6 rest of the sentence that the PTAB quoted in that 7 decision on page 43. 8 Do you see that? 9 A Yeah, uh-huh. 10 Q So that's the context of the statement 11:27:51 11 "therapeutically effective amount." Do you see that? 12 A Yep. 13 Q So you wanted to know the context. 14 A Yes, thank you. 15 Q So wouldn't you agree then that your 11:28:00 16 interpretation of "effective amount" -- by the way, do 17 you perceive "effective amount" to be different than 18 "therapeutically effective amount", that phrase? 19 Do they mean the same thing? 20 MR. BRAUSA: Objection to form. 11:28:12 21 A No, by and large, they're the same thing. 22 Q In the context of this patent would you 23 agree with me that the term "effective amount" is the 24 same as "therapeutically effective amount"? 25 MR. BRAUSA: Objection, form, and outside 11:28:24 Page 119	1 A In this case I think it is, yes. 11:29:54 2 Q Well, in the case of the 601 patent at 3 Column 6, lines 64 to 65, the phrase "a dose of VEGF 4 antagonist that inhibits, prevents, lessens or delays 5 the progression of an angiogenic eye disorder," you 11:30:10 6 believe that "angiogenic eye disorder" in that context 7 refers to DR only? 8 A No, it would be macular degeneration, 9 because our early endpoints for macular degeneration 10 were stability of vision. 11:30:30 11 So macular degeneration is also going to 12 be -- is going to be to prevent progression or 13 stabilize. DR is the same way. We're looking to 14 prevent progression, to stabilize. So those are two 15 conditions. 11:30:46 16 The DME, our objectives in DME are 17 different, because our objectives in DME are to 18 improve the vision. Because that's what already was 19 out there in the literature and we're looking to match 20 that. 11:30:58 21 Q What in the patent says that for Claim 10 22 you're looking to match what was done, for example, 23 with Lucentis? 24 A That's my interpretation of "effective". It 25 doesn't say that, but that's my interpretation of 11:31:07 Page 121

1 "effective". 11:31:09 2 Q Okay. So is there anything in the 3 specification you can point to that says that the 4 interpretation of "effective" is a comparator to 5 Lucentis or Avastin? 11:31:21 6 A Not that I recall, no. 7 Q If we go to the next page, the bottom half 8 of the page, there's a paragraph that begins on page 9 44, "We conclude that they do not." 10 Do you see that paragraph? 11:32:03 11 A I see that. 12 Q And then there's a recitation of Claim 1, 13 where the board quotes Claim 1, which is for macular 14 degeneration, right? 15 A Uh-huh. 11:32:15 16 Q Yes? 17 A Yes. 18 Q And what they're highlighting in ital is the 19 phrase "which is." 20 A Yes. 11:32:26 21 Q And they mention that Claim 10 uses 22 virtually identical language. You see that? 23 A Just about, not quite. 24 Q In terms of the "which is"? 25 A I believe the "which is" is in both. 11:32:34 Page 122	1 the statement -- I'm going to read it again -- that 11:33:58 2 the "claims are silent with respect to any additional 3 metric of required efficacy of the effective amount, 4 requiring only the amount delivered at the prescribed 5 intervals"? 11:34:14 6 MR. BRAUSA: Objection, form, and outside 7 the scope. 8 A Well, again, the claim says "effective". 9 The claims do not define "effective". 10 Q So then you would agree with the PTAB 11:34:29 11 statement? 12 A No, because -- 13 MR. BRAUSA: Objection, form. 14 (Discussion off the record.) 15 THE WITNESS: So is there an additional 11:34:59 16 metric beyond the term "effective"? Not that I 17 know of. 18 BY MR. NIMROD: 19 Q Then the PTAB -- 20 A Let me just qualify that, if I may. 11:35:16 21 Q Go ahead. 22 A But it says "requiring only the amount 23 delivered at the prescribed intervals." It's almost 24 as though that's contradictory. 25 "Effective" is itself a qualifier to say 11:35:25 Page 124
1 Q On the next page it says that, "The claims 11:32:42 2 are silent with respect to any additional metric" -- 3 this is the next page, on page 45 of the PTAB 4 decision: 5 "The claims are silent with respect to any 11:32:52 6 additional metric of required efficacy of this 7 effective amount, requiring only the amount delivered 8 at the prescribed intervals." 9 A I see that. 10 Q Do you agree with that statement of the 11:33:04 11 PTAB? 12 A Well, the claim -- Claim 10, for example -- 13 says "an effective amount." I mean, it specifies. It 14 doesn't say what the specification of "effective" is, 15 but it says "effective". 11:33:13 16 Q Would you think that other persons 17 reading -- skilled persons, POSAs, reading the 601 18 patent might come to a different conclusion than you 19 as to what "effective" meant for DME in Claim 10? 20 MR. BRAUSA: Objection, form. 11:33:35 21 A I think that would be unlikely, because when 22 we're treating DME, we're looking to improving vision. 23 That's our standard, and that was the standard back at 24 that time. 25 Q So if we go to page 45, would you agree with 11:33:53 Page 123	1 that you need a degree of effectiveness. And then it 11:35:27 2 says "while requiring only the amount delivered at 3 prescribed intervals," as though it's ignored the 4 "effective", or have I misread that? 5 Q Let me take you back to page 44. I think I 11:35:42 6 was trying to explain what the PTAB was saying and see 7 if you agree with it. 8 So if you see, they italicize the "which is" 9 in that quote? 10 A Yep. 11:35:51 11 Q So I'll say my understanding of the claim is 12 that an effective amount of aflibercept is in fact 13 defined by the claim because it ways "which is," and 14 that effective amount is defined to be 2 milligrams 15 approximately every four weeks for the first three 11:36:06 16 months, followed by 2 milligrams approximately once 17 every eight weeks or once every two months. 18 Do you understand that? 19 A I understand that. 20 Q Would you agree that the claim defines an 11:36:17 21 effective amount of aflibercept to be that dosage that 22 is recited after "which is"? 23 MR. BRAUSA: Objection, form. 24 A So I would agree it is that dosage and that 25 regimen which produces -- and the "effective" is in my 11:36:32 Page 125

1 opinion, the visual acuity improvement that's on par 11:36:39 2 with Lucentis and Avastin. 3 So there's that link for me that has to be a 4 link to what's in the prior art. 5 Q It's a link, though, that's not recited in 11:36:51 6 the claim, right? 7 MR. BRAUSA: Objection, form. 8 A To my understanding, yes. 9 Q You're agreeing with me when you say my 10 understanding, yes? 11:36:58 11 A Yes. I have not found any link in the claim 12 or in the patent. 13 Q I'm going to go back to Stewart Exhibit 4, 14 which is the institution decision in this IPR that you 15 reviewed in connection with your opinion, Exhibit 4. 11:38:11 16 A Got it. 17 Q Okay, great. Could you go to page 36, 18 please. In paragraph 36, the PTAB -- actually, going 19 back to -- 20 A I'm sorry, 36, 38? 11:38:40 21 Q Yeah. Let's go to page 32, actually. 22 There's a section that says Section 6, "Analysis." 23 Do you see that? 24 A Yes. 25 Q So this is the PTAB's analysis with respect 11:38:50 Page 126	1 Dr. Chaum goes on, "The principal way to 11:39:59 2 treat DME effectively in the first instance therefore 3 was to dry the liquid and stop the leakage with a 4 series of anti-VEGF injections." 5 Do you see that? 11:40:14 6 A Yes. 7 Q Do you agree with that? 8 A Partially. 9 Q What part do you not agree with? 10 A Because many of these eyes are not going to 11:40:20 11 become dry, we know that, yet they exhibit very good 12 improvements in visual acuity. And there's several 13 trials that show that. 14 So when we start injecting, we think we're 15 going to dry the eye, but ultimately we realize in 11:40:35 16 many of these that we're not going to do that but the 17 patient is going to get a satisfactory result 18 nonetheless. 19 Q For patients that you're using an 20 individualized treatment -- for your own practice you 11:40:50 21 have an individualized treatment protocol for DME and 22 you have a patient that you're giving monthly 23 injections to, what do you do if the patient's eye 24 doesn't dry? 25 MR. BRAUSA: Objection, form. 11:41:06 Page 128
1 to ground two of the IPR petition. 11:38:53 2 You see the first sentence, it says "having 3 considered the parties' arguments," etc., then it 4 talks about a likelihood of prevailing at trial on 5 ground two. Do you see that? 11:39:07 6 A Yes. 7 Q So then if we turn now to page 36, part of 8 the analysis -- it's in that section. 9 It says at the top of the page: 10 "Petitioner's declarant Dr. Chaum testifies with 11:39:23 11 respect to the scheduling of dosage regimens and the 12 treatment of DME and related diseases," and then 13 there's a block quote. 14 Do you see that? 15 A Yes. 11:39:35 16 Q The first sentence says: "DME is 17 characterized by leakage of fluid and blood and 18 swelling from damage to blood vessels at the back 19 inner wall of the eye (retina)." 20 Do you see that? 11:39:51 21 A Yes. 22 Q Do you agree with that statement? 23 A Yes. 24 Q "The principal way to treat DME 25 effectively" -- sorry. 11:39:57 Page 127	1 BY MR. NIMROD: 11:41:06 2 Q In a general matter? 3 A So for patients with DME getting monthly 4 injections and they're not dry, then we begin to look 5 at stability and we say that we have stable fluid, 11:41:16 6 stable visual acuity, and then at that point on an 7 individualized basis we can then switch to the prn or 8 the treat and extend side and then continue 9 injections. 10 That's one option. Another option is to add 11:41:35 11 laser photocoagulation, and many of the trials will do 12 that. For patients who are incompletely dry, they'll 13 add photocoagulation at some point in time once the 14 initial series of injections has been completed. 15 The third option means changing drugs, but 11:41:52 16 those are less commonly used. 17 Q Wouldn't one option be just to continue 18 doing monthly doses instead of some more extended 19 dosing? 20 MR. BRAUSA: Objection, form. 11:42:05 21 A That is an option, yes. 22 Q For your -- you mentioned that 10 percent or 23 less of your DME treatments are fixed, predetermined 24 dosing regimens, right? 25 A Correct. 11:42:20 Page 129

1 Q When you do -- for your patients where 11:42:22 2 you've done a predetermined dosing regimen, do you 3 follow any particular dosing regimen? 4 You know, five-plus then going to eight or 5 three or four, or does it just depend on the patient, 11:42:34 6 like the 20/50 versus 20/30? Help me with that. 7 MR. BRAUSA: Objection, form. 8 A It depends on the patient. And again, the 9 strategy that I employ for those patients for whom I'm 10 going to use individualized therapy -- 11:42:54 11 Q Predetermined? 12 A Predetermined, I'm sorry, thank you. 13 Q So when you say less than 10 percent of the 14 time you use predetermined for DME -- 15 A Right, yep. 11:43:03 16 Q -- for those patients where you do 17 predetermined, do you have specified dosing regimens 18 for DME? 19 A No. 20 Q All right. So let's go back to Dr. Chaum's 11:43:11 21 quote here. 22 The next sentence says, "VEGF antagonists 23 are relatively short-acting compared to focal laser 24 treatment, thus a less series of injections are 25 required." 11:43:33 Page 130	1 A Well, I don't agree there's a need to dry 11:44:36 2 the retina, because many patients can be treated 3 effectively without ever drying and when they're 4 stable, meaning the fluid is stable, the visual acuity 5 is stable, we can then effectively go on and extend 11:44:49 6 the interval. 7 Q Then would you -- if I modify the sentence 8 to say because there's a need to dry or stabilize the 9 retina before proceeding to reduce the frequency of 10 injections, a POSA would thus -- would have thus 11:45:08 11 sought through routine variation of the number of 12 initial doses to determine the optimum number of 13 initial injections before moving to eight-week dosing? 14 MR. BRAUSA: Objection, form. 15 A So what you've done is -- the first part, 11:45:24 16 you've then gotten to the point where now one can 17 consider going ahead and changing the follow-up 18 frequencies, the follow-up durations. 19 What we're doing here is this is an 20 individualized therapy and so you can't routine -- you 11:45:47 21 can't from individualized therapy go backwards and say 22 okay, this number of injections is the one that I want 23 to use routinely. 24 And I think that's what he's suggesting 25 here, that you learn from your therapy what the best 11:46:05 Page 132
1 Do you agree with that? 11:43:34 2 A Yes. 3 Q The prior sentence you said you agreed in 4 part or disagreed in part or something to that effect. 5 What part do you agree with in the prior sentence? 11:43:41 6 A The principal way to treat DME effectively 7 was to dry the liquid. We get lots of patients who 8 were effectively treated without ever drying. 9 Q In terms of ratios for your practice, do 10 most of your patients get to dryness for DME or not? 11:43:54 11 A So 25 to 40 percent of patients never get to 12 dryness. 13 Q Okay. The next quote or sentence in that 14 quote from Dr. Chaum states: 15 "Because there was a need to dry the retina 11:44:12 16 before proceeding to reduce the frequency of 17 injections, POSAs would have thus sought through 18 routine variation in the number of initial doses to 19 determine the optimal number of initial injections 20 before moving to eight-week dosing." 11:44:27 21 Do you see that? 22 A I see that. 23 Q Do you agree with that? 24 A No. 25 Q What part of it don't you agree with? 11:44:34 Page 131	1 number is and then you apply that in the future, and 11:46:13 2 that's not the case, not when using individualized 3 therapy, because now it's individualized for every 4 patient. 5 Q So then do you disagree with the statement 11:46:31 6 I made or -- 7 A You mean reading his statement? 8 Q Reading his and adding -- let me ask it 9 again. 10 A Yeah, okay. 11:46:40 11 Q So if I asked you if you would agree with 12 this statement -- because there was a need to dry or 13 stabilize the retina before proceeding to reduce the 14 frequency of injections, POSAs would have thus sought 15 through routine variation the number of initial doses 11:46:55 16 to determine the optimal number of initial injections 17 before moving to eight-week doses -- you would agree 18 or disagree with that? 19 A I agree with the first part. I'm having 20 problems with the latter part, "to determine the 11:47:15 21 optimum number of initial injections." 22 Now, I don't know -- 23 Q I think I can rephrase it then based on what 24 you're saying. 25 A Okay, go ahead. 11:47:21 Page 133

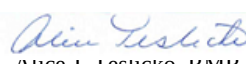
1 Q I'm getting it, I think. I'll ask you if 11:47:21 2 you agree with this. 3 Because there was a need to dry or stabilize 4 the retina before proceeding to reduce the frequency 5 of injections, POSAs would have thus sought through 11:47:29 6 injection of initial doses to determine the optimal 7 number of doses for a particular patient before moving 8 on to eight-week dosing; is that right? 9 MR. BRAUSA: Objection, form. 10 A So now you're starting to go to 11:47:54 11 individualized therapy, which makes sense. But once 12 you get to individualized therapies you would never 13 then say now I'm going to do eight-week dosing. 14 Because you're in individual mode and to go to eight 15 weeks is completely contradictory -- it's contrary to 11:48:09 16 individualized therapy. 17 You're using individualized therapy to 18 determine the number of injections you're doing in the 19 beginning. Once you get the patient treated 20 satisfactorily and you've defined that at the first 11:48:22 21 part of the statement, now you're going to go ahead 22 and you're going to extend. 23 But you wouldn't say I'm going to extend to 24 eight-week intervals. You'd say I'd extend to 25 six-week intervals and then I'm going to reassess, or 11:48:33 Page 134	1 Q Okay. 11:49:45 2 A So -- because once you're in the 3 individualized therapy mode, which is what this is, 4 you're going back past eight. If it works at eight, 5 you're going to go to nine or ten to prove you can't 11:49:56 6 go longer, and if it doesn't work at nine or ten, then 7 you're going to fall back to eight and it could be you 8 stay at eight forever. That could be the case. But 9 you've tested something else. 10 That's individualized therapy, and that's 11:50:08 11 what this is. 12 Q If you proved it worked at eight, why would 13 you go to nine or ten? 14 MR. BRAUSA: Objection, form. 15 A Because your rationale, your thought process 11:50:19 16 here with individualized therapy is to extend 17 intervals as much as possible and to minimize the 18 number of injections, and to do that you've got to 19 push your interval as long as you can go and that 20 means going beyond eight. 11:50:35 21 If it works at eight, you go further, 22 because that's what your strategy is. 23 Q Wouldn't that be a goal for a predetermined 24 dosing regimen as well? 25 A No. So a predetermined dosing interval, 11:50:47 Page 136
1 an eight-week interval and I'm going to reassess. 11:48:37 2 But the way this sounds is that it now goes 3 into eight-week dosing, and you would never do that. 4 Q You would never choose eight-week dosing 5 once you stabilize the eye? 11:48:48 6 A That's not the way people think about when 7 they start with individualized therapy, and that's 8 what we're starting with here, is individualized 9 therapy. People don't transition to fixed intervals 10 going forward. They stick with individual therapy. 11:49:00 11 That's not the way a POSA would work. 12 Q You agreed with me earlier, though, a POSA 13 who is using individualized therapy could give five 14 initial doses and then based on examination of the eye 15 each time, go to eight-week dosing upon each visit? 11:49:16 16 MR. BRAUSA: Objection, form. 17 BY MR. NIMROD: 18 Q A POSA could do that, correct? 19 A That would be a very unusual, rare 20 circumstance that might happen, but -- well, let me 11:49:27 21 qualify that. 22 You could end up that way, but I think I 23 also said that once you get to eight weeks, you would 24 probably go to nine or ten before dropping back to 25 eight if the disease were recurring. 11:49:41 Page 135	1 predetermined dosing regimen -- 11:50:56 2 Q I mean, let me rephrase that. I'll strike 3 that question. 4 Would you agree that when deciding on what 5 dosing regimen to use in a clinical trial, one would 11:51:06 6 try to use a dosing regimen that extended the dosing 7 for the tertiary doses, the maintenance doses, as far 8 as you expect it to be efficacious so that you reduce 9 the number of injections for the patient? 10 MR. BRAUSA: Objection, form, calls for 11:51:26 11 speculation. 12 A So if you could repeat, because I'm trying 13 to figure out if you're talking about fixed interval 14 dosing. 15 Q Yes. 11:51:39 16 A You are? 17 Q Yes. 18 A All right. So you want to try to -- if 19 you're creating the protocol, you want to try to 20 balance going as long as you can that's also going to 11:51:49 21 be as effective as monthly therapy, because that's 22 going to be your comparator. You want to beat laser. 23 But the assumption here is everything can 24 beat laser, so you want it to be as good as monthly. 25 You'd like the interval to be as long as possible but 11:52:05 Page 137

1 you don't want it to fail, and so you make an educated 11:52:07 2 guess as to what you think you can get, and the 3 educated guess in this case was eight weeks. 4 Q Based on what? 5 A Based on DA VINCI from -- the phase two, 11:52:20 6 which was the DA VINCI trial, where they used eight 7 weeks after three monthly injections. 8 Q But what was the basis for the educated 9 guess to try eight weeks versus seven? 10 MR. BRAUSA: Objection, form. 11:52:37 11 A Because we had a drug that we thought had 12 longer durability, longer duration of action. Seven 13 doesn't fit the calendar very well. Eight does, 14 monthly does, three-monthly does. 11 weeks doesn't. 15 So when you're doing this, there's a 11:52:56 16 strategy to try to make it simple to follow for both 17 physicians and patients as well. 18 Q So if you knew that the monthly dosing 19 worked for DME, then the next idea that one would try 20 would be to go monthly dosing for loading, followed by 11:53:15 21 eight-week dosing? 22 MR. BRAUSA: Objection, form. 23 A That's a logical way to do it, and that's 24 the way that the investigators at Regeneron decided to 25 do it. 11:53:29 Page 138	1 that says "Monthly until dryness attained, then T&E 11:54:58 2 for centrally involved DME and Eylea," right? 3 Let's just refresh our recollection. This 4 is a table on page 22. 5 A Yeah, page 22, the table. Okay, go ahead. 11:55:13 6 Q "Centrally involved DME anti-VEGF treated 7 eye." 8 A Right. 9 Q The third column or bar is Eylea, right? 10 A Yep. 11:55:23 11 Q And -- you have to say "yes", not "yep". 12 A I'm sorry, yes. 13 Q And then the light blue one says "Monthly 14 until dryness attained then T&E." 15 Do you see that? It's right here on the 11:55:37 16 side. 17 A Oh, I'm looking on the side. Thank you. 18 Q Do you see it? 19 A "Monthly dryness, then T&E." Yes, I do. 20 Q So based on your understanding then, 11:55:46 21 "monthly until dryness attained and then T&E," the T&E 22 would most likely or very rarely be eight-week dosing 23 that was actually used by the physician? 24 MR. BRAUSA: Objection, form, and lacks 25 foundation. 11:56:04 Page 140
1 Q You mentioned that for individualized 11:53:29 2 treatment after the monthly loading doses, it would be 3 rare to go to eight-week dosing. This is for 4 individualized, not predetermined, okay. 5 A Uh-huh. 11:53:42 6 Q Yes? Is that right? 7 A Yes. 8 Q So when we looked at all those in that 9 market study and there was the prn, there was the T&E, 10 there was immediate prn, immediate T&E, there's all 11:53:54 11 those different ones there, is it your understanding 12 then that most of those with prn and T&E wouldn't 13 include any kind of eight-week dosing results? 14 MR. BRAUSA: Objection, form, and outside 15 the scope and lacks foundation. 11:54:15 16 A I'm -- 17 Q Let's just go to it real fast to make sure 18 we're on the same page. 19 A Okay. 20 Q This is Stewart Exhibit -- we already marked 11:54:23 21 it. It's this one here. Is that three? 22 A Exhibit 3. 23 Q Thank you. So let's go back to page 23 of 24 that -- page 22, sorry. 25 Okay. So on page 22 there is a light blue 11:54:53 Page 139	1 A That's correct. It would be very unusual 11:56:05 2 and the physicians would have tried nine or ten or 3 something else to determine if eight was ultimately 4 where they ended up. 5 Q And the same is true then with the one below 11:56:16 6 it in green, "Monthly dryness attained, then prn" -- 7 MR. BRAUSA: Objection, form. 8 Q -- that it would be very rare for that to 9 then by happenstance of examinations have resulted in 10 eight-week dosing after the initial monthly doses? 11:56:31 11 MR. BRAUSA: Objection, form, lacks 12 foundation. 13 A That's correct. It would be very unusual 14 that it would settle in eight weeks based on prn 15 protocol. 11:56:42 16 Q All right. Could you go to your expert 17 report at page 56, please, Stewart Exhibit 1. Okay, 18 your header three states: 19 "A POSA would not have a reasonable 20 expectation of success in using a fixed extended 11:58:14 21 dosing regimen in order to treat effectively while 22 minimizing the number of loading doses." 23 Do you see that? 24 A Yes. 25 Q Now, we've talked about patient populations, 11:58:28 Page 141

1 right? 11:58:32 2 A Yes. 3 Q So would you agree that a POSA in 2011 who 4 was considering fixed extended dosing regimens for 5 five initial doses and then followed by eight-week 11:58:51 6 treatments would expect that some portion of the 7 patient population would be effectively treated, if 8 not the whole? 9 MR. BRAUSA: Objection, form. 10 A So a POSA I think could assume that a 11:59:08 11 portion of the patient population would be effectively 12 treated by that regimen. But I think a POSA would 13 also understand that there are probably some patients 14 who aren't going to respond well. 15 Q Let me understand. In 2011, if a POSA 11:59:28 16 thought of using a five-week initial loading dose -- 17 strike that, that's bad. 18 Let me start over, okay, yes? 19 A Okay. 20 Q If in 2011 a POSA thought of using five 11:59:43 21 initial doses on a monthly basis followed by 22 eight-week doses for a patient population, the POSA 23 would expect success for some patients but not 24 necessarily all of them; is that correct? 25 MR. BRAUSA: Objection, form. 11:59:59 Page 142	1 Q So Claim 10 requires for the first five 12:39:31 2 injections -- that's week 16, right? 3 So in Claim 10, the first five injections, 4 zero, 4, 8, 12, and 16 weeks -- 5 A Yes. 12:39:48 6 Q -- would be the first five injections, 7 right, and that's required by Claim 10 to be monthly, 8 yes? 9 A Correct. 10 Q Then it says "followed by 2 milligrams 12:39:56 11 approximately once every eight weeks." 12 Do you see that? 13 A Uh-huh. 14 Q Yes? 15 A Yes, sorry. 12:40:01 16 Q The next time period for Claim 1 would be at 17 24 weeks, if I'm doing my math right, to give an 18 injection after the first five, right? 19 A 16, 24 -- so 16 would be the last of the 20 five and then you would give it at 24. 12:40:18 21 Q Okay. So then Claim 12 depends from 22 Claim 10, which means it incorporates the limitations 23 into it. So what is the regimen that Claim 12 is 24 describing where it says "after 20 weeks, 25 administering 2 milligrams of aflibercept once every 12:40:36 Page 144
1 A That's correct. 12:00:01 2 MR. NIMROD: Do you mind if we break for 3 lunch now? I think I may have an hour left of 4 questioning. 5 MR. BRAUSA: All right. 12:00:37 6 THE VIDEOGRAPHER: We're off the record at 7 12 p.m. 8 (Whereupon a recess was taken from 12 p.m. 9 to 12:38 p.m.) 10 THE VIDEOGRAPHER: This begins media unit 12:38:32 11 four. We're back on the record at 12:38 p.m. 12 BY MR. NIMROD: 13 Q Dr. Stewart, could you go to Stewart 14 Exhibit 2, which you have in your hands, and go to the 15 claims. 12:38:47 16 Look at Claim 10, please. It's in 17 Column 22. 18 A Claim 10, yes. 19 Q Then if you can go down two more, there is a 20 Claim 12 that says: "The method of Claim 10, further 12:39:08 21 comprising after 20 weeks, administering via 22 intravitreal injection 2 milligrams of aflibercept 23 once every four weeks." 24 Do you see that? 25 A Yes. 12:39:31 Page 143	1 four weeks"? 12:40:41 2 What would be that fixed regimen? 3 A I don't know. Meaning that it could be the 4 fixed regimen of monthly forever. Beyond that, I 5 can't tell you. 12:41:03 6 Q So Claim 10 would include a predetermined 7 dosage regimen where you did five -- strike that. 8 For the predetermined that's required for 9 Claim 10, in your view, it would cover a predetermined 10 regimen where you did five initial doses monthly, 12:41:22 11 followed by a predetermined one dose after eight 12 weeks. That would be within the scope of Claim 10, 13 and then everything after that prn, so to speak? 14 MR. BRAUSA: Objection, form. 15 BY MR. NIMROD: 12:41:39 16 Q Let me ask it -- so I'm a physician and I 17 decide I'm going to give five monthly doses and then 18 I'm going to give one dose at eight weeks and after 19 that I'm going to do prn. 20 Would that fall within the scope of 12:41:53 21 Claim 1 -- Claim 10, sorry? 22 MR. BRAUSA: Objection, form. 23 MR. NIMROD: Let me ask it again. 24 BY MR. NIMROD: 25 Q Does Claim 10 cover a predetermined regimen 12:42:00 Page 145

1 where you predetermine five initial doses and then one 12:42:04 2 extended dose eight weeks later and then leave 3 everything else as prn? 4 MR. BRAUSA: Objection, form. 5 A No. 12:42:16 6 Q So how many regimens are required to be 7 predetermined for the extended dosing for Claim 10; 8 that is, the eight-week dosing? 9 MR. BRAUSA: Objection, form. 10 A So your question as I understand it is how 12:42:34 11 many eight-week intervals do you need to treat once 12 you've passed your five monthly injections? 13 Q To be within the scope of Claim 10. 14 A So it doesn't state. But from the 15 standpoint of a POSA looking to treat patients, we 12:42:52 16 know this is something we're going to be giving over 17 the course of a year to years, because diabetes and 18 diabetic retinopathy is not a disease that goes away 19 quickly. 20 So the assumption that we have is we're 12:43:06 21 going to continue the Q8 week injections for an 22 extended period of time, usually on the order of a 23 couple of years. 24 Q So in your view, does Claim 10 require -- 25 cover a predetermined dosing regimen, where it says 12:43:22 Page 146	1 going to ask just to make sure I understand your 12:44:56 2 views. Are you ready? 3 A Go ahead. 4 Q If a physician were to follow the regimen of 5 Claim 10 to treat DME and for an individualized 12:45:10 6 patient -- strike that. I'm going to start over. 7 Individualized, let me try that again. I 8 guess I can't go too much longer because I won't be 9 able to ask questions. 10 If a physician followed the regimen of 12:45:31 11 Claim 10 to treat DME and the result for an individual 12 patient was no letter gain or letter loss but the eye 13 was stable, would that treatment fall within the scope 14 of Claim 10? 15 MR. BRAUSA: Objection, form, and outside 12:45:53 16 the scope. 17 A So as I think I mentioned before, we see a 18 considerable amount of variability with individual 19 patients and it's really -- when we're talking about 20 effectiveness, we're talking about average and so we 12:46:07 21 expect some patients to be zero. 22 It's not a common result, but it would not 23 be a rare result either, and it would it still be 24 treating within the claim. 25 Q And then the same would be true, I think 12:46:22 Page 148
1 that I will treat predetermined five initial monthly 12:43:26 2 doses followed by two predetermined doses every eight 3 weeks thereafter and that's it? That's all that's 4 predetermined? 5 MR. BRAUSA: Objection, form. 12:43:44 6 A So a physician could do that if he felt that 7 the disease were under control at that point and he 8 were to deviate away from Claim 10. But once he's 9 done that, he's deviated away. 10 So Claim 10 is Q8 weeks. The phase three 12:44:07 11 trial did that for three years. So I think our 12 reference ultimately is going to be three years and 13 then anything after three years then, if you will, 14 it's up to the discretion of the individual physician. 15 Q Okay. So then a physician who predetermines 12:44:24 16 five initial doses monthly followed by two doses every 17 eight weeks and then prn thereafter would not be 18 practicing Claim 10; is that right? 19 MR. BRAUSA: Objection, form, and outside 20 the scope. 12:44:42 21 A That's what I believe, yes. 22 Q All right. And then I asked you this 23 question earlier -- a question earlier about 24 four-letter gains. 25 I think I've asked these before, but I'm 12:44:54 Page 147	1 based on what you just said, that if a physician 12:46:24 2 treated a patient with a regimen of Claim 10 for 3 treatment of DME and found that there was only a 4 four-letter loss over the period of treatment but 5 there was then stability, would that treatment be 12:46:42 6 within the scope of Claim 10? 7 MR. BRAUSA: Objection, form, and outside 8 the scope. 9 A Yeah. For the same reasons I just 10 mentioned, yes. 12:46:51 11 Q There's a reference to the AMD, which is 12 what? 13 A Age-related macular degeneration. 14 Q And then we talked about DME, right? 15 A Right. 12:47:11 16 Q And DR. And then you also mentioned 17 something that was I think CRVO or something. 18 What was the other one? 19 A That's correct. 20 Q And what's CRVO again? 12:47:19 21 A Central retinal vein occlusion. 22 Q That's not centrally-involved DME, right, or 23 is that different? 24 A No, totally different disease. 25 Q Got it. Are there other diseases that one 12:47:30 Page 149

1 uses Eylea to treat? 12:47:32 2 A There are currently seven indications. 3 Other ones include retinopathy prematurity, myopic 4 macular degeneration -- 5 Q Can we call that MMD? 12:47:49 6 A No, we call it -- we don't. It's small 7 mCNV, is what it is, believe it or not. 8 Q Small mCNV? 9 A CNV. Choroidal neovascularization. Myopic 10 choroidal neovascularization, mCNV. 12:48:07 11 Q CM, not "N"? 12 A "N", I'm sorry. "N" as in neo, neo. 13 Q "N" as in Nimrod. 14 A Yep. 15 Q So I've got DR, DME, AMD, ROP, CVRO, and 12:48:17 16 then mCNV? 17 A And mCNV, correct. 18 Q One, two, three, four, five, six. 19 A And then the other one is branch retinal 20 vein occlusion. 12:48:33 21 Q Can I just called that BRVO? 22 A BRVO. 23 Q Thank you. 24 As of 2011, would there be an expectation 25 from a POSA that any of these would be easier to treat 12:48:48 Page 150	1 fine. 12:50:09 2 Based on that understanding of the DME 3 patients responding slower, would that suggest that 4 you would want to give DME patient populations as a 5 whole more initial monthly doses than AMD patients? 12:50:22 6 MR. BRAUSA: Objection, form. 7 A So generally that was the belief in 2011; is 8 that if you were to use individualized therapy, for 9 example, you're probably going to give more individual 10 doses. And if you're going to -- 12:50:44 11 Q For what? 12 A For DME. 13 Q Than you would for AMD? 14 A For AMD. 15 Q So for individualized therapy in 2011, a 12:50:53 16 POSA understood that you were more likely to give more 17 initial loading doses for DME than AMD? 18 MR. BRAUSA: Objection, form, 19 mischaracterizes the testimony. 20 A Yes. 12:51:06 21 Q For individualized regimens or treatment, is 22 there any way to know in advance when dryness will 23 occur in an individual patient? 24 A No. We wish. 25 Q For individualized therapy, is there any way 12:51:39 Page 152
1 than others? 12:48:50 2 MR. BRAUSA: Objection, form. 3 A It depends on how you define "easy". 4 Certainly there are different response rates based on 5 the disease process. 12:49:03 6 Q So starting with -- what was the first 7 indication that Eylea was approved for? 8 A AMD. 9 Q And what was the second, do you know? 10 A DME. 12:49:15 11 Let me take that back. I believe it was DME 12 was the second. 13 Q And then what was the third, as you recall? 14 A CRVO. 15 Q As between AMD and DME, was it thought in 12:49:27 16 the 2011 timeframe that it would be harder to treat 17 DME than AMD for patient populations as a whole? 18 MR. BRAUSA: Objection, form. 19 A The general consensus at that point with 20 regard to treating the two different diseases was that 12:49:44 21 patients with DME responded slower, but responded with 22 better long-term stability of vision compared to 23 patients with AMD, who responded quicker but had a 24 decrease in vision over time. 25 Q How about whether -- strike that. That's 12:50:07 Page 151	1 to know in advance when stability will occur in an 12:51:42 2 individual patient? 3 A No. 4 Q Can we go back to the 601 patent again and 5 go to Table 2. 12:52:02 6 Table 2 includes a line four that you 7 referenced earlier that had three initial loading 8 doses one month apart and then eight weeks thereafter, 9 right? 10 A Correct. 12:52:32 11 Q And then line two is just monthly -- sorry, 12 line three is monthly dosing of 2 milligrams -- let me 13 start over. 14 The line four that you were referring to was 15 2 milligrams, right? The three initial plus 12:52:45 16 eight-week thereafter, that was 2 milligrams, right? 17 A Correct. 18 Q Line three is the 2 milligram monthly, 19 right? 20 A Correct. 12:52:56 21 Q And the three -- the 2 milligram monthly got 22 better results than the 2 milligram three initial, 23 eight week thereafter, both at 24 and at 52 weeks, 24 right? 25 A So the devil is in the statistics and when 12:53:12 Page 153

1 you do statistical analyses, I'm pretty sure you find 12:53:16 2 that those are not statistically significantly 3 different. 4 So though there is a numerical difference or 5 delta as you're looking at the chart, it is not 12:53:28 6 statistically significant, and this is a small trial 7 with a relatively few number of patients, which makes 8 for that problem. 9 Q If you had a monthly dosing regimen, let's 10 say in 2011, that achieved success for DME, would you 12:53:45 11 be motivated to try initial loading doses monthly and 12 then go to some kind of extended dosing to see if that 13 worked as well? 14 MR. BRAUSA: Objection, form. 15 BY MR. NIMROD: 12:54:05 16 Q This is for a patient population, not for a 17 fixed predetermined dose. 18 A So the goal is to try to minimize or lessen 19 the number of injections, which again, minimizes cost 20 and complications. And if you can end up with the 12:54:23 21 same efficacy with fewer injections, then that's a 22 goal that pretty much everybody agrees upon. 23 We had not found that prior to this date, 24 but people were considering that this drug may be 25 able to achieve that. 12:54:42 Page 154	1 opportunity. 12:55:44 2 Q I'm sorry, I meant for a predetermined dose. 3 Let me try over again. 4 So in 2009, would a POSA who was considering 5 clinical trials have been motivated to go from monthly 12:55:53 6 dosing to an option where it was instead initial 7 monthly dosing, followed by extended dosing? 8 MR. BRAUSA: Objection, form. 9 A Yes. 10 MR. NIMROD: I have no further questions at 12:56:18 11 this time. 12 MR. BRAUSA: Nothing. 13 MR. NIMROD: Thank you very much. 14 THE VIDEOGRAPHER: And Counsel, will we have 15 any video or transcript orders today? 12:56:25 16 MR. NIMROD: Whatever -- 17 MR. BRAUSA: Yeah. 18 THE VIDEOGRAPHER: We are off the record at 19 12:56 p.m. This concludes the deposition. 20 THE COURT REPORTER: Are you going to 12:56:39 21 reserve signature? 22 THE WITNESS: Yes. 23 (Whereupon, the taking of the deposition was 24 concluded at 12:56 p.m.) 25 - - - Page 156
1 Q Why was that? 12:54:43 2 A Because the characteristics of the drug that 3 suggested a longer duration of action. 4 Q When was that known, the characteristics of 5 the drug that suggested a longer duration of action? 12:54:51 6 A Well, it was known at the time of the press 7 release. 8 Q In 2009? 9 A 2009. 10 Q Right. Then so at the time of the press 12:54:59 11 release would it have been -- would a POSA have been 12 motivated to go from monthly dosing of 2 milligrams to 13 something with initial monthly dosing and then 14 extended dosing after that? 15 MR. BRAUSA: Objection, form, calls for a 12:55:14 16 legal conclusion. 17 A Just ask the question again, please. 18 Q At that time of the press release in 2009 19 would a POSA have been motivated to go from monthly 20 dosing, which was shown to be successful -- this is 12:55:32 21 for aflibercept -- to some initial monthly dosing 22 followed by extended dosing after that? 23 MR. BRAUSA: Objection, form. 24 A So in 2009 the drug was not available for 25 general use, so a POSA would not have had that 12:55:41 Page 155	1 CERTIFICATE OF OATH 2 3 I, Alice J. Teslicko, RMR, a Notary Public 4 for the State of Florida at large, do hereby 5 certify that the witness, Michael Stewart, M.D., 6 appeared personally before me and was duly sworn. 7 Signed and sealed this 30th day of March, 8 2024. 9 10 11  12 ALICE J. TESLICKO, RMR 13 Commission No. HH300672 14 My Commission Expires: 15 December 14, 2026 16 17 18 19 20 21 22 23 24 25 Page 157

1 CERTIFICATE 2 STATE OF FLORIDA)) ss. 3 COUNTY OF NASSAU) 4 I, ALICE TESLICKO, RMR, a Registered 5 Merit Reporter and Notary Public for the State of 6 Florida at Large, do hereby certify that I reported 7 the deposition of Michael Stewart, M.D., a witness 8 called by the Petitioner in the above-styled cause; 9 and that the foregoing pages constitute a true and 10 correct transcription of my shorthand report of the 11 deposition of said witness. 12 I further certify that I am not an attorney 13 or counsel of any of the parties, nor a relative or 14 employee of counsel connected with the action, nor 15 financially interested in the action. 16 WITNESS my hand and official seal in the 17 City of Fernandina Beach, County of Nassau, State of 18 Florida, this 30th day of March, 2024. 19  20 My commission expires: 21 December 14, 2026 22 Commission No. HH300672 23 24 25 Page 158	1 ERRATA SHEET 2 RE: Samsung Bioepis Co. Ltd. vs. Regeneron 3 Pharmaceuticals, Inc. 4 DEPO OF: Michael Stewart, M.D. 5 TAKEN: March 29, 2024 6 JOB NO.: 6622813 7 PAGE LINE CHANGE REASON 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 MICHAEL STEWART, M.D. 24 SUBSCRIBED AND SWORN TO BEFORE ME 25 THIS __ DAY OF __, 20__. (NOTARY PUBLIC) MY COMMISSION EXPIRES: Page 160
1 TO: Adam R. Brausa, Esq. 2 abrausa@mofo.com 3 RE: Samsung Bioepis Co. Ltd. vs. Regeneron 4 Pharmaceuticals, Inc. 5 DEPO OF: Michael Stewart, M.D. 6 TAKEN: March 29, 2024 7 JOB NO.: 6622813 8 Dear Mr. Brausa: 9 The above-referenced transcript is available for 10 review. The witness should read the testimony to 11 verify its accuracy. If there any changes, the 12 witness should note those with the reason on the 13 attached Errata Sheet. 14 The witness should please date and sign the 15 Errata Sheet and email to the deposing attorney, as 16 well as to Transcripts-fl@veritext.com, and copies 17 will be emailed to all ordering parties. 18 It is suggested that the completed errata be 19 returned 30 days from receipt of testimony, as 20 considered reasonable under Federal Rule of Civil 21 Procedure Rule 30(e)/Florida Rules of Civil Procedure 22 1.310(e). However, there is no Florida statute to 23 this regard. 24 If the witness should fail to do so, the 25 transcript may be used as if signed. Sincerely, Veritext Legal Solutions Page 159	

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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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