

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

9  
10  
11 Hampton Inn Ponte Vedra  
1220 Marsh Landing Parkway  
12 Jacksonville Beach, FL 32250  
March 29, 2024  
8:17 a.m. - 12:56 p.m.  
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16  
17

18 VIDEOTAPED DEPOSITION OF MICHAEL W. STEWART, M.D.  
19

20 Taken on behalf of the Petitioner before  
21 Alice J. Teslicko, Registered Professional Reporter,  
22 Registered Merit Reporter, and Notary Public in and  
23 for the State of Florida at Large, pursuant to a  
24 Notice of Taking Deposition in the above cause.  
25

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

<p>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</p> <p style="text-align: right;">Page 6</p>	<p>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</p> <p style="text-align: right;">Page 8</p>
<p>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</p> <p style="text-align: right;">Page 7</p>	<p>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</p> <p style="text-align: right;">Page 9</p>

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

<p>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</p> <p style="text-align: right;">Page 14</p>	<p>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</p> <p style="text-align: right;">Page 16</p>
<p>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</p> <p style="text-align: right;">Page 15</p>	<p>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</p> <p style="text-align: right;">Page 17</p>

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