

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

3 SAMSUNG BIOEPIS CO, LTD.,

4 Petitioner,

5 vs.

6 REGENERON PHARMACEUTICALS, INC.,

7 Patent Owner.

8 Case IPR2023-008844

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

10 VIDEO-RECORDED

11 DEPOSITION OF: MICHAEL STEWART, MD

12 DATE: May 30, 2024

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

14 CONCLUDED: 2:03 p.m.

15 TAKEN BY: Petitioner

16 PLACE: Hampton Inn Jacksonville/Ponte Vedra
Beach

17 1220 Marsh Landing Parkway
Jacksonville Beach, Florida 32250

18 REPORTED BY: Mae Fisher, RMR, CRR

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Veritext Legal Solutions

<p>1 APPEARANCES:</p> <p>2 RAYMOND NIMROD, ESQUIRE</p> <p>3 Of: Quinn, Emanuel, Urquart & Sullivan, LLP</p> <p>4 51 Madison Avenue</p> <p>5 22nd Floor</p> <p>6 New York, New York 10010</p> <p>7 (212) 849-7000</p> <p>8 Raynimrod@quinnemanuel.com</p> <p>9 Counsel for the PETITIONER</p> <p>10 ADAM BRAUSA, ESQUIRE</p> <p>11 REBECCA WEIRES, ESQUIRE</p> <p>12 Of: Morrison & Foerster, LLP</p> <p>13 425 Market Street</p> <p>14 San Francisco, CA 94105</p> <p>15 (415) 268-6053</p> <p>16 Abrausa@mofo.com</p> <p>17 Rweires@mofo.com</p> <p>18</p> <p>19 Counsel for the PATENT OWNER</p> <p>20</p> <p>21 ALSO PRESENT:</p> <p>22 JOSEPH MACKIN</p> <p>23 Videographer</p> <p>24</p> <p>25</p> <p style="text-align: right;">Page 2</p>	<p>1 Exhibit 9 - Article entitled Ranibizumab versus</p> <p>2 Verteporfin Photodynamic Therapy</p> <p>3 For Neovascular Age-Related</p> <p>4 Macular Degeneration: Two-Year</p> <p>5 Results of the ANCHOR Study 153</p> <p>6 Exhibit 10 - Article entitled Randomized,</p> <p>7 Double-Masked, Sham-Controlled Trial</p> <p>8 of Ranibizumab for Neovascular</p> <p>9 Age-related Macular Degeneration:</p> <p>10 PIER Study Year 1 163</p> <p>11</p> <p>12 STIPULATIONS</p> <p>13 It is hereby stipulated and agreed by and</p> <p>14 between counsel present for the respective parties, and</p> <p>15 the deponent, that the reading and signing of the</p> <p>16 deposition are hereby RESERVED.</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p> <p style="text-align: right;">Page 4</p>
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<p>1 Do you solemnly swear or affirm that the</p> <p>2 testimony you are about to give in this cause will be</p> <p>3 the truth, the whole truth, and nothing but the truth?</p> <p>4 THE WITNESS: I do. 08:50:48</p> <p>5 MICHAEL STEWART, MD, 08:50:48</p> <p>6 a witness herein, having been first duly sworn, was</p> <p>7 examined, and testified as follows: 08:50:49</p> <p>8 DIRECT EXAMINATION 08:50:49</p> <p>9 BY MR. NIMROD: 08:50:49</p> <p>10 Q. Good morning, Dr. Stewart. 08:50:50</p> <p>11 A. Good morning, Mr. Nimrod. 08:50:51</p> <p>12 MR. NIMROD: I'd like to mark as Stewart 08:50:55</p> <p>13 Exhibit 1 a copy of the 572 patent. 08:50:56</p> <p>14 (Exhibit No. 1 was marked for identification.) 08:51:08</p> <p>15 MR. NIMROD: I'd also like to mark as Stewart 08:51:22</p> <p>16 Exhibit 2 a copy of Dr. Stewart's declaration. 08:51:23</p> <p>17 (Exhibit No. 2 was marked for identification.) 08:51:34</p> <p>18 BY MR. NIMROD: 08:51:34</p> <p>19 Q. Here you go. 08:51:36</p> <p>20 A. Thank you. 08:51:37</p> <p>21 MR. BRAUSA: Thank you. 08:51:37</p> <p>22 BY MR. NIMROD:</p> <p>23 Q. Dr. Stewart, if you could turn in your 08:51:42</p> <p>24 declaration to paragraph 65, please -- 64. 08:51:44</p> <p>25 A. Okay. 08:51:56</p> <p style="text-align: right;">Page 6</p>	<p>1 in the dependent claim only two secondary doses are 08:53:24</p> <p>2 administered to the patient. 08:53:28</p> <p>3 Do you see that? 08:53:29</p> <p>4 A. Yes, I do. 08:53:29</p> <p>5 Q. So what is the predetermined fixed dosing regimen 08:53:31</p> <p>6 required by claim 27? 08:53:35</p> <p>7 MR. BRAUSA: Objection; form. 08:53:39</p> <p>8 THE WITNESS: So since 27 depends on 26, my 08:53:41</p> <p>9 understanding is that this is a method of treating 08:53:48</p> <p>10 age-related macular degeneration and the patient need 08:53:53</p> <p>11 thereof, comprising sequential administration of a 08:53:56</p> <p>12 single dose of 2 milligrams of Aflibercept. 08:54:00</p> <p>13 And then 27 says: Wherein, only two secondary 08:54:03</p> <p>14 doses are administered to the patient and then 08:54:07</p> <p>15 followed by one or more tertiary doses of 2 milligrams 08:54:14</p> <p>16 of Aflibercept. 08:54:19</p> <p>17 And then you have the qualifier: And those 08:54:20</p> <p>18 doses, the tertiary doses, are given at eight weeks 08:54:24</p> <p>19 intervals. Each secondary dose is four weeks 08:54:27</p> <p>20 following immediate preceding dose. 08:54:30</p> <p>21 And then you have a qualifier for a visual 08:54:32</p> <p>22 result at the end. 08:54:35</p> <p>23 BY MR. NIMROD: 08:54:36</p> <p>24 Q. Okay. So for claim 27, the fixed regimen 08:54:36</p> <p>25 requires three initial doses that are a month apart and 08:54:42</p> <p style="text-align: right;">Page 8</p>
<p>1 Q. You state in paragraph 64: It is my opinion 08:51:56</p> <p>2 based on the claims and specification of the 572 patent 08:52:00</p> <p>3 that a POSA would understand that challenged claims, 08:52:04</p> <p>4 specifically claim 15 and thereby claim 25, be limited 08:52:08</p> <p>5 to a predetermined fixed dosing schedules. 08:52:14</p> <p>6 Do you see that? 08:52:16</p> <p>7 A. Yes, I do. 08:52:17</p> <p>8 Q. And then on paragraph 74, you state -- seems more 08:52:18</p> <p>9 broadly, in the last sentence of paragraph 74. Are you 08:52:26</p> <p>10 with me? 08:52:29</p> <p>11 A. I see it. 08:52:30</p> <p>12 Q. It says: In my opinion -- it is my opinion that 08:52:30</p> <p>13 a POSA would see this as further evidence that the 572 08:52:33</p> <p>14 patent claims are drawn to predetermined fixed interval 08:52:37</p> <p>15 dosing regimens. 08:52:41</p> <p>16 Do you see that? 08:52:42</p> <p>17 A. I see it. 08:52:42</p> <p>18 Q. Is it your opinion that all the claims of the 572 08:52:43</p> <p>19 patent are directed to predetermined fixed interval 08:52:47</p> <p>20 dosing regimens? 08:52:52</p> <p>21 A. Yes, it is, it's my opinion. 08:52:56</p> <p>22 Q. So if we could turn to Exhibit 1, which is the 08:52:58</p> <p>23 patent, the 572 patent. And go to claim 27, claims near 08:53:02</p> <p>24 the end. You're already there. Good. 08:53:13</p> <p>25 Claim 27 depends from claim 26. And it requires 08:53:16</p> <p style="text-align: right;">Page 7</p>	<p>1 then followed by dosing every eight weeks till the end 08:54:44</p> <p>2 of treatment; is that right? 08:54:48</p> <p>3 MR. BRAUSA: Objection; form. 08:54:50</p> <p>4 THE WITNESS: So 27 when combined with 26 08:54:51</p> <p>5 requires three initial doses, a primary, two 08:54:56</p> <p>6 secondaries, and then followed by tertiary doses at 08:54:59</p> <p>7 eight-week intervals. 08:55:03</p> <p>8 BY MR. NIMROD: 08:55:04</p> <p>9 Q. And to be within the scope of claim 27, I think 08:55:05</p> <p>10 we talked about this last time, it's your opinion that 08:55:13</p> <p>11 if by happenstance or by treatment by PRN, a physician 08:55:16</p> <p>12 does not have a predetermined regimen but simply through 08:55:21</p> <p>13 observation of the patient decides on an ongoing basis 08:55:26</p> <p>14 to do first dose, two secondary doses and then have 08:55:30</p> <p>15 eight-week dosing after that, that would not fall within 08:55:35</p> <p>16 the scope of the claims; is that right? 08:55:37</p> <p>17 MR. BRAUSA: Objection; form. 08:55:39</p> <p>18 THE WITNESS: Would you repeat the question, 08:55:40</p> <p>19 please? You combined a couple of different factors 08:55:43</p> <p>20 there. 08:55:46</p> <p>21 BY MR. NIMROD: 08:55:46</p> <p>22 Q. Right. So if a physician does not have a 08:55:47</p> <p>23 predetermined dosing regimen, does that mean that the 08:55:48</p> <p>24 treatment does not fall within the scope of claim 27? 08:55:52</p> <p>25 MR. BRAUSA: Objection; form. 08:55:56</p> <p style="text-align: right;">Page 9</p>

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

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

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