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

-----)
SAMSUNG BIOEPIS COMPANY, LTD.,)
Petitioner,) IPR NOS.
vs.) 2023-00739
REGENERON PHARMACEUTICALS, INC.) 2023-00884
Patent Owner.)
-----)

DEPOSITION OF RICHARD MANNING, Ph.D.
WASHINGTON, D.C.
MARCH 27, 2024

REPORTED BY: Tina Alfaro, RPR, CRR, RMR



1 Videotaped deposition of
 2 RICHARD MANNING, Ph.D., held at the offices of:
 3
 4 ARNOLD & PORTER KAYE SCHOLER, LLP
 5 601 Massachusetts Avenue, NW
 6 Washington, D.C. 20001
 7
 8 Taken pursuant to notice before Tina M.
 9 Alfaro, a Notary Public within and for the District
 10 of Columbia.
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 5 By Mr. Erwine 6
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 15 Declaration of Michael Stewart M.D.
 regarding '572 Patent
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 18 Exhibit 2172 86
 DME Market Assessment Quarter 3 2017
 19
 Exhibit 2224 91
 20 Wet AMD Physician ATU Q4 2017
 21
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 23
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1 APPEARANCES:
 2 ON BEHALF OF THE PETITIONER:
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 16 MORRISON FOERSTER
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 20
 21 ALSO PRESENT: Orson Braithwaite (videographer)
 22
 23
 24
 25

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1 THE VIDEOGRAPHER: Good morning. We are 09:05:23
 2 going on the record at 9:05 a.m. on March 27, 2024. 09:05:24
 3 Please note that the microphones are sensitive and 09:05:30
 4 may pick up whispering and private conversations. 09:05:32
 5 Please mute your phones at this time. Audio and 09:05:36
 6 video recording will continue to take place unless 09:05:38
 7 all parties agree to go off the record. 09:05:41
 8 This is media unit 1 of the video-recorded 09:05:44
 9 deposition of Dr. Richard Manning in the matter of 09:05:46
 10 Samsung Bioepis Company, Ltd. versus Regeneron 09:05:51
 11 Pharmaceuticals, Inc. filed in the United States 09:05:56
 12 Patent and Trademark Office before the Patent Trial 09:05:59
 13 and Appeal Board, Case No. IPR-203 -- excuse me -- 09:06:03
 14 2023-00884. 09:06:07
 15 My name is Orson Braithwaite representing 09:06:12
 16 Veritext Legal Solutions, and I'm the videographer. 09:06:15
 17 The court reporter is Tina Alfaro from the firm 09:06:16
 18 Veritext Legal Solutions. 09:06:19
 19 Counsel will now state their appearances 09:06:20
 20 and affiliations for the record. 09:06:23
 21 MR. ERWINE: Richard Erwine of Quinn 09:06:25
 22 Emanuel on behalf of the Petitioner Samsung 09:06:28
 23 Bioepis. With me is my colleague Mr. Elliot Choi. 09:06:31
 24 MR. WILK: Matthew Wilk of Arnold & Porter 09:06:37
 25 on behalf of Patent Owner Regeneron. With me is my 09:06:40

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1 colleague David Caine. Also joining is Drew 09:06:44
2 Hillier from the law firm of Morrison & Foerster 09:06:47
3 and remotely is Eileen Woo from Regeneron. 09:06:52
4 THE VIDEOGRAPHER: Thank you. 09:06:54
5 Will you the court reporter please swear 09:06:55
6 in the witness. 09:06:57
7 (Witness sworn.) 09:07:04
8 WHEREUPON: 09:07:04
9 RICHARD MANNING, Ph.D., 09:07:04
10 called as a witness herein, having been first duly 09:07:04
11 sworn, was examined and testified as follows: 09:07:04
12 EXAMINATION 09:07:04
13 BY MR. ERWINE: 09:07:07
14 Q. Good morning. Could you please state your 09:07:07
15 name for the record. 09:07:09
16 A. My name is Richard Manning. 09:07:10
17 Q. And is it okay if I refer to you as 09:07:12
18 Dr. Manning today? 09:07:15
19 A. Sure. 09:07:16
20 Q. Excellent. 09:07:17
21 Dr. Manning, is there anything restricting 09:07:21
22 you from providing complete and truthful testimony 09:07:23
23 today? 09:07:23
24 A. No. 09:07:23
25 Q. Are you taking any medication that would 09:07:25

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1 impede your ability to provide complete and 09:07:27
2 truthful testimony? 09:07:30
3 A. No. 09:07:32
4 Q. And Dr. Manning, I understand you've been 09:07:33
5 deposed a number of times before? 09:07:37
6 A. Yes. 09:07:38
7 Q. Do you recall how many? 09:07:38
8 A. Not exactly. Probably between 15 and 20, 09:07:40
9 but I don't know the exact number. 09:07:43
10 Q. And do you recall how many times you've 09:07:45
11 been deposed with respect to the Regeneron/Samsung 09:07:47
12 disputes at the PTAB? 09:07:53
13 A. Regeneron/Samsung, I'd have to go back and 09:07:55
14 look. I've been deposed by -- on Regeneron matters 09:07:58
15 at the PTAB for different Petitioners. I don't 09:08:03
16 remember the exact number. 09:08:08
17 Q. And with respect to those depositions, the 09:08:11
18 ones concerning Regeneron, did you review your 09:08:14
19 deposition transcripts after the depositions to 09:08:20
20 check for any errors? 09:08:22
21 A. Yes. 09:08:24
22 Q. And did you find any? 09:08:24
23 A. I submitted errata for each of them. 09:08:27
24 Nothing major, but I did have erratas for each of 09:08:30
25 them. 09:08:34

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1 Q. Okay. And I think you -- in your CV 09:08:35
2 you've indicated that you've testified a few times 09:08:38
3 at trial; is that correct? 09:08:39
4 A. Yes. 09:08:41
5 Q. And is that -- have you testified at the 09:08:41
6 PTAB for purposes of an IPR petition? 09:08:43
7 A. So my understanding is that there is no 09:08:45
8 live testimony at the PTAB, but I've submitted 09:08:47
9 several declarations before the PTAB. 09:08:50
10 Q. And how about District Court? 09:08:54
11 A. I've testified in District Court four or 09:08:55
12 five times. I'd have to, again, go back and look. 09:08:58
13 Q. And were those patent cases? 09:08:59
14 A. No. 09:09:01
15 Q. Do you recall the general subject matter 09:09:02
16 of those cases? 09:09:04
17 A. Commercial litigation of various kinds. 09:09:05
18 Q. And I think that you may have said this 09:09:12
19 already, but you -- you've provided several 09:09:15
20 declarations concerning the purported commercial 09:09:20
21 success of Eylea? 09:09:25
22 A. Yes, I have. 09:09:27
23 Q. And do you recall how many declarations 09:09:28
24 you've submitted with respect to commercial success 09:09:30
25 of Eylea? 09:09:35

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1 A. I would have to go count them on my CV. 09:09:36
2 They're reflected on my CV. I believe it's six or 09:09:38
3 seven, maybe five, in that neighborhood. 09:09:42
4 Q. Do all of those declarations relate to the 09:09:45
5 dosing regimen of Eylea? 09:09:47
6 A. Generally the dosing regimen is an 09:09:51
7 important element. It's not the only element that 09:09:54
8 I discuss, but it is an important element. 09:10:00
9 Q. Do you recall any of the other elements 09:10:02
10 you discussed? 09:10:03
11 A. Well, the elements that were at issue in 09:10:05
12 each of the proceedings. I'd have to go back and 09:10:07
13 look at those reports and verify, but dosing has 09:10:12
14 been a very important one. 09:10:16
15 Q. And do you recall the time period for 09:10:17
16 which you submitted those declarations? 09:10:18
17 A. I believe the first one was a couple years 09:10:21
18 ago. Again, my CV reflects the exact date. 09:10:22
19 Q. Would it be fair to say it was February of 09:10:27
20 2022; does that sound right? 09:10:29
21 A. If that's what my -- if that's what the 09:10:31
22 record reflects. I don't remember the exact date. 09:10:34
23 Q. And Dr. Manning, have your views changed 09:10:37
24 at all over that time period with respect to the 09:10:43
25 commercial success of Eylea? 09:10:46

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<p>1 A. No. 09:10:49</p> <p>2 Q. So if I were to go back and look at one of 09:10:49</p> <p>3 your deposition transcripts or one of your 09:10:51</p> <p>4 declarations from a couple years ago, there isn't 09:10:53</p> <p>5 anything in there that you'd want to modify or 09:10:55</p> <p>6 change? 09:10:57</p> <p>7 A. Not that I'm aware of, no. 09:10:58</p> <p>8 Q. What did you do to prepare for today's 09:11:04</p> <p>9 deposition? 09:11:06</p> <p>10 A. I reviewed my declarations. I understand 09:11:07</p> <p>11 there are two declarations at issue here and I 09:11:09</p> <p>12 reviewed each of those. I reviewed Dr. Stewart's 09:11:13</p> <p>13 declarations. I reviewed some of the materials 09:11:17</p> <p>14 that I had used before or for -- in preparing the 09:11:20</p> <p>15 declaration. I reviewed -- I believe I reviewed my 09:11:26</p> <p>16 last deposition transcript. I met with counsel. 09:11:31</p> <p>17 Q. And when you say your last deposition 09:11:36</p> <p>18 transcript, do you recall which patent that was 09:11:38</p> <p>19 for? 09:11:40</p> <p>20 A. I'm sorry. I'm not remembering the number 09:11:42</p> <p>21 off the top of my head. Again, it's on my CV and 09:11:49</p> <p>22 in the record, but it was the one that was in 09:11:52</p> <p>23 December I believe. 09:11:55</p> <p>24 Q. The '681 Patent, does that sound close? 09:11:58</p> <p>25 A. I would want to make sure I looked at the 09:12:01</p> <p style="text-align: right;">Page 10</p>	<p>1 Q. Okay. Great. 09:12:55</p> <p>2 And Dr. Manning, did you speak to anyone 09:12:57</p> <p>3 in preparation for today's deposition? 09:12:59</p> <p>4 A. Counsel, my staff. No one else that I 09:13:03</p> <p>5 recall. 09:13:08</p> <p>6 Q. So, for instance, did you speak to 09:13:09</p> <p>7 Dr. Stewart at all in preparation for today's 09:13:12</p> <p>8 deposition? 09:13:14</p> <p>9 A. Not in preparation for the deposition, 09:13:15</p> <p>10 no. 09:13:19</p> <p>11 Q. And you mentioned that you spoke to 09:13:19</p> <p>12 counsel. Did you meet with them in person? 09:13:20</p> <p>13 A. Yes. 09:13:22</p> <p>14 Q. And when was that? 09:13:23</p> <p>15 A. Yesterday. 09:13:24</p> <p>16 Q. And who did you meet with? 09:13:25</p> <p>17 A. The gentlemen here at the table. 09:13:27</p> <p>18 Q. And how long did you meet for? 09:13:29</p> <p>19 A. Three hours perhaps, the morning. 09:13:33</p> <p>20 Q. And you mentioned staff that you may have 09:13:38</p> <p>21 spoken to in preparation. Who on your staff did 09:13:40</p> <p>22 you speak to? 09:13:43</p> <p>23 A. Ryan Marsh. He's a Ph.D. economist that 09:13:44</p> <p>24 works for Intensity. 09:13:49</p> <p>25 Q. When you did speak to him? 09:13:50</p> <p style="text-align: right;">Page 12</p>
<p>1 record to be certain. 09:12:03</p> <p>2 Q. Okay. And do you recall, would it have 09:12:04</p> <p>3 been my colleague -- 09:12:05</p> <p>4 A. Yes. 09:12:06</p> <p>5 Q. -- Mr. Choi that took the deposition? 09:12:06</p> <p>6 A. Yes. 09:12:09</p> <p>7 Q. Okay. Great. 09:12:09</p> <p>8 Now, you mentioned that you reviewed was 09:12:11</p> <p>9 it two declarations, that's the '572 and '601 09:12:14</p> <p>10 declarations that are at issue today? 09:12:19</p> <p>11 A. Yes. 09:12:22</p> <p>12 Q. Did you review any other declarations in 09:12:22</p> <p>13 preparation for today's deposition? 09:12:23</p> <p>14 A. I don't believe so, no. 09:12:25</p> <p>15 Q. I think you mentioned that you reviewed 09:12:26</p> <p>16 Dr. Stewart's declarations? 09:12:29</p> <p>17 A. Stewart? 09:12:32</p> <p>18 Q. Yes. Was it just his declarations for the 09:12:33</p> <p>19 '572 and '601 Patents? 09:12:36</p> <p>20 A. Yes. 09:12:41</p> <p>21 Q. And I think you indicated some materials 09:12:41</p> <p>22 that you have used that were part of your two 09:12:43</p> <p>23 declarations; is that correct? 09:12:45</p> <p>24 A. In the appendices or the attachments to my 09:12:50</p> <p>25 declarations, those are what I reviewed. 09:12:53</p> <p style="text-align: right;">Page 11</p>	<p>1 A. Yesterday and I may have talked to him a 09:13:51</p> <p>2 couple days before, but intermittently throughout 09:13:53</p> <p>3 the last few days. 09:13:56</p> <p>4 Q. Was he part of the meeting with counsel 09:13:59</p> <p>5 yesterday? 09:14:01</p> <p>6 A. No. Oh yes, he was. Yeah. He was 09:14:04</p> <p>7 remote, but he was not physically there. 09:14:05</p> <p>8 Q. And did you -- and apologies if I'm going 09:14:11</p> <p>9 too fast. Did you speak to Mr. Marsh independently 09:14:11</p> <p>10 of your meeting with counsel? 09:14:13</p> <p>11 A. Yes. 09:14:16</p> <p>12 Q. When was that? 09:14:16</p> <p>13 A. Intermittently. 09:14:19</p> <p>14 Q. All right. 09:14:29</p> <p>15 So let me give you some documents to start 09:14:29</p> <p>16 the day. I think many of these have already been 09:14:31</p> <p>17 designated as exhibits. The first exhibit I'm 09:14:36</p> <p>18 going to hand you is Exhibit 2067. This is your 09:14:38</p> <p>19 declaration concerning the '572 Patent. So that's 09:14:45</p> <p>20 from the case IPR-2023-884. 09:14:50</p> <p>21 I'm also going to hand you your 09:15:05</p> <p>22 declaration from -- or for the '601 Patent and that 09:15:08</p> <p>23 is Exhibit 2043, IPR-2023-739. We'll get these 09:15:17</p> <p>24 all knocked out to begin with. 09:15:42</p> <p>25 I'm going to hand you this is United 09:15:44</p> <p style="text-align: right;">Page 13</p>

1 States Patent No. 11,253,572, and it's 09:15:49
2 Exhibit 1001 and I believe it's just from the 09:15:53
3 '572 IPR. And also United States Patent 09:16:00
4 No. 10,888,601, which is Exhibit 1001 from the 09:16:16
5 '601 IPR. And let's just do them all. 09:16:26
6 This is Exhibit 2027. This is the 09:16:49
7 declaration of Michael W. Stewart, M.D., and this 09:16:54
8 is for the '601 Patent and I believe this is just 09:17:01
9 from the '601 IPR, which is 739. We're killing a 09:17:05
10 lot of trees here. 09:17:12
11 And last but not least, this is the 09:17:18
12 declaration of Michael W. Stewart for the 09:17:21
13 '572 Patent, this is Exhibit 2065 and it's just 09:17:25
14 in the '572 IPR, which is the 884 IPR. 09:17:31
15 Now, Dr. Manning, I was going to start 09:17:54
16 with your '572 IPR declaration and before I get 09:17:57
17 started, so there appears to be a lot of similarity 09:18:03
18 between the '572 and the '601 declarations. Is 09:18:07
19 that your understanding? 09:18:13
20 A. Yes. 09:18:14
21 Q. I think a lot of my questions are probably 09:18:14
22 going to overlap on the two. So is that all right 09:18:15
23 with you if I combine some of those questions, or 09:18:21
24 do you prefer that I go, you know, one by one in 09:18:24
25 terms of the declarations? 09:18:28

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1 A. I'm happy to have you ask the questions as 09:18:28
2 you like. 09:18:31
3 Q. Okay. Great. 09:18:31
4 I guess first turning to paragraph 8 of 09:18:35
5 your declaration and this is, again, the '572 09:18:37
6 declaration, but I think it's hopefully similar. I 09:18:44
7 wanted to ask you about your hourly rate. So in 09:18:49
8 the '572 declaration it's listed at 1,150 an hour; 09:18:56
9 is that right? 09:19:01
10 A. That's correct. 09:19:01
11 Q. In the '601 declaration it's listed as 09:19:03
12 1,050 an hour. I'm just curious. Was that a typo 09:19:06
13 or what was the reason for the difference? 09:19:11
14 A. I believe that is because the '601 09:19:13
15 declaration was completed in 2023. Let me look at 09:19:16
16 the date to be sure I'm not getting this wrong. 09:19:27
17 Well, it's good a thing that I checked the 09:19:39
18 date because that specific statement is not quite 09:19:41
19 accurate, but the work was done based on an 09:19:43
20 earlier -- on the billing rates that were in place 09:19:48
21 during 2023. My billing rate was changed as of the 09:19:52
22 end of the year. So that would explain the 09:19:57
23 difference. 09:20:00
24 Q. And with respect to the '572 IPR, do you 09:20:04
25 know about how many hours you've spent on that in 09:20:10

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1 that particular matter? 09:20:14
2 A. I don't. 09:20:15
3 Q. Ballpark? 09:20:16
4 A. You know, I haven't looked at the record 09:20:17
5 and I really don't know. 09:20:19
6 Q. Same for '601? 09:20:20
7 A. Yeah. Same answer, yes. 09:20:24
8 Q. Okay. In terms of your overall work for 09:20:27
9 Regeneron, do you have a sense for overall hours, 09:20:29
10 amount of time you spent? 09:20:34
11 A. I don't know that either. 09:20:35
12 Q. All right. 09:20:36
13 In paragraph 8 you reference some work by 09:20:39
14 other members of your team; do you see that? 09:20:42
15 A. Yes. 09:20:46
16 Q. Is Mr. -- is it Mr. or Dr. Marsh? 09:20:46
17 A. Dr. Marsh. 09:20:50
18 Q. Dr. Marsh, is he one of the members of 09:20:50
19 your team? 09:20:53
20 A. He is. 09:20:54
21 Q. Do you know what his billing rate is? 09:20:54
22 A. Off the top of my head I do not. 09:20:56
23 Q. Okay. Are there other members of your 09:20:57
24 team? 09:20:58
25 A. Yes. 09:20:59

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1 Q. Who are those? 09:20:59
2 A. Elizabeth Parker has worked on it, Max 09:21:01
3 Allman -- Urman has worked on it, on these cases. 09:21:04
4 I don't know who has spent the more time on each 09:21:06
5 declaration. I haven't managed the workflow to the 09:21:10
6 extent -- at the level of detail that would help me 09:21:20
7 remember that -- the answer to that question. 09:21:23
8 Q. And was there one of the members of your 09:21:27
9 team that was particularly focused on either '572 09:21:29
10 or '601? 09:21:34
11 A. I believe they each focused on both 09:21:37
12 reports. 09:21:39
13 Q. Got it. 09:21:40
14 A. Or both declarations. 09:21:41
15 Q. So let me ask you turning to paragraph 10 09:21:42
16 of your report. That is on page -- looks like it's 09:21:45
17 on page 9 of the document. You indicate that you 09:21:53
18 relied on the declaration of -- of Michael W. 09:21:59
19 Stewart, M.D., Exhibit 2065; do you see that? 09:22:05
20 A. Yes. 09:22:09
21 Q. And you have that exhibit in front of you. 09:22:09
22 A. Uh-huh. 09:22:13
23 Q. You also mentioned you had a conversation 09:22:13
24 with Dr. Stewart; is that right? 09:22:13
25 A. Yes. 09:22:14

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5 (Pages 14 - 17)

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