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

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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

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|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p>1 Videotaped deposition of</p> <p>2 RICHARD MANNING, Ph.D., held at the offices of:</p> <p>3</p> <p>4 ARNOLD &amp; PORTER KAYE SCHOLER, LLP</p> <p>5 601 Massachusetts Avenue, NW</p> <p>6 Washington, D.C. 20001</p> <p>7</p> <p>8 Taken pursuant to notice before Tina M.</p> <p>9 Alfaro, a Notary Public within and for the District</p> <p>10 of Columbia.</p> <p>11</p> <p>12</p> <p>13</p> <p>14</p> <p>15</p> <p>16</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 2</p>                                                                                                                                                                                                                    | <p>1 I N D E X</p> <p>2 EXAMINATION</p> <p>3 WITNESS PAGE</p> <p>4 RICHARD MANNING, Ph.D.</p> <p>5 By Mr. Erwine 6</p> <p>6 EXHIBITS</p> <p>7 DEPOSITION EXHIBITS PAGE</p> <p>8 Exhibit 1001-A 14</p> <p>9 '572 Patent</p> <p>10 Exhibit 1001 14</p> <p>11 '601 Patent</p> <p>12 Exhibit 2027 14</p> <p>13 Declaration of Michael Stewart, M.D.</p> <p>14 regarding '601 Patent</p> <p>15 Exhibit 2043 13</p> <p>16 Declaration regarding '601 Patent</p> <p>17 Exhibit 2065 14</p> <p>18 Declaration of Michael Stewart M.D.</p> <p>19 regarding '572 Patent</p> <p>20 Exhibit 2067 13</p> <p>21 Declaration regarding '572 Patent</p> <p>22 Exhibit 2172 86</p> <p>23 DME Market Assessment Quarter 3 2017</p> <p>24 Exhibit 2224 91</p> <p>25 Wet AMD Physician ATU Q4 2017</p> <p style="text-align: right;">Page 4</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| <p>1 APPEARANCES:</p> <p>2 ON BEHALF OF THE PETITIONER:</p> <p>3 QUINN EMANUEL URQUHART &amp; SULLIVAN, LLP</p> <p>4 BY: RICHARD ERWINE, ESQ.</p> <p>5 ELLIOT CHOI, ESQ.</p> <p>6 51 Madison Avenue, 22nd Floor</p> <p>7 New York, NY 10010</p> <p>8</p> <p>9 ON BEHALF OF THE PATENT OWNER:</p> <p>10 ARNOLD &amp; PORTER KAYE SCHOLER, LLP</p> <p>11 BY: MATTHEW WILK, ESQ.</p> <p>12 DAVID CAINE, ESQ.</p> <p>13 250 West 55th Street</p> <p>14 New York, NY 10019</p> <p>15 and</p> <p>16 MORRISON FOERSTER</p> <p>17 BY: DREW HILLIER, ESQ.</p> <p>18 12531 High Bluff Drive, Suite 100</p> <p>19 San Diego, CA, 92130-2040</p> <p>20</p> <p>21 ALSO PRESENT: Orson Braithwaite (videographer)</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p> <p style="text-align: right;">Page 3</p> | <p>1 THE VIDEOGRAPHER: Good morning. We are 09:05:23</p> <p>2 going on the record at 9:05 a.m. on March 27, 2024. 09:05:24</p> <p>3 Please note that the microphones are sensitive and 09:05:30</p> <p>4 may pick up whispering and private conversations. 09:05:32</p> <p>5 Please mute your phones at this time. Audio and 09:05:36</p> <p>6 video recording will continue to take place unless 09:05:38</p> <p>7 all parties agree to go off the record. 09:05:41</p> <p>8 This is media unit 1 of the video-recorded 09:05:44</p> <p>9 deposition of Dr. Richard Manning in the matter of 09:05:46</p> <p>10 Samsung Bioepis Company, Ltd. versus Regeneron 09:05:51</p> <p>11 Pharmaceuticals, Inc. filed in the United States 09:05:56</p> <p>12 Patent and Trademark Office before the Patent Trial 09:05:59</p> <p>13 and Appeal Board, Case No. IPR-203 -- excuse me -- 09:06:03</p> <p>14 2023-00884. 09:06:07</p> <p>15 My name is Orson Braithwaite representing 09:06:12</p> <p>16 Veritext Legal Solutions, and I'm the videographer. 09:06:15</p> <p>17 The court reporter is Tina Alfaro from the firm 09:06:16</p> <p>18 Veritext Legal Solutions. 09:06:19</p> <p>19 Counsel will now state their appearances 09:06:20</p> <p>20 and affiliations for the record. 09:06:23</p> <p>21 MR. ERWINE: Richard Erwine of Quinn 09:06:25</p> <p>22 Emanuel on behalf of the Petitioner Samsung 09:06:28</p> <p>23 Bioepis. With me is my colleague Mr. Elliot Choi. 09:06:31</p> <p>24 MR. WILK: Matthew Wilk of Arnold &amp; Porter 09:06:37</p> <p>25 on behalf of Patent Owner Regeneron. With me is my 09:06:40</p> <p style="text-align: right;">Page 5</p> |

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| <p>1 colleague David Caine. Also joining is Drew 09:06:44</p> <p>2 Hillier from the law firm of Morrison &amp; Foerster 09:06:47</p> <p>3 and remotely is Eileen Woo from Regeneron. 09:06:52</p> <p>4 THE VIDEOGRAPHER: Thank you. 09:06:54</p> <p>5 Will you the court reporter please swear 09:06:55</p> <p>6 in the witness. 09:06:57</p> <p>7 (Witness sworn.) 09:07:04</p> <p>8 WHEREUPON: 09:07:04</p> <p>9 RICHARD MANNING, Ph.D., 09:07:04</p> <p>10 called as a witness herein, having been first duly 09:07:04</p> <p>11 sworn, was examined and testified as follows: 09:07:04</p> <p>12 EXAMINATION 09:07:04</p> <p>13 BY MR. ERWINE: 09:07:07</p> <p>14 Q. Good morning. Could you please state your 09:07:07</p> <p>15 name for the record. 09:07:09</p> <p>16 A. My name is Richard Manning. 09:07:10</p> <p>17 Q. And is it okay if I refer to you as 09:07:12</p> <p>18 Dr. Manning today? 09:07:15</p> <p>19 A. Sure. 09:07:16</p> <p>20 Q. Excellent. 09:07:17</p> <p>21 Dr. Manning, is there anything restricting 09:07:21</p> <p>22 you from providing complete and truthful testimony 09:07:23</p> <p>23 today? 09:07:23</p> <p>24 A. No. 09:07:23</p> <p>25 Q. Are you taking any medication that would 09:07:25</p> <p style="text-align: right;">Page 6</p>                                                                                                                | <p>1 Q. Okay. And I think you -- in your CV 09:08:35</p> <p>2 you've indicated that you've testified a few times 09:08:38</p> <p>3 at trial; is that correct? 09:08:39</p> <p>4 A. Yes. 09:08:41</p> <p>5 Q. And is that -- have you testified at the 09:08:41</p> <p>6 PTAB for purposes of an IPR petition? 09:08:43</p> <p>7 A. So my understanding is that there is no 09:08:45</p> <p>8 live testimony at the PTAB, but I've submitted 09:08:47</p> <p>9 several declarations before the PTAB. 09:08:50</p> <p>10 Q. And how about District Court? 09:08:54</p> <p>11 A. I've testified in District Court four or 09:08:55</p> <p>12 five times. I'd have to, again, go back and look. 09:08:58</p> <p>13 Q. And were those patent cases? 09:08:59</p> <p>14 A. No. 09:09:01</p> <p>15 Q. Do you recall the general subject matter 09:09:02</p> <p>16 of those cases? 09:09:04</p> <p>17 A. Commercial litigation of various kinds. 09:09:05</p> <p>18 Q. And I think that you may have said this 09:09:12</p> <p>19 already, but you -- you've provided several 09:09:15</p> <p>20 declarations concerning the purported commercial 09:09:20</p> <p>21 success of Eylea? 09:09:25</p> <p>22 A. Yes, I have. 09:09:27</p> <p>23 Q. And do you recall how many declarations 09:09:28</p> <p>24 you've submitted with respect to commercial success 09:09:30</p> <p>25 of Eylea? 09:09:35</p> <p style="text-align: right;">Page 8</p>                                                                                                                                                 |
| <p>1 impede your ability to provide complete and 09:07:27</p> <p>2 truthful testimony? 09:07:30</p> <p>3 A. No. 09:07:32</p> <p>4 Q. And Dr. Manning, I understand you've been 09:07:33</p> <p>5 deposed a number of times before? 09:07:37</p> <p>6 A. Yes. 09:07:38</p> <p>7 Q. Do you recall how many? 09:07:38</p> <p>8 A. Not exactly. Probably between 15 and 20, 09:07:40</p> <p>9 but I don't know the exact number. 09:07:43</p> <p>10 Q. And do you recall how many times you've 09:07:45</p> <p>11 been deposed with respect to the Regeneron/Samsung 09:07:47</p> <p>12 disputes at the PTAB? 09:07:53</p> <p>13 A. Regeneron/Samsung, I'd have to go back and 09:07:55</p> <p>14 look. I've been deposed by -- on Regeneron matters 09:07:58</p> <p>15 at the PTAB for different Petitioners. I don't 09:08:03</p> <p>16 remember the exact number. 09:08:08</p> <p>17 Q. And with respect to those depositions, the 09:08:11</p> <p>18 ones concerning Regeneron, did you review your 09:08:14</p> <p>19 deposition transcripts after the depositions to 09:08:20</p> <p>20 check for any errors? 09:08:22</p> <p>21 A. Yes. 09:08:24</p> <p>22 Q. And did you find any? 09:08:24</p> <p>23 A. I submitted errata for each of them. 09:08:27</p> <p>24 Nothing major, but I did have erratas for each of 09:08:30</p> <p>25 them. 09:08:34</p> <p style="text-align: right;">Page 7</p> | <p>1 A. I would have to go count them on my CV. 09:09:36</p> <p>2 They're reflected on my CV. I believe it's six or 09:09:38</p> <p>3 seven, maybe five, in that neighborhood. 09:09:42</p> <p>4 Q. Do all of those declarations relate to the 09:09:45</p> <p>5 dosing regimen of Eylea? 09:09:47</p> <p>6 A. Generally the dosing regimen is an 09:09:51</p> <p>7 important element. It's not the only element that 09:09:54</p> <p>8 I discuss, but it is an important element. 09:10:00</p> <p>9 Q. Do you recall any of the other elements 09:10:02</p> <p>10 you discussed? 09:10:03</p> <p>11 A. Well, the elements that were at issue in 09:10:05</p> <p>12 each of the proceedings. I'd have to go back and 09:10:07</p> <p>13 look at those reports and verify, but dosing has 09:10:12</p> <p>14 been a very important one. 09:10:16</p> <p>15 Q. And do you recall the time period for 09:10:17</p> <p>16 which you submitted those declarations? 09:10:18</p> <p>17 A. I believe the first one was a couple years 09:10:21</p> <p>18 ago. Again, my CV reflects the exact date. 09:10:22</p> <p>19 Q. Would it be fair to say it was February of 09:10:27</p> <p>20 2022; does that sound right? 09:10:29</p> <p>21 A. If that's what my -- if that's what the 09:10:31</p> <p>22 record reflects. I don't remember the exact date. 09:10:34</p> <p>23 Q. And Dr. Manning, have your views changed 09:10:37</p> <p>24 at all over that time period with respect to the 09:10:43</p> <p>25 commercial success of Eylea? 09:10:46</p> <p style="text-align: right;">Page 9</p> |

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

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| <p>1 States Patent No. 11,253,572, and it's 09:15:49</p> <p>2 Exhibit 1001 and I believe it's just from the 09:15:53</p> <p>3 '572 IPR. And also United States Patent 09:16:00</p> <p>4 No. 10,888,601, which is Exhibit 1001 from the 09:16:16</p> <p>5 '601 IPR. And let's just do them all. 09:16:26</p> <p>6 This is Exhibit 2027. This is the 09:16:49</p> <p>7 declaration of Michael W. Stewart, M.D., and this 09:16:54</p> <p>8 is for the '601 Patent and I believe this is just 09:17:01</p> <p>9 from the '601 IPR, which is 739. We're killing a 09:17:05</p> <p>10 lot of trees here. 09:17:12</p> <p>11 And last but not least, this is the 09:17:18</p> <p>12 declaration of Michael W. Stewart for the 09:17:21</p> <p>13 '572 Patent, this is Exhibit 2065 and it's just 09:17:25</p> <p>14 in the '572 IPR, which is the 884 IPR. 09:17:31</p> <p>15 Now, Dr. Manning, I was going to start 09:17:54</p> <p>16 with your '572 IPR declaration and before I get 09:17:57</p> <p>17 started, so there appears to be a lot of similarity 09:18:03</p> <p>18 between the '572 and the '601 declarations. Is 09:18:07</p> <p>19 that your understanding? 09:18:13</p> <p>20 A. Yes. 09:18:14</p> <p>21 Q. I think a lot of my questions are probably 09:18:14</p> <p>22 going to overlap on the two. So is that all right 09:18:15</p> <p>23 with you if I combine some of those questions, or 09:18:21</p> <p>24 do you prefer that I go, you know, one by one in 09:18:24</p> <p>25 terms of the declarations? 09:18:28</p> <p style="text-align: right;">Page 14</p> | <p>1 that particular matter? 09:20:14</p> <p>2 A. I don't. 09:20:15</p> <p>3 Q. Ballpark? 09:20:16</p> <p>4 A. You know, I haven't looked at the record 09:20:17</p> <p>5 and I really don't know. 09:20:19</p> <p>6 Q. Same for '601? 09:20:20</p> <p>7 A. Yeah. Same answer, yes. 09:20:24</p> <p>8 Q. Okay. In terms of your overall work for 09:20:27</p> <p>9 Regeneron, do you have a sense for overall hours, 09:20:29</p> <p>10 amount of time you spent? 09:20:34</p> <p>11 A. I don't know that either. 09:20:35</p> <p>12 Q. All right. 09:20:36</p> <p>13 In paragraph 8 you reference some work by 09:20:39</p> <p>14 other members of your team; do you see that? 09:20:42</p> <p>15 A. Yes. 09:20:46</p> <p>16 Q. Is Mr. -- is it Mr. or Dr. Marsh? 09:20:46</p> <p>17 A. Dr. Marsh. 09:20:50</p> <p>18 Q. Dr. Marsh, is he one of the members of 09:20:50</p> <p>19 your team? 09:20:53</p> <p>20 A. He is. 09:20:54</p> <p>21 Q. Do you know what his billing rate is? 09:20:54</p> <p>22 A. Off the top of my head I do not. 09:20:56</p> <p>23 Q. Okay. Are there other members of your 09:20:57</p> <p>24 team? 09:20:58</p> <p>25 A. Yes. 09:20:59</p> <p style="text-align: right;">Page 16</p>                                                                                                                                                                                                                          |
| <p>1 A. I'm happy to have you ask the questions as 09:18:28</p> <p>2 you like. 09:18:31</p> <p>3 Q. Okay. Great. 09:18:31</p> <p>4 I guess first turning to paragraph 8 of 09:18:35</p> <p>5 your declaration and this is, again, the '572 09:18:37</p> <p>6 declaration, but I think it's hopefully similar. I 09:18:44</p> <p>7 wanted to ask you about your hourly rate. So in 09:18:49</p> <p>8 the '572 declaration it's listed at 1,150 an hour; 09:18:56</p> <p>9 is that right? 09:19:01</p> <p>10 A. That's correct. 09:19:01</p> <p>11 Q. In the '601 declaration it's listed as 09:19:03</p> <p>12 1,050 an hour. I'm just curious. Was that a typo 09:19:06</p> <p>13 or what was the reason for the difference? 09:19:11</p> <p>14 A. I believe that is because the '601 09:19:13</p> <p>15 declaration was completed in 2023. Let me look at 09:19:16</p> <p>16 the date to be sure I'm not getting this wrong. 09:19:27</p> <p>17 Well, it's good a thing that I checked the 09:19:39</p> <p>18 date because that specific statement is not quite 09:19:41</p> <p>19 accurate, but the work was done based on an 09:19:43</p> <p>20 earlier -- on the billing rates that were in place 09:19:48</p> <p>21 during 2023. My billing rate was changed as of the 09:19:52</p> <p>22 end of the year. So that would explain the 09:19:57</p> <p>23 difference. 09:20:00</p> <p>24 Q. And with respect to the '572 IPR, do you 09:20:04</p> <p>25 know about how many hours you've spent on that in 09:20:10</p> <p style="text-align: right;">Page 15</p>                   | <p>1 Q. Who are those? 09:20:59</p> <p>2 A. Elizabeth Parker has worked on it, Max 09:21:01</p> <p>3 Allman -- Urman has worked on it, on these cases. 09:21:04</p> <p>4 I don't know who has spent the more time on each 09:21:06</p> <p>5 declaration. I haven't managed the workflow to the 09:21:10</p> <p>6 extent -- at the level of detail that would help me 09:21:20</p> <p>7 remember that -- the answer to that question. 09:21:23</p> <p>8 Q. And was there one of the members of your 09:21:27</p> <p>9 team that was particularly focused on either '572 09:21:29</p> <p>10 or '601? 09:21:34</p> <p>11 A. I believe they each focused on both 09:21:37</p> <p>12 reports. 09:21:39</p> <p>13 Q. Got it. 09:21:40</p> <p>14 A. Or both declarations. 09:21:41</p> <p>15 Q. So let me ask you turning to paragraph 10 09:21:42</p> <p>16 of your report. That is on page -- looks like it's 09:21:45</p> <p>17 on page 9 of the document. You indicate that you 09:21:53</p> <p>18 relied on the declaration of -- of Michael W. 09:21:59</p> <p>19 Stewart, M.D., Exhibit 2065; do you see that? 09:22:05</p> <p>20 A. Yes. 09:22:09</p> <p>21 Q. And you have that exhibit in front of you. 09:22:09</p> <p>22 A. Uh-huh. 09:22:13</p> <p>23 Q. You also mentioned you had a conversation 09:22:13</p> <p>24 with Dr. Stewart; is that right? 09:22:13</p> <p>25 A. Yes. 09:22:14</p> <p style="text-align: right;">Page 17</p> |

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| <p>1 Q. When was that conversation? 09:22:14</p> <p>2 A. I don't remember the date. It was within 09:22:16</p> <p>3 the weeks leading up to the submission of the 09:22:22</p> <p>4 declaration. 09:22:24</p> <p>5 Q. Okay. So for this particular -- this 09:22:24</p> <p>6 declaration was signed in February of 2024; is that 09:22:28</p> <p>7 right? 09:22:32</p> <p>8 A. Yes, February 22nd. 09:22:36</p> <p>9 Q. Okay. So possibly sometime in February 09:22:38</p> <p>10 2024? 09:22:40</p> <p>11 A. Could be. I'd have to go back and look at 09:22:41</p> <p>12 my calendar, but I don't remember the exact date. 09:22:43</p> <p>13 Q. And what did you and Dr. Stewart talk 09:22:45</p> <p>14 about? 09:22:49</p> <p>15 A. We talked about the issues that I have 09:22:51</p> <p>16 mentioned in the declaration. There's a summary of 09:22:53</p> <p>17 the points that I took from him. We talked about, 09:22:56</p> <p>18 you know, his declaration, the main points of his 09:23:01</p> <p>19 declaration, those sorts of things. 09:23:03</p> <p>20 Q. And was that the only time you talked to 09:23:06</p> <p>21 him? 09:23:08</p> <p>22 A. I talked to him once for each of the 09:23:08</p> <p>23 declarations. 09:23:10</p> <p>24 Q. And do you recall for each the duration of 09:23:10</p> <p>25 those conversations? 09:23:14</p> <p style="text-align: right;">Page 18</p>                                                                                              | <p>1 framework within which my economic analysis is 09:24:31</p> <p>2 done. 09:24:35</p> <p>3 Q. Okay. And in terms of setting forth that 09:24:37</p> <p>4 legal framework, is that based on a conversation 09:24:43</p> <p>5 you had with counsel, or how did you establish that 09:24:47</p> <p>6 framework? 09:24:51</p> <p>7 A. So I have understood the framework for 09:24:52</p> <p>8 commercial success for a number of years. I 09:24:57</p> <p>9 have -- I don't remember the exact conversation 09:25:02</p> <p>10 that took place for these particular declarations, 09:25:05</p> <p>11 but I know that in prior declarations I've 09:25:07</p> <p>12 discussed with counsel what the legal framework of 09:25:09</p> <p>13 commercial success is and those are very similar 09:25:15</p> <p>14 across -- well, those are the same. So I take 09:25:17</p> <p>15 those as -- essentially as instruction from 09:25:21</p> <p>16 counsel. 09:25:24</p> <p>17 Q. And in addition to discussion with 09:25:26</p> <p>18 counsel, did you review anything else to help you 09:25:28</p> <p>19 with this framework? 09:25:33</p> <p>20 A. Well, I do have some footnotes in those 09:25:36</p> <p>21 paragraphs. So those materials are things that 09:25:38</p> <p>22 I -- for these projects and prior projects relating 09:25:41</p> <p>23 to commercial success that I have looked at and 09:25:47</p> <p>24 come to understand the appropriate framework for an 09:25:52</p> <p>25 economic analysis of commercial success. 09:25:57</p> <p style="text-align: right;">Page 20</p> |
| <p>1 A. They were scheduled for half an hour. I 09:23:17</p> <p>2 don't recall whether they went the full time or 09:23:19</p> <p>3 not. 09:23:21</p> <p>4 Q. And were they by telephone? 09:23:21</p> <p>5 A. By electronic or Zoom. I don't know 09:23:24</p> <p>6 whether it was actually Zoom or some other method, 09:23:26</p> <p>7 but there was a video conversation. 09:23:30</p> <p>8 Q. And was anybody else present for those 09:23:32</p> <p>9 Zoom conferences? 09:23:34</p> <p>10 A. Counsel was there. 09:23:36</p> <p>11 Q. Got it. 09:23:37</p> <p>12 A. And Ryan Marsh may have been on as well. 09:23:40</p> <p>13 Q. Now, I want to ask you some questions 09:23:46</p> <p>14 about particularly paragraphs 11 and 12, and I 09:23:49</p> <p>15 believe those paragraphs are identical for both the 09:23:58</p> <p>16 '572 and '601. I'm not going to burden you with 09:24:02</p> <p>17 checking, but does that sound about right? 09:24:06</p> <p>18 A. That wouldn't surprise me. 09:24:11</p> <p>19 Q. All right. And is it fair to say that 09:24:12</p> <p>20 those -- paragraphs 11 and 12, those set forth the 09:24:15</p> <p>21 legal framework for your opinions? 09:24:20</p> <p>22 MR. WILK: Objection to form. 09:24:23</p> <p>23 A. Well, I wouldn't say that I have a legal 09:24:24</p> <p>24 opinion. I would say that they represent my 09:24:26</p> <p>25 understanding of the legal framework or the 09:24:28</p> <p style="text-align: right;">Page 19</p> | <p>1 Q. And as an example I think one of the cases 09:26:00</p> <p>2 that you footnote is -- looks like Demaco Corp 09:26:04</p> <p>3 versus F. Von Langsdorff from 1988; is that 09:26:09</p> <p>4 correct? 09:26:14</p> <p>5 A. That is one of the citations, yes. 09:26:15</p> <p>6 Q. Merck v. Teva from 2005? 09:26:17</p> <p>7 A. That's one of the citations, yes. 09:26:21</p> <p>8 Q. And you've got a reference to a citation 09:26:22</p> <p>9 from the Manual of Patent Examining Procedure; is 09:26:27</p> <p>10 that right? 09:26:33</p> <p>11 A. Yes. 09:26:34</p> <p>12 Q. And it also looks like Yita v. MacNeil 09:26:34</p> <p>13 from 2023? 09:26:36</p> <p>14 A. Yes. 09:26:39</p> <p>15 Q. Ormco Corp versus Align from 2006? 09:26:39</p> <p>16 A. That's correct. 09:26:42</p> <p>17 Q. And then it looks like you have a number 09:26:43</p> <p>18 of citations to an article from 2009 that is titled 09:26:45</p> <p>19 "The Economics of Commercial Success in 09:26:52</p> <p>20 Pharmaceutical Patent Litigation"; is that right? 09:26:55</p> <p>21 A. There are two, yes. 09:26:57</p> <p>22 Q. Got it. You said there are two citations, 09:27:02</p> <p>23 but it's the same article, right? 09:27:04</p> <p>24 A. Yes. 09:27:09</p> <p>25 Q. Now, in paragraph 11 of your declaration 09:27:09</p> <p style="text-align: right;">Page 21</p>                                                                                                                                                                                                                |

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| <p>1 you indicate that you understand that for 09:27:13</p> <p>2 commercial success to constitute evidence of 09:27:15</p> <p>3 nonobviousness of a patent there must be a nexus 09:27:19</p> <p>4 between the claimed technology and evidence of 09:27:24</p> <p>5 commercial success; do you see that? 09:27:27</p> <p>6 A. I do see that. 09:27:29</p> <p>7 Q. All right. So before I get to that let me 09:27:31</p> <p>8 ask you, are you aware of the burden that is on the 09:27:33</p> <p>9 patent owner with respect to establishing 09:27:37</p> <p>10 commercial success for purposes of secondary 09:27:39</p> <p>11 considerations? 09:27:42</p> <p>12 MR. WILK: Objection to form. 09:27:43</p> <p>13 A. That's a legal issue. You know, I have 09:27:44</p> <p>14 some general understanding of it, but I don't 09:27:48</p> <p>15 actually know the details of who owns -- who has 09:27:50</p> <p>16 the burden of demonstrating what, no. 09:27:54</p> <p>17 Q. Okay. So you don't know, first of all, 09:27:56</p> <p>18 who has the burden? 09:27:57</p> <p>19 MR. WILK: Objection to form. 09:27:59</p> <p>20 A. As I sit here I'm not recalling that, no. 09:27:59</p> <p>21 Q. All right. And so setting aside who has 09:28:03</p> <p>22 the burden, you also don't know what the standard 09:28:05</p> <p>23 is, in other words, what's required to prove it? 09:28:08</p> <p>24 MR. WILK: Objection to form. 09:28:10</p> <p>25 A. The legal standard I don't recall. 09:28:15</p> <p style="text-align: right;">Page 22</p>                                                                                      | <p>1 developed them and would have brought them to the 09:29:32</p> <p>2 market sooner. 09:29:34</p> <p>3 And so it is incumbent upon me as an 09:29:36</p> <p>4 expert to evaluate the nexus between the patented 09:29:39</p> <p>5 features and the commercial performance of the 09:29:44</p> <p>6 product and to reach an opinion about the extent to 09:29:47</p> <p>7 which that nexus is reasonably determined. And so 09:29:51</p> <p>8 my role is to think about the economics of that 09:29:59</p> <p>9 question, not the legalities of it. And so that's 09:30:04</p> <p>10 the sense in which I don't know and haven't focused 09:30:07</p> <p>11 on whose burden it is necessarily. 09:30:09</p> <p>12 Q. All right. And I just want to make sure I 09:30:14</p> <p>13 understand your answer. You said commercial 09:30:18</p> <p>14 success is a secondary indicator of obviousness. 09:30:21</p> <p>15 So I want to make sure that we're on the same page. 09:30:28</p> <p>16 Is it your understanding that secondary -- I'm 09:30:31</p> <p>17 sorry -- that commercial success can be an 09:30:34</p> <p>18 indicator of obviousness, nonobviousness, or both? 09:30:35</p> <p>19 MR. WILK: Objection to form. 09:30:40</p> <p>20 A. Well, as I say in the declaration, I 09:30:42</p> <p>21 understand that evidence of commercial success is 09:30:47</p> <p>22 one of the objective indicators that a patent owner 09:30:50</p> <p>23 may rely upon to support an argument of 09:30:53</p> <p>24 nonobviousness of a claimed invention. 09:30:59</p> <p>25 Q. Okay. Again, you just said obviousness in 09:31:00</p> <p style="text-align: right;">Page 24</p> |
| <p>1 Q. Okay. You said you had some general 09:28:19</p> <p>2 understanding about the legal issue. What's your 09:28:21</p> <p>3 general understanding? 09:28:23</p> <p>4 A. Well, what do you mean? 09:28:25</p> <p>5 Q. I'm just going back to what you said. You 09:28:27</p> <p>6 said "You know, I have some general understanding 09:28:30</p> <p>7 of it," and I'm just curious what your general 09:28:32</p> <p>8 understanding is. 09:28:36</p> <p>9 A. I'm sorry. Can you remind me what I said? 09:28:37</p> <p>10 What was the preceding question? 09:28:39</p> <p>11 Q. The preceding question was "Are you aware 09:28:41</p> <p>12 of the burden that is on the patent owner with 09:28:43</p> <p>13 respect to establishing commercial success for 09:28:47</p> <p>14 purposes of secondary considerations," and you said 09:28:49</p> <p>15 "That's a legal issue. You know, I have some 09:28:51</p> <p>16 general understanding of it, but I don't actually 09:28:53</p> <p>17 know the details of who owns -- who has the burden 09:28:55</p> <p>18 of demonstrating what, no." 09:28:59</p> <p>19 A. Okay. My understanding is that, as I 09:29:02</p> <p>20 indicated in my declaration, commercial success is 09:29:08</p> <p>21 a secondary indicator of obviousness, that there 09:29:11</p> <p>22 are primary indicators that are also at issue, and 09:29:16</p> <p>23 that the economics of the question is, as I 09:29:19</p> <p>24 describe in the report, that if the patented 09:29:21</p> <p>25 features were obvious then someone else would have 09:29:28</p> <p style="text-align: right;">Page 23</p> | <p>1 your initial response and I think your declaration 09:31:02</p> <p>2 says nonobviousness. 09:31:04</p> <p>3 A. Right. 09:31:06</p> <p>4 Q. That's why I was asking whether it was 09:31:06</p> <p>5 your understanding that it was applicable to a 09:31:07</p> <p>6 showing of nonobvious- -- nonobviousness, excuse 09:31:10</p> <p>7 me, or obviousness or both? 09:31:13</p> <p>8 A. As the declaration says nonobviousness, 09:31:18</p> <p>9 I -- you know, if there's a legal distinction there 09:31:22</p> <p>10 that I haven't focused on, again, that's a legal 09:31:26</p> <p>11 issue that -- I'm not a lawyer. 09:31:28</p> <p>12 Q. Okay. 09:31:32</p> <p>13 Now, with respect to this nexus, do you 09:31:33</p> <p>14 understand that evidence of commercial success must 09:31:37</p> <p>15 relate to the practice of a claimed invention? 09:31:41</p> <p>16 MR. WILK: Objection, form. 09:31:45</p> <p>17 A. I guess I would go again to my declaration 09:31:50</p> <p>18 where it says "I understand that for the commercial 09:31:52</p> <p>19 success to constitute evidence of nonobviousness of 09:31:55</p> <p>20 a patent there must be a nexus between the claimed 09:31:58</p> <p>21 technology and evidence of commercial success. 09:32:01</p> <p>22 Moreover, the evidence must demonstrate that the 09:32:09</p> <p>23 commercial success is due, at least in part, to the 09:32:12</p> <p>24 claimed features of the invention and not entirely 09:32:15</p> <p>25 to factors unrelated to the claimed invention." 09:32:18</p> <p style="text-align: right;">Page 25</p>                                                                  |

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| <p>1 So that reflects my understanding and my 09:32:22</p> <p>2 opinion. I guess I'm not sure how to answer the 09:32:24</p> <p>3 question beyond that. 09:32:27</p> <p>4 Q. Do you not understand the question? 09:32:29</p> <p>5 A. Well, ask it again, if you would. 09:32:31</p> <p>6 Q. Sure. I was asking about with respect to 09:32:33</p> <p>7 nexus, do you understand that the evidence of 09:32:37</p> <p>8 commercial success must relate to the practice of 09:32:40</p> <p>9 the claimed invention? 09:32:42</p> <p>10 MR. WILK: Objection to form. 09:32:43</p> <p>11 A. Again, I think "practice" is a matter for 09:32:44</p> <p>12 technical or legal experts. My assignment and my 09:32:46</p> <p>13 understanding is that I should evaluate the claimed 09:32:50</p> <p>14 invention, the claims as a whole, and to evaluate 09:32:53</p> <p>15 the product's commercial success with respect to 09:32:57</p> <p>16 the claims as a whole. 09:32:59</p> <p>17 Q. All right. Let me ask it a different way. 09:33:01</p> <p>18 If you were looking at evidence of commercial 09:33:03</p> <p>19 success for a product that does not practice the 09:33:09</p> <p>20 '572 Patent, do you consider that a factor for 09:33:11</p> <p>21 commercial success? 09:33:17</p> <p>22 MR. WILK: Objection to form. 09:33:17</p> <p>23 A. If I were looking at a product that does 09:33:19</p> <p>24 not practice the patent? What do you mean? I 09:33:22</p> <p>25 guess that's a little vague for me. 09:33:25</p> <p style="text-align: right;">Page 26</p> | <p>1 the legal scope of a patent? 09:34:42</p> <p>2 MR. WILK: Objection to form. 09:34:44</p> <p>3 A. I understand that. 09:34:45</p> <p>4 Q. And do you understand that in order for a 09:34:46</p> <p>5 product to practice the patent it must practice one 09:34:51</p> <p>6 or more of those claims? 09:34:53</p> <p>7 MR. WILK: Objection to form. 09:34:54</p> <p>8 A. I understand that my assignment is to 09:34:55</p> <p>9 evaluate the claims as a whole and that I do that 09:34:58</p> <p>10 by looking at the economic evidence of the product 09:35:03</p> <p>11 and its performance in the marketplace and its 09:35:05</p> <p>12 relationship to those claims, yes. 09:35:09</p> <p>13 Q. And is it your understanding that if a 09:35:12</p> <p>14 particular product does not practice any of the 09:35:14</p> <p>15 claims of the '572 Patent that that would -- those 09:35:19</p> <p>16 products would not be evidence of commercial 09:35:25</p> <p>17 success? 09:35:27</p> <p>18 MR. WILK: Objection to form. 09:35:29</p> <p>19 A. That has legal -- that question has legal 09:35:32</p> <p>20 elements that I, again, wouldn't opine on because 09:35:35</p> <p>21 I'm not an attorney, but generally if none of the 09:35:37</p> <p>22 claims are practiced I'd have to think about what 09:35:44</p> <p>23 that means. Again, it's a legal question. 09:35:48</p> <p>24 Q. So you don't know, for example, if none of 09:35:50</p> <p>25 the claims are practiced whether or not you should 09:35:53</p> <p style="text-align: right;">Page 28</p>           |
| <p>1 Q. You don't understand what it means to 09:33:27</p> <p>2 practice a patent? 09:33:28</p> <p>3 A. I have a general understanding, but that 09:33:30</p> <p>4 is a legal distinction. So a product -- do you 09:33:33</p> <p>5 mean another product? 09:33:35</p> <p>6 Q. Well, let me ask you this question. You 09:33:37</p> <p>7 said you have a general understanding of practicing 09:33:39</p> <p>8 the patent. What's your general understanding? 09:33:40</p> <p>9 A. That the patented features are reflected 09:33:43</p> <p>10 in the product, and I guess I would also, you know, 09:33:46</p> <p>11 go back to Dr. Stewart's declaration where he says 09:33:54</p> <p>12 that his view is that -- his opinion is that Eylea 09:33:57</p> <p>13 does embody or practice the patented invention. 09:34:03</p> <p>14 Q. Okay. And he says that generally, that 09:34:08</p> <p>15 Eylea generally practices the patented invention; 09:34:14</p> <p>16 is that your understanding? 09:34:19</p> <p>17 MR. WILK: Objection to form. 09:34:20</p> <p>18 A. I would go to his statement and not 09:34:20</p> <p>19 characterize it beyond what he says. 09:34:22</p> <p>20 Q. Okay. We can look at his declaration in a 09:34:25</p> <p>21 bit. Let me ask it this way. Do you understand 09:34:28</p> <p>22 that the '572 Patent includes a number of claims at 09:34:34</p> <p>23 the end of the patent? 09:34:38</p> <p>24 A. Yes. 09:34:40</p> <p>25 Q. And do you understand that the claims are 09:34:40</p> <p style="text-align: right;">Page 27</p>   | <p>1 consider that product for purposes of commercial 09:35:54</p> <p>2 success? 09:35:57</p> <p>3 MR. WILK: Objection to form. 09:35:57</p> <p>4 A. I guess that sounds like a hypothetical 09:35:59</p> <p>5 because I have a hard time imagining a product that 09:36:04</p> <p>6 practices none of the claims of a patent, yet 09:36:06</p> <p>7 there's an assertion of the patent's relevance for 09:36:09</p> <p>8 the product. 09:36:13</p> <p>9 Q. So you say that you "have a hard time 09:36:19</p> <p>10 imagining a product that practices none of the 09:36:21</p> <p>11 claims of a patent, yet there's an assertion of the 09:36:23</p> <p>12 patent's relevance for the product." What do you 09:36:26</p> <p>13 mean by that? 09:36:29</p> <p>14 A. For example, if I have a patent on a form 09:36:33</p> <p>15 of tennis shoe, I have a hard time understanding 09:36:35</p> <p>16 how a basketball -- which claims could be 09:36:38</p> <p>17 associated with the patent on a tennis shoe. You 09:36:43</p> <p>18 know, if none of the claims for the tennis shoe 09:36:47</p> <p>19 relate to the product's -- to the basketball's 09:36:51</p> <p>20 characteristics, I would have a hard time 09:36:57</p> <p>21 understanding how those two could be at issue in 09:36:59</p> <p>22 the same case. 09:37:02</p> <p>23 So that's what I mean by saying I don't 09:37:03</p> <p>24 understand how a product that doesn't practice the 09:37:05</p> <p>25 claims of a specific patent could be identified or 09:37:07</p> <p style="text-align: right;">Page 29</p> |

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| <p>1 related to the patent. 09:37:10</p> <p>2 Q. Let me ask it this way. If the Eylea 09:37:13</p> <p>3 product did not practice any claims of the 09:37:19</p> <p>4 '572 Patent, would the sales of that product still 09:37:22</p> <p>5 be relevant to commercial success from your 09:37:26</p> <p>6 perspective? 09:37:29</p> <p>7 MR. WILK: Objection to form. 09:37:30</p> <p>8 A. That sounds like a legal issue. My 09:37:32</p> <p>9 understanding is that it does practice the claims. 09:37:38</p> <p>10 I rely on Dr. Stewart's assessment of that. So 09:37:41</p> <p>11 it's kind of a hard question to answer because it 09:37:45</p> <p>12 seems at odds with the facts as I understand them. 09:37:47</p> <p>13 Q. If a court determined that none of the 09:37:50</p> <p>14 claims of the '572 are practiced by the Eylea 09:37:54</p> <p>15 product, would it still be your opinion that the 09:37:58</p> <p>16 sales of those products are relevant to commercial 09:38:01</p> <p>17 success? 09:38:04</p> <p>18 MR. WILK: Objection to form. 09:38:04</p> <p>19 A. Well, it sounds to me -- again, that's a 09:38:06</p> <p>20 legal question, but if the Court decides something, 09:38:08</p> <p>21 then the Court decides it and I wouldn't have any 09:38:11</p> <p>22 opinion to offer. 09:38:14</p> <p>23 Q. So if the product does not practice 09:38:18</p> <p>24 the '572 Patent, then in your view the sales of that 09:38:20</p> <p>25 product would not be relevant to commercial 09:38:24</p> <p style="text-align: right;">Page 30</p> | <p>1 A. Well, that's a complicated hypothetical. 09:39:23</p> <p>2 I wouldn't want to speculate about what the legal 09:39:26</p> <p>3 implications of the two parties' positions are. 09:39:30</p> <p>4 You know, if you're telling me that one side 09:39:38</p> <p>5 believes that the patents are not relevant or the 09:39:46</p> <p>6 claims are not relevant and the other believes that 09:39:48</p> <p>7 they are, I would say that's a legal question, not 09:39:51</p> <p>8 mine. 09:39:53</p> <p>9 Q. Okay. 09:39:54</p> <p>10 Let me ask you about something else you 09:39:55</p> <p>11 say in paragraph 11. Let me make sure I find the 09:39:57</p> <p>12 right spot. You state -- and this is the 09:40:03</p> <p>13 "Moreover" sentence, which I think is the -- maybe 09:40:08</p> <p>14 the fourth sentence in the paragraph. You state 09:40:14</p> <p>15 that "Commercial success must be due, at least in 09:40:16</p> <p>16 part, to the claimed features of the invention"; do 09:40:21</p> <p>17 you see that? 09:40:26</p> <p>18 A. Yes. 09:40:26</p> <p>19 Q. Okay. When you say "in part," what do you 09:40:26</p> <p>20 mean by "in part"? 09:40:29</p> <p>21 A. I mean that the claimed features don't 09:40:32</p> <p>22 have to explain all of the commercial success. It 09:40:34</p> <p>23 has to be -- in economic terms it has to be a 09:40:37</p> <p>24 driver of demand. It has to be something that 09:40:40</p> <p>25 contributes to the commercial success, but other 09:40:44</p> <p style="text-align: right;">Page 32</p>                                                               |
| <p>1 success? 09:38:26</p> <p>2 MR. WILK: Objection to form. 09:38:26</p> <p>3 A. That's not something I've thought about 09:38:30</p> <p>4 because I don't think it's an economic question. I 09:38:32</p> <p>5 think it's a legal question. If you're telling me 09:38:35</p> <p>6 that there's no link between -- kind of like the 09:38:40</p> <p>7 tennis shoe and the basketball example, I would 09:38:44</p> <p>8 wonder why I was here. 09:38:46</p> <p>9 Q. Do you understand that there may be 09:38:48</p> <p>10 dispute about the scope of the claims of the 09:38:50</p> <p>11 '572 Patent? 09:38:53</p> <p>12 MR. WILK: Objection to form. 09:38:54</p> <p>13 A. Sure. 09:38:55</p> <p>14 Q. Okay. And one side may think that it 09:38:56</p> <p>15 covers certain things, the other side may think 09:38:59</p> <p>16 that it covers something else. Does that make 09:39:01</p> <p>17 sense? 09:39:04</p> <p>18 A. Sure. 09:39:04</p> <p>19 Q. All right. And in the instance where one 09:39:05</p> <p>20 side prevails and it's determined that the Eylea 09:39:07</p> <p>21 product or portions of the Eylea product don't 09:39:11</p> <p>22 practice the claims, then it would be your 09:39:14</p> <p>23 understanding that commercial success is not 09:39:16</p> <p>24 relevant for purposes of those sales? 09:39:19</p> <p>25 MR. WILK: Objection to form. 09:39:21</p> <p style="text-align: right;">Page 31</p>                                                                                                                             | <p>1 things could also contribute. 09:40:46</p> <p>2 Q. And from an economic perspective does it 09:40:57</p> <p>3 matter how much the patented features contribute to 09:41:01</p> <p>4 the commercial success versus the other things? 09:41:08</p> <p>5 MR. WILK: Objection to form. 09:41:10</p> <p>6 A. For the purposes of demonstrating 09:41:12</p> <p>7 commercial success my understanding is that it does 09:41:13</p> <p>8 not, that, you know, there's not a requirement for 09:41:15</p> <p>9 apportioning or identifying the share of a 09:41:18</p> <p>10 product's success that is related to the product's 09:41:22</p> <p>11 patented features and things that might be related 09:41:27</p> <p>12 to something else. 09:41:29</p> <p>13 Q. So in your view the patented features 09:41:30</p> <p>14 could contribute 1 percent to commercial success 09:41:31</p> <p>15 and the other features could contribute 99 percent 09:41:34</p> <p>16 and would still be relevant for purposes of your 09:41:38</p> <p>17 evaluation? 09:41:42</p> <p>18 MR. WILK: Objection to form. 09:41:42</p> <p>19 A. Again, that presumes some apportionment. 09:41:44</p> <p>20 I think one would want to look at the situation in 09:41:47</p> <p>21 play and ask whether or not the evidence was 09:41:55</p> <p>22 compelling or reasonable to an economist, from an 09:41:58</p> <p>23 economist's perspective that the patented features 09:42:01</p> <p>24 meaningfully contributed to the product's 09:42:05</p> <p>25 commercial success. I don't -- I don't have a 09:42:07</p> <p style="text-align: right;">Page 33</p> |

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| <p>1 number to place on something like that. I just 09:42:11</p> <p>2 don't have that. 09:42:17</p> <p>3 Q. Okay. Can you elaborate on what you mean 09:42:18</p> <p>4 by "meaningfully contributed to the product's 09:42:20</p> <p>5 commercial success"? 09:42:23</p> <p>6 A. Meaning looking at the product's 09:42:26</p> <p>7 performance as a whole, looking at the patented 09:42:28</p> <p>8 features as a whole is there reasonable evidence 09:42:30</p> <p>9 from an economic perspective that the patented 09:42:37</p> <p>10 features contributed to the product's commercial 09:42:43</p> <p>11 success. 09:42:48</p> <p>12 Q. Okay. You said "meaningfully contribute." 09:42:49</p> <p>13 What do you use to establish whether or not it's 09:42:51</p> <p>14 meaningful? 09:42:53</p> <p>15 A. Evidence from an economic perspective, 09:42:54</p> <p>16 looking at the sales of the product, looking at 09:42:56</p> <p>17 things that I describe here in the -- in the 09:42:58</p> <p>18 report, looking at what -- how the product has 09:43:03</p> <p>19 performed relative to competitors, looking at how 09:43:06</p> <p>20 the product has performed over time, looking at the 09:43:08</p> <p>21 number of patients or the impact the product has on 09:43:12</p> <p>22 patient outcomes, those sorts of things. 09:43:16</p> <p>23 Q. Let me ask you this. In your view is the 09:43:20</p> <p>24 degree of commercial success relevant to your 09:43:22</p> <p>25 evaluation? 09:43:25</p> <p style="text-align: right;">Page 34</p>                                                                                                                             | <p>1 A. Again, taking note of the fact that you 09:44:58</p> <p>2 mentioned that it is -- that my declaration makes a 09:45:03</p> <p>3 point of it being an indicator of nonobviousness, I 09:45:05</p> <p>4 guess I would say that the degree to which the link 09:45:10</p> <p>5 is present in the data and present in the analysis 09:45:16</p> <p>6 makes it easier to decide -- or to conclude that 09:45:21</p> <p>7 the patented features are or may not be related to 09:45:26</p> <p>8 commercial success, but, again, I don't have a 09:45:30</p> <p>9 specific number to put on that. 09:45:34</p> <p>10 Q. Okay. Let me ask it this way. If the 09:45:36</p> <p>11 commercial success for a particular product let's 09:45:38</p> <p>12 say was in the billions versus another product that 09:45:41</p> <p>13 sold a hundred dollars. Would you view the value 09:45:48</p> <p>14 of that millions or billions of commercial success 09:45:51</p> <p>15 as a stronger piece of evidence for purposes of 09:45:53</p> <p>16 nonobviousness than the hundred dollar sales? 09:45:58</p> <p>17 MR. WILK: Objection to form. 09:46:03</p> <p>18 A. It would depend on the situation, it would 09:46:04</p> <p>19 depend on the marketplace, it would depend upon how 09:46:06</p> <p>20 broad the market was for that product, it would 09:46:09</p> <p>21 depend upon how that product -- the hundred-dollar 09:46:13</p> <p>22 product had performed relative to others that were 09:46:16</p> <p>23 addressing the same need. It would depend upon how 09:46:19</p> <p>24 all the indicators of commercial success looked. I 09:46:25</p> <p>25 couldn't tell you whether or not a hundred-dollar 09:46:28</p> <p style="text-align: right;">Page 36</p> |
| <p>1 A. What do you mean by "degree"? 09:43:27</p> <p>2 Q. I mean how much commercial success must 09:43:30</p> <p>3 there be? What's the framework that you use? 09:43:33</p> <p>4 A. There is an understanding that there's not 09:43:36</p> <p>5 a specific number but that commercial success must 09:43:42</p> <p>6 have a link to the patented features and there must 09:43:47</p> <p>7 be a clear nexus that is identifiable. 09:43:50</p> <p>8 Q. Understood that there's a link. My 09:43:55</p> <p>9 question's a little bit different. It's more to 09:43:56</p> <p>10 the degree of commercial success, meaning how much 09:43:59</p> <p>11 commercial success must there be for it to be 09:44:00</p> <p>12 relevant or meaningful? What's your framework? 09:44:04</p> <p>13 A. I don't believe there is a number to 09:44:09</p> <p>14 attach to that. There is a concept of what is 09:44:11</p> <p>15 sufficient economic evidence to me as the 09:44:16</p> <p>16 evaluator. And so I would look at the evidence in 09:44:19</p> <p>17 play and make -- reach a determination about 09:44:25</p> <p>18 whether or not the link is sufficient to convince 09:44:28</p> <p>19 me as the evaluator whether or not the commercial 09:44:31</p> <p>20 success is -- whether there's a nexus between that 09:44:36</p> <p>21 success and the patented features. 09:44:42</p> <p>22 Q. And do you believe that the degree of 09:44:44</p> <p>23 commercial success is relevant to the evaluation of 09:44:47</p> <p>24 the obviousness for purposes of commercial success? 09:44:52</p> <p>25 MR. WILK: Objection to form. 09:44:56</p> <p style="text-align: right;">Page 35</p> | <p>1 product was or wasn't a commercial success simply 09:46:30</p> <p>2 on the basis of the fact that it sold a hundred 09:46:32</p> <p>3 dollars. Likewise I couldn't tell you just on the 09:46:34</p> <p>4 basis of the fact that something else sold a 09:46:37</p> <p>5 billion dollars worth of revenue. I would need to 09:46:39</p> <p>6 know more. 09:46:42</p> <p>7 Q. Okay. So let's say all things considered, 09:46:43</p> <p>8 same product, all the other situation -- all the 09:46:45</p> <p>9 other factors are constant. In one instance its 09:46:49</p> <p>10 sales are 10 billion, in the other instance its 09:46:52</p> <p>11 sale is a hundred dollars. Would that greater 09:46:56</p> <p>12 degree of commercial success impact your opinion 09:46:58</p> <p>13 with respect to nonobviousness? 09:47:02</p> <p>14 MR. WILK: Objection to form. 09:47:04</p> <p>15 A. With respect to commercial success, you're 09:47:10</p> <p>16 asking me a hypothetical again and I don't -- I 09:47:13</p> <p>17 have a hard time understanding a market or an 09:47:17</p> <p>18 economic set of products in which, as you said, 09:47:20</p> <p>19 everything else -- well, you said everything else 09:47:26</p> <p>20 considered rather than everything else the same, 09:47:29</p> <p>21 and the economist methodology is to hold everything 09:47:31</p> <p>22 else the same. I have a hard time understanding 09:47:34</p> <p>23 how one product could sell \$10 billion in a given 09:47:37</p> <p>24 point of time and another could sell a hundred 09:47:41</p> <p>25 dollars in the same period of time and be in the 09:47:43</p> <p style="text-align: right;">Page 37</p>                                                             |

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| <p>1 same product category. So, you know, I can't -- I 09:47:45</p> <p>2 can't perform that complicated hypothetical 09:47:55</p> <p>3 analysis because I don't understand the situation 09:47:57</p> <p>4 that that could be real. 09:47:59</p> <p>5 Q. Let me ask it this way. Sorry. I didn't 09:48:02</p> <p>6 mean to interrupt you. Is it fair to say the 09:48:04</p> <p>7 higher degree of commercial success the stronger 09:48:06</p> <p>8 indicator of nonobviousness? 09:48:10</p> <p>9 MR. WILK: Objection to form. 09:48:12</p> <p>10 A. I think that's fair. 09:48:18</p> <p>11 Q. Okay. 09:48:21</p> <p>12 Let me turn you to paragraph 12 of your 09:48:24</p> <p>13 report -- sorry -- declaration, and I wanted to ask 09:48:26</p> <p>14 you some questions about the first sentence. In 09:48:35</p> <p>15 the first sentence in paragraph 12 you state "It is 09:48:38</p> <p>16 my understanding that the Courts commonly accept 09:48:40</p> <p>17 indicators including significant sales levels, 09:48:44</p> <p>18 significant sales growth, substitution toward the 09:48:48</p> <p>19 novel product or method and away from alternative 09:48:52</p> <p>20 products or methods, persistent premiums or the 09:48:56</p> <p>21 absence of substantial discounting, and other 09:49:01</p> <p>22 economic indicators as evidence of commercial 09:49:04</p> <p>23 success of a novel product." I hope I read that 09:49:06</p> <p>24 correctly. 09:49:08</p> <p>25 A. You did drop the word "price." 09:49:09</p> <p style="text-align: right;">Page 38</p> | <p>1 of the product, the share of sales that a product 09:50:44</p> <p>2 gets over time. You look at whether or not the 09:50:46</p> <p>3 product is gaining sales from competing products or 09:50:49</p> <p>4 alternative products. You get -- you look at the 09:50:54</p> <p>5 other factors that are described there in that 09:50:59</p> <p>6 sentence. 09:51:01</p> <p>7 Q. In your two declarations you speak of the 09:51:02</p> <p>8 demand for the patented features as a driver of 09:51:06</p> <p>9 commercial success, correct? 09:51:09</p> <p>10 A. Those exact words I would want to see in 09:51:14</p> <p>11 the -- in the declaration, but that's 09:51:18</p> <p>12 understandable -- that's consistent with my 09:51:22</p> <p>13 understanding, yes. 09:51:25</p> <p>14 Q. Okay. For the '572 and '601 Patents is 09:51:26</p> <p>15 that the demand of the patient? 09:51:33</p> <p>16 A. It can be, yes. 09:51:35</p> <p>17 Q. When you say "can be," is there someone 09:51:37</p> <p>18 else it could be? 09:51:41</p> <p>19 A. Sure. 09:51:42</p> <p>20 Q. Who would that be? 09:51:42</p> <p>21 A. The physician, perhaps the payer. You 09:51:43</p> <p>22 know, the market for medical products is 09:51:48</p> <p>23 complicated. A variety of people end up being 09:51:50</p> <p>24 affected by which among alternative treatments 09:51:54</p> <p>25 might be chosen and each of them has an influence 09:51:57</p> <p style="text-align: right;">Page 40</p>                                                                                                      |
| <p>1 Q. Okay. All right. So hopefully the record 09:49:12</p> <p>2 reflects that. 09:49:17</p> <p>3 You use the word "significant" multiple 09:49:20</p> <p>4 times, and I want to better understand what you 09:49:22</p> <p>5 mean there. First of all, you said "significant 09:49:24</p> <p>6 sales levels." What did you mean by "significant"? 09:49:26</p> <p>7 A. I think a useful synonym would be 09:49:30</p> <p>8 substantial. I mean, it doesn't reflect any 09:49:35</p> <p>9 specific number. It means within the context of 09:49:39</p> <p>10 the product's space in the economic environment 09:49:45</p> <p>11 that it's in substantial or significant sales are 09:49:47</p> <p>12 an indicator of commercial success. 09:49:52</p> <p>13 Q. And how do you determine whether something 09:49:55</p> <p>14 is significant or substantial? 09:49:57</p> <p>15 A. You evaluate that product in the context 09:50:02</p> <p>16 of the other products that are also being chosen to 09:50:05</p> <p>17 meet the consumer's needs or meet the consumer's 09:50:10</p> <p>18 desires for whatever that product is being sold 09:50:15</p> <p>19 for. 09:50:20</p> <p>20 Q. Okay. So one of the things you look at is 09:50:31</p> <p>21 competitive products? 09:50:34</p> <p>22 A. Sure. 09:50:35</p> <p>23 Q. Anything else? 09:50:36</p> <p>24 A. You look at the things that I did look at 09:50:39</p> <p>25 in this declaration. You look at the performance 09:50:42</p> <p style="text-align: right;">Page 39</p>                                               | <p>1 over what product is ultimately used. So the 09:52:00</p> <p>2 demand would want to consider the impact on all of 09:52:03</p> <p>3 those people. 09:52:06</p> <p>4 Q. Okay. Great. So it's the -- I think you 09:52:07</p> <p>5 said it's the patient, it's the physician, and 09:52:10</p> <p>6 possibly the payer. Those are the three 09:52:13</p> <p>7 categories? 09:52:16</p> <p>8 A. Well, I wouldn't want to limit it to that. 09:52:17</p> <p>9 There might be family members who care, there might 09:52:19</p> <p>10 be employers who care. There are -- the demand for 09:52:22</p> <p>11 medical products is complicated. 09:52:26</p> <p>12 Q. All right. So just to go through the 09:52:27</p> <p>13 list, it's patients, physicians, payers, family 09:52:29</p> <p>14 members, employers? 09:52:38</p> <p>15 MR. WILK: Objection to form. 09:52:39</p> <p>16 MR. ERWINE: I understand it's not 09:52:40</p> <p>17 exhaustive, but this is at least some of the 09:52:41</p> <p>18 potential folks that are relevant to demand? 09:52:45</p> <p>19 A. Those are all people who might have an 09:52:50</p> <p>20 interest in this product category in the treatment 09:52:52</p> <p>21 of the patient and which treatment is chosen. You 09:52:57</p> <p>22 know, you could expand that to caregivers. There 09:53:02</p> <p>23 are -- particularly because the elements of this 09:53:07</p> <p>24 product, meaning, you know, the frequency with 09:53:09</p> <p>25 which a patient has to go to the doctor, go to the 09:53:14</p> <p style="text-align: right;">Page 41</p> |

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| <p>1 treating physician has an impact on multiple 09:53:17</p> <p>2 people, multiple types of people. All of those 09:53:20</p> <p>3 people may have an interest in which choice -- 09:53:24</p> <p>4 which product is chosen. 09:53:26</p> <p>5 And so, you know, that -- again, if I 09:53:28</p> <p>6 thought about it longer I might come up with more 09:53:33</p> <p>7 people, but that's -- those are all elements of the 09:53:35</p> <p>8 demand for the products in this space. 09:53:38</p> <p>9 Q. Okay. And for purposes of your two 09:53:41</p> <p>10 declarations I know that you relied on evidence 09:53:45</p> <p>11 from doctors, correct? 09:53:48</p> <p>12 A. Yes. 09:53:50</p> <p>13 Q. For instance, you relied on the opinion of 09:53:50</p> <p>14 Dr. Stewart, correct? 09:53:53</p> <p>15 A. Yes. 09:53:54</p> <p>16 Q. And you relied on some surveys that are 09:53:54</p> <p>17 based on scanning physicians, correct? 09:53:57</p> <p>18 A. Yes. 09:54:03</p> <p>19 Q. Did you rely on any direct evidence from 09:54:03</p> <p>20 any patients? 09:54:05</p> <p>21 A. There isn't evidence from patients that 09:54:08</p> <p>22 I'm aware of other than the fact that they were 09:54:10</p> <p>23 treated with specific products. So the Medicare 09:54:12</p> <p>24 data, for example, shows the number of unique 09:54:16</p> <p>25 patients who are treated, but, again, as I said, 09:54:19</p> <p style="text-align: right;">Page 42</p>                                             | <p>1 A. Well, I have been thinking about this as 09:55:36</p> <p>2 we've talked for a long time and for the purposes 09:55:37</p> <p>3 of these declarations I did not do that, but I do 09:55:41</p> <p>4 understand the nature of payment and the nature of 09:55:44</p> <p>5 coverage for products. And so I've seen evidence 09:55:50</p> <p>6 that payers are willing to reimburse the products 09:55:56</p> <p>7 in this space. So that's evidence of the payer 09:56:01</p> <p>8 demand. 09:56:08</p> <p>9 Q. But you don't rely on any direct evidence 09:56:08</p> <p>10 of payers for purposes of your declaration? 09:56:12</p> <p>11 MR. WILK: Objection to form. 09:56:15</p> <p>12 A. That's correct. 09:56:15</p> <p>13 Q. And I know you didn't speak to or rely on 09:56:16</p> <p>14 evidence from patients. Did you speak to or rely 09:56:18</p> <p>15 on any evidence from family members of patients? 09:56:21</p> <p>16 A. I did not. 09:56:26</p> <p>17 Q. Okay. How about employers of patients? 09:56:27</p> <p>18 A. I didn't. 09:56:28</p> <p>19 Q. And caregivers of patients? 09:56:29</p> <p>20 A. Not directly, no. 09:56:30</p> <p>21 Q. And did you indirectly? 09:56:31</p> <p>22 A. Well, I mean, I've read over time about 09:56:36</p> <p>23 how employers care about the treatment the patients 09:56:46</p> <p>24 get and the interest that employers have in 09:56:49</p> <p>25 productivity or other elements of care. So I'm not 09:56:58</p> <p style="text-align: right;">Page 44</p>                    |
| <p>1 while the patients themselves have influence on the 09:54:23</p> <p>2 product choice, probably none of those -- well, in 09:54:28</p> <p>3 the demand for the products none of those people or 09:54:33</p> <p>4 types of people that we discussed have absolute 09:54:37</p> <p>5 control over which product is chosen. 09:54:39</p> <p>6 Q. But you're not aware of any patient 09:54:43</p> <p>7 surveys or direct evidence from patients about the 09:54:45</p> <p>8 demand of the patented feature? 09:54:48</p> <p>9 MR. WILK: Objection to form. 09:54:52</p> <p>10 A. As I sit here I'm not recalling any 09:54:54</p> <p>11 patient surveys, but I would be very surprised if 09:54:57</p> <p>12 patients didn't want to be -- want to have 09:55:05</p> <p>13 something injected into their eye less often than 09:55:09</p> <p>14 more often. 09:55:12</p> <p>15 Q. And did you speak to any patients about 09:55:13</p> <p>16 the patented features? 09:55:14</p> <p>17 A. Not for purposes of these declarations, 09:55:16</p> <p>18 no. 09:55:18</p> <p>19 Q. And I think you mentioned the payers. Did 09:55:19</p> <p>20 you speak to any of the payers for purposes of the 09:55:22</p> <p>21 declaration? 09:55:24</p> <p>22 A. Not for these declarations, no. 09:55:26</p> <p>23 Q. Okay. And did you gather any evidence 09:55:28</p> <p>24 from the payers about the patented features for 09:55:29</p> <p>25 purposes of this declaration? 09:55:34</p> <p style="text-align: right;">Page 43</p> | <p>1 talking specifically about this condition, but 09:57:03</p> <p>2 generally my work in the industry, in the 09:57:07</p> <p>3 pharmaceutical industry, and as an academic and as 09:57:11</p> <p>4 a consultant I've heard lots of discussions about 09:57:13</p> <p>5 how employers interact with the healthcare system 09:57:16</p> <p>6 and with their employees' treatment. So that gives 09:57:20</p> <p>7 me a general understanding of why or how employers 09:57:26</p> <p>8 might care. I did not rely on that for the 09:57:30</p> <p>9 specific declaration. 09:57:33</p> <p>10 Q. In your declarations, Dr. Manning, you 09:57:33</p> <p>11 focused pretty heavily on dosing in your 09:57:35</p> <p>12 declarations; is that fair? 09:57:39</p> <p>13 MR. WILK: Objection to form. 09:57:41</p> <p>14 MR. ERWINE: Eylea dosing. 09:57:41</p> <p>15 MR. WILK: Objection to form. 09:57:43</p> <p>16 A. There is a discussion -- there is a lot of 09:57:44</p> <p>17 discussion about the dosing as an element of the 09:57:46</p> <p>18 overall patented framework, yes. 09:57:51</p> <p>19 Q. Okay. And you -- your opinion is that the 09:57:59</p> <p>20 dosing regimen is one of the key drivers of the 09:58:01</p> <p>21 patented demand or patented feature? 09:58:07</p> <p>22 MR. WILK: Objection to form. 09:58:10</p> <p>23 A. Sorry. Did you say patented demand or 09:58:11</p> <p>24 patented features? 09:58:12</p> <p>25 Q. Sorry. I'll be more precise. Your 09:58:13</p> <p style="text-align: right;">Page 45</p> |

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| <p>1 opinion is that dosing is a key driver of demand? 09:58:15</p> <p>2 MR. WILK: Same objection. 09:58:21</p> <p>3 A. Yes. 09:58:22</p> <p>4 Q. And also that dosing is a key contributor 09:58:22</p> <p>5 to commercial success? 09:58:28</p> <p>6 MR. WILK: Same objection. 09:58:31</p> <p>7 A. That's correct. 09:58:32</p> <p>8 Q. Now, you agree that various other factors 09:58:33</p> <p>9 and attributes aside from dosing can contribute to 09:58:37</p> <p>10 a product's economic success? 09:58:40</p> <p>11 MR. WILK: Objection to form. 09:58:44</p> <p>12 A. It can. 09:58:44</p> <p>13 Q. Okay. And some of those things might be 09:58:45</p> <p>14 other product attributes? 09:58:48</p> <p>15 A. Sure. 09:58:52</p> <p>16 Q. The competitive market facing the product? 09:58:53</p> <p>17 A. Sure. 09:58:56</p> <p>18 Q. Marketing efforts? 09:58:58</p> <p>19 A. That matters, yes. 09:59:00</p> <p>20 Q. Pricing? 09:59:01</p> <p>21 A. Yes. 09:59:02</p> <p>22 Q. Discount and rebate practices? 09:59:04</p> <p>23 A. Yes. 09:59:07</p> <p>24 Q. But in your opinion none of those factors 09:59:07</p> <p>25 support Eylea's commercial success, correct? 09:59:11</p> <p style="text-align: right;">Page 46</p>                                                                                                                                                                                                                                                                                                                                                                                                                | <p>1 that established a baseline of sorts. 10:00:42</p> <p>2 The innovation that I see in Eylea is the 10:00:46</p> <p>3 introduction of a maintenance level of dosing that 10:00:50</p> <p>4 occurs on a bimonthly basis or that the clinical 10:00:53</p> <p>5 trials demonstrated that here's a product that in 10:00:58</p> <p>6 the maintenance phase can be dosed less frequently 10:01:02</p> <p>7 when dosing is a burdensome process for the patient 10:01:05</p> <p>8 and for many others. 10:01:12</p> <p>9 So that that innovation is the -- is an 10:01:14</p> <p>10 important part of the framework of the patented 10:01:19</p> <p>11 claims for this product, those are the -- that's 10:01:22</p> <p>12 the most observable and most -- well, it is a very 10:01:26</p> <p>13 important element of the patented features. 10:01:32</p> <p>14 Q. Is the claimed dosing regimen of the 10:01:36</p> <p>15 '572 Patent the sole driver of Eylea's commercial 10:01:40</p> <p>16 success? 10:01:45</p> <p>17 A. I haven't evaluated whether others or the 10:01:45</p> <p>18 extent to which others contribute. What I've 10:01:48</p> <p>19 evaluated is whether or not the patented features 10:01:54</p> <p>20 are a driver, and clearly in my opinion they are. 10:01:55</p> <p>21 Q. So you don't know if there are other 10:01:57</p> <p>22 drivers of Eylea's commercial success? 10:01:58</p> <p>23 MR. WILK: Objection to form. 10:02:01</p> <p>24 A. Well, as I said, I have not evaluated 10:02:03</p> <p>25 whether there are other -- or the extent to which 10:02:07</p> <p style="text-align: right;">Page 48</p> |
| <p>1 MR. WILK: Objection to form. 09:59:15</p> <p>2 A. Well, the exercise is not to -- the 09:59:16</p> <p>3 exercise is to establish or to inquire about the 09:59:20</p> <p>4 link between the patented features and the 09:59:22</p> <p>5 product's commercial success. So that is the 09:59:25</p> <p>6 exercise that is undertaken is to evaluate the 09:59:30</p> <p>7 patented features and evaluate the extent to which 09:59:32</p> <p>8 or whether or not there is a link between the 09:59:36</p> <p>9 patented features and the commercial success. I 09:59:39</p> <p>10 don't think about, you know, the color of the 09:59:42</p> <p>11 liquid or whatever. Those other features that 09:59:48</p> <p>12 might be -- have an impact on the product's demand 09:59:50</p> <p>13 are not specifically evaluated. 09:59:58</p> <p>14 Q. So other features can contribute to the 09:59:59</p> <p>15 commercial success, but for your purposes you only 10:00:02</p> <p>16 focused on the eight-week dosing regimen; is that 10:00:06</p> <p>17 fair? 10:00:12</p> <p>18 MR. WILK: Objection to form. 10:00:12</p> <p>19 A. Well, I think it's important to keep in 10:00:13</p> <p>20 context, you know, the patent -- the eight-week 10:00:15</p> <p>21 dosing element is a feature of the patented claims 10:00:18</p> <p>22 in the sense -- in the following sense. So prior 10:00:24</p> <p>23 to the introduction of Eylea, you know, the typical 10:00:28</p> <p>24 treatment for a patient was to be injected on a 10:00:32</p> <p>25 monthly basis with an anti-VEGF therapy and that 10:00:38</p> <p style="text-align: right;">Page 47</p> | <p>1 other characteristics of the product contribute to 10:02:11</p> <p>2 the product's commercial success. My understanding 10:02:14</p> <p>3 is that that's outside the scope of my role. 10:02:16</p> <p>4 Q. So you haven't compared the degree of the 10:02:22</p> <p>5 dosing regimen's commercial success to other 10:02:24</p> <p>6 factors that may contribute to Eylea's commercial 10:02:26</p> <p>7 success? 10:02:29</p> <p>8 MR. WILK: Objection to form. 10:02:30</p> <p>9 A. Well, for example, what other factors do 10:02:33</p> <p>10 you mean? 10:02:35</p> <p>11 Q. Other product attributes. 10:02:36</p> <p>12 A. For example, what product attribute do you 10:02:45</p> <p>13 have in mind? 10:02:48</p> <p>14 Q. I don't have one in particular. I'm 10:02:49</p> <p>15 asking if you use that as part of your comparison. 10:02:50</p> <p>16 A. Well, I focused on the patented features 10:02:54</p> <p>17 and, as I just described, the innovation in those 10:02:55</p> <p>18 patented features -- a key innovation in those 10:02:57</p> <p>19 patented features is the introduction of an 10:03:00</p> <p>20 extended dosing interval, eight-week dosing 10:03:02</p> <p>21 interval in the maintenance phase that is an 10:03:05</p> <p>22 important driver of commercial success would be an 10:03:08</p> <p>23 important driver of demand. 10:03:14</p> <p>24 So I have not looked at other elements of 10:03:17</p> <p>25 the product and compared how those elements relate 10:03:19</p> <p style="text-align: right;">Page 49</p>                                                                       |

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| <p>1 to alternatives and whether those alternatives -- 10:03:23</p> <p>2 the impact they had on commercial success. I 10:03:26</p> <p>3 focused it on -- I focused on the patented 10:03:28</p> <p>4 features. 10:03:30</p> <p>5 Q. Okay. Other than the patented features, 10:03:31</p> <p>6 are you aware of any other features or factors that 10:03:33</p> <p>7 contribute to the commercial success of the Eylea 10:03:37</p> <p>8 product? 10:03:43</p> <p>9 A. I guess that's a broad question. I've 10:03:50</p> <p>10 considered a variety of alternative explanations, 10:03:52</p> <p>11 and I have a footnote here that talks about some of 10:04:00</p> <p>12 those alternative explanations. I think it's 33 or 10:04:03</p> <p>13 35, somewhere. You know, there are -- as I 10:04:06</p> <p>14 mentioned, there are other potential explanations. 10:04:09</p> <p>15 So did marketing drive success? I've 10:04:13</p> <p>16 considered that and nothing that I've seen makes me 10:04:17</p> <p>17 believe that that's true. Is pricing or other -- 10:04:19</p> <p>18 or the absence of a price difference or the 10:04:21</p> <p>19 presence of a price difference, does that drive the 10:04:25</p> <p>20 success? I don't believe that that's driving 10:04:28</p> <p>21 success to the exclusion of the patented features, 10:04:30</p> <p>22 and that's an important point is do those other 10:04:33</p> <p>23 things that might contribute to success exclude the 10:04:36</p> <p>24 conclusion or preclude the conclusion that it is 10:04:40</p> <p>25 the patented features, and my opinion is that none 10:04:42</p> <p style="text-align: right;">Page 50</p> | <p>1 it's important to understand whether or not they 10:05:53</p> <p>2 preclude the conclusion that the patented features 10:05:55</p> <p>3 are driving -- are a driver of success, and I do 10:05:57</p> <p>4 not believe they are. 10:06:07</p> <p>5 Q. Okay. Setting aside whether or 10:06:10</p> <p>6 not they -- we'll take a break in a few minutes. I 10:06:12</p> <p>7 just want to finish this line of questioning. 10:06:15</p> <p>8 Setting aside whether or not they preclude 10:06:18</p> <p>9 the commercial success of the patented features, I 10:06:20</p> <p>10 still want to get back to are you aware of any 10:06:24</p> <p>11 other factors besides the claimed dosing regimen 10:06:28</p> <p>12 that contribute to the commercial success of the 10:06:31</p> <p>13 Eylea product? It's a yes-or-no question. 10:06:35</p> <p>14 A. Well, I don't actually think it is a 10:06:40</p> <p>15 yes-or-no question because there are -- certainly 10:06:42</p> <p>16 there are other things that contribute to 10:06:44</p> <p>17 commercial success, but that's not the question I 10:06:46</p> <p>18 was asked to evaluate and it's not the question 10:06:52</p> <p>19 that's relevant for my assignment. 10:06:54</p> <p>20 Q. So for your assignment and your opinions 10:06:56</p> <p>21 in your view it's not relevant to consider other 10:07:00</p> <p>22 factors aside from the claimed dosing regimen that 10:07:03</p> <p>23 may contribute to Eylea's commercial success? 10:07:06</p> <p>24 MR. WILK: Objection to form. 10:07:09</p> <p>25 A. I wouldn't say that, no. 10:07:09</p> <p style="text-align: right;">Page 52</p> |
| <p>1 of those other things do. 10:04:45</p> <p>2 Q. Okay. So let me go back to my original 10:04:47</p> <p>3 question. Is it your understanding that the 10:04:49</p> <p>4 claimed dosing regimen of the '572 Patent is the 10:04:51</p> <p>5 sole driver of commercial success for the Eylea 10:04:54</p> <p>6 product? 10:04:58</p> <p>7 MR. WILK: Objection to form. 10:04:59</p> <p>8 A. So I have not -- it's not my assignment to 10:04:59</p> <p>9 evaluate every potential driver and to eliminate 10:05:02</p> <p>10 all others. My assignment is to evaluate the 10:05:06</p> <p>11 commercial success of Eylea and to decide whether 10:05:10</p> <p>12 or not -- to opine about whether or not there's a 10:05:16</p> <p>13 nexus between the patented features and that 10:05:19</p> <p>14 commercial success. 10:05:21</p> <p>15 So, you know, whether -- as I said, 10:05:22</p> <p>16 whether the -- what color the liquid is was not 10:05:25</p> <p>17 something -- that's obviously a fanciful example, 10:05:30</p> <p>18 but those other things that are not related to the 10:05:32</p> <p>19 patented features are not things that I evaluated 10:05:35</p> <p>20 and have an opinion about. 10:05:38</p> <p>21 Q. Is it your opinion that those other 10:05:41</p> <p>22 factors are relevant to the evaluation of 10:05:42</p> <p>23 commercial success? 10:05:46</p> <p>24 MR. WILK: Objection to form. 10:05:48</p> <p>25 A. Well, they're relevant in the sense that 10:05:49</p> <p style="text-align: right;">Page 51</p>                                                                                                                                     | <p>1 Q. Okay. Why not? 10:07:11</p> <p>2 A. Because as I said before, there are -- you 10:07:12</p> <p>3 do want to know whether other things preclude the 10:07:16</p> <p>4 conclusion that -- whether other things are doing 10:07:19</p> <p>5 what you might think the patented features are 10:07:23</p> <p>6 doing. So you do think about what's the pricing 10:07:25</p> <p>7 environment, what's the marketing environment, you 10:07:28</p> <p>8 think about those other things, and I did consider 10:07:30</p> <p>9 those other things and I conclude that none of 10:07:33</p> <p>10 those things preclude the conclusion that Eylea's 10:07:35</p> <p>11 patented features are a driver of its commercial 10:07:40</p> <p>12 success. 10:07:41</p> <p>13 Q. Okay. And assuming that those other 10:07:42</p> <p>14 factors do not preclude the patented features but 10:07:44</p> <p>15 they still contribute to the commercial success, do 10:07:47</p> <p>16 you consider those factors to be relevant to your 10:07:50</p> <p>17 evaluation? 10:07:51</p> <p>18 MR. WILK: Objection to form. 10:07:52</p> <p>19 A. Well, they are relevant in the sense that 10:07:55</p> <p>20 they -- the question is not whether they 10:07:59</p> <p>21 contribute. The question is whether they stand in 10:08:01</p> <p>22 the place of or whether they prohibit the 10:08:04</p> <p>23 reasonable conclusion that it is the patented 10:08:06</p> <p>24 features that are a driver of commercial success. 10:08:08</p> <p>25 Q. And assuming they don't prohibit the 10:08:10</p> <p style="text-align: right;">Page 53</p>                                  |

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| <p>1 patented features -- that's my question. Setting 10:08:12</p> <p>2 aside whether or not they prohibit or preclude the 10:08:16</p> <p>3 patented features, are they relevant to your 10:08:19</p> <p>4 evaluation if they contribute to the commercial 10:08:21</p> <p>5 success of the Eylea product but don't preclude the 10:08:23</p> <p>6 patented features? 10:08:27</p> <p>7 MR. WILK: Objection to form. 10:08:28</p> <p>8 A. Well, my understanding is that the 10:08:29</p> <p>9 question is whether or not the patented features 10:08:31</p> <p>10 contribute to the demand for the product or 10:08:37</p> <p>11 contribute to its commercial success. So as I've 10:08:41</p> <p>12 said, I do consider those things and I do think 10:08:44</p> <p>13 they're important, but they're important in a 10:08:47</p> <p>14 different way. I mean, they're important in the 10:08:49</p> <p>15 way of understanding whether or not they make it 10:08:51</p> <p>16 impossible or unlikely to conclude that the 10:08:56</p> <p>17 patented features are a driver of commercial 10:08:58</p> <p>18 success. 10:09:04</p> <p>19 So yes, you do think about pricing, you do 10:09:04</p> <p>20 think about marketing, you do think about a variety 10:09:06</p> <p>21 of things that affect the demand for the product, 10:09:08</p> <p>22 but the job or the task is not to rank the various 10:09:11</p> <p>23 contributors and to say, well, this one is more 10:09:20</p> <p>24 important than that one, that one is more important 10:09:23</p> <p>25 than the other one. It is to identify whether any 10:09:25</p> <p style="text-align: right;">Page 54</p> | <p>1 the '572 Patent? 10:10:42</p> <p>2 MR. WILK: Objection to form. 10:10:43</p> <p>3 A. I'm sorry, but I think the answer is the 10:10:45</p> <p>4 same that I've already given and I don't understand 10:10:48</p> <p>5 how I can say it differently. There are other 10:10:51</p> <p>6 things that matter, you know, a demand for a 10:10:53</p> <p>7 product has a variety of things that you'd think 10:10:56</p> <p>8 about. The question here is do any of those other 10:10:59</p> <p>9 things take the place of the patented features, and 10:11:01</p> <p>10 my conclusion is that they do not. So they are 10:11:03</p> <p>11 important to consider, they were -- I did consider 10:11:06</p> <p>12 them, and there's nothing that I've seen that 10:11:09</p> <p>13 suggests that any of those alternative factors 10:11:12</p> <p>14 preclude the conclusion that the patented features 10:11:18</p> <p>15 are a driver of commercial success. 10:11:21</p> <p>16 MR. ERWINE: Why don't we take a break. 10:11:24</p> <p>17 THE WITNESS: Okay. 10:11:27</p> <p>18 THE VIDEOGRAPHER: The time is 10:12 a.m. 10:11:28</p> <p>19 This ends unit 1. We're off the record. 10:11:31</p> <p>20 (A break was had.) 10:24:05</p> <p>21 THE VIDEOGRAPHER: The time is 10:29 a.m. 10:28:59</p> <p>22 This begins unit No. 2. We're on the record. 10:29:01</p> <p>23 MR. WILK: Counsel, before we begin, the 10:29:06</p> <p>24 videographer said that this proceeding covered 10:29:07</p> <p>25 the -- this deposition covered the 884 proceeding, 10:29:10</p> <p style="text-align: right;">Page 56</p> |
| <p>1 of those other things stand in the way of the 10:09:28</p> <p>2 conclusion that the patented features are driving 10:09:31</p> <p>3 commercial success. 10:09:33</p> <p>4 Q. But is it your opinion that there are 10:09:34</p> <p>5 other factors that indeed contribute to the 10:09:36</p> <p>6 commercial success of the Eylea product other than 10:09:39</p> <p>7 the patented dosing regimen? 10:09:41</p> <p>8 A. Within the context of the question of 10:09:49</p> <p>9 whether these patented features are -- whether 10:09:51</p> <p>10 there's a link between the patented features and 10:09:56</p> <p>11 the commercial success, they are as I've described 10:09:57</p> <p>12 it. They are important and, you know, if a 10:10:00</p> <p>13 specific factor of the marketplace changes the 10:10:04</p> <p>14 utilization of this product, as long as that 10:10:10</p> <p>15 doesn't stand in the way of the patented features 10:10:14</p> <p>16 also contributing to the commercial success, it 10:10:18</p> <p>17 doesn't need to be parsed out. It doesn't need to 10:10:21</p> <p>18 be separated. 10:10:24</p> <p>19 Q. That's a great answer, but it doesn't 10:10:26</p> <p>20 answer my question. So I'm going to ask it again. 10:10:28</p> <p>21 A. Okay. 10:10:31</p> <p>22 Q. It's a very simple question. Is it your 10:10:31</p> <p>23 opinion that there are other factors that indeed 10:10:34</p> <p>24 contribute to the commercial success of the Eylea 10:10:36</p> <p>25 product other than the patented dosing regimen of 10:10:39</p> <p style="text-align: right;">Page 55</p>                                                   | <p>1 but I just want to confirm that it also will cover 10:29:13</p> <p>2 the 739 proceeding? 10:29:16</p> <p>3 MR. ERWINE: Correct. 10:29:17</p> <p>4 BY MR. ERWINE: 10:29:19</p> <p>5 Q. Dr. Manning, welcome back. 10:29:19</p> <p>6 A. Thank you. 10:29:20</p> <p>7 Q. We were talking about some of the drivers 10:29:21</p> <p>8 of Eylea's commercial success, and I wanted to ask 10:29:22</p> <p>9 you about, aside from the dosing regimen that I 10:29:27</p> <p>10 think is the subject matter of your declaration, 10:29:33</p> <p>11 some other possible drivers of commercial success 10:29:36</p> <p>12 of the Eylea product. Can efficacy be one of the 10:29:38</p> <p>13 drivers of commercial success? 10:29:43</p> <p>14 MR. WILK: Objection to form. 10:29:45</p> <p>15 A. Sure. 10:29:47</p> <p>16 Q. And is that something that you considered 10:29:48</p> <p>17 for purposes of your declaration? 10:29:51</p> <p>18 A. Well, the -- the fact that, as I describe, 10:29:54</p> <p>19 the product performs at a level of effectiveness -- 10:29:59</p> <p>20 efficacy might have some technical or medical 10:30:06</p> <p>21 meanings that I wouldn't be the right person to ask 10:30:10</p> <p>22 about, but the fact that it performs and the 10:30:12</p> <p>23 clinical trials demonstrated that it was not 10:30:17</p> <p>24 inferior to Lucentis, which was the preceding 10:30:19</p> <p>25 labeled product or approved product, clearly that 10:30:23</p> <p style="text-align: right;">Page 57</p>                                                                        |

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| <p>1 was an important factor into driving success. So 10:30:27</p> <p>2 yeah, I did consider that. 10:30:30</p> <p>3 Q. Okay. And that's something that can be -- 10:30:32</p> <p>4 let me rephrase. 10:30:35</p> <p>5 So efficacy is a driver of Eylea's 10:30:37</p> <p>6 commercial success? 10:30:39</p> <p>7 MR. WILK: Objection to form. 10:30:40</p> <p>8 A. Certainly. If it were not -- in the sense 10:30:41</p> <p>9 that if it were not effective, I can't imagine that 10:30:46</p> <p>10 it would be as successful as it is. 10:30:48</p> <p>11 Q. And how about as another factor the 10:30:52</p> <p>12 reduction in frequency of injections distinct from 10:30:53</p> <p>13 the claimed dosing regimen, is that a contributor 10:30:57</p> <p>14 to commercial success? 10:30:59</p> <p>15 MR. WILK: Objection to form. 10:31:00</p> <p>16 A. I don't know how you could divorce those 10:31:02</p> <p>17 two. I mean, the number of injections is 10:31:03</p> <p>18 determined by the frequency between which they are 10:31:07</p> <p>19 administered. 10:31:10</p> <p>20 Q. So what if it's every six weeks instead of 10:31:11</p> <p>21 every eight weeks? 10:31:15</p> <p>22 MR. WILK: Objection to form. 10:31:16</p> <p>23 MR. ERWINE: That's less than once a 10:31:17</p> <p>24 month, right? 10:31:18</p> <p>25 MR. WILK: Same objection. 10:31:19</p> <p style="text-align: right;">Page 58</p>             | <p>1 Are these factors that contribute to the commercial 10:32:22</p> <p>2 success of the Eylea product? 10:32:24</p> <p>3 A. I've not specifically evaluated the side 10:32:28</p> <p>4 effects as they compare to the side effects of 10:32:30</p> <p>5 other potential products, but I have thought about 10:32:40</p> <p>6 in the context of the market environment in which 10:32:43</p> <p>7 the products are sold -- and Dr. Stewart talks 10:32:50</p> <p>8 about this -- the fact that more frequent injection 10:32:55</p> <p>9 raises the likelihood of having adverse effects or 10:32:59</p> <p>10 adverse side effects you might say. 10:33:03</p> <p>11 So yes, that matters and it -- you know, 10:33:07</p> <p>12 that's tied to the frequency of injection in the 10:33:10</p> <p>13 sense that the lower the frequency of injection or 10:33:13</p> <p>14 the longer time between the injections the lower is 10:33:15</p> <p>15 the likelihood of having those adverse side 10:33:18</p> <p>16 effects. So I did consider that and I think that's 10:33:23</p> <p>17 an important contributor to demand. 10:33:25</p> <p>18 Q. You also understand that there are 10:33:28</p> <p>19 instances where Eylea is injected every nine weeks, 10:33:30</p> <p>20 correct? 10:33:38</p> <p>21 MR. WILK: Objection to form. 10:33:38</p> <p>22 A. I do. 10:33:40</p> <p>23 Q. And you understand that that falls outside 10:33:40</p> <p>24 the scope of the claimed invention, right? 10:33:42</p> <p>25 MR. WILK: Objection to form. 10:33:46</p> <p style="text-align: right;">Page 60</p> |
| <p>1 A. Well, are you asking as an economic 10:31:20</p> <p>2 question? 10:31:22</p> <p>3 Q. Yeah. 10:31:22</p> <p>4 A. As an economic question, you know, the 10:31:23</p> <p>5 notion that someone might be less often injected 10:31:27</p> <p>6 would certainly be better than being injected more 10:31:32</p> <p>7 often. 10:31:36</p> <p>8 Q. And you understand that there are 10:31:37</p> <p>9 instances where Eylea is used where it's every six 10:31:38</p> <p>10 weeks as opposed to every eight weeks, right? 10:31:40</p> <p>11 A. Yes. 10:31:42</p> <p>12 MR. WILK: Objection to form. 10:31:44</p> <p>13 THE REPORTER: Make sure you let him get 10:31:46</p> <p>14 his objections in, please. 10:31:48</p> <p>15 THE WITNESS: Okay. 10:31:49</p> <p>16 Q. All right. What about safety, is that a 10:31:49</p> <p>17 factor that contributes to the commercial success 10:31:50</p> <p>18 of the Eylea product? 10:31:52</p> <p>19 A. The safety of any product -- any medical 10:31:58</p> <p>20 product I would expect would have an impact on its 10:32:01</p> <p>21 desirability or the commercial success, yes. 10:32:05</p> <p>22 Q. Lack of side effects? 10:32:07</p> <p>23 A. Depending upon how important those side 10:32:14</p> <p>24 effects might be, those could play a role, yes. 10:32:16</p> <p>25 Q. Okay. Do they? My question is for Eylea. 10:32:20</p> <p style="text-align: right;">Page 59</p> | <p>1 MR. ERWINE: Of the '572 Patent. 10:33:47</p> <p>2 MR. WILK: Same objection. 10:33:48</p> <p>3 A. I guess I would want to look at the 10:33:49</p> <p>4 patent. My recollection was that it said that the 10:33:51</p> <p>5 claim is approximately every eight weeks. And so 10:33:55</p> <p>6 I -- whether a doctor interprets every nine weeks 10:33:59</p> <p>7 as approximately eight I don't know. 10:34:04</p> <p>8 Q. Okay. But that would be something that 10:34:07</p> <p>9 would contribute to the commercial success, that 10:34:10</p> <p>10 reduction in frequency in the instance where it's 10:34:12</p> <p>11 every nine weeks, correct? 10:34:15</p> <p>12 MR. WILK: Objection to form. 10:34:17</p> <p>13 A. As I've said, less frequent dosing is 10:34:19</p> <p>14 not -- from an economic perspective is a positive 10:34:25</p> <p>15 attribute. 10:34:27</p> <p>16 Q. Does price contribute to the commercial 10:34:28</p> <p>17 success of the Eylea product? 10:34:30</p> <p>18 A. It affects the commercial success of the 10:34:33</p> <p>19 product. When you say "contribute," I guess I 10:34:34</p> <p>20 would want to know what you really mean by -- what 10:34:37</p> <p>21 price, what -- compared to what? 10:34:39</p> <p>22 Q. Do you think the price of the Eylea 10:34:43</p> <p>23 product contributes to its commercial success? 10:34:45</p> <p>24 A. Well, that's a complicated question in the 10:34:53</p> <p>25 sense that commercial -- price in a commercial 10:34:57</p> <p style="text-align: right;">Page 61</p>                                |

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| <p>1 success analysis can or needs to be considered 10:35:01</p> <p>2 within the framework of the other products that are 10:35:06</p> <p>3 available and whether the price that is being paid 10:35:08</p> <p>4 for the product under consideration is higher or 10:35:10</p> <p>5 lower than the price of other competing products, 10:35:14</p> <p>6 but it -- so it can either be an impediment to 10:35:18</p> <p>7 commercial success or it can contribute depending 10:35:22</p> <p>8 upon how the people who end up being affected by 10:35:26</p> <p>9 that price view the product and its price 10:35:29</p> <p>10 characteristics relative to its other 10:35:32</p> <p>11 characteristics. 10:35:34</p> <p>12 Q. And did you do an evaluation of price for 10:35:34</p> <p>13 purposes of the commercial success of the Eylea 10:35:37</p> <p>14 product? 10:35:39</p> <p>15 A. I considered it, and it does not preclude 10:35:40</p> <p>16 the -- as we talked about previously, the 10:35:44</p> <p>17 conclusion that the patented features are a driver 10:35:49</p> <p>18 of commercial success. 10:35:54</p> <p>19 Q. Can the price of Eylea be a factor or 10:35:56</p> <p>20 driver of commercial success along with the claimed 10:36:02</p> <p>21 dosing regimen? 10:36:07</p> <p>22 A. Yes. 10:36:10</p> <p>23 Q. Okay. And in the instance where -- well, 10:36:10</p> <p>24 let me ask it this way. Is it -- is it your 10:36:11</p> <p>25 opinion that the price precludes the patented 10:36:15</p> <p style="text-align: right;">Page 62</p> | <p>1 Q. Does availability contribute to the 10:37:41</p> <p>2 commercial success of the Eylea product? 10:37:44</p> <p>3 MR. WILK: Objection to form. 10:37:46</p> <p>4 MR. ERWINE: Availability. 10:37:48</p> <p>5 A. Well, obviously if the product were not 10:37:49</p> <p>6 available it could not have success. So 10:37:53</p> <p>7 availability is a -- is a requirement for any 10:37:56</p> <p>8 product's success. 10:38:01</p> <p>9 Q. How about a doctor's recommendation, does 10:38:02</p> <p>10 that contribute to the commercial success of the 10:38:03</p> <p>11 Eylea product? 10:38:06</p> <p>12 A. A doctor who recommends a product, 10:38:10</p> <p>13 depending upon the relationship between the patient 10:38:13</p> <p>14 and the doctor, I would expect would have a -- 10:38:16</p> <p>15 would contribute to a product's commercial success. 10:38:18</p> <p>16 Q. And is it your opinion that doctor 10:38:22</p> <p>17 recommendations contribute to the commercial 10:38:27</p> <p>18 success of the Eylea product? 10:38:29</p> <p>19 A. Now, that's not a specific element that I 10:38:30</p> <p>20 have done a careful evaluation of other than the 10:38:33</p> <p>21 general observation that physicians have a 10:38:38</p> <p>22 favorable view of the product. They believe it 10:38:41</p> <p>23 offers the opportunity to dose less frequently and 10:38:45</p> <p>24 therefore lowers the burden on the patient and 10:38:49</p> <p>25 lowers the burden on them. 10:38:51</p> <p style="text-align: right;">Page 64</p>               |
| <p>1 features from contributing to the commercial 10:36:19</p> <p>2 success of the Eylea product? 10:36:22</p> <p>3 A. No. 10:36:24</p> <p>4 MR. WILK: Objection to form. 10:36:25</p> <p>5 THE WITNESS: Sorry. No. 10:36:26</p> <p>6 Q. What about discounts and rebates, is that 10:36:27</p> <p>7 something that you believe contributes to the 10:36:28</p> <p>8 commercial success of the Eylea product? 10:36:31</p> <p>9 A. It can. It does not preclude the 10:36:36</p> <p>10 contribution of the patented features. 10:36:38</p> <p>11 Q. But is it your understanding that it does 10:36:40</p> <p>12 contribute? 10:36:42</p> <p>13 A. Based on basic economic analysis and just 10:36:46</p> <p>14 understanding how the pharmaceutical industry 10:36:49</p> <p>15 works, it is common for manufacturers to negotiate 10:36:51</p> <p>16 rebates with payers and depending upon the terms of 10:36:56</p> <p>17 those negotiations a product can benefit from 10:37:03</p> <p>18 having negotiated rebates with payers. 10:37:05</p> <p>19 Q. Does Eylea? 10:37:07</p> <p>20 A. I haven't specifically evaluated the 10:37:10</p> <p>21 extent to which -- you know, which payers pay which 10:37:13</p> <p>22 rebates, but I would expect that the rebates do 10:37:16</p> <p>23 contribute to the product's commercial success, 10:37:23</p> <p>24 although my recollection is that rebates are not 10:37:25</p> <p>25 large in the milieu of rebates generally. 10:37:31</p> <p style="text-align: right;">Page 63</p>                                   | <p>1 So although I have not specifically 10:38:55</p> <p>2 evaluated the nature of the doctor-patient 10:39:01</p> <p>3 relationship, I believe a doctor's recommendation 10:39:06</p> <p>4 for many patients would be Eylea because the 10:39:10</p> <p>5 doctors in many surveys that I've looked at prefer 10:39:15</p> <p>6 it. 10:39:18</p> <p>7 Q. What about Eylea's brand reputation, do 10:39:19</p> <p>8 you believe that contributes to its commercial 10:39:22</p> <p>9 success? 10:39:28</p> <p>10 A. What do you mean by brand reputation? 10:39:28</p> <p>11 Q. Do you understand what the word -- the 10:39:30</p> <p>12 phrase "brand reputation" -- what is your 10:39:32</p> <p>13 understanding of brand reputation? 10:39:35</p> <p>14 A. Well, a brand is an economic -- as an 10:39:37</p> <p>15 economic concept is a package of information 10:39:42</p> <p>16 essentially that conveys something to people who 10:39:45</p> <p>17 use or will influence the use of a product. And so 10:39:47</p> <p>18 what I'm hanging up on is whether reputation and 10:39:53</p> <p>19 brand are really important to people in this 10:40:00</p> <p>20 environment. My guess is that many patients don't 10:40:05</p> <p>21 know the name of the product and so don't -- 10:40:09</p> <p>22 doesn't really matter to them. What matters to 10:40:13</p> <p>23 them is what their doctor tells them is the 10:40:15</p> <p>24 appropriate treatment. 10:40:19</p> <p>25 Now, a brand to a doctor probably means 10:40:20</p> <p style="text-align: right;">Page 65</p> |

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| <p>1 something, that's a way of remembering what a 10:40:25</p> <p>2 product is, but -- and brand reputation is -- as I 10:40:28</p> <p>3 suppose you mean, would develop over time as 10:40:35</p> <p>4 patients or doctors have experience with something 10:40:39</p> <p>5 and therefore come to rely on something based on 10:40:41</p> <p>6 their experience or come to decide something based 10:40:45</p> <p>7 on their experience. So it would be hard to 10:40:48</p> <p>8 distinguish between the cumulative impact of the 10:40:54</p> <p>9 experience a doctor might have with a product and 10:40:59</p> <p>10 just its brand what you might call reputation. 10:41:02</p> <p>11 Q. You understand that Eylea has commercials 10:41:06</p> <p>12 touting its product, television commercials? 10:41:13</p> <p>13 A. I have not seen a television advertisement 10:41:18</p> <p>14 for Eylea. So I don't know that. 10:41:21</p> <p>15 Q. Okay. So you're not aware? 10:41:25</p> <p>16 A. Well, I'm aware that there have been 10:41:26</p> <p>17 historically -- and I don't know for sure whether 10:41:30</p> <p>18 they were broadcast on television or through other 10:41:32</p> <p>19 Internet or other means. There have historically 10:41:36</p> <p>20 been advertisements. And actually, I need to 10:41:40</p> <p>21 reframe what I said before because I have seen 10:41:44</p> <p>22 those in a court proceeding, but that's the 10:41:47</p> <p>23 framework in which I've seen them. 10:41:48</p> <p>24 Q. But you're not aware of, for example, 10:41:50</p> <p>25 television commercials that have appeared, say, in 10:41:53</p> <p style="text-align: right;">Page 66</p> | <p>1 Q. Okay. And did you do anything as part of 10:43:14</p> <p>2 your evaluation to confirm that any patients of 10:43:18</p> <p>3 Eylea met this requirement? 10:43:21</p> <p>4 MR. WILK: Objection to form. 10:43:25</p> <p>5 A. Not specifically. I took that as that's a 10:43:25</p> <p>6 medical opinion that I did not offer. 10:43:29</p> <p>7 Q. Okay. So you're not aware of whether or 10:43:31</p> <p>8 not patients practice this aspect of the claimed 10:43:34</p> <p>9 invention? 10:43:38</p> <p>10 MR. WILK: Objection to form. 10:43:39</p> <p>11 A. Well, patients -- I'm not aware that 10:43:40</p> <p>12 patients practice the patent, but I would defer 10:43:43</p> <p>13 that question to one of the medical experts. 10:43:49</p> <p>14 Q. Let me ask you this question. Do you 10:43:53</p> <p>15 understand that in order to practice the claims the 10:43:55</p> <p>16 patients must follow predetermined fixed dosing 10:43:58</p> <p>17 schedules? 10:44:03</p> <p>18 MR. WILK: Objection to form. 10:44:05</p> <p>19 A. Again, I don't know that patients 10:44:06</p> <p>20 unilaterally determine dosing. So I would -- I'm 10:44:09</p> <p>21 not sure that I would say that patients follow 10:44:13</p> <p>22 the -- or practice the patent. I understand that 10:44:16</p> <p>23 there is an element of a fixed dosing regimen in 10:44:20</p> <p>24 the patent. 10:44:26</p> <p>25 Q. Okay. And you understand that it's not 10:44:27</p> <p style="text-align: right;">Page 68</p> |
| <p>1 the last year? 10:41:56</p> <p>2 A. For Eylea? 10:41:57</p> <p>3 Q. Yeah. 10:41:57</p> <p>4 A. I've seen television commercials for Eylea 10:41:58</p> <p>5 HD, which is a higher dose version of Eylea, but I 10:42:01</p> <p>6 don't believe I've seen a commercial for Eylea, the 10:42:05</p> <p>7 product that is at issue here. 10:42:10</p> <p>8 Q. Let me take you back to the '572 10:42:12</p> <p>9 declaration and I'm going to direct your attention 10:42:17</p> <p>10 to paragraph 14. Let me know when you're there. 10:42:20</p> <p>11 A. I'm there. 10:42:36</p> <p>12 Q. Okay. And I think in paragraph 14 you 10:42:37</p> <p>13 reference claims 1 through 30 of the '572 Patent; 10:42:40</p> <p>14 is that correct? 10:42:43</p> <p>15 A. Yes. 10:42:44</p> <p>16 Q. Now, is it your understanding, 10:42:44</p> <p>17 Dr. Manning, that in order to practice the '572 10:42:46</p> <p>18 claims the patients must achieve a gain in visual 10:42:52</p> <p>19 acuity within 52 weeks following an initial dose 10:42:55</p> <p>20 with aflibercept? 10:42:59</p> <p>21 MR. WILK: Objection to form. 10:43:04</p> <p>22 A. I would want to look at the claims to 10:43:05</p> <p>23 confirm that that's true, but I do believe those 10:43:07</p> <p>24 are -- those are -- those claims are in the -- in 10:43:10</p> <p>25 the patent, yes. 10:43:13</p> <p style="text-align: right;">Page 67</p>                                                                                                                                                                                                                                                                            | <p>1 just fixed, it's predetermined fixed dosing 10:44:29</p> <p>2 schedules, right? 10:44:35</p> <p>3 MR. WILK: Objection to form. 10:44:36</p> <p>4 A. Well, what do you mean by "predetermined"? 10:44:37</p> <p>5 Q. Well, why don't we look at 10:44:41</p> <p>6 Dr. Stewart's -- I think I pronounced that 10:44:42</p> <p>7 strangely again. 10:44:46</p> <p>8 A. You can pronounce it however you like. 10:44:47</p> <p>9 Q. Let's look at Dr. Stewart's declaration 10:44:49</p> <p>10 for the '572 Patent, and let me direct your 10:44:51</p> <p>11 attention to paragraph 65. And actually, let me 10:44:55</p> <p>12 start with paragraph 64, which is page 30. This is 10:45:14</p> <p>13 Exhibit 2065. 10:45:17</p> <p>14 A. Okay. 10:45:20</p> <p>15 Q. All right. Do you see that he says "It is 10:45:20</p> <p>16 my opinion based on the claims and specification of 10:45:22</p> <p>17 the '572 Patent that a POSA would understand the 10:45:26</p> <p>18 challenged claims, specifically claims 15 and 10:45:29</p> <p>19 thereby claim 25, to be limited to predetermined 10:45:32</p> <p>20 fixed dosing schedules"; do you see that? 10:45:37</p> <p>21 A. I do. 10:45:38</p> <p>22 Q. Okay. So do you understand that the 10:45:38</p> <p>23 claims are, in fact, limited to predetermined fixed 10:45:40</p> <p>24 dosing schedules? 10:45:44</p> <p>25 MR. WILK: Objection to form. 10:45:44</p> <p style="text-align: right;">Page 69</p>                                                       |

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| <p>1 A. So I understand that that's his testimony. 10:45:46</p> <p>2 Q. Okay. Is that your understanding? 10:45:48</p> <p>3 A. I accept that as, you know, his 10:45:51</p> <p>4 interpretation of the claim. I don't have a legal 10:45:54</p> <p>5 interpretation of the claim. 10:45:57</p> <p>6 Q. Okay. And did you establish that any -- 10:45:58</p> <p>7 well, let me take a step back. I think -- I asked 10:46:07</p> <p>8 you about patients practicing the claims and you 10:46:09</p> <p>9 said it could be more than patients. I assume you 10:46:11</p> <p>10 mean physicians prescribing; is that your 10:46:14</p> <p>11 understanding? 10:46:16</p> <p>12 MR. WILK: Objection to form. 10:46:16</p> <p>13 A. Generally, yes. 10:46:17</p> <p>14 Q. Okay. Do you have any evidence of sales 10:46:18</p> <p>15 in which the dosing schedule was predetermined? 10:46:25</p> <p>16 A. Well, my understanding of the label -- of 10:46:32</p> <p>17 Eylea's label is that it describes a loading phase 10:46:39</p> <p>18 wherein patients are dosed on a monthly basis and 10:46:44</p> <p>19 then a maintenance phase during which patients are 10:46:48</p> <p>20 dosed on a bimonthly schedule and that to the 10:46:52</p> <p>21 extent that that is how the label is written I 10:47:01</p> <p>22 would understand that to mean predetermined in that 10:47:07</p> <p>23 sense, that there is a -- there is a way to treat a 10:47:12</p> <p>24 patient that has been studied in clinical trial 10:47:18</p> <p>25 settings and that that clinical trial result is 10:47:20</p> <p style="text-align: right;">Page 70</p> | <p>1 predetermined? 10:48:36</p> <p>2 MR. WILK: Objection to form. 10:48:37</p> <p>3 A. Well, what my declaration does is 10:48:38</p> <p>4 evaluates the economics of the dosing framework, 10:48:42</p> <p>5 the dosing regimen that I described previously 10:48:46</p> <p>6 where there is a loading period during which the 10:48:50</p> <p>7 doses are given on a monthly basis and then a 10:48:54</p> <p>8 maintenance phase during which they're given on 10:48:58</p> <p>9 eight-week interval. 10:49:01</p> <p>10 Now, from an economic perspective what 10:49:02</p> <p>11 I've said and what I believe is that the -- you 10:49:04</p> <p>12 know, the option -- optionality of being able to 10:49:11</p> <p>13 dose at an eight-week interval is an important 10:49:15</p> <p>14 factor, an important feature of the -- of the 10:49:19</p> <p>15 product. And so I recognize the fixed dosing -- or 10:49:22</p> <p>16 the predetermined fixed dosing schedule is an 10:49:29</p> <p>17 element of the innovation, is an element of the 10:49:33</p> <p>18 label, but -- and that is an important element of 10:49:35</p> <p>19 the commercial success. 10:49:39</p> <p>20 Q. Okay. And you agree that if doctors and 10:49:41</p> <p>21 physicians are using Eylea but not practicing a 10:49:44</p> <p>22 predetermined fixed dosing schedule that they're 10:49:49</p> <p>23 not practicing the claims of the '572 Patent? 10:49:52</p> <p>24 MR. WILK: Objection to form. 10:49:54</p> <p>25 A. I would leave that to the legal people to 10:49:54</p> <p style="text-align: right;">Page 72</p> |
| <p>1 what led to the label and that label is consistent 10:47:23</p> <p>2 with this interpretation or this description of the 10:47:27</p> <p>3 dosing regime. 10:47:35</p> <p>4 Q. So your understanding of predetermined is 10:47:35</p> <p>5 not based on what the physician or patient does, 10:47:38</p> <p>6 it's based on the label? 10:47:40</p> <p>7 MR. WILK: Objection to form. 10:47:45</p> <p>8 A. No. What I was saying is that my 10:47:45</p> <p>9 understanding of the label is that reflects my -- 10:47:47</p> <p>10 or my interpretation of the notion predetermined is 10:47:54</p> <p>11 exemplified in the label. 10:47:59</p> <p>12 Q. Okay. Let me -- let me turn you to 10:48:02</p> <p>13 paragraph 65 of Dr. Stewart's declaration, and do 10:48:03</p> <p>14 you see the second sentence that says "Fixed 10:48:08</p> <p>15 regimens are those where doses are administered on 10:48:11</p> <p>16 a predetermined schedule regardless of observed 10:48:15</p> <p>17 outcomes at any given visit"? 10:48:19</p> <p>18 A. I do see that. 10:48:22</p> <p>19 Q. Okay. Do you agree with that statement? 10:48:24</p> <p>20 MR. WILK: Objection to form. 10:48:25</p> <p>21 A. I see that as definitional for him and 10:48:26</p> <p>22 that's his -- I don't have a reason to disagree 10:48:29</p> <p>23 with him. 10:48:31</p> <p>24 Q. And is that the understanding that you 10:48:31</p> <p>25 adopted in your declaration, that understanding of 10:48:33</p> <p style="text-align: right;">Page 71</p>                                                                                                     | <p>1 decide what practicing means or doesn't. 10:49:57</p> <p>2 Q. Okay. But Dr. Stewart says it, right? 10:50:00</p> <p>3 A. He does. 10:50:03</p> <p>4 Q. Okay. And you agree with Dr. Stewart? 10:50:03</p> <p>5 A. I don't have a reason to disagree, but -- 10:50:07</p> <p>6 and I rely upon him for those kinds of 10:50:10</p> <p>7 determinations. I don't offer an independent view 10:50:12</p> <p>8 on that. 10:50:15</p> <p>9 Q. Understood. So for purposes of your 10:50:15</p> <p>10 declaration, if doctors and patients are not 10:50:18</p> <p>11 practicing a predetermined fixed dosing schedule, 10:50:20</p> <p>12 then you understand that they're not practicing the 10:50:25</p> <p>13 claims of the '572 Patent, correct? 10:50:29</p> <p>14 MR. WILK: Objection to form. 10:50:30</p> <p>15 A. Again, that's a legal question that I 10:50:31</p> <p>16 don't have an opinion about. What I do have an 10:50:35</p> <p>17 opinion about is that the -- the patented features, 10:50:37</p> <p>18 including the eight-week dosing interval, provides 10:50:44</p> <p>19 an opportunity to treat people in a better way. 10:50:49</p> <p>20 And if a patient can't make it to eight weeks, that 10:50:53</p> <p>21 patient is benefited by the eight-week dosing 10:50:57</p> <p>22 interval because that is an option or an 10:51:04</p> <p>23 opportunity that wasn't previously available. 10:51:07</p> <p>24 So it may be because of an individual 10:51:09</p> <p>25 circumstance that a patient cannot be treated on an 10:51:11</p> <p style="text-align: right;">Page 73</p>       |

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| <p>1 eight-week dosing schedule and achieve desirable 10:51:14</p> <p>2 outcomes, but the opportunity to have that 10:51:18</p> <p>3 available allows the physician and the patient to 10:51:22</p> <p>4 try to extend treatment beyond the regular monthly 10:51:25</p> <p>5 injections and that that is from an economic 10:51:31</p> <p>6 perspective a contributor to demand. 10:51:34</p> <p>7 Q. But in that situation the doctor and 10:51:39</p> <p>8 patient are not practicing the claims of the 10:51:42</p> <p>9 '572 Patent, correct? 10:51:44</p> <p>10 MR. WILK: Objection to form. 10:51:45</p> <p>11 A. That's a legal question. I don't have an 10:51:47</p> <p>12 opinion about that. 10:51:49</p> <p>13 Q. But you agree that if they're not 10:51:50</p> <p>14 practicing a fixed -- a predetermined fixed dosing 10:51:52</p> <p>15 schedule that they're not practicing the claims of 10:51:55</p> <p>16 the '572 Patent as set forth in Dr. Stewart's 10:52:00</p> <p>17 declaration? 10:52:01</p> <p>18 MR. WILK: Objection to form. 10:52:01</p> <p>19 A. As I've said, I don't have an opinion 10:52:04</p> <p>20 about that. What practices or doesn't practice is 10:52:06</p> <p>21 a legal issue. I focused on the economics of the 10:52:10</p> <p>22 question, and the economics of the question are, as 10:52:13</p> <p>23 I said, the eight-week dosing interval, that fixed 10:52:16</p> <p>24 dosing interval that exists allows for physicians 10:52:20</p> <p>25 and patients to try to reach that eight-week dosing 10:52:25</p> <p style="text-align: right;">Page 74</p> | <p>1 here. 10:53:33</p> <p>2 Q. How about other Regeneron products in 10:53:33</p> <p>3 general that are used for something else? 10:53:35</p> <p>4 A. I haven't evaluated any other Regeneron 10:53:37</p> <p>5 products. 10:53:39</p> <p>6 Q. Because they're not relevant because they 10:53:39</p> <p>7 don't practice the claims of the patent, correct? 10:53:41</p> <p>8 MR. WILK: Objection to form. 10:53:43</p> <p>9 A. That's not why I didn't evaluate them, but 10:53:44</p> <p>10 that's -- it's a fact that I have not evaluated any 10:53:46</p> <p>11 other Regeneron products. 10:53:49</p> <p>12 Q. Did you consider any evidence of products 10:53:51</p> <p>13 that do not practice the claims of the '572 Patent? 10:53:54</p> <p>14 MR. WILK: Objection to form. 10:53:58</p> <p>15 A. I'm sorry. I don't understand the 10:54:00</p> <p>16 question. 10:54:01</p> <p>17 Q. Is all the evidence that you relied on 10:54:03</p> <p>18 geared towards products that practice the claims of 10:54:05</p> <p>19 the '572 Patent? 10:54:09</p> <p>20 MR. WILK: Objection to form. 10:54:10</p> <p>21 A. Well, I relied upon the evidence about the 10:54:12</p> <p>22 commercial performance of Eylea, which is the 10:54:17</p> <p>23 product at issue here, and the patented features of 10:54:19</p> <p>24 that product. So that's the framework in which I 10:54:22</p> <p>25 did my analysis. So anything that's outside of 10:54:26</p> <p style="text-align: right;">Page 76</p> |
| <p>1 interval and my understanding is that that is 10:52:31</p> <p>2 typical treatment, that -- as Dr. Stewart said, 10:52:33</p> <p>3 that the product -- that corresponds to typical 10:52:38</p> <p>4 treatment of patients, but I recognize that not 10:52:41</p> <p>5 every patient makes it. 10:52:44</p> <p>6 Q. And those patients that don't make it, 10:52:45</p> <p>7 they're not practicing the claims of the 10:52:47</p> <p>8 '572 Patent, correct? 10:52:50</p> <p>9 MR. WILK: Objection to form. 10:52:50</p> <p>10 A. Again, I don't have an opinion about what 10:52:51</p> <p>11 does or doesn't practice the patent. I have an 10:52:53</p> <p>12 opinion about how the economics of the availability 10:52:56</p> <p>13 of that dosing interval contributes to the economic 10:52:58</p> <p>14 performance of the product. 10:53:06</p> <p>15 Q. Okay. Are there other Regeneron products 10:53:07</p> <p>16 that don't practice the claims of the '572 Patent 10:53:09</p> <p>17 that you considered for purposes of commercial 10:53:11</p> <p>18 success? 10:53:14</p> <p>19 MR. WILK: Objection to form. 10:53:15</p> <p>20 A. Other Regeneron products that treat 10:53:17</p> <p>21 angiogenic eye disorders? 10:53:22</p> <p>22 Q. Yep. 10:53:24</p> <p>23 A. I'm not aware that there are other 10:53:24</p> <p>24 Regeneron products that treat angiogenic eye 10:53:26</p> <p>25 disorders at least during the time period covered 10:53:31</p> <p style="text-align: right;">Page 75</p>                                                                                           | <p>1 that framework I did not consider. 10:54:28</p> <p>2 Q. Okay. And you see that, again, 10:54:30</p> <p>3 Dr. Stewart says that the claims are limited to 10:54:33</p> <p>4 predetermined fixed dosing schedules, right? 10:54:36</p> <p>5 A. He does. 10:54:37</p> <p>6 Q. Okay. And he distinguishes predetermined 10:54:38</p> <p>7 fixed dosing schedules from PRN regimens, correct? 10:54:42</p> <p>8 MR. WILK: Objection to form. 10:54:46</p> <p>9 A. Yes. 10:54:50</p> <p>10 Q. He also distinguishes predetermined fixed 10:54:50</p> <p>11 regimens from treat-and-extend regimens, correct? 10:55:02</p> <p>12 A. Well, he discusses PRN regimens and 10:55:05</p> <p>13 treat-and-extend regimens again, but those are his 10:55:08</p> <p>14 opinions and, as I've said, they're not the 10:55:13</p> <p>15 economic questions that I considered. 10:55:16</p> <p>16 Q. But his opinion is that PRN or 10:55:17</p> <p>17 treat-and-extend does not practice the claims of 10:55:20</p> <p>18 the '572 Patent, correct? 10:55:28</p> <p>19 MR. WILK: Objection to form. 10:55:28</p> <p>20 A. I would want him to answer that question, 10:55:29</p> <p>21 not me. 10:55:30</p> <p>22 Q. Well, he does. It's in his declaration, 10:55:31</p> <p>23 right? 10:55:33</p> <p>24 A. Well, it says -- can you point me to 10:55:34</p> <p>25 exactly where he says that? 10:55:35</p> <p style="text-align: right;">Page 77</p>                                                              |

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| <p>1 Q. Yeah. He says -- so in paragraph 64 he 10:55:37<br/> 2 says that the claims are limited to predetermined 10:55:39<br/> 3 fixed dosing schedules, correct? 10:55:41<br/> 4 A. He does say that. 10:55:43<br/> 5 Q. Okay. And then in paragraph 65 he says -- 10:55:44<br/> 6 sorry -- he says "Fixed regimens are those where 10:56:02<br/> 7 doses are administered on a predetermined schedule 10:56:10<br/> 8 regardless of observed outcomes at any given 10:56:12<br/> 9 visit," correct? 10:56:15<br/> 10 A. But he also says in the -- 10:56:16<br/> 11 Q. I'll get to it. We'll go sentence by 10:56:17<br/> 12 sentence. 10:56:19<br/> 13 A. Okay. 10:56:20<br/> 14 Q. He says "Fixed regimens include monthly 10:56:20<br/> 15 doses as well as regimens involving a set number of 10:56:24<br/> 16 loading doses followed by dosing on a longer fixed 10:56:29<br/> 17 interval as described by the Eylea label," correct? 10:56:31<br/> 18 A. Those are the words that he said, yes. 10:56:34<br/> 19 Q. Okay. He says "Individualized regimens 10:56:36<br/> 20 including predominantly PRN regimens in treating -- 10:56:39<br/> 21 include predominantly PRN regimens and 10:56:42<br/> 22 treat-and-extend, T&amp;E, regimens," right? 10:56:46<br/> 23 A. He does, but you skipped an important 10:56:50<br/> 24 sentence. 10:56:55<br/> 25 Q. Okay. What sentence did I skip? 10:56:56</p> <p style="text-align: right;">Page 78</p>                                                            | <p>1 MR. WILK: Objection to form. 10:58:13<br/> 2 A. He does -- he does describe those three 10:58:13<br/> 3 regimens. I'm not a physician. I don't have an 10:58:16<br/> 4 opinion about the extent to which those three 10:58:20<br/> 5 things are distinct or not. 10:58:27<br/> 6 Q. Well, you're a smart guy. You can see 10:58:28<br/> 7 he's distinguishing fixed from individualized, 10:58:30<br/> 8 correct? 10:58:32<br/> 9 MR. WILK: Objection to form. 10:58:32<br/> 10 A. Well, but I also see that he said that 10:58:34<br/> 11 sometimes adherence to the predetermined schedule 10:58:37<br/> 12 isn't perfect. So I'm not sure whether or not he 10:58:39<br/> 13 would make that kind of categorical distinction 10:58:42<br/> 14 that you are asking me about. 10:58:46<br/> 15 Q. Well, I know he's being deposed on Friday. 10:58:48<br/> 16 So if he says that PRN and treat-and-extend are not 10:58:50<br/> 17 covered by claims requiring predetermined fixed 10:58:56<br/> 18 dosing schedules like the one in the '572 Patent, 10:59:00<br/> 19 then you'd agree that they're not covered by the 10:59:02<br/> 20 '572 Patent? 10:59:05<br/> 21 MR. WILK: Objection to form. 10:59:06<br/> 22 A. I'm not -- I don't think I will have an 10:59:08<br/> 23 opinion about a legal matter at any time. I think 10:59:11<br/> 24 legal matters are for the Court or the PTAB and the 10:59:14<br/> 25 attorneys to determine. 10:59:19</p> <p style="text-align: right;">Page 80</p> |
| <p>1 A. "Sometimes adherence to 10:56:57<br/> 2 the predetermined" -- 10:56:57<br/> 3 THE REPORTER: Okay. Guys, I have to ask 10:56:57<br/> 4 you to slow down, please. 10:56:57<br/> 5 THE WITNESS: Okay. "Sometimes adherence 10:56:57<br/> 6 to the predetermined schedule isn't perfect, but 10:56:59<br/> 7 the regimens are still considered fixed when the 10:57:01<br/> 8 intended dosing interval is based on a schedule 10:57:05<br/> 9 rather than on patient outcomes." 10:57:08<br/> 10 So to me -- and, again, I'm not offering 10:57:11<br/> 11 his opinion, he offers his opinion, but he seems to 10:57:13<br/> 12 suggest, as I understand from the economic 10:57:18<br/> 13 perspective, that the existence of this fixed 10:57:21<br/> 14 eight-week dosing interval may not be -- may not 10:57:24<br/> 15 lead to perfect following of it in all cases, but 10:57:29<br/> 16 that doesn't make it not the -- not a -- sorry -- 10:57:33<br/> 17 the intended dosing interval. 10:57:43<br/> 18 Q. But he distinguishes fixed regimens from 10:57:45<br/> 19 individualized regimens, correct? 10:57:50<br/> 20 A. He does draw -- he does explain a fixed 10:57:52<br/> 21 dosing regimen. He also explains a PRN and 10:57:58<br/> 22 treat-and-extend regimen. 10:58:04<br/> 23 Q. Right. And his view is that PRN and 10:58:05<br/> 24 treat-and-extend fall under individualized regimens 10:58:07<br/> 25 rather than fixed regimens? 10:58:11</p> <p style="text-align: right;">Page 79</p> | <p>1 Q. In your current opinion do you take into 10:59:21<br/> 2 account Eylea's sales that fall under either the 10:59:25<br/> 3 PRN or treat-and-extend regimens? 10:59:29<br/> 4 A. I look at the sales of the product in 10:59:34<br/> 5 certain cases and sales of the product generally 10:59:39<br/> 6 where the data don't allow one to determine the 10:59:42<br/> 7 exact nature of the use. There are some cases in 10:59:45<br/> 8 which the survey data do make those distinctions, 10:59:50<br/> 9 there are many in which they don't. So I do when I 10:59:54<br/> 10 can, I don't when I can't. 11:00:00<br/> 11 Q. And you don't discount commercial sales 11:00:01<br/> 12 that include either PRN or treat-and-extend? 11:00:03<br/> 13 MR. WILK: Objection to form. 11:00:09<br/> 14 A. By "discount" you mean ignore? 11:00:10<br/> 15 Q. Take them out of your commercial success 11:00:12<br/> 16 evaluation. 11:00:14<br/> 17 MR. WILK: Same objection. 11:00:16<br/> 18 A. I do not. 11:00:17<br/> 19 Q. Okay. So for purposes of commercial 11:00:18<br/> 20 success, if a sale of an Eylea product includes 11:00:20<br/> 21 dosing that involves PRN or treat-and-extend, you 11:00:25<br/> 22 consider that commercial success for purposes of 11:00:29<br/> 23 the '572 Patent? 11:00:32<br/> 24 MR. WILK: Objection to form. 11:00:33<br/> 25 A. What I did is I evaluated the availability 11:00:35</p> <p style="text-align: right;">Page 81</p>                             |

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| <p>1 of the eight-week dosing interval among the 11:00:38</p> <p>2 constellation of claims, among the totality of the 11:00:43</p> <p>3 claims, how does that -- whether or not there is a 11:00:47</p> <p>4 nexus between that and commercial success, and 11:00:50</p> <p>5 consistent with what Dr. Stewart said about 11:00:53</p> <p>6 adherence to the predetermined schedule being 11:00:57</p> <p>7 imperfect, my view is that the availability of that 11:01:01</p> <p>8 eight-week maintenance dosing, whether or not it 11:01:05</p> <p>9 can be obtained in every particular case is an 11:01:08</p> <p>10 indicator of that product's commercial success. 11:01:14</p> <p>11 And so it was appropriate to include them. 11:01:17</p> <p>12 Q. Okay. So your view is that his reference 11:01:20</p> <p>13 to predetermined schedules being imperfect, that 11:01:22</p> <p>14 can include treat-and-extend and PRN? 11:01:26</p> <p>15 MR. WILK: Objection to form. 11:01:28</p> <p>16 A. So that would be a medical interpretation 11:01:29</p> <p>17 that I wouldn't draw, but I would say that from an 11:01:34</p> <p>18 economic perspective the medical, technical, legal 11:01:37</p> <p>19 distinctions are less important to me than is the 11:01:42</p> <p>20 availability of the patented claims, the claims 11:01:45</p> <p>21 that allow for an extended treatment. Sometimes 11:01:53</p> <p>22 that will get the patient to an eight-week 11:01:59</p> <p>23 interval, sometimes it might get them to nine, 11:02:01</p> <p>24 sometimes it might get them to ten. You know, 11:02:03</p> <p>25 approximately eight weeks is how I understand the 11:02:06</p> <p style="text-align: right;">Page 82</p> | <p>1 what was in the mind of the physician and the 11:03:16</p> <p>2 patient as maintenance dose -- maintenance phase 11:03:18</p> <p>3 dosing was determined. 11:03:24</p> <p>4 Q. Well, you understand that the surveys you 11:03:27</p> <p>5 relied on in many instances tell us whether it's a 11:03:30</p> <p>6 fixed predetermined dosing schedule or PRN and T&amp;E, 11:03:35</p> <p>7 correct? 11:03:39</p> <p>8 MR. WILK: Objection to form. 11:03:40</p> <p>9 A. Sorry. Some of them do, yes. 11:03:40</p> <p>10 Q. Okay. And you didn't use any of that 11:03:42</p> <p>11 information for purposes of your commercial success 11:03:43</p> <p>12 evaluation, correct? 11:03:46</p> <p>13 MR. WILK: Objection to form. 11:03:47</p> <p>14 A. That's not correct. 11:03:48</p> <p>15 Q. Okay. Where in your declaration do you 11:03:49</p> <p>16 address those? 11:03:51</p> <p>17 A. Well, there are -- I use a couple of 11:03:53</p> <p>18 examples of slides from those surveys that show the 11:03:56</p> <p>19 dosing frequency. 11:04:09</p> <p>20 Q. Okay. If you can point me to a specific 11:04:14</p> <p>21 instance where you rely on the percentage of PRN or 11:04:16</p> <p>22 treat-and-extend for purposes of your commercial 11:04:25</p> <p>23 success evaluation, that would be great. 11:04:28</p> <p>24 MR. WILK: Objection to form. 11:04:30</p> <p>25 A. So I don't draw that distinction, but I 11:04:31</p> <p style="text-align: right;">Page 84</p>                                                                                                                                                                                                           |
| <p>1 patent to read. So that -- the availability of 11:02:09</p> <p>2 that is the driver of commercial success from my 11:02:12</p> <p>3 perspective, from an economic perspective. 11:02:17</p> <p>4 Q. So if Dr. Stewart told you that there was 11:02:20</p> <p>5 a subset of sales that fall outside the scope of 11:02:23</p> <p>6 the claims of the '572 Patent, would you have 11:02:28</p> <p>7 discounted the sales of those products? 11:02:30</p> <p>8 MR. WILK: Objection to form. 11:02:33</p> <p>9 A. Would I have ignored them? 11:02:35</p> <p>10 Q. Discounted. 11:02:37</p> <p>11 MR. WILK: Same objection. 11:02:38</p> <p>12 A. Discounting means different things to an 11:02:39</p> <p>13 economist. So I'm not sure -- so you can discount 11:02:42</p> <p>14 over time, means you take discount rates and change 11:02:44</p> <p>15 numbers by them. So I guess I want to know what 11:02:48</p> <p>16 you really mean by "discount." 11:02:51</p> <p>17 Q. You didn't discount any of the commercial 11:02:52</p> <p>18 sales of products that practice PRN or T&amp;E, 11:02:54</p> <p>19 correct? 11:03:00</p> <p>20 MR. WILK: Objection to form. 11:03:01</p> <p>21 A. Again, recognizing that you and I might 11:03:01</p> <p>22 mean the word "discount" differently, I didn't 11:03:04</p> <p>23 treat them differently than -- in many cases there 11:03:06</p> <p>24 are not data that allow one to know -- in fact, 11:03:11</p> <p>25 typically there are not data that allow one to know 11:03:16</p> <p style="text-align: right;">Page 83</p>                                                                                                                                                  | <p>1 thought you were asking me if there were examples 11:04:35</p> <p>2 of analyses where the distinction between fixed 11:04:41</p> <p>3 interval and a treat-and-extend or PRN methodology 11:04:47</p> <p>4 for maybe lack of a better word is used. 11:04:54</p> <p>5 And so on page 30 of the '572 declaration 11:04:59</p> <p>6 is one example of one of those charts, and on page 11:05:03</p> <p>7 31 is another where the dosing frequency -- overall 11:05:10</p> <p>8 dosing frequency is presented that shows that 11:05:14</p> <p>9 the -- on page 35 the Eylea seven- to eight-week 11:05:20</p> <p>10 dosing interval has 37 percent of dosing and has 11:05:27</p> <p>11 42 percent on page 30 -- sorry. I was looking at 11:05:36</p> <p>12 the wrong page. I was looking at the wrong page 11:05:39</p> <p>13 number. 11:05:44</p> <p>14 So in my report page number 30 is where 11:05:45</p> <p>15 the first chart is and then page 31 is where the 11:05:48</p> <p>16 next chart is where the dosing frequency is seven 11:05:53</p> <p>17 to eight weeks for 42 percent of the patients. 11:06:00</p> <p>18 So what I'm saying -- what I intended to 11:06:06</p> <p>19 communicate there is that there are -- within the 11:06:08</p> <p>20 record there are slides that show sometimes these 11:06:11</p> <p>21 numbers broken out by fixed dosing, sometimes by 11:06:16</p> <p>22 treat-and-extend or other methods that generally 11:06:25</p> <p>23 show the same thing, that the eight-week dosing 11:06:27</p> <p>24 interval is the most common, the most frequently 11:06:30</p> <p>25 used interval for Eylea. 11:06:32</p> <p style="text-align: right;">Page 85</p> |

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| <p>1 Q. What you showed me on page 30, this says 11:06:33</p> <p>2 nothing about PRN or treat-and-extend versus fixed, 11:06:35</p> <p>3 correct? 11:06:39</p> <p>4 MR. WILK: Objection to form. 11:06:39</p> <p>5 A. It does not, yeah. 11:06:40</p> <p>6 Q. Okay. Same thing with the chart on page 11:06:41</p> <p>7 31 of your declaration, it says nothing about PRN 11:06:43</p> <p>8 or treat-and-extend, right? 11:06:48</p> <p>9 MR. WILK: Objection to form. 11:06:49</p> <p>10 A. It shows the overall dosing, yes. 11:06:50</p> <p>11 Q. Okay. So why don't we pull another 11:06:57</p> <p>12 exhibit. All right. So Dr. Manning, this is 11:06:58</p> <p>13 Exhibit 2172 and this is from the '884 IPR, which 11:07:25</p> <p>14 I think is the '572 IPR. Let's see. It's entitled 11:07:33</p> <p>15 "DME Market Assessment, Quarter 3 2017." I'll give 11:07:40</p> <p>16 you that and I'd ask you if you could turn to 11:07:53</p> <p>17 slide -- or page 22, and this is -- this is one of 11:08:05</p> <p>18 the surveys you relied on, correct? 11:08:39</p> <p>19 A. There are various surveys. These are done 11:08:42</p> <p>20 every quarter I believe, and I've looked at several 11:08:45</p> <p>21 of these over the time that I've been working on 11:08:48</p> <p>22 these questions, yes. 11:08:50</p> <p>23 Q. Okay. And so you're familiar with the 11:08:51</p> <p>24 slide on page 22? 11:08:54</p> <p>25 A. Generally. I don't know that I've looked 11:08:56</p> <p style="text-align: right;">Page 86</p> | <p>1 what's in gray, it's -- 8 percent is monthly dosing 11:10:04</p> <p>2 throughout; is that right? 11:10:08</p> <p>3 A. Yes. 11:10:09</p> <p>4 Q. Okay. And that's different than the 11:10:09</p> <p>5 eight-week dosing regimen, right? 11:10:11</p> <p>6 MR. WILK: Objection to form. 11:10:13</p> <p>7 A. Monthly is not eight weeks, that's 11:10:13</p> <p>8 correct. 11:10:15</p> <p>9 Q. Okay. And then for 59 percent of it it's 11:10:16</p> <p>10 monthly until dryness attained, then T&amp;E, right? 11:10:18</p> <p>11 A. Yes. 11:10:23</p> <p>12 Q. Again, that would fall outside of the 11:10:24</p> <p>13 eight-week dosing schedule, correct? 11:10:26</p> <p>14 MR. WILK: Objection to form. 11:10:28</p> <p>15 A. You know, I'm not sure that it would. 11:10:29</p> <p>16 Q. Why not? 11:10:31</p> <p>17 A. I don't know the frequency with which 11:10:34</p> <p>18 dryness is obtained, and, you know, you'd need -- 11:10:36</p> <p>19 I'd need more information, in particular medical 11:10:47</p> <p>20 information that I don't have. 11:10:47</p> <p>21 Q. Well, it says monthly, right? 11:10:48</p> <p>22 A. Well, monthly until dryness attained. You 11:10:49</p> <p>23 know, there is -- sorry. There is a loading phase 11:10:56</p> <p>24 which is monthly, and I don't know what that refers 11:10:59</p> <p>25 to in terms of how long dryness is typically 11:11:01</p> <p style="text-align: right;">Page 88</p>                                                                                                                   |
| <p>1 at this specific slide recently, but I'm familiar 11:08:57</p> <p>2 with the type of slide it is, yes. 11:09:00</p> <p>3 Q. Okay. And you see that it says -- I'm 11:09:03</p> <p>4 looking at the bar graphs on the left and you see 11:09:07</p> <p>5 that what's designated in gray is "Monthly dosing 11:09:12</p> <p>6 throughout"; do you see that? 11:09:19</p> <p>7 A. I do. 11:09:20</p> <p>8 THE REPORTER: Monthly dosing -- 11:09:20</p> <p>9 MR. ERWINE: Monthly dosing throughout. 11:09:22</p> <p>10 BY MR. ERWINE: 11:09:24</p> <p>11 Q. And then what's labeled in blue is 11:09:24</p> <p>12 "Monthly until dryness attained, then T&amp;E," 11:09:26</p> <p>13 right? 11:09:32</p> <p>14 A. Those are the words there, yes. 11:09:33</p> <p>15 Q. Okay. And you understand that T&amp;E stands 11:09:34</p> <p>16 for treat-and-extend? 11:09:37</p> <p>17 A. I believe that's correct, yes. 11:09:38</p> <p>18 Q. All right. And then what's in green is 11:09:40</p> <p>19 "Monthly until dryness attained, then PRN"? 11:09:41</p> <p>20 A. I see that. 11:09:46</p> <p>21 Q. And I believe PRN stands for pro re nata; 11:09:46</p> <p>22 is that right? 11:09:55</p> <p>23 A. It's a Latin phrase that I understand to 11:09:55</p> <p>24 mean as -- you know, as needed. 11:09:58</p> <p>25 Q. Okay. And the bar graph for Eylea for 11:09:59</p> <p style="text-align: right;">Page 87</p>                                                                                                                        | <p>1 obtained. 11:11:07</p> <p>2 Q. But this 59 percent there's no 11:11:08</p> <p>3 predetermined or fixed eight-week dosing schedule, 11:11:10</p> <p>4 correct? 11:11:15</p> <p>5 MR. WILK: Objection to form. 11:11:15</p> <p>6 A. I don't know how the respondents to that 11:11:16</p> <p>7 survey would have responded in view of a dosing 11:11:17</p> <p>8 regimen which is a loading dose of four weeks -- or 11:11:25</p> <p>9 monthly doses and then a phase of eight-week doses. 11:11:29</p> <p>10 You know, I just -- I can't say one way or the 11:11:33</p> <p>11 other because I'm not the physicians -- I'm not a 11:11:36</p> <p>12 physician. 11:11:39</p> <p>13 Q. So you don't know whether this 59 percent 11:11:40</p> <p>14 does or does not practice the claims of the '572 or 11:11:44</p> <p>15 '601 Patents? 11:11:47</p> <p>16 MR. WILK: Objection to form. 11:11:49</p> <p>17 A. So, again, practicing the claim is a legal 11:11:50</p> <p>18 question. I do not know -- what I don't know is 11:11:52</p> <p>19 whether or not physicians responding to that survey 11:11:55</p> <p>20 who treated according to a four-week loading 11:11:58</p> <p>21 phase -- sorry -- a four-week interval loading 11:12:05</p> <p>22 phase transitioning to an eight-week maintenance 11:12:09</p> <p>23 phase might have said yeah, that's monthly dosing 11:12:12</p> <p>24 until dryness was obtained, which may or may not 11:12:16</p> <p>25 happen on the -- during the loading phrase, and 11:12:22</p> <p style="text-align: right;">Page 89</p> |

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| <p>1 then I went -- then I extended to eight weeks. I 11:12:24</p> <p>2 just don't know how the physicians responded to 11:12:26</p> <p>3 that and that's -- so I would -- 11:12:30</p> <p>4 Q. Well, monthly means monthly, right? 11:12:30</p> <p>5 A. It does. 11:12:32</p> <p>6 Q. It's not eight-week? 11:12:33</p> <p>7 A. Well, as I just said, there's a loading 11:12:34</p> <p>8 phase during which dosing is monthly. 11:12:36</p> <p>9 Q. Okay. 11:12:39</p> <p>10 A. Then there's the maintenance phase during 11:12:40</p> <p>11 which dosing is eight weeks and -- 11:12:41</p> <p>12 Q. Right. And this tells you that 11:12:43</p> <p>13 59 percent -- 11:12:45</p> <p>14 MR. WILK: He wasn't done with his answer. 11:12:46</p> <p>15 A. And I was just going to say that whether a 11:12:49</p> <p>16 physician responding to this survey would -- who 11:12:50</p> <p>17 practices the four- to eight-week interval would 11:12:54</p> <p>18 perhaps say that, yes, I do monthly until dryness 11:12:59</p> <p>19 is attained and then I extend to eight weeks, I 11:13:06</p> <p>20 just don't know how the physician -- I would have 11:13:09</p> <p>21 to have an opinion of a physician to describe 11:13:12</p> <p>22 whether or not that is consistent with the dosing 11:13:14</p> <p>23 regimen that I described or not. 11:13:18</p> <p>24 Q. So you're saying it's possible that the 11:13:19</p> <p>25 eight weeks would follow under the treat-and-extend 11:13:21</p> <p style="text-align: right;">Page 90</p> | <p>1 it says "Monthly until dryness attained, then T&amp;E"? 11:15:03</p> <p>2 A. I do. 11:15:07</p> <p>3 Q. Okay. And so you understand that what's 11:15:07</p> <p>4 in the gray is actually a prescribed fixed 11:15:08</p> <p>5 interval, whereas what's shown in the blue is 11:15:14</p> <p>6 monthly until dryness is obtained or attained and 11:15:18</p> <p>7 then it's treat-and-extend? 11:15:22</p> <p>8 MR. WILK: Objection to form. 11:15:24</p> <p>9 A. I see that those are the words on the 11:15:25</p> <p>10 chart, yes. 11:15:26</p> <p>11 Q. Okay. And is it your understanding that 11:15:27</p> <p>12 what's in gray after the monthly period that's 11:15:30</p> <p>13 followed by some predetermined fixed interval? 11:15:35</p> <p>14 A. I see that those are the words on the -- 11:15:41</p> <p>15 on the chart. 11:15:44</p> <p>16 Q. Okay. And then you see that for the blue 11:15:44</p> <p>17 it says that it's monthly until dryness attained 11:15:46</p> <p>18 and then treat-and-extend? 11:15:50</p> <p>19 A. I do see that. 11:15:51</p> <p>20 Q. All right. And so is it your opinion 11:15:52</p> <p>21 based on Dr. Stewart's declaration that what's 11:15:55</p> <p>22 shown in gray practices the claims of the 11:16:00</p> <p>23 '572 Patent? 11:16:05</p> <p>24 MR. WILK: Objection to form. 11:16:06</p> <p>25 A. I don't know that I would make that 11:16:07</p> <p style="text-align: right;">Page 92</p>       |
| <p>1 period? 11:13:27</p> <p>2 MR. WILK: Objection to form. 11:13:27</p> <p>3 A. Again, I'm not a physician. So I don't 11:13:28</p> <p>4 have a medical opinion about that. What I'm saying 11:13:29</p> <p>5 is that from an economics perspective, from, you 11:13:32</p> <p>6 know, a nonmedical person's perspective I can 11:13:35</p> <p>7 imagine a situation in which that would be 11:13:41</p> <p>8 something a physician would say. 11:13:45</p> <p>9 Q. Yeah. Let's take a look at a different -- 11:13:51</p> <p>10 slightly different exhibit and this is 11:13:55</p> <p>11 Exhibit 2224. This is from -- also from the '572 11:14:05</p> <p>12 IPR or IPR-2023-884. It's entitled "Wet AMD 11:14:10</p> <p>13 Physician ATU Q4 2017." And, Dr. Manning, I'd ask 11:14:15</p> <p>14 you to turn to page 20 of this particular document. 11:14:26</p> <p>15 Let me know when you're there. 11:14:31</p> <p>16 A. I'm there. 11:14:38</p> <p>17 Q. Okay. And these surveys are all pretty 11:14:38</p> <p>18 similar, correct? 11:14:44</p> <p>19 A. Fairly, yes. 11:14:46</p> <p>20 Q. Okay. Do you see the bar graph on the 11:14:47</p> <p>21 left side we have a similar designation of a 11:14:49</p> <p>22 portion in gray and it says "Monthly followed by 11:14:54</p> <p>23 fixed interval"? 11:15:00</p> <p>24 A. I do. 11:15:01</p> <p>25 Q. Okay. And then you see that in the blue 11:15:01</p> <p style="text-align: right;">Page 91</p>                                                                             | <p>1 connection necessarily. 11:16:14</p> <p>2 Q. Okay. So you don't know if this is a 11:16:14</p> <p>3 predetermined fixed dosing schedule, what's shown 11:16:17</p> <p>4 in gray? 11:16:18</p> <p>5 A. Well, as we said, the words followed by 11:16:20</p> <p>6 "fixed interval" are on the chart. So it is on the 11:16:23</p> <p>7 chart, but -- 11:16:26</p> <p>8 Q. Okay. And this is chart -- 11:16:26</p> <p>9 MR. WILK: He wasn't done with his 11:16:28</p> <p>10 answer. 11:16:29</p> <p>11 A. But as I said previously, Dr. Stewart does 11:16:30</p> <p>12 say that -- I'd have to go back and read his exact 11:16:34</p> <p>13 words again. In the sentence I mentioned earlier 11:16:39</p> <p>14 that I thought you had skipped over he says -- 11:16:46</p> <p>15 Q. It's on page 31 of his declaration if 11:16:59</p> <p>16 that's helpful. 11:17:01</p> <p>17 A. Okay. Thank you. 11:17:03</p> <p>18 "Sometimes adherence to the predetermined 11:17:05</p> <p>19 schedule is imperfect, but the regimens are still 11:17:07</p> <p>20 considered fixed when the intended dosing interval 11:17:12</p> <p>21 is based on a schedule rather than on patient 11:17:15</p> <p>22 outcomes." 11:17:18</p> <p>23 So you need -- I would need to be a 11:17:19</p> <p>24 physician -- you would have to ask him how to 11:17:20</p> <p>25 categorize these things as you're asking me to do, 11:17:26</p> <p style="text-align: right;">Page 93</p> |

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| <p>1 and I don't know that. 11:17:29</p> <p>2 Q. So you think that it's possible that PRN 11:17:30</p> <p>3 and treat-and-extend could fall under his 11:17:33</p> <p>4 definition of fixed dosing schedule? 11:17:37</p> <p>5 MR. WILK: Objection to form. 11:17:41</p> <p>6 A. Well, I don't know how they -- how 11:17:42</p> <p>7 physicians interpret those questions because I'm 11:17:45</p> <p>8 not a physician. I would ask him. 11:17:48</p> <p>9 Q. Right, but you're saying based on what's 11:17:49</p> <p>10 in his declaration you think that it's possible 11:17:52</p> <p>11 that PRN and treat-and-extend fall under his 11:17:54</p> <p>12 definition of a fixed dosing schedule? 11:17:59</p> <p>13 MR. WILK: Objection to form. 11:18:01</p> <p>14 A. Well, I think it's possible that a 11:18:02</p> <p>15 physician responding to this survey may interpret 11:18:04</p> <p>16 things in a way that might not be the same as 11:18:10</p> <p>17 you're asking me to interpret them. And so it's 11:18:15</p> <p>18 hard for me -- I would say impossible for me to say 11:18:17</p> <p>19 this means that, that means that because I'm not 11:18:21</p> <p>20 the physician, I'm not the physicians who were 11:18:24</p> <p>21 responding to the survey, I don't know the -- you 11:18:28</p> <p>22 know, in the clinical environment in which the 11:18:31</p> <p>23 physicians are responding to the survey, I don't 11:18:37</p> <p>24 know that they have in mind the same concepts that 11:18:39</p> <p>25 you have in mind that you're asking me to make the 11:18:42</p> <p style="text-align: right;">Page 94</p> | <p>1 MR. WILK: Objection to form. 11:20:07</p> <p>2 A. So as I've said, my interpretation of 11:20:08</p> <p>3 Dr. Stewart -- and I would ask you to ask him if my 11:20:13</p> <p>4 interpretation is correct or not, but my 11:20:16</p> <p>5 interpretation of Dr. Stewart is that he says there 11:20:18</p> <p>6 is a fixed dosing schedule. But even if it isn't 11:20:21</p> <p>7 always followed that doesn't mean it's not -- that 11:20:25</p> <p>8 the -- that the fixed dosing schedule wasn't -- 11:20:30</p> <p>9 isn't appropriate to label a treatment even if it 11:20:33</p> <p>10 isn't followed in some cases because that was the 11:20:38</p> <p>11 intent. 11:20:41</p> <p>12 Now, given that, I don't know how 11:20:43</p> <p>13 people -- how doctors responding to this survey in 11:20:47</p> <p>14 a different setting would have thought of 11:20:50</p> <p>15 themselves as trying to use the fixed dosing 11:20:53</p> <p>16 schedule and maybe not being able to or maybe not 11:20:56</p> <p>17 being able to get the patient to respond as 11:20:58</p> <p>18 intended or how they would have interpreted these 11:21:01</p> <p>19 questions in terms of the patented treatment 11:21:05</p> <p>20 regime. 11:21:13</p> <p>21 Q. Is it your understanding under 11:21:14</p> <p>22 Dr. Stewart's -- pursuant to Dr. Stewart's 11:21:16</p> <p>23 declaration that PRN and treat-and-extend regimens 11:21:21</p> <p>24 fall under a predetermined fixed dosing schedule? 11:21:22</p> <p>25 MR. WILK: Objection to form. 11:21:24</p> <p style="text-align: right;">Page 96</p> |
| <p>1 link to the dosing regime. 11:18:46</p> <p>2 Q. But I'm not asking you about other 11:18:50</p> <p>3 physicians. I'm asking you about Dr. Stewart. I 11:18:52</p> <p>4 said "But you're saying based on what's in his 11:18:58</p> <p>5 declaration, Dr. Stewart's declaration, you think 11:19:02</p> <p>6 that it's possible that PRN and treat-and-extend 11:19:05</p> <p>7 fall under his definition of a fixed dosing 11:19:08</p> <p>8 schedule?" 11:19:11</p> <p>9 MR. WILK: Objection to form. 11:19:11</p> <p>10 A. Well, again, I wouldn't want to tell you 11:19:12</p> <p>11 what Dr. Stewart means or doesn't mean, I would 11:19:16</p> <p>12 leave that to him, but what I am saying is that as 11:19:18</p> <p>13 I read Dr. Stewart, it is possible that a physician 11:19:22</p> <p>14 responding to this survey could say -- could have 11:19:27</p> <p>15 an interpretation of his or her practice that 11:19:31</p> <p>16 reflects the patented treatment regimen but they 11:19:36</p> <p>17 nevertheless choose one of these answers that may 11:19:45</p> <p>18 look like they don't. 11:19:48</p> <p>19 Q. That's still not answering my question, 11:19:50</p> <p>20 Dr. Manning. I'm asking you a simple question. 11:19:52</p> <p>21 I'm asking you -- I'll ask you again. 11:19:55</p> <p>22 If we look at Dr. Stewart's declaration, 11:19:58</p> <p>23 is it your understanding that PRN and 11:20:01</p> <p>24 treat-and-extend fall under his definition of a 11:20:03</p> <p>25 fixed dosing schedule? 11:20:06</p> <p style="text-align: right;">Page 95</p>                                               | <p>1 A. So he does describe a fixed treatment 11:21:25</p> <p>2 schedule and a PRN and T&amp;E or treat-and-extend 11:21:28</p> <p>3 approach. As I've said, I don't think it's 11:21:32</p> <p>4 necessary for an economist to be able to 11:21:38</p> <p>5 distinguish among those when there is very good 11:21:43</p> <p>6 indication that the ability -- the availability of 11:21:51</p> <p>7 that eight-week dosing interval of that patented 11:21:55</p> <p>8 treatment regimen is a driver of demand. 11:22:01</p> <p>9 Q. Let me direct your attention, Dr. Manning, 11:22:25</p> <p>10 to paragraph 16 of your report. 11:22:29</p> <p>11 A. '572? 11:22:36</p> <p>12 Q. Yeah. 11:22:37</p> <p>13 A. Okay. 11:22:50</p> <p>14 Q. All right. And about the middle of the 11:22:51</p> <p>15 paragraph you state "This commercial success is 11:22:54</p> <p>16 demonstrated by the large number of patients who 11:23:00</p> <p>17 have benefited from Eylea since its launch as shown 11:23:02</p> <p>18 from Eylea sales since launch and by its 11:23:08</p> <p>19 performance relative to other available 11:23:10</p> <p>20 treatments." Hopefully I've read that correctly. 11:23:12</p> <p>21 A. You did. 11:23:15</p> <p>22 Q. Excellent. Then you say "These sales have 11:23:17</p> <p>23 a nexus to the method of treatment covered by the 11:23:18</p> <p>24 claims of the '572 Patent, including the eight-week 11:23:22</p> <p>25 fixed dosing interval"; do you see that? 11:23:28</p> <p style="text-align: right;">Page 97</p>                                                         |

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| <p>1 A. I do. 11:23:30</p> <p>2 Q. Is it your view that the PRN and T&amp;E 11:23:31</p> <p>3 methods of treatment are covered by the claims of 11:23:36</p> <p>4 the '572 Patent? 11:23:39</p> <p>5 MR. WILK: Objection to form. 11:23:40</p> <p>6 A. You know, the medical distinction across 11:23:48</p> <p>7 those three treatment regimens is really something 11:23:50</p> <p>8 I would rather you ask a doctor about, but I can 11:23:58</p> <p>9 imagine a world in which a physician who considers 11:24:01</p> <p>10 him or herself to be a practitioner of the 11:24:08</p> <p>11 treat-and-extend or PRN process follows the -- or 11:24:14</p> <p>12 is enabled to use Eylea in a way that they could 11:24:25</p> <p>13 not use the prior products and therefore make their 11:24:29</p> <p>14 patient better off and that that is an element of 11:24:33</p> <p>15 the commercial success. 11:24:42</p> <p>16 Q. Okay. So is your view that PRN and 11:24:43</p> <p>17 treat-and-extend are covered by the claims of the 11:24:46</p> <p>18 '572 Patent? 11:24:49</p> <p>19 MR. WILK: Objection to form. 11:24:49</p> <p>20 A. That's not what I said. 11:24:49</p> <p>21 Q. Okay. Well, let me ask you again and I 11:24:51</p> <p>22 don't know if I can say it any simpler. Based on 11:24:55</p> <p>23 this sentence, is it your view that the PRN and 11:24:58</p> <p>24 treat-and-extend methods of treatment are covered 11:25:04</p> <p>25 by the claims of the '572 Patent? 11:25:06</p> <p style="text-align: right;">Page 98</p>             | <p>1 A. No. 11:26:30</p> <p>2 MR. ERWINE: Okay. Another quick break? 11:26:35</p> <p>3 THE WITNESS: Sure. 11:26:37</p> <p>4 MR. ERWINE: All right. I've got 11:26. 11:26:37</p> <p>5 So we'll go 11:35. 11:26:40</p> <p>6 THE WITNESS: Sure. 11:26:42</p> <p>7 THE VIDEOGRAPHER: The time is 11:27 a.m. 11:26:44</p> <p>8 This ends unit 2. We're off the record. 11:26:46</p> <p>9 (A break was had.) 11:39:43</p> <p>10 THE VIDEOGRAPHER: The time is 11:40 a.m. 11:39:51</p> <p>11 This begins unit No. 3. We're on the record. 11:39:54</p> <p>12 BY MR. ERWINE: 11:39:57</p> <p>13 Q. Welcome back, Dr. Manning. 11:39:57</p> <p>14 A. Thank you. 11:39:58</p> <p>15 Q. I want to go back to paragraph 16 of your 11:40:00</p> <p>16 declaration for the '572 Patent and that same 11:40:02</p> <p>17 sentence in paragraph 16 we were focused on, "These 11:40:09</p> <p>18 sales have a nexus to the method of treatment 11:40:13</p> <p>19 covered by the claims of the '572 Patent, including 11:40:15</p> <p>20 the eight-week fixed dosing interval." Do you 11:40:17</p> <p>21 recall that? 11:40:23</p> <p>22 A. I do. 11:40:23</p> <p>23 Q. And do you understand that in order for 11:40:24</p> <p>24 the method of treatment to be covered by the claims 11:40:30</p> <p>25 of the '572 Patent that that would require a 11:40:33</p> <p style="text-align: right;">Page 100</p>                                                                                       |
| <p>1 MR. WILK: Objection to form. 11:25:08</p> <p>2 A. And, again, I'd say I do not make the 11:25:10</p> <p>3 distinction that you're asking me to make in my 11:25:14</p> <p>4 declaration. What I said is that the eight-week 11:25:16</p> <p>5 dosing interval -- the method of treatment covered 11:25:21</p> <p>6 by the patent that includes the eight-week dosing 11:25:27</p> <p>7 interval and doesn't ask, well, how do we get to 11:25:30</p> <p>8 eight weeks or can we always get to eight weeks or 11:25:33</p> <p>9 can we get beyond eight weeks, those are questions 11:25:38</p> <p>10 that are not specific to the question I evaluated. 11:25:41</p> <p>11 The question I evaluated is does the 11:25:46</p> <p>12 patented treatment regime have a link, have a nexus 11:25:55</p> <p>13 to the product's commercial success. It doesn't 11:25:57</p> <p>14 ask -- I don't ask whether PRN or treat-and-extend 11:26:00</p> <p>15 are the same as fixed dosing. That's a medical 11:26:05</p> <p>16 question that I don't have an answer for. 11:26:09</p> <p>17 Q. Okay. You used the word in your answer 11:26:11</p> <p>18 "patented treatment regimen," right? 11:26:15</p> <p>19 A. Yes. 11:26:17</p> <p>20 Q. Does patented treatment regimen include 11:26:17</p> <p>21 PRN or treat-and-extend? 11:26:18</p> <p>22 MR. WILK: Objection to form. 11:26:21</p> <p>23 A. That's a legal question I don't have an 11:26:25</p> <p>24 answer for. 11:26:27</p> <p>25 Q. You don't know? 11:26:29</p> <p style="text-align: right;">Page 99</p> | <p>1 patient gaining visual acuity within 52 weeks? 11:40:36</p> <p>2 MR. WILK: Objection to form. 11:40:39</p> <p>3 A. I do recognize that there are those 11:40:39</p> <p>4 provisions in the -- in the claims, yes. 11:40:41</p> <p>5 Q. Okay. And you understand that if that 11:40:44</p> <p>6 doesn't happen, then in that instance the sale of 11:40:45</p> <p>7 the Eylea product would not fall under the scope of 11:40:52</p> <p>8 the claim? 11:40:54</p> <p>9 MR. WILK: Objection to form. 11:40:56</p> <p>10 A. You know, I -- again, what counts in a 11:40:57</p> <p>11 legal determination is not something I've analyzed 11:41:02</p> <p>12 because I'm not an attorney. 11:41:05</p> <p>13 Q. So in terms of whether or not a patient 11:41:15</p> <p>14 does or does not gain visual acuity within 11:41:19</p> <p>15 52 weeks, that's not something you considered? 11:41:24</p> <p>16 MR. WILK: Objection to form. 11:41:26</p> <p>17 A. It's not something I had data to evaluate. 11:41:26</p> <p>18 So it's not part of my declaration. 11:41:31</p> <p>19 Q. So in the past I know you've considered 11:41:41</p> <p>20 other Regeneron patents that are related to dosing 11:41:45</p> <p>21 that you opine contributed to Eylea's commercial 11:41:49</p> <p>22 success, correct? 11:41:54</p> <p>23 A. Yes. 11:41:56</p> <p>24 Q. For example, the '338 Patent is one 11:41:56</p> <p>25 example? 11:41:58</p> <p style="text-align: right;">Page 101</p> |

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| <p>1 A. I think I've talked about five of the 11:41:59</p> <p>2 patents. That is one of them. 11:42:01</p> <p>3 Q. Okay. Did you evaluate the impact of 11:42:03</p> <p>4 those patents versus the '572 Patent in your 11:42:06</p> <p>5 analysis here? 11:42:11</p> <p>6 MR. WILK: Objection to form. 11:42:12</p> <p>7 A. I did not. 11:42:13</p> <p>8 Q. And did you evaluate any of those patents 11:42:15</p> <p>9 versus the '601 in your analysis, the '601 Patent? 11:42:18</p> <p>10 MR. WILK: Objection to form. 11:42:23</p> <p>11 A. I did not. 11:42:24</p> <p>12 Q. And for the '572 did you consider the 11:42:25</p> <p>13 '601 Patent? 11:42:28</p> <p>14 MR. WILK: Objection to form. 11:42:29</p> <p>15 A. Well, the '601 Patent is the other patent 11:42:30</p> <p>16 at issue today, and if you mean did I compare the 11:42:32</p> <p>17 two and try to say one is better or worse or 11:42:37</p> <p>18 different than the other, I would say I did not. 11:42:40</p> <p>19 Q. Okay. 11:42:44</p> <p>20 Let me turn you to paragraph 35 of your 11:42:49</p> <p>21 report. Sorry. I keep calling it your report. 11:42:54</p> <p>22 It's your declaration. I apologize. 11:42:57</p> <p>23 A. I understand. 11:43:00</p> <p>24 Q. Too much time in District Court. So in 11:43:01</p> <p>25 paragraph 35 you reference some of these Regeneron 11:43:10</p> <p style="text-align: right;">Page 102</p> | <p>1 MR. ERWINE: Sorry. 11:44:13</p> <p>2 MR. WILK: That's okay. 11:44:13</p> <p>3 BY MR. ERWINE: 11:44:13</p> <p>4 Q. And with respect to the percentages, so 11:44:13</p> <p>5 50 percent efficacy, is that right, for this 11:44:18</p> <p>6 particular survey? 11:44:22</p> <p>7 A. Well, I haven't looked at this survey in 11:44:26</p> <p>8 the last few hours, but the -- my recollection is 11:44:28</p> <p>9 that they were asked what, if any, key benefits do 11:44:31</p> <p>10 you see with the different products, and as it 11:44:37</p> <p>11 says, efficacy and dosing frequency were 11:44:41</p> <p>12 approximately tied as the main perceived benefits 11:44:43</p> <p>13 of Eylea with 50 percent saying efficacy was a key 11:44:46</p> <p>14 benefit and 48 percent saying dosing was a key 11:44:51</p> <p>15 benefit. So they have roughly the same response 11:44:54</p> <p>16 rate by the physicians in that survey. 11:45:00</p> <p>17 Q. And do you know what dosing they were 11:45:02</p> <p>18 talking about, the scope of that term? 11:45:03</p> <p>19 A. I would have to go back and look at the 11:45:08</p> <p>20 survey instrument to confirm, but my understanding 11:45:11</p> <p>21 is that it referenced the dosing framework that is 11:45:14</p> <p>22 presented in typical practice or in the label or in 11:45:19</p> <p>23 the patent of Eylea. 11:45:23</p> <p>24 Q. Okay. And could it include something 11:45:24</p> <p>25 other than predetermined dosing schedules? 11:45:28</p> <p style="text-align: right;">Page 104</p>    |
| <p>1 ATU surveys, right? 11:43:14</p> <p>2 A. I do. 11:43:16</p> <p>3 Q. And in particular in the section 35A 11:43:17</p> <p>4 there's a sentence where you state that "Efficacy 11:43:25</p> <p>5 and dosing frequency were approximately tied as the 11:43:30</p> <p>6 main perceived benefits of Eylea with 50 percent of 11:43:33</p> <p>7 respondents naming efficacy as a key benefit and 11:43:38</p> <p>8 48 percent of respondents naming dosing as a key 11:43:41</p> <p>9 benefit"; is that right? 11:43:45</p> <p>10 A. That is what it says, yes. 11:43:48</p> <p>11 Q. Okay. And in terms of the respondents, 11:43:49</p> <p>12 again, these are physicians, right? 11:43:52</p> <p>13 A. Yes. 11:43:57</p> <p>14 Q. Not patients or caregivers? 11:43:57</p> <p>15 MR. WILK: Object- -- 11:44:00</p> <p>16 A. That's my understanding, yes. 11:44:00</p> <p>17 Q. Okay. And -- 11:44:01</p> <p>18 THE REPORTER: I'm sorry. 11:44:09</p> <p>19 MR. WILK: Objection to form. 11:44:09</p> <p>20 MR. ERWINE: Was there a question? 11:44:13</p> <p>21 MR. WILK: It was the -- 11:44:13</p> <p>22 THE REPORTER: I can't get the objections 11:44:13</p> <p>23 in. 11:44:13</p> <p>24 MR. WILK: He cut off, yeah. It's okay 11:44:13</p> <p>25 now. 11:44:13</p> <p style="text-align: right;">Page 103</p>                                                                                                        | <p>1 MR. WILK: Objection, form. 11:45:33</p> <p>2 A. "Could" is a pretty broad term. So... 11:45:34</p> <p>3 Q. Do you know if it does? 11:45:37</p> <p>4 A. I don't -- I'd have to go look at the 11:45:40</p> <p>5 survey instrument to see exactly how it is phrased, 11:45:42</p> <p>6 but I interpret that to mean the dosing frequency 11:45:44</p> <p>7 is the distinguishing factor, especially with 11:45:48</p> <p>8 respect to the sentence which is the other product 11:45:53</p> <p>9 referenced there. The distinguishing 11:45:55</p> <p>10 characteristic in dosing between the two is that 11:46:01</p> <p>11 Eylea has the eight-week fixed dosing interval in 11:46:03</p> <p>12 the maintenance phase and the sentence does not. 11:46:07</p> <p>13 Q. Okay. But it's not your understanding 11:46:09</p> <p>14 that this is limited to the eight-week dosing 11:46:11</p> <p>15 schedule, right? 11:46:14</p> <p>16 MR. WILK: Objection to form. 11:46:15</p> <p>17 A. As I said before, the availability of the 11:46:16</p> <p>18 eight-week dosing schedule is an important driver, 11:46:19</p> <p>19 an important opportunity that may or may not always 11:46:23</p> <p>20 be followed, be able to be followed based on the 11:46:28</p> <p>21 physician's -- sorry -- the patient's response to 11:46:31</p> <p>22 treatment. 11:46:34</p> <p>23 Q. Okay. But if it's not followed, then it 11:46:34</p> <p>24 does practice the patent, right? 11:46:36</p> <p>25 MR. WILK: Objection to form. 11:46:38</p> <p style="text-align: right;">Page 105</p> |

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| 1 A. I don't have a view on the legality of 11:46:40            | 1 claim. 11:49:16                                              |
| 2 that question. 11:46:44                                       | 2 Q. So, again, it's your understanding that it 11:49:16       |
| 3 Q. Let me ask you about paragraph 36 of your 11:46:46         | 3 could be five to six weeks? 11:49:20                         |
| 4 report and that starts on page 29 of your report, 11:46:50    | 4 MR. WILK: Objection to form. 11:49:23                        |
| 5 and I'm focused on -- I think it was the chart that 11:47:00  | 5 MR. ERWINE: Five to six weeks could fall 11:49:24            |
| 6 you showed that's actually on page 30 of the 11:47:06         | 6 under the scope of the claims of the '572 or 11:49:25        |
| 7 report, this DME dosing update. 11:47:10                      | 7 '601 Patents? 11:49:29                                       |
| 8 A. Yes. 11:47:14                                              | 8 MR. WILK: Same objection. 11:49:30                           |
| 9 Q. Do you recall pointing that out to me? 11:47:14            | 9 A. As I've said, I don't have an opinion 11:49:30            |
| 10 A. I do. 11:47:17                                            | 10 about what legally approximately eight means. 11:49:35      |
| 11 Q. And am I reading this correctly that this 11:47:18        | 11 Q. Similar questions for the screenshot that 11:49:38       |
| 12 is saying that for the Eylea product that 11:47:22           | 12 you include on page 31. Actually, let me -- let me 11:49:42 |
| 13 approximately 37 percent fall within dosing of 11:47:26      | 13 go back. I just had one follow-up question about 11:49:48   |
| 14 seven to eight weeks? 11:47:30                               | 14 that first chart on page 30. 11:49:50                       |
| 15 MR. WILK: Objection to form. 11:47:32                        | 15 So for the ones that fall within -- I 11:49:57              |
| 16 A. That's my understanding, yes. 11:47:32                    | 16 think 37 percent fall within the seven- to 11:50:00         |
| 17 Q. Okay. And then 26 percent fall within -- 11:47:33         | 17 eight-week range; is that right? 11:50:02                   |
| 18 sorry -- five to six weeks? 11:47:41                         | 18 A. That's correct. 11:50:05                                 |
| 19 A. That's how I understand that chart, yes. 11:47:43         | 19 Q. And your understanding is that the 11:50:05              |
| 20 Q. All right. And 19 percent fall within the 11:47:47        | 20 '572 Patent references a specific eight-week 11:50:07       |
| 21 nine-plus weeks? 11:47:49                                    | 21 schedule, correct? 11:50:10                                 |
| 22 A. That's my understanding, yes. 11:47:51                    | 22 MR. WILK: Objection to form. 11:50:12                       |
| 23 Q. So it's your understanding that 63 percent 11:47:52       | 23 A. My recollection was that it was 11:50:13                 |
| 24 of what's represented here falls outside of the 11:47:54     | 24 approximately eight weeks, but -- so can I look at 11:50:14 |
| 25 scope of the claim of the '572 Patent? 11:47:56              | 25 that patent? 11:50:22                                       |
| Page 106                                                        | Page 108                                                       |
| 1 MR. WILK: Objection to form. 11:47:58                         | 1 Q. Sure. 11:50:23                                            |
| 2 A. I would not say that. 11:48:01                             | 2 A. Claim 1 references approximately eight 11:50:39           |
| 3 Q. Why not? 11:48:02                                          | 3 weeks, claim 26 references approximately eight 11:50:40      |
| 4 A. As I've discussed several times, 11:48:03                  | 4 weeks, claim 15 as well. So I -- I take that -- 11:50:51     |
| 5 approximately eight weeks is what I understand the 11:48:07   | 5 again, I'm not trying to interpret the patent 11:51:01       |
| 6 claim to be. I don't know that -- legally whether 11:48:09    | 6 language legally, but from an economic perspective 11:51:05  |
| 7 nine-plus is approximately eight, and so I wouldn't 11:48:13  | 7 I see approximately eight weeks as the issue. 11:51:09       |
| 8 say whether or not it falls inside or outside the 11:48:18    | 8 Q. Okay. So looking at what's shown on 11:51:12              |
| 9 scope of the patent. What I think is important 11:48:21       | 9 page 31, that particular screenshot, wet AMD dosing 11:51:17 |
| 10 from my perspective is that the eight-week dosing 11:48:23   | 10 summary, for the Eylea product according to this 11:51:22   |
| 11 interval is substantially more common for Eylea 11:48:29     | 11 approximately 42 percent of the Eylea sales fall 11:51:29   |
| 12 than it is for either Lucentis or Avastin, as is 11:48:31    | 12 within dosing of seven to eight weeks; is that 11:51:32     |
| 13 the nine-plus-week dosing interval. 11:48:37                 | 13 right? 11:51:36                                             |
| 14 So as I've talked about before, the 11:48:39                 | 14 A. Approximately 42 percent of the 11:51:40                 |
| 15 innovation that I see provided by the patented 11:48:41      | 15 respondents said the survey identified that, yeah. 11:51:42 |
| 16 claims -- or the patented features is the ability 11:48:45   | 16 Q. Okay. And that's, again, physician 11:51:45              |
| 17 to extend treatment or extend the dosing interval, 11:48:48  | 17 surveys? 11:51:46                                           |
| 18 and that is reflected in this chart. 11:48:53                | 18 A. Yes. 11:51:47                                            |
| 19 Q. So it's your understanding that a five- to 11:48:55       | 19 Q. And so, again, 58 percent would fall 11:51:47            |
| 20 six-week dosing schedule could fall under the scope 11:49:01 | 20 within a different range? 11:51:50                          |
| 21 of the claims of the '572 Patent? 11:49:06                   | 21 MR. WILK: Objection to form. 11:51:52                       |
| 22 MR. WILK: Objection to form. 11:49:07                        | 22 A. 58 percent would not be 78 -- seven or 11:51:55          |
| 23 A. Again, I'm not -- I don't have an opinion 11:49:07        | 23 eight weeks, yes. 11:51:58                                  |
| 24 about how -- beyond that that I've already 11:49:09          | 24 Q. Got it. Okay. 11:52:00                                   |
| 25 explained how legally one would interpret that 11:49:14      | 25 So let me drop down a little bit in 11:52:09                |
| Page 107                                                        | Page 109                                                       |

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| <p>1 your -- in your declaration and if I could take you 11:52:11</p> <p>2 to page 56. This is some of the underlying data I 11:52:14</p> <p>3 just had a few questions about. 11:52:18</p> <p>4 A. Uh-huh. 11:52:20</p> <p>5 Q. So this is attachment B1, which I think 11:52:24</p> <p>6 are specific dosing directions on the FDA labels, 11:52:30</p> <p>7 and I just had a question about the dosing 11:52:37</p> <p>8 direction for RVO. Do you know what RVO stands 11:52:39</p> <p>9 for? 11:52:44</p> <p>10 A. I do. 11:52:45</p> <p>11 Q. What does it stand for? 11:52:45</p> <p>12 A. Retinal vein occlusion. 11:52:48</p> <p>13 THE REPORTER: One more time. 11:52:49</p> <p>14 THE WITNESS: Retinal vein occlusion. 11:52:51</p> <p>15 Q. Just looking at page 56 for the label, do 11:52:53</p> <p>16 you see that it says the recommended dose for Eylea 11:52:59</p> <p>17 is 2 -- is it micrograms? 11:53:01</p> <p>18 A. Milligrams. 11:53:03</p> <p>19 Q. Milligrams. Sorry. Administered by 11:53:03</p> <p>20 intravitreal injection once every four weeks, 11:53:07</p> <p>21 approximately every 25 days monthly; do you see 11:53:12</p> <p>22 that? 11:53:15</p> <p>23 A. I was looking at the first label. You 11:53:16</p> <p>24 were reading from the most recent label. 11:53:19</p> <p>25 Q. Yeah. 11:53:21</p> <p style="text-align: right;">Page 110</p>                                                                                                           | <p>1 patients to not follow the label in that 11:54:36</p> <p>2 circumstance. 11:54:40</p> <p>3 Q. So Dr. Stewart, let's go back to -- sorry. 11:54:41</p> <p>4 I called you Dr. Stewart. Dr. Manning. 11:54:47</p> <p>5 Let's go back to Dr. Stewart's declaration 11:54:47</p> <p>6 and I want to direct your attention to 11:54:52</p> <p>7 paragraph 189. Just to be clear, you read 11:54:56</p> <p>8 Dr. Stewart's entire declaration, right? 11:55:02</p> <p>9 A. I didn't read every word. I've read 11:55:04</p> <p>10 the -- I've read it fairly carefully. 11:55:07</p> <p>11 Q. Okay. And this was a declaration that you 11:55:09</p> <p>12 relied on for purposes of your report, correct? 11:55:13</p> <p>13 A. Yes. 11:55:18</p> <p>14 Q. When did you first review Dr. Stewart's 11:55:18</p> <p>15 declaration for the '572 Patent? 11:55:23</p> <p>16 A. The actual declaration, the day my report 11:55:25</p> <p>17 was submitted. 11:55:28</p> <p>18 Q. Okay. 11:55:29</p> <p>19 A. But the -- I'd had a conversation with him 11:55:30</p> <p>20 previously as we said. 11:55:32</p> <p>21 Q. Okay. And did you guys talk about any of 11:55:33</p> <p>22 the claim construction issues that we referenced in 11:55:35</p> <p>23 paragraph 63 or 65 with respect to the 11:55:38</p> <p>24 predetermined fixed dosing regimens? 11:55:42</p> <p>25 MR. WILK: Objection to form. 11:55:44</p> <p style="text-align: right;">Page 112</p>                                                                                      |
| <p>1 A. I do see that. 11:53:22</p> <p>2 Q. Okay. So is it your understanding that 11:53:23</p> <p>3 this particular version of Eylea does not practice 11:53:26</p> <p>4 the claims of the '572 Patent? 11:53:28</p> <p>5 MR. WILK: Objection to form. 11:53:31</p> <p>6 A. Well, my understanding is that the label 11:53:32</p> <p>7 indicates a four-week dosing interval, but I also 11:53:35</p> <p>8 understand that it is common for physicians to use 11:53:40</p> <p>9 an eight-week dosing interval anyway. So not 11:53:44</p> <p>10 consistent with that label. 11:53:50</p> <p>11 Q. And when you say it's common for 11:53:50</p> <p>12 physicians to use an eight-week dosing schedule, 11:53:53</p> <p>13 what's the basis for that? 11:53:57</p> <p>14 A. Discussions with physicians about RVO 11:54:00</p> <p>15 specifically. 11:54:02</p> <p>16 Q. And does that include Dr. Stewart? 11:54:03</p> <p>17 A. I don't believe I talked about that with 11:54:06</p> <p>18 Dr. Stewart. 11:54:09</p> <p>19 Q. Okay. And did you talk to any of those 11:54:10</p> <p>20 other physicians about the scope of the claims of 11:54:12</p> <p>21 the '572 or '601 Patents? 11:54:15</p> <p>22 MR. WILK: Objection, form. 11:54:19</p> <p>23 A. What I'm remembering is discussions about 11:54:20</p> <p>24 RVO and what we were seeing in data as eight-week 11:54:23</p> <p>25 dosing intervals and that it was common for 11:54:31</p> <p style="text-align: right;">Page 111</p> | <p>1 A. I don't believe we did, no. 11:55:44</p> <p>2 Q. All right. So let me ask you, if we look 11:55:51</p> <p>3 at the paragraph 189 -- and just to give context, 11:55:55</p> <p>4 this is in Dr. Stewart's commercial success 11:56:03</p> <p>5 section, right, section 12 of his declaration 11:56:09</p> <p>6 beginning on page 85? 11:56:14</p> <p>7 A. Yes. 11:56:22</p> <p>8 Q. Okay. And do you see in paragraph 189 11:56:22</p> <p>9 Dr. Stewart says that "Therefore it is my opinion 11:56:28</p> <p>10 that Eylea embodies the claim limitations in the 11:56:31</p> <p>11 '572 Patent. The claimed features including the 11:56:34</p> <p>12 dosing amount, dosing regimen, disease indications, 11:56:37</p> <p>13 gains in visual acuity, formulation, and exclusion 11:56:43</p> <p>14 criteria have all contributed to Eylea's widespread 11:56:47</p> <p>15 adoption by physicians." 11:56:52</p> <p>16 A. I'm sorry. Was there a question? 11:56:59</p> <p>17 Q. Yeah. Did I read that correctly? 11:57:01</p> <p>18 A. Yes. 11:57:03</p> <p>19 Q. All right. So it's your understanding 11:57:03</p> <p>20 that each of those features contributes to the 11:57:04</p> <p>21 commercial success of the Eylea product? 11:57:07</p> <p>22 MR. WILK: Objection to form. 11:57:11</p> <p>23 A. It's my understanding that that's his 11:57:12</p> <p>24 statement, that that's his interpretation, yes. 11:57:13</p> <p>25 Q. Okay. And you relied on his declaration 11:57:16</p> <p style="text-align: right;">Page 113</p> |

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| <p>1 for purposes of your declaration? 11:57:19</p> <p>2 A. I did. 11:57:21</p> <p>3 Q. Okay. So you understand that in addition 11:57:22</p> <p>4 to dosing amount and dosing regimen that 11:57:23</p> <p>5 Dr. Stewart relied on other factors contributing to 11:57:30</p> <p>6 the commercial success of the Eylea product, right? 11:57:35</p> <p>7 MR. WILK: Objection to form. 11:57:36</p> <p>8 A. I understand him to be saying that these 11:57:38</p> <p>9 features that he has laid out as reflected in the 11:57:41</p> <p>10 '572 Patent have all contributed to Eylea's 11:57:44</p> <p>11 widespread adoption, yes. 11:57:52</p> <p>12 Q. Okay. And so, for example, do you see 11:57:53</p> <p>13 that he references gains in visual acuity? 11:57:55</p> <p>14 A. I do. 11:57:58</p> <p>15 Q. Okay. But that's not something you 11:57:58</p> <p>16 considered for purposes of your report, correct? 11:58:00</p> <p>17 MR. WILK: Objection to form. 11:58:03</p> <p>18 A. Well, it's something, as I said before, 11:58:05</p> <p>19 about which I did not have any data, but I relied 11:58:07</p> <p>20 upon his opinion that the gains in visual acuity 11:58:11</p> <p>21 are an element of the success of the product and 11:58:18</p> <p>22 the clinical experience of physicians and patients. 11:58:23</p> <p>23 Q. All right. He also references 11:58:26</p> <p>24 formulation. Do you know what he means by 11:58:28</p> <p>25 formulation? 11:58:32</p> <p style="text-align: right;">Page 114</p>                                                                                                                                                       | <p>1 have them or don't have them differ, I can't 12:00:09</p> <p>2 analyze that, but they're part of the package, part 12:00:12</p> <p>3 of the claim as a whole that I did analyze. 12:00:16</p> <p>4 Q. So from -- in your opinion the surveys 12:00:18</p> <p>5 that you relied on, they don't have any evidence 12:00:22</p> <p>6 about formulations, correct? 12:00:25</p> <p>7 MR. WILK: Objection to form. 12:00:29</p> <p>8 A. I'm not aware of any evidence from the 12:00:29</p> <p>9 surveys about formulation. As I said before, there 12:00:31</p> <p>10 is one formulation that has been approved and 12:00:34</p> <p>11 marketed. And so you wouldn't be able to ask 12:00:37</p> <p>12 people, well, how do you feel about some other 12:00:39</p> <p>13 formulation that doesn't exist. 12:00:41</p> <p>14 Q. And from your perspective the evidence you 12:00:42</p> <p>15 relied on there isn't anything in there about 12:00:46</p> <p>16 exclusion criteria? 12:00:49</p> <p>17 MR. WILK: Objection to form. 12:00:50</p> <p>18 A. Well, aside from Dr. Stewart's statement 12:00:51</p> <p>19 that he considers exclusion criteria to have 12:00:53</p> <p>20 contributed, that's correct. 12:00:57</p> <p>21 Q. Okay. And Dr. Stewart in paragraph 190 of 12:00:58</p> <p>22 his declaration, he says "Eylea has achieved 12:01:06</p> <p>23 widespread commercial success due to its impressive 12:01:09</p> <p>24 medical efficacy and ability to treat patients on 12:01:11</p> <p>25 less frequent, easier-to-follow dosing regimens"; 12:01:14</p> <p style="text-align: right;">Page 116</p> |
| <p>1 A. Broadly I presume he means how the product 11:58:35</p> <p>2 is put together or how it is formulated. 11:58:38</p> <p>3 Q. Okay. And that's something else you 11:58:40</p> <p>4 didn't consider as a driver of commercial success 11:58:43</p> <p>5 in your declaration? 11:58:46</p> <p>6 A. Well, the product is formulated as 11:58:49</p> <p>7 something that can be used and can be effectively 11:58:55</p> <p>8 used to treat patients. So in the sense that its 11:58:59</p> <p>9 formulation contributes to Eylea's ability to 11:59:06</p> <p>10 benefit patients I did consider that, but there 11:59:11</p> <p>11 aren't any data I'm aware of that would allow me to 11:59:17</p> <p>12 distinguish formulation as it currently exists from 11:59:22</p> <p>13 formulation as it might have otherwise existed. So 11:59:27</p> <p>14 that's not something that would be analyzable from 11:59:32</p> <p>15 an economic perspective. 11:59:35</p> <p>16 Q. Is that the same for exclusion criteria? 11:59:37</p> <p>17 MR. WILK: Objection to form. 11:59:41</p> <p>18 A. Well, the exclusion criteria are -- you 11:59:41</p> <p>19 know, Dr. -- Dr. Stewart talks about -- mentions 11:59:44</p> <p>20 them and they're in the label or their similar 11:59:47</p> <p>21 exclusion criteria or contraindications are in the 11:59:54</p> <p>22 label. So I take those as part of the package of 11:59:56</p> <p>23 the product and, again, there's no data that would 11:59:59</p> <p>24 allow me to say, well, do those exclusion 12:00:03</p> <p>25 criteria -- how does -- how do products that either 12:00:05</p> <p style="text-align: right;">Page 115</p> | <p>1 do you see that? 12:01:20</p> <p>2 A. I do. 12:01:20</p> <p>3 Q. And you agree with that statement? 12:01:21</p> <p>4 A. Well, I agree that that's his opinion and 12:01:22</p> <p>5 my analysis is consistent with that, that a product 12:01:24</p> <p>6 that was not efficacious would not be successful 12:01:30</p> <p>7 and the dosing interval, the dosing regimen is an 12:01:35</p> <p>8 important component of the product's ability to 12:01:38</p> <p>9 treat patients on a less frequent, easier-to-follow 12:01:44</p> <p>10 regime. So I would agree with that. 12:01:51</p> <p>11 Q. Okay. Let me turn you to your other 12:01:54</p> <p>12 declaration, this is for the '601 Patent, and that 12:01:56</p> <p>13 was Exhibit 2043. Did you -- did you write these 12:02:04</p> <p>14 declarations or did someone draft them for you? 12:02:12</p> <p>15 A. I wrote them. I'm the author. 12:02:14</p> <p>16 Q. And I assume you relied on a lot of 12:02:17</p> <p>17 cutting and pasting between the two? 12:02:20</p> <p>18 A. They are very similar. 12:02:22</p> <p>19 Q. Yeah. 12:02:23</p> <p>20 All right. And just looking quickly at 12:02:31</p> <p>21 paragraph 10 of your declaration, that, again, 12:02:33</p> <p>22 references a conversation with Dr. Stewart. Was 12:02:37</p> <p>23 that the same conversation you had with Dr. Stewart 12:02:42</p> <p>24 with respect to the '572 Patent? 12:02:44</p> <p>25 A. No. I had a second conversation. Very 12:02:46</p> <p style="text-align: right;">Page 117</p>                                                                    |

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| <p>1 similar second conversation, but I did have a 12:02:47</p> <p>2 second conversation. 12:02:50</p> <p>3 Q. All right. And this -- let's see. This 12:02:50</p> <p>4 particular declaration, the '601, was signed 12:02:55</p> <p>5 earlier I believe, was signed in January; is that 12:03:02</p> <p>6 correct? January 26th? 12:03:04</p> <p>7 A. Yes. 12:03:10</p> <p>8 Q. And Dr. Stewart's declaration for the 12:03:12</p> <p>9 '601 Patent is January 25th? 12:03:26</p> <p>10 A. Yes, a day before mine. 12:03:27</p> <p>11 Q. So, again, you had a similar one-day 12:03:29</p> <p>12 turnaround time to review? 12:03:32</p> <p>13 A. Yes. 12:03:33</p> <p>14 Q. But, of course, you had this conversation? 12:03:33</p> <p>15 A. Uh-huh. 12:03:35</p> <p>16 Q. And do you recall -- 12:03:36</p> <p>17 THE REPORTER: Yes? 12:03:36</p> <p>18 THE WITNESS: Yes. 12:03:37</p> <p>19 MR. ERWINE: Sorry. 12:03:38</p> <p>20 Do you recall when you had the 12:03:40</p> <p>21 conversation with Dr. Stewart? 12:03:41</p> <p>22 A. I don't recall the exact date, but it was, 12:03:43</p> <p>23 again, within the weeks leading up to the signing 12:03:47</p> <p>24 of the declaration. 12:03:49</p> <p>25 Q. But it was before he signed his 12:03:50</p> <p style="text-align: right;">Page 118</p>                                                                                                                                                                                                                                               | <p>1 economic question that I was asked to assess is 12:05:50</p> <p>2 whether there is a link or a nexus between the 12:05:54</p> <p>3 patented features and the commercial success of the 12:05:59</p> <p>4 product. And so, you know, whether each and every 12:06:02</p> <p>5 treatment that follows that claim -- or follows 12:06:10</p> <p>6 that regime needs to be counted in that way is a 12:06:14</p> <p>7 legal question, not an economic question. 12:06:20</p> <p>8 Q. All right. Let me turn your attention to 12:06:23</p> <p>9 Dr. Stewart's declaration for the '601 IPR. That's 12:06:26</p> <p>10 Exhibit 2027 for the '601 IPR, which is 2023-00739. 12:06:33</p> <p>11 In particular I would turn you to page 30 and 12:06:45</p> <p>12 paragraph 58. 12:06:49</p> <p>13 A. Okay. 12:06:52</p> <p>14 Q. And you see that in paragraph 30 and it 12:06:52</p> <p>15 rolls into -- I'm sorry -- paragraph 58, page 30, 12:06:57</p> <p>16 and this sentence rolls on to page 31. Dr. Stewart 12:07:02</p> <p>17 declares "It is my opinion based on the claims and 12:07:08</p> <p>18 specification of the '601 Patent that a POSA would 12:07:10</p> <p>19 understand the challenged claims to be limited to 12:07:15</p> <p>20 predetermined fixed dosing schedules"; do you see 12:07:17</p> <p>21 that? 12:07:18</p> <p>22 A. I do see that. 12:07:22</p> <p>23 Q. Okay. And this is obviously similar to 12:07:23</p> <p>24 the '572, but is it your understanding that PRN and 12:07:24</p> <p>25 T&amp;E, treat-and-extend, are covered by predetermined 12:07:29</p> <p style="text-align: right;">Page 120</p> |
| <p>1 January 25th declaration? 12:03:52</p> <p>2 A. Yes. 12:04:04</p> <p>3 Q. Okay. 12:04:04</p> <p>4 And taking you to paragraph 14 of the '601 12:04:05</p> <p>5 declaration, I think it's similar -- similar to 12:04:12</p> <p>6 your paragraph about the '572, but let's talk a 12:04:17</p> <p>7 little bit about it. In that paragraph you state 12:04:24</p> <p>8 that "I understand the following claims are under 12:04:30</p> <p>9 review in this proceeding, claims 10 through 12, 17 12:04:36</p> <p>10 through 19, 21, 25 to 28, and 33." And a little 12:04:40</p> <p>11 bit later in the paragraph you say "Specifically I 12:04:49</p> <p>12 understand that these claims relate to the use of a 12:04:52</p> <p>13 VEGF antagonist to treat DME, DR, and DR in 12:04:58</p> <p>14 patients with DME according to the methods of 12:05:08</p> <p>15 treatment recited in the claims." Did I read -- 12:05:16</p> <p>16 hopefully I read that correctly. 12:05:18</p> <p>17 A. I believe so. 12:05:22</p> <p>18 Q. And kind of a similar question for the 12:05:24</p> <p>19 '601 Patent, but is it your understanding that in 12:05:25</p> <p>20 order to practice the claims of the '601 Patent 12:05:30</p> <p>21 that patients must follow predetermined fixed 12:05:33</p> <p>22 dosing schedules? 12:05:37</p> <p>23 MR. WILK: Objection to form. 12:05:37</p> <p>24 A. I would go back to the statement I made 12:05:41</p> <p>25 with respect to the '572 declaration, that the 12:05:43</p> <p style="text-align: right;">Page 119</p> | <p>1 fixed dosing schedules as defined by Dr. Stewart? 12:07:35</p> <p>2 MR. WILK: Objection to form. 12:07:37</p> <p>3 A. I would refer to my answer previously that 12:07:39</p> <p>4 I understand those are medical distinctions and 12:07:42</p> <p>5 that I would want a doctor to tell me when they 12:07:47</p> <p>6 might overlap or not. I would not venture to tell 12:07:50</p> <p>7 you that they are distinct necessarily or that 12:07:55</p> <p>8 there might be overlap across the three. 12:07:59</p> <p>9 Q. And is it fair to say that essentially 12:08:03</p> <p>10 your answers are the same with respect to the 12:08:06</p> <p>11 '572 Patent for purposes of what is and is not 12:08:10</p> <p>12 covered by the claims of the '601 Patent? 12:08:12</p> <p>13 MR. WILK: Objection to form. 12:08:15</p> <p>14 A. That's a pretty broad question, but my 12:08:18</p> <p>15 declarations are very similar. 12:08:21</p> <p>16 Q. Okay. 12:08:22</p> <p>17 A. My conclusions are generally the same. 12:08:22</p> <p>18 Q. All right. 12:08:24</p> <p>19 And you're -- for the '601 Patent, similar 12:08:27</p> <p>20 to the '572 Patent, you rely on evidence from 12:08:29</p> <p>21 physicians, correct? 12:08:32</p> <p>22 A. Yes. 12:08:34</p> <p>23 Q. And not from patients? 12:08:34</p> <p>24 A. That's correct. 12:08:35</p> <p>25 Q. Not from insurance payers? 12:08:36</p> <p style="text-align: right;">Page 121</p>                                                                                                                                                                                 |

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| <p>1 A. I would answer those questions the same 12:08:40<br/> 2 way I answered them for the '601, yes -- or for the 12:08:42<br/> 3 '572, that's correct. 12:08:45<br/> 4 Q. Same for caregivers? 12:08:47<br/> 5 A. Yes. 12:08:49<br/> 6 Q. Employers of patients? 12:08:49<br/> 7 A. Yes. 12:08:49<br/> 8 Q. Family of patients? 12:08:50<br/> 9 A. Yes, but I would want to re-emphasize that 12:08:51<br/> 10 all of those parties would be included to the 12:08:55<br/> 11 extent that they influence demand for the product. 12:08:58<br/> 12 So their influence, although not parsed out, would 12:09:01<br/> 13 have been considered and would have contributed to 12:09:04<br/> 14 the analysis that I did. 12:09:09<br/> 15 Q. The '572 Patent claims include that 12:09:11<br/> 16 reference to visual acuity that we talked about; do 12:09:20<br/> 17 you recall that? 12:09:22<br/> 18 A. Yes. 12:09:22<br/> 19 Q. And the '601 claims do not include that, 12:09:22<br/> 20 correct? 12:09:25<br/> 21 A. I would have to go back and verify that, 12:09:26<br/> 22 but since I didn't have data about visual acuity I 12:09:29<br/> 23 wasn't able to evaluate anything about that. So I 12:09:32<br/> 24 don't remember off the top of my head. If you'd 12:09:38<br/> 25 like to go look at the claims, we could. 12:09:40</p> <p style="text-align: right;">Page 122</p>                                                                                                              | <p>1 Q. And my question is did you draw any 12:10:51<br/> 2 distinction for the '572 Patent versus the 12:10:53<br/> 3 '601 Patent in terms of that difference in breadth? 12:10:58<br/> 4 MR. WILK: Objection to form. 12:11:05<br/> 5 A. Other than the data that we're focused on, 12:11:06<br/> 6 which are very similar and in some -- in many cases 12:11:09<br/> 7 the same data, no. 12:11:12<br/> 8 Q. Okay. 12:11:19<br/> 9 And if we look at a little bit later in 12:11:19<br/> 10 your declaration for the '601 and that's page 30, 12:11:22<br/> 11 and that's a -- I think it's the same screenshot as 12:11:38<br/> 12 the '572, the one on page 30, this DME dosing 12:11:44<br/> 13 update; do you see that? 12:11:49<br/> 14 A. Yes. 12:11:51<br/> 15 Q. And it looks like -- yes. These are both 12:11:51<br/> 16 from -- these are identical. So would your answers 12:12:05<br/> 17 to my questions about this screenshot be the same 12:12:09<br/> 18 for '601 as '572? 12:12:13<br/> 19 A. Yes. 12:12:16<br/> 20 MR. WILK: Objection to form. 12:12:17<br/> 21 THE WITNESS: Sorry. 12:12:18<br/> 22 Q. Okay. 12:12:36<br/> 23 Then let me take you to -- back to 12:12:37<br/> 24 Dr. Stewart's declaration and in particular 12:12:39<br/> 25 paragraph 185. 12:12:46</p> <p style="text-align: right;">Page 124</p>                                                                                         |
| <p>1 Q. So for purposes of these two declarations 12:09:42<br/> 2 you didn't draw any distinction between one that 12:09:44<br/> 3 captures visual acuity and one that does not? 12:09:48<br/> 4 MR. WILK: Objection to form. 12:09:51<br/> 5 A. Well, for the purposes of these 12:09:52<br/> 6 declarations they were focused on the -- the 12:09:54<br/> 7 '601 Patent was focused on the diabetic diseases 12:09:59<br/> 8 and the '572 Patent was focused on all angiogenic 12:10:01<br/> 9 eye disorders, angiogenic eye disorders. So I 12:10:05<br/> 10 didn't distinguish between visual acuity gains in 12:10:14<br/> 11 the first and their absence in the second because I 12:10:17<br/> 12 didn't have data in either case to think about 12:10:21<br/> 13 whether or not patients had experienced those gains 12:10:25<br/> 14 as indicated in the patent. 12:10:27<br/> 15 Q. And what about the distinction between 12:10:28<br/> 16 diabetic diseases and angiogenic eye disorders, did 12:10:30<br/> 17 you draw any distinction there in terms of your 12:10:35<br/> 18 analysis? 12:10:36<br/> 19 A. Well, angiogenic eye disorders include 12:10:38<br/> 20 diabetic eye disorders. So -- 12:10:40<br/> 21 Q. Understood, but you agree that angiogenic 12:10:43<br/> 22 eye disorders is broader than diabetic diseases, 12:10:46<br/> 23 correct? 12:10:49<br/> 24 A. I do. 12:10:50<br/> 25 MR. WILK: Objection to form. 12:10:51</p> <p style="text-align: right;">Page 123</p> | <p>1 A. Of his '601? 12:12:49<br/> 2 Q. His '601, yeah, exactly. 12:12:52<br/> 3 And in paragraph -- tell me if you're 12:13:13<br/> 4 there. It's on page 96. 12:13:15<br/> 5 A. Yes, I'm there. 12:13:17<br/> 6 Q. Similar to the '572 Patent, Dr. Stewart 12:13:19<br/> 7 states "Therefore it is my opinion that Eylea 12:13:23<br/> 8 embodies the claim limitations in the '601 Patent. 12:13:27<br/> 9 The claimed features including the dosing amount, 12:13:31<br/> 10 dosing regimen, and disease indications have all 12:13:36<br/> 11 contributed to Eylea's medical success and adoption 12:13:40<br/> 12 by physicians"; do you see that? 12:13:42<br/> 13 A. I do. 12:13:46<br/> 14 Q. And you understand Dr. Stewart to be 12:13:46<br/> 15 saying that those are the things he's saying 12:13:48<br/> 16 contribute to Eylea's commercial success? 12:13:51<br/> 17 MR. WILK: Objection to form. 12:13:53<br/> 18 A. I understand him to say that those are 12:13:56<br/> 19 things that contribute to the success, they have 12:13:59<br/> 20 all contributed, yes. 12:14:03<br/> 21 Q. Okay. And he -- contrary to what he 12:14:04<br/> 22 included for the '572 Patent, he didn't include for 12:14:07<br/> 23 this patent gains in visual acuity, right? 12:14:12<br/> 24 A. That is not indicated in this paragraph, 12:14:16<br/> 25 that's correct. 12:14:19</p> <p style="text-align: right;">Page 125</p> |

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| <p>1 Q. And he didn't include formulation, 12:14:20</p> <p>2 correct? 12:14:22</p> <p>3 A. That's not in this paragraph, that's 12:14:23</p> <p>4 correct. 12:14:25</p> <p>5 Q. And he didn't include exclusion criteria, 12:14:25</p> <p>6 correct? 12:14:27</p> <p>7 A. That's, again, not included in this 12:14:29</p> <p>8 paragraph. 12:14:30</p> <p>9 Q. So those were factors that were specific 12:14:31</p> <p>10 to the '572 Patent but not the '601 Patent, 12:14:34</p> <p>11 correct? 12:14:37</p> <p>12 MR. WILK: Objection to form. 12:14:38</p> <p>13 A. I don't know what was in his mind when he 12:14:40</p> <p>14 chose to emphasize these and not the others. So I 12:14:42</p> <p>15 wouldn't have a conclusion to draw about that. 12:14:45</p> <p>16 Q. But for purposes of the '572 declaration, 12:14:47</p> <p>17 I think you testified that you didn't consider the 12:14:53</p> <p>18 gains in visual acuity, formulation, or exclusion 12:14:55</p> <p>19 criteria because you didn't have evidence on those 12:14:58</p> <p>20 factors; is that correct? 12:15:01</p> <p>21 MR. WILK: Objection to form. 12:15:03</p> <p>22 A. It is correct that I said I do not have 12:15:03</p> <p>23 data that would allow me to identify the impact of 12:15:06</p> <p>24 those factors in either case. So -- and I could 12:15:11</p> <p>25 not have evaluated them. 12:15:15</p> <p style="text-align: right;">Page 126</p> | <p>1 ACKNOWLEDGEMENT OF DEPONENT</p> <p>2 I, RICHARD MANNING, Ph.D., being first</p> <p>3 duly sworn, on oath say that I am the deponent in</p> <p>4 the aforesaid deposition taken on the 27th day of</p> <p>5 March, 2024; that I have read the foregoing</p> <p>6 transcript of my deposition consisting of pages 1</p> <p>7 through 129, inclusive, and affix my signature to</p> <p>8 same.</p> <p>9</p> <p>10</p> <p>11 RICHARD MANNING, Ph.D.</p> <p>12</p> <p>13</p> <p>14 _____</p> <p>14 DATE</p> <p>15</p> <p>16</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 128</p>                                                                                                                                                                                                                                                                                                                                                                                                  |
| <p>1 MR. ERWINE: Thank you, Dr. Manning. I 12:15:19</p> <p>2 don't have any further questions. 12:15:20</p> <p>3 MR. WILK: Nothing here. Thank you, 12:15:24</p> <p>4 Dr. Manning. Thank you court reporter and the 12:15:25</p> <p>5 videographer. 12:15:27</p> <p>6 THE VIDEOGRAPHER: The time is 12:16 p.m. 12:15:28</p> <p>7 We're off the record. 12:15:30</p> <p>8 (Whereupon, at 12:16 p.m., the</p> <p>9 taking of the instant</p> <p>10 deposition ceased.)</p> <p>11</p> <p>12</p> <p>13</p> <p>14</p> <p>15</p> <p>16</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 127</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | <p>1 C E R T I F I C A T E</p> <p>2 I, TINA M. ALFARO, Registered Professional</p> <p>3 Reporter, Certified Realtime Reporter, and</p> <p>4 Registered Merit Reporter, the officer before whom</p> <p>5 the foregoing deposition was taken, do hereby</p> <p>6 certify that the foregoing transcript is a true and</p> <p>7 correct record of the testimony given; that said</p> <p>8 testimony was taken by me stenographically and</p> <p>9 thereafter reduced to typewriting under my</p> <p>10 direction; that reading and signing was requested;</p> <p>11 and that I am neither counsel for, related to, nor</p> <p>12 employed by any of the parties to this case and</p> <p>13 have no interest, financial or otherwise, in its</p> <p>14 outcome.</p> <p>15 IN WITNESS WHEREOF, I have hereunto set my</p> <p>16 hand on this 7th day of April, 2024.</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22 <i>Tina M. Alfaro</i></p> <p>22 Tina M. Alfaro, RPR, CRR, RMR</p> <p>23</p> <p>24</p> <p>25</p> <p style="text-align: right;">Page 129</p> |

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[adverse - assume]

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[assuming - broad]

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[considered - cumulative]

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[describes - dosing]

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[dosing - economist's]

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[effective - evidence]

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[evidence - eylea's]

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[f - form]

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**[patent - perform]**

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[performance - preclude]

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[remotely - says]

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[says - similar]

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[similar - stronger]

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[studied - task]

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[team - treat]

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[treat - unit]

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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

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