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

- - - - - X
SAMSUNG BIOEPIS CO., LTD., :
Petitioner, :
v. : No. IPR2023-00442
REGENERON PHARMACEUTICALS, INC., :
Patent Owner. :
- - - - - X

Washington, D.C.
Tuesday, December 12, 2023
Videotaped deposition of RICHARD MANNING,
PH.D., a witness herein, called for examination by
counsel for Petitioner in the above-entitled matter,
pursuant to notice, the witness being duly sworn by
MARY GRACE CASTLEBERRY, a Notary Public in and for
the District of Columbia, taken at the offices of
Arnold & Porter Kaye Scholer, 601 Massachusetts
Avenue, N.W., Washington, D.C., at 9:12 a.m.,
Tuesday, December 12, 2023, and the proceedings being
taken down by Stenotype by MARY GRACE CASTLEBERRY,
RPR, and transcribed under her direction.

<p>1 APPEARANCES:</p> <p>2</p> <p>3 On behalf of the Petitioner:</p> <p>4 ELLIOT CHOI, ESQ.</p> <p>5 LAURA FAIRNENY, ESQ. (Remote)</p> <p>6 Quinn, Emanuel, Urquhart & Sullivan, LLP</p> <p>7 51 Madison Avenue, 22nd Floor</p> <p>8 New York, New York 10010</p> <p>9 (212) 849-7322</p> <p>10 (212) 849-7546</p> <p>11 elliotchoi@quinnemanuel.com</p> <p>12 laura.fairneny@quinnemanuel.com</p> <p>13</p> <p>14 On behalf of Patent Owner:</p> <p>15 DAVID A. CAINE, ESQ.</p> <p>16 Arnold & Porter Kaye Scholer LLP</p> <p>17 3000 El Camino Real</p> <p>18 Five Palo Alto Square, Suite 500</p> <p>19 Palo Alto, California 94306-3807</p> <p>20 (650) 319-4551</p> <p>21 david.caine@arnoldporter.com</p> <p>22 and</p> <p style="text-align: right;">Page 2</p>	<p>1 C O N T E N T S</p> <p>2 WITNESS EXAMINATION BY COUNSEL FOR</p> <p>3 RICHARD MANNING, PH.D. PETITIONER</p> <p>4 BY MR. CHOI 8</p> <p>5 AFTERNOON SESSION - 119</p> <p>6</p> <p>7</p> <p>8 E X H I B I T S</p> <p>9 EXHIBIT PAGE</p> <p>10 Exhibit 1001 United States Patent Number 28</p> <p>11 10,130,681</p> <p>12 Exhibit 2058 Expert Declaration of Richard 14</p> <p>13 Manning, Ph.D.</p> <p>14 Exhibit 2059 Expert Declaration of Richard 13</p> <p>15 Manning, Ph.D. in Mylan v.</p> <p>16 Regeneron matter</p> <p>17 Exhibit 2138 Eylea Physician ATU: Wave 2, 108</p> <p>18 Full report, February 2013</p> <p>19 Exhibit 2185 Eylea label 24</p> <p>20 Exhibit 2250 PAT Survey Policies and 102</p> <p>21 Guidelines</p> <p>22</p> <p style="text-align: right;">Page 4</p>
<p>1 APPEARANCES: (Continued)</p> <p>2</p> <p>3 MATTHEW M. WILK, ESQ.</p> <p>4 Arnold & Porter Kaye Scholer LLP</p> <p>5 250 West 55th Street</p> <p>6 New York, New York 10019-9710</p> <p>7 (212) 836-7152</p> <p>8 matthew.wilk@arnoldporter.com</p> <p>9</p> <p>10 ALSO PRESENT:</p> <p>11 EILEEN WOO, Regeneron In-House Counsel</p> <p>12 (Remote)</p> <p>13 RYAN J. HEATHCOCK, Videographer</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 style="text-align: right;">Page 3</p>	<p>1 E X H I B I T S (Continued)</p> <p>2 EXHIBIT PAGE</p> <p>3 MANNING EXHIBIT PAGE</p> <p>4 Exhibit 1 July 19, 2023 Decision of the USPTO 49</p> <p>5 PTAB</p> <p>6</p> <p>7</p> <p>8</p> <p>9</p> <p>10</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 style="text-align: right;">Page 5</p>

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<p>1 PROCEEDINGS</p> <p>2 THE VIDEOGRAPHER: Good morning. We are</p> <p>3 now going on the record at 9:12 a.m. Eastern and</p> <p>4 today's date is December 12th, 2023. Please note</p> <p>5 that the microphones are sensitive and they pick up</p> <p>6 whispering and private conversations. Please be sure</p> <p>7 to mute your phones by time. Audio and video</p> <p>8 recording will continue to take place unless all</p> <p>9 parties agree to go off the record.</p> <p>10 And so this begins media unit number 1 in</p> <p>11 the video recorded deposition of Mr. Richard Manning.</p> <p>12 This is being taken by counsel for the petitioner in</p> <p>13 the matter of Samsung Bioepis Company, Limited,</p> <p>14 versus Regeneron Pharmaceuticals Incorporated. This</p> <p>15 case is filed before the United States Patent and</p> <p>16 Trademark Office before the Patent Trial and Appeal</p> <p>17 Board. The case number is IPR2023-00442.</p> <p>18 The location for today's deposition is</p> <p>19 601 Massachusetts Avenue, Northwest, in Washington,</p> <p>20 D.C., and my name is Ryan Heathcock. I represent</p> <p>21 Veritext Legal Solutions and I am the videographer.</p> <p>22 Our court reporter today is Ms. Mary Grace</p> <p style="text-align: right;">Page 6</p>	<p>1 and having been duly sworn by the Notary Public, was</p> <p>2 examined and testified as follows:</p> <p>3 THE VIDEOGRAPHER: Counsel, you may</p> <p>4 proceed.</p> <p>5 EXAMINATION BY COUNSEL FOR PETITIONER</p> <p>6 BY MR. CHOI:</p> <p>7 Q. Thank you for being here with us,</p> <p>8 Dr. Manning.</p> <p>9 Could you please state your name for the</p> <p>10 record?</p> <p>11 A. My name is Richard L. Manning.</p> <p>12 Q. Okay. Can you spell your name?</p> <p>13 A. R-i-c-h-a-r-d, the letter L,</p> <p>14 M-a-n-n-i-n-g.</p> <p>15 Q. Great. So just a few ground rules to help</p> <p>16 us get through today. Please provide verbal answers.</p> <p>17 It's hard for the reporter to take down a nod or a</p> <p>18 gesture. Is that fair?</p> <p>19 A. It is.</p> <p>20 Q. And also, it's hard for the reporter to</p> <p>21 record multiple people at a time so please allow me</p> <p>22 to finish my questions before starting to answer. Is</p> <p style="text-align: right;">Page 8</p>
<p>1 Castleberry, also representing Veritext Legal</p> <p>2 Solutions. I am not related to any party in this</p> <p>3 action, nor am I financially interested in the</p> <p>4 outcome. If there are any objections to proceeding,</p> <p>5 please state them at the time of your appearance.</p> <p>6 Counsel all present including remotely,</p> <p>7 would you now state your appearances and affiliations</p> <p>8 for the record beginning with the noticing attorney.</p> <p>9 MR. CHOI: This is Elliot Choi of Quinn</p> <p>10 Emanuel on behalf of petitioner, Samsung Bioepis.</p> <p>11 MS. FAIRNENY: Laura Fairneny also of</p> <p>12 Quinn Emanuel.</p> <p>13 MR. CAINE: This is David Caine with</p> <p>14 Arnold & Porter for Regeneron, and with me is Matthew</p> <p>15 Wilk. And then either on the line now or potentially</p> <p>16 joining now is Eileen Woo who is with Regeneron.</p> <p>17 THE VIDEOGRAPHER: If there are no more</p> <p>18 introductions, will our court reporter please swear</p> <p>19 in the witness.</p> <p>20 Whereupon,</p> <p>21 RICHARD MANNING, PH.D.,</p> <p>22 was called as a witness by counsel for Petitioner,</p> <p style="text-align: right;">Page 7</p>	<p>1 that fair?</p> <p>2 A. I will do my best.</p> <p>3 Q. And if you have any -- if you want to take</p> <p>4 a break, just let me know. I'll try my best to</p> <p>5 accommodate that. Sounds good?</p> <p>6 A. That's fine.</p> <p>7 Q. Is there any reason you can't testify</p> <p>8 truthfully today?</p> <p>9 A. No.</p> <p>10 Q. Are you being compensated for being here</p> <p>11 today?</p> <p>12 A. Yes.</p> <p>13 Q. By who?</p> <p>14 A. By Regeneron.</p> <p>15 Q. Do you have any interest in the outcome of</p> <p>16 this proceeding?</p> <p>17 A. No.</p> <p>18 Q. Tell me everything that you did to prepare</p> <p>19 for the deposition today.</p> <p>20 A. I met with counsel yesterday. I reviewed</p> <p>21 my statement, reviewed the documents referred to in</p> <p>22 that statement, so the declaration of Dr. Do and</p> <p style="text-align: right;">Page 9</p>

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<p>1 Dr. Brown, and I also reviewed the report that I</p> <p>2 filed in -- I don't remember the case number at the</p> <p>3 moment but the IPR regarding Patent Number '338.</p> <p>4 Q. Okay. So did you speak with any of the</p> <p>5 other experts in this proceeding?</p> <p>6 A. In preparation, no.</p> <p>7 Q. So in preparation for declaration, did you</p> <p>8 speak with other experts in this proceeding?</p> <p>9 A. Not this declaration, no.</p> <p>10 Q. Did you speak with anyone at Regeneron for</p> <p>11 this proceeding?</p> <p>12 A. Ms. Woo was at the preparation session</p> <p>13 yesterday, but aside from her, no. Well, for -- in</p> <p>14 preparation for the deposition, only her.</p> <p>15 Q. Did you look through any files or</p> <p>16 documents in prep for today's deposition?</p> <p>17 A. Well, to the extent that my declaration</p> <p>18 and the statements of Dr. Do and declarations of</p> <p>19 Dr. Do and Dr. Brown are on the -- my computer</p> <p>20 system, I looked at those files and, you know, my own</p> <p>21 declaration and the attachments are on the computer</p> <p>22 file so I looked at those files, yes.</p> <p style="text-align: right;">Page 10</p>	<p>1 IPR covering the '338 patent. Then there is another</p> <p>2 declaration covering the '601 and '681 patent, and</p> <p>3 there were two declarations filed for that</p> <p>4 proceeding. And then this, the declaration for this</p> <p>5 proceeding. I've reviewed all of those.</p> <p>6 BY MR. CHOI:</p> <p>7 Q. How are your declarations submitted in</p> <p>8 this proceeding different from the other ones that</p> <p>9 you've submitted in other IPRs?</p> <p>10 MR. CAINE: Objection, form.</p> <p>11 THE WITNESS: Well, what do you mean, how</p> <p>12 are they different?</p> <p>13 BY MR. CHOI:</p> <p>14 Q. Are they different substantively?</p> <p>15 A. I guess I would like to understand what</p> <p>16 you mean by substantively.</p> <p>17 Q. So you gave your opinion on the commercial</p> <p>18 success of Eylea --</p> <p>19 A. I did.</p> <p>20 Q. -- with regard to the '338 patent,</p> <p>21 correct?</p> <p>22 A. I did.</p> <p style="text-align: right;">Page 12</p>
<p>1 Q. So you understand that this proceeding</p> <p>2 concerns the patentability of U.S. Patent Number</p> <p>3 10,130,681, correct?</p> <p>4 A. That's my understanding, yes.</p> <p>5 Q. And I'll refer to that patent as '681</p> <p>6 patent going forward. Is that fair?</p> <p>7 A. That's fair.</p> <p>8 Q. And you submitted a declaration in this</p> <p>9 proceeding concerning the commercial success of Eylea</p> <p>10 in relation to the '681 patent, correct?</p> <p>11 A. I did.</p> <p>12 Q. And did you rely on any other</p> <p>13 declarations -- or strike that.</p> <p>14 In prep -- in drafting the declaration</p> <p>15 submitted in this proceeding, did you rely on any</p> <p>16 other declarations or testimony that you gave in the</p> <p>17 past?</p> <p>18 MR. CAINE: Objection, form.</p> <p>19 THE WITNESS: So I did have -- so I</p> <p>20 submitted -- I think in my report or my declaration,</p> <p>21 I referred to the other declarations that I've</p> <p>22 submitted beginning with the '338 declaration or the</p> <p style="text-align: right;">Page 11</p>	<p>1 Q. And with regard to the '601 patent,</p> <p>2 correct?</p> <p>3 A. Yes.</p> <p>4 Q. And as well as '681 patent, right?</p> <p>5 A. Yes.</p> <p>6 Q. So in the other proceedings, you provided</p> <p>7 opinion as to the commercial success of Eylea, and</p> <p>8 how is your opinion regarding success of --</p> <p>9 commercial success of Eylea different from your</p> <p>10 opinion here that's submitted in this proceeding?</p> <p>11 MR. CAINE: Objection, form.</p> <p>12 THE WITNESS: Well, if you turn to my or</p> <p>13 if I could turn to my declaration, I could read to</p> <p>14 you how this declaration fits into the constellation</p> <p>15 of the other declarations that have been filed.</p> <p>16 BY MR. CHOI:</p> <p>17 Q. Okay. Sure. I will introduce a document</p> <p>18 marked 2059.</p> <p>19 (Exhibit No. 2059 was identified for</p> <p>20 the record.)</p> <p>21 THE WITNESS: So this is not what I had in</p> <p>22 mind.</p> <p style="text-align: right;">Page 13</p>

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<p>1 BY MR. CHOI:</p> <p>2 Q. Okay. And I will also introduce document</p> <p>3 Exhibit 2058.</p> <p>4 (Exhibit No. 2058 was identified for</p> <p>5 the record.)</p> <p>6 BY MR. CHOI:</p> <p>7 Q. Could you point to me a summary of your</p> <p>8 reliance on other declarations in this proceeding?</p> <p>9 A. Yes. So on page 11.</p> <p>10 Q. Okay.</p> <p>11 A. Section 3 of the declaration, it reads --</p> <p>12 I state that I have submitted declarations as part of</p> <p>13 three prior USPTAB proceedings, namely IPR2021-00881</p> <p>14 regarding U.S. Patent Number 9,254,338, IPR2022-1226</p> <p>15 regarding U.S. Patent Number 10,888,601 and</p> <p>16 IPR2022-01225 regarding U.S. Patent Number</p> <p>17 10,130,681, parenthetical, the same patent at issue</p> <p>18 in this proceeding.</p> <p>19 And then I go on to describe how, as part</p> <p>20 of my declaration in the '881 proceeding or the 00881</p> <p>21 proceeding, I demonstrated substantial commercial</p> <p>22 success for Eylea and that analysis is the same</p> <p style="text-align: right;">Page 14</p>	<p>1 contained in the '338 declaration is relevant.</p> <p>2 Q. How about the '601 patent declaration?</p> <p>3 A. That's very similar. I don't have that</p> <p>4 one in front of me but also the differentiating</p> <p>5 factor as I recall is the eight-week dosing interval,</p> <p>6 and the eight-week dosing interval is one of the key</p> <p>7 elements that I analyze in the '338 matter.</p> <p>8 Q. Okay. Is that the same for the '681</p> <p>9 patent declarations you gave in prior proceeding?</p> <p>10 A. It is also very similar.</p> <p>11 Q. Okay. I understand that you've been</p> <p>12 deposed as part of those three proceedings, correct,</p> <p>13 '338, '601 and the other '681, correct?</p> <p>14 A. That's correct.</p> <p>15 Q. And do you have any changes to your prior</p> <p>16 testimony given in that -- in those proceedings?</p> <p>17 A. No.</p> <p>18 Q. Did you review any additional materials in</p> <p>19 preparation for this declaration that's submitted in</p> <p>20 this case?</p> <p>21 MR. CAINE: Objection, form.</p> <p>22 THE WITNESS: Not that I'm recalling. I</p> <p style="text-align: right;">Page 16</p>
<p>1 analysis that is relevant for this matter, and so I</p> <p>2 reference that analysis as part of my declaration in</p> <p>3 this matter.</p> <p>4 Q. So is it your opinion that your</p> <p>5 declaration submitted with regard to the '338 patent</p> <p>6 is equally applicable to issues in this case?</p> <p>7 A. Well, as I said, the -- actually, let me</p> <p>8 go back and put it in more specific context. So</p> <p>9 section 2 of my declaration describes the patent and</p> <p>10 its abstract, and there is a place where I describe</p> <p>11 that -- on page 12, I say -- referencing the prior</p> <p>12 declarations, "In that declaration I discussed the</p> <p>13 relative dosing intervals for commonly-used anti-VEGF</p> <p>14 agents, noting that the FDA-approved labels for each</p> <p>15 approved agent recommend monthly loading doses prior</p> <p>16 to maintenance phases with potentially different</p> <p>17 dosing intervals such that Eylea's eight-week</p> <p>18 recommended maintenance dosing interval was the</p> <p>19 differentiating aspect of its dosing."</p> <p>20 So to the extent that the eight-week</p> <p>21 dosing interval is a part of the claims here, that</p> <p>22 analysis of the eight-week dosing interval that is</p> <p style="text-align: right;">Page 15</p>	<p>1 mean, the materials that are -- that were relevant</p> <p>2 for these prior -- the prior declarations are the</p> <p>3 same materials that were relevant here. I don't have</p> <p>4 a memory of going beyond that, if that's the</p> <p>5 question.</p> <p>6 BY MR. CHOI:</p> <p>7 Q. So there are no new documents that you've</p> <p>8 reviewed as part of drafting this new declaration in</p> <p>9 this proceeding, correct?</p> <p>10 A. I would have to go back and compare. I</p> <p>11 think there are some new references to -- so, for</p> <p>12 example, I think footnote number 1 is a -- was a new</p> <p>13 reference, but I'm not absolutely certain. I would</p> <p>14 have to go back and -- maybe it's reference number 4</p> <p>15 or sorry, footnote number 4. But those are not</p> <p>16 central to the analysis that I did.</p> <p>17 Q. Okay. So is it your opinion that you had</p> <p>18 no changes to the substance of your declarations in</p> <p>19 prior proceedings, correct?</p> <p>20 A. Not that I'm thinking of, although I</p> <p>21 suppose if you showed me something, I might --</p> <p>22 Q. Okay.</p> <p style="text-align: right;">Page 17</p>

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<p>1 A. -- be reminded. But not that I'm thinking</p> <p>2 of now.</p> <p>3 Q. The same is true for the testimony you</p> <p>4 gave in prior proceedings, correct?</p> <p>5 A. That's true.</p> <p>6 Q. So in your declaration submitted in this</p> <p>7 proceeding, you rely on your declaration submitted in</p> <p>8 the '338 patent IPR primarily, correct?</p> <p>9 A. That's correct.</p> <p>10 Q. And did you include -- in this declaration</p> <p>11 or the '338 declaration, did you include any analysis</p> <p>12 of any particular claims of the '681 patent?</p> <p>13 A. Well --</p> <p>14 MR. CAINE: Objection, form.</p> <p>15 THE WITNESS: Well, I'm not an attorney,</p> <p>16 so I am not a technical expert so it is not my role</p> <p>17 to evaluate the particular language in the claims as</p> <p>18 regards their legal implications. It is my role as</p> <p>19 an economist to rely on others to describe the</p> <p>20 technical implications of the claims and so I've</p> <p>21 relied upon, as I mentioned earlier, Dr. Do and</p> <p>22 Dr. Brown for the technical aspects of that.</p> <p style="text-align: right;">Page 18</p>	<p>1 four weeks after the preceding dose, and then one or</p> <p>2 more tertiary doses are administered at least eight</p> <p>3 weeks following the preceding dose."</p> <p>4 So though I do not do a legal analysis of</p> <p>5 the claims, I do understand that that is the impact,</p> <p>6 that's the -- those are the totality of the claims</p> <p>7 that are relevant here and that is what I evaluated.</p> <p>8 BY MR. CHOI:</p> <p>9 Q. So in paragraph 11 of your declaration, on</p> <p>10 page 4, could you read out loud the last sentence on</p> <p>11 page 4?</p> <p>12 A. "I understand that, for commercial success</p> <p>13 to constitute evidence of non-obviousness of a</p> <p>14 patent, there must be a nexus between the claimed</p> <p>15 technology and evidence of commercial success."</p> <p>16 Is that the one you meant?</p> <p>17 Q. Yes. So here, you state that there must</p> <p>18 be a nexus between claimed technology and evidence of</p> <p>19 commercial success, correct?</p> <p>20 A. Yes.</p> <p>21 Q. And what is your understanding of nexus</p> <p>22 between the claimed technology and the evidence of</p> <p style="text-align: right;">Page 20</p>
<p>1 But my assignment here, as I describe, I</p> <p>2 was asked to -- on page 3 of my declaration,</p> <p>3 paragraph 9, "I was asked to evaluate and, if called</p> <p>4 upon, to testify concerning commercial success as an</p> <p>5 objective indicator of non-obviousness in inter</p> <p>6 partes review No. IPR 2023-00442 regarding U.S.</p> <p>7 Patent Number 10,130,681 (the '681 patent)."</p> <p>8 I'm sorry, I thought it was going to go to</p> <p>9 somewhere else, so -- let me skip to paragraph 15.</p> <p>10 I'm sorry for that brief side note.</p> <p>11 "The '681 patent has 26 claims. Of these</p> <p>12 26 claims, 22 are currently under review." I'll skip</p> <p>13 the case notation. And then it goes on to</p> <p>14 describe -- to identify those claims. And then I</p> <p>15 say, "Generally I understand that the '681 patent</p> <p>16 describes a dosing regimen directed to treating</p> <p>17 angiogenic eye disorders in patients who do not have</p> <p>18 three exclusion criteria by administration of a</p> <p>19 sequential dosing regimen of the VEGF antagonist.</p> <p>20 Under the claimed dosing regimen, an initial dose of</p> <p>21 the claimed VEGF antagonist is administered, followed</p> <p>22 by one or more secondary doses administered two to</p> <p style="text-align: right;">Page 19</p>	<p>1 commercial success in this context?</p> <p>2 A. It is that the patented features must be,</p> <p>3 in economics terms, a driver of the demand for the</p> <p>4 product or there must be a link between the patented</p> <p>5 features and the commercial success or the commercial</p> <p>6 performance, the economic performance of the product</p> <p>7 in the marketplace.</p> <p>8 Q. So is it fair to say that a product has to</p> <p>9 embody the claimed features?</p> <p>10 A. As a general term, I wouldn't disagree</p> <p>11 with that, but the term "embody" is a legal term that</p> <p>12 I may or may not understand all of the intricacies</p> <p>13 of.</p> <p>14 Q. Okay. So which patented feature did you</p> <p>15 focus on in your declaration?</p> <p>16 A. Well, as I said, I was asked to review the</p> <p>17 methods of treatment as a whole as they are</p> <p>18 identified here in the section that I just read. But</p> <p>19 also in the section that I read previously, the key</p> <p>20 distinguishing characteristic between Eylea and its</p> <p>21 preceding products, primarily Lucentis and Avastin,</p> <p>22 but primarily Lucentis because Lucentis is approved</p> <p style="text-align: right;">Page 21</p>

<p>1 for this use, is the eight-week dosing interval in</p> <p>2 the maintenance phase of treatment.</p> <p>3 Q. Okay. But your paragraph 15 says,</p> <p>4 "Generally I understand the '681 patent describes a</p> <p>5 dosing regimen directed to treating angiogenic eye</p> <p>6 disorders in patients who do not have three exclusion</p> <p>7 criteria by administration of a sequential dosing</p> <p>8 regimen of the VEGF antagonist," correct?</p> <p>9 A. Yes, it does.</p> <p>10 Q. So is it your opinion that the '681 patent</p> <p>11 is directed to the dosing regimen as well as the</p> <p>12 exclusion criteria, right?</p> <p>13 A. My understanding of the patent claims are</p> <p>14 characterized in that paragraph.</p> <p>15 Q. So the '681 patent does include three</p> <p>16 exclusion criteria by administration of a sequential</p> <p>17 dosing regimen of the VEGF antagonist, correct?</p> <p>18 A. That's what I understand, yes.</p> <p>19 Q. So did you consider the excluding criteria</p> <p>20 as part of your commercial success analysis?</p> <p>21 A. So I did rely upon Dr. Do. Dr. Do</p> <p>22 discusses the exclusion criteria in her declaration</p> <p style="text-align: right;">Page 22</p>	<p>1 MR. CAINE: Objection, form.</p> <p>2 THE WITNESS: Well, I have the -- as I</p> <p>3 said, my assignment was to evaluate the claim as a</p> <p>4 whole. That is a part of the claim. And not having</p> <p>5 data, I relied upon the testimony of another expert</p> <p>6 who does have information about it. So finding</p> <p>7 that -- I think she said 1 percent of patients are</p> <p>8 treated outside of the -- 1 percent of patients are</p> <p>9 found, in her experience, to both have the infection</p> <p>10 and to receive treatment anyway, so that claim</p> <p>11 applies 99 percent of the time by that math.</p> <p>12 BY MR. CHOI:</p> <p>13 Q. It is true that your declaration doesn't</p> <p>14 include any data associating commercial success of</p> <p>15 Eylea with exclusion criteria as recited, correct?</p> <p>16 A. No data other than reference to Dr. Do's</p> <p>17 declaration, that's true.</p> <p>18 Q. I'm going to introduce an exhibit marked</p> <p>19 2185.</p> <p>20 (Exhibit No. 2185 was identified for</p> <p>21 the record.)</p> <p>22 MR. CAINE: Can I get a copy?</p> <p style="text-align: right;">Page 24</p>
<p>1 and that I relied upon her opinion about -- her</p> <p>2 statements about the role of the exclusion criteria</p> <p>3 in treatment.</p> <p>4 Q. And what is that specifically?</p> <p>5 A. She said that for her practice and as she</p> <p>6 understands typical practice, that patients are</p> <p>7 evaluated for three exclusion criteria, periocular</p> <p>8 and intraocular infection or recent history of the</p> <p>9 same, and that in -- when those are present, the</p> <p>10 doctor has to decide whether or not to actually</p> <p>11 administer the administration outside --</p> <p>12 administration in the presence of those is outside</p> <p>13 the claim.</p> <p>14 Q. Okay. But in your declaration, did you</p> <p>15 provide an analysis of whether the exclusion criteria</p> <p>16 have any effect on the commercial success of Eylea?</p> <p>17 A. I did not have data on that. I relied</p> <p>18 upon Dr. Do for that.</p> <p>19 Q. So you have no data to suggest that</p> <p>20 commercial success has anything to do with the</p> <p>21 exclusion criteria as cited in the '681 patent,</p> <p>22 correct?</p> <p style="text-align: right;">Page 23</p>	<p>1 MR. CHOI: Oh, yeah. Sure.</p> <p>2 BY MR. CHOI:</p> <p>3 Q. So Dr. Manning, have you reviewed this</p> <p>4 document?</p> <p>5 A. This looks to be the Eylea label. I know</p> <p>6 there are various approved labels and I have reviewed</p> <p>7 many of them. I'm not sure if I -- I don't see a</p> <p>8 specific date of this approval, but I've reviewed the</p> <p>9 Eylea label, yes.</p> <p>10 Q. Okay. And where does it show that -- or</p> <p>11 strike that.</p> <p>12 Does the Eylea label show that Eylea</p> <p>13 practices the '681 patent?</p> <p>14 A. Dr. Do discusses the relationship between</p> <p>15 the claims of the patent and the label and medical</p> <p>16 practice generally. That's not my -- that's not an</p> <p>17 economic question, so I don't -- other than what</p> <p>18 Dr. Do says, I don't have a view of that.</p> <p>19 Q. But you reviewed these labels to confirm</p> <p>20 that certain indications follow the extended</p> <p>21 eight-week dosing in your declaration, correct?</p> <p>22 A. I reviewed the labels for a variety of</p> <p style="text-align: right;">Page 25</p>

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<p>1 reasons, among them to distinguish between the dosing 2 interval for Eylea and that of Lucentis. So maybe I 3 don't understand your question.</p> <p>4 Q. So you reviewed these documents and 5 confirmed that Eylea follows a certain extended 6 dosing regimen, correct?</p> <p>7 A. I've reviewed the labels and I've observed 8 that the labels indicate a dosing regimen that has 9 some unique characteristics for Eylea, yes.</p> <p>10 Q. And as you noted earlier, you have not 11 done any analysis as to whether the Eylea label has 12 the recited exclusion criteria, correct?</p> <p>13 A. Well, what do you mean by analysis?</p> <p>14 Q. Just to confirm that Eylea product itself 15 embodies the exclusion criteria.</p> <p>16 A. I'm sorry --</p> <p>17 MR. CAINE: Objection, form.</p> <p>18 THE WITNESS: -- I didn't understand the 19 question.</p> <p>20 BY MR. CHOI:</p> <p>21 Q. I'll rephrase that. So you have not done 22 an analysis of Eylea label teaching or indicating to</p> <p style="text-align: right;">Page 26</p>	<p>1 BY MR. CHOI:</p> <p>2 Q. Okay. So I'll introduce Exhibit 1001. 3 This is the '681 patent. 4 (Exhibit No. 1001 was marked for 5 identification.)</p> <p>6 BY MR. CHOI:</p> <p>7 Q. So if you take a look at page 14 of 8 Exhibit 1001, and take a look at claim 1. Earlier 9 you had indicated that the label's contraindications 10 include ocular or periocular infection and active 11 intraocular inflammation, correct?</p> <p>12 MR. CAINE: Objection, form.</p> <p>13 THE WITNESS: Well, what I did is I read 14 what the label says. I don't testify to that. I 15 just read what the label says.</p> <p>16 BY MR. CHOI:</p> <p>17 Q. Sure. And the two contraindications in 18 the label do not match the three excluding criteria 19 in claim 1, correct?</p> <p>20 A. That's a question for a medical expert, 21 not me.</p> <p>22 Q. As you said, the verbatim, you can see</p> <p style="text-align: right;">Page 28</p>
<p>1 doctors to exclude certain patients as claimed by the 2 '681 patent, correct?</p> <p>3 MR. CAINE: Objection, form.</p> <p>4 THE WITNESS: Well, I don't know what you 5 mean by analysis again. As I said, the declaration 6 of Dr. Do, who is a practitioner, does describe how 7 the label corresponds to the patented claims. And, 8 you know, again, I'm not a physician and so I don't 9 have an opinion about medical technicalities here.</p> <p>10 I do note that the contraindications 11 include ocular or periocular infection and active 12 intraocular inflammation on the label. I couldn't 13 tell you from a medical perspective. I would defer 14 to Dr. Do. But as, again, analysis, relying upon -- 15 would include relying upon Dr. Do's description of 16 how physicians treat patients with this condition. 17 And, you know, clearly she describes patients who, 18 when they present with these conditions, which are, 19 you know, among those in the exclusionary criteria, 20 how that relates to her practice and she identifies 21 that when she treats them anyway, she considers that 22 to be outside the patented claims.</p> <p style="text-align: right;">Page 27</p>	<p>1 that the first two exclusion criteria are listed but 2 the third exclusion criteria is not listed in the 3 label, correct?</p> <p>4 MR. CAINE: Objection, form.</p> <p>5 THE WITNESS: I would agree that the words 6 that are printed as exclusion criteria number 3 are 7 not the same words as appear on the indications. On 8 the other hand, I do not know and am not in a 9 position to know, because I'm not a physician, how 10 active or recent infection relates to those 11 conditions so I wouldn't -- I mean, I wouldn't think 12 that is important. I would -- at least from an 13 economic perspective, that doesn't cause me any 14 pause.</p> <p>15 BY MR. CHOI:</p> <p>16 Q. So you haven't --</p> <p>17 A. I would ask the doctor about that.</p> <p>18 Q. So you haven't done any sales or, strike 19 that, any analysis -- strike that.</p> <p>20 So you haven't done any analysis of the 21 exclusion criteria other than your reliance on 22 Dr. Do's testimony or opinion, correct?</p> <p style="text-align: right;">Page 29</p>

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<p>1 A. Other than observing that, given the 2 rarity of, as she describes these conditions, that 3 roughly 99 percent of the time patients either don't 4 have the exclusionary conditions or they are excluded 5 from treatment according to the label's indication or 6 label's claims, sorry, according to the claims of the 7 patent, I've not done more analysis than that. 8 Q. And is it correct that you haven't done 9 any analysis to confirm that if the exclusion 10 criteria are the driving aspect of commercial success 11 of Eylea? Or I'll rephrase that. 12 So you haven't done analysis to confirm 13 that the exclusion criteria of the '681 patent is a 14 driver of Eylea sales? 15 A. So I wouldn't quite say it that way. I'd 16 say what I've done is I have evaluated the claims as 17 described in my statement and the distinguishing -- 18 the key distinguishing characteristic of the product, 19 Eylea, relative to its competitors is the eight-week 20 dosing interval in the maintenance phase. So that is 21 the primary element on which I focus. The exclusion 22 criteria are covered by Dr. Do and so my analysis, as Page 30</p>	<p>1 criteria are in keeping with what's in the claim, 2 that -- the entirety of the claim, the entirety of 3 the treatment method is what I evaluated and the -- 4 it turns out that the eight-week dosing interval is 5 the key distinguishing characteristic. So that is 6 the thing that is easiest for an economist to look at 7 or most relevant for an economist to look at in terms 8 of evaluating the commercial success. 9 Q. So how are excluding criteria a driver of 10 Eylea sales? 11 A. What do you mean, how are they? 12 Q. Well, you had mentioned that you relied on 13 Dr. Do's opinion on the excluding criteria, right? 14 A. Uh-huh. 15 Q. And that the eight-week dosing you thought 16 used -- opined on was a distinguishing factor for 17 Eylea, correct? 18 A. Yes. 19 Q. And when I asked whether the exclusion 20 criteria are not a driver of sales, you wouldn't 21 agree with that, correct? 22 A. To the extent that the question is, is Page 32</p>
<p>1 was done in the prior declaration, is relevant here 2 because it represents the primary -- the key 3 distinguishing characteristic between Eylea and its 4 competitors. 5 Q. So you agree that the claimed exclusion 6 criteria are not a driver of Eylea sales? 7 MR. CAINE: Objection, form. 8 THE WITNESS: No, I wouldn't say that. 9 BY MR. CHOI: 10 Q. So you had testified you focused on the 11 eight-week dosing as a key distinguishing factor, 12 correct? 13 A. Yes. 14 Q. And you said that you relied on the 15 analysis of excluding criteria of Dr. Do, correct? 16 A. Yes. 17 Q. And you haven't done any analysis of 18 whether the excluding criteria was a driver of Eylea 19 sales in your declaration, correct? 20 A. As I said, my reliance on Dr. Do gets to 21 that issue. And as I said, the fact that the vast 22 majority of the time the product or the exclusion Page 31</p>	<p>1 this treatment method that's covered by the patent a 2 driver of sales, that includes the eight-week dosing 3 interval in the maintenance phase. And that 4 eight-week dosing interval in the maintenance key is 5 a key distinguishing characteristic between Eylea and 6 particularly Lucentis, but also Avastin used off 7 label. That is what I evaluated in the '338 8 declaration and that is the primary source of 9 evidence for the conclusion that this treatment 10 method drives success. 11 Now, this treatment method includes the 12 initial -- the initial and the loading doses and it 13 also includes the excluding criteria so to the extent 14 that those form a whole, they represent the method of 15 treatment that is evaluated in my opinion. 16 Q. So in your analysis, are you saying that 17 you took into account whether each sale of Eylea was 18 associated with the practicing of excluding criteria? 19 A. I wouldn't say it that way, no. I would 20 say I did not do an individual analysis of each sale. 21 Q. How about just overall sale? 22 MR. CAINE: Objection, form. Page 33</p>

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<p>1 THE WITNESS: Well, again, I would go back</p> <p>2 to Dr. Do who says that 99 percent of the time -- my</p> <p>3 understanding is that her statement is consistent</p> <p>4 with the conclusion that 99 percent of the time the</p> <p>5 exclusion criteria are satisfied. So that is part of</p> <p>6 the treatment methodology or treatment regime or</p> <p>7 regimen that is covered in the claims.</p> <p>8 BY MR. CHOI:</p> <p>9 Q. So when you were analyzing the commercial</p> <p>10 success of Eylea, you did not consider whether sales</p> <p>11 were tied to the exclusion criteria, correct?</p> <p>12 MR. CAINE: Objection, form.</p> <p>13 THE WITNESS: I, again, would say that I</p> <p>14 relied upon Dr. Do and her conclusion that 99 percent</p> <p>15 of the time, use of the product is consistent with</p> <p>16 the exclusion criteria.</p> <p>17 BY MR. CHOI:</p> <p>18 Q. Okay. So the only data point that you can</p> <p>19 reference with regard to the commercial success of</p> <p>20 Eylea and the excluding criteria are -- is Dr. Do's</p> <p>21 opinion, correct?</p> <p>22 A. I wouldn't say it that way. I did not</p> <p style="text-align: right;">Page 34</p>	<p>1 exclusion were followed or not?</p> <p>2 MR. CAINE: Objection, form.</p> <p>3 THE WITNESS: Again, I'm not aware of</p> <p>4 individual-level data that would allow me to do that</p> <p>5 analysis. And then -- so I rely upon Dr. Do.</p> <p>6 BY MR. CHOI:</p> <p>7 Q. Do you have any surveys saying that</p> <p>8 doctors do or do not practice these excluding</p> <p>9 criteria?</p> <p>10 A. I'm not aware of any. As I mentioned,</p> <p>11 Dr. Do references her practice and the practice of</p> <p>12 others that she considers typical.</p> <p>13 Q. But, so the primary opinion in your</p> <p>14 declaration here is that the eight-week dosing is a</p> <p>15 distinguishing factor compared to other products in</p> <p>16 the market, correct?</p> <p>17 A. Well, as I've said before, my conclusion</p> <p>18 is that the -- well, let me actually go to the --</p> <p>19 give you my three conclusions. In paragraph 18 of my</p> <p>20 statement, page 13, "Regarding the analyses and</p> <p>21 opinions presented in my prior declaration, I</p> <p>22 maintain my opinions that (1) Eylea has been a</p> <p style="text-align: right;">Page 36</p>
<p>1 suggest the minimization of her opinion. I think her</p> <p>2 opinion is well founded and she's a highly qualified</p> <p>3 expert, so I think relying on her is a reasonable</p> <p>4 thing to do.</p> <p>5 Q. But you don't have any data to support</p> <p>6 your position -- or, okay, strike that.</p> <p>7 But you don't have any data to show that</p> <p>8 exclusion criteria -- practicing exclusion criteria</p> <p>9 actually drives sales of Eylea, correct?</p> <p>10 MR. CAINE: Objection, form.</p> <p>11 THE WITNESS: I'm not aware of data that</p> <p>12 would allow that, allow an analysis of that -- of the</p> <p>13 type that I think you mean, but maybe I should ask</p> <p>14 what exactly you mean.</p> <p>15 BY MR. CHOI:</p> <p>16 Q. Okay. So, for example, can you explain</p> <p>17 how exclusion criteria drives sales? Like, for</p> <p>18 example, I mean, actually to elaborate, isn't</p> <p>19 exclusion, by definition, there is no sale, correct?</p> <p>20 A. If the exclusion is followed, that's</p> <p>21 correct.</p> <p>22 Q. So how would you determine whether those</p> <p style="text-align: right;">Page 35</p>	<p>1 commercially successful biologic therapy for</p> <p>2 angiogenic eye disorders; (2) Eylea's patented dosing</p> <p>3 regimen, including the differentiating eight-week</p> <p>4 recommended dosing interval in the maintenance phase</p> <p>5 has been an important driver of demand (and hence of</p> <p>6 commercial success); and (3) potential alternative</p> <p>7 explanations are not sufficient to explain Eylea's</p> <p>8 commercial success to the exclusion of the eight-week</p> <p>9 maintenance dosing interval."</p> <p>10 So, yes, the eight-week dosing interval is</p> <p>11 included in that opinion, but it is part of the</p> <p>12 analysis of the claim as a whole.</p> <p>13 Q. Do you have -- did you have any -- do you</p> <p>14 have any opinion as to whether the excluding criteria</p> <p>15 included in the '681 patent were a distinguishing</p> <p>16 factor compared to other products in the market?</p> <p>17 A. I do not. I identified the eight-week</p> <p>18 dosing interval as the key distinguishing factor.</p> <p>19 Q. So you have no opinion as to the</p> <p>20 excluding -- whether excluding criteria were a</p> <p>21 distinguishing factor compared to other products in</p> <p>22 the market for the Eylea commercial success analysis?</p> <p style="text-align: right;">Page 37</p>

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<p>1 A. Well, as indicated there, I identified the 2 eight-week dosing interval as the key distinguishing 3 factor. I don't actually know whether Lucentis has 4 similar exclusion criteria in its patents.</p> <p>5 Q. So you cannot associate the exclusion 6 criteria as relevant to whether it drives Eylea sales 7 or not, right?</p> <p>8 MR. CAINE: Objection. Excuse me. 9 Objection, form.</p> <p>10 THE WITNESS: To the extent that, as 11 again, I rely upon Dr. Do and her recitation of how 12 the exclusion criteria enter into the clinical 13 practice. I rely on her for that conclusion.</p> <p>14 BY MR. CHOI:</p> <p>15 Q. But, as you've said, you couldn't identify 16 exclusion criteria as the distinguishing factor 17 compared to other products in the market, correct? 18 You testified to that, correct?</p> <p>19 A. That is what I said. As I said, the 20 eight-week dosing interval is the distinguishing 21 characteristic among the characteristics of the 22 treatment regimen that I focused on.</p> <p style="text-align: right;">Page 38</p>	<p>1 Q. And if I understand you correctly, your 2 opinion is that by practicing the eight-week dosing, 3 you, based on Dr. Do's opinion that the exclusion 4 criteria are also practiced, correct?</p> <p>5 MR. CAINE: Objection, form.</p> <p>6 THE WITNESS: She describes a setting in 7 which the exclusion criteria are practiced nearly all 8 the time.</p> <p>9 BY MR. CHOI:</p> <p>10 Q. Okay. So Dr. Do doesn't talk about 11 whether the exclusion criteria were the 12 distinguishing factor for Eylea, correct?</p> <p>13 A. I don't recall her saying that. That's 14 true.</p> <p>15 Q. So is it your opinion that based on 16 Dr. Do's opinion, Eylea sales are not driven by the 17 inclusion of exclusion criteria --</p> <p>18 MR. CAINE: Object --</p> <p>19 BY MR. CHOI:</p> <p>20 Q. -- of the '681 patent, correct?</p> <p>21 MR. CAINE: Object to form.</p> <p>22 THE WITNESS: I wouldn't say that.</p> <p style="text-align: right;">Page 40</p>
<p>1 Q. So if you have no data to suggest that the 2 excluding criteria were not a distinguishing factor, 3 how is it possible the excluding criteria actually 4 drive sales of Eylea?</p> <p>5 A. Well, as Dr. Do describes, the exclusion 6 criteria are part of the treatment regimen. 7 Evaluating the patients to see whether or not the 8 exclusion criteria apply are part of the treatment 9 regimen that, you know, if -- I suppose you might 10 imagine a world in which there were no such exclusion 11 criteria and things went wrong, that could hurt 12 sales.</p> <p>13 So the fact that she describes them as she 14 does and understands and explains them as she does is 15 a way to conclude that the label -- or, sorry, the 16 patented claim as a whole, the treatment method as a 17 whole drives sales, drives success.</p> <p>18 Q. But again, I understand that your opinion 19 is that the eight-week dosing was a key 20 distinguishing factor for Eylea's commercial success, 21 correct?</p> <p>22 A. Correct.</p> <p style="text-align: right;">Page 39</p>	<p>1 BY MR. CHOI:</p> <p>2 Q. So what is your opinion?</p> <p>3 A. As I've said, I rely upon Dr. Do's 4 analysis and description of how the exclusion 5 criteria come into play in clinical treatment and the 6 evaluation of patients and whether or not they're 7 appropriate for -- to be appropriate to be treated 8 with Eylea and that, as part of the claimed treatment 9 regimen is what I have evaluated as to commercial 10 success of the product. But she identifies and 11 discusses the role of the exclusion criteria.</p> <p>12 Q. But you didn't specifically analyze the 13 extent to which the exclusion criteria drive 14 commercial success, correct?</p> <p>15 A. Beyond referencing her description and her 16 discussion that almost all the time patients either 17 are not excluded or, when they are excluded, it's 18 outside the patent in maybe 1 percent of cases, 19 that's what I concluded.</p> <p>20 Q. But you analyzed the extent to which the 21 eight-week dosing impacts sales of Eylea, correct?</p> <p>22 A. I did.</p> <p style="text-align: right;">Page 41</p>

<p>1 Q. But you did not do the same for the 2 exclusion criteria, correct?</p> <p>3 A. The same kind of analysis is not available 4 for exclusion criteria. I relied on Dr. Do for that 5 analysis.</p> <p>6 Q. So not available meaning you weren't able 7 to do the analysis, correct?</p> <p>8 A. Well, my reliance on her expertise and her 9 description of the typical practice is adequate in my 10 mind.</p> <p>11 Q. But as you said or as -- strike that. 12 So Dr. Do did not opine on whether the 13 exclusion criteria were a key distinguishing factor 14 for Eylea, correct?</p> <p>15 A. As I said, my recollection is I didn't see 16 that, but you'd have to ask her. I don't have that. 17 I don't know what's in her mind.</p> <p>18 Q. So if you had relied on her opinion that 19 it is not a key distinguishing factor, how is it 20 possible that exclusion criteria drive Eylea sales?</p> <p>21 MR. CAINE: Objection, form.</p> <p>22 THE WITNESS: I'm sorry, that's a</p> <p style="text-align: right;">Page 42</p>	<p>1 her describing the practice and the typical behavior 2 of physicians treating patients with the relevant 3 angiogenic eye disorders.</p> <p>4 Q. So Dr. Do's opinion is that it was not a 5 key distinguishing factor to include exclusion 6 criteria. Is that correct?</p> <p>7 MR. CAINE: Object to form.</p> <p>8 THE WITNESS: I don't remember her saying 9 that. I wouldn't agree with that.</p> <p>10 BY MR. CHOI:</p> <p>11 Q. But she didn't specifically call out 12 exclusion criteria as a key distinguishing factor for 13 Eylea, correct?</p> <p>14 A. I would have to review her testimony. I 15 don't remember seeing that. But, again, she may not 16 have said it in her testimony, but you would have to 17 ask her what she -- whether she views that as a key 18 distinguishing feature or not.</p> <p>19 Q. So what part of the exclusion criteria -- 20 or strike that.</p> <p>21 What part of Dr. Do's opinion about 22 exclusion criteria did you rely on to analyze the</p> <p style="text-align: right;">Page 44</p>
<p>1 hypothetical. You have to be -- give me a little 2 more detail.</p> <p>3 BY MR. CHOI:</p> <p>4 Q. Well, if you relied on her opinion that 5 the exclusion criteria are not a novel or key 6 distinguishing factor for Eylea, how is it possible 7 that you can say that exclusion criteria contributes 8 to the commercial success of Eylea?</p> <p>9 MR. CAINE: Objection, form.</p> <p>10 THE WITNESS: And I wouldn't agree that I 11 relied upon her opinion that it is not a 12 distinguishing characteristic. I don't recall her 13 saying that.</p> <p>14 BY MR. CHOI:</p> <p>15 Q. So you did not do an analysis of whether 16 the exclusion criteria are a key distinguishing 17 factor, correct?</p> <p>18 A. I think I said before that I don't know 19 the exclusion criteria if any that applied to 20 Lucentis or Avastin or other treatments. I don't 21 remember her saying that it is or is not an exclusion 22 criteria or a distinguishing factor. I just remember</p> <p style="text-align: right;">Page 43</p>	<p>1 commercial success of Eylea in relation to the '681 2 patent?</p> <p>3 A. So she describes the exclusion criteria 4 and how they play a role in treating patients. She 5 describes how, when a patient comes in and presents 6 with this condition or when they come in for a repeat 7 visit, she would analyze their eye health, do various 8 testing to determine whether or not their eyes were 9 healthy, whether or not they had these exclusionary 10 criteria, these infections, as I understand them, and 11 then make a determination about whether or not 12 treatment was appropriate.</p> <p>13 And her conclusion was that roughly, as I 14 recall -- I could -- I might not get these details 15 quite right -- but roughly 2 percent of the time 16 patients have what would be exclusionary conditions 17 and roughly half of that time or maybe 1 percent she 18 decides to treat anyway and she recognizes that when 19 she's doing that, she's going outside the bounds of 20 the patented treatment regimen. So that is -- the 21 fact that 99 percent of the time she follows this 22 treatment regimen means that that treatment regimen</p> <p style="text-align: right;">Page 45</p>

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<p>1 is part of the process that leads to the success of 2 the product.</p> <p>3 Q. So would you agree that physicians chose 4 Eylea because of the exclusion criteria?</p> <p>5 A. Again, I have not evaluated physician 6 choice based on that. I relied upon Dr. Do and her 7 description of how the exclusion criteria played a 8 role in treatment.</p> <p>9 Q. But you opined on the distinguishing -- 10 eight-week dosing as a distinguishing factor for 11 physicians and for Eylea's commercial success, 12 correct?</p> <p>13 A. Well, what I did is I, as I have said, I 14 identified the eight-week dosing interval in the 15 maintenance phase as the key distinguishing factor of 16 Eylea from Lucentis and Avastin, and evaluated the 17 relationship between that dosing interval and the 18 commercial success of the product.</p> <p>19 Q. Okay. So without the analysis of the 20 exclusion criteria, would your opinion of commercial 21 success of Eylea be different?</p> <p>22 MR. CAINE: Objection, form.</p> <p style="text-align: right;">Page 46</p>	<p>1 BY MR. CHOI:</p> <p>2 Q. So what would your opinion be if you 3 didn't consider the exclusion criteria?</p> <p>4 MR. CAINE: Objection, form.</p> <p>5 THE WITNESS: I would have to think about 6 that. I don't have an answer to that.</p> <p>7 BY MR. CHOI:</p> <p>8 Q. Didn't you provide the same opinion -- 9 well, strike that.</p> <p>10 So as part of your '338 IPR declaration, 11 didn't you provide your opinion as to the eight-week 12 dosing regimen being the driver of Eylea commercial 13 success to the exclusion of the exclusion criteria as 14 recited in the '681 patent, correct?</p> <p>15 MR. CAINE: Objection, form.</p> <p>16 THE WITNESS: So my recollection is that 17 the dosing regimen in the '338 patent is different. 18 So I don't think I -- I don't believe I discuss the 19 exclusion criteria.</p> <p>20 BY MR. CHOI:</p> <p>21 Q. Okay. I'm going to introduce -- well, 22 sorry. This is the institution decision that's</p> <p style="text-align: right;">Page 48</p>
<p>1 THE WITNESS: Well, I would like to keep 2 in mind that my assignment was to evaluate the 3 patented method of treatment and the patented method 4 of treatment has some different characteristics. I 5 have not done -- I've not gone through the steps of 6 saying, well, suppose this piece was not relevant, 7 how would my opinion change. So I don't really have 8 an answer to that.</p> <p>9 BY MR. CHOI:</p> <p>10 Q. But your declaration doesn't really talk 11 about anything related to exclusion criteria being 12 part of the driving force behind the Eylea commercial 13 sales, correct?</p> <p>14 A. I do reference Dr. Do and her description 15 of the treatment mechanism. That's the way in which 16 it is referenced there.</p> <p>17 Q. So is it your opinion that without the 18 exclusion criteria, there would still be commercial 19 success of Eylea, correct?</p> <p>20 MR. CAINE: Objection, form.</p> <p>21 THE WITNESS: I've not evaluated that 22 question.</p> <p style="text-align: right;">Page 47</p>	<p>1 issued in this IPR.</p> <p>2 MR. CAINE: Do you want to go off the 3 record?</p> <p>4 MR. CHOI: I'm okay, actually. (Manning Exhibit No. 1 was marked for the record.)</p> <p>7 BY MR. CHOI:</p> <p>8 Q. So if we take a look at page 15. So do 9 you recognize this document, Dr. Manning?</p> <p>10 A. I see what it is. I'm not certain that 11 I've reviewed it. I may have. I don't have a 12 specific memory of whether or not I reviewed it.</p> <p>13 Q. Okay. So on page 14, do you see a table 14 there?</p> <p>15 A. I do.</p> <p>16 Q. And do you see that the board is comparing 17 claim 1 of the '338 patent and claim 1 of the '681 18 patent?</p> <p>19 A. I do.</p> <p>20 Q. And on page 15, the first paragraph, could 21 you read the first sentence?</p> <p>22 A. "As should be readily apparent to the</p> <p style="text-align: right;">Page 49</p>

<p>1 reader, challenged claim 1 of the present petition</p> <p>2 and claim 1 of the '338 patent are identical, with</p> <p>3 the sole exception in the '681 patent of the</p> <p>4 additional limitation reciting the exclusion</p> <p>5 criteria. Because, in the 00881 decision, we</p> <p>6 concluded that claim 1 of the '338 patent is</p> <p>7 anticipated by Dixon, we incorporate here by</p> <p>8 reference and adopt our reasoning in the 00881</p> <p>9 decision with respect to the corresponding</p> <p>10 limitations of claim 1 of the '681 patent. See 00881</p> <p>11 Decision, 26-46. We therefore conclude that</p> <p>12 petitioner has demonstrated sufficiently that those</p> <p>13 limitations of claim 1 of the '681 patent are taught</p> <p>14 by Dixon."</p> <p>15 Q. So here you see the comparison of the</p> <p>16 claims of the '681 patent and the '338 patent,</p> <p>17 correct?</p> <p>18 A. I do see a table that shows parallel</p> <p>19 columns with claims, with claim 1 headings that have</p> <p>20 various entries but, you know, the legal implications</p> <p>21 of that, I -- I'm not a lawyer.</p> <p>22 Q. In the last row of the table, which is</p> <p style="text-align: right;">Page 50</p>	<p>1 A. The eight-week dosing interval, as I've</p> <p>2 said, in the maintenance phase is the key</p> <p>3 distinguishing factor, and so it does apply. It was</p> <p>4 relevant in the '338 patent and it is relevant here.</p> <p>5 Q. So the same -- so is it your opinion in</p> <p>6 this case that the '338 patent, without the exclusion</p> <p>7 criteria, drove Eylea sales, correct?</p> <p>8 A. I'm sorry --</p> <p>9 MR. CAINE: Object to form.</p> <p>10 THE WITNESS: I said I'm sorry, I didn't</p> <p>11 understand the question.</p> <p>12 BY MR. CHOI:</p> <p>13 Q. So when I asked earlier about whether your</p> <p>14 opinion would change if you didn't consider excluding</p> <p>15 criteria of '681 patent, you said you don't know,</p> <p>16 correct?</p> <p>17 A. I said I hadn't evaluated that and would</p> <p>18 have to think about it.</p> <p>19 Q. But isn't your declaration for the '338</p> <p>20 patent essentially that same analysis without the</p> <p>21 excluding criteria?</p> <p>22 A. The '338 patent declaration does evaluate</p> <p style="text-align: right;">Page 52</p>
<p>1 page 15, do you see that '681 patent has the recited</p> <p>2 excluding criteria we've been talking about, and the</p> <p>3 '338 patent is identical other than those excluding</p> <p>4 criteria, correct?</p> <p>5 A. What I see is that there is no entry in</p> <p>6 the second row or second column of the last row and</p> <p>7 that the first column, which appears to be the claims</p> <p>8 of the '681 patent, does have the three exclusion</p> <p>9 criteria.</p> <p>10 Q. So the '681 patent has the same dosing</p> <p>11 regimen but also includes the excluding criteria,</p> <p>12 correct?</p> <p>13 A. The words look the same on that table,</p> <p>14 yes.</p> <p>15 Q. So you have submitted a declaration in the</p> <p>16 '338 patent IPR and rely on that declaration in</p> <p>17 support of your opinions here in this proceeding,</p> <p>18 correct?</p> <p>19 A. Yes.</p> <p>20 Q. And the '338 patent is essentially the</p> <p>21 same eight-week dosing regimen without the excluding</p> <p>22 criteria, correct?</p> <p style="text-align: right;">Page 51</p>	<p>1 the eight-week dosing interval in the maintenance</p> <p>2 phase. That is the key distinguishing characteristic</p> <p>3 that I identify in this declaration between Eylea and</p> <p>4 Lucentis, and Avastin by extension, again noting that</p> <p>5 Avastin used off label. But are there other elements</p> <p>6 of it that I would think about if I spent time trying</p> <p>7 to distinguish between the two? I don't know. I</p> <p>8 haven't carefully thought through that question.</p> <p>9 Q. So it's your opinion that you -- your</p> <p>10 opinion wouldn't change without -- I mean, your</p> <p>11 opinion wouldn't change if you don't consider the</p> <p>12 exclusion criteria, correct?</p> <p>13 MR. CAINE: Objection, form.</p> <p>14 THE WITNESS: And I would say that within</p> <p>15 the context of this particular proceeding, I have not</p> <p>16 evaluated that question.</p> <p>17 BY MR. CHOI:</p> <p>18 Q. But you evaluated that question as part of</p> <p>19 the '338 patent IPR, correct, which you rely on in</p> <p>20 this proceeding?</p> <p>21 MR. CAINE: Objection, form.</p> <p>22 THE WITNESS: Well, in that proceeding, I</p> <p style="text-align: right;">Page 53</p>

<p>1 relied upon the same evidence that I rely upon in 2 this proceeding, that's correct. 3 BY MR. CHOI: 4 Q. But as you see here in this page 14 and 15 5 of the institution decision, you see that the claims 6 are identical other than the excluding criteria, 7 correct? 8 A. As I said before, I'm not an attorney and 9 I don't -- so there may be reasons that one would 10 want to think about from a legal perspective that I'm 11 either not aware of or not equipped to consider and 12 determine, but I do see that as you have -- as is 13 illustrated on this table, that that is the only 14 difference that is highlighted here. 15 Q. And you didn't consider the exclusion 16 criteria as part of your analysis for the '338 patent 17 IPR, correct? 18 A. My recollection is that I did not. The 19 exclusion criteria were not part of that proceeding. 20 Q. And your opinion as to the '338 patent's 21 extended eight-week dosing applies equally to the -- 22 to the analysis of commercial success with regard to</p> <p style="text-align: right;">Page 54</p>	<p>1 if the commercial success is due to an unclaimed 2 feature or device, the commercial success is 3 irrelevant." 4 Q. So when you say I understand that the 5 commercial success but not relate exclusively to a 6 feature that was known in the prior art, what do you 7 mean by that? 8 A. Well, that's largely a legal concept that 9 I was given by counsel as a guideline, guide rail 10 perhaps to follow, but that if something is not 11 novel, then it can't be the basis of a commercial 12 success analysis. That's my economist's 13 understanding. 14 Q. So what is your understanding of something 15 being novel? 16 A. Again, there might be legal definitions 17 but to an economist, something that is novel is 18 something that is new or not generally understood to 19 be available or true or in use or -- but, again, 20 that's an economist's description of the term. 21 Q. Okay. And so going back to page 15 of the 22 institution decision, so the Board states, "As should</p> <p style="text-align: right;">Page 56</p>
<p>1 the '681 patent, correct? 2 A. I'm sorry, that's a long question. I -- 3 Q. Yeah. So your opinion as to the '338 4 patent's -- strike that. 5 So your opinion as to the '338 patent's 6 extended eight-week dosing applies equally to the 7 analysis of the '681 patent in this proceeding, 8 correct? 9 A. I believe that's correct, yes. The key 10 distinguishing feature, as I describe in my 11 declaration, is the eight-week dosing interval. 12 Q. So if you go back to page 6 and 13 paragraph 11 of your declaration in this proceeding, 14 could you state -- could you read the -- I guess the 15 top of page 6, please? 16 A. "Additionally" -- that's where you want me 17 to read? 18 Q. Yes. 19 A. "Additionally, I understand that the 20 commercial success must not relate exclusively to a 21 feature that was known in the prior art. I further 22 understand that Federal Circuit case law holds that</p> <p style="text-align: right;">Page 55</p>	<p>1 be readily apparent to the reader, challenged claim 1 2 of the present petition and claim 1 of the '338 3 patent are identical." And then it states, "We 4 incorporate here by reference and adopt our reasoning 5 in the 00881 decision with respect to the 6 corresponding limitations of claim 1 of the '681 7 patent. We therefore conclude that petitioner has 8 demonstrated sufficiently that those limitations of 9 claim 1 of the '681 patent are taught by Dixon." 10 Do you see that? 11 A. I do. 12 Q. So would your opinion change here if the 13 eight-week extended dosing was known in the art? 14 A. Well, I guess my opinion about the 15 relevance of its important for driving success would 16 not change, no. 17 Q. But on -- in paragraph 11, didn't you 18 state that, "I further" -- "I understand that the 19 commercial success must not relate exclusively to a 20 feature that was known in the prior art," correct? 21 A. Well, I would differentiate between what 22 the economics analysis suggests and what the legal</p> <p style="text-align: right;">Page 57</p>

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<p>1 implications or ramifications might be. It seems to 2 me from an economic perspective that it is 3 essentially indisputable that the eight-week dosing 4 interval as embodied in this set of claims is a 5 driver of success, and beyond that seems to be a 6 legal question.</p> <p>7 Q. But in your declaration, you said that if 8 a feature that was known in the art is related to the 9 commercial success of the product, then the 10 commercial success cannot be shown or has no nexus, 11 right?</p> <p>12 MR. CAINE: Objection, form.</p> <p>13 THE WITNESS: It -- well, no, what I say 14 is that the commercial success but not relate 15 exclusively to a feature that was known in the prior 16 art. So for -- as a legal guideline, legal guide 17 rail, that's one question. As an economic 18 phenomenon, it is highly -- it is, as I said, from my 19 perspective, indisputable that the eight-week dosing 20 interval is a key driver of success for -- of the 21 product Eylea.</p> <p>22 BY MR. CHOI:</p> <p style="text-align: right;">Page 58</p>	<p>1 was known in the art. Will that change your opinion 2 here?</p> <p>3 A. Well, what do you mean, "say that it was"? 4 I mean --</p> <p>5 Q. Well, so you say, "I understand that the 6 commercial success must not relate exclusively to a 7 feature that was known in the prior art." Say that 8 the feature that you're -- that's referenced here is 9 the eight-week extended dosing. If it was known in 10 the prior art, according to what you say here in your 11 declaration, would that change your opinion in this 12 case?</p> <p>13 A. I'm having a little trouble because the -- 14 with your question because the -- it has a legal 15 component that I differentiate from the economic 16 component of it. I mean, if it was known in the 17 art -- and that's a legal issue that is not for me to 18 address -- then I'm not sure why I would even be 19 here. If it were not -- if it were not an element of 20 commercial success -- or not an element that was 21 eligible for consideration as part of commercial 22 success, then my opinion wouldn't matter.</p> <p style="text-align: right;">Page 60</p>
<p>1 Q. So in assessing your -- in assessing 2 commercial success of Eylea, did you take into 3 account what was known or not known in the prior art?</p> <p>4 A. Known or not known in the prior art is a 5 legal issue that is not my expertise or assignment.</p> <p>6 Q. So you did not consider that?</p> <p>7 A. Well, I understand there are others such 8 as Dr. Brown who discuss the prior art and I relied 9 upon his view of that. My analysis was to look at 10 the claims as embodied in the -- as described in the 11 patent and to evaluate the key distinguishing feature 12 of those claims. And that's an economic exercise. 13 It's not a legal exercise.</p> <p>14 Q. But your declarations say that the 15 commercial success must not relate exclusively to a 16 feature that was known in the prior art, right?</p> <p>17 A. Those words are there, yes.</p> <p>18 Q. So that -- I mean, those are your words?</p> <p>19 A. Well, those are the understanding I have 20 about the legal issues. That's not the economic -- 21 that's not necessarily the economic issue.</p> <p>22 Q. Say that the eight-week extended dosing</p> <p style="text-align: right;">Page 59</p>	<p>1 Q. So you agree that if the eight-week 2 extended dosing was found to be known in the art, 3 your opinion as to the commercial success of Eylea 4 would irrelevant?</p> <p>5 MR. CAINE: Objection, form.</p> <p>6 THE WITNESS: No, I wouldn't say that. I 7 would say that if there are legal reasons why 8 commercial success is no longer relevant, then my 9 opinion would not be relevant. But I -- you know, 10 those are legal issues. Those are not economic 11 issues.</p> <p>12 MR. CHOI: Okay. Why don't we take a 13 10-minute break.</p> <p>14 MR. CAINE: Yeah, let's do that.</p> <p>15 THE VIDEOGRAPHER: The time is 10:21 a.m. 16 We are now off the record.</p> <p>17 (Recess.)</p> <p>18 THE VIDEOGRAPHER: This is the beginning 19 of media unit 2 in the video recorded deposition of 20 Mr. Richard Manning. The time is 10:37 a.m. Eastern. 21 We're now back on the record.</p> <p>22 Counsel, you may proceed.</p> <p style="text-align: right;">Page 61</p>

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<p>1 BY MR. CHOI:</p> <p>2 Q. Welcome back, Dr. Manning. So before the</p> <p>3 break, you had mentioned that the eight-week extended</p> <p>4 dosing was a key distinguishing feature of the '681</p> <p>5 patent, correct?</p> <p>6 A. That's what I say in my report and my</p> <p>7 declaration, yes.</p> <p>8 Q. Hold on. I think -- is this not working?</p> <p>9 The live feed. Apologies.</p> <p>10 So you had opined that the eight-week</p> <p>11 extended dosing was the key distinguishing feature,</p> <p>12 correct?</p> <p>13 A. A key distinguishing feature of the</p> <p>14 patented claims, yes.</p> <p>15 Q. How about the Eylea product?</p> <p>16 A. The Eylea product is, as I understand, the</p> <p>17 VEGF inhibitor that is covered by the claim so, yes,</p> <p>18 Eylea as a product is part of the claim and that is</p> <p>19 the product that I evaluated.</p> <p>20 Q. So in your opinion, what does it mean by</p> <p>21 key distinguishing feature?</p> <p>22 A. Something that is different, distinct.</p> <p style="text-align: right;">Page 62</p>	<p>1 A. It contributes to those sales, yes.</p> <p>2 That's the -- that's what my opinion says.</p> <p>3 Q. So what other key distinguishing features</p> <p>4 are there with respect to Eylea?</p> <p>5 A. I have not identified any that were</p> <p>6 observable in the economic analysis that I did.</p> <p>7 There might be other distinguishing features that are</p> <p>8 either not observably different or for which there</p> <p>9 are not data that are observable, but that is the</p> <p>10 observable feature within this treatment paradigm or</p> <p>11 treatment regime that I focused on.</p> <p>12 Q. So would you agree that the only key</p> <p>13 distinguishing feature that you focus on in your</p> <p>14 declaration in this proceeding is the eight-week</p> <p>15 extended dosing?</p> <p>16 A. Well, in this proceeding, as I've said</p> <p>17 before, my assignment was to focus on the claimed</p> <p>18 method of treatment as a whole and so that's what I</p> <p>19 did, including relying upon Dr. Do's assessment of</p> <p>20 the exclusionary criteria and looking at the, you</p> <p>21 know, all of the treatment regime from initiation to</p> <p>22 maintenance dosing and observing that the eight-week</p> <p style="text-align: right;">Page 64</p>
<p>1 Q. Different compared to what?</p> <p>2 A. Well, in this context, it was different</p> <p>3 compared to the other products in the competitive</p> <p>4 space or that are alternatively used to treat these</p> <p>5 same conditions, so primarily Avastin and Lucentis in</p> <p>6 my work.</p> <p>7 Q. So is it the fact that the eight-week</p> <p>8 dosing is a key distinguishing feature of Eylea, is</p> <p>9 that relevant to the commercial success analysis of</p> <p>10 Eylea?</p> <p>11 A. I believe it is, yes. So the product at</p> <p>12 issue here is Eylea and Eylea is the only product</p> <p>13 that I'm aware of -- well, there might be biosimilars</p> <p>14 or potential biosimilars, I guess, but the only -- of</p> <p>15 other products. But Eylea is the product that is</p> <p>16 covered by this patent and this method of treatment</p> <p>17 and the eight-week distinguishing feature is part of</p> <p>18 Eylea's characteristics. And so in my analysis, I</p> <p>19 looked at the performance of Eylea compared to the</p> <p>20 other products.</p> <p>21 Q. So would you say the key distinguishing</p> <p>22 feature of Eylea drives sales of Eylea?</p> <p style="text-align: right;">Page 63</p>	<p>1 dosing interval was the key distinguishing feature</p> <p>2 that was observable and that I had analyzed for the</p> <p>3 '338 patent.</p> <p>4 Q. So you didn't do an economics analysis of</p> <p>5 the exclusion criteria other than your reliance on</p> <p>6 Dr. Do's opinion, correct?</p> <p>7 A. Well, I guess I would want to know what</p> <p>8 you really mean by economic analysis.</p> <p>9 Q. So in your '338 declaration which you rely</p> <p>10 on, you go through surveys and potentially other</p> <p>11 evidence, alleged evidence that suggests that doctors</p> <p>12 do practice these extended dosing and that these</p> <p>13 extending dosing of Eylea is a reason that Eylea has</p> <p>14 become such a big commercial success in the market,</p> <p>15 correct?</p> <p>16 A. I do evaluate the -- what the data say</p> <p>17 about the performance of the product relative to its</p> <p>18 competitors and I did look at how that eight-week</p> <p>19 dosing interval from an economic perspective would</p> <p>20 play into demand for the product, establishing the</p> <p>21 basis that a product that has less of the negative</p> <p>22 characteristic than other products but have a greater</p> <p style="text-align: right;">Page 65</p>

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<p>1 demand than those other products and went through a</p> <p>2 variety of other analyses to show that the product</p> <p>3 had been a commercial success. So those were all</p> <p>4 economic analyses of different types.</p> <p>5 Q. Okay. And you just stated, quote, I did</p> <p>6 look at how the eight-week dosing interval between --</p> <p>7 sorry. Okay. So you stated just now, quote, I did</p> <p>8 look at how that eight-week dosing interval from an</p> <p>9 economic perspective would play into demand for</p> <p>10 product.</p> <p>11 Did you do the same analysis for the</p> <p>12 exclusion criteria?</p> <p>13 A. In the '338 IPR?</p> <p>14 Q. For this proceeding.</p> <p>15 A. Well, as I said, looking at Dr. Do's</p> <p>16 statement and considering that there's a treatment</p> <p>17 method that includes evaluation of that -- those</p> <p>18 exclusionary criteria that is in place 99 percent of</p> <p>19 the time or that is applied 99 percent of the time,</p> <p>20 that suggests that that is part of the constellation</p> <p>21 of factors that leads to the demand for and therefore</p> <p>22 the commercial success of the product.</p> <p style="text-align: right;">Page 66</p>	<p>1 Q. Well, you had said earlier that you're</p> <p>2 able to do an economics -- you're able to do an</p> <p>3 evaluation of whether the eight-week dosing</p> <p>4 contributes to Eylea's commercial success from an</p> <p>5 economic perspective, so I defer to you what your</p> <p>6 understanding of economics analysis is.</p> <p>7 A. So --</p> <p>8 MR. CAINE: Objection, form.</p> <p>9 THE WITNESS: So an economic analysis can</p> <p>10 take a variety of forms. There are times at which</p> <p>11 data are -- so the data that I analyzed to</p> <p>12 demonstrate the relationship between the dosing</p> <p>13 interval and the maintenance dosing interval of Eylea</p> <p>14 as compared to the other products and its commercial</p> <p>15 performance is one way to do that.</p> <p>16 The analysis that I've just described</p> <p>17 wherein you think about the demand for the product</p> <p>18 and how, based on economic theory or economic</p> <p>19 principles, a product that has less of a negative</p> <p>20 characteristic is going to be more demanded than a</p> <p>21 product that doesn't have a negative characteristic,</p> <p>22 that's not necessarily reliant upon data, but upon</p> <p style="text-align: right;">Page 68</p>
<p>1 Q. But you didn't specifically analyze the</p> <p>2 exclusion criteria as a driving factor for the</p> <p>3 commercial success, right?</p> <p>4 A. As I said previously, I'm not aware of any</p> <p>5 data that would have allowed that kind of analysis.</p> <p>6 Although looking at Dr. Do and recognizing that</p> <p>7 essentially this is a consideration that applies to</p> <p>8 virtually all of the use, then that is a form of</p> <p>9 economic analysis or thinking about this criteria or</p> <p>10 this process is evaluating -- is associated with</p> <p>11 almost all of the use of this product.</p> <p>12 Q. But Dr. Do's opinion is not one of</p> <p>13 economics, right?</p> <p>14 A. That's true. She is a physician.</p> <p>15 Q. And how is it possible that you provide an</p> <p>16 economics analysis of the exclusion criteria where</p> <p>17 you don't rely on any data or opinion of Dr. Do that</p> <p>18 is not in the economics nature?</p> <p>19 MR. CAINE: Objection, form.</p> <p>20 THE WITNESS: Well, when you say it's not</p> <p>21 economic in nature, I guess -- how do you mean that?</p> <p>22 BY MR. CHOI:</p> <p style="text-align: right;">Page 67</p>	<p>1 the logic and principles of economics.</p> <p>2 Another feature that has -- that is always</p> <p>3 present or virtually always present can likewise be</p> <p>4 thought of as having economic content, if not the</p> <p>5 same type of analysis, but it is the analysis that an</p> <p>6 economist could look at and say, well, here is a</p> <p>7 feature of this treatment regimen that applies almost</p> <p>8 all the time and it contributes to the product's</p> <p>9 utilization which contributes to the product's</p> <p>10 commercial success.</p> <p>11 BY MR. CHOI:</p> <p>12 Q. So where in your declaration do you do an</p> <p>13 analysis, economics analysis of the exclusion</p> <p>14 criteria?</p> <p>15 A. Well, as I just explained, economic</p> <p>16 analysis can take different forms and reliance</p> <p>17 upon -- when there are no other data, just as I</p> <p>18 explained to you that the economic theory of demand</p> <p>19 in terms of having less of a negative characteristic</p> <p>20 can lead to the conclusion that having that less of a</p> <p>21 negative characteristic can drive demand, having a</p> <p>22 feature that is always present or virtually always</p> <p style="text-align: right;">Page 69</p>

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<p>1 present likewise can be thought of as contributing to 2 demand.</p> <p>3 Q. So where do you state that in your 4 declaration?</p> <p>5 A. I don't know that I say that explicitly, 6 but it is in my reference to Do, to Dr. Do's 7 declaration as her description of the use of the 8 product in clinical practice.</p> <p>9 Q. Can you point to me to a specific 10 paragraph that where you discuss the relevance of the 11 exclusion criteria for a driving factor as you just 12 testified?</p> <p>13 MR. CAINE: Objection, form.</p> <p>14 THE WITNESS: I would point to paragraph 15 16, top of page 10, referencing footnote 14, 16 referencing Dr. Do's declaration where I stated that 17 I understand that Eylea is administered according to 18 the claimed dosing regimen. That is my link to 19 Dr. Do and her description of how the various 20 features of the product dosing schedule as described 21 in the patent relate to the product's clinical 22 utilization.</p> <p style="text-align: right;">Page 70</p>	<p>1 between the exclusion criteria and the commercial 2 success of Eylea?</p> <p>3 A. Well, there is another place in which I 4 reference the exclusion criteria, but that -- you 5 know, as I said, there aren't data that would allow a 6 specific evaluation of that question and so I rely on 7 Dr. Do.</p> <p>8 Q. So again, your analysis of the exclusion 9 criteria is based on Dr. Do's opinion only, correct?</p> <p>10 A. I think Dr. Brown also references the 11 patented dosing regime and so there is consistency 12 between them about the clinical practice and the 13 dosing regimen that is outlined in the patent.</p> <p>14 Q. But with respect to the exclusion 15 criteria, you only rely on Dr. Do's opinion, correct?</p> <p>16 A. I go back to my prior statement that, you 17 know, I wouldn't use the word "only" in the sense 18 that she's a well regarded, highly-qualified expert 19 and so to only rely on her, I wouldn't minimize it in 20 that way.</p> <p>21 Q. Well, you would rely on her expert opinion 22 about the exclusion criteria when you're providing</p> <p style="text-align: right;">Page 72</p>
<p>1 BY MR. CHOI:</p> <p>2 Q. So this paragraph, paragraph 16, doesn't 3 talk about a product utilization or whether you have 4 any data to support the notion that Eylea sales is 5 tied to the specific exclusion criteria as claimed by 6 the patent, correct?</p> <p>7 A. I wouldn't agree with that, no.</p> <p>8 Q. So where does it say utilization?</p> <p>9 A. Well, what you said is I don't -- you said 10 it's not related to the product's use, but it does 11 say that. It says I understand that Eylea is 12 administered according to the claimed dosing regimen, 13 which means its use is consistent with the claimed 14 dosing regimen. So its utilization, its demand is 15 related to the dosing regimen. And that dosing 16 regimen is included in the -- sorry, the exclusion 17 criteria are included in the dosing regimen in the 18 patent.</p> <p>19 Q. So this is just one sentence. I 20 understand that Eylea is administered according to 21 the claimed dosing regimen. That's the only instance 22 you can refer to that talk about the relationship</p> <p style="text-align: right;">Page 71</p>	<p>1 your opinion on the -- strike that.</p> <p>2 So is it accurate to state that you only 3 rely on her expert opinion on the exclusion criteria 4 as relevant factor for the commercial success of 5 Eylea?</p> <p>6 A. No. No. I rely on her opinion for her 7 description of how the claim in total relates to 8 clinical practice and her claim in total or the claim 9 in total includes the exclusion criteria, and she 10 does address those exclusion criteria. She also 11 addresses the other elements of the claim, and all of 12 those are relevant to how physicians in practice 13 follow the claimed method of treatment.</p> <p>14 Q. But you agree that exclusion criteria are 15 not part of the key distinguishing factor for the 16 Eylea product, correct?</p> <p>17 MR. CAINE: Objection, form.</p> <p>18 THE WITNESS: In the '338 patent 19 analysis --</p> <p>20 BY MR. CHOI:</p> <p>21 Q. No, for the '681 patent. For this patent.</p> <p>22 A. Well, my answer was that in the '338</p> <p style="text-align: right;">Page 73</p>

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<p>1 analysis, which is what I refer to, that was not 2 identified as a key distinguishing factor. And I did 3 not identify that as a key distinguishing factor in 4 this analysis, that's correct.</p> <p>5 Q. Okay. So have you done any analysis from 6 Regeneron's technical experts confirming that the 7 sales of Eylea that you analyzed actually fall within 8 the scope of the claims?</p> <p>9 A. I guess I don't understand the question.</p> <p>10 Q. So have you talked to any experts, 11 including Dr. Do, whether Eylea practices the claims 12 of the '681 patent?</p> <p>13 A. Well, practice is a legal term. I guess 14 I -- you know, what I -- I'm not sure I understand 15 the point of the question.</p> <p>16 Q. Well, so in order for there to be a nexus 17 between commercial success and the patented invention 18 of the '681 patent, you have to recognize that the 19 product itself has to embody multiple features of the 20 '681 patent, correct?</p> <p>21 MR. CAINE: Objection, form.</p> <p>22 BY MR. CHOI:</p> <p style="text-align: right;">Page 74</p>	<p>1 use the product in accordance with the patented 2 dosing regimen.</p> <p>3 Q. Okay. So you did talk to other experts 4 about the scope of the '681 patent and whether the 5 sales of Eylea actually fall within the scope?</p> <p>6 MR. CAINE: Objection, form.</p> <p>7 THE WITNESS: As I said, I did not talk to 8 them as to -- for this -- as I was preparing this 9 declaration. I spoke to them in the process of doing 10 the first declaration for the '338 patent.</p> <p>11 And again, I wouldn't say -- I don't know 12 necessarily what, you know, legally you mean when you 13 say "within the scope." What I would have talked 14 about is, you know, so tell me about this product, 15 its use and how, from an economic perspective, I 16 might understand how this product fits into the 17 constellation of other products that are available. 18 And then I would have been told about what typical 19 use is, what typical prescribing patterns and 20 administration patterns are like. I wouldn't have 21 asked in legal terms, you know, whether it was within 22 the scope of the patent or not because that's not my</p> <p style="text-align: right;">Page 76</p>
<p>1 Q. That is what your declaration says. I'm 2 just confirming that with you.</p> <p>3 A. Well, I do believe that the -- while your 4 original question was whether I had talked to any of 5 the Regeneron experts for this specific declaration? 6 No. I only referred to their statements. For prior 7 work, I have spoken with Dr. Do and Dr. Brown but --</p> <p>8 Q. And in your prior work for the '338 9 patent, for example, did you talk about whether the 10 sales of Eylea that you rely on for your commercial 11 success analysis fall within the scope of the claims 12 of the '681 patent or through the '338 patent?</p> <p>13 MR. CAINE: Objection, form.</p> <p>14 THE WITNESS: Did I ask them whether the 15 sales fell within the scope?</p> <p>16 BY MR. CHOI:</p> <p>17 Q. Yep.</p> <p>18 A. I guess there are legal/technical words 19 there that I'm not sure I would -- I wouldn't have 20 asked about. But, again, I've referenced their 21 statements that clearly demonstrate that the common 22 clinical practice, typical clinical practice is to</p> <p style="text-align: right;">Page 75</p>	<p>1 area of expertise.</p> <p>2 BY MR. CHOI:</p> <p>3 Q. So based on your discussions with your -- 4 with other experts and your understanding of the 5 declarations both here and in prior IPRs, is it your 6 understanding that typical clinical practice is to 7 follow the claimed dosing regimen of the '681 patent?</p> <p>8 A. In particular, Dr. Do goes through the 9 claims of the '681 patent and does describe how 10 clinical practice lines up with those claims.</p> <p>11 Q. Okay. So have you seen any data 12 confirming that Eylea sales were actually used 13 according to the claimed dosing regimen?</p> <p>14 A. I'm sorry, the Eylea -- I didn't 15 understand your question.</p> <p>16 Q. I'm sorry. Yeah, I'll repeat. 17 Have you seen any data confirming that 18 Eylea sales were actually used according to the 19 dosing regimen in the '681 patent?</p> <p>20 MR. CAINE: Objection, form.</p> <p>21 THE WITNESS: That Eylea's sales were 22 used? I guess I'm not understanding what you mean.</p> <p style="text-align: right;">Page 77</p>

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<p>1 BY MR. CHOI:</p> <p>2 Q. Eylea sales were associated with the</p> <p>3 dosing regimen of the '681 patent?</p> <p>4 A. Well, as you know, my analysis in the '338</p> <p>5 patent looks at a variety of indicators of how the</p> <p>6 sales of the product grow over time and how the key</p> <p>7 distinguishing feature is related to the growth in</p> <p>8 those sales, and there are survey data and others</p> <p>9 that show that the -- that feature is a driver of</p> <p>10 demand, that physicians were looking for or wanted a</p> <p>11 longer treatment interval in the maintenance phase</p> <p>12 and that in fact physicians use it in the --</p> <p>13 according to that dosing interval that's in the</p> <p>14 claimed methods of treatment.</p> <p>15 So, yes, I guess I would say I've seen</p> <p>16 quite a few data points or elements of data that</p> <p>17 confirm that.</p> <p>18 Q. So it's your understanding that the</p> <p>19 eight-week dosing is typical practice for physicians</p> <p>20 nowadays?</p> <p>21 MR. CAINE: Objection, form.</p> <p>22 THE WITNESS: It is the most common dosing</p> <p style="text-align: right;">Page 78</p>	<p>1 based on that, did you determine how many of these</p> <p>2 sales were made -- these sales are associated with</p> <p>3 the extended dosing of the '681 patent?</p> <p>4 A. In this table, that's not the question.</p> <p>5 This table is setting the stage, providing background</p> <p>6 for, you know, how many total injections are given by</p> <p>7 different disease state or different indications for</p> <p>8 which it might be used. It's also for -- you know,</p> <p>9 it's -- and so it includes initial doses, secondary</p> <p>10 doses, tertiary doses and my recollection is that</p> <p>11 it -- well, it is not -- it is not at this point</p> <p>12 concerned with the question of whether or not the</p> <p>13 dosing is being done on an eight-week interval or not</p> <p>14 for Eylea. So it's -- and it's also for anti-VEGFs.</p> <p>15 It's not just for Eylea.</p> <p>16 So this is just trying to set the stage</p> <p>17 and explain that what AMD is the most prominent</p> <p>18 condition for which these products are used, followed</p> <p>19 by the others as indicated in the percent of total</p> <p>20 injections in 2021.</p> <p>21 Q. So in your declaration, did you do an</p> <p>22 analysis of sales that are associated with the dosing</p> <p style="text-align: right;">Page 80</p>
<p>1 interval in the maintenance phase. Eight weeks or</p> <p>2 longer is the most common dosing interval according</p> <p>3 to the data that I've seen. It is not always used,</p> <p>4 obviously, but it is a very common and, from the data</p> <p>5 I've seen, the most common treatment interval in the</p> <p>6 maintenance phase.</p> <p>7 BY MR. CHOI:</p> <p>8 Q. Okay. Did you do any analysis to</p> <p>9 determine how many Eylea sales were attributable to</p> <p>10 each indication that's approved for Eylea?</p> <p>11 A. My '338 report does show market share or,</p> <p>12 sorry, sales shares by indication, and some of, many,</p> <p>13 not all of the survey data, the ATU surveys that I</p> <p>14 used in that analysis look at the utilization by</p> <p>15 indication. Some of the data don't allow that</p> <p>16 disaggregated look but some of them do.</p> <p>17 Q. Okay. So let's take a look at table 1 of</p> <p>18 your '338 patent declaration. It is on page 26 of</p> <p>19 289.</p> <p>20 So for -- to come up with this analysis</p> <p>21 here, table 1, which shows the total injections per</p> <p>22 indication and division of percent total injections</p> <p style="text-align: right;">Page 79</p>	<p>1 regimen of the '681 patent specifically?</p> <p>2 A. What do you mean?</p> <p>3 Q. So here in this table, it seems like</p> <p>4 sales, or the injection -- is per-injection basis</p> <p>5 statistics, correct?</p> <p>6 A. Yes.</p> <p>7 Q. And have you done an analysis of</p> <p>8 per-dosing regimen basis sales analysis of Eylea?</p> <p>9 A. Well, there are a variety of places where</p> <p>10 the utilization rates or the most frequent dosing</p> <p>11 intervals are discussed in the report where I talk</p> <p>12 about the eight-week dosing interval being the most</p> <p>13 common dosing interval for Eylea. And so, yes.</p> <p>14 Q. But you don't have any sales data that</p> <p>15 reflect the fact that physicians followed the</p> <p>16 extended dosing regimen of the '681 patent, right?</p> <p>17 MR. CAINE: Objection, form.</p> <p>18 THE WITNESS: Well, the extended dosing</p> <p>19 regimen in the '338 analysis is the same as the</p> <p>20 extended dosing analysis for the '681 patent and that</p> <p>21 is how -- that's why I rely on the '338 analysis.</p> <p>22 BY MR. CHOI:</p> <p style="text-align: right;">Page 81</p>

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<p>1 Q. Right. But my question was you don't have 2 actual sales data to reflect that, to reflect the 3 fact that physicians actually used Eylea according to 4 the specific eight-week extended dosing, correct? 5 MR. CAINE: Objection, form. 6 THE WITNESS: I wouldn't say that. I 7 would concede that I don't think anybody collects 8 data on, you know, was this individual patient 9 treated for any specific -- with any specific 10 treatment regimen. I don't think that level of data 11 are ever collected. But what I do have are data on 12 the frequency of administration and what I have said 13 there is that the most common and the most -- the 14 most common dosing interval for Eylea is eight weeks 15 or eight weeks or longer, and that that is what I 16 rely on to conclude that the eight-week dosing 17 interval is an important driver of demand. 18 BY MR. CHOI: 19 Q. So, but -- so my question is, so your 20 basis for the notion that physicians use the extended 21 eight-week dosing is based on physician surveys, 22 correct?</p> <p style="text-align: right;">Page 82</p>	<p>1 this was a tertiary dose. I don't believe those data 2 exist so you couldn't do that analysis. 3 Q. So the only data exists right now for the 4 Eylea sales relate to just use of the product without 5 with regard to the dosing regimen of the '681 patent, 6 correct? 7 MR. CAINE: Object to form. 8 THE WITNESS: No, I don't agree with that. 9 BY MR. CHOI: 10 Q. Well, didn't you say that in the initial 11 dose or the loading dose, a use is a use, so there 12 was initial dose, and there was secondary dose and 13 there was tertiary dose. I don't believe those data 14 exist so you couldn't do that analysis. 15 That's your testimony, right? 16 A. That is what I said, yes. But what you 17 said back to me I don't think is consistent with 18 that. 19 Q. So my question is, the sales data that you 20 have do not specify whether physicians or patients 21 received Eylea injections according to the '681 22 patent? I'm talking about the sales data</p> <p style="text-align: right;">Page 84</p>
<p>1 A. Well, the surveys confirm that but also 2 Dr. Do and Dr. Brown discuss that as well, so there 3 is a good deal of evidence that the eight-week dosing 4 interval is important and is a key distinguishing 5 feature. 6 Q. Right. But you don't have actual sales 7 data to suggest -- the sales -- okay. Strike that. 8 The sales data are based on per-injection 9 statistics, correct? 10 A. The sales data are based on per-injection 11 statistics? I guess I'm not understanding -- 12 Q. So sales data are accrued based on how 13 many injections are made, correct? 14 A. Sales would depend upon the use of the 15 product, yes. 16 Q. But then the sales data would not 17 distinguish between whether someone received extended 18 dosing at what interval, correct? 19 A. Well, as I said, in the initial doses or 20 in the loading phase, a use is a use and so you 21 wouldn't -- and I don't think anybody records, oh, 22 this was the initial dose, this was a secondary dose,</p> <p style="text-align: right;">Page 83</p>	<p>1 specifically. I'm not talking about the surveys. 2 A. The dollar sales data? 3 Q. Correct. 4 A. As I said, I don't believe anybody 5 collects data that would allow you to say, you know, 6 these were the dollars that were spent on initial 7 dosing, these are the dollars that were spent on 8 maintenance dosing. I don't think those exist and I 9 would be really surprised if they did because it just 10 wouldn't be typical business practice in my 11 experience. So I don't think that could be done. 12 But that's not -- that doesn't mean that 13 you can't look at data and determine that it is the 14 eight-week dosing interval that is driving 15 utilization. You can't look at data and other 16 evidence as I've described earlier, the drivers of 17 demand that I laid out in this report. 18 Q. Would you say that physicians usually 19 follow the label dosing regimen? 20 A. So I have not -- I'm not a physician and 21 so I don't have the personal experience to say that. 22 I rely on Dr. Do and Dr. Brown, Dr. Do in particular</p> <p style="text-align: right;">Page 85</p>

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<p>1 who says that it's typical for physicians to follow 2 the dosing regimen that's described in the patent. 3 Q. And do you understand that the label 4 indication for retinal vein occlusion specifies 5 monthly injection of Eylea, correct? 6 A. That's the label, yes. 7 Q. So do you understand that if physicians 8 were to treat RVO, they would not follow the extended 9 dosing regimen as claimed by the '681 patent, right? 10 MR. CAINE: Objection, form. 11 THE WITNESS: Well, of course that depends 12 upon the specific action that the physician is 13 undertaking. But I recognize also that Dr. Do said 14 that even though the label says four weeks is the 15 recommended maintenance level, the maintenance 16 frequency that many doctors treat on an eight-week 17 interval anyway. 18 BY MR. CHOI: 19 Q. So is it your opinion that then labels 20 don't matter as to how physicians administer the 21 drug? 22 A. I didn't say that.</p> <p style="text-align: right;">Page 86</p>	<p>1 Q. And did you consider whether physicians 2 administered Eylea with an extended dosing interval 3 of seven weeks? 4 A. There are data that talk about the 5 frequency of dosing on a variety of intervals and 6 there are -- seven is one of the options. There are 7 patients whose individual needs differ and so I'm not 8 surprised that there are times when a different 9 interval is used. 10 Q. So did you subtract out -- well, actually, 11 strike that. 12 How about six-week extended dosing. Was 13 that accounted for in your commercial success 14 analysis? 15 MR. CAINE: Objection, form. 16 THE WITNESS: Yes. 17 BY MR. CHOI: 18 Q. How about five weeks? 19 A. Yes. 20 Q. So you did not discount those Eylea sales 21 that do not practice the '681 patent dosing regimen, 22 correct?</p> <p style="text-align: right;">Page 88</p>
<p>1 Q. But you rely on Dr. Do's opinion that even 2 though the label indication for RVO is monthly 3 dosing, doctors would still nonetheless use extended 4 dosing, correct? 5 A. I recognize that that's what she said, 6 yes. 7 Q. And do you have any data to support that 8 notion economically? 9 A. Some of the survey data that are in the -- 10 that are referenced in the '338 patent do discuss the 11 fact that although indicated for four-week 12 maintenance dosing interval for RVO, it's not 13 uncommon to see eight-week dosing. 14 Q. And is that the majority? 15 A. I'd have to go back and relined myself of 16 exactly what the data are there, but it's not -- it's 17 not uncommon. 18 Q. Okay. So earlier you said that the '681 19 patent claims covers the at least eight-week extended 20 dosing, correct? 21 A. I believe that's how it's said in my 22 declaration, that eight-week or longer.</p> <p style="text-align: right;">Page 87</p>	<p>1 A. Well, that's -- 2 MR. CAINE: Object to form. 3 THE WITNESS: That's not the assignment 4 and it's not what commercial success is about: That 5 would be an apportionment and apportionment is not 6 relevant to a commercial success analysis. 7 Commercial success is about what -- about 8 establishing a nexus between patented features and 9 the product's commercial success. 10 It doesn't mean that every sale has to be 11 done according to the patented features and, as we've 12 talked about before, Dr. Do describes this 1 percent 13 of her patients where she does not follow the 14 patented exclusionary conditions. So it's -- and as 15 I've said, there are dosing intervals short of eight 16 weeks that may not practice or may not be consistent 17 with the claimed treatment regimen, that there's a -- 18 but the claimed treatment regimen is used frequently 19 and typically the most common, the eight-week dosing 20 interval is the most common dosing interval for Eylea 21 and so -- and eight weeks and longer reach the 22 majority in some cases so that it's not necessary to</p> <p style="text-align: right;">Page 89</p>

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<p>1 say, well, how much is -- and subtract out how much</p> <p>2 is -- because of an individual patient need, how much</p> <p>3 is administered less frequently than on the</p> <p>4 eight-week or longer dosing interval.</p> <p>5 BY MR. CHOI:</p> <p>6 Q. Right. So you said that you didn't do</p> <p>7 apportionment across whether Eylea is administered at</p> <p>8 a less extended dosing regimen, for example, at five</p> <p>9 weeks, six weeks, seven weeks, right?</p> <p>10 A. I did not do an apportionment, that's</p> <p>11 correct.</p> <p>12 Q. And you haven't done apportionment for</p> <p>13 whether there are instances physicians administer the</p> <p>14 drug that do not practice a '681 dosing regimen,</p> <p>15 right?</p> <p>16 MR. CAINE: Objection, form.</p> <p>17 THE WITNESS: I have not done an analysis</p> <p>18 of the situations in which they do not practice it,</p> <p>19 is that the question?</p> <p>20 BY MR. CHOI:</p> <p>21 Q. Yes.</p> <p>22 A. Well, that wasn't part of my assignment</p> <p style="text-align: right;">Page 90</p>	<p>1 THE WITNESS: There are a variety of</p> <p>2 reasons why I can conclude that. First, I would say</p> <p>3 that the most common dosing interval in the</p> <p>4 eight-week -- in the maintenance phase is the</p> <p>5 eight-week dosing interval or longer and so that</p> <p>6 clearly is consistent with the claims.</p> <p>7 There's also a notion, as I said before,</p> <p>8 some patients aren't able, for whatever reason, their</p> <p>9 physiology or their disease that they have doesn't</p> <p>10 allow them to reach the eight-week dosing interval,</p> <p>11 but it does allow them to get beyond the four-week</p> <p>12 dosing that is the typical and the labeled indication</p> <p>13 for Lucentis. And so being able to maintain a</p> <p>14 Lucentis level of health outcomes with a longer</p> <p>15 dosing interval is a very valuable economic</p> <p>16 phenomenon, a very valuable thing to both patients</p> <p>17 and doctors.</p> <p>18 So even if I have a patient who can't get</p> <p>19 to eight weeks, the availability or the potential</p> <p>20 availability of eight-week dosing interval allows a</p> <p>21 doctor and a patient to extend beyond four weeks. It</p> <p>22 is the potential, the optionality or the option value</p> <p style="text-align: right;">Page 92</p>
<p>1 and I don't see how that would affect my decision or</p> <p>2 my opinion given that what I observe is very common</p> <p>3 use of the distinguishing feature in the treatment</p> <p>4 regime.</p> <p>5 Q. Well, what I'm trying to understand is you</p> <p>6 didn't do an apportionment analysis because you said</p> <p>7 that it is not part of your analysis. But if the</p> <p>8 apportionment shows that the majority or substantial</p> <p>9 part of the Eylea dosing regimen that is practiced by</p> <p>10 the physicians don't practice -- don't fall under the</p> <p>11 scope of the '681 patent, how could that drive</p> <p>12 commercial success of Eylea, is my question?</p> <p>13 A. I'm sorry, I don't -- I didn't follow the</p> <p>14 question. I'm going to have to ask you to ask it</p> <p>15 again.</p> <p>16 Q. So if -- okay. So -- strike that.</p> <p>17 If the substantial part of Eylea sales are</p> <p>18 associated with a dosing regimen not within the scope</p> <p>19 of the '681 patent, how could you say that the</p> <p>20 extended dosing which falls under the '681 patent</p> <p>21 drives sales of Eylea?</p> <p>22 MR. CAINE: Objection, form.</p> <p style="text-align: right;">Page 91</p>	<p>1 of maybe being able to get to eight weeks -- or if</p> <p>2 I've got a patient who can't get to eight, but can</p> <p>3 get to seven, that's a lot better than being stuck at</p> <p>4 four -- that is how that dosing interval contributes</p> <p>5 to the commercial success of the product, even if</p> <p>6 they cannot get to eight or longer weeks.</p> <p>7 So, you know, from an economic</p> <p>8 perspective, it is important that the eight-week or</p> <p>9 longer dosing interval is the most common interval</p> <p>10 and that supports very strongly a conclusion that the</p> <p>11 product's commercial success is tied to that ability.</p> <p>12 But also that, you know, you cannot be able, because</p> <p>13 of the patient's specific characteristics, to get to</p> <p>14 eight weeks, but you're still getting value from the</p> <p>15 eight-week dosing interval because there's an option</p> <p>16 that you might be able to.</p> <p>17 So if someone might be able to get</p> <p>18 something but can't, they're better off because that</p> <p>19 eight-week dosing interval exists and that label --</p> <p>20 that labeled indication exists and that label</p> <p>21 treatment method exists that allows a patient and a</p> <p>22 doctor to extend beyond what they would be able to</p> <p style="text-align: right;">Page 93</p>

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<p>1 using Lucentis or another product that has a 2 four-week dosing interval. 3 BY MR. CHOI: 4 Q. Right. But so the '681 patent itself 5 actually doesn't discuss the optionality of the 6 extended dosing, correct? 7 A. Well, that's an economic notion. That's 8 to me a fairly clear economic reality and a value to 9 patients that is derived from the availability of an 10 eight-week dosing potential. 11 Q. And as part of your commercial success 12 analysis, have you considered seven weeks to satisfy 13 the eight-week dosing regimen limitation? 14 A. Well, again, the -- as I've just said, it 15 is important to me that eight weeks or longer is the 16 most common dosing interval. And if it were true 17 that it's only eight and everybody who's at seven or 18 six or five are only at four, I would still be able 19 to conclude that the eight-week dosing interval was a 20 driver of commercial success. 21 But the fact that there are people who are 22 at seven or six or five but longer than four are</p> <p style="text-align: right;">Page 94</p>	<p>1 eight-week dosing then, right? You're saying that 2 because the extended dosing is possible, more than 3 four weeks, five weeks, six weeks, eight weeks, that 4 extended dosing itself allows for the commercial 5 success of Eylea, that's correct? 6 A. No. 7 MR. CAINE: Objection, form. 8 THE WITNESS: Sorry. 9 BY MR. CHOI: 10 Q. So what do you think is so special about 11 the eight-week dosing of Eylea -- 12 MR. CAINE: Objection to form. 13 BY MR. CHOI: 14 Q. -- that drives sales -- that drives its 15 commercial success? 16 A. I'm not sure I understand the question. 17 What's so special? 18 Q. Right. So why is it the key 19 distinguishing factor that the eight-week dosing 20 contributes to the Eylea's commercial success when 21 you say that the optionality is so important? 22 MR. CAINE: Objection to form.</p> <p style="text-align: right;">Page 96</p>
<p>1 benefitting from the potential, that is strong 2 evidence that -- or the potential of an eight-week 3 dosing interval -- that's strong evidence that that 4 potential of that eight-week dosing interval does in 5 fact contribute to commercial success. 6 Q. So is it accurate to say that your opinion 7 is the optionality of eight-week dosing contributes 8 to commercial success of Eylea? 9 A. It is consistent with my opinion that the 10 eight-week dosing interval, as I've said, is the most 11 common use, the most common interval and that that, 12 in and of itself, would be sufficient to reach a 13 conclusion of commercial success, that the seven or 14 long -- or shorter, between seven and four-week 15 intervals that might be occasionally observed are 16 derivative of the -- in an economic sense, are 17 derived from the eight-week dosing interval 18 potential. 19 Now, legally, that might be a different 20 question, but from an economic perspective, that is 21 what I think. 22 Q. So your opinion is not specific to the</p> <p style="text-align: right;">Page 95</p>	<p>1 THE WITNESS: So I've not said that the 2 optionality is so important in the sense that it is 3 more important than the eight-week dosing interval. 4 I've said that the eight-week dosing interval is very 5 important, and it is the most common -- most commonly 6 observed dosing interval for patients in the 7 maintenance phase. 8 So what I've said is that -- and of course 9 there's lots of good economic reason that I discuss 10 in the report about why -- or in the '338 declaration 11 about why consumer demand would be higher for a 12 product that has less of a negative characteristic. 13 The treatment burden for this disease is very high. 14 Having less of a treatment burden suggests that there 15 would be more demand for the product. 16 So the eight-week dosing interval is 17 vitally important. It is the key -- the fact that it 18 can be dosed at eight weeks for the majority of 19 patients and maintain the same outcomes or similar 20 outcomes, not inferior outcomes to Lucentis in the -- 21 that dose, that four-week -- a four-week interval is 22 very important. And it's important because it</p> <p style="text-align: right;">Page 97</p>

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<p>1 reduces the treatment burden on patients. It reduces 2 the treatment burden on their caregivers, on maybe 3 physicians' offices. It's very important. 4 Going blind is a really bad outcome and 5 being able to avoid that with a less frequent 6 injection into your eye, with a less frequent time to 7 be spent at the doctor, with less frequent imposition 8 of time and attention from caregivers or people who 9 help transport you to a physician, all of those 10 reasons are why it would be very good to have a less 11 frequent dosing. 12 So the eight-week dosing interval is the 13 key -- the patented feature that drives that process. 14 And I've not said that the optionality is so 15 important that it is more important than the 16 eight-week dosing interval, but it is not 17 unimportant. 18 BY MR. CHOI: 19 Q. Okay. And you just testified that less 20 frequent dosing was important, right? 21 A. Less frequent dosing is important, yes, as 22 an economic phenomenon.</p> <p style="text-align: right;">Page 98</p>	<p>1 THE WITNESS: Well, I don't know. I 2 haven't analyzed that because eight weeks is the 3 patented -- is part of the patented method. Seven is 4 not. Now -- 5 BY MR. CHOI: 6 Q. What I'm trying to understand is what you 7 think is the key feature that actually drove sales of 8 Eylea here. So you had testified that Eylea is -- 9 Eylea allows for less frequent dosing on a longer 10 term, and I'm trying to see whether, if there is 11 anything special tied to the eight-week extended 12 dosing as opposed to other extended dosing, for 13 example, seven, six or five weeks. 14 MR. CAINE: Objection, form. 15 THE WITNESS: Well, eight weeks is better 16 than any lower number, but eight weeks is the 17 patented feature and that's what I evaluated. 18 BY MR. CHOI: 19 Q. Okay. So are you familiar with a 20 treat-and-extend dosing regimen, Dr. Manning? 21 A. It's a medical practice. I have some 22 understanding of it, but I'm not a physician so I</p> <p style="text-align: right;">Page 100</p>
<p>1 Q. So wouldn't your analysis be the same if 2 it were seven-week dosing instead of eight? 3 MR. CAINE: Objection, form. 4 THE WITNESS: The analysis would not be 5 the same, no. 6 BY MR. CHOI: 7 Q. But seven-week is also -- allows for less 8 frequent dosing, doesn't it? 9 A. Sure. 10 Q. And you said that the reason -- the reason 11 the eight-week extended dosing was so critical to 12 Eylea's commercial success was because it allows for 13 less frequent injection, correct? 14 A. I did. 15 Q. So if it were seven weeks instead of 16 eight, how would that be different? 17 MR. CAINE: Objection. 18 BY MR. CHOI: 19 Q. Is that one week going to make a big 20 difference as to whether Eylea is a commercial 21 success? 22 MR. CAINE: Objection, form.</p> <p style="text-align: right;">Page 99</p>	<p>1 don't -- I don't fully understand it. 2 Q. Okay. Well, do you understand the 3 difference between treat-and-extend dosing versus the 4 eight-week dosing as claimed by the '681 patent? 5 A. I would be hesitant to try and describe it 6 because I might get it wrong not being a doctor. But 7 I understand that there is a -- that the -- there is 8 a difference between going from the secondary -- from 9 the loading doses directly to the eight weeks and 10 extending gradually, if that's what treat and extend 11 means. 12 Q. Okay. So what is the dosing regimen of 13 the '681 patent in your opinion? 14 MR. CAINE: Objection, form. 15 THE WITNESS: I don't have an opinion 16 about it. I read it as it specifies one or more 17 secondary doses on two- or four-week interval and 18 then one or more doses in the tertiary or maintenance 19 phase on an eight-week or longer interval. 20 BY MR. CHOI: 21 Q. Okay. So would you consider that to be a 22 fixed dosing?</p> <p style="text-align: right;">Page 101</p>

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<p>1 A. Again, that's a medical distinction that</p> <p>2 is not really critically important for an economic</p> <p>3 analysis. I mean, I understand that, you know, you</p> <p>4 might call it that, but that's a medical issue.</p> <p>5 Q. Okay. Are you familiar with the term PRN</p> <p>6 dosing?</p> <p>7 A. Generally, yes. It's the same caveats</p> <p>8 about treat and extend. I mean, I understand what</p> <p>9 the term means and -- but exactly -- I wouldn't want</p> <p>10 to take a quiz on what qualified as one or the other.</p> <p>11 Q. Okay.</p> <p>12 (Exhibit No. 2250 was identified for</p> <p>13 the record.)</p> <p>14 BY MR. CHOI:</p> <p>15 Q. I'm going to introduce an exhibit marked</p> <p>16 2250. Dr. Manning, have you seen this document?</p> <p>17 A. I've seen many similar documents if not</p> <p>18 this one in particular. I couldn't tell you that</p> <p>19 I've seen this one specifically.</p> <p>20 Q. Do you reference this document in your</p> <p>21 '338 patent declaration?</p> <p>22 A. I would have to check. I know I reference</p> <p style="text-align: right;">Page 102</p>	<p>1 and treat only if there is activity, right?</p> <p>2 A. That is the number.</p> <p>3 Q. Okay. And 77.9 percent uses</p> <p>4 treat-and-extend treatment strategy for wet AMD, is</p> <p>5 that right?</p> <p>6 A. That is what the bar says, yes.</p> <p>7 Q. So do any of these treatment strategies</p> <p>8 fall within the scope of the '681 patent extended</p> <p>9 dosing regimen?</p> <p>10 A. I don't know.</p> <p>11 Q. You don't know, right?</p> <p>12 A. I don't know what is meant specifically by</p> <p>13 treat and extend or -- and I don't see a description</p> <p>14 that matches my understanding of the patented dosing</p> <p>15 regimen as one of the choices. So I don't know what</p> <p>16 the doctors would have thought.</p> <p>17 Q. So based on this data or any data relied</p> <p>18 upon in your declaration, you don't know whether</p> <p>19 treat and extend or monthly treatment fall within the</p> <p>20 scope of the '681 patent dosing regimen?</p> <p>21 MR. CAINE: Objection, form.</p> <p>22 THE WITNESS: Well, in the maintenance</p> <p style="text-align: right;">Page 104</p>
<p>1 other similar ASRS studies, so I wouldn't be</p> <p>2 surprised if I do.</p> <p>3 Q. Okay. Let's take a look at page 17 of 90</p> <p>4 of Exhibit 2250. Are you there?</p> <p>5 A. Is that page 17 of 90, the one that has</p> <p>6 number 7 on the --</p> <p>7 Q. Yes, that's correct.</p> <p>8 A. Okay.</p> <p>9 Q. Do you see that this slide shows the</p> <p>10 treatment strategy employed by -- treatment</p> <p>11 strategies for wet AMD employed by physicians, right?</p> <p>12 A. The question appears to be which statement</p> <p>13 best describes your treatment strategy regarding</p> <p>14 anti-VEGF therapy for neurovascular AMD.</p> <p>15 Q. All right. And 2 percent of U.S. all use</p> <p>16 of -- strike that.</p> <p>17 So if you take a look at the graphs,</p> <p>18 you'll see that 2 percent of U.S. physicians or</p> <p>19 2 percent of AMD treatment in the U.S. follow, see,</p> <p>20 and treat patients monthly, right?</p> <p>21 A. That's what it says.</p> <p>22 Q. And 16.4 percent is see patients monthly</p> <p style="text-align: right;">Page 103</p>	<p>1 phase, the patented dosing regimen calls for an</p> <p>2 eight-week or longer interval.</p> <p>3 BY MR. CHOI:</p> <p>4 Q. Okay.</p> <p>5 A. So that would mean that somebody following</p> <p>6 that treatment schedule would not choose to see</p> <p>7 patients and treat them monthly, at least -- again,</p> <p>8 I'm not a doctor and I don't know how the doctor</p> <p>9 would evaluate these various choices but I don't know</p> <p>10 that this question allows the doctors who are</p> <p>11 responding to the survey to discriminate their</p> <p>12 practice based on, you know, if -- if the doctor were</p> <p>13 using the patented treatment interval, he or she</p> <p>14 might choose treat and extend because it might</p> <p>15 describe to them something that looks like the</p> <p>16 patented treatment interval. I just don't know.</p> <p>17 Q. So you did not do analysis of whether</p> <p>18 treat and extend or other dosing regimen as listed</p> <p>19 here would fall under the '681 patent, right?</p> <p>20 A. Well, as you're asking me here, I don't</p> <p>21 see the patented dosing regimen as reflected in any</p> <p>22 of these responses and so I couldn't have done that</p> <p style="text-align: right;">Page 105</p>

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<p>1 analysis.</p> <p>2 Q. Or any other data or -- strike that.</p> <p>3 Do you have any data that show what</p> <p>4 proportion of treat and extend and other dosing</p> <p>5 regimen follow the extended dosing regimen of the</p> <p>6 '681 patent?</p> <p>7 A. There are data in the ATU surveys that I</p> <p>8 reference in my report that shows that the most</p> <p>9 common maintenance phase interval is eight weeks.</p> <p>10 And that's the -- or eight weeks or longer. And that</p> <p>11 is what I rely upon.</p> <p>12 Q. But you don't discount other dosing</p> <p>13 regimen from your commercial success analysis, right?</p> <p>14 A. What do you mean, discount?</p> <p>15 Q. Dosing regimen practiced by physicians</p> <p>16 that do not fall under the scope of the '681 patent.</p> <p>17 A. That don't follow the --</p> <p>18 Q. Correct.</p> <p>19 MR. CAINE: Objection, form.</p> <p>20 THE WITNESS: As I've said, I don't do an</p> <p>21 apportionment analysis. I don't try and assess how</p> <p>22 many doctors do or do not the -- follow that</p> <p style="text-align: right;">Page 106</p>	<p>1 weeks.</p> <p>2 Q. Okay. And did you subtract these Eylea</p> <p>3 sales associated with wet AMD from your commercial</p> <p>4 success analysis?</p> <p>5 A. Well, I don't see that there are sales</p> <p>6 broken out by product, so I don't see that there's</p> <p>7 any opportunity to subtract the Eylea sales of</p> <p>8 whatever percent they are. And I also -- as I've</p> <p>9 said before, I do not do an apportionment and so it</p> <p>10 is not necessary or appropriate to subtract those out</p> <p>11 for a commercial success analysis.</p> <p>12 Q. I'm going to introduce Exhibit 2138.</p> <p>13 (Exhibit No. 2138 was identified for</p> <p>14 the record.)</p> <p>15 BY MR. CHOI:</p> <p>16 Q. Let's take a look at page 15 of 53.</p> <p>17 Dr. Manning, you recognize this document, do you?</p> <p>18 A. I've seen many -- just many that are</p> <p>19 similar to this. This specific one, I'm not certain.</p> <p>20 I would have to verify that it's the same one that</p> <p>21 I've seen.</p> <p>22 Q. And the graph on the left, the diagram, it</p> <p style="text-align: right;">Page 108</p>
<p>1 treatment schedule because it's not necessary and not</p> <p>2 appropriate for a commercial success analysis.</p> <p>3 BY MR. CHOI:</p> <p>4 Q. So here at least -- you have at least</p> <p>5 testified that 2 percent of U.S. sales -- of U.S. --</p> <p>6 2 percent of treatment strategy for wet AMD is</p> <p>7 attributable to monthly dosing, right?</p> <p>8 MR. CAINE: Objection, form.</p> <p>9 THE WITNESS: I haven't testified to that,</p> <p>10 no. I mean --</p> <p>11 BY MR. CHOI:</p> <p>12 Q. Well, you see that see, treat and patients</p> <p>13 monthly, that's 2 percent, right?</p> <p>14 A. I see that that is the number on this</p> <p>15 slide, yes.</p> <p>16 Q. And monthly doesn't mean extended dosing,</p> <p>17 right?</p> <p>18 A. Well, it doesn't mean more than four.</p> <p>19 Q. Right. So what I'm saying is monthly</p> <p>20 doesn't mean the -- doesn't correspond to the</p> <p>21 eight-week extended dosing of the '681 patent, right?</p> <p>22 A. That's correct. Monthly is not eight</p> <p style="text-align: right;">Page 107</p>	<p>1 breaks down eye treatment based on dosing schedule.</p> <p>2 Do you see that?</p> <p>3 A. I do.</p> <p>4 Q. And do you see that 28 percent of Eylea</p> <p>5 follows monthly dosing level, right?</p> <p>6 A. It says monthly followed by fixed</p> <p>7 interval.</p> <p>8 Q. And so what do you -- by looking at this</p> <p>9 data, could you figure out what percentage of Eylea</p> <p>10 is associated with extended eight-week dosing?</p> <p>11 A. Well, what I have said is that, you know,</p> <p>12 the 43 percent that is reflected in every eight weeks</p> <p>13 plus is an indication that the eight-week dosing</p> <p>14 interval or the patented dosing regime or eight weeks</p> <p>15 or longer dosing is a very important driver of demand</p> <p>16 and that this is evidence of that importance.</p> <p>17 Q. Did you say 41 percent?</p> <p>18 A. 43.</p> <p>19 Q. Where did you get the 43?</p> <p>20 A. On the right-hand panel here where it</p> <p>21 shows the frequency percent of eyes on fixed dosing</p> <p>22 interval dose at various points in time and the 43</p> <p style="text-align: right;">Page 109</p>

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<p>1 percent is Eylea's number for every eight weeks 2 plus -- every eight-plus weeks.</p> <p>3 Q. So does that indicate that 57 percent of 4 Eylea dosing is associated with dosing regimen not 5 claimed by the '681 patent?</p> <p>6 A. Well, it says that 43 percent of the 7 patients are dosed on an eight-week or longer 8 interval. And as I said before, you know, there 9 are -- it's not requisite that every needs to be done 10 according to the patent. It's not requisite that 11 even necessarily the majority be done according to 12 the patent, but a large share is done according to 13 the patent. And that combined with the optionality 14 argument that I made before is pretty good evidence 15 that this eight-week dosing interval is a driver of 16 success.</p> <p>17 Q. But you agree that 47 percent of Eylea 18 sales -- well, strike that.</p> <p>19 So you agree that this graph shows 47 20 percent of Eylea sales follow the every eight week 21 plus dosing. And that means that the other 57 22 percent do not follow the extended dosing, right?</p> <p style="text-align: right;">Page 110</p>	<p>1 Q. Did you subtract out the 57 percent that 2 do not follow the eight-week extended dosing?</p> <p>3 A. I did not.</p> <p>4 Q. So is it your opinion that 73 -- I mean, 5 43 percent of Eylea sales associated with the 6 extended dosing of the '681 patent is sufficient to 7 show commercial success of Eylea?</p> <p>8 A. As I stated in my declaration, it is 9 sufficient. The fact that it is the most common 10 dosing interval, that there is solid economic basis 11 for concluding that a less frequent dosing, a lower 12 burden of care would be associated with greater 13 utilization, that those things come together to 14 demonstrate that it is this characteristic, it is the 15 patented features that are driving demand for the 16 product and therefore contribute to its commercial 17 success.</p> <p>18 Q. But 57 percent do not follow the 19 eight-week dosing regimen, right? So how is it that 20 the eight-week or plus week -- eight-week or more 21 dosing interval is a majority? It's not.</p> <p>22 A. I didn't say it was.</p> <p style="text-align: right;">Page 112</p>
<p>1 MR. CAINE: Objection, form.</p> <p>2 THE WITNESS: So just to be careful, you 3 said 47 percent?</p> <p>4 BY MR. CHOI:</p> <p>5 Q. I'm sorry, 43 percent.</p> <p>6 A. Again, I would stand by what I answered -- 7 how I answered the question before. The commercial 8 success analysis asks the question, is the patented 9 feature, which includes the eight-week dosing 10 interval, important -- an important driver of the 11 demand for the product or the commercial success of 12 the product.</p> <p>13 And the fact that 43 percent, the most 14 common dosing interval of all here, is eight weeks or 15 longer, is consistent with the patented dosing regime 16 and so that is sufficient to be able to conclude that 17 that is a driver of success. It doesn't matter that, 18 you know, 19 percent are dosed at six or seven weeks 19 or that, you know, 7 percent are dosed at five weeks. 20 Those are fine, but they're not determinative of 21 whether or not the patented features are driving 22 commercial success.</p> <p style="text-align: right;">Page 111</p>	<p>1 Q. Well, you said the most common dosing 2 interval, right?</p> <p>3 A. I did.</p> <p>4 Q. So it is not the most common dosing 5 interval, right?</p> <p>6 A. It is. It is more common than six to 7 seven. It is more common than five. It is more 8 common than monthly. It is more common than other 9 fixed interval.</p> <p>10 Q. Understood. But what we should compare is 11 before -- or dosing regimen less than eight weeks 12 interval all combined versus dosing interval on 13 eight-week or more, right? So if you compare that, 14 it's actually not the most common.</p> <p>15 A. I don't agree with that.</p> <p>16 MR. CAINE: Objection to form.</p> <p>17 BY MR. CHOI:</p> <p>18 Q. Pardon?</p> <p>19 MR. CAINE: I made an objection to form.</p> <p>20 MR. CHOI: Oh, sorry.</p> <p>21 MR. CAINE: He answered the question.</p> <p>22 THE WITNESS: I said I don't agree with</p> <p style="text-align: right;">Page 113</p>

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<p>1 that.</p> <p>2 BY MR. CHOI:</p> <p>3 Q. But do you agree that 57 percent of Eylea</p> <p>4 sales are made -- are not associated with the</p> <p>5 eight-week dosing, correct?</p> <p>6 MR. CAINE: Objection, form.</p> <p>7 THE WITNESS: I would go back to the</p> <p>8 answer I've given already, that it is very important</p> <p>9 that eight weeks is the most common of the dosing</p> <p>10 intervals considered there. It is 43 percent in this</p> <p>11 chart. It is sizable. 43 percent of Eylea sales</p> <p>12 would still be a very large number.</p> <p>13 The fact that there are some patients who</p> <p>14 cannot make it to eight weeks or whose condition does</p> <p>15 not allow eight-week dosing, I think there's -- you</p> <p>16 know, from an economic perspective -- and that might</p> <p>17 be different from the legal perspective -- but from</p> <p>18 the economic perspective, that option value of being</p> <p>19 able to get beyond four towards eight is very</p> <p>20 valuable. And so from an economic perspective, I</p> <p>21 think that is relevant.</p> <p>22 But even setting that aside, the fact that</p> <p style="text-align: right;">Page 114</p>	<p>1 under the '681 extended dosing regimen, correct?</p> <p>2 MR. CAINE: Objection, form.</p> <p>3 THE WITNESS: I'd go back again to this</p> <p>4 question -- the answer I've given already.</p> <p>5 BY MR. CHOI:</p> <p>6 Q. Understood.</p> <p>7 A. I don't believe it is necessary to</p> <p>8 apportion the sales by dosing frequency, noting that</p> <p>9 43 percent and larger is a substantial share and,</p> <p>10 even if you had to simply consider that, would be big</p> <p>11 enough to demonstrate commercial success. But I</p> <p>12 think there's an important option consideration from</p> <p>13 an economic perspective that your supposition</p> <p>14 ignores.</p> <p>15 Q. Well, so my question wasn't whether 43</p> <p>16 percent was substantial or not. My question was, as</p> <p>17 reflected in this slide, 57 percent of Eylea sales or</p> <p>18 Eylea sales are associated with dosing regimen that</p> <p>19 do not fall under the '681 patent, correct?</p> <p>20 MR. CAINE: Objection, form.</p> <p>21 THE WITNESS: I guess I'd be a little</p> <p>22 hesitant to draw that legal conclusion. I can tell</p> <p style="text-align: right;">Page 116</p>
<p>1 43 percent of the patients are dosed on an eight-week</p> <p>2 interval is -- and that that is far more than our</p> <p>3 dose on that interval for the other products is a</p> <p>4 factor that, in my opinion, drives the success of the</p> <p>5 product, is a key element of the dosing schedule that</p> <p>6 leads to the commercial success of the product.</p> <p>7 BY MR. CHOI:</p> <p>8 Q. Okay. So you will agree with me that the</p> <p>9 eight-week dosing as reflected here is not a majority</p> <p>10 of Eylea sales, right?</p> <p>11 MR. CAINE: Objection, form.</p> <p>12 THE WITNESS: Again, this measures dosing,</p> <p>13 not sales. But I agree that 57 is larger than 43, if</p> <p>14 that's the question, but that is not the relevant</p> <p>15 measure, relevant comparison from an economic</p> <p>16 perspective. It's not relevant for the commercial</p> <p>17 success analysis.</p> <p>18 BY MR. CHOI:</p> <p>19 Q. So would you agree that 57 percent being</p> <p>20 the majority of dosing regimen used by physicians in</p> <p>21 administering Eylea, the majority of Eylea sales</p> <p>22 associated with these dosing regimens do not fall</p> <p style="text-align: right;">Page 115</p>	<p>1 you that from an economist's perspective, 43 is</p> <p>2 bigger than 19 is bigger than 15, is less than 57</p> <p>3 obviously. But it is an important number that is</p> <p>4 sufficient to lead me to the conclusion that</p> <p>5 commercial success is tied to it.</p> <p>6 BY MR. CHOI:</p> <p>7 Q. Right. So my question wasn't whether it</p> <p>8 was a substantial driver of commercial success or</p> <p>9 not. Is the eight-week dosing regimen the majority</p> <p>10 according to this slide? No, correct?</p> <p>11 MR. CAINE: Objection, form.</p> <p>12 THE WITNESS: Is the majority in this</p> <p>13 sample? It is not. There are other slides that we</p> <p>14 could look at where it would be, where if you looked</p> <p>15 at eight weeks or longer, there would be more than 50</p> <p>16 percent.</p> <p>17 BY MR. CHOI:</p> <p>18 Q. Could you point me to any slides that show</p> <p>19 that?</p> <p>20 A. Yeah, I could. It might take me some time</p> <p>21 to get there. Do you happen to have Exhibit 2176 I</p> <p>22 think might be the number?</p> <p style="text-align: right;">Page 117</p>

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<p>1 Q. Actually, I do not.</p> <p>2 A. And again, it's been a long time since I</p> <p>3 wrote this and I might --</p> <p>4 Q. Well, let's just move on, actually.</p> <p>5 MR. CAINE: If you're going to do that,</p> <p>6 why don't we take a break.</p> <p>7 THE VIDEOGRAPHER: The time is 11:50 a.m.</p> <p>8 Eastern. We're now off the record.</p> <p>9 (Whereupon, at 11:50 a.m., the deposition</p> <p>10 in the above-entitled matter was recessed, to</p> <p>11 reconvene at 12:45 p.m., this same day.)</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 style="text-align: right;">Page 118</p>	<p>1 MR. CAINE: Objection, form.</p> <p>2 THE WITNESS: Yeah, I believe that</p> <p>3 misstates what I had said and, you know, I would like</p> <p>4 to differentiate between my testimony and what you</p> <p>5 see on this chart. The fact that what I testified to</p> <p>6 is that the 43 percent on the eight-week dosing</p> <p>7 interval or eight-week-plus dosing interval is an</p> <p>8 important number and it is true that the numbers to</p> <p>9 the left of that add up to less than, but it wouldn't</p> <p>10 be 43 -- 57 because there is 1 percent on the other</p> <p>11 fixed dosing interval to the right, so it would be</p> <p>12 56.</p> <p>13 But I don't dispute the fact that if you</p> <p>14 add those numbers up, you get a number that's larger</p> <p>15 than 43, but I do not believe that is a critically</p> <p>16 important fact.</p> <p>17 BY MR. CHOI:</p> <p>18 Q. Well, that wasn't the question. I was</p> <p>19 asking, just based on this chart alone, whether -- I</p> <p>20 mean, this chart shows that 43 percent of Eylea</p> <p>21 follows -- Eylea sales follow the eight-week extended</p> <p>22 dosing, and logic dictates that the other 57 percent</p> <p style="text-align: right;">Page 120</p>
<p>1 AFTERNOON SESSION</p> <p>2 (12:45 p.m.)</p> <p>3 EXAMINATION BY COUNSEL FOR PETITIONER (RESUMED)</p> <p>4 THE VIDEOGRAPHER: This is the beginning</p> <p>5 of media unit number 3 in the video recorded</p> <p>6 deposition of Mr. Richard Manning. The time is</p> <p>7 12:45 p.m. Eastern. We are now back on the record.</p> <p>8 Counsel, you may proceed.</p> <p>9 BY MR. CHOI:</p> <p>10 Q. Welcome back, Dr. Manning.</p> <p>11 A. Thank you.</p> <p>12 Q. So before the break, we were discussing</p> <p>13 Exhibit 2138.</p> <p>14 A. Sorry. I don't know that I have the</p> <p>15 number.</p> <p>16 MR. CAINE: There it is.</p> <p>17 THE WITNESS: Okay.</p> <p>18 BY MR. CHOI:</p> <p>19 Q. And if you could turn to page 15 of that</p> <p>20 exhibit. Earlier you had testified that 57 percent</p> <p>21 of Eylea sales are not associated with the claimed</p> <p>22 dosing regimen of the '681 patent, correct?</p> <p style="text-align: right;">Page 119</p>	<p>1 did not follow it, is that right?</p> <p>2 MR. CAINE: Objection, form.</p> <p>3 THE WITNESS: As I've said, I don't</p> <p>4 dispute the fact that eight-plus weeks is 43 percent</p> <p>5 and one minus -- 100 minus 43 is 57, sure.</p> <p>6 BY MR. CHOI:</p> <p>7 Q. Okay.</p> <p>8 A. But again, that's not, to me, a highly</p> <p>9 important fact.</p> <p>10 Q. Well, that wasn't -- I wasn't asking</p> <p>11 whether it's an important fact, whether it's</p> <p>12 57 percent are not practiced by the Eylea sales or</p> <p>13 not. My question was, 57 percent do not practice the</p> <p>14 eight-week extended dosing, yes or no?</p> <p>15 MR. CAINE: Objection, form.</p> <p>16 THE WITNESS: I would agree that something</p> <p>17 other than eight-plus weeks is the sum of the other</p> <p>18 intervals that are represented on that chart.</p> <p>19 BY MR. CHOI:</p> <p>20 Q. And that's 43 percent, correct?</p> <p>21 A. Eight-plus weeks is 43 percent.</p> <p>22 Q. And the remainder is 57 percent, correct?</p> <p style="text-align: right;">Page 121</p>

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<p>1 A. Yes.</p> <p>2 Q. Okay. And did you subtract out those</p> <p>3 57 percent from the commercial success analysis of</p> <p>4 Eylea?</p> <p>5 MR. CAINE: Objection, form.</p> <p>6 THE WITNESS: Well, did I subtract it out</p> <p>7 from the commercial success analysis? Can you be</p> <p>8 more precise than that?</p> <p>9 BY MR. CHOI:</p> <p>10 Q. So when you were determining -- when you</p> <p>11 were analyzing commercial success of Eylea, you took</p> <p>12 into account the sales data of Eylea, correct?</p> <p>13 A. The utilization data, the dollar sales,</p> <p>14 profitability, a variety of factors, yes.</p> <p>15 Q. So my question is, this -- my question is,</p> <p>16 the 57 percent of Eylea sales do not practice the</p> <p>17 claimed dosing -- extended dosing regimen. So did</p> <p>18 you subtract out those sales that do not practice the</p> <p>19 claimed dosing regimen?</p> <p>20 A. So as I've said before, I did not subtract</p> <p>21 out anything. I do not believe that that's an</p> <p>22 appropriate thing to do in a commercial success</p> <p style="text-align: right;">Page 122</p>	<p>1 A. I do. I do.</p> <p>2 Q. Did you analyze or provide analysis of</p> <p>3 whether this patent covers the Eylea product?</p> <p>4 A. I did not.</p> <p>5 Q. Did you provide an analysis as to whether</p> <p>6 the protection afforded by this patent precluded</p> <p>7 other competitors from entering the market?</p> <p>8 A. I didn't. I don't know what that patent</p> <p>9 covers.</p> <p>10 Q. Do you know whether anyone was able to</p> <p>11 commercialize a drug or commercialize Aflibercept</p> <p>12 without infringing upon Regeneron's patents?</p> <p>13 A. I have heard the existence of other</p> <p>14 patents that have been filed for Aflibercept. I</p> <p>15 don't know the details about them or Aflibercept</p> <p>16 being put forth by other parties. I don't remember</p> <p>17 the details but I don't know enough to speak</p> <p>18 authoritatively about it.</p> <p>19 Q. So as part of your commercial success</p> <p>20 analysis, you didn't evaluate the impact of any</p> <p>21 earlier patent protections that Regeneron obtained</p> <p>22 for Eylea, correct?</p> <p style="text-align: right;">Page 124</p>
<p>1 analysis.</p> <p>2 Q. Okay. So if you could go back to</p> <p>3 Exhibit 2185. I had introduced that exhibit earlier</p> <p>4 today. It's the Eylea label and this reflected that</p> <p>5 this was revised in November of 2011. Do you see</p> <p>6 that?</p> <p>7 A. I do.</p> <p>8 Q. If you take a look at the last page,</p> <p>9 page 15. Are you there?</p> <p>10 A. I am.</p> <p>11 Q. Do you see that there are patents listed</p> <p>12 here on the last page?</p> <p>13 A. I do.</p> <p>14 Q. Do you have any opinion as to whether</p> <p>15 these patents cover Eylea?</p> <p>16 A. I haven't evaluated any of them that I</p> <p>17 recognize. On the other hand, they're listed here as</p> <p>18 Regeneron U.S. patents, so I presume they have some</p> <p>19 relationship but I don't know what they cover. I</p> <p>20 have not evaluated them.</p> <p>21 Q. Do you see that there is a patent with the</p> <p>22 number 7,070,959? Do you see that listed there?</p> <p style="text-align: right;">Page 123</p>	<p>1 A. That's correct. My assignment was related</p> <p>2 to these products and -- these patents I mean, and I</p> <p>3 guess if you're suggesting that there were other</p> <p>4 patents that would have precluded a competitor, I</p> <p>5 would like to know more about the question. I guess</p> <p>6 I don't understand quite the question.</p> <p>7 Q. Well, I'm just -- my question is whether</p> <p>8 your analysis included consideration of other patents</p> <p>9 that Regeneron holds. Did it?</p> <p>10 MR. CAINE: Objection, form.</p> <p>11 THE WITNESS: Aside from the three patents</p> <p>12 that have been treated in the IPRs and the district</p> <p>13 court litigation that I've been involved in, I have</p> <p>14 not evaluated any other patents. I have heard</p> <p>15 claims, I've been asked questions about whether or</p> <p>16 not I thought other patents blocked innovation. My</p> <p>17 response to that, as I thought about that, has</p> <p>18 generally been I don't see that -- I've never seen a</p> <p>19 patent, I've never seen an argument that was</p> <p>20 compelling to me to indicate that there was</p> <p>21 meaningful foreclosure of potential innovation by</p> <p>22 others.</p> <p style="text-align: right;">Page 125</p>

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<p>1 I note that Regeneron was a company 2 without very much revenue stream in the early days of 3 Eylea's development and that I would not be 4 surprised -- in fact, I wouldn't -- in fact, I 5 understand there were some partnerships formed with 6 other companies to help in the development of the 7 product, and so I sense that -- my understanding is 8 that there would have been an eagerness for them to 9 engage other parties in codevelopment or developing 10 the product as a commercial product.</p> <p>11 So I guess that understanding makes me 12 think that, again, not having evaluated those patents 13 in particular, I've not seen a patent that I believe 14 would have prevented some other party from partnering 15 with Regeneron in developing the product.</p> <p>16 BY MR. CHOI:</p> <p>17 Q. So, but you haven't analyzed any patents, 18 right?</p> <p>19 MR. CAINE: Objection, form.</p> <p>20 THE WITNESS: Well, again, I -- to be 21 clear again that analyzing patents as a legal 22 expert -- legal exercise is not what I do. I'm not a</p> <p style="text-align: right;">Page 126</p>	<p>1 A. I do.</p> <p>2 Q. Did you evaluate any regulatory 3 exclusivity in relation to Eylea?</p> <p>4 MR. CAINE: Objection, form.</p> <p>5 THE WITNESS: What do you mean, did I 6 evaluate it?</p> <p>7 BY MR. CHOI:</p> <p>8 Q. So what is your understanding of 9 regulatory exclusivity?</p> <p>10 A. For a biologic, the first -- the reference 11 product, the first product approved for -- under a 12 BLA is granted 12 years of data exclusivity from the 13 time of approval, which means that the FDA cannot 14 approve another product that refers to the same data, 15 that refers to the same clinical evidence that the 16 referenced products does for 12 years after -- until 17 the first product has been on the market for 12 18 years. That's approximately -- well, that's my 19 understanding of the data exclusivity for biologics. 20 It's different for drugs, for small molecule drugs. 21 There is a distinction between small molecules and 22 large molecules or drugs and biologics.</p> <p style="text-align: right;">Page 128</p>
<p>1 lawyer. But analyzing the economic effect of various 2 patents, I've not been asked to analyze the economic 3 effects of any patents, at least as I recall, any of 4 the patents on this list.</p> <p>5 BY MR. CHOI:</p> <p>6 Q. Or any other patents not listed in this 7 label?</p> <p>8 A. That's my --</p> <p>9 MR. CAINE: Objection to form.</p> <p>10 THE WITNESS: That's my recollection, yes. 11 The only patents that I recall -- unless I'm 12 forgetting something, the only patents that I recall 13 analyzing or reviewing from an economic perspective 14 are the three that have been discussed here.</p> <p>15 BY MR. CHOI:</p> <p>16 Q. So you only considered the three patents 17 that you've had referenced today, '338, '601 and 18 '681, correct?</p> <p>19 A. That's my recollection, yes.</p> <p>20 Q. Okay. Dr. Manning, do you understand that 21 once a drug is approved, there is regulatory 22 exclusivity that's associated with it?</p> <p style="text-align: right;">Page 127</p>	<p>1 Q. So did you consider regulatory exclusivity 2 as part of your commercial success analysis?</p> <p>3 A. What do you mean, consider?</p> <p>4 Q. Did you consider whether competitors were 5 not able to enter the market because there was 6 regulatory exclusivity, as you say, with Eylea?</p> <p>7 A. Well, were not able to? Clearly, as I've 8 just described, a biosimilar could not during the 9 period of data exclusivity because that was a 10 congressional choice to protect the incentives for 11 innovation. And without that incentive, there would 12 be, you know, based on economic theory and based on 13 evidence, much less innovation and so Congress 14 provided for a period of data exclusivity for the 15 first innovative product of its type. So that -- you 16 know, that's just a fact. That's not something to be 17 considered. It's a fact.</p> <p>18 Now, did that preclude someone from 19 partnering with Regeneron? I wouldn't think so. I 20 mean, if someone had something to offer that was 21 valuable, I would imagine Regeneron would have 22 decided whether it was worth doing or not.</p> <p style="text-align: right;">Page 129</p>

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<p>1 Q. So my question really isn't about 2 partnership with Regeneron. It's about whether 3 regulatory exclusivity associated with Eylea 4 precluded or discouraged other competitors from 5 entering the market with a biosimilar or a product 6 that has -- products similar to Eylea. 7 A. Well, that clearly didn't preclude the 8 entry of other products similar to Eylea, at least as 9 I understand it. Beovu came on the market and there 10 are other products that use different molecules that 11 come onto the market, so it clearly didn't preclude 12 that kind of competition. 13 Q. How about specific to Eylea? 14 MR. CAINE: Objection, form. 15 THE WITNESS: Well, what do you mean 16 specific to Eylea? 17 BY MR. CHOI: 18 Q. Other competitors -- 19 A. So a copy of Eylea? 20 Q. Yeah. A copy or the Eylea molecule 21 itself. Were there -- did you consider whether 22 regulatory exclusivity precluded other competitors</p> <p style="text-align: right;">Page 130</p>	<p>1 it to be relevant to your commercial success 2 analysis, right? 3 A. I do not consider it to be relevant to the 4 commercial success analysis. 5 Q. So therefore you did not consider the 6 regulatory exclusivity aspect or economic aspect as 7 relevant to the commercial success of Eylea, right? 8 A. I don't agree with that. I believe it is 9 not relevant. I mean, I considered it and decided it 10 was not relevant. 11 Q. Okay. So just to be clear, so you do not 12 think that regulatory exclusivity is relevant to the 13 commercial success analysis of Eylea, correct? 14 A. Well, I believe that regulatory 15 exclusivity is a fact and is a congressionally and 16 FDA administered reality of the pharmaceutical 17 industry marketplace. Eylea has a regulatory 18 exclusivity period based on the law, based on the 19 regulations. So that is a fact. 20 Does it mean that the patented features 21 are not relevant to determining commercial success? 22 It does not. Clearly if the patented features were</p> <p style="text-align: right;">Page 132</p>
<p>1 from being able to enter the market with the same 2 molecule as Eylea? 3 A. Well, as I said, I understand that that is 4 the case, that the FDA will not -- is not able to 5 approve a biosimilar during the 12 years of data 6 exclusivity. That is the law, that's the regulation, 7 that's -- that is a fact and so I'm aware of it, I 8 considered it. I realize that that is the truth. 9 Q. So where in your report did you consider 10 the regulatory exclusivity of Eylea? 11 A. It was not relevant to my analysis of 12 commercial success so I didn't explicitly state it 13 because it's a fact that I understand and is simply 14 sort of orthogonal to the question of commercial 15 success. 16 Q. Didn't you just say you considered whether 17 regulatory exclusivity -- or you considered that it 18 was a fact that regulatory exclusivity existed, 19 right? 20 A. Yes, I'm aware of that and I have been 21 aware of that. 22 Q. And yet you said that you didn't consider</p> <p style="text-align: right;">Page 131</p>	<p>1 not valuable, it wouldn't matter whether there were 2 regulatory exclusivity or not. 3 So the fact -- the underlying fact is that 4 the patented features drive demand for this product. 5 And the fact that it has regulatory exclusivity is 6 different, is -- does not stand, does not explain to 7 the exclusion of the patented features the product's 8 commercial success. 9 Q. Again, my question is, was regulatory 10 exclusivity associated with Eylea taken into account 11 when you were analyzing the commercial success of 12 Eylea? 13 A. And my answer is it was, as I just 14 described. 15 Q. You said it was a fact. You didn't say it 16 was relevant, correct? 17 A. Well, I said it was a fact, that it did 18 not stand -- that it does not supplant or take the 19 place of the patented features as an explanation for 20 commercial success. As I said, if the patented 21 features were not important, regulatory exclusivity 22 wouldn't matter. If the product didn't work, it</p> <p style="text-align: right;">Page 133</p>

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<p>1 wouldn't matter whether it had regulatory exclusivity 2 or not. If the product didn't provide value, it 3 wouldn't matter whether it had regulatory exclusivity 4 or not. So that's the sense in which it does not 5 matter.</p> <p>6 Q. So regulatory exclusivity does not matter 7 in relation to the commercial success of Eylea, 8 right? So is your opinion that the extended dosing 9 of Eylea is relevant to the commercial success of 10 Eylea and that the exclusion -- the regulatory 11 exclusivity does not have anything to do with the 12 commercial success of Eylea, is that right?</p> <p>13 MR. CAINE: Objection, form.</p> <p>14 THE WITNESS: So my task was to evaluate 15 the patented features, the patented dosing regimen, 16 and to opine about whether that patented dosing 17 regimen has a nexus with commercial success. Now, 18 that is what I did and that is what the conclusions 19 of my declarations say.</p> <p>20 And the fact that there is regulatory 21 exclusivity, as I've said, it is not -- in and of 22 itself, it does not stand in the place of, it does</p> <p style="text-align: right;">Page 134</p>	<p>1 from competition or not because if it doesn't give 2 somebody something, nobody will buy it or very few 3 people will buy it. And so that's the sense in which 4 the two are different and important to draw the 5 distinction between the two.</p> <p>6 BY MR. CHOI:</p> <p>7 Q. So you did not consider exclusion 8 criteria -- I mean, strike that.</p> <p>9 You did not consider regulatory 10 exclusivity as a relevant factor to the commercial 11 success or nexus of Eylea to the '681 patent, 12 correct?</p> <p>13 MR. CAINE: Objection, form.</p> <p>14 THE WITNESS: You know, I don't believe I 15 can say it more clearly than I just did.</p> <p>16 BY MR. CHOI:</p> <p>17 Q. It's a yes or no question, I mean.</p> <p>18 A. And the answer is more complicated than a 19 yes or no question or answer could give.</p> <p>20 Q. Okay. Specifically where in your 21 declaration can you point me to that shows that you 22 considered the regulatory exclusivity of Eylea?</p> <p style="text-align: right;">Page 136</p>
<p>1 not supplant the patented features as an explanation 2 for commercial success. So that's the sense in which 3 it is not relevant.</p> <p>4 I mean, it's a fact and so clearly, you 5 know, it was put in place in order to incentivize 6 innovation and it has that effect. If -- you know, 7 in the small molecule space, if a generic drug could 8 come on the market the day after the innovator does, 9 there would be far fewer innovative drugs developed. 10 If the same thing happened in the biologics space, 11 there would be far fewer innovative biologics 12 developed.</p> <p>13 So clearly that incentive for innovation 14 is important and necessary to incentivize the 15 investments that are required to bring new products 16 to market. But only new products come to market that 17 provide value to people and to patients and to 18 doctors and to the healthcare system are rewarded 19 with revenues.</p> <p>20 If a product comes that doesn't provide 21 value, it doesn't matter how long it has exclusivity 22 or not. It doesn't matter whether it's protected</p> <p style="text-align: right;">Page 135</p>	<p>1 A. I don't believe it's there, but I'd have 2 to go back and verify. But as I said, I considered 3 it. It is a fact that applies broadly across the 4 pharmaceutical landscape and it, in and of itself, is 5 not more important than the patented features in 6 the -- among the claimed -- claims of the patent.</p> <p>7 Q. So then did you consider the effect of 8 regulatory exclusivity on the commercial success of 9 Eylea? In other words, because there was regulatory 10 exclusivity associated with Eylea, isn't it possible 11 that Eylea was able to gain more popularity and 12 achieve higher commercial success?</p> <p>13 A. No. I think the key -- and it's important 14 as an economist to identify -- to, A, hold everything 15 else the same and then to identify what the key 16 drivers are. As I said before, if this was a product 17 that didn't provide any additional value, then having 18 regulatory exclusivity would not have been helpful.</p> <p>19 I mean, if I have a product that nobody 20 wants to use, it doesn't matter whether or not it has 21 regulatory exclusivity. So regulatory exclusivity in 22 and of itself does not provide the value. Regulatory</p> <p style="text-align: right;">Page 137</p>

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<p>1 exclusivity is a fact, as I've said. But the value 2 derives from the patented feature that people want to 3 use or that drives the desire to use the product. 4 Q. So wouldn't you agree that regulatory 5 exclusivity precludes other competitors from entering 6 the market with the same drug, Eylea? 7 A. Well, as I said, that's a fact. I do 8 agree that if you have a product like Eylea or like 9 any other covered product under the FDA regulations 10 and under the law, if the FDA is precluded from 11 approving a copy, yep, that's true. And that is long 12 established law and regulatory process. 13 Q. So you didn't consider what effect that 14 would have on commercial success of Eylea, right? 15 A. Yes, I did. 16 MR. CAINE: Objection, form. 17 BY MR. CHOI: 18 Q. Well, can you point to me a paragraph or 19 analysis section of your '338 or '681 declarations 20 that show that, that show your analysis of the 21 exclusion -- I mean, regulatory exclusivity as being 22 relevant to commercial success of Eylea or as a</p> <p style="text-align: right;">Page 138</p>	<p>1 commercial success." 2 A. I don't disagree with that. 3 Q. But that's still -- you said it was not 4 important. 5 A. It -- 6 Q. I mean, compared to relatively speaking, 7 compared to the extended dosing, was it important to 8 consider the regulatory exclusivity? 9 A. The patented features are far more 10 important as a driver of success than is regulatory 11 exclusivity. Regulatory exclusivity, as I've said, 12 always exists for a new product. If the product is 13 not worth buying, people won't buy it. So regulatory 14 exclusivity does not -- does not cause success. It 15 is not the cause of your product's success. The 16 patent -- the features of the product are the cause 17 of the success. 18 Now, the regulatory exclusivity protects a 19 product from competition, but only a product that has 20 value needs or would benefit from the protection from 21 that competition. So a product that doesn't provide 22 any value, regulatory exclusivity wouldn't help it.</p> <p style="text-align: right;">Page 140</p>
<p>1 factor to commercial success of Eylea? 2 A. No. As I've said, I evaluated it. I 3 decided it was not important. It was not necessary 4 to describe because it is not in and of itself a 5 driver of commercial success. 6 Q. So you didn't think it was important, 7 correct? You didn't think it was important to 8 consider the regulatory exclusivity of Eylea when you 9 were analyzing the commercial success of Eylea, 10 correct? 11 MR. CAINE: Objection, form. 12 THE WITNESS: No, that's not correct. 13 BY MR. CHOI: 14 Q. Well, isn't that what you just said? You 15 said, "No. As I've said, I evaluated it. I decided 16 it was not important." That's your words just now. 17 MR. CAINE: That's not the entirety of his 18 answer. If you want to just read back his answer, go 19 ahead and read back his answer. 20 BY MR. CHOI: 21 Q. "It was not necessary to describe it 22 because it is not in and of itself a driver of</p> <p style="text-align: right;">Page 139</p>	<p>1 So that's the sense in which the 2 regulatory exclusivity per se is not a contributor in 3 and of itself to the commercial success. The 4 commercial success derives from the qualities, the 5 patented features of the product itself. The 6 regulatory exclusivity doesn't drive that. It's, in 7 some sense, parallel to it. 8 Q. So is it your opinion that then regulatory 9 exclusivity does not have any effect on sales of 10 Eylea? 11 A. As I have tried to explain, the product 12 sales are driven by the qualities of the product that 13 cause it to be used by physicians and want to be used 14 by patients. Now, the regulatory exclusivity is a 15 parallel fact that, but for the product's qualities, 16 would not matter. So -- and that's what maybe we're 17 not understanding each other, is that I do not think 18 it is not economically relevant, but it is not 19 relevant in the sense that, well, does this explain 20 the commercial success? Because the commercial 21 success critically derives from or depends upon the 22 product having some value to contribute to patients.</p> <p style="text-align: right;">Page 141</p>

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<p>1 If this product did nothing for people, even if it 2 had regulatory exclusivity, it would be not helpful. 3 And so that's the sense in which 4 regulatory exclusivity being there, always there, is 5 not relevant to the question of the commercial 6 success of the product. 7 Q. So is it your opinion that regulatory 8 exclusivity is not as an important factor as the 9 extended dosing of Eylea, is that right? 10 MR. CAINE: Objection, form. 11 THE WITNESS: Yeah, it's not as important. 12 BY MR. CHOI: 13 Q. Okay. And do you understand that the '681 14 patent covers Eylea molecule, or aflibercept 15 molecule? 16 MR. CAINE: Objection, form. 17 THE WITNESS: You know, I am not the 18 technical expert to tell you exactly what the details 19 of the coverage are with respect to the molecule. I 20 do understand from an economic perspective that it 21 covers the product that is sold as Eylea, so that's 22 what I understand.</p> <p style="text-align: right;">Page 142</p>	<p>1 regulatory exclusivity preventing others from 2 marketing aflibercept with a different dosing 3 regimen, right, as different than the '681 patent? 4 A. Sorry, just to restate so I'm clear, did I 5 analyze the ability of a competitor to, you know, put 6 forth a product that uses the same information as is 7 the basis for the approval of Eylea but with a 8 different dosing regimen than is covered in the 9 patent? 10 Q. No, but I'm specifically asking about 11 Eylea. 12 A. Okay. 13 Q. So have you considered whether regulatory 14 exclusivity would have prevented competitors from 15 entering the market with Eylea with a different 16 dosing regimen than the '681 patent? 17 A. I haven't specifically considered that. 18 But just to be clear, I'm not sure I understand the 19 question still. But suppose -- let me give you back 20 a hypothetical. I mean, suppose someone wanted to 21 sell Eylea with a 10-week dosing interval or, I don't 22 know, maybe that's covered by the patent, so a</p> <p style="text-align: right;">Page 144</p>
<p>1 BY MR. CHOI: 2 Q. So you agree that the product covers the 3 molecule and the patent covers the molecule, right? 4 A. Again, I -- you know, if there are 5 technicalities about what the molecule is called or 6 named, and I wouldn't want to delve into the 7 economics or, sorry, the law or the technical 8 chemistry of that. What I understand and what my 9 analysis is based on is an understanding that the 10 product that is sold as Eylea is what is covered by 11 the patent. 12 Q. Okay. And you didn't analyze the extent 13 to which marketing exclusivity or regulatory 14 exclusivity by Regeneron prevented others from 15 marketing aflibercept with different dosing regimen, 16 right? 17 MR. CAINE: Objection, form. 18 THE WITNESS: I'm not sure I understand 19 the question. 20 BY MR. CHOI: 21 Q. Let me rephrase. So your commercial 22 success analysis did not include an analysis of</p> <p style="text-align: right;">Page 143</p>	<p>1 seven-week dosing interval. Have I considered 2 whether the patents would preclude that? I have not. 3 Q. Patents or the regulatory exclusivity, 4 right? 5 A. You know, I guess I would have to go 6 review what the regulatory exclusivity would have 7 precluded, but I believe that, at minimum, it would 8 have required someone to do the studies that would 9 demonstrate to the FDA's satisfaction safety and 10 efficacy on whatever dosing schedule that was. But I 11 don't know whether or not that would have been 12 precluded by the regulatory exclusivity given the 13 differences in the dosing regimens. 14 Q. So you did not consider it as part of your 15 analysis in this proceeding, right? 16 MR. CAINE: Objection, form. 17 THE WITNESS: Well, I suppose did I 18 consider that hypothetical, that specific 19 hypothetical? I did not. But as I said, there are 20 things I would really need to know to evaluate that. 21 BY MR. CHOI: 22 Q. Okay. Is it correct that you didn't cite</p> <p style="text-align: right;">Page 145</p>

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<p>1 or discuss the most recent Eylea label in your 2 declaration?</p> <p>3 A. My understanding is the most recent Eylea 4 declaration -- sorry, most recent Eylea patent -- 5 label was issued not that long ago for -- that 6 included retinopathy prematurity, and that that comes 7 after the time period of my prior analysis. So 8 that's correct, I didn't --</p> <p>9 Q. Okay.</p> <p>10 A. -- review that.</p> <p>11 Q. So because you didn't review it, the 12 current label will not change your opinions, right?</p> <p>13 A. I would have to think about that. I 14 haven't carefully reviewed the label to see how it 15 compared to the labels that were in place at the 16 time.</p> <p>17 Q. Okay. So what's the time frame of your 18 opinion, just to be clear?</p> <p>19 A. Well, the original report or declaration 20 about the '338 patent -- well, the specific analysis 21 of Eylea begins with Eylea's launch in 2011, but 22 the -- you know, I talk about the preceding products</p> <p style="text-align: right;">Page 146</p>	<p>1 A. Not specifically. That sounds like a 2 technical aspect that I'm not equipped to evaluate.</p> <p>3 Q. How about efficacy?</p> <p>4 A. Well, efficacy is, again, a technical term 5 that has meaning within the context of the medical 6 and regulatory environment that, you know, as a 7 general term, I wouldn't want to be -- I wouldn't 8 have a view about what efficacy means as opposed to 9 effectiveness. Those are all technical things that I 10 don't have a specific opinion about.</p> <p>11 Q. So you did not consider it as part of your 12 commercial success analysis?</p> <p>13 A. Well, as I've said, you know, the 14 product's ability to treat the product -- sorry, to 15 treat the condition is important and it is 16 fundamental, as I've said before, to why the 17 eight-week dosing interval is important. And so the 18 product's ability to satisfy the needs of patients 19 and the desire of doctors to treat those patients is 20 important. Whether that is technically or the 21 technical definition of efficacy, I wouldn't want to 22 get into a -- my specific definition of it because it</p> <p style="text-align: right;">Page 148</p>
<p>1 or products that preceded it. I guess I don't know 2 when the exact first reference to the -- I guess 2005 3 when I talk about the beginning of Avastin being 4 treated or being used to treat angiogenic eye 5 disorders.</p> <p>6 And then the data end I believe in 2019 7 or -- let me see. Maybe '20. Well, the different 8 data sets have different termination points. I see 9 there are 2021 data for some of the -- some of the 10 references so I think that's -- and the report was in 11 2022. So that's the time frame.</p> <p>12 Q. Okay. So between 2011 through 2022, 13 right?</p> <p>14 A. Or depending upon what you really mean by 15 the question, maybe 2005 or maybe before as you think 16 about some of the earlier approaches to angiogenic 17 eye disorders.</p> <p>18 Q. Got it. For the other products, right?</p> <p>19 A. Uh-huh.</p> <p>20 Q. Okay. Did you consider aflibercept's 21 binding properties as part of your commercial success 22 analysis?</p> <p style="text-align: right;">Page 147</p>	<p>1 might not be consistent or there might be some 2 differences between that and what I would think it 3 would mean and what a practitioner might mean or what 4 the technical expert might mean.</p> <p>5 Q. But in your analysis of commercial 6 success, you did not attribute commercial success of 7 Eylea to efficacy of Eylea, right?</p> <p>8 MR. CAINE: Objection, form.</p> <p>9 THE WITNESS: Well, as the -- you know, 10 the claims reference the treatment of a -- of 11 angiogenic eye disorders for appropriate patients, 12 and that implies an effective treatment. Or again, I 13 want to be careful about using terms that might mean 14 something to a physician or to a technical person 15 that might be different from what I think but, yeah, 16 the ability to treat the condition is fundamental to 17 my view. Again, if it didn't treat the condition, it 18 wouldn't have demand.</p> <p>19 BY MR. CHOI:</p> <p>20 Q. Well, but then you didn't consider a 21 specific efficacy associated with Eylea being the 22 factor in driving sales of Eylea, right? I don't see</p> <p style="text-align: right;">Page 149</p>

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<p>1 anything in your declaration that speaks to, for</p> <p>2 example, the vision gained or vision lost, vision</p> <p>3 maintained, all these metrics related to efficacy of</p> <p>4 Eylea, right?</p> <p>5 MR. CAINE: Objection, form.</p> <p>6 THE WITNESS: Well, the claimed treatment</p> <p>7 method includes a treatment that is not inferior to</p> <p>8 Lucentis for -- dosed on a four-week interval. So</p> <p>9 the fact that the product claims to treat at that</p> <p>10 level, a noninferiority standard, is important and it</p> <p>11 is a fundamental driver of demand. As I have said</p> <p>12 before, if it didn't work, nobody would buy it. And</p> <p>13 so the fact that it works is an element of demand, is</p> <p>14 an element of the product's characteristics.</p> <p>15 BY MR. CHOI:</p> <p>16 Q. Would you say that then the efficacy of</p> <p>17 Eylea was a reason the extended dosing worked?</p> <p>18 MR. CAINE: Objection, form.</p> <p>19 THE WITNESS: You know, I'm not the</p> <p>20 technical expert so I -- is that why the product</p> <p>21 works? You mean technically --</p> <p>22 BY MR. CHOI:</p> <p style="text-align: right;">Page 150</p>	<p>1 THE WITNESS: I'm not the technical</p> <p>2 expert. I can't tell you why it works.</p> <p>3 BY MR. CHOI:</p> <p>4 Q. You can't tell me why it works even though</p> <p>5 the product at issue is Eylea, right? Is that your</p> <p>6 opinion?</p> <p>7 MR. CAINE: Objection, form.</p> <p>8 THE WITNESS: You're asking me why it</p> <p>9 works. I can't tell you that any more than, you</p> <p>10 know, I could tell you why any number of other</p> <p>11 complicated things work.</p> <p>12 BY MR. CHOI:</p> <p>13 Q. So why do you think the extended dosing</p> <p>14 was a critical factor for Eylea?</p> <p>15 A. Because it is a key differentiator of</p> <p>16 Eylea relative to the competing products, the</p> <p>17 alternative use, the alternative products that were</p> <p>18 available.</p> <p>19 Q. So you have no opinion as to why the</p> <p>20 extended dosing worked for Eylea?</p> <p>21 MR. CAINE: Objection, form.</p> <p>22 THE WITNESS: Well, is that a technical</p> <p style="text-align: right;">Page 152</p>
<p>1 Q. Or -- I'll rephrase the question.</p> <p>2 Would you say that the efficacy of Eylea</p> <p>3 is one of the factors that made the extended dosing a</p> <p>4 key distinguishing factor compared to other</p> <p>5 treatments for Eylea?</p> <p>6 MR. CAINE: Objection, form.</p> <p>7 THE WITNESS: Well, if the product didn't</p> <p>8 work, I would expect that it wouldn't have the same</p> <p>9 level of commercial success. So the product working</p> <p>10 or being able to treat people with angiogenic eye</p> <p>11 disorders, the appropriate population, that is</p> <p>12 important to the product's commercial success. It's</p> <p>13 sort of embedded in the analysis in the product</p> <p>14 itself. I mean, if it -- again, if it didn't work,</p> <p>15 it wouldn't matter what the dosing interval was</p> <p>16 because people wouldn't buy it. People wouldn't use</p> <p>17 it.</p> <p>18 BY MR. CHOI:</p> <p>19 Q. And you would agree that the reason Eylea</p> <p>20 works is because of the underlying molecule, right?</p> <p>21 A. Again --</p> <p>22 MR. CAINE: Objection, form.</p> <p style="text-align: right;">Page 151</p>	<p>1 question or an economic question?</p> <p>2 BY MR. CHOI:</p> <p>3 Q. Or economic question, either. I mean,</p> <p>4 whatever your opinion is here.</p> <p>5 A. I do have an opinion about why</p> <p>6 economically eight-week dosing mattered and I already</p> <p>7 discussed that.</p> <p>8 Q. No, what I'm saying is -- so my question</p> <p>9 is more of why was it possible for Eylea to be</p> <p>10 administered on extended dosing, is my question.</p> <p>11 A. That doesn't sound like an economic</p> <p>12 question to me. That sounds like a technical</p> <p>13 question and I don't know why it was possible to have</p> <p>14 the eight-week dosing. I mean, from an economic</p> <p>15 perspective, that's not an economic question. That's</p> <p>16 a technical question.</p> <p>17 Q. You think that higher efficacy would have</p> <p>18 contributed to the extended dosing of Eylea?</p> <p>19 MR. CAINE: Objection, form.</p> <p>20 THE WITNESS: I don't know. I mean,</p> <p>21 that's a technical question. But I would note that</p> <p>22 my recollection, my understanding is that the</p> <p style="text-align: right;">Page 153</p>

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<p>1 standard was noninferiority, not better than. It 2 was -- so not worse than Lucentis dosed on a 3 four-week interval so that the -- it's not -- my 4 recollection is that Eylea dosed on a four-week 5 interval is not better than Eylea dosed on an 6 eight-week interval. 7 BY MR. CHOI: 8 Q. So you had testified that the extended 9 eight-week dosing of Eylea was a distinguishing 10 factor. And you cannot testify -- I guess strike 11 that. 12 So why do you think the extended 13 eight-week dosing was a distinguishing factor for 14 Eylea economically speaking? 15 A. Because it is a characteristic of the 16 product that does not exist in the other competing 17 products. 18 Q. And why do you think other products 19 couldn't be dosed at an extended dosing interval? 20 MR. CAINE: Objection, form. 21 THE WITNESS: Well, again, that's a 22 medical/technical question. Why did it not work? I Page 154</p>	<p>1 MR. CAINE: Objection, form. 2 THE WITNESS: Very long question, but I 3 would not agree with where you ended up. 4 BY MR. CHOI: 5 Q. So, I mean, how -- so what -- in terms of 6 your analysis of efficacy -- I mean, well, you said 7 that you analyzed efficacy of aflibercept or Eylea in 8 this proceeding as part of your declaration, right? 9 MR. CAINE: Objection, form. 10 THE WITNESS: What I said is that I 11 observed that it is, based on clinical studies, based 12 on the testimony of the medical experts, noninferior 13 to a different drug, to Lucentis, based on a more -- 14 dosed on a four-week interval in the maintenance 15 phase, and Eylea achieves that noninferior level of 16 outcomes based on an eight-week level of -- or 17 interval of dosing. So effectiveness or ability to 18 reach that level of treatment is important, is 19 fundamental to the success of the product. 20 BY MR. CHOI: 21 Q. Now you're sounding like you're opining on 22 the technicality of -- Page 156</p>
<p>1 can only say Dr. Brown discussed a number of efforts 2 to try and extend the maintenance dosing phase -- 3 maintenance dosing interval for Lucentis that failed. 4 I don't know technically why it can't be done. I 5 just know that it can't. And I don't know why Eylea 6 can be dosed on an eight-week dosing schedule 7 successfully or -- and produce noninferior results to 8 Lucentis based on a four-week dosing schedule. Those 9 are technical questions. All I know is that it can 10 be and that is a clear economic advantage and that 11 therefore there's demand for the product because of 12 that advantage. 13 BY MR. CHOI: 14 Q. So would you agree that the efficacy of 15 Eylea was not relevant to your analysis of commercial 16 success, right? So your opinion here is that -- is a 17 fact or based on your discussions with experts, an 18 eight-week dosing for Eylea was possible, right, and 19 that is relevant to the economic analysis of the 20 commercial success. But the reason why those 21 eight-week dosing is possible, for example, efficacy 22 of Eylea, wasn't considered by your opinion, right? Page 155</p>	<p>1 A. Not at all. 2 Q. -- of Eylea being more effective as 3 compared to other molecules in the market, right? 4 A. No, that's an absolute misstatement of my 5 testimony. 6 Q. So what is your testimony? 7 A. As I just said, there is a -- there's 8 clinical evidence that on an eight-week dosing 9 interval, Eylea provides noninferior results to 10 Lucentis based on a four-week interval. That's an 11 economic difference. That difference is a 12 fundamental driver of demand for Eylea. That's the 13 testimony. 14 Q. So would you say that noninferior is not 15 related to efficacy of -- or strike that. 16 Would you say that noninferiority of Eylea 17 to Lucentis has nothing to do with efficacy of Eylea? 18 MR. CAINE: Objection, form. 19 THE WITNESS: No, I wouldn't say that. 20 BY MR. CHOI: 21 Q. So what would you say? 22 A. I would say that clinical evidence Page 157</p>

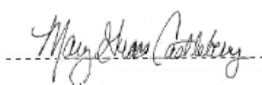
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<p>1 suggests or indicates that the level of effectiveness 2 or outcome or treatment ability that is -- that 3 results from using Lucentis on a four-week dosing 4 interval can be achieved by using Eylea on an 5 eight-week interval.</p> <p>6 Q. So how can you separate out eight-week 7 dosing from efficacy, is my question?</p> <p>8 MR. CAINE: Objection, form.</p> <p>9 BY MR. CHOI:</p> <p>10 Q. Because you had said that while Lucentis 11 for -- Eylea was able to achieve the same level of 12 efficacy on extended dosing regimen compared to the 13 monthly dosing regimen of Lucentis. So how is it 14 possible that the efficacy of Eylea be divorced from 15 the idea that extended dosing worked because of the 16 efficacy that it imparts as compared to Lucentis?</p> <p>17 MR. CAINE: Objection, form.</p> <p>18 THE WITNESS: I'm not sure I understand 19 the question.</p> <p>20 BY MR. CHOI:</p> <p>21 Q. I'm trying to -- so you're saying that the 22 clinical trial data showed that Eylea was noninferior</p> <p style="text-align: right;">Page 158</p>	<p>1 A. I would be a little more careful in how I 2 said that. I would say that the question here is the 3 patented dosing regime. The eight-week dosing 4 interval is a key differentiator in that regime. And 5 I would say that because Eylea is able to achieve no 6 worse outcomes than Lucentis on a less frequent 7 dosing schedule in the maintenance phase, that is a 8 key driver of demand.</p> <p>9 Q. So is it your opinion that efficacy of 10 Eylea was considered as part of the reason that Eylea 11 was so commercially successful or not?</p> <p>12 MR. CAINE: Objection, form.</p> <p>13 THE WITNESS: I think I've said yes to 14 that many times. I mean, if it were not effective, 15 if it didn't have that same level of -- if it weren't 16 able to do what Lucentis does on a less frequent 17 basis, demand would be lower.</p> <p>18 BY MR. CHOI:</p> <p>19 Q. Okay. All right. Sounds good. 20 I understand that you provided a 21 declaration or testimony as part of the district 22 court case in the Western District of Virginia,</p> <p style="text-align: right;">Page 160</p>
<p>1 in terms of efficacy compared to Lucentis monthly 2 dosing, and Eylea was able to achieve the same result 3 with the extended dosing, correct?</p> <p>4 MR. CAINE: Objection, form.</p> <p>5 THE WITNESS: Eylea was able to 6 demonstrate noninferior outcomes with extended 7 dosing. That --</p> <p>8 BY MR. CHOI:</p> <p>9 Q. And the noninferior outcome is related to 10 efficacy of Eylea, right?</p> <p>11 A. The product works on an eight-week dosing 12 interval, that -- it works in a noninferior way to 13 Lucentis based on a four-week schedule. So I don't 14 understand what the -- I don't understand --</p> <p>15 Q. How is it -- so when you're comparing the 16 noninferiority of Eylea with Lucentis, there has to 17 be a comparison of efficacy, right, that's associated 18 with a dosing regimen. So the whole reason that 19 Eylea is, according to you, a commercially successful 20 product is because it's able to achieve the extended 21 dosing that other products, for example, Lucentis, 22 could not achieve, right?</p> <p style="text-align: right;">Page 159</p>	<p>1 correct?</p> <p>2 A. I provided a report and a supplemental 3 report, yes.</p> <p>4 Q. And did that report discuss efficacy of 5 Eylea?</p> <p>6 A. In the same sense that we've been 7 discussing it here, that's my recollection, yeah.</p> <p>8 Q. You did consider that the efficacy of 9 Eylea was a driving factor for the commercial success 10 of Eylea, is that right?</p> <p>11 A. Well, in the same sense that we've been 12 discussing here. If it didn't work, it wouldn't 13 be -- it wouldn't have the same demand. But I 14 haven't read that report recently so there might be 15 other fine points that I'm not remembering.</p> <p>16 Q. Okay. In your report, did you consider 17 any copay programs available for Eylea?</p> <p>18 A. In the '338 declaration, there is a 19 discussion of the copayment programs that are 20 included in the P&L that was provided. Those were 21 relatively small numbers. I did talk about discounts 22 of rebates. I did not address the more recent -- or</p> <p style="text-align: right;">Page 161</p>

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<p>1 maybe not more recent. The other copay allegations</p> <p>2 that have been made.</p> <p>3 Q. What allegations are you talking about?</p> <p>4 A. Well, there's litigation in Massachusetts.</p> <p>5 Q. Okay. How about Eylea4U, is that a copay</p> <p>6 program that you considered as part of your</p> <p>7 declaration?</p> <p>8 A. Eylea4U is part of their copay programs as</p> <p>9 I understand it, yes.</p> <p>10 Q. Did you consider it as part of your</p> <p>11 declaration here?</p> <p>12 A. In this matter, it's not in my statement</p> <p>13 here. I don't know whether Eylea4U -- I don't recall</p> <p>14 whether Eylea4U is referenced in the '338 declaration</p> <p>15 or not.</p> <p>16 Q. Okay.</p> <p>17 MR CHOI: Let's take a 10-minute break.</p> <p>18 MR. CAINE: Okay.</p> <p>19 THE VIDEOGRAPHER: The time is 1:41 p.m.</p> <p>20 Eastern. We are now off the record.</p> <p>21 (Recess.)</p> <p>22 THE VIDEOGRAPHER: This is the beginning</p> <p style="text-align: right;">Page 162</p>	<p>1 (Reading and signing reserved.)</p> <p>2 (Whereupon, at 1:55 p.m., the taking of</p> <p>3 the instant deposition ceased.)</p> <p>4</p> <p>5</p> <p>6</p> <p>7</p> <p>8</p> <p>9</p> <p>10</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 style="text-align: right;">Page 164</p>
<p>1 of media unit number 4 in the video recorded</p> <p>2 deposition of Mr. Richard Manning. The time is</p> <p>3 1:54 p.m. Eastern. We are now back on the record.</p> <p>4 Counsel, you may proceed.</p> <p>5 MR. CHOI: I have no further questions.</p> <p>6 MR. CAINE: Okay. Thank you. No</p> <p>7 questions for me.</p> <p>8 And I don't think we really got into</p> <p>9 anything confidential on the transcript so I'm not</p> <p>10 going to mark the transcript itself confidential. I</p> <p>11 note that some of the exhibits that you went through</p> <p>12 do have a confidentiality designation, so we maintain</p> <p>13 the designation with respect to those exhibits.</p> <p>14 MR. CHOI: All right. Sounds good to me.</p> <p>15 THE VIDEOGRAPHER: All right. If there</p> <p>16 are no more questions, this will conclude today's</p> <p>17 deposition as given to us by Mr. Richard Manning.</p> <p>18 There were a total of four media units used today and</p> <p>19 they will be retained by Veritext Legal Solutions.</p> <p>20 The time is 1:55 p.m. Eastern and we are now off the</p> <p>21 record.</p> <p>22 Thank you all very much.</p> <p style="text-align: right;">Page 163</p>	<p>1 CERTIFICATE OF DEPONENT</p> <p>2</p> <p>3 I hereby certify that I have read</p> <p>4 and examined the foregoing transcript and:</p> <p>5 (Check one of the following)</p> <p>6 () The same is a true and</p> <p>7 accurate record of the testimony given by</p> <p>8 me, and I have made no corrections to this</p> <p>9 transcript.</p> <p>10 -OR-</p> <p>11 () Any additions or</p> <p>12 corrections that I feel are necessary, I</p> <p>13 have listed on the attached Errata Sheet.</p> <p>14 As witness my hand and signature</p> <p>15 this _____ day of _____.</p> <p>16</p> <p>17</p> <p>18 -----</p> <p>19 RICHARD MANNING</p> <p>20</p> <p>21</p> <p>22</p> <p style="text-align: right;">Page 165</p>

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<p>1 DATE SENT: December 13, 2023</p> <p>2 ERRATA SHEET</p> <p>3 DEPOSITION OF: Richard Manning</p> <p>4 DATE: December 12, 2023</p> <p>5 CASE: Samsung Bioepis, Co. vs. Regeneron Pharmaceuticals</p> <p>6 INSTRUCTIONS:</p> <p>7 1. Please read the transcript of your deposition and make note of any 8 corrections or changes on this Errata Sheet.</p> <p>9</p> <p>10 2. Indicate below general reason for change, such as:</p> <p>11 A. To correct stenographic error.</p> <p>12 B. To clarify record.</p> <p>13 C. To conform to the facts.</p> <p>14 3. Sign the Certificate of Deponent page.</p> <p>15 4. Within 30 days of the Date Sent, return this Errata Sheet, and signed Certificate of Deponent, to the address listed below AND to all Counsel listed on the Appearances page.</p> <p>16</p> <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 10%;">17 PAGE #</td> <td style="width: 10%;">18 LINE #</td> <td style="width: 40%;">19 CORRECTION</td> <td style="width: 40%;">20 REASON</td> </tr> <tr> <td>21</td> <td></td> <td></td> <td></td> </tr> <tr> <td>22</td> <td></td> <td></td> <td></td> </tr> </table> <p style="text-align: right;">Page 166</p>	17 PAGE #	18 LINE #	19 CORRECTION	20 REASON	21				22				<p>1 CERTIFICATE OF REPORTER</p> <p>2</p> <p>3 I, MARY GRACE CASTLEBERRY, RPR, the officer</p> <p>4 before whom the foregoing deposition was taken, do</p> <p>5 hereby certify that the witness whose testimony</p> <p>6 appears in the foregoing deposition was duly sworn by</p> <p>7 me; that the testimony of said witness was taken by</p> <p>8 me to the best of my ability and thereafter reduced</p> <p>9 to typewriting under my direction; that I am neither</p> <p>10 counsel for, related to, nor employed by any of the</p> <p>11 parties for the action in which this deposition was</p> <p>12 taken, and further that I am not a relative or</p> <p>13 employee of any attorney or counsel employed by the</p> <p>14 parties thereto, nor financially or otherwise</p> <p>15 interested in the outcome of the action.</p> <p>16</p> <p>17 </p> <p>18</p> <p>19 Notary Public in and for</p> <p>20 The District of Columbia</p> <p>21</p> <p>22 My commission expires: 07/14/2026</p> <p style="text-align: right;">Page 168</p>																																																				
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<p>1 ERRATA SHEET</p> <p>2 DEPOSITION OF BRIAN MONTGOMERY:</p> <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 10%;">3 PAGE #</td> <td style="width: 10%;">4 LINE #</td> <td style="width: 40%;">5 CORRECTION</td> <td style="width: 40%;">6 REASON</td> </tr> <tr><td>7</td><td></td><td></td><td></td></tr> <tr><td>8</td><td></td><td></td><td></td></tr> <tr><td>9</td><td></td><td></td><td></td></tr> <tr><td>10</td><td></td><td></td><td></td></tr> <tr><td>11</td><td></td><td></td><td></td></tr> <tr><td>12</td><td></td><td></td><td></td></tr> <tr><td>13</td><td></td><td></td><td></td></tr> <tr><td>14</td><td></td><td></td><td></td></tr> <tr><td>15</td><td></td><td></td><td></td></tr> <tr><td>16</td><td></td><td></td><td></td></tr> <tr><td>17</td><td></td><td></td><td></td></tr> <tr><td>18</td><td></td><td></td><td></td></tr> <tr><td>19</td><td></td><td></td><td></td></tr> <tr><td>20</td><td></td><td></td><td></td></tr> <tr><td>21</td><td></td><td></td><td></td></tr> </table> <p>22 Richard Manning Date</p> <p style="text-align: right;">Page 167</p>	3 PAGE #	4 LINE #	5 CORRECTION	6 REASON	7				8				9				10				11				12				13				14				15				16				17				18				19				20				21				Empty space for page 167 content
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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.

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VERITEXT LEGAL SOLUTIONS

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Veritext Legal Solutions represents that the foregoing transcript is a true, correct and complete transcript of the colloquies, questions and answers as submitted by the court reporter. Veritext Legal Solutions further represents that the attached exhibits, if any, are true, correct and complete documents as submitted by the court reporter and/or attorneys in relation to this deposition and that the documents were processed in accordance with our litigation support and production standards.

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Errata Sheet
Deposition of Richard Manning

I wish to make the following changes to the transcript of my deposition given on December 12, 2023, for the following reasons:

Page	Line	Changes or Correction	Reason
33	4	Change “maintenance key” to “maintenance phase”	Misspoke
33	13	Change “excluding” to “exclusion”	Correct transcription error
39	8	Change “are” to “is”	Misspoke
41	7	Change “to be appropriate” to “appropriate”	Misspoke
45	9	Change “exclusionary” to “exclusion”	Correct transcription error
58	14	Change “but” to “must”	Correct transcription error
64	11	Change “regime” to “regimen”	Correct transcription error
64	21	Change “regime” to “regimen”	Correct transcription error
66	18	Change “exclusionary” to “exclusion”	Correct transcription error
72	11	Change “regime” to “regimen”	Correct transcription error
80	17	Change “that what AMD” to “that AMD”	Correct transcription error
82	15	Change “leaks” to “weeks”	Correct transcription error
87	15	Change “relined” to “remind”	Correct transcription error
91	4	Change “regime” to “regimen”	Correct transcription error
102	7	Change “It’s the same” to “With the same”	Correct transcription error
109	14	Change “regime” to “regimen”	Correct transcription error
111	15	Change “regime” to “regimen”	Correct transcription error
115	2	Change “our” to “are”	Correct transcription error
115	3	Change “dose” to “dosed”	Correct transcription error

117	21	Add “?” after “Exhibit 2176”	Add missing question mark
125	6	Change “understand quite” to “quite understand”	Correct transcription error
141	16	Change “what” to “why”	Correct transcription error
145	6	Change “retinopathy prematurity” to “retinopathy of prematurity”	Correct transcription error
160	3	Change “regime” to “regimen”	Correct transcription error
160	4	Change “regime” to “regimen”	Correct transcription error
161	22	Change “of” to “or”	Correct transcription error

Dated: 1/12/2024



Richard Manning