

<p style="text-align: right;">97</p> <p>1 attributes that are key drivers of marketplace 2 performance, that clinical data showed that Eylea 3 was noninferior and clinically equivalent but not 4 superior to ranibizumab? 5 MR. MARX: Objection. Outside the scope 6 of Mr. Hofmann's expertise, lack of foundation. 7 BY THE WITNESS: 8 A I don't know if you're reading from 9 Paragraph 58, but I can't find or I certainly 10 didn't follow what you were saying relative to any 11 particular language in Paragraph 58. 12 BY MR. CAINE: 13 Q Well, you offered an opinion in 58 that 14 was a critique of Dr. Manning, that Dr. Manning 15 didn't consider attributes such as safety and 16 efficacy that explained, I think, in your view 17 Eylea's marketplace performance; is that right? 18 MR. MARX: Objection. Mischaracterizes 19 the document. 20 BY THE WITNESS: 21 A I think you're paraphrasing but I think 22 paraphrasing in a way that I can live with.</p>	<p style="text-align: right;">99</p> <p>1 know how to interpret it, and I don't know -- you 2 know, I think these are far better questions for 3 Drs. Gerritsen and Albin if these are things they 4 reviewed. I don't recall seeing references to 5 them one way or the other in their declarations, 6 but I don't know that I can respond to your 7 question as asked. 8 BY MR. CAINE: 9 Q Did you review Dr. Do's declaration? 10 A I did. 11 Q Did you review her discussion of 12 Exhibit 1018? 13 A I don't remember. 14 Q Did you ask to see Exhibit 1018 after 15 reviewing Dr. Do's declaration? 16 A I don't remember one way or the other. 17 Q Do you understand there to be a difference 18 between efficacy of treatment and the duration at 19 which that efficacy is maintained? 20 MR. MARX: Objection. Outside the scope. 21 And further, this is completely improper. It's 22 seeking a legal conclusion with respect to the</p>
<p style="text-align: right;">98</p> <p>1 BY MR. CAINE: 2 Q In this exhibit that we're looking at -- 3 A Among other things. 4 Q In this exhibit that we're looking at, 5 Exhibit 1018, the results that are being reported 6 are that aflibercept was noninferior and 7 clinically equivalent to monthly ranibizumab, not 8 that it was superior, right? 9 MR. MARX: Objection. Outside the scope. 10 BY THE WITNESS: 11 A I don't feel comfortable commenting on 12 Exhibit 1018. I haven't reviewed it. I'm not a 13 scientist. I'm not a POSA. I've relied in 14 developing my opinions in Paragraph 58 as well as 15 the entirety of my report and the relevant 16 sections contained therein. 17 I've referenced the technical experts and 18 their opinions that helped shape and form my 19 opinions on technical issues as well as making 20 sure that they were consistent with what I saw in 21 the documents that I saw. 22 I haven't seen this document. I don't</p>	<p style="text-align: right;">200</p> <p>1 pending claim construction argument that Regeneron 2 is trying to make. 3 BY THE WITNESS: 4 A I just -- I don't have the scientific 5 expertise to answer that question. 6 BY MR. CAINE: 7 Q You didn't have that scientific expertise 8 when you formed the opinions that are set forth in 9 your declaration, right? 10 MR. MARX: Objection. Mischaracterizes 11 the witness testimony. 12 BY THE WITNESS: 13 A No. What I'm saying is I had sufficient 14 basis to form all the opinions in my report, and 15 as is normally done by economists who are dealing 16 with complex technical issues is I relied on 17 technical experts. 18 I reviewed other documents to make sure 19 that there wasn't anything that kind of stood out 20 or didn't seem to make sense in my ability to 21 interpret as an economist, not as a scientist, not 22 as a POSA, and based on what I reviewed and</p>

20	<p>1 explain and cite to in my report was supported.</p> <p>2 BY MR. CAINE:</p> <p>3 Q What did you do from an economic</p> <p>4 perspective to differentiate between the impact of</p> <p>5 efficacy and the impact of duration?</p> <p>6 MR. MARX: Objection to the extent it</p> <p>7 seeks a legal conclusion and form.</p> <p>8 BY THE WITNESS:</p> <p>9 A I think I have to go on the attack here a</p> <p>10 bit with Manning. He didn't do anything.</p> <p>11 BY MR. CAINE:</p> <p>12 Q I'm asking, sir, what you did for the</p> <p>13 purposes of your declaration to differentiate</p> <p>14 between efficacy and duration for the purposes of</p> <p>15 offering opinions on Eylea's marketplace</p> <p>16 performance?</p> <p>17 MR. MARX: Objection to the extent it</p> <p>18 seeks a legal conclusion, form and</p> <p>19 mischaracterizes the witness testimony.</p> <p>20 BY THE WITNESS:</p> <p>21 A That's inherent in – my role here is to</p> <p>22 respond and rebut the opinions expressed in the</p>	203	<p>1 to differentiate between efficacy and duration for</p> <p>2 the purpose of offering opinions on marketplace</p> <p>3 performance.</p> <p>4 Did you consider those two to be different</p> <p>5 attributes?</p> <p>6 MR. MARX: Objection. Asked and answered,</p> <p>7 outside the scope of Mr. Hofmann's expertise.</p> <p>8 BY THE WITNESS:</p> <p>9 A I'm not a scientist and I'm not a POSA. I</p> <p>10 was afforded the luxury of having Dr. Manning's</p> <p>11 deposition transcript and Dr. Manning's</p> <p>12 declaration before I issued my declaration. He</p> <p>13 didn't do anything with this. I was rebutting</p> <p>14 him. So what I did was I explained what I</p> <p>15 observed in his failures. Whether or not he's</p> <p>16 here to defend himself, I think the record is</p> <p>17 pretty clear from his deposition he didn't do</p> <p>18 anything with respect to this. And so we have</p> <p>19 that in sworn testimony because I think he was</p> <p>20 asked about that.</p> <p>21 I think that what we have here is the</p> <p>22 situation where I – so absent him doing anything</p>
202	<p>1 Manning declaration, and so for you to say you're</p> <p>2 not asking what he did, that's the role I played</p> <p>3 here. I looked at what he did. He did nothing.</p> <p>4 So then I looked at what Drs. Gerritsen</p> <p>5 and Dr. Albini did and expressed and explained my</p> <p>6 understanding from what they did. I reviewed and</p> <p>7 considered other documents and information, and I</p> <p>8 explain that, I think, in pretty good detail in my</p> <p>9 declaration.</p> <p>10 So it is – it is a defect and a flaw that</p> <p>11 Manning didn't address any of this, and I'm</p> <p>12 highlighting so he didn't address any of it. And</p> <p>13 from what I've seen in the record, there's</p> <p>14 evidence that these are attributes that are</p> <p>15 attributable to the aflibercept molecule, as I</p> <p>16 explained, and have references to their</p> <p>17 declarations. And I'm just – I'm not sure what</p> <p>18 more to say about that.</p> <p>19 BY MR. CAINE:</p> <p>20 Q Dr. Manning is not here to defend himself.</p> <p>21 I'm sure he would have a response. But I'm really</p> <p>22 asking about what you did as part of your critique</p>	204	<p>1 to address how much we would look at the efficacy</p> <p>2 and safety as flowing from the aflibercept</p> <p>3 molecule, I looked to what I saw from technical</p> <p>4 experts. I'm not a scientist or a POSA, so that's</p> <p>5 the place I go to first.</p> <p>6 And then I reviewed the rest of the</p> <p>7 record, and everything I saw was consistent with</p> <p>8 what I was looking at in the documents and</p> <p>9 information that were produced that suggest that</p> <p>10 it's not the '338 patent. It's, in fact, things</p> <p>11 that were associated with prior blocking patents,</p> <p>12 things that were known in the prior art, among</p> <p>13 them being efficacy and safety associated with the</p> <p>14 aflibercept molecule, as I explain in detail in my</p> <p>15 report.</p> <p>16 BY MR. CAINE:</p> <p>17 Q In forming your critiques, did you do</p> <p>18 anything to differentiate between efficacy on the</p> <p>19 one hand and duration on the other as a basis for</p> <p>20 Eylea's marketplace performance?</p> <p>21 MR. MARX: Objection. Asked and answered,</p> <p>22 outside the expert's expertise. And furthermore,</p>

<p style="text-align: right;">205</p> <p>1 to the extent this relates to the pending claim 2 construction issue, it seeks a legal conclusion. 3 It's an improper line of questioning. 4 BY THE WITNESS: 5 A It is – you know, my opinions are laid 6 out in, I think, copious detail in my declaration, 7 and I explain the things that I considered, relied 8 upon, reviewed. Among them were the opinions of 9 technical experts where those finer points, if 10 their issues were part of what I considered 11 because I considered the entirety of their 12 opinions and declarations. But I'm not a 13 scientist. I'm not a POSA. I'm not weighing in 14 on any of that affirmatively one way or the other. 15 BY MR. CAINE: 16 Q Let me ask the question one more time 17 because I don't believe you've yet answered it. 18 In forming your critiques, did you do 19 anything to differentiate between efficacy on the 20 one hand and duration on the other as a basis for 21 Eylea's marketplace performance? 22 MR. MARX: Objection. Asked and answered.</p>	<p style="text-align: right;">207</p> <p>1 Exhibit -- just so I have it right -- 2086, 2 correct? 3 MR. MARX: Objection. Form. 4 BY THE WITNESS: 5 A Nor would it be anywhere near normal for 6 an economist to do so. I'm not getting into the 7 weeds of the technical issues and arguments 8 because I'm not a POSA. I'm not a scientist. I'm 9 relying on their opinions, as I've referenced and 10 explained, having reviewed their declarations. 11 They've considered all this stuff, and that stuff, 12 you know, is something they considered in forming 13 the opinions on which I ultimately rely. 14 I'm not going to reasonably replicate what 15 a scientist who is a skilled clinician, who is a 16 skilled microbiologist does in their review of 17 scientific articles. We just have differing 18 expertise. I rely on their expertise, and then I 19 do a check by looking at other documents and 20 information that are provided in this case by 21 Regeneron, and I didn't see anything that 22 suggested otherwise to the conclusions that they</p>
<p style="text-align: right;">206</p> <p>1 Objection. It seeks a legal conclusion as it 2 relates to the pending claim construction issue 3 and further outside the scope of Mr. Hofmann's 4 expertise. 5 BY THE WITNESS: 6 A I'm not a scientist. I'm not a POSA. I'm 7 not a patent lawyer. I'm taking what was, I 8 think, failure by Dr. Manning in addressing the 9 things that were known in the prior art and the 10 important role that efficacy and safety played 11 with respect to the aflibercept molecule. 12 And then I relied on technical experts 13 with confirmatory review through my review of 14 documents and information that were provided by 15 Regeneron in forming my opinions. 16 It's all laid out in my report, and I 17 don't really have anything to add beyond that. 18 BY MR. CAINE: 19 Q As part of your analysis and your review 20 of the declarations of Dr. Albini and 21 Dr. Gerritsen, you did not -- you did not go into 22 detail on Exhibit 1018, which we've looked at, or</p>	<p style="text-align: right;">208</p> <p>1 reached, and so, I think, reasonably relied on 2 that information collectively, as I explain in 3 detail in my declaration. 4 Q You talked about relying on the technical 5 experts with confirmatory review through your 6 review of documents and information that were 7 provided by Regeneron. And I'm asking did that 8 confirmatory review and your review of documents 9 include Exhibits 1018 or 2086? 10 A I don't remember whether I specifically 11 looked at those documents. I mean, I looked at 12 the Do report. I looked at the technical experts. 13 I don't have these documents listed in my table as 14 something that I separately reviewed, so I don't 15 know if I've seen these before. I don't believe I 16 have. 17 But either way, like, I think what you're, 18 I guess, suggesting is that I needed to check or 19 double-check what the POSAs and scientists viewed 20 with respect to information like these articles. 21 That isn't what an economist would do. 22 I'm relying on their expertise for their lane that</p>

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<p>1 they're in, and I'm providing my perspective</p> <p>2 through an economic lens on the lane that I'm in.</p> <p>3 Q You didn't ask Dr. Albin or Dr. Gerritsen</p> <p>4 to explain to you the difference between efficacy</p> <p>5 and duration; is that right?</p> <p>6 MR. MARX: Objection. Asked and answered.</p> <p>7 BY THE WITNESS:</p> <p>8 A I feel like we've talked about this -- I</p> <p>9 don't know how many dozens of times, but Manning</p> <p>10 did nothing. I'm rebutting --</p> <p>11 BY MR. CAINE:</p> <p>12 Q You didn't answer my question.</p> <p>13 Did you ask Dr. Albin or Dr. Gerritsen to</p> <p>14 explain to you the difference between efficacy and</p> <p>15 duration?</p> <p>16 MR. MARX: Objection. And I ask counsel</p> <p>17 not to interrupt Mr. Hofmann while he's answering</p> <p>18 questions.</p> <p>19 BY THE WITNESS:</p> <p>20 A I'm a rebuttal witness to Dr. Manning. He</p> <p>21 did nothing. So if anything, I did more by doing</p> <p>22 what I did and explaining what I found by looking</p>	<p>1 appears to be a document I haven't seen before</p> <p>2 from 2009. It's a hundred-page document that I'm</p> <p>3 unfamiliar with. So are you going to -- yes, I</p> <p>4 have something labeled 2259 in front of me, but I</p> <p>5 have not reviewed any of the hundred pages.</p> <p>6 Q You understand that Exhibit 2259 was</p> <p>7 submitted in this proceeding by Regeneron? I'll</p> <p>8 represent to you that it was.</p> <p>9 A I assume so based on the fact that it's</p> <p>10 got an IPR Bates or whatever the exhibit</p> <p>11 referencing scheme is.</p> <p>12 Q You'd recognize Exhibit 2259 as one that</p> <p>13 Dr. Manning cited in his declaration?</p> <p>14 A I don't remember if he did one way or the</p> <p>15 other.</p> <p>16 Q You would agree with me that you've had an</p> <p>17 opportunity to review Exhibit 2259 prior to the</p> <p>18 preparation of your declaration?</p> <p>19 A I mean, I guess show me where he</p> <p>20 references it in his report.</p> <p>21 Q I'll represent to you that it's referenced</p> <p>22 in his report.</p>
2 0	2 2
<p>1 at their declarations and looking at the documents</p> <p>2 and information that was available to me in the</p> <p>3 record.</p> <p>4 You already know the answer that I have</p> <p>5 had no live discussions with Dr. Albin or</p> <p>6 Dr. Gerritsen, so no, I didn't have discussions</p> <p>7 with them, but I had more than adequate</p> <p>8 information and above and beyond addressing of</p> <p>9 this issue compared to Dr. Manning, who did</p> <p>10 nothing.</p> <p>11 MR. CAINE: Can we see Exhibit 2259,</p> <p>12 please.</p> <p>13 BY MR. CAINE:</p> <p>14 Q I'm going to hand you what's been marked</p> <p>15 as Exhibit 2259.</p> <p>16 MR. MARX: No comment. The labels</p> <p>17 are consistent with Exhibit 2259.</p> <p>18 BY MR. CAINE:</p> <p>19 Q Mr. Hofmann, do you have Exhibit 2259 in</p> <p>20 front of you? Is that a yes, no? Do you have it</p> <p>21 in front of you?</p> <p>22 A So I can answer that question, but this</p>	<p>1 A Okay. But maybe show me because I</p> <p>2 don't -- you know, a 2009 study for American</p> <p>3 Society of Retina Specialists -- I don't know --</p> <p>4 that was long before the launch of Eylea, and I</p> <p>5 just -- I don't recall this document. Maybe I</p> <p>6 looked at it; maybe I didn't. But I'm unfamiliar</p> <p>7 with it as I sit here right now given that it's a</p> <p>8 hundred pages and there's a whole bunch of stuff</p> <p>9 here.</p> <p>10 Q I'll represent to you that it was</p> <p>11 referenced in Paragraph 89 of Dr. Manning's</p> <p>12 report.</p> <p>13 Do you agree?</p> <p>14 A Yeah. I mean, I see the reference. I</p> <p>15 just I don't -- I don't recall --</p> <p>16 Q You are familiar --</p> <p>17 A -- this as I sit here right now.</p> <p>18 Q You are familiar with ASRS PAT surveys?</p> <p>19 MR. MARX: Excuse me one second,</p> <p>20 Mr. Hofmann. I'm just going to note for the</p> <p>21 record that this section of the Manning report is</p> <p>22 under heading "Eylea's Patented Dosing Regimen</p>

<p style="text-align: right;">2 3</p> <p>1 Addressed an Unmet Need For Longer Dose 2 Intervals," and Mr. Hofmann has offered no 3 opinions in this case concerning unmet need. So 4 outside the scope, this whole line of questioning 5 and the use of this document. 6 MR. CAINE: I disagree. 7 BY MR. CAINE: 8 Q Have you seen ASRS PAT surveys previously? 9 A I don't recall as I sit here right now one 10 way or the other. 11 Q Would you turn for me to Page 93 of 12 Exhibit 2259. 13 A So do you mean Page 93 or Slide 93? 14 Because they seem to be one off. 15 Q Page 93, which is Slide 92. 16 A Okay. 17 Q Do you understand this is a survey from 18 2009? 19 MR. MARX: Objection. Lack of foundation, 20 outside the scope of Mr. Hofmann's opinions in 21 this matter. 22 BY THE WITNESS:</p>	<p style="text-align: right;">2 5</p> <p>1 visual acuity? 2 MR. MARX: Objection. Still to the use of 3 this document, with respect to unmet need. 4 Mr. Hofmann has offered no opinions in this case 5 on unmet need. Further, I don't recall this page 6 being cited by Dr. Manning. 7 To the extent you're trying to elicit 8 technical expert testimony from Mr. Manning {sic}, 9 he is not a technical expert, as he has stated 10 numerous times today. 11 BY THE WITNESS: 12 A I'm too unfamiliar with this document to 13 even know how to respond. How the study was 14 conducted, what the control questions were aren't 15 even listed, which usually is part of a survey. 16 Like, I don't know what to say. You can read 17 words from what's there. 18 I don't remember Dr. Manning citing to 19 this slide. I don't remember this being something 20 that was an area of focus for the purposes of my 21 opinions on commercial success. 22 BY MR. CAINE:</p>
<p style="text-align: right;">2 4</p> <p>1 A I mean, the footer says 2009. So that's 2 all I can say, is that's what it says in the 3 footer. 4 BY MR. CAINE: 5 Q Do you see that on this slide, there is a 6 question about "the current unmet need in the 7 treatment of wet AMD today"? 8 MR. MARX: Same objection. Outside the 9 scope of Mr. Hofmann's opinions in this matter. 10 BY THE WITNESS: 11 A I mean, you can read the words that are on 12 here. I don't remember seeing this, and I don't 13 recall anywhere in my declaration I address unmet 14 need. That's usually something that's addressed 15 by clinicians, if there is an unmet need, 16 long-felt unmet need, but I don't – if you read 17 words, I can tell you whether you've read them as 18 they appear. 19 BY MR. CAINE: 20 Q Do you see that for the response to that 21 question, 33.56 of respondents said "reduces 22 frequency of injections, maintains VA," meaning</p>	<p style="text-align: right;">2 6</p> <p>1 Q You see above it, it says -- you see the 2 words "improves visual outcomes"? 3 MR. MARX: Same objection. Outside the 4 scope of Mr. Hofmann's opinions in this matter and 5 seeking testimony -- scientific technical 6 testimony from Mr. Hofmann which is not his 7 expertise. 8 And I'll further note for the record that 9 this study, PAT study, lack of foundation. I do 10 not know who the respondents to this survey are. 11 My understanding of these PAT surveys is actually 12 anybody can go online and submit responses to 13 these surveys, not just a retina specialist. So 14 with those objections -- 15 MR. CAINE: Mr. Marx, I've only asked him 16 the question, first of all, whether he sees the 17 words on the page. And I think that objection is 18 improper. I think you are engaging in improper 19 speaking objections. So I would ask you again to 20 stop. 21 MR. MARX: I would ask you to stick to 22 Mr. Hofmann's opinions in this case.</p>

<p style="text-align: right;">2 7</p> <p>1 MR. CAINE: I'm happily doing so.</p> <p>2 MR. MARX: I disagree. This is clearly</p> <p>3 unmet need from Mr. Manning's declaration.</p> <p>4 Mr. Hofmann has offered no opinions on unmet need.</p> <p>5 MR. CAINE: I disagree with you.</p> <p>6 MR. MARX: You're free to disagree.</p> <p>7 You're free to ask questions you want. I'm free</p> <p>8 to object as outside the scope of Mr. Hofmann's</p> <p>9 opinions. I'm doing so.</p> <p>10 MR. CAINE: Absolutely. That's fine. If</p> <p>11 you limit your objection to objection outside the</p> <p>12 scope and don't include the speaking objection</p> <p>13 about who can go online and fill out the surveys,</p> <p>14 I'm fine with that. So that's what I would ask</p> <p>15 you to do.</p> <p>16 MR. MARX: I'll take that under</p> <p>17 advisement, but I'll object how I see fit. Thank</p> <p>18 you.</p> <p>19 MR. CAINE: I understand you're going to</p> <p>20 object how you see fit. It's just going to make</p> <p>21 the objection go more smoothly if you make your</p> <p>22 objections and don't litter the record with</p>	<p style="text-align: right;">2 9</p> <p>1 questioning. Mr. Hofmann cannot confirm or deny</p> <p>2 these numbers, what they mean, what their import</p> <p>3 is. Outside the scope of his expertise, outside</p> <p>4 the scope of his opinions in this case.</p> <p>5 BY THE WITNESS:</p> <p>6 A I'm kind of at a loss here because I don't</p> <p>7 recall Dr. Manning referencing this in his report.</p> <p>8 I don't see in this survey document or purported</p> <p>9 survey something that explains what the parameters</p> <p>10 were for the survey itself and how it was</p> <p>11 conducted, what the questions were, what the</p> <p>12 control questions were, which is all stuff I said</p> <p>13 before you guys started objecting to each other.</p> <p>14 I don't know what you expect me to do with</p> <p>15 this. It seems like we could read the letters on</p> <p>16 the page, but I don't know what to say beyond</p> <p>17 that.</p> <p>18 BY MR. CAINE:</p> <p>19 Q Do you agree that in 2009, both Lucentis</p> <p>20 and Avastin were treatments that were being used</p> <p>21 to treat eye disorders, right?</p> <p>22 MR. MARX: Objection to the extent it's</p>
<p style="text-align: right;">2 8</p> <p>1 speaking objections about what people can and</p> <p>2 can t respond -- which people can and can t</p> <p>3 respond.</p> <p>4 MR. MARX: I would ask that you stick to</p> <p>5 Mr. Hofmann's opinions in this matter, and I won't</p> <p>6 have to object so often.</p> <p>7 MR. CAINE: I will happily do so.</p> <p>8 MR. MARX: Okay. Well, focus on unmet</p> <p>9 need. Outside his expertise, outside his opinions</p> <p>10 in this case.</p> <p>11 But go ahead and ask your questions.</p> <p>12 MR. CAINE: Thank you.</p> <p>13 BY MR. CAINE:</p> <p>14 Q Mr. Hofmann, do you see the words</p> <p>15 "improves visual outcomes"?</p> <p>16 A I see the words as they appear on that</p> <p>17 slide. Again, I don't --</p> <p>18 Q Do you see that the response to both A</p> <p>19 and B below reduces frequency of injections,</p> <p>20 maintains VA, which is below improves visual</p> <p>21 outcomes, is 62.73 percent?</p> <p>22 MR. MARX: Objection to this line of</p>	<p style="text-align: right;">220</p> <p>1 outside the scope of Mr. Hofmann's expertise.</p> <p>2 BY MR. CAINE:</p> <p>3 Q I'm asking you about the marketplace as it</p> <p>4 existed in 2009.</p> <p>5 A I'm not a clinician, but from what I've</p> <p>6 reviewed, I think Avastin was off label to the</p> <p>7 extent it was being used in this space and</p> <p>8 Lucentis did have, and you're just making a very</p> <p>9 vague kind of eye disorders. There are specific</p> <p>10 labeled indications from my review of the labels.</p> <p>11 Q Well, at least in 2009, both Avastin and</p> <p>12 Lucentis were being used in the treatment of</p> <p>13 wet AMD, correct?</p> <p>14 MR. MARX: Objection to the extent it's</p> <p>15 outside Mr. Hofmann's expertise.</p> <p>16 BY THE WITNESS:</p> <p>17 A I'm not a clinician. I believe -- I don't</p> <p>18 have the label in front of me from 2009 for</p> <p>19 Lucentis, but I believe it was on label for</p> <p>20 Lucentis. I believe it was off label for Avastin</p> <p>21 at that point.</p> <p>22</p>

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1 BY MR. CAINE:
 2 Q Both were being used to treat wet AMD at
 3 that point in time?
 4 MR. MARX: Objection. Outside the scope
 5 of Mr. Hofmann's expertise.
 6 BY THE WITNESS:
 7 A I'm not a clinician, but from what I've –
 8 and that's a better question for a clinician. I
 9 don't know why you're asking me this, but I
 10 believe that there are some documents that suggest
 11 that Avastin was being used off label for wet AMD,
 12 and I believe Lucentis was on label. But I don't
 13 have the Lucentis label in front of me.
 14 BY MR. CAINE:
 15 Q You have -- you said earlier that you
 16 don't know whether you are familiar with ASRS
 17 surveys; is that right?
 18 MR. MARX: Objection. Mischaracterizes
 19 the witness testimony.
 20 BY THE WITNESS:
 21 A You asked me specifically whether I'm
 22 familiar with ASRS PAT surveys. I look at this

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1 and I don't know that I've seen one before. Maybe
 2 I have. I've done other ocular products, but as I
 3 sit here right now, I'm not – I'm not remembering
 4 them one way or the other.
 5 MR. CAINE: Well, why don't we do this.
 6 We've been going for a little bit more than an
 7 hour. Why don't we take a break and we'll come
 8 back and keep going after.
 9 THE VIDEOGRAPHER: Please stand by. We
 10 are going off the record. The time is 2:46 p.m.
 11 (A recess was had.)
 12 THE VIDEOGRAPHER: We are back on the
 13 record. The time is 3:01 p.m.
 14 BY MR. CAINE:
 15 Q Mr. Hofmann, welcome back. Did you review
 16 Exhibit 2176 for the purposes of preparing your
 17 declaration?
 18 A I did.
 19 Q I'm going to hand you Exhibit 2176.
 20 Do you recognize Exhibit 2176 as a Q4 2020
 21 performance update?
 22 A Yeah. I mean, it's 137 pages. I haven't

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1 reviewed every page, but that's what it's titled.
 2 Q Are you saying you didn't review every
 3 page prior to preparing and submitting your
 4 declaration?
 5 A No. I'm saying as I sit here right now, I
 6 didn't do so.
 7 Q Did you review every page before
 8 submitting your declaration?
 9 MR. MARX: Asked and answered.
 10 BY THE WITNESS:
 11 A Yeah. So to the extent that I have it
 12 labeled in my table on pages -- in the "Documents
 13 Reviewed" section of my report, I would have
 14 reviewed, yeah, every page prior to the issuance
 15 of my declaration.
 16 BY MR. CAINE:
 17 Q Would you turn to Page 92. Do you have
 18 it?
 19 A Yeah. Just give me a second to take a
 20 look and I think I'm there.
 21 Okay. Yeah, I'm there.
 22 Q You see it's titled "Wet AMD Dosing

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1 Update"?

2 A I do see that.
 3 Q Do you see that there is a line graph or a
 4 series of line graphs for different treatments for
 5 wet AMD?
 6 A I do see that.
 7 Q And the yellow line is the line graph for
 8 Eylea?
 9 A With the triangles as the points, yes.
 10 Q Do you see that for eight-week dosing, the
 11 percentage of physicians that use eight-week
 12 maintenance dosing to treat wet AMD with Eylea is
 13 [REDACTED] ?
 14 MR. MARX: Objection. Mischaracterizes
 15 the document, lack of foundation.
 16 BY THE WITNESS:
 17 A I mean, there's a lot of caveats and
 18 footnotes and everything else in this. If you
 19 look at it a little closer about what is what and
 20 what can be precisely ascertained from this, but I
 21 do see at least directionally Eylea being slightly
 22 behind -- how do you pronounce it, brolucizumab?

225

1 **BY MR. CAINE:**
 2 Q Brolocizumab.
 3 **A There we go.**
 4 Q The percentage for Eylea in terms of
 5 dosing schedule, according to the asterisk, it
 6 says "ongoing following initiation of therapy" is
 7 [REDACTED], right?
 8 MR. MARX: Objection. Lack of foundation.
 9 **BY THE WITNESS:**
 10 **A With many other caveats and probably other**
 11 **information within this document that explain the**
 12 **limited sampling that was done to source this.**
 13 Q And just because my question may have been
 14 imprecise, the [REDACTED] refers to the eight-week
 15 dosing schedule using Eylea?
 16 MR. MARX: Objection. Lack of foundation
 17 and mischaracterizes the document.
 18 **BY THE WITNESS:**
 19 **A The number [REDACTED] or the percent**
 20 **[REDACTED] does appear there, but there are many**
 21 **footnotes that explain that there is a very**
 22 **limited sample size here. There is very little**

226

1 **confidence, I think, in that number as expressly**
 2 **stated below and that these are more so**
 3 **directional percentages.**
 4 **BY MR. CAINE:**
 5 Q The [REDACTED] that you see for eight-week
 6 dosing with Eylea is higher than any of the other
 7 percentages associated with other weeks, right?
 8 MR. MARX: Objection. Lack of foundation.
 9 **BY THE WITNESS:**
 10 **A That's not what I'm seeing. I'm seeing**
 11 **brolocizumab is higher, not that much but --**
 12 **BY MR. CAINE:**
 13 Q I'm talking about just limited to the
 14 Eylea line.
 15 MR. MARX: Same objection.
 16 **BY MR. CAINE:**
 17 Q Let me reask the question.
 18 **A You're saying for the yellow Line,**
 19 **[REDACTED] is the highest of the -- that's the**
 20 **apex with respect to the Eylea line.**
 21 Q That's right. Do you agree?
 22 **A Yes. It's a little bit above the**

227

1 [REDACTED] at six weeks, but, yeah, [REDACTED] is
 2 **the highest for Eylea in week 8.**
 3 Q And if we were to add the percentages for
 4 weeks 8, 9 through 11, 12 and 13, we would see
 5 that over [REDACTED] of physicians use maintenance
 6 dosing regimen of eight weeks or longer to treat
 7 wet AMD with Eylea, right?
 8 MR. MARX: Objection. Lack of foundation,
 9 mischaracterizes the document.
 10 **BY THE WITNESS:**
 11 **A There is a few things there that probably**
 12 **need to be unpacked. One, I just don't think**
 13 **mathematically it goes over [REDACTED]. Two, I**
 14 **think that the footnotes are important that say**
 15 **these are directional, and they're based on sample**
 16 **sizes of a few dozen ophthalmologists and a little**
 17 **over 150 retina specialists, which I don't know**
 18 **how representative that sample is. I don't know**
 19 **what the questions were, what the control**
 20 **questions were. So there's a lot of unknowns.**
 21 **BY MR. CAINE:**
 22 Q Let's deal with the math.

228

1 Do you agree that for 9 to 11 weeks, the
 2 percentage reported for Eylea is [REDACTED]?
 3 MR. MARX: Objection. Lack of foundation.
 4 **BY THE WITNESS:**
 5 **A Based on the caveats that I explained in**
 6 **my last question that pretty much are outlined in**
 7 **the footnotes that say these are directional, they**
 8 **are not statistically significant, the [REDACTED]**
 9 **is the point that they put there for 9 to 11.**
 10 Q For 12, the percentage for Eylea is
 11 [REDACTED], right?
 12 MR. MARX: Objection. Lack of foundation,
 13 mischaracterizes the document.
 14 **BY THE WITNESS:**
 15 **A Yeah. I guess -- I guess, again, just**
 16 **optically observing numbers that clearly on the**
 17 **face of this document say they're not actually**
 18 **precise and that they're just kind of giving you a**
 19 **directional flavor, to my last point to where I**
 20 **said it probably isn't over [REDACTED], I was**
 21 **looking at [REDACTED] for that period. But now**
 22 **when I take off my glasses and look a little**

229

1 closer, I can see that the [REDACTED] is probably
 2 attributable to the yellow triangle there.
 3 **BY MR. CAINE:**
 4 Q So you agree with me at least that if we
 5 combine the periods 8, 9 to 11 weeks, 12 and
 6 13-plus weeks, the percentage of physicians using
 7 maintenance dosing of 8 or greater is over
 8 [REDACTED] ?
 9 MR. MARX: Objection. Mischaracterizes
 10 the document.
 11 **BY MR. CAINE:**
 12 Q With Eylea for wet AMD.
 13 **A I mean, that's the math of the percentages**
 14 **that appear here with all the caveats that appear**
 15 **here that these are not really statistically**
 16 **significant. They are more so directional, as**
 17 **explained in the footnotes.**
 18 Q And the -- for both Lucentis and Avastin,
 19 the percent of physicians reporting usage of a
 20 dosing schedule of eight weeks or greater to treat
 21 wet AMD is less than [REDACTED], right?
 22 MR. MARX: Objection. Lack of foundation.

230

1 **BY THE WITNESS:**
 2 **A Again, subject to all the caveats that**
 3 **these are not statistically significant, they're**
 4 **based on a very limited sample, the numbers as**
 5 **they appear in the line graph do kind of run below**
 6 **[REDACTED] if you add those up, whereas**
 7 **brolocizumab -- I'm butchering it, I know -- is at**
 8 **least as high, if not higher, than Eylea.**
 9 **BY MR. CAINE:**
 10 Q Would you turn for me to Page 94. This is
 11 the DME dosing update.
 12 Do you see that?
 13 **A I do.**
 14 Q Do you see that the dosing schedule for
 15 Eylea which is, again, represented in the yellow
 16 line has the highest percentage for eight-week
 17 dosing to treat DME?
 18 MR. MARX: Objection. Lack of foundation,
 19 form.
 20 **BY THE WITNESS:**
 21 **A According to the numbers that appear on**
 22 **this page with the sample of probably 200 or so**

23

1 physicians, without the benefit of seeing what the
 2 control questions are, what the actual questions
 3 are, those are the numbers that appear on this
 4 page.
 5 **BY MR. CAINE:**
 6 Q And the percentage for Eylea dosing at
 7 eight weeks for DME is [REDACTED], right?
 8 MR. MARX: Objection. Lack of foundation.
 9 **BY THE WITNESS:**
 10 **A With all the caveats from my last answer,**
 11 **that's the number that appears here.**
 12 **BY MR. CAINE:**
 13 Q If we do the same as we did for wet AMD
 14 for DME and look at the percentages for Eylea
 15 dosing schedule for eight weeks and beyond and add
 16 those up, over [REDACTED] of physicians use
 17 maintenance dosing regimen of eight weeks or more
 18 to treat DME with Eylea, correct?
 19 MR. MARX: Objection. Lack of foundation.
 20 **BY THE WITNESS:**
 21 **A Again, subject to all the caveats and all**
 22 **the footnotes as to what limited significance one**

232

1 **can ascertain with respect to the very limited**
 2 **sample here and without the benefit of the control**
 3 **questions and the questions themselves, that so,**
 4 **falling far behind brolocizumab.**
 5 **BY MR. CAINE:**
 6 Q The percentage of physicians reporting the
 7 usage of Avastin to treat DME with a dosing
 8 schedule of eight weeks or more is less than
 9 [REDACTED], right?
 10 MR. MARX: Objection. Lack of foundation.
 11 **BY THE WITNESS:**
 12 **A Are you talking about eight weeks and**
 13 **above?**
 14 **BY MR. CAINE:**
 15 Q Yes.
 16 MR. MARX: Same objection.
 17 **BY THE WITNESS:**
 18 **A I mean, with all the caveats on the**
 19 **limited reliability and statistical significance**
 20 **associated with the numbers that appear on this**
 21 **line graph, it seems to me that it's greater than**
 22 **[REDACTED] because it looks like it's -- oh,**

233

1 Avastin, okay, I'm sorry. Yes, it is less than
 2 [REDACTED] subject to the limitations on what one
 3 can ascertain from these data points.
 4 BY MR. CAINE:
 5 Q The results reflect that physicians use an
 6 eight-week or greater dosing regimen to treat DME
 7 with Lucentis at a percentage of less than
 8 [REDACTED], right?
 9 MR. MARX: Objection. Lack of foundation,
 10 outside the scope.
 11 BY THE WITNESS:
 12 A Subject to, like I said, all the
 13 limitations and lack of information regarding to
 14 the questions, the control questions, I mean, the
 15 percentages as plotted on a line graph look to be
 16 around [REDACTED].
 17 BY MR. CAINE:
 18 Q And if we look at Page 95, please. This
 19 is a dosing update for macular edema following
 20 CRVO, right?
 21 A I believe that's what that acronym stands
 22 for.

234

1 Q You see the Eylea line is again in yellow?
 2 A I do.
 3 Q And the percentage of physicians
 4 responding that they use a dosing schedule of
 5 eight weeks with Eylea to treat MEfCRVO is
 6 [REDACTED], right?
 7 MR. MARX: Objection. Lack of foundation.
 8 BY THE WITNESS:
 9 A Wait. What's that? Oh, okay.
 10 You know, again, similar to some of my
 11 prior answers, there are a lot of caveats in the
 12 footnotes and limitations on whether any of this
 13 is statistically significant or reliable other
 14 than directional [REDACTED] is the number that
 15 appears for eight weeks.
 16 BY MR. CAINE:
 17 Q The percentage of physicians responding
 18 that they used Eylea to treat MEfCRVO with a
 19 dosing schedule of eight weeks or more is over
 20 [REDACTED], right?
 21 MR. MARX: Objection. Lack of foundation.
 22 BY THE WITNESS:

235

1 A Subject to the limitations or
 2 qualifications that appear in the footnotes and
 3 the reliability of the information trailing soon
 4 after week 8 from brolocizumab, the numbers add up
 5 to what you said.
 6 BY MR. CAINE:
 7 Q And the results reported here reflect that
 8 physicians did not use -- well, let me rephrase
 9 that.
 10 The results reported here reflect that
 11 physicians used eight-week or longer maintenance
 12 dosing to treat MEfCRVO with either Avastin or
 13 Lucentis less than [REDACTED] of the time,
 14 correct?
 15 MR. MARX: Objection. Lack of foundation.
 16 BY THE WITNESS:
 17 A Subject to all the caveats with the
 18 statistical significance or lack of statistical
 19 significance and the limited population from which
 20 this was sampled, certainly all the products, it's
 21 less than [REDACTED].
 22 BY MR. CAINE:

236

1 Q When you said "all the products," were you
 2 answering my question that was in reference to
 3 Avastin and Lucentis?
 4 A I mean, I think all the products,
 5 including Eylea and brolocizumab. I know I'm
 6 saying it wrong.
 7 Q I think earlier you agreed with me that
 8 Eylea -- that physicians responded that -- over
 9 [REDACTED] of physicians responded that they were
 10 using an eight-week or greater dosing schedule to
 11 treat MEfCRVO with Eylea; is that right?
 12 A Eight-week or --
 13 MR. MARX: Objection. Lack of foundation,
 14 outside of Mr. Hofmann's expertise.
 15 BY THE WITNESS:
 16 A Subject to the caveats that I gave, I
 17 guess I was saying in my last answer at eight
 18 weeks, everybody was below [REDACTED]. If you're
 19 looking at eight weeks or greater, subject to the
 20 fact that there are limitations on the sample size
 21 and caveats with respect to the size of the
 22 population and not being aware of the questions

237

1 and whether there were proper control questions
 2 and whether this was a properly designed study,
 3 that's what the numbers add up to.
 4 BY MR. CAINE:
 5 Q Let me ask the question about Avastin and
 6 Lucentis again because I don't think we got to the
 7 answer on that question.
 8 So the percentage of physicians responding
 9 about the use of Avastin and Lucentis at eight
 10 weeks or more in each case was under [REDACTED],
 11 right?
 12 MR. MARX: Objection. Lack of foundation,
 13 outside the scope of Mr. Hofmann's expertise.
 14 BY THE WITNESS:
 15 A Subject to the fact that we don't know
 16 what the questions were and we don't know what the
 17 control questions were, we can tell that the
 18 population that was sampled is a very small group.
 19 And so I don't know how much we can glean from
 20 this, and they even include their own caveats as
 21 to the lack of statistical significance. The
 22 numbers as they appear do fall below [REDACTED].

238

1 BY MR. CAINE:
 2 Q Would you turn for me to Page 96, please.
 3 This is the macular edema following BRVO dosing
 4 update, correct?
 5 A It is.
 6 Q And you see that the familiar yellow Eylea
 7 line on this page?
 8 A I do.
 9 Q And you see that at eight weeks -- for an
 10 eight-week dosing schedule, [REDACTED] of the
 11 physicians reported using Mylan to treat MEfBRVO,
 12 right?
 13 MR. MARX: Objection. Lack of foundation,
 14 outside the scope.
 15 BY THE WITNESS:
 16 A Do I see the [REDACTED] ?
 17 BY MR. CAINE:
 18 Q Corresponding to the physicians who said
 19 they used an eight-week dosing schedule with Eylea
 20 to treat MEfBRVO?
 21 A Subject to the fact that we don't know
 22 what the questions were, we don't know what the

239

1 control questions were, whether this was a
 2 properly designed study and whether the population
 3 is adequately representative, how they were
 4 selected, et cetera, et cetera, I can read the
 5 [REDACTED] number there.
 6 Q The percentage of physicians who responded
 7 as treating MEfBRVO with Eylea for eight weeks or
 8 greater is over [REDACTED], correct?
 9 MR. MARX: Objection. Lack of foundation,
 10 outside the scope.
 11 BY THE WITNESS:
 12 A Subject to the fact that we don't have
 13 questions, we don't have control questions, we
 14 don't know how the study was designed, we don't
 15 know whether it was a representative group of
 16 ophthalmologists or retinal specialists and by
 17 their own admission it's limited, limited group
 18 that they were looking at, I think the numbers as
 19 they appear on that line graph do exceed
 20 [REDACTED].
 21 BY MR. CAINE:
 22 Q And the number of physicians who reported

240

1 using Avastin to treat MEfBRVO with a maintenance
 2 dosing regimen of eight weeks or longer is less
 3 than [REDACTED], correct?
 4 MR. MARX: Objection. Lack of foundation.
 5 Outside of Mr. Hofmann's expertise and outside the
 6 scope.
 7 BY THE WITNESS:
 8 A I don't -- I'm just eyeballing this. I
 9 would put in all the same caveats I did before.
 10 We don't know the questions, we don't know the
 11 control questions, we don't know whether this is a
 12 representative group that was being asked these
 13 questions. Were you asking about Avastin or --
 14 BY MR. CAINE:
 15 Q Avastin.
 16 A Yeah. The numbers as they appear here,
 17 and whether these are statistically significant or
 18 valid when you add up the percentage and line
 19 graph, they're less than [REDACTED], just shy.
 20 Q And for Lucentis, the percentage of
 21 physicians saying that they used Lucentis to treat
 22 MEfBRVO with a dosing schedule of eight weeks or

24

1 greater for the maintenance period was less than
 2 [REDACTED], right?
 3 MR. MARX: Objection. Lack of foundation,
 4 outside the scope.
 5 BY THE WITNESS:
 6 A Again, not knowing the questions, whether
 7 there were control questions, whether there was a
 8 properly designed study, whether there's
 9 statistical significance to any of the percentages
 10 that appear here, if you add up the numbers
 11 according to the line graph, they're just shy of
 12 [REDACTED].
 13 BY MR. CAINE:
 14 Q And in forming your -- the opinions that
 15 you state in your declaration, you actually relied
 16 on Exhibit 2176, right?
 17 A I think I do have a reference here or
 18 there to it, yes.
 19 Q In fact, you referenced Page 92 and the
 20 statistical information contained therein?
 21 A If you want to point me to it, that might
 22 help us all.

242

1 Q Sure.
 2 Why don't you look at Paragraph 82 of your
 3 declaration. Paragraph 82 of your declaration,
 4 this is on numbered Page 62 at the bottom right.
 5 You cite to in Footnote 126, Exhibit 2176.
 6 Actually, you cite to pages 92, 94 and 96, right?
 7 A That is correct.
 8 Q Same pages as among those that we looked
 9 at, I think we also looked at 95?
 10 A I don't recall what all we looked at.
 11 Q We just looked at 92, wet AMD dosing. We
 12 looked at 94, which was -- let's make sure I've
 13 got this right. 94 was DME and we looked at --
 14 A Uh-huh, correct.
 15 Q Thank you.
 16 And we looked at 96, which was macular
 17 edema following BRVO, right?
 18 A We did.
 19 Q When you made references to these pages in
 20 your declaration, you didn't put in any caveats to
 21 your use of the data there, correct?
 22 A They are reference points. I'm just

243

1 saying that there are limitations on what one can
 2 glean for the reasons that I explain. And again,
 3 I'm responding to Dr. Manning, and I think that
 4 the point I'm using it for requires a little less
 5 precision to try and make the points you just
 6 tried to make in those questions in that I'm just
 7 saying, look, more than half aren't being used at
 8 eight weeks and that's consistent across the
 9 board, and I think --
 10 Q What do you mean more than half aren't
 11 being used at eight weeks?
 12 A Every chart we just looked at, if you look
 13 at the eight-week --
 14 Q I understand your point. You're saying
 15 only eight weeks, not eight weeks and beyond?
 16 A Eight weeks or more, those are different
 17 numbers that we've gone through, but it's very
 18 clear that as of an eight-week interval for
 19 tertiary dosing, it's less than [REDACTED].
 20 Q But it's equally clear that if it's eight
 21 weeks or more, then the number is greater than
 22 [REDACTED] for all of those indications?

244

1 MR. MARX: Objection. Mischaracterizes
 2 the witness testimony.
 3 BY THE WITNESS:
 4 A Well, I think you have to pull in all the
 5 caveats that I gave in that, you know, we don't
 6 know the control questions. We don't know the
 7 actual questions. We don't know how
 8 representative this sample of prescribers was one
 9 way or the other, and even the documents
 10 themselves present very clear caveats as to their
 11 statistical significance.
 12 And so the distinction I'm drawing between
 13 what you're trying to, I think, point out in terms
 14 of greater than [REDACTED] is that, okay, I guess
 15 if you add those up using the percentage here,
 16 they squeak by [REDACTED]. It's a little less
 17 clear, though, because we don't know the answers
 18 to all those questions and caveats I just gave.
 19 Whereas at the eight-week point, it's, I think,
 20 hard to imagine that those percentages could
 21 somehow be statistically higher than [REDACTED] as
 22 of that point in time. Not to say it's

245

1 impossible.
 2 **BY MR. CAINE:**
 3 Q I'm not sure I understood the last part of
 4 your answer when you said "at the eight-week
 5 point, I think it's hard to imagine that those
 6 percentages could somehow be statistically be
 7 higher than [REDACTED]."
 8 Are you just saying at the eight-week
 9 period or --
 10 **A Correct.**
 11 Q Okay. I understand your point. I didn't
 12 ask -- at least I didn't mean to ask exactly at
 13 the eight-week period. I just want to make sure
 14 we're clear that eight weeks and greater is over
 15 [REDACTED] for each of the indications that we
 16 went through.
 17 **A You were asking me about my report, and in**
 18 **my report I am talking about the eight-week period**
 19 **in Footnote 126. And I'm saying in all those**
 20 **instances, it is less than [REDACTED], that the**
 21 **majority of uses is either above or below eight**
 22 **weeks.**

246

1 Q What you actually say is -- I'm reading
 2 from Paragraph 82 of your declaration, last
 3 sentence: "Based upon the above, a significant
 4 number of patients are not treated on a schedule
 5 that would be consistent with what I understand to
 6 be the challenged claims of the '338 patent."
 7 Do you see that?
 8 **A I do.**
 9 Q And that's because you are -- you were
 10 looking only at the data for eight weeks --
 11 **MR. MARX: Objection. Mischaracterizes**
 12 **the witness testimony.**
 13 **BY MR. CAINE:**
 14 Q -- is that right?
 15 **A You can look at it either way, but it's a**
 16 **significant number. I think -- I mean, I defer to**
 17 **technical experts, but I understand that the**
 18 **eight-week interval for the tertiary doses is**
 19 **something that is of note.**
 20 **But whether it's eight weeks or more than**
 21 **eight weeks, I think the point would stand that a**
 22 **significant number of patients aren't treated**

247

1 within -- certainly the majority are not treated
 2 at the eight-week interval based on this ATU,
 3 which I still am not a hundred percent confident
 4 in from a statistical and sample size.
 5 **But then even if you include greater than**
 6 **eight weeks, there's still a hugely significant**
 7 **portion that are treated in intervals less than**
 8 **eight weeks even by using your numbers.**
 9 Q Right. But it would be a minority that
 10 are treated less than eight weeks?
 11 **MR. MARX: Objection.**
 12 **BY MR. CAINE:**
 13 Q For each of the indications that we went
 14 through, correct?
 15 **MR. MARX: Objection. Mischaracterizes**
 16 **the document.**
 17 **BY THE WITNESS:**
 18 **A Barely a minority. You are eeking over**
 19 **[REDACTED] when you bundle in everything eight**
 20 **weeks or greater, so it'd still be, like,**
 21 **whatever, [REDACTED], which is about half.**
 22 **And again, we're going off statistics that the**

248

1 **document itself says, hey, this isn't really all**
 2 **that reliable. It's based on a sample size of 200**
 3 **prescribers and, oh, by the way, most of the data**
 4 **that appears in this graph is directional not**
 5 **statistically significant.**
 6 **BY MR. CAINE:**
 7 Q It was significant enough for you to rely
 8 on it in your declaration, correct?
 9 **MR. MARX: Objection. Mischaracterizes**
 10 **the witness testimony.**
 11 **BY THE WITNESS:**
 12 **A I'm not suggesting that it's statistically**
 13 **significant at all. I'm saying that for the**
 14 **purposes of my declaration, the point I was making**
 15 **in Footnote 126 and in Paragraph 82 of my -- my**
 16 **declaration is that at the eight-week interval**
 17 **specifically, the majority clearly even with the**
 18 **flaws and shortcomings of this ATU get to the**
 19 **majority or a significant portion being used for**
 20 **intervals other than eight weeks.**
 21 **BY MR. CAINE:**
 22 Q You use the data to talk about the number

249

1 of patients that are administered Eylea at dosing
 2 intervals between five and seven weeks for AMD,
 3 DME and RVO, right?
 4 **A I'm sorry. Could you point me to what**
 5 **you're referring.**
 6 Q Yes, Paragraph 82 of your declaration.
 7 **A Okay. Ah, fair enough, okay.**
 8 Q Now, you reviewed a number of surveys for
 9 the purposes of your opinions, correct?
 10 MR. MARX: Objection. Form.
 11 BY THE WITNESS:
 12 **A I reviewed a number of --**
 13 **BY MR. CAINE:**
 14 Q Surveys?
 15 **A Surveys? I mean, I think -- you got to be**
 16 **careful of the word "survey" because there is like**
 17 **surveys that maybe are conducted informally and**
 18 **through the marketing organization or business**
 19 **group, and then there are surveys that are like --**
 20 **meet the criteria that are admissible as**
 21 **litigation surveys like that are conducted more so**
 22 **by like a survey expert that demonstrates proper**

250

1 **design, control, et cetera, and I'm not a survey**
 2 **expert.**
 3 Q Why don't we pull out, if we can find it
 4 in our stack, Exhibit 2197.
 5 **A Dang it. I thought when I'd moved it to**
 6 **the side, I didn't have to look at it again.**
 7 Q It looks like this (indicating).
 8 MR. MARX: What was the date on that,
 9 Mr. Caine?
 10 MR. CAINE: September 15th of 2011.
 11 BY THE WITNESS:
 12 **A Which number?**
 13 MR. MARX: This is the document --
 14 BY MR. CAINE:
 15 Q This is the one with the, kind of,
 16 misnumbering that Mr. Marx identified.
 17 **A 2197?**
 18 MR. MARX: Yeah, on the left.
 19 THE WITNESS: On the left, okay yeah.
 20 MR. MARX: And on the right side of this
 21 document, it includes Exhibit 2294, just to
 22 clarify for the record.

25

1 MR. CAINE: Fair point.
 2 BY MR. CAINE:
 3 Q Okay. This is the Physician ATU Benchmark
 4 Wave Full Report, September 15, 2011?
 5 **A Yes.**
 6 Q Would you turn for me to Page 18 of 47.
 7 You agree that [REDACTED] of respondents
 8 identified dosing schedule as one of the key
 9 benefits of Eylea?
 10 MR. MARX: Objection. Lack of foundation,
 11 mischaracterizes the document, form.
 12 BY THE WITNESS:
 13 **A The bar that you're referring to and the**
 14 **[REDACTED], it looks like this was based on the**
 15 **selection of 99 or so respondents with efficacy**
 16 **being dominant at [REDACTED].**
 17 BY MR. CAINE:
 18 Q You would agree that Eylea's dosing
 19 schedule was at least one significant benefit
 20 identified by the respondents as reflected on this
 21 page, right?
 22 MR. MARX: Objection. Lack of foundation.

252

1 BY THE WITNESS:
 2 **A I mean, "significant" is a subjective**
 3 **term. Efficacy is listed as the clear most**
 4 **important respondent benefit, but dosing is**
 5 **listed. It's also unclear from anything I see**
 6 **here that the dosing schedule question is really**
 7 **tailored to whatever the contours are of the**
 8 **claims of the '338 patent. So, I mean, we got to**
 9 **be careful.**
 10 BY MR. CAINE:
 11 Q And this is, again, from September 15,
 12 2011, this particular exhibit that we're looking
 13 at?
 14 **A It is.**
 15 Q Would you look at Exhibit 2138 which I
 16 will hand you.
 17 Do you have Exhibit 2138 in front of you?
 18 **A I do.**
 19 Q This is a Physician ATU Wave 2 Full
 20 Report, February 2013, right?
 21 **A That's the title.**
 22 Q And as of February 2013, Eylea had been on

253

1 the market for about 15 months, correct?

2 **A Yeah, that sounds about right.**

3 **Q** Would you turn to Page 13, please.

4 Do you agree that when respondents were

5 asked about Eylea, they identified the main reason

6 of treatment as the dosing period/admin for

7 patients at a percentage of [REDACTED] for newly

8 diagnosed patients and [REDACTED] for previously

9 diagnosed patients?

10 **MR. MARX:** Objection. Lack of foundation.

11 **BY THE WITNESS:**

12 **A Well, here again, it's a pretty limited**

13 **sample size. I'm not sure about the exact design**

14 **of the survey and everything. I can read off the**

15 **percentages as well as you can. I think this is a**

16 **document that Manning cites, and I find lots of**

17 **other documents that are inconsistent with this.**

18 **At the end of the day, I still don't see**

19 **anything here that tells me that this is tailored**

20 **to the '338 patent. So we, again, have to be very**

21 **careful in what we can make of this.**

22 **BY MR. CAINE:**

254

1 **Q** Do you see that for the same question for

2 Avastin and Lucentis, the percentages are [REDACTED] or

3 [REDACTED]?

4 **MR. MARX:** Objection. Lack of foundation.

5 **BY THE WITNESS:**

6 **A I mean, like I said, I think we can see**

7 **the percentages as they appear here, but you do**

8 **have to be careful that this is but one document,**

9 **15 months after launch, also, on the heels of the**

10 **tremendous marketing effort by Regeneron to invest**

11 **heavily in messaging to certain things to try and**

12 **get product into patients, and in any event,**

13 **nothing here really shows me that this is specific**

14 **to the '338 patent just dosing in general.**

15 **BY MR. CAINE:**

16 **Q** You reviewed Exhibit 2138 for the purposes

17 of preparing your declaration?

18 **A I did.**

19 **Q** And I think we already that -- let me

20 frame it a little more broadly.

21 Other than counsel for Mylan, did you have

22 any discussion of these percentages with anyone

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1 about -- I'll stop it right there. Let me

2 rephrase so we have a clear question.

3 Aside from counsel for Mylan, did you have

4 any discussion about the percentages reflected on

5 Page 13 with respect to the main reasons to choose

6 treatment for Eylea?

7 **MR. MARX:** Objection to the extent it asks

8 Mr. Hofmann to disclose any privileged

9 communications.

10 Otherwise, you can answer.

11 **BY THE WITNESS:**

12 **A I mean, there's my internal team.**

13 **BY MR. CAINE:**

14 **Q** Okay. But outside of your internal team

15 and counsel for Mylan?

16 **A Yeah. I mean, from what I remember,**

17 **that's the folks -- to be clear, my discussions**

18 **were with -- my review and reliance was on**

19 **documents, data, information and declarations from**

20 **this litigation.**

21 **Q** Let's stay on this page for just a second.

22 **MR. MARX:** Mr. Caine, just for the record,

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1 this page --

2 **MR. CAINE:** Page 13.

3 **MR. MARX:** Page 13 of Exhibit 2138?

4 **MR. CAINE:** Yep, that's right.

5 **BY MR. CAINE:**

6 **Q** Do you see that respondents were also

7 asked about efficacy as a main reason to choose

8 treatment?

9 **MR. MARX:** Objection. Lack of foundation.

10 **BY THE WITNESS:**

11 **A I mean, I don't know if it's exactly fair,**

12 **the way your question was asked. If I'm reading**

13 **the question that's listed in the bottom footnote,**

14 **it wasn't like a leading question, like is**

15 **efficacy what's driving your prescribing**

16 **decisions. It was what drives your prescribing**

17 **decisions.**

18 **BY MR. CAINE:**

19 **Q** Fair enough.

20 **A So a slight nuance from how your question**

21 **was phrased.**

22 **Q** Let me rephrase it, then.

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1 In the case of each of Eylea, Avastin and
 2 Lucentis, respondents identified efficacy as a
 3 main reason to choose those treatments, right?
 4 MR. MARX: Objection. Foundation,
 5 mischaracterizes the document.
 6 BY THE WITNESS:
 7 **A In this one particular survey which,**
 8 **again, we know little about, efficacy certainly**
 9 **came back as a reason to choose the treatment for**
 10 **all those products.**
 11 **BY MR. CAINE:**
 12 Q We can see on the page -- I won't ask you
 13 about it, but we can see on the page the
 14 percentage of respondents who identified efficacy
 15 for -- as the main reason to choose treatment for
 16 each of Eylea, Avastin and Lucentis, right?
 17 MR. MARX: Objection. Lack of foundation,
 18 mischaracterizes the document.
 19 BY THE WITNESS:
 20 **A I'm sorry. Say that again.**
 21 **BY MR. CAINE:**
 22 Q Sure.

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1 We can see the answers that respondents
 2 gave for each of Eylea, Avastin and Lucentis --
 3 let me start over.
 4 We can see the percentage of respondents
 5 who identified efficacy as the main reason to
 6 choose treatment for each of Eylea, Avastin and
 7 Lucentis on this Page 13, right?
 8 MR. MARX: Same objection.
 9 BY THE WITNESS:
 10 **A There are percentages that appear here.**
 11 **Again, not knowing too, too much about how the**
 12 **survey or study was designed, but, yes, efficacy**
 13 **was a predominant reason to prescribe.**
 14 **BY MR. CAINE:**
 15 Q And the efficacy numbers -- the efficacy
 16 response percentage as between Eylea and Lucentis
 17 is within a few percentage points for both newly
 18 diagnosed and previously diagnosed patients,
 19 right?
 20 MR. MARX: Objection. Form, lack of
 21 foundation.
 22 BY THE WITNESS:

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1 **A Again, not having better insight into how**
 2 **the study was designed, yeah, they are within a**
 3 **few percentage points as the numbers appear on**
 4 **this page.**
 5 **BY MR. CAINE:**
 6 Q And with respect to Eylea and Avastin, the
 7 main reason to choose percentage identifying
 8 efficacy, somewhere between [redacted] and [redacted],
 9 correct?
 10 MR. MARX: Objection. Lack of foundation.
 11 BY THE WITNESS:
 12 **A I don't know what percentages you're**
 13 **talking about.**
 14 **BY MR. CAINE:**
 15 Q So what I'm talking about is the Avastin
 16 percentages for efficacy as compared to the Eylea
 17 percentages identifying efficacy.
 18 **A Ah, okay. Yeah, I can do that math.**
 19 MR. MARX: Same objection.
 20 BY MR. CAINE:
 21 Q Thank you.
 22 Can we do Exhibit 2140.

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1 Can you see you have Exhibit 2140 in front
 2 of you?
 3 **A Okay.**
 4 Q Do you have Exhibit 2140 in front of you?
 5 **A I do.**
 6 Q Exhibit 2140 is a physician ATU Wave 5
 7 Full Report from November 2013, right?
 8 **A That's the title.**
 9 Q At this point in time, Eylea had been on
 10 the market for about two years, correct?
 11 **A Yeah, maybe a little bit longer. It**
 12 **depends on which data set you're looking at but**
 13 **about two years.**
 14 Q Would you turn to Page 4. Do you have the
 15 page that has "Key Findings" at the top?
 16 **A I do.**
 17 Q Among the key findings reported are that
 18 first bullet: "Findings have remained largely
 19 consistent with recent waves and continue to show
 20 positive momentum for Eylea as evidenced by."
 21 And then the third subbullet, "less
 22 frequent dosing, fewer injections."

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1 Do you see that?
 2 MR. MARX: Objection. Lack of foundation.
 3 BY THE WITNESS:
 4 A You read those words as they appear there.
 5 There is three other bullets that you skipped
 6 over.
 7 BY MR. CAINE:
 8 Q I did.
 9 A And a whole bunch of other bullets on the
 10 page.
 11 Q Do you agree that the findings reported
 12 here include that less frequent dosing and fewer
 13 injections were important components of Eylea's
 14 marketplace performance?
 15 MR. MARX: Objection. The lack of
 16 foundation and mischaracterizes the document.
 17 BY THE WITNESS:
 18 A "Important" is a subjective term, and
 19 there is about a dozen other bullets on this page.
 20 But among the considerations, it does seem like
 21 they have recognized that to some degree.
 22

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1 BY MR. CAINE:
 2 Q Would you turn to Page 22 of this
 3 document. Page 22 is showing the percentage of
 4 eyes on a fixed dosing interval preparing and
 5 differentiating by what that fixed dosing interval
 6 is, correct?
 7 MR. MARX: Objection. Lack of foundation,
 8 mischaracterizes the document.
 9 BY THE WITNESS:
 10 A I'm not a clinician, but I think what I'm
 11 seeing here is various criteria of various, I
 12 guess, dosing regimens.
 13 BY MR. CAINE:
 14 Q In the line chart on the right reflects
 15 that for Lucentis, [REDACTED] of eyes are dosed
 16 monthly, right?
 17 MR. MARX: Objection. Mischaracterizes
 18 the document, lack of foundation. This is limited
 19 to the fixed dosing with respect to the bar chart
 20 on the left.
 21 BY THE WITNESS:
 22 A You have to be, like, careful. The bar

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1 chart on the left – first off, you have to be
 2 overall just careful with ATUs because they are
 3 not precise, in my experience. They are a
 4 reference point and something to look at.
 5 But what's happening, as I read this page,
 6 is there's a stratification, if you will, on the
 7 various, whatever, six categories, half-dozen
 8 categories that are covered by the key on the
 9 left. And then what they're doing in the line
 10 chart is blowing it out – or not blowing it
 11 out – digging deeper, essentially unpacking.
 12 So like, for example, with Lucentis what
 13 it's saying is [REDACTED] of [REDACTED] – no, no,
 14 of [REDACTED] because Lucentis, that's the top
 15 dark blue category, [REDACTED] would hit the fixed
 16 dosing criteria of the line chart on the right.
 17 So it's [REDACTED] of [REDACTED], if that makes
 18 sense.
 19 BY MR. CAINE:
 20 Q And of those patients who are on a fixed
 21 dosing interval with Avastin, [REDACTED] are dosed
 22 monthly, correct?

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1 MR. MARX: Objection. Lack of foundation.
 2 BY THE WITNESS:
 3 A Again, subject to all the caveats on ATUs
 4 and the questions of the design study and
 5 everything else, that would be [REDACTED] of
 6 [REDACTED]. So, again, you have to be careful for
 7 lots of reasons with ATUs, but what we're seeing
 8 here is in all instances, based on the bar chart,
 9 as to all uses, it's [REDACTED] or more of all
 10 three products are used not on a fixed interval
 11 but more so on a T and E or as needed kind of
 12 schedule.
 13 And then but of those that do get on a
 14 fixed schedule, what they're doing is unpacking
 15 the percentage of the vast minority of sales which
 16 are on a fixed interval and how much of those fall
 17 within various regimens of that [REDACTED] or less
 18 of the three products listed here that go to a
 19 fixed dosing interval.
 20 Q And for those patients who are being dosed
 21 on a fixed dosing interval following monthly
 22 treatment with Eylea, [REDACTED] are dosed every

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1 eight-plus weeks, correct, as of, again,
 2 November of 2013?
 3 MR. MARX: Objection. Lack of foundation,
 4 mischaracterizes the document.
 5 BY THE WITNESS:
 6 A Tried to be super careful here and want to
 7 make sure that you understand what I'm saying as
 8 the way the numbers tumble. But what that
 9 translates to is if all the uses of Eylea are a
 10 hundred percent, what this tells me is [REDACTED]
 11 are monthly followed by fixed dosing interval, and
 12 so of the [REDACTED], [REDACTED] would be at eight
 13 weeks plus.
 14 And then if you do the math on that, then
 15 that means – I don't know – [REDACTED], [REDACTED], [REDACTED]
 16 of uses would fall within that schedule, the
 17 corollary being [REDACTED] or more uses of Eylea
 18 don't fall into that category.
 19 MR. CAINE: Why don't we take a break.
 20 THE WITNESS: Okay.
 21 THE VIDEOGRAPHER: Please stand by. We
 22 are going off the record. The time is 4:02 p.m.

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1 (A recess was had.)
 2 THE VIDEOGRAPHER: We're back on the
 3 record. The time is 4:18 p.m.
 4 BY MR. CAINE:
 5 Q Mr. Hofmann, did you consider Regeneron's
 6 marketing efforts that promoted Eylea on the basis
 7 of dosing schedule?
 8 MR. MARX: Objection. Lack of foundation,
 9 vague.
 10 I'm also going to note for the record that
 11 we have requested the full complement of marketing
 12 materials that Mr. Manning was able to refer to
 13 and review, and Regeneron has refused to produce
 14 that. So to the extent you're seeking
 15 Mr. Hofmann's consideration of Regeneron's
 16 marketing material, he's been denied that
 17 opportunity to do so.
 18 BY THE WITNESS:
 19 A So I think I would refer to or defer to
 20 what I mention in my declaration. I think there
 21 was a limited number of marketing materials that I
 22 was able to review, and among the things I

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1 considered was the messaging.
 2 BY MR. CAINE:
 3 Q Did you consider Regeneron marketing
 4 materials that promoted Eylea on the basis of its
 5 dosing schedule?
 6 MR. MARX: Same objection. Regeneron has
 7 failed to produce the full complement of marketing
 8 materials, in particular, the marketing materials
 9 that Mr. Manning reviewed.
 10 BY THE WITNESS:
 11 A So there were limited marketing materials
 12 that were available to me, and what I looked at
 13 included messaging on lots of things. Among them,
 14 dosing was part of the information that I reviewed
 15 and considered, but there were many other aspects
 16 of it as well as a significant investment in terms
 17 of like a [REDACTED] dollars.
 18 BY MR. CAINE:
 19 Q "A significant investment in terms of like
 20 a [REDACTED] dollars." Are you referring
 21 to the people and external expenses?
 22 MR. MARX: Objection. Form.

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1 BY THE WITNESS:
 2 A From what I recall, what limited marketing
 3 information was provided in the product P&L, it
 4 included certainly detailing by personnel costs as
 5 well as internal and external costs.
 6 BY MR. CAINE:
 7 Q I'm just asking what you're referring to.
 8 You said a [REDACTED] dollars?
 9 A Yes. It's from the product P&L. I think
 10 it was [REDACTED], so maybe just shy of –
 11 Q Okay. So you're talking about some number
 12 from the product P&L?
 13 A Correct.
 14 Q Let's look at Exhibit 2136.
 15 Do you recognize Exhibit 2136 as a
 16 Regeneron document pertaining to Eylea?
 17 MR. MARX: I'm going to object to the use
 18 of this document and also object to the use and
 19 reliance by Regeneron of all the ATU surveys that
 20 have been discussed today. Regeneron has failed
 21 to produce to Mylan the full complement of
 22 marketing materials, in particular, the marketing

<p style="text-align: right;">269</p> <p>1 materials that Mr. Manning relied on. To the 2 extent that this is selective production, it is 3 inappropriate and prejudicial to Mylan. 4 BY THE WITNESS: 5 A I don't -- I don't remember this 6 particular document one way or the other. Whether 7 it was cited in Manning, I don't know if I have 8 that handy, but I didn't cite it in my report. 9 BY MR. CAINE: 10 Q This is a Regeneron piece of material; 11 would you agree? 12 MR. MARX: Objection. Lack of foundation. 13 And I further object to this line of questioning 14 and reliance on this document for the reasons 15 stated. 16 BY THE WITNESS: 17 A I mean, like I said, I don't know that -- 18 I can't remember if I've seen this before. If I'm 19 a guessing man and looking at the footers, it 20 seems like it's from Regeneron. 21 BY MR. CAINE: 22 Q And this Exhibit 2136 is talking about the</p>	<p style="text-align: right;">27</p> <p>1 MR. MARX: Objection. Lack of foundation. 2 Same objection with respect to the use of 3 marketing documents. 4 MR. CAINE: Again, I m fully -- I m 5 granting you a standing objection, if you d like 6 it. That way, you don t have to repeat it every 7 time. 8 MR. MARX: All right. Then I'll take that 9 opportunity. For the record, Mylan objects to the 10 use of Exhibit 2136 as well as the ATU surveys and 11 other Regeneron marketing materials that were 12 cited by Dr. Manning in this proceeding. Mylan s 13 requested the production of all Eylea marketing 14 materials which Regeneron has refused. 15 Mylan also limited -- limitedly requested 16 the production of marketing materials that 17 Dr. Manning was given, and that was also refused 18 by Regeneron. So Mylan objects and will maintain 19 its objection to Regeneron s reliance on these 20 documents and their use in this proceeding. 21 MR. CAINE: Okay. By giving you a 22 standing objection, that means you don t have to</p>
<p style="text-align: right;">270</p> <p>1 use of Eylea for the treatment of wet AMD looking 2 towards the top and the middle of the page. 3 Do you see that? 4 MR. MARX: Objection. Lack of foundation. 5 Outside the scope of Mr. Hofmann's declaration, 6 and same objection with respect to the use of this 7 document and the other marketing documents, such 8 as the ATU surveys, for failure to provide Mylan 9 with the full complement of marketing materials. 10 MR. CAINE: If you'd like, you can have a 11 standing objection on that basis. 12 BY THE WITNESS: 13 A I mean, you know, again, I haven't studied 14 or read all the stuff here. As I sit here right 15 now, I think it's certainly not limited to the 16 treatment of wet AMD. They talk about other stuff 17 in the bottom half of the pamphlet, if you will, 18 and then they have the summary of full prescribing 19 information on the second page of the pamphlet. 20 BY MR. CAINE: 21 Q It includes the use of Eylea for wet AMD, 22 Exhibit 2136?</p>	<p style="text-align: right;">272</p> <p>1 repeat the objection. 2 MR. MARX: I understand. I've now made my 3 standing objection. I've put it on the record. 4 MR. CAINE: Fair enough. 5 BY MR. CAINE: 6 Q Mr. Hofmann, does Exhibit 2136 include 7 marketing with respect to the use of Eylea for the 8 treatment of wet AMD? 9 A Among other -- 10 MR. MARX: Lack of foundation. 11 BY THE WITNESS: 12 A Among other uses, that's what it appears. 13 BY MR. CAINE: 14 Q Do you see the trademark phrase below the 15 vial of Eylea says "time between treatments"? 16 MR. MARX: Objection. Lack of foundation 17 and to the extent it mischaracterizes the 18 document. 19 BY MR. CAINE: 20 Q I notice you're flipping to the second 21 page. I'm on the first page right under the vial 22 of Eylea?</p>

273	<p>1 A I was just trying to see if there's --</p> <p>2 again, I don't know that I've seen this document</p> <p>3 before, and I'm trying to see if next to the</p> <p>4 circle R for restricted trademark there is like a</p> <p>5 lower case "t" or cross, and I'm trying to see if</p> <p>6 that's defined anywhere.</p> <p>7 There it is, okay. It's the bullet under</p> <p>8 "Important Prescribing Information."</p> <p>9 Q Do you see the phrase "time between</p> <p>10 treatments" under the vial of Eylea on</p> <p>11 Exhibit 2136?</p> <p>12 MR. MARX: Objection. Lack of foundation,</p> <p>13 mischaracterizes the document.</p> <p>14 BY THE WITNESS:</p> <p>15 A I see the words there as you've read them,</p> <p>16 and then it's kind of unpacked a little bit more</p> <p>17 in the first bullet under "Important Prescribing</p> <p>18 Information For Eylea," and then there's obviously</p> <p>19 a bunch of other information in this pamphlet.</p> <p>20 BY MR. CAINE:</p> <p>21 Q Do you understand the phrase "time between</p> <p>22 treatments" to refer to the extended eight-week</p>	275	<p>1 the page, first page of 2136?</p> <p>2 MR. MARX: Objection. Lack of foundation,</p> <p>3 mischaracterizes the document.</p> <p>4 BY THE WITNESS:</p> <p>5 A I can certainly read April and June in</p> <p>6 those graphical representations.</p> <p>7 BY MR. CAINE:</p> <p>8 Q The interval between April and June is an</p> <p>9 eight-week or two-month period, correct?</p> <p>10 A Depends. I mean, the way a calendar</p> <p>11 works, if you're April 1st to June 30th, it's more</p> <p>12 than eight weeks. If you're April 30th to</p> <p>13 June 1st, it's five weeks or four weeks, so...</p> <p>14 Q Do you understand that the graphical</p> <p>15 representations of portions of the calendar months</p> <p>16 April and June in relation to the phrase "time</p> <p>17 between treatments" and the prescribing</p> <p>18 information below reflects that after four weeks,</p> <p>19 monthly for 12 weeks, the first three months,</p> <p>20 Eylea can be administered once every eight weeks</p> <p>21 or two months for the treatment of wet AMD?</p> <p>22 MR. MARX: Objection. Objection. Form,</p>
274	<p>1 maintenance dosing available with Eylea for the</p> <p>2 treatment of wet AMD?</p> <p>3 MR. MARX: Objection. Lack of foundation,</p> <p>4 mischaracterizes the document and the witness</p> <p>5 testimony.</p> <p>6 BY THE WITNESS:</p> <p>7 A I mean, I think time between treatments is</p> <p>8 pretty vague, and I don't see anything here that</p> <p>9 necessarily ties it to the specifics of the '338</p> <p>10 patent.</p> <p>11 BY MR. CAINE:</p> <p>12 Q Do you see the calendars where the</p> <p>13 calendar months up at the top left and the top</p> <p>14 right, April and June?</p> <p>15 MR. MARX: Objection. Lack of foundation.</p> <p>16 BY THE WITNESS:</p> <p>17 A I see those graphical. They're not really</p> <p>18 calendars. They're just, like, I don't know,</p> <p>19 graphical portions of a calendar month.</p> <p>20 BY MR. CAINE:</p> <p>21 Q You see the graphical portions of calendar</p> <p>22 months April and June on the left and right top of</p>	276	<p>1 lack of foundation, mischaracterizes the document,</p> <p>2 asked and answered.</p> <p>3 BY THE WITNESS:</p> <p>4 A I'm not sure that that's fair for me to, I</p> <p>5 guess, interpret that one way or the other. It</p> <p>6 could be what's trying to be suggested, but</p> <p>7 there's also the data sets and other documents</p> <p>8 that I looked at, some of which we've discussed,</p> <p>9 that show that that isn't the dosing interval that</p> <p>10 is actually utilized for a lot of the</p> <p>11 prescriptions for Eylea.</p> <p>12 BY MR. CAINE:</p> <p>13 Q Let's look at 2137. Here is 2137.</p> <p>14 MR. MARX: For the record, the same</p> <p>15 standing objection with respect to Regeneron's</p> <p>16 reliance on these marketing materials and their</p> <p>17 failure to produce to Mylan --</p> <p>18 MR. CAINE: You've got a standing</p> <p>19 objection. So you don't need to repeat it.</p> <p>20 MR. MARX: I understand that. I'm allowed</p> <p>21 to state on the record that this document is</p> <p>22 covered by that standing objection, and I'm doing</p>

<p style="text-align: right;">277</p> <p>1 so.</p> <p>2 This is another marketing document, and</p> <p>3 Mylan requested production of all highly marketing</p> <p>4 materials and, in particular, the materials</p> <p>5 considered by Dr. Manning. Regeneron refused to</p> <p>6 do so. Mylan objects to Regeneron's reliance on</p> <p>7 this exhibit, Exhibit 2137.</p> <p>8 BY MR. CAINE:</p> <p>9 Q Would you turn, Mr. Hofmann, to Page 29,</p> <p>10 please. It's the second-to-last page of the</p> <p>11 exhibit.</p> <p>12 A It's the smallest font I've ever seen.</p> <p>13 Q The page number is, yes.</p> <p>14 A Yes. Okay.</p> <p>15 Q Do you see this piece of marketing</p> <p>16 material in Exhibit 2137?</p> <p>17 A I do.</p> <p>18 Q You don't cite to Exhibit 2137 in your</p> <p>19 declaration, do you?</p> <p>20 A I don't see it listed. I know I looked at</p> <p>21 this. Maybe it was in review of the Manning</p> <p>22 declaration.</p>	<p style="text-align: right;">279</p> <p>1 injectable.</p> <p>2 BY MR. CAINE:</p> <p>3 Q You see the two graphical representations,</p> <p>4 this time for October and December?</p> <p>5 MR. MARX: Objection. Lack of foundation</p> <p>6 to the extent it mischaracterizes the document.</p> <p>7 BY THE WITNESS:</p> <p>8 A Well, there's a lot of graphical</p> <p>9 representations here. I do see the October and</p> <p>10 December. There's also what I assume is a grandma</p> <p>11 with a granddaughter and a lighthouse and what</p> <p>12 looks to be a very nice beach.</p> <p>13 BY MR. CAINE:</p> <p>14 Q And you agree with me that there's a</p> <p>15 two-month period between October and December?</p> <p>16 MR. MARX: Objection. Lack of foundation,</p> <p>17 mischaracterizes the document, asked and answered.</p> <p>18 BY THE WITNESS:</p> <p>19 A It's the same as the last time, where I</p> <p>20 don't know -- these are just like graphical</p> <p>21 representations of a portion of the months on the</p> <p>22 calendar, and I don't know how you get to just two</p>
<p style="text-align: right;">278</p> <p>1 Q Do you see that this is advertising Eylea</p> <p>2 for the treatment of wet AMD?</p> <p>3 A I mean --</p> <p>4 MR. MARX: Objection. Lack of foundation.</p> <p>5 BY THE WITNESS:</p> <p>6 A You've taken me all the way to Page 29,</p> <p>7 and there's all kinds of other stuff in the</p> <p>8 28 pages that precede it. This appears to be an</p> <p>9 internal document because it's labeled "Precall,"</p> <p>10 for whatever that means. It includes the label,</p> <p>11 which includes certainly wet AMD as well as all</p> <p>12 the other label indications.</p> <p>13 BY MR. CAINE:</p> <p>14 Q I'm focusing for the moment on</p> <p>15 Exhibit 2137, Page 29.</p> <p>16 Do you see that it has the phrase "time</p> <p>17 between treatments" under Eylea?</p> <p>18 MR. MARX: Objection. Lack of foundation.</p> <p>19 BY THE WITNESS:</p> <p>20 A I think those words appear there. There</p> <p>21 is also the molecule itself and the fact that it's</p> <p>22 an injectable and how it is administered as an</p>	<p style="text-align: right;">280</p> <p>1 months because you can span as much as three</p> <p>2 months or as little as, you know, 31 or 32 days in</p> <p>3 this stretch.</p> <p>4 BY MR. CAINE:</p> <p>5 Q When you couple that, the graphical</p> <p>6 calendar representations of October and</p> <p>7 December with the recommended dosing which</p> <p>8 includes 2 milligrams every eight weeks, does that</p> <p>9 suggest to you that what Eylea is promoting in</p> <p>10 this, on this page of Exhibit 2137, is the</p> <p>11 eight-week or two-month treatment period for Eylea</p> <p>12 when used to treat wet AMD?</p> <p>13 MR. MARX: Objection. Lack of foundation,</p> <p>14 outside the scope, speculative.</p> <p>15 BY THE WITNESS:</p> <p>16 A I think that's a leap in terms of the</p> <p>17 inconsistency that that would be versus what we</p> <p>18 see in some of the data sets that we looked at</p> <p>19 earlier that suggests that the majority of uses</p> <p>20 are, in fact, not on an eight-week regimen, as I</p> <p>21 explained earlier and as I explain in my report.</p> <p>22 BY MR. CAINE:</p>

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1 Q What we actually saw, and I think you
 2 agreed with me, is that the majority of uses in
 3 the document that we looked at were eight weeks or
 4 more, right, for each of the indications that we
 5 looked at?
 6 MR. MARX: Objection. Mischaracterizes
 7 the document and further objection with respect to
 8 Mylan's standing objection.
 9 BY THE WITNESS:
 10 A You have to be careful because that's a
 11 different question than what you're trying to
 12 insinuate here with these excerpts of graphical
 13 depictions of calendars, portions of calendars,
 14 because the eight weeks or more, now we're
 15 talking, what, 12 weeks, 20 weeks, I don't know.
 16 You know, the point is -- is that it was
 17 very clear from the documents we looked at before
 18 that eight weeks was less than half across the
 19 board based on, again, all the caveats I explained
 20 with respect to the limitations on those ATUs.
 21 And then I don't disagree with you that
 22 you had me walk through some math that said if you

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1 do eight weeks or more, it gets to greater than
 2 [REDACTED], but that's with all the caveats on the
 3 reasonableness or reliability and lack of clarity
 4 on what the questions were, what the control
 5 questions were, how representative the targets
 6 were, how prescribers were that responded to the
 7 questionnaires.
 8 BY MR. CAINE:
 9 Q Mr. Hofmann, I think you said you saw the
 10 grandmother figure and the granddaughter figure in
 11 the middle of the page with the book open?
 12 A I assume that that's what they're
 13 suggesting. Maybe they're just friends. I don't
 14 know.
 15 Q An older woman and a younger girl are
 16 shown there?
 17 A Yes.
 18 Q And they have a book open. They're
 19 reading. It looks like the older woman, perhaps
 20 the grandmother, is reading the book to the girl,
 21 right?
 22 MR. MARX: Objection. Lack of foundation,

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1 speculative.
 2 BY THE WITNESS:
 3 A I mean, I'm not a marketing specialist,
 4 and I don't know what -- I've studied lots of
 5 marketing --
 6 BY MR. CAINE:
 7 Q Is that what it looks like to you?
 8 MR. MARX: Objection.
 9 BY THE WITNESS:
 10 A There's all kinds of nuances that I'm not
 11 going to weigh in on, but yeah, I mean, it looks
 12 like grandma is reading the book because the
 13 younger girl is looking up at grandma. So she
 14 can't be reading it.
 15 BY MR. CAINE:
 16 Q Does this suggest to you that what Eylea
 17 is promoting here is that, given the time between
 18 treatments, there's more time allowed for the
 19 older woman, perhaps grandmother figure, to read a
 20 book to the younger girl, perhaps granddaughter
 21 figure?
 22 MR. MARX: Objection. Lack of foundation,

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1 speculative, outside the scope.
 2 BY THE WITNESS:
 3 A I'm not going to interpret whatever
 4 marketing scheme there is to this one slide out
 5 of, whatever, 30 slides on this draft -- appears
 6 to be a draft document. And whether it's
 7 targeting a notion that aflibercept is very
 8 efficacious and it can help you with wet AMD and
 9 other ocular maladies, there is a whole bunch of
 10 stuff in here that gets into all the different
 11 indications.
 12 BY MR. CAINE:
 13 Q This advertisement doesn't say anything
 14 about Eylea being safer or more effective than
 15 Lucentis or Avastin, does it?
 16 MR. MARX: Objection. Lack of foundation,
 17 speculative, outside the scope.
 18 BY THE WITNESS:
 19 A I think you're jumping way too far. This
 20 is called a precall document that suggests to me
 21 that it's not even a final form, and peppered
 22 throughout this is the label. And the label, you

<p style="text-align: right;">285</p> <p>1 know, is replete with stuff about safety and 2 efficacy. The vast majority of this, as I flip 3 through it, is focused on what's in the label, 4 what's in the clinical trials and everything else. 5 I mean, I'm not -- 6 BY MR. CAINE: 7 Q I'm asking you about Page 29 of 8 Exhibit 2137. 9 MR. MARX: Same objection. 10 BY THE WITNESS: 11 A I think that's incredibly unfair. It's 12 the second-to-the-last page that has one -- I 13 don't know if this was ever even distributed. I 14 don't know what I'm looking at here. And there's 15 all kinds of other information about efficacy and 16 safety that's throughout this 30-page document. 17 So I understand you're asking me about 18 Page 29 now, but I don't understand how that helps 19 anyone when the rest of the document -- again, I'm 20 just flipping through it as I sit here. There's 21 all kinds of things about efficacy and safety on 22 the vast majority of the slides, and it's not</p>	<p style="text-align: right;">287</p> <p>1 graph. I think that there's, like I said, copies 2 of the whole label within this 30-page document. 3 So I'm not -- I just don't want to create a 4 misleading record or answer that doesn't recognize 5 that in this document there's plenty, plenty, 6 plenty of stuff that appears to address safety and 7 efficacy. 8 BY MR. CAINE: 9 Q Let's look at the page that you're looking 10 at, Page 20 of 30. The heading above the chart 11 says: "Eylea, 2 milligrams every two months 12 following three initial monthly doses and monthly 13 ranibizumab" -- which I think we can agree is 14 Lucentis -- "achieves similar improvements and 15 maintenance of visual acuity." 16 Right? 17 MR. MARX: Objection. Lack of foundation. 18 BY THE WITNESS: 19 A Again, I'm not a clinician. You're 20 putting a document in front of me that I don't 21 know that I've even seen. I'm just flipping 22 through it. And you're asking me about the</p>
<p style="text-align: right;">286</p> <p>1 until we get to Page 29 that we see grandma 2 reading the book. And like I said, I don't even 3 know if this was even used. 4 BY MR. CAINE: 5 Q I didn't ask you if there were any claims 6 about safety or efficacy. I asked if there were 7 any claims that Eylea was safer or more effective 8 than Lucentis or Avastin on Exhibit 2137, Page 29. 9 MR. MARX: Objection. Lack of foundation. 10 BY MR. CAINE: 11 Q Can you answer that question? 12 MR. MARX: Objection. Lack of foundation. 13 BY THE WITNESS: 14 A First off, I'm not -- I'm not a clinician. 15 I'm not a POSA. On Page 29 within the four 16 corners of that document or that page of the 17 30-page document, no, there isn't something there. 18 But whether that's followed by the label in order 19 to be distributed as a pamphlet -- and I believe 20 the label does include the head-to-head study 21 with -- with Lucentis and you can see on Page 22 20 -- I can't read that -- Page 20 there is a line</p>	<p style="text-align: right;">288</p> <p>1 grandma picture, and I'm just saying there's 2 plenty of information, again, on Slide 21 that's 3 talking about Lucentis. I mean, the label itself, 4 I think, talks about the comparator study, but all 5 these are better questions for the clinicians, not 6 me. 7 BY MR. CAINE: 8 Q But you pointed me to this page, so I 9 asked you about it and you still haven't answered 10 my question which is: Doesn't the information 11 right above the chart reflect the notion that 12 using maintenance dosing with Eylea every eight 13 weeks achieves the same results as monthly use of 14 Lucentis? 15 MR. MARX: Objection. Lack of foundation, 16 mischaracterizes the witness testimony and outside 17 the scope. 18 BY THE WITNESS: 19 A I haven't -- I don't know that I have seen 20 this document, and the only reason I pointed it 21 out was because I felt like you were, like, trying 22 to direct me to just Page 29.</p>

<p style="text-align: right;">289</p> <p>1 BY MR. CAINE: 2 Q I was. 3 A And the point is that even the page that I 4 spotted that talks about Lucentis has some 5 footnotes or endnotes attached to it that has 6 further explanation. I mean, I haven't studied 7 this document to weigh in on it, and I don't – I 8 just don't think it's fair to just fixate on what 9 appears to be a draft document that appears to 10 have information that may or may not have ever 11 been disseminated externally. I don't know 12 what – 13 Q Why is it unfair? Dr. Manning relied on 14 Exhibit 2137. You read the Manning declaration. 15 You had access to Exhibit 2137. 16 All of those statements are true, correct? 17 MR. MARX: Objection to the extent it 18 mischaracterizes Mr. Hofmann's testimony and 19 further objection to the extent it's cited by 20 Dr. Manning in a portion of his report that 21 Mr. Hofmann did not review, for example, unmet 22 need.</p>	<p style="text-align: right;">29</p> <p>1 think my point, as I explain in detail in my 2 report, is that there's a clear focus on efficacy 3 and safety. 4 I'm not saying there isn't any discussion 5 of dosing regimen in some of the marketing 6 materials, but what's driving the sales here are 7 things that, as I explain in detail in my report, 8 are things that were known in the prior art, are 9 things that were prevented – preventing others 10 through the existence of the blocking patents, the 11 significant investment in marketing and the fact 12 that even this Page 29 here doesn't necessarily 13 comport with what I saw in the data as to 14 frequency of dosing and frequency of uses. And 15 nothing in this particular page, either, mentions 16 the '338 patent. 17 But if you want to try and read into it 18 that it is consistent with the dosing regimen of 19 the '338 patent, that's inconsistent with what we 20 see in terms of the majority of uses with respect 21 to the Eylea product based on some of the other 22 documents that we looked at.</p>
<p style="text-align: right;">290</p> <p>1 I'll rephrase that. 2 Mr. Hofmann did not respond to -- 3 Mr. Hofmann may have taken a look, but he did not 4 respond to that section. I can speak for him. 5 BY THE WITNESS: 6 A Yeah. Okay, so, now I do recall. But he 7 just kind of cherry-picked Page 29 in his report. 8 It's still unclear to me -- 9 BY MR. CAINE: 10 Q There's nothing unfair in my questioning 11 you about something that Dr. Manning reproduced in 12 his report from a document cited in his report to 13 which you had the opportunity to review in advance 14 of preparing your declaration, right? 15 A No, no, you're twisting -- you're twisting 16 it around. 17 What I am saying is your prior question 18 that got us onto this sideshow is -- was very 19 narrowly focused on Page 29 of this document which 20 Manning clearly does cite to in his report. But I 21 think that that's not necessarily reflective of 22 what's in the entirety of the document. And I</p>	<p style="text-align: right;">292</p> <p>1 BY MR. CAINE: 2 Q Mr. Hofmann, you are familiar with data in 3 the pharmaceutical and life sciences industry from 4 IQVIA and others, right? 5 MR. MARX: Objection. Form. 6 BY THE WITNESS: 7 A Yes. 8 BY MR. CAINE: 9 Q You are aware that those data sources 10 don't differentiate between loading doses and 11 maintenance doses, right? 12 MR. MARX: Objection form. 13 BY THE WITNESS: 14 A I'm just pausing because I think depending 15 on the data set and information, it does 16 distinguish between NRx and TRx, NRx is new 17 prescriptions which I think would include the 18 loading dose, and then TRx would be total 19 prescriptions. 20 BY MR. CAINE: 21 Q Well, NRx, a new prescription, would 22 include both the loading dose and the maintenance</p>

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1 dose phase, wouldn't it?
 2 MR. MARX: Objection. Lack of foundation,
 3 hypothetical. I'll note for the record that
 4 Regeneron has not produced the data that is trying
 5 to be discussed here, and Mr. Hofmann has not had
 6 the chance to review it.
 7 BY THE WITNESS:
 8 **A I mean, I would have to dig into that a**
 9 **little bit. I think the way that I think about it**
 10 **is the NRx is literally the new prescription, and**
 11 **then the way that NRx and TRx are set up is they**
 12 **are common sized to a 30-day script, and the TRx**
 13 **would be the annual amount common sized to**
 14 **14 30 days.**
 15 **I don't know if we can take a quick break.**
 16 MR. CAINE: If you'd like to, we can.
 17 THE WITNESS: I just -- the light -- the
 18 green light is off on the phone, so I don't know
 19 if we lost everybody who was participating by --
 20 MR. CAINE: Why don't we go off the
 21 record.
 22 THE VIDEOGRAPHER: Stand by. We are going

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1 off the record. The time is 4:52 p.m.
 2 (A recess was had.)
 3 THE VIDEOGRAPHER: We are back on the
 4 record. The time is 4:54 p.m.
 5 BY MR. CAINE:
 6 Q We were talking a moment ago about IQVIA
 7 and other data sources from the pharmaceutical and
 8 life sciences industry. Do you recall that?
 9 **A Yes.**
 10 Q You say in your declaration that you are
 11 familiar with those sources, right?
 12 **A Yes. I list a number of them.**
 13 Q Being familiar with those sources, can you
 14 say one way or another whether they differentiate
 15 between the administration of loading doses for
 16 injecting eye treatments like Eylea, Lucentis,
 17 Avastin and maintenance doses?
 18 MR. MARX: Objection. Lack of foundation,
 19 speculative. Mr. Manning did not provide this --
 20 let me rephrase that. I apologize.
 21 Objection. Lack of foundation,
 22 speculative for the reasons noted above in the

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1 transcript, that Regeneron did not produce this
 2 data.
 3 BY MR. CAINE:
 4 Q I'm talking about your experience.
 5 **A Like I said, I'd have to dig into that**
 6 **because there's also sometimes in the situation of**
 7 **injectables, IQVIA data, for example, is mostly**
 8 **the retail pharmacy level as opposed to going into**
 9 **the office and getting an injection which is more**
 10 **of a buy-and-bill dynamic that sometimes isn't**
 11 **captured in IQVIA. So I think it's something I**
 12 **would have to, if I had the data, look at and**
 13 **study.**
 14 Q When a physician and a patient make a
 15 decision about which treatment to use -- and I'm
 16 limiting myself to treatments of eye disorders
 17 like we're talking about today -- they don't know
 18 before beginning the treatment whether extended
 19 dosing will be effective at maintaining visual
 20 gains that the patient achieves during the initial
 21 loading dose phase; is that right?
 22 MR. MARX: Objection. Form, lack of

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1 foundation, outside the scope.
 2 BY THE WITNESS:
 3 **A That's a far better question for a**
 4 **clinician.**
 5 BY MR. CAINE:
 6 Q So from the standpoint of marketplace
 7 dynamics, though, do you agree with me that -- we
 8 have and we've looked at some of the industry
 9 average data, but for any particular patient,
 10 until the physician and patient try the treatment,
 11 they don't know if eight-week extended dosing is
 12 going to work with Eylea, for example?
 13 MR. MARX: Objection. Form, lack of
 14 foundation, outside the scope.
 15 BY MR. CAINE:
 16 Q Do you agree?
 17 **A I'm not a clinician. I mean, the last**
 18 **document we looked at, the PowerPoint that had,**
 19 **whatever, [REDACTED] to [REDACTED] being on an extended**
 20 **regimen, suggests to me that the vast majority of**
 21 **uses, at least according to that study, would**
 22 **suggest that fixed dosing regimen doesn't work for**

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1 most patients. To the extent it does, I imagine
2 people will try and follow it or they can just do
3 PRN or T and E.
 4 Q Do you agree with me that for any
 5 particular patient at the outset of treatment, the
 6 physician and patient don't know whether
 7 eight-week extended dosing, maintenance dosing
 8 will maintain the patient's level of visual acuity
 9 or not?
 10 MR. MARX: Objection. Lack of foundation,
 11 outside the scope, improper hypothetical.
 12 BY THE WITNESS:
13 A I'm an economist. I'm not a clinician.
14 If you want to explore that, explore that with a
15 clinician.
16 BY MR. CAINE:
 17 Q I think you offer an opinion in your
 18 declaration that "Dr. Manning fails to analyze or
 19 quantify the number of uses of Eylea that
 20 allegedly practice the challenged claims of the
 21 '338 patent."
 22 Did you make that statement?

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1 A I can't remember the exact language. If
2 you want to take me to where it is in my
3 declaration, I'm happy to go there.
 4 Q Did you calculate the number of uses of
 5 Eylea that practice the challenged claims of the
 6 '338 patent?
7 A That's the point that I'm making in my
8 declaration, is that he's the one asserting
9 commercial success, he's the one that has to
10 establish a nexus between the alleged commercial
11 success and the patent at issue in this IPR, the
12 '338 patent.
13 He didn't do that. And it's not on me to
14 do that for him. So no, I didn't separately go
15 about and undertake that exercise because I'm not
16 asserting commercial success. If anything, what
17 I've found is a number of failures on
18 Dr. Manning's part, as I explain in detail in my
19 report. So, no, I didn't do a separate
20 quantification of that on my own.
 21 Q Now, earlier we looked at some data. I
 22 believe it was from 2020, where we were looking

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1 at. And, again, you cite this in your
 2 declaration, if you remember. We were talking
 3 about pages 92, 94, 95 and 96.
 4 Do you recall what I'm talking about?
5 A Generally, yes.
 6 Q We did some math on the percentage of
 7 people -- percentage of physicians who said that
 8 they were treating patients using Eylea at eight
 9 weeks or longer.
 10 Do you recall that?
 11 MR. MARX: Objection. Lack of foundation.
 12 Same objections made earlier on the record with
 13 respect to the use of those documents.
 14 BY THE WITNESS:
15 A I recall you putting certain parameters or
16 preambles to fix those based on all the caveats I
17 explained as to the limitations with respect to
18 those ATUs, yeah, I remember that.
19 BY MR. CAINE:
 20 Q We saw that in each case for each of those
 21 treatments for eight weeks or greater, physicians
 22 said -- the physician response was [REDACTED] or

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1 more, right?
 2 MR. MARX: Objection. Mischaracterizes
 3 those documents, lack of foundation and further
 4 objection to the use of those documents.
 5 BY THE WITNESS:
6 A These are -- these are -- I think there
7 were two that we looked at that were points in
8 time, sometime in 2011, sometime in 2013 based on
9 ATUs that we don't know what the questions that
10 were asked, whether there were control questions,
11 what the representation was of the physicians in
12 that.
13 You put in the parameter for greater than
14 eight weeks, and I think -- so there is a lot of
15 uncertainty as to the reliability and what we can
16 put on those particular ATUs one way or the other.
17 And in any event, those ATUs also -- I
18 don't remember -- you know, they were vaguely just
19 saying dosing regimen. They didn't -- I didn't
20 see anything in those that really got you into the
21 contours of what I understand to be the claims of
22 the '338 patent. So I think you're just stacking

30

1 and making a bunch of leaps looking to those.
2 BY MR. CAINE:
 3 Q If Eylea is administered with an
 4 eight-week or greater maintenance dosing period
 5 for 50 percent of the patient population, then
 6 Eylea's gross sales over time would be more than
 7 [REDACTED], correct?
 8 MR. MARX: Objection. Lack of foundation,
 9 mischaracterizes the documents and outside the
 10 scope.
 11 BY THE WITNESS:
12 A That's -- so there's a number of false
13 presuppositions in your question and potential
14 hazards in your question.
15 First off, you can't look at gross sales.
16 Gross sales don't reflect patient assistance,
17 discounts, rebates, and in particular for
18 geriatric population that is primarily those that
19 are suffering with these ocular afflictions.
20 Then you can't kind of look at it in the
21 way that you're describing it, because as I
22 understand it, and I'm not a technical expert, I'm

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1 not a clinician, a lot of the benefits, as I
2 understand it, are the long half-life of the
3 aflibercept molecule which are inherent properties
4 of aflibercept.
5 So let's not put too much weight on saying
6 that that all somehow falls within the '338 patent
7 when as I defer to Dr. Gerritsen and Dr. Albin
8 with respect to their technical perspectives on
9 all of that. So I don't know that I can buy into
10 your hypothetical number crunching exercise that
11 is, I think, horribly constructed.
12 BY MR. CAINE:
 13 Q If Eylea -- if we only count sales of
 14 Eylea that resulted in administration with an
 15 eight-week dosing, eight-week maintenance dosing
 16 period or greater, we said that occurred
 17 50 percent of the time, the gross profits
 18 attributable to such use would be over
 19 [REDACTED], correct?
 20 MR. MARX: Objection. Lack of foundation,
 21 mischaracterizes the documents, speculative,
 22 improper hypothetical.

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1 BY THE WITNESS:
2 A I don't -- I don't know how you get there
3 because you say that there's 50 percent. That's
4 one document, but then we looked at other
5 documents that said [REDACTED] of sales would
6 potentially fall in that based on the other ATU.
7 And that's the problem with ATUs and these
8 statistics, is it's hard to know if we have a good
9 set of control questions, a good set of actual
10 questions.
11 And like I said, a lot of the questions
12 didn't seem to -- you're suggesting that it, in
13 particular, said "eight-week dosing." A lot of
14 them just said "dosing regimen." So I think
15 you're just making leaps into these documents that
16 I can't -- I can't agree with.
17 And the failures, the repeated failures of
18 Manning in not addressing what was known in the
19 prior art, the effect of the molecule, things the
20 technical experts have addressed, the blocking
21 patents and all of that just really you're asking,
22 you know, I think questions that make it hard for

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1 me to accept the assumptions that you're placing
2 within the question to fairly answer it to get the
3 right information in front of those that have to
4 review and make decisions on this case.
5 BY MR. CAINE:
 6 Q Let me ask you about the Chronic Disease
 7 Fund litigation. You mentioned that in your
 8 declaration, right?
9 A I did.
 10 Q As of 2021, approximately 42 percent of
 11 Medicare beneficiaries are enrolled in Medicare
 12 Advantage plans, right?
 13 MR. MARX: Objection. Lack of foundation.
 14 BY THE WITNESS:
15 A I don't remember the exact percentages.
16 If you want to remind me by putting something in
17 front of me.
 18 MR. CAINE: Do we have 2026 -- 2226.
 19 BY MR. CAINE:
 20 Q I'll hand you Exhibit 2226.
 21 MR. CAINE: Why don't we do 2210 as well.
 22 BY MR. CAINE:

<p style="text-align: right;">305</p> <p>1 Q I'll also hand you Exhibit 2210. 2 First, Exhibit 2210 which I've put in 3 front of you is discussing Medicare Advantage in 4 2021. 5 Do you see that? 6 MR. MARX: Objection. Lack of foundation. 7 BY THE WITNESS: 8 A I'm sorry. Which one? 9 BY MR. CAINE: 10 Q 2210. 11 A Okay. 12 MR. MARX: With respect to 2210, lack of 13 foundation. And furthermore this appears to be a 14 printout from a website, KFF.org. So I'm not 15 familiar with what that organization is or the 16 veracity of this document or the information 17 discussed therein. 18 BY MR. CAINE: 19 Q I'm going to direct you because you asked 20 me to direct you to it, Page 2 of Exhibit 2210. 21 Do you see the report here that says: "In 22 2021, more than four in ten, 42 percent Medicare</p>	<p style="text-align: right;">307</p> <p>1 for patients? 2 MR. MARX: Objection. Lack of foundation. 3 BY THE WITNESS: 4 A I think the way – the way I would frame 5 it is if you don't have a Medicare Advantage plan, 6 it's an 80/20 split with Uncle Sam. 7 BY MR. CAINE: 8 Q If you do have a Medicare Advantage plan, 9 the Medicare Advantage plan limits out-of-pocket 10 costs? 11 MR. MARX: Same objection. 12 BY THE WITNESS: 13 A Yes. But there are varying degrees of how 14 much that sharing covers that 20 percent. And 15 there is a whole bunch of complications with 16 Medicare doughnut hole – I don't know – all the 17 different things that exist in the way that the 18 Medicare system, you know, does and doesn't 19 reimburse patients. 20 BY MR. CAINE: 21 Q Are you aware that Medicare beneficiaries 22 also can enroll in supplemental coverage?</p>
<p style="text-align: right;">306</p> <p>1 beneficiaries" -- and then it goes on -- "are 2 enrolled in Medicare Advantage plans"? 3 MR. MARX: Same objection. 4 BY MR. CAINE: 5 Q Mr. Hofmann, do you see what I was 6 pointing you to? 7 A I do see what I'm pointing you to. I'm 8 just reviewing it. I mean, I'll just point out 9 that some of these appear to be -- like, for 10 example, the graph that appears above is truncated 11 at the bottom. I don't know if there's anything 12 of note that's missing. There's also, like, 13 graphical links you can hit on that aren't 14 reflected here. 15 I'm not -- I mean, I guess maybe so that 16 we can move along, I don't disagree that many, 17 many people do have Medicare Advantage programs. 18 I don't know that I can sanction 42 percent as 19 being an exact figure, but -- 20 Q Fair enough. 21 Now, can you agree or do you agree that 22 Medicare Advantage plans limit out-of-pocket costs</p>	<p style="text-align: right;">308</p> <p>1 A Sure. 2 MR. MARX: Objection. Lack of foundation. 3 BY MR. CAINE: 4 Q And that supplemental coverage would apply 5 to co-pays, correct? 6 MR. MARX: Objection. Lack of foundation, 7 speculative. 8 BY THE WITNESS: 9 A I mean, again, I'm just speaking in very 10 broad strokes based on my knowledge of 11 pharmaceutical economics that you can agree to pay 12 a monthly supplemental amount to essentially 13 defray some of that 20 percent. 14 BY MR. CAINE: 15 Q You talk about the Chronic Disease Fund in 16 your declaration. 17 Were you aware that the Chronic Disease 18 Fund provides co-pay assistance for treatment 19 using Lucentis? 20 A I don't remember whether that's something 21 I came across specifically one way or the other. 22 My focus was on the DOJ complaint against</p>

<p style="text-align: right;">309</p> <p>1 Regeneron with respect to their involvement in the 2 fund. 3 Q And in that complaint that you looked at, 4 there are allegations that the CDF fund issues 5 grants for Lucentis, aren't there? 6 A I think there is some language to that 7 regard, but my focus -- like I said, since I'm 8 dealing with the Eylea product, that was my focus. 9 Q Okay. And as alleged in the complaint, 10 prior to 2011, Genentech was the only financier 11 for the Chronic Defense Fund's AMD fund, right? 12 MR. MARX: Objection. Form. 13 BY THE WITNESS: 14 A I don't have that in front of me. 15 BY MR. CAINE: 16 Q Okay. Well, why don't we give you a copy 17 of Exhibit 1154. 18 A It's a thick double-sided document, so can 19 you point me to where you want me to focus? 20 Q Yes, Page 10, Paragraph 33. 21 Do you see -- are you at that paragraph? 22 A I am.</p>	<p style="text-align: right;">3</p> <p>1 MR. MARX: Objection. Form. 2 BY THE WITNESS: 3 A I'm not -- I'm not saying that the DOJ 4 doesn't view Eylea alone or Regeneron alone as a 5 bad actor here. Clearly they also, if you read 6 this complaint, have there's numerous allegations 7 against both Regeneron and Genentech, but yeah, I 8 mean, you read that as it appears. 9 BY MR. CAINE: 10 Q Are you aware that the Chronic Disease 11 Fund is a non-profit organization? 12 A I don't -- I don't know a hundred percent 13 as I sit here right now. What I know is that the 14 United States, you know, DOJ, HHS, has brought 15 this claim against these entities. And even if 16 it's a not-for-profit, sometimes you can set up 17 organizations that appear as a not-for-profit, but 18 there's still a benefit that's inured to the 19 entity. 20 And, again, I'm not weighing in on the 21 exact claims that are here. I'm just pointing out 22 that as I was doing research, I found the DOJ</p>
<p style="text-align: right;">3 0</p> <p>1 Q It starts: "Since at least 2010, CDF has 2 operated a fund that covers Medicare co-pays for 3 patients taking drugs for AMD." 4 Do you see that? 5 MR. MARX: Objection. Form. 6 BY THE WITNESS: 7 A You've read those words as they appear. 8 BY MR. CAINE: 9 Q It says: "Prior to the FDA's approval of 10 Eylea, Genentech's Lucentis was the only 11 FDA-approved therapy for AMD, and Genentech alone 12 financed CDF's AMD fund." 13 Do you see that? 14 MR. MARX: Objection. Form. 15 BY THE WITNESS: 16 A You've read those words as they appear 17 there. 18 BY MR. CAINE: 19 Q So this reflects the allegation that 20 Genentech was financing the Chronic Disease Fund's 21 AMD fund in and around the time period that's 22 referenced in Paragraph 33, right?</p>	<p style="text-align: right;">3 2</p> <p>1 claim. 2 And so you can set up a not-for-profit, 3 but if that not-for-profit is essentially 4 channeling or funding money to you to the 5 detriment of the US government, you can run into 6 some trouble. 7 Q Mr. Hofmann, I'll ask you just to focus on 8 my question and answer my question. 9 Are you aware that donors to the Chronic 10 Disease Fund have no control over how the 11 donations are used? 12 MR. MARX: Objection. Lack of foundation. 13 BY THE WITNESS: 14 A I don't -- I don't know about that one way 15 or the other as I sit here right now. I'd have to 16 go back through the complaints and the information 17 and see if that's consistent with things. But I 18 was working off of the -- you know, what the 19 United States government calls factual 20 allegations, allegations specifically with respect 21 to Eylea with my particular focus, and then 22 certainly reviewed the discussion regarding the</p>

3 3

1 other parties that are involved in the DOJ
2 complaint.
3 Q Are you aware that the time period at
4 issue in this complaint, Exhibit 1154, is 2013 and
5 the first part of 2014?
6 A **Can you point me to --**
7 Q Page 20, Paragraph 61. And the
8 surrounding slide above it and discussion below
9 it.
10 A **I mean, it appears that at least what the**
11 DOJ brought action on is from 2013 and 2014. It
12 doesn't mean they can't expand it or maybe it's
13 been dismantled. I don't know.
14 Q You're not aware of any allegations
15 pertaining to 2012, 2015, 2016, 2017, 2018, 2019,
16 2020 or 2021, are you?
17 MR. MARX: Objection. Form.
18 BY THE WITNESS:
19 A **As I sit here right now, this is -- this**
20 is the document that I found that Manning, you
21 know, didn't mention at all in his declaration and
22 pertain to the product at issue. Like I said, the

3 4

1 way that the DOJ works is they focus on putting
2 the evidence in for their case for certain
3 periods, but they can always expand it. But I
4 don't disagree -- I don't have any amended
5 complaints or information that supplements this.
6 BY MR. CAINE:
7 Q You don't take the allegations in this
8 complaint as proven facts, do you?
9 A **I think we all know or at least the**
10 lawyers in the room know that the allegations are
11 not proven facts, but what we do know is that DOJ,
12 you know, when they're bringing an action against
13 a party, in this case it's a pretty significant
14 number of exhibits that accompany the complaint.
15 Everybody gets their day in court. I will
16 grant you that. I'm not taking it as a proven
17 fact, but I'm just pointing out the DOJ has made
18 these allegations with accompanying exhibits.
19 Q The complaint that you discuss at
20 Paragraph 63, Page 20, says that in 2013,
21 Regeneron --
22 A **Hold on. Let me catch up to where you**

3 5

1 are.
2 Q Page 20, Paragraph 63, just where we were.
3 Page 20, Paragraph 63. Are you there?
4 A **Okay, yep.**
5 Q You agree that the DOJ alleges that in
6 2013, Regeneron contributed \$35 million to the
7 Chronic Disease Fund, right?
8 MR. MARX: Objection. Form.
9 BY THE WITNESS:
10 A **In 2013, yes, that appears to be so.**
11 BY MR. CAINE:
12 Q And you are -- you agree that above it, in
13 the slide that we see from the DOJ complaint, the
14 potential sales from 2013 donations were
15 \$198.5 million?
16 MR. MARX: Objection. Form, foundation.
17 BY MR. CAINE:
18 Q That's the allegation, right?
19 A **That's what appears in that slide.**
20 Q Now, we can look at -- if you'd like to
21 pull out Dr. Manning's declaration, which is
22 Exhibit 2052 in your stack, you can turn to

3 6

1 Attachment D-1. Attachment D-1 is on Page 171.
2 Eylea's net sales for 2013 were over
3 \$1.4 billion, correct?
4 MR. MARX: Objection. Lack of foundation.
5 BY THE WITNESS:
6 A **Going off the net sales figures from D-1,**
7 that is the number. Having said that, the point
8 of this is the taint that comes with the
9 potential -- what the allegations are that appear
10 here as to the CDF and the -- you know, that can
11 have broader implications than the exact amounts
12 that are at issue in the DOJ complaint because,
13 you know, these physicians are prescribing to lots
14 of people.
15 BY MR. CAINE:
16 Q There's no allegation in Exhibit 1154 that
17 Regeneron's alleged donations of \$35 million to
18 the Chronic Disease Fund impacted over
19 \$1.21 billion in sales in 2013, is there?
20 MR. MARX: Objection to the extent it
21 mischaracterizes the document and seeks a legal
22 conclusion, speculative.

<p style="text-align: right;">3 7</p> <p>1 BY THE WITNESS:</p> <p>2 A Like I said, I mean, I'm not in the weeds</p> <p>3 with the DOJ to know what all they have decided to</p> <p>4 do with respect to what they perceive as bad</p> <p>5 actors as reflected in the complaint. Sometimes</p> <p>6 they'll just prove what they know they have solid</p> <p>7 evidence on, but there are broader implications.</p> <p>8 I'm just saying that there's a taint.</p> <p>9 There is a negative that affects the objectivity</p> <p>10 of the evidence with respect to the marketplace</p> <p>11 performance. I'm not saying that every dime of</p> <p>12 Eylea's sales was the result of this alleged</p> <p>13 kickback scheme, if that's where you're going.</p> <p>14 I'm saying that this is not immaterial,</p> <p>15 hundreds of millions of dollars at least that DOJ</p> <p>16 is pressing for and complaining about, and that's</p> <p>17 the extent of it.</p> <p>18 BY MR. CAINE:</p> <p>19 Q You don't identify even a single physician</p> <p>20 who identified co-pay assistance as the reason --</p> <p>21 as their reason for prescribing Eylea, correct?</p> <p>22 MR. MARX: Objection. Outside the scope,</p>	<p style="text-align: right;">3 9</p> <p>1 BY THE WITNESS:</p> <p>2 A I don't remember if Dr. Albini addressed</p> <p>3 it one way or the other.</p> <p>4 BY MR. CAINE:</p> <p>5 Q Do you remember that Dr. Albini testified</p> <p>6 that he prescribed Eylea because it was best in</p> <p>7 class?</p> <p>8 A I don't have his testimony in front of me.</p> <p>9 I think he testified about a lot of things, and I</p> <p>10 certainly reviewed his report. I think I</p> <p>11 understand he was only deposed yesterday.</p> <p>12 Q How about at his first deposition?</p> <p>13 A Oh. I haven't looked at that in a while.</p> <p>14 I just don't -- I don't remember.</p> <p>15 Q Now, if you consider the sales of Eylea</p> <p>16 and its market share outside of 2013 and 2014,</p> <p>17 still it would be considered to have significant</p> <p>18 marketplace performance, right?</p> <p>19 MR. MARX: Objection. Form, to the extent</p> <p>20 it seeks a legal conclusion, and speculative to</p> <p>21 the extent that Mylan was denied the opportunity</p> <p>22 to review Regeneron's materials as requested.</p>
<p style="text-align: right;">3 8</p> <p>1 mischaracterizes witness testimony.</p> <p>2 BY THE WITNESS:</p> <p>3 A I mean, I think there were some slides</p> <p>4 that we looked at throughout the day and that I</p> <p>5 looked at in my report that talk about price and</p> <p>6 co-pay, but I mean with respect to this specific</p> <p>7 complaint, no, it's not like I was going about the</p> <p>8 job of the DOJ to identify specific physicians</p> <p>9 that would fall under this or how that fits into</p> <p>10 their case or theory of the case. I was just</p> <p>11 relying on what the DOJ put in their complaint</p> <p>12 against Regeneron.</p> <p>13 BY MR. CAINE:</p> <p>14 Q You didn't read anything in Dr. Albini's</p> <p>15 declaration or deposition about prescribing Eylea</p> <p>16 because of the existence of co-pay assistance, did</p> <p>17 you?</p> <p>18 MR. MARX: Objection. Lack of foundation,</p> <p>19 outside the scope. And also note for the record</p> <p>20 this also pertains to Regeneron's marketing</p> <p>21 efforts, which despite Mylan's request, Regeneron</p> <p>22 has refused to produce.</p>	<p style="text-align: right;">320</p> <p>1 BY THE WITNESS:</p> <p>2 A I think we started the day to some extent</p> <p>3 on this topic. I think that the numbers are what</p> <p>4 they are. They've had a good run, but it's</p> <p>5 because of the existence of the blocking patents</p> <p>6 that really has nothing to do with the '338</p> <p>7 patent.</p> <p>8 It prevented other -- anyone other than</p> <p>9 Regeneron as a gating issue from pursuing the</p> <p>10 alleged invention of the '338 patent, and as I</p> <p>11 explain in detail in my declaration, there are so</p> <p>12 many failures in the Manning declaration and then</p> <p>13 admissions in his deposition that simply there --</p> <p>14 whether or not there have been the significant</p> <p>15 sales, Manning has done a very poor job of</p> <p>16 establishing nexus to the '338 patent for all the</p> <p>17 reasons that I've explained in my declaration and</p> <p>18 today.</p> <p>19 BY MR. CAINE:</p> <p>20 Q Eylea's marketplace performance outside of</p> <p>21 2013 and 2014 includes \$30 billion in net sales,</p> <p>22 correct?</p>

32

1 MR. MARX: Objection. Lack of foundation.
 2 BY THE WITNESS:
 3 A Are you talking gross sales or net sales?
 4 BY MR. CAINE:
 5 Q Net sales.
 6 A I mean, it's somewhere in that ballpark,
 7 recognizing that they were able to do so on the
 8 heels of the patent thicket that they had
 9 established and the other extrinsic factors that I
 10 explain in my report.
 11 Q Are you aware that physicians don't know
 12 whether a patient will receive co-pay assistance
 13 when they prescribe Eylea or Lucentis for that
 14 matter?
 15 MR. MARX: Objection. Form, lack of
 16 foundation, hypothetical and speculative.
 17 BY THE WITNESS:
 18 A I mean, I'm not a clinician. My
 19 experience has been, though, that maybe sometimes
 20 that's true, but then if they get a sticker shock
 21 on how much they have to come up with, that can
 22 change a course of treatment.

322

1 And I'm not speaking about Eylea
 2 specifically. I'm just talking about in general,
 3 that's where co-pay assistance comes in from an
 4 economic perspective, is to insulate patients from
 5 the cost of products, particularly patients that
 6 either can't afford or don't want the burden of
 7 the cost associated with the medications.
 8 So sometimes they explore other treatments
 9 or that's where sometimes physicians – and,
 10 again, I'm not speaking about Eylea specifically.
 11 I'm just saying there are techniques and schemes
 12 that the pharma companies will do to help assist
 13 patients in being shielded from the true cost of
 14 the medication.
 15 BY MR. CAINE:
 16 Q Are you aware that physicians don't know
 17 whether a patient will qualify for co-pay
 18 assistance when the physician prescribes
 19 treatment?
 20 MR. MARX: Objection. Lack of foundation,
 21 speculative and incomplete hypothetical, outside
 22 the scope.

323

1 BY THE WITNESS:
 2 A That's a better question – yeah, a better
 3 question for a clinician. All I was saying in my
 4 last answer, and, again, not specific to Eylea, is
 5 that there are situations where a patient gets
 6 prescribed something, finds out what their share
 7 of the cost is, and then they get counseled from
 8 their physician what are my options to hopefully
 9 defray the costs.
 10 BY MR. CAINE:
 11 Q Are you aware of any allegations in the
 12 complaints that you cite that physicians were
 13 influenced in their prescribing decisions by any
 14 Regeneron co-pay assistance donation?
 15 MR. MARX: Objection to the extent it
 16 seeks a legal conclusion.
 17 BY THE WITNESS:
 18 A I'm not making any affirmative statement
 19 in that regard. I'm simply pointing to the
 20 existence of the complaint and the allegations
 21 being made by DOJ.
 22 BY MR. CAINE:

324

1 Q You don't cite or identify any facts or
 2 even allegations that physicians had knowledge of
 3 donations made by Regeneron, correct?
 4 MR. MARX: Objection. To the extent it
 5 mischaracterizes the document, seeks a legal
 6 conclusion.
 7 BY THE WITNESS:
 8 A I think the better way to look at it is
 9 the allegations by the DOJ clearly show the belief
 10 by DOJ that Regeneron did see huge ROI and did see
 11 influence with respect to prescribing decisions
 12 because that's where you get the ROI. Again, I
 13 haven't, you know, dug into the details beyond
 14 what is in the plain language of the complaint
 15 which I cite to in my report.
 16 BY MR. CAINE:
 17 Q You don't cite any facts in your
 18 declaration or even any allegations that
 19 physicians had knowledge of donations made by
 20 Regeneron, correct?
 21 MR. MARX: Objection. Mischaracterizes
 22 the witness testimony.

325	<p>1 BY THE WITNESS:</p> <p>2 A I don't know that I cite to physician</p> <p>3 knowledge or testimony one way or the other, but</p> <p>4 that's the whole point of the DOJ's allegations.</p> <p>5 If you read the complaint, essentially they're</p> <p>6 saying Regeneron and Genentech used tens of</p> <p>7 millions of dollars to influence physician</p> <p>8 behavior which cost the US government a bunch of</p> <p>9 money. And so whether there is, I guess,</p> <p>10 knowledge by the physician, I don't understand how</p> <p>11 that's, I guess, something that needs to even be</p> <p>12 shown.</p> <p>13 The point as I read the complaint is that</p> <p>14 they were doing this because they saw enhancements</p> <p>15 in prescribing behavior, which is, I guess, an</p> <p>16 indirect way of pointing to influencing</p> <p>17 prescribing behavior based on the observation</p> <p>18 existence of the fund and the contributions that</p> <p>19 were made to it, whether or not they had</p> <p>20 acknowledgment or knowledge or awareness of the</p> <p>21 payments being made to the fund.</p> <p>22 Q I was talking not about Regeneron's or</p>	327	<p>1 talked to or that I have testimony from. I have</p> <p>2 the broader scheme documents that are explained</p> <p>3 and listed as exhibits to the Regeneron complaint</p> <p>4 that tell the story, and in their view they were</p> <p>5 able to get a 430, whatever percent ROI by</p> <p>6 throwing money at the CDF, which means they viewed</p> <p>7 it as very much influencing prescribing behavior.</p> <p>8 BY MR. CAINE:</p> <p>9 Q I still haven't heard any response to my</p> <p>10 question about any fact or allegation about</p> <p>11 physicians having knowledge of the donations</p> <p>12 Regeneron made, but be that as it may, let me ask</p> <p>13 you a question about guidance from the Department</p> <p>14 of Health and Human Services, Office of Inspector</p> <p>15 General.</p> <p>16 Are you aware of guidance from 2005 that</p> <p>17 makes clear that pharmaceutical manufacturers can</p> <p>18 effectively contribute to the pharmaceutical</p> <p>19 safety net by making cash donations to independent</p> <p>20 bona fide charitable assistance programs?</p> <p>21 MR. MARX: Objection to the extent it</p> <p>22 seeks a legal conclusion and outside the scope.</p>
326	<p>1 Genentech's knowledge. I was talking about</p> <p>2 physician's knowledge.</p> <p>3 A So was I.</p> <p>4 Q Do you cite to any fact or allegation that</p> <p>5 suggests that physicians had any knowledge of</p> <p>6 donations made by Regeneron to the Chronic Disease</p> <p>7 Fund?</p> <p>8 MR. MARX: Objection. Asked and answered</p> <p>9 and outside the scope.</p> <p>10 BY THE WITNESS:</p> <p>11 A I don't think you understood my answer</p> <p>12 because what I said -- and I don't know. We can</p> <p>13 read it back if you want, but the point I was</p> <p>14 making is the allegations are that there were</p> <p>15 these dollars contributed to the fund. There were</p> <p>16 documents created by Regeneron where they believed</p> <p>17 that they were going to get a huge ROI on</p> <p>18 contributing to this fund, which is a way of, I</p> <p>19 think -- I don't know if it's even implicit, but</p> <p>20 it's indirectly implicating the influence that</p> <p>21 that had on prescribing behavior.</p> <p>22 I don't have a particular physician that I</p>	328	<p>1 BY THE WITNESS:</p> <p>2 A I would say you would have to put</p> <p>3 something in front of me, but off the top of my</p> <p>4 head, if that was sanctioned and what was being</p> <p>5 done by Regeneron and Genentech was A-okay, why</p> <p>6 did they file this complaint?</p> <p>7 BY MR. CAINE:</p> <p>8 Q Are you aware of the guidance or are you</p> <p>9 not aware of it?</p> <p>10 MR. MARX: Objection. Asked and answered.</p> <p>11 BY THE WITNESS:</p> <p>12 A Like I said, you'd have to put something</p> <p>13 in front of me. As I sit here right now, I'm not</p> <p>14 familiar off the top of my head with respect to</p> <p>15 the IG guidance that you claim exists. But I</p> <p>16 guess my reaction is that if -- even if there was</p> <p>17 such guidance, you don't get charged by DOJ the</p> <p>18 way that Regeneron has if they were complying with</p> <p>19 the guidance.</p> <p>20 BY MR. CAINE:</p> <p>21 Q I mean, it sounds to me like you're taking</p> <p>22 the allegations in the complaint as proven facts.</p>

329	<p>1 MR. MARX: Objection. Mischaracterizes</p> <p>2 witness testimony.</p> <p>3 BY MR. CAINE:</p> <p>4 Q Is that what you're doing?</p> <p>5 A I didn't say that at all.</p> <p>6 Q Are you saying that they are liable and</p> <p>7 violated the law because of the allegations in the</p> <p>8 complaint?</p> <p>9 MR. MARX: Objection. Mischaracterizes</p> <p>10 witness testimony.</p> <p>11 BY THE WITNESS:</p> <p>12 A I don't know how many questions back we'd</p> <p>13 have to go to, but I'm saying exactly what I said</p> <p>14 when we started talking about this, which is the</p> <p>15 DOJ filed a lengthy complaint that had a bunch of</p> <p>16 exhibits that asserted numerous allegations. It</p> <p>17 may -- it may, you know, not proceed or it may</p> <p>18 settle or there may be some kind of settlement</p> <p>19 agreement where they're able to kind of get away</p> <p>20 with whatever the allegations were that DOJ made.</p> <p>21 I'm not -- I'm not -- I'm not trying to be</p> <p>22 judge or jury on that complaint. I'm just saying</p>	33	<p>1 the blocking patents, then it's what was known in</p> <p>2 the prior art, a lack of demonstration of nexus</p> <p>3 with respect to '338, and then you start to add to</p> <p>4 the list the heavy marketing, the heavy reliance</p> <p>5 on this alleged kickback scheme.</p> <p>6 When you look at it all together, there's</p> <p>7 just no way, despite the sales levels of Eylea,</p> <p>8 that you should be finding commercial success with</p> <p>9 respect to the '338 patent for all the reasons</p> <p>10 that I pore through in my report.</p> <p>11 Q The existence of co-pay assistance did not</p> <p>12 lead physicians to conclude that Eylea was a lower</p> <p>13 cost treatment than Avastin, correct?</p> <p>14 MR. MARX: Objection. Outside the scope,</p> <p>15 speculative, incomplete hypothetical.</p> <p>16 BY THE WITNESS:</p> <p>17 A I mean, that's a tricky thing to address</p> <p>18 because there are different ways that patients are</p> <p>19 affected with respect to the cost of their</p> <p>20 medications. I think I can grant you that Avastin</p> <p>21 almost in all cases was less expensive to the</p> <p>22 patient based on the data sets that I've seen.</p>
330	<p>1 that it puts a pall and a taint on the sales</p> <p>2 because clearly if you look at the exhibits and</p> <p>3 you look at the allegations in that complaint, DOJ</p> <p>4 felt that it was worth them pursuing the</p> <p>5 litigation against Regeneron and Genentech because</p> <p>6 of the different things that are cited in the body</p> <p>7 of the complaint and the exhibits attached</p> <p>8 thereto.</p> <p>9 BY MR. CAINE:</p> <p>10 Q And are you saying that it put a pall and</p> <p>11 a taint on Regeneron's sales from late 2011</p> <p>12 through the present?</p> <p>13 A I think that's for the trier of fact to</p> <p>14 consider.</p> <p>15 Q What's your opinion?</p> <p>16 A My opinion is you don't get to the spot</p> <p>17 that they're in unless there's something that DOJ</p> <p>18 felt was worthy of complaining. I'm not saying</p> <p>19 every last dime of Eylea, you know, is completely</p> <p>20 a taint. I mean, it's one thing that I looked at</p> <p>21 on many things that I looked at.</p> <p>22 You know, to me, first and foremost, it's</p>	332	<p>1 But there are plenty of instances where</p> <p>2 the patient is completely shielded from the cost</p> <p>3 of the product because of whether it's the CTG or</p> <p>4 whether it's other schemes and discounts that are</p> <p>5 being done to insulate the patient.</p> <p>6 So I don't know how better I can say that.</p> <p>7 Like I said, I will grant you that in -- overall</p> <p>8 Avastin is cheaper than Eylea, but there are</p> <p>9 probably plenty of patients that are fully</p> <p>10 insulated from the cost of Eylea.</p> <p>11 BY MR. CAINE:</p> <p>12 Q Mr. Hofmann, you looked at marketing</p> <p>13 expenditures, correct?</p> <p>14 A I did.</p> <p>15 Q Did you do any comparison between</p> <p>16 Regeneron's marketing expenditures for Eylea and</p> <p>17 those marketing expenditures for other classes of</p> <p>18 drugs that you believe are comparable?</p> <p>19 MR. MARX: Objection. This is among the</p> <p>20 information that Mylan requested Regeneron</p> <p>21 produce. Dr. Manning didn't cite any of this.</p> <p>22 Regeneron has failed to produce it to Mylan</p>

333	<p>1 despite our requests.</p> <p>2 BY THE WITNESS:</p> <p>3 A The frustration I had in this case is that</p> <p>4 typically the brand sponsor will produce either</p> <p>5 IQVIA or Symphony data that provides estimated</p> <p>6 marketing spending for competing products within</p> <p>7 the therapeutic area.</p> <p>8 As I explained in my declaration, the</p> <p>9 updated incomparable articles cited by Dr. Manning</p> <p>10 are really not instructive, but I didn't have</p> <p>11 access to the data sets that I typically expect</p> <p>12 and almost all the time get with respect to being</p> <p>13 able to look at some comparator metrics for things</p> <p>14 like Share of Voice and marketing the sales</p> <p>15 rations, et cetera. I just didn't have the data</p> <p>16 sets to look at it.</p> <p>17 BY MR. CAINE:</p> <p>18 Q Did you request that an attempt be made to</p> <p>19 provide you with Genentech's marketing</p> <p>20 expenditures for Lucentis?</p> <p>21 MR. MARX: Objection. Outside the scope.</p> <p>22 And to the extent it seeks privileged</p>	335	<p>1 Q -- with respect to Genentech, Lucentis as</p> <p>2 compared to Regeneron's spend with respect to</p> <p>3 Eylea?</p> <p>4 MR. MARX: Same objection. Lack of</p> <p>5 foundation. This information was requested and it</p> <p>6 was not produced by Regeneron.</p> <p>7 BY THE WITNESS:</p> <p>8 A This all falls within the frustration that</p> <p>9 I just complained about in my last answer. I</p> <p>10 don't know because I don't have access to data</p> <p>11 that I would -- I would typically expect Regeneron</p> <p>12 to have provided IQVIA or Symphony data that would</p> <p>13 give me information regarding marketing spend,</p> <p>14 various categories of marketing spend, various</p> <p>15 categories of how that relates to, you know, Share</p> <p>16 of Voice and as a percentage of sales revenues,</p> <p>17 but I simply -- it wasn't made available to me.</p> <p>18 MR. MARX: If I could interrupt,</p> <p>19 Mr. Caine.</p> <p>20 If the videographer can confirm that we've</p> <p>21 gone seven hours on the record.</p> <p>22 THE VIDEOGRAPHER: 6:59.</p>
334	<p>1 communications, I'd ask you not to disclose those,</p> <p>2 Mr. Hofmann.</p> <p>3 BY THE WITNESS:</p> <p>4 A I think broadly, it's almost like a</p> <p>5 strange question because typically, I would expect</p> <p>6 that the brand who is trying to advance maybe the</p> <p>7 argument that extrinsic factors such as marketing</p> <p>8 didn't drive the sales of the product would be</p> <p>9 eager to produce any data sets that they have that</p> <p>10 tell that story.</p> <p>11 For whatever reason, this information was</p> <p>12 not made available to me. I think I've heard</p> <p>13 Mr. Marx object several times today that such</p> <p>14 information was requested from Regeneron, but it</p> <p>15 simply wasn't made available to us, and I don't</p> <p>16 understand why.</p> <p>17 BY MR. CAINE:</p> <p>18 Q Do you know if Genentech spends more or</p> <p>19 less per year than what Regeneron does on</p> <p>20 marketing --</p> <p>21 MR. MARX: Same objection. Sorry.</p> <p>22 BY MR. CAINE:</p>	336	<p>1 MR. MARX: Okay.</p> <p>2 BY MR. CAINE:</p> <p>3 Q Mr. Hofmann, are you aware that among</p> <p>4 Eylea's -- marketing expenditure for Eylea, there</p> <p>5 has been direct-to-consumer marketing?</p> <p>6 A There has.</p> <p>7 MR. MARX: Objection. Lack of foundation.</p> <p>8 BY MR. CAINE:</p> <p>9 Q And have you seen direct-to-consumer</p> <p>10 television marketing?</p> <p>11 MR. MARX: Same objection. Lack of</p> <p>12 foundation. Mylan requested this information, and</p> <p>13 Regeneron failed to produce it.</p> <p>14 BY THE WITNESS:</p> <p>15 A I don't -- I mean, like I said, the spotty</p> <p>16 amount of marketing materials that appeared in</p> <p>17 what was made available to me, there's seemingly</p> <p>18 some direct to consumer in some shape or form, but</p> <p>19 it's not the type of data set or information that</p> <p>20 I would normally expect to get in this type of</p> <p>21 situation.</p> <p>22 BY MR. CAINE:</p>

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1 Q Do you agree --

2 MR. MARX: Mr. Caine, I believe we've gone

3 seven hours on the record and you've used your

4 full time now.

5 MR. CAINE: Mr. Marx, I'm going to leave

6 the deposition open. I believe there's been an

7 effort to obstruct the deposition, both

8 unfortunately by yourself and Mr. Hofmann's

9 answers or nonresponsive answers to my question.

10 So if your position is the deposition is

11 going to stop right now, I understand your

12 position, but I will not be closing the deposition

13 at this time.

14 MR. MARX: On behalf of Mylan, we

15 respectfully disagree. My objections have been

16 appropriate all day long. You made the election

17 to focus on issues that were not in Mr. Hofmann's

18 report and his opinions, and that is for you to

19 deal with. Otherwise, we disagree that this

20 deposition remains open.

21 I do have some questions for redirect, but

22 with respect to your direct -- your examination of

338

1 Mr. Hofmann, it is closed per Mylan.

2 MR. CAINE: I think we've reflected our

3 disagreement. Go ahead.

4 EXAMINATION

5 BY MR. MARX:

6 Q Mr. Hofmann, I know you have a lot of

7 documents in front of you, just very brief

8 questions. If we could look at Exhibit 2176, it

9 was the January 29, 2021 ATU survey. Let me know

10 when you have that document.

11 Mr. Manning {sic}, do you have Exhibit 7

12 in front of you?

13 **A Hofmann.**

14 Q Mr. Hofmann, yes.

15 Can you turn to Page 92 of this document?

16 **A Okay.**

17 Q Counsel for Regeneron asked you some

18 questions about this page. On the right-hand side

19 of this page, do you see a heading "Mean

20 Frequency"?

21 **A I do.**

22 Q Mr. Hofmann, what is the mean frequency

339

1 for the dosed interval for Eylea that is provided

2 on this page notwithstanding Mylan's objections to

3 the use of this document and also the caveats that

4 you gave on the record?

5 **A [REDACTED].**

6 Q And is [REDACTED] less than eight weeks?

7 **A It is.**

8 Q And this implies, again, subject to your

9 caveats, that [REDACTED] of the interval level

10 for Eylea is less than eight weeks; is that

11 correct?

12 MR. CAINE: Objection. Lacks foundation.

13 BY THE WITNESS:

14 **A That's what this appears based on this**

15 **subject and the caveats that I gave on the**

16 **reliability of this data set.**

17 **BY MR. MARX:**

18 Q Mr. Hofmann, if we could turn to Page 94

19 of this same document, Exhibit 2176.

20 Mr. Hofmann, do you see on Page 94 a

21 similar heading, "Mean Frequency"?

22 **A I do.**

340

1 Q Mr. Hofmann, what is the mean frequency

2 for the dosing interval for Eylea that's provided

3 on this page notwithstanding the caveats that you

4 gave?

5 **A [REDACTED].**

6 Q And this information implies that [REDACTED]

7 [REDACTED] of Eylea doses are given at less than

8 eight weeks; is that correct?

9 MR. CAINE: Objection. Lacks foundation.

10 BY THE WITNESS:

11 **A That's what it appears.**

12 **BY MR. MARX:**

13 Q Mr. Hofmann, if you could turn to the next

14 page, Page 95 of Exhibit 2176.

15 **A Yes.**

16 Q Do you similarly see a "Mean Frequency"

17 heading on the right-hand side of this page?

18 **A I do.**

19 Q What is the mean dosing frequency that's

20 provided on this page for Eylea, again,

21 notwithstanding your caveats and Mylan's

22 objections to the use of this document?

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1 A [REDACTED].

2 Q This implies that [REDACTED] of the

3 doses for Eylea are given at less than eight

4 weeks; is that correct?

5 MR. CAINE: Objection. Foundation.

6 BY THE WITNESS:

7 A Yes.

8 BY MR. MARX:

9 Q Again, just generally, none of the

10 information in Exhibit 2176 is correlated to the

11 specific dosing schedule in the '338 patent; is

12 that correct?

13 MR. MARX: Objection. Lacks foundation.

14 BY THE WITNESS:

15 A The language that I see there doesn't tie

16 it specifically to '338, no.

17 BY MR. MARX:

18 Q Did Mr. Manning opine that information

19 here is directly correlated to the '338 patent

20 dosing schedule?

21 A No.

22 Q Mr. Hofmann, if you could pull up

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1 Exhibit 2140.

2 A Okay.

3 Q This is the November 2013 ATU. And if I

4 could turn to Page 22 of this document, please.

5 A Yes.

6 Q I believe counsel directed you to the data

7 point for Eylea for fixed dosing interval, it was

8 [REDACTED] for every eight weeks.

9 Do you see that on this page?

10 A [REDACTED]. Yes, as a subset of the total

11 dosing. So that's [REDACTED] of [REDACTED].

12 Q And that is approximately 12 percent?

13 A [REDACTED] to [REDACTED], somewhere in between.

14 Q And if you could look at the table that's

15 provided in the bottom of this page, Page 22, with

16 respect to the column for Eylea.

17 Do you see that the mean number of annual

18 doses for PRN is [REDACTED]?

19 A Yes, yes.

20 Q And does that imply that physician's dose,

21 Eylea, at least PRN, less than every eight weeks?

22 MR. CAINE: Objection. Foundation.

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1 BY THE WITNESS:

2 A Yeah, yeah, yeah. So the way to look at

3 that is annual doses would be for as-needed, which

4 is what PRN, I think, means, some Latin acronym

5 for that. But that would get us to dividing

6 12 months for annual dosing is far less than eight

7 weeks.

8 BY MR. MARX:

9 Q And the similar question with respect to

10 the mean annual doses for T and E, do you see that

11 the mean annual doses for T and E provided in this

12 document, again subject to the caveats and Mylan's

13 objections, is [REDACTED] annual doses for Eylea?

14 A That's what it says.

15 Q And that would imply that Eylea is dosed

16 less than every eight weeks?

17 MR. CAINE: Objection. Foundation.

18 BY THE WITNESS:

19 A Yes. So if you, again, think about annual

20 doses as 12 months, the [REDACTED] would be as annual

21 doses would work out to far less than eight weeks.

22 BY MR. MARX:

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1 Q And then, Mr. Hofmann, do you see the last

2 row on this table, overall dosing frequency. This

3 document states Eylea's overall dosing frequency

4 is [REDACTED].

5 Do you see that?

6 A I do see that.

7 Q And that is less than eight weeks?

8 A It is.

9 Q Again, Mr. Hofmann, with respect to

10 Exhibit 2140, none of the data in this document

11 was correlated or tied to the '338 patent by

12 Dr. Manning?

13 A I didn't see anything in that regard, no.

14 Q Mr. Hofmann, if you could pull up

15 Exhibit 2138.

16 This is the February 2013 physician ATU?

17 A Yes.

18 Q Again, subject to Mylan's objections and

19 the caveats that you gave, if you could turn to

20 Page 15 of this document.

21 A Okay.

22 Q And I believe you testified with respect

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1 to this page, at least, that the data here
 2 indicates that less than ██████ of individuals
 3 who are dosed with Eylea are at every eight weeks
 4 or more.
 5 Do you recall that testimony?
 6 **A I do.**
 7 Q And there's nothing on this page or no
 8 analysis that Dr. Manning provided that tied any
 9 of the data on this document to the '338 claimed;
 10 is that correct?
 11 **A Yes. Again, this is similar to what we**
 12 **looked at before where the ██████ at eight**
 13 **weeks is ██████ of ██████, so it's a**
 14 **fraction of total Eylea sales.**
 15 Q You can set that document aside.
 16 Do you recall at the very end Mr. Caine
 17 asked you about TV spots for Eylea?
 18 **A I do.**
 19 Q I'd like to play for the record a TV spot
 20 for Eylea.
 21 (Video played.)
 22 "Your eyes are a beautiful pair, and

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1 they've seen a lot together from the biggest
 2 events to countless new moments. Over time,
 3 diabetic macular edema, also known as DME, entered
 4 the picture. It brought some unwelcome symptoms
 5 like black spots, blurriness or wavy lines. But
 6 your eyes can fight back because there's more they
 7 want to see, and they have Eylea on their side.
 8 On average, people with DME gain ten more letters
 9 on the eye chart after one year on Eylea and still
 10 had these improvements a year later when staying
 11 on treatment.
 12 "Do not use Eylea if you have an eye
 13 infection, eye pain or redness or known allergies
 14 to any ingredients in Eylea. Injection in the eye
 15 with Eylea can cause infection and separation of
 16 the retina. Eylea may cause an increase in eye
 17 pressure. Potential risk of fatal heart attack or
 18 stroke related to blood clots may occur. Serious
 19 side effects are rare. Most common side effects
 20 are eye pain, redness, cataract, decreased optimal
 21 field of vision and increased eye pressure and
 22 inner-eye gel detachment.

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1 "Fight for your eyes and ask your retina
 2 specialist if Eylea is right for you."
 3 BY MR. MARX:
 4 Q Mr. Hofmann, did Regeneron produce this
 5 advertisement in this matter?
 6 **A I don't recall seeing that, no.**
 7 Q Mr. Hofmann, having listened to this ad,
 8 did you hear anything in this advertisement about
 9 a dosing schedule or eight weeks dosing?
 10 **A No. It seemed to be focused on efficacy**
 11 **and safety.**
 12 MR. MARX: I have no further questions.
 13 MR. CAINE: I have a couple of follow-ups.
 14 MR. MARX: I'm sorry. Your seven hours on
 15 the record is done.
 16 MR. CAINE: I get to recross after your
 17 redirect.
 18 MR. MARX: No. You have to reserve time.
 19 You did not reserve time. You're done.
 20 MR. CAINE: I get to follow up on your
 21 examination.
 22 MR. MARX: No. You had to reserve time to

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1 do so. You did not. Your seven hours are done.
 2 MR. CAINE: I m going to ask the question,
 3 and you can decide what you d like to do.
 4 MR. MARX: Okay.
 5 **FURTHER EXAMINATION**
 6 BY MR. CAINE:
 7 Q Mr. Hofmann, by virtue of the fact that
 8 Mr. Marx played that advertisement, I think we can
 9 both agree that the advertising is publicly
 10 available, right?
 11 **A Apparently so, yes.**
 12 MR. CAINE: Thank you.
 13 THE VIDEOGRAPHER: Please stand by.
 14 This marks the end of the deposition of
 15 Ivan Hofmann. We are going off the record at
 16 6:04 p.m.
 17 (Deposition concluded at 6:04 p.m. CST.)
 18
 19
 20
 21
 22

<p style="text-align: right;">349</p> <p>CERTIFICATE OF SHORTHAND REPORTER NOTARY PUBLIC</p> <p>2 I, Theresa A Vorkapic, Certified</p> <p>3 Reporter and Notary Public within and for the</p> <p>4 State of Illinois do hereby certify:</p> <p>5 That IVAN HOFMANN, the witness whose</p> <p>6 deposition is hereinbefore set forth,</p> <p>7 Was duly sworn by me before the</p> <p>8 commencement of such deposition and that such</p> <p>9 deposition was taken before me and is a true</p> <p>0 record of the testimony given by such witness</p> <p>I further certify that the adverse</p> <p>2 party, Regeneron, was represented by counsel at</p> <p>3 the deposition</p> <p>4 I further certify that the deposition of</p> <p>5 IVAN HOFMANN, occurred at the offices of RMMS, LLP</p> <p>6 on Thursday, June 23, 2022, commencing at 9:06</p> <p>7 a m to 6:04 p m CST</p> <p>8 I further certify the inspection,</p> <p>9 reading and signing of said deposition was</p> <p>20 waived on the record by agreement of all parties</p> <p>2 I further certify that I am not related</p> <p>22 to any of the parties to this action by blood</p>	
<p style="text-align: right;">350</p> <p>1 or marriage, I am not employed by or an attorney</p> <p>2 to any of the parties to this action, and that I</p> <p>3 am in no way interested, financially or otherwise,</p> <p>4 in the outcome of this matter.</p> <p>5</p> <p>6 </p> <p>7</p> <p>8 IN WITNESS WHEREOF, I have hereunto set</p> <p>9 my hand this 24th day of June, 2022.</p> <p>10</p> <p>11 Theresa A. Vorkapic</p> <p>12 My commission expires 11/6/23.</p> <p>13 NOTARY PUBLIC IN AND FOR THE</p> <p>14 COUNTY OF KANE, ILLINOIS</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>	

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