

<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 <b>A I don't know if you're reading from</b>                  9 <b>Paragraph 58, but I can't find or I certainly</b>                  10 <b>didn't follow what you were saying relative to any</b>                  11 <b>particular language in Paragraph 58.</b>                  12 <b>BY MR. CAINE:</b>                  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 <b>A I think you're paraphrasing but I think</b>                  22 <b>paraphrasing in a way that I can live with.</b></p>	<p style="text-align: right;">99</p> <p>1 <b>know how to interpret it, and I don't know -- you</b>                  2 <b>know, I think these are far better questions for</b>                  3 <b>Drs. Gerritsen and Albini if these are things they</b>                  4 <b>reviewed. I don't recall seeing references to</b>                  5 <b>them one way or the other in their declarations,</b>                  6 <b>but I don't know that I can respond to your</b>                  7 <b>question as asked.</b>                  8 <b>BY MR. CAINE:</b>                  9 Q Did you review Dr. Do's declaration?                  10 <b>A I did.</b>                  11 Q Did you review her discussion of                  12 Exhibit 1018?                  13 <b>A I don't remember.</b>                  14 Q Did you ask to see Exhibit 1018 after                  15 reviewing Dr. Do's declaration?                  16 <b>A I don't remember one way or the other.</b>                  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 <b>BY MR. CAINE:</b>                  2 Q In this exhibit that we're looking at --                  3 <b>A Among other things.</b>                  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 <b>A I don't feel comfortable commenting on</b>                  12 <b>Exhibit 1018. I haven't reviewed it. I'm not a</b>                  13 <b>scientist. I'm not a POSA. I've relied in</b>                  14 <b>developing my opinions in Paragraph 58 as well as</b>                  15 <b>the entirety of my report and the relevant</b>                  16 <b>sections contained therein.</b>                  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 <b>I haven't seen this document. I don't</b></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 <b>A I just -- I don't have the scientific</b>                  5 <b>expertise to answer that question.</b>                  6 <b>BY MR. CAINE:</b>                  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 <b>A No. What I'm saying is I had sufficient</b>                  14 <b>basis to form all the opinions in my report, and</b>                  15 <b>as is normally done by economists who are dealing</b>                  16 <b>with complex technical issues is I relied on</b>                  17 <b>technical experts.</b>                  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 <b>BY MR. CAINE:</b></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 <b>BY THE WITNESS:</b></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 <b>BY MR. CAINE:</b></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 <b>BY THE WITNESS:</b></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 <b>BY THE WITNESS:</b></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 <b>BY MR. CAINE:</b></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 <b>BY MR. CAINE:</b></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>



205	<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 <b>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.</b></p>	207	<p>1 Exhibit -- just so I have it right -- 2086,                  2 correct?                  3 MR. MARX: Objection. Form.                  4 BY THE WITNESS:                  5 <b>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</b></p>
206	<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 <b>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</b></p>	208	<p>1 <b>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</b></p>

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1 they're in, and I'm providing my perspective  
 2 through an economic lens on the lane that I'm in.  
 3 Q You didn't ask Dr. Albini or Dr. Gerritsen  
 4 to explain to you the difference between efficacy  
 5 and duration; is that right?  
 6 MR. MARX: Objection. Asked and answered.  
 7 BY THE WITNESS:  
 8 A I feel like we've talked about this -- I  
 9 don't know how many dozens of times, but Manning  
 10 did nothing. I'm rebutting --  
 11 BY MR. CAINE:  
 12 Q You didn't answer my question.  
 13 Did you ask Dr. Albini or Dr. Gerritsen to  
 14 explain to you the difference between efficacy and  
 15 duration?  
 16 MR. MARX: Objection. And I ask counsel  
 17 not to interrupt Mr. Hofmann while he's answering  
 18 questions.  
 19 BY THE WITNESS:  
 20 A I'm a rebuttal witness to Dr. Manning. He  
 21 did nothing. So if anything, I did more by doing  
 22 what I did and explaining what I found by looking

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1 at their declarations and looking at the documents  
 2 and information that was available to me in the  
 3 record.  
 4 You already know the answer that I have  
 5 had no live discussions with Dr. Albini or  
 6 Dr. Gerritsen, so no, I didn't have discussions  
 7 with them, but I had more than adequate  
 8 information and above and beyond addressing of  
 9 this issue compared to Dr. Manning, who did  
 10 nothing.  
 11 MR. CAINE: Can we see Exhibit 2259,  
 12 please.  
 13 BY MR. CAINE:  
 14 Q I'm going to hand you what's been marked  
 15 as Exhibit 2259.  
 16 MR. MARX: No comment. The labels  
 17 are consistent with Exhibit 2259.  
 18 BY MR. CAINE:  
 19 Q Mr. Hofmann, do you have Exhibit 2259 in  
 20 front of you? Is that a yes, no? Do you have it  
 21 in front of you?  
 22 A So I can answer that question, but this

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1 appears to be a document I haven't seen before  
 2 from 2009. It's a hundred-page document that I'm  
 3 unfamiliar with. So are you going to -- yes, I  
 4 have something labeled 2259 in front of me, but I  
 5 have not reviewed any of the hundred pages.  
 6 Q You understand that Exhibit 2259 was  
 7 submitted in this proceeding by Regeneron? I'll  
 8 represent to you that it was.  
 9 A I assume so based on the fact that it's  
 10 got an IPR Bates or whatever the exhibit  
 11 referencing scheme is.  
 12 Q You'd recognize Exhibit 2259 as one that  
 13 Dr. Manning cited in his declaration?  
 14 A I don't remember if he did one way or the  
 15 other.  
 16 Q You would agree with me that you've had an  
 17 opportunity to review Exhibit 2259 prior to the  
 18 preparation of your declaration?  
 19 A I mean, I guess show me where he  
 20 references it in his report.  
 21 Q I'll represent to you that it's referenced  
 22 in his report.

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1 A Okay. But maybe show me because I  
 2 don't -- you know, a 2009 study for American  
 3 Society of Retina Specialists -- I don't know --  
 4 that was long before the launch of Eylea, and I  
 5 just -- I don't recall this document. Maybe I  
 6 looked at it; maybe I didn't. But I'm unfamiliar  
 7 with it as I sit here right now given that it's a  
 8 hundred pages and there's a whole bunch of stuff  
 9 here.  
 10 Q I'll represent to you that it was  
 11 referenced in Paragraph 89 of Dr. Manning's  
 12 report.  
 13 Do you agree?  
 14 A Yeah. I mean, I see the reference. I  
 15 just I don't -- I don't recall --  
 16 Q You are familiar --  
 17 A -- this as I sit here right now.  
 18 Q You are familiar with ASRS PAT surveys?  
 19 MR. MARX: Excuse me one second,  
 20 Mr. Hofmann. I'm just going to note for the  
 21 record that this section of the Manning report is  
 22 under heading "Eylea's Patented Dosing Regimen



<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 <b>A I don't recall as I sit here right now one                  10 way or the other.</b>                  11 Q Would you turn for me to Page 93 of                  12 Exhibit 2259.                  13 <b>A So do you mean Page 93 or Slide 93?</b>                  14 <b>Because they seem to be one off.</b>                  15 Q Page 93, which is Slide 92.                  16 <b>A Okay.</b>                  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 <b>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.</b>                  18 <b>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.</b>                  22 <b>BY MR. CAINE:</b></p>
<p style="text-align: right;">2 4</p> <p>1 <b>A I mean, the footer says 2009. So that's</b>                  2 <b>all I can say, is that's what it says in the</b>                  3 <b>footer.</b>                  4 <b>BY MR. CAINE:</b>                  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 <b>A I mean, you can read the words that are on</b>                  12 <b>here. I don't remember seeing this, and I don't</b>                  13 <b>recall anywhere in my declaration I address unmet</b>                  14 <b>need. That's usually something that's addressed</b>                  15 <b>by clinicians, if there is an unmet need,</b>                  16 <b>long-felt unmet need, but I don't – if you read</b>                  17 <b>words, I can tell you whether you've read them as</b>                  18 <b>they appear.</b>                  19 <b>BY MR. CAINE:</b>                  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

224

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 **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 **subject to the limitations on what one**, 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 subject to the limitations on what one**.  
 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 **subject to the limitations on what one**, 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 subject to the limitations on what one** 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 **subject to the limitations on what one**, 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 **subject to the limitations on what one** 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 subject to the limitations on what one**.  
 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 **subject to the limitations on what one** 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 subject to the limitations on what one**. 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

255

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,

256

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.

257

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.

260

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

262

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

263

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?

264

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

265

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 <b>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.</b>                  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 <b>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.</b>                  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 <b>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.</b>                  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 <b>A Among other --</b>                  10 MR. MARX: Lack of foundation.                  11 BY THE WITNESS:                  12 <b>A Among other uses, that's what it appears.</b>                  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>



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1 so.  
 2 This is another marketing document, and  
 3 Mylan requested production of all highly marketing  
 4 materials and, in particular, the materials  
 5 considered by Dr. Manning. Regeneron refused to  
 6 do so. Mylan objects to Regeneron's reliance on  
 7 this exhibit, Exhibit 2137.  
 8 BY MR. CAINE:  
 9 Q Would you turn, Mr. Hofmann, to Page 29,  
 10 please. It's the second-to-last page of the  
 11 exhibit.  
 12 A It's the smallest font I've ever seen.  
 13 Q The page number is, yes.  
 14 A Yes. Okay.  
 15 Q Do you see this piece of marketing  
 16 material in Exhibit 2137?  
 17 A I do.  
 18 Q You don't cite to Exhibit 2137 in your  
 19 declaration, do you?  
 20 A I don't see it listed. I know I looked at  
 21 this. Maybe it was in review of the Manning  
 22 declaration.

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1 Q Do you see that this is advertising Eylea  
 2 for the treatment of wet AMD?  
 3 A I mean --  
 4 MR. MARX: Objection. Lack of foundation.  
 5 BY THE WITNESS:  
 6 A You've taken me all the way to Page 29,  
 7 and there's all kinds of other stuff in the  
 8 28 pages that precede it. This appears to be an  
 9 internal document because it's labeled "Precall,"  
 10 for whatever that means. It includes the label,  
 11 which includes certainly wet AMD as well as all  
 12 the other label indications.  
 13 BY MR. CAINE:  
 14 Q I'm focusing for the moment on  
 15 Exhibit 2137, Page 29.  
 16 Do you see that it has the phrase "time  
 17 between treatments" under Eylea?  
 18 MR. MARX: Objection. Lack of foundation.  
 19 BY THE WITNESS:  
 20 A I think those words appear there. There  
 21 is also the molecule itself and the fact that it's  
 22 an injectable and how it is administered as an

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1 injectable.  
 2 BY MR. CAINE:  
 3 Q You see the two graphical representations,  
 4 this time for October and December?  
 5 MR. MARX: Objection. Lack of foundation  
 6 to the extent it mischaracterizes the document.  
 7 BY THE WITNESS:  
 8 A Well, there's a lot of graphical  
 9 representations here. I do see the October and  
 10 December. There's also what I assume is a grandma  
 11 with a granddaughter and a lighthouse and what  
 12 looks to be a very nice beach.  
 13 BY MR. CAINE:  
 14 Q And you agree with me that there's a  
 15 two-month period between October and December?  
 16 MR. MARX: Objection. Lack of foundation,  
 17 mischaracterizes the document, asked and answered.  
 18 BY THE WITNESS:  
 19 A It's the same as the last time, where I  
 20 don't know -- these are just like graphical  
 21 representations of a portion of the months on the  
 22 calendar, and I don't know how you get to just two

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1 months because you can span as much as three  
 2 months or as little as, you know, 31 or 32 days in  
 3 this stretch.  
 4 BY MR. CAINE:  
 5 Q When you couple that, the graphical  
 6 calendar representations of October and  
 7 December with the recommended dosing which  
 8 includes 2 milligrams every eight weeks, does that  
 9 suggest to you that what Eylea is promoting in  
 10 this, on this page of Exhibit 2137, is the  
 11 eight-week or two-month treatment period for Eylea  
 12 when used to treat wet AMD?  
 13 MR. MARX: Objection. Lack of foundation,  
 14 outside the scope, speculative.  
 15 BY THE WITNESS:  
 16 A I think that's a leap in terms of the  
 17 inconsistency that that would be versus what we  
 18 see in some of the data sets that we looked at  
 19 earlier that suggests that the majority of uses  
 20 are, in fact, not on an eight-week regimen, as I  
 21 explained earlier and as I explain in my report.  
 22 BY MR. CAINE:

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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 <b>BY MR. CAINE:</b>                  7 Q I'm asking you about Page 29 of                  8 Exhibit 2137.                  9 MR. MARX: Same objection.                  10 <b>BY THE WITNESS:</b>                  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 <b>BY MR. CAINE:</b>                  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 <b>BY THE WITNESS:</b>                  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 <b>BY MR. CAINE:</b>                  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 <b>BY MR. CAINE:</b>                  11 Q Can you answer that question?                  12 MR. MARX: Objection. Lack of foundation.                  13 <b>BY THE WITNESS:</b>                  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 <b>BY MR. CAINE:</b>                  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 <b>BY THE WITNESS:</b>                  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>

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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.

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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

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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.

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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



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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**



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**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:

305	<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 <b>A I'm sorry. Which one?</b>                  9 <b>BY MR. CAINE:</b>                  10 Q 2210.                  11 <b>A Okay.</b>                  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>	307	<p>1 for patients?                  2 MR. MARX: Objection. Lack of foundation.                  3 BY THE WITNESS:                  4 <b>A I think the way – the way I would frame</b>                  5 <b>it is if you don't have a Medicare Advantage plan,</b>                  6 <b>it's an 80/20 split with Uncle Sam.</b>                  7 <b>BY MR. CAINE:</b>                  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 <b>A Yes. But there are varying degrees of how</b>                  14 <b>much that sharing covers that 20 percent. And</b>                  15 <b>there is a whole bunch of complications with</b>                  16 <b>Medicare doughnut hole – I don't know – all the</b>                  17 <b>different things that exist in the way that the</b>                  18 <b>Medicare system, you know, does and doesn't</b>                  19 <b>reimburse patients.</b>                  20 <b>BY MR. CAINE:</b>                  21 Q Are you aware that Medicare beneficiaries                  22 also can enroll in supplemental coverage?</p>
306	<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 <b>A I do see what I'm pointing you to. I'm</b>                  8 <b>just reviewing it. I mean, I'll just point out</b>                  9 <b>that some of these appear to be -- like, for</b>                  10 <b>example, the graph that appears above is truncated</b>                  11 <b>at the bottom. I don't know if there's anything</b>                  12 <b>of note that's missing. There's also, like,</b>                  13 <b>graphical links you can hit on that aren't</b>                  14 <b>reflected here.</b>                  15 <b>I'm not -- I mean, I guess maybe so that</b>                  16 <b>we can move along, I don't disagree that many,</b>                  17 <b>many people do have Medicare Advantage programs.</b>                  18 <b>I don't know that I can sanction 42 percent as</b>                  19 <b>being an exact figure, but --</b>                  20 Q Fair enough.                  21 Now, can you agree or do you agree that                  22 Medicare Advantage plans limit out-of-pocket costs</p>	308	<p>1 <b>A Sure.</b>                  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 <b>A I mean, again, I'm just speaking in very</b>                  10 <b>broad strokes based on my knowledge of</b>                  11 <b>pharmaceutical economics that you can agree to pay</b>                  12 <b>a monthly supplemental amount to essentially</b>                  13 <b>defray some of that 20 percent.</b>                  14 <b>BY MR. CAINE:</b>                  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 <b>A I don't remember whether that's something</b>                  21 <b>I came across specifically one way or the other.</b>                  22 <b>My focus was on the DOJ complaint against</b></p>



<p style="text-align: right;">309</p> <p>1 <b>Regeneron with respect to their involvement in the</b>  2 <b>fund.</b>  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 <b>A I think there is some language to that</b>  7 <b>regard, but my focus -- like I said, since I'm</b>  8 <b>dealing with the Eylea product, that was my focus.</b>  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 <b>A I don't have that in front of me.</b>  15 <b>BY MR. CAINE:</b>  16 Q Okay. Well, why don't we give you a copy  17 of Exhibit 1154.  18 <b>A It's a thick double-sided document, so can</b>  19 <b>you point me to where you want me to focus?</b>  20 Q Yes, Page 10, Paragraph 33.  21 Do you see -- are you at that paragraph?  22 <b>A I am.</b></p>	<p style="text-align: right;">3</p> <p>1 MR. MARX: Objection. Form.  2 BY THE WITNESS:  3 <b>A I'm not -- I'm not saying that the DOJ</b>  4 <b>doesn't view Eylea alone or Regeneron alone as a</b>  5 <b>bad actor here. Clearly they also, if you read</b>  6 <b>this complaint, have there's numerous allegations</b>  7 <b>against both Regeneron and Genentech, but yeah, I</b>  8 <b>mean, you read that as it appears.</b>  9 <b>BY MR. CAINE:</b>  10 Q Are you aware that the Chronic Disease  11 Fund is a non-profit organization?  12 <b>A I don't -- I don't know a hundred percent</b>  13 <b>as I sit here right now. What I know is that the</b>  14 <b>United States, you know, DOJ, HHS, has brought</b>  15 <b>this claim against these entities. And even if</b>  16 <b>it's a not-for-profit, sometimes you can set up</b>  17 <b>organizations that appear as a not-for-profit, but</b>  18 <b>there's still a benefit that's inured to the</b>  19 <b>entity.</b>  20 <b>And, again, I'm not weighing in on the</b>  21 <b>exact claims that are here. I'm just pointing out</b>  22 <b>that as I was doing research, I found the DOJ</b></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 <b>A You've read those words as they appear.</b>  8 <b>BY MR. CAINE:</b>  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 <b>A You've read those words as they appear</b>  17 <b>there.</b>  18 <b>BY MR. CAINE:</b>  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 <b>claim.</b>  2 <b>And so you can set up a not-for-profit,</b>  3 <b>but if that not-for-profit is essentially</b>  4 <b>channeling or funding money to you to the</b>  5 <b>detriment of the US government, you can run into</b>  6 <b>some trouble.</b>  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 <b>A I don't -- I don't know about that one way</b>  15 <b>or the other as I sit here right now. I'd have to</b>  16 <b>go back through the complaints and the information</b>  17 <b>and see if that's consistent with things. But I</b>  18 <b>was working off of the -- you know, what the</b>  19 <b>United States government calls factual</b>  20 <b>allegations, allegations specifically with respect</b>  21 <b>to Eylea with my particular focus, and then</b>  22 <b>certainly reviewed the discussion regarding the</b></p>

<p style="text-align: right;">3 3</p> <p><b>1 other parties that are involved in the DOJ</b></p> <p><b>2 complaint.</b></p> <p>3 Q Are you aware that the time period at</p> <p>4 issue in this complaint, Exhibit 1154, is 2013 and</p> <p>5 the first part of 2014?</p> <p><b>6 A Can you point me to --</b></p> <p>7 Q Page 20, Paragraph 61. And the</p> <p>8 surrounding slide above it and discussion below</p> <p>9 it.</p> <p><b>10 A I mean, it appears that at least what the</b></p> <p><b>11 DOJ brought action on is from 2013 and 2014. It</b></p> <p><b>12 doesn't mean they can't expand it or maybe it's</b></p> <p><b>13 been dismantled. I don't know.</b></p> <p>14 Q You're not aware of any allegations</p> <p>15 pertaining to 2012, 2015, 2016, 2017, 2018, 2019,</p> <p>16 2020 or 2021, are you?</p> <p>17 MR. MARX: Objection. Form.</p> <p>18 BY THE WITNESS:</p> <p><b>19 A As I sit here right now, this is -- this</b></p> <p><b>20 is the document that I found that Manning, you</b></p> <p><b>21 know, didn't mention at all in his declaration and</b></p> <p><b>22 pertain to the product at issue. Like I said, the</b></p>	<p style="text-align: right;">3 5</p> <p><b>1 are.</b></p> <p>2 Q Page 20, Paragraph 63, just where we were.</p> <p>3 Page 20, Paragraph 63. Are you there?</p> <p><b>4 A Okay, yep.</b></p> <p>5 Q You agree that the DOJ alleges that in</p> <p>6 2013, Regeneron contributed \$35 million to the</p> <p>7 Chronic Disease Fund, right?</p> <p>8 MR. MARX: Objection. Form.</p> <p>9 BY THE WITNESS:</p> <p><b>10 A In 2013, yes, that appears to be so.</b></p> <p><b>11 BY MR. CAINE:</b></p> <p>12 Q And you are -- you agree that above it, in</p> <p>13 the slide that we see from the DOJ complaint, the</p> <p>14 potential sales from 2013 donations were</p> <p>15 \$198.5 million?</p> <p>16 MR. MARX: Objection. Form, foundation.</p> <p>17 BY MR. CAINE:</p> <p>18 Q That's the allegation, right?</p> <p><b>19 A That's what appears in that slide.</b></p> <p>20 Q Now, we can look at -- if you'd like to</p> <p>21 pull out Dr. Manning's declaration, which is</p> <p>22 Exhibit 2052 in your stack, you can turn to</p>
<p style="text-align: right;">3 4</p> <p><b>1 way that the DOJ works is they focus on putting</b></p> <p><b>2 the evidence in for their case for certain</b></p> <p><b>3 periods, but they can always expand it. But I</b></p> <p><b>4 don't disagree -- I don't have any amended</b></p> <p><b>5 complaints or information that supplements this.</b></p> <p><b>6 BY MR. CAINE:</b></p> <p>7 Q You don't take the allegations in this</p> <p>8 complaint as proven facts, do you?</p> <p>9 A I think we all know or at least the</p> <p>10 lawyers in the room know that the allegations are</p> <p>11 not proven facts, but what we do know is that DOJ,</p> <p>12 you know, when they're bringing an action against</p> <p>13 a party, in this case it's a pretty significant</p> <p>14 number of exhibits that accompany the complaint.</p> <p>15 Everybody gets their day in court. I will</p> <p>16 grant you that. I'm not taking it as a proven</p> <p>17 fact, but I'm just pointing out the DOJ has made</p> <p>18 these allegations with accompanying exhibits.</p> <p>19 Q The complaint that you discuss at</p> <p>20 Paragraph 63, Page 20, says that in 2013,</p> <p>21 Regeneron --</p> <p><b>22 A Hold on. Let me catch up to where you</b></p>	<p style="text-align: right;">3 6</p> <p>1 Attachment D-1. Attachment D-1 is on Page 171.</p> <p>2 Eylea's net sales for 2013 were over</p> <p>3 \$1.4 billion, correct?</p> <p>4 MR. MARX: Objection. Lack of foundation.</p> <p>5 BY THE WITNESS:</p> <p><b>6 A Going off the net sales figures from D-1,</b></p> <p><b>7 that is the number. Having said that, the point</b></p> <p><b>8 of this is the taint that comes with the</b></p> <p><b>9 potential -- what the allegations are that appear</b></p> <p><b>10 here as to the CDF and the -- you know, that can</b></p> <p><b>11 have broader implications than the exact amounts</b></p> <p><b>12 that are at issue in the DOJ complaint because,</b></p> <p><b>13 you know, these physicians are prescribing to lots</b></p> <p><b>14 of people.</b></p> <p><b>15 BY MR. CAINE:</b></p> <p>16 Q There's no allegation in Exhibit 1154 that</p> <p>17 Regeneron's alleged donations of \$35 million to</p> <p>18 the Chronic Disease Fund impacted over</p> <p>19 \$1.21 billion in sales in 2013, is there?</p> <p>20 MR. MARX: Objection to the extent it</p> <p>21 mischaracterizes the document and seeks a legal</p> <p>22 conclusion, speculative.</p>



3 7

1 BY THE WITNESS:  
 2 A Like I said, I mean, I'm not in the weeds  
 3 with the DOJ to know what all they have decided to  
 4 do with respect to what they perceive as bad  
 5 actors as reflected in the complaint. Sometimes  
 6 they'll just prove what they know they have solid  
 7 evidence on, but there are broader implications.  
 8 I'm just saying that there's a taint.  
 9 There is a negative that affects the objectivity  
 10 of the evidence with respect to the marketplace  
 11 performance. I'm not saying that every dime of  
 12 Eylea's sales was the result of this alleged  
 13 kickback scheme, if that's where you're going.  
 14 I'm saying that this is not immaterial,  
 15 hundreds of millions of dollars at least that DOJ  
 16 is pressing for and complaining about, and that's  
 17 the extent of it.  
 18 BY MR. CAINE:  
 19 Q You don't identify even a single physician  
 20 who identified co-pay assistance as the reason --  
 21 as their reason for prescribing Eylea, correct?  
 22 MR. MARX: Objection. Outside the scope,

3 8

1 mischaracterizes witness testimony.  
 2 BY THE WITNESS:  
 3 A I mean, I think there were some slides  
 4 that we looked at throughout the day and that I  
 5 looked at in my report that talk about price and  
 6 co-pay, but I mean with respect to this specific  
 7 complaint, no, it's not like I was going about the  
 8 job of the DOJ to identify specific physicians  
 9 that would fall under this or how that fits into  
 10 their case or theory of the case. I was just  
 11 relying on what the DOJ put in their complaint  
 12 against Regeneron.  
 13 BY MR. CAINE:  
 14 Q You didn't read anything in Dr. Albin's  
 15 declaration or deposition about prescribing Eylea  
 16 because of the existence of co-pay assistance, did  
 17 you?  
 18 MR. MARX: Objection. Lack of foundation,  
 19 outside the scope. And also note for the record  
 20 this also pertains to Regeneron's marketing  
 21 efforts, which despite Mylan's request, Regeneron  
 22 has refused to produce.

3 9

1 BY THE WITNESS:  
 2 A I don't remember if Dr. Albin addressed  
 3 it one way or the other.  
 4 BY MR. CAINE:  
 5 Q Do you remember that Dr. Albin testified  
 6 that he prescribed Eylea because it was best in  
 7 class?  
 8 A I don't have his testimony in front of me.  
 9 I think he testified about a lot of things, and I  
 10 certainly reviewed his report. I think I  
 11 understand he was only deposed yesterday.  
 12 Q How about at his first deposition?  
 13 A Oh. I haven't looked at that in a while.  
 14 I just don't -- I don't remember.  
 15 Q Now, if you consider the sales of Eylea  
 16 and its market share outside of 2013 and 2014,  
 17 still it would be considered to have significant  
 18 marketplace performance, right?  
 19 MR. MARX: Objection. Form, to the extent  
 20 it seeks a legal conclusion, and speculative to  
 21 the extent that Mylan was denied the opportunity  
 22 to review Regeneron's materials as requested.

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1 BY THE WITNESS:  
 2 A I think we started the day to some extent  
 3 on this topic. I think that the numbers are what  
 4 they are. They've had a good run, but it's  
 5 because of the existence of the blocking patents  
 6 that really has nothing to do with the '338  
 7 patent.  
 8 It prevented other -- anyone other than  
 9 Regeneron as a gating issue from pursuing the  
 10 alleged invention of the '338 patent, and as I  
 11 explain in detail in my declaration, there are so  
 12 many failures in the Manning declaration and then  
 13 admissions in his deposition that simply there --  
 14 whether or not there have been the significant  
 15 sales, Manning has done a very poor job of  
 16 establishing nexus to the '338 patent for all the  
 17 reasons that I've explained in my declaration and  
 18 today.  
 19 BY MR. CAINE:  
 20 Q Eylea's marketplace performance outside of  
 21 2013 and 2014 includes \$30 billion in net sales,  
 22 correct?

32	<p>1 MR. MARX: Objection. Lack of foundation.</p> <p>2 BY THE WITNESS:</p> <p>3 A Are you talking gross sales or net sales?</p> <p>4 BY MR. CAINE:</p> <p>5 Q Net sales.</p> <p>6 A I mean, it's somewhere in that ballpark,</p> <p>7 recognizing that they were able to do so on the</p> <p>8 heels of the patent thicket that they had</p> <p>9 established and the other extrinsic factors that I</p> <p>10 explain in my report.</p> <p>11 Q Are you aware that physicians don't know</p> <p>12 whether a patient will receive co-pay assistance</p> <p>13 when they prescribe Eylea or Lucentis for that</p> <p>14 matter?</p> <p>15 MR. MARX: Objection. Form, lack of</p> <p>16 foundation, hypothetical and speculative.</p> <p>17 BY THE WITNESS:</p> <p>18 A I mean, I'm not a clinician. My</p> <p>19 experience has been, though, that maybe sometimes</p> <p>20 that's true, but then if they get a sticker shock</p> <p>21 on how much they have to come up with, that can</p> <p>22 change a course of treatment.</p>	323	<p>1 BY THE WITNESS:</p> <p>2 A That's a better question – yeah, a better</p> <p>3 question for a clinician. All I was saying in my</p> <p>4 last answer, and, again, not specific to Eylea, is</p> <p>5 that there are situations where a patient gets</p> <p>6 prescribed something, finds out what their share</p> <p>7 of the cost is, and then they get counseled from</p> <p>8 their physician what are my options to hopefully</p> <p>9 defray the costs.</p> <p>10 BY MR. CAINE:</p> <p>11 Q Are you aware of any allegations in the</p> <p>12 complaints that you cite that physicians were</p> <p>13 influenced in their prescribing decisions by any</p> <p>14 Regeneron co-pay assistance donation?</p> <p>15 MR. MARX: Objection to the extent it</p> <p>16 seeks a legal conclusion.</p> <p>17 BY THE WITNESS:</p> <p>18 A I'm not making any affirmative statement</p> <p>19 in that regard. I'm simply pointing to the</p> <p>20 existence of the complaint and the allegations</p> <p>21 being made by DOJ.</p> <p>22 BY MR. CAINE:</p>
322	<p>1 And I'm not speaking about Eylea</p> <p>2 specifically. I'm just talking about in general,</p> <p>3 that's where co-pay assistance comes in from an</p> <p>4 economic perspective, is to insulate patients from</p> <p>5 the cost of products, particularly patients that</p> <p>6 either can't afford or don't want the burden of</p> <p>7 the cost associated with the medications.</p> <p>8 So sometimes they explore other treatments</p> <p>9 or that's where sometimes physicians – and,</p> <p>10 again, I'm not speaking about Eylea specifically.</p> <p>11 I'm just saying there are techniques and schemes</p> <p>12 that the pharma companies will do to help assist</p> <p>13 patients in being shielded from the true cost of</p> <p>14 the medication.</p> <p>15 BY MR. CAINE:</p> <p>16 Q Are you aware that physicians don't know</p> <p>17 whether a patient will qualify for co-pay</p> <p>18 assistance when the physician prescribes</p> <p>19 treatment?</p> <p>20 MR. MARX: Objection. Lack of foundation,</p> <p>21 speculative and incomplete hypothetical, outside</p> <p>22 the scope.</p>	324	<p>1 Q You don't cite or identify any facts or</p> <p>2 even allegations that physicians had knowledge of</p> <p>3 donations made by Regeneron, correct?</p> <p>4 MR. MARX: Objection. To the extent it</p> <p>5 mischaracterizes the document, seeks a legal</p> <p>6 conclusion.</p> <p>7 BY THE WITNESS:</p> <p>8 A I think the better way to look at it is</p> <p>9 the allegations by the DOJ clearly show the belief</p> <p>10 by DOJ that Regeneron did see huge ROI and did see</p> <p>11 influence with respect to prescribing decisions</p> <p>12 because that's where you get the ROI. Again, I</p> <p>13 haven't, you know, dug into the details beyond</p> <p>14 what is in the plain language of the complaint</p> <p>15 which I cite to in my report.</p> <p>16 BY MR. CAINE:</p> <p>17 Q You don't cite any facts in your</p> <p>18 declaration or even any allegations that</p> <p>19 physicians had knowledge of donations made by</p> <p>20 Regeneron, correct?</p> <p>21 MR. MARX: Objection. Mischaracterizes</p> <p>22 the witness testimony.</p>



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1 BY THE WITNESS:  
 2 A I don't know that I cite to physician  
 3 knowledge or testimony one way or the other, but  
 4 that's the whole point of the DOJ's allegations.  
 5 If you read the complaint, essentially they're  
 6 saying Regeneron and Genentech used tens of  
 7 millions of dollars to influence physician  
 8 behavior which cost the US government a bunch of  
 9 money. And so whether there is, I guess,  
 10 knowledge by the physician, I don't understand how  
 11 that's, I guess, something that needs to even be  
 12 shown.  
 13 The point as I read the complaint is that  
 14 they were doing this because they saw enhancements  
 15 in prescribing behavior, which is, I guess, an  
 16 indirect way of pointing to influencing  
 17 prescribing behavior based on the observation  
 18 existence of the fund and the contributions that  
 19 were made to it, whether or not they had  
 20 acknowledgment or knowledge or awareness of the  
 21 payments being made to the fund.  
 22 Q I was talking not about Regeneron's or

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1 Genentech's knowledge. I was talking about  
 2 physician's knowledge.  
 3 A So was I.  
 4 Q Do you cite to any fact or allegation that  
 5 suggests that physicians had any knowledge of  
 6 donations made by Regeneron to the Chronic Disease  
 7 Fund?  
 8 MR. MARX: Objection. Asked and answered  
 9 and outside the scope.  
 10 BY THE WITNESS:  
 11 A I don't think you understood my answer  
 12 because what I said -- and I don't know. We can  
 13 read it back if you want, but the point I was  
 14 making is the allegations are that there were  
 15 these dollars contributed to the fund. There were  
 16 documents created by Regeneron where they believed  
 17 that they were going to get a huge ROI on  
 18 contributing to this fund, which is a way of, I  
 19 think -- I don't know if it's even implicit, but  
 20 it's indirectly implicating the influence that  
 21 that had on prescribing behavior.  
 22 I don't have a particular physician that I

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1 talked to or that I have testimony from. I have  
 2 the broader scheme documents that are explained  
 3 and listed as exhibits to the Regeneron complaint  
 4 that tell the story, and in their view they were  
 5 able to get a 430, whatever percent ROI by  
 6 throwing money at the CDF, which means they viewed  
 7 it as very much influencing prescribing behavior.  
 8 BY MR. CAINE:  
 9 Q I still haven't heard any response to my  
 10 question about any fact or allegation about  
 11 physicians having knowledge of the donations  
 12 Regeneron made, but be that as it may, let me ask  
 13 you a question about guidance from the Department  
 14 of Health and Human Services, Office of Inspector  
 15 General.  
 16 Are you aware of guidance from 2005 that  
 17 makes clear that pharmaceutical manufacturers can  
 18 effectively contribute to the pharmaceutical  
 19 safety net by making cash donations to independent  
 20 bona fide charitable assistance programs?  
 21 MR. MARX: Objection to the extent it  
 22 seeks a legal conclusion and outside the scope.

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1 BY THE WITNESS:  
 2 A I would say you would have to put  
 3 something in front of me, but off the top of my  
 4 head, if that was sanctioned and what was being  
 5 done by Regeneron and Genentech was A-okay, why  
 6 did they file this complaint?  
 7 BY MR. CAINE:  
 8 Q Are you aware of the guidance or are you  
 9 not aware of it?  
 10 MR. MARX: Objection. Asked and answered.  
 11 BY THE WITNESS:  
 12 A Like I said, you'd have to put something  
 13 in front of me. As I sit here right now, I'm not  
 14 familiar off the top of my head with respect to  
 15 the IG guidance that you claim exists. But I  
 16 guess my reaction is that if -- even if there was  
 17 such guidance, you don't get charged by DOJ the  
 18 way that Regeneron has if they were complying with  
 19 the guidance.  
 20 BY MR. CAINE:  
 21 Q I mean, it sounds to me like you're taking  
 22 the allegations in the complaint as proven facts.

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 <b>A The frustration I had in this case is that</b></p> <p>4 <b>typically the brand sponsor will produce either</b></p> <p>5 <b>IQVIA or Symphony data that provides estimated</b></p> <p>6 <b>marketing spending for competing products within</b></p> <p>7 <b>the therapeutic area.</b></p> <p>8 <b>As I explained in my declaration, the</b></p> <p>9 <b>updated incomparable articles cited by Dr. Manning</b></p> <p>10 <b>are really not instructive, but I didn't have</b></p> <p>11 <b>access to the data sets that I typically expect</b></p> <p>12 <b>and almost all the time get with respect to being</b></p> <p>13 <b>able to look at some comparator metrics for things</b></p> <p>14 <b>like Share of Voice and marketing the sales</b></p> <p>15 <b>rations, et cetera. I just didn't have the data</b></p> <p>16 <b>sets to look at it.</b></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 <b>A This all falls within the frustration that</b></p> <p>9 <b>I just complained about in my last answer. I</b></p> <p>10 <b>don't know because I don't have access to data</b></p> <p>11 <b>that I would -- I would typically expect Regeneron</b></p> <p>12 <b>to have provided IQVIA or Symphony data that would</b></p> <p>13 <b>give me information regarding marketing spend,</b></p> <p>14 <b>various categories of marketing spend, various</b></p> <p>15 <b>categories of how that relates to, you know, Share</b></p> <p>16 <b>of Voice and as a percentage of sales revenues,</b></p> <p>17 <b>but I simply -- it wasn't made available to me.</b></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 <b>A I think broadly, it's almost like a</b></p> <p>5 <b>strange question because typically, I would expect</b></p> <p>6 <b>that the brand who is trying to advance maybe the</b></p> <p>7 <b>argument that extrinsic factors such as marketing</b></p> <p>8 <b>didn't drive the sales of the product would be</b></p> <p>9 <b>eager to produce any data sets that they have that</b></p> <p>10 <b>tell that story.</b></p> <p>11 <b>For whatever reason, this information was</b></p> <p>12 <b>not made available to me. I think I've heard</b></p> <p>13 <b>Mr. Marx object several times today that such</b></p> <p>14 <b>information was requested from Regeneron, but it</b></p> <p>15 <b>simply wasn't made available to us, and I don't</b></p> <p>16 <b>understand why.</b></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 <b>A There has.</b></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 <b>A I don't -- I mean, like I said, the spotty</b></p> <p>16 <b>amount of marketing materials that appeared in</b></p> <p>17 <b>what was made available to me, there's seemingly</b></p> <p>18 <b>some direct to consumer in some shape or form, but</b></p> <p>19 <b>it's not the type of data set or information that</b></p> <p>20 <b>I would normally expect to get in this type of</b></p> <p>21 <b>situation.</b></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?



34

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

342

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:

344

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

345

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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