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attributes that are key drivers of marketplace performance, that clinical data showed that Eylea was noninferior and clinically equivalent but not superior to ranibizumab?
MR. MARX: Objection. Outside the scope of Mr. Hofmann's expertise, lack of foundation.
BY THE WITNESS:
A I don't know if you're reading from Paragraph 58, but I can't find or I certainly didn't follow what you were saying relative to any particular language in Paragraph 58.
BY MR. CAINE:
Q Well, you offered an opinion in 58 that was a critique of Dr. Manning, that Dr. Manning didn't consider attributes such as safety and efficacy that explained, I think, in your view Eylea's marketplace performance; is that right?
MR. MARX: Objection. Mischaracterizes the document.
BY THE WITNESS:
A I think you're paraphrasing but I think paraphrasing in a way that I can live with.

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BY MR. CAINE:
Q In this exhibit that we're looking at --
A Among other things.
Q In this exhibit that we're looking at, Exhibit 1018, the results that are being reported are that aflibercept was noninferior and clinically equivalent to monthly ranibizumab, not that it was superior, right?
MR. MARX: Objection. Outside the scope.
BY THE WITNESS:
A I don't feel comfortable commenting on Exhibit 1018. I haven't reviewed it. I'm not a scientist. I'm not a POSA. I've relied in developing my opinions in Paragraph 58 as well as the entirety of my report and the relevant sections contained therein.
I've referenced the technical experts and their opinions that helped shape and form my opinions on technical issues as well as making sure that they were consistent with what I saw in the documents that I saw.
I haven't seen this document. I don't

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know how to interpret it, and I don't know -- you know, I think these are far better questions for Drs. Gerritsen and Albini if these are things they reviewed. I don't recall seeing references to them one way or the other in their declarations, but I don't know that I can respond to your question as asked.
BY MR. CAINE:
Q Did you review Dr. Do's declaration?
A I did.
Q Did you review her discussion of Exhibit 1018?
A I don't remember.
Q Did you ask to see Exhibit 1018 after reviewing Dr. Do's declaration?
A I don't remember one way or the other.
Q Do you understand there to be a difference between efficacy of treatment and the duration at which that efficacy is maintained?
MR. MARX: Objection. Outside the scope. And further, this is completely improper. It's seeking a legal conclusion with respect to the

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pending claim construction argument that Regeneron is trying to make.
BY THE WITNESS:
A I just -- I don't have the scientific expertise to answer that question.
BY MR. CAINE:
Q You didn't have that scientific expertise when you formed the opinions that are set forth in your declaration, right?
MR. MARX: Objection. Mischaracterizes the witness testimony.
BY THE WITNESS:
A No. What I'm saying is I had sufficient basis to form all the opinions in my report, and as is normally done by economists who are dealing with complex technical issues is I relied on technical experts.
I reviewed other documents to make sure that there wasn't anything that kind of stood out or didn't seem to make sense in my ability to interpret as an economist, not as a scientist, not as a POSA, and based on what I reviewed and

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explain and cite to in my report was supported.
BY MR. CAINE:
Q What did you do from an economic perspective to differentiate between the impact of efficacy and the impact of duration?
MR. MARX: Objection to the extent it seeks a legal conclusion and form.
BY THE WITNESS:
A I think I have to go on the attack here a bit with Manning. He didn't do anything.
BY MR. CAINE:
Q I'm asking, sir, what you did for the purposes of your declaration to differentiate between efficacy and duration for the purposes of offering opinions on Eylea's marketplace performance?
MR. MARX: Objection to the extent it seeks a legal conclusion, form and mischaracterizes the witness testimony.
BY THE WITNESS:
A That's inherent in -- my role here is to respond and rebut the opinions expressed in the

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Manning declaration, and so for you to say you're not asking what he did, that's the role I played here. I looked at what he did. He did nothing.
So then I looked at what Drs. Gerritsen and Dr. Albini did and expressed and explained my understanding from what they did. I reviewed and considered other documents and information, and I explain that, I think, in pretty good detail in my declaration.
So it is -- it is a defect and a flaw that Manning didn't address any of this, and I'm highlighting so he didn't address any of it. And from what I've seen in the record, there's evidence that these are attributes that are attributable to the aflibercept molecule, as I explained, and have references to their declarations. And I'm just -- I'm not sure what more to say about that.
BY MR. CAINE:
Q Dr. Manning is not here to defend himself. I'm sure he would have a response. But I'm really asking about what you did as part of your critique

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to differentiate between efficacy and duration for the purpose of offering opinions on marketplace performance.
Did you consider those two to be different attributes?
MR. MARX: Objection. Asked and answered, outside the scope of Mr. Hofmann's expertise.
BY THE WITNESS:
A I'm not a scientist and I'm not a POSA. I was afforded the luxury of having Dr. Manning's deposition transcript and Dr. Manning's declaration before I issued my declaration. He didn't do anything with this. I was rebutting him. So what I did was I explained what I observed in his failures. Whether or not he's here to defend himself, I think the record is pretty clear from his deposition he didn't do anything with respect to this. And so we have that in sworn testimony because I think he was asked about that.
I think that what we have here is the situation where I -- so absent him doing anything

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to address how much we would look at the efficacy and safety as flowing from the aflibercept molecule, I looked to what I saw from technical experts. I'm not a scientist or a POSA, so that's the place I go to first.
And then I reviewed the rest of the record, and everything I saw was consistent with what I was looking at in the documents and information that were produced that suggest that it's not the '338 patent. It's, in fact, things that were associated with prior blocking patents, things that were known in the prior art, among them being efficacy and safety associated with the aflibercept molecule, as I explain in detail in my report.
BY MR. CAINE:
Q In forming your critiques, did you do anything to differentiate between efficacy on the one hand and duration on the other as a basis for Eylea's marketplace performance?
MR. MARX: Objection. Asked and answered, outside the expert's expertise. And furthermore,

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to the extent this relates to the pending claim construction issue, it seeks a legal conclusion. It's an improper line of questioning.
BY THE WITNESS:
A It is -- you know, my opinions are laid out in, I think, copious detail in my declaration, and I explain the things that I considered, relied upon, reviewed. Among them were the opinions of technical experts where those finer points, if their issues were part of what I considered because I considered the entirety of their opinions and declarations. But I'm not a scientist. I'm not a POSA. I'm not weighing in on any of that affirmatively one way or the other.
BY MR. CAINE:
Q Let me ask the question one more time because I don't believe you've yet answered it.
In forming your critiques, did you do anything to differentiate between efficacy on the one hand and duration on the other as a basis for Eylea's marketplace performance?
MR. MARX: Objection. Asked and answered.

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Objection. It seeks a legal conclusion as it relates to the pending claim construction issue and further outside the scope of Mr. Hofmann's expertise.
BY THE WITNESS:
A I'm not a scientist. I'm not a POSA. I'm not a patent lawyer. I'm taking what was, I think, failure by Dr. Manning in addressing the things that were known in the prior art and the important role that efficacy and safety played with respect to the aflibercept molecule.
And then I relied on technical experts with confirmatory review through my review of documents and information that were provided by Regeneron in forming my opinions.
It's all laid out in my report, and I don't really have anything to add beyond that.
BY MR. CAINE:
Q As part of your analysis and your review of the declarations of Dr. Albini and Dr. Gerritsen, you did not -- you did not go into detail on Exhibit 1018, which we've looked at, or

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Exhibit -- just so I have it right -- 2086, correct?
MR. MARX: Objection. Form.
BY THE WITNESS:
A Nor would it be anywhere near normal for an economist to do so. I'm not getting into the weeds of the technical issues and arguments because I'm not a POSA. I'm not a scientist. I'm relying on their opinions, as I've referenced and explained, having reviewed their declarations. They've considered all this stuff, and that stuff, you know, is something they considered in forming the opinions on which I ultimately rely.
I'm not going to reasonably replicate what a scientist who is a skilled clinician, who is a skilled microbiologist does in their review of scientific articles. We just have differing expertise. I rely on their expertise, and then I do a check by looking at other documents and information that are provided in this case by Regeneron, and I didn't see anything that suggested otherwise to the conclusions that they

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reached, and so, I think, reasonably relied on that information collectively, as I explain in detail in my declaration.
Q You talked about relying on the technical experts with confirmatory review through your review of documents and information that were provided by Regeneron. And I'm asking did that confirmatory review and your review of documents include Exhibits 1018 or 2086?
A I don't remember whether I specifically looked at those documents. I mean, I looked at the Do report. I looked at the technical experts. I don't have these documents listed in my table as something that I separately reviewed, so I don't know if I've seen these before. I don't believe I have.
But either way, like, I think what you're, I guess, suggesting is that I needed to check or double-check what the POSAs and scientists viewed with respect to information like these articles.
That isn't what an economist would do. I'm relying on their expertise for their lane that

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they're in, and I'm providing my perspective through an economic lens on the lane that I'm in.

Q You didn't ask Dr. Albini or Dr. Gerritsen to explain to you the difference between efficacy and duration; is that right?

MR. MARX: Objection. Asked and answered.

BY THE WITNESS:

A I feel like we've talked about this -- I don't know how many dozens of times, but Manning did nothing. I'm rebutting --

BY MR. CAINE:

Q You didn't answer my question.

Did you ask Dr. Albini or Dr. Gerritsen to explain to you the difference between efficacy and duration?

MR. MARX: Objection. And I ask counsel not to interrupt Mr. Hofmann while he's answering questions.

BY THE WITNESS:

A I'm a rebuttal witness to Dr. Manning. He did nothing. So if anything, I did more by doing what I did and explaining what I found by looking at their declarations and looking at the documents and information that was available to me in the record.

You already know the answer that I have had no live discussions with Dr. Albini or Dr. Gerritsen, so no, I didn't have discussions with them, but I had more than adequate information and above and beyond addressing of this issue compared to Dr. Manning, who did nothing.

MR. CAINE: Can we see Exhibit 2259, please.

BY MR. CAINE:

Q I'm going to hand you what's been marked as Exhibit 2259.

MR. MARX: No comment. The labels are consistent with Exhibit 2259.

BY MR. CAINE:

Q Mr. Hofmann, do you have Exhibit 2259 in front of you? Is that a yes, no? Do you have it in front of you?

A So I can answer that question, but this appears to be a document I haven't seen before from 2009. It's a hundred-page document that I'm unfamiliar with. So are you going to -- yes, I have something labeled 2259 in front of me, but I have not reviewed any of the hundred pages.

Q You understand that Exhibit 2259 was submitted in this proceeding by Regeneron? I'll represent to you that it was.

A I assume so based on the fact that it's got an IPR Bates or whatever the exhibit referencing scheme is.

Q You'd recognize Exhibit 2259 as one that Dr. Manning cited in his declaration?

A I don't remember if he did one way or the other.

Q You would agree with me that you've had an opportunity to review Exhibit 2259 prior to the preparation of your declaration?

A I mean, I guess show me where he references it in his report.

Q I'll represent to you that it's referenced in his report.

A Okay. But maybe show me because I don't -- you know, a 2009 study for American Society of Retina Specialists -- I don't know -- that was long before the launch of Eylea, and I just -- I don't recall this document. Maybe I looked at it; maybe I didn't. But I'm unfamiliar with it as I sit here right now given that it's a hundred pages and there's a whole bunch of stuff here.

Q I'll represent to you that it was referenced in Paragraph 89 of Dr. Manning's report.

Do you agree?

A Yeah. I mean, I see the reference. I just I don't -- I don't recall --

Q You are familiar --

A -- this as I sit here right now.

Q You are familiar with ASRS PAT surveys?

MR. MARX: Excuse me one second, Mr. Hofmann. I'm just going to note for the record that this section of the Manning report is under heading "Eylea's Patented Dosing Regimen

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Addressed an Unmet Need For Longer Dose Intervals," and Mr. Hofmann has offered no opinions in this case concerning unmet need. So outside the scope, this whole line of questioning and the use of this document.

MR. CAINE: I disagree.

BY MR. CAINE:

Q Have you seen ASRS PAT surveys previously?

A I don't recall as I sit here right now one way or the other.

Q Would you turn for me to Page 93 of Exhibit 2259.

A So do you mean Page 93 or Slide 93? Because they seem to be one off.

Q Page 93, which is Slide 92.

A Okay.

Q Do you understand this is a survey from 2009?

MR. MARX: Objection. Lack of foundation, outside the scope of Mr. Hofmann's opinions in this matter.

BY THE WITNESS:

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A I mean, the footer says 2009. So that's all I can say, is that's what it says in the footer.

BY MR. CAINE:

Q Do you see that on this slide, there is a question about "the current unmet need in the treatment of wet AMD today"?

MR. MARX: Same objection. Outside the scope of Mr. Hofmann's opinions in this matter.

BY THE WITNESS:

A I mean, you can read the words that are on here. I don't remember seeing this, and I don't recall anywhere in my declaration I address unmet need. That's usually something that's addressed by clinicians, if there is an unmet need, long-felt unmet need, but I don't – if you read words, I can tell you whether you've read them as they appear.

BY MR. CAINE:

Q Do you see that for the response to that question, 33.56 of respondents said "reduces frequency of injections, maintains VA," meaning

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visual acuity?

MR. MARX: Objection. Still to the use of this document, with respect to unmet need. Mr. Hofmann has offered no opinions in this case on unmet need. Further, I don't recall this page being cited by Dr. Manning.

To the extent you're trying to elicit technical expert testimony from Mr. Manning {sic}, he is not a technical expert, as he has stated numerous times today.

BY THE WITNESS:

A I'm too unfamiliar with this document to even know how to respond. How the study was conducted, what the control questions were aren't even listed, which usually is part of a survey. Like, I don't know what to say. You can read words from what's there.

I don't remember Dr. Manning citing to this slide. I don't remember this being something that was an area of focus for the purposes of my opinions on commercial success.

BY MR. CAINE:

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Q You see above it, it says -- you see the words "improves visual outcomes"?

MR. MARX: Same objection. Outside the scope of Mr. Hofmann s opinions in this matter and seeking testimony -- scientific technical testimony from Mr. Hofmann which is not his expertise.

And I ll further note for the record that this study, PAT study, lack of foundation. I do not know who the respondents to this survey are. My understanding of these PAT surveys is actually anybody can go online and submit responses to these surveys, not just a retina specialist. So with those objections --

MR. CAINE: Mr. Marx, I ve only asked him the question, first of all, whether he sees the words on the page. And I think that objection is improper. I think you are engaging in improper speaking objections. So I would ask you again to stop.

MR. MARX: I would ask you to stick to Mr. Hofmann s opinions in this case.

MR. CAINE: I'm happily doing so.
MR. MARX: I disagree. This is clearly unmet need from Mr. Manning's declaration. Mr. Hofmann has offered no opinions on unmet need.
MR. CAINE: I disagree with you.
MR. MARX: You're free to disagree. You're free to ask questions you want. I'm free to object as outside the scope of Mr. Hofmann's opinions. I'm doing so.
MR. CAINE: Absolutely. That's fine. If you limit your objection to objection outside the scope and don't include the speaking objection about who can go online and fill out the surveys, I'm fine with that. So that's what I would ask you to do.
MR. MARX: I'll take that under advisement, but I'll object how I see fit. Thank you.
MR. CAINE: I understand you're going to object how you see fit. It's just going to make the objection go more smoothly if you make your objections and don't litter the record with

speaking objections about what people can and can t respond -- which people can and can t respond.
MR. MARX: I would ask that you stick to Mr. Hofmann s opinions in this matter, and I won t have to object so often.
MR. CAINE: I will happily do so.
MR. MARX: Okay. Well, focus on unmet need. Outside his expertise, outside his opinions in this case.
But go ahead and ask your questions.
MR. CAINE: Thank you.
BY MR. CAINE:
Q Mr. Hofmann, do you see the words "improves visual outcomes"?
A I see the words as they appear on that slide. Again, I don't --
Q Do you see that the response to both A and B below reduces frequency of injections, maintains VA, which is below improves visual outcomes, is 62.73 percent?
MR. MARX: Objection to this line of

questioning. Mr. Hofmann cannot confirm or deny these numbers, what they mean, what their import is. Outside the scope of his expertise, outside the scope of his opinions in this case.
BY THE WITNESS:
A I'm kind of at a loss here because I don't recall Dr. Manning referencing this in his report. I don't see in this survey document or purported survey something that explains what the parameters were for the survey itself and how it was conducted, what the questions were, what the control questions were, which is all stuff I said before you guys started objecting to each other.
I don't know what you expect me to do with this. It seems like we could read the letters on the page, but I don't know what to say beyond that.
BY MR. CAINE:
Q Do you agree that in 2009, both Lucentis and Avastin were treatments that were being used to treat eye disorders, right?
MR. MARX: Objection to the extent it's

outside the scope of Mr. Hofmann's expertise.
BY MR. CAINE:
Q I'm asking you about the marketplace as it existed in 2009.
A I'm not a clinician, but from what I've reviewed, I think Avastin was off label to the extent it was being used in this space and Lucentis did have, and you're just making a very vague kind of eye disorders. There are specific labeled indications from my review of the labels.
Q Well, at least in 2009, both Avastin and Lucentis were being used in the treatment of wet AMD, correct?
MR. MARX: Objection to the extent it's outside Mr. Hofmann's expertise.
BY THE WITNESS:
A I'm not a clinician. I believe – I don't have the label in front of me from 2009 for Lucentis, but I believe it was on label for Lucentis. I believe it was off label for Avastin at that point.

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BY MR. CAINE:
Q Both were being used to treat wet AMD at that point in time?
MR. MARX: Objection. Outside the scope of Mr. Hofmann's expertise.
BY THE WITNESS:
A I'm not a clinician, but from what I've -- and that's a better question for a clinician. I don't know why you're asking me this, but I believe that there are some documents that suggest that Avastin was being used off label for wet AMD, and I believe Lucentis was on label. But I don't have the Lucentis label in front of me.
BY MR. CAINE:
Q You have -- you said earlier that you don't know whether you are familiar with ASRS surveys; is that right?
MR. MARX: Objection. Mischaracterizes the witness testimony.
BY THE WITNESS:
A You asked me specifically whether I'm familiar with ASRS PAT surveys. I look at this and I don't know that I've seen one before. Maybe I have. I've done other ocular products, but as I sit here right now, I'm not -- I'm not remembering them one way or the other.
MR. CAINE: Well, why don't we do this. We've been going for a little bit more than an hour. Why don't we take a break and we'll come back and keep going after.
THE VIDEOGRAPHER: Please stand by. We are going off the record. The time is 2:46 p.m.
(A recess was had.)
THE VIDEOGRAPHER: We are back on the record. The time is 3:01 p.m.
BY MR. CAINE:
Q Mr. Hofmann, welcome back. Did you review Exhibit 2176 for the purposes of preparing your declaration?
A I did.
Q I'm going to hand you Exhibit 2176.
Do you recognize Exhibit 2176 as a Q4 2020 performance update?
A Yeah. I mean, it's 137 pages. I haven't

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reviewed every page, but that's what it's titled.
Q Are you saying you didn't review every page prior to preparing and submitting your declaration?
A No. I'm saying as I sit here right now, I didn't do so.
Q Did you review every page before submitting your declaration?
MR. MARX: Asked and answered.
BY THE WITNESS:
A Yeah. So to the extent that I have it labeled in my table on pages -- in the "Documents Reviewed" section of my report, I would have reviewed, yeah, every page prior to the issuance of my declaration.
BY MR. CAINE:
Q Would you turn to Page 92. Do you have it?
A Yeah. Just give me a second to take a look and I think I'm there.
Okay. Yeah, I'm there.
Q You see it's titled "Wet AMD Dosing Update"?
A I do see that.
Q Do you see that there is a line graph or a series of line graphs for different treatments for wet AMD?
A I do see that.
Q And the yellow line is the line graph for Eylea?
A With the triangles as the points, yes.
Q Do you see that for eight-week dosing, the percentage of physicians that use eight-week maintenance dosing to treat wet AMD with Eylea is [redacted]?
MR. MARX: Objection. Mischaracterizes the document, lack of foundation.
BY THE WITNESS:
A I mean, there's a lot of caveats and footnotes and everything else in this. If you look at it a little closer about what is what and what can be precisely ascertained from this, but I do see at least directionally Eylea being slightly behind -- how do you pronounce it, brolucizumab?

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BY MR. CAINE:
Q Brolucizumab.
A There we go.
Q The percentage for Eylea in terms of dosing schedule, according to the asterisk, it says "ongoing following initiation of therapy" is [redacted], right?
MR. MARX: Objection. Lack of foundation.
BY THE WITNESS:
A With many other caveats and probably other information within this document that explain the limited sampling that was done to source this.
Q And just because my question may have been imprecise, the [redacted] refers to the eight-week dosing schedule using Eylea?
MR. MARX: Objection. Lack of foundation and mischaracterizes the document.
BY THE WITNESS:
A The number [redacted] or the percent [redacted] does appear there, but there are many footnotes that explain that there is a very limited sample size here. There is very little

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confidence, I think, in that number as expressly stated below and that these are more so directional percentages.
BY MR. CAINE:
Q The [redacted] that you see for eight-week dosing with Eylea is higher than any of the other percentages associated with other weeks, right?
MR. MARX: Objection. Lack of foundation.
BY THE WITNESS:
A That's not what I'm seeing. I'm seeing brolucizumab is higher, not that much but --
BY MR. CAINE:
Q I'm talking about just limited to the Eylea line.
MR. MARX: Same objection.
BY MR. CAINE:
Q Let me reask the question.
A You're saying for the yellow Line, [redacted] is the highest of the -- that's the apex with respect to the Eylea line.
Q That's right. Do you agree?
A Yes. It's a little bit above the

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

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

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

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BY THE WITNESS:
A Again, subject to all the caveats that these are not statistically significant, they're based on a very limited sample, the numbers as they appear in the line graph do kind of run below [redacted] if you add those up, whereas brolucizumab -- I'm butchering it, I know -- is at least as high, if not higher, than Eylea.
BY MR. CAINE:
Q Would you turn for me to Page 94. This is the DME dosing update.
Do you see that?
A I do.
Q Do you see that the dosing schedule for Eylea which is, again, represented in the yellow line has the highest percentage for eight-week dosing to treat DME?
MR. MARX: Objection. Lack of foundation, form.
BY THE WITNESS:
A According to the numbers that appear on this page with the sample of probably 200 or so

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physicians, without the benefit of seeing what the control questions are, what the actual questions are, those are the numbers that appear on this page.
BY MR. CAINE:
Q And the percentage for Eylea dosing at eight weeks for DME is [redacted], right?
MR. MARX: Objection. Lack of foundation.
BY THE WITNESS:
A With all the caveats from my last answer, that's the number that appears here.
BY MR. CAINE:
Q If we do the same as we did for wet AMD for DME and look at the percentages for Eylea dosing schedule for eight weeks and beyond and add those up, over [redacted] of physicians use maintenance dosing regimen of eight weeks or more to treat DME with Eylea, correct?
MR. MARX: Objection. Lack of foundation.
BY THE WITNESS:
A Again, subject to all the caveats and all the footnotes as to what limited significance one

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can ascertain with respect to the very limited sample here and without the benefit of the control questions and the questions themselves, that so, falling far behind brolucizumab.
BY MR. CAINE:
Q The percentage of physicians reporting the usage of Avastin to treat DME with a dosing schedule of eight weeks or more is less than [redacted], right?
MR. MARX: Objection. Lack of foundation.
BY THE WITNESS:
A Are you talking about eight weeks and above?
BY MR. CAINE:
Q Yes.
MR. MARX: Same objection.
BY THE WITNESS:
A I mean, with all the caveats on the limited reliability and statistical significance associated with the numbers that appear on this line graph, it seems to me that it's greater than [redacted] because it looks like it's -- oh,

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

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Q You see the Eylea line is again in yellow?
A I do.
Q And the percentage of physicians responding that they use a dosing schedule of eight weeks with Eylea to treat MEfCRVO is [redacted], right?
MR. MARX: Objection. Lack of foundation.
BY THE WITNESS:
A Wait. What's that? Oh, okay.
You know, again, similar to some of my prior answers, there are a lot of caveats in the footnotes and limitations on whether any of this is statistically significant or reliable other than directional [redacted] is the number that appears for eight weeks.
BY MR. CAINE:
Q The percentage of physicians responding that they used Eylea to treat MEfCRVO with a dosing schedule of eight weeks or more is over [redacted], right?
MR. MARX: Objection. Lack of foundation.
BY THE WITNESS:

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A Subject to the limitations or qualifications that appear in the footnotes and the reliability of the information trailing soon after week 8 from brolucizumab, the numbers add up to what you said.
BY MR. CAINE:
Q And the results reported here reflect that physicians did not use -- well, let me rephrase that.
The results reported here reflect that physicians used eight-week or longer maintenance dosing to treat MEfCRVO with either Avastin or Lucentis less than [redacted] of the time, correct?
MR. MARX: Objection. Lack of foundation.
BY THE WITNESS:
A Subject to all the caveats with the statistical significance or lack of statistical significance and the limited population from which this was sampled, certainly all the products, it's less than [redacted].
BY MR. CAINE:

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Q When you said "all the products," were you answering my question that was in reference to Avastin and Lucentis?
A I mean, I think all the products, including Eylea and brolucizumab. I know I'm saying it wrong.
Q I think earlier you agreed with me that Eylea -- that physicians responded that -- over [redacted] of physicians responded that they were using an eight-week or greater dosing schedule to treat MEfCRVO with Eylea; is that right?
A Eight-week or --
MR. MARX: Objection. Lack of foundation, outside of Mr. Hofmann's expertise.
BY THE WITNESS:
A Subject to the caveats that I gave, I guess I was saying in my last answer at eight weeks, everybody was below [redacted]. If you're looking at eight weeks or greater, subject to the fact that there are limitations on the sample size and caveats with respect to the size of the population and not being aware of the questions

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and whether there were proper control questions and whether this was a properly designed study, that's what the numbers add up to.

BY MR. CAINE:

Q Let me ask the question about Avastin and Lucentis again because I don't think we got to the answer on that question.

So the percentage of physicians responding about the use of Avastin and Lucentis at eight weeks or more in each case was under [redacted], right?

MR. MARX: Objection. Lack of foundation, outside the scope of Mr. Hofmann's expertise.

BY THE WITNESS:

A Subject to the fact that we don't know what the questions were and we don't know what the control questions were, we can tell that the population that was sampled is a very small group. And so I don't know how much we can glean from this, and they even include their own caveats as to the lack of statistical significance. The numbers as they appear do fall below [redacted].

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BY MR. CAINE:

Q Would you turn for me to Page 96, please. This is the macular edema following BRVO dosing update, correct?

A It is.

Q And you see that the familiar yellow Eylea line on this page?

A I do.

Q And you see that at eight weeks -- for an eight-week dosing schedule, [redacted] of the physicians reported using Mylan to treat MEfBRVO, right?

MR. MARX: Objection. Lack of foundation, outside the scope.

BY THE WITNESS:

A Do I see the [redacted]?

BY MR. CAINE:

Q Corresponding to the physicians who said they used an eight-week dosing schedule with Eylea to treat MEfBRVO?

A Subject to the fact that we don't know what the questions were, we don't know what the control questions were, whether this was a properly designed study and whether the population is adequately representative, how they were selected, et cetera, et cetera, I can read the [redacted] number there.

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Q The percentage of physicians who responded as treating MEfBRVO with Eylea for eight weeks or greater is over [redacted], correct?

MR. MARX: Objection. Lack of foundation, outside the scope.

BY THE WITNESS:

A Subject to the fact that we don't have questions, we don't have control questions, we don't know how the study was designed, we don't know whether it was a representative group of ophthalmologists or retinal specialists and by their own admission it's limited, limited group that they were looking at, I think the numbers as they appear on that line graph do exceed [redacted].

BY MR. CAINE:

Q And the number of physicians who reported

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using Avastin to treat MEfBRVO with a maintenance dosing regimen of eight weeks or longer is less than [redacted], correct?

MR. MARX: Objection. Lack of foundation. Outside of Mr. Hofmann's expertise and outside the scope.

BY THE WITNESS:

A I don't -- I'm just eyeballing this. I would put in all the same caveats I did before. We don't know the questions, we don't know the control questions, we don't know whether this is a representative group that was being asked these questions. Were you asking about Avastin or --

BY MR. CAINE:

Q Avastin.

A Yeah. The numbers as they appear here, and whether these are statistically significant or valid when you add up the percentage and line graph, they're less than [redacted], just shy.

Q And for Lucentis, the percentage of physicians saying that they used Lucentis to treat MEfBRVO with a dosing schedule of eight weeks or

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

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

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

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

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impossible.
BY MR. CAINE:
Q I'm not sure I understood the last part of your answer when you said "at the eight-week point, I think it's hard to imagine that those percentages could somehow be statistically be higher than [redacted]."
Are you just saying at the eight-week period or --
A Correct.
Q Okay. I understand your point. I didn't ask -- at least I didn't mean to ask exactly at the eight-week period. I just want to make sure we're clear that eight weeks and greater is over [redacted] for each of the indications that we went through.
A You were asking me about my report, and in my report I am talking about the eight-week period in Footnote 126. And I'm saying in all those instances, it is less than [redacted], that the majority of uses is either above or below eight weeks.

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

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

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

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of patients that are administered Eylea at dosing intervals between five and seven weeks for AMD, DME and RVO, right?

A I'm sorry. Could you point me to what you're referring.

Q Yes, Paragraph 82 of your declaration.

A Okay. Ah, fair enough, okay.

Q Now, you reviewed a number of surveys for the purposes of your opinions, correct?

MR. MARX: Objection. Form.

BY THE WITNESS:

A I reviewed a number of --

BY MR. CAINE:

Q Surveys?

A Surveys? I mean, I think -- you got to be careful of the word "survey" because there is like surveys that maybe are conducted informally and through the marketing organization or business group, and then there are surveys that are like -- meet the criteria that are admissible as litigation surveys like that are conducted more so by like a survey expert that demonstrates proper

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design, control, et cetera, and I'm not a survey expert.

Q Why don't we pull out, if we can find it in our stack, Exhibit 2197.

A Dang it. I thought when I'd moved it to the side, I didn't have to look at it again.

Q It looks like this (indicating).

MR. MARX: What was the date on that, Mr. Caine?

MR. CAINE: September 15th of 2011.

BY THE WITNESS:

A Which number?

MR. MARX: This is the document --

BY MR. CAINE:

Q This is the one with the, kind of, misnumbering that Mr. Marx identified.

A 2197?

MR. MARX: Yeah, on the left.

THE WITNESS: On the left, okay yeah.

MR. MARX: And on the right side of this document, it includes Exhibit 2294, just to clarify for the record.

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MR. CAINE: Fair point.

BY MR. CAINE:

Q Okay. This is the Physician ATU Benchmark Wave Full Report, September 15, 2011?

A Yes.

Q Would you turn for me to Page 18 of 47.

You agree that [redacted] of respondents identified dosing schedule as one of the key benefits of Eylea?

MR. MARX: Objection. Lack of foundation, mischaracterizes the document, form.

BY THE WITNESS:

A The bar that you're referring to and the [redacted], it looks like this was based on the selection of 99 or so respondents with efficacy being dominant at [redacted].

BY MR. CAINE:

Q You would agree that Eylea's dosing schedule was at least one significant benefit identified by the respondents as reflected on this page, right?

MR. MARX: Objection. Lack of foundation.

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BY THE WITNESS:

A I mean, "significant" is a subjective term. Efficacy is listed as the clear most important respondent benefit, but dosing is listed. It's also unclear from anything I see here that the dosing schedule question is really tailored to whatever the contours are of the claims of the '338 patent. So, I mean, we got to be careful.

BY MR. CAINE:

Q And this is, again, from September 15, 2011, this particular exhibit that we're looking at?

A It is.

Q Would you look at Exhibit 2138 which I will hand you.

Do you have Exhibit 2138 in front of you?

A I do.

Q This is a Physician ATU Wave 2 Full Report, February 2013, right?

A That's the title.

Q And as of February 2013, Eylea had been on

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the market for about 15 months, correct?
A Yeah, that sounds about right.
Q Would you turn to Page 13, please.
Do you agree that when respondents were asked about Eylea, they identified the main reason of treatment as the dosing period/admin for patients at a percentage of [redacted] for newly diagnosed patients and [redacted] for previously diagnosed patients?
MR. MARX: Objection. Lack of foundation.
BY THE WITNESS:
A Well, here again, it's a pretty limited sample size. I'm not sure about the exact design of the survey and everything. I can read off the percentages as well as you can. I think this is a document that Manning cites, and I find lots of other documents that are inconsistent with this.
At the end of the day, I still don't see anything here that tells me that this is tailored to the '338 patent. So we, again, have to be very careful in what we can make of this.
BY MR. CAINE:

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Q Do you see that for the same question for Avastin and Lucentis, the percentages are [redacted] or [redacted]?
MR. MARX: Objection. Lack of foundation.
BY THE WITNESS:
A I mean, like I said, I think we can see the percentages as they appear here, but you do have to be careful that this is but one document, 15 months after launch, also, on the heels of the tremendous marketing effort by Regeneron to invest heavily in messaging to certain things to try and get product into patients, and in any event, nothing here really shows me that this is specific to the '338 patent just dosing in general.
BY MR. CAINE:
Q You reviewed Exhibit 2138 for the purposes of preparing your declaration?
A I did.
Q And I think we already that -- let me frame it a little more broadly.
Other than counsel for Mylan, did you have any discussion of these percentages with anyone

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about -- I'll stop it right there. Let me rephrase so we have a clear question.
Aside from counsel for Mylan, did you have any discussion about the percentages reflected on Page 13 with respect to the main reasons to choose treatment for Eylea?
MR. MARX: Objection to the extent it asks Mr. Hofmann to disclose any privileged communications.
Otherwise, you can answer.
BY THE WITNESS:
A I mean, there's my internal team.
BY MR. CAINE:
Q Okay. But outside of your internal team and counsel for Mylan?
A Yeah. I mean, from what I remember, that's the folks -- to be clear, my discussions were with -- my review and reliance was on documents, data, information and declarations from this litigation.
Q Let's stay on this page for just a second.
MR. MARX: Mr. Caine, just for the record,

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this page --
MR. CAINE: Page 13.
MR. MARX: Page 13 of Exhibit 2138?
MR. CAINE: Yep, that's right.
BY MR. CAINE:
Q Do you see that respondents were also asked about efficacy as a main reason to choose treatment?
MR. MARX: Objection. Lack of foundation.
BY THE WITNESS:
A I mean, I don't know if it's exactly fair, the way your question was asked. If I'm reading the question that's listed in the bottom footnote, it wasn't like a leading question, like is efficacy what's driving your prescribing decisions. It was what drives your prescribing decisions.
BY MR. CAINE:
Q Fair enough.
A So a slight nuance from how your question was phrased.
Q Let me rephrase it, then.

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In the case of each of Eylea, Avastin and Lucentis, respondents identified efficacy as a main reason to choose those treatments, right?
MR. MARX: Objection. Foundation, mischaracterizes the document.
BY THE WITNESS:
A In this one particular survey which, again, we know little about, efficacy certainly came back as a reason to choose the treatment for all those products.
BY MR. CAINE:
Q We can see on the page -- I won't ask you about it, but we can see on the page the percentage of respondents who identified efficacy for -- as the main reason to choose treatment for each of Eylea, Avastin and Lucentis, right?
MR. MARX: Objection. Lack of foundation, mischaracterizes the document.
BY THE WITNESS:
A I'm sorry. Say that again.
BY MR. CAINE:
Q Sure.

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

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A Again, not having better insight into how the study was designed, yeah, they are within a few percentage points as the numbers appear on this page.
BY MR. CAINE:
Q And with respect to Eylea and Avastin, the main reason to choose percentage identifying efficacy, somewhere between [redacted] and [redacted], correct?
MR. MARX: Objection. Lack of foundation.
BY THE WITNESS:
A I don't know what percentages you're talking about.
BY MR. CAINE:
Q So what I'm talking about is the Avastin percentages for efficacy as compared to the Eylea percentages identifying efficacy.
A Ah, okay. Yeah, I can do that math.
MR. MARX: Same objection.
BY MR. CAINE:
Q Thank you.
Can we do Exhibit 2140.

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

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Do you see that?
MR. MARX: Objection. Lack of foundation.
BY THE WITNESS:
A You read those words as they appear there. There is three other bullets that you skipped over.
BY MR. CAINE:
Q I did.
A And a whole bunch of other bullets on the page.
Q Do you agree that the findings reported here include that less frequent dosing and fewer injections were important components of Eylea's marketplace performance?
MR. MARX: Objection. The lack of foundation and mischaracterizes the document.
BY THE WITNESS:
A "Important" is a subjective term, and there is about a dozen other bullets on this page. But among the considerations, it does seem like they have recognized that to some degree.

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BY MR. CAINE:
Q Would you turn to Page 22 of this document. Page 22 is showing the percentage of eyes on a fixed dosing interval preparing and differentiating by what that fixed dosing interval is, correct?
MR. MARX: Objection. Lack of foundation, mischaracterizes the document.
BY THE WITNESS:
A I'm not a clinician, but I think what I'm seeing here is various criteria of various, I guess, dosing regimens.
BY MR. CAINE:
Q In the line chart on the right reflects that for Lucentis, [redacted] of eyes are dosed monthly, right?
MR. MARX: Objection. Mischaracterizes the document, lack of foundation. This is limited to the fixed dosing with respect to the bar chart on the left.
BY THE WITNESS:
A You have to be, like, careful. The bar chart on the left -- first off, you have to be overall just careful with ATUs because they are not precise, in my experience. They are a reference point and something to look at.
But what's happening, as I read this page, is there's a stratification, if you will, on the various, whatever, six categories, half-dozen categories that are covered by the key on the left. And then what they're doing in the line chart is blowing it out -- or not blowing it out -- digging deeper, essentially unpacking.
So like, for example, with Lucentis what it's saying is [redacted] of [redacted] -- no, no, of [redacted] because Lucentis, that's the top dark blue category, [redacted] would hit the fixed dosing criteria of the line chart on the right. So it's [redacted] of [redacted], if that makes sense.
BY MR. CAINE:
Q And of those patients who are on a fixed dosing interval with Avastin, [redacted] are dosed monthly, correct?

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

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

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(A recess was had.)
THE VIDEOGRAPHER: We're back on the record. The time is 4:18 p.m.
BY MR. CAINE:
Q Mr. Hofmann, did you consider Regeneron's marketing efforts that promoted Eylea on the basis of dosing schedule?
MR. MARX: Objection. Lack of foundation, vague.
I'm also going to note for the record that we have requested the full complement of marketing materials that Mr. Manning was able to refer to and review, and Regeneron has refused to produce that. So to the extent you're seeking Mr. Hofmann's consideration of Regeneron's marketing material, he's been denied that opportunity to do so.
BY THE WITNESS:
A So I think I would refer to or defer to what I mention in my declaration. I think there was a limited number of marketing materials that I was able to review, and among the things I considered was the messaging.
BY MR. CAINE:
Q Did you consider Regeneron marketing materials that promoted Eylea on the basis of its dosing schedule?
MR. MARX: Same objection. Regeneron has failed to produce the full complement of marketing materials, in particular, the marketing materials that Mr. Manning reviewed.
BY THE WITNESS:
A So there were limited marketing materials that were available to me, and what I looked at included messaging on lots of things. Among them, dosing was part of the information that I reviewed and considered, but there were many other aspects of it as well as a significant investment in terms of like a [redacted] dollars.
BY MR. CAINE:
Q "A significant investment in terms of like a [redacted] dollars." Are you referring to the people and external expenses?
MR. MARX: Objection. Form.

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BY THE WITNESS:
A From what I recall, what limited marketing information was provided in the product P&L, it included certainly detailing by personnel costs as well as internal and external costs.
BY MR. CAINE:
Q I'm just asking what you're referring to. You said a [redacted] dollars?
A Yes. It's from the product P&L. I think it was [redacted], so maybe just shy of --
Q Okay. So you're talking about some number from the product P&L?
A Correct.
Q Let's look at Exhibit 2136.
Do you recognize Exhibit 2136 as a Regeneron document pertaining to Eylea?
MR. MARX: I'm going to object to the use of this document and also object to the use and reliance by Regeneron of all the ATU surveys that have been discussed today. Regeneron has failed to produce to Mylan the full complement of marketing materials, in particular, the marketing

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materials that Mr. Manning relied on. To the extent that this is selective production, it is inappropriate and prejudicial to Mylan.
BY THE WITNESS:
A I don't -- I don't remember this particular document one way or the other. Whether it was cited in Manning, I don't know if I have that handy, but I didn't cite it in my report.
BY MR. CAINE:
Q This is a Regeneron piece of material; would you agree?
MR. MARX: Objection. Lack of foundation. And I further object to this line of questioning and reliance on this document for the reasons stated.
BY THE WITNESS:
A I mean, like I said, I don't know that -- I can't remember if I've seen this before. If I'm a guessing man and looking at the footers, it seems like it's from Regeneron.
BY MR. CAINE:
Q And this Exhibit 2136 is talking about the

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use of Eylea for the treatment of wet AMD looking towards the top and the middle of the page.
Do you see that?
MR. MARX: Objection. Lack of foundation. Outside the scope of Mr. Hofmann's declaration, and same objection with respect to the use of this document and the other marketing documents, such as the ATU surveys, for failure to provide Mylan with the full complement of marketing materials.
MR. CAINE: If you'd like, you can have a standing objection on that basis.
BY THE WITNESS:
A I mean, you know, again, I haven't studied or read all the stuff here. As I sit here right now, I think it's certainly not limited to the treatment of wet AMD. They talk about other stuff in the bottom half of the pamphlet, if you will, and then they have the summary of full prescribing information on the second page of the pamphlet.
BY MR. CAINE:
Q It includes the use of Eylea for wet AMD, Exhibit 2136?

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MR. MARX: Objection. Lack of foundation. Same objection with respect to the use of marketing documents.
MR. CAINE: Again, I m fully -- I m granting you a standing objection, if you d like it. That way, you don t have to repeat it every time.
MR. MARX: All right. Then I ll take that opportunity. For the record, Mylan objects to the use of Exhibit 2136 as well as the ATU surveys and other Regeneron marketing materials that were cited by Dr. Manning in this proceeding. Mylan s requested the production of all Eylea marketing materials which Regeneron has refused.
Mylan also limited -- limitedly requested the production of marketing materials that Dr. Manning was given, and that was also refused by Regeneron. So Mylan objects and will maintain its objection to Regeneron s reliance on these documents and their use in this proceeding.
MR. CAINE: Okay. By giving you a standing objection, that means you don t have to

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repeat the objection.
MR. MARX: I understand. I've now made my standing objection. I've put it on the record.
MR. CAINE: Fair enough.
BY MR. CAINE:
Q Mr. Hofmann, does Exhibit 2136 include marketing with respect to the use of Eylea for the treatment of wet AMD?
A Among other --
MR. MARX: Lack of foundation.
BY THE WITNESS:
A Among other uses, that's what it appears.
BY MR. CAINE:
Q Do you see the trademark phrase below the vial of Eylea says "time between treatments"?
MR. MARX: Objection. Lack of foundation and to the extent it mischaracterizes the document.
BY MR. CAINE:
Q I notice you're flipping to the second page. I'm on the first page right under the vial of Eylea?

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A I was just trying to see if there's -- again, I don't know that I've seen this document before, and I'm trying to see if next to the circle R for restricted trademark there is like a lower case "t" or cross, and I'm trying to see if that's defined anywhere.
There it is, okay. It's the bullet under "Important Prescribing Information."
Q Do you see the phrase "time between treatments" under the vial of Eylea on Exhibit 2136?
MR. MARX: Objection. Lack of foundation, mischaracterizes the document.
BY THE WITNESS:
A I see the words there as you've read them, and then it's kind of unpacked a little bit more in the first bullet under "Important Prescribing Information For Eylea," and then there's obviously a bunch of other information in this pamphlet.
BY MR. CAINE:
Q Do you understand the phrase "time between treatments" to refer to the extended eight-week

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maintenance dosing available with Eylea for the treatment of wet AMD?
MR. MARX: Objection. Lack of foundation, mischaracterizes the document and the witness testimony.
BY THE WITNESS:
A I mean, I think time between treatments is pretty vague, and I don't see anything here that necessarily ties it to the specifics of the '338 patent.
BY MR. CAINE:
Q Do you see the calendars where the calendar months up at the top left and the top right, April and June?
MR. MARX: Objection. Lack of foundation.
BY THE WITNESS:
A I see those graphical. They're not really calendars. They're just, like, I don't know, graphical portions of a calendar month.
BY MR. CAINE:
Q You see the graphical portions of calendar months April and June on the left and right top of

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the page, first page of 2136?
MR. MARX: Objection. Lack of foundation, mischaracterizes the document.
BY THE WITNESS:
A I can certainly read April and June in those graphical representations.
BY MR. CAINE:
Q The interval between April and June is an eight-week or two-month period, correct?
A Depends. I mean, the way a calendar works, if you're April 1st to June 30th, it's more than eight weeks. If you're April 30th to June 1st, it's five weeks or four weeks, so...
Q Do you understand that the graphical representations of portions of the calendar months April and June in relation to the phrase "time between treatments" and the prescribing information below reflects that after four weeks, monthly for 12 weeks, the first three months, Eylea can be administered once every eight weeks or two months for the treatment of wet AMD?
MR. MARX: Objection. Objection. Form,

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lack of foundation, mischaracterizes the document, asked and answered.
BY THE WITNESS:
A I'm not sure that that's fair for me to, I guess, interpret that one way or the other. It could be what's trying to be suggested, but there's also the data sets and other documents that I looked at, some of which we've discussed, that show that that isn't the dosing interval that is actually utilized for a lot of the prescriptions for Eylea.
BY MR. CAINE:
Q Let's look at 2137. Here is 2137.
MR. MARX: For the record, the same standing objection with respect to Regeneron's reliance on these marketing materials and their failure to produce to Mylan --
MR. CAINE: You've got a standing objection. So you don't need to repeat it.
MR. MARX: I understand that. I'm allowed to state on the record that this document is covered by that standing objection, and I'm doing

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so.
This is another marketing document, and Mylan requested production of all highly marketing materials and, in particular, the materials considered by Dr. Manning. Regeneron refused to do so. Mylan objects to Regeneron's reliance on this exhibit, Exhibit 2137.
BY MR. CAINE:
Q Would you turn, Mr. Hofmann, to Page 29, please. It's the second-to-last page of the exhibit.
A It's the smallest font I've ever seen.
Q The page number is, yes.
A Yes. Okay.
Q Do you see this piece of marketing material in Exhibit 2137?
A I do.
Q You don't cite to Exhibit 2137 in your declaration, do you?
A I don't see it listed. I know I looked at this. Maybe it was in review of the Manning declaration.

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

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injectable.
BY MR. CAINE:
Q You see the two graphical representations, this time for October and December?
MR. MARX: Objection. Lack of foundation to the extent it mischaracterizes the document.
BY THE WITNESS:
A Well, there's a lot of graphical representations here. I do see the October and December. There's also what I assume is a grandma with a granddaughter and a lighthouse and what looks to be a very nice beach.
BY MR. CAINE:
Q And you agree with me that there's a two-month period between October and December?
MR. MARX: Objection. Lack of foundation, mischaracterizes the document, asked and answered.
BY THE WITNESS:
A It's the same as the last time, where I don't know -- these are just like graphical representations of a portion of the months on the calendar, and I don't know how you get to just two

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

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

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do eight weeks or more, it gets to greater than [redacted], but that's with all the caveats on the reasonableness or reliability and lack of clarity on what the questions were, what the control questions were, how representative the targets were, how prescribers were that responded to the questionnaires.
BY MR. CAINE:
Q Mr. Hofmann, I think you said you saw the grandmother figure and the granddaughter figure in the middle of the page with the book open?
A I assume that that's what they're suggesting. Maybe they're just friends. I don't know.
Q An older woman and a younger girl are shown there?
A Yes.
Q And they have a book open. They're reading. It looks like the older woman, perhaps the grandmother, is reading the book to the girl, right?
MR. MARX: Objection. Lack of foundation,

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

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

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know, is replete with stuff about safety and efficacy. The vast majority of this, as I flip through it, is focused on what's in the label, what's in the clinical trials and everything else. I mean, I'm not --
BY MR. CAINE:
Q I'm asking you about Page 29 of Exhibit 2137.
MR. MARX: Same objection.
BY THE WITNESS:
A I think that's incredibly unfair. It's the second-to-the-last page that has one -- I don't know if this was ever even distributed. I don't know what I'm looking at here. And there's all kinds of other information about efficacy and safety that's throughout this 30-page document.
So I understand you're asking me about Page 29 now, but I don't understand how that helps anyone when the rest of the document -- again, I'm just flipping through it as I sit here. There's all kinds of things about efficacy and safety on the vast majority of the slides, and it's not

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until we get to Page 29 that we see grandma reading the book. And like I said, I don't even know if this was even used.
BY MR. CAINE:
Q I didn't ask you if there were any claims about safety or efficacy. I asked if there were any claims that Eylea was safer or more effective than Lucentis or Avastin on Exhibit 2137, Page 29.
MR. MARX: Objection. Lack of foundation.
BY MR. CAINE:
Q Can you answer that question?
MR. MARX: Objection. Lack of foundation.
BY THE WITNESS:
A First off, I'm not -- I'm not a clinician. I'm not a POSA. On Page 29 within the four corners of that document or that page of the 30-page document, no, there isn't something there. But whether that's followed by the label in order to be distributed as a pamphlet -- and I believe the label does include the head-to-head study with -- with Lucentis and you can see on Page 20 -- I can't read that -- Page 20 there is a line

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graph. I think that there's, like I said, copies of the whole label within this 30-page document. So I'm not -- I just don't want to create a misleading record or answer that doesn't recognize that in this document there's plenty, plenty, plenty of stuff that appears to address safety and efficacy.
BY MR. CAINE:
Q Let's look at the page that you're looking at, Page 20 of 30. The heading above the chart says: "Eylea, 2 milligrams every two months following three initial monthly doses and monthly ranibizumab" -- which I think we can agree is Lucentis -- "achieves similar improvements and maintenance of visual acuity."
Right?
MR. MARX: Objection. Lack of foundation.
BY THE WITNESS:
A Again, I'm not a clinician. You're putting a document in front of me that I don't know that I've even seen. I'm just flipping through it. And you're asking me about the

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grandma picture, and I'm just saying there's plenty of information, again, on Slide 21 that's talking about Lucentis. I mean, the label itself, I think, talks about the comparator study, but all these are better questions for the clinicians, not me.
BY MR. CAINE:
Q But you pointed me to this page, so I asked you about it and you still haven't answered my question which is: Doesn't the information right above the chart reflect the notion that using maintenance dosing with Eylea every eight weeks achieves the same results as monthly use of Lucentis?
MR. MARX: Objection. Lack of foundation, mischaracterizes the witness testimony and outside the scope.
BY THE WITNESS:
A I haven't -- I don't know that I have seen this document, and the only reason I pointed it out was because I felt like you were, like, trying to direct me to just Page 29.

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BY MR. CAINE:
Q I was.
A And the point is that even the page that I spotted that talks about Lucentis has some footnotes or endnotes attached to it that has further explanation. I mean, I haven't studied this document to weigh in on it, and I don't -- I just don't think it's fair to just fixate on what appears to be a draft document that appears to have information that may or may not have ever been disseminated externally. I don't know what --
Q Why is it unfair? Dr. Manning relied on Exhibit 2137. You read the Manning declaration. You had access to Exhibit 2137.
All of those statements are true, correct?
MR. MARX: Objection to the extent it mischaracterizes Mr. Hofmann's testimony and further objection to the extent it's cited by Dr. Manning in a portion of his report that Mr. Hofmann did not review, for example, unmet need.

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I'll rephrase that.
Mr. Hofmann did not respond to --
Mr. Hofmann may have taken a look, but he did not respond to that section. I can speak for him.
BY THE WITNESS:
A Yeah. Okay, so, now I do recall. But he just kind of cherry-picked Page 29 in his report. It's still unclear to me --
BY MR. CAINE:
Q There's nothing unfair in my questioning you about something that Dr. Manning reproduced in his report from a document cited in his report to which you had the opportunity to review in advance of preparing your declaration, right?
A No, no, you're twisting -- you're twisting it around.
What I am saying is your prior question that got us onto this sideshow is -- was very narrowly focused on Page 29 of this document which Manning clearly does cite to in his report. But I think that that's not necessarily reflective of what's in the entirety of the document. And I

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think my point, as I explain in detail in my report, is that there's a clear focus on efficacy and safety.
I'm not saying there isn't any discussion of dosing regimen in some of the marketing materials, but what's driving the sales here are things that, as I explain in detail in my report, are things that were known in the prior art, are things that were prevented -- preventing others through the existence of the blocking patents, the significant investment in marketing and the fact that even this Page 29 here doesn't necessarily comport with what I saw in the data as to frequency of dosing and frequency of uses. And nothing in this particular page, either, mentions the '338 patent.
But if you want to try and read into it that it is consistent with the dosing regimen of the '338 patent, that's inconsistent with what we see in terms of the majority of uses with respect to the Eylea product based on some of the other documents that we looked at.

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BY MR. CAINE:
Q Mr. Hofmann, you are familiar with data in the pharmaceutical and life sciences industry from IQVIA and others, right?
MR. MARX: Objection. Form.
BY THE WITNESS:
A Yes.
BY MR. CAINE:
Q You are aware that those data sources don't differentiate between loading doses and maintenance doses, right?
MR. MARX: Objection form.
BY THE WITNESS:
A I'm just pausing because I think depending on the data set and information, it does distinguish between NRx and TRx, NRx is new prescriptions which I think would include the loading dose, and then TRx would be total prescriptions.
BY MR. CAINE:
Q Well, NRx, a new prescription, would include both the loading dose and the maintenance

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

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

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

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

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most patients. To the extent it does, I imagine people will try and follow it or they can just do PRN or T and E.

Q Do you agree with me that for any particular patient at the outset of treatment, the physician and patient don't know whether eight-week extended dosing, maintenance dosing will maintain the patient's level of visual acuity or not?

MR. MARX: Objection. Lack of foundation, outside the scope, improper hypothetical.

BY THE WITNESS:

A I'm an economist. I'm not a clinician. If you want to explore that, explore that with a clinician.

BY MR. CAINE:

Q I think you offer an opinion in your declaration that "Dr. Manning fails to analyze or quantify the number of uses of Eylea that allegedly practice the challenged claims of the '338 patent."

Did you make that statement?

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A I can't remember the exact language. If you want to take me to where it is in my declaration, I'm happy to go there.

Q Did you calculate the number of uses of Eylea that practice the challenged claims of the '338 patent?

A That's the point that I'm making in my declaration, is that he's the one asserting commercial success, he's the one that has to establish a nexus between the alleged commercial success and the patent at issue in this IPR, the '338 patent.

He didn't do that. And it's not on me to do that for him. So no, I didn't separately go about and undertake that exercise because I'm not asserting commercial success. If anything, what I've found is a number of failures on Dr. Manning's part, as I explain in detail in my report. So, no, I didn't do a separate quantification of that on my own.

Q Now, earlier we looked at some data. I believe it was from 2020, where we were looking

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at. And, again, you cite this in your declaration, if you remember. We were talking about pages 92, 94, 95 and 96.

Do you recall what I'm talking about?

A Generally, yes.

Q We did some math on the percentage of people -- percentage of physicians who said that they were treating patients using Eylea at eight weeks or longer.

Do you recall that?

MR. MARX: Objection. Lack of foundation. Same objections made earlier on the record with respect to the use of those documents.

BY THE WITNESS:

A I recall you putting certain parameters or preambles to fix those based on all the caveats I explained as to the limitations with respect to those ATUs, yeah, I remember that.

BY MR. CAINE:

Q We saw that in each case for each of those treatments for eight weeks or greater, physicians said -- the physician response was [redacted] or

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more, right?

MR. MARX: Objection. Mischaracterizes those documents, lack of foundation and further objection to the use of those documents.

BY THE WITNESS:

A These are -- these are -- I think there were two that we looked at that were points in time, sometime in 2011, sometime in 2013 based on ATUs that we don't know what the questions that were asked, whether there were control questions, what the representation was of the physicians in that.

You put in the parameter for greater than eight weeks, and I think -- so there is a lot of uncertainty as to the reliability and what we can put on those particular ATUs one way or the other.

And in any event, those ATUs also -- I don't remember -- you know, they were vaguely just saying dosing regimen. They didn't -- I didn't see anything in those that really got you into the contours of what I understand to be the claims of the '338 patent. So I think you're just stacking

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

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

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

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

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Q I'll also hand you Exhibit 2210.
First, Exhibit 2210 which I've put in front of you is discussing Medicare Advantage in 2021.
Do you see that?
MR. MARX: Objection. Lack of foundation.
BY THE WITNESS:
A I'm sorry. Which one?
BY MR. CAINE:
Q 2210.
A Okay.
MR. MARX: With respect to 2210, lack of foundation. And furthermore this appears to be a printout from a website, KFF.org. So I'm not familiar with what that organization is or the veracity of this document or the information discussed therein.
BY MR. CAINE:
Q I'm going to direct you because you asked me to direct you to it, Page 2 of Exhibit 2210.
Do you see the report here that says: "In 2021, more than four in ten, 42 percent Medicare

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beneficiaries" -- and then it goes on -- "are enrolled in Medicare Advantage plans"?
MR. MARX: Same objection.
BY MR. CAINE:
Q Mr. Hofmann, do you see what I was pointing you to?
A I do see what I'm pointing you to. I'm just reviewing it. I mean, I'll just point out that some of these appear to be -- like, for example, the graph that appears above is truncated at the bottom. I don't know if there's anything of note that's missing. There's also, like, graphical links you can hit on that aren't reflected here.
I'm not -- I mean, I guess maybe so that we can move along, I don't disagree that many, many people do have Medicare Advantage programs. I don't know that I can sanction 42 percent as being an exact figure, but --
Q Fair enough.
Now, can you agree or do you agree that Medicare Advantage plans limit out-of-pocket costs

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for patients?
MR. MARX: Objection. Lack of foundation.
BY THE WITNESS:
A I think the way -- the way I would frame it is if you don't have a Medicare Advantage plan, it's an 80/20 split with Uncle Sam.
BY MR. CAINE:
Q If you do have a Medicare Advantage plan, the Medicare Advantage plan limits out-of-pocket costs?
MR. MARX: Same objection.
BY THE WITNESS:
A Yes. But there are varying degrees of how much that sharing covers that 20 percent. And there is a whole bunch of complications with Medicare doughnut hole -- I don't know -- all the different things that exist in the way that the Medicare system, you know, does and doesn't reimburse patients.
BY MR. CAINE:
Q Are you aware that Medicare beneficiaries also can enroll in supplemental coverage?

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A Sure.
MR. MARX: Objection. Lack of foundation.
BY MR. CAINE:
Q And that supplemental coverage would apply to co-pays, correct?
MR. MARX: Objection. Lack of foundation, speculative.
BY THE WITNESS:
A I mean, again, I'm just speaking in very broad strokes based on my knowledge of pharmaceutical economics that you can agree to pay a monthly supplemental amount to essentially defray some of that 20 percent.
BY MR. CAINE:
Q You talk about the Chronic Disease Fund in your declaration.
Were you aware that the Chronic Disease Fund provides co-pay assistance for treatment using Lucentis?
A I don't remember whether that's something I came across specifically one way or the other. My focus was on the DOJ complaint against

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Regeneron with respect to their involvement in the fund.

Q And in that complaint that you looked at, there are allegations that the CDF fund issues grants for Lucentis, aren't there?

A I think there is some language to that regard, but my focus -- like I said, since I'm dealing with the Eylea product, that was my focus.

Q Okay. And as alleged in the complaint, prior to 2011, Genentech was the only financier for the Chronic Defense Fund's AMD fund, right?

MR. MARX: Objection. Form.

BY THE WITNESS:

A I don't have that in front of me.

BY MR. CAINE:

Q Okay. Well, why don't we give you a copy of Exhibit 1154.

A It's a thick double-sided document, so can you point me to where you want me to focus?

Q Yes, Page 10, Paragraph 33.

Do you see -- are you at that paragraph?

A I am.

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Q It starts: "Since at least 2010, CDF has operated a fund that covers Medicare co-pays for patients taking drugs for AMD."

Do you see that?

MR. MARX: Objection. Form.

BY THE WITNESS:

A You've read those words as they appear.

BY MR. CAINE:

Q It says: "Prior to the FDA's approval of Eylea, Genentech's Lucentis was the only FDA-approved therapy for AMD, and Genentech alone financed CDF's AMD fund."

Do you see that?

MR. MARX: Objection. Form.

BY THE WITNESS:

A You've read those words as they appear there.

BY MR. CAINE:

Q So this reflects the allegation that Genentech was financing the Chronic Disease Fund's AMD fund in and around the time period that's referenced in Paragraph 33, right?

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MR. MARX: Objection. Form.

BY THE WITNESS:

A I'm not -- I'm not saying that the DOJ doesn't view Eylea alone or Regeneron alone as a bad actor here. Clearly they also, if you read this complaint, have there's numerous allegations against both Regeneron and Genentech, but yeah, I mean, you read that as it appears.

BY MR. CAINE:

Q Are you aware that the Chronic Disease Fund is a non-profit organization?

A I don't -- I don't know a hundred percent as I sit here right now. What I know is that the United States, you know, DOJ, HHS, has brought this claim against these entities. And even if it's a not-for-profit, sometimes you can set up organizations that appear as a not-for-profit, but there's still a benefit that's inured to the entity.

And, again, I'm not weighing in on the exact claims that are here. I'm just pointing out that as I was doing research, I found the DOJ

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claim.

And so you can set up a not-for-profit, but if that not-for-profit is essentially channeling or funding money to you to the detriment of the US government, you can run into some trouble.

Q Mr. Hofmann, I'll ask you just to focus on my question and answer my question.

Are you aware that donors to the Chronic Disease Fund have no control over how the donations are used?

MR. MARX: Objection. Lack of foundation.

BY THE WITNESS:

A I don't -- I don't know about that one way or the other as I sit here right now. I'd have to go back through the complaints and the information and see if that's consistent with things. But I was working off of the -- you know, what the United States government calls factual allegations, allegations specifically with respect to Eylea with my particular focus, and then certainly reviewed the discussion regarding the

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

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

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are.
Q Page 20, Paragraph 63, just where we were. Page 20, Paragraph 63. Are you there?
A Okay, yep.
Q You agree that the DOJ alleges that in 2013, Regeneron contributed $35 million to the Chronic Disease Fund, right?
MR. MARX: Objection. Form.
BY THE WITNESS:
A In 2013, yes, that appears to be so.
BY MR. CAINE:
Q And you are -- you agree that above it, in the slide that we see from the DOJ complaint, the potential sales from 2013 donations were $198.5 million?
MR. MARX: Objection. Form, foundation.
BY MR. CAINE:
Q That's the allegation, right?
A That's what appears in that slide.
Q Now, we can look at -- if you'd like to pull out Dr. Manning's declaration, which is Exhibit 2052 in your stack, you can turn to

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

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

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

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

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

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And I'm not speaking about Eylea specifically. I'm just talking about in general, that's where co-pay assistance comes in from an economic perspective, is to insulate patients from the cost of products, particularly patients that either can't afford or don't want the burden of the cost associated with the medications.

So sometimes they explore other treatments or that's where sometimes physicians -- and, again, I'm not speaking about Eylea specifically. I'm just saying there are techniques and schemes that the pharma companies will do to help assist patients in being shielded from the true cost of the medication.

BY MR. CAINE:

Q Are you aware that physicians don't know whether a patient will qualify for co-pay assistance when the physician prescribes treatment?

MR. MARX: Objection. Lack of foundation, speculative and incomplete hypothetical, outside the scope.

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BY THE WITNESS:

A That's a better question -- yeah, a better question for a clinician. All I was saying in my last answer, and, again, not specific to Eylea, is that there are situations where a patient gets prescribed something, finds out what their share of the cost is, and then they get counseled from their physician what are my options to hopefully defray the costs.

BY MR. CAINE:

Q Are you aware of any allegations in the complaints that you cite that physicians were influenced in their prescribing decisions by any Regeneron co-pay assistance donation?

MR. MARX: Objection to the extent it seeks a legal conclusion.

BY THE WITNESS:

A I'm not making any affirmative statement in that regard. I'm simply pointing to the existence of the complaint and the allegations being made by DOJ.

BY MR. CAINE:

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Q You don't cite or identify any facts or even allegations that physicians had knowledge of donations made by Regeneron, correct?

MR. MARX: Objection. To the extent it mischaracterizes the document, seeks a legal conclusion.

BY THE WITNESS:

A I think the better way to look at it is the allegations by the DOJ clearly show the belief by DOJ that Regeneron did see huge ROI and did see influence with respect to prescribing decisions because that's where you get the ROI. Again, I haven't, you know, dug into the details beyond what is in the plain language of the complaint which I cite to in my report.

BY MR. CAINE:

Q You don't cite any facts in your declaration or even any allegations that physicians had knowledge of donations made by Regeneron, correct?

MR. MARX: Objection. Mischaracterizes the witness testimony.

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

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

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

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

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MR. MARX: Objection. Mischaracterizes witness testimony.
BY MR. CAINE:
Q Is that what you're doing?
A I didn't say that at all.
Q Are you saying that they are liable and violated the law because of the allegations in the complaint?
MR. MARX: Objection. Mischaracterizes witness testimony.
BY THE WITNESS:
A I don't know how many questions back we'd have to go to, but I'm saying exactly what I said when we started talking about this, which is the DOJ filed a lengthy complaint that had a bunch of exhibits that asserted numerous allegations. It may -- it may, you know, not proceed or it may settle or there may be some kind of settlement agreement where they're able to kind of get away with whatever the allegations were that DOJ made.
I'm not -- I'm not -- I'm not trying to be judge or jury on that complaint. I'm just saying

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that it puts a pall and a taint on the sales because clearly if you look at the exhibits and you look at the allegations in that complaint, DOJ felt that it was worth them pursuing the litigation against Regeneron and Genentech because of the different things that are cited in the body of the complaint and the exhibits attached thereto.
BY MR. CAINE:
Q And are you saying that it put a pall and a taint on Regeneron's sales from late 2011 through the present?
A I think that's for the trier of fact to consider.
Q What's your opinion?
A My opinion is you don't get to the spot that they're in unless there's something that DOJ felt was worthy of complaining. I'm not saying every last dime of Eylea, you know, is completely a taint. I mean, it's one thing that I looked at on many things that I looked at.
You know, to me, first and foremost, it's

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the blocking patents, then it's what was known in the prior art, a lack of demonstration of nexus with respect to '338, and then you start to add to the list the heavy marketing, the heavy reliance on this alleged kickback scheme.
When you look at it all together, there's just no way, despite the sales levels of Eylea, that you should be finding commercial success with respect to the '338 patent for all the reasons that I pore through in my report.
Q The existence of co-pay assistance did not lead physicians to conclude that Eylea was a lower cost treatment than Avastin, correct?
MR. MARX: Objection. Outside the scope, speculative, incomplete hypothetical.
BY THE WITNESS:
A I mean, that's a tricky thing to address because there are different ways that patients are affected with respect to the cost of their medications. I think I can grant you that Avastin almost in all cases was less expensive to the patient based on the data sets that I've seen.

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But there are plenty of instances where the patient is completely shielded from the cost of the product because of whether it's the CTG or whether it's other schemes and discounts that are being done to insulate the patient.
So I don't know how better I can say that. Like I said, I will grant you that in -- overall Avastin is cheaper than Eylea, but there are probably plenty of patients that are fully insulated from the cost of Eylea.
BY MR. CAINE:
Q Mr. Hofmann, you looked at marketing expenditures, correct?
A I did.
Q Did you do any comparison between Regeneron's marketing expenditures for Eylea and those marketing expenditures for other classes of drugs that you believe are comparable?
MR. MARX: Objection. This is among the information that Mylan requested Regeneron produce. Dr. Manning didn't cite any of this. Regeneron has failed to produce it to Mylan

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despite our requests.
BY THE WITNESS:
A The frustration I had in this case is that typically the brand sponsor will produce either IQVIA or Symphony data that provides estimated marketing spending for competing products within the therapeutic area.
As I explained in my declaration, the updated incomparable articles cited by Dr. Manning are really not instructive, but I didn't have access to the data sets that I typically expect and almost all the time get with respect to being able to look at some comparator metrics for things like Share of Voice and marketing the sales rations, et cetera. I just didn't have the data sets to look at it.
BY MR. CAINE:
Q Did you request that an attempt be made to provide you with Genentech's marketing expenditures for Lucentis?
MR. MARX: Objection. Outside the scope.
And to the extent it seeks privileged

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communications, I'd ask you not to disclose those, Mr. Hofmann.
BY THE WITNESS:
A I think broadly, it's almost like a strange question because typically, I would expect that the brand who is trying to advance maybe the argument that extrinsic factors such as marketing didn't drive the sales of the product would be eager to produce any data sets that they have that tell that story.
For whatever reason, this information was not made available to me. I think I've heard Mr. Marx object several times today that such information was requested from Regeneron, but it simply wasn't made available to us, and I don't understand why.
BY MR. CAINE:
Q Do you know if Genentech spends more or less per year than what Regeneron does on marketing --
MR. MARX: Same objection. Sorry.
BY MR. CAINE:

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Q -- with respect to Genentech, Lucentis as compared to Regeneron's spend with respect to Eylea?
MR. MARX: Same objection. Lack of foundation. This information was requested and it was not produced by Regeneron.
BY THE WITNESS:
A This all falls within the frustration that I just complained about in my last answer. I don't know because I don't have access to data that I would -- I would typically expect Regeneron to have provided IQVIA or Symphony data that would give me information regarding marketing spend, various categories of marketing spend, various categories of how that relates to, you know, Share of Voice and as a percentage of sales revenues, but I simply -- it wasn't made available to me.
MR. MARX: If I could interrupt, Mr. Caine.
If the videographer can confirm that we've gone seven hours on the record.
THE VIDEOGRAPHER: 6:59.

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MR. MARX: Okay.
BY MR. CAINE:
Q Mr. Hofmann, are you aware that among Eylea's -- marketing expenditure for Eylea, there has been direct-to-consumer marketing?
A There has.
MR. MARX: Objection. Lack of foundation.
BY MR. CAINE:
Q And have you seen direct-to-consumer television marketing?
MR. MARX: Same objection. Lack of foundation. Mylan requested this information, and Regeneron failed to produce it.
BY THE WITNESS:
A I don't -- I mean, like I said, the spotty amount of marketing materials that appeared in what was made available to me, there's seemingly some direct to consumer in some shape or form, but it's not the type of data set or information that I would normally expect to get in this type of situation.
BY MR. CAINE:

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Q Do you agree --
MR. MARX: Mr. Caine, I believe we ve gone seven hours on the record and you ve used your full time now.
MR. CAINE: Mr. Marx, I m going to leave the deposition open. I believe there s been an effort to obstruct the deposition, both unfortunately by yourself and Mr. Hofmann s answers or nonresponsive answers to my question.
So if your position is the deposition is going to stop right now, I understand your position, but I will not be closing the deposition at this time.
MR. MARX: On behalf of Mylan, we respectfully disagree. My objections have been appropriate all day long. You made the election to focus on issues that were not in Mr. Hofmann s report and his opinions, and that is for you to deal with. Otherwise, we disagree that this deposition remains open.
I do have some questions for redirect, but with respect to your direct -- your examination of

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Mr. Hofmann, it is closed per Mylan.
MR. CAINE: I think we've reflected our disagreement. Go ahead.
EXAMINATION
BY MR. MARX:
Q Mr. Hofmann, I know you have a lot of documents in front of you, just very brief questions. If we could look at Exhibit 2176, it was the January 29, 2021 ATU survey. Let me know when you have that document.
Mr. Manning {sic}, do you have Exhibit 7 in front of you?
A Hofmann.
Q Mr. Hofmann, yes.
Can you turn to Page 92 of this document?
A Okay.
Q Counsel for Regeneron asked you some questions about this page. On the right-hand side of this page, do you see a heading "Mean Frequency"?
A I do.
Q Mr. Hofmann, what is the mean frequency

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for the dosed interval for Eylea that is provided on this page notwithstanding Mylan's objections to the use of this document and also the caveats that you gave on the record?
A [redacted].
Q And is [redacted] less than eight weeks?
A It is.
Q And this implies, again, subject to your caveats, that [redacted] of the interval level for Eylea is less than eight weeks; is that correct?
MR. CAINE: Objection. Lacks foundation.
BY THE WITNESS:
A That's what this appears based on this subject and the caveats that I gave on the reliability of this data set.
BY MR. MARX:
Q Mr. Hofmann, if we could turn to Page 94 of this same document, Exhibit 2176.
Mr. Hofmann, do you see on Page 94 a similar heading, "Mean Frequency"?
A I do.

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Q Mr. Hofmann, what is the mean frequency for the dosing interval for Eylea that's provided on this page notwithstanding the caveats that you gave?
A [redacted].
Q And this information implies that [redacted] of Eylea doses are given at less than eight weeks; is that correct?
MR. CAINE: Objection. Lacks foundation.
BY THE WITNESS:
A That's what it appears.
BY MR. MARX:
Q Mr. Hofmann, if you could turn to the next page, Page 95 of Exhibit 2176.
A Yes.
Q Do you similarly see a "Mean Frequency" heading on the right-hand side of this page?
A I do.
Q What is the mean dosing frequency that's provided on this page for Eylea, again, notwithstanding your caveats and Mylan's objections to the use of this document?

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A [redacted].
Q This implies that [redacted] of the doses for Eylea are given at less than eight weeks; is that correct?
MR. CAINE: Objection. Foundation.
BY THE WITNESS:
A Yes.
BY MR. MARX:
Q Again, just generally, none of the information in Exhibit 2176 is correlated to the specific dosing schedule in the '338 patent; is that correct?
MR. MARX: Objection. Lacks foundation.
BY THE WITNESS:
A The language that I see there doesn't tie it specifically to '338, no.
BY MR. MARX:
Q Did Mr. Manning opine that information here is directly correlated to the '338 patent dosing schedule?
A No.
Q Mr. Hofmann, if you could pull up

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Exhibit 2140.
A Okay.
Q This is the November 2013 ATU. And if I could turn to Page 22 of this document, please.
A Yes.
Q I believe counsel directed you to the data point for Eylea for fixed dosing interval, it was [redacted] for every eight weeks.
Do you see that on this page?
A [redacted]. Yes, as a subset of the total dosing. So that's [redacted] of [redacted].
Q And that is approximately 12 percent?
A [redacted] to [redacted], somewhere in between.
Q And if you could look at the table that's provided in the bottom of this page, Page 22, with respect to the column for Eylea.
Do you see that the mean number of annual doses for PRN is [redacted]?
A Yes, yes.
Q And does that imply that physician's dose, Eylea, at least PRN, less than every eight weeks?
MR. CAINE: Objection. Foundation.

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BY THE WITNESS:
A Yeah, yeah, yeah. So the way to look at that is annual doses would be for as-needed, which is what PRN, I think, means, some Latin acronym for that. But that would get us to dividing 12 months for annual dosing is far less than eight weeks.
BY MR. MARX:
Q And the similar question with respect to the mean annual doses for T and E, do you see that the mean annual doses for T and E provided in this document, again subject to the caveats and Mylan's objections, is [redacted] annual doses for Eylea?
A That's what it says.
Q And that would imply that Eylea is dosed less than every eight weeks?
MR. CAINE: Objection. Foundation.
BY THE WITNESS:
A Yes. So if you, again, think about annual doses as 12 months, the [redacted] would be as annual doses would work out to far less than eight weeks.
BY MR. MARX:

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Q And then, Mr. Hofmann, do you see the last row on this table, overall dosing frequency. This document states Eylea's overall dosing frequency is [redacted].
Do you see that?
A I do see that.
Q And that is less than eight weeks?
A It is.
Q Again, Mr. Hofmann, with respect to Exhibit 2140, none of the data in this document was correlated or tied to the '338 patent by Dr. Manning?
A I didn't see anything in that regard, no.
Q Mr. Hofmann, if you could pull up Exhibit 2138.
This is the February 2013 physician ATU?
A Yes.
Q Again, subject to Mylan's objections and the caveats that you gave, if you could turn to Page 15 of this document.
A Okay.
Q And I believe you testified with respect

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to this page, at least, that the data here indicates that less than [redacted] of individuals who are dosed with Eylea are at every eight weeks or more.

Do you recall that testimony?

A I do.

Q And there's nothing on this page or no analysis that Dr. Manning provided that tied any of the data on this document to the '338 claimed; is that correct?

A Yes. Again, this is similar to what we looked at before where the [redacted] at eight weeks is [redacted] of [redacted], so it's a fraction of total Eylea sales.

Q You can set that document aside.

Do you recall at the very end Mr. Caine asked you about TV spots for Eylea?

A I do.

Q I'd like to play for the record a TV spot for Eylea.

(Video played.)

"Your eyes are a beautiful pair, and

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they've seen a lot together from the biggest events to countless new moments. Over time, diabetic macular edema, also known as DME, entered the picture. It brought some unwelcome symptoms like black spots, blurriness or wavy lines. But your eyes can fight back because there's more they want to see, and they have Eylea on their side. On average, people with DME gain ten more letters on the eye chart after one year on Eylea and still had these improvements a year later when staying on treatment.

"Do not use Eylea if you have an eye infection, eye pain or redness or known allergies to any ingredients in Eylea. Injection in the eye with Eylea can cause infection and separation of the retina. Eylea may cause an increase in eye pressure. Potential risk of fatal heart attack or stroke related to blood clots may occur. Serious side effects are rare. Most common side effects are eye pain, redness, cataract, decreased optimal field of vision and increased eye pressure and inner-eye gel detachment.

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"Fight for your eyes and ask your retina specialist if Eylea is right for you."

BY MR. MARX:

Q Mr. Hofmann, did Regeneron produce this advertisement in this matter?

A I don't recall seeing that, no.

Q Mr. Hofmann, having listened to this ad, did you hear anything in this advertisement about a dosing schedule or eight weeks dosing?

A No. It seemed to be focused on efficacy and safety.

MR. MARX: I have no further questions.

MR. CAINE: I have a couple of follow-ups.

MR. MARX: I'm sorry. Your seven hours on the record is done.

MR. CAINE: I get to recross after your redirect.

MR. MARX: No. You have to reserve time. You did not reserve time. You're done.

MR. CAINE: I get to follow up on your examination.

MR. MARX: No. You had to reserve time to

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do so. You did not. Your seven hours are done.

MR. CAINE: I m going to ask the question, and you can decide what you d like to do.

MR. MARX: Okay.

FURTHER EXAMINATION

BY MR. CAINE:

Q Mr. Hofmann, by virtue of the fact that Mr. Marx played that advertisement, I think we can both agree that the advertising is publicly available, right?

A Apparently so, yes.

MR. CAINE: Thank you.

THE VIDEOGRAPHER: Please stand by.

This marks the end of the deposition of Ivan Hofmann. We are going off the record at 6:04 p.m.

(Deposition concluded at 6:04 p.m. CST.)

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CERTIFICATE OF SHORTHAND REPORTER NOTARY PUBLIC

I, Theresa A Vorkapic, Certified Reporter and Notary Public within and for the State of Illinois do hereby certify:

That IVAN HOFMANN, the witness whose deposition is hereinbefore set forth,

Was duly sworn by me before the commencement of such deposition and that such deposition was taken before me and is a true record of the testimony given by such witness

I further certify that the adverse party, Regeneron, was represented by counsel at the deposition

I further certify that the deposition of IVAN HOFMANN, occurred at the offices of RMMS, LLP on Thursday, June 23, 2022, commencing at 9:06 a m to 6:04 p m CST

I further certify the inspection, reading and signing of said deposition was waived on the record by agreement of all parties

I further certify that I am not related to any of the parties to this action by blood

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or marriage, I am not employed by or an attorney to any of the parties to this action, and that I am in no way interested, financially or otherwise, in the outcome of this matter.

Theresa A Vorkapic

IN WITNESS WHEREOF, I have hereunto set my hand this 24th day of June, 2022.

Theresa A. Vorkapic
My commission expires 11/6/23.
NOTARY PUBLIC IN AND FOR THE COUNTY OF KANE, ILLINOIS

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