

Exhibit 10

1 IN THE UNITED STATES DISTRICT COURT
2 FOR THE NORTHERN DISTRICT OF
3 WEST VIRGINIA

4 Civil Action No. 1:22-cv-00061-TSK

5 -----X

6 REGENERON PHARMACEUTICALS, INC.,

7 Plaintiff,

8 -against-

9 MYLAN PHARMACEUTICALS INC.,

10 Defendant.

11 -----X

12 650 Fifth Avenue

New York, New York

13 December 16, 2022

14 9:12 a.m.

15
16 VIDEOTAPED HYBRID DEPOSITION of
17 KAREN CHU, a witness in the
18 above-entitled action, held at the above
19 time and place, taken before Dawn Matera,
20 a Shorthand Reporter and Notary Public of
21 the State of New York.

22 * * *

Page 2 1 A P P E A R A N C E S : (Continued) 2 3 WILLIAMS & CONNOLLY LLP 4 Attorneys for Regeneron Pharmaceuticals, 5 Inc. 6 680 Maine Ave S.W. 7 Washington, D.C. 20024 8 By: ELLEN E. OBERWETTER, ESQ. 9 eoberwetter@wc.com 10 KATHRYN S. KAYALI, ESQ. 11 kkayali@wc.com 12 13 RAKOCZY MOLINO MAZZOCHI SIWIK LLP 14 Attorneys for Mylan Pharmaceuticals 15 6 W. Hubbard Street 16 Suite 500 17 Chicago, Illinois 60654 18 By: DEANNE M. MAZZOCHI, ESQ. 19 dmazzochi@rmmslegal.com 20 (Remote Attendance) 21 JEFFREY A. MARX, ESQ. 22 jmarx@rmmslegal.com 23 HEINZ J. SALMEN, ESQ. 24 hsalmen@rmmslegal.com 25 (Remote Attendance) CAREY DOUGLAS KESSLER & RUBY PLLC Local Counsel for Regeneron Pharmaceuticals, Inc. 707 Virginia Street East 901 Chase Tower Charleston, West Virginia 25301 By: DAVID POGUE, ESQ. drpogue@cdkrlaw.com (Remote Attendance.)	Page 4 1 THE VIDEOGRAPHER: Good morning. 2 We are going on the record at 3 a.m. Eastern Standard Time. Please 4 note that the microphones are 5 sensitive and may pick up whispering 6 and private conversations. Please 7 mute your phones at this time. Audio 8 and video recording will continue to 9 take place unless all parties agree to 10 go off the record. 11 This is media unit 1 of the 12 video-recorded deposition of Karen Chu 13 taken by counsel in the matter of 14 Regeneron Pharmaceuticals, Inc. versus 15 Mylan Pharmaceuticals, Inc., filed in 16 the United States District Court for 17 the Northern District of West 18 Virginia, civil action number 19 1:22-CV-00061-TSK. 20 The location of this deposition 21 is in the offices of Williams & 22 Connolly, 650 Fifth Avenue, New York, 23 New York. My name is Zef Cota and I 24 am the videographer. The court 25 reporter is Dawn Matera, from the firm
Page 3 1 A P P E A R A N C E S : (Continued) 2 3 STEPTOE & JOHNSON PLLC 4 Local Counsel for Mylan 5 707 Virginia Street East 6 Chase Tower, 17th Floor 7 Charleston, West Virginia 25301 8 By: JOHN PIZZO, ESQ. 9 john.pizzo@steptoe-johnson.com 10 (Remote Attendance) 11 12 Also Present: 13 ADAM BERNSTEIN, Regeneron 14 PETRA SCAMBOROVA, Regeneron 15 ZEF COTA, Videographer 16 ~oOo~ 17 18 19 20 21 22 23 24 25	Page 5 1 of Veritext. 2 I am not authorized to 3 administer an oath. I am not related 4 to any party in this action nor am I 5 financially interested in the outcome. 6 Counsel and all present in the 7 room have been noted for the 8 stenographic record. 9 Will the court reporter please 10 swear in the witness and then counsel 11 may proceed. 12 K A R E N C H U, the Witness herein, 13 having first been duly sworn by the 14 Notary Public, was examined and testified 15 as follows: 16 EXAMINATION BY MS. MAZZOCHI: 17 Q. Thank you. Good morning, 18 Ms. Chu, my name is Deanne Mazzochi. 19 Can you please state your full 20 name and address for the record. 21 A. Yes, Karen Chu, and my home 22 address is 73 Richbell Road, White 23 Plains, New York 10605. 24 Q. Is this your first time given 25 testimony under oath?

Page 6 1 A. I previously gave testimony 2 under oath in a different case many, many 3 years ago. 4 Q. Okay. Do you recall -- did 5 that case involve Regeneron? 6 A. It did not. 7 Q. Did it involve any VEGF 8 inhibitors? 9 A. It did not. It involved a 10 personal liability suit against the 11 summer camp I went to. 12 Q. Have you participated at all in 13 any FTC proceedings prior to being 14 deposed in this case? 15 A. No, I have not. 16 Q. Have you been asked to provide 17 documents or records in connection with 18 any matter involving the United States 19 government and Regeneron? 20 A. I have not. 21 Q. How about any claims involving 22 a state government? 23 A. No, not that I am aware. 24 Q. How about any litigation 25 involving Regeneron and an insurer or an	Page 8 1 company here on the East Coast, Purdue 2 Pharma. And then worked for them for 3 approximately a little over two years 4 before moving to a small contract 5 research organization called Barton & 6 Polansky, located here in New York City. 7 After that, I joined a company 8 that was headquartered in Gaithersburg, 9 Maryland called GenVec. They were a gene 10 therapy company. And after I left -- I 11 was with GenVec for four years before 12 joining Regeneron. 13 Q. How did you get involved in or 14 what training did you receive in 15 connection with clinical -- human 16 clinical trials? 17 MS. OBERWETTER: Object to the 18 form. 19 You can answer it. 20 A. Okay. Just a clarification, 21 are you asking about training I received 22 throughout my career or specific to 23 Regeneron? 24 Q. Right, throughout your career, 25 because with an MS in nutrition, jumping
Page 7 1 HMO? 2 A. Not that I am aware of. 3 Q. Have you received any subpoenas 4 to appear before a state or federal grand 5 jury? 6 A. I have not received any 7 subpoenas. 8 Q. Can you please state for the 9 record your educational background post 10 high school? 11 A. Sure. I have a bachelor's of 12 science degree in biology from Cal Poly 13 San Luis Obispo and a master's in human 14 nutrition from Columbia University. 15 Q. And can you please describe 16 your employment history after you 17 graduated from Columbia University with 18 you are your MS in human nutrition? 19 A. Sure. After graduation and 20 completion of my degree, I joined a small 21 biotech company located in the San 22 Francisco Bay area called Seqirus 23 Pharmaceuticals. 24 After working at that company 25 for a little over a year, I moved to a	Page 9 1 into quality assurance roles and clinical 2 research roles such as at GenVec, you 3 know, how did you -- what type of 4 training did you get in order to -- 5 either in connection with those roles? 6 A. Sure. So the very first 7 position I had in clinical research was 8 as a clinical trial assistant. And as 9 part of my role I helped with the 10 operations of clinical trials and 11 received good clinical practice training 12 as part of my role. 13 So GCP training was provided 14 both by in-house individuals as well as 15 I've attended external courses on both 16 good clinical practice, as well as 17 international conference on harmonization 18 practices. 19 Q. Do you have any certifications 20 in connection with either clinical 21 practice work or the international 22 harmonization standards? 23 A. I do not hold any current 24 certifications. 25 Q. Have you previously?

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Page 10 1 A. Previously I did have a 2 certified contract research associate 3 certification. 4 Q. And how did you get that? 5 A. That required a certain number 6 of hours as well as taking an exam 7 through the Association of Clinical 8 Research Professionals. 9 Q. Is there a reason why you 10 allowed your certification on that to 11 lapse? 12 A. So in my over 25 years of 13 experience in clinical development, it 14 was not critical to the role I have now 15 and felt that it was not necessary to 16 keep that certification. 17 Q. All right. Tell me how you 18 came to be employed at Regeneron? 19 A. So the company I worked for 20 just prior to Regeneron, GenVec, was a 21 small biotechnology firm, and they were 22 having some, as many biotechnology 23 companies do, some troubles with funding 24 as well as some hiccups in terms of being 25 able to move products forward in their	Page 12 1 for a lot of small companies, in that 2 role wore several different hats and had 3 a broad range of responsibilities as it 4 related to clinical development. And 5 over the years moved into more of a 6 clinical project management role and then 7 finally into my current role. 8 Q. Okay. And was your initial 9 title, what was it, director of 10 therapeutic area, project management? 11 A. So that was not my first title 12 at Regeneron. 13 Q. Okay. What was your first 14 title? 15 A. My recollection is that my 16 first title was senior clinical trial 17 manager. But the director of therapeutic 18 area project management was a promotion 19 into a broader clinical project 20 management role. 21 Q. And then did you ever have any 22 individuals who reported to you in those 23 roles? 24 A. At the time that I was a 25 clinical trial manager I had a group of
Page 11 1 pipeline. And at the time I was working 2 both on a product they had in development 3 for oncology as well as ophthalmology. 4 And when the company conducted a round of 5 layoffs I personally was not laid off, 6 but it certainly signaled some 7 uncertainty in the company's future. I 8 made a decision to start looking 9 potentially for another position. 10 At the time I was already 11 living in the New York area and Regeneron 12 was very much in the news because of 13 their -- because of the VEGF-Trap 14 molecule and their work in oncology. And 15 so I networked with a friend of mine and 16 contacted a few people in the company to 17 see if they had a need for somebody with 18 my background. Dr. Jesse Cedarbaum was 19 the person who hired me first at 20 Regeneron. 21 Q. And then what was your initial 22 role and responsibilities at Regeneron? 23 A. So when I joined the company I 24 joined as a senior clinical trial 25 manager. And then as is true, I think,	Page 13 1 people that reported to me who, who were 2 more junior clinical trial managers and 3 involved in the operations of the 4 clinical trials. 5 Q. Okay. How do you differentiate 6 what your role was versus what you call 7 the operations of the clinical trials? 8 A. So within clinical research, 9 there are several people who contribute 10 to any aspect of conducting a clinical 11 trial. So the actual operations of the 12 clinical trial, which includes everything 13 from ensuring that clinical study sites 14 are identified and trained appropriately 15 to providing supplies for the clinical 16 study sites, to deciding which 17 laboratories to use or how labs will be 18 collected. That typically is considered 19 part of the operations role. So they're 20 really, that, you know, they really 21 oversee the actual execution of the 22 clinical trials. 23 Q. Okay. And then who -- when you 24 were at Regeneron, say, in the -- when 25 you first joined Regeneron, who was

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Page 14 1 responsible for the actual design of 2 clinical trials? 3 MS. OBERWETTER: Object to the 4 form. 5 You can answer. 6 A. Could you be more specific? Do 7 you mean broadly all clinical trials at 8 Regeneron or are you asking specifically 9 about trials with VEGF-Trap. 10 Q. Let's focus on VEGF-Trap. If I 11 call VEGF-Trap aflibercept, is that all 12 right as well? 13 A. That's all right. I understand 14 it to be the same molecule. 15 Q. Okay. Got it. So we can focus 16 on aflibercept? 17 A. At the time I joined Regeneron, 18 Dr. Jesse Cedarbaum was the vice 19 president responsible for designing 20 clinical trials, but all clinical trial 21 designs were also vetted with senior 22 management including individuals like Len 23 Schleifer and George Yancopoulos. 24 Q. Okay. And Len at the time was 25 the CEO?	Page 16 1 seen this document in the context of my 2 preparation for my deposition and this 3 does appear to be the '601 patent. 4 MS. MAZZOCHI: Great. Let me 5 put in front of you a document that 6 we'll mark as Defendant's Exhibit 5, 7 U.S. Patent Number is 11,253,572, and 8 can you confirm that Exhibit 5 placed 9 before you is the '572 patent? 10 (Defendant's Exhibit 5, U.S. 11 Patent Number 11,253,572, was so 12 marked for identification, as of this 13 date.) 14 MS. OBERWETTER: Can I just ask 15 by way of exhibit numbering, are these 16 sequential of what happened yesterday? 17 MS. MAZZOCHI: Ellen, because we 18 have so many depositions going on, 19 several of the exhibits that we know 20 are likely to get used over and over 21 again, we've premarked them. So we're 22 not marking the same one over and 23 over. 24 MS. OBERWETTER: That's fine. 25 MS. MAZZOCHI: With different
Page 15 1 A. Yes, Dr. Schleifer was the CEO 2 then as he is now. 3 Q. And George Yancopoulos was the 4 senior, I think, chief scientific 5 officer? 6 A. I actually don't remember what 7 his title was when I joined the company, 8 but his current title is chief scientific 9 officer. 10 MS. MAZZOCHI: That's fine. I 11 would like to put in front of you a 12 document I will mark as Defendant's 13 Exhibit 4, which is United States 14 patent number 10,888,601B2. If you 15 can just confirm that's a document 16 that was put in front of you. 17 (Defendant's Exhibit 4, United 18 States Patent Number 10,888,601 B2, 19 was so marked for identification, as 20 of this date.) 21 Q. Have you confirmed that you 22 have seen that document before and that 23 Exhibit 4 is the '601 patent? 24 (Witness reviews document.) 25 A. I can confirm that yes I have	Page 17 1 numbers. 2 MS. OBERWETTER: Okay. Makes 3 sense. 4 A. So, sorry, Deanne, can you ask 5 your question again? 6 Q. Sure. Ms. Chu, can you just 7 confirm Exhibit 5 placed before you is 8 the '572 patent? 9 A. Yes, this appears to be the 10 '572 patent. 11 Q. And you have seen this document 12 before? 13 A. I have seen this document in 14 preparation for this deposition. 15 MS. MAZZOCHI: Okay. And let me 16 provide you with a document that I 17 will mark as DX 200, which is titled 18 "Plaintiff's Rule 26(a) Initial 19 Disclosures." 20 (Defendant's Exhibit 200, 21 Plaintiff's Rule 26(a) Initial 22 Disclosures, was so marked for 23 identification, as of this date.) 24 Q. And can you confirm the 25 document before you marked as DX 200 is

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Page 18 1 titled "Plaintiff's Rule 26(a) Initial 2 Disclosures"? 3 MS. OBERWETTER: Object to the 4 foundation. 5 You can answer. 6 A. So I can confirm that the 7 document says Plaintiff's Rule 26(a) 8 Initial Disclosures. 9 Q. Okay. If you can take a look 10 at the third page of the exhibit, there 11 is a table there and the second entry in 12 the table says Karen Chu. Let me know 13 when you've gotten to that entry? 14 A. I see that entry. 15 Q. Okay. Now it states, for you, 16 Karen Chu, that one of the subject 17 matters that you have knowledge of is the 18 conception and reduction of practice of 19 the inventions disclosed and/or claimed 20 in the '879, '338, '069, '681, '205, '601 21 and '572 patents and the clinical 22 properties of aflibercept. 23 Do you see that? 24 A. I do see that. 25 Q. Do you know if that's a true	Page 20 1 mind, the term "conception" when it comes 2 to any inventions disclosed? 3 MS. OBERWETTER: Object to the 4 form. 5 A. I mean, I understand the word 6 and what it could mean. 7 Q. Okay. What's your 8 understanding? 9 MS. OBERWETTER: Object to the 10 form. 11 You can answer it. 12 A. Okay. Obviously, the 13 conception would be certainly the idea or 14 the decision to move forward with any 15 specific aspect of a clinical study 16 design or development for a product. 17 Q. And what's your understanding 18 of the term "reduction to practice" when 19 it comes to the inventions disclosed in 20 the patents listed here in association 21 with you? 22 MS. OBERWETTER: Object to the 23 form and foundation. 24 You can answer. 25 A. I don't think I can adequately
Page 19 1 statement, that you have knowledge on 2 those issues? 3 MS. OBERWETTER: Object to the 4 foundation with this witness. 5 You can answer. 6 A. So it's difficult for me to 7 answer this question because I don't know 8 precisely the content of the listed 9 patents, as well as the legal concept of 10 conception and reduction of practice are 11 not terms I am familiar with. 12 Q. Okay. Well, do you have a 13 layperson's understanding of conception 14 and reduction to practice? 15 MS. OBERWETTER: Object to the 16 form. 17 A. I don't know what the 18 layperson's understanding of those would 19 be. However, I can say that my entire 20 almost 20-year career at Regeneron was in 21 clinical development of aflibercept. 22 Q. Okay. All right. Well, maybe 23 we can get at it this way. 24 Do you have an understanding as 25 to what it means, you know, in your own	Page 21 1 speak to the meaning of that phrase. 2 Q. Right. I am just asking for 3 your understanding. Do you have any 4 understanding as to what that term means? 5 MS. OBERWETTER: Same objection. 6 A. I have a very rudimentary 7 understanding of what that means -- 8 Q. Okay. 9 A. -- in the context of the 10 patent. 11 Q. What's your understanding? 12 MS. OBERWETTER: Same objection. 13 A. Just that the reduction to 14 practice of the inventions would mean how 15 exactly the patent translates to the 16 products used. 17 Q. Do you have an understanding of 18 whether you will be called to testify at 19 trial in this case? 20 MS. OBERWETTER: Object to the 21 form and foundation. 22 A. My understanding is that I am 23 on the witness list but I am not aware 24 that it's been confirmed that I would be 25 called to testify.

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Page 22 1 Q. Okay. Do you have any 2 understanding as to what types of issues 3 we can expect you to offer testimony on 4 when it comes to trial in this case? 5 MS. OBERWETTER: Object to the 6 form and foundation. 7 To the extent your answer would 8 reveal any discussions with counsel, 9 calls for attorney/client privileged 10 information and work product. 11 Q. You can answer. 12 A. Sorry, could you ask your 13 question again? 14 Q. Sure. Do you have any 15 understanding of what types of issues you 16 will be offering -- you will be offering 17 testimony on during trial in this case? 18 MS. OBERWETTER: Object to the 19 foundation. Same objection I just 20 made. 21 To the extent your answer would 22 reveal any discussions with counsel, 23 instruct the witness not to answer. 24 Q. You can answer. 25 A. My understanding is that I	Page 24 1 exactly this witness is going to be 2 offering factual testimony on at 3 trial. So if she has an understanding 4 as to why and what facts she's going 5 to be, or what issues she's going to 6 be discussing at trial, we have a 7 right to know and that doesn't -- that 8 doesn't invade any of your 9 conversations that you may have had 10 with her. 11 MS. OBERWETTER: That's 12 completely incorrect. So please reask 13 your question and I will make the 14 appropriate instruction. 15 MS. MAZZOCHI: Sure. 16 Q. Outside of any conversations 17 that you had with counsel, do you have 18 any understanding as to what types of 19 issues you might be discussing at trial 20 in this case? 21 MS. OBERWETTER: Object to the 22 foundation. 23 Q. You can answer. 24 A. My only understanding of my 25 role is that I would be offering --
Page 23 1 would be asked questions -- 2 MS. OBERWETTER: You are 3 instructed not to answer if it 4 would -- if it would reveal any 5 discussions with counsel. 6 THE WITNESS: Okay. 7 MS. MAZZOCHI: Fine. 8 Q. Separate and apart from your 9 discussions with counsel, do you have any 10 understanding as to what knowledge you 11 are going to be offering at trial in this 12 case? 13 MS. OBERWETTER: Deanne, you 14 know this is improper. 15 MS. MAZZOCHI: Actually, Ellen, 16 I don't know that it's improper 17 because we, you know, she just 18 indicated that you identified her as 19 someone who had knowledge on 20 conception and reduction to practice 21 issues and she doesn't necessarily 22 know what that means. 23 We're in the discovery phase in 24 a very expedited schedule. We are 25 trying to get an understanding of what	Page 25 1 MS. OBERWETTER: To the 2 extent -- Ms. Chu, to the extent your 3 answer is informed by conversations 4 with counsel, I will instruct you not 5 to answer. 6 THE WITNESS: Okay. 7 A. I would prefer not to answer 8 based on counsel instructions. 9 Q. Well, are you saying that you 10 have no information to give outside of 11 any conversations you had with legal 12 counsel? 13 A. In regards to this specific 14 topic, that is correct. 15 Q. And just with regard to your 16 role or experience with aflibercept, to 17 the extent it might relate to any of 18 these patents, you don't have any 19 knowledge or understanding outside of 20 your conversations with counsel as to 21 what topics or issues you might have 22 knowledge of to testify about at trial? 23 MS. OBERWETTER: Object to the 24 form and foundation of the question. 25 MS. MAZZOCHI: You can answer.

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Page 26 1 A. Can you ask the question again, 2 please? 3 MS. MAZZOCHI: Yeah, I will ask 4 the court reporter to repeat it, 5 please. 6 (The record was read as follows: 7 "Question: And just with regard 8 to your role or experience with 9 aflibercept, to the extent it might 10 relate to any of these patents, you 11 don't have any knowledge or 12 understanding outside of your 13 conversations with counsel as to what 14 topics or issues you might have 15 knowledge of to testify about at 16 trial?") 17 MS. OBERWETTER: Same objection. 18 A. So outside of my conversations 19 with counsel, I have spent almost 20 20 years at Regeneron working on the 21 development of aflibercept, most 22 specifically in ophthalmology. 23 Q. Okay. And, again, setting 24 aside any conversations or knowledge that 25 you gained from counsel, do you have any	Page 28 1 circumstances that lead to the invention 2 of anything set forth in this '601 patent 3 that you might testify to at trial. 4 MS. OBERWETTER: Is there a 5 question? 6 MS. MAZZOCHI: Yeah, I am asking 7 her to identify what knowledge she 8 might have relating -- that she could 9 potentially testify to at trial 10 relating to the circumstances 11 involving the inventions set forth in 12 the '601 patent, DX 4. 13 MS. OBERWETTER: May I suggest, 14 do you want to just ask her what she 15 knows instead of asking her about what 16 she might testify to at trial? 17 MS. MAZZOCHI: No, because, 18 Ellen, our concern is that we don't 19 necessarily know why this witness 20 would be the person called to testify 21 on various issues in connection with 22 these patents at trial because she's 23 not listed as the named inventor. So 24 we want to get an understanding so 25 we're not surprised at trial, as to,
Page 27 1 understanding as to what issues or topics 2 you might be testifying about with regard 3 to the aflibercept molecule that would be 4 relevant to any of these patents? 5 MS. OBERWETTER: Again, outside 6 of any conversations with counsel, to 7 the extent you can answer. 8 A. Yeah, I do not have any 9 knowledge outside of conversations with 10 counsel. 11 Q. Okay. Do you have any 12 knowledge relating to the circumstances 13 leading to the invention of what's 14 described in the '601 patent that's 15 before you, DX 4? 16 MS. OBERWETTER: Object to the 17 form and foundation. 18 You can answer. 19 A. Could you be more specific 20 about what aspect of the patent you're 21 referring to? 22 Q. Well, I think that's part of 23 the problem. You know, I'm trying to get 24 an understanding as to where you might 25 actually have knowledge relating to the	Page 29 1 you know, what knowledge or facts she 2 may have relating to the circumstances 3 involving the invention of the '601 4 patent, inventions set forth in the 5 '601 patent. 6 MS. OBERWETTER: There are ways 7 that do that don't involve asking her 8 what she would testify about at trial. 9 I have no interest in disrupting 10 your examination. There are ways to 11 do it where I don't have to object 12 every time, because you're asking her 13 what she's going to testify about at 14 trial, which is not something this 15 witness possibly could know. She 16 knows what she knows. You can ask her 17 about what she knows. 18 MS. MAZZOCHI: Well, I like 19 the -- the frame of my questions 20 stand. 21 MS. OBERWETTER: All right. 22 Q. You can answer. 23 MS. OBERWETTER: What's the 24 pending question? 25 MS. MAZZOCHI: I'll ask the

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Page 30 1 court reporter to read it back. 2 (The record was read as follows: 3 "Question: I'm trying to get an 4 understanding as to where you might 5 actually have knowledge relating to 6 the circumstances that lead to the 7 invention of anything set forth in 8 this '601 patent that you might 9 testify to at trial.") 10 MS. OBERWETTER: Object to the 11 form and foundation. 12 A. So the claims in the '601 13 patent cover methods and treatment for 14 age-related macular degeneration, 15 diabetic macular edema and 16 diabetic retinopathy with aflibercept. 17 And in my role at Regeneron, I was part 18 of the team that designed the studies and 19 conducted the studies related to these 20 claims in the patent. 21 Q. Okay. Do you have any 22 understanding as to what part of that 23 design process was inventive? 24 MS. OBERWETTER: Object to the 25 form and foundation.	Page 32 1 potential advantages and designed the 2 trial in a way that we felt we could 3 demonstrate those unique properties to 4 the best extent possible. 5 Q. Do you recall any unusual 6 obstacles or anything that you had to 7 overcome when designing the clinical 8 trials for aflibercept particularly with 9 regard to uses in the eye? 10 MS. OBERWETTER: Object to the 11 form. Compound. And it appears to 12 sweep in every trial for aflibercept. 13 Q. You can answer. 14 A. Sorry, can you just repeat your 15 question one more time? 16 Q. Sure. Do you recall there 17 being any particular obstacles or 18 challenges that you encountered when 19 designing any clinical trials for 20 aflibercept in the eye? 21 MS. OBERWETTER: Object to the 22 form. 23 A. So that's a very broad 24 question. I'm not sure I can answer it 25 adequately. Just to say that in
Page 31 1 A. I'm not sure I completely 2 understand the use of the word 3 "inventive" in your question. Could you 4 be more specific? 5 Q. Sure. Again, I'm just trying 6 to get at what are identified as alleged 7 inventions in Defendant's Exhibit 4, the 8 '601 patent. You said that in your role 9 you participated in the design of the 10 studies, for example. 11 Can you tell me anything that 12 you recall about anything inventive or 13 unique, or new or different about those 14 particular trials that relate to the 15 inventions set forth in the '601 patent? 16 MS. OBERWETTER: Object to the 17 form and foundation. 18 You can answer that, if you can. 19 A. Certainly with every new 20 molecule, the properties of the molecule 21 as well as considerations around its 22 clinical use go into the design of any 23 trial. 24 And Eylea represented a new 25 anti-VEGF treatment that we felt had real	Page 33 1 designing any clinical trial there are 2 various challenges that one considers or 3 faces. 4 In the aflibercept clinical 5 trials some of those had to do with 6 clinical practice that -- at the time, as 7 well as considerations around how, how to 8 optimally design the trials to 9 demonstrate, you know, the optimal 10 outcomes for both patients and for the 11 product itself. 12 Q. Was the hardest part -- let me 13 rephrase it. 14 When it comes to clinical 15 trials, is the hardest part the design 16 process, in your opinion? 17 MS. OBERWETTER: Object -- 18 Q. Or in your experience? 19 MS. OBERWETTER: Object to the 20 form. 21 A. In my experience every aspect 22 of clinical development comes with 23 different challenges, so I can't say that 24 design is necessarily the hardest part, 25 because there are different challenges

Page 34 1 along the entire clinical development 2 spectrum. 3 Q. Okay. Well, is it fair to say, 4 though, that by the time Regeneron did 5 actually commit to a particular clinical 6 trial design, it represented the best 7 efforts based on the best information 8 that Regeneron had at that time? 9 MS. OBERWETTER: Object to the 10 form, foundation. 11 You can answer it. 12 A. I can say that at the time that 13 we designed clinical trials we try to 14 take into consideration the best 15 information we have at the time for both 16 internal and external sources to design 17 the best trials that we can. 18 Q. And is it fair to say that your 19 clinical trials were designed to try to 20 optimize or maximize the chance of 21 success? 22 MS. OBERWETTER: Object to the 23 form. 24 A. So I think it's true that in 25 clinical development you're always trying	Page 36 1 A. So, again, every clinical 2 trial, you know, we try to design it for 3 success. But there is always a risk that 4 a clinical trial would fail for one 5 reason or another, whether that's safety 6 or efficacy. 7 Q. Okay. When it comes to 8 aflibercept, were there any clinical 9 trials you designed that led to failure 10 as opposed to success? 11 MS. OBERWETTER: Object to the 12 form. 13 Q. With regard to the 14 ophthalmology category? 15 MS. OBERWETTER: Same objection. 16 A. Can I ask for some limitations 17 on the extent of my answer? Is there a 18 time frame that we are referring to? 19 Q. Sure, let's say 2006 forward. 20 MS. OBERWETTER: Same objection. 21 A. So actually, most recently 22 Regeneron has reported two clinical 23 trials with aflibercept that did not meet 24 their primary endpoint. 25 Q. And which were those?
Page 35 1 to maximize your chances of success. 2 Q. Would Regeneron have followed 3 or pursued a clinical trial that it 4 thought it was going to fail? 5 MS. OBERWETTER: Object to the 6 form. 7 A. So there is always a risk of 8 failure. Clearly, you know, the -- 9 especially for Phase III trials, there is 10 a statistical threshold that you must 11 meet and there's always a chance that you 12 would not meet that for various reasons. 13 So I don't think it's true that 14 Regeneron would not have pursued a trial 15 that had a chance of failure. 16 Q. Yeah, maybe we can phrase it 17 this way. Is it fair to say that in your 18 time at Regeneron, if Regeneron was going 19 to pursue a clinical trial, they believed 20 they would be able to meet that, the 21 clinical endpoints they put in place? 22 They wouldn't have spent the money on a 23 clinical trial if they didn't? 24 MS. OBERWETTER: Object to the 25 form.	Page 37 1 A. Those are trials in the 2 treatment of retinopathy of prematurity. 3 Q. And what was the dosing regimen 4 for those? 5 A. It's .4 milligrams either 6 unilaterally or bilaterally for up to 7 three monthly doses. 8 Q. When you say for up to three 9 monthly doses, you mean with three 10 monthly doses or doses separated by three 11 months between them? 12 A. Sorry. In retinopathy of 13 prematurity physicians treat initially 14 with a single dose. If that does not 15 regress the retinopathy of prematurity 16 sufficiently, they can give a second dose 17 a month later and a third dose a month 18 later with similar considerations. 19 Q. Does Regeneron have any 20 understanding as to why that trial 21 failed? 22 MS. OBERWETTER: Object to the 23 form. 24 You can answer. 25 A. The laser comparator group in

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Page 38 1 those studies overperformed compared to 2 historical controls. And the design of 3 those studies was based on a very 4 conservative noninferiority margin. So 5 from a statistical perspective we did not 6 meet our noninferiority margin. 7 Q. Okay. And has Regeneron 8 proposed any studies of aflibercept for 9 purposes of securing a pediatric 10 extension? 11 A. These studies were conducted 12 under a pediatric written request issued 13 by the FDA and we were awarded a 14 pediatric exclusivity extension this 15 fall. 16 Q. Okay. Was the FDA responsible 17 for any aspect of the clinical trial 18 design on this one? 19 MS. OBERWETTER: Object to the 20 form. 21 A. By virtue of the fact that we 22 conducted the trials under a pediatric 23 written request, the FDA, as well as the 24 pediatric committee, designates specific 25 aspects of the trials that they wish us	Page 40 1 A. Not that I'm aware of. 2 MS. MAZZOCHI: Okay. Let me 3 mark as Defendant's Exhibit 201 a 4 document titled "Regeneron's 5 stipulation regarding case narrowing 6 and injunctive relief." 7 (Defendant's Exhibit 201, 8 Regeneron's stipulation regarding case 9 narrowing and injunctive relief, was 10 so marked for identification, as of 11 this date.) 12 A. So I see the document in front 13 of me. It says, "Regeneron's stipulation 14 regarding case narrowing and injunctive 15 relief." 16 Q. Okay. And there is two patents 17 that are listed here that were also on 18 those initial disclosures where you are 19 identified as having knowledge of the 20 conception or reduction of practice. One 21 is 10,888,601 at line number 1 and at 22 line number 5, 11,253,572. 23 Have you done preparation to be 24 able to testify about the conception and 25 reduction of practice in connection with
Page 39 1 to complete. 2 Q. Okay. Was this a trial that 3 Regeneron thought would have any 4 particular commercial benefits? 5 MS. OBERWETTER: Object to the 6 form. 7 A. I can't speak to the commercial 8 valuation in this case. 9 Q. Was Regeneron hoping to get a 10 pediatric clinical indication on its 11 label as a result of this particular 12 trial that it ran to get the pediatric 13 extension? 14 MS. OBERWETTER: Object to the 15 form. 16 A. Yes, Regeneron hoped to be able 17 to commercialize aflibercept for the 18 treatment of retinopathy in prematurity. 19 Q. Okay. So besides this 20 particular study that Regeneron conducted 21 for the -- at the request of the FDA for 22 pediatric patients, are there any other 23 studies that Regeneron has pursued for 24 aflibercept in the eye that have failed 25 to meet their clinical endpoints?	Page 41 1 the '601 and '572 patents? 2 MS. OBERWETTER: Object to the 3 form and foundation. 4 A. I think I have a limited 5 understanding of the legal concept of 6 conception and reduction to practice. So 7 I'm not sure that I can fully answer your 8 question. 9 Q. Well, let's take a look at a 10 document that I will mark -- do you have 11 an understanding that you've been 12 designated to testify on behalf of 13 Regeneron as what's referred to as a Rule 14 30(b)(6) witness? 15 MS. OBERWETTER: I'm just going 16 to interpose for a moment. You know, 17 you all have our position on the 18 30(b)(6) topics that you sent over, 19 which are really two things, that the 20 notice is abusively overbroad and 21 defective. In our view it's not a 22 valid 30(b)(6) notice. 23 It is also the case that we are 24 trying to get you the information that 25 you need and that you're entitled to

Page 42 1 in this case and this witness is well 2 equipped to do that. So I don't know 3 exactly how you're intending to use 4 the 30(b)(6) topics in this 5 examination. You obviously have our 6 objections on those. 7 So I'll let you proceed. I may 8 ask for a running objection so that I 9 do not interfere with your questions. 10 MS. MAZZOCHI: I understand that 11 Regeneron has put in the record, in a 12 letter addressed to Mylan, that they 13 object in various ways to our 30(b)(6) 14 deposition topics. But nonetheless, 15 Regeneron has indicated that Ms. Chu 16 would be identified as a responsive 17 witness for various of these topics. 18 I understand you have an objection to 19 them generally. Let's try to at least 20 go through them and see what Ms. Chu 21 actually has some knowledge and can 22 testify to. 23 MS. OBERWETTER: I would say our 24 position is not exactly as you just 25 stated. It's as set forth in the	Page 44 1 topics." 2 Q. Okay. Now, one of the topics 3 for which you were designated, obviously 4 understanding that counsel has objections 5 to the scope of the topic generally, was 6 conception, development and reduction of 7 practice associated with the method-of- 8 treatment patents. 9 And is it your understanding 10 that the method-of-treatment patents are 11 the '601 and the '572 patents, DX 4 and 12 5? 13 MS. OBERWETTER: I'm going to 14 object again. I think topic number 1 15 is not actually what was written in 16 topic number 1 of the 30(b)(6) topics 17 that were sent over. So our letter 18 modifies the scope of what we said 19 Ms. Chu might be in a position to 20 address. 21 Q. You can answer, Ms. Chu. 22 A. Can you restate your question, 23 please. 24 Q. Well, let's try to get at it 25 this way. For the method-of-treatment
Page 43 1 letter that I sent. 2 MS. MAZZOCHI: Well, it was a 3 lengthy letter, so I'm not going to 4 read it all into the record. 5 Q. Let me put before you a 6 document that I'm going to mark as 7 Defendant's Exhibit 202, which is a list 8 of our deposition topics for which, 9 Ms. Chu, you are identified as someone 10 who has knowledge. 11 MS. MAZZOCHI: And of course 12 with the understanding, Counsel, that 13 you issued a far more lengthy 14 objection letter that goes along with 15 this. 16 (Defendant's Exhibit 202, Karen 17 Chu 30(b)(6) deposition topics, was so 18 marked for identification, as of this 19 date.) 20 Q. All right. Ms. Chu, can you 21 just confirm that you have a document 22 before you marked DX 202 that is marked 23 Karen Chu, 30(b)(6) deposition topics? 24 A. Yes, the title of the document 25 is "Karen Chu 30(b)(6) deposition	Page 45 1 patents, do you have an understanding 2 that those in this case are the '601 and 3 '572 patents marked as DX 4 and DX 5 4 before you? 5 A. I'm aware that the patent '601 6 and '572 are both method-of-treatment 7 patents. 8 Q. Okay. And what did you do to 9 prepare to discuss the conception of any 10 inventions set forth in the '601 patent 11 on behalf of Regeneron? 12 MS. OBERWETTER: Object to the 13 form. 14 You can answer. 15 A. So in preparation, I spoke -- I 16 had meetings with Neil Stahl and George 17 Yancopoulos briefly, on Monday. And then 18 reviewed documents with counsel on 19 Wednesday and Thursday. 20 Q. The documents that you reviewed 21 with counsel, were any of them new to you 22 or had you seen them before? 23 A. Some of the documents were new 24 to me. 25 Q. What were the documents -- did

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Page 46 1 you get any -- what information were you 2 provided to prepare for this deposition 3 that was new to you with regard to the 4 issue of conception of the '601 patent? 5 MS. OBERWETTER: Object to the 6 form. 7 You can answer. 8 A. So the preparation for the 9 deposition was not specifically directed 10 at one patent over any other topic. So I 11 can't answer specifically what documents 12 I prepared in response to the '601 patent 13 specifically. 14 Q. What is Regeneron's position as 15 to the circumstances relating to the 16 conception of any inventions set forth in 17 the '601 patent? 18 MS. OBERWETTER: Object to the 19 form and foundation with this witness. 20 A. Can you ask me the question in 21 terms I could understand better? I feel 22 there is a lot of legal jargon. 23 Q. I'm trying to stick with 24 conception. That's what you were 25 identified as having knowledge on in the	Page 48 1 set forth in the '601 patent? And to 2 make it easier, you can take a look at 3 the '601 patent Claim 1, if that's 4 helpful. 5 MS. OBERWETTER: Object to the 6 form and foundation with this witness. 7 You can answer. 8 A. So Claim 1 in the '601 patent 9 details the dosing regimen for 10 age-related macular degeneration, which 11 included an initial 2 milligram dose 12 every four weeks for the first three 13 months, followed by 2 milligrams 14 approximately once every eight weeks or 15 every two months. That relates to the 16 design of the VIEW 1 and VIEW 2 clinical 17 trials of which I participated in 18 discussions regarding the study design. 19 I don't recall specifically the 20 meetings or exactly the decisions that 21 were made around the study design. But 22 more generally, this would have been a 23 discussion between the clinical study 24 team as well as our regulatory 25 colleagues, and we would have discussed
Page 47 1 initial disclosures and that's one of the 2 topics you were designated on. 3 So, again -- and if you don't 4 know, you don't know, but do you have an 5 understanding as to what Regeneron's 6 position is as to the circumstances that 7 led to the conception of any inventions 8 set forth in the '601 patent? 9 MS. OBERWETTER: Object to the 10 characterization. There are all sorts 11 of questions you could be asking this 12 witness that don't involve words that 13 she has told you repeatedly she is not 14 proficient with. 15 You can answer. 16 A. So the '601 patent covers 17 several indications, age-related macular 18 degeneration, diabetic macular edema and 19 diabetic retinopathy. I can speak to the 20 fact that I was involved in discussions 21 related to the design of these clinical 22 trials and the claims, to the extent that 23 they support the patent claims. 24 Q. Do you know who came up with 25 the idea for the dosing regimens that are	Page 49 1 any proposals with our senior management 2 to gain approval. 3 Q. Right. But who was the 4 individual who ultimately came up with 5 the idea of dosing 2 milligrams 6 approximately every four weeks for the 7 first three months and then the 2 8 milligram dose approximately every eight 9 weeks once every two months thereafter? 10 MS. OBERWETTER: Object to the 11 form. 12 You can answer. 13 A. So again, Regeneron operates in 14 a, you know, cross-functional team 15 environment, so there was input given by 16 many different functions and many 17 different people. But George Yancopoulos 18 and Len Schleifer were definitely heavily 19 involved in these discussions and no 20 approval would have been needed to be 21 given by George to move ahead with the 22 study design. 23 Q. Right. I understand they had 24 to give approval, but who actually came 25 up with the idea of this particular

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Page 50 1 regimen in Regeneron's view? 2 A. I don't recall. 3 Q. Do you know whether any 4 invention disclosure forms were prepared 5 in connection with the '601 patent? 6 A. I don't know if any invention 7 disclosure forms were prepared. 8 Q. Do you know if any information 9 disclosure forms -- I'm sorry, invention 10 disclosure forms were ever prepared in 11 connection with the regimen, generally, 2 12 milligrams, approximately, every four 13 weeks for the first three months followed 14 by 2 milligrams approximately every eight 15 weeks or every two months thereafter? 16 A. I don't know if any invention 17 disclosure forms were prepared. 18 Q. And is it fair to say that in 19 connection with your preparation for this 20 deposition today, you didn't see any 21 invention disclosure forms? 22 A. In my preparation for the 23 deposition, I did not see any invention 24 disclosure forms. 25 Q. When it comes to DX 5, the '572	Page 52 1 what has been posed with reasonable 2 particularity. Is that acceptable? 3 MS. MAZZOCHI: I think to ensure 4 that the record is clear on a going- 5 forward basis, why don't you just say, 6 you know, objection, not speaking for 7 Regeneron or something along those 8 lines, so I have clarity as to where 9 she's talking on her own as opposed to 10 responsive to the 30(b)(6) topics? 11 MS. OBERWETTER: Well, I believe 12 the clarity should be she's speaking 13 on her own unless you have clarified 14 that it's a 30(b)(6) question. 15 Because I can't tell when you're 16 switching back and forth. 17 Q. All right. So to Regeneron's 18 knowledge -- 19 MS. OBERWETTER: I don't want to 20 disrupt with every -- if you want me 21 to object every time, I will. I would 22 rather not. 23 MS. MAZZOCHI: Well, I would 24 like the record to be clear as to what 25 Regeneron is or isn't doing, is or
Page 51 1 patent, would your answers be the same 2 with regard to who came up with the 3 actual -- what person actually came up 4 with the actual specific regimen listed 5 in the claims? 6 A. Again, this patent covers 7 multiple indications, could you be more 8 specific? 9 Q. I'm just talking about the 10 dosing regimen to begin with. 11 A. So yes, my answer is the same 12 in that I can give you an idea of what 13 the process was for discussions, but I 14 don't recall a specific meeting or moment 15 where the decision was made regarding 16 this dosing regimen. 17 MS. OBERWETTER: I would add at 18 this point, to the extent that 19 you're -- I think I clarified this 20 adequately earlier -- if you're 21 treating these as topics you're 22 purporting to ask her under the 23 30(b)(6), I will take a running 24 objection and we are objecting to 25 every question about the scope and	Page 53 1 isn't objecting to, and frankly, you 2 know, for the record, you were the 3 ones who identified her as having 4 knowledge on conception and reduction 5 to practice with no caveats or legal 6 qualifications or anything along those 7 lines. Our Rule 30(b)(6) notice was 8 directly in response to that, on that 9 particular topic, is directly 10 responsive to how you designated her 11 in your initial disclosures. You 12 haven't amended those disclosures. We 13 relied on those disclosures. For 14 Regeneron now to, all of a sudden, 15 take the position, oh, gee, talking 16 about conception, reduction of 17 practice, et cetera, et cetera is 18 somehow improper, we think that 19 objection and position is improper. 20 And if we need to go to the Court to 21 try to get this resolved, we will do 22 that, but that's exactly why I want to 23 make sure this record is in fact clear 24 as to, you know, this is -- this is 25 entirely basically a problem of

Page 54 1 Regeneron's own making in my opinion. 2 But we will continue on. 3 MS. OBERWETTER: I have a 4 difficult time thinking that our 5 position isn't clear from the detailed 6 letter that I wrote. 7 So I will object, I will object 8 on -- I will do a shorthand to make 9 this as not obstructive as possible. 10 I will say object to the form and 11 30(b)(6) objection, I guess, to every 12 question. I would rather not. 13 MS. MAZZOCHI: Okay. 14 Q. All right. So Ms. Chu, when it 15 comes to Regeneron's position with regard 16 to the '601 patent, does Regeneron have a 17 position as to who was responsible for 18 the conception of the full claims set 19 forth in Claim 1 of the '601 patent? 20 MS. OBERWETTER: Object to the 21 form. Foundation. 30(b)(6) 22 objection. 23 A. George Yancopoulos is the named 24 inventor on the '601 patent. 25 Q. And why does Regeneron believe	Page 56 1 design. 2 A. So my knowledge is that George 3 had tremendous input and ultimately it 4 was his decision to move forward with the 5 final study design for the VIEW 1 and the 6 VIEW 2 studies. 7 Q. Any other reason why its 8 Regeneron's position that George 9 Yancopoulos is the person who allegedly 10 conceived of the method in Claim 1? 11 MS. OBERWETTER: Object to the 12 form. Foundation. 13 Q. In the '601 patent? 14 MS. OBERWETTER: And a 30(b)(6) 15 objection. 16 A. So, again, George was regularly 17 involved in discussions regarding the 18 product and development plans and gave 19 tremendous input in terms of ultimately 20 what the study design was for the VIEW 1 21 and 2 trials which supported the claims 22 in the '601 patent. 23 Q. Are there any documents that 24 showed that it was George Yancopoulos as 25 opposed to someone else who specifically
Page 55 1 that George Yancopoulos is the person who 2 conceived of the methods set forth in 3 Claim 1 of the '601 patent? 4 MS. OBERWETTER: Object to the 5 form. Foundation. 30(b)(6) 6 objection. 7 A. George has always and continues 8 to play a very hands-on role in all 9 research and development, including the 10 development of aflibercept, and he was 11 personally involved in many, many 12 discussions related to the development of 13 aflibercept across all phases of clinical 14 trials, including the design of the Phase 15 III studies. 16 Q. So is it Regeneron's position 17 that the reason -- that the reason for 18 George Yancopoulos being the named 19 inventor is because he's the one who did 20 the signoff on the Phase III clinical 21 design study? 22 MS. OBERWETTER: Object to the 23 form. Foundation. 24 You can speak to your knowledge. 25 Q. Sorry, Phase III clinical study	Page 57 1 put together the 2 milligrams every four 2 weeks for the first six months followed 3 by 2 milligrams once every eight weeks or 4 every two months thereafter? 5 MS. OBERWETTER: Objection. 6 Q. That dosing regimen? 7 MS. OBERWETTER: Object to the 8 form. Foundation. 30(b)(6) 9 objection. 10 A. Off the top of my head, I don't 11 recall specific documents. 12 THE WITNESS: Can we take a 13 break? 14 Q. When it comes to -- 15 MS. OBERWETTER: I don't know if 16 you can hear that, Deanne, the witness 17 has said she's about ready for a 18 break. 19 MS. MAZZOCHI: Sure. 20 THE VIDEOGRAPHER: Going off the 21 record at 10:09 a.m. 22 (Off the record.) 23 THE VIDEOGRAPHER: Back on the 24 record at 10:22 a.m. 25 BY MS. MAZZOCHI:

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Page 58 1 Q. Thank you. Ms. Chu, did you 2 discuss your testimony at all with 3 counsel during the break? 4 A. I did not discuss my testimony 5 with counsel during the break. 6 Q. Okay. Before we broke one of 7 the things that you said that you did to 8 prepare as a 30(b)(6) witness was that 9 you talked to George Yancopoulos. What 10 information did he give you? 11 A. So I met with George 12 Yancopoulos on Monday for approximately 13 30 minutes. We discussed his 14 recollection of the data that led to the 15 design of the VIEW 1 and the VIEW 2 16 trials, and we reviewed an e-mail that he 17 wrote to Darlene Jody, who was a Bayer 18 employee at the time. 19 Q. How do you spell Darlene's last 20 name? 21 A. J-O-D-Y. 22 Q. What was the date of that 23 e-mail between Darlene Jody at Bayer? 24 A. I don't recall the date of the 25 e-mail.	Page 60 1 that Jesse Cedarbaum was on or wrote. 2 Q. The e-mail that you're 3 referring to Darlene Jody at Bayer, did 4 it actually mention VIEW 1 and VIEW 2 or 5 did you just know that it was referring 6 to the VIEW 1 and VIEW 2 clinical 7 studies? 8 A. I don't recall if the e-mail 9 specifically referred to the VIEW 1 and 10 VIEW 2 studies, but I understood it to be 11 referring to the Phase III neovascular 12 AMD studies. 13 Q. You also said that you met with 14 Len -- I always mispronounce his last 15 name -- Schleifer, and what did you talk 16 about with him? 17 MS. OBERWETTER: Object to the 18 foundation. 19 A. I did not meet with Len 20 Schleifer. 21 Q. Did you talk to him at all? 22 A. No, I did not. 23 Q. Okay. So the only person you 24 met with to prepare to testify as a 25 30(b)(6) witness beyond counsel is
Page 59 1 Q. Do you recall the year? 2 A. I don't recall the year. 3 Q. Was that an e-mail that you had 4 or one that Mr. Yancopoulos had? 5 A. It was an e-mail that 6 Dr. Yancopoulos had. 7 Q. Was it something that he pulled 8 out of his files? How did you get a copy 9 of it? 10 A. It was in the meeting room 11 before I arrived, so I don't know exactly 12 how the copy came to be. 13 Q. And what was it about this 14 e-mail that was so significant? 15 MS. OBERWETTER: Object to the 16 foundation. 17 A. So the content of the e-mail, 18 from my recollection of reviewing it on 19 Monday, was that it detailed to Ms. Jody 20 George's thoughts regarding the design of 21 the Phase III VIEW 1 and VIEW 2 studies. 22 Q. Did you go back to look at any 23 of Jesse Cedarbaum's e-mails? 24 A. In my preparation for this 25 deposition, I did review some e-mails	Page 61 1 Mr. Yancopoulos? 2 A. I also met with Neil Stahl. 3 Q. I'm sorry, Neil Stahl. Okay. 4 And what was Neil Stahl's role with 5 Regeneron? 6 A. So again, I don't recall Neil's 7 exact title but his role has always been 8 to help oversee research and development 9 alongside George. His current title is 10 executive vice president research and 11 development. 12 Q. And what did Mr. Stahl recall 13 or tell you about? 14 A. So in my conversation with 15 Dr. Stahl, we discussed his recollection 16 of the considerations around the time 17 that we were designing the Phase III 18 studies in neovascular AMD. 19 Q. And what was that recollection 20 or the things that were being considered? 21 A. So Dr. Stahl recalled that 22 there were many considerations around 23 safety that were taken into 24 consideration, as well as the fact that 25 we wanted to maximize efficacy for

Page 62 1 patients, the competitive landscape at 2 the time and his recollection of the 3 high-level results from preclinical 4 studies that demonstrated that 5 aflibercept had a longer half life in the 6 eye of animals, at least, and how that 7 translated into our decisions around the 8 Phase III study design. 9 Q. At some point the Phase III 10 study design was going to have a 12-week 11 interval. Who does Regeneron contend was 12 the one who came up with the idea first 13 of shortening it to an eight-week 14 interval? 15 MS. OBERWETTER: Objection to 16 form. Foundation. 30(b)(6) 17 objection. 18 A. My recollection is that there 19 were many, many discussions about the 20 appropriate dosing regimen for the Phase 21 III studies, and in discussions relating 22 to the third arm of the study, where we 23 were hoping to test a longer dosing 24 interval, it was George Yancopoulos who 25 ultimately lobbied for and made the	Page 64 1 where Jesse Cedarbaum suggested he could 2 get behind an eight-week interval? 3 MS. OBERWETTER: Object to the 4 form. Foundation. 30(b)(6) 5 objection. 6 A. I do not recall seeing 7 documents that specifically indicated 8 that Jesse was in favor of the every- 9 eight-week interval. 10 Q. Do you remember him advocating 11 for the eight-week interval? 12 MS. OBERWETTER: Object to the 13 form. Foundation. 30(b)(6) 14 objection. 15 A. I don't recall what 16 Dr. Cedarbaum's specific position was at 17 that time. 18 Q. Did you try to reach out to 19 Dr. Cedarbaum to prepare as a 30(b)(6) 20 witness? 21 MS. OBERWETTER: Object to the 22 form. Foundation. 30(b)(6) 23 objection. 24 A. I did not reach out to 25 Dr. Cedarbaum in preparation for this
Page 63 1 decision that we should test in an 2 eight-week interval. 3 Q. And was he the only person who 4 was lobbying for that position or were 5 there others? 6 MS. OBERWETTER: Object to the 7 form. Foundation. 30(b)(6) 8 objection. 9 A. My recollection at the time was 10 that George was the primary person 11 advocating for an every-eight-week 12 regimen. 13 Q. And is there any documentation 14 that reflects the fact that George was 15 one of the individuals advocating for 16 having, for going with the eight-week 17 interval as opposed to the 12-week 18 interval? 19 MS. OBERWETTER: Object to the 20 form. Foundation. 30(b)(6) 21 objection. 22 A. I don't recall if there are 23 specific documents that would relate to 24 that. 25 Q. Did you see any documentation	Page 65 1 deposition. 2 Q. What about Mr. Ingerman, Avner 3 Ingerman? 4 A. Right, Avner Ingerman. 5 Q. Wasn't he also one of the 6 individuals who was in favor of the 7 eight-week interval? 8 MS. OBERWETTER: Object to the 9 form. Foundation. 30(b)(6) 10 objection. 11 A. My recollection of 12 Dr. Ingerman's position at that time is 13 that he was lobbying for an as-needed or 14 PRN dosing regimen, although he was part 15 of many discussions about alternative 16 dosing regimens that could be employed. 17 Q. Such as? 18 MS. OBERWETTER: Object to the 19 form. Foundation. 30(b)(6) 20 objection. 21 A. Such as every eight weeks or 22 other potential dosing regimens. 23 Q. Well, with all of these 24 individuals who are talking about dosing 25 regimens, how do you know or does

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Page 66 1 Regeneron know that Dr. Yancopoulos was 2 the first person to suggest it as opposed 3 to somebody else, such as Dr. Cedarbaum 4 or Avner Ingberman? 5 MS. OBERWETTER: Object to the 6 form. Foundation. 30(b)(6) 7 objection. 8 A. I don't recall exactly who was 9 the first person to mention the every- 10 eight-week regimen. But I do recall that 11 George Yancopoulos was specifically, he 12 felt very strongly that that was the 13 interval that should be tested. 14 Q. Did your key opinion leaders 15 and the individuals who were going to be 16 running the VIEW 1 and VIEW 2 Phase III 17 trials have a perspective on what they 18 believe would be an appropriate dosing 19 interval? 20 MS. OBERWETTER: Objection to 21 form. Foundation. 30(b)(6) 22 objection. 23 A. The consultants or experts that 24 we consulted with in relation to the 25 Phase III study design certainly had	Page 68 1 the collaboration. 2 Q. Was some of the recommendation 3 or were some of the suggestions to go for 4 the fixed dosing in part driven by some 5 of the European medical authorities who 6 were concerned about having PRN dosing as 7 opposed to a fixed interval? 8 MS. OBERWETTER: Object to the 9 form. Foundation. 30(b)(6) 10 objection. 11 A. My recollection is that input 12 from European authorities was not a 13 factor in deciding on study designs. 14 Q. What about input from the FDA? 15 MS. OBERWETTER: Same 16 objections. 17 A. Could you just rephrase your 18 full question, sorry? 19 Q. Sure. When it came to the type 20 of dosing interval to use after the first 21 three monthly doses, did Regeneron also 22 get input back from the FDA as to what 23 they would like to see in that dosing 24 interval? 25 MS. OBERWETTER: Object to the
Page 67 1 opinions regarding what potential dosing 2 regimen should be included as well as 3 what doses should be included. But 4 ultimately the decision with what to move 5 forward with was something that was made 6 by George. 7 Q. Did Bayer have input as to what 8 the dosing regimen would look like? 9 MS. OBERWETTER: Object to the 10 form. 11 Q. In the Phase III clinical 12 studies or AMD? 13 MS. OBERWETTER: Objection to 14 form. Foundation. 30(b)(6) 15 objection. 16 A. We had begun discussions -- my 17 recollection is that we had begun 18 discussions about the Phase III study 19 designs prior to the finalization of the 20 Bayer collaboration. 21 The Bayer team was consulted 22 regarding the study designs. However, 23 the nature of our collaboration was such 24 that Regeneron retains final decisions 25 regarding all scientific decisions for	Page 69 1 form. Foundation. 30(b)(6) 2 objection. 3 A. My memory is that the FDA did 4 not give specific input on the dosing 5 regimen. 6 Q. Was your main contact at the 7 FDA someone named Wiley Chambers? 8 MS. OBERWETTER: Same 9 objections. 10 A. Our main clinical reviewer at 11 the FDA was Dr. Chambers. 12 Q. All right. Was there concern 13 at Regeneron, based on the data that they 14 had available, that if they went for a 15 full 12-week dosing they may not meet 16 their noninferiority endpoint as compared 17 to Lucentis? 18 MS. OBERWETTER: Object to the 19 form. Foundation. 30(b)(6) 20 objection. 21 A. At Regeneron we looked very 22 carefully at data from the Phase II study 23 in neovascular AMD where we had dosing 24 intervals of every 12 weeks to guide what 25 we thought was appropriate for the Phase

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Page 70 1 III study design. And as a result of 2 very carefully looking at that data, we 3 made decisions about the appropriate 4 dosing regimen to include in the VIEW 1 5 and VIEW 2 studies. 6 Q. Right. And based on the 7 results you saw with the Phase II, 12 8 weeks data, isn't it true that there was 9 a belief that the eight-week interval 10 would increase the likelihood that that 11 arm would be noninferior to the Lucentis 12 arm? 13 MS. OBERWETTER: Object to the 14 form. Foundation. 30(b)(6) 15 objection. 16 A. So based on the Phase II study 17 data, we saw that patients that were 18 dosed monthly initially had larger visual 19 acuity gains than patients who received 20 only a single dose at baseline and then 21 were not dosed again until week 12. 22 We looked also very carefully 23 at not only the visual acuity data, but 24 the anatomic data, so central reduction 25 in what we called back then central	Page 72 1 interval from 12 weeks to eight weeks? 2 MS. OBERWETTER: Object to the 3 form. Foundation. 30(b)(6) 4 objection. 5 A. So my recollection of the data 6 that really guided the decision around 7 the eight-week interval was data after 8 the initial doses had been given in the 9 Phase II study. And primarily, that was 10 the OCT data, but also the visual acuity 11 data. 12 Q. And the visual acuity data, 13 which specific aspect of the visual 14 acuity data were you looking at? 15 MS. OBERWETTER: Object to the 16 form. Foundation. 30(b)(6) 17 objection. 18 Q. What measurement? 19 MS. OBERWETTER: Same 20 objections. 21 A. So for visual acuity we used 22 the number of letters as the data point, 23 and so we looked at the mean change in 24 visual acuity in letters from baseline 25 over the duration of the study and looked
Page 71 1 retinal lesion thickness over time to 2 inform what we tested in Phase III. 3 But I would say that our goals 4 in designing the Phase III study, while 5 of course we hoped for a statistically 6 positive outcome, it was more related to 7 what we thought would give optimal safety 8 and efficacy outcomes for patients. 9 Q. Okay. And you relied -- and to 10 make that decision for the eight-week 11 interval, the data relating to the first 12 initial dosing in that first 12-week 13 interval was some of the critical data? 14 MS. OBERWETTER: Object to the 15 form. Foundation. 30(b)(6) 16 objection. 17 A. My recollection is it was the 18 totality of the data from that study that 19 really helped inform our decisions 20 related to the Phase III study design. 21 Q. Right. Okay. Then besides the 22 visual acuity and the central reduction, 23 and the central retinol data, what was 24 the other data that you recall was 25 compelling information to shorten the	Page 73 1 really at, you know, gains and losses 2 over time to inform us about the Phase 3 III study design. 4 Q. So were you looking at the 5 gains or losses within that first dosing 6 interval, the first three months monthly 7 versus the 12-week mark, or were you 8 looking at other time points as well? 9 MS. OBERWETTER: Can I just, are 10 you asking her, who is the "you" in 11 that question? 12 MS. MAZZOCHI: You at Regeneron. 13 MS. OBERWETTER: Object to the 14 form. Foundation. 30(b)(6) 15 objection. 16 A. So my recollection is that we 17 looked at all of the data. So data after 18 the first -- after the monthly doses, as 19 well as data related, you know, data 20 after the longer interval without a dose. 21 Q. And what within the visual 22 acuity data prompted shortening the 23 interval from 12 weeks to eight? 24 MS. OBERWETTER: Object to form. 25 Foundation. 30(b)(6) objection.

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Page 74 1 A. So within the visual acuity 2 data, even though visual acuity is a 3 highly variable measure and this was a 4 relatively small study, in that there 5 were about 30 patients per group, we 6 looked for trends to inform us of what's 7 happening. And my recollection is that 8 the most important aspect of the visual 9 acuity was that the groups that were 10 dosed with monthly injections first 11 overall had a greater gain in visual 12 acuity. 13 Secondly, that when those 14 patients were allowed to go longer than 15 four weeks without a dose, we saw some 16 decline in visual acuity over that 17 period. 18 Q. Okay. And was the period a 19 12-week period, an eight-week period, or 20 was it a PRN period? 21 MS. OBERWETTER: Object to the 22 form. Foundation. 30(b)(6) 23 objection. 24 A. So in this study, after week 25 12, patients were dosed PRN. So the	Page 76 1 objection. 2 A. So we did include two monthly 3 dosing groups in the VIEW 1 and VIEW 2 4 study. We tested two separate doses, .5 5 milligrams and 2 milligrams. As I 6 mentioned before, there were many 7 considerations that went into the study 8 design. And some of those considerations 9 have to do with the constraints of study 10 conduct. 11 So one aspect of the study is 12 we must conduct them as what we called 13 double-mask studies, and we perform sham 14 injections at visits where patients are 15 not receiving an active injection. And 16 it was impractical to include a group 17 where we had a six-week dosing interval 18 because it would have necessitated visits 19 essentially every two weeks for all 20 patients. 21 Q. So the every eight weeks just 22 made the clinical trial design easier in 23 terms of maintaining the mask? 24 MS. OBERWETTER: Objection to 25 form. Foundation. 30(b)(6).
Page 75 1 duration between that week 12 dose and 2 subsequent doses was variable. 3 Q. Okay. And did you see any 4 clear distinction in terms of patient 5 performance between 8 weeks and 12 weeks? 6 MS. OBERWETTER: Object to the 7 form. Foundation. 30(b)(6) 8 objection. 9 A. Are you asking specifically 10 about visual acuity? 11 Q. Yes. 12 MS. OBERWETTER: Same 13 objections. 14 A. So I don't recall specifically 15 making a distinction between how patients 16 did at 8 versus 12. But over that longer 17 dosing interval, the trend in visual 18 acuity, along with other data from the 19 study, gave us some insight into how we 20 should design the Phase III study. 21 Q. Okay. Well, why go with eight 22 weeks as opposed to six weeks or just 23 sticking with monthly? 24 MS. OBERWETTER: Objection to 25 form. Foundation. 30(b)(6)	Page 77 1 A. It was both a dosing interval 2 that we felt was supported by the data 3 and also created a more practical way to 4 conduct the study. 5 Q. And who recognized that it 6 would be more practical to conduct the 7 study that way? 8 MS. OBERWETTER: Object to form. 9 Foundation. 30(b)(6) objection. 10 A. So I should -- from my 11 recollection, the primary consideration 12 for the dosing arms was really the 13 scientific considerations around what we 14 felt was optimal for patients. 15 Secondary considerations were 16 those around what was reasonable to ask 17 of sites and patients in terms of 18 frequency of visits and number of visits. 19 Q. That's fine. But who -- 20 MS. OBERWETTER: Ms. Chu -- 21 Ms. Chu, were you finished with your 22 answer? 23 Q. Who were the individuals 24 driving the discussion of whether it was 25 reasonable?

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Page 78 1 MS. OBERWETTER: I think you cut 2 off the witness. 3 Were you finished with your 4 answer? 5 THE WITNESS: Yes, I was 6 finished. 7 MS. MAZZOCHI: Right. 8 Q. So who was the individual -- 9 but what individuals, though, were the 10 ones driving the conversation on, from a 11 masking perspective it wouldn't be 12 reasonable to do a different type of 13 interval such as six weeks? 14 MS. OBERWETTER: Objection to 15 form. Foundation. 30(b)(6) 16 objection. 17 A. So I don't remember 18 specifically which individuals were 19 involved in that discussion. 20 Q. Okay. And who were the 21 individuals involved in the scientific 22 discussion of what was optimal? 23 MS. OBERWETTER: Object to the 24 form. Foundation. 30(b)(6) 25 objection.	Page 80 1 MS. OBERWETTER: Object to the 2 form. Foundation. 30(b)(6) 3 objection. 4 A. So this regimen is different in 5 that it is for 2 milligrams given every 6 four weeks for the first five injections, 7 followed by approximately once every 8 eight weeks or every two months. And my 9 recollection is that, again, there were 10 several discussions about the optimal 11 study design for treating diabetic 12 macular edema. And those conversations 13 would have included both people from the 14 clinical team, as well as senior 15 management. 16 Q. Right. Who decided that the 17 dosing was going to be for the first five 18 injections as opposed to three or four? 19 MS. OBERWETTER: Object to the 20 form. Foundation. 30(b)(6) 21 objection. 22 A. My recollection is that George 23 Yancopoulos made that decision. 24 Q. Is that documented anywhere? 25 MS. OBERWETTER: Object to the
Page 79 1 A. So I don't recall everyone who 2 was involved in those discussions, but I 3 do remember that George Yancopoulos, Neil 4 Stahl, Len Schleifer, Avner Ingerman, 5 myself, Bill Roberts, and potentially 6 others, were all involved in those 7 discussions. 8 Q. What about the external 9 clinicians? 10 MS. OBERWETTER: Object to the 11 form. Foundation. 30(b)(6) 12 objection. 13 A. I do not recall specifically if 14 we consulted external experts concerning 15 that aspect of study design. 16 Q. Now, in the '601 patent, Claim 17 10, we have the same dosing regimen, but 18 this time it's for a method of treating 19 diabetic macular edema in a patient in 20 need thereof. 21 Who was the one who -- what is 22 Regeneron's position as to who was the 23 person who actually came up with the idea 24 of applying this regimen to the DME 25 indication?	Page 81 1 form. Foundation. 30(b)(6) 2 objection. 3 A. I don't recall if there is 4 specific documentation of that. 5 MS. MAZZOCHI: I would like to 6 put in front of you what I will mark 7 as Defendant's Exhibit 19. United 8 States Patent 10,973,879. 9 (Defendant's Exhibit 19, United 10 States Patent Number 10,973,879, was 11 so marked for identification, as of 12 this date.) 13 Q. And Ms. Chu, can you confirm 14 that you have seen this document before? 15 A. I can confirm that I have seen 16 this document in preparation for this 17 deposition. 18 Q. Well, you're also a named 19 inventor on this patent, right? 20 A. I am, yes, that's correct. 21 Q. All right. Now, if you take a 22 look at the method and regimen for 23 diabetic retinopathy that appears in 24 Claim 1, how does your regimen differ 25 from the one that's in Claim 10 of the

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Page 82 1 '601 patent? 2 MS. OBERWETTER: Is this -- is 3 this a 30(b)(6) question or in her 4 individual capacity? 5 MS. MAZZOCHI: No, this is for 6 her. 7 MS. OBERWETTER: Object to the 8 form. 9 A. So first I should say that 10 diabetic macular edema and diabetic 11 retinopathy, while related, are very 12 different diseases in terms of their 13 presentation and goals of treatment. 14 Diabetic macular edema is an 15 immediate vision-threatening condition, 16 whereas diabetic retinopathy can lead to 17 vision-threatening outcomes but it is one 18 where patients generally have good vision 19 to begin with. 20 The dosing regimen that is 21 described in Patent '879 is an initial 22 dose followed by a second dose one month 23 later, a third dose one month after the 24 second dose and a fourth dose eight weeks 25 after the third dose, followed by one or	Page 84 1 MS. OBERWETTER: I'm sorry, are 2 you going to tell me when you go back 3 to asking 30(b)(6) questions? 4 MS. MAZZOCHI: Sure. 5 MS. OBERWETTER: Great. Object 6 to the form. 7 A. Sorry, can you restate your 8 question one more time? 9 Q. Sure. What's the difference 10 between your method in Claim 1 of the 11 '879 patent and the method in Claim 26 of 12 the '601 patent? 13 MS. OBERWETTER: Object to form. 14 A. So in the '601 patent, in Claim 15 26, a method for treating diabetic 16 retinopathy describes a treatment regimen 17 of aflibercept 2 milligrams given 18 approximately every four weeks for the 19 first five injections, followed by 2 20 milligrams approximately every eight 21 weeks or two months. 22 That differs from the treatment 23 regimen claimed in the '879 patent, in 24 that in the '879 patent, patients receive 25 three initial monthly doses followed by a
Page 83 1 more doses every 16 weeks. 2 And in designing the PANORAMA 3 clinical trial, which supported adding 4 the diabetic retinopathy indications to 5 the Eylea USPI, we designed the dosing 6 regimen for this disease based on the 7 goals and the objectives of optimal 8 outcomes in this particular disease state 9 versus diabetic macular edema, which is 10 very different. 11 Q. Okay. Well, take a look then 12 and compare your Claim 1 in the '879 13 patent, the regimen set forth there, to 14 the regimen that's set forth in Claim 26 15 of the '601 patent that relates to 16 diabetic retinopathy. 17 MS. OBERWETTER: Is this a 18 30(b)(6) question? 19 MS. MAZZOCHI: This is just her. 20 MS. OBERWETTER: Do you want to 21 tell me when you go back? 22 MS. MAZZOCHI: Yes. 23 Q. Can you tell me what the 24 differences are between those methods set 25 forth there?	Page 85 1 q8-week dose and then thereafter doses 2 every 16 weeks. 3 Q. What drove the decision in the 4 '879 patent to extend the monthly doses 5 out, the fourth dose to q8 and the fifth 6 dose to q16? 7 A. So my recollection is that, 8 again, the diseases are very different 9 and the goals of treatment are very 10 different. 11 So in diabetic retinopathy, our 12 primary goal was both to improve the 13 underlying diabetic retinopathy severity 14 as well as to prevent vision-threatening 15 complications such as vitreous hemorrhage 16 or neovascular glaucoma, as well as the 17 development of what's termed 18 proliferative diabetic retinopathy, which 19 is more, a more severe state of diabetic 20 retinopathy. 21 Q. Now, take -- okay. Well, what 22 then justified in your '879 patent, what 23 data justified taking that fourth dose 24 and making it q8 and the fifth dose q16? 25 MS. OBERWETTER: Object to the

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Page 86 1 form and foundation. 2 A. So the data that informed the 3 PANORAMA study came from information 4 related to diabetic retinopathy severity 5 improvements in the Vivid and Vista 6 trials which were the Phase III DME 7 studies. And when we were designing the 8 PANORAMA study, we both -- we felt it was 9 important for patients to receive more 10 intensive treatment initially. But we 11 felt given the disease state and the 12 practicalities of treatment for these 13 patients, that a longer dosing interval 14 thereafter was possible. And that's why 15 we chose to test it. 16 Q. Going back to the '601 patent, 17 let's take a look at Claim 18. Who came 18 up with the idea for the diabetic 19 retinopathy indication that we see in 20 Claim 18 to simply have 2 milligrams 21 every four weeks for the first five 22 injections followed by 2 milligrams every 23 eight weeks thereafter? 24 A. So the trial -- in my memory, 25 the trials that related to both diabetic	Page 88 1 form. 2 A. So the results of the PANORAMA 3 trial indicated that both dosing regimens 4 were statistically significant at week 24 5 and week 52 in proportion of patients 6 with a two-or-more-step improvement in 7 diabetic retinopathy. 8 Q. If you can take a look at the 9 '601 patent, is the clinical trial 10 protocol for the Phase III VIVID or VISTA 11 studies set forth in any of the patent 12 examples? 13 MS. OBERWETTER: Object to the 14 form and foundation. 15 A. To answer that question, I 16 would have to go through the entire 17 patent, is that something I should do? 18 Q. Sure. You can start with 19 example 1 which begins at Column 8. 20 (Witness reviews document.) 21 A. So in my review of patent '601, 22 I do not see a description or the VIVID 23 and VISTA trials given as an example. 24 But I do see the Phase II clinical trial 25 in diabetic macular edema described as
Page 87 1 macular edema and diabetic retinopathy 2 included the Phase III VIVID and VISTA 3 studies, where, in addition to monthly 4 dosing, we also looked at the treatment 5 regimen described in Claim 18, which is 2 6 milligrams approximately, given 7 approximately every four weeks for the 8 first five injections followed by 2 9 milligrams approximately every eight 10 weeks or two months. In those studies, 11 we did see a significant number of 12 patients with at least a two-or-more-step 13 improvement in diabetic retinopathy 14 severity. 15 In designing the PANORAMA 16 trial, where -- the dosing regimen 17 described in Claim 1 of patent '879, we 18 also included the dosing regimen 19 described that we used in the VIVID and 20 VISTA studies, so five injections monthly 21 followed by every-eight-week injections. 22 Q. And did you see any meaningful 23 results between the two injection 24 regimes? 25 MS. OBERWETTER: Object to the	Page 89 1 example 5. 2 Q. And if I understand you, it was 3 the data from this Phase II study that 4 justified the dosing regimen for the 5 VIVID and VISTA studies for diabetic 6 retinopathy? 7 MS. OBERWETTER: Object to the 8 form and foundation. 9 A. So data from this Phase II 10 study did inform decisions regarding the 11 VIVID and VISTA study designs. 12 Q. Okay. And why is it that 13 Regeneron believed that the DME data 14 could be transferred over to the diabetic 15 retinopathy indication? 16 MS. OBERWETTER: Object to the 17 form and foundation. 18 A. So as I mentioned, data from 19 the VIVID and VISTA studies included a 20 secondary endpoint of a proportion of 21 patients with two-or-more-step 22 improvement in diabetic retinopathy. 23 Patients with diabetic macular 24 edema do have underlying diabetic 25 retinopathy at various severities. And

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Page 90 1 we did see a statistically significant 2 outcome of improvement in patients that 3 were treated with aflibercept in the 4 VIVID and VISTA studies -- I'm sorry, 5 yes, in the VIVID and VISTA studies, 6 sorry. 7 Q. What does that two-step 8 improvement have to do with diabetic -- 9 I'm sorry, with diabetic retinopathy? 10 MS. OBERWETTER: Object to the 11 form and foundation. 12 A. So there is a standard method 13 of grading diabetic retinopathy severity 14 based on fundus photography. And the FDA 15 accepts an anatomic improvement of two or 16 more steps as an endpoint, as an 17 acceptable endpoint for Phase III trials 18 in diabetic retinopathy. 19 Q. And was that published anywhere 20 or is that something that you just 21 learned in negotiations with the agency? 22 MS. OBERWETTER: Object to form. 23 A. So the grading for diabetic 24 retinopathy severity is described in the 25 early treatment diabetic retinopathy	Page 92 1 input into what this particular 2 methodology in the PANORAMA study was 3 going to look like? 4 A. I don't recall the specific 5 meeting, but we most certainly would have 6 discussed it with him. 7 Q. Okay. Do you have an 8 understanding as to why he is somebody 9 who is identified as the one Regeneron 10 points to saying has conceived of the 11 dosing regimen in the '601 patent, but 12 he's not identified as someone who 13 contributed to the conception of the 14 dosing regimen for your '879 patent? 15 MS. OBERWETTER: Object to the 16 form and foundation. 17 A. So I'm aware that Regeneron has 18 grown very much as a company and George's 19 responsibilities have become broader over 20 time. 21 His involvement in the details 22 of the clinical development programs, 23 certainly during the conception of the 24 VIEW 1 and VIEW 2 trials, as well as 25 early phase studies, was much more of a,
Page 91 1 studies. 2 Q. Right. But I'm saying is that 3 something that was FDA clinical guidance 4 that was generally applicable or was that 5 a standard that was written down 6 somewhere, or is that one that you just 7 came up with as part of your negotiations 8 with the agency? 9 A. So I don't recall specifically 10 if there is a publication or an FDA 11 guidance that specifically speaks to that 12 as an acceptable endpoint. 13 We did have interactions with 14 the FDA related to the development in 15 diabetic retinopathy where we understood 16 that that was an acceptable endpoint. 17 Q. Now, when it comes to your '879 18 patent, was that also the clinical -- did 19 Dr. Yancopoulos also have to sign off on 20 that clinical study, Phase III clinical 21 study? 22 A. It's our practice at Regeneron 23 that Phase III clinical trials are 24 approved by George. 25 Q. Okay. And did he have any	Page 93 1 of a direct day-to-day involvement. 2 In the case of the '879 patent, 3 like I said, we would have certainly 4 discussed the design of the clinical 5 trials and the proposed dosing regimen 6 with him and he would have approved it. 7 But the day-to-day involvement was really 8 more with the clinical team, myself and 9 Dr. Vitti, who are listed as inventors on 10 the patent. 11 Q. When it came to the VIEW 1 and 12 VIEW 2 Phase III clinical studies, who 13 else besides Dr. Yancopoulos was involved 14 in the day-to-day activities and design 15 work? 16 A. Can you be more specific as to 17 the time frame you're referring to? 18 Q. The time period of cultivating 19 or designing of clinical trial protocol 20 for VIEW 1 and VIEW 2. 21 A. So my recollection of the time 22 is that would have been at the team 23 level, myself, Jesse Cedarbaum, 24 Dr. Engleman. Dr. Vitti joined us just 25 as we were initiating the VIEW trials.

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Page 94 1 Bill Roberts, who was the head of 2 regulatory and safety at the time, as 3 well as George, Len and Neil, who were 4 all part of our team. 5 It would have also included our 6 preclinical colleagues Stan Wiegand, Eric 7 Furfine, as well as others that I don't 8 specifically recall. 9 Q. What is Regeneron's position as 10 to why none of the other individuals who 11 were involved with the day-to-day 12 cultivation of the VIEW 1 and VIEW 2 13 Phase III clinical trial design are 14 listed as inventors on the '601 patent? 15 MS. OBERWETTER: Object to the 16 foundation with this witness. 17 You can answer. 18 A. I can only speak to my 19 perspective because I don't know the 20 formal company position. But ultimately, 21 George was the one who made the final 22 decision about what dosing regimen we 23 would proceed with in the VIEW 1 and VIEW 24 2 studies. 25 Q. Okay. And likewise, when it	Page 96 1 MS. MAZZOCHI: Jeff, do you have 2 the Bates numbers on that one? 3 MR. MARX: Which one? 4 MS. MAZZOCHI: The ophthalmology 5 2012. 6 MR. MARX: Yeah. Was that 7 Addison or Dixon? 8 MS. MAZZOCHI: No, Heier. I got 9 it. Let me mark, I believe we are up 10 to 203. Let me mark as Defendant's 11 Exhibit 203 a document with production 12 numbers MYL-AFL 6405 through 16. 13 (Defendant's Exhibit 203, 14 Document Bates stamped MYL-AFL 6405 15 through 16, was so marked for 16 identification, as of this date.) 17 MR. MARX: Deanne, which 18 document is that? 19 MS. MAZZOCHI: It's the Heier 20 2012 American Academy of 21 Ophthalmology. I think the citation 22 is Ophthalmology 2012 1192537 to 2548. 23 MS. OBERWETTER: We're calling 24 this what exhibit number? 25 MR. MARX: 203.
Page 95 1 comes to the '572 patent, all of those 2 individuals who were involved in the VIEW 3 1 and VIEW 2 studies, do you have any 4 understanding as to why they were 5 considered by Regeneron to not also have 6 contributed to the conception of the 7 dosing regimens set forth in the '572 8 patent? 9 MS. OBERWETTER: Object to the 10 form. 11 A. Again, I can't speak to the 12 company position at the time. But my 13 recollection is that George made the 14 final decisions regarding the VIEW 1 and 15 VIEW 2 study designs. 16 Q. Okay. Now, was George 17 Yancopoulos the individual listed as a 18 co-author on the VIEW 1 and 2 Phase III 19 clinical trial publications? 20 A. I would be happy to answer that 21 if you could provide me with the 22 publication. 23 Q. Sure. Let's take a look at -- 24 Mr. Marx will probably get it to you 25 before I do.	Page 97 1 Q. Now, Ms. Chu, do you have a 2 copy of what I marked as Defendant's 3 Exhibit 203 in front of you? 4 A. Yes, I do have that exhibit. 5 Q. Okay. Now here we have a whole 6 series of authors who are listed on 7 there, as well as individuals from 8 Regeneron beyond Dr. Yancopoulos, 9 including Neil Stahl, Robert Vitti, 10 Alyson Berliner and Yuhwen Soo. 11 Do you have any understanding 12 as to why all of those individuals are 13 listed as being part of -- having 14 co-authorship on this Phase III study but 15 are not listed as having contributed to 16 the conception on the '601 patent? 17 MS. OBERWETTER: Object to the 18 foundation. 19 A. I can -- I'm not aware of why 20 that is, but to say that I'm not -- I 21 can't speak to the company's policy 22 around, you know, deciding inventors on 23 patents versus authors on publications. 24 MS. MAZZOCHI: I would like to 25 put before you a document that I'm

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Page 98 1 going to mark as Defendant's Exhibit 2 204, which is Dixon 2009. It has 3 production numbers MYL-AFL 5010 4 through 18. 5 (Defendant's Exhibit 204, 6 Document Bates stamped MYL-AFL 5010 7 through 18, was so marked for 8 identification, as of this date.) 9 Q. Let me know when you have that 10 exhibit in front of you. 11 A. I have Exhibit 204 in front of 12 me. 13 Q. If you could take a look at the 14 page, it's page 1576 from the article and 15 page 5013 in the lower-right-hand corner. 16 And by the way, you've read 17 this article before, right? 18 A. I briefly reviewed this article 19 in preparation for this deposition. 20 Q. And can you confirm that the 21 Phase III VIEW 1, VIEW 2 clinical trial 22 dosing regimen is set forth under header 23 2.6.3, Phase III, in Dixon, DX 204? 24 MS. OBERWETTER: Object to the 25 form.	Page 100 1 weeks for the first three weeks followed 2 by 2 milligrams once every eight weeks or 3 once every two months. 4 Q. Right. So are the dosing 5 regimens the same for aflibercept in the 6 '601 patent Claim 1 that we see for the 7 aflibercept 2 milligram dose in Dixon for 8 the Phase III VIEW 1 trial? 9 MS. OBERWETTER: Object to the 10 form. 11 A. The arm of the trial that 12 included 2 milligrams administered every 13 four weeks for three initial monthly 14 doses followed by every-eight-week dosing 15 is described similarly between the 16 patent, patent '601 and the Dixon 17 publication. 18 Q. And the VIEW 1 study was 19 directed to age-related macular 20 degeneration, right? 21 A. Correct. Neovascular or wet 22 age-related macular degeneration. 23 Q. Right. And then the Phase III 24 VIEW 1 trial with the arm of 2 milligram 25 aflibercept being dosed at a four-week
Page 99 1 A. So in section 2.6.3 of this 2 publication, I see that the VIEW 1 study 3 is described with the dosing regimens 4 described as doses of .5 and 2 milligrams 5 administered at 4-week intervals and 2 6 milligrams at an 8-week dosing interval 7 following three monthly doses, compared 8 with .5 milligram of ranibizumab 9 administered every four weeks. 10 Q. When it comes to the Phase III 11 protocol here in terms of the dosing 12 regimen for VEGF-Trap eye, is that any 13 different than the dosing regimen for 14 aflibercept that we see in Claim 1 of the 15 '601 patent? 16 MS. OBERWETTER: Object to the 17 form. 18 A. Give me a minute to find that. 19 To confirm, you were referring to Claim 1 20 in patent '601? 21 Q. Yes, the dosing regimen for 22 VEGF-Trap I/Aflibercept? 23 MS. OBERWETTER: Same objection. 24 A. So the dosing regimen described 25 here is 2 milligrams approximately four	Page 101 1 dosing interval and then 2 milligrams at 2 an eight-week dosing interval following 3 three monthly doses, that was also being 4 done by intravitreal injection, right? 5 A. Yes. In the VIEW 1 study, 6 aflibercept was administered via 7 intravitreal injection. 8 Q. And was one of the established 9 clinical endpoints in VIEW 1 a particular 10 BCVA score, best corrected visual acuity 11 score? 12 MS. OBERWETTER: Object to the 13 form. 14 A. So the primary endpoint in the 15 VIEW 1 study was actually the proportion 16 of patients avoiding a 15-or-more-letter 17 loss but the measure for that was visual 18 acuity measure. 19 Q. What happened if a patient was 20 actually at 15, was that considered to be 21 a treatment failure or a success? 22 MS. OBERWETTER: Object to the 23 form. 24 A. So my recollection is that for 25 the purpose of the primary endpoint in

Page 102 1 the VIEW 1 study, we categorized patients 2 in two categories, losing 15 or more 3 letters at week 52 or avoiding that 4 letter loss. 5 Q. And you say that was measured 6 at week 52? 7 A. That was the time point at 8 which we performed the statistical 9 analysis. 10 Q. Okay. On the group of patients 11 enrolled in the clinical trial cohort? 12 A. Right. So for -- 13 Q. Let me ask you this, in the 14 '601 patent -- 15 MS. OBERWETTER: The witness had 16 not completed her answer. 17 MS. MAZZOCHI: Sorry, go ahead. 18 A. I just wanted to clarify that 19 in clinical trials, we would wait until 20 all patients enrolled in the study 21 reached the week 52 endpoint or sometimes 22 they discontinue before that, but that 23 all patients would have had an 24 opportunity to complete that visit before 25 any analysis of the data would occur.	Page 104 1 vision loss. 2 Q. Okay. But when was that -- I'm 3 just trying to get a more simple question 4 I guess. 5 If there is no -- we 6 established that there is no time limit 7 or restrictions on when you have to 8 measure the BCVA score. Is that 9 something that you would measure at month 10 one? 11 MS. OBERWETTER: Object to the 12 form and characterization of the prior 13 question and answer. 14 A. So in the clinical studies, we 15 measured visual acuity at every visit. 16 In practice, clinicians would evaluate 17 visual acuity at clinic visits when the 18 patient is being evaluated. 19 Q. Okay. But from a time 20 perspective, can you say when a patient 21 is going to gain at least 15 letters, do 22 they have to go through a full 52 weeks 23 of treatment? 24 MS. OBERWETTER: Object to the 25 form and foundation.
Page 103 1 Q. Sure. If you take a look at 2 Claim 5 of the '601 patent, does that 3 have any time limit as to, or time 4 requirement as to when you have to 5 achieve the at-least-15-letters standard? 6 MS. OBERWETTER: Object to the 7 form. 8 A. In my review of Claim 6, there 9 is no time limit included. 10 Q. Okay. The patients who are 11 participating in VIEW, did they achieve 12 this, at least 15 letters of best 13 corrected visual acuity, BCVA score, 14 within the first month? 15 MS. OBERWETTER: Object to the 16 form. 17 A. So I'm hesitating to answer 18 your question because I think we are 19 conflating two different measures of -- 20 that were used as clinical trial 21 endpoints. Mean change and best 22 corrected visual acuity was a secondary 23 endpoint in the VIEW studies. However, 24 the primary endpoint was the proportion 25 of patients avoiding a 15-or-more-letter	Page 105 1 A. So AMD is a very heterogenous 2 disease and I can't speak to the 3 individual patient's experience. 4 Q. Why not? 5 A. The results of the VIEW 1 and 6 the VIEW 2 clinical trials were based on 7 the overall performance of the treatment 8 groups. 9 Q. Okay. Well, how can we 10 ascertain when an individual patient has 11 gained or lost 15 letters? What's the 12 appropriate time to measure that as we 13 see here in Claim 5 of the '601 patent? 14 MS. OBERWETTER: Object to the 15 form. 16 A. So when patients initiate 17 treatments with ante VEGF, the clinician 18 determines exactly what the follow-up 19 schedule for that specific patient should 20 be and would measure visual acuity both 21 at that initial visit and subsequent 22 visits to determine response to 23 treatment. 24 Q. Well, how many weeks do you 25 have to follow the regimen in order to

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Page 106 1 ensure that the patient gains at least 15 2 letters in the BCVA score? 3 MS. OBERWETTER: Object to the 4 form. 5 A. Again, I can't speak to an 6 individual patient's experience. 7 Q. Well, is there anything about 8 this regimen that you can do to it or 9 tweak it or modify it to ensure that a 10 patient is actually going to achieve 15 11 letters of a BCVA score? 12 MS. OBERWETTER: Object to the 13 form and foundation. 14 A. So, again, I'm struggling a 15 little bit with the concept of a patient 16 gaining 15 letters because, as I stated 17 previously, this concept of 15 letters 18 really comes from avoiding a loss of 15 19 letters from baseline. So that's not a 20 gain, right? That's a patient losing 21 vision. 22 If you're asking me what 23 results from the VIEW 1 and the VIEW 2 24 trial -- well, I should -- I don't know 25 what you're asking me. So maybe we	Page 108 1 once every eight weeks or once every two 2 months, is every patient who follows that 3 dosing regimen going to be able to reach 4 the result we see in Claim 5 where the 5 patient gains at least 15 letters of BCVA 6 score? 7 MS. OBERWETTER: Object to the 8 form and foundation. 9 A. So, again, in the treatment 10 of -- my understanding of the treatment 11 for individual patients is that there is 12 variability in the course of treatment 13 and response to treatment. So I can't 14 say -- I can't say specifically when that 15 would be expected. 16 Q. Well, are there any 17 restrictions we can put on the method to 18 guarantee that a patient is going to gain 19 at least 15 letters of BCVA score when 20 they follow the regimen? Does it have to 21 be if they follow it for 52 weeks, if 22 they follow it for 100 weeks, if they 23 follow it for five weeks? 24 MS. OBERWETTER: Object to the 25 form and foundation.
Page 107 1 should start over. 2 Q. All right. Well, maybe we can 3 get at it this way. I'm trying to -- 4 well, every time you practice this dosing 5 regimen of 2 milligrams every four weeks 6 for the first three months followed by 2 7 milligrams approximately once every eight 8 weeks or once every two months, is every 9 patient going to then be able to reach 10 the standard in Claim 5 where the patient 11 gains at least 15 letters of BCVA score? 12 MS. OBERWETTER: Object to the 13 form and foundation. 14 A. Sorry, what claim are you 15 referring to? 16 Q. Claim 5 in the '601 patent. 17 MS. OBERWETTER: Same objection. 18 A. Sorry, could you just restate 19 your question one more time? 20 Q. Sure. For any patients who are 21 following the dosing regimen that we see 22 in Claim 1 of aflibercept, where 2 23 milligrams is dosed approximately every 24 four weeks for the first three months 25 following by 2 milligrams approximately	Page 109 1 A. Again, my understanding of the 2 clinical experience and treatment of 3 individual patients is that it's 4 variable. So I can't speak to that here. 5 MS. OBERWETTER: Ms. Mazzochi, 6 we have been going -- 7 Q. But the question is, are there 8 any -- 9 MS. OBERWETTER: Ms. Mazzochi, I 10 know you can't hear me because you're 11 remote. 12 Q. Are there any restrictions 13 imposed on the method that in fact that 14 the patient will be able to meet the 15 standard on Claim 5? 16 MS. OBERWETTER: Ms. Mazzochi, 17 we have been talking over each other. 18 We have begun going a little over an 19 hour, I started to talk and I think 20 you didn't hear me. 21 MS. MAZZOCHI: Let's finish this 22 part up and I think we can take a 23 break. 24 MS. OBERWETTER: Can we hear the 25 question back, please.

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Page 110 1 MS. MAZZOCHI: Sure. 2 Q. Is there any additional step or 3 restriction you can impose on either the 4 method or the patient to ensure that the 5 patient is going to actually achieve the 6 gain of at least 15 letters of best 7 corrected visual acuity score? 8 MS. OBERWETTER: Objection to 9 form. Asked and answered. 10 You can answer again. 11 A. I would just answer the same 12 way, that for individual patients, the 13 course of response to treatment is 14 variable. 15 MS. MAZZOCHI: All right. I 16 view that as nonresponsive. But, 17 okay. Let's take a break. 18 THE VIDEOGRAPHER: We are going 19 off the record at 11:27 a.m. 20 (Off the record.) 21 THE VIDEOGRAPHER: Back on the 22 record at 11:44 a.m. 23 BY MS. MAZZOCHI: 24 Q. Ms. Chu, did you talk with your 25 counsel over the break?	Page 112 1 form. Foundation. Asked and 2 answered. 3 A. So in the treatment and 4 monitoring of an individual patient with 5 neovascular age-related macular 6 degeneration, visual acuity would be 7 assessed prior to treatment initiation, 8 and at an interval deemed appropriate by 9 the treating physician during the course 10 of treatment. 11 Q. Are physicians, if they want to 12 use Eylea, are they required to use this 13 BCVA and early-treatment diabetic 14 retinopathy study letter score to assess 15 their patients? 16 MS. OBERWETTER: Object to the 17 form. Foundation. Calls for expert 18 testimony. 19 A. Physicians are not required to 20 use ETDRS, best corrected visual acuity. 21 But there are multiple ways to assess 22 visual function that they would most 23 certainly use in their clinical treatment 24 of a patient. 25 Q. And what are some of the ways
Page 111 1 A. I spoke with counsel over the 2 break. 3 Q. Did you discuss the substance 4 of your testimony at all? 5 A. No, I did not. 6 Q. I would like to take a look at 7 Claim 6 of the '601 patent. 8 A. Okay. I see that. 9 Q. Yeah, and so here again, I just 10 have the question, what can be done to 11 the dosing regimen in Claim 1 to ensure 12 that a patient is going to be able to 13 meet these requirements of Claim 5 and 14 Claim 6, and specifically using this 15 measurement technique that's set forth in 16 Claim 6? 17 MS. OBERWETTER: Object to the 18 form. Asked and answered. 19 A. So I would respond the same 20 way, that the response to treatment is 21 highly variable with individual patients. 22 Q. How are we going to know then 23 if an individual patient actually meets 24 the standard? 25 MS. OBERWETTER: Object to the	Page 113 1 that you're aware of? 2 A. So, Snellen Visual Acuity, as 3 well as potentially other assessments of 4 visual acuity, like microperimetry or 5 visual field. In addition to potentially 6 contrast sensitivity and other ways of 7 assessing visual function. 8 MS. MAZZOCHI: Okay. I would 9 like to put before you a document that 10 has -- that I will mark as Defendant's 11 Exhibit 205. And for the record, it 12 has production numbers MYL-AFL 0005242 13 through 70. 14 (Defendant's Exhibit 205, 15 Document Bates stamped MYL-AFL 0005242 16 through 70, was so marked for 17 identification, as of this date.) 18 MS. MAZZOCHI: And while that is 19 being marked, I would also like to 20 note for the record at that Ms. Chu is 21 designated on topic number 26 relating 22 to the content of the label for EYLEA 23 and any draft label submitted to the 24 FDA. So these are certainly going to 25 include questions to Regeneron in the

Page 114 1 30(b)(6) capacity for this next 2 exhibit. 3 MS. OBERWETTER: So just so 4 we're clear, you know, I will repeat 5 my objections that you have our 6 objections to what the witness might 7 be able to speak to and to the 8 30(b)(6) notice in its entirety as it 9 has been put together. 10 I will repeat my offer to do a 11 running objection instead of having to 12 object every time. Will you take me 13 up on that? 14 MS. MAZZOCHI: No, I want 15 objections on every question if you're 16 going to be objecting because, again, 17 I think it's an improper objection 18 given that she was designated to 19 testify on the EYLEA labeling and 20 that's what I'm putting in front of 21 her. 22 MS. OBERWETTER: That's not 23 accurate and I'm not going to let you 24 misrepresent the content of my prior 25 letter. You may proceed.	Page 116 1 objection. 2 A. So the indications and usage 3 section states that EYLEA is a vascular 4 endothelial growth factor inhibitor 5 indicated for the treatment of patients 6 with neovascular or wet age-related 7 macular degeneration, macular edema 8 following retinol vein occlusion, 9 diabetic macular edema and diabetic 10 retinopathy. 11 Q. Right. So there is nothing in 12 there about BCVA scores; is that fair? 13 MS. OBERWETTER: Object to the 14 form and foundation. 30(b)(6) 15 objection. 16 A. In the indications and usage 17 section of the highlights of prescribing 18 information there is no information 19 regarding BCVA. 20 Q. And likewise, if we look at the 21 dosage and administration instructions 22 for neovascular wet age-related macular 23 degeneration, is there any instruction in 24 there that the patient has to gain at 25 least 15 letters of best corrected visual
Page 115 1 Q. Ms. Chu, can you take a look at 2 DX 205 and confirm it's the FDA-approved 3 EYLEA labeling? 4 MS. OBERWETTER: Object to the 5 form. Foundation. 30(b)(6) 6 objection. 7 A. So I have Exhibit 205 in front 8 of me and this appears to be the EYLEA 9 USPI revised as of May 2019. 10 Q. Do you see the section of the 11 prescribing information that says 12 indications and usage on the first page 13 of DX 205? 14 MS. OBERWETTER: Object to the 15 form. Foundation. 30(b)(6) 16 objection. 17 A. Yes, I see the section 18 Indications and Usage in the highlights 19 of prescribing information. 20 Q. And for indications and usage, 21 is there any requirement in there for 22 gaining or achieving a particular BCVA 23 score? 24 MS. OBERWETTER: Object to the 25 form. Foundation. 30(b)(6)	Page 117 1 acuity score? 2 MS. OBERWETTER: 30(b)(6) 3 objection. 4 A. In the dosage and 5 administration section, which details the 6 dosage and administration for neovascular 7 AMD, macular edema following RVO, 8 diabetic macular edema and diabetic 9 retinopathy, I do not see any information 10 related to visual acuity in this section. 11 Q. And would your answer be the 12 same for the indication of macular edema 13 following retinol vein occlusion, that 14 there is nothing there obligating the 15 patients or the physicians to achieve a 16 BCVA, a particular BCVA letter score? 17 MS. OBERWETTER: 30(b)(6) 18 objection. 19 A. In the highlights of 20 prescribing information under dosage and 21 administration for macular edema 22 following RVO, I don't see any 23 information related to BCVA. 24 Q. And would your answer be the 25 same for the diabetic macular edema

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Page 118 1 indications and diabetic retinopathy 2 indications? 3 MS. OBERWETTER: 30(b)(6) 4 objection. 5 A. So similarly, in this same 6 section of dosage and administration and 7 the highlights of prescribing information 8 for diabetic macular edema and diabetic 9 retinopathy, I do not see any information 10 related to visual acuity. 11 Q. Okay. And likewise, in the 12 dosing and administration section, is 13 there anything in that particular section 14 about excluding patients who have active 15 intraocular inflammation? 16 MS. OBERWETTER: Object to the 17 form and foundation. 30(b)(6) 18 objection. 19 A. Are you asking specifically 20 about the dosage and administration 21 section? 22 Q. Correct. We will get to the 23 contraindications section next. 24 A. In the dosage and 25 administration sections in this	Page 120 1 "Contraindications." 2 A. I'm at that section of the 3 USTI. 4 Q. Okay. Now, it says "EYLEA is 5 contraindicated in patients with ocular 6 or periocular infections"; do you see 7 that? 8 A. Yes, I see that section as 9 section 4.1. 10 Q. Okay. What's the basis for 11 that contraindication? 12 MS. OBERWETTER: Objection. 13 30(b)(6) objection. 14 A. So in my experience and with my 15 knowledge of intravitreal injections, 16 there are certain contraindications that 17 would need to be assessed in order to 18 determine if moving forward with any 19 intravitreal injection was advisable for 20 an individual patient. 21 Q. If it's contraindicated, does 22 that mean that doctors are prohibited 23 from ever giving EYLEA to a patient? 24 MS. OBERWETTER: Objection. 25 30(b)(6) objection. Calls for expert
Page 119 1 highlights of prescribing information 2 section of the USPI, for neovascular 3 macular -- macular edema following RVO, 4 diabetic macular edema and diabetic 5 retinopathy, I don't see any information 6 about active information or inflammation. 7 Q. Okay. And is there anything in 8 the dosage and administration section on 9 the front page of DX 205 that 10 specifically talks about exclusion 11 criteria for any patient? 12 MS. OBERWETTER: 30(b)(6) 13 objection. 14 A. In the dosage and 15 administration section of the highlights 16 of prescribing information for 17 neovascular AMD, macular edema following 18 RVO, DMV or diabetic retinopathy, I do 19 not see any information related to the 20 exclusion of patients. 21 Q. Now, let's take a look at 22 section 4.1 within Defendant's Exhibit 23 205, which is at page 5248 in the lower 24 right-hand corner and let me know when 25 you get to the heading that's titled	Page 121 1 testimony. 2 A. Again, in my experience, it 3 does not mean that they are prohibited. 4 They would make clinical assessment and 5 evaluation. 6 Q. And likewise, heading 4.2 7 contraindication that talks about an 8 active intraocular inflammation, are 9 doctors, in real world practice, must 10 they exclude patients from EYLEA 11 treatment as a result of this 12 contraindication listed here in 4.2? 13 MS. OBERWETTER: Objection. 14 30(b)(6) objection. Calls for expert 15 testimony. 16 A. So again, it would be a 17 clinical assessment of whether the 18 physician felt that whatever intraocular 19 inflammation was present would preclude a 20 safe intravitreal injection or not. 21 Q. Now, let's go back to the '601 22 patent and I would like to take a look at 23 Claim 9. 24 A. Yes, I see that section in 25 patent '601.

Page 122 1 Q. There is a reference there to 2 "Exclusion criteria for the patient 3 include active intraocular inflammation 4 or active ocular or periocular 5 infection." 6 Do you see that? 7 A. I do see that in Claim 9. 8 Q. Now, were those exclusion 9 criteria part of the VIEW 1/VIEW 2 Phase 10 III clinical trial? 11 MS. OBERWETTER: Objection. 12 30(b)(6) objection. 13 A. My recollection is that, yes, 14 these were exclusion criteria included in 15 the VIEW 1 and VIEW 2 clinical trial. I 16 could confirm if I could see the 17 protocol. 18 Q. Okay. And what's the rationale 19 for putting -- do you recall the 20 rationale for having the exclusion 21 criteria of active intraocular 22 inflammation for the VIEW 1 and VIEW 2 23 clinical trials? 24 MS. OBERWETTER: Object to the 25 form. 30(b)(6) objection.	Page 124 1 MS. MAZZOCHI: Sure. 2 MS. OBERWETTER: Thanks. 3 A. So one of the most important 4 objectives of the VIEW 1 trial was to 5 assess safety. And this particular 6 aspect of eligibility ensured that we had 7 a population of patients enrolled in the 8 clinical trial in which we could clearly 9 assess the safety of the product. 10 Q. And then likewise, the 11 exclusion criteria for active ocular or 12 periocular injection, what is your 13 understanding as to why that was part of 14 the exclusion criteria for VIEW 1 and 15 VIEW 2? 16 A. Right. So similarly, if you, 17 if a patient has an active infection at 18 the time of an intravitreal injection, 19 there is an additional safety risk. And 20 in order to adequately assess the safety 21 outcomes related to aflibercept in the 22 VIEW 1 trial, we felt it was important to 23 exclude patients who had active ocular or 24 periocular infection. 25 Q. Do you know whether there is
Page 123 1 A. Just to clarify your question, 2 you're asking if there was a rationale 3 for why that was an exclusion criteria in 4 the VIEW 1/VIEW 2? 5 Q. Correct. 6 MS. OBERWETTER: Same objection. 7 A. So as I already mentioned, for 8 a patient that had active intraocular 9 inflammation, that would be potentially 10 contraindicated with giving an 11 intravitreal injection of any agent, and 12 in order to understand the 13 interpretability of the results in the 14 VIEW 1 clinical trial, we felt it was 15 important to exclude patients that may 16 have these contraindications. 17 Q. And why would that influence 18 the interpretability of the VIEW 1/VIEW 2 19 clinical trial, to your understanding? 20 MS. OBERWETTER: Is that a 21 30(b)(6) question? 22 MS. MAZZOCHI: That's hers. 23 MS. OBERWETTER: Will you tell 24 me when you go back to asking 30(b)(6) 25 questions?	Page 125 1 any clinical trial data in the EYLEA 2 labeling where patients who did have 3 active intraocular inflammation or active 4 ocular or periocular infection were 5 injected with EYLEA? 6 A. I'm not aware of any data in 7 the label where patients with intraocular 8 inflammation or active ocular or 9 periocular infection were injected with 10 EYLEA. 11 Q. Did Regeneron ever consider 12 putting a black box warning in the EYLEA 13 label to warn physicians to exclude 14 dosing to patients who have active 15 intraocular inflammation or active ocular 16 or periocular infection? 17 MS. OBERWETTER: Object to the 18 form and foundation. 19 A. So the decision to include a 20 black box warning would not have been 21 Regeneron's. That would have been a 22 decision on the part of the FDA. 23 Q. Let's go ahead and put the 24 labeling aside for now. Actually, no, 25 I'm sorry.

Page 126 1 Before we do that, if you could 2 take a look at page -- section 11, which 3 is on page 5254 over to 5255. 4 A. This is of the USPI, correct? 5 Q. Yes. 2019 labeling that we 6 marked as DX 205. 7 A. Right, I see section 11. 8 Q. Okay. So the first thing 9 that's in the EYLEA dose is aflibercept, 10 right? 11 A. This is a description of the 12 product which would include the active 13 agent, as well as any excipients. 14 Q. Right. And the active agent is 15 aflibercept, right? 16 MS. OBERWETTER: Object to the 17 form. 18 A. Right. 19 Q. And does the chemical 20 composition of aflibercept change when it 21 is put into solution? 22 MS. OBERWETTER: Object to the 23 form and foundation. 24 You can answer. 25 A. I'm not the expert on the	Page 128 1 development that might be able to answer 2 that question, but I can't say off the 3 top of my head who would be the best 4 person. 5 Q. Who is in charge of formulation 6 development for Regeneron for EYLEA at 7 this point in time? 8 A. I actually can't say who is 9 responsible at this time. 10 Q. Has EYLEA -- has the EYLEA 11 product been assessed on stability for 12 FDA purposes? 13 A. So as part of our application 14 to the FDA, we are required to submit 15 detailed manufacturing information in 16 module 3 of the BLA and that would 17 include stability data. 18 Q. And do you have any 19 understanding as to whether the chemical 20 composition of EYLEA, particularly with 21 regards to the aflibercept molecule, has 22 chemically changed over time while it's 23 been on stability? 24 MS. OBERWETTER: Object to the 25 form.
Page 127 1 molecular structure of aflibercept, but 2 we deliver aflibercept in solution. 3 Q. Okay. And do you have any 4 understanding as to whether the content 5 of what is inside the dose changes any of 6 the molecular structure of EYLEA? 7 MS. OBERWETTER: Object to the 8 form. 9 A. I don't have a -- 10 Q. I'm sorry, let me rephrase that 11 one. 12 Within a dose of the EYLEA drug 13 product, do you know whether any of the 14 other ingredients, whether it be water, 15 sodium phosphate, sodium chloride, 16 polysorbate 20 or sucrose, change any 17 part of the aflibercept chemical 18 structure? 19 A. I don't have the expertise to 20 answer that question. 21 Q. Who would within Regeneron, to 22 your knowledge, have the expertise to 23 answer that question? 24 A. So we have scientific 25 colleagues that work in formulation	Page 129 1 You can answer. 2 A. I don't have the expertise to 3 answer your question. 4 Q. And when it comes to the 5 composition of the EYLEA drug product, do 6 you have an understanding as to what the 7 ingredients besides water have as a 8 function within the formulation? 9 MS. OBERWETTER: Object to the 10 form and foundation of this witness. 11 A. I have a rudimentary 12 understanding of the excipients included 13 in the formulation, but not necessarily 14 their individual functions or reason for 15 inclusion. 16 Q. Okay. And do you know whether 17 this particular formulation exists as a 18 prefilled syringe? 19 A. Yes, so the development of the 20 prefilled syringe was based on a safety 21 consideration, as well as -- as well as 22 providing physicians with a more 23 efficient preparation of EYLEA. 24 Q. But did the chemical 25 composition of what was in the prefilled

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Page 130 1 syringe change as between this 2 description here versus what was used in 3 the VIEW 1/VIEW 2 clinical trials? 4 MS. OBERWETTER: Object to the 5 form. 6 A. I can't say for sure what may 7 have changed in the formulation 8 specifically between the VIEW 1 and VIEW 9 2 clinical trials and what is currently 10 in the prefilled syringe. 11 Q. Okay. Well, are you aware of 12 any change to the formulation description 13 that appears here as compared to when the 14 EYLEA product was first approved in 2011? 15 A. In my experience and knowledge, 16 I'm not aware of any changes to the 17 formulation as described here in the 18 USPI. 19 Q. Okay. You can go ahead and set 20 that aside for now. Let's start taking a 21 look at some internal documents from 22 Regeneron. 23 I would like to put before 24 you -- actually, before we get to that -- 25 I know that we saw one of your patents	Page 132 1 MS. OBERWETTER: Object to the 2 foundation. 3 A. So in clinical development, we 4 design clinical trials, but we have 5 contact with our patent attorneys to 6 discuss the ongoing development and there 7 would be a determination based on their 8 assessment, as well as others, to move 9 forward with any particular attempt to 10 patent any aspect of clinical trial 11 design or use. 12 MS. MAZZOCHI: Let me put in 13 front of you a document that I will 14 mark as Defendant's Exhibit 206, which 15 has production numbers RGN-EYLEA-MYLAN 16 00518628 through 640. Let me know 17 when you have DX 206 in front of you. 18 (Defendant's Exhibit 206, 19 Document Bates stamped 20 RGN-EYLEA-MYLAN-00518628 through 640, 21 was so marked for identification, as 22 of this date.) 23 Q. Do you have it? 24 A. I have Exhibit 206 in front of 25 me.
Page 131 1 earlier. You know, we talked about how 2 some of these other clinical protocols in 3 the '601 patent correspond to other 4 clinical trials. 5 Was it your understanding that 6 Regeneron was attempting to file patent 7 applications on all of the methods that 8 it was going to test in Phase III human 9 clinical trials? 10 A. Can you just say your question 11 one more time? 12 Q. Yes. Was it Regeneron's custom 13 and practice to file patent applications 14 on all of the methods that it was going 15 to test in human Phase III clinical 16 trials? 17 MS. OBERWETTER: Object to the 18 foundation. 19 A. It's my understanding that 20 Regeneron always seeks to patent any 21 novel, inventive aspects of both our -- 22 of any aspect of our development process. 23 Q. And how do you determine that 24 something is novel and inventive, using 25 the phrasing that you just used?	Page 133 1 Q. Now, you just mentioned that 2 Regeneron would seek out input from your 3 patent attorneys; would that go through 4 Stuart Kolinski, who is listed on this 5 org chart as being a part of the legal 6 department? 7 MS. OBERWETTER: I just want to 8 pause, I don't believe I have a 9 problem with that question. I just 10 want to caution the witness not to 11 reveal the content of any actual 12 conversations with counsel. 13 A. I don't recall the exact years, 14 but when I joined Regeneron in 2003, 15 Stuart Kolinski was our general counsel 16 and any legal concerns would have, it 17 would have been his responsibility. 18 Q. Okay. Did Regeneron ever have 19 any in-house patent attorneys, to your 20 knowledge? 21 A. At this time we have in-house 22 patent attorneys, but I'm not exactly 23 sure when we established in-house patent 24 attorneys. 25 Q. In this organizational chart,

Page 134 1 do you see your name on it as manager of 2 clinical trials? 3 A. Yes, I see my name. 4 Q. Approximately how long did you 5 have that title as manager of clinical 6 trials? 7 A. I don't recall exactly how long 8 I have that title. 9 Q. It says here that you reported 10 to Jesse Cedarbaum? 11 A. Yes, he was the hiring manager 12 that I first worked for at Regeneron. 13 Q. Okay. And he was there until 14 around the 2007 time frame? 15 A. I don't recall exactly when he 16 left, but that seems approximately when. 17 Q. Did he ever tell you why he was 18 leaving Regeneron? 19 A. At the time Jesse left the 20 company, he was offered another position. 21 And my understanding is that he didn't 22 think that position was suitable for him. 23 Q. When you say he was offered 24 another position, you mean another 25 position within Regeneron?	Page 136 1 her role? 2 A. So Sri's role in the context of 3 project management was to help keep 4 timelines and budgets, as well as to keep 5 the cadence of meetings related to 6 Regeneron programs moving consistently 7 forward. 8 Q. On the right there is a 9 reference to Imogene Grimes, 10 biostatistician. In your role as manager 11 of clinical trials, how did you interact 12 with Imogene Grimes? 13 A. So Imogene was, at this time, 14 the head of our biostatistics department. 15 And we interacted with her to advise on 16 the design of clinical trials, mostly 17 about any statistical considerations like 18 sample size, as well as the planned 19 analyses. 20 We also would have worked with 21 her on the analysis of data from any 22 clinical trial. Her group was 23 responsible for generating the outputs 24 for the statistical analyses outlined in 25 the protocols and the statistical
Page 135 1 A. Right, that's what I meant. 2 Q. That was a promotion or 3 demotion? 4 MS. OBERWETTER: Object to the 5 foundation. 6 A. I don't recall. 7 Q. There is another person listed 8 here, Anthony Lucarell, who is he? 9 A. So his name is actually 10 misspelled, it's Anthony Lucarelli, there 11 should be an "i" on the end. And he was 12 a clinical trial manager that also worked 13 for Dr. Cedarbaum, mostly on the oncology 14 trials with VEGF-Trap. 15 Q. Okay. And then there is a 16 reference to Bill Roberts, Susan Kassner 17 and Laura Pologe on the regulatory side. 18 Did they report to you? 19 A. No, I'm not sure why this is 20 represented this way. Bill Roberts, I 21 believe, reported directly to Len 22 Schleifer. Susan and Laura reported to 23 Bill. 24 Q. And there is also a Sri 25 Vuthoori, project management; what was	Page 137 1 analysis plans. 2 Q. All right. Did she have any 3 reporting line to you or did you have to 4 go through Mr. Cedarbaum or her superior 5 in order to utilize her skills? 6 A. There was no reporting line 7 between myself and Imogene Grimes, but 8 our teams were always assembled with 9 cross-functional representation from 10 functions that would have different 11 responsibilities for any clinical trial. 12 Q. If you look at the senior 13 management, we have Len Schleifer listed 14 as president and CEO. Is he still in 15 that role? 16 A. Yes. Len still has the title 17 of CEO. And I have to say, I'm not 100 18 percent certain about, if he's still 19 designated as president. 20 Q. Okay. And then we got George 21 Yancopoulos, who is listed at least on 22 this occupancy chart the CSO; is he still 23 the CSO today or does he have a better 24 title? 25 A. My understanding today, he

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Page 138 1 still has the title chief scientific 2 officer. 3 Q. We have Neil Stahl, senior VP 4 of preclinical development. Is that 5 still his title today? 6 A. My understanding is that his 7 title is now executive vice president of 8 research and development. 9 Q. Okay. And what was his role in 10 or around the time period when you were, 11 say, like 2007 to 2010, when you were in 12 the midst of getting all of these 13 clinical trials pulled together? 14 A. So you're asking specifically 15 about Neil Stahl; is that right? 16 Q. Yes. 17 A. So Neil's role was to help 18 oversee preclinical development as it 19 related to toxicology, formulation, as 20 well as pharmacology. 21 Q. You mentioned earlier that he 22 was one of the individuals you talked to 23 to prepare for your deposition today. 24 Why did some of this preclinical or how 25 did -- what do you recall about how this	Page 140 1 that would have helped inform 2 characteristics of aflibercept that we 3 felt were advantageous or indicated that 4 it was worthwhile to take that molecule 5 into human testing. 6 Q. Was there anything in the 7 preclinical data that was used to justify 8 putting aflibercept on an eight-week or 9 12-week dosing regimen? 10 MS. OBERWETTER: Object to the 11 form. 12 Q. For intravitreal injections 13 into the eye? 14 MS. OBERWETTER: Object to the 15 form. 16 A. So certainly the outcomes in 17 the toxicology studies, where we saw very 18 little adverse effects in nonhuman 19 primates with intravitreally delivered 20 aflibercept was very supported from a 21 safety perspective of going into the 22 clinical trials. 23 Q. Okay. Anything, though, that 24 would justify having the longer dosing 25 interval that you recall?
Page 139 1 preclinical data would influence the 2 development of the aflibercept human 3 clinical trials, particularly for Phase 4 II or Phase III? 5 MS. OBERWETTER: Object to the 6 form. 7 A. Could you be more specific 8 about what preclinical data you're 9 referring to? 10 Q. Anything that he was 11 overseeing? 12 MS. OBERWETTER: Object to the 13 form. 14 A. So from a toxicology 15 perspective, we are required to perform 16 certain toxicology studies to support an 17 investigational new drug application that 18 would allow us to move forward with 19 clinical testing. 20 So Neil's group would have 21 helped design and perform the toxicology 22 studies that supported moving into the 23 clinic with aflibercept. As well as his 24 group was responsible for pharmacokinetic 25 analysis from preclinical studies and	Page 141 1 MS. OBERWETTER: Object to the 2 form and foundation. 3 A. I can't remember if this was 4 specifically in Neil's purview, but we 5 did know that based on the aflibercept 6 molecule, comparing to Lucentis, that it 7 did have a longer half life in the eye of 8 animals. And so that gave us an 9 indication that potentially a longer 10 dosing interval might be possible, but 11 certainly animal studies are only 12 somewhat translatable to human studies. 13 Q. And then from Regeneron's 14 perspective, which clinical trial was it 15 that allowed you to conclude that 16 aflibercept might have a longer half life 17 in the human eye that might justify a 18 longer dosing interval? 19 MS. OBERWETTER: Object to the 20 form and foundation. 21 A. So we -- during the course of 22 EYLEA clinical development, we did not 23 measure half life in the human eye. That 24 would have required sampling from ocular 25 fluids, which to do serially in patients

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Page 142 1 is very difficult and causes additional 2 safety risk for patients. So the data 3 from the 0508 or CLEAR-IT 2 study was 4 really the clinical data that we looked 5 at in order to decide which dosing 6 regimens to test in Phase III. 7 Q. And were you a co-author on 8 publications discussing the CLEAR-IT 2 9 study? 10 A. I believe I was. But I would 11 have to see the publications to confirm. 12 Q. Okay. And do you recall 13 presenting CLEAR-IT 2 study data? 14 A. I personally did not present 15 CLEAR-IT 2 study data. Our practice was 16 to use usually investigators in the trial 17 or advisors to present data at scientific 18 conferences. 19 Q. Do you recall what was the 20 first scientific congress where the 21 CLEAR-IT 2 study data was presented? 22 MS. OBERWETTER: Object to the 23 form. 24 A. I do not recall. 25 MS. MAZZOCHI: Okay. I would	Page 144 1 to review the entire e-mail? 2 Q. Sure, go ahead. 3 (Witness reviews document.) 4 A. Okay. What was your question 5 again? 6 Q. Sure, at this stage, was 7 Regeneron planning to start a Phase III 8 trial for wet AMD with aflibercept? 9 A. So this e-mail is referring to 10 the start of a study, a Phase I study for 11 the treatment of wet AMD, but with 12 intravenous administration of 13 aflibercept. 14 Q. Okay. And then on the front of 15 this e-mail there is a reference to a 16 Stanley Wiegand, who is he? 17 A. Stan Wiegand was the head of 18 ophthalmology research. 19 Q. And who is Charles Pool? 20 A. I don't recall who Charles Pool 21 was. 22 Q. Okay. Was it common for 23 Regeneron to prepare press releases when 24 they were about to start clinical trials? 25 MS. OBERWETTER: Object to the
Page 143 1 like to put before you a document that 2 I will mark as Defendant's Exhibit 3 206, which has production numbers 4 RGN-EYLEA-MYLAN 518348 through 350. 5 (Defendant's Exhibit 207, 6 Document Bates stamped RGN-EYLEA-MYLAN 7 518348 through 350, was so marked for 8 identification, as of this date.) 9 MS. OBERWETTER: I believe we're 10 on to 207. 11 MS. MAZZOCHI: I'm sorry, 207. 12 Q. Do you have Exhibit 207? 13 A. Yes, I have Exhibit 207. 14 Q. Okay. Can you confirm that 15 Exhibit 207 is a Friday, January 30th, 16 2004 e-mail from Jesse Cedarbaum to you 17 and others involving what was described 18 as draft VEGF-Trap AMD press and some 19 thoughts on the release of an AMD trial? 20 A. I see that e-mail is dated 21 Friday, January 30th, 2004 and that I'm 22 one of the recipients of e-mail. 23 Q. So at this point in time, was 24 an AMD trial proposed or underway? 25 A. Do you mind if I take a minute	Page 145 1 form. 2 A. Regeneron was a small company 3 back then, so the initiation of a 4 clinical development program would have 5 been something that we would have 6 disclosed. 7 Q. Okay. And at this point in 8 time, was -- you had a corporate 9 partnership with Aventis. Was Aventis 10 going to be also funding or participating 11 in this intravenous aflibercept trial? 12 MS. OBERWETTER: Object to the 13 form. 14 A. I can't speak to the details of 15 the collaboration, I guess agreements 16 back then. 17 MS. MAZZOCHI: Okay. You can go 18 ahead and put that one aside. I would 19 like to put before you a document that 20 I will mark as Defendant's Exhibit 21 208, which has production number 22 RGN-EYLEA-MYLAN 00521881. 23 (Defendant's Exhibit 208, 24 Document Bates stamped 25 RGN-EYLEA-MYLAN-00521881, was so

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Page 146 1 marked for identification, as of this 2 date.) 3 Q. Do you have it? 4 A. Yes, I have Exhibit 208 in 5 front of me. 6 Q. Can you confirm it's a Monday, 7 March 1st, 2004 e-mail from Jesse 8 Cedarbaum, cc'ing and copying others, and 9 it says, "Barring any unforeseen 10 circumstances, we will dose our first AMD 11 patient in the VEGF-Trap study tomorrow. 12 Karen Chu will be in attendance." 13 Do you see that? 14 A. Yes, I see that. 15 Q. Do you recall whether this 16 first dosing of the AMD patient was an 17 intravitreal injection or an IV systemic? 18 A. My recollection is this is 19 referring to the first patient that we 20 dosed intravenously with aflibercept. 21 Q. Okay. And what recall -- well, 22 were you in attendance? 23 A. Yes, I was in attendance. 24 Q. All right. And what do you 25 recall about that?	Page 148 1 A. So I don't recall exactly how 2 long this took, but we did conduct this 3 initial Phase I study in AMD as well as 4 another Phase I study in DME with 5 intravenous administration. And my 6 recollection is that in parallel, we were 7 working on the intravitreal formulation 8 and performing preclinical studies in 9 preparation for potentially moving 10 forward with an intravitreal program. 11 Q. Okay. And why was it important 12 to do the intravenous studies before 13 going to the intravitreal program? 14 MS. OBERWETTER: Object to the 15 foundation. 16 A. So at the time there was a lot 17 of discussion about the safety of VEGF 18 inhibitors. And with systemic 19 administration we understood, all right, 20 that some of the typical effects that you 21 would see were increased blood pressure 22 and increased proteinuria or protein in 23 the urine. However, there was, at this 24 time, a lot of skepticism around the 25 safety of intravitreal administration,
Page 147 1 A. So I recall that the first 2 patient in the '0305 study, which was the 3 AMD Phase I study of intravenous 4 VEGF-Trap, this first patient was 5 enrolled and treated at Wilmer Eye 6 Institute. 7 Q. Okay. 8 A. And I attended this initial 9 visit to ensure that the clinical study 10 team on site had support for 11 understanding the protocol requirements 12 as well as the dosing requirements. 13 In particular, with intravenous 14 administration, we used an infusion pump, 15 and so part of my role was to make sure 16 that the pump worked properly and ensure 17 that if there was -- if there were any 18 issues, that I could assist with 19 troubleshooting. 20 Q. Okay. And for approximately 21 how long did Regeneron pursue the 22 intravenous program before it decided to 23 start doing an intravitreal approach for 24 aflibercept when it came to wet AMD? 25 MS. OBERWETTER: Objection.	Page 149 1 especially for the treatment of diseases 2 like neovascular AMD and DME, where we 3 envisioned that chronic treatment would 4 be necessary. 5 So at least as an initial Phase 6 I study to explore the safety of 7 aflibercept dosed intravenously in these 8 patients, we felt this was a step that we 9 could take because we had the intravenous 10 formulation already in the clinic for 11 oncology indications at the time. 12 Q. Okay. And again, this was in 13 the 2004 time period that this skepticism 14 was out there? 15 A. That's correct. These 16 discussions were concurrent and predated 17 2004. 18 MS. MAZZOCHI: I would like to 19 mark as Exhibit 209 a document with 20 production numbers RGN-EYLEA-MYLAN 21 518954 through 959. 22 (Defendant's Exhibit 209, 23 Document Bates stamped RGN-EYLEA-MYLAN 24 518954 through 959, was so marked for 25 identification, as of this date.)

Page 150 1 Q. Let me know when you have that 2 document. Do you have Exhibit 209 in 3 front of you? 4 A. Yes, I have Exhibit 209 in 5 front of me. 6 Q. Can you confirm the top e-mail 7 was copied to you and others on Tuesday, 8 August 31st, 2004? 9 A. Yes, I'm on the cc line of this 10 e-mail dated August 31st, 2004. 11 Q. Okay. And you were being 12 forwarded a document or an e-mail that 13 was titled "DIA dispatch," referring to 14 the Drug Information Association 15 dispatch; do you see that? 16 A. I do see that here in the 17 e-mail. 18 Q. All right. And what was the 19 purpose of your team at Regeneron getting 20 this DIA dispatch? 21 A. Give me a moment to review the 22 e-mail. 23 Q. Sure. 24 (Witness reviews document.) 25 A. Okay, sorry, if you could ask	Page 152 1 with aflibercept. 2 Q. Macugen was dosing its product 3 intravitally, correct? 4 A. That is correct. 5 Q. Did these results cause 6 Regeneron to start thinking more closely 7 of doing an intravitreal injection? 8 MS. OBERWETTER: Object to the 9 form. 10 A. I believe that the results from 11 the Macugen trials gave us more 12 information about the safety and 13 feasibility of intravitreal injections 14 given regularly to these, to the -- to 15 AMD patients over the course of a year of 16 treatment. 17 Q. Did the Macugen results give 18 you any sense that there might be more 19 willingness in the marketplace to accept 20 an intravitreal injection? 21 A. The Macugen results from these 22 Phase III studies definitely supported 23 that intravitreal administration of a 24 product in wet AMD patients was possible. 25 Q. If you could also take a look
Page 151 1 your question again, that would be great. 2 Q. Yeah, if we look at the 3 description, was the goal of the service 4 to give people comprehensive summaries of 5 USFDA Drugs and Biologics Advisory 6 Committee meetings just hours after their 7 completion? 8 A. It says here that "In our 9 effort to provide you with comprehensive 10 summaries of USFDA Drugs and Biologics 11 Advisory Committee meetings just hours 12 after their completion, DIA has licensed 13 content from Lipient, parent of the IDRAC 14 regulatory database." 15 Q. Why was Regeneron trying to get 16 this type of data information in close to 17 realtime? 18 MS. OBERWETTER: Object to the 19 form and foundation. 20 A. So this appears to be a summary 21 of the Macugen FDA advisory meeting where 22 they reviewed the Macugen Phase III 23 studies. This would have been of great 24 interest to Regeneron because Macugen was 25 viewed as a potential competitive product	Page 153 1 at the page, it's the second-to-last page 2 of the exhibit, it ends with the number 3 518958. 4 A. Okay. 5 Q. There is a heading near the 6 bottom of the page titled "Market 7 Issues"; do you see that? 8 A. I do see that. 9 Q. And in talking about -- in the 10 second paragraph it says, "There are 11 several novel products in development for 12 AMD, such as Genaera's squalamine and 13 Genentech's Lucentis (ranibizumab)." 14 Do you see that? 15 A. Yes, I see that sentence in the 16 e-mail. 17 Q. All right. And at this time it 18 was known to Regeneron that ranibizumab 19 was also out there in Phase III trials, 20 right? 21 A. Yes, the Lucentis trials were 22 being conducted concurrently at this 23 time. 24 Q. And Lucentis was also being 25 done as an intravitreal injection of a

Page 154 1 VEGF inhibitor? 2 A. Yes, that's correct. 3 Q. And it also mentions at the end 4 of the paragraph that Regeneron's 5 VEGF-Trap was also currently in clinical 6 and preclinical trials, right? 7 A. Yes, the last sentence is 8 "Other anti-angiogenic agents currently 9 in clinical and preclinical trials are 10 Angstrom's A6, OXiGene's CA4P and 11 Regeneron's VEGF-Trap." 12 Q. Okay. At this point in time, 13 were you looking at the Lucentis dosing 14 regimen as one that you might want to 15 copy or emulate? 16 MS. OBERWETTER: Object to the 17 form. 18 A. I would say at this time we 19 were monitoring the Lucentis clinical 20 development program closely from a 21 competitive intelligence perspective. 22 Q. Okay. And who was responsible 23 for competitive intelligence within 24 Regeneron in, say, the 2004 to 2007 time 25 frame?	Page 156 1 neovascular AMD is that patients lose 2 vision rapidly after diagnosis, also 3 proceeding to legal blindness within 4 months after diagnosis. So the Macugen 5 trials were of great interest to everyone 6 in the retina community, physicians as 7 well as researchers as ourselves, because 8 Macugen represented the first anti-VEGF 9 pharmacologic agent that was delivered in 10 Phase III studies. 11 And the outcome of these 12 studies was very disappointing to the 13 entire community because they did not 14 demonstrate vision gain as people had 15 hoped, and instead had results that were 16 very similar to prior treatments that 17 simply slowed vision loss in these 18 patients. 19 Q. Right. But then Lucentis, 20 ranibizumab, that data was certainly much 21 more promising in AMD in terms of the 22 early reports that came out, correct? 23 MS. OBERWETTER: Object to the 24 form. 25 A. So I don't recall exactly what
Page 155 1 A. I don't recall that anyone was 2 specifically responsible for that. It 3 was all -- I would say we were all very 4 interested in our competitors' progress 5 as it related to anti-VEGF products. 6 Q. And one of the reasons you were 7 all very interested is because you wanted 8 to see what the competitive landscape 9 would look like, right? 10 A. Yes, we were very interested in 11 the competitive landscape. 12 Q. And were you also interested in 13 seeing what their dosing regimen looked 14 like, correct? 15 A. Yes, but I should give some 16 background here since we're reviewing an 17 e-mail that includes information 18 regarding the Macugen studies. 19 So up to this point nobody had 20 demonstrated that consistent vision gain 21 with treatment. So the goal of treatment 22 up to this point was really just to 23 prevent patients from losing visual 24 acuity. 25 The natural course of	Page 157 1 Lucentis data was available in this 2004 2 time frame. But it certainly was a 3 molecule that we were very interested in, 4 again, from a competitive perspective. 5 Q. And certainly by the time we 6 got to the 2010 time frame, at the time 7 that you had submitted your Phase III 8 clinical trials, ranibizumab had been 9 shown to produce some consistent vision 10 gain, right, when injected intravitally? 11 MS. OBERWETTER: Object to the 12 form. 13 A. So the pivotal Lucentis trials 14 in neovascular AMD were the Anchor and 15 Marina trials. And they demonstrated 16 vision gain with ranibizumab dosed every 17 four weeks or monthly for the -- for a 18 year, so week 52 was their primary 19 endpoint. 20 MS. OBERWETTER: Just a quick -- 21 just a quick, we have been going about 22 another hour, if you have a little bit 23 more to do. We're well into lunch 24 hour, so whenever you have a breaking 25 point, that would be great.

Page 158 1 MS. MAZZOCHI: Yeah, let me just 2 whip out a couple of these and then we 3 can take a lunch break. 4 MS. OBERWETTER: So I just want 5 to be clear, I don't want to do a 6 couple more exhibits. If you've got 7 some more stuff to do before you get 8 into a bunch more exhibits, that would 9 be -- 10 MS. MAZZOCHI: If you want to 11 take your lunch break now, we can take 12 a lunch break now. 13 MS. OBERWETTER: I didn't want 14 to interrupt you in a particular line 15 of questions, but I don't want to do 16 more exhibits, that's what I'm saying. 17 MS. MAZZOCHI: That's fine. I 18 was about to start another exhibit, so 19 we can take a lunch break. 20 THE VIDEOGRAPHER: Going off the 21 record at 12:44 p.m. 22 (Lunch recess: 12:44 p.m.) 23 24 25	Page 160 1 of this e-mail from Ilham Zoughi. 2 Q. And was he forwarding to you 3 and others a publication titled "New 4 treatment for wet age-related macular 5 degeneration shows promising early 6 results, vision improves for patients 7 going blind from wet AMD"? 8 A. Just give me a minute to review 9 the full document, but Ilham is a she. 10 Q. Okay. 11 A. Okay. Sorry, what was your 12 question again? 13 Q. So can you confirm you received 14 a copy of this article titled "New 15 treatment for wet age-related macular 16 degeneration shows promising early 17 results, vision improves for patients 18 going blind from wet AMD"? 19 A. So I don't recall receiving 20 this e-mail, but I see that I was one of 21 the people that e-mail was addressed to. 22 Q. Okay. And do you recall 23 anything about this particular study 24 where Avastin was dosed in patients and 25 their average vision improved over the
Page 159 1 Afternoon Session 2 1:29 p.m. 3 K A R E N C H U, having been 4 previously duly sworn, was examined and 5 testified further as follows: 6 THE VIDEOGRAPHER: We are back 7 on the record at 1:29 p.m. 8 MS. MAZZOCHI: Thank you. I 9 would like to mark as DX 210 a 10 document with production numbers 11 RGN-EYLEA-MYLAN 540875 through 877. 12 (Defendant's Exhibit 210, 13 Document Bates stamped RGN-EYLEA-MYLAN 14 540875 through 877, was so marked for 15 identification, as of this date.) 16 EXAMINATION (Continued) 17 BY MS. MAZZOCHI: 18 Q. Do you have that exhibit before 19 you? 20 A. Yes, I have Exhibit 210. 21 Q. Can you confirm that Exhibit 22 210 contains an e-mail string including 23 an e-mail from Ilham Zoughi, Z-O-U-G-H-I, 24 to you and others dated March 3rd, 2005? 25 A. Yes, I see that I'm a recipient	Page 161 1 study? 2 A. I don't recall anything about 3 this study. 4 Q. If you look at the bottom line, 5 the author there said -- the study 6 clinician was quoted as saying, "We have 7 been injecting anti-VEGF drugs into the 8 eye for the past three years with very 9 encouraging results." 10 MS. OBERWETTER: Object to the 11 form. 12 Q. Do you see that? 13 A. I do see that as part of the 14 quote here. 15 Q. Right, and that quote is 16 attributed to Philip J. Rosenfeld, M.D., 17 Ph.D.? 18 A. So this e-mail just said 19 Rosenfeld, which assume to mean Phil 20 Rosenfeld. 21 Q. Did Regeneron also reach out to 22 get input from Phil Rosenfeld in the 23 context of its clinical trial work? 24 MS. OBERWETTER: Object to the 25 form.

Page 162 1 You can answer. 2 A. Dr. Rosenfeld was a respected 3 key opinion leader in the retina 4 community, and he is someone that we 5 interacted with occasionally to discuss 6 aspects of the clinical development 7 program. 8 Q. Do you recall there being any 9 impact within Regeneron when it was 10 reported that Avastin, a VEGF inhibitor, 11 was producing positive results in the 12 eye? 13 A. I don't remember this study or 14 the data from this study having a 15 specific impact at Regeneron. 16 Q. All right. But what about 17 Avastin generally, the experience that 18 clinicians were having with Avastin? 19 MS. OBERWETTER: Object to the 20 form. 21 Q. Injecting it into the eye to 22 get -- to stop vision loss? 23 A. So this press release is 24 referring to systemic administration of 25 Avastin.	Page 164 1 number RGN-EYLEA-MYLAN 541876 through 2 889. 3 (Defendant's Exhibit 211, 4 Document Bates stamped RGN-EYLEA-MYLAN 5 541876 through 889, was so marked for 6 identification, as of this date.) 7 Q. If you can confirm the first 8 page of this exhibit includes an April 9 26th, 2005 e-mail from Ms. Zoughi to you 10 and others with a subject line 11 "Communication brief for ARVO"? 12 A. Yes, I see that this e-mail 13 from Ilham Zoughi dated April 26th, 2005 14 includes myself as one of the recipients, 15 and is the subject -- the subject is 16 "Communication brief for ARVO." 17 Q. Okay. And what is ARVO? 18 A. ARVO is referring to the 19 Association for Research in Vision and 20 Ophthalmology. 21 Q. And also included in this 22 e-mail was the briefing document. If you 23 can take a look at the -- well, do you 24 remember if you actually attended ARVO in 25 this year?
Page 163 1 Q. Right. 2 A. But Dr. Rosenfeld was involved 3 in running his own investigator-initiated 4 studies with intravitreal Avastin. 5 Q. Right, right. And he indicates 6 in this document at least that he had 7 been doing that for at least three years? 8 A. That is what the document says. 9 Q. Right. So did the fact that 10 someone like Dr. Rosenfeld and others 11 were injecting Avastin directly into the 12 eye, did that influence their thinking as 13 to whether it would be useful to dose 14 VEGF-Trap into the eye? 15 MS. OBERWETTER: Object to the 16 form of the question. 17 A. Dr. Rosenfeld, as well as other 18 retinal specialists in the community, 19 provided information that gave Regeneron 20 more confidence regarding the feasibility 21 of moving forward with an intravitreally 22 delivered product. 23 MS. MAZZOCHI: You can set that 24 aside and let me mark as Defendant's 25 Exhibit 211 a document with production	Page 165 1 A. I don't remember specifically 2 my attendance in 2005, but this is one of 3 the industry meetings or one of the 4 meetings in the field that I would attend 5 regularly. 6 Q. Can you take a look at the 7 second page of Exhibit 211, at page 877, 8 it indicates that Quan Nguyen from the 9 Wilmer Eye Institute would be presenting 10 data from the Phase I study at the ARVO 11 meeting, right? 12 A. Yes, it does state that. 13 Q. All right. And if you could 14 take a look at page 881 -- 15 A. Can I just clarify that the 16 document states that Dr. Nguyen will be 17 presenting OCT data from the systemic 18 Phase I wet AMD study. 19 Q. Okay. Well, if you can take a 20 look at page 881 within Defendant's 21 Exhibit 211. Do you see the title there 22 that says "Appendix 1, Phase I data"? 23 A. I do see Appendix 1 titled 24 "Phase I data." 25 Q. Okay. And that was going to be

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Page 166 1 part of the ARVO presentation set for 2 Tuesday, May 3rd, 2005? 3 A. Yes, I do see here that it 4 indicates that the presentation start and 5 end time would be Tuesday, May 3rd, 2005. 6 Q. All right. And if you take a 7 look at the method and results presented 8 here, can you confirm that this clinical 9 trial protocol and results corresponds to 10 the Phase I trial that's described in the 11 '601 patent at example 3, columns 8 to 9? 12 MS. OBERWETTER: Object to the 13 form and foundation. 14 A. I'll need a minute just to get 15 oriented here. 16 Q. Sure. 17 (Witness reviews document.) 18 A. So the study that's described 19 in Appendix 1 on the page ending in 881 20 does correspond to example 3 in the '601 21 patent. 22 Q. Okay. And then while we're on 23 this -- was there a particular name given 24 to that clinical trial that's example 3? 25 A. I don't recall that there was a	Page 168 1 that it demonstrated that VEGF inhibition 2 in these patients had the potential to 3 improve visual acuity and cause 4 reductions in central or, in this study 5 called excess retinal thickness, which 6 was an indication of an anti-VEGF affect 7 on the underlying disease. 8 Q. Now, in the '601 patent, so we 9 saw example 3 was the one from -- the 10 study from Dr. Nguyen that was presented 11 at ARVO. The example 2, Phase II 12 clinical study that's in the '601 patent, 13 did that clinical study have a name? 14 MS. OBERWETTER: Object to the 15 form and the characterization in the 16 first part of your question. 17 You can answer. 18 A. The study described in example 19 2 of the '601 patent, which was the Phase 20 II trial of repeated doses of 21 intravitreally administered VEGF-T in 22 subjects with neovascular AMD, this trial 23 was referred to as the CLEAR-IT 1 study. 24 Q. And you were a co-author on 25 publications involving the CLEAR-IT 1
Page 167 1 specific name given to this trial, 2 although the clear designation was 3 something that Dr. Cedarbaum in 4 particular used for many of the early 5 phase clinical trials. 6 Q. Okay. If we look in Exhibit 7 211 at page 882 under the Conclusions 8 section, last two lines state: "A trend 9 towards a dose-related improvement in 10 BCVA was also observed. Clinical trials 11 using intravitreal administration of 12 VEGF-Trap are underway." 13 A. I do see that portion of the 14 Conclusion section. 15 Q. So was it Regeneron's position 16 that this Phase I intravenous data that 17 Dr. Nguyen presented, that we see here in 18 DX 211, Appendix 1, was a justification 19 to continue with the intravitreal 20 administration of VEGF-Trap? 21 MS. OBERWETTER: Object to the 22 form and foundation. 23 A. The results from the Phase I 24 interavenous study in wet age-related 25 macular degeneration was informative in	Page 169 1 study, right? 2 A. My recollection is that I was, 3 but I would have to see the publication 4 to confirm. 5 Q. Okay. And then if you look at 6 example 1, the Phase I clinical trial, 7 intravitreally administered receptor 8 VEGF-T in subjects with neovascular AMD, 9 do you recall what study name that one 10 was given? 11 A. Sorry, I made an error 12 actually. 13 Q. Okay. 14 A. So the study in example 1 was 15 referred to as the CLEAR-IT 1 study. The 16 study in example 2 was the CLEAR-IT 2 17 study. 18 Q. Okay. Perfect. Thank you. 19 And then if we go on to the 20 next column, example 4, the Phase III 21 clinical trials, was that the VIEW 1 22 study or VIEW 2? 23 A. So this section under example 4 24 refers to two parallel Phase III clinical 25 trials carried out to investigate the use

Page 170 1 of VEGF-T to treat patients with the 2 neovascular form of age-related macular 3 degeneration, so this section appears to 4 be referring to both the VIEW 1 and the 5 VIEW 2 studies. 6 Q. Okay. And then if you can jump 7 forward to column 14, there is an example 8 5 provided there. Did that clinical 9 study also have a name? 10 A. Example 5 is the Phase II 11 clinical trial of VEGF-T in subjects with 12 diabetic macular edema. This study was 13 referred to as the DaVinci trial. 14 Q. Okay. And then example 6, did 15 that clinical trial have a name? 16 A. So in example 6, it's referring 17 to a randomized multi-centered double- 18 masked trial in treatment of patients 19 with macular edema secondary to CRVO. 20 And I believe this is referring 21 to a study that we called the Copernicus 22 study, although there was a second CRVO 23 study conducted called the Galileo study. 24 MS. MAZZOCHI: That's fine. All 25 right. I would like to put in front	Page 172 1 to try to provide a more informed 2 response. 3 Q. Sure. 4 (Witness reviews document.) 5 A. Okay. Could you ask your 6 question again? 7 Q. Sure. Why did Regeneron have 8 this expert advisory group in connection 9 with the AMD indication? 10 MS. OBERWETTER: Object to the 11 form and foundation. 12 A. I don't recall specifically why 13 we conducted this particular meeting with 14 external experts. 15 Q. Okay. One of the questions 16 that Neil Stahl said that he wanted to 17 have answered is "What exactly is the 18 reimbursement situation of Lucentis 19 likely to be, e.g., what is copay by 20 patient, et cetera?" 21 Do you have any recollection of 22 that? 23 A. I do not have any recollection 24 of that specific topic. 25 Q. Do you recall generally any
Page 171 1 of you a document that I will mark as 2 Defendant's Exhibit 212, which has 3 production numbers RGN-EYLEA-MYLAN 4 634608 through 611. 5 (Defendant's Exhibit 212, 6 Document Bates stamped RGN-EYLEA-MYLAN 7 634608 through 611, was so marked for 8 identification, as of this date.) 9 Q. Can you confirm this is a 10 document with an e-mail string with the 11 first one dated Sunday, January 8th, 12 2006, regarding an AMD expert meeting 13 from Neil Stahl to Jesse Cedarbaum, you 14 and others? 15 A. I can confirm that the date of 16 this e-mail is Sunday, January 8th, 2006. 17 The subject is regarding AMD expert 18 meeting. It's from Neil Stahl. And I'm 19 one of the recipients of this e-mail. 20 Q. Why did Regeneron want to have 21 this AMD advisory expert meeting? 22 MS. OBERWETTER: Object to the 23 form and foundation. 24 A. I don't recall. If you like, I 25 can review the e-mail a little bit more	Page 173 1 discussion about the copay-type 2 arrangements that patients might 3 experience with Lucentis? 4 A. I was not involved in 5 discussions regarding pricing. 6 Q. Okay. One of the other 7 questions to ask these experts was "Do 8 they think that the PIER regimen of 9 Lucentis will work." 10 Do you see that? 11 A. I do see that question. 12 Q. What was your understanding of 13 the PIER regimen for Lucentis? 14 MS. OBERWETTER: Object to the 15 form. 16 You can answer. 17 A. So the PIER study was an 18 investigator-initiated study conducted by 19 Dr. Phil Rosenfeld that, my understanding 20 of that regimen is that it was three 21 initial monthly doses of .3 milligrams of 22 Lucentis followed by quarterly dosing, so 23 every-three-month dosing. 24 Q. Then they -- then there is also 25 a line item under that question that

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Page 174 1 says, "Their thoughts on our Phase II 2 trial and endpoint, do they concur with 3 our perspective that it is impossible to 4 get meaningful visual acuity data without 5 doing a Phase III study?" 6 Do you see that? 7 A. I see that question in the 8 e-mail. 9 Q. Do you recall what the expert's 10 opinion was on that issue? 11 A. I do not recall what the 12 expert's opinion was on that issue. 13 Q. If you can take a look at the 14 e-mail underneath it from Jesse Cedarbaum 15 from January 8th, 2006 to you and others. 16 He said "We never got to 17 discuss this on Friday afternoon. We 18 really need to get a background package 19 out to our advisors on Monday at the 20 latest." 21 Do you recall whether you ever 22 did get a briefing package or a 23 background package to the advisors on 24 this issue? 25 A. I don't recall if we	Page 176 1 form. 2 You can answer. 3 A. So my understanding of these 4 three options is that the first one would 5 be the endpoint proposed was practice 6 portion of patients with a 15-letter 7 loss. 8 The second one would be the 9 proportion of patients with at least a 10 15-letter gain. 11 And the third one would be a 12 15-letter difference between treatment 13 arms in the study. 14 Q. Right. What's the difference 15 between the 15-letter loss, gain or 16 delta? 17 MS. OBERWETTER: Objection. 18 Asked and answered. 19 A. So the first two would rely on, 20 basically, counting the number of 21 participants in any treatment group that 22 met this threshold. And so patients who 23 had a 15 or more letter loss would be 24 counted for the first one versus those 25 that didn't.
Page 175 1 specifically got a background package out 2 to the advisors. 3 Q. How would we be able to figure 4 that out? 5 MS. OBERWETTER: Object to the 6 form. 7 You can answer, if you can. 8 A. My speculation is that 9 Dr. Cedarbaum would have sent that 10 package at some later date after this 11 e-mail. So I can only assume that it 12 would potentially be part of Jesse's 13 e-mail. 14 Q. Okay. If you can take a look 15 at the last page of Exhibit 212. One of 16 the items on the proposed agenda was a 17 choice of endpoints for Phase III, 18 15-letter loss, 15-letter gain, 15-letter 19 delta. Do you see that? 20 A. Yes, I see that as item 3 on 21 the proposed agenda. 22 Q. What's your understanding of 23 the differences between those three 24 different types of endpoints? 25 MS. OBERWETTER: Object to the	Page 177 1 And for the second one, the 2 same kind of idea, that you would count 3 the patients that were able to achieve at 4 least a 15-letter gain versus those that 5 didn't. 6 The third one is actually 7 comparing the results from the overall 8 treatment group to determine a delta 9 between treatment groups. 10 Q. How do you measure the 11 15-letter loss for item 3A? 12 MS. OBERWETTER: Object to the 13 form and foundation. Are you asking 14 about what was intended by this 15 document or what are you asking? 16 Q. No, what's your understanding 17 of how you measure a 15-letter loss in 18 the context of these types of endpoints? 19 MS. OBERWETTER: Object to the 20 form and foundation. 21 Q. What measurement technique is 22 used? 23 MS. OBERWETTER: Same objection. 24 A. So in the context of clinical 25 trials, we use ETDRS. It's the method of

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Page 178 1 measuring visual acuity known as the 2 ETDRS visual acuity assessment. 3 Q. And would that same ETDRS 4 methodology apply to 15-letter loss, 5 15-letter gain or 15-letter delta? 6 A. Yes, visual acuity would be 7 measured with the same methodology for 8 each of those potential endpoints. 9 Q. Is there only one published 10 methodology for doing this or are there 11 multiple techniques that could be used to 12 assess ETDRS visual acuity? 13 MS. OBERWETTER: Object to the 14 form. Calls for expert testimony. 15 You can answer. 16 A. So the ETDRS method of 17 measuring visual acuity is a published 18 method. However, there is another method 19 that is considered equivalent to ETDRS. 20 It's based on the ETDRS method called the 21 electronic visual acuity assessment. So 22 there are multiple methods that could 23 have been employed. 24 Q. Is the electronic one, the one 25 where the patient is standing at 3 --	Page 180 1 I would like to put before you 2 a document that I will mark as DX 213, 3 which has production numbers 4 RGN-EYLEA-MYLAN 634629 through 632. 5 (Defendant's Exhibit 213, 6 Document Bates stamped RGN-EYLEA-MYLAN 7 634629 through 632, was so marked for 8 identification, as of this date.) 9 Q. Let me know when you have that. 10 A. I have Exhibit 213 in front of 11 me. 12 Q. Are you identified as one of 13 the individuals who participated in this 14 advisory panel meeting? 15 MS. OBERWETTER: Object to the 16 form and foundation. 17 A. Give me a moment to review 18 this. I am listed as one of the 19 Regeneron attendees for this meeting. 20 Q. Do you remember anything about 21 this meeting? 22 A. I don't really remember 23 specifics about this meeting. 24 Q. Do you recall one way or the 25 other whether you actually did
Page 179 1 assessed at 3 meters as opposed to 4 2 meters? 3 A. I don't recall specifically 4 what the distance was for the electronic 5 visual acuity. 6 Q. At some point did Regeneron ask 7 to conduct an ETDRS assessment at the 8 2-meter mark as opposed to 4 meters? 9 A. So part of the ETDRS assessment 10 of visual acuity involves starting a 11 patient at a 4-meter distance from the 12 eye chart. If they are unable to read 13 letters at that distance, they would be 14 moved closer to a 2-meter distance. 15 Q. Right. And at one point do you 16 recall whether there were discussions 17 about trying to have an ETDRS protocol 18 where the patients would start at the 19 2-meter distance, not the 4-meter 20 distance? 21 A. I don't recall discussions 22 about that, specifically. 23 Q. Okay. Maybe we'll get to that 24 later. All right. Go ahead and put DX 25 212 aside.	Page 181 1 participate? 2 A. I don't recall my specific 3 participation, but given my role at the 4 company, I assume that I was in 5 attendance. 6 Q. One of the items listed here 7 that Regeneron wanted to get the 8 consultant's impressions of was how will 9 Lucentis be used in practice, monthly as 10 in ANCHOR or MARINA, induction followed 11 by quarterly maintenance as in PIER or 12 induction followed by PIER and criteria 13 based dosing as in SAILOR. 14 Do you see that? 15 A. I do see that under 3A. 16 Q. All right. Now, was it your 17 understanding when there is a reference 18 to an induction period, was that the 19 monthly doses of Lucentis? 20 MS. OBERWETTER: Object to the 21 form and foundation. 22 A. My understanding is that that 23 would be referring to some number of 24 initial monthly doses, but not 25 specifically to three initial monthly

Page 182 1 doses. 2 Q. All right. In the PIER study, 3 it was three initial monthly doses, 4 though, and then extended out to 12 5 weeks, right? 6 A. The PIER regimen was three 7 initial monthly doses, followed by doses 8 of Lucentis every three months. 9 Q. Right. And then was the SAILOR 10 study also three monthly doses, and then 11 followed by PRN dosing? 12 A. I don't recall the exact dosing 13 regimen used in SAILOR. 14 Q. Okay. If you can take a look 15 at the second page of this exhibit, one 16 of the agenda items listed for the 17 Regeneron expert meeting in January of 18 2006 was how important is dose frequency. 19 Do you remember any discussions 20 within Regeneron and its experts, and its 21 external experts about dose frequency 22 that Regeneron should be targeting for 23 AMD? 24 A. I remember discussions about 25 dose frequency with external experts to	Page 184 1 practice to keep minutes from this 2 meeting? 3 MS. OBERWETTER: Object to the 4 form. 5 A. It was the practice to keep 6 minutes from such meetings. 7 MS. MAZZOCHI: Counsel, we will 8 request that the minutes from this 9 advisory panel meeting from January 10 15th, 2006, that you conduct a search 11 for them and produce them, because we 12 were not able to locate them in your 13 production set. 14 (Production request) 15 MS. MAZZOCHI: You can set that 16 aside. 17 I would like to mark as 18 Defendant's Exhibit 214 a document 19 with production numbers MYLAN 5699 -- 20 I'm sorry, RGN-EYLEA-MYLAN 569973 21 through 975. 22 (Defendant's Exhibit 214, 23 Document Bates stamped RGN-EYLEA-MYLAN 24 569973 through 975, was so marked for 25 identification, as of this date.)
Page 183 1 gain information that we could 2 incorporate in the context of designing 3 clinical trials. 4 Q. What do you recall about those 5 discussions? 6 A. I don't recall specific 7 discussions. 8 Q. Do you recall any specific 9 external experts that Regeneron was 10 consulting with on that issue? 11 A. I don't recall experts that we 12 engaged with specifically about dose 13 frequency. 14 Q. Now, the title of this was 15 "CLEAR-IT 3 Advisory Panel Meeting." 16 What was CLEAR-IT 3? 17 A. My recollection is that 18 CLEAR-IT 3 was the initial name that 19 Dr. Cedarbaum wanted to give the Phase 20 III AMD studies. 21 Q. So CLEAR-IT 3 eventually became 22 known as the VIEW 1 and VIEW 2 studies? 23 A. The Phase III studies were 24 eventually named VIEW 1 and VIEW 2, yes. 25 Q. Would it have been Regeneron's	Page 185 1 Q. Let me know when you have that. 2 A. I have Exhibit 214 in front of 3 me. 4 Q. Can you confirm it's dated 5 Friday, February 10th, 2006 from Srilatha 6 Vuthoori to you and many others at 7 Regeneron? 8 A. This e-mail is dated Friday, 9 February 10th, 2006. The subject is 10 "Actions and Decisions VGT Team Meeting." 11 It's from Srilatha Vuthoori, and I am one 12 of the recipients. 13 Q. And she's forwarding what she 14 calls a summary of the key actions and 15 decisions from this week's VGT team 16 meeting, right? 17 A. That is what the e-mail says. 18 Q. Now VGT, was that for both 19 oncology and ophthalmology? 20 A. So the VGT designation was 21 shorthand for VEGF-Trap. So it's 22 possible that this was in reference to 23 both oncology and ophthalmology. 24 Q. And how often did these 25 meetings happen?

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Page 186 1 A. I don't recall exactly their 2 frequency. 3 Q. Take a look at the second page 4 under the heading "Summary of Key Action 5 Items and Decisions. Items will be 6 documented in the action item and 7 decision logs. Item number 1. Clinical 8 Updates, Karen/Jesse." 9 Do you see that? 10 A. Yes, I see "Item 1, clinical 11 updates with Karen/Jesse." 12 Q. And that is something that you 13 would be responsible for along with Jesse 14 Cedarbaum? 15 A. Yes. Jesse and I would have 16 been responsible for giving updates on 17 the clinical development program. 18 Q. Okay. And then there is a 19 reference there to a patient who was 20 participating in the 0512 Phase I pilot 21 DME study. 22 What was the 0512 Phase I pilot 23 DME study? 24 A. 0512 was a very small study, 25 Phase I study, that was conducted in DME	Page 188 1 Q. All right. And what was the 2 0502 Phase I study? 3 A. So 0502 was the Phase I study 4 in neovascular AMD with intravitreal 5 aflibercept. 6 And just one clarification, it 7 looks like 1B, but I believe that's an 8 IB, which is referring to the 9 investigator's brochure. 10 Q. Got it. Was there a separate 11 investigator's brochure for intravitreal 12 dosing versus intravenous dosing? 13 A. So the investigators brochure 14 is updated regularly, at least annually. 15 And my recollection is that we may have 16 initially for this systemic clinical 17 trials combined the IB with the 18 investigators brochure that was being 19 used for the oncology trials. But that 20 once we were in development for 21 intravitreal aflibercept we had a 22 separate investigators brochure for 23 intravitreal aflibercept. 24 Q. And when do you think that 25 split happened?
Page 187 1 patients with intravitreal aflibercept. 2 Q. Was that study eventually 3 published? 4 A. I believe that study was 5 eventually published, but I don't recall 6 exactly whether it was published 7 independently or whether it was combined 8 with another publication. 9 Q. Do you recall whether any 10 results from that were presented at any 11 of these clinical meetings such as ARVO 12 or the Angiogenesis or the Bascom? 13 MS. OBERWETTER: Object to the 14 form. 15 A. I don't recall specifically if 16 we presented results from that study. 17 Q. Okay. One of the -- if you 18 look at the regulatory submissions 19 section, there is a statement that says, 20 "Review summary of the 0502 Phase I, 21 4-milligram cohort safety data to be 22 included in the updated ITV 1B. Karen." 23 Is that referring to you? 24 A. Yes, I believe that is 25 referring to me.	Page 189 1 MS. OBERWETTER: Object to the 2 form. 3 A. I don't recall exactly when 4 that split happened. 5 Q. Was it before 2010 or after 6 2010? 7 A. In my assessment it would be 8 before 2010, because it would have made 9 sense for us to do that at the time that 10 we filed the intravitreal aflibercept 11 IND. 12 Q. Okay. And who was -- were you 13 the person responsible for that 14 investigators brochure on the 15 intravitreal side? 16 A. I was a contributor to the 17 investigators brochure, but the 18 responsibility of generating and 19 finalizing the document was a regulatory 20 responsibility. 21 Q. And who in regulatory? 22 MS. OBERWETTER: Object to the 23 form. 24 A. I mean, at this time, so was 25 February 10th, 2006, our regulatory team

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Page 190 1 members were Laura Pologe and then she 2 reported to Bill Roberts. 3 MS. MAZZOCHI: Counselor, we 4 have seen a lot of the intravenous 5 investigator brochures, but we haven't 6 necessarily seen a full set of all of 7 the split ones, so we will request a 8 full set of all of the intravitreal 9 directed investigator brochures as 10 well. 11 (Production request) 12 Q. Within Defendant's Exhibit 214, 13 on page 975, there is also a discussion 14 in item 6 of "Generic VEGF-Trap WHO," 15 World Health Organization, 16 "recommendation aflibercept." 17 Do you see that? 18 A. I do see item 6 titled, 19 "Generic VEGF-Trap WHO Recommendation." 20 Q. Now, it says "The team has 21 reluctantly concedes to moving forward 22 with the aflibercept in light of Sanofi's 23 position that the name is acceptable, 24 pending approval by George and Len." 25 Why was there only a reluctant	Page 192 1 A. I see that the document is 2 labeled in the upper right-hand corner 3 "WHO Drug Information Volume 20, number 4 2, 2006." 5 Q. And then this was titled, 6 "International Non-Proprietary Names For 7 Pharmaceutical Substances." 8 A. I see the document is titled, 9 "International Non-Proprietary Names For 10 Pharmaceutical Substances." 11 Q. All right. Can you go ahead, 12 and turn to page 8706 as the Bates 13 number. It's page 118 within this 14 volume. And do you see a reference on 15 this page to aflibercept? 16 A. Yes, I see on the second half 17 of the page there is a reference to 18 aflibercept. 19 Q. Okay. And when it comes to the 20 structure of VEGF Trap-Eye, is there any 21 dispute that it has a chemical structure 22 that corresponds to the chemical 23 description provided for aflibercept 24 here? 25 MS. OBERWETTER: Object to the
Page 191 1 concession to move forward with 2 aflibercept as the name for VEGF-Trap? 3 A. I don't recall why there was 4 any reluctance. 5 Q. Okay. And is it fair to say 6 that the link between the name 7 aflibercept and VEGF-Trap was established 8 by 2006? 9 MS. OBERWETTER: Object to the 10 form and foundation. 11 A. I don't recall exactly when the 12 generic name was established. 13 Q. Okay. Let me give you a 14 document that has production numbers 15 MYL-AFL 8703 through 8711, which I will 16 mark as DX 215. 17 (Defendant's Exhibit 215, 18 Document Bates stamped MYL-AFL 8703 19 through 8711, was so marked for 20 identification, as of this date.) 21 A. I have Exhibit 215 in front of 22 me. 23 Q. Do you see the citation in the 24 upper right-hand corner says "WHO Drug 25 Information Volume 20, Number 2, 2006"?	Page 193 1 form and foundation with this witness. 2 A. I am not the expert on the 3 molecular structure of aflibercept, so I 4 can't confirm that this is correct. 5 Q. In the context of your clinical 6 work, would you have -- using the term 7 "aflibercept" -- strike that. Let me 8 start over. 9 In the context of your clinical 10 work did you ever use the term 11 "aflibercept" to refer to any chemical 12 structure other than VEGF Trap-Eye? 13 MS. OBERWETTER: Object to the 14 form and foundation. 15 A. So the terms VEGF-Trap, VGFT, 16 VEGF Trap-Eye, and aflibercept, depending 17 on the time period, were used somewhat 18 synonymously. VEGF Trap-Eye was almost 19 always used to distinguish between the 20 systemic formulation of aflibercept 21 versus the intravitreal formulation. 22 Q. Right. But the underlying 23 structure of aflibercept the molecule 24 didn't change whether it was VEGF 25 Trap-Eye or just VEGF-Trap or

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Page 194 1 aflibercept; is that fair? 2 MS. OBERWETTER: Object to the 3 form and foundation with this witness. 4 A. It is my understanding that the 5 active ingredient was the same in VEGF 6 Trap-Eye and aflibercept whether that was 7 referring to the oncology product or the 8 intravitreally-delivered product. 9 Q. Okay. And can you think of any 10 clinical trial that you ran in the 11 ophthalmology context involving -- strike 12 that. Let's move on. 13 I would like to put in front of 14 you a document that I am going to mark as 15 DX 216, which has production numbers 16 RGN-EYLEA-MYLAN 551796 through 798. 17 (Defendant's Exhibit 216, 18 Document Bates stamped RGN-EYLEA-MYLAN 19 551796 through 798, was so marked for 20 identification, as of this date.) 21 Q. Let me know when you have that. 22 A. So I have Exhibit 216 in front 23 of me. 24 Q. Okay. And can you confirm that 25 this is an e-mail from Jesse Cedarbaum to	Page 196 1 Q. And do you know why those were 2 chosen, that particular starting number 3 was chosen? 4 A. I don't recall specifically 5 about that starting number. But the 6 considerations around patients enrolled 7 in this trial is that it was a Phase I 8 study. So we would have selected 9 patients for which participation in a 10 Phase I study with a new investigational 11 drug was appropriate. 12 Q. So their eyesight was really, 13 really bad and deteriorating if they got 14 that score? 15 MS. OBERWETTER: Object to the 16 form. 17 A. Not necessarily. But just that 18 these were patients in which we felt, 19 again, participation in this Phase I 20 study was appropriate. 21 Q. Well, was there a hope or an 22 expectation that if you were using 23 patients that had already lost or whose 24 BCVA was already less than or equal to 73 25 ETDRS letters, that you were more likely
Page 195 1 you and others, dated March 21st, 2006? 2 A. Yes, this is an e-mail dated 3 March 21st, 2006 with the "Subject: 4 Final ASRS 0508 Abstract" from Jesse 5 Cedarbaum, and I am one of the recipients 6 on the e-mail. 7 Q. And if you take a look at the 8 abstract on the next page, are you also 9 identified as one of the authors? 10 A. Give me a moment to take a look 11 here. 12 Q. Sure. 13 A. I see here on the proposed 14 abstract that I am listed as one of the 15 authors. 16 Q. And this is for the CLEAR-IT 1 17 study? 18 A. Yes, this abstract is referring 19 to the CLEAR-IT 1 study. 20 Q. Okay. Now, in the method 21 section it refers to a BCVA number less 22 than or equal to 73 ETDRS letters. 23 Do you see that? 24 A. Yes, I see where it says, "BCVA 25 less than or equal to 73 ETDRS letters."	Page 197 1 to see an increase after dosing the drug? 2 MS. OBERWETTER: Object to the 3 form. 4 Q. Sorry, more likely to see an 5 improvement after dosing the drug? 6 MS. OBERWETTER: Object to the 7 form and foundation. 8 A. This was a Phase I dose 9 escalation study with very small numbers 10 of patients in each cohort for each dose 11 level. So the primary objective of this 12 study would have been safety. Regeneron 13 always hopes to get as much information 14 from clinical trials as we possibly can. 15 But this particular eligibility criteria 16 would not have been directly related to 17 any efficacy outcomes that we aspired to 18 have from this study. 19 Q. But nevertheless you reported 20 three of six patients who received single 21 2 or 4-milligram doses, achieved gains of 22 greater than 15 letters in BCVA at four 23 weeks as well, right? 24 A. I do see in the results that we 25 did report that in this abstract.

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Page 198 1 Q. Okay. So that information 2 became publicly known by the time you got 3 to the end of the ASRS conference; is 4 that fair? 5 MS. OBERWETTER: Object to the 6 foundation. 7 A. I can't actually tell from this 8 e-mail if this abstract was presented or 9 in what format it was presented. So I 10 can't say definitively that that specific 11 statement was delivered as part of the 12 presentation. 13 Q. But if it was presented as an 14 abstract, the abstracts were given to all 15 the meeting participants, right? 16 MS. OBERWETTER: Object to the 17 foundation. 18 A. I don't recall how abstracts 19 were provided as part of the ASRS meeting 20 in 2006. 21 Q. Do you recall what type of 22 response Regeneron got in response to the 23 release of this Phase I data, the 24 CLEAR-IT 1 trial? 25 MS. OBERWETTER: Object to the	Page 200 1 Q. Did Dr. Nguyen have any say in 2 how this study was going to be conducted? 3 MS. OBERWETTER: Object to the 4 form. 5 A. I don't recall if Dr. Nguyen 6 had specific input into the design of the 7 study. 8 Q. How about Julia Haller? 9 A. I don't recall if Dr. Haller 10 had specific input into the design of 11 this study. 12 Q. Okay. And how about 13 Dr. Campochiaro? 14 A. I don't recall if 15 Dr. Campochiaro had specific input into 16 the design of this study. 17 Q. Was it common for your clinical 18 trial investigators to just run the study 19 as Regeneron presented it to them with no 20 input from them? 21 A. We would ask for, we would 22 consult with experts in a confidential 23 manner to gain input related to the 24 design of clinical trials. And in the 25 process of selecting sites and
Page 199 1 foundation. 2 A. I don't remember specifically 3 the response to any presentation at ASRS 4 in 2006. But my recollection of the 5 general response or assessment of the 6 results from this Phase I study was that 7 the results were very promising. That 8 the safety data from these studies 9 supported additional investigation. And 10 that's my recollection. 11 Q. Who actually did the design of 12 this particular clinical trial? 13 A. When you say this particular 14 clinical trial, you're referring to the 15 CLEAR-IT 1 study? 16 Q. Yes, that's in DX 216. 17 A. As we discussed previously, the 18 process was that there would be 19 discussions amongst clinical development 20 along with the cross-functional team in 21 conjunction with senior management to 22 ultimately propose and determine the 23 design of any study, so that would have 24 been the process for designing this study 25 as well.	Page 201 1 investigators, we would have discussions 2 about the clinical trial design. But 3 once a study design was finalized, we did 4 not put input from clinical investigators 5 into the protocol. 6 Q. How early in that design 7 process did you start consulting with 8 some of the investigators to just get 9 their input? 10 MS. OBERWETTER: Object to the 11 form. Are you talking about this 12 trial? 13 MS. MAZZOCHI: Sure. 14 A. I can't speak to exactly when, 15 but I can say that during the course of 16 clinical development for aflibercept, we 17 have periodically consulted with external 18 experts to advise us on aspects of trial 19 design throughout the program. 20 Q. Including dosing and clinical 21 endpoints, right? 22 MS. OBERWETTER: Objection to 23 form and foundation. 24 A. Again, my recollection is that 25 we would have consulted with them on, you

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Page 202 1 know, many aspects of the study design. 2 Q. Do you recall anyone ever 3 telling you that they thought your 4 conclusions about the CLEAR-IT 1 study 5 were wrong? 6 A. I don't recall anyone telling 7 us that our conclusions about the 8 CLEAR-IT 1 study were wrong. 9 Q. Okay. Take a look at what I 10 will mark as Defendant's Exhibit 217, 11 which has production number -- 12 RGN-EYLEA-MYLAN 545220 through 221. 13 (Defendant's Exhibit 217, 14 Document Bates stamped RGN-EYLEA-MYLAN 15 545220 through 221, was so marked for 16 identification, as of this date.) 17 Q. And can you confirm that 18 Exhibit 217 is an e-mail string where the 19 top e-mail is dated Thursday, April 27th, 20 2006, from Neil Stahl to you and others 21 regarding the clinical ITV VGT plan 22 060427? 23 A. So I have Exhibit 217 in front 24 of me, and it's an e-mail string with the 25 date Thursday, April 27th, 2006. The	Page 204 1 Q. Now, it says in here in the 2 e-mail from Neil Stahl to you that in 3 this plan, whatever it was, it says, the 4 first bullet point, "The VGT 4Q4 versus 5 Lucentis needs to start as soon as 6 Lucentis is approved, like July 2006 in 7 order to support first Phase III." 8 Do you see that? 9 A. The first bullet does read the 10 VGT 4Q4 versus Luc needs to start as soon 11 as Lucentis is approved. 12 Q. Okay. So at that time were you 13 considering for intravitreal purposes 14 having a dosing every 12 -- 4 milligrams 15 dosed every 12 weeks versus Lucentis as a 16 Phase II study? 17 MS. OBERWETTER: Object to the 18 form. 19 A. My interpretation of this is 20 that it's referring to 4 milligrams every 21 four weeks versus Lucentis as a study 22 needed to support Phase III. That's my 23 interpretation. 24 Q. And was that study of 4 25 milligrams every four weeks versus
Page 203 1 subject is regarding "Clinical ITV VGT 2 Plan 060427" from Neil Stahl, and I am 3 one of the recipients on the e-mail. 4 Q. And now, is this a clinical 5 plan intravenous or intravitreal? 6 A. Give me a second to review the 7 document. 8 (Witness reviews document.) 9 A. So in the second e-mail in this 10 string from Kathleen DeWald, dated 11 Thursday, 27th of April, 2006, to myself 12 and others, it says "Attached is the 13 proposed clinical development ITV plan 14 for discussions later this week." 15 So I would interpret that to 16 mean this was the clinical development 17 plan for intravitreal aflibercept. 18 Q. Okay. 19 MS. MAZZOCHI: Counsel, again, 20 we looked for the e-mail that was 21 supposed to be attached to it. We 22 didn't see it in your production set. 23 So we will request that it be 24 produced. 25 (Production request)	Page 205 1 Lucentis ever done? 2 A. To my knowledge, the study was 3 never conducted. 4 Q. Why not? 5 A. I don't recall the reason why. 6 MS. OBERWETTER: We have been 7 going an hour since our lunch break. 8 I don't know if you're moving on to 9 another document. If you're still on 10 this document, I won't stop you. 11 MS. MAZZOCHI: No, I was going 12 to move to another document. 13 MS. OBERWETTER: If this is a 14 good time for a break, let's take a 15 break. 16 MS. MAZZOCHI: Sure. 17 THE VIDEOGRAPHER: We are going 18 off the record at 2:30 p.m. 19 (Off the record.) 20 THE VIDEOGRAPHER: We are back 21 on the record at 2:47 p.m. 22 BY MS. MAZZOCHI: 23 Q. Ms. Chu, did you talk to your 24 counsel about the substance of your 25 testimony over the break?

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Page 206 1 A. I did not discuss the substance 2 of my testimony with counsel over the 3 break. 4 MS. MAZZOCHI: Okay. I would 5 like to mark as Defendant's Exhibit 6 218, a document with production 7 numbers RGN-EYLEA-MYLAN 553211 through 8 212. 9 (Defendant's Exhibit 218, 10 Document Bates stamped RGN-EYLEA-MYLAN 11 553211 through 212, was so marked for 12 identification, as of this date.) 13 Q. And can you confirm this is a 14 May 9th, 2006 e-mail from Jesse Cedarbaum 15 to you and others discussing Rosenfeld's 16 Lucentis pronto press release? 17 A. This is an e-mail dated 18 Tuesday, May 9th, 2006 with "Subject: 19 Rosenfeld Lucentis Pronto Press Release," 20 from Jesse Cedarbaum and I am listed as 21 one of the recipients. 22 Q. Now, according to this press 23 release it says, "Open label on 24 Controlled Study of Lucentis showed 25 Improvement in Vision With Five to Six	Page 208 1 Dr. Rosenfeld with Lucentis in patients 2 with AMD. 3 Q. Now, one of the metrics that he 4 was using to evaluate vision improvement 5 is, according to the second paragraph, 6 "Average vision improved in the treated 7 eye almost two lines after one year. 8 Additional 82 percent of patients had the 9 same or better vision after one year and 10 35 percent of patients experienced a 11 two-fold improvement of vision as defined 12 by gaining three lines of vision on a 13 standardized visual acuity chart." 14 Do you see that? 15 A. I do see where the press 16 release refers to an overall average 17 vision improved in the treated eye almost 18 two lines after one year. 19 Q. And how does gaining two lines 20 of vision or three lines of vision on the 21 visual acuity chart compare to the BCVA 22 letter standard that Regeneron was using? 23 MS. OBERWETTER: Object to the 24 form. Calls for expert testimony. 25 A. So typically, the reference of
Page 207 1 Doses At One Year." 2 Do you see that? 3 A. I see that -- the title is 4 "Open Label on Controlled Study of 5 Lucentis Showed Improvement in Vision in 6 Five to Six Doses in One Year." 7 Q. And again, we have 8 Dr. Rosenfeld from Miami's Bascom Palmer 9 Eye Institute doing some more clinical 10 studies on his own. And in this 11 instance, it appears that he was able to 12 dose Lucentis on a less than monthly 13 dosing schedule; is that fair? 14 MS. OBERWETTER: Object to the 15 form. 16 A. I don't recall the exact study 17 design of this study. 18 Q. Well, it's being preferred to 19 as the pronto study. What was your 20 recollection as to the pronto study and 21 what it was about with Lucentis, based on 22 your experience at Regeneron? 23 A. My recollection of the pronto 24 study was it was a small single arm 25 investigator initiated study conducted by	Page 209 1 a line of vision would correspond with 2 five letters. 3 Q. Okay. Can a line improvement 4 also correlate to anything else -- 5 MS. OBERWETTER: Same objection. 6 Q. -- in your experience? 7 MS. OBERWETTER: Same objection. 8 A. Again, typically a line of 9 vision on the ETDRS visual acuity chart 10 is five letters. But the press release 11 doesn't specifically say the standardized 12 visual acuity chart being used in this 13 study. 14 Q. How many standardized visual 15 acuity charts are you aware of that are 16 used in the field? 17 MS. OBERWETTER: Object to the 18 form. Calls for expert testimony. 19 A. There are multiple standardized 20 visual acuity charts used in the ETDRS 21 visual acuity method. But I am also 22 aware that the visual acuity chart 23 commonly used in clinical practice, the 24 Snellen visual acuity chart is another 25 standardized method of determining visual

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Page 210 1 acuity. 2 Q. Now, obviously, Dr. Cedarbaum 3 forwarded this to you and others on the 4 clinical trial team for some purpose. 5 Do you recall having any 6 discussions about this? 7 A. I do not recall any specific 8 discussions about this press release. 9 Q. Well, how about in general, 10 this idea that Lucentis could be dosed at 11 a rate of five or six injections over a 12 one-year period? 13 A. I don't recall specific 14 discussions about the Lucentis dosing 15 outcomes in this study. 16 Q. Did any of this type of 17 extended dosing regimen with Lucentis 18 cause Regeneron to start thinking about 19 extending its own dosing intervals 20 further or trying to push its own dosing 21 intervals further? 22 MS. OBERWETTER: Object to the 23 form. 24 A. It was not the Lucentis data 25 that factored into our decision regarding	Page 212 1 FDA-approved regimen for Lucentis? 2 A. We thought it was possible that 3 aflibercept could be superior to 4 ranibizumab. And the design of the Phase 5 III clinical trials was such that we did 6 include a 2 milligram every four-week 7 dosing group as well as a .5 milligram 8 every four-week dosing group with the 9 ability, if we met noninferiority in 10 those groups, to then be able to test for 11 superiority. 12 And I should just clarify, that 13 that would have been true for all of the 14 groups, including the third treatment 15 group, which was three initial monthly 16 doses followed by a dosing every eight 17 weeks. 18 Q. Right. Has Regeneron ever 19 established that aflibercept dose 2 20 milligrams every four weeks is superior 21 to Lucentis dose -- the FDA-approved dose 22 given every four weeks? 23 MS. OBERWETTER: Object to the 24 form. Foundation. Calls for expert 25 testimony.
Page 211 1 the design of the clinical, of the VIEW 1 2 and VIEW 2 clinical trials. 3 Q. Well, the VIEW 1 and VIEW 2 4 clinical trials, obviously, had a 5 Lucentis arm, right? 6 A. Yes, the Lucentis arm was .5 7 milligrams dosed monthly. 8 Q. And did you choose that because 9 that was the FDA-approved version of the 10 Lucentis dosing regimen? 11 MS. OBERWETTER: Object to the 12 form and foundation. 13 A. Yes, that comparator was 14 selected because of the design of the 15 clinical trials, which was noninferiority 16 trials, which meant that we were 17 comparing, we were comparing to an active 18 comparator. And that paradigm 19 necessitates being able to compare, by 20 proxy, to the reference studies. So that 21 would be the Lucentis AMD Phase III 22 studies. 23 Q. Do you recall whether anybody 24 ever talked about a dosing regimen that 25 you thought might be superior to the	Page 213 1 A. The outcome in the VIEW 1 study 2 demonstrated that 2 milligrams Q4 was 3 statistically superior to .5 milligrams 4 Lucentis dosed every four weeks. 5 Q. If so, why then did you not or 6 why then did Regeneron not seek a label 7 claim for dosing aflibercept 2 milligrams 8 every four weeks? 9 MS. OBERWETTER: Object to the 10 foundation. 11 A. That outcome was not replicated 12 in the VIEW 2 trial. So while all 13 aflibercept dosing groups or treatment 14 groups in the VIEW 2 study were 15 noninferior to Lucentis, the 2 milligram 16 every four-week group did not demonstrate 17 superiority in that study. So we did not 18 pursue a regulatory approval claiming 19 that aflibercept was superior to 20 Lucentis. 21 Q. During your time at Regeneron, 22 has Regeneron identified any head-to-head 23 dosing regimen where it believes 24 aflibercept can demonstrate superiority 25 to Lucentis --

Page 214 1 MS. OBERWETTER: Object to the 2 form. 3 Q. -- in a manner that the FDA or 4 clinicians would accept? 5 A. In the protocol T study, which 6 was a study conducted by the Diabetic 7 Retinopathy Clinical Research Network 8 with aflibercept and ranibizumab and 9 Bevacizumab dosed in the same paradigm, 10 which was a different paradigm than 11 Regeneron has tested in our trials, 12 aflibercept was superior to both 13 ranibizumab and Bevacizumab. 14 Q. And in that particular dosing 15 regimen of aflibercept that you just 16 mentioned it was shown to be superior to 17 Lucentis, is that an FDA-approved dosing 18 regimen or no? 19 A. That dosing regimen is not 20 specifically reflected in our labeling. 21 Q. What was the regimen? 22 A. If I could see the protocol, I 23 could answer that question or the study 24 report, I could answer that question more 25 precisely.	Page 216 1 RGN-EYLEA-MYLAN 571549. 2 (Defendant's Exhibit 219, 3 Document Bates stamped RGN-EYLEA-MYLAN 4 571549, was so marked for 5 identification, as of this date.) 6 Q. And can you confirm this is an 7 e-mail from Michael Roosevelt to you, 8 amongst others, dated Tuesday, May 9th, 9 2006? 10 A. Okay. I have Exhibit 219 and 11 the date of the e-mail is Tuesday, May 12 9th, 2006 with "Subject: Action Items," 13 May 9th, 2006, from Michael Roosevelt. 14 And I am one of the recipients of this 15 e-mail. 16 Q. And who is Michael Roosevelt? 17 A. Michael Roosevelt was a project 18 manager who worked for Regeneron at this 19 time. 20 Q. Now, if we look at the summary 21 of action items and decisions for 22 ophthalmology, first we have the 0502 23 study for the 0502 project and that I 24 believe was the wet AMD? 25 A. 0502 was the Phase I study in
Page 215 1 Q. Okay. Do you remember 2 generally what was, what they were doing 3 in that one, in terms of did it deviate 4 from monthly dosing, was it number of 5 injections? 6 A. My recollection is it that it 7 was monthly dosing for a certain number 8 of doses. And then criteria based dosing 9 based on the protocol -- 10 Q. Okay. 11 A. -- which allowed for a longer 12 treatment interval. 13 Q. Okay. Do you recall what the 14 maximum treatment interval was for 15 aflibercept in that protocol T study? 16 A. I don't recall what the maximum 17 treatment interval was. 18 Q. Okay. Was it more than 16 19 weeks? 20 MS. OBERWETTER: Object to the 21 form. 22 A. I don't recall. 23 Q. Okay. Let's take a look at 24 what I will mark as Defendant's Exhibit 25 219 which has production numbers	Page 217 1 wet AMD -- 2 Q. Okay. 3 A. -- with intravitreal 4 aflibercept. 5 Q. Right. And then we have the 6 0508 study and that was one of the DME 7 studies? 8 A. 0508 was the Phase II study in 9 wet AMD with intravitreal aflibercept. 10 Q. Okay. There is a reference to 11 an 0509 study, what was that one? 12 A. I don't recall exactly what 13 that study was. 14 Q. Okay. Now, for the 0508 study, 15 the Phase II AMD intravitreal, one of the 16 things that's identified here is it says, 17 "The second amendment should deal with 18 statistical changes due to PRN dosing and 19 the addition of one year of dosing, due 20 to the change in subject's original plan 21 to move into 0509, now staying on the 22 0508 study." 23 What were the statistical 24 changes due to PRN dosing you were 25 looking at at that time that necessitated

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Page 218 1 an amendment? 2 A. I don't recall exactly what the 3 planned statistical changes were. 4 Q. Did that Phase II study, 0508, 5 ultimately have PRN dosing in it? 6 A. Yes. So 0508 did eventually 7 include PRN dosing after week 12. 8 Q. And is that with the study arm 9 where physicians were allowed to dose 10 every 12 weeks? 11 A. So the design of that study was 12 that there were five treatment groups. 13 After all of the patients received a dose 14 at week 12, and all five treatment groups 15 then went to PRN dosing after that time 16 point. 17 Q. Okay. And what was the name of 18 that trial? 19 A. We referred to that as the 20 CLEAR-IT 2 trial. 21 Q. And again, do you recall any 22 concerns from clinicians that patients 23 were not meeting their endpoints when 24 they were getting out to the 12-week mark 25 with the aflibercept dosing?	Page 220 1 form. 2 A. So primarily, we were looking 3 at central retinal lesion thickness 4 measured by optical coherence tomography 5 which was a very quantitative measure of 6 the fluid in the retina. And one aspect 7 of that data is that we would see a rapid 8 reduction in retinal fluid after dosing 9 with aflibercept. And over the longer 10 time period without treatment, we would 11 see some of that fluid begin to 12 reaccumulate. 13 Q. And when it came to the visual 14 acuity metrics, what were you starting to 15 see in terms of a change that caused 16 concern? 17 MS. OBERWETTER: Object to the 18 form. Foundation. 19 A. So from the 0508 study results, 20 so we looked at the visual acuity very 21 carefully, and across treatment groups 22 noted that the patients that were dosed 23 initially every four weeks gained more 24 vision over the course of the study than 25 those patients that were only dosed at
Page 219 1 MS. OBERWETTER: Object to the 2 form. Foundation. 3 A. I do not recall any concerns. 4 Q. Okay. Do you recall any 5 concerns expressed internally at 6 Regeneron about Aflibercept's ability to 7 achieve any efficacy endpoints by the 8 12-week -- with a 12-week dosing 9 interval? 10 A. Are you referring to during the 11 ongoing study? 12 Q. Yeah, either while the study 13 was conducted or afterwards. 14 A. So once we had the -- so this 15 e-mail is referring to a time when the 16 studies were ongoing. Once we received 17 data from the studies and analyzed it, we 18 did have some concerns that based on the 19 OCT data and an assessment of the visual 20 acuity data, that the 12-week interval 21 was one where we were seeing some loss of 22 efficacy over that duration. 23 Q. And how were you defining loss 24 of efficacy? 25 MS. OBERWETTER: Object to the	Page 221 1 baseline and week 12 as mandatory dosing, 2 as I already stated, all groups were then 3 dosed PRN after week 12. 4 But importantly we looked at 5 really trends in visual acuity over 6 intervals where patients were not 7 receiving doses. 8 Q. And do you recall what the 9 drop-off was in terms of the number of 10 letters on average as compared to the 11 ones that got the initial monthly dosing 12 versus the 12-week initial dose? 13 A. I do not specifically recall 14 the difference between those treatment 15 groups. If you have the clinical study 16 report, I can answer it more 17 specifically. 18 Q. Maybe we'll get to that. All 19 right, let's continue on. 20 I would like to put before you 21 a document that I'll mark as Defendant's 22 Exhibit 220, which has production number 23 RGN-EYLEA-MYLAN 553399 through 400. 24 (Defendant's Exhibit 220, 25 Document Bates stamped RGN-EYLEA-MYLAN

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Page 222 1 553399 through 400, was so marked for 2 identification, as of this date.) 3 Q. On this one, I would like to 4 start with the e-mail at the end of the 5 chain from George Yancopoulos to you and 6 others, dated Tuesday, May 16th, 2006. 7 So let me know when you're there. 8 A. I have Exhibit 220 in front of 9 me and I see the e-mail in the string 10 from George Yancopoulos dated Wednesday, 11 May 17th, 2006 and I am one of the 12 recipients. 13 Q. And they are also talking about 14 the pronto data, which was 15 Dr. Rosenfeld's Lucentis study, right? 16 A. Yes, this e-mail is referring 17 to the pronto study. 18 Q. Now they are referring to some 19 data that they saw in slides. Do you 20 know what slides these were from? 21 A. I don't know exactly which 22 slides these were from. 23 Q. And it looks like 24 Dr. Yancopoulos is saying about the 25 pronto data, that "Lucentis was not	Page 224 1 continued on your merry way? 2 MS. OBERWETTER: Object to the 3 form. 4 A. We were excited about the 5 possibility of aflibercept having a 6 longer treatment interval, based on the 7 properties of the molecule itself, as 8 well as the emerging data from the 9 clinical development program. 10 I believe that Lucentis was 11 approved in 2006 and was, because of 12 their clinical trial results, slated to 13 become standard of care. So I think 14 that, you know, it wasn't specifically 15 any outcome from Lucentis trials that 16 made us excited, but we were certainly 17 monitoring the competitive landscape 18 closely. 19 Q. What was your -- to your 20 recollection, what was Regeneron's 21 rationale for why the VEGF-Trap 22 aflibercept molecule would be able to 23 last longer as compared to Lucentis? 24 MS. OBERWETTER: Object to form. 25 Q. Ranibizumab.
Page 223 1 lasting for two months which could 2 provide a major opportunity for VEGF-Trap 3 interval advantage." 4 Do you see that? 5 A. Yes, so this is an e-mail in 6 the string dated Tuesday, May 16th, 2006, 7 "Subject: Pronto Data." 8 Q. Okay. Was Dr. Yancopoulos's 9 assessment of the Lucentis pronto data 10 something that caused everybody to start 11 saying, okay, we know Lucentis can't go 12 for more than two months? 13 MS. OBERWETTER: Object to the 14 form and foundation. 15 A. So we were -- I don't recall 16 specifically if this data in any way 17 translated to further discussions about 18 the dosing regimens planned in the VIEW 1 19 and VIEW 2 studies. 20 Q. Well, he says "This indeed may 21 provide us a major opportunity for 22 VEGF-Trap interval advantage." 23 Did you look at that and get 24 excited and say, yeah, it will? Or was 25 it more like whatever, and you just	Page 225 1 A. My understanding of Regeneron's 2 rationale is that first aflibercept is a 3 larger molecule, and as a result has a 4 longer half life than Lucentis does as 5 well as the fact that we have a much, 6 much higher binding affinity and other 7 kinetic properties of binding to VEGF 8 that we felt would be advantageous for 9 aflibercept, and contribute to 10 potentially a longer duration of action. 11 Q. To date, as far as you're 12 aware, has Regeneron ever validated that 13 those two things, having a longer half 14 life and increased binding affinity 15 actually, is what's allowing aflibercept 16 to be dosed at these longer intervals as 17 compared to ranibizumab? 18 A. So the evidence we have of the 19 longer duration of action is from the 20 clinical trial results, based on outcomes 21 in the clinical studies. 22 Q. Has Regeneron surveyed any 23 clinicians to see whether they also 24 believe that this longer duration of 25 action is tied to the molecule's longer

Page 226 1 half life and stronger binding affinity 2 to VEGF? 3 MS. OBERWETTER: Object to the 4 form. 5 Q. Compared to ranibizumab? 6 A. I don't know if we specifically 7 surveyed physicians to answer that 8 specific question. 9 Q. Do you know if that's been part 10 of any of your marketing messages to 11 clinicians? 12 A. I am not familiar with the 13 marketing materials sufficient to answer 14 your question. 15 Q. If we can go to the front page 16 of Defendant's Exhibit 220, you were also 17 cc'd again on the e-mail string, this 18 time on May 17th, 2006 from George 19 Yancopoulos about the pronto data. And 20 he was responding to an e-mail from Avner 21 Ingerman. 22 Do you see that? 23 A. I do see the e-mail dated 17th 24 May 2006, from George to Avner and 25 others, where Avner is responding to an	Page 228 1 A. The MARINA and ANCHOR studies 2 were the studies sponsored by Genentech 3 for Lucentis in neovascular AMD. 4 Q. "In discussing those trials, it 5 may suggest that the so-called clinician 6 PRN practice following 'induction dose' 7 is as good as monthly injections for at 8 least the first year, and that is 9 probably the take home message that the 10 market will follow." 11 Do you see that? 12 A. I do see that sentence in the 13 e-mail. 14 Q. Do you know whether anybody 15 agreed or disagreed with Avner's 16 assessments that that's how clinicians 17 would likely respond to this data? 18 A. Sorry, could you just restate 19 the question? 20 Q. Sure. Do you recall within 21 Regeneron whether people agreed or 22 disagreed with Dr. Ingerman's view that 23 clinicians would probably perceive the 24 clinician PRN practice following the 25 induction dose was as good as monthly
Page 227 1 e-mail from -- or sorry, George is 2 responding to an e-mail from Avner. 3 Q. Okay. Now, what was Avner's 4 role and title at this point in time? 5 A. I don't recall exactly what his 6 title was, but he was brought on as an 7 ophthalmologist to assist with clinical 8 development for intravitreal aflibercept. 9 Q. Did you report to him at all or 10 did he report to you? 11 A. I did eventually report to 12 Dr. Ingerman after Jesse Cedarbaum left 13 Regeneron. 14 Q. Did Avner report to Jesse 15 Cedarbaum at this point in time? 16 A. I don't recall if that was true 17 exactly on May 17th, 2006. But when 18 Avner joined the company, he did report 19 to Dr. Cedarbaum. 20 Q. Now, Avner was discussing, not 21 just pronto, but also the MARINA and 22 ANCHOR trials. Those were official 23 Lucentis trials run by Genentech, 24 right? 25 MS. OBERWETTER: Object to form.	Page 229 1 injections for at least the first year, 2 when it came to ranibizumab? 3 A. My understanding is that Dr. 4 Yancopoulos strongly disagreed with the 5 concept that PRN dosing was as good as 6 monthly dosing as studied in the ANCHOR 7 and MARINA trials. 8 Q. Okay. Well, if we take a look 9 at the top e-mail here, this is Len 10 Schleifer telling Dr. Yancopoulos, this 11 is in the second sentence, he says "His 12 summaries" referring to Dr. Ingerman 13 "from ARVO were very useful and indeed 14 his views on the data are likely 15 reflective of our prescribing community, 16 of how our prescribing community views 17 the data." 18 So whether or not 19 Dr. Yancopoulos agreed or not, did anyone 20 else within Regeneron think that this 21 induction dose followed by PRN dosing 22 would be as, would be perceived by 23 clinicians as comparable to just monthly 24 dosing, at least for that first year? 25 MS. OBERWETTER: Object to the

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Page 230 1 form and foundation. And you're now 2 asking the witness about a part of the 3 e-mail string that she's not included 4 on. 5 Q. You can answer, if you can. 6 A. Sorry, could you just state 7 your question one more time? 8 Q. Sure. I understand, you know, 9 that Dr. Yancopoulos didn't think that 10 PRN dosing was as good as monthly. But 11 here it was at least believed that 12 physicians who were practicing in the 13 field might actually believe that to be 14 true. 15 So when Regeneron was looking 16 at or considering its clinical trials, 17 did it take the clinician view into 18 account or the clinician perceptions or 19 was it just how Dr. Yancopoulos viewed 20 the data? 21 MS. OBERWETTER: Object to the 22 foundation. Object to the form. 23 A. So my recollection is that at 24 this time it was general clinical 25 practice to dose, to treat AMD patients	Page 232 1 groups were allowed to, they were dosed 2 quarterly with fixed dosing with a 3 possibility of additional doses given up 4 to monthly, based on protocol-defined 5 criteria. 6 Q. So why did Dr. Yancopoulos 7 agree to any type of PRN-type dosing in 8 the later part of the VIEW studies, if he 9 was adamant that it wasn't going to work? 10 MS. OBERWETTER: Inadequate 11 foundation. Calls for speculation. 12 A. My recollection is that the 13 most critical portion of the study and 14 the portion of the studies that defined 15 our initial-dosing regimen in our 16 application to the FDA was the one-year 17 data from the VIEW 1 and the VIEW 2 18 studies. 19 Q. Now, in DX 220, when they are 20 talking about the -- when Mr. Ingeman is 21 talking -- when Dr. Ingeman is talking 22 about the induction dose, did you 23 understand that to also be referring to 24 the three monthly doses given first 25 before allowing the PRN dosing?
Page 231 1 with a PRN-dosing regimen. However, I 2 don't recall other people who 3 specifically agreed or disagreed with 4 that internally at Regeneron. But I do 5 remember that Dr. Yancopoulos felt very 6 strongly that that was not the optimal 7 treatment regimen to take going forward 8 in designing our Phase III study. 9 Q. But Regeneron did ultimately 10 have a PRN dosing study arm, right? 11 A. Are you asking about the VIEW 1 12 and the VIEW 2 studies? 13 Q. Right. 14 A. So the treatment groups 15 included in the study were .5 milligram 16 aflibercept every four weeks. 2 17 milligrams every four weeks. 2 18 milligrams given initially monthly for 19 the first three doses. And then that was 20 followed by Q8 week dosing, which was 21 compared to Lucentis given monthly. 22 Those treatment regimens were maintained 23 through the primary endpoint, which was 24 at week 52. 25 After week 52, all treatment	Page 233 1 MS. OBERWETTER: Object to the 2 form. 3 A. I can't say what the induction 4 dose is referring to. It's in 5 quotations, and I am not exactly sure 6 what he was referring to. 7 Q. Now one of the things that 8 Mr. Ingeman said is that "This provides 9 us with a potential advantage of showing 10 comparable efficacy or even a slightly 11 lower efficacy, and have a win on label 12 dosing interval." 13 Do you remember having any 14 discussions of whether it would be 15 preferable to get a win on label dosing 16 interval, even if it meant that you would 17 have some slightly lower efficacy in 18 comparing to essential Lucentis? 19 A. My recollection of the 20 considerations around the design of the 21 clinical trials was always to design them 22 with the intent of having optimal 23 outcomes for patients, both in terms of 24 safety and efficacy. 25 Q. You can go ahead -- well, and

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Page 234 1 who determined that the eight-week 2 interval might be an optimal outcome, 3 what data was that based on? 4 MS. OBERWETTER: Object to the 5 form and foundation. 6 A. So again the CLEAR-IT 2 study 7 data, was the data that was available 8 with aflibercept that helped inform the 9 Phase III study designs. However, a Q8 10 regimen was not tested in that study. So 11 the experimental group that included 12 every eight-week dosing was just that. 13 We felt it was important to include, 14 because there was the possibility of a 15 longer dosing interval. But we were not 16 certain of the outcome -- 17 Q. Okay. 18 A. -- until we received the study 19 results. 20 Q. From CLEAR-IT 2? 21 A. No, sorry, from the VIEW 1 and 22 VIEW 2 studies. 23 Q. Okay. Take a look at what I 24 will mark as Defendant's Exhibit 221 25 which has production numbers	Page 236 1 indicate the year -- 2 Q. Okay. 3 A. -- and then the second two 4 numbers just indicate what number 5 protocol that was generated internally at 6 Regeneron for that year. 7 Q. Okay. So in this instance, we 8 got the draft clinical trial protocol, 9 dated August 29th, 2006. It says, "The 10 study director is Avner Ingerman." 11 So was he responsible for the 12 design of this protocol? 13 A. He was involved in the design 14 of this protocol, and as M.D. within 15 clinical research, he was designated as 16 the study director. 17 Q. Now, if we take a look on page 18 523364 in the wet AMD study protocol as 19 it stood in August of 2006, you didn't 20 have the loading dose followed by 21 eight-week dosing; did you? 22 A. I'll need a minute just to 23 orient myself here. 24 Q. Sure. Look at the page ending 25 in 634, where it says "Study Design."
Page 235 1 RGN-EYLEA-MYLAN 00523361 through 508. 2 (Defendant's Exhibit 221, 3 Document Bates stamped 4 RGN-EYLEA-MYLAN-00523361 through 508, 5 was so marked for identification, as 6 of this date.) 7 Q. And can you confirm that the 8 covering e-mail is from Deborah Fix, 9 dated August 25th, 2006 to you, among 10 many others. 11 A. So Exhibit 221 has a first page 12 that has an e-mail dated Friday, August 13 25th, 2006 with "Subject: PRC August 14 29th VGFT-OD-0605," and I am one of the 15 recipients. 16 Q. Okay. Now we've got a new 17 clinical trial number, 0605, so what did 18 that one refer to? 19 A. This refers to the VIEW 1 20 clinical trial. 21 Q. Okay. And what was the 22 rationale behind the nomenclature for 23 these various clinical trials, 0508 or 24 0605? 25 A. Sure, so the first two numbers	Page 237 1 (Witness reviews document.) 2 MS. OBERWETTER: I think you 3 misspoke. You mean 364? 4 MS. MAZZOCHI: 364. 5 A. So in the synopsis of the draft 6 clinical protocol, this version states 7 that "Subjects will be randomly assigned 8 to one of three dosing regimens: 4 9 milligrams VEGF-Trap, 1 milligram of 10 VEGF-Trap or ranibizumab. For the first 11 12 months, subjects will be given an 12 intravitreal injection in the study eye 13 every four weeks. During the second 12 14 months of the study, subjects will be 15 evaluated every four weeks and will 16 receive an intravitreal injection at 17 least every 12 weeks." 18 Q. Okay. So at this stage you 19 weren't even looking at putting the 2 20 milligram dose in the Phase III trials? 21 A. I don't recall all of the 22 considerations at the time that this 23 draft was generated. 24 Q. Do you recall what the impetus 25 was for changing to the 2 milligram dose

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Page 238 1 as opposed to the 1 or 4 milligram dose? 2 A. I recall that from the 0508 3 study, it was noted that the 4 milligram 4 treatment group did not seem to perform 5 notably better than the 2 milligram 6 treatment group albeit from a small 7 exploratory study. And that in 8 determining the doses to carry forward 9 into the Phase III trials, there were 10 still concerns regarding safety of 11 aflibercept, in particular in regards to 12 systemic adverse affects. 13 Q. Do you recall whether you 14 sought any input on which particular dose 15 to use in the Phase III clinical trials 16 from any outside experts? 17 A. I don't recall if we explicitly 18 solicited feedback from outside experts 19 on the dose. 20 Q. Well, also here in terms of 21 your study design you have a loss of less 22 than five ETDRS letters in conjunction 23 with recurrent fluid as indicated by OCT. 24 Why were you picking a loss of 25 less or equal to five ETDRS letters	Page 240 1 exclusion criteria are used to define the 2 population that will be used in any 3 clinical trial. 4 Q. And when it comes to the 5 inclusion criteria of ETDRS best 6 corrected visual acuity of 20/40 to 7 20/320 (letter score of 73 to 25.) 8 What was the rationale for 9 setting that as the inclusion criteria 10 threshold? 11 MS. OBERWETTER: Object to the 12 form and foundation. 13 A. So one aspect of this study is 14 that we wanted to include patients that 15 had the possibility for vision gain. And 16 as a result of that, the lower threshold 17 was set at 25 letters or a Snellen 18 equivalent of 20/320. As many patients 19 with visual acuity below that threshold, 20 are limited in their potential to gain 21 visual acuity. 22 Q. And why is that? 23 A. Neovascular AMD is a 24 multi-factorial disease process of which 25 the hallmark is pathologic
Page 239 1 instead of 15? 2 A. So you're referring to the 3 retreatment criteria proposed for use 4 during the second year of this study. 5 And this is the second criteria listed. 6 The reason why we would have 7 selected five letters was that it's 8 generally understood that the measurement 9 of visual acuity has a lot of 10 variability. And that a difference of 11 five letters is one that reliably would 12 tell you if a patient's vision was 13 increasing or decreasing. 14 Q. Take a look at the page that 15 ends in 366. 16 A. Okay. 17 Q. For key subject eligibility 18 criteria there is a list of inclusion 19 criteria and exclusion criteria. 20 What was the rationale for 21 having this kind of inclusion and 22 exclusion criteria? 23 MS. OBERWETTER: Object to the 24 form and foundation. 25 A. So generally the inclusion and	Page 241 1 neovascularization, in particular 2 choroidal neovascularization. But there 3 is a parallel atrophic process that is 4 the hallmark of the disease. And so 5 often patients will have vision loss, due 6 to that atrophic component of the 7 disease, as well as the neovascular 8 component. 9 Q. Okay. If you can take a look 10 at page 367, there is a description 11 stated there of "Primary endpoint 12 efficacy" near the bottom of the page. 13 And it says, "The primary endpoint will 14 be prevention of moderate vision loss 15 defined as loss than 15 letters on the 16 ETDRS chart compared to baseline at 12 17 months." 18 Do you see that? 19 A. Yes, I see where it describes 20 the primary endpoint. 21 Q. Now, earlier when we had been 22 looking at that '601 patent, there was a 23 reference to the patient gains at least 24 15 letters of best corrected visual 25 acuity score.

Page 242 1 Is that the same thing as this 2 primary endpoint for efficacy here? 3 A. It is not the same thing. 4 Q. What's different about them? 5 A. So if you look at the next page 6 with the numbers ending 368 in the 7 secondary endpoint -- 8 Q. Yes. 9 A. -- this first endpoint, first 10 bullet "Gain of 15 or more letters on the 11 ETDRS chart compared to baseline at 12 12 months," that represents a patient that 13 gained 15 letters or more. 14 The primary endpoint in this 15 draft protocol is referring to the 16 prevention of vision loss. So a patient 17 losing less than 15 letters on the ETDRS 18 chart compared to baseline. 19 Q. Well, is the drug still being 20 effective if all you have done is prevent 21 vision loss as opposed to allowing 22 patients to gain letters? 23 MS. OBERWETTER: Object to the 24 form. Vague. 25 You can answer.	Page 244 1 certainly believed that achieving that 2 primary endpoint would demonstrate that 3 the study drug was safe and effective 4 right, such that it would be in condition 5 for approval? 6 MS. OBERWETTER: Object to the 7 form. 8 A. So Regeneron -- my recollection 9 of Regeneron's position at the time was 10 that the studies would have been 11 considered a success if we demonstrated 12 noninferiority based on this primary 13 endpoint of proportion of patients losing 14 less than 15 letters at week 52. 15 However, based on the ANCHOR and MARINA 16 results, we knew how critical it was to 17 demonstrate not only that we were 18 preventing patients from losing vision, 19 but also to demonstrate vision gains over 20 time. 21 MS. MAZZOCHI: Let's put that 22 one aside. 23 I would like to mark as 24 Defendant's Exhibit 222 a document 25 with the production numbers
Page 243 1 A. So in the context of the VIEW 1 2 and the VIEW 2 clinical trials, the 3 endpoint of proportion of patients 4 avoiding a 15 or more letter loss was 5 based on the endpoint utilized in the 6 ANCHOR and MARINA studies, and that was 7 necessitated by the noninferiority design 8 of those studies. 9 Q. So that noninferiority standard 10 still demonstrates that the drug 11 aflibercept was effective? 12 MS. OBERWETTER: Object to the 13 form. Vague. 14 You can answer. 15 A. The fact that the FDA accepted 16 the VIEW 1 and VIEW 2 data as sufficient 17 evidence of efficacy and safety to 18 approve aflibercept for the treatment of 19 neovascular AMD, I think it confirms that 20 that was acceptable. 21 Q. And effective? 22 MS. OBERWETTER: Object to the 23 form. Vague. Asked and answered. 24 Q. Let me put it to you this way, 25 with that primary endpoint, Regeneron	Page 245 1 RGN-EYLEA-MYLAN 00523302 through 304. 2 (Defendant's Exhibit 222, 3 Document Bates stamped 4 RGN-EYLEA-MYLAN-00523302 through 304, 5 was so marked for identification, as 6 of this date.) 7 Q. Let me know when you have that. 8 A. I have Exhibit 222 in front of 9 me. 10 Q. And can you confirm that you 11 were forwarded by Jesse Cedarbaum on or 12 around September 5, 2006, a message -- an 13 e-mail message involving Jesse Cedarbaum 14 and Phil Rosenfeld, dated September is, 15 2006? 16 A. So I see the second sort of 17 message in this string as a forwarded 18 message from Jesse Cedarbaum dated the 19 5th of September 2006. It was primarily 20 to Len Schleifer, but I am copied. 21 Q. Okay. It appears that Jesse 22 Cedarbaum reached out to Phil Rosenfeld, 23 and must have shared with him some of the 24 VEGF-Trap data that you guys had? 25 MS. OBERWETTER: Object to the

Page 246 1 form and foundation. 2 A. The e-mail between Jesse and 3 Phil Rosenfeld dated September 1st, 2006 4 states "Thanks for sharing the VEGF-Trap 5 data on Wednesday." 6 Q. Do you have any understanding 7 of what that VEGF-Trap data might have 8 been? 9 A. I don't recall what that data 10 might have been. 11 Q. Do you know whether it was 12 subject to any confidentiality 13 restrictions? 14 A. So I don't know specifically in 15 this case, but it was our practice to 16 only engage with external experts under 17 confidentiality agreements. 18 Q. Do you know if this was data 19 that was actually presented at one of the 20 clinician conferences, the CLEAR-IT 2 21 data? 22 A. So again, I don't have a 23 recollection of this e-mail string, but 24 from reading the e-mail, Jesse is 25 corresponding with Dr. Rosenfeld about	Page 248 1 A. I do see where the e-mail 2 states that phrasing. 3 Q. Do you remember internally ever 4 discussing the possibility of using a 2 5 milligram dose in your Phase III clinical 6 trials before Jesse Cedarbaum got this 7 feedback from Dr. Rosenfeld? 8 MS. OBERWETTER: Object to the 9 foundation. 10 You can answer. 11 A. I don't recall specifically the 12 timing of the discussions regarding dose 13 selection for Phase III. 14 Q. If you look at the top e-mail, 15 this is Len Schleifer saying this is Phil 16 Rosenfeld's view of our diabetes 17 opportunity. And then he says in the 18 second line Jesse showed him the 19 four-week, five-patient DME data, which 20 showed a nice response at four weeks and 21 then a small loss by six weeks. 22 Do you see that? 23 A. I do see where that sentence 24 is. 25 Q. Do you know which clinical
Page 247 1 the angiogenesis conference that 2 Dr. Rosenfeld organizes. 3 Q. Do you recall whether the 4 CLEAR-IT 2 data was presented at the 5 angiogenesis conference in 2006? 6 MS. OBERWETTER: Object to the 7 form. 8 A. I do not recall if that data 9 was presented at that conference. 10 Q. Okay. Well, one of the things 11 that Dr. Rosenfeld told Jesse Cedarbaum 12 which was passed on to you, is he said 13 "You have a chance of using a 4-milligram 14 dose which is a 4-fold molar excess over 15 Lucentis with a good chance of better 16 durability. The more I thought about 17 your dilemma, I would go with the 2 18 milligram and 4 milligram dose every two 19 weeks or four weeks for a fixed number of 20 doses. Then see the patients back every 21 four weeks and dose as needed. With the 22 competition closing in on you, I think 23 your only choice is to go for the gold 24 and design a Phase III now." 25 Do you see that?	Page 249 1 trial data that was, that was the four 2 week, five-patient DME? 3 MS. OBERWETTER: Object to the 4 form and foundation. You're asking 5 the witness about another e-mail she 6 is not included on. 7 A. My assessment is that is 8 referring to the 0512 study, which was 9 the Phase I study with intravitreal 10 aflibercept in DME. 11 Q. Okay. And if you can take a 12 look at the '601 patent. DME Phase I 13 study that you just referred to, the 0512 14 study, was that the precursor to example 15 5 in the '601 patent? 16 MS. OBERWETTER: Object to the 17 form and foundation to the extent 18 you're still asking her about a 19 document that she was not included on. 20 A. So the 0512 Phase I study in 21 DME was conducted prior to the Phase II 22 clinical trial of VGFT, and subject was 23 DME described in example 5. 24 Q. And in example 5 the dose that 25 was being given in this in the DaVinci

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Page 250 1 trial, was 2 milligrams of VEGF-Trap once 2 every four weeks. 3 How did you get from the 1 and 4 4 milligram dose in the Phase I study to 5 choosing to use a 2 milligram dose in the 6 Phase II DME study? 7 MS. OBERWETTER: Object to the 8 form. 9 A. So I don't recall specifically 10 the discussions or the decision-making 11 between completing the 0512 study and the 12 design of the Phase II clinical trial in 13 DME. 14 Q. Is it possible -- well, do you 15 recall who was responsible for designing 16 the Phase II DME study that's referred to 17 here in example 5 of the '601 patent? 18 A. So again, I don't recall 19 specifically who was involved at that 20 time, but it would have included members 21 of the clinical development group, 22 including myself and Dr. Vitti. Alyson 23 Berlinger, I believe, was the study 24 director. We consulted with our 25 regulatory colleagues, as well as senior	Page 252 1 trial manager assigned to ophthalmology. 2 Q. Did she play any role in 3 discussing the Phase II, DME clinical 4 trials with aflibercept? 5 A. The clinical trial manager role 6 was limited to operationalizing the 7 clinical trials. 8 Q. Do you recall having any say in 9 what would be the appropriate dosing to 10 use in the Phase II DME trial? 11 MS. OBERWETTER: Object to the 12 form. 13 A. I recall having input on the 14 overall study design. 15 Q. And what was the nature of your 16 input? 17 A. I don't recall specifically. 18 Q. So you know you participated in 19 the design of the DaVinci trial, you just 20 don't know what your contribution was? 21 MS. OBERWETTER: Object to the 22 form. 23 You can answer. 24 A. I know that I was involved in 25 the discussions regarding the protocol.
Page 251 1 management and others regarding the study 2 design. 3 Q. And you certainly had consulted 4 with Dr. Cedarbaum, right? 5 A. I don't recall precisely, but I 6 believe Dr. Cedarbaum was not with the 7 company when the DaVinci study was 8 conducted. 9 Q. Right. How about Avner 10 Ingerman? 11 A. Again, I don't recall exactly 12 where Dr. Ingerman's tenure at Regeneron 13 began and ended. 14 Q. Do you recall Dr. Ingerman 15 having any involvement in the DME studies 16 or study design or having discussions 17 about it? 18 A. I don't specifically recall, 19 you know, conversations or, I guess, him 20 having input. But in his capacity at 21 Regeneron, I would have expected that he 22 would have had input. 23 Q. All right. And who was 24 Jennifer Buskey? 25 A. Jennifer Buskey was a clinical	Page 253 1 I don't specifically remember exactly 2 what my contributions were. But my input 3 would have been related to all aspects of 4 the design of the study, including the 5 study assessments, the planned schedule 6 of visits, any considerations around 7 masking, et cetera. 8 MS. OBERWETTER: Sorry, we have 9 been going another hour, so if you're 10 in the middle of a line and you have a 11 couple more, please keep going. 12 MS. MAZZOCHI: All right. Well, 13 I was about to do another exhibit. So 14 if you want to take a break, we can 15 take a break. 16 MS. OBERWETTER: That would be 17 great. 18 THE VIDEOGRAPHER: Going off the 19 record, 3:49 p.m. 20 (Off the record.) 21 THE VIDEOGRAPHER: Back on the 22 record at 4:06 p.m. 23 [Off the record.] 24 MS. MAZZOCHI: Thank you. I 25 would like to mark as Defendant's

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Page 254 1 Exhibit 223 a document with production 2 number RGN-EYLEA-MYLAN 525700. 3 (Defendant's Exhibit 223, 4 Document Bates stamped RGN-EYLEA-MYLAN 5 525700, was so marked for 6 identification, as of this date.) 7 Q. And Ms. Chu, can you confirm 8 that Defendant's Exhibit 223 is an e-mail 9 chain where the top e-mail in the chain 10 is dated Thursday, March 8th, 2007. 11 "Subject: Planned Activities For First 12 AMD Pivotal Study" from Caroline Saxton, 13 and you are cc'd or you are copied on it. 14 A. So I have Exhibit 223, which is 15 an e-mail dated Thursday, March 8th, 2007 16 with the subject, "Forwarded Planned 17 Activities For First AMD Pivotal Study," 18 from Caroline Saxton and I am listed as 19 one of the recipients. 20 Q. And who was Caroline Saxton? 21 A. Caroline Saxton was the, was 22 one of our project managers at Regeneron 23 at the time. 24 Q. Okay. Now, if we look at the 25 e-mail that she was forwarding to you	Page 256 1 A. The first bullet in this e-mail 2 describes 4Q4 and a 1Q4 VEGF-Trap arm. 3 Q. Right. Neither of which is the 4 2 milligram Q4 VEGF-Trap for three months 5 followed by Q8, 2 milligrams Q8 dosing 6 thereafter, right? 7 A. I understand these treatment 8 groups to indicate 4 milligrams every 9 four weeks and 1 milligram every four 10 weeks, which is different from the 2 11 milligram three initial monthly dose and 12 then every eight week dosing group, 13 eventually included in the VIEW 1 study. 14 Q. All right. Now, if we look at 15 the fifth bullet point down, the third 16 hashtag in, one of the things it says is 17 "Thoughts on using a PIER-like dosing as 18 a second study." 19 Do you see that? 20 A. I do see the third hash or 21 subbullet saying "Thoughts on using a 22 PIER-like dosing regimen as a second 23 study. 24 Q. All right. And a PIER-like 25 dosing regimen would be one where there
Page 255 1 that was also dated March 8th, 2007, 2 there is a reference again to the 0605 3 pivotal study. Now, was that the Phase 4 III study for AMD? 5 A. 0605 was the study number for 6 the VIEW 1 Phase III study in AMD. 7 Q. Okay. But here, again, the 8 three-arm noninferiority pivotal study 9 design is still listed at .5 every four 10 weeks Lucentis, 4 milligrams monthly 11 VEGF-Trap, and 1 milligram every four 12 weeks VEGF-Trap, right? 13 A. The first bullet in this e-mail 14 reads "As agreed upon in the JSC, our 15 current plan is to initiate a three-arm 16 noninferiority pivotal study (0605) using 17 .5 Q4 Lucentis, 4Q4 VEGF-Trap and 1Q4 18 VEGF-Trap." 19 Q. So we still don't have the 20 loading dose yet that ultimately came to 21 be the VIEW protocol of having a study 22 arm with three monthly 2 milligram doses 23 by 2 milligrams every eight weeks, right? 24 MS. OBERWETTER: Object to the 25 form and foundation.	Page 257 1 was monthly dosing initially and then at 2 least PRN dosing thereafter? 3 A. So the PIER-dosing regimen was 4 three initial monthly doses and then 5 every 12 weeks. 6 Q. Do you know who initiated the 7 question on thoughts on using PIER-like 8 dosing as a second study? 9 A. I do not know who initiated 10 that bullet. 11 MS. MAZZOCHI: All right. You 12 can go ahead and set that one aside. 13 I would like to mark as DX 224, 14 a document with production numbers 15 RGN-EYLEA-MYLAN 635438 through 449. 16 Q. Were you ever a member of the 17 global project team meetings? 18 A. Can you be more specific about 19 the time frame that you're referring to? 20 Q. Yeah, in the 2007 time period, 21 do you recall ever being a part of the 22 global project team meetings with regard 23 to VEGF-Trap? 24 A. I was considered part of the 25 global project team. But I don't recall

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Page 258 1 exactly whether I attended all global 2 project team meetings. 3 Q. What was the purpose of the 4 global project team? 5 MS. OBERWETTER: Object to the 6 form. 7 A. The global project team was a 8 cross-functional team established as part 9 of the Bayer collaboration to oversee 10 development for aflibercept with our 11 co-development partner. 12 Q. And did the Bayer people have 13 input into what your Phase III clinical 14 trial would look like in terms of dosing 15 regimen? 16 MS. OBERWETTER: Objection. 17 Asked and answered. 18 A. As part of the Bayer 19 collaboration, they had input into 20 aspects of the clinical development 21 planning, including study designs. But 22 the ultimate scientific decision-making 23 remained with Regeneron. 24 Q. But they were giving you 25 feedback from, for example, the European	Page 260 1 Document Bates stamped RGN-EYLEA-MYLAN 2 635438 through 449, was so marked for 3 identification, as of this date.) 4 Q. Let me show you a document that 5 I've marked as Defendant's Exhibit 224 6 which has production numbers 7 RGN-EYLEA-MYLAN 635438 through 449. 8 Can you confirm that you have 9 that in front of you? 10 A. I have Exhibit 224 with the 11 title in the box listed as "Minutes of 12 VEGF-Trap for AMD/DE 05113 Global Project 13 Team Meeting 3, 9 March 2007." 14 Q. And it says "Final Version of 15 The Minutes" underneath that box was 16 dated March 29th, 2007? 17 A. I do see that stated here. 18 Q. Let's take a look at the 19 executive summary on the next page. 20 Third paragraph. It says, "The proposed 21 Phase III program consists of two 22 noninferiority studies with three arms, 23 (VEGF-Trap high, low, and Lucentis) 24 performed in 900 patients each. The 25 studies differ regarding their dosing
Page 259 1 regulatory authorities, right? 2 MS. OBERWETTER: Object to the 3 form. 4 A. Part of Bayer's responsibility 5 during the development was to interact 6 with ex-U.S. health authorities. And 7 they did seek advice from EMA, as well as 8 other health authorities outside of the 9 United States. 10 Q. And Bayer, before Regeneron, 11 was planning on doing a pivotal study or 12 proposing doing a pivotal study with 13 aflibercept that would have three monthly 14 doses followed by quarterly injections of 15 the Lucentis PIER regimen, right? 16 MS. OBERWETTER: Object to the 17 form. 18 A. Could you restate your question 19 one more time? 20 Q. Sure. 21 MS. MAZZOCHI: Hey, Jeff, were 22 you able to find the document, I want 23 to mark it? 24 MR. MARX: Yes. 25 (Defendant's Exhibit 224,	Page 261 1 regimens with pivotal 1 (U.S. study, 2 Regeneron) having monthly dosing 3 intervals for the first year and capped 4 PRN dosing (up to three months) the 5 second year. Pivotal 2 ('EU' study, BSP) 6 dosing is three monthly doses followed by 7 quarterly injections (Lucentis PIER 8 regimen)." 9 Do you see that? 10 A. I do see where the document 11 states pivotal, pivotal 2 dosing is three 12 monthly doses followed by quarterly 13 injections, Lucentis PIER regimen. 14 Q. Okay. So initially, it was 15 Bayer who wanted at least for Europe to 16 have the Phase III study that was three 17 monthly doses followed by a longer 18 injection period in that first year, 19 right? 20 MS. OBERWETTER: Objection. 21 Form and foundation. 22 A. So my recollection was that 23 replicate trials -- so two pivotal 24 studies were needed for registration of 25 the product in the U.S. as well as

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Page 262 1 outside the United States. 2 So the EU designation here, 3 it's my recollection, does not 4 specifically refer to a study intended to 5 support EU approval. It simply is a 6 designation of roughly where the study 7 would be conducted. 8 Q. Okay. Well, the European study 9 was going to be three monthly doses 10 followed by quarterly injections, what 11 was called the Lucentis PIER regimen, 12 right? 13 MS. OBERWETTER: Object to the 14 form and foundation. 15 A. I see in this document that 16 pivotal study 2 is referred to as having 17 three monthly doses followed by quarterly 18 injections designated as the Lucentis 19 PIER regimen. 20 Q. Okay. And was that study ever 21 done at the Phase III level? 22 A. No, this study was never 23 conducted. 24 Q. Do you know why not? 25 A. I don't specifically recall why	Page 264 1 MS. OBERWETTER: Object to the 2 form and foundation. 3 A. I don't recall. 4 MS. MAZZOCHI: Okay. Let's take 5 a look at what I will mark as DX 225 a 6 document with production number 7 RGN-EYLEA-MYLAN 635373. 8 (Defendant's Exhibit 225, 9 Document Bates stamped RGN-EYLEA-MYLAN 10 635373, was so marked for 11 identification, as of this date.) 12 Q. And can you confirm this is an 13 e-mail from Caroline Saxton to you and 14 others dated March 28th, 2007, "Subject: 15 Final Decision Required for AMD Pivotal 1 16 Protocol"? 17 MS. OBERWETTER: If you can give 18 me a second, I have only just gotten 19 the document. So just give me a 20 second, one second. 21 THE WITNESS: Yeah, I need a 22 minute just to review this as well. 23 (Witness reviews document.) 24 A. Okay, I have Exhibit 225 in 25 front of me.
Page 263 1 not. But I do recall that it was felt 2 very strongly that the PIER regimen had 3 the potential to result in sub-optimal 4 outcomes for patients. 5 Q. Okay. And likewise, the U.S. 6 study that's noted here for Regeneron, 7 having monthly dosing intervals for the 8 first year, and capped PRN dosing up to 9 three months for the second year, that 10 was also not done as a Phase III study, 11 right? 12 A. The design of the VIEW 1 and 13 VIEW 2 studies did include treatment 14 groups that received monthly dosing for 15 the first year and then in the second 16 year all treatment groups received 17 quarterly mandatory dosing with the 18 potential to give additional doses in 19 between based on criteria. 20 Q. Okay. But if we look at, at 21 least, as of what was in place as of 22 March 9th, 2007, we still didn't have the 23 dosing regimen that was 2 milligrams 24 dosed for three monthly doses followed by 25 an eight-week interval, right?	Page 265 1 Q. Can you confirm it's a March 2 28th e-mail from Caroline Saxton to you 3 amongst others, "Subject: Final decision 4 required for AMD Pivotal 1 Protocol"? 5 A. So this is an e-mail dated 6 March 28th, 2007, with the "Subject: 7 Final decision required for AMD Pivotal 1 8 Protocol." It's from Caroline Saxton, 9 and I am copied on the e-mail. 10 Q. Okay. And one of the things 11 that she wrote to Peter, George, Len and 12 Neil, was that, again, Regeneron was 13 targeting to try to start the first 14 pivotal study, meaning the Phase III 15 studies in AMD in August of 2007, right? 16 A. That is what is stated in this 17 e-mail, yes. 18 Q. And Caroline is saying "We need 19 two events in order to meet this 20 deadline. One, final CRO bid awarded 21 Thursday, April 5th." 22 Do you see that? 23 A. I see the first item reads 24 "Final CRO bid awarded Thursday, April 25 5th," yes.

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Page 266 1 Q. And is that something that you 2 were working on? 3 A. Yes. My team was responsible 4 for selecting the CRO and overseeing the 5 CRO's activities for the VIEW 1 study. 6 Q. And which CRO did you select? 7 A. For this study, my recollection 8 is that we selected PPD. 9 Q. And why were you using a CRO? 10 A. Regeneron was a small company 11 with limited clinical operations 12 capabilities. So in order to adequately 13 oversee and conduct this pivotal trial, 14 we felt that engaging a CRO to conduct 15 activities like study, monitoring, et 16 cetera, was needed. 17 Q. All right. And do you recall 18 how much that cost? 19 A. I don't recall the exact budget 20 for the CRO. 21 Q. Was it in the tens of millions 22 of dollars? 23 A. I don't recall the exact budget 24 for the CRO. 25 Q. Who paid for it, was it	Page 268 1 Q. Who put that on the list of an 2 interval to start considering? 3 MS. OBERWETTER: Objection to 4 foundation. 5 A. I don't recall. 6 MS. MAZZOCHI: Go ahead and put 7 that one aside. 8 I am going to mark as 9 Defendant's Exhibit 226, a document 10 with production numbers 11 RGN-EYLEA-MYLAN 631170 through 631175. 12 (Defendant's Exhibit 226, 13 Document Bates stamped RGN-EYLEA-MYLAN 14 631170 through 631175, was so marked 15 for identification, as of this date.) 16 Q. Can you confirm on the first 17 page of DX 226, there is an e-mail from 18 you dated March 29th, 2007 to Jesse 19 Cedarbaum, where you were forwarding the 20 conversation on VEGF-Trap executive 21 summary of scientific advice meeting with 22 Swedish MPA? 23 A. Yes, so I have Exhibit 226 in 24 front of me. And I see the second e-mail 25 in the string is a forwarded e-mail from
Page 267 1 Regeneron or Bayer? 2 A. I am not absolutely the expert 3 of the details on the collaboration 4 agreement. But my understanding is that 5 development costs are shared 50/50 6 between Bayer and Regeneron. 7 Q. Item number 2, finalize study 8 design Friday, April 13th or Thursday 9 April the 12th if you are superstitious. 10 So some of the things that 11 Caroline identified needed to be decided 12 were the doses of .5 milligram, 2 13 milligram, 4 milligram VGT, as well as an 14 interval Q4, Q8 or Q12. 15 Do you see that? 16 A. Yes, I see those as items C and 17 D in item number 2 in the e-mail. 18 Q. Who decided to put the Q8 19 interval on the table at this meeting? 20 MS. OBERWETTER: Object to the 21 form and foundation. 22 A. So I don't recall who 23 specifically added Q8 to the bullet in 24 this e-mail. I don't believe this is 25 referring to a meeting.	Page 269 1 me to Jesse Cedarbaum on the 29th of 2 March 2007 with the "Subject: VEGF-Trap 3 Executive Summary of Scientific Advice 4 Meeting with Swedish MPA," on the 28th 5 March '07. 6 Q. Do you recall what influence 7 the Swedish regulatory feedback on the 8 clinical trial design had on exactly what 9 Regeneron wanted to do in its own 10 clinical trial design -- 11 MS. OBERWETTER: Object to the 12 form. 13 Q. -- in the Phase III wet AMD 14 with aflibercept? 15 MS. OBERWETTER: Object to the 16 form and foundation. 17 A. I do not recall the impact the 18 Swedish MPA advice had on the study 19 designs of the VIEW 1 and VIEW 2 studies. 20 Q. Well, if we take a look at 21 Jesse Cedarbaum's responsive e-mail, can 22 you confirm that that's dated March 29th, 23 2007, and went to individuals such as 24 Avner Ingberman and George Yancopoulos? 25 A. Yes. The first e-mail in the

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Page 270 1 string here is dated Thursday, March 2 29th, 2007 forwarding VEGF-Trap executive 3 summary of scientific advice meeting with 4 Swedish MPA from Jesse Cedarbaum to Peter 5 Powchik, Avner Ingerman and others. 6 Q. Do you remember discussing 7 these results with Jesse Cedarbaum? 8 A. I do not recall discussing 9 these results with Jesse Cedarbaum. 10 Q. All right. Well, one of the 11 things that he noted in this e-mail is he 12 said "With respect to the point about the 13 safety margin for tox coverage, perhaps 14 we should take this as an opportunity to 15 reconsider making the top dose in our 16 studies be 2 milligrams." 17 Do you see that? 18 A. Yes, I see that as the first 19 sentence in the second paragraph. 20 Q. Do you recall if one of the 21 rationales behind having the 2 milligram 22 dose in the Phase III clinical studies 23 was for toxicity-related reasons? 24 MS. OBERWETTER: Object to the 25 foundation, if you're still asking the	Page 272 1 milligram, you would only lose one half 2 life of exposure, somewhere around eight 3 to 10 days? 4 MS. OBERWETTER: Object to the 5 foundation. 6 A. I do not recall this being a 7 specific consideration. 8 Q. All right. And Mr. Cedarbaum 9 also puts down "P.S.: I could get behind 10 an eight-week interval in place of 12." 11 Do you see that? 12 A. I do see his postscript, yes. 13 Q. So do you have any -- do you 14 recall ever discussing with Dr. Cedarbaum 15 why he preferred an eight -- why he could 16 get behind an eight-week interval in 17 place of a 12-week interval? 18 MS. OBERWETTER: Object to the 19 foundation. 20 A. I do not recall a specific 21 discussion with Dr. Cedarbaum regarding 22 his rationale for an eight-week interval 23 instead of 12 weeks. 24 Q. Well, how about a general 25 discussion that it would be okay to go
Page 271 1 witness about this top e-mail that 2 she's not on. 3 A. I do not recall this being a 4 specific consideration regarding the 2 5 milligram dose in the VIEW 1 and the VIEW 6 2 studies. 7 Q. If you look at the fifth bullet 8 point down, it says "As has been pointed 9 out by others, we would lose only one 10 half life of exposure. Somewhere around 11 eight to 10 days, based upon 12 extrapolations in the literature between 13 rabbit and human vitreous clearance of 14 drugs by using 2 instead of 4 15 milligrams." 16 Do you see that? 17 A. Yes, I see that as the fifth 18 bullet down, which states as has been 19 pointed out by others we would only lose 20 one half life of exposure. 21 Q. Okay. Do you recall in 22 conjunction with a Phase III VIEW 1, VIEW 23 2 study clinical trial designs, this 24 being an issue that was raised, that if 25 you had the 2 milligram dose instead of 4	Page 273 1 with the eight -- in connection with 2 preparing the dosing regimen for the VIEW 3 1, VIEW 2 clinical trials, that it would 4 be acceptable to have the eight-week 5 interval, because it wouldn't necessarily 6 -- well, just about the eight-week 7 interval? 8 MS. OBERWETTER: Object to the 9 form. 10 A. I don't specifically recall 11 Dr. Cedarbaum's position at this time. 12 Q. Yeah, I know you're kind of 13 qualifying your answer by saying, I don't 14 specifically recall what he said. 15 I am just asking you generally, 16 including as a 30(b)(6) witness for 17 Regeneron on the clinical trials, do you 18 have an understanding as to whether any 19 of these reasons listed here in 20 Dr. Cedarbaum's e-mail were reasons that 21 people put forward to advocate for having 22 an eight-week interval instead of the 23 12-week interval? 24 MS. OBERWETTER: Object to the 25 form. Foundation. And if we're back

Page 274 1 into 30(b)(6) questioning, a 30(b)(6) 2 objection. 3 A. My recollection at this time is 4 that there were multiple considerations 5 around the doses and dosing interval. We 6 were conducting a small Phase IB study, 7 referred to in this e-mail as the 0603 8 study, that was testing new formulation 9 and concentration of aflibercept that 10 would allow a 4-milligram dose to be 11 delivered in 50 microliters. 12 And so one aspect is that 13 moving forward with the 4-milligram dose 14 in the Phase III studies, would have 15 necessitated waiting for that study to 16 complete and that formulation to be 17 available. 18 Q. Is Regeneron aware of anybody 19 who put together the idea of dosing a 20 2-milligram dose every eight weeks in the 21 Phase III clinical trials before Jesse 22 Cedarbaum in this e-mail? 23 MS. OBERWETTER: Object to the 24 form foundation. I assume you're 25 still asking 30(b)(6) questions, a	Page 276 1 objection. 2 And I will note the court 3 reporter said she needs to break for 4 an emergency. 5 A. I can't speak on behalf of 6 Regeneron, I can only speak for myself, 7 and I do not recall a person who 8 specifically put that together in this 9 time frame. 10 (Off the record.) 11 THE VIDEOGRAPHER: Back on the 12 record at 4:42 p.m. 13 MS. MAZZOCHI: I will ask the 14 court reporter to mark as Defendant's 15 Exhibit 227, a document with 16 production number RGN-EYLEA-MYLAN 17 631182. 18 (Defendant's Exhibit 227, 19 Document Bates stamped RGN-EYLEA-MYLAN 20 631182, was so marked for 21 identification, as of this date.) 22 Q. And Ms. Chu, if you can confirm 23 this is an e-mail from Kathleen Lawrence 24 to you and others, dated Monday, April 25 2nd, 2007?
Page 275 1 30(b)(6) objection. 2 A. Can you just restate your 3 question one more time? 4 Q. Sure. Is Regeneron aware of 5 anyone who put together for the Phase III 6 VIEW 1, VIEW 2 clinical trial design, a 7 2-milligram dose and an eight-week dosing 8 interval before Dr. Cedarbaum's e-mail 9 we're looking at here of March 29th, 10 2007? 11 MS. OBERWETTER: Object to the 12 form. Foundation. 30(b)(6) 13 objection. 14 A. I don't recall exactly the 15 discussions around the eight-week 16 interval or whether Dr. Cedarbaum by 17 virtue of this e-mail was the first 18 person to suggest the eight-week 19 interval. 20 Q. Can Regeneron identify anybody 21 who did it, who put those two pieces 22 together, a 2- milligram dose/eight-week 23 interval before Dr. Cedarbaum did? 24 MS. OBERWETTER: Object to the 25 form. Foundation. A 30(b)(6)	Page 277 1 A. So I have Exhibit 227 in front 2 of me with a date April 2nd, 2007. 3 "Subject: Decisions and Actions, AMD 4 Phase III Program Meeting - April 2nd, 5 '07" from Kathleen Lawrence, and I am a 6 recipient of this e-mail. 7 Q. Do you recall if you were a 8 participant in this AMD Phase III program 9 meeting on April 2nd, 2007? 10 A. I don't recall this specific 11 meeting. But in my role, I would have 12 attended such meetings. 13 Q. Who else would have attended 14 such meetings -- 15 MS. OBERWETTER: Object to the 16 form and foundation. 17 Q. -- in this time period? 18 MS. OBERWETTER: Same objection. 19 A. So the people that would have 20 attended this kind of meeting would be 21 anyone internally who had 22 responsibilities for the Phase III study. 23 Myself, Avner Ingerman, as well as 24 others. For instance, in this particular 25 case, Peter Powchik, Bob Vitti. It might

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Page 278 1 also include cross-functional 2 representatives like from our statistics 3 group or from the clinical trial 4 management group. 5 Q. Anyone else you can think of? 6 MS. OBERWETTER: Same objection. 7 A. Not off the top of my head. 8 But that list is not exhaustive. 9 Q. Okay. If you take a look at 10 one of these items down here, it says 11 "Decision 0605 design" and that's 12 referring to the VIEW 1, VIEW 2 clinical 13 studies, right? 14 A. 0605 is the study number for 15 the VIEW 1 study. 16 Q. And that was the Phase III 17 pivotal study? 18 A. That was one of the Phase III 19 studies in neovascular AMD. 20 Q. Okay. And it says that the 21 decisions on the arms, one of them was 22 going to be Lucentis, right? 23 A. So this e-mail on the first 24 bullet states that the assumptions are to 25 be used with contract and budgeting with	Page 280 1 lead-in (dose monthly for first three 2 months)." 3 Q. All right. Who put, who 4 actually assembled that particular 5 regimen as one of the arms to consider 6 for the VIEW 1, Phase III clinical trial? 7 MS. OBERWETTER: Object to the 8 form. Foundation. 9 I want to clarify since we had 10 an off the record interim here: Are 11 you asking 30(b)(6) questions or are 12 you asking her her personal memory? 13 MS. MAZZOCHI: 30(b)(6). 14 MS. OBERWETTER: A 30(b)(6) 15 objection. 16 A. I don't recall specifically who 17 proposed that dosing regimen. 18 Q. Could it have been Avner? 19 MS. OBERWETTER: Object to the 20 form. Calls for speculation. A 21 30(b)(6) objection. 22 A. I don't recall specifically. 23 At this time, there were many discussions 24 about the design of this, of these 25 trials.
Page 279 1 the CRO. And the first bullet under the, 2 under arms is Lucentis. 3 Q. And then the next decision in 4 terms of one of the arms to use is .5 5 milligrams, Q4 weeks. 6 A. Yes, that is the second bullet 7 in the e-mail. 8 Q. And is that referring to the 9 Lucentis dose, .5 milligrams every four 10 weeks? 11 A. I believe -- I don't know for 12 sure. But my understanding would be that 13 this would be referring to the .5 14 milligram every four week aflibercept 15 group included in the VIEW 1 study. 16 Q. Okay. Now, the third bullet 17 point down says -- this is for the first 18 time we see this: "2 milligrams Q8 weeks 19 with PIER lead-in (dose monthly for first 20 three months)." 21 Do you see that? 22 MS. OBERWETTER: Object to the 23 form and the characterization. 24 A. I do see the third bullet 25 states: "2 milligram Q8 weeks with PIER	Page 281 1 Q. Could it have been you who put 2 those three dose conditions together? 3 MS. OBERWETTER: Is that a 4 30(b)(6) question or an individual 5 question? 6 MS. MAZZOCHI: Her. 7 MS. OBERWETTER: Would you tell 8 me when you go back to 30(b)(6) 9 questions, Ms. Mazzochi? 10 MS. MAZZOCHI: Sure. 11 You can answer. 12 A. I do not recall specifically 13 proposing this characterization of the 14 regimen. 15 Q. And in your personal capacity, 16 you don't recall who put this combination 17 together of 2 milligrams every eight 18 weeks with the PIER lead-in of dosing 19 monthly for the first three months? 20 A. I don't recall specifically who 21 proposed this. 22 Q. Would anyone from Bayer have 23 been part of this discussion in terms of 24 proposing these particular arms to go 25 send out to the contract resource

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Page 282 1 organization. 2 MS. OBERWETTER: Object to the 3 form. 4 A. In their role as our 5 co-developer partner, Bayer would have 6 had input on the study design, but they 7 did not specifically have input into our 8 interactions with the CRO. 9 Q. Okay. Do you know if your CRO 10 contract actually did include this two 11 milligrams Q8 weeks with the PIER lead-in 12 dosing monthly for the first three 13 months? 14 A. I don't recall whether the CRO 15 contract specifically included details 16 about the dosing regimen. 17 Q. Did you review the CRO contract 18 in connection with preparing for your 19 deposition in this case? 20 A. I did not review the CRO 21 contract in preparation for this 22 deposition. 23 Q. Okay. Do you know who has a 24 copy of that CRO contract? 25 A. So this is going back many	Page 284 1 Q. And do you recall whether that 2 issue was discussed and cleared with EU 3 authorities? 4 A. I don't recall if that specific 5 topic was discussed with EU authorities. 6 Q. And then the last bullet point 7 says: "4 milligram dose group not 8 completely ruled out. Base file decision 9 on additional 0508 data." 10 Do you see that? 11 A. I see that that is the last 12 bullet in this section. 13 Q. And the 0508 study, that was 14 the Phase II AMD study? 15 A. So 508 was the study number for 16 the Phase II study in neovascular AMD. 17 Q. And what information were you 18 hoping to see from the Phase II, wet AMD 19 data, to rule in or rule out the 4 20 milligram dose? 21 MS. OBERWETTER: Object to the 22 form and foundation. 23 A. My recollection is that we were 24 looking very closely at safety data as 25 well as the outcomes of visual acuity and
Page 283 1 years, so I can't say for certain, but it 2 would have been Regeneron's procurement 3 group that interacted with CROs at this 4 time. 5 Q. And do you recall anyone who 6 was in the procurement group at this 7 time. 8 A. I don't recall specifically who 9 was in the procurement group at this 10 time. 11 MS. MAZZOCHI: Counsel, we will 12 request a copy of the CRO contract 13 referred to here specifically for the 14 Phase III VIEW clinical studies be 15 produced. 16 (Production request) 17 Q. The next bullet point listed is 18 "2 milligram Q4 weeks (only 6X) safety 19 margin based on tox, will need to discuss 20 with EU authorities." 21 Do you see that? 22 A. I do see that the fourth bullet 23 states, "2 milligram Q4 weeks (only 6X) 24 safety margin based on tox, will need to 25 discuss with EU authorities."	Page 285 1 central retinal lesion thickness as 2 measured on OCT for the purpose of 3 evaluating the Phase II data. 4 MS. MAZZOCHI: Go ahead and put 5 that one aside. 6 I would like to mark as DX 228, 7 a document with production numbers 8 RGN-EYLEA-MYLAN 526319 through 321. 9 (Defendant's Exhibit 228, 10 Document Bates stamped RGN-EYLEA-MYLAN 11 526319 through 321, was so marked for 12 identification, as of this date.) 13 Q. This is an e-mail dated 14 Wednesday, April 4th, 2007, from George 15 Yancopoulos to Darlene Jody; do you have 16 that? 17 A. Yes, so I have Exhibit 228, 18 dated Wednesday, April 4th, 2007 with the 19 "Subject: Summary of Issues For Call, 20 AMD P3 Planning," from George Yancopoulos 21 to Darlene Jody. 22 Q. Now, earlier in the deposition 23 today, you referred to an e-mail that you 24 recalled seeing that you discussed with 25 George Yancopoulos, was this one of the

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Page 286 1 e-mails? 2 A. Yes. This was the e-mail I 3 reviewed in preparation for this 4 deposition. 5 Q. Okay. And is this the document 6 that Regeneron contends demonstrates that 7 George Yancopoulos is the person who 8 conceived of the invention set forth in 9 the '601 and '572 patents? 10 MS. OBERWETTER: Object to the 11 form and foundation. 12 A. I can't speak to the Regeneron 13 position regarding this e-mail. 14 Q. What is your understanding of 15 the significance of this e-mail in your 16 capacity as the Regeneron Rule 30(b)(6) 17 witness? 18 MS. OBERWETTER: Object to the 19 form. Foundation. A 30(b)(6) 20 objection. 21 A. I need a minute just to take 22 another look at this e-mail. 23 (Witness reviews document.) 24 A. Okay. I'm sorry, what was your 25 question again?	Page 288 1 Q12w versus the Lucentis PIER regimen, 2 which might suffice for EMEA and also 3 simultaneously serve as a second study 4 for the FDA, based on using a separate 5 superiority analysis. Our view on this 6 is that while such a second study is 7 indeed likely to be noninferior to 8 Lucentis' PIER regimen it is at high risk 9 for not achieving superiority and thus 10 not being useful for the U.S. approval in 11 any way." 12 Do you see that? 13 A. I do see that sentence in the 14 e-mail. 15 Q. So was Dr. Yancopoulos actually 16 opposed to having any type of PIER 17 regimen appended to the 2 milligram 18 dosing regimens that were going to be 19 proposed in the Phase III clinical 20 studies? 21 MS. OBERWETTER: Object to the 22 form. Foundation. A 30(b)(6) 23 objection. 24 A. I can't speak to George's state 25 of mind or intent. It was my
Page 287 1 Q. Sure. In your capacity as 2 Regeneron's 30(b)(6) witness, what's the 3 significance of this April 4th, 2007 4 e-mail from George Yancopoulos to Darlene 5 Jody? 6 MS. OBERWETTER: Object to the 7 form, foundation. A 30(b)(6) 8 objection. 9 You can answer the question, if 10 you can. 11 A. So this e-mail from George to 12 Darlene Jody, who was a senior executive 13 responsible for the Bayer collaboration 14 with us, is communicating the Regeneron 15 proposal and decisions around the optimal 16 designs for the VIEW 1 and the VIEW 2 17 trials. 18 Q. Okay. But according to this 19 e-mail, if we look at the last paragraph 20 at the bottom of the second page of 21 Exhibit 228, George Yancopoulos says, "I 22 know there has been extensive discussion 23 at the team level about the second study 24 being an NI study," referring to 25 noninferiority study, "using doses of VT	Page 289 1 recollection that George was very much 2 advocating for a dosing regimen that was 3 felt to be optimal for patient outcomes. 4 He did not view the PIER regimen as 5 achieving that. 6 Q. Is there anywhere here where 7 Dr. Yancopoulos is advocating for 8 starting off the regimen with three 9 monthly 2-milligram doses, and then going 10 to the eight-week interval? 11 MS. OBERWETTER: Object to the 12 form and foundation with this witness. 13 A 30(b)(6) objection. 14 A. Sorry, could you ask your 15 question one more time? 16 Q. Sure. 17 MS. MAZZOCHI: Can the court 18 reporter read it back? 19 [The requested portion of the 20 record was read back as follows: 21 "Question: Is there anywhere 22 near where Dr. Yancopoulos is 23 advocating for starting off the 24 regimen with three monthly 2-milligram 25 doses, and then going to the

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Page 290 1 eight-week interval?"] 2 MS. OBERWETTER: Same objection. 3 A. In my review of this e-mail, I 4 do not see that it includes mention of 5 the three initial monthly doses for the 6 Q8 week group. 7 MS. MAZZOCHI: You can go ahead 8 and set that aside. 9 I would next like to mark as 10 Defendant's Exhibit 229, a document 11 with production numbers 12 RGN-EYLEA-MYLAN 00526220 through 223. 13 (Defendant's Exhibit 229, 14 Document Bates stamped RGN-EYLEA-MYLAN 15 00526220 through 223, was so marked 16 for identification, as of this date.) 17 Q. And did you review this e-mail 18 in connection with preparing for your 19 deposition in this case? 20 A. I have Exhibit 229, dated 21 Tuesday, April 10th, 2007, "Subject: 22 Forward: VEGF-Trap-Eye GDP for 23 REGN/Bayer," from George Yancopoulos to 24 Darlene Jody. 25 And, no, I did not review this	Page 292 1 e-mails where Dr. Yancopoulos is 2 proposing a schedule for the Phase III 3 clinical studies that has 2 milligrams 4 being dosed three times monthly, followed 5 by the eight-week dosing interval? 6 MS. OBERWETTER: Object to the 7 form, foundation. A 30(b)(6) 8 objection. You're asking the witness 9 to interpret the document that she's 10 not been given before. 11 A. My understanding of George's 12 e-mail, as I just reviewed it, is that he 13 is communicating the Regeneron position 14 regarding the design of the Phase III, 15 VIEW 1 and VIEW 2 studies to Darlene Jody 16 from Bayer. 17 Q. Right. And he's still 18 advocating for just a 2Q8 regimen, not 19 one with a loading dose, right? 20 MS. OBERWETTER: Object to the 21 form and foundation. A 30(b)(6) 22 objection. 23 A. So again, just in my review of 24 this e-mail, I can't speak to George's 25 intent, but he was building upon the
Page 291 1 e-mail in preparation for today's 2 deposition. 3 Q. Can you see anywhere -- well, 4 can you identify anywhere in here on 5 behalf of Regeneron whether 6 Dr. Yancopoulos was advocating or 7 proposing a regimen that involved 8 2-milligram doses being dosed monthly, 9 followed by dosing at an eight-week 10 interval in any of the Phase III clinical 11 studies? 12 MS. OBERWETTER: Object to the 13 form. Foundation. A 30(b)(6) 14 objection. 15 You're asking a witness to 16 interpret a document she just told you 17 that she has not seen. 18 A. And I will need a minute to 19 review this. 20 Q. Sure. 21 (Witness reviews document.) 22 A. Sorry, this was a dense set of 23 e-mails. 24 Q. The question was, did you 25 identify anywhere in this string of	Page 293 1 e-mail from Bob Terifay, Robert Terifay, 2 dated Thursday, 5th April 2007 to George 3 Yancopoulos, relating the outcome of a 4 VEGF-Trap-Eye joint development committee 5 meeting, where the proposed dosing 6 regimens for the two studies are Lucentis 7 .5 milligrams every four weeks versus 8 VEGF-Trap .5 milligrams every four weeks, 9 2 milligrams every four weeks, and 2 10 milligrams every four weeks times three, 11 which I understand to be three initial 12 monthly doses and then every eight weeks. 13 Q. Right. And just to be clear, 14 that dosing regimen of VEGF-Trap, 2 15 milligrams dosed every four weeks times 16 three, then Q8 thereafter, that was a 17 dosing regimen drafted by Bob Terifay, 18 right -- 19 MS. OBERWETTER: Objection to 20 form and foundation. 21 Q. -- in this e-mail string? 22 MS. OBERWETTER: Object to the 23 form and foundation with this witness. 24 A 30(b)(6) objection. Calls for 25 speculation.

Page 294 1 A. Can I answer? 2 MS. OBERWETTER: You can answer 3 the question. 4 A. My recollection of how 5 decisions were made at Regeneron at the 6 time was that this proposal would not 7 have been discussed at the joint 8 development committee meeting unless 9 George had had input and agreed that this 10 was the proposal for the Phase III 11 studies. 12 Q. Well, if George Yancopoulos had 13 signed off on that as the dosing regimen, 14 why is he actually arguing against that 15 then on April 10th, 2007 to Darlene Jody? 16 MS. OBERWETTER: Object to the 17 form. Foundation. The question on 18 its face calls for speculation. A 19 30(b)(6) objection. 20 A. My read of the e-mail didn't 21 give me the impression that George was 22 arguing against it. If you can point to 23 what specifically you're referring to, I 24 would be happy to review it again? 25 Q. Sure. On the first bullet	Page 296 1 A 30(b)(6) objection. Asked and 2 answered. 3 MS. MAZZOCHI: You can answer. 4 A. It is correct that that is what 5 is written in this e-mail is the sentence 6 that is based on both U.S. and EU 7 regulatory interactions. Such a study 8 will definitively fulfill their 9 requirements as one of the studies while 10 final dose/interval for the fourth arm of 11 this study are a bit unsettled, we could 12 use 2Q8 for now as the most likely 13 dose/interval." 14 MS. MAZZOCHI: You can go ahead 15 and set that aside. All right. 16 I would like to mark as DX 230, 17 a document with production numbers 18 RGN-EYLEA-MYLAN 526332 through 334. 19 (Defendant's Exhibit 230, 20 Document Bates stamped RGN-EYLEA-MYLAN 21 526332 through 334, was so marked for 22 identification, as of this date.) 23 Q. I would like you to take a look 24 at the e-mail from Robert Terifay that is 25 dated April 17th, 2007 to George
Page 295 1 point on page DX 229, he says "While the 2 final dose interval for the fourth arm of 3 this study are a bit unsettled, we could 4 use 2Q8 for now as most likely dose 5 interval." 6 Do you see that? 7 A. I do see that. 8 Q. Right. Nowhere in this April 9 10th, 2007 e-mail to Darlene Jody is 10 George Yancopoulos advocating for the 11 dosing regimen that Bob Terifay 12 identified as an aflibercept dose of 2 13 milligrams dosed every four weeks three 14 times, followed by a dosing every 15 eight-week regimen, true? 16 MS. OBERWETTER: Object to the 17 form and foundation with this witness, 18 A 30(b)(6) objection. 19 A. I can't speak to George's 20 intent. 21 Q. It's not a question of intent. 22 It's a question of what's written here in 23 the e-mail. 24 MS. OBERWETTER: Object to the 25 form. Foundation with this witness.	Page 297 1 Yancopoulos, Len Schleifer, Peter 2 Powchik, Avner Ingerman and Neil Stahl, 3 "Subject: U.S. Commercial Concerns 4 Regarding the Bayer Compromise." 5 Let me know when you are there. 6 A. I see the e-mail beginning on 7 page -- the second page of this e-mail, 8 the last three numbers are 333 from 9 Robert Terifay, dated 17th of April 2007 10 to George Yancopoulos with others copied. 11 Q. Okay. And what was 12 Mr. Terifay's position at this time? 13 A. I don't recall Mr. Terifay's 14 position at this time. 15 Q. Okay. Do you know why -- do 16 you have an understanding as to why he 17 was involved in these discussions of 18 trying to figure out what would be the 19 best dose, best doses to include in the 20 Phase III clinical studies? 21 MS. OBERWETTER: Object to the 22 form. Foundation. I will repeat the 23 30(b)(6) objection that we ask 24 repeatedly for information about what 25 you wanted to ask this witness, within

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Page 298 1 the scope of incredibly broad topics. 2 We were not given that information. 3 MS. MAZZOCHI: Now you're doing 4 a speaking objection. 5 MS. OBERWETTER: This is for 6 you, not for the witness. 7 And to the contrary, your 8 colleague Ms. Lesko says we don't have 9 to give you a roadmap. 10 So you're asking this witness 11 about another document that she is not 12 on. It's outside the scope of any 13 topic described with reasonable 14 particularity. 15 MS. MAZZOCHI: We disagree. We 16 think it relates to this question of 17 Regeneron's basis in connection with 18 conception of the dosing regimen or 19 lack thereof. 20 Q. Do you have an understanding as 21 to why Robert Terifay would have been 22 involved in these discussions over 23 selecting the Phase III clinical trial 24 regimen? 25 MS. OBERWETTER: Object to the	Page 300 1 MS. OBERWETTER: Object to the 2 form. Foundation. A 30(b)(6) 3 objection. 4 A. I don't recall what specific 5 FDA discussion that would be referring 6 to. 7 Q. Do you recall whether the FDA 8 had expressed a concern about allowing 9 Regeneron to do a 2 milligram every 10 eight-week dosing without going through 11 some type of special proposal 12 consideration -- 13 MS. OBERWETTER: Are you asking 14 -- 15 Q. -- I'm sorry, special protocol 16 review? 17 MS. OBERWETTER: Are you asking 18 her or is that a 30(b)(6) -- 19 MS. MAZZOCHI: Yes. 20 MS. OBERWETTER: Not as a 21 30(b)(6), you're asking her? 22 MS. MAZZOCHI: Both. 23 MS. OBERWETTER: Okay, 24 objection, form, foundation. A 25 30(b)(6) objection.
Page 299 1 form. Foundation of the question. A 2 30(b)(6) objection. 3 A. Bob Terifay was the head of our 4 commercial group at that time. And as 5 such he would have had input on the 6 clinical development program as it 7 related to commercial viability and 8 commercial considerations. 9 Q. Okay. If you look in the 10 second paragraph he says, "Until the 11 recent FDA discussion, the labeled claims 12 in the U.S. were anticipated to be the 13 same." 14 Do you see that? 15 MS. OBERWETTER: Object to the 16 form. Foundation. A 30(b)(6) 17 objection. 18 A. I see that sentence in the 19 e-mail that states "Until the recent FDA 20 discussion, the label claims in the U.S. 21 were anticipated to be the same." 22 Q. Now, when it says, when it's 23 referring to the recent FDA discussion, 24 do you know what's being referred to 25 there?	Page 301 1 A. I do not recall any specific 2 concerns the FDA had regarding our 3 proposed study designs. 4 Q. Do you remember whether the FDA 5 was asked or anyone at the FDA was asked 6 through letter communications, if they 7 would be amenable to Regeneron including 8 the two week -- I'm sorry, the 9 2-milligram eight-week dosing regimen 10 without a further protocol amendment or 11 special protocol review? 12 MS. OBERWETTER: Object to the 13 form. Foundation. A 30(b)(6) 14 objection. 15 A. Sorry, could you ask the 16 question one more time, I think I lost 17 it? 18 MS. MAZZOCHI: I will ask the 19 court reporter to read it back. 20 [The requested portion of the 21 record was read back as follows: 22 "Question: Do you remember 23 whether the FDA was asked or anyone at 24 the FDA was asked through letter 25 communications, if they would be

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Page 302 1 amenable to Regeneron including the 2 two week -- I'm sorry, the 2-milligram 3 eight-week dosing regimen without a 4 further protocol amendment or special 5 protocol review?" 6 MS. OBERWETTER: Same 7 objections. 8 A. So, sorry, I am having trouble 9 answering your question, only because the 10 process by which we would solicit 11 feedback from the FDA would be, 12 typically, through formal meetings with 13 the FDA, through which an end of Phase II 14 meeting would be one of those 15 interactions. And that would have been 16 the opportunity for us to get feedback on 17 potentially the proposed Phase III study 18 designs. 19 Q. Do you recall ever receiving 20 any e-mail correspondence with the FDA 21 where they discussed whether they were, 22 in response to questions from Regeneron, 23 whether they were amenable to permitting 24 your 2 milligram every eight-week dose 25 proposal without an independent protocol	Page 304 1 would have been primarily Laura Pologe 2 and Bill Roberts, at this time. 3 MS. OBERWETTER: Ms. Mazzochi, 4 whenever you are at a good point. We 5 have been going another hour, so if we 6 can take a break, you know. 7 Q. If you can take a look at Peter 8 Powchik's e-mail in DX 230, that was sent 9 to Len Schleifer, Robert Terifay and 10 George Yancopoulos, cc'ing Avner 11 Ingerman, Neil Stahl and Laura Pologe. 12 He's talking about trying to diffuse some 13 of the concerns, right? 14 MS. OBERWETTER: Objection to 15 form. Foundation. A 30(b)(6) 16 objection. And continued objection to 17 asking this witness about a document 18 she's never seen before. 19 A. I'll need a minute just to 20 review this e-mail. 21 So I see as part of Exhibit 230 22 an e-mail, it's the second in the string, 23 from Peter Powchik, dated April 17th, 24 2007, to Len Schleifer, Bob Terifay, 25 George Yancopoulos, with others copied.
Page 303 1 review -- 2 MS. OBERWETTER: Object to the 3 form. 4 Q. -- or a special protocol 5 assessment? 6 MS. OBERWETTER: Object to the 7 form. Foundation. A 30(b)(6) 8 objection. 9 A. I did not receive any e-mails 10 from the FDA requesting that. 11 Q. Who was responsible on your 12 team for corresponding with the FDA? 13 MS. OBERWETTER: I assume we're 14 still doing 30(b)(6) topics? 15 Q. In the context of the 16 generation of the Phase III clinical 17 studies? 18 MS. OBERWETTER: Are you still 19 asking 30(b)(6) questions? 20 MS. MAZZOCHI: Yes. 21 MS. OBERWETTER: Object to the 22 form. Foundation. A 30(b)(6) 23 objection. 24 A. Interactions with the FDA were 25 led by our regulatory department. That	Page 305 1 Q. All right. Now, do you recall 2 there being discussions about concerns 3 over the 2Q8 dosing for aflibercept -- 4 MS. OBERWETTER: Object to the 5 form. Foundation. 6 Q. -- when it came to the Phase 7 III clinical studies? 8 MS. OBERWETTER: Object to the 9 form foundation. A 30(b)(6) 10 objection. 11 A. I recall there being many 12 discussions regarding the dosing regimens 13 and doses for the Phase III studies. 14 Q. Right. Do you remember people 15 being concerned about them or whether to 16 include the monthly loading dose versus 17 not? 18 MS. OBERWETTER: Object to the 19 form. Foundation. A 30(b)(6) 20 objection. 21 A. I recall discussions about the 22 interpretation of data from the Phase II 23 study. And how that translated into what 24 we felt were the optimal dosing regimens 25 to test in the Phase III studies, that

Page 306 1 would result in the best outcomes for 2 patients. 3 Q. Again, if we look at DX 230, 4 the top e-mail, dated Wednesday, April 5 8th, 2007 from Robert Terifay, to Peter 6 Powchik, Len Schleifer and George 7 Yancopoulos, Avner Ingerman, Neil Stahl 8 and Laura Pologe, the second paragraph, 9 he says "From an 0508 perspective, it 10 appears that 2Q8 (especially if initiated 11 as a 2Q4 loading dose for the first three 12 months) can offer similar improvement in 13 visual acuity and maintain that level 14 similarly to 2Q4 and Lucentis Q4. This 15 would be a major win for VT," referring 16 to aflibercept, "versus Ran," referring 17 to ranibizumab "in Phase III," right? 18 MS. OBERWETTER: Object to the 19 form. Foundation. A 30(b)(6) 20 objection. 21 A. I see the e-mail dated 22 Wednesday, April 18th, 2007 from Bob 23 Terifay to Peter Powchik and others with 24 the first bullet stating that "From an 25 0508 perspective, it appears that 2Q8	Page 308 1 right? 2 MS. OBERWETTER: Object to the 3 form and foundation of that question. 4 A 30(b)(6) objection. 5 A. In this particular e-mail, in 6 the first bullet, I see that he is 7 stating that 2Q8, if initiated as the 2Q4 8 loading dose for the first three months, 9 is a potential regimen that would offer 10 similar improvement in visual acuity to 11 2Q4 and Lucentis Q4. 12 Q. Right. And that dosing regimen 13 of a 2Q4 loading dose for the first three 14 months followed by 2Q8 dosing, that's a 15 dosing regimen we see in the '601 patent 16 claims, right? 17 MS. OBERWETTER: Object to the 18 form and foundation, to the extent 19 you're still asking this witness to 20 interpret an e-mail that she's never 21 seen before. A 30(b)(6) objection. 22 Q. '601 patent, in Claim 1? 23 A. So in patent '601, Claim 1, 24 it's stated that "A method for treating 25 age-related macular degeneration in a
Page 307 1 (especially if initiated as a 2Q4 loading 2 dose for the first three months) can 3 offer similar improvement in visual 4 acuity and maintain that level similarly 5 to 2Q4 and Lucentis Q4." 6 Q. And again, the 05 -- when he's 7 talking about an 0508 perspective, he's 8 referring to the Phase II clinical study 9 with aflibercept, right? 10 MS. OBERWETTER: Object to the 11 form. Object to the form. 12 Foundation. A 30(b)(6) objection. 13 And you're continuing to ask the 14 witness about a document she has 15 testified she has not seen before. 16 A. The 0508 study was the Phase II 17 study with intravitreal aflibercept in 18 neovascular AMD. 19 Q. And again, it's Robert Terifay, 20 at least as of April 18th, 2007, who is 21 urging, initiating the Phase III clinical 22 dosing arm of 2 milligrams as a loading 23 dose, where it's dosed monthly for the 24 first three months, then followed by a 2 25 milligram dose every eight-weeks regimen,	Page 309 1 patient in either comprising intravitally 2 administering an effective amount of 3 aflibercept, which is 2 milligrams 4 approximately every four weeks for the 5 first three months, followed by 2 6 milligrams approximately once every eight 7 weeks or once every two months." 8 Q. Right. And that dosing regimen 9 matches the one that Robert Terifay is 10 advocating for in DX 230, his April 8th, 11 2007 e-mail of 2Q8 initiated as a 2Q4 12 loading dose for the first three months, 13 right? 14 MS. OBERWETTER: Object to the 15 form. Foundation. Characterization 16 of the document. A 30(b)(6) 17 objection. 18 A. My interpretation of the e-mail 19 from Bob Terifay is that he is describing 20 the same dosing regimen. 21 Q. Okay. You can go ahead and set 22 that one aside. 23 MS. OBERWETTER: Let's take our 24 break at this point. 25 MS. MAZZOCHI: Sure.

Page 310 1 THE VIDEOGRAPHER: We are going 2 off the record at 5:29 p.m. 3 (Off the record.) 4 THE VIDEOGRAPHER: We are back 5 on the record at 5:36 p.m. 6 MS. MAZZOCHI: Thank you. I 7 would like to mark as Defendant's 8 Exhibit 231, a document with 9 production numbers RGN-EYLEA-MYLAN 10 528309 through 316. 11 (Defendant's Exhibit 231, 12 Document Bates stamped RGN-EYLEA-MYLAN 13 528309 through 316, was so marked for 14 identification, as of this date.) 15 BY MS. MAZZOCHI: 16 Q. Ms. Chu, can you confirm that 17 this document DX 231 is an e-mail to you 18 and others from Avner Ingerman, dated 19 Thursday, August 2nd, 2007? 20 A. So I have Exhibit 231, which is 21 an e-mail dated August 2nd, 2007. The 22 subject is "E-Mailing: NCT00509795.HTM" 23 from Avner Ingerman, and I am copied on 24 this e-mail. 25 Q. Okay. And in the text of this	Page 312 1 A. I can't say whether or not this 2 was released publicly based on the date 3 of the e-mail. 4 Q. The information that's 5 published in clinicaltrials.gov is 6 released publicly, right? 7 MS. OBERWETTER: Object to the 8 form. 9 A. It is correct that postings in 10 clinicaltrials.gov are released publicly. 11 However, there is a period of time upon 12 which we submitted the posting, but it 13 has not yet gone live. So I don't know 14 specifically on this date if this posting 15 was available publicly. 16 Q. And what's your experience in 17 terms of how long it takes between the 18 day of posting to when it goes live -- 19 MS. OBERWETTER: Object to the 20 form. 21 Q. -- on clinicaltrials.gov? 22 MS. OBERWETTER: Object to the 23 form. Are you still asking about 24 30(b)(6) questions? 25 MS. MAZZOCHI: I am asking her
Page 311 1 e-mail, is he providing the information 2 that was published at clinicaltrials.gov 3 in connection with clinicaltrials.gov 4 identifier NCT00509795? 5 A. So my review of this e-mail 6 this minute indicates that this is 7 Dr. Ingerman forwarding the 8 clinicaltrials.gov posting of the VIEW 1 9 Phase III study. 10 Q. Okay. And if you can take a 11 look at the second page of the e-mail, 12 can you confirm that one of the inclusion 13 criteria listed in the fourth bullet 14 point was "ETDRS best corrected visual 15 acuity of 20/40 to 20/320 (letter score 16 of 73 to 25) in the study eye"? 17 A. Yes, the fourth bullet under 18 key inclusion criteria is "ETDRS best 19 corrected visual acuity of 20/40 to 20 20/320 (letter score of 73 to 25) in the 21 study eye." 22 Q. And that was released publicly 23 as of this date? 24 MS. OBERWETTER: Object to the 25 form and foundation.	Page 313 1 experience. 2 MS. OBERWETTER: Not as a 3 30(b)(6) witness? 4 MS. MAZZOCHI: I am asking in 5 her experience. 6 MS. OBERWETTER: So you made 7 clear earlier you wanted to have a 8 clear record about what was 30(b)(6) 9 and what wasn't. 10 MS. MAZZOCHI: If I was asking 11 in Regeneron's experience, I would ask 12 in Regeneron's experience. I am 13 asking in her experience. 14 MS. OBERWETTER: You've also 15 been inconsistent today in switching 16 back and forth. You've been doing 17 periods -- 18 MS. MAZZOCHI: Ellen, you're 19 wasting my time, in her experience. 20 MS. OBERWETTER: So it's not a 21 30(b)(6) question, you can answer the 22 question. 23 A. In my experience, it's a 24 relatively short period of time. Less 25 than a month. But I don't recall

Page 314 1 specifically for this posting or other 2 postings what that time period was. 3 Q. Okay. And can you also confirm 4 that Regeneron released for public 5 consumption on clinicaltrials.gov that 6 the key exclusion criteria for the Phase 7 III AMD clinical trial, including any 8 prior ocular in the study eye for 9 systemic treatment or surgery for 10 neovascular AMD except dietary 11 supplements or vitamins? 12 MS. OBERWETTER: Object to the 13 form. A 30(b)(6) objection. 14 A. So in this posting that's part 15 of this e-mail, the first listed 16 exclusion, key exclusion criteria, is any 17 prior ocular in the study eye or systemic 18 treatment or surgery for neovascular AMD 19 except dietary supplements or vitamins. 20 Q. Okay. And likewise, Regeneron 21 published in around this time at 22 clinicaltrials.gov, exclusion criteria 23 for its Phase III clinical study that 24 included any prior or concomitant therapy 25 with another investigational agent to	Page 316 1 tears or rips involving the macula or the 2 study eye." 3 Q. And then furthermore, there 4 were, it was publicly noted in 5 clinicaltrials.gov in the 2007 time 6 period that there were, I think, over 200 7 different study sites that were 8 participating in this Phase III clinical 9 trial, right? 10 MS. OBERWETTER: Object to the 11 form. A 30(b)(6) objection. 12 A. Are you referring to this 13 posting that is a part of Exhibit 231? 14 Q. Yes. 15 A. So I just would like to state 16 again, I am not certain that this was the 17 version that was publicly available on 18 this specific date. 19 Do you want me to count the 20 number of study sites listed to confirm 21 it's the number you stated? 22 Q. To your prior point, can you 23 take a look at the last page of 24 Defendant's Exhibit 231? 25 Can you confirm above the last
Page 315 1 treat neovascular AMD in the study eye 2 except for dietary supplements or 3 vitamins? 4 MS. OBERWETTER: Object to the 5 form. A 30(b)(6) objection. 6 A. The second key exclusion 7 criteria listed in this posting that's 8 part of this e-mail is any prior or 9 concomitant therapy with another 10 investigational agent to treat 11 neovascular AMD in the study eye except 12 for dietary supplements or vitamins. 13 Q. And likewise, one of the 14 exclusion criteria that was listed 15 publicly by Regeneron on 16 clinicaltrials.gov included the presence 17 of retinal pigment, epithelial tears or 18 rips involving the macula in the study 19 eye? 20 MS. OBERWETTER: Object to the 21 form. A 30(b)(6) objection. 22 A. So in this posting that's part 23 of this e-mail, I see there is a bullet 24 under "Key Exclusion Criteria" that reads 25 "Presence of retinal pigment, epithelial	Page 317 1 three lines it says "clinicaltrials.gov 2 processed this record on August 1st, 3 2007"? 4 A. I do see where it says, 5 "clinicaltrials.gov processed this record 6 on August 1st, 2007." 7 Q. So after it was processed, it 8 would become public record, right? 9 MS. OBERWETTER: Objection to 10 form and foundation. A 30(b)(6) 11 objection. 12 A. I do not know for sure if that 13 indicates that that would be the date it 14 would be made public. 15 Q. Do you have any reason to 16 believe it was not public as of that 17 date, or does Regeneron have any reason 18 to believe that the text that 19 Mr. Ingerman copied and then sent to 20 everybody was not actually retrieved from 21 what was publicly available on the 22 clinicaltrials.gov website as of August 23 1st to 2nd, 2007? 24 MS. OBERWETTER: Object to the 25 form. Foundation. A 30(b)(6)

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Page 318 1 objection. Not a topic anybody raised 2 with us. 3 A. Sorry, can you state the 4 question one more time? 5 Q. Yes. Does Regeneron have any 6 basis to believe that this information 7 that Mr. Ingerman forwarded to you was 8 not public after its processing date on 9 August 1st, 2007? 10 MS. OBERWETTER: Same 11 objections. 12 A. Speaking for myself, it is 13 reasonable that this posting would be 14 made public in this time frame. But I 15 can't say for sure exactly what date that 16 was. 17 Q. And under the inclusion 18 criteria, the signed informed consent, 19 were patients obligated to keep secret 20 their participation in Regeneron's 21 clinical trials? 22 MS. OBERWETTER: Object to the 23 form. A 30(b)(6) objection. 24 A. No. Patients were not 25 obligated in any way to keep their	Page 320 1 A. This appears to be a poster and 2 I am listed as an author. 3 Q. Do you know when this poster 4 presentation was given? 5 MS. OBERWETTER: Object to the 6 form. A 30(b)(6) objection. 7 A. I do not recall exactly when 8 this poster was presented. 9 Q. Do you recall if it was before 10 2010? 11 MS. OBERWETTER: Object to the 12 form. A 30(b)(6) objection. 13 A. I do not recall when this 14 poster was presented. 15 Q. Do you recall who was presented 16 the poster or at what conference it was 17 presented? 18 MS. OBERWETTER: Objection to 19 form. A 30(b)(6) objection. 20 A. It's customary that the first 21 author would present a poster. So 22 Dr. Matthew Benz, who is listed as the 23 first author, would have been the likely 24 person to present this poster, but I do 25 not recall the precise meeting where this
Page 319 1 participation in the study a secret. 2 MS. MAZZOCHI: Okay. You can go 3 ahead and put that one aside. 4 I would like to mark as 5 Defendant'S Exhibit 232, a document 6 with production number RGN-EYLEA-MYLAN 7 526744. It is titled "CLEAR-IT 2: 8 Interim Results of the Phase II, 9 Randomized, Controlled Dose-and 10 Interval-Ranging Study of Repeated 11 Intravitreal VEGF-Trap Administration 12 in Patients With Neovascular 13 Age-Related Macular Degeneration 14 (AMD)." 15 (Defendant's Exhibit 232, 16 Document Bates stamped RGN-EYLEA-MYLAN 17 526744, was so marked for 18 identification, as of this date.) 19 Q. Do you have that document? 20 A. Not yet. 21 Q. Do you have it now? 22 A. I have Exhibit 232 in front of 23 me. 24 Q. And are identified as a 25 co-author on this presentation?	Page 321 1 was presented. 2 Q. Do you have a resume or CV 3 listing all of your publications and 4 poster presentations such as this? 5 A. I do have a CV that lists 6 publications upon which, where I am an 7 author. But not listing all poster 8 presentations or abstracts upon which I 9 am an author. 10 Q. Okay. 11 MS. MAZZOCHI: We will request a 12 copy of that be provided, since she 13 can't remember dates or locations of 14 when some of her presentations were 15 provided. 16 (Production requested) 17 Q. Again, do you recall getting 18 any feedback from anybody about Matthew 19 Benz's presentation on the CLEAR-IT 2 20 results of the Phase II data? 21 MS. OBERWETTER: Object to the 22 form and -- form, foundation, 23 characterization of the prior 24 testimony. A 30(b)(6) objection. 25 A. I don't recall feedback

Page 322 1 specific to Matthew Benz's presentation 2 of this poster of the CLEAR-IT 2 interim 3 results. 4 Q. Okay. Now, when Matthew Benz 5 presented this poster, did he do it to a 6 group of other scientists? 7 MS. OBERWETTER: Objection to 8 form. Foundation. A 30(b)(6) 9 objection. 10 I would also renew my offer that 11 if you would like a running 30(b)(6) 12 objection rather than me saying it 13 every time, I am happy to do that. 14 Q. You can answer, Ms. Chu. 15 A. Sorry, what was the question 16 again? 17 MS. MAZZOCHI: I'll ask the 18 court reporter to read back the 19 question, so we don't have to hear the 20 objections again. 21 [The requested portion of the 22 record was read back as follows: 23 "Question: Now, when Matthew 24 Benz presented this poster, did he do 25 it to a group of other scientists?"]	Page 324 1 form. Foundation. A 30(b)(6) 2 objection. 3 A. I was not involved in any 4 investor relations or efforts to partner 5 any Regeneron products during my career 6 at Regeneron. 7 Q. Okay. Did Bayer become 8 involved with Regeneron before or after 9 your CLEAR-IT 2 studies were published, 10 Regeneron's CLEAR-IT 2 studies were 11 published? 12 MS. OBERWETTER: Objection to 13 form. Foundation. A 30(b)(6) 14 objection. 15 A. I would have to see the date of 16 the executed Bayer collaboration 17 agreement as well as the publication from 18 the CLEAR-IT 2 study to answer your 19 question. 20 Q. Do you recall who funded the 21 CLEAR-IT 2 study? 22 MS. OBERWETTER: Object to form. 23 Foundation. A 30(b)(6) objection. 24 A. My recollection is that the 25 CLEAR-IT 2 study was funded by Regeneron.
Page 323 1 A. So a poster like this would 2 have been presented at a Scientific 3 Congress. 4 Q. And why did Regeneron want to 5 present its data involving aflibercept 6 and its clinical trial data at these 7 scientific conferences? 8 MS. OBERWETTER: Object to the 9 form. Foundation. A 30(b)(6) 10 objection. 11 A. So it's scientific practice 12 that we share our results in the context 13 of Scientific Congresses and 14 publications. And thus this was part of 15 this scientific exchange that we were 16 contributing to. 17 Q. Was Regeneron trying to get 18 investors interested in or partners 19 interested in investing in Regeneron and 20 its clinical trial activities -- 21 MS. OBERWETTER: Object to the 22 form. 23 Q. -- in the 2007 to 2010 time 24 period? 25 MS. OBERWETTER: Object to the	Page 325 1 MS. MAZZOCHI: I would like to 2 mark as DX 233, a document with 3 production numbers RGN-EYLEA-MYLAN 4 526815 through 838. 5 (Defendant's Exhibit 233, 6 Document Bates stamped RGN-EYLEA-MYLAN 7 526815 through 838, was so marked for 8 identification, as of this date.) 9 Q. Is this the slide presentation 10 that Matthew Benz presented to go along 11 with your poster presentation for the 12 CLEAR-IT 2 trial? 13 MS. OBERWETTER: Object to the 14 form. Foundation. A 30(b)(6) 15 objection. 16 A. So I see that Exhibit 233 is a 17 copy of a slide presentation of the 18 "CLEAR-IT 2: Interim results of the 19 Phase II, randomized, controlled dose-and 20 interval-ranging study of repeated 21 intravitreal VEGF-Trap administration in 22 patients with neovascular AMD." 23 From my experience, the poster 24 would have been presented without an 25 accompanying presentation. So typically,

Page 326 1 the format of poster presentations is 2 that this, in Exhibit 232, that this 3 would have been printed on a much, much 4 larger scale and hung on a board. And 5 the first author would have been 6 available during a certain period of time 7 to answer questions from other scientists 8 at the meeting regarding the specific 9 poster. 10 MS. MAZZOCHI: Go ahead and set 11 that one aside. 12 I would like to mark as 13 Defendant's Exhibit 234, a document 14 with production number RGN-EYLEA-MYLAN 15 526745. 16 Q. Can you identify what this 17 document is? 18 MS. OBERWETTER: We don't have 19 it yet. 20 MS. MAZZOCHI: Sorry. 21 MR. MARX: The document that I 22 have starts 526743. 23 MS. MAZZOCHI: Oh, that's fine. 24 (Defendant's Exhibit 234, 25 Document Bates stamped RGN-EYLEA-MYLAN	Page 328 1 form. Foundation. A 30(b)(6) 2 objection. 3 A. So the first poster on page 4 ending in 744 is "CLEAR-IT 2: Interim 5 results of the Phase II, randomized, 6 controlled dose-and interval-ranging 7 study of repeated intravitreal VEGF-Trap 8 administration in patients with 9 neovascular age-related macular 10 degeneration." 11 Q. And what's the second one on 12 page 745? 13 MS. OBERWETTER: Object to the 14 form. Foundation. A 30(b)(6) 15 objection. 16 A. The second poster included in 17 this printout is "An exploratory study of 18 the safety, tolerability and biological 19 effect of a single intravitreal 20 administration of VEGF-Trap in patients 21 with diabetic macular edema." 22 Q. Okay. And having seen these 23 attachments to the covering e-mail, does 24 that help to refresh your recollection as 25 to where these poster presentations were
Page 327 1 526743, was so marked for 2 identification, as of this date.) 3 Q. Can you tell me what this 4 document is? 5 MS. OBERWETTER: Object to the 6 form. Foundation. This is not a 7 document that was on a list of topics. 8 A 30(b)(6) objection. 9 A. So this is Exhibit 234, which 10 is an e-mail dated Monday, I'm sorry, May 11 7th, 2007, with the "Subject: ARVO," 12 from Charles Pool to George Yancopoulos. 13 Q. And are any poster or slide 14 presentations where you're listed as an 15 author attached to that e-mail? 16 MS. OBERWETTER: Object to the 17 form. Foundation. A 30(b)(6) 18 objection. 19 A. So I am not included on the 20 e-mail, but from this printout, I see 21 that there are two poster presentations 22 included where I am a coauthor on both. 23 Q. And what's the title of the 24 first presentation you see? 25 MS. OBERWETTER: Object to the	Page 329 1 given? 2 MS. OBERWETTER: Object to the 3 form. Foundation. A 30(b)(6) 4 objection. 5 A. Based on the date and subject 6 of the e-mail, it's logical that the 7 presentations were intended for 8 presentations at the ARVO meeting. 9 Q. In what year? 10 MS. OBERWETTER: Object to the 11 form. Foundation. A 30(b)(6) 12 objection. 13 A. The date of e-mail is May 7th, 14 2007. 15 MS. MAZZOCHI: Let's take a 16 quick five-minute break. 17 THE VIDEOGRAPHER: We are going 18 off the record at 6 p.m. 19 (Off the record.) 20 THE VIDEOGRAPHER: Back on the 21 record at 6:06 p.m. 22 BY MS. MAZZOCHI: 23 Q. Ms. Chu, in connection with 24 your '879 patent that we looked at 25 earlier, DX 19, do you recall ever doing

Page 330 1 a search of your files to disclose 2 information to the PTO in connection with 3 that patent application? 4 MS. OBERWETTER: Object to the 5 form. 6 A. You're going to have to give me 7 a minute to find it. Okay. 8 Can you just restate your 9 question. 10 Q. Yeah. Do you recall ever doing 11 a search of your files to identify 12 material information in connection with 13 the filing of your '879 patent 14 application? 15 MS. OBERWETTER: Object to the 16 form. 17 A. I do not recall doing a search 18 of my files in relation to the '879 19 patent. 20 Q. Do you know what, if anything, 21 you did to comply with your duty to 22 disclose to the PTO in connection with 23 the '879 patent? 24 MS. OBERWETTER: Object to the 25 form. Foundation. To the extent any	Page 332 1 anything, or presented at scientific 2 meetings or anything you along those 3 lines? 4 A. I do not recall performing any 5 search for prior publications 6 specifically in relation to the '879 7 patent. 8 Q. Okay. Do you have an 9 understanding as to how much money 10 Regeneron and Bayer actually spent in 11 connection, and Sanofi, for that matter, 12 actually spent in connection with U.S. 13 clinical trials involving aflibercept? 14 MS. OBERWETTER: Object to the 15 form. Foundation. A 30(b)(6) 16 objection. 17 A. I do not have knowledge of the 18 amount, the total amount spent by Sanofi, 19 Bayer and Regeneron on clinical trials 20 with VEGF-Trap. 21 Q. Okay. Do you know whether in 22 the aggregate the amount of money that 23 Regeneron has spent on clinical trials 24 has exceeded 100 million dollars? 25 MS. OBERWETTER: Object to the
Page 331 1 answer would entail discussions with 2 counsel, I instruct you not to answer 3 to that extent. 4 Q. You can answer. 5 A. So we provided data to our 6 internal patent attorneys as content for 7 this application. And I participated in 8 the review of the sections pertaining to 9 clinical data. 10 Q. Okay. But you didn't actually 11 go through to see whether any of this 12 clinical data had been published 13 previously, for example, such as in 14 poster presentations or discussed at any 15 scientific meetings? 16 MS. OBERWETTER: Object to the 17 form and foundation. 18 A. Sorry, could you just restate 19 your question? 20 Q. Yeah. As part of this process 21 of applying for and receiving your '879 22 patent application, you never went back 23 to see whether any of your clinical data 24 had ever been previously published in, 25 for example, any poster presentations or	Page 333 1 form. Foundation. A 30(b)(6) 2 objection. 3 A. Based on my knowledge of the 4 clinical trial budgets, the amount would 5 have exceeded 100 million dollars. 6 Q. Do you know if it exceeded 500 7 million dollars? 8 MS. OBERWETTER: Object to the 9 form. Foundation. A 30(b)(6) 10 objection. 11 A. I don't have a specific 12 knowledge of the total amount. 13 Q. Okay. And in connection with 14 providing your testimony today, are you 15 being compensated anything above and 16 beyond your current salary at Regeneron? 17 A. I am not being compensated 18 above my salary at Regeneron for any of 19 my participation in today's activities. 20 Q. Okay. And is it your present 21 intention that you're going to continue 22 to be employed by Regeneron for the 23 foreseeable future? 24 A. It is my present intention to 25 continue to be employed by Regeneron for

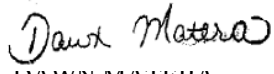
Page 334 1 the foreseeable future. 2 Q. All right. If you are no 3 longer employed by Regeneron at the time 4 it comes to trial, would you be willing 5 to appear at trial in this case? 6 MS. OBERWETTER: Object to the 7 form. Calls for speculation. There 8 is no possible way to answer that 9 today. 10 MS. MAZZOCHI: You can answer. 11 A. My intention is to be employed 12 by Regeneron for the foreseeable future. 13 Q. Sure. And my question is 14 whether you're employed by Regeneron or 15 not, are you willing to appear at trial 16 in this matter if you are asked to do so? 17 MS. OBERWETTER: Object the 18 form. I do not know how a witness can 19 answer such a speculative question. 20 A. Based on the information I have 21 today, I would say yes. But I can't 22 speak to what the future might hold. 23 MS. MAZZOCHI: Well, my 24 understanding is that we are at the 25 end of our permitted time for today.	Page 336 1 like you're done. There have been, 2 obviously, you have a lengthy letter, 3 we both know what it is, that sets 4 forth our position on the 30(b)(6) 5 topics and their appropriateness or 6 lack thereof. 7 On top of which it sound like 8 you came into the deposition knowing 9 there were some documents you wanted, 10 without having told us in advance that 11 you would want to have access to them. 12 So we will take today's requests 13 under advisement. If you are 14 completed, we are going to go off the 15 record and discuss whether we have 16 redirect. We will go off the record. 17 THE VIDEOGRAPHER: We are -- 18 MS. MAZZOCHI: We can go off the 19 record, that's fine. 20 THE VIDEOGRAPHER: We are going 21 off the record at 6:13 p.m. 22 (Off the record.) 23 THE VIDEOGRAPHER: Back on the 24 record at 6:19 p.m. 25 EXAMINATION BY
Page 335 1 I am just going to note for the record 2 that we have, well, counsel for 3 Regeneron has issued a whole host of 4 objections today. We, too have a 5 whole host of objections based, in 6 part, on Regeneron's own disclosures 7 and ways in which we believe that 8 Regeneron has frustrated our ability 9 to actually get at information in a 10 competent manner in this case. 11 So I understand, Ms. Oberwetter, 12 that you're going to disagree, but 13 when a witness can't even testify as 14 to certain issues that you 15 specifically designated her on, we 16 have a problem with that. So I want 17 to be clear that we're not waiving any 18 of our objections and furthermore, we 19 reserve the right to reopen this 20 deposition in the event that new 21 information or new documents are 22 produced in connection with Ms. Chu. 23 MS. OBERWETTER: So just to be 24 clear, I have not cut off the 25 deposition for the day. It sounds	Page 337 1 MS. OBERWETTER: 2 Q. Ms. Chu, good afternoon. For 3 the record, this is Ellen Oberwetter from 4 Williams and Connolly. 5 I am going to direct you to, on 6 behalf of Regeneron, I am going to direct 7 you just to couple of documents that Ms. 8 Mazzochi covered with you earlier. 9 Could you try to find in your 10 stack what they labeled as Defense 11 Exhibit 232. 12 A. Okay. I have Exhibit 232. 13 Q. Ms. Mazzochi, had some 14 questions for you about Defense Exhibit 15 232. 16 Do you know if this is a draft 17 or a final document? 18 A. I don't know if Exhibit 232 is 19 a draft or final. 20 Q. Okay. You can put that 21 document aside. 22 If you could take out Defense 23 Exhibit 233, which was a Power Point 24 document that Ms. Mazzochi put in front 25 of you, and just let me know when you

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Page 338 1 have that Power Point? 2 A. I have Exhibit 233 in front of 3 me. 4 Q. Okay. Do you know if Exhibit 5 233 was a draft or final document? 6 A. I do not know if this was a 7 draft or a final document. 8 Q. Okay. Do you know the 9 circumstances of any presentation of this 10 document? 11 MS. MAZZOCHI: Object to form. 12 A. I don't know the exact 13 circumstances of the presentation of this 14 document. 15 Q. Okay. You can put that 16 document aside. 17 If you can find in your stack 18 Defense Exhibit 234. 19 A. I have 234. 20 Q. This is another document that 21 Ms. Mazzochi asked you about. There is a 22 cover e-mail, you are not one of the 23 recipients on this e-mail, correct? 24 A. I am not one of the recipients 25 of this e-mail.	Page 340 1 as "Draft 7." 2 MS. OBERWETTER: Thank you. You 3 can put that document aside. Nothing 4 further. 5 MS. MAZZOCHI: Just a couple of 6 re-cross questions. 7 EXAMINATION (Continued) 8 BY MS. MAZZOCHI: 9 Q. On Defendant's Exhibit 234, do 10 you have a habit of letting people put 11 your name on documents or scientific 12 presentations that you don't review and 13 approve? 14 MS. OBERWETTER: Object to the 15 form and foundation. 16 You can answer. 17 A. No, if I am an author, I 18 definitely would have reviewed and 19 provided input into the content of the 20 document. 21 Q. All right. And you would have 22 made sure that any statements, at least 23 to the extent that they were within your 24 area of operation, were truthful and 25 accurate, right?
Page 339 1 Q. And you are not the sender of 2 this e-mail, correct? 3 A. I am not the sender of this 4 e-mail. 5 Q. Ms. Mazzochi, directed you to 6 the attachments to this document. Do you 7 know if the attachments to this document 8 are drafts or final versions of what they 9 purport to be? 10 MS. MAZZOCHI: Object to form. 11 A. I do not know if the two poster 12 presentations, the first one titled, 13 "CLEAR-IT 2: Interim Results of the 14 Phase II, Randomized, Controlled Dose-and 15 Interval-ranging Study of Repeated 16 Intravitreal VEGF-Trap Administration in 17 Patients With Neovascular Age-Related 18 Macular Degeneration" or the poster 19 titled "An Exploratory Study of the 20 Safety, Tolerability and Biological 21 Effect of the Single Intravitreal 22 Administration of VEGF-Trap in Patients 23 with Diabetic Macular Edema" are drafts 24 or final. 25 The third attachment is labeled	Page 341 1 MS. OBERWETTER: Object to the 2 form. 3 A. Yes, part of my review would be 4 for accuracy. 5 Q. And how could the authors of 6 the e-mail in DX 234 have gotten ahold of 7 your presentations if you or your 8 co-authors wouldn't have authorized 9 release of them to those individuals? 10 MS. OBERWETTER: Object to the 11 foundation of the document. 12 A. So I was not included as a 13 recipient of this e-mail, but it was 14 routine practice for versions and drafts 15 of scientific presentations and 16 publications to be circulated internally, 17 either for information or for review. 18 Q. Okay. And would a document be 19 marked "Final," if it wasn't actually 20 final in your normal custom and practice 21 and experience at Regeneron? 22 MS. OBERWETTER: Objection to 23 form. Foundation. A 30(b)(6) 24 objection, if this is a 30(b)(6) 25 question.

Page 342 1 A. I am having -- are these 2 documents marked "Final"? I don't see 3 them marked as "Final" anywhere. 4 Q. In the cover e-mail. 5 A. Again, I don't see where it 6 states that these are final. 7 Q. But it does indicate that they 8 are going to be presented at scientific 9 conference, right? 10 MS. OBERWETTER: Object to the 11 form and foundation. 12 A. The e-mail states "George: 13 Here are the files Bayer is reviewing. 14 Would you send these to Darlene as well. 15 Thanks, CP." 16 Q. Okay. Is it possible that 17 Regeneron clinical data that was in your 18 group was released in multiple places 19 without your knowledge? 20 MS. OBERWETTER: Object to the 21 form and foundation. 22 A. Are you speaking specifically 23 to these two posters for the results that 24 they include? 25 Q. If it's easier for you, we can	Page 344 1 Q. Who at Regeneron did have that 2 authority to disclose information? 3 MS. OBERWETTER: Object to the 4 form. A 30(b)(6) objection. 5 A. I don't recall specifically one 6 person who would have made that decision. 7 Several people would have had input into 8 any decision to publicly present data. 9 Q. Okay. And when it comes to 10 these exhibits that we were looking at, 11 whether the poster presentations and 12 Power Point presentations were draft or 13 not, how did you come to work with 14 Matthew Benz and Dr. Nyugen and A. Cahn, 15 D. Nadler, and the CLEAR-IT 2 16 investigators to put these materials 17 together? 18 MS. OBERWETTER: Objection. 19 We're now outside the scope of 20 redirect. 21 MS. MAZZOCHI: I will wrap it up 22 to make it inside the scope, that's 23 why I am asking this question first. 24 A. Are you referring specifically 25 to Exhibit 233?
Page 343 1 start with those two posters. 2 A. So if I was included as an 3 author, I would have been aware at the 4 time of the intention and been involved 5 in the generation of the poster or 6 presentation for any Scientific Congress. 7 Q. But you didn't -- you weren't 8 the one who was trying to control whether 9 or not any data, clinical data, you 10 collected was disclosed publicly, right? 11 MS. OBERWETTER: Object to the 12 form and foundation. 13 A. Again, sorry, can you just 14 restate your question? 15 Q. For any of the clinical data 16 involving aflibercept that you were 17 working with, looking at, discussing, did 18 you have any control over whether that 19 data was released to the public or not? 20 MS. OBERWETTER: Object to the 21 form and foundation. 22 A. I did not alone make decisions 23 regarding the presentation or disclosure 24 publicly of data from any Regeneron 25 clinical trials.	Page 345 1 Q. Sure. We can use that as an 2 example. 3 A. So Dr. Benz and Dr. Nguyen were 4 investigators in the CLEAR-IT 2 clinical 5 trial. Myself, Abby Cahn, Doug Nadler, 6 Jesse Cedarbaum and Avner Ingerman were 7 all employees of Regeneron. The CLEAR-IT 8 2 investigators refers to the 9 investigators that participated in the 10 CLEAR-IT 2 clinical trial. 11 Q. Sure. Well, were you 12 responsible for drafting any parts of 13 this poster presentation or slide show 14 presentation? 15 MS. OBERWETTER: Objection. 16 Vague. Which document are we talking 17 about right now? 18 MS. MAZZOCHI: DX 233. 19 MS. OBERWETTER: Object to the 20 form. Foundation. 21 A. I don't recall specifically 22 drafting this slide presentation. 23 Q. Well, then why were you listed 24 as a co-author? 25 MS. OBERWETTER: Object to the

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Page 346 1 form. Foundation. 2 A. In my capacity at Regeneron, I 3 certainly would have reviewed the content 4 of this presentation as well as I was 5 involved in actually executing the 6 clinical trial for which this 7 presentation is presenting data from. 8 Q. Well, whoever prepared this 9 slide deck, how did they actually get the 10 clinical trial data from you? 11 MS. OBERWETTER: Object to the 12 form and foundation. 13 A. I don't know who specifically 14 generated this slide deck, so I can't 15 speak to how that process worked. 16 Q. Okay. And for the poster 17 presentations that counsel directed you 18 to, did you prepare those poster 19 presentations, you personally? 20 A. I did not personally prepare 21 these poster presentations. 22 Q. Okay. Then how did your data 23 and information get to the other doctors 24 or whoever did actually create the poster 25 presentation?	Page 348 1 off the record at 6:31 p.m. This 2 concludes today's testimony given by 3 Karen Chu. 4 (Time noted: 6:31 p.m.) 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25
Page 347 1 MS. OBERWETTER: Object to the 2 form and foundation. 3 A. So, again, we would have worked 4 with internal team members as well as the 5 external authors on the paper to assemble 6 the information you see in the posters 7 from sources related to the clinical 8 trials. 9 Q. And when you were assembling 10 that information, that was done with an 11 understanding that the data would become 12 public, right? 13 MS. OBERWETTER: Object to the 14 form and foundation. Calls for 15 speculation. 16 You can answer. 17 A. Sure. So in assembling data 18 for the purpose of a presentation at the 19 Scientific Congress, it was understood 20 that that data would become public. 21 MS. MAZZOCHI: Thank you. 22 Nothing further on recross. 23 MS. OBERWETTER: Nothing 24 further. 25 THE VIDEOGRAPHER: We are going	Page 349 1 CERTIFICATION 2 3 I, DAWN MATERA, a Notary Public for 4 and within the State of New York, do hereby 5 certify: 6 That the witness whose testimony as 7 herein set forth, was duly sworn by me; and 8 that the within transcript is a true record of 9 the testimony given by said witness. 10 I further certify that I am not 11 related to any of the parties to this action 12 by blood or marriage, and that I am in no way 13 interested in the outcome of this matter. 14 IN WITNESS WHEREOF, I have hereunto 15 set my hand this 18th day of December, 2022. 16  DAWN MATERA 17 18 19 20 21 22 23 24 25

Page 350 1 I N D E X 2 Witness Page 3 KAREN CHU 5 4 5 E X H I B I T S 6 Defendant's Page 7 Exhibit 4 United States Patent 15 8 Number 10,888,601B2 9 Exhibit 5 U.S. Patent Number 16 10 11,253,572 11 Exhibit 200 Plaintiff's Rule 26(a) 17 12 Initial Disclosures 13 Exhibit 201 Regeneron's stipulation 40 14 regarding case narrowing 15 and injunctive relief 16 Exhibit 202 Karen Chu 30(b)(6) 43 17 deposition topics 18 Exhibit 19 United States Patent 81 19 Number 10,973,879 20 Exhibit 203 Document Bates stamped 96 21 MYL-AFL 6405 through 16 22 Exhibit 204 Document Bates stamped 98 23 MYL-AFL 5010 through 18 24 Exhibit 205 Document Bates stamped 113 25 MYL-AFL0005242-70 26 Exhibit 206 Document Bates stamped 132 27 RGN-EYLEA-MYLAN00518628 28 through 640 29 Exhibit 207 Document Bates stamped 143 30 RGN-EYLEA-MYLAN 518348 31 through 350	Page 352 1 Exhibit 221 Document Bates stamped 235 2 RGN-EYLEA-MYLAN00523361 3 through 508 4 Exhibit 222 Document Bates stamped 245 5 RGN-EYLEA-MYLAN00523302 6 through 304 7 Exhibit 223 Document Bates stamped 254 8 RGN-EYLEA-MYLAN 525700 9 Exhibit 224 Document Bates stamped 260 10 RGN-EYLEA-MYLAN 635438 11 through 449 12 Exhibit 225 Document Bates stamped 264 13 RGN-EYLEA-MYLAN 635373 14 Exhibit 226 Document Bates stamped 268 15 RGN-EYLEA-MYLAN 631170 16 through 631175 17 Exhibit 227 Document Bates stamped 276 18 RGN-EYLEA-MYLAN 631182 19 Exhibit 228 Document Bates stamped 285 20 RGN-EYLEA-MYLAN 526319 21 through 321 22 Exhibit 229 Document Bates stamped 290 23 RGN-EYLEA-MYLAN00526220 24 through 223 25 Exhibit 230 Document Bates stamped 296 26 RGN-EYLEA-MYLAN 526332 27 through 334 28 Exhibit 231 Document Bates stamped 310 29 RGN-EYLEA-MYLAN 528309 30 through 316 31 Exhibit 232 Document Bates stamped 319 32 RGN-EYLEA-MYLAN 526744 33 Exhibit 233 Document Bates stamped 325 34 RGN-EYLEA-MYLAN 526815 35 through 838
Page 351 1 Exhibit 208 Document Bates stamped 145 2 RGN-EYLEA-MYLAN00521881 3 Exhibit 209 Document Bates stamped 149 4 RGN-EYLEA-MYLAN 518954 5 through 959 6 Exhibit 210 Document Bates stamped 159 7 RGN-EYLEA-MYLAN 540875 8 through 877 9 Exhibit 211 Document Bates stamped 164 10 RGN-EYLEA-MYLAN 541876 11 through 889 12 Exhibit 212 Document Bates stamped 171 13 RGN-EYLEA-MYLAN 634608 14 through 611 15 Exhibit 213 Document Bates stamped 180 16 RGN-EYLEA-MYLAN 634629 17 through 632 18 Exhibit 214 Document Bates stamped 184 19 RGN-EYLEA-MYLAN 569973 20 through 975 21 Exhibit 215 Document Bates stamped 191 22 MYL-AFL 8703 through 8711 23 Exhibit 216 Document Bates stamped 194 24 RGN-EYLEA-MYLAN 551796 25 through 798 26 Exhibit 217 Document Bates stamped 202 27 RGN-EYLEA-MYLAN 545220 28 through 221 29 Exhibit 218 Document Bates stamped 206 30 RGN-EYLEA-MYLAN 553211 31 through 212 32 Exhibit 219 Document Bates stamped 216 33 RGN-EYLEA-MYLAN 571549 34 Exhibit 220 Document Bates stamped 221 35 RGN-EYLEA-MYLAN 553399 36 through 400	Page 353 1 Exhibit 234 Document Bates stamped 326 2 RGN-EYLEA-MYLAN 526743 3 ~oOo~ 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25