

1 UNITED STATES PATENT AND TRADEMARK OFFICE

2
3 BEFORE THE PATENT TRIAL AND APPEAL BOARD

4
5 MYLAN PHARMACEUTICALS INC. and CELLTRION, INC.,
6 Petitioner

7 v.

8 REGENERON PHARMACEUTICALS, INC.,
9 Patent Owner

10 Case IPR2022-1225
11 Patent No. 10,130,681 B2

12 AND

13
14 MYLAN PHARMACEUTICALS INC. and CELLTRION, INC.,
15 and SAMSUNG BIOEPIS CO., LTD.,
16 Petitioner

17 v.

18 REGENERON PHARMACEUTICALS, INC.,
19 Patent Owner

20 Case IPR2022-1226
21 Patent No. 10,888,601 B2

22 Thursday, June 1, 2023

23 CONFIDENTIAL - UNDER PROTECTIVE ORDER
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Page 2	Page 4
1 2 3 Thursday, June 1, 2023 4 5 Video-recorded Deposition of RICHARD 6 MANNING, PH.D., taken at the offices of Arnold & 7 Porter LLP, 601 Massachusetts Ave NW, Washington, 8 DC, beginning at 9:11 a m., Eastern Standard 9 Time, before Ryan K. Black, a Registered 10 Professional Reporter, Certified Livenote 11 Reporter and Notary Public in and for the 12 District of Columbia. 13 14 15 16 17 18 19 20 21 22 23 24 25	1 I N D E X 2 TESTIMONY OF: RICHARD MANNING, PH.D. PAGE 3 By Mr. Marx.....7 4 E X H I B I T S 5 EXHIBIT DESCRIPTION PAGE 6 Manning 101 a copy of Dr. Manning's '338 7 patent IPR deposition transcript, 8 with errata attached.....45 9 Manning 102 a copy of the Patent Trial and 10 Appeal Board's final written 11 decision in IPR2021-881 for the 12 '338 patent.....77 13 14 Manning 103 a copy of Regeneron's April 26th 15 stipulation filed in the pending 16 West Virginia litigation.....83 17 18 Manning 104 a 2019 article with first-named 19 author Ohji.....116 20 Manning 105 Exhibit 34 to ECF Number 275 in 21 the CDF litigation.....154 22 23 PREVIOUSLY MARKED EXHIBITS 24 EXHIBIT DESCRIPTION PAGE 25 2059 IPR2022-1225 for the '681 patent.....43 26 2059 IPR2022-1226 for the '601 patent.....43 27 1001 '681 Patent to 1225 IPR.....89 28 1001 '601 Patent to 1226 IPR.....100 29 2138 1225 IPR.....124 30 2176 1225 IPR.....132 31 2139 1225 IPR.....135 32 2185 1225 IPR.....142 33 34 35
Page 3	Page 5
1 A P P E A R A N C E S: 2 3 RAKOCZY MOLINO MAZZOCHI SIWIK LLP 4 BY: JEFFREY A MARX, ESQ 5 DEANNE M MAZZOCHI, ESQ - Via Telephone 6 6 West Hubbard Street 7 Suite 500 8 Chicago, Illinois 60654 9 312 527 2157 10 jmarx@rmmslegal.com 11 dmazzoichi@rmmslegal.com 12 13 Representing - Petitioner 14 15 ARNOLD & PORTER LLP 16 BY: DAVID A CAINE, ESQ 17 3000 El Camino Real 18 Five Palo Alto Square 19 Suite 500 20 Palo Alto, California 94306 21 650 319 4710 22 david.caine@arnoldporter.com 23 24 ARNOLD & PORTER LLP 25 BY: MATTHEW WILK, ESQ 26 250 West 55th Street 27 New York, New York 10019 28 212 836 7152 29 matthew.wilk@arnoldporter.com 30 Representing - Patent Owner 31 32 33 34 35	1 THE VIDEOGRAPHER: Good morning. We are 2 going on the record at 9:11 a m. on June 1st, 3 2023. Please note that the microphones are 4 sensitive and may pick up whispering and private 5 conversations. Please mute your phones at this 6 time. Audio and video recording will continue to 7 take place unless all parties agree to go off the 8 record. 9 This is Media Unit 1 of the 10 video-recorded deposition of Dr. Richard Manning, 11 taken by counsel for petitioner in the matter 12 of Mylan Pharmaceuticals Inc., et al. versus 13 Regeneron Pharmaceuticals Inc., filed in the 14 United States Patent and Trademark Office, Case 15 Numbers IPR2022-01225 and IPR2022-01226. 16 The location of this deposition is 17 Arnold & Porter, 601 Massachusetts Avenue 18 Northwest, Washington, D.C. 19 My name is Gene Aranov, representing 20 Veritext, and I'm the videographer. The court 21 reporter is Ryan Black, from the firm Veritext. 22 I'm not authorized to administer an 23 oath. I'm not related to any party in this 24 action, nor am I financially interested in the 25 outcome.

2 (Pages 2 - 5)

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Mylan Exhibit 1121

Mylan v. Regeneron, IPR2022-01225

Page 2

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Page 2

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Page 6 1 If there are any objections to 2 proceeding, please state them at the time of your 3 appearance. 4 Counsel and all present, including 5 remotely, will now state their appearances and 6 affiliations for the record, beginning with the 7 noticing attorney. 8 MR. MARX: Jeffrey Marx, on behalf of 9 the petitioner Mylan, of the Law Firm Rakoczy 10 Molino, Mazzochi, Siwik. And my colleague Deanne 11 Mazzochi may join on the dial-in line, but has 12 not done so. 13 MR. CAINE: David Caine, with Arnold & 14 Porter, for Regeneron, the patent owner. 15 MR. WILK: Matt Wilk, from Arnold & 16 Porter, also on behalf of the patent owner, 17 Regeneron. 18 THE VIDEOGRAPHER: Will the court 19 reporter please swear in the witness, and then 20 counsel may proceed. 21 * * * 22 Whereupon -- 23 RICHARD MANNING, PH.D., 24 called to testify, having been first duly sworn 25 or affirmed, via remote Zoom video conference,	Page 8 1 testimony concerning Eylea? 2 A. I'm sorry. Can I go back? And -- I 3 did fill out an errata sheet for all of our prior 4 depositions so to that -- to that extent, I did 5 -- I have reviewed them. I did not review 6 them again in preparation for today if that's 7 -- that's how I interpreted your question, so 8 just to be clear. 9 Q. Okay. With the inclusion of your 10 errata sheets correcting any errors in those 11 depositions, do you believe your opinions in 12 these matters concerning the '681 patent and 13 '601 patent are consistent with your prior expert 14 reports and deposition testimony? 15 A. I do. 16 Q. Okay. I expect that counsel, 17 Mr. Caine's, also briefed you on the procedure 18 today. Is there any reason you cannot provide 19 honest and complete testimony today? 20 A. No. 21 Q. Did you meet with anyone to prepare for 22 today's deposition? 23 A. I did. 24 Q. Who did you meet with? 25 A. Counsel.
Page 7 1 was examined and testified as follows: 2 * * * 3 EXAMINATION 4 BY MR. MARX: 5 Q. Good morning, Dr. Manning. 6 A. Good morning. 7 Q. You've been deposed before, correct? 8 A. I have. 9 Q. In fact, this is your fourth deposition 10 concerning your opinions that Eylea is a 11 commercial success, correct? 12 A. Something on that order, yes. 13 Q. Okay. Have you reviewed your deposition 14 tr -- your prior depo -- deposition transcripts 15 concerning your opinions that Eylea is a 16 commercial success? 17 A. Not recently. I took a quick look, but 18 I haven't pored over them in detail. 19 Q. Okay. Sitting here today, do you have 20 any changes to those deposition transcripts? 21 A. Not that I'm aware of, no. 22 Q. Okay. And you don't be -- you believe 23 your -- your opinions concerning the commercial 24 success of the '681 patent and the '601 patent 25 are consistent with your prior expert reports and	Page 9 1 Q. Mr. Caine and Mr. Wilk? 2 A. Mr. Caine and Mr. Wilk, yes. 3 Q. Anyone else? 4 A. Ryan Marsh, from my firm, was in 5 attendance as well. 6 Q. And who is Mr. Marsh? 7 A. He is a vice president -- a vice 8 president at Intensity, where I work. 9 Q. And what was Mr. Marsh's -- did 10 Mr. Marsh have a role in drafting your 11 declarations in this matter? 12 A. Well, he assisted me. We -- he's 13 assisted -- 14 (Whereupon teleconference disconnected.) 15 MR. MARX: We'll fix that at the break. 16 THE WITNESS: He assisted me on -- he 17 has assisted me on all of the Regeneron-related 18 matters, and he assisted me in preparing these 19 two declarations as well. 20 BY MR. MARX: 21 Q. But the -- the opinions that you've 22 issued respect to the commercial success of Eylea 23 earlier on? 24 A. They are. 25 Q. How long did you meet with Mr. Wilk and

3 (Pages 6 - 9)

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Mylan v. Regeneron, IPR2022-01225

Page 3

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Page 3

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Page 10 1 Mr. Caine? 2 A. Three -- three or four hours that 3 morning, most of the morning. 4 Q. And how much time did you spend overall 5 preparing for this deposition today? 6 A. Oh, I don't know, another half day, a 7 day maybe. I don't -- I -- 8 Q. Okay. 9 A. Something on that order. 10 Q. Did you review any documents preparing 11 for your deposition today? 12 A. Yes. 13 Q. Were there any documents that you had 14 not seen before? 15 A. Not that I recall, no. 16 Q. You understand, Dr. Manning, that 17 you're being deposed today, with respect to your 18 declarations submitted in two pending IPRs, inter 19 partes reviews, correct? 20 A. Yes. 21 Q. And those two IPRs are -1225 with 22 respect to U.S. Patent 10,130,681? 23 A. That's the first, yes. 24 Q. And then -- are we comfortable if I call 25 that patent the '681 patent today?	Page 12 1 I will mark as a Manning Deposition Exhibit with 2 a new exhibit number. 3 Now, Dr. Manning, the document that you 4 brought with you, is that a true and complete 5 copy of your expert declaration submitted in the 6 1225 and 1226 IPRs? 7 A. I believe it is, yes. It looks to be. 8 Q. Does it include any appendices or 9 attachments as well? 10 A. It has my CV, which is Attachment A1 in, 11 I believe, both -- yes, it is Attachment A1 in 12 both of the declarations. 13 Q. And I understand that you have two 14 documents before you. Is it correct that you 15 prepared a single expert declaration for both the 16 '681 and '601 patent IPRs? 17 A. The declarations are very -- there are 18 -- there are some minor differences and the names 19 of the petitioners are different, but they are 20 essentially the same, yes. 21 Q. Can you identify the differences that 22 you're referring to? 23 A. The only ones I'm currently thinking 24 about are the fact that the petitioner in the 25 -225 IPR includes Celltrion in addition to Mylan,
Page 11 1 A. I am. 2 Q. Okay. And the -- the second IPR 3 is -1226, with respect to U.S. Patent Number 4 10,888,601, correct? 5 A. Yes. 6 Q. And could we refer to that patent as the 7 '601 patent today? 8 A. Sure. 9 Q. Excellent. I see you've brought a few 10 documents with you today. Which document -- what 11 documents do you have in front of you? 12 A. I have clean copies that were provided 13 by counsel of the declarations in the two matters 14 that you just referred to. 15 Q. Okay. And are those two documents you 16 have in front of you Exhibit 2058 to the 1225 17 IPR? 18 A. Yes. 19 Q. And Exhibit 2058 with respect to the 20 1226 IPR? 21 A. They are. 22 Q. Okay. I'm just going to note for the 23 record that any documents that were exhibits to 24 the pending IPRs, we'll use the existing exhibit 25 numbers, such as Exhibit 2058. Any new exhibits	Page 13 1 and that in -226 it includes Celltrion and 2 Samsung Bioepis, if I'm saying that correctly, in 3 the -226 IPR. 4 Q. But otherwise, the two declarations that 5 you filed, your Exhibits 2058, are identical with 6 the exception of the parties? 7 A. If I'm -- unless I'm forgetting 8 something, I -- I believe they are, yes. 9 Q. Okay. And for purposes of today's 10 deposition, the answers you give will apply to 11 both pending IPRs for the '601 and '681 patent 12 unless you clarify. Is that okay? 13 A. To the extent that the question is 14 clear, yes. 15 Q. We were discussing some differences 16 between the -- the two declarations, but there's 17 no difference in your opinions for the '601 and 18 '681 patents in your Exhibit 2058 declaration, 19 correct? 20 A. That's correct. 21 Q. And the declaration you prepared for 22 IPR-1225, for the '681 patent, does that have any 23 analysis for any particular claims of the '681 24 patent? 25 A. Well, both of the declarations refer

4 (Pages 10 - 13)

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Mylan v. Regeneron, IPR2022-01225

Page 4

Samsung Bioepis Exhibit 1075

Page 4

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Page 14 1 back to the analysis that was done for the '338 2 patent in that prior IPR. And the analysis is 3 the same -- the analysis that I rely on to 4 reach the opinions in both of these matters is 5 contained within the -- the declaration that was 6 done for that IPR. 7 Q. But your -- your opinions in your 8 Exhibit 2058 declarations don't provide any 9 analysis respect to the -- the claim elements 10 that are listed in the '681 and '601 patents? 11 MR. CAINE: Objection; form. 12 THE WITNESS: In all of my declarations, 13 my opinion is based on economics rather than 14 legal issues. And those claim-by-claim analysis, 15 to me, is a legal issue, and I don't -- I don't 16 undertake that kind of analysis. 17 BY MR. MARX: 18 Q. So it's correct that you did not do a 19 claim-by-claim analysis for the '338 patent, '601 20 patent or '681 patent? 21 A. That's correct. 22 Q. When did counsel for Regeneron ask you 23 to prepare these Exhibit 2058 declarations? 24 A. I'm not remembering exactly. It was 25 couple months ago. I don't remember exactly.	Page 16 1 Q. Okay. Did you speak with anyone at 2 Regeneron preparing your Exhibit 2058 3 declarations? 4 A. I don't believe so, but I could be wrong 5 there. You know, I've spoken with Regeneron 6 counsel from time to time. I don't believe 7 they were involved as we prepared these. 8 Q. When you say "Regeneron counsel," are 9 you referring to Mr. Caine and Mr. Wilk? 10 A. No. Internal counsel. 11 Q. Internal in-house counsel for Regeneron? 12 A. Yes. 13 Q. Who are those individuals? 14 A. Andrew -- I'm sorry. I'm forgetting 15 his last name. And another Andy, and I'm not 16 remembering his last name either. I'm sorry. 17 Q. And was counsel from Arnold & Porter 18 present for those conversations as well? 19 A. Yes. 20 Q. Did you speak with any litigation 21 counsel for Regeneron from the pending litigation 22 in West Virginia in preparing your Exhibit 2058 23 declarations? 24 A. No. 25 Q. Did you speak with any experts retained
Page 15 1 Q. Okay. And did you draft the 2 declarations that are in front of you? 3 A. Yes, with the assistance of my support 4 staff. 5 Q. How long did you spend, approximately, 6 preparing these declarations? 7 A. I don't have record of that. I don't 8 remember. 9 Q. Do you recall your testimony with 10 respect to your '338 patent IPR declaration that 11 you billed Regeneron approximately \$500,000? 12 A. I do. 13 Q. So you spent at least 500 hours, if we 14 use your billing rate, preparing your opinions in 15 this matter? 16 A. No. 17 Q. No? 18 Well, you spent -- how much time did you 19 spend preparing your opinions for the '338 patent 20 IPR declaration? 21 A. I don't know. 22 Q. What's your billing rate, Mr. -- or 23 Dr. Manning? 24 A. My present billing rate is \$1,050 per 25 hour.	Page 17 1 by Regeneron in the pending patent litigation in 2 West Virginia -- 3 A. For these -- 4 Q. -- in preparing your Exhibit 2058 5 declarations? 6 A. No. 7 Q. And you're not relying on any opinions 8 from experts in the pending West Virginia 9 litigation with respect to your opinions in these 10 IPRs? 11 A. Not explicitly, no. Although, as I'm 12 sure you could understand, I've learned a lot 13 about the entire constellation of issues, and 14 what I know may or may not depend upon things 15 that I've heard from a variety of people. And I 16 couldn't segregate them in -- in all cases, I 17 suppose. But, you know, this fact I learned 18 there; this expert testified to that. It's not 19 like I can forget it and say, oh, well, I don't 20 know that anymore. 21 So I'm sure that, to some extent, my 22 view was already shaped by all of the experiences 23 I've had in all of these different cases, but 24 I've not explicitly reviewed -- I've not 25 explicitly relied upon statements by counsel in

5 (Pages 14 - 17)

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Mylan Exhibit 1121

Mylan v. Regeneron, IPR2022-01225

Page 5

Samsung Bioepis Exhibit 1075

Page 5

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Page 18 1 -- or experts in those other cases for preparing 2 these two declarations. 3 Q. But the -- your complete opinions in 4 these pending IPRs are reflected in the text of 5 your Exhibit 2058 declarations? 6 A. Well, it also referred -- these 7 declarations also -- also refer to the 8 declaration in the '338 IPR, as I mentioned 9 before. So my opinion reflects those as well 10 -- or is reflected in -- in that report -- that 11 declaration as well. 12 Q. Correct. Your Exhibit 2058 declarations 13 incorporate the -- your '338 patent IPR 14 declaration by referring to it, correct? 15 A. Yes. 16 Q. And sitting here today, that -- sitting 17 here today, your Exhibit 2058 declarations, as 18 well as your '338 patent IPR declaration, is that 19 the full extent of your opinions in these pending 20 IPRs? 21 A. It's my affirmative opinion, yes. 22 Q. Well, you referred to "you haven't 23 explicitly relied on any experts from the pending 24 West Virginia litigation." I want -- do these 25 documents in front of you reflect your full	Page 20 1 A. Again, to the extent that it 2 incorporates the declaration in the '338 patent, 3 yes. I -- well, I do not. 4 Q. Okay. If you could turn to Paragraph 7 5 of one of those documents in front of you, 6 Exhibit 2058. In Paragraph 7 you state you've 7 provided testimony in some different legal 8 forums; is that correct? 9 A. Yes. 10 Q. Have you ever testified at trial in a 11 patent case? 12 A. No. 13 Q. Have you ever testified in an ITC 14 proceeding? 15 A. ITC meaning? 16 Q. International Trade Commission. 17 A. I -- no. I believe I -- just to be 18 clear, I was making sure you didn't mean the 19 International Chamber of Commerce. 20 Q. Okay. And when you say you testified in 21 a U.S. District Court proceeding, what are you 22 referring to? 23 A. Well, there are a couple of different 24 cases that are listed on my CV. I testified in a 25 case in the Western District of Michigan and --
Page 19 1 opinions in these pending IPRs? 2 A. To the extent it's also incorporating 3 that -- the declaration from the '338 patent, 4 yes. 5 Q. And you don't have anything to add to 6 your Exhibit 2058 declaration sitting here today, 7 do you? 8 A. I do not. 9 Q. And you still agree with the opinions 10 set forth in your Exhibit 2058 declarations? 11 A. I do. 12 Q. Do you have any corrections to your 13 Exhibit 2058 declarations? 14 A. I do not. 15 Q. And you don't have any modifications to 16 your declarations? 17 A. I do not. 18 Q. Do you have plans to provide any 19 written supplementation to your Exhibit 2058 20 declarations? 21 A. Not presently, no. 22 Q. And sitting here today, you don't have 23 any additional opinions or comments that you 24 intend to provide in these pending IPRs that 25 aren't stated in your declarations, correct?	Page 21 1 sorry. Let me go to my CV to remind myself. 2 I may have been thinking of the Chancery 3 Court in Delaware. So as is reflected on my CV, 4 I -- I testified in the Chancery Court in 5 Delaware on Item Number 2; the Western District 6 of -- of Michigan, Item Number 4. I submitted my 7 declaration, which I -- which I understand is 8 testimony in Item Number 14, the '338 IPR. 9 And also in the Western -- in the -- in 10 a hearing -- a deposition -- a -- a trial-like 11 hearing in Item Number 22 in the U.S. Bankruptcy 12 Court for the District of Delaware. 13 Q. Were those patent litigations, 14 Dr. Manning? 15 A. No. 16 Q. And when you say in Paragraph 7 you 17 provided testimony -- 18 A. Well, other than PT -- other than, 19 sorry, the IPR on '338 was a patent litigation, 20 yes -- well, of sorts. 21 Q. When you say the IPR '338, you're -- you 22 provided testimony -- are you referring to the 23 declaration you submitted in the '338 patent IPR? 24 A. Yes. 25 Q. Are there any other Patent and Trademark

6 (Pages 18 - 21)

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Mylan Exhibit 1121

Mylan v. Regeneron, IPR2022-01225

Page 6

Samsung Bioepis Exhibit 1075

Page 6

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Page 22 1 Patent Trials and Appeals Board declarations that 2 you submitted outside of the '338 patent IPR 3 declaration? 4 A. Not -- no. 5 Q. Does your Exhibit 2058 declaration 6 include a list of documents that you reviewed in 7 preparing that declaration? 8 A. By reference to the IPR in patent number 9 '338, it doesn't have -- that -- that has a list 10 of documents considered. This has references in 11 the footnotes to documents, but it does not 12 include a -- you know, a list of documents 13 considered beyond that. 14 Q. Okay. But everything you've considered 15 is cited in your Exhibit 2058 declarations, 16 correct? 17 A. To the extent that it includes the 18 materials in the -- the declaration for the '338 19 patent IPR, yes. 20 Q. Okay. And the '338 patent IPR 21 declaration is cited in your Exhibit 2058 22 declarations, correct? 23 A. It's referenced, yes. 24 Q. So it's correct that everything you've 25 considered is cited or mentioned in your Exhibit	Page 24 1 was the key economic characteristic that forms my 2 -- that forms my opinion -- on -- on which I base 3 my opinions, recognizing that that link takes 4 -- incorporates -- incorporates all of the -- the 5 discussion and analysis that was done in the '338 6 declaration, I relied primarily on those. 7 There are -- as we wrote -- as I wrote 8 this declaration being a -- a summary, I cited to 9 those things that seemed relevant and important. 10 As I do in all of my -- my reports or 11 declarations, I used my judgment. 12 Q. Does -- did you provide any updated 13 Regeneron financial information in your Exhibit 14 2058 declarations since -- 15 A. Updated -- 16 Q. -- your '338 patent IPR declaration? 17 A. No. 18 Q. Did you request any document -- a yes 19 or no question: Did you request any additional 20 documents from Regeneron counsel with respect to 21 your IPR Exhibit 2038 declarations? 22 A. Not that I recall, no. 23 Q. You mentioned Dr. Do, did you speak with 24 Dr. Do? 25 A. Prior -- in relation to the '338
Page 23 1 2058 declarations in these matters? 2 A. Is that not the same question you just 3 asked? 4 Q. Well, you -- you said, well, the '338 5 patent, but the '338 patent IPR declaration is 6 cited there as well, correct? 7 A. It is. 8 Q. So it's correct that everything you've 9 considered in these pending IPRs is cited in your 10 Exhibit 2058 declarations, correct? 11 A. To the extent that the '338 declaration 12 encompasses the materials that I considered for 13 that declaration. So every document that is 14 in that declaration is not cited here, but 15 everything -- so citing to that document 16 incorporates -- my understanding is that I 17 intended to incorporate all of the documents 18 cited there. 19 Q. Okay. How did you determine what 20 documents to review in connection with your 21 Exhibit 2058 declarations? 22 A. Knowing that -- well, understanding that 23 Dr. Do, whose opinion I relied upon for the link 24 between the patents and the extended dose -- the 25 eight-week dosing feature, recognizing that that	Page 25 1 declaration, I did, yes. 2 Q. Did you speak to Dr. Do with respect to 3 her opinions on the '601 and '681 patents? 4 A. I did not. 5 Q. Did you review a draft of her 6 declaration -- 7 A. Um -- 8 Q. -- in the '601 and '681 patent IPRs? 9 A. I did review a declaration. I'm not 10 remembering at the moment whether it was a draft 11 or a final. 12 Q. Have you reviewed Dr. Do's final 13 declaration submitted in the '601 and '681 patent 14 IPRs? 15 A. As I said, I -- I've reviewed a 16 declaration. I don't recall whether it was a 17 draft or final or, in fact, whether -- whether I 18 cite to it here. 19 I cite to her declaration in IPR-1225 20 -- sorry, Exhibit 2056. So I presume that is the 21 final, April 1st, 2023. 22 Q. But you can't re -- you can't recall 23 whether you reviewed Dr. Do's final declaration 24 or a draft of her declaration? 25 A. Well, I may have seen a draft. But I

7 (Pages 22 - 25)

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Mylan v. Regeneron, IPR2022-01225

Page 7

Samsung Bioepis Exhibit 1075

Page 7

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Page 26 1 cited to her final, so I've seen her final as 2 well. 3 Q. Okay. Your Exhibit 2058 declarations 4 also cite a declaration from Jennifer Colyer? 5 A. Yes. 6 Q. Did you speak with Ms. Colyer? 7 A. Not in preparing this, no. 8 Q. Have you ever spoken with Ms. Colyer? 9 A. I can't be certain. She may have been 10 one of the people I spoke to in preparing for the 11 '338 declaration. I did speak to a handful of 12 Regeneron business executives. She may have been 13 one of them. I don't remember exactly. 14 Q. Okay. So sitting here today, you can't 15 recall if you've spoken to Ms. Colyer before or 16 not? 17 A. Not by -- not -- not with certainty, but 18 I did -- I did speak with people that would be in 19 similar roles, I -- as I understand. 20 Q. But at least with respect to your 21 Exhibit 2058 declarations, you did not speak with 22 Ms. Colyer? 23 A. No. 24 Q. Okay. Did you review a draft of 25 Ms. Colyer's declaration?	Page 28 1 THE WITNESS: Not that aren't -- not 2 that aren't reflected in the declaration -- the 3 prior declaration for the '338 patent. I'd say 4 that her -- her declarations strengthen my view 5 as expressed there. 6 BY MR. MARX: 7 Q. You mentioned that you reviewed Dr. Do's 8 declaration, correct? 9 A. Yes. 10 Q. And I believe you said that she opined 11 on a link between the '601 patent, the '681 12 patent and the eight-week dosing regimen. Is 13 that an accurate summary of what you relied on 14 Dr. Do for? 15 A. I believe so. I mean, I -- I take her 16 as a medical and technical expert to provide a 17 link between the patents and its claims and the 18 eight-week dosing. 19 Q. You mentioned the eight-week dosing. Is 20 there any other link between the '601 patents and 21 '681 patents and Eylea that you are providing, 22 other than the eight-week dosing regimen? 23 A. My understanding is that the eight-week 24 dosing regimen is the issue at -- before the 25 PTAB, so, no, my -- my opinion is focused on the
Page 27 1 A. I believe I reviewed the final, but I 2 may have seen a draft as well. 3 Q. What opinions are you relying on 4 Ms. Colyer for in this matter? 5 A. Well, I saw her opinion as -- her -- her 6 declaration, which is fairly short, as something 7 that provided context to the -- the marketing and 8 advertising efforts that Eylea had -- or that 9 Regeneron had done for Eylea. She refers to some 10 direct-to-consumer -- her television advertising 11 efforts that have been done on -- in a couple of 12 specific years, and I took note of that. And so 13 they shaped my general view; didn't change my 14 view, but informed my thinking about marketing 15 and advertising. 16 Q. What is your opinion concerning 17 marketing and advertising for Eylea? 18 A. Well, it's complicated. I mean, 19 it's -- that would take me -- do you have a more 20 specific answer -- or question? 21 Q. Well, out -- outside of your citations 22 to Ms. Colyer's declaration, do you have any 23 additional opinions concerning marketing and 24 advertising for Eylea? 25 MR. CAINE: Objection; form. Go ahead.	Page 29 1 eight-week dosing interval. 2 Q. And it's not focused on any other 3 elements in the '601 patent and '681 patent 4 claims; is that correct? 5 A. Again, I don't have opinions about 6 specific claim-by-claim analysis. I take from 7 Dr. Do the implication that the patents relate to 8 the eight-week dosing interval, as I've stated in 9 my -- in the declaration here. 10 So if there are other things there 11 that -- I wouldn't have an opinion about them. 12 Q. We briefly discussed, you're aware of 13 additional documents as Regeneron's expert in the 14 pending West Virginia litigation, correct? 15 A. Yes. 16 Q. You're aware of additional Regeneron 17 financial information and additional marketing 18 studies that Regeneron's produced in the 19 litigation, correct? 20 A. As I sit here, I -- I'm not thinking of 21 anything -- I'm not remembering anything that is 22 substantial. I know there -- there are some 23 slight differences in that declaration, as 24 opposed to the '338 deposition -- or sorry, '338 25 declaration. But additional studies, I -- if --

8 (Pages 26 - 29)

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Mylan Exhibit 1121

Mylan v. Regeneron, IPR2022-01225

Page 8

Samsung Bioepis Exhibit 1075

Page 8

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Page 30 1 I'd need to be -- need to be reminded if there's 2 something significant. 3 Q. What "slight differences" between your 4 expert report in the West Virginia litigation and 5 your Exhibit 2058 declarations are you referring 6 to? 7 A. Well, in particular, I'm thinking of 8 -- so the Medicare Part B utilization data, a new 9 year had become available of product utilization, 10 as had another year of Medicare pricing data. 11 And so since those were available and they were 12 pri -- pre -- previously lagging the other 13 analyses by a year, I did update in that 14 litigation the -- those two series, but those are 15 not Regeneron data. Those were Medicare data. 16 Q. Why didn't you refer to that additional 17 information that was available in your Exhibit 18 2058 declarations? 19 A. It didn't seem necessary. I already had 20 the information sufficient, in my opinion, to 21 reach my opinion in the '338 declaration, and so 22 I stood there. 23 Q. And you're familiar with the term ATU, 24 correct? 25 A. Yes.	Page 32 1 commercial successes and objective indicia of 2 nonobviousness. And I take that to mean 3 evaluating the product, the patented features 4 of the product and its link or nexus to the 5 commercial success of the product. 6 Q. What "patent features" are you referring 7 to? 8 A. Well, as I describe in the report, 9 Paragraph 14 recites the abstract of the '681 10 patent. The present invention provides methods 11 for treating angiogenic eye disorders by 12 sequentially administering multiple doses of the 13 VEGF antagonist to a patient. The methods of the 14 present invention include the administration of 15 multiple doses of a VEGF antagonist to a patient 16 at a frequency of once every eight or more weeks. 17 The methods of the present invention are useful 18 for the treatment of angiogenic eye disorders 19 such as age-related macular degeneration, 20 diabetic retinopathy, diabetic macular edema, 21 central vein -- vein occlusion, branch retinal 22 vein occlusion and corneal neovascularization. 23 I then go on to say that I understand, 24 generally -- in Paragraph 17, "Generally, I 25 understand that the '681 patent describes a
Page 31 1 Q. And you're aware that Regeneron provi 2 -- conducts quarterly ATU surveys, correct? 3 A. Yes. 4 Q. And you did not discuss ATU surveys in 5 your Exhibit 2058 declaration except for 2013 and 6 one from 2020, correct? 7 A. I'd have to go back and confirm that, 8 but there are, as I recall, several others that 9 are referred to in the '338 declaration. 10 So I -- I would want to go back and look 11 at the '338 declaration to see exactly how many 12 or what I've referred to, but, you know, since 13 this refers to that, I don't think that's 14 accurate that I've only referred to those two 15 IPRs -- or, sorry, ATU surveys. I've certainly 16 reviewed many more than two. 17 Q. Dr. Manning, could you turn to 18 Paragraph 9 in your Exhibit 2058 declarations? 19 Is it correct that in these pending 20 IPRs, you're only offering opinions, quote, 21 concerning commercial success as an objective 22 indicia of non-obvious [sic], closed quote; is 23 that correct? 24 A. My opinion is -- well, it says here I 25 was asked to evaluate and testify concerning the	Page 33 1 dosing regimen directed to treat -- treating 2 angiogenic eye disorders in patients who do not 3 have three exclusion criteria." And I described 4 there -- going on, finishing with the statement 5 that "The doses are administered at at least 6 eight week -- eight weeks following the preceding 7 dose in the tertiary dosing phase," or what I 8 also have referred to as the "maintenance phase." 9 So the eight-week dosing interval is the 10 primary feature that I evaluate and that my 11 opinion concludes has a clear link to the 12 commercial success of Eylea. 13 Q. Okay. And just to clarify, I believe 14 you said Paragraph 17 but you refer -- you were 15 reading from Paragraph 15, correct? 16 A. If I said 17, I was incorrect. 17 Q. Okay. And the -- the patented features 18 for the '681 patent that are relevant to your 19 commercial success opinions is the eight-week 20 dosing regimen; is that correct? 21 A. Well, I would point out that it does 22 say -- the abstract reads once every eight weeks 23 or -- eight or more weeks, but the eight-week 24 dosing regimen is a -- a fundamental feature 25 about which I am -- that I am analyzing in

9 (Pages 30 - 33)

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Mylan Exhibit 1121

Mylan v. Regeneron, IPR2022-01225

Page 9

Samsung Bioepis Exhibit 1075

Page 9

Page 34 1 reaching my opinions. 2 Q. What other patented features, with 3 respect to the '681 patent, are relevant to your 4 commercial success opinions in this pending IPR? 5 A. In these IPRs, the eight-week dosing 6 feature is -- the eight-week dosing is the 7 feature that is at issue. 8 Q. Okay. Have you offered any opinions on 9 other patented features outside the eight-week 10 dosing regimen? 11 A. In this matter? 12 Q. Yeah. In these pending IPRs? 13 A. No. Well, not that I recall, but these 14 -- that -- that is the -- that is the feature 15 that is at issue here. There's probably some 16 reference -- well, there is some reference in 17 the '338 declaration about Eylea being more 18 efficacious in some settings and that might have 19 an impact on some of the data that I see, more 20 efficacious than the alternative products in some 21 settings. And so there is a -- to the extent 22 that I talk about efficacy or the efficacy of the 23 product in those settings, those are not one of 24 the patented features covered by these two 25 patents, but it is a feature of the product that	Page 36 1 the product that extended beyond eight-week 2 dosing -- dosing. And since I had expressed that 3 in the prior '338 patent IPR, I wanted to make 4 sure that you didn't misunderstand. 5 Q. Sure. And so just to clarify, with 6 respect to your opinions for the '601 patent and 7 '681 patents, efficacy is not one of the features 8 that you evaluated, correct? 9 A. That's correct. 10 Q. And when you say "Eylea has superior 11 efficacy to Lucentis," are you referring to 12 Dr. Do's opinions? 13 A. No. I'm referring back to the -- my 14 declaration in the '338 patent -- '338 IPR. I 15 believe Dr. Brown cites to that. But I've also 16 looked at the study in its published form, and so 17 my recollection is based on reading -- looking at 18 that. And to the -- I'm -- and I know that I 19 cite to that or I discuss that in -- in the -- in 20 the declaration for the '338 patent. 21 Q. Why, in your opinion, does Eylea have 22 superior efficacy to Lucentis? 23 A. I'm not a technical expert. I can't 24 tell you the chemical or medical reasons -- or 25 biologic -- biochemical, I should say.
Page 35 1 I do mention in th -- in that report or that 2 declaration. 3 Q. What do you mean when you say 4 "efficacy"? 5 A. I mean effectiveness at treating an -- 6 certain angiogenic eye disorders. 7 Q. Okay. And that efficacy is -- is that a 8 feature of the '681 patent? 9 A. As I have said, the features of '681 and 10 the '601 patent that I'm concerned with here is 11 the eight-week dosing. But as I interpreted your 12 question to ask me whether I had any opinions 13 about anything outside of those, I said that the 14 -- so, for example, the protocol T study, which I 15 do refer to in the '338 patent declaration, shows 16 that Eylea has superior efficacy to Avastin 17 -- or, sorry, to Lucentis in diabetic macular 18 edema for patients with worse initial visual 19 acuity. That was something that I talked about 20 in that -- in that declaration. 21 Again, it is not one of the covered 22 features that I evaluate for these IPRs, but 23 since you asked me whether I had an opinion 24 -- I interpreted your question, anyway, as asking 25 whether I had any views that -- on features of	Page 37 1 Q. So what is the basis for your opinions 2 that Eylea has superior efficacy to Lucentis? 3 A. Well, as we talked, I do not -- I'm 4 not expressing an opinion that there's a general 5 -- within the context of these IPRs and the prior 6 -- the '338 patent IPR, that's not a part of 7 my analysis, with -- with the exception of 8 discussing how that affects data that might show 9 utilization of -- of Eylea, as opposed to 10 Lucentis or Avastin. 11 So I guess I don't really understand the 12 question in the sense that "why do I think it is 13 more efficacious"? Well, there is evidence to 14 suggest that, at least in some circumstances, it 15 is. So I would just go back to the discussion I 16 already went through on the protocol T study. 17 Q. So the protocol T study is the basis for 18 your opinion that Eylea is more efficacious than 19 Lucentis; is that correct? 20 MR. CAINE: Objection; form. 21 THE WITNESS: So whether -- I think I've 22 answered the question in terms of whether there's 23 something outside of -- whether I'm expressing in 24 this proceeding an opinion about efficacy, and 25 I'm not. I simply said that there is evidence

10 (Pages 34 - 37)

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Mylan Exhibit 1121

Mylan v. Regeneron, IPR2022-01225

Page 10

Samsung Bioepis Exhibit 1075

Page 10

Page 38 1 that bears to some of the utilization data that 2 I reviewed for the '338 proceeding that 3 demonstrates a level of efficacy in a 4 setting that might have a bearing on what data 5 show. 6 BY MR. MARX: 7 Q. All right. But you testified you're not 8 a clinician, correct, Dr. Manning? 9 A. I'm not. 10 Q. You're not a medical doctor? 11 A. I'm not. 12 Q. You're not a chemist? 13 A. I'm not. 14 Q. And you're not a drug formulator, 15 correct? 16 A. I'm not. 17 Q. And with respect to your Exhibit 2058 18 declarations, is it correct that your opinions 19 concern -- concerning commercial success of Eylea are 20 Paragraphs 20 through 22 of that declaration -- those 21 declarations? 22 A. Well, Paragraphs 20 through 22 do 23 summarize my views about commercial success, referring 24 -- referring to and incorporating the declaration 25 that I submitted as part of the 2021 '881 PTAB	Page 40 1 use the declarations of Exhibit 2058 and the '338 2 patent as the entirety of my -- sorry, the '338 3 declaration as the entirety of my opinion. But I 4 do believe that the analysis and -- and opinions 5 expressed, as it -- as it says in Paragraph 22, 6 expressed in that prior declaration, do capture 7 my opinion about the issue at hand. 8 Q. Dr. Manning, what additional opinions 9 concerning commercial success of Eylea with 10 respect to the '601 patent do you have that are 11 not included in your '338 patent IPR declaration? 12 A. As I sit here, I -- I can't think of 13 any. 14 Q. And would the same be true for the '681 15 patent, your opinions concerning the commercial 16 success of Eylea are with respect to your '338 17 patent IPR declaration? 18 A. Yes. As I sit here, as Paragraph 22 19 says, my opinions regarding the link between 20 commercial success and the dosing interval, the 21 eight-week dosing interval, are 22 reflected/captured in my declaration for the '338 23 patent. 24 Q. And your Exhibit 2058 declarations 25 provide no additional opinions with respect to
Page 39 1 hearing -- PTAB proceeding, which is the -- 2 regards the '338 patent. 3 So I wouldn't say that those three 4 paragraphs capture my entire -- the entirety of 5 my opinion, but they summarize it and reflect and 6 refer to the prior declaration where my opinion 7 is expressed in greater -- to a greater extent -- 8 in greater detail. 9 Q. Okay. Yeah. And, correct, in 10 Paragraph 22, it cites to your prior '338 patent 11 IPR declaration as to why, in your opinion, 12 Eylea's commercial success for the '681 and 13 '601 patents, correct? 14 A. 22 says, "In light of this 15 understanding, the opinions and analyses 16 presented in my prior declaration for 17 IPR2021-00881 also apply to the claims of the 18 '681 patent and the '601 patent." 19 Q. And sitting here today, that's a correct 20 statement? 21 A. Yes. 22 Q. Do you have any additional opinions with 23 respect to the '601 and '681 patents beyond 24 what's in your '338 patent IPR declaration? 25 A. To the extent -- well, I would want to	Page 41 1 commercial success for the '601 and '681 patents, 2 correct? 3 A. I wouldn't say that. I would -- I would 4 refer to Paragraph 20 in saying that I maintain 5 my opinions that Eylea has been commercially 6 successful -- a commercially successful biologic 7 therapy for angiogenic eye disorders; 8 that the 8-week dosing interval in the 9 maintenance phase has been an important driver of 10 demand; and that potential explanations are 11 not sufficient to explain Eylea's commercial 12 success to the exclusion of the 8-week 13 maintenance dosing interval. 14 Those are my opinions, incorporating the 15 analysis and opinions of the '338 declaration. 16 Q. Right. And those opinions are based on 17 what's set forth in your '338 patent IPR 18 declaration, correct? 19 A. Yes. 20 Q. Do you have any additional opinions 21 concerning Eylea's commercial success with 22 respect to the '601 patent and '681 patents that 23 is not set forth in your '338 patent IPR 24 declaration? 25 A. There is no new analysis in these

11 (Pages 38 - 41)

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Mylan Exhibit 1121

Mylan v. Regeneron, IPR2022-01225

Page 11

Samsung Bioepis Exhibit 1075

Page 11

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Page 42 1 declarations. There is reference to the 2 framework to what patents are, to my 3 understanding of how the dosing reflects -- is 4 reflected in those. And then I reference back to 5 the '338. 6 So the thing I want to be careful about 7 is just to say that I don't -- I don't want it to 8 be understood that I don't have an opinion about 9 the '601 and the '681 patents. My understanding, 10 from an economic perspective, is that the 11 -- these patents embody an economic 12 characteristic of the product that is also 13 embodied in the '338 patent. And so to the 14 extent that these declarations tie that opinion 15 to these patents, that's what I want to be 16 careful not to say that I don't have an opinion 17 about. 18 Q. Well, that -- the characteristic you're 19 referring to is the dosing regimen for Eylea, 20 correct? 21 A. The eight-week dosing interval, yes. 22 Q. Is there any other characteristic that 23 you're referring to as the basis for your 24 commercial success opinions in these IPRs? 25 A. No.	Page 44 1 in color in my original declaration, they seem to 2 be -- or it -- sorry, it -- it appears to be the 3 same document for each of the two proceedings. 4 And with the exception of the color -- absence of 5 color, it does seem to be the same. 6 Q. All right. And did you re -- did you 7 review this document in preparing for today's 8 deposition? 9 A. I did. 10 Q. And Exhibit 2059, the pending IPRs, 11 that's what you rely on with respect to your 12 commercial success opinions for the '601 patent 13 and '681 patent, correct? 14 A. Yes. 15 Q. And except for the cover page on these 16 documents, Exhibit 2059 is identical in both 17 pending IPRs? 18 A. Unless I'm missing something, the cover 19 pages are identical in these two -- on these two 20 documents. 21 Q. I believe one -- they have different 22 -- they refer to different IPRs -- that's the 23 only difference, correct -- on the bottom 24 right-hand corner. 25 A. In the exhibit rectangle, yes.
Page 43 1 Q. And you don't have any analysis of 2 additional claim elements in the '601 patent and 3 '681 patent claims beyond the dosing regimen, 4 correct? 5 A. That's correct. 6 Q. I'm going to have the court reporter 7 hand you two documents. 8 MR. MARX: No exhibit number. Sorry. 9 This is -- the first document is Exhibit 10 2059 to IPR 2022-1225 for the '681 patent. 11 The second document is Exhibit 2059 to 12 IPR 2022-1226. That's for the '601 patent. 13 (Previously marked Exhibit No. 2059 to 14 IPR2022-1225 for the '681 patent was introduced.) 15 (Previously marked Exhibit No. 2059 to 16 IPR2022-1226 for the '601 patent was introduced.) 17 BY MR. MARX: 18 Q. And, Dr. Manning, we've been talking 19 about your '338 patent IPR declaration. Is 20 Exhibit 2059 from both the pending IPRs in this 21 matter a copy of your '338 patent declaration 22 that we've been discussing? 23 A. Let me look at them for a moment. 24 Well, with the exception of the fact 25 that the figures are not in color and they were	Page 45 1 Q. But otherwise, Exhibit 2059 is the same 2 between both pending IPRs? 3 A. They appear to be. I would have to do a 4 more careful review to make sure there's no 5 difference but, yes. 6 Q. Okay. And sitting here today, do you 7 have any corrections to Exhibit 2059, your '338 8 patent IPR declaration? 9 A. No. Not -- not that I currently have in 10 mind, no. 11 Q. And sitting here today, do you have any 12 modifications to Exhibit 2059? 13 A. No. 14 Q. I'm going to have the court reporter 15 mark as Manning Exhibit 101 -- this is a copy of 16 your '338 patent IPR deposition transcript with 17 the errata appended to the end of it. 18 (Manning Exhibit No. 101, a copy of Dr. 19 Manning's '338 patent IPR deposition transcript, 20 with errata attached, was introduced.) 21 BY MR. MARX: 22 Q. Dr. Manning, do you have Exhibit 101 in 23 front of you? 24 A. I do. 25 Q. And have you seen this document before?

12 (Pages 42 - 45)

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Mylan Exhibit 1121

Mylan v. Regeneron, IPR2022-01225

Page 12

Samsung Bioepis Exhibit 1075

Page 12

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Page 46 1 A. Yes. 2 Q. Can you confirm that this is a copy of 3 your deposition transcript from IPR 2021-881 and 4 also includes your errata sheet to that 5 deposition? 6 A. It looks to be. 7 Q. Did you review your -- your deposition 8 transcript from the '881 patent proceeding -- or 9 '881 IPR proceeding to prepare for today's 10 deposition? 11 A. No, not specifically. 12 Q. When's the last time you reviewed your 13 deposition transcript from the '881 IPR 14 proceeding? 15 A. Probably when I submitted the errata on 16 May 4th of 2022. 17 I may have looked at it again since 18 then, but I don't have a clear memory of doing 19 so. 20 Q. Well, does your testimony in Manning 21 Exhibit 101 accurately reflect your opinions 22 today? 23 A. As far as I recall, yes. 24 Q. And do you still agree with your 25 testimony you provided in Manning Exhibit 101?	Page 48 1 bounds of what were my opinions at the time. 2 And so I guess I'd just want to be careful not to 3 make -- be careful to make sure that things that 4 might have seemed outside -- or seemed to me to 5 be outside the bounds of that proceeding would 6 also seem to me to be outside the bounds of this 7 proceeding. 8 Q. Okay. But you don't have any 9 corrections or changes to that testimony in your 10 Manning Exhibit 101, correct? 11 A. Not as I sit here, no. 12 I'm sorry. I just noticed that I had 13 said that May 4th was the last time I reviewed 14 this, and I -- I was looking at the date of the 15 deposition. And my -- the signature date is 16 actually May 24th, so that would be the last 17 time. Just to be correct, that would be the last 18 time I had a clear memory of reviewing this 19 transcript. 20 Q. And any changes or corrections or errors 21 in the deposition transcript would be noted in 22 your errata sheet from May 24th, correct? 23 A. Yes. 24 MR. MARX: We've been going about an 25 hour, David.
Page 47 1 A. I don't have any specific recollection 2 of things that I missed -- said by mistake or 3 something, but -- or other -- otherwise would 4 want to restate. But, you know, pending that, 5 yeah, I would stand by it. 6 Q. Right. So sitting here right at this 7 moment, you don't have any corrections to the 8 testimony you provided in Manning Exhibit 101, 9 correct? 10 A. I do not. Not beyond the errata. 11 Q. And you don't have any modifications to 12 the testimony you provided in Manning Exhibit 101 13 outside of the errata that's included, correct? 14 A. No. 15 Q. And do you agree that since your 16 opinions on the commercial success for the '601 17 and '681 patent are based on your analysis for 18 the '338 patent, that your testimony in Manning 19 Exhibit 101 applies, likewise, to these pending 20 IPR proceedings? 21 A. To the -- to the extent that it stays 22 within the bounds of these proceedings, yes. I 23 mean, I -- I don't have a clear memory, but I can 24 -- I -- I know there were a couple of questions 25 that, as I recall, seemed to go outside the	Page 49 1 MR. CAINE: Yep. 2 MR. MARX: We'll take a break, and I'll 3 open up the phone line again. 4 MR. CAINE: Sounds good. Thank you. 5 THE VIDEOGRAPHER: Did you want to go 6 off the record? 7 MR. MARX: Yeah. Off the record, 8 please. 9 THE VIDEOGRAPHER: We're going off the 10 record. This is the end of Media Unit 1. The 11 time is 10:14 a.m. 12 (Recess taken.) 13 THE VIDEOGRAPHER: We're back on the 14 record. This is the beginning of Media Unit 2. 15 The time is 10:27 a.m. 16 BY MR. MARX: 17 Q. Dr. Manning, now that you have your '338 18 patent IPR declaration, Exhibit 2059, in front of 19 you, since you issued that declaration you 20 haven't cited in your Exhibit 2058 declarations 21 any updated Regeneron information, correct? 22 A. No. My understanding -- well, no, 23 I don't -- not to my current recollection and 24 understanding, unless I -- I -- you know, I think 25 I looked through it once before and didn't see

13 (Pages 46 - 49)

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Mylan Exhibit 1121

Mylan v. Regeneron, IPR2022-01225

Page 13

Samsung Bioepis Exhibit 1075

Page 13

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Page 50 1 anything. But if -- I mean, it wouldn't be 2 impossible that someone would say, well, look, 3 this declar -- this exhibit is different from 4 that exhibit and I would have to say, oh, yes, 5 but my understanding is that not. 6 Q. Okay. And, for example, in Exhibit 7 2059, if you could turn to Page 157, this is the 8 end of your attachment B1. 9 A. I'm sorry. Page what? 10 Q. 157 of 289. 11 A. Okay. 12 Q. And in Exhibit 2059, you discuss, quote, 13 most recent label, closed quote, and for Eylea 14 that was March 2021, correct? 15 A. That is what it says on the page. 16 Q. You don't provide any analysis in your 17 Exhibit 2058 or 2059 of Eylea's current label, 18 correct? 19 A. In this matter -- just to make sure I 20 didn't include any updated label information -- I 21 do know there's been be an update to the label 22 since then. 23 So I believe my only reference to the 24 label is to that same March of '21 label. Let me 25 make --	Page 52 1 Q. And you didn't provide any discussion of 2 copay programs of Eylea in your Exhibit 2058 3 declarations, correct? 4 A. I do not. 5 Q. But you're aware that copay programs 6 exist for Eylea? 7 A. I am. 8 Q. Are you aware of the EYLEA4U copay 9 program that Regeneron provides? 10 A. Let me go back and maybe amend my 11 pre -- prior answer, because I -- EYLEA4U is 12 something that I have been aware of. I don't 13 -- as I sit here, I don't remember exactly 14 whether or not it was discussed in -- I'd have to 15 go back and review '338 again to make sure I'm 16 speaking correctly. But I wouldn't say I was 17 unaware of it, but it was not a major discussion 18 point in the '338 declaration. 19 Q. So when you issued your Exhibit 2059 20 declaration for the '338 patent, were you aware 21 that copay programs were available for Eylea? 22 A. Well, to the extent that -- well, what 23 kind of co- -- what do you mean, specifically? 24 Q. Well, you're -- you're aware that 25 Regeneron offers a program called EYLEA4U
Page 51 1 Q. You don't cite or discuss the current 2 label for Eylea, correct? 3 A. To the extent that it has been modified 4 since then, I do not. 5 Q. Why didn't you provide any opinions 6 concerning the current Eylea label with respect 7 to your Exhibit 2058 and 2059 declarations? 8 A. My understanding is that the only 9 modification to the label since then is relevant 10 to a small -- a relatively small modification to 11 another indication for a pediatric indication, 12 retinopathy prematurity, or I'm not sure I'm 13 saying that correctly or remembering exactly, but 14 my recollection is that that was the change to 15 the label, is the added -- the addition of one 16 new indication that wasn't relevant to my opinion 17 in these matters. 18 Q. So the -- the current label from August 19 of 2022 for Eylea does not change the opinions 20 that you've expressed in Exhibit 2058 and 2059? 21 A. Not to my understanding, no. 22 Q. Okay. And in your Exhibit 2059 23 declaration, you don't discuss any copay programs 24 available for Eylea, correct? 25 A. I do not.	Page 53 1 E-Y-L-E-A the number 4 and the letter U, correct? 2 A. Yes. 3 Q. And that's a copay program, correct? 4 A. I believe it encompasses other things in 5 addition to copay assistance, but I -- I'm aware 6 of it. 7 Q. And in your ex -- your Exhibit 2059 8 declarations, as well as your Exhibit 2058 9 declarations, you don't discuss any copay 10 support available for Eylea, do you? 11 A. Let me go back to the '338 declaration 12 for a moment. 13 Well, in Section 10 I do discuss various 14 issues that I explain cannot be -- that Eylea's 15 commercial success cannot be explained by factors 16 not related to the claimed methods of treatment. 17 And so I discuss sampling and discounting and 18 rebate programs and marketing efforts in that 19 section, all of which I conclude are not -- do 20 not explain Eylea's commercial success to the 21 exclusion of the patented features at issue here. 22 I'd have to go back and look at those 23 pages again to see what exactly I said and 24 whether I referenced EYLEA4U or not, but those 25 are the kinds of issues that I would have been

14 (Pages 50 - 53)

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Mylan Exhibit 1121

Mylan v. Regeneron, IPR2022-01225

Page 14

Samsung Bioepis Exhibit 1075

Page 14

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Page 54 1 thinking about. So -- 2 Q. Well, I -- I've looked through your 3 declaration and I don't see EYLEA4U or copays 4 discussed anywhere, so I -- I'm -- 5 A. Yeah. I -- I don't dispute that. 6 I -- I would want to look at it again to make 7 sure. But they are -- it is of the sort of thing 8 that I considered and concluded that it was not. 9 Q. Well, if you considered it, why is it 10 not discussed in your -- your declarations in 11 these matters? 12 A. Well, it is discussed in the sense that 13 Section 10 discusses issues such as discounts and 14 rebate programs such as sampling, other ways that 15 might be thought of that someone might think of 16 as assisting patients in a similar way -- in the 17 same way that a copay assistance program might. 18 But I -- sorry. Just a moment. 19 So in Attachment D1, Page 171 of 289, 20 there is a line for Eylea copay assistance. 21 So they are considered. I did not discuss them 22 specifically, but they are -- I -- I was aware of 23 them and they are in the report. But I do not 24 believe -- did not believe and do not believe 25 that they, to the exclusion of the patented	Page 56 1 Q. Have you ever heard of the term "field 2 support team"? 3 A. I've heard of similar terms. It could 4 mean different things. So I'd like to know what 5 you mean by it. 6 Q. What's your understanding of a -- a 7 field support team? 8 A. It could be any number of things: Sales 9 representatives. It could be physicians who 10 speak with other physicians about issues that 11 arise. It could be, you know, people who help 12 patients with questions they have. I would want 13 to know spe -- it could mean a number of 14 different things. 15 Q. Are you aware that Regeneron has sales 16 representatives for Eylea? 17 A. Yes. 18 Q. And do you discuss Regeneron sales 19 representatives at all in your declarations? 20 A. To the extent that they are part of the 21 "people expenses," they would have been included 22 in -- in that part of the marketing effort. I 23 don't know that I specifically identify sales 24 reps in the report. I -- I'd have to go back and 25 look.
Page 55 1 features, are the source of Eylea's commercial 2 success. 3 Q. Okay. And just so I'm clear, Exhibit 4 -- Page 171 of Exhibit 2059, rebates are a 5 separate line item from copays, correct? 6 A. Yes. 7 Q. And chargebacks are a separate line item 8 from copays? 9 A. Yes. 10 Q. And discounts are a separate line item 11 from copays? 12 A. Yes. 13 Q. But in the -- the text of your reports 14 or your declarations in these matters, you 15 haven't discussed copay assistance available for 16 Eylea, have you? 17 A. I would accept your representation with 18 the proviso that I'd want to go back and verify 19 it. 20 Q. Are you -- 21 A. Because it was not important -- it was 22 not important enough to address specifically. 23 Q. Are you aware Regeneron has a field 24 support team for Eylea? 25 A. What do you mean by field support team?	Page 57 1 Q. Do you know how much Regeneron spends on 2 sales reps for Eylea? 3 A. Not specifically, no. I know they're 4 -- I know the total reported people expenditures 5 for -- in the Eylea P&L that was produced. 6 Q. Do you know if that line item 7 incorporate -- includes sales representatives? 8 A. My understanding is that it does. 9 Q. In your Exhibit 2058 and 2059 10 declaration, you don't discuss the pending 11 litigation between the United States and 12 Regeneron concerning the Chronic Disease Fund, 13 do you? 14 A. I do not. 15 Q. But when you prepared your Exhibit 2059 16 declaration -- or 2058 declarations in these 17 matters, you're aware -- you were aware of the 18 -- the litigation concerning the CDF between U.S. 19 and Regeneron, correct? 20 A. Yes. 21 Q. And your declarations do not address any 22 of that information for the CDF litigations, 23 correct? 24 A. They do not. 25 Q. Why didn't you think it was important to

15 (Pages 54 - 57)

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Mylan Exhibit 1121

Mylan v. Regeneron, IPR2022-01225

Page 15

Samsung Bioepis Exhibit 1075

Page 15

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Page 58 1 address the -- the pending litigation between the 2 U.S. and Regeneron? 3 A. Well, I did testify about -- I did 4 in the District Court litigation, I provided a 5 supplemental report and a supplemental deposition 6 on -- about documents that were produced in that 7 litigation as a result of that -- of that -- just 8 of the -- the CDF litigation -- the CDF case. 9 It didn't -- it was not -- I was not at 10 issue here. I -- I understood it was part of a 11 different proceeding. 12 Q. Well, you're aware that in the '338 13 patent -- '338 patent IPR proceeding, Mylan's 14 commercial success expert, Mr. Hoffman, offered 15 opinions concerning the CDF litigation, correct? 16 A. He did mention them. He didn't provide 17 detailed analysis. 18 Q. And when you prepared your Exhibit 2058 19 declarations in these IPRs for the '601 and '681 20 patents, you were aware of the CDF litigation, 21 correct? 22 A. I was. 23 Q. But you have not addressed it in your 24 declarations, correct? 25 A. I have not.	Page 60 1 declaration, your -- your '338 patent IPR 2 declaration. In that declaration, you assigned 3 Eylea's commercial success to the '338 patent and 4 patent claims, correct? 5 A. I assigned it to the eight-week dosing 6 interval that I understood was reflective of the 7 '338 patent. 8 Q. So you -- you identified the '338 patent 9 as having commercial success, correct? 10 A. I identified Eylea as having commercial 11 success, and I identified a nexus between the 12 patented features of '338 -- the patented 13 features of the product as reflected in patent 14 '338 and the product. 15 Q. What are those patented features you're 16 referring to? 17 A. The eight-week dosing interval. 18 Q. So you identified the 3 -- the 19 eight-week dosing patent interval as the patented 20 feature for the '338 patent, correct? 21 A. So that sounds like you're asking a 22 legal question. I did not reach a legal 23 conclusion. I relied upon the technical expert 24 to provide that. The -- what I did is I 25 evaluated the product, from an economic
Page 59 1 Q. Do you think it's not important for the 2 PTAB to have that information? 3 MR. CAINE: Objection; form. 4 THE WITNESS: To -- to have what 5 information? I don't -- what do you mean? 6 BY MR. MARX: 7 Q. Well, you haven't mentioned at all in 8 your declarations that Regeneron is involved in 9 litigation concerning copay support with the 10 United States, correct? 11 A. That's correct. 12 Q. And do you think that information isn't 13 relevant to your opinions in this matter? 14 A. As I said, I testified to that point in 15 a different matter, and my testimony there was 16 that it did not -- it did not change my opinion. 17 Q. But you haven't provided any testimony 18 in your Exhibit 2059 declarations about the CDF 19 litigation, correct? 20 A. That's correct. I did not know about 21 the CDF litigation when I prepared Exhibit 2059. 22 Q. But you did know about it for your 2058 23 declaration and didn't discuss it, correct? 24 A. That's correct. 25 Q. If we could focus on your Exhibit 2059	Page 61 1 perspective, on the drivers of success and took 2 the -- the technical expert's opinion about the 3 patented feature of being related to the 4 eight-week dosing being related to the '338 5 patent. 6 Q. So do you agree that for purposes of 7 your Exhibit 2058 declarations for the '601 8 patent and '681 patent, the -- your opinions for 9 the '338 patent, they relate to the same fixed 10 eight-week dosing schedule? 11 MR. CAINE: Objection; form. 12 THE WITNESS: The same eight-week dosing 13 schedule, yes. 14 BY MR. MARX: 15 Q. And it's your opinion that the primary 16 driver for Eylea sales that you're focusing on 17 for the '601 and '681 patents is the fixed 18 eight-week dosing interval? 19 MR. CAINE: Objection; form. 20 THE WITNESS: As I've said in -- in 21 the declarations, the -- my opinion is that the 22 eight-week dosing schedule has a nexus between 23 the product's commercial success -- or there is a 24 nexus between the product's commercial success 25 and its eight-week dosing schedule, which is

16 (Pages 58 - 61)

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Mylan Exhibit 1121

Mylan v. Regeneron, IPR2022-01225

Page 16

Samsung Bioepis Exhibit 1075

Page 16

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Page 62 1 reflected in the patents at issue. 2 BY MR. MARX: 3 Q. Are there any other factors driving 4 sales of Eylea? 5 A. There may be. I -- I've evaluated -- my 6 opinion is focused here on identifying a nexus 7 between the eight-week dosing schedule and the 8 product's commercial success. 9 Q. Well, you've identified safety and 10 efficacy as factors driving Eylea's sales, 11 correct? 12 A. In the West Virginia lit -- litigation 13 where there is a formulation patent that I took 14 to reflect safety and efficacy, I did have an 15 opinion about it in that matter. But I 16 understand that question is not at issue here. 17 Q. Well, you haven't -- well, do you 18 believe that safety and efficacy is driving sales 19 of Eylea? 20 A. Well, recognizing that that's not the 21 question for this matter, I do believe that 22 safety and efficacy matter, yes. 23 Q. And do you believe that the formulation 24 for Eylea drives sales of Eylea? 25 A. I would refer you to that litigation	Page 64 1 A. That is not one of the patented features 2 at -- before the PTAB in this -- in this 3 matter, -- 4 Q. Correct. 5 A. -- so I did not. 6 Q. You didn't think it was important to 7 -- to tell the PTAB that you've attributed some 8 of Eylea's commercial success to safety and 9 efficacy? 10 MR. CAINE: Objection; form. 11 THE WITNESS: Well, I'm hanging up on 12 your saying "some of." I mean, that implies some 13 apportionment or some or allocation of success to 14 different elements, and that's not at issue in a 15 commercial success analysis. That might be at 16 issue for other kinds of analyses, but it is not 17 at issue for commercial success. 18 So that's not the question they are 19 deciding, and it is not relevant to this matter, 20 as far as I understand. 21 BY MR. MARX: 22 Q. Well, why isn't it important -- well, 23 why isn't it important that you've opined Eylea's 24 sales are due to safety and efficacy in these 25 matters?
Page 63 1 for that. I mean, what -- what you mean by do I 2 believe formulation matters, I would go back to 3 the experts in that case who draw the link, 4 Dr. Psaki [phonetic], I believe his name is said, 5 but I could be saying that incorrectly -- no, I'm 6 sorry, Dr. Trout -- Dr. Trout draws that link in 7 that matter. And relying on Dr. Trout's opinion, 8 that's where I got a link between the patents at 9 issue there -- patent at issue there and the 10 commercial success of the product. 11 Q. Correct. So in the West Virginia 12 litigation, you've attributed some of Eylea's 13 commercial success to the formulation, correct? 14 A. As I have said, in interpreting 15 Dr. Trout's equation of the formulation to the 16 safety and efficacy of the product, yes. 17 Q. And you haven't told the PTAB here with 18 respect to the '601 and '681 patents that you've 19 assigned value to Eylea's safety and efficacy, 20 have you? 21 A. I've not assigned value. I've not 22 determined values of any feature. 23 Q. Well, you didn't inform the PTAB that -- 24 that you've opined that safety and el -- efficacy 25 drive Eylea sales, have -- did you?	Page 65 1 MR. CAINE: Objection; form. 2 THE WITNESS: I'm sorry. Ask again, 3 please. 4 BY MR. MARX: 5 Q. Sure. In these pending IPRs for the 6 '601 and '681 patent, why isn't it important that 7 you've opined that safety and efficacy is 8 responsible for Eylea sales? 9 A. Well, I haven't opined that it is 10 entirely responsible for Eylea sales. I have 11 opined that safety and efficacy also contribute, 12 so does the eight-week dosing interval. And this 13 matter concerns the eight-week dosing interval. 14 And that is the question before the panel, and 15 that is the question that I addressed. I did not 16 address questions that were not before the panel. 17 Q. Right. So you don't -- you don't think 18 it's important for the PTAB to know that some of 19 Eylea's sales, in your opinion, are related to 20 safety and efficacy? 21 MR. CAINE: Objection; form. 22 THE WITNESS: That's a legal issue. 23 I -- I -- I don't have an opinion about what is 24 or isn't important for them to know as they 25 evaluate the case. I -- I have a -- my

17 (Pages 62 - 65)

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Mylan Exhibit 1121

Mylan v. Regeneron, IPR2022-01225

Page 17

Samsung Bioepis Exhibit 1075

Page 17

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Page 66 1 assignment is to evaluate whether or not the 2 patented feature here, the eight-week dosing 3 interval, has a nexus to the commercial success 4 of the product. 5 BY MR. MARX: 6 Q. But you admit that in the patent 7 litigation, you've opined that Eylea's commercial 8 success may be due to safety and efficacy, 9 correct? 10 A. In part, but not to the exclusion of the 11 dosing frequency or the dosing interval. 12 Q. So is it your opinion the dosing 13 interval is the primary driver of Eylea sales? 14 A. So that suggests that I've done some 15 kind of ranking, and I have not. So I don't 16 have a ranking of what is more important or less 17 important. I have an opinion that there is a 18 nexus between the eight-week dosing interval and 19 the product's commercial success. 20 Q. Well, is the dosing interval in the top 21 five drivers for Eylea sales? 22 A. Again, that assumes or -- or suggests 23 that I've done some kind of ranking, and I have 24 not done that, so I can't tell you. 25 Q. Okay. So is it your opinions that	Page 68 1 the '338 declaration, and I simply wanted to be 2 complete in my answer. And so I told you that I 3 had discussed in the '338 declaration that there 4 was some evidence of -- in some settings, of 5 superior patient outcomes for patients using 6 Eylea as opposed to Avastin -- or, sorry, 7 Lucentis. And so to be complete in my answer, I 8 didn't want to omit the fact that there was that 9 discussion of an efficacy-related factor to the 10 data that were not analyzed in that -- in that 11 report -- in that declaration. 12 BY MR. MARX: 13 Q. So if I understand correctly, the 14 safety and efficacy that you offered opinions on 15 in the West Virginia litigation as relevant to 16 commercial success, in your opinion, aren't 17 relevant to the '601 and '681 patents? 18 A. Again, I -- I don't have an opinion 19 about the legal relevance of various issues. 20 I'll leave that to the lawyers to discuss and the 21 PTAB members to determine. 22 My opinion is related in this matter to 23 the link between the eight-week dosing interval 24 and the product's commercial success. 25 Q. Okay. And in the West Virginia
Page 67 1 Eylea's commercial success is due to safety and 2 efficacy and dosing and various other factors as 3 well? 4 A. For this matter, my concern is whether 5 the eight-week dosing feature is a driver of 6 commercial success, and I believe it is. 7 Q. And in the West Virginia litigation, 8 you've opined that safety and efficacy is a 9 feature -- oh, safety and efficacy is a driver 10 of commercial success, correct? 11 A. Because there is a patent at issue in 12 that matter where -- that I understand to be 13 related to safety and efficacy, and I do believe 14 safety and efficacy do contribute, though not at 15 issue in this matter. 16 Q. Well, you mentioned efficacy earlier 17 today, didn't you? 18 A. I did. 19 Q. So is it your opinion efficacy is a part 20 of the '601 and '681 patents? 21 MR. CAINE: Objection; form. 22 THE WITNESS: I -- I discussed efficacy 23 in terms of what the -- you had asked me whether 24 or not I had expressed any opinions outside the 25 question of the eight-week dosing interval in	Page 69 1 litigation, you've drawn a link between safety 2 and efficacy and eylea's commercial success, 3 correct? 4 A. I've drawn a link between the patent 5 that is identified by Dr. Trout as related to 6 safety and efficacy and the product's commercial 7 success. 8 Q. And that patent, is that the '865 9 patent, if you recall? 10 A. That sounds right, but to tell you the 11 truth I'd want to go make sure. 12 Q. So in the West Virginia litigation, 13 you've attributed some of Eylea's commercial 14 success to the '865 patent, correct? 15 A. I testified in that case that there was 16 a nexus between the features of that patent and 17 its commercial success. 18 Q. Do you have any opinion whether the 19 aspects of the aflibercept molecule are driving 20 sales of Eylea? 21 A. Well, beyond the fact that aflibercept 22 is the active ingredient of Eylea, no. 23 Q. Do you have any opinion whether a 24 indication is on-label or off-label is driving 25 sales of Eylea?

18 (Pages 66 - 69)

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Mylan Exhibit 1121

Mylan v. Regeneron, IPR2022-01225

Page 18

Samsung Bioepis Exhibit 1075

Page 18

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Page 70 1 A. Well, I guess, you know, I'm -- on-label 2 and off-label utilization is a -- a complicated 3 subject. I do know something about it based on 4 my experience, other than I'm not a regulatory 5 expert and so -- not that I don't know anything 6 about the regulatory process, but I do think it 7 matters that a -- that a -- a product is approved 8 by the FDA for specific uses or not. But I guess 9 I would want to know much more specifically 10 about, you know, what the question is before I 11 said whether -- how it might relate to Eylea. 12 Q. Sure, well, you're familiar with 13 insurance coverage, correct? 14 A. Sure. 15 Q. Sure. 16 And insurance companies can't force 17 doctors to use a product that's off label, 18 correct? 19 A. I don't think insurance companies can 20 force doctors to do anything. 21 Q. Well, insurance companies can't -- can't 22 provide guidance to doctors to use a product that 23 is off label, correct? 24 A. I don't agree with that. 25 Q. Why don't you agree?	Page 72 1 A. Well, prior art is a legal concept. 2 I don't really know what you mean there. 3 Q. Is it fair to say that in offering your 4 opinions in your '601 and '681 declarations in 5 this matter regarding Eylea's commercial success, 6 you didn't differentiate -- or you didn't exclude 7 factors that were already known in the prior art, 8 did you? 9 A. Again, you're asking about prior art 10 as though it were an economic concept, and it is 11 not. It's a legal concept. And -- and you're 12 asking about excluding factors which sounds like 13 an apportionment issue to me, not part of the 14 analysis that I did. 15 Q. If we could go to your Exhibit 2058 16 declaration. If you could go to Paragraph 12. 17 Let me know when you're there. 18 A. Yes. 19 Q. You used the term "novel" in that 20 paragraph, correct? 21 A. "Substitution towards the novel product 22 or method away from alternative products or 23 methods," yes. 24 Q. And then again at the end of the 25 sentence you used the term "novel product"?
Page 71 1 A. Because I'm aware of cases in which 2 insurance companies place off-label indication 3 -- or products with off-label indications on more 4 favorable -- in more favorable coverage status 5 than products that are indicated for a specific 6 use. 7 Q. Dr. Manning, we've been discussing the 8 eight-week dosing interval as a driver of Eylea 9 sales. That's your opinion in this matter, 10 correct? 11 A. What's my opinion? I don't -- I didn't 12 hear a question. 13 Q. That the eight-week dosing interval 14 drives Eylea sales. 15 A. My opinion is that the eight-week dosing 16 interval is a contributor to Eylea's commercial 17 success. 18 Q. But do you have any opinions whether 19 it's the primary contributor to Eylea's success? 20 A. As I said a couple times already, the 21 -- that suggests a ranking of various factors 22 that I did not do. 23 Q. Have you investigated at all whether the 24 eight-week dosing interval was known in the prior 25 art?	Page 73 1 A. And other economic indicators as 2 evidence of commercial success of a novel 3 product, yes. 4 Q. What does the term "novel" mean in that 5 paragraph? What are you referring to? 6 A. Something that I guess another way to 7 say it is new -- new product. 8 Q. Well, with -- if something is known in 9 the prior art, is it new? 10 A. That's a legal question. 11 Q. You don't have any opinion whether 12 something that is known in the prior art isn't 13 new? 14 A. Not as a matter of legality. I'm not a 15 patent lawyer. 16 Q. So in your offering your commercial 17 success opinions in these pending IPRs, you 18 didn't exclude any things that were not new, did 19 you? 20 MR. CAINE: Objection; form. 21 THE WITNESS: I don't understand the 22 question. I'm sorry. I didn't exclude anything 23 that was not new. That's pretty broad. Can you 24 be more specific? 25 BY MR. MARX:

19 (Pages 70 - 73)

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Mylan Exhibit 1121

Mylan v. Regeneron, IPR2022-01225

Page 19

Samsung Bioepis Exhibit 1075

Page 19

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Page 74 1 Q. Did you talk to Dr. Do at all whether 2 the eight-week dosing interval for Eylea was 3 something already known by clinicians? 4 MR. CAINE: Objection; form. 5 THE WITNESS: For this matter or for the 6 '338? 7 BY MR. MARX: 8 Q. For both. 9 A. I did not speak to Dr. Do in preparing 10 the most recent report or declarations. I did 11 have a conversation with her some time ago now in 12 preparing the '338 declaration. My recollection 13 is that she talked about the eight-week dosing 14 interval being something new, something 15 contributing -- something important in the 16 treatment of these angiogenic eye disorders. My 17 recollection is also that Dr. Brown talks at some 18 extent about the eight-week dosing -- dosing 19 interval being something that -- that made an 20 important contribution to the treatment of these 21 disorders. 22 So I did talk to and read about those 23 experts' opinions that the eight-week dosing 24 interval was -- that was available with Eylea was 25 important and new.	Page 76 1 BY MR. MARX: 2 Q. Well, let's go to Paragraph 13 of your 3 Exhibit 2058 declarations. 4 A. Okay. 5 Q. And do you see in the last sentence 6 of that paragraph you state, in part, the '681 7 patent claims a priority date of January 13th, 8 2011. Do you see that? 9 A. I do. 10 Q. So you didn't exclude anything that may 11 have been known prior to January 13th, 2011, from 12 your commercial success opinions in these pending 13 IPRs, did you? 14 MR. CAINE: Objection; form. 15 THE WITNESS: Again, I -- those -- I 16 mean, things that might have been known aren't 17 economic things that are sold -- sold in the 18 marketplace. So they were not something that I 19 could analyze. They were -- those are legal 20 questions. They're not economic questions. 21 BY MR. MARX: 22 Q. Well, how can a patented feature drive 23 sales if it was already known? 24 A. That's -- whether it's patentable or 25 not is a legal question, and that's not my
Page 75 1 Q. And the fact that the eight-week dosing 2 interval for Eylea was important and new, is that 3 relevant in your commercial success opinions 4 here? 5 A. To the extent that it -- it provides a 6 differentiating factor for Eylea, yes. 7 Q. Would it change your opinions if Eylea 8 -- the eight-week dosing schedule for Eylea is 9 not new? 10 A. I don't understand the question. 11 Q. Sure. Well, in your commercial success 12 opinions for the '601 and '681 patents here, you 13 haven't excluded anything that was known prior to 14 the priority date for the '601 and '681 patents, 15 have you? 16 MR. CAINE: Objection; form. 17 THE WITNESS: Again, those are legal 18 questions about what priority dates were and when 19 what things were known or not known. What I 20 observed is that there was a product that was 21 new. And that product, as I take from the 22 medical experts and technical experts, presents 23 a novel feature compared to the other products 24 that were available at the time; and that that 25 product exhibits substantial commercial success.	Page 77 1 assignment. 2 MR. MARX: I'm going to have the court 3 reporter mark as Manning Exhibit 102 -- it's a 4 copy of the Patent Trial and Appeal Board's final 5 written decision in IPR 2021-881 for the '338 6 patent. 7 (Manning Exhibit No. 102, a copy of the 8 Patent Trial and Appeal Board's final written 9 decision in IPR 2021-881 for the '338 patent, was 10 introduced.) 11 BY MR. MARX: 12 Q. Dr. Manning, have you seen this document 13 before? 14 A. I don't believe I have. 15 Q. Are you aware that in Manning Exhibit 16 102 the Patent Trial and Appeal Board determined 17 that the claims for the '338 patent were 18 unpatentable? 19 A. I have heard that the -- that that was 20 -- I've heard something associated with the 21 -- with that fact or that outcome. But I also 22 understood that it was subject to appeal and on 23 appeal. 24 Q. So is the PTAB's findings that the '338 25 patent claims were unpatentable relevant to your

20 (Pages 74 - 77)

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Mylan Exhibit 1121

Mylan v. Regeneron, IPR2022-01225

Page 20

Samsung Bioepis Exhibit 1075

Page 20

Page 78 1 commercial success opinions? 2 A. Again, that's a legal question. I don't 3 know whether, you know, the finality -- I don't 4 know the finality of this finding. I don't know 5 the status of the appeal. I don't know the 6 technical legal implications of the outcome in 7 that matter and how it relates to the outcomes in 8 this matter. 9 Q. Well, here we're back before the Patent 10 Trial and Appeal Board, correct? 11 A. We are. 12 Q. And Manning Exhibit 102 is the same 13 Patent Trial and Appeal Board's decision that the 14 '338 patent claims were unpatentable, correct? 15 A. I'll take your representation of that. 16 Q. And you didn't find the Manning Exhibit 17 102 relevant to your commercial success opinions 18 for the '601 and '681 patents? 19 A. No. 20 Q. I'm going to hand you what is Paper 21 21 in the 1225 patent IPR. It's the Patent Trial 22 and Appeal Board's decision granting institution 23 of inter partes review. 24 And, Dr. Manning, you reviewed this 25 document when you prepared your Exhibit 2058	Page 80 1 with the exception of the exclusion criteria 2 limitation, which petitioner has credibly 3 demonstrated is likely to be nonlimiting upon 4 the claims under the Printed Matter Doctrine." 5 Do you see that? 6 A. I do. 7 Q. And so here the PTAB is saying that the 8 '681 patent challenge claims are substantially 9 similar to the '338 patent claims, correct? 10 A. I don't know what they mean by that. 11 I'm not an attorney. 12 Q. But you reviewed this document when you 13 prepared your Exhibit 2058 declaration, correct? 14 A. As I said, I -- I'm not an attorney. 15 This is a legal document. And I didn't -- don't 16 form an opinion based on -- I don't form an 17 opinion about what that means. 18 Q. But this document, Paper 21, is cited in 19 your Exhibit 2058 declarations, correct? 20 A. Yes, it is. 21 Q. And so you would have reviewed this then 22 in preparing your Exhibit 2058 declarations? 23 A. But I wouldn't have formed an opinion 24 about it. 25 Q. But you would have been aware that the
Page 79 1 declaration, correct? That's cited in Footnote 2 13. 3 A. Yes. It is cited into -- in -- in 4 Footnote 13. 5 Q. So you reviewed this preparing your 6 Exhibit 2058 declarations, correct? 7 A. So I would have looked at it. It is a 8 legal issue and not part of my economic analysis, 9 but I recognize that it has relevance for 10 completeness. 11 Q. So it's not part of your economic 12 analysis -- what do you mean by it's not part of 13 your economic analysis? 14 A. I mean the legal conclusions are legal 15 issues. I don't see anything here that says that 16 my analysis is unsound or not correct. 17 Q. If you could go to Page 27 in Paper 21, 18 the PTAB's institution decision? 19 A. Mm-hmm. 20 Q. And the first full paragraph there, 21 the introductory sentence, in part, reads, In 22 short, we concluded in the '881 decision that all 23 limitations of the claim as substantially similar 24 to the present challenged Claim 1" -- referring 25 to the '681 patent Claim 1 -- "are unpatentable,	Page 81 1 PTAB has said that the '681 patent claims are, 2 quote, substantially similar, unquote, to the 3 '681 patent claims, correct, or that the '68 4 -- let me rephrase that. I'm sorry. 5 You would have been aware that the 6 PTAB said that the '681 patent claims are, quote, 7 substantially similar, closed quote, to the '338 8 patent claims, correct? 9 A. No. 10 Q. Why not? 11 A. Because those are legal concepts that I 12 am not expert in and not qualified to opine 13 about. 14 Q. So you wouldn't have read this portion 15 of the PTAB's institution decision? 16 A. Whether I did or not, I don't have a 17 clear memory, but I would have thought of this as 18 not directly relevant to my analysis. 19 Q. Why is this not relevant to your 20 analysis? 21 A. Because it's a legal document. 22 Q. But you're offering opinions with 23 respect to the '601 and '681 patents that Eylea 24 sales are due to an eight-week dosing schedule, 25 correct?

21 (Pages 78 - 81)

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Mylan Exhibit 1121

Mylan v. Regeneron, IPR2022-01225

Page 21

Samsung Bioepis Exhibit 1075

Page 21

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Page 82 1 A. I am. 2 Q. And it does -- doesn't change your 3 opinions that the PTAB found the eight-week 4 dosing schedule was known in the prior art, does 5 it? 6 MR. CAINE: Objection; form. 7 THE WITNESS: I don't know that this 8 says that. 9 BY MR. MARX: 10 Q. Well, we looked at the final written 11 decision for the '338 patent that was Exhibit 12 102, correct? 13 A. We did look at it. 14 Q. And the PTAB there said the '338 patent 15 claims are unpatentable, correct? 16 A. Again, you're talking about legal 17 issues that are not my area of expertise or 18 qualification. 19 Q. So is it correct, then, you haven't 20 considered whether claim limitations are in the 21 prior art in issuing your commercial success 22 opinions for the '601 and '681 patents? 23 A. It is true that I have not considered 24 legal issues in doing my evaluation. 25 Q. And one of those legal issues is whether	Page 84 1 in that matter. That was the first I had heard 2 of them. 3 Q. And do you see the -- the second bullet 4 on this page states "Regeneron accepts summary 5 judgment of invalidity of Claims 5 through 6 and 6 9 of U.S. Patent Number 10,888,601"? 7 A. I do. 8 Q. And are you aware that the '601 patent 9 Claims 5, 3, 6 and 9 are part of the challenge 10 claims in your Exhibit 2058 declaration? 11 A. I understand that that -- that -- I 12 guess if you want to go back and review and make 13 sure that they are, but I -- I accept that as a 14 -- as a representation. 15 Q. Well, sure. Go to Paragraph 18 of 16 Exhibit 2058. 17 A. Yes. 18 Q. And here you state the claims of the 19 '601 patent that are at issue, and those include 20 Claims 5 through 6 and 9, correct? 21 A. It does include Claims 5 through 9 which 22 would encompass 5 through 6 and 9, yes. 23 Q. And in Manning Exhibit 103, Regeneron 24 stipulated that Claims 5 through 6 and 9 are 25 invalid, correct?
Page 83 1 something's in the prior art, correct? 2 A. I think I've said that a couple of 3 times, but, yes, a legal determination is beyond 4 my analysis. 5 Q. I'm going to have the court reporter 6 mark as Manning Exhibit 103 a copy of Regeneron's 7 April 26th stipulation filed in the pending West 8 Virginia litigation. 9 (Manning Exhibit No. 103, a copy of 10 Regeneron's April 26th stipulation filed in the 11 pending West Virginia litigation, was 12 introduced.) 13 BY MR. MARX: 14 Q. Do you have a copy of that in front of 15 you, Dr. Manning? 16 A. I do. 17 Q. Have you seen this document before? 18 A. I -- I'm aware of the stipulations. 19 I -- I'm not certain I've seen this -- this 20 document per se, but I'm aware that there were 21 stipulations in that case. I don't remember 22 seeing this specific document as I sit here. 23 Q. How did you become aware of the 24 stipulations in the case? 25 A. Mr. Hoffman mentioned them in his report	Page 85 1 A. I also note that it says "Subject to all 2 appellate rights including but not limited to 3 rights of appeal concerning claim construction." 4 So all of this seems to me to be legal 5 proceedings that are apart from my economic 6 analysis. 7 Q. So Regeneron's stipulation in Manning 8 Exhibit 103 doesn't change your opinions in these 9 pending IPRs? 10 A. It does not. 11 Q. That Regeneron stipulated that the 12 eight-week dosing schedule was already known by 13 clinicians before the '601 and '681 patents 14 doesn't change your opinions in these IPRs, does 15 it? 16 A. Again, I'm not sure that that is the 17 proper reading. Again, I'm not a lawyer. 18 Q. Sitting here today, in the '601 and '681 19 patents, can you pinpoint any claim element that 20 drives sales of Eylea that's different from the 21 dosing schedule in the '338 patent? 22 A. As I've said, I do not do a 23 claim-by-claim analysis. That is something for 24 someone else to do. And so I -- I don't point to 25 any specific claim elements in my analysis.

22 (Pages 82 - 85)

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Mylan Exhibit 1121

Mylan v. Regeneron, IPR2022-01225

Page 22

Samsung Bioepis Exhibit 1075

Page 22

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Page 86 1 Q. And your analysis that you're referring 2 to is based on your opinions that the '338 patent 3 -- well, let me rephrase that. Your analysis 4 that you're referring to is based on your 5 opinions that the dosing schedule in the 6 '338 patent drove sales of Eylea, correct? 7 A. My opinion is that the dosing schedule, 8 and I rely upon the medical experts to tell me 9 that dosing schedule is tied to the claims of the 10 '338 patent, drives success of the product. 11 Q. And those same opinions that the dosing 12 schedule is tied to the claims of the '338 patent 13 and drives sales is the same opinion you're 14 offering for the '601 and '681 patents, correct? 15 A. Yes. 16 Q. If we could go to Paragraph 15 of your 17 Exhibit 2058 declaration. And in Paragraph 15 18 you recite the 22 claims of the '608 -- '681 19 patent are under review in the 22 -- -1225 IPR 20 proceeding. Do you see that? 21 A. I do. 22 Q. Did you do anything to confirm that each 23 sale of Eylea that you're relying on actually 24 falls within the scope of the '681 patent claims? 25 A. I did not.	Page 88 1 determinant of use. 2 Q. You say "most common." You don't 3 disagree that the eight-week dosing schedule is 4 not the majority of dosing that clinicians use, 5 correct? 6 MR. CAINE: Objection; form. 7 THE WITNESS: If you add up all of the 8 other -- I mean, it -- it is the plurality. It 9 is not the majority, based on my recollection of 10 the data that I reviewed. But it is clearly the 11 most common of the various dosing schedules or 12 dosing periods. 13 BY MR. MARX: 14 Q. But you don't have any data confirming 15 that Eylea sales were used according to the 16 specific dosing regimen that's in the claims, 17 correct? 18 MR. CAINE: Objection; form. 19 THE WITNESS: Again, I do not -- my -- I 20 do not do a claim-by-claim analysis. My analysis 21 is reliant upon Dr. Do's drawing the link between 22 the claims and the eight-week dosing interval, so 23 I do not do a claim-by-claim analysis. 24 BY MR. MARX: 25 Q. Okay. I'm going to hand you what's
Page 87 1 Q. Have you seen any analysis from 2 Regeneron's technical experts confirming that the 3 sales of Eylea that you're relying on actually 4 fall within the scope of the claims? 5 A. So my reliance on Dr. Do's linking the 6 claims of the patent -- so I rely on Dr. Do's 7 analysis of the claims linking those claims to 8 the eight-week dosing interval of the product. 9 Q. But Dr. Do hasn't offered any opinions 10 confirming that Eylea sales actually fall within 11 the scope of the claims, correct? 12 A. I don't know the extent of the total 13 -- total -- totality of what Dr. Do might have 14 said. I don't have any recollection of seeing 15 her say that. 16 Q. Have you seen any surveys or other data 17 confirming that Eylea sales were actually used 18 according to the dosing regimens in the '601 and 19 '681 patent claims? 20 A. There is quite a bit of evidence, as 21 discussed in the '338 declaration, that the 22 eight-week dosing interval is important to 23 physicians in choosing Eylea as a product; that 24 it is the most common of the dosing intervals for 25 Eylea, and there -- that it's an important	Page 89 1 Exhibit 1001 in the 1225 IPR. 2 (Previously marked Exhibit No. 1001 to 3 the '681 Patent to the 1225 IPR was introduced.) 4 MR. MARX: This is a copy of the '681 5 patent. 6 BY MR. MARX: 7 Q. And, Dr. Manning, if you could go to 8 Claim 7 in the '681 patent. Let me know when 9 you're there. It's on Page 14. 10 A. Uh-huh. I'm there. 11 Q. And do you see that Claim 7 limits the 12 angiogenic eye disorder to age-related macular 13 degeneration? 14 A. I see that it says, "Method of Claim 6 15 wherein the angiogenic eye disorder is 16 age-related macular degeneration." 17 Q. Is it okay if I abbreviate age-related 18 macular degeneration to AMD? 19 A. Sure. 20 Q. Did you do any analysis to determine 21 how many Eylea sales are attributable to the 22 treatment of AMD? 23 A. There are, within the ATU surveys and 24 the Vestrum data that I used for the '338 report 25 -- declaration breakdowns of product utilization

23 (Pages 86 - 89)

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Mylan Exhibit 1121

Mylan v. Regeneron, IPR2022-01225

Page 23

Samsung Bioepis Exhibit 1075

Page 23

Page 90 1 by therapeutic area. And I have in my report 2 -- sorry, in my declaration, a table that shows a 3 sample of how the utilization of the products 4 break down across indications. AMD is one of 5 those indications, and so there are -- those data 6 are reflected in my analysis. 7 Q. What table are you referring to in, I 8 assume, your Exhibit 2059, the '338 patent IPR 9 declaration? 10 A. Yes. Table 1 on Page 20 shows for 11 2021 the total injections by four -- for four 12 different indications or diseases; wet AMD being 13 the most common; DME being about █ percent; 14 DR, diabetic retinopathy, being about 15 █ percent; and retinal vein 16 occlusion being about █ percent. 17 There are also in the pending -- in the 18 attachments measures of utilization by similar 19 -- by those same indications. 20 Q. And so Table 1 here -- it's Page 26 of 21 Exhibit 2059, Page Number 20 of your declaration 22 -- that Table 1, that's with respect to Anti-VEGF 23 injections generally, not specific to Eylea, 24 correct? 25 A. Yes, that's -- that's correct. But	Page 92 1 don't understand the question. What -- what do 2 you mean? I mean, beyond what I've just shown 3 you, what -- what do you mean? 4 Q. Well, you haven't done any calculations 5 saying that a certain percentage of Eylea sales 6 are related to the treatment of AMD, have you? 7 A. Well, those -- that -- X1 shows you the 8 sales share in the Vestrum data of each product 9 by utilization. So wet AMD and the charts that 10 are accompanying show the sales share of Eylea 11 for the various indications. 12 Q. But you haven't done any calculations 13 for the number of Eylea sales that are related to 14 the treatment of AMD, have you? 15 MR. CAINE: Objection; form. 16 THE WITNESS: I guess I -- I still 17 don't -- I mean, the -- I have -- what -- I still 18 don't understand this -- the question, I guess. 19 Have I not shown in, for example, the 20 charts that are in Attachments C8, C9, C10, C7? 21 I guess I -- I think I have. I guess I'm not 22 understanding the question. 23 BY MR. MARX: 24 Q. And you haven't done any analysis that 25 these sales of Eylea were for the treatment of
Page 91 1 there are product-specific -- let me make sure I 2 find them so I don't misspeak. 3 So Attachment X1, for example, shows by 4 quarter Vestrum sales data shares by indication 5 for Avastin, Lucentis and Eylea and BEOVU for 6 limited data. 7 Q. Have you done that calculation in your 8 declarations in this matter on the number of 9 sales of Eylea that are related to the treatment 10 of AMD? 11 A. I'm sorry. What -- can you be more 12 specific? What -- what's the question again? 13 Q. Sure. Well, you were referring to 14 Table 1, -- 15 A. Mm-hmm. 16 Q. -- which is for Anti-VEGF treatments 17 generally, correct? 18 A. Yes, right. 19 Q. And your Attachment X1 provides some 20 additional data, correct? 21 A. Yes. 22 Q. And have you done any calculation 23 attributing sales of Eylea to the treatment of 24 wet AM -- or of AMD? 25 A. I -- I guess I don't under -- I still	Page 93 1 AMD and were used according to the dosing regimen 2 that's recited in these claims, have you? 3 A. Well, again, I have not done any 4 claim-specific analysis of anything. That's a 5 legal exercise that I don't do. 6 Q. And you don't know if doctors, in fact, 7 followed the claimed eight-week dosing schedule, 8 do you, for each of those Eylea sales? 9 A. I do know that Dr. Do opined that she 10 herself and other physicians do follow that 11 dosing schedule. 12 Q. But you -- you stated earlier that 13 eight-week dosing, in your opinion, is a 14 plurality but not the majority, correct? 15 A. From the data that are in -- are 16 referenced in my '338 report or declaration, 17 they are not the majority, but they are in the 18 neighborhood of █ percent of, if I'm remembering 19 correctly, of Eylea dosing. 20 Q. And you haven't, in your declarations, 21 even offered the opinions that, at █ percent of 22 Eylea sales, Eylea's still a commercial success? 23 You haven't offered that opinion, have you? 24 A. That, again, gets to a question of 25 apportionment that is not part of a commercial

24 (Pages 90 - 93)

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Mylan Exhibit 1121

Mylan v. Regeneron, IPR2022-01225

Page 24

Samsung Bioepis Exhibit 1075

Page 24

Page 94 1 success analysis. 2 Q. So you've done no apportionment with 3 respect to the '338 patent, '601 patent or '681 4 patent, correct? 5 A. That's correct. 6 Q. And if we could stay on Table 20 that 7 you identified -- or Table 1 that you identified 8 on Exhibit 2059 at Page 26, -- 9 A. Mm-hmm. 10 Q. -- you included there a, approximately, 11 [REDACTED] total injections for RVO, correct? 12 A. Yes. 13 Q. Are you aware that the dosing schedule 14 or the treatment interval for RVO is every four 15 weeks for -- on Eylea's label? 16 A. I am aware of that. 17 Q. And you've included those sales in your 18 commercial success opinions even though the 19 claims are limited to an eight-week dosing 20 schedule, correct? 21 A. That is correct, but it's also the case 22 that Dr. Do and other data suggests that the 23 eight-week dosing interval is used for RVO 24 frequently. 25 Q. But that would be an off-label use,	Page 96 1 Q. Well, looking here at your Table 2 that 2 you've identified, Eylea was approved for the 3 treatment of RVO in September 2012, correct? 4 A. Yes. 5 Q. And the label for Eylea provides a 6 treatment interval of four weeks for RVO, 7 correct? 8 A. That's my understanding, yes. But as I 9 said, Dr. Do and other data suggests that it is 10 used on an eight-week interval. 11 MR. CAINE: I think we've been going 12 more than an hour. Could we get to a point 13 shortly and take a break? 14 MR. MARX: Sure. Let me just finish up 15 one question. 16 MR. CAINE: Yep. 17 MR. MARX: We can go ahead and take a 18 break now. 19 THE VIDEOGRAPHER: We're going off the 20 record. This is the end of Media Unit 2. The 21 time is 11:39 a.m. 22 (Recess taken.) 23 THE VIDEOGRAPHER: We're back on the 24 record. This is the beginning of Media Unit 3. 25 The time is 11:50 a.m.
Page 95 1 correct? 2 A. It would be. 3 Q. And have you considered any off-label 4 use for the treatment of AMD, DME or DR without 5 DME? 6 A. Well, the Table 2 in my report show 7 -- sorry, in my declaration for the '338 patent 8 shows the dates on which various products were 9 approved for various indications, I believe. I'm 10 trying to find that. 11 Q. I think it's on Page 44 of Exhibit 2059. 12 A. No. 41 -- nope. Sorry. 38. 13 Q. Oh, right. I apologize. I'm referring 14 to the exhibit number in the bottom left-hand 15 corner -- 16 A. Okay. You're right. 17 Q. -- which is the exhibit that went with 18 it? 19 A. Okay. You're correct. 20 And so, for example -- let me go to it 21 again -- so diabetic retinopathy, or DR, Eylea 22 didn't get approval until May of 2019, but we do 23 show utilization of DR -- of Eylea for DR in 24 years prior to that. So that would apparently be 25 another off-label utilization. So --	Page 97 1 BY MR. MARX: 2 Q. Dr. Manning, before the break, do you 3 recall we were -- we briefly discussed RVO? 4 A. Mm-hmm. 5 Q. Do you agree that RVO -- on-label 6 treatment for the treatment of RVO with Eylea is 7 every four-week dosing? 8 A. Let me go to the label just to make 9 sure. I believe that's correct, but -- yeah. 10 That's what I have in Exhibit 2059, Page 152 of 11 289, the recommended dose for Eylea is two 12 milligrams administered by intravitreal injection 13 once every four weeks; approximately 25 days 14 monthly. 15 Q. Okay. And any treatment that is not 16 four weeks would be an off-label use of Eylea for 17 the treatment of RVO? 18 A. According to my understanding of the 19 label and what it means to be off-label, I 20 wouldn't disagree with that. 21 Q. And if you could turn to -- make sure I 22 get the right page number -- Page 76 of 289 in 23 Exhibit 2059. 24 A. Okay. 25 Q. I apologize. If you could turn to

25 (Pages 94 - 97)

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Mylan Exhibit 1121

Mylan v. Regeneron, IPR2022-01225

Page 25

Samsung Bioepis Exhibit 1075

Page 25

Page 98 1 Paragraph 69, which is on Page 84 of 289. 2 A. Okay. 3 Q. And it begins, "As shown in Chart 6, for 4 RVO." Do you see that? 5 A. Mm-hmm. I do. 6 Q. And on Page 85 you recite in part, 7 "Eylea's sale shares by the end of '21 -- 2021 8 were somewhere between 46 percent and [REDACTED] 9 percent." Do you see that? 10 A. I do. 11 Q. And that was for RVO? 12 A. Just making sure that -- yes. 13 Q. So at monthly dosing for treatment 14 of RVO, Eylea's obtained, according to your 15 calculations, at least 46 percent of the share of 16 sales? 17 A. In 2021? 18 Q. Was that -- I apologize. Was that a 19 question or a response? 20 A. I was just looking at the data again to 21 make sure I -- Chart 6 puts it -- 2021 between 46 22 and [REDACTED] percent, which is what those numbers are 23 on that paragraph. 24 Q. And so do you agree that with respect to 25 the treatment of RVO, Eylea has a significant	Page 100 1 declaration, which is your '601 and '681 patent 2 declaration, and you could turn to Paragraph 18 3 where you recite the challenge claims for the 4 '601 patent. 5 And you haven't done anything in your 6 analysis to confirm that each sale of Eylea that 7 you're relying on falls within the scope of the 8 '601 patent claims here in Paragraph 18, have 9 you? 10 A. I do not do any analysis of 11 claim-by-claim utilization or analysis. 12 Q. I'm going to hand you what is Exhibit 13 1001 in the 1226 IPR proceeding. It's the '601 14 patent. 15 (Previously marked Exhibit No. 1001 to 16 the '601 patent 1226 IPR was introduced.) 17 BY MR. MARX: 18 Q. If you could turn to Page 20 of Exhibit 19 1001 from the 1226, the section -- 20 A. Okay. 21 Q. -- that's got the claims for the '601 22 patent. 23 A. Mm-hmm. 24 Q. If we could look at Claims 5 and 6 which 25 are challenge claims for the '601 patent in the
Page 99 1 share of sales? 2 A. I prefer -- although I know I used 3 the word "significant," I prefer the word 4 "substantial." 5 Q. So you would agree, then, that RVO 6 -- Eylea has substantial sales -- share -- let me 7 rephrase that question using your term. 8 So you would agree that, for the 9 treatment of RVO, Eylea has a substantial share 10 of sales? 11 A. Yes. 12 Q. And you haven't done any apportionment 13 to determine what share of those sales for the 14 treatment of RVO would -- let me rephrase the 15 question again. 16 You haven't done any apportionment to 17 determine what share of Eylea sales may be for 18 the treatment of RVO and may be off label, as 19 Dr. Do opined, have you? 20 A. I have not done apportionment in my 21 analysis. 22 Q. You haven't done any apportionment in 23 your analysis, correct? 24 A. That's correct. 25 Q. If we could go back to your Exhibit 2058	Page 101 1 IPR proceeding. Let me know when you've 2 -- you're there? 3 A. I'm there. 4 Q. Did you do anything to ensure that 5 the Eylea sales that you relied on in your 6 declarations involve patients meeting the 7 criteria for achieving a gain in visual acuity 8 as recited in Claims 5 and 6? 9 A. I did not. 10 Q. And, again, you didn't do any 11 claim-by-claim analysis for the '601 and '681 12 patents, correct? 13 A. I did not. 14 Q. And, likewise, for your '338 patent 15 declaration, Exhibit 2059, you didn't do a 16 claim-by-claim analysis, did you? 17 A. I did not. 18 Q. And you haven't cited to any analysis 19 from Regeneron's experts confirming that sales of 20 Eylea actually fall within the scope of the 21 claims, have -- do you? 22 A. I rely upon and refer to Dr. Do, who did 23 the claim-by-claim analysis and concludes that 24 the eight-week dosing interval is covered by the 25 claims.

26 (Pages 98 - 101)

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Mylan Exhibit 1121

Mylan v. Regeneron, IPR2022-01225

Page 26

Samsung Bioepis Exhibit 1075

Page 26

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Page 102 1 Q. But Dr. Do didn't confirm that Eylea 2 sales practiced the eight-week dosing -- the 3 claimed eight-week dosing regimen, did she? 4 A. To my knowledge, no. 5 Well, she said that it is common 6 practice in her practice to practice the 7 eight-week dosing schedule, and there's plenty of 8 other evidence to indicate that the eight-week 9 dosing schedule is practiced -- is used. 10 Q. But you don't have anything that -- any 11 information or data that confirms that Eylea 12 sales practiced the eight-week dosing schedule, 13 do you? 14 A. Yes, I do. 15 Q. What is that data? 16 A. Well, there are lots of data that are 17 referred to in the '338 declaration that show 18 that the eight-week dosing schedule is, as we've 19 spoken earlier, the most common of the dosing 20 frequencies; that it is a driver of physician 21 choice. It is a -- it's a driver of the product 22 sales. 23 Q. When you say "it's a driver of physician 24 choice and a driver of product sales," you don't 25 -- you said you didn't do a ranking, correct?	Page 104 1 Q. Did you do any analysis of any 2 differences between the challenge claims for the 3 '338, '601 and '681 patents? 4 A. As I've said, I didn't do any 5 claim-by-claim analysis. I relied upon the 6 medical expert, Dr. Do, to form the link between 7 the patented claims and the eight-week dosing 8 interval. 9 Q. If you could keep that '601 patent 10 handy. If you could go to Paragraph 19 in your 11 2059 declaration, your '881 patent declaration? 12 A. I'm sorry. What page? 13 Q. Paragraph 19. 14 A. Mm-hmm. 15 Q. Let me know when you're at Paragraph 19. 16 A. I'm there. 17 Q. And there you recite the claims of the 18 '338 patent and, in part, the last part of this 19 paragraph 19 you recite, "one or more tertiary 20 doses administered at least eight weeks after the 21 preceding dose." Do you see that? 22 A. I do. 23 Q. And with respect to the '601 patent that 24 you have, Exhibit 1001 from the 1226 patent -- 25 A. I'm sorry?
Page 103 1 A. That's -- I didn't do an apportionment, 2 yes. 3 Q. So you don't have an opinion whether the 4 dosing frequency is a top five/top ten driver of 5 product sales, do you? 6 A. As I -- I -- I did not do a ranking, I 7 didn't apportion them, so I wouldn't have a 8 ranking. 9 Q. And you didn't attempt to understand the 10 novelty of any of the challenged '601 and '681 11 patent claims, did you? 12 MR. CAINE: Objection; form. 13 THE WITNESS: I -- novelty is a -- as a 14 legal concept is not part of my charge. 15 BY MR. MARX: 16 Q. Correct. So you didn't do any analysis 17 to understand the novelty of any of the '601 and 18 '681 patent claims, correct? 19 MR. CAINE: Objection; form. 20 THE WITNESS: As I've said, I didn't do 21 any claim-by-claim analysis. 22 BY MR. MARX: 23 Q. And that would include determining what 24 may be novel in those patent claims, correct? 25 A. It would.	Page 105 1 Q. The '601 patent. 2 A. Mm-hmm. 3 Q. If you could turn to Page 20 there, it's 4 Claim 1. 5 A. Yes. 6 Q. Do you agree that it recites that the -- 7 as you call them, the maintenance doses or the 8 tertiary doses are administered once every eight 9 weeks? 10 A. I'm sorry. Which claim? 11 Q. Claim 1. Once every eight weeks or once 12 every two months. 13 A. It says at least eight weeks after the 14 immediately preceding dose. 15 Q. I apologize. What patent number are you 16 looking at? 17 A. '601 -- oh, I'm sorry, '681. Is that 18 not the one you were referring to? 19 Q. No. The '601 patent, please. 20 A. Oh. I'm sorry. 21 Claim 1 ends with, "Followed by two 22 milligrams approximately every -- once every 23 eight weeks or once every two months." 24 Q. Do you have any opinions whether once 25 every eight weeks is different from once every

27 (Pages 102 - 105)

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Mylan Exhibit 1121

Mylan v. Regeneron, IPR2022-01225

Page 27

Samsung Bioepis Exhibit 1075

Page 27

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Page 106 1 two months? 2 A. I don't have a legal opinion about the 3 definition of those terms. Commonly, I -- I 4 mean, I understand that two months is a different 5 time interval than eight weeks, but I don't know 6 whether the legal or medical interpretation of 7 that is significant. 8 Q. All right. And you haven't drawn any 9 distinction for that between -- in your analysis, 10 have you? 11 A. No. 12 Q. Okay. So do you agree that, as we saw 13 in your Exhibit 2059 declaration, the '338 patent 14 tertiary doses or maintenance doses are once 15 every eight weeks or more, correct? 16 A. It says tertiary doses administered at 17 least eight weeks after the preceding dose, yes. 18 Q. At least eight weeks, correct? 19 A. Yes. 20 Q. And in the '601 patent claims that we 21 just looked at, Claim 1, recites tertiary doses 22 once every eight weeks, correct? 23 A. Approximately once every eight weeks or 24 every two months. 25 Q. So the '601 patent doesn't include the	Page 108 1 A. I'm sorry. At least every how many? 2 Q. At least every eight weeks would include 3 nine weeks, correct? 4 A. Yes. 5 Q. And 10, 11, 12 or more weeks are 6 included in the claim term "at least every eight 7 weeks," correct? 8 A. I -- again, I'd be careful about 9 asserting that I know the legal interpretation of 10 the claims as a matter of common logic. 11 Something that is at least some number includes 12 every number bigger than that. But I don't know 13 whether, legally, that would be a -- a reasonable 14 interpretation or not. 15 Q. So do you have any opinions that the 16 '601 patent claims have a more restrictive dosing 17 schedule than the '338 patent claims? 18 A. Again, my -- I do not do a 19 claim-by-claim analysis. I rely upon Dr. Do to 20 tie the claims of the patents to the eight-week 21 dosing interval that Eylea has available, and 22 that's where I do my analysis in economics. 23 Q. Right. But you haven't done any 24 analysis that the sales of Eylea that you're 25 relying on fall within the -- the eight-week
Page 107 1 -- the broader, "at least once every eight weeks" 2 from the '338 patent, does it? 3 A. I don't draw a distinction between 4 those terms. I mean, from the data that I've 5 seen and the number of days different that might 6 be between approximately every eight weeks or 7 approximately every two months, those seem to be 8 functionally equivalent from an economic 9 perspective. 10 MR. MARX: Can I go just off the record 11 for a sec? 12 Can you help me with my Live Note. 13 We can stay on the video. I'm fine. 14 THE REPORTER: We should probably go 15 off. 16 MR. MARX: Oh, go off the record. Sure. 17 THE VIDEOGRAPHER: We're going off the 18 record. The time is 12:05 p m. 19 (Recess taken.) 20 THE VIDEOGRAPHER: We're back on the 21 record. The time is 12:09 p m. 22 BY MR. MARX: 23 Q. Dr. Manning, you don't dispute that at 24 least every weeks [sic] would include nine weeks, 25 correct?	Page 109 1 dosing -- the fixed eight-week dosing schedule in 2 the '601 patent versus the broader at least every 3 eight weeks dosing schedule from the '338 patent, 4 have you? 5 A. I have done analysis of the utilization 6 of the eight-week dosing schedule and of the role 7 that that plays in physicians choosing it. That 8 is clearly in the '338 declaration. 9 Q. But the '601 patent declaration includes 10 a more limited dosing regimen. Do you agree? 11 A. As a legal matter, I -- I don't agree. 12 I don't have an opinion about what the legal 13 distinctions are. I -- as I've said, I rely on 14 Dr. Do to draw the link between the eight-week 15 dosing interval and the patented claims. 16 Q. In your opinions that Eylea is a 17 commercial success with the '601 -- with respect 18 to the '601 patent, you haven't excluded dosing 19 schedules that include dosing more than every 20 eight weeks. Have you excluded those? 21 A. I have observed that the dosing schedule 22 -- the eight-week dosing schedule is the most 23 common of the various -- or the eight-week 24 dosing utilization is the most common dosing 25 utilization, and that is the link that I take

28 (Pages 106 - 109)

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Mylan v. Regeneron, IPR2022-01225

Page 28

Samsung Bioepis Exhibit 1075

Page 28

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Page 110 1 from Dr. Do, so that is where my analysis rested. 2 Q. So for the sales figures that you relied 3 on, did you apportion them so that you were only 4 relying on sales limited to uses by a physician 5 that were hitting the eight-week dosing schedule 6 as recited by the '601 patent? 7 A. As I've said, I did not do any 8 apportionment. 9 Q. And you didn't remove any sales of Eylea 10 for doses that were given at something other than 11 an eight-week dosing schedule from your 12 commercial success analysis, did you? 13 A. I did not. 14 Q. Did you do anything to exclude Eylea 15 seams that may have occurred for dosing every 16 four/five/six weeks? 17 A. As I've said, I did not do an 18 apportionment. I believe the eight-week dosing 19 schedule is a driver of success. 20 Q. So you think it's okay to include sales 21 for Eylea in your commercial success illness -- 22 analysis that don't practice the claimed dosing 23 regimen? 24 A. Again, practicing the claimed dosing 25 regimen is a legal construct. I focus on	Page 112 1 perspective, that eight-week dosing interval 2 provides a benefit that is not available with the 3 alternative therapies. 4 Q. So it's your opinion that just because 5 an eight-week dosing schedule may be possible, 6 that you do not need to confirm that sales of 7 Eylea actually practiced that dosing schedule? 8 A. As I said, it is the case that the 9 eight-week dosing schedule is used, and it is 10 used more commonly than any other dosing 11 schedule. 12 What I said was that there are reasons, 13 sound economic reasons why an opportunity to 14 -- or an option to dose on eight weeks would be 15 valuable to doctors and patients, even if the 16 patient's medical condition were such that it 17 could not -- would not allow an eight-week 18 -- reaching all the way to an eight-week dosing 19 interval. 20 Q. Got it. So your commercial success 21 opinions in this -- in these pending IPRs include 22 Eylea sales that don't practice the claimed 23 dosing regimen, correct? 24 A. Again, practicing the claimed dosing 25 regimen is a legal construct. And as I've said,
Page 111 1 economics. I observed that Eylea is dosed on a 2 range of intervals. There are lots of reasons 3 for that, I'm sure. The most important finding 4 in my analysis is that the most common dosage is 5 eight weeks -- the most common dosing interval is 6 eight weeks. 7 Q. But you didn't exclude from your 8 commercial success analysis the Eylea doses that 9 were not at the claimed interval, did you? 10 A. I did not, because that wouldn't be 11 appropriate. 12 Q. Why isn't that appropriate? 13 A. Well, there are a variety of reasons 14 why patients might not be able to reach the 15 eight-week dosing interval. Individuals are 16 individuals, and not everybody responds to 17 therapy in the exactly the same way. 18 So if a patient on Lucentis could -- 19 had to be dosed every four weeks but -- just 20 hypothetically -- but on Eylea could get to seven 21 weeks but not eight, it is the ability to extend 22 dosing, in general, to eight weeks, that offers 23 that opportunity; that optionality. That's a 24 valuable option. 25 And so in that sense from an economic	Page 113 1 there are good economic reasons why a dosing that 2 doesn't reach eight weeks is made available by 3 the eight-week dosing interval and that that 4 contributes to success and that that's a 5 perfectly legitimate benefit of having an 6 eight-week dosing schedule. 7 Q. Right. So you've included dosing that 8 doesn't reach eight weeks in your commercial 9 success analysis, correct? 10 A. In my analysis, I observed that eight 11 weeks is the most common dosing interval. I also 12 observe that there are good reasons why a patient 13 might not be able to get to eight weeks. That 14 does not mean that the eight-week dosing interval 15 didn't allow that to happen. 16 Q. So, again, you're including those Eylea 17 sales for patients who don't reach eight weeks in 18 your commercial success analysis, correct? 19 A. Again, I have not done an apportionment 20 so I do not know why a patient does or doesn't 21 make it to eight weeks. What I've said is that 22 there are good economic reasons why that option 23 would be valuable and that that is relevant 24 to -- to evaluating commercial success of the 25 product.

29 (Pages 110 - 113)

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Mylan Exhibit 1121

Mylan v. Regeneron, IPR2022-01225

Page 29

Samsung Bioepis Exhibit 1075

Page 29

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Page 114 1 Q. Are you familiar with treat-and-extend 2 dosing regimens? 3 A. I've heard of it, yes. 4 Q. Are they -- are treat-and-extend dosing 5 regimens part of your commercial success 6 analysis? 7 A. What do you mean, part of it? 8 Q. Well, what's your understanding of 9 treat-and-extend dosing regimens? 10 A. That -- I'm not sure I understand 11 exactly the technical definition, but, generally, 12 that a patient is treated and then tries to 13 extend treatment into a -- over a longer period 14 of time to reduce the dosing interval over 15 -- over time. 16 Q. Is treat-and-extend synonymous with a 17 fixed eight-week dosing schedule? 18 MR. CAINE: Objection; form. 19 THE WITNESS: I'm not familiar with 20 -- with the medical definition well enough to 21 -- to say one way or the other. 22 BY MR. MARX: 23 Q. So you have no opinion whether 24 treat-and-extend is the same as a fixed 25 eight-week dosing schedule?	Page 116 1 dosing? 2 A. No. 3 Q. And did you exclude from your commercial 4 success analysis Eylea sales related to 5 treat-and-extend dosing? 6 A. No. 7 MR. MARX: I'm going to have the court 8 reporter mark as Manning Exhibit 104, a 2019 9 article. First named author is O-H-J-I, 10 Ohji. -- 11 (Manning Exhibit No. 104, a 2019 article 12 with first-named author Ohji, was introduced.) 13 BY MR. MARX: 14 Q. Dr. Manning, have you ever seen this 15 article before? 16 A. I'd have to go back and look at my 17 materials considered. There are a lot of them 18 there. I don't -- as I sit here -- well, wait a 19 minute. As I sit here, I don't have a 20 recollection of having read it, but that doesn't 21 mean I didn't see it. 22 Q. All right. If you could go to the -- I 23 apologize, I don't have page numbers here, but if 24 you go to the page immediately before the 25 conclusion.
Page 115 1 A. Well, again, it's a medical issue that 2 -- I'm not a medical doctor, but I can imagine a 3 treat-and-extend approach getting you to eight 4 weeks. So if that, either legally or medically, 5 satisfies what you mean by an eight-week dosing 6 interval, I can see how they can be the same or 7 reach the same outcome. 8 Q. But treat-and-extend isn't a 9 fixed-dosing interval, is it? 10 MR. CAINE: Objection; form. Outside 11 the scope. 12 THE WITNESS: Again, I don't know 13 precisely what it means, so I -- I don't have an 14 answer to that. 15 BY MR. MARX: 16 Q. Have you ever heard of the term PRN 17 dosing? 18 A. Yes. 19 Q. What is your understanding of PRN 20 dosing? 21 A. Well, my understanding is that PRN is 22 -- stands for a Latin term means as needed or 23 something in that -- something like that. 24 Q. Did you exclude from your commercial 25 success analysis Eylea sales related to PRN	Page 117 1 A. Okay. 2 Q. On the first full paragraph on this 3 page, the second -- the second sentence there, it 4 recites, "In clinical practice, fixed dosing is 5 associated with burdens for both the patient and 6 the clinic. Therefore, in real world practice, 7 regimens such as T&E, proactive, and PRN, 8 reactive, are often adopted to reduce treatment 9 burden while maintaining functional outcomes." 10 Do you see that sentence? 11 A. I do. 12 Q. And you didn't do any analysis of how 13 many Eylea sales may be attributable to a 14 treat-and-extend dosing regimen? 15 A. Well, the -- the survey data that I 16 looked at does show treatment intervals in some 17 cases by different approaches, treat-and-extend 18 or PRN, as I recall. Eight-week dosing tended to 19 be a common dosing interval under those 20 approaches, as well. 21 Q. But T and -- treat-and-extend and PRN, 22 those are different than a fixed dosing regimen, 23 aren't they? 24 A. Well, as -- as indicated here, yes. 25 Although to tell you the truth, I don't know

30 (Pages 114 - 117)

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Mylan Exhibit 1121

Mylan v. Regeneron, IPR2022-01225

Page 30

Samsung Bioepis Exhibit 1075

Page 30

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Page 118 1 -- again, I said -- as I said, I'm not a medical 2 expert and not a medical practitioner, so I don't 3 know exactly what the distinction is. 4 So, for example, if fixed dosing means 5 you have to come in every four weeks, and no 6 matter what else you have to come in every four 7 weeks, then I can -- that would be consistent 8 with the conclusion that is here saying that 9 fixed dosing is associated with burdens for both 10 the patient and the clinic; therefore, under real 11 world practice, regimens such as treat-and-extend 12 and PRN are often adopted to reduce treatment 13 burden. That could mean that, well, you know, 14 rather than making the patient come in every four 15 weeks regardless of outcome, if you can extend to 16 six weeks, extend to eight weeks, that's better; 17 that makes perfect sense, again, to a lay 18 economist who thinks about healthcare but who is 19 not a physician. 20 So I did observe that the eight-week 21 dosing interval is common. I did not do 22 apportionment, as I've said many times, but 23 eight-week dosing matters. It's helpful. It 24 contributes to commercial success. 25 Q. So your understanding -- understand	Page 120 1 A. Because the key distinguishing feature, 2 in my opinion, was the eight-week dosing 3 interval. That is the interval that -- that's 4 the feature of the product that is most distinct 5 and most relevant, in my opinion. 6 Q. When you use the word in response "key 7 distinguishing feature," what do you mean by "key 8 distinguishing feature"? 9 A. Well, the ability to be treated less 10 frequently is, in this condition, in this therapy 11 area, an important benefit that is distinct in 12 Eylea's case, as opposed to Lucentis or Avastin. 13 Q. What you did you mean by the word "key" 14 when you refer to distinguishing feature? 15 A. Important. 16 Q. To the exclusion of any other 17 distinguishing features? 18 A. Well, for this particular IPR, it is the 19 patented feature that seems most relevant, and it 20 is the -- the feature on which, as I understand, 21 Dr. Do focused her attention. 22 Q. And you haven't focused your attention 23 on any other patented feature, have you? 24 A. No. 25 Q. If you could stay on that Ohji article,
Page 119 1 -- acknowledging that you're not a clinician, the 2 treat-and-extend and PRN, those aren't 3 fixed-dosing schedules, are they? 4 A. As just described there, no. 5 Q. And do you have any reason to dispute 6 this exhibit, the Ohji article, that T&E and PRN 7 are quote, often adopted, closed quote, as -- as 8 dosing regimens? 9 A. I don't. 10 Q. Have you done any analysis or surveys of 11 how many Eylea sales are attributable to a 12 fixed-dosing regimen? 13 A. The data that I looked at in -- for the 14 '338 declaration does include data looking at 15 fixed eight-week -- fixed intervals as opposed to 16 treat-and-extend or PRN. And as I said, eight 17 weeks is a common dosing interval across all 18 types. 19 Q. Did you exclude any dosing regimens from 20 your commercial success analysis that don't use 21 the claimed number of loading doses? 22 A. I did not focus on the loading doses, so 23 I did not. 24 Q. Why did you not focus on the loading 25 doses?	Page 121 1 that same page, the page immediately before the 2 conclusion section, about just a little over 3 halfway down the left-hand column, you'll see a 4 Footnote 7, a number 7. 5 A. Yes. 6 Q. And I'm going to read the sentence after 7 that Footnote 7 says, "The molecular attributes 8 of aflibercept allow for extended injection 9 goals," do you see that? 10 A. I do. 11 Q. Do you have any opinions whether Eylea 12 sales are due to the molecular attributes of 13 aflibercept? 14 A. I'm sorry. What do you mean by that? 15 Q. Do you have any opinions whether the 16 molecular attributes of aflibercept drive Eylea 17 sales? 18 A. Beyond recognizing that aflibercept is 19 the active ingredient in Eylea, and recognizing 20 that the formulation patents are not at issue 21 here -- or the formulation patent is not at issue 22 here, and recognizing that physicians, in 23 particular -- I presume this is written by 24 physicians -- well, the authors are in 25 departments of ophthalmology -- tend to use the

31 (Pages 118 - 121)

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Mylan Exhibit 1121

Mylan v. Regeneron, IPR2022-01225

Page 31

Samsung Bioepis Exhibit 1075

Page 31

Page 122 1 generic name or the name of an active ingredient 2 rather than a branded name, I mean, I don't -- I 3 don't know that I have an opinion about whether 4 the molecular attributes of aflibercept, per se, 5 -- I'm not a science -- I'm not a -- either a 6 biochemist or a chemist or a medical scientist 7 who would know the difference between the 8 molecular properties of aflibercept as apart from 9 the product Eylea. I'm an economist, and 10 economists think about products that are sold. 11 The product that is sold is Eylea. 12 Q. Well, so you haven't offered any 13 opinions in your declarations here that the 14 molecular tributes of aflibercept drive Eylea -- 15 drive Eylea sales, have you? 16 A. I don't have an opinion about the 17 molecular attributes of aflibercept, beyond the 18 fact that it is the active ingredient in Eylea. 19 Q. Do you have any reason to dispute that 20 the molecular attributes of Eylea allow for 21 extended injection intervals, as the Ohji article 22 states? 23 A. I'm not a physician or technically 24 qualified to -- to express an opinion either way. 25 Q. Have you considered that the molecular	Page 124 1 observe in the data that I reviewed for the '338 2 IPR that -- that, as I've said, the eight-week 3 dosing interval is the most common of the dosing 4 intervals. 5 Q. Why didn't you include a citation here 6 to your '338 patent declaration, then? 7 A. Well, I do include a reference to the 8 entire '338 declaration at the outset. 9 Q. Well, here with respect to Dr. Do's 10 opinions, does Dr. Do provide any opinion on the 11 frequency that clinicians used a fixed-week eight 12 dosing schedule -- a eight-week dosing schedule? 13 A. I'd have to go back to the declaration 14 to remind myself. I don't have a recollection of 15 that. 16 Q. I'm going to hand you what is Exhibit 17 2138 to the 1225 IPR. 18 (Previously marked Exhibit No. 2138 to 19 1225 IPR was introduced.) 20 BY MR. MARX: 21 Q. And, Dr. Manning, you've seen this 22 exhibit before, correct? 23 A. I've seen many such exhibits, yes. 24 Q. If you could turn to Page 15 in Exhibit 25 2138.
Page 123 1 attributes of Eylea -- let me rephrase the 2 question. 3 Have you considered, in rendering your 4 opinions here, that the molecular attributes of 5 aflibercept allow for extended injection 6 intervals? 7 A. I have considered that Eylea allows for 8 extended injection intervals. Again, I'm not 9 technically qualified to parse the molecular 10 attributes of aflibercept. 11 Q. Did you ask Regeneron's technical 12 experts whether the molecular attributes of 13 aflibercept may be responsible for an extended 14 dosing regimen? 15 A. No. 16 Q. You can set that article aside. 17 In Exhibit 2058, which is your -- your 18 declaration for the '601 and '681 patents, if you 19 could go to Paragraph 19 there. 20 A. Okay. 21 Q. Is it correct that your understanding 22 that Eylea is administered according to the 23 claimed dosing regimen is based on Dr. Do's 24 analysis? 25 A. That is what I cite to here. I also	Page 125 1 A. Okay. 2 Q. Do you agree that this -- this slide on 3 Page 15 reflects that only █ percent of eyes are 4 treated on a fixed dosing schedule with Eylea? 5 A. Yes. 6 Q. And you didn't do any analysis 7 reflecting that only █ percent of Eylea sales 8 may be attributable to a fixed dosing regimen, 9 did you? 10 MR. CAINE: Objection; form. 11 THE WITNESS: I don't know what you 12 mean. I mean, this slide shows that █ percent 13 of eyes in this sample period were treated on a 14 fixed dosing schedule or monthly followed by 15 fixed interval. 16 BY MR. MARX: 17 Q. And this -- this -- this chart for Eylea 18 dosing reflects that the majority of eyes were 19 treated on a treat-and-extend schedule, correct, 20 █ percent of eyes? 21 A. That's not a majority, but it's a larger 22 share than -- it's a plurality. 23 Q. So you agree that treat-and-extend was 24 the most common dosing schedule for Eylea -- 25 MR. CAINE: Objection; form.

32 (Pages 122 - 125)

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Mylan Exhibit 1121

Mylan v. Regeneron, IPR2022-01225

Page 32

Samsung Bioepis Exhibit 1075

Page 32

Page 126 1 BY MR. MARX: 2 Q. -- according to this slide? 3 A. In this time period, that's what these 4 data say. I would point out that, if not here, 5 then in other slides, the patients who were 6 treated on treat-and-extend or PRN also are 7 commonly treated on -- reached an eight-week 8 dosing schedule. 9 Q. What data do you have that shows that 10 patients on a T&E or PRN dosing schedule reach 11 eight weeks? 12 A. I've seen it in these ATU survey data. 13 Whether it is reflected in this one, let me look. 14 I'm not finding the slide that I 15 expected to find here, but I know I've seen a 16 slide that shows a -- an eight-week dosing 17 frequency for the other approaches being a very 18 common dosing interval. 19 Q. But treat-and-extend and PRN dosing, 20 even if they hit eight weeks once, they're not a 21 fixed dosing schedule, correct? 22 A. Again, I -- I -- I guess I don't know 23 the medical distinctions between the different 24 approaches. I mean, if you get to eight weeks 25 and you stay on eight weeks, to the layperson	Page 128 1 And this Regeneron data in Exhibit 2138 reflects 2 that, correct? 3 A. Well, I don't know how they define 4 "often." It -- 5 Q. Well, it -- 6 A. It -- "often" is, you know, a relative 7 term. It's not -- it doesn't tell you what the 8 relative frequency of other things are -- is or 9 are. 10 Q. Well, you don't dispute that the data 11 here on this Regeneron ATU shows that T and E is 12 a -- is more often used as a dosing schedule for 13 Eylea than a fixed dosing schedule? 14 A. Well, I observed that the light blue 15 section of those bars, which is "monthly until 16 dryness attained," then treat-and-extend, is 17 larger than the darkest of the blue or the larger 18 dark blue sections which says "monthly followed 19 by fixed interval." 20 Q. And if we add up all the -- those 21 treat-and-extend and PRN dosing schedules in that 22 bar chart for Eylea, you don't disagree that it 23 shows that Eylea is dosed █ percent of the time 24 on a treat-and-extend and PRN basis, do you? 25 A. I'm sorry. Say again.
Page 127 1 that sounds like fixed. But, you know, I don't 2 know -- I guess I don't know what technical 3 definitions might imply. 4 Q. Well, a treat-and-extend patient who 5 receives a maintenance dose at eight weeks and 6 then a maintenance dose at six weeks, is that 7 included in your commercial success opinions 8 here? 9 A. My opinions evaluate -- or my analysis 10 evaluates all of the utilization. 11 Q. And you haven't excluded any sales, 12 correct? 13 A. I have not done any apportionment. 14 Q. And the -- well, the data presented on 15 this Page 15 in Exhibit 2138, this is consistent 16 with the Ohji article we looked at, correct, that 17 treat-and-extend and PRN are the -- the most 18 common dosing regimens for Eylea? 19 A. I don't remember reading that in the 20 Ohji article. What I remember you asked me 21 to read was about how treat-and-extend offers 22 greater flexibility than a fixed dosing interval 23 and that that might be less burdensome. 24 Q. Well, the Ohji article said that T and E 25 and PRN are quote, often adopted, closed quote.	Page 129 1 Q. Sure. If we add up all those 2 treat-and-extend and PRN dosing for Eylea, that 3 total is █ percent of eyes treated by Eylea, 4 correct? 5 A. Well, are you adding the █ -- the other 6 schedule? 7 Q. Sure. █ percent. 8 A. Plus █. 9 Q. Plus █ percent plus █ plus █, yes? 10 That's █ percent. 11 A. Those numbers do add up to █, yes. 12 Q. So this Regeneron ATU survey reflects 13 that Eylea is dosed on a T&E and PRN basis █ 14 percent of the time, correct? 15 MR. CAINE: Objection; form. 16 THE WITNESS: That -- that is what the 17 data say for this particular period of time, yes. 18 BY MR. MARX: 19 Q. And is it your opinion that a fixed 20 dosing schedule, which accounts for █ percent of 21 Eylea-treated eyes, is driving sales for Eylea? 22 MR. CAINE: Objection; form. 23 THE WITNESS: I'm sorry. Ask it again, 24 please. 25 BY MR. MARX:

33 (Pages 126 - 129)

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Mylan Exhibit 1121

Mylan v. Regeneron, IPR2022-01225

Page 33

Samsung Bioepis Exhibit 1075

Page 33

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Page 130 1 Q. Sure. How can a fixed dosing regimen be 2 driving Eylea sales when it's only █ percent? 3 A. How can? 4 Q. Yeah. How can a dosing regimen 5 That's only █ percent be driving sales of Eylea? 6 A. As I've said a couple times now, I 7 -- the frequency of dosing is what I focus on. 8 I -- there are other data that show that eight 9 weeks is a common dosing interval for patients 10 treated with these other methods. And the option 11 of being able to get to eight weeks, which is 12 available using Eylea and not the other 13 treatments, leads people -- leads doctors, leads 14 patients to choose Eylea, and that contributes to 15 its commercial success. 16 Q. But you have no way of confirming that 17 the sales of Eylea that you rely on, that those 18 were for a fixed eight-week dosing schedule, do 19 you? 20 A. I observed that the fixed dosing 21 interval is important. It is a large share 22 of sales. It is a distinguishing factor, 23 distinguishing it from the other treatment 24 product -- other treatment -- other treatments in 25 the product category. And it, in my opinion,	Page 132 1 THE WITNESS: As far as I know, there 2 are not data that show duration of treatment 3 -- or dur -- duration of staying on any 4 particular treatment interval. But the 5 eight-week dosing interval is important. 6 MR. MARX: You can set that exhibit 7 aside. 8 (Previously marked Exhibit No. 2176 to 9 1225 IPR was introduced.) 10 BY MR. MARX: 11 Q. I'm going to hand you what is Exhibit 12 2176 in the 1225 IPR. 13 And, Dr. Manning, have you seen this 14 document before? 15 A. Yes. 16 Q. Can you turn to Page 48 of 137, please, 17 in Exhibit 2176? The heading on that slide reads 18 Anti-VEGF Market Source of Business? 19 A. Yes. 20 Q. And you agree with me that the share of 21 new patients for Eylea on this page is comparable 22 to those for Lucentis? 23 A. Well, those numbers are similar, but 24 what this says is source of business, projected 25 share allocation by product by segment. So how
Page 131 1 account -- or drives -- is a driver of the 2 product's utilization and its commercial success. 3 Q. And so is it your opinion that █ 4 percent is a large share of sales? 5 A. It's not small, but, again, it is not 6 the entirety of the eight-week dosing interval 7 -- eight-week dosing utilization. 8 Q. What do you mean "that's why it's not 9 the entirety of the eight-week dosing 10 utilization"? 11 A. As I've said before, there are people 12 -- patients treated on the other treatment 13 methods that get to eight weeks, and that that 14 eight-week dosing interval contributes to Eylea's 15 commercial success. 16 Q. But you don't know if they stay on 17 eight-week maintenance dosing, do you? 18 A. I know that eight weeks is a very common 19 dosing interval, that both in actuality and in 20 its optionality, it contributes to Eylea's 21 commercial success. 22 Q. But you haven't confirmed that the sales 23 of Eylea that you rely on stay on an eight-week 24 dosing maintenance schedule, have you? 25 MR. CAINE: Objection; form.	Page 133 1 many patients are new to treatment, and what 2 percentage of the total -- of this product's 3 patients are new to treatment. That -- that's 4 how I read this. 5 Q. So the percent of patients who are new 6 to Eylea is comparable to those for Lucentis, 7 correct? 8 A. I read this as the percent of patients 9 who are new to Anti-VEGF treatment. It's higher 10 for Avastin than it is for -- oh, sorry, you said 11 Lucentis. Yes, that's -- so Lucentis and Eylea, 12 roughly █ or █ percent of -- as I read this 13 -- of their patient share are new to treatment. 14 Q. And do you have any opinion why the 15 share of new patients is similar between Eylea 16 and Lucentis? 17 A. I haven't carefully analyzed that 18 question, but, you know, it -- it -- there are -- 19 new patients who come to be treated are allocated 20 across products by -- probably by -- well, by an 21 assessment of physician and the patient and the 22 various conditions that the patient has and what 23 the physician thinks might be best for the -- for 24 the patient. 25 Q. Do you have any opinion whether it might

34 (Pages 130 - 133)

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Mylan Exhibit 1121

Mylan v. Regeneron, IPR2022-01225

Page 34

Samsung Bioepis Exhibit 1075

Page 34

Page 134 1 be the doctor is having concerns about patient 2 succeeding on an eight-week dosing schedule? 3 A. That might be something that patients 4 -- that doctors consider, but there are -- there 5 are clearly data that show that physicians have a 6 strong preference for Eylea as a -- as an initial 7 therapy. I have in mind a -- a chart that shows 8 that [REDACTED] to [REDACTED] percent of doctors would choose 9 Eylea as a first therapy if the costs were the 10 same. So that suggests that, in addition to what 11 we do observe, that in a -- a world where cost 12 were not an obstacle to using Eylea, that it 13 would be the first choice by a -- a large 14 majority of doctors. 15 Q. So is it your opinion that the cost of 16 Eylea is a hurdle? 17 A. Well, physicians say that, yes. 18 Q. And you agree that, based on data you've 19 seen, that Avastin is a first-line therapy for 20 the treatment of angiogenic eye disease? 21 A. Yes. 22 Q. Do you know if doctors who prescribe 23 Eylea to treatment-naïve patients go straight to 24 eight-week dosing? 25 A. From initiation?	Page 136 1 Q. All right. I'm going to hand you 2 Exhibit 2139 from the 1225 IPR. 3 And, Dr. Manning, do you recognize this 4 document? Let's do this: If you have Exhibit 5 2059, your '338 patent declaration, the big one 6 in front of you, and if you'll go to Paragraph 7 94? 8 A. Okay. 9 Q. Do you see there you -- you recite 10 a Regeneron presentation meant for an 11 external-facing audience, and you cite 12 Exhibit 2139? 13 A. In Paragraph 94? 14 Q. Correct. That's the second bullet on 15 Page 111 of 289. 16 A. On Page 111, right. I was looking at 17 the prior page. 18 Yes, I do see that. 19 Q. Okay. So this is a document you've 20 reviewed before? 21 A. Yes. 22 Q. And that your understanding is that 23 this is a Regeneron presentation meant for an 24 external-facing audience, correct? 25 A. That was my understanding, yes.
Page 135 1 Q. After loading doses? 2 A. I know that Dr. Do cites it as a common 3 practice; cites it as her own practice. 4 Q. Do you have any data that doctors other 5 than Dr. Do go straight to eight-week dosing 6 after the loading doses? 7 A. I'd have to go back and look at the 8 various surveys to find whether or not -- how 9 -- how -- what exists on that point, but I know 10 that Dr. Do says so. 11 Q. And do you have any opinion whether 12 treat-and-extend or PRN dosing schedule is within 13 the scope of the '601 and '681 patent claims? 14 A. Again, I don't have a legal opinion on 15 anything. The scope of the claims is something I 16 rely on Dr. Do for. 17 MR. MARX: I just have one more 18 document, a few questions to go through before 19 lunch break, is that okay? 20 MR. CAINE: That's okay with me. 21 THE WITNESS: I thought you were going 22 to stay until we're done. 23 (Previously marked Exhibit No. 2139 was 24 introduced.) 25 BY MR. MARX:	Page 137 1 Q. Okay. If you could turn to Page 17 of 2 61. 3 Let me know when you're there. 4 A. I'm there. 5 Q. Do you see on this slide, this Regeneron 6 slide cites that aflibercept has a low incidence 7 of immunogenicity? 8 A. I do. 9 Q. Did you consider that aflibercept has a 10 low incidence of immunogenicity with respect to a 11 driver for Eylea sales? 12 A. Not in this matter, but in the district 13 court litigation where safety and efficacy are 14 also at issue, yes. 15 Q. So is it your opinion that aflibercept's 16 low incidence of immunogenicity is responsible 17 for its safety and efficacy? 18 A. Again, I'm not a medical expert. To me, 19 a layperson who knows something about healthcare, 20 immunogenicity is something you would want to 21 avoid, and so that suggests safety. 22 Q. And that -- that low immunogenicity is 23 with respect to aflibercept. It's the active 24 ingredient in Eylea, correct? 25 A. That's what this slide says.

35 (Pages 134 - 137)

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Mylan Exhibit 1121

Mylan v. Regeneron, IPR2022-01225

Page 35

Samsung Bioepis Exhibit 1075

Page 35

Page 138 1 Q. Okay. Did you consider in your opinions 2 that Eylea contains all human amino acid 3 sequences? 4 A. I did not. 5 Q. Are you aware that Lucentis and Avastin 6 contain some mouse sequence antibodies? 7 A. I did not. 8 Q. So you didn't address any possible 9 benefit Eylea might have because it's a fully 10 human molecule? 11 A. That's a technical issue that I wouldn't 12 be the right person to ask about. 13 Q. Well, then you have -- you haven't 14 considered whether the fact that aflibercept, 15 the active ingredient in Eylea, is a fully human 16 amino acid sequence might have affected 17 physicians' treatment decisions? 18 A. As I said, in this matter, safety is not 19 an issue. Safety and efficacy are not at issue. 20 Q. When you say they're not at issue, is 21 that because they're not encompassed by the -- in 22 your opinion the '601 and '681 patent claims? 23 A. That's my understanding, yes. 24 Q. But in the West Virginia litigation, 25 that is part of the -- the issues in dispute?	Page 140 1 Q. Well, we saw the Ohji article stated 2 that the aflibercept's molecular property is 3 responsible for extended dosing intervals, 4 correct? 5 A. Can I go back and look at that and 6 remind myself what it says? 7 Q. Sure. It was on the page immediately 8 before the conclusion section. 9 A. "The molecular attributes of aflibercept 10 allow for extended injection intervals." 11 If that means binding properties, okay, 12 but that's, again, a medical-technical issue that 13 is beyond the economic analysis. 14 Q. Why is that beyond your economic 15 analysis? 16 A. Well, because the economic analysis gets 17 to does the eight-week dosing interval have a 18 nexus with commercial success. Eight-week dosing 19 provides things for people that is not available 20 in other products. It drives economic util -- it 21 drives utilization, which drives commercial 22 success. 23 Q. So in your -- so your opinions 24 concerning the optionality of eight-week dosing 25 are for Eylea, it doesn't matter whether that
Page 139 1 A. Again, my understanding is that 2 Dr. Trout has tied the formulation to safety 3 and efficacy; that I interpret that to mean the 4 formulation patents cover issues like this or 5 relate to issues like this. 6 Q. If you could go to the next page in this 7 Exhibit 2139, do you see the header to the slide 8 states Aflibercept Binding Properties, in part? 9 A. I do. 10 Q. Okay. And did you consider whether 11 Regeneron promoting aflibercept's binding 12 properties was relevant to commercial success of 13 Eylea? 14 A. In this matter? 15 Q. Yes. 16 A. No. As I've said, my focus was on 17 whether the eight-week dosing interval 18 demonstrated a nexus with the product's 19 commercial success. And my understanding of the 20 binding properties, again, a medical term or 21 scientific term that I can take a guess at, does 22 not have to do with the -- I would expect does 23 not have to do with the eight-week dosing 24 interval. But if I'm wrong about that, I'm happy 25 to be educated.	Page 141 1 comes from the aflibercept molecule or the 2 formulation, just so long as that's a potential 3 option for the use of Eylea? 4 A. I wouldn't say that. I would say that 5 Eylea, the product, has an eight-week dosing 6 interval that is not available in other products. 7 That contributes to demand, to utilization, to 8 commercial success. 9 Q. And your opinion's unchanged whether 10 that eight-week dosing schedule is -- let me 11 rephrase the question. 12 Your opinions are unchanged whether 13 it's the aflibercept molecule that provides that 14 eight-week dosing schedule versus something else? 15 MR. CAINE: Objection; form. 16 THE WITNESS: My opinion is that Eylea 17 provides the eight-week dosing interval. 18 BY MR. MARX: 19 Q. And aflibercept's the active ingredient 20 in Eylea, correct? 21 A. Aflibercept is the active ingredient in 22 Eylea. 23 Q. And have you considered whether -- and 24 you said -- have you considered whether the 25 eight-week dosing regimen with respect to Eylea

36 (Pages 138 - 141)

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Mylan Exhibit 1121

Mylan v. Regeneron, IPR2022-01225

Page 36

Samsung Bioepis Exhibit 1075

Page 36

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Page 142 1 may be due to something other than the active 2 ingredient aflibercept? 3 A. I wouldn't be equipped to opine on that. 4 Q. Did you ask Regeneron's technical 5 experts? 6 A. I did not. 7 MR. MARX: All right. We can take a 8 break for lunch now, if that's okay? 9 MR. CAINE: Yeah. 10 THE VIDEOGRAPHER: We're going off the 11 record. This is the end of Media Unit 3. The 12 time is 1:03 p.m. 13 (Lunch recess.) 14 THE VIDEOGRAPHER: We're back on the 15 record. This is the beginning of Media Unit 4. 16 The time is 1:40 p.m. 17 (Previously marked Exhibit No. 2185 to 18 1225 IPR was introduced.) 19 BY MR. MARX: 20 Q. Dr. Manning, I'm going to hand you what 21 is Exhibit 2185 in the 1225 IPR. 22 This is the November 2011 label for 23 Eylea. 24 And, Dr. Manning, you've seen this 25 document, correct?	Page 144 1 as covering Eylea, correct? 2 A. Well, I see a listing of patents and 3 other patents pend -- other pending patents. 4 Q. Do you have any opinion whether these 5 patents cover Eylea? 6 A. I don't. 7 Q. And you don't dispute that Regeneron 8 listed these patents on the label for Eylea, 9 correct? 10 A. I don't. 11 Q. Do you dispute that when Eylea was 12 launched in November of 2011 that it enjoyed 13 patent protection? 14 A. I guess I don't know what you mean by 15 "enjoyed patent protection." 16 Q. Well, do you -- do you -- do you agree 17 that when Eylea was launched in November 2011 18 that there were Regeneron patents that covered 19 Eylea? 20 A. My concern is that you're asking me for 21 an -- a conclusion about whether patents might be 22 valid or not or did they cover the product or 23 not. And I -- I wouldn't have an opinion about 24 those kinds of things. 25 Q. Why don't you have an opinion about
Page 143 1 A. I've seen various labels for Eylea. 2 I probably have seen this one. I don't have a 3 specific memory of seeing this particular 4 version. 5 Q. Well, it's cited in -- in your Exhibit 6 2059, your '338 patent declaration at Footnote 7 61, -- 8 A. Okay. 9 Q. -- if you'd like to confirm. 10 A. No, that's -- I'm comfortable. 11 Q. Okay. Did you review this document in 12 preparing for today's deposition? 13 A. Specific to this particular deposition, 14 I did not review this. 15 Q. Are you aware that this is the label for 16 Eylea when it launched in November of 2011? 17 A. I see that as the date. So, yeah, I 18 would accept that. 19 Q. Okay. And if you could turn to the last 20 page of this label? 21 A. Mm-hmm. 22 Q. Do you see there are patents listed 23 there? 24 A. I do. 25 Q. And Regeneron has listed certain patents	Page 145 1 those type of things? 2 A. Because I'm not an attorney. I'm not a 3 patent examiner. I don't know -- I mean, I know 4 that these are patents listed on the label -- 5 that's all I can observe -- and that there are 6 -- it says that there are other pending patents. 7 Q. All right. Well, let's look at the 8 patents on this label. So there's patent listed 9 there, 7,070,959. Do you see that listed on this 10 Regeneron Eylea label? 11 A. I do. 12 Q. And you haven't analyzed this '959 13 patent at all about what it covers or how it 14 relates to Eylea? 15 A. Not to my recollection, although, you 16 know, there are other patents that I've looked 17 at. I -- I don't recognize any of the patents on 18 this list. 19 Q. What other patents are you referring to? 20 A. Well, there was a -- the -- the other 21 patent in the -- the formulation patent in the 22 District Court case. I'm blanking on the number. 23 Q. Sure. So you've analyzed the '338 24 patent, correct? 25 A. Well, I've looked at it.

37 (Pages 142 - 145)

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Mylan Exhibit 1121

Mylan v. Regeneron, IPR2022-01225

Page 37

Samsung Bioepis Exhibit 1075

Page 37

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Page 146 1 Q. Well, you've looked at -- you've opined 2 that -- with respect to the commercial success 3 for the '338 patent, correct? 4 A. Yes. 5 Q. And you've opined with respect to 6 commercial success for the '601 and '681 patents 7 in these pending IPRs, correct? 8 A. Yes. 9 Q. And in the -- the pending District Court 10 litigation, you've offered commercial success 11 opinions with respect to the '601, '572 and '865 12 patents, correct? 13 A. I believe those are the right numbers. 14 Q. And outside of those patents have you 15 analyzed any Regeneron patents with respect to 16 Eylea? 17 A. No. 18 Q. Do you know whether anyone could 19 commercialize a drug with aflibercept without 20 infringing upon any Regeneron patents? 21 A. I do not. 22 Q. Do you know what patents Regeneron has 23 that cover the aflibercept molecule? 24 A. I don't. 25 Q. And all of these patents that appear	Page 148 1 Q. Are you familiar with the Acorda Factors 2 from the Acorda Roxane -- versus Roxane case? 3 A. I have some basic familiarity, but I 4 couldn't list them. But I know that Mr. Hoffman 5 referenced them. 6 Q. Okay. And you've seen them in Ms. 7 -- at least you've seen them in Mr. Hoffman's 8 '338 IPR patent declaration? 9 A. Yes. 10 Q. And it comes to your Exhibit 2059 and 11 2058 declarations, in these IPRs you haven't 12 addressed any of the Acorda factors when it comes 13 to your commercial success opinions, correct? 14 A. That's correct. 15 Q. Do you dispute it that when Eylea was 16 launched in November 2011 that it enjoyed a 17 regulatory exclusivity period? 18 A. Well, what do you mean by "regulatory 19 exclusivity period"? 20 Q. Do you know if Eylea's still covered by 21 any regulatory exclusivity? 22 A. Well, I haven't affirmatively confirmed, 23 but my understanding is that new biologics obtain 24 12 years of data exclusivity. There are some 25 other possible -- possible data -- or, sorry,
Page 147 1 on this November 2011 Eylea label, you have not 2 looked at or analyzed these patents, correct? 3 A. I have not. 4 Q. And then the pending IPRs that we're 5 here for today, you've not offered an opinion 6 related to any other patents outside of the 7 '601 patent, the '681 patent and the '338 patent, 8 correct? 9 A. That's correct. 10 Q. And you haven't offered any opinion in 11 your declarations why Regeneron competitors might 12 have been dissuaded from developing their own 13 aflibercept product because of any Regeneron 14 patent, correct? 15 A. I have not. 16 Q. When it comes to your commercial success 17 opinions in these pending IPRs, did you evaluate 18 the impact of any earlier patent protection that 19 Regeneron obtained for Eylea? 20 A. I did not. 21 Q. And with respect to your commercial 22 success opinions, did you evaluate the impact of 23 any regulatory exclusivity Regeneron had for 24 Eylea on your commercial success opinions? 25 A. I did not.	Page 149 1 regulatory exclusivities for pediatric 2 indications, for example. I haven't carefully 3 examined those, so I -- I don't know their 4 current status. 5 Q. But you agree that every new product 6 that's approved by FDA that -- enjoys a 7 regulatory exclusivity period? 8 A. Well, it depends on the nature of the 9 product. I mean, if it's a -- and a biologic 10 gets a different data exclusivity period than 11 does a small molecule drug; a reformulation of 12 an existing product gets different levels of 13 exclusivity, or, you know, an orphan drug has 14 different kinds of exclusivity. So there are a 15 variety of different exclusivities that can 16 apply. 17 Q. But with respect to Eylea, do you 18 dispute that Eylea's enjoyed regulatory 19 exclusivity? 20 A. I would expect that it has, but I 21 haven't carefully tracked or evaluated what 22 regulatory exclusivities exist for it. 23 Q. So sitting here today, you don't know 24 whether Eylea still enjoys -- or still is covered 25 by regulatory exclusivity?

38 (Pages 146 - 149)

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Mylan v. Regeneron, IPR2022-01225

Page 38

Samsung Bioepis Exhibit 1075

Page 38

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Page 150 1 A. Well, just as I said, there's a 12-year 2 data exclusivity period. The product launched in 3 2011. They would have 'til 2023, just adding 4 12 to 11. And if there's a -- a pediatric 5 exclusivity that, I think, would extend it 6 another six months. But those are just my 7 general understandings of the nature of 8 regulatory exclusivity. I don't know if 9 something unusual has happened in Eylea's case 10 that would change any of that. 11 Q. So you haven't offered any analysis on 12 the regulatory exclusivity for Eylea? 13 A. I have not. 14 Q. And you don't have any opinions whether 15 a company other than Regeneron could have 16 commercialized an aflibercept product from, like, 17 2005 to currently? 18 A. I'm sorry. What -- what do you mean by 19 that? 20 Q. Sure. Do you have any opinions whether 21 a company other than Regeneron could have 22 commercialized an aflibercept product since 2005? 23 A. I -- any company? 24 Q. Beyond Regeneron. 25 A. I guess I don't know -- not knowing what	Page 152 1 claiming the right to do it. 2 Q. Do you have any opinions whether other 3 companies would have been aware that Regeneron 4 was claiming the right to exclusively develop 5 aflibercept? 6 A. When? 7 Q. Since 2005. 8 A. My focus was on the product Eylea, which 9 was launched in 2011. I don't know that I've 10 looked prior to that. 11 Q. Well, since 2011, do you have any 12 opinion whether other companies would have been 13 aware that Regeneron was claiming exclusive 14 rights to the commercialized aflibercept? 15 A. Aflibercept as separate from Eylea? 16 I would want to draw that distinction. I'm not 17 aware that post 2011 when Eylea was launched that 18 anybody has claimed that they had rights to 19 Eylea. I -- but, you know, I -- that's not been 20 a focus of my work. 21 Q. Right. And so your work also didn't 22 focus on any statements that Regeneron publicly 23 made concerning their exclusive rights to develop 24 aflibercept, correct? 25 A. Aflibercept or Eylea? I'm asking.
Page 151 1 patents would have been in play or not, I don't 2 know for sure, but I can imagine there might have 3 been ways to do it. 4 Q. Would it be fair to say that that 5 type of analysis is outside the scope of your 6 opinions? 7 A. I have not written about those issues in 8 my current declarations, yes. 9 Q. Have you analyzed any public statements 10 Regeneron made about their rights to develop and 11 commercialize aflibercept? 12 A. Not that I recall. I could be 13 forgetting something, but I don't have anything 14 currently in mind. 15 Q. And have you analyzed any scientific 16 publications concerning Eylea? 17 A. Well, scientific publication's a 18 pretty broad term. I don't know what you mean. 19 Concerning Eylea? What do you mean more 20 specifically? 21 Q. Well, do you have any opinion as to 22 whether companies other than Regeneron would have 23 been aware that Regeneron was claiming that they 24 had the right to exclusively develop aflibercept? 25 A. I'm not aware of any other company	Page 153 1 Q. Aflibercept. 2 A. I'm not aware of any statements by 3 Eylea -- by -- sorry, by Regeneron or -- or 4 others claiming whether they had or had not 5 rights to aflibercept. 6 Q. Okay. When you say you're not aware, 7 that's -- you can't -- you didn't analyze that as 8 part of your opinions in this -- in these IPRs? 9 A. I did not. 10 Q. And, likewise, you don't have any 11 opinion whether other companies would have 12 been aware that Regeneron was investigating 13 aflibercept for the treatment of eye diseases? 14 A. I -- I don't know the extent to which 15 other people knew or didn't know. 16 Q. And that's because you didn't analyze 17 that with respect to your opinions in these IPRs, 18 correct? 19 A. I did not analyze it, right. 20 Q. We discussed earlier the Chronic Disease 21 Fund or CDF litigation, do you recall that? 22 A. I do. 23 Q. And you're familiar with the litigation 24 the U.S. government filed against Regeneron 25 concerning the CDF?

39 (Pages 150 - 153)

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Mylan Exhibit 1121

Mylan v. Regeneron, IPR2022-01225

Page 39

Samsung Bioepis Exhibit 1075

Page 39

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Page 154 1 A. Broadly. I don't know the details, but 2 I'm broadly familiar with it. 3 Q. And you've been aware of that litigation 4 since at least the '338 patent IPR, correct? 5 A. Since my deposition on that IPR. 6 Q. And you haven't done any analysis in 7 your declaration here to assess any impact that 8 Regeneron's payments to CDF may have had on 9 Eylea's commercial success? 10 A. As I -- we talked earlier today, I have 11 not. That was not part of my analysis in the 12 '338. And I have adopted the '338 as the 13 relevant analysis for these two IPRs, so that 14 analysis is not included. 15 Q. Okay. Dr. Manning, I'm going to hand 16 you what we'll mark as Manning Exhibit 105. 17 It is Exhibit 34 to ECF Number 275 in 18 the CDF litigation. And this was filed with the 19 United States' response to Regeneron's statement 20 of facts for summary judgment. 21 (Manning Exhibit No. 105, Exhibit 34 to 22 ECF Number 275 in the CDF litigation, was 23 introduced.) 24 BY MR. MARX: 25 Q. And, Dr. Manning, have you seen that	Page 156 1 A. That's what I understand this to say. 2 Q. And this document reflects that, in 3 total, Regeneron made payments to CDF over \$200 4 million from 2011 to April 2017? 5 A. I'm sorry. Did you say 2011? 6 Q. Yes. 7 A. That's what it says. The total is 200 8 million or more, give or take. 9 Q. Okay. Now keeping this document, if you 10 could go to your '338 patent IPR declaration, the 11 big document in front of you, and Attachment D1 12 which is Page 175 of 289 -- 171 of 289. 13 And let me know when you're there. 14 A. I'm there. 15 Q. And this is your Eylea Profit and Loss 16 Data that's included as Attachment D1 to your 17 '338 patent IPR? 18 A. It is Regeneron's data, yes. 19 Q. Looking at your Attachment D1, can you 20 identify in your Attachment D1 the \$35 million 21 Regeneron gave to CDF in 2013? 22 A. No, -- 23 Q. Okay. 24 A. -- not specifically. 25 Q. For 2014, Manning Exhibit 105 reflects
Page 155 1 document before? 2 A. I believe I have. 3 Q. When have you seen it? 4 A. At least in the deposition for the 5 District Court litigation, perhaps before. 6 Actually, I do think before, but I don't remember 7 exactly when the first time I saw it was. 8 Q. Okay. And you didn't consider this 9 document when rendering your opinions in Exhibits 10 2058 and 2059? 11 A. I did not include this. 12 Q. Okay. And do you dispute that, as 13 reflected in this document, since at least 14 Eylea's launch in 2011, copay assistance has been 15 available to patients that have been prescribed 16 Eylea? 17 A. I'm not sure I would characterize it 18 that way. I mean, I would say that the Chronic 19 Disease Fund provides assistance to patients, as 20 I understand, on a first-come first-serve basis, 21 and so -- so it may or may not be available to 22 patients who were prescribed Eylea. 23 Q. You don't dispute that this documents 24 reflects that Regeneron's provided funds to CDF 25 since 2011, do you?	Page 157 1 that Regeneron provided \$27.75 million to the 2 Chronic Disease Fund. Can you identify in your 3 Attachment D1 where Regeneron's \$27.75 million 4 payment to Regeneron is captured? 5 A. Not in this document, no. 6 Q. Can you identify any of Regeneron's 7 payments to the Chronic Disease Fund in your 8 Attachment D1? 9 A. No. They don't appear to be here. 10 Q. Do you know whether this information 11 should have been accounted for? 12 A. I don't. 13 Q. In your analysis of Eylea's profits, you 14 don't know whether the -- the P&L statements 15 include any of these payments to CDF, correct? 16 A. Well, the line that shows Chronic 17 Disease Fund apparently does not land on Eylea's 18 P&L. That doesn't mean it doesn't land on 19 Regeneron's P&L somewhere. Whether those are 20 corporate donations that are not specific to the 21 product, I'm not an accountant and I don't know 22 what the appropriate treatment of such donations 23 would be. But as -- as we've discussed, 24 they don't appear to show up on the Eylea 25 product-specific P&L unless they're put somewhere

40 (Pages 154 - 157)

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Mylan Exhibit 1121

Mylan v. Regeneron, IPR2022-01225

Page 40

Samsung Bioepis Exhibit 1075

Page 40

Page 158 1 that I don't know about. 2 Q. Got it. So at least the Eylea profit 3 and loss statements don't reflect Regeneron's 4 contributions to the Chronic Disease Fund? 5 A. Well, I'd say I don't know where -- if 6 they are here, I don't know where they are. 7 Q. Do you know where Regeneron's clinical 8 trial costs for Eylea are accounted for in the 9 Eylea profit and loss statements? 10 A. Well, what do you mean by "clinical 11 trial"? 12 Q. Well, research and development. 13 A. So prelaunch? 14 Q. Well, prelaunch, and then, as you're 15 aware, that -- Regeneron's obtained additional 16 indications for Eylea, correct? 17 A. Mm-hmm. Yes. 18 Q. Do you know where the clinical trial 19 costs for Eylea are accounted for in any of 20 Eylea's profit and loss statements? 21 MR. CAINE: Objection; form. 22 THE WITNESS: You know, I -- I -- I 23 don't know exactly. My inclination is that work 24 toward a new indication would be a -- an R&D 25 expense at the corporate level, although I'm	Page 160 1 A. Well, for a variety of reasons, but 2 -- and I don't know what it -- what Regeneron 3 -- what Genentech does. But my understanding is 4 that it is not necessarily determined whether or 5 not a company can make true and nonmisleading 6 claims about a product even if it's not off 7 label, so I don't know -- sorry, even if it's 8 not on label. So I don't know for sure what 9 Genentech does or doesn't do with respect to 10 marketing Avastin. 11 I suspect that payers, insurance 12 companies, make some effort to in -- to encourage 13 the use of Avastin since it is such a low price. 14 I don't know what efforts compounding pharmacies 15 might go to to advertise or promote their 16 particular Avastin -- repackaging -- repackaged 17 Avastin. I presume there's some effort to make 18 physicians aware of their services. So I guess I 19 can't -- so I wouldn't say that nobody promotes 20 Avastin. 21 Q. Well, you're familiar with the term 22 "share of voice," correct? 23 A. I've heard of it before, but I'm not a 24 marketer. 25 Q. All right. Well, do you know Avastin
Page 159 1 -- I'm not an accountant, so I don't know for 2 sure. But I wouldn't expect to see them on the 3 product-specific P&L. 4 BY MR. MARX: 5 Q. Why would you expect them -- why 6 would you not expect to see them on the 7 product-specific P&L for Eylea? 8 A. Well, like I said, I'm not an 9 accountant, and so I don't know where such things 10 would be. But I wouldn't be surprised to see 11 them show up at a higher level of aggregation 12 for the corporation's investigating in new 13 indications or some other -- something else that 14 applies to a new opportunity for the corporation. 15 Q. More focused on the profit and loss 16 statements, do you know how much Genentech spent 17 on their marketing and promotion of the Lucentis 18 between 2012 through 2021? 19 A. I do not. 20 Q. And you would agree that if Avastin is 21 used off label, there can be no marketing for 22 Avastin for the treatment of angiogenic diseases, 23 correct? 24 A. No. 25 Q. Why is that?	Page 161 1 -- Avastin wouldn't have any advertising share of 2 voice for treatment of angiogenic eye disease if 3 it's off label, correct? 4 A. As I've just said, there are reasons 5 why it would be promoted, or ways it might be 6 promoted. So zero is probably the wrong number. 7 Q. Well, is it your opinion that companies 8 can promote off-label use? 9 A. It's my understanding that companies 10 can make true nonmisleading statements about 11 products. Now, that's a legal question, but 12 -- so I want to be careful about offering a legal 13 opinion. But I don't know for sure that they 14 cannot say true, nonmisleading statements about 15 their products. 16 Q. So you don't know whether Avastin can be 17 promoted for off-label use or not? 18 A. "Can be" is a pretty definitive 19 statement. I don't know that it cannot be. And 20 I've said -- as I've said, my -- I'd be surprised 21 if compounding pharmacies, for example, don't 22 promote the availability of it to physicians to 23 whom they provide it. 24 Q. Sitting here today, are you aware of any 25 promotion of Avastin for off-label use?

41 (Pages 158 - 161)

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Mylan Exhibit 1121

Mylan v. Regeneron, IPR2022-01225

Page 41

Samsung Bioepis Exhibit 1075

Page 41

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Page 162 1 A. I'm not aware of it, no. But, as I 2 said, I would not be surpr -- I would be surprised 3 if there's literally none -- 4 Q. You haven't discussed -- 5 A. -- by the various parties. 6 Q. You haven't discussed in your 7 declarations the promotion of Avastin for 8 off-label use, have you? 9 A. No. 10 Q. Have you ever heard of an Eylea 11 advertising campaign called "A Beautiful Pair"? 12 A. I'm sorry? 13 Q. Have you ever heard of an advertising 14 campaign for Eylea called, quote, "A Beautiful 15 Pair," closed quote? 16 A. Pair, p-a-i-r? 17 Q. P-a-i-r. 18 A. I have not. 19 Q. Have you ever visited the website for 20 Eylea? 21 A. Yes. 22 Q. When's the last time you visited that 23 website? 24 A. I don't recall. 25 Q. Did you revisit -- did you visit	Page 164 1 Regeneron has at least two websites for Eylea, 2 one for potential patients and one for healthcare 3 providers? 4 A. To the extent that any product that 5 I -- it's pretty common for manufacturers to have 6 a bifurcated website, one for providers and one 7 for patients, or potential patients. And I think 8 I -- I'm pretty sure I've seen and even gone to 9 the provider website on Eylea -- on Regeneron's 10 website -- on Eylea's website. 11 Q. Okay. Are you aware that there is a 12 YouTube channel associated with Eylea that 13 Regeneron launched? 14 A. I -- I can't say that I've been to it. 15 I think I've heard about it, but I don't have a 16 specific memory of it. 17 Q. Okay. If you could go to the '601 18 patent in front of you. It's Exhibit 1001, from 19 the -- from the 1226 IPR. 20 And if you could go to the claims that 21 start on Page 20. 22 A. I'm there. 23 Q. Claim 7 recites, in part, "Wherein 24 approximately every four weeks comprises 25 approximately every 28 days or approximately
Page 163 1 that website since preparing your Exhibit 2058 2 declarations for the '601 and '681 patents? 3 A. I don't recall. I -- I've gone through 4 it occasionally. I don't remember when the last 5 time was. 6 Q. Did you offer any opinions on the -- 7 Regeneron's advertising promotion from their 8 website in your opinions in this matter? 9 A. There are references to the website in 10 my '338 declaration. The -- I'd have to go back 11 and look to see for sure whether the couple of 12 advertisements that I focused -- that I include 13 come from the website or not. So I'm looking on 14 Page 113 of 289 in my report. I don't see it 15 referencing the -- no, that's from the trial 16 exhibit -- or from the -- an exhibit. So these 17 do not reference the website, so I don't know 18 that. 19 Q. Have you ever visited the -- the 20 healthcare provider website that Regeneron has 21 for Eylea? 22 A. You mean when you go onto a website, it 23 asks whether you are a customer or a healthcare 24 provider? 25 Q. Well, correct. Are you aware that	Page 165 1 monthly." Do you see that? 2 A. Yes. 3 Q. In your commercial success analysis, 4 have you drawn any distinction between "every 5 four weeks" meaning anything other than 6 approximately monthly or every 28 days? 7 A. No. 8 Q. We've discussed that you've offered 9 opinions in this case concerning the eight-week 10 dosing interval for -- for Eylea, correct? 11 A. We have. 12 Q. Why did you decide to focus on the 13 eight-week dosing interval for Eylea as a driver 14 for commercial success? 15 A. I believe I've discussed that already, 16 that it is an important differentiating factor 17 between Eylea and Lucentis and Avastin, 18 which were the two products that -- that were 19 alternative -- major alternatives to it over the 20 course of the period I reviewed. 21 Q. Did Dr. Do ask you to focus on that 22 eight-week dosing interval? 23 A. Dr. Do didn't ask me to do anything. 24 Q. How did you determine that the 25 eight-week dosing interval was an important thing

42 (Pages 162 - 165)

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Mylan Exhibit 1121

Mylan v. Regeneron, IPR2022-01225

Page 42

Samsung Bioepis Exhibit 1075

Page 42

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Page 166 1 to offer opinions on? 2 A. Well, it is economically an important 3 distinction. As I go through the economics of my 4 reasoning and my opinion in the '338 declaration, 5 being able to be treated with a -- a treatment 6 that is burdensome and invasive less frequently 7 is something that would have significant 8 -- important value to people, especially 9 considering the alternative is to potentially 10 lose one's eyesight, which is -- which is a very 11 substantial burden to be placed on someone. If 12 one can avoid that substantial burden by having a 13 very invasive treatment done less frequently, 14 that would be something that economics would tell 15 you is an important distinction. 16 Q. How did you determine that was an 17 important distinction with respect to the claims 18 of the '338 patent? 19 A. As I've said, Dr. Do drew the -- drew 20 the link between the patents and the eight-week 21 week dosing. 22 Q. Did you ask Dr. Do to do that analysis? 23 A. I did not. 24 Q. So you focused on eight-week dosing 25 interval based on what Dr. Do commented on the	Page 168 1 record. This is the beginning of Media Unit 5. 2 The time is 2:23 p.m. 3 BY MR. MARX: 4 Q. Dr. Manning, if you could find in your 5 collection the '681 patent. It's Exhibit 1001 6 from the 1225 IPR. 7 A. '601 did you say? 8 Q. '681. 9 A. Sorry. 10 Q. That's okay. We can wait. There's no 11 rush. 12 A. Somehow it is not here. 13 Q. Okay. 14 A. Unless it is stuck to the back of 15 something. 16 MR. CAINE: It may have migrated over to 17 my stuff. 18 BY MR. MARX: 19 Q. I have an extra. 20 A. All that effort. 21 Q. All right. Exhibit 1001 from the 1225 22 IPR, the '681 patent. 23 A. Yes. 24 Q. Dr. Manning if you could flip to the 25 claims which begin on Page 14 of this document?
Page 167 1 claims covering? 2 A. Well, I think it's -- as I said, 3 the eight-week dosing interval is an important 4 economic distinction. It provides opportunities 5 to people that they otherwise wouldn't have. And 6 that is -- as I discussed in the '338 7 declaration, is an important economic 8 characteristic. 9 Q. Were there other important economic 10 characteristics of Eylea that are covered by the 11 '338 patent claims? 12 A. To my understanding, the eight-week 13 dosing interval was the most important and the 14 -- the -- the issue that I was assigned to think 15 about. 16 Q. Who assigned you to think about that? 17 A. Counsel. 18 MR. MARX: Could we take a ten-minute 19 break? I might be finishing up. 20 MR. CAINE: Okay. 21 THE VIDEOGRAPHER: Going off the record. 22 This is the end of Media Unit 4. The time is 23 2:15 p.m. 24 (Recess taken.) 25 THE VIDEOGRAPHER: We're back on the	Page 169 1 A. Yes. 2 Q. And if you could look at Claim 5, and it 3 recites, in part, "Wherein at least five tertiary 4 doses are administered to the patient. Wherein 5 the first four tertiary doses are administered 6 eight weeks after the immediately preceding dose, 7 and wherein each subsequent tertiary dose 8 administered eight or twelve weeks after the 9 immediate preceding dose." 10 Do you see that terminology in claim 5? 11 A. I do. 12 Q. Have you done any analysis what 13 percentage of sales of Eylea satisfy that dosing 14 regimen in Claim 5? 15 A. I have not. 16 Q. And if we could turn to Claim 19. It's 17 on the next page? 18 This claim recites, in part, "Wherein 19 the first four tertiary doses are administered 20 eight weeks after the immediately preceding dose, 21 and wherein each subsequent tertiary dose is 22 administered eight or twelve weeks after the 23 immediately preceding dose." Do you see that? 24 A. I do. 25 Q. Have you done any analysis on what

43 (Pages 166 - 169)

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Mylan Exhibit 1121

Mylan v. Regeneron, IPR2022-01225

Page 43

Samsung Bioepis Exhibit 1075

Page 43

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Page 170 1 percentage of Eylea sales satisfy the claimed 2 dosing regimen for Claim 19? 3 A. As I've said, I've done no 4 claim-by-claim analysis, so I've not done that. 5 Q. Dr. Manning, I believe earlier today we 6 discussed your Declarations 2058 and 2059 cite to 7 the March 2021 label for Eylea? 8 A. Yeah. We did talk about that, yes. 9 Q. And I believe you -- you testified that 10 you're familiar with a more current label for 11 Eylea? 12 A. I'm familiar with the addition of 13 retinopathy and prematurity, I believe is what 14 it's called. And that is not on the 2021 label 15 as I understand -- as I recall. 16 Q. Are you familiar with the Regeneron list 17 of U.S. Patents that is linked to in the current 18 2022 label? 19 A. I'm not. 20 Q. Okay. Do you know why Regeneron has 21 recently updated that list of patents for the 22 2022 label? 23 A. I do not know why Regeneron does things 24 like that. 25 Q. Okay. So you don't know why Regeneron	Page 172 1 that given the -- the timing for Mylan's reply 2 papers that counsel for Regeneron provide us with 3 a redacted copy of the deposition transcript once 4 available. 5 MR. CAINE: Sure. 6 THE VIDEOGRAPHER: Finished? 7 Please stand by. 8 We're off the record at 2:28 p.m., 9 and this concludes today's testimony given by 10 Dr. Richard Manning. The total number of media 11 units used was five and will be retained by 12 Veritext. 13 (Deposition concluded -- 2:28 p.m.) 14 15 16 17 18 19 20 21 22 23 24 25
Page 171 1 has added the '338 patent as a representative 2 Regeneron U.S. product patent related to Eylea? 3 A. I do not know. 4 Q. And you also don't know why Regeneron 5 has recently added the -- the '601 and '572 6 patents as representative Regeneron patents 7 covering Eylea? 8 A. I do not know Regeneron's motivation for 9 anything. 10 Q. Did you know that Regeneron recently 11 updated that patent list? 12 A. I did not. 13 MR. MARX: All right. No further 14 questions. 15 MR. CAINE: Okay. No questions for 16 the patent owner. I am going to designate the 17 transcript confidential under the protective 18 order, because there was some discussion of 19 conf -- the subject matter of confidential 20 exhibits, and we'll work with you on that. 21 MR. MARX: Yeah. 22 MR. CAINE: I think that's -- I think 23 that's it in terms of what I need to say on the 24 record. 25 MR. MARX: I would only respectfully ask	Page 173 1 CERTIFICATE 2 3 I do hereby certify that I am a Notary 4 Public in good standing, that the aforesaid 5 testimony was taken before me, pursuant to 6 notice, at the time and place indicated; that 7 said deponent was by me duly sworn to tell the 8 truth, the whole truth, and nothing but the 9 truth; that the testimony of said deponent was 10 correctly recorded in machine shorthand by me and 11 thereafter transcribed under my supervision with 12 computer-aided transcription; that the deposition 13 is a true and correct record of the testimony 14 given by the witness; and that I am neither of 15 counsel nor kin to any party in said action, nor 16 interested in the outcome thereof. 17 18 WITNESS my hand and official seal this 19 1st day of 20 21  22 Notary Public 23 24 25

44 (Pages 170 - 173)

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Mylan Exhibit 1121

Mylan v. Regeneron, IPR2022-01225

Page 44

Samsung Bioepis Exhibit 1075

Page 44

CONFIDENTIAL - UNDER PROTECTIVE ORDER

Page 174 1 Veritext Legal Solutions 1100 Superior Ave 2 Suite 1820 3 Cleveland, Ohio 44114 4 Phone: 216-523-1313 5 June 2, 2023 6 To: DAVID A. CAINE 7 Case Name: Mylan Pharmaceuticals, Inc., et al. v. Regeneron 8 Pharmaceuticals, Inc. 9 Veritext Reference Number: 5905488 10 Witness: Richard Manning, Ph.D. Deposition Date: 6/1/2023 11 Dear Sir/Madam: 12 Enclosed please find a deposition transcript. Please have the witness 13 review the transcript and note any changes or corrections on the 14 included errata sheet, indicating the page, line number, change, and 15 the reason for the change. Have the witness' signature notarized and 16 forward the completed page(s) back to us at the Production address 17 shown 18 above, or email to production-midwest@veritext.com. 19 If the errata is not returned within thirty days of your receipt of 20 this letter, the reading and signing will be deemed waived. 21 Sincerely, 22 Production Department 23 24 25 NO NOTARY REQUIRED IN CA	Page 176 1 DEPOSITION REVIEW 2 CERTIFICATION OF WITNESS 3 ASSIGNMENT REFERENCE NO: 5905488 4 CASE NAME: Mylan Pharmaceuticals, Inc , et al v Regeneron 5 Pharmaceuticals, Inc 6 DATE OF DEPOSITION: 6/1/2023 7 WITNESS' NAME: Richard Manning, Ph D 8 In accordance with the Rules of Civil 9 Procedure, I have read the entire transcript of 10 my testimony or it has been read to me 11 I have listed my changes on the attached 12 Errata Sheet, listing page and line numbers as 13 well as the reason(s) for the change(s) 14 I request that these changes be entered 15 as part of the record of my testimony 16 I have executed the Errata Sheet, as well 17 as this Certificate, and request and authorize 18 that both be appended to the transcript of my 19 testimony and be incorporated therein 20 Date Richard Manning, Ph D 21 Sworn to and subscribed before me, a 22 Notary Public in and for the State and County, 23 the referenced witness did personally appear 24 and acknowledge that: 25 They have read the transcript; They have listed all of their corrections in the appended Errata Sheet; They signed the foregoing Sworn Statement; and Their execution of this Statement is of their free act and deed I have affixed my name and official seal this _____ day of _____, 20____ _____ Notary Public _____ Commission Expiration Date
Page 175 1 DEPOSITION REVIEW 2 CERTIFICATION OF WITNESS 3 ASSIGNMENT REFERENCE NO: 5905488 4 CASE NAME: Mylan Pharmaceuticals, Inc , et al v Regeneron 5 Pharmaceuticals, Inc 6 DATE OF DEPOSITION: 6/1/2023 7 WITNESS' NAME: Richard Manning, Ph D 8 In accordance with the Rules of Civil 9 Procedure, I have read the entire transcript of 10 my testimony or it has been read to me 11 I have made no changes to the testimony 12 as transcribed by the court reporter 13 Date Richard Manning, Ph D 14 Sworn to and subscribed before me, a 15 Notary Public in and for the State and County, 16 the referenced witness did personally appear 17 and acknowledge that: 18 They have read the transcript; 19 They signed the foregoing Sworn 20 Statement; and 21 Their execution of this Statement is of 22 their free act and deed 23 I have affixed my name and official seal 24 this _____ day of _____, 20____ 25 _____ Notary Public _____ Commission Expiration Date	Page 177 1 ERRATA SHEET 2 VERITEXT LEGAL SOLUTIONS MIDWEST 3 ASSIGNMENT NO: 5905488 4 PAGE/LINE(S) / CHANGE /REASON 5 _____ 6 _____ 7 _____ 8 _____ 9 _____ 10 _____ 11 _____ 12 _____ 13 _____ 14 _____ 15 _____ 16 _____ 17 _____ 18 _____ 19 _____ 20 Date Richard Manning, Ph.D. 21 SUBSCRIBED AND SWORN TO BEFORE ME THIS _____ 22 DAY OF _____, 20____ . 23 _____ 24 Notary Public 25 _____ Commission Expiration Date

45 (Pages 174 - 177)

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888-391-3376

Mylan Exhibit 1121
Mylan v. Regeneron, IPR2022-01225
Page 45
Samsung Bioepis Exhibit 1075
Page 45

&	104 4:12 116:8	13 76:2 79:2,4	20 38:20,22
& 2:6 3:9,13	116:11	90:16	41:4 90:10,21
5:17 6:13,15	105 4:14	132 4:23	94:6 100:18
16:17	154:16,21	135 4:24	105:3 164:21
1	156:25	137 132:16	175:16 176:22
1 1:21 2:3 5:9	10:14 49:11	13th 76:7,11	177:22
49:10 79:24,25	10:27 49:15	14 21:8 32:9	200 156:3,7
90:10,20,22	11 108:5 150:4	89:9 168:25	2005 150:17,22
91:14 94:7,11	1100 174:1	142 4:25	152:7
105:4,11,21	111 136:15,16	15 33:15 86:16	2011 76:8,11
106:21	113 163:14	86:17 124:24	142:22 143:16
1,050 15:24	11516 173:21	125:3 127:15	144:12,17
10 53:13 54:13	116 4:13	152 97:10	147:1 148:16
108:5	11:39 96:21	154 4:14	150:3 152:9,11
10,130,681 1:10	11:50 96:25	157 50:7,10	152:17 155:14
10:22	12 72:16 108:5	17 32:24 33:14	155:25 156:4,5
10,888,601 1:19	148:24 150:1,4	33:16 137:1	2012 96:3
11:4 84:6	1225 4:20,22,23	171 54:19 55:4	159:18
100 4:21	4:24,25 10:21	156:12	2013 31:5
1001 4:20,21	11:16 12:6	175 156:12	156:21
89:1,2 100:13	13:22 25:19	18 84:15 100:2	2014 156:25
100:15,19	78:21 86:19	100:8	2017 156:4
104:24 164:18	89:1,3 124:17	1820 174:2	2019 4:12
168:5,21	124:19 132:9	19 104:10,13,15	95:22 116:8,11
10019 3:15	132:12 136:2	104:19 123:19	2020 31:6
101 4:6 45:15	142:18,21	169:16 170:2	2021 38:25
45:18,22 46:21	168:6,21	1:03 142:12	50:14 90:11
46:25 47:8,12	1226 4:21 11:3	1:40 142:16	98:7,17,21
47:19 48:10	11:20 12:6	1st 5:2 25:21	159:18 170:7
102 4:8 77:3,7	100:13,16,19	173:19	170:14
77:16 78:12,17	104:24 164:19	2	2021-881 46:3
82:12	124 4:22	2 21:5 49:14	77:5,9
103 4:10 83:6,9	12:05 107:18	95:6 96:1,20	2022 46:16
84:23 85:8	12:09 107:21	174:4	51:19 170:18
			170:22

Veritext Legal Solutions

www.veritext.com

888-391-3376

Mylan Exhibit 1121

Mylan v. Regeneron, IPR2022-01225

Page 46

Samsung Bioepis Exhibit 1075**Page 46**

2022-1225 43:10	2059 4:18,19 43:10,11,13,15	40:5,18 86:18 86:19	312.527.2157 3:5
2022-1226 43:12	43:20 44:10,16 45:1,7,12	225 12:25 226 13:1,3	338 4:6,9 14:1 14:19 15:10,19
2023 1:21 2:3 5:3 25:21 150:3 173:19 174:4	49:18 50:7,12 50:17 51:7,20 51:22 52:19 53:7 55:4 57:9 57:15 59:18,21	24 133:12 24th 48:16,22 25 97:13 133:12	18:8,13,18 19:3 20:2 21:8 21:19,21,23 22:2,9,18,20 23:4,5,11 24:5 24:16,25 26:11 28:3 29:24,24 30:21 31:9,11 34:17 35:15 36:3,14,14,20 37:6 38:2 39:2 39:10,24 40:1 40:2,11,16,22 41:15,17,23 42:5,13 43:19 43:21 45:7,16 45:19 47:18 49:17 52:15,18 52:20 53:11 58:12,13 60:1 60:3,7,8,12,14 60:20 61:4,9 68:1,3 74:6,12 77:5,9,17,24 78:14 80:9 81:7 82:11,14 85:21 86:2,6 86:10,12 87:21 89:24 90:8 93:16 94:3 95:7 101:14
2038 24:21	59:25 90:8,21 94:8 95:11 97:10,23 101:15 104:11 106:13 136:5 143:6 148:10 155:10 170:6	250 3:14 26 90:20 94:8 26th 4:10 83:7 83:10 27 79:17 27.75 157:1,3 275 4:14 154:17,22	
2056 25:20	21 50:24 78:20 79:17 80:18 98:7	28 125:3,7,12 129:8,9,20 130:2,5 131:3 164:25 165:6	
2058 11:16,19 11:25 13:5,18 14:8,23 16:2 16:22 17:4 18:5,12,17 19:6,10,13,19 20:6 22:5,15 22:21 23:1,10 23:21 24:14 26:3,21 30:5 30:18 31:5,18 38:17 40:1,24 49:20 50:17 51:7,20 52:2 53:8 57:9,16 58:18 59:22 61:7 72:15 76:3 78:25 79:6 80:13,19 80:22 84:10,16 86:17 99:25 123:17 148:11 155:10 163:1 170:6	212.836.7152 3:15 2138 4:22 124:17,18,25 127:15 128:1 2139 4:24 135:23 136:2 136:12 139:7 216-523-1313 174:3 2176 4:23 132:8,12,17 2185 4:25 142:17,21 22 21:11 38:20 38:22 39:10,14	289 50:10 54:19 97:11,22 98:1 136:15 156:12,12 163:14 2:15 167:23 2:23 168:2 2:28 172:8,13	
		3	
		3 60:18 84:9 96:24 129:9 142:11 30 90:13 3000 3:10	

Veritext Legal Solutions

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888-391-3376

Mylan Exhibit 1121

Mylan v. Regeneron, IPR2022-01225

Page 47

Samsung Bioepis Exhibit 1075**Page 47**

102:17 104:3 104:18 106:13 107:2 108:17 109:3,8 119:14 124:1,6,8 136:5 143:6 145:23 146:3 147:7 148:8 154:4,12,12 156:10,17 163:10 166:4 166:18 167:6 167:11 171:1 34 4:14 154:17 154:21 35 156:20 38 95:12	100:24 101:8 168:1 169:2,10 169:14 500 3:4,11 15:13 500,000 15:11 51.8 98:8,22 55th 3:14 572 146:11 171:5 5905488 174:8 175:2 176:2 177:2	67:20 68:17 72:4 75:12,14 78:18 81:23 82:22 84:8,19 85:13,18 86:14 87:18 94:3 100:1,4,8,13,16 100:21,25 101:11 103:10 103:17 104:3,9 104:23 105:1 105:17,19 106:20,25 108:16 109:2,9 109:17,18 110:6 123:18 135:13 138:22 146:6,11 147:7 163:2 164:17 168:7 171:5 60654 3:5 608 86:18 61 137:2 143:7 650.319.4710 3:12 68 81:3 128:23 129:3,10,11,13 681 4:18,20 7:24 8:12 10:25 12:16 13:11,18,22,23 14:10,20 25:3 25:8,13 28:11 28:21 29:3 32:9,25 33:18	34:3 35:8,9 36:7 39:12,18 39:23 40:14 41:1,22 42:9 43:3,10,14 44:13 47:17 58:19 61:8,17 63:18 65:6 67:20 68:17 72:4 75:12,14 76:6 78:18 79:25 80:8 81:1,3,6,23 82:22 85:13,18 86:14,18,24 87:19 89:3,4,8 94:3 100:1 101:11 103:10 103:18 104:3 105:17 123:18 135:13 138:22 146:6 147:7 163:2 168:5,8 168:22 69 98:1
4	6		
4 21:6 53:1 129:9 142:15 167:22 40 93:18,21 41 95:12 125:20 129:7 43 4:18,19 44 95:11 44114 174:2 45 4:7 46 98:8,15,21 48 132:16 4th 46:16 48:13	6 3:4 84:5,9,20 84:22,24 89:14 98:3,21 100:24 101:8 6/1/2023 174:9 175:3 176:3 60 129:5 601 2:7 4:19,21 5:17 7:24 8:13 11:7 12:16 13:11,17 14:10 14:19 25:3,8 25:13 28:11,20 29:3 35:10 36:6 39:13,18 39:23 40:10 41:1,22 42:9 43:2,12,16 44:12 47:16 58:19 61:7,17 63:18 65:6		
5			7
5 84:5,9,20,21 84:22,24			7 4:3 20:4,6 21:16 89:8,11 121:4,4,7 164:23 7,070,959 145:9 70 134:8 76 97:22 77 4:9

Veritext Legal Solutions

www.veritext.com

888-391-3376

Mylan Exhibit 1121

Mylan v. Regeneron, IPR2022-01225

Page 48

Samsung Bioepis Exhibit 1075**Page 48**

8	abstract 32:9 33:22	active 69:22 121:19 122:1	addressed 58:23 65:15
8 41:8,12	accept 55:17 84:13 143:18	122:18 137:23	148:12
80 134:8	accepts 84:4	138:15 141:19	administer
83 4:11	accompanying 92:10	141:21 142:1	5:22
84 98:1	accordance 175:5 176:5	actuality 131:19	administered 33:5 97:12
85 98:6	account 131:1	actually 48:16 86:23 87:3,10	104:20 105:8
865 69:8,14 146:11	accountant 157:21 159:1,9	87:17 101:20	106:16 123:22
881 38:25 46:8 46:9,13 79:22 104:11	accounted 157:11 158:8	112:7 155:6	169:4,5,8,19,22
89 4:20	158:19	acuity 35:19 101:7	administering 32:12
9	accounts 129:20	add 19:5 88:7 128:20 129:1	administration 32:14
9 31:18 84:6,9 84:20,21,22,24	accurate 28:13 31:14	129:11	admit 66:6
94 136:7,13	accurately 46:21	added 51:15 171:1,5	adopted 117:8 118:12 119:7
94306 3:11	achieving 101:7	adding 129:5 150:3	127:25 154:12
959 145:12	acid 138:2,16	addition 12:25 51:15 53:5	advertise 160:15
9:11 2:8 5:2	acknowledge 175:11 176:16	134:10 170:12	advertisements 163:12
a	acknowledging 119:1	additional 19:23 24:19	advertising 27:8,10,15,17
a.m. 2:8 5:2 49:11,15 96:21 96:25	acorda 148:1,2 148:12	27:23 29:13,16	27:24 161:1
a1 12:10,11	act 175:14 176:20	29:17,25 30:16	162:11,13
abbreviate 89:17	action 5:24 173:15	39:22 40:8,25	163:7
ability 111:21 120:9		41:20 43:2	affected 138:16
able 111:14 113:13 130:11 166:5		91:20 158:15	affects 37:8
above 174:17		address 55:22 57:21 58:1	affiliations 6:6
absence 44:4		65:16 138:8 174:16	affirmative 18:21
			affirmatively 148:22

affirmed 6:25	109:11 125:2	analysis 13:23	169:25 170:4
affixed 175:15	125:23 132:20	14:1,2,3,9,14	analyze 76:19
176:21	134:18 144:16	14:16,19 24:5	153:7,16,19
affibercept	149:5 159:20	29:6 37:7 40:4	analyzed 68:10
69:19,21 121:8	ahead 27:25	41:15,25 43:1	133:17 145:12
121:13,16,18	96:17	47:17 50:16	145:23 146:15
122:4,8,14,17	aided 173:12	58:17 64:15	147:2 151:9,15
123:5,10,13	al 5:12 174:6	72:14 79:8,12	analyzing
137:6,9,23	175:3 176:3	79:13,16 81:18	33:25
138:14 139:8	allocated	81:20 83:4	andrew 16:14
140:9 141:1,13	133:19	85:6,23,25	andy 16:15
141:21 142:2	allocation	86:1,3 87:1,7	angio 41:7
146:19,23	64:13 132:25	88:20,20,23	angiogenic
147:13 150:16	allow 112:17	89:20 90:6	32:11,18 33:2
150:22 151:11	113:15 121:8	92:24 93:4	35:6 41:7
151:24 152:5	122:20 123:5	94:1 99:21,23	74:16 89:12,15
152:14,15,24	140:10	100:6,10,11	134:20 159:22
152:25 153:1,5	allows 123:7	101:11,16,18	161:2
153:13	alternative	101:23 103:16	answer 27:20
affibercept's	34:20 72:22	103:21 104:1,5	52:11 68:2,7
137:15 139:11	112:3 165:19	106:9 108:19	115:14
140:2 141:19	166:9	108:22,24	answered
aforesaid 173:4	alternatives	109:5 110:1,12	37:22
age 32:19 89:12	165:19	110:22 111:4,8	answers 13:10
89:16,17	alto 3:10,11	113:9,10,18	antagonist
aggregation	amd 89:18,22	114:6 115:25	32:13,15
159:11	90:4,12 91:10	116:4 117:12	anti 90:22
ago 14:25	91:24 92:6,9	119:10,20	91:16 132:18
74:11	92:14 93:1	123:24 125:6	133:9
agree 5:7 19:9	95:4	127:9 140:13	antibodies
46:24 47:15	amend 52:10	140:15,16	138:6
61:6 70:24,25	amino 138:2,16	150:11 151:5	anybody
97:5 98:24	analyses 30:13	154:6,11,13,14	152:18
99:5,8 105:6	39:15 64:16	157:13 165:3	anymore 17:20
106:12 109:10		166:22 169:12	

anyway 35:24 apart 85:5 122:8 apologize 95:13 97:25 98:18 105:15 116:23 apparently 95:24 157:17 appeal 1:3 4:8 77:4,8,16,22,23 78:5,10,13,22 85:3 appeals 22:1 appear 45:3 146:25 157:9 157:24 175:11 176:15 appearance 6:3 appearances 6:5 appears 44:2 appellate 85:2 appended 45:17 176:11 176:18 appendices 12:8 applies 47:19 159:14 apply 13:10 39:17 149:16 apportion 103:7 110:3 apportionment 64:13 72:13	93:25 94:2 99:12,16,20,22 103:1 110:8,18 113:19 118:22 127:13 approach 115:3 approaches 117:17,20 126:17,24 appropriate 111:11,12 157:22 approval 95:22 approved 70:7 95:9 96:2 149:6 approximately 15:5,11 94:10 97:13 105:22 106:23 107:6,7 164:24,25,25 165:6 april 4:10 25:21 83:7,10 156:4 aranov 3:25 5:19 area 82:17 90:1 120:11 arnold 2:6 3:9 3:13 5:17 6:13 6:15 16:17 arnoldporter.... 3:12,16	art 71:25 72:1 72:7,9 73:9,12 82:4,21 83:1 article 4:12 116:9,11,15 119:6 120:25 122:21 123:16 127:16,20,24 140:1 aside 123:16 132:7 asked 23:3 31:25 35:23 67:23 127:20 asking 35:24 60:21 72:9,12 144:20 152:25 asks 163:23 aspects 69:19 asserting 108:9 assess 154:7 assessment 133:21 assigned 60:2,5 63:19,21 167:14,16 assignment 66:1 77:1 175:2 176:2 177:2 assistance 15:3 53:5 54:17,20 55:15 155:14 155:19	assisted 9:12 9:13,16,17,18 assisting 54:16 associated 77:20 117:5 118:9 164:12 assume 90:8 assumes 66:22 attached 4:7 45:20 176:7 attachment 12:10,11 50:8 54:19 91:3,19 156:11,16,19 156:20 157:3,8 attachments 12:9 90:18 92:20 attained 128:16 attempt 103:9 attendance 9:5 attention 120:21,22 attorney 6:7 80:11,14 145:2 attributable 89:21 117:13 119:11 125:8 attributed 63:12 64:7 69:13 attributes 121:7,12,16 122:4,17,20 123:1,4,10,12
---	--	--	---

140:9 attributing 91:23 atu 30:23 31:2 31:4,15 89:23 126:12 128:11 129:12 audience 136:11,24 audio 5:6 august 51:18 author 4:13 116:9,12 authorize 176:11 authorized 5:22 authors 121:24 availability 161:22 available 30:9 30:11,17 51:24 52:21 53:10 55:15 74:24 75:24 108:21 112:2 113:2 130:12 140:19 141:6 155:15 155:21 172:4 avastin 35:16 37:10 68:6 91:5 120:12 133:10 134:19 138:5 159:20 159:22 160:10	160:13,16,17 160:20,25 161:1,16,25 162:7 165:17 ave 2:7 174:1 avenue 5:17 avoid 137:21 166:12 aware 7:21 29:12,16 31:1 52:5,8,12,20,24 53:5 54:22 55:23 56:15 57:17,17 58:12 58:20 71:1 77:15 80:25 81:5 83:18,20 83:23 84:8 94:13,16 138:5 143:15 151:23 151:25 152:3 152:13,17 153:2,6,12 154:3 158:15 160:18 161:24 162:1 163:25 164:11 b b 4:4 30:8 b1 50:8 b2 1:10,19 back 8:2 14:1 31:7,10 36:13 37:15 42:4 49:13 52:10,15	53:11,22 55:18 56:24 63:2 78:9 84:12 96:23 99:25 107:20 116:16 124:13 135:7 140:5 142:14 163:10 167:25 168:14 174:16 bankruptcy 21:11 bar 128:22 bars 128:15 base 24:2 based 14:13 36:17 41:16 47:17 70:3 80:16 86:2,4 88:9 123:23 134:18 166:25 basic 148:3 basis 37:1,17 42:23 128:24 129:13 155:20 bearing 38:4 bears 38:1 beautiful 162:11,14 beginning 2:8 6:6 49:14 96:24 142:15 168:1 begins 98:3 behalf 6:8,16	believe 7:22 8:11 12:7,11 13:8 16:4,6 20:17 27:1 28:10,15 33:13 36:15 40:4 44:21 50:23 53:4 54:24,24 54:24 62:18,21 62:23 63:2,4 67:6,13 77:14 95:9 97:9 110:18 146:13 155:2 165:15 170:5,9,13 benefit 112:2 113:5 120:11 138:9 beovu 91:5 best 133:23 better 118:16 beyond 22:13 36:1 39:23 43:3 47:10 69:21 83:3 92:2 121:18 122:17 140:13 140:14 150:24 bifurcated 164:6 big 136:5 156:11 bigger 108:12 billed 15:11
---	---	--	--

billing 15:14,22 15:24	97:2 135:19 142:8 167:19	ca 174:25	campaign 162:11,14
binding 139:8 139:11,20 140:11	breakdowns 89:25	caine 3:9 6:13 6:13 9:1,2 10:1 14:11 16:9 27:25 37:20 49:1,4 59:3 61:11,19 64:10 65:1,21 67:21 73:20 74:4 75:16 76:14 82:6 88:6,18 92:15 96:11,16 103:12,19 114:18 115:10 125:10,25 129:15,22 131:25 135:20 141:15 142:9 158:21 167:20 168:16 171:15 171:22 172:5 174:5	capture 39:4 40:6 captured 40:22 157:4 careful 42:6,16 45:4 48:2,3 108:8 161:12 carefully 133:17 149:2 149:21 case 1:9,19 5:14 20:11,25 58:8 63:3 65:25 69:15 83:21,24 94:21 112:8 120:12 145:22 148:2 150:9 165:9 174:6 175:3 176:3 cases 17:16,23 18:1 20:24 71:1 117:17 category 130:25 cdf 4:14 57:18 57:22 58:8,8 58:15,20 59:18 59:21 153:21 153:25 154:8 154:18,22 155:24 156:3 156:21 157:15
biochemical 36:25	briefed 8:17		
biochemist 122:6	briefly 29:12 97:3		
bioepis 1:14 13:2	broad 73:23 151:18		
biolog 36:25	broader 107:1 109:2		
biologic 41:6 149:9	broadly 154:1 154:2		
biologics 148:23	brought 11:9 12:4		
bit 87:20	brown 36:15 74:17		
black 2:9 5:21	bullet 84:3 136:14		
blanking 145:22	burden 117:9 118:13 166:11 166:12		
blue 128:14,17 128:18	burdens 117:5 118:9		
board 1:3 22:1 77:16 78:10	burdensome 127:23 166:6		
board's 4:8 77:4,8 78:13 78:22	business 26:12 132:18,24		
bottom 44:23 95:14	c		
bounds 47:22 48:1,5,6	c 3:1 173:1,1 c10 92:20 c7 92:20 c8 92:20 c9 92:20	caine's 8:17 calculation 91:7,22 calculations 92:4,12 98:15 california 3:11 call 10:24 105:7 called 6:24 52:25 162:11 162:14 170:14 camino 3:10	
branch 32:21			
branded 122:2			
break 9:15 49:2 90:4 96:13,18			

celltrion 1:5,14 12:25 13:1	characteristics 167:10	23:14,18 24:8 26:1 49:20	123:23 152:18 170:1
central 32:21	characterize 155:17	79:1,3 80:18 101:18 143:5	claiming 151:23 152:1,4 152:13 153:4
certain 26:9 35:6 83:19 92:5 143:25	charge 103:14	cites 36:15 39:10 135:2,3 137:6	claims 13:23 28:17 29:4 39:17 43:3 60:4 76:7 77:17,25 78:14 80:4,8,9 81:1,3 81:6,8 82:15 84:5,9,10,18,20 84:21,24 86:9 86:12,18,24 87:4,6,7,7,11 87:19 88:16,22 93:2 94:19 100:3,8,21,24 100:25 101:8 101:21,25 103:11,18,24 104:2,7,17 106:20 108:10 108:16,17,20 109:15 135:13 135:15 138:22 160:6 164:20 166:17 167:1 167:11 168:25
certainly 31:15	chargebacks 55:7	civil 175:5 176:5	
certainty 26:17	chart 98:3,21 125:17 128:22 134:7	citing 23:15	
certificate 176:11	charts 92:9,20	claim 14:9,14 14:14,19,19 29:6,6 43:2 79:23,24,25 82:20 85:3,19 85:23,23,25 88:20,20,23,23 89:8,11,14 93:4 100:11,11 101:11,11,16 101:16,23,23 103:21,21 104:5,5 105:4 105:10,11,21 106:21 108:6 108:19,19 164:23 169:2 169:10,14,16 169:18 170:2,4 170:4	
certification 175:1 176:1	chemical 36:24		
certified 2:10	chemist 38:12 122:6		
certify 173:3	chicago 3:5		
challenge 80:8 84:9 100:3,25 104:2	choice 102:21 102:24 134:13		
challenged 79:24 103:10	choose 130:14 134:8		
chamber 20:19	choosing 87:23 109:7		
chancery 21:2 21:4	chronic 57:12 153:20 155:18 157:2,7,16 158:4		
change 27:13 51:14,19 59:16 75:7 82:2 85:8 85:14 150:10 174:14,15 176:8 177:3	circumstances 37:14		
changes 7:20 48:9,20 174:13 175:7 176:7,9	citation 124:5		
channel 164:12	citations 27:21		
characteristic 24:1 42:12,18 42:22 167:8	cite 25:18,19 26:4 36:19 51:1 123:25 136:11 170:6	claimed 53:16 93:7 102:3 110:22,24 111:9 112:22 112:24 119:21	clarify 13:12 33:13 36:5
	cited 22:15,21 22:25 23:6,9		clean 11:12 clear 8:8 13:14 20:18 33:11

46:18 47:23 48:18 55:3 81:17 clearly 88:10 109:8 134:5 cleveland 174:2 clinic 117:6 118:10 clinical 117:4 158:7,10,18 clinician 38:8 119:1 clinicians 74:3 85:13 88:4 124:11 closed 31:22 50:13 81:7 119:7 127:25 162:15 colleague 6:10 collection 168:5 color 43:25 44:1,4,5 columbia 2:12 column 121:3 colyer 26:4,6,8 26:15,22 27:4 colyer's 26:25 27:22 come 118:5,6 118:14 133:19 155:20 163:13 comes 141:1 147:16 148:10	148:12 comfortable 10:24 143:10 commented 166:25 comments 19:23 commerce 20:19 commercial 7:11,16,23 9:22 31:21 32:1,5 33:12 33:19 34:4 38:19,23 39:12 40:9,15,20 41:1,11,21 42:24 44:12 47:16 53:15,20 55:1 58:14 60:3,9,10 61:23,24 62:8 63:10,13 64:8 64:15,17 66:3 66:7,19 67:1,6 67:10 68:16,24 69:2,6,13,17 71:16 72:5 73:2,16 75:3 75:11,25 76:12 78:1,17 82:21 93:22,25 94:18 109:17 110:12 110:21 111:8 112:20 113:8	113:18,24 114:5 115:24 116:3 118:24 119:20 127:7 130:15 131:2 131:15,21 139:12,19 140:18,21 141:8 146:2,6 146:10 147:16 147:21,24 148:13 154:9 165:3,14 commercialize 146:19 151:11 commercializ... 150:16,22 152:14 commercially 41:5,6 commission 20:16 175:19 176:25 177:25 common 87:24 88:2,11 90:13 102:5,19 108:10 109:23 109:24 111:4,5 113:11 117:19 118:21 119:17 124:3 125:24 126:18 127:18 130:9 131:18 135:2 164:5	commonly 106:3 112:10 126:7 companies 70:16,19,21 71:2 151:22 152:3,12 153:11 160:12 161:7,9 company 150:15,21,23 151:25 160:5 comparable 132:21 133:6 compared 75:23 competitors 147:11 complete 8:19 12:4 18:3 68:2 68:7 completed 174:16 completeness 79:10 complicated 27:18 70:2 compounding 160:14 161:21 comprises 164:24 computer 173:12 con 38:19
--	--	---	---

concept 72:1,10 72:11 103:14	conditions 133:22	consistent 7:25 8:13 118:7 127:15	copay 51:23 52:2,5,8,21 53:3,5,9 54:17 54:20 55:15 59:9 155:14
concepts 81:11	conducts 31:2	constellation 17:13	copays 54:3 55:5,8,11
concern 67:4 144:20	conf 171:19	construct 110:25 112:25	copies 11:12
concerned 35:10	conference 6:25	construction 85:3	copy 4:6,8,10 12:5 43:21 45:15,18 46:2 77:4,7 83:6,9 83:14 89:4 172:3
concerning 7:10,15,23 8:1 8:12 27:16,23 31:21,25 38:19 40:9,15 41:21 51:6 57:12,18 58:15 59:9 85:3 140:24 151:16,19 152:23 153:25 165:9	confidential 1:23 171:17,19	contain 138:6	corneal 32:22
concerns 65:13 134:1	confirmed 131:22 148:22	contained 14:5	corner 44:24 95:15
conclude 53:19	confirming 87:2,10,17 88:14 101:19 130:16	contains 138:2	corporate 157:20 158:25
concluded 54:8 79:22 172:13	confirms 102:11	context 27:7 37:5	corporation 159:14
concludes 33:11 101:23 172:9	connection 23:20	continue 5:6	corporation's 159:12
conclusion 60:23 116:25 118:8 121:2 140:8 144:21	considers 134:4 137:9 138:1 139:10 155:8	contribute 65:11 67:14	correct 7:7,11 10:19 11:4 12:14 13:19,20 14:18,21 18:12 18:14 19:25 20:8 22:16,22 22:24 23:6,8 23:10 28:8 29:4,14,19 30:24 31:2,6 31:19,23 33:15 33:20 36:8,9
conclusions 79:14	considered 22:10,13,14,25 23:9,12 54:8,9 54:21 82:20,23 95:3 116:17 122:25 123:3,7 138:14 141:23 141:24	contributes 113:4 118:24 130:14 131:14 131:20 141:7	
condition 112:16 120:10	considering 166:9	contributing 74:15	
		contribution 74:20	
		contributions 158:4	
		contributor 71:16,19	
		conversation 74:11	
		conversations 5:5 16:18	

37:19 38:8,15 38:18 39:9,13 39:19 41:2,18 42:20 43:4,5 44:13,23 47:9 47:13 48:10,17 48:22 49:21 50:14,18 51:2 51:24 52:3 53:1,3 55:5 57:19,23 58:15 58:21,24 59:10 59:11,19,20,23 59:24 60:4,9 60:20 62:11 63:11,13 64:4 66:9 67:10 69:3,14 70:13 70:18,23 71:10 72:20 78:10,14 79:1,6,16 80:9 80:13,19 81:3 81:8,25 82:12 82:15,19 83:1 84:20,25 86:6 86:14 87:11 88:5,17 90:24 90:25 91:17,20 93:14 94:4,5 94:11,20,21 95:1,19 96:3,7 97:9 99:23,24 101:12 102:25 103:16,18,24 106:15,18,22	107:25 108:3,7 112:23 113:9 113:18 123:21 124:22 125:19 126:21 127:12 127:16 128:2 129:4,14 133:7 136:14,24 137:24 140:4 141:20 142:25 144:1,9 145:24 146:3,7,12 147:2,8,9,14 148:13,14 152:24 153:18 154:4 157:15 158:16 159:23 160:22 161:3 163:25 165:10 173:13 correcting 8:10 corrections 19:12 45:7 47:7 48:9,20 174:13 176:17 correctly 13:2 51:13 52:16 68:13 93:19 173:10 cost 134:11,15 costs 134:9 158:8,19 counsel 5:11 6:4,20 8:16,25 11:13 14:22	16:6,8,10,11,17 16:21 17:25 24:20 167:17 172:2 173:15 county 175:10 176:15 couple 14:25 20:23 27:11 47:24 71:20 83:2 130:6 163:11 course 165:20 court 5:20 6:18 20:21 21:3,4 21:12 43:6 45:14 58:4 77:2 83:5 116:7 137:13 145:22 146:9 155:5 175:7 cover 44:15,18 139:4 144:5,22 146:23 coverage 70:13 71:4 covered 34:24 35:21 101:24 144:18 148:20 149:24 167:10 covering 144:1 167:1 171:7 covers 145:13 credibly 80:2 criteria 33:3 80:1 101:7	current 49:23 50:17 51:1,6 51:18 149:4 151:8 170:10 170:17 currently 12:23 45:9 150:17 151:14 customer 163:23 cv 12:10 20:24 21:1,3 d d 4:1 d.c. 5:18 d1 54:19 156:11,16,19 156:20 157:3,8 dark 128:18 darkest 128:17 data 30:8,10,15 30:15 34:19 37:8 38:1,4 68:10 87:16 88:10,14 89:24 90:5 91:4,6,20 92:8 93:15 94:22 96:9 98:20 102:11 102:15,16 107:4 117:15 119:13,14 124:1 126:4,9 126:12 127:14 128:1,10
---	--	---	---

129:17 130:8 132:2 134:5,18 135:4 148:24 148:25 149:10 150:2 156:16 156:18 date 48:14,15 75:14 76:7 143:17 174:9 175:3,9,19 176:3,13,25 177:20,25 dates 75:18 95:8 david 3:9 6:13 48:25 174:5 david.caine 3:12 day 10:6,7 173:19 175:16 176:22 177:22 days 97:13 107:5 164:25 165:6 174:19 dc 2:8 deanne 3:3 6:10 dear 174:10 dec 38:20 decide 165:12 deciding 64:19 decision 4:9 77:5,9 78:13 78:22 79:18,22 81:15 82:11	decisions 138:17 declar 50:3 declaration 12:5,15 13:18 13:21 14:5 15:10,20 18:8 18:11,14,18 19:3,6 20:2 21:7,23 22:3,5 22:7,18,21 23:5,11,13,14 24:6,8,16 25:1 25:6,9,13,16,19 25:23,24 26:4 26:11,25 27:6 27:22 28:2,3,8 29:9,23,25 30:21 31:5,9 31:11 34:17 35:2,15,20 36:14,20 38:24 39:6,11,16,24 40:3,6,11,17,22 41:15,18,24 43:19,21 44:1 45:8 49:18,19 51:23 52:18,20 53:11 54:3 57:10,16 59:23 60:1,2,2 68:1,3 68:11 72:16 74:12 79:1 80:13 84:10 86:17 87:21	89:25 90:2,9 90:21 93:16 95:7 100:1,2 101:15 102:17 104:11,11 106:13 109:8,9 119:14 123:18 124:6,8,13 136:5 143:6 148:8 154:7 156:10 163:10 166:4 167:7 declarations 9:11,19 10:18 11:13 12:12,17 13:4,16,25 14:8,12,23 15:2,6 16:3,23 17:5 18:2,5,7 18:12,17 19:10 19:13,16,20,25 22:1,15,22 23:1,10,21 24:11,14,21 26:3,21 28:4 30:5,18 31:18 38:18,21 40:1 40:24 42:1,14 49:20 51:7 52:3 53:8,9 54:10 55:14 56:19 57:16,21 58:19,24 59:8 59:18 61:7,21 72:4 74:10	76:3 79:6 80:19,22 91:8 93:20 101:6 122:13 147:11 148:11 151:8 162:7 163:2 170:6 deed 175:14 176:20 deemed 174:20 define 128:3 definition 106:3 114:11 114:20 definitions 127:3 definitive 161:18 degeneration 32:19 89:13,16 89:18 delaware 21:3 21:5,12 demand 41:10 141:7 demonstrated 80:3 139:18 demonstrates 38:3 department 174:22 departments 121:25 depend 17:14
--	--	---	--

depends 149:8	details 154:1	56:4,14 58:11	162:4,6 165:8
depo 7:14	determinant	59:15 64:14	165:15 167:6
deponent 173:7	88:1	85:20 90:12	170:6
173:9	determination	105:25 106:4	discusses 54:13
deposed 7:7	83:3	107:5 117:17	discussing
10:17	determine	117:22 126:23	13:15 37:8
deposition 2:5	23:19 68:21	149:10,12,14	43:22 71:7
4:6 5:10,16 7:9	89:20 99:13,17	149:15	discussion 24:5
7:13,14,20	165:24 166:16	differentiate	37:15 52:1,17
8:14,22 10:5	determined	72:6	68:9 171:18
10:11 12:1	63:22 77:16	differentiating	disease 57:12
13:10 21:10	160:4	75:6 165:16	134:20 153:20
29:24 44:8	determining	direct 27:10	155:19 157:2,7
45:16,19 46:3	103:23	directed 33:1	157:17 158:4
46:5,7,10,13	develop 151:10	directly 81:18	161:2
48:15,21 58:5	151:24 152:4	disagree 88:3	diseases 90:12
143:12,13	152:23	97:20 128:22	153:13 159:22
154:5 155:4	developing	disconnected	disorder 89:12
172:3,13	147:12	9:14	89:15
173:12 174:9	development	discounting	disorders 32:11
174:12 175:1,3	158:12	53:17	32:18 33:2
176:1,3	diabetic 32:20	discounts 54:13	35:6 41:7
depositions 8:4	32:20 35:17	55:10	74:16,21
8:11	90:14 95:21	discuss 31:4	dispute 54:5
describe 32:8	dial 6:11	36:19 50:12	107:23 119:5
described 33:3	difference	51:1,23 53:9	122:19 128:10
119:4	13:17 44:23	53:13,17 54:21	138:25 144:7
describes 32:25	45:5 122:7	56:18 57:10	144:11 148:15
description 4:5	differences	59:23 68:20	149:18 155:12
4:17	12:18,21 13:15	discussed 29:12	155:23
designate	29:23 30:3	52:14 54:4,10	dissuaded
171:16	104:2	54:12 55:15	147:12
detail 7:18 39:8	different 12:19	67:22 68:3	distinct 120:4
detailed 58:17	17:23 20:7,23	87:21 97:3	120:11
	44:21,22 50:3	153:20 157:23	

distinction 106:9 107:3 118:3 152:16 165:4 166:3,15 166:17 167:4	78:25 80:12,15 80:18 81:21 83:17,20,22 132:14 135:18 136:4,19	106:14,16,21 110:10 111:8 119:21,22,25 135:1,6 169:4 169:5,19	102:19 103:4 104:7 108:16 108:21 109:1,1 109:3,6,10,15 109:18,19,21
distinctions 109:13 126:23	142:25 143:11 155:1,9,13	dosing 23:25 28:12,18,19,22	109:22,24,24 110:5,11,15,18
distinguishing 120:1,7,8,14,17 130:22,23	156:2,9,11 157:5 168:25	28:24 29:1,8 33:1,7,9,20,24 34:5,6,10	110:22,24 111:5,15,22 112:1,5,7,9,10
district 2:12 20:21,25 21:5 21:12 58:4 137:12 145:22 146:9 155:5	documents 10:10,13 11:10 11:11,15,23 12:14 18:25 20:5 22:6,10 22:11,12 23:17	35:11 36:2,2 40:20,21 41:8 41:13 42:3,19 42:21 43:3 60:5,17,19	112:18,23,24 113:1,3,6,7,11 113:14 114:2,4 114:9,14,17,25 115:5,9,17,20
dmazzoichi 3:6	23:20 24:20	61:4,10,12,18	116:1,5 117:4
dme 90:13 95:4 95:5	29:13 43:7 44:16,20 58:6 155:23	61:22,25 62:7 65:12,13 66:2 66:11,11,12,18	117:14,18,19 117:22 118:4,9 118:21,23
do's 25:12,23 28:7 36:12 87:5,6 88:21 123:23 124:9	doing 46:18 82:24	66:20 67:2,5 67:25 68:23 71:8,13,15,24	119:3,8,12,17 119:19 120:2 123:14,23
doctor 38:10 115:2 134:1	donations 157:20,22	74:2,13,18,18 74:23 75:1,8	124:3,3,12,12 125:4,8,14,18
doctors 70:17 70:20,22 93:6 112:15 130:13 134:4,8,14,22 135:4	dosage 111:4 dose 23:24 33:7 97:11 104:21 105:14 106:17 112:14 127:5,6 169:6,9,20,21 169:23	81:24 82:4 85:12,21 86:5 86:7,9,11 87:8 87:18,22,24 88:3,4,11,12,16 88:22 93:1,7	125:24 126:8 126:10,16,18 126:19,21 127:18,22 128:12,13,21 129:2,20 130:1
doctrine 80:4	dosed 111:1,19 128:23 129:13	93:11,13,19 94:13,19,23 97:7 98:13	130:4,7,9,18,20 131:6,7,9,14,17 131:19,24
document 11:10 12:3 23:13,15 24:18 43:9,11 44:3,7 45:25 77:12	doses 32:12,15 33:5 104:20 105:7,8 106:14	101:24 102:2,3 102:7,9,12,18	132:5 134:2,24 135:5,12

139:17,23 140:3,17,18,24 141:5,10,14,17 141:25 165:10 165:13,22,25 166:21,24 167:3,13 169:13 170:2 dr 4:6 5:10 7:5 10:16 12:3 15:23 21:14 23:23 24:23,24 25:2,12,23 28:7,14 29:7 31:17 36:12,15 38:8 40:8 43:18 45:18,22 49:17 63:4,6,6 63:7,15 69:5 71:7 74:1,9,17 77:12 78:24 83:15 87:5,6,9 87:13 88:21 89:7 90:14 93:9 94:22 95:4,21,23,23 96:9 97:2 99:19 101:22 102:1 104:6 107:23 108:19 109:14 110:1 116:14 120:21 123:23 124:9 124:10,21 132:13 135:2,5	135:10,16 136:3 139:2 142:20,24 154:15,25 165:21,23 166:19,22,25 168:4,24 170:5 172:10 draft 15:1 25:5 25:10,17,24,25 26:24 27:2 drafting 9:10 draw 63:3 107:3 109:14 152:16 drawing 88:21 drawn 69:1,4 106:8 165:4 draws 63:6 drew 166:19,19 drive 63:25 76:22 121:16 122:14,15 driver 41:9 61:16 66:13 67:5,9 71:8 102:20,21,23 102:24 103:4 110:19 131:1 137:11 165:13 drivers 61:1 66:21 drives 62:24 71:14 85:20 86:10,13 131:1	140:20,21,21 driving 62:3,10 62:18 69:19,24 129:21 130:2,5 drove 86:6 drug 38:14 146:19 149:11 149:13 dryness 128:16 due 64:24 66:8 67:1 81:24 121:12 142:1 duly 6:24 173:7 dur 132:3 duration 132:2 132:3 e e 3:1,1 4:1,4 53:1,1 127:24 128:11 173:1,1 earlier 9:23 67:16 93:12 102:19 147:18 153:20 154:10 170:5 eastern 2:8 ec 38:3 ecf 4:14 154:17 154:22 economic 24:1 42:10,11 60:25 72:10 73:1 76:17,20 79:8 79:11,13 85:5 107:8 111:25	112:13 113:1 113:22 140:13 140:14,16,20 167:4,7,9 economically 166:2 economics 14:13 108:22 111:1 166:3,14 economist 118:18 122:9 economists 122:10 edema 32:20 35:18 educated 139:25 effectiveness 35:5 efficacious 34:18,20 37:13 37:18 efficacy 34:22 34:22 35:4,7 35:16 36:7,11 36:22 37:2,24 38:3 62:10,14 62:18,22 63:16 63:19,24 64:9 64:24 65:7,11 65:20 66:8 67:2,8,9,13,14 67:16,19,22 68:9,14 69:2,6 137:13,17
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888-391-3376

Mylan Exhibit 1121

Mylan v. Regeneron, IPR2022-01225

Page 61

Samsung Bioepis Exhibit 1075**Page 61**

138:19 139:3 effort 56:22 160:12,17 168:20 efforts 27:8,11 53:18 160:14 eight 23:25 28:12,18,19,22 28:23 29:1,8 32:16 33:6,6,9 33:19,22,23,23 34:5,6,9 35:11 36:1 40:21 42:21 60:5,17 60:19 61:4,10 61:12,18,22,25 62:7 65:12,13 66:2,18 67:5 67:25 68:23 71:8,13,15,24 74:2,13,18,23 75:1,8 81:24 82:3 85:12 87:8,22 88:3 88:22 93:7,13 94:19,23 96:10 101:24 102:2,3 102:7,8,12,18 104:7,20 105:8 105:11,13,23 105:25 106:5 106:15,17,18 106:22,23 107:1,6 108:2 108:6,20,25	109:1,3,6,14,20 109:22,23 110:5,11,18 111:5,6,15,21 111:22 112:1,5 112:9,14,17,18 113:2,3,6,8,10 113:13,14,17 113:21 114:17 114:25 115:3,5 117:18 118:16 118:20,23 119:15,16 120:2 124:2,11 124:12 126:7 126:11,16,20 126:24,25 127:5 130:8,11 130:18 131:6,7 131:9,13,14,17 131:18,23 132:5 134:2,24 135:5 139:17 139:23 140:17 140:18,24 141:5,10,14,17 141:25 165:9 165:13,22,25 166:20,24 167:3,12 169:6 169:8,20,22 either 16:16 115:4 122:5,24 el 3:10 63:24	element 85:19 elements 14:9 29:3 43:2 64:14 85:25 email 174:17 embodied 42:13 embody 42:11 enclosed 174:12 encompass 84:22 encompassed 138:21 encompasses 23:12 53:4 encourage 160:12 ends 105:21 enjoyed 144:12 144:15 148:16 149:18 enjoys 149:6,24 ensure 101:4 entered 176:9 entire 17:13 39:4 124:8 175:5 176:5 entirely 65:10 entirety 39:4 40:2,3 131:6,9 equation 63:15 equipped 142:3 equivalent 107:8	errata 4:7 8:3 8:10 45:17,20 46:4,15 47:10 47:13 48:22 174:14,19 176:7,10,18 177:1 errors 8:10 48:20 especially 166:8 esq 3:3,3,9,14 essentially 12:20 et 5:12 174:6 175:3 176:3 evaluate 31:25 33:10 35:22 65:25 66:1 127:9 147:17 147:22 evaluated 36:8 60:25 62:5 149:21 evaluates 127:10 evaluating 32:3 113:24 evaluation 82:24 everybody 111:16 evidence 37:13 37:25 68:4 73:2 87:20
---	---	--	---

102:8	exclusion 33:3	30:5,17 31:5	136:12 139:7
ex 41:10 53:7	41:12 53:21	31:18 38:17	142:17,21
exactly 14:24	54:25 66:10	40:1,24 43:8,9	143:5 148:10
14:25 26:13	80:1 120:16	43:11,13,15,20	154:16,17,21
31:11 51:13	exclusive	44:10,16,25	154:21 156:25
52:13 53:23	152:13,23	45:1,7,12,15,18	163:1,16,16
111:17 114:11	exclusively	45:22 46:21,25	164:18 168:5
118:3 155:7	151:24 152:4	47:8,12,19	168:21
158:23	exclusivities	48:10 49:18,20	exhibits 4:16
examination	149:1,15,22	50:3,4,6,12,17	11:23,25 13:5
7:3	exclusivity	51:7,20,22	75:25 124:23
examined 7:1	147:23 148:17	52:2,19 53:7,8	155:9 171:20
149:3	148:19,21,24	55:3,4 57:9,15	exist 52:6
examiner 145:3	149:7,10,13,14	58:18 59:18,21	149:22
example 35:14	149:19,25	59:25 61:7	existing 11:24
50:6 91:3	150:2,5,8,12	72:15 76:3	149:12
92:19 95:20	executed	77:3,7,15	exists 135:9
118:4 149:2	176:10	78:12,16,25	expect 8:16
161:21	execution	79:6 80:13,19	139:22 149:20
excellent 11:9	175:14 176:19	80:22 82:11	159:2,5,6
except 31:5	executives	83:6,9 84:10	expected
44:15	26:12	84:16,23 85:8	126:15
exception 13:6	exercise 93:5	86:17 89:1,2	expenditures
37:7 43:24	exhibit 4:5,14	90:8,21 94:8	57:4
44:4 80:1	4:17 11:16,19	95:11,14,17	expense 158:25
exclude 72:6	11:24,25 12:1	97:10,23 99:25	expenses 56:21
73:18,22 76:10	12:2 13:18	100:12,15,18	experience 70:4
110:14 111:7	14:8,23 16:2	101:15 104:24	experiences
115:24 116:3	16:22 17:4	106:13 116:8	17:22
119:19	18:5,12,17	116:11 119:6	expert 7:25
excluded 75:13	19:6,10,13,19	123:17 124:16	8:13 12:5,15
109:18,20	20:6 22:5,15	124:18,22,24	17:18 28:16
127:11	22:21,25 23:10	127:15 128:1	29:13 30:4
excluding	23:21 24:13,21	132:6,8,11,17	36:23 58:14
72:12	25:20 26:3,21	135:23 136:2,4	60:23 70:5

81:12 104:6	125:19,23	eylea 7:10,15	109:16 110:9
118:2 137:18	126:6,19 127:4	8:1 9:22 27:8,9	110:14,21
expert's 61:2	127:17,21	27:17,24 28:21	111:1,8,20
expertise 82:17	128:16,21,24	33:12 34:17	112:7,22
experts 16:25	129:2 135:12	35:16 36:10,21	113:16 115:25
17:8 18:1,23	150:5	37:2,9,18	116:4 117:13
63:3 74:23	extended 23:24	38:19 40:9,16	119:11 121:11
75:22,22 86:8	36:1 121:8	41:5 42:19	121:16,19
87:2 101:19	122:21 123:5,8	50:13 51:2,6	122:9,11,14,15
123:12 142:5	123:13 140:3	51:19,24 52:2	122:18,20
expiration	140:10	52:6,21 53:10	123:1,7,22
175:19 176:25	extent 8:4	54:20 55:16,24	125:4,7,17,24
177:25	13:13 17:21	56:16 57:2,5	127:18 128:13
explain 41:11	18:19 19:2	60:10 61:16	128:22,23
53:14,20	20:1 22:17	62:4,19,24,24	129:2,3,13,21
explained	23:11 34:21	63:25 65:8,10	129:21 130:2,5
53:15	39:7,25 42:14	66:13,21 68:6	130:12,14,17
explanations	47:21 51:3	69:20,22,25	131:23 132:21
41:10	52:22 56:20	70:11 71:8,14	133:6,11,15
explicitly 17:11	74:18 75:5	74:2,24 75:2,6	134:6,9,12,16
17:24,25 18:23	87:12 153:14	75:7,8 81:23	134:23 137:11
express 122:24	164:4	85:20 86:6,23	137:24 138:2,9
expressed 28:5	external 136:11	87:3,10,17,23	138:15 139:13
36:2 39:7 40:5	136:24	87:25 88:15	140:25 141:3,5
40:6 51:20	extra 168:19	89:21 90:23	141:16,20,22
67:24	eye 32:11,18	91:5,9,23 92:5	141:25 142:23
expressing 37:4	33:2 35:6 41:7	92:10,13,25	143:1,16 144:1
37:23	74:16 89:12,15	93:8,19,22	144:5,8,11,17
extend 111:21	134:20 153:13	95:21,23 96:2	144:19 145:10
114:1,4,9,13,16	161:2	96:5 97:6,11	145:14 146:16
114:24 115:3,8	eyes 125:3,13	97:16 98:25	147:1,19,24
116:5 117:14	125:18,20	99:6,9,17	148:15 149:17
117:17,21	129:3,21	100:6 101:5,20	149:24 150:12
118:11,15,16	eyesight 166:10	102:1,11	151:16,19
119:2,16		108:21,24	152:8,15,17,19

152:25 153:3 155:16,22 156:15 157:24 158:2,8,9,16,19 159:7 162:10 162:14,20 163:21 164:1,9 164:12 165:10 165:13,17 167:10 169:13 170:1,7,11 171:2,7 eylea's 39:12 41:11,21 50:17 53:14,20 55:1 60:3 62:10 63:12,19 64:8 64:23 65:19 66:7 67:1 69:2 69:13 71:16,19 72:5 93:22 94:15 98:7,14 120:12 131:14 131:20 148:20 149:18 150:9 154:9 155:14 157:13,17 158:20 164:10 eylea4u 52:8,11 52:25 53:24 54:3	fact 7:9 12:24 17:17 25:17 43:24 68:8 69:21 75:1 77:21 93:6 122:18 138:14 factor 68:9 75:6 130:22 165:16 factors 53:15 62:3,10 67:2 71:21 72:7,12 148:1,12 facts 154:20 fair 72:3 151:4 fairly 27:6 fall 87:4,10 101:20 108:25 falls 86:24 100:7 familiar 30:23 70:12 114:1,19 148:1 153:23 154:2 160:21 170:10,12,16 familiarity 148:3 far 46:23 64:20 132:1 favorable 71:4 71:4 fda 70:8 149:6 feature 23:25 33:10,24 34:6 34:7,14,25	35:8 60:20 61:3 63:22 66:2 67:5,9 75:23 76:22 120:1,4,7,8,14 120:19,20,23 features 32:3,6 33:17 34:2,9 34:24 35:9,22 35:25 36:7 53:21 55:1 60:12,13,15 64:1 69:16 120:17 field 55:23,25 56:1,7 figures 43:25 110:2 filed 4:11 5:13 13:5 83:7,10 153:24 154:18 fill 8:3 final 4:8 25:11 25:12,17,21,23 26:1,1 27:1 77:4,8 82:10 finality 78:3,4 financial 24:13 29:17 financially 5:24 find 78:16 91:2 95:10 126:15 135:8 168:4 174:12	finding 78:4 111:3 126:14 findings 77:24 fine 107:13 finish 96:14 finished 172:6 finishing 33:4 167:19 firm 5:21 6:9 9:4 first 4:12 6:24 10:23 43:9 79:20 84:1 116:9,12 117:2 134:9,13,19 155:7,20,20 169:5,19 five 3:10 66:21 103:4 110:16 169:3 172:11 fix 9:15 fixed 61:9,17 109:1 114:17 114:24 115:9 117:4,22 118:4 118:9 119:3,12 119:15,15 124:11 125:4,8 125:14,15 126:21 127:1 127:22 128:13 128:19 129:19 130:1,18,20 flexibility 127:22
f			
f 173:1 facing 136:11 136:24			

flip 168:24	80:16,16 82:6	frequencies	genentech
focus 59:25	88:6,18 92:15	102:20	159:16 160:3,9
110:25 119:22	103:12,19	frequency	general 27:13
119:24 130:7	104:6 114:18	32:16 66:11	37:4 111:22
139:16 152:8	115:10 125:10	103:4 124:11	150:7
152:20,22	125:25 129:15	126:17 128:8	generally 32:24
165:12,21	129:22 131:25	130:7	32:24 90:23
focused 28:25	141:15 158:21	frequently	91:17 114:11
29:2 62:6	formed 80:23	94:24 120:10	generic 122:1
120:21,22	forms 24:1,2	166:6,13	getting 115:3
159:15 163:12	formulation	front 11:11,16	give 13:10
166:24	62:13,23 63:2	15:2 18:25	156:8
focusing 61:16	63:13,15	20:5 45:23	given 110:10
follow 93:10	121:20,21	49:18 83:14	172:1,9 173:14
followed 93:7	139:2,4 141:2	136:6 156:11	go 5:7 8:2 21:1
105:21 125:14	145:21	164:18	27:25 31:7,10
128:18	formulator	full 18:19,25	32:23 37:15
following 33:6	38:14	79:20 117:2	47:25 49:5
follows 7:1	forth 19:10	fully 138:9,15	52:10,15 53:11
footnote 79:1,4	41:17,23	functional	53:22 55:18
121:4,7 143:6	forums 20:8	117:9	56:24 63:2
footnotes 22:11	forward 174:16	functionally	69:11 72:15,16
force 70:16,20	found 82:3	107:8	76:2 79:17
foregoing	four 10:2 90:11	fund 57:12	84:12,15 86:16
175:13 176:18	90:11 94:14	153:21 155:19	89:7 95:20
forget 17:19	96:6 97:7,13	157:2,7,17	96:17 97:8
forgetting 13:7	97:16 110:16	158:4	99:25 104:10
16:14 151:13	111:19 118:5,6	fundamental	107:10,14,16
form 14:11	118:14 164:24	33:24	116:16,22,24
27:25 36:16	165:5 169:5,19	funds 155:24	123:19 124:13
37:20 59:3	fourth 7:9	further 171:13	134:23 135:5,7
61:11,19 64:10	framework	g	135:18 136:6
65:1,21 67:21	42:2	gain 101:7	139:6 140:5
73:20 74:4	free 175:14	gene 3:25 5:19	156:10 160:15
75:16 76:14	176:20		163:10,22

164:17,20 166:3 goals 121:9 going 5:2 11:22 33:4 43:6 45:14 48:24 49:9 77:2 78:20 83:5 88:25 96:11,19 100:12 107:17 116:7 121:6 124:16 132:11 135:21 136:1 142:10,20 154:15 167:21 171:16 good 5:1 7:5,6 49:4 113:1,12 113:22 173:4 government 153:24 granting 78:22 greater 39:7,7 39:8 127:22 guess 37:11 48:2 70:1,8 73:6 84:12 91:25 92:16,18 92:21,21 126:22 127:2 139:21 144:14 150:25 160:18 guidance 70:22	h h 4:4 116:9 half 10:6 90:15 halfway 121:3 hand 40:7 43:7 44:24 78:20 88:25 95:14 100:12 121:3 124:16 132:11 136:1 142:20 154:15 173:18 handful 26:11 handy 104:10 hanging 64:11 happen 113:15 happened 150:9 happy 139:24 header 139:7 heading 132:17 healthcare 118:18 137:19 163:20,23 164:2 hear 71:12 heard 17:15 56:1,3 77:19 77:20 84:1 114:3 115:16 160:23 162:10 162:13 164:15 hearing 21:10 21:11 39:1 help 56:11 107:12	helpful 118:23 higher 133:9 159:11 hit 126:20 hitting 110:5 hmm 79:19 91:15 94:9 97:4 98:5 100:23 104:14 105:2 143:21 158:17 hoffman 58:14 83:25 148:4 hoffman's 148:7 honest 8:19 hour 15:25 48:25 96:12 hours 10:2 15:13 house 16:11 hubbard 3:4 huh 89:10 human 138:2 138:10,15 hurdle 134:16 hypothetically 111:20 i identical 13:5 44:16,19 identified 60:8 60:10,11,18 62:9 69:5 94:7 94:7 96:2	identify 12:21 56:23 156:20 157:2,6 identifying 62:6 illinois 3:5 illness 110:21 imagine 115:2 151:2 immediate 169:9 immediately 105:14 116:24 121:1 140:7 169:6,20,23 immunogeni... 137:7,10,16,20 137:22 impact 34:19 147:18,22 154:7 implication 29:7 implications 78:6 implies 64:12 imply 127:3 important 24:9 41:9 55:21,22 57:25 59:1 64:6,22,23 65:6,18,24 66:16,17 74:15 74:20,25 75:2 87:22,25 111:3
--	---	--	--

120:11,15 130:21 132:5 165:16,25 166:2,8,15,17 167:3,7,9,13 impossible 50:2 incidence 137:6 137:10,16 inclination 158:23 include 12:8 22:6,12 32:14 50:20 84:19,21 103:23 106:25 107:24 108:2 109:19 110:20 112:21 119:14 124:5,7 155:11 157:15 163:12 included 40:11 47:13 56:21 94:10,17 108:6 113:7 127:7 154:14 156:16 174:14 includes 12:25 13:1 22:17 46:4 57:7 108:11 109:9 including 6:4 85:2 113:16 inclusion 8:9 incorporate 18:13 23:17 57:7	incorporated 176:12 incorporates 20:2 23:16 24:4,4 incorporating 19:2 38:24 41:14 incorrect 33:16 incorrectly 63:5 indicate 102:8 indicated 71:5 117:24 173:6 indicating 174:14 indication 51:11,11,16 69:24 71:2 91:4 158:24 indications 71:3 90:4,5,12 90:19 92:11 95:9 149:2 158:16 159:13 indicators 73:1 indicia 31:22 32:1 individuals 16:13 111:15 111:16 inform 63:23 information 24:13 29:17 30:17,20 49:21	50:20 57:22 59:2,5,12 102:11 157:10 informed 27:14 infringing 146:20 ingredient 69:22 121:19 122:1,18 137:24 138:15 141:19,21 142:2 initial 35:18 134:6 initiation 134:25 injection 97:12 121:8 122:21 123:5,8 140:10 injections 90:11,23 94:11 institution 78:22 79:18 81:15 insurance 70:13,16,19,21 71:2 160:11 intend 19:24 intended 23:17 intensity 9:8 inter 10:18 78:23 interested 5:24 173:16	internal 16:10 16:11 international 20:16,19 interpret 139:3 interpretation 106:6 108:9,14 interpreted 8:7 35:11,24 interpreting 63:14 interval 29:1,8 33:9 40:20,21 41:8,13 42:21 60:6,17,19 61:18 65:12,13 66:3,11,13,18 66:20 67:25 68:23 71:8,13 71:16,24 74:2 74:14,19,24 75:2 87:8,22 88:22 94:14,23 96:6,10 101:24 104:8 106:5 108:21 109:15 111:5,9,15 112:1,19 113:3 113:11,14 114:14 115:6,9 117:19 118:21 119:17 120:3,3 124:3 125:15 126:18 127:22 128:19 130:9
--	---	--	---

130:21 131:6 131:14,19 132:4,5 139:17 139:24 140:17 141:6,17 165:10,13,22 165:25 166:25 167:3,13 intervals 87:24 111:2 117:16 119:15 122:21 123:6,8 124:4 140:3,10 intravitreal 97:12 introduced 43:14,16 45:20 77:10 83:12 89:3 100:16 116:12 124:19 132:9 135:24 142:18 154:23 introductory 79:21 invalid 84:25 invalidity 84:5 invasive 166:6 166:13 invention 32:10 32:14,17 investigated 71:23 investigating 153:12 159:12	involve 101:6 involved 16:7 59:8 ipr 4:6,20,21,22 4:23,24,25 11:2,17,20 12:25 13:3,22 14:2,6 15:10 15:20 18:8,13 18:18 21:8,19 21:21,23 22:2 22:8,19,20 23:5 24:16,21 25:19 34:4 36:3,14 37:6 39:11,24 40:11 40:17 41:17,23 43:10,12,19 45:8,16,19 46:3,9,13 47:20 49:18 58:13 60:1 77:5,9 78:21 86:19 89:1,3 90:8 100:13,16 101:1 120:18 124:2,17,19 132:9,12 136:2 142:18,21 148:8 154:4,5 156:10,17 164:19 168:6 168:22 ipr2021-00881 39:17	ipr2021-881 4:9 ipr2022-01225 5:15 ipr2022-01226 5:15 ipr2022-1225 1:9 4:18 43:14 ipr2022-1226 1:19 4:19 43:16 iprs 10:18,21 11:24 12:6,16 13:11 17:10 18:4,20 19:1 19:24 23:9 25:8,14 31:15 31:20 34:5,12 35:22 37:5 42:24 43:20 44:10,17,22 45:2 58:19 65:5 73:17 76:13 85:9,14 112:21 146:7 147:4,17 148:11 153:8 153:17 154:13 issue 14:15 28:24 34:7,15 40:7 53:21 58:10 62:1,16 63:9,9 64:14 64:16,17 65:22 67:11,15 72:13	79:8 84:19 115:1 121:20 121:21 137:14 138:11,19,19 138:20 140:12 167:14 issued 9:22 49:19 52:19 issues 14:14 17:13 53:14,25 54:13 56:10 68:19 79:15 82:17,24,25 138:25 139:4,5 151:7 issuing 82:21 itc 20:13,15 item 21:5,6,8 21:11 55:5,7 55:10 57:6 j j 116:9 january 76:7 76:11 jeffrey 3:3 6:8 jennifer 26:4 jmarx 3:6 join 6:11 judgment 24:11 84:5 154:20 june 1:21 2:3 5:2 173:19 174:4
--	--	---	---

k	126:22 127:1,2	knows 137:19	law 6:9
k 2:9	127:2 128:3,6	l	lawyer 73:15
keep 104:9	131:16,18	l 53:1	85:17
keeping 156:9	132:1 133:18	label 50:13,17	lawyers 68:20
key 24:1 120:1	134:22 135:2,9	50:20,21,24,24	lay 118:17
120:6,7,13	137:3 144:14	51:2,6,9,15,18	layperson
kin 173:15	145:3,3,16	69:24,24 70:1	126:25 137:19
kind 14:16	146:18,22	70:2,17,23	leads 130:13,13
52:23 66:15,23	148:4,20 149:3	71:2,3 94:15	130:13
kinds 53:25	149:13,23	94:25 95:3,25	learned 17:12
64:16 144:24	150:8,25 151:2	96:5 97:5,8,16	17:17
149:14	151:18 152:9	97:19,19 99:18	leave 68:20
knew 153:15	152:19 153:14	142:22 143:15	left 95:14 121:3
know 10:6	153:15 154:1	143:20 144:8	legal 3:25
15:21 16:5	156:13 157:10	145:4,8,10	14:14,15 20:7
17:14,17,20	157:14,21	147:1 159:21	60:22,22 65:22
22:12 29:22	158:1,5,6,7,18	160:7,8 161:3	68:19 72:1,11
31:12 36:18	158:22,23	161:8,17,25	73:10 75:17
47:4,24 49:24	159:1,9,16	162:8 170:7,10	76:19,25 78:2
50:21 56:4,11	160:2,7,8,14,25	170:14,18,22	78:6 79:8,14
56:13,23 57:1	161:13,16,19	labels 143:1	79:14 80:15
57:3,4,6 59:20	163:17 170:20	lagging 30:12	81:11,21 82:16
59:22 65:18,24	170:23,25	land 157:17,18	82:24,25 83:3
70:1,3,5,9,10	171:3,4,8,10	large 130:21	85:4 93:5
72:2,17 78:3,3	knowing 23:22	131:4 134:13	103:14 106:2,6
78:4,4,5 80:10	150:25	larger 125:21	108:9 109:11
82:7 87:12	knowledge	128:17,17	109:12 110:25
89:8 93:6,9	102:4	latin 115:22	112:25 135:14
99:2 101:1	known 71:24	launch 155:14	161:11,12
104:15 106:5	72:7 73:8,12	launched	174:1 177:1
108:9,12	74:3 75:13,19	143:16 144:12	legality 73:14
113:20 115:12	75:19 76:11,16	144:17 148:16	legally 108:13
117:25 118:3	76:23 82:4	150:2 152:9,17	115:4
118:13 122:3,7	85:12	164:13	legitimate
125:11 126:15			113:5

letter 53:1 174:20 level 38:3 158:25 159:11 levels 149:12 light 39:14 128:14 likely 80:3 likewise 47:19 101:14 153:10 limitation 80:2 limitations 79:23 82:20 limited 85:2 91:6 94:19 109:10 110:4 limits 89:11 line 6:11 49:3 54:20 55:5,7 55:10 57:6 134:19 157:16 174:14 176:7 177:3 link 23:23 24:3 28:11,17,20 32:4 33:11 40:19 63:3,6,8 68:23 69:1,4 88:21 104:6 109:14,25 166:20 linked 170:17 linking 87:5,7 list 22:6,9,12 145:18 148:4	170:16,21 171:11 listed 14:10 20:24 143:22 143:25 144:8 145:4,8,9 176:7,17 listing 144:2 176:7 lit 62:12 literally 162:3 litigation 4:11 4:14 16:20,21 17:1,9 18:24 21:19 29:14,19 30:4,14 57:11 57:18 58:1,4,7 58:8,15,20 59:9,19,21 62:12,25 63:12 66:7 67:7 68:15 69:1,12 83:8,11 137:13 138:24 146:10 153:21,23 154:3,18,22 155:5 litigations 21:13 57:22 little 121:2 live 107:12 livenote 2:10 llp 2:7 3:2,9,13 loading 119:21 119:22,24	135:1,6 location 5:16 logic 108:10 long 9:25 15:5 141:2 longer 114:13 look 7:17 31:10 43:23 50:2 53:22 54:6 56:25 82:13 100:24 116:16 126:13 135:7 140:5 145:7 163:11 169:2 looked 36:16 46:17 49:25 54:2 79:7 82:10 106:21 117:16 119:13 127:16 145:16 145:25 146:1 147:2 152:10 looking 36:17 48:14 96:1 98:20 105:16 119:14 136:16 156:19 163:13 looks 12:7 46:6 lose 166:10 loss 156:15 158:3,9,20 159:15 lot 17:12 116:17	lots 102:16 111:2 low 137:6,10,16 137:22 160:13 lucentis 35:17 36:11,22 37:2 37:10,19 68:7 91:5 111:18 120:12 132:22 133:6,11,11,16 138:5 159:17 165:17 lunch 135:19 142:8,13
m			
m 3:3 machine 173:10 macular 32:19 32:20 35:17 89:12,16,18 madam 174:10 made 74:19 113:2 151:10 152:23 156:3 175:7 maintain 41:4 maintaining 117:9 maintenance 33:8 41:9,13 105:7 106:14 127:5,6 131:17 131:24			

major 52:17 165:19 majority 88:4,9 93:14,17 125:18,21 134:14 make 36:3 45:4 48:3,3 50:19 50:25 52:15 54:6 69:11 84:12 91:1 97:8,21 98:21 113:21 160:5 160:12,17 161:10 makes 118:17 making 20:18 98:12 118:14 manning 2:6 4:2,6,8,10,12 4:14 5:10 6:23 7:5 10:16 12:1 12:3 15:23 21:14 31:17 38:8 40:8 43:18 45:15,18 45:22 46:20,25 47:8,12,18 48:10 49:17 71:7 77:3,7,12 77:15 78:12,16 78:24 83:6,9 83:15 84:23 85:7 89:7 97:2 107:23 116:8	116:11,14 124:21 132:13 136:3 142:20 142:24 154:15 154:16,21,25 156:25 168:4 168:24 170:5 172:10 174:9 175:4,9 176:4 176:13 177:20 manning's 4:6 45:19 manufacturers 164:5 march 50:14,24 170:7 mark 12:1 45:15 77:3 83:6 116:8 154:16 marked 4:16 43:13,15 89:2 100:15 124:18 132:8 135:23 142:17 market 132:18 marketer 160:24 marketing 27:7 27:14,17,23 29:17 53:18 56:22 159:17 159:21 160:10 marketplace 76:18	marsh 9:4,6,10 marsh's 9:9 marx 3:3 4:3 6:8,8 7:4 9:15 9:20 14:17 28:6 38:6 43:8 43:17 45:21 48:24 49:2,7 49:16 59:6 61:14 62:2 64:21 65:4 66:5 68:12 73:25 74:7 76:1,21 77:2 77:11 82:9 83:13 88:13,24 89:4,6 92:23 96:14,17 97:1 100:17 103:15 103:22 107:10 107:16,22 114:22 115:15 116:7,13 124:20 125:16 126:1 129:18 129:25 132:6 132:10 135:17 135:25 141:18 142:7,19 154:24 159:4 167:18 168:3 168:18 171:13 171:21,25 massachusetts 2:7 5:17	materials 22:18 23:12 116:17 matt 6:15 matter 5:11 9:11 15:15 27:4 34:11 43:21 50:19 59:13,15 62:15 62:21,22 63:7 64:3,19 65:13 67:4,12,15 68:22 71:9 72:5 73:14 74:5 78:7,8 80:4 84:1 91:8 108:10 109:11 118:6 137:12 138:18 139:14 140:25 163:8 171:19 matters 8:12 9:18 11:13 14:4 23:1 51:17 54:11 55:14 57:17 63:2 64:25 70:7 118:23 matthew 3:14 matthew.wilk 3:16 mazzochi 3:2,3 6:10,11 mean 20:18 27:18 28:15 32:2 35:3,5
--	---	---	--

47:23 50:1 52:23 55:25 56:4,5,13 59:5 63:1,1 64:12 72:2 73:4 76:16 79:12,14 80:10 88:8 92:2,2,3,17 106:4 107:4 113:14 114:7 115:5 116:21 118:13 120:7 120:13 121:14 122:2 125:12 125:12 126:24 131:8 139:3 144:14 145:3 148:18 149:9 150:18 151:18 151:19 155:18 157:18 158:10 163:22 meaning 20:15 165:5 means 80:17 97:19 115:13 115:22 118:4 140:11 meant 136:10 136:23 measures 90:18 media 5:9 49:10,14 96:20 96:24 142:11 142:15 167:22	168:1 172:10 medical 28:16 36:24 38:10 75:22 86:8 104:6 106:6 112:16 114:20 115:1,2 118:1 118:2 122:6 126:23 137:18 139:20 140:12 medically 115:4 medicare 30:8 30:10,15 meet 8:21,24 9:25 meeting 101:6 members 68:21 memory 46:18 47:23 48:18 81:17 143:3 164:16 mention 35:1 58:16 mentioned 18:8 22:25 24:23 28:7,19 59:7 67:16 83:25 method 72:22 89:14 methods 32:10 32:13,17 53:16 72:23 130:10 131:13	michigan 20:25 21:6 microphones 5:3 midwest 174:17 177:1 migrated 168:16 milligrams 97:12 105:22 million 94:11 156:4,8,20 157:1,3 mind 45:10 134:7 151:14 minor 12:18 minute 116:19 167:18 missed 47:2 missing 44:18 misspeak 91:2 mistake 47:2 misunderstand 36:4 mm 79:19 91:15 94:9 97:4 98:5 100:23 104:14 105:2 143:21 158:17 modification 51:9,10 modifications 19:15 45:12 47:11	modified 51:3 molecular 121:7,12,16 122:4,8,14,17 122:20,25 123:4,9,12 140:2,9 molecule 69:19 138:10 141:1 141:13 146:23 149:11 molino 3:2 6:10 moment 25:10 43:23 47:7 53:12 54:18 monthly 97:14 98:13 125:14 128:15,18 165:1,6 months 14:25 105:12,23 106:1,4,24 107:7 150:6 morning 5:1 7:5,6 10:3,3 motivation 171:8 mouse 138:6 multiple 32:12 32:15 mute 5:5 mylan 1:5,14 5:12 6:9 12:25 174:6 175:3 176:3
--	---	--	---

mylan's 58:13 172:1	133:1,3,5,9,13 133:15,19 148:23 149:5 158:24 159:12 159:14	noticed 48:12 noticing 6:7 novel 72:19,21 72:25 73:2,4 75:23 103:24 novelty 103:10 103:13,17 november 142:22 143:16 144:12,17 147:1 148:16 number 4:14 11:3 12:2 21:5 21:6,8,11 22:8 43:8 53:1 56:8 56:13 84:6 90:21 91:8 92:13 95:14 97:22 105:15 107:5 108:11 108:12 119:21 121:4 145:22 154:17,22 161:6 172:10 174:8,14 numbers 5:15 11:25 98:22 116:23 129:11 132:23 146:13 176:7 nw 2:7	objection 14:11 27:25 37:20 59:3 61:11,19 64:10 65:1,21 67:21 73:20 74:4 75:16 76:14 82:6 88:6,18 92:15 103:12,19 114:18 115:10 125:10,25 129:15,22 131:25 141:15 158:21 objections 6:1 objective 31:21 32:1 observe 113:12 118:20 124:1 134:11 145:5 observed 75:20 109:21 111:1 113:10 128:14 130:20 obstacle 134:12 obtain 148:23 obtained 98:14 147:19 158:15 obvious 31:22 occasionally 163:4 occlusion 32:21 32:22 90:16 occurred 110:15
n	nexus 32:4 60:11 61:22,24 62:6 66:3,18 69:16 139:18 140:18 nine 107:24 108:3 non 31:22 nonlimiting 80:3 nonmisleading 160:5 161:10 161:14 nonobviousn... 32:2 nope 95:12 northwest 5:18 notarized 174:15 notary 2:11 173:3,22 174:25 175:10 175:18 176:15 176:23 177:23 note 5:3 11:22 27:12 85:1 107:12 174:13 noted 48:21 notice 173:6	o o 116:9 oath 5:23	
n 3:1 4:1 naive 134:23 name 5:19 16:15,16 63:4 122:1,1,2 174:6 175:3,4 175:15 176:3,4 176:21 named 4:12 116:9,12 names 12:18 nature 149:8 150:7 necessarily 160:4 necessary 30:19 need 30:1,1 112:6 171:23 needed 115:22 neighborhood 93:18 neither 173:14 neovasculari... 32:22 new 3:15,15 11:25 12:2 30:8 41:25 51:16 73:7,7,9 73:13,18,23 74:14,25 75:2 75:9,21 132:21			

offer 163:6 166:1 offered 34:8 58:14 68:14 87:9 93:21,23 122:12 146:10 147:5,10 150:11 165:8 offering 31:20 72:3 73:16 81:22 86:14 161:12 offers 52:25 111:22 127:21 office 1:1 5:14 offices 2:6 official 173:18 175:15 176:21 oh 10:6 17:19 50:4 67:9 95:13 105:17 105:20 107:16 133:10 ohio 174:2 ohji 4:13 116:10,12 119:6 120:25 122:21 127:16 127:20,24 140:1 okay 7:13,19 7:22 8:9,16 10:8 11:2,15 11:22 13:9,12 15:1 16:1 20:4	20:20 22:14,20 23:19 26:3,14 26:24 33:13,17 34:8 35:7 39:9 45:6 48:8 50:6 50:11 51:22 55:3 66:25 68:25 76:4 88:25 89:17 95:16,19 97:15 97:24 98:2 100:20 106:12 110:20 117:1 123:20 125:1 135:19,20 136:8,19 137:1 138:1 139:10 140:11 142:8 143:8,11,19 148:6 153:6 154:15 155:8 155:12 156:9 156:23 164:11 164:17 167:20 168:10,13 170:20,25 171:15 omit 68:8 once 32:16 33:22 49:25 97:13 105:8,11 105:11,22,23 105:24,25 106:14,22,23 107:1 126:20	172:3 one's 166:10 ones 12:23 open 49:3 ophthalmology 121:25 opine 81:12 142:3 opined 28:10 63:24 64:23 65:7,9,11 66:7 67:8 93:9 99:19 146:1,5 opinion 14:13 18:9,21 23:23 24:2 27:5,16 28:25 29:11 30:20,21 31:24 33:11 35:23 36:21 37:4,18 37:24 39:5,6 39:11 40:3,7 42:8,14,16 51:16 59:16 61:2,15,21 62:6,15 63:7 65:19,23 66:12 66:17 67:19 68:16,18,22 69:18,23 71:9 71:11,15 73:11 80:16,17,23 86:7,13 93:13 93:23 103:3 106:2 109:12	112:4 114:23 120:2,5 122:3 122:16,24 124:10 129:19 130:25 131:3 133:14,25 134:15 135:11 135:14 137:15 138:22 141:16 144:4,23,25 147:5,10 151:21 152:12 153:11 161:7 161:13 166:4 opinion's 141:9 opinions 7:10 7:15,23 8:11 9:21 13:17 14:4,7 15:14 15:19 17:7,9 18:3,19 19:1,9 19:23 24:3 25:3 27:3,23 29:5 31:20 33:19 34:1,4,8 35:12 36:6,12 37:1 38:18 39:15,22 40:4 40:8,15,19,25 41:5,14,15,16 41:20 42:24 44:12 46:21 47:16 48:1 51:5,19 58:15 59:13 61:8
--	--	---	--

66:25 67:24 68:14 71:18 72:4 73:17 74:23 75:3,7 75:12 76:12 78:1,17 81:22 82:3,22 85:8 85:14 86:2,5 86:11 87:9 93:21 94:18 105:24 108:15 109:16 112:21 121:11,15 122:13 123:4 124:10 127:7,9 138:1 140:23 141:12 146:11 147:17,22,24 148:13 150:14 150:20 151:6 152:2 153:8,17 155:9 163:6,8 165:9 166:1 opportunities 167:4 opportunity 111:23 112:13 159:14 opposed 29:24 37:9 68:6 119:15 120:12 option 111:24 112:14 113:22 130:10 141:3	optionality 111:23 131:20 140:24 order 1:23 7:12 10:9 171:18 original 44:1 orphan 149:13 outcome 5:25 77:21 78:6 115:7 118:15 173:16 outcomes 68:5 78:7 117:9 outset 124:8 outside 22:2 27:21 34:9 35:13 37:23 47:13,25 48:4 48:5,6 67:24 115:10 146:14 147:6 151:5 overall 10:4 own 135:3 147:12 owner 1:8,17 3:17 6:14,16 171:16 p p 3:1,1 162:16 162:17 p&l 57:5 157:14,18,19 157:25 159:3,7 p.m. 107:18,21 142:12,16	167:23 168:2 172:8,13 page 4:2,5,17 44:15 50:7,9 50:15 54:19 55:4 79:17 84:4 89:9 90:10,20,21 94:8 95:11 97:10,22,22 98:1,6 100:18 104:12 105:3 116:23,24 117:3 121:1,1 124:24 125:3 127:15 132:16 132:21 136:15 136:16,17 137:1 139:6 140:7 143:20 156:12 163:14 164:21 168:25 169:17 174:14 174:16 176:7 177:3 pages 44:19 53:23 pair 162:11,15 162:16 palo 3:10,11 panel 65:14,16 paper 78:20 79:17 80:18 papers 172:2	paragraph 20:4,6 21:16 31:18 32:9,24 33:14,15 39:10 40:5,18 41:4 72:16,20 73:5 76:2,6 79:20 84:15 86:16,17 98:1,23 100:2 100:8 104:10 104:13,15,19 117:2 123:19 136:6,13 paragraphs 38:20,22 39:4 parse 123:9 part 30:8 37:6 38:25 56:20,22 58:10 66:10 67:19 72:13 76:6 79:8,11 79:12,21 84:9 93:25 98:6 103:14 104:18 104:18 114:5,7 138:25 139:8 153:8 154:11 164:23 169:3 169:18 176:9 partes 10:19 78:23 particular 13:23 30:7 120:18 121:23 129:17 132:4
---	---	---	--

[particular - patients]

Page 32

143:3,13	43:10,12,14,16	121:21 124:6	68:17 75:12,14
160:16	43:19,21 44:12	135:13 136:5	78:18 81:23
parties 5:7 13:6	44:13 45:8,16	138:22 143:6	82:22 85:13,19
162:5	45:19 46:8	144:13,15	86:14 101:12
party 5:23	47:17,18 49:18	145:3,8,13,21	104:3 108:20
173:15	52:20 58:13,13	145:21,24	121:20 123:18
patent 1:1,3,8	60:1,3,4,7,8,13	146:3 147:7,7	139:4 143:22
1:10,17,19	60:19,20 61:5	147:7,14,18	143:25 144:2,3
3:17 4:6,8,9,18	61:8,8,9 62:13	148:8 154:4	144:3,5,8,18,21
4:19,20,21	63:9 65:6 66:6	156:10,17	145:4,6,8,16,17
5:14 6:14,16	67:11 69:4,8,9	164:18 166:18	145:19 146:6
7:24,24 8:12	69:14,16 73:15	167:11 168:5	146:12,14,15
8:13 10:22,25	76:7 77:4,6,8,9	168:22 171:1,2	146:20,22,25
10:25 11:3,6,7	77:16,17,25	171:11,16	147:2,6 151:1
12:16 13:11,22	78:9,13,14,21	patentable	163:2 166:20
13:24 14:2,19	78:21 79:25	76:24	170:17,21
14:20,20 15:10	80:8,9 81:1,3,6	patented 32:3	171:6,6
15:19 17:1	81:8 82:11,14	33:17 34:2,9	patient 32:13
18:13,18 19:3	84:6,8,19	34:24 53:21	32:15 68:5
20:2,11 21:13	85:21 86:2,6	54:25 60:12,12	111:18 113:12
21:19,23,25	86:10,12,19,24	60:15,19 61:3	113:20 114:12
22:1,2,8,19,20	87:6,19 89:3,5	64:1 66:2	117:5 118:10
23:5,5 24:16	89:8 90:8 94:3	76:22 104:7	118:14 127:4
25:8,13 28:3	94:3,4 95:7	109:15 120:19	133:13,21,22
28:11,12 29:3	100:1,4,8,14,16	120:23	133:24 134:1
29:3 32:6,10	100:22,25	patents 13:18	169:4
32:25 33:18	101:14 103:11	14:10 23:24	patient's
34:3 35:8,10	103:18,24	25:3 28:17,20	112:16
35:15 36:3,6	104:9,11,18,23	28:21 29:7	patients 33:2
36:14,20 37:6	104:24 105:1	34:25 36:7	35:18 54:16
39:2,10,18,18	105:15,19	39:13,23 41:1	56:12 68:5
39:24 40:2,10	106:13,20,25	41:22 42:2,9	101:6 111:14
40:11,15,17,23	107:2 108:16	42:11,15 58:20	112:15 113:17
41:17,22,23	108:17 109:2,3	61:17 62:1	126:5,10 130:9
42:13 43:2,3	109:9,18 110:6	63:8,18 67:20	130:14 131:12

Veritext Legal Solutions

www.veritext.com

888-391-3376

Mylan Exhibit 1121

Mylan v. Regeneron, IPR2022-01225

Page 77

Samsung Bioepis Exhibit 1075**Page 77**

[patients - practiced]

Page 33

132:21 133:1,3 133:5,8,15,19 134:3,23 155:15,19,22 164:2,7,7 payers 160:11 payment 157:4 payments 154:8 156:3 157:7,15 pediatric 51:11 149:1 150:4 pend 144:3 pending 4:11 10:18 11:24 13:11 16:21 17:1,8 18:4,19 18:23 19:1,24 23:9 29:14 31:19 34:4,12 43:20 44:10,17 45:2 47:4,19 57:10 58:1 65:5 73:17 76:12 83:7,11 85:9 90:17 112:21 144:3 145:6 146:7,9 147:4,17 people 17:15 26:10,18 56:11 56:21 57:4 130:13 131:11 140:19 153:15 166:8 167:5	percent 90:13 90:15,16 93:18 93:21 98:8,9 98:15,22 125:3 125:7,12,20 128:23 129:3,7 129:9,10,14,20 130:2,5 131:4 133:5,8,12 134:8 percentage 92:5 133:2 169:13 170:1 perfect 118:17 perfectly 113:5 period 114:13 125:13 126:3 129:17 148:17 148:19 149:7 149:10 150:2 165:20 periods 88:12 person 138:12 personally 175:11 176:15 perspective 42:10 61:1 107:9 112:1 petitioner 1:5 1:15 3:7 5:11 6:9 12:24 80:2 petitioners 12:19 ph.d. 2:6 4:2 6:23 174:9	175:4,9 176:4 176:13 177:20 pharmaceutic... 1:5,7,14,17 5:12,13 174:6 174:7 175:3,3 176:3,3 pharmacies 160:14 161:21 phase 33:7,8 41:9 phone 49:3 174:3 phones 5:5 phonetic 63:4 physician 102:20,23 110:4 118:19 122:23 133:21 133:23 physicians 56:9 56:10 87:23 93:10 109:7 121:22,24 134:5,17 138:17 160:18 161:22 pick 5:4 pinpoint 85:19 place 5:7 71:2 173:6 placed 166:11 plans 19:18 play 151:1	plays 109:7 please 5:3,5 6:2 6:19 49:8 65:3 105:19 129:24 132:16 172:7 174:12,12 plenty 102:7 plurality 88:8 93:14 125:22 plus 129:8,9,9 129:9 point 33:21 52:18 59:14 85:24 96:12 126:4 135:9 pored 7:18 porter 2:7 3:9 3:13 5:17 6:14 6:16 16:17 portion 81:14 possible 112:5 138:8 148:25 148:25 post 152:17 potential 41:10 141:2 164:2,7 potentially 166:9 practice 102:6 102:6,6 110:22 112:22 117:4,6 118:11 135:3,3 practiced 102:2 102:9,12 112:7
---	--	---	--

Veritext Legal Solutions

www.veritext.com

888-391-3376

Mylan Exhibit 1121

Mylan v. Regeneron, IPR2022-01225

Page 78

Samsung Bioepis Exhibit 1075**Page 78**

[practicing - product's]

Page 34

practicing 110:24 112:24	163:1	prior 7:14,25	46:9,14 48:5,7
practitioner 118:2	prescribe 134:22	8:3,13 14:2	58:11,13 86:20
pre 30:12 52:11	prescribed 155:15,22	24:25 28:3	100:13 101:1
preceding 33:6	present 3:24	36:3 37:5 39:6	proceedings 44:3 47:20,22
104:21 105:14	6:4 15:24	39:10,16 40:6	85:5
106:17 169:6,9	16:18 32:10,14	52:11 71:24	process 70:6
169:20,23	32:17 79:24	72:1,7,9 73:9	produced 29:18 57:5
precisely 115:13	presentation 136:10,23	73:12 75:13	58:6
prefer 99:2,3	presented 39:16 127:14	76:11 82:4,21	product 30:9
preference 134:6	presently 19:21	83:1 95:24	32:3,4,5 34:23
prelaunch 158:13,14	presents 75:22	136:17 152:10	34:25 36:1
prematurity 51:12 170:13	president 9:7,8	priority 75:14	42:12 60:13,14
preparation 8:6	presume 25:20	75:18 76:7	60:25 63:10,16
prepare 8:21	121:23 160:17	private 5:4	66:4 70:7,17
14:23 46:9	pretty 73:23	prn 115:16,19	70:22 72:21,25
prepared 12:15	151:18 161:18	115:21,25	73:3,7 75:20
13:21 16:7	164:5,8	117:7,18,21	75:21,25 86:10
57:15 58:18	previously 4:16	118:12 119:2,6	87:8,23 89:25
59:21 78:25	30:12 43:13,15	119:16 126:6	91:1 92:8
80:13	89:2 100:15	126:10,19	102:21,24
preparing 9:18	124:18 132:8	127:17,25	103:5 113:25
10:5,10 15:6	135:23 142:17	128:21,24	120:4 122:9,11
15:14,19 16:2	pri 30:12	129:2,13	130:24,25
16:22 17:4	price 160:13	135:12	132:25 141:5
18:1 22:7 26:7	pricing 30:10	proactive 117:7	144:22 147:13
26:10 44:7	primarily 24:6	probably 34:15	149:5,9,12
74:9,12 79:5	primary 33:10	46:15 107:14	150:2,16,22
80:22 143:12	61:15 66:13	133:20 143:2	152:8 157:21
	71:19	161:6	157:25 159:3,7
	printed 80:4	procedure 8:17	160:6 164:4
		175:5 176:5	171:2
		proceed 6:20	product's 61:23,24 62:8
		proceeding 6:2	
		20:14,21 37:24	
		38:2 39:1 46:8	

Veritext Legal Solutions

www.veritext.com

888-391-3376

Mylan Exhibit 1121

Mylan v. Regeneron, IPR2022-01225

Page 79

Samsung Bioepis Exhibit 1075**Page 79**

[product's - quote]

Page 35

66:19 68:24 69:6 131:2 133:2 139:18 production 174:16,17,22 products 34:20 71:3,5 72:22 75:23 90:3 95:8 122:10 133:20 140:20 141:6 161:11 161:15 165:18 professional 2:10 profit 156:15 158:2,9,20 159:15 profits 157:13 program 52:9 52:25 53:3 54:17 programs 51:23 52:2,5 52:21 53:18 54:14 projected 132:24 promote 160:15 161:8 161:22 promoted 161:5,6,17 promotes 160:19	promoting 139:11 promotion 159:17 161:25 162:7 163:7 proper 85:17 properties 122:8 139:8,12 139:20 140:11 property 140:2 protection 144:13,15 147:18 protective 1:23 171:17 protocol 35:14 37:16,17 provi 31:1 provide 8:18 14:8 19:18,24 24:12 28:16 40:25 50:16 51:5 52:1 58:16 60:24 70:22 124:10 161:23 172:2 provided 11:12 20:7 21:17,22 27:7 46:25 47:8,12 58:4 59:17 155:24 157:1 provider 163:20,24 164:9	providers 164:3,6 provides 32:10 52:9 75:5 91:19 96:5 112:2 140:19 141:13,17 155:19 167:4 providing 28:21 proviso 55:18 psaki 63:4 pt 21:18 ptab 28:25 38:25 39:1 59:2 63:17,23 64:2,7 65:18 68:21 80:7 81:1,6 82:3,14 ptab's 77:24 79:18 81:15 public 2:11 151:9 173:4,22 175:10,18 176:15,23 177:23 publication's 151:17 publications 151:16 publicly 152:22 published 36:16 purposes 13:9 61:6	pursuant 173:5 put 157:25 puts 98:21 q qualification 82:18 qualified 81:12 122:24 123:9 quarter 91:4 quarterly 31:2 question 8:7 13:13 23:2 24:19 27:20 35:12,24 37:12 37:22 60:22 62:16,21 64:18 65:14,15 67:25 70:10 71:12 73:10,22 75:10 76:25 78:2 91:12 92:1,18 92:22 93:24 96:15 98:19 99:7,15 123:2 133:18 141:11 161:11 questions 47:24 56:12 65:16 75:18 76:20,20 135:18 171:14 171:15 quick 7:17 quite 87:20 quote 31:20,22 50:12,13 81:2
---	--	---	--

Veritext Legal Solutions

www.veritext.com

888-391-3376

[quote - referencing]

Page 36

81:6,7 119:7,7 127:25,25 162:14,15	reads 33:22 79:21 132:17 real 3:10 117:6 118:10 really 37:11 72:2 reason 8:18 119:5 122:19 174:15 176:8 177:3 reasonable 108:13 reasoning 166:4 reasons 36:24 111:2,13 112:12,13 113:1,12,22 160:1 161:4 rebate 53:18 54:14 rebates 55:4 recall 10:15 15:9 24:22 25:16,22 26:15 31:8 34:13 46:23 47:25 69:9 97:3 117:18 151:12 153:21 162:24 163:3 170:15 receipt 174:19 receives 127:5 recent 50:13 74:10	recently 7:17 170:21 171:5 171:10 recess 49:12 96:22 107:19 142:13 167:24 recite 86:18 98:6 100:3 104:17,19 136:9 recited 93:2 101:8 110:6 recites 32:9 105:6 106:21 117:4 164:23 169:3,18 recognize 79:9 136:3 145:17 recognizing 23:25 24:3 62:20 121:18 121:19,22 recollection 36:17 47:1 49:23 51:14 74:12,17 87:14 88:9 116:20 124:14 145:15 recommended 97:11 record 5:2,8 6:6 11:23 15:7 49:6,7,10,14 96:20,24 107:10,16,18	107:21 142:11 142:15 167:21 168:1 171:24 172:8 173:13 176:9 recorded 2:5 5:10 173:10 recording 5:6 rectangle 44:25 redacted 172:3 reduce 114:14 117:8 118:12 ref 38:23 refer 11:6 13:25 18:7 30:16 33:14 35:15 39:6 41:4 44:22 62:25 101:22 120:14 reference 22:8 34:16,16 42:1 42:4 50:23 124:7 163:17 174:8 175:2 176:2 referenced 22:23 53:24 93:16 148:5 175:11 176:15 references 22:10 163:9 referencing 163:15
--	---	--	--

Veritext Legal Solutions

www.veritext.com

888-391-3376

Mylan Exhibit 1121

Mylan v. Regeneron, IPR2022-01225

Page 81

Samsung Bioepis Exhibit 1075**Page 81**

referred 11:14 18:6,22 31:9 31:12,14 33:8 102:17	regarding 40:19 72:5 regardless 118:15	170:20,23,25 171:2,4,6,10 172:2 174:6 175:3 176:3	regulatory 70:4 70:6 147:23 148:17,18,21 149:1,7,18,22 149:25 150:8 150:12
referring 12:22 16:9 18:14 20:22 21:22 30:5 32:6 36:11,13 38:24 42:19,23 60:16 73:5 79:24 86:1,4 90:7 91:13 95:13 105:18 145:19	regards 39:2 regeneron 1:7 1:17 5:13 6:14 6:17 9:17 14:22 15:11 16:2,5,8,11,21 17:1 24:13,20 26:12 27:9 29:16 30:15 31:1 49:21 52:9,25 55:23 56:15,18 57:1 57:12,19 58:2 59:8 84:4,23 85:11 128:1,11 129:12 136:10 136:23 137:5 139:11 143:25 144:7,18 145:10 146:15 146:20,22 147:11,13,19 147:23 150:15 150:21,24 151:10,22,23 152:3,13,22 153:3,12,24 156:3,21 157:1 157:4 160:2 163:20 164:1 164:13 170:16	regeneron's 4:10 29:13,18 83:6,10 85:7 87:2 101:19 123:11 142:4 154:8,19 155:24 156:18 157:3,6,19 158:3,7,15 163:7 164:9 171:8 regimen 28:12 28:22,24 33:1 33:20,24 34:10 42:19 43:3 88:16 93:1 102:3 109:10 110:23,25 112:23,25 117:14,22 119:12 123:14 123:23 125:8 130:1,4 141:25 169:14 170:2 regimens 87:18 114:2,5,9 117:7 118:11 119:8,19 127:18 registered 2:9	relate 29:7 61:9 70:11 139:5 related 5:23 9:17 32:19 53:16 61:3,4 65:19 67:13 68:9,22 69:5 89:12,16,17 91:9 92:6,13 115:25 116:4 147:6 171:2 relates 78:7 145:14 relation 24:25 relative 128:6,8 relatively 51:10 relevance 68:19 79:9 relevant 24:9 33:18 34:3 51:9,16 59:13 64:19 68:15,17 75:3 77:25 78:17 81:18,19 113:23 120:5 120:19 139:12 154:13 reliance 87:5
refers 27:9 31:13 reflect 18:25 39:5 46:21 62:14 158:3 reflected 18:4 18:10 21:3 28:2 40:22 42:4 60:13 62:1 90:6 126:13 155:13 reflecting 125:7 reflective 60:6 reflects 18:9 42:3 125:3,18 128:1 129:12 155:24 156:2 156:25 reformulation 149:11			

reliant 88:21	repackage	representing	responsible
relied 17:25	160:16	3:7,17 5:19	65:8,10 123:13
18:23 23:23	repackaged	reps 56:24 57:2	137:16 140:3
24:6 28:13	160:16	request 24:18	restate 47:4
60:23 101:5	rephrase 81:4	24:19 176:9,11	rested 110:1
104:5 110:2	86:3 99:7,14	required	restrictive
rely 14:3 44:11	123:1 141:11	174:25	108:16
86:8 87:6	reply 172:1	research	result 58:7
101:22 108:19	report 18:10	158:12	retained 16:25
109:13 130:17	30:4 32:8 35:1	respect 9:22	172:11
131:23 135:16	54:23 56:24	10:17,22 11:3	retinal 32:21
relying 17:7	58:5 68:11	11:19 14:9	90:15
27:3 63:7	74:10 83:25	15:10 17:9	retinopathy
86:23 87:3	89:24 90:1	24:20 25:2	32:20 51:12
100:7 108:25	93:16 95:6	26:20 34:3	90:14 95:21
110:4	163:14	36:6 38:17	170:13
remember	reported 57:4	39:23 40:10,16	returned
14:25 15:8	reporter 2:10	40:25 41:22	174:19
26:13 52:13	2:11 5:21 6:19	44:11 51:6	review 8:5
83:21 127:19	43:6 45:14	63:18 81:23	10:10 23:20
127:20 155:6	77:3 83:5	90:22 94:3	25:5,9 26:24
163:4	107:14 116:8	98:24 104:23	44:7 45:4 46:7
remembering	175:7	109:17 124:9	52:15 78:23
14:24 16:16	reports 7:25	137:10,23	84:12 86:19
25:10 29:21	8:14 24:10	141:25 146:2,5	143:11,14
51:13 93:18	55:13	146:11,15	174:13 175:1
remind 21:1	representation	147:21 149:17	176:1
124:14 140:6	55:17 78:15	153:17 160:9	reviewed 7:13
reminded 30:1	84:14	166:17	8:5 17:24 22:6
remote 6:25	representative	respectfully	25:12,15,23
remotely 6:5	171:1,6	171:25	27:1 28:7
remove 110:9	representatives	responds	31:16 38:2
rendering	56:9,16,19	111:16	46:12 48:13
123:3 155:9	57:7	response 98:19	78:24 79:5
		120:6 154:19	80:12,21 88:10

[reviewed - schedule]

Page 39

124:1 136:20 165:20 reviewing 48:18 reviews 10:19 revisit 162:25 richard 2:5 4:2 5:10 6:23 172:10 174:9 175:4,9 176:4 176:13 177:20 right 38:7 41:16 44:6,24 47:6,6 65:17 69:10 91:18 95:13,16 97:22 106:8 108:23 113:7 116:22 136:1,16 138:12 142:7 145:7 146:13 151:24 152:1,4 152:21 153:19 160:25 168:21 171:13 rights 85:2,3 151:10 152:14 152:18,23 153:5 rmmslegal.com 3:6,6 role 9:10 109:6 roles 26:19 roughly 133:12	roxane 148:2,2 rules 175:5 176:5 rush 168:11 rvo 94:11,14,23 96:3,6 97:3,5,6 97:17 98:4,11 98:14,25 99:5 99:9,14,18 ryan 2:9 5:21 9:4 s s 3:1 4:4 174:16 176:8,8 177:3 safety 62:9,14 62:18,22 63:16 63:19,24 64:8 64:24 65:7,11 65:20 66:8 67:1,8,9,13,14 68:14 69:1,6 137:13,17,21 138:18,19 139:2 sale 86:23 98:7 100:6 sales 56:8,15,18 56:23 57:2,7 61:16 62:4,10 62:18,24 63:25 64:24 65:8,10 65:19 66:13,21 69:20,25 71:9 71:14 76:23 81:24 85:20	86:6,13 87:3 87:10,17 88:15 89:21 91:4,9 91:23 92:5,8 92:10,13,25 93:8,22 94:17 98:16 99:1,6 99:10,13,17 101:5,19 102:2 102:12,22,24 103:5 108:24 110:2,4,9,20 112:6,22 113:17 115:25 116:4 117:13 119:11 121:12 121:17 122:15 125:7 127:11 129:21 130:2,5 130:17,22 131:4,22 137:11 169:13 170:1 sample 90:3 125:13 sampling 53:17 54:14 samsung 1:14 13:2 satisfies 115:5 satisfy 169:13 170:1 saw 27:5 106:12 140:1 155:7	saying 13:2 41:4 51:13 63:5 64:12 80:7 92:5 118:8 says 31:24 39:14 40:5,19 50:15 79:15 82:8 85:1 89:14 105:13 106:16 121:7 128:18 132:24 135:10 137:25 140:6 145:6 156:7 schedule 61:10 61:13,22,25 62:7 75:8 81:24 82:4 85:12,21 86:5 86:7,9,12 88:3 93:7,11 94:13 94:20 102:7,9 102:12,18 108:17 109:1,3 109:6,21,22 110:5,11,19 112:5,7,9,11 113:6 114:17 114:25 124:12 124:12 125:4 125:14,19,24 126:8,10,21 128:12,13 129:6,20
---	--	--	--

Veritext Legal Solutions

www.veritext.com

888-391-3376

Mylan Exhibit 1121

Mylan v. Regeneron, IPR2022-01225

Page 84

Samsung Bioepis Exhibit 1075**Page 84**

[schedule - signed]

Page 40

130:18 131:24 134:2 135:12 141:10,14 schedules 88:11 109:19 119:3 128:21 science 122:5 scientific 139:21 151:15 151:17 scientist 122:6 scope 86:24 87:4,11 100:7 101:20 115:11 135:13,15 151:5 se 83:20 122:4 seal 173:18 175:15 176:21 seams 110:15 sec 107:11 second 11:2 43:11 84:3 117:3,3 136:14 section 53:13 53:19 54:13 100:19 121:2 128:15 140:8 sections 128:18 see 11:9 31:11 34:19 49:25 53:23 54:3 76:5,8 79:15 80:5 84:3 86:20 89:11,14	98:4,9 104:21 115:6 116:21 117:10 121:3,9 136:9,18 137:5 139:7 143:17 143:22 144:2 145:9 159:2,6 159:10 163:11 163:14 165:1 169:10,23 seeing 83:22 87:14 143:3 seem 30:19 44:1,5 48:6 107:7 seemed 24:9 47:25 48:4,4 seems 85:4 120:19 seen 10:14 25:25 26:1 27:2 45:25 77:12 83:17,19 87:1,16 107:5 116:14 124:21 124:23 126:12 126:15 132:13 134:19 142:24 143:1,2 148:6 148:7 154:25 155:3 164:8 segment 132:25 segregate 17:16 selled 76:17	sense 37:12 54:12 111:25 118:17 sensitive 5:4 sentence 72:25 76:5 79:21 117:3,10 121:6 separate 55:5,7 55:10 152:15 september 96:3 sequence 138:6 138:16 sequences 138:3 sequentially 32:12 series 30:14 serve 155:20 services 160:18 set 19:10 41:17 41:23 123:16 132:6 setting 38:4 settings 34:18 34:21,23 68:4 seven 111:20 several 31:8 shaped 17:22 27:13 share 92:8,10 98:15 99:1,6,9 99:13,17 125:22 130:21 131:4 132:20 132:25 133:13	133:15 160:22 161:1 shares 91:4 98:7 sheet 8:3 46:4 48:22 174:14 176:7,10,18 177:1 sheets 8:10 short 27:6 79:22 shorthand 173:10 shortly 96:13 show 37:8 38:5 92:10 95:6,23 102:17 117:16 130:8 132:2 134:5 157:24 159:11 shown 92:2,19 98:3 174:16 shows 35:15 90:2,10 91:3 92:7 95:8 125:12 126:9 126:16 128:11 128:23 134:7 157:16 sic 31:22 107:24 signature 48:15 173:21 174:15 signed 175:13 176:18
--	--	--	---

Veritext Legal Solutions

www.veritext.com

888-391-3376

significant 30:2 98:25 99:3 106:7 166:7 signing 174:20 similar 26:19 54:16 56:3 79:23 80:9 81:2,7 90:18 132:23 133:15 simply 37:25 68:1 sincerely 174:21 single 12:15 sir 174:10 sit 29:20 40:12 40:18 48:11 52:13 83:22 116:18,19 sitting 7:19 18:16,16 19:6 19:22 26:14 39:19 45:6,11 47:6 85:18 149:23 161:24 siwik 3:2 6:10 six 110:16 118:16 127:6 150:6 slide 125:2,12 126:2,14,16 132:17 137:5,6 137:25 139:7 slides 126:5	slight 29:23 30:3 small 51:10,10 131:5 149:11 sold 76:17 122:10,11 solutions 174:1 177:1 something's 83:1 sorry 8:2 16:14 16:16 21:1,19 25:20 29:24 31:15 35:17 40:2 43:8 44:2 48:12 50:9 54:18 63:6 65:2 68:6 73:22 81:4 90:2 91:11 95:7,12 104:12 104:25 105:10 105:17,20 108:1 121:14 128:25 129:23 133:10 148:25 150:18 153:3 156:5 160:7 162:12 168:9 sort 54:7 sorts 21:20 sound 112:13 sounds 49:4 60:21 69:10 72:12 127:1	source 55:1 132:18,24 spe 56:13 speak 16:1,20 16:25 24:23 25:2 26:6,11 26:18,21 56:10 74:9 speaking 52:16 specific 27:12 27:20 29:6 47:1 70:8 71:5 73:24 83:22 85:25 88:16 90:23 91:1,12 93:4 143:3,13 157:20,25 159:3,7 164:16 specifically 46:11 52:23 54:22 55:22 56:23 57:3 70:9 151:20 156:24 spend 10:4 15:5,19 spends 57:1 spent 15:13,18 159:16 spoke 26:10 spoken 16:5 26:8,15 102:19 square 3:10 staff 15:4	stand 47:5 172:7 standard 2:8 standing 173:4 stands 115:22 start 164:21 state 6:2,5 20:6 76:6 84:18 175:10 176:15 stated 19:25 29:8 93:12 140:1 statement 33:4 39:20 154:19 161:19 175:13 175:14 176:19 176:19 statements 17:25 151:9 152:22 153:2 157:14 158:3,9 158:20 159:16 161:10,14 states 1:1 5:14 57:11 59:10 84:4 122:22 139:8 154:19 status 71:4 78:5 149:4 stay 94:6 107:13 120:25 126:25 131:16 131:23 135:22 staying 132:3
---	---	---	---

[stays - surprised]

Page 42

stays 47:21	substantial	110:12,19,21	supervision
stipulated	29:22 75:25	111:8 112:20	173:11
84:24 85:11	99:4,6,9	113:4,9,18,24	supplemental
stipulation	166:11,12	114:5 115:25	58:5,5
4:11 83:7,10	substantially	116:4 118:24	supplementat...
85:7	79:23 80:8	119:20 127:7	19:19
stipulations	81:2,7	130:15 131:2	support 15:3
83:18,21,24	substitution	131:15,21	53:10 55:24,25
stood 30:22	72:21	139:12,19	56:2,7 59:9
straight 134:23	succeeding	140:18,22	suppose 17:17
135:5	134:2	141:8 146:2,6	sure 11:8 17:12
street 3:4,14	success 7:11,16	146:10 147:16	17:21 20:18
strengthen	7:24 9:22	147:22,24	36:4,5 45:4
28:4	31:21 32:5	148:13 154:9	48:3 50:19
strong 134:6	33:12,19 34:4	165:3,14	51:12 52:15
stuck 168:14	38:19,23 39:12	successes 32:1	54:7 65:5
studies 29:18	40:9,16,20	successful 41:6	69:11 70:12,14
29:25	41:1,12,21	41:6	70:15 75:11
study 35:14	42:24 44:12	sufficient 30:20	84:13,15 85:16
36:16 37:16,17	47:16 53:15,20	41:11	89:19 91:1,13
stuff 168:17	55:2 58:14	suggest 37:14	96:14 97:9,21
subject 70:3	60:3,9,11 61:1	suggests 66:14	98:12,21
77:22 85:1	61:23,24 62:8	66:22 71:21	107:16 111:3
171:19	63:10,13 64:8	94:22 96:9	114:10 129:1,7
submitted	64:13,15,17	134:10 137:21	130:1 140:7
10:18 12:5	66:3,8,19 67:1	suite 3:4,11	145:23 150:20
21:6,23 22:2	67:6,10 68:16	174:2	151:2 155:17
25:13 38:25	68:24 69:2,7	summarize	159:2 160:8
46:15	69:14,17 71:17	38:23 39:5	161:13 163:11
subscribed	71:19 72:5	summary 24:8	164:8 172:5
175:10 176:14	73:2,17 75:3	28:13 84:4	surp 162:2
177:21	75:11,25 76:12	154:20	surprised
subsequent	78:1,17 82:21	superior 35:16	159:10 161:20
169:7,21	86:10 93:22	36:10,22 37:2	162:2
	94:1,18 109:17	68:5 174:1	

Veritext Legal Solutions

www.veritext.com

888-391-3376

Mylan Exhibit 1121

Mylan v. Regeneron, IPR2022-01225

Page 87

Samsung Bioepis Exhibit 1075**Page 87**

survey 117:15 126:12 129:12 surveys 31:2,4 31:15 87:16 89:23 119:10 135:8 suspect 160:11 swear 6:19 sworn 6:24 173:7 175:10 175:13 176:14 176:18 177:21 synonymous 114:16	taken 2:6 5:11 49:12 96:22 107:19 167:24 173:5 takes 24:3 talk 34:22 74:1 74:22 170:8 talked 35:19 37:3 74:13 154:10 talking 43:18 82:16 talks 74:17 team 55:24,25 56:2,7 technical 28:16 36:23 60:23 61:2 75:22 78:6 87:2 114:11 123:11 127:2 138:11 140:12 142:4 technically 122:23 123:9 teleconference 9:14 telephone 3:3 television 27:10 tell 36:24 64:7 66:24 69:10 86:8 117:25 128:7 166:14 173:7 ten 103:4 167:18	tend 121:25 tended 117:18 term 30:23 56:1 72:19,25 73:4 99:7 108:6 115:16 115:22 128:7 139:20,21 151:18 160:21 terminology 169:10 terms 37:22 56:3 67:23 106:3 107:4 171:23 tertiary 33:7 104:19 105:8 106:14,16,21 169:3,5,7,19,21 testified 7:1 17:18 20:10,13 20:20,24 21:4 38:7 59:14 69:15 170:9 testify 6:24 31:25 58:3 testimony 4:2 8:1,14,19 15:9 20:7 21:8,17 21:22 46:20,25 47:8,12,18 48:9 59:15,17 172:9 173:5,9 173:13 175:6,7 176:6,9,12	text 18:4 55:13 th 35:1 thank 49:4 therapeutic 90:1 therapies 112:3 therapy 41:7 111:17 120:10 134:7,9,19 thereof 173:16 thing 42:6 54:7 165:25 things 17:14 24:9 29:10 47:2 48:3 53:4 56:4,8,14 73:18 75:19 76:16,17 128:8 140:19 144:24 145:1 159:9 170:23 think 31:13 37:12,21 40:12 49:24 54:15 57:25 59:1,12 64:6 65:17 70:6,19 83:2 92:21 95:11 96:11 110:20 122:10 150:5 155:6 164:7,15 167:2,14,16 171:22,22 thinking 12:23 21:2 27:14
t t 4:4 35:14 37:16,17 117:21 127:24 128:11 173:1,1 t&e 117:7 119:6 126:10 129:13 table 90:2,7,10 90:20,22 91:14 94:6,7 95:6 96:1 take 5:7 27:19 28:15 29:6 32:2 49:2 75:21 78:15 96:13,17 109:25 139:21 142:7 156:8 167:18			

[thinking - truth]

Page 44

29:20 30:7 54:1 thinks 118:18 133:23 thirty 174:19 thought 54:15 81:17 135:21 three 10:2,2 33:3 39:3 90:15 thursday 1:21 2:3 tie 42:14 108:20 tied 86:9,12 139:2 time 2:9 5:6 6:2 10:4 15:18 16:6,6 46:12 48:1,13,17,18 49:11,15 74:11 75:24 96:21,25 106:5 107:18 107:21 114:14 114:15 126:3 128:23 129:14 129:17 142:12 142:16 155:7 162:22 163:5 167:22 168:2 173:6 times 71:20 83:3 118:22 130:6	timing 172:1 today 7:19 8:6 8:18,19 10:5 10:11,17,25 11:7,10 18:16 18:17 19:6,22 26:14 39:19 45:6,11 46:22 67:17 85:18 147:5 149:23 154:10 161:24 170:5 today's 8:22 13:9 44:7 46:9 143:12 172:9 told 63:17 68:2 took 7:17 27:12 61:1 62:13 top 66:20 103:4 103:4 total 57:4 87:12 87:13 90:11 94:11 129:3 133:2 156:3,7 172:10 totality 87:13 toward 158:24 towards 72:21 tr 7:14 tracked 149:21 trade 20:16 trademark 1:1 5:14 21:25 transcribed 173:11 175:7	transcript 4:6 45:16,19 46:3 46:8,13 48:19 48:21 171:17 172:3 174:12 174:13 175:5 175:12 176:5 176:11,17 transcription 173:12 transcripts 7:14,20 treat 33:1 114:1,4,9,16,24 115:3,8 116:5 117:14,17,21 118:11 119:2 119:16 125:19 125:23 126:6 126:19 127:4 127:17,21 128:16,21,24 129:2 135:12 treated 114:12 120:9 125:4,13 125:19 126:6,7 129:3,21 130:10 131:12 133:19 166:5 treating 32:11 33:1 35:5 treatment 32:18 53:16 74:16,20 89:22 91:9,23 92:6	92:14,25 94:14 95:4 96:3,6 97:6,6,15,17 98:13,25 99:9 99:14,18 114:13 117:8 117:16 118:12 130:23,24 131:12 132:2,4 133:1,3,9,13 134:20,23 138:17 153:13 157:22 159:22 161:2 166:5,13 treatments 91:16 130:13 130:24 trial 1:3 4:8 20:10 21:10 77:4,8,16 78:10,13,21 158:8,11,18 163:15 trials 22:1 tributes 122:14 tries 114:12 trout 63:6,6 69:5 139:2 trout's 63:7,15 true 12:4 40:14 82:23 160:5 161:10,14 173:13 truth 69:11 117:25 173:8,8
--	--	---	--

Veritext Legal Solutions

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888-391-3376

173:9 trying 95:10 turn 20:4 31:17 50:7 97:21,25 100:2,18 105:3 124:24 132:16 137:1 143:19 169:16 twelve 169:8,22 two 9:19 10:18 10:21 11:13,15 12:13 13:4,16 18:2 30:14 31:14,16 34:24 43:7 44:3,19 44:19 97:11 105:12,21,23 106:1,4,24 107:7 154:13 164:1 165:18 type 145:1 151:5 types 119:18	under 1:23 80:4 86:19 91:25 117:19 118:10 171:17 173:11 understand 10:16 12:13 17:12 21:7 26:19 32:23,25 37:11 62:16 64:20 67:12 68:13 73:21 75:10 84:11 92:1,18 103:9 103:17 106:4 114:10 118:25 120:20 155:20 156:1 170:15 understanding 23:16,22 28:23 39:15 42:3,9 49:22,24 50:5 51:8,21 56:6 57:8 92:22 96:8 97:18 114:8 115:19 115:21 118:25 123:21 136:22 136:25 138:23 139:1,19 148:23 160:3 161:9 167:12 understandings 150:7	understood 42:8 58:10 60:6 77:22 undertake 14:16 unit 5:9 49:10 49:14 96:20,24 142:11,15 167:22 168:1 united 1:1 5:14 57:11 59:10 154:19 units 172:11 unpatentable 77:18,25 78:14 79:25 82:15 unquote 81:2 unsound 79:16 unusual 150:9 update 30:13 50:21 updated 24:12 24:15 49:21 50:20 170:21 171:11 use 11:24 15:14 40:1 70:17,22 71:6 88:1,4 94:25 95:4 97:16 119:20 120:6 121:25 141:3 160:13 161:8,17,25 162:8	used 24:11 72:19,25 87:17 88:15 89:24 93:1 94:23 96:10 99:2 102:9 112:9,10 124:11 128:12 159:21 172:11 useful 32:17 uses 70:8 110:4 using 68:5 99:7 130:12 134:12 util 140:20 utilization 30:8 30:9 37:9 38:1 70:2 89:25 90:3,18 92:9 95:23,25 100:11 109:5 109:24,25 127:10 131:2,7 131:10 140:21 141:7
u			v
u 53:1 u.s. 10:22 11:3 20:21 21:11 57:18 58:2 84:6 153:24 170:17 171:2 uh 89:10 um 25:7 unaware 52:17 unchanged 141:9,12			v 1:6,16 174:6 175:3 176:3 valid 144:22 valuable 111:24 112:15 113:23 value 63:19,21 166:8 values 63:22 variety 17:15 111:13 149:15

[variety - weeks]

Page 46

160:1 various 53:13 67:2 68:19 71:21 88:11 92:11 95:8,9 109:23 133:22 135:8 143:1 162:5 vegf 32:13,15 90:22 91:16 132:18 133:9 vein 32:21,21 32:22 90:15 verify 55:18 veritext 5:20,21 172:12 174:1,8 177:1 veritext.com. 174:17 version 143:4 versus 5:12 109:2 141:14 148:2 vestrum 89:24 91:4 92:8 vice 9:7,7 video 2:5 5:6 5:10 6:25 107:13 videographer 3:25 5:1,20 6:18 49:5,9,13 96:19,23 107:17,20 142:10,14	167:21,25 172:6 view 17:22 27:13,14 28:4 views 35:25 38:23 virginia 4:11 16:22 17:2,8 18:24 29:14 30:4 62:12 63:11 67:7 68:15,25 69:12 83:8,11 138:24 visit 162:25 visited 162:19 162:22 163:19 visual 35:18 101:7 voice 160:22 161:2 w wait 116:18 168:10 waived 174:20 want 18:24 31:10 39:25 42:6,7,15 47:4 48:2 49:5 54:6 55:18 56:12 68:8 69:11 70:9 84:12 137:20 152:16 161:12 wanted 36:3 68:1	washington 2:7 5:18 way 54:16,17 73:6 111:17 112:18 114:21 122:24 130:16 155:18 ways 54:14 151:3 161:5 we've 43:18,22 48:24 71:7 96:11 102:18 157:23 165:8 website 162:19 162:23 163:1,8 163:9,13,17,20 163:22 164:6,9 164:10,10 websites 164:1 week 23:25 28:12,18,19,22 28:23 29:1,8 33:6,9,19,23 34:5,6,9 35:11 36:1 40:21 41:8,12 42:21 60:5,17,19 61:4,10,12,18 61:22,25 62:7 65:12,13 66:2 66:18 67:5,25 68:23 71:8,13 71:15,24 74:2 74:13,18,23 75:1,8 81:24	82:3 85:12 87:8,22 88:3 88:22 93:7,13 94:19,23 96:10 97:7 101:24 102:2,3,7,8,12 102:18 104:7 108:20,25 109:1,6,14,22 109:23 110:5 110:11,18 111:15 112:1,5 112:9,17,18 113:3,6,14 114:17,25 115:5 117:18 118:20,23 119:15 120:2 124:2,11,12 126:7,16 130:18 131:6,7 131:9,14,17,23 132:5 134:2,24 135:5 139:17 139:23 140:17 140:18,24 141:5,10,14,17 141:25 165:9 165:13,22,25 166:20,21,24 167:3,12 weeks 32:16 33:6,22,23 94:15 96:6 97:13,16
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888-391-3376

Mylan Exhibit 1121

Mylan v. Regeneron, IPR2022-01225

Page 91

Samsung Bioepis Exhibit 1075**Page 91**

[weeks - zoom]

Page 47

104:20 105:9	when's 46:12	written 4:8
105:11,13,23	162:22	19:19 77:5,8
105:25 106:5	whispering 5:4	82:10 121:23
106:15,17,18	wilk 3:14 6:15	151:7
106:22,23	6:15 9:1,2,25	wrong 16:4
107:1,6,24,24	16:9	139:24 161:6
108:2,3,5,7	witness 6:19	wrote 24:7,7
109:3,20	9:16 14:12	x
110:16 111:5,6	28:1 37:21	x 4:1,4
111:19,21,22	59:4 61:12,20	x1 91:3,19 92:7
112:14 113:2,8	64:11 65:2,22	y
113:11,13,17	67:22 73:21	y 53:1
113:21 115:4	74:5 75:17	yeah 34:12
118:5,7,15,16	76:15 82:7	39:9 47:5 49:7
118:16 119:17	88:7,19 92:16	54:5 97:9
126:11,20,24	103:13,20	130:4 142:9
126:25 127:5,6	114:19 115:12	143:17 170:8
130:9,11	125:11 129:16	171:21
131:13,18	129:23 132:1	year 30:9,10,13
164:24 165:5	135:21 141:16	150:1
169:6,8,20,22	158:22 173:14	years 27:12
went 37:16	173:18 174:9	95:24 148:24
95:17	174:12 175:1,4	yep 49:1 96:16
west 3:4,14	175:11 176:1,4	york 3:15,15
4:11 16:22	176:15	youtube 164:12
17:2,8 18:24	witness' 174:15	z
29:14 30:4	word 99:3,3	zero 161:6
62:12 63:11	120:6,13	zoom 6:25
67:7 68:15,25	work 9:8	
69:12 83:7,11	152:20,21	
138:24	158:23 171:20	
western 20:25	world 117:6	
21:5,9	118:11 134:11	
wet 90:12	worse 35:18	
91:24 92:9		

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888-391-3376

Mylan Exhibit 1121

Mylan v. Regeneron, IPR2022-01225

Page 92

Samsung Bioepis Exhibit 1075**Page 92**

Federal Rules of Civil Procedure

Rule 30

(e) Review By the Witness; Changes.

(1) Review; Statement of Changes. On request by the deponent or a party before the deposition is completed, the deponent must be allowed 30 days after being notified by the officer that the transcript or recording is available in which:

(A) to review the transcript or recording; and

(B) if there are changes in form or substance, to sign a statement listing the changes and the reasons for making them.

(2) Changes Indicated in the Officer's Certificate. The officer must note in the certificate prescribed by Rule 30(f)(1) whether a review was requested and, if so, must attach any changes the deponent makes during the 30-day period.

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THE ABOVE RULES ARE CURRENT AS OF APRIL 1, 2019. PLEASE REFER TO THE APPLICABLE FEDERAL RULES OF CIVIL PROCEDURE FOR UP-TO-DATE INFORMATION.

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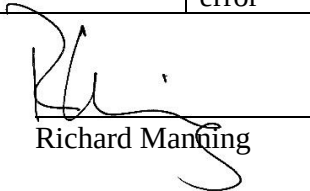
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Errata Sheet
Deposition of Richard Manning

I wish to make the following changes to the transcript of my deposition given on June 1, 2023, for the following reasons:

Page	Line	Changes or Correction	Reason
32	24	Change "Paragraph 17" to "Paragraph 15"	Misspoke
63	4	Change "his name is said" to "his name is that"	Correct transcription error
97	13-14	Change "25 days monthly" to "every 25 days, monthly"	Misspoke and correct transcription error
115	23	Omit "something in that"	Misspoke
128	8	Change "frequency" to "frequencies"	Correct transcription error
128	8-9	Omit "-- is or are"	Misspoke
130	23-24	Omit "other treatment product -- other treatment --"	Misspoke
131	1	Omit "account -- or drives --"	Misspoke
140	16-17	Change "gets to does the eight-week dosing interval have a nexus with commercial success." to "gets to "does the eight-week dosing interval have a nexus with commercial success?""	Misspoke and correct transcription error
170	13	Change "retinopathy and prematurity" to "retinopathy of prematurity"	Correct transcription error

Dated: 6/26/2023_____


Richard Manning