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**CONFIDENTIAL - PROTECTIVE ORDER MATERIAL**

# Transcript of Ivan Hofmann

**Date:** June 23, 2022

**Case:** Mylan Pharmaceuticals Inc. -v- Regeneron Pharmaceuticals, Inc. (PTAB)

**Planet Depos**

**Phone:** 888.433.3767

**Email:** [transcripts@planetdepos.com](mailto:transcripts@planetdepos.com)

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Mylan v. Regeneron  
IPR2021-00881  
U.S. Pat. 9,254,338  
Exhibit 2289

WORLDWIDE COURT REPORTING & LITIGATION TECHNOLOGY

<p style="text-align: center;">1</p> <p>UNITED STATES PATENT AND TRADEMARK OFFICE</p> <p>-----</p> <p>BEFORE THE PATENT TRIAL AND APPEAL BOARD</p> <p>-----</p> <p>MYLAN PHARMACEUTICALS, INC.</p> <p style="padding-left: 40px;">Petitioner,</p> <p style="text-align: center;">v.</p> <p>REGENERON PHARMACEUTICALS, INC.</p> <p style="padding-left: 40px;">Patent Owner.</p> <p>-----</p> <p>IPR202 00880, Patent No. 9,699,069</p> <p>IPR202 0088 , Patent No. 9,254,338 B2</p> <p>-----</p> <p>CONFIDENTIAL PROTECTIVE ORDER MATERIAL</p> <p>Videotaped Deposition of IVAN HOFMANN</p> <p style="padding-left: 40px;">Chicago, Illinois</p> <p style="padding-left: 40px;">Thursday, June 23, 2022</p> <p style="padding-left: 40px;">9:06 a.m. CST</p> <p>Job No.: 452029</p> <p>Pages: 350</p> <p>Reported by: THERESA A. VORKAPIC,</p> <p style="padding-left: 40px;">CSR, RMR, CRR, RPR</p>	<p style="text-align: right;">3</p> <p>1 APPEARANCES</p> <p>2 ON BEHALF OF THE PETITIONER:</p> <p>3 JEFFREY A. MARX, ESQUIRE</p> <p>4 DEANNE M. MAZZOCHI, ESQUIRE (VIA PHONE)</p> <p>5 RAKOCZY MOLINO MAZZOCHI SIWIK, LLP</p> <p>6 6 West Hubbard Street, Suite 500</p> <p>7 Chicago, Illinois 60654</p> <p>8 312-527-2157</p> <p>9 ON BEHALF OF THE PATENT OWNER:</p> <p>10 DAVID A CAINE, ESQUIRE</p> <p>11 ARNOLD &amp; PORTER KAYE SCHOLER, LLP</p> <p>12 3000 El Camino Real</p> <p>13 Five Palo Alto Square, Suite 500</p> <p>14 Palo Alto, California 94306-3807</p> <p>15 650-319-4710</p> <p>16 and</p> <p>17 MATTHEW M. WILK, ESQUIRE</p> <p>18 ARNOLD &amp; PORTER KAYE SCHOLER, LLP</p> <p>19 250 West 55th Street</p> <p>20 New York, NY 10019-9710</p> <p>21 212-836-7152</p> <p>22</p>
<p style="text-align: center;">2</p> <p>1 Videotaped deposition of Ivan Hofmann,</p> <p>2 held at the location of:</p> <p>3</p> <p>4</p> <p>5 RAKOCZY MOLINO MAZZOCHI SIWIK, LLP</p> <p>6 6 West Hubbard Street</p> <p>7 Suite 500</p> <p>8 Chicago, Illinois 60654</p> <p>9 312-527-2157</p> <p>10</p> <p>11</p> <p>12 Pursuant to notice before Theresa A. Vorkapic,</p> <p>13 a Certified Shorthand Reporter, Registered Merit</p> <p>14 Reporter, Certified Realtime Reporter, Registered</p> <p>15 Professional Reporter and a Notary Public in and</p> <p>16 for the State of Illinois.</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p>	<p style="text-align: right;">4</p> <p>1 APPEARANCES (Continued)</p> <p>2 ALSO PRESENT:</p> <p>3 Eileen Woo, Director at Regeneron</p> <p>4 Pharmaceuticals, Inc. (Via</p> <p>5 teleconference)</p> <p>6 Vinny Lee, In-house Counsel, Mylan</p> <p>7 Pharmaceuticals (Via teleconference)</p> <p>8 Rachel O Sullivan, Summer Associate RKMS</p> <p>9 Austin Olijar, Videographer, Planet Depos,</p> <p>10</p> <p>11</p> <p>12</p> <p>13</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p>

5			7		
1	CONTENTS		1	PROCEEDINGS	
2	EXAMINATION OF IVAN HOFMANN	PAGE	2	THE VIDEOGRAPHER: Here begins Disk No. 1	
3	Examination By Mr. Caine	8	3	in the videotaped deposition of Ivan Hofmann in	
4	Examination By Mr. Marx	338	4	the matter of Mylan Pharmaceuticals, Inc. versus	
5	Further Examination By Mr. Caine	348	5	Regeneron Pharmaceuticals, Inc. in the	
6			6	United States Patent and Trademark Office before	
7	EXHIBITS		7	the Patent Trial and Appeal Board, Cause Nos.	
8	(Attached to transcript.)		8	IPR 2021-00880 and IPR 2021-00881.	
9	HOFMANN DEPOSITION EXHIBITS	PAGE	9	Today's dated is June 23, 2022. The time	
10			10	on the video monitor is 9:07 a.m. Central Standard	
11	Exhibit 1 Janssen V Teva New Jersey	54	11	Time. The videographer today is Austin Olijar	
12	Transcript		12	representing Planet Depos. This videotaped	
13	Exhibit 2 Memorandum Opinion,	76	13	deposition is taking place at RMMS, LLP, Chicago,	
14	Concordia V Method		14	Illinois 60604.	
15	Exhibit 3 Charlottesville Concordia v	80	15	Would counsel please voice-identify	
16	Method trial transcript		16	themselves and state whom they represent.	
17	4-21-16		17	MR. CAINE: Sure. David Caine with Arnold	
18	Exhibit 4 "FDA Approves Genentech's	107	18	& Porter. We represent Regeneron. With me today	
19	Vabysmo, the First		19	is Matthew Wilk, and on the phone is Eileen Woo	
20	Bispecific Antibody For the		20	from Regeneron.	
21	Eye to Treat Two Leading		21	MR. MARX: Jeffrey Marx on behalf of	
22	Causes of Vision Loss"		22	Petitioner, Mylan. With me today is our summer	
6			8		
1	INDEX (Continued)		1	associate, Rachel O'Sullivan. On the line as well	
2	PREVIOUSLY MARKED EXHIBITS	PAGE	2	is Deanne Mazzochi from RMMS and Vinny Lee,	
3	1018 Scientific publication	187	3	in-house counsel for Mylan.	
4	1023 '959 Patent	113	4	The court reporter today is Theresa	
5	1136 CV	40	5	Vorkapic representing Planet Depos. Would the	
6	1137 Hoffman Declaration	41	6	reporter please swear in the witness.	
7	1154 (not identified on the	309	7	THE REPORTER: Would you raise your right	
8	record)		8	hand, please.	
9	2086 (not identified on the	179	9	(The witness was duly sworn.)	
10	record)		10	IVAN HOFMANN,	
11	2136 Eylea Marketing Materials	268	11	called as a witness herein, having been first duly	
12	2137 Marketing Materials	276	12	sworn, was examined and testified as follows:	
13	2138 Physician Atu-Wave 2	252	13	EXAMINATION	
14	2140 Physician Atu Wave 5	259	14	BY MR. CAINE:	
15	2176 Q4 2020 Performance Update	222	15	Q Good morning, Mr. Hofmann.	
16	2197 Physician Atu Benchmark	163	16	<b>A Good morning.</b>	
17	Wave Full Report 9/15/11		17	Q Eylea is a commercial success, right?	
18	2210 (not identified on the	305	18	<b>A That is not my opinion, and that is</b>	
19	record)		19	<b>inconsistent with the facts and information as I</b>	
20	2226 (not identified on the	304	20	<b>explain in detail in my declaration.</b>	
21	record)		21	Q You're aware that Eylea has generated	
22	2259 ASRS PAT Surveys	210	22	[REDACTED] in gross sales?	

<p style="text-align: right;">9</p> <p>1 MR. MARX: Objection. Foundation.  2 BY THE WITNESS:  3 <b>A That number sounds a little bit unfamiliar</b>  4 <b>to me. I recognize that it's had a marketplace</b>  5 <b>performance that is relatively significant, but</b>  6 <b>the question that is the subject of this inquiry</b>  7 <b>is whether there is -- commercial success is a</b>  8 <b>term of art in an obviousness inquiry in a patent</b>  9 <b>case. And based on my analysis, as I explain in</b>  10 <b>detail in my declaration, that is not so.</b>  11 Q Let's look at Exhibit 2052 which is  12 Dr. Manning's report. Let me give you a copy of  13 Exhibit 2052.  14 You've seen Exhibit 2052 before?  15 <b>A It's lengthy. I haven't flipped through</b>  16 <b>every page, but yes, I've certainly reviewed the</b>  17 <b>Manning declaration.</b>  18 Q If we turn to Attachment D-1 which is  19 going to be on Page 171.  20 Are you there?  21 <b>A I'm there.</b>  22 Q Do you see on the total line for gross</p>	<p>1 <b>A Well, I mean, there was very limited</b>  2 <b>information produced by Regeneron. You know, I</b>  3 <b>didn't find mathematical errors in how these</b>  4 <b>numbers were compiled from the information that</b>  5 <b>was cited, but there was not a ton of information</b>  6 <b>produced by Regeneron to support the information.</b>  7 <b>BY MR. CAINE:</b>  8 Q You had access to the exhibits that are  9 cited on Page 172 of the Manning declaration,  10 Exhibits 2285 and 2170?  11 MR. MARX: Objection. Form.  12 BY THE WITNESS:  13 <b>A I did.</b>  14 <b>BY MR. CAINE:</b>  15 Q You didn't perform a calculation on your  16 own to determine whether the figures that were  17 reported by Dr. Manning were correct; is that  18 right?  19 <b>A I think that's kind of a negative</b>  20 <b>characterization. I did look at the information,</b>  21 <b>and like I said, mathematically the numbers added</b>  22 <b>up from what was cited from the limited</b></p>
<p style="text-align: right;">0</p> <p>1 sales, the number is just under [REDACTED]?  2 MR. MARX: Objection. Foundation.  3 BY THE WITNESS:  4 <b>A I can agree that the number reads on that</b>  5 <b>of. Of course, that's gross sales before</b>  6 <b>deducting all the things that need to be deducted</b>  7 <b>to get to net sales and all the things that need</b>  8 <b>to be deducted to get to gross profit and all the</b>  9 <b>things that need to get deducted to get to</b>  10 <b>operating profit and beyond.</b>  11 <b>BY MR. CAINE:</b>  12 Q You also see a net sales figure of  13 33,169,380,000?  14 MR. MARX: Objection. Foundation.  15 BY THE WITNESS:  16 <b>A That's what appears in this schedule</b>  17 <b>before deducting other expenses.</b>  18 <b>BY MR. CAINE:</b>  19 Q You have no disagreement with those  20 calculations, correct?  21 MR. MARX: Same objection.  22 BY THE WITNESS:</p>	<p style="text-align: right;">2</p> <p>1 <b>information that was produced by Regeneron.</b>  2 Q Now, your position, to be clear, is that a  3 product that over the course of a nine-to-ten-year  4 period has sold more than [REDACTED] worth of  5 gross sales and more than \$33 billion worth of net  6 sales is not a commercial success; is that right?  7 MR. MARX: Objection. Mischaracterizes  8 witness testimony.  9 BY THE WITNESS:  10 <b>A I think that I would defer to the complete</b>  11 <b>entirety of my declaration where I explain in</b>  12 <b>detail why one has to be careful that even if a</b>  13 <b>product has, you know, some level of sales in the</b>  14 <b>market, you're just kind of flippantly using</b>  15 <b>"commercial success" as a colloquial term.</b>  16 <b>I mean, commercial success is a term of</b>  17 <b>art, and an obviousness inquiry requires that one</b>  18 <b>look at certainly sales figures, as well as cost</b>  19 <b>to deduct from those figures and then determine</b>  20 <b>whether there is a nexus and a demonstrable nexus</b>  21 <b>that wasn't done by Manning, as I explain in</b>  22 <b>detail in my report, that fails to provide</b></p>



3

**1 evidence of commercial success as a term of art in**  
**2 an obviousness inquiry.**  
**3 BY MR. CAINE:**  
 4 Q Now, you mention operating profit. The  
 5 operating profit, as you can see from  
 6 Attachment D-1 to Dr. Manning's declarations, is  
 7 on Page 171, is [REDACTED]; is that right?  
 8 MR. MARX: Objection. Lack of foundation.  
**9 BY THE WITNESS:**  
**10 A According to Attachment D-1, that is the**  
**11 number that appears there.**  
**12 BY MR. CAINE:**  
 13 Q And you didn't perform your own  
 14 calculation to test that number, did you?  
**15 A Well, I don't think that's -- sorry.**  
 16 MR. MARX: Sure. Objection. Lack of  
 17 foundation.  
**18 BY THE WITNESS:**  
**19 A I don't think that's fair. I certainly**  
**20 looked at what was -- everything that was in the**  
**21 Manning declaration and I -- you know, like I**  
**22 said, I didn't find mathematical errors. I found**

4

**1 a lot of mischaracterization errors and a lot of**  
**2 problems in the conclusions that he reached**  
**3 relative to the lack of nexus and lack of a basis**  
**4 to find commercial success as a term of art in an**  
**5 obviousness inquiry for the reasons that I explain**  
**6 in great detail in my declaration.**  
**7 BY MR. CAINE:**  
 8 Q Your position is that a pharmaceutical  
 9 treatment that's achieved a profit of  
 10 [REDACTED] over the course of a nine- to  
 11 ten-year period is not a commercial success; is  
 12 that right?  
 13 MR. MARX: Objection. Lack of foundation,  
 14 form, mischaracterizes the witness testimony.  
**15 BY THE WITNESS:**  
**16 A What it seems like you're missing or**  
**17 you're trying to impose on me or the presumption**  
**18 in the question is lacking is that there's, I**  
**19 don't know, the ability to discuss marketplace**  
**20 performance and how a product is sold. I'm not --**  
**21 I'm not saying [REDACTED] in operating profit is**  
**22 an insignificant volume of profits.**

5

**1 What I'm saying is that there has been**  
**2 no -- no reliable, complete assessment or opinion**  
**3 provided by Dr. Manning and, in fact, tremendous**  
**4 defects in what Dr. Manning put forth to establish**  
**5 commercial success as a term of art in an**  
**6 obviousness inquiry, and that's a very important**  
**7 thing.**  
**8 You can't just fixate on the numbers of**  
**9 sales or numbers of profits without fully**  
**10 assessing and properly considering all the things**  
**11 that Manning failed to do in his declaration with**  
**12 respect to the marketplace performance of Eylea.**  
**13 BY MR. CAINE:**  
 14 Q What level of sales are needed for a  
 15 pharmaceutical treatment to obtain commercial  
 16 success?  
 17 MR. MARX: Objection. Hypothetical.  
**18 BY THE WITNESS:**  
**19 A There is no hard and fast rule, and I**  
**20 don't think you can even think about it in the way**  
**21 your question presupposes. You have to look at**  
**22 the facts and circumstances, the market dynamics,**

6

**1 and all the different things that exist with**  
**2 respect to the particular product and the market**  
**3 within which it competes.**  
**4 BY MR. CAINE:**  
 5 Q One of the things you look at in  
 6 evaluating whether a product is commercially  
 7 successful is sales share; is that right?  
 8 MR. MARX: Objection. Form, lack of  
 9 foundation.  
**10 BY THE WITNESS:**  
**11 A I think that sometimes is a metric that is**  
**12 looked at, and that kind of falls in what I said**  
**13 in my last answer, relative performance.**  
**14 BY MR. CAINE:**  
 15 Q Right. And so gain of sales share is one  
 16 of the things that you can look at to evaluate  
 17 whether a product is commercially successful,  
 18 right?  
 19 MR. MARX: Objection. Form,  
 20 mischaracterizes the witness testimony.  
**21 BY THE WITNESS:**  
**22 A I think it can be.**

<p style="text-align: right;">7</p> <p><b>1 BY MR. CAINE:</b>                  2 Q Let's look at Attachment C-1 to                  3 Dr. Manning's report which is on Page 158.                  4 Do you have Attachment C-1?  <b>5 A I do.</b>                  6 Q Okay. Let's look at the ATU survey data                  7 which is in the middle of the table.                  8 Do you have that?  <b>9 A I do.</b>                  10 Q In 2011, Eylea's sales share was                  11 0 percent, right?                  12 MR. MARX: Objection. Lack of foundation.                  13 BY THE WITNESS:  <b>14 A Well, I mean, there's a host of issues. I</b>  <b>15 mean, I will agree with you, that is the number</b>  <b>16 that appears in this chart, but, I mean, there's a</b>  <b>17 host of questions and problems with ATUs and how</b>  <b>18 complete and reliable they are in getting to</b>  <b>19 what -- wherever you're going with this, but, yes,</b>  <b>20 0 is what appears as of 2011.</b>  <b>21 BY MR. CAINE:</b>                  22 Q And for 2011, Avastin had a 63 percent</p>	<p style="text-align: right;">9</p> <p>1 Q In that same period, 2012, Avastin's sales                  2 share went from 63 percent in 2011 to                  3 48.48 percent in 2012, right?                  4 MR. MARX: Objection. Lack of foundation.                  5 BY THE WITNESS:  <b>6 A Pulling information from ATUs, which like</b>  <b>7 I said, I don't know how reliable they are or</b>  <b>8 accurate or that we should be treating them as</b>  <b>9 perfection the way your question presupposes. I</b>  <b>10 can read the numbers here, and yes, that's the</b>  <b>11 number that appear in this chart for 2012.</b>  <b>12 BY MR. CAINE:</b>                  13 Q From 2011 to 2012, Lucentis's sales share                  14 went from 37 percent to 30.30 percent, right?                  15 MR. MARX: Objection. Lack of foundation.                  16 BY THE WITNESS:  <b>17 A With all the caveats I gave in my last</b>  <b>18 answer as to the danger in putting too much weight</b>  <b>19 on these ATUs which are subject to limited</b>  <b>20 questions to a limited number of physicians that</b>  <b>21 result in quantitative numbers, those are the</b>  <b>22 numbers that appear.</b></p>
<p style="text-align: right;">8</p> <p>1 sales share, and Lucentis had a 37 percent sales                  2 share, correct?                  3 MR. MARX: Objection. Lack of foundation.                  4 BY THE WITNESS:  <b>5 A Like I said, I mean, I can read numbers as</b>  <b>6 well as you can as to what appears there, but,</b>  <b>7 again, these ATUs are helpful in some ways but</b>  <b>8 incomplete in many ways as to properly reflecting</b>  <b>9 what is going on in the market.</b>  <b>10 BY MR. CAINE:</b>                  11 Q In 2012, Eylea went from a 0 percent sales                  12 share to a 21.21 percent sales share, right?                  13 MR. MARX: Objection. Lack of foundation.                  14 BY THE WITNESS:  <b>15 A For all the reasons I explained in my last</b>  <b>16 couple of answers, you know, I don't know how much</b>  <b>17 we can look at ATUs as the most reliable thing.</b>  <b>18 They are relatively incomplete and sometimes</b>  <b>19 biased surveys. You know, I can read the numbers</b>  <b>20 off of what appears here for 2012, and, yes, that</b>  <b>21 is the number that appears in the Attachment C-1.</b>  <b>22 BY MR. CAINE:</b></p>	<p style="text-align: right;">20</p> <p><b>1 BY MR. CAINE:</b>                  2 Q Between 2011 and 2012, Eylea gained sales                  3 share from both Avastin and Lucentis, right?                  4 MR. MARX: Objection. Lack of foundation.                  5 BY THE WITNESS:  <b>6 A I think -- I don't know where to begin.</b>  <b>7 There's -- mathematically I don't disagree that</b>  <b>8 that's how the percentages fall according to the</b>  <b>9 ATUs which are subject to all of the</b>  <b>10 incompleteness and defects that exist with respect</b>  <b>11 to ATUs.</b>  <b>12 BY MR. CAINE:</b>                  13 Q If we look at 2021, that period of time,                  14 Eylea's sales share was 41.89 percent; Avastin's                  15 was 39.05 percent; and Lucentis's was                  16 14.88 percent.                  17 Do you see that?                  18 MR. MARX: Objection. Lack of foundation.                  19 MR. CAINE: I'm sorry. Let me correct it.                  20 BY MR. CAINE:                  21 Q 15.4 percent.                  22 MR. MARX: Objection. Lack of foundation.</p>

2	<p>1 BY THE WITNESS:</p> <p>2 <b>A I mean, like I said, I can read the</b></p> <p>3 <b>numbers off of this chart the same as you. The</b></p> <p>4 <b>problems I have, have to do with, one, the</b></p> <p>5 <b>reliability and usefulness of the ATUs; and, two,</b></p> <p>6 <b>probably most importantly, this doesn't really</b></p> <p>7 <b>demonstrate that the '338 patent influenced or</b></p> <p>8 <b>makes the percentages have further weight.</b></p> <p>9 <b>BY MR. CAINE:</b></p> <p>10 Q I'm not talking about nexus now. So I</p> <p>11 want to differentiate between whether a product is</p> <p>12 commercially successful and the nexus for that</p> <p>13 commercial success. So here is the question:</p> <p>14 Between 2011 and 2021, both Avastin and</p> <p>15 Lucentis lost sales share to Eylea, correct?</p> <p>16 MR. MARX: Objection. Form, lack of</p> <p>17 foundation.</p> <p>18 BY THE WITNESS:</p> <p>19 <b>A I think an important semantics thing that</b></p> <p>20 <b>you and I should try and establish is "commercial</b></p> <p>21 <b>success" is a term of art in an obviousness</b></p> <p>22 <b>inquiry, and so there is a distinction that we</b></p>	23	<p>1 <b>must have marketplace performance tied to the</b></p> <p>2 <b>patent at issue in order to establish commercial</b></p> <p>3 <b>success as a term of art in an obviousness</b></p> <p>4 <b>inquiry.</b></p> <p>5 <b>BY MR. CAINE:</b></p> <p>6 Q Eylea has achieved substantial marketplace</p> <p>7 performance relative to Avastin and Lucentis,</p> <p>8 right?</p> <p>9 MR. MARX: Objection. Form, vague, lack</p> <p>10 of foundation.</p> <p>11 BY THE WITNESS:</p> <p>12 <b>A I think I'm not going to disagree that the</b></p> <p>13 <b>dollar sales and relative sales have some level of</b></p> <p>14 <b>significance, you know, given the volumes that we</b></p> <p>15 <b>see, but there is a tremendous hazard in landing</b></p> <p>16 <b>just there because the lack of establishment of</b></p> <p>17 <b>nexus and all the different things that I explain</b></p> <p>18 <b>in detail in my report, in my declaration show</b></p> <p>19 <b>that they aren't tied to the patent at issue.</b></p> <p>20 <b>BY MR. CAINE:</b></p> <p>21 Q I'm trying to use your term, and I think</p> <p>22 you used the term "marketplace performance."</p>
22	<p>1 <b>have to be very careful about with respect to</b></p> <p>2 <b>marketplace performance, whether it's dollars,</b></p> <p>3 <b>whether that's percentages versus commercial</b></p> <p>4 <b>success, because commercial success as a term of</b></p> <p>5 <b>art in an obviousness inquiry does require nexus</b></p> <p>6 <b>and does require that the patent at issue is the</b></p> <p>7 <b>driver of sales.</b></p> <p>8 <b>So I think it would be helpful if, because</b></p> <p>9 <b>you keep saying commercial success, we should</b></p> <p>10 <b>understand that I don't disagree that the</b></p> <p>11 <b>underlying ATU which has its own defects and</b></p> <p>12 <b>everything else, as I've said in my many prior</b></p> <p>13 <b>answers reflects some of the percentages that are</b></p> <p>14 <b>here. But we have to be careful because, one,</b></p> <p>15 <b>these ATUs are imperfect and only have so much in</b></p> <p>16 <b>terms of people that were interviewed and how the</b></p> <p>17 <b>questions were framed and all the different things</b></p> <p>18 <b>that are within those.</b></p> <p>19 <b>And, in any event, you sounded like in</b></p> <p>20 <b>your question you didn't want me to address the</b></p> <p>21 <b>question of nexus to the '366 patent and that</b></p> <p>22 <b>seems like a hazardous place to go because you</b></p>	24	<p>1 <b>A Yes.</b></p> <p>2 Q And -- because you aren't comfortable with</p> <p>3 the term "commercial success"; I understand that.</p> <p>4 So from a marketplace performance</p> <p>5 perspective, Eylea has been successful in taking</p> <p>6 market share from competitors and in its overall</p> <p>7 revenue, gross, net and operating profit</p> <p>8 performance?</p> <p>9 MR. MARX: Objection. Form,</p> <p>10 mischaracterizes the witness testimony.</p> <p>11 BY THE WITNESS:</p> <p>12 <b>A The numbers are what they are. There is a</b></p> <p>13 <b>certain subjectivity in what your question asks,</b></p> <p>14 <b>but I'm not -- I'm not suggesting that</b></p> <p>15 <b>multibillion dollars in sales or profits is</b></p> <p>16 <b>insignificant. The problem I have is that that</b></p> <p>17 <b>does not equal commercial success.</b></p> <p>18 <b>Commercial success must be tied to the</b></p> <p>19 <b>claimed invention to the patents at issue, and</b></p> <p>20 <b>that has not been established, as I explained in</b></p> <p>21 <b>detail in my report.</b></p> <p>22 <b>BY MR. CAINE:</b></p>

25	<p>1 Q With respect to treatments for eye                  2 disorders that we're talking about here today, wet                  3 AMD, DME, et cetera, is there a better performing                  4 treatment on the market?                  5 MR. MARX: Objection. Form, vague, lack                  6 of foundation.                  7 BY MR. CAINE:                  8 Q From an economic standpoint.                  9 MR. MARX: Same objections.                  10 BY THE WITNESS:                  11 <b>A Well, I mean, that's a little bit</b>                  12 <b>confusing. I mean, it is certainly -- looking at</b>                  13 <b>the Schedule C-1 that you have in front of me, it</b>                  14 <b>has achieved over time a greater percentage,</b>                  15 <b>again, but that's based on ATUs. The dollar sales</b>                  16 <b>are what they are. There's a lot of -- this is a</b>                  17 <b>huge market, and many have profited greatly from</b>                  18 <b>it in this huge market, but the thing that one has</b>                  19 <b>to be particularly careful about is whether that's</b>                  20 <b>tied to the claims of the patent at issue or not,</b>                  21 <b>and that has clearly not been established by</b>                  22 <b>Manning.</b></p>	27	<p>1 relative to Avastin and Lucentis, right?                  2 MR. MARX: Objection. Lack of foundation,                  3 form.                  4 BY THE WITNESS:                  5 <b>A From one data source, and all the data</b>                  6 <b>sources are helpful but also incomplete, but</b>                  7 <b>that's what's reflected in this schedule.</b>                  8 <b>BY MR. CAINE:</b>                  9 Q Are you aware of any data source that                  10 shows that Eylea hasn't obtained the largest sales                  11 share for a treatment of the diseases that we're                  12 talking about today, wet AMD, DME, et cetera?                  13 MR. MARX: Objection. Form.                  14 BY THE WITNESS:                  15 <b>A In terms of what's publicly available, you</b>                  16 <b>also have to be careful because these data sets</b>                  17 <b>don't reflect discounts, rebates, kickback</b>                  18 <b>schemes. There are things are being done to</b>                  19 <b>influence sales, but these are the data sets that</b>                  20 <b>I think are available. One just has to look at</b>                  21 <b>them with a cautious eye.</b>                  22 <b>BY MR. CAINE:</b></p>
26	<p>1 <b>BY MR. CAINE:</b>                  2 Q We don't have on exhibit -- excuse me --                  3 Attachment C-1 only the data from the ATU survey.                  4 You also see Medicare Part B data and Vestrum                  5 data; right?                  6 MR. MARX: Objection. Lack of foundation.                  7 BY THE WITNESS:                  8 <b>A That's what appears here, yes.</b>                  9 <b>BY MR. CAINE:</b>                  10 Q The Vestrum data for 2021 shows that                  11 Eylea's sales share is actually higher than ATU;                  12 it's just under [REDACTED], right?                  13 MR. MARX: Objection. Lack of foundation.                  14 BY THE WITNESS:                  15 <b>A I don't have the underlying data in front</b>                  16 <b>of me, but that's what appears on C-1, but, again,</b>                  17 <b>you have to be very careful because if that's not</b>                  18 <b>tied to the claims of the patents at issue, then</b>                  19 <b>that doesn't get you nexus, doesn't get you</b>                  20 <b>commercial success.</b>                  21 <b>BY MR. CAINE:</b>                  22 Q It does establish marketplace performance</p>	28	<p>1 Q You don't report any different percentages                  2 in your declaration, right?                  3 <b>A I did not.</b>                  4 Q Now, why don't we turn to Attachment D-8,                  5 please, which is on Page 180 of Dr. Manning's                  6 report, Exhibit 2052.                  7 Attachment D-8 sets out the payment limits                  8 for, among others, Eylea, Lucentis and Avastin                  9 over time. These are Medicare payment limits, I                  10 believe; is that right?                  11 MR. MARX: Objection. Lack of foundation.                  12 BY THE WITNESS:                  13 <b>A Yes. So -- I'm sorry for the -- the way</b>                  14 <b>these exhibits or attachments are set up. They</b>                  15 <b>build on one another, and so I just wanted to make</b>                  16 <b>sure.</b>                  17 <b>I think building off of -- I guess, it's</b>                  18 <b>D-4 to D-6 to D-8, they are the Medicare limits.</b>                  19 <b>BY MR. CAINE:</b>                  20 Q The payment limits for Eylea and Lucentis                  21 for wet AMD and RVO are fairly comparable over                  22 time, right?</p>

29	<p>1 MR. MARX: Objection. Form, lack of                  2 foundation, vague.                  3 BY THE WITNESS:                  4 <b>A I mean, there is a subjectivity in that,                  5 but generally, Eylea and Lucentis for wet AMD and                  6 RVO are closer certainly than DME and DR, and we                  7 don't -- that doesn't address the other available                  8 treatments.</b>                  9 <b>BY MR. CAINE:</b>                  10 Q For the period from 2012 to 2016, Eylea                  11 and Lucentis for wet AMD and RVO both have payment                  12 limits of over \$1,900 per injection, correct?                  13 MR. MARX: Objection. Lack of foundation,                  14 form and mischaracterizes the document as well.                  15 BY THE WITNESS:                  16 <b>A What was the time frame you were asking                  17 about?</b>                  18 <b>BY MR. CAINE:</b>                  19 Q 2012 to 2016.                  20 MR. MARX: Same objection.                  21 BY THE WITNESS:                  22 <b>A According to this bar chart, I'm not a</b></p>	3
30	<p>1 payment limit for Lucentis has been under \$1,200                  2 per injection, right?                  3 MR. MARX: Objection. Mischaracterizes                  4 the document, lack of foundation.                  5 BY THE WITNESS:                  6 <b>A Can you repeat that.</b>                  7 <b>BY MR. CAINE:</b>                  8 Q Sure. The payment limit for Lucentis for                  9 DME and DR has been under \$1,200 since 2012,                  10 correct?                  11 MR. MARX: Objection. Lack of foundation.                  12 BY THE WITNESS:                  13 <b>A I mean, obviously you're reading off the                  14 numbers that appear in this bar chart. Whether or                  15 not they reflect all the discounts, I don't know                  16 as I sit here right now, but they are lower than                  17 1,200.</b>                  18 <b>BY MR. CAINE:</b>                  19 Q Avastin's payment limit has been eight to                  20 \$10 from the entire period from 2012 to 2021,                  21 right?                  22 MR. MARX: Objection. Mischaracterizes</p>	3
30	<p>1 <b>hundred percent sure as I sit here whether those                  2 reflect discounts, but according to what's in the                  3 bar chart, the numbers are above 1,900, but, like                  4 I said, I'm just not a hundred percent sure if                  5 those reflect discounts.</b>                  6 <b>BY MR. CAINE:</b>                  7 Q From 2017 to 2021, both Eylea and Lucentis                  8 for wet AMD and RVO are in the range of \$1,600 to                  9 over \$1,900 per injection in terms of a payment                  10 limit, correct?                  11 MR. MARX: Objection. Lack of foundation,                  12 mischaracterizes the document.                  13 BY THE WITNESS:                  14 <b>A Again, not sure if this data set reflects                  15 the discounts that are provided, but, I mean, the                  16 numbers on the bar chart show the numbers -- I                  17 mean, it's just shy of 1,600 in 2021. Like I                  18 said, I'm just not -- I'm not able to see whether                  19 he's explained whether discounts are fully                  20 reflected here.</b>                  21 <b>BY MR. CAINE:</b>                  22 Q For the period from 2012 through 2021, the</p>	32
32	<p>1 the document, lack of foundation.                  2 BY THE WITNESS:                  3 <b>A I mean, I think -- and this is probably                  4 some combination of discussions with technical                  5 experts, but Avastin, I don't believe, is on label                  6 for this --</b>                  7 <b>BY MR. CAINE:</b>                  8 Q That's not my question. My question was                  9 simply if the payment limit for Avastin has been                  10 in the range of eight to \$10 during the entire                  11 period from 2012 to 2021.                  12 MR. MARX: Objection. Mischaracterizes                  13 the document, lack of foundation, asked and                  14 answered.                  15 BY THE WITNESS:                  16 <b>A My only point, as I explain in my report,                  17 I don't disagree that Avastin has long been                  18 generic and, therefore, is at a lower                  19 reimbursement level than products that are still                  20 on label and are indicated for the treatment and                  21 aren't subject to generic competition. So the                  22 numbers, I think, are reflected as they show</b></p>	32

33

**1 subject to, I guess, all those caveats.**  
**2 BY MR. CAINE:**  
 3 Q From at least 2016 through 2021, Eylea's  
 4 price limit per injection has been higher than  
 5 that of Lucentis and Avastin, correct?  
 6 MR. MARX: Objection. Lack of foundation,  
 7 form.  
 8 BY THE WITNESS:  
**9 A I'm sorry. Say that again.**  
**10 BY MR. CAINE:**  
 11 Q Sure.  
 12 From 2016 through 2021, Eylea's payment  
 13 limit has been higher than that of Lucentis and  
 14 Avastin?  
 15 MR. MARX: Objection. Lack of foundation,  
 16 form.  
 17 BY THE WITNESS:  
**18 A I think, you know, just looking at the bar**  
**19 graph, directionally that's so. Again, without**  
**20 doing anything to establish that that has anything**  
**21 to do with the '338 patent, I think that's what**  
**22 the numbers in the bar chart show.**

34

**1 BY MR. CAINE:**  
 2 Q During that same period, 2016 to 2021,  
 3 Eylea has gained sales share relative to both  
 4 Lucentis and Avastin, correct?  
 5 MR. MARX: Objection. Lack of foundation,  
 6 form.  
 7 BY THE WITNESS:  
**8 A I don't -- I don't think that is shown in**  
**9 D-8.**  
**10 BY MR. CAINE:**  
 11 Q It's shown in the attachment we looked at  
 12 just a moment ago, which is C-1.  
 13 During that period, 2016 to 2021, Eylea's  
 14 sales share has grown relative to Lucentis and  
 15 Avastin?  
 16 MR. MARX: Objection. Lack of foundation,  
 17 mischaracterizes document.  
 18 BY THE WITNESS:  
**19 A I mean, these are scattershot sources of**  
**20 information. I don't know that in broad strokes**  
**21 you can say that. I mean, I can look at**  
**22 particular numbers and particular parts of the**

35

**1 chart, but it does seem like at least**  
**2 directionally what you're saying is consistent**  
**3 with the data sets that are here, but these data**  
**4 sets are also, you know, from varying sources and**  
**5 with varying limited information that is of**  
**6 varying probably completeness and reliability.**  
**7 BY MR. CAINE:**  
 8 Q Eylea's increasing sales share over time  
 9 at the expense of Avastin and Lucentis,  
 10 particularly considering the data that we looked  
 11 at on payment limits, demonstrates that Eylea  
 12 has -- Eylea's marketplace performance has  
 13 exceeded that of Lucentis and Aventis, correct?  
 14 MR. MARX: Objection. Form, lack of  
 15 foundation and mischaracterizes the witness  
 16 testimony.  
 17 BY THE WITNESS:  
**18 A Though I think I've said it in numerous**  
**19 answers, we don't -- we don't have underlying, you**  
**20 know, confidence in what the levels of discounts,**  
**21 what the levels of other aspects are in getting to**  
**22 these data sets, and we don't have any**

36

**1 demonstration from the Manning declaration that**  
**2 any of this is really attributable to the patent**  
**3 at issue that we're talking about.**  
**4 So I guess there's so many embedded**  
**5 hazards in your question that I think -- you know,**  
**6 I can read off percentages or numbers if you want**  
**7 me to, but I'm not sure that we should be putting**  
**8 great weight on what is being characterized here,**  
**9 because as I explain in detail in my report, I**  
**10 think it's being mischaracterized and improperly**  
**11 attributed to the patent at issue.**  
**12 BY MR. CAINE:**  
 13 Q I think you are mixing two things that you  
 14 yourself separated. You asked that we not use the  
 15 term "commercial success." I used the term  
 16 "marketplace performance."  
 17 That's the term that you used in your  
 18 testimony, right?  
**19 A I appreciate that.**  
 20 Q Okay. So I didn't ask you about  
 21 commercial success. I asked you about marketplace  
 22 performance. So let me repeat my question.

<p style="text-align: right;">37</p> <p>1 Eylea has increasing sales share over time                  2 at the expense of Avastin and Lucentis,                  3 particularly considering -- let me start over.                  4 Eylea's increasing sales share over time                  5 at the expense of Avastin and Lucentis,                  6 particularly considering the data on payment                  7 limits, demonstrates that Eylea's marketplace                  8 performance has exceeded that of Avastin and                  9 Lucentis, correct?                  10 MR. MARX: Objection. Lack of foundation,                  11 form, asked and answered.                  12 BY THE WITNESS:                  13 <b>A I don't -- I don't -- I mean, look, there</b>                  14 <b>are a number of metrics that I think have some</b>                  15 <b>utility but limited utility for other limitations,</b>                  16 <b>as I was referring to before.</b>                  17 <b>According to what he's put in his charts</b>                  18 <b>or attachments, there's some level of that</b>                  19 <b>directional point that I think your question</b>                  20 <b>presupposes, but there's still a tremendous</b>                  21 <b>hazard, and you're telling me -- like, I</b>                  22 <b>appreciate you using my terminology of</b></p>	<p style="text-align: right;">39</p> <p><b>1 know, there is some subjectivity to that. But,</b>  <b>2 yes, I'm not denying that there has been fairly</b>  <b>3 significant sales and profits that have been made</b>  <b>4 by Eylea in the marketplace.</b>  <b>5 But you cannot and should not stop there.</b>  <b>6 You have to consider whether that is driven by and</b>  <b>7 due to the claims of the patented -- patent at</b>  <b>8 issue in this IPR, and that has not been</b>  <b>9 established at all.</b>  <b>10 BY MR. CAINE:</b>                  11 Q You don't have an engineering degree,                  12 right?                  13 <b>A I do not.</b>                  14 Q You don't have an advanced degree in                  15 biotechnology, correct?                  16 <b>A I do not.</b>                  17 Q You don't have an advanced degree in                  18 pharmaceuticals, do you?                  19 <b>A I mean, I don't have a formal degree in</b>                  20 <b>that space, but all I do is study -- I mean, most</b>                  21 <b>of what I do is study pharmaceutical economics and</b>                  22 <b>I have, I think, very deep experience and</b></p>
<p style="text-align: right;">38</p> <p><b>1 "marketplace performance," but at the same time,</b>  <b>2 one has to be very cautious to mistake that for</b>  <b>3 commercial success as a term of art in an</b>  <b>4 obviousness inquiry, and there are many, many</b>  <b>5 utter failures in the Manning report with respect</b>  <b>6 to providing that nexus, providing that link.</b>                  7 <b>So numbers-wise, the numbers are what they</b>  <b>8 are and, you know, there are details we can get</b>  <b>9 into on why this or that metric that he's using is</b>  <b>10 informative or not. But at the end of the day,</b>  <b>11 the full and complete analysis requires linking</b>  <b>12 the performance to the patent at issue, and that</b>  <b>13 hasn't been established, as I explain in detail in</b>  <b>14 my declaration.</b>  <b>15 BY MR. CAINE:</b>                  16 Q Has Eylea achieved success from the                  17 standpoint of its marketplace performance, yes or                  18 no?                  19 MR. MARX: Objection. Form, asked and                  20 answered.                  21 BY THE WITNESS:                  22 <b>A I think -- I think I acknowledged, you</b></p>	<p style="text-align: right;">40</p> <p><b>1 knowledge through applied economics in that space.</b>  <b>2 But, no, I don't have a formal advanced degree.</b>                  3 Q No advanced engineering or science degree                  4 in pharmaceuticals, correct?                  5 <b>A I'm not a scientist or an engineer, no.</b>                  6 Q Do you possess a medical degree?                  7 <b>A I don't.</b>                  8 Q You're not offering any opinions                  9 concerning the scope, content or disclosure of any                  10 purported prior art references, correct?                  11 <b>A I would say I defer to the language in my</b>  <b>12 declaration. I wouldn't consider myself</b>  <b>13 affirmatively doing so, but I certainly reviewed</b>  <b>14 technical expert reports, and I've cited to a lot</b>  <b>15 of the technical expert opinions with respect to</b>  <b>16 prior art references and what was known in the</b>  <b>17 prior art. But it's not me personally expressing</b>  <b>18 an affirmative opinion.</b>                  19 Q Let me show you Exhibit 1136 which is                  20 your CV.                  21 You have a list of cases in your CV for                  22 which you've provided expert testimony. Is that</p>

4	<p>1 list up to date?</p> <p>2 <b>A I doubt it. I can't remember the date of</b></p> <p>3 <b>my report, but I've been to trial and I've</b></p> <p>4 <b>testified probably since the issuance of his</b></p> <p>5 <b>declaration.</b></p> <p>6 Q So I believe that your declaration was</p> <p>7 issued in late May. We can look at it for the</p> <p>8 date. Why don't we just give you a copy of your</p> <p>9 declaration which is Exhibit 1137.</p> <p>10 Do you see on Page 73 you signed your</p> <p>11 declaration on May 27, 2022?</p> <p>12 <b>A Yes.</b></p> <p>13 Q Have you testified since then?</p> <p>14 <b>A Yes. I've had two trials, I think.</b></p> <p>15 Q In what matters?</p> <p>16 <b>A Oh, no. I've only had one trial beyond</b></p> <p>17 <b>this because the Tris happened, I think, in late</b></p> <p>18 <b>May. Then I testified at a trial involving</b></p> <p>19 <b>eslicarbazepine, I don't know, I guess a week or</b></p> <p>20 <b>two go.</b></p> <p>21 Q Sorry. Say that last part again, please.</p> <p>22 <b>A I testified in eslicarbazepine a week or</b></p>	43	<p>1 <b>assist both companies individually as well as</b></p> <p>2 <b>companies as part of joint defense groups. So I</b></p> <p>3 <b>certainly have worked for Mylan as well as dozens</b></p> <p>4 <b>and dozens of other pharmaceutical companies over</b></p> <p>5 <b>the last several decades.</b></p> <p>6 Q You were also retained by Mylan in the</p> <p>7 AstraZeneca case listed down towards the bottom of</p> <p>8 Page 2?</p> <p>9 MR. MARX: Objection. Form.</p> <p>10 BY THE WITNESS:</p> <p>11 <b>A I was and I think I was also retained in a</b></p> <p>12 <b>parallel Delaware litigation on the same molecule</b></p> <p>13 <b>by dozens of others that were part of that joint</b></p> <p>14 <b>defense group. This one was just in West</b></p> <p>15 <b>Virginia.</b></p> <p>16 BY MR. CAINE:</p> <p>17 Q Turning to Page 3, do you see at the</p> <p>18 bottom and third from the bottom the Vifor</p> <p>19 International AG case?</p> <p>20 <b>A I do.</b></p> <p>21 Q You were retained by Mylan in that case?</p> <p>22 <b>A As well as Sandoz, that's correct.</b></p>
42	<p>1 <b>two ago before Judge Connolly in Delaware.</b></p> <p>2 (Reporter clarification.)</p> <p>3 THE WITNESS: Tris, T-r-i-s.</p> <p>4 BY MR. CAINE:</p> <p>5 Q Your Exhibit 1136, CV, is complete?</p> <p>6 <b>A I believe so, yes.</b></p> <p>7 Q How many times have you been retained by</p> <p>8 Mylan or its counsel?</p> <p>9 <b>A I don't know.</b></p> <p>10 Q Why don't we look at your Exhibit 1136.</p> <p>11 Let's turn to Page 2 of your CV.</p> <p>12 Do you see the -- let's see if I can find</p> <p>13 it here. I'm sorry. I directed you to the wrong</p> <p>14 page. It is Page 2, but it's your numbered</p> <p>15 Page 1, the In re: Entresto litigation.</p> <p>16 <b>A Right.</b></p> <p>17 Q Were you retained by Mylan in that matter?</p> <p>18 <b>A That was a huge defense group. And Mylan</b></p> <p>19 <b>was part of that. I mean, which -- Mylan's one of</b></p> <p>20 <b>the largest pharmaceutical companies in the world,</b></p> <p>21 <b>and I'm regularly engaged by large pharmaceutical</b></p> <p>22 <b>companies to draw my knowledge and experience to</b></p>	44	<p>1 (Reporter clarification.)</p> <p>2 BY MR. CAINE:</p> <p>3 Q If you turn to Page 5, second from the</p> <p>4 top, another AstraZeneca matter.</p> <p>5 <b>A It's the same one, I think. That was just</b></p> <p>6 <b>the deposition versus the trial.</b></p> <p>7 Q Just to be clear, the AstraZeneca case we</p> <p>8 were talking about before on Page 1 lists</p> <p>9 Mylan Pharmaceuticals and Kindeva Drug Delivery,</p> <p>10 LP, and on Page 5 it lists Mylan Pharmaceuticals</p> <p>11 and 3M Company.</p> <p>12 <b>A Oh, fair point.</b></p> <p>13 Q That's a different case?</p> <p>14 <b>A It is a different case. I stand</b></p> <p>15 <b>corrected.</b></p> <p>16 Q And then on Page 6, it looks like you were</p> <p>17 retained by Mylan -- well, let me ask the question</p> <p>18 this way.</p> <p>19 Were you retained by Mylan in the Biogen</p> <p>20 v. Mylan case, third from the top?</p> <p>21 MR. MARX: Objection. Mischaracterizes</p> <p>22 the document.</p>



45

1 BY THE WITNESS:  
 2 **A I was retained by counsel for Mylan in the**  
 3 **Biogen matter. I'm just trying to remember**  
 4 **because I've had a few Biogen matters, whether the**  
 5 **joint defense groups had parallel litigations, but**  
 6 **like I said, I'm regularly obtained {sic} by large**  
 7 **pharmaceutical companies to apply my knowledge and**  
 8 **expertise in this space. And Mylan being one of**  
 9 **the largest in the world, I certainly have had**  
 10 **some level of repeat, you know, work with them and**  
 11 **their counsel, but it's certainly not a**  
 12 **concentration of the work that I do.**  
 13 **As you can see from the rest of my CV, I**  
 14 **have dozens and dozens of large pharmaceutical**  
 15 **companies retaining me to apply my knowledge and**  
 16 **expertise on a regular basis.**  
 17 **BY MR. CAINE:**  
 18 **Q Mr. Hofmann, were you retained, looking at**  
 19 **Page 7 of your CV, by Mylan in the case that**  
 20 **starts with BTG International, Limited?**  
 21 **MR. MARX: Objection to the extent it**  
 22 **mischaracterizes the document.**

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1 BY THE WITNESS:  
 2 **A Yeah. I mean, it's a bunch of parties.**  
 3 **Among the parties, I think Mylan was part of the**  
 4 **GDG.**  
 5 **BY MR. CAINE:**  
 6 **Q Looking at Page 8, the Bayer intellectual**  
 7 **property case, third from the bottom, were you**  
 8 **retained as an expert by Mylan in that case?**  
 9 **MR. MARX: Objection to the extent it**  
 10 **mischaracterizes the document.**  
 11 **BY THE WITNESS:**  
 12 **A Here, again, there were maybe a half-dozen**  
 13 **defendants as part of the joint defense group, and**  
 14 **I think Mylan, who is one of the largest**  
 15 **pharmaceutical companies in the world, was part of**  
 16 **that joint defense group, yes.**  
 17 **BY MR. CAINE:**  
 18 **Q At the top of that page, there is another**  
 19 **case involving BTG International.**  
 20 **Is that case the same as the one we looked**  
 21 **at previously on Page 7 of your CV?**  
 22 **A I believe it is. I testified at trial on**

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1 **behalf of, I don't know, eight or nine defendants.**  
 2 **I haven't counted it up. That was, I think,**  
 3 **related to abiraterone, so what appears on Page 8**  
 4 **is there, like I said, on behalf of many, many**  
 5 **large pharmaceutical companies.**  
 6 **And then I think on Page 7, just**  
 7 **temporally, that was an appeal and, I think, a**  
 8 **preliminary injunction declaration that I gave on**  
 9 **the same abiraterone molecule.**  
 10 **Q So I count at least on your CV seven**  
 11 **different matters in which you were retained as an**  
 12 **expert by Mylan; is that right?**  
 13 **MR. MARX: Objection. Mischaracterizes**  
 14 **the witness testimony.**  
 15 **BY THE WITNESS:**  
 16 **A Again, Mylan, among large numerous**  
 17 **pharmaceutical companies being part of those**  
 18 **groups. I'll take your word for it on the math,**  
 19 **but that would be unsurprising to me that I have**  
 20 **done that number of cases given that people rely**  
 21 **on my knowledge and expertise in this space on a**  
 22 **regular basis.**

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1 **BY MR. CAINE:**  
 2 **Q In any of those proceedings, were you**  
 3 **asked to opine on the issue of commercial success?**  
 4 **A I think it would be a mix. Some of them**  
 5 **certainly relate to commercial success, but I'm**  
 6 **also asked to look at things like damages, things**  
 7 **like preliminary injunction or irreparable harm,**  
 8 **those types of things.**  
 9 **Q In any of these proceedings where you did**  
 10 **opine on commercial success, was your opinion in**  
 11 **each case that there was no commercial success?**  
 12 **MR. MARX: Objection to form.**  
 13 **BY THE WITNESS:**  
 14 **A I have to be careful because I can't**  
 15 **recall off the top of my head which matured into**  
 16 **trial testimony, which, if I've given trial**  
 17 **testimony in public I could talk about freely, but**  
 18 **to the extent the others didn't mature into trial**  
 19 **testimony, I am subject to protective orders in**  
 20 **those cases, and so I can't really get into the**  
 21 **details of what my opinions were if they only**  
 22 **matured into, say, deposition.**

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<p>1 <b>BY MR. CAINE:</b>                  2 Q Putting aside any confidential details                  3 which I don't want to hear about, are you aware of                  4 any instance in which you've offered an opinion                  5 that a product is a commercial success?                  6 MR. MARX: Same objection. And, again,                  7 the witness has already testified that he's                  8 subject to various protective orders and                  9 confidentiality agreements that may limit his                  10 ability to respond to the question fully.                  11 BY THE WITNESS:                  12 <b>A I guess the best -- the best way I think I</b>                  13 <b>can answer your question, trying to be helpful, is</b>                  14 <b>that I have collected in Exhibit 1136 those cases</b>                  15 <b>that have matured into testimony. There's lots of</b>                  16 <b>work that I do that doesn't mature into testimony,</b>                  17 <b>including cases where, you know, I find that a</b>                  18 <b>product maybe does represent commercial success.</b>                  19 <b>And depending on who has called me or who has</b>                  20 <b>asked for my opinion, you know, may not be</b>                  21 <b>helpful, in terms of the ones that are here in</b>                  22 <b>broad strokes, I just -- I don't -- I think we</b></p>	<p>1 point you have not offered him.                  2 But to the extent, Mr. Hofmann, you can                  3 otherwise answer, you may do so.                  4 BY THE WITNESS:                  5 <b>A The problem I have with your question,</b>                  6 <b>again, is like the last trial I just had on</b>                  7 <b>eslicarbazepine, they sealed the courtroom. I</b>                  8 <b>doubt that the trial testimony has been unsealed</b>                  9 <b>since then, so I think I am under the Protective</b>                  10 <b>Order in the sealed courtroom unable to talk about</b>                  11 <b>what my opinions were on that matter.</b>                  12 <b>If you have any published testimony, I'm</b>                  13 <b>happy to talk at whatever length you want to talk</b>                  14 <b>about, but I can't -- I can't run afoul of the</b>                  15 <b>protective orders which are pretty strict and</b>                  16 <b>particularly on commercial success because they</b>                  17 <b>often include confidential financial information</b>                  18 <b>of the companies that are involved. I don't know</b>                  19 <b>how I can answer that effectively.</b>                  20 I mean, I can tell you I certainly have in                  21 very broad strokes testified as to the commercial                  22 success of products, whether it's in the</p>
50	52
<p>1 <b>have to go case by case if you want to, and then I</b>                  2 <b>have to think about whether I'm subject to</b>                  3 <b>Protective Order -- you know, if there's live</b>                  4 <b>trial testimony you want to put in front of me,</b>                  5 <b>I'm happy to look at that and refresh my memory,</b>                  6 <b>but I don't know that I can kind of give you a</b>                  7 <b>complete answer because I haven't cataloged or</b>                  8 <b>thought about it in the way your question asks.</b>                  9 <b>BY MR. CAINE:</b>                  10 Q Well, in terms of -- let's limit ourselves                  11 to trial testimony, then, and understanding that                  12 you can only remember what you can remember. Do                  13 you recall any instance in which you testified at                  14 trial that a product or treatment or method was a                  15 commercial success?                  16 MR. MARX: Same objection. The witness                  17 has already testified that he may be subject to                  18 confidentiality agreements.                  19 And, Mr. Caine, as you're aware, certain                  20 trials also occur under seal with closed                  21 courtrooms. The witness has asked if you could                  22 refresh his memory about documents, which to this</p>	<p>1 obviousness inquiry or whether it's in the context                  2 of damages where that's part of Georgia Pacific                  3 factors on behalf of patent holders. And I've                  4 also testified on behalf of patent challengers on                  5 this issue many times because people do draw on my                  6 knowledge and experience in this space on a                  7 regular basis.                  8 <b>BY MR. CAINE:</b>                  9 Q Is the following statement true: There                  10 has never been a time between 2015 and 2019 where                  11 you've testified on commercial success without                  12 opining that there was no commercial success?                  13 MR. MARX: Objection. Mischaracterizes                  14 the witness testimony. And as Mr. Hofmann has                  15 already stated, there are several matters in which                  16 he cannot disclose his opinions which limit his                  17 ability to answer that question fully.                  18 BY THE WITNESS:                  19 <b>A I don't remember. I would say that, you</b>                  20 <b>know, again, the list that we have in Exhibit 1136</b>                  21 <b>is only those that have matured into testimony.</b>                  22 <b>And I'm happy to walk through one by one, if you</b></p>

<p style="text-align: right;">53</p> <p>1 want to, the cases. And maybe I'll remember,                  2 maybe I won't. I am uncertain one way or the                  3 other.                  4 I think I can grant you that on the                  5 majority of cases that have matured into                  6 testimony, it has been on behalf of the patent                  7 challenger where my finding was that there was not                  8 commercial success as a term of art in an                  9 obviousness inquiry based on the facts and                  10 circumstances in those particular matters.                  11 BY MR. CAINE:                  12 Q You testified in the Janssen versus Teva                  13 case, correct?                  14 A Which one was that?                  15 Q Janssen Pharmaceuticals and Janssen                  16 Pharmaceutica NV as plaintiffs versus Teva                  17 Pharmaceuticals, USA, Inc., defendant?                  18 A Before which judge?                  19 Q Jude Cecchi in, it looks like, New Jersey.                  20 MR. MARX: A couple of things, Mr. Caine,                  21 you can hand Mr. Hofmann a copy of the exhibit. I                  22 don't think he has one. And then if we could also</p>	<p style="text-align: right;">55</p> <p>1 Q Sure. So why don't you go to Page 2735 to                  2 start off with.                  3 MR. MARX: Again, I'm going to counsel the                  4 witness to take his time to review this document                  5 as he has never seen it before, and it's quite                  6 voluminous. I don't know the exact number of                  7 pages, 399, 400 pages.                  8 BY MR. CAINE:                  9 Q Tell me when you're at Page 2735.                  10 MR. MARX: I also want to note for the                  11 record that certain portions of this document have                  12 been redacted. To the extent Mr. Hofmann                  13 recalls this matter and his testimony, there                  14 may be certain aspects which he is not permitted                  15 to disclose that are not otherwise in this                  16 document.                  17 BY MR. CAINE:                  18 Q This is the public transcript. Are you on                  19 Page 2735?                  20 A Not yet, sir. Again, I have never seen                  21 this 400-page document. I obviously testified.                  22 And I assuming that's what you're taking me to,</p>
<p style="text-align: right;">54</p> <p>1 have the court reporter label it so we know what                  2 we're discussing.                  3 MR. CAINE: Sure. Absolutely. We can                  4 label it as Hofmann Exhibit 1.                  5 (A certain document was marked Hofmann                  6 Deposition Exhibit 1 for identification,                  7 as of 06/23/2022.)                  8 BY MR. CAINE:                  9 Q Do you have Hofmann Exhibit 1 in front of                  10 you?                  11 A Yeah. I mean --                  12 Q The question is: Do you have the exhibit                  13 in front of you?                  14 A I have the exhibit in front of me, but --                  15 Q Wait for my next question, please.                  16 A I'm just trying to orient myself. I don't                  17 think I've ever seen this.                  18 Q Okay. Would you turn to Page 2783,                  19 please.                  20 A This is like a 500-page document that I've                  21 never seen before -- or 400-page document. Let me                  22 orient myself to what it is I'm looking at.</p>	<p style="text-align: right;">56</p> <p>1 but I'm just trying to reorient myself. This was,                  2 you know, a year-and-a-half ago.                  3 Q I just want to know -- the first question                  4 is: Did you testify as reflected in Page 2735?                  5 So I would appreciate it if you could answer that                  6 question.                  7 MR. MARX: Counsel, if you would give                  8 Mr. Hofmann a chance to familiarize himself with                  9 this document, which he has noted he has never                  10 seen before.                  11 MR. CAINE: Well, I will, but we re going                  12 to go off the record then, if that s what he wants                  13 to do.                  14 MR. MARX: Well, we re not going to go off                  15 the record at all. You ve put a 400-page document                  16 in front of him and have asked him to testify                  17 about the contents in it.                  18 MR. CAINE: No, I have not.                  19 MR. MARX: To the extent he needs to                  20 review it --                  21 MR. CAINE: Counsel, Counsel.                  22 MR. MARX: To the extent you asked him to</p>

57	<p>1 provide testimony about this document, he's</p> <p>2 permitted on the record to familiarize himself</p> <p>3 with it.</p> <p>4 MR. CAINE: He's not permitted to</p> <p>5 filibuster the deposition and the question by</p> <p>6 reading the entire transcript when the question</p> <p>7 is: Did he testify at this hearing? And I'm</p> <p>8 pointing him to a place where he can identify that</p> <p>9 that's the case.</p> <p>10 MR. MARX: And he is taking the time to</p> <p>11 confirm this document. He's not filibustering.</p> <p>12 This is a 400-page document he's never seen</p> <p>13 before.</p> <p>14 BY MR. CAINE:</p> <p>15 Q Sir, you testified at the Janssen</p> <p>16 Pharmaceuticals versus Teva Pharmaceuticals case,</p> <p>17 correct? It's on your CV, Page 4.</p> <p><b>18 A I've testified at several Janssen v.</b></p> <p><b>19 defendant trials. So I'm just -- I'm trying to</b></p> <p><b>20 reorient myself. This was a year-and-a-half ago</b></p> <p><b>21 that it was at trial. I'm certainly not</b></p> <p><b>22 suggesting I didn't if it's reflected in here that</b></p>	59	<p>1 MR. MARX: Objection to the extent it</p> <p>2 calls for a legal conclusion.</p> <p>3 BY THE WITNESS:</p> <p><b>4 A I'm sure I was. I don't -- I haven't</b></p> <p><b>5 gotten there.</b></p> <p><b>6 BY MR. CAINE:</b></p> <p>7 Q Go to Page 2780.</p> <p>8 Do you see that your cross-examination</p> <p>9 begins on Page 2780?</p> <p><b>10 A Okay. So I'm just skipping over my whole</b></p> <p><b>11 direct exam.</b></p> <p><b>12 It looks like a Mr. Fischer cross-examined</b></p> <p><b>13 me starting at Row 20.</b></p> <p>14 Q I would like you to go to Page 2783 of</p> <p>15 your cross-examination. The question that you</p> <p>16 were asked starting on Line 2 is:</p> <p>17 "But in any case, there has never been a</p> <p>18 time between 2015 and 2019 where you testified on</p> <p>19 commercial success without opining that there was</p> <p>20 no commercial success, right?"</p> <p>21 Do you see that?</p> <p>22 MR. MARX: I'm going to object to the</p>
58	<p><b>1 I did. I'm just trying to remember the context,</b></p> <p><b>2 and I definitely do recall testifying at this</b></p> <p><b>3 trial.</b></p> <p><b>4 I do recall -- I don't even remember if it</b></p> <p><b>5 was -- it might have been remotely. The drug was</b></p> <p><b>6 INVEGA SUSTENNA as the branded name which was an</b></p> <p><b>7 antischizophrenic.</b></p> <p>8 Q Sir, I didn't ask you any of those</p> <p>9 questions. I asked you if you testified at the</p> <p>10 Janssen Pharmaceuticals versus Teva</p> <p>11 Pharmaceuticals case in 2020.</p> <p>12 MR. MARX: Objection.</p> <p>13 BY MR. CAINE:</p> <p>14 Q Your CV says you did. Did you?</p> <p><b>15 A I did.</b></p> <p>16 Q Okay. You see that on Page 2735, your</p> <p>17 direct testimony begins?</p> <p><b>18 A I do.</b></p> <p>19 Q Look at Line 10. Do you see that?</p> <p><b>20 A Yes, called as a witness.</b></p> <p>21 Q You were also cross-examined in that case,</p> <p>22 right?</p>	60	<p>1 extent Mr. Hofmann has already testified about the</p> <p>2 matters he's been involved in and is not able to</p> <p>3 disclose the contents of.</p> <p>4 And I would also note for the record that</p> <p>5 of the 60 or so pages of direct testimony in this</p> <p>6 matter, a number of them from Mr. Hofmann's</p> <p>7 testimony are redacted. So there are clearly</p> <p>8 portions of this testimony that Mr. Hofmann cannot</p> <p>9 disclose in this proceeding here today.</p> <p>10 BY MR. CAINE:</p> <p>11 Q Mr. Hofmann, is that the question that you</p> <p>12 were asked, what I just read?</p> <p><b>13 A Yeah, I'm sorry. I'm still trying to put</b></p> <p><b>14 this in context because there were a number of</b></p> <p><b>15 questions that are before it, and you're drawing</b></p> <p><b>16 me into a limited number of lines of testimony.</b></p> <p><b>17 I think consistent with what I explained</b></p> <p><b>18 before, I have --</b></p> <p>19 Q I'm just asking you if that was the</p> <p>20 question you were asked.</p> <p>21 MR. MARX: Mr. Hofmann, you may answer as</p> <p>22 you were previously going to.</p>

<p style="text-align: right;">6</p> <p>1 BY THE WITNESS:</p> <p>2 <b>A And it goes on for pages and pages as to</b></p> <p>3 <b>other questions about prior testimony. So I think</b></p> <p>4 <b>that it's a little unfair, the way your question</b></p> <p>5 <b>is being asked, and it's hugely unfair that you're</b></p> <p>6 <b>putting a 400-page document in front of me that</b></p> <p>7 <b>I've never seen before, that I'm trying to, you</b></p> <p>8 <b>know, process and reorient myself to.</b></p> <p>9 <b>At the end of the day, I think I explained</b></p> <p>10 <b>that I have testified on behalf of patent holders;</b></p> <p>11 <b>I've testified on behalf of patent challengers.</b></p> <p>12 <b>More often than not, it is those that have matured</b></p> <p>13 <b>into testimony, which is consistent with my answer</b></p> <p>14 <b>here, is that those that have matured into</b></p> <p>15 <b>testimony have been on behalf of patent</b></p> <p>16 <b>challengers in that particular time period that</b></p> <p>17 <b>that question asked about.</b></p> <p>18 <b>But there's plenty of cases that don't</b></p> <p>19 <b>mature into testimony, and there's plenty of cases</b></p> <p>20 <b>where I've testified on behalf of the patent</b></p> <p>21 <b>holders. I think both --</b></p> <p>22 <b>BY MR. CAINE:</b></p>	<p style="text-align: right;">63</p> <p>1 that apply to this proceeding, you're to limit</p> <p>2 your objections to form and privilege, and you are</p> <p>3 not to make speaking objections.</p> <p>4 MR. MARX: I'm going to object how I want</p> <p>5 to object, the same that counsel for Regeneron has</p> <p>6 objected at depositions, similarly. I'm permitted</p> <p>7 to object if I want to. Nothing I'm doing is</p> <p>8 outside the bounds of what Regeneron counsel has</p> <p>9 done in prior depositions.</p> <p>10 MR. CAINE: I recommend that you look at</p> <p>11 the rules that apply to the proceedings on the</p> <p>12 break --</p> <p>13 MR. MARX: I'm familiar with the rules.</p> <p>14 Thank you very much.</p> <p>15 MR. CAINE: -- and adhere to them.</p> <p>16 Thank you.</p> <p>17 BY MR. CAINE:</p> <p>18 Q Mr. Hofmann, the answer to the question?</p> <p>19 <b>A I'm, again, trying to process this</b></p> <p>20 <b>399-page document, but, like, when I look at</b></p> <p>21 <b>Page 216, Rows 9 to 16, it's exactly what I've</b></p> <p>22 <b>explained. And I've put context around the, look,</b></p>
<p style="text-align: right;">62</p> <p>1 Q Mr. Hofmann, the question I asked is --</p> <p>2 MR. MARX: You cannot interrupt the</p> <p>3 witness while he s responding to your question.</p> <p>4 BY MR. CAINE:</p> <p>5 Q If you give me a responsive answer, I will</p> <p>6 not interrupt. But I need to get a responsive</p> <p>7 answer to the simple question that I asked.</p> <p>8 Do you see that you were asked the</p> <p>9 question: "But in any case, there has never been</p> <p>10 a time between 2015 and 2019 where you ve</p> <p>11 testified on commercial success without opining</p> <p>12 that there was no commercial success, right?"</p> <p>13 MR. MARX: Mr. Hofmann has already</p> <p>14 answered that the surrounding pages give context</p> <p>15 to the lines that you re reading. He s permitted</p> <p>16 to answer accordingly with a qualified answer.</p> <p>17 MR. CAINE: Mr. Marx, you need to limit</p> <p>18 your objections to form per the rules.</p> <p>19 MR. MARX: No. You have to let the</p> <p>20 witness answer the question. And you re</p> <p>21 interrupting his answers.</p> <p>22 MR. CAINE: Per the rules, per the rules</p>	<p style="text-align: right;">64</p> <p>1 <b>I've testified on behalf of patent holders, patent</b></p> <p>2 <b>challengers. I've done work for patent holders</b></p> <p>3 <b>and patent challengers that doesn't mature into</b></p> <p>4 <b>testimony. Then as a follow-up question, I think</b></p> <p>5 <b>they asked of the ones that did mature into</b></p> <p>6 <b>testimony, can you identify those that were on</b></p> <p>7 <b>behalf of the patent holder.</b></p> <p>8 <b>And as I was sitting there at that time, I</b></p> <p>9 <b>said of the cases that matured into testimony, I</b></p> <p>10 <b>couldn't identify one off the top of my head. But</b></p> <p>11 <b>I hadn't cataloged it or thought about it. I can</b></p> <p>12 <b>run through my CV in more detail, if you would</b></p> <p>13 <b>like. I don't --</b></p> <p>14 Q No. I would just like you to answer the</p> <p>15 question, which I think you've not been wanting to</p> <p>16 do. So let's move on.</p> <p>17 The answer that you gave to that question</p> <p>18 is on Lines 5 and 6: "Of the cases that matured</p> <p>19 into testimony with my prior work, yes."</p> <p>20 Was that your testimony then?</p> <p>21 MR. MARX: Objection. The document speaks</p> <p>22 for itself.</p>

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1 BY THE WITNESS:  
 2 **A As I sat there at that time, but --**  
 3 **BY MR. CAINE:**  
 4 Q Is there any reason why that testimony,  
 5 sitting here now, was incorrect?  
 6 **A I mean, I think part of the problem is I**  
 7 **haven't cataloged it or thought about it. I mean,**  
 8 **as I was sitting there at that time, that was my**  
 9 **response and I stand by it, but, you know, I think**  
 10 **that looking at the prior page and kind of**  
 11 **explaining the context is an important aspect, and**  
 12 **then it looks like it went on for a period of**  
 13 **time.**  
 14 **And you haven't given me a chance to even**  
 15 **review the testimony that I have never seen, and**  
 16 **other than experiencing it live, I just don't -- I**  
 17 **don't remember the details.**  
 18 **BY MR. CAINE:**  
 19 Q In any case, since the period in which you  
 20 testified here in 2020 in the Janssen  
 21 Pharmaceuticals v. Teva Pharmaceuticals case, have  
 22 you testified publicly that a product, process or

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1 treatment was commercially successful?  
 2 **A I haven't -- I haven't thought about that**  
 3 **or cataloged it.**  
 4 Q To the best of your recollection.  
 5 **A As I sit here right now, I don't remember**  
 6 **one way or the other. I work regularly with**  
 7 **patent holders. I work regularly with patent**  
 8 **challengers. Some of it matures into testimony;**  
 9 **most of it does not because a lot of things**  
 10 **settle.**  
 11 Q Is there any case since the time of your  
 12 testimony here in 2020 that you remember having  
 13 publicly testified there was commercial success?  
 14 MR. MARX: Objection. Asked and answered.  
 15 BY THE WITNESS:  
 16 **A I simply haven't thought about it, and so**  
 17 **I can't -- I mean, obviously I work a lot on**  
 18 **patent matters. Some of them mature into**  
 19 **testimony; some of them don't. I work for both**  
 20 **patent holders and patent challengers, and I**  
 21 **can't, as I sit here right now, think about**  
 22 **something that matured all the way into trial**

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1 **testimony one way or the other. I'd have to go**  
 2 **back and examine that specific inquiry.**  
 3 **BY MR. CAINE:**  
 4 Q If you could remember such a case where  
 5 you testified there was commercial success, you  
 6 would tell me, right? You're under oath, you  
 7 would give me that answer; is that right?  
 8 MR. MARX: Objection. The witness has  
 9 already testified that there are a number of  
 10 matters where he is under a Protective Order or  
 11 confidentiality agreement and is not permitted to  
 12 disclose those matters in this proceeding.  
 13 BY MR. CAINE:  
 14 Q Where you've testified publicly?  
 15 **A Well, that's the thing. I issue reports a**  
 16 **lot. I give depositions a lot. What matures into**  
 17 **trial testimony is very rare, and so I'm trying to**  
 18 **think and give you my best ability as I sit here**  
 19 **right now, but I just don't -- I just haven't**  
 20 **cataloged or thought about it in a way where I can**  
 21 **give you an answer one way or the other as I sit**  
 22 **here right now.**

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1 Q If there was such a case where you  
 2 testified publicly that you can recall that there  
 3 was commercial success, you would tell me, right?  
 4 MR. MARX: Objection. Asked and answered.  
 5 BY THE WITNESS:  
 6 **A Of course. I'm giving you my best and**  
 7 **most thorough answers possible. There's no reason**  
 8 **I wouldn't do so. I just -- I haven't thought**  
 9 **about it or cataloged it in the way your question**  
 10 **is asking.**  
 11 MR. CAINE: Why don't we take a break.  
 12 THE VIDEOGRAPHER: Stand by. We are going  
 13 off the record. The time is 10:29 a.m.  
 14 (A recess was had.)  
 15 THE VIDEOGRAPHER: We are back on the  
 16 record. The time is 10:44 a.m.  
 17 BY MR. CAINE:  
 18 Q Welcome back, Mr. Hofmann.  
 19 **A Thank you.**  
 20 Q Of the prior proceedings in which you've  
 21 been designated as an expert witness, has your  
 22 testimony ever been limited or excluded?

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1 A So I've given testimony many, many times,  
 2 and in all situations involving commercial  
 3 success, I've never been excluded. And just more  
 4 broadly, I've never been excluded as to  
 5 qualifications or things like that.  
 6 As to other matters of the dozens and  
 7 dozens and dozens of where I've testified, there  
 8 are two that come to mind where there were some  
 9 pretrial findings – construction or –  
 10 MR. MARX: That's construction upstairs.  
 11 BY THE WITNESS:  
 12 A There were some pretrial findings that  
 13 maybe limited some of my testimony, but ultimately  
 14 I did appear at trial in both of those proceedings  
 15 and testified to the full extent of my opinions.  
 16 BY MR. CAINE:  
 17 Q What were those two proceedings?  
 18 A The two that come to mind are Concordia  
 19 Pharmaceuticals which I think was in 2016, a false  
 20 advertising case, and then Grant Street Group,  
 21 which – oh, boy, that goes way back more than a  
 22 decade ago – a software patent case, Grant Street

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1 Group in the Western District of PA. Concordia  
 2 was in the Western District of Virginia.  
 3 Q And the Grant Street case, in what way was  
 4 your testimony limited or excluded?  
 5 A So like I said, it was a software patent  
 6 case. I was working on behalf of the patent  
 7 holder, and I provided opinions on lost profits  
 8 and reasonable royalty. Now, it switched judges  
 9 and so there was some pretrial stuff where there  
 10 were Daubert motions. This was at the time where  
 11 entire market value rule was evolving in the  
 12 Fed Circuit, and I think one of the judges kind of  
 13 found that the opinion I had on reasonable royalty  
 14 didn't follow what was then the standard for  
 15 entire market value rule.  
 16 So what they did was on a pretrial basis,  
 17 said, look, you can testify to the full and  
 18 complete opinion you have on lost profits on  
 19 behalf of the patent holder, and if the other side  
 20 brings up reasonable royalty, you can respond to  
 21 it. So they didn't let me affirmatively present  
 22 it is kind of where it landed.

7

1 The way things panned out, I presented my  
 2 lost profits opinion. There was a jury trial.  
 3 The opposing expert presented her lost profits and  
 4 reasonable royalty opinion, and so because she  
 5 gave that opinion, I was allowed to respond and  
 6 give my reasonable royalty opinion.  
 7 The jury ended up awarding lost profits.  
 8 So, again, the entirety of my opinion came in  
 9 ultimately at trial. But there are some pretrial  
 10 things that, if you stiff around Westlaw, you will  
 11 see some of the reasonable royalty stuff was  
 12 limited pretrial.  
 13 BY MR. CAINE:  
 14 Q In the Concordia case, your opinion about  
 15 the amount of lost profit damages was excluded,  
 16 correct?  
 17 MR. MARX: I'm just going to make an  
 18 objection to the extent that these call for legal  
 19 conclusions.  
 20 BY THE WITNESS:  
 21 A Fair enough. In the Concordia matter  
 22 which was a false advertising case where, again, I

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1 was working for the patent holder and working on  
 2 behalf of the patent holder to claim lost profits  
 3 on like nutraceutical, if you will, what the judge  
 4 did in pretrial papers was said, look, I don't --  
 5 I don't know that there's sufficient basis to get  
 6 to the numbers that Hofmann put forth, but Hofmann  
 7 seems like a really smart guy and seems like he  
 8 really knows a lot about pharmaceuticals and  
 9 nutraceuticals, and so he can come to trial and  
 10 we'll figure it out as we go as to how he might  
 11 help the jury come to their decision.  
 12 So I did go to trial. I testified in  
 13 Charlottesville. I was there for several days and  
 14 expressed -- and based on whatever sidebars and  
 15 everything else, you know, gave the full extent of  
 16 my opinions. The jury awarded lost profits, which  
 17 was the opinion that I expressed. It wasn't the  
 18 number that I expressed, but they did award lost  
 19 profits.  
 20 And so in both instances, even though  
 21 there were some pretrial, I think things -- there  
 22 hasn't been a situation, certainly with respect to

73	<p>1 <b>commercial success, where I've been excluded. And</b></p> <p>2 <b>then in those two damages cases involving jury</b></p> <p>3 <b>trials, there were some pretrial limitations that</b></p> <p>4 <b>ultimately, as they resolved themselves, I</b></p> <p>5 <b>expressed the entirety of my opinions.</b></p> <p>6 <b>BY MR. CAINE:</b></p> <p>7 Q You weren't allowed in the Concordia case</p> <p>8 to express an opinion about the amount of lost</p> <p>9 profit damages, correct?</p> <p>10 MR. MARX: Objection. Mischaracterizes</p> <p>11 the witness testimony.</p> <p>12 BY THE WITNESS:</p> <p>13 <b>A I disagree. I think I expressed the exact</b></p> <p>14 <b>amount.</b></p> <p>15 <b>BY MR. CAINE:</b></p> <p>16 Q Okay. In the Concordia case, your opinion</p> <p>17 was excluded because it was determined that your</p> <p>18 lost profit calculations were not the product of</p> <p>19 reliable principles and methods that were readily</p> <p>20 applied to the particular facts of the case,</p> <p>21 correct?</p> <p>22 MR. MARX: Objection. Mischaracterizes</p>	75	<p>1 chosen data and unsupported assumptions, correct?</p> <p>2 MR. MARX: Objection. Mischaracterizes</p> <p>3 the witness testimony and to the extent it seeks a</p> <p>4 legal conclusion.</p> <p>5 BY THE WITNESS:</p> <p>6 <b>A I don't have the pretrial opinion in front</b></p> <p>7 <b>of me. I don't even want to see it. But, you</b></p> <p>8 <b>know, the situation was pretty unique because it</b></p> <p>9 <b>was a false advertising case, and I think</b></p> <p>10 <b>Judge Conrad didn't like the position of the</b></p> <p>11 <b>plaintiffs, the patent holders who I was</b></p> <p>12 <b>representing in claiming damages against the</b></p> <p>13 <b>defendant where the defendant hadn't launched.</b></p> <p>14 <b>Again, being deeply knowledgeable about</b></p> <p>15 <b>the Byzantine structure of pharmaceutical products</b></p> <p>16 <b>and pharmaceutical reimbursement, there was harm.</b></p> <p>17 <b>And I respectfully disagree with Judge Conrad as</b></p> <p>18 <b>to what he said in his pretrial statement, but</b></p> <p>19 <b>ultimately, I testified to the full extent of my</b></p> <p>20 <b>opinions and the jury awarded lost profits.</b></p> <p>21 MR. CAINE: Let's mark as Exhibit 2,</p> <p>22 Hofmann Exhibit 2, the Memorandum Opinion from</p>
74	<p>1 the witness testimony and to the extent it calls</p> <p>2 for a legal conclusion.</p> <p>3 BY THE WITNESS:</p> <p>4 <b>A I don't remember the exact words the judge</b></p> <p>5 <b>used, but he did -- he did -- he was skeptical of</b></p> <p>6 <b>the lost profits opinion because the defendant</b></p> <p>7 <b>ended up not launching their product, and my</b></p> <p>8 <b>opinion was more around the contours of, look, if</b></p> <p>9 <b>you notify the supply chain that you're going to</b></p> <p>10 <b>launch that can have implications to the patent</b></p> <p>11 <b>holder, but, you know, he also -- I think within</b></p> <p>12 <b>the language you're talking about, I think there's</b></p> <p>13 <b>a footnote at the end, like I said, where he says,</b></p> <p>14 <b>"But I think Hofmann could help inform the jury</b></p> <p>15 <b>about pharmaceutical economics, and so he can come</b></p> <p>16 <b>to trial and we'll figure it out along the way."</b></p> <p>17 <b>BY MR. CAINE:</b></p> <p>18 Q Okay. Now, he also -- the Court also</p> <p>19 determined that you failed to take into account</p> <p>20 numerous market factors that could have affected</p> <p>21 sales and prescriptions of the product at issue</p> <p>22 and that your opinions were based on selectively</p>	76	<p>1 Concordia Pharmaceuticals versus Method</p> <p>2 Pharmaceuticals, LLC dated April 13, 2016.</p> <p>3 (A certain document was marked Hofmann</p> <p>4 Deposition Exhibit 2 for identification,</p> <p>5 as of 06/23/2022.)</p> <p>6 MR. MARX: I'm going to reiterate what</p> <p>7 Mr. Caine said, that this is a memorandum opinion.</p> <p>8 It is a legal document. And as Mr. Hofmann has</p> <p>9 testified already, he is not an attorney. So I'm</p> <p>10 going to object to this line of questioning to the</p> <p>11 extent it seeks legal conclusions or pertains to</p> <p>12 legal conclusions made in this matter.</p> <p>13 BY MR. CAINE:</p> <p>14 Q Do you have Hofmann Exhibit 2 in front of</p> <p>15 you?</p> <p>16 <b>A I've flipped through it very quickly. I</b></p> <p>17 <b>do have Hofmann 2 in front of me.</b></p> <p>18 Q If you turn to Page 11, do you see that</p> <p>19 Section 3 has the heading "Hofmann"?</p> <p>20 <b>A I do.</b></p> <p>21 Q And the first paragraph starts "Concordia</p> <p>22 retained Ivan Hofmann"?</p>



<p style="text-align: right;">77</p> <p>1 <b>A It does.</b></p> <p>2 Q That's you?</p> <p>3 <b>A Uh-huh.</b></p> <p>4 Q And then the second paragraph says:</p> <p>5 "After carefully considering Hofmann's report and</p> <p>6 the portions of his deposition testimony provided</p> <p>7 by the parties, the Court concludes that Hofmann's</p> <p>8 opinion regarding the amount of lost profit</p> <p>9 damages incurred by Concordia must be excluded.</p> <p>10 Specifically, the Court finds that Concordia has</p> <p>11 failed to establish that Hofmann's lost profit</p> <p>12 calculations were the product of reliable</p> <p>13 principles and methods that were reliably applied</p> <p>14 to the particular facts of the case."</p> <p>15 Do you see that?</p> <p>16 MR. MARX: Objection to the extent it</p> <p>17 calls for a legal conclusion and the document</p> <p>18 speaks for itself. This, again, is a memorandum</p> <p>19 opinion from a court of law, and Mr. Hofmann is</p> <p>20 not an attorney.</p> <p>21 BY THE WITNESS:</p> <p>22 <b>A I think you read that as it appears.</b></p>	<p style="text-align: right;">79</p> <p>1 unsupported assumptions."</p> <p>2 Correct?</p> <p>3 MR. MARX: Same objection. The document</p> <p>4 speaks for itself and to the extent it seeks a</p> <p>5 legal conclusion.</p> <p>6 BY THE WITNESS:</p> <p>7 <b>A I don't know what to add beyond what I</b></p> <p>8 <b>said before. I respectfully disagree with</b></p> <p>9 <b>Judge Conrad, but he did acknowledge and recognize</b></p> <p>10 <b>that I had knowledge and information and I</b></p> <p>11 <b>ultimately testified to the full scope of my</b></p> <p>12 <b>opinions.</b></p> <p>13 BY MR. CAINE:</p> <p>14 Q He did exclude your opinion on the amount</p> <p>15 of lost profit damages, correct?</p> <p>16 MR. MARX: Objection. Mischaracterizes</p> <p>17 the witness testimony.</p> <p>18 BY THE WITNESS:</p> <p>19 <b>A That's what it says in this, I guess,</b></p> <p>20 <b>pretrial opinion. I don't know the semantics, but</b></p> <p>21 <b>when we were at trial, I gave the full scope of my</b></p> <p>22 <b>opinions.</b></p>
<p style="text-align: right;">78</p> <p>1 <b>This, I think, was -- I don't -- like we heard,</b></p> <p>2 <b>I'm not a lawyer. I think this was a pretrial</b></p> <p>3 <b>document, and the way I recall it is -- what we</b></p> <p>4 <b>see, if you go to Page 15, is there was some</b></p> <p>5 <b>discussion, but the judge acknowledged in</b></p> <p>6 <b>Footnote 3 on Page 15, essentially his, being me,</b></p> <p>7 <b>specialized knowledge can still assist the jury in</b></p> <p>8 <b>ways.</b></p> <p>9 <b>And so they could call me as a witness,</b></p> <p>10 <b>which, in fact, I did come as a witness. And</b></p> <p>11 <b>after there were numerous sidebars, I gave the</b></p> <p>12 <b>full extent of my expert testimony during the</b></p> <p>13 <b>trial.</b></p> <p>14 BY MR. CAINE:</p> <p>15 Q We'll get to that in a minute.</p> <p>16 <b>A Okay.</b></p> <p>17 Q The next sentence after the citation says:</p> <p>18 "The methodology employed by Hofmann," which is</p> <p>19 you, "in reaching his conclusions failed to take</p> <p>20 into account numerous market factors that could</p> <p>21 have affected Donnatal sales and prescriptions and</p> <p>22 was based on selectively chosen data and</p>	<p style="text-align: right;">80</p> <p>1 MR. CAINE: We're going to mark as Hofmann</p> <p>2 Exhibit 3 a transcript of jury trial proceedings,</p> <p>3 day 4, before the Honorable Glen E. Conrad, United</p> <p>4 States District Judge, in Concordia</p> <p>5 Pharmaceuticals versus Method Pharmaceuticals.</p> <p>6 (A certain document was marked Hofmann</p> <p>7 Deposition Exhibit 3 for identification,</p> <p>8 as of 06/23/2022.)</p> <p>9 BY MR. CAINE:</p> <p>10 Q Do you have Hofmann Exhibit 3 in front of</p> <p>11 you?</p> <p>12 MR. MARX: I'm going to object to the use</p> <p>13 of this document again. This is a legal document.</p> <p>14 Mr. Hofmann is not an attorney, and more or less</p> <p>15 it's a 174-page legal document that has just been</p> <p>16 placed in front of Mr. Hofmann.</p> <p>17 BY MR. CAINE:</p> <p>18 Q Do you have Hofmann Exhibit 3 in front of</p> <p>19 you?</p> <p>20 <b>A I mean, I have what's labeled as Hofmann</b></p> <p>21 <b>Exhibit 3. I certainly have not studied this or</b></p> <p>22 <b>seen this in years. But it's the document -- it's</b></p>

8	<p>1 <b>a 175-page document labeled Hofmann Exhibit 3.</b></p> <p>2 Q If you turn to Page 102, at the very</p> <p>3 bottom starting at Line 25, your direct testimony</p> <p>4 begins?</p> <p>5 MR. MARX: Objection to the extent it</p> <p>6 seeks a legal conclusion and further</p> <p>7 mischaracterizes the document as it's picking out</p> <p>8 a small snippet of a 174-page document.</p> <p>9 BY THE WITNESS:</p> <p>10 <b>A Again, I know I've seen this before, but</b></p> <p>11 <b>it's been several years. It's a lengthy document.</b></p> <p>12 <b>And there's lots of testimony and lots of stuff</b></p> <p>13 <b>that's in here that I cannot possibly</b></p> <p>14 <b>refamiliarize myself, unless you want me to spend</b></p> <p>15 <b>more time with it. But I'm familiar with the</b></p> <p>16 <b>issue and, yes, like I said, I testified to the</b></p> <p>17 <b>full scope of my opinions at trial.</b></p> <p>18 BY MR. CAINE:</p> <p>19 Q My question was this and I'd ask you to</p> <p>20 focus on my question:</p> <p>21 Does your direct testimony start at the</p> <p>22 bottom of Page 102, Line 25?</p>	83	<p>1 Q It says -- it goes on on Line 8: "And I</p> <p>2 thought it was speculative and not obtained</p> <p>3 through the science of forensic accounting."</p> <p>4 That's a reference to the methodology you</p> <p>5 employed, right?</p> <p>6 MR. MARX: Objection. Mischaracterizes</p> <p>7 the document. Again, this is a 174-page document,</p> <p>8 and you've read a single sentence in and to the</p> <p>9 extent it seeks a legal conclusion.</p> <p>10 BY THE WITNESS:</p> <p>11 <b>A And I think the -- as I explained, I mean,</b></p> <p>12 <b>I can go into further detail if you want as to the</b></p> <p>13 <b>specific facts and circumstances and the</b></p> <p>14 <b>uniqueness of this case. Importantly this has</b></p> <p>15 <b>nothing to do with commercial success. It's a</b></p> <p>16 <b>false advertising case on behalf of the brand</b></p> <p>17 <b>patent holder.</b></p> <p>18 No, it wasn't even a patent case; it was a</p> <p>19 false advertising case. So the issues that were</p> <p>20 surrounding it involved a generic who was coming</p> <p>21 in and was falsely advertising that they had a</p> <p>22 product that was going to be available, and so</p>
82	<p>1 MR. MARX: Objection to the extent it</p> <p>2 seeks a legal conclusion and mischaracterizes the</p> <p>3 document.</p> <p>4 BY THE WITNESS:</p> <p>5 <b>A From what I can tell as a nonlawyer, it</b></p> <p>6 <b>appears to, yes.</b></p> <p>7 BY MR. CAINE:</p> <p>8 Q And if you go to Page 108, please, Line 7,</p> <p>9 you see it says:</p> <p>10 "THE COURT: Right. I ruled out his</p> <p>11 profitability analysis."</p> <p>12 That's a reference to your profitability</p> <p>13 analysis, correct?</p> <p>14 MR. MARX: Objection to the extent it</p> <p>15 mischaracterizes the witness testimony and seeks a</p> <p>16 legal conclusion.</p> <p>17 BY THE WITNESS:</p> <p>18 <b>A Look, I haven't seen this document in</b></p> <p>19 <b>years. When it says "his," the pronoun is me, but</b></p> <p>20 <b>like I said, I testified as to the full extent of</b></p> <p>21 <b>lost profits and that's what the jury awarded.</b></p> <p>22 BY MR. CAINE:</p>	84	<p>1 pharmaceutical companies were delisting the brand</p> <p>2 product.</p> <p>3 And my opinion was that that caused harm</p> <p>4 to the brand product because they were improperly</p> <p>5 delisting the product based on the false</p> <p>6 advertising claims which I relied on a survey</p> <p>7 expert to -- you know, and a pharmacy -- a Pharm.D</p> <p>8 expert to define the liability and I quantified</p> <p>9 the amount.</p> <p>10 Ultimately, I gave my testimony and the</p> <p>11 jury awarded lost profits. So, yes, you can read</p> <p>12 the words as they appear there. But I think it's</p> <p>13 important to, particularly with respect to this</p> <p>14 case, understand, one, I've never been -- you</p> <p>15 know, had an exclusion for my qualifications.</p> <p>16 Two, the situation here, in fact, he touted my</p> <p>17 qualifications in the memorandum opinion that we</p> <p>18 looked at.</p> <p>19 Here, he did not like the fact that the</p> <p>20 defendant had not actually launched their generic</p> <p>21 product, and I respectfully disagree with him, but</p> <p>22 that was Judge Conrad's opinion.</p>

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**1 BY MR. CAINE:**  
 2 Q Ultimately, he says on Lines 9 and 10 of  
 3 Page 108: "I just thought it was not admissible,"  
 4 referring to your opinion, correct?  
 5 MR. MARX: Objection. Mischaracterizes  
 6 the document to the extent it seeks a legal  
 7 conclusion. I'm just going to note that this  
 8 Page 108 is in the middle of what appears to be a  
 9 five-page sidebar discussion between attorneys and  
 10 the Court, and Mr. Hofmann has stated he is not an  
 11 attorney.  
 12 To the extent you're asking him to  
 13 interpret these pages and the Court's ruling, he  
 14 is not qualified to do so, and he's already  
 15 testified about the substance of his testimony in  
 16 that case.  
 17 BY THE WITNESS:  
**18 A All I can say is that there were numerous**  
**19 sidebars. I don't -- I don't know the ins and**  
**20 outs of how things work. I'm not a lawyer, but,**  
**21 you know, from my experience, I gave the full**  
**22 scope of my opinions before the jury and the jury**

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**1 ended up awarding lost profits. So I don't know**  
**2 that I can add much more than that.**  
**3 BY MR. CAINE:**  
 4 Q It is the case that Judge Conrad  
 5 maintained the exclusion of your opinion as  
 6 reflected in the memorandum order at trial, right?  
 7 MR. MARX: Same objection.  
 8 Mischaracterizes the witness testimony and seeks a  
 9 legal conclusion.  
 10 BY THE WITNESS:  
**11 A I'm not a lawyer, but from my experience**  
**12 appearing at that trial, I gave the full extent of**  
**13 my opinions. I don't know what all happened at**  
**14 sidebar. They do the white noise. They do the,**  
**15 you know, stuff especially at a jury trial, so I**  
**16 don't know that I've even seen what was discussed**  
**17 at sidebar. I know that my testimony was elicited**  
**18 from the attorneys to the full extent of my**  
**19 opinion, and then I left Charlottesville.**  
**20 BY MR. CAINE:**  
 21 Q Have you seen what's been marked as  
 22 Hofmann 3 prior to today?

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**1 A Maybe.**  
 2 Q Have you been asked about the Concordia  
 3 case at prior depositions or trials?  
 4 MR. MARX: Objection to the extent you can  
 5 disclose what's been discussed at prior  
 6 depositions that may be confidential under seal.  
 7 BY THE WITNESS:  
**8 A I mean, I guess I can broadly say yes, it**  
**9 has been asked about before. It's never really**  
**10 come up at trial or in a hearing because there's**  
**11 nothing to see here.**  
**12 BY MR. CAINE:**  
 13 Q Do you recall any other cases in which  
 14 your testimony has been limited or excluded?  
**15 A The Concordia and Grant Street Group, out**  
**16 of probably having provided testimony more than**  
**17 200 times, are the ones that come to mind. I've**  
**18 certainly been challenged because that's a pretty**  
**19 normal course in patent damages cases, but I can't**  
**20 think of anything else as I sit here right now.**  
 21 Q Do you recall any other case in which a  
 22 court or arbitral tribunal has determined that the

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1 methodology you employed in reaching your  
 2 decisions was faulty?  
 3 MR. MARX: Objection. Form,  
 4 mischaracterizes witness testimony and to the  
 5 extent it seeks a legal conclusion.  
 6 BY THE WITNESS:  
**7 A As I sit here right now, those are the two**  
**8 that come to mind.**  
**9 BY MR. CAINE:**  
 10 Q You cite in your declaration to the  
 11 declarations of Drs. Albini and Gerritsen,  
 12 correct?  
**13 A I do.**  
 14 Q Have you spoken with Drs. Albini and  
 15 Gerritsen?  
**16 A I haven't spoken directly. I've reviewed**  
**17 what they've issued in this matter.**  
 18 Q You never had a single conversation with  
 19 either Dr. Albini or Dr. Gerritsen, correct?  
**20 A I don't believe so, no.**  
 21 Q Can commercial success ever be  
 22 attributable to a patented method of treatment?

89	<p>1 MR. MARX: Objection. Form.</p> <p>2 BY THE WITNESS:</p> <p>3 <b>A I'm not sure exactly how to respond to</b></p> <p>4 <b>that. I mean, in broad strokes, commercial</b></p> <p>5 <b>success is facts and circumstances-based. There</b></p> <p>6 <b>is a possibility, sure, it can be, but there is a</b></p> <p>7 <b>lot of stuff you have to look at surrounding said</b></p> <p>8 <b>hypothetical abstract of method of treatment in</b></p> <p>9 <b>order to determine whether there are things like</b></p> <p>10 <b>blocking patents; whether there are other</b></p> <p>11 <b>extrinsic factors that are driving, you know, the</b></p> <p>12 <b>sales of that method; whether the method itself is</b></p> <p>13 <b>what's driving sales or other things. So, I mean,</b></p> <p>14 <b>it's hypothetically possible, but that's a pretty</b></p> <p>15 <b>undefined abstract hypothetical.</b></p> <p>16 <b>BY MR. CAINE:</b></p> <p>17 Q What are the circumstances in which a --</p> <p>18 in which commercial success can be attributable to</p> <p>19 a patented method of treatment?</p> <p>20 MR. MARX: Objection. Form, hypothetical.</p> <p>21 BY THE WITNESS:</p> <p>22 <b>A I mean, it's a very abstract hypothetical.</b></p>	9	<p>1 <b>A I mean, from an economic perspective --</b></p> <p>2 <b>and there's probably a whole bunch of legal</b></p> <p>3 <b>wranglings that go into this that I'm not weighing</b></p> <p>4 <b>in on. But from an economic perspective, it's</b></p> <p>5 <b>highly facts and circumstances-based, and for all</b></p> <p>6 <b>the reasons I explain in detail in my report, this</b></p> <p>7 <b>is not such a situation.</b></p> <p>8 <b>BY MR. CAINE:</b></p> <p>9 Q But that situation can exist where you</p> <p>10 have a composition of matter in the pharmaceutical</p> <p>11 or biopharmaceutical space, and then there is a</p> <p>12 subsequent invention surrounding a way to use that</p> <p>13 pharmaceutical or biopharmaceutical product. In</p> <p>14 that situation, you can have commercial success</p> <p>15 attributable to the method of treatment, right?</p> <p>16 MR. MARX: Objection. Form, hypothetical.</p> <p>17 BY THE WITNESS:</p> <p>18 <b>A It's such an abstract hypothetical. And I</b></p> <p>19 <b>think it's better to focus on -- okay, in the</b></p> <p>20 <b>facts and circumstances that we have here and</b></p> <p>21 <b>what's germane to the issues we have here. And</b></p> <p>22 <b>what's germane to the issues we have here is you</b></p>
90	<p>1 <b>I mean, the example that typically comes to mind</b></p> <p>2 <b>is that the molecule that was in Viagra was</b></p> <p>3 <b>originally indicated for hypertension. And then</b></p> <p>4 <b>it was discovered that it had the ability to be</b></p> <p>5 <b>used for ED, and they obtained a patent on the use</b></p> <p>6 <b>of, what was it, sildenafil for the treatment of</b></p> <p>7 <b>ED. I think there is a pretty good argument</b></p> <p>8 <b>there.</b></p> <p>9 <b>I haven't studied it but, you know, like</b></p> <p>10 <b>that would be a situation where I could see kind</b></p> <p>11 <b>of, okay, it was originally thought that it was</b></p> <p>12 <b>just going to be used for hypertension, but they</b></p> <p>13 <b>obtained an indication, and obviously Viagra has</b></p> <p>14 <b>performed rather well.</b></p> <p>15 <b>BY MR. CAINE:</b></p> <p>16 Q So you can't have commercial success for a</p> <p>17 method of treatment where you discover a</p> <p>18 pharmaceutical or biopharmaceutical product but</p> <p>19 then later determine how it can be used?</p> <p>20 <b>A It's possible --</b></p> <p>21 MR. MARX: Objection. Hypothetical.</p> <p>22 BY THE WITNESS:</p>	92	<p>1 have a company, Regeneron, with a patent thicket,</p> <p>2 a host of blocking patents that wouldn't encourage</p> <p>3 anyone other than Regeneron to pursue the alleged</p> <p>4 invention of the '338 patent. And so in this</p> <p>5 situation, that's a gating issue, and so for you</p> <p>6 to ask an abstract hypothetical that gives no</p> <p>7 parameters and no reasonable boundaries to what</p> <p>8 you're asking is kind of hard to responsibly or</p> <p>9 reasonably answer.</p> <p>10 <b>I think that what we have here is, as I</b></p> <p>11 <b>explain in detail in my declaration, a situation</b></p> <p>12 <b>where those blocking patents are a gating issue</b></p> <p>13 <b>and then there are other factors, things that were</b></p> <p>14 <b>known in the prior art, things that were extrinsic</b></p> <p>15 <b>factors that explain the marketplace performance</b></p> <p>16 <b>of Eylea in such a way that you can't find</b></p> <p>17 <b>commercial success from an economic perspective in</b></p> <p>18 <b>this set of facts and circumstances.</b></p> <p>19 <b>BY MR. CAINE:</b></p> <p>20 Q Do you have an understanding of the scope</p> <p>21 of the '388 patent?</p> <p>22 MR. MARX: Objection to the extent it</p>

93	<p>1 seeks a legal conclusion.</p> <p>2 BY THE WITNESS:</p> <p>3 <b>A Did you say '388?</b></p> <p>4 <b>BY MR. CAINE:</b></p> <p>5 Q Let me restate it.</p> <p>6 Do you have an understanding of the scope</p> <p>7 of the '338 patent?</p> <p>8 MR. MARX: Same objection. Outside the</p> <p>9 scope of Mr. Hofmann's opinions.</p> <p>10 BY THE WITNESS:</p> <p>11 <b>A I'm not a POSA. As we talked about</b></p> <p>12 <b>earlier, I'm not a medical doctor; I'm not a</b></p> <p>13 <b>formulator or clinician. My understanding comes</b></p> <p>14 <b>from what has been asserted by plaintiffs,</b></p> <p>15 <b>Regeneron, where they suggest that the dosing</b></p> <p>16 <b>regimen with very specific and narrow limitations</b></p> <p>17 <b>is what the alleged novelty is of the claimed</b></p> <p>18 <b>invention.</b></p> <p>19 <b>BY MR. CAINE:</b></p> <p>20 Q And your understanding is based on the --</p> <p>21 what Regeneron's characterization was of the '338</p> <p>22 patent; is that right?</p>	95	<p>1 scope of the patents that you identified as</p> <p>2 blocking patents, correct?</p> <p>3 MR. MARX: Objection. Mischaracterizes</p> <p>4 the witness testimony.</p> <p>5 BY THE WITNESS:</p> <p>6 <b>A There again -- I mean, I certainly have</b></p> <p>7 <b>been around the block in terms of reviewing</b></p> <p>8 <b>patents and everything else, but I'm not a patent</b></p> <p>9 <b>lawyer. I'm not a technical expert. I did review</b></p> <p>10 <b>the patents themselves, both the blocking patents</b></p> <p>11 <b>and the patent at issue here in this case. And</b></p> <p>12 <b>then I reviewed the technical expert reports in</b></p> <p>13 <b>forming my opinions through my economic lens.</b></p> <p>14 <b>BY MR. CAINE:</b></p> <p>15 Q So from a technical perspective, you</p> <p>16 relied on Dr. Gerritsen and Dr. Albini with</p> <p>17 respect to the blocking patents --</p> <p>18 MR. MARX: Objection.</p> <p>19 BY MR. CAINE:</p> <p>20 Q -- the scope of the blocking patents,</p> <p>21 correct?</p> <p>22 MR. MARX: Objection to the extent it</p>
94	<p>1 MR. MARX: Objection. Mischaracterizes</p> <p>2 the witness testimony.</p> <p>3 BY THE WITNESS:</p> <p>4 <b>A I think that's the first place I looked.</b></p> <p>5 <b>You know, I also reviewed, obviously, the</b></p> <p>6 <b>technical experts of the defendants as well.</b></p> <p>7 <b>BY MR. CAINE:</b></p> <p>8 Q Did you review the '338 patent?</p> <p>9 <b>A Of course, yes.</b></p> <p>10 Q You understand, then, that the challenged</p> <p>11 claims of the '338 patent are directed to the</p> <p>12 administration of a single amino acid sequence,</p> <p>13 right?</p> <p>14 MR. MARX: Objection to the extent it</p> <p>15 seeks a legal conclusion and also outside the</p> <p>16 scope of Mr. Hofmann's report.</p> <p>17 BY THE WITNESS:</p> <p>18 <b>A I don't think I'm the right person to be</b></p> <p>19 <b>studying that with beyond what I explain in my</b></p> <p>20 <b>report as to my understanding.</b></p> <p>21 <b>BY MR. CAINE:</b></p> <p>22 Q You are also not qualified to assess the</p>	96	<p>1 mischaracterizes the witness testimony.</p> <p>2 BY THE WITNESS:</p> <p>3 <b>A I think I do rely on their technical</b></p> <p>4 <b>expertise and the knowledge and opinions that they</b></p> <p>5 <b>brought through the different declarations that I</b></p> <p>6 <b>reviewed submitted by them. I'm not an</b></p> <p>7 <b>affirmative technical expert, but I'm also not</b></p> <p>8 <b>just blindly looking at things. I'm reviewing the</b></p> <p>9 <b>patents themselves that I'm, like I said, putting</b></p> <p>10 <b>my economic lens on.</b></p> <p>11 <b>BY MR. CAINE:</b></p> <p>12 Q You are not offering any technical</p> <p>13 opinions about the scope of what you've called the</p> <p>14 blocking patents, right?</p> <p>15 MR. MARX: Objection. To the extent it</p> <p>16 seeks a legal conclusion, form.</p> <p>17 BY THE WITNESS:</p> <p>18 <b>A Like I said, I'm not a POSA. I'm not a</b></p> <p>19 <b>technical expert. I'm an economist who is</b></p> <p>20 <b>applying the information that I see both from</b></p> <p>21 <b>those technical experts as well as the documents</b></p> <p>22 <b>and information that I cite throughout my</b></p>

<p style="text-align: right;">97</p> <p><b>1 declaration in forming my economic opinions. I'm</b></p> <p><b>2 not giving technical affirmative opinions one way</b></p> <p><b>3 or the other.</b></p> <p><b>4 BY MR. CAINE:</b></p> <p>5 Q Do you agree it's common practice for drug</p> <p>6 manufacturers to obtain a portfolio of patents</p> <p>7 that pertain to a particular drug product?</p> <p>8 MR. MARX: Objection. Form, foundation.</p> <p>9 BY THE WITNESS:</p> <p><b>10 A Again, it's a highly facts and</b></p> <p><b>11 circumstances-based thing. Certainly with</b></p> <p><b>12 biologics, in particular, it has become an issue.</b></p> <p><b>13 And setting up a patent thicket, as it's commonly</b></p> <p><b>14 referred to, is something that is done, but that</b></p> <p><b>15 has economic implications.</b></p> <p><b>16 BY MR. CAINE:</b></p> <p>17 Q Eylea is not the first anti-VEGF treatment</p> <p>18 to come to market, correct?</p> <p>19 MR. MARX: Objection to the lack of</p> <p>20 foundation to the extent it seeks -- to the extent</p> <p>21 it's outside the scope.</p> <p>22 BY THE WITNESS:</p>	<p style="text-align: right;">99</p> <p>1 off-label treatment for wet AMD, diabetic eye</p> <p>2 disease and other problems of the retina in 2005,</p> <p>3 correct?</p> <p>4 MR. MARX: Objection. Form, outside the</p> <p>5 scope.</p> <p>6 BY THE WITNESS:</p> <p><b>7 A I'm not a clinician, and I don't know the</b></p> <p><b>8 exact date that it started to be used. But I can</b></p> <p><b>9 at least agree with you that Avastin is used off</b></p> <p><b>10 label for wet AMD based on the documents I</b></p> <p><b>11 reviewed and information I considered.</b></p> <p><b>12 BY MR. CAINE:</b></p> <p>13 Q If we make the date less specific, it was</p> <p>14 in use as an off-label treatment for eye disorders</p> <p>15 in the mid-2000s. Can we agree on that?</p> <p>16 MR. MARX: Objection to the extent it's</p> <p>17 outside scope.</p> <p>18 BY THE WITNESS:</p> <p><b>19 A I think that's a better question for</b></p> <p><b>20 technical experts and a better question for a</b></p> <p><b>21 clinician, but from what I've seen in terms of the</b></p> <p><b>22 documents I've reviewed and information that I've</b></p>
<p style="text-align: right;">98</p> <p><b>1 A I'm not a clinician. I think there was</b></p> <p><b>2 both off-label and on-label use before Eylea.</b></p> <p><b>3 BY MR. CAINE:</b></p> <p>4 Q Macugen is a treatment that came to market</p> <p>5 as an anti-VEGF treatment in late 2004, early</p> <p>6 2005, correct?</p> <p>7 MR. MARX: Objection. Lack of foundation,</p> <p>8 outside the scope.</p> <p>9 BY THE WITNESS:</p> <p><b>10 A Again, I'm not a clinician. I don't</b></p> <p><b>11 remember the dates that that launched. I'll take</b></p> <p><b>12 your word for it.</b></p> <p><b>13 BY MR. CAINE:</b></p> <p>14 Q Macugen came on the market before Eylea,</p> <p>15 right?</p> <p>16 MR. MARX: Same objection.</p> <p>17 BY THE WITNESS:</p> <p><b>18 A Yeah, like I said, I'm not a clinician,</b></p> <p><b>19 but that sounds right from the research I</b></p> <p><b>20 conducted.</b></p> <p><b>21 BY MR. CAINE:</b></p> <p>22 Q And Avastin began to be used as an</p>	<p style="text-align: right;">00</p> <p><b>1 considered, with very little specificity as to</b></p> <p><b>2 dates, I can agree with you that it was before</b></p> <p><b>3 Eylea launched.</b></p> <p><b>4 BY MR. CAINE:</b></p> <p>5 Q Lucentis came onto the market as an</p> <p>6 anti-VEGF treatment in 2006, correct?</p> <p>7 MR. MARX: Objection to the extent it</p> <p>8 seeks testimony that's beyond the scope.</p> <p>9 BY THE WITNESS:</p> <p><b>10 A It depends on the specificity. I can look</b></p> <p><b>11 it up in my declaration because I think I lay it</b></p> <p><b>12 out there, but I can agree with you that I think</b></p> <p><b>13 as a nonclinician, non-POSA, that it was available</b></p> <p><b>14 before Eylea.</b></p> <p><b>15 BY MR. CAINE:</b></p> <p>16 Q In or around 2006?</p> <p><b>17 A I just don't remember the exact date.</b></p> <p>18 Q Now, the patents that you identified as</p> <p>19 blocking patents did not deter Genentech from</p> <p>20 developing Lucentis as an anti-VEGF treatment,</p> <p>21 right?</p> <p><b>22 A I think here we start to get a little bit</b></p>

<p style="text-align: right;">0</p> <p>1 where -- this is where I do rely on the technical                  2 experts who have more knowledge of the contours of                  3 the patents --                  4 <b>Sorry. My microphone fell.</b>                  5 MR. CAINE: Why don't we go off the record                  6 for a minute.                  7 THE WITNESS: It's okay.                  8 My ankle hit it. Sorry. I'm sorry. Can                  9 you repeat the question.                  10 BY MR. CAINE:                  11 Q Sure.                  12 The patents that you identified as                  13 blocking patents did not deter Genentech from                  14 developing Lucentis as an anti-VEGF treatment,                  15 correct?                  16 MR. MARX: Objection. Form.                  17 BY THE WITNESS:                  18 A So I think, like I said, the specific                  19 contours of the claims of the patents and how                  20 those factored into what related to Genentech's                  21 ability to develop and launch Lucentis is a better                  22 question for the technical experts.</p>	<p style="text-align: right;">03</p> <p>1 exhibits. I think 2019 is correct, that that's                  2 when it was commercialized.                  3 <b>BY MR. CAINE:</b>                  4 Q And the patents that you identified as                  5 blocking patents did not deter Novartis from                  6 developing Beovu as an anti-VEGF treatment,                  7 correct?                  8 MR. MARX: Objection. Outside the scope,                  9 to the extent it mischaracterizes the witness                  10 testimony.                  11 BY THE WITNESS:                  12 A Again, I think you're mixing apples and                  13 oranges or something. I'm not sure exactly what.                  14 The point of the role of the blocking patents that                  15 I've identified is that a patent thicket was set                  16 up around aflibercept, and that no one other than                  17 Regeneron would have really had the economic                  18 motivation to come up with a particular dosing                  19 regimen for aflibercept. So you're talking about                  20 other biologics. That isn't what I'm asserting.                  21 What I'm asserting is that the particular                  22 and very narrow dosing regimen that is claimed in</p>
<p style="text-align: right;">02</p> <p>1 I think that the import of the blocking                  2 patents centers around aflibercept and aflibercept                  3 itself as a potential treatment for the labeled                  4 indications that did, you know, and -- and what                  5 that would mean to someone to pursue the alleged                  6 novelty of the '338 patents. And clearly that is                  7 a different question than your question just now.                  8 Clearly Lucentis launched. There is no                  9 doubt that's so. But the germane inquiry here                  10 from an economic perspective is what economic                  11 incentive from a potential objective indicia of                  12 nonobviousness through commercial success as a                  13 term of art would have been of interest to a POSA                  14 as of the priority date of the '338 patent, and                  15 clearly the blocking patents would have                  16 discouraged such pursuit.                  17 BY MR. CAINE:                  18 Q Beovu came on the market in October 2019                  19 to treat patients with wet AMD, correct?                  20 MR. MARX: Objection. Outside the scope.                  21 BY THE WITNESS:                  22 A I think -- I'm just picturing some of the</p>	<p style="text-align: right;">04</p> <p>1 the '338 patents would have been something that                  2 Regeneron and only Regeneron would have been                  3 motivated to pursue for commercialization as                  4 opposed to the other examples you're just giving                  5 where, sure, there's other treatments for                  6 intraocular injections, but those are with                  7 different large molecules.                  8 Q Are you aware of the development of                  9 conbercept by Chengdu Kanghong as an anti-VEGF                  10 treatment?                  11 MR. MARX: Objection. Beyond the scope.                  12 BY THE WITNESS:                  13 A That's something I'm aware of just from my                  14 review of all the documents and information that I                  15 studied. My understanding is that's for use in                  16 China. It's not available in the US, and that's                  17 not something that's been commercialized in the                  18 US.                  19 I also understand that, again, what I'm                  20 kind of more narrowly focused on is whether or not                  21 the '338 patent and the dosing regimen for                  22 aflibercept would have been something that others</p>



05	<p>1 would have been discouraged from pursuing from an                  2 economic perspective.                  3 BY MR. CAINE:                  4 Q I think you make a point, which is that                  5 what you identified as the blocking patents would                  6 not have prevented someone from commercializing a                  7 biosimilar to aflibercept for sale outside of the                  8 United States, right?                  9 MR. MARX: Objection. Mischaracterizes                  10 the witness testimony.                  11 BY THE WITNESS:                  12 A I wouldn't -- I wouldn't say that. I                  13 mean, I don't -- I actually don't know exactly                  14 what international patents or PCT stuff was out                  15 there one way or the other.                  16 BY MR. CAINE:                  17 Q You didn't identify any international or                  18 PCT patents as blocking patents, right?                  19 MR. MARX: Objection. Mischaracterizes                  20 the witness testimony, outside the scope.                  21 BY THE WITNESS:                  22 A I think that I deferred the entirety of my</p>	07	<p>1 BY THE WITNESS:                  2 A In 2022?                  3 BY MR. CAINE:                  4 Q January of 2022.                  5 A It just isn't coming to my mind one way or                  6 the other.                  7 MR. CAINE: Let's mark as Exhibit                  8 Hofmann 4 a press release dated January 28, 2022.                  9 BY MR. CAINE:                  10 Q It says: "FDA approves Genentech's                  11 Vabysmo, the First Bispecific Antibody for the Eye                  12 to Treat Two Leading Causes of Vision Loss."                  13 MR. MARX: I'm going to object to the use                  14 of this document and all questions pertaining to                  15 it. As counsel is aware, the most recent PTAB                  16 hearing, counsel is not permitted to introduce new                  17 supplementary evidence, and this is far outside                  18 the scope of Mr. Hofmann's opinions in this                  19 matter, and so I'm going to object to all the                  20 questions related to this document and to its use.                  21 (A certain document was marked Hofmann                  22 Deposition Exhibit 4 for identification,</p>
06	<p>1 report, and I think I explain in detail that my                  2 focus -- given that we're in a US Patent PTAB                  3 proceeding is that I was focused on, okay, who                  4 would have been economically motivated to pursue                  5 the '338 patent alleged invention.                  6 BY MR. CAINE:                  7 Q And economic motivation to invent doesn't                  8 stop at the borders of this country. It goes on                  9 outside of this country.                  10 We can agree on that, right?                  11 A It can, yes.                  12 Q Okay. Now, are you also aware that the                  13 FDA approved Vabysmo for the treatment of wet AMD                  14 and DME in January of 2022?                  15 MR. MARX: Objection. Outside the scope.                  16 BY THE WITNESS:                  17 A They approved what?                  18 BY MR. CAINE:                  19 Q Vabysmo. Maybe I'm pronouncing it                  20 incorrectly. Feel free to correct me if I've done                  21 so.                  22 MR. MARX: Objection. Outside the scope.</p>	08	<p>1 as of 06/23/2022.)                  2 MR. MARX: And to the extent counsel asks                  3 questions about Hofmann Exhibit 4, I'm further                  4 going to move to strike that line of questioning.                  5 BY MR. CAINE:                  6 Q Mr. Hofmann, do you have Hofmann Exhibit 4                  7 in front of you? Mr. Hofmann, do you have                  8 Exhibit 4 in front of you?                  9 A It's a seven-page document with a small                  10 font that I don't think I've seen before. I mean,                  11 I can answer the basic question, yes, something                  12 labeled Exhibit 4 is in front of me, but I haven't                  13 read it, studied it or am familiar with it.                  14 Q Does Exhibit 4 reflect that Genentech's                  15 Vabysmo was approved to treat wet AMD and DME in                  16 January of 2022?                  17 MR. MARX: Objection. Outside the scope.                  18 Further move to strike. Mr. Hofmann has opined                  19 that his opinions to this matter relate to                  20 aflibercept. This is a completely different                  21 molecule. Mr. Hofmann is not a technical expert,                  22 and furthermore, counsel is aware that PTAB has</p>



<p style="text-align: right;">09</p> <p>1 denied their request to introduce supplementary                  2 evidence. This is an improper attempt to get new                  3 evidence into the record.                  4 BY THE WITNESS:                  5 <b>A I don't know what to say about this                  6 document. It's a seven-page document that has                  7 lots of technical information. I haven't seen it                  8 before. I think I'm not the right person to be                  9 talking about this, and I don't see anything that                  10 has anything directly to do with aflibercept, and                  11 so I don't -- I don't know what more I can say.                  12 BY MR. CAINE:</b>                  13 Q You agree that Genentech was not deterred                  14 by the patents you have identified as blocking                  15 patents from developing Vabysmo, right?                  16 MR. MARX: Objection. Form, outside the                  17 scope, improper use of this document, and we move                  18 to strike.                  19 BY THE WITNESS:                  20 <b>A I don't -- I don't -- like I said, I'm not                  21 a POSA. I'm not a technical expert. It's a                  22 better question for someone other than me because</b></p>	<p>1 <b>BY MR. CAINE:</b>                  2 Q I don't think you answered the question.                  3 MR. MARX: I think Mr. Hofmann did answer                  4 the question.                  5 MR. CAINE: Hold on, hold on. You can                  6 make your objection, but let me state my question,                  7 please.                  8 BY MR. CAINE:                  9 Q Agree or disagree, that Genentech was not                  10 deterred by the patents you've identified as                  11 blocking patents from developing Vabysmo, correct?                  12 MR. MARX: Objection. Outside the scope,                  13 improper attempt by counsel to get supplementary                  14 evidence into the record after the request was                  15 denied by the PTAB and further move to strike this                  16 line of questioning.                  17 BY THE WITNESS:                  18 <b>A I don't know that I can add anything to my                  19 prior answers, and like I said, I'm looking at                  20 this for the first time. I don't know if this                  21 product is even launched. I don't know what the                  22 labeled indication is. It seems like it's one</b></p>
<p style="text-align: right;">0</p> <p>1 the -- what is it, faricimab-svoa? That doesn't                  2 seem to have anything to do necessarily with                  3 aflibercept, but I'm not a microbiologist. I'm                  4 not a chemist. I'm not a formulator. I'm just                  5 not the right person to be asked about the                  6 questions the way you're framing them.                  7 BY MR. CAINE:                  8 Q Well, do you agree or disagree that                  9 Genentech was not deterred by the patents you've                  10 identified as blocking patents from developing                  11 Vabysmo?                  12 MR. MARX: Objection. Lack of foundation.                  13 The witness has already testified he's not a                  14 technical expert, has never seen this document                  15 before, and furthermore doesn't know what Vabysmo,                  16 faricimab-svo {sic}. And, also, move to strike,                  17 improper attempt by counsel to move a document,                  18 supplementary evidence, into the record that the                  19 PTAB has already denied.                  20 BY THE WITNESS:                  21 <b>A I don't know that I have anything to add                  22 from my prior answer, sir.</b></p>	<p style="text-align: right;">2</p> <p>1 month apart to four months apart for dosing                  2 regimen. I don't -- I don't know anything about                  3 this to weigh in on it one way or the other, and                  4 it seems like you should be exploring this with                  5 technical experts if you're allowed to explore it.                  6 I don't know.                  7 BY MR. CAINE:                  8 Q You agree that according to the table                  9 provided in your declaration and your opinions --                  10 we'll just make it more general -- all but one of                  11 the patents you identified as blocking patents                  12 have expired?                  13 <b>A As of today, I think that's probably                  14 correct. I mean, I can double-check it, but I                  15 think that's right.</b>                  16 Q The only patent that's still active is the                  17 '959 patent, correct?                  18 <b>A Right. Others kind of recently expired,                  19 but yeah.</b>                  20 MR. MARX: Objection to the extent it                  21 seeks a legal conclusion.                  22 BY MR. CAINE:</p>

3	<p>1 Q The '959 patent, we can take a look at it</p> <p>2 if you want. The application for that patent</p> <p>3 published on December 14 of 2020. Does that sound</p> <p>4 right to you?</p> <p>5 I'm sorry. Let me strike it because</p> <p>6 that's not right. We'll just show you the patent</p> <p>7 to make it easy. 2020 is a bit too late. I'm</p> <p>8 going to hand you Exhibit 1023.</p> <p>9 Do you have the '959 patent?</p> <p>10 <b>A It appears so, yes.</b></p> <p>11 Q The application for the '959 patent was</p> <p>12 published on December 14 of 2000?</p> <p>13 MR. MARX: Objection to the extent it</p> <p>14 seeks a legal conclusion.</p> <p>15 BY THE WITNESS:</p> <p>16 <b>A Yes, the PCT application is dated</b></p> <p>17 <b>December 14 based on the date that appears on the</b></p> <p>18 <b>face, but I'm not a patent lawyer.</b></p> <p>19 <b>BY MR. CAINE:</b></p> <p>20 Q That's the publication date, right?</p> <p>21 MR. MARX: Same objection.</p> <p>22 BY THE WITNESS:</p>	5	<p>1 <b>with patents, at least from my economic knowledge</b></p> <p>2 <b>of the life sciences industry and patents in</b></p> <p>3 <b>general, that is my understanding.</b></p> <p>4 <b>BY MR. CAINE:</b></p> <p>5 Q Competitors and others interested in</p> <p>6 developing treatments for anti-VEGF treatments</p> <p>7 would have had access to the disclosure that led</p> <p>8 to the '959 patent as of late 2001, correct?</p> <p>9 MR. MARX: Objection to the extent it</p> <p>10 seeks a legal conclusion.</p> <p>11 BY THE WITNESS:</p> <p>12 <b>A I'm not a patent lawyer. I'm not weighing</b></p> <p>13 <b>in on any definitive or expertise way, but I think</b></p> <p>14 <b>my understanding is once published, that's the</b></p> <p>15 <b>idea, that you could review that information and</b></p> <p>16 <b>history.</b></p> <p>17 <b>BY MR. CAINE:</b></p> <p>18 Q Competitors and others interested in</p> <p>19 developing anti-VEGF treatments would have also</p> <p>20 had a rough idea of when any patent that issued</p> <p>21 would expire based on the application date, right?</p> <p>22 MR. MARX: Objection. To the extent it</p>
4	<p>1 <b>A Again, I'm not a patent lawyer, but that's</b></p> <p>2 <b>the way it reads to me.</b></p> <p>3 <b>BY MR. CAINE:</b></p> <p>4 Q As of that date, that PCT application was</p> <p>5 open to the public for review, correct?</p> <p>6 <b>A I mean, I think that – again, I'm not a</b></p> <p>7 <b>patent lawyer. I'm not a POSA. But I guess the</b></p> <p>8 <b>theory is that yes, that disclosed to the world</b></p> <p>9 <b>the alleged invention.</b></p> <p>10 Q And as -- you see the date December 6,</p> <p>11 2001 a few lines above it?</p> <p>12 <b>A I do.</b></p> <p>13 Q As of that date, when the national stage</p> <p>14 application that resulted in the '959 patent was</p> <p>15 filed, any member of the public could review the</p> <p>16 file history, correct?</p> <p>17 MR. MARX: Objection to the extent it</p> <p>18 seeks a legal conclusion and outside the scope.</p> <p>19 BY THE WITNESS:</p> <p>20 <b>A I'm not a patent lawyer. I'm not a POSA.</b></p> <p>21 <b>I'm not the best person to be asking these</b></p> <p>22 <b>questions about, but I think given my familiarity</b></p>	6	<p>1 seeks a legal conclusion and outside the scope,</p> <p>2 hypothetical.</p> <p>3 BY THE WITNESS:</p> <p>4 <b>A I don't know that I can agree with you</b></p> <p>5 <b>there. Maybe they'd have a -- I'm not a patent</b></p> <p>6 <b>lawyer. I'm not a technical expert. I'm not a</b></p> <p>7 <b>POSA. Maybe they have a no less than rough idea,</b></p> <p>8 <b>but at this stage, you wouldn't know patent term</b></p> <p>9 <b>extensions that may be there or other things that</b></p> <p>10 <b>could affect the patent.</b></p> <p>11 <b>BY MR. CAINE:</b></p> <p>12 Q Absent a terminal disclaimer or a term</p> <p>13 adjustment or a term extension, a competitor or</p> <p>14 someone else interested in developing treatments</p> <p>15 would understand that the term of the patent would</p> <p>16 be 20 years from the date of application, right?</p> <p>17 MR. MARX: Objection to the extent it</p> <p>18 states a legal conclusion. Further, I believe at</p> <p>19 the time this patent was filed, the law was not</p> <p>20 20 years from the date of filing but 17 years from</p> <p>21 the date of issuance. So I believe that's</p> <p>22 incorrect to begin with.</p>



<p style="text-align: right;">7</p> <p>1 But, again, that's another reason this is</p> <p>2 completely outside the scope of Mr. Hofmann's</p> <p>3 expertise.</p> <p>4 BY THE WITNESS:</p> <p>5 A I'm not a patent lawyer. I do know and am</p> <p>6 familiar that there was a change in the patent</p> <p>7 terms both in terms of the – whether it was date</p> <p>8 of filing or date of issuance, and I just don't</p> <p>9 remember what year that occurred in.</p> <p>10 I do know that at least as of this point,</p> <p>11 there's also the possibility of extensions, but</p> <p>12 I'm just not the right person for you to be asking</p> <p>13 these questions of whether it's a legal argument</p> <p>14 or a POSA or a technical expert. It's not me.</p> <p>15 BY MR. CAINE:</p> <p>16 Q A competitor or other person working in</p> <p>17 the field of anti-VEGF treatments could have had</p> <p>18 an understanding of -- absent terminal disclaimer</p> <p>19 or adjustment or extension what the term would be</p> <p>20 for the patent, either as of the date that -- of</p> <p>21 the application or the date the patent issued.</p> <p>22 Do you agree?</p>	<p style="text-align: right;">9</p> <p>1 timeline on Page 28 of my report, where I have an</p> <p>2 understanding that – that the '959 patent is set</p> <p>3 to expire about a year from now, in June of 2023.</p> <p>4 BY MR. CAINE:</p> <p>5 Q Did you consider what information that</p> <p>6 competitors and others working to develop</p> <p>7 anti-VEGF treatments, to the extent there were any</p> <p>8 in the early 2000s, would have had about patent</p> <p>9 term for the '959 patent?</p> <p>10 MR. MARX: Objection. Form, outside the</p> <p>11 scope, seeks a legal conclusion.</p> <p>12 BY THE WITNESS:</p> <p>13 A I mean, I guess the best I could do for</p> <p>14 you there is to say, look, I reviewed Gerritsen,</p> <p>15 Albini, as well as other technical experts. I</p> <p>16 figured out that from an economic perspective,</p> <p>17 yes, there was a patent thicket. There was a</p> <p>18 number of patents, including the '959 patent, that</p> <p>19 would have discouraged others. And the duration</p> <p>20 of those patents is, I think, set forth in the</p> <p>21 timeline that I have on Page 28 of my declaration.</p> <p>22 BY MR. CAINE:</p>
<p style="text-align: right;">8</p> <p>1 MR. MARX: Objection. Asked and answered,</p> <p>2 seeks a legal conclusion, incomplete hypothetical</p> <p>3 and further fails to note the change in law that</p> <p>4 occurred during the pendency of this application.</p> <p>5 BY THE WITNESS:</p> <p>6 A I mean, again, I'm not a POSA. I'm not a</p> <p>7 patent lawyer. I'm not someone who probably</p> <p>8 should be asked to weigh in on any affirmative or</p> <p>9 definitive way on this.</p> <p>10 I do indicate that my understanding is</p> <p>11 based on this patent and an understanding from</p> <p>12 counsel that the '959 is set to expire in</p> <p>13 June 2023. How abundantly clear or not that would</p> <p>14 be as of the issuance date is a better question</p> <p>15 for lawyers or POSAs.</p> <p>16 BY MR. CAINE:</p> <p>17 Q It's not a question that you considered in</p> <p>18 forming your opinions?</p> <p>19 MR. MARX: Objection. Mischaracterizes</p> <p>20 the witness testimony.</p> <p>21 BY THE WITNESS:</p> <p>22 A No. I said that I'm looking at the</p>	<p style="text-align: right;">20</p> <p>1 Q Did you consider what a competitor or</p> <p>2 other person in the field would -- the information</p> <p>3 that they would have in the early 2000s period</p> <p>4 concerning the term or potential term for the</p> <p>5 '959 patent?</p> <p>6 MR. MARX: Objection. Seeks a legal</p> <p>7 conclusion, outside the scope, hypothetical.</p> <p>8 BY THE WITNESS:</p> <p>9 A I think I defer to the language in my</p> <p>10 declaration. I mean, I'm not holding myself out</p> <p>11 as a POSA or a patent lawyer. I'm looking at the</p> <p>12 Gerritsen and Albini reports which helped inform</p> <p>13 my opinions with respect to technical aspects of,</p> <p>14 I think, the question you ask.</p> <p>15 It's not me making an independent</p> <p>16 conclusion with respect to that or affirmative</p> <p>17 opinion. It's shaping my understanding and</p> <p>18 informing my opinions, as I explain in detail</p> <p>19 throughout my report.</p> <p>20 BY MR. CAINE:</p> <p>21 Q Would a company know about a company</p> <p>22 that's working in a particular field doing</p>

2	<p>1 research about competitor patents?</p> <p>2 MR. MARX: Objection. Lack of foundation,</p> <p>3 outside the scope, hypothetical.</p> <p>4 BY MR. CAINE:</p> <p>5 Q Is that typical?</p> <p>6 A I think it is something that I think is</p> <p>7 highly facts and circumstances-based. Certainly</p> <p>8 it's not uncommon for companies to undertake kind</p> <p>9 of freedom-to-operate searches or things like</p> <p>10 that, but I'm not a patent lawyer and I'm not a</p> <p>11 POSA and I'm not the right person to be asking</p> <p>12 that.</p> <p>13 Q In the biopharmaceutical and the</p> <p>14 pharmaceutical space, is it typical for persons in</p> <p>15 that field, entities in that field to monitor</p> <p>16 competitor patent applications?</p> <p>17 MR. MARX: Objection. Outside the scope,</p> <p>18 lack of foundation, hypothetical.</p> <p>19 BY THE WITNESS:</p> <p>20 A Again, I'm not a patent lawyer. I'm not a</p> <p>21 POSA. I will say that biologics are evolving to</p> <p>22 whereas for small molecules, the Orange Book has</p>	23
22	<p>1 been around for a long time, and that could be a</p> <p>2 go-to place to figure out what patents cover.</p> <p>3 The Purple Book is evolving. I'm not a</p> <p>4 regulatory expert, but, you know, there can be</p> <p>5 information gathered at least today as of that,</p> <p>6 but certainly over the last 10 or 20 years that</p> <p>7 was not the case.</p> <p>8 BY MR. CAINE:</p> <p>9 Q Information is available and has been</p> <p>10 available from the last 20 years from the Patent</p> <p>11 Office itself, right?</p> <p>12 MR. MARX: Objection. Outside the scope,</p> <p>13 seeks a legal conclusion.</p> <p>14 BY MR. CAINE:</p> <p>15 Q If you're aware.</p> <p>16 A I'm not a patent lawyer. I'm not a POSA,</p> <p>17 but certainly, as I understand it, the idea of</p> <p>18 patents' public disclosure of both the</p> <p>19 applications and the patents themselves.</p> <p>20 Q In the biopharmaceutical industry, it can</p> <p>21 take ten years or more to develop and obtain</p> <p>22 regulatory approval for a biopharmaceutical</p>	24
	<p>1 treatment, correct?</p> <p>2 MR. MARX: Objection. Hypothetical,</p> <p>3 outside the scope.</p> <p>4 BY THE WITNESS:</p> <p>5 A I'm not a formulator. I'm not a research</p> <p>6 scientist. I mean, the time period that it can</p> <p>7 take to develop, I think, is highly facts and</p> <p>8 circumstances-based.</p> <p>9 BY MR. CAINE:</p> <p>10 Q You would agree with me that developing a</p> <p>11 drug takes many years?</p> <p>12 MR. MARX: Objection. Form.</p> <p>13 BY THE WITNESS:</p> <p>14 A It certainly doesn't happen overnight,</p> <p>15 but, you know, I think it's a very highly facts</p> <p>16 and circumstances situation that involves both --</p> <p>17 you know, all the clinical trials, all the</p> <p>18 regulatory pathway issues, et cetera, et cetera.</p> <p>19 But that's a better question for maybe a</p> <p>20 regulatory person, formulator or POSA.</p> <p>21 BY MR. CAINE:</p> <p>22 Q Often it can take ten years or more to</p>	
	<p>1 develop a drug, correct?</p> <p>2 MR. MARX: Objection. Hypothetical,</p> <p>3 outside the scope.</p> <p>4 BY THE WITNESS:</p> <p>5 A It's kind of a subjective when you say</p> <p>6 "often." I mean, it's certainly not unheard of</p> <p>7 that it can take that long, but there are things</p> <p>8 that gets to -- take the COVID vaccine. That came</p> <p>9 to market rather quickly, so I mean, it's just</p> <p>10 facts and circumstances-based.</p> <p>11 BY MR. CAINE:</p> <p>12 Q In the biopharmaceutical space, it can</p> <p>13 often take ten years or more to develop a product?</p> <p>14 A Better question --</p> <p>15 MR. MARX: Objection. Outside the scope,</p> <p>16 hypothetical.</p> <p>17 BY THE WITNESS:</p> <p>18 A Better question for a technical expert.</p> <p>19 BY MR. CAINE:</p> <p>20 Q But it could certainly take ten years or</p> <p>21 more to develop a biopharmaceutical product,</p> <p>22 right?</p>	



<p style="text-align: right;">25</p> <p>1 MR. MARX: Same objection.</p> <p>2 BY THE WITNESS:</p> <p>3 <b>A Better question for a technical expert.</b></p> <p>4 <b>BY MR. CAINE:</b></p> <p>5 Q Let's go back to Hofmann 1. Would you</p> <p>6 turn for me to Page 2823.</p> <p>7 MR. MARX: I'll note for the record</p> <p>8 Hofmann 1, again, is the 400-page document, and</p> <p>9 Mr. Hofmann was asked to turn to a single page in</p> <p>10 that legal document.</p> <p>11 BY THE WITNESS:</p> <p>12 <b>A That I've never seen before.</b></p> <p>13 <b>BY MR. CAINE:</b></p> <p>14 Q You testified in the Janssen versus Teva</p> <p>15 case, right?</p> <p>16 <b>A Yes. I think we talked about that before.</b></p> <p>17 <b>What page did you ask me to turn to, sir?</b></p> <p>18 Q 2823. Could you look at Line 22.</p> <p>19 The question is: "Now, Mr. Hofmann, would</p> <p>20 you agree with me that developing a drug takes</p> <p>21 many years?"</p> <p>22 Answer: "Yes."</p>	<p style="text-align: right;">27</p> <p>1 Again, it's a legal document, 400 pages long, and</p> <p>2 we're being asked to discuss three lines of it.</p> <p>3 BY THE WITNESS:</p> <p>4 <b>A I think that consistent with my testimony</b></p> <p>5 <b>earlier – look, I'm not a scientist. I'm not a</b></p> <p>6 <b>developer. I'm not a formulator, but in my</b></p> <p>7 <b>experience in pharmaceutical economics, it's not</b></p> <p>8 <b>unheard of that it can take ten years or more, but</b></p> <p>9 <b>it often takes far less.</b></p> <p>10 <b>BY MR. CAINE:</b></p> <p>11 Q Mr. Hofmann, you don't disagree with the</p> <p>12 testimony you gave that I just read to you in the</p> <p>13 Janssen case, right?</p> <p>14 MR. MARX: Objection. Asked and answered,</p> <p>15 same objections as before to the use of this</p> <p>16 document.</p> <p>17 BY THE WITNESS:</p> <p>18 <b>A Like I said, I haven't been afforded the</b></p> <p>19 <b>opportunity to study the entirety of this very</b></p> <p>20 <b>large document, but nothing that I see there is</b></p> <p>21 <b>inconsistent with what I've explained to you</b></p> <p>22 <b>today.</b></p>
<p style="text-align: right;">26</p> <p>1 That was your testimony?</p> <p>2 MR. MARX: Objection. Outside the scope.</p> <p>3 Again, this is a -- now three lines of a 400-page</p> <p>4 document. Lack of foundation.</p> <p>5 BY THE WITNESS:</p> <p>6 <b>A Yeah. I think if you look at Rows 2</b></p> <p>7 <b>through 25 and then the carryover answer on 2824,</b></p> <p>8 <b>it's exactly what I just said to you, that it's</b></p> <p>9 <b>certainly not unheard of that it can take ten</b></p> <p>10 <b>years or more, but it varies. It's a facts and</b></p> <p>11 <b>circumstances-based thing, and there are different</b></p> <p>12 <b>experiences that go on and on and on.</b></p> <p>13 <b>And I think I talk about it further in my</b></p> <p>14 <b>testimony in this case even though I haven't had a</b></p> <p>15 <b>chance to review it.</b></p> <p>16 <b>BY MR. CAINE:</b></p> <p>17 Q Now, the next question and answer are,</p> <p>18 Line 25: "Often ten years or more?"</p> <p>19 And your answer is: "I mean, it varies</p> <p>20 but it certainly can take ten years or more."</p> <p>21 Do you see that?</p> <p>22 MR. MARX: Objection. Outside, the scope.</p>	<p style="text-align: right;">28</p> <p>1 <b>BY MR. CAINE:</b></p> <p>2 Q And you understand that this document is</p> <p>3 publicly available?</p> <p>4 MR. MARX: Objection. Lack of foundation.</p> <p>5 BY THE WITNESS:</p> <p>6 <b>A I haven't seen it before. The header</b></p> <p>7 <b>makes it seems like, yes, you printed it off Pacer</b></p> <p>8 <b>or so, so it seems like a publicly available</b></p> <p>9 <b>document subject to massive redactions.</b></p> <p>10 <b>BY MR. CAINE:</b></p> <p>11 Q So the point here is this document was</p> <p>12 equally as available to you as it was to us to</p> <p>13 review at your leisure prior to today.</p> <p>14 Do you agree?</p> <p>15 MR. MARX: Objection. I don't -- outside</p> <p>16 the scope. This is a legal document, again,</p> <p>17 outside of Mr. Hofmann's expertise.</p> <p>18 BY THE WITNESS:</p> <p>19 <b>A I mean, I don't disagree with you that I</b></p> <p>20 <b>can go on Pacer and pull this. I typically, after</b></p> <p>21 <b>I testify on something, don't go back and review</b></p> <p>22 <b>it.</b></p>

<p style="text-align: right;">29</p> <p>1 MR. CAINE: We've been going -- it's                  2 almost 12:00. Why don't we take a break for                  3 everyone's sake.                  4 THE VIDEOGRAPHER: Stand by. We are going                  5 off the record. The time is 11:57 a.m.                  6 (A recess was had.)                  7 THE VIDEOGRAPHER: We are back on the                  8 record. The time is 12:13 p.m.                  9 MR. CAINE: Okay. Before we get back to                  10 the questions and answers, we're going to                  11 designate the transcript as Protective Order                  12 material, confidential. And we'll do what we've                  13 done before in terms of fine-tuning it, but there                  14 was at least some discussion in the first session                  15 that is confidential.                  16 MR. MARX: Yes. Understood.                  17 BY MR. CAINE:                  18 Q Mr. Hofmann, you're familiar with                  19 35 USC Section 271(e)(1)?                  20 MR. MARX: Objection. Seeks a legal                  21 conclusion.                  22</p>	<p style="text-align: right;">3</p> <p>1 MR. MARX: Objection. Outside the scope                  2 and seeks a legal conclusion, hypothetical.                  3 BY THE WITNESS:                  4 A I would defer to patent lawyers to                  5 interpret that. And, I mean, I do believe that                  6 the restrictions are on commercialization, not                  7 precommercialization activities.                  8 BY MR. CAINE:                  9 Q Persons interested in innovating in the                  10 biopharmaceutical industry can do so without risk                  11 of infringement liability during the development,                  12 testing and regulatory approval process, correct?                  13 MR. MARX: Objection. Form and outside                  14 the scope, seeks a legal conclusion.                  15 BY THE WITNESS:                  16 A I'm not a -- I'm not a patent lawyer, as                  17 we've established, I think, pretty clearly. But                  18 you know, through my economic lens, there is an                  19 implication of an inability to commercialize,                  20 whether it's due to regulatory exclusivities or                  21 patent exclusivities, blocking patents, et cetera,                  22 that while it's theoretically possible to do some</p>
<p style="text-align: right;">30</p> <p>1 BY THE WITNESS:                  2 A I mean, it sounds familiar. I don't know                  3 that I have memorized the regs. I know it's                  4 patent-law-related, but if you want to put                  5 something in front of me to show me exactly, that                  6 might refresh myself, but.                  7 BY MR. CAINE:                  8 Q You are familiar that under the                  9 Patent Act, there is a safe harbor provision,                  10 right?                  11 MR. MARX: Objection. Seeks a legal                  12 conclusion, outside the scope.                  13 BY THE WITNESS:                  14 A I'm sorry. Yes, as a nonlawyer, I do have                  15 familiarity with safe harbor provisions that exist                  16 within the patent rules and Hatch-Waxman, in                  17 particular.                  18 BY MR. CAINE:                  19 Q Under those safe harbor rules, it's not an                  20 infringement to develop, test or submit a                  21 biopharmaceutical treatment for regulatory                  22 approval, correct?</p>	<p style="text-align: right;">32</p> <p>1 R&amp;D maybe ahead of the expiration of blocking                  2 patents, it isn't -- that's a different issue than                  3 like, in this case, the priority date that we're                  4 dealing with relative to the lengthy period of                  5 time that they had before anyone could have                  6 conceived of the alleged invention and                  7 commercialized.                  8 BY MR. CAINE:                  9 Q The development, testing and regulatory                  10 activities are permitted to occur in the                  11 biopharmaceutical space without there being a risk                  12 of infringement liability under the safe harbor,                  13 correct?                  14 MR. MARX: Objection. Form, incomplete                  15 hypothetical, outside the scope, seeking a legal                  16 conclusion.                  17 BY THE WITNESS:                  18 A I'm not a patent lawyer, and I don't have                  19 the specific language of the regs in front of me.                  20 I do understand that there is some ability to do                  21 so, but you also have to put the economic lens hat                  22 on, you know, as of 2011, 2006, like the</p>



<p style="text-align: right;">33</p> <p>1 protection that existed was great.</p> <p>2 And so while you could theoretically</p> <p>3 tinker with molecules, you're not going to be able</p> <p>4 to see a dollar from that work. And so that</p> <p>5 really discourages others from doing that until</p> <p>6 you get closer to whether in the case of ANDAs,</p> <p>7 generic filers or, in the case of biologics,</p> <p>8 biosimilar filers closer to the expiration.</p> <p>9 BY MR. CAINE:</p> <p>10 Q You could tinker for ten years and face no</p> <p>11 liability for patent infringement under the safe</p> <p>12 harbor, right?</p> <p>13 MR. MARX: Objection. Form, outside the</p> <p>14 scope and seeks a legal conclusion, improper</p> <p>15 hypothetical.</p> <p>16 BY THE WITNESS:</p> <p>17 A I'm not a patent lawyer, but I think as I</p> <p>18 understand it is that there is an ability to do</p> <p>19 research and development but without</p> <p>20 commercialization opportunity for ten years.</p> <p>21 That's a less attractive situation than being able</p> <p>22 to try and capitalize on the investment of time</p>	<p style="text-align: right;">35</p> <p>1 covering the branded product, right?</p> <p>2 MR. MARX: Objection. Outside the scope,</p> <p>3 hypothetical, lack of foundation.</p> <p>4 BY THE WITNESS:</p> <p>5 A I mean, it's an evolving market. I'm not</p> <p>6 a research scientist. I'm not a clinician. I'm</p> <p>7 not someone that's really the right person to be</p> <p>8 asking that question.</p> <p>9 I can say from my experience that there is</p> <p>10 some level of biologic and biosimilar research</p> <p>11 that goes on within the industry depending on the</p> <p>12 facts and circumstances. It's all just highly</p> <p>13 facts and circumstances-based.</p> <p>14 BY MR. CAINE:</p> <p>15 Q You are aware of circumstances in which</p> <p>16 biosimilar makers have conducted research and</p> <p>17 development notwithstanding the existence of a</p> <p>18 composition of matter patent pursuant to the safe</p> <p>19 harbor?</p> <p>20 MR. MARX: Objection. Form, foundation,</p> <p>21 outside the scope.</p> <p>22 BY THE WITNESS:</p>
<p style="text-align: right;">34</p> <p>1 and money on said R&amp;D activities.</p> <p>2 BY MR. CAINE:</p> <p>3 Q You could do -- one can do development on</p> <p>4 methods of treatments using biopharmaceuticals</p> <p>5 under the safe harbor without having any liability</p> <p>6 for patent infringement, correct?</p> <p>7 MR. MARX: Objection. Form, incomplete</p> <p>8 hypothetical, outside the scope and seeking a</p> <p>9 legal conclusion.</p> <p>10 BY THE WITNESS:</p> <p>11 A I'm not a patent lawyer, but I think you</p> <p>12 have to be very careful on that broad incomplete</p> <p>13 hypothetical in that, you know, why am I going to</p> <p>14 do that if someone else already has such a head</p> <p>15 start, if someone else already has the ability to</p> <p>16 commercialize the product, I'm going to just go</p> <p>17 other avenues.</p> <p>18 BY MR. CAINE:</p> <p>19 Q In the biopharmaceutical industry,</p> <p>20 biosimilar makers routinely conduct research and</p> <p>21 development into biosimilars notwithstanding the</p> <p>22 existence of a composition of matter patent</p>	<p style="text-align: right;">36</p> <p>1 A I think you have to be very careful. I</p> <p>2 think that there is -- you know, the timeline and</p> <p>3 the timeline I present in my report is very</p> <p>4 helpful because it helps us see that temporally</p> <p>5 there's a -- okay, at the period of the initial</p> <p>6 filings of the BLA, et cetera, et cetera, there</p> <p>7 can be activity and a patent thicket set up like</p> <p>8 we have in this situation.</p> <p>9 And then sure, like, did Mylan ultimately</p> <p>10 pursue a biosimilar? Yes. But that was at a much</p> <p>11 later date. That was after understanding that the</p> <p>12 earlier issued patents were closing in or closer</p> <p>13 to expiration.</p> <p>14 BY MR. CAINE:</p> <p>15 Q So Mylan itself conducted research and</p> <p>16 development during the period in which the</p> <p>17 blocking patents were in effect -- what you call</p> <p>18 the blocking patents were in effect under the safe</p> <p>19 harbor; is that your testimony?</p> <p>20 MR. MARX: Objection. Lack of foundation,</p> <p>21 mischaracterizes the witness testimony, seeks a</p> <p>22 legal conclusion.</p>

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1 BY THE WITNESS:  
 2 A I'm not a patent lawyer, but, I mean, you  
 3 know, as is typical -- and this is where you have  
 4 to be careful not to conflate issues, is that the  
 5 companies like Mylan have the need to do some of  
 6 their R&D and prepping their product, whether it's  
 7 an ANDA product or a biosimilar product. That has  
 8 to commence before -- and that's encouraged,  
 9 essentially, to happen under the BPCIA. But,  
 10 again, I'm not a lawyer. Just explaining my  
 11 experience.  
 12 BY MR. CAINE:  
 13 Q You agree that Regeneron at one point  
 14 listed all of the patents that you identified as  
 15 blocking patents on its label for Eylea, right?  
 16 A I think that's right because the  
 17 Purple Book only came out more recently, but they  
 18 were on their label.  
 19 Q A competitor would have known about those  
 20 patents, correct?  
 21 A But I don't think they listed '338, which  
 22 is fascinating, but, yeah, as far as the labeled

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1 patents, they would have seen those on the label  
 2 for Eylea.  
 3 Q Competitors would have been aware of the  
 4 expiration dates of these patents as of the dates  
 5 they issued?  
 6 MR. MARX: Objection. Asked and answered.  
 7 BY THE WITNESS:  
 8 A I think that the exact expiration dates, I  
 9 don't know, sometimes that takes some digging --  
 10 I'm not a patent lawyer -- to whereas like the  
 11 Orange Book and now the Purple Book does  
 12 explicitly lay that out. There is a little bit of  
 13 sleuthing, if you will, that they had to do before  
 14 they were listed.  
 15 BY MR. CAINE:  
 16 Q Competitors could do that sleuthing,  
 17 right?  
 18 A I think that there is an ability to do a  
 19 patent search, sure.  
 20 Q All the patents you identified as blocking  
 21 patents issued at least one-and-a-half years  
 22 before the priority date for the '338 patent which

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1 is January 13, 2011 per your declaration?  
 2 A Yes. I think more than a year-and-a-half,  
 3 but yes.  
 4 Q If a biosimilar maker developed and  
 5 conceived a method of treatment using a  
 6 biosimilar, the biosimilar could negotiate a  
 7 cross-license with the branded manufacturer for  
 8 the method of treatment in exchange for a license  
 9 to a composition of matter, right?  
 10 MR. MARX: Objection. Incomplete  
 11 hypothetical, form.  
 12 BY MR. CAINE:  
 13 Q Composition of matter patent, I should  
 14 say.  
 15 A I'm not a lawyer. I'm not a formulator.  
 16 I'm not a POSA. I'm not a scientist. So who  
 17 knows what my perspective is on this matters at  
 18 all? But from an economist's lens, it seems  
 19 really, really strained to argue that because, you  
 20 know, Regeneron sat in a unique position with a  
 21 patent thicket fortress surrounding the  
 22 aflibercept molecule and it was telegraphed to the

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1 world that they were working on it, developing it,  
 2 they had patents, they had the IP, they had all  
 3 these things in place such that -- like I said, at  
 4 best it's a strained argument.  
 5 Someone else -- if I'm at, whatever, a  
 6 scientist at Pfizer, that I'm going to say, hey,  
 7 CFO, give me some money to pursue this, they're  
 8 going to say, well, no, don't do that. Because  
 9 Regeneron has all their thicket or fortress set up  
 10 around it, so I think it's a strained way to go.  
 11 Is it a strained possibility? I'm not  
 12 saying it's impossible, but it seems like with a  
 13 company like Regeneron, who had the ability to  
 14 develop and commercialize the product, that that  
 15 would be a realistic hypothetical.  
 16 Q If one could obtain a cross-license to  
 17 permit entry into a market that ended up producing  
 18 over ██████████ in sales, there would be some  
 19 economic incentive to do so, correct?  
 20 MR. MARX: Objection. Incomplete  
 21 hypothetical.  
 22 BY THE WITNESS:



4	<p>1 A Well, I mean, there's a lot missing from</p> <p>2 what you're asking me to hypothetically consider,</p> <p>3 and we know that, in fact, Regeneron is the</p> <p>4 company that has commercialized and -- developed</p> <p>5 and commercialized this product. And Mylan is</p> <p>6 only coming in as a later entrant with a potential</p> <p>7 biosimilar.</p> <p>8 So the whole point why I'm here is to look</p> <p>9 for objective evidence, and what the objective</p> <p>10 evidence most closely tells us is that Regeneron</p> <p>11 had their patent thicket fortress, whatever you</p> <p>12 want to call it, that deterred others from</p> <p>13 pursuing the alleged novelty of the '338 patent</p> <p>14 and that there wasn't, objectively speaking,</p> <p>15 anyone other than later biosimilar potential</p> <p>16 entrants like Mylan to come there, not other</p> <p>17 biologic, you know, cross-license candidates, if</p> <p>18 you will, rather people who were taking advantage</p> <p>19 of the BPCIA.</p> <p>20 BY MR. CAINE:</p> <p>21 Q You didn't cite any evidence in your</p> <p>22 declaration of anyone who was actually deterred by</p>	43	<p>1 A That's correct.</p> <p>2 Q Amgen has attempted to develop a</p> <p>3 biosimilar to Eylea, correct?</p> <p>4 A Again, this is --</p> <p>5 Q Just focus on my question, please.</p> <p>6 Has Amgen attempted to develop a</p> <p>7 biosimilar to Eylea?</p> <p>8 A But you have to -- I am going to include</p> <p>9 an answer in my answer to your question, which is</p> <p>10 you're mixing apples and oranges. The timeline, I</p> <p>11 think, is very informative in my report where</p> <p>12 sure, I acknowledge that there are several people</p> <p>13 that have moved to develop biosimilars, as I</p> <p>14 understand it, to Eylea, but that's long after the</p> <p>15 priority date. That's long after the dates that</p> <p>16 are informative to whether there's an ability to</p> <p>17 find potential objective indicia as a form of --</p> <p>18 in the form of commercial success as a term of art</p> <p>19 in an obviousness inquiry.</p> <p>20 That's a totally different dynamic.</p> <p>21 They're doing that because the market has now been</p> <p>22 established, and they are able to try and get a</p>
42	<p>1 any of the blocking patents; is that right?</p> <p>2 A Well, that's a -- that's like proving a</p> <p>3 negative.</p> <p>4 Q Do you cite any?</p> <p>5 A I think that, like I said, it's proving a</p> <p>6 negative. I mean, how do I -- how do I show that</p> <p>7 an R&amp;D scientist at Pfizer went to their CFO and</p> <p>8 said, hey, maybe we can do something with</p> <p>9 aflibercept. I don't know. I don't have evidence</p> <p>10 of that.</p> <p>11 What I've observed is market behavior and</p> <p>12 market forces, and I've explained what the market</p> <p>13 behavior and market forces have shown. And what</p> <p>14 they've shown fully supports and fully explains</p> <p>15 the blocking nature of the blocking patents that</p> <p>16 have issued that would have and, in fact, did</p> <p>17 deter anyone from, as I can see it, pursuing the</p> <p>18 specific claims of the '338 patent.</p> <p>19 Q Let's talk about market factors.</p> <p>20 Momenta Pharmaceuticals and Mylan have</p> <p>21 attempted to develop a biosimilar to Eylea,</p> <p>22 correct?</p>	44	<p>1 BLA for their biosimilar equivalent.</p> <p>2 Q You don't mention Amgen in your</p> <p>3 declaration, do you?</p> <p>4 A I don't remember one way or the other.</p> <p>5 Q Formycon has attempted to develop a</p> <p>6 biosimilar for Eylea?</p> <p>7 MR. MARX: Objection. Foundation.</p> <p>8 BY MR. CAINE:</p> <p>9 Q Correct?</p> <p>10 A I mean, I would repeat what I said in my</p> <p>11 last answer. Others that have more recently</p> <p>12 pursued biosimilars, that's just not the relevant</p> <p>13 temporal period to the question that we're facing</p> <p>14 with respect to the '338 patent. If you're</p> <p>15 telling me they have, I'll take your word for it,</p> <p>16 but I don't remember that name.</p> <p>17 Q Samsung Bioepis has attempted to develop a</p> <p>18 biosimilar to Eylea, correct?</p> <p>19 MR. MARX: Objection. Form.</p> <p>20 THE WITNESS: I would give the same</p> <p>21 answer.</p> <p>22 BY MR. CAINE:</p>

45	<p>1 Q You didn't look into that?</p> <p>2 A <b>That's not germane to the question. The</b></p> <p>3 <b>economic question here is as of the priority date</b></p> <p>4 <b>of the '338 patent, which is January 2011, would</b></p> <p>5 <b>others have been motivated to conceive that the</b></p> <p>6 <b>alleged invention or pursue the alleged invention</b></p> <p>7 <b>of the '338 patent. And from what I saw, from</b></p> <p>8 <b>what I understood, from everything I've done, that</b></p> <p>9 <b>wasn't so.</b></p> <p>10 Q Sandoz has attempted to develop a</p> <p>11 biosimilar to Eylea, correct?</p> <p>12 MR. MARX: Objection. Form.</p> <p>13 BY THE WITNESS:</p> <p>14 A <b>Here again, you're mixing apples and</b></p> <p>15 <b>oranges because these are all biosimilar – sure,</b></p> <p>16 <b>ten years after the launch, there's biosimilars</b></p> <p>17 <b>that are surfacing which is the intended result of</b></p> <p>18 <b>BPCIA and, I guess, collaterally Hatch-Waxman.</b></p> <p>19 <b>But from an economic perspective, what</b></p> <p>20 <b>we're trying to look at is whether there is an</b></p> <p>21 <b>economic motivation to pursue the '338 patent as</b></p> <p>22 <b>of 2011, January 2011. And so whether or not</b></p>	47	<p>1 biosimilar to Eylea, correct?</p> <p>2 MR. MARX: Objection. Form, outside the</p> <p>3 scope.</p> <p>4 BY THE WITNESS:</p> <p>5 A <b>Same answer. Through my economic lens,</b></p> <p>6 <b>it's not germane to the question at hand.</b></p> <p>7 BY MR. CAINE:</p> <p>8 Q Did you attempt to determine whether</p> <p>9 Alteogen had made efforts to develop a biosimilar</p> <p>10 to Eylea?</p> <p>11 MR. MARX: Objection. Outside the scope.</p> <p>12 BY THE WITNESS:</p> <p>13 A <b>I don't remember that company's name one</b></p> <p>14 <b>way or the other. Maybe it was in some of the</b></p> <p>15 <b>documents I reviewed, but as I sit here right now,</b></p> <p>16 <b>I don't remember that. And, again, I think that</b></p> <p>17 <b>there's a real hazard in trying to look at what</b></p> <p>18 <b>later biosimilar follow-on products have surfaced</b></p> <p>19 <b>as being pursued versus the priority dates of the</b></p> <p>20 <b>patents at issue.</b></p> <p>21 BY MR. CAINE:</p> <p>22 Q Ocumension Therapies has attempted to</p>
46	<p>1 <b>other biosimilar filers surfaced many years later</b></p> <p>2 <b>is just simply not germane to the question that's</b></p> <p>3 <b>being analyzed.</b></p> <p>4 Q Did you look into whether Sandoz had</p> <p>5 attempted to develop a biosimilar to Eylea?</p> <p>6 A <b>I feel like I did see a document or two</b></p> <p>7 <b>that talked about that, but I don't remember that</b></p> <p>8 <b>being a focus of my report because it's so long</b></p> <p>9 <b>after the date. Like, you're just mixing up</b></p> <p>10 <b>concepts and you're mixing up things temporally</b></p> <p>11 <b>that don't make sense relative to the economic</b></p> <p>12 <b>question that's in front of us.</b></p> <p>13 Q Celltrion has attempted to develop a</p> <p>14 biosimilar to Eylea, correct?</p> <p>15 A <b>Same answer.</b></p> <p>16 Q Did you investigate whether Celltrion had</p> <p>17 attempted to develop a biosimilar to Eylea?</p> <p>18 A <b>I don't remember one way or the other if</b></p> <p>19 <b>that's in some of the documents I reviewed or not.</b></p> <p>20 <b>But it, again, is not germane to the question</b></p> <p>21 <b>relative to the priority date of the '338 patent.</b></p> <p>22 Q Alteogen has attempted to develop a</p>	48	<p>1 develop a biosimilar to Eylea, correct?</p> <p>2 MR. MARX: Objection. Outside the scope.</p> <p>3 BY THE WITNESS:</p> <p>4 A <b>Here again, I don't recall that company's</b></p> <p>5 <b>name, but the same, I think, reaction I have from</b></p> <p>6 <b>my prior answers would apply. So if they did</b></p> <p>7 <b>pursue biosimilars after the dates of the alleged</b></p> <p>8 <b>invention or the priority dates of the alleged</b></p> <p>9 <b>invention, then that's essentially what is</b></p> <p>10 <b>encouraged by BPCIA. And as a follow-on to</b></p> <p>11 <b>Hatch-Waxman, you know, that's what supposed to be</b></p> <p>12 <b>happening. But that doesn't mean that they are</b></p> <p>13 <b>sitting there looking to be the NDA or initial BLA</b></p> <p>14 <b>filer under the regulatory scheme, as I understand</b></p> <p>15 <b>it.</b></p> <p>16 <b>And everything we've just talked about --</b></p> <p>17 <b>I'm not a patent lawyer, not a regulatory expert.</b></p> <p>18 <b>This is just through my economic lens.</b></p> <p>19 Q Any of those companies could have filed a</p> <p>20 BLA, couldn't they have?</p> <p>21 MR. MARX: Objection. Hypothetical,</p> <p>22 outside the scope.</p>



49	<p>1 BY THE WITNESS:</p> <p>2 A So, I mean, I will grant you that the</p> <p>3 biologic space is different than the ANDA space</p> <p>4 and there is a greater, I guess, economic</p> <p>5 motivation to file ANDAs where you can get a</p> <p>6 B-rated substitution. As to BLAs, yes, they could</p> <p>7 file them just like they could under Hatch-Waxman.</p> <p>8 And, again, I'm not a patent lawyer. I'm</p> <p>9 not a regulatory expert. And maybe I've spoken</p> <p>10 too much, but the economic incentive of filing a</p> <p>11 BLA that isn't for anything other than a</p> <p>12 biosimilar is hard to fathom because biologics are</p> <p>13 so much more expensive to develop than ANDA</p> <p>14 products.</p> <p>15 So the idea that others would be -- I</p> <p>16 don't know what you're insinuating or implying,</p> <p>17 but the idea that, okay, I can invent the '338</p> <p>18 alleged invention of that patent and then file a</p> <p>19 BLA and then either cross-license or somehow</p> <p>20 launch commercially -- so there's so many problems</p> <p>21 with that.</p> <p>22 There's a 12-year exclusivity for the</p>	5	<p>1 what I saw in the documents the product is not</p> <p>2 available in the United States.</p> <p>3 BY MR. CAINE:</p> <p>4 Q The patents that you identify as blocking</p> <p>5 patents didn't dissuade Kanghong from attempting</p> <p>6 to develop its conbercept product, correct?</p> <p>7 MR. MARX: Objection. Outside the scope.</p> <p>8 BY THE WITNESS:</p> <p>9 A That's a better question for a technical</p> <p>10 expert.</p> <p>11 BY MR. CAINE:</p> <p>12 Q If such a product exists and has been</p> <p>13 developed, certainly the blocking patents did not</p> <p>14 dissuade Kanghong from developing it?</p> <p>15 MR. MARX: Objection. Outside the scope,</p> <p>16 lack of foundation.</p> <p>17 BY THE WITNESS:</p> <p>18 A I'm unaware as I sit here right now one</p> <p>19 way or the other whether that's been</p> <p>20 commercialized outside the US. I don't believe</p> <p>21 it's been commercialized within the US, and I</p> <p>22 don't believe that that changes anything with</p>
50	<p>1 aflibercept product, first and foremost, that</p> <p>2 still has yet to expire, and then there's all</p> <p>3 these other patents in the patent thicket that</p> <p>4 would be stopping them from doing so.</p> <p>5 I mean, could you theoretically in a very</p> <p>6 strained, insane world pursue a BLA for</p> <p>7 aflibercept with the dosing regimen claimed in the</p> <p>8 '338 patent with the hopes of potentially</p> <p>9 launching in 2023? I guess that's theoretically</p> <p>10 possible, but that seems just -- you're just</p> <p>11 heaping so many amounts of speculation onto that</p> <p>12 possibility that just strains credulity from an</p> <p>13 economic perspective.</p> <p>14 BY MR. CAINE:</p> <p>15 Q Are you aware of Kanghong's</p> <p>16 conbercept product?</p> <p>17 MR. MARX: Objection. Outside the scope.</p> <p>18 BY THE WITNESS:</p> <p>19 A I think I've heard of it and seen it in</p> <p>20 documents, but I'm not -- I'm not a POSA and I'm</p> <p>21 not, you know, one that's familiar with intimately</p> <p>22 the details of that product. I do believe from</p>	52	<p>1 respect to the points that I've made in all my</p> <p>2 answers thus far.</p> <p>3 BY MR. CAINE:</p> <p>4 Q Well, you testified about</p> <p>5 commercialization just now, but my question asked</p> <p>6 about development, so let me reask the question.</p> <p>7 The blocking -- what you identified as</p> <p>8 blocking patents did not dissuade Kanghong from</p> <p>9 developing the conbercept product, correct?</p> <p>10 MR. MARX: Objection. Outside the scope,</p> <p>11 lack of foundation, asked and answered.</p> <p>12 BY THE WITNESS:</p> <p>13 A I think you have to talk to technical</p> <p>14 experts about this because what I'm talking about</p> <p>15 is aflibercept. And even there, I'm not the</p> <p>16 microbiologist or chemist or whatever, the right</p> <p>17 expertise is to talk about that, but whether there</p> <p>18 is a product that your technical experts are</p> <p>19 suggesting somehow nibbles around the patents at</p> <p>20 issue, let's just the technical experts talk about</p> <p>21 that.</p> <p>22 From my perspective, I'm looking at what</p>

<p style="text-align: right;">53</p> <p>1 the economics are in pursuing the alleged novelty                  2 of the '338 patent as of the priority date, and I                  3 haven't seen any evidence that that has occurred.                  4 <b>BY MR. CAINE:</b>                  5 Q Regulatory exclusivity, let's talk about                  6 regulatory exclusivity.                  7 When did regulatory exclusivity come into                  8 the law?                  9 MR. MARX: Outside the scope, seeking a                  10 legal conclusion. Are you referring to Eylea                  11 regulatory exclusivity or just regulatory --                  12 MR. CAINE: Regulatory exclusivity.                  13 MR. MARX: Same objection. Outside the                  14 scope, seeking a legal conclusion.                  15 <b>BY MR. CAINE:</b>                  16 Q Do you know?                  17 <b>A I'm not a lawyer and I'm not a regulatory</b>                  18 <b>expert. I don't remember the exact date that -- I</b>                  19 <b>believe it was the BPCIA that established the</b>                  20 <b>12-year regulatory exclusivity, but I don't have</b>                  21 <b>the year off the top of my head that that started</b>                  22 <b>to be applied.</b></p>	<p style="text-align: right;">55</p> <p>1 BY THE WITNESS:                  2 A I mean, my reaction is no. The BPCIA                  3 didn't come about overnight. There was tons of                  4 discussion and articles.                  5 <b>BY MR. CAINE:</b>                  6 Q How long?                  7 A I mean, I don't remember the exact time                  8 frame, and I'm not a patent lawyer or someone that                  9 is the right person to kind of give you the exact                  10 time frame, but, you know, the point that I think                  11 I make rather clearly in my declaration is that                  12 there were published patent applications -- or I'm                  13 sorry -- published patents, so fully issued                  14 patents that set up a patent thicket around this                  15 product and then --                  16 <b>BY MR. CAINE:</b>                  17 Q Did the BPCIA come to -- was it being                  18 contemplated as early as 2001?                  19 MR. MARX: Mr. Hofmann, please finish your                  20 answer.                  21 BY THE WITNESS:                  22 A There was very clearly BPCIA discussion in</p>
<p style="text-align: right;">54</p> <p>1 Q So if it was the BPCIA, when did that come                  2 into effect?                  3 MR. MARX: Objection. Seeks a legal                  4 conclusion.                  5 BY THE WITNESS:                  6 <b>A I don't remember the exact date.</b>                  7 <b>BY MR. CAINE:</b>                  8 Q Was it 2011 or after or before?                  9 MR. MARX: Objection. Asked and answered,                  10 outside the scope, seeks a legal conclusion.                  11 BY THE WITNESS:                  12 <b>A I don't remember. That sounds like you're</b>                  13 <b>in the ballpark, and I will trust what you</b>                  14 <b>represent to me, but that sounds about right.</b>                  15 <b>BY MR. CAINE:</b>                  16 Q If regulatory exclusivity didn't come into                  17 effect until after the priority date, would you                  18 agree that the regulatory exclusivity would not                  19 have impacted a competitor's frame of mind prior                  20 to it becoming -- it coming into effect?                  21 <b>A No --</b>                  22 MR. MARX: Objection. Form, hypothetical.</p>	<p style="text-align: right;">56</p> <p>1 the 2000s. I just don't remember the exact timing                  2 that that pertained to as to what was happening.                  3 And I recognize there is a little bit of                  4 uncertainty as to how it would look, how it would                  5 be implemented.                  6 But my point is between the numerous --                  7 seven or so patents that had issued that were set                  8 up as a thicket around aflibercept combined with                  9 the writing on the wall that there was going to be                  10 biologic regulatory exclusivity for a much greater                  11 period than, you know, like the 30 months there or                  12 NCE minus one that exists for Orange Book patents,                  13 that it was going to be longer.                  14 I think it was known in the 2000s. It was                  15 just a matter of, I think -- I don't know,                  16 Congress and regulators to settle on what that                  17 would be.                  18 <b>BY MR. CAINE:</b>                  19 Q When was it known?                  20 MR. MARX: Objection. Outside the scope.                  21 BY THE WITNESS:                  22 <b>A I told you many times I'm not a legal</b></p>



57	<p>1 expert or regulatory expert, and I don't remember</p> <p>2 the exact date in time. But from the earliest I</p> <p>3 can recall researching and spending time on this,</p> <p>4 it was generally understood that the regulatory</p> <p>5 exclusivity for biologics, because of the far</p> <p>6 greater cost of developing them compared to small</p> <p>7 molecule drugs, was going to be greater. But it</p> <p>8 wasn't exactly known right away what the period</p> <p>9 would be.</p> <p>10 BY MR. CAINE:</p> <p>11 Q So you can't tell me a year when</p> <p>12 regulatory exclusivity first began to be</p> <p>13 discussed?</p> <p>14 MR. MARX: Objection.</p> <p>15 BY MR. CAINE:</p> <p>16 Q Is that fair to say?</p> <p>17 MR. MARX: Objection. Asked and answered,</p> <p>18 seeks a legal conclusion.</p> <p>19 BY THE WITNESS:</p> <p>20 A I think certainly I could dig that up, and</p> <p>21 whether it first being discussed versus it</p> <p>22 crystalizing more is the right place to look. I</p>	59	<p>1 BY MR. CAINE:</p> <p>2 Q Regulatory exclusivity does not prevent</p> <p>3 the development of a biosimilar molecule, correct?</p> <p>4 MR. MARX: Objection to the extent it</p> <p>5 seeks a legal conclusion.</p> <p>6 BY THE WITNESS:</p> <p>7 A I'm not a lawyer and I'm not a regulatory</p> <p>8 expert. My understanding is there are safe harbor</p> <p>9 protections to develop a biosimilar during the</p> <p>10 pendency of the regulatory exclusivity to the</p> <p>11 biologic under the biologics BLA, but you couldn't</p> <p>12 commercialize until the expiration of the BLA</p> <p>13 regulatory exclusivity, as I understand it.</p> <p>14 BY MR. CAINE:</p> <p>15 Q Regulatory exclusivity does not prevent an</p> <p>16 applicant from conducting clinical trials using</p> <p>17 the biopharmaceutical subject to the filing of an</p> <p>18 investigational new drug application if the</p> <p>19 clinical trials are to be conducted in the</p> <p>20 United States, correct?</p> <p>21 MR. MARX: Objection. Outside the scope,</p> <p>22 form, seeks a legal conclusion.</p>
58	<p>1 would defer to lawyers and regulatory experts, but</p> <p>2 it certainly has been an issue that's been around</p> <p>3 for some time since the 2000s. And I don't</p> <p>4 remember when it was formally implemented.</p> <p>5 BY MR. CAINE:</p> <p>6 Q Well, my question wasn't when it was</p> <p>7 formally implemented. My question was: When was</p> <p>8 it first raised as a possibility?</p> <p>9 MR. MARX: Asked and answered.</p> <p>10 BY THE WITNESS:</p> <p>11 A I mean, it goes back. From what I can</p> <p>12 recall as I sit here right now – I don't have a</p> <p>13 document and I don't have a basis and just because</p> <p>14 it was discussed doesn't mean that it was kind of</p> <p>15 closer to crystalizing.</p> <p>16 I don't know, sometime in the 2000s, it</p> <p>17 was known that biologics were going to be a new</p> <p>18 animal, if you will, relative to the Hatch-Waxman</p> <p>19 scheme that had been in place for small molecules</p> <p>20 because large molecules have a greater set of</p> <p>21 different issues that come with them and,</p> <p>22 therefore, there would be longer exclusivity.</p>	60	<p>1 BY THE WITNESS:</p> <p>2 A I'm not a lawyer. I'm not a regulatory</p> <p>3 expert. I believe that that's embodied in my</p> <p>4 prior answer, that there's an ability to conduct</p> <p>5 some work before expiration of the BLA regulatory</p> <p>6 exclusivity, but you can't commercialize it. And</p> <p>7 so within that would be subsumed potential – the</p> <p>8 ability to conduct clinical trials, but that's a</p> <p>9 better question for a lawyer or a clinical</p> <p>10 regulatory expert.</p> <p>11 BY MR. CAINE:</p> <p>12 Q Regulatory exclusivity does not prevent an</p> <p>13 applicant from conducting clinical trials using a</p> <p>14 biopharmaceutical outside of the United States,</p> <p>15 correct?</p> <p>16 MR. MARX: Objection. Outside the scope</p> <p>17 and seeks a legal conclusion.</p> <p>18 BY THE WITNESS:</p> <p>19 A I mean, I don't know. I don't know</p> <p>20 100 percent. I think that the answers I just gave</p> <p>21 to the last two answers, I think, would apply</p> <p>22 equally. It's not like because it's allowed in</p>

<p style="text-align: right;">6</p> <p>1 the US it would be precluded outside the US, but I                  2 just -- I don't know.                  3 MR. CAINE: Why don't we take our lunch                  4 break here and come back. We can talk about when                  5 off the record.                  6 THE VIDEOGRAPHER: Please stand by.                  7 We are going off the record. The time is                  8 12:52 p.m.                  9 (A lunch recess was had from 12:52 p.m. to                  10 1:32 p.m.)                  11                  12                  13                  14                  15                  16                  17                  18                  19                  20                  21                  22</p>	<p style="text-align: right;">63</p> <p>1 A I think that it's not for me as an                  2 economist to weigh in on that, you know, in any                  3 affirmative way. I think that obviously there's                  4 plenty of technical experts that are involved that                  5 are probably better served to answer those                  6 questions.                  7 BY MR. CAINE:                  8 Q Could we have Exhibit 2197, please.                  9 MR. MARX: Mr. Caine, you asked for 2197.                  10 I note this has two exhibit labels, 2294 and 2197,                  11 just to make it clear for the record.                  12 MR. CAINE: Sure. Let's see if this is                  13 the one I wanted. I think it is.                  14 BY MR. CAINE:                  15 Q Would you look at what's been marked                  16 both -- we'll have to clarify it -- Exhibit 2197                  17 and then 2294. This is a -- the document says                  18 "Physician ATU Benchmark Wave Full Report                  19 September 15, 2011."                  20 Do you have that in front of you?                  21 A Yes. Just give me a minute because I'm                  22 trying to -- I looked at a couple of ATUs and want</p>
<p style="text-align: right;">62</p> <p>1 AFTERNOON SESSION                  2 THE VIDEOGRAPHER: We're back on the                  3 record. The time is 1:33 p.m.                  4 IVAN HOFMANN,                  5 called as a witness herein, having been previously                  6 duly sworn and having testified, was examined and                  7 testified further as follows:                  8 DIRECT EXAMINATION (Resumed)                  9 BY MR. CAINE:                  10 Q Mr. Hofmann, the key differentiator for                  11 Eylea relative to Lucentis and Avastin is clinical                  12 data showing that Eylea is as effective at                  13 maintaining visual acuity with an eight-week                  14 maintenance dosing regimen as Lucentis is with a                  15 four-week maintenance dosing regimen, correct?                  16 MR. MARX: Objection. Outside scope.                  17 BY THE WITNESS:                  18 A That's a better question for a clinician.                  19 BY MR. CAINE:                  20 Q You don't have any opinion?                  21 MR. MARX: Same objection.                  22 BY THE WITNESS:</p>	<p style="text-align: right;">64</p> <p>1 to make sure I reorient myself to what year it's                  2 from and what some of the findings are. And it's                  3 a 47-page document, so I need to --                  4 BY MR. CAINE:                  5 Q Mr. Hofmann, I'm looking at Page 2 of the                  6 exhibit which I do believe is 2197. This page has                  7 the heading "Background and Objectives."                  8 I want to confirm that --                  9 A I'm still flipping through the document,                  10 sir.                  11 Q I haven't asked you a question yet.                  12 A Okay. I'm just saying. I'm not on                  13 Page 2. I need an opportunity to look at the                  14 document.                  15 MR. CAINE: Let's go off the record.                  16 MR. MARX: No, absolutely not. We're not                  17 going off the record.                  18 MR. CAINE: Yes, we are.                  19 MR. MARX: The witness is allowed to                  20 review the documents.                  21 MR. CAINE: He hasn't even had a question                  22 yet.</p>



<p style="text-align: right;">65</p> <p>1 MR. MARX: Well, you put it in front of</p> <p>2 him, and before he answers any question, he s</p> <p>3 allowed to review the document.</p> <p>4 MR. CAINE: We re going to go off record,</p> <p>5 please.</p> <p>6 MR. MARX: No, we re not.</p> <p>7 MR. CAINE: Okay. Well, if this is the</p> <p>8 way this is going to play out, then we will have</p> <p>9 to go to the board and ask for more time because</p> <p>10 he s reviewing material I haven t even asked him a</p> <p>11 question about.</p> <p>12 MR. MARX: He s entitled to review</p> <p>13 documents you put before him.</p> <p>14 MR. CAINE: He doesn t know what my</p> <p>15 question is. If he needs to review the document</p> <p>16 after I ve asked my question, I think that s fair.</p> <p>17 But to spend time looking through a document the</p> <p>18 question may not even implicate, I don t think</p> <p>19 that s reasonable.</p> <p>20 MR. MARX: I think Mr. Hofmann is entitled</p> <p>21 to review a document. We ve looked at 400-page</p> <p>22 documents. You asked questions about three lines.</p>	<p style="text-align: right;">67</p> <p>1 Q Why don't we start at Page 1.</p> <p>2 Date of the report is September 15, 2011,</p> <p>3 correct?</p> <p>4 A Yes.</p> <p>5 Q That was before Eylea launched, correct?</p> <p>6 A Yes.</p> <p>7 Q Now turn to Page 2.</p> <p>8 Do you see in the background and</p> <p>9 objectives it says: "In clinical trials," second</p> <p>10 bullet, "Eylea has shown similar efficacy and</p> <p>11 safety levels when compared to a key market</p> <p>12 player, Lucentis."</p> <p>13 MR. MARX: Objection. Lack of</p> <p>14 foundation -- oh, is there a question pending?</p> <p>15 Was there a question?</p> <p>16 MR. CAINE: Yeah. It was, do you see that</p> <p>17 it says that?</p> <p>18 MR. MARX: Objection. Lack of foundation.</p> <p>19 BY THE WITNESS:</p> <p>20 <b>A From what I can recall, those are the --</b></p> <p>21 <b>the words are there, and I think you read them</b></p> <p>22 <b>accurately. I just wasn't quite there.</b></p>
<p style="text-align: right;">66</p> <p>1 MR. CAINE: Exactly.</p> <p>2 MR. MARX: He's entitled to consult the</p> <p>3 document and understand the context of what you're</p> <p>4 going to ask.</p> <p>5 MR. CAINE: That's precisely my point. I</p> <p>6 may ask him about a couple of lines, not the</p> <p>7 entire document.</p> <p>8 THE WITNESS: I've tried to quickly leaf</p> <p>9 through this document which I am familiar with,</p> <p>10 but where in particular do you want me to focus</p> <p>11 for answering your question?</p> <p>12 BY MR. CAINE:</p> <p>13 Q So you've now taken the time to leaf</p> <p>14 through the document, right?</p> <p>15 <b>A I mean, not in -- it's a 50-page document.</b></p> <p>16 <b>I've quickly, quickly leafed through it, so</b></p> <p>17 <b>depending on your question, I may need more time</b></p> <p>18 <b>to look at it, but I'm trying to move things</b></p> <p>19 <b>along.</b></p> <p>20 Q Have you gotten to the very last page?</p> <p>21 <b>A Leafing through it by flipping through</b></p> <p>22 <b>several pages at a time. You said Page 2?</b></p>	<p style="text-align: right;">68</p> <p>1 <b>BY MR. CAINE:</b></p> <p>2 Q Do you have any basis to dispute that</p> <p>3 Eylea showed similar efficacy and safety levels</p> <p>4 when compared to a key market player, Lucentis?</p> <p>5 MR. MARX: Objection. Outside the scope,</p> <p>6 lack of foundation.</p> <p>7 BY THE WITNESS:</p> <p>8 <b>A I'm not a clinician. I think that you're</b></p> <p>9 <b>better off asking the clinical experts about that</b></p> <p>10 <b>question.</b></p> <p>11 <b>BY MR. CAINE:</b></p> <p>12 Q Still on Page 2, it says: "The main</p> <p>13 differentiating characteristic that Eylea will</p> <p>14 bring to the market is a less frequent dosing</p> <p>15 schedule (two months versus one month)."</p> <p>16 Do you see that?</p> <p>17 <b>A I see what you read.</b></p> <p>18 Q Do you have any reason to disagree with</p> <p>19 that statement?</p> <p>20 MR. MARX: Objection. Outside the scope,</p> <p>21 lack of foundation.</p> <p>22 BY THE WITNESS:</p>

<p style="text-align: right;">69</p> <p>1 A I think that's a better question for a                  2 clinician or a technical expert, but as I was                  3 leafing through, I mean, I don't know, I look at                  4 Page 12 and I see a pretty similar number of                  5 annual injections between Avastin, Lucentis. I                  6 don't know – I think Eylea hasn't yet launched,                  7 so I'm not sure what the actual stuff – actual                  8 regimen is, but that's where I think you should                  9 talk to a clinician.                  10 BY MR. CAINE:                  11 Q Have you seen any data showing that if you                  12 inject Lucentis or Avastin, for that matter, less                  13 frequently than monthly, the efficacy or the                  14 visual acuity that was achieved during the initial                  15 loading dose period stays the same?                  16 MR. MARX: Objection. Form, outside the                  17 scope.                  18 BY THE WITNESS:                  19 A I'm not a clinician and I don't – I'm                  20 confused by your question because, again, I'm not                  21 a clinician. I'm not weighing in as a clinician.                  22 But what I see in the stats that exist here from</p>	<p style="text-align: right;">7</p> <p>1 BY MR. CAINE:                  2 Q Now, Avastin's key differentiator is                  3 price. Do you agree?                  4 MR. MARX: Objection. Outside the scope                  5 and lack of foundation.                  6 BY THE WITNESS:                  7 A There is some subjectivity baked into your                  8 question. Again, this is 2011. I'm trying to                  9 remember when exactly they went generic.                  10 Certainly from the time that –                  11 BY MR. CAINE:                  12 Q What do you mean by "went generic"?                  13 A Generic products were – I guess, products                  14 were available at a lower cost alternative.                  15 Q What do you mean by "generic"?                  16 A Just in general or –                  17 Q No, in the context of Avastin.                  18 A I think what we see is that Avastin ended                  19 up being priced far lower based on its product                  20 life cycle at some point in time. I don't                  21 remember the exact point in time.                  22 Q Do you think Avastin at some point in time</p>
<p style="text-align: right;">70</p> <p>1 this ATU which, again, I don't know that I'm fully                  2 capable of understanding the information that was                  3 collected what the questions were, et cetera,                  4 et cetera, but I mean, I think your question asked                  5 about once monthly, but at least according to                  6 Slide 12, it seems like it's bimonthly, at least                  7 for the second year.                  8 BY MR. CAINE:                  9 Q What did the data show on visual acuity                  10 when Avastin was -- I'm sorry, when Lucentis was                  11 dosed less frequently than monthly?                  12 MR. MARX: Objection. Outside the scope.                  13 BY THE WITNESS:                  14 A I'm not –                  15 BY MR. CAINE:                  16 Q Does the slide you're looking at say                  17 anything about that?                  18 MR. MARX: Objection. Outside the scope                  19 and lack of foundation.                  20 BY THE WITNESS:                  21 A I'm not a technical expert. I'm not the                  22 clinician.</p>	<p style="text-align: right;">72</p> <p>1 had a higher price for the treatment of eye                  2 disease?                  3 MR. MARX: Objection. Mischaracterizes                  4 the witness testimony. Outside the scope.                  5 BY MR. CAINE:                  6 Q I'm just trying to understand your                  7 testimony.                  8 A No. I'm saying that we looked at exhibits                  9 earlier in the Manning report where we could see                  10 that the price is lower, quite a bit lower. At                  11 what point in time it had that shift, I don't                  12 remember.                  13 Q The shift is the part that's throwing me                  14 off. When was Avastin ever priced at a                  15 substantially different level from what we saw?                  16 MR. MARX: Objection. Mischaracterizes                  17 the witness testimony.                  18 BY THE WITNESS:                  19 A I don't know that I have a data set that                  20 gets me to that –                  21 BY MR. CAINE:                  22 Q Was it ever?</p>



<p style="text-align: right;">73</p> <p>1 MR. MARX: Same objection. Outside the 2 scope. 3 BY THE WITNESS: 4 <b>A I don't – I don't – like for the period</b> 5 <b>that's important to my analysis, I don't know that</b> 6 <b>I have it back far enough. I guess I was just</b> 7 <b>assuming at some point it was priced higher, but</b> 8 <b>for all the periods that I have data sets, it has</b> 9 <b>been lower.</b> 10 <b>BY MR. CAINE:</b> 11 Q Lucentis did not compete with Avastin on 12 the basis of price. Would you agree? 13 MR. MARX: Objection. Foundation, outside 14 the scope. 15 BY THE WITNESS: 16 <b>A I guess I'd say it differently, that at</b> 17 <b>least in the data sets I saw, Lucentis was priced</b> 18 <b>higher than Avastin based on available data sets</b> 19 <b>subject to, you know, whether or not discounts and</b> 20 <b>other things are included in those numbers.</b> 21 <b>BY MR. CAINE:</b> 22 Q Lucentis could not demonstrate through</p>	<p style="text-align: right;">75</p> <p>1 extensively today in response to numerous 2 questions, he is not a technical expert and has 3 relied on technical experts' opinions elucidated 4 in their reports and declarations. So to the 5 extent counsel intends to ask questions about a 6 scientific publication outside the scope of 7 Mr. Hofmann's expertise, we object. 8 BY MR. CAINE: 9 Q Do you have Exhibit 2086 in front of you? 10 <b>A I have a single-spaced, dual-column</b> 11 <b>scientific journal article that is labeled 2086 in</b> 12 <b>front of me that I don't think I've ever seen</b> 13 <b>before. It's 15 pages, has tons of tables, tons</b> 14 <b>of data, tons of information that I don't – I</b> 15 <b>certainly have not had the ability to read, review</b> 16 <b>or process.</b> 17 Q Did you have any discussion with 18 Dr. Albini or Dr. Gerritsen about whether Lucentis 19 was able to maintain visual acuity gains that were 20 achieved during the loading dose phase with 21 greater than four-week maintenance doses? 22 MR. MARX: Objection. Outside the scope.</p>
<p style="text-align: right;">74</p> <p>1 clinical data the same efficacy as Eylea when 2 Eylea -- when Lucentis was administered with a 3 dosing interval greater than four weeks, correct? 4 MR. MARX: Objection. Lack of foundation 5 and outside the scope of Mr. Hofmann's expertise. 6 BY THE WITNESS: 7 <b>A That's a better question for a clinician.</b> 8 <b>BY MR. CAINE:</b> 9 Q You didn't consider that in offering your 10 opinions? 11 <b>A I mean, I reviewed this information, like</b> 12 <b>I said, and there are some limitations on how much</b> 13 <b>one can rely on an ATU that's based on selective</b> 14 <b>data, but I don't think that I'm the one that</b> 15 <b>should be weighing in on – the way your question</b> 16 <b>was framed as to clinical differentiation one way</b> 17 <b>or the other.</b> 18 Q Let's look at Exhibit 2086. Do you have 19 Exhibit 2086 in front of you? 20 MR. MARX: I'm just going to note for the 21 record that Exhibit 2086 is a scientific 22 publication. As Mr. Hofmann has testified</p>	<p style="text-align: right;">76</p> <p>1 BY THE WITNESS: 2 <b>A I think – I think you already asked me</b> 3 <b>whether I spoke with them, and I did not speak</b> 4 <b>with them. I reviewed their declarations. I</b> 5 <b>reviewed what they asserted and relied on their</b> 6 <b>technical expertise. But no, I didn't have any</b> 7 <b>separate discussions.</b> 8 <b>BY MR. CAINE:</b> 9 Q Do you recall any assertion or statement 10 in either of those declarations about whether 11 Lucentis was able to maintain visual acuity gains 12 achieved during an initial loading dose phase when 13 anything -- any maintenance dosing was used 14 greater than four weeks? 15 MR. MARX: Objection. Outside the scope. 16 Again, these are questions Mr. Hofmann has 17 testified are for technical experts. He's offered 18 opinions relative to commercial success in this 19 case. And you're free to ask him questions about 20 commercial success, but to the extent you keep 21 asking questions that are outside of his report, 22 outside of the opinions of Dr. Manning, who he's</p>

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1 replied to, I'm going to keep objecting.  
 2 BY THE WITNESS:  
 3 **A I don't – I don't think that, you know,**  
 4 **again, through my economic lens that's something**  
 5 **that I should be asked to weigh in on. I talked**  
 6 **to the technical experts, talked to clinicians and**  
 7 **others that have knowledge and skills in this**  
 8 **space.**  
 9 **BY MR. CAINE:**  
 10 Q Isn't the ability to obtain -- to maintain  
 11 efficacy in a maintenance dosing period a  
 12 consideration in this case that is important to  
 13 determining whether commercial success is  
 14 attributable to the methods of treatment claimed  
 15 in the '338 patent?  
 16 MR. MARX: Objection. Outside the scope.  
 17 BY THE WITNESS:  
 18 **A I'm not a patent lawyer, and I'm not a**  
 19 **clinical expert or a POSA. I've relied on the**  
 20 **technical knowledge and skills of experts as cited**  
 21 **and referenced throughout my declaration, and my**  
 22 **understandings are outlined therein.**

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1 MR. MARX: I m also going to note for the  
 2 record counsel asked a question concerning  
 3 efficacy and maintenance dosing. And counsel is  
 4 well aware that s a claim construction issue in  
 5 this case relevant to the technical experts.  
 6 To the extent you re trying to use  
 7 Mr. Manning {sic} to circumvent that, that s  
 8 completely improper. I m going to object to this  
 9 line of questioning to the extent it seeks a legal  
 10 conclusion or at all relates to Regeneron s  
 11 argument concerning efficacy and as it relates to  
 12 the 338 patent claims.  
 13 BY MR. CAINE:  
 14 Q Mr. Hofmann, would you turn to Page 7 of  
 15 Exhibit 2086, please.  
 16 **A Just so the record's, I guess, clear, you**  
 17 **called me Manning instead of Hofmann.**  
 18 MR. MARX: I apologize.  
 19 THE WITNESS: I ve been called worse. I m  
 20 sorry. Where --  
 21 BY MR. CAINE:  
 22 Q Page 7, please.

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1 **A Page 7.**  
 2 Q Yes.  
 3 MR. MARX: And, again, Counsel, this  
 4 Exhibit 2086, to my recollection, never in  
 5 Dr. Manning's report, completely new to  
 6 Mr. Hofmann. So to the extent you want to keep  
 7 wasting time asking about technical issues, you're  
 8 free to do so, but I unfortunately will keep  
 9 objecting on the record, that this is an improper  
 10 line of questioning and far outside of  
 11 Mr. Hofmann's declaration in this matter and his  
 12 expertise.  
 13 BY MR. CAINE:  
 14 Q Mr. Hofmann, would you put Exhibit 2086 in  
 15 front of you and turn to Page 7 as I asked a  
 16 minute ago.  
 17 Do you have Page 7?  
 18 **A I'm at Page 7 of this 15-page,**  
 19 **dual-column, single-spaced document that I've**  
 20 **never seen before with a bunch of information that**  
 21 **I'm sure I'm not the right person to be asking**  
 22 **questions about, but what do you want – where do**

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1 **you want me to focus or can I be permitted to**  
 2 **spend the time to review this 15-page,**  
 3 **single-spaced, dual-column document or like I**  
 4 **don't know –**  
 5 Q May I ask my question, sir?  
 6 **A Okay.**  
 7 Q Because you understand that this is my  
 8 opportunity to ask you questions and you have an  
 9 obligation to answer my questions.  
 10 Do you understand that?  
 11 **A I'm trying to be as full, fair and**  
 12 **complete as I can be.**  
 13 Q Then I would appreciate it if you would  
 14 listen to my question and answer the question that  
 15 I've asked you, okay?  
 16 **A Let's see where we go.**  
 17 Q Can we agree to that?  
 18 **A Let's see where we go.**  
 19 Q We can't agree to that?  
 20 **A I'm going to answer all your questions as**  
 21 **thoroughly and completely as I can.**  
 22 Q Then let me ask it.



<p style="text-align: right;">8</p> <p>1 <b>A I'm just unfamiliar with this document,</b>                  2 <b>and it's certainly not within my skills and</b>                  3 <b>experience.</b>                  4 MR. MARX: Okay. Mr. Hofmann, Counsel,                  5 I've already noted that this is a document that                  6 Mr. Hofmann has not reviewed. It's a 15-page                  7 scientific publication. He is not a technical                  8 expert. If you can point me to where it's                  9 discussed in his declaration, we're happy to                  10 review it and talk about it. But otherwise,                  11 you're far afield from his opinions in this case,                  12 and it's an improper line of questioning.                  13 MR. CAINE: Counsel, you've made your                  14 objection. I don't really think you need to                  15 belabor the record further with making the same                  16 objection.                  17 MR. MARX: I'm going to keep belaboring                  18 the record --                  19 MR. CAINE: -- in a hostile tone.                  20 MR. MARX: -- making the same objections                  21 because these are not his opinions in this case.                  22 MR. CAINE: Then I would ask you to keep</p>	<p style="text-align: right;">83</p> <p>1 right-hand column, it says: "Comparisons between                  2 3 -- month 3 and month 12 for the VA," which I'll                  3 represent to you is visual acuity, "endpoints were                  4 considered indicative of the efficacy of the                  5 quarterly dosing schedule as a maintenance therapy                  6 and therefore several prespecified exploratory                  7 analyses were conducted."                  8 Next sentence: "On average, there was a                  9 4.5 letter decline in VA between month 3 and                  10 month 12 for both ranibizumab dose scripts."                  11 Do you see that?                  12 MR. MARX: Objection to this line of                  13 questioning. This scientific publication is not                  14 at all relevant and not cited at all in                  15 Dr. Manning's opinion in this case. And further,                  16 to the extent it relates to legal issues in this                  17 case concerning efficacy in the claim language in                  18 the 338 patent, this is completely improper.                  19 To the extent you can, you can answer,                  20 Mr. Hofmann.                  21 BY THE WITNESS:                  22 <b>A All I can say --</b></p>
<p style="text-align: right;">82</p> <p>1 your tone civil.                  2 MR. MARX: I would ask you to stop                  3 badgering the witness.                  4 MR. CAINE: I don't think I am.                  5 MR. MARX: I think the record reflects                  6 that you are --                  7 MR. CAINE: I'm trying to ask a question,                  8 and I think you're trying to obstruct me asking a                  9 question.                  10 MR. MARX: I'm not obstructing asking                  11 questions, only to focus on Mr. Hofmann's opinions                  12 on this case.                  13 MR. CAINE: May I continue?                  14 MR. MARX: Certainly. Ask your question                  15 and I'll object accordingly.                  16 MR. CAINE: Thank you. You may make your                  17 objection as you see fit.                  18 BY MR. CAINE:                  19 Q Mr. Hofmann, I'm going to ask you a                  20 question now, okay?                  21 <b>A Okay.</b>                  22 Q All right. First full paragraph on the</p>	<p style="text-align: right;">84</p> <p>1 <b>BY MR. CAINE:</b>                  2 Q Well, I just asked if you saw it and I'll                  3 ask you a question. I'm trying to orient you.                  4 So here is my question.                  5 Do you understand that ranibizumab is the                  6 same as Lucentis?                  7 <b>A Look, you're taking me to one particular</b>                  8 <b>column in this document. I do understand that</b>                  9 <b>that is the active molecule in Lucentis, but I</b>                  10 <b>mean, I haven't looked at this document. I'm not</b>                  11 <b>a clinician. I'm not a POSA. I'm not someone</b>                  12 <b>that should be weighing in on this, but I believe</b>                  13 <b>that Lucentis, the active is ranibizumab.</b>                  14 Q In offering your opinions about nexus in                  15 this case, did you consider that Lucentis lacks                  16 any clinical data to show that it can maintain                  17 visual acuity gains achieved during the loading                  18 dose period when greater than four-week                  19 maintenance dosing is utilized?                  20 MR. MARX: Objection. Outside the scope                  21 of Mr. Hofmann's expertise and opinions in this                  22 matter.</p>

<p style="text-align: right;">85</p> <p>1 BY THE WITNESS:</p> <p>2 <b>A As I have said numerous times -- and I</b></p> <p>3 <b>don't mean to have to repeat myself, but you're</b></p> <p>4 <b>asking me things that I've not seen this article.</b></p> <p>5 <b>I've not weighed in affirmatively in any clinical</b></p> <p>6 <b>or POSA way with respect to the product and</b></p> <p>7 <b>various, I don't know, findings that exist in this</b></p> <p>8 <b>article and maybe many other articles. I</b></p> <p>9 <b>considered the opinions, as I've referenced in</b></p> <p>10 <b>great detail in my declaration, that rely on the</b></p> <p>11 <b>knowledge and expertise of Drs. Albini and</b></p> <p>12 <b>Gerritsen, and that's as far as I can go.</b></p> <p>13 <b>BY MR. CAINE:</b></p> <p>14 Q Do you agree that generally patients would</p> <p>15 prefer a treatment that involved fewer injections</p> <p>16 in the eye?</p> <p>17 MR. MARX: Objection. Outside the scope.</p> <p>18 THE WITNESS: I'm not a clinician. That's</p> <p>19 a better question for a clinician.</p> <p>20 <b>BY MR. CAINE:</b></p> <p>21 Q As an economist, do you believe that</p> <p>22 patients would prefer a treatment that involved</p>	<p style="text-align: right;">87</p> <p>1 treatment that allows you to maintain visual</p> <p>2 acuity with four be preferred to the one that</p> <p>3 allows you to maintain visual acuity but requires</p> <p>4 eight?</p> <p>5 MR. MARX: Objection. Lack of foundation,</p> <p>6 outside the scope and improper hypothetical.</p> <p>7 <b>BY THE WITNESS:</b></p> <p>8 <b>A That's a better question for a technical</b></p> <p>9 <b>expert clinician.</b></p> <p>10 <b>BY MR. CAINE:</b></p> <p>11 Q Can we have Exhibit 1018, please.</p> <p>12 Do you have Exhibit 1018?</p> <p>13 MR. MARX: I'm going to note again</p> <p>14 Exhibit 1018, similar to the prior exhibit, is</p> <p>15 another scientific publication not cited anywhere</p> <p>16 in Mr. Hofmann's opinions in this case and is far</p> <p>17 afield from his commercial success opinions in</p> <p>18 this case.</p> <p>19 So to the extent, Counsel, you want to</p> <p>20 spend time on this, you're free to do so, but this</p> <p>21 is a new document to Dr. Manning, 11 pages,</p> <p>22 single-spaced, two columns. He's entitled to his</p>
<p style="text-align: right;">86</p> <p>1 fewer injections into the eye while maintaining</p> <p>2 the same level of visual acuity than greater?</p> <p>3 MR. MARX: Objection. Form, lack of</p> <p>4 foundation, outside the scope and it's an</p> <p>5 incomplete or improper hypothetical.</p> <p>6 <b>BY THE WITNESS:</b></p> <p>7 <b>A I don't think that's so much an economic</b></p> <p>8 <b>question. I think that the points that I've made</b></p> <p>9 <b>and explained in my report is a lot of the aspects</b></p> <p>10 <b>that I understand from technical experts and POSAs</b></p> <p>11 <b>and clinicians are attributes of the aflibercept</b></p> <p>12 <b>molecule or things that were known in the prior</b></p> <p>13 <b>art and that they are able to achieve much of what</b></p> <p>14 <b>has been done based on those things as well as the</b></p> <p>15 <b>extrinsic factors and other things I explain it in</b></p> <p>16 <b>my report.</b></p> <p>17 <b>As to the '338 patent, I haven't seen</b></p> <p>18 <b>anything that points to demonstration, and</b></p> <p>19 <b>certainly Manning hasn't done so to put -- to</b></p> <p>20 <b>nexus the question that your question implies.</b></p> <p>21 Q If you could maintain visual acuity with</p> <p>22 four injections as opposed to eight, would the</p>	<p style="text-align: right;">88</p> <p>1 time to review it.</p> <p>2 <b>BY MR. CAINE:</b></p> <p>3 Q Mr. Hofmann, did you offer an opinion in</p> <p>4 this proceeding that Eylea has superior efficacy</p> <p>5 to Lucentis and Avastin?</p> <p>6 <b>A That isn't something that I would be the</b></p> <p>7 <b>one to weigh in on. That's more of a technical</b></p> <p>8 <b>expert clinician. I may have references to</b></p> <p>9 <b>various findings that they have in their</b></p> <p>10 <b>declarations, but I certainly wouldn't be offering</b></p> <p>11 <b>any affirmative opinion in that regard.</b></p> <p>12 Q Did you offer opinions that Eylea's</p> <p>13 commercial success is attributable to its superior</p> <p>14 efficacy?</p> <p>15 MR. MARX: Objection to the extent it</p> <p>16 mischaracterizes the witness testimony and also to</p> <p>17 the extent it seeks a legal conclusion with</p> <p>18 respect to the pending claim construction issue.</p> <p>19 <b>BY THE WITNESS:</b></p> <p>20 <b>A There's a host of problems I have with</b></p> <p>21 <b>that question, so I'm going to ask for it to be</b></p> <p>22 <b>repeated because I think it presupposes things</b></p>



<p style="text-align: right;">89</p> <p>1 that I don't believe are in my report. But if it                  2 can be read back.                  3 BY MR. CAINE:                  4 Q Sure. I can say it.                  5 Did you offer opinions in this proceeding                  6 that Eylea's commercial success is attributable to                  7 its superior efficacy?                  8 MR. MARX: Same objection.                  9 BY THE WITNESS:                  10 A So the presupposition – and maybe it's                  11 semantics. I'm not agreeing with you that it's a                  12 commercial success as a term of art in an                  13 obviousness inquiry, and I believe the way I'm                  14 hearing your question, you are suggesting that is                  15 a conclusion that I reached. And I would say that                  16 my declaration is entirely the opposite of that,                  17 and so let's see if we can try and reword it or                  18 rephrase it or try and get to a place where I can                  19 even start with the question because that, to me,                  20 is a nonstarter.                  21 BY MR. CAINE:                  22 Q Did you offer opinions that Eylea's</p>	<p style="text-align: right;">9</p> <p>1 the witness testimony.                  2 BY THE WITNESS:                  3 A No, I don't think that's fair to say. I                  4 said that I relied – I don't know what I said.                  5 You have LiveNote; I don't. Among other things,                  6 what I relied on was the technical experts who                  7 weighed in on this.                  8 But I also looked at a great deal of                  9 documents and information that was produced in                  10 this matter, conducted my own independent                  11 research. But I would say if on balance I needed                  12 to point to one of the main things I relied upon                  13 is definitely the opinions of the technical                  14 experts, Drs. Gerritsen and Albin.                  15 BY MR. CAINE:                  16 Q Turn to Paragraph 58 of your declaration,                  17 Exhibit 1137, which is on Page 43 if you use the                  18 pages down at the bottom right.                  19 Are you there?                  20 A I'm at Paragraph 58, yep.                  21 Q The first sentence in Paragraph 58 says:                  22 "Based upon my analysis, the Manning declaration</p>
<p style="text-align: right;">90</p> <p>1 marketplace performance is attributable to its                  2 superior efficacy?                  3 MR. MARX: Objection. Mischaracterizes                  4 the witness testimony.                  5 BY THE WITNESS:                  6 A I do have some references in my report                  7 that do refer to technical experts, including                  8 Dr. Gerritsen and Dr. Albin, which do reference                  9 aspects and attributes of aflibercept as having                  10 superior efficacy and safety, and that those are                  11 attributes that are tied to the molecule                  12 aflibercept. So those aren't my affirmative                  13 opinions. Like, I'm not the scientist or                  14 technical expert or clinician. I'm relying on                  15 their knowledge and expertise.                  16 BY MR. CAINE:                  17 Q So to the extent that you offer opinions                  18 about whether efficacy drives the performance of                  19 Eylea, in your declaration, those opinions are                  20 based solely on what technical experts told you or                  21 what you read from technical experts, fair to say?                  22 MR. MARX: Objection. Mischaracterizes</p>	<p style="text-align: right;">92</p> <p>1 fails to appropriately address what I understand                  2 was known in the prior art as well as attributes,                  3 i.e., efficacy and safety, that are key drivers of                  4 the marketplace performance of Eylea and I                  5 understand are not tied to the challenged claims                  6 of the '338 patent."                  7 Do you see that?                  8 A I do.                  9 Q Now, you haven't assessed whether the                  10 efficacy of Eylea differs from the efficacy --                  11 well, let me start over.                  12 You haven't assessed whether the efficacy                  13 and safety of Eylea differs from the efficacy and                  14 safety of Lucentis or Avastin, have you?                  15 MR. MARX: Objection. Mischaracterizes                  16 the witness testimony.                  17 BY THE WITNESS:                  18 A I mean, you're plucking one sentence out                  19 of a pretty lengthy section of my report that I                  20 think I did assess and I did admittedly rely on                  21 Drs. Gerritsen and Drs. Albin to help inform my                  22 decision because I'm not a POSA and I'm not a</p>

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1 **clinician.**  
 2 **I also cite to a number of documents that**  
 3 **I think establish pretty clearly and that the**  
 4 **efficacy and safety is at the level that it's at**  
 5 **because of the aflibercept molecule.**  
 6 **I think that more importantly, I don't**  
 7 **know if you're weighing on what's important or**  
 8 **not, the other criticism here is that Manning did**  
 9 **nothing to attempt to address this issue of what**  
 10 **was known in the prior art, what drove the**  
 11 **efficacy and safety and I think had a lot of**  
 12 **acknowledgment and admissions to that effect at**  
 13 **his deposition.**  
 14 **BY MR. CAINE:**  
 15 **Q** Let's look at Exhibit 1018 which I gave  
 16 you just a moment ago.  
 17 **Would you turn to -- you can look at the**  
 18 **first page, please.**  
 19 **A** **To be clear, I've never seen this**  
 20 **document, and it's a scientific publication that**  
 21 **is 12 pages long, single-spaced, two columns. I**  
 22 **haven't read it. I haven't looked at it or**

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1 **studied it. So ask your question. I don't know**  
 2 **how much help I can be here.**  
 3 **Q** Let's look at the first page. Do you see  
 4 the results?  
 5 **A** **Mr. Caine, I'm sorry. My microphone fell**  
 6 **off. Wardrobe malfunction.**  
 7 **Q** I'm focusing on the results section on the  
 8 first page.  
 9 **A** **All right.**  
 10 **Q** It says: "All aflibercept groups were  
 11 noninferior and clinically equivalent to monthly  
 12 ranibizumab for the primary end point." And it  
 13 goes on from there.  
 14 **Do you see that?**  
 15 **MR. MARX:** Let the record reflect that  
 16 this is Exhibit 1018 again. I objected to this on  
 17 the record before. That objection stands. Again,  
 18 this is outside the scope of Mr. Hofmann's  
 19 expertise and his opinions in this matter, cited  
 20 nowhere in his declaration.  
 21 **So, again, Counsel, you're free to ask**  
 22 **your questions about this scientific publication,**

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1 but this line of questioning is completely  
 2 improper and outside the scope of Mr. Hofmann's  
 3 commercial success opinions in this case.  
 4 **THE WITNESS:** Can you repeat your  
 5 question.  
 6 **BY MR. CAINE:**  
 7 **Q** Sure.  
 8 **Do you see that the results reported on**  
 9 **the first page are: "All aflibercept groups were**  
 10 **noninferior and clinically equivalent to monthly**  
 11 **ranibizumab for the primary end point"?** And it  
 12 goes on from there.  
 13 **Do you see that?**  
 14 **MR. MARX:** Same objection.  
 15 **BY THE WITNESS:**  
 16 **A** **I mean, sir, with all due respect, I don't**  
 17 **know how that's -- you read those words as they**  
 18 **appear from that one sentence there, but I don't**  
 19 **know anything about this study, anything about the**  
 20 **design, anything about all the other aspects that**  
 21 **are in the summary.**  
 22 **I haven't read the 15-page document. I**

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1 **don't know, like, that I'm even a person that**  
 2 **could interpret this document as a non-POSA,**  
 3 **nonscientist. So I can agree that you read a**  
 4 **truncated portion of the sentence under "Results"**  
 5 **accurately.**  
 6 **I don't know what the following**  
 7 **information is in that sentence or what the rest**  
 8 **of the article says or concludes and I just -- I**  
 9 **can't comfortably give a full and complete answer**  
 10 **to your questions without having ever seen this**  
 11 **document that is clearly beyond my knowledge and**  
 12 **expertise. I'm an economist. I'm not a**  
 13 **scientist, I'm not a POSA. I'm not a clinician.**  
 14 **So, I guess, at bottom, yes, you read**  
 15 **those words as they appear in the truncated**  
 16 **portion of that sentence.**  
 17 **BY MR. CAINE:**  
 18 **Q** I'm going to ask you another question now.  
 19 **Did you consider in forming your opinions**  
 20 **about whether Eylea's -- let's see. The opinions**  
 21 **that you expressed in Paragraph 58 of your**  
 22 **declaration, that efficacy and safety are**