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Transcript of Garnett H. Kelsoe, Ph.D.

Date: February 5, 2026
Case: Merck Sharp & Dohme LLC -v- Halozyme Inc. (PTAB)

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Halozyme EX2302
Merck v. Halozyme
PGR2025-00046

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE PATENT TRIAL AND APPEAL BOARD

MERCK SHARP & DOHME LLC, Case Nos. PGR2025-00003;

Petitioner, 00004; 00006; 00009

v.

HALOZYME INC., U.S. Patent Nos.

Patent Owner. 11,952,600; 12,018,298;

_____ 12,152,262; 12,123,035

* * * * *

ZOOM VIDEO DEPOSITION

Taken on behalf of the Patent Owner Halozyme Inc.

GARNETT H. KELSOE, Ph.D.

Chapel Hill, North Carolina

February 5, 2026

9:09 a.m.

Job No.: 619072

Reported by: Audra M. Smith, RPR, CRR, FCRR

Video by: Matthew Weedon, Videographer

Concierge: Charese Harrison and Richard Kuritz

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1 I N D E X

2 *****

3 PAGE

GARNETT H. KELSOE, Ph.D.

4

Examination By Mr. Powers 7

5

6 E X H I B I T S

7 NUMBER DESCRIPTION PAGE

8 Exhibit 2215 MF59 Adjuvant enhances 85
lDiversity and Affinity of
9 Mediated Immune Response to
Pandemic Influenza Vaccines

10

11 P R E V I O U S L Y M A R K E D E X H I B I T S

12 NUMBER PAGE

13 Exhibit 1001 38

14 Exhibit 1170 63

15 Exhibit 2114 113

16 Exhibit 2116 109

17

18

19

20

21

22

1 P R O C E E D I N G S

2 CONCIERGE HARRISON: Thank you to 09:07:56

3 everyone for attending this proceeding 09:08:02

4 remotely, which we anticipate will run 09:08:04

5 smoothly. 09:08:07

6 Please remember to speak slowly and do 09:08:09

7 your best not to talk over one another. 09:08:11

8 Please be aware that we are recording this 09:08:13

9 proceeding for backup purposes. Any 09:08:13

10 off-the-record discussions should be had away 09:08:14

11 from the computer. Please remember to mute 09:08:16

12 your mic for those conversations. 09:08:19

13 Please have your video enabled to help 09:08:20

14 the reporter identify who's speaking. If you 09:08:23

15 are unable to connect with video and are 09:08:23

16 connecting via phone, please identify 09:08:25

17 yourself each time before speaking. 09:08:28

18 I apologize in advance for any 09:08:28

19 technical-related interruptions. 09:08:31

20 Thank you. 09:08:37

21 THE VIDEOGRAPHER: Stand by for video 09:08:38

22 read-on. 09:08:38

1 Here begins Media Number 1 in the 09:08:38
2 videotaped deposition of Dr. Garnett Kelsoe 09:08:45
3 in the matter of Merck Sharp & Dohme, LLC vs. 09:08:49
4 Halozyme, Inc., in the United States Patent 09:08:55
5 and Trademark Office for the Patent Trial and 09:08:57
6 Appeal Board. Case Number PGR2025-00003, 09:08:59
7 00004, 00006, 00009. 09:09:04
8 Today's date is February 5, 2026. The 09:09:15
9 time on the video monitor is 9:09 a.m. The 09:09:19
10 remote videographer today is Richard Kuritz 09:09:23
11 representing Planet Depos. 09:09:29
12 Would counsel please voice identify 09:09:31
13 themselves and state whom they represent. 09:09:34
14 MR. POWERS: Sure. I'm Ralph Powers, 09:09:37
15 III, from Sterne, Kessler, Goldstein & Fox, 09:09:39
16 on behalf of patent owner Halozyme. With me 09:09:39
17 in the room is Tyler Liu, also with Sterne 09:09:43
18 Kessler, and Nancy Zhang from Quinn Emanuel. 09:09:43
19 Joining us on the line today, Eldora Ellison 09:09:48
20 from Sterne Kessler, Aubrey Haddach and Josh 09:09:51
21 Mack from Halozyme. 09:09:54
22 MS. WANG: And this is Sue Wang from 09:09:56

1 the law firm of Sidley Austin, here on behalf 09:09:58
2 of petitioner, Merck Sharp & Dohme, LLC. 09:10:00
3 With me today are Chelsea Himes and Amit 09:10:03
4 Bhatla, both also from the Sidley Austin law 09:10:06
5 firm. Also here for the witness, Dr. Garnett 09:10:09
6 Kelsoe. 09:10:11
7 THE VIDEOGRAPHER: The court reporter 09:10:15
8 today is Audra Smith representing Planet 09:10:16
9 Depos. 09:10:17
10 GARNETT H. KELSOE, Ph.D., 09:10:18
11 having declared under penalty of perjury to tell the truth, 09:10:18
12 the whole truth and nothing but the truth, was examined and 09:10:18
13 testified as follows: 09:10:18
14 EXAMINATION 09:10:18
15 BY MR. POWERS: 09:10:31
16 Q Good morning, Dr. Kelsoe. 09:10:31
17 A Good morning. 09:10:37
18 I'm actually -- I'm terribly sorry. I 09:10:37
19 was told to instruct the following: That there 09:10:39
20 were errors in the declaration. 09:10:43
21 Q Okay. 09:10:52
22 A And -- 09:10:53

1 Q So you have some documents prepared in 09:10:54
2 front of you? 09:10:55
3 A Yes. 09:10:58
4 Q Is that right? 09:10:58
5 A Yep. 09:10:58
6 Q Okay. So let's talk about what those 09:10:58
7 are. So I see you have a binder in front of you? 09:11:00
8 A Yes, this is my declaration. 09:11:02
9 Q Okay. I see several documents in that 09:11:03
10 binder. Can you tell me what those are, please? 09:11:05
11 A Yes. It's the declaration and the 09:11:07
12 patent. 09:11:12
13 Q When you say "declaration," there -- 09:11:13
14 A Kelsoe Declaration. 09:11:18
15 (Overlapping speakers.) 09:11:18
16 Q -- there are four declarations involved 09:11:18
17 in today's proceedings? 09:11:21
18 A Yes. 09:11:22
19 Q And we're going to go over ground 09:11:22
20 rules, but one of the things we have to be mindful 09:11:24
21 of today is to not talk over each other just so 09:11:26
22 that there's a clear record. 09:11:28

A Very good. 09:11:30
Q So let me try that question again 09:11:31
because I think we were talking over each other a 09:11:32
little bit. 09:11:34
A May I ask one favor of you? I'm 09:11:34
terribly sorry. I'm hard of hearing. If you 09:11:38
could speak up, it would be helpful. 09:11:40
Q Yes, sir, I will do that. 09:11:42
A Thank you. 09:11:43
Q If you have trouble understanding my 09:11:43
question for any reason throughout today, feel 09:11:45
free to ask me to repeat it. 09:11:47
A Yes. 09:11:49
Q Okay. So I see that there are some 09:11:49
documents in front of you. You said, I think, 09:11:50
there are some declarations in front of you. What 09:11:57
are those declarations? 09:11:59
A These are my declarations in response 09:12:01
to the patent claims, what I understand to be the 09:12:04
several patents that have been made by Halozyme. 09:12:09
Q Are those the four declarations that 09:12:15
you submitted in relation to the four PGR 09:12:16

1 proceedings we're here to talk about today? 09:12:20
2 A Yes, sir, they are. 09:12:22
3 Q Okay. And so I think we have the 09:12:25
4 exhibit numbers for those. And if you look at the 09:12:27
5 bottom right corner of each of those documents, 09:12:29
6 maybe you could say what the exhibit numbers are 09:12:32
7 there in front of you. 09:12:34
8 A The Exhibit 1134. 09:12:36
9 Q What case is that for? 09:12:42
10 A I'm terribly sorry? 09:12:43
11 Q No problem. What PGR number is that 09:12:45
12 for? 09:12:47
13 A I don't know what a PGR number is, I'm 09:12:48
14 sorry. 09:12:50
15 Q Do you know what a PGR is? 09:12:50
16 A No. 09:12:52
17 Q Okay. 09:12:52
18 A I'm an immunologist. 09:12:52
19 Q No problem. If you look at the face 09:12:55
20 page of that document, the one that you just are 09:12:57
21 on. 09:12:59
22 A Yes. Ah, yes. 09:13:03

1 Q Should have a PGR number on it. 09:13:03
2 A I beg your pardon. Yes. 09:13:05
3 Q No problem. We'll get through it. 09:13:07
4 What PGR number is there? 09:13:08
5 A This is PGR2025-00003. 09:13:08
6 Q Okay. And what exhibit number is that? 09:13:14
7 A The exhibit number is 1134. 09:13:16
8 Q And that's your declaration? 09:13:20
9 A This is my declaration. 09:13:21
10 Q Okay. If you go to the signature page 09:13:22
11 of that declaration. 09:13:26
12 A Yes. 09:13:43
13 Q Is that your signature on that page? 09:13:44
14 A That is my signature. 09:13:45
15 Q Did you sign that document? 09:13:46
16 A I did. 09:13:47
17 Q Okay. And what's the date on that? 09:13:48
18 A 20 January 2026. 09:13:51
19 Q Okay. Is that when you put in this 09:13:53
20 declaration? 09:13:55
21 A Yes. 09:13:55
22 Q Signed this declaration? 09:13:55

1 Okay. And now we've got the first one 09:13:57
2 down. There's some others, right? 09:13:59
3 A That is correct. 09:14:01
4 Q All right. Let's do the same thing for 09:14:02
5 each of the others. 09:14:03
6 A Yes. Second is case number 09:14:06
7 PGR2025-00004. Again, Exhibit 1134. 09:14:08
8 Q Okay. And your signature page? 09:14:23
9 A Signed by me on January 20, 2026. 09:14:37
10 Q Okay. Very good. Let's move to the 09:14:39
11 next one. 09:14:42
12 A PGR2025-00006, Exhibit 1134. My 09:14:49
13 signature of 20, 2026, January 2026. 09:15:09
14 Q Okay. And the next one? 09:15:13
15 A PGR number PGR2025-00009, Exhibit 1134. 09:15:15
16 And pardon me, my signature of 20 January 2026. 09:15:44
17 Q Are there any other documents -- so 09:15:51
18 we've gone through the four declarations that you 09:15:53
19 submitted in association with each of these PGRs 09:15:55
20 we're here to talk about today. Are there any 09:15:58
21 other documents in front of you that you brought 09:16:00
22 into the room? 09:16:02

1 A I have a list of errata, an errata 09:16:07
2 list. 09:16:10
3 Q Okay. Is that the list that counsel 09:16:10
4 presented me? 09:16:12
5 A Yes. 09:16:18
6 Q Okay. And let's talk about what that 09:16:18
7 errata list contains. 09:16:21
8 A It is an exchange of exhibit numbers in 09:16:25
9 the paragraph 125, Exhibit 1194, was listed to a 09:16:33
10 paper, Chowpongpang, et al., 2004, and that is now 09:16:39
11 numbered Exhibit 1150, referring to exactly the 09:16:44
12 same reference. 09:16:49
13 Q So is it true that the reference was 09:16:50
14 labeled Exhibit 1194 but it should have been 1150? 09:16:53
15 A That is correct. 09:16:58
16 Q Okay. Who discovered that error? 09:17:00
17 A The Merck Sharp Dohme counsel did. 09:17:08
18 Q Okay. And when did Merck Sharp Dohme 09:17:11
19 counsel alert you to the error? 09:17:12
20 A I was told this yesterday. 09:17:16
21 Q Okay. Any other errors that you found 09:17:19
22 in your declaration? 09:17:21

1 A It's the second error in Appendix A, 09:17:26
2 which is the same renumbering of Chowpongpang, et 09:17:30
3 al. 09:17:35
4 Q Right. So this transposition of the 09:17:35
5 exhibit number was in two places; is that right? 09:17:38
6 A That is correct. 09:17:40
7 Q Any other errors that you found in your 09:17:40
8 declarations? 09:17:42
9 A None to my knowledge. 09:17:42
10 Q Did you review declarations in 09:17:44
11 preparation for today's meeting? 09:17:46
12 A I certainly did. 09:17:48
13 Q Okay. Have you ever been deposed 09:17:48
14 before? 09:17:52
15 A Yes. 09:17:52
16 Q When was that? 09:17:53
17 A The most recent was several years ago, 09:17:56
18 five or seven years ago. 09:17:58
19 Q Any other times? 09:18:01
20 A I've been deposed twice. 09:18:03
21 Q Were those related to patent cases? 09:18:06
22 A Yes, they were. 09:18:09

1 Q What was the name of the first case you 09:18:10
2 were deposed in? 09:18:12
3 A The first -- I don't remember the name 09:18:13
4 of the first case. The first case I was a 09:18:14
5 consultant for a firm called Fish & Neave, and it 09:18:20
6 had to do with a dispute between a particular 09:18:25
7 molecule that might have had therapeutic benefit, 09:18:29
8 CD154, a costimulatory molecule. 09:18:34
9 Q Do you remember if you were on the side 09:18:39
10 of the patent owner or the patent challenger? 09:18:41
11 A I don't remember. 09:18:44
12 Q And do you remember the name of the 09:18:46
13 litigants in that case? 09:18:57
14 A I don't -- my recollection is the 09:19:06
15 litigants were two large biotech firms. I 09:19:09
16 actually -- my area of expertise was the two 09:19:12
17 individual research groups. One identified the 09:19:18
18 human form of CD154 and the other the mouse form 09:19:22
19 of CD154. 09:19:25
20 So the dispute was between the -- 09:19:27
21 who -- my understanding was, if you knew one, did 09:19:32
22 you know both. That was -- I don't know how else 09:19:36

1 to say it, but that was sort of what -- yeah. 09:19:39
2 Q Do you remember the gist of your 09:19:43
3 opinion in that case? 09:19:44
4 A My opinion was that there were 09:19:46
5 significant differences between the two 09:19:52
6 species-specific CD154s, and knowledge of one did 09:19:53
7 not guarantee knowledge of the other. 09:19:57
8 Q Was that called a "patent interference 09:20:00
9 proceeding"? 09:20:05
10 A I have no idea. 09:20:07
11 Q Do you remember if it was a District 09:20:08
12 Court proceeding? 09:20:09
13 A No. I was deposed, and later I 09:20:16
14 accompanied the lawyers from Fish & Neave to the 09:20:21
15 International Patent Office in Munich, and -- but 09:20:25
16 I wasn't called to speak there, so I don't have -- 09:20:28
17 I don't really know. 09:20:31
18 Q Was that a case proceeding in the 09:20:32
19 United States, or was that a case proceeding 09:20:34
20 abroad? 09:20:36
21 A My understanding is the original 09:20:37
22 deposition had to do with United States, and then 09:20:40

1 the later deposition had to do with international 09:20:43
2 patent. I don't really know. 09:20:47
3 Q You're -- sorry. Were you finished? 09:20:50
4 A Yes. 09:20:53
5 Q Okay. Were you deposed only once as 09:20:53
6 part of that case? 09:20:57
7 A That is correct. 09:20:58
8 Q Did you ever testify at trial as part 09:20:59
9 of that case? 09:21:01
10 A I've never testified at trial. 09:21:02
11 Q Okay. And you said you'd been deposed 09:21:04
12 twice before, right? 09:21:06
13 A Yes. 09:21:07
14 Q So that was the first time. 09:21:07
15 A Yes. 09:21:08
16 Q What was the second? What was the 09:21:08
17 second time or the other time? 09:21:09
18 A The second time was -- I was contacted 09:21:11
19 by lawyers from Morrison Foerster and was -- and I 09:21:21
20 actually don't remember the -- I don't remember 09:21:29
21 the case very well. It was. It had to do with a 09:21:35
22 protein of potential therapeutic utility, but I 09:21:49

1 think there was a question of whether or not how 09:21:53
2 the protein was discovered was somehow relevant to 09:21:57
3 this, but I just don't remember my testimony. 09:22:02
4 Q Okay. And when was that time? When 09:22:04
5 was that? 09:22:07
6 A That was the most recent, and that was 09:22:07
7 five, seven, eight years ago. 09:22:09
8 Q Okay. Somewhere between five and 09:22:12
9 eight? 09:22:14
10 A Actually, here at Duke. 09:22:14
11 Q Here in this hotel? 09:22:17
12 A Yes. 09:22:18
13 Q I see. 09:22:18
14 Did you testify at trial as part of 09:22:19
15 that case? 09:22:23
16 A No, I did not. 09:22:24
17 Q So you've been deposed twice before but 09:22:25
18 never testified at trial, right? 09:22:28
19 A That is correct. 09:22:30
20 Q Okay. So you've done this before, but 09:22:30
21 I'll go over some ground rules with you. So I'll 09:22:33
22 ask questions. Your counsel may object, but you 09:22:36

1 need to answer my question unless the instruction 09:22:42
2 is not to answer the question. Is that clear? 09:22:44
3 A That is clear. 09:22:46
4 Q All right. And as we alluded to 09:22:47
5 earlier, as you can see, this is all being taken 09:22:50
6 down by a court reporter, so it's important we 09:22:54
7 don't talk over each other. So I'll do my best 09:22:56
8 not to interrupt you, and I ask that you not 09:22:59
9 interrupt me. Is that fair? 09:23:01
10 A Yes. 09:23:03
11 Q Okay. If at any point you need a break 09:23:04
12 today, just let me know. I'll be happy to take a 09:23:08
13 break. I might just try to finish up a few more 09:23:11
14 questions, and I also ask that if I have a 09:23:14
15 question pending, you answer that before we take a 09:23:16
16 break. Is that fair? 09:23:18
17 A Yes. 09:23:20
18 Q Okay. Great. 09:23:20
19 Any reason you can't give truthful 09:23:20
20 testimony today? 09:23:24
21 A No. 09:23:25
22 Q Besides the documents that we went over 09:23:28

1 previously, is there anything else that you 09:23:30
2 brought to the deposition today? 09:23:32
3 A I have only this in my possession. 09:23:39
4 Q The four declarations? 09:23:41
5 A The four declarations, yes. 09:23:42
6 Q And the errata sheet? 09:23:42
7 A Yes, yes. 09:23:44
8 Q No other papers are in front of you? 09:23:44
9 A No, sir. 09:23:47
10 Q Okay. What did you do to prepare for 09:23:47
11 today's deposition? 09:23:49
12 A I reviewed my declaration and I was -- 09:23:54
13 I met with the Merck Sharp & Dohme attorneys 09:24:01
14 yesterday, and they helped me prepare for this. 09:24:05
15 Q Okay. About how long did you meet with 09:24:10
16 counsel? 09:24:12
17 A Yesterday? 09:24:14
18 Q Yes, sir. 09:24:15
19 A 9:00 until 5:00. 09:24:15
20 Q Okay. Did you meet with counsel in 09:24:18
21 preparation for today's deposition prior to 09:24:20
22 that -- prior to yesterday's meeting? 09:24:22

1 A We've had Zoom meetings from time to 09:24:25
2 time over the last several months. 09:24:28
3 Q In preparation for today's deposition, 09:24:32
4 did you meet with counsel -- 09:24:34
5 A Oh. 09:24:36
6 Q -- other than yesterday? 09:24:36
7 A No. 09:24:38
8 Q Okay. About how long did you spend 09:24:38
9 reading your declarations in preparation for 09:24:41
10 today's deposition? 09:24:43
11 A The two times -- I've read the 09:24:47
12 declaration twice, one prior to the signatures 09:24:51
13 to -- and corrections there. The declaration's 09:24:55
14 approximately 100 pages long. It takes me about 09:24:59
15 three and a half hours to read that carefully. 09:25:02
16 And so three and a half hours previously and three 09:25:05
17 and a half hours yesterday. 09:25:08
18 Q As part of your preparation for today's 09:25:14
19 deposition, did you look at any other documents 09:25:16
20 beyond your declaration? 09:25:19
21 A I have refreshed my memory of the 09:25:24
22 papers that I cite and the declaration as evidence 09:25:28

1 for my opinion. 09:25:31
2 Q Any documents that you didn't cite in 09:25:36
3 your declaration that you reviewed as part of your 09:25:38
4 preparation for today's deposition? 09:25:40
5 A No. 09:25:44
6 Q Now, there are four declarations that 09:25:44
7 we're going to be talking about today, and is it 09:25:46
8 fair to say that those are highly similar 09:25:49
9 declarations? 09:25:53
10 A I would say they're highly similar, 09:25:53
11 yes, sir. 09:25:55
12 Q And if there are any differences in any 09:25:55
13 of the declarations that would affect any answer 09:25:57
14 to a question today, will you let me know? 09:26:00
15 A I shall. 09:26:02
16 Q Otherwise, is it fair that we consider 09:26:03
17 the questions answered for all four of the 09:26:05
18 declarations? 09:26:08
19 A That is correct. 09:26:08
20 Q Okay. Did you talk to anyone besides 09:26:14
21 counsel regarding the substance of your deposition 09:26:16
22 today? 09:26:18

1 A I did not. 09:26:18
2 Q Do you intend to offer any new opinions 09:26:36
3 today that are not contained in your declarations? 09:26:39
4 A No. 09:26:41
5 Q And if I refer to "this case" in any of 09:26:42
6 my questions today, you'll understand me to mean 09:26:47
7 collectively the four PGR proceedings we're here 09:26:50
8 to talk about. Is that fair? 09:26:53
9 A I so understand. 09:26:55
10 Q Okay. When were you first approached 09:27:01
11 to provide a declaration in this case? 09:27:03
12 A It was sometime in October of 2025. 09:27:08
13 Q Okay. And who approached you? 09:27:11
14 A Ms. Wang and Jeff Kushan. 09:27:14
15 Q Kushan. 09:27:22
16 A Kushan, thank you. 09:27:23
17 Q And when did you start working on your 09:27:25
18 declarations in this case? 09:27:28
19 A The process for making my declaration 09:27:34
20 was to review -- I was told to review the portions 09:27:36
21 of the -- I guess the patent claim -- I don't know 09:27:44
22 the appropriate term -- that dealt with 09:27:46

1 immunocontraceptives and to read the declarations 09:27:58
2 of Dr. Moon and Dr. Sharer -- Cherr. And then 09:28:01
3 that was the initial -- my initial, I guess, 09:28:06
4 beginning of this. 09:28:12
5 Q Do you remember when that was? 09:28:13
6 A It would have been in mid-October. I 09:28:15
7 don't remember exactly. 09:28:18
8 Q How long did you spend preparing your 09:28:19
9 declaration? 09:28:23
10 A In toto? 09:28:24
11 Q Yes, sir. 09:28:26
12 A Oh, probably 60 or 70 hours. 09:28:27
13 Q And besides counsel, did you speak with 09:28:33
14 anyone in order to create your declarations? 09:28:35
15 A No, I did not. 09:28:38
16 Q Did you speak with anyone at Merck? 09:28:39
17 A Oh. No, I did not. 09:28:41
18 Q Have you ever heard of Dr. Michael 09:28:45
19 Hecht? 09:28:47
20 A Could you repeat the question? 09:28:49
21 Q Sure. 09:28:51
22 Have you ever heard of Dr. Michael 09:28:51

1 Hecht? 09:28:52
2 A I have not. Let me rephrase that. I 09:28:55
3 never met or interacted with Dr. Hecht. I don't 09:29:01
4 know who he is. 09:29:04
5 Q Have you ever heard of him? 09:29:06
6 A I can't recall. 09:29:08
7 Q Are you aware that he provided a 09:29:11
8 declaration in this case? 09:29:12
9 A No. 09:29:14
10 Q Have you ever heard of Dr. Sheldon 09:29:17
11 Park? 09:29:20
12 A No. 09:29:21
13 Q Are you aware that he provided a 09:29:21
14 declaration in these cases? 09:29:23
15 A I am not. 09:29:25
16 Q Have you ever heard of Dr. James 09:29:28
17 Naismith? 09:29:31
18 A I know the name. I don't -- I've never 09:29:35
19 met Dr. Naismith. 09:29:37
20 Q How do you know the name? 09:29:38
21 A He's a distinguished structural 09:29:40
22 biologist. 09:29:44

1 Q Are you aware that he provided a 09:29:45
2 declaration in this case? 09:29:47
3 A No. 09:29:53
4 Q Did you speak with anyone at all 09:29:57
5 besides counsel regarding your declaration in this 09:29:59
6 case? 09:30:02
7 A No. 09:30:04
8 Q Have you ever interacted with 09:30:09
9 Dr. Naismith? 09:30:11
10 A No. 09:30:12
11 Q You don't describe yourself 09:30:23
12 professionally as a reproductive biologist, right? 09:30:25
13 A I am not. 09:30:29
14 Q You're not an expert in reproductive 09:30:30
15 biology, correct? 09:30:32
16 A I'm not an expert in reproductive 09:30:32
17 biology. 09:30:34
18 Q You have no expertise in ovarian 09:30:34
19 function, right? 09:30:37
20 A I do not. 09:30:37
21 Q You have no expertise in ovulation, 09:30:38
22 right? 09:30:41

1 A No. 09:30:41
2 Q No, you don't have expertise? 09:30:46
3 A No, I don't have expertise. 09:30:47
4 Q You don't have expertise in the female 09:30:49
5 reproductive tract, right? 09:30:51
6 A No, I do not. 09:30:53
7 Q You don't have expertise in female 09:30:55
8 reproductive hormones, correct? 09:30:57
9 A I do not. 09:31:00
10 Q You have no expertise in 09:31:00
11 spermatogenesis, correct? 09:31:01
12 A Beyond my master's thesis of 09:31:05
13 spermatogenesis in cestodes, no. 09:31:07
14 Q What is a cestode? 09:31:11
15 A Cestode's a tapeworm. 09:31:12
16 Q You have no expertise in 09:31:14
17 spermatogenesis in mammals, correct? 09:31:15
18 A I do not. 09:31:19
19 Q You have no expertise in sperm function 09:31:19
20 in mammals, correct? 09:31:20
21 A At what level do you mean "no 09:31:22
22 knowledge"? 09:31:23

1 Q Oh, I didn't say "no knowledge." I 09:31:24
2 said "no expertise." 09:31:26
3 A No expertise. I do not have expertise. 09:31:28
4 Q And you're not an expert in male 09:31:30
5 reproductive hormones, correct? 09:31:32
6 A I am not. 09:31:34
7 Q You're not an expert in mammalian sperm 09:31:35
8 physiology, correct? 09:31:38
9 A I am not. 09:31:39
10 Q You're not an expert in acrosome 09:31:40
11 biology, correct? 09:31:44
12 A I am not. 09:31:45
13 Q Before being retained in this case, had 09:31:46
14 you heard of PH20? 09:31:47
15 A I have not. 09:31:50
16 Q So the first time you heard of PH20 was 09:31:51
17 after you were retained in this case; is that 09:31:53
18 correct? 09:31:55
19 A That is correct. 09:31:55
20 Q And that would have been sometime in 09:31:56
21 October 2025, right? 09:31:57
22 A Yes. 09:31:59

1 Q The first time you heard of PH20 was in 09:32:00
2 October of 2025, right? 09:32:02
3 A That is correct. 09:32:05
4 Q You're not an expert in mammalian 09:32:06
5 fertilization, correct? 09:32:09
6 A No, I am not. 09:32:10
7 Q Do you understand that fertilization is 09:32:11
8 a sequence of time-ordered biological events? 09:32:13
9 A In a general way, yes. 09:32:17
10 Q Is it your understanding that those 09:32:21
11 events must occur in a specific order? 09:32:22
12 A In a general way, yes. 09:32:25
13 Q You're not an expert in those -- in the 09:32:28
14 sequence of those molecular events required for 09:32:30
15 mammalian fertilization, correct? 09:32:35
16 A I am not. 09:32:37
17 Q If you were interested in designing an 09:32:38
18 immunocontraceptive, you would have to rely on a 09:32:47
19 reproductive physiologist or reproductive 09:32:48
20 biologist to understand the details of the 09:32:52
21 science, right? 09:32:54
22 MS. WANG: Objection to form. 09:32:55

1 A Could you repeat the question? I want 09:32:57
2 to make sure I understood it correctly. 09:32:59
3 BY MR. POWERS: 09:33:02
4 Q If you were interested in designing an 09:33:02
5 immunocontraceptive, you would have to rely on a 09:33:06
6 reproductive physiologist or reproductive 09:33:08
7 biologist to understand the details of the science 09:33:10
8 involved, right? 09:33:13
9 MS. WANG: Same objection. 09:33:16
10 A If I were -- I'm repeating because I'm 09:33:26
11 trying to work my way through the question. I beg 09:33:29
12 your pardon. 09:33:31
13 Yes. To determine -- to determine the 09:33:31
14 target of the immunocontraceptive, I would 09:33:40
15 certainly, since that lies outside of my field of 09:33:41
16 expertise, I would rely on a reproductive 09:33:43
17 biologist, yes. 09:33:49
18 BY MR. POWERS: 09:33:50
19 Q You don't describe yourself as an 09:33:50
20 expert in fertility or infertility, correct? 09:33:52
21 A That is correct. 09:33:55
22 Q And you don't describe yourself as an 09:33:56

1 expert in contraception, correct? 09:33:57
2 A That is correct. 09:34:00
3 Q You've not authored a peer-reviewed 09:34:01
4 paper about mammalian reproductive biology, 09:34:04
5 correct? 09:34:04
6 A I have not. 09:34:07
7 Q You've not authored a review article on 09:34:08
8 mammalian fertilization or sperm function, 09:34:10
9 correct? 09:34:12
10 A I have not. 09:34:13
11 Q You've not conducted fertility studies 09:34:14
12 in mammals, right? 09:34:16
13 A I have not. 09:34:17
14 Q You've not designed experiments to 09:34:19
15 study sperm-egg interaction in mammals, correct? 09:34:21
16 A I have not. 09:34:25
17 Q Do you know what an acrosome reaction 09:34:26
18 assay is? 09:34:29
19 A No. Not precisely. 09:34:30
20 Q So I bet it's fair to say you've never 09:34:33
21 performed an acrosome reaction? 09:34:35
22 A It is fair to say that, yes. 09:34:38

1 Q Do you know what a sperm motility assay 09:34:40
2 is? 09:34:42
3 A Only in general terms. 09:34:42
4 Q Have you ever -- 09:34:43
5 A Performed -- 09:34:44
6 Q Have you ever performed one? 09:34:44
7 A I have never performed a sperm motility 09:34:46
8 assay. 09:34:48
9 Q Do you know what a sperm penetration 09:34:49
10 assay is? 09:34:50
11 A I do not. 09:34:51
12 Q Have you ever performed one? 09:34:53
13 A I have not. 09:34:55
14 Q Do you know what a sperm capacitation 09:34:55
15 assay is? 09:34:58
16 A I do not. 09:34:58
17 Q Have you ever performed one? 09:34:59
18 A I have not. 09:35:00
19 Q Do you know what a Huhner test is? 09:35:02
20 A I beg your pardon. Could you repeat, 09:35:05
21 please? 09:35:07
22 Q Sure. A Huhner test? 09:35:08

1 A I do not. 09:35:09
2 Q Have you ever performed a Huhner test? 09:35:10
3 A I have not. 09:35:13
4 Q In any of the work that you've done as 09:35:23
5 a scientist, have you ever measured fertilization 09:35:25
6 outcomes? 09:35:27
7 A I have not. 09:35:28
8 Q You're not an expert in hyaluronidases, 09:35:31
9 correct? 09:35:33
10 A I am not. 09:35:35
11 Q And you've never published a paper on 09:35:38
12 PH20, right? 09:35:40
13 A I have never published a paper on PH20. 09:35:41
14 Q Let's look at your declaration. If we 09:36:00
15 go to paragraph 8 of your declaration. You can 09:36:06
16 use the one from the 003 case. 09:36:08
17 You say you relied on your "familiarity 09:36:17
18 with scientific literature in my field and further 09:36:19
19 reviewed a number of publications in developing my 09:36:23
20 analysis." 09:36:27
21 What is your field that you referred to 09:36:27
22 in that statement? 09:36:29

1 A I am an expert in antibody responses 09:36:30
2 and antibody maturation. 09:36:34
3 Q You're an immunologist? 09:36:37
4 A I'm an immunologist. 09:36:38
5 Q In that statement we just read, you 09:36:40
6 seem to imply that you relied on publications 09:36:41
7 outside of your field. Is that fair? 09:36:43
8 MS. WANG: Objection to form. 09:36:45
9 A I relied on the publications describing 09:36:47
10 the effects of PH20 vaccination in various 09:36:51
11 species, yes, and that's literature I would not 09:36:56
12 normally read. 09:36:59
13 BY MR. POWERS: 09:36:59
14 Q Because that literature is outside of 09:36:59
15 your field; is that correct? 09:37:01
16 A That literature is outside my field. 09:37:02
17 Q In paragraph 9 of your declaration, you 09:37:06
18 say: I have been asked by counsel to provide my 09:37:09
19 opinions from the perspective of a person having 09:37:11
20 ordinary skill in the art before December 30, 09:37:14
21 2011. I have also been asked -- 09:37:19
22 THE VIDEOGRAPHER: We lost you guys for 09:37:21

1 a second. I believe your guys' connection is 09:37:23
2 unstable. 09:37:25
3 (Off-the-record discussion.) 09:38:01
4 THE VIDEOGRAPHER: We're back on the 11:46:27
5 record. The time is 9:38 a.m. 09:38:05
6 BY MR. POWERS: 09:38:06
7 Q I'll repeat that question for you. 09:38:09
8 A Thank you. 09:38:11
9 Q Paragraph 9 of your declaration -- 09:38:15
10 Exhibit 1134 -- you say: I have been asked by 09:38:17
11 counsel to provide my opinions from the 09:38:22
12 perspective of a person of having ordinary skill 09:38:25
13 in the art before December 30, 2011. I have also 09:38:28
14 been asked to consider that perspective as of 09:38:33
15 December 28, 2012. 09:38:35
16 Do you see that? 09:38:37
17 A Yes. 09:38:38
18 Q And you provide two dates there, right? 09:38:40
19 A (Nonverbal response.) 09:38:43
20 Q Need a verbal answer. 09:38:45
21 A Oh, yes. I'm sorry. Yes. 09:38:46
22 Q Oh, that's one of the ground rules I 09:38:48

1 should have said. 09:38:50
2 A I beg your pardon. 09:38:51
3 Q This is being transcribed, so a verbal 09:38:52
4 answer is needed. 09:38:56
5 So you provide two dates there. Why 09:38:59
6 did you consider the perspective of a person of 09:39:01
7 ordinary skill in the arts before December 30, 09:39:03
8 2011? 09:39:07
9 A I was instructed by Merck Sharp & Dohme 09:39:08
10 counsel. 09:39:12
11 Q Do you know why that date might be 09:39:12
12 relevant? 09:39:16
13 A I don't. 09:39:16
14 Q What about December 28, 2012? 09:39:16
15 A Same answer. I was instructed, and I 09:39:18
16 don't have any relevant reason to understand why. 09:39:22
17 Q Okay. So you don't know why you 09:39:25
18 considered two different dates in forming the 09:39:30
19 opinions that you express in your declaration? 09:39:32
20 A I do not. 09:39:34
21 Q In your view, there was no development 09:39:39
22 between December 30, 2011, and December 28, 2012, 09:39:41

1 that alters any of your opinions, correct? 09:39:44
2 A Yes. That's my opinion, that there was 09:39:49
3 no -- that was there was no increase in knowledge 09:39:52
4 that would significantly alter my opinions. That 09:39:55
5 is correct. 09:39:58
6 Q There was no advance in the art that 09:39:58
7 you considered that might have changed any of your 09:40:02
8 opinions; is that right? 09:40:06
9 A In the art relevant to PH20 antibody 09:40:08
10 responses, no. 09:40:13
11 Q Do you have any experience using 09:40:15
12 techniques and tools to analyze protein structure? 09:40:17
13 A I have some limited expertise. 09:40:21
14 Q Have you ever done sequence searching 09:40:23
15 and sequence alignments at the protein level? 09:40:26
16 A Yes. 09:40:29
17 Q Have you ever used protein modeling 09:40:30
18 software? 09:40:33
19 A I have not. We use AlphaFold 3, but I 09:40:34
20 do that through a colleague who is an expert as a 09:40:38
21 bioengineer. 09:40:41
22 Q So you're not an expert in AlphaFold 3? 09:40:42

1 A In predicting, no, I am not. 09:40:46
2 Q Did you review -- you say, I believe, 09:41:10
3 in your declaration that you reviewed the '600 09:41:13
4 patent; is that right? 09:41:16
5 A Yes. 09:41:17
6 Q You understand that modified PH20 09:41:20
7 polypeptides are recited in the claims of the '600 09:41:23
8 patent, right? 09:41:26
9 A That's my understanding. Yes, that's 09:41:27
10 what I understood. 09:41:28
11 Q I'm going to hand you what's previously 09:41:37
12 been marked Exhibit 1001. 09:41:38
13 (Previously marked Exhibit Number 1001 09:41:53
14 was identified.) 09:41:53
15 BY MR. POWERS: 09:41:53
16 Q Do you recognize this document, Doctor? 09:41:53
17 A Yes. 09:41:56
18 Q What is this document? 09:41:56
19 A This is one of the patents that I was 09:41:57
20 told to inspect. 09:41:58
21 Q Which patent? Go to the second page, 09:42:00
22 you might see a number. 09:42:04

1 A Yes. This is the 6 -- the so-called 09:42:06
2 11,952,600 patent. 09:42:14
3 Q We can call that the '600 patent today? 09:42:17
4 Is that okay? 09:42:19
5 A That's fine. Thank you. 09:42:20
6 Q It's a lot easier to say. 09:42:20
7 And you reviewed the patent as part of 09:42:22
8 your work in this case, right? 09:42:26
9 A I did. 09:42:28
10 Q Do you see that the patent has column 09:42:39
11 numbers, if you look through the patent? 09:42:42
12 A I'm not an expert, but -- I don't 09:42:49
13 actually. 09:42:55
14 Q If you look at the top of the pages in 09:42:55
15 sort of the body of the patent -- 09:42:58
16 A Okay. 09:42:59
17 Q -- the column numbers. 09:42:59
18 It might be easier if we use page 09:43:02
19 numbers. 09:43:04
20 A That would be helpful for a nonexpert. 09:43:05
21 Q Those are all in the document as well 09:43:08
22 at the bottom right corner. If you go to 09:43:10

1 page 182. Actually, the very last page. 09:43:13
2 A Oh, this. 09:43:21
3 Q The end of the document. 09:43:21
4 A Oh, yes. 09:43:28
5 Q And did you previously review the 09:43:29
6 claims of this patent? 09:43:31
7 A Only those claims related to the use of 09:43:33
8 PH20 variants as an immunocontraceptive. 09:43:37
9 Q Did you review claim 1 of this patent? 09:43:40
10 A If that -- I don't remember what 09:43:46
11 claim 1 is, but if I -- whatever claim I reviewed 09:43:47
12 only dealt with the contraceptive function of the 09:43:52
13 potential contraceptive function of PH20 09:43:57
14 immunogen. 09:44:00
15 Q Can you take your time and tell me 09:44:01
16 which claim that is in the '600 patent? Which 09:44:04
17 claim that you reviewed? 09:44:10
18 A What is this? 09:44:38
19 (Sotto voce reading.) 09:45:38
20 Q I'll withdraw the question. 09:45:41
21 A Yes. 09:45:43
22 Q So you told me that you reviewed the 09:45:43

1 '600 patent and you reviewed at least some of the 09:45:46
2 claims. Is that fair? 09:45:48
3 A Yes. 09:45:49
4 MS. WANG: Objection to form. 09:45:50
5 BY MR. POWERS: 09:45:51
6 Q And I'd like you to review claim 1 of 09:45:51
7 the '600 patent and tell me if claim 1 requires 09:45:56
8 the modified PH20 polypeptides to contain any 09:46:00
9 hyaluronidase activity? 09:46:04
10 MS. WANG: Objection to form and scope. 09:46:08
11 A It does not. It simply claims 09:46:09
12 95 percent identity. 09:46:33
13 Q There's no -- 09:46:35
14 (Stenographer requested clarification.) 09:46:35
15 A It does not. It claims 95 percent 09:46:35
16 identity. 09:46:35
17 BY MR. POWERS: 09:46:36
18 Q There's no activity requirement in the 09:46:36
19 claim, right? 09:46:38
20 MS. WANG: Objection to form and scope. 09:46:39
21 A That is the claim, that's correct. 09:46:42
22 BY MR. POWERS: 09:46:44

1 Q Okay. Let's see the next patent, 09:46:44
2 please. Doctor, I'm going to hand you what's been 09:46:53
3 previously marked Exhibit 1001, the 0004 case, 09:47:02
4 we're going to just do the same exercise with 09:47:12
5 respect to claim 1. 09:47:17
6 A Uh-huh. 09:47:20
7 Q Is it your understanding that the 09:47:24
8 specification between -- among all the patents at 09:47:25
9 issue today is the same? 09:47:29
10 A Yes, that is correct. 09:47:29
11 Q The claims differ, right? 09:47:34
12 A Modestly so, but yes. 09:47:35
13 Q And so I'd like you to read claim 1. 09:47:39
14 First of all, do you recognize this document in 09:47:48
15 front of you? 09:47:50
16 A I do. 09:47:50
17 Q And what is this document? 09:47:50
18 A This is either a patent or a patent 09:47:51
19 application. I don't know the difference. This 09:47:53
20 is the -- one of the patents to the '298 patent of 09:48:03
21 the utility of PH20. 09:48:05
22 Q Right. It's the '298 patent we can 09:48:07

1 call it today? 09:48:09
2 A Yes, sir. 09:48:10
3 Q Okay. And if you look at claim 1 -- 09:48:11
4 first of all, you reviewed the claims of the '298 09:48:14
5 patent, right? 09:48:16
6 A That is correct. 09:48:17
7 Q And if you look at claim 1 of the '298 09:48:19
8 patent, can I tell me if that claim requires any 09:48:22
9 hyaluronidase activity? 09:48:31
10 MS. WANG: Objection to form and scope. 09:48:35
11 A No. Claim 1 simply establishes a 09:48:47
12 series of polypeptides that -- I beg your 09:48:52
13 pardon -- have 95 percent sequence identity to the 09:48:56
14 parental PH20 -- modified PH20 polypeptide. 09:49:01
15 BY MR. POWERS: 09:49:08
16 Q So it claims a structure, correct? 09:49:08
17 MS. WANG: Objection to form and scope. 09:49:15
18 A Could you repeat that, please? 09:49:17
19 BY MR. POWERS: 09:49:18
20 Q The claim claims a structure? 09:49:18
21 A It does not claim a structure. It 09:49:20
22 claims amino acid sequence. 09:49:23

1 Q A sequence, I see. 09:49:25
2 But there's no requirement for any 09:49:27
3 hyaluronidase activity, right? 09:49:37
4 A No. 09:49:38
5 MS. WANG: Objection to form and scope. 09:49:39
6 A I do not see that in claim 1. 09:49:41
7 BY MR. POWERS: 09:49:43
8 Q Okay. I'm going to hand you the next 09:49:43
9 patent. 09:49:46
10 A Thank you. 09:49:58
11 Q And this has been previously marked 09:49:58
12 Exhibit 1001 in the 0006 case. 09:50:00
13 A Uh-huh. 09:50:08
14 MR. POWERS: I'm getting a message to 09:50:14
15 go off the record to fix a technical issue 09:50:15
16 with the video. 09:50:17
17 THE WITNESS: All right. 09:50:20
18 THE STENOGRAPHER: Okay. Off the 09:50:20
19 record at 9:50 a.m. 09:50:21
20 (Whereupon, a brief recess was taken.) 10:07:49
21 THE VIDEOGRAPHER: We are back on the 10:10:59
22 record. The time is 10:11. 10:11:08

1 BY MR. POWERS: 10:11:10
2 Q Welcome back, Dr. Kelsoe. 10:11:10
3 A Thank you. 10:11:13
4 Q Sorry about that technical 10:11:14
5 interruption. Did you speak to counsel during the 10:11:15
6 break? 10:11:18
7 A I did. 10:11:20
8 Q Did you speak about the substance of 10:11:21
9 your testimony today? 10:11:23
10 A I did not. 10:11:24
11 Q What did you speak about? 10:11:25
12 A How nice this room looks. 10:11:29
13 Q I agree. It's nice. 10:11:32
14 I think before we left I had just 10:11:33
15 handed you a document that is marked Exhibit 1001 10:11:38
16 in the 0006 case. Do you have that document in 10:11:43
17 front of you still? 10:11:49
18 A 1001. Yes. This is the patent. This 10:11:51
19 '262, and this is '298, and this is -- 10:12:06
20 Q It should be the '600 there. 10:12:18
21 A '600. 10:12:20
22 Q Yes. If we go back to '262, that's the 10:12:21

1 document that I want to ask you about. 10:12:24
2 A I beg your pardon. 10:12:26
3 Q Now, that's the third of -- 10:12:30
4 A '298. 10:12:30
5 Q -- the four patents. 10:12:30
6 A Yes. I'm sorry. '262. 10:12:33
7 Q Okay. And you reviewed this patent in 10:12:34
8 association with preparation of your declarations, 10:12:36
9 right? 10:12:39
10 A In the aspects that were relevant to my 10:12:40
11 testimony, yes. 10:12:43
12 Q And you say in your declaration that 10:12:45
13 you reviewed the claims of the patent, too, right? 10:12:49
14 MS. WANG: Objection to form. 10:12:57
15 A Could you direct me to where in my 10:13:01
16 declaration I say that I've reviewed the claims? 10:13:05
17 BY MR. POWERS: 10:13:09
18 Q If you go to paragraph 15 of your 10:13:09
19 declaration. 10:13:11
20 A Okay. 10:13:12
21 Yes. 10:13:19
22 Q And so you reviewed the claims of the 10:13:20

1 patent, right? 10:13:22
2 MS. WANG: Objection to form. 10:13:23
3 A I looked -- well, I mean, I think 10:13:31
4 paragraph 15 is pretty clear. I looked at the -- 10:13:33
5 my understanding is, is that I have commented on 10:13:44
6 and my declaration states that I was focusing on 10:13:50
7 the utility of the variant PH20 polypeptides as a 10:13:54
8 successful immunogen. 10:14:01
9 BY MR. POWERS: 10:14:04
10 Q Would you take a look at claim 1 of the 10:14:04
11 '262 patent for me, please? 10:14:07
12 A Make sure I'm going to the right one 10:14:15
13 here. 10:14:16
14 Q As we did with the previous claims that 10:14:16
15 we talked about today, can you confirm that 10:14:19
16 claim 1 does not require the modified PH20 10:14:23
17 polypeptide to contain any hyaluronidase activity? 10:14:27
18 MS. WANG: Objection to form, scope. 10:14:31
19 A My reading says that's not stated. 10:14:33
20 It's just a series of amino acid sequence 10:14:35
21 variability. 10:14:40
22 BY MR. POWERS: 10:14:40

1 Q So you don't read claim 1 to require 10:14:40
2 any hyaluronidase activity, right? 10:14:44
3 MS. WANG: Objection to form, scope. 10:14:45
4 A To the best of my understanding, no. 10:14:47
5 BY MR. POWERS: 10:14:49
6 Q Can you set that aside? Let's look at 10:14:49
7 the fourth patent. 10:14:52
8 A Thank you. 10:14:54
9 BY MR. POWERS: 10:15:12
10 Q I just handed you what's been 10:15:12
11 previously marked Exhibit 1001 in the 00009 PGR. 10:15:14
12 Do you have the document in front of 10:15:19
13 you? 10:15:22
14 A Yes, I do. 10:15:23
15 Q And have you seen this document before? 10:15:23
16 A Yes. 10:15:27
17 Q What is this document? 10:15:27
18 A This is the patent regarding the PH20 10:15:29
19 polypeptide. 10:15:39
20 Q It's the '035 patent, right? 10:15:39
21 A Yes. 10:15:42
22 Q And you reviewed this document before 10:15:43

1 signing your declaration? 10:15:45
2 A Those sections relative to what my 10:15:46
3 testimony is about, yes. 10:15:51
4 Q And if you look at the claims of this 10:15:52
5 patent -- so back to the end of the patent on the 10:15:55
6 second-to-last page. 10:15:58
7 A Uh-huh. 10:15:59
8 Q It's going to start. I'm going to ask 10:15:59
9 you the same question about claim 1 of this 10:16:04
10 patent. Take a moment to review that claim, and 10:16:08
11 please let me know if there's any requirement for 10:16:10
12 the recited modified PH20 polypeptides to contain 10:16:13
13 hyaluronidase activity? 10:16:17
14 MS. WANG: Objection to form, scope. 10:16:20
15 A There is none. 10:16:22
16 BY MR. POWERS: 10:16:22
17 Q So there's no requirement for 10:16:22
18 hyaluronidase activity in claim 1 of the 10:16:26
19 '035 patent, right? 10:16:28
20 MS. WANG: Objection to form. 10:16:29
21 A My understanding, claim 1 does not 10:16:30
22 address whether or not hyaluronidase activity is 10:16:32

1 present. 10:16:37
2 BY MR. POWERS: 10:16:42
3 Q Thank you. You can set that aside. 10:16:42
4 Dr. Kelsoe, what's a monoclonal 10:16:44
5 antibody? 10:16:54
6 A Monoclonal antibody is the product of 10:16:55
7 the single B cell that is traditionally generated 10:16:59
8 by fusion of an active B cell with a myeloma line 10:17:03
9 or, more usually now, an antibody that is made as 10:17:15
10 recombinant protein and expressed in a cell line. 10:17:19
11 Q Monoclonal antibodies have been widely 10:17:23
12 used in biomedical research for decades, right? 10:17:27
13 A That's correct. 10:17:30
14 Q What are monoclonal antibodies useful 10:17:31
15 for? 10:17:36
16 MS. WANG: Objection to form. 10:17:36
17 A Monoclonal antibodies have a lot of 10:17:39
18 use. The biggest use, from my perspective, is 10:17:41
19 they got a Nobel Prize for two of my friends. But 10:17:43
20 they're useful in diagnostics. They're useful in 10:17:49
21 therapeutics. 10:17:52
22 BY MR. POWERS: 10:17:53

1 Q When was that Nobel Prize awarded? 10:17:53
2 A It must have been in the 1990s. I 10:17:57
3 don't remember when. 10:18:00
4 Q What was the breakthrough that led to 10:18:01
5 that Nobel Prize? 10:18:03
6 A Georges K hler trying to see if he 10:18:06
7 could get antibodies produced by fusion between 10:18:09
8 these two cells in Cesar Milstein's lab. 10:18:12
9 Q A hybridoma in a B cell? 10:18:14
10 A Yes. 10:18:17
11 Q And obviously it worked? 10:18:17
12 A Worked very well, yes. 10:18:18
13 Q And that research was conducted when? 10:18:20
14 A Cambridge University. 10:18:25
15 Q Oh, I'm sorry, when? When was that 10:18:26
16 research? 10:18:27
17 A When? That would have been -- for me 10:18:27
18 it's a long time ago. In the late 1970s, early 10:18:32
19 1980s, yes. 10:18:35
20 Q And you mentioned earlier that 10:18:37
21 monoclonal antibodies are useful for diagnostics. 10:18:41
22 Can you elaborate on that a little bit? 10:18:44

1 MS. WANG: Objection to form. 10:18:47
2 A Yes. Monoclonal antibodies are used, 10:18:47
3 for example, in histology for labeling tissue 10:18:51
4 sections for antigens associated with tumors. 10:18:56
5 They are useful in diagnosis of particular kinds 10:19:01
6 of pathogens. They're useful for the 10:19:05
7 identification of cell products appropriated in 10:19:08
8 appropriate places. 10:19:15
9 BY MR. POWERS: 10:19:15
10 Q You mentioned also that monoclonal 10:19:15
11 antibodies are useful as therapeutic agents? 10:19:18
12 A That is correct. 10:19:21
13 Q Can you elaborate on that a little bit 10:19:22
14 more? 10:19:23
15 MS. WANG: Objection to form. 10:19:25
16 A All right. The passive administration 10:19:26
17 of monoclonal antibodies have been used most, I 10:19:30
18 guess, interestingly as a therapeutic for 10:19:35
19 snakebite. The snakebite venoms can be 10:19:43
20 neutralized by monoclonal antibodies, decreasing 10:19:49
21 the damage done by the -- by the toxins, by the 10:19:52
22 venom toxins. 10:19:54

1 BY MR. POWERS: 10:19:56
2 Q Are there any other uses, therapeutic 10:19:56
3 uses for monoclonal antibodies? 10:19:58
4 A Oh, there are many. But most famously 10:20:00
5 and most recently the costimulatory molecules PDL1 10:20:03
6 CTLA4 -- 10:20:11
7 (Stenographer requested clarification.) 10:20:11
8 A PDL1. Antibodies for PDL1, antibodies 11:46:27
9 for CTLA4. These antibodies are significant in 10:20:16
10 terms of reordering the immune status of people 10:20:21
11 with either chronic infection or with tumors. 10:20:26
12 BY MR. POWERS: 10:20:28
13 Q Are monoclonal antibodies useful as 10:20:31
14 research tools? 10:20:34
15 A They are highly useful. 10:20:35
16 Q What kind of research tools can be used 10:20:36
17 with monoclonal antibodies? 10:20:38
18 A What kind of research? 10:20:41
19 Q Yes. 10:20:42
20 A Just about everything except physics. 10:20:43
21 Q Well, are monoclonal antibodies used 10:20:48
22 frequently by molecular biologists in their 10:20:51

1 research? 10:20:54
2 A Molecular biologists do, yes, use 10:20:56
3 monoclonal antibodies. 10:20:59
4 Q What kind of assays are these 10:21:01
5 monoclonal antibodies useful for? 10:21:03
6 MS. WANG: Objection to form. 10:21:05
7 A I don't quite -- the question is rather 10:21:06
8 broad, so could you -- could you be specific? 10:21:08
9 BY MR. POWERS: 10:21:11
10 Q Well, do monoclonal antibodies have 10:21:11
11 broad use in research? 10:21:13
12 MS. WANG: Objection to form. 10:21:15
13 A Yes, they do. 10:21:16
14 BY MR. POWERS: 10:21:17
15 Q Can you give me some specific examples 10:21:17
16 of how monoclonal antibodies are useful as 10:21:20
17 research tools? 10:21:23
18 A Yes. Monoclonal antibodies are 10:21:24
19 routinely used, for example, in transplantation to 10:21:25
20 identify the specific -- the specific MAC types of 10:21:31
21 the transplantee and the donor. 10:21:39
22 Monoclonal antibodies, as I mentioned, 10:21:41

1 are used in pathology regularly to diagnose and to 10:21:43
2 understand pathologic conditions. 10:21:47
3 Immunologists use monoclonal antibodies 10:21:50
4 routinely to measure other antibodies, for 10:21:54
5 example, the presence and location of antigen, or 10:21:56
6 to type the kinds of lymphocytes that are 10:22:00
7 recovered from secondary lymphoid tissues. 10:22:04
8 Q Is it fair to say that monoclonal 10:22:08
9 antibodies are useful to bind proteins? 10:22:09
10 A The great majority of useful monoclonal 10:22:14
11 antibodies are probably directed towards protein. 10:22:17
12 Q And that can be also -- yeah -- to 10:22:20
13 detect proteins? 10:22:22
14 A And to detect protein, yes. 10:22:24
15 Q Can monoclonal antibodies be useful to 10:22:28
16 neutralize biological targets? 10:22:30
17 A Yes. Monoclonal antibodies are used, 10:22:34
18 at least experimentally, as protective agents 10:22:36
19 against certain infections. 10:22:44
20 Monoclonal antibodies, as I've already 10:22:47
21 said, are useful for snake venom and are 10:22:50
22 administered in such a way. 10:22:54

1 Q Are monoclonal antibodies useful for 10:22:56
2 immunoassays? 10:22:59
3 A Monoclonal antibodies are critical in 10:23:02
4 immunoassays, yes. 10:23:03
5 Q Are they useful for western blots? 10:23:05
6 A Some antibodies are useful for western 10:23:10
7 blots. Some antibodies are not, monoclonal or 10:23:13
8 otherwise. 10:23:15
9 Q Right. How -- in, let's say, 10:23:16
10 December 11, 2012, how did one go about generating 10:23:26
11 monoclonal antibodies? 10:23:31
12 MS. WANG: Objection to form. 10:23:33
13 A At that time, the great majority of 10:23:36
14 monoclonal antibodies were made by the 10:23:38
15 immunization of an animal. At the time, rabbit 10:23:40
16 serum, hamster, and mouse were the predominant 10:23:44
17 three animals. The activated B cells were 10:23:47
18 removed, and under conditions that allows membrane 10:23:53
19 fusion, fused with myeloma cell line. 10:23:57
20 There's a selection step. The myeloma 10:24:01
21 cell line carries a drug marker that allows the 10:24:02
22 fused cells to survive. And one then screens the 10:24:07

1 clones that grow out for antigen specificity 10:24:14
2 isotype, that sort of thing. 10:24:18
3 BY MR. POWERS: 10:24:21
4 Q That was a process that led to the 10:24:21
5 Nobel Prize that you talked about, right? 10:24:23
6 A That is correct. 10:24:26
7 Q And that research was published in the 10:24:26
8 '70s and '80s? 10:24:28
9 A Yes. That's the -- well -- by the time 10:24:30
10 of the 1980s, hybridoma technology was a new and 10:24:33
11 growing thing, yes. 10:24:40
12 Q So by 2011, 2012, generating a 10:24:42
13 monoclonal antibody was considered routine 10:24:46
14 laboratory work, right? 10:24:50
15 MS. WANG: Objection to form. 10:24:52
16 A I mean, it would -- there would be 10:24:53
17 nothing novel. It may not be routine, but there 10:24:54
18 would be nothing novel in making a monoclonal 10:24:57
19 antibody in 2011. 10:25:01
20 BY MR. POWERS: 10:25:03
21 Q A person of ordinary skill in the art 10:25:03
22 would know how to generate monoclonal antibodies 10:25:04

1 in 2012? 10:25:07
2 A In principle, yes. 10:25:08
3 Q There were commercially available 10:25:09
4 services that generated monoclonal antibodies by 10:25:10
5 2012, right? 10:25:15
6 A That is correct. 10:25:16
7 Q Would you agree that monoclonal 10:25:16
8 antibodies, in their creation, was a mature and 10:25:18
9 established technology by December 2011? 10:25:20
10 MS. WANG: Objection to form. 10:25:23
11 A In 2011, was it a -- yes, I do, yes. 10:25:28
12 BY MR. POWERS: 10:25:30
13 Q You're familiar with the AIRE pathway, 10:25:30
14 right? The AIRE -- 10:25:46
15 A AIRE, yes, uh-huh, I am familiar. 10:25:50
16 Q And that refers to an autoimmune 10:25:52
17 regulator; is that right? 10:25:56
18 A That is correct. 10:25:57
19 Q And AIRE is expressed in medullary 10:25:58
20 thymic epithelial cells, right? 10:26:01
21 A That is correct. May I -- 10:26:06
22 Q Yes. 10:26:08

1 A -- extend? 10:26:08
2 Q Please. 10:26:08
3 A It's expressed in several tissues, but 10:26:09
4 its importance in T cell -- 10:26:12
5 Q Tolerance? 10:26:14
6 A -- maturation and tolerance occurs 10:26:15
7 solely in the thymus. 10:26:18
8 Q Okay. You referred to it just a second 10:26:21
9 ago, but AIRE's role is to promote thymic 10:26:23
10 expression of certain peripheral tissue antigens, 10:26:25
11 correct? 10:26:30
12 A That is correct. 10:26:30
13 Q And that thymic expression enables 10:26:31
14 central T-cell tolerance if the protein is 10:26:34
15 expressed in the medullar thymic epithelial cells, 10:26:37
16 correct? 10:26:45
17 A Yes. Although, AIRE doesn't always 10:26:45
18 express the entire protein, but probably only 10:26:47
19 individual exons. 10:26:50
20 Q Okay. 10:26:52
21 A So one gets short products rather than 10:26:52
22 the entire protein. 10:26:55

1 Q But the protein has to be expressed in 10:26:57
2 order to be tolerized by AIRE? 10:26:59
3 A That is correct. 10:27:01
4 Q Some part of the -- 10:27:02
5 A Some fraction of it, yes. 10:27:04
6 Q Do you agree that not all 10:27:08
7 tissue-specific antigens are regulated by AIRE? 10:27:09
8 A I don't know that they're not regulated 10:27:17
9 by AIRE. There are 33,000-some-odd proteins in 10:27:18
10 the average animal, and to say that exhaustively 10:27:22
11 it has been excluded, I -- that, I don't know. 10:27:27
12 We do know from the papers referenced 10:27:30
13 that many protein fragments that are not normally 10:27:37
14 expressed are expressed later in life, 10:27:42
15 postadolescence, are expressed in the thymus. But 10:27:45
16 exhaustively I do not know that every, every 10:27:50
17 protein is expressed there. 10:27:52
18 Q So certain proteins are probably not 10:27:57
19 expressed by AIRE, right? 10:28:00
20 MS. WANG: Objection to form. 10:28:01
21 A I cannot agree with that. I don't -- I 10:28:02
22 simply don't know whether they are or they are 10:28:03

1 not. 10:28:05
2 BY MR. POWERS: 10:28:06
3 Q I see. 10:28:06
4 You don't know one way or the other 10:28:06
5 whether a protein is expressed by AIRE or not? 10:28:08
6 A I do know that many proteins are. I do 10:28:10
7 not know that a specific protein is. 10:28:13
8 Q I see. 10:28:14
9 You don't cite any study in your 10:28:15
10 declaration showing that PH20 is expressed by 10:28:18
11 AIRE? 10:28:20
12 A I do not. 10:28:21
13 Q And in your declaration, you don't cite 10:28:23
14 any data showing that PH20 is expressed in the 10:28:25
15 thymus, right? 10:28:28
16 A I do not. 10:28:29
17 Q Demonstrating AIRE mediation requires 10:28:33
18 evidence of thymic expression; don't you agree? 10:28:35
19 MS. WANG: Objection to form. 10:28:38
20 A Could you repeat? I'm sorry. Couldn't 10:28:39
21 hear that. 10:28:41
22 BY MR. POWERS: 10:28:41

1 Q Sure. 10:28:41
2 Demonstrating AIRE-mediated tolerance 10:28:42
3 requires evidence of thymic expression, correct? 10:28:45
4 MS. WANG: Objection to form. 10:28:51
5 A No. Simply because we know that T 10:28:56
6 cells are tolerant to many, many, many peripheral 10:28:58
7 antigens without identifying them individually in 10:29:04
8 the thymus. There are potential exceptions. And 10:29:06
9 those T cells should not be tolerant, or we would 10:29:12
10 not have T regulatory cells for them. Two 10:29:16
11 different pathways. 10:29:20
12 That's all I can say. You would not 10:29:21
13 have to demonstrate it. What you would want to 10:29:26
14 show is that peripheral T cells in, for example, a 10:29:31
15 preadolescent, pre -- before sperm is produced, 10:29:37
16 those T cells -- if those T cells were tolerant to 10:29:42
17 a cell pathogen, then one would presume that the 10:29:44
18 associated antigens were at least, in part, 10:29:48
19 expressed in the thymus. 10:29:50
20 BY MR. POWERS: 10:29:53
21 Q I see. But sitting here today, you 10:29:53
22 have no data that indicate that any fragment of 10:29:54

1 PH20 or PH20 as a whole is expressed in thymus, 10:29:58
2 right? 10:30:01
3 A I do not. 10:30:02
4 Q Dr. Kelsoe, I'm going to hand you 10:30:30
5 what's previously been marked as Exhibit 1170. 10:30:32
6 A Thank you. 10:30:36
7 (Previously marked Exhibit Number 1170 10:30:36
8 was identified.) 10:30:36
9 BY MR. POWERS: 10:30:37
10 Q Now, you cite 1170 in your declaration, 10:30:37
11 right? 10:30:49
12 A Yes. 10:30:50
13 Q What is 1170? 10:30:52
14 A 1170 is the standard textbook for 10:30:56
15 immunology, Janeway's Immunobiology. 10:30:59
16 Q I think I remember it from undergrad. 10:31:04
17 Let's go to page 313. To be clear, 10:31:07
18 that's 313, based on Janeway's numbers, which are 10:31:19
19 on the top. 10:31:22
20 A Ah, okay. 10:31:22
21 Q -- in a moment. 10:31:22
22 A Okay. They're irregularly -- actually, 10:31:22

1 I can't find the Janeway numbers, so could you 10:31:22
2 give me the -- 10:31:37
3 Q Yes, just a moment. 10:31:43
4 A Thank you. 10:31:49
5 Q Happy to. 10:31:49
6 A 128, 127. 10:31:49
7 Q It's page 110. 10:31:50
8 A Yes. 10:32:04
9 Q Get into the exhibit number now. 10:32:06
10 A Yes. 10:32:06
11 Q If you go to the second full paragraph 10:32:06
12 of that page, it states: It is unlikely that all 10:32:14
13 possible self-antigens -- I'm sorry. I'll start 10:32:20
14 over. 10:32:23
15 It is unlikely that all possible 10:32:23
16 self-proteins are expressed in the thymus. Thus, 10:32:25
17 negative selection of the thymus may not remove 10:32:30
18 all T cells reactive to self-antigens that appear 10:32:32
19 exclusively in other tissues or are expressed at 10:32:36
20 different stages of development. 10:32:39
21 Do you see that? 10:32:41
22 A Yes, I do. 10:32:41

1 Q So this reference that you cited is 10:32:44
2 saying that not all self-proteins are expressed in 10:32:46
3 the thymus, right? 10:32:48
4 MS. WANG: Objection to form. 10:32:50
5 A They say that it is unlikely that not 10:32:51
6 all protein -- not all possible 33,000 10:32:52
7 polypeptides are expressed on the thymus; that is 10:32:59
8 correct. 10:33:02
9 BY MR. POWERS: 10:33:02
10 Q And, therefore, the AIRE pathway would 10:33:02
11 not apply to antigens that appear in other 10:33:04
12 tissues, are express -- or are expressed at 10:33:06
13 different stages of development, right? 10:33:07
14 MS. WANG: Objection to form. 10:33:10
15 A Well, so it goes on to say that later 10:33:10
16 there are other peripheral regulatory mechanisms, 10:33:19
17 T regulatory cells that minimize any loss of the 10:33:21
18 thymus. But, yes, it's perfectly -- it's unlikely 10:33:26
19 that every polypeptide is expressed in the thymus, 10:33:31
20 and I'm sure that's what my declaration states. 10:33:34
21 BY MR. POWERS: 10:33:37
22 Q But you're aware, sitting here today, 10:33:37

1 of no evidence showing expression of PH20 in the 10:33:41
2 thymus, right? 10:33:43
3 A Well, the evidence that there is -- no. 10:33:51
4 I'm sorry. Yes. There is no evidence of -- 10:33:56
5 direct evidence of PH20 expression in the thymus; 10:34:00
6 that is correct. 10:34:03
7 Q Okay. You can set this document aside. 10:34:03
8 A Okay. 10:34:06
9 Q You are familiar with vaccine 10:34:07
10 adjuvants, right? 10:34:11
11 A Yes, I am. 10:34:12
12 Q What's the role of adjuvant in vaccine 10:34:12
13 formulation? 10:34:15
14 MS. WANG: Objection to form. 10:34:16
15 A An adjuvant is an analog of an 10:34:17
16 inflammatory response, normally mediated by either 10:34:21
17 pathogen structures called PAMPs or 10:34:24
18 self-structures, damaged structures called DAMPs. 10:34:29
19 Because it activates the innate immune response, 10:34:33
20 it amplifies, generally, immune responses. 10:34:37
21 BY MR. POWERS: 10:34:42
22 Q So just to put it in simple plain 10:34:42

1 English, what does an adjuvant do in a vaccine? 10:34:44
2 A An adjuvant increases the amount of the 10:34:51
3 response -- the size of the -- the magnitude of 10:34:54
4 the response. 10:34:56
5 Q Would you agree that adjuvants were 10:34:58
6 widely used before 2012? 10:34:59
7 A Yes. 10:35:01
8 Q Would you agree that adjuvants are 10:35:04
9 capable of breaking tolerance? 10:35:06
10 A Not all adjuvants are easily capable of 10:35:10
11 breaking tolerance. The most inflammatory 10:35:14
12 adjuvants are, the famously complete Freund's is 10:35:17
13 very good at this. 10:35:27
14 (Stenographer requested clarification.) 10:35:27
15 A A complete Freund's adjuvant. 10:21:57
16 But any adjuvant does promote the 10:35:28
17 capacity to break tolerance, yes. 10:35:35
18 BY MR. POWERS: 10:35:39
19 Q Before December 2012, 2011, antigens -- 10:35:39
20 sorry. Strike that. 10:35:44
21 Before December 2011, 2012, adjuvants 10:35:45
22 were known that were capable of breaking 10:35:51

1 tolerance, right? 10:35:55
2 A That is correct. 10:35:56
3 Q PH20 is a sperm-specific protein, 10:36:13
4 correct? 10:36:15
5 A Yes, it is. 10:36:17
6 Q Females do not produce sperm, correct? 10:36:20
7 A They do not. 10:36:23
8 Q Therefore, PH20 is not expressed in 10:36:26
9 females, correct? 10:36:29
10 MS. WANG: Objection to form. 10:36:32
11 A The mature form of the protein cannot 10:36:33
12 be expressed in females. That is correct. 10:36:35
13 BY MR. POWERS: 10:36:40
14 Q There's no form of PH20 that's 10:36:40
15 expressed in females, correct? 10:36:45
16 A Only if AIRE does not activate 10:36:47
17 expression of PH20 in the thymus. 10:36:48
18 Q Which you have no data for, right? 10:36:52
19 A Which I do not have data for. 10:36:53
20 Q Okay. Let's go back to your 10:36:55
21 declaration, paragraph 90. 10:37:04
22 A 9-0? 10:37:08

1 Q Yes, sir. 10:37:09
2 A Yes. 10:37:17
3 Q I see -- Okay. So had you heard of 10:37:21
4 DEFB126 before reading Dr. Cherr's declaration? 10:37:27
5 A I don't know what you said. 10:37:32
6 Q No problem. 10:37:33
7 Had you heard of DEFB126 before reading 10:37:34
8 Dr. Cherr's declaration? 10:37:40
9 A I have not. 10:37:42
10 Q Would you agree with me that sperm is 10:37:43
11 coated with a glycol protein called DEFB126? 10:37:46
12 A I have no knowledge of that. I would 10:37:53
13 have to review Dr. Cherr's statements. 10:37:55
14 Q Do you understand that DEFB126 is 10:38:00
15 linked to negatively charged oligosaccharides that 10:38:03
16 facilitate sperm movement and cloak sperm from 10:38:07
17 immune surveillance of the female reproductive 10:38:10
18 tract? 10:38:13
19 A Again, I would have to review 10:38:14
20 Dr. Cherr's statement in this. 10:38:15
21 Q Do you have any understanding that 10:38:22
22 because sperm is coated by DEFB126, it's not 10:38:24

1 considered a foreign invading cell? 10:38:27
2 A Well, I will say that -- I can't answer 10:38:32
3 it because I have no real knowledge of the 10:38:50
4 particular agent in mind. On the other hand, 10:38:52
5 there are a large number of women -- fortunately, 10:38:59
6 the antisperm antibodies in many women are not 10:39:02
7 functionally contraceptive -- some are, some are 10:39:09
8 not. And so somehow these individuals became 10:39:13
9 sensitized to sperm. 10:39:15
10 Q Do you agree that antibody binding to 10:39:21
11 sperm is a significant cause of infertility in 10:39:25
12 women? 10:39:28
13 MS. WANG: Objection to form. 10:39:29
14 A I'm told that there are -- I don't know 10:39:32
15 what the frequencies are because I'm not a 10:39:33
16 reproductive biologist, but I know that there is 10:39:37
17 an association. I think it's only an association 10:39:38
18 between women with antibodies to sperm and reduced 10:39:42
19 fertility, yes. 10:39:49
20 BY MR. POWERS: 10:39:52
21 Q Do you agree that a larger protein is 10:39:52
22 going to have more epitopes than a smaller protein 10:40:22

1 as a general matter? 10:40:25
2 MS. WANG: Objection to form. 10:40:27
3 A In the general sense, yes. 10:40:29
4 BY MR. POWERS: 10:40:33
5 Q In 2011, would a person of ordinary 10:40:33
6 skill in the art have appreciated that? 10:40:36
7 A Yes, they would. 10:40:38
8 Q If you go to paragraph 34 of your 10:40:53
9 declaration. 10:40:57
10 A Could you repeat the page number again, 10:40:57
11 please? 10:40:59
12 Q Yes, sir. 34. 10:40:59
13 A 34. 10:41:01
14 Q Paragraph 34. 10:41:02
15 A Oh. All right. 10:41:05
16 Yes. 10:41:19
17 Q Okay. And that chart is from Janeway, 10:41:19
18 right? 10:41:22
19 A That is correct. 10:41:23
20 Q Thank you. 10:41:23
21 Second row down under Parameter, 10:41:24
22 Janeway mentions Dose. 10:41:38

1 Do you see that? 10:41:40
2 A Yes. 10:41:41
3 Q What do you understand dosage -- strike 10:41:44
4 that. 10:41:46
5 What do you understand "dose" to mean 10:41:46
6 here? 10:41:51
7 A Dose is the amount of antigen provided 10:41:51
8 as the immune stimulus. 10:41:54
9 Q And just to back up, this is a chart 10:41:57
10 that is entitled "Factors that influence the 10:42:00
11 immunogenicity of proteins," right? 10:42:03
12 A Yes. 10:42:07
13 Q Reproduced from Janeway, correct? 10:42:07
14 A I'm terribly sorry? 10:42:11
15 Q Yeah, no problem. 10:42:12
16 Reproduced from the Janeway reference? 10:42:12
17 A That is correct. 10:42:15
18 Q Exhibit 1170. And you've put it in 10:42:16
19 your declaration here, correct? 10:42:19
20 A Yes. 10:42:21
21 Q And under Dose, you said that -- dose 10:42:22
22 is the amount of antigen provided as the immune 10:42:34

1 stimulus, right? 10:42:37
2 A Yes. 10:42:38
3 Q By December 2011, a person of ordinary 10:42:42
4 skill in the art would have been able to optimize 10:42:45
5 the dose given to improve immunogenicity of an 10:42:48
6 antigen, correct? 10:42:52
7 MS. WANG: Objection to form. 10:42:53
8 A Experiments exactly establishing the 10:42:54
9 sort of a normal distribution for antigen quantity 10:42:58
10 and response were performed well before that, yes. 10:43:05
11 BY MR. POWERS: 10:43:09
12 Q One way to improve the immunogenicity 10:43:09
13 of a vaccine is to give more antigen, correct? 10:43:12
14 A To a certain point, then it becomes 10:43:15
15 worse. 10:43:18
16 Q Right. But a person of ordinary skill 10:43:18
17 in the art would have understood that in 2011, 10:43:19
18 right? 10:43:23
19 A Yes. 10:43:23
20 Q Is frequency of dose or serial dosing 10:43:37
21 another way a person of ordinary skill in the art 10:43:40
22 would have known how to improve immunogenicity of 10:43:44

1 an antigen? 10:43:49
2 MS. WANG: Objection to form. 10:43:50
3 A At the time, 2011, it was clear that 10:43:51
4 after a first injection, a first administration of 10:43:56
5 antigen, a second administration -- generally 10:44:00
6 there was a time limit. It had to be greater than 10:44:04
7 a couple of weeks. A second -- a second dose of 10:44:08
8 antigen, the response was larger, was greater, was 10:44:13
9 higher in magnitude, yes. 10:44:16
10 BY MR. POWERS: 10:44:19
11 Q And these are so-called "booster 10:44:19
12 doses," right? 10:44:21
13 A That is correct. 10:44:23
14 Q Next row down in Janeway is "Route." 10:44:38
15 Do you see that? 10:44:41
16 A Yes, I do. 10:44:42
17 Q What do you understand route to mean 10:44:44
18 here? 10:44:47
19 A This basically refers to the way or the 10:44:48
20 method of introduction of antigen. Subcutaneous 10:44:54
21 is beneath the skin, intraperitoneal is into the 10:44:58
22 peritoneal cavity, intravenous is directly into 10:45:02

1 the blood, and intragastric would be via the 10:45:06
2 stomach, so-called enteral exposure of antigen. 10:45:11
3 Q Do you agree that in December 2011 -- 10:45:15
4 by December 2011, a person of ordinary skill in 10:45:17
5 the art could choose different routes of 10:45:21
6 administration to maximize the immunogenicity of 10:45:23
7 an antigen? 10:45:26
8 A They could use different routes of 10:45:30
9 administration to maximize the response. The 10:45:33
10 immunogenicity of the antigen is a factor of the 10:45:37
11 antigen, not of the route, yes. 10:45:40
12 Q Does immunogenicity of the antigen 10:45:42
13 correlate with response? 10:45:44
14 A Yes, to a large degree. 10:45:49
15 Q Now, one known way of administering an 10:45:50
16 antigen is through the mucosal route, right? 10:45:54
17 A The enteral pathway shown here, yes. 10:45:57
18 Intragastric. 10:45:59
19 Q Intragastric is one example of a 10:46:03
20 mucosal route? 10:46:05
21 A Yes. 10:46:07
22 Q But there are other mucosal routes 10:46:07

1 known, correct? 10:46:10
2 A There are. There are the nasopharynx 10:46:12
3 route for lungs. There are sublingual routes, 10:46:17
4 which become intragastric, and there's suppository 10:46:24
5 routes that are directly into the intestine. 10:46:28
6 Q Those routes were known as of 2011? 10:46:37
7 A Yes, they were. 10:46:40
8 Q A few more rows down, I see adjuvants 10:46:47
9 on this chart. 10:46:50
10 A Yes. 10:46:51
11 Q Actually, before we get there, do you 10:46:54
12 have any -- do you remember if in the '600 10:47:00
13 patents, and the other patents in the proceeding, 10:47:05
14 they disclosed that administration to mucosa is 10:47:07
15 contemplated? 10:47:09
16 A Yes, I do. In reference to the Moon 10:47:11
17 declaration, the Cherr declaration especially, but 10:47:16
18 also in the -- in the part that describes the 10:47:19
19 potential for the PH20 as a contraceptive vaccine. 10:47:23
20 Q And the patents articulate a mucosal 10:47:30
21 route is contemplated, correct? 10:47:32
22 MS. WANG: Objection. 10:47:37

1 A I don't remember. 10:47:38
2 BY MR. POWERS: 10:47:38
3 Q If we go to the '600 patents in front 10:47:38
4 of you there. If we look at column 169. Up at 10:47:40
5 the top of the pages, there are column numbers. 10:47:53
6 And then we go to -- down on column 169, line 7 to 10:47:55
7 11. 10:48:08
8 There it says: Topical administration 10:48:08
9 is contemplated for transdermal delivery and also 10:48:16
10 for administration into the eyes or mucosa -- 10:48:19
11 A Yes. 10:48:22
12 Q -- or for inhalation therapies. 10:48:22
13 A Uh-huh. 10:48:25
14 Q Nasal solutions of active compound 10:48:25
15 alone or in combination with other 10:48:28
16 pharmaceutically acceptable excipients can also be 10:48:30
17 administered. 10:48:34
18 Do you see that? 10:48:34
19 A Yes. 10:48:35
20 Q So the patent does talk about mucosal 10:48:35
21 administration, correct? 10:48:37
22 A Yes, it does. 10:48:37

1 MS. WANG: Objection to form. 10:48:38
2 BY MR. POWERS: 10:48:38
3 Q Let's see. 10:48:38
4 A Excuse me. But I read this not to be 10:48:39
5 immunization at all but simply a pathway for 10:49:07
6 exposure. 10:49:10
7 Q Okay. If we go to -- now, you say that 10:49:11
8 an effective therapeutic response depends on 10:49:17
9 antibody concentration and binding strength. 10:49:26
10 A Yes. 10:49:29
11 Q And binding strength is affinity and 10:49:31
12 avidity, correct? 10:49:33
13 A That is correct. 10:49:35
14 Q The relationship between antibody titer 10:49:36
15 and binding affinity was well understood before 10:49:38
16 2012, correct? 10:49:41
17 MS. WANG: Objection to form. 10:49:43
18 A There's no relationship between 10:49:46
19 quantity and affinity. Affinity is an intrinsic 10:49:47
20 property of the antibody combining side. Quantity 10:49:52
21 is how many antibodies are present. But they are 10:49:56
22 independently -- they segregate independently. 10:49:58

1 BY MR. POWERS: 10:50:01
2 Q Do you agree that increasing antibody 10:50:01
3 titers can offset concerns about moderate binding 10:50:08
4 affinity in eliciting an effective biological 10:50:11
5 response? 10:50:15
6 A I do not. 10:50:16
7 Q Do you agree that the greater 10:50:19
8 concentration of the antibody, the less need there 10:50:20
9 is for high binding affinity? 10:50:22
10 A In what context are you asking the 10:50:27
11 question? As a therapeutic agent? 10:50:29
12 Q In a general context. 10:50:33
13 A So as you -- I'm sure you know, the 10:50:39
14 affinity is simply the equilibrium constant of the 10:50:41
15 antigen binding to and falling off of the 10:50:45
16 antibody. And if you have more antibody, the 10:50:48
17 equilibrium constant stays the same because the 10:50:54
18 equilibrium constant is measured by the 10:50:59
19 concentration of the ligand. 10:51:02
20 So the answer is no. That's why I 10:51:04
21 wanted to make sure I understood the context of 10:51:08
22 what you're saying. 10:51:11

1 Q You didn't testify in your declaration 10:51:15
2 that antibodies must reach a particular affinity 10:51:16
3 or avidity to elicit an effective therapeutic 10:51:19
4 response, correct? 10:51:23
5 A I did not state a threshold. I did 10:51:24
6 not. 10:51:26
7 Q You agree that it was known -- well, do 10:51:30
8 you agree that it was known by 2012 that adjuvants 10:51:40
9 can be used not only to raise titers but influence 10:51:42
10 how well antibodies bind to antigen? 10:51:47
11 A Actually, I can't agree with that. The 10:51:51
12 magnitude of the response is increased. Whether 10:51:55
13 or not there is affinity maturation, the increase 10:51:58
14 in binding strength is proportional to a different 10:52:02
15 part of the response, a so-called germinal center 10:52:06
16 response. 10:52:11
17 (Stenographer requested clarification.) 10:52:11
18 BY MR. POWERS: 10:52:11
19 Q Can adjuvants increase a germinal 10:52:13
20 center response? 10:52:16
21 A No. 10:52:17
22 Q Can adjuvants promote B-cell maturation 10:52:18

1 in clonal expansion? 10:52:23
2 A So that is an issue of great debate. 10:52:30
3 Mostly people believe now that adjuvants work by 10:52:33
4 increased recruitment of unstimulated cells to 10:52:38
5 become stimulated. Broadening, if you will, the 10:52:42
6 base of the response so that it's bigger. 10:52:45
7 I don't think there is any evidence 10:52:49
8 that it accentuates the process of selection in 10:52:52
9 germinal centers. 10:52:58
10 Q Does -- is there evidence that 10:53:02
11 adjuvants increase somatic hypermutation in B-cell 10:53:04
12 maturation? 10:53:14
13 A None whatsoever. 10:53:18
14 Q You're not aware of any evidence that 10:53:18
15 suggests that B-cell maturation and somatic 10:53:20
16 hypermutation is increased by adjuvants; is that 10:53:22
17 correct? 10:53:25
18 A Only the magnitude of the response. 10:53:26
19 Never the rate of -- the rate of somatic 10:53:29
20 hypermutation is determined by a different 10:53:31
21 process. 10:53:37
22 Q All right. Let's take a break. 10:53:37

1 A Thank you. 10:53:39
2 THE VIDEOGRAPHER: We're going off the 10:53:41
3 record. The time is 10:53. 10:53:42
4 (Whereupon, a brief recess was taken.) 10:53:44
5 THE VIDEOGRAPHER: We are back on the 11:18:32
6 record. The time is 11:18. 11:18:33
7 BY MR. POWERS: 11:18:36
8 Q Dr. Kelsoe, what is affinity 11:18:36
9 maturation? 11:18:39
10 A Affinity maturation is the general 11:18:40
11 process of antibodies acquiring higher and higher 11:18:42
12 affinity for their antigen ligand through a 11:18:49
13 process of somatic evolution in a germinal center. 11:18:52
14 Q And was it known that adjuvants can 11:19:00
15 increase affinity maturation as of 2011? 11:19:06
16 A Adjuvants increase the magnitude of the 11:19:09
17 response. They cannot intrinsically increase the 11:19:12
18 affinity maturation. 11:19:16
19 Q Can adjuvants help generate broadly 11:19:17
20 neutralized antibodies? 11:19:19
21 A Almost all immunogens use -- let me 11:19:22
22 rephrase what I'm trying to say. 11:19:26

1 Adjuvants are routinely used and are 11:19:27
2 instead of soluble proteins to elicit the germinal 11:19:29
3 center response and to make high affinity 11:19:34
4 antibodies. 11:19:38
5 Q Those high affinity antibodies include 11:19:40
6 broadly neutralized antibodies, correct? 11:19:42
7 MS. WANG: Objection to form. 11:19:45
8 A Broadly neutralizing antibodies are a 11:19:46
9 subset of high affinity antibodies, yes. 11:19:49
10 BY MR. POWERS: 11:19:52
11 Q So we agree that somatic evolution 11:19:52
12 happens in a germinal center, right? 11:20:02
13 A Yes, we do. 11:20:04
14 Q And adjuvants, you said, are routinely 11:20:07
15 used to elicit a germinal center response, 11:20:11
16 correct? 11:20:15
17 A No. Adjuvants are used to initiate -- 11:20:19
18 to initiate the immune response and to magnify the 11:20:22
19 size of that initiation. The TB collaboration 11:20:27
20 that leads up to the germinal center reaction is 11:20:30
21 not much impacted by adjuvant. 11:20:34
22 In fact, if I can expand on that. 11:20:40

1 Immunization with soluble proteins does not lead 11:20:47
2 generally to very good antibody responses. In 11:20:50
3 fact, sometimes it leads to tolerance. So 11:20:53
4 adjuvants are routinely used to elicit all sorts 11:20:56
5 of antibody responses in animals and humans. 11:20:59
6 Q As part of their use in vaccines, 11:21:03
7 though, do you agree that adjuvants can promote 11:21:06
8 antibody affinity maturation? 11:21:09
9 MS. WANG: Objection to form. 11:21:13
10 A No. They promote -- the magnitude of 11:21:14
11 the response and the affinity maturation is 11:21:20
12 determined by the interaction of T and B cells 11:21:22
13 within the germinal center. 11:21:26
14 BY MR. POWERS: 11:21:27
15 Q Is it your position that adjuvants do 11:21:27
16 not impact the interaction of T and B cells within 11:21:30
17 the germinal center to promote antibody affinity 11:21:34
18 maturation? 11:21:37
19 A They do not. 11:21:38
20 Q Do you agree that adjuvants can be used 11:21:48
21 not only to raise titers but influence how well 11:21:50
22 antibodies bind to antigen? 11:21:54

1 MS. WANG: Objection to form. 11:21:56
2 A That question is simply rephrasing of 11:21:57
3 the question you just asked me, and the answer is 11:21:59
4 no. Adjuvants may increase the diversity of 11:22:04
5 B cells responding to an antigen, but they don't 11:22:08
6 change the somatic evolution within the germinal 11:22:11
7 center. 11:22:14
8 BY MR. POWERS: 11:22:15
9 Q Are you familiar with the journal 11:22:15
10 Science Translational Medicine? 11:22:20
11 A I am. 11:22:22
12 Q Is that a peer-reviewed journal? 11:22:23
13 A It is. 11:22:24
14 Q Is it considered a good journal? 11:22:25
15 A It is. 11:22:26
16 Q I'd like to introduce a new exhibit. 11:22:27
17 This will get number 2215. 11:22:27
18 (Exhibit Number 2215 was identified as 11:22:27
19 of this date.) 09:30:46
20 A Thank you. 09:22:20
21 BY MR. POWERS: 09:22:20
22 Q Dr. Kelsoe, you've been handed what's 09:22:20

1 been marked 2215. Have you seen this document 11:23:09
2 before? 11:23:13
3 A I have not. 11:23:13
4 Q This is a publication from Science 11:23:17
5 Translational Medicine, right? 11:23:18
6 A Yes. 11:23:21
7 Q And it's dated June 1, 2011, right? 11:23:21
8 A Yes. 11:23:24
9 Q Do you agree that a person of ordinary 11:23:25
10 skill in the art, as of December 2011, would have 11:23:26
11 known of this reference? 11:23:29
12 A Yes. 11:23:31
13 Q The first author on this reference is? 11:23:32
14 Surender Khurana, right? 11:23:36
15 A Yes. 11:23:39
16 Q Are you familiar with that person? 11:23:44
17 A No. 11:23:45
18 Q The senior author is Hana Golding. Do 11:23:45
19 you see that? 11:23:48
20 A Yes. 11:23:49
21 Q Are you familiar with that person? 11:23:49
22 A I am not. 11:23:50

1 Q The first and senior author -- the 11:24:06
2 first and senior authors are out of the FDA, Food 11:24:09
3 and Drug Administration, in Bethesda, Maryland, 11:24:12
4 correct? 11:24:16
5 A Yes. Jon Yewdell is at the NIAID. I 11:24:25
6 know Jon Yewdell well. And Rino Rappuoli is 11:24:28
7 Novartis, and I know of Rino Rappuoli. 11:24:33
8 Q You referred to Jon Yewdell? 11:24:36
9 A Yes. 11:24:38
10 Q Do you respect him as a scientist? 11:24:38
11 A He's a good scientist. 11:24:41
12 Q And he's one of the authors on this 11:24:43
13 paper, correct? 11:24:45
14 A Yes, he is. 11:24:46
15 Q Let's look at the abstract of this 11:24:53
16 paper. It discusses MF59; do you see that? 11:24:54
17 A Yes, I do. 11:25:03
18 Q MF59 is an adjuvant, correct? 11:25:04
19 A That is correct. 11:25:06
20 Q About two-thirds of the way down in the 11:25:10
21 abstract, it says: Moreover, MF59 also improved 11:25:12
22 antibody affinity maturation after each sequential 11:25:17

1 vaccination against avian H5N1 in adults. 11:25:20
2 Correct? 11:25:26
3 A Yes. 11:25:26
4 Q So here the authors report that an 11:25:27
5 adjuvant is improving antibody affinity 11:25:29
6 maturation, correct? 11:25:32
7 MS. WANG: Objection to form. 11:25:33
8 A I need to read the paper to see what 11:25:34
9 the comparison is to. 11:25:37
10 BY MR. POWERS: 11:25:39
11 Q Take your time. 11:25:39
12 A Thank you. 11:25:40
13 Yes. 11:25:59
14 Q Okay. 11:26:01
15 A So the comparator here is 11:26:01
16 unimmunized -- unadjuvanted hemagglutinin vaccine. 11:26:03
17 That's the standard vaccine form that is given to 11:26:09
18 humans against influenza. As I told you recently, 11:26:13
19 the role of adjuvant is significantly greater in 11:26:18
20 magnifying the size of the immune response as 11:26:24
21 compared to unadjuvanted -- unadjuvanted antigens, 11:26:28
22 which you can all see -- also see here. The 11:26:32

1 oil-and-water vaccine is simply another form of 11:26:38
2 slow-release and inflammatory signal. 11:26:43
3 So the comparison here now is not 11:26:45
4 against two different kinds of adjuvant or it's 11:26:52
5 compared to a suboptimal point of immunization 11:26:55
6 with an adjuvanted immunization. 11:26:59
7 Q Well, none of my questions before were 11:27:01
8 about comparing two different types of adjuvant. 11:27:03
9 I asked you before if an adjuvant could improve 11:27:06
10 antibody affinity maturation, and these authors, 11:27:10
11 you would agree, indicate that MF59 improved 11:27:13
12 antibody affinity maturation, correct? 11:27:19
13 MS. WANG: Objection to form. 11:27:21
14 A So improvement -- yes. So improvement 11:27:22
15 by definition requires a comparator. 11:27:25
16 Q Uh-huh. 11:27:28
17 A So when I say that an adjuvant does not 11:27:28
18 change the rate of affinity maturation, I'm 11:27:33
19 precisely correct in that: Adjuvants don't change 11:27:36
20 the interaction of B cells in germinal centers. 11:27:41
21 The initial -- what the adjuvant has done in this 11:27:44
22 particular case is it increases the size of the 11:27:47

1 response, the number and the diversity, which 11:27:50
2 you'll notice that it says "enhances diversity" as 11:27:53
3 a part of the title. It increases the diversity 11:27:57
4 of B cells recruited to the immune response and to 11:28:01
5 the germinal center. 11:28:07
6 BY MR. POWERS: 11:28:08
7 Q Uh-huh. 11:28:08
8 A But it doesn't change the somatic 11:28:09
9 evolution, per se, going in the germinal center. 11:28:13
10 Q You agree, though, that the authors 11:28:17
11 wrote "MF59 also improved antibody affinity 11:28:19
12 maturation," correct? 11:28:23
13 A That is the title of the paper. 11:28:25
14 Q You can set that aside. 11:28:29
15 What are neutralizing antibodies? 11:28:31
16 A Neutralizing antibodies are antibodies 11:28:36
17 that block, for example, the increase site of a 11:28:39
18 virus into their target cell or an antibody that 11:28:42
19 blocks the toxin activity of a specific 11:28:48
20 pathogenetic toxin. 11:28:51
21 Q And why are neutralizing antibodies 11:28:53
22 important? 11:28:56

1 A Neutralizing antibodies in the case of 11:28:56
2 pathogens prevent infection or, in the case of a 11:28:59
3 toxin, prevent the effect of the toxin on organ 11:29:05
4 systems. 11:29:09
5 Q By 2012, adjuvants were known that 11:29:13
6 could break peripheral tolerance, correct? 11:29:15
7 A Adjuvants were known capable of 11:29:20
8 breaking peripheral tolerance; that is correct. 11:29:22
9 Q And before 2012, 2011 adjuvants were 11:29:24
10 known that could induce broadly neutralizing 11:29:27
11 antibodies, right? 11:29:30
12 A That is correct. 11:29:31
13 Q And that's even to self-proteins, 11:29:32
14 correct? 11:29:35
15 A I'm not sure I know an example of a 11:29:35
16 broad -- a so-called "broadly neutralizing 11:29:38
17 antibody" to a self-protein. 11:29:41
18 Q But you do agree that adjuvants could 11:29:46
19 break peripheral tolerance, correct? 11:29:48
20 MS. WANG: Objection to form. 11:29:53
21 A As a matter of course, the adjuvants 11:29:54
22 are capable of doing so. Routinely they do not; 11:29:55

1 otherwise, we would break tolerance every time we 11:30:00
2 got our annual flu shots or MMR shots or any other 11:30:03
3 standard childhood vaccination. So they only 11:30:11
4 break tolerance when, one, the ligand is a 11:30:15
5 self-antigen, and, two, the inflammation that it 11:30:17
6 induces is sufficient to overcome the regulatory 11:30:20
7 factors that prevent that. 11:30:23
8 BY MR. POWERS: 11:30:26
9 Q Skilled artisans knew of adjuvants that 11:30:26
10 could break tolerance? 11:30:28
11 A Yes, they did. 11:30:30
12 Q B cells generate antibody diversity 11:30:30
13 through site-specific recombination, correct? 11:30:59
14 A In what context do you mean 11:31:10
15 site-dependent recombination? 11:31:12
16 Q Site-specific recombination called 11:31:14
17 V(D)J joining? 11:31:18
18 A Yes. Yes. B-cell receptors are 11:31:19
19 generated during the development of B cells by 11:31:22
20 this V(D)J recombination process. 11:31:25
21 Q And would you agree that creates a 11:31:27
22 diverse B cell repertoire? 11:31:29

1 A It certainly does. 11:31:32
2 Q That repertoire is capable of 11:31:33
3 recognizing a wide variety of protein antigens, 11:31:35
4 correct? 11:31:38
5 A That is correct. 11:31:38
6 Q After antigen exposure, B cells undergo 11:31:39
7 antigen-driven somatic hypermutation, correct? 11:31:43
8 A B cells alone cannot -- cannot drive 11:31:46
9 somatic hypermutation. They need a special T cell 11:31:50
10 and special environment for that to happen, yes. 11:31:54
11 Q That's the helper T cell, correct? 11:31:56
12 A That is the T follicular helper cell, 11:31:58
13 yes. 11:31:59
14 Q Special helper T cell? 11:32:01
15 A Yes. 11:32:02
16 Q Okay. And so that special helper 11:32:03
17 T cell in the follicular environment drives B-cell 11:32:04
18 hyper -- somatic hypermutation, correct? 11:32:09
19 A No. It activates the B cell. The 11:32:12
20 B cell is entered into a differentiated state in 11:32:15
21 which a particular enzyme, activation-induced 11:32:20
22 cytidine deaminase, is deregulated during one 11:32:24

1 phase of the B cell -- it's a follicular phase in 11:32:28
2 the germinal center. The T cells are required to 11:32:33
3 maintain this state, but the B cells entered the 11:32:37
4 state after the initial -- so -- I'm going to 11:32:40
5 rephrase it. 11:32:43
6 When AICDA is expressed, the B cells 11:32:44
7 are not in contact with T cells; they do so 11:32:48
8 independently. 11:32:51
9 Q I see. 11:32:51
10 But I think the answer to my question 11:32:54
11 is, yes, that the helper T cells promote B cell 11:33:03
12 somatic hypermutation, right? 11:33:09
13 MS. WANG: Objection to form. 11:33:14
14 A Well, my answer to your question is 11:33:14
15 they are necessary for B cells' mutation, but they 11:33:16
16 do not promote it. 11:33:20
17 BY MR. POWERS: 11:33:21
18 Q I see. 11:33:21
19 And somatic hypermutation is the 11:33:21
20 process by which point mutations are introduced 11:33:31
21 into antibody variable regions, right? 11:33:34
22 A That is correct. 11:33:36

1 Q Those mutations can increase antibody 11:33:37
2 affinity for a target antigen, correct? 11:33:41
3 A They both increase and decrease, yes. 11:33:43
4 Q Right. 11:33:45
5 The increased binders are selected? 11:33:46
6 A That is correct. 11:33:48
7 Q So the immune system has an 11:33:49
8 evolutionary mechanism to select for increased 11:33:51
9 binding affinity to a target antigen? 11:33:54
10 A That is correct. 11:33:57
11 Q And B cells with improved affinity in 11:34:07
12 their antibodies are selected for survival and 11:34:10
13 expansion, correct? 11:34:13
14 A B cells that are selected -- if I may 11:34:18
15 be precise, there are two outcomes for selected 11:34:22
16 B cells, and that is either to leave the germinal 11:34:25
17 center and differentiate into a memory cell or an 11:34:29
18 antibody-secreting cell or to return to the 11:34:31
19 portion of the germinal center in which additional 11:34:36
20 mutations are accrued. And then to return for a 11:34:38
21 second round or a third round or a fourth round of 11:34:42
22 selection, yes. 11:34:46

1 Q I see. So those B cells can undergo 11:34:46
2 multiple rounds of selection to continuously 11:34:48
3 select for better binders to the antigen? 11:34:51
4 A That is correct. 11:34:54
5 MS. WANG: Objection to form. 11:34:55
6 BY MR. POWERS: 11:34:56
7 Q And this process is referred to as 11:34:56
8 affinity maturation, correct? 11:34:59
9 A That is correct. 11:35:01
10 Q An affinity maturation ideally results 11:35:04
11 in antibodies that binds effectively to a 11:35:06
12 particular antigen, correct? 11:35:09
13 A That is correct. 11:35:11
14 Q Successful B cell activation leads to 11:35:14
15 clonal expansion, correct? 11:35:17
16 A Depends on what kind of antigen. What 11:35:21
17 kind of antigen do you have in mind? 11:35:23
18 I'll rephrase. I'll reexplain. 11:35:27
19 Contact with the so-called 11:35:30
20 T-independent antigen drives clonal proliferation 11:35:32
21 independently of the B cell and its 11:35:36
22 differentiation into an antibody-secreting set. 11:35:39

1 Response to a T-dependent antigen 11:35:43
2 activates the B cell, requires the survival signal 11:35:46
3 from a matched T helper cell, and then those cells 11:35:51
4 transit back to the follicle to create the 11:35:55
5 germinal center, in which that process is repeated 11:35:59
6 as we just described -- 11:36:02
7 Q I see. 11:36:03
8 A -- over and over. 11:36:04
9 Q Can you give me an example of a 11:36:05
10 T-independent antigen? 11:36:07
11 A Polysaccharide of -- pneumoniae 11:36:08
12 polysaccharide. 11:36:11
13 Q What makes an antigen T cell 11:36:12
14 independent? 11:36:15
15 A The product is capable of stimulating 11:36:17
16 an alternative pathway of survival and activation 11:36:20
17 usually through toll-like receptor ligands. 11:36:25
18 (Stenographer requested clarification.) 11:36:33
19 BY MR. POWERS: 11:36:33
20 Q Can you give me an example of a 11:36:35
21 T-dependent antigen? 11:36:37
22 A The influenza hemagglutinin. 11:36:39

1 Q What makes an antigen T cell dependent? 11:36:46
2 A The T cell -- the hemagglutinin is 11:36:49
3 capable of activating the B cell, but not 11:36:53
4 providing the so-called second survival and 11:36:56
5 proliferation signal that is dependent on the T 11:36:59
6 cell. 11:37:03
7 Q I see. So the second survival signal 11:37:11
8 in the first case comes from some interaction with 11:37:14
9 the toll-like receptor? 11:37:16
10 A It can be. So, for example, the 11:37:18
11 interaction with -- there are receptors for a 11:37:21
12 T-independent antigen called Flagellin. 11:37:25
13 Flagellin, a bacterial product, not only is it 11:37:28
14 recognized by the B cell-cell antigen receptor, 11:37:32
15 but it also interacts directly with toll-like 11:37:34
16 receptors. 11:37:37
17 Q In a T cell dependent antigen, the 11:37:41
18 second survival signal comes from the T cell, 11:37:44
19 correct? 11:37:46
20 A That is correct. 11:37:46
21 Q Just going back to the B cell-cell 11:38:10
22 somatic hypermutation we were talking about 11:38:12

1 earlier, was that phenomenon well known in the 11:38:16
2 literature prior to 2012? 11:38:21
3 A Yes. 11:38:23
4 MS. WANG: Objection to form. 11:38:24
5 BY MR. POWERS: 11:38:36
6 Q Sorry? 11:38:36
7 A Yes. Originally published in '91 or 11:38:37
8 '96 in Cell and in Nature. 11:38:42
9 Q I see. So it had been out there for a 11:38:45
10 while? 11:38:47
11 A Yes. 11:38:47
12 Q The female genital tract is considered 11:38:52
13 mucosal tissue, right? 11:38:55
14 A Yes. 11:38:57
15 Q You agree that mucosal tissues have 11:38:58
16 immune characteristics that differ from systemic 11:39:00
17 tissues? 11:39:03
18 A Yes. 11:39:05
19 Q One of those differences is the 11:39:06
20 predominance of mucosal antibodies, correct? 11:39:08
21 A The way I interpret it, that's sort of 11:39:19
22 a circular -- a circular statement. There are 11:39:20

1 antibodies on the surface, the mucosal surface of 11:39:25
2 mucosa. That's for sure. Some are produced 11:39:29
3 locally and some are systemic and transported 11:39:33
4 there. 11:39:36
5 Q Right. So you would agree that mucosal 11:39:39
6 surfaces have distinct set of antibodies compared 11:39:41
7 to systemic tissues, right? 11:39:44
8 MS. WANG: Objection to form. 11:39:46
9 A Yes. In the sense that mucosal 11:39:50
10 surfaces are not inside, they're outside of us, 11:39:52
11 and so much like the interior of our mouth, 11:39:55
12 they're exposed to different antigens routinely, 11:39:58
13 whereas your lymph nodes generally are not, yes. 11:40:01
14 BY MR. POWERS: 11:40:05
15 Q One of those mucosal antibody isotypes 11:40:05
16 is IgA, correct? 11:40:10
17 A That is correct. 11:40:12
18 Q Generating antibodies at mucosal sites 11:40:16
19 often requires mucosal immune activation, correct? 11:40:20
20 A It depends on the species. So there's 11:40:25
21 a receptor called the neonatal Fc receptor, which 11:40:29
22 is abundant in humans, for example, and in 11:40:36

1 rabbits. 11:40:39
2 The neonatal receptor is responsible 11:40:40
3 for two things: One, transport of maternal IgG 11:40:43
4 into the fetus early on. It's not all -- not all 11:40:48
5 animals. For example, mice get their maternal IgG 11:40:54
6 by milk suckling, and it's transported into the 11:40:58
7 blood from the lumen of the gut backwards into the 11:41:02
8 blood. Humans and rabbits give it directly from 11:41:05
9 the placenta. 11:41:11
10 So the amount of -- the amount of -- 11:41:12
11 the immunoglobulin is produced locally in both 11:41:17
12 ways is what I'm trying to say. I'm sorry, yeah. 11:41:20
13 Q Locally in both ways. What do you mean 11:41:23
14 by that? 11:41:25
15 A I'm sorry, that was -- that was 11:41:26
16 terribly confusing. 11:41:26
17 There are local patches of lymphoid 11:41:28
18 tissues along the guts of all vertebrates. We 11:41:34
19 often think of Peyer's patches as -- as guts. 11:41:39
20 These are essentially fixed lymph nodes that are 11:41:44
21 closely approximated to the internal lining of the 11:41:48
22 mucosa. They contain standard germinal centers 11:41:54

1 that persist chronically because of the bacterial 11:41:58
2 antigens that are chronically stimulating -- the 11:42:01
3 gut is not a sterile place. 11:42:04
4 These secrete antibodies. They also 11:42:07
5 secrete IgG. And that antibody is transported by 11:42:09
6 two different mechanisms into the lumen of the 11:42:13
7 gut. 11:42:16
8 The same thing occurs in systemic 11:42:17
9 immunization. It's just that there's no -- 11:42:21
10 generally for us there's no chronic stimulation 11:42:24
11 because there's no chronic exposure to outside 11:42:27
12 antigen with lymph nodes or spleen. 11:42:31
13 Q These lymphoid tissues that exist in 11:42:34
14 the mucosal lining, are they able to host B 11:42:36
15 cell-cell maturation? 11:42:43
16 A B cell-cell maturation in the sense of 11:42:48
17 activation by antigen differentiation, yes, they 11:42:50
18 do. 11:42:53
19 Q And is it your understanding that those 11:42:54
20 lymphoid tissues exist in the reproductive tract 11:42:57
21 of the female? 11:43:02
22 A My understanding is that they do. 11:43:03

1 Q Are you unsure about that? 11:43:08
2 A I don't know -- all mucosal surfaces 11:43:10
3 that I know, the nasopharynx, the gut, all have 11:43:12
4 these lymphoid patches. I do not know 11:43:15
5 specifically that the female reproductive tract 11:43:18
6 does. 11:43:21
7 Q You didn't consider as part of your 11:43:21
8 opinion whether or not the female reproductive 11:43:23
9 tract does host such lymphoid tissues, correct? 11:43:25
10 A No. That was not relevant to my 11:43:28
11 declaration. 11:43:30
12 Q Do you agree that mucosal vaccines can 11:43:34
13 preferentially stimulate mucosal immune response? 11:43:37
14 A They are designed to do so, yes. 11:43:41
15 Q That was the intent -- that would be 11:43:42
16 the intent of giving a mucosal vaccine, correct? 11:43:44
17 A That is correct. 11:43:47
18 Q You agree that intranasal vaccination 11:43:50
19 is a form of mucosal vaccine delivery, right? 11:43:53
20 A They are. 11:43:56
21 Q Do you agree that intranasal 11:43:57
22 vaccination can be efficient at inducing 11:43:59

1 antigen-specific antibody responses? 11:44:02
2 A They can be, yes. 11:44:04
3 MS. WANG: Objection to form. 11:44:06
4 BY MR. POWERS: 11:44:08
5 Q And same question but with regard to 11:44:08
6 the female genital tract. So do you understand 11:44:10
7 that intranasal vaccination can be efficient at 11:44:14
8 inducing antigen-specific antibody responses in 11:44:18
9 the female reproductive tract? 11:44:21
10 MS. WANG: Objection to form. 11:44:23
11 A I don't know. 11:44:26
12 BY MR. POWERS: 11:44:28
13 Q You don't know whether or not that was 11:44:28
14 reported in the prior art? 11:44:30
15 A I know it was discussed in the prior 11:44:32
16 art. It was claimed that this might be a way to 11:44:34
17 increase antibody titers. I know -- yes, that's 11:44:39
18 the extent that I know. 11:44:44
19 Q You didn't consider such references in 11:44:48
20 offering your opinions in your declaration; is 11:44:51
21 that correct? 11:44:53
22 MS. WANG: Objection to form. 11:44:54

1 A I didn't consider it to be relevant to 11:44:54
2 my declaration. 11:44:58
3 BY MR. POWERS: 11:45:00
4 Q There were studies that showed that 11:45:00
5 intranasal administration of antigen elicited a 11:45:02
6 stronger AGG -- sorry. Try that again. 11:45:05
7 There were studies that showed that 11:45:08
8 intranasal administration of an antigen elicited 11:45:10
9 stronger IgA responses than for IgG, right? 11:45:15
10 A That would be expected, yes. 11:45:18
11 Q What's the importance of an IgA 11:45:26
12 response in mucosal tissue? 11:45:28
13 MS. WANG: Objection to form. 11:45:30
14 A The -- so the response is that in the 11:45:39
15 mucosal lymphoid aggregates, the mucosal tissues, 11:45:41
16 the T follicular helper cells that are resident 11:45:46
17 there, and the T helper cells that are resident 11:45:50
18 there, are specialized to promote class switch to 11:45:52
19 IgA. 11:46:04
20 (Stenographer requested clarification.) 11:46:04
21 A And that's based on the cytokine 11:46:27
22 profile that they do. And that specialization is 11:46:11

1 not seen in parental lymphoid sites to a great 11:46:14
2 deal. So they're biased to producing IgA. They 11:46:21
3 also produce IgG and they produce IgM. 11:46:28
4 BY MR. POWERS: 11:46:31
5 Q I see. 11:46:31
6 So IgA is the predominant isotype 11:46:32
7 produced in mucosal lining; is that right? 11:46:39
8 A It is the prominent -- it is the 11:46:41
9 predominant resident B cell-cell population, yes, 11:46:43
10 plasmacyte population. 11:46:46
11 Q But IgA and IgM exist as well, right? 11:46:50
12 A And IgG, yes. 11:46:52
13 Q And IgG. 11:46:54
14 A Yes. 11:46:55
15 Q I see. That's what I meant. 11:46:56
16 So just evolutionarily, though, what is 11:46:59
17 the role of IgA in the mucosal lining? 11:47:02
18 MS. WANG: Objection to form. 11:47:08
19 A Yeah. So the imputed role of IgA is 11:47:11
20 there's a special joining piece that allows it to 11:47:13
21 be secreted across the mucosal barrier into the 11:47:17
22 luminal contents, and we presume that -- we know 11:47:21

1 that antigen is taken into these local germinal 11:47:30
2 centers from the luminal contents, activates the B 11:47:34
3 cells, they proliferate, they mutate, they class 11:47:36
4 switch, and the antibodies, as those cells leave 11:47:39
5 the germinal centers, some significant population 11:47:41
6 of them stay locally, and the antibodies that they 11:47:43
7 secrete Crete with the so-called secretory piece 11:47:46
8 are transmitted into the lumen of the gut. So 11:47:49
9 they're -- in that sense, they are a local 11:47:54
10 producer of mucosal antibodies. 11:47:56
11 BY MR. POWERS: 11:48:00
12 Q And those -- so IgA exists as a dimer, 11:48:00
13 correct? 11:48:05
14 A In its native form, it is -- it's an 11:48:07
15 IgG-like dimeric -- what am I trying to say -- 11:48:13
16 identical symmetrical molecule. It can be joined 11:48:22
17 together by the so-called J chain, and that makes 11:48:26
18 it a four-valent antibody. 11:48:29
19 Q Quadrivalent; is that correct? 11:48:33
20 A It would be quadrivalent in that case, 11:48:35
21 yes. 11:48:37
22 Q Does the quadrivalency of the IgA dimer 11:48:40

1 assist with binding to antigen? 11:48:45
2 A The quadrivalency increases the 11:48:50
3 apparent binding strength, the so-called avidity, 11:48:53
4 which is the sum of binding of the individual 11:48:57
5 combining sites, which is affinity, yes. 11:49:00
6 Q And does the quadrivalency help 11:49:02
7 agglutinate antigen as well? 11:49:07
8 MS. WANG: Objection to form. 11:49:10
9 A Multivalents antibodies, IgM, IgA, are 11:49:11
10 efficient agglutinators, yes. 11:49:15
11 MR. POWERS: It's 11:50. Would you 11:49:18
12 like to take a break for lunch? 11:49:30
13 THE WITNESS: I would be happy with 11:49:31
14 that. 11:49:32
15 MR. POWERS: Okay. Me too. Thank you. 11:49:32
16 THE WITNESS: Thank you. 11:49:35
17 THE VIDEOGRAPHER: We're going off the 11:49:36
18 record. Time is 11:49. 11:49:36
19 (Whereupon, a recess was taken.) 11:51:25
20 THE VIDEOGRAPHER: Okay. We're back on 12:42:57
21 the record. The time is 1:04 p.m. 01:04:30
22 BY MR. POWERS: 01:04:34

1 Q Welcome back, Dr. Kelsoe. 01:04:35
2 A Thank you. 01:04:37
3 Q During the lunch break or at any break 01:04:37
4 so far today, have you spoken with counsel about 01:04:40
5 the substance of your testimony? 01:04:42
6 A I have not. 01:04:43
7 Q Dr. Kelsoe, by 2012, it was well known 01:04:47
8 that antisperm antibodies could impair fertility 01:04:50
9 through multiple mechanisms, correct? 01:04:55
10 A To my knowledge, no. I'm not an expert 01:04:59
11 on the antisperm antibody and fertility. I know 01:05:02
12 the association, but I don't know the mechanism. 01:05:06
13 Q I'm going to hand you a document that's 01:05:23
14 been previously marked in this case as 01:05:24
15 Exhibit 2116. 01:05:27
16 (Previously marked Exhibit Number 2116 01:05:33
17 was identified.) 01:05:33
18 BY MR. POWERS: 01:05:33
19 Q Here it is. 01:05:33
20 Could you pass this to Madam Court 01:05:33
21 Reporter? Thank you. 01:05:34
22 Do you recognize this document, Doctor? 01:05:39

1 A Yes. 01:05:41
2 Q What is this document? 01:05:41
3 A This is a review paper on antisperm 01:05:43
4 antibodies and fertility. 01:05:48
5 Q You didn't cite this document in your 01:05:51
6 declaration, did you? 01:05:53
7 A I don't think so, no. 01:05:54
8 Q Dr. Cherr did cite it in his 01:05:55
9 declaration, though, correct? 01:05:57
10 A I'm sorry, was that a question? 01:06:05
11 Q It was. 01:06:07
12 Dr. Cherr cited this document in his 01:06:07
13 declaration, right? 01:06:10
14 A All right. Yes. 01:06:10
15 Q Now, if you look at page 174 in this 01:06:15
16 document? 01:06:21
17 A Yes. 01:06:31
18 Q Just to back up, is it your 01:06:32
19 understanding that this is a review article? 01:06:33
20 A Yes. 01:06:35
21 Q Exhibit 2116 is a review article, 01:06:36
22 right? 01:06:39

1 A (Nonverbal response.) 01:06:40
2 Did I say yes? 01:06:43
3 Q You need to -- 01:06:44
4 A I'm sorry. Yes. 01:06:44
5 Q I just asked a slightly different and 01:06:45
6 better question. So 2116 is a review article, 01:06:47
7 right? 01:06:52
8 A 2116, "Antisperm antibodies and 01:06:52
9 conception" is a review article. 01:06:57
10 Q Thank you. 01:06:59
11 And on page 174, in the first paragraph 01:06:59
12 on the left side, about the middle of that 01:07:12
13 paragraph, the sentence starts "Jager, et al." 01:07:15
14 Do you see that? 01:07:22
15 A The middle of the paper Jager... 01:07:23
16 Q One, two, three, four, five, six, 01:07:28
17 seven -- eight lines down in that paragraph. 01:07:30
18 A One, two, three, four, five, six, 01:07:33
19 seven, eight... 01:07:35
20 Yes, Jager, et al., I beg your pardon. 01:07:37
21 Uh-huh. 01:07:39
22 Q Yes. It says: Jager, et al. reported 01:07:40

1 that IgG can also induce a shaking phenomenon but 01:07:42
2 suggested that the fragment crystallizable (Fc) 01:07:47
3 region of the IgG molecule may be impairing the 01:07:51
4 motility of the antibody-bound sperm in the 01:07:54
5 cervical mucus. 01:07:57
6 A Yes. 01:07:59
7 Q Is that correct? 01:07:59
8 A That is correct. 01:07:59
9 Q Okay. So antibodies were thought to 01:08:00
10 impair the motility of the antibody-bound sperm in 01:08:04
11 the cervical mucus, correct? 01:08:07
12 A That is the claim, yes. 01:08:08
13 Q Do you agree that antisperm antibodies 01:08:16
14 can inhibit sperm motility? 01:08:17
15 MS. WANG: Objection to form. 01:08:23
16 A I have no direct knowledge of that. 01:08:24
17 BY MR. POWERS: 01:08:25
18 Q Do you agree that antisperm antibodies 01:08:25
19 can induce sperm agglutination? 01:08:27
20 MS. WANG: Objection to form. 01:08:32
21 A In vitro, that's an assay I know that 01:08:33
22 has been used, yes. 01:08:36

1 BY MR. POWERS: 01:08:37
2 Q So antibodies that bind sperm can cause 01:08:37
3 agglutination? 01:08:43
4 A Ex vivo, that's for sure. 01:08:44
5 Q Do you have any knowledge of whether 01:08:47
6 that can happen in vivo? 01:08:48
7 A I do not. 01:08:51
8 Q You don't know one way or the other? 01:08:51
9 A I do know that it's -- ex vivo is an 01:08:52
10 actual test that's been performed by various 01:08:55
11 laboratories. I do not know whether it occurs in 01:08:58
12 vivo. 01:09:01
13 Q Okay. Are you aware of the Frayne 01:09:02
14 reference? 01:09:21
15 A A frame reference? 01:09:24
16 Q I'm going to hand you -- 01:09:26
17 A Okay, thank you. 01:09:26
18 Q -- Exhibit 2114. 01:09:26
19 (Previously marked Exhibit Number 2114 01:09:28
20 was identified.) 01:09:28
21 A Very good, thank you. 01:09:29
22 Yes. This is another review, yes. 01:09:43

1 BY MR. POWERS: 01:09:44
2 Q Another review -- what's the title? So 01:09:44
3 you've seen this document before? 01:09:46
4 A I don't think so, no. 01:09:47
5 Q You actually cited this document in 01:09:51
6 your declaration. 01:09:53
7 A Then it's slipped my memory, then, 01:09:54
8 because there's been dozens of those, yes. 01:09:56
9 Q No problem. 01:09:59
10 So what's the title of this document? 01:10:00
11 A "The potential use of sperm antigens as 01:10:03
12 targets for immunocontraception; past, present, 01:10:06
13 and future." 01:10:12
14 Q If you go to page 3 of that document. 01:10:14
15 A Yes. 01:10:21
16 Q In the first full paragraph of that -- 01:10:22
17 of text on that page, it says: However, the 01:10:28
18 detrimental effect of such antibodies on fertility 01:10:33
19 is primarily caused by their ability to trap or 01:10:37
20 agglutinate sperm in semen and cervical mucous 01:10:40
21 rather than specifically inhibiting -- rather than 01:10:44
22 by specifically inhibiting gamete interactions. 01:10:46

1 Correct? 01:10:51
2 A I'm trying to find this. This is on 01:10:51
3 page 3? 01:10:53
4 Q Page 3 of the document. 01:10:54
5 A One, two -- oh, I'm sorry. I was on 01:10:57
6 the wrong page. Beg your pardon. 01:10:58
7 And the paragraph is the center -- 01:11:00
8 Q The first full paragraph on page 3, and 01:11:07
9 I'd like to direct you to the text at the bottom 01:11:09
10 of that paragraph starting with "However." 01:11:11
11 A Hmm. Yes. "However, the detrimental 01:11:14
12 effects of such antibodies on fertility is 01:11:18
13 primarily caused by their ability to trap or 01:11:20
14 agglutinate sperm in semen and cervical..." 01:11:23
15 That's what the sentence says. 01:11:29
16 Q And this article was published in 1999, 01:11:30
17 correct? 01:11:34
18 A That is correct. 01:11:34
19 Q So a person of ordinary skill in the 01:11:34
20 art in 2011 or 2012 would have known of this 01:11:36
21 article, correct? 01:11:40
22 A Yes. 01:11:40

1 Q And so would you agree with me that it 01:11:42
2 was reported in the literature that antibodies can 01:11:44
3 agglutinate sperm in vivo? 01:11:48
4 A Is that what this actually says? 01:11:52
5 That is the claim of this review, 01:12:39
6 absolutely. 01:12:44
7 Q Do you agree that interference with 01:12:51
8 sperm capacitation was another recognized 01:12:52
9 mechanism? 01:12:55
10 A From my reading -- I'm not intimately 01:12:57
11 familiar with that, but from my reading that was 01:13:01
12 proposed as a second possibility, yes. 01:13:02
13 Q A mechanism of infertility? 01:13:04
14 A Yes. 01:13:07
15 Q And interference with the acrosome 01:13:09
16 reaction was also a known mechanism of 01:13:10
17 interference with fertility, correct? 01:13:14
18 A I think in terms of in vitro fertility 01:13:17
19 studies, acrosome inhibition, the penetrating part 01:13:22
20 of the sperm, that was shown to inhibit in vitro 01:13:24
21 fertilization. 01:13:28
22 Q And do you agree that antisperm 01:13:35

1 antibodies were known to simulate 01:13:38
2 complement-mediated sperm lysis? 01:13:40
3 A No. I do not know that. 01:13:44
4 Q Okay. I'm going to direct you back to 01:13:56
5 Exhibit 2116. 01:13:58
6 A Yes. 01:14:01
7 Q The Chamley reference -- 01:14:02
8 A Yes. 01:14:05
9 Q -- which was cited by Dr. Cherr? 01:14:05
10 A Uh-huh. 01:14:07
11 Q On page 174 of that reference -- 01:14:13
12 A Yes. 01:14:16
13 Q Forgive me. 175 on that reference, on 01:14:16
14 the left column, in the left column. 01:14:37
15 A Uh-huh. 01:14:39
16 Q Eight lines down, there's a sentence 01:14:39
17 that starts with "D'Cruz, et al." 01:14:44
18 A Yes. 01:14:48
19 Q It says: D'Cruz, et al. have also 01:14:52
20 demonstrated that sperm-bound ASA obtained from 01:14:55
21 the ejaculates of men with ASA are capable of 01:14:58
22 activating complement. 01:15:02

1 A Uh-huh. 01:15:04
2 Q Do you see that statement? 01:15:05
3 A Yes, I do. 01:15:06
4 Q So isn't it true that antisperm 01:15:07
5 antibodies were known to simulate 01:15:09
6 complement-mediated sperm lysis? 01:15:11
7 A These were all in vitro assays, and so 01:15:14
8 in vitro, yes. Evidently that's been reported. 01:15:18
9 Q Do you have any knowledge of whether or 01:15:23
10 not such results were found in vivo? 01:15:24
11 A Not to my knowledge. I do not have 01:15:31
12 that knowledge. 01:15:33
13 Q PH20 is a sperm-associated protein, 01:15:33
14 correct? 01:15:36
15 A That is correct. 01:15:39
16 Q And PH20 is expressed on the surface of 01:15:39
17 sperm, correct? 01:15:42
18 A That is correct. 01:15:44
19 Q PH20 is localized on the sperm 01:15:47
20 acrosome, correct? 01:15:49
21 A I thought it was in the posterior head, 01:15:53
22 which is below the acrosome. That's where the 01:15:55

1 PH20 antibody binds anyway. 01:16:00
2 Q Okay. Do you know where on the sperm 01:16:02
3 PH20 binds and -- or sorry -- PH20 is localized? 01:16:05
4 A My understanding from the Primakoff 01:16:11
5 paper in which the original antibodies -- the 01:16:15
6 sperm antibodies were described, all the PH 01:16:20
7 antibodies -- PH20 is the relevant one -- bind on 01:16:24
8 the posterior head. 01:16:28
9 Q Anywhere else where you know, one way 01:16:30
10 or the other, whether PH20 is localized in the 01:16:33
11 sperm? 01:16:36
12 A Only by those antibodies. I just know 01:16:37
13 from the immunofluorescence image that they 01:16:41
14 provided as a result. 01:16:45
15 Q But you do understand that PH20 is a 01:16:47
16 surface protein on sperm -- 01:16:50
17 A I do. 01:16:53
18 Q -- correct? 01:16:53
19 A person of ordinary skill in the art 01:16:57
20 would expect that an antibody bound to PH20 on 01:17:00
21 sperm would be an antisperm antibody, correct? 01:17:03
22 A By definition, yes. 01:17:06

1 MS. WANG: Objection to form. 01:17:08
2 BY MR. POWERS: 01:17:08
3 Q And once bound an antibody bound to 01:17:08
4 PH20 could impair motility like other sperm 01:17:12
5 antibodies, correct? 01:17:17
6 MS. WANG: Objection to form. 01:17:20
7 A So -- despite my old master's thesis, I 01:17:22
8 am not an expert on sperm motility. 01:17:26
9 Basically, the binding of PH20 01:17:32
10 antibodies that were described by Primakoff 01:17:36
11 originally show bindings on the head, not on the 01:17:38
12 tail, and I would have guessed that antisperm 01:17:41
13 antibodies that bind to the tail would more likely 01:17:45
14 inhibit motility than those that bind to its head. 01:17:49
15 BY MR. POWERS: 01:17:52
16 Q But you don't know one way or the other 01:17:52
17 sitting here today? 01:17:55
18 A Beyond what I just explained, I do not 01:17:56
19 know. 01:17:57
20 Q Do you know if an antibody bound to 01:18:01
21 PH20 on sperm could cause sperm agglutination? 01:18:05
22 A If the sperm were in close enough 01:18:12

1 approximation and the antibody could span the 01:18:14
2 distance between the two, yes. 01:18:17
3 Q It could cause agglutination? 01:18:20
4 A Under the ideal conditions, absolutely. 01:18:22
5 Q Do you know if an antibody bound to 01:18:26
6 PH20 on sperm could produce sperm penetration 01:18:28
7 through cervical mucus? 01:18:30
8 A I have no firsthand knowledge of this 01:18:37
9 at all. It would surprise me. But these are tiny 01:18:39
10 molecules. You know, these are less than a few 01:18:48
11 angstroms long. Why this would delay the antibody 01:18:51
12 migrating through cervical mucus, I just -- 01:18:55
13 perhaps it could, but I find it -- these are 01:18:59
14 molecules. 01:19:06
15 Q This isn't really your field, correct? 01:19:06
16 MS. WANG: Objection to form. 01:19:10
17 A This is not my field, that is correct. 01:19:11
18 BY MR. POWERS: 01:19:13
19 Q Do you know if an anti-PH20 antibody 01:19:13
20 could interfere with capacitation of sperm? 01:19:17
21 A From my reading, my understanding is 01:19:24
22 that the binding that has been studied is post 01:19:27

1 capacitation, so I don't know. I mean, I simply 01:19:30
2 don't know whether it could or not. 01:19:35
3 Q You don't know one way or the other? 01:19:37
4 A I do not. 01:19:38
5 Q Do you know if an anti-PH20 antibody 01:19:39
6 binding to sperm could interfere with the acrosome 01:19:41
7 reaction? 01:19:46
8 A The acrosome is at the apex of the 01:19:48
9 head. The antibodies are at the posterior head. 01:19:51
10 I would assume not. Given the fact that -- no, 01:19:53
11 that's it. I don't know. Yeah. 01:20:00
12 Q You don't know one way or the other? 01:20:02
13 A Only from sort of general biological 01:20:04
14 principles. 01:20:07
15 Q Do you know if an anti-PH20 antibody 01:20:09
16 bound to sperm could activate complement and 01:20:13
17 promote sperm lysis? 01:20:18
18 A The antibody, in theory, if complement 01:20:21
19 is available, could promote sperm lysis, depending 01:20:25
20 on, of course, the isotype and the density of 01:20:29
21 antibody on the sperm. 01:20:32
22 Q So, yes, it's a possibility, right? 01:20:34

1 A It is a possibility. 01:20:35
2 MS. WANG: Objection to form. 01:20:36
3 BY MR. POWERS: 01:20:36
4 Q Do you know what the zona pellucida is? 01:20:36
5 A In general terms. I know it's the 01:20:43
6 region that surrounds the ovum prior to 01:20:46
7 fertilization. 01:20:50
8 Q Do you know what the zona pellucida is 01:20:51
9 made of? 01:20:53
10 A Hyaluronans, my understanding is. 01:20:54
11 Mucous, sort of. 01:20:57
12 Q Do you know if an anti-PH20 antibody 01:21:01
13 bound to sperm could interfere with the sperm's 01:21:03
14 penetration of the zona pellucida? 01:21:06
15 A My understanding from the readings is 01:21:10
16 that it slows -- ex vivo, it slows penetration of 01:21:11
17 the zona pellucida. 01:21:14
18 Q But you're not an expert in the biology 01:21:17
19 of the zona pellucida? 01:21:19
20 A I'm certainly not. 01:21:21
21 Q Do you still have your declarations in 01:21:55
22 front of you? 01:21:56

1 A Yes. 01:22:01
2 Q Would you go to paragraph 63 of your 01:22:01
3 declaration? In that paragraph you talk about 01:22:03
4 ZP3, right? 01:22:15
5 A Let me just read the paragraph to make 01:22:17
6 sure I'm with you on this. 01:22:18
7 Q Sure. 01:22:19
8 A Yes. I've read the paragraph now. 01:22:35
9 Q In that paragraph you talk about ZP3, 01:22:40
10 correct? 01:22:43
11 A mZP3, yes. 01:22:45
12 Q ZP3 is an ovarian antigen, correct? 01:22:51
13 A I certainly don't know. As an 01:22:56
14 immunologist, I simply took that as an immunogen. 01:22:59
15 A sperm associated or -- of a -- not a sperm 01:23:04
16 associated -- a fertilization associated 01:23:07
17 immunogen. 01:23:10
18 Q Do you know what ZP stands for in mZP3? 01:23:11
19 A Zona pellucida, I suppose. 01:23:15
20 Q Yeah. So applying that logic, would 01:23:17
21 you agree that ZP3 is an ovarian antigen? 01:23:19
22 A It surrounds the ovum, yes. 01:23:23

1 Q So ZP3 is expressed by female ovarian 01:23:27
2 tissue, right? 01:23:33
3 A Uh-huh. 01:23:34
4 Q So it's a self-antigen in females, 01:23:34
5 correct? 01:23:36
6 A It would be, yes. 01:23:37
7 Q Do you agree that this group that you 01:23:42
8 referred to in this paragraph was able to raise 01:23:45
9 antibodies against ZP3 even though it was a 01:23:47
10 self-antigen in females? 01:23:50
11 A That's what their claim is, yes. 01:23:52
12 Q Do you agree that a mucosal antibody 01:23:54
13 response isn't relevant for ovarian tissue? 01:23:57
14 A Could you repeat the question. 01:24:00
15 Q In this context or this -- where you're 01:24:02
16 talking about this paper, is a mucosal antibody 01:24:05
17 response relevant or is systemic antibody 01:24:08
18 response? 01:24:12
19 A To my recollection, this was not a 01:24:13
20 mucosal immunization. This was a systemic 01:24:15
21 immunization. 01:24:17
22 Q So a mucosal antibody response isn't 01:24:19

1 relevant for this paper that you're talking about 01:24:21
2 in this paragraph, right? 01:24:22
3 A Right. 01:24:23
4 MS. WANG: Objection to form. 01:24:24
5 A So what is relevant is the presence -- 01:24:25
6 presumably is the presence of antibody. The 01:24:29
7 mechanism is not shown, as I recall. It's simply 01:24:31
8 there's a correlation. 01:24:35
9 So the question is, is can you get 01:24:37
10 antibody into the fallopian tubes, the oviducts? 01:24:43
11 Do you require an immune response that is 01:24:47
12 mucosally associated, or can you have a systemic 01:24:52
13 immune response? And systemic immune response, 01:24:57
14 certainly in this case and in many other -- and in 01:25:01
15 human vaccines can produce strong IgG responses in 01:25:03
16 the mucosal surfaces. 01:25:10
17 So would a mucosal immunization be 01:25:12
18 necessary in this case, the paper says it's not. 01:25:16
19 Would it have been official? I can't speculate. 01:25:19
20 BY MR. POWERS: 01:25:24
21 Q Okay. Fair to say that the ovary is 01:25:24
22 not subject to a mucosal immune response? 01:25:26

1 A The oviducts are connected to the 01:25:31
2 outside like anything else. I would -- I don't 01:25:34
3 know about the -- if there's any associated 01:25:38
4 lymphoid tissue. I just don't know that. 01:25:44
5 Q Do you know where the ovum matures in a 01:25:47
6 woman? 01:25:51
7 A Actually, no. Travels from the ovary 01:25:57
8 through the fallopian tubes and it embeds 01:26:02
9 somewhere in the plumbing going down, but I don't 01:26:04
10 know for sure, no. 01:26:06
11 Q So you can't say one way or the other 01:26:08
12 whether a mucosal immune response would be 01:26:10
13 relevant to the paper that you address in 01:26:14
14 paragraph 63 of your declaration? 01:26:18
15 MS. WANG: Objection to form. 01:26:21
16 BY MR. POWERS: 01:26:21
17 Q Right? 01:26:21
18 A I'm not sure that -- maybe I'm not -- 01:26:22
19 the antifertilization state that's referenced here 01:26:29
20 was achieved by systemic fertilization. 01:26:33
21 Q Right. 01:26:37
22 A If the antigen is an ovarian antigen, 01:26:37

1 then somehow the systemic antibody reached, 01:26:40
2 presumably, prohibited fertilization. 01:26:43
3 Q And I'm trying to explore that with 01:26:51
4 you. 01:26:53
5 A Okay. 01:26:53
6 Q Is that necessarily true if the oocyte 01:26:54
7 matures in the ovary before it reaches any kind of 01:26:58
8 mucosal secretion? 01:27:04
9 A I'm sorry. I understand the question 01:27:06
10 now. 01:27:07
11 If the oocyte is prohibited from being 01:27:07
12 released from the ovary, for example, I guess one 01:27:10
13 would also see an anticonceptive state. 01:27:13
14 Q So simply by impairing the maturation 01:27:18
15 of the oocyte to prevent it from releasing into 01:27:21
16 the oviduct, you could see a decline in fertility, 01:27:25
17 correct? 01:27:33
18 MS. WANG: Objection to form. 01:27:35
19 A Again, I'm not an expert. But that -- 01:27:36
20 if one blocks sperm production, one sees a loss of 01:27:38
21 fertility. If one block's ovum maturation and 01:27:44
22 release, one would also see a loss of fertility. 01:27:47

1 BY MR. POWERS: 01:27:50
2 Q Another way of asking the question is, 01:27:50
3 the developing oocyte is not subject to the 01:27:52
4 mucosal compartment, right? 01:27:55
5 A Again, I don't know what is exposed to 01:27:59
6 the oviduct. I just don't know. 01:28:01
7 Q Do you agree that a useful 01:28:32
8 contraceptive doesn't require complete 01:28:34
9 infertility? 01:28:38
10 MS. WANG: Objection to form. 01:28:41
11 A I suppose that depends on what the 01:28:46
12 intent of the complete contraceptive activity is. 01:28:49
13 I would think in the case of, like, a human drug, 01:28:58
14 that 100 percent -- very high efficacy would be 01:29:04
15 required, 90-some-odd plus percent, much like 01:29:10
16 normal birth control, hormonal birth control. 01:29:14
17 If the immunization was used to reduce 01:29:17
18 wildlife populations, maybe 50 percent reduction 01:29:21
19 would be an ecological good thing. So I think it 01:29:26
20 depends on what the intent of the -- of the -- the 01:29:29
21 immune state is intended to address. 01:29:35
22 BY MR. POWERS: 01:29:36

1 Q So you can imagine a useful 01:29:36
2 contraceptive that has efficacy as low as 01:29:38
3 50 percent? 01:29:42
4 MS. WANG: Objection to form. 01:29:44
5 BY MR. POWERS: 01:29:44
6 Q Is that right? 01:29:44
7 A That simply is a question relating to 01:29:45
8 my prior answer. If you're controlling rabbit 01:29:48
9 populations in Australia, maybe a 50 percent 01:29:54
10 reduction would be ecologically beneficial. If 01:29:56
11 you're trying to control human birth, for example, 01:30:02
12 50 percent reduction would probably not be useful. 01:30:05
13 It certainly wouldn't -- it wouldn't match already 01:30:10
14 standing mechanisms, hormonal mechanisms for 01:30:14
15 contraception. 01:30:18
16 Q So it would depend on the use case? 01:30:19
17 A The intended use, I think so. 01:30:22
18 Q But at least some uses would be 01:30:25
19 beneficial in a 50 percent reduction in fertility, 01:30:30
20 right? 01:30:33
21 MS. WANG: Objection to form. 01:30:34
22 A 50 percent reduction would be good -- 01:30:35

1 or have a potential benefit only in those 01:30:39
2 conditions. And I would imagine if you reduce the 01:30:42
3 pigeon population of New York, a 50 percent 01:30:49
4 reduction would be both beneficial and 01:30:53
5 appreciated. If you reduce the fecundity of a 01:30:57
6 married couple, a human married couple by 01:31:02
7 50 percent, that probably would not have any 01:31:05
8 utility. 01:31:08
9 BY MR. POWERS: 01:31:11
10 Q Most contraceptives do not have 01:31:11
11 100 percent effectiveness, correct? 01:31:14
12 A I think hormonal contraceptives are -- 01:31:20
13 and in my personal experience, greater than 01:31:23
14 99 percent effectiveness or something like that. 01:31:28
15 Surgical resection vasectomies, 90-something 01:31:32
16 percent positive. Tying the fallopian tubes are 01:31:37
17 pretty close to 100 percent. I think those are 01:31:44
18 all mechanisms of contraception. 01:31:46
19 Q So surgical interventions, you'd 01:31:50
20 consider that contraception. 01:31:52
21 A It certainly stops conception. 01:31:54
22 Q Would it surprise you to know that the 01:32:00

1 real-world efficacy of birth control pills is only 01:32:01
2 around 93 percent? 01:32:05
3 MS. WANG: Objection to form. 01:32:07
4 A It would surprise me. I'm obviously 01:32:13
5 not an expert in reproductive biology, and I 01:32:16
6 wonder, like all drug studies, how much of this is 01:32:19
7 due to patient error in taking the drug versus the 01:32:22
8 efficacy of the drug, per se. 01:32:25
9 BY MR. POWERS: 01:32:30
10 Q Do you agree that condoms don't have 01:32:30
11 100 percent effectiveness? 01:32:32
12 A I do. But that is condom use. As a 01:32:34
13 physical barrier, it's 100 percent effective. 01:32:40
14 Q Are you aware of how effective condoms 01:32:46
15 are with typical real-world use? 01:32:48
16 A No. 01:32:52
17 Q Would it surprise you that condoms are 01:32:53
18 only around 87 percent effective with typical -- 01:32:54
19 A It would not surprise me. 01:32:58
20 Q Do you understand that contraceptives 01:33:00
21 are sometimes used in combination? 01:33:02
22 MS. WANG: Objection to form. 01:33:09

1 BY MR. POWERS: 01:33:09
2 Q With one another? 01:33:09
3 Let me try that again. 01:33:12
4 A I mean, I'm not -- 01:33:13
5 Q Let me ask a different question. 01:33:14
6 A Yes, okay. 01:33:15
7 Q Do you understand that multiple modes 01:33:16
8 of contraceptive devices or interventions are used 01:33:18
9 in combination sometimes? 01:33:23
10 A I have no personal experience or 01:33:26
11 professional experience to say yes or no. I just 01:33:27
12 don't know. 01:33:33
13 Q You don't know one way or another? 01:33:33
14 A I mean, I'm thinking like -- I do not 01:33:36
15 know one way or the other. 01:33:40
16 Q You've never heard of somebody using a 01:33:42
17 condom in a spermicidal lubricant? 01:33:45
18 A You're absolutely correct. Only in the 01:33:55
19 context of HIV transmission, but yes. 01:33:57
20 Q So is it fair to say that frequently 01:34:00
21 multiple modes of contraception are used together? 01:34:03
22 MS. WANG: Objection to form. 01:34:07

1 A I don't know what the frequency is, but 01:34:10
2 it's certainly frequent enough for me to know that 01:34:12
3 this occurs. 01:34:14
4 BY MR. POWERS: 01:34:16
5 Q And you would agree that contraceptives 01:34:16
6 have been and are still used today as tools for 01:34:18
7 population control in animals, correct? 01:34:22
8 A Contraceptives? 01:34:25
9 Q Yes. 01:34:26
10 A Yes. 01:34:26
11 Q And you would agree that a method for 01:34:30
12 population control in animals would not need to 01:34:33
13 cause complete infertility to be useful -- 01:34:37
14 MS. WANG: Objection to form. 01:34:40
15 A That's my -- 01:34:40
16 (Stenographer requested clarification.) 01:34:40
17 Q You would agree that, as a method for 01:34:48
18 population control, a contraceptive would not need 01:34:51
19 to cause incomplete fertility to be useful, 01:34:59
20 correct? 01:35:02
21 MS. WANG: Objection to form. 01:35:04
22 A I think that -- and, again, as I 01:35:04

1 described in the sense of ecological control for a 01:35:07
2 species, a 50 percent reduction of the fecundity 01:35:12
3 would have an important and valuable role. 01:35:18
4 BY MR. POWERS: 01:36:08
5 Q Do you agree that certain contraceptive 01:36:08
6 methods are not designed to last for more than a 01:36:10
7 few minutes? 01:36:12
8 MS. WANG: Objection to form. 01:36:13
9 A In my experience, condoms, for example, 01:36:26
10 are employed for contraception on the order of 01:36:28
11 minutes, yes. 01:36:32
12 Q Similar for spermicides? 01:36:35
13 A That would be my understanding. 01:36:40
14 Q What about the sponge method? 01:36:49
15 A I have no personal knowledge of the 01:36:51
16 sponge method. 01:36:55
17 Q You have no expertise in the sponge 01:36:56
18 method? 01:36:57
19 A I'm a male. We don't do that, but, no, 01:36:58
20 I do not. 01:37:01
21 Q And what about spermicides? They're 01:37:06
22 designed to only have efficacy for a few minutes, 01:37:09

1 correct? 01:37:11
2 A They should have a short half-life, 01:37:12
3 yes. 01:37:14
4 Q So you would agree that a persistent 01:37:14
5 response is not necessarily required for 01:37:16
6 contraception, right? 01:37:18
7 MS. WANG: Objection to form. 01:37:20
8 A Persistent... 01:37:21
9 Well, again, I think this gets to 01:37:22
10 intention. You just told me that condom use is 01:37:34
11 87 percent effective, whereas hormonal control is 01:37:41
12 93 percent effective. Both of those have the 01:37:46
13 potential of misuse, forgetting a pill or a 01:37:51
14 fracture of the condom or a loss of the condom. 01:37:55
15 But, yeah, if you think about 01:38:09
16 contraception, I think most people -- at least I 01:38:12
17 think about it as a family, someone who has a 01:38:13
18 family, is something that is lasting and not -- 01:38:16
19 relies at the last minute. 01:38:21
20 I couldn't imagine giving condoms to a 01:38:23
21 population of Australian rabbits and expecting any 01:38:27
22 sort of efficacy at all. 01:38:32

1 BY MR. POWERS: 01:38:34
2 Q That would be silly. 01:38:34
3 But you do agree that contraception 01:38:35
4 does not necessarily require a very long duration, 01:38:42
5 correct? 01:38:46
6 MS. WANG: Objection to form. 01:38:49
7 A In my understanding of contraception to 01:38:50
8 block, for example, the product of a single 01:38:53
9 coitus, it needs -- 01:39:02
10 (Stenographer requested clarification.) 01:39:07
11 A If the point was to only involve 01:25:38
12 contraception at that point, a relatively 01:39:13
13 short-acting contraceptive would be appropriate. 01:39:15
14 BY MR. POWERS: 01:39:20
15 Q Do you agree that condoms are a useful 01:39:20
16 contraception? 01:39:26
17 MS. WANG: Objection to form. 01:39:29
18 A I think that they have been used as a 01:39:29
19 useful contraceptive, at least in my world, in the 01:39:33
20 HIV world. They're more often used as 01:39:39
21 preventive-transmission block basically. 01:39:42
22 BY MR. POWERS: 01:39:48

1 Q And even at an 87 percent effective 01:39:48
2 rate, they're considered useful, correct? 01:39:53
3 MS. WANG: Objection to form. 01:39:56
4 A They are considered useful given the 01:39:59
5 consequences, for example, of HIV transmission, 01:40:02
6 yes. 01:40:04
7 BY MR. POWERS: 01:40:08
8 Q As far as immunocontraception goes, you 01:40:08
9 would agree that immunocontraception does not 01:40:21
10 require lifelong antibodies, right? 01:40:23
11 MS. WANG: Objection to form. 01:40:25
12 A No. Putative contraceptive state and 01:40:28
13 the one originally described by Primakoff was in 01:40:35
14 guinea pigs, was reversible after a period of 01:40:37
15 time. One could see how that would mean that the 01:40:41
16 product would be a contraceptive and not a 01:40:46
17 sterilizing product. 01:40:49
18 BY MR. POWERS: 01:40:53
19 Q Right. And you, therefore, might not 01:40:53
20 want high titers of antibodies as part of your 01:40:56
21 immune contraception at all times, right? 01:41:01
22 MS. WANG: Objection to form. 01:41:03

1 A The body takes care of that all by 01:41:03
2 itself. There are very few antigens that have 01:41:09
3 persistent antibody titers for periods of time 01:41:12
4 longer than, let's say, five years. 01:41:16
5 BY MR. POWERS: 01:41:20
6 Q Do you agree that transient or even 01:41:20
7 moderate antibody levels could be sufficient in an 01:41:23
8 immunocontraceptive as long as they disrupt 01:41:26
9 fertilization? 01:41:31
10 A Antibodies that -- 01:41:31
11 MS. WANG: Objection to form. 01:41:32
12 A -- effectively disrupt fertilization 01:41:32
13 would be useful only if they persisted in 01:41:38
14 sufficient amount for some period of time X, yes. 01:41:41
15 MR. POWERS: Let's take a little break. 01:41:47
16 THE VIDEOGRAPHER: We're going off the 01:41:52
17 record. The time is 1:41 p.m. 01:41:53
18 (Whereupon, a brief recess was taken.) 01:56:23
19 THE VIDEOGRAPHER: We're back on the 01:56:34
20 record. The time is 1:56 p.m. 01:56:35
21 BY MR. POWERS: 01:56:37
22 Q Dr. Kelsoe, during any of the breaks 01:56:37

1 today did you speak about the substance of your 01:56:39
2 testimony with counsel? 01:56:41
3 A I did not. 01:56:42
4 MR. POWERS: Thank you very much. We 01:56:42
5 have no further questions for you at this 01:56:44
6 time. Pass the witness. 01:56:45
7 MS. WANG: Can you give us a few 01:56:50
8 minutes? 01:56:51
9 THE VIDEOGRAPHER: Going off the 01:56:54
10 record. The time is 1:56 p.m. 01:56:55
11 (Whereupon, a brief recess was taken.) 02:03:01
12 THE VIDEOGRAPHER: Back on the record. 02:03:01
13 The time is 2:03 p.m. 02:03:41
14 MS. WANG: Thank you, Dr. Kelsoe. We 02:03:46
15 have no questions. So the witness will read 02:03:47
16 and sign. 02:03:50
17 THE VIDEOGRAPHER: This marks the end 02:03:53
18 of the deposition of Dr. Garnett Kelsoe. 02:03:53
19 We're going off the record at 2:04 p.m. 02:03:55
20 (Reserved signature.)
21 (The deposition concluded at 2:04 p.m.)
22

STATE OF NORTH CAROLINA)
COUNTY OF FORSYTH)

REPORTER'S CERTIFICATE

I, Audra Smith, Registered Professional Reporter in and for the above county and state, do hereby certify:

That GARNETT H. KELSOE, Ph.D., the witness whose deposition is hereinbefore set forth, was duly sworn by me before the commencement of such deposition and that such deposition was taken before me and is a true record of the testimony given by such witness.

I further certify that the adverse party, the Petitioner MERCK SHARP & DOHME LLC, was represented by counsel at the deposition.

I further certify that the deposition of GARNETT H. KELSOE, Ph.D., occurred at Washington Duke Inn 3001 Cameron Blvd Durham, NC 27705 on Thursday, February 5, 2026, commencing at 9:09 AM to 2:04 PM.

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

IN WITNESS WHEREOF, I have hereto set my hand this 5th day of February, 2026.

Audra Smith
_____

Audra Smith, RPR, CRR, FCRR
Notary Number: 201329000033
Commission Expires: June 26, 2031

A

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