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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  
PGR2025-00003

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

3 -----  
4 MERCK SHARP & DOHME LLC, Case Nos. PGR2025-00003;

5           Petitioner,                   00004; 00006; 00009

6 v.

7 HALOZYME INC.,                   U.S. Patent Nos.

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

9 -----                   12,152,262; 12,123,035  
10  
11

12                           \* \* \* \* \*

13                           ZOOM VIDEO DEPOSITION

14           Taken on behalf of the Patent Owner Halozyme Inc.

15                           GARNETT H. KELSOE, Ph.D.

16                           Chapel Hill, North Carolina

17                           February 5, 2026

18                           9:09 a.m.

19           Job No.:   619072

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

21           Video by:       Matthew Weedon, Videographer

22           Concierge:     Charese Harrison and Richard Kuritz

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11 Esq., Halozyme Inc. Patent Litigation Counsel

I N D E X

\*\*\*\*\*

PAGE

GARNETT H. KELSOE, Ph.D.

Examination By Mr. Powers

7

E X H I B I T S

NUMBER

DESCRIPTION

PAGE

Exhibit 2215 MF59 Adjuvant enhances  
Diversity and Affinity of  
Mediated Immune Response to  
Pandemic Influenza Vaccines

85

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

NUMBER

PAGE

Exhibit 1001

38

Exhibit 1170

63

Exhibit 2114

113

Exhibit 2116

109

Transcript of Garnett H. Kelsoe, Ph.D.  
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P R O C E E D I N G S

CONCIERGE HARRISON: Thank you to  
everyone for attending this proceeding  
remotely, which we anticipate will run  
smoothly.

Please remember to speak slowly and do  
your best not to talk over one another.  
Please be aware that we are recording this  
proceeding for backup purposes. Any  
off-the-record discussions should be had away  
from the computer. Please remember to mute  
your mic for those conversations.

Please have your video enabled to help  
the reporter identify who's speaking. If you  
are unable to connect with video and are  
connecting via phone, please identify  
yourself each time before speaking.

I apologize in advance for any  
technical-related interruptions.

Thank you.

THE VIDEOGRAPHER: Stand by for video  
read-on.

09:07:56  
09:08:02  
09:08:04  
09:08:07  
09:08:09  
09:08:11  
09:08:13  
09:08:13  
09:08:14  
09:08:16  
09:08:19  
09:08:20  
09:08:23  
09:08:23  
09:08:25  
09:08:28  
09:08:28  
09:08:31  
09:08:37  
09:08:38  
09:08:38

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Transcript of Garnett H. Kelsoe, Ph.D.  
Conducted on February 5, 2026

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|    |                                               |          |
|----|-----------------------------------------------|----------|
| 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 |

Transcript of Garnett H. Kelsoe, Ph.D.  
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|    |                                                             |          |
|----|-------------------------------------------------------------|----------|
| 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 |

Transcript of Garnett H. Kelsoe, Ph.D.  
Conducted on February 5, 2026

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|    |   |                                                    |          |
|----|---|----------------------------------------------------|----------|
| 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 |

|    |   |                                                   |          |
|----|---|---------------------------------------------------|----------|
| 1  | A | Very good.                                        | 09:11:30 |
| 2  | Q | So let me try that question again                 | 09:11:31 |
| 3  |   | because I think we were talking over each other a | 09:11:32 |
| 4  |   | little bit.                                       | 09:11:34 |
| 5  | A | May I ask one favor of you? I'm                   | 09:11:34 |
| 6  |   | terribly sorry. I'm hard of hearing. If you       | 09:11:38 |
| 7  |   | could speak up, it would be helpful.              | 09:11:40 |
| 8  | Q | Yes, sir, I will do that.                         | 09:11:42 |
| 9  | A | Thank you.                                        | 09:11:43 |
| 10 | Q | If you have trouble understanding my              | 09:11:43 |
| 11 |   | question for any reason throughout today, feel    | 09:11:45 |
| 12 |   | free to ask me to repeat it.                      | 09:11:47 |
| 13 | A | Yes.                                              | 09:11:49 |
| 14 | Q | Okay. So I see that there are some                | 09:11:49 |
| 15 |   | documents in front of you. You said, I think,     | 09:11:50 |
| 16 |   | there are some declarations in front of you. What | 09:11:57 |
| 17 |   | are those declarations?                           | 09:11:59 |
| 18 | A | These are my declarations in response             | 09:12:01 |
| 19 |   | to the patent claims, what I understand to be the | 09:12:04 |
| 20 |   | several patents that have been made by Halozyme.  | 09:12:09 |
| 21 | Q | Are those the four declarations that              | 09:12:15 |
| 22 |   | 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 |

Transcript of Garnett H. Kelsoe, Ph.D.  
Conducted on February 5, 2026

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|    |   |                                        |          |
|----|---|----------------------------------------|----------|
| 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 |

Transcript of Garnett H. Kelsoe, Ph.D.  
Conducted on February 5, 2026

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|    |                                                   |          |
|----|---------------------------------------------------|----------|
| 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, Chowpongpan, 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 |

Transcript of Garnett H. Kelsoe, Ph.D.  
Conducted on February 5, 2026

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|    |   |                                                  |          |
|----|---|--------------------------------------------------|----------|
| 1  | A | It's the second error in Appendix A,             | 09:17:26 |
| 2  |   | which is the same renumbering of Chowpongpan, 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 |

Transcript of Garnett H. Kelsoe, Ph.D.  
Conducted on February 5, 2026

20

|    |                                                 |          |
|----|-------------------------------------------------|----------|
| 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 |

Transcript of Garnett H. Kelsoe, Ph.D.  
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21

|    |   |                                                    |          |
|----|---|----------------------------------------------------|----------|
| 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 |

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|    |                                                 |          |
|----|-------------------------------------------------|----------|
| 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 |

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|    |   |                                         |          |
|----|---|-----------------------------------------|----------|
| 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

Transcript of Garnett H. Kelsoe, Ph.D.  
Conducted on February 5, 2026

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|    |                                                  |          |
|----|--------------------------------------------------|----------|
| 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 |

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|    |                                                   |          |
|----|---------------------------------------------------|----------|
| 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 |

Transcript of Garnett H. Kelsoe, Ph.D.  
Conducted on February 5, 2026

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|    |                                                   |          |
|----|---------------------------------------------------|----------|
| 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 Kohler 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  
2 understand pathologic conditions.

3 Immunologists use monoclonal antibodies  
4 routinely to measure other antibodies, for  
5 example, the presence and location of antigen, or  
6 to type the kinds of lymphocytes that are  
7 recovered from secondary lymphoid tissues.

8 Q Is it fair to say that monoclonal  
9 antibodies are useful to bind proteins?

10 A The great majority of useful monoclonal  
11 antibodies are probably directed towards protein.

12 Q And that can be also -- yeah -- to  
13 detect proteins?

14 A And to detect protein, yes.

15 Q Can monoclonal antibodies be useful to  
16 neutralize biological targets?

17 A Yes. Monoclonal antibodies are used,  
18 at least experimentally, as protective agents  
19 against certain infections.

20 Monoclonal antibodies, as I've already  
21 said, are useful for snake venom and are  
22 administered in such a way.

10:21:43

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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 |

Transcript of Garnett H. Kelsoe, Ph.D.  
Conducted on February 5, 2026

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|    |   |                                                    |          |
|----|---|----------------------------------------------------|----------|
| 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  
3       it because I have no real knowledge of the  
4       particular agent in mind. On the other hand,  
5       there are a large number of women -- fortunately,  
6       the antisperm antibodies in many women are not  
7       functionally contraceptive -- some are, some are  
8       not. And so somehow these individuals became  
9       sensitized to sperm.

10:38:32

10:38:50

10:38:52

10:38:59

10:39:02

10:39:09

10:39:13

10:39:15

10       Q       Do you agree that antibody binding to  
11       sperm is a significant cause of infertility in  
12       women?

10:39:21

10:39:25

10:39:28

13           MS. WANG: Objection to form.

10:39:29

14       A       I'm told that there are -- I don't know  
15       what the frequencies are because I'm not a  
16       reproductive biologist, but I know that there is  
17       an association. I think it's only an association  
18       between women with antibodies to sperm and reduced  
19       fertility, yes.

10:39:32

10:39:33

10:39:37

10:39:38

10:39:42

10:39:49

20       BY MR. POWERS:

10:39:52

21       Q       Do you agree that a larger protein is  
22       going to have more epitopes than a smaller protein

10:39:52

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  
3 titers can offset concerns about moderate binding  
4 affinity in eliciting an effective biological  
5 response?

10:50:01

10:50:08

10:50:11

10:50:15

6 A I do not.

10:50:16

7 Q Do you agree that the greater  
8 concentration of the antibody, the less need there  
9 is for high binding affinity?

10:50:19

10:50:20

10:50:22

10 A In what context are you asking the  
11 question? As a therapeutic agent?

10:50:27

10:50:29

12 Q In a general context.

10:50:33

13 A So as you -- I'm sure you know, the  
14 affinity is simply the equilibrium constant of the  
15 antigen binding to and falling off of the  
16 antibody. And if you have more antibody, the  
17 equilibrium constant stays the same because the  
18 equilibrium constant is measured by the  
19 concentration of the ligand.

10:50:39

10:50:41

10:50:45

10:50:48

10:50:54

10:50:59

10:51:02

20 So the answer is no. That's why I  
21 wanted to make sure I understood the context of  
22 what you're saying.

10:51:04

10:51:08

10:51:11

1           Q       You didn't testify in your declaration  
2       that antibodies must reach a particular affinity  
3       or avidity to elicit an effective therapeutic  
4       response, correct?

5           A       I did not state a threshold. I did  
6       not.

7           Q       You agree that it was known -- well, do  
8       you agree that it was known by 2012 that adjuvants  
9       can be used not only to raise titers but influence  
10      how well antibodies bind to antigen?

11          A       Actually, I can't agree with that. The  
12      magnitude of the response is increased. Whether  
13      or not there is affinity maturation, the increase  
14      in binding strength is proportional to a different  
15      part of the response, a so-called germinal center  
16      response.

17                   (Stenographer requested clarification.)

18 BY MR. POWERS:

19          Q       Can adjuvants increase a germinal  
20      center response?

21          A       No.

22          Q       Can adjuvants promote B-cell maturation

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  
2 antigens that are chronically stimulating -- the  
3 gut is not a sterile place.

4 These secrete antibodies. They also  
5 secrete IgG. And that antibody is transported by  
6 two different mechanisms into the lumen of the  
7 gut.

8 The same thing occurs in systemic  
9 immunization. It's just that there's no --  
10 generally for us there's no chronic stimulation  
11 because there's no chronic exposure to outside  
12 antigen with lymph nodes or spleen.

13 Q These lymphoid tissues that exist in  
14 the mucosal lining, are they able to host B  
15 cell-cell maturation?

16 A B cell-cell maturation in the sense of  
17 activation by antigen differentiation, yes, they  
18 do.

19 Q And is it your understanding that those  
20 lymphoid tissues exist in the reproductive tract  
21 of the female?

22 A My understanding is that they do.

11:41:58

11:42:01

11:42:04

11:42:07

11:42:09

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11:42:54

11:42:57

11:43:02

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  
2       centers from the luminal contents, activates the B  
3       cells, they proliferate, they mutate, they class  
4       switch, and the antibodies, as those cells leave  
5       the germinal centers, some significant population  
6       of them stay locally, and the antibodies that they  
7       secrete Crete with the so-called secretory piece  
8       are transmitted into the lumen of the gut. So  
9       they're -- in that sense, they are a local  
10      producer of mucosal antibodies.

11 BY MR. POWERS:

12           Q       And those -- so IgA exists as a dimer,  
13      correct?

14           A       In its native form, it is -- it's an  
15      IgG-like dimeric -- what am I trying to say --  
16      identical symmetrical molecule. It can be joined  
17      together by the so-called J chain, and that makes  
18      it a four-valent antibody.

19           Q       Quadrivalent; is that correct?

20           A       It would be quadrivalent in that case,  
21      yes.

22           Q       Does the quadrivalency of the IgA dimer

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

Transcript of Garnett H. Kelsoe, Ph.D.  
Conducted on February 5, 2026

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|    |                |                                                  |          |
|----|----------------|--------------------------------------------------|----------|
| 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 |

Transcript of Garnett H. Kelsoe, Ph.D.  
Conducted on February 5, 2026

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|    |                                                  |          |
|----|--------------------------------------------------|----------|
| 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 |

Transcript of Garnett H. Kelsoe, Ph.D.  
Conducted on February 5, 2026

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|    |                                                 |          |
|----|-------------------------------------------------|----------|
| 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 |                                                 |          |

1 STATE OF NORTH CAROLINA )  
COUNTY OF FORSYTH )

2 REPORTER'S CERTIFICATE

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

4 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  
5 such deposition was taken before me and is a true record  
of the testimony given by such witness.

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

8 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  
9 5, 2026, commencing at 9:09 AM to 2:04 PM.

10 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  
11 to this action, and that I am in no way interested,  
financially or otherwise, in the outcome of this matter.

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

13  
14   
15

16 Audra Smith, RPR, CRR, FCRR  
Notary Number: 201329000033  
17 Commission Expires: June 26, 2031  
18  
19  
20  
21  
22

| A                  |                          |                       |                      |
|--------------------|--------------------------|-----------------------|----------------------|
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Transcript of Garnett H. Kelsoe, Ph.D.  
Conducted on February 5, 2026

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Transcript of Garnett H. Kelsoe, Ph.D.  
Conducted on February 5, 2026

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Transcript of Garnett H. Kelsoe, Ph.D.  
Conducted on February 5, 2026

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Conducted on February 5, 2026

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Conducted on February 5, 2026

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Transcript of Garnett H. Kelsoe, Ph.D.  
Conducted on February 5, 2026

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Conducted on February 5, 2026

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Transcript of Garnett H. Kelsoe, Ph.D.  
Conducted on February 5, 2026

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