UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

_____

Merck Sharp & Dohme LLC,
Petitioner,

v.

Halozyme, Inc.
Patent Owner.

_____

Case PGR2025-00003
U.S. Patent No. 11,952,600

_____

Case PGR2025-00004
U.S. Patent No. 12,018,298

_____

Case PGR2025-00006
U.S. Patent No. 12,152,262

_____

Case PGR2025-00009
U.S. Patent No. 12,123,035

_____

VIDEO DEPOSITION OF GARY N. CHERR, Ph.D.,
San Francisco, California

Wednesday, November 12, 2025

STENOGRAPHICALLY REPORTED BY:
REBECCA L. ROMANO, RPR, CSR, CCR
California CSR No. 12546
Nevada CCR No. 827
Oregon CSR No. 20-0466
Washington CCR No. 3491

JOB NO. 7005263-001

PAGES 1 - 167

Petitioner Merck, Ex. 1129, p. 1
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

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Case PGR2025-00003
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Case PGR2025-00009
U.S. Patent No. 12,123,035

VIDEO DEPOSITION OF GARY N. CHERR, Ph.D., taken on behalf of the Petitioner, at Quinn Emanuel Urquhart & Sullivan, LLP, 50 California Street, 22nd Floor, San Francisco, California, commencing at 9:03 a.m., Wednesday, November 12, 2025 before REBECCA L. ROMANO, a Registered Professional Reporter, Certified Shorthand Reporter, Certified Court Reporter.

Petitioner Merck, Ex. 1129, p. 2
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

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Petitioner Merck, Ex. 1129, p. 3
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

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Petitioner Merck, Ex. 1129, p. 4
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

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ALSO PRESENT:

Eldora Ellison, Ph.D. at Sterne Kessler Goldstein & Fox(via Web videoconference)
Zachariah Fuson, Videographer
Aubrey Haddach, In-House Counsel at Halozyme, Inc.(via Web videoconference)
Josh Mack, Executive Director, Patent Litigation Counsel at Halozyme, Inc.

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Petitioner Merck, Ex. 1129, p. 5
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

I N D E X

DEPONENT — EXAMINATION
GARY N. CHERR, PH.D. — PAGE

BY MS. WANG — 10

E X H I B I T S

(Exhibits Premarked)

NUMBER — PAGE
Exhibit 1019
Exhibit 1020
Exhibit 1026
Exhibit 1061
Exhibit 2072
Exhibit 2103

COURT REPORTER'S NOTE: All quotations from exhibits are reflected in the manner in which they were read into the record and do not necessarily indicate an exact quote from the document.

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Petitioner Merck, Ex. 1129, p. 6
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

San Francisco, California;

Wednesday, November 12, 2025

9:03 a.m.

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THE VIDEOGRAPHER: We are on the record at 9:03 a.m. Pacific time on November 12th, 2025. Audio and video recording will continue to take place until all parties agree to go off the record.

Please note that microphones are sensitive and may pick up whispering and private conversations.

This is the video-recorded proceedings of Gary N. Cherr, Ph.D., taken by counsel for Plaintiff, Merck Sharp & Dohme LLC, v. Halozyme Inc., filed before the Patent Trial and Appeal Board.

This proceeding is being held at Quinn Emanuel Urquhart & Sullivan, LLP, located at 50 California Street, 22nd Floor, San Francisco, California 94111.

My name is Zachariah Fuson. I am the videographer on behalf of U.S. Legal Support, located at 16825 North Chase Drive, Suite 900, Houston, Texas 77060. I am not related to any

Petitioner Merck, Ex. 1129, p. 7
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

party in this action, nor am I financially interested in the outcome.

The court reporter today is Rebecca Romano on behalf of U.S. Legal Support.

Counsel will state their appearances for the record, after which the court reporter will enter the statement for remote proceedings into the record and swear in the witness.

MS. WANG: Good morning.

My name is Sue Wang. Also with me is Chelsea Himes. We are both from the Sidley Austin firm, here for Petitioner Merck Sharp & Dohme.

I believe we also have in remote attendance Mr. Jeff Kushan, also from the Sidley firm, as well as Brian Goldberg from the Dechert firm, both also for Petitioner.

MR. POWERS: Good morning.

My name is Ralph Powers, III, from Sterne Kessler Goldstein & Fox, on behalf of Patent Owner Halozyme Inc.

Also in the room for Halozyme we have Nancy Zhang from Quinn Emanuel and Josh Mack from Halozyme.

Attending on the line for Halozyme are Eldora Ellison from Sterne Kessler,

Pratibha Khanduri from Sterne Kessler, and Aubrey Haddach from Halozyme.

THE COURT REPORTER: My name is Rebecca Romano. I am a California-licensed Stenographic Court Reporter, No. 12546. I will be producing a transcript that is automatically admissible in court.

If you could raise your right hand for me, please.

THE DEPONENT: (Complies.)

THE COURT REPORTER: You do solemnly state, under penalty of perjury, that the testimony you are about to give in this deposition shall be the truth, the whole truth and nothing but the truth?

THE DEPONENT: I do.

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Petitioner Merck, Ex. 1129, p. 9
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

GARY N. CHERR, Ph.D.,
having been administered an oath, was examined and testified as follows:

EXAMINATION

BY MS. WANG:

Q. Good morning.

Can you please state your full name for the record.

A. Yes, Gary Neil Cherr.

Q. Have you been deposed before, Dr. Cherr?

A. Yes, I have.

Q. How many times?

A. Twice.

Q. Were both in connection with patent proceedings?

A. No, not related at all.

Q. So you've never been deposed before in connection with a patent proceeding?

A. No.

Q. I'll go over a few ground rules for this deposition.

So the first one is that we shouldn't talk over one another. That allows the court reporter to create a clear record.

If you don't understand one of my

Petitioner Merck, Ex. 1129, p. 10
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

questions, please ask me to clarify. Otherwise, I will assume that you understand it when you answer; is that fair?

A. Yes.

Q. Okay. I'll try to take a break every hour or so, but definitely, if you need a break, please let me know.

A. I will.

Q. The only time we can't take a break if there's -- is if there's a question pending.

And in this deposition format, you have to answer my questions unless counsel instructs you not to answer.

Do you understand that?

A. Yes.

Q. Do you understand you're here having your deposition taken regarding declarations that you submitted in four post-grant review proceedings?

A. Yes, I do.

Q. Okay. And those four post-grant review proceedings are PGR2025-00003, -00004, -00006 and -00009.

A. Yes.

Q. Do you understand that?

Okay. I see you have binder in front of

Petitioner Merck, Ex. 1129, p. 11
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

you. What is that that you have in front of you?
A. This is the -- the four declarations put together.
That's all.
Q. Okay. So it's your four declarations in the four PGR proceedings?
A. Yes, correct.
Q. And each of them is marked Exhibit 2072?
A. Yes, that's correct.
Q. Thank you.
And what, if anything, did you do to prepare for today's deposition?
A. Primarily, review my -- my declaration and -- and all the references that were in my declaration. And then I had some preparation with the attorneys that are in the room.
Q. And that would be Mr. Powers, Ms. Zhang and Mr. Mack?
A. Yes, correct.
Q. Did you meet with anyone else besides the attorneys in the room?
A. No, there -- well, with several people remotely. But in person, just these three.
Q. And who did you meet with remotely?
A. Lauren Martin and Prati -- pronouncing

Petitioner Merck, Ex. 1129, p. 12
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

her last name -- Khandu -- sorry.

MR. POWERS: "Khanduri."

THE DEPONENT: Yeah.

Q. (By Ms. Wang) And approximately how long did you meet with all of the attorneys?

A. For probably about six hours total.

Q. And when was that?

A. Over -- over two days, yeah.

Q. Which two days?

A. Monday and Tuesday of this week.

Q. And besides your declaration and the references cited in your declaration, did you review anything else?

A. Not -- not for today. I was primarily focused on that.

And I did review Dr. Moon's -- or where I -- which is a citation in my declaration. But Dr. Moon's declaration, one portion of it.

Q. Did you review any of the references cited in the portion of Dr. Moon's declaration that you reviewed?

A. No, I did not.

Q. And let me make sure I have that -- ask a better question.

Before today's deposition, had you

Petitioner Merck, Ex. 1129, p. 13
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

reviewed any of the exhibits cited in Dr. Moon's declaration?

A. Well, I did, because some of them were ones that I also cited in my declaration.

Q. Did you review any exhibits cited in Dr. Moon's declaration that were not the ones cited in your declaration?

A. No, I did not.

Q. When were you retained for this matter?

A. Let's see, I guess it would have been in 2023, which would have been, I believe, January 2023.

Q. And approximately how long did it take for you to prepare your declarations?

A. Altogether, probably three months.

Q. Is that three months of daily work?

A. Well, not daily work, but yes, three -- three months' time. But it was over an extended period because of a lot of literature review, et cetera.

Q. Do you have a rough estimate of how many hours you spent?

A. Probably about -- I want to say about 36 hours, 40 hours, roughly.

Q. And did you write your declaration

Petitioner Merck, Ex. 1129, p. 14
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

yourself?
A. It was a collaborative effort with counsel. But the science -- the substance of it was mine.
Q. And did you type it yourself?
A. Yes.
Q. Okay. So I'd like you to turn to the -- your declaration in the -003 proceeding.
A. Okay.
Q. That's Exhibit 2072.
And in paragraph 3 of your declaration --
A. Yes.
Q. Are you there?
You understand you submitted this declaration in a post-grant review proceeding involving U.S. Patent No. 11,952,600?
A. Yes.
Q. Is it okay if I call it the '600 patent?
And I just want to confirm, the '600 patent is not listed in your exhibits referenced, correct?
A. No, I did not review the patent.
Q. You did not review the '600 patent --
A. No.
Q. -- before you signed your declaration?

Petitioner Merck, Ex. 1129, p. 15
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

A. No, I did not.
Q. Have you reviewed it since?
A. No, I have not.
Q. Okay. So your opinion is not based on any disclosure --
A. No.
Q. -- in the '600 patent?
And is it fair to say the same is true of the other three patents involved in the other three proceedings?
A. Correct.
Q. So your opinions in the other three proceedings, also not based on what's disclosed in those patents?
A. Correct.
Q. Did you review any materials not cited in your declaration?
MR. POWERS: Objection. Form.
THE DEPONENT: I -- could you be a little bit more clear on what you mean by "materials."
Q. (By Ms. Wang) Did you review any literature other than what is cited in your declaration?
MR. POWERS: Objection. Form.
THE DEPONENT: I did -- I did review

Petitioner Merck, Ex. 1129, p. 16
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

other papers that were relevant or potentially relevant to my opinion. But if it's not included -- it's really the important papers were the ones that I included in my declaration.

Q. (By Ms. Wang) So there are papers that you thought were potentially relevant that are not cited in your declaration?

A. I didn't know --

MR. POWERS: Objection -- just a second.

THE DEPONENT: Excuse me.

MR. POWERS: Let me interpose my objection.

Objection. Form.

THE DEPONENT: So at -- I did literature searching. So I didn't -- to determine which ones would be relevant and which ones wouldn't be.

Q. (By Ms. Wang) Are there papers that you determined to be relevant that are not cited in your declaration?

A. No.

Q. So I'm handing to you Exhibit 1026. It's --

MR. POWERS: Do you have a copy, please? Thank you, Counsel.

Q. (By Ms. Wang) And I'll represent to you

Petitioner Merck, Ex. 1129, p. 17
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

that Exhibit 1026 is U.S. Application No. 13/694731 filed December 28th, 2012.

A. Okay.

Q. Have you seen Exhibit 1026 before today?

A. No, I have not.

Q. So you didn't review it in connection with your declaration or --

A. Well, of course --

Q. Let me restate.

You did not review this exhibit in connection with preparing your declaration?

A. Well, I can't offer a complete opinion because I would have to look through this. I don't know if there's sections -- you handed me a very large stack, so I don't know what's in here. But I -- it doesn't look familiar.

Q. It doesn't look...

A. Yeah.

Q. And Exhibit 1026 is not listed as a reference in your declaration?

A. Correct.

Q. Okay. Do you recall reviewing any patent applications?

A. No.

MR. POWERS: Object to form.

Petitioner Merck, Ex. 1129, p. 18
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

THE DEPONENT: No, I did not.
Q. (By Ms. Wang) You did not review any patent applications in connection with preparing your declaration?
A. I did not.
Q. So you have no opinion on whether there are any differences between the patent applications that led to the '600 patent?
MR. POWERS: Objection. Form.
THE DEPONENT: No, because I did not review them, so I can't talk about the...
Q. (By Ms. Wang) So your opinion doesn't depend on any differences between the patent applications that led to the '600 application?
MR. POWERS: Objection. Form.
THE DEPONENT: That is correct.
Q. (By Ms. Wang) Did you review any patent or patent applications after you signed your declarations in these proceedings?
A. No.
MR. POWERS: Objection.
Okay.
Q. (By Ms. Wang) So for the rest of today, I'm going to use your declaration in the -003 proceeding for the '600 patent.

Petitioner Merck, Ex. 1129, p. 19
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

If your answer to one of my questions would be different for a different patent, please let me know, and we can go over to that declaration. Otherwise, I'm going to assume that your answer is going to be the same in all four proceedings.

Understood?

A. Yes, I understand.

Q. Dr. Cherr, were you instructed on any legal principles in developing your opinion?

A. No, I was not.

Q. Do you understand for what purpose your opinion is being offered?

A. I do.

Q. And what is that?

A. Well, it's to support, fairly narrow, the idea that the PH20 polyamino acid sequences, polypeptides, could be used for immunocontraception.

Q. And do you know what purpose your opinion is being offered in connection with the '600 patent?

MR. POWERS: Objection. Form.

THE DEPONENT: I don't know the specifics relating to the patent, no.

Petitioner Merck, Ex. 1129, p. 20
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

Q. (By Ms. Wang) You were not -- you were not instructed on what is legally required for an invention to be useful?
A. No, I was not.
Q. And you were not instructed on the legal standard for utility?
A. No.
Q. I'd like you to turn to paragraph 12 of your declaration.
A. Okay.
Q. It states, "I have been asked to consider whether a person of ordinary skill in the art," or a POSA, "would have expected any of the 'modified PH20 polypeptides' to be useful as contraceptive vaccines in female mammals."
Do you see that?
A. Yes, I see that.
Q. Where did this question come from?
A. I'm sorry, the question?
MR. POWERS: Object to form.
Q. (By Ms. Wang) Yes.
Where did this question that you were asked to answer come from?
MR. POWERS: Same objection.
THE DEPONENT: It was provided by

Petitioner Merck, Ex. 1129, p. 21
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

counsel.

Q. (By Ms. Wang) So you did not formulate the question?

A. No, I did not.

Q. The paragraph continues, "I have read Dr. James J. Moon's declaration as presented by counsel."

Do you see that?

A. Yes.

Q. What does "as presented by counsel" mean?

A. I was presented to me or it was given to me to read by counsel.

Q. Were you given a signed declaration from Dr. Moon?

A. Oh, his -- I received -- what was termed a near-final declaration just prior to his signature.

Q. And is that the only version of Dr. Moon's declaration that you reviewed?

A. I -- I reviewed his signed version, which was a few weeks later.

Q. Did you review any earlier versions before the near-final version of the declaration?

A. No, I did not.

Q. Around when did you review -- let me

Petitioner Merck, Ex. 1129, p. 22
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

rephrase.

How long before you signed your declaration was it before you reviewed Dr. Moon's near-final declaration?

A. Just to -- yeah.

MR. POWERS: Objection. Form.

THE DEPONENT: Approximately one week.

Q. (By Ms. Wang) So you reviewed Dr. Moon's near-final declaration approximately one week before signing your own declaration?

A. Yes.

Q. Did you speak to Dr. Moon before signing your declaration?

A. Never spoken with him.

Q. Did you speak to Dr. Gregory Petsko before signing your declaration?

A. No.

Q. Did you speak to Dr. Melanie Simpson before signing your declaration?

A. No.

Q. Did you speak to Dr. Barbara Triggs-Raine before signing your declaration?

A. No.

Q. Did you review Dr. Petsko's declaration at any point?

Petitioner Merck, Ex. 1129, p. 23
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

A. I did not.
Q. Did you review Dr. Simpson's declaration?
A. I did not.
Q. Did you review Dr. Triggs-Raine's declaration?
A. No, I didn't.
Q. And have you spoken to any of them since signing your declaration?
A. No.
Q. Have you reviewed any of their declarations since signing yours?
A. No, I have not.
Q. Did you speak to any Halozyme employee before signing your declaration?
A. No, I did not.
Q. Have you spoken to any Halozyme employee after signing your declaration?
A. No, I have not.
Q. And I should ask you a better question, because I understand Mr. Mack might be a Halozyme employee.
A. Yeah, when you -- yeah.
Q. Yes.
Other than Halozyme's lawyers, have you spoken to any Halozyme --

Petitioner Merck, Ex. 1129, p. 24
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

A. No, I have not.
Q. Thank you.
(Discussion off the stenographic record.)
MR. POWERS: Yeah, please slow down.
Q. (By Ms. Wang) I'd like to direct your attention to paragraph 30 of your declaration.
A. Yes.
Q. The paragraph 30 begins, "In light of Dr. Moon's declaration, I have been asked to opine..."
Do you see that?
A. Yes, I see that.
Q. And what do you mean by, "In light of Dr. Moon's declaration"?
A. I mean that in -- in that context that his expertise in -- as an immunologist in opining on immune responses that -- and regarding his -- his words regarding modified PH20 polypeptides.
So I -- you know, I was asked, essentially, to opine on what was in his declaration within mine.
Q. You said in the context of Dr. Moon's expertise as an immunologist in opining on immune responses.
Do you have an independent opinion on

Petitioner Merck, Ex. 1129, p. 25
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

immune responses?
A. Yes, and -- and in my declaration, my -- the opinion I gave in terms of immune responses as related to contraception were all my views.
Q. You also said, in regards to Dr. Moon, you were opining on his words regarding modified PH20 polypeptides.
Do I understand that correctly?
MR. POWERS: Object to form.
THE DEPONENT: So could you -- I'm sorry, could you repeat the question.
Q. (By Ms. Wang) Sure, let me try to ask a better question.
Does your opinion depend on something Dr. Moon has opined on?
A. No, absolutely not.
Q. So your opinions are completely independent of Dr. Moon's opinions?
A. Yes, correct.
Q. Okay. Do you have opinions on Dr. Moon's opinions?
THE DEPONENT: I'm sorry, could you repeat that.
Q. (By Ms. Wang) Sure.
Do you have opinions --

Petitioner Merck, Ex. 1129, p. 26
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

A. Yes.
Q. -- on the opinions in Dr. Moon's declaration?
MR. POWERS: Object to form.
THE DEPONENT: I -- don't -- yeah.
So I -- I don't have opinions on -- on his opinions except there's a few areas that independently we agree on. So in paragraph 30 of your declaration, you would say, "I have been asked to opine on whether, by December 28th, 2012 POSAs would have expected any of the modified PH20 polypeptides (defined in paragraph 12) to be useful as contraceptive vaccines in female mammals, such as human, chimpanzee, Cynomolgus monkey, rhesus monkey, marmoset, orangutan, gibbon, cow, mouse, rat, rabbit, guinea pig, and red fox."
Do you see that?
A. Yes.
Q. So this opinion includes a list of mammals.
Who gave you this --
MR. POWERS: Objection. Form.
Q. (By Ms. Wang) Who gave you list of assorted female mammals?
A. That's -- that's -- that list of mammals

Petitioner Merck, Ex. 1129, p. 27
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

are -- are mammals are well known to -- where PH20 sequence and expression has been studied. So that's information that I was well aware of.

Q. So you generated this list?

A. Well, so I -- no, actually I did not generate the full list, but part of the list.

Q. And where did the rest of the list come from?

A. And --

MR. POWERS: Objection. Form.

THE DEPONENT: So that was -- as a collaborative effort with counsel in terms of the -- the other species added in.

Q. (By Ms. Wang) The other species added in came from counsel?

A. Yes.

Q. Do you recall which species came from counsel?

A. I'm -- I believe it was marmoset and red fox.

Q. Any others?

MR. POWERS: Object to form.

THE DEPONENT: No. I think that's it.

Q. (By Ms. Wang) So Dr. Cherr, is it your opinion that all of the modified PH20 polypeptides

Petitioner Merck, Ex. 1129, p. 28
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

would display multiple epitopes to the host immune system and stimulate anti-PH20 polyclonal antibodies against these different epitopes?

A. Yes, it is.

Q. It's your opinion that all of the modified PH20 polypeptides would do so?

A. Yes.

Q. Is it your opinion that the polyclonal antibodies generated against any of the modified PH20 polypeptides would bind to the PH20 polypeptide of sperm in the reproductive tract of the female mammal?

A. Yes, if antibodies were of sufficient titer in the reproductive tract.

Q. Any of the PH20 polypeptide would cause polyclonal antibodies, any of those polyclonal antibodies would cause reproduction?

MR. POWERS: Objection. Form.

Q. (By Ms. Wang) Would cause contraception?

MR. POWERS: Same objection.

THE DEPONENT: So -- yeah. So -- could you ask that one more time.

Q. (By Ms. Wang) Sure. It's your opinion that any of the modified PH20 polypeptides would cause polyclonal antibodies that bind to PH20 on

Petitioner Merck, Ex. 1129, p. 29
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

sperm and that would then cause contraception?

MR. POWERS: Objection. Form.

THE DEPONENT: Could you -- that's a pretty broad question. So are you -- because we were just talking about all these different species. Could you more specific about what species you are referring to or -- or group of species?

Q. (By Ms. Wang) Does the species matter?

A. It shouldn't matter, but I'm just trying to understand -- I want to make sure I give you the most accurate answer possible.

Q. I would like to direct your attention to paragraph 32 of your declaration.

A. Okay.

Q. The last sentence you state, "Thus, POSAs would have known that the binding of antibodies to sperm PH20 polypeptide in the female reproductive tract would cause contraception irrespective where the antibodies bind on the PH20 polypeptides."

Do you see that?

A. Yes, I see that.

Q. And that statement is not qualified by species.

Is it?

Petitioner Merck, Ex. 1129, p. 30
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

A. No, it is not.
Q. So your opinion would apply all female mammals?
A. Yes, of the ones listed there, yes.
Q. Of the ones listed of paragraph 30 in your declaration?
A. Yes, because -- because to say all mammals regardless of the class, you know, or the phylum or...
Yeah, I mean, I don't know. And it hasn't been studied in all of them. So in that list, yes.
Q. So your opinion is limited only to the female mammals listed in paragraph 30 of your declaration?
A. Yes.
Q. And you don't know if the female mammals outside of those listed in paragraph 30 of your declaration, if the PH20 would work as contraception?
MR. POWERS: Objection. Scope.
THE DEPONENT: Yeah, I -- I -- I opined on animal groups where PH20 had been identified in the males in the sperm or in testes. So beyond that, I wouldn't want to offer an opinion.

Petitioner Merck, Ex. 1129, p. 31
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

Q. (By Ms. Wang) Are there any species not listed in paragraph 30 in which you believe PH20 would not work as a contraception?

MR. POWERS: Objection. Scope.

THE DEPONENT: I really -- I can't really give you an opinion on that because it would -- it would need to have -- I would need to have information regarding expression of PH20 in the males of those species, and it may not be available, that -- that kind of scientific information.

Q. (By Ms. Wang) And you did not independently investigate other species to determine if the PH20 would work as a contraception?

MR. POWERS: Objection. Form.

THE DEPONENT: When you say --

MR. POWERS: Scope.

THE DEPONENT: -- "investigate other species," if you could define that.

Q. (By Ms. Wang) You did not investigate species outside of the list in paragraph 30 to determine if additional -- if there are additional species in which modified PH20 polypeptides would work as contraception?

Petitioner Merck, Ex. 1129, p. 32
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

MR. POWERS: Objection. Form. Scope.
THE DEPONENT: No, I did not.
Q. (By Ms. Wang) So your opinion is that the binding of any antibodies to sperm PH20 polypeptide in the female reproductive tract would cause contraception, right?
MR. POWERS: Objection. Form.
THE DEPONENT: Sorry. One more time.
Q. (By Ms. Wang) Your opinion is that the binding of any antibodies to sperm PH20 polypeptide in the female reproductive tract would cause contraception --
MR. POWERS: Same objection.
Q. (By Ms. Wang) -- correct?
A. Yes, it has the potential to do that.
Q. Does the amount of antibodies that bind to sperm matter?
MR. POWERS: Objection. Form.
THE DEPONENT: Conceptually, yes. But quantitatively, I think that's unknown.
Q. (By Ms. Wang) So you don't know quantitatively how much antibody would have to bind to sperm PH20 in order to cause contraception?
MR. POWERS: Objection. Form.
THE DEPONENT: So are you -- are you

Petitioner Merck, Ex. 1129, p. 33
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

speaking in vivo, in the reproductive tract?

Q. (By Ms. Wang) Yes.

A. Yes, that's not known.

Q. Is it your opinion that all modified PH20 polypeptide would be effective as contraception vaccines in female mammals?

MR. POWERS: Objection. Form.

THE DEPONENT: Yes.

Q. (By Ms. Wang) All of them would cause contraception in female humans?

MR. POWERS: Objection. Form.

THE DEPONENT: They would if they were administered in the proper way and elicited the proper immune response.

Q. (By Ms. Wang) So just having modified PH20 polypeptide is not sufficient?

MR. POWERS: Objection. Form.

THE DEPONENT: They would have to be administered in an appropriate way so that there would be mucosal response in the reproductive tract.

Q. (By Ms. Wang) So in your opinion, you need not only modified PH20 polypeptide, but also an appropriate administration of it in order for there to be contraception?

Petitioner Merck, Ex. 1129, p. 34
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

A. Yes, that's correct.
Q. You have only opined on whether the modified PH20 polypeptides would have been useful as contraception vaccines in female mammals, correct?
A. Yes, that is correct.
Q. The studies you cited demonstrating contraception from PH20 in guinea pigs was done in both male and female guinea pigs, correct?
A. Yes, that's correct.
Q. But you have no opinion on whether modified PH20 polypeptides would be effective contraception vaccine in male mammals?
A. I -- I did not opine on males in here because typically the response to immunization in males with PH20 polypeptides create pathogenic situation, and so there may be infertility, but may not be mechanistically related to what would occur in a female, and it maybe be certainly problematic for human use.
Q. Modified PH20 polypeptides would be problematic for human male use as a contraception?
MR. POWERS: Objection. Form. Scope.
MS. WANG: Counsel, scope is not a proper objection. Please keep your objections to scope --

Petitioner Merck, Ex. 1129, p. 35
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

MR. POWERS: I disagree, Counsel.
THE DEPONENT: Could you ask -- could you ask it another way or ask it again?
Q. (By Ms. Wang) Modified PH20 polypeptides would be problematic as a contraception vaccine for human males?
MR. POWERS: Objection. Form. Scope.
MS. WANG: Again, Counsel, scope is not a proper objection here.
MR. POWERS: I disagree, Counsel.
MS. WANG: Well, okay.
MR. POWERS: Go ahead.
MS. WANG: We take it --
MR. POWERS: I'm saying it one word or term, just like in the trial practice.
MS. WANG: You are instructing -- you are coaching your witness --
MR. POWERS: I am not.
MS. WANG: -- on -- it's not a proper objection.
MR. POWERS: I disagree.
Q. (By Ms. Wang) Do you need me to repeat the question?
A. Yes, please.
Q. Yes.

Petitioner Merck, Ex. 1129, p. 36
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

Modified PH20 polypeptides would be problematic as a contraception vaccine for human males?

MR. POWERS: Objection. Form. Scope.

THE DEPONENT: So that's a statement.

Are you -- is that a question you're asking or...

Q. (By Ms. Wang) I'm asking you if that is a correct statement --

A. Oh.

Q. -- of what you have told me.

A. Yes, it is.

Q. Would the POSA have expected PH20 -- let me rephrase.

Would the POSA have expected modified PH20 polypeptides to not be useful as contraceptive vaccines in human males?

MS. WANG: Objection. Form. Scope.

THE DEPONENT: No, I think it would be useful. But in human males, you would not want to create a pathogenic situation.

Q. (By Ms. Wang) So the POSA would think it would useful but also problematic in human males; is that right?

MR. POWERS: Same objections.

Petitioner Merck, Ex. 1129, p. 37
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

THE DEPONENT: In humans, yes.
Q. (By Ms. Wang) And what is the pathogenic issue you are referring to with respect to human males?
MR. POWERS: Objection. Form. Scope.
THE DEPONENT: So in -- you referred to the guinea pig males that were injected with PH20. And there was epididymitis and orchitis in the testes with massive inflammation. And that was what was deemed to be responsible for the contraceptive effect rather than any sort of antibody binding to cells, per se.
Q. (By Ms. Wang) And you wouldn't want to cause epididymitis or orchitis in humans?
MR. POWERS: Objection. Form.
THE DEPONENT: I would not.
Q. (By Ms. Wang) So the POSA would not think that modified PH20 polypeptides would be a viable contraceptive vaccine in humans?
MR. POWERS: Objection.
Q. (By Ms. Wang) Human males?
MR. POWERS: Form.
THE DEPONENT: I -- that is correct.
Q. (By Ms. Wang) I would like to direct your attention to paragraph 12 of your declaration.

Petitioner Merck, Ex. 1129, p. 38
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

And you state here that you "use the phrase 'modified PH20 polypeptides' to refer to polypeptides comprising an amino acid sequence that is at least 95 percent identical to the amino acid sequence of any one of Sequence ID No.: 3 and 32 through 66, and includes a modification at position 320 such that D is replaced with H, K, R, or S."

Do you see that?

A. Yes, I do.

Q. Would you agree that modified PH20 polypeptides can contain more than one amino acid modification?

A. Yes, I'm aware of that.

Q. Do you agree that modified PH20 polypeptides can contain between 70 -- 17 to 23 amino acid modifications?

MR. POWERS: Objection. Form.

THE DEPONENT: Yes, but the percent identity is what's important for the immune response.

Q. (By Ms. Wang) Did you calculate the number of different possible modified PH20 polypeptides?

A. No, I did not.

Petitioner Merck, Ex. 1129, p. 39
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

Q. Do you know the number of possible different PH20 polypeptides?
MR. POWERS: Objection. Form.
Q. (By Ms. Wang) Let me rephrase.
Do you know the number of different possible modified PH20 polypeptides?
A. No, I do not know the number.
Q. Do you think it's a large number?
A. Yes, I do.
Q. Do you know what differences there are between the four patents that are at issue in each of the PGR proceedings that you provided a declaration in?
MR. POWERS: Objection. Form.
THE DEPONENT: So I'm aware that there's, at -- at several sites, replacement amino acids that are -- that are different.
Q. (By Ms. Wang) Is it your understanding that each of the four patents requires a different amino acid modification at a different site?
A. I can't opine on that because I did not look at the patent.
Q. But you understand that the four patents have differences at the sites of replacement amino acids?

Petitioner Merck, Ex. 1129, p. 40
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

MR. POWERS: Objection. Form.
THE DEPONENT: Yes, in terms of what was provided to me by counsel.
Q. (By Ms. Wang) Is it fair to say that these differences at the sites of replacement amino acids didn't matter to your opinion?
MR. POWERS: My opinion, it did not matter, because of their high -- very high percent identity.
Q. (By Ms. Wang) So your opinion doesn't change as between a required modification at position 30 versus a required modification at position 313?
A. Right.
MR. POWERS: Objection. Form.
Just give me a minute.
Q. (By Ms. Wang) If a modified PH20 polypeptide had 95 percent sequence identity to Sequence ID No. 3 and 32 through 66 but did not have a mutation at position 320, your opinion would still be the same, correct?
MR. POWERS: Objection. Form.
THE DEPONENT: You're -- I'm -- could you -- you're referring to my opinion.
What -- what opinion were you referring

Petitioner Merck, Ex. 1129, p. 41
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

to?

Q. (By Ms. Wang) The opinions in your declaration --

A. Yeah.

Q. -- are all about modified PH20 polypeptides, correct?

A. Correct.

Q. And if a modified PH20 polypeptide had 95 percent sequence similarity to Sequence ID No. 3 or 32 through 66, but did not have a mutation at position 320, the opinions in your declaration would not change, would they?

MR. POWERS: Objection. Form.

THE DEPONENT: Yes, that's correct.

Q. (By Ms. Wang) And your opinions in your declaration don't depend where on the PH20 polypeptide there are modifications; is that right?

MR. POWERS: Objection. Form.

THE DEPONENT: That is correct.

Q. (By Ms. Wang) And you would agree that modified PH20 polypeptides can have amino acid modifications anywhere along the sequence?

A. Yes, as long as that high percent identity is maintained.

Q. You did not independently evaluate the

Petitioner Merck, Ex. 1129, p. 42
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

structure of PH20 in developing your opinions?
A. I did not.
Q. You did not identify the number of surface-successful residues on human PH20?
A. I did not.
Q. You did not identify the number of surface-successful residues on modified PH20 polypeptides?
A. I did not.
Q. You did not identify any particular epitopes on human PH20 that would be relevant to the contraceptive effect?
A. No, I did not.
Q. You did not identify any epitopes on modified PH20 polypeptides that would be relevant to contraception?
A. No, I did not.
Q. Would you have been able to identify such epitopes in 2012?
MR. POWERS: Objection. Form.
THE DEPONENT: I'm sorry, could you ask that again, or maybe in a slightly different way.
Q. (By Ms. Wang) Would you have been able to identify epitopes on PH20 relevant to conception -- let me rephrase.

Petitioner Merck, Ex. 1129, p. 43
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

A. Okay.
Q. Would you have been able to identify epitopes on PH20 necessary for contraception in 2012?
MR. POWERS: Objection. Foundation. Form.
THE DEPONENT: I think it would be -- generally, it would be essentially any of the epitopes as long as there was an immune response, as long as antibodies were binding to PH20 on sperm.
Q. (By Ms. Wang) In your opinion, are you assuming that the modified PH20 polypeptides are folded?
MR. POWERS: Objection. Form.
THE DEPONENT: I don't know; I can't opine on that.
But that doesn't necessarily matter for triggering an immune response.
Q. (By Ms. Wang) So in your opinion, unfolded modified PH20 polypeptides would still trigger an immune responses?
A. Yes.
Q. And unfolded modified PH20 polypeptides would cause polyclonal antibodies that could bind

Petitioner Merck, Ex. 1129, p. 44
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

to the native PH20?

A. Yes.

Q. Is it also your opinion that misfolded modified PH20 polypeptides would trigger an immune response?

A. Yes, misfolded, and denatured, actually, as well.

Q. And it's your opinion that misfolded and denatured modified PH20 polypeptides would trigger an immune responses that would cause polyclonal antibodies that could bind to the native PH20?

MR. POWERS: Object to form.

THE DEPONENT: Yes.

Q. (By Ms. Wang) It's your opinion that these misfolded and denatured modified PH20 polypeptides would cause contraception?

A. Yes, if -- as long as the antibodies bound to sperm in the reproductive tract and there were sufficient antibodies in the reproductive tract.

Q. Is it your opinion that misfolded and aggregated modified PH20 polypeptides would still cause contraception in a female?

MR. POWERS: Objection. Form. Foundation.

Petitioner Merck, Ex. 1129, p. 45
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

THE DEPONENT: I can't really offer an opinion on the aggregation. It -- it depends on solubility, et cetera.

Q. (By Ms. Wang) Would you agree that misfolded proteins can aggregate?

A. Yes, I'm aware of that.

Q. And aggregated proteins are not soluble?

MR. POWERS: Objection. Form.

THE DEPONENT: May -- may not be, yes, that's correct.

Q. (By Ms. Wang) And aggregated misfolded PH20 polypeptides that are not soluble would not cause contraception in a female, would they?

MR. POWERS: Objection. Form.

THE DEPONENT: They could be solubilized, though, and -- with denaturation. So aggregates can still be useful, potentially, just not as an aggregate.

Q. (By Ms. Wang) And aggregated misfolded modified PH20 polypeptide, without further processing, would not be useful as a contraceptive in females?

MR. POWERS: Objection. Form.

THE DEPONENT: May not be because of the form it's in and how it would be administered.

Petitioner Merck, Ex. 1129, p. 46
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

Q. (By Ms. Wang) Do you know how many amino acid modifications to an epitope in a modified PH20 polypeptide can be made in order for an antibody against that modified epitope to still bind to the corresponding epitope in a native PH20?

MR. POWERS: Objection. Form.

THE DEPONENT: Sorry, just need some clarification from you.

Are -- you're talking -- I mean, it sounds like you're talking about monoclonal antibodies to specific epitopes, not polyclonals to multiple epitopes?

Q. (By Ms. Wang) Well, I'm asking just about one epitope to another.

An epitope on a modified PH20 polypeptide, do you know how different that epitope can be before the antibody to that epitope doesn't bind to PH20?

MR. POWERS: Objection. Form.

THE DEPONENT: No, I don't know that number exactly.

MR. POWERS: Counsel, it's been about an hour.

Ready for a break?

MS. WANG: One more question, please.

Petitioner Merck, Ex. 1129, p. 47
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

MR. POWERS: Okay.

Q. (By Ms. Wang) Is it a fair understanding that an epitope on modified PH20 polypeptide can be so different that an antibody to that epitope would not bind to the native PH20?

MR. POWERS: Objection. Form.

THE DEPONENT: I think, similar to what I answered before, that if you have that 95 percent identity, regardless of individual epitopes being altered, but if overall there's that 95 percent identity, there's going to be a consistent -- should be a consistent polyclonal response when injected into a female, and it should react with sperm surface PH20.

MR. POWERS: Are you ready for that break?

MS. WANG: Yes.

MR. POWERS: Thank you very much.

THE VIDEOGRAPHER: Okay. The time is 10:00 o'clock -- 10:01 a.m. Pacific time. We are off the record.

(Recess taken.)

THE VIDEOGRAPHER: The time is 10:15 a.m. Pacific time. We are on record.

Q. (By Ms. Wang) Dr. Cherr, during the

Petitioner Merck, Ex. 1129, p. 48
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

break just now, did you speak with counsel?
A. No, I did not.
Q. Earlier this morning, I asked you about the number of possible modified PH20 polypeptides.
And you agreed that it's a large number?
A. It's a large number.
Q. Do you know how many modified PH20 polypeptides within that large number would aggregate?
A. No, I do not.
Q. Do you know how many modified PH20 polypeptides within that large number could be made?
MR. POWERS: Objection. Form. Foundation.
THE DEPONENT: Could you please define what you mean by "could be made."
Q. (By Ms. Wang) Do you know if any modified PH20 polypeptide could not be made?
MR. POWERS: Objection. Form.
THE DEPONENT: No, I can't offer an opinion on that because I haven't done any sort of analysis on that.
Q. (By Ms. Wang) I'd like to turn to paragraph 31 of your declaration.

Petitioner Merck, Ex. 1129, p. 49
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

A. Okay.
Q. I apologize, I sent you to the wrong part of your declaration.
It's paragraph 19.
A. Okay.
Q. Okay. And you here you state that "PH20 is a multi functional protein," correct?
A. Yes, correct.
Q. And that means PH20 has more than one function?
A. Yes.
Q. It has a hyaluronidase function?
A. Correct.
Q. It has a hyaluronic acid, HA, binding function to simulate sperm signaling activity?
A. Yes.
Q. And PH20 also acts as a sperm receptor for an egg's zona pellucida on acrosome-reacted sperm?
A. Yes.
Q. And all of these PH20 functions are involved in fertilization, correct?
A. Yes, they are.
Q. In order for fertilization to occur, the PH20 needs to have all of these functions?

A. No.

So they're all involved in fertilization, but from the standpoint of antibody binding to PH20, not all of them need to be inhibited.

Q. So my question was, in order for fertilization to occur, the PH20 needs to have all three of these functions; is that correct?

MR. POWERS: Object to form.

THE DEPONENT: So there -- all three of those functions are involved in the process of fertilization. I don't know if inhibition of any one of them alone would inhibit that fertilization.

Q. (By Ms. Wang) So PH20 has three functions involved in fertilization?

A. Correct.

Q. And you don't know if inhibiting just one of those three functions would be sufficient to inhibit fertilization?

MR. POWERS: Objection. Form.

THE DEPONENT: It doesn't matter, because if antibodies are bound to PH20 when it's on the sperm at the time of fertilization, the presence of antibodies bound pretty much anywhere to the PH20 protein and sperm, there would be an effect on fertilization, most likely a complete inhibition,

Petitioner Merck, Ex. 1129, p. 51
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

or contraception.

Q. (By Ms. Wang) So I appreciate that's your opinion.

But the question I asked was, you don't know if inhibiting just one of the three PH20 functions would be sufficient to inhibit fertilization --

MR. POWERS: Objection. Form.

Q. (By Ms. Wang) -- correct?

THE DEPONENT: I think what I was referring to is, when antibodies bind to PH20, and it may or may not bind to regions of the polypeptide that are responsible for that -- for those different functions, just having antibodies present on the entire PH20 will directly or indirectly have an effect on fertilization.

Q. (By Ms. Wang) Dr. Cherr, my question was, you don't know if inhibiting just one of the three PH20 functions would be sufficient to inhibit fertilization.

Do you have that question in mind?

A. It would -- it would --

MR. POWERS: Objection. Form.

THE DEPONENT: So inhibition of one of those functions would have, potentially, an effect

on fertility.

Q. (By Ms. Wang) But you don't know if inhibition of just one of those functions would cause contraception?

MR. POWERS: Objection. Form.

THE DEPONENT: Correct.

I -- again, having an antibody bound anywhere along the PH20 polypeptide on sperm should have an impact on contraception or fertility.

Q. (By Ms. Wang) Am I correct in understanding that you think it would have an impact but not cause infertility?

MR. POWERS: Objection. Form.

THE DEPONENT: Sorry, can you -- when you say "it," could you please explain that.

Q. (By Ms. Wang) So I asked, you don't know if inhibition of just one of the functions of PH20 would cause contraception.

And your answer was?

A. So --

MR. POWERS: Objection. Form.

THE DEPONENT: So in my opinion in my declaration, I'm referring to antibodies that would bind -- polyclonal antibodies that would bind --

Q. (By Ms. Wang) Dr. Cherr, I understand --

Petitioner Merck, Ex. 1129, p. 53
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

MR. POWERS: Whoa, whoa, whoa, please let him finish his answer.
MS. WANG: I --
MR. POWERS: Were you finished?
THE DEPONENT: No.
MR. POWERS: Okay. Please continue.
Yeah, Counsel, don't interrupt the witness.
MS. WANG: I understand, and we'll get to -- no, we'll get to your opinion, Dr. Cherr, but I need my question --
MR. POWERS: You're not going to let the witness finish his answer?
MS. WANG: I'm going to --
MR. POWERS: Please don't interrupt the witness.
MS. WANG: The witness is not answering my question, so I'd like the witness to --
MR. POWERS: He's --
MS. WANG: -- answer my question.
MR. POWERS: -- answering your question. You may not like the answers, but he's answering.
Please continue with your answer.
THE DEPONENT: So the idea is that if you have polyclonal antibodies that are bound to the

Petitioner Merck, Ex. 1129, p. 54
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

PH20 polypeptide on sperm, regardless of what domain or what function they may or may not be inhibiting, they're still going to affect successful fertilization by just hav- -- by -- simply by the presence of immunoglobulin molecules bound to the sperm surface.

Is that --

Q. (By Ms. Wang) My question, Dr. Cherr -- yeah, just could listen to my question, please.

A. Yeah.

Q. My question is, if you inhibit just one of the functions of PH20 -- I'm not asking about antibodies.

If you inhibit just one of the functions of PH20, do you know if that inhibition alone will cause contraception?

MR. POWERS: Objection. Form. Asked and answered.

THE DEPONENT: I don't know about contraception, but it would probably reduce the efficiency of fertilization.

Q. (By Ms. Wang) It would reduce the efficiency of fertilization but not cause infertility?

A. I don't know, but --

Petitioner Merck, Ex. 1129, p. 55
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

MR. POWERS: Objection. Form.
THE DEPONENT: -- yes, that would be my opinion, that it would reduce efficiency of fertilization.
Q. (By Ms. Wang) On the PH20 protein, the HA binding domain is separate from the hyaluronidase domain, correct?
MR. POWERS: Objection. Form.
THE DEPONENT: That is correct.
Q. (By Ms. Wang) The HA binding domain is in a separate part of the protein from the hyaluronidase domain?
A. Yes.
Q. In your opinion, for a modified PH20 polypeptide to be useful as a contraceptive, does it have to cause infertility?
MR. POWERS: Objection. Form.
THE DEPONENT: So I -- I think your question is, is contraception and infertility the same thing? Is that what you are asking?
Q. (By Ms. Wang) In your mind, are contraception and infertility the same thing?
A. Yes, although there's -- there are other methods of contraception that are -- are quite a distance from the process of fertilization.

Petitioner Merck, Ex. 1129, p. 56
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

Q. In your opinion, for a modified PH20 polypeptide to be useful as a contraception, is there a certain level of reduction in infertility that would need to be achieved?

A. So are you asking whether something would be all or nothing versus varying degrees; is that -- I am not clear on exactly what you are getting at.

Q. I'm trying to understand your opinion that a modified PH20 polypeptide would be useful as a contraceptive vaccine.

A. Yes, I believe it would. Again, that's with the understanding that it would be an appropriate immune response in the reproductive tract that combined the sperm.

Q. And I am trying to understand how do you define "useful"?

A. Yes, so -- I define "useful" -- I mean, there's -- in the literature with experimental animals reducing litter size, people still use the term as an effective contraception. But in my mind, when it comes to human biology, it needs to be close to 100 percent.

Q. So from modified PH20 polypeptide to be a useful contraceptive in humans, it would need to

Petitioner Merck, Ex. 1129, p. 57
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

cause 100 percent infertility?
MR. POWERS: Object to form.
THE DEPONENT: Or close to 100 percent, yes.
Q. (By Ms. Wang) For a modified PH20 polypeptide to be a useful contraceptive in nonhuman mammals, how much or what percentage of reduction in fertility would need to be achieved?
MR. POWERS: Objection. Form.
THE DEPONENT: It would be similar ideally.
Q. (By Ms. Wang) It would need to be 100 percent or close to it?
A. Similar to what hormone contraceptives are.
Q. PH20 structure changes depending on the stage of sperm maturation, correct?
A. Yes.
Q. Native PH20 is proteolytically cleaved late in sperm maturation?
A. I believe that's correct.
Q. PH20 can also take on different glycosylation during maturation?
A. Right.
Q. PH20 structure also changes depending on

Petitioner Merck, Ex. 1129, p. 58
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

the stage of fertilization, correct?

MR. POWERS: Objection. Form.

THE DEPONENT: Sorry. Could I -- I just want to make sure your question -- I understand your question. Can you repeat it or reword it?

Q. (By Ms. Wang) PH20 structure changes depending on where it is in the female reproductive tract, correct?

MR. POWERS: Objection. Form.

THE DEPONENT: Well, it's associated with sperm. So do you mean in terms of the -- where the sperm are or --

Q. (By Ms. Wang) Yes.

A. Okay. So yes, it can, is the answer.

Q. PH20 structure can be different depending on where the sperm is in the -- in the female reproductive tract?

A. Yeah. Maybe it's more the physiology of the sperm at those locations, not just its location in the female tract.

Q. Sperm has a different physiology depending on where it is in the female reproductive tract?

A. Correct.

Q. And the PH20 on the sperm can have a

Petitioner Merck, Ex. 1129, p. 59
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

different structure depending on the different sperm physiology?

A. I would say sperm -- sorry, I would say PH20 that -- that's either on or in the sperm just to be precise because it's in several places, the sperm.

Q. PH20 on or in the sperm can have a different structure depending on the sperm's physiology?

A. It could be -- yes, it can be asthmatically processed.

Q. PH20 is endoproteolytically cleaved at the time of the acrosome reaction?

A. Yes, that's correct.

Q. And this endoproteolysis may alter the three-dimensional structure of PH20?

A. Yes.

Q. Which form of the native PH20 must be engaged by antibodies in order for to be effective contraception?

MR. POWERS: Objection. Form. Foundation.

THE DEPONENT: So polyclonal antibodies react similarly with all forms of PH20, whether it's cleaved or endoproteolytically cleaved or not

Petitioner Merck, Ex. 1129, p. 60
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

cleaved, so there is -- again, with polyclonal antibodies, there isn't an issue in terms of recognition of any -- any of the PH, whether it's interact or some other membrane or plasma membrane PH20.

Q. (By Ms. Wang) Is it your opinion that polyclonal antibodies against any of the modified PH20 polypeptides would be able to bind all forms of PH20 regardless of sperm physiology?

A. Yes, that is my opinion.

Q. I would like to direct your attention to paragraph 24 of your declaration.

It's actually the figure --

A. Oh, okay.

Q. -- on page 17 of your declaration.

A. Yes.

Q. And that is a reproduction of Figure 3 of Exhibit 2103, correct?

A. Yes, correct.

Q. And the figures shows the reproductive tract of female primates, right?

A. Yes, correct.

Q. Would this graphic look different for nonprimate mammals?

A. Yes, it would.

Petitioner Merck, Ex. 1129, p. 61
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

Q. In what ways?
A. Depending on where the sperm are processed, different mammals -- some sperm are deposited in the vagina, but others, most of the rodents' sperm, are deposited in the uterus so that there's not cervical mucus.
Q. Cervical mucus identified at step B of Figure 3 would not be in rodents?
A. Right.
Q. Would steps C, D, E, and F of Figure 3 look different in nonprimate mammals?
A. It might --
MR. POWERS: Object to form.
Go ahead.
THE DEPONENT: Yes, it might. In some species -- many species have that binding of sperm to the oviduct epithelium shown in the figure, but that's to varying degrees depending on the species or the mammal.
Q. (By Ms. Wang) So sperm of all mammals has a glycocalyx, correct?
A. Of most. We don't know about some mammals.
Q. The sperm of all of the mammals that you have opined on in this declaration has a

Petitioner Merck, Ex. 1129, p. 62
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

glycocalyx?

A. It's unclear about the guinea pig. Guinea pig is one that may not have that. Nobody -- nobody has looked at that.

Q. So in 2012, no one knew if the guinea pig sperm add a glycocalyx?

A. Right.

Q. Is it fair to say that in 2012 they also didn't know that the guinea pig sperm didn't have a glycocalyx?

MR. POWERS: Object to form.

THE DEPONENT: It was known -- it was known in 2012 that guinea pig were -- sperm were a little bit different than other mammals in that they're capable of undergoing an acrosome reaction very rapidly after insemination. For other mammals, there has to be a residence time in the female tract. So guinea pigs were known to be -- for some decades known to be different than other -- other mammals.

Q. (By Ms. Wang) So in 2012 guinea pig reproduction was known to be different from other mammals?

A. Potentially.

MR. POWERS: Objection. Form.

Petitioner Merck, Ex. 1129, p. 63
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

Go ahead.
Q. (By Ms. Wang) In 2012 guinea pig sperm was known to be different from other mammals?
MR. POWERS: Objection. Form.
THE DEPONENT: It -- it was hypothesized that they're different, not known for a fact.
Q. (By Ms. Wang) There was an expectation that it could be different?
MR. POWERS: Objection. Form.
THE DEPONENT: Potentially, yes.
Q. (By Ms. Wang) Looking back at the figure of page 17 of your declaration, the PH20 in steps A through D would all be protected by glycocalyx, and the PH20 on the sperm would be inaccessible, right?
MR. POWERS: Objection. Form.
THE DEPONENT: I'm sorry, inaccessible to -- or you said "inaccessible"?
Q. (By Ms. Wang) Yes.
A. Inaccessible to -- to what? Sorry.
Q. Sure.
The PH20 in steps A through D are protected by a glycocalyx, right?
A. Yes, correct.
Q. So they're not accessible outside of the glycocalyx?

MR. POWERS: Objection. Form.
THE DEPONENT: Yes. They're not exposed, right.
Q. (By Ms. Wang) So because they are not exposed, you would not expect antibodies to be able to bind to PH20 while the glycocalyx is intact?
A. Yes, that's correct.
Q. And in Figure 3, the glycocalyx is removed at step E?
A. Yes.
Q. So at that point in step E, PH20 is exposed on the sperm surface?
A. Yes.
Q. Is PH20 endoproteolitically cleaved at step F at Figure 3?
A. Step F in endoproteolitically cleaved at the time of the acrosome reaction, which would be at step -- within step F.
Q. So within step F, there would be a endoproteolysis and the PH20 structure could change?
A. Yes, when at the zona pellucida.
Q. And the steps where antibodies could access PH20 to impede fertilization would be at steps E and F?

Petitioner Merck, Ex. 1129, p. 65
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

A. Yes, at steps E and F.
Q. At step F some PH20 is also released from the sperm surface as soluble PH20, correct?
A. From the acrosome; soluble PH20 come from the acrosome.
Q. So at step F -- let me rephrase.
The acrosome reaction occurs during step F?
A. Yes -- yes.
Q. And then releases soluble PH20?
A. Correct.
Q. Do antibodies need to bind these soluble PH20 in order to prevent fertilization?
MR. POWERS: Object to form.
THE DEPONENT: No, but the antibodies, polyclonal antibodies, should bind equally well to soluble PH20 or to membrane associated PH20.
Q. (By Ms. Wang) Is your opinion that polyclonal antibodies would bind to both the soluble PH20 and sperm PH20?
A. Yes.
Q. The site of fertilization is an oviduct?
A. Correct.
Q. Polyclonal antibodies against PH20 would have to engage sperm in the oviduct to prevent

fertilization, right?

A. Yes, as -- as stage E there throughout the oviduct. But -- but yes, in the oviduct.

Q. So there has to be polyclonal antibody against PH20 in the oviduct to prevent fertilization?

A. Yes.

Q. How much anti-PH20 antibody would need to be able in the oviduct for fertilization to be prevented?

A. I can't offer an opinion on that, because that's -- that's unknown.

Q. Because you don't have an opinion because you don't know?

A. I don't know.

Q. Do you know how much sperm would need to be bound by antibodies in order to prevent fertilization?

MR. POWERS: Objection. Form.

THE DEPONENT: I'm sorry. Could you repeat that? I'm -- I don't know if that was turned around. Go ahead.

Q. (By Ms. Wang) Do you know how much sperm would need to be bound by antibodies to prevent fertilization?

Petitioner Merck, Ex. 1129, p. 67
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

MR. POWERS: Same objection.
THE DEPONENT: So at the stage E -- E there, there's very few sperm that are present on the oviduct on the order of 100 or 200. So any -- any sort of significant antibody titer throughout that -- the fluids there would have an immediate impact or binding to the sperm at that low sperm density.
Q. (By Ms. Wang) Did you say there are about 100 or 200 sperm?
A. Yes.
Q. Would all of that 100 or 200 sperm need to be bound by antibody in order for there to be -- in order to prevent fertilization?
A. Well --
MR. POWERS: Objection. Form.
THE DEPONENT: Out of that handful of relatively small proportion of the total sperm that were introduced into the reproductive tract at insemination, perhaps only one to three sperm actually get to stage F there. So very few migrate and actually interact with the oocyte cumulus complex.
Q. (By Ms. Wang) What trying to understand, Doctor, is what amount of the sperm that's there in

Petitioner Merck, Ex. 1129, p. 68
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

the oviduct needs to be bound by antibody in order to prevent fertilization?

A. Again, I can't opine on that because I -- I don't know. But if there was an antibody -- adequate antibody response in the reproductive tract and an antibody -- and present antibodies with that low sperm density, the assumption would be all of them would be coated with antibody.

Q. But you don't know?

A. I don't know.

Q. What antibody titer would be needed in order to engage all of the sperm available in the oviduct?

A. Yeah, I -- I don't -- I can't opine on that because I don't have -- I don't know those quantitative data. I'm not sure anybody does.

Q. Would the quantity differ by species?

MR. POWERS: Objection. Form.

THE DEPONENT: Sure, it may depending on the response.

Q. (By Ms. Wang) And would it differ by individual?

MR. POWERS: Objection. Form.

THE DEPONENT: It would always be some variability, individual variability, unless you are

Petitioner Merck, Ex. 1129, p. 69
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

dealing with a genetically inbred line of some sort.

Q. (By Ms. Wang) And it would be fair to say you wouldn't know until you do the test to quantify it?

MR. POWERS: Objection. Form.

THE DEPONENT: No, I think if you had sufficient antibody titers in the reproductive tract fluids or in the oviduct, I think one could be fairly certainly that that's going to have a contraception effect and certainly a POSA would have expected that.

Q. (By Ms. Wang) Would a POSA have known in 2012 how much antibody titer would be needed?

MR. POWERS: Objection. Relevance.

THE DEPONENT: Probably not, but it didn't -- wouldn't matter as long as there was a response in the reproductive tract.

Q. (By Ms. Wang) It is your opinion that you would need a sufficient antibody titer in order to cause contraception, correct?

A. Yes.

Q. I am trying to understand what the POSA would have expected a sufficient antibody titer to be?

Petitioner Merck, Ex. 1129, p. 70
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

A. Well, I -- I -- I can't opine on that in vivo because that's not known. But there -- one could look in vitro at antibody titers that might affect sperm function and fertilization in vitro. But other than that, I don't believe there's any studies that have been in vivo with sperm and antibodies.

Q. So in 2012 the POSA so would not have known in vivo what antibody titer was needed against sperm --

MR. POWERS: Objection.

Q. (By Ms. Wang) -- to cause contraception?

MR. POWERS: Form.

THE DEPONENT: Right. I don't believe that information for in vivo studies would be available at the time or -- or now.

Q. (By Ms. Wang) It was your testimony earlier that in your opinion polyclonal antibodies against PH20 raised in reaction to modified PH20 polypeptides would bind both soluble and sperm-bound PH20?

A. Yes, correct.

Q. Would you expect there to be some antibodies that only bind the soluble PH20 but not the sperm-bound PH20?

Petitioner Merck, Ex. 1129, p. 71
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

A. Not in the polyclonal response, no.
Q. All of the antibodies in the polyclonal response in your opinion would bind both the soluble and the sperm bound PH20?
A. Yes.
Q. Antibody that binds the soluble PH20 would not impair the sperm's ability to fertilize the egg, correct?
A. No, it would.
Q. In what way?
A. So soluble PH20 at the time of the acrosome reaction is an acid-active form, and it digest the cumulus extracellular matrix immediately surrounding the sperm. So prior to that, the tail of the sperm is -- is beating at a high frequency but not a whiplike -- whiplash-like fashion. And as the immediate -- there's an immediate clearing right around the sperm of the extracellular matrix in this acid-active form, which then of course, as it becomes exposed to neutral conditions in the cumulus, it loses its activity so the soluble activity declines, but it clears a region around the sperm. So the tail can beat at a very high amplitude, and that's what help thrust -- helps to thrust the sperm forward through the zona

Petitioner Merck, Ex. 1129, p. 72
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

pellucida.

Q. So it your opinion that soluble PH20 would also have to be bound by antibodies in order for there to be a reduction of fertilization?

A. Well, as -- as stated earlier, it would be bound by antibodies similar as to the membrane-bound form.

Q. The amount of sperm in the vaginal cavity is significantly higher than it would be in the oviduct, correct?

A. Yes.

Q. So you would need substantially more antibody in the vaginal cavity to bind sperm if you were trying to achieve contraception in the vaginal cavity?

MR. POWERS: Objection. Form.

THE DEPONENT: Potentially, yes.

Q. (By Ms. Wang) Are you saying "potentially" because you don't know?

A. No. I'm just saying that you would need more. Again, but PH20 would need to be exposed, so...

Q. And PH20 is not exposed --

A. Normally, no --

Q. -- in the vaginal cavity?

Petitioner Merck, Ex. 1129, p. 73
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

A. -- but it could be.

MS. WANG: Okay to take a break?

MR. POWERS: Sure.

THE VIDEOGRAPHER: The time is 11:00 o'clock a.m. Pacific time. We are off the record.

(Recess taken.)

THE VIDEOGRAPHER: The time is 11:15 a.m. Pacific time. We are on record.

Q. (By Ms. Wang) Dr. Cherr, on the break, did you speak with counsel?

A. No, I did not.

Q. Okay. And just to confirm, the answers that you gave in the earlier sessions, would any of those have differed for any of the four different patents at issue?

A. No.

Q. So you state in paragraph 35 of your declaration that by December 28th, 2012, PH20 polypeptide vaccines have been successfully used for contraception in female guinea pigs?

A. Yes, yes.

Q. And as we discussed earlier, the studies you cite also indicated successful contraception in male guinea pigs?

Petitioner Merck, Ex. 1129, p. 74
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

A. Yes, correct.
Q. And in these studies with guinea pigs, the scientists used unmodified guinea pig PH20 purified from sperm, correct?
A. Yes, that's correct.
Q. And the PH20 was injected subcutaneously into guinea pigs.
A. Correct.
Q. Do you know how similar the guinea pig PH20 is to human PH20?
A. I think it's about -- roughly 60 percent, similar.
Q. Do you know how similar the guinea pig PH20 sequence is to modified PH20 polypeptides?
A. I don't know that. I can't -- I can't offer an opinion. I don't know.
Q. You did not make that --
A. No, I didn't.
Q. -- determination?
The guinea pigs that were injected with PH20, both male and female, generated polyclonal antibodies, correct?
MR. POWERS: Objection. Form.
THE DEPONENT: Generated antibodies, circulating antibodies, in the serum.

Petitioner Merck, Ex. 1129, p. 75
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

Q. (By Ms. Wang) The male guinea pigs generated polyclonal antibodies against PH20?
A. Yes, they did.
Q. And the female guinea pigs also generated polyclonal antibodies against PH20?
A. Yes, they did.
Q. Would you agree that PH20 is a self-antigen?
MR. POWERS: Objection. Form.
THE DEPONENT: Excuse me, sorry.
It's a self-anti- -- self-antigen in males.
Q. (By Ms. Wang) And that's because male guinea pigs naturally express PH20?
A. Yes.
Q. And that means a self-antigen in male guinea pigs would have to overcome immune tolerance in order to be successful?
A. Well, they -- they generate an inflammatory response when PH20's administered. So that -- but that also involves an antibody response.
Q. Would you agree that a vaccine using a self-antigen must overcome immune tolerance to be successful?

Petitioner Merck, Ex. 1129, p. 76
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

MR. POWERS: Objection. Form.
THE DEPONENT: It -- it doesn't have to. It -- depending on how it's presented to the animal.
Q. (By Ms. Wang) What do you mean by "depending on how it is presented"?
A. Well, if it's presented as, for example, a denatured protein or as a linear polypeptide, an animal may see that as a foreign antigen even though it's a self-antigen.
Q. A denatured protein or a linear polypeptide would not have the three-dimensional structure of the self-antigen, would it?
A. That is correct.
Q. You testified that in the guinea pig studies in males, injection with PH20 generated an inflammatory response; is that correct?
A. Yes, it is.
Q. And is that the orchitis and epididymitis we discussed earlier?
A. Yes.
Q. And that inflammatory response was an immune response against tissues in the guinea pig that naturally expressed PH20?
MR. POWERS: Object to form.

Petitioner Merck, Ex. 1129, p. 77
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

THE DEPONENT: I believe they also had circulating polyclonal antibodies, as well, in the serum. But, yes, there -- there was what's called breakthrough in the male reproductive tract.

Q. (By Ms. Wang) The inflammatory response seen orchitis and epididymitis -- epididymi- -- let me rephrase.

The inflammatory response seen in the orchitis in male guinea pigs, that was because the guinea pig raised an immune response -- I'm sorry.

Let me rephrase again.

The inflammatory response seen in orchitis in male guinea pigs was due to a response against tissue in the guinea pig expressing PH20, right?

A. Yes.

Q. Do you know whether guinea pigs have a unique immune system compared to other mammals?

MR. POWERS: Objection. Form.

THE DEPONENT: They don't have a unique immune system, but the lumen of the male tract is not a barrier to circulating immunoglobulin as it is in any other animals.

Q. (By Ms. Wang) But you don't think guinea pigs have a different immune system compared to

Petitioner Merck, Ex. 1129, p. 78
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

other mammals?

MR. POWERS: Object to form.

THE DEPONENT: No, I don't believe they have a different immune system. It may just be the testes-blood barrier that's common in most mammals.

Q. (By Ms. Wang) You cited the guinea pigs studies in your declaration as evidence of successful use of PH20 polypeptides as contraceptive vaccines before 2012, correct?

A. Yes.

Could you point to where you're looking?

I just want to make sure --

Q. Paragraph 35.

A. Okay. Yes.

Q. You did not cite any other study before 2012 demonstrating PH20 polypeptide as an effective contraceptive vaccine in other species?

A. The guinea pig was the -- kind of the proof-of-concept animal model where it worked exceedingly well.

Q. But you did not cite any study in any other animal model where the PH20 polypeptide worked as a contraceptive vaccine?

MR. POWERS: Object to form.

THE DEPONENT: That is correct, but that

Petitioner Merck, Ex. 1129, p. 79
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

has to do with administration or the route of administration.

Q. (By Ms. Wang) You did not identify any other successful animal study in which PH20 polypeptide worked as a contraceptive vaccine?

A. That is correct.

Q. At paragraph 49 of your declaration --

A. Yes.

Q. -- you talk about the Pomering 2002 paper, which is Exhibit 1020.

A. Yes.

Q. And you agree that Pomering 20- -- of 2002 reports that "rabbits receiving PH20 polypeptides via the subcutaneous route induced high levels of" polyclonal antibodies?

A. Yes, in the plasma.

Q. And Pomering used recombinant rabbit PH20?

A. Yes, correct.

Q. And you agree this was unmodified rabbit PH20?

A. Yes.

Q. And the rabbits were injected subcutaneously?

A. Yes.

Petitioner Merck, Ex. 1129, p. 80
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

Q. And you agree they were injected with an adjuvant?
A. They were.
Q. You agree they were also injected with booster immunizations?
A. Yes, they were.
Q. And both male and female rabbits were immunized?
A. Yes, correct.
Q. And Pomering 2002 reported that the rabbits generated polyclonal antibodies that bound native PH20, correct?
A. Circulating in the plasma, yes, but not in the reproductive tract.
Q. Regardless of where it was, the rabbits generated polyclonal antibodies that bound native PH20, correct?
MR. POWERS: Objection. Form.
THE DEPONENT: Yes, they did.
Q. (By Ms. Wang) And you agree that even though the rabbits generated polyclonal antibodies to PH20, this did not result in infertility in any of the rabbits?
MR. POWERS: Objection. Form.
THE DEPONENT: They -- they only -- the

Petitioner Merck, Ex. 1129, p. 81
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

only stimulation of polyclonal antibodies was in the plasma, not in the reproductive tract, which is where it needs to be for contraception.

Q. (By Ms. Wang) So is it your opinion that for there to be successful contraception, there must be polyclonal antibodies in the reproductive tract?

A. Yes, and Pomering addresses that extensively in their paper.

Q. And it is your opinion that subcutaneous injection can never be an effective way to deliver a contraceptive vaccine?

MR. POWERS: Objection. Form.

THE DEPONENT: Can you define "never."

Q. (By Ms. Wang) Well, I'm trying to understand.

So the rabbits were injected subcutaneously, and you acknowledge they raised polyclonal antibodies.

A. In the plasma, yes.

Q. And it's your opinion that they were not raised in the right location?

A. That's correct.

Q. So in your opinion, the location of the immune responses matters to whether modified PH20

polypeptide can be a successful contraceptive?
A. Yes.
Q. Just raising polyclonal -- rephrase.
Just inducing a polyclonal antibody response is insufficient for there to be successful contraception?
MR. POWERS: Objection. Form.
THE DEPONENT: That's a very broad question. I think it needs to be defined a little bit more.
In other words, raising polyclonal antibodies where and how?
Q. (By Ms. Wang) Well, that's what I'm trying to understand.
Just raising polyclonal antibodies against PH20 is, by itself, in your opinion, insufficient for there to be contraception?
MR. POWERS: Objection.
THE DEPONENT: I can't agree or --
MR. POWERS: Form.
THE DEPONENT: -- disagree with that statement. It's too -- it's too broad.
So, I mean, the location has to be part of that question.
Q. (By Ms. Wang) Raising a polyclonal

Petitioner Merck, Ex. 1129, p. 83
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

antibody response to PH20 in the wrong location would be insufficient to cause contraception?

MR. POWERS: Object to form.

THE DEPONENT: I mean, I -- I would answer "yes," but there's further details that -- with that question.

Q. (By Ms. Wang) Is it fair that generating polyclonal antibodies against PH20 is necessary but not sufficient to cause contraception?

MR. POWERS: Objection to form.

THE DEPONENT: If -- if the polyclonal antibodies are generated in the female tract, particularly the upper female tract, it would be sufficient.

Q. (By Ms. Wang) It's your opinion that polyclonal antibodies need to be generated in the upper female tract, and that would be sufficient for contraception?

A. Yes, that is correct.

Q. I will direct your attention to paragraph 50 of your declaration.

A. Okay.

Q. And paragraph 50 refers to the Hardy 2004 paper, which is Exhibit 1019.

A. Yes.

Petitioner Merck, Ex. 1129, p. 84
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

Q. You agree that Hardy 2004 reports testing mice with PH20?

MR. POWERS: Objection. Form.

THE DEPONENT: Well, that was the heading of the overall study, but in this case, Hardy clearly states the mouse PH20 antibodies generated in the reproductive tract were insufficient to cause infertility.

Q. (By Ms. Wang) My question was, Hardy 2004 reports the testing of mice with PH20 as a contraceptive --

A. Yes.

Q. -- correct?

And they used unmodified mouse PH20?

A. Recombinant, yes.

Q. And you agree Hardy 2004 tested both male and female mice?

A. Yes.

Q. They delivered the mouse PH20 by intraperitoneal injection?

A. Yes, correct.

Q. And you agree they used an adjuvant?

A. They did.

Q. And you agree they used three booster doses?

Petitioner Merck, Ex. 1129, p. 85
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

A. Yes.
Q. And you agree they tested a formulation involving direct injection of the protein --
MR. POWERS: Objection. Form.
Q. (By Ms. Wang) -- right?
A. I'm sorry, could you repeat that.
Q. The Hardy authors tested a formulation of PH20 involving direct injection of the protein into mice?
MR. POWERS: Objection. Form.
THE DEPONENT: Intraperitoneal, yes.
Q. (By Ms. Wang) They also tested a formulation of PH20 using recombinant virus administration?
A. Yes.
Q. And Hardy 2004 reported neither recombinant mouse PH20 vaccine formulation significantly reduced the fertility of either male or female mice?
MR. POWERS: Objection. Form.
THE DEPONENT: Yes, that is correct.
Q. (By Ms. Wang) It's your opinion, though, that Hardy 2004 did not use an optimized immunization strategy, right?
A. That's my opinion, and that's also what

Petitioner Merck, Ex. 1129, p. 86
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

Hardy indicates in their discussion, as well.

Q. It's your testimony that the Hardy authors claim that immunization strategy is the reason they were unable to achieve infertility?

MR. POWERS: Objection. Form.

THE DEPONENT: When you say "immunization strategy," could you define that, what you mean by that.

Q. (By Ms. Wang) Well, I asked you, it's your opinion that Hardy did not use an optimized immunization strategy, right?

And you said that's also what Hardy indicates in their discussion, as well.

Do you recall that testimony?

A. Yes.

Q. And so it is your testimony that Hardy says that they did not use an optimized immunization strategy, and that was the reason they couldn't --

MR. POWERS: Objection.

Q. (By Ms. Wang) -- achieve effective contraception?

MR. POWERS: Objection. Form.

THE DEPONENT: It's my view that they were not -- unable -- and Hardy says the same

Petitioner Merck, Ex. 1129, p. 87
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

thing. They were unable to elicit a response in the female tract because of the intraperitoneal approach.

Q. (By Ms. Wang) Hardy says that their inability to cause contraception was due to the intraperitoneal approach?

MR. POWERS: Objection. Form.

THE DEPONENT: Well, again, I probably -- I would like to look at that reference just -- before I offer an answer.

Q. (By Ms. Wang) We can move on.

You don't disagree that the Hardy authors still generated a polyclonal antibody response in mice with PH20, do you?

A. In plasma they did, yes.

Q. So the mice still raised polyclonal antibodies against PH20?

A. Yes, that is correct.

Q. It's your opinion that the antibodies were not in the right location?

A. Yes.

Q. In your declaration, you also discuss the Rosengren 2015 paper.

Do you recall that?

A. Yes, I do.

Petitioner Merck, Ex. 1129, p. 88
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

Q. And that's Exhibit 1061?
A. Yes.
Q. Rosengren 2015 tested serum antibody of human patients who were injected with PH20, correct?
A. Yes.
Could you provide me with that paragraph you're looking at.
Q. Paragraph 45.
A. Thank you.
Yes, thank you.
Q. So Rosengren 2015 tested serum antibody of human patients who were injected with PH20?
A. Yes, correct.
Q. And the human patients were injected with unmodified recombinant human PH20?
A. Yes, without an adjuvant.
Q. And serum antibody means the patient had an immune response to the injected PH20, correct?
MR. POWERS: Objection. Form.
THE DEPONENT: Yes, it -- it could mean that.
Q. (By Ms. Wang) The serum antibody -- let me rephrase.
The serum antibodies that were tested

Petitioner Merck, Ex. 1129, p. 89
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

were anti-PH20?

MR. POWERS: Objection. Form.

THE DEPONENT: Yes, in some of the patients.

Q. (By Ms. Wang) Meaning the Rosengren 2015 authors found that the serum antibodies in some of the patients bound native PH20?

MR. POWERS: Object to form.

THE DEPONENT: I -- I think bound recombinant PH20.

Q. (By Ms. Wang) You don't think any of the serum antibodies found in patients bound native PH20?

A. I don't think -- I don't think they looked at that in terms of sperm -- native being sperm PH20.

Q. Do you think antibodies that bind recombinant PH20 would not bind native sperm PH20?

A. Native serum.

MR. POWERS: Objection. Form.

THE DEPONENT: Sorry, say that again.

I just want to...

Q. (By Ms. Wang) So you testified that you think Rosengren 2015 tested serum antibodies and found that they bound recombinant PH20, correct?

Petitioner Merck, Ex. 1129, p. 90
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

A. I believe that's right, yes.
Q. And you don't think that they tested whether the serum antibody bound native sperm --
A. That is --
Q. -- PH --
A. Right, that is correct.
Q. And do you think that the testing that found that serum antibody bound recombinant PH20 does not prove that the antibodies would have bound native sperm PH20?
MR. POWERS: Objection. Form.
THE DEPONENT: Well, that wasn't tested, so I -- I can't really offer an opinion on that.
Q. (By Ms. Wang) I understand that binding to native sperm PH20 was not tested.
But what I'm trying to understand is, testing of the serum -- or binding of the serum antibodies to recombinant human PH20, does that tell you something about whether those serum antibodies would bind sperm PH20?
A. Yes, in a theoretical way, that's true.
I believe, though, the titers they identified in these patients were extremely low titers.
Q. Well, I'm not asking about titers.

Petitioner Merck, Ex. 1129, p. 91
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

A. Yeah.
Q. I'm just asking about binding, so --
A. Just theoretically, yeah.
Q. So serum antibodies that bound recombinant human PH20 antibody would theoretically also bind human sperm PH20, correct?
MR. POWERS: Object to form.
THE DEPONENT: Could, yes.
Q. (By Ms. Wang) You said it "could."
Are there instances where it wouldn't?
A. Well, I would -- I would say that a POSA would have predicted that it would.
But also, the Rosengren -- both Rosengren studies were well after 2012. So in principle, a POSA wouldn't have even looked at those, you know, to think about PH20 binding in humans.
Q. So setting aside the timing -- and I appreciate you have your opinions on that -- what I'm trying to understand is, someone looking at serum antibodies that bound recombinant human PH20 antibody, is there any reason they would think it would not also bind human sperm PH20?
MR. POWERS: Object to form.
THE DEPONENT: No.
Q. (By Ms. Wang) Would one need to test

Petitioner Merck, Ex. 1129, p. 92
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

polyclonal antibodies raised against recombinant PH20 to know if they would bind to the PH20 on sperm?

MR. POWERS: Objection. Form.

THE DEPONENT: No, it would be -- a POSA would predict that it would or expect that it would.

Q. (By Ms. Wang) The Rosengren authors found that serum antibodies bound recombinant human PH20, but they found no instance in any serum sample of antibodies that neutralized PH20 enzyme activity, did they?

MR. POWERS: Object to form.

THE DEPONENT: I believe that's true.

Q. (By Ms. Wang) Are you aware that Rosengren 2015 was authored by employees of Halozyme?

A. Yes, I was.

Q. And Halozyme is the patent owner in this proceeding, correct?

A. Yes.

Q. So inducing a polyclonal antibody response against PH20 does not always result in infertility in the subject, correct?

MR. POWERS: Objection. Form.

THE DEPONENT: Well, the qualifier is, if it's a serum response, there -- there has to be a response and a significant response in the reproductive tract to affect sperm. And the responses they report in the papers were very minimal, barely detectable. They were present, but ti- -- yeah, the antibodies were present but very low levels, even in the serum.

Q. (By Ms. Wang) So your opinion is, you need the polyclonal antibody response against PH20 to be in a particular location in the body for there to be effective contraception?

A. Yes, similar to what I stated earlier, right.

Q. And also said a "significant response."

So does that mean you need a particular amount of polyclonal antibody response against PH20 in a particular location for there to be effective contraception?

MR. POWERS: Objection. Form.

THE DEPONENT: Well, an adequate -- adequate response for -- to have enough to bind to sperm.

Q. (By Ms. Wang) So just a little bit of polyclonal antibody in the reproductive tract would

Petitioner Merck, Ex. 1129, p. 94
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

not be enough to be effective as a contraception?
A. Well, I can't opine on that specifically, but it's similar in -- I've talked about the mucosal response eliciting -- or an intranasal administration and a mucosal response eliciting a high -- relatively high level of antibody that is -- that's been shown for other antigens. Not related to sperm, but to HIV and herpes.
And that's plenty of antibody response to completely neutralize HIV and herpes virus.
Q. Do you know how much antibody response would be needed against PH20 for there to be an effective contraception?
MR. POWERS: Object to form.
THE DEPONENT: Again, I can't opine on that because I don't have specific amounts.
Q. (By Ms. Wang) You don't know what the specific amounts are?
A. No, I don't.
Q. Across the studies that we have talked about, subcutaneous administration of native PH20 did not cause contraception in several species, right?
A. Yes, that's true.
Q. So is it your opinion that the route of

Petitioner Merck, Ex. 1129, p. 95
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

administration matters to getting effective contraception with a modified PH20 polypeptide?

A. Yes, I believe that's one of the most important factors.

Q. So the usefulness of the modified PH20 polypeptides as contraceptive vaccines depends on how they are delivered?

MR. POWERS: Object to form.

THE DEPONENT: Yes, I believe it is.

Q. (By Ms. Wang) Is it your opinion that in 2012, the POSA would have understood that subcutaneous immunization would never work to cause contraception?

MR. POWERS: Objection. Form.

THE DEPONENT: Are you referring -- excuse me, are you referring to human or to animals or general or...

Q. (By Ms. Wang) Well, is it your opinion that a POSA would have understood in 2012 that subcutaneous immunization would not work in humans to cause contraception?

A. So based on the papers that were published that had used subcu and intraperitoneal and even intramuscular, there was not an adequate response in the reproductive tract to result in

contraception.

And, again, that's discussed in -- in the discussions of the papers from 2002, 2004 and -- and other papers, even from the late '90s. So a POSA would have been aware that that is a major issue.

Q. And a POSA in 2012 would not expect subcutaneous immunization to be -- to work in humans to cause contraception?

MR. POWERS: Objection. Form.

THE DEPONENT: Yes, in humans. It might work in guinea pigs but not humans.

Q. (By Ms. Wang) A POSA in 2012 would not expect subcutaneous immunization to work in mice to cause contraception?

MR. POWERS: Objection. Form.

THE DEPONENT: Probably, yes. Again, based on the discussions of -- of those studies that did not elicit an adequate immune response in the reproductive tract.

Q. (By Ms. Wang) We've talked about your opinion that where the location in the body, where the polyclonal response is generated, matters to contraception, right?

A. Yes.

Petitioner Merck, Ex. 1129, p. 97
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

Q. And it's your testimony that the route of administration also matters to contraception?
A. So those are interrelated, yes.
Q. Is it also your opinion that the use of adjuvants matters to effective use of modified PH20 polypeptide as a contraceptive vaccine?
A. Yes. That would increase the efficiency of the response tremendously.
Q. Does a depend on a particular adjuvant?
A. Depends -- again, it depends. In your question, are you talking about in mucosal response or the reproductive tract, or are you talking the circulating plasma?
Q. Well, your opinion is that there needs to be a mucosal response for there to be effective contraception, right?
A. Yes, correct.
Q. And you need adjuvants with the mucosal route as well, right?
A. That's what's been used, yes.
Q. Would you use the same adjuvants in the mucosal route as were used in the subcutaneous route?
A. Probably not.
Q. But it is your opinion that even

Petitioner Merck, Ex. 1129, p. 98
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

subcutaneous administration with adjuvants would be insufficient to cause contraception in animals other than guinea pigs?

MR. POWERS: Object to form.

THE DEPONENT: Yes, essentially that's what was done with the Hardy and Pomering studies.

Q. (By Ms. Wang) In your opinion, does the particular dosage matter to effective contraception with a modified PH20 polypeptide?

A. Well, I can't give an opinion on specific amounts that would be necessary for an adequate response, but yes. I mean, if it's an extremely low level, there may not be a response. It may have to be of an adequate level, but I can say what that is. Or I can't offer an opinion on w is.

Q. So you do need enough modified PH20 polypeptide for an adequate immune response?

A. Yes, and I think would be probably on par to what have been used to achieve plasma levels circulating.

Q. But you don't know what amount that would be --

A. Well --

Q. -- sitting here today?

A. They're in the microgram -- microgram per million quantities.
Q. But you don't specific quantities?
MR. POWERS: Objection. Form.
THE DEPONENT: Again, I -- I need to look through references to -- to tell you specifically what was used in those studies.
Q. (By Ms. Wang) So we discussed this earlier, but it's your opinion that the polyclonal antibodies generated against any of the modified PH20 polypeptides would bind to the PH20 poly- -- PH20 polypeptide of sperm in the reproductive tract of the female mammal and cause contraception?
A. Yes. If it's an adequate response, yes, that's correct.
Q. And that would include humans?
A. Yeah.
Q. Are you aware of any evidence published before 2012 of modified PH20 polypeptides causing polyclonal antibodies that bind native human PH20?
MR. POWERS: Objection. Form.
THE DEPONENT: I am not other than recombinant -- just recombinant proteins, native protein structure.
Q. (By Ms. Wang) You are aware of

Petitioner Merck, Ex. 1129, p. 100
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

recombinant native proteins but not of modified PH20 polypeptides generating --

A. Yeah.

Q. -- polyclonal responses against native human PH20?

MR. POWERS: Objection. Form.

THE DEPONENT: Correct, or at least I'm unaware.

Q. (By Ms. Wang) Are you aware of any evidence published after 2012 of modified PH20 polypeptides causing antibodies that bind native human PH20?

A. No, I am not aware of that.

Q. Are you aware of any evidence published before 2012, of successful contraception in humans using native PH20 as a vaccine?

A. I am not aware of any studies on that.

Q. And you are not aware of studies before 2012 of successful contraception in humans using modified PH20 polypeptides as a vaccine?

A. I'm not aware, no.

Q. Are you aware of any evidence published after 2012 of successful use of a modified PH20 polypeptide as a vaccine?

MR. POWERS: Object to form.

Petitioner Merck, Ex. 1129, p. 101
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

THE DEPONENT: No, I am not.
Q. (By Ms. Wang) In humans or in any other mammals?
A. No, I am not.
Q. So is fair to say there's no evidence of modified PH20 polypeptide being used successfully for contraception in humans?
MR. POWERS: Objection. Form.
THE DEPONENT: Not that I'm aware of.
Q. (By Ms. Wang) Your opinion that polyclonal antibodies generated against any of the modified PH20 polypeptides would cause contraception also applied to nonhuman mammals, correct?
A. You mean using -- so using the modified human PH20 polypeptides in other mammals?
Q. Yes.
A. Yes. It -- that's right.
Q. So your opinion is you can take the modified human polypeptide -- PH20 polypeptide, use it as contraception in nonhuman mammals, and it would be effective?
A. Yes, as long it was done, again, in the appropriate -- getting the antibodies in the appropriate place in the reproductive tract.

Petitioner Merck, Ex. 1129, p. 102
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

Q. And those mammals would include rabbits, right?
A. Uh-huh.
Q. Mice?
A. Yes.
Q. Rats?
A. Yes.
Q. And cynomolgus monkeys?
A. Yes.
Q. And that opinion is based on the opinion that immunization with recombinant human modified PH20 would cause the nonhuman mammal to generate polyclonal antibodies in response and those polyclonal antibodies would bind the nonhuman mammals native PH20 on sperm?
MR. POWERS: Objection. Form.
THE DEPONENT: Yes. Again, if it's administered in the appropriate way to elicit a response in the reproductive tract of those animals.
Q. (By Ms. Wang) Do you agree that in 2012 the POSA's expectation would have been that in order to test contraception efficiency in a certain species, PH20 from that species must be used as an immunogen?

Petitioner Merck, Ex. 1129, p. 103
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

MR. POWERS: Objection. Form.
THE DEPONENT: No, because of the percent homology of the human PH20 to those other animals theoretically is high enough, kind of in the 50 percent and higher range, and that should elicit an immune response, and those polyclonal antibodies should bind to that animal's PH20 that's in their sperm.
Q. (By Ms. Wang) Are you aware of any evidence published before 2012 investigating the effect of human PH20 on fertility in nonhuman mammals?
MR. POWERS: Objection. Form.
THE DEPONENT: No, I am not aware.
Q. (By Ms. Wang) Are you aware of any evidence published before 2012 of using modified human PH20 polypeptide to see its effect on fertility in nonhuman mammal?
MR. POWERS: Same objection.
THE DEPONENT: No, I am not.
Q. (By Ms. Wang) Are you aware of any instances in which immunogens with less than 60 percent sequence identity to the native PH20 in an animal were used in vivo and caused infertility in that animal?

MR. POWERS: Same objection.
THE DEPONENT: No. I am not aware of that.
Q. (By Ms. Wang) Would you agree that an immunogen with a higher sequence identity to the native PH20 would be more likely to present epitopes that would cause the production of antibodies that would bind to the native PH20?
MR. POWERS: Objection. Form.
THE DEPONENT: I think for -- excuse me -- for polyclonal antibodies, that kind of sequence identity should be sufficient in -- in a theory -- in theory to result in antibody production, and those antibodies would bind to the animal's PH20.
Q. (By Ms. Wang) You said "that kind of sequence identity," what sequence identity --
A. Kind of -- in the -- 50 percent or higher. Most of those animals are above 60 percent.
Q. And the opinion that most animal are above 60 percent identity, is that something you independently developed?
A. No, I did not do that.
Q. Where did you -- rephrase.

Petitioner Merck, Ex. 1129, p. 105
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

How did you come to the belief that most animals have above 60 percent identity?

A. You mean with those animals that were listed originally, or which animals?

Q. I think you -- I think your testimony was that most animals are in the 50 percent or higher identity; is what you said?

A. I think I was referring to the animals that were listed in my declaration, not -- I can't really speak to all the other ones.

Q. Fair enough.

So it's your belief that the animals listed in paragraph 30 of your declaration all have above 50 percent sequence identity to human PH20?

A. Yes, approximately.

Q. And you did not form that belief independently?

A. No, Dr. Moon refers to that in his declaration.

MR. POWERS: Sue, is now a good time for lunch?

MS. WANG: Just a couple more questions from me.

MR. POWERS: Okay.

Q. (By Ms. Wang) If that's okay, Dr. Cherr?

Petitioner Merck, Ex. 1129, p. 106
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

A. That's fine.
Q. Your opinion that modified PH20 polypeptides would cause contraception in nonhuman mammals is based on the belief that those nonhuman mammals have above 50 percent sequence identity, right?
A. Or -- or near 50 percent, yes.
Q. And that belief that those human -- nonhuman mammals in paragraph 30 -- are near or above 50 percent sequence identity; that is from Dr. Moon?
A. Yes, that's right.
Q. Are you aware of any evidence published after 2012 investigating the effect of native human PH20 on fertility in nonhuman mammals?
A. No, I am not aware.
Q. What about any evidence after 2012 of using modified PH20 polypeptides to investigate fertility in nonhuman mammals?
A. No, I am not aware of that.
Q. Are you aware of any evidence published after 2012 that immunizing nonhuman mammals with recombinant human PH20 caused infertility in those nonhuman mammals?
MR. POWERS: Objection. Form.

Petitioner Merck, Ex. 1129, p. 107
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

THE DEPONENT: I'm sorry. Can you say that again?

Q. (By Ms. Wang) Are you aware of any evidence published after 2012 --

A. After.

Q. -- that immunizing nonhuman mammals with recombinant human PH20 caused infertility in the nonhuman mammals?

MR. POWERS: Same objection.

THE DEPONENT: I'm not aware.

MR. POWERS: That's a lot more than a couple questions, Sue, for me. Can we have lunch now?

Would you like a break, Doctor?

THE DEPONENT: Sure.

MS. WANG: Okay.

THE VIDEOGRAPHER: Okay. The time is 12:13 p.m. Pacific time. We are off the record.

(Recess taken.)

THE VIDEOGRAPHER: The time is 1:06 p.m. Pacific time. We are on record.

Q. (By Ms. Wang) Welcome back, Dr. Cherr.

During the lunch break, did you speak with counsel?

A. No, I did not.

Petitioner Merck, Ex. 1129, p. 108
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

Q. So before the break, we were talking -- I was asking about evidence published regarding the effect of human PH20 on fertility in nonhuman mammals.

Do you recall that?

A. I do.

Q. And you are not aware of any evidence published regarding using human PH20 and its effect on fertility in nonhuman mammals?

MR. POWERS: Objection. Form.

THE DEPONENT: Could you -- I'm sorry.

Q. (By Ms. Wang) Let me rephrase that.

You are not aware of any published evidence before 2012 regarding the effect of native human PH20 on fertility in nonhuman mammals --

MR. POWERS: Objection. Form.

Q. (By Ms. Wang) -- right?

A. Cor- -- I'm not aware, yes.

Q. Are you aware of any evidence published after 2012 describing non- -- describing immunizing nonhuman mammals with recombinant human PH20 to investigate the effect on infertility in those nonhuman mammals?

MR. POWERS: Objection. Form.

THE DEPONENT: I'm not aware.

Petitioner Merck, Ex. 1129, p. 109
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

Q. (By Ms. Wang) Would you agree that experimental evidence testing human PH20 and its effect on fertility would be useful to determining whether the PH20 would work as a contraception?

MR. POWERS: Objection. Form.

THE DEPONENT: I -- I really can't offer an opinion on that because there's so many details regarding how those kinds of approaches would be taken. So just to make a blanket statement, I -- I can't necessarily offer an opinion.

Q. (By Ms. Wang) You don't think evidence showing PH20's effect on fertility experimentally would be useful to know whether it would be useful as a contraceptive?

A. Again, it would have -- it would depend on how -- how those experts were done. And, again, I come back to this routinely, that -- if they were able to -- so making a general statement about that, I don't agree with. But it was done where there was mucosal -- appropriate mucosal response, that it could be. But, again, those details -- not very simple. Those are complicated details.

Q. So experimentation -- experimental evidence showing PH20's effect on fertility that is not delivered mucosally in your opinion would just

Petitioner Merck, Ex. 1129, p. 110
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

not be relevant?

MR. POWERS: Objection. Form.

THE DEPONENT: Would not be -- I think based on what a POSA would know in -- by 2012 that an administration, that did not elicit a mucosal response, there would be failure or no contraception.

Q. (By Ms. Wang) Is it your opinion that the POSA would ignore experimental evidence using PH20 in various animals but injected subcutaneously?

MR. POWERS: Object to form.

THE DEPONENT: I don't know if a POSA would ignore, but I think that a POSA -- their expectation would be that you would need to elicit a mucosal response in order to see it or observe an effect.

Q. (By Ms. Wang) So in your mind, experimental evidence showing the effect of PH20 injected subcutaneously on fertility in an animal would not be relevant to the POSA's determination of whether PH20 would be useful as a contraceptive vaccine?

MR. POWERS: Objection. Form.

THE DEPONENT: I'm sorry. Could you --

Petitioner Merck, Ex. 1129, p. 111
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

can you further define "relevant," what you mean by that?

Q. (By Ms. Wang) Well, would experimental evidence showing the effect of the PH20 injected subcutaneously be probative for the POSA in determining whether PH20 would be useful as a contraceptive vaccine?

A. I'm sorry. "Prohibitive"?

Q. "Probative."

A. "Probative." You're talking about prior to 2012?

Q. Well, I'm asking generally about experimental evidence.

MR. POWERS: Objection. Form.

THE DEPONENT: I think it -- I think that assessing the immune response and the location of the immune response would be absolutely critical; otherwise, it may not be very useful.

Q. (By Ms. Wang) Are you saying the POSA would look at experimental evidence generated from injecting PH20 subcutaneously to assess the location of the immune response to determine if it was probative?

MR. POWERS: Objection. Form.

THE DEPONENT: No, because -- well,

Petitioner Merck, Ex. 1129, p. 112
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

again, prior to 2012, it -- it was, in my mind, clear that a POSA would understand that experiments with -- with experimental animals, subcutaneous injections are not successful in eliciting an appropriate response in the reproductive tract. And I don't think that would change after 2012 either.

Q. (By Ms. Wang) Are you aware of any evidence, period, whether published or not, investigating the effect of native human PH20 on fertility in nonhuman mammals?

MR. POWERS: Object to form.

THE DEPONENT: No, I am not.

Q. (By Ms. Wang) Are you aware of any such evidence for modified PH20 polypeptide on fertility in nonhuman mammals?

A. No, I am not.

Q. Are you aware that scientists at Halozyme investigated whether immunization of nonhuman mammals with recombinant human PH20 would cause infertility in those mammals?

A. I'm not aware of that. Is that published or --

Q. So you haven't review any expert --

A. I haven't reviewed it, no.

Q. Were informed these experiments had been performed?

MR. POWERS: Objection. Form.

(Court Reporter asks for clarification.)

THE DEPONENT: No.

Q. (By Ms. Wang) And confirm you have not spoken to any Halozyme scientists in connection with this case?

A. No, no.

Q. So in connection with your opinion that by December 2012 POSAs would have expected the polyclonal antibodies generated female mammals in response to any of the modified PH20 polypeptides would cause contraception, did you thoroughly investigate the literature before 2012 in forming your opinions?

MR. POWERS: Objection. Form.

THE DEPONENT: I did.

Q. (By Ms. Wang) And you thoroughly investigated the literature before 2012 on efforts to use PH20 as an immunocontraception before you prepared your declaration?

A. Yes, that's correct.

Q. And do you believe that the evidence you presented in your declaration is the most probative

on the question?
A. I believe so.
Q. And that question would be whether a POSA would have considered PH20 to be a useful antigen for inclusion in immunocontraceptive vaccines?
MR. POWERS: Objection. Form.
THE DEPONENT: Yes, with -- well, with the caveat of, again, coming back to the immune response in the female tract. So that -- that would be critical.
Q. (By Ms. Wang) Right.
But you believe the evidence cited in your declaration is the most probative of the question, whether a POSA would have considered modified PH20 polypeptides to be useful for inclusion in immunocontraceptive vaccines?
A. Yes, I believe so.
Q. And you identified no studies outside of the guinea pigs where a polyclonal antibody response to PH20 caused contraception, correct?
MR. POWERS: Objection. Form.
THE DEPONENT: That is correct based on the literature I reviewed, yes.
Q. (By Ms. Wang) And you don't think it's possible that someone before 2012 reviewing the

Petitioner Merck, Ex. 1129, p. 115
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

data from nonprimate models would conclude that PH20 is not a useful antigen for inclusion in immunocontraceptive vaccines?

MR. POWERS: Objection. Relevance.

THE DEPONENT: I think if you look at the discussion in those key papers that I've presented in my declaration, they're very clear in their discussion of potentially why they did not have contraceptive effects. And, again, it comes back to the antibodies being at the right place at the right time in sufficient quantities.

Q. (By Ms. Wang) So you don't think someone reviewing those key papers would conclude that PH20 is not a useful antigen for inclusion in immunocontraceptive vaccines?

MR. POWERS: Objection. Relevance.

THE DEPONENT: I just want to make sure I have it right. Say it, please.

Q. (By Ms. Wang) Yeah.

You don't think it's possible someone reviewing the key papers you cited in your declaration would conclude that PH20 is not a useful antigen for inclusion in immunocontraceptive vaccines?

MR. POWERS: Same objection.

Petitioner Merck, Ex. 1129, p. 116
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

THE DEPONENT: Correct, if they did a careful analysis of what was in those papers.

Q. (By Ms. Wang) Earlier we talked about the Hardy 2004 paper.

Do you recall that?

A. Yes.

Q. And you confirmed for me that the Hardy authors delivered mirroring PH20 by virus administration?

A. But I think the -- the actual route of exposure in the Hardy paper was intraperitoneal, I believe. But, again, I -- I'd like to look at the reference.

Q. I'll direct your attention to page 328 of Exhibit 1019.

A. Yes.

Q. Let me ask the question again so I can get the right answer.

So Hardy -- the Hardy authors delivered PH20 using recombinant virus administration, correct?

A. That was one of the ways they did, yes.

Q. And recombinant virus administration also generates polyclonal antibodies in serum?

A. It looks like it triggered an antibody

Petitioner Merck, Ex. 1129, p. 117
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

response in a proportion of the animals, not in all of them.

Q. My question is, the recombinant viral administration generates polyclonal antibodies in serum, right?

MR. POWERS: Objection. Form.

THE DEPONENT: Right.

So I believe they found that serum from several mice did not contain immunoglobulin antibodies using that approach.

Q. (By Ms. Wang) And serum from other mice did --

A. Did, yes.

Q. But this recombinant viral approach results in antibodies in serum and not the reproductive tract, right?

A. Well, it only -- it only elicited antibodies in serum in a proportion. I think it was two out of the six of the animals, I believe.

Q. And it did not elicit antibody response in the reproductive tract?

A. They didn't -- they did not study that.

Q. Okay. Is it your opinion that the POSA would not view recombinant viral delivery of PH20 as a viable mechanism for causing contraception?

Petitioner Merck, Ex. 1129, p. 118
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

MR. POWERS: Objection. Form.
THE DEPONENT: No, I don't believe so, because whether that was the recombinant viral or just the recombinant expressed PH20, either way, even if there was a serum titer, they did not achieve contraception.
And, again, it had to do with the route of exposure not -- not triggering mucosal response in the reproductive tract.
Q. (By Ms. Wang) So the POSA would use not recombinant viral delivery of PH20 because it would not raise sufficient titer in the reproductive tract?
MR. POWERS: Objection. Form.
THE DEPONENT: No, they might -- they might use it because it may elicit a response through a very different route of exposure than what was used in the study. Again, coming back to the -- an intranasal type of exposure.
Q. (By Ms. Wang) So your opinion is the POSA could use recombinant viral delivery of PH20 as long as they delivered the recombinant virus intranasally?
MR. POWERS: Object to form.
THE DEPONENT: To trigger, yes, a mucosal

Petitioner Merck, Ex. 1129, p. 119
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

response. So it might be effective -- very effective for that.

Q. (By Ms. Wang) I'd like to direct your attention to paragraph 33 -- you can set that aside.

A. Okay.

Q. Paragraph 33 of your declaration.

A. Yes.

Q. And, actually, just before paragraph 33, the last sentence of paragraph 32, you state, "POSAs would have known that the binding of antibodies to sperm PH20 polypeptide in the female reproductive tract would cause contraception irrespective of where the antibodies bind on the PH20 polypeptides."

Do you see that?

A. Yes.

Q. And that is your opinion?

A. That is my opinion.

Q. In order for anti-PH20 antibodies to cause contraception, those antibodies have to bind sperm surface PH20, correct?

A. Sperm surface or inside the acrosome. But probably all -- all places, wherever PH20 is.

Q. And on the sperm surface, there is a

Petitioner Merck, Ex. 1129, p. 120
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

portion of PH20 that is not exposed, correct?
MR. POWERS: Objection. Form.
THE DEPONENT: A portion?
I would -- what do you mean by "a portion"?
Q. (By Ms. Wang) There's a part of the PH20 protein structure on sperm that is not exposed to the surface?
MR. POWERS: Objection. Form.
THE DEPONENT: Okay. Are you referring to sperm in -- that are coated with, like, a glycocalyx coat?
Q. (By Ms. Wang) No.
Maybe let me ask a different question.
In your opinion, are there epitopes of PH20 on sperm that are not available for antibody binding, assuming the glycocalyx has been removed?
A. Assuming the glycocalyx has been removed.
Potentially, a small portion of the lipid anchor, where it anchors to the membrane, the outer leaflet of the membrane, that small region may not be recognized by antibodies. But also maybe is a -- it's a small portion of the molecule.
Q. In your opinion, does soluble PH20 have the exact same epitopes as sperm PH20?

Petitioner Merck, Ex. 1129, p. 121
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

MR. POWERS: Objection. Form.
THE DEPONENT: That is not known. It is endoproteolytically cleaved, but still connected with a disulfide bond. But I'm not aware of studies that have done a complete analysis
Q. (By Ms. Wang) So you don't know whether soluble PH20 has different epitopes from sperm PH20?
MR. POWERS: Object to form.
THE DEPONENT: I don't -- well, I don't think it does.
Any sort of changes that occur during the acrosome reaction, it really is not very relevant, assuming there's a polyclonal antibody response, because it would be expected that polyclonal antibodies would bind to that soluble form as well as the membrane-bound form. There's multiple -- multiple regions along the protein that would available.
Q. (By Ms. Wang) Right.
I'm not asking about polyclonal antibodies.
A. Right.
Q. I'm just asking about protein structure.
A. Okay.

Petitioner Merck, Ex. 1129, p. 122
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

Q. So do you know whether soluble PH20 has the same epitopes as sperm PH20?

MR. POWERS: Objection. Asked and answered.

THE DEPONENT: I don't know.

I can't say for sure.

Q. (By Ms. Wang) In paragraph 33 of your opinion, you say the POSA would have known that antibodies "would prevent sperm from fertilizing the oocyte by, e.g., inhibiting sperm motility, inducing sperm agglutination, reducing penetration of cervical mucus by sperm, interfering with sperm capacitation or the acrosome reaction, or stimulating sperm lysis via the complement pathway," correct?

A. Yes, yeah.

Q. Do you know which of these mechanisms actually prevents fertilization?

A. Well, certainly, they all could, because they could prevent sperm from getting up into the oviduct or, once it's in the oviduct, prevent it from -- prevent sperm from getting to the oocyte itself.

So any sort of effect on mobility, on -- if it induced sperm agglutination, for example, any

Petitioner Merck, Ex. 1129, p. 123
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

sort of effect on cervical mucus penetration by sperm, and then, of course, inhibition of either capacitation or the acrosome reaction, all those could contribute to lack of fertilization.

Q. Does contraception require all of these mechanisms to occur?

MR. POWERS: Object to form.

THE DEPONENT: No, I don't believe there's a requirement for all of them, but any -- any one or any one combination of them could contribute to contraception.

Q. (By Ms. Wang) If only one of the mechanisms occurred, is that, in your opinion, enough to prevent fertilization?

A. If it was a mechanism that either prevented sperm from reaching the oviduct or within the oviduct caused agglutination or lysed killing of sperm, of course that would have an effect.

But also, even if it was a mechanism -- I mean, again, you're talking about choosing one of the mechanisms. But if it was a mechanism on -- in terms of the acrosome reaction or binding to the zona pellucida, anything like that, that would be -- that would definitely affect fertilization.

Q. Right.

But I'm trying to understand if there's one mechanism that alone would prevent fertilization.

A. Yeah, I -- I don't want to speculate, but I -- I believe that if you have antibodies binding to PH20 on sperm that potentially numerous mechanisms are impacted, not just one, necessarily.

Q. Do you know which mechanisms are impacted?

MR. POWERS: Object to form.

THE DEPONENT: Well, I don't -- I don't know myself.

But a POSA would have derived that once PH20 is exposed in the oviduct when sperm undergo capacitation, and they bind those antibodies, they're probably not going to be able to move forward in the oviduct, and they certainly couldn't enter the cumulus matrix. And then they wouldn't acrosome-react and bind to the zona pellucida.

So I think from the basic mechanisms of sperm and how they fertilize an oocyte that that kind of information with -- with -- and antibodies bound to them, that would be what -- what would be expected, that you would have an effect at multiple levels.

Petitioner Merck, Ex. 1129, p. 125
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

Q. (By Ms. Wang) Am I understanding you correctly that the POSA would expect multiple mechanisms but not know which one was actually working?

A. Yes, I think that's right, yeah.

Q. They don't know the mechanism -- the actual mechanism of action without testing for it?

MR. POWERS: Object to form.

THE DEPONENT: I don't -- I think they don't need to know that to at least be able to move forward with -- with the approach of developing a contraceptive vaccine.

Q. (By Ms. Wang) Just to confirm, this is your opinion for any and all of the modified PH20 polypeptides?

A. Yes, I think it would be the same sort of thing we've been talking about, where those would elicit a very similar level of antibody of response in the upper tract, again, appropriately administered to elicit a mucosal response.

Q. Is it your opinion that the contraceptive -- rephrase.

Is it your opinion that modified PH20 polypeptides have to raise an antibody response in the upper reproductive tract to be effective as

Petitioner Merck, Ex. 1129, p. 126
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

contraception?

MR. POWERS: Objection. Form.

THE DEPONENT: I believe it has to be throughout the reproductive tract, ideally.

Q. (By Ms. Wang) Would modified PH20 polypeptides be effective as contraception if they only raised antibody response in the upper reproductive tract?

A. Yes, they would be effective, but that -- that would also be unlikely because of the mucosal response and where that -- and that's throughout the reproductive tract.

Q. Would modified PH20 polypeptides be effective as contraception if they only raised antibody response in the lower reproductive tract?

MR. POWERS: Object to form.

THE DEPONENT: I think that's kind of an unlikely scenario if its administered in the -- again, in the appropriate way, whether -- to elicit a mucosal response, because the upper reproductive tract and the oviduct and the uterus are known to be places where there's high secretion of mucosal immunoglobulin A, IgA.

Q. (By Ms. Wang) Is it your belief that mucosal administration of an antigen -- rephrase,

Petitioner Merck, Ex. 1129, p. 127
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

sorry.

Is it your belief that any mucosal administration of an antigen would result in antibody production in both the upper and lower reproductive tracts?

A. I just want to be clear.

Could you please define your definition of "lower."

I guess there's different regions to the reproductive tract, so I just want to be sure I'm understanding what you're referring to.

Q. Right.

Well, let me rephrase my question, then.

Your belief is that any mucosal administration of modified PH20 polypeptides would generate antibodies throughout the reproductive tract?

A. If -- if administered to elicit a mucosal response, yes, there would be -- and there may be varying levels in different regions. But, yes, it would be throughout the reproductive tract.

Q. But there would be varying levels in different regions of the reproductive tract, correct?

MR. POWERS: Objection. Form.

Petitioner Merck, Ex. 1129, p. 128
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

THE DEPONENT: Yes, because of where mucosal secretion of antibodies occurs, which is in the upper, in the oviduct and in the uterus and, to some degree, in the cervix, there would be throughout much of it, as well as, you know, some movement of those antibodies down to the vagina, as well.

Q. (By Ms. Wang) And the form of mucosal administration doesn't matter to the level of antibody production in different regions of the reproductive tract?

A. So I think you need to define "form" --

Q. Okay.

A. -- when you say that.

Q. The type of administration that causes a mucosal response, does it matter?

A. Well, as I opined in my declaration, intranasal has been the most common, and it's known to elicit the strongest response. But there's also vaginal administration, rectal, you know. But all of those will elicit at some different levels.

But intranasal has been the one that seems to have really a high efficiency on antibody production, IgA antibody production.

Q. Oral administration is also a form of

Petitioner Merck, Ex. 1129, p. 129
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

mucosal --

A. Oral can, probably less so than the intranasal route.

Q. So oral administration would not elicit --

A. Would not --

Q. -- would not elicit the necessary antibody response in the reproductive tract?

MR. POWERS: Object to form.

THE DEPONENT: It could.

I mean, it hasn't -- oral has been used with certain antigens, certain viral path- -- and pathogens.

But, again, intranasal, in the -- for the reproductive tract, intranasal seems to be the strongest response that's been documented to date.

Q. (By Ms. Wang) Vaginal administration would not elicit a strong enough antibody response in the reproductive tract?

MR. POWERS: Objection. Form.

THE DEPONENT: It could, and they -- people have used intranasal and vaginal in combination to elicit a very strong response.

Q. (By Ms. Wang) How about vaginal alone?

MR. POWERS: Same objection.

Petitioner Merck, Ex. 1129, p. 130
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

THE DEPONENT: I'm not sure, but I don't think it's as effective as intranasal.

Q. (By Ms. Wang) Does vaginal administration elicit an antibody response in a different region of the reproductive tract than intranasal?

A. So my understanding is that vaginal administration elicits a mucosal response. So that would be throughout -- not necessarily in the vagina, but throughout the upper reproductive tract where those -- as I mentioned, those secretory centers are. But, again, it may just not be as strong as the intranasal.

Q. And I guess I should confirm with you, how are you defining "upper reproductive tract"?

A. Oh, I -- so I usually think of it as the uterus and fallopian tube.

Q. And is the amount of mucosal secretion different between the uterus and the fallopian tube?

A. Those are pretty similar. It's that -- the iliac system in terms of secretion. And there's also some in the cervix, but none in the vagina.

Q. So if the POSA were able to elicit a

Petitioner Merck, Ex. 1129, p. 131
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

mucosal response, is it your opinion that there would be similar amounts of antibody in the uterus and the fallopian tube?

A. Yes, I mean, that would be the expectation.

Q. You mentioned in your declaration at paragraph 33 agglutination as a mechanism by which antibody binding to sperm could cause contraception.

A. Yes.

Q. What causes agglutination?

A. So this is -- a lot of this is known from antisperm antibodies that women -- and this goes back to the '60s and '70s. And their partners' sperm tend to be agglutinated if they have auto sperm -- or anti -- sorry, antisperm antibodies.

And it's usually because of the immunoglobulin molecule having -- being polyvalent. And so antibody bound to one sperm, especially when they're so dense in the lower reproductive tract, that the antibodies will essentially cross-link sperm and cause them to agglutinate.

Q. So agglutination requires a large amount of sperm?

A. That's right, and that's where it's

Petitioner Merck, Ex. 1129, p. 132
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

mainly been observed down in the lower tract.
Q. Would you expect agglutination in the oviduct?
A. Probably less likely than the lower tract. I mean, it certainly could happen, but...
Q. You said the earlier, the sperm density in the oviduct is fairly low, right?
A. It's fairly low, but just -- as you recall that figure, they're bound to those oviductal cells, and so they're close to each other when they're bound there. There's not that many of them, but the ones that are bound there, they're close.
So if antibodies are present as soon as DEFB126 comes off, there's a possibility for cross-linking of sperm and some degree of agglutination there.
Q. You also talk in paragraph 34 of your declaration about binding of antibodies to sperm PH20 polypeptide causing allosteric effects irrespective of where the antibodies bound on PH20 polypeptide.
A. Yeah.
Q. What do you mean "allosteric effect"?
A. Well, so there's kind of -- the idea of

Petitioner Merck, Ex. 1129, p. 133
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

steric effects of -- when an antibody's binding, say, to an enzyme. In this case, it's a hyaluronidase. But it's -- it's been more -- it's been better studied in something like an enzyme protease.

And it can bind to -- an antibody can bind to the active site or to sites adjacent to the active site and can induce some sort of steric -- sorry, confirmational change in the protein that will affect the active site without actually binding to the active site.

So that's just an example.

Q. Has the allosteric effect been studied in PH20?

A. Not that I'm aware of.

Q. And in your opinion, the allosteric effect interfering with PH20 enzyme activity could occur regardless of where the antibody binds on PH20?

MR. POWERS: Object to form.

THE DEPONENT: Yes, particularly in relation to the size of the substrate, which is many millions molecular weight the hyaluronic acid. So, you know, it's not a small protein that's being hydrolyzed. And so physically, antibodies bound

Petitioner Merck, Ex. 1129, p. 134
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

along much of PH20 could inhibit that interaction with hyaluronic acid.

Q. (By Ms. Wang) Does your opinion assume that there would be multiple antibodies bound to PH20 in order for there to be an allosteric effect?

A. Yes, in terms of polyclonals, yes.

Q. So just one antibody may not generate an allosteric effect?

MR. POWERS: Object to form.

THE DEPONENT: Again, that's -- the -- the assumption is that if you have a polyclonal response and polyclonal antibodies are binding along the PH20 protein, you know, it wouldn't just be one, or one site.

Q. (By Ms. Wang) But if only one antibody binds to PH20, that antibody may not cause an allosteric effect?

A. Yeah, it's hard to opine on that kind of speculation. I -- I, you know, I mean, that's -- that might be from -- from an in vivo perspective, that probably wouldn't -- wouldn't happen, is not relevant. One might study that in vitro, but, again, it's -- you know, there's a disconnect there because that just -- with a polyclonal response, that just wouldn't happen.

Petitioner Merck, Ex. 1129, p. 135
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

Q. Well, you have an opinion also on monoclonal antibodies, right?
A. Yes.
Q. A monoclonal antibody means an antibody with one specificity --
A. Yes.
Q. -- right?
So a monoclonal antibody that only binds one place on PH20 may not cause an allosteric effect, right?
A. It might or might not.
The -- the full antibody is still -- is -- because of -- again, because of kind of a steric sort of effect can certainly impact the substrate hyaluronic acid of other functions of the PH20 protein.
Q. But a monoclonal antibody may not because it may not bind in the right place to cause a steric effect, right?
MR. POWERS: Objection. Form.
THE DEPONENT: Again, I wouldn't want to speculate. I mean, one can come up with some hypothesis that it might not, but I really don't know data that directly support that.
Q. (By Ms. Wang) Do you know data that --

sorry, let me rephrase.

Do you know one way or the other, without testing it, that a monoclonal antibody binding to PH20 would cause an allosteric effect?

MR. POWERS: Object to form.

THE DEPONENT: Well, as it relates -- it depends.

As a relation to the different functions of PH20, it might have an effect on the HA binding site, it might have an effect on the enzymatic site, or both.

Q. (By Ms. Wang) But do you know the actual effect it has without testing for it?

MR. POWERS: Objection. Form.

THE DEPONENT: No.

One would have to screen the monoclonals for activity in binding.

Q. (By Ms. Wang) When we're talking about allosteric effects from a polyclonal response, is it your opinion that binding location on the PH20 doesn't matter?

A. So again -- sorry, could you just -- I just want to make sure I'm clear on that.

Q. Sure.

You have an opinion that polyclonal

Petitioner Merck, Ex. 1129, p. 137
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

antibodies will cause an allosteric effect, irrespective where the antibodies bind, on page 20, right?

A. Because they are going to binding to many regions on the PH20 polypeptide.

Q. And in your opinion, binding specificity of those polyclonal antibodies doesn't matter?

A. No, because they're -- they are going to be multiple epitopes. So functionally it should inhibit PH20 function. Or when it's on sperm, bind to it on sperm.

Q. Affinity of the polyclonal antibodies, also doesn't matter?

MR. POWERS: Object to form. Foundation.

THE DEPONENT: I would think most of those would be relatively high avidity.

Q. (By Ms. Wang) Avidity of the polyclonal antibodies wouldn't matter?

A. What did you say?

Q. Avidity.

A. Avidity, yeah.

MR. POWERS: Same objection.

THE DEPONENT: Probably not.

MS. WANG: Okay to take a break?

MR. POWERS: Sure.

Petitioner Merck, Ex. 1129, p. 138
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

THE DEPONENT: Thanks.
THE VIDEOGRAPHER: Time is 1:56 p.m. Pacific time. We are off the record.
(Recess taken.)
THE VIDEOGRAPHER: The time is 2:11 p.m. Pacific time. We are on record.
Q. (By Ms. Wang) Dr. Cherr, in the last break did you speak with counsel?
A. I did not.
Q. Okay. In order for modified PH20 polypeptides to be useful as contraceptive vaccines in female mammals, they have to generate a polyclonal immune response at the right place at the right time in sufficient quantities, correct?
MR. POWERS: Objection. Form.
THE DEPONENT: I would agree with that.
Q. (By Ms. Wang) Your opinion on paragraph 43 of your declaration is that a POSA would have expected the modified PH20 polypeptides with optimized administration to be useful as contraceptive vaccines in female mammals.
That's your opinion, right?
A. Yes.
Q. What did you mean by "optimized administration"?

Petitioner Merck, Ex. 1129, p. 139
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

A. Well, meaning mucosal and, again, talked about it in -- in here, but primarily an intranasal route since that's been shown to be most effective for other types of antigens.

Q. Would the POSA have expected the modified PH20 polypeptides to be useful as contraceptive vaccines in female mammals without optimized administration?

MR. POWERS: Objection. Form.

THE DEPONENT: I think in looking through the papers I cite, they would have an understanding that there's a need to elicit a response in the reproductive tract which, again, would be a mucosal response.

Q. (By Ms. Wang) So the modified PH20 polypeptides, without optimized administration, would not be use useful as contraception?

MR. POWERS: Objection. Form.

THE DEPONENT: With -- without -- without mucosal -- without triggering a mucosal response, yes, that would be true. Wouldn't -- probably wouldn't be useful.

Q. (By Ms. Wang) Does your concept of optimized administration require adjuvants?

A. Yes, that's how we are defining it here

Petitioner Merck, Ex. 1129, p. 140
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

with -- adjuvants that have been used successfully in mucosal and eliciting mucosal responses.

Q. So optimized administration requirements intranasal?

A. That's what I'm referring to here, to stimulate a mucosal response.

Q. And it requires adjuvants for mucosal response?

MR. POWERS: Object to form.

THE DEPONENT: (Nods head.)

Q. (By Ms. Wang) Right?

A. Yes.

Q. And you also state that the POSA would use an agent that removes beta-defensin, DEFB126.

Is that part of your optimized administration?

A. And that -- and that is an optional step to remove beta-defensin 126, but it's not mandatory.

Q. But mandatory for optimized administration, in your mind, is intranasal plus adjuvant?

A. Yes, I think that's the step -- the main step.

Q. Is the optimized administration of

Petitioner Merck, Ex. 1129, p. 141
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

modified PH20 polypeptides the same for all mammals that are covered, in your opinion?

A. So again, "optimized" as defined, or what was referred to here, is dealing with intranasal administration. And yes, that -- that -- because that's known that that would stipulate a mucosal response in -- in most mammals that have been studied.

Q. So in your opinion for modified PH20 polypeptides to be useful as contraceptive vaccines, they would have to be delivered intranasally to female mammals?

MR. POWERS: Object to form.

THE DEPONENT: Sorry, one more time. I just want to make sure I heard the right word, please.

Q. (By Ms. Wang) For modified PH20 polypeptides to be useful as contraception vaccines, they would have to be delivered intranasally to female mammals?

MR. POWERS: Same objection.

THE DEPONENT: They would have to be administered such that an adequate immune response occurred. An intranasal would be the primary way. But as we talked about before, there could be a

Petitioner Merck, Ex. 1129, p. 142
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

vaginal delivery as well.

Q. (By Ms. Wang) But in your opinion for modified PH20 polypeptides to be useful as contraception, they would have to be delivered mucosally?

A. Yes.

Q. Is your optimized administration the same for all modified PH20 polypeptides?

A. Yes.

Q. And that would include modified PH20 polypeptides that are unfolded?

A. Yes.

Q. With regard to an adjuvant for intranasal administration, would any adjuvant work?

A. Well --

MR. POWERS: Objection. Form.

Go ahead.

THE DEPONENT: When you say "any adjuvant," you mean literally any -- anything or known intranasal -- or known adjuvants that have been used intranasally?

Q. (By Ms. Wang) I'm trying to understand your opinion that adjuvants -- that the POSA would know to include adjuvants.

THE DEPONENT: So typically cholera

Petitioner Merck, Ex. 1129, p. 143
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

toxin B the, nontoxic form -- portion of cholera toxin is commonly used intranasally, and it has been very successful.

Q. (By Ms. Wang) Is that the only one?

A. Well, there's -- there's others. There's -- from E. coli. There's flagellin/MAGELLAN, which is a toll receptor protein. So there's several others that have been used, but cholera toxin, at least for antiviral usage or stimulation for antiviral antigens, cholera toxin B has been very successful.

Q. Are you aware of any evidence of cholera toxin B as a successful adjuvant with the delivery of a -- of a self-antigen?

MR. POWERS: Object to form.

THE DEPONENT: I am not aware of -- you know, I haven't look into that, right.

Q. (By Ms. Wang) Are you aware of any intranasal contraceptive vaccines that existed before 2012?

A. Are you referring -- when you say "contraceptive vaccines," you're referring to eliciting an antibody response?

Q. Yes.

A. No, I am not.

Petitioner Merck, Ex. 1129, p. 144
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

Q. Are you aware of any intranasal immunocontraceptive vaccines today?
A. Today? I'm sorry, today? Or --
Q. Yeah.
A. You meant recently or --
Q. After 2012 --
A. Oh, okay.
Q. -- are you aware of any intranasal immunocontraceptive vaccines?
A. No, I am not.
Q. Are you aware of any mucosal immunocontraceptive vaccines before 2012?
MR. POWERS: Object to form.
THE DEPONENT: No, I am not.
Q. (By Ms. Wang) How about after 2012?
MR. POWERS: Same objection.
THE DEPONENT: I am not aware of one.
Q. (By Ms. Wang) Are you aware of any intranasal vaccines using an enzyme antigen before 2012?
A. I'm not.
Q. How about after 2012?
A. No, I am not aware of.
Q. Are you aware of any evidence published before 2012 of the successful mucosal delivery of

Petitioner Merck, Ex. 1129, p. 145
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

PH20 to humans?

MR. POWERS: Objection. Form.

THE DEPONENT: I don't believe so. I don't know of any.

Q. (By Ms. Wang) Any evidence of successful mucosal delivery of modified PH20 polypeptides to humans?

A. No, I am not.

Q. Are you aware of any evidence of mucosal delivery of modified PH20 peptides to nonhumans?

A. No, I am not.

Q. Are you aware of any evidence published before 2012 that PH20 is expressed in the female reproductive tract of any mammal?

A. The only -- the only one I know of is the BALB/c mice, genetically -- highly modified genetic strain of mice that was used in the Hardy study.

Q. So besides the mice in the Hardy study, you're not aware of any other evidence published before 2012 of PH20 expression in female reproductive tracts?

A. No, I'm not.

Q. You stated earlier that the POSA would have optionally delivered an anti beta-defensin, DFB126 agent, to the vaginal cavity of vaccinated

Petitioner Merck, Ex. 1129, p. 146
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

women just before intercourse to make modified PH20 polypeptides an effective contraceptive; is that correct?

MR. POWERS: Object to form.

THE DEPONENT: Yeah.

Q. (By Ms. Wang) You identified in your declaration, at paragraph 39, sialidase.

A. Yes, that's right.

Q. You didn't cite any study where sialidase was administered vaginally to female primates before 2012, did you?

A. That's correct. It has been found in the vagina in humans, but not administered.

Q. And so there's also no study administering sialidase to the human vagina before 2012?

A. Not that I'm wear of, no.

Q. And sialidase treatment of sperm prevents sperm from penetrating cervical mucosal because of removal of the negative charge on the sperm surface, right?

A. Yes, that's correct.

Q. The sialidase prevention of sperm from penetrating cervical mucus occurs whether or not PH20 is bound by antibodies, right?

Petitioner Merck, Ex. 1129, p. 147
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

MR. POWERS: Object to form.
THE DEPONENT: No. It's -- so it's a way of further enhancing any sort of antibody effect down in the lower tract. I have a sialidase there.
Q. (By Ms. Wang) But just to confirm, sialidase alone prevent sperm from penetrating cervical mucus?
A. That is correct.
Q. In your opinion, would the POSA only select sialidase to administered to humans?
MR. POWERS: Objection. Form.
THE DEPONENT: Probably not, because the sialidase -- sialidase treatment is an optional or enhancing approach. If there were sperm that got through to the upper tract, you would still ideally really want an antibody response in that upper tract. And then whatever sperm did get up in the upper tract, if they are lacking their sialic acid, would be highly susceptible to any sort of antibodies that would be present there. So I viewed this as both working together.
Q. (By Ms. Wang) So if a POSA wanted to use an anti-defensin agent, would they only select sialidase?
MR. POWERS: Objection. Form.

Petitioner Merck, Ex. 1129, p. 148
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

THE DEPONENT: If you could define "anti-defensin agent" or what you mean by that.

Q. (By Ms. Wang) Well, if a POSA wanted to deliver an anti-beta-defensin, DEFB126 agent, would they only select sialidase?

A. Sorry. I just push back a little bit on the term "anti-beta-defensin" because it makes it sound like you're talking about an antibody?

Q. No.

A. No?

Q. I'm talking about an agent that removes --

A. That removes or affects its function, yeah.

Q. Right.

So if a POSA wanted to use an agent that removes the anti-defensin -- sorry, the beta-defensin, would only select sialidase?

A. There's only approaches that could be taken in terms of, you know, bicarbonate levels and different incubation procedures that kind of mimic what normally occurs in the upper tract. But the sialidase is by far the more straightforward and easiest has a single enzyme treatment versus more complicated culture medium.

Petitioner Merck, Ex. 1129, p. 149
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

Q. You identified caffeine as an agent known to expose sperm surface protein?
A. Right. And that's not -- that's kind of an in vitro mimic of the physiology of what happens. It's not referring to drinking a lot of coffee. Sorry.
Q. The POSA would not be putting caffeine up the vagina?
A. Right.
Q. Okay. Same for Dibutyryl cAMP?
A. Cyclic. Yeah, same thing. So these are all kind of the normal metabolic physiological processes that are occurring up in the upper tract, and those are all in vitro chemicals that elicit a similar response.
Q. But the POSA would not be using them in vivo?
MR. POWERS: Object to form.
THE DEPONENT: I mean, it's a known possible treatment, but it would be very difficult. A sialidase would be much more straightforward.
Q. (By Ms. Wang) Do you think the delivery of an agent to remove the beta-defensin from sperm surface PH20 prior to intercourse would be practical in a wild animal population?

Petitioner Merck, Ex. 1129, p. 150
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

A. In -- in a what population?
Q. In a wild animal population.
A. Oh, wild.
Are you -- I guess, are you -- I'm trying to understand the context. Are you talking about wild animal, feral animal control?
Q. Well, your opinion is that the modified PH20 polypeptides would be useful as contraception in nonhuman mammals, right?
A. Right.
Q. And that would include primates?
A. Yes.
Q. Right?
A. Yes.
Q. And so do you think that delivery of an agent to remove beta-defensin would be practical to achieve contraception in wild primates?
MR. POWERS: Objection -- Objection. Form.
THE DEPONENT: Yeah, I think the operative term is "practical" and "wild." Because if you're talking about laboratory animals that are used for, you know, developing a certain drugs and procedures, then yes. But when we're talking about a disc or a ring, a vaginal ring, or even a gel,

Petitioner Merck, Ex. 1129, p. 151
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

you know, that probably wouldn't be practical in a wild population for, I think, hopefully obvious reasons, but...

Q. (By Ms. Wang) I'm trying to understand though, is -- so is your opinion that modified PH20 polypeptides would be a useful contraception in nonhuman mammals? Does that include wild mammals?

A. Well -- so, again, I think we are kind of -- I just want to make sure we are kind of on the same path here. You are talking about -- yes, and I mentioned this appropriate, if there's an appropriate mucosal response and it's administered in an appropriate way. So I guess the optional sialidase treatment certainly could be done in population -- laboratory population of wild animal -- or sorry, not wild animals -- laboratory populations of nonhuman animals. But -- and that would be irregardless of which polypeptides were used.

Q. But the optional sialidase treatment would not be used for wild mammals?

A. Well, I guess my opinion is theoretically it could be, but it's not very practical.

Q. So your opinion is that modified PH20 polypeptides, in order for them to be effective as

Petitioner Merck, Ex. 1129, p. 152
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

contraceptive vaccines, the POSA would expect to have to administer them mucosally with a potent mucosal adjuvant?

MR. POWERS: Objection. Form.

THE DEPONENT: Well, it's not administering them a mucosal -- administering them so that there was a sufficient mucosal response, yes.

Q. (By Ms. Wang) And that was not done in the guinea pig studies reported by Primakov (phonetic), correct?

MR. POWERS: Objection. Form.

THE DEPONENT: No that was not.

Q. (By Ms. Wang) The guinea pigs did not receive mucosally administered or intranasally administered PH20?

A. That's correct.

Q. Suppose the POSA wanted to use modified PH20 polypeptides to make a rat contraceptive vaccine.

Would they administer the PH20 polypeptide intranasally?

A. For controlling rats, you say, or for rendering rats infertile?

Q. For controlling rats.

Petitioner Merck, Ex. 1129, p. 153
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

A. So yes, in rats they would want a -- intranasal or mucosal response to optimize that.

Q. So the POSA would administer modified polypeptides intranasally to rats?

For a rat contraceptive vaccine, what mucosal adjuvant would the POSA include?

A. I think in literature, again, for other types of antigens, people have used the cholera toxin B quite successfully for antiviral antigens.

Q. And how often would they -- sorry, let me rephrase.

The POSA would also expect to need to boost the rat population with vaccine, right?

MR. POWERS: Object to form.

THE DEPONENT: Potentially. There are some studies that have found a single nasal administration triggers a very long-lasting antibody response. But certainly an option would be to boost.

Q. (By Ms. Wang) So boosting is not a part of your optimized administration?

A. No. I -- it would be part of it to -- to maintain -- again, there's -- there's levels of the immune response, and then there's time frame maintaining it, and boosting comes in potentially

Petitioner Merck, Ex. 1129, p. 154
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

to both of those.

Q. And how would a POSA developing a rat contraceptive vaccine boost the rat population with vaccine?

MR. POWERS: Objection. Form.

THE DEPONENT: It's -- it's hard for me to opine on that because I'm not familiar with how -- you know, using it as a feral population control, how these things would be done. So I can -- I don't want to speculate on exactly how that would be done.

Q. (By Ms. Wang) Earlier we talked about you have an opinion regarding monoclonal antibodies.

A. Uh-huh.

Q. And you state in your declaration -- let's go to paragraph 14 -- that you were asked to consider -- I will wait.

A. Yes.

Q. You were asked to consider whether a POSA would have expected anti-PH20 monoclonal antibodies against any of the modified PH20 polypeptides when administered into the vaginal cavity of human females to cause contraception.

Do you see that?

Petitioner Merck, Ex. 1129, p. 155
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

A. Yes.
Q. Where did this question come from?
A. Well, I was asked to comment on that from counsel.
Q. So counsel formulated the question for you?
A. Not in those exact words, but the -- conceptually.
Q. Were you asked to consider administration of monoclonal antibodies to any place other than the vaginal cavity of human females?
A. No.
Q. Your opinion on monoclonal antibodies we've -- let me start over.
As we talk about before, monoclonal antibodies only have one specificity, right?
A. Yes, correct.
Q. And so they would have to be made and screened in order to find the right antibody that would cause contraception?
MR. POWERS: Object to form.
THE DEPONENT: I believe where this is discussed further back -- this is just at the beginning. Where this is discussed further back, I think I talked about a mixture of different --

Petitioner Merck, Ex. 1129, p. 156
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

different monoclonal antibodies that would bind to different epitopes would be used in the vaginal cavity or delivered in the -- a gel or a vaginal ring or vaginal disc.

Q. (By Ms. Wang) Is it your opinion that you would need more than one monoclonal antibody with more than one specificity in order to have effective contraception?

A. I think would be advantageous to have a number of -- that bind to different epitopes.

Q. Can you have effective contraception with only one monoclonal antibody that only binds one epitope?

A. Potentially, yes.

Q. That one monoclonal antibody would have to be made and screened to determine if it could potentially work, right?

MR. POWERS: Object to form.

THE DEPONENT: Well, I think the monoclonal antibodies one would develop for this kind of purpose, the POSA would be screening numerous antibodies and then could decide how many they wanted to employ for this purpose.

Q. (By Ms. Wang) The POSA would be making numerous antibodies and screening them?

Petitioner Merck, Ex. 1129, p. 157
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

MR. POWERS: Same objection.
Q. (By Ms. Wang) Right?
A. Yes.
Q. These monoclonal antibodies are not being administered as immunocontraceptive vaccines, right?
A. Correct, they are being added to the vaginal cavity.
Q. And modified PH20 polypeptides are not monoclonal antibodies, right?
A. Yes, you're right on that.
Q. Did you, in forming your opinions, investigate any differences in the location of expression of PH20 on the sperm of different species?
MR. POWERS: Objection. Form.
THE DEPONENT: Sorry, could you ask that again.
Q. (By Ms. Wang) In forming your opinions, did you investigate any differences in the location of expression of PH20 on the sperm of different species?
MR. POWERS: Same objection.
THE DEPONENT: Yes.
I was aware of differences between

Petitioner Merck, Ex. 1129, p. 158
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

rodents and primates, in particular.

Q. (By Ms. Wang) Are you aware that the location of expression of PH20 on guinea pig sperm is different from the sperm of other mammals?

MR. POWERS: Objection. Form.

THE DEPONENT: Yes, I am aware.

Q. (By Ms. Wang) You did not investigate any differences in the immune system of guinea pigs versus other mammals, did you?

MR. POWERS: Objection. Form.

THE DEPONENT: I did not investigate it.

There's very little known, but like -- as I mentioned earlier, it is known that guinea pigs have leakage or breakthrough from the circulating plasma if there's antibodies circulating into the reproductive tract lumens of both males and females.

Q. (By Ms. Wang) Right, and I'm just asking about the immune system.

A. Yeah.

Q. You didn't investigate any differences in the immune system between --

A. No.

I don't know, and I don't think that's known.

Petitioner Merck, Ex. 1129, p. 159
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

Q. Okay.
MS. WANG: Okay to take a break?
MR. POWERS: Sure.
THE DEPONENT: Sure.
THE VIDEOGRAPHER: The time is 2:44 p.m. Pacific time. We are off the record.
(Recess taken.)
THE VIDEOGRAPHER: The time is 3:06 p.m. Pacific time. We are on the record.
Q. (By Ms. Wang) Dr. Cherr, did you speak with counsel during the last break?
A. I did not.
Q. The answers that you gave today, would any of them have been different for any of the four patents in the four proceedings?
A. For any of the -- yeah, I --
Q. Let me rephrase.
A. Yeah.
Q. The answers that you gave today would not have been different for any of the four patents in the four different proceedings, right?
A. Yes, that is correct.
Q. You provided your opinions from the perspective of a POSA in December 2012, right?
MR. POWERS: Object to form.

Petitioner Merck, Ex. 1129, p. 160
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

THE DEPONENT: Yes, that's true.
Q. (By Ms. Wang) Would your opinions have been different from the perspective of a POSA in December 2011?
MR. POWERS: Object to form.
THE DEPONENT: Probably need to think about that, but I -- my response would be, no, wouldn't be any different.
Q. (By Ms. Wang) Okay.
MS. WANG: All right. Thank you.
Those are all the questions I have for you today, Dr. Cherr.
Before we go off the record, I would like to ask for counsel for production of the near-final Moon declaration that Dr. Cherr testified he reviewed before signing his declaration.
MR. POWERS: We'll consider it, Counsel.
MS. WANG: Okay.
THE VIDEOGRAPHER: And before I read us off, I just need to grab --
MR. POWERS: We need time to consider whether or not there's going to be any redirect.
THE VIDEOGRAPHER: Okay.
MR. POWERS: So let's take a break.
MS. WANG: Okay.

Petitioner Merck, Ex. 1129, p. 161
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

THE VIDEOGRAPHER: Take a break?
Copy that.
The time is 3:08 p.m. Pacific time. We are off the record.
(Recess taken.)
THE VIDEOGRAPHER: The time is 3:13 p.m. Pacific time. We are on the record.
MR. POWERS: Thank you very for your time to, Dr. Cherr. We have no questions for you.
The witness will read and sign.
MS. WANG: Okay.
MR. POWERS: Thank you, Counsel.
MS. WANG: And, sorry, one quick thing before we go off the record.
Can we have Dr. Cherr's versions of his declaration be part of the record.
MR. POWERS: Sure.
They're unmarked versions of his declaration.
MS. WANG: That's fine, thank you.
THE VIDEOGRAPHER: Okay. If there is nothing else, I will just grab orders real quickly.
Ms. Wang, you get the video, standard. Did you need it synced to the transcript?
MS. WANG: Yes, I believe so.

Petitioner Merck, Ex. 1129, p. 162
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

THE VIDEOGRAPHER: All right. And then, Mr. Powers, did you need a copy of the video and/or transcript at this time?

MR. POWERS: Yes, we will.

THE VIDEOGRAPHER: Okay. Did you want them synced, as well?

MR. POWERS: Let me check about that.

THE VIDEOGRAPHER: Okay. I'll put you down for a follow-up.

And then will it just be the one order for both sides, or --

MR. POWERS: Yes.

THE VIDEOGRAPHER: Okay. Perfect.

In which case, this ends Volume 1 of the video deposition of Gary N. Cherr, Ph.D., in the matter of Merck Sharp & Dohme LLC v. Halozyme Incorporated.

The time is 3:14 p.m. Pacific time. We are off the record.

(TIME NOTED: 3:14 P.M.)

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Petitioner Merck, Ex. 1129, p. 163
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

I, GARY N. CHERR, Ph.D., do hereby declare under penalty of perjury that I have read the foregoing transcript; that I have made any corrections as appear notes; that my testimony as contained herein, as corrected, is true and correct.

Executed this _____ day of _____, 2025, at _____, _____.

_____
GARY N. CHERR, Ph.D.

Petitioner Merck, Ex. 1129, p. 164
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

I, Rebecca L. Romano, a Registered Professional Reporter, Certified Shorthand Reporter, Certified Court Reporter, do hereby certify:

That the foregoing proceedings were taken before me at the time and place herein set forth; that any deponents in the foregoing proceedings, prior to testifying, were administered an oath; that a record of the proceedings was made stenographically by me and which was thereafter transcribed under my direction; that the foregoing transcript is a true record of the testimony given.

Further, that if the foregoing pertains to the original transcript of a deposition in a Federal Case, before completion of the proceedings, review of the transcript [ ] was [ ] was not requested.

I further certify I am neither financially interested in the action nor a relative or employee of any attorney or any party to this action.

IN WITNESS WHEREOF, I have this date subscribed my name.

Dated: November 17, 2025

Rebecca L. Romano, RPR, CCR
CSR. No 12546

Petitioner Merck, Ex. 1129, p. 165
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

DEPOSITION ERRATA SHEET

Case Name: Merck Sharp & Dohme LLC vs. Halozyme Inc.
Name of Deponent: Gary N. Cherr, Ph.D.
Date of Deposition: November 12, 2025
Job No.: 7005263-001
Reason Codes: 1. To clarify the record.
2. To conform to the facts.
3. To correct transcript errors.

Page _____ Line _____ Reason _____

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Page _____ Line _____ Reason _____

From _____ to _____

Page _____ Line _____ Reason _____

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Page _____ Line _____ Reason _____

From _____ to _____

Petitioner Merck, Ex. 1129, p. 166
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

DEPOSITION ERRATA SHEET

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_____ Subject to the above changes, I certify that the transcript is true and correct

_____ No changes have been made. I certify that the transcript is true and correct.

_____

GARY N. CHERR, Ph.D.

Petitioner Merck, Ex. 1129, p. 167
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

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7:4 163:23
-00004
11:21
-00006
11:21
-00009
11:22
-003
15:8 19:24

1

1
163:14
100
57:23 58:1, 3,12 68:4, 10,12
1019
84:24 117:15
1020
80:10
1026
17:21 18:1, 4,19
1061
89:1
10:00
48:20
10:01
48:20
10:15
48:23
11,952,600
15:16
11:00
74:5
11:15
74:8
12
7:2 21:8 27:12 38:25
12546
9:5
126
141:18
12:13
108:18
12th
7:7
13/694731
18:1
14
155:17
16825
7:24
17
39:16 61:15 64:12
19
50:4
1:06
108:20
1:56
139:2

2

20
138:2
20-
80:12
200
68:4,10,12
2002
80:9,13 81:10 97:3
2004
84:23 85:1, 10,16 86:16, 23 97:3 117:4
2011
161:4
2012
18:2 27:10 43:19 44:4 63:5,8,13,21 64:2 70:14 71:8 74:19 79:9,16 92:14 96:11, 19 97:7,13 100:19 101:10,15, 19,23 103:21 104:10,16 107:14,17,22 108:4 109:14,20 111:4 112:11 113:1,6 114:11,15,20 115:25 144:20 145:6,12,15, 20,22,25 146:13,20 147:11,16 160:24
2015
88:23 89:3, 12 90:5,24 93:16
2023
14:11,12
2025
7:2,7
2072
12:8 15:10
2103
61:18
22nd
7:20
23
39:16
24
61:12
28th
18:2 27:10 74:19
2:11
139:5
2:44
160:5

3

3
15:11 39:5 41:19 42:9 61:17 62:8, 10 65:8,15
30
25:6,8 27:8 31:5,14,18 32:2,22 41:12 106:13 107:9
31
49:25
313
41:13
32
30:14 39:5 41:19 42:10 120:10
320
39:7 41:20 42:11
328
117:14
33
120:4,7,9 123:7 132:7
34
133:18
35
74:18 79:13
36
14:24
39
147:7
3:06
160:8
3:08
162:3
3:13
162:6
3:14
163:18,20

Petitioner Merck, Ex. 1129, p. 168
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

4

40
14:24
43
139:18
45
89:9
49
80:7

5

50
7:20 84:21, 23 104:5 105:18 106:6,14 107:5,7,10

6

60
75:11 104:23 105:20,22 106:2
600
15:18,20,23 16:7 19:8, 14,25 20:22
60s
132:14
66
39:6 41:19 42:10

7

70
39:16
70s
132:14
77060
7:25

9

900
7:24
90s
97:4
94111
7:21
95
39:4 41:18 42:9 48:8,10
9:03
7:3,7

A

a.m.
7:3,7 48:20, 23 74:5,8
ability
72:7
able
43:18,23 44:2 61:8 65:5 67:9 110:18 125:16 126:10 131:25
above
105:19,22 106:2,14 107:5,10
absolutely
26:16 112:17
access
65:24
accessible
64:24
accurate
30:12
achieve
73:14 87:4, 21 99:20 119:6 151:17
achieved
57:4 58:8
acid
20:17 39:3, 4,12,17 40:20 42:21 47:2 50:14 134:23 135:2 136:15 148:18
acid-active
72:12,19
acids
40:16,25 41:6
acknowledge
82:18
acrosome
60:13 63:15 65:17 66:4, 5,7 72:12 120:23 122:13 123:13 124:3,22
acrosome-react
125:19
acrosome-reacted
50:18
Across
95:20
action
8:1 126:7
active
134:7,8,10, 11
activity
50:15 72:21, 22 93:12 134:17 137:17
acts
50:17
actual
117:10 126:7 137:12
add
63:6
added
28:13,14 158:7
additional
32:23
addresses
82:8
adequate
69:5 94:21, 22 96:24 97:19 99:11, 14,18 100:14 142:23
adjacent
134:7
adjuvant
81:2 85:22 89:17 98:9 141:22 143:13,14,19 144:13 153:3 154:6
adjuvants
98:5,18,21 99:1 140:24 141:1,7 143:20,23,24
administer
153:2,21 154:3
administered
10:2 34:13, 19 46:25 76:20 103:18 126:20 127:18 128:18 142:23 147:10,13 148:10 152:12 153:15,16 155:23 158:5
administering

Petitioner Merck, Ex. 1129, p. 169
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

147:15 153:6
administration
34:24 80:1,2 86:14 95:5, 21 96:1 98:2 99:1 111:5 117:9,20,23 118:4 127:25 128:3,15 129:9,15,20, 25 130:4,17 131:4,8 139:20,25 140:8,16,24 141:3,16,21, 25 142:5 143:7,14 154:17,21 156:9
admissible
9:7
advantageous
157:9
affect
55:3 71:4 94:4 124:24 134:10
affects
149:13
Affinity
138:12
agent
141:14 146:25 148:23 149:2,4,11, 16 150:1,23 151:16
agglutinate
132:22
agglutinated
132:15
agglutination
123:11,25 124:17 132:7,11,23 133:2,17
aggregate
46:5,18 49:9
aggregated
45:22 46:7, 11,19
aggregates
46:16
aggregation
46:2
agree
7:9 27:8 39:11,15 42:20 46:4 76:7,23 80:12,20 81:1,4,20 83:19 85:1, 16,22,24 86:2 103:21 105:4 110:1, 19 139:16
agreed
49:5
ahead
36:12 62:14 64:1 67:22 143:17
allosteric
133:20,24 134:13,16 135:5,8,17 136:9 137:4, 19 138:1
allows
10:23
alter
60:15
altered
48:10
Altogether
14:15
amino
39:3,4,12,17 40:16,20,24 41:5 42:21 47:1
amount
33:16 68:25 73:8 94:17 99:22 131:18 132:23
amounts
95:16,18 99:11 132:2
amplitude
72:24
analysis
49:23 117:2 122:5
anchor
121:20
anchors
121:20
and/or
163:2
animal
31:23 77:4,9 79:19,22 80:4 104:24, 25 105:21 111:20 150:25 151:2,6 152:16
animal's
104:7 105:15
animals
57:20 78:23 96:16 99:2 103:20 104:3 105:19 106:2,3,4,6, 8,12 111:10 113:3 118:1, 19 151:22 152:16,17
answer
11:2,12,13 20:1,5 21:23 30:12 53:19 54:2,13,20, 23 59:14 84:5 88:10 117:18
answered
48:8 55:18 123:4
answering
54:17,21,22
answers
54:22 74:13 160:13,19
anti
132:16 146:24
anti-beta-defensin
149:4,7
anti-defensin
148:23 149:2,17
anti-ph20
29:2 67:8 90:1 120:20 155:21
antibodies
29:3,9,13, 16,17,25 30:17,20 33:4,10,16 44:10,25 45:11,17,19 47:11 51:21, 23 52:11,14 53:23,24 54:25 55:13 60:19,23 61:2,7 65:5, 23 66:12,15, 16,19,24 67:17,24 69:6 71:7, 18,24 72:2 73:3,6 75:22,24,25 76:2,5 78:2 80:15 81:11, 16,21 82:1, 6,19 83:12, 15 84:8,12, 16 85:6 88:17,19

Petitioner Merck, Ex. 1129, p. 170
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

89:25 90:6, 12,17,24 91:9,18,20 92:4,20 93:1,9,11 94:7 100:10, 20 101:11 102:11,24 103:13,14 104:6 105:8, 11,14 114:12 116:10 117:24 118:4,10,15, 18 120:12, 14,20,21 121:22 122:16,22 123:9 125:5, 15,22 128:16 129:2,6 132:13,16,21 133:14,19,21 134:25 135:4,12 136:2 138:1, 2,7,12,18 147:25 148:20 155:14,21 156:10,13,16 157:1,20,22, 25 158:4,10 159:15

antibody 33:22 38:12 47:3,17 48:4 51:3 53:7 67:4,8 68:5, 13 69:1,4,5, 6,8,11 70:8, 14,20,24 71:3,9 72:6 73:13 76:21 83:4 84:1 88:13 89:3, 12,18,23 91:3,8 92:5, 21 93:22 94:10,17,25 95:6,9,11 105:13 115:19 117:25 118:20 121:16 122:14 126:18,24 127:7,15 128:4 129:10,23,24 130:8,18 131:4 132:2, 8,19 134:6, 18 135:7,15, 16 136:4,8, 12,17 137:3 144:23 148:3,16 149:8 154:18 156:19 157:6,12,15

antibody's 134:1

antigen 77:9 115:4 116:2,14,23 127:25 128:3 145:19

antigens 95:7 130:12 140:4 144:10 154:8,9

antisperm 132:13,16

antiviral 144:9,10 154:9

anybody 69:16

anyone 12:20

apologize 50:2

Appeal 7:17

appearances 8:5

application 18:1 19:14

applications 18:23 19:3, 7,14,18

applied 102:13

apply 31:2

appreciate 52:2 92:18

approach 88:3,6 118:10,14 126:11 148:14

approaches 110:8 149:19

appropriate 34:19,24 57:14 102:24,25 103:18 110:20 113:5 127:19 152:11,12,13

appropriately 126:19

approximately 13:4 14:13 23:7,9 106:15

areas 27:7

around 22:25 67:22 72:18,22

art 21:12

asked 21:11,23 25:9,19 27:9 49:3 52:4 53:16 55:17 87:9 123:3 155:17,20 156:3,9

asking 37:7,8 47:13 55:12 56:20 57:5 91:25 92:2 109:2 112:12 122:21,24 159:18

asks 114:4

assess 112:21

assessing 112:16

associated 59:10 66:17

assorted 27:24

assume 11:2 20:4 135:3

assuming 44:13 121:17,18 122:14

assumption 69:7 135:11

asthmatically 60:11

attendance 8:14

Attending 8:24

attention 25:6 30:13 38:25 61:11 84:20 117:14 120:4

attorneys 12:16,21 13:5

Aubrey 9:2

Audio 7:8

Petitioner Merck, Ex. 1129, p. 171
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

Austin
8:11
authored
93:16
authors
86:7 87:3
88:12 90:6
93:8 117:8,
19
auto
132:15
automatically
9:6
available
32:10 69:12
71:16 121:16
122:19
avidity
138:16,17,
20,21
aware
28:3 39:14
40:15 46:6
93:15 97:5
100:18,25
101:9,13,14,
17,18,21,22
102:9 104:9,
14,15,21
105:2
107:13,16,
20,21 108:3,
10 109:7,13,
18,19,25
113:8,14,18,
22 122:4
134:15
144:12,16,18
145:1,8,11,
17,18,23,24
146:9,12,19
158:25
159:2,6

B

back
64:11 108:22
110:17 115:8
116:9 119:18
132:14 149:6
156:23,24
BALB/C
146:16
Barbara
23:21
barely
94:6
barrier
78:22 79:5
based
16:4,13
96:22 97:18
103:10 107:4
111:4 115:22
basic
125:20
beat
72:23
beating
72:15
beginning
156:24
begins
25:8
behalf
7:23 8:4,19
belief
106:1,12,16
107:4,8
127:24
128:2,14
believe
8:13 14:11
28:19 32:2
57:12 58:21
71:5,14 78:1
79:3 91:1,22
93:14 96:3,9
114:24
115:2,12,17
117:12
118:8,19
119:2 124:8
125:5 127:3
146:3 156:22
162:25
besides
12:20 13:11
146:18
beta-defensin
141:14,18
146:24
149:18
150:23
151:16
better
13:24 24:19
26:13 134:4
bicarbonate
149:20
bind
29:10,25
30:20 33:16,
22 44:25
45:11 47:4,
18 48:5
52:11,12
53:24 61:8
65:6 66:12,
16,19 71:20,
24 72:3
73:13 90:17,
18 91:20
92:6,22 93:2
94:22
100:11,20
101:11
103:14 104:7
105:8,14
120:14,21
122:16
125:15,19
134:6,7
136:18
138:2,10
157:1,10
binder
11:25
binding
30:17 33:4,
10 38:12
44:10 50:14
51:3 56:6,10
62:16 68:7
91:14,17
92:2,16
120:11
121:17
124:22 125:5
132:8 133:19
134:1,11
135:12
137:3,9,17,
20 138:4,6
binds
72:6 134:18
135:16 136:8
157:12
biology
57:22
bit
16:20 63:14
83:10 94:24
149:6
blanket
110:9
Board
7:17
body
94:11 97:22
bond
122:4
boost
154:13,19
155:3
booster
81:5 85:24
boosting
154:20,25
bound
45:18 51:21,
23 53:7
54:25 55:6
67:17,24
68:13 69:1
72:4 73:3,6
81:11,16
90:7,9,12,25

Petitioner Merck, Ex. 1129, p. 172
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

91:3,8,9
92:4,20 93:9
125:23
132:19
133:9,11,12,
21 134:25
135:4 147:25
break
11:5,6,9
47:24 48:16
49:1 74:2,10
108:14,23
109:1 138:24
139:8 160:2,
11 161:24
162:1
breakthrough
78:4 159:14
Brian
8:15
broad
30:4 83:8,22

C

caffeine
150:1,7
calculate
39:22
California
7:1,20,21
California-licensed
9:4
call
15:18
called
78:3
camp
150:10
capable
63:15
capacitation
123:13 124:3
125:15
careful
117:2
case
85:5 114:8
134:2 163:14
caused
104:24
107:23 108:7
115:20
124:17
causing
100:19
101:11
118:25
133:20
caveat
115:8
cavity
73:8,13,15,
25 146:25
155:23
156:11 157:3
158:8
cells
38:12 133:10
centers
131:12
certain
57:3 103:23
130:12
151:23
certainly
35:19 70:10,
11 123:19
125:17 133:5
136:14
152:14
154:18
cervical
62:6,7
123:12 124:1
147:19,24
148:7
cervix
129:4 131:23
cetera
14:20 46:3
change
41:11 42:12
65:21 113:6
134:9
changes
58:16,25
59:6 122:12
charge
147:20
Chase
7:24
check
163:7
Chelsea
8:11
chemicals
150:14
Cherr
7:14 10:1,9,
10 20:9
28:24 48:25
52:17 53:25
54:10 55:8
74:10 106:25
108:22 139:7
160:10
161:12,15
162:9 163:15
Cherr's
162:15
chimpanzee
27:14
cholera
143:25
144:1,9,11,
12 154:8
choosing
124:20
circulating
75:25 78:2,
22 81:13
98:13 99:21
159:14,15
citation
13:17
cite
74:24 79:15,
21 140:11
147:9
cited
13:12,20
14:1,4,5,6
16:16,22
17:7,18 35:7
79:6 115:12
116:21
claim
87:3
clarification
47:8 114:4
clarify
11:1
class
31:8
clear
10:24 16:20
57:7 113:2
116:7 128:6
137:23
clearing
72:17
clearly
85:6
clears
72:22
cleaved
58:19 60:12,
25 61:1
65:14,16
122:3
close
57:23 58:3,
13 133:10,13
coaching
36:17
coat
121:12
coated
69:8 121:11
coffee
150:6
coli
144:6
collaborative
15:2 28:12

Petitioner Merck, Ex. 1129, p. 173
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

combination
124:10
130:23
combined
57:15
come
21:18,23
28:7 66:4
106:1 110:17
136:22 156:2
comes
57:22 116:9
133:15
154:25
comment
156:3
common
79:5 129:18
commonly
144:2
compared
78:18,25
complement
123:14
complete
18:12 51:25
122:5
completely
26:17 95:10
complex
68:23
complicated
110:22
149:25
Complies
9:10
comprising
39:3
concept
140:23
conception
43:25
conceptually
33:19 156:8
conclude
116:1,13,22
conditions
72:20
confirm
15:19 74:13
114:6 126:13
131:14 148:5
confirmational
134:9
confirmed
117:7
connected
122:3
connection
10:14,18
18:6,11 19:3
20:21 114:7,
10
consider
21:11
155:18,20
156:9
161:17,21
considered
115:4,14
consistent
48:11,12
context
25:15,22
151:5
continue
7:8 54:6,23
continues
22:5
contraception
26:4 29:19
30:1,19
31:20 32:3,
15,25 33:6,
12,23 34:5,
10,25 35:4,
8,13,22 36:5
37:2 43:16
44:3 45:16,
23 46:13
52:1 53:4,9,
18 55:16,20
56:19,22,24
57:2,21
60:20 70:11,
21 71:12
73:14 74:21,
24 82:3,5
83:6,17
84:2,9,18
87:22 88:5
94:12,19
95:1,13,22
96:2,13,21
97:1,9,15,24
98:2,16
99:2,8
100:13
101:15,19
102:7,13,21
103:23 107:3
110:4 111:7
114:14
115:20
118:25 119:6
120:13,21
124:5,11
127:1,6,14
132:9 140:17
142:18 143:4
151:8,17
152:6 155:24
156:20
157:8,11
contraceptive
21:14 27:13
37:16 38:11,
19 43:12
46:21 56:15
57:11,25
58:6 79:9,
17,23 80:5
82:12 83:1
85:11 96:6
98:6 110:14
111:22 112:7
116:9
126:12,22
139:11,21
140:6 142:10
144:19,22
147:2 153:1,
19 154:5
155:3
contraceptives
58:14
contribute
124:4,11
control
151:6 155:9
controlling
153:23,25
conversations
7:12
copy
17:23 162:2
163:2
Cor-
109:18
correct
12:7,9,19
15:21 16:11,
15 18:21
19:16 26:19
33:14 35:1,
5,6,9,10
37:9 38:23
41:21 42:6,
7,14,19
46:10 50:7,
8,13,22
51:7,15 52:9
53:6,10
56:7,9
58:17,21
59:1,8,24
60:14 61:18,
19,22 62:21
64:23 65:7
66:3,11,23
70:21 71:22
72:8 73:10
75:1,4,5,8,
22 77:14,17
79:9,25
80:6,19
81:9,12,17
82:23 84:19

Petitioner Merck, Ex. 1129, p. 174
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

85:13,21
86:21 88:18
89:5,14,19
90:25 91:6
92:6 93:20,
24 98:17
100:15 101:7
102:14
114:23
115:20,22
117:1,21
120:22 121:1
123:15
128:24
139:14
147:3,12,22
148:8
153:11,17
156:17 158:7
160:22
correctly
26:8 126:2
corresponding
47:5
counsel
7:14 8:5
11:12 15:3
17:24 22:1,
7,10,12
28:12,15,18
35:24 36:1,
8,10 41:3
47:22 49:1
54:7 74:11
108:24 139:8
156:4,5
160:11
161:14,17
162:12
couple
106:22
108:12
course
18:8 72:19
124:2,18
court
8:3,6 9:3,5,
7,11 10:24
114:4
covered
142:2
cow
27:15
create
10:24 35:16
37:21
critical
112:17
115:10
cross-link
132:21
cross-linking
133:16
culture
149:25
cumulus
68:22 72:13,
21 125:18
Cyclic
150:11
cynomolgus
27:14 103:8

D

daily
14:16,17
data
69:16 116:1
136:24,25
date
130:16
days
13:8,9
dealing
70:1 142:4
decades
63:19
December
18:2 27:10
74:19 114:11
160:24 161:4
Dechert
8:15
decide
157:22
declaration
12:13,15
13:11,12,17,
18,20 14:2,
4,6,7,25
15:8,11,15,
25 16:17,23
17:4,7,19
18:7,11,20
19:4,24 20:4
21:9 22:6,
13,16,19,23
23:3,4,9,10,
13,16,19,22,
24 24:2,5,8,
14,17 25:6,
9,14,21 26:2
27:3,9 30:14
31:6,15,19
38:25 40:13
42:3,11,16
49:25 50:3
53:23 61:12,
15 62:25
64:12 74:19
79:7 80:7
84:21 88:22
106:9,13,19
114:22,25
115:13
116:7,22
120:7 129:17
132:6 133:19
139:18 147:7
155:16
161:15,16
162:16,19
declarations
11:17 12:2,5
14:14 19:19
24:11
declines
72:22
deemed
38:10
DEFB126
133:15
141:14 149:4
define
32:20 49:16
57:17,18
82:14 87:7
112:1 128:7
129:12 149:1
defined
27:12 83:9
142:3
defining
131:15
140:25
definitely
11:6 124:24
definition
128:7
degree
129:4 133:16
degrees
57:6 62:18
deliver
82:11 149:4
delivered
85:19 96:7
110:25
117:8,19
119:22
142:11,19
143:4 146:24
157:3
delivery
118:24
119:11,21
143:1 144:13
145:25
146:6,10
150:22
151:15
demonstrating
35:7 79:16
denaturation
46:16
denatured
45:6,9,15

Petitioner Merck, Ex. 1129, p. 175
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

77:8,11
dense
132:20
density
68:8 69:7
133:6
depend
19:13 26:14
42:16 98:9
110:15
depending
58:16,25
59:7,15,22
60:1,8 62:2,
18 69:19
77:3,6
depends
46:2 96:6
98:10 137:7
DEPONENT
9:10,16 13:3
16:19,25
17:10,14
19:1,10,16
20:24 21:25
23:7 26:10,
22 27:5
28:11,23
29:21 30:3
31:22 32:5,
17,19 33:2,
8,19,25
34:8,12,18
36:2 37:5,19
38:1,6,16,23
39:19 40:15
41:2,23
42:14,19
43:21 44:7,
16 45:13
46:1,9,15,24
47:7,20 48:7
49:16,21
51:9,20
52:10,24
53:6,14,22
54:5,24
55:19 56:2,
9,18 58:3,10
59:3,10
60:23 62:15
63:12 64:5,
10,16 65:2
66:15 67:20
68:2,17
69:19,24
70:7,16
71:14 73:17
75:24 76:10
77:2 78:1,20
79:3,25
81:19,25
82:14 83:8,
19,21 84:4,
11 85:4
86:11,21
87:6,24 88:8
89:21 90:3,
9,21 91:12
92:8,24
93:5,14
94:1,21
95:15 96:9,
15 97:11,17
99:5 100:5,
22 101:7
102:1,9
103:17
104:2,14,20
105:2,10
108:1,10,15
109:11,25
110:6 111:3,
13,25
112:15,25
113:13
114:5,18
115:7,22
116:5,17
117:1 118:7
119:2,15,25
121:3,10
122:2,10
123:5 124:8
125:11 126:9
127:3,17
129:1
130:10,21
131:1 134:21
135:10
136:21
137:6,15
138:15,23
139:1,16
140:10,19
141:10
142:14,22
143:18,25
144:16
145:14,17
146:3 147:5
148:2,12
149:1 150:19
151:20
153:5,13
154:15 155:6
156:22
157:19
158:17,24
159:6,11
160:4 161:1,
6
deposed
10:10,17
deposited
62:4,5
deposition
9:13 10:21
11:11,17
12:12 13:25
163:15
derived
125:13
describing
109:20
details
84:5 110:7,
21,22
detectable
94:6
determination
75:19 111:21
determine
17:15 32:14,
23 112:22
157:16
determined
17:18
determining
110:3 112:6
develop
157:20
developed
105:23
developing
20:10 43:1
126:11
151:23 155:2
DFB126
146:25
Dibutyryl
150:10
differ
69:17,21
differed
74:15
differences
19:7,13
40:10,24
41:5 158:13,
20,25 159:8,
21
different
20:2 29:3
30:5 39:23
40:2,5,17,
19,20 43:22
47:16 48:4
52:14 58:22
59:15,21
60:1,8 61:23
62:3,11
63:14,19,22
64:3,6,8
74:15 78:25
79:4 119:17
121:14 122:7
128:9,20,23
129:10,21
131:5,19
137:8 149:21
156:25

Petitioner Merck, Ex. 1129, p. 176
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

157:1,2,10
158:14,21
159:4
160:14,20,21
161:3,8
difficult
150:20
digest
72:13
direct
25:5 30:13
38:24 61:11
84:20 86:3,8
117:14 120:3
directly
52:15 136:24
disagree
36:1,10,21
83:21 88:12
disc
151:25 157:4
disclosed
16:13
disclosure
16:5
disconnect
135:23
discuss
88:22
discussed
74:23 77:20
97:2 100:8
156:23,24
discussion
25:3 87:1,13
116:6,8
discussions
97:3,18
display
29:1
distance
56:25
disulfide
122:4
Doctor
68:25 108:14
documented
130:16
Dohme
7:15 8:12
163:16
domain
55:2 56:6,7,
10,12
dosage
99:8
doses
85:25
drinking
150:5
Drive
7:24
drugs
151:23
due
78:13 88:5

E

e.g.
123:10
earlier
22:22 49:3
71:18 73:5
74:14,23
77:20 94:13
100:9 117:3
133:6 146:23
155:12
159:13
easiest
149:24
effect
38:11 43:12
51:24 52:16,
25 70:11
104:11,17
107:14
109:3,8,14,
22 110:3,12,
24 111:17,19
112:4 113:10
123:24
124:1,18
125:24
133:24
134:13,17
135:5,8,17
136:10,14,19
137:4,9,10,
13 138:1
148:3
effective
34:5 35:12
57:21 60:19
79:16 82:11
87:21 94:12,
18 95:1,13
96:1 98:5,15
99:8 102:22
120:1,2
126:25
127:6,9,14
131:2 140:3
147:2 152:25
157:8,11
effects
116:9 133:20
134:1 137:19
efficiency
55:21,23
56:3 98:7
103:23
129:23
effort
15:2 28:12
efforts
114:20
egg
72:8
egg's
50:18
either
60:4 86:18
113:7 119:4
124:2,15
Eldora
8:25
elicit
88:1 97:19
103:18 104:5
111:5,15
118:20
119:16
126:18,20
127:19
128:18
129:19,21
130:5,7,18,
23 131:4,25
140:12
150:14
elicited
34:13 118:17
eliciting
95:4,5 113:4
141:2 144:23
elicits
131:8
Ellison
8:25
Emanuel
7:19 8:22
employ
157:23
employee
24:13,16,21
employees
93:16
endoproteolitically
65:14,16
endoproteolysis
60:15 65:20
endoproteolytically
60:12,25
122:3
ends
163:14
engage
66:25 69:12
engaged
60:19
enhancing
148:3,14

Petitioner Merck, Ex. 1129, p. 177
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

enter
8:7 125:18
entire
52:15
enzymatic
137:10
enzyme
93:11 134:2, 4,17 145:19 149:24
epididymi-
78:6
epididymitis
38:8,14 77:19 78:6
epithelium
62:17
epitope
47:2,4,5,14, 15,16,17 48:3,4 157:13
epitopes
29:1,3 43:11,14,19, 24 44:3,9 47:11,12 48:9 105:7 121:15,25 122:7 123:2 138:9 157:2, 10
equally
66:16
essentially
25:20 44:8 99:5 132:21
estimate
14:21
et
14:20 46:3
evaluate
42:25
evidence
79:7 100:18 101:10,14,22 102:5 104:10,16 107:13,17,21 108:4 109:2, 7,14,19 110:2,11,24 111:9,19 112:4,13,20 113:9,15 114:24 115:12 144:12 145:24 146:5,9,12, 19
exact
121:25 156:7
exactly
47:21 57:7 155:10
EXAMINATION
10:4
examined
10:2
exceedingly
79:20
excuse
17:10 76:10 96:16 105:10
exhibit
12:8 15:10 17:21 18:1, 4,10,19 61:18 80:10 84:24 89:1 117:15
exhibits
14:1,5 15:20
existed
144:19
expect
65:5 71:23 93:6 97:7,14 126:2 133:2 153:1 154:12
expectation
64:7 103:22 111:15 132:5
expected
21:13 27:11 37:13,15 70:12,24 114:11 122:15 125:24 139:19 140:5 155:21
experimental
57:19 110:2, 23 111:9,19 112:3,13,20 113:3
experimentall y
110:12
experimentati on
110:23
experiments
113:2 114:1
expert
113:24
expertise
25:16,23
experts
110:16
explain
53:15
expose
150:2
exposed
65:2,5,12 72:20 73:21, 23 121:1,7 125:14
exposure
117:11 119:8,17,19
express
76:14
expressed
77:24 119:4 146:13
expressing
78:14
expression
28:2 32:8 146:20 158:14,21 159:3
extended
14:18
extensively
82:9
extracellular
72:13,18
extremely
91:23 99:12

F

fact
64:6
factors
96:4
failure
111:6
fair
11:3 16:8 41:4 48:2 63:8 70:3 84:7 102:5 106:11
fairly
20:16 70:10 133:7,8
fallopian
131:17,19 132:3
familiar
18:16 155:7
far
149:23
fashion
72:16
female
21:15 27:13, 24 29:12 30:18 31:2, 14,17 33:5, 11 34:6,10 35:4,9,19

Petitioner Merck, Ex. 1129, p. 178
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

45:23 46:13 48:13 59:7, 16,20,22 61:21 63:18 74:21 75:21 76:4 81:7 84:12,13,17 85:17 86:19 88:2 100:13 114:12 115:9 120:12 139:12,21 140:7 142:12,20 146:13,20 147:10
females 46:22 155:24 156:11 159:17
feral 151:6 155:8
fertility 53:1,9 58:8 86:18 104:11,18 107:15,19 109:3,9,15 110:3,12,24 111:20 113:11,15
fertilization 50:22,24 51:2,6,11, 12,14,18,22, 25 52:7,16, 20 55:4,21, 23 56:4,25 59:1 65:24 66:13,22 67:1,6,9,18, 25 68:14 69:2 71:4 73:4 123:18 124:4,14,24 125:3
fertilize 72:7 125:21
fertilizing 123:9
figure 61:13,17 62:8,10,17 64:11 65:8, 15 133:9
figures 61:20
filed 7:16 18:2
financially 8:1
find 156:19
fine 107:1 162:20
finish 54:2,13
finished 54:4
firm 8:12,15,16
first 10:22
flagellin/ magellan 144:7
Floor 7:20
fluids 68:6 70:9
focused 13:15
folded 44:14
follow-up 163:9
follows 10:3
foreign 77:9
form 16:18,24 17:13 18:25 19:9,15 20:23 21:20 23:6 26:9 27:4,22 28:10,22 29:18 30:2 32:16 33:1, 7,18,24 34:7,11,17 35:23 36:7 37:4,18 38:5,15,22 39:18 40:3, 14 41:1,15, 22 42:13,18 43:20 44:6, 15 45:12,24 46:8,14,23, 25 47:6,19 48:6 49:14, 20 51:8,19 52:8,23 53:5,13,21 55:17 56:1, 8,17 58:2,9 59:2,9 60:18,21 62:13 63:11, 25 64:4,9,15 65:1 66:14 67:19 68:16 69:18,23 70:6 71:13 72:12,19 73:7,16 75:23 76:9 77:1,25 78:19 79:2, 24 81:18,24 82:13 83:7, 20 84:3,10 85:3 86:4, 10,20 87:5, 23 88:7 89:20 90:2, 8,20 91:11 92:7,23 93:4,13,25 94:20 95:14 96:8,14 97:10,16 99:4 100:4, 21 101:6,25 102:8 103:16 104:1,13 105:9 106:16 107:25 109:10,16,24 110:5 111:2, 12,24 112:14,24 113:12 114:3,17 115:6,21 118:6 119:1, 14,24 121:2, 9 122:1,9, 16,17 124:7 125:10 126:8 127:2,16 128:25 129:8,12,25 130:9,20 134:20 135:9 136:20 137:5,14 138:14 139:15 140:9,18 141:9 142:13 143:16 144:1,15 145:13 146:2 147:4 148:1, 11,25 150:18 151:19 153:4,12 154:14 155:5 156:21 157:18 158:16 159:5,10 160:25 161:5
format 11:11
forming 114:15 158:12,19

Petitioner Merck, Ex. 1129, p. 179
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

forms
60:24 61:8
formulate
22:2
formulated
156:5
formulation
86:2,7,13,17
forward
72:25 125:17
126:11
found
90:6,12,25
91:8 93:9,10
118:8 147:12
154:16
Foundation
44:5 45:25
49:15 60:22
138:14
four
11:18,20
12:2,5,6
20:5 40:11,
19,23 74:15
160:14,15,
20,21
fox
8:19 27:16
28:20
frame
154:24
Francisco
7:1,21
frequency
72:15
front
11:25 12:1
full
10:7 28:6
136:12
function
50:10,12,15
55:2 71:4
138:10
149:13
functional
50:7
functionally
138:9
functions
50:21,25
51:7,10,14,
17 52:6,14,
19,25 53:3,
17 55:12,14
136:15 137:8
Fuson
7:22

G

Gary
7:14 10:1,9
163:15
gave
26:3 27:21,
23 74:14
160:13,19
gel
151:25 157:3
general
96:17 110:18
generally
44:8 112:12
generate
28:6 76:19
103:12
128:16 135:7
139:12
generated
28:4 29:9
75:21,24
76:2,4 77:16
81:11,16,21
84:12,16
85:6 88:13
97:23 100:10
102:11
112:20
114:12
generates
117:24 118:4
generating
84:7 101:2
genetic
146:16
genetically
70:1 146:16
getting
57:8 96:1
102:24
123:20,22
gibbon
27:15
give
9:13 30:11
32:6 41:16
99:10
given
22:11,13
glycocalyx
62:21 63:1,
6,10 64:13,
22,25 65:6,8
121:12,17,18
glycosylation
58:23
goes
132:13
going
19:24 20:4,5
48:11 54:12,
14 55:3
70:10 125:16
138:4,8
161:22
Goldberg
8:15
Goldstein
8:19
good
8:9,17 10:6
106:20
grab
161:20
162:22
graphic
61:23
Gregory
23:15
ground
10:20
group
30:7
groups
31:23
guess
14:10 128:9
131:14 151:4
152:13,22
guinea
27:16 35:8,9
38:7 63:2,3,
5,9,13,18,21
64:2 74:21,
25 75:2,3,7,
9,13,20
76:1,4,14,17
77:15,23
78:9,10,13,
14,17,24
79:6,18
97:12 99:3
115:19
153:10,14
159:3,8,13

H

HA
50:14 56:6,
10 137:9
Haddach
9:2
Halozyme
7:16 8:20,
21,23,24 9:2
24:13,16,20,
25 93:17,19
113:18 114:7
163:16
Halozyme's
24:24
hand
9:8

Petitioner Merck, Ex. 1129, p. 180
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

handed
18:14
handful
68:17
handing
17:21
happen
133:5
135:21,25
hard
135:18 155:6
Hardy
84:23 85:1,
5,9,16 86:7,
16,23 87:1,
2,10,12,16,
25 88:4,12
99:6 117:4,
7,11,19
146:17,18
hav-
55:4
head
141:10
heading
85:4
heard
142:15
held
7:18
help
72:24
helps
72:24
herpes
95:8,10
high
41:8 42:23
72:15,23
80:15 95:6
104:4 127:22
129:23
138:16
higher
73:9 104:5
105:5,19
106:6
highly
146:16
148:19
Himes
8:11
HIV
95:8,10
homology
104:3
hormone
58:14
host
29:1
hour
11:6 47:23
hours
13:6 14:22,
24
Houston
7:25
human
27:14 35:20,
22 36:6
37:2,17,20,
23 38:3,21
43:4,11
57:22 75:10
89:4,13,15,
16 91:18
92:5,6,20,22
93:9 96:16
100:20
101:5,12
102:16,20
103:11
104:3,11,17
106:14
107:8,14,23
108:7 109:3,
8,15,21
110:2
113:10,20
147:15
155:23
156:11
humans
34:10 38:1,
14,19 57:25
92:16 96:20
97:9,11,12
100:16
101:15,19
102:2,7
146:1,7
147:13
148:10
hyaluronic
50:14 134:23
135:2 136:15
hyaluronidase
50:12 56:7,
12 134:3
hydrolyzed
134:25
hypothesis
136:23
hypothesized
64:5

I

ID
39:5 41:19
42:9
idea
20:17 54:24
133:25
ideally
58:11 127:4
148:15
identical
39:4
identified
31:23 62:7
91:23 115:18
147:6 150:1
identify
43:3,6,10,
14,18,24
44:2 80:3
identity
39:20 41:9,
18 42:24
48:9,11
104:23
105:5,12,17,
22 106:2,7,
14 107:5,10
Iga
127:23
129:24
ignore
111:9,14
III
8:18
iliac
131:22
immediate
68:6 72:17
immediately
72:13
immune
25:17,23
26:1,3 29:1
34:14 39:20
44:9,19,22
45:4,10
57:14 76:17,
24 77:23
78:10,18,21,
25 79:4
82:25 89:19
97:19 99:18
104:6
112:16,17,22
115:8 139:13
142:23
154:24
159:8,19,22
immunization
35:15 86:24
87:3,6,11,18
96:12,20
97:8,14
103:11
113:19
immunizations
81:5
immunized
81:8
immunizing
107:22 108:6

Petitioner Merck, Ex. 1129, p. 181
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

109:20
immunocontraception 20:19 114:21
immunocontraceptive 115:5,16 116:3,15,23 145:2,9,12 158:5
immunogen 103:25 105:5
immunogens 104:22
immunoglobulin 55:5 78:22 118:9 127:23 132:18
immunologist 25:16,23
impact 53:9,12 68:7 136:14
impacted 125:7,9
impair 72:7
impede 65:24
important 17:3 39:20 96:4
inability 88:5
inaccessible 64:14,16,17, 19
inbred 70:1
include 100:16 103:1 143:10,24 151:11 152:7 154:6
included 17:3,4
includes 27:19 39:6
inclusion 115:5,16 116:2,14,23
Incorporated 163:17
increase 98:7
incubation 149:21
independent 25:25 26:18
independently 27:8 32:13 42:25 105:23 106:17
indicated 74:24
indicates 87:1,13
indirectly 52:16
individual 48:9 69:22, 25
induce 134:8
induced 80:14 123:25
inducing 83:4 93:22 123:11
infertile 153:24
infertility 35:17 53:12 55:24 56:16, 19,22 57:3 58:1 81:22 85:8 87:4 93:24 104:24 107:23 108:7 109:22 113:21
inflammation 38:9
inflammatory 76:20 77:17, 22 78:5,8,12
information 28:3 32:8,11 71:15 125:22
informed 114:1
inhibit 51:12,18 52:6,19 55:11,14 135:1 138:10
inhibited 51:4
inhibiting 51:16 52:5, 18 55:3 123:10
inhibition 51:11,25 52:24 53:3, 17 55:15 124:2
injected 38:7 48:13 75:6,20 80:23 81:1,4 82:17 89:4, 13,15,19 111:10,20 112:4
injecting 112:21
injection 77:16 82:11 85:20 86:3,8
injections 113:4
insemination 63:16 68:20
inside 120:23
instance 93:10
instances 92:10 104:22
instructed 20:9 21:2,5
instructing 36:16
instructs 11:12
insufficient 83:5,17 84:2 85:7 99:2
intact 65:6
interact 61:4 68:22
interaction 135:1
intercourse 147:1 150:24
interested 8:2
interfering 123:12 134:17
interpose 17:11
interrelated 98:3
interrupt 54:7,15
intramuscular 96:24
intranasal 95:4 119:19 129:18,22 130:3,14,15, 22 131:2,6, 13 140:2 141:4,21 142:4,24 143:13,20 144:19 145:1,8,19 154:2
intranasally 119:23 142:12,20 143:21 144:2 153:15,22

Petitioner Merck, Ex. 1129, p. 182
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

154:4
intraperitoneal
85:20 86:11 88:2,6 96:23 117:11
introduced
68:19
invention
21:3
investigate
32:13,19,21 107:18 109:22 114:15 158:13,20 159:7,11,21
investigated
113:19 114:20
investigating
104:10 107:14 113:10
involved
16:9 50:22 51:2,10,14
involves
76:21
involving
15:16 86:3,8
irregardless
152:18
irrespective
30:19 120:14 133:21 138:2
issue
38:3 40:11 61:2 74:16 97:6

J

James
22:6
January
14:12
Jeff
8:14
Josh
8:22

K

keep
35:25
Kessler
8:19,25 9:1
key
116:6,13,21
Khandu
13:1
Khanduri
9:1 13:2
killing
124:17
kind
32:10 79:18 104:4 105:11,16,18 125:22 127:17 133:25 135:18 136:13 149:21 150:3,12 152:8,9 157:21
kinds
110:8
knew
63:5
know
11:7 17:8 18:14,15 20:3,20,24 25:19 31:8,10,17 33:21 40:1,5,7,10 44:16 47:1,16,20 49:7,11,18 51:11,16 52:5,18 53:2,16 55:15,19,25 62:22 63:9 67:14,15,16,21,23 69:4,9,10,15 70:4 73:19 75:9,13,15,16 78:17 92:15 93:2 95:11,17 99:22 110:13 111:4,13 122:6 123:1,5,17 125:8,12 126:3,6,10 129:5,20 134:24 135:13,19,23 136:24,25 137:2,12 143:24 144:17 146:4,15 149:20 151:23 152:1 155:8 159:24
known
28:1 30:17 34:3 63:12,13,18,19,22 64:3,6 70:13 71:2,9 120:11 122:2 123:8 127:21 129:18 132:12 142:6 143:20 150:1,19 159:12,13,25
Kushan
8:14

L

laboratory
151:22 152:15,16
lack
124:4
lacking
148:18
large
18:15 40:8 49:5,6,8,12 132:23
late
58:20 97:4
Lauren
12:25
lawyers
24:24
leaflet
121:21
leakage
159:14
led
19:8,14
legal
7:23 8:4 20:10 21:5
legally
21:2
level
57:3 95:6 99:13,14 126:18 129:9
levels
80:15 94:8 99:20 125:25 128:20,22 129:21 149:20 154:23
light
25:8,13
limited
31:13
line
8:24 70:1
linear
77:8,11
lipid
121:19

Petitioner Merck, Ex. 1129, p. 183
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

list
27:19,23,25
28:4,6,7
31:12 32:22
listed
15:20 18:19
31:4,5,14,18
32:2 106:4,
9,13
listen
55:9
literally
143:19
literature
14:19 16:22
17:14 57:19
114:15,20
115:23 154:7
litter
57:20
little
16:19 63:14
83:9 94:24
149:6 159:12
LLC
7:15 163:16
LLP
7:19
located
7:19,24
location
59:19 82:22,
24 83:23
84:1 88:20
94:11,18
97:22
112:16,22
137:20
158:13,20
159:3
locations
59:19
long
13:4 14:13
23:2 42:23
44:9,10
45:17 70:17
102:23
119:22
long-lasting
154:17
look
18:13,16,17
40:22 61:23
62:11 71:3
88:9 100:5
112:20 116:5
117:12
144:17
looked
63:4 90:15
92:15
looking
64:11 79:11
89:8 92:19
140:10
looks
117:25
loses
72:21
lot
14:19 108:11
132:12 150:5
low
68:7 69:7
91:23 94:8
99:13 133:7,
8
lower
127:15
128:4,8
132:20
133:1,4
148:4
lumen
78:21
lumens
159:16
lunch
106:21
108:12,23
lysed
124:17
lysis
123:14

M

Mack
8:22 12:18
24:20
made
47:3 49:13,
17,19 156:18
157:16
main
141:23
maintain
154:23
maintained
42:24
maintaining
154:25
major
97:5
make
13:23 30:11
59:4 75:17
79:12 110:9
116:17
137:23
142:15 147:1
152:9 153:19
makes
149:7
making
110:18
157:24
male
35:9,13,22
74:25 75:21
76:1,13,16
78:4,9,13,21
81:7 85:16
86:18
males
31:24 32:9
35:14,16
36:6 37:3,
17,20,23
38:4,7,21
76:12 77:16
159:16
mammal
29:12 62:19
100:13
103:12
104:18
146:14
mammals
21:15 27:13,
20,24,25
28:1 31:3,8,
14,17 34:6
35:4,13 58:7
61:24 62:3,
11,20,23,24
63:14,17,20,
23 64:3
78:18 79:1,5
102:3,13,16,
21 103:1,15
104:12
107:4,5,9,
15,19,22,24
108:6,8
109:4,9,15,
21,23
113:11,16,
20,21 114:12
139:12,21
140:7 142:1,
7,12,20
151:9 152:7,
21 159:4,9
mandatory
141:19,20
marked
12:8
marmoset
27:15 28:19
Martin
12:25
massive
38:9
materials
16:16,20

Petitioner Merck, Ex. 1129, p. 184
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

matrix
72:13,18
125:18
matter
14:9 30:9,10
33:17 41:6,8
44:18 51:20
70:17 99:8
129:9,16
137:21
138:7,13,18
163:16
matters
82:25 96:1
97:23 98:2,5
maturation
58:17,20,23
mean
16:20 22:10
25:13,15
31:10 47:9
49:17 57:18
59:11 77:5
83:23 84:4
87:7 89:21
94:16 99:12
102:15 106:3
112:1 121:4
124:20
130:11 132:4
133:5,24
135:19
136:22
139:24
143:19 149:2
150:19
meaning
90:5 140:1
means
50:9 76:16
89:18 136:4
meant
145:5
mechanism
118:25
124:15,19,21
125:2 126:6,
7 132:7
mechanisms
123:17
124:6,13,21
125:7,8,20
126:3
mechanistically
35:18
medium
149:25
meet
12:20,24
13:5
Melanie
23:18
membrane
61:4 66:17
121:20,21
membrane-bound
73:7 122:17
mentioned
131:11 132:6
152:11
159:13
Merck
7:15 8:12
163:16
metabolic
150:12
methods
56:24
mice
85:2,10,17
86:9,19
88:14,16
97:14 103:4
118:9,11
146:16,17,18
microgram
100:1
microphones
7:10
migrate
68:21
million
100:2
millions
134:23
mimic
149:21 150:4
mind
52:21 56:21
57:22 111:18
113:1 141:21
mine
15:4 25:21
minimal
94:6
minute
41:16
mirroring
117:8
misfolded
45:3,6,8,15,
21 46:5,11,
19
mixture
156:25
mobility
123:24
model
79:19,22
models
116:1
modification
39:6,13
40:20 41:11,
12
modifications
39:17 42:17,
22 47:2
modified
21:13 25:18
26:6 27:11
28:25 29:6,
9,24 32:24
34:4,15,23
35:3,12,21
36:4 37:1,15
38:18 39:2,
11,15,23
40:6 41:17
42:5,8,21
43:7,15
44:13,21,24
45:4,9,15,22
46:20 47:2,
4,15 48:3
49:4,7,11,19
56:14 57:1,
10,24 58:5
61:7 71:19
75:14 82:25
96:2,5 98:5
99:9,17
100:10,19
101:1,10,20,
23 102:6,12,
15,20 103:11
104:16
107:2,18
113:15
114:13
115:15
126:14,23
127:5,13
128:15
139:10,19
140:5,15
142:1,9,17
143:3,8,10
146:6,10,16
147:1 151:7
152:5,24
153:18 154:3
155:22 158:9
molecular
134:23
molecule
121:23
132:18
molecules
55:5
Monday
13:10
monkey
27:14,15
monkeys
103:8
monoclonal
47:10 136:2,

Petitioner Merck, Ex. 1129, p. 185
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

4,8,17 137:3 155:13,21 156:10,13,15 157:1,6,12, 15,20 158:4, 10
monoclonals 137:16
months 14:15,16
months' 14:18
Moon 22:14 23:12 26:5,15 106:18 107:11 161:15
Moon's 13:16,18,20 14:1,6 22:6, 19 23:3,8 25:9,14,22 26:18,20 27:2
morning 8:9,17 10:6 49:3
motility 123:10
mouse 27:15 85:6, 14,19 86:17
move 88:11 125:16 126:10
movement 129:6
mucosal 34:20 95:4,5 98:11,15,18, 22 110:20 111:5,16 119:8,25 126:20 127:10,20, 22,25 128:2, 14,18 129:2, 8,16 130:1 131:8,18 132:1 140:1, 13,20 141:2, 6,7 142:6 145:11,25 146:6,9 147:19 152:12 153:3,6,7 154:2,6
mucosally 110:25 143:5 153:2,15
mucus 62:6,7 123:12 124:1 147:24 148:7
multi 50:7
multiple 29:1 47:12 122:17,18 125:24 126:2 135:4 138:9
mutation 41:20 42:10

N

name 7:22 8:10,18 9:3 10:7 13:1
Nancy 8:22
narrow 20:16
nasal 154:16
native 45:1,11 47:5 48:5 58:19 60:18 81:12, 16 90:7,12, 15,18,19 91:3,10,15 95:21 100:20,23 101:1,4,11, 16 103:15 104:23 105:6,8 107:14 109:14 113:10
naturally 76:14 77:24
near-final 22:16,23 23:4,9 161:14
necessarily 44:18 110:10 125:7 131:9
necessary 44:3 84:8 99:11 130:7
need 11:6 32:7 34:23 36:22 47:7 51:4 54:11 57:4, 25 58:8,12 66:12 67:8, 16,24 68:12 70:20 73:12, 20,21 84:16 92:25 94:10, 16 98:18 99:17 100:5 111:15 126:10 129:12 140:12 154:12 157:6 161:6,20,21 162:24 163:2
needed 69:11 70:14 71:9 95:12
needs 50:25 51:6 57:22 69:1 82:3 83:9 98:14
negative 147:20
Neil 10:9
neutral 72:20
neutralize 95:10
neutralized 93:11
never 10:17 23:14 82:11,14 96:12
nods 141:10
non- 109:20
nonhuman 58:7 102:13, 21 103:12,14 104:11,18 107:3,4,9, 15,19,22,24 108:6,8 109:3,9,15, 21,23 113:11,16,19 151:9 152:7, 17
nonhumans 146:10
nonprimate 61:24 62:11 116:1
nontoxic 144:1
normal 150:12
North 7:24
note 7:10
NOTED 163:20

Petitioner Merck, Ex. 1129, p. 186
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

November
7:2,7
number
39:23 40:1, 5,7,8 43:3,6 47:21 49:4, 5,6,8,12 157:10
numerous
125:6 157:22,25

O

oath
10:2
Object
18:25 21:20 26:9 27:4 28:22 45:12 51:8 58:2 62:13 63:11 66:14 77:25 79:2,24 84:3 90:8 92:7,23 93:13 95:14 96:8 99:4 101:25 111:12 113:12 119:24 122:9 124:7 125:10 126:8 127:16 130:9 134:20 135:9 137:5 138:14 141:9 142:13 144:15 145:13 147:4 148:1 150:18 154:14 156:21 157:18 160:25 161:5
objection
16:18,24 17:9,12,13 19:9,15,21 20:23 21:24 23:6 27:22 28:10 29:18, 20 30:2 31:21 32:4, 16 33:1,7, 13,18,24 34:7,11,17 35:23,25 36:7,9,20 37:4,18 38:5,15,20 39:18 40:3, 14 41:1,15, 22 42:13,18 43:20 44:5, 15 45:24 46:8,14,23 47:6,19 48:6 49:14,20 51:19 52:8, 23 53:5,13, 21 55:17 56:1,8,17 58:9 59:2,9 60:21 63:25 64:4,9,15 65:1 67:19 68:1,16 69:18,23 70:6,15 71:11 73:16 75:23 76:9 77:1 78:19 81:18,24 82:13 83:7, 18 84:10 85:3 86:4, 10,20 87:5, 20,23 88:7 89:20 90:2, 20 91:11 93:4,25 94:20 96:14 97:10,16 100:4,21 101:6 102:8 103:16 104:1,13,19 105:1,9 107:25 108:9 109:10,16,24 110:5 111:2, 24 112:14,24 114:3,17 115:6,21 116:4,16,25 118:6 119:1, 14 121:2,9 122:1 123:3 127:2 128:25 130:20,25 136:20 137:14 138:22 139:15 140:9,18 142:21 143:16 145:16 146:2 148:11,25 151:18 153:4,12 155:5 158:1, 16,23 159:5, 10
objections
35:25 37:25
observe
111:16
observed
133:1
obvious
152:2
occur
35:18 50:24 51:6 122:12 124:6 134:18
occurred
124:13 142:24
occurring
150:13
occurs
66:7 129:2 147:24 149:22
offer
18:12 31:25 46:1 49:21 67:11 75:16 88:10 91:13 99:15 110:6, 10
offered
20:13,21
okay
11:5,20,25 12:5 15:7,9, 18 16:4 18:3,22 19:22 21:10 26:20 30:15 36:11 44:1 48:1,19 50:1,5,6 54:6 59:14 61:14 74:2, 13 79:14 84:22 106:24,25 108:16,17 118:23 120:6 121:10 122:25 129:13 138:24 139:10 145:7 150:10 160:1,2 161:9,18,23, 25 162:11,21 163:5,8,13
once
123:21 125:13
one
10:22,23,25 13:18 20:1 23:7,9 29:22 33:8 36:14 39:5,12 47:14,25 50:9 51:12, 16 52:5,18,

Petitioner Merck, Ex. 1129, p. 187
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

24 53:3,17 55:11,14 63:3,5 68:20 70:9 71:2 92:25 96:3 117:22 124:10,12,20 125:2,7 126:3 129:22 132:19 135:7,14,15, 22 136:5,9, 22 137:2,16 142:14 144:4 145:17 146:15 156:16 157:6,7,12, 15,20 162:13 163:10

ones
14:4,6 17:4, 15,16 31:4,5 106:10 133:12

oocyte
68:22 123:10,22 125:21

operative
151:21

opine
25:10,20 27:10 35:14 40:21 44:17 69:3,14 71:1 95:2,15 135:18 155:7

opined
26:15 31:22 35:2 62:25 129:17

opining
25:16,23 26:6

opinion
16:4 17:2 18:12 19:6, 12 20:10,13, 20 25:25 26:3,14 27:19 28:25 29:5,8,23 31:2,13,25 32:6 33:3,9 34:4,22 35:11 41:6, 7,10,20,24, 25 44:12,20 45:3,8,14,21 46:2 49:22 52:3 53:22 54:10 56:3, 14 57:1,9 61:6,10 66:18 67:11, 13 70:19 71:18 72:3 73:2 75:16 82:4,10,21, 24 83:16 84:15 86:22, 25 87:10 88:19 91:13 94:9 95:25 96:10,18 97:22 98:4, 14,25 99:7, 10,15 100:9 102:10,19 103:10 105:21 107:2 110:7,10,25 111:8 114:10 118:23 119:20 120:18,19 121:15,24 123:8 124:13 126:14,21,23 132:1 134:16 135:3 136:1 137:20,25 138:6 139:17,22 142:2,9 143:2,23 148:9 151:7 152:5,22,24 155:13 156:13 157:5

opinions
16:12 26:17, 18,20,21,25 27:2,6,7 42:2,11,15 43:1 92:18 114:16 158:12,19 160:23 161:2

optimize
154:2

optimized
86:23 87:10, 17 139:20,24 140:7,16,24 141:3,15,20, 25 142:3 143:7 154:21

option
154:18

optional
141:17 148:13 152:13,20

optionally
146:24

oral
129:25 130:2,4,11

orangutan
27:15

orchitis
38:8,14 77:19 78:6, 9,13

order
33:23 34:24 47:3 50:24 51:5 60:19 66:13 67:17 68:4,13,14 69:1,12 70:20 73:3 76:18 103:23 111:16 120:20 135:5 139:10 152:25 156:19 157:7 163:10

orders
162:22

ordinary
21:12

originally
106:4

outcome
8:2

outer
121:20

outside
31:18 32:22 64:24 115:18

overcome
76:17,24

oviduct
62:17 66:22, 25 67:3,5,9 68:4 69:1,13 70:9 73:10 123:21 124:16,17 125:14,17 127:21 129:3 133:3,7

oviductal
133:10

owner
8:20 93:19

P

p.m.
108:18,20 139:2,5 160:5,8 162:3,6 163:18,20

Pacific
7:7 48:20,24 74:5,9

Petitioner Merck, Ex. 1129, p. 188
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

108:18,21
139:3,6
160:6,9
162:3,7
163:18
page
61:15 64:12
117:14 138:2
paper
80:10 82:9
84:24 88:23
117:4,11
papers
17:1,3,5,17
94:5 96:22
97:3,4
116:6,13,21
117:2 140:11
par
99:19
paragraph
15:11 21:8
22:5 25:6,8
27:8,12
30:14 31:5,
14,18 32:2,
22 38:25
49:25 50:4
61:12 74:18
79:13 80:7
84:21,23
89:7,9
106:13 107:9
120:4,7,9,10
123:7 132:7
133:18
139:18 147:7
155:17
part
28:6 50:2
56:11 83:23
121:6 141:15
154:20,22
162:16
particular
43:10 94:11,
16,18 98:9
99:8 159:1
parties
7:9
partners
132:14
party
8:1
patent
7:16 8:19
10:14,18
15:16,18,20,
22,23 16:7
18:22 19:3,
7,8,13,17,
18,25 20:2,
22,25 40:22
93:19
patents
16:9,14
40:11,19,23
74:16
160:15,20
path
152:10
path-
130:12
pathogenic
35:16 37:21
38:2
pathogens
130:13
pathway
123:15
patient
89:18
patients
89:4,13,15
90:4,7,12
91:23
pellucida
50:18 65:22
73:1 124:23
125:19
penalty
9:12
pending
11:10
penetrating
147:19,24
148:6
penetration
123:11 124:1
people
12:22 57:20
130:22 154:8
peptides
146:10
percent
39:4,19
41:8,18
42:9,23
48:8,10
57:23 58:1,
3,13 75:11
104:2,5,23
105:18,20,22
106:2,6,14
107:5,7,10
percentage
58:7
Perfect
163:13
performed
114:2
period
14:19 113:9
perjury
9:12
person
12:23 21:12
perspective
135:20
160:24 161:3
Petitioner
8:12,16
Petsko
23:15
Petsko's
23:24
PGR
12:6 40:12
PGR2025-00003
11:21
PH
61:3 91:5
Ph.d.
7:14 10:1
163:15
PH20
20:17 21:14
25:18 26:7
27:11 28:1,
25 29:6,10,
15,24,25
30:18,20
31:19,23
32:2,8,14,24
33:4,10,23
34:4,16,23
35:3,8,12,
16,21 36:4
37:1,13,16
38:7,18
39:2,11,15,
23 40:2,6
41:17 42:5,
8,16,21
43:1,4,7,11,
15,24 44:3,
10,13,21,24
45:1,4,9,11,
15,22 46:12,
20 47:2,5,
15,18 48:3,
5,14 49:4,7,
11,19 50:6,
9,17,21,25
51:4,6,13,
21,23 52:5,
11,15,19
53:8,17
55:1,12,15
56:5,14
57:1,10,24
58:5,16,19,
22,25 59:6,
15,25 60:4,
7,12,16,18,
24 61:5,8,9
64:12,14,21
65:6,11,14,

Petitioner Merck, Ex. 1129, p. 189
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

20,24 66:2,
3,4,10,13,
17,20,24
67:5 71:19,
21,24,25
72:4,6,11
73:2,21,23
74:19 75:3,
6,10,14,21
76:2,5,7,14
77:16,24
78:14 79:8,
16,22 80:4,
13,18,21
81:12,17,22
82:25 83:16
84:1,8 85:2,
6,10,14,19
86:8,13,17
88:14,17
89:4,13,16,
19 90:7,10,
13,16,18,25
91:8,10,15,
18,20 92:5,
6,16,20,22
93:2,10,11,
23 94:10,17
95:12,21
96:2,5 98:5
99:9,17
100:11,12,
19,20 101:2,
5,10,12,16,
20,23 102:6,
12,16,20
103:12,15,24
104:3,7,11,
17,23 105:6,
8,15 106:14
107:2,15,18,
23 108:7
109:3,8,15,
21 110:2,4
111:10,19,22
112:4,6,21
113:10,15,20
114:13,21
115:4,15,20
116:2,13,22
117:8,20
118:24
119:4,11,21
120:12,15,
22,24 121:1,
6,16,24,25
122:7,8
123:1,2
125:6,14
126:14,23
127:5,13
128:15
133:20,21
134:14,17,19
135:1,5,13,
16 136:9,16
137:4,9,20
138:5,10
139:10,19
140:6,15
142:1,9,17
143:3,8,10
146:1,6,10,
13,20 147:1,
25 150:24
151:8 152:5,
24 153:16,
19,21 155:22
158:9,14,21
159:3

PH20's
76:20
110:12,24

phonetic
153:11

phrase
39:2

phylum
31:9

physically
134:25

physiological
150:12

physiology
59:18,21
60:2,9 61:9
150:4

pick
7:11

pig
27:16 38:7
63:2,3,5,9,
13,21 64:2
75:3,9,13
77:15,23
78:10,14
79:18 153:10
159:3

pigs
35:8,9 63:18
74:21,25
75:2,7,20
76:1,4,14,17
78:9,13,17,
25 79:6
97:12 99:3
115:19
153:14
159:8,13

place
7:9 102:25
116:10
136:9,18
139:13
156:10

places
60:5 120:24
127:22

Plaintiff
7:15

plasma
61:4 80:16
81:13 82:2,
20 88:15
98:13 99:20
159:15

please
7:10 9:9
10:7 11:1,7
17:23 20:2
25:4 35:25
36:24 47:25
49:16 53:15
54:1,6,15,23
55:9 116:18
128:7 142:16

plenty
95:9

point
23:25 65:11
79:11

poly-
100:11

polyamino
20:17

polyclonal
29:2,8,16,25
44:25 45:10
48:12 53:24
54:25 60:23
61:1,7
66:16,19,24
67:4 71:18
72:1,2 75:21
76:2,5 78:2
80:15 81:11,
16,21 82:1,
6,19 83:3,4,
11,15,25
84:8,11,16
88:13,16
93:1,22
94:10,17,25
97:23 100:9,
20 101:4
102:11
103:13,14
104:6 105:11
114:12
115:19
117:24 118:4
122:14,15,21
135:11,12,24
137:19,25
138:7,12,17
139:13

polyclonals
47:11 135:6

polypeptide
29:11,15
30:18 33:5,
10 34:5,16,
23 41:18

Petitioner Merck, Ex. 1129, p. 190
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

42:8,17
46:20 47:3,
16 48:3
49:19 52:13
53:8 55:1
56:15 57:2,
10,24 58:6
74:20 77:8,
12 79:16,22
80:5 83:1
96:2 98:6
99:9,18
100:12
101:24
102:6,20
104:17
113:15
120:12
133:20,22
138:5 153:22
polypeptides
20:18 25:18
26:7 27:12
28:25 29:6,
10,24 30:20
32:24 35:3,
12,16,21
36:4 37:1,16
38:18 39:2,
3,12,16,24
40:2,6 42:6,
21 43:8,15
44:13,21,24
45:4,9,16,22
46:12 49:4,
8,12 61:8
71:20 75:14
79:8 80:14
96:6 100:11,
19 101:2,11,
20 102:12,16
107:3,18
114:13
115:15
120:15
126:15,24
127:6,13
128:15
139:11,19
140:6,16
142:1,10,18
143:3,8,11
146:6 147:2
151:8 152:6,
18,25 153:19
154:4 155:22
158:9
polypeptides'
21:14
polyvalent
132:18
Pomering
80:9,12,17
81:10 82:8
99:6
population
150:25
151:1,2
152:2,15
154:13
155:3,8
populations
152:17
portion
13:18,20
121:1,3,5,
19,23 144:1
POSA
21:13 37:13,
15,22 38:17
70:11,13,23
71:8 92:11,
15 93:5
96:11,19
97:5,7,13
111:4,9,13,
14 112:5,19
113:2 115:3,
14 118:23
119:10,21
123:8 125:13
126:2 131:25
139:18 140:5
141:13
143:23
146:23
148:9,22
149:3,16
150:7,16
153:1,18
154:3,6,12
155:2,20
157:21,24
160:24 161:3
POSA's
103:22
111:21
POSAS
27:10 30:16
114:11
120:11
position
39:7 41:12,
13,20 42:11
possibility
133:15
possible
30:12 39:23
40:1,6 49:4
115:25
116:20
150:20
post-grant
11:18,20
15:15
potent
153:2
potential
33:15
potentially
17:1,6 46:17
52:25 63:24
64:10 73:17,
19 116:8
121:19 125:6
154:15,25
157:14,17
Powers
8:17,18
12:17 13:2
16:18,24
17:9,11,23
18:25 19:9,
15,21 20:23
21:20,24
23:6 25:4
26:9 27:4,22
28:10,22
29:18,20
30:2 31:21
32:4,16,18
33:1,7,13,
18,24 34:7,
11,17 35:23
36:1,7,10,
12,14,18,21
37:4,25
38:5,15,20,
22 39:18
40:3,14
41:1,7,15,22
42:13,18
43:20 44:5,
15 45:12,24
46:8,14,23
47:6,19,22
48:1,6,15,18
49:14,20
51:8,19
52:8,23
53:5,13,21
54:1,4,6,12,
15,19,21
55:17 56:1,
8,17 58:2,9
59:2,9 60:21
62:13 63:11,
25 64:4,9,15
65:1 66:14
67:19 68:1,
16 69:18,23
70:6,15
71:11,13
73:16 74:3
75:23 76:9
77:1,25
78:19 79:2,
24 81:18,24
82:13 83:7,
18,20 84:3,
10 85:3
86:4,10,20
87:5,20,23
88:7 89:20

Petitioner Merck, Ex. 1129, p. 191
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

90:2,8,20
91:11 92:7,
23 93:4,13,
25 94:20
95:14 96:8,
14 97:10,16
99:4 100:4,
21 101:6,25
102:8 103:16
104:1,13,19
105:1,9
106:20,24
107:25
108:9,11
109:10,16,24
110:5 111:2,
12,24
112:14,24
113:12
114:3,17
115:6,21
116:4,16,25
118:6 119:1,
14,24 121:2,
9 122:1,9
123:3 124:7
125:10 126:8
127:2,16
128:25
130:9,20,25
134:20 135:9
136:20
137:5,14
138:14,22,25
139:15
140:9,18
141:9
142:13,21
143:16
144:15
145:13,16
146:2 147:4
148:1,11,25
150:18
151:18
153:4,12
154:14 155:5
156:21
157:18
158:1,16,23
159:5,10
160:3,25
161:5,17,21,
24 162:8,12,
17 163:2,4,
7,12

practical
150:25
151:16,21
152:1,23

practice
36:15

Prati
12:25

Pratibha
9:1

precise
60:5

predict
93:6

predicted
92:12

preparation
12:15

prepare
12:12 14:14

prepared
114:22

preparing
18:11 19:3

presence
51:22 55:5

present
52:15 68:3
69:6 94:6,7
105:6 133:14
148:20

presented
22:6,10,11
77:3,6,7
114:25 116:6

pretty
30:4 51:23
131:21

prevent
66:13,25
67:5,17,24
68:14 69:2
123:9,20,21,
22 124:14
125:2 148:6

prevented
67:10 124:16

prevention
147:23

prevents
123:18
147:18

Primakov
153:10

primarily
12:13 13:14
140:2

primary
142:24

primates
61:21 147:10
151:11,17
159:1

principle
92:14

principles
20:10

prior
22:16 72:14
112:10 113:1
150:24

private
7:11

probably
13:6 14:15,
23 55:20
70:16 88:8
97:17 98:24
99:19 120:24
125:16 130:2
133:4 135:21
138:23
140:21
148:12 152:1
161:6

probative
112:5,9,10,
23 114:25
115:13

problematic
35:19,22
36:5 37:2,23

procedures
149:21
151:24

proceeding
7:18 10:18
15:8,15
19:25 93:20

proceedings
7:13 8:7
10:15 11:18,
21 12:6
16:10,13
19:19 20:6
40:12
160:15,21

process
51:10 56:25

processed
60:11 62:3

processes
150:13

processing
46:21

producing
9:6

production
105:7,14
128:4
129:10,24
161:14

Prohibitive
112:8

pronouncing
12:25

proof-of-concept
79:19

proper
34:13,14
35:24 36:9,
19

Petitioner Merck, Ex. 1129, p. 192
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

proportion
68:18 118:1, 18
protease
134:5
protected
64:13,22
protein
50:7 51:24 56:5,11 77:8,11 86:3,8 100:24 121:7 122:18,24 134:9,24 135:13 136:16 144:8 150:2
proteins
46:5,7 100:23 101:1
proteolytically
58:19
prove
91:9
provide
89:7
provided
21:25 40:12 41:3 160:23
published
96:23 100:18 101:10,14,22 104:10,16 107:13,21 108:4 109:2, 8,13,19 113:9,22 145:24 146:12,19
purified
75:4
purpose
20:12,20 157:21,23
push
149:6
put
12:2 163:8
putting
150:7

Q

qualified
30:23
qualifier
94:1
quantify
70:5
quantitative
69:16
quantitatively
33:20,22
quantities
100:2,3 116:11 139:14
quantity
69:17
question
11:10 13:24 21:18,19,22 22:3 24:19 26:11,13 30:4 36:23 37:6 47:25 51:5 52:4, 17,21 54:11, 18,20,21 55:8,9,11 56:19 59:4,5 83:9,24 84:6 85:9 98:11 115:1,3,14 117:17 118:3 121:14 128:13 156:2,5
questions
11:1,12 20:1 106:22 108:12 161:11 162:9
quick
162:13
quickly
162:22
Quinn
7:19 8:22
quite
56:24 154:9

R

rabbit
27:16 80:17, 20
rabbits
80:13,23 81:7,11,15, 21,23 82:17 103:1
raise
9:8 119:12 126:24
raised
71:19 78:10 82:18,22 88:16 93:1 127:7,14
raising
83:3,11,15, 25
Ralph
8:18
range
104:5
rapidly
63:16
rat
27:16 153:19 154:5,13 155:2,3
rats
103:6 153:23,24,25 154:1,4
reaching
124:16
react
48:13 60:24
reaction
60:13 63:15 65:17 66:7 71:19 72:12 122:13 123:13 124:3,22
read
22:5,12 161:19 162:10
ready
47:24 48:15
real
162:22
reason
87:4,18 92:21
reasons
152:3
Rebecca
8:4 9:4
recall
18:22 28:17 87:14 88:24 109:5 117:5 133:9
receive
153:15
received
22:15
receiving
80:13
recently
145:5
receptor
50:17 144:7
recess
48:22 74:7 108:19 139:4 160:7 162:5
recognition
61:3

Petitioner Merck, Ex. 1129, p. 193
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

recognized
121:22
recombinant
80:17 85:15
86:13,17
89:16 90:10,
18,25 91:8,
18 92:5,20
93:1,9
100:23 101:1
103:11
107:23 108:7
109:21
113:20
117:20,23
118:3,14,24
119:3,4,11,
21,22
record
7:6,9 8:6,8
10:8,24 25:3
48:21,24
74:6,9
108:18,21
139:3,6
160:6,9
161:13
162:4,7,14,
16 163:19
recording
7:8
rectal
129:20
red
27:16 28:19
redirect
161:22
reduce
55:20,22
56:3
reduced
86:18
reducing
57:20 123:11
reduction
57:3 58:8
73:4
refer
39:2
reference
18:20 88:9
117:13
referenced
15:21
references
12:14 13:12,
19 100:6
referred
38:6 142:4
referring
30:7 38:3
41:24,25
52:11 53:23
96:15,16
106:8 121:10
128:11 141:5
144:21,22
150:5
refers
84:23 106:18
regard
143:13
regarding
11:17 25:17,
18 26:6 32:8
109:2,8,14
110:8 155:13
region
72:22 121:21
131:5
regions
52:12 122:18
128:9,20,23
129:10 138:5
related
7:25 10:16
26:4 35:18
95:8
relates
137:6
relating
20:25
relation
134:22 137:8
released
66:2
releases
66:10
Relevance
70:15 116:4,
16
relevant
17:1,2,6,16,
18 43:11,15,
24 111:1,21
112:1 122:13
135:22
remote
8:7,13
remotely
12:23,24
removal
147:20
remove
141:18
150:23
151:16
removed
65:9 121:17,
18
removes
141:14
149:12,13,17
rendering
153:24
repeat
26:11,23
36:22 59:5
67:21 86:6
rephrase
23:1 37:14
40:4 43:25
66:6 78:7,11
83:3 89:24
105:25
109:12
126:22
127:25
128:13 137:1
154:11
160:17
replaced
39:7
replacement
40:16,24
41:5
report
94:5
reported
81:10 86:16
153:10
reporter
8:3,6 9:3,5,
11 10:24
114:4
reports
80:13 85:1,
10
represent
17:25
reproduction
29:17 61:17
63:22
reproductive
29:11,14
30:18 33:5,
11 34:1,20
45:18,19
57:14 59:7,
17,22 61:20
68:19 69:5
70:8,18 78:4
81:14 82:2,6
85:7 94:4,25
96:25 97:20
98:12 100:12
102:25
103:19 113:5
118:16,21
119:9,12
120:13
126:25
127:4,8,12,
15,20 128:5,
10,16,21,23
129:11
130:8,15,19
131:5,10,15
132:20

Petitioner Merck, Ex. 1129, p. 194
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

140:13
146:14,21
159:16
require
124:5 140:24
required
21:2 41:11,
12
requirement
124:9
requirements
141:3
requires
40:19 132:23
141:7
residence
63:17
residues
43:4,7
respect
38:3
response
34:14,20
35:15 39:21
44:9,19 45:5
48:12 57:14
69:5,20
70:18 72:1,3
76:20,22
77:17,22,23
78:5,8,10,
12,13 83:5
84:1 88:1,13
89:19 93:23
94:2,3,10,
15,17,22
95:4,5,9,11
96:25 97:19,
23 98:8,11,
15 99:12,13,
18 100:14
103:13,19
104:6 110:20
111:6,16
112:16,17,22
113:5 114:13
115:9,20
118:1,20
119:8,16
120:1 122:14
126:18,20,24
127:7,11,15,
20 128:19
129:16,19
130:8,16,18,
23 131:4,8
132:1
135:12,24
137:19
139:13
140:12,14,20
141:6,8
142:7,23
144:23
148:16
150:15
152:12 153:7
154:2,18,24
161:7
responses
25:17,24
26:1,3 44:22
45:10 82:25
94:5 101:4
141:2
responsible
38:10 52:13
rest
19:23 28:7
restate
18:9
result
81:22 93:23
96:25 105:13
128:3
results
118:15
retained
14:9
review
11:18,20
12:13 13:13,
16,19 14:5,
19 15:15,22,
23 16:16,21,
25 18:6,10
19:2,11,17
22:22,25
23:24 24:2,4
113:24
reviewed
13:21 14:1
16:2 22:19,
20 23:3,8
24:10 113:25
115:23
161:16
reviewing
18:22 115:25
116:13,21
reword
59:5
rhesus
27:14
right
9:8 33:6
37:24 41:14
42:17 58:24
61:21 62:9
63:7 64:14,
22 65:3 67:1
71:14 72:18
78:15 82:22
86:5,24
87:11 88:20
91:1,6 94:14
95:23 97:24
98:16,19
102:18 103:2
107:6,12
109:17
115:11
116:10,11,18
117:18
118:5,7,16
122:20,23
124:25 126:5
128:12
132:25 133:7
136:2,7,10,
18,19 138:3
139:13,14,22
141:11
142:15
144:17
147:8,21,25
149:15
150:3,9
151:9,10,13
154:13
156:16,19
157:17
158:2,6,10,
11 159:18
160:21,24
161:10 163:1
ring
151:25 157:4
rodents
62:8 159:1
rodents'
62:5
Romano
8:4 9:4
room
8:21 12:16,
21
Rosengren
88:23 89:3,
12 90:5,24
92:13 93:8,
16
rough
14:21
roughly
14:24 75:11
route
80:1,14
95:25 98:1,
19,22,23
117:10
119:7,17
130:3 140:3
routinely
110:17
rules
10:20

Petitioner Merck, Ex. 1129, p. 195
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

S

sample
93:11
San
7:1,21
saying
36:14 73:18, 20 112:19
says
87:17,25 88:4
scenario
127:18
science
15:3
scientific
32:10
scientists
75:3 113:18 114:7
scope
31:21 32:4, 18 33:1 35:23,24,25 36:7,8 37:4, 18 38:5
screen
137:16
screened
156:19 157:16
screening
157:21,25
searching
17:15
second
17:9
secretion
127:22 129:2 131:18,22
secretory
131:11
sections
18:14
see
11:25 14:10 21:16,17 22:8 25:11, 12 27:17 30:21,22 39:9 77:9 104:17 111:16 120:16 155:25
select
148:10,23 149:5,18
self-anti-
76:11
self-antigen
76:8,11,16, 24 77:10,13 144:14
sensitive
7:11
sentence
30:16 120:10
separate
56:6,11
sequence
28:2 39:3,5 41:18,19 42:9,22 75:14 104:23 105:5,12,17 106:14 107:5,10
sequences
20:17
serum
75:25 78:3 89:3,12,18, 23,25 90:6, 12,19,24 91:3,8,17,19 92:4,20 93:9,10 94:2,8 117:24 118:5,8,11, 15,18 119:5
sessions
74:14
set
120:4
setting
92:17
several
12:22 40:16 60:5 95:22 118:9 144:8
Sharp
7:15 8:12 163:16
showing
110:12,24 111:19 112:4
shown
62:17 95:7 140:3
shows
61:20
sialic
148:18
sialidase
147:7,9,15, 18,23 148:4, 6,10,13,24 149:5,18,23 150:21 152:14,20
sides
163:11
Sidley
8:11,14
sign
162:10
signaling
50:15
signature
22:17
signed
15:25 19:18 22:13,20 23:2
significant
68:5 94:3,15
significantly
73:9 86:18
signing
23:10,12,16, 19,22 24:8, 11,14,17 161:16
similar
48:7 58:10, 14 73:6 75:9,12,13 94:13 95:3 126:18 131:21 132:2 150:15
similarity
42:9
similarly
60:24
simple
110:22
simply
55:5
Simpson
23:18
Simpson's
24:2
simulate
50:15
single
149:24 154:16
site
40:20 66:22 134:7,8,10, 11 135:14 137:10,11
sites
40:16,24 41:5 134:7
sitting
99:25
situation
35:17 37:21
size
57:20 134:22

Petitioner Merck, Ex. 1129, p. 196
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

skill
21:12
slightly
43:22
slow
25:4
small
68:18
121:19,21,23
134:24
solemnly
9:11
solubility
46:3
solubilized
46:15
soluble
46:7,12
66:3,4,10,
12,17,20
71:20,24
72:4,6,11,21
73:2 121:24
122:7,16
123:1
sort
38:11 49:22
68:5 70:2
122:12
123:24 124:1
126:16 134:8
136:14
148:3,19
sound
149:8
sounds
47:10
speak
23:12,15,18,
21 24:13
49:1 74:11
106:10
108:23 139:8
160:10
speaking
34:1
species
28:13,14,17
30:6,7,8,9,
24 32:1,9,
13,20,22,24
62:16,18
69:17 79:17
95:22 103:24
158:15,22
specific
30:6 47:11
95:16,18
99:10 100:3
specifically
95:2 100:6
specificity
136:5 138:6
156:16 157:7
specifics
20:24
speculate
125:4 136:22
155:10
speculation
135:19
spent
14:22
sperm
29:11 30:1,
18 31:24
33:4,10,17,
23 44:11
45:18 48:14
50:15,17,19
51:22,24
53:8 55:1,6
57:15 58:17,
20 59:11,12,
16,19,21,25
60:2,3,4,6,7
61:9 62:2,3,
5,16,20,24
63:6,9,13
64:2,14
65:12 66:3,
20,25 67:16,
23 68:3,7,
10,12,18,20,
25 69:7,12
71:4,6,10
72:4,14,15,
18,23,25
73:8,13 75:4
90:15,16,18
91:3,10,15,
20 92:6,22
93:3 94:4,23
95:8 100:12
103:15 104:8
120:12,22,
23,25 121:7,
11,16,25
122:7 123:2,
9,10,11,12,
14,20,22,25
124:2,16,18
125:6,14,21
132:8,15,16,
19,22,24
133:6,16,19
138:10,11
147:18,19,
20,23 148:6,
14,17 150:2,
23 158:14,21
159:3,4
sperm's
60:8 72:7
sperm-bound
71:21,25
spoken
23:14 24:7,
16,25 114:7
stack
18:15
stage
58:17 59:1
67:2 68:2,21
standard
21:6 162:23
standpoint
51:3
start
156:14
state
8:5 9:12
10:7 30:16
39:1 50:6
74:18 120:10
141:13
155:16
stated
73:5 94:13
146:23
statement
8:7 30:23
37:5,9 83:22
110:9,18
states
21:11 85:6
stenographic
9:5 25:3
step
62:7 65:9,
11,15,16,18,
19 66:2,6,8
141:17,23,24
steps
62:10 64:12,
21 65:23,25
66:1
steric
134:1,8
136:14,19
Sterne
8:19,25 9:1
stimulate
29:2 141:6
stimulating
123:14
stimulation
82:1 144:10
stipulate
142:6
**straightforwa
rd**
149:23
150:21
strain
146:17
strategy
86:24 87:3,
7,11,18

Petitioner Merck, Ex. 1129, p. 197
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

Street
7:20
strong
130:18,23
131:13
strongest
129:19
130:16
structure
43:1 58:16,
25 59:6,15
60:1,8,16
65:20 77:13
100:24 121:7
122:24
studied
28:2 31:11
134:4,13
142:8
studies
35:7 71:6,15
74:23 75:2
77:16 79:7
92:14 95:20
97:18 99:6
100:7
101:17,18
115:18 122:5
153:10
154:16
study
79:15,21
80:4 85:5
118:22
119:18
135:22
146:17,18
147:9,14
subcu
96:23
subcutaneous
80:14 82:10
95:21 96:12,
20 97:8,14
98:22 99:1
113:3
subcutaneously
75:6 80:24
82:18
111:11,20
112:5,21
subject
93:24
submitted
11:18 15:14
substance
15:3
substantially
73:12
substrate
134:22
136:15
successful
55:4 74:24
76:18,25
79:8 80:4
82:5 83:1,5
101:15,19,23
113:4 144:3,
11,13 145:25
146:5
successfully
74:20 102:6
141:1 154:9
Sue
8:10 106:20
108:12
sufficient
29:13 34:16
45:19 51:17
52:6,19
70:8,20,24
84:9,14,17
105:12
116:11
119:12
139:14 153:7
Suite
7:24
Sullivan
7:19
support
7:23 8:4
20:16 136:24
Suppose
153:18
sure
13:23 26:12,
24 29:23
30:11 59:4
64:20 69:16,
19 74:3
79:12 108:15
116:17 123:6
128:10 131:1
137:23,24
138:25
142:15 152:9
160:3,4
162:17
surface
48:14 55:6
65:12 66:3
120:22,23,25
121:8 147:21
150:2,24
surface-successful
43:4,7
surrounding
72:14
susceptible
148:19
swear
8:8
synced
162:24 163:6
system
29:2 78:18,
21,25 79:4
131:22
159:8,19,22

T

tail
72:14,23
take
7:8 11:5,9
14:13 36:13
58:22 74:2
102:19
138:24 160:2
161:24 162:1
taken
7:14 11:17
48:22 74:7
108:19 110:9
139:4 149:20
160:7 162:5
talk
10:23 19:11
80:9 133:18
156:15
talked
95:3,20
97:21 117:3
140:1 142:25
155:12
156:25
talking
30:5 47:9,10
98:11,12
109:1 112:10
124:20
126:17
137:18
149:8,11
151:5,22,24
152:10
tell
91:19 100:6
tend
132:15
term
36:15 57:21
149:7 151:21
termed
22:15
terms
26:3 28:12
41:2 59:11
61:2 90:15
124:22
131:22 135:6

Petitioner Merck, Ex. 1129, p. 198
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

149:20
test
70:4 92:25 103:23
tested
85:16 86:2, 7,12 89:3, 12,25 90:24 91:2,12,15
testes
31:24 38:9
testes-blood
79:5
testified
10:3 77:15 90:23 161:15
testimony
9:12 71:17 87:2,14,16 98:1 106:5
testing
85:1,10 91:7,17 110:2 126:7 137:3,13
Texas
7:25
thank
12:10 17:24 25:2 48:18 89:10,11 161:10 162:8,12,20
Thanks
139:1
theoretical
91:21
theoretically
92:3,5 104:4 152:22
theory
105:13
thing
56:20,22 88:1 126:17 150:11 162:13
things
155:9
think
28:23 33:20 37:19,22 38:18 40:8 44:7 48:7 52:10 53:11 56:18 70:7,9 75:11 78:24 83:9 90:9, 11,14,17,24 91:2,7 92:16,21 99:19 105:10 106:5,8 110:11 111:3,14 112:15 113:6 115:24 116:5,12,20 117:10 118:18 122:11 125:20 126:5,9,16 127:17 129:12 131:2,16 138:15 140:10 141:23 150:22 151:15,20 152:2,8 154:7 156:25 157:9,19 159:24 161:6
thoroughly
114:14,19
thought
17:6
three
12:23 14:15, 16,17,18 16:9,12 51:7,9,13,17 52:5,19 68:20 85:24
three-dimensional
60:16 77:12
thrust
72:24,25
ti-
94:7
time
7:7 11:9 14:18 29:22 33:8 48:19, 20,23,24 51:22 60:13 63:17 65:17 71:16 72:11 74:4,5,8,9 106:20 108:17,18, 20,21 116:11 139:2,3,5,6, 14 142:14 154:24 160:5,6,8,9 161:21 162:3,6,7,8 163:3,18,19, 20
times
10:12
timing
92:17
tissue
78:14
tissues
77:23
titer
29:14 68:5 69:11 70:14, 20,24 71:9 119:5,12
titers
70:8 71:3 91:22,24,25
today
8:3 13:14 18:4 19:23 99:25 145:2, 3 160:13,19 161:12
today's
12:12 13:25
told
37:11
tolerance
76:17,24
toll
144:7
total
13:6 68:18
toxin
144:1,2,9, 11,13 154:9
tract
29:11,14 30:19 33:5, 11 34:1,21 45:18,20 57:15 59:8, 17,20,23 61:21 63:18 68:19 69:6 70:9,18 78:4,21 81:14 82:2,7 84:12,13,17 85:7 88:2 94:4,25 96:25 97:20 98:12 100:12 102:25 103:19 113:5 115:9 118:16,21 119:9,13 120:13 126:19,25 127:4,8,12, 15,21 128:10,17, 21,23 129:11 130:8,15,19 131:5,10,15 132:20 133:1,5

Petitioner Merck, Ex. 1129, p. 199
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

140:13
146:14
148:4,15,17,
18 149:22
150:13
159:16
tracts
128:5 146:21
transcript
9:6 162:24
163:3
treatment
147:18
148:13
149:24
150:20
152:14,20
tremendously
98:8
trial
7:16 36:15
trigger
44:22 45:4,9
119:25
triggered
117:25
triggering
44:19 119:8
140:20
triggers
154:17
Triggs-raine
23:21
Triggs-raine's
24:4
true
16:8 91:21
93:14 95:24
140:21 161:1
truth
9:14,15
try
11:5 26:12
trying
30:10 57:9,
16 68:24
70:23 73:14
82:15 83:14
91:16 92:19
125:1 143:22
151:4 152:4
tube
131:17,20
132:3
Tuesday
13:10
turn
15:7 21:8
49:24
turned
67:22
Twice
10:13
two
13:8,9
118:19
type
15:5 119:19
129:15
types
140:4 154:8
typically
35:15 143:25

U

U.S.
7:23 8:4
15:16 18:1
Uh-huh
103:3 155:15
unable
87:4,25 88:1
unaware
101:8
unclear
63:2
undergo
125:14
undergoing
63:15
understand
10:25 11:2,
14,16,24
15:14 20:8,
12 24:20
26:8 30:11
40:23 53:25
54:9 57:9,16
59:4 68:24
70:23 82:16
83:14 91:14,
16 92:19
113:2 125:1
143:22 151:5
152:4
understanding
40:18 48:2
53:11 57:13
126:1 128:11
131:7 140:11
understood
20:7 96:11,
19
unfolded
44:21,24
143:11
unique
78:18,20
unknown
33:20 67:12
unmarked
162:18
unmodified
75:3 80:20
85:14 89:16
upper
84:13,17
126:19,25
127:7,20
128:4 129:3
131:10,15
148:15,16,18
149:22
150:13
Urquhart
7:19
usage
144:10
usefulness
96:5
uterus
62:5 127:21
129:3
131:17,19
132:2
utility
21:6

V

vaccinated
146:25
vaccine
35:13 36:5
37:2 38:19
57:11 76:23
79:17,23
80:5 82:12
86:17 98:6
101:16,20,24
111:23 112:7
126:12
153:20
154:5,13
155:3,4
vaccines
21:15 27:13
34:6 35:4
37:17 74:20
79:9 96:6
115:5,16
116:3,15,24
139:11,21
140:7
142:11,19
144:19,22
145:2,9,12,
19 153:1
158:5
vagina
62:4 129:6
131:10,24
147:13,15
150:8
vaginal
73:8,13,14,
25 129:20

Petitioner Merck, Ex. 1129, p. 200
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

130:17,22,24
131:3,7
143:1 146:25
151:25
155:23
156:11
157:2,3,4
158:8
vaginally
147:10
variability
69:25
various
111:10
varying
57:6 62:18
128:20,22
version
22:18,20,23
versions
22:22
162:15,18
versus
41:12 57:6
149:24 159:9
viable
38:19 118:25
video
7:8 162:23
163:2,15
video-recorded
7:13
videographer
7:6,23
48:19,23
74:4,8
108:17,20
139:2,5
160:5,8
161:19,23
162:1,6,21
163:1,5,8,13
view
87:24 118:24
viewed
148:21
views
26:4
viral
118:3,14,24
119:3,11,21
130:12
virus
86:13 95:10
117:8,20,23
119:22
vitro
71:3,4
135:22
150:4,14
vivo
34:1 71:2,6,9,15 104:24
135:20
150:17
Volume
163:14

W

wait
155:18
Wang
8:9,10 10:5
13:4 16:21
17:5,17,25
19:2,12,17,23 21:1,21
22:2 23:8
25:5 26:12,24 27:23
28:14,24
29:19,23
30:9 32:1,12,21 33:3,9,14,21
34:2,9,15,22
35:24 36:4,8,11,13,16,19,22 37:8,18,22 38:2,13,17,21,24
39:22 40:4,18 41:4,10,17 42:2,15,20 43:23
44:12,20
45:14 46:4,11,19 47:1,13,25 48:2,17,25 49:18,24 51:13
52:2,9,17
53:2,10,16,25 54:3,9,14,17,20
55:8,22
56:5,10,21
58:5,12
59:6,13 61:6
62:20 63:21
64:2,7,11,18
65:4 66:18
67:23 68:9,24 69:21
70:3,13,19
71:12,17
73:18 74:2,10 76:1,13
77:5 78:5,24
79:6 80:3
81:20 82:4,15 83:13,25
84:7,15 85:9
86:5,12,22
87:9,21
88:4,11
89:23 90:5,11,23 91:14
92:9,25
93:8,15
94:9,24
95:17 96:10,18 97:13,21
99:7 100:8,25 101:9
102:2,10
103:21
104:9,15,21
105:4,16
106:22,25
108:3,16,22
109:12,17
110:1,11
111:8,18
112:3,19
113:8,14
114:6,19
115:11,24
116:12,19
117:3 118:11
119:10,20
120:3 121:6,13 122:6,20
123:7 124:12
126:1,13
127:5,24
129:8
130:17,24
131:3 135:3,15 136:25
137:12,18
138:17,24
139:7,17
140:15,23
141:11
142:17
143:2,22
144:4,18
145:15,18
146:5 147:6
148:5,22
149:3 150:22
152:4 153:9,14 154:20
155:12
157:5,24
158:2,19
159:2,7,18
160:2,10
161:2,9,10,18,25
162:11,13,20,23,25
want
14:23 15:19
30:11 31:25
37:20 38:13
59:4 79:12
90:22 116:17
125:4 128:6,10 136:21

Petitioner Merck, Ex. 1129, p. 201
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003

137:23
142:15
148:16 152:9
154:1 155:10
163:5
wanted
148:22
149:3,16
153:18
157:23
way
34:13,19
36:3 43:22
72:10 82:11
91:21 103:18
119:4 127:19
137:2 142:24
148:2 152:13
ways
62:1 117:22
wear
147:17
Wednesday
7:2
week
13:10 23:7,9
weeks
22:21
weight
134:23
whiplash-like
72:16
whiplike
72:16
whispering
7:11
whoa
54:1
wild
150:25
151:2,3,6,
17,21 152:2,
7,15,16,21
witness
8:8 36:17
54:8,13,16,
17,18 162:10
women
132:13 147:1
word
36:14 142:15
words
25:18 26:6
83:11 156:7
work
14:16,17
31:19 32:3,
14,25 96:12,
20 97:8,12,
14 110:4
143:14
157:17
worked
79:19,23
80:5
working
126:4 148:21
write
14:25
wrong
50:2 84:1

Y

yeah
13:3,8 18:18
23:5 24:22
25:4 27:5
29:21 31:10,
22 42:4 54:7
55:9,10
59:18 69:14
92:1,3 94:7
100:17 101:3
116:19
123:16 125:4
126:5 133:23
135:18
138:21 145:4
147:5 149:14
150:11
151:20
159:20
160:16,18

Z

Zachariah
7:22
Zhang
8:22 12:17
zona
50:18 65:22
72:25 124:23
125:19

Petitioner Merck, Ex. 1129, p. 202
Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00003