UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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MERCK SHARP & DOHME LLC,

Petitioner,

v.

HALOZYME, INC.,

Patent Owner.

_____

ORAL AND VIDEOTAPED 30(B)(6) and 30(B)(1)

DEPOSITION OF

JAMES J. MOON, PH.D

November 18, 2025

Reported By: SUSAN ASHE, CER

Job No.: 7005314

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Merck Sharp & Dohme LLC v. Halozyme Inc.
PGR2025-00053

Tuesday, November 18, 2025

8:40 a.m. Eastern Standard Time

Oral and videotaped deposition of JAMES J. MOON, PH.D. taken on behalf of the Petitioner, beginning at 8:40 a.m., on Tuesday, November 18, 2025, at the law offices of Sterne Kessler Goldstein & Fox, 1101 K~Street, Northwest, Washington, D.C., before Susan Ashe, Certified Electronic Reporter and a Notary Public of the District of Columbia.

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APPEARANCE OF COUNSEL:

On behalf of the Petitioner:

SIDLEY AUSTIN LLP
BY: JEFFREY P. KUSHAN, ESQ.
BY: CHELSEA M. HIMES, ESQ.
BY: AMIT BHATLA, ESQ.
1501 K Street, Northwest, Suite 600
Washington, D.C. 20005
(202) 736-8000
jkushan@sidley.com
chimes@sidley.com
abhatla@sidley.com

- and -

DECHERT LLP
BY: BRIAN M. GOLDBERG, ESQ.
Cira Centre
2929 Arch Street
Philadelphia, Pennsylvania 19104-2808
(215)994-4000
brian.goldberg@dechert.com

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APPEARANCE OF COUNSEL (Continued):

On behalf of the Patent Owner and the Witness:

STERNE KESSLER GOLDSTEIN & FOX
BY: PRATIBHA KHANDURI, PH.D., ESQ.
BY: R. WILSON "TREY" POWERS, III, PH.D, ESQ.
BY: ELDORA L. ELLISON, PH.D., ESQ.
1101 K Street, Northwest, Tenth Floor
Washington, D.C. 20005
(202) 371-2600
pkhanduri@sternekessler.com
tpowers@sternekessler.com
eellison@sternekessler.com

- and -

QUINN EMANUEL URQUHART & SULLIVAN, LLP
BY: ELLIOT CHOI, ESQ.
295 5th Avenue, Ninth Floor
New York, New York 10016
(212) 849-7000
elliotchoi@quinnemanuel.com

- and -

BY: NANCY L. ZHANG, ESQ.
50 California Street, Suite 22
San Francisco, California 94111
(415) 875-6600
nancyzhang@quinnemanuel.com

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ALSO PRESENT:

Aubrey Haddach, Esq., Halozyme (Via Zoom)

Joshua Mack, Esq., Halozyme (Via Zoom)

Sue Wang (Via Zoom)

Jason Levin, Videographer

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

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TUESDAY, NOVEMBER 18, 2025;
8:40 A.M. EASTERN STANDARD TIME
--o0o--

VIDEOGRAPHER: We are now on the record. The time is 8:40 a.m. Eastern on November 18, 2025.

This is the video-recorded deposition of James Moon, Ph.D., in the matter of Merck Sharp & Dohme LLC versus Halozyme, Incorporated.

This proceeding is being held at the offices of Sterne Kessler in Washington, D.C.

My name is Jason Levin. I'm a videographer on behalf of U.S. Legal Support. The court reporter is Susan Ashe, also on behalf of U.S. Legal Support.

Will counsel please state their appearances for the record, then the court reporter will swear in the witness.

MR. KUSHAN: Jeff Kushan, from Sidley Austin, for the Petitioner. With me is Amit Bhatla, Chelsea Himes, and Brian Goldberg of Dechert.

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DR. KHANDURI: This is Pratibha Khanduri, from Sterne Kessler, on behalf of patent owner Halozyme. Also in the room for Halozyme are Eldora Ellison, Ralph Powers, III, from Sterne Kessler; Nancy Zhang and Elliot Choi from Quinn Emanuel; and attending remotely are Josh Mack and Aubrey Haddach from Halozyme.

Whereupon,

JAMES J. MOON, PH.D.

having been first duly sworn, was examined and testified as follows:

EXAMINATION

BY MR. KUSHAN:

Q. Good morning. Could you state your name for the record.

A. I'm James Moon.

Q. And where do you reside?

A. I reside in Ann Arbor, Michigan.

Q. Have you ever been deposed before?

A. Yes, I have been deposed before.

Q. How many times?

A. I've been deposed twice before.

Q. Okay. Were you a patent expert in that role?

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A. Yes. I served as a patent expert in those two depositions.
Q. Okay. Were those in connection with court proceedings?
(No audible response.)
Q. Let me start with this -- let me give you a little bit of background.
A. Yes.
Q. So you've been deposed. You know the process. I will ask you questions, and you have to respond to my questions.
A. Right. Right.
Q. Okay? Your counsel may have -- make objections. Once she's finished the objection, proceed to answer my question, unless you've been instructed not to answer. Okay?
(No audible response.)
Q. If you don't understand a question I've presented to you, please let me know, and I'll try to give you a better question. Okay?
A. Okay. I understand.
Q. If you need a break, just let me know. Generally, we'll finish the answer to your question before we break, but I'll try to always take a break when you ask me for a break. Okay?

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A. Okay. Thank you.
Q. If I need to have a conversation with your counsel, sometimes I may excuse you from the room. I'll just let you know. Okay?
A. Okay. Thank you.
Q. So you understand you're under oath today?
A. Yes, I understand that.
Q. And you have to provide truthful testimony in response to the questions I pose to you.
Do you understand that?
A. Yes, I understand that.
Q. Is there any reason you cannot testify truthfully today?
A. I will always truthfully testify.
Q. When were you retained by Halozyme or by Sterne Kess- -- well, actually, who retained you?
A. I was contacted by my counsel, Pratibha.
Q. When was that?
A. I don't know the exact date, but it was a few months ago. Sometime early 2025, this year.
Q. Do you think it was in the summer of this year?
A. I don't know the exact date, but summer of this year -- between summer and fall of this year, yeah.

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Q. Okay. If you had to give me an estimate of how many hours you've worked on the matter for this proceeding, how many hours would that be?

A. I don't remember the exact hours, but I can give you a range.

I would say less than 100 hours, between 50 to 100-ish hours.

Q. Okay.

A. Yeah.

Q. What did you do to prepare for today's deposition? Just give me a general description of that.

A. To prepare for the deposition today?

Q. Yes.

A. I reviewed the literature. I reviewed the exhibits that I cited in the declaration. I met and discussed these with my counsel.

Q. Is the literature that you reviewed limited to the literature that you had cited in your declarations?

DR. KHANDURI: Dr. Moon, I would caution you to not divulge the substance of communication with counsel.

To the extent you can answer the question without revealing substance or

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communications with counsel, you can do so.

A. So I read many papers. That's part of my daily job.

And then I also reviewed the exhibits that I listed in my declaration. And they form the basis of my opinion.

Q. I just want to understand: The literature that you reviewed recently in connection with preparing for this deposition, were all the papers and other materials the ones that are on your exhibit list on your declarations?

A. Once again, I read the many papers, but the papers that I rely on for forming opinions related to this matter are stated in the exhibit list.

MR. KUSHAN: I'm going to introduce....

(Whereupon, Halozyme Exhibit 2074, previously marked, was presented to the witness.)

DR. KHANDURI: Thank you.

Q. This is your -- either four --

MR. KUSHAN: Yeah, I just want the four declarations. Can I just have them. Okay.

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Q. So the first one was your declaration in PGR2025-0003. It's this one.

The second one is your declaration -- your second one, this is the -- let's try this again.

That declaration is your declaration in the second proceeding, the -0004 proceeding.

DR. KHANDURI: Counsel, Dr. Moon has copies of his declaration. And I represent they are -- these are clean copies. Do you mind if we use that?

MR. KUSHAN: That's fine with me. And do you need copies --

DR. KHANDURI: You can take the file.

MR. KUSHAN: All right. Perfect. That saves a lot of time.

Q. All right. So you have before you --

A. Thank you.

MR. POWERS: Yes.

Q. You have before you the four declarations you have prepared in connection with the proceedings we're addressing today. Right?

That's the 2025-0003, -0004, -0006, and -0009 proceedings. Correct?

A. Yes. I have my declarations here.

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Q. And those are the declarations you prepared and signed in each of these proceedings. Correct?

A. Yes, I prepared and signed those declarations.

Q. Before you signed each of those declarations, did you review each carefully?

A. Yes, I -- I prepared and reviewed them carefully before signing them.

Q. And are there any errors in the four declarations, to your knowledge?

A. To my knowledge, there are no errors in any of these declarations.

Q. All right. During the course of the deposition today, I'm going to ask you questions, and I'll reference the declaration in the -0003 proceeding.

If any of your answers with regard to the other declarations would be different, please let me know. Otherwise, I'm going to assume that your answer with respect to the 0003 proceeding will apply to all four of the declarations you filed.

Is that fair?

A. Yes, I understand that.

Q. Okay. So, if you could, go to Page 5 of

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your declaration in the 0003 proceeding.

And do you see, at the bottom of that page is a -- it goes to the next page. You'll see a list of all the materials you say that you've reviewed in the declaration?

A. Yes. I see the list of documents considered.

Q. You reviewed each of the documents that list -- that is listed in that section of your declaration. Right?

A. Yes. I reviewed each of the documents cited here.

Q. And again, were there any other documents that you reviewed in connection with forming your opinions in this declaration and the other three declarations that are not listed on that list of exhibits?

A. Once again, I read many papers as part of my job. And all the papers that I read that allowed me to form the opinions in this declaration are listed here.

Q. And do you recall any specific papers that are not on that list that you reviewed between the sign -- time you signed your declaration and now that relate to the opinions that you're providing

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today?

A. I don't recall any other papers that are not cited here that I can think of.

Q. Okay. If you look at the list of exhibits, there's no exhibit with the number EX0-~--1001. Is that right?

A. I don't see that number in the exhibit list.

Q. Do you understand that the four proceedings that you provided declarations in relate to four different patents owned by Halozyme?

A. I understand there are four different patents that are in discussion today, yes.

Q. Have you reviewed those four different patents in connection with preparing your opinions in these four proceedings?

A. No, I have not reviewed the patents.

Q. Have you been given any information about what is in, or described in, the four patents that are the subject of these four proceedings?

DR. KHANDURI: Objection; form.

A. No. I was not given any information on these patents, and I have not reviewed them.

Q. So it's correct that none of the opinions you're expressing in your four declarations concerns

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information that's actually in any of those four patents that are the subject of these four proceedings. Is that right?

DR. KHANDURI: Objection; form.

A. I was asked by my counsel to opine whether:

> ...polyclonal antibodies generated in human females against any of the modified PH20 polypeptides to bind to wild-type human PH20 polypeptide in vivo.

And that's what I opined on in my declaration.

Q. So you limited your opinions to that question in your declaration.

And I'll also point out you have other statements following that one on Paragraph 15, other --

DR. KHANDURI: Objection --

Q. With respect to the questions that you framed in your declaration that you were asked to address, that's the basis of your opinions. Right?

DR. KHANDURI: Objection; form.

A. In addition to what I stated earlier and

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also in Paragraph 14, I have been asked to consider and opine whether...polyclonal antibodies generated in non-human female mammals against any of the modified PH20 polypeptides to bind to wild-type PH20 polypeptide in vivo, as stated in Paragraph 15.

And also, I've been asked to opine whether a POSA would have expected successful delivery of monoclonal antibodies to the vaginal cavity of human females.

So I reviewed the literature, formed my opinions, and prepared these four declarations.

Q. So you don't know whether any of the opinions you're providing in your four declarations concern any information that is in the four patents in the four proceedings. Is that right?

DR. KHANDURI: Objection; form.

A. Once again, I've been asked by my counsel these three main questions that I mentioned earlier, as stated in Paragraph 14, 15, and 16 of my declaration, and I rendered my opinions in my declaration.

I have not had a chance to review the four patents you mentioned.

Q. Okay. Did you review any documents titled "Institution Decisions" that were in the records of

the four proceedings that you're providing testimony in?

A. Could you repeat the question?

Q. Sure. Did you review any documents that have the title "Institution Decision" in any of the four proceedings that you're providing testimony?

A. I did not review those documents that you mentioned.

Q. Okay. Did you review any declarations that were prepared by an individual named Dr. Michael Hecht?

A. No, I have not reviewed any declaration that you mentioned.

Q. Did you review any declarations from a person named Dr. Sheldon Park?

A. No, I have not reviewed that.

Q. Did you review a declaration from an individual named Dr. Gary Cherr?

A. No, I have not reviewed them.

Q. Do you know who Dr. Cherr is?

A. I don't know that person.

Q. Have you ever heard his name?

A. I don't recall that name.

Q. You've never spoken to Dr. Cherr?

A. I don't recall speaking to Dr. Cherr.

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Q. Do you recall speaking to any scientist in connection with these proceedings who is not counsel?

DR. KHANDURI: Objection; form.

A. No. I only discussed these matters with the counsel here.

Q. And just to confirm, you did not review a declaration from an individual named Gregory Petsko?

A. I did not review declarations of that individual.

Q. Do you know who Dr. Petsko is?

A. I do not know Dr. Petsko.

Q. Have you ever heard his name?

A. I don't recall his name.

Q. And you haven't reviewed a declaration from Dr. Melanie Simpson. Is that right?

A. I have not reviewed declarations of that individual.

Q. And you've never -- have you ever heard her name?

A. I don't recall her name.

Q. Okay. All right. So I want to go over your educational and training background.

A. Um-hum.

Q. You have an undergraduate degree in

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bioengineering from UC Berkeley?

A. Yes, I have an undergraduate degree from UC Berkeley in bioengineering.

Q. And was that -- so that program, what was that focused on?

A. The bioengineering program at UC Berkeley focuses on different ways to come up with novel therapeutics, different ways to come up with preventive therapeutics against many different diseases.

And I was trained to develop new engineering tools to improve human health.

Q. Did you have any particular focus in your undergraduate work?

A. During my undergrad studies, I performed the research in a laboratory that studies endothelial cells in blood vessels.

Q. Endothelial cells in what?

A. In blood vessels.

Q. In blood vessels. Okay.

And then, I'm going to actually give you your CV while I have it. This is Exhibit 2075.

Just confirm that is your CV.

(Whereupon, Halozyme Exhibit 2075, previously marked, was presented to the witness.)

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DR. KHANDURI: Thank you.

A. Yes, this is my CV.

Q. Okay.

A. Exhibit No. 2075.

Q. All right. And you got your Ph.D. at Rice --

A. Yes.

Q. -- in 2008. Is that right?

A. Yes, I obtained my Ph.D. from Rice University in 2008.

Q. Okay. And it says that your dissertation was directed to synthesis of biomimetic hydrogels for neovascularization in vivo.

That's the focus you had in your dissertation. Is that right?

A. Yes. My dissertation was on synthesis of biomimetic hydrogels for neovascularization in vivo.

Q. What are the hydrogels made out of?

A. In my own work, we used a polymer called polyethylene glycol to form hydrogels.

Q. Okay. And these hydrogels, do they have a medical application?

A. Yes. These hydrogels have many potential biomedical applications.

In my own work, we use those hydrogels to

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promote new blood vessel formation.

Q. Okay. And then in 2008 -- from 2008 to 2012, you were a postdoctoral associate at MIT in the lab of Dr. Darrell Irvine. Is that right?

A. Yes. I was a postdoctoral associate in the laboratory of Dr. Darrell Irvine at MIT.

Q. And that was for a four-year postdoc?

A. It was roughly four and a half years of postdoc training.

Q. And your focus -- what was your focus in your postdoctoral work?

A. My postdoctoral work focused on vaccine development and vaccine delivery.

Q. Before you got to MIT in 2008, had you take -- had you taken courses in immunology?

A. Yes, I took courses in immunology.

Q. Was that in your postdoctoral work -- I'm sorry, in your doctoral work or in your undergraduate work?

A. I took courses in immunology in undergrad at UC Berkeley.

I also took courses on biomaterials, how -- and how they impact host systems, including immune system, during my Ph.D. work at Rice University.

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I took courses in cell biology in undergrad as well as in grad education.

Q. Did you take any coursework during your time in your postdoctoral work?

A. I attended workshops. I may have sat in a few courses during my postdoctoral work, but I did not take formal classes for credit.

Q. Were any of those courses in the field of immunology?

A. Most workshops and seminars that I attended during my postdoctoral training were related to immunology and vaccinology.

Q. And that was in that period 2008 to 2012. Right?

A. That's correct. I took those workshops and seminars between that time frame.

MR. KUSHAN: I'm going to introduce a new exhibit. This will be Exhibit 1118.

COURT REPORTER: Do you want me to put a sticker on it?

MR. KUSHAN: Yes, please.

(Whereupon, Exhibit 1118 was marked for identification.)

WITNESS: Thank you.

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Q. This is a paper entitled "Engineering Nano- and Microparticles to Tune Immunity," published in "Advanced Materials," Vol. 24, Pages 3724 to 3746, in 2012. First author, James J. Moon.

Is this a paper you authored, Dr. Moon?

A. Yes, I authored this paper in this exhibit. Yeah.

Q. Does this exhibit describe the work that you did during your postdoctoral period?

DR. KHANDURI: Objection; form.

A. I haven't reviewed this article for many years. This was published in 2012.

Q. And I'm just getting -- does this generally -- generally relate to the work that you were doing in your postdoctoral work?

A. Oh, as the title suggests, we focused on engineering nano- and microparticles to tune immune responses in this review article.

And I believe we covered many topics related to immunology and vaccine development in this review article.

Q. So the nanoparticles and microparticles you were developing were physical materials that might be included in a vaccine. Is that right?

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A. In general, in my own postdoctoral work, we developed nano- and microparticles to deliver vaccine components to improve vaccine responses.

Q. And what kinds of immunogens were you delivering in these vaccines on those particles?

A. We delivered a variety of agents, including vaccine antigens, adjuvant molecules, to boost immune responses.

Q. Were any of the immunogens proteins?

A. Yes. I worked with protein antigens during my postdoctoral training.

Q. What kind of proteins were they? Were they from humans or viruses, or what -- just give me a sense of what kind of proteins you were working with.

DR. KHANDURI: Objection; form.

A. We used the proteins from a variety of sources. One example is a protein from a infectious pathogen to boost immune responses.

Q. And those would be viral pathogens?

A. We used viral pathogens, as one of the example, for protein-based vaccines.

Q. Right. So none of your degrees are in immunology. Right?

A. My degrees are in bioengineering.

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But we use the principles of engineering to improve immune responses and use that as a basis for vaccine development.

Q. Do you believe that in December of 2012 you were an expert in -- on the human immune system?

DR. KHANDURI: Objection; form. Relevance.

A. As part of my postdoctoral training, we studied how to optimize and develop vaccines for potential applications in humans.

Q. Do you think that the education and training you obtained by December of 2012 made you an expert in the human immune system?

DR. KHANDURI: Objection; relevance.

A. As I mentioned, during my education and my postdoctoral training, I applied principles of engineering -- in particular, biomedical engineering -- to develop better vaccines.

And we do that for the purpose of developing vaccines in humans.

So whenever we design these vaccines, we have that in mind, that we want to apply our technologies to improve human health.

And I --

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Q. I'm sorry.
A. And I --
Q. Go ahead.
A. And I meet at least the qualifications of a POSA, as I stated in the declaration.
Q. Let's go to the declaration and look at that paragraph.
So do you see, at Paragraph 18, you state:

> I have been asked to apply the following definition of a POSA for purposes of my analysis provided here.

And then that is:

> A person of ordinary skill in the art would have had an undergraduate degree, a Ph.D., and post-doctoral experience in scientific fields relevant to study of protein structure and function, such as chemistry, biochemistry, biology, biophysics.

So none of your degrees are in chemistry, biochemistry, biology, or biophysics, are they?
DR. KHANDURI: Objection; form.

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A. Bioengineering is a very interdisciplinary field. It applies principles of chemistry, biochemistry, biology, and biophysics to study protein structure and function.

And in my own studies, we used principles of biochemistry -- biochemistry, biology, and biophysics, and immunology to come up with better vaccines.

Therefore, I meet at least the qualifications of a POSA as it's stated here.

Q. So if you look at the remainder of that explanation in Paragraph 18, are -- in 2012, in December of 2012, were you familiar with factors that influence protein structure, folding, and activity?

DR. KHANDURI: Objection; form, relevance.

A. Yes.

Whether it's by 2012, you mentioned -- yes, I was familiar with the factors influencing protein structure, folding, and activity.

And we use these principles to develop vaccines.

Q. So the materials that you were developing were not proteins. Right?

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A. The materials we developed were designed to contain and deliver antigens, including protein antigens, for vaccine applications.

Q. Do you recall the biggest protein that you used in one of your experimental efforts to produce a vaccine during the period before December of 2012?

DR. KHANDURI: Objection; form.

A. I used many different protein antigens as a vaccine component during my postdoctoral training.

One antigen that can -- I can think of is ovalbumin as a model antigen.

Q. Were any of the protein antigens you investigated during your work prior to December of 2012 a human protein?

A. I primarily used -- well, one of the examples that I used were infectious pathogen-derived viral antigens for vaccine applications.

I may have used a human protein in some of the studies, but I don't recall specific protein at this point.

Q. Okay. In your work before 2000- -- sorry.

When I say "2012," let's just assume it's going to be December of 2012, if I don't state that explicitly.

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So by December of 2012, had you used protein homology models in your work?

A. Yes. I used protein homology models, such as UniProt, prior to 2012.

Q. UniProt is the website that houses data about protein sequences. Right?

A. Using UniProt, one can study the sequence identity between different proteins.

Q. Had you used a protein structural model produced using a service such as SWISS-MODEL?

DR. KHANDURI: Objection; form.

Q. By December 2000- and -- December of 2012?

DR. KHANDURI: Objection; form.

A. I was in a disciplinary team, multidisciplinary team, that developed vaccines.

And there were other members who were using SWISS-MODELs for protein antigens. And I interacted with them to design vaccines.

Q. But you didn't ever personally create the models, the protein models, using SWISS-MODEL before December of 2012. Right?

DR. KHANDURI: Objection; form.

A. I did not use SWISS-MODELs personally, but I was in a multidisciplinary team.

They used SWISS-MODELs and other softwares

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to study protein structure with respect to protein antigens for vaccine applications.

Q. And I'm asking primarily about your personal experiences.

Based on your personal experiences, had you ever studied a protein structure created in SWISS-MODEL using a tool such as PyMOL or another visualization tool?

DR. KHANDURI: Objection; form.

A. Once again, I was in a multidisciplinary team, and I interacted with other researchers who are using these models, including SWISS-MODEL, to study antigen structure for vaccine applications.

And I basically perform this research in collaboration with other individuals in the multidisciplinary team.

Q. Okay. Again, just to be clear, I'm trying to understand: You were not the person doing the visualization of the protein structure with a tool like PyMOL in these teams. That was somebody else. Is that right?

DR. KHANDURI: Objection; form.

A. I mean, we, as a team, analyze the protein structure with respect to protein antigens.

I did not personally use SWISS-MODEL. But

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I was in a multidisciplinary team that used protein modeling softwares to better design vaccines.

Q. Do you know what PyMOL is?

A. I understand there are many models for protein modeling software.

Q. Do you recall if you had used, personally, PyMOL to inspect or study a protein structure before December of 2012?

DR. KHANDURI: Objection; form.

A. I -- once again, I did not personally use PyMOL, but I was in a multidisciplinary team that used protein modeling software to study protein antigens.

Q. Before December -- or by December of 2012, had you ever performed sequence alignments of two proteins?

A. Yes. By 2012, I performed the sequence alignment of proteins.

Q. Okay. By December of 2012 -- well, have you ever -- by December of 2012, had you ever -- had -- try that one again.

By December of 2012, had you ever produced, through expression techniques, a protein that incorporated mutations into it?

DR. KHANDURI: Objection; form.

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A. So I was in a multidisciplinary team that developed the vaccines.

And, for example, one of the antigens we focused on was HIV. So our team would make mutations to the antigen to better deliver the HIV antigens.

Q. Were you the person who personally produced those proteins with mutations in it -- in the protein?

DR. KHANDURI: Objection; form.

A. I worked with proteins that were mutated for HIV vaccine applications.

I did not personally produce mutated proteins, but I closely worked in a multidisciplinary team to design and develop mutated antigens for vaccine applications.

Q. Was that in the period of your postdoctoral work?

A. Yes. I worked on HIV vaccines during my postdoctoral work.

Q. By December of 2012, had you personally performed experiments where you denatured or refolded proteins?

A. Yes. By 2012, I did denatured proteins and refolded proteins.

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Q. By December of 2012, had you ever personally done work to map epitopes on a protein structure using a protein structural model?

DR. KHANDURI: Objection; form.

A. Once again, I was in a multidisciplinary team that worked on vaccine development.

Other researchers were using protein modeling softwares to study protein structures within the team.

And together, we studied how antibodies are binding to epitopes to target antigens.

Q. So somebody on the team may have done the work to determine where the epitopes on the protein structure were, and then you would discuss that within this team. Is that right?

DR. KHANDURI: Objection; form.

A. So once again, I was in a multidisciplinary team. There were researchers in the team that were primarily responsible for the modeling of software. And together with the team, we studied antibody epitope interactions.

I also studied protein epitope interactions using other tools, including ELISA.

Q. These are -- so you would test binding of antibodies to the protein using the ELISA technique?

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A. Yes. We would use ELISA as one of the techniques.

Q. And you would -- you personally performed that work, that experimental work?

A. Yes, I personally performed ELISA.

Q. And again, this was in the postdoctoral period of your career. Right?

A. Yes. It's during the postdoctoral period of my training.

Q. By December of 2012, had you ever identified a linear epitope on a protein structure?

A. Yes, I worked with linear epitopes in a protein structure by 2012.

Q. And to be clear, I'm asking if you had identified the -- let me -- I'll make it a better question.

By December of 2012, had you identified the location of a linear epitope on a protein structure?

A. Yes. By 2012, I'd identified and worked with linear epitopes in a protein structure.

Q. How did you do -- how did you do that work? How did you determine the linear epitope's location in the protein?

A. For example, you can study linear epitopes

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using ELISA.

Q. Is that how you did it?

A. I personally performed the ELISA to study linear epitopes.

I also collaborated with other researchers working on protein modeling to study linear epitopes.

Q. When you did that work, were you working with an enzymatic digest of the protein to identify fragments that the antibodies might bind to?

DR. KHANDURI: Objection; form.

A. Could you repeat the question?

Q. Sure. I'm trying to understand how you -- what the experimental technique was that you used to identify the linear epitopes.

My question was: Did you identify the linear epitopes by reacting the antibodies with fragments of the protein antigen?

A. Yes. You can study linear epitope protein -- linear epitope of a protein interacting with antibodies using fragmented protein.

Q. And just to be clear, I'm asking you: Is that how you did it back before 2012, in your experimental work?

A. In my own experiments, we do use peptide

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sequences responsible for the linear epitopes and use that as a substrate for ELISA using the antibody.

Q. Okay. How did you identify the peptides you selected to screen with in the ELISA, in your own work?

A. I first review the literature, and then study linear epitopes that have been identified in the past by other researchers, and then design peptide epitopes around those reported epitopes, and then perform ELISA.

Q. Okay. Before December of 2012, had you ever characterized the antibody repertoire created in a polyclonal response in a mammal?

DR. KHANDURI: Objection; form.

A. Yes. I studied protein repertoire of polyclonal antibodies by 2012.

Q. And to make sure I -- my question is clear, when I use the word "repertoire," I'm using it in connection with the set of antibodies produced by the polyclonal anti- -- the polyclonal response.

Is that the meaning you understood in my last question?

DR. KHANDURI: Objection; form.

Also, Counsel, do you mind

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speaking a bit louder?

MR. KUSHAN: Sure.

DR. KHANDURI: I'm having a hard time.

A. Could you repeat the question?

Q. Of course.

A. Yeah.

Q. In the last question, I asked you -- or the -- I had asked about the repertoire of antibodies produced by a polyclonal response, and your answer used the word "polypeptide" -- or "protein."

I just want to make sure that you understood my question.

I was asking if you would characterize the set of antibodies produced in the mammal in response to the immunization, that -- that polyclonal sera, did you characterize antibodies in that polyclonal response?

DR. KHANDURI: Objection; form.

A. Yes, I characterized polyclonal antibodies in sera.

Q. And that was before December of 2012?

A. Yes, that's right, before December 2012.

Q. Okay. And had you compare -- did you

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compare the diversity of the antibodies within the polyclonal sera one to the other for their ability to bind to the target protein?

DR. KHANDURI: Objection; form.

A. I characterized polyclonal antibodies developed in sera and compared polyclonal epitopes from different sera.

Q. So you were screening the collection of antibodies against, for example, an antigen that had been immobilized. Is that one --

DR. KHANDURI: Objection; form.

A. I would have study/studied how polyclonal antibodies in sera were to bind to target protein antigen.

Q. All right. Before 2013 -- by December of 2012, had you done experimental work where you had induced a polyclonal response to a mutated form of a protein?

DR. KHANDURI: Objection; form.

A. By 2012, I studied how mutated form of antigens affect polyclonal antibody responses.

Q. By December of 2012, had you performed any research that investigated the effects of immunization of an individual or a mammal as to the effects of the antibody production within the

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reproductive tract of the animal?

DR. KHANDURI: Objection; form.

A. Yes, I studied how vaccine can induce antibody responses in vaginal tract in animals, by 2012.

Q. All right. Do you have any medical training?

DR. KHANDURI: Objection; form.

A. I have my degree in bioengineering in undergrad and Ph.D. And that's interdisciplinary major that trains engineers in biomedical applications.

Q. Before this case, had you ever investigated the PH20 polypeptide?

A. I have not performed any research on PH20 polypeptide.

Q. Had you performed any research on any enzymes?

A. Yes, I performed research on enzymes before 2012.

Q. Did you perform research on enzymes that had been mutated before 2012?

A. I don't recall if I worked with mutated enzymes before 2012. I worked with mutated antigens before 2012.

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Q. And just to reiterate, do you believe that you are a person of ordinary skill in the art as of December of 2012, according to this set of patents?

DR. KHANDURI: Objection; form.

A. Yeah. As I stated in Paragraph 19 in my declaration, I had a list of qualifications of a POSA by December 2012.

MR. KUSHAN: We've been going for about an hour. Do you want to take a break?

WITNESS: Sure.

MR. KUSHAN: Okay. We can just -- five minutes or so?

WITNESS: Yeah.

DR. KHANDURI: Sure.

WITNESS: Thank you.

VIDEOGRAPHER: We're off the record at 9:37 a.m.

(Whereupon, a recess was taken.)

VIDEOGRAPHER: We are going back on the record at 9:55 a.m.

BY MR. KUSHAN:

Q. Dr. Moon, during the break, did you speak with anybody?

A. Yeah. During the break, I spoke with

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counsel, a few members of the counsel.

Q. What did you speak about?

A. We spoke about matters not related to the case.

Q. What was that?

A. We talked about life extension. Yeah.

Q. Before the break, we were discussing some of your work with identification of linear epitopes.

Were there any other techniques you can recall using, before December of 2012, to identify or characterize linear epitopes on protein?

A. Do you mean, other than protein modeling in ELISA, what other technique's available?

Q. Correct.

A. There are approaches to study peptide epitopes. And one of the techniques would be something called "ELISpots."

It's a variation of ELISA that immunologists use to study peptide linear epitopes in B lymphocytes and other lymphocytes.

Q. And did you use those techniques, personally, before December of 2012?

A. Yes, I used those techniques before 2012.

Q. That was the -- I'm sorry. Could you spell the technique?

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A. "ELISpot" is spelled E-L-I-S-p-o-t.
Q. And that was done with peptides that were synthesized?
A. Yes. ELISpots can be done using peptides, as well as the whole protein as well.
Q. How were the peptides selected for those experiments?
A. As we discussed before, these linear epitopes, as well as peptides used by ELISpots, can be selected based on prior work done in the literature, as well as other techniques where those linear epitopes are varied and synthesized and tested using ELISpot or ELISA.
Q. And I'm interested in understanding how the particular sequence of the peptide was selected that would be then used and made and tested.
DR. KHANDURI: Objection; form.
Q. Could you just explain that?
DR. KHANDURI: Objection; form.
A. So, in general, immunologists and vaccinologists would fragment proteins into smaller domains and incubate B cells or T cells using those fragments, and then study cytokine production.
And once you find the specific fragments that are inducing cytokine production, you can dig

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deeper into smaller and smaller fragments until you find those linear epitopes.

Q. So that technique involves basically making enzymatic -- enzymatic fragments of the protein, and then that would be the starting point for that line of investigation?

DR. KHANDURI: Objection; form.

A. Yes, you can use enzymatic degradation of a protein to arrive at fragmented proteins for those experiments.

Q. And in the work that you did before December of 2012, did you use any computational techniques to identify linear epitopes that you would then study?

A. As I mentioned before, I was in a multidisciplinary team of vaccine development, and we, as a team, used protein modeling software and use that to find epitopes that are bound by antibodies.

Q. How did you find the epitopes using computational methods in the -- in your -- in that work that you just described?

A. For example, you could perform docking experiments to see how specific antibody is binding to specific domains with -- within the target

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antigen.

Q. Is that a computational method?

A. That's a --

DR. KHANDURI: Objection; form.

A. That's a computationally based protein modeling approach where antibodies docking to a specific protein antigen can be studied.

But as I mentioned, there are other tools available to study, including ELISA and ELISpots.

Q. Okay. In that answer you just provided, I just want to make sure that you understood my question, which was: Did you use, personally, those techniques, such as the docking technique that you just mentioned, in your work before 2012?

A. As I mentioned before, I did not personally perform protein modeling or computationally based docking experiments in silico.

But I was in a team that performed these studies, and I would follow up their results using ELISA and ELISpot.

Q. All right. Could I ask you -- that you pick up your declaration in the 600- -- in the 6- -- sorry, -0003 proceeding, and go to Paragraph 14.

And do you see, at the bottom of Page 4, in Paragraph 14, there's a statement:

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Throughout, I use the phrase "modified PH20 polypeptides" to refer to polypeptides comprising an amino acid sequence that is at least 95% identical to the amino acid sequence of any one of SEQ ID NO: 3 and 32-66, and include a modification at position 320 such that D is replaced by [sic] H, K, R, or S.

So this is defining a set of modified PH20 polypeptides that can have different amino acid sequences. Right?

A. Yes. This is referring to modify the polypeptide PH20 with different peptide sequences.

Q. Do you know how many changes to the amino acid sequence are permitted by the language that you have used to associate with the phrase "modified PH20 polypeptides"?

DR. KHANDURI: Objection; form.

A. I understand the phrase "modified PH20 polypeptides" refer to polypeptides comprising an amino acid sequence that is at least 95% identical

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to the amino acid sequence of any one of Sequence ID 3 and 32-66, and include modification at position 320, such that these replaced with H, K, R, or S.

And based on this description, as long as there is modification at position 320 and potential modifications so that at least 95% is identical to the Sequence ID 3 and 32-66, that would meet the definition of modified polypeptide PH20.

Q. So in that set of modified PH20 polypeptides, what is the maximum number of amino acid changes that are permitted to the -- any individual PH20 polypeptide?

DR. KHANDURI: Objection; form.

A. I have not calculated the maximum number of mutations allowed to meet the definition of modified PH20 polypeptides.

But I -- I can go through calculations, if I'm given enough information and time.

Q. So before you signed your declarations, you had not performed that calculation?

A. I have not calculated the maximum number of mutations allowed under this definition.

Q. Do you know or have an understanding of how many different amino acid sequences are captured

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by the definition of the modified poly- -- PH20 polypeptides that you use in your declaration?

A. I know the Sequence ID No. 3 and 32-66 comprise at least 430 amino acid long sequences.

And as long as modified PH20 polypeptide meet the definition of 95% sequence identity and modification at position 320, that would meet the definition of modified PH20.

Q. Right. My question was a little bit different.

I'm asking if you know how many different polypeptide sequences will satisfy those parameters that you've set forth in the definition of modified PH20 polypeptides.

A. Once again, I have not calculated the maximum number of mutations or different variations of modified PH20 that meet the definition.

Q. Do you understand that the modifications that may be covered by this language include additional amino acid substitutions in the sequence?

DR. KHANDURI: Objection; form.

Q. Besides the one at position 320, for example?

A. As long as there are at least 95% sequence identity and position modification at 320, that

would meet the definition of modified PH20.

Q. So amino -- other amino acid substitutions would be permitted, then. Right?

(No audible response.)

Q. Other positions in the protein sequence?

A. Under this definition, of course I would understand amino acid substitutions.

Q. And other kinds of modifications could include a deletion of amino acids from the amino acid sequence. Is that right?

A. Deletions -- of course I would understand amino acid modifications or deletions are allowed under modified PH20 polypeptide definition, as long as there is 95% sequence identity and modification at 320.

Q. And the amino acid substitutions that would be covered by this language would include a change from the wild-type amino acid at any position to any of the other 19 amino acids. Correct?

DR. KHANDURI: Objection; form.

A. Yeah. Of course, I would expect modified PH20 with amino acid substitutions would meet the definition of modified PH20, as long as there is 95% sequence identity and modification at position 320.

Q. In your other three declarations, you use

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a similar definition of modified PH20 polypeptides. But those refer to other specific positions, such as 313, 317, and 312. Correct?

DR. KHANDURI: Objection; form, foundation.

Q. They're all in Paragraph 14 of each declaration.

A. In the case -004, in Paragraph 14, I understand "modified PH20 polypeptide" refers to polypeptides comprising of an amino acid sequence that is at least 95% identical to the amino acid sequence of any of Sequence ID No. 3, 32-66, and include the modification of position 313 selected from A, H, K, L, P, R, and Y.

In the case of -006, in Paragraph 14, I understand the "modified PH20 polypeptide" refers to polypeptides comprising of an amino acid sequence that is at least 95% identical to the amino acid sequence of any of Sequence ID No. 3, 32-66, and include a modification at position 317 selected from H, I, K, M, Q, R, and S.

In the case of -009, in Paragraph 14, I understand "modified PH20 polypeptide" refers to polypeptides comprising of an amino acid sequence that is at least 91% identical to the amino acid

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sequence of any one of Sequence ID No. 3, 7, and 32-66, and include a modification at position 312 selected from G, K, L, N, and T.

So those are the differences in those four cases.

Q. Based on your understanding of those four definitions, do you believe that the size of the set of modified PH20 polypeptides covered by the phrase "modified PH polypeptides" is different in a meaningful way?

DR. KHANDURI: Objection; form.

A. I understand, in those four cases, the specific amino acid modifications required are different.

In particular, the single amino acid mutation position is different from one to another, and the sequence identity percentage allowed is also different.

Q. But it's a similar size, 95, 91 --

DR. KHANDURI: Objection; form, foundation.

A. The ranges are different from at least 91% to 95%, and specific amino acid modification positions are also different in four cases.

Q. Would it surprise you to learn that the

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number of distinct polypeptide sequences within each of these sets that are modified PH20 polypeptides is on the scale of 1049 or higher sequences?

A. I have not done the --

DR. KHANDURI: Form --

A. -- calculations.

DR. KHANDURI: Sorry.

Objection; form.

Q. When you formed your opinions, were you visualizing the set of modified PH polypeptides to have that many different polypeptide sequences in each set?

DR. KHANDURI: Objection; form.

A. I didn't personally calculate the number of mutations allowed.

But I understood this definition allows many different variations of modified PH20, and I used that definition to form the basis of my opinion.

Q. But you didn't have a specific number of different amino acid sequences in the set of modified PH20 polypeptides in mind when you were forming your opinions?

DR. KHANDURI: Objection; form.

A. I applied the definitions of modified PH20

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given by my counsel. And I understood there are many variants of modified PH20 in each case.

And I factored that into forming my opinions.

Q. When you formed your opinions in the four declarations, did you contemplate any particular modified PH20 polypeptide that included 15 or more substitutions, additions, or deletions to the amino acid sequence?

DR. KHANDURI: Objection; form.

A. So in each of these four cases, modified PH20 allows for single epitope mutations at a specified position, with sequence identity ranging from 91 to 95%.

Q. All right. Dr. Moon, I was asking you a little bit different question.

So I'm asking you to tell me: When you were considering the effect of changes to this set of polypeptide sequences, did you contemplate one example of a PH20 polypeptide that incorporated, in addition to one of those single mutations at positions 3, 23, 13, 317, or 312, addition -- 15 additional changes to the protein sequence?

That's what I'm asking.

Did you consider --

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DR. KHANDURI: Objection --
MR. KUSHAN: Sorry.
Q. I want you to consider -- like I want you to -- I want you to tell me whether you had visualized in your mind that particular type of modification to the modified PH20 polypeptide when you were forming your opinions --
DR. KHANDURI: Object --
Q. -- 15 additional substitutions besides the one that's specified.
DR. KHANDURI: Objection; form.
A. It's my understanding that addition of 15 additional amino acid sequences into definition of PH- -- modified PH20 would still meet the definition of modified PH20, as long as there is the sequence identity ranging from 91 to 95% and amino acid modifications and specify the location.
So 15 amino acid modifications would still meet the definition of modified polypeptide PH20 under each case.
Q. All right. Let me try this again.
Go back to the time before you signed your declaration.
At that point in time, when you signed your declaration, had you evaluated any single

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modified PH20 polypeptide that incorporated a substitution at position 320 and also imported -- incorporated 15 or more additional substitutions into the amino acid sequence?

DR. KHANDURI: Objection; form.

A. It's my understanding that the structure you described meet the definition of modified PH20 polypeptide.

Q. Do you understand my question is asking you about whether you considered that specific example of a PH20 polypeptide before you signed your declaration?

DR. KHANDURI: Objection; form.

A. I mean, I considered many different variations of modified PH20. And as long as you meet the definition outlined in Paragraph 14, that -- that is what I used to form the opinions of my declaration.

Whether I specifically imagined 15 amino acid modifications -- 15 amino acid modifications would fall within the range of modifications I would have considered.

Q. I'm asking you a slightly different question. I'm only asking you what you did back then before you signed your declaration, not whether

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it is possible that one that has 15 additional changes meet the definition.

What specific examples of modified PH20 polypeptides did you consider before you signed your declaration when you were forming your opinions?

DR. KHANDURI: Objection; form.

A. I considered many different variations of modified PH20. I considered, for example, adding a PADRE peptide, as an example.

I also considered deletion of specific amino acid, as that meets the definition of modified PH20.

So I considered many possibilities of modified PH20.

Q. So in the example where you're adding the PADRE sequence, what was the sequence that you were adding to the starting PH20 polypeptide sequence?

If you want to look at Paragraph 32 of your declaration, that's where you discussed the PADRE.

A. Thank you.

Could you repeat your question?

Q. I'm asking: So you mentioned a specific example where you added a PADRE sequence to the amino acid sequence of PH20.

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Was this inserted into the middle of the sequence, or was it put at the end, either end, of the PH20 sequence? Which -- what was the addition?

DR. KHANDURI: Objection; form.

A. PADRE is known as a pan-DR binding epitope peptide, a strong helper T cell epitope peptide.

So the location of PADRE within polypeptide would not matter that much, if that -- that's what you're asking.

Q. No. Let me try my question again.

You mentioned -- you indicated that you had considered, before you signed your declarations, an example of a PH polypeptide that you had added the -- a PADRE sequence to.

And I'm just trying to understand: What was that example that you were discussing?

Was the PADRE sequence added at the end, or C-terminus, of the protein, or was it inserted into the sequence?

Just explain what the example was.

DR. KHANDURI: Objection; form.

A. I don't recall the exact locations of where PADRE was inserted in this particular exhibit.

But I, as well as a POSA, would understand, regardless of location of where PADRE

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was inserted -- either at N-terminus or in the middle or at C-terminus -- having PADRE would result in antibody responses to the antigen.

Q. Again, my question is about the example that you mentioned that you had considered, not possible changes.

So for the example that you considered before you signed your declaration, how many amino acid sequences were in the PADRE sequence that you added to the PH20 polypeptide?

DR. KHANDURI: Objection; form, foundation.

A. I don't recall the exact amino acid length of the PADRE. I think it ranges from 10 -- amino acid sequence 10 to 20.

And I considered adding PADRE to various locations within modified PH20 and still meet the definitions of modified PH20 specified in Paragraph 14.

Q. And what -- would it be -- what -- those locations, were they all just an insert of the PADRE sequence into the PH20 sequence?

DR. KHANDURI: Objection; form.

A. I considered the insertion of PADRE into N-terminus or at C-terminus or in the middle of

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modified PH20.

I also considered replacing specific amino acids within PH20 with the PADRE sequences; hence, to meet the definition of modified PH20 outlined in Paragraph 14.

And that's what I went -- what I considered when I formed my opinions.

Q. Do you recall if you had kind of constructed the sequence of all these different examples in order to evaluate each one?

DR. KHANDURI: Objection; form.

Q. And -- sorry. Let me clarify my question.

I assume you didn't synthesize the polypeptide. But I want to understand if you created a digital listing of the amino acid sequences of all these examples that you considered.

DR. KHANDURI: Objection; form.

A. Could you repeat the question?

Q. Sure. I'm just trying to understand: When you did this, you made these sequences that you referred to, did you type them up to have the sequence on your computer of the three or four examples that you just mentioned?

DR. KHANDURI: Objection; form.

A. I pictured them in my mind rather than

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using computer.

Q. So you --

A. I pictured introducing PADRE into modified PH20.

Q. Was there a particular PADRE sequence that you were picturing in your mind being added into the PH20 sequence?

DR. KHANDURI: Objection; form.

A. PADRE is a well-known peptide sequence with ability to bind to helper T cell epitopes.

I don't recall the exact amino acid sequence, but that's just an example of potential modifications to modified PH20.

Q. Did you construct a structural model of the PH20 polypeptide which incorporated the PADRE sequence in it?

DR. KHANDURI: Objection; form.

A. I did not use any computational modeling software to study modified PH20 containing PADRE sequence.

But I basically pictured modified PH20 containing PADRE sequence and how that would generate polyclonal antibody responses.

Q. In the example that you mentioned of inserting the sequence within the middle of -- or

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inside of the sequence of PH20, do you remember where you would have positioned the PADRE sequence in the overall PH20 sequence?

DR. KHANDURI: Objection; form.

A. As I mentioned, as long as there's a PADRE sequence within any locations within modified PH20, that would result in very strong antibody responses.

So I pictured inserting PADRE into -- either at N-terminus, C-terminus, or anywhere along the internal residues of modified PH20.

Q. But am I correct in understanding that you created no written or digital records of the sequences that you were contemplating as part of this assessment of the PADRE sequence in the PH20 sequence?

DR. KHANDURI: Objection; form.

A. Once again, I pictured inserting PADRE sequences to any locations within at least 430 amino acid long modified PH20.

I did not write them down or recorded them in my computer.

Q. Did you consider, in the course of your work in this case, sequences -- starting PH20 polypeptide sequences other than the one that terminates at position 430?

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DR. KHANDURI: Objection; form.

A. My understanding is Sequence ID No. 3 and Sequence ID 32-66 describe polypeptides that are at least 430 amino acid long -- at least 430 amino acid long.

Q. Was there a maximum length of the sequence in -- in the PH20 polypeptide that you considered?

A. It's my understanding that Sequence ID No. 7 is the longer version of PH20.

Q. Do you know whether SEQ ID 7 contains the GPI anchor sequence of PH20?

DR. KHANDURI: Objection; form.

A. I do not know that.

Q. Did you consider each of those sequences that you just listed -- 3 and 32-66 -- individually when you were forming your opinions in this case?

A. When I formed my opinions in this case, I examined all the sequences listed in the exhibit, including Sequence ID No. 3, 7, and 32-66.

Q. So using, for example, the 95% sequence identity boundary, do you understand that accommodates up to 22 changes to the starting polypeptide sequence?

DR. KHANDURI: Objection; form.

A. I need to do the calculations to arrive at

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maximum number of allowed modifications that still meet the definition of modified PH20.

Q. Okay. But I'm -- am I correct in understanding that in the work that you did to prepare your opinions, you did not write out a series of amino acid sequences that incorporated one, two, five, 10, or more discrete changes within the amino acid sequence of the PH20 polypeptide?

DR. KHANDURI: Objection; form.

A. Once again, I mentally pictured making modifications to PH20. I did not write down all the possible sequence variations of modified PH20.

Q. If you were a person of ordinary skill working in a lab, and you were asked in December of 2012 to identify a PH20 polypeptide that would tolerate 20 changes to it that could be used as an immunogen in a vaccine, would you only evaluate that in your mind?

DR. KHANDURI: Objection; form, relevance.

A. Could you repeat the question?

Q. Sure. So if you were a person of skill in the art --

A. Um-hum.

Q. -- and you were asked to devise a modified

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PH20 polypeptide with 20 changes in it in order to evaluate whether that modified PH20 polypeptide would be a suitable immunogen in a vaccine, would you only consider the changes to that polypeptide sequence in your mind?

DR. KHANDURI: Objection; form, relevance.

A. As I mentioned in Paragraph 14, a POSA would have expected that polyclonal antibodies generated in human females against any one of the -- any of the modified PH20 polypeptides would bind to the wild-type human PH20 polypeptide in vivo.

And looking at potential modifications of PH20 to meet the definition of modified PH20 polypeptides, a POSA would have expected to generate polyclonal antibodies using all the variations allowed under the definition of modified PH20.

Q. So, Dr. Moon, I was asking you a very different question than the one you just answered.

My question was: In how you would go about identifying modified PH20 polypeptides that have up to, let's say, 20 changes in the sequence, in December of 2012, as a person of ordinary skill in the art, in order to evaluate those modified PH20 polypeptides as candidates for a potential vaccine,

you certainly wouldn't have only considered these possible changes to the sequence in your mind. Right?

DR. KHANDURI: Objection; form, relevance.

A. As I mentioned before, a POSA would expect to generate polyclonal antibodies using a --

Q. I'm sorry. I'm going to interrupt you because you're --

A. Yeah.

Q. -- not answering the question I'm presenting to you. And I'd like you to understand my question.

So I'm asking -- my question is --

DR. KHANDURI: Counsel, please let --

MR. KUSHAN: Yeah.

Q. My question was -- I -- my question was asking you about how you would go about designing and evaluating a particular modified PH20 polypeptide, in December of 2012, that incorporated up to 15 or 20 changes to the amino acid sequence.

I was asking how you would go about that process, and whether you would only consider the sequence in your mind as far as the change sequence.

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That's the question I'm asking.

Do you understand that question?

DR. KHANDURI: Objection; form.

And, Counsel, please do not interrupt the witness.

MR. KUSHAN: Counsel, you've done it to our witnesses, and we don't want to waste time.

I understand you wanted to start early, so I'm to get an efficient examination conducted. So if he's answering a question I didn't ask, I'm going to ask him to answer the question I asked.

Q. So, Dr. Moon, I just want to understand: If you were going about the process of considering a modified PH20 polypeptide that had 15 changes in it, in December of 2012, as a person of ordinary skill in the art, as to whether that modified PH20 polypeptide would be a suitable immunogen in a vaccine, would you only consider the sequence of that change -- protein in your mind?

DR. KHANDURI: Objection; form, relevance.

A. I mean, as I outlined and written in my

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declaration, so modified PH20 can generate polyclonal antibodies. And there are many tools available for a POSA to generate polyclonal antibodies using modified PH20.

And PADRE is just one example where short amino acid sequences are introduced in modified PH20 to generate polyclonal antibody responses.

So there is a reasonable expectation that a POSA would have that all modified PH20 that meet the definition of Paragraph 14 would generate polyclonal antibody responses.

Q. Dr. Moon, what did you understand my last question to be asking you?

DR. KHANDURI: Objection; form.

A. I think you are asking whether modified PH20 would generate antibody responses.

Q. See, that's where we may have a disconnect. That was not what I was asking.

I was asking about a person of skill in the art, in 2012, trying to figure out which changes to a modified PH20 could be made that would render it suitable as an immunogen in a vaccine.

And my focus was the methodology you would follow to devise those amino acid sequences.

I wanted to confirm, if you're a person of

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skill in the art being asked to devise a new PH20 polypeptide sequence with 15 changes to it, in December of 2012, you would not do all that work in your mind. You would create the sequence and you would evaluate the sequence using your computer and other tools.

Is that fair?

DR. KHANDURI: Objection; form, relevance.

A. I understand your question, yes. Yes. So let me answer that. Yeah?

Q. Sure.

A. Yeah. So as of 2012, a POSA would have understood modified PH20 that meet the definition of that shown in Paragraph 14 would all generate polyclonal antibodies.

If your question is how to choose the best candidate for vaccine applications, a POSA would have tested them.

But if you are asking -- but you are not asking, what's the best candidate antigen. Right? You are asking whether making these modifications -- oh, no. I take that back.

The question you are asking is: How to choose the best candidate antigen that generates

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strongest antibody responses?

If that's the question, a POSA would run the study.

But as I understand, modified PH20 that meet the definition shown in Paragraph 14 would be expected to generate polyclonal antibodies after vaccination.

Q. So, Dr. Moon, I -- there's a significant disconnect between what I'm saying and what you're understanding. And I want to work through this so we can have a more efficient deposition.

What I'm asking about is the procedures a person of skill would have followed in evaluating a possible change to the PH20 polypeptide; not whether it would cause an effect as an immunogen in the future, as to the process they go about to evaluate a modified PH20 polypeptide sequence.

I'm asking you, very simply: Would they have written out a variety of different possible amino acid sequences and considered those individual sequences as to the impact those changes would have on the PH20, just as a methodology to consider the sequences?

DR. KHANDURI: Objection; form, relevance.

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A. I was asked by my counsel to opine whether modified PH20 would generate polyclonal antibodies in human female tract.

And it's my opinion that -- and also a POSA would agree that modified PH20 polypeptides would generate polyclonal antibodies in human female reproductive tract.

We are not asking what is the best candidate antigen among all these variations.

I think your question is whether -- which one is the best candidate antigen? In that case, you could write down the sequences and perform studies.

But a POSA would expect all modified version of PH20 would generate polyclonal antibodies in human female tract, as outlined in the declaration.

Q. And when you say "all" modified PH20 polypeptides in that answer you just provided, you're speaking of the 1049 different amino acid sequences that meet the requirements of the modified PH20 polypeptides in Paragraph 14 of your declarations. Right?

DR. KHANDURI: Objection; form, foundation.

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A. I have not done calculations to variations of modified PH20.

But it's my opinion that all the modified PH20 polypeptides that meet the definition as outlined in Paragraph 14 would generate polyclonal antibodies.

Q. And it's your opinion that if that set of modified PH20 polypeptides includes 1049 different polypeptide sequences, every one of those polypeptide sequences, when administered to a mammal, will induce antibodies that binds to the wild-type PH20.

Is that your testimony?

DR. KHANDURI: Objection; form.

A. Once again, I have not calculated the number of potential mutations and variations of modified PH20.

But it's my opinion that all the allowed modifications to PH20, as outlined in 14, would result in polyclonal antibodies generated in female mammals against any of the modified PH20 polypeptides, would bind to the wild-type PH20 polypeptide in vivo.

DR. KHANDURI: Counsel, it's been about an hour. Can we take a break

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soon?

MR. KUSHAN: Would you like to take a break?

WITNESS: Yes.

MR. KUSHAN: Okay. We'll take a break.

VIDEOGRAPHER: Off the record at 10:52 a.m.

(Whereupon, a recess was taken.)

VIDEOGRAPHER: We are going back on the record at 11:18 a.m.

BY MR. KUSHAN:

Q. So, Dr. Moon, did you speak to anybody over the break?

A. Yes. I talked briefly with my counsel during the break.

Q. What did you talk about?

A. We continued to talk about lifespan extension, yeah. Nothing related to the cases.

Q. All right. So do you remember earlier, at the beginning of the deposition today, I told you that, in the deposition, I ask you a question and you have to answer the question I put to you.

Do you understand that?

A. Yes, I understand that.

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Q. All right. And you understand that over the last session of questions and answers, there was a disconnect between the questions I put to you and the answers you were providing to me. You were not answering my questions.

Do you appreciate that?

DR. KHANDURI: Objection; form, foundation.

A. I think I answered your question during the last session.

Q. So do you recall I asked you one question about the methodology someone might use in evaluating a mutated poly- -- PH20 polypeptide, and your understanding of my question seemed to be, would I -- how do I find the best version of a PH20 polypeptide to use as a vaccine? And that's a disconnect.

So I'd like you to please listen carefully to the question that I present to you and answer the question that I present to you directly.

If you don't understand the question I've presented to you, tell me you don't understand it, and I'll try to give you a better question.

If we go through the day today and you cannot answer the question that I'm asking you, we

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may need to have another deposition.

So I wanted you to understand that you have to -- we're entitled to ask you questions, and we're entitled to get your answers to my questions that I've put to you.

Do you understand that?

DR. KHANDURI: Objection; form.

A. I understand that.

Q. Great. Could you go to your declaration and go to Page 12 and look at Paragraph 22.

A. This is Case -0004?

Q. -0003.

A. -3?

Q. Yes. Do you have the -0003?

A. I used to have. Wait.

Q. Did you put those back?

A. Yeah.

MR. KUSHAN: Could you go look and see if there's a -000- --

DR. KHANDURI: Oh. You want me to take....

MR. BHATLA: -- -03 is down there.

COURT REPORTER: I'm sorry.

MR. BHATLA: Six.

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WITNESS: Thank you.
MR. KUSHAN: It's always important to have the same document.
WITNESS: Yeah.
DR. KHANDURI: Counsel, could you give all four declarations to the witness, please.
(Exhibits handed to the witness.)
DR. KHANDURI: Thank you.

BY MR. KUSHAN:

Q. All right. So go to Page 12, Paragraph 22.

A. Yes. I'm looking at Paragraph 22.

Q. All right. Do you see there's a figure above Paragraph 22?

A. Yes, I see the figure.

Q. Okay. And it's illustrating different -- different antibodies, each binding to a distinct epitope on the antigen, as it's depicted in the picture -- figure. Right?

A. The figures are showing monoclonal antibodies, the antigen with the different epitopes, and polyclonal antibodies.

Q. Okay. So when you immunize a subject with an antigen, you'll produce B cells that each

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individually produce one antibody. Right?

A. Each B cell produces one type of monoclonal antibody.

Q. Okay. And using the illustration you have on Page 12, different B cells will be the source of each of the different antibodies binding to a different epitope on the antigen. Right?

DR. KHANDURI: Objection; form.

A. Yes. In general, B cells produce monoclonal antibodies to each epitope. And when you have a collection of B cells, they would cover polyclonal antibodies.

Q. Okay. So if I have immunized a mammal with an antigen and there's polyclonal antibody response to that immunization, it creates a repertoire of B cells that produce, each of them, a different antibody that collectively make up the antibodies in the polyclonal antisera.

Is that a fair statement?

DR. KHANDURI: Objection; form.

A. After vaccination, each B cell will produce monoclonal antibody, and collection of the B cells will produce polyclonal antibodies with a diverse repertoire.

Q. Okay. Now, if you go to Paragraph 42 of

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your declaration. This is on Page 24.

Do you see, in the middle -- in the second sentence, you state:

> ...POSAs would have expected that each of these polypeptides would present numerous epitopes to the host's immune system when administered as a vaccine to a human female.

And that's referencing the set of modified PH20 polypeptides -- well, sorry, the set -- that's referring to the set of wild-type polypeptides that are in SEQ ID 3 and 32-66. Right?

(Witness reading.)

A. I see the sentence in Paragraph 42.

Q. And you understand -- and your testimony there is that a POSA would have expected that the different polypeptides in that set would each present numerous epitopes to the host's immune system when that polypeptide was administered as a vaccine to a human female. Right?

A. In Paragraph 42:

> PH20 polypeptide with amino acid sequence of any of Sequence ID No. 3 and 32 and --

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to 66 are at least 430 amino acids long. Thus, POSA would have expected that each of these polypeptides would present numerous epitopes to the host's immune system when administered as a vaccine to a human female.

Q. Okay. So when a mammal is immunized with one of those PH20 polypeptides, will antibodies to every one of the epitopes on the modified PH20 polypeptide be produced during that polyclonal antibody response?

DR. KHANDURI: Objection; form.

A. As I mentioned earlier, modified PH20 polypeptides will generate polyclonal antibody responses.

And every one of modified PH20 would be expected to generate polyclonal antibody responses.

Q. And my question was: Would the immunization with the PH20 polypeptide cause the mammal to produce antibodies to every epitope on the PH20 polypeptide?

Do you understand my question?

A. I understand your question.

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Q. Could you answer my question now?
A. When you perform immunizations with polypeptides with multiple epitopes, as in PH20, you expect to get polyclonal antibody responses to multiple epitopes within that polypeptide.
There may be some epitopes that may not generate antibody response. But, collectively, the polypeptide has numerous multi-epitopes. Therefore, a POSA would expect to get polyclonal antibody responses covering a multitude of epitopes.
Q. What types of epitopes on the PH20 would not induce production of antibodies against them?
DR. KHANDURI: Objection; form.
A. In general, when there are multiple epitopes present in an antigen, they will generate polyclonal antibodies against the multiple epitopes.
There may be some epitopes that do not generate antibody response, but the majority of epitopes found within the polypeptide will generate antibody responses.
And we are focused on the mixture of antibodies within the polyclonal repertoire. So you anticipate generating polyclonal antibodies covering the majority of epitopes found within that polypeptide.

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Q. Okay. And my question, again, is focused on -- not the majority of the epitopes being bound by the antibodies in the polyclonal.

I'm speaking to the -- what you acknowledge, there are some epitopes that may not induce production of an antibody against those epitopes. I'm asking you about those epitopes.

And then, my specific question is: What might cause the immune system to not produce antibodies against those epitopes?

Do you understand my question?

A. Yes, I understand your question. Yeah.

Q. So please answer my question.

A. In general, there are multiple epitopes present within polypeptide.

And when you vaccinate individual, they will generate polyclonal antibodies covering a multitude of epitopes within the polypeptide.

And there are many research tools available that a POSA would use to generate polyclonal antibody responses to even broader number of epitopes present within that polypeptide structures.

Q. So that answer does not an- -- that does not answer the question I asked.

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I was asking you about the epitopes on the PH20 polypeptide that may not induce production of an antibody response against those particular epitopes.

And I'm asking you: What are the reasons why the immune system might not produce antibodies against certain of those epitopes on the PH20 polypeptide?

DR. KHANDURI: Objection; form.

A. There are some epitopes that could generate high antibody response with high affinity. There are some epitopes that could generate lower affinity response.

But, collectively, these are still polyclonal antibodies that are binding to multitude of epitopes available in polypeptides.

Q. So is one of the reasons why the immune system may not produce, in the polyclonal response, antibodies to certain epitopes that the antibodies don't form with sufficient affinity to the epitope?

DR. KHANDURI: Objection; form.

A. There may be certain epitopes that generate lower affinity antibody response.

But, collectively, when you look at large complex antigens, such as PH20, they present

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multiple epitopes.

And, collectively, there are whole polyclonal repertoires that will allow binding to PH20.

Q. Dr. Moon, I want to make sure you understand: I wasn't asking you about the majority of the epitopes. I wasn't asking about the collective response. My questions are pretty narrow.

I'm only asking about the epitopes that do not induce formation of antibodies within the polyclonal antibody response.

So one reason may be that the antibodies that are -- the B cells produced have insufficient affinity.

That's one reason. Is that right?

DR. KHANDURI: Objection; form.

A. Once again, there may be some epitopes that generate low affinity response.

But, collectively, there are multiple epitopes in PH20 that would allow generation of polyclonal antibodies.

Q. Dr. Moon --

MR. KUSHAN: All right. I'm going to move to strike.

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Q. The last answer just illustrates that I didn't -- I explicitly asked you to focus on not the collective response, but the particular epitopes that are not inducing a response.

And I just want you to focus on the questions I'm presenting and answer those, if you could.

If you can't answer the question, you can tell me that, but I need you to answer the question that I'm presenting to you.

So are there any other reasons why the immune system will not produce an antibody to an epitope on the PH20 protein when the PH20 protein is used in a vaccine?

DR. KHANDURI: Objection; form.

A. I gave you my response, that there may be some epitopes that generates low affinity antibody response.

Q. Have you ever heard of the concept of "immune tolerance"?

A. Yes.

Q. What is immune tolerance in the context of the polyclonal antibody response?

A. In Paragraph 32, I stated:

The "immune system is

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trained not to respond to self molecules (in order to avoid autoimmunity)." However, under certain conditions, an antibody response against self-antigens is desired to counter overexpression of the self-antigen in a disease (such as, TNF-alpha overexpression causing chronic inflammation in cachexia, Crohn's disease, and rheumatoid arthritis).

And:

> By December 2021 [sic], a POSA would have known of techniques to elicit a polyclonal antibody response against a self-antigen.

Q. Dr. Moon, is it your understanding that the human PH20 protein is a self-antigen in humans?

A. I understand PH20 is a sperm-associated protein.

Q. Dr. Moon, my question was: Do you understand that the PH20 -- human PH20 protein is a self-antigen in humans?

Can you answer that question.

DR. KHANDURI: Objection; form.

A. I understand PH20 is a sperm-associated protein.

As for whether it's expressed in females, I do not know.

Q. Did you investigate whether the human PH20 protein is expressed in females before you prepared your opinions?

A. I understand PH20 is a sperm-associated protein.

I do not know whether PH20 is expressed in females.

But my opinions stay the same, that modified PH20 will generate polyclonal antibody responses.

Q. Do you know if the PH20 protein is on the Y chromosome of human males?

That's -- sorry.

Do you know if the PH20 gene is on the Y chromosome in humans?

A. I do not know that.

Q. Do you know what chromosome the human PH20 gene is located on in humans?

A. I do not know that.

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MR. KUSHAN: I'm going to mark as Exhibit 1119 a paper in the journal "Matrix Biology," Vol. 20, Pages 499 to 508, 2001; the first author Csoka, C-s-o-k-a.

(Whereupon, Exhibit 1119 was marked for identification.)

Q. If you could, Dr. Moon, review the first portion of the abstract of this paper.

And once -- and I'm going to ask you, as you read that: Does this give you information about where -- what chromosomes the genes of the PH20 -- encodes the PH20 protein are located on?

(Witness reading.)

Q. Dr. Moon, have you determined if this information in Exhibit 1119 identifies the chromosome on which the PH20 gene is located?

DR. KHANDURI: Objection; form.

A. This is first time I'm seeing this document, so I'd like to finish reading it.

Q. So you're incapable of reading the sentence and understanding in the abstract:

Three genes (HYAL1, HYAL2 and HYAL3) are clustered on chromosome 3p21.3, and another

two genes (HYAL4 and PH-20/SPAM1) and one expressed pseudogene (HYALP1) are similarly clustered on chromosome 7q31.3.

DR. KHANDURI: Objection; form.

Q. That information is insufficient to tell you what gene -- or what chromosome the PH20 gene is located on in the human?

DR. KHANDURI: Objection; form.

A. I see that sentence in the abstract.

Q. Do you have reason --

A. But before I can give my opinions, I'd like to read the paper.

Q. So you have not previously investigated whether the PH20 gene is expressed in human females. Right?

DR. KHANDURI: Objection; form.

A. Once again, I have not seen this document before. So I do not know whether PH20 is expressed in females or not.

Q. All right. Let's move on.

So, before, we were speaking of the polyclonal antibody response to the PH20 protein and whether antibodies will form in that polyclonal

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response against every epitope on the PH20 protein.

Is it true that in a polyclonal antibody response, some epitopes will induce a stronger immune response than other epitopes on the protein?

DR. KHANDURI: Objection; form.

A. In a protein antigen, there are multiple epitopes. And a complex antigen, including PH20, would also have multiple epitopes that may have higher -- that may generate high antibody affinity monoclonals or lower affinity monoclonals.

But, collectively, a complex antigen like PH20 will generate polyclonal antibodies.

Q. In the -- in that response, the epitopes that induced the stronger responses, do those have a term that's used in connection with those epitopes in immunology?

A. Immunol- -- in immunological terms, people generally refer to them as immunodominant epitopes.

Q. "Immunodominant epitopes." Okay.

If you immunize a mammal with a mutated form of PH20, are the epitopes associated with the locations of mutations in the PH20 protein typically the immunodominant epitopes?

DR. KHANDURI: Objection; form.

A. Could you repeat the question?

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Q. Sure. If you're immunizing a mammal with a mutated form of the PH20 protein, is it true that the epitopes that are associated with the sites of mutation on the structure of the PH20 protein are the immunodominant epitopes in a polyclonal response?

A. So there are multiple epitopes in a large complex protein like PH20. And when you introduce mutations, as specified in Paragraph 14, that will generate polyclonal antibody responses.

There may be some epitopes that are immunodominant. There may be epitopes that are less immunodominant.

But, collectively, you still get polyclonal antibodies that will bind to wild-type PH20.

Q. Dr. Moon, that didn't answer my question.

I was asking you whether the sites of the mutations on the modified PH20 polypeptide are the locations where the -- those epitopes associated with those modified structures are typically the immunodominant epitopes in a polyclonal antibody response.

Can you answer that question.

DR. KHANDURI: Objection; form.

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A. Once again, when you immunize someone with a large, complex antigen like PH20, there are multiple epitopes that are present.

And there are epitopes that may generate high affinity antibodies. There are epitopes that may generate a bit lower affinity antibodies.

But, collectively, the polyclonal antibodies will cover multiple epitopes.

So even if you make mutations that are less immunodominant, they would still generate antibody responses covering multiple epitopes within PH20.

Q. Dr. Moon, that's the second time I asked you the question, and you've still not answered my question.

So my question is asking whether the sites of the mutations of the modified PH20 create epitopes that are immunodominant epitopes in a polyclonal antibody response.

Are you able to answer that question, please?

DR. KHANDURI: Objection; form.

A. As I responded before, there are multiple epitopes in PH20.

There are epitopes that are -- that may

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generate high affinity. There are epitopes that are less immunodominant and generate less affinities.

But, collectively, these mutated, modified PH20 would contain multiple epitopes. And even if the mutations are less immunodominant, the modified PH20 would generate polyclonal antibodies that cover multiple epitopes in multi- -- in wild-type PH20.

Q. So that is the third time I've asked you the question, and you've still not answered the question I presented to you.

I want you to just tell me: Are you able to answer the question whether epitopes associated with the modifications made to a modified PH20 polypeptide are usually the immunodominant epitopes on a modified PH20 polypeptide when it's used as the immunogen in a polyclonal antibody response?

Can you answer that question.

DR. KHANDURI: Objection; form.

A. I think I answered your question already.

It's my opinion that there are multiple epitopes present in PH20.

And even if you make mutations in immunodominant epitope or less immunodominant epitope, the resulting polypeptide will generate polyclonal antibody responses.

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Q. And that -- for the fourth time, that is not my question.

I'm asking you: So -- do you understand that I'm asking you about an epitope that is associated with the mutation made to the PH20 polypeptide?

Do you understand that is part of my question being put to you?

A. Yes, I understand that.

Q. Okay. So I'm asking whether that epitope associated with a muta- -- with the mutation in the PH20 protein is typically an immunodominant epitope when you use the PH20 as an immunogen to raise a polyclonal antibody response.

Do you understand the question?

A. Yes.

Q. Okay. Please answer that question.

DR. KHANDURI: Objection; form.

A. I'll give you the same answer: Regardless of whether mutated position reside within --

Q. I'm going to interrupt you, because that -- you've -- you just told me you're going to give me the same answer, and I've told you before that's not responding to my question.

My question is asking you whether you know

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that a site of a mutation that gives rise to an epitope -- so this is the epitope associated with the site of the mutation in the PH20 polypeptide -- is that epitope associated with the mutation, typically an immunodominant epitope, if you use the protein, the PH20 protein, as the immunogen?

Can you answer that question.

DR. KHANDURI: Objection; form.

Counsel, this is the second time you have interrupted the witness. He's answering the question the best he can. Please let him complete his answer.

Q. So go ahead. Can you answer my question.

A. So going back to Paragraph 14 --

Q. Okay.

MR. KUSHAN: I'm going to --

Counsel, I'm going to -- I'm going to ask the witness again to answer the question I put to him. And ask him --

Q. Are you able to answer the question whether the -- an epitope associated with the site of a mutation on the PH20 protein is typically an immunodominant epitope when the modified PH20 is used as an immunogen to raise a polyclonal antibody response?

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Do you understand my question to you?

DR. KHANDURI: Objection; form.

Please, Counsel, for the third time, do not interrupt the witness. Let him complete his answer.

MR. KUSHAN: We're going to recall the witness if he refuses to answer questions. I just want to put you on notice.

DR. KHANDURI: He is answering the question --

MR. KUSHAN: No, he's not.

DR. KHANDURI: -- the best he can.

MR. KUSHAN: So I'm going to excuse the witness. We're going to go on the record.

Can you step out of the room, please.

WITNESS: Sure.

MR. KUSHAN: Thank you, Dr. Moon.

(Witness leaves the conference room.)

MR. KUSHAN: We're going to ask for another deposition of this witness if

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he refuses to answer the questions we're putting to him.

You can tell me he's answering the question, but you know absolutely that every single answer he gives me is ignoring the question I'm putting to him.

He's refusing to answer literally every question I'm asking.

So I'm putting you on notice that this is not an acceptable behavior for a witness in a deposition.

And we will reserve our right to recall the witness for an additional deposition if he refuses to -- continues to refuse to answer our questions.

DR. KHANDURI: We disagree.

He's answering the question the way you are presenting him.

Ask clearer questions, and hopefully you'll get the answer that you're hoping for.

He's answering that -- he's answering the best he can.

MR. KUSHAN: He's refusing to answer.

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DR. KHANDURI: We disagree.
MR. KUSHAN: Recall your witness.
DR. KHANDURI: Are you ready?
MR. KUSHAN: Yeah.
(Pause.)
BY MR. KUSHAN:
Q. Dr. Moon, when you were retrieved, did your counsel give you any instructions?
A. No.
Q. Any -- did she say anything to you?
A. No.
Q. All right. So if I introduce a mutation into the PH20 polypeptide, an amino acid substitution, or a series of them, I can alter the structure of the protein. Is that correct?
A. I assume, depending on where you introduce mutations, you could alter the structure of the resulting protein.
Q. And that structure may be a structure not present in the wild-type PH20 protein. Correct?
DR. KHANDURI: Objection; form.
A. Depending on where you introduce mutations, the resulting structure may be similar or -- similar to PH20 or not. Yes.

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Q. So in the scenario where the structure is not similar to the corresponding structure, in the wild-type protein, can that structure, that modified structure, become an epitope recognized by an antibody if you use that modified PH20 protein as an immunogen?

A. Could you repeat the question?

Q. So in the scenario where the structure that has been introduced with the mutation is not a structure found in the wild-type protein, could that modified structure become an epitope recognized by an antibody if you used the modified PH20 protein as the immunogen?

DR. KHANDURI: Objection; form.

A. Yes. If you introduce any mutation and the resulting structures are different from wild-type PH20, that can be used to generate antibody responses.

Q. And the epitope, the new epitope that we've been discussing, the one that's associated with the modified structure, could that epitope be an immunodominant epitope?

DR. KHANDURI: Objection; form.

A. The mutations could be an immunodominant epitope or not, as I mentioned before. And that

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doesn't matter whether it generates polyclonal antibody responses or not.

Q. Do you know whether changed structures on a modified PH20 polypeptide are typically immunodominant relative to the native structure or structures on the PH20 polypeptide?

DR. KHANDURI: Objection; form.

A. When you introduce a mutation to a protein, regardless of where the mutation occurs, a POSA would find ways to generate polyclonal antibody responses.

Q. So my question was whether the changed structures associated with the mutation tend to be immunodominant epitopes on the immunogen.

Can you answer that question.

A. Could you repeat the question again?

Q. Sure. Is it typical that the changed structure on a protein like PH20 that is associated with the mutation -- those changed structures, do they tend to be immunodominant epitopes when you use the mutated protein as an immunogen compared to the wild-type structure?

DR. KHANDURI: Objection; form.

A. When you introduce mutations to a protein, in general, and if that results in changes in the

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structure, that mutated protein will generate polyclonal antibody responses.

Q. Right. And I'm asking if the responses -- well, I'm asking you if the changed structure is an -- typically an immunodominant epitope in that response.

DR. KHANDURI: Objection; form.

A. If the mutation results in protein structures that are distinct from the wild-type protein, regardless of where the mutation occurs, whether it's an immunodominant or less immunodominant epitope, that will result in polyclonal antibody responses.

Q. Right. And I'm asking if responses -- I'm asking you if the changed structure is an -- typically an immunodominant epitope in that response.

DR. KHANDURI: Objection; form.

A. If the mutation results in protein structures that are distinct from the wild-type protein, regardless of where the mutation occurs, whether it's an immunodominant or less immunodominant epitope, that will result in polyclonal antibody responses.

Q. Right. And that does not answer my

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question, again.

I'm asking whether the changed structure typically is an immunodominant epitope.

DR. KHANDURI: Objection; form.

A. Could you repeat the question again?

Q. Yes. So we were referring to the changed structure on the protein.

A. Right.

Q. You're with me. Right?

A. Right.

Q. Okay. I'm asking if that changed structure is typically an immunodominant epitope.

DR. KHANDURI: Objection; form.

A. If a mutation introduced the protein results and changed the structure, in general, that changed structure will trigger more antibody responses.

Q. So it would be an immunodominant epitope?

DR. KHANDURI: Objection; form.

A. There are multiple epitopes within a given protein.

And to say a specific domain is an immunodominant epitope, you will need to test other epitopes and compare.

Q. So you --

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A. I --
Q. Are you finished?
A. Yes. Yes.
Q. So you would have to test each mutated PH20 protein to know what kind of repertoire the body would produce in the polyclonal antibody response.
Is that fair?
DR. KHANDURI: Objection; form, foundation.
A. As I mentioned, each of the modified PH20 will generate polyclonal antibody responses.
Q. But you would not know what antibodies are in the polyclonal antibody repertoire unless you tested it, the mutated protein?
DR. KHANDURI: Objection; form.
A. Mutated protein will generate polyclonal antibody responses that are binding to multiple epitopes within the target protein.
Q. So you don't know one way or another -- sorry.
So I asked you:
Would you have to test each mutated PH20 protein to know what kind of repertoire of

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antibodies in the body --
Sorry.
You would have to test each mutated PH20 protein to know what kind of repertoire the body would produce in the polyclonal antibody response.
Is that fair?
And your answer was:
As I mentioned, each of the modified PH20 polypeptides would generate a polyclonal antibody response.
So I was asking whether you would need to test the particular modified PH20 polypeptide to understand what the particular antibody repertoire was in the polyclonal response. And you gave me a general answer.
I'm just wondering -- or, can you answer the question I put to you.
DR. KHANDURI: Objection; form.
A. If your scientific question is whether each antibody binds to specific domains in the target protein -- and there are ways to test them.
But what I'm saying is: All modified

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version of PH20 will generate polyclonal antibodies that will bind to wild-type PH20.

Q. Dr. Moon, are you familiar with vaccines against the human papillomavirus?

A. In general, I'm familiar with vaccine efforts against papillomavirus.

Q. Okay. And there's an FDA-approved vaccine available for the HPV virus. Right?

A. Yes. There's an FDA-approved vaccine product against HPV.

Q. Do you know what it's called?

A. I believe it's called Gardasil.

Q. Have you studied the Gardasil vaccine or its behavior as a vaccine previously in your professional work?

DR. KHANDURI: Objection; form.

A. I have not studied Gardasil vaccine specifically in the past.

Q. Do you know how Gardasil is administered to patients?

A. It's my understanding that it's administered parenterally.

Q. Where does the virus associated with HPV manifest itself in the human body?

A. It's my understanding that HPV infection

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can occur in many parts in the body, including reproductive tract.

Q. Does that include the reproductive tract in females?

A. Yes. I understand HPV infection can occur in female reproductive tract.

MR. KUSHAN: I'm going to introduce an exhibit, which is 1120.

(Whereupon, Exhibit 1120 was marked for identification.)

DR. KHANDURI: You can drop it. Thank you.

WITNESS: Thank you.

BY MR. KUSHAN:

Q. This is a paper in PL- -- the journal "PLOS," first author Huo, H-u-o, Vol. 7, Issue 3. Page e33736 is the first page. March of 2012.

This paper is reporting on a comparison of administration of HPV antigens to human subjects by a sublingual route and by an intramuscular route.

Dr. Moon, a sublingual route is a mucosal administration route. Right?

A. Sublingual route is considered a mucosal route.

Q. Okay. And an intramuscular is an

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intra- -- is a systemic exposure of the antigen. Right?

A. Intramuscular is considered a systemic exposure.

Q. All right. Could you go to Page e33736.

And do you see there's a figure, Figure 2, on the top half of this page.

And I'll just walk you through this. On the -- in Panel -- are you there?

A. Figure 2?

Q. Figure 2, yeah.

A. Yes, I'm looking at Figure 2.

Q. And it's Figure 2.

And Panel A is showing responses of subjects immunized intramuscularly.

And Panel B is showing responses of subjects immunized sublingually.

And it's showing the frequency -- all these bars are showing the frequency of antibody secreting cells in the assay.

Is this kind of data something that you are familiar with, generally, in your work?

DR. KHANDURI: Objection; form.

A. Yes. In my lab, we study similar results in vaccine studies.

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Q. And so, the responses being shown are over a 20-day period with different -- with the vaccine, with different -- different formulation of the HPV16 VLP.

And, just generally, does the response seen with the intramuscular administration appear to be at or above the level of the response observed with the sublingual administration of the vaccines?

DR. KHANDURI: Objection; scope.

(Witness reading.)

A. In general, the data points associated with the intramuscular in Panel A seem to be higher than what's shown in Panel B with the sublingual route.

Q. Look at the paragraph on the right column, at the bottom of the page, that starts, "One of the potential translational advantages...."

Do you see that paragraph?

A. Yes, I see that paragraph.

Q. And there's a statement in there. It says:

> ...while intramuscular immunization was capable of inducing measurable virus neutralizing activity in

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cervical and/or vaginal secretions in 3/6 subjects (concomitant with high serum neutralizing titers suggesting transudation of serum IgG)....

Do you know what "transudation of serum IgG" is referring to?

A. I assume it refers to translocation from serum to cervical and/or vaginal sites, in this sentence.

Q. Okay. So that's one way antibodies in the circulation that result from a systemic immunization can get into the mucosal compartment within the reproductive tract of human females. Right?

DR. KHANDURI: Objection; form, scope.

A. In general, serum IgG can translocate to reproductive tract.

Q. If you could go to the next page, and there's a figure there, Figure 3.

And again, it's comparing the effects of immunization by the intramuscular route -- those are the three graphs on the left side -- and sublingual immunization on the right side.

And in this graph, "A" refers to the

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response in the serum of the antibodies.

In the "B" segment, that's labeled as being antibody in the cervical secretions.

And in "C," it's antibody in vaginal secretions.

Do you see that?

A. I see that -- I see that in Figure Caption 3.

Q. Okay. And look at the scales of the plots on the left side, associated with intramuscular administration, as compared to the scales of the sublingual administration.

Do the responses of the Ig [sic] measured in serum cervical secretions and vaginal secretions -- are those higher than the levels observed for sublingual administration in those three locations?

DR. KHANDURI: Objection; form, scope.

A. I see that, in general, in Figure 3, the values shown on the left column is higher than the values shown on the right column.

Q. So do you see any impediments of systemic administration of the immunogen in this HPV vaccine at creating sufficient levels of IgG in the female

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reproductive tract?

DR. KHANDURI: Objection; form -- objection; form.

A. This is first time I see this document. But I see, in the case of this particular immunogen, Gardasil, the figures in 3 show intramuscular immunization has high antibody titers compared with the sublingual.

Q. There's high antibody titers in the female reproductive tract. Right?

A. In this particular data set, they show higher antibody IgG responses in serum, cervical, and vaginal sites for intramuscular sites, in this -- in this particular assay.

Q. Have you -- are you familiar with the term "transcytosis"?

A. Yes. In general, I'm familiar with the term "transcytosis."

Q. What is "transcytosis"?

A. That usually refers to a cell that's binding to a protein or target agent and shuttling it to the other side of the cell body.

Q. Is transcytosis a mechanism that can transport immun- -- immunoglobulin G in the circulatory system into the human female

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reproductive tract?

DR. KHANDURI: Objection; form.

A. In general, transcytosis can be used to shuttle antibodies from one site to another across the cell membrane.

Q. Do you know how that occurs?

A. I'm generally familiar with the process of transcytosis.

Q. How does that -- how does transcytosis move immunoglobulin from the circulatory system into the human female reproductive tract?

A. Once again, I'm generally familiar with the term "transcytosis."

And antibodies can bind to Fc receptors on cell membrane, resulting in transcytosis.

MR. KUSHAN: Okay. I'm going to introduce Exhibit 1121. This is a paper published in "PNAS," Vol. 108, No. 11, Pages 4388 to 4393, March 15, 2011. First author is Li.

(Whereupon, Exhibit 1121 was marked for identification.)

Q. And if you want to look at -- just look at the abstract of this paper.

Is this referring -- this is referring to

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the role of FcRn in mediating transcytosis of IgG.

Just read the abstract and then let me know if that's generally what this paper is addressing.

DR. KHANDURI: Objection; scope.

(Witness reading.)

A. Okay. I read the abstract.

Q. So you see, in the middle of the abstract, about halfway down, it says:

> Furthermore, endosomal acidification appears to be a prerequisite for FcRn-mediated IgG transcytosis; IgG transcytosis was demonstrated in vivo by translocation of systemically administered IgG into the genital lumen in wild-type but not FcRn-KO -- or knockout -- mice.

Is that point consistent with the explanation you provided a bit ago about how transcytosis works using the FcRn receptor?

DR. KHANDURI: Objection; form, scope.

A. I see that sentence in the abstract. This

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is first time I'm seeing this document.

But, in general, FcRn is involved in IgG transcytosis.

Q. Okay.

DR. KHANDURI: Counsel, is this a good time to take a break?

MR. KUSHAN: I was just thinking that.

DR. KHANDURI: Okay.

MR. KUSHAN: Would this be a good time for you, Dr. Moon, for lunch?

WITNESS: Yes.

MR. KUSHAN: Okay. Why don't we break for lunch.

DR. KHANDURI: Half an hour?

MR. KUSHAN: That's fine.

VIDEOGRAPHER: Going off the record at 12:28 p.m.

(Whereupon, a recess was taken for lunch at 12:28 p.m.)

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A F T E R N O O N S E S S I O N

(Time noted: 1:13 p.m.)

VIDEOGRAPHER: We are going back on the record at 1:13 p.m.

BY MR. KUSHAN:

Q. Dr. Moon, did you speak with anybody over the break, lunch break?

A. I spoke with counsel about the lunch menu. Other than that, we didn't discuss any cases.

Q. If you could turn to Page 19 of your declaration, Paragraph 32. I think we discussed this a bit earlier today.

A. So Case No. -003?

Q. Yeah, we'll go with -0003.

A. Page 19?

Q. 19. Paragraph 32.

A. Okay.

Q. So this is where you're discussing immune tolerance. Correct?

A. In this paragraph, I discuss self molecules and how to generate immune responses.

Q. In the normal functioning of the immune system, immune tolerance functions to prevent the immune system from mounting immune responses against the host's own proteins. Right?

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A. As I wrote in Paragraph 32:

> The "immune system is trained not to respond to self molecules...."

Q. And is it fair to say that the immune tolerance mechanisms in the body function to prevent the survival and activation of B cells that would produce antibodies against self-antigens?

DR. KHANDURI: Objection; form.

A. Could you repeat the question.

Q. Is it fair to say that the immune tolerance mechanisms in the body function to prevent the survival and activation of B cells that produce antibodies that bind to self-antigens?

DR. KHANDURI: Objection; form.

A. So, in general, the immune system is trained not to respond to self molecules, as I stated in Paragraph 32.

Q. And my question was: There are mechanisms in the immune system that implement immune tolerance. Right?

DR. KHANDURI: Objection; form.

A. There are mechanisms in place related to immune tolerance.

Q. And some of those mechanisms function to

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remove B cells that produce antibodies that bind to self-antigens. Right?

A. There are mechanisms that can remove T cells responding to self-antigens.

Q. And these immune tolerance mechanisms are both in central and peripheral tolerance immune systems. Right?

DR. KHANDURI: Objection; form.

A. There are multiple mechanisms in place. And central and peripheral tolerance are involved in immune tolerance.

Q. Immune tolerance mechanisms operate both in the mucosal and systemic immune responses. Right?

A. Both the mucosal and cell compartments are involved in immune tolerance.

Q. Would you agree that immune tolerance mechanisms can alter the populations of both long-lived plasma cells and memory B cells?

DR. KHANDURI: Objection; form.

A. There are mechanisms involved in regulation of long-lived plasma and memory B cells.

Q. So is it fair to say that immune tolerance mechanisms can influence the antibodies that are within the antibody repertoire produced by a

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polyclonal response to the PH20 protein?

DR. KHANDURI: Objection; form.

A. There are mechanisms involved in self tolerance to self-proteins, but I do not know whether PH20 is a self-protein or not in females.

Q. But, just generally -- not just for PH20, but just generally, if someone is attempting to vaccinate somebody with a self-protein and there are not efforts made to overcome immune tolerance, the body will not produce antibodies to the self-protein.

Is that how self- -- is that how immune tolerance works?

DR. KHANDURI: Objection; form.

A. In general, there are mechanisms in place to control and modulate induction of antibodies to self molecules.

But as I stated in Paragraph 32, under certain conditions, an antibody response to self-antigen can be induced and sometimes desired.

And there are multiple ways that a POSA could have used to induce polyclonal antibody responses against the multitude of antigens, including a self-antigen.

Q. If I administered a self-protein to a

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human in saline -- without adjuvants, without other things in the composition -- would you expect the human immune system to produce a polyclonal antibody response against that self-protein?

DR. KHANDURI: Objection; form.

A. So, in general, there are mechanisms in place to limit induction of antibody responses to self molecules.

But as I mentioned, there are multiple ways that a POSA could have used to induce polyclonal antibody responses to protein antigens, including a self-antigen.

Q. And to be clear, if they -- if the POSA did not use those additional ways to overcome immune tolerance, the human body would not mount a polyclonal antibody response to that self-antigen. Right?

A. In general, if you inject self-protein into an individual, you don't expect to generate antibody responses to the self-antigen.

Q. If I take a human prot- -- a human self-protein that is found in other animals in the -- well, sorry. Let me try that one again.

So if I have two species, and they have -- they both make the same protein, but they're

different species' versions of each protein -- in that hypothetical -- kind of like PH20. There's a human PH20. There's a mouse PH20. There are other species of PH20.

If the two proteins, like the two PH20s, mouse and human, have common epitopes in their native wild-type form, would you expect antibodies in the mouse to form against that common epitope if you inject the human protein into the mouse?

DR. KHANDURI: Objection --

Q. Do you understand my question?

DR. KHANDURI: Objection; form.

A. If you inject proteins from different species with 100% sequence identity, a POSA would think injection of unmodified protein in saline would not generate strong antibody responses.

But in most cases, proteins in different species have less than 100% sequence identity. So in those cases, you expect to get antibody responses.

Q. If there is an epitope shared between the human and mouse species of the native protein, would the antibody -- antibodies in the mouse not be produced against that epitope, which is shared between the two species as a self epitope?

DR. KHANDURI: Objection; form.
A. Could you repeat the question?
Q. Of course. It's a complicated question, so let me break it up for you.
So there could be, on two species of a protein, a common epitope found on both species of protein. Right?
A. Okay.
Q. And in each mammal, they could have an antibody form -- or an antibody could recognize that epitope as a self epitope. Right? Theoretically?
DR. KHANDURI: Objection; form.
A. So as long as there is a single epitope mutation in those two proteins, a POSA would expect to see generation of antibody responses.
Q. So if you mutate the common epitope shared by the two proteins, that will induce production of antibodies when you take one species' protein and inject it in the other mammal?
DR. KHANDURI: Objection; form.
A. Oh, that's not what I stated.
Q. Okay.
A. I stated that as long as there is a single epitope mutation anywhere within the protein --
Q. So --

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A. -- that may -- that single mutation would allow induction of antibodies to "multi" epitopes.

Q. So that would override immune tolerance against the shared epitope between the two species?

DR. KHANDURI: Objection; form.

A. Once again, there's -- as long as there is one single epitope, a single amino acid mutation in the proteins, anywhere in the protein, that will result in antibody responses spreading to multiple epitopes found in the protein.

Q. So T cells and -- where do T cells and B cells originate?

A. T cells are known to generate in -- T cells and B cells are known to generate in bone marrow.

Q. And are both T cells and B cells trained by the immune system?

DR. KHANDURI: Objection; form.

A. Both T cells and B cells are trained and interact with immune systems.

Q. Does that training occur before T cells and B cells migrate into the mucosal immune system?

A. Generally, T cells and B cells can be trained in different parts of the body, including bone marrow, thymus, spleen, and potentially mucosal

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tissues, too.

Q. So you would expect immune tolerance to function in mucosal -- in mucosal environment as well. Right?

DR. KHANDURI: Objection; form.

A. There are mechanisms in place to maintain immune tolerance in various tissues, including mucosal compartments.

Q. Would you agree, in general, that most proteins are poorly immunogenic or nonimmunogenic when administered by themselves?

DR. KHANDURI: Objection; form.

A. Could you repeat the question?

Q. Sure. Would you agree with the statement that most proteins are poorly immunogenic or nonimmunogenic when administered by themselves?

A. I think this depends on the protein.

If you are injecting self-antigen protein, without any modification, by itself, it may not generate strong antibody responses, due to mechanisms of immune tolerance.

But as long as there is a single epitope mutation, of course I would find good ways to induce antibody responses.

Q. Do you commonly try to overcome immune

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tolerance using an adjuvant when you administer the protein?

A. Yes. Adjuvants are used to induce antibody responses with protein antigens.

Q. Can adjuvants have varying degrees of impact on the magnitude of the immune response against a protein?

DR. KHANDURI: Objection; form.

A. In general, adjuvants are used to induce higher antibody titers, together with protein antigens.

Q. Can you use, in a vaccine in a human, a highly potent adjuvant?

DR. KHANDURI: Objection; form.

Q. And to be clear, something that would overcome immune tolerance to the injected protein.

DR. KHANDURI: Objection; form.

A. There are strong adjuvants that are well reported in the literature.

Q. Are there any risks of using a strong adjuvant in a vaccine for a human?

A. There are adjuvants that are known to cause injection inflammation.

So, in those cases, researchers have to be cautious on selection of adjuvants.

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Q. Can you induce autoimmunity to a self-protein that is other than the one being injected, if you use a powerful adjuvant, in a human?

DR. KHANDURI: Objection; form.

A. When you use a very strong adjuvant, there is concern of potential side effects, including inflammation and induction of antibodies to other proteins.

Q. So does that limit the choices for adjuvants that could be used in human vaccines?

A. There are many choices of adjuvants that are in development. And many, but not all, can be used in humans.

Q. Could you go to Paragraph 23 of your declaration on Page 12.

A. Paragraph 22?

Q. 23.

A. 23? Okay.

Q. You make a reference at the bottom of that paragraph to epitopes that are linear?

A. Yes, I mentioned linear epitopes here.

Q. What do you mean by "linear" epitope?

A. What I mean by "linear" is that these are contiguous amino acid sequences within the antigen.

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Q. And those are -- there's another kind of epitope called "conformational" epitope. Right?
A. Yes. Conformational epitope is another kind of epitope in an antigen.
Q. And what's the difference between a linear epitope and a conformational epitope?
A. Linear epitopes refer to contiguous domain of antigen that -- that will induce antibody responses.
Configuration -- configurational epitopes refer to epitopes that are formed by three-dimensional structure of the antigen inducing antibody responses.
Q. Will conformational epitopes in a protein be preserved in a protein that has been denatured?
A. Some conformational epitopes in a protein can still be maintained after denaturization.
Q. Would you say the majority of the conformational epitopes will be maintained in a denatured protein?
DR. KHANDURI: Objection; form.
A. I think it depends on the method of denaturization. There are some techniques that will disrupt more conformational epitopes compared with others.

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Q. Is it fair to say that the -- a disruption of the structure of the protein can destroy conformational epitopes?

A. If you denature a protein, you could disrupt conformational epitopes of a certain region.

And once again, depending on the techniques of denaturization, the extent to have disruption in conformational epitopes may be different.

Q. So the number of antibodies that might form to a denatured PH20 protein may be different than the number of antibodies that would form to the undenatured wild-type PH20 protein?

DR. KHANDURI: Objection; form.

A. Once again, depending on the method of denaturization, number of epitopes in one form of antigen versus other may be different, the number of configuration of epitopes.

Q. If you could look at Paragraph 22 of your declaration, also on Page 12.

No. I'm sorry. Hold on one second.

This always happens in depositions, where your pages become disordered. Just bear with me.

(Pause.)

Q. All right. If I could have you do this:

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Go to Page 25 and look at Paragraph 44.

A. Okay. I'm looking at Paragraph 44.

Q. Okay. Do you see, about five or six lines down, there's -- you say:

> ...or the modified PH20 polypeptide underwent a conformational change (e.g., due to intentional denaturation)....

Do you see that?

A. Yes, I see that.

Q. I see that word -- those two words being used together at several places in your declaration, "intentional denaturation."

What do you mean by the words "intentional denaturation," as you're using it in your declaration?

A. In vaccine studies, researchers could intentionally denature a given protein for vaccine applications as well.

So researchers could use undisrupted antigen or antigen that is intentionally disrupted or intentionally denatured to generate antibody responses.

And as I mentioned, there are many

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techniques available to achieve denaturization of a protein.

Q. Can mutations into -- introduced into the amino acid sequence of a protein cause denaturation of the protein?

A. I would assume some amino acid modifications to a protein can result in unfolding or denaturization of the antigen.

Q. And if those amino acid mutations caused unfolding or denaturation of the protein, would the denatured or unfolded protein have a different number of epitopes on it compared to the wild-type protein?

DR. KHANDURI: Objection; form.

A. As I mentioned in Paragraph 44, even if you intentionally denature a protein, the vast majority of the epitopes would be still present for induction of antibody responses.

Q. Are the majority of epitopes on a protein like PH20 linear epitopes or conformational epitopes?

A. In general, large complex proteins like PH20 have both conformational and linear epitopes.

Q. Do you know whether there are more conformational epitopes than linear epitopes, or

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vice versa, on the PH20 protein?

A. I do not know, for the case of specific PH20, whether there are more configurational or linear epitopes.

Q. Did you investigate the epitopes that are present on the human PH20 protein as part of your preparation of your declaration -- of your declaration here?

DR. KHANDURI: Objection; form.

A. PH20 is a large, complex protein.

So, in general, those complex proteins have multiple epitopes, including linear and configurational epitopes.

As for the number of epitopes on PH20, I didn't look into number of epitopes.

But I understand there are multiple epitopes that can serve as both configurational and linear epitopes.

Q. If you intentionally denature a protein antigen like PH20, can you refold the protein by removing or changing the conditions in which it's found?

DR. KHANDURI: Objection; form.

A. I think it -- I think it depends on the method of denaturization, whether you can refold

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disrupted protein or not.

Q. Have you personally refolded proteins that have been denatured?

A. I have not personally refolded proteins that were denatured.

But I examined literature. I worked in a multidisciplinary research lab that worked on protein antigens.

Q. Can a denatured modified PH20 protein form aggregates?

DR. KHANDURI: Objection; form.

A. In general, denatured proteins could or could not result in aggregation.

Q. Can mutations introduced into the PH20 protein induce the protein to form aggregates?

DR. KHANDURI: Objection; form.

A. In general, mutations in any given protein could result in protein aggregation.

Q. Do aggregated proteins present different epitopes relative to the native, properly folded protein; for example, in PH20?

DR. KHANDURI: Exam- -- excuse me. Objection; form.

A. Once again, large proteins have multiple epitopes. And that will be the same for PH20.

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Q. Do you know how protein aggregates form?
A. In general, when hydrophobic domains are exposed to external surface, that can result in protein aggregation.
Q. And those can -- those hydrophobic portions that get exposed can form complexes between multiple molecules of the protein in a random way. Right?
A. There may be some proteins that aggregate, resulting in some changes.
But, in general, even after protein aggregation, the aggregated proteins will still present epitopes that will induce polyclonal antibody responses to the parent protein.
Q. Can an aggregated protein present new epitopes not originally present on the wild-type protein?
A. In some cases, aggregated proteins could present some new configurational epitopes.
Q. Could you look at Paragraph 44 again.
A. Okay.
Q. Do you see, in the first sentence, you state:
Moreover, given the high degree of amino acid sequence

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identity (at least 95%) between the administered modified PH20 polypeptides and the wild-type human PH [sic] polypeptide (SEQ ID 7), even if some epitopes on the modified PH20 polypeptide were changed or disrupted....

And then you continue on.

When you were forming your opinions, did you consider the modified PH20 polypeptides that you were addressing to be those that were 95% sequence identity with SEQ ID 7?

DR. KHANDURI: Objection; form.

(Witness reading.)

A. I understand the modified PH20 polypeptides have the definitions given in Paragraph 14.

Q. So you're referring to proteins that have 95% sequence identity that are admin- -- sorry.

You're speaking of proteins being administered, which are the modified PH20 polypeptides.

And you're saying those, in this sentence, are those with 95% sequence identity with the

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wild-type PH20 polypeptide SEQ ID 7. Right?

DR. KHANDURI: Objection; form.

A. I understand polypeptides shown in Sequence No. 3 and 32-66 are truncated version of PH20 found in human sperm, which is indicated by Sequence ID No. 7.

And I understand there's a high degree of amino acid sequence identity, at least 95%, between modified PH20 polypeptides and wild-type human PH20 polypeptide, as shown in ID No. 7.

But, by extension, because Sequence ID No. 3 and 32-66 are truncated version of Sequence ID No. 7, there would be also high degree of amino acid sequence identity between modified PH20 and PH20 shown in Sequence 3 and 32-66.

Q. But in Paragraph 44 in your declaration, you're referring to modified PH20 polypeptides that have 95% sequence identity to SEQ ID 7. Right?

(Witness reading.)

A. I understand there is a high degree of sequence identity between modified PH20 and wild-type human PH20 polypeptide sequence shown in 7, as well as truncated version of wild-type human PH20 shown in Sequence No. 3 and 32-66.

And by that extension, a POSA would think

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the vast majority of the epitopes on the modified PH20 polypeptides to be the same or similar to those on the wild-type human PH20 polypeptide shown in Sequence No. 7, as well as the truncated version, Sequence No. 3, and 20, 32-66.

Q. So just to be clear, what you're addressing in Paragraph 44 is the set of modified PH20 polypeptides that are 95% identical to SEQ ID 7.

And you also believe that polypeptides that are 95% sequence identity with SEQ ID 3 and 32-66 also would induce antibodies that bind to the wild-type PH20.

Is that what you're saying?

DR. KHANDURI: Objection; form.

A. Could you repeat the question.

Q. So --

A. Yeah.

Q. -- what's -- so what's written in Paragraph 44 is addressing modified PH20 polypeptides that are 95% sequence identity -- or have 95% sequence identity with SEQ ID 7. Right?

(Witness reading.)

A. There is a high degree of amino acid sequence identity between modified PH20 and

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wild-type human PH20 shown in Sequence No. 7, but -- in addition, not "but" -- in addition, there's high degree of sequence identity between modified PH20 and wild-type PH20 polypeptide shown in Sequence No. 3 and 32-66.

Q. Okay. Do you know if SEQ ID 7 is a soluble form of human PH20?

A. I do not know whether it's a soluble form.

Q. Did you investigate how many of the modified PH20 polypeptides that you described in Paragraph 14 will become denatured because of the changes to the protein?

DR. KHANDURI: Objection; form.

A. I do not know how many of the modified PH20, as described in Paragraph 14, are in soluble form.

Q. Did you investigate how many of the modified PH20 polypeptides you defined in Paragraph 14 that will become aggregated?

A. I do not know how many of those variants described in Paragraph 14 will result in protein aggregation.

Q. Did you investigate how many of the modified PH20 polypeptides in the set defined in Paragraph 14 will become misfolded because of the

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mutations made to them?

DR. KHANDURI: Objection; form.

A. I do not know how many of the modified PH20 will result in disruption or misfolding.

Q. But it's your testimony that regardless of that uncertainty, every single modified PH20 polypeptide within the definition in Paragraph 4 -- 14 will cause production of polyclonal antibodies in a human that bind to the wild-type PH20 on sperm?

DR. KHANDURI: Objection; form.

A. It's my opinion that modified PH20 polypeptide, as defined in Paragraph 14, will result in polyclonal antibodies that will bind to wild-type human PH20 polypeptide in vivo.

Q. So if you look in Paragraph 45, please. And just....

If you can look, there's -- you say "irrespective of," and then you list three conditions:

> ...the location of an amino acid difference on any of the admin- -- on any of the administered modified PH20 polypeptides relative to the wild-type, whether any of the

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administered PH20 polypeptides are enzymatically active, or whether the administered modified PH20 polypeptide has a conformational change (such as due to intentional denaturation)....

So you're saying, regardless of those three things happening when you make mutations to the PH20 protein, you believe administering any of the PH20 polypeptides within the scope of what you say in Paragraph 14 will raise antibodies that bind to the wild-type PH20 on human sperm?

DR. KHANDURI: Objection; form.

A. It is my opinion that a POSA would have expected the polyclonal antibodies generated against the administered modified PH20 polypeptides, regardless of the three conditions I listed in Paragraph 45, will result in antibodies that bind to wild-type PH20 polypeptide.

Q. Do you also personally believe that to be true?

DR. KHANDURI: Objection; form.

A. This is my personal opinion that I stated in the declaration.

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Q. And just to be clear, I'm just confirming that you're not telling -- you're not just saying your opinion is that the POSA would believe it.

I just -- I'm asking: You personally believe it, regardless of whether a POSA believes it?

A. I personally believe this as well.

Q. Did you evaluate any structural models of the PH20 protein in forming your opinions in your declarations?

DR. KHANDURI: Objection; form.

A. As I mentioned, modified PH20 will have multiple epitopes. And even after denaturation, the modified PH20 will have multiple epitopes that will generate polyclonal antibody responses.

Therefore, the structure of modified PH20 does not play a major role in forming my opinions.

A POSA would have used modified PH20 as -- without further modification.

What I mean by is that a POSA would have used a denatured or nondenatured modified PH20 to generate polyclonal antibody responses.

Q. Does it matter to you how many, or the locations of amino acid modifications, are in the modified PH20 in -- as to the ability of the

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modified PH20 to create antibodies and a polyclonal response against the wild-type protein?

DR. KHANDURI: Objection; form.

A. As I mentioned in Paragraph 14, as long as there is single epitope amino acid modification, a modified PH20, all the variations of that would result in polyclonal antibody responses.

Q. So your opinion is: As long as the PH20 in that -- sorry.

As you just said -- strike that.

So you just stated that as long as there is the one amino acid substitution in the modified PH20 being used.

Are you assuming that the modified PH20 that's being administered in your example to the human has only one amino acid substitution in it?

DR. KHANDURI: Objection; form.

A. Regardless of number of mutations, as long as it meets the definition stated in Paragraph 14, it's my -- it's my opinion that modified PH20 injected into human females will result in polyclonal antibody responses.

Q. So just to be clear, are you saying that your opinions are based on a modified PH20 polypeptide that has only the one identified change

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at position 320 in it?

DR. KHANDURI: Objection; form.

A. My opinion stays the same, whether modified PH20 has only one modification at position 320 or many modifications, so that up to 95% is identical to the Sequence ID No. 3 and 32-66.

All these variants would be expected to generate polyclonal antibody responses.

Q. Is it your opinion that any sequence -- any contiguous sequence of amino acids within the PH20 protein sequence can be a linear epitope?

DR. KHANDURI: Objection; form.

A. Any potential linear contiguous sequences in a given protein could be a linear epitope.

And, same thing can be generally said to PH20 as well.

Q. So anywhere in the -- so if I pick any stretch of contiguous amino acids within the PH20, the native PH20 polypeptide sequence, any stretch of amino acids will be a linear epitope, as we've --

DR. KHANDURI: Object --

Q. -- been using that term in the -- in your declarations?

DR. KHANDURI: Objection; form.

A. There are multiple linear and

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configurational epitopes in any given protein.

Q. I'm just trying to clarify.

Are there a smaller number of linear epitopes on the modified -- or in the native PH20 polypeptide than as many as you can derive from just picking any stretch of the amino acid sequence?

That's a bad question. Let me try it again.

In order to be a B cell epitope, does the linear sequence have to be bound by a B cell?

DR. KHANDURI: Objection; form.

A. In general, B cells need to bind to their target epitope to generate antibody responses.

Q. So not every -- not any sequence within the PH20 sequence will provide that as a place where a B cell can bind. Right?

DR. KHANDURI: Objection; form.

A. So again, there are multiple epitopes in a complex protein. There are multiple linear epitopes that B cells can bind to.

Q. Let me try a better question.

Do you agree that in order for antibodies specific to a linear epitope on PH20 to be produced, the B cells must recognize the linear epitope through their BCR?

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DR. KHANDURI: Objection; form.
A. In general, BCR on B cells need to bind to an epitope to generate antibody responses.
Q. Do you know how many linear B-cell epitopes are on the PH20 wild-type protein sequence?
DR. KHANDURI: Objection; form.
A. I don't know how many B-cell epitopes there are in wild-type PH20, but I understand there are many potential epitopes.
Q. In December of 2012, could a person of ordinary skill have determined how many B-cell epitopes are present on the wild-type PH20 sequence?
I'm sorry.
In December 2012, could a person of ordinary skill have determined how many linear B-cell epitopes are present on the wild-type PH20 sequence?
A. All the linear epitopes within a given protein could serve as a B-cell epitope.
Q. Could linear sequences of amino acids buried within the protein interior function as a linear B-cell epitope on the human PH20 protein?
DR. KHANDURI: Objection; form.
A. Even if you have linear epitopes buried in 3D structure of a protein, if you denature the

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protein and expose the linear epitope, that will serve as a linear B-cell epitope.

Q. Will the antibody that forms against that buried linear epitope bind to the native wild-type PH20 on sperm?

DR. KHANDURI: Objection; form.

A. Could you repeat the question?

Q. Yes. You gave me an example of forming an antibody to a linear B-cell epitope on the interior of the protein where you used the denatured form of the protein.

And my question is whether that antibody that binds to the linear B-cell epitope that is on the denatured form, but in the folded protein, is on the interior of the protein -- I'm asking if that antibody will bind to the native PH20 protein on sperm.

A. So once you denature a protein and expose internal linear epitopes, that can generate antibody responses to that epitope. And that can trigger subsequent immune responses to other domains found in that antigen, resulting in polyclonal antibody responses to multiple other epitopes.

So if you were to use modified PH20 and denature it, it will generate antibody responses

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that will trigger subsequent polyclonal antibodies that bind to wild-type PH20 bound -- found in sperm.

Q. But the antibody that binds to the linear B-cell epitope that's ordinarily in a buried site will not bind to the native structure found on -- PH20 found on sperm. Right?

DR. KHANDURI: Objection; form.

A. As I mentioned, when you denature a protein, that can result in internal domains to be exposed, resulting in B-cell responses, then that will trigger other B-cell activations that result in polyclonal antibodies against the multiple epitopes.

Q. All right. Let's take --

A. And I can see the similar conditions can occur in the case of a modified PH20.

Q. But I'm trying to just -- let's take the other antibodies that might also form off the table for a minute.

I'm just asking about the antibody that you referred to that formed to the linear B-cell epitope on the interior of the protein that was made with the denatured PH20.

That antibody will not bind to the folded PH20 protein on sperm. Right?

DR. KHANDURI: Objection; form.

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A. I do not know enough about biology or PH20 in sperm to answer that particular hypothetical question.

DR. KHANDURI: Counsel, can we take a break soon?

MR. KUSHAN: I have just one or two more questions, then we can take a break.

Q. Do you -- so did you investigate whether PH20 on sperm, after it enters the reproductive tract until it fertilizes the egg, undergoes any kind of structural change?

DR. KHANDURI: Objection; form.

A. I just know PH20 is a sperm-associated protein.

Q. So you don't know whether the protein itself undergoes structural changes to its sequence between the time it enters the reproductive tract until it fertilizes the egg?

A. I did not study the structure of PH20 in human female reproductive tract.

But it's my opinion that regardless of the sequence variance within modified PH20, those would serve as antigens that will generate polyclonal antibodies that will bind to wild-type PH20

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associated with sperm.

MR. KUSHAN: Do you want to take a break?

WITNESS: Sure.

MR. KUSHAN: Okay.

VIDEOGRAPHER: Off the record at 2:21 p.m.

(Whereupon, a recess was taken.)

VIDEOGRAPHER: We are going back on the record at 2:54 p.m.

BY MR. KUSHAN:

Q. Dr. Moon, did you speak with counsel during the break?

A. No, I did not.

Q. To prepare your declarations in this case -- I just want to confirm a couple of your answers from before.

One question I asked you is whether you had looked at a PH20 homology model as part of the work that you did to prepare your declarations.

Did you look at a PH20 homology model?

DR. KHANDURI: Objection; form.

A. Could you clarify the question?

Q. Right. So, you know, proteins exist in three dimensions. Right?

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A. Proteins exist in three-dimensional structure.

Q. And so, if you did a X-ray crystallography study of the protein, you could get information that is used to create a three-dimensional image of the protein. Right?

DR. KHANDURI: Objection; form.

A. You can study 3D structure of a protein using crystallography.

Q. Right. And you can use SWISS-MODEL to also create a model of a protein structure using its amino acid sequence. Right?

DR. KHANDURI: Objection; form.

A. That's another method of looking at protein structure.

Q. So all I'm asking is: Did you look at one of those PH20 structural models in the course of preparing your opinions in this case?

DR. KHANDURI: Objection; form.

A. I did not need to look into structure of PH20 to arrive at my opinion that I stated in the declaration that modified PH20 will generate polyclonal antibody responses that will bind to wild-type human PH20 polypeptide.

Q. So, Dr. Moon, my question wasn't whether

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you had an opinion about this, but my question was just a question about whether you did something.

And I asked -- and it's very simple: Did you look at a PH20 homology model in the course of preparing your opinions in this case?

DR. KHANDURI: Objection; form.

A. I used the UniProt to look at sequence identity between modified PH20 polypeptides and other sequences listed in my declaration.

Q. But you --

A. I did not use crystallography or SWISS-MODEL to examine PH20 during preparation of this declaration.

Q. And you didn't view a PH20 model -- sorry.

You did not view a structural model of PH20 in forming your opinions in the declaration. Is that right?

DR. KHANDURI: Objection; form.

(Witness reading.)

A. I did not use SWISS-MODEL or crystallography model to study PH20 in order to form my opinion that modified PH20 polypeptide will generate polyclonal antibodies that will bind to wild-type human PH20.

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Q. So at the very beginning of the deposition today, you explained that in your -- some of the work that you did during your postdoc phase, that you investigated the location of linear epitopes.

Do you remember that explanation you gave us?

A. I remember our exchange.

Q. And that involves making fragments of the protein that you were trying to locate the linear epitopes in. Right?

DR. KHANDURI: Objection; form.

A. In the postdoctoral training time, I used fragmented proteins for vaccine applications.

Q. So in February -- I'm sorry.

In December of 2012, a POSA could have used other techniques to locate linear B-cell epitopes on the surface of the human PH20 protein. Right?

DR. KHANDURI: Objection; form.

A. There are tools available to study epitopes in any given protein.

Q. Are those computational tools?

A. Those tools would include the computational tools.

Q. So a person of skill in the art could have

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used computational tools in 2012 to locate the positions of linear B-cell epitopes on the PH20 protein that are on the surface of the protein. Right?

DR. KHANDURI: Objection; form.

A. Computational tools can be used to study structure of a protein, including PH20.

Q. And also to find the locations of the B-cell epitopes on the surface of the protein. Right?

A. Computational tools can be used to study structure of a protein, as well as epitopes in a given protein.

Q. And the location of the epitopes as well. Right?

A. Computational tools can be used to study structure of a protein and potential epitopes.

But as I mentioned in my declaration, modified PH20 polypeptide will degenerate polypeptides that will bind to wild-type human PH20.

And I did not need to examine computational models to arrive at this opinion.

Q. As part of your work in this case forming opinions about linear epitopes that give rise to B cells -- sorry. Try that one again.

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As part of your work in this case, did you look for any reports of investigations into the locations of B-cell epitopes on the human PH20 protein?

DR. KHANDURI: Objection; form.

A. PH20, I understand, is a large protein with multiple epitopes. And modified PH20 also has multiple epitopes that will induce polyclonal antibody responses.

And I didn't need to use computational tools to arrive at my opinion that modified PH20 polypeptides will induce polyclonal antibodies against the wild-type human PH20.

Q. So, Dr. Moon, my question is much simpler, and you don't need to repeat what you already have said many times today.

I'm just asking about what you did to prepare these declarations. And one thing -- I'm asking a very specific thing.

Did you look for information published in the literature that describe the location of B-cell epitopes on the human PH20 protein?

DR. KHANDURI: Objection; form.

A. I did not look into published epitopes within PH20.

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Q. Okay.
A. But I understand there are multiple epitopes in PH20 that can serve as epitopes for generating polyclonal antibody responses.
MR. KUSHAN: We're going to mark Exhibit 1122.
(Whereupon, Exhibit 1122 was marked for identification.)
MR. KUSHAN: Sorry.
DR. KHANDURI: Thank you.
MR. KUSHAN: This is a paper published in the "AAPS Journal," Vol. 24 -- numbered 110, starting at Page 109, published in 2022, first author Marie Printz.
BY MR. KUSHAN:
Q. Dr. Moon, could you look down at the left corner of the paper and tell me what affiliation -- what company affiliation Marie Printz has?
A. I see Halozyme Therapeutics as an author affiliation for Dr. Marie Printz.
Q. Halozyme owns the patents that are the subject of these proceedings. Right?
A. I understand Halozyme is the owner of the patent that I -- the case, -0003.

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Q. Look in the abstract, and do you see that the authors reported that they had identified -- or they stated:

> Fifteen epitopes in the rHuPH20 --

That's the recombinant human PH20.

> -- sequence had the potential to cross-react with B cells.

Do you see that?

(No audible response.)

Q. It's about four lines from the bottom of the paragraph, left column.

A. I see the sentence:

> Fifteen epitopes in the rHuPH20 sequence had the potential to cross-react to B cells.

But this is the first time I'm seeing this document.

Q. Okay. Could you turn to Page 110. I just want to focus you on -- in the left column of Page 110, under the heading "B Cell Epitope Prediction."

A. Which page, please?

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Q. Page 110. The page number is in the top right corner.
A. They're all 110.
Q. Oh, wait. That's right.
There it is, Page 5 of 15.
Do you see that?
A. Okay.
Q. And in the left column, they're talking about B Cell Epitope Prediction and B Cell Epitope Mapping.
And about halfway down the paragraph of the B Cell Epitope Prediction paragraph, in the middle of the page, it says:

> Potential antigenic epitopes for rHuPH20 were identified by employing a model of the 3D crystal structure of recombinant human PH20, which was based on the crystal structure of HYAL1....

Do you see that?
(Witness reading.)
A. Yes, I see that sentence.
Q. And that's performing an inspection of a PH20 homology model that we were talking about a

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couple minutes ago. Right?

DR. KHANDURI: Objection; form.

(Witness reading.)

A. I see here that they used a model of the 3D crystal structure of rHuPH20.

Q. And do you see that the crystal structure model was based on the crystal structure of the HYAL1 protein?

That's the clause -- that's the part of the sentence after that parenthetical. The part that says "which was based on the crystal structure of HYAL1."

DR. KHANDURI: Objection; form, relevance.

A. I see the sentence. It reads, "which was based on the crystal structure of HYAL1 using amino acids 2-403 of rHuPH20."

Q. Okay. And then, in the next sentence, they said:

> Potential epitopes were identified on the basis of structure and solvent accessibility....

In February of 20- -- I'm sorry.

In December of 2012, could a POSA have

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performed these steps of inspecting the PH20 model in evaluating structure and solvent accessibility of the protein to identify linear B-cell epitopes?

DR. KHANDURI: Objection; form, scope.

(Witness reading.)

Q. Dr. Moon, I want to make sure you understood -- I'm just asking a simpler question: In December of 2012, could a person of skill in the art have used a PH20 homology model and inspected the structure and solvent accessibility of the protein to identify linear B-cell epitopes on the human PH20 protein?

DR. KHANDURI: Objection; form, scope, relevance.

(Witness reading.)

Q. Dr. Moon, my -- the answer to my question, I don't believe, is in this paper. I'm asking -- I want to make sure you understood my question.

Can you tell me what my question was?

DR. KHANDURI: Objection; form.

A. Could you repeat your question?

Q. Sure.

A. Yeah.

Q. I just want to know if a person of skill

in the art, a POSA, in December of 2012 could have used a PH20 homology model, and by inspecting the structure and solvent accessibility of the protein, they could have identified the linear B-cell epitopes on the surface of the human PH20 protein.

DR. KHANDURI: Objection; form, scope, relevance.

(Witness reading.)

A. Can I spend more time to read this paper?

Q. I don't believe that's necessary. I just want to know --

A. Okay.

Q. -- were -- you were a person of skill in the art in 20- -- December 2012. Right?

A. Yes.

Q. If you look at that description, I'm asking -- I'm only asking you: As a person skilled in the art, could you have performed those steps that are listed in the bottom half of the paragraph under B-cell epitope prediction in February of 20- -- in December of 2012?

DR. KHANDURI: Objection; form, scope, relevance.

A. I think I need to read the whole paper.

Q. So you're -- so do you know -- are you

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aware of any reason why a POSA could not have performed these steps of using a PH20 homology model and looking at the structure and solvent accessibility of the protein to identify the linear B-cell epitopes on PH20, on its surface?

DR. KHANDURI: Objection; form, scope, relevance.

A. This is the first time I'm looking at this particular document, and I'd like to read it through before answering your questions related to this document.

Q. So I'm allowed to ask you questions about what you believe. And my questions are focused on the capabilities of a POSA in December of 2012 -- which you say you were, right? -- that -- you're maintaining you're a person of skill in the art in 2012?

DR. KHANDURI: Objection; form.

A. I meet at least the qualifications of a POSA.

Q. And so, I'm asking you if you could have performed those steps that are described in that one paragraph to identify the linear B-cell epitopes on PH20. Yes or no, could you have done that?

DR. KHANDURI: Objection; form,

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scope.
A. Yeah, I'll need to read the entire document before --
Q. Why?
A. -- answering that.
DR. KHANDURI: Objection; form.
Q. Why do you need to read the other -- the rest of the document to answer my question?
DR. KHANDURI: Objection; form, scope.
Q. Let me help you.
Were -- was it possible to inspect a model of the 3D crystal structure of PH20, based on the crystal structure of HYAL1 in December of 2012 --
DR. KHANDURI: Objection; form, scope.
Q. -- based on your knowledge and understanding as a POSA in December of 2012?
DR. KHANDURI: Objection; form, scope.
A. I'd like to read the document before --
Q. Dr. Park [sic] --
A. -- answering.
Q. -- let me ask -- I'm -- you're avoiding answering the question.

MR. KUSHAN: It's not funny. Okay? Just --

MS. ZHANG: You got his name wrong.

MR. CHOI: His name's not "Dr.~Park."

MR. KUSHAN: Sorry. I apologize. I'll withdraw that.

Q. Dr. Moon, if you could just listen very carefully. My question is asking whether you, as a person skilled in the art, could have performed these steps in December of 2012.

DR. KHANDURI: Objection; form, scope.

A. I would like to read the entire document before answering the question.

Q. So you're unable to answer that question without reading the entire document. That's your testimony?

DR. KHANDURI: Objection; form.

Q. About something you would know in December of 2012.

DR. KHANDURI: Objection; form.

A. I would like to read the entire document before answering specific questions.

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Q. I'll take that as a you cannot answer my question based on knowledge you had in December of 2012.

DR. KHANDURI: Objection; form.

Q. Is that fair?

DR. KHANDURI: Objection; form.

A. Once again, you're asking about a specific experiment described in one paragraph out of 15 pages of document. And I'd like to read the entire document before answering your question.

Q. So I'm not asking you about the results at this point. What I'm asking you, if you're familiar with the tools that were used and referenced in that paragraph.

Do you know what a homology model is, Dr. Moon?

DR. KHANDURI: Objection; form, foundation.

(Witness reading.)

A. Where does it say "homology model"?

Q. It says that:

> Potential antigenic epitopes for recombinant human PH20 were identified by employing a model of the 3D

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crystal structure of rHuPH20, which was based on the crystal structure of HYAL1 using amino acids 2-403....

Do you understand that to be describing a homology model that is based on the crystal structure of HYAL1?

DR. KHANDURI: Objection; form, scope.

A. It doesn't say "homology model" in the document.

Q. So you don't recognize, from that description, that they're referring to a PH20 homology model. Is that right?

DR. KHANDURI: Objection; form, scope.

A. Before answering particular question about this document, I would like to read the whole document.

Q. All right. So I'm going to take your answer -- you are refusing to answer my question or you do not know the answer to my question. And I will take that as your testimony.

DR. KHANDURI: Objection; form.

A. The document -- paragraph you mention

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doesn't mention "homology model."

Q. Do you know what a homology model is and how they're prepared?

A. So I would like to read the whole document before I answer --

Q. No, no. My --

A. -- that question.

Q. Dr. Moon, my question was: Do you know what a homology model based on a crystal structure is?

DR. KHANDURI: Objection; form.

A. I would like to read the whole document before answering any --

Q. Dr. -- Dr. Moon, I'm not asking -- this is a question that's not based on this document. This is a question based on your knowledge.

Do you know what a homology model is?

A. Are you referring to sequence alignment models --

Q. No.

A. -- used in UniProt?

Q. No. I'm referring to a model that is produced by SWISS-MODEL based on an amino acid sequence and the structure -- the crystal structure of HYAL1, which produces a model of the PH20

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protein.

DR. KHANDURI: Objection; form, scope.

Q. Do you know what that is?

A. Before answering specific questions, I would like to read this whole document.

Q. Is it your testimony that in December of 2012, a POSA would not know what a homology model is?

DR. KHANDURI: Objection; form.

(Witness reading.)

Q. Just to be clear, my question that's pending right now is based on your personal knowledge and not anything on a piece of paper in front of you.

My question is: Do you know what a homology model is, Dr. Moon?

DR. KHANDURI: Objection; form, scope.

A. As I mentioned, as of 2012, I used many different tools to analyze protein structure, looking at sequence searching and alignments, protein modeling software, and etc.

Q. So --

A. And I was in a part of multidisciplinary

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team that examined protein modeling softwares to design vaccine antigens.

Q. Have you ever used a software program called PyMOL?

A. Could you repeat that?

Q. Have you ever used a software program called PyMOL?

A. I have not used PyMOL --

Q. Have you used --

A. -- personally.

Q. Have you ever used any software program to view a protein structural model?

DR. KHANDURI: Objection; form.

A. I was in a multidisciplinary research group, as of 2012, to study protein structure using modeling softwares.

But I have not personally used three-dimensional structure models.

Q. All right. So if you could go to Paragraph 36 of your declaration.

Sorry. Let's go back a couple of paragraphs.

If you look at Paragraph 34 that's on Page 20, and you're discussing in this paragraph and two paragraphs that follow it:

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...polyclonal antibodies generated against a polypeptide antigen were known to cross-react with another polypeptide having as low as ~46 – 49% sequence identity to the stimulating polypeptide, irrespective of whether the polypeptides are from a different animal species.

Do you see what --

A. Yes, I see that sentence.

Q. All right. And then, if you could go to Paragraph 55, referring back to that Section VI:

...polyclonal antibodies --

This is what you state in Paragraph 55:

...polyclonal -- polyclonal antibodies were known to cross-react with a polypeptide having as low as ~46 – 49% sequence identity with the polypeptide that stimulated the polyclonal antibody response.

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A. Yes, I see that sentence.
Q. All right. So an antibody that binds to two proteins, two different proteins, you're referring to that as a cross-reactive antibody. Right?
DR. KHANDURI: Objection; form.
A. "Cross-reactive antibody" generally refers to antibodies that bind to two different proteins.
Q. So the one antibody is recognizing two -- the same antigenic determinant on two different proteins.
Is that fair?
DR. KHANDURI: Objection; form.
A. "Cross-reactive antibody" generally refers to antibodies that bind to two different proteins.
Q. And it's able to bind to two different proteins because the same epitope is present on both proteins. Right?
A. In general, cross-reactive antibodies bind to similar or the same domains found within two different proteins.
Q. Is it your opinion that any pair of proteins that share 46% sequence identity will induce production of cross-reactive antibodies that bind to both proteins?

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DR. KHANDURI: Objection; form.

A. I listed multiple examples where polyclonal antibodies were known to cross-react with other proteins in my declaration. And polyclonal antibodies were known to cross-react to the polypeptide having as low as about 46 to 49% sequence identity with a polypeptide that stimulated the polyclonal antibody response.

Q. So could you also ask -- answer my question?

DR. KHANDURI: Objection; form.

A. Could you repeat your question?

Q. Yes. So you -- your answer to my last question was explaining that you had found some examples of proteins that induce production of cross-reactive antibodies. Right?

A. There are examples that I listed in my declaration.

Q. Right. And so, my question was actually different. My question was: Is it your opinion that any pair of two proteins that share 46% sequence identity will induce production of cross-reactive antibodies that bind to both proteins?

That's my question. Could you please

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answer that question.

DR. KHANDURI: Objection; form, scope.

A. It is my opinion that proteins with a sequence homology as low as about 46% sequence identity will generate polyclonal antibodies that cross-react with the other protein.

Q. So you list three examples of those types of pairs of proteins that produced cross-reactive antibodies in your declaration. Right?

DR. KHANDURI: Objection; form.

A. I listed three different examples where antibodies generated cross-reactive polyclonal antibody responses.

Q. How did you find the example of the proteins that had 46% sequence identity?

DR. KHANDURI: Objection; form.

And I would caution Dr. Moon to not divulge the substance of communication with the counsel.

To the extent you can answer the question without revealing the substance of communications with counsel, you can do so.

A. I searched the literature to find examples

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where antibodies having various sequence identity generates cross-reactive antibody responses.

Q. Did you find any other examples of two proteins that had 46% sequence identity that induced production of cross-reactive antibodies?

DR. KHANDURI: Dr. Moon, I will caution you to not divulge the substance of any --

MR. KUSHAN: Wait, wait, wait, wait. He was describing his -- he said he did a search, and I'm asking about his search.

I'm not asking about his conversations with you. So --

DR. KHANDURI: Yeah. Let me put what I want to say on record. Okay?

MR. KUSHAN: I -- go ahead.

DR. KHANDURI: Dr. Moon, I will caution you to not divulge the substance of communication with counsel.

To the extent you can answer the question without revealing the substance of communications, you can do so.

BY MR. KUSHAN:

Q. And I'm clarifying: My question is about

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what you did, Dr. Moon.

So based on your last answer, you said you performed a search of the literature, looking for examples of production of cross-reactive epitopes. Right?

DR. KHANDURI: Objection; form.

A. I reviewed the literature where cross-reactive antibody responses were generated.

Q. Dr. Moon, let me just clarify: Did you perform a search of the literature to look for examples of two proteins that share sequence identity and produce cross-reactive antibodies?

DR. KHANDURI: Objection; form.

A. Could you repeat your question?

Q. Yeah, sure. I just want to know: Did you do a literature search yourself to look for examples of proteins from different sources that produced cross-reactive antibodies?

DR. KHANDURI: Objection; form.

A. I did a literature search myself to look for cases and examples where polyclonal antibodies were generated.

Q. And you found three examples?

DR. KHANDURI: Objection; form.

A. I found at least three examples that I

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listed in the declaration.

Q. Did you find any examples, other than the one you list, where the sequence identity was between 46 and 49% of the two proteins?

DR. KHANDURI: Objection; form.

A. There may be -- there may have been more examples like this. But in my declaration, I put one example where polypeptides having as low as 46 to 49 sequence identity generating polyclonal cross-reactive antibody responses.

Q. Dr. Moon, did you find any other papers, besides the three that you list in your declaration, that reported results, from testing of two different proteins, a capability to produce cross-reactive epitopes that you did not include in your declaration?

DR. KHANDURI: Objection; form.

A. There may have been other examples. But I don't recall a specific example at the moment.

Q. Did you find any examples of two proteins that had 90% sequence identity which failed to produce cross-reactive antibodies?

(Witness reading.)

A. As I wrote in Paragraph 35, this is an example where proteins with a 90% sequence identity

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between mouse MOG domain and human MOG domain generating polyclonal cross-reactive antibody responses.

I also list another example in Paragraph 36, where a protein with a sequence homology -- sequence identity at 90%, 95%, or 98% with a chicken, human, and rat type II collagen inducing cross-reactive antibody responses --

Q. You did not --

A. -- in this --

Q. -- identify any examples other than these three. Right?

DR. KHANDURI: Objection; form.

A. There may have been other examples like this, but I don't recall the specific examples.

Q. Why did you not include them in your declaration?

DR. KHANDURI: Objection; form.

(Witness reading.)

A. Once again, I may have seen other examples in the literature. But I provided three concrete examples in my declaration.

Q. Right. My question was trying to understand why, if you saw other examples that supported this idea that two proteins with 46%

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sequence identity will induce production of cross-reactive epitopes, why did you not include those other examples in your declaration?

(Witness reading.)

A. Once again, I may have seen other examples, other than those three cases, during my search, but these three cases were sufficient to help me form my opinions outlined in this declaration.

Q. Are you speculating that there might have been other examples that you could find, or are you telling us under oath that you found other examples besides these three and you chose not to discuss them?

Which of those two situations are you describing to us?

DR. KHANDURI: Objection; form.

A. Could you repeat the question?

Q. Yes. I'm trying to determine if you are speculating if you -- there might be additional examples that could be found, as opposed to you found other examples of two proteins with 46% or higher sequence identity producing cross-reactive epitopes.

I'm trying to figure out: Which scenario

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are we speaking of? You did -- you might find more, or you did find more examples in your search?

DR. KHANDURI: Objection; form.

(Pause.)

A. So these three examples allowed me to form opinions outlined in this declaration.

There may have been other examples. But I don't recall the specific example at the moment, sitting here today.

Q. And it's your opinion that any two proteins that have at least 46% sequence identity will induce production of cross-reactive epitopes when you immunize a mammal with those two different antigens?

DR. KHANDURI: Objection; form.

Q. Sorry. Let me strike that question.

(Pause.)

Q. Could you confirm that after performing your literature search, you found no publications or other information indicating that antibodies raised against one species of PH20 induced production of any antibody that bound to another species like PH20?

DR. KHANDURI: Objection; form.

A. I didn't look into specific examples of

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PH20 injected into animals to form my opinions that proteins with a sequence identity greater than at least 46% will generate cross-reactive polyclonal antibody responses.

Modified -- based on these, modified PH20 would be expected to generate polyclonal antibody responses that will bind to wild-type PH20.

Q. Are you aware of any examples of PH20 proteins from different species producing cross-reactive antibodies through immunization of a mammal?

A. Once again, I didn't look into specific examples of PH20 generating antibody responses in animals.

But reviewing the literature, I found at least three examples, outlined here, showing that protein with a sequence homology of at least 46% would generate cross-reactive antibody responses.

And those three examples allowed me to form the opinion that modified PH20 will generate polyclonal antibody responses that will bind to wild-type PH20 when injected in human females, as well as in other --

Q. All right.

A. -- female mammals.

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MR. KUSHAN: Why don't we take a break?
VIDEOGRAPHER: We'll go off?
MR. KUSHAN: Yeah.
VIDEOGRAPHER: Off the record at 3:53 p.m.
(Whereupon, a recess was taken.)
VIDEOGRAPHER: We are going back on the record at 4:27 p.m.
BY MR. KUSHAN:
Q. Dr. Moon, I'm going to hand you an exhibit that's already been marked Exhibit EX2153.
(Whereupon, Halozyme Exhibit EX2153, previously marked, was presented to the witness.)
DR. KHANDURI: Thank you.
Q. I believe this is the paper that you rely on in Paragraph 34 of your declaration. Is that right?
A. Exhibit 2153 is one of the exhibits that I reviewed.
Q. So you relied on the information in Exhibit 2153 to support your opinions in your declaration. Right?
A. Exhibit 2153 is one of the exhibits that I used to form my opinions.

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Q. Okay. Now, this is a very simple question: Did you find this paper, or was this paper provided to you?

DR. KHANDURI: Dr. Moon, I will caution you not to divulge the substance of communication with counsel.

To the extent you can answer the question without revealing the substance of communications with the counsel, you can do so.

MR. KUSHAN: Sorry. Are you alleging there is a privilege basis relating to my question?

DR. KHANDURI: Could be.

MR. KUSHAN: Could you step out, Dr. Park -- I'm sorry. I'm so sorry.

Dr. Moon, could you please step out of the room for one minute? And I just have to talk to your counsel.

(Witness leaves the conference room.)

MR. KUSHAN: I just want to understand, get it on the record, why you believe there could be an assertion of privilege of work product relating to the

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question I asked, which was: How did he get this paper?

DR. KHANDURI: I'm just cautioning the witness --

MR. KUSHAN: No --

DR. KHANDURI: -- do not divulge the substance of communication. That's all.

MR. KUSHAN: You're signaling to the witness that there may be privilege. And I want to understand the basis that you have for privilege to that statement.

DR. KHANDURI: Yeah. I want to make sure Dr. Moon understands the bounds of the answer that he -- he should give in response to your question. That's all.

MR. KUSHAN: So my question is not very complicated. It's: Where did he get the paper?

And there's no basis of -- there's no theory of privilege that would suggest that is privileged.

DR. KHANDURI: I asserted my -- I stated my caution to Dr. Moon on record. It's on record.

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And I think we can move on.

MR. KUSHAN: I'm asking you to not say it again, because you're coaching your witness. And I'm just --

DR. KHANDURI: I'm not --

MR. KUSHAN: There's no -- there's no conceivable basis of privilege in the source of the document that he's using to support his opinions in this proceeding. That's my point.

And by you saying -- cautioning him not to reveal privilege, you're coaching him. And I believe that's improper, and I would just ask that you not do that anymore.

DR. KHANDURI: I disagree. It's fully appropriate, I think.

MR. KUSHAN: All right.

DR. KHANDURI: Let's just move on.

MR. KUSHAN: But you've not identified -- there's no theory you have why his answer could be privileged.

DR. KHANDURI: I'm cautioning the witness to be aware that his

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answers -- in case his answers lead to communications with counsel, he should be aware of that. That's all.

MR. KUSHAN: Well, if you hear him say that in his answer, you can intervene.

DR. KHANDURI: So --

MR. KUSHAN: That's the proper way.

DR. KHANDURI: -- let's just move on --

MR. KUSHAN: That's the -- no. That's the proper way to deal with it. If you sense that he's going to start revealing privileged communications, you can interrupt the witness and instruct me [sic] not to answer. Okay?

DR. KHANDURI: It would be too late by then.

MR. KUSHAN: No. It's not. You -- you can jump in. It's not --

DR. KHANDURI: It could be too late by then. Let's just move on.

I've made my point.

MR. KUSHAN: Can you go get --

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DR. KHANDURI: Yep.
MR. KUSHAN: -- your witness.
(Witness returns to the conference room.)
DR. KHANDURI: Thank you.
BY MR. KUSHAN:
Q. Dr. Moon, do you recall the question I asked you before the break? Or --
A. Could you --
Q. -- just before you left?
A. Could you repeat the question?
Q. Yes. The question is: Did you find Exhibit 2153 yourself, or was Exhibit 2153 provided to you?
DR. KHANDURI: Dr. Moon, the same caution.
(Witness reading.)
A. I believe this is one of the papers I found during the literature search.
Q. And do you have any recollection of finding any other paper, besides this and the other two papers that are cited in your declaration, that showed that two different proteins with less than 90% sequence identity generated cross-reactive antibodies?

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DR. KHANDURI: Objection; form.

(Pause.)

Q. I'm going to read the question again to be clear.

Do you have any recollection of -- other than Exhibit 2153 and the other two papers cited in your declaration, of a paper that you found in your search that had less than 90% sequence identity -- sorry.

MR. KUSHAN: Yeah, (sotto voce) we lost antibodies.

Q. Yeah. All right. So let's try it one more time.

So, Dr. Moon, you performed a search for literature that resulted in you finding, as you just testified, Exhibit 2153. Right?

A. Yes. I did a literature search, and I believe this is one of the papers I found during the literature search.

MR. KUSHAN: And I'm going to hand you Exhibit 2154.

(Whereupon, Halozyme Exhibit EX2154, previously marked, was presented to the witness.)

DR. KHANDURI: Thanks.

Q. This is another one of the papers that is

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cited in your declaration. And you addressed this one in Paragraph 35. Right?

This is the same paper that you cited in Paragraph 35. Right?

A. I cited this paper in Paragraph 35.

Q. And you relied on this paper to support your opinion that two proteins with 90% sequence identity or higher will generate cross-reactive -- cross-reactive antibodies. Correct?

(Pause.)

DR. KHANDURI: Objection; form.

A. I cited, in Paragraph 35, this paper, 2154, showed that two proteins with a sequence identity of about 90% is generating cross-reactive antibody responses.

Q. And so, you relied on the information in Exhibit 2154 to support your opinions in your declaration. Correct?

A. Exhibit 2154 is one of the documents that I relied on to prepare my declaration.

And as outlined in Paragraph 35, this exhibit showed that proteins with about 90% sequence identity generates cross-reactive antibody responses.

Q. Dr. Moon, did you find Exhibit 2154, or

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was it provided to you?

(Witness reading.)

A. I believe this is one of the papers I found during my literature search.

MR. KUSHAN: Okay. I'm going to hand you another exhibit. This is Exhibit 2155.

(Whereupon, Halozyme Exhibit EX2155, previously marked, was presented to the witness.)

Q. And I believe this is the paper by Trentham that is addressed in Paragraph 36 of your declaration.

Did you rely on Exhibit 2155 to support your opinions in your declaration?

(Witness reading.)

A. I relied on many papers to prepare my declaration, and this is one of the papers that I used.

Q. Dr. Moon, did you find Exhibit 2155, or was Exhibit 2155 provided to you?

(Witness reading.)

A. I believe this is one of the papers that I found during the literature search that allowed me to form the opinions outlined in the declaration.

Q. And to be clear: As you sit here today,

you have no recollection of any other paper that shows two proteins with a low 90% sequence identity generating cross-reactive antibodies?

DR. KHANDURI: Objection; form.

A. Well, Exhibit 2153 shows proteins with --

MR. KUSHAN: I apologize. I'll withdraw that question. That was certainly imprecise.

Q. Other than the three papers that you cite in your declaration, you cannot identify any other paper, after you performed your search, that shows two proteins with sequence identity of 46% to 90% that generated cross-reactive antibodies.

DR. KHANDURI: Objection; form.

Q. Is that right?

DR. KHANDURI: Objection; form.

A. During my search, I may have found other examples like these, but I don't recall the specific reports at the moment.

Q. Can you -- do you recall what proteins -- what kind of proteins they were, if you remember a paper?

(Witness reading.)

A. I may have seen other papers along these line performed in mice, but I do not recall what

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specific protein was used in those examples.

Q. If you could go to Exhibit 2153, which is the heat shock protein paper.

Do you have that?

A. Yes, I have that.

Q. When you prepared your opinions in your declaration, did you compare the proteins that were discussed in Exhibit 2153 to PH20 proteins?

DR. KHANDURI: Objection; form.

A. Could you repeat the question?

(Pause.)

Q. Okay. My question was: When you formed your opinions in your declaration about this topic we've been discussing, did you compare the proteins that were discussed in Exhibit 2153 in any way to the PH20 proteins?

DR. KHANDURI: Objection; form.

A. Could you be more specific -- by comparison?

Q. Sure. Did you -- did you see if they were -- these proteins were enzymes like the PH20 proteins?

A. These studies are about use of proteins for vaccine applications, how proteins of different sequence identity are inducing cross-reactive

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antibody responses.

Q. Were the heat shock proteins being used as -- in a vaccine, or were they just being studied because people had observed autoantibodies to be produced against them?

DR. KHANDURI: Objection; form.

(Witness reading.)

A. In this particular report, the researchers were studying heat shock protein in the setting of infection with microbes.

And they are reporting mice can generate antibody responses to heat shock protein.

Q. Dr. Moon, did you compare the length of the protein sequences being discussed in the Exhibit 23- -- 2153 paper to the length of the PH20 proteins as part of your analysis?

(Witness reading.)

A. I did not directly compare the length of the heat shock protein to PH20 to arrive at my opinions outlined in the declaration.

What this paper is showing is that, as long as proteins have sequence identity as low as 46%, these antigens can generate cross-reactive antibody responses.

And similar principles can be applied to

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modify the PH20.

Q. And under the same reasoning, any two proteins that have 46% sequence identity would also generate cross-reactive antibodies. Correct?

DR. KHANDURI: Objection; form.

A. This paper clearly reported that proteins with a sequence identity as low as 46% can generate cross-reactive antibody responses.

Q. And I'm just exploring your reasoning why that suggests that PH20 proteins with 46% sequence identity to other proteins will generate cross-reactive antibodies that bind to other PH20 proteins.

Why?

DR. KHANDURI: Objection; form.

A. Basically, these three papers, including Exhibit 2153, are showing that when you use proteins with sequence homology ranging from as low as 46% to 90% and higher, they are generating cross-reactive antibody responses.

So the same principles could be expected to work for modified PH20.

Q. Now, you're saying that because the two proteins have 46% sequence identity or because they're homologous proteins that have 46% sequence

identity?

DR. KHANDURI: Objection; form.

Q. I think, in your declarations, you just refer to "sequence identity." Right?

(No audible response.)

Q. So if you look at Paragraph 34, you say:

> ...polyclonal antibodies generated against a polypeptide antigen were known to cross-react with another polypeptide having as low as ~46 – 49% sequence identity to the stimulating polypeptide, irrespective of whether the polypeptides are from a different animal species.

Right?

So that's sequence identity you're referring to. Correct?

A. I'm referring to the sequence identity in that statement.

Q. Right. And then, in the Oliver paper, which is Exhibit 2154, you're referring to the existence of 90% sequence identity between the mouse and human MOG proteins. Right?

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Again, it was the sequence identity that you were pointing to to support your opinion that the two proteins would generate cross-reactive antibodies. Right?

A. In this exhibit, they used mouse MOG protein and human MOG protein with a sequence identity of about 90% to show cross-reactivity.

Q. And in Paragraph 36, regarding the Exhibit 2155, which is the Trentham paper, again, you're using sequence identities as a basis for your opinion that the three proteins will generate cross-reactive antibodies. Right?

A. This paper, 2155, showed that proteins with a sequence identity 90%, 95%, or 98% generate cross-reactive antibody responses.

Q. So again, your opinions are based on sequence identity as the critical question above 46%?

DR. KHANDURI: Objection -- objection; form.

A. As I stated in Paragraph 37, based on these reports:

> ...POSA would have expected that polyclonal antibodies generated in a

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subject against a polypeptide would cross-react with polypeptides having as low as ~46 – 49% sequence identity....

Q. And that's true for any polypeptide that meets that threshold of 46 to 49% sequence identity. Right?

DR. KHANDURI: Objection; form.

A. (Reading):

...POSA would have expected that polyclonal antibodies generated in a subject against a polypeptide would cross-react with polypeptides having as low as ~46 – 49% sequence identity....

Q. Okay. Now, we talked a bit earlier about the alignments that you -- are in your declaration in the appendix.

I just want to ask: Did you prepare the alignments that are reported in Appendix B and Appendix -- yeah.

So there are three alignments in Appendix B. And did you prepare all these alignments yourself?

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(Witness reading.)
A. Yes, I recall I prepared the alignments myself.
DR. KHANDURI: All right. Why don't we take about a five-ish minute break.
VIDEOGRAPHER: We're going off the record --
DR. KHANDURI: Okay.
VIDEOGRAPHER: -- at 4:58 p.m.
(Whereupon, a recess was taken.)
VIDEOGRAPHER: We are going back on the record at 5:13 p.m.
BY MR. KUSHAN:
Q. Dr. Moon, did you speak with anybody on the break?
A. No.
MR. KUSHAN: Okay. I'm going to mark as Exhibit 1123 an excerpt from a textbook by Janeway -- Janeway's, consisting of Chapters 8, 10, 12, 15, and Appendix I.
(Whereupon, Exhibit 1123 was marked for identification.)
Q. This is the 8th Edition of Janeway's

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"Immunobiology," published in 2011 -- 2012, by Garland Science.

Yes. There are portions of Chapters 8, 10, 12, 15, and Appendix I.

Dr. Park [sic], are you familiar with the Janeway's Immunobiology textbook?

A. By the way, I'm Dr. Moon.

Q. I'm sorry. I'm so --

A. Yeah.

Q. I -- sorry. I've said that a couple times today. I wanted to apologize.

A. Okay.

Q. Dr. Moon, can I just clarify: Have you seen or are you familiar with this Immunobiology textbook from Janeway's?

A. I may have read this a long time ago.

Q. Would this have been one of the textbooks you might have used in the 2008 to 2012 time frame, or earlier versions of it?

A. I don't --

DR. KHANDURI: Objection; form.

A. -- recall the exact text, but I may have seen this long, long time ago.

Q. Okay. Could I ask that you go to the very back, Page 721. And if you need to -- you can take

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the paper -- the clip off.

I'm just going to ask you a couple questions about the table that -- I'm sorry.

In the directory, it's --

A. What page?

Q. -- Page 719. It's Figure A.2.

A. So Figure A.2.

Figure A.2. Yeah, I'm looking at that.

Q. And this is a table that compiles "Factors that influence the immunogenicity of proteins."

And I just want to go over some of these characteristics and see if they are consistent with your familiarity of this phenomenon of immunogenicity of proteins. Okay?

(No audible response.)

Q. Do you agree, as it's being represented in Figure A.2, that the size of a protein can influence the immunogenicity of the protein?

(Witness reading.)

A. In general, size of antigen may affect immunogenicity.

Q. Okay. And larger proteins are labeled "increased immunogenicity."

Is that consistent with your experience?

(Witness reading.)

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A. Could you repeat the question?
Q. Sure. Is it consistent with your experiences in the field of immunology that larger proteins are generally more immunogenic -- more -- more immunogenic than smaller proteins?
A. In general, larger proteins are more immunogenic than smaller proteins.
Q. Okay. If you go a few rows down, there's a row called "Form," and it has four boxes.
"Particulate" is described as being increased immunogenicity compared to "soluble," as to the -- I'm sorry -- yeah, particularly as compared -- let me start over.
The table is describing proteins that are in particulate form to be -- to have increased immunogenicity relative to proteins that are soluble. Is that right?
A. In general, particulate form of antigens are known to be more immunogenic than soluble proteins.
Q. And similarly, denatured forms of proteins are known to be more immunogenic -- more immunogenic than the native form of the protein. Correct?
A. In general, denatured proteins are more immunogenic than native proteins.

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Q. Okay. And the next row is describing similarity to self-protein.

That's addressing the self-protein questions we were discussing earlier today. Right?

A. I see that row, "Similarity to self protein."

Q. And it's reporting that where a protein has multiple differences relative to a self-protein, that's increased immunogenic -- it has increased immunogenicity. Correct?

A. It's been generally known that proteins with multiple differences are more immunogenic.

Q. And proteins that have fewer differences and are more similar to the native wild-type protein have decreased immunogenicity. Right?

A. So this is a very general table that describes immunogenicity of proteins.

The proteins with multiple differences are known to be more immunogenic. A POSA would have used proteins with fewer differences as an effective antigen using different approaches that I outlined in the declaration.

Q. And is it correct that these are principles that someone who was a POSA in 2012 would have been familiar with?

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A. These are general concepts in immunology.

MR. KUSHAN: Okay. I have no further questions.

DR. KHANDURI: We'll take -- we'll take a break.

Let's go off record.

VIDEOGRAPHER: Going off the record at 5:23 p.m.

(Whereupon, a recess was taken.)

VIDEOGRAPHER: We are going back on the record at 5:29 p.m.

DR. KHANDURI: Thank you, Dr. Moon, for your time. We don't have any questions for you. We invoke the witness's right to read and sign.

MR. KUSHAN: Okay.

DR. KHANDURI: Thank you.

VIDEOGRAPHER: We are going off the record --

DR. KHANDURI: We're off.

MR. KUSHAN: Yeah.

VIDEOGRAPHER: -- off the record at 5:29 p.m.

(Whereupon the deposition concluded at 5:29 p.m.)

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DEPONENT'S SIGNATURE

Please be advised I have read the foregoing deposition, pages 1 through 201, inclusive. I hereby state there are:

(Check one)

_____ No corrections

_____ Corrections per attached

_____

JAMES J. MOON, PH.D.

(X) Reading and signing was requested.

( ) Reading and signing was waived.

( ) Reading and signing was not requested.

Should the signature of the witness not be affixed to the deposition, the witness shall not have availed himself of the opportunity to sign or the signature has been waived.

--oOo--

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ERRATA SHEET

NAME OF CASE: Merck Sharp & Dohme LLC v. Halozyme, Inc.

DATE OF DEPOSITION: November 18, 2025

NAME OF WITNESS: JAMES J. MOON, PH.D.

Reason Codes:

1: To clarify the record.

2: To conform to the facts.

3: To correct transcription error.

Page _____ Line _____ Reason _____

From _____ to _____

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JAMES J. MOON, PH.D. DATE

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DECLARATION UNDER PENALTY OF PERJURY

I am the witness in the foregoing deposition.

I have read the foregoing deposition or have had read to me the foregoing deposition, and having made such changes and corrections as I desired, I certify that the same is true in my own knowledge.

I hereby declare under penalty of perjury that the foregoing is true and correct.

In witness whereof, I hereby subscribe my name this _____ day of _____, 2025.

_____

JAMES J. MOON, PH.D.

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CERTIFICATE

I, SUSAN ASHE, a Registered Merit Reporter and Notary Public, hereby certify that the foregoing is a true and accurate transcript of the deposition of said witness, who was first duly sworn by me on the date and place hereinbefore set forth.

I FURTHER CERTIFY that I am neither attorney nor counsel, nor related to or employed by any of the parties to the action in which this deposition was taken, and further that I am not a relative or employee of any attorney or counsel employed in this action, nor am I financially interested in this case.

Dated this 24th day of November 2025.

Susan Ashe, Notary Public
of the District of Columbia

My commission expires: May 14, 2028.

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