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.

_____

VIDEOCONFERENCE AND VIDEOTAPED 30(B)(6)

DEPOSITION OF

MELANIE ANN SIMPSON, PH.D

December 9, 2025

Reported By: SUSAN ASHE, CER

Job No.: 7005333

Petitioner Merck, Ex. 1130, p. 1
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PGR2025-00024

Tuesday, December 9, 2025

9:13 a.m. Eastern Standard Time

Videoconference and videotaped deposition of MELANIE ANN SIMPSON, PH.D. taken on behalf of the Petitioner, beginning at 9:13 a.m., on Tuesday, December 9, 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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INSTRUCT THE WITNESS

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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, DECEMBER 9, 2025;
9:13 A.M. EASTERN STANDARD TIME
--o0o--
VIDEOGRAPHER: We are now on the record. The time is 9:13 a.m. The date is December 9, 2025.
This is the video deposition of Melanie A. Simpson, Ph.D., taken in the matter of Merck Sharp & Dohme LLC versus Halozyme, Incorporated. Case filed with the U.S. Patent and Trademark Office before the Patent and -- Patent Trial and Appeal Board. It'll be Case No. PGR2025-00003 and related cases PGR2025-00004, -00006, and -00009.
We are at the offices of Sterne Kessler, located at 1101 K Street, Northwest, in Washington, D.C.
The videographer is Jonathan Perry, and the court reporter is Susan Ashe, both here on behalf of U.S. Legal Support, located at 16825 Northchase Drive, Suite 900, in Houston, Texas 77060.
And would counsel present please introduce themselves and state whom they

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represent.

MR. KUSHAN: Jeff Kushan from Sidley Austin for Petitioner.

With me is Amy Mahan and Kalen Sullivan from Sidley, and Brian Goldberg from Dechert.

MS. MARTIN: Lauren Martin from Quinn Emanuel on behalf of Halozyme.

And with me, I have Eldora Ellison, Ralph Powers, III, and Haley Ball from Sterne Kessler; Zach Summers and Elliot Choi from Quinn Emanuel.

Whereupon,

MELANIE ANN SIMPSON, PH.D.

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

EXAMINATION

BY MR. KUSHAN:

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

A. My full name is Melanie Ann Simpson.

Q. And what is your present employer?

A. My present employer is North Carolina State University.

Q. And you're based in Raleigh?

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A. I am based in Raleigh.
Q. Have you been deposed before?
A. I have not been deposed before.
Q. Okay. We'll go over some ground rules.
First, I'll ask you questions. If you don't understand my question, let me know. I'll try to give you a better question.
You should proceed to answer my question after you've heard it and understood it.
Your counsel may raise an objection. Once she's finished, you proceed to answer the question I've asked you.
If she instructs you to not answer the question on the basis of privilege, of course you can follow the guidance of your counsel. But I'll want to confirm that you're doing that.
I'll show you exhibits during the course of the day. I hope to not overwhelm the space you have there. So if we need to move some of them off of the table, we can do that. They'll be handed to you, and then you can review them.
You understand that today you're under oath, and you're obligated to tell the truth to the best of your knowledge?
A. I do understand that.

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Q. Okay. Is there any reason you cannot testify truthfully today?
A. No.
Q. Okay. No medical issues?
A. No.
Q. Okay. If I need to, I may ask you to step out of the room, if I need to have a conversation with opposing counsel. But we'll try to minimize those.
Also, anytime you need a break, just let us know. We can take a break. We'll finish answering the question that is presented to you, and then, once you finish that, we can -- that's the normal time for a break. Okay?
Do you understand all of these procedural steps here we've got?
A. Yes.
Q. Okay. Now, do you understand that you have provided declarations in four different proceedings in front of the Patent Trial and Appeal Board?
A. Yes, I do.
MR. KUSHAN: Okay. I'm going to call that the "PTAB." That's the entity that's going to be evaluating the

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different sides of this dispute.

This is Exhibit 2068 in "PGR2025-0003" concerning the U.S. Patent 11,952,600.

It's already marked.

(Whereupon, Halozyme Exhibit 2068, previously marked, was presented to the witness.)

MR. KUSHAN: I'm also going to hand to you Exhibit 2068 in "PGR2025-0004," Exhibit 2068 in "PGR2025-0006," finally, Exhibit 2068 in "PGR2025-0009."

(Whereupon, Halozyme Exhibits 2068, previously marked, were presented to the witness.)

MS. MARTIN: So, Counsel, we have bound versions of all four of these.

I don't know if you have a preference for which one it is that she uses, but those are the four documents that we brought.

MR. KUSHAN: Are there any markings in the four that you brought with you?

WITNESS: There are no markings.

MR. KUSHAN: Then if you wish to

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use the spiral-bound version -- whichever one is more comfortable for you.

WITNESS: Thank you. I would prefer to use the spiral version.

MR. KUSHAN: All right. Then why don't we put those on the ground --

WITNESS: Thank you.

MR. KUSHAN: -- Ms. Court Reporter.

BY MR. KUSHAN:

Q. So my question today, these four declarations, are the opinions you've expressed in them generally the same except for particular position numbers in the PH20 sequence that may be relevant to particular patents?

A. They are substantively the same, with that exception, and, in one case, with the exception of the percent identity of the sequence.

Q. Okay. What I would propose to do is we'll use your declaration in the -0003 proceeding. I'll make reference to that with -- for page numbers so we can direct you to the right paragraph and the right document. Okay?

A. I understand.

Q. Could you go to your declaration in the

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-0003 proceeding and go to the last page that -- where you've signed the declaration, which is Page 173.

Is that -- is that your signature?

A. That is my signature.

Q. And when you signed this declaration, did you confirm that you believed the statement above your signature was correct?

A. I did so confirm.

Q. Great. Great.

And you signed this on September 23rd of 2025?

A. Yes.

Q. Did you form opinions in your declaration before September 22, 2025?

MS. MARTIN: Object to form.

A. So the declaration documents the summary of my opinions. They were not all formed in one day.

Q. Yeah. So I just want to confirm. You formed the bulk of your opinions prior to September 23rd of 2025. Right?

MS. MARTIN: Object to form.

Q. Let me give you a better question.

Were there any opinions that you had

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formed only on the 23rd of September of 2025?

A. Ah. I understand your question.

There were no opinions that were changed on September 23, 2025.

Q. Okay. Can you recall when you were retained to work on this matter?

A. Yes. I was first contacted in January 2025 and formally retained in February 2025.

Q. All right. If you had -- if you could, just give me an estimate of how many hours you've worked on the matters that resulted in these declarations.

A. My estimate to date would be about 150 hours.

Q. And do you recall when you began to prepare a declaration that ultimately became this declaration in the -0003 proceeding?

A. I don't recall a specific date, but the time frame would have been about in April or May of 2025.

Q. Are you aware of any errors in your declarations?

A. I am not aware of any errors in my declarations.

Q. Okay. And you understand that these four

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declarations each cons- -- there are four patents at issue in the four proceedings. Correct? You understand that?

MS. MARTIN: Object to form.

Q. You understand that each of the four proceedings has one patent involved in it. Right?

A. I understand that each of these declarations pertains to one specific patent.

Q. All right. Great.

MR. KUSHAN: I'm going to just introduce the patents so that we have them accessible. These are all numbered Exhibit 1001, so I'll have to refer to the other proceedings they're in.

First, we're going to introduce U.S. Patent No. 11,952,600, which is the patent at issue in the -0003 proceeding.

(Whereupon, Petitioner Exhibit 1001, previously marked, was presented to the witness.)

COURT REPORTER: Is it previously marked?

MR. KUSHAN: Yes.

COURT REPORTER: Thank you.

MR. KUSHAN: Also, Exhibit 1001 in the -0004 proceeding is U.S. Patent

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12,018,298.
(Whereupon, Petitioner Exhibit 1001, previously marked, was presented to the witness.)
MR. KUSHAN: Exhibit 1001 in the 2025-00006 proceeding, U.S. Patent 12,152,262.
(Whereupon, Petitioner Exhibit 1001, previously marked, was presented to the witness.)
WITNESS: Thank you.
MR. KUSHAN: And finally, Exhibit 1001, U.S. Patent 12,123,035 in the -00009 proceeding.
(Whereupon, Petitioner Exhibit 1001, previously marked, was presented to the witness.)
WITNESS: Thank you.
BY MR. KUSHAN:
Q. Just to start with these, did you review each of these patents in their entirety?
A. I did review each of these patents in their entirety.
Q. They're long, aren't they?
A. They are.
Q. All right. But you understand that the four patents have the same drawings and specification, and then they each have a different

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set of claims at the end.

You understand that?

A. Yes, I understand that.

Q. And so, that -- that drawing and specifications that are the same across those four patents, those you've reviewed, basically, once. There may be different numbers and columns and things for each of the patents, but across the four of them, you're looking at that as the same information. Is that right?

A. I did actually review each one --

Q. Yeah.

A. -- carefully, page by page. But I do recognize that, yes.

Q. Okay. And each of the patents is -- has a claim set where they have identified a particular position within the PH20 polypeptide sequence. Right?

For example, in the '600 patent, they refer to a position at 320. Right?

A. Yes.

Q. Okay. So we're familiar with the claims that differ in each patent relative to the common specification that they share. Right?

A. Yes.

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Q. Okay. If you could -- if you could, go to the '600 patent.

Can you go to the second page of this -- you know, just on the front of the '600 patent, you see the -- there's a bunch of information, like the number of the patent and the inventors, and then there's a section on the left column under the Item 60 that says "Related U.S. Application Data."

Do you see that?

A. Yes.

Q. If you could turn the page, and....

Do you see that there is a continuation of the related information -- application information?

A. Yes, in the left column.

Q. And if you go to the very bottom of that, you see a patent application that has the number 13/694,731?

(No audible response.)

Q. I'm at the bottom of that paragraph.

A. "13/694,731."

Q. Correct.

A. Yes.

Q. And that was filed on December 28th of 2012. Right?

A. Yes.

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Q. Okay. And then below that, you see there is another paragraph that lists two provisional applications. They were filed on November 1, 2012 and December 30, 2011?

A. Yes.

MR. KUSHAN: All right. I'm going to introduce the application that has the number 13/694,731. This is Exhibit 1026.

(Whereupon, Petitioner Exhibit 1026, previously marked, was presented to the witness.)

Q. This -- you understand that the '731 application was the very first thing that was filed by Halozyme in the patent office? This was their first patent application -- well, the patent application they filed on December 28th of 2012. Right?

MS. MARTIN: Object to form.

Q. Sorry. You understand that the thing I've handed you is the application that was filed with the Patent and Trademark Office by Halozyme as the '731 application?

A. Yes.

Q. Have you seen that document before?

A. Yes, I have.

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Q. Great. I'm going to use that document because it is the original filing, and the specification and drawings in that are the same as the four patents. Okay?

I'm going to refer to this, all the specification and drawings of that, along with the four patents, as the "common disclosure." Okay?

A. Okay.

Q. And I think you've used a term like that as well, right, in your declarations?

A. Yes.

Q. I just want to make sure we're speaking about the same thing when I ask you a question. So we'll just use that as a reference point. Okay?

A. Yes.

Q. All right.

A. I understand.

MS. MARTIN: Counsel, is it possible for you to speak up? I'm having a really hard time hearing you.

MR. KUSHAN: Sure.

MS. MARTIN: Thank you.

Q. Do you recall if you reviewed the two provisional applications that were referenced in the patents?

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A. I did not specifically review the provisional applications.

Q. Would any of your opinions in your declarations change between the dates of December of 2011 and December of 2012?

A. I don't --

MS. MARTIN: Object to form.

A. Okay. Could you ask me again? I'm sorry.

Q. Yeah. So the original application -- the provisional applications were filed in December of 2011. Then there was another one. The '731 application was filed in December of 2012.

I just want to make sure if you have different opinions about the state of the art or what a person of skill might have believed between those two dates.

Do you have a recollection if you have a difference of opinion around those two dates?

MS. MARTIN: Object to form and scope.

A. The majority of my opinions would not be substantively different between 2011 and 2012 consideration times.

Q. If I ask you a question today and there is a difference of your opinion between those two

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dates, will you please let me know?

A. Yes.

Q. All right. Are you familiar with the fact that these patents have also been filed with sequences of -- amino acid sequences and nucleotide sequences?

A. Yes.

Q. Do you know how many sequences were filed with each of these patents?

A. The sequence identification numbers are given for each of the patents within the claims.

And so, I understand that each patent covers some of the same sequence identification numbers and some different sequence identification numbers.

The sequences -- the reference sequences are given -- sometimes they're the same, sometimes they're different -- for modified PH20 polypeptides in each of the patents.

Q. Do you know how many sequences are actually included with the patent?

A. I know how many sequences are listed in this patent. There's a summary of them in the -- on the Appendix A page of my declaration.

And I haven't counted them line by line,

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but I think it's somewhere around 30 sequences.

Q. Would it surprise you to know that there's about 800 sequences listed with this patent?

A. Actually, it does not surprise me to know that. I know that the sequences that are listed here are reference sequences and that additional sequences are also referred to within the patent that have presumably also been filed alongside these sequences.

What -- so my uncertainty actually is with respect to what is considered filed with this patent versus what is part of the sequence IDs that they are referencing in their specifications.

Q. You didn't look at all the 800 sequences and evaluate them as part of your opinions, did you?

MS. MARTIN: Object to form.

A. I was not asked to evaluate all 800 sequences.

Q. Okay. Did you review any documents from -- issued by the Patent Trial and Appeal Board, the PTAB, in connection with these four proceedings?

A. I reviewed the prosecution history of the patent -- patents.

Q. You didn't review any decisions coming out of the Patent Trial and Appeal Board concerning

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these four proceedings, did you?

A. The materials I reviewed are in my table of exhibits.

Q. That's at Page 174 of your declaration?

A. 174 and 175. Yes.

Q. Well, I can just make it easier. Are the materials you used in connect- -- sorry.

Are the materials that you reviewed in connection with preparing your opinions what you have listed on Pages 174 and 175 of your declaration?

A. In combination with my general knowledge and expertise in the field, these specific documents are what I reviewed to prepare my declaration and to prepare for this discussion.

Q. You reviewed a declaration from Dr. Petsko. Right?

A. Yes. I reviewed Dr. Petsko's declaration.

Q. Do you recall being given Dr. Petsko's declaration from counsel?

MS. MARTIN: Oh, objection, to the extent that that's calling for privileged information.

That sounds like a yes-or-no question.

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A. Yes.
Q. Do you recall when you were given the declaration from Dr. Petsko?
A. I don't recall a specific date. It was certainly prior to my completion of my declaration.
Q. Do you recall if you were given more than one version of Dr. Petsko's declaration?
A. Yes.
Q. You were?
A. No, I was not.
Q. Oh, you were not.
A. I recall.
Q. I apologize. Thank you for that.
So you were given more than one version of Dr. Petsko's declaration, and you do not recall which dates you received them? Is that your testimony?
MS. MARTIN: Object to form.
A. I was given only the final signed declaration from Dr. Petsko, which I received and -- at a date I'm not certain of, and reviewed prior to finalizing my declaration.
Q. Do you recall how much time you spent reviewing Dr. Petsko's declaration?
A. I don't recall specifically.

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Q. Can you give me a ballpark number?
A. I can. Each of the -- including Dr. Petsko's declaration, required several hours for me to review.
Q. Do you recall providing any feedback on the declaration to counsel about Dr. Petsko's declaration?
MS. MARTIN: Objection. That's calling for the contents of communications with counsel. I'm going to instruct the witness not to answer.
MR. KUSHAN: All right.
Q. Do you recall seeing a spreadsheet that Dr. Petsko created that compiled information from the patent in it?
A. Yes.
MR. KUSHAN: I'm going to introduce what is Exhibit 2166.
(Whereupon, Halozyme Exhibit 2166, previously marked, was presented to the witness.)
Q. Do you recall if you received this document in paper form or PDF or in an Excel sheet format?
A. I received a PDF. I have since received a paper copy. I have also seen the spreadsheet

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document, which I received at the same time of the signed declaration.

Q. And you reviewed the spreadsheet?

A. Yes.

Q. Did you review the version in the Excel format?

A. Yes.

Q. Okay. Did you -- when you reviewed this spreadsheet, did you inspect like the formula that are embedded in the cells?

(Speakerphone voice.)

COURT REPORTER: Was there someone speaking online?

(No response.)

COURT REPORTER: Thank you.

(Witness reading.)

Q. So I had asked you a question whether, when you received the spreadsheet in Excel format, did you inspect the formulas used in the cells of the spreadsheet?

A. In some cases, yes.

Q. When you reviewed this document, did you identify any errors in it?

A. I did not detect errors in the document.

Q. Did you compare the information in this

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document to the information in the common disclosure when you reviewed it?

A. I did do that comparison, yes.

Q. And what was the nature of that comparison? What did you do when you were -- what were you looking for when you were comparing them?

A. I was looking to make the comparison between the arrangement of data by Dr. Petsko with respect to the data that were reported and how the data were collected, as reported within the patent specification.

Q. Did you identify -- or -- identify any classifications of the information that you saw in the declaration as being inaccurate with what had been described in the common disclosure?

A. I did not identify inaccuracies in Dr. Petsko's spreadsheet.

Q. All right. Between the time you were retained by counsel and the time you signed your declaration in September of 2025, have you had any conversations with Dr. Petsko?

A. No, I have not.

Q. Did you have any questions about Dr. Petsko's spreadsheet when -- after you had reviewed it?

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A. No, I didn't.
Q. Did you have any questions about Dr. Petsko's declaration that you reviewed?
A. No, I didn't.
Q. So you were able to use the spreadsheet and his declaration as they were written, without getting any clarifications from Dr. Petsko?
A. The declaration and the spreadsheet presented information that was, to me, very clear.
Q. Do you understand that Dr. Petsko was deposed last week, similar to what you're going through now?
A. I didn't know the date of his deposition. I knew that he was to be deposed.
Q. Are you -- have you been given a deposition transcript from his deposition?
A. No, I have not.
Q. Are you aware in any way of what Dr. Petsko said during his deposition?
A. No, not in any way. It would be pure speculation.
Q. All right. So you have not been given any information about what he said in his deposition?
A. No, I have not been given information about Petsko's deposition.

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Q. In Dr. Petsko's declaration, there are images of protein structures.

Do you recall that that is the case?

A. Yes, I do.

Q. Were you -- and are you familiar with the file format used for those types of image structures?

A. Yes, I am.

Q. What is it?

A. He used PyMOL to present the structures that he presented.

Q. Were you given PDB files that have in them information that reflects coloring and residues or orientations of the protein structure?

A. No. The PDB file for the HYAL1 crystal structure is available, obviously, in the PDB. It's public domain information.

The models that were made by Dr. Petsko were shared with me with specific images, not the specific files that he generated.

The specific images he generated were part of my consideration and analysis.

Q. So you received the PDB files of the modeled PH20 protein. Correct?

MS. MARTIN: Object to form.

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A. I did not receive Dr. Petsko's PDB files of his modeled PH20.

Q. Did you receive any PDB files having a model of PH20?

A. I did not.

Q. Did you inspect the -- so you didn't inspect the structure of the PD- -- sorry.

You did not inspect the model PH20 structure in PyMOL. Is that right?

A. As an expert in the study of the structure and function of hyaluronidases, I have myself modeled PH20 against the crystal structure of HYAL1 previously, quite a number of years ago.

I have done the exercise of considering the model in three dimensions. I did not use that information to influence my review in this -- my declaration.

I used, exclusively, the analysis in Dr. Petsko's declaration and the images he presented to form my opinions.

Q. I think that mostly answers my question, but I just want to make sure I understand -- I'm just kind of trying to understand how you went about your process of evaluating and forming your opinions.

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I want to just understand whether, in the course of forming your opinions, you used a tool like PyMOL to inspect a PH20 model at all in connection with your opinions that you've filed in this case.

A. Not in connection with forming my opinions for filing in this case.

Q. Did you look at a structure of HYAL1 in PyMOL as part of your work in preparing your opinions?

A. I did not. I did not look at any structures in PyMOL in preparation for these proceedings. I considered solely the analysis in Dr. Petsko's declaration as I prepared my declaration --

Q. And so --

A. -- coupled with my general knowledge and preexisting knowledge in the field.

Q. And so, when you were addressing or expressing opinions about the structure of PH20 that were addressed by Dr. Petsko, you were using his images of those structures that are in his declaration?

A. Yes. I relied on his images.

Q. And you didn't rely on other images of the

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structures in forming your opinions?

A. Other than the ones that are the published crystal structure and my own published work that are listed within the list of exhibits that I have declared.

Q. Okay. So when you were forming your opinions, you didn't, for example, have a session -- use a session with PyMOL where you were inspecting the different residues or the orientation of residues relative to the -- a particular area of the structure of the protein?

A. I did not personally do that, that analysis. I relied on Dr. Petsko's analysis, in which he did do that.

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

A. I did.

Q. Did you speak to Dr. Cherr?

A. I did not.

Q. Did you review a declaration from Dr. James Moon?

A. Yes, I did.

Q. Did you speak to Dr. Moon at any point?

A. I did not.

Q. Are you aware in any way of what Dr. Cherr

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said at his deposition?
A. Not in any way.
Q. You haven't been given a deposition transcript from Dr. Cherr?
A. I have not.
Q. And what about Dr. Moon; have you learned of anything that he said at his deposition in any way?
A. I have not.
Q. Have you reviewed a deposition transcript from Dr. Moon's deposition?
A. No, I have not.
Q. Have you spoken with any scientist from Halozyme?
MS. MARTIN: Object to form.
A. In connection with this matter?
Q. Yes.
A. No, I have not.
Q. Have you ever spoken with scientists from Halozyme?
A. Yes.
Q. Do you recall when?
A. I frequently attend a meeting of the International Society for Hyaluronan Sciences. The most recent time I would have spoken with a

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scientist from Halozyme would have been at our most recent meeting in June 2025.

Q. Do you recall speaking with scientists from Halozyme in the 2011-2012 time frame?

A. I could not give you a specific date or event, but this is a biannual meeting, and Halozyme attends it, as do I and others in the field of hyaluronan sciences. It is likely.

Q. Okay. Were you aware in the 2011-2012 time frame of any activities, any efforts by companies such as Halozyme to engineer modified forms of the PH20 protein?

A. Yes. I was aware of that type of an activity, yes.

Q. Do you have recollections about what the goal of those efforts were that you referred to?

MS. MARTIN: Object to form.

A. Could you be more specific?

Q. Sure. Were people developing those molecules for a particular reason?

MS. MARTIN: Object to the form.

A. It's -- that's a very general question.

In general, the engineering of proteins does have a reason associated with it.

And I could not necessarily name a

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specific goal, but I can certainly say with certainty that the scientists I know always have a goal in that type of an experiment.

Q. I was wondering whether some of the activities you were referring to were efforts to make a more stable form of the PH20 protein, for example.

Was that something you were aware of in the 2011-2012 time frame?

A. I was not aware of it. If it was occurring, if my colleagues were engaged in that research, it was not something I discussed with them.

Q. Have you reviewed any experimental records obtained from or provided by Halozyme, other than what might be reflected in the body of the common disclosure?

A. No.

Q. On your list of exhibits, you've reviewed declarations from two experts from Merck. One is -- who have provided testimony in this proceeding on behalf of Merck -- one is Dr. Park and one is Dr. Hecht. Right?

A. Yes.

Q. Did you review the entirety of their

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declarations?
A. Yes.
Q. Did you review the annexes in their declarations?
A. Meaning the appendices?
Q. Appendices, yes.
A. Yes.
Q. Okay. Do you have any reason to doubt the scientific credentials of Dr. Hecht or Dr. Park?
A. No.
Q. Are you aware of Dr. Hecht from your -- working in this field?
A. I was not actually previously aware of Dr. Hecht's work.
Q. You also reviewed deposition transcripts from the depositions of Dr. Hecht and Dr. Park. Right?
A. Yes.
Q. Did you review the entirety of each of their deposition?
A. Yes.
Q. Did you review -- review the exhibits to the declarations -- sorry, to the depositions? Sorry.
For the deposition transcripts, there are

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often a list of exhibits that were discussed in the deposition. And I'm just wondering if you had reviewed those deposition exhibits for any of these proceedings.

A. I looked to see what the exhibits were. And in some cases, they were documents I've reviewed. In some cases, they were not.

Q. All right. Why don't we go to your declaration in the -0003 proceeding. Let me know when you have that in front of you.

Could you turn to Paragraph 50 of your declaration, Page 17.

A. Yes.

Q. This is a section of your declaration -- you're discussing the person of ordinary skill in the art, which is abbreviated "POSA." Right?

A. Yes.

Q. Okay. If I say "POSA," you'll know what I'm referring to. Right?

A. Yes.

Q. Okay. And you quote what is Merck's definition of a POSA in your declaration at Paragraph 50. Right?

A. Yes.

Q. Would you consider yourself a person of

ordinary skill in the art in the 2011-2012 time frame?

A. In Paragraph 53:

> Considering my ample practical experience with hyaluronidases as described in my background and qualifications, I'm more experienced than a POSA under Merck's definition and was before 2011.

Q. Are the opinions you're presenting in your declaration being presented from the perspective of a POSA in the 2011-2012 time frame?

A. Yes; throughout my declaration.

Q. You refer to a POSA working as part of a multidisciplinary team. Right?

A. Yes.

Q. So if I'm looking at the team that I see here, you have yourself, Dr. Hecht -- I'm sorry. I'll try that one again.

The multidisciplinary team that you have here would be yourself, Dr. Petsko, Dr. Moon, and Dr. Cherr. Right?

A. Yes, I would look at it that way. That is

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a multidisciplinary team.

Q. So in this multidisciplinary team, do the individuals have particular roles?

MS. MARTIN: Object to form.

A. In this specific multidisciplinary team?

Q. Yes.

A. Each of us was asked to review a certain aspect of each of these patents and a certain experimental aspect of those patents that was within our areas of expertise. In that sense, each of us had a role.

In the sense that we did not discuss among each other what our individual roles were, which is what a multidisciplinary team often would do, it's more or less assumed, based on our expertise, that we had individual roles.

Q. What is your understanding of the role of Dr. Moon in this team?

MS. MARTIN: Object to form.

A. Dr. Moon, in his declaration, states what his role was and what he was asked to analyze and what opinions he was asked to provide.

His -- a review of his CV shows me that his expertise is in immunology. And so, I view his role as an expert in immunology.

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Q. What about Dr. Cherr; what do you see his role to be, based on your understanding?

A. Similarly to Dr. Moon, Dr. Cherr was engaged with a specific scope that he was asked to form opinions around.

In reviewing his CV, I can also see that his expertise is in reproductive biology, in generation of polyclonal antibodies, and especially in the role of PH20 in reproductive biology.

Q. And what is the role of Dr. Petsko in this team?

A. Dr. Petsko is a leading expert in structural entomology, and in analysis of structure/function relationships, in protein crystallography, and in the use of crystal structures to provide models and predictive -- use of predictive tools and statistical frameworks to provide confidence intervals for the results of those -- the application of those statistical tools, to provide confidence in his modeling.

He's an expert in redox biology and the study of Parkinson's disease and other neuro- -- neurological disorders.

Q. And then, finally, what's your role in this multidisciplinary -- disciplinary team?

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A. My role has been as a person who has been studying the family of hyaluronidase enzymes, specifically mammalian hyaluronidases, since approximately 1998, so as an expert in extracellular matrix biology, in biochemistry and molecular biology, with a special attention to structure and enzymology, and the use of those tools in the study of the hyaluronidase family, as well as other research areas.

Q. Do you believe that your role or your skill set is overlapping in some sense with Dr. Petsko's?

A. Every multidisciplinary team is most effective if there is sufficient overlap in their expertise that they can speak to each other and understand each other, develop a common language, to be able to use each other's opinions in an intelligent and independent way.

It is certainly the case that I have reviewed Dr. Petsko's textbook and used it in some of my teaching, some of my courses in the past, and that, with great humility, I would say Dr. Petsko and I do have some overlapping expertise.

Q. And just to be clear, in this setting, there was no what I would call ordinary interaction

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that would occur between this multidisciplinary team in the course of the work that you prepared in this proceeding?

MS. MARTIN: Object to form.

Q. You haven't spoken to each other?

A. No. Thank you.

Q. Normally, the members of the team would speak to each other. Right?

A. At least email each other. Yes, there would be some communication among the members of the team.

Q. Okay. I forgot to mention this, but at the beginning, one thing we do want to make sure we do is take periodic breaks.

And we've been going for about -- almost an hour. If you'd like to take a break now, we can do that, before I move on to my next topic.

A. Sure. That sounds great. Thank you.

MR. KUSHAN: All right. Why don't we do that.

VIDEOGRAPHER: Off the record at 10:02.

(Whereupon, a recess was taken.)

VIDEOGRAPHER: On the record at 10:19.

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BY MR. KUSHAN:

Q. Dr. Simpson, did you speak with counsel during the break?

A. Not about any matters concerning the case.

Q. What did you speak about?

A. How cute the decorations were in the corridor.

Q. Could I have you go to your declaration in the -00003 proceeding. And if you could turn to Page 109, Paragraph 260.

Do you see, in Paragraph 260, you have reproduced the text of claim 1 of the '600 patent?

A. Yes, I see that.

Q. Okay. I just want to go through some of the language in the claim with you. Okay?

A. Yes.

Q. So the first clause in the claim states:

> A modified PH20 polypeptide comprising an amino acid sequence....

Right?

A. Yes.

Q. Okay. And then, in the next three paragraphs, you see parameters relating to that amino acid sequence. Right?

A. Yes.
Q. Okay. So in the first paragraph, that requires the amino acid sequence to have 95% sequence identity to one of a number of reference sequences. Right?
MS. MARTIN: Object to form.
A. Could you please repeat your question?
Q. Sure. In Paragraph (a) of the claim, it specifies that the amino acid sequence must have 95% sequence identity to one of a list of reference sequences. Right?
MS. MARTIN: Object to form.
A. So Part (a) specifies that:
> At least 95% of the residues of the amino acid sequence of the modified PH20 polypeptide are identical to the residues in an amino acid sequence selected from the group consisting of SEQ ID NOs: 3 and 32-66.

And then specifies that they should be aligned to maximize identical residues and treating terminal gaps as non-identical.
Q. So the amino acid sequence of the modified

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PH20 polypeptide must have 95% sequence identity relative to the -- one of those reference sequences. Right?

MS. MARTIN: Object to form.

A. It's my understanding that the claim in Part (a) states that the modified PH20 polypeptide comprises an amino acid sequence that is 95% identical to the sequence of SEQ ID NO: 3 and -- and/or one of the sequences from among 32-66.

Q. Okay. And you're familiar with this concept of sequence identity between two amino acid sequences?

A. Yes.

Q. Okay. So if I refer to 95% sequence identity in the claim, you'll know what I'm referring to. Right?

A. Yes.

Q. Okay. So the -- in Paragraph (b), there is a requirement that the amino acid sequence have a modification at position 320. Right?

A. Yes.

Q. And then the third paragraph adds the requirement of that modification has to be a replacement of the wild-type amino acid at position 322, one of four alternative amino acids.

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Right?

A. Yes.

Q. Okay. And then, the claims in the other patents have similar style to this format. Right?

MS. MARTIN: Object to form.

Q. They have a sequence identity parameter, they have a particular residue that's been identified, and there are often choices for which amino acids could be replaced at that position, in those other claims. Right?

A. Yes. If that's what you're referring to with the word -- the term "style," that's my understanding, yes.

Q. Perfect. If you could go to Page 110, which is the next page, and go to Paragraph 264 -- I'm sorry.

Go to Page 111, which is where 264 is located.

In this paragraph, you're referring to a passage in the common disclosure. Right?

MS. MARTIN: Object to form.

A. Yes. The passage is excerpted from the '600 patent.

Q. And what you're saying is -- in Paragraph 64 [sic], you're saying that in this

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passage from the '600 patent, it is, like the claims, referring to a modified PH20 polypeptide by reference to an amino acid sequence, its primary structure. Right?

A. Yes.

Q. And then it only describes the structural features of the sequence of amino acids, the existence in that amino acid sequence of an amino acid modification relative -- relative to a reference sequence. Right?

MS. MARTIN: Object to form.

A. The passage:

> ...defines "modified PH20 polypeptide" by reference to its primary structure, amino acid sequence, not a particular function. It describes structural features:
>
> (i) a sequence of amino acids (ii) with at least one modification (iii) relative to a reference sequence.

Q. Okay. So the focus in your comment on Paragraph 20 -- 264 is that this passage is referring to the amino acid sequence of the modified

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PH20 polypeptide and attributes of that amino acid sequence. Is that fair?

A. Yes.

Q. Okay. Could I have you go to Page 11 at the front of your declaration, Paragraph 28.

A. Yes.

Q. And you state that it's your:

> ...opinion that a POSA would have understood that claims define the invention by reference to its structure, without regard to a particular function....

And then, in the second sentence, you identify those structural components as being:

> (i) a sequence of amino acids (ii) with at least one amino acid modification (iii) having 95% identity relative to a reference sequence.

Right?

Those are the structural features of the sequence that you've identified?

MS. MARTIN: Object to form.

A. As you've recited from this paragraph,

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that is accurate.

Q. Okay. So you believe that any polypeptide that has an amino acid sequence with 95% sequence identity to SEQ ID 3, for example, plus a replacement of aspartic acid at 320 to any of histidine, lysine, arginine, or serine would meet all the requirements of claim 1. Is that right?

A. Any polypeptide with 95% sequence identity to the reference sequence, SEQ ID 3, for example, with position 320 modified 95% identity, those are the polypeptides covered in claim 1.

Q. Okay. So in the first line of the claim, does the word "PH20" add any requirements to claim 1?

MS. MARTIN: Object to form. Objection; scope. Objection; relevance.

A. Can you repeat the question? I'm not actually sure what you mean.

Q. Sure. In claim 1, it refers to "a modified PH20 polypeptide comprising an amino acid sequence." Right?

A. Yes.

Q. And I asked you if a polypeptide that met the sequence requirements in the claim met the claim requirements. Right?

You answered "yes."

A. I understand.

So the term "modified PH20 polypeptide" is specifically defined by the patent.

Q. Right. I want to -- I'm focusing on just the word "PH20."

Does PH20 add any requirements into the amino acid sequence or the protein beyond what's recited as to the requirements of the amino acid sequence in the claim?

MS. MARTIN: Object to form.

A. I'm still not sure I understand your question. Could -- maybe be specific about what....

Q. Sure. So you see the words "modified PH20" and "polypeptide." Right?

Those are three different words.

A. Yeah.

Q. Okay. So if PH20 were not in the phrase, would you identify a different set of amino acid sequences compared to if it is present in the phrase "modified PH20 polypeptide"?

MS. MARTIN: Object to --

Q. I'm trying to understand whether PH20 is imposing any additional requirement beyond the features of the amino acid sequences that are

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recited in the claims.

MS. MARTIN: Object to form.

A. Because there is a specific sequence given, the term "PH20" doesn't impose any greater restraints. That is the sequence of PH20 in a modified polypeptide, as defined by the claims and by the patent.

Q. So if I'm visualizing claim 1 as defining a set of amino acid sequences -- is that term conceptually accessible to you, that the claim is defining a set of amino acid sequences that share these features? Is that -- you understand that?

A. Yes.

Q. Okay. So that set of amino acid sequences defined by the parameters in claim 1 does not vary based on the presence of the word "PH20" in the first line of the claim. Right?

MS. MARTIN: Object to form.

A. The term "PH20" is embedded in the phrase "modified PH20 polypeptide," which has a specific definition as defined in the patent disclosure.

Q. So it's not -- "PH20" is not adding anything as a requirement into the features of the polypeptide or the amino acid sequence defined by the claim. Is that right?

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MS. MARTIN: Object to form.

A. I'm still not sure I understand what you're getting at.

Q. Why don't -- why don't you -- why don't you go back to Paragraph 260, where you see the language of the claim. And I'll try to make a better question for you.

A. Thank you.

Q. If I were to remove the word "PH20" from the first line of the claim, would you see a different set of amino acid sequences relative to what is there in the claim?

MS. MARTIN: Object to form.

Objection; scope.

A. The claim is on the basis of sequences that are identified and given. The sequences are absolute.

The nomenclature of "modified PH20 polypeptide" helps a POSA understand what the context is for those sequences and where they're found biologically, but the sequence structure itself doesn't necessarily require the term "PH20" to define it.

And the patent claim would not change if the word "PH20" wasn't there, but it is defined

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within the disclosure of the patent. So it's part of the specific phrase used to define this polypeptide sequence and refer to it throughout the patent disclosure.

Q. Okay. Could I have you go to Paragraph 263 of your declaration. And that's what we mentioned a minute ago.

You say that the '600 patent explicitly defines, quote, modified PH [sic] polypeptide, and then you reproduce your -- the definition in the patent of that phrase. Right?

A. Yes.

Q. And you read -- the first sentence of the paragraph that you've quoted is the portion that is defining the meaning of the phrase "modified PH20 polypeptide." Is that right?

A. I'm sorry. Could you repeat that, please?

Q. The section that you've quoted --

A. Yes.

Q. -- is a paragraph. It has more than one sentence. Right?

A. Yes.

Q. Do you see that?

A. Yes.

Q. Okay. I'm asking you: Is your

understanding that the phrase "modified PH20 polypeptide" is defined by the first sentence of that paragraph?

(Witness reading.)

A. Yes, the phrase "modified PH20 polypeptide" is defined by the first sentence.

Q. Do you view the additional sentences in this paragraph to not alter the definition of that term, "modified PH20 polypeptide"?

A. I do view that, yes.

Q. Could you go to Exhibit 1026, which is the very big '731 application.

A. Yes.

Q. If you could go to Page 54 of Exhibit 1026.

A. Yes.

Q. If you want to take the binder clip off, it might be easier, but it's up to you.

Okay. And do you see, at Lines 5 to 14, that's the paragraph you had reproduced in Paragraph 263 of your declaration?

(Witness reading.)

A. Yes.

Q. Okay.

A. The two appear identical.

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Q. So you're using a portion of the common disclosure that defines this term, "modified PH20 polypeptide," in a particular paragraph in the disclosure. Right?

MS. MARTIN: Object to the form.

A. So this is -- the paragraph from Lines 5 to 14 of the '731 application is the paragraph reproduced in my declaration.

Q. And you're treating the first sentence of that paragraph as being the definition of the term "modified PH20 polypeptide." Right?

A. The first sentence of this paragraph is the definition, yes, of "modified PH20 polypeptide."

Q. Could you go to Page 50 of the common disclosure. It's 1026.

And at the bottom of the page, do you see a definition of the word "PH20" around Line 31?

A. Yes.

Q. And what is the definition of PH20 that the common disclosure provides?

A. (Reading:)

> As used herein, PH20 refers to a type of hyaluronidase that occurs in sperm and is neutral-active.

Q. So as the term "PH20" is defined in the common disclosure, it's PH20 on sperm cells. Right?

MS. MARTIN: Object to form.

A. As PH20 is defined?

Q. Yes.

A. That was the --

Q. Yes.

A. -- question. As PH20 is defined here in this sentence, it refers to a type of hyaluronidase that occurs in sperm and is neutral-active.

It does state that it occurs on the sperm surface as well.

Q. So when the PH20 is on the sperm surface, is it a folded protein?

A. Yes.

Q. And it's enzymatically active. Correct?

A. In normal biology, surface-associated PH20 would be enzymatically active.

Q. And it's -- because it is properly folded, it is enzymatically active. Right?

MS. MARTIN: Object to form.

A. Properly folded PH20 should have enzymatic activity, yes.

Q. Okay. And this is how the common disclosure defines the term "PH20." Right?

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MS. MARTIN: Object to form.

A. PH20 is defined as a type of hyaluronidase that occurs in sperm and is neutral-active.

It explains further that it occurs on the sperm surface. In this particular paragraph, the folded structure is not specified.

Q. But it would just be the folded structure that occurs naturally with the PH20?

A. If PH20 is active on the sperm surface, it is assumed to be folded.

Q. Okay. Could you go to Page 110 of your declaration.

And just take a look at Paragraphs 262 and 263. We talked about 263, but look at 262 as well.

And when you finish reading that, let me know.

(Witness reading.)

A. Yes.

Q. Is it your opinion that Dr. Hecht's opinion is that the phrase "modified PH20 polypeptide" by itself imposes a requirement for enzymatically active proteins, as you state in Paragraph 262?

MS. MARTIN: Object to form.

A. I understand that Dr. Hecht's position is

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that the term "modified PH20 polypeptide" in the claim requires greater than equal to 40% hyaluronidase activity compared to wild type.

Q. And I'm just asking: Do you understand Dr. Hecht to be saying that the phrase "modified PH20 polypeptide" by itself is what requires it to have enzymatic activity?

MS. MARTIN: Object to form.

A. I think I see what you're saying. Could you repeat the question once more, please?

Q. Sure. Is it your opinion that Dr. Hecht is relying on the words "modified PH20 polypeptide" by themselves to be imposing the requirement in the claims that the enzyme be enzymatically active?

MS. MARTIN: Object to form.

A. My opinion is that Dr. Hecht formed his opinion by making an interpretation for himself of what modified PH20 polypeptide referred to.

Q. And so, your understanding is that he formed his opinion about the words "modified PH20 polypeptide," and when they occur in the claim, those words by themselves imposed a requirement that the PH20 polypeptide was enzymatically active.

MS. MARTIN: Object to --

Q. Is that right?

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MS. MARTIN: Object to form.

A. Without looking directly, at the moment, at Dr. Hecht's declaration, I don't recall whether he specifically said that he was defining modified PH20 polypeptide differently than I have defined modified PH20 polypeptide according to the first sentence of the claim.

The way in which he has rendered his opinions certainly reflects that he is interpreting modified PH20 polypeptide to mean an active PH20 polypeptide.

Q. Do you believe he relied on anything else in the claim to reach his conclusion that the claim required the PH20 polypeptide to be enzymatically active?

MS. MARTIN: Object to form.

A. I didn't try to understand what motivated Dr. Hecht to form his opinions.

Q. Could you go to Paragraph 257 of your declaration. It's back a few pages.

You make a similar observation in Paragraph 257 [sic] to what you referred to in 262, where you say you:

Do not see any reason why a POSA would understand the

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claims to require a particular type of function, let alone 40% or more activity.

And that's what you're stating in Paragraph 257. Right?

MS. MARTIN: Object to form.

A. In Paragraph 257, I am stating my understanding of Dr. Hecht's tested -- testimony at deposition that the claims require greater than or equal to 40% hyaluronidase activity compared to wild type, such that if it had less than 40% activity, it would not be covered by the claims.

I did not, in that paragraph, disagree with his opinion --

Q. Look at --

A. -- but I did in the following.

Q. -- Paragraph 258.

A. And could you please repeat your question?

Q. Sure. You stated in 258 that you don't agree with Dr. Hecht. Right?

A. Yes.

Q. And you say, based on your review of the claims and the specification, it's your conclusion that the claims are defined by the recited structure: The amino acid sequences, the mutation

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at 3 -- D320, in reference to SEQ ID 3, and the 95% sequence identification.

Right?

A. Yes.

Q. Okay. And then you state:

> I don't -- I do not see any reason why a POSA would understand the claims to require a particular type of function, let alone 40% or more activity. There's no language in the claim suggesting it.

Right?

A. Yes, that was my stated opinion.

Q. So it was your understanding that Dr. Hecht based his opinion that the claim required enzymatic activity solely on his use -- or the claim's use of the phrase "modified PH20 polypeptide"?

MS. MARTIN: Object to the form.

A. Again, difficult for me to offer an opinion about how Dr. Hecht formed his opinions.

Q. Well, you're offering opinions -- opinions about his opinion in your declaration. Right?

A. I offered an opinion about what he stated

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as his opinion. I did not speculate on how he formed it.

Q. Do you believe, when -- well, when you reviewed Dr. Hecht's declaration, did you identify any explanation in his declaration as to why he concluded that the claim required enzymatic activity?

A. I would prefer to have his declaration in front of me before commenting.

Q. Sure. We'll do that in a second.

As you state your opinion in Paragraph 257, you're referring to the thing he said in his deposition. Right?

MS. MARTIN: Object to form.

(Witness reading.)

A. The opinion that I stated does reflect a statement that Dr. Hecht made in his deposition.

Q. You also state you:

> ...don't see any reason why a POSA would understand the claims to require a particular type of function, let alone 40% or more activity.

Is there any reason, from your review of the patent -- of the common disclosure to -- for a

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person of ordinary skill to conclude that 40% activity has significance for PH20 polypeptides?

A. In my review of the common disclosure, there is not a reason to consider a specific activity level in interpreting the statement in claim 1.

Q. Do you recall if the common disclosure uses that 40% activity number in any context to characterize the polypeptides, the PH20 polypeptides that it's describing?

A. I do.

Q. And what was that role? What is it using that 40% number for?

MS. MARTIN: Object to form.

(Witness reading.)

A. As an example, on Page 93 of the common disclosure in the '731 application, Table 3 lists active mutants of PH20 polypeptides, wherein they are listing mutants and characterizing activity as 40% of the hyaluronidase activity of the PH20 polypeptide set forth in SEQ ID 3.

Q. And that SEQ ID 3 is the wild-type sequence truncated at position 447 of PH20, human PH20?

Make it easier: Wild-type -- it's the

wild-type sequence except for the truncation. Right?

A. Yes, that's correct.

Q. Okay. So it's measuring the mutant activity relative to the activity of the wild-type human PH20, truncated PH20. Right?

A. Yes.

Q. Okay. So does the common disclosure differentiate those modified PH20 polypeptides from other kinds of PH20 polypeptides?

MS. MARTIN: Object to form.

A. In what way?

Q. Is there another class of modified PH20 polypeptides identified in the common disclosure, besides active mutants?

A. Yes.

Q. And what are they?

A. They also list, for example, in Table 5 of '731 application in the common disclosure, on Page 132, inactive mutants of PH20.

Q. And are inactive mutants of PH20 defined by some enzymatic characteristic?

A. The disclosure states, for this specific table, that the term "inactive" refers to exhibiting less than 20%, and generally less than 10%, of the

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hyaluronidase activity of the PH20 polypeptide in SEQ ID 3.

Q. So inactive mutants -- inactive mutants are the modified PH20 polypeptides that have less than 20% activity relative to the wild-type PH20?

MS. MARTIN: Object to form.

A. As defined in Table 5.

Q. Is that -- it's limited to Table 5?

A. There are additional tables in the disclosure in which there may be other definitions of inactive or criteria for inactive.

Here in this table, inactive is defined as less than 20%, generally less than 10%, hyaluronidase activity.

Q. Do you recall if there's another table compiling inactive mutants in the patent?

A. Yes.

Q. Table 10? Is that the one you're thinking of?

A. Yes. Thank you.

Q. If you want -- and does Table 10 define inactive mutants differently than Table 5 defines inactive mutants?

A. Within this table are listed other -- other mutants of PH20 that also exhibit less than

20% hyaluronidase activity. So it's a similar definition.

Q. So the patent is classifying modified PH20 polypeptides as active mutants if they have activity above 40% relative to the wild-type sequence. Right?

MS. MARTIN: Object to form.

A. The patent lists the mutants in a table as active mutants if they have 40% or more activity.

The patent also discloses polypeptides with activity that is not 40%.

Q. Do you, as you sit here now -- I want to probe this a little bit later today -- but are you aware that -- of the classification procedure they use for putting modified PH20 polypeptides into Table 9?

(Witness reading.)

A. Yes.

Q. So there are two samples measured in the example they describe here for the experimentation that was done. Right?

MS. MARTIN: Object to form.

Q. For each mutant, there were two samples measured. Right?

A. Each mutant was tested in duplicate, yes.

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Q. And if one of the two samples -- one of the two duplicates recorded activity above 40% of the wild type, it was classified, at that position in that mutant, as an active mutant. Right?

A. Following normalization and within the overall experimental context, which we haven't discussed -- but, yes.

Q. All right. So the patent is classifying as one kind of PH20 polypeptide those that had activity measured above 40% relative to the wild type. Right?

MS. MARTIN: Object to form.

A. The patent provides a table that lists all of the mutants that were tested that exhibited greater than or equal to 40% activity.

Q. Could you go to -- go to your declaration, please. And if you could, go to Page 127 and Paragraph 303.

This is a fairly long paragraph, so if you want to just take a minute and review it. It extends on to the next page.

(Witness reading.)

A. Yes.

Q. Okay. So in this Paragraph 303, you're discussing inactive mutants. Right?

A. As you said, it's a lengthy paragraph. It does touch on inactive mutants. That's not the exclusive topic of the paragraph.

Q. You're addressing some attributes of inactive mutants. Let me just do a terminology check.

You use the word "inactive variants."

Are you using inactive variants to mean something different than inactive mutants in the patent?

A. No.

Q. Okay.

A. No, it's --

Q. Okay.

A. -- the same term.

Q. And then, in your Paragraph 303, you're identifying a number of positions in PH20 that are essential to the enzymatic -- enzymatic activity of PH20. Right?

A. Yes. There are a number of known -- known substitutions that are known to inactivate the enzyme, yes.

Q. And these are positions that, if you change them from their wild-type amino acid, it will cause problems for the protein. Right?

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A. I just want to be clear what you mean by "cause problems."

Q. So there are a couple things you mentioned here. One is that you could disrupt the folding of the protein. Right?

A. Yes.

Q. Another thing, you may cause a loss of enzymatic activity of the native protein by making a mutation at one of these essential positions. Right?

A. Yes.

Q. Those are perhaps not exclusive scenarios. Right? Fold --

A. Correct.

Q. -- to -- okay. Go ahead.

A. Yes. That's correct.

They could occur together.

Q. All right. They could destabilize disulfide bond formation as well. That would be another impact that would be adverse for the protein structure. Right?

A. Yes.

Q. And you say that the common disclosure identifies several of these positions that have this essential characteristic for the either folding or

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activity of the PH20 protein. Right?
A. Yes.
Q. And your view is that a POSA would not consider any of those essential positions to be tolerant to change. Is that fair?
MS. MARTIN: Object to form.
A. My view is that where there are published data available, in particular, a POSA would already be aware of those published data. And that included where there were invariant residues in the sequence that had been functionally demonstrated to be required for enzymatic activity and/or for disulfide bond formation and proper folding of the protein. A POSA would be aware of that.
Q. Which -- so those were residues that have been identified before this patent was filed in 2011 -- first filed in 2011?
A. Yes.
Q. How would the person of skill in the art identify those positions from the literature?
(No audible response.)
Q. Well, I'll make it simpler: How would they identify those positions?
A. So a literature search. Is that what you're asking?

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Q. Let me make you -- let me give you a better question.

How would a person of skill in the art identify the essential residues we've been discussing from available information as it existed in 2011?

A. A number of publications were available that either had identified experimentally, within the context of PH20 polypeptide, what the specific catalytic residues were, together with the available crystal structure for HYAL1, in addition to critical residues demonstrated in the context of HYAL1, and then being able to superimpose a model of PH20 and its active site residues onto the active site residues of the HYAL1 structure.

We would have a full picture, as POSAs, of what residues were responsible for catalytic activity.

Q. What about folding; how would you identify which positions were important or necessary for folding of the protein?

A. One of the ways that can be used, especially in the hyaluronidase family, in which the structures are relatively invariant, is to align the sequences, as has been done by not only the authors

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of the Chao paper, the HYAL1 crystal structure paper, but also by probably everyone involved in writing a declaration in this case.

The alignments are also super -- reproduced within this declaration. By looking at the alignments, there are a number of invariant residues. A knowledge of which invariant residues are the active site residues allows us to exclude those from consideration as active site residues.

There are a number of other invariant residues using the structure that can be deduced to be responsible for substrate docking.

Those may or may not be folding determinants, but additional residues that don't appear to be directly in contact with the substrate and are not directly defined as active site residues within 5 angstroms of a docked substrate are likely candidates for structural determinants.

Q. When you're using structural determinants here, those are the residues that are essentially necessary for the protein to fold and adopt its three-dimensional structure. Right?

MS. MARTIN: Object to form.

A. When I say "structural determinants," I do generally mean amino acids and/or elements of

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secondary structure or tertiary structure that are involved in the fold that's adopted by the family of hyaluronidases.

Structural determinants can be atomic, molecular, or elements of folded structure within the polypeptide. I'll try to be more precise.

Q. So they can be -- the determinants can be due to the chemical character of the residue and the atoms in it. Right? That's one variable?

MS. MARTIN: Object to form.

A. The structural determinants, if I'm talking about just the amino acid sequence -- so we were talking about sequence alignment and how I would identify structural determinants.

If I'm looking just at the amino acid residue as the structural determinant I'm considering, then, yes, its -- its physicochemical properties and its position within the folded structure are informing my decision about whether I consider it a structural determinant.

Q. All right. If you could go to the '731 application again and go to Page 93.

By the way, there are two numbers on every one of these pages. I'm referring to the number on the bottom right corner, 93.

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And if there's ever any confusion, just let me know. I'll try to make sure we don't have any confusion in the record.

So this is Page 80 in the printed document, and it's Page 93 on the exhibit.

A. Thank you.

Q. So at this -- on this page, you'll see a sentence -- or a paragraph that begins, "The results herein confirm the requirement of PH20 amino acids corresponding to positions," and then it gives a list of them.

You've reviewed that paragraph before?

A. Yes.

Q. Okay. And this is reporting that the testing in the patent has confirmed that all of these positions in the PH20 sequence are required for hyaluronidase activity. Right?

(Witness reading.)

A. Sorry. Could you please repeat your question?

Q. Sure. This paragraph is stating that the experimental results in the patent are confirming these positions that are listed as being required for hyaluronidase activity in the PH20 protein. Right?

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MS. MARTIN: Object to form.

A. This paragraph asserts that the results herein -- meaning, within the application, at those positions -- I think you said "PH20," but it specifically says that the residues refer to the mature PH20 lacking signal sequence, such as set forth in those specific references required for hyaluronidase activity.

Q. So these are the positions -- the amino acid residues at these positions are required for hyaluronidase activity, according to this paragraph. Right?

MS. MARTIN: Object to form.

A. So the paragraph refers to results within the disclosure that show amino acids that are required for hyaluronidase activity, which is dependent on hyaluronidase correct expression as a soluble polypeptide.

And this particular paragraph doesn't distinguish from among these residues with respect to which of them is required for activity in the successfully secreted soluble protein versus the expressed but not successfully secreted polypeptide.

Q. And it's confirming that these residues had been previously identified -- it's confirming

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the -- the connection between these particular positions and their necessity for hyaluronidase activity that had been published before or known before 2011. Right?

(Witness reading.)

A. I want to use precise language in answering your question.

I can't recall the exact content of the references cited with respect to the residues involved in disulfide bond formation.

It's possible to implicate those residues in disulfide bond formation by nature of their being cysteines, which are capable of disulfide bonds, and being conserved and with reduction of the bonds and testing of activity without specifically mutagenizing each residue.

In this paragraph, it doesn't state whether those cysteines were mutagenized in those prior publications.

So the listing of these residues is confirming their requirement for activity as previously published, without specifically implicating them in solubilized activity versus expression.

Q. Okay. So -- and this paragraph is kind of

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at the end of a section that's kind of doing a survey of what had been known before the patent was filed. Right?

MS. MARTIN: Object to form.

A. The purpose of this section overall is to explain the state of the art with respect to what's known about PH20 and specifically about its structure.

Q. Okay.

MS. MARTIN: So, Counsel, we've been going for almost exactly an hour. Is it time for a break?

MR. KUSHAN: Yeah. Why don't we -- if it's okay, let's just -- I have a couple quick questions to finish this. Maybe a couple minutes, if that's all right.

MS. MARTIN: Would you like a break? Or....

MR. KUSHAN: Can you just go for another minute or two?

WITNESS: I've been advised to --

MS. MARTIN: Let's take a break.

WITNESS: -- stick with what my

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counsel advises.

MS. MARTIN: Let's take a break.

WITNESS: We'll take a break.

MR. KUSHAN: All right.

VIDEOGRAPHER: Off the record at 11:16.

(Whereupon, a recess was taken.)

VIDEOGRAPHER: On the record at 11:37.

BY MR. KUSHAN:

Q. Dr. Simpson, did you speak with counsel during the break?

A. Not on matters relevant to the case.

Q. What did you speak about?

A. Still on the decor of the building. Those interesting tube lights and the living moss.

Q. Are you still on Page 93/80 of the common disclosure? That paragraph we were looking at, at -- starting at Line 19, can you go there? Okay.

A. Yes.

Q. Are any of the positions listed in that section we were discussing before the break position 320?

A. No.

Q. What about position 313?

A. Specifically in this paragraph? No.
Q. And is position 317 in that set?
A. No; 317 is not there.
Q. What about position 312; is that in that set?
A. No; 312 is not.
Q. What about position 324?
A. Position 324 also is not in this set.
Q. What about position 307?
A. Position 307 is not in this set.
Q. And then, what about position 309?
A. Position 309 is not in this set.
Q. All right. Earlier today we had a discussion about Dr. Petsko's declaration.
Do you remember that?
A. Yes.
MR. KUSHAN: Okay. I'm going to introduce Exhibit 2070.
(Whereupon, Halozyme Exhibit 2070, previously marked, was presented to the witness.)
Q. And I had asked you previously if you had reviewed Dr. Petsko's declaration. I believe you said you had reviewed what was the final version of the declaration?
A. Yes.

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Q. Could you turn to Page 226 of Exhibit 2070.

Do you see that Dr. Petsko executed the -- his declaration on September 22nd?

A. Yes.

Q. And that was a day before you executed your declaration. Right?

A. Yes.

Q. Did you conduct your review of Dr. Petsko's declaration for the purposes of forming your opinions in your declaration between the 22nd of September and the 23rd of September of 2025?

A. I reviewed Dr. Petsko's declaration between September 22nd and 23rd.

However, the section that addresses the opinions on structure and function within my declaration were formed prior to September 22nd.

Q. Did you review only the section of Dr. Petsko's declaration that corresponds to the region you just mentioned that you used for your opinions?

A. I reviewed the full declaration from Dr. Petsko.

Q. Do you know if the full version of Dr. Petsko's declaration that you reviewed is

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identical to the one that he executed on the 23rd -- sorry, the 22nd of September 2025?

A. Yes. I confirmed that.

Q. Did you have a red line or something of the two documents?

A. I reviewed the full declaration as he had signed it. I reviewed a red-lined copy of a draft that he -- that was completed prior to his signature being appended.

Q. And they were identical?

A. They were not substantively different.

Q. Do you have any recollections of what was different?

MS. MARTIN: Object to....

Q. I'm just asking about what you just mentioned.

A. I do not have a recollection. Given that they were not substantive, it didn't impact my final declaration.

Q. So the version that you reviewed before he attached his signature to it, do you remember when you reviewed that version?

A. Not precisely.

Q. Like a week or two ahead of the 22nd, or was it further away from -- earlier -- I'm sorry.

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Was it within a week or two of him signing the declaration on the 22nd of September?

MS. MARTIN: Object to form.

A. It was -- I don't recall the date precisely. I can estimate that it was within a couple of weeks of the declaration's signature.

I can say that it was a near-final draft, and I can recall that the differences that I state as nonsubstantive were typographical.

Q. Do you recall if you saw a version of his spreadsheet at that time, when you were reviewing this draft you just mentioned?

MS. MARTIN: Object to form.

A. Yes.

Q. And did you check the version of the spreadsheet that you used at that time, relative to the version that was -- the final version, which we showed you earlier today?

MS. MARTIN: Object to form.

A. I carefully reviewed all documents, particularly those that I cited in my list of exhibits, in the final 24 hours before signing my declaration, and particularly attended to details such as whether representative tables were identical to the tables that were being cited in the list of

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exhibits, yes.

Q. And they were identical?

A. They were identical.

Q. Okay. Could I have you go to Page 13 of your declaration and look at Paragraph 33.

A. Yes.

Q. Just some terminology. What do you mean by "claimed genus" in the first sentence?

MS. MARTIN: Object to form.

A. I'm referring to the claimed genus as the set of modified PH20 polypeptides that are defined within claim 1.

Q. So that's the set of polypeptides that meet the claim parameters in claim 1. Right?

A. Yes.

Q. Okay. You -- in this Paragraph 33, you indicate that the claimed genus --

(Reading:)

A POSA would have understood that the claimed genus is a narrow set of PH20 variants and sub-variants that are structurally homogeneous.

Are you referring to the primary structure being the basis of structural homogeneity?

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A. In the first sentence, I'm referring to the primary structure.

Q. And you understand that the 95% sequence identity permits up to 21 or 22 or 23 changes, depending on which reference sequence it is -- is used as the reference point for that 95% identity requirement. Right?

A. I understand what 95% identity means numerically.

Q. And that translates into up to 20, 21, 22 changes in the primary sequence relative to the wild type of PH20. Right?

A. In the case of the modified PH20 polypeptide claimed here with respect to the sequence, the reference sequence, yes.

Q. You portray this as a narrow set of PH20 variants.

Do you mean that the number of different polypeptide sequences that are in that set is a narrow set of sequences?

MS. MARTIN: Object to form.

A. I maintain that -- or have expressed that POSAs would have understood the claimed genus to be a narrow set of PH20 variants and subvariants, structurally homogeneous.

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Q. Is the set of distinct polypeptides in that set a small number?

MS. MARTIN: Object to form.

A. The theoretical maximum number of sequences that can potentially be defined within that claimed set is potentially not a small number.

The theoretical maximum is a large number.

Q. Do you have an understanding of what that number is?

A. I understand Dr. Hecht and Dr. Park calculated it.

Q. Did you find any errors in their calculations?

A. I don't disagree with the method they used to calculate the theoretical maximum in the number of variants.

Q. And you agree that in the modified PH20 polypeptides, the changes that might exist between the wild type and the claimed modified PH20 can be either a substitution of an amino acid or more than one substitution of amino acid. Is that -- that's one possibility?

MS. MARTIN: Object to form.

A. Could you repeat it?

Q. Sure. The changes that constitute the

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difference that translates into the 5% difference from the amino acid sequences of the wild-type PH20, there could be substitutions, deletions, or additions of amino acids. Right?

A. Yes. Those are possibilities.

Q. So in the set of those modified PH20 polypeptides, you may have polypeptides that have a deletion of three or five amino acids from the wild-type residue. That's within the set of PH20 polypeptides being claimed. Right?

A. That is a potential scenario for one of the claimed polypeptides.

MS. MARTIN: Counsel, I'm going to ask you again to speak up. I'm sorry. I'm having a really difficult time hearing the whole question.

MR. KUSHAN: All right.

Q. And just so we're on the same page, that theoretical maximum you referred to a minute ago, that's a number bigger than 1049 different polypeptide sequences. Right?

A. I don't have Dr. Park's declaration in front of me, but the number is something in that ballpark.

Q. It's of that scale. Right?

A. Yes.
Q. Would you agree that in the claimed genus of modified polypeptides, there are some number of modified PH20 polypeptides that are enzymatically active?
A. Yes. I agree.
Q. Do you know how many of the 1049 or so different polypeptide sequences are enzymatically active?
MS. MARTIN: Object to form.
A. Neither Drs. Park nor Hecht were asked to offer an opinion on that.
I also haven't considered an opinion on that.
Q. How would you go about determining which of those 1049 sequences are enzymatically active PH20 polypeptides?
MS. MARTIN: Object to form.
A. As a POSA taking a first step, I would consider the amino acid sequence in the context of the crystal structure and the likely folded structure.
So in doing that comparison, superimposing the model of PH20, its sequence, onto the model for HYAL1, and comparing the sequence, I would be able

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to identify residues that would likely maintain the activity of the enzyme.

And that would significantly narrow the scope down from 10 to the 49th to a very small number of reasonable polypeptides that would fit that criterion.

That would be my first step as a POSA.

Q. Did you do that in preparing your opinions?

MS. MARTIN: Object to the form.

A. I'm sorry. I actually missed part of that question.

Q. Did you perform that analysis you just described of comparing the possible sequences to some smaller number of them that match the structure of the model of PH20?

MS. MARTIN: Object to the form.

A. I did not go sequence by sequence and do that.

I guess maybe I need to say that no POSA would start with the theoretical maximum number of potential sequence variants as a starting point for making a comparative analysis of what amino acids would retain activity in a PH20 polypeptide.

Q. Can you give me an approximation of the

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number of different PH20 polypeptides that would be in that smaller set that you believe the POSA would focus upon?

MS. MARTIN: Object to form.

A. I could not possibly give you an absolute number without doing a calculation to determine how many exactly there would be relative to the 10 to the 49th. I can tell you it's orders of magnitude.

Q. So it would be 10 to the 40th or 10 to the 35th? Where -- give me just a sense of scale, where we are relative to the theoretical maximum.

MS. MARTIN: Object to form.

A. Without doing a calculation, I'm unwilling to give a number.

Q. But you believe it's a number that could be determined?

MS. MARTIN: Object to form.

A. I believe that a POSA could determine, using the information in the claim, using the information in the disclosure, what would be reasonable locations to narrow down -- to make mutations such that the POSA would be able to narrow down the set of variant PH20 polypeptides to a manageable set that was fully accessible to them experimentally.

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Q. So they could select a set of sequences that match these criteria that you're referring to.

Is that what you're saying?

MS. MARTIN: Object to form.

A. I'm saying that a POSA would have had the information to choose to make a set of PH20 polypeptides that fit the criteria of the claim, and to be able to use them in the manner they intended.

They would be able to visualize the species within the claim.

Q. They'd be able to visualize discrete sequences that have, let's say, 10 or 15 changes in them as being within the claim.

Is that what you're saying?

MS. MARTIN: Object to form.

A. A POSA could use the information in the patent, as well as the structural knowledge of HYAL1 with PH20's model superimposable on the HYAL1 crystal structure, to determine how they could make a 95% identical PH20 polypeptide that would have the parameters or the criteria that they set in their experimental objectives.

They would be able to use the claim, the scope of the claim.

Q. So the parameters they're using in

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their -- in that experimental -- have -- let me make sure I get this correct.

So the person would have in their mind parameters of the experiment they were doing. Are those parameters the particular modification locations and the nature of the modifications they are contemplating making?

I'm just trying to understand the parameter reference you made.

A. A POSA attempting to make and use the polypeptides that are claimed would have an objective for making those polypeptides.

They would have internal experimental criteria that they would be seeking to meet in generating a polypeptide that met the claims.

Q. Just to be clear, are you saying these criteria they're seeking to try to meet are the -- are they the -- that the modified PH20 polypeptide has activity?

Or are you speaking of it's a PH20 polypeptide with a particular sequence that they were trying to make?

A. I would hesitate to constrain the imagination of the POSA by attempting to articulate on their behalf what their experimental objective

would be.

I could actually see a POSA seeking any and all of those possible experimental goals.

Q. I'm just trying to track the process you're describing the POSA would go through.

Is the POSA approaching the task of evaluating a particular amino acid sequence by asking if that sequence will exhibit a property, such as enzymatic activity, or will fold, or is inactive?

Or are you saying that the task is simply devising a sequence and comparing it to see if it matches the criteria of the claims?

A. My view of the goal of the POSA is that they have an experimental design plan in mind, and that this patent discloses an enormous amount of data that help them beyond what was published in the literature at the time, which was the sequence, the sequence alignment to other hyaluronidases for PH20, as well as the knowledge of where it can be truncated to make it a soluble polypeptide, the fact that it retained activity as a soluble PH20 polypeptide.

And now, in addition, mutagenesis at every single residue of the polypeptide that gives data on

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whether or not that single substitution remained active.

The POSA could then use that information to choose, depending on whether their goal was to have the protein remain active or whether they did not care about having activity retained and had a different experimental goal. They would have information that would allow them to make the 95% identical polypeptide that would meet those criteria for them.

Q. So they could pick, out of the 1049 theoretical maximum sequences, which of those will have the characteristics necessary for those selected sequences to be enzymatically active modified PH20 polypeptides? That's what you're saying?

A. I'm saying that a POSA would not start with that calculation of 10 to the 46th or 10 to the 49th or 10 to the 63rd. A POSA would not start by calculating the theoretical maximum number of sequences.

A POSA would start with the knowledge of the PH20 polypeptide sequence, the knowledge of its truncated sequence, the knowledge of its mature sequence, and the ability to superimpose the PH20

sequence onto the model for the HYAL1 crystal structure.

And the POSA would know exactly what every one of those modified PH20 polypeptides looked like. And they would have all the information they needed with respect to its activity to create a sequence that was 95% identical, that would either adopt the fold and be enzymatically active, or adopt the fold and not be enzymatically active, or not adopt the fold.

Q. And so, you're saying a person of ordinary skill in the art, looking at the sequence and comparing it to homology models in 2012, could differentiate sequences that will not fold from those that will?

A. That is actually not a yes-or-no question. I think it depends.

But, yes, a POSA could potentially identify sequences that would be certain to fold and could identify sequences that would certainly not fold.

Q. And there will also be a third category of sequences where they wouldn't be able to tell one way or the other. Is that fair?

MS. MARTIN: Object to form.

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A. In every polypeptide, there are places where you could make a mutation and predict -- the vast majority of places, you can make a mutation and predict what's going to happen to the protein.

Given the amount of activity data and the amount of structural homology and the sequence information, you would be able to predict the vast majority of activity structure, function relationships, for that family of modified PH20s.

There's always going to be a mutant that -- very few, but always -- I could come up with one in every data set -- that is going to be something that I didn't expect.

For the most part, a POSA is going to look at the data set that they have in hand and choose conservatively, strategically, where they will place mutations.

Given all of the information they have at hand, which is considerable, they will strategically choose positions that will meet the criteria of their experiment.

Q. And they'll do that based on -- like, what drives their selection of the place of mutations?

Is it just the information in the patent?

I'm just trying to understand: What's

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guiding the design of the sequences in your description there?

A. What would guide the POSA is the POSA's experimental design goal.

Again, I don't want to limit the imagination of the POSA by articulating specific goals on behalf of the POSA.

Q. So if I'm trying -- if I'm a POSA trying to make an enzymatically active modified PH20 polypeptide that is going to meet the requirements of the claims -- let's stick with that as their -- that would be a design objective that you've been describing. Right?

A. That is one possibility, yes.

Q. All right. So you're saying the POSA could take the information in the patent and then devise sequences of the modified PH20 polypeptides with an expectation that they would become enzymatically active modified PH20 polypeptides?

A. Yes.

Q. So the information in the patent is kind of like a starting point for them to then devise the sequences that will be enzymatically active PH20 polypeptides?

A. The information in the patent, yes, is a

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starting point.

However, the POSA would also need their ability to look at the structure of HYAL1, develop a model of PH20 structurally overlaid on HYAL1.

I'd look at the bee venom hyaluronidase structure, in which the tetrasaccharide substrate is docked, compare where the substrate binding domain is.

And they would have the information from alignments, sequence alignments among the hyaluronidases; their knowledge of the structural features conserved within the family of hyaluronidase proteins, possibly by doing an -- homology modeling of all five human hyaluronidases to increase their confidence in their model.

Then, coupled with the data from the patent on activity, the POSA would have strong certainty about their likelihood of success in creating a 95% identical mutant polypeptide -- PH20 polypeptide soluble that would be enzymatically active.

Q. You've mentioned a few times the homology models of PH20.

And these are models that are created using the human HYAL1 structure published in Chao?

A. The structural model of PH20 is based -- would have been, at the time, based on the crystal structure of HYAL1 by Chao, published by Chao, yes.

The alignments are also present in Chao. But the POSA would have been independently able to do those alignments.

And those types of sequence alignments had also been published earlier by Stern and Jedrzejas, in particular, in a 2006 review article.

Q. Thank you for pronouncing that man's name. I've not been able to figure out how to do that.

I imagine you know him. Right?

A. I do know Dr. Jedrzejas.

Q. Okay. In the homology models that are developed based on or used -- I'm sorry.

In the homology models that use the Chao HYAL1 as the template, is that terminology accurate?

A. A HYAL -- so --

Q. So a PH20 --

A. -- a homology --

Q. Let me make sure I get my question clean.

A. Okay.

Q. The PH20 homology model is a model devised by software that uses the structure published in Chao of the HYAL1 protein. Right?

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A. Yes. It's -- it uses the coordinates from the Protein Data Bank, which are the published coordinates that were used by Chao to provide models of HYAL1 in the 2007 paper.

Q. Got it. In the 2011-2012 time frame, how accurate were the PH20 models as an indicator of the actual protein structure?

MS. MARTIN: Object to form.

A. I haven't experimentally examined the accuracy of the PH20 versus HYAL1 model, because that would entail a look at an actual PH20 structure.

What we can say from the model, the superimposed model of PH20, on the basis of HYAL's structure, is to what extent there is a root mean square deviation in elements of secondary structure, alpha helices, beta sheets, loops, as well as the RMS deviation in locations of specific atoms within side chains that are exposed or not exposed, that are part of the hydrophobic core that's folded, that are part of the substrate binding domain, where the substrate docks, and that are part of surface aspects of the polypeptide.

We can look at RMSD as a measure of variability in different aspects of the protein

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structures. And with that RMSD value, we can estimate to what extent the quality of the model is reproduced -- is highly reliable on the basis of the HYAL1 structure.

Q. In preparing your opinions, did you perform that kind of assessment?

A. I relied on Dr. Petsko's declaration, in which Dr. Petsko evaluated the reliability of the PH20 model on the basis of the HYAL1 crystal structure.

Q. Is the reliability of the PH20 homology model consistent throughout the entire sequence of the PH20 sequence?

Let me ask you a better question.

So the PH20 homology model that is built from the HYAL1 template structure, is it giving you an accurate depiction of the structure of the PH20 throughout its entire sequence?

A. PH20 and HYAL1 have identity over only a portion of their sequence, which is up to the 4- -- 447 position of the soluble PH20 -- modified PH20 polypeptide.

The region beyond amino acid 447 in that sequence is not modeled onto the HYAL1 crystal structure because HYAL1 lacks that portion of

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sequence.

In fact, a portion of HYAL1 sequence, a short region in the C-terminus, is also not visible in the electron density. And so, that region also cannot be fully modeled because it's not even modeled for HYAL1.

But the region that can be modeled between PH20 and HYAL1 is virtually superimposable.

Q. When you do your modeling, do you rely on the portions of a sequence that can't be modeled?

MS. MARTIN: Object to the form.

A. With respect to hyaluronidases, we use SWISS-MODEL to do modeling on HYAL1 crystal structure.

So in modeling the other hyaluronidases, there's no other way, then, to consider the reference template.

And the regions that are not part of the reference template can't be modeled on the reference template.

Q. So you can't derive conclusions for those portions of the protein that don't have the structure from -- the HYAL1 structure that correspond to that portion of the sequence?

MS. MARTIN: Object to the form.

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A. Let me clarify.

The structural model, the modeling software only allows you to model the portion that's reproduced by the template.

That doesn't mean you can't derive any information about the portion that is not modeled according to the template. But it isn't necessarily part of the model.

So the additional information would be derived from your knowledge of that sequence, possibly the knowledge of function.

Q. But you don't have a reliable basis for knowing what the structure of that portion of the protein is beyond the boundary of the template structure being used to create the model?

A. So again, in the context of PH20, what we know about PH20 is that the portion -- from 447. So we know the first 35 amino acids are cleaved as a signal peptide.

So not being able to model that is irrelevant because it's not part of the mature protein.

Similarly, we know, in the mature, full-length protein, if we're talking about modeling the full-length PH20 polypeptide, we know that that

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polypeptide has the -- an attachment site for a GPI anchor, a glycosylphosphatidylinositol.

That GPI anchor has a predictable -- a known biology for its -- for its attachment and a known biology for what happens to the signal peptide for GPI attachment following its attachment.

And so, it's known that that portion of PH20 is relatively unstructured because it's a signal peptide for the GPI attachment machinery before the protein is secreted to the cell surface.

So we can say we do know what happens to that portion of the protein. It's cleaved off before it gets secreted as a mature polypeptide.

In the case of the modified PH20 polypeptide defined in claim 1, this is a polypeptide that doesn't contain the GPI attachment site.

And so, the -- essentially, the full spectrum of the amino acids that are contained within that polypeptide are fully able to be modeled against the HYAL1 structure.

Q. So the -- in that region near the GPI anchoring sequence, that is how far away from the 447 termination? Do you know?

A. Yes.

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(Witness reading.)

A. Yes. The position at which the GPI is attached is position 490 in the precursor sequence, which is approximately eight residues away from 447 --

Q. Okay.

A. -- in the mature sequence.

MR. KUSHAN: All right. I'm going to introduce Exhibit 1006, which is the Chao paper we've been mentioning.

Sorry.

(Whereupon, Petitioner Exhibit 1006, previously marked, was presented to the witness.)

Q. This is the -- just to confirm, this is the Chao paper that we've been discussing this morning. Right?

A. Yes.

Q. And you're familiar with this paper. Right?

A. Yes.

Q. This was published in 2007, when you were doing work -- I believe you said in your declaration you were doing work that was modeling the PH20 protein based on the bee venom structure?

A. Yes.

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Q. So this came out while that work was underway?
A. Yes.
Q. Had you produced a PH20 homology model based on the bee venom structure?
A. At the time this was published?
Q. Yes.
A. I don't recall exactly when I first produced models of the different hyaluronidases relative to HYAL1.
It may have been later than 2007.
Q. Do you recall if the work that was eventually published in the Zhang paper had progressed to the point where you were identifying specific positions you were investigating for possible mutation, before Chao became available?
A. Yes.
Q. Okay. So you had identified potential sites of mutation as part of your investigation of HYAL1 before the Chao paper was published. Is that right?
A. Yes.
Q. And you identified those positions using a homology model of PH20 or another protein?
A. Our specific interest was in HYAL1, so we

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used alignments that I said Stern and Jedrzejas had already published.

They had also published models of PH20 and the other hyaluronidases on the basis of the bee venom structure in that same review article.

We used that information, as well as the model of HYAL1 on the basis of the bee venom structure, to determine residues that we test functionally.

Q. Okay. So you used those existing models of the different human hyaluronidases to -- well, you focused on HYAL1. Right? Okay.

A. Yes, correct.

Q. So you were selecting positions in HYAL1 that you were interested in mutating to see the effect of those mutations. Is that right?

A. Yes.

Q. Okay. Chao published, in its paper, a characteristic sequence that's associated what -- with what it calls the "HYAL EGF domain." Is that right?

A. Yes.

Q. Is that the first time that a group had published this characteristic sequence as kind of correlating to that region of the human

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hyaluronidase family?

MS. MARTIN: Object to form.

A. The EGF-like domain had been previously identified as a domain.

Is that what you're asking?

Q. No. I'm just -- if you look at Page 6912, on the bottom -- sorry -- left column, toward the second-to-bottom paragraph, there's a discussion there of a cysteine-rich pattern.

This was the first publication that identified that pattern as correlating to that EGF domain. Right?

MS. MARTIN: Object to form.

A. I'm not totally sure I'm understanding your question. I think you're asking me about sequence.

The sequence was already identified and noted as an EGF-like domain.

Q. Right. Let's just look at what Chao is saying here.

It says -- about halfway down into that second-to-last paragraph, it says:

No sequence homology has been reported in the scientific literature for the C-terminal

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domains of the mammalian hyaluronidases.

Right? That's what they're stating there -- is that accurate, in 2007?

MS. MARTIN: Objection; scope.

A. Is it accurate? The cysteine-rich domain was noted. The presence of cysteines was noted.

When Chao uses that specific verbiage, that no sequence homology had been reported for the C-terminal domains, it's looking at the homology irrespective of the cysteines.

And so, it appears that there's no other homology, other than the cysteines.

Q. And then they -- so Chao deduced that there's actually this characteristic pattern of amino acid and cysteine residues that is depicted in the next sentence, where it states, "This region contains a cysteine-rich pattern," and then has a -- the pattern described, with a bit of a formula for what the different residues can be and how they're spaced apart. Right?

MS. MARTIN: Object to form.

A. I guess I'm still not exactly sure what you're asking me.

Q. So Chao is the first group that published

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a description of the pattern of residues in the C-terminal region of mammalian hyaluronidases that was associated with that HYAL EGF domain. Right?

MS. MARTIN: Object to form.

(Witness reading.)

A. The Stern and Jedrzejas -- Jedrzejas review article in 2006 did homology modeling of each mammalian hyaluronidase on the basis of the bee venom crystal structure.

When they did those homology models, they modeled the domain that had identity to bee venom hyaluronidase structurally. Bee venom hyaluronidase lacks the EGF-like domain.

So that domain was modeled separately, without context for what it would look like, other than the disulfide bonds potentially being present.

That review article also referred to that domain separately. So it had been observed.

I believe what Chao is doing is defining that according to the ability to use algorithms such as SMART and PROSITE to identify that motif in a database.

Q. It's the first paper that correlated this pattern of residues to the HYAL EGF domain in mammalian hyaluronidases, Chao. Right?

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MS. MARTIN: Object to form.

A. This is a minor detail that I would have to specifically check in the Jedrzejas paper. They were published around the same time.

So my recollection is that the EGF-like domain had been discussed, whether or not it had been reported by Chao.

The structure had never been visualized, however.

Q. In fact, if you go over to Page 6913 of Chao and look at the paragraph -- a small paragraph in the middle of the right column, do you see that Chao is observing that:

> The HYAL EGF-like fold does not remem- -- does not resemble the Hyal-1 C-terminal fold predicted by ab initio approaches.

And then, if you want to look at Reference No. 33, that's the Jedrzejas and Stern paper that you've been referring to. Right?

It says -- 6913, paragraph in the right column, first sentence of that middle paragraph.

A. Gotcha. Right there.

(Witness reading.)

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A. Yes, that is what it says. Yes.
Q. Okay. So they had -- this paper had pointed out that the ab initio modeling in the Jedrzejas and Stern paper wasn't resembling what they actually observed in the HYAL1 structure. Right?
A. That is among the things that this paper showed for us. Yes, it was a huge breakthrough in the field.
Q. Got it. Is the information about this pattern of position -- of residues that Chao identified reported in the common disclosure?
MS. MARTIN: Object to form.
A. Yeah, could you reask that? I'm not sure what you're specifically asking me.
Q. Is the information associating this cysteine-rich pattern of residues in the Chao paper also reported in the common disclosure?
MS. MARTIN: Object to form.
A. It's -- the information in the Chao paper is summarized in the disclosure. The patent authors are different authors than those who made this discovery about HYAL1.
Q. Do you believe that the inventors -- or the -- let me be sure it's precise.

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Do you believe that the common disclosure refers to the work that was published in Chao?

A. Yes.

Q. If you could go to Figure 3 of Chao. This is a sequence alignment.

I think you mentioned the sequence alignment a minute ago. Right?

A. Yes.

Q. All right. So in Figure 3, these are the five human hyaluronidases that are aligned. Right?

A. Yes.

Q. Chao's alignment identifies the invariant residues in this protein family. Right?

A. Yes.

Q. And let's just go through the color coding.

Most of them are blue. Right?

A. Most of the invariant -- yes, are blue.

Q. So the red coloring denotes the ones -- the positions or residues that are involved in the catalytic function of the proteins. Right?

A. Three key catalytic residues are identified in red.

Q. And then the disulfide bond-implicated cysteine residues are in gold. Right?

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A. Cysteine residues are go- -- yellow, gold.
Q. Yeah. And then the N-glycosylated asparagine residues are in turquoise?
A. Yes.
Q. These are all of the essential residues we've been talking about from earlier this morning that are shared by these five human hyaluronidases. Right?
MS. MARTIN: Object to form.
A. They're showing invariant residues, without making a judgment on essential residues.
Q. They're showing the invariant -- and some of the invariant residues do have a functional connection to them. Those are the catalytic residues, for example?
A. Yes, the catalytic residues do have a function associated with them as invariant residues. Yes.
Q. And the gold residues also are ones that are implicated for folding, in some sense, because they form disulfide bonds. Right?
A. So all of the cysteines are shown in gold.
The ones that are implicated as participants in disulfide bonds are separately indicated by stars underneath those gold cysteines.

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Q. Got it. How would a person -- how would a POSA view these positions marked in blue, gold, red, and turquoise in Chao's figure --

MS. MARTIN: Object --

Q. -- in terms of positions to modify for making enzymatically active forms of the protein?

MS. MARTIN: Object to form.

A. I'm not sure what you mean by "how would they view them."

Q. If a person -- if a POSA was attempting to make a modified PH20 that had enzymatic activity, would they choose to modify the protein at the positions marked in blue, red, and gold?

MS. MARTIN: Object to form.

Objection; scope.

A. Could you please reask your question?

Q. Of course.

If you were a person of skill in the art and you were attempting to make a modified PH20 that was enzymatically active, would you select positions that are marked in blue, red, or gold as positions to modify the protein?

MS. MARTIN: Object to form.

Objection; scope.

A. If my objective was to make a modified

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PH20 polypeptide, I would need more information than is given in the alignment.

The alignment also is supported by actual previously published functional data that demonstrated which residues of PH20 are inactive residues or are key catalytic residues. So that's why they're colored separately.

To retain enzymatic activity, certainly you would not mutagenize those, because it's previously been confirmed that mutagenesis at those sites eliminates hyaluronidase activity.

Similarly, with respect to the cysteines, because of the prior implication, whether or not it was by mutagenesis or by general reduction of disulfides and loss of activity in PH20, it's been shown that cysteine disulfides are important for enzymatic activity of PH20.

Again, a POSA would not choose one of the cysteines involved in a disulfide as a site to mutagenize to retain enzymatic activity of PH20.

When I say that you would need more information than what this has, this structure, this alignment, does not indicate the position of the GPI anchor attachment site, which is important to a POSA's knowledge of how to make a modified PH20 as

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defined in the patent, which is soluble.

Q. So do you think a POSA would choose to make modifications at the blue positions -- the blue marked residues in the PH20 if they're trying to make an enzymatically active form of the PH20 protein?

MS. MARTIN: Object to form.

A. It is my opinion that a POSA would use the information about this structure, use the sequence alignment, and model PH20 according to this new structural information, and evaluate whether the blue invariant residues were located in a position of critical -- of a critical nature to the folded structure of PH20, and evaluate them individually, potentially, for their location in the structure, if they wanted absolute certainty about their role in maintaining the structure.

It's also my opinion, though, that if I have this information about invariant residues in an alignment and about functional data that implicates certain of those invariant residues in maintaining enzymatic activity of the enzyme, that a POSA would avoid residues that are invariant if they wish to maintain activity of the polypeptide.

MR. KUSHAN: Okay.

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MS. MARTIN: So, Counsel, we've been going for about another hour.

MR. KUSHAN: Yeah. You need to give me some credit, Lauren. I was about to propose we take a break for lunch. So....

MS. MARTIN: All right.

MR. KUSHAN: Why don't we take a break for lunch, if that makes sense.

VIDEOGRAPHER: Off the record at 12:38.

(Whereupon, a recess was taken for lunch at 12:38 p.m.)

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

(Time noted: 1:37 p.m.)

VIDEOGRAPHER: On the record at 1:37.

BY MR. KUSHAN:

Q. Dr. Simpson, did you have lunch with counsel?

A. Yes.

Q. Can you just give me a brief summary of what you discussed during lunch.

A. A variety of topics, including the physical accuracy of some of the decor and several theological topics.

Q. Did you discuss anything relating to the deposition so far?

A. Absolutely nothing.

MR. KUSHAN: Okay. I'm going to introduce your Zhang paper. This is Exhibit 1010.

(Whereupon, Petitioner Exhibit 1010, previously marked, was presented to the witness.)

WITNESS: Thank you.

Q. You're an author on this paper?

A. Yes.

Q. Are you the principal author? Or, no.

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What -- how do you describe yourself, as being the last author?

A. The corresponding author.

Q. "Corresponding author."

Did Mr. Zhang -- or Dr. Zhang, is he the person who did a lot of this work? Was he the -- as a principal author?

A. He was a graduate student, yes.

Q. Then he was -- why was he designated lead author?

A. It's typical in -- particularly in the discipline of biochemistry and experimental research, for the primary author to be the person that is most significantly involved in generating the data that comprised the manuscript.

So as the leading author, he generated a majority of the data that are published in the paper.

Q. Okay. So in the Zhang paper, you're describing work you did where you use the -- a model of the HYAL1 structure to identify specific positions that you're interested in investigating as far as the effect they have on activity or structure of the protein. Right?

A. That was the goal of the paper, yes.

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Q. And you -- so you selected positions' residues in the HYAL1 sequence based on use of a model at the structure. Right?

A. We used a combination of information from sequence alignments, as well as then, subsequent to the alignment, other functional data implicating specific residues in maintaining key elements of the catalytic activity, in addition to this examination of where that -- those sequences place those residues in the context of the HYAL1 crystal structure.

Q. Okay. Thank you. That was helpful.

So you used the alignment data -- sorry.

You used information about -- from alignments, you used published information from prior mutagenesis studies, and you used the homology model.

Those are the three main sources that you used to identify the positions that you wanted to investigate. Is that fair?

MS. MARTIN: Object to the form.

A. So we used the PH20 HYAL1 through 4 alignment to -- particularly PH20, because that was the sequence in which specific active site residues with specific roles in catalysis had been

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functionally identified.

And then we used the HYAL1 crystal structure, ultimately, for the interpretations that are documented in the paper as our structural visualization tool to interpret the results of our studies.

Q. But the process you went through was you did the analysis of the alignments, you had the model of the structure, along with the work prior to your work, and you used all that information to select specific mutations to make into the HYAL1 sequence. Right?

A. One additional piece of information was the bee venom crystal structure, in which the tetrasaccharide substrate had been docked, because that information was not available in the HYAL1 structure and provided support to our choice of residues and our interpretation of what we would expect to happen by mutagenizing those residues.

Q. Got it. So you selected these positions to mutate, and then you actually made the HYAL1 mutants, each of which has one amino acid change in the HYAL1 sequence. Right?

A. That's true. Yes --

Q. Yeah.

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A. It was --
Q. You also did a truncation mutant, which removed the HYAL EGF region of HYAL1. Right?
A. Yes.
Q. Okay. So for this -- these questions, I'm focusing on the mutations you did that were the single mutations into specific locations of HYAL1.
You made the mutants with the single amino acid changes, and then you characterized the mutants by their activity?
A. Yes --
Q. Okay.
A. -- among other things. That was one of the things we characterized, was their activity.
Q. So if you look at your paper, 9433. And this is in the section where you're describing, at the bottom, your focus on Glu131 and aspartic acid at 129. Right?
These are two residues within -- implicated in catalysis. Right?
A. Yes. So the -- you're talking about the second paragraph of the introduction, describing -- discussing the roles of aspartate and glutamate -- 129, 131, respectively -- yes.
Q. Can you say -- there's a depiction of the

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Scheme 1, which is on the next page.

That's the catalytic reaction that's being mediated by HYAL1?

A. Yes.

Q. Okay. In this paragraph we were at on 9433, you say:

Briefly --

There's a description kind of in the middle of the paragraph.

You say:

> Briefly, in the resting state at its optimal pH of 4.0, aspartate 129 and glutamate 131 essentially share a proton. Catalysis is thought to require initiation of intramolecular resonance of the amide bond of N-acetylglucosamine in the bound HA polymer.

So this is kind of the hypothesis you had about how the reaction was going to proceed that was being mediated at the active site.

MS. MARTIN: Object to form.

A. So in formulating a hypothesis for what we would expect from our mutagenesis results, we looked

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at the information that was available in the structure, and any additional mechanistic information from prior studies, to formulate our hypothesis.

We also looked at the structure, in which you can actually determine that two acidic residues are oriented such that they must share a proton in -- at a particular pH, as defined in the crystal solution, the solution from which the protein crystallized.

And so, the distance between the two carboxylates -- you can't see the proton in a crystal structure --

Q. Right.

A. -- in an X-ray crystal structure, so you have to deduce by the distance of those two carboxylate moieties that they're sharing a proton.

Q. Okay.

A. If that makes sense.

Q. Yeah. Yeah, I understand.

So when you tested the glutamate -- the glutamate at 131, that mutant lost all activity.

And if you want to look at Table 1 of your paper, which is on 9438.

A. Yes.

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Q. So that -- that mutation abolished the activity of HYAL1. Right?

A. The mutation almost completely abolished the activity we could detect in HYAL1.

It retained a small percentage of activity that we considered insignificant in the context of the work, to the extent that we could implicate that residue as a key catalytic component.

Q. The mutation at position 129 did not abolish the activity of the HYAL1 enzyme. Right?

A. So it's difficult to put -- you put it on a spectrum.

It's difficult to say it did not abolish activity. But because it retains 5% activity, we described it in the manuscript as not having fully abolished activity.

Q. So based on your hypothesis, the mutation at E1- -- E131 was consistent with your hypothesis. Right?

A. In that our hypothesis was that both aspartate and glutamate would be critical residues for catalytic activity, yes, that was consistent.

Q. And is the result for the D129N mutation -- that's not consistent with your hypothesis because it retained 5% of the activity.

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Right?

A. It isn't that it's inconsistent with our hypothesis.

When we looked at the active site docked with the tetrasaccharide, we could see that it was very likely that one of the residues, likely glutamate, would be a -- the key proton donor during the catalytic reaction, and that the residues aspartate and the proximal tyrosine 247 were going to be key residues that would function to polarize the N-acetyl group of the substrate, which is a critical step in substrate-assisted cleavage, which is the mechanism by which this family of enzymes hydrolyzes hyaluronan.

In that sense, we expected that activity would be significantly diminished by mutagenizing that residue because it wouldn't be able to perform its role as we expected in the mechanism.

But we did not actually expect, necessarily, that it would fully abolish activity. And so, in that sense, it was consistent with our hypothesis.

Q. And is it fair to say, from what you published, that the D- -- the -- sorry.

So is it fair to say, from what you

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published, that the aspartic at position 129 was not essential to the HYAL1 activity?

A. We expressed the interpretation -- articulated the interpretation that it was important for activity, but not essential, because the enzyme retained activity if -- in the D129N mutant, if we had mutagenized D to a different amino acid, it's possible that it would not have retained any activity.

So in the context of the D20- -- D129N mutant, we interpreted that as implicating that as a key residue, though it did not appear to be essential if you replaced it with another polar group like asparagine.

Q. Okay.

A. I'm trying to be very precise. Sorry.

Q. Thank you.

You also -- you had a hypothesis that there was a disulfide bond that was near the substrate -- potentially substrate binding groove.

And in this experiment, you didn't change the residues. You just reduced the disulfide bonds and then measured the effect of that. Right?

A. In this paper, we used a reducing agent to reduce all the disulfide bonds and measured activity

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in the presence and absence of the reducing agent, and saw no loss of activity.

So for that reason, we did not specifically mutagenize the cysteines; not because they aren't important or the disulfides aren't important, but in the context of our experiment, those residues could be reduced, implying that the folded structure, once folded in that secreted soluble protein, was relatively stable.

Q. And the finding you had was that that disulfide bond which you -- and just to be clear, you identified that disulfide bond in the structure that you were visualizing. Right?

A. So we were guided by Chao's paper, in which Chao pointed out where cysteines were likely or were certainly, depending on the electron -- the resolution at that region and whether they could see electron density between the cysteines that -- that supported direct visualization of the disulfide.

It isn't always possible to see it. But you can -- you can quantify the distance, measure the distance, between the two sulfurs.

And again, same way as for sharing a proton. You can see that the sulfurs must be in a disulfide because there isn't sufficient distance

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for them to each have their own proton as well.

Q. All right.

A. So based on where Chao said disulfides were and where we visualized a cysteine association as a disulfide, that was how we identified the residues that were involved.

Q. In -- what you have in your paper on Page 9438, in this left column, you have a summary of that experiment. Right?

The di- -- this disul- -- disulfide stabilization is not critical for activity.

A. Yes. Gotcha.

Q. Okay.

A. Yes.

Q. And what you concluded, in the very last sentence, is that the disulfide bonds probably affect the folding of the enzyme and long-term stability of the hyaluronidases. Right?

And then you also observed that it did not intrinsically appear to require the disulfide bonds for optimal conformation of the protein. Right?

A. That was our conclusion -- our interpretation on the basis of the data, that the secreted polypeptide would not have been secreted if the disulfide bonds could not form during maturation

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of the protein intracellularly.

Q. Okay.

A. And that because we could secrete and purify abundant soluble protein that had a certain amount of wild-type activity, and we could add a reducing agent following the secretion of the protein, following the purification of the protein, and not affect its activity over whatever period of time we tested it in this particular assay....

It's in the experimental....

You may or may not care about that detail, how long we tested activity after disulfide reduction.

(Witness reading.)

So for one hour at 37 degrees, we treated with DTT and then did our activity analysis. So it was stable to a reducing agent for up to an hour without having any loss of activity.

And so from that, we concluded that once the protein was in its folded structure, the disulfides were not essential for a period of an hour at least to keeping it in that fold such that it still had activity.

MR. KUSHAN: Okay. Let's go --

I'm going to introduce two documents which

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you've addressed in your declaration.

First is Exhibit 1005, which is U.S. Patent 7,767,429, sometimes called the '429 patent.

(Whereupon, Petitioner Exhibit 1005, previously marked, was presented to the witness.)

MR. KUSHAN: And also introducing Exhibit 2165, which is a published U.S. patent application ending with '457.

(Whereupon, Halozyme Exhibit 2165, previously marked, was presented to the witness.)

MR. KUSHAN: We call that the '457 publication.

'429 patent, '457 publication.

Q. And you've reviewed both of these documents?

A. Yes, I have.

Q. Okay. If you look at the front -- if you look at the front of the patent, you see this is a patent owned by Halozyme. Right?

Under "Assignee" in the left column?

A. Yes.

Q. Now, are you aware that Halozyme also owns the '457 publication?

(No audible response.)
Q. I can represent to you that Halozyme owns that application too.
A. Okay. Yes.
Q. All right. Both of these applications -- both the application and the publi- -- and the patent were referenced in the common disclosure. Right?
I'm just asking if you recall that.
A. Yes, they're incorporated by reference in the common disclosure.
Q. Got it.
A. Yes.
Q. So if a POSA was interested in making modified PH20 proteins, they would consider both of these, the '429 patent and the '457 application. Right?
MS. MARTIN: Object to form.
A. Depending on the objective of the POSA, they would have access to the data and the disclosures of this patent and this publication.
Q. And they would consider both of them. Right?
MS. MARTIN: Object to the form.
A. Again, depending on the objective,

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depending on the data desired for their experimental objective, they would consider these references, particularly if they're considering the -- implementing the invention in the '600 patent.

Q. If they -- if a person wanted to make soluble active forms of PH20, would they consider the '429 patent?

MS. MARTIN: Object to form.

A. What do you mean by "consider"?

Q. When you do an experiment, do you kind of go into a place where you ignore everything that published before you, or do you look in the literature to become aware of what work has preceded the time of your experiment?

MS. MARTIN: Object to form, and scope.

A. So you asked me about a POSA --

Q. Yes.

A. -- what a POSA would do. With that experimental objective, the POSA would seek all available information about how to construct a modified soluble PH20.

Q. And some of that information is reported in the '429 patent. Right?

A. Yes.

Q. So this would be something they would consult as part of that body of knowledge about soluble human PH20 proteins. Right?

MS. MARTIN: Object to form.

A. If it's -- so if the objective, again, is to make a soluble hyaluronidase, PH20 hyaluronidase, there are data in this patent that would be relevant to consult.

Q. Okay. Could you go to column 153 of this patent.

It's toward the very end.

A. At the very end.

I'm sorry. Could you tell me again?

Q. Go to column 153.

And if you could look at claim 1 of the patent, it's on -- under column 153, toward the bottom of the page.

When you reviewed the '429 patent, did you review the claims of the '429 patent?

A. Yes.

Q. Okay. Do you see, in claim 1, that it defines a substantially purified hyaluronidase protein?

That's the first line of claim 1.

MS. MARTIN: Object to form.

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And objection; scope.

A. Can you repeat your question, please?

Q. Yeah. If you look at Line 1 of claim 1, it's -- it says "a substantially purified hyaluronidase glycoprotein."

So this is a claim directed to substantially purified hyaluronidase glycoproteins. Right?

MR. KUSHAN: Object -- object to form. Objection; scope.

(Witness reading.)

A. Okay. Can you please repeat your question one more time?

Q. I'm just -- this is very basic.

This claim is directed to substantially purified hyaluronidase glycoproteins. Right?

MS. MARTIN: Object to form. Objection; scope.

A. Claim 1 is directed to a substantially purified hyaluronidase glycoprotein that consists of a sequence of amino acids set forth as a specific set of amino acids that refer to a reference sequence, SEQ ID NO: 1.

Q. Right. And I'll represent -- you can consider this -- SEQ ID 1 is the precursor sequence

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of the human wild-type protein.

And if you want to look, look at -- you see these strings of residues. There's one there that's 36 to 42. That would be 1-447 if you have a 35 amino acid leader sequence. Right?

If you want to go to SEQ ID 1 -- the description of it, obviously -- it's column 99.

And I -- you know, if your counsel wants to object to you -- me representing to you that this is the same sequence of human precursor PH20, we can have a conversation about that, but I'm pretty sure it's correct.

So if we --

A. 509, mature full length -- sorry -- precursor full length....

In PH20, yes.

Q. Okay. Great.

So if you look at Lines 36 to 40, that's referring to a form of the purified hyaluronidase glycoprotein that has the wild-type sequence with the start and termination positions in those different sets of numbers. Right?

MS. MARTIN: Objection; scope.

Object to form.

Q. Do you understand that?

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A. No. Could you please repeat it and show me --
Q. Sure.
A. -- again what you're --
Q. So in that very first clause, it says -- up until Line 41 -- you see the SEQ ID 1, and then there's a comma?
A. That's -- so that I can confirm what page you're on, this is --
Q. 153.
A. 153.
Q. Claim 1.
A. Thank you.
Q. Are we in the same place?
A. In the same place. Thank you.
Q. Okay. Great.
I'm looking at the first few lines of the claim, and that is referring to sequences that are of the wild-type sequence in human PH20, which is the portion of the claim that goes from about 36 to about 40, the line numbers. Right?
MS. MARTIN: Object to form.
Objection; scope.
Q. It's -- it just says, has -- "consists of the sequence of amino acids set forth" in the

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sequence, which is SEQ ID 1, at those specified positions.

So that's referring to the wild type, the sequence that's unmodified. Right?

MS. MARTIN: Object to form.

Objection; scope.

A. The reference sequence, SEQ ID NO: 1, is referring to the precursor full-length human PH20 sequence.

Q. Correct.

So these sequence ranges that are in that first portion of the claim are the wild-type sequences. Right?

MS. MARTIN: Object to form.

Objection; scope.

A. So the full claim --

Q. I'm not asking about the full claim. I'm just asking about this portion of --

A. It's a full sentence. You -- you are asking me -- I'm sorry to interrupt.

You are asking me if this sentence refers only to wild type. And I was going to --

Q. No, no.

A. Okay.

Q. Then you may have misunderstood my

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question.

I'm asking you about this portion of the claim before the comma, before some -- it says:

> A substantially purified hyaluronidase glycoprotein that consists of the sequence of amino acids in these ranges of SEQ ID 1....

Do you see that clause?

A. I do see that, yes.

Q. All right. So that's referring to where the amino acid sequence is the same as the one in SEQ ID 1 bounded by the numbers of each range. Right?

MS. MARTIN: Object to form. Objection; scope.

(Witness reading.)

A. You're asking me if the numbers refer to SEQ ID 1, the location of amino acids in SEQ ID 1?

Q. Okay. Let me ask you -- just so we're understanding how you read patent claims -- because you have 200-and-some pages devoted to that in your declaration for the common disclosure, so I want to just go back to maybe how we work through this.

I'm just asking you if, in this region of

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the claim, where it's listing the range of amino acids within a SEQ ID number, you can decipher what that's referring to.

MS. MARTIN: Object to form. Objection; scope.

Q. So if I said -- for example, if we're in the common disclosure and it said positions 1-447 of SEQ ID 3, do you know what that is referring to?

Not in this patent, but in the common disclosure.

MS. MARTIN: Object to form.

A. If I -- I'm sorry. If we can --

Q. Let's just walk -- I want to understand how you understand some of these terms. Okay?

A. Okay.

Q. Because we've spent five minutes trying to confirm that we're just looking at a range in SEQ ID 1, I want to make sure we are speaking the same language here.

So when you reviewed the claims in the disclosure of the '600 patent -- you don't have to look at it right now; it's just a very basic question -- there was a SEQ ID 3 that you referenced, which is disclosed in that common disclosure.

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That's the 1-447 length human PH20 wild-type sequence. Right?

SEQ ID 3 in the common disclosure?

A. SEQ ID 3 in the common disclosure refers to the PH20 sequence, with very specific definitions about what it constitutes.

Q. Great. So when I say "SEQ ID 3" and "positions 1-447 of SEQ ID 3," you know what I'm referring to. Right?

A. When I look at SEQ ID 3, it has numerical designation of what the amino acids are in the sequence ID.

So I know which numbers those are. I know how to find them in the SEQ ID.

Q. Right. And if you see a reference, for example, in claim 1 of the '429 patent that says "positions 1-44- -- 1-477 of SEQ ID 1," are you able to understand what that's referring to?

(Witness reading.)

A. Yes.

Q. Okay. So in the first five lines of claim 1, it's referring to a substantially purified hyaluronidase glycoprotein that consists of the sequence of amino acids set forth at -- as amino acids 1-477, for example, of SEQ ID 1. Right?

A. Yes.
Q. Okay.
A. As an example, that -- that is one. Yes.
Q. So then -- and you look at Line 41, as an alternative, it says -- this is basically taking the first line of the claim, "a substantially purified hyaluronidase glycoprotein that...contains amino acid substitutions in the sequence of amino acids set forth as amino acids 1-477," etc., of SEQ ID NO: 1. Right?
MS. MARTIN: Object to form. Objection; scope.
A. So:
A substantially purified hyaluronidase glycoprotein that consists of the amino acid -- the sequence of amino acids set forth as amino acids with given numbers of ranges, SEQ ID 1, or contains amino acid substitutions in the sequence of amino acids set forth as amino acids --
-- again, in these ranges of SEQ ID NO: 1.
Q. Okay. So this is a substantially purified

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hyaluronidase glycoprotein that has at least one amino acid substitution in it relative to the wild-type sequence. Right?

MS. MARTIN: Object to form. Objection; scope.

A. You said "this" is.

Specifically, what do you mean by "this"?

Q. The claim is to a substantially purified hyaluronidase glycoprotein, and one of them is covered by the middle section, where it allows for an amino acid substitution in the sequence. Right?

MS. MARTIN: Object to form. Objection; scope.

A. So the claim allows for one of these ranges of sequences, one or more of all of these ranges of sequences of SEQ ID NO: 1, in the wild-type context or containing amino acid substitutions in the same sequence, where the sequence is at least 95% identical with the --

Q. Right.

A. -- with the sequence in the range -- ranges in SEQ ID 1.

Q. So this claim covers both proteins that have the wild-type sequence, as well as proteins with substitutions in them, as long as the overall

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sequence identity is below -- or above 95%. Right?
A. Above 95 --
MS. MARTIN: Object to form. Objection; scope.
COURT REPORTER: Did you say an answer?
WITNESS: I was repeating the "above 95%," yes.
Q. All right.
A. (Reading:)
...wherein -- there's also another clause -- the glycoprotein contains at least one sugar moiety...attached to an asparagine.
Q. When you produce human PH20 in a CHO cell, does that glycosylate that position?
A. There isn't a specific position given for the glycosylation in this -- in this location.
Q. Are there residues in the PH20, if not mutated, will become glycosylated when you produce it in a CHO cell?
MS. MARTIN: Object to form. Objection; scope.
A. In which form of PH20?

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Q. A form in which a mutation does not remove the residues that are ordinarily glycosylated in human PH20.

A. So it depends.

Q. All right. Well, I'll withdraw that question, because we're -- what I'm interested in is just confirming that this claim language is not only claiming the wild-type version of the PH20, but also mutations -- those that have mutations, as long as they're 95% or higher sequence identity to the reference sequence. Right?

MS. MARTIN: Object to form.

Objection; scope.

A. So the claim -- claims sequences with reference to SEQ ID 1 that are either identical to the wild type or contain a mutation, where the sequence is 95% or more sequence identity, with specific ranges of sequences in SEQ ID 1, and the glycoprotein contains at least one sugar moiety attached to an asparagine that is not specified.

Q. Okay. So some of the proteins that are in the scope of this claim would be modified PH20 polypeptides that are addressed in the '600 patent. Right?

MS. MARTIN: Object to form.

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Q. Assuming that there -- one of those substitutions was D320K?

MS. MARTIN: Object to form. Objection; scope.

A. So I'm going to need you to reask your question, please.

Q. Of course. If one of the substitutions specified or allowed in this claim were made at position 320 and went from D at 320 in the wild type to lysine, K, at that position, then one of the -- that -- that particular substitution addressed in this claim is also covered by the claims of this '600 patent. Right?

MS. MARTIN: Object to form. Objection; scope.

A. The '600 patent -- the scope of the '600 patent claims....

(Witness reading.)

Q. I can try to make it easier for you.

Do you believe that the '600 patent covers a single substitution mutation in the 1-447 human PH20 sequence where the -- that substitution is D to lysine, K, D320K?

MS. MARTIN: Object to form.

A. I'm sorry. Which patent are we talking

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about now?

Q. In the '600 patent --

A. Yes.

Q. That's the patent that specifies that the position where a mutation could occur is -- is required to occur is at position 320. Right?

A. Yes.

Q. Okay. And one of the permitted or required changes is from the wild-type aspartic acid to lysine. Right?

A. That's correct.

Q. Okay. So if I have a PH20, 447 residues in length, with a D320K mutation in it, is that protein in the scope of claim 1 of the '600 patent?

A. So claim 1 of the '600 patent refers to a different reference sequence than claim 1 of the '429 patent.

Q. Right. I'm asking: The human PH20 sequence is the same -- it was the same in 2000 and -- it is same today. Right?

A. The human PH20 sequence is the same.

Q. Okay.

A. The SEQ ID sequences are not the same.

Q. Correct. So I asked if the 1-447 in the mature protein sequencing of the human PH20 with the

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D320K substitution in it -- if that protein with that mutation is within the scope of the claims of the '600 patent.

Are you with me?

A. So you're asking me about 1-447 in the '600 patent, which refers to SEQ ID 3, in which the numbering sequence is relative to the start of the mature polypeptide.

Q. Correct.

A. And asking me, if it has a D320K mutation, is that covered by the claims of the '600 patent?

Q. Exactly. Yes.

A. If it's 1-447, relative to SEQ ID 3, with a D320K?

Q. Yes.

A. Yes, I think I follow you.

Q. And is it in the scope of the claims of the '600 patent?

A. That would be in the scope of the claims.

Q. And it would also be in the scope of the claims of the '429 patent. Right?

MS. MARTIN: Object to form.

Objection; scope.

A. So the numbering system you used is -- refers to a different thing in the context of the

'600 patent than it does in the context of the '429 patent.

Q. Yes. So in the SEQ ID 1, it includes the leader sequence. So that's 35 amino acids in the human precursor sequence. Right?

A. The leader sequence is 35 amino acids, yes.

Q. Right. So if you look at the range in the middle clause here, 41 -- in the 41 to 45 range of the claim, one of the ranges is 36-482 -- right? -- and that translates to 1-447 in the mature sequence numbering. Right?

A. Yes.

Q. All right.

A. Yes. And with the D320K. Yes.

Q. Okay. So that -- so this clause would include -- because it doesn't restrict what substitutions are made in this claim, it would include the D320K substitution in the 1-447 form of the PH20 protein and its mature sequence numbering?

MS. MARTIN: Object to form. Objection; scope.

A. So D320 also is a numeric position that is relative to the start of the -- actually, the precursor polypeptide, the D320 position -- sorry,

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the mature polypeptide D320 position.

So it would be a different residue in the context of SEQ ID 1.

Q. So it would be 320 plus 35: 355.

MS. MARTIN: Object to form. Objection; scope.

Q. Is that right?

MS. MARTIN: Object to form. Objection; scope.

A. Can we go back to the original question, because I --

Q. Yeah.

A. -- think it's changed with the numbering system.

Q. Yeah. My question is: If you look at 36-478 in the SEQ ID 1, which has the leader sequence, that translates to 1-447 in SEQ ID 3 without the leader sequence. Right?

A. Okay. I think you just said 36-477.

Q. No, no.

A. I'm getting --

Q. Sorry. I apologize.

A. The numbers are messed up.

Q. I'm just trying to -- I mean, this is the challenge whenever you have two different numbering

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schemes. So I don't want to have any confusion.
So I'm just trying to confirm that the sequence 36-482 in the full-length precursor sequence, with the leader sequence, is the same sequence as the 1-447 in the mature sequence of human PH20. Right?
MS. MARTIN: Object to form.
Objection; scope.
A. Human PH20 sequence SEQ ID 1 is the full length, from start to finish, signal peptide intact, GPI anchor site intact. SEQ ID 3 is a modified PH20 polypeptide.
So SEQ ID 3 has a different numbering system than SEQ ID 1.
320, in the -- is designated -- is so designated in the context of SEQ ID 3.
You're asking if it could be designated as 355 in the context of the full-length protein, PH20 sequence in SEQ ID 1, and if 36-482 in SEQ ID 1 corresponds to 1-1- -- 1-447 in SEQ ID 3.
D320K in SEQ ID 3, D355K in SEQ ID 1, 36-482, would that be the same?
Q. Yes.
A. It is my interpretation that those are the same.

Q. Okay. So these two different patents have claims that encompass the same D320K 1-447 mature sequence human PH20 protein?

MS. MARTIN: Object to form.

Objection; scope.

A. So in the '429 patent, there's no stipulation on what amino acid should be modified to be compliant with the claim -- to meet this, the requirements of the claim -- to produce and use the invention.

In the '600 patent, there is a specific requirement for a specific amino acid to be modified to one of four potential other amino acids in order to meet the claims of the invention.

So, no, they're not the same thing.

Q. They're not the same claims, but they -- both claims cover the same single D320K mutant. Right?

MS. MARTIN: Object to form.

Objection; scope.

A. If a D320 -- if a D355K, not even a D320, were selected and made under this claim, it would be covered under this claim in reference to SEQ ID 1.

Q. Yeah.

A. Is that what you're asking?

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Q. Yeah, I was just confirming that.
Let's -- if you could, put that aside for a moment, the '429, and go to the '457 publication.
And if you look at -- if you have your -- do you have the '457 publication?
A. Yes.
Q. Why don't we clean up a little bit.
So you have the '457 available?
A. Yes.
Q. Okay. And do you have your declaration available?
A. Yes.
Q. Go to your declaration and look at Paragraph 180.
A. Yes.
Q. And now take a -- you've -- so 180 refers to:

> The '429 patent Example 4 as describing using ELISA assays to measure hyaluronidase activity for C-terminal truncation mutants.

You say that. Right?
A. Yes.
Q. Okay. And then in 185, take a look at

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that paragraph.

(Witness reading.)

A. Okay.

Q. Okay. And that paragraph, 185, is indicating that:

> The '457 patent examples also used an ELISA assay to measure HA activity.

Right?

A. Yes.

Q. Do you know what they were referring to as the ELISA assays to measure hyaluronidase activity?

MS. MARTIN: Object to form.

A. Yes.

Q. Can you just describe that assay?

(Witness reading.)

A. So in this assay, hyaluronan, the substrate for PH20 and other hyaluronidases, is biotinylated, labeled. The substrate is adsorbed to a microwell plate and transfected supernatants from cells transfected with human PH20 hyaluronidase is added at a specified -- in specified buffer conditions, particularly specifying pH.

But all the other compositions are also given in the disclosure.

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Following an incubation period of 90 minutes at 37, the reaction is terminated by the addition of a strong denaturant.

The wells are washed, and then the remaining biotin is detected by the addition of streptavidin-horseradish peroxidase conjugate, followed by the addition of tetramethylbenzidine, which is a substrate for horseradish peroxidase that is colorimetric, produces a color that can be read at an absorbance value of 450 nanometers in a microwell plate reader.

The absorbance values are compared to a standard curve that's generated by the inclusion of specific amounts -- known amounts of hyaluronidase and the amount of activity -- known amount of wild-type PH20 hyaluronidase.

The activity is then calculated as a percentage, or fraction, or in units per mil. In this case, it's in units per mil relative to the standard and the -- the amount -- the units per mil that were in the standard that it equated to on the standard curve.

Q. Okay. So the biotinylated HA assay is used in both the '429 patent and in the '457 publication to measure the activity of the

hyaluronidase PH20 enzymes?

A. Both the '429 and the '457?

Q. Yeah. And you cite to -- in the '429, you can go to column 86, Line 4, to column 88, 24. You can just confirm that is what you said in your declaration.

(Witness reading.)

A. The assay is -- it is a similar assay that's used in both -- both patents, yes.

Q. Is it similar to the assay that's used in the common disclosure, as well, for the primary screen of the mutants?

And you can look at Example 3.

(Witness reading.)

That's....

(Witness reading.)

Q. It starts at Page 248. Are you there?

A. Yes.

Q. Okay.

A. Yes. The assays are similar.

Q. Okay. In your own work where you're characterizing hyaluronidase enzyme, do you use this type of biotinylated HA assay?

A. We use several assays. Among them is this one, or one that is similar to it.

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Q. So you're familiar with this -- use of this assay. Right?
A. Yes.
Q. Okay.
MS. MARTIN: Counsel, we've been going for, I think, exactly an hour.
MR. KUSHAN: Can -- I'm in -- no, just give me about five minutes, if that's okay.
MS. MARTIN: Would you like a break?
MR. KUSHAN: Counsel, I just would prefer to finish this line of questioning. It'll be five minutes, if that's all right.
MS. MARTIN: Well, the witness --
MR. KUSHAN: Can you --
MS. MARTIN: -- can take a break if she would like a break, Counsel, so....
MR. KUSHAN: Would a --
MS. MARTIN: It's not an interrogation.
MR. KUSHAN: I'm in the middle of a question. Could I just --

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MS. MARTIN: Actually, you weren't --

MR. KUSHAN: -- finish --

MS. MARTIN: -- in the middle of a question.

MR. KUSHAN: Okay.

MS. MARTIN: If you were in the middle of a question, I would -- I wouldn't say anything.

MR. KUSHAN: Dr. Simpson, are you okay if I ask you one or two more questions while we're on this point?

WITNESS: I would like to take the advice of my counsel.

MR. KUSHAN: All right. I'm not asking -- your counsel suggests you can take a break. That's not the type of legal advice we should be dealing -- I'm just asking you if you can -- we've gotten to this point. I just want -- I have one or two more questions.

If you really need a break, we'll take a break. It's just up to you.

WITNESS: I would like to take a break. Thank you.

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

Counsel, if you do this again, I'm going to raise an issue with the Board, okay --

MS. MARTIN: Fine.

MR. KUSHAN: -- because you're disrupting the --

MS. MARTIN: No, I'm not.

MR. KUSHAN: -- examination of the witness.

Yes, you are. Absolutely.

MS. MARTIN: No, I'm not. Absolutely not. So --

MR. KUSHAN: Hundred percent.

MS. MARTIN: -- go for it. You can --

MR. KUSHAN: We can go off the record.

MS. MARTIN: -- complain to the Board all you want --

MR. KUSHAN: Thank you.

MS. MARTIN: -- but....

VIDEOGRAPHER: Going off the record at 2:38.

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(Whereupon, a recess was taken.)

VIDEOGRAPHER: On the record at 3:01.

BY MR. KUSHAN:

Q. Dr. Simpson, did you speak with counsel during the break?

A. Yes, briefly.

Q. And did you discuss anything relating to this proceeding?

A. Nothing related.

Q. All right. Could you go to your declaration and go to Paragraph 182.

It's at Page 67.

A. Yes.

Q. Are you with me?

A. Yes.

Q. Okay.

A. I want to make a correction to earlier testimony.

Q. Right. What about?

A. Earlier, I had testified that position 320 was relative to the signal peptide cleaved sequence numbering system.

I want to correct that it's not. It's relative to the full-length numbering system. And

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it's the same -- 320 is the same in both SEQ ID 1 and SEQ ID 3 in terms of its position relative to the start site of the full-length polypeptide PH20.

This was in the context of asking me to construe claims from the '429 patent, which was not part of the scope of my assignment.

Q. Did you discuss any aspect of this point you just raised with me with counsel during the break? And I'll just remind you, you're under oath.

A. I am under oath, and I did not.

Q. Okay. And what are you trying to tell me, that you have reached a different conclusion that the -- there's a D320K mutation that's in a different location, depending on the numbering scheme?

A. I'm not trying to tell you that.

Q. Okay. It's the same position in the same -- it's the same position in context of whether there's a leader sequence or not leader sequence present in the protein?

Sorry. That's a bad question.

What are you trying to tell me? Why don't you just explain it.

A. That -- so we were talking about whether a mutation at position 320 meant the same thing in the

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'600 patent as it did in the '429 patent.

It does.

Q. Okay. Great.

A. But I did not construe the claims of the '429 patent as part of the scope of what I was asked to provide for the declaration in this matter.

Q. Okay. So you didn't prepare to do that prior to your deposition today, and during the course of the deposition day, you just provided that answer as you were reviewing the information that I was giving you in the documents. Right?

A. As you asked about the claim, I responded to your questions.

Q. Perfect. Could you go -- let's go to Paragraph 182 of your declaration, if that's okay, on Page 67.

A. Yes.

Q. Do you see that -- you're discussing some testimony from Dr. Hecht. In the second sentence of the paragraph, you say:

> The degree -- or -- but that degree of variability is expected in hyaluronidase activity ELISA assays like this and is in line with what a POSA

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would expect.

Do you see that?

A. I do see that.

Q. And do you understand you're referring to a degree of variability in the biotinylated HA assays we've been discussing -- we were discussing just before the break. Right?

A. These results were generated in -- using a microtiter assay, which was the one we were discussing before the break, yes.

Q. Okay. What is -- what do you mean -- what would the POSA believe to be the degree of variability in the hyaluronidase assay that's referenced in Paragraph 82 -- 182?

A. There would not be a precise value, per se, that a POSA would have in mind.

Because of the nature of the assay as an ELISA, and because of the nature of the enzyme and its mechanism, there is inherent variability possible within the assay. There are ways to control for the impact of the variability within the assay.

So there are ways to evaluate, as a POSA, whether the variability is significant in the context of the results in the assay.

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Q. In your experience using these types of assays, what kind of range in activity have you typically seen with the assay as to the measurement of the hyaluronidase activity?

MS. MARTIN: Object to the form.

A. The range in activity is very much dependent on which enzyme you're assaying.

So my experience has been largely in the context of the other members of the hyaluronidase family, and not specifically with respect to PH20.

Q. When you said in your declaration that the degree of variability is expected in hyaluronidase activity ELISA assays, was that tied to the enzyme being tested in the assay or to the assays generally, regardless of which enzyme was being tested?

A. When I'm speaking of that degree of variability in that specific paragraph, I'm referring generally to the microtiter plate assay for hyaluronidase activity.

Q. Are you able to give me kind of a percentage range of variability that a POSA would expect to exist, based on that type of biotinylated HA assay?

A. It's not so much that we would look for a

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percentage variability in the range.

It is more so that as you look at -- so, for example, in the context of this series of data, the experiment is looking at successive C-terminal truncations and the impact of that on the residual activity of the enzyme.

Because it's a series of successive mutations that have comparable activity on either side of a single value, it's likely that a minor variation such as is present in this column of data in the table that's also presented above this paragraph -- because it's in a different order of magnitude of conditions in which the enzyme is relatively -- has relatively low activity, and it's within a trend of successive truncations that have similar values, it's more likely that it's a variability in the assay.

Q. Do you -- if I was just testing the activity of the -- of a wild-type positive control PH20 in multiple tests, what would be the variability you would expect to see in the hyaluronidase assay in that setting?

A. So in a microwell assay, using multiple conditions of the exact same enzyme, with the exact same substrate, depending on the quality of the

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substrate, the quality of the enzyme purification, preparation, the skill of the person performing the assays, a number of conditions such as those, there can be variability that is in the same order of magnitude as the value, the average value.

So you would look for changes in -- in activity that were greater than one or two standard deviations of the mean of a number of replicates within the assay.

So the degree of variability can change -- can be different from day to day.

Q. So you're going to take the set of samples -- in this case, the set of positive samples, you calculate the mean, and then you calculate standard deviations around the mean?

You're looking for the values to stay within one or two standard deviations of the mean?

A. That is one way to estimate the variability on a given day within a microtiter plate assay.

Q. All right. Could you go to Paragraph 225 and 226 of your declaration, which is on Page 87 and it goes over to 88.

A. 225?

Q. Correct, 225.

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A. Yes.
Q. And 226.
And just a simple question: In these paragraphs, you make an observation about an assay being run in the presence of a denaturing agent like m-cresol.
Do you see that?
A. Yes.
Q. And was the basis of your comment, responding to Dr. Hecht's statements, your belief that Dr. Hecht was just addressing the variability of the assay when the m-cresol was present in the samples being tested?
(Witness reading.)
A. So the previous example that you called my attention to in Paragraph 182 was an assay performed in the absence of m-cresol, in which Dr. Hecht was criticizing the variability of the assay.
Q. Right. I'm asking now about what you're saying with respect to his comments about Example 5.
And I'm just trying to understand: Is your -- is your criticism -- is your statement in Paragraph 225 assuming that his comments about the variability observed in the assay was only for the samples that had m-cresol in the sample being

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measured?

MS. MARTIN: Object to form.

A. Dr. Hecht criticized results in both of these experiments, specifically as it -- commenting on the significance and variability in his opinion.

Q. Correct.

A. One of the examples contained m-cresol; the other one did not.

Q. So I'm just trying to understand: Is your -- your comment -- in 225, you say:

> But I -- as I have explained repeatedly, POSAs expect variability for these types of assays. And for this assay in particular, which involves incubating PH20 for four hours with a reagent known to denature PH20 (i.e., m-cresol), a POSA would expect even greater levels of variability.

I'm just trying to understand: Is your underst- -- is your criticism focused on his comments about the samples that were tested in the presence of m-cresol or all the samples that were

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tested in that assay?

A. Dr. Hecht was evaluating all of the data for variability, all of the data within the tables, the example, Example 5, and criticizing the variability in all of the conditions, particularly because, within -- within the experiment, there appeared to him to be significant variability.

He specifies it in his declaration, and I'm not comfortable paraphrasing Dr. Hecht without looking at his declaration.

Q. Yeah. I'm just trying -- so I think you've answered.

So your comments in this paragraph are not limited just to his comments about the m-cresol-containing samples. Right?

A. Which specific comments?

Q. The ones I read in a minute ago:

> And for this assay in particular, which involves incubating PH20 for four hours with a reagent known to denature PH20, a POSA would expect even greater levels of variability.

You're not focusing only on his comments

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for the samples that have the m-cresol in them. Right?

A. Within the assay that contains the data for samples containing m-cresol, there are also data for samples that do not contain it. And he's concerned about variability across all the conditions.

Q. And you're addressing all of the comments he made about both the samples with m-cresol and without m-cresol. Right?

A. He was criticizing the variability of the assay.

I'm addressing the variability of the assay.

Q. Okay.

A. I put in a superlative, "even greater," to address that this assay was done in a different set of conditions than the assay in consideration in the previous example, where I defended the -- or explained the variability in the assay and what a POSA would expect.

Q. When you run the biotinylated HA microtiter assay, do you typically run it at 37 degrees C?

A. Are you speaking of me personally?

Q. You personally, or would a POSA use that, that temperature?
A. My research team, which I think is representative of what a POSA would do, runs the assay at 37 degrees.
Q. Okay. Earlier, you referred to a standard -- use of a standard curve.
And I believe you were explaining this is how you translate the measured density, optical density, the reading that you get, and turns -- turn a sample of that measured -- optical measurement into an activity measurement. Right?
A. Yes.
Q. So if I -- feel free to correct my description of it.
I just want to understand: When you perform that conversion using a standard curve, how do you set up the standard curve?
A. So it depends on the assay.
Q. Let's just go with this assay we've been discussing, the biotinylated microtiter assay.
A. So the biotinylated microtiter assay also is set up in a very context-dependent way.
How you set up the standard curve needs to be representative of the conditions in which you're

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measuring the actual activity, so that the activity relates to the amount of activity in the standard curve.

MR. KUSHAN: All right. I'm going to -- I'm going to introduce an exhibit.

This is Frost and Stern, Analytical Biochemistry, Volume 251, Pages 263 to 269, from 1997.

This will be Exhibit 1128.

Can you put a sticker on that?

(Whereupon, Petitioner Exhibit 1128 was marked for identification.)

MR. KUSHAN: Sorry.

I believe this is also Exhibit No. 2096.

Q. I just -- have you ever seen this paper before?

A. Yes.

Q. Okay. I had a feeling you might have.

So do you see a standard curve on Page 266?

(Witness reading.)

A. Yes. The authors state that Figure 2 is a standard curve.

Q. And so, as you said before, you would use -- you would take a measurement, the optical reading of the well, and you'd get a -- the density, I guess, of the optical -- the density of the material in the well dictates the reading you get out of it. Right?

(No audible response.)

Q. Correct my description. You know what I'm trying to ask. Right?

A. The absorbance value.

Q. Right.

A. It's slightly different from the density. But, yes, the absorbance value.

Q. Okay. So you get an absorbance value for a well.

And then you take that absorbance value, and you use it to then figure out what the activity is by matching it onto the standard curve. Right?

A. Correct.

Q. Is there a particular part of this curve that you have to use for that process?

A. So the standard curve has a curve fit associated with it that depends on all points in the curve. In that sense, it's dependent on all points in the curve.

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Ideally, the region of the curve that maintains the greatest contiguous linearity is the region that would be where you would use on a standard if you were comparing the values for unknowns.

Q. In Figure 2, can you tell what that range would be using the hyaluronidase TRU/well range numbers?

A. I can tell approximately.

Q. That's fine.

A. I would probably use a -- the actual data from the graph to dial it in more specifically, but I can tell approximately.

Q. Okay. What, approximately, would it be?

A. I would use a -- an a range -- a range approximately from slightly below .001 to slightly above .01.

Q. Okay. And that's like the -- that's the linear part of the curve?

A. Approximately.

Q. Approximately linear part of the curve. Okay.

Can you go to Page 175 of your declaration.

Hold on. Just one -- bear with me for one

second.

(Pause.)

Q. I had the wrong page number.

Could you go to Page 169 of your declaration.

Paragraph 412, do you see that?

A. Yes.

Q. You also see there's a reference to Exhibit 2077 and 2078. Those are transcripts from Dr. Park -- Dr. Park's declaration -- sorry.

Those are transcripts from Dr. Park's depositions. Right?

A. Yes.

MR. KUSHAN: Okay. I'm going to give you Exhibit 2176.

(Whereupon, Halozyme Exhibit 2176, previously marked, was presented to the witness.)

Q. Do you recognize Exhibit 2176?

A. Yes.

Q. This is the worksheet that Dr. Park created when he was preparing his analysis of single substitution mutations of the PH20 protein. Right?

(Witness reading.)

Q. If you want to look at Paragraphs 413 and 414, you discuss this there.

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(Witness reading.)

A. Yes. Yes. Thank you.

Q. Great. If you could go back to Paragraph 412 on Page 169 of your declaration, you're discussing your opinion that Dr. Park did -- had a motiva- -- certain motivation about picking positions to assess changes into the PH20 protein sequence as a single substitution in his project. Right?

MS. MARTIN: Object to form.

A. So Dr. Park did a full analysis -- excuse me -- of essential and nonessential positions.

This paragraph is specifically referring to his analysis in the context of establishing motivation.

Q. Look at the footnote 19. You say:

> I further note Dr. Park admitted that his focus on position 320 was not based on an independent scientific analysis, but that he was "asked by counsel to report [his] conclusions with respect to position 320.

Considering this Exhibit 2176 as his

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output, are you aware that Dr. Park looked at a number of positions in the PH20 sequence, analyzed it with a PH20 homology model, and assessed the impact of particular amino acid substitutions at those positions?

MS. MARTIN: Object to form.

A. The spreadsheet provided by Dr. Park offers comments that he provided about specific residues within the PH20 sequence, as modeled on the HYAL1 sequence, with PH20 residues given relative to HYAL1 residues.

Q. Let's go into this. Go to Page 4 of the spreadsheet.

Do you see that in the column headers there's a column H, which is "Rating." And then you see, at certain rows, there are numbers in that column associated with particular substitutions at particular positions. Right?

So, for example, at row 29, you see there's an entry there corresponding to position 8 of PH20. And it's going from the wild-type valine to isoleucine. Right?

MS. MARTIN: Object to form.

Objection; scope.

A. So point me again to which one -- which

valine you're talking about.

Q. Yeah. And I apologize for the small print.

But if you look at, in the spreadsheet column -- sorry -- spreadsheet row number 29, from the far left column, you kind of go across the row, you see "8" in bold.

That's the position number in PH20 under column D. Right?

A. Yes.

Q. Okay. And you see two [sic] rows ahead -- above that, you see the PH20 is valine. That's the wild type amino acid at that position in PH20. Right?

MS. MARTIN: Object to form.

A. So in Line 28, PH20 residue 8, PH20 residue valine?

Q. Yes.

A. That's the line you're talking about?

Q. And then in row 29, you see "Alternative Residue" in column F is I, or isoleucine. Right?

A. Yes, I see that.

Q. Okay. And then a few columns over, you see a rating of "2" for that substitution of valine at position 8 to isoleucine at that same position.

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Right?

A. Yes, I see that.

Q. And then you see his comments "gain: increased hydrophobic contacts" in column I. Right?

A. Yes, I see that.

Q. And do you understand this spreadsheet basically to be compiling his conclusions on particular single amino acid substitutions at positions throughout the PH20 sequence?

MS. MARTIN: Object to form.

(Witness reading.)

A. Dr. Park was compiling his conclusions about substitution at certain residues with respect to their -- the frequency with which an alternative residue appeared in his alignment models, his homology alignments, and with respect to its position within the PH20 structure modeled -- the PH20 model modeled on the structure of HYAL1.

Q. Do you know if Dr. Park did his analysis and compiled all of his results in this spreadsheet prior to the point in time that you reference in footnote 19, where he was asked about his views about position 320?

MS. MARTIN: Object to form.

A. So please ask your question again --

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Q. Sure.
A. -- because I want to be sure I understand you.
Q. Do you know -- so just that we're on the same foundation, you're expressing your views in footnote 19 based on a certain understanding you have of how Dr. Park came to express a view about changes at position 320. Right?
MS. MARTIN: Object to form.
A. I am noting a comment from Dr. Park about his focus on PH20 --
Q. Sure. And I'm just trying --
A. -- with respect to position 320.
Q. Correct. So I just want to understand whether you appreciate that Dr. Park created this spreadsheet and captured his views from his assessments before he was asked about these positions, and including the one at position 320.
MS. MARTIN: Object to form, scope.
A. I don't know that.
Q. You don't know that.
MR. KUSHAN: Okay. Why don't we take a short break; maybe five minutes.
WITNESS: Okay.

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VIDEOGRAPHER: Going off the record at 3:37.

(Whereupon, a recess was taken.)

VIDEOGRAPHER: On the record at 3:48.

BY MR. KUSHAN:

Q. Dr. Simpson, you had conversations with counsel on the break?

A. Nothing pertaining to the case.

Q. All right. Could you go to Page 100 of your declaration.

And in Paragraph 243, you explain that you've reviewed the declaration of Dr. Petsko, including the spreadsheet containing data from Patent Tables 3, 5, 9, and 10.

This section of your declaration, Section F, is addressing some of your views about his analysis of positions for tolerance to substitutions. Right?

(No audible response.)

Q. Is that right?

A. Yes.

Q. Okay. You have 2166, which is the spreadsheet, if you need it.

Can you -- why don't you see if you can

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find the spread- -- I'm sorry -- Dr. Petsko's spreadsheet.

A. Dr. Petsko's. 2166.

Yes.

Q. Why don't you -- okay. Do you have that?

A. I have it.

Q. Great. Do you have Paragraph 244 up from your declaration as well?

A. Yes.

Q. Okay. So following on Page 101 and 1- -- 102, you see a chart with coloring of positions of the PH20 sequence. Right?

A. Yes.

Q. And in 244, you're describing what the colors mean. Right?

A. Yes.

Q. Okay. So the colors that are assigned in the table at Pages 102 and 103 reflect percentages of substitutions as active and inactive mutants as they were classified in the common disclosure. Right?

A. Yes.

Q. Okay. Tables 3 and 9 provided the list of active mutants. Right?

(Pause.)

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A. Table 3, active mutants. Table 9, active mutants.

Q. Okay. So those are the two tables devoted to compiling the active mutants as they were classified in the common disclosure. Right?

A. Correct.

Q. Okay. And then Tables 5 and 10 are compiling the inactive mutants in the patent -- or in the common disclosure?

A. Table 5....

(Pause.)

A. Tables 5 and 10 compiling inactive mutants. Yes.

Q. Okay. And these are the sources for the inactive and active mutant counts that are used to create the coloring scheme for the table at Pages 102 and 103, right, of your dec?

A. From Dr. Petsko's declaration, spreadsheet containing data from 3, 5, 9, 10.

This is excerpted from Dr. Petsko's declaration.

Q. And the coloring is based on the counts of the active and inactive mutants at each position. Right?

A. The coloring scheme is explained in

Paragraph 244.

Q. And is -- and those colors are based on counts at each position of the active and inactive mutants, right; a percentage?

For example, the dark green; what does the dark green indicate on your chart?

A. Yes. So -- yes.

So positions that are color green are the positions at which each of the substitutions that were made were -- resulted in active protein, active PH20 polypeptide.

Q. Okay. If you could go down to Paragraph 246, you say -- and this is Page 104, after your table.

You say:

> The '600 patent provides a detailed functional map of PH20 through its comprehensive and systematic analysis of PH20, achieved through large-scale mutagenesis and enzymatic activity testing of thousands of variants, with up to 18 mutations per position.

And then you say:

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The results show positions that a POSA would understand are critical and tolerate minimal modification or no modification, as well as residues that do tolerate substitution, and particular substitutions that substantially increase activity.

Right? Okay.

A. Yes.

Q. And the table with the coloring at the individual positions is conveying the nature of this guidance in the patent. Right?

MS. MARTIN: Object to form.

A. The table indicates the percentage of amino acids that were tolerated at that position on the basis of the color assigned to it, which is the same color scheme that was applied to the structural analysis.

Q. So the residues in the table and on the structure that are shown in green -- or dark -- well, just say green -- are the positions at which many different amino acids are tolerated. Right?

A. Yes. The positions in green on the structure, as well as on the spreadsheet, are the ones at which almost all the positions were tolerated to re- -- to retain activity.

Q. Okay. Why don't you go to your -- go to the table, and go to Page 103.

What -- if you look at -- look up position 431.

What color is used at position 431?

A. Light green is used at 431.

Q. So if a POSA was trying to make a modified PH20 polypeptide that retained hyaluronidase activity, would Dr. Petsko's table at position 431 tell her she could make substitutions at position 431?

A. Potentially, yes.

Q. Look at position 282 in the chart.

And what color is used in position 282?

A. That position is not colored.

Q. What does that signify?

A. The uncolored boxes signify that there were more than 30%, but fewer than 60%, of the mutations -- the substitutions tested that were tolerated to retain activity.

Q. So if a POSA was trying to make an

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enzymatically active modified PH20 polypeptide that retained -- is going to retain hyaluronidase activity, would Dr. Petsko's table tell her she might be able to introduce substitutions at position 282?

A. With disclaimers and qualifications, it could tell her that.

Q. Okay. Let's go to position 303 in the table.

What color is used at position 303?

A. 303 is colored orange.

Q. If a POSA was trying to make a modified PH20 polypeptide that retained hyaluronidase activity, Dr. Petsko's table would tell her to proceed with caution because substitutions are likely to not be tolerated at position 303. Right?

MS. MARTIN: Object to form.

A. So it depends on the POSA's motivation for creating a substitution.

If the objective was to retain PH20 hyaluronidase activity, the POSA would want to look at the structural environment surrounding that amino acid change and look at the specific amino acids that were tolerated at that position.

If there were some tolerated, then it's

not the case, necessarily, that they would need to proceed with caution, were they to choose one of the tolerated ones.

Q. So the POSA, at position 303, might change position 303, based on what they see in the data set?

A. A POSA would use all of the data, both in the table and in the structural analysis of where those particular residues were located within the structure.

Q. So the POSA wouldn't rule out changing an amino acid at position 303, right, based on the analysis you provided?

A. Particularly if their objective did not require retaining activity --

Q. Well --

A. -- a POSA would not have to rule out position 303.

Q. Yeah. Well, in my question, I was assuming they wanted to retain activity.

A. And even if they want to retain activity, there is sufficient guidance within the information available through a structural model, combined with the mutagenesis data that have been provided, as well as alignment data, that could inform the POSA

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about what their strategy might need to be to retain activity by changing that location.

Q. Okay. So that's -- that conclusion based on your analysis of all of the data in the patent?

A. All of the data in the patent are definitely informative.

Q. Okay. One last one: Look at position 299. What color is used at position 299?

A. That one is pink.

Q. And if a POSA was trying to make a modified PH20 polypeptide that retained hyaluronidase activity, Dr. Petsko's table would tell her not to introduce a substitution at position 299. Is that right?

MS. MARTIN: Object to form.

(Witness reading.)

A. To retain activity of the enzyme at position 299.

Q. Correct.

A. Caution. Dr. Petsko would advise caution --

Q. So they still might --

A. -- in making a substitution.

Q. So a POSA -- so you believe the -- based on Dr. Petsko's analysis, a POSA might change

position 299. It wouldn't rule it out completely?

A. Based on Dr. Petsko's analysis, which also included looking at each residue in the context of its environment, offered scenarios in which a mutation, even in an invariant residue, could be made if a compensatory mutation was also made in the local environment to neutralize the effect of the first mutation.

This is why Dr. Petsko would advise greater scrutiny before considering undertaking that mutation.

Q. So if I understand your answer, you're saying that a POSA might change the residue of position 299, despite it being marked in red in the table?

A. I'm saying that a POSA might change that residue if their objective to -- is to retain hyaluronidase activity in careful examination with what additional residues might need to be also concurrently mutagenized to compensate for that, the effects of that mutation.

I'm saying a POSA could predict that by examining the area around that residue and considering what they were seeking to substitute it with.

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MR. KUSHAN: Okay. We have no further questions.

MS. MARTIN: All right. We'll take a quick break.

VIDEOGRAPHER: Off the record at 4:04.

(Whereupon, a recess was taken.)

VIDEOGRAPHER: On the record at 4:08.

MS. MARTIN: We don't have any questions.

VIDEOGRAPHER: All right. Going off the record at 4:08. And this ends today's testimony.

(Whereupon the deposition concluded at 4:08 p.m.)

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DEPONENT'S SIGNATURE

Please be advised I have read the foregoing deposition, pages 1 through 196, inclusive. I hereby state there are:

(Check one)

_____ No corrections

_____ Corrections per attached

_____

MELANIE ANN SIMPSON, PH.D.

( ) Reading and signing was requested.

( ) Reading and signing was waived.

(X) Reading and signing was not requested.

Should the signature of the witness not be affixed to the deposition, the witness shall not have availed herself 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: December 9, 2025

NAME OF WITNESS: MELANIE ANN SIMPSON, 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 _____

Page _____ Line _____ Reason _____

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Page _____ Line _____ Reason _____

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MELANIE ANN SIMPSON, PH.D. DATE

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.

_____

MELANIE ANN SIMPSON, PH.D.

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CERTIFICATE

I, SUSAN ASHE, a Certified Electronic 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 11th day of December 2025.



Susan Ashe, Notary Public
of the District of Columbia

My commission expires: May 14, 2028.

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