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Transcript of James Naismith, Ph.D.

Date: June 13, 2026
Case: Merck Sharp & Dohme LLC -v- Halozyme Inc. (PTAB)

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Halozyme EX2304
Merck v. Halozyme
PGR2025-00024

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MERCK SHARP & DOHME LLC,
Petitioner,

v.

HALOZYME, INC.,
Patent Owner.

Case Nos.: PGR2025-00042 Patent Nos.: 12,037,618
PGR2025-00046 12,091,692
PGR2025-00052 12,264,345

VIDEO DEPOSITION OF JAMES NAISMITH, Ph.D.

Saturday, June 13, 2026
12:41 p.m. (BST)

The Randolph Hotel
Beaumont Street
Oxford, OX1 2LN
United Kingdom

Job No.: 638140
Court Reporter:
Chanelle Malliff, CLR, ACR, QRR2*

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2

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1 A P P E A R A N C E S

2 (continued)

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13 Videographer, Planet Depos

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16 (Via Zoom) Aubrey Haddach, Halozyme

17

18

19

20

21

22

C O N T E N T S

Deponent Page

DR. JAMES NAISMITH (sworn) 6

Examination by Ms. Martin 6

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E X H I B I T I N D E X
(Previously marked)

No. Description Page

Exhibit 1133 Naismith Declaration 10
PGR2025-00004, US Patent No.
12,018,298

Exhibit 1133 Naismith Declaration 11
PGR2025-00046, US Patent No.
12,091,692

Exhibit 1001 US Patent No. 12,018,298, ...12
Date of Patent: June 25, 2024

Exhibit 1001 US Patent No. 12,091,692, ...13
Date of Patent: Sep. 17, 2024

Exhibit 1026 Common disclosure 59

1 Saturday, June 13, 2026
2 P R O C E E D I N G S
3 (On the record at 12:41 p.m.)
4 VIDEOGRAPHER: Here begins media 1 in the 12:41:07
5 videotaped deposition Dr. James Naismith, in the 12:41:09
6 matter of Merck Sharp & Dohme LLC v Halozyme, Inc. in 12:41:11
7 the United States Patent and Trademark Office, case 12:41:16
8 numbers PGR2025-0042, PGR2025-0046 and PGR2025-0052. 12:41:19
9 Today's date is June 13, 2026 and the time is 12:41:37
10 12:41 p.m. This video deposition is taking place at 12:41:41
11 The Randolph Hotel, Beaumont Street, Oxford, UK. 12:41:46
12 The videographer today is Wendy Viner on 12:41:51
13 behalf of Planet Depos. 12:41:54
14 Could I ask counsel to please identify 12:41:56
15 themselves and state whom they represent, beginning 12:41:57
16 with the attorney in the room, followed by our Zoom 12:41:59
17 participants. 12:42:03
18 MR. KUSHAN: Jeff Kushan from Sidley Austin, 12:42:09
19 representing Merck Sharp & Dohme LLC. 12:42:11
20 MS. MARTIN: Lauren Martin from 12:42:21
21 Quinn Emanuel, representing Halozyme. 12:42:22
22 MR. KUSHAN: Can we also -- you can probably 12:42:29

1 get all the names of the rest of the people attending 12:42:31
2 from the Zoom. 12:42:33
3 VIDEOGRAPHER: Of course. No worries. 12:42:35
4 Our court reporter today is Chanelle Malliff 12:42:36
5 on behalf of Planet Depos. 12:42:38
6 Will the court reporter please swear in the 12:42:40
7 witness and we can proceed. 12:42:42
8 DR. JAMES NAISMITH 12:42:45
9 having duly sworn to tell the truth, 12:42:55
10 was examined and testified as follows: 12:42:55
11 EXAMINATION 12:43:01
12 BY MS. MARTIN: 12:43:01
13 Q. Good afternoon, Dr. Naismith. 12:43:03
14 A. Good afternoon. I realize it's very early in 12:43:05
15 the morning for you, so thank you for being flexible. 12:43:06
16 Q. No worries. Thank you for making yourself 12:43:09
17 available on a Saturday. We really appreciate that. 12:43:11
18 All right, so under the Patent Trial and 12:43:17
19 Appeal Board standing order in this matter 12:43:20
20 I'm obligated to give you the following instruction, 12:43:23
21 which I'm going to read: 12:43:26
22 "You must ask me, the deposing counsel, 12:43:29

1 rather than your own counsel for any clarifications, 12:43:31
2 definitions or explanations of any words, questions 12:43:34
3 or documents presented during the cross-examination." 12:43:38
4 Do you understand that instruction? 12:43:44
5 A. Yes, I do. 12:43:45
6 Q. Okay, great. Who is present with you in the 12:43:46
7 room right now? 12:43:49
8 A. So opposite me is the videographer. Opposite 12:43:50
9 and to the right is the court reporter. And to my 12:43:53
10 right, right of my eye line, is Mr. Kushan. 12:43:57
11 Q. Is there anything open on your computer 12:44:05
12 besides Zoom? 12:44:06
13 A. It isn't my computer that is being used here. 12:44:07
14 My computer is in my bag, not here. 12:44:09
15 Q. Okay. So you were provided a computer by 12:44:13
16 the -- by somebody at Planet Depos? 12:44:16
17 A. I'm looking to check. It's their computer 12:44:22
18 but yeah, they say yes it's their computer. 12:44:24
19 Q. Oh okay, got it. Got it. So did you bring 12:44:26
20 any materials with you besides the exhibits that 12:44:36
21 we've talked about? 12:44:38
22 A. No. 12:44:44

1 Q. Have you marked anything on any of those 12:44:45
2 exhibits? 12:44:46
3 A. No. They were provided to me this morning, 12:44:47
4 brought in by Mr. Kushan, so I haven't touched them. 12:44:50
5 Q. Okay. What did you do to prepare for the 12:44:55
6 deposition today? 12:44:57
7 A. I reread my declarations in the three 12:45:00
8 matters. I looked back through the patents, the 12:45:04
9 disclosure -- the common disclosure. I looked again 12:45:11
10 at the declarations, particularly from Hecht, Simpson 12:45:15
11 and Petsko. And I looked again through my 12:45:20
12 deposition -- um, and scanned through my own 12:45:25
13 deposition and my previous declarations for I think 12:45:28
14 matter 4 but I would say "the '600 patent". So if 12:45:31
15 that's the wrong thing, my apologies. 12:45:36
16 Q. Who did - did you meet with anyone to prepare 12:45:42
17 for this deposition? 12:45:45
18 A. Yes, I did. 12:45:46
19 Q. Who did you meet with? 12:45:47
20 A. I met with Mr. Kushan and, I forget his 12:45:48
21 second name but Leif and Amy from Sidley Austin. 12:45:53
22 Q. For how long did you meet with them? 12:46:00

1 A. Mr. Kushan and I spent about five hours 12:46:03
2 yesterday evening in Oxford with Amy -- and 12:46:06
3 I forget -- Mahan I think online, and I can't 12:46:10
4 remember Leif's second name but they were online for 12:46:14
5 most but not all of that time. 12:46:17
6 Q. And was that the only meeting that you had 12:46:19
7 with counsel to prepare for this deposition? 12:46:20
8 A. No, we'd had -- when I was told there would 12:46:23
9 be -- there would be a deposition in this matter, we 12:46:26
10 had a couple of Zoom meetings online to discuss what 12:46:29
11 timing arrangements and also what the scope would be, 12:46:36
12 so where I should focus my attention. 12:46:40
13 MR. KUSHAN: I'm gonna counsel the witness to 12:46:46
14 not reveal any attorney-client privileged 12:46:47
15 communications. 12:46:51
16 BY MS. MARTIN: 12:46:55
17 Q. Dr. Naismith, are you aware that the board 12:46:55
18 has issued final written decisions in some of the 12:46:57
19 PGRs? 12:47:02
20 A. Yes, I'm aware that there is a final 12:47:02
21 judgment, yes. 12:47:06
22 Q. Have you read any of the final written 12:47:10

1 decisions? 12:47:12
2 A. I read the last page, I think. I haven't 12:47:13
3 read through the document, no. 12:47:16
4 Q. Did you consider the contents of the final 12:47:24
5 written decisions in preparing your declarations in 12:47:26
6 the 42, 46 and 52 matters? 12:47:30
7 A. No, I did not. 12:47:34
8 Q. Did you consider the contents of the final 12:47:37
9 written decisions in preparing for your deposition 12:47:40
10 today? 12:47:42
11 A. No, I did not. 12:47:43
12 Q. Can you please find the matter 4 declaration, 12:47:59
13 which was in the box labeled Exhibit 1 for the '298 12:48:05
14 patent. 12:48:12
15 (Previously marked Exhibit 1133 identified.) 12:48:13
16 A. Of course. If you give me just a second. 12:48:13
17 VC TECHNICIAN: Would you like me to pull 12:48:22
18 that up on the screen, Ms. Martin? 12:48:23
19 MS. MARTIN: Yeah, that would be great. 12:48:26
20 A. So I have, just to check we're on the same 12:48:27
21 one, PGR2025-00004, US Patent ends in '298; is that 12:48:29
22 correct? 12:48:36

1 BY MS. MARTIN: 12:48:39
2 Q. Yes, that's correct. Okay, so please keep 12:48:39
3 that handy. And then also please find the 12:48:41
4 declaration for matter 46, which is for the '692 12:48:52
5 patent. And that should be one of the ones that you 12:48:57
6 brought with you. 12:49:00
7 (Reporter clarification.) 12:49:24
8 MS. MARTIN: So the first document, the 12:49:26
9 declaration from matter 4, is Exhibit 1133. 12:49:27
10 So all of the Naismith declarations are 12:49:31
11 Exhibit 1133 and their respective matters. 12:49:33
12 So then the second document is the 12:49:41
13 declaration from matter 46, so that's also 12:49:44
14 Exhibit 1133 in the matter 46 case. 12:49:48
15 COURT REPORTER: Is the technician 12:50:05
16 electronically marking them or are they already 12:50:06
17 marked? 12:50:09
18 MR. KUSHAN: They're already marked. 12:50:10
19 COURT REPORTER: They're already marked. 12:50:11
20 Okay. 12:50:11
21 MS. MARTIN: They're already marked. 12:50:12
22 (Previously marked Exhibit 1133 identified.) 12:50:13

1 THE WITNESS: So I see I need to just correct 12:50:14
2 myself, which was when I looked at this case -- 12:50:15
3 I don't know the case number but it was the '600 12:50:17
4 patent and this is the '298. But I now understand 12:50:19
5 the declarations are essentially the same. 12:50:22
6 BY MS. MARTIN: 12:50:23
7 Q. Yeah, yeah, I think the '600 was for -- 12:50:24
8 I think was matter 3. 12:50:25
9 A. Yeah, it was just so that I didn't -- okay. 12:50:26
10 Q. Understood. Okay, so do you have your matter 12:50:31
11 46 declaration? 12:50:37
12 A. Yes. 12:50:38
13 Q. Okay. And then for ease of reference here, 12:50:40
14 if you could also pull out the '298 patent, which was 12:50:46
15 Exhibit 2 in the box, and that's Exhibit 1001 from 12:50:51
16 matter 4. 12:50:56
17 (Previously marked Exhibit 1001 identified.) 12:51:11
18 A. So there are three copies. Will I give one 12:51:17
19 to Mr. Kushan? 12:51:19
20 Q. Sure. Thank you. 12:51:20
21 A. So this is what is in the box and it ends in 12:51:23
22 '298; is that correct? 12:51:26

1 Q. Yes. Yes, perfect. And then if you want to 12:51:29
2 also get the '692 patent, which you should have in 12:51:36
3 the materials that Mr. Kushan provided. And that's 12:51:41
4 Exhibit 1001 from matter 46. So do you have all of 12:51:43
5 those? 12:52:08
6 (Previously marked Exhibit 1001 identified.) 12:52:08
7 A. I have four things in front of me. 12:52:09
8 Q. Perfect. Okay, so can you please turn in the 12:52:11
9 matter 46 declaration to paragraph 90? 12:52:22
10 VC TECHNICIAN: Ms. Martin, do you have a 12:52:38
11 page number, by any chance? 12:52:40
12 THE WITNESS: It begins on page 57 in my copy 12:52:56
13 in front of me, "Defined Terms ..." headed. 12:53:00
14 BY MS. MARTIN: 12:53:18
15 Q. Dr. Naismith, do you have paragraph 90? 12:53:18
16 A. Yes, I do. 12:53:22
17 Q. All right. The terms "PH20" and "modified 12:53:23
18 PH20 polypeptide" are defined in the common 12:53:30
19 disclosure, correct? 12:53:34
20 A. That's ... I said that's right. The common 12:53:35
21 disclosure defines these two terms. 12:53:38
22 Q. And if you then continue on, I think under 12:53:43

1 paragraph 90 on page 58 in your declaration, you 12:53:47
2 excerpted the paragraphs in the common disclosure 12:53:52
3 that include those definitions, is that right? 12:53:57
4 A. That's correct, I've highlighted two long 12:54:01
5 paragraphs where those are talked about and defined. 12:54:03
6 Q. And then if you go to paragraph 91, which is 12:54:09
7 on page 59. You said: 12:54:12
8 "Dr. Simpson testified at her deposition 12:54:18
9 that the first sentence in each 12:54:21
10 paragraph above (highlighted in yellow) 12:54:22
11 is the definition of each term." 12:54:25
12 Is that right? 12:54:27
13 A. That's what Dr. Simpson stated, I think in 12:54:27
14 her deposition, and I've excerpted the relevant 12:54:30
15 portion from the deposition. 12:54:33
16 Q. Okay. Can you then go back to page 58 that 12:54:42
17 has the portions from the common disclosure? 12:54:45
18 A. Yes, I have. 12:54:48
19 Q. So do you agree with Dr. Simpson that the 12:54:49
20 first sentence in each paragraph is the definition of 12:54:51
21 each of the terms? 12:54:57
22 A. It's not a complete definition. I think you 12:55:00

1 have to read the whole paragraph to get the complete 12:55:02
2 definition, but the first definition, the first 12:55:04
3 sentence, captures essential features of it. That it 12:55:08
4 is: 12:55:12
5 "... PH20 ..." 12:55:14
6 When it's used in the patent: 12:55:14
7 "... refers to a type of hyaluronidase 12:55:15
8 that occurs in sperm and is 12:55:19
9 neutral-active." 12:55:21
10 But there are important other parts of the 12:55:22
11 definition spelt out in the paragraph. 12:55:24
12 Q. Okay, so are you saying that the complete 12:55:30
13 paragraph for each of those terms is the definition? 12:55:33
14 A. So I said that you read -- the first sentence 12:55:36
15 is key but you have to read -- you read through the 12:55:39
16 full paragraph and it helps you clarify the 12:55:42
17 definition of what it is being used in the common 12:55:44
18 disclosure. 12:55:47
19 Q. So then can you turn to paragraph 100, which 12:55:51
20 is on pages 65 to 66? 12:55:54
21 A. I'm on paragraph 100. 12:56:09
22 Q. Okay. And then below paragraph 100, on 12:56:13

1 page 66, you've excerpted again that paragraph from 12:56:17
2 the specification that has the definition for 12:56:21
3 modified PH20 polypeptide? 12:56:25
4 A. I've excerpted part of that paragraph, that's 12:56:28
5 correct. 12:56:31
6 Q. And you've highlighted the second sentence in 12:56:43
7 that paragraph, that starts: 12:56:46
8 "A modified PH20 polypeptide can have up 12:56:48
9 to [100](sic) amino acid 12:56:52
10 replacements ..." 12:56:55
11 Is that right? 12:56:56
12 A. In my declaration that has a yellow 12:56:58
13 highlighter for that sentence. 12:57:01
14 Q. All right, so let's turn back to 12:57:10
15 paragraph 100. Perfect. Do you see the second 12:57:11
16 sentence in paragraph 100? 12:57:19
17 A. It begins: 12:57:22
18 "After defining the phrase ..." 12:57:22
19 Q. Yes. So you say: 12:57:25
20 "After defining the phrase 'modified 12:57:30
21 PH20 polypeptide,' the common disclosure 12:57:34
22 explains that modified PH20 proteins 12:57:37

1 'can have up to 150 amino acid 12:57:38
2 replacements, so long as the resulting 12:57:43
3 modified PH20 polypeptide exhibits 12:57:45
4 hyaluronidase activity' (below)." 12:57:48
5 Correct? 12:57:51
6 A. Yeah, those are the words that are written in 12:57:51
7 my declaration, yes. 12:57:56
8 Q. So when you wrote the declaration, you stated 12:58:00
9 that the sentence that starts -- the sentence that 12:58:04
10 says: 12:58:10
11 "A modified PH20 polypeptide can have up to [100] 12:58:10
12 (sic) amino acid replacements ..." 12:58:14
13 That sentence appears after the phrase "modified 12:58:16
14 PH20 polypeptide" is defined; correct? 12:58:21
15 A. When you say "after" in terms of the 12:58:26
16 paragraph that is excerpted the sentence follows -- 12:58:28
17 one follows the other, is that what you mean? When 12:58:32
18 you -- 12:58:35
19 Q. Well you use -- 12:58:35
20 A. -- say "after", I want to check. 12:58:35
21 Q. Sorry. I don't want to talk over you. 12:58:41
22 A. My apologies. My question was, when you say 12:58:43

1 "after", so the paragraph I've excerpted begins: 12:58:46
2 "As used herein, 'modified PH20 12:58:50
3 polypeptide' ... refers to a PH20 12:58:54
4 polypeptide that contains at least ..." 12:58:57
5 Blah, blah, blah, and then it goes on to 12:59:00
6 further define. But you need to read the entire 12:59:02
7 paragraph to understand the definition that's being 12:59:05
8 applied here. 12:59:07
9 Q. So I'm asking you about the phrase that you 12:59:11
10 used in your declaration, which is after defining the 12:59:14
11 phrase "modified PH20 polypeptide"? 12:59:18
12 A. Yes, so that's right, so the first sentence 12:59:22
13 begins that definition, which is the first 12:59:25
14 definition, and then you get this additional sentence 12:59:28
15 that helps you understand that definition and 12:59:30
16 clari -- so you're clear in your mind what it says. 12:59:32
17 Q. So I think we can all agree that the first 12:59:38
18 sentence: 12:59:40
19 "As used herein, 'modified PH20 polypeptide' ..." 12:59:42
20 Is the definition, right? 12:59:44
21 MR. KUSHAN: Objection, foundation. 12:59:47
22 THE WITNESS: No, I don't agree with that. 12:59:49

1 I think you have to, as I've said, read the entire 12:59:50
2 paragraph in this case and it clearly tells you 12:59:54
3 that -- it tells you at the first sentence it begins 12:59:58
4 what it's talking about is a concept of modified 13:00:02
5 polypeptide and then it gives you a clear limitation 13:00:05
6 to that, which says it has "up to 150 amino acid 13:00:09
7 replacements, so long as [it] ... exhibits 13:00:12
8 hyaluronidase activity". And it further begins to 13:00:15
9 tell you what the other amino acid replacements are 13:00:17
10 and can include any one or more of those 13:00:23
11 modifications or at least one replacement. 13:00:26
12 BY MS. MARTIN: 13:00:27
13 Q. So in your declaration when you said that 13:00:34
14 that sentence about the 150 replacements comes after 13:00:35
15 the definition, you were wrong, right? 13:00:38
16 A. No, I don't think I was wrong. I said that 13:00:43
17 that sentence is the beginning of the definition so 13:00:46
18 there is a definition but you have to read the whole 13:00:49
19 paragraph to understand what the full meaning is. 13:00:51
20 That's why I have excerpted the whole paragraph. 13:00:53
21 Q. So let's keep page 66 handy but then if you 13:01:06
22 can go to paragraph 109, which is on page 74? 13:01:09

1 A. Yes. 13:01:26
2 Q. You say in paragraph 109: 13:01:38
3 "I recognize that the definition of 13:01:40
4 'modified PH20 polypeptide' in the 13:01:42
5 common disclosure considered in 13:01:46
6 isolation does not explicitly state that 13:01:47
7 each modified PH20 polypeptide is 13:01:51
8 enzymatically active." 13:01:54
9 Correct? 13:01:57
10 A. That's correct, that's what the sentence 13:01:58
11 says. 13:02:01
12 Q. So in paragraph 109 you state that the term 13:02:07
13 "modified PH20 polypeptide" is not defined to require 13:02:10
14 enzymatic activity; correct? 13:02:15
15 MR. KUSHAN: Objection, foundation. 13:02:19
16 THE WITNESS: No, that's not what I state in 13:02:21
17 that paragraph. I said that it does not, when 13:02:23
18 considered in isolation does not explicitly state 13:02:25
19 that each modified PH20 polypeptide is enzymatically 13:02:28
20 active. And I did not base my opinion solely on 13:02:35
21 that. Instead, I pointed out that only when 13:02:38
22 I considered all the language in certain claims, and 13:02:40

1 then in conjunction with the common disclosure 13:02:42
2 I would have considered that the claims as a whole 13:02:45
3 define a set of modified PH20s that exhibit 13:02:49
4 hyaluronidase activity. 13:02:54
5 What the point I make in paragraph 109 is 13:02:55
6 that the phrase in isolation does not explicitly 13:02:57
7 state enzymatically active. I didn't base my opinion 13:03:02
8 on a single isolated phrase. 13:03:06
9 Q. Well, so you say the definition of modified 13:03:14
10 PH20 polypeptide considered in isolation. So when 13:03:17
11 you said the definition of modified PH20 polypeptide 13:03:20
12 in paragraph 109, what language from the common 13:03:23
13 disclosure were you referring to? 13:03:28
14 A. So the phrase "modified PH20 polypeptide" 13:03:31
15 appears multiple times in the common disclosure. My 13:03:34
16 point was that I didn't use simply that phrase on its 13:03:40
17 own in isolation to form my -- how I have read and 13:03:43
18 understood the patent. I set out the reasons for 13:03:47
19 my -- how I have approached this analysis in the 13:03:50
20 previous paragraphs and I said that it was important 13:03:53
21 that you had to read the entire common disclosure. 13:03:56
22 Q. That was not my question. My question was, 13:04:01

1 when you used the word "definition" in paragraph 109, 13:04:03
2 what portion -- what portion of the paragraph that 13:04:09
3 has the definition of modified PH20 were you talking 13:04:11
4 about when you said -- when you used the word 13:04:15
5 "definition" in paragraph 109? 13:04:18
6 MR. KUSHAN: Objection to form. 13:04:20
7 THE WITNESS: So what I'm talking about is 13:04:25
8 the phrase in isolation -- a definition in isolation 13:04:26
9 of modified PH20 polypeptide occurs in the common 13:04:29
10 disclosure in different places. But on its own, just 13:04:34
11 that isolated phrase, doesn't, how I understand the 13:04:38
12 requirement for enzyme activity, that I didn't base 13:04:42
13 my opinion simply in that words "modified PH20 13:04:45
14 polypeptide". 13:04:50
15 BY MS. MARTIN: 13:04:54
16 Q. Well, your sentence doesn't say -- that's not 13:04:54
17 what the sentence says. Do you agree with the 13:04:57
18 sentence that you wrote at the start of 13:05:01
19 paragraph 109: 13:05:03
20 "... that the definition of 'modified PH20 13:05:04
21 polypeptide' in the common disclosure considered in 13:05:07
22 isolation does not explicitly state that each 13:05:11

1 modified PH20 polypeptide is enzymatically active"? 13:05:14
2 A. Yes, I agreed with that, I've just said so. 13:05:18
3 That I agreed that in isolation that that phrase 13:05:20
4 where it is used doesn't on its own define -- 13:05:23
5 doesn't -- sorry, doesn't explicitly state that each 13:05:27
6 is enzymatically active. 13:05:29
7 Q. And so you agree that the definition of 13:05:33
8 modified PH20 polypeptide in the common disclosure 13:05:36
9 does not explicitly state that the modified PH20 13:05:41
10 polypeptides are enzymatically active? 13:05:45
11 MR. KUSHAN: Objection to foundation. 13:05:48
12 THE WITNESS: No, my point is that in 13:05:50
13 isolation if you just cap just that isolated phrase, 13:05:53
14 it doesn't itself explicitly state that. But 13:05:57
15 I didn't use the isolated phrase to make that 13:06:00
16 definition. I said that you had -- 13:06:04
17 BY MS. MARTIN: 13:06:07
18 Q. So you -- 13:06:07
19 A. Sorry my -- sorry, not definition, 13:06:09
20 understanding. So the definition on its own 13:06:11
21 "modified PH20 polypeptide" in isolation is not how 13:06:12
22 I understood and read that; that you have to read the 13:06:16

1 common disclosure to fully understand what is being 13:06:20
2 referred to with the meaning modified PH20 13:06:24
3 polypeptides, and having done that I conclude that 13:06:29
4 they are directed to active forms of the protein. 13:06:32
5 Q. Can we turn back to page 66? 13:06:38
6 A. Yes. 13:06:43
7 Q. And do you agree that the first sentence: 13:06:55
8 "As used herein, 'modified PH20 13:06:58
9 polypeptide' ... refers to a PH20 13:07:02
10 polypeptide that contains at least one 13:07:04
11 amino acid modification, such as at 13:07:07
12 least one amino acid replacement as 13:07:10
13 described herein, in its sequence of 13:07:12
14 amino acids compared to a reference 13:07:15
15 unmodified PH20 polypeptide." 13:07:18
16 Do you agree that that statement from the common 13:07:20
17 disclosure defining modified PH20 polypeptide does 13:07:22
18 not include any limitation regarding activity? 13:07:26
19 MR. KUSHAN: Objection, foundation. 13:07:31
20 THE WITNESS: So what my understanding is, as 13:07:35
21 I read it and in my opinion, is that that in 13:07:37
22 isolation -- and I didn't rely on that sentence in 13:07:39

1 isolation -- that sentence in isolation does not, as 13:07:44
2 you say, state that enzymatic activity is required in 13:07:48
3 isolation. But my understanding and my opinion is 13:07:53
4 not based solely on that sentence in isolation. 13:07:56
5 BY MS. MARTIN: 13:08:06
6 Q. Can you please turn to paragraph 104? 13:08:06
7 I think it's on the next page, page 68. 13:08:10
8 A. Yes, I am there. 13:08:14
9 Q. And in paragraph 104 you state, in the third 13:08:19
10 sentence, you state that: 13:08:33
11 "PH20 is expressly defined in the common 13:08:35
12 disclosure to ..." 13:08:41
13 Sorry, it's moving on the screen. Strike that. 13:08:48
14 Let me start it again. Can you scroll back up? 13:08:48
15 A. That's why I use paper and I'm not very good 13:08:52
16 with the screen. My apologies. 13:08:55
17 Q. Fine. Okay, let me start again. 13:08:57
18 "PH20 is expressly defined in the common 13:08:59
19 disclosure to have a form a POSA would understand is 13:09:03
20 folded." 13:09:06
21 Correct? 13:09:06
22 A. That's what the sentence says, yes. 13:09:08

1 Q. So do you agree that PH20 is expressly 13:09:09
2 defined in the common disclosure to have a form a 13:09:11
3 POSA would understand is folded? 13:09:16
4 A. It is active, which means it is also folded. 13:09:18
5 So it's expressly in the disclosure as an active form 13:09:20
6 of the protein which is enzymatically active and 13:09:25
7 folded. 13:09:28
8 Q. But you don't use the word "active" here, 13:09:30
9 right, you just use the word "folded"? 13:09:34
10 A. That's correct, the language is different 13:09:37
11 because I was -- the language relates to the patent 13:09:38
12 I was asked to assess. But PH20 is properly 13:09:41
13 understood as the folded active form on the surface 13:09:44
14 of the sperm cell, neutral-active. 13:09:48
15 (Reporter clarification.) 13:09:58
16 Neutral-active. It's neutral-active. 13:09:58
17 Q. If PH20 is properly understood as folded 13:10:02
18 active form, then why didn't you put the word 13:10:05
19 "active" in that sentence in paragraph 104? 13:10:08
20 A. In a long report of many things I honestly 13:10:13
21 can't remember all my word choices but I do make it 13:10:16
22 clear in my conclusion and elsewhere that PH20 is the 13:10:20

express -- is an active form found on the surface of 13:10:24
the sperm cell. We in fact looked at that at 13:10:28
paragraph -- on page 58: 13:10:37
"As used herein, PH20 refers to a type 13:10:39
of hyaluronidase ..." 13:10:44
It goes on, sperm cell neutral-active: 13:10:46
"... truncated forms thereof [which] 13:10:48
have activity ... includes ... 13:10:48
variants ..." 13:10:50
Etc. So that's all in there. And also later on 13:10:52
I state the require -- as I read the claims, they're 13:10:58
directed to the active form of the protein. 13:11:01
For activity you have to have folding. 13:11:06
Q. So it's your testimony now that for matter 13:11:09
46, which is the '692 patent, that those claims are 13:11:13
limited to the active PH20, active modified PH20? 13:11:17
A. So it's my opinion, and as I set out in my 13:11:23
declaration and I've quite clearly stated in my 13:11:28
declaration, that as I read the claims they are 13:11:31
directed to the active mutants or modified PH -- 13:11:33
active modified PH20. 13:11:39
Now I do understand, and I set out in 13:11:41

1 paragraph 110 that claim scope is of course a matter 13:11:42
2 for the board, right. I'm not a lawyer and 13:11:46
3 I don't -- I'm not offering a legal opinion, only a 13:11:51
4 scientific one. And if the board were to enlarge the 13:11:53
5 claim scope, but I think we all agree that within the 13:11:58
6 claims are these folded active forms of the protein 13:12:02
7 then since the bulk of my opinions address written 13:12:06
8 description and enablement, my opinions are that 13:12:13
9 those things are not properly described for that 13:12:14
10 subset. So adding other subsets wouldn't change my 13:12:16
11 opinion as regards enablement and written 13:12:20
12 description. But I understand that my opinions and 13:12:24
13 how I have read the claim scope are not -- it's for 13:12:27
14 the patent board to decide how that should be read or 13:12:30
15 what the legal threshold is. 13:12:33
16 MS. MARTIN: So we agreed to limit the scope 13:12:37
17 of this deposition to claim construction. And so, 13:12:39
18 Mr. Kushan, if your witness is going to start talking 13:12:42
19 about 112 then I should be able to question him on 13:12:46
20 112, meaning that I should have more than 2 hours. 13:12:49
21 MR. KUSHAN: No. No. No. 13:12:52
22 MS. MARTIN: I feel that if we agreed to 13:12:52

1 limit it to claim construction, that's what we should 13:12:53
2 be doing. 13:12:56
3 MR. KUSHAN: He's addressing claim 13:12:57
4 construction. You can ask the questions focused on 13:12:58
5 claim construction. If you -- just continue your 13:13:00
6 deposition. 13:13:04
7 MS. MARTIN: That's fine. Just make sure 13:13:06
8 that we're all on the same page here. 13:13:07
9 BY MS. MARTIN: 13:13:21
10 Q. Okay, can you please turn to paragraph 43. 13:13:21
11 A. Paragraph 43 is on page 19 and it begins: 13:14:00
12 "As I explain ..." 13:14:03
13 Is that correct? 13:14:05
14 Q. Yes. Okay, so in paragraph 43, in your 13:14:06
15 declaration for the -- in matter 46, you say that 13:14:16
16 you: 13:14:20
17 "... read the claims as a whole as being 13:14:20
18 directed to modified PH20 polypeptides 13:14:23
19 that (i) contain an amino acid sequence 13:14:28
20 that satisfies the sequence identity 13:14:31
21 claim parameters, (ii) meet the position 13:14:32
22 313 substitution requirement, and (iii) 13:14:36

1 have folded to adopt the same tertiary 13:14:38
2 fold found in the native state of the 13:14:41
3 wild-type PH20 protein." 13:14:44
4 Correct? 13:14:46
5 A. That's what I say, yes. 13:14:47
6 Q. And that's accurate, right? 13:14:52
7 A. So it's not the complete analysis in 43, as 13:14:55
8 the first sentence begins I point you to D and E. So 13:14:58
9 in this declaration for this matter I considered -- 13:15:04
10 I separated out my analysis to focus on the early 13:15:06
11 stages in the first paragraphs 43 to 48 on folding 13:15:09
12 things, understanding the folding subset, and then 13:15:15
13 I moved to consider activity in 104 to 108. And 13:15:19
14 I've produced my conclusions at the end of 13:15:22
15 paragraph 108 for how I read the claims as a whole 13:15:24
16 there. So my final conclusion about how a POSA would 13:15:27
17 read it is set there. I just split my analysis for 13:15:33
18 this particular patent into two sections. 13:15:35
19 Q. So when you included romanettes (i) through 13:15:38
20 (iii) in paragraph 43, you're saying that you instead 13:15:44
21 you intended to include a fourth romanette and you 13:15:50
22 didn't? 13:15:54

1 MR. KUSHAN: Objection to foundation. 13:15:56
2 THE WITNESS: So that's not what I'm saying. 13:15:58
3 I'm saying that I have set out my opinions as to the 13:15:59
4 full -- my full understanding of the claims in these 13:16:02
5 series of paragraphs. This is my analysis paragraph 13:16:08
6 which focuses -- this part focuses on folding. 13:16:12
7 I deal with activity later on, which I point to in E 13:16:16
8 which is the activity analysis and I end up in 13:16:22
9 paragraph 108 where I give you my conclusions and it 13:16:24
10 says a POSA would conclude. 13:16:28
11 BY MS. MARTIN: 13:16:30
12 Q. So when you say in paragraph 43 that you read 13:16:30
13 the claims as a whole as being directed to modified 13:16:33
14 PH20 polypeptides that satisfy three features -- 13:16:39
15 MR. KUSHAN: Objection to foundation. 13:16:45
16 BY MS. MARTIN: 13:16:49
17 Q. I haven't -- sorry, let me start again 13:16:49
18 because I didn't finish my question. When you say in 13:16:51
19 paragraph 43 that you read the claims as a whole as 13:16:53
20 being directed to modified PH20 polypeptides that 13:16:57
21 satisfy the three romanettes that you've listed 13:17:01
22 there -- 13:17:04

1 A. Oh I see what you mean by "romanettes". My 13:17:05
2 apologies. 13:17:08
3 Q. I'm sorry, (i), (ii) and (iii), you are 13:17:09
4 reading the claims as a whole as being directed to 13:17:13
5 modified PH20 polypeptides that have -- that meet the 13:17:17
6 sequence identity claim parameters, have the position 13:17:23
7 313 substitution, and have folded to adopt the same 13:17:26
8 tertiary fold, right? 13:17:30
9 A. I understand now. So this is not my complete 13:17:32
10 conclusion on the claims. In this paragraph I set 13:17:34
11 out my analys -- so this paragraph is the beginning 13:17:38
12 of me -- I talk about in the next few paragraphs 13:17:41
13 about my analysis, how I constructed my analysis on 13:17:48
14 folding. I then move in -- as at the beginning it 13:17:50
15 says "in ...D and ...E" and in E I separate out my 13:17:53
16 activity analysis. And my conclusion for what the 13:17:58
17 claims are read, how I have read the claims, are set 13:18:00
18 out in the -- entirely in the conclusion in 13:18:03
19 paragraph 108. 13:18:07
20 Q. So let's turn to paragraph 108 which starts 13:18:11
21 on page 71. Are you there? 13:18:13
22 A. Nearly. My apologies, the pages are starting 13:18:28

1 to come -- 13:18:31
2 Q. You're fine, sorry. It's just hard to tell 13:18:32
3 when you're not in person. 13:18:32
4 A. I'm on paragraph 108 now. 13:18:37
5 Q. Okay, perfect. And so in paragraph 108 you 13:18:41
6 say: 13:18:42
7 "I believe Dr. Hecht more accurately 13:18:44
8 describes why a POSA would have read the 13:18:46
9 claims as a whole as being directed to 13:18:49
10 modified PH20 polypeptides that are 13:18:51
11 properly folded, and certain of those 13:18:53
12 being enzymatically active." 13:18:57
13 Right? 13:18:59
14 A. That's what my sentence says, yes. 13:19:00
15 Q. So certain claims are directed to PH20 -- 13:19:03
16 modified PH20s that are properly folded and 13:19:06
17 enzymatically active, right? 13:19:10
18 A. No. 13:19:12
19 Q. Are you saying now all claims are directed to 13:19:19
20 PH20s that are properly folded and enzymatically 13:19:22
21 active? 13:19:25
22 A. That's the conclusion I rendered in 13:19:26

1 paragraph 109, which I said that the claims -- the 13:19:27
2 last sentence of paragraph 109 is that -- can I just 13:19:31
3 read it? That a POSA "... would have concluded that 13:19:35
4 the claims define a set of modified PH20s that 13:19:38
5 exhibit hyaluronidase activity." And that's 13:19:41
6 consistent with the sentence I've written in 13:19:44
7 paragraph 108. 13:19:46
8 Q. Okay, so let's go to -- I just want to 13:19:49
9 understand because in this declaration you say that 13:19:55
10 "... certain claims (e.g., claim 5) ...", which is 13:19:58
11 what you've written in 109 -- 13:20:05
12 A. Sorry, we're on to paragraph 109? 13:20:09
13 Q. Sorry. Sorry, yeah, let me start again. The 13:20:11
14 last sentence in paragraph 109 you say that a POSA: 13:20:14
15 "... when a POSA considers all of the 13:20:18
16 language used in certain claims (e.g., 13:20:20
17 claim 5) and does that in conjunction 13:20:23
18 with the common disclosure, she would 13:20:26
19 have concluded that the claims define a 13:20:28
20 set of modified PH20s that exhibit 13:20:31
21 hyaluronidase activity." 13:20:33
22 Right? 13:20:34

1 A. Yes, that's what this sentence says, and 13:20:35
2 concluded that the claims, meaning all the claims, 13:20:38
3 define a set of modified PH20s that exhibit 13:20:41
4 hyaluronidase activity. 13:20:45
5 Q. Okay, so you're now saying that all of the 13:20:47
6 claims require hyaluronidase activity and not just 13:20:51
7 claim 5? 13:20:55
8 A. I'm not now saying that, that's what the 13:20:57
9 declaration says. 13:21:00
10 Q. So in paragraph 108, when you've said that 13:21:13
11 the claims -- would understand the "claims as a whole 13:21:17
12 as being directed to modified PH20 polypeptides that 13:21:21
13 are properly folded, and certain of [them] being 13:21:26
14 enzymatically active", you meant to say that all of 13:21:28
15 them would be enzymatically active? 13:21:31
16 A. Oh, sorry, I see now. Sorry, my apologies. 13:21:36
17 So they're directed to modified PH20 polypeptides and 13:21:37
18 those that are enzymatically active. So that's what 13:21:42
19 it says, is that they're properly folded and are -- 13:21:44
20 certain of -- and the ones within that population are 13:21:46
21 properly folded that are enzymatically active. So 13:21:51
22 it's the certain of the modified PH20 polypeptides 13:21:54

1 that are folded. There is a subset of those that are 13:21:58
2 enzymatically active. 13:22:00
3 So if we go back to -- sorry, I see the point. 13:22:02
4 I think it is the little box diagram on page 49. At 13:22:07
5 the top of page 49. 13:22:17
6 Q. Yes. 13:22:27
7 A. So we've drawn a big universe of various 13:22:28
8 sub-populations and I've shown "Natively folded 13:22:31
9 modified PH20 polypeptides", and what I'm referring 13:22:35
10 to and those that are stably enzymatically active is 13:22:40
11 the little green highlighted box, "adequate 13:22:42
12 stability", enzymatic stability. That's to where 13:22:44
13 I think the claims are directed in that box which is 13:22:48
14 a subset of the folded ones. Sorry, that's the 13:22:49
15 "certain", if that helps. 13:22:56
16 Q. Okay, so let's go back to -- actually let's 13:23:05
17 go to paragraph 100. 13:23:10
18 A. That's page 65? 13:23:26
19 Q. Yes, I think. Then, sorry, can you go to the 13:23:42
20 next page because I'm looking for the fourth sentence 13:23:45
21 in paragraph 100. So do you see the sentence that 13:23:49
22 starts: 13:23:56

1 "I agree with Dr. Hecht ..." 13:23:56
2 A. "... that this passage ... also supports ... 13:23:59
3 certain claims ... as defining modified PH20 13:24:02
4 polypeptides [as requiring] hyaluronidase activity." 13:24:02
5 Yes, I see that. 13:24:06
6 Q. Do you see that sentence? 13:24:08
7 A. I can read that, yes. 13:24:12
8 Q. All right. So you stated in your matter 13:24:13
9 46 declaration that: 13:24:16
10 "... certain claims (e.g., claim 5) ... [define] 13:24:18
11 modified PH20 polypeptides that exhibit hyaluronidase 13:24:23
12 activity." 13:24:28
13 Correct? 13:24:28
14 A. No, that's not what I'm saying. I'm saying 13:24:28
15 that -- 13:24:31
16 Q. You literally said the words "certain 13:24:32
17 claims". Are you saying that you didn't use the 13:24:34
18 language "certain claims"? 13:24:36
19 MR. KUSHAN: Objection to foundation. 13:24:38
20 Objection as to form. 13:24:39
21 THE WITNESS: So what I'm saying is that that 13:24:42
22 particular passage I've highlighted helps understand 13:24:44

1 particular claim 5, for example claim 5, as defining 13:24:48
2 them to have hyaluronidase activity. I don't, in my 13:24:52
3 opinion, that having read the common disclosure in 13:24:57
4 its entirety, as I conclude in paragraph 109 that the 13:25:01
5 claims are -- all the claims are directed to the 13:25:04
6 active form of the protein. 13:25:10
7 There are -- different paragraphs dwell on 13:25:12
8 different points but it doesn't -- I've given you 13:25:16
9 what I conclude to be the analysis. 13:25:18
10 BY MS. MARTIN: 13:25:25
11 Q. So when you said in your declaration "that 13:25:25
12 this passage ... supports reading certain claims 13:25:30
13 (e.g., claim 5) as defining modified PH20 13:25:36
14 polypeptides that exhibit hyaluronidase activity", 13:25:39
15 what you meant to say was that it supports reading 13:25:42
16 all of the claims as defining modified PH20 13:25:45
17 polypeptides that exhibit hyaluronidase activity? 13:25:48
18 A. No. What I meant was that you read this, and 13:25:52
19 particularly Dr. Hecht cited this, but I have 13:25:55
20 previously stated that the modified PH20 polypeptide 13:26:01
21 as I have read the claims requires activity for a 13:26:06
22 whole host of reasons that I set out in 13:26:10

1 paragraph 108, and that this phrasing here helps you 13:26:12
2 understand that reading. It's part of the common 13:26:16
3 disclosure. It's part of what forms my opinions for 13:26:18
4 the claims. But that phrase in isolation doesn't 13:26:20
5 help -- doesn't -- isn't what I rest on for the 13:26:24
6 entire patent. 13:26:27
7 Q. Okay. Can you turn to page 69. 13:26:31
8 A. Yes, I'm on page 69. 13:26:49
9 Q. I think you had said before -- actually -- 13:26:52
10 yeah, okay, perfect. You had said before that 13:26:55
11 subsection -- okay -- that subsection E addresses the 13:26:59
12 activity; is that right? 13:27:07
13 A. That's correct, that this series of 13:27:08
14 paragraphs addresses my activity analysis. 13:27:11
15 Q. And you say the claims -- in the header for 13:27:14
16 subsection E is that "The Claims Include 13:27:18
17 Enzymatically Active Modified PH20 Polypeptides", 13:27:21
18 right? 13:27:25
19 A. Yes, that's correct, that's what the header 13:27:25
20 says. 13:27:28
21 Q. So the claims include enzymatically active 13:27:29
22 modified PH20 polypeptides but they are not limited 13:27:32

1 to enzymatically active modified PH20 polypeptides, 13:27:36
2 right? 13:27:42
3 MR. KUSHAN: Objection to foundation. 13:27:42
4 THE WITNESS: That isn't my conclusion and my 13:27:44
5 conclusion that I spell out when I say the 13:27:45
6 "conclusion" is, that the claims define a set of 13:27:47
7 modified PH20s that exhibit hyaluronidase activity, 13:27:50
8 and I give my reasons for reaching that conclusion at 13:27:54
9 the end. 13:27:57
10 BY MS. MARTIN: 13:28:01
11 Q. Sorry, what paragraph are you reading from 13:28:01
12 that says that the claims require hyaluronidase 13:28:03
13 activity? 13:28:06
14 A. As I read the claims, that is paragraph 109 13:28:06
15 where I say "and ... she would have concluded", so 13:28:12
16 that is a conclusion of my analysis in paragraph 109. 13:28:15
17 So the paragraphs are the underlying ideas and 13:28:21
18 analysis that go to reach my conclusion, and I spell 13:28:24
19 out my conclusion in 109. 13:28:27
20 Q. So based on the language that was used in 13:28:33
21 claim 5 a POSA would have concluded that all of the 13:28:35
22 claims define a set of modified PH20 polypeptides 13:28:40

1 that exhibit hyaluronidase activity? 13:28:44
2 A. That's not what I said. So in 109 I say that 13:28:46
3 "the language ... and ... in conjunction with the 13:28:51
4 common disclosure", you have to read the common 13:28:54
5 disclosure, you would have concluded or at least my 13:28:57
6 opinion is the POSA would have concluded that the 13:29:01
7 claims are directed to modified PH20s that are 13:29:03
8 enzymatic -- that exhibit hyaluronidase activity. 13:29:07
9 Q. But you used the language -- you used the 13:29:11
10 phrase "certain claims" in this paragraph, correct? 13:29:14
11 A. Yeah, that's correct, that is there but 13:29:18
12 I also state my conclusion for "the claims". I don't 13:29:21
13 say this claim or that claim, I say "the claims 13:29:24
14 define a"-- are directed to "a set of modified PH20s 13:29:27
15 that exhibit hyaluronidase activity". That is the 13:29:34
16 conclusion of my opinion or on how I have read the 13:29:36
17 claim scope. 13:29:41
18 Q. So why did you refer to "language used in 13:29:42
19 certain claims" in this sentence? 13:29:45
20 A. Because I read -- my understanding was I had 13:29:47
21 to read the patent that I was asked to and I wrote my 13:29:51
22 declaration on that. I drew attention to claim 5 as 13:29:55

1 particularly interesting but I didn't use it to 13:29:57
2 inform how I read claim 1. How I read the other 13:30:02
3 claims was to properly read the common disclosure and 13:30:07
4 test that claim independently. 13:30:10
5 Q. So then why did you call out claim 5 in this 13:30:14
6 sentence? 13:30:17
7 A. I thought it was an interesting claim to 13:30:17
8 call. I can't remember more than that, that 13:30:19
9 I remember claim 5 specifically calls out specific 13:30:21
10 mutations that are all active, and that position, 13:30:24
11 313, is one of the ones that I think Dr. Petsko 13:30:28
12 flagged as particularly tolerant, and in that claim 5 13:30:33
13 these call out the substitutions that are active. So 13:30:37
14 I thought it was worth noting but it isn't -- my 13:30:41
15 conclusion is that the claims define a set of 13:30:44
16 modified PH20s that exhibit hyaluronidase activity. 13:30:46
17 Q. Okay. Can you -- actually can you turn to 13:31:11
18 paragraph 104 in this declaration and then just keep 13:31:13
19 it handy. (Pause). And then at the same time pull 13:31:16
20 up your matter 4 declaration on the '298 patent? 13:31:28
21 A. Okay. 13:31:33
22 Q. It's Exhibit 1 for the tech. 13:31:53

1 A. Can I just check it is -- this is 13:31:56
2 PGR2025-00004, US Patent '298, my declaration, yes? 13:31:56
3 Q. Yes. 13:32:03
4 A. Yes, I've got it. Thank you. 13:32:05
5 Q. Then can you turn to paragraph 104? 13:32:06
6 A. I don't know if you can see, I'm in -- 13:32:08
7 drowning in a sea of paper. I'll just move some 13:32:11
8 things is okay? 13:32:13
9 Q. I can imagine. 13:32:16
10 A. I've got paragraph 104 in my PGR2025-00004. 13:32:44
11 Q. Perfect. Okay. So do you have two 13:32:53
12 declarations side-by-side with two paragraph 104s? 13:32:55
13 A. Yes, I've got four bundles of papers but the 13:32:59
14 104 is visible to me in both, although I have to turn 13:33:03
15 the page in the PGR2025-00004 because paragraph 104 13:33:06
16 goes over to 67 and 68. So if you hear me turn the 13:33:14
17 page, it's just because the paragraph splits across 13:33:20
18 the two. 13:33:22
19 Q. Okay, yeah, that's fine. I just want to make 13:33:23
20 sure that we're -- you've got them both. All right. 13:33:24
21 So in matter 4, in paragraph 104, you say in the 13:33:28
22 third sentence: 13:33:34

1 "PH20 is expressly defined in the common 13:33:35
2 disclosure to have a form [that the] 13:33:38
3 POSA would understand ..." 13:33:43
4 Sorry. 13:33:54
5 A. Yeah, I've got the sentence. 13:33:54
6 "PH20 is expressly defined in the common 13:33:56
7 disclosure ... would understand is 13:33:58
8 folded and is enzymatically active." 13:34:02
9 Q. Yes, thank you. So that's what you say in 13:34:05
10 your matter 4 declaration, you say: 13:34:06
11 "... folded and is enzymatically active". 13:34:07
12 But in your matter 46 declaration you say that: 13:34:09
13 "PH20 is expressly defined ... to have a 13:34:17
14 form a POSA would understand is folded." 13:34:26
15 And you don't say -- you don't include the 13:34:29
16 language "enzymatically active"; correct? 13:34:31
17 A. That's correct, in the 0046 that, the words 13:34:34
18 after "is folded" aren't -- "and is enzymatically 13:34:39
19 active" are not added here, that's correct. 13:34:44
20 Q. So why did you not include the phrase 13:34:48
21 "enzymatically active" in the matter 46 declaration? 13:34:50
22 A. Because, as I said, I split my analysis 13:34:54

1 because each declaration I have to consider the test 13:34:57
2 separately, the case, and formulate my opinions for 13:35:02
3 the patent in front of me. So I split my analysis 13:35:05
4 here. So I focus mainly on the folding for this 13:35:08
5 patent in 46, and then I dealt with the enzymatic 13:35:11
6 activity in paragraphs 105 to 109. And as I've said, 13:35:14
7 at the end of paragraph 109 I give you my conclusions 13:35:20
8 to how the claims are read, which is they're 13:35:24
9 enzymatically active proteins. 13:35:27
10 Q. So you agree that PH20 has the same 13:35:29
11 definition in both the '298 patent and the '692 13:35:32
12 patent, correct, it's the same definition? 13:35:35
13 A. Yes, I do. 13:35:38
14 Q. All right. Yet in the matter 46 declaration 13:35:40
15 for the '692 patent you said that "PH20 is expressly 13:35:47
16 defined ... to have a form a POSA would understand is 13:35:51
17 folded". 13:35:55
18 And in the matter 4 declaration for the '298 13:35:57
19 patent you said "PH20 is expressly defined ... to 13:36:00
20 have a form a POSA would understand is folded and is 13:36:07
21 enzymatically active." 13:36:12
22 Correct? 13:36:13

A. That's correct, in those paragraphs I use 13:36:14
different words because I was dealing with different 13:36:16
patents, and I constructed my report differently 13:36:18
because each report I understand has to be 13:36:22
independently stand on its own. So my -- the way 13:36:24
I conducted my analysis was different here and 13:36:29
I wrote my report differently but my conclusion which 13:36:31
is given in 109 integrates across that and gives you 13:36:34
my analysis. 13:36:38
Q. So you said that you used different language 13:36:41
because there are different patents but it's the 13:36:43
same -- the patents have the same common disclosure 13:36:44
and they have the same definition for PH20, right? 13:36:48
A. That's correct, I've said that the PH20 is 13:36:51
the same, but I was talking about my analysis of 13:36:53
claim construction here. And so I analyzed my claim 13:36:56
construction differently here but I reach the same 13:37:03
conclusion and it's because the claims are 13:37:06
differently spelt out here, I thought -- my 13:37:07
understanding is I have to conduct an independent 13:37:10
analysis for each patent and that's what I did. 13:37:12
Q. So is it your testimony that PH20 is defined 13:37:15

1 in the specification to require folding and activity? 13:37:18
2 A. So PH20 is defined in the common disclosure 13:37:22
3 as in neutral-active form found in the surface of the 13:37:27
4 cell which is both folded and enzymatically active. 13:37:30
5 Q. So in your matter 46 declaration when you 13:37:37
6 just said that it's defined to include forms that are 13:37:39
7 active -- I'm sorry, forms that are folded -- 13:37:44
8 A. Yeah, that's part of it because, as I said, 13:37:51
9 I separated out my analysis of folding up to 13:37:53
10 paragraph 104 and then from heading E, I then moved 13:37:56
11 on to my analysis before rendering my final opinion 13:38:00
12 as to how I read claim construction. So it's just 13:38:04
13 that I split my analysis in folding and activity 13:38:07
14 differently in this report because I considered a 13:38:11
15 different claim language than in the '298 I think it 13:38:15
16 is -- '298. So, that is why there's a difference in 13:38:18
17 words. But my conclusion for 46 is that the claims 13:38:24
18 are directed to enzymatically active modified PH20 13:38:29
19 polypeptides. 13:38:36
20 Q. Okay. Can you turn to paragraph 43 in the 13:38:44
21 '298 declaration? 13:38:51
22 A. That's matter 4, is that correct? 13:38:53

1 Q. Yes. 13:38:54
2 (Reporter clarification) 13:39:13
3 A. Paragraph 43. Is that correct, Ms Martin? 13:39:14
4 Q. Yes. Yes, thank you. 13:39:15
5 A. That's page 19 and it splits over on to 13:39:15
6 page 20. 13:39:16
7 Q. Yes. Perfect. Then if you could turn to 13:39:20
8 paragraph 43 in the matter 46 declaration as well? 13:39:22
9 A. Yes, I'm on those two. 13:39:58
10 Q. Perfect. Okay, so in the matter 4 13:40:00
11 declaration, in paragraph 43 you say that you 13:40:02
12 "... read the claims as a whole as being directed to 13:40:06
13 modify PH20 polypeptides that ..." meet four 13:40:10
14 requirements, right? 13:40:15
15 A. That's correct. 13:40:16
16 Q. And the fourth requirement is that they "are 13:40:18
17 enzymatically active", correct? 13:40:20
18 A. That's what the paragraph says in matter 4, 13:40:23
19 yes. 13:40:25
20 Q. Okay. And then in matter 46, in 13:40:27
21 paragraph 43, as we discussed, you say that the 13:40:31
22 claims -- you "read the claims as a whole as being 13:40:35

1 directed to modified PH20 polypeptides that" satisfy 13:40:38
2 three criteria, correct? 13:40:44
3 MR. KUSHAN: Objection to foundation. 13:40:46
4 THE WITNESS: So again I'm going to come back 13:40:48
5 and say at the start I set out where I discuss my 13:40:50
6 analysis in this analysis for this patent which is 13:40:54
7 matter 46. I separated out the folding analysis from 13:40:57
8 the activity analysis. I did so because the claim 13:41:01
9 language was different. I had to consider it 13:41:05
10 independently. And my conclusion as to how I've read 13:41:07
11 the claim scope is given in paragraph 109. But the 13:41:10
12 words are different between those two paragraphs 13:41:15
13 because I approached the reading of this patent 13:41:17
14 independently from the matter 4. 13:41:20
15 BY MS. MARTIN: 13:41:26
16 Q. In any event, in paragraph 43 in the matter 13:41:23
17 46 declaration, you say that the claims as a whole 13:41:33
18 are directed to modified PH20 polypeptides that 13:41:38
19 satisfy three of your requirements, correct? 13:41:42
20 A. The sentence in this paragraph which is 13:41:44
21 beginning my analysis of folding, states that how 13:41:47
22 I have read the claims and is given in the conclusion 13:41:56

1 of the section in paragraph 109. So that is correct, 13:41:58
2 in this sentence it talks about this because 13:42:03
3 I'm gonna focus on the folding analysis here, and 13:42:05
4 then I separate out my activity analysis in this 13:42:10
5 matter and I give my conclusion at the end of 13:42:13
6 paragraph 109. 13:42:15
7 Q. But in paragraph 43 in matter 46, you say: 13:42:18
8 "As I explain in [subsections] ...D and 13:42:23
9 ...E below ..." 13:42:26
10 So, as you explain in your folding and 13:42:27
11 activity sections, right, that's how you start this 13:42:30
12 paragraph? And then you still conclude, in 13:42:35
13 paragraph 43, that you read the claims as a whole as 13:42:37
14 being directed to modified PH20 polypeptides that 13:42:41
15 satisfy three criteria; correct? 13:42:45
16 A. No, I didn't say conclude here. The 13:42:47
17 conclusion is given in the end, in paragraph 108 13:42:49
18 (sic), once I have completed my analysis. But this 13:42:52
19 section deals with the folding and the latter section 13:42:56
20 deals with activity. And my conclusion is given at 13:43:01
21 the end of the section 108 -- 109, sorry. So this is 13:43:05
22 not the conclusion, this is the prefix to beginning 13:43:10

1 to think about folding. 13:43:12
2 Q. Okay. Can you turn to paragraph 108 then in 13:43:27
3 both the matter 4 and the matter 46 declarations. 13:43:43
4 A. In the 46 that's in page 71 and goes over on 13:44:04
5 to page 73. 13:44:07
6 Q. Yes. 13:44:20
7 A. I'm just turning there in matter 4. That 13:44:21
8 begins on page 70 and ends on page 73. 13:44:23
9 Q. So do you see the first sentence in your 13:44:46
10 matter 4 declaration? 13:44:48
11 A. Yes. 13:44:51
12 Q. You say: 13:44:52
13 "I believe Dr. Hecht more accurately 13:44:53
14 describes why a POSA would have read the 13:44:55
15 claims as a whole as being directed to 13:44:57
16 modified PH20 polypeptides that are 13:45:00
17 enzymatically active." 13:45:03
18 Correct? 13:45:05
19 A. Yes, I can see that's what I've said in 13:45:05
20 declaration 4. 13:45:08
21 Q. And then in the matter 46 declaration you 13:45:10
22 say: 13:45:14

1 "I believe Dr. Hecht more accurately 13:45:16
2 describes why a POSA would have read the 13:45:18
3 claims as a whole as being directed to 13:45:20
4 modified PH20 polypeptides that are 13:45:23
5 properly folded, and certain of those 13:45:27
6 being enzymatically active." 13:45:28
7 Right? 13:45:30
8 A. That's right. 13:45:31
9 Q. So in the matter 4 declaration, you say that 13:45:31
10 the claims as a whole are directed to modified PH20 13:45:41
11 polypeptides that are enzymatically active. But in 13:45:43
12 matter 46 declaration you say a POSA would have read 13:45:51
13 the claims as a whole as being directed to modified 13:45:53
14 PH20 polypeptides that are properly folded, and 13:45:56
15 certain of those are enzymatically active. Right? 13:45:59
16 A. So I have said how I -- what the -- how 13:46:03
17 I meant the sentence to read. How it reads to me is 13:46:07
18 that in the matter 46 we're going back to the box and 13:46:10
19 I'm directing you to the specific top left-hand box, 13:46:15
20 that is the green box colored, active proteins that 13:46:19
21 are -- so the properly folded is a bigger universe. 13:46:23
22 And then -- but the claims here are directed to the 13:46:28

1 enzymatically active portion of that universe in that 13:46:31
2 corner, in this paragraph 108, that's why I used my 13:46:35
3 analysis differently because I consider different 13:46:40
4 claim language, separated out folding from the 13:46:43
5 activity analysis. 13:46:46
6 Q. I'm still trying to understand. Are you 13:46:49
7 saying that -- so you said that certain of those are 13:46:51
8 enzymatically active, meaning that the claims as 13:46:55
9 a whole are directed to properly folded PH20 13:46:57
10 polypeptides of which certain of them are 13:47:02
11 enzymatically active, right? 13:47:04
12 A. No, that's not what I meant. So what 13:47:06
13 I'm saying is that because I separated my analysis in 13:47:10
14 matter 46 to folding and activity, that I read the 13:47:15
15 claims as being directed to folded and active 13:47:19
16 proteins that just folded proteins is a bigger -- has 13:47:22
17 sub-categories within it but I -- so that's what 13:47:28
18 I dealt with in the first sections. And then when 13:47:32
19 I deal with my analysis around activity I am focused 13:47:35
20 down and the claims are directed to enzymatically 13:47:39
21 active which are also folded. 13:47:43
22 So to have activity you must be folded, but not 13:47:45

1 all folded proteins have enzymatic activity. 13:47:48
2 So what I'm doing is saying the claims are 13:47:51
3 directed to folding and within that subset of folding 13:47:53
4 only those that are enzymatically active. 13:47:57
5 Q. But that's not what you say in paragraph 108, 13:47:59
6 you say "certain of those being enzymatically 13:48:02
7 active"? 13:48:05
8 A. Yes, it's directed to certain of those that 13:48:05
9 are enzymatically active. That's how I read my 13:48:08
10 sentence. It's directed to those that are modified 13:48:14
11 and folded as well as having -- and directed to those 13:48:17
12 that are enzymatically active. 13:48:21
13 Q. So you're reading out the "certain of those"? 13:48:24
14 A. No, "certain of those" -- so as I tried to 13:48:26
15 explain what the language is meant to convey, is if 13:48:30
16 we go back to the box, page 49, that I've boxed 13:48:33
17 "Natively folded ... PH20 polypeptides" and within 13:48:47
18 that there are different types of them, and it's the 13:48:51
19 certain of those that are enzymatically active, 13:48:53
20 properly folded and stable that I believe the claims 13:48:55
21 are directed to. And because -- and that's -- so 13:48:58
22 that's what that sentence says: the certain of those 13:49:01

1 boxes that are folded, only those that are 13:49:05
2 enzymatically active is how I have construed the 13:49:07
3 claims. 13:49:10
4 Q. So if that's how you're construing the claims 13:49:16
5 here why didn't you just use the same language that 13:49:18
6 you used in the matter 4 declaration? 13:49:21
7 A. My understanding is that I have to approach 13:49:23
8 each patent independently. The claim language was 13:49:26
9 different. I read it differently and did my analysis 13:49:29
10 differently. I reached a conclusion that I rendered 13:49:31
11 in paragraph 109, which was that my conclusion is the 13:49:34
12 claims are directed to enzymatically active 13:49:39
13 hyaluronidase activity. 13:49:43
14 Q. Can you turn to paragraph 110 in the matter 13:50:37
15 46 declaration. 13:50:43
16 A. Yes. 13:50:59
17 Q. In the second sentence you say: 13:51:00
18 "I understand the panel conducting this 13:51:01
19 proceeding could conclude that the 13:51:05
20 claims are not ..." 13:51:07
21 Defined to modified PH -- or, I'm sorry: 13:51:07
22 "... that the claims are not limited to 13:51:10

1 modified PH20 polypeptides that have 13:51:12
2 stably folded." 13:51:14
3 Correct? 13:51:16
4 A. Yes, that's what I said. The panel could 13:51:17
5 conclude that. I'm not a lawyer. 13:51:19
6 Q. And you didn't say anything about enzymatic 13:51:22
7 activity in that sentence, did you? 13:51:24
8 A. That sentence doesn't have enzymatic activity 13:51:27
9 in it. And it's not my conclusion, it just meant you 13:51:30
10 know that I obviously have to be respectful of what 13:51:32
11 the board can decide. 13:51:35
12 Q. Is it possible for a PH20 to have adopted the 13:51:40
13 stable -- to have stably folded and not be 13:51:44
14 enzymatically active? 13:51:48
15 A. As a scientific point there are variants of 13:51:52
16 PH20 known in the literature that are stably folded 13:51:58
17 but have no enzymatic activity. In fact that's 13:52:02
18 known. 13:52:06
19 MS. MARTIN: We've been going for over 13:52:10
20 an hour so can we take a quick break? 13:52:12
21 MR. KUSHAN: Sure. 13:52:16
22 VIDEOGRAPHER: We are going off the record. 13:52:17

1 The time is 1:52. 13:52:18
2 (A short break) 13:52:29
3 VIDEOGRAPHER: We are back on the record. 14:06:44
4 The time is 2:06 14:06:45
5 BY MS. MARTIN: 14:06:50
6 Q. Welcome back, Dr. Naismith. 14:06:50
7 A. Hello. 14:06:52
8 Q. Did you discuss the substance of your 14:06:54
9 deposition with counsel during the break? 14:06:56
10 A. I did not. 14:06:58
11 Q. All right, so you have the common disclosure 14:06:59
12 in front of you, right? 14:07:03
13 A. It's in a folder, yes. 14:07:04
14 Q. Perfect. And so we've been talking about 14:07:07
15 your declaration in matter 46 and that covers the 14:07:09
16 '692 patent, correct? 14:07:15
17 A. Yes, I mean I believe so but I obviously want 14:07:18
18 to just turn to my front piece to check. Yes, '692, 14:07:20
19 that's correct. 14:07:25
20 Q. And the position at issue in that declaration 14:07:26
21 is position 313, correct? 14:07:28
22 A. The position that's called out in the claims, 14:07:33

1 claim 1, yes, is 313, that's correct. 14:07:35
2 Q. Okay. And actually do you have the '692 14:07:38
3 patent somewhere? 14:07:42
4 A. I have it here. 14:07:52
5 Q. Can you turn to the claims in the '692 14:07:54
6 patent? It should be on page 185. It's the 14:07:55
7 second-to-last page. 14:07:59
8 A. To make it easier, do you mind if I just 14:08:00
9 remove matter 4 from in front of me and put it to the 14:08:02
10 side. 14:08:06
11 Q. Mm-hmm, that's fine. 14:08:08
12 A. Okay, I'm on the '692 patent. 14:08:20
13 Q. Okay, and you've got the claim 1? 14:08:22
14 A. Let me find the claims, sorry. 14:08:25
15 Q. Okay. The second-to-last page. 14:08:28
16 A. Okay. There's bulldog clips. (Pause). 14:08:31
17 Yes. 14:08:35
18 VC TECHNICIAN: Would you like me to share 14:08:46
19 this on screen, Ms Martin? 14:08:47
20 BY MS. MARTIN: 14:08:48
21 Q. Yeah, if you want to, that's fine. Thank 14:08:48
22 you. Okay, are you there, Dr. Naismith? 14:08:49

1 A. Yes, I am, I'm on the claims section. 14:08:52
2 Q. Perfect. And so just confirming the '692 14:08:54
3 patent, the position at issue is position 313? 14:08:56
4 A. I'm confirming, yes, that in claim 1 it says 14:09:00
5 the modified position and it spells out 313 with 14:09:03
6 reference to SEQ ID No:3. 14:09:07
7 Q. Okay, thank you. And just to confirm we're 14:09:12
8 all on the same page here. That you interpret claim 14:09:13
9 1 of the '692 patent which requires modified PH20 14:09:16
10 polypeptides with a modification at position 313, you 14:09:23
11 interpret claim 1 to be limited to properly folded 14:09:26
12 and enzymatically active proteins, correct? 14:09:31
13 A. That's correct, that's how I read the claim. 14:09:36
14 Q. All right. Now can you turn in the common 14:09:42
15 disclosure, Exhibit 1026, to page 135. 14:09:48
16 (Previously marked Exhibit 1026 identified.) 14:09:53
17 A. I'm going to put aside the patent 692, if 14:09:56
18 that's okay? 14:09:59
19 Q. Yes. 14:10:01
20 A. What page of the common disclosure, please, 14:10:08
21 sorry? 14:10:11
22 Q. Page 135. 14:10:11

1 A. What numbers do you want me to use, the 14:10:17
2 bottom right, which says Petitioner Merck extract 14:10:20
3 page numbers, or the column page numbers in the 14:10:24
4 center? There's two numbers on each page so I just 14:10:26
5 want to be sure I get the right one for you. 14:10:33
6 Q. Sorry, I had it and then -- one second here. 14:10:36
7 (Pause). Okay, on the Petitioner Merck Ex. 1026, 14:10:54
8 page 148. 14:11:09
9 A. Okay, I'll get there. 14:11:14
10 Q. And to orient ourselves, if you look at 14:11:16
11 Merck's page 145, you see that this is Table 5, 14:11:22
12 inactive mutants? 14:11:27
13 A. Yes, I can see that's what it says. It's 14:11:30
14 Table 5, yeah. 14:11:32
15 Q. Okay. Now if you turn back to Merck's 14:11:37
16 page 148. Do you see maybe about a little bit of the 14:11:41
17 ways down the page, position 313, the right-hand 14:11:49
18 column? 14:11:56
19 A. Yes, I do. 14:11:57
20 Q. And there is one amino acid listed in that 14:11:57
21 column for inactive mutants, and that one variant is 14:12:04
22 cysteine; correct? 14:12:08

1 A. So the patent has classified that variant 313 14:12:11
2 as inactive in its classification. 14:12:15
3 Q. So the patent teaches that modifying position 14:12:18
4 313 to a cysteine results in an inactive PH20, 14:12:24
5 correct? 14:12:32
6 A. I disagree, I don't think that's what the 14:12:33
7 patent teaches. The patent teaches that it is at 313 14:12:35
8 less than 20% activity in the assay they deployed. 14:12:42
9 Q. I understand. So it's -- so position 313 14:12:54
10 mutation to cysteine is classified as an inactive 14:12:57
11 mutant but the classification was based on less than 14:13:02
12 20% activity; is that right? 14:13:05
13 A. That's correct, that's how the patent 14:13:07
14 classifies inactive mutants. 14:13:10
15 Q. So under your construction of claim 1 of the 14:13:19
16 '692 patent would the mutation to cysteine at 14:13:23
17 position 313 that is taught in the patent, would that 14:13:28
18 variant satisfy claim 1? 14:13:36
19 A. It might do because the reasons for why it 14:13:39
20 was under 20% activity were not disclosed or 14:13:41
21 investigated by the -- in the disclosure. So if the 14:13:44
22 mutant was 19% active it would have been classified 14:13:50

1 as inactive, but I would have classified 19% as 14:13:54
2 an active form of the protein. 14:13:59
3 Q. I think you said that the reasons why it was 14:14:06
4 under 20% activity were not disclosed. What did you 14:14:12
5 mean by that? 14:14:17
6 A. What I meant was that in the assay that is in 14:14:19
7 the patent, they imposed their own threshold, so I've 14:14:23
8 got no numbers to know what was actually measured. 14:14:27
9 Was the protein secreted, folded, made? Was it 19% 14:14:29
10 active? Any one of those, and other factors, could 14:14:34
11 have led to a protein being classified as inactive. 14:14:37
12 And what I mean here is that the M313 cysteine which 14:14:40
13 was 19% active would have still ended up in this 14:14:46
14 table as classified inactive but if it was 19% then 14:14:49
15 I would have included that as within the scope 14:14:54
16 because that is an active form of the protein. 14:14:57
17 Q. So you don't know one way or the other 14:15:06
18 whether the variant with the cysteine at position 313 14:15:08
19 falls within the scope of claim 1 of the '692 patent? 14:15:13
20 A. I believe that the patent doesn't give me the 14:15:17
21 information necessary to make that call for the M313, 14:15:19
22 that's correct. 14:15:23

1 Q. You said M313, but I just want to make sure 14:15:25
2 that we're clear that it's M313 to cysteine, correct? 14:15:29
3 A. Yes, sorry, to be -- that's just -- my 14:15:35
4 apologies. M313C, the patent doesn't give me the 14:15:36
5 information or disclose the information that would 14:15:42
6 allow me to tell you whether it is active or not, and 14:15:45
7 since 19% activity would be classified as inactive by 14:15:48
8 the patent, 19% activity would be in my terms active 14:15:51
9 and any POSA would see it so that would be within the 14:15:55
10 scope. 14:15:59
11 Q. And I believe we discussed in your last 14:16:04
12 deposition that your threshold for activity was 14:16:06
13 around -- was 5%, am I remembering that right? 14:16:09
14 A. So we discussed that and we talked about a 14:16:13
15 POSA tends to think around 5. But Dr. Petsko said, 14:16:20
16 "Sort of, well, maybe 5 up to 10". But Dr. Simpson's 14:16:24
17 paper, design paper, uses 5. And I said that most 14:16:30
18 POSAs would use 5, but my analysis wouldn't change if 14:16:34
19 we said 10 here because it's, you know, anything 14:16:37
20 below 20 would be classified as inactive. So I gave 14:16:41
21 you 19% which I think all of us, Dr. Simpson, 14:16:45
22 Dr. Petsko, myself, any POSA would agree is an active 14:16:52

1 protein. 14:16:55
2 Q. Is an active protein. 14:16:56
3 A. An ac -- is active. Sorry, "an". My 14:16:59
4 apologies. 14:17:02
5 Q. That's fine. No, it's just for the 14:17:03
6 transcript. I'm having the same difficulty. 14:17:04
7 A. Okay, sorry. M313C if it had 19% activity 14:17:09
8 would be, by my definition and I believe any POSAs, 14:17:13
9 an active protein, therefore would be in the scope. 14:17:16
10 Q. Thank you. 14:17:20
11 A. Is that hopefully clear? 14:17:21
12 Q. Yes. Thank you. And before the break you 14:17:23
13 said that there are variants of PH20 known in the 14:17:28
14 literature that are stably folded but have no 14:17:34
15 enzymatic activity, correct? 14:17:37
16 A. Yes, I said that. 14:17:38
17 Q. Was that known before the priority date? 14:17:40
18 A. Let me -- I want to check the Simpson paper, 14:17:46
19 if it had been investigated. I think it was known 14:17:49
20 because people had mutated the key glutamate residue 14:17:54
21 that was identified as a catalytic mechanism in 14:18:00
22 ArMing. They had made that mutation so it was known 14:18:04

1 that that could be expressed and purified but had no 14:18:07
2 activity. 14:18:10
3 Q. How do you know that it was stably folded if 14:18:21
4 it had no activity? 14:18:24
5 A. It was able to be isolated, it was able to be 14:18:26
6 secreted and analyzed so I assumed therefore it would 14:18:29
7 be folded. And you can do other tests -- I'd have to 14:18:32
8 familiarize myself with the ArMing paper to check all 14:18:38
9 the things that were done in it. 14:18:42
10 Q. I'm just trying to understand as a general 14:18:43
11 matter. 14:18:45
12 A. Okay, as a general matter then if the protein 14:18:46
13 can be purified or can behave on a size exclusion 14:18:50
14 column then you would assume that it was properly 14:18:56
15 folded. If you had made a single mutation at the 14:18:59
16 catalytic site, for publications in science, 14:19:02
17 sometimes you will see people do circular dichroism 14:19:07
18 measurements. In other papers people will accept a 14:19:11
19 simple what's called blue native or blue native 14:19:14
20 SDS-page, or you can do gel filtration 14:19:23
21 chromatography, and so those may be acceptable. 14:19:29
22 For very precise enzymatic studies, sometimes 14:19:32

1 people like to determine a crystal structure of the 14:19:35
2 mutant. 14:19:38
3 So you will see a variety of things used in the 14:19:39
4 literature but as a minimum threshold that the 14:19:42
5 protein has to be isolated because unfolded proteins 14:19:45
6 tend to aggregate and don't behave normally on 14:19:49
7 purification. 14:19:54
8 Q. Would you say that a crystal structure is 14:20:06
9 necessary to know whether or not a protein has been 14:20:08
10 stably folded? 14:20:13
11 A. No, I didn't say that. I said that for 14:20:14
12 people who are very interested in particular 14:20:20
13 subtleties of enzyme mechanism, they might go on and 14:20:24
14 determine the crystal structure of a properly folded 14:20:27
15 inactive protein, and so you sometimes see that in 14:20:31
16 publications, but it's not a threshold test. 14:20:32
17 Q. Do you know one way or the other whether 14:20:37
18 changing the methionine at position 313 to a 14:20:40
19 cysteine, would you expect that to result in 14:20:44
20 an unfolded protein? 14:20:49
21 A. So we know that that position tolerates quite 14:20:56
22 a few changes and there are a number of active 14:20:58

1 mutants described for that protein, and Dr. Petsko 14:21:01
2 I think highlights it in his box as one of the -- not 14:21:07
3 the most tolerated but one of the more tolerated 14:21:10
4 positions for change. If I made that mutant then 14:21:14
5 I think maybe -- I don't have any reason to suspect 14:21:17
6 it would be unfolded but I don't know. I would be 14:21:20
7 surprised, but surprises happen in science, so. 14:21:27
8 Q. Would you expect that mutant to be active 14:21:32
9 under your threshold? 14:21:36
10 MR. KUSHAN: Objection to the foundation. Go 14:21:37
11 ahead. 14:21:39
12 THE WITNESS: So I didn't consider whether 14:21:41
13 the mutant made here would be active above 5%. What 14:21:44
14 I said was that the patent, it could well be in the 14:21:48
15 patent declaration, the patent's common disclosure, 14:21:53
16 that it could be above 5%. Would I suspect it? 14:21:58
17 That's a good question, you know. Maybe -- I hadn't 14:22:02
18 thought a lot about whether -- I'd have to think 14:22:04
19 about that. Cysteine can be tricky sometimes. You 14:22:09
20 might have to adjust the buffers because cysteine can 14:22:12
21 stick to itself or tubes. You know, it's quite 14:22:16
22 inactive so sometimes you can just slip in a bit of 14:22:20

1 reductant to keep the solution reduced. That can 14:22:22
2 prevent aggregation. 14:22:27
3 So this position does tolerate quite a few 14:22:28
4 changes so I can't see an obvious reason why it would 14:22:30
5 inactivate or unfold but these things sometimes are 14:22:33
6 unexpected, as I pointed out previously. 14:22:36
7 Q. And if it were the case that the cysteine -- 14:22:58
8 the M313C variant had less than 5% activity then you 14:22:59
9 would agree that it would not satisfy claim 1 under 14:23:04
10 your construction? 14:23:08
11 MR. KUSHAN: Objection to foundation. 14:23:09
12 THE WITNESS: So what I would say is if you 14:23:16
13 isolated M313C and in a robust well-performed assay 14:23:17
14 the enzyme had less than 5% activity then I would 14:23:19
15 agree that is an inactive protein. And since my 14:23:24
16 reading of the claims are they are directed to the 14:23:27
17 active forms of these mutants, then that -- in that 14:23:29
18 case, where you'd done that experiment, it would be 14:23:32
19 excluded, correct. 14:23:36
20 BY MS. MARTIN: 14:23:38
21 Q. Okay. And then can you turn, please, in 14:23:38
22 Exhibit 1026 to, I wrote down page 67 but I'm not 14:23:42

1 sure if that's -- 14:23:49
2 A. Well I'll turn to both pages and we can find 14:23:51
3 out which one. I don't want to waste your time. So 14:23:53
4 67 is full of text and that is the patent numbering. 14:23:56
5 So at the top it says where the full length sequence 14:24:09
6 is compared. In the exhibit -- 14:24:11
7 Q. Yes, it looks like the exhibit page 67. 14:24:15
8 A. Okay, perfect. So the exhibit, page 67, has 14:24:17
9 95%, 96%, 97%, 98% or 99%. Is that -- 14:24:21
10 Q. Yes. 14:24:27
11 A. Yes, we're on the same page. Perfect. 14:24:28
12 Q. Perfect. Then do you see the paragraph that 14:24:30
13 says: 14:24:32
14 "As used herein, modified PH20 14:24:33
15 polypeptide ..." 14:24:37
16 A. That begins on line 5. 14:24:40
17 Q. Yes. 14:24:43
18 A. Yes, that I think is one of the paragraphs 14:24:43
19 I excerpted in my declaration. 14:24:46
20 Q. Yes, and so that paragraph you agree provides 14:24:49
21 the definition for a modified PH20 polypeptide? 14:24:52
22 A. It is -- that paragraph is one of the places 14:24:58

1 where you -- in forming my opinion for how to read 14:25:00
2 the claims that I read, yes, and relied on. It was 14:25:04
3 part of the evidence for it in forming my opinion. 14:25:07
4 Q. So you agreed that modified PH20 polypeptide 14:25:13
5 is a defined term in the common disclosure, correct? 14:25:18
6 A. So within the common disclosure it is 14:25:22
7 defined, yes. 14:25:26
8 Q. And the definition appears in the paragraph 14:25:27
9 that we are looking at, starting at line 5, on 14:25:29
10 page 67, correct? 14:25:33
11 A. So it's one of the places that you can find 14:25:36
12 in the patent where that is defined but, as I said, 14:25:39
13 it's not the -- that isolated phrase or isolated 14:25:43
14 sentence isn't the basis for how I read the claims 14:25:46
15 but here is a definition of it given. 14:25:49
16 Q. Okay, so what I would like you to do is to 14:25:52
17 read into the record whatever portion of this 14:25:55
18 paragraph, starting at line 5, you believe is the 14:25:59
19 definition for a modified PH20 polypeptide? So 14:26:02
20 please start reading and then stop at what you 14:26:07
21 believe to be the end of the definition for modified 14:26:11
22 PH20 polypeptide? 14:26:14

1 A. Of course. 14:26:17
2 MR. KUSHAN: Objection to form. Objection to 14:26:18
3 foundation. 14:26:21
4 THE WITNESS: So, I'm going to read the 14:26:22
5 paragraph, and I said that it appears elsewhere, but 14:26:23
6 I'm going to read this entire paragraph because this 14:26:26
7 was part of the things that went into my analysis. 14:26:29
8 "As used herein, 'modified PH20 polypeptide' 14:26:32
9 or 'variant PH20 polypeptide' refers to a PH20 14:26:37
10 polypeptide that contains at least one amino acid 14:26:43
11 modification, such as at least one amino acid 14:26:46
12 replacement as described herein, in its sequence of 14:26:49
13 amino acids compared to a reference unmodified PH20 14:26:52
14 polypeptide. A modified PH20 polypeptide can have up 14:26:57
15 to 150 amino acid replacements, so long as the 14:27:01
16 resulting modified PH20 polypeptide exhibits 14:27:05
17 hyaluronidase activity. Typically, a modified PH20 14:27:10
18 polypeptide contains 1 ..." 14:27:14
19 And I'm just going to abridge the numbers: 14:27:17
20 "... or 50 amino acid replacements. It is 14:27:19
21 understood that a modified PH20 polypeptide ... can 14:27:22
22 include one or more other modifications, in ... at 14:27:27

1 least one amino acid replacement as described 14:27:30
2 herein." 14:27:33
3 BY MS. MARTIN: 14:27:43
4 Q. So you read the full paragraph as the 14:27:43
5 definition of "modified PH20 polypeptide"? 14:27:44
6 MR. KUSHAN: Objection to foundation. 14:27:49
7 THE WITNESS: No, I read the full paragraph 14:27:51
8 as where the definition is set out and it is one of 14:27:52
9 the things that went into forming my opinion as to 14:27:54
10 how the claims should be read, but I pointed out that 14:27:57
11 I read the disclosure as a whole in forming my 14:28:01
12 opinion as to how the claims were read. 14:28:05
13 MS. MARTIN: All right, can we go off the 14:28:08
14 record and take a quick break? 14:28:11
15 VIDEOGRAPHER: We are going off the record. 14:28:13
16 The time is 2:28. 14:28:14
17 (A short break) 14:28:18
18 VIDEOGRAPHER: We are back on the record. 14:33:29
19 The time is 2:33. 14:33:30
20 MS. MARTIN: Perfect. I don't have any 14:33:33
21 further questions. 14:33:35
22 MR. KUSHAN: And we have no questions. 14:33:38

1 THE VIDEOGRAPHER: Okay. This concludes the 14:33:40
2 deposition. We are going off the record. The time 14:33:41
3 is 2:33 p.m. 14:33:42
4 COURT REPORTER: Before we go off the record, 14:33:43
5 can I have the orders obtained on the record? 14:33:43
6 MR. KUSHAN: If you could send a rough, that 14:33:54
7 would be great. 14:33:55
8 MS. MARTIN: Yes, please. 14:33:57
9 MR. KUSHAN: Lauren, do you need to order, 14:33:59
10 timing wise? 14:34:00
11 MS. MARTIN: Oh yeah. Can we get the 14:34:02
12 expedited or whatever -- (Off the record discussion). 14:34:02
13 If you could do the one day, that would be 14:34:42
14 great. (Off the record discussion). So if we can 14:34:42
15 get the final on Monday, that would be great. Thanks 14:35:12
16 so much everybody. Do you need anything else from 14:35:23
17 us? 14:35:24
18 MR. KUSHAN: No. 14:35:31
19 COURT REPORTER: No, thank you. 14:35:32
20 VIDEOGRAPHER: Thank you. 14:35:32
21 (Whereupon, the deposition concluded at 2:35 p.m.)
22

1 CERTIFICATE OF DEPONENT
2
3 I, JAMES NAISMITH, Ph.D., hereby certify that I have
4 read and examined the entire transcript of my
5 deposition and attest that it is a true and correct
6 transcription of my deposition testimony given on
7 Saturday, June 13, 2026, save and except for the
8 changes and/or corrections, if any, listed on the
9 Errata Sheet attached.
10
11
12
13 Signed _____
14 JAMES NAISMAITH, PH.D.
15
16
17
18 Dated this _____ day of _____, 2026.
19
20
21
22

1 ERRATA SHEET

2 Case Name: Merck Sharp & Dohme LLC v. Halozyme, Inc.

3 Witness Name: James Naismith, Ph.D.

4

5 Page / Line From To

6 ____ /_____ _____ _____

7 ____ /_____ _____ _____

8 ____ /_____ _____ _____

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11 ____ /_____ _____ _____

12 ____ /_____ _____ _____

13 ____ /_____ _____ _____

14 ____/_____ _____ _____

15 ____/_____ _____ _____

16 ____/_____ _____ _____

17 ____/_____ _____ _____

18 Subscribed and sworn to before

19 me this _____ day of _____, 2026.

20

21 _____

22 JAMES NAISMITH, PH.D.

1 CERTIFICATE OF COURT REPORTER

2 I, CHANELLE MALLIFF, a Certified LiveNote
Reporter, Accredited Court Reporter, and Qualified
3 Realtime Reporter, hereby certify that:

4 JAMES NAISMITH, Ph.D., the witness whose
deposition is hereinbefore set forth, was duly sworn
5 by me before the commencement of such deposition and
that such deposition was taken before me and is a true
6 record of the testimony given by such witness.

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

9 I further certify that the deposition of
JAMES NAISMITH, Ph.D., occurred at the offices of The
10 Randolph Hotel Beaumont Street Oxford, OX1 2LN, United
Kingdom on Saturday, June 13, 2026, commencing at 12:41
11 p.m. to 2:35 p.m.

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

15

16 _____

17 CHANELLE MALLIFF

18 CLR, ACR, QRR2*

19 June 14, 2026

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22

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