

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

3 -----
4 MYLAN PHARMACEUTICALS INC.,
5 Petitioner

6 vs

7 NOVO NORDISK A/S,
8 Patent Owner
9 -----

10 Case IPR2023-00724

11 U.S. Patent No. 10,335,462
12

13 Oral deposition of

14 JOHN P. BANTLE, M.D.
15

16 VIA VIDEO/TELECONFERENCE

17 THURSDAY, JULY 11, 2024

18 10:05 a.m. EASTERN TIME
19

20 Job No.: 534504

21 Pages: 1 - 78

22 Reported by: Lisa V. Feissner, RDR, CRR, CLR

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2
3 Oral deposition of JOHN P. BANTLE, M.D.,
4 held REMOTELY, via ZOOM, on THURSDAY, JULY 11, 2024,
5 BEGINNING at 10:05 a.m., pursuant to NOTICE, before
6 Lisa V. Feissner, RDR, CRR, CLR, Notary Public.
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1 A P P E A R A N C E S:

2 ON BEHALF OF PETITIONER:

3 EMILY J. GREB, ESQUIRE

4 AARON SCHINDLER, ESQUIRE

5 BRYAN D. BEEL, Ph.D., ESQUIRE (Portland ofc)

6 PERKINS COIE LLP

7 33 East Main Street, Suite 201

8 Madison, WI 53703-3095

9 608.663.7494

10 egreb@perkinscoie.com

11 aschindler@perkinscoie.com

12 bbeel@perkinscoie.com

13
14 ON BEHALF OF PATENT OWNER:

15 MEGAN F. RAYMOND, ESQUIRE

16 JOSHUA REICH, ESQUIRE (NY office)

17 GROOMBRIDGE WU BAUGHMAN & STONE LLP

18 801 17th Street, NW, Suite 1050

19 Washington, DC 20006

20 202.505.5878

21 megan.raymond@groombridgewu.com

22 joshua.reich@groombridgewu.com

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C O N T E N T S		
EXAMINATION OF JOHN P. BANTLE, M.D.		PAGE
By Ms. Raymond		5
P R E V I O U S L Y		
M A R K E D E X H I B I T S		
(identified but not attached)		
EXHIBITS		PAGE
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P R O C E E D I N G S

JOHN P. BANTLE, M.D.,

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

EXAMINATION

BY MS. RAYMOND:

Q Good morning, Dr. Bantle.

A Good morning.

Q Is it your understanding that you're here
to testify about the '462 patent today?

A Yes.

Q And the report you submitted in IPR
2023-00724, marked as Exhibit 1300, you're prepared
to testify about that today?

A Yes.

Q Okay. And are you aware of an expert
named Dr. Jusko?

MS. GREB: Object to form.

A Yes.

Q Have you talked to Dr. Jusko in
connection with your testimony about the '462
patent?

1	A	No.	10:06:21
2	Q	Have you read any of Dr. Jusko's reports	10:06:21
3		regarding the '462 patent?	10:06:24
4	A	Yes.	10:06:28
5	Q	Which reports are those?	10:06:29
6	A	I cannot tell you specifically which	10:06:35
7		report. I think it was his first report from some	10:06:39
8		many months ago.	10:06:43
9	Q	So the first report in this IPR?	10:06:45
10	A	I think so. If you'd like to know with	10:06:50
11		certainty, I could look at my report to see which	10:06:52
12		one it was.	10:06:55
13	Q	If you could take a look at your report	10:07:16
14		and tell me which report of Dr. Jusko you reviewed.	10:07:19
15		Could you please do that.	10:07:24
16	A	Yes.	10:07:28
17	MS. GREB:	So for clarity on the record,	10:07:35
18		Dr. Bantle, are you taking out a paper copy of	10:07:38
19		Exhibit 1300, your reply declaration?	10:07:40
20	THE WITNESS:	No. Right now I'm looking	10:07:45
21		at the first declaration, the original declaration.	10:07:46
22	MS. GREB:	And that's Exhibit 1003?	10:07:50

1	THE WITNESS: Yes.	10:07:54
2	Well, I'm not finding it in the original	10:08:52
3	declaration. I'm looking now in the reply	10:08:55
4	declaration to see if I can find it there.	10:08:57
5	BY MS. RAYMOND:	10:09:01
6	Q Thank you.	10:09:01
7	A I didn't find it there either. May	10:09:40
8	counsel direct me to where I would find it?	10:09:42
9	Q I was just asking whether you recalled	10:09:45
10	which Jusko report you'd reviewed. So you're not	10:09:49
11	finding it as listed in the materials considered,	10:09:53
12	but you do recall reviewing a report of Dr. Jusko's	10:09:55
13	on the '462 patent?	10:10:00
14	A Yes.	10:10:01
15	Q And do you recall whether that report was	10:10:02
16	for an IPR or whether it was for litigation in	10:10:07
17	another forum?	10:10:11
18	MS. GREB: I'm going to object to form.	10:10:14
19	Certainly any questions related to litigations in	10:10:18
20	another forum would not be appropriate in this	10:10:20
21	deposition.	10:10:25
22	MS. RAYMOND: There aren't speaking	10:10:25

1	objections. If you want to --	10:10:26
2	(Cross-talk.)	10:10:28
3	MS. GREB: I know.	10:10:28
4	You can answer the question yes or no.	10:10:30
5	A Could you ask it again?	10:10:33
6	Q Yes. Do you recall whether that report	10:10:36
7	that you reviewed of Dr. Jusko's was for an IPR or	10:10:40
8	whether it was for another -- a litigation in	10:10:44
9	another forum?	10:10:47
10	MS. GREB: Same objection.	10:10:49
11	A I believe it was for the IPR.	10:10:52
12	Q Do you recall reviewing any deposition	10:10:55
13	transcripts of Dr. Jusko?	10:10:59
14	MS. GREB: Object to form.	10:11:05
15	A No.	10:11:06
16	Q Do you recall, when reviewing Dr. Jusko's	10:11:09
17	report, reviewing Dr. Jusko's background?	10:11:18
18	MS. GREB: Object to form.	10:11:23
19	A I do recall reviewing a little bit about	10:11:29
20	his background, yes.	10:11:33
21	Q And do you have a view as to whether your	10:11:37
22	expertise is different from Dr. Jusko's?	10:11:40

1	MS. GREB: Object to form.	10:11:43
2	A Yes. We are different.	10:11:46
3	Q And how are you different?	10:11:48
4	A I'm an M.D., and I think he is a	10:11:51
5	pharmacist, has a Ph.D. degree in pharmacy, I	10:11:55
6	believe.	10:12:02
7	Q Do you recall the opinions in his report	10:12:02
8	being about different topics than you opined on or	10:12:05
9	the same topics?	10:12:09
10	MS. GREB: Object to form.	10:12:10
11	A I think some were similar or the same,	10:12:13
12	and others were quite different.	10:12:15
13	Q Do you know why you and Dr. Jusko	10:12:21
14	testified about some of the same topics in your	10:12:23
15	report?	10:12:27
16	MS. GREB: Object to form. Object to	10:12:28
17	foundation.	10:12:30
18	A Well, I think in some instances, the	10:12:32
19	topic was relevant to both of us, and we both have	10:12:34
20	knowledge about it. And in other instances --	10:12:37
21	MS. GREB: And I'm going to also caution	10:12:41
22	the witness not to reveal the contents of any	10:12:42

1 communications with attorneys. 10:12:46

2 To the extent you can answer the question 10:12:50

3 based on your personal knowledge and any reading of 10:12:52

4 Dr. Jusko's report outside of communications with 10:12:55

5 attorneys, that's fine. But if you're veering into 10:12:58

6 communications with attorneys, you should not answer 10:13:01

7 the question. 10:13:03

8 A And would you ask the question again? 10:13:07

9 Q Do you know why you and Dr. Jusko 10:13:10

10 testified about some of the same topics in your 10:13:12

11 reports? 10:13:15

12 MS. GREB: Same instruction, and same 10:13:17

13 objections. 10:13:19

14 A I think it was because in some areas, our 10:13:20

15 knowledge and experience overlap. 10:13:24

16 Q And do you know why there are multiple 10:13:33

17 expert reports on the same areas where the knowledge 10:13:39

18 and experience of the experts overlaps? 10:13:42

19 MS. GREB: So I'm going to instruct you 10:13:47

20 not to answer that question, Dr. Bantle. Any 10:13:48

21 communications with attorneys would be not 10:13:52

22 discoverable, and the question asks for 10:13:56

1 communications that would be work product protected 10:14:01

2 and not discoverable under the PTAB rules. 10:14:06

3 Q Are you going to follow your attorney's 10:14:12

4 instruction? 10:14:14

5 A Yes. 10:14:14

6 (Previously marked Exhibit 1300 presented 10:14:14

7 to the witness.) 10:14:14

8 BY MS. RAYMOND: 10:14:16

9 Q Could you please turn to paragraph 30 of 10:14:16

10 your report. And when I'm saying "your report," 10:14:19

11 paragraph 30 of your second report marked 10:14:27

12 Exhibit 1300. 10:14:31

13 A Got it. 10:14:40

14 Q And do you see the phrase "critical to 10:14:41

15 the operability of the claimed invention" in 10:14:47

16 paragraph 30? 10:14:50

17 A Yes. 10:14:54

18 Q Is it your understanding that the 10:14:55

19 operability of the claimed invention must itself be 10:14:57

20 claimed? 10:15:01

21 MS. GREB: Object to form, foundation. 10:15:03

22 A I don't understand the question. Could 10:15:08

1	you rephrase it?	10:15:10
2	Q What do you mean by "critical to the	10:15:12
3	operability of the claimed invention"?	10:15:15
4	MS. GREB: Object to form.	10:15:18
5	A This paragraph states that it must be	10:15:25
6	critical to the operability of the claimed	10:15:28
7	intervention [sic].	10:15:32
8	Q Yes. And what do you mean by that?	10:15:32
9	MS. GREB: Object to form.	10:15:35
10	A I think it means that the claimed	10:15:45
11	intervention [sic] must in some way be critical.	10:15:50
12	Q What do you mean by, it means that the	10:16:17
13	claimed intervention must in some way be critical?	10:16:20
14	MS. GREB: Object to form.	10:16:24
15	A Well, it must be more than what -- let me	10:16:26
16	state it in a different way.	10:16:36
17	It must create a difference relative to	10:16:37
18	the broader prior art.	10:16:44
19	Q It must create a difference in what	10:16:51
20	relative to the broader prior art?	10:16:53
21	MS. GREB: Object to form.	10:16:56
22	A Some feature of the intervention [sic].	10:17:01

1 Q Does that feature need to be claimed in 10:17:05
2 the patent at issue? 10:17:08

3 MS. GREB: Object to form, foundation. 10:17:11

4 A Well, that seems to be more a legal 10:17:14
5 question than a medical question. And so I don't 10:17:16
6 feel completely confident of how to answer the 10:17:19
7 question. 10:17:23

8 But yes, I think it must. 10:17:23

9 Q In forming your opinions, did you assume 10:17:29
10 that the feature needed to be claimed in the patent 10:17:31
11 at issue? 10:17:33

12 MS. GREB: Object to form. 10:17:36

13 A Yes. 10:17:38

14 Q Could you please turn to paragraph 56 of 10:17:51
15 your report marked Exhibit 1300. 10:17:54

16 A Yes, I've got it. 10:18:05

17 Q And there you refer to the Board's claim 10:18:06
18 construction, and you say, the once-weekly 10:18:16
19 1.0 milligram dose of semaglutide achieve a 10:18:20
20 particular level of efficacy. 10:18:22

21 Do you see that language at the end of 10:18:24
22 paragraph 56? 10:18:25

1	A	I see that it states there's no	10:18:31
2		requirement that the 1 milligram dose of semaglutide	10:18:34
3		achieve a particular level of efficacy.	10:18:41
4	Q	And is it your position that no efficacy	10:18:43
5		at all is required by the '462 claims under this	10:18:46
6		construction?	10:18:50
7		MS. GREB: Object to form.	10:18:51
8	A	Well, I'm of the opinion that no	10:18:58
9		particular level of efficacy is necessary.	10:19:00
10	Q	And is it your position that no efficacy	10:19:03
11		at all is required by the '462 claims under this	10:19:05
12		construction?	10:19:10
13		MS. GREB: Object to form.	10:19:12
14	A	I think, looking at that language	10:19:23
15		literally, yes, there would be no level of efficacy	10:19:25
16		required.	10:19:29
17	Q	And do the claims require an expectation	10:19:32
18		that type 2 diabetes is treated by giving the	10:19:35
19		patient semaglutide at 1 milligram once weekly?	10:19:39
20		MS. GREB: Object to form, foundation.	10:19:44
21	A	Yes.	10:19:49
22	Q	Would claim 1 of the '462 patent be met,	10:20:12

1	in your opinion, if the 1 milligram once-weekly	10:20:17
2	semaglutide actually made diabetes worse in a	10:20:21
3	patient?	10:20:25
4	MS. GREB: Object to form, foundation.	10:20:26
5	A I need to look at claim 1 before I answer	10:20:29
6	that question. So shall I search for it?	10:20:31
7	(Previously marked Exhibit 1001 presented	10:20:31
8	to the witness.)	10:20:38
9	Q Sure. Claim 1 is Exhibit 1001, if you'd	10:20:38
10	like to look at it.	10:20:42
11	A So I now have the patent, and I now have	10:21:05
12	to go back and find the claims, which I believe are	10:21:08
13	at the end.	10:21:11
14	Here it is. Column 35. A method for	10:21:13
15	treating type 2 diabetes, comprising administering	10:21:19
16	semaglutide once weekly in the amount of	10:21:24
17	1.0 milligram to a subject in need thereof.	10:21:26
18	So your question is, again -- can you	10:21:30
19	restate it?	10:21:33
20	Q Sure. Would claim 1 of the '462 patent	10:21:34
21	be met, in your opinion, if the 1 milligram	10:21:38
22	once-weekly semaglutide actually made diabetes worse	10:21:41

1	in patients?	10:21:44
2	MS. GREB: Object to form.	10:21:46
3	A Well, I'm not sure how to answer that	10:21:55
4	question. I guess the key word there is "treating."	10:21:58
5	And if a treatment makes a condition worse, is it	10:22:02
6	still a treatment.	10:22:06
7	I would say yes, it is; it's just not a	10:22:08
8	good treatment.	10:22:11
9	Q So that would -- in your opinion, if the	10:22:13
10	semaglutide made the diabetes worse, that would	10:22:18
11	still meet claim 1 of the '462 patent?	10:22:20
12	MS. GREB: Object to form.	10:22:24
13	A Yes. No level of efficacy is required,	10:22:34
14	and so a negative effect, I guess, would still meet	10:22:38
15	that claim.	10:22:43
16	And I guess, as I think about this, I	10:22:56
17	might add, I'm aware of treatments for a variety of	10:22:58
18	conditions that do make the condition worse, not	10:23:01
19	better. So that is in the realm of possibility, I	10:23:03
20	would say.	10:23:08
21	Q Could you please turn to paragraph 66 of	10:23:10
22	your report.	10:23:14

1	A	Of the reply report or the opening	10:23:20
2		report?	10:23:23

3	Q Sorry. Of the reply report,	10:23:23
4	Exhibit 1300.	10:23:27

5	For the purpose of today, if I just refer	10:23:27
6	to one of your reports as your report, can we just	10:23:29
7	understand that that's the reply report,	10:23:32
8	Exhibit 1300?	10:23:33

9	A	Yes. And I'm sorry, which paragraph?	10:23:36
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10	Q	Sure. If you could turn to paragraph 66,	10:23:38
11		please.	10:23:41

12	A	Yes, I have it.	10:23:47
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13	Q And my question is, are you aware of any	10:23:48
14	disclosures in the prior art of dosing a GLP-1	10:24:09
15	analog in anything other than tenths of a milligram	10:24:13
16	doses?	10:24:17

17	MS. GREB: Object to form.	10:24:20
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18	A Yes.	10:24:21
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19	Q	What disclosures are those?	10:24:25
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20	MS. GREB: Object to form.	10:24:30
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21	A The only example of which I know is	10:24:32
22	dulaqlutide, which was dosed in increments as small	10:24:37

1	as 0.	10:24:44
2	Q Would you please turn to paragraph 109 of	10:24:45
3	your report.	10:24:47
4	(Reporter interruption.)	10:25:03
5	A I'm sorry. Which paragraph?	10:25:10
6	Q Sorry. And so your last answer was about	10:25:11
7	dulaglutide?	10:25:15
8	A Dulaglutide, d-u-l.	10:25:17
9	Q Thank you.	10:25:23
10	If we could turn to paragraph 109 of your	10:25:23
11	report, Exhibit 1300.	10:25:28
12	A Yes, I have it.	10:25:43
13	Q And it's your opinion that when --	10:25:47
14	despite seeing that the phase 3 semaglutide studies	10:25:52
15	were postponed, that a POSITA nevertheless would	10:26:00
16	have thought that the results from that study were	10:26:05
17	good?	10:26:09
18	MS. GREB: Object to form.	10:26:11
19	A Well, before I answer the question, I	10:26:14
20	think I must read paragraph 109, which is actually	10:26:16
21	quite long. So it will take a moment.	10:26:19
22	I've read it now. Would you repeat the	10:27:13

1 question since it's been a moment since you 10:27:16

2 initially stated it? 10:27:18

3 Q Sure. Is it your opinion that despite 10:27:19

4 the semaglutide phase 3 studies being on hold, a 10:27:21

5 POSA nevertheless would have thought that the 10:27:25

6 results from the semaglutide studies were good? 10:27:27

7 MS. GREB: Object to form. 10:27:32

8 A Yes. 10:27:34

9 Q Okay. And -- 10:27:35

10 A If I may qualify my answer. 10:27:37

11 A POSA may have initially been disturbed 10:27:40

12 by the word "postponed." But as a POSA looked more 10:27:44

13 into the situation, a POSA would have discovered 10:27:50

14 three things, all of which would have been 10:27:53

15 encouraging. 10:27:56

16 First of all, a POSA would have seen the 10:27:57

17 2009 Novo Nordisk Securities and Exchange Commission 10:28:02

18 filing of a Form 6-K, which indicated that the 10:28:10

19 phase 2 trial of semaglutide had been successfully 10:28:16

20 completed with a favorable outcome, and semaglutide 10:28:20

21 showing efficacy and safety comparable to 10:28:24

22 liraglutide. 10:28:29

1 Secondly, a POSA would have been aware of 10:28:29
2 the 2010 Novo Nordisk annual report, which also 10:28:34
3 stated that the phase 2 trial of semaglutide had 10:28:39
4 been completed successfully, and that Novo Nordisk 10:28:43
5 was awaiting data on long-acting liraglutide to 10:28:49
6 decide between to two and which to develop for its 10:28:55
7 long-acting portfolio. 10:28:59

8 And then thirdly, a 2012 call between 10:29:01
9 Novo Nordisk executives and various other people, 10:29:14
10 investors, I believe, stated that semaglutide had 10:29:18
11 successfully completed the phase 2 trial and was 10:29:23
12 ready to enter phase 3 trial, but Novo Nordisk was 10:29:26
13 postponing a decision about when to start that trial 10:29:31
14 until it saw data about long-acting liraglutide and 10:29:34
15 wanted to decide between the two as to which it 10:29:41
16 should develop as a long-acting analog. 10:29:44

17 And I think the Novo Nordisk executives 10:29:47
18 summed up the position as a nice spot for Novo 10:29:52
19 Nordisk to be in. 10:29:54

20 So a POSA would not have been discouraged 10:29:58
21 even though the word "postponed" was used. 10:30:02

22 Q So how long was Novo going to wait or to 10:30:11

1 postpone the phase 3 semaglutide studies to see the 10:30:16
2 results for the long-acting liraglutide studies? 10:30:19

3 MS. GREB: Object to form, foundation. 10:30:28

4 A I don't know. But I think the call was 10:30:29
5 in early 2012, and maybe in February, I believe, and 10:30:31
6 the speaker for Novo Nordisk said they would be 10:30:35
7 waiting until summer. 10:30:39

8 So it was some months. 10:30:41

9 Q Okay. But in 2010, the annual report 10:30:43
10 referred to postponing the phase 3 trials pending a 10:30:47
11 long-acting portfolio development strategy decision, 10:30:52
12 right? 10:30:56

13 MS. GREB: Object to form, foundation. 10:30:57

14 A Yes. 10:31:02

15 Q And that long-acting portfolio 10:31:02
16 development strategy decision had to do with the 10:31:05
17 long-acting liraglutide results. 10:31:08

18 Is that correct? 10:31:11

19 MS. GREB: Object to form, foundation. 10:31:15

20 A Yes. There was no problem with 10:31:16
21 semaglutide. Actually, the data on semaglutide 10:31:18
22 looked very favorable. But they waited to make a 10:31:20

1 decision as to which of the molecules to develop 10:31:24
2 because they wanted to see data on long-acting 10:31:27
3 liraglutide. 10:31:30

4 And I think a POSA would have realized 10:31:31
5 that was fine because they had limited resources and 10:31:34
6 wanted to invest in the molecule that was the most 10:31:37
7 promising of the two. 10:31:40

8 Q So in your opinion, a POSA would have 10:31:42
9 assumed that Novo would have waited years to get the 10:31:45
10 liraglutide long-acting results, even though the 10:31:51
11 semaglutide results would have been assumed to be 10:31:55
12 very favorable by a POSA. 10:31:58

13 Is that correct? 10:32:00

14 MS. GREB: Object to form. 10:32:02

15 A Well, I can't speak to Novo Nordisk and 10:32:07
16 its intent. But it would appear so. 10:32:10

17 Q And what's your basis for the data 10:32:14
18 looking very favorable for semaglutide? 10:32:16

19 A Well, the first and perhaps most 10:32:25
20 important is the SEC 6-K filing from 2009 where they 10:32:27
21 reported that the results of the phase 2 trial of 10:32:33
22 semaglutide were very favorable. 10:32:37

1	Q	Is that the language from that SEC	10:32:43
2		report, "very favorable"?	10:32:45
3	MS. GREB:	Object to form, foundation.	10:32:47
4	A	I'd need to look at the report if you	10:32:51
5		want me to quote the language exactly. Would you	10:32:53
6		like me to do so?	10:32:56
7	Q	Yes, please.	10:32:57
8	MR. SCHINDLER:	Here's the 6-K.	10:32:57
9	THE WITNESS:	Thank you.	10:32:57
10	MS. GREB:	What exhibit number?	10:33:10
11	MR. SCHINDLER:	Exhibit 1282.	10:33:10
12	MS. GREB:	Okay. So Dr. Bantle --	10:33:10
13	MS. RAYMOND:	Excuse me. It's not proper	10:33:13
14		for you all to be giving him exhibit numbers. He	10:33:13
15		has his report in front of him, and he has the	10:33:15
16		exhibits. If you'd like to look at the 6-K report,	10:33:18
17		we can have a conversation. But it's not	10:33:20
18		appropriate for you all to be having on one end --	10:33:22
19	MS. GREB:	Oh. I think we thought that's	10:33:26
20		what you wanted him to do when you said, "Yes,	10:33:28
21		please."	10:33:30
22	MS. RAYMOND:	I think he asked about if	10:33:30

1	he could look at his 6-K report, and I said, yes, he	10:33:32
2	could look at his 6-K report.	10:33:35
3	MS. GREB: Yeah, I guess we thought the	10:33:37
4	6-K report was the SEC filing. But if you don't	10:33:39
5	want him to have it, we can move it away. I think	10:33:42
6	that was just a misunderstanding.	10:33:45
7	What do you want him to look at it?	10:33:47
8	MS. RAYMOND: He can look at it. It just	10:33:49
9	sounded like there were conversations going on on	10:33:51
10	your end, which aren't appropriate during a	10:33:52
11	deposition with your witness.	10:33:55
12	MS. GREB: No, we were just looking for	10:33:56
13	the 6-K report.	10:33:57
14	MS. RAYMOND: Okay.	10:33:58
15	MS. GREB: So what exhibit is in front of	10:33:58
16	you, Dr. Bantle?	10:34:00
17	THE WITNESS: 1282.	10:34:02
18	MS. GREB: Okay. And that's the 6-K	10:34:04
19	report?	10:34:06
20	THE WITNESS: Yes.	10:34:08
21	MS. GREB: Do we want to put it up on the	10:34:12
22	screen so everybody is looking at the same thing?	10:34:14

1 MS. RAYMOND: That's fine. We can do 10:34:15
2 that. 10:34:17

3 (Previously marked Exhibit 1282 presented 10:34:17
4 to the witness.) 10:34:17

5 THE WITNESS: So I think the relative 10:34:21
6 portion is on page 12, in the middle of that page. 10:34:23

7 BY MS. RAYMOND: 10:34:30

8 Q Okay. 10:34:30

9 A And it says, Novo Nordisk recently 10:34:31

10 finalized a phase 2 study investigating safety and 10:34:34

11 efficacy of five doses of semaglutide (NN9535), a 10:34:48

12 once-weekly human GLP-1 analogue, versus placebo and 10:34:58

13 open-label liraglutide add-on therapy in people with 10:35:04

14 type 2 diabetes. At study start, patients were 10:35:09

15 treated with metformin or controlled with diet and 10:35:17

16 exercise. 10:35:20

17 The 12-week multi-center, multi-national 10:35:21

18 double-blind, placebo-controlled, randomized 10:35:26

19 dose-finding trial, which included a little more 10:35:29

20 than 400 patients, demonstrated that clinical 10:35:31

21 efficacy and safety of semaglutide was broadly in 10:35:33

22 line with liraglutide. Semaglutide was well 10:35:37

1 tolerated and was not associated with an increase in 10:35:41
2 injection site reactions, antibody formation or 10:35:44
3 calcitonin levels. 10:35:50

4 After more detailed analysis of the 10:35:51
5 dose-response findings on efficacy and safety, Novo 10:35:54
6 Nordisk will discuss the future plans for 10:35:58
7 semaglutide development with regulatory authorities 10:36:01
8 before initiation of phase 3 development. 10:36:04

9 Q And that's -- 10:36:09

10 A That's the end of the paragraph. 10:36:11

11 Q Okay. And that's the basis for your 10:36:12
12 stating that the SEC report -- the SEC report 10:36:14
13 reported very favorable results for semaglutide, 10:36:18
14 correct? 10:36:22

15 MS. GREB: Object to form. 10:36:24

16 A Yes. That's my interpretation. It says 10:36:25
17 efficacy and safety were comparable to liraglutide, 10:36:27
18 and liraglutide was a very successful drug. 10:36:31

19 Q And does it say what doses of semaglutide 10:36:34
20 were comparable -- had comparable results to what 10:36:37
21 doses of liraglutide? 10:36:41

22 A No, it does not. But a POSA would have 10:36:46

1	known that the doses were from 0.1 milligrams to	10:36:49
2	1.6 milligrams.	10:36:55
3	Q And was liraglutide approved in 2009?	10:36:56
4	A No. It was approved in 2010.	10:37:02
5	Q In paragraph 109 of your report, in the	10:37:47
6	middle of page 49, if we can go back and pull that	10:37:51
7	up on the screen.	10:37:55
8	A Yes, I have it.	10:38:03
9	Q Do you see the reference to something	10:38:04
10	being equally consistent with Novo pausing to	10:38:11
11	consider alternative long-acting products in its	10:38:15
12	portfolio or to confirm it has plans and resources	10:38:17
13	in place to meet eventual demand for an anticipated	10:38:21
14	successful product?	10:38:26
15	Do you see that?	10:38:28
16	A Yes.	10:38:39
17	Q Would a POSITA have expected that Novo	10:38:40
18	was concerned about having resources in place to	10:38:44
19	meet demand for semaglutide?	10:38:46
20	MS. GREB: Object to form, foundation.	10:38:50
21	A Would you ask the question again, please.	10:39:06
22	Q Sure. Would a POSITA have expected that	10:39:08

1	Novo was concerned about having resources in place	10:39:14
2	to meet demand for semaglutide?	10:39:17
3	MS. GREB: Object to form, foundation.	10:39:20
4	A Yes.	10:39:28
5	Q And could that concern about having	10:39:30
6	resources in place to meet demand for semaglutide	10:39:33
7	impact the doses that were tested in the semaglutide	10:39:36
8	trials?	10:39:42
9	MS. GREB: Object to form, foundation.	10:39:45
10	A No, I don't think so.	10:39:50
11	Q So you wouldn't test lower doses because	10:39:57
12	you thought that there might be difficulty meeting	10:40:00
13	demand for a drug?	10:40:02
14	MS. GREB: Object to form, foundation.	10:40:07
15	A You're suggesting that demand would be	10:40:12
16	easier to meet if the lower doses were being	10:40:16
17	prescribed and it was not necessary to manufacture	10:40:20
18	as much semaglutide?	10:40:24
19	Q That's correct.	10:40:26
20	MS. GREB: Object to form, foundation.	10:40:33
21	A Well, I'm certainly no expert on	10:40:35
22	pharmaceutical production of products. But I don't	10:40:39

1	think that would have been a rate-limiting factor.	10:40:44
2	But again, that's beyond my area of expertise and	10:40:47
3	nothing that I spoke to in my report.	10:40:51
4	Q If you could turn to paragraph 111 of	10:40:58
5	your report.	10:41:01
6	A Yes, I have it.	10:41:07
7	Q And you refer to a quote that says,	10:41:08
8	clinical efficacy and safety of semaglutide was	10:41:14
9	broadly in line with liraglutide.	10:41:18
10	Do you see that?	10:41:22
11	A Yes.	10:41:29
12	Q For what dose of liraglutide was clinical	10:41:31
13	safety and efficacy broadly in line with	10:41:36
14	semaglutide?	10:41:40
15	MS. GREB: Object to form, foundation.	10:41:42
16	A That's not stated.	10:41:45
17	Q So you don't know.	10:41:48
18	Is that correct?	10:41:51
19	MS. GREB: Object to form.	10:41:51
20	A I do know, and a POSA would have, that	10:41:54
21	the usual doses of liraglutide were 1.2 milligrams,	10:41:57
22	and if diabetes control was not satisfactory with	10:42:03

1	that, 1.8 milligrams.	10:42:08
2	So I would and I think a POSA would have	10:42:10
3	known it was one of those two doses.	10:42:12
4	Q Do you discuss that in your report?	10:42:18
5	A Not that I recall.	10:42:26
6	Q And going back to that quote about	10:42:28
7	clinical efficacy and safety of semaglutide being	10:42:32
8	broadly in line with liraglutide, what dose of	10:42:35
9	semaglutide was broadly in line with what dose of	10:42:37
10	liraglutide?	10:42:41
11	MS. GREB: Object to form.	10:42:43
12	A Well, I think a POSA would have known	10:42:46
13	that the dose of semaglutide would be in the upper	10:42:49
14	half of the range of doses tested in NCT657, that	10:42:57
15	is, between 0.8 and 1.6 milligrams, because that's	10:43:05
16	the area of the dose range where semaglutide would	10:43:09
17	be expected to have efficacy that was consistent	10:43:14
18	with its intended purpose.	10:43:20
19	That would have perhaps been modified by	10:43:23
20	knowledge from the NCT773 trial, that the is	10:43:25
21	1.6 milligram dose of semaglutide was dropped.	10:43:34
22	Although reasons were not specified, a POSA would	10:43:37

1 have been concerned that that was because of side
2 effects or difficult of tolerability at the high
3 dose. And in 773, then 1.2 milligrams became the
4 highest dose used.

5 So I think a POSA would have expected the
6 range of optimal doses of semaglutide to be between
7 0.8 milligrams and 1.2 milligrams, and within that
8 range, 1.0 milligrams would have been obvious.

9 Q This statement that we're looking at, the
10 quote in paragraph 111 of your report, this is
11 before the NCT773 trial.

12 Is that correct?

13 MS. GREB: Object to form.

14 A I'm not sure. This statement, I think,
15 is from the SEC 6-K filing, which was in 2009. And
16 I would have to look at 773 to tell you with
17 certainty when it finished. But I think it was at
18 about the same time.

19 So I think it was before, but I'd have to
20 look to be sure. Do you want me to do so?

21 Q Well, what if -- what I'm trying to
22 understand is the basis of your saying that one

1 would have understood -- and maybe I'll just ask it
2 this way.

3 Exactly what dose of semaglutide was
4 broadly in line with liraglutide with respect to
5 efficacy and safety?

6 MS. GREB: Object to form.

7 A Well, I think I've already answered that
8 question. I think it was obvious the 1.0 milligram
9 dose would have been in line with the efficacy and
10 safety. That dose was obvious.

11 Q That's not my question. I'm talking
12 about this quote here, which says there was a
13 12-week multicenter, multinational trial that
14 demonstrated that clinical efficacy and safety of
15 semaglutide was broadly in line with liraglutide.

16 What dose of semaglutide would have
17 been -- was broadly in line with what dose of
18 liraglutide with respect to clinical efficacy and
19 safety?

20 MS. GREB: Object to form.

21 A It's not stated. But I think the doses
22 of liraglutide that were known to be efficacious

1 were the 1.2 and 1.8 milligrams. So I think a POSA
2 would have known that it was probably the
3 0.8 milligram dose of semaglutide or the
4 1.6 milligram dose of semaglutide.

5 Q But there's no way to actually know which
6 dose of semaglutide and which dose of liraglutide
7 were, quote -- that had efficacy and safety that
8 were broadly in line, correct?

9 MS. GREB: Object to form.

10 A Well, that's not stated. So I have to
11 agree, there's probably no way to know with
12 certainty.

13 But I think it would be -- I think a POSA
14 would have known it was probably doses of both
15 medications at the upper end of their dosing ranges.

16 Q Please turn to paragraph 122 of your
17 report.

18 A I have it.

19 Q You say at the end of that paragraph, If
20 a change in dosage was due to ethnicity, a POSA
21 would have expected that other dosages would also
22 have been modified.

1	Do you see that?	10:47:49
2	A Yes.	10:47:55
3	Q How would other doses have been modified?	10:47:56
4	MS. GREB: Object to form.	10:48:03
5	A Other doses might have been reduced in a	10:48:09
6	way proportional to the reduction of the highest	10:48:13
7	dose from 1.6 to 1.2 milligrams.	10:48:16
8	Q So what doses, then, would have been	10:48:21
9	tested, in your view?	10:48:24
10	A The dosage range might have been modified	10:48:31
11	to something like 0.1, 0.2, 0.4, 0.8, and 1.2, which	10:48:49
12	I guess is the dosage ranges that were used.	10:48:59
13	So I'll restate my answer to say maybe	10:49:04
14	0.1, 0.2, 0.3, 0.6, and 1.2.	10:49:08
15	But I also would like to add that there's	10:49:15
16	no reason to conclude that ethnicity influenced that	10:49:17
17	decision, as 773 was a trial that involved Japanese	10:49:24
18	subjects, but it also involved Caucasian subjects.	10:49:29
19	It was conducted in Great Britain, and it's not	10:49:32
20	clear how many of each type were included in the	10:49:36
21	snide. So --	10:49:40
22	Q This is now beyond my question, which was	10:49:41

1 just about how the doses would have been modified. 10:49:43

2 You've answered my question. Thank you. 10:49:45

3 MS. GREB: Counsel, if Dr. Bantle feels 10:49:46

4 he needs to add to his answer, he should be allowed 10:49:49

5 to provide his full answer. 10:49:51

6 MS. RAYMOND: If you want to ask him 10:49:53

7 questions on redirect within the scope, you can do 10:49:55

8 so. 10:49:58

9 MS. GREB: It's not appropriate to cut a 10:49:58

10 witness off from answering a question. 10:50:00

11 A And what I wished to say before I was cut 10:50:05

12 off is that it's not clear that ethnicity had 10:50:09

13 anything to do with the decision. 10:50:11

14 And I would also say that the patent 10:50:12

15 makes no mention of it, this ethnicity, at any point 10:50:15

16 in the patent. 10:50:18

17 Q That's fine. That has nothing to do with 10:50:19

18 my question about how the doses would have been 10:50:21

19 modified. Thank you. 10:50:23

20 Moving on, do you cite any reference 10:50:28

21 saying dose finding studies use the lower and upper 10:50:32

22 bounds of a dose-response curve? 10:50:36

1	MS. GREB: Object to form.	10:50:42
2	A Yes.	10:50:42
3	Q Okay. What studies are those that say	10:50:43
4	dose finding -- excuse me.	10:50:51
5	What references are those that say dose	10:50:53
6	finding studies use the lower and upper bounds of a	10:50:55
7	dose-response curve?	10:50:58
8	A I'm sorry. Maybe I misunderstood your	10:51:02
9	previous question. I thought you were asking if any	10:51:04
10	of the arts here had used lower doses in the range	10:51:08
11	of doses tested. That wasn't your question?	10:51:15
12	Q No. My question --	10:51:17
13	(Cross-talk.)	10:51:19
14	Q Sorry. Go ahead.	10:51:19
15	A That's it.	10:51:22
16	Q My question was, do you cite any	10:51:23
17	reference saying dose finding studies use the lower	10:51:25
18	and upper bounds of a dose-response curve for the	10:51:29
19	dosing?	10:51:32
20	A I don't recall.	10:51:39
21	Q Could you turn to paragraph 151 of your	10:51:41
22	report, please.	10:51:44

1	A	Yes.	10:51:51
2	Q	And there, you say, a POSA would have	10:51:54
3		expected that dosing albiglutide once monthly at the	10:52:01
4		recited doses would have been expected to cause	10:52:07
5		problems.	10:52:11
6		Do you see that towards the end of	10:52:12
7		paragraph 151?	10:52:14
8	A	Yes.	10:52:18
9	Q	And you would agree that the albiglutide	10:52:20
10		was tested once monthly despite there being an	10:52:23
11		expectation that it would cause problems?	10:52:27
12	A	Well, it was tested once monthly. I	10:52:33
13		don't contend that the people conducting the trial	10:52:38
14		thought it would cause problems because I don't	10:52:40
15		think they would have done it had they done so.	10:52:42
16		But to look at this trial and see that	10:52:45
17		they were giving a large dose of albiglutide once a	10:52:49
18		month when it had a half-life of five days would, to	10:52:52
19		me, be a very unwise plan because the dose given	10:52:57
20		would have to be very high. The drug would go	10:53:03
21		through six half-lives in a month.	10:53:07
22		So to keep the drug level in the	10:53:10

1	therapeutic range, one would have to start with a	10:53:12
2	very high dose, and that very high dose would be	10:53:14
3	very likely to produce side effects.	10:53:17
4	Q And you said, that very high dose would	10:53:41
5	be very likely to produce side effects.	10:53:44
6	In choosing doses for a trial, does one	10:53:48
7	avoid choosing doses that would be very likely to	10:53:53
8	produce side effects?	10:53:56
9	MS. GREB: Object to form, foundation.	10:53:59
10	A Yes.	10:54:04
11	Q Could you please turn to paragraph 186 to	10:54:07
12	189 of your report.	10:54:10
13	A I've got it.	10:54:17
14	Q And in paragraphs 186 to 189, you discuss	10:54:18
15	a variety of GLP-1 analogs, correct?	10:54:29
16	A I'll have to read the paragraphs.	10:54:33
17	Q Sure. Let me know when you've finished	10:54:36
18	that.	10:54:38
19	A I'm finished, but I'm afraid I'll have to	10:56:00
20	ask you to restate the question. I've not got it	10:56:04
21	clear in my mind.	10:56:06
22	Q Not a problem at all.	10:56:07

1 In paragraphs 186 to 189 of your report, 10:56:08
2 you discuss a variety of GLP-1 analogs, correct? 10:56:10

3 A GLP-1 analogs and extended analogs. So 10:56:15
4 both are discussed. 10:56:21

5 Q Okay. And with respect to the GLP-1 10:56:21
6 analogs, those are each modified from the native 10:56:24
7 GLP-1 structure, correct? 10:56:28

8 MS. GREB: Object to form, foundation. 10:56:32

9 A That is my understanding. 10:56:34

10 Q And those modifications made from the 10:56:36
11 native GLP-1 structure to the GLP-1 analogs 10:56:39
12 discussed in those paragraphs of your report, do 10:56:44
13 those modifications impact the potency of the GLP-1 10:56:46
14 analog? 10:56:51

15 MS. GREB: Object to form, foundation. 10:56:53

16 A Not necessarily. My understanding is, 10:56:57
17 the modifications were intended primarily to 10:57:00
18 increase the duration of action so that they would 10:57:03
19 last longer in the circulation. 10:57:06

20 Now, that would increase potency compared 10:57:10
21 to giving native GLP-1 unless you are able to give 10:57:13
22 native GLP-1 in a continuous way, keep it in the 10:57:17

1	circulation.	10:57:20
2	Q So you said, not necessarily, but they	10:57:36
3	would last longer in circulation which would	10:57:40
4	increase potency.	10:57:45
5	So if I could just ask you again, for	10:57:46
6	clarity of the record.	10:57:49
7	Are the modifications made in GLP-1	10:57:50
8	analogs ones that impact the potency of the analog?	10:57:55
9	MS. GREB: Object to form.	10:58:02
10	A No. Native GLP-1 and the analogs would	10:58:04
11	have the same potency. The problem is that native	10:58:08
12	GLP-1 has a half-life of three or four minutes, and	10:58:12
13	so its effect quickly disappears. The analogs were	10:58:16
14	designed to maintain a circulating concentration and	10:58:19
15	keep the effect active for hours and days.	10:58:24
16	Q Do the modifications made to GLP-1	10:58:26
17	analogs impact dosing?	10:58:30
18	MS. GREB: Object to form, foundation.	10:58:33
19	A Yes, I think so.	10:58:37
20	Q And I think you've said this already, but	10:58:39
21	the modifications made to GLP-1 analogs impact	10:58:41
22	half-life.	10:58:45

1	Is that correct?	10:58:46
2	MS. GREB: Object to form.	10:58:49
3	A Yes. I think that was the intent of the	10:58:49
4	modifications, to prolong half-life.	10:58:52
5	Q And different modifications in different	10:58:57
6	GLP analogs have different half-lives.	10:59:02
7	Is that correct?	10:59:07
8	MS. GREB: Object to form.	10:59:08
9	A Yes, I think so.	10:59:08
10	Q If you could please turn to paragraph 209	10:59:09
11	of your report.	10:59:13
12	A Got it.	10:59:20
13	Q And this is, as I understand it, the	10:59:21
14	section of your report discussing criticality. It's	10:59:28
15	under the header, The 1.0 milligram dose is not	10:59:32
16	critical. Just to make sure we're all in the same	10:59:36
17	place.	10:59:41
18	MS. GREB: Object to form.	10:59:42
19	A I think that's correct.	10:59:43
20	Q Okay. Is it your understanding that the	10:59:44
21	claimed 1 milligram dose has to be critical over all	10:59:52
22	other doses in the disclosed prior art range to meet	10:59:57

1	the test for criticality?	11:00:00
2	MS. GREB: Object to form, foundation.	11:00:02
3	A I have to think about that for a moment.	11:00:08
4	And it would help if you restated it.	11:00:10
5	Q Sure. I'll restate it. If you need me	11:00:14
6	to state it in other words, just let me know.	11:00:18
7	Is it your understanding that the claimed	11:00:20
8	1 milligram dose has to be critical over all other	11:00:22
9	doses in the disclosed prior art range to meet the	11:00:26
10	test for criticality?	11:00:29
11	MS. GREB: Object to form, foundation.	11:00:32
12	A Please define again for me the meaning of	11:00:36
13	"criticality."	11:00:40
14	Q Well, what's your understanding of	11:00:40
15	"criticality" as you used it to perform your	11:00:42
16	analysis and determine that the 1 milligram dose is	11:00:45
17	not critical?	11:00:48
18	MS. GREB: Object to form.	11:00:49
19	A My understanding is that for the dose to	11:00:54
20	be critical, must have greater efficacy or	11:00:58
21	tolerability than other doses.	11:01:02
22	Q Than other doses in the prior art range?	11:01:07

1	MS. GREB: Object to form.	11:01:12
2	A Yes.	11:01:13
3	Q Would you please go to paragraph 210 of	11:01:46
4	your report.	11:01:49
5	A I have it. It's on the same page.	11:01:51
6	Q Okay. And do you see, you use the	11:01:54
7	language "tied to the claimed invention" in that	11:01:57
8	paragraph?	11:02:00
9	A Yes.	11:02:02
10	Q What do you mean by "tied to the claimed	11:02:04
11	invention"?	11:02:07
12	MS. GREB: Object to form.	11:02:09
13	A I think what it means is, the invention,	11:02:13
14	according to the patent, is 1.0 milligrams of	11:02:16
15	semaglutide. So criticality must be tied to that	11:02:20
16	dose of semaglutide.	11:02:24
17	Q In your opinion, is HbA1c reduction tied	11:02:33
18	to the claimed invention?	11:02:39
19	MS. GREB: Object to form.	11:02:42
20	A No. The claims construction says that no	11:02:45
21	level of efficacy is necessary for the invention.	11:02:50
22	And so A1c -- or reduction in A1c would be a measure	11:02:58

1 of efficacy, which is not necessary to demonstrate.

11:03:04

2 Q Could you please turn to paragraph --

11:03:23

3 Actually, before we do this, are you
4 doing well? Would you like a break, or would you
5 like to keep going for a little bit?

11:03:26

11:03:28

11:03:31

6 MS. GREB: I think we've been going about
7 an hour.

11:03:33

11:03:34

8 A I'm fine.

11:03:35

9 Q Okay. Well, we'll go for maybe a few
10 minutes longer, and we can take a break shortly.

11:03:39

11:03:42

11 Actually, going back to your previous
12 question, I had asked if, in your opinion, is HbA1c
13 reduction tied to the claimed invention.

11:03:45

11:03:52

11:03:56

14 Let me ask you a follow-up to that, which
15 is, in your opinion, is weight loss tied to the
16 claimed invention?

11:03:59

11:04:01

11:04:04

17 MS. GREB: Object to form, foundation.

11:04:06

18 A No.

11:04:07

19 Q If you could please turn to paragraph 265
20 now of your report, if you haven't already.

11:04:12

11:04:15

21 A I have it.

11:04:26

22 Q At the very end of paragraph 265, you

11:04:27

1	have a statement using the language, would have	11:04:34
2	motivated a POSA to optimize the dose within that	11:04:38
3	range to a value that would have been 1 milligram.	11:04:42
4	Do you see that?	11:04:47
5	A Yes.	11:04:48
6	Q What do you mean by "to optimize the dose	11:04:49
7	within that range to a value that would have been	11:04:52
8	1 milligram"?	11:04:55
9	MS. GREB: Object to form.	11:04:58
10	A Before I answer, I'd like to read the	11:05:00
11	paragraph.	11:05:03
12	Q Certainly. Just let me know when you're	11:05:04
13	done.	11:05:05
14	A What I think I mean in that paragraph is	11:05:24
15	that a POSA would have known that the range of doses	11:05:25
16	to be used for semaglutide were from 0.1 to	11:05:30
17	1.6 milligrams.	11:05:36
18	A POSA would have known that doses in the	11:05:38
19	lower part of that range were not likely to have the	11:05:40
20	desired effects, and so doses in the higher part of	11:05:47
21	that range would have been preferred. That would be	11:05:51
22	doses from 0.8 to 1.6 milligrams.	11:05:55

1 A POSA would also have known that in 11:05:57
2 NCT773, the 1.6 milligram dose had been dropped, 11:06:00
3 raising concerns about tolerability of that dose. 11:06:04

4 So that would mean a POSA would have 11:06:08
5 honed in on a range of 0.8 to 1.2 milligrams, and 11:06:10
6 within that range, 1.0 milligrams of semaglutide was 11:06:15
7 obvious. 11:06:19

8 Q Okay. So when you say, to optimize the 11:06:21
9 dose within that range to a value that would have 11:06:25
10 been 1 milligram, what do you mean by, would have 11:06:28
11 been -- what do you mean by, to a value that would 11:06:33
12 have been 1 milligram? 11:06:36

13 MS. GREB: Object to form. 11:06:38

14 A I think there are multiple doses that 11:06:45
15 would have been obvious, 0.8, for instance, and 1.2 11:06:47
16 as well as 1.0. All of those doses would have been 11:06:51
17 obvious. 11:06:54

18 Q Would all of those doses have been 11:06:54
19 optimized? 11:06:57

20 MS. GREB: Object to form. 11:06:58

21 A I don't have an opinion about what dose 11:07:05
22 is optimal. I simply have an opinion about what 11:07:08

1	dose is obvious. And clearly, the 1.0 milligram	11:07:11
2	dose was obvious.	11:07:14
3	MS. GREB: Is this an okay time for a	11:07:26
4	break?	11:07:28
5	MS. RAYMOND: Sure. We can take a break	11:07:29
6	now.	11:07:30
7	(Recess from 11:07 a.m. until 11:21 a.m.)	11:09:14
8	BY MS. RAYMOND:	11:21:28
9	Q Dr. Bantle, going back to your report,	11:21:30
10	and if we could turn to paragraph 280.	11:21:35
11	A Got it.	11:21:51
12	Q And my question -- I'm trying to find the	11:21:52
13	exact quote for you. Just one second.	11:22:16
14	In that paragraph 280, there's a sentence	11:22:39
15	spanning page 128 to 129 that says, First, a POSA	11:22:44
16	would have known there would be an optimal dose,	11:22:48
17	understood in the context of the claims, based on	11:22:51
18	the extended history of the use of GLP-1 receptor	11:22:54
19	agonists to treat diabetes, and the field's	11:22:59
20	experience with liraglutide, and then it goes on.	11:23:04
21	Do you see that?	11:23:07
22	A Yes.	11:23:08

1 Q Did every known GLP-1 receptor agonist at 11:23:09
2 the time have a dose that treats diabetes? 11:23:19

3 MS. GREB: Object to form, foundation. 11:23:24

4 A I don't understand the question. Could 11:23:30
5 you restate it? 11:23:31

6 Q Sure. You mention the extended history 11:23:32
7 of the use of GLP-1 receptor agonists to treat 11:23:39
8 diabetes. And you say that a POSA would have known 11:23:43
9 there would be an optimal dose of semaglutide 11:23:47
10 because of that. 11:23:49

11 And what I'm trying to understand is 11:23:50
12 whether it's your opinion that every GLP-1 receptor 11:23:52
13 agonist known at the time had a dose that treated 11:23:56
14 diabetes? 11:24:00

15 MS. GREB: Object to form, foundation. 11:24:02

16 A Yes. I think each GLP-1 analog would 11:24:08
17 have had a dose that treated diabetes. Not all of 11:24:12
18 them were approved, and some didn't make it to the 11:24:18
19 approval state. But in development, they would have 11:24:22
20 had a dose that treated diabetes. 11:24:25

21 Q And which GLP-1 receptor agonists were 11:24:32
22 known to treat diabetes as of the priority date of 11:24:38

1	the '462 patent?	11:24:41
2	MS. GREB: Object to form, foundation.	11:24:44
3	A I'm sorry. Did you say GLP-1 analogs or	11:24:48
4	GLP-1 receptor agonists?	11:24:54
5	Q GLP-1 receptor agonists.	11:24:56
6	MS. GREB: Object to form, foundation.	11:25:00
7	A Well, as of the priority date, exenatide	11:25:04
8	and liraglutide had been approved and were in	11:25:13
9	clinical use. That is, if we assume the July 1,	11:25:15
10	2012 priority date.	11:25:22
11	Q And were there any other GLP-1 receptor	11:25:24
12	agonists that were known at the time to treat	11:25:26
13	diabetes?	11:25:29
14	A Yes.	11:25:31
15	MS. GREB: Object to form, foundation.	11:25:32
16	A Yes. There were receptor agonists that	11:25:34
17	were in development that were known to treat	11:25:38
18	diabetes. They just weren't available yet.	11:25:40
19	Q And how long had the known GLP-1 receptor	11:25:42
20	agonists --	11:25:46
21	A I'm sorry. I didn't understand the	11:25:51
22	question.	11:25:52

1	Q	Sorry. I stopped in the middle of it.	11:25:53
2		How long had the GLP-1 receptor agonists	11:25:55
3		known at the time actually been known?	11:25:59
4		MS. GREB: Object to form, foundation.	11:26:03
5	A	That's a question I can't answer. I can	11:26:06
6		tell you that the first exenatide, Byetta, was	11:26:09
7		approved in 2005. But the art goes back way beyond	11:26:13
8		that as these drugs were in development.	11:26:18
9	Q	When you say in paragraph 280, based on	11:26:20
10		the extended history of the use of GLP-1 receptor	11:26:25
11		agonists to treat diabetes, what are you referring	11:26:31
12		to when you refer to the extended history of the use	11:26:33
13		of GLP-1 receptor agonists?	11:26:36
14	A	I'm sorry. Where is that in the	11:26:43
15		paragraph? I guess I better read the whole	11:26:44
16		paragraph.	11:26:47
17	Q	It's towards the top of page 129.	11:26:52
18	A	And I'm sorry. Repeat the question,	11:27:08
19		please.	11:27:09
20	Q	You refer to the extended history of the	11:27:09
21		use of GLP-1 receptor agonists to treat diabetes.	11:27:17
22		And what I'd like to know is what you are referring	11:27:23

1 to when you refer to the extended history of the use 11:27:25

2 of GLP-1 receptor agonists to treat diabetes. 11:27:28

3 A I'd be referring to the experience with 11:27:35

4 exenatide or Byetta, and liraglutide or Victoza. 11:27:39

5 Exenatide available since 2005 was used extensively. 11:27:46

6 I had so many conversations with patients 11:27:51

7 about its merits, and my efforts to convince 11:27:54

8 patients to take it were regular experiences for me. 11:28:00

9 Q And before, I asked you whether it's your 11:28:14

10 opinion that every GLP-1 receptor agonist known at 11:28:20

11 the time had a dose that treated diabetes, and you 11:28:24

12 said that you thought each GLP-1 analog would have 11:28:26

13 had a dose that treated diabetes. 11:28:30

14 Is it your opinion that each GLP-1 11:28:32

15 receptor agonist known at the time would have had a 11:28:37

16 dose that treated diabetes? 11:28:41

17 MS. GREB: Object to form. 11:28:43

18 A Yes. 11:28:45

19 Q If you can go to paragraph 269 of your 11:29:15

20 report? 11:29:42

21 A I'm sorry. 269? 11:29:45

22 Q Yeah. Sorry. We're going a little bit 11:29:46

1	backwards.	11:29:49
2	A Got it.	11:29:52
3	Q You say, a POSA -- at the end of that	11:29:53
4	paragraph, a POSA would have been motivated to	11:29:55
5	optimize within the finite prior art dosage range to	11:29:58
6	identify an optimal dose.	11:30:03
7	Do you see that?	11:30:05
8	A Yes.	11:30:14
9	Q Is it your opinion that a POSA would not	11:30:16
10	have been motivated to optimize outside of that	11:30:19
11	prior art dosage range to identify an optimal dose?	11:30:26
12	MS. GREB: Object to form.	11:30:31
13	A I have to read the paragraph. So give me	11:30:33
14	a moment, please.	11:30:34
15	I'm done. And I guess I'll ask you to	11:31:10
16	restate the question for me.	11:31:12
17	Q Is it your opinion that a POSA would not	11:31:14
18	have been motivated to optimize outside of that	11:31:19
19	prior art dosage range to identify an optimal dose?	11:31:23
20	MS. GREB: Object to form.	11:31:26
21	A I'm sorry. I couldn't hear the first	11:31:27
22	part.	11:31:28

1	Q	Sorry. Is it your opinion that a POSA	11:31:29
2		would not have been motivated to optimize outside of	11:31:32
3		that prior art dosage range to identify an optimal	11:31:36
4		dose?	11:31:40
5		MS. GREB: Object to form.	11:31:41
6	A	Yes. I think a POSA would not have gone	11:31:44
7		outside that range to identify a dose.	11:31:48
8	Q	Turning to paragraph 281 of your report.	11:31:54
9	A	Got it.	11:32:05
10	Q	At the bottom of page 129 to the top of	11:32:06
11		130, you say, But I understand that a POSA's	11:32:09
12		motivation to optimize a dose in the prior art need	11:32:14
13		not be directed at a particular dose.	11:32:18
14		Do you see that?	11:32:21
15	A	Yes.	11:32:23
16	Q	What do you mean by that?	11:32:26
17	A	I've got to read the paragraph.	11:32:27
18		I think I mean that there may be more	11:32:31
19		than one dose that a POSA would be motivated to use.	11:32:55
20		More than one dose that would have been obvious.	11:33:07
21		In this instance, I think 0.8, 1.0, and	11:33:13
22		1.2 would all have been obvious doses of semaglutide	11:33:19

1	to use.	11:33:22
2	Q Turning to paragraph 285, please.	11:33:23
3	A Yes.	11:33:31
4	Q And here, you say, while clinical trials	11:33:31
5	may well be, and often are, expensive and time	11:33:41
6	consuming, they are routine.	11:33:46
7	Do you see that?	11:33:49
8	A Yes.	11:34:02
9	Q And is it your opinion that with no prior	11:34:03
10	art data on any dose, it is routine to identify an	11:34:11
11	optimal dose because one can run a full-scale	11:34:15
12	clinical trial?	11:34:20
13	MS. GREB: Object to form, foundation.	11:34:21
14	A No. There were doses defined in the	11:34:25
15	prior art by WO421, Lovshin, and NCT657. A POSA	11:34:28
16	would have known that the doses of semaglutide to	11:34:37
17	consider would be 0.1 to 1.6 milligrams.	11:34:40
18	Q And I apologize. I should have phrased	11:34:45
19	that better.	11:34:48
20	Is it your opinion that with no prior art	11:34:48
21	data on the results from any dose, it is routine to	11:34:51
22	identify an optimal dose because one can run a	11:34:55

1	full-scale clinical trial?	11:34:57
2	MS. GREB: Object to form, foundation.	11:34:59
3	A I didn't understand. Could you restate	11:35:03
4	it?	11:35:05
5	Q Is it your opinion that with no prior art	11:35:05
6	data on the results from using any particular dose,	11:35:14
7	it is routine to identify an optimal dose because	11:35:18
8	one can run a full-scale clinical trial?	11:35:21
9	MS. GREB: Object to form, foundation.	11:35:25
10	A Well, clinical trials may be expensive	11:35:32
11	and time consuming, but they are routine.	11:35:34
12	In this instance, however, though, I	11:35:38
13	think a POSA would have known that the optimal dose	11:35:41
14	was probably between 0.8 and 1.2 milligrams. And	11:35:46
15	within that range, 1.0 milligram would have been	11:35:52
16	obvious.	11:35:56
17	Q In your opinion, would any clinical trial	11:35:57
18	not be routine?	11:35:59
19	MS. GREB: Object to form, foundation.	11:36:03
20	A Well, the word "any" requires me to say	11:36:07
21	that, yes, there probably would be clinical trials	11:36:12
22	that are not routine. Most are routine. But I	11:36:15

1	guess one could dream up the possible clinical trial	11:36:18
2	that would be not routine.	11:36:20
3	Q But a standard phase 1, phase 2, or	11:36:29
4	phase 3 trial, in your opinion, those would be	11:36:33
5	routine?	11:36:35
6	MS. GREB: Object to form.	11:36:40
7	A Yes.	11:36:40
8	Q Would you please turn to paragraph 292 of	11:36:41
9	your report.	11:36:44
10	A I'm sorry. 292?	11:36:46
11	Q 292.	11:36:47
12	A Got it.	11:36:49
13	Q And if you could just read that	11:36:50
14	paragraph, to yourself is fine, and let me know when	11:37:01
15	you've read it.	11:37:07
16	A I've finished.	11:37:45
17	Q And you see at the end, you cite to a	11:37:46
18	table showing that liraglutide and semaglutide	11:38:04
19	shared amino acids known from earlier work to be	11:38:08
20	essential for binding.	11:38:12
21	Do you see that?	11:38:13
22	A Yes.	11:38:15

1	Q	In your opinion, would any GLP-1 analog	11:38:17
2		that shares these same amino acids be expected to	11:38:25
3		behave in the same way?	11:38:30
4		MS. GREB: Object to form, foundation.	11:38:32
5	A	No.	11:38:35
6	Q	Could you please turn to paragraph 327.	11:38:42
7	A	Got it.	11:39:02
8	Q	And this again refers to the semaglutide	11:39:11
9		study being on hold.	11:39:13
10		Do you see that?	11:39:14
11	A	Yes.	11:39:15
12	Q	And it's still your opinion that	11:39:17
13		postponing a decision as to whether to pursue the	11:39:19
14		semaglutide phase 3 study is an indicator that was	11:39:23
15		positive?	11:39:27
16		MS. GREB: Object to form.	11:39:28
17	A	Say again, please.	11:39:30
18	Q	And it's still your opinion that	11:39:33
19		postponing a decision as to whether to pursue the	11:39:37
20		semaglutide phase 3 study is an indicator that was	11:39:40
21		positive?	11:39:43
22		MS. GREB: Object to form.	11:39:45

1 A Well, it was a business decision, and 11:39:48
2 that's the decision they made. 11:39:50

3 Q Going back just briefly to anticipation, 11:40:00
4 do you recall that I asked you if it's your 11:40:06
5 understanding that the claimed 1 milligram dose has 11:40:09
6 to be critical over all other doses in the disclosed 11:40:14
7 prior art range to meet the test for criticality? 11:40:17

8 MS. GREB: Object to form. 11:40:23

9 Q Do you recall my asking that question? 11:40:24

10 A Yes. 11:40:26

11 Q And you responded, Please define again 11:40:27
12 for me the meaning of "criticality." 11:40:30

13 And I asked, What's your understanding of 11:40:33
14 "criticality" as you used it to perform your 11:40:35
15 analysis and determine that the 1 milligram dose is 11:40:39
16 not critical? 11:40:42

17 Do you recall that? 11:40:43

18 A Yes. 11:40:45

19 Q And you responded, My understanding is 11:40:46
20 that the dose to be critical, must have greater 11:40:49
21 efficacy or tolerability than other doses. 11:40:52

22 Do you recall that? 11:40:56

1 MS. GREB: Object to form. 11:40:58

2 A Yes. 11:40:59

3 Q Okay. And my follow-up question to that 11:41:00

4 is, When you said that the dose has to be -- for the 11:41:06

5 dose to be critical, it must have greater efficacy 11:41:13

6 or tolerability than other doses, did you mean than 11:41:16

7 all the other doses in the prior art range? 11:41:19

8 MS. GREB: Object to form, foundation. 11:41:23

9 A Yes. 11:41:29

10 Q Dr. Bantle, how many hours have you spent 11:41:42

11 analyzing the validity of the '462 patent? 11:41:45

12 MS. GREB: Object to form. 11:41:49

13 And I would caution you, Dr. Bantle, not 11:41:50

14 to reveal the contents of any discussions with 11:41:53

15 attorneys. I don't think the question is seeking 11:42:00

16 that. I just want to make sure you heard correctly. 11:42:03

17 A As I understood the question, you were 11:42:07

18 asking how many hours from the beginning I've spent 11:42:09

19 analyzing the '462 patent. 11:42:11

20 Q The validity of the '462 patent, yes. 11:42:14

21 MS. GREB: Object to form. 11:42:18

22 A I can't say with any certainty, but I 11:42:22

1 would estimate in total, it's been 40 to 50 hours.

11:42:24

2 Q And all that work was for Mylan?

11:42:33

3 MS. GREB: Object to form.

11:42:36

4 And again, I would caution you,

11:42:38

5 Dr. Bantle, not to reveal the contents of any

11:42:40

6 communications with attorneys.

11:42:43

7 A I believe some other pharmaceutical

11:42:49

8 companies were involved.

11:42:52

9 Q Have you been paid by anyone but Mylan to

11:43:00

10 analyze the validity of the '462 patent?

11:43:02

11 MS. GREB: So I'm going to stop here,

11:43:05

12 Megan. I think maybe we should have Dr. Bantle

11:43:10

13 leave the room and have a discussion outside of his

11:43:13

14 presence.

11:43:16

15 I'm going to instruct the witness not to

11:43:19

16 answer questions related to any pending District

11:43:21

17 Court litigation, and I think your question is

11:43:25

18 seeking that.

11:43:27

19 THE WITNESS: Shall I leave the room?

11:43:31

20 MS. RAYMOND: Sure. Then we can discuss.

11:43:33

21 (The witness left the deposition room.)

11:43:38

22 MS. RAYMOND: And we can go off the

11:43:41

1 record.

11:43:42

2 MS. GREB: We can stay on the record.

11:43:42

3 MS. RAYMOND: Okay. That's fine.

11:43:44

4 MS. GREB: Certainly, soliciting
5 testimony outside the scope of Dr. Bantle's report
6 is inappropriate. The IPR, as you know, has
7 involved Mylan. I know there are joinders to it.
8 And I'm just not sure if you're seeking information
9 from the District Court or if you're seeking
10 information from the IPR.

11:43:49

11:43:51

11:43:57

11:44:03

11:44:07

11:44:10

11:44:13

11 If you're seeking IPR information, I
12 think you need to ask really -- ask really clear
13 questions because I'm going to instruct him not to
14 answer anything related to the District Court.

11:44:15

11:44:17

11:44:20

11:44:22

15 MS. RAYMOND: So, I mean, I'll ask him
16 questions. You can object based on scope. But we
17 have an open deposition going. So I don't think
18 that there's authority allowing you to object and
19 instruct him not to answer based on scope.

11:44:25

11:44:27

11:44:33

11:44:38

11:44:41

20 MS. GREB: Well, I'm certainly allowed to
21 contact the Board and make a motion to limit the
22 testimony. And if you're intending to seek

11:44:44

11:44:47

11:44:49

1 discovery into the District Court litigation, I 11:44:52

2 fully intend to move to limit the testimony. 11:44:55

3 MS. RAYMOND: I'm not. I'm trying to 11:44:59

4 understand. He said here that he was -- his 11:45:01

5 declaration says that he was retained by Mylan for 11:45:04

6 this. And I'm exploring that. 11:45:06

7 MS. GREB: Okay. I just want to be clear 11:45:09

8 that he is not answering questions about the 11:45:11

9 District Court. And I think given the situation -- 11:45:14

10 (Cross-talk.) 11:45:22

11 (Reporter interruption.) 11:45:23

12 MS. GREB: I want to be clear, he's not 11:45:26

13 answering questions about the District Court. And I 11:45:29

14 think, given the situation, you need to ask clear 11:45:31

15 questions. The front of his reply declaration has 11:45:34

16 the header, Mylan Pharmaceuticals and Dr. Reddy's 11:45:38

17 Labs on it. 11:45:42

18 And your questions are unclear about 11:45:43

19 whether you're trying to ask about the District 11:45:45

20 Court, which is out of bounds for this deposition, 11:45:47

21 or whether you're trying to ask about the IPR. 11:45:50

22 MS. RAYMOND: Well, I think I'm certainly 11:45:52

1 entitled to know how many hours he spent analyzing 11:45:54
2 the '462 patent, regardless of whether it's for this 11:45:57
3 proceeding or another one. So, I mean -- 11:45:59

4 MS. GREB: And I let him answer that 11:46:03
5 question. And then you started asking about who he 11:46:05
6 was retained on behalf of. 11:46:07

7 If you want to show him something and ask 11:46:10
8 him about the IPR, that's -- so I think we're clear 11:46:12
9 with each other. I'm just letting you know -- 11:46:16

10 MS. RAYMOND: Okay. 11:46:18

11 MS. GREB: -- that we're not going to be 11:46:19
12 answering questions about the District Court today. 11:46:20

13 MS. RAYMOND: Okay. 11:46:22

14 MS. GREB: Would you like him to come 11:46:24
15 back? 11:46:26

16 MS. RAYMOND: Yes, he can come back. 11:46:26

17 MS. GREB: Okay. 11:46:28

18 (The witness returned to the deposition 11:46:34
19 room.) 11:46:37

20 MS. GREB: We're ready to resume. 11:47:14

21 BY MS. RAYMOND: 11:47:18

22 Q Have you been retained by anyone but 11:47:51

1 Mylan to analyze the invalidity of the '462 patent,
2 just yes or no?

3 MS. GREB: No, I think that's not a yes
4 or no. Based on our discussion, I want to clarify
5 that the question is related to the IPR, if you
6 know.

7 MS. RAYMOND: My position is that I'm
8 entitled to know what invalidity work he's done for
9 the '462 patent in connection with this proceeding,
10 but it's not limited to this proceeding.

11 MS. GREB: Well, your question, in order
12 for him to answer it, needs to be limited to this
13 proceeding. If you're asking him who he was
14 retained by in other proceedings, I'm going to
15 instruct him not to answer the question.

16 So you need to ask a clear question.

17 MS. RAYMOND: So you're going to instruct
18 him to not answer any question about who he was
19 retained by to analyze the invalidity of the '462
20 patent outside of the '462 IPR?

21 MS. GREB: Correct.

22 MS. RAYMOND: Okay.

1	Q	Dr. Bantle, you said -- of the 40 or	11:48:53
2		50 hours you've spent analyzing the validity of the	11:48:57
3		'462 patent, could you tell me how many of those	11:49:02
4		hours were spent working on the '462 IPR?	11:49:10
5		MS. GREB: Object to form.	11:49:19
6	A	The majority, probably all but maybe five	11:49:24
7		hours.	11:49:31
8		MS. GREB: And this is -- Megan, this is	11:49:35
9		treading into information about the District Court.	11:49:39
10		So if you intend to continue this line of	11:49:41
11		questioning, I've made my position clear that	11:49:43
12		Dr. Bantle is going to be instructed not to answer	11:49:46
13		any questions related to the IPR.	11:49:48
14		And I am going to move to exclude the	11:49:52
15		answer that he just provided. I didn't get my	11:49:56
16		objection in in time.	11:49:59
17		And I think it's completely inappropriate	11:50:00
18		to use this as a fishing expedition into discovery	11:50:02
19		that you know you need relief from for the Board to	11:50:05
20		answer.	11:50:08
21		MS. RAYMOND: This isn't -- I think this	11:50:09
22		is fully within the scope. If you're instructing	11:50:13

1 him -- I'm going to ask questions. If you instruct 11:50:15
2 him not to answer, then we can decide whether to 11:50:17
3 call the Board or how to proceed. But I'm going to 11:50:20
4 get my questions out. You're entitled to object. 11:50:23
5 And then we can figure out how to proceed from 11:50:26
6 there. 11:50:28

7 I don't have very many more questions. 11:50:29

8 Q Dr. Bantle, did you separately track the 11:50:37
9 hours you spent working on the '462 IPR? 11:50:39

10 MS. GREB: Dr. Bantle, I would instruct 11:50:43
11 you not to answer that question for the reasons that 11:50:44
12 I've stated on the record. 11:50:47

13 It's outside the scope. And if this line 11:50:49
14 of questioning continues, I intend to call the Board 11:50:52
15 to terminate. And I intend to move to exclude any 11:50:55
16 questions that discuss anything related to the 11:50:59
17 District Court and expunge them from the record. 11:51:02

18 MS. RAYMOND: And Emily, I assume you'll 11:51:07
19 also not allow him to answer the questions, did he 11:51:09
20 bill for the IPR and litigation separately and 11:51:12
21 whether he was paid separately for the IPR and 11:51:14
22 litigation. 11:51:17

1	Is that correct?	11:51:18
2	MS. GREB: That's correct. Also instruct	11:51:19
3	not to answer.	11:51:20
4	MS. RAYMOND: Okay.	11:51:21
5	Q And Dr. Bantle, were you retained by	11:51:22
6	anyone but Mylan for the '462 IPR?	11:51:25
7	MS. GREB: Object to form.	11:51:29
8	A Mylan --	11:51:36
9	MS. GREB: And Dr. Bantle, I just want to	11:51:38
10	caution you, given the questions and what you've	11:51:40
11	heard, if you know the answer to that yes or no, you	11:51:44
12	can answer the question. But if it's going to	11:51:47
13	require you to make any comments about the District	11:51:49
14	Court litigation, you should not answer.	11:51:52
15	A Could you restate your question.	11:51:57
16	Q Were you retained by anyone other than	11:52:02
17	Mylan for the '462 IPR?	11:52:05
18	MS. GREB: Same objection and same	11:52:09
19	caution and instruction.	11:52:10
20	A Yes.	11:52:13
21	Q Who else were you retained by for the	11:52:15
22	'462 IPR?	11:52:18

1	MS. GREB: Object to form.	11:52:19
2	A Dr. Reddy's Laboratory and Dr. Reddy's	11:52:28
3	Laboratory LTD.	11:52:32
4	Q Were you retained by Sun Pharmaceuticals	11:52:37
5	for the '462 IPR?	11:52:40
6	MS. GREB: Object to form.	11:52:43
7	A Not to the best of my knowledge.	11:52:45
8	Q And when were you retained by Dr. Reddy's	11:52:52
9	Laboratories and the other Dr. Reddy's party for	11:52:56
10	this IPR?	11:52:59
11	MS. GREB: So object to form.	11:53:01
12	And I'm going to caution you not to	11:53:02
13	reveal the contents of any discussions with	11:53:03
14	attorneys. But you can provide the date.	11:53:06
15	A I wish I could, but I don't know.	11:53:12
16	Q Do you know whether it was since the last	11:53:16
17	time you were deposed by me in this IPR?	11:53:19
18	MS. GREB: Object to form.	11:53:25
19	A Yes, I think it was.	11:53:27
20	Q Do you think it was within the last three	11:53:30
21	months?	11:53:32
22	MS. GREB: Object to form.	11:53:37

1	A	I don't know. I paid little or no	11:53:38
2		attention to these sorts of issues.	11:53:43
3	Q	And so your report says, I have been	11:53:47
4		retained -- this is paragraph 1 -- by Mylan	11:53:51
5		Pharmaceuticals Inc. in the Inter Partes Review	11:53:55
6		identified in the caption above.	11:53:58
7		And so to complete that, we would need to	11:54:02
8		add the two Dr. Reddy's parties.	11:54:06
9		Is that correct?	11:54:09
10		MS. GREB: Object to form.	11:54:10
11	A	I think so. I'm not sure. But in my	11:54:13
12		reply report, Dr. Reddy's Laboratories is listed.	11:54:20
13	Q	Okay. And I was just looking at	11:54:27
14		paragraph 1, which says that you are retained by	11:54:30
15		Mylan. But you were retained by Mylan and the two	11:54:33
16		Dr. Reddy's parties, correct?	11:54:36
17		MS. GREB: Object to form.	11:54:39
18	A	Yes, I think so.	11:54:43
19	Q	And have you been retained by anyone else	11:54:45
20		for the '462 IPR beyond the two Dr. Reddy's parties	11:54:48
21		and Mylan?	11:54:52
22		MS. GREB: Object to form.	11:54:54

1	A	Not insofar as I am aware.	11:54:56
2	Q	Okay. Thank you.	11:54:58
3		MS. RAYMOND: Let's go off the record for	11:55:00
4		ten minutes.	11:55:02
5		(Recess from 11:55 a.m. until 12:13 p.m.)	11:55:02
6		MS. RAYMOND: I have just a couple more	12:13:31
7		questions.	12:13:32
8		MS. GREB: So Megan, before you do that,	12:13:32
9		a quick thing, now that we're back on the record. I	12:13:35
10		just want to note Dave Anstaett has joined us in the	12:13:39
11		room, so I just want that to be clear.	12:13:43
12		And I also want to note for the record	12:13:45
13		that there were a number of questions related to	12:13:47
14		discovery in the District Court where I instructed	12:13:49
15		the witness not to answer.	12:13:52
16		And I want to be clear that if patent	12:13:53
17		owner intends to raise some sort of dispute in the	12:13:57
18		future about the propriety of those objections or	12:14:00
19		intends to use them in some sort of motion practice,	12:14:05
20		our view is that those questions were made in bad	12:14:08
21		faith because they are about a topic in which patent	12:14:11
22		owner has indicated an intent to seek discovery but	12:14:14

1 has not actually moved the Board for that, and 12:14:18

2 certainly has not received it. 12:14:21

3 And that if patent owner intends to use 12:14:23

4 any of those questions in the future or my 12:14:25

5 objections as fodder for a motion or dispute, we 12:14:28

6 should pause the deposition now and contact the 12:14:32

7 Board regarding petitioner's motion to terminate. 12:14:34

8 MS. RAYMOND: I mean, I dispute the basis 12:14:38

9 of your issues and the foundations. And, you know, 12:14:42

10 you've made your decision to instruct the witness 12:14:48

11 not to answer, and, you know, that's your decision. 12:14:50

12 So we'll proceed. I think I just have a 12:14:57

13 couple more questions. 12:15:03

14 MS. GREB: Okay. So since I didn't hear 12:15:04

15 agreement about patent owner's future use of those 12:15:06

16 objections, I want to pause the deposition and 12:15:10

17 contact the Board about our motion to terminate that 12:15:13

18 line of questioning. 12:15:15

19 MS. RAYMOND: I'm not continuing to ask 12:15:18

20 you that question today, so I don't think that's -- 12:15:20

21 I'm going to ask my last three questions, which I 12:15:25

22 think are very clearly within the scope of 12:15:29

1 Dr. Bantle's work on this IPR. 12:15:32

2 And I don't -- to the extent that there 12:15:37
3 is a dispute later, we can fight that down the road. 12:15:43
4 I'm not anticipating there will be one. Obviously, 12:15:46
5 we'll be seeking discovery. 12:15:49

6 I don't even know the basis for your 12:15:52
7 calling the Board right now. So I'm just going to 12:15:56
8 proceed with my last three questions. 12:15:58

9 MS. GREB: Okay. I just want to be 12:16:00
10 clear, the basis for calling the Board would be that 12:16:02
11 the rules indicate that when there's a dispute and 12:16:06
12 instructions not to answer certain questions that 12:16:09
13 are related to a motion to terminate, that the 12:16:13
14 process is to call the Board. 12:16:15

15 And I don't want there to be some 12:16:17
16 argument later that, you know, I am somehow 12:16:18
17 operating in bad faith or against the Board rules by 12:16:22
18 instructing him not to answer. 12:16:26

19 So if you're not going to use that as 12:16:27
20 later fodder, I don't think we need to call the 12:16:30
21 Board today. But if it's your intent to somehow -- 12:16:34

22 (Cross-talk.) 12:16:40

1 MS. GREB: -- us of not appropriately 12:16:40
2 objecting, then I think we need to call the Board 12:16:42
3 and get their view on those objections and 12:16:44
4 instructions not to answer today. 12:16:46

5 MS. RAYMOND: It's your prerogative to 12:16:49
6 instruct him not to answer. We will be seeking the 12:16:51
7 discovery that we have identified as, you know, that 12:16:54
8 we were seeking. 12:16:57

9 MS. GREB: Okay. So you intend to seek 12:17:00
10 that discovery at another time? 12:17:01

11 MS. RAYMOND: Yes. 12:17:03

12 MS. GREB: And you're not planning on 12:17:03
13 using my instructions not to answer today to argue 12:17:05
14 some sort of bad faith, not following the Board 12:17:09
15 rules during this deposition. 12:17:13

16 Is that correct? 12:17:14

17 MS. RAYMOND: I don't anticipate saying 12:17:15
18 that there was a failure to follow the Board -- I'm 12:17:27
19 not even sure what your concern is or what the issue 12:17:39
20 is. 12:17:43

21 If your concern is that we're going to 12:17:47
22 seek sanctions for your instructions to tell him not 12:17:49

1 to answer, I obviously haven't consulted with my
2 client, but I do not anticipate that we would be
3 seeking sanctions for your instruction to not --
4 your instructions to not answer.

5 MS. GREB: Okay. Why don't we proceed
6 for now.

7 MS. RAYMOND: Okay.

8 BY MS. RAYMOND:

9 Q Dr. Bantle, sorry about that. Just a
10 couple more questions on your work on the '462 IPR.

11 I assume, and can you please confirm,
12 that Mylan has paid you for your work in the '462
13 IPR?

14 MS. GREB: Object to form.

15 And again, I think the question is
16 limited to the IPR and that you can answer that
17 question.

18 A Yes.

19 Q And has Dr. Reddy's paid you for your
20 work in this '462 IPR?

21 MS. GREB: Object to form.

22 A I don't know. The checks come from

1	Perkins Coie, and whether or not Reddy's	12:18:51
2	Laboratories has provided funds to them is beyond my	12:18:55
3	knowledge.	12:18:59
4	Q Do you provide separate bills for this	12:19:02
5	'462 IPR for Mylan and Dr. Reddy's?	12:19:05
6	MS. GREB: Object to form.	12:19:10
7	A No.	12:19:11
8	MS. RAYMOND: I have no further	12:19:14
9	questions.	12:19:15
10	MS. GREB: We'd like to take a brief	12:19:16
11	break.	12:19:19
12	(Recess from 12:19 p.m. until 12:26 p.m.)	12:26:24
13	MS. GREB: We have no questions for	12:26:24
14	Dr. Bantle today.	12:26:26
15	Thank you for your time, Doctor.	12:26:27
16	MS. RAYMOND: Thank you so much,	12:26:29
17	everyone.	12:26:31
18	COURT REPORTER: Anything else for the	12:26:31
19	record?	12:26:32
20	MS. RAYMOND: Nothing else for the	12:26:35
21	record.	12:26:36
22	(Transcript orders discussed.)	12:26:50

1 COURT REPORTER: Thank you. That's all I
2 need.

12:27:08

12:27:11

3 (Off the record at 12:27 p.m.)
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1 CERTIFICATE OF SHORTHAND REPORTER - NOTARY PUBLIC

2
3 I, Lisa V. Feissner, RDR, CRR and Notary
4 Public in and for the District of Columbia, do
5 hereby certify:

6
7 That JOHN P. BANTLE, M.D., the witness
8 whose deposition is hereinbefore set forth, was duly
9 sworn by me before the commencement of such
10 deposition, and that such deposition was taken
11 before me and is a true record of the testimony
12 given by such witness.

13
14 I further certify that the adverse party,
15 MYLAN PHARMACEUTICALS INC., was represented by
16 counsel at the deposition.

17
18 I further certify that the deposition of
19 JOHN P. BANTLE, M.D., occurred REMOTELY on THURSDAY,
20 JULY 11, 2024, commencing at 10:05 and concluding at
21 12:27.

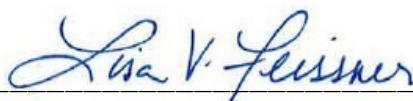
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Novo Nordisk Exhibit 2552
Mylan Pharms. Inc. v. Novo Nordisk A/S
IPR2023-00724
Page 00077

1 I further certify that I am not related
2 to any of the parties to this action by blood or
3 marriage, I am not employed by or an attorney to any
4 of the parties to this action, and that I am in no
5 way interested, financially or otherwise, in the
6 outcome of this matter.

7
8 IN WITNESS WHEREOF, I have hereunto set
9 my hand this 15TH day of JULY, 2024.

10
11
12 

13 NOTARY PUBLIC IN AND FOR

14 THE DISTRICT OF COLUMBIA

15 MY COMMISSION EXPIRES JUNE 15, 2028
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