

1 UNITED STATES PATENT AND TRADEMARK OFFICE
2 BEFORE THE PATENT TRIAL AND APPEAL BOARD
3

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

7 vs

8 NOVO NORDISK A/S,
9 Patent Owner
10 -----

11 Case IPR2023-00724

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

13 Oral deposition of
14 WILLIAM J. JUSKO, Ph.D.

15
16 VIA VIDEO/TELECONFERENCE

17 FRIDAY, JULY 12, 2024

18 10:02 a.m. EASTERN TIME
19

20 Job No.: 534506

21 Pages: 1 - 59

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

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3 Oral deposition of WILLIAM J. JUSKO,
4 Ph.D., held REMOTELY, via ZOOM, on FRIDAY, JULY 12,
5 2024, BEGINNING at 10:02 a.m., pursuant to NOTICE,
6 before Lisa V. Feissner, RDR, CRR, CLR, Notary
7 Public.
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C O N T E N T S		
EXAMINATION OF WILLIAM J. JUSKO, Ph.D.		PAGE
By Ms. Raymond		6
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

WILLIAM J. JUSKO, Ph.D.,

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

EXAMINATION

BY MS. RAYMOND:

Q Good morning, Dr. Jusko.

A Good morning.

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

A That is correct.

Q And the report you submitted in IPR
2023-00724, which is marked as Exhibit 1301, that's
your report, correct?

A I don't remember all those numbers you
recited, but this is an IPR hearing --

Q Okay.

A -- that I'm giving testimony.

Q Sorry for interrupting.

Can you put in front of you your report
for this case, your reply report.

(Previously marked Exhibit 1301 presented

1	to the witness.)	10:02:50
2	THE WITNESS: Okay. So I have -- very	10:02:50
3	good.	10:02:58
4	BY MS. RAYMOND:	10:02:59
5	Q And the report you have in front of you,	10:02:59
6	that's one of the reports at least you're here to	10:03:02
7	testify about today?	10:03:04
8	A Yes, it is.	10:03:06
9	Q And that says Exhibit 1301 at the bottom.	10:03:07
10	Is that correct?	10:03:12
11	A Correct.	10:03:14
12	Q And it references IPR 2023-00724.	10:03:14
13	Is that correct?	10:03:20
14	A That's correct.	10:03:22
15	Q Great. Are you aware of a Dr. Bantle?	10:03:23
16	Does that name ring a bell?	10:03:32
17	A Sometimes your voice is not coming	10:03:34
18	through clearly. But I believe you asked something	10:03:35
19	about Dr. Bantle.	10:03:39
20	Q Yes. Are you aware of a Dr. Bantle?	10:03:40
21	A I am aware of him, yes.	10:03:43
22	Q Have you read any of his reports in this	10:03:45

1	IPR?	10:03:49
2	A No.	10:03:50
3	Q Have you read any of his deposition	10:03:52
4	transcripts in this IPR?	10:03:54
5	A No.	10:03:58
6	Q Have you read any other materials	10:03:58
7	prepared by Dr. Bantle in connection with the	10:04:01
8	invalidity of the '462 patent?	10:04:04
9	MS. PROCHNOW: Objection, form.	10:04:08
10	A Not that I know of.	10:04:10
11	Q Could you turn to paragraph 17 of your	10:04:33
12	report.	10:04:36
13	And just as a note, are you hearing me	10:04:41
14	okay now?	10:04:44
15	A Yes.	10:04:45
16	Q Okay.	10:04:46
17	A Okay. I'm on paragraph 17.	10:04:55
18	Q Okay. And paragraph 17 includes the	10:04:57
19	phrase "critical to the operability of the claimed	10:05:01
20	invention."	10:05:05
21	Do you see that?	10:05:06
22	A Yes.	10:05:08

1	Q	And what do you mean by that phrase?	10:05:10
2		MS. PROCHNOW: Objection, form.	10:05:13
3	A	Well, as I state in 17, it's such that it	10:05:18
4		is not anticipated by a prior art disclosure. The	10:05:24
5		question is whether the difference is critical to	10:05:30
6		the operability of the claimed invention.	10:05:32
7	Q	Okay. So in the context of the '462	10:05:37
8		claims, what must be critical?	10:05:41
9		MS. PROCHNOW: Objection, form.	10:05:45
10	A	It's sort of a vague question. Please	10:05:50
11		rephrase.	10:06:00
12	Q	What do you mean by "critical to the	10:06:02
13		operability of the claimed invention" in paragraph	10:06:07
14		17?	10:06:10
15		MS. PROCHNOW: Objection, form.	10:06:10
16	A	That there are specifics regarding how	10:06:18
17		the claimed invention will work.	10:06:21
18	Q	Could you elaborate on what you mean by	10:06:27
19		"there are specifics regarding how the claimed	10:06:31
20		invention will work."	10:06:34
21		MS. PROCHNOW: Objection, form.	10:06:35
22	A	Well, it might mean specific quantitative	10:06:38

1 factors that might have been recited. 10:06:43

2 Q Are you saying that the -- I'm still 10:07:27

3 having trouble understanding what your understanding 10:07:32

4 is. 10:07:35

5 When you say "critical to the operability 10:07:36

6 of the claimed invention," is it your understanding 10:07:43

7 that that operability itself must be claimed in 10:07:45

8 the -- sorry. 10:07:45

9 Is it your understanding that that 10:07:53

10 operability itself must be claimed? 10:07:54

11 MS. PROCHNOW: Objection, form. 10:07:56

12 A Those words in quotation are legal 10:08:00

13 languages. It's my understanding that the first 10:08:06

14 claim of the patent does not require any level of 10:08:10

15 therapeutic activity. So it's not critical. 10:08:15

16 Q So can one prove criticality of claim 1 10:08:21

17 by showing a particularly high therapeutic activity 10:08:27

18 in practicing the claim? 10:08:41

19 MS. PROCHNOW: Objection, form. 10:08:43

20 A Maybe you could say that again. 10:08:46

21 Q Sure. To prove criticality of claim 1, 10:08:50

22 can one do that by showing a particularly high 10:08:56

1	therapeutic activity in practicing the	10:08:59
2	administration of 1 milligram of semaglutide once	10:09:04
3	weekly?	10:09:09
4	MS. PROCHNOW: Objection, form.	10:09:10
5	A Again, you're asking me what would need	10:09:16
6	to reflect criticality for that claim?	10:09:20
7	Q Right. I'll just ask you in this way.	10:09:24
8	You opined that the dose in claim 1 is	10:09:28
9	not critical, correct?	10:09:36
10	A Correct.	10:09:39
11	Q And how did you determine that the dose	10:09:41
12	in claim 1 was not critical?	10:09:44
13	A Because the patent claim does not require	10:09:49
14	any specific degree of efficacy or tolerability.	10:09:53
15	Q So for the dose in claim 1 to be	10:10:03
16	critical, the patent would need to require a	10:10:06
17	specific degree of efficacy or tolerability, based	10:10:08
18	on your understanding.	10:10:11
19	Is that correct?	10:10:12
20	MS. PROCHNOW: Objection, form.	10:10:12
21	A That's correct.	10:10:16
22	Q Would you please turn to paragraph 33 of	10:10:37

1	your report.	10:10:40
2	A Okay.	10:11:00
3	Q And there, you say that you understand	10:11:03
4	the Board agreed with Novo Nordisk and Mylan that	10:11:06
5	the preamble does not require any particular level	10:11:11
6	of efficacy.	10:11:14
7	Do you see that?	10:11:16
8	A Yes. That's what's stated here.	10:11:17
9	Q Okay. And is it your understanding that	10:11:19
10	no efficacy at all is required by the '462 claims	10:11:22
11	under this construction?	10:11:28
12	MS. PROCHNOW: Objection, form.	10:11:29
13	A You're asking me if there was no	10:11:35
14	efficacy? Doesn't make sense.	10:11:41
15	Q I'm trying to understand what your	10:11:49
16	understanding is of the meaning of the Board's	10:11:53
17	construction when you say, the Board found that the	10:11:57
18	preamble does not require any particular level of	10:12:03
19	efficacy.	10:12:07
20	So in the Board finding, the preamble	10:12:07
21	does not require any particular level of efficacy,	10:12:10
22	is it your understanding that the preamble doesn't	10:12:13

1 require any efficacy at all? 10:12:15

2 A A level of efficacy means something is 10:12:19
3 happening. It can't mean nothing is going on. 10:12:22

4 Q Okay. And is it your understanding that 10:12:26
5 the preamble requires an expectation that type 2 10:12:35
6 diabetes is treated by administering semaglutide 10:12:35
7 once weekly at 1 milligram? 10:12:43

8 MS. PROCHNOW: Objection, form. 10:12:44

9 A The preamble calls for treatment of -- 10:12:55
10 some level of efficacy for treatment of diabetes. 10:13:04

11 Q And so does that require an expectation 10:13:10
12 that the type 2 diabetes is treated under this claim 10:13:14
13 language? 10:13:25

14 MS. PROCHNOW: Objection, form. 10:13:25

15 A Yes, it would. 10:13:33

16 Q Would administering semaglutide once 10:14:24
17 weekly at a 1 milligram dose have to be somewhat 10:14:26
18 tolerable in order to be a treatment under your 10:14:30
19 understanding of claim 1? 10:14:33

20 MS. PROCHNOW: Objection, form. 10:14:36

21 A It calls for treatment of diabetes. It 10:14:44
22 doesn't specify tolerability. 10:14:51

1	Q	Can you treat diabetes with a drug that's	10:14:53
2		entirely intolerable --	10:14:56
3		MS. PROCHNOW: Objection, form.	10:14:59
4	Q	-- at a dose --	10:14:59
5		MS. PROCHNOW: Sorry.	10:15:01
6		MS. RAYMOND: I'll ask that again.	10:15:01
7	Q	Can you treat diabetes with a drug that's	10:15:02
8		entirely intolerable on a dosing schedule that's	10:15:04
9		entirely intolerable?	10:15:08
10		MS. PROCHNOW: Objection, form.	10:15:09
11	A	It would be a very rare patient that	10:15:17
12		would accept such treatment.	10:15:19
13	Q	Is it your understanding of claim 1 that	10:15:32
14		a drug that's entirely intolerable on a dosing	10:15:36
15		schedule that's entirely intolerable could meet the	10:15:40
16		treatment requirement of the preamble?	10:15:43
17		MS. PROCHNOW: Objection, form.	10:15:46
18	A	Well, the preamble calls for treating	10:15:50
19		diabetes; it doesn't specify the tolerance issue.	10:15:55
20	Q	So can you treat diabetes with an	10:16:03
21		intolerable drug?	10:16:06
22		MS. PROCHNOW: Objection, form.	10:16:07

1	A	Well, you're getting into the realm where	10:16:13
2		a clinician would be needed to help answer that	10:16:16
3		question. But in my view, if the patient won't	10:16:20
4		accept treatment, then it's not a treatment.	10:16:24
5	Q	Could you turn to paragraph 215 of your	10:16:37
6		report, please.	10:16:40
7	A	All right. I'm at 216.	10:17:10
8	Q	Okay. Sorry, 215.	10:17:13
9	A	Paragraph 216.	10:17:18
10	Q	Paragraph -- could you look at paragraph	10:17:21
11		215, please.	10:17:23
12	A	I'm looking at my paragraph 216.	10:17:29
13	Q	Okay. Could you please look at your	10:17:32
14		paragraph 215.	10:17:34
15	A	Oh. All right.	10:17:39
16	Q	Okay. And in preparing your report, you	10:17:58
17		reviewed the '462, correct?	10:18:02
18	A	I reviewed the patent, yes.	10:18:09
19	Q	And you reviewed the specification of the	10:18:11
20		patent.	10:18:13
21		Is that correct?	10:18:14
22	A	Yes.	10:18:16

1 Q Okay. And do you recall seeing anything 10:18:19
2 in the specification about tolerability? 10:18:23

3 A I'd have to look back at the patent to 10:18:30
4 remember, you know, specific wording like that. 10:18:34

5 Q Okay. Do you have access to 10:18:38
6 Exhibit 1001? 10:18:42

7 MS. PROCHNOW: Do you want me to give him 10:18:45
8 the hard copy, Megan? 10:18:47

9 MS. RAYMOND: Sure. 10:18:51

10 (Previously marked Exhibit 1001 presented 10:18:51
11 to the witness.) 10:19:49

12 THE WITNESS: I have the patent. 10:19:49

13 BY MS. RAYMOND: 10:19:51

14 Q You're welcome to look at whatever 10:19:51
15 portions of the patent you want. I might point you 10:19:54
16 to column 23, lines 1 through 5. 10:19:58

17 And my question is going to be whether 10:20:01
18 the '462 discusses or discloses that the proportion 10:20:04
19 of subjects with GI side effects increases with the 10:20:11
20 dose of semaglutide? 10:20:15

21 A I'm on page 19 looking at column 23. I 10:20:23
22 don't see that. 10:20:28

1	Q	Okay. At the top of column 23, do you	10:20:30
2		see where it says, the Proportion of subjects with	10:20:34
3		nausea and vomiting increased with dose, but were	10:20:38
4		generally mild or moderate and ameliorated by	10:20:41
5		titration?	10:20:44
6		Do you see that?	10:20:46
7	A	Okay. I see what you have on the screen	10:20:53
8		as well. Oh, there it is. Mild or moderated,	10:20:57
9		ameliorated by titration.	10:21:04
10		Okay, I see that.	10:21:06
11	Q	So is it your understanding that side	10:21:07
12		effects increased with dose with respect to GI	10:21:10
13		issues, nausea and vomiting?	10:21:16
14		MS. PROCHNOW: Objection, form.	10:21:19
15	A	It's a common phenomenon with GL-1	10:21:22
16		agonists -- GLP-1 agonists.	10:21:27
17	Q	Could you please look at paragraph 222 of	10:22:03
18		your report. So we're going back to Exhibit 1301.	10:22:05
19	A	Okay. 222. All right.	10:22:22
20	Q	And the last sentence of that says,	10:22:26
21		Moreover, there is nothing to suggest that the	10:22:29
22		1 milligram dose is critical as opposed to other	10:22:32

1	doses greater than 0.8 milligrams semaglutide.	10:22:36
2	Do you see that?	10:22:41
3	A Yes.	10:22:43
4	Q And it's your understanding that the	10:22:44
5	prior art disclosed -- or it's your position that	10:22:48
6	the prior art disclosed a range of 0.1 milligram to	10:22:50
7	either 1.2 or 1.6 milligrams of semaglutide.	10:22:54
8	Is that correct?	10:22:58
9	MS. PROCHNOW: Objection, form,	10:22:59
10	foundation.	10:23:00
11	A Yes, the prior art disclosed that dosing	10:23:05
12	range of 0.1 to 1.6 milligrams.	10:23:08
13	Q And with respect to criticality, is it	10:23:11
14	your understanding that the 1 milligram dose had to	10:23:14
15	be different than every other dose in the range	10:23:18
16	disclosed in the prior art to be critical?	10:23:21
17	MS. PROCHNOW: Objection, form.	10:23:25
18	A Please state that again.	10:23:28
19	Q Sure. With respect to criticality, is it	10:23:31
20	your understanding that the 1 milligram dose had to	10:23:37
21	be different than every other dose in the range	10:23:40
22	disclosed in the prior art to be critical?	10:23:44

1 MS. PROCHNOW: Objection, form. 10:23:47

2 A Yes, I would... 10:23:55

3 Q And is it your understanding that because 10:24:34

4 the claims don't require a particular level of 10:24:36

5 efficacy, that efficacy and tolerability can't be 10:24:37

6 used to show criticality of the '462 claims? 10:24:41

7 MS. PROCHNOW: Objection, form. 10:24:44

8 A Please say that again. 10:24:56

9 Q Is it your understanding that because the 10:24:57

10 claims don't require a particular level of efficacy, 10:25:00

11 that efficacy and tolerability can't be used to show 10:25:03

12 criticality of the '462 claims? 10:25:06

13 MS. PROCHNOW: Objection, form. 10:25:08

14 A The spectrum of what happens during 10:25:21

15 patient treatment would include those elements of 10:25:26

16 responsiveness. I'm not sure how to answer your 10:25:36

17 question, though. 10:25:41

18 Q Are those elements of responsiveness 10:26:14

19 relevant to the criticality analysis, as you 10:26:16

20 understood it? 10:26:20

21 MS. PROCHNOW: Objection, form. 10:26:21

22 A Well, semaglutide produces various levels 10:26:25

1 of efficacy and tolerability. And again, what those 10:26:30

2 are are not part of the claim 1. 10:26:37

3 Q And so is it your understanding, then, 10:26:51

4 that efficacy and tolerability can't be used to 10:26:54

5 establish criticality of claim 1? 10:26:57

6 MS. PROCHNOW: Objection, form. 10:27:00

7 A Not at all. One has to have specifics 10:27:07

8 for patient responsiveness in order to establish 10:27:12

9 criticality. 10:27:16

10 Q One has to have specifics for patient 10:27:21

11 responsiveness in the claims themselves in order to 10:27:23

12 establish criticality? 10:27:27

13 MS. PROCHNOW: Objection, form. 10:27:29

14 A It's my understanding that there would 10:27:33

15 have to be specific quantitative criteria to 10:27:35

16 establish criticality. 10:27:40

17 Q And is it your understanding that those 10:27:43

18 specific quantitative criteria would need to be in 10:27:45

19 the claims themselves? 10:27:48

20 MS. PROCHNOW: Objection, form. 10:27:50

21 A Probably. It makes sense, although I'm 10:27:55

22 not sure about the legal depiction of that. 10:28:02

1 Q Could you please turn to paragraph 274 of 10:28:15
2 your report. 10:28:20

3 A Okay. 10:28:38

4 Q And towards the end, you have a quote 10:28:39
5 from Exhibit 1282 that says -- that refers to -- 10:28:44
6 well, I'll just read the whole sentence. 10:28:52

7 At the end of that paragraph you say, 10:28:54
8 Additionally, before the priority date, skilled 10:28:56
9 artisans would have been aware that Novo Nordisk 10:28:59
10 reported that the NCT657 phase 2 study, quote, 10:29:01
11 demonstrated that clinical efficacy and safety of 10:29:08
12 semaglutide was broadly in line with liraglutide, 10:29:10
13 end quote. 10:29:15

14 Do you see that? 10:29:15

15 A Yes, I do. 10:29:17

16 Q Do you know which dose of liraglutide had 10:29:18
17 clinical safety and efficacy broadly in line with 10:29:25
18 which dose of semaglutide? 10:29:28

19 MS. PROCHNOW: Objection, form. 10:29:30

20 A My interpretation of that phrase is that 10:29:34
21 a range of doses of both drugs have been studied, 10:29:38
22 and there were distinct similarities between the two 10:29:42

1 types of compounds, especially so that they have the 10:29:46
2 same mechanism of action. 10:29:50

3 Q Which range of doses of liraglutide had 10:29:52
4 similarity with which range of doses of semaglutide? 10:29:55

5 MS. PROCHNOW: Objection, form. 10:29:59

6 A There was an established dose-response 10:30:03
7 range for liraglutide, and the study range of 0.1 to 10:30:07
8 1.6 of semaglutide had broad similarities to -- in 10:30:15
9 the dose-response for liraglutide. 10:30:22

10 Q So is it your understanding that a dose 10:30:32
11 of 0.1 milligrams semaglutide had similarities to 10:30:35
12 some dose of liraglutide? 10:30:43

13 MS. PROCHNOW: Objection, form. 10:30:45

14 A It's more general than that. It means 10:30:52
15 that low doses of both compounds would produce 10:30:54
16 modest effects and higher doses would produce 10:30:58
17 greater effects in a classical sigmoidal 10:31:00
18 dose-response relationship. 10:31:04

19 Q But it doesn't give any information about 10:31:10
20 the specific doses that were being compared in this 10:31:13
21 quote, correct? 10:31:16

22 MS. PROCHNOW: Objection, form. 10:31:17

1	A	Well, there was general knowledge that	10:31:21
2		the dosing range of semaglutide was 0.1 to 1.6. So	10:31:23
3		it was those doses that were being compared.	10:31:29
4	Q	And with apologies, skipping back to a	10:32:04
5		question that I asked you earlier. While we were	10:32:07
6		talking about criticality, I asked you, Is it your	10:32:10
7		understanding that those specific quantitative	10:32:14
8		criteria would need to be in the claims themselves?	10:32:17
9		And you responded, after an objection,	10:32:22
10		Probably. It makes sense, although I'm not sure	10:32:26
11		about the legal depiction of that.	10:32:28
12		Do you recall that testimony?	10:32:31
13	MS. PROCHNOW:	Objection, form.	10:32:32
14	A	Yes.	10:32:35
15	Q	In performing your analysis, did you	10:32:37
16		assume that those specific quantitative criteria	10:32:41
17		would need to be in the claims themselves to find	10:32:45
18		criticality?	10:32:48
19	MS. PROCHNOW:	Objection, form.	10:32:49
20	A	As I stated, criticality would have	10:32:55
21		specific quantitative criteria that would have to be	10:32:58
22		listed.	10:33:03

1	Q	So you assumed that those quantitative	10:33:05
2		criteria would need to be listed in the claim,	10:33:08
3		correct?	10:33:10
4		MS. PROCHNOW: Objection, form.	10:33:10
5	A	That is my belief.	10:33:12
6	Q	Okay. Thank you.	10:33:15
7		Returning to paragraph 274, and we were	10:33:16
8		discussing the quote about clinical efficacy and	10:34:37
9		safety of semaglutide being broadly in line with	10:34:41
10		liraglutide.	10:34:44
11		Do you recall that?	10:34:46
12	A	Yes.	10:34:48
13	Q	Was it possible that the announcement was	10:34:51
14		referring to a smaller portion of the range of	10:34:55
15		semaglutide being broadly in line with liraglutide?	10:34:58
16		MS. PROCHNOW: Objection, form.	10:35:02
17	A	I interpret this -- the word "broadly" as	10:35:07
18		meaning the whole array of dose-response	10:35:10
19		relationship and types of responses obtained.	10:35:14
20	Q	Could you turn to paragraph 267 of your	10:35:35
21		report, please.	10:35:37
22	A	Okay.	10:36:00

1	Q	And in about the middle of that	10:36:01
2		paragraph, do you see your statement, a skilled	10:36:03
3		artisan would have been motivated to optimize the	10:36:06
4		dose in that range to 1 milligram?	10:36:09
5	A	I see that.	10:36:14
6	Q	What do you mean by, motivate to optimize	10:36:15
7		the dose in that range to 1 milligram?	10:36:18
8		MS. PROCHNOW: Objection, form.	10:36:21
9	A	Well, the 0.1 to 1.6 milligram range of	10:36:27
10		doses was enacted in the phase 2 study in order to	10:36:32
11		assess basically what happens over that range and	10:36:39
12		what might be a later preferred dose.	10:36:46
13		And certainly, the doses towards the	10:36:51
14		higher end are likely to have the best efficacy, but	10:36:54
15		that has to be balanced with tolerability.	10:37:04
16		So the doses studied went from 0.8 to	10:37:08
17		1.6 milligrams. So one would be inclined to pick a	10:37:15
18		dose somewhere in that range, but probably between	10:37:23
19		0.8 and 1.2. 1 milligram is a nice round number, it	10:37:26
20		would be one obvious to try.	10:37:32
21	Q	And in your report, do you provide the	10:37:41
22		opinion that 1 milligram is the optimal dose?	10:37:44

1	MS. PROCHNOW: Objection, form.	10:37:47
2	A I do not claim it as the optimum dose.	10:37:51
3	It is a possible optimum dose. But 0.8, 0.9, 1.1	10:37:56
4	are also feasible.	10:38:06
5	Q And they're also feasible as optimal	10:38:11
6	doses based on what metric?	10:38:14
7	MS. PROCHNOW: Objection, form.	10:38:16
8	A Well, the general expectation that when a	10:38:18
9	successful dose-response study has been	10:38:22
10	accomplished, somewhere near the higher doses,	10:38:29
11	somewhere near a plateau would be a preferred dose	10:38:32
12	to use. And it then becomes a decision between	10:38:35
13	efficacy and tolerability.	10:38:40
14	The fact that -- to get to 1.6, titration	10:38:45
15	was involved, means that they were reaching an upper	10:38:52
16	level of tolerability at the upper range of the	10:38:58
17	dose-response curve.	10:39:02
18	Q Did you look at any efficacy and	10:39:28
19	tolerability data to determine whether 1 milligram	10:39:32
20	is an optimal dose?	10:39:43
21	MS. PROCHNOW: Objection, form.	10:39:45
22	A Are you asking, did I look at specific	10:39:48

1	data of that nature?	10:39:50
2	Q That's correct.	10:39:52
3	MS. PROCHNOW: Objection, form.	10:39:53
4	A I'm sorry. I heard you say okay?	10:39:58
5	Q I said, that's correct.	10:40:02
6	Did you look at any efficacy and	10:40:04
7	tolerability data to determine whether 1 milligram	10:40:06
8	is an optimal dose?	10:40:10
9	MS. PROCHNOW: Objection, form.	10:40:12
10	A No, I did not.	10:40:15
11	Q Could you please turn to paragraph 281 of	10:40:40
12	your report.	10:40:46
13	A Okay.	10:41:10
14	Q And you see where it says, skilled	10:41:10
15	artisans would have been motivated with a reasonable	10:41:12
16	expectation of success to optimize the weekly dose	10:41:15
17	to 1 milligram for treating type 2 diabetes?	10:41:19
18	A Yes. The 1 milligram would have been a	10:41:27
19	good dose to select.	10:41:36
20	Q Okay. What do you mean when you say, to	10:41:38
21	optimize the weekly dose to 1 milligram?	10:41:41
22	MS. PROCHNOW: Objection, form.	10:41:46

1	A	Well, because of the nature of	10:41:51
2		phase 1/phase 2 studies, something towards the	10:41:54
3		higher end of the studied dose-response relationship	10:41:59
4		and data generated would have been -- would have	10:42:06
5		been an optimal dose. 1 milligram is a very	10:42:11
6		reasonable choice.	10:42:19
7	Q	Okay. Could you please turn to paragraph	10:42:36
8		312 of your report.	10:42:38
9	A	Okay.	10:42:57
10	Q	And at the end of that paragraph, you	10:42:57
11		say, a dose closer to the 0.8 milligram dose, such	10:43:01
12		as 1.0 milligram, which would have a better balance	10:43:05
13		between efficacy and side effects.	10:43:10
14		Do you see that?	10:43:12
15	A	Yes.	10:43:14
16	Q	And again, just to confirm my	10:43:15
17		understanding of your analysis, when you say,	10:43:20
18		1.0 milligram would have had a better balance	10:43:25
19		between efficacy and side effects, it's your opinion	10:43:26
20		that that's what a POSITA or a person of skill would	10:43:31
21		have expected, not that you looked at actual data	10:43:35
22		and concluded that 1 milligram had a better balance	10:43:37

1 between efficacy and side effects, correct? 10:43:39

2 MS. PROCHNOW: Objection, form. 10:43:43

3 A Well, a POSA would have the choices, 10:43:45

4 where I specify that somewhere between 0.8 and 1.2 10:43:51

5 milligram would be the most obvious range within to 10:43:55

6 make a choice, and settling on 1.0 milligrams is one 10:44:00

7 that I would expect to be a successful treatment. 10:44:06

8 Q So when you say there that 1 milligram 10:44:13

9 would have had a better balance between efficacy and 10:44:15

10 side effects, that's based on an expectation of a 10:44:18

11 POSA as of the priority date? 10:44:23

12 MS. PROCHNOW: Objection, form. 10:44:25

13 A It's an expectation of a POSA who 10:44:29

14 realizes that a very capable pharmaceutical company 10:44:32

15 like Novo Nordisk, with an array of background 10:44:39

16 information, the extensive experience with 10:44:43

17 liraglutide, would come down to this as a dose where 10:44:46

18 there's a very reasonable expectation of success. 10:44:52

19 Q Could you please turn to paragraph 314 of 10:44:57

20 your report. 10:45:00

21 A Did you say 314? 10:45:04

22 Q 314, yes. 10:45:07

1	A	Okay.	10:45:22
2	Q	Do you see where it says, in your	10:45:23
3		opinion, a skilled artisan would also have	10:45:27
4		understood that prior to undergoing any phase 1 or	10:45:29
5		phase 2 human studies, Novo Nordisk would have	10:45:32
6		collected a substantial amount of preclinical data	10:45:36
7		(i.e., in vitro and healthy and diseased animal	10:45:40
8		models) related to the pharmacokinetics and	10:45:45
9		pharmacodynamics of semaglutide?	10:45:49
10		Do you see that?	10:45:51
11	A	Indeed, I see it.	10:45:51
12	Q	And would you agree that it's typical for	10:45:53
13		an entity running a phase 1 or phase 2 study to have	10:45:55
14		collected substantial preclinical data on	10:45:58
15		pharmacokinetics and pharmacodynamics?	10:46:00
16	A	I'm not clear on the first part of your	10:46:06
17		question.	10:46:10
18	Q	Would it be -- sorry, go ahead.	10:46:11
19	A	Who are you talking about again?	10:46:14
20	Q	I'm just asking if typically -- you say	10:46:16
21		Novo Nordisk would have gathered this information or	10:46:19
22		had this information before the phase 1 and phase 2	10:46:22

1 studies.

10:46:26

2 And what I'm trying to understand is
3 whether it's your position that it would be typical
4 for an entity running a phase 1 or phase 2 study to
5 have collected substantial preclinical data or
6 whether that was something specific to Novo Nordisk
7 itself.

10:46:26

10:46:29

10:46:32

10:46:36

10:46:39

10:46:42

8 MS. PROCHNOW: Objection, form.

10:46:43

9 A First of all, the investigators carrying
10 out the study would have been acquainted with the
11 Investigator's Brochure that summarizes the state of
12 knowledge about the compound.

10:46:49

10:46:51

10:46:55

10:46:59

13 Much of the preclinical work would have
14 been carried out by Novo Nordisk. But some of
15 what's -- information is available could be from the
16 literature as well. Some could be from, let's say,
17 ancillary studies that others have performed with
18 semaglutide.

10:47:01

10:47:04

10:47:09

10:47:12

10:47:18

10:47:24

19 My own experience is that I've been -- I
20 helped do preclinical studies for investigational
21 compounds several times.

10:47:26

10:47:31

10:47:38

22 Q And when you helped with those studies,

10:47:39

1 did the entity running those phase 1 or phase 2 10:47:41
 2 studies have in hand substantial preclinical data on 10:47:44
 3 pharmacokinetics and pharmacodynamics before 10:47:48
 4 pursuing the phase 1 or phase 2 study? 10:47:51

5 MS. PROCHNOW: Objection, form. 10:47:54

6 A Very, very likely. 10:48:00

7 Q So would you agree that an entity 10:48:05
 8 performing a phase 1 or phase 2 trial would 10:48:07
 9 typically have collected a substantial amount of 10:48:10
 10 preclinical data related to pharmacokinetics and 10:48:13
 11 pharmacodynamics before pursuing those studies? 10:48:17

12 MS. PROCHNOW: Objection, form. 10:48:20

13 A The investigators would have been given 10:48:24
 14 all of that information. The clinical investigators 10:48:26
 15 may not have done it themselves. 10:48:29

16 Q But the investigators would have -- you 10:48:33
 17 would expect the investigators would have that 10:48:36
 18 information regardless of whether it's a study 10:48:38
 19 conducted by Novo on semaglutide or a study 10:48:42
 20 conducted by some other entity on another drug. 10:48:45

21 Is that correct? 10:48:48

22 MS. PROCHNOW: Objection, form. 10:48:49

1 A Well, the clinical investigators are 10:48:53
2 people who are -- typically have broad experience 10:48:56
3 relevant to the potential therapeutic actions of the 10:49:00
4 drug. So they would have a knowledge base that is 10:49:06
5 appreciable to some extent. 10:49:14

6 Q Try this a little bit differently. 10:49:23

7 So it's your opinion that Novo would have 10:49:25
8 collected a substantial amount of preclinical data 10:49:28
9 regarding pharmacokinetics and pharmacodynamics of 10:49:32
10 semaglutide before undertaking a phase 1 or phase 2 10:49:34
11 study, correct? 10:49:38

12 MS. PROCHNOW: Objection, form. 10:49:40

13 A Novo Nordisk would have collected that, 10:49:45
14 as stated here, yes. They would have collected a 10:49:47
15 substantial amount of preclinical data. 10:49:50

16 Q Let's say some other entity was 10:49:52
17 developing another diabetes treatment. Is it your 10:49:56
18 opinion that that other entity would have collected 10:50:02
19 a substantial amount of preclinical data regarding 10:50:06
20 pharmacokinetics and pharmacodynamics before 10:50:10
21 undertaking a phase 1 or phase 2 study? 10:50:13

22 MS. PROCHNOW: Objection, form. 10:50:16

1	A	Some other entity -- well, there would	10:50:24
2		have to be special circumstances where an entity	10:50:31
3		other than Novo Nordisk would be carrying out the	10:50:33
4		clinical studies. That happens sometimes when	10:50:36
5		government agencies get involved.	10:50:39
6	Q	Okay. Do other pharmaceutical companies	10:50:42
7		also collect a substantial amount of preclinical	10:50:45
8		data on pharmacokinetics and pharmacodynamics prior	10:50:49
9		to entering phase 1 or 2 trials?	10:50:53
10		MS. PROCHNOW: Objection, form.	10:50:56
11	A	All companies do that.	10:50:59
12	Q	So you're not saying in paragraph 314	10:51:05
13		that Novo is special with respect to the amount of	10:51:07
14		preclinical data it would have collected for the	10:51:10
15		phase 1 or 2 trials.	10:51:12
16		Is that correct?	10:51:14
17		MS. PROCHNOW: Objection, form.	10:51:15
18	A	I don't agree, because Novo Nordisk is --	10:51:18
19		has a wealth of experience in the diabetes area. So	10:51:23
20		they developed liraglutide. So they would have	10:51:30
21		wonderful data about any agents for treating	10:51:36
22		diabetes.	10:51:41

1 Q So it's your assumption that Novo would 10:51:42
2 have had more preclinical data prior to phase 1 or 10:51:44
3 phase 2 trials than a pharmaceutical company would 10:51:49
4 typically have? 10:51:51

5 MS. PROCHNOW: Objection, form. 10:51:53

6 A All pharmaceutical companies have to 10:51:56
7 evolve a considerable database regarding 10:52:00
8 experimental compounds they're developing. 10:52:06

9 The diabetes area is a specialty of Novo 10:52:09
10 Nordisk. But I'm not sure it would be -- it could 10:52:13
11 be greater than others would have developed, but 10:52:19
12 possibly not. 10:52:24

13 Q Would you please turn to paragraph 320 of 10:52:26
14 your report. 10:53:14

15 A Okay. 10:53:29

16 Q And do I understand your opinion 10:53:30
17 correctly that semaglutide would have been expected 10:53:34
18 to have the same dose-response curve shape as 10:53:41
19 liraglutide? 10:53:47

20 MS. PROCHNOW: Objection, form. 10:53:49

21 A It would be roughly the same shape, 10:53:52
22 sigmoidal, but not with identical numbers. 10:53:55

1	Q	And what's the basis for your opinion	10:54:00
2		that the two dose-response curves would have been	10:54:06
3		expected to have roughly the same shape as of the	10:54:11
4		priority date?	10:54:14
5		MS. PROCHNOW: Objection, form.	10:54:14
6	A	That's the basic expectation for all	10:54:17
7		drugs, that nearly all have a sigmoidal	10:54:21
8		dose-response curve, and they would typically differ	10:54:26
9		from each other, but still have the same shape.	10:54:32
10	Q	Did you investigate whether semaglutide	10:54:42
11		does, in fact, have a sigmoidal dose-response curve?	10:54:44
12		MS. PROCHNOW: Objection, form.	10:54:50
13	A	The fact that it was a GLP-1 agonist and	10:54:55
14		the fact that a dose-response curve was being	10:55:02
15		examined, you know, for the 0.1 to 1.6 milligram	10:55:07
16		range, the fact that there were -- the need for	10:55:12
17		titration at the higher doses was evident, leads to	10:55:17
18		the expectation that, like liraglutide, there would	10:55:21
19		be a sigmoidal dose-response curve.	10:55:25
20	Q	And you didn't investigate for your	10:55:28
21		report what semaglutide's dose-response curve	10:55:33
22		actually looks like, correct?	10:55:37

1	MS. PROCHNOW: Objection, form.	10:55:38
2	A Not with data up to the priority date of	10:55:47
3	the patent.	10:55:50
4	Q And you didn't look at data after the	10:55:52
5	priority date of the patent with respect to the	10:55:55
6	shape of the semaglutide dose-response curve,	10:55:57
7	correct?	10:56:00
8	MS. PROCHNOW: Objection, form.	10:56:01
9	A I probably have.	10:56:06
10	Q Did you do so for the purpose of your	10:56:13
11	report here?	10:56:16
12	MS. PROCHNOW: Objection, form.	10:56:16
13	A Please repeat that.	10:56:19
14	Q Did you look at data after the priority	10:56:20
15	date of the patent with respect to the shape of the	10:56:22
16	semaglutide dose-response curve in forming your	10:56:25
17	opinions here?	10:56:29
18	MS. PROCHNOW: Objection, form.	10:56:30
19	A No. I teach -- I give lectures about	10:56:34
20	pharmacokinetics and pharmacodynamics, and I have a	10:56:41
21	special interest in antidiabetic drugs. But I did	10:56:44
22	not need that later information to inform my	10:56:49

1	opinions in this case.	10:56:52
2	(Reporter interruption.)	10:56:59
3	Q And in your report, do you recall	10:57:17
4	discussing a variety of GLP-1 analogs?	10:57:19
5	MS. PROCHNOW: Objection, form.	10:57:22
6	A Indeed so.	10:57:24
7	Q And each of those GLP-1 analogs have	10:57:26
8	structures that differ from the native GLP-1.	10:57:30
9	Is that correct?	10:57:33
10	MS. PROCHNOW: Objection, form.	10:57:35
11	A I believe so.	10:57:37
12	Q And is it your opinion that those	10:57:39
13	modifications impact the potency of the GLP-1	10:57:41
14	analog?	10:57:45
15	MS. PROCHNOW: Objection, form.	10:57:46
16	A Probably, but I have not looked at that	10:57:49
17	information specifically for the others.	10:57:53
18	Q Do you have an opinion about whether the	10:57:57
19	modifications impact the dosing of the GLP-1 analog?	10:58:00
20	MS. PROCHNOW: Objection, form.	10:58:07
21	A I've seen the range of doses that are	10:58:11
22	being -- were being studied for the analog. So they	10:58:14

1 must impact the dose-response relationship. 10:58:20

2 Q Do you have an opinion about whether the 10:58:24
3 modifications impact the half-life of GLP-1 analog? 10:58:26

4 MS. PROCHNOW: Objection, form. 10:58:30

5 A The fact that the newer ones were being 10:58:35
6 touted or developed for once-weekly dosing, even 10:58:39
7 once-monthly dosing, means that the half-lives would 10:58:45
8 have been sufficiently long to allow that. 10:58:49

9 Q And the difference in structure impacted 10:58:53
10 the difference in half-life. 10:58:56

11 Is that correct? 10:58:57

12 MS. PROCHNOW: Objection, form. 10:58:59

13 A That would be so. 10:59:04

14 MS. RAYMOND: Thank you. 10:59:05

15 Could we please take a break, maybe about 10:59:06
16 ten minutes. 10:59:09

17 MS. PROCHNOW: Yes. 10:59:09

18 (Recess from 10:59 a.m. until 11:12 a.m.) 11:12:04

19 BY MS. RAYMOND: 11:12:04

20 Q Dr. Jusko, we were talking earlier about 11:12:05
21 the claim construction of the preamble and the 11:12:09
22 requirement for treating type 2 diabetes. 11:12:14

1 Do you recall that? 11:12:16

2 MS. PROCHNOW: Objection, form. 11:12:17

3 A Yes, I do. 11:12:20

4 But before we continue, I want to 11:12:22

5 apologize for all the repetitions of the questions, 11:12:24

6 because I have a hearing impairment, and even with 11:12:28

7 these, it's not perfect. 11:12:30

8 Q No worries. Well, if you need me to 11:12:32

9 repeat further, just let me know. 11:12:37

10 But going back to the preamble, and I 11:12:42

11 believe earlier you said that your understanding of 11:12:47

12 the construction of the preamble is that no 11:12:52

13 particular level of efficacy is required to meet the 11:12:55

14 treating type 2 diabetes limitation, correct? 11:12:58

15 MS. PROCHNOW: Objection, form. 11:13:01

16 A That's correct. 11:13:03

17 Q Okay. Is it your understanding that a 11:13:04

18 statistically insignificant decrease in HbA1c would 11:13:09

19 be sufficient to meet the requirement for treating 11:13:13

20 type 2 diabetes under that construction? 11:13:16

21 MS. PROCHNOW: Objection, form. 11:13:18

22 A That would be a clinical decision that 11:13:23

1 the doctor would make, depending on the severity of 11:13:28
2 the patient's illness, I suppose. 11:13:36

3 Q Okay. But in terms of your understanding 11:13:39
4 of what the claim construction of the preamble 11:13:42
5 means, would claim 1 be met if administering the 11:13:46
6 semaglutide as claimed resulted in a statistically 11:13:52
7 insignificant decrease in HbA1c? 11:13:57

8 MS. PROCHNOW: Objection, form. 11:14:01

9 A Probably not. 11:14:07

10 Q And why is that? 11:14:12

11 MS. PROCHNOW: Objection, form. 11:14:14

12 A Statistical significance is often a very 11:14:19
13 small change that may or may not correspond to 11:14:24
14 clinical significance. But treating diabetes 11:14:28
15 requires clinically meaningful change. 11:14:35

16 Q We were talking earlier about the shape 11:14:43
17 of the dose-response curve for semaglutide. 11:14:45

18 Do you recall that? 11:14:49

19 A Certainly. 11:14:52

20 Q Would you be surprised if semaglutide's 11:14:53
21 dose-response curve actually had a second plateau? 11:14:55

22 MS. PROCHNOW: Objection, form. 11:14:59

1 A Would you repeat that. 11:15:05

2 Q Would you be surprised if semaglutide's 11:15:06
3 dose-response curve actually had a second plateau? 11:15:08

4 A I would have to see what the data looked 11:15:21
5 like and what you mean by that. 11:15:24

6 Q With respect to the -- what you call the 11:15:35
7 range of doses that were used in the semaglutide 11:15:39
8 trials, would it have been possible to test doses at 11:15:44
9 intervals of less than 0.1 milligram? 11:15:51

10 MS. PROCHNOW: Objection, form. 11:15:55

11 A That possibility exists, but clinical 11:16:01
12 trials have to be reasonable in terms of the number 11:16:07
13 of increments and doses that it's feasible to 11:16:12
14 examine. 11:16:16

15 Q Would it be possible to administer to a 11:16:17
16 patient a dose of semaglutide that's in an interval 11:16:20
17 of less than 0.1 milligram? 11:16:28

18 MS. PROCHNOW: Objection, form. 11:16:30

19 A Doses less than 0.1 milligram would not 11:16:38
20 make any sense. 11:16:40

21 Q But you could administer a dose in less 11:16:43
22 than a 0.1 milligram increment to a patient, 11:16:45

1	correct?	11:16:50
2	MS. PROCHNOW: Objection, form.	11:16:50
3	A By "increment," you mean 8.1 versus 8.0?	11:16:52
4	Q For instance, it would be possible to	11:16:58
5	give a patient 0.27 milligrams of semaglutide,	11:17:01
6	correct?	11:17:08
7	MS. PROCHNOW: Objection, form.	11:17:08
8	A It's a theoretical possibility, but not a	11:17:15
9	very practical one.	11:17:18
10	Q Could you tell me how many hours you've	11:17:25
11	spent analyzing the validity of the '462 patent?	11:17:27
12	MS. PROCHNOW: Objection, form, scope.	11:17:31
13	And Megan, we discussed this. This came	11:17:33
14	up with Dr. Bantle yesterday. And if you intend to	11:17:37
15	ask questions about Dr. Jusko's District Court	11:17:40
16	report, these are -- we feel like these are	11:17:44
17	inappropriate for Dr. Jusko's IPR deposition.	11:17:48
18	They're outside of the scope of his reports.	11:17:52
19	And if you agree to limit the scope to	11:17:55
20	his IPR declaration and IPR work, he can answer the	11:18:00
21	questions.	11:18:05
22	MS. RAYMOND: Okay. Well, to make the	11:18:05

1	record, I'm going to ask the questions, and you can	11:18:07
2	object as you need and give the instructions that	11:18:10
3	you see fit.	11:18:13
4	MS. PROCHNOW: Well, maybe we should have	11:18:17
5	a conversation with Dr. Jusko outside of the room	11:18:18
6	about this, then. So we feel like it might be a	11:18:21
7	good idea to have this discussion not in front of	11:18:24
8	Dr. Jusko, so we can ask him to leave the room.	11:18:27
9	MS. RAYMOND: Okay.	11:18:32
10	MS. PROCHNOW: Okay.	11:18:33
11	Dr. Jusko, can you just give us a few	11:18:35
12	minutes.	11:18:37
13	THE WITNESS: I'm not offended.	11:18:38
14	(The witness left the deposition room.)	11:18:40
15	MS. PROCHNOW: Megan, this came up	11:18:57
16	yesterday, as you know, in Dr. Bantle's.	11:18:59
17	What we don't want to happen is for you	11:19:01
18	to, you know, ask the questions and then us object	11:19:04
19	and -- you know, Dr. Jusko's not going to be	11:19:07
20	answering questions about the District Court	11:19:10
21	proceeding.	11:19:12
22	We feel like that's entirely in bad	11:19:12

1 faith, considering that you've -- Novo has, you 11:19:14
2 know, given us their -- has told us that they're 11:19:20
3 intending to seek -- move to a motion for discovery 11:19:24
4 for -- regarding discovery from the Board. They 11:19:28
5 haven't done that yet. They don't have permission. 11:19:35

6 And if you continue to ask questions, you 11:19:38
7 know, we're going to instruct Dr. Jusko to not 11:19:43
8 answer those questions in District Court -- related 11:19:47
9 to District Court. But we'll also call the Board 11:19:50
10 and seek to move to terminate this line of 11:19:54
11 questioning. 11:19:58

12 MS. RAYMOND: Okay. Well -- and I think 11:19:58
13 I'm entitled to know what sort of analysis he's done 11:20:01
14 on, you know, the '462. What I will try to do is -- 11:20:04
15 I'll try to do my best. If I get to a series of 11:20:14
16 questions that are ones that I'm going to guess 11:20:18
17 you're not going to allow him to answer, I will try 11:20:21
18 to say -- you know, just ask you, like, is it 11:20:23
19 correct that you would not allow him to answer this 11:20:25
20 question, that question, or the third question. 11:20:28

21 MS. PROCHNOW: Well, I think that that's 11:20:30
22 the problem here is, you know, we want to make sure 11:20:33

1 that you're not then using that against us in some 11:20:35
2 motion later to say that's bad faith that we're, you 11:20:39
3 know, instructing our witness not to answer, because 11:20:43
4 what we would do is then seek leave right now, 11:20:45
5 before you keep asking these continued questions, 11:20:48
6 and seek leave from the Board or, you know, a motion 11:20:51
7 to terminate this line of questioning right now with 11:20:55
8 the Board. We can call the Board if you're going to 11:20:57
9 continue to ask these questions related to District 11:20:59
10 Court. 11:21:03

11 MS. RAYMOND: I'm going to try to get 11:21:03
12 through these questions. I will try to limit them 11:21:06
13 to the '462 IPR and what he's done. 11:21:09

14 MS. PROCHNOW: Okay. Well, that's what 11:21:15
15 we'd like you to do. 11:21:19

16 MS. RAYMOND: I do think it's fair for me 11:21:20
17 to make a record so that I know -- I don't know 11:21:22
18 right now, you know, exactly what I can ask with 11:21:25
19 your thinking it's proper or improper. I have some 11:21:28
20 ideas, but I don't know exactly. I can't know. 11:21:31

21 MS. PROCHNOW: Well, when you're asking 11:21:33
22 general questions the '462 patent and how much time, 11:21:35

1 it's so general that it sounds like you're trying to 11:21:39

2 figure out how much time he's spent -- 11:21:43

3 MS. RAYMOND: And yesterday, the witness 11:21:47

4 was allowed to answer that question. So you're 11:21:48

5 saying he's not allowed to answer today? 11:21:52

6 MS. PROCHNOW: That was because we didn't 11:21:53

7 know what direction you're taking, and you continued 11:21:54

8 to ask questions about the District Court 11:21:56

9 proceeding, trying to figure out, okay, this is the 11:21:58

10 total time you spent on the '462 patent, then how 11:22:01

11 much time -- 11:22:04

12 MS. RAYMOND: Just because something 11:22:05

13 impacts -- is it your position that just because 11:22:07

14 something impacts the District Court litigation or 11:22:09

15 may be indicative of something that's going on in 11:22:11

16 the District Court litigation that I'm not entitled 11:22:14

17 to know it even though it relates to the '462 11:22:16

18 invalidity analysis and the work that this expert 11:22:20

19 has done on analyzing the '462 patent? 11:22:23

20 MS. PROCHNOW: We think it's proper for 11:22:27

21 you to ask questions that relate to the '462 patent 11:22:29

22 analysis with respect to the IPR proceeding. 11:22:33

1 MS. RAYMOND: Okay. 11:22:38

2 MS. PROCHNOW: And that's what you said 11:22:39

3 that you would try to limit your questions to, and I 11:22:40

4 appreciate that. And that's what we wanted to make 11:22:43

5 sure happens because it wasn't happening yesterday 11:22:45

6 in Dr. Bantle's deposition. 11:22:47

7 MS. RAYMOND: Well, I think we have a 11:22:49

8 little bit of a -- I don't know if we fully see eye 11:22:51

9 to eye on that, but I will do my best with these 11:22:56

10 questions to not ask things that are particular to 11:23:00

11 the litigation. 11:23:10

12 I do think I'm entitled to get 11:23:11

13 information, but I understand that you're not going 11:23:14

14 to let me ask those questions, and we'll take that 11:23:16

15 up in our discovery requests to the extent that -- 11:23:20

16 we'll be seeking the discovery that you're not going 11:23:25

17 to give us here. 11:23:28

18 MS. PROCHNOW: You've already said that 11:23:30

19 you intend to seek that discovery. You know that 11:23:31

20 you need to from the Board. You haven't. And we 11:23:33

21 feel like you're going on a fishing expedition here 11:23:36

22 to try to get the answers through the witnesses 11:23:40

1 inappropriately and in bad faith. And so that's why

11:23:42

2 if it continues --

11:23:45

3 MS. RAYMOND: I understand your position.

11:23:46

4 I think I'm entitled to ask simple questions about

11:23:47

5 how much time he spent analyzing the '462 patent

11:23:50

6 validity and things like that, but I will try to

11:23:55

7 limit my questions, and we will seek discovery in a

11:23:57

8 way that may be more burdensome.

11:24:00

9 MS. PROCHNOW: Well, I think you're

11:24:03

10 entitled to ask that question with respect to the

11:24:05

11 IPR proceeding.

11:24:07

12 MS. RAYMOND: But -- no, I'm entitled to

11:24:09

13 ask him about what other work he's done, other

11:24:12

14 consulting work he's done, you know, a list -- if he

11:24:16

15 has a list of previous cases. I'm allowed to ask

11:24:17

16 him about that. So the litigation is no different

11:24:20

17 than a list of other cases in which he's previously

11:24:22

18 testified and done analysis.

11:24:25

19 MS. PROCHNOW: But you're not asking for

11:24:26

20 a list of cases. You were asking for something that

11:24:28

21 is specific to the District Court proceeding. And

11:24:32

22 we know that you're --

11:24:35

1 MS. RAYMOND: Right. But just because 11:24:37
2 it's specific to the District Court proceeding 11:24:39
3 doesn't make it any different than any other 11:24:40
4 analysis that he has done for another proceeding, 11:24:42
5 and I am entitled to ask certain questions about 11:24:45
6 that. 11:24:47

7 But I understand we have a difference, 11:24:47
8 and I will try to limit my questions to the '462 IPR 11:24:49
9 proceedings. 11:24:55

10 MS. PROCHNOW: Okay. We'll get 11:24:56
11 Dr. Jusko. 11:25:03

12 (The witness returned to the deposition 11:25:31
13 room.) 11:25:34

14 BY MS. RAYMOND: 11:25:58

15 Q Okay. Dr. Jusko, are you ready? Can you 11:25:59
16 hear me? 11:26:02

17 A Yes, I can. 11:26:03

18 Q Okay. Have you been retained by anyone 11:26:04
19 but Mylan to perform analysis on the '462 IPR? 11:26:07

20 A Not that I know of. 11:26:13

21 Q And have you communicated with any 11:26:17
22 attorneys other than the ones from Perkins Coie in 11:26:45

1 connection with analyzing the invalidity of the '462 11:26:48

2 patent in connection with the IPR? 11:26:52

3 A The only attorneys I have interacted with 11:26:56

4 regarding the IPR are the Perkins Coie attorneys, 11:26:59

5 that I know of. 11:27:04

6 Q And do you provide a bill to Mylan or 11:27:53

7 Perkins Coie specifically for the IPR? 11:27:58

8 A Yes, I have. 11:28:02

9 Q And that bill has only time for the IPR 11:28:09

10 on it, correct? 11:28:11

11 MS. PROCHNOW: Objection, form, scope. 11:28:12

12 A I have not been aware of the need for 11:28:19

13 billing other than for the IPR. 11:28:22

14 Q And how much time have you spent 11:28:25

15 performing your analysis for the '462 IPR? 11:28:29

16 A Please repeat that. 11:28:35

17 Q How much time have you spent working on 11:28:37

18 your analysis for the '462 IPR? In this case, how 11:28:40

19 much time have you spent? 11:28:46

20 A 30 to 40 hours that I've billed for. 11:28:48

21 MS. RAYMOND: If we could take a short 11:29:50

22 break, then I think we can wrap up quickly after 11:29:52

1	that.	11:29:56
2	MS. PROCHNOW: Okay.	11:29:56
3	(Recess from 11:29 a.m. until 11:54 a.m.)	11:54:24
4	BY MS. RAYMOND:	11:54:24
5	Q Dr. Jusko, during the break, did you	11:54:24
6	speak with counsel about the substance of your	11:54:26
7	testimony today?	11:54:28
8	A No, I did not.	11:54:29
9	Q How much has Mylan paid you for your work	11:54:32
10	on the '462 IPR?	11:54:34
11	MS. PROCHNOW: Objection, form.	11:54:38
12	A Oh, they haven't paid me everything they	11:54:46
13	owe me yet. But it's probably about 30,000.	11:54:51
14	Q So have you billed about \$30,000 to Mylan	11:54:55
15	for the '462 IPR?	11:54:59
16	A No. I would have billed for more than	11:55:01
17	that.	11:55:04
18	Q Approximately how much have you billed	11:55:05
19	Mylan for your work on the '462 IPR?	11:55:07
20	MS. PROCHNOW: Objection, form.	11:55:10
21	A I'm thinking it could be between 30- and	11:55:19
22	\$40,000 for the IPR.	11:55:24

1	Q And other than your work for Mylan on the	11:55:35
2	'462 IPR, has Mylan paid you for -- how much total	11:55:40
3	has Mylan paid you for all of your expert work	11:55:46
4	across any work you've done for them as an expert?	11:55:51
5	MS. PROCHNOW: Okay. I'm going to object	11:55:53
6	to form and scope and instruct Dr. Jusko not to	11:55:55
7	answer that question.	11:55:57
8	And if you continue that line of	11:55:58
9	questioning, we can call the Board and move to	11:55:59
10	terminate the line of questioning.	11:56:04
11	MS. RAYMOND: So I can't know how much	11:56:08
12	he's been paid total by Mylan for expert work,	11:56:11
13	correct? That's a yes?	11:56:14
14	MS. PROCHNOW: If you're intending to	11:56:16
15	seek his expert work with respect to the '462	11:56:18
16	patent, and with respect to generally, because, you	11:56:28
17	know -- we feel that it's inappropriate because	11:56:33
18	you're trying to go on a fishing expedition and	11:56:37
19	trying to get the answers about District Court in	11:56:40
20	other ways.	11:56:44
21	MS. RAYMOND: So I can't ask if he's been	11:56:44
22	retained by Mylan for expert work other than for the	11:56:47

1	'462 patent?	11:56:49
2	MS. PROCHNOW: You can ask that.	11:56:50
3	MS. RAYMOND: Okay.	11:56:53
4	Q Have you been retained by Mylan for	11:56:53
5	expert work for anything other than the '462 patent?	11:56:55
6	A Only for the '462 patent.	11:57:04
7	Q And I think these questions are okay	11:57:14
8	because they don't get into the issues -- I'll try	11:57:21
9	this.	11:57:23
10	You're also an expert on invalidity in	11:57:24
11	the '462 litigation, correct? Just yes or no.	11:57:27
12	MS. PROCHNOW: Objection, form.	11:57:32
13	Q Are you also an expert -- sorry.	11:57:32
14	MS. PROCHNOW: You can ask your question.	11:57:34
15	Q Are you also an expert on invalidity on	11:57:37
16	the '462 in District Court litigation?	11:57:41
17	MS. PROCHNOW: Objection, form.	11:57:44
18	Objection, scope.	11:57:47
19	And Dr. Jusko, you can answer yes or no.	11:57:53
20	A I guess yes.	11:58:02
21	Q And have you provided expert reports on	11:58:04
22	the validity of the '462 patent in District Court?	11:58:07

1	Yes or no.	11:58:14
2	MS. PROCHNOW: Megan, again, this is	11:58:15
3	outside of the scope of his IPR proceeding, and he's	11:58:17
4	not going to be answering questions about District	11:58:21
5	Court litigation today.	11:58:25
6	MS. RAYMOND: Okay. This is the question	11:58:27
7	that I have. I'm not going to follow up from there.	11:58:30
8	So...	11:58:32
9	MS. PROCHNOW: Well, I don't know that,	11:58:33
10	so -- yesterday it went a different direction. So,	11:58:34
11	you know, if this is the only question that you're	11:58:40
12	asking, he can --	11:58:42
13	Q Yes or no, Dr. Jusko. Have you provided	11:58:44
14	reports on the validity of the '462 patent in	11:58:47
15	District Court litigation?	11:58:50
16	MS. PROCHNOW: Objection, form.	11:58:51
17	Objection, scope.	11:58:53
18	You can answer yes or no, Dr. Jusko.	11:58:54
19	A Yes.	11:58:56
20	MS. RAYMOND: And Courtney, I assume you	11:58:59
21	won't let him answer if he's been retained by anyone	11:59:00
22	but Mylan for work analyzing the validity of the	11:59:03

1	'462 patent or if he's been paid by anyone but Mylan	11:59:05
2	or Perkins Coie for work analyzing the validity of	11:59:08
3	the '462 patent. Correct?	11:59:11
4	MS. PROCHNOW: That would be outside of	11:59:12
5	the scope.	11:59:13
6	And if you continue to do this, Megan,	11:59:13
7	we'll call the Board. We can ask Dr. Jusko to	11:59:15
8	leave. And this is continuing --	11:59:18
9	MS. RAYMOND: I understand. I have no	11:59:20
10	further questions. I was just trying to make sure	11:59:22
11	that those were questions that I can't ask today.	11:59:24
12	So that's fine. I have no further questions.	11:59:29
13	MS. PROCHNOW: Okay. We'll take a break	11:59:33
14	and -- do you have no further questions at all or no	11:59:35
15	further questions on that line?	11:59:43
16	MS. RAYMOND: I have no further questions	11:59:44
17	at all. I pass the witness.	11:59:45
18	MS. PROCHNOW: Okay. We'll take a break.	11:59:46
19	(Recess from 11:59 a.m. until 12:36 p.m.)	12:36:46
20	MS. PROCHNOW: We have no questions.	12:36:46
21	Thank you for your time, Dr. Jusko.	12:36:47
22	THE WITNESS: You're welcome.	12:36:52

1	(Transcript orders discussed.)	12:36:56
2	COURT REPORTER: Thank you. That's all I	12:37:33
3	need.	12:37:35
4	(Off the record at 12:37 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

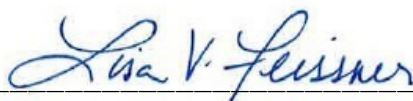
7 That WILLIAM J. JUSKO, Ph.D., the witness
8 whose deposition is hereinbefore set forth, was duly
9 sworn by me before the commencement of such
10 deposition, and that such deposition was taken
11 before me and is a true record of the testimony
12 given by such witness.
13

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 WILLIAM J. JUSKO, Ph.D., occurred REMOTELY on
20 FRIDAY, JULY 12, 2024, commencing at 10:02 and
21 concluding at 12:37.
22

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 

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