

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 [REDACTED]

13
14 Oral deposition of
15 DeFOREST McDUFF, Ph.D.

16
17 WASHINGTON, DC

18 FRIDAY, JULY 19, 2024

19 10:13 a.m. EASTERN TIME

20 Job No.: 543602

21 Pages: 1 - 72

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

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2
3 Oral deposition of DeFOREST McDUFF,
4 Ph.D., held at the offices of:

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C O N T E N T S

EXAMINATION OF DeFOREST McDUFF, Ph.D. PAGE

By Mr. May 6

E X H I B I T S

(Attached to transcript)

EXHIBIT PAGE

Ex. 2610 trackdrugs.com printout (two pages) 45

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)

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Transcript of DeForest McDuff, Ph.D.
Conducted on July 19, 2024

6

P R O C E E D I N G S

DeFOREST McDUFF, Ph.D.,

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

EXAMINATION

BY MR. MAY:

Q Can you please state and spell your name
for the record.

A Yes. DeForest McDuff, D-E capital
F-O-R-E-S-T, M-C capital D-U-F-F.

Q Who is your current employer?

A Insight Economics LLC and University of
North Carolina at Chapel Hill.

Q Dr. McDuff, you've been deposed before,
correct?

A Yes.

Q So I won't go over the full ground rules.
I assume you're familiar with the deposition
process, give yes, no answers, not speaking over
each other.

A Yes, that's fine.

Q I will do my best today to ask clear

10:13:47

10:13:47

10:13:47

10:13:47

10:13:50

10:13:50

10:13:55

10:13:59

10:14:01

10:14:05

10:14:08

10:14:12

10:14:12

10:14:13

10:14:17

10:14:18

10:14:23

10:14:23

10:14:24

PLANET DEPOS

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Novo Nordisk Exhibit 2555
Mylan Pharms. Inc. v. Novo Nordisk A/S
IPR2023-00724
Page 00006

1	questions. However, in the event that I do not do	10:14:29
2	so or you have any questions, please ask me for	10:14:31
3	clarification, okay?	10:14:34
4	A I'll do my best.	10:14:34
5	Q If you don't ask me for clarification,	10:14:35
6	I'm going to assume that you understood the	10:14:37
7	questions I've posed.	10:14:39
8	Is that fair?	10:14:39
9	A Again, I'll do my best.	10:14:40
10	Q Is there anything that would prevent you	10:14:42
11	from giving truthful and accurate testimony today?	10:14:56
12	A No.	10:14:59
13	(Previously marked Exhibit 1308 presented	10:14:59
14	to the witness.)	10:14:59
15	BY MR. MAY:	10:14:59
16	Q You have in front of you a copy of your	10:14:59
17	declaration in this case marked as Exhibit 1308?	10:15:03
18	A Yes, that's right.	10:15:08
19	Q And that's a full copy, including all	10:15:11
20	appendices?	10:15:14
21	A Yes.	10:15:15
22	Q So Dr. McDuff, if I can turn you to	10:15:20

1 paragraph 15 of your declaration. 10:15:30

2 A Okay. 10:15:44

3 Q So it's your opinion that there is only a 10:15:45

4 limited connection between the claimed commercial 10:15:48

5 success and novel contributions of the claimed 10:15:51

6 subject matter of the patent at issue here? 10:15:53

7 MR. WHITE: Objection to form. 10:15:56

8 A Yes. 10:15:58

9 Q And what do you mean by "a limited 10:16:02

10 connection"? 10:16:06

11 A In evaluating nexus, we refer to the 10:16:09

12 degree of connection between the claimed subject 10:16:12

13 matter and the product performance. And here I'm 10:16:15

14 saying that that is a limited or somewhat weak 10:16:17

15 connection. 10:16:22

16 Q Do you dispute marketplace success for 10:16:23

17 Ozempic? 10:16:28

18 MR. WHITE: Object to form. 10:16:29

19 A What do you mean by that? 10:16:32

20 Q Is it your opinion that Ozempic has not 10:16:33

21 been a commercial success? 10:16:36

22 A It depends what you mean by "commercial 10:16:38

1 success" in that context. Could you clarify?

10:16:41

2 Q Well, how can I clarify for you better?

10:16:43

3 I think that question is pretty clear.

10:16:47

4 A I would say it like this. As indicated

10:16:49

5 in my declaration, I agree that Ozempic has achieved

10:16:53

6 a certain amount of product success overall, but

10:16:57

7 that that product success does not necessarily bear

10:16:59

8 on the claimed invention of the '462 patent.

10:17:05

9 Q What do you mean by "a certain amount of

10:17:07

10 product success"?

10:17:09

11 A What I mean is, clearly Ozempic has

10:17:11

12 earned significant sales, yet there are some

10:17:22

13 limitations to Dr. Vellturo's analysis, which I set

10:17:28

14 forth in my declaration.

10:17:33

15 Q So just to make sure I understand, you're

10:17:35

16 not disputing that Ozempic, as the drug, is a

10:17:37

17 commercial success, right?

10:17:39

18 MR. WHITE: Objection, form.

10:17:40

19 A It depends what you mean by "commercial

10:17:41

20 success." As a secondary consideration, I think

10:17:43

21 it's more complicated. In terms of its product

10:17:45

22 performance, I am not disputing that it has achieved

10:17:50

1	a certain product success overall.	10:17:53
2	Q You keep saying "a certain product	10:17:54
3	success." What do you mean by "certain"?	10:17:57
4	A Well, "product success" is not very well	10:18:00
5	defined. It depends what you mean by "product	10:18:03
6	success."	10:18:06
7	Q Is it your opinion that Ozempic is not	10:18:06
8	successful as a product?	10:18:08
9	MR. WHITE: Object to the form.	10:18:10
10	A I'm not putting it that way.	10:18:11
11	Q So it's not -- it is not your opinion	10:18:14
12	that Ozempic is not commercially successful?	10:18:17
13	MR. WHITE: Object to the form.	10:18:22
14	A That's a hard question to answer. I'm	10:18:23
15	not sure what you're asking.	10:18:25
16	Q Yeah, that's fair. So let me try that	10:18:26
17	again.	10:18:29
18	You are not opining that Ozempic has not	10:18:30
19	been commercially successful, correct?	10:18:37
20	MR. WHITE: Objection to form.	10:18:40
21	A It depends what you mean by that. I'm	10:18:43
22	evaluating commercial success as a secondary	10:18:46

1 consideration. And I've got many opinions on that. 10:18:49
2 It's not a black or white, yes or no type of 10:18:51
3 opinion. 10:18:54

4 Q If you can turn to paragraph 21 of your 10:19:02
5 declaration, please. 10:19:05

6 And for today's purposes, when I say 10:19:08
7 "your declaration," you'll understand that that's 10:19:10
8 Exhibit 1308, right? 10:19:12

9 A Yes, of course. 10:19:13

10 Q So in paragraph 21 of your declaration, 10:19:14
11 you identify some criticisms of Dr. Vellturo's 10:19:19
12 opinion. Specifically starting at around the second 10:19:24
13 sentence, you criticize him for not providing an 10:19:27
14 analysis of profits, costs, or risk-adjusted returns 10:19:29
15 associated with the claimed subject matter, even 10:19:33
16 though these factors are commonly evaluated for 10:19:36
17 commercial success. 10:19:39

18 Do you see that? 10:19:39

19 A Yes. 10:19:40

20 Q What's your basis for saying that those 10:19:42
21 factors are commonly evaluated for commercial 10:19:46
22 success? 10:19:48

1	A	I've worked on many cases as an expert on	10:19:55
2		the topic of commercial success. I'm very familiar	10:19:59
3		with case law on commercial success. I'm familiar	10:20:02
4		with publications on commercial success.	10:20:04
5		And profits and the profit motive is a	10:20:08
6		core part of what commercial success is about, from	10:20:10
7		an economic perspective.	10:20:13
8	Q	Have you undertaken an analysis of the	10:20:16
9		profits, costs, or risk-adjusted returns associated	10:20:19
10		with the claimed subject matter?	10:20:22
11	A	I have not because that information was	10:20:24
12		not provided by Dr. Vellturo.	10:20:25
13	Q	If you can turn to paragraph 26 of your	10:20:44
14		declaration.	10:20:47
15		In paragraph 26, you criticize	10:20:53
16		Dr. Vellturo for evaluating Ozempic in the context	10:21:01
17		of the modern noninsulin antidiabetics market, the	10:21:05
18		MNIAD market.	10:21:16
19		Do you see that?	10:21:17
20	A	Yes.	10:21:17
21	Q	And it's your opinion that that market is	10:21:17
22		unnecessarily limiting?	10:21:18

1	A	Yes.	10:21:21
2	Q	What do you believe the appropriate	10:21:22
3		market would be?	10:21:24
4	A	In my view, the right market definition	10:21:30
5		would be treatments of type 2 diabetes.	10:21:33
6	Q	All treatments of type 2 diabetes?	10:21:37
7	A	Generally, yes, with some limitations.	10:21:43
8	Q	What are those limitations?	10:21:46
9	A	For example, you might not include things	10:21:48
10		like exercise and diet, but treatments that are	10:21:50
11		medicines or insulins would be included in that	10:21:53
12		definition.	10:21:56
13	Q	And what's your basis for using that as	10:21:57
14		the market definition rather than the MNIAD market	10:22:01
15		definition?	10:22:06
16	A	That's how economists think about market	10:22:06
17		definition in the pharmaceuticals industry, which	10:22:09
18		is, what are the potential products available to	10:22:12
19		treat the diagnosis of interest. That's how	10:22:15
20		economists think about the market.	10:22:20
21	Q	Did you cite any sources in your	10:22:22
22		declaration that confirm that that's how economists	10:22:25

1	think about the market?	10:22:27
2	A I don't recall, but I think that's pretty	10:22:33
3	well understood.	10:22:35
4	Q Turning to the second half of the	10:22:43
5	paragraph 26 on page 15 of your declaration, you	10:22:52
6	state that, The low share of GLP-1s in the diabetes	10:22:55
7	market at priority would have provided more limited	10:23:00
8	incentives for development.	10:23:02
9	Do you see that?	10:23:05
10	A Yes.	10:23:06
11	Q So "at priority," you're referring --	10:23:07
12	what date are you referring to for "at priority"?	10:23:11
13	A Give me just a minute to look at my	10:23:15
14	declaration.	10:23:25
15	I'm referring to the claimed priority of	10:23:34
16	the '462 patent. To my understanding, that's in or	10:23:38
17	around 2012.	10:23:40
18	Q Why would the low share of GLP-1s in the	10:23:46
19	diabetes market, according to you, as of 2012	10:23:50
20	provide more limited incentives for development?	10:23:51
21	(Reporter interruption.)	10:24:29
22	Q Why would the low share of GLP-1s in the	10:24:31

1	diabetes market, according to you, as of 2012	10:24:36
2	provide more limited incentives for development?	10:24:39
3	A Because that represents a relatively	10:24:43
4	smaller market opportunity, all else being equal.	10:24:45
5	Q So I want to unpack that a little bit.	10:24:49
6	How does it represent a relatively	10:24:57
7	smaller market opportunity?	10:24:59
8	A If GLP-1s have a low share of the market,	10:25:00
9	that's a smaller opportunity for GLP-1s.	10:25:03
10	Q It's not possible for the GLP-1 share to	10:25:07
11	grow?	10:25:10
12	A I'm not saying it's not possible.	10:25:13
13	Q How does the fact that it's low as of	10:25:18
14	2012 mean that it disincentivized a researcher from	10:25:22
15	exploring GLP-1 opportunities?	10:25:28
16	MR. WHITE: Object to form.	10:25:31
17	A If one thinks about the market	10:25:34
18	opportunity for GLP-1s and it's relatively small	10:25:37
19	around the time of the priority because the share is	10:25:39
20	low, that represents a smaller opportunity for	10:25:41
21	products.	10:25:45
22	Q You would agree the GLP-1 share of the	10:25:46

1	diabetes treatment marketplace has exploded since	10:25:49
2	2012, correct?	10:25:52
3	MR. WHITE: Objection to form.	10:25:53
4	A I haven't used that language.	10:25:55
5	Q That's fair. You would agree that the	10:25:57
6	share of GLP-1s in the diabetes marketplace has	10:25:59
7	increased since 2012, correct?	10:26:02
8	A I agree with that.	10:26:04
9	Q Are you aware of by what degree it has	10:26:05
10	increased since 2012?	10:26:09
11	MR. WHITE: Objection to form.	10:26:19
12	A I don't have the figures in front of me	10:26:19
13	right now.	10:26:21
14	Q You included a figure in your declaration	10:26:33
15	on page 16. This is Figure 1. And this comes from	10:26:35
16	a Novo Nordisk 2017 market overview presentation?	10:26:41
17	A Yes.	10:26:45
18		10:26:49
19		10:26:51
20		10:26:56
21		10:26:59
22		10:27:02

1	[REDACTED]	10:27:03
2	[REDACTED]	10:27:06
3	[REDACTED]	10:27:15
4	Q If you can turn to paragraph 31 of your	10:27:29
5	declaration. About halfway down the paragraph on	10:27:32
6	page 18, you have a statement that says, Notably,	10:27:45
7	Dr. Goland testified that she had not reviewed any	10:27:48
8	prior art to the '462 patent.	10:27:51
9	Do you see that?	10:27:54
10	A Yes.	10:27:55
11	Q Why was that notable to you?	10:27:56
12	A It's notable because the idea of	10:28:04
13	coextensiveness is whether the claimed invention	10:28:07
14	aligns with the product overall.	10:28:13
15	And if Dr. Goland is advising	10:28:15
16	Dr. Vellturo on coextensiveness and she has not	10:28:19
17	reviewed the prior art, I don't see how she can make	10:28:22
18	a conclusion of coextensiveness if she doesn't	10:28:24
19	compare what is allegedly innovative about the '462	10:28:29
20	patent to what existed before the '462 patent.	10:28:32
21	Q Do you have any independent opinions on	10:28:37
22	what is new in the '462 patent as opposed to what	10:28:41

1	existed in the prior art?	10:28:45
2	A I'm not providing a technical opinion of	10:28:48
3	that kind. I'm providing an economic analysis.	10:28:50
4	Q And who are you relying on for your	10:28:56
5	technical information?	10:28:58
6	A Give me just a moment.	10:29:12
7	I'm relying upon Dr. Spiegel and	10:29:22
8	Dr. Schwartzbard.	10:29:26
9	Q And are you relying solely on their	10:29:28
10	declarations submitted in this IPR?	10:29:31
11	A Yes.	10:29:35
12	Q Did you ever have any communications with	10:29:36
13	either Dr. Spiegel or Dr. Schwartzbard?	10:29:39
14	A No.	10:29:41
15	Q And did you only review the declarations	10:29:42
16	from them in their final signed form?	10:29:45
17	A Yes.	10:29:47
18	Q You didn't review any drafts at all	10:29:48
19	during your process of drafting your report?	10:29:50
20	A I did not.	10:29:52
21	Q Aside from the information you've	10:29:54
22	received from Dr. Spiegel and Dr. Schwartzbard, you	10:30:02

1	don't have any independent technical opinions	10:30:04
2	regarding coextensiveness, right?	10:30:08
3	A That's correct.	10:30:10
4	Q And you also -- aside from the	10:30:11
5	information you received from Dr. Spiegel and	10:30:13
6	Dr. Schwartzbard, you don't have any independent	10:30:16
7	opinions on how the '462 patent reads onto Ozempic,	10:30:18
8	right?	10:30:27
9	A In terms of technical opinions, I'm not	10:30:30
10	providing those.	10:30:32
11	Q So if you turn to paragraph 33 of your	10:30:50
12	declaration.	10:30:56
13	A Okay.	10:31:00
14	Q About halfway down the paragraph, you	10:31:01
15	state, At best, the novel aspects of the '462 patent	10:31:03
16	are limited to the 1.0 milligram dosing regimen (and	10:31:07
17	even this is disputed).	10:31:13
18	Do you see that?	10:31:14
19	A Yes.	10:31:15
20	Q What's your basis for that opinion?	10:31:15
21	A My basis is my understanding from counsel	10:31:22
22	and the Spiegel reply declaration as well as what is	10:31:27

1 being asserted by Novo Nordisk here in this
2 proceeding.

3 Q I guess -- so what is your understanding
4 of what that means for the novel aspects of the '462
5 patent to be limited to the 1.0 milligram dosing
6 regimen?

7 A What I understand that to mean is that in
8 terms of what's claimed and novel for the '462
9 patent, it's only the specific amount of dosing, the
10 1.0 milligrams, compared to prior art, which prior
11 art includes the active ingredient, dosing ranges,
12 and other elements of treatment.

13 Q What's your basis for understanding that
14 the prior art includes the active ingredient, dosing
15 range, and other elements of treatment?

16 A That's described elsewhere in my
17 declaration. I believe I go into it in some detail.

18 Q You said your basis for understanding
19 from this sentence was based on Dr. Schwartzbard and
20 Dr. Spiegel and also from counsel.

21 Is that right?

22 A Yes.

1 Q How did counsel inform your
2 understanding?

3 A I discussed my declaration with counsel
4 as I was writing it, and they helped me understand
5 the technical aspects in terms of what was alleged
6 to be novel about the '462 patent.

7 Q So this is not an independent opinion
8 that you have regarding the novel aspects of the
9 '462 patent, correct?

10 A I agree with that. This is my
11 understanding as an economist.

12 Q If you can turn to paragraph 39 of your
13 declaration.

14 A Okay.

15 Q And specifically the second half of
16 paragraph 39 on page 24.

17 You write that, absent a 1.0 milligram
18 dosing regimen, certain of the same patients could
19 have been treated with alternative dosing regimens
20 that do not fall within the scope of the '462 patent
21 (e.g., by remaining on a 0.5 milligram dose...)

22 Do you see that?

1	A	Yes.	10:34:43
2	Q	And for that sentence, you cite to	10:34:44
3		Dr. Spiegel's reply declaration at paragraphs 220 to	10:34:49
4		222.	10:34:52
5		Is that right?	10:34:54
6	A	Yes.	10:34:54
7		MR. MAY: If we can take a look at	10:34:55
8		Dr. Spiegel's declaration, which is Exhibit 1302.	10:34:57
9		(Previously marked Exhibit 1302 presented	10:34:57
10		to the witness.)	10:35:11
11		BY MR. MAY:	10:35:11
12	Q	So I've handed you Exhibit 1302, which is	10:35:19
13		Dr. Spiegel's reply declaration. And if we can	10:35:22
14		please turn to paragraphs 220 through 222 located on	10:35:25
15		page 76.	10:35:28
16	A	Okay, I'm there.	10:35:40
17	Q	All right. In paragraph 220,	10:35:41
18		Dr. Spiegel, second sentence from the bottom,	10:35:47
19		writes, The label instructs to depart from this	10:35:53
20		initial treatment dose only if, with emphasis on	10:35:56
21		only if, quote, additional glycemic control is	10:35:59
22		needed after at least four weeks on the 0.5	10:36:03

1	milligram dosage, end quote.	10:36:06
2	Do you see that?	10:36:08
3	A Yes.	10:36:09
4	Q So Dr. Spiegel is saying that you only	10:36:10
5	depart from the 0.5 milligram dosage to the 1.0	10:36:14
6	milligram dosage only if additional glycemic control	10:36:19
7	is needed, right?	10:36:23
8	A I see that language here.	10:36:24
9	Q And then in paragraph 222, Dr. Spiegel	10:36:29
10	also explains, starting towards the end of the	10:36:35
11	second line of that paragraph, the 1.0 milligram	10:36:39
12	dose is reached only if additional glycemic control	10:36:42
13	is needed after a patient uses the 0.5 milligram	10:36:46
14	dose for at least four weeks.	10:36:49
15	Do you see that?	10:36:52
16	A Yes.	10:36:53
17	Q And you don't have any reason to disagree	10:36:54
18	with Dr. Spiegel, right?	10:36:56
19	A I'm not offering any disagreement with	10:36:58
20	Dr. Spiegel.	10:37:00
21	Q So you understand that Dr. Spiegel says	10:37:04
22	that the only reason you would go to 1.0 milligram	10:37:06

1 is if additional glycemic control is needed after 10:37:09

2 having tried the 0.5 milligram dose, right? 10:37:13

3 A I would defer to Dr. Spiegel for whether 10:37:18
4 that's an accurate paraphrase. I see some of the 10:37:20
5 language here that you just said in his declaration. 10:37:23

6 Q You can put Dr. Spiegel's declaration 10:37:29
7 away for right now. Well, we're going to come back 10:37:31
8 to it soon. 10:37:46

9 If you turn to paragraph 44 of your 10:37:47
10 declaration. And specifically the portion on 10:37:51
11 page 26. 10:37:57

12 You write that you understand that other 10:38:02
13 Ozempic patents listed in the FDA Orange Book cover 10:38:06
14 the compound, device, and other features. 10:38:09

15 Do you see that? 10:38:12

16 A Yes. 10:38:14

17 Q Do you have any technical understanding 10:38:17
18 for how the other Ozempic patents listed in the FDA 10:38:20
19 Orange Book relate to Ozempic? 10:38:23

20 A No. I'm not providing a technical 10:38:29
21 evaluation of those patents. In this paragraph, I'm 10:38:31
22 simply pointing out that Dr. Vellturo should have 10:38:35

1 analyzed the other patents listed in the Orange Book
2 as part of his nexus analysis.

3 Q If you can turn back to Dr. Spiegel's
4 declaration, which is Exhibit 1302. And if you can
5 turn to paragraph 49 of Dr. Spiegel's declaration,
6 and section heading V.

7 A Okay, I'm there.

8 Q And section heading V, is Relevant Novo
9 Nordisk Patents and Claims.

10 Do you see that?

11 A Yes.

12 Q And then in paragraph 49, Dr. Spiegel
13 goes on to say that, Among the patents listed --
14 sorry. Strike that.

15 In paragraph 49, starting at the bottom
16 of page 24, Dr. Spiegel says, Among the patents
17 listed in the Orange Book for Ozempic, are U.S.
18 Patent Nos. 8,114,833, 8,129,343, 8,536,122 and
19 10,335,462.

20 Do you see that?

21 A Yes.

22 Q And then Dr. Spiegel has a footnote,

1	footnote number 5, states that, I am informed that	10:39:56
2	other Orange Book patents relate to devices and so	10:40:00
3	are not relevant here.	10:40:03
4	Do you see that?	10:40:05
5	A Yes.	10:40:06
6	Q Do you have any basis to disagree with	10:40:06
7	Dr. Spiegel?	10:40:08
8	A I'm not disagreeing with Dr. Spiegel's	10:40:12
9	perspective here, yet they still may be relevant to	10:40:16
10	an economic evaluation of nexus.	10:40:20
11	Q And Dr. Spiegel is who you rely on for	10:40:23
12	your technical understanding of the patents involved	10:40:25
13	here, correct?	10:40:27
14	A That's true.	10:40:28
15	Q Okay. I want to shift gears for a little	10:40:30
16	bit to talk about your opinions regarding off-label	10:40:51
17	usage. So can we turn to paragraph 53.	10:40:56
18	You cite to a Washington Post article in	10:41:04
19	support of your opinions.	10:41:08
20	Is that correct?	10:41:10
21	A Yes.	10:41:10
22	Q The Washington Post article, is that a	10:41:12

1	peer-reviewed journal article?	10:41:16
2	A No, it's not.	10:41:21
3	Q And the Washington Post article is	10:41:22
4	relying on data from Trilliant Health, as you note,	10:41:24
5	correct?	10:41:29
6	A Yes.	10:41:29
7	Q And then you cite to the Trilliant Health	10:41:30
8	report itself, right?	10:41:33
9	A Yes.	10:41:33
10	MR. MAY: So if we can take a look at	10:41:35
11	that, Exhibit 1184.	10:41:37
12	(Previously marked Exhibit 1184 presented	10:41:37
13	to the witness.)	10:42:13
14	BY MR. MAY:	10:42:13
15	Q So Exhibit 1184, this is the Trilliant	10:42:14
16	Health report that you reference and that the	10:42:19
17	Washington Post referenced?	10:42:21
18	A Yes.	10:42:23
19	Q So if we can look at page 43 of	10:42:25
20	Exhibit 1184, which you cited to in your report.	10:42:37
21	A Yes.	10:42:45
22	Q This chart states -- this graphic states	10:42:47

1 that, Across major markets, there has been an
2 increase in the number of unique patients taking
3 Ozempic (semaglutide) who have a history of
4 overweight, obesity and other hyperalimentation.

5 Do you see that?

6 A Yes.

7 Q What percentage of patients with type 2
8 diabetes have a history of overweight, obesity, and
9 other hyperalimentation?

10 A I don't know, sitting here.

11 Q How does this tell you that the usage of
12 Ozempic in patients who have a history of
13 overweight, obesity and other hyperalimentation is
14 off-label usage?

15 A As you can see in the title, this study
16 is explaining that Ozempic uptake is often
17 disproportionate to diabetes prevalence. So what
18 they're saying is that increases in Ozempic use does
19 not depend on the prevalence of diabetes in an area.

20 And the idea there is, that's because
21 nondiabetic patients are using Ozempic, and the
22 growth is being driven by patients that do not have

1 diabetes.

10:44:22

2 Q This doesn't state that these patients
3 that have a history of overweight, obesity and other
4 hyperalimentation do not have type 2 diabetes,
5 correct?

10:44:23

10:44:25

10:44:28

10:44:31

6 A Which patients are you talking about?

10:44:31

7 Q I'm reading from the figure. It says
8 that there's been an increase in the number of
9 unique patients taking Ozempic who have a history of
10 overweight, obesity and other hyperalimentation.

10:44:33

10:44:38

10:44:40

10:44:43

11 That doesn't tell you whether or not
12 those unique patients do or do not have type 2
13 diabetes, correct?

10:44:47

10:44:48

10:44:51

14 A The way I read this is that there is
15 on-label use and there is off-label use which varies
16 by market. You can see that in the third sentence.
17 And that because the uptake of Ozempic is not
18 proportional to diabetes prevalence, that's clear
19 evidence of off-label use. That's the point of this
20 slide, as I understand it.

10:44:56

10:45:01

10:45:03

10:45:07

10:45:10

10:45:14

10:45:16

21 Q You'd agree with me, this does not tell
22 you that the increase in the number of unique

10:45:21

10:45:23

1 patients taking Ozempic who have a history of 10:45:26
2 overweight, obesity and other hyperalimentation does 10:45:28
3 not include patients who have type 2 diabetes? 10:45:34

4 A My reading of this is that it includes 10:45:38
5 some patients that have type 2 diabetes and some 10:45:41
6 patients who do not. 10:45:43

7 Q Is this direct evidence of off-label 10:45:52
8 usage? 10:45:56

9 MR. WHITE: Objection to form. 10:45:56

10 A Yes, as I think of the term. 10:45:59

11 Q How do you think of the term "direct 10:46:03
12 evidence"? 10:46:07

13 A I think of that as evaluations of data 10:46:09
14 that indicate off-label use directly. I'm using 10:46:19
15 that term in contrast to Dr. Vellturo's analysis of 10:46:23
16 Ozempic use before and after Wegovy coming to the 10:46:29
17 market. I view that as an indirect analysis. 10:46:32

18 Q Dr. Vellturo looked at actual prescribing 10:46:36
19 data, correct? 10:46:39

20 A He looked at overall prescribing data, 10:46:40
21 but he did not distinguish between on-label and 10:46:43
22 off-label prescribing data. 10:46:46

1 Q Does this chart distinguish between 10:46:47
2 off-label and on-label prescribing data? 10:46:51

3 A It does not provide a breakdown, yet it 10:47:06
4 does indicate that there's both on-label and 10:47:09
5 off-label use. 10:47:12

6 Q How many patients are included in here 10:47:14
7 who do not have type 2 diabetes? 10:47:15

8 A I don't believe the number of patients is 10:47:20
9 provided here. 10:47:22

10 Q What percentage of patients that's 10:47:23
11 included here does not have type 2 diabetes? 10:47:24

12 A In this particular study? Is that what 10:47:29
13 you're asking? 10:47:31

14 Q Yes. 10:47:32

15 A I don't see that figure here in the 10:47:33
16 study. 10:47:36

17 Q Is that figure anywhere in this report? 10:47:37

18 A I'm not sure. 10:47:41

19 Q You also cite to, in paragraph 55, an 10:48:08
20 analysis by Komodo Health? 10:48:11

21 A Yes. 10:48:17

22 Q And you use that to come up with -- 10:48:18

1	strike that.	10:48:24
2	You use that to explain numbers of	10:48:24
3	off-label usage that you describe further in	10:48:31
4	Appendix C-1.	10:48:35
5	Is that right?	10:48:36
6	A Yes.	10:48:36
7	Q So if we could turn to Appendix C-1.	10:48:37
8	A Okay.	10:48:50
9	Q So your source for the off-label Ozempic	10:48:51
10	prescriptions is identified in bracketed note A, and	10:48:56
11	it indicates, Exhibit 1172, Komodo Health, and	10:49:00
12	Exhibit 1185, Track Drugs.	10:49:05
13	Is that right?	10:49:09
14	A Yes.	10:49:09
15	Q Did you rely on -- those are the only two	10:49:10
16	sources you relied on for the data provided here in	10:49:13
17	Appendix C-1 for off-label Ozempic prescriptions?	10:49:16
18	A Yes.	10:49:19
19	MR. MAY: So let's go ahead and take a	10:49:20
20	look at Exhibit 1172, the Komodo Health article.	10:49:21
21	(Previously marked Exhibit 1172 presented	10:49:21
22	to the witness.)	10:49:35

1 BY MR. MAY:

10:49:35

2 Q Apologies that it's tiny print, but
3 that's how we got it.

10:49:35

10:49:37

4 A No problem. I can read it.

10:49:41

5 Q So if you look at -- so you've got in
6 front of you Exhibit 1172. That's the Komodo Health
7 report that you cite, correct?

10:49:49

10:49:53

10:49:58

8 A Yes.

10:49:59

9 Q And looks like on page 2, there is a bar
10 graph that says, Prescriptions in Non-Diabetic
11 Adults.

10:50:02

10:50:09

10:50:16

12 Is that right?

10:50:17

13 A Yes.

10:50:17

14 Q Is this the source of the data that
15 you're saying for off-label Ozempic prescriptions?

10:50:18

10:50:21

16 A Yes, I believe so.

10:50:29

17 Q Nothing about this -- strike that.

10:50:33

18 This bar graph also includes
19 prescriptions for Wegovy, right?

10:50:37

10:50:41

20 A Yes.

10:50:44

21 Q And prescribing Wegovy in nondiabetic
22 adults is not off-label usage, right?

10:50:45

10:50:49

1	A	I don't have an opinion on that.	10:50:53
2	Q	Does this chart state that this is --	10:50:56
3		strike that.	10:51:04
4		Did you look at any of the underlying	10:51:05
5		data supporting this Komodo Health article?	10:51:11
6	A	What are you referring to?	10:51:19
7	Q	Did you look at any of the data that	10:51:20
8		underlies what Komodo Health is reporting here in	10:51:24
9		their bar charts?	10:51:28
10	A	I don't recall doing that, no.	10:51:36
11	Q	What's your understanding for how Komodo	10:51:37
12		Health has determined the number of prescriptions in	10:51:42
13		nondiabetic adults?	10:51:45
14	A	As indicated in the article, they have a	10:52:03
15		health care analytics platform where they are able	10:52:04
16		to track prescriptions for patients with and without	10:52:07
17		diabetes over the last five years. You can see that	10:52:11
18		on page 1.	10:52:13
19		And then on page 1, they indicate that	10:52:14
20		roughly 25 percent of all prescriptions were written	10:52:17
21		for patients without diabetes, suggesting off-label	10:52:20
22		use for at least Ozempic, Mounjaro and Rybelsus.	10:52:25

1 Q 25 percent of all prescriptions for 10:52:33
2 Ozempic, Mounjaro, Rybelsus, and Wegovy combined, 10:52:36
3 right? 10:52:40

4 A I don't think Wegovy is included in that 10:52:41
5 list. They're just saying Ozempic, Mounjaro, and 10:52:44
6 Rybelsus. 10:52:52

7 Q You would agree the bold statement above 10:52:52
8 that says that more than 5 million prescriptions for 10:52:54
9 Ozempic, Mounjaro, Rybelsus, or Wegovy were written 10:52:57
10 for weight management? 10:53:01

11 A Yes, I see that. 10:53:02

12 Q So when they say 25 percent of all 10:53:04
13 prescriptions, your understanding is that that 10:53:15
14 excludes Wegovy? 10:53:17

15 A It may. Looking at this, it seems a bit 10:53:20
16 ambiguous. 10:53:42

17 Q Do you have an understanding of how 10:53:46
18 Komodo Health's health care analytics platform 10:53:50
19 evaluates whether or not a patient does or does not 10:53:54
20 have diabetes? 10:53:56

21 A I've not gone into that level of detail, 10:54:12
22 yet I presume that they have patient information, 10:54:15

1 either patient or prescription information, if 10:54:17
2 they're able to categorize it as with or without 10:54:18
3 diabetes. 10:54:21

4 Q But you don't have any firsthand 10:54:25
5 knowledge of that, correct? 10:54:27

6 A I don't know the details beyond what's 10:54:29
7 written in this article. 10:54:30

8 Q This bar chart doesn't include any 10:54:42
9 specific numbers for the different drug segments. 10:54:44

10 You would agree with that, right? 10:54:46

11 A What do you mean by "that"? 10:54:51

12 Q Sorry. The bar chart is not labeled to 10:54:52
13 tell you what exactly, for example, the size of the 10:54:54
14 bar in 2019 is? 10:55:00

15 A The bars themselves are not labeled, but 10:55:04
16 there is a Y axis with figures that are labeled. 10:55:06

17 Q And so the specific numbers in 10:55:09
18 Appendix C-1, do those specific numbers come from 10:55:15
19 this bar chart? 10:55:18

20 A They may have. They certainly appear to 10:55:33
21 correspond with the size of the bars. 10:55:35

22 Q But the exact size of the bars is not 10:55:41

1	indicated in this Komodo Health article, correct?	10:55:45
2	A What do you mean by that? I can see the	10:55:50
3	size of the bars in this figure.	10:55:52
4	Q The Y axis is labeled with increments of	10:55:55
5	2 million, correct?	10:55:59
6	A Yes.	10:56:01
7	Q So looking, for example, at the bar in	10:56:03
8	2019, just looking at the bar, how are you able to	10:56:08
9	assess that that bar is equivalent to 230,000?	10:56:11
10	A There's one of two ways.	10:56:17
11	One is doing a proportionality analysis.	10:56:19
12	Sometimes my team does an analysis where you can	10:56:23
13	zoom in on the figure and determine the ratio of the	10:56:26
14	size of the bar to the Y axis to get a best estimate	10:56:30
15	of what is the number underlying that bar. It's	10:56:33
16	very possible that's what our team did here.	10:56:37
17	The second alternative is that there's a	10:56:40
18	second source cited in Appendix C-1. I'd want to	10:56:41
19	look at that source to see whether the figures are	10:56:44
20	directly reported in that source.	10:56:46
21	Either way, the figures in Appendix C-1	10:56:48
22	provide a good representation of what is reported by	10:56:52

1 Komodo Health.

10:56:57

2 Q So looking at this bar chart, are you
3 able to tell how many Wegovy prescriptions in
4 nondiabetic adults were written in 2021?

10:57:04

10:57:06

10:57:09

5 A Yes. Around 1,200,000.

10:57:20

6 Q Are you able to say how many Wegovy
7 prescriptions were written for nondiabetic adults in
8 2022?

10:57:24

10:57:26

10:57:29

9 A Yes. As indicated in my Appendix C-1,
10 around 2.2 million.

10:57:29

10:57:32

11 Q Sorry. Wegovy prescriptions.

10:57:34

12 A I'm sorry. You're asking about Wegovy,
13 or you're asking about Ozempic?

10:57:36

10:57:38

14 Q I'm asking about Wegovy.

10:57:40

15 MR. WHITE: Objection, scope.

10:57:42

16 A I haven't recorded those values. But you
17 can approximate them based on the size of the green
18 bar.

10:57:44

10:57:47

10:57:50

19 Q And that would be an approximation?

10:57:50

20 A Yes.

10:57:55

21 MR. MAY: If we can take a look at
22 Exhibit 1185, which is the other source cited in

10:57:56

10:57:58

1 Appendix C-1.

10:58:03

2 (Previously marked Exhibit 1185 presented
3 to the witness.)

10:58:03

10:58:06

4 BY MR. MAY:

10:58:06

5 Q This is an article from TrackDrugs.

10:58:08

6 Is that right?

10:58:11

7 A Yes.

10:58:12

8 Q What is TrackDrugs?

10:58:12

9 A TrackDrugs is a company that reports on
10 pharmaceutical data.

10:58:31

10:58:33

11 Q Have you ever used TrackDrugs in any of
12 your other economic analyses?

10:58:34

10:58:37

13 A I don't recall.

10:58:40

14 Q Have you ever used a report from
15 TrackDrugs outside of this specific article reported
16 at Exhibit 1185?

10:58:42

10:58:45

10:58:50

17 A I don't know. I don't remember.

10:58:51

18 Q Does TrackDrugs say -- strike that.

10:58:53

19 Does TrackDrugs have any reports
20 available besides a report on Ozempic?

10:58:59

10:59:02

21 A I'm not sure.

10:59:12

22 Q Do you know who the team is behind

10:59:14

1	TrackDrugs?	10:59:16
2	A No, not sitting here.	10:59:19
3	Q Do you know if there are any economists	10:59:21
4	that support TrackDrugs?	10:59:24
5	A I don't know.	10:59:26
6	Q Do you know if there are any health care	10:59:27
7	professionals that support TrackDrugs?	10:59:29
8	A I don't know, not sitting here.	10:59:33
9	Q So if you turn in the Exhibit 1185 to, I	10:59:35
10	believe it's page 5, there's a heading that says,	10:59:50
11	Ozempic Prescriptions for Non-Diabetic Adults.	11:00:00
12	A Yes.	11:00:04
13	Q If you turn to page 6, it states, Here's	11:00:08
14	a table that contains the full prescriptions data.	11:00:11
15	And it provide years 2019 through 2022 with numbers	11:00:18
16	that match those in your Appendix C-1.	11:00:21
17	Do you see that?	11:00:23
18	A Yes.	11:00:24
19	Q And then for source, it says, Komodo	11:00:25
20	Health. Correct?	11:00:30
21	A Correct.	11:00:32
22	Q It doesn't provide any details on what in	11:00:33

1 Komodo Health -- or how Komodo Health provided those 11:00:37
2 numbers, correct? 11:00:40

3 A There's no detail here, yet the figures 11:00:42
4 do appear to match the Komodo Health report that we 11:00:44
5 were looking at in the prior exhibit. 11:00:48

6 Q What's your understanding of how these 11:00:58
7 numbers are report -- strike that. 11:01:02

8 What's your understanding of how the 11:01:04
9 numbers in the TrackDrugs article, Exhibit 1185, 11:01:07
10 were derived from the -- from Komodo Health? 11:01:11

11 A That level of detail is not reported 11:01:19
12 here. Yet looking at the figures in comparison with 11:01:21
13 the chart from the Komodo Health report, they do 11:01:23
14 appear to match up. 11:01:27

15 Q And you have no information on where -- 11:01:30
16 strike that. 11:01:35

17 And you've never reviewed the underlying 11:01:36
18 data in the Komodo Health article, right? 11:01:39

19 A I have reviewed the Komodo Health article 11:01:45
20 and their descriptions of the data, but I have not 11:01:56
21 seen the underlying data that they used to create 11:02:00
22 their charts. 11:02:03

1	Q	And this chart -- strike that.	11:02:08
2		This chart provides, according to you,	11:02:14
3		identification of off-label Ozempic prescriptions,	11:02:26
4		correct?	11:02:29
5	A	Which chart are you referring to?	11:02:32
6	Q	The chart in TrackDrugs at 1185, page 6,	11:02:33
7		which you just stated reflects the bar chart from	11:02:41
8		Komodo Health, 1172.	11:02:45
9	A	So in response to your prior question,	11:02:49
10		yes, because these are Ozempic prescriptions for	11:02:52
11		nondiabetic adults.	11:02:55
12	Q	This doesn't break down the prescriptions	11:02:58
13		into specific dosage forms of Ozempic, does it?	11:03:00
14	A	It does not.	11:03:05
15	Q	This doesn't tell you how many of these	11:03:06
16		alleged off-label Ozempic prescriptions are for the	11:03:08
17		1 milligram dose, correct?	11:03:11
18	A	It does not.	11:03:13
19	Q	And it doesn't tell you if any of this	11:03:14
20		alleged off-label usage is higher or lower for the	11:03:16
21		1 milligram dose as opposed to any other strength,	11:03:19
22		correct?	11:03:22

1	A	Correct, it does not.	11:03:22
2	Q	Is there a reason you didn't endeavor to	11:03:23
3		break that information down any further?	11:03:26
4	A	It wasn't necessary for my opinions.	11:03:28
5	Q	It wasn't necessary for you to look at	11:03:31
6		the individual dosage forms?	11:03:33
7	A	Not for the opinions I'm providing in my	11:03:36
8		section on off-label use.	11:03:38
9	Q	Why is it not relevant to your opinions	11:03:44
10		on off-label use?	11:03:46
11		MR. WHITE: Objection to form.	11:03:48
12	A	Because even if a dosage form is	11:03:52
13		1.0 milligrams, it would still be off-label use for	11:03:57
14		a patient that does not have diabetes.	11:04:00
15	Q	It is mathematically possible that none	11:04:03
16		of these off-label usage -- none of these off-label	11:04:07
17		usage prescriptions are for the 1 milligram dosage,	11:04:10
18		correct?	11:04:13
19	A	That does not strike me as likely.	11:04:15
20	Q	I didn't ask if it's likely. But it is	11:04:17
21		mathematically possible, correct?	11:04:19
22	A	I don't know what you mean by that.	11:04:21

1 Q You don't have any information in here 11:04:23
2 about the relative share of off-label usage between 11:04:24
3 any of the dosage strengths that you're reporting in 11:04:27
4 Exhibit C-1, correct? 11:04:30

5 A I don't have a breakdown of these 11:04:32
6 prescriptions, yet I assume that they are for a 11:04:34
7 range of dosage strengths, just like Ozempic is when 11:04:36
8 used for diabetes patients. 11:04:41

9 Q How would you assess what 1 milligram 11:04:42
10 prescriptions were being written off-label, based on 11:04:44
11 this data? 11:04:47

12 A The summary tables don't report that 11:04:48
13 level of detail. You'd have to have more detailed 11:04:50
14 data to run that analysis. 11:04:54

15 Q And you don't think that analysis is 11:04:56
16 necessary for your opinion on off-label usage? 11:04:57

17 A Correct. 11:05:00

18 MR. MAY: Why don't we go ahead and take 11:05:02
19 a short break. 11:05:04

20 THE WITNESS: Okay. 11:05:06

21 (Recess from 11:05 a.m. until 11:19 a.m.) 11:19:31

22 MR. MAY: I'm going to go ahead and mark 11:19:31

1	a document as Exhibit 2610.	11:19:34
2	(Exhibit 2610 marked for identification	11:19:34
3	and attached to the transcript.)	11:19:47
4	MR. WHITE: We reserve our rights to	11:19:47
5	object to this.	11:19:50
6	BY MR. MAY:	11:19:50
7	Q Dr. McDuff, this is the home page for	11:19:52
8	trackdrugs.com, as indicated by the URL on the	11:19:57
9	bottom left-hand corner of the document.	11:19:59
10	Do you see that?	11:20:02
11	A Yes, I see the URL.	11:20:03
12	Q Have you visited the home page for	11:20:07
13	trackdrugs.com before?	11:20:08
14	A I don't remember.	11:20:10
15	Q Looking here, you see that there's a	11:20:11
16	reference to -- there's an option to, Read our	11:20:15
17	latest [sic] report on page 1 of this document.	11:20:20
18	A Yes.	11:20:24
19	Q And then it refers you to -- then there's	11:20:24
20	a section called, Our Latest Reports. It says a	11:20:27
21	report on, Ozempic Statistics and Trends in 2024.	11:20:31
22	Do you see that?	11:20:40

1	A	Yes.	11:20:40
2	Q	Do you see any other reports listed on	11:20:40
3		this home page for trackdrugs.com other than this	11:20:45
4		Ozempic report?	11:20:48
5	A	No, nothing else in this exhibit.	11:20:49
6	Q	You can put that aside.	11:20:52
7		If I can turn you to paragraph 60 in your	11:21:01
8		declaration.	11:21:22
9		Now, in paragraph 60 of your declaration,	11:21:29
10		you provide your opinion that Novo Nordisk was	11:21:31
11		engaging in a strategy of product conversion from	11:21:35
12		Victoza?	11:21:37
13	A	Yes.	11:21:38
14	Q	[REDACTED]	11:21:40
15		[REDACTED]	11:21:45
16		[REDACTED]	11:21:49
17		[REDACTED], and then you copy in a clip of a	11:21:52
18		document as Figure 4 in your declaration, correct?	11:21:56
19	A	Yes.	11:21:58
20	Q	And it's indicated that that figure comes	11:21:59
21		from an Exhibit 2332?	11:22:03
22	A	Yes.	11:22:06

1 MR. MAY: Let's go ahead and take a look 11:22:09
2 at Exhibit 2332. 11:22:10
3 (Previously marked Exhibit 2332 presented 11:22:11
4 to the witness.) 11:22:13
5 BY MR. MAY: 11:22:13
6 Q So if you look at Exhibit 2332, you've 11:22:31
7 cited to page 19 of this document for this figure. 11:22:34
8 Is that correct? 11:22:39
9 A Yes. 11:22:40
10 Q And it's your opinion that [REDACTED] 11:22:41
11 [REDACTED] 11:22:46
12 [REDACTED]? 11:22:52
13 A Can you repeat the question, please? 11:22:59
14 Q It's your opinion that [REDACTED] 11:23:03
15 [REDACTED] 11:23:07
16 [REDACTED]? 11:23:12
17 A Yes, it's one piece of evidence towards 11:23:20
18 that opinion. 11:23:23
19 Q If you can look at page 20 of that same 11:23:24
20 document, Exhibit 2332. Sorry. Can you look at 11:23:32
21 page 21 using the exhibit numbers on the bottom 11:23:42
22 right-hand corner of the page looking vertically at 11:23:46

1	it. Sorry. I appreciate it's confusing. Let me	11:23:50
2	try this over again.	11:23:53
3	There is page numbers underneath the Novo	11:23:54
4	Nordisk logo, and then there's page numbers	11:23:57
5	underneath the IPR number.	11:23:59
6	So if you can please turn to page 21 of	11:24:00
7	Exhibit 2332 using the IPR page number.	11:24:03
8	A Page 21?	11:24:06
9	Q Yes.	11:24:07
10	A Okay, I'm there.	11:24:08
11	Q You see that reading across, this says	11:24:09
12	that [REDACTED]	11:24:12
13	[REDACTED],	11:24:15
14	correct?	11:24:20
15	A Yes, I see that.	11:24:20
16	Q And if you turn to the next page,	11:24:22
17	page 22, again, you see that the [REDACTED]	11:24:29
18	[REDACTED]	11:24:32
19	[REDACTED], correct?	11:24:36
20	A Yes. These appear to be for different	11:24:40
21	categories.	11:24:42
22	Q You would agree, then, that [REDACTED]	11:24:46

1	[REDACTED] -- strike that.	11:24:50
2	Accepting your interpretations document,	11:24:56
3	you would agree that [REDACTED]	11:24:59
4	[REDACTED]	11:25:02
5	[REDACTED]?	11:25:05
6	A Yes, I think that's fair.	11:25:08
7	Q You also cite to -- in paragraph 62 of	11:25:15
8	your declaration, you indicated that, a 2018 Novo	11:25:32
9	Nordisk Ozempic confidential product development	11:25:41
10	plan [REDACTED]	11:25:43
11	[REDACTED].	11:25:46
12	Do you see that?	11:25:48
13	A Yes.	11:25:48
14	Q How does that support your opinion on --	11:25:50
15	that [REDACTED]	11:25:55
16	[REDACTED]?	11:25:57
17	A It's part of the evidence I present in my	11:26:06
18	declaration of [REDACTED]	11:26:12
19	[REDACTED]	11:26:17
20	[REDACTED]	11:26:24
21	[REDACTED].	11:26:27
22	MR. MAY: If we can take a look at	11:26:36

1	Exhibit 2308.	11:26:38
2	(Previously marked Exhibit 2308 presented	11:26:38
3	to the witness.)	11:26:41
4	BY MR. MAY:	11:26:41
5	Q So Exhibit 2308, this is the Confidential	11:26:54
6	Product Development Plan that you referenced --	11:26:58
7	A Yes.	11:27:00
8	Q -- correct?	11:27:01
9	I want to take you to page 6 of this	11:27:06
10	document.	11:27:09
11	A Okay.	11:27:14
12	Q If you can look under the heading of	11:27:14
13	Executive Summary, and the final paragraph, it says,	11:27:17
14	[REDACTED]	11:27:23
15	[REDACTED]	11:27:28
16	[REDACTED]	11:27:31
17	[REDACTED]	11:27:34
18	[REDACTED].	11:27:37
19	Do you see that?	11:27:40
20	A Yes.	11:27:41
21	Q You would agree that [REDACTED]	11:27:41
22	[REDACTED]	11:27:45

1	[REDACTED]?	11:27:48
2	A I see that language here in the document.	11:27:58
3	[REDACTED]	11:28:04
4	[REDACTED].	11:28:08
5	Q Under what circumstances, in your	11:28:12
6	opinion, could a pharmaceutical company release a	11:28:27
7	second-generation product that is superior to its	11:28:30
8	first-generation product [REDACTED]	11:28:34
9	[REDACTED]?	11:28:42
10	MR. WHITE: Objection, form, foundation,	11:28:44
11	scope.	11:28:46
12	A Every situation is different. I'm not	11:28:47
13	trying to opine on all situations or give a global	11:28:49
14	opinion of that kind. I'm just commenting on what I	11:28:52
15	see here [REDACTED]	11:28:55
16	[REDACTED].	11:28:59
17	Q What do you mean by [REDACTED]	11:28:59
18	[REDACTED]?	11:29:03
19	A [REDACTED]	11:29:04
20	[REDACTED]	11:29:07
21	[REDACTED]	11:29:09
22	[REDACTED]	11:29:14

1		11:29:16
2		11:29:18
3		11:29:23
4		11:29:27
5		11:29:28
6		11:29:31
7		11:29:33
8	MR. WHITE: Objection, form, scope.	11:29:35
9		11:29:36
10		11:29:38
11	MR. WHITE: Same objections.	11:29:39
12		11:29:40
13		11:29:43
14		11:29:45
15		11:29:47
16		11:29:50
17	MR. WHITE: Objection, form, scope.	11:29:52
18		11:29:54
19		11:29:56
20	Q Are there any benefits to Ozempic as	11:30:01
21	opposed to Victoza?	11:30:04
22	MR. WHITE: Objection to form.	11:30:07

1	A	There may be. I'm not providing an	11:30:11
2		assessment of that.	11:30:14
3	Q	Are there reasons why patients would want	11:30:14
4		to be on Ozempic as opposed to Victoza?	11:30:17
5	MR. WHITE:	Objection, form.	11:30:19
6	A	That strikes me as a clinical question.	11:30:20
7		I'm not providing opinions on that.	11:30:22
8	Q	And you haven't considered that in	11:30:24
9		forming your opinion on product conversion?	11:30:25
10	A	I haven't gone into any detail on that.	11:30:28
11	MR. MAY:	If we can pull up Exhibit 2314.	11:30:55
12		(Previously marked Exhibit 2314 presented	11:30:55
13		to the witness.)	11:31:01
14	BY MR. MAY:		11:31:01
15	Q	Dr. McDuff, Exhibit 2314 is a document we	11:31:14
16		discussed a little earlier as a source for Figure 1	11:31:18
17		in your report.	11:31:22
18		Do you recall that?	11:31:23
19	A	Yes.	11:31:23
20	Q	Now, using the IPR exhibit page numbers,	11:31:24
21		could you please turn to page 9 of Exhibit 2314.	11:31:30
22	A	Okay.	11:31:37

1	Q	You see this is a slide headed, GLP-	11:31:37
2		[REDACTED]	11:31:45
3	A	Yes.	11:31:48
4		[REDACTED]	11:31:49
5		[REDACTED]	11:31:53
6		[REDACTED]	11:31:58
7		[REDACTED]	11:32:04
8		[REDACTED]	11:32:08
9		[REDACTED]	11:32:09
10		[REDACTED]	11:32:09
11		[REDACTED]	11:32:10
12		[REDACTED]	11:32:12
13		[REDACTED]	11:32:15
14		MR. WHITE: Objection, form.	11:32:17
15		[REDACTED]	11:32:18
16		[REDACTED]	11:32:21
17		[REDACTED]	11:32:24
18		[REDACTED]	11:32:26
19	Q	You relied on this document in forming	11:32:27
20		your opinions, correct?	11:32:29
21	A	Yes.	11:32:30
22	Q	And in forming your opinions, you	11:32:40

1 reviewed Dr. Vellturo's report, correct?

11:32:43

2 A Yes.

11:32:45

3 MR. MAY: If we can grab Dr. Vellturo's
4 report, which is 1308. No, that's the wrong number.
5 2300.

11:32:47

11:32:49

11:32:56

6 (Previously marked Exhibit 2300 presented
7 to the witness.)

11:32:56

11:33:00

8 BY MR. MAY:

11:33:00

9 Q All right. So Exhibit 2300 is
10 Dr. Vellturo's declaration in this IPR proceeding,
11 correct?

11:33:11

11:33:15

11:33:19

12 A Yes.

11:33:20

13 Q And if we can turn to page 89 of
14 Dr. Vellturo's report. And just to be confusing,
15 there I'm referring to the internal pagination, not
16 the IPR exhibit number.

11:33:23

11:33:36

11:33:51

11:33:54

17 A Understood. I think I'm on the right
18 page.

11:33:56

11:33:58

19 Q Okay. You see a figure here, [REDACTED]

11:33:58

20 [REDACTED]

11:34:03

21 [REDACTED]

11:34:06

22 A Yes.

11:34:08

1	[REDACTED]	11:34:09
2	[REDACTED]	11:34:19
3	[REDACTED]	11:34:22
4	[REDACTED]	11:34:23
5	[REDACTED]	11:34:24
6	[REDACTED]	11:34:24
7	[REDACTED]	11:34:32
8	[REDACTED]	11:34:36
9	[REDACTED]	11:34:42
10	MR. WHITE: Objection, form.	11:34:43
11	[REDACTED]	11:34:45
12	[REDACTED]	11:34:48
13	[REDACTED]	11:34:52
14	[REDACTED]	11:34:58
15	[REDACTED]	11:35:04
16	[REDACTED]	11:35:07
17	[REDACTED]	11:35:08
18	[REDACTED]	11:35:16
19	[REDACTED]	11:35:25
20	[REDACTED]	11:35:40
21	[REDACTED]	11:35:41
22	[REDACTED]	11:35:46

1	[REDACTED]	11:35:49
2	[REDACTED]	11:35:55
3	[REDACTED]	11:35:56
4	[REDACTED]	11:36:03
5	[REDACTED]	11:36:07
6	[REDACTED]	11:36:16
7	[REDACTED]	11:36:34
8	[REDACTED]	11:36:41
9	[REDACTED]	11:36:44
10	[REDACTED]	11:36:48
11	[REDACTED]	11:36:49
12	[REDACTED]	11:36:54
13	[REDACTED]	11:37:01
14	[REDACTED]	11:37:06
15	[REDACTED]	11:37:08
16	[REDACTED]	11:37:10
17	[REDACTED]	11:37:11
18	[REDACTED]	11:37:26
19	[REDACTED]	11:37:39
20	[REDACTED]	11:37:42
21	[REDACTED]	11:37:52
22	[REDACTED]	11:37:58

1	[REDACTED]	11:38:04
2	[REDACTED]	11:38:10
3	[REDACTED]	11:38:14
4	[REDACTED]	11:38:15
5	[REDACTED]	11:38:16
6	[REDACTED]	11:38:21
7	Q If you can turn to paragraph 66 of your	11:38:45
8	declaration.	11:38:56
9	Here you're criticizing Dr. Vellturo for	11:39:07
10	relying on a promotion-to-sales ratio as opposed to	11:39:10
11	absolute marketing?	11:39:14
12	Is that a fair assessment of your	11:39:15
13	opinions in paragraph 66?	11:39:17
14	A I wouldn't describe it quite like that.	11:39:23
15	I'm just saying that he ignores the absolute	11:39:27
16	marketing level and only focuses on the ratio.	11:39:29
17	Q Do you think the ratio is irrelevant to	11:39:33
18	the question of whether marketing spend impacts	11:39:37
19	commercial success?	11:39:42
20	A No, I wouldn't say that.	11:39:43
21	[REDACTED]	11:39:45
22	[REDACTED]	11:39:54

1	[REDACTED]	11:39:59
2	[REDACTED]	11:40:01
3	[REDACTED]	11:40:14
4	[REDACTED]	11:40:21
5	[REDACTED]	11:40:26
6	MR. WHITE: Objection to form.	11:40:31
7	[REDACTED]	11:40:33
8	[REDACTED]	11:40:36
9	[REDACTED]	11:40:40
10	[REDACTED]	11:40:42
11	[REDACTED]	11:40:43
12	[REDACTED]	11:40:46
13	[REDACTED]	11:40:49
14	[REDACTED]	11:40:52
15	[REDACTED]	11:40:56
16	[REDACTED]	11:40:57
17	[REDACTED]	11:40:58
18	[REDACTED]	11:41:00
19	[REDACTED]	11:41:03
20	[REDACTED]	11:41:06
21	MR. WHITE: Objection to form.	11:41:08
22	[REDACTED]	11:41:20

1	[REDACTED]	11:41:21
2	[REDACTED]	11:41:24
3	Q I want to shift gears and talk about your	11:41:54
4	opinions related to blocking patents. If you can	11:42:00
5	turn to paragraph 73.	11:42:08
6	In your declaration, you identify, in	11:42:19
7	addition to the '343 and '122 patents that	11:42:22
8	Dr. Vellturo analyzed, you state that at least one	11:42:25
9	other patent also provided blocking disincentives,	11:42:29
10	the '833 patent.	11:42:33
11	Do you see that?	11:42:35
12	A Yes, I do.	11:42:35
13	Q What is the basis for your understanding	11:42:36
14	that the '833 patent provided blocking	11:42:41
15	disincentives?	11:42:44
16	A The basis is described throughout this	11:42:47
17	section of my declaration because I analyze multiple	11:42:49
18	aspects of the '833 patent.	11:42:53
19	In terms of the scope of the '833 patent,	11:42:55
20	which is what's written here in paragraph 73, I'm	11:42:58
21	relying upon the Spiegel reply declaration.	11:43:01
22	Q So your understanding, as you've written	11:43:06

1 it here, is that the '833 patent covers certain
2 pharmaceutical formulations of a GLP-1 agonist like
3 semaglutide.

11:43:08

11:43:11

11:43:20

4 Do you see that?

11:43:21

5 A Yes.

11:43:21

6 Q Now, you note in paragraph 80 -- with
7 respect to the '833 patent, you note that the '833
8 patent was known at least as early as June 2005,
9 correct?

11:43:22

11:43:34

11:43:38

11:43:43

10 A Yes.

11:43:44

11 Q And it's your opinion that as of June
12 2005, the '833 patent provided a disincentive --
13 strike that.

11:43:45

11:43:48

11:44:01

14 It's your opinion that as of June 2005,
15 the '833 patent would have disincentivized
16 development of products within the scope of the '833
17 patent, correct?

11:44:01

11:44:04

11:44:08

11:44:12

18 A Correct.

11:44:16

19 Q Since June 2005, are you aware of how
20 many GLP-1 pharmaceutical formulations have been
21 approved?

11:44:21

11:44:30

11:44:32

22 A No, not sitting here. I don't know the

11:44:36

1	number.	11:44:38
2	Q Is it greater than three?	11:44:38
3	A I don't know.	11:44:42
4	Q Since June 2005, are you aware of other	11:44:44
5	companies besides Novo Nordisk researching in the	11:44:49
6	GLP-1 space?	11:44:52
7	A I believe there's been at least some	11:44:58
8	other GLP-1 products that have come to market. So I	11:45:03
9	presume there's related research by other companies	11:45:07
10	to bring those products to market.	11:45:09
11	Q And those are non-Novo Nordisk companies,	11:45:11
12	correct?	11:45:13
13	A That's what I had in mind, yes.	11:45:14
14	Q Such as Eli Lilly?	11:45:15
15	A Potentially. I don't know which	11:45:18
16	companies, sitting here. I've not listed them in my	11:45:21
17	report.	11:45:23
18	Q But you would agree that since June 2005,	11:45:24
19	other non-Novo Nordisk companies have conducted	11:45:29
20	research in the GLP-1 space, correct?	11:45:32
21	A That's my understanding.	11:45:34
22	Q Do you have any understanding of what	11:45:35

1	formulations are or are not within the scope of the	11:45:39
2	'833 patent?	11:45:42
3	A Not in detail more than described in my	11:45:46
4	declaration.	11:45:49
5	Q So turning back to paragraph 76 in your	11:46:03
6	declaration, it's your opinion that a focus on U.S.	11:46:06
7	Patent issuance dates is too restrictive?	11:46:12
8	A Yes.	11:46:16
9	Q And you base -- what's the basis for your	11:46:18
10	opinion that focusing on U.S. Patent issuance dates	11:46:23
11	is too restrictive?	11:46:26
12	A This is my opinion as an economic expert.	11:46:27
13	I have substantial experience in intellectual	11:46:31
14	property. And in my opinion, Dr. Vellturo's focus	11:46:34
15	on patent issuance does not take into account the	11:46:38
16	period leading up to patent issuance where patent	11:46:40
17	applications were filed and known and available, and	11:46:43
18	there would be some expectation of patents issuing	11:46:48
19	in this space, which would be a deterrent for	11:46:51
20	others.	11:46:54
21	Q Does every published patent application	11:46:54
22	result in an issued U.S. Patent?	11:46:56

1	A	No, not every single one.	11:46:59
2	Q	Is there any way to know, looking at a	11:47:01
3		published U.S. patent application, whether or not	11:47:04
4		it's going to result in an issued U.S. Patent?	11:47:06
5	A	I'm sure there are ways to assess that.	11:47:11
6	Q	How would you assess that?	11:47:16
7	A	I'm not an attorney, yet I suspect that	11:47:19
8		an attorney that's experienced in patent issuance	11:47:23
9		would have a way to evaluate whether a patent	11:47:27
10		application was likely to be issued or not.	11:47:30
11	Q	Do issued U.S. patents -- strike that.	11:47:34
12		Do the claims in issued U.S. patents	11:47:37
13		always match the claims that are published in	11:47:40
14		published patent applications?	11:47:44
15	A	There is some matching in the sense that	11:47:47
16		the application obviously leads to an issued patent.	11:47:49
17		So there's a strong relationship there, of course.	11:47:52
18		They're not always identical between the issued	11:47:55
19		patent and the application.	11:47:58
20	Q	Have you reviewed the publication of the	11:48:01
21		application that led to the '343 patent?	11:48:05
22	A	Yes.	11:48:10

1	Q	Are you aware of whether or not the	11:48:11
2		published claims in the application are the same as	11:48:14
3		the issued claims in the '343 patent?	11:48:16
4	A	No, I'm not.	11:48:20
5	Q	Do you have the technical expertise to	11:48:24
6		explain how the claims may have changed from	11:48:31
7		publication to issuance?	11:48:36
8	A	No, and I'm not putting forth such an	11:48:39
9		opinion.	11:48:43
10	Q	You state that other -- in paragraph 76,	11:48:47
11		you state, Other developers reasonably considered	11:48:53
12		the likelihood that a patent may issue.	11:48:56
13		What is that likelihood that a patent may	11:49:02
14		issue from a published application?	11:49:04
15	A	What I'm referring to there is that	11:49:10
16		patent applications often do issue as patents, and	11:49:13
17		in many cases are likely to issue as patents.	11:49:18
18		So I'm saying that other developers would	11:49:21
19		consider that likelihood or that reasonable	11:49:24
20		expectation that a patent may issue.	11:49:26
21	Q	As of the publication of the -- as of the	11:49:29
22		publication of the -- strike that.	11:49:36

1 What was the likelihood that a patent
2 would issue from the published '343 application?

11:49:39

11:49:45

3 MR. WHITE: Objection to form.

11:49:49

4 A Are you asking for a percentage
5 likelihood or a probability?

11:49:52

11:49:54

6 Q Yes.

11:49:56

7 A I don't know. I've not quantified them
8 in that way.

11:49:56

11:50:00

9 Q How would you be able to quantify that?

11:50:03

10 A I would have to give that some thought.
11 I've not sought to do that. That's not necessary
12 for my opinions.

11:50:06

11:50:08

11:50:10

13 Q It's not necessary for your opinion to
14 consider the likelihood of whether or not a patent
15 will or will not issue for it to serve as a blocking
16 patent when it exists as an application?

11:50:12

11:50:14

11:50:17

11:50:20

17 A I wouldn't say it like that. I think the
18 likelihood is relevant. And given that many patent
19 applications do issue, I think that's sufficient to
20 be an economic deterrent.

11:50:22

11:50:25

11:50:28

11:50:30

21 Q So is it necessary to consider the
22 likelihood of whether or not a published application

11:50:33

11:50:43

1 will issue to assess whether or not that published
2 application has a blocking patent effect?

11:50:47

11:50:50

3 A It depends what you mean by that. I
4 don't think it's necessary to quantify the exact
5 probability, if that's what you're asking. But I do
6 think it's reasonable to consider that many patent
7 applications, but not all patent applications, issue
8 as published patents.

11:50:53

11:50:55

11:50:58

11:51:01

11:51:06

11:51:10

9 Q Do you know how many patent applications
10 issue as published patents in the United States?

11:51:11

11:51:14

11 A I don't know the numbers, not sitting
12 here.

11:51:18

11:51:22

13 Q But you think it's reasonable to consider
14 that many patent applications issue as published
15 patents?

11:51:23

11:51:25

11:51:29

16 A Yes.

11:51:29

17 Q But you don't know what percentage of
18 published applications issue as U.S. patents?

11:51:31

11:51:34

19 A I don't.

11:51:36

20 Q Can you turn to paragraph 86.

11:51:53

21 You discuss here and in this section, FDA
22 exclusivity. And you state -- in paragraph 86, you

11:52:08

11:52:13

1 state, Ozempic was granted a five-year new chemical
2 entity exclusivity that did not expire until
3 December 2022.

11:52:18

11:52:21

11:52:24

4 Do you see that?

11:52:25

5 A Yes.

11:52:25

6 Q You would agree that meant that the
7 five-year new chemical entity exclusivity was
8 granted in December 2017?

11:52:26

11:52:29

11:52:31

9 A Yes, I agree.

11:52:34

10 Q December 2017 is after the priority date
11 of the '462 patent?

11:52:35

11:52:39

12 A Yes.

11:52:41

13 Q So how does FDA exclusivity deter the
14 invention of the '462 patent?

11:52:42

11:52:46

15 A It deters it because if you are
16 considering the commercialization of a third-party
17 developer that's contemplating whether to develop a
18 1 milligram dosage of semaglutide back in 2012 or
19 sooner, they wouldn't be able to come to market with
20 a semaglutide product until after the five-year new
21 chemical entity exclusivity expires.

11:52:51

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11:53:02

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22 So knowing that, even back in 2012, the

11:53:15

1 third-party developer would know it would be many,
2 many years until they could bring a product to
3 market. In fact, in the world, it was not until
4 December 2022, which is ten years after the priority
5 of the '462 patent. And that's an economic
6 deterrent to that third-party developer if they
7 can't bring a product to market for over a decade.

8 Q Are you aware of how new chemical entity
9 is granted -- excuse me -- how new chemical entity
10 exclusivity is granted by FDA?

11 A I'm aware of the basics, yes.

12 Q What's your understanding of the basics
13 of how new chemical entity exclusivity is granted by
14 FDA?

15 A My understanding is that FDA reviews new
16 products that get approved. If it is a new chemical
17 entity, then FDA grants the new chemical entity
18 exclusivity, and then other companies are not
19 allowed to be on the market with the same chemical
20 entity for a five-year period, sometimes a
21 seven-year period.

22 Q It's your opinion that the grant of new

1 chemical exclusivity five years after the invention 11:54:33
2 date would have deterred someone from inventing -- 11:54:37
3 other than Novo Nordisk from inventing the claimed 11:54:42
4 inventions of the '462 patent? 11:54:45

5 A Yes. I think what you're missing is, 11:54:48
6 it's the expectation that a five-year chemical 11:54:51
7 entity exclusivity period will exist at some point. 11:54:55
8 It's that length of time that acts as an economic 11:54:58
9 deterrent, knowing that that would occur if and when 11:55:01
10 Novo Nordisk comes to market. 11:55:05

11 MR. MAY: Why don't we go ahead and take 11:55:38
12 a break. 11:55:40

13 (Recess from 11:55 a.m. until 12:07 p.m.) 12:07:09

14 MR. MAY: Thank you for your time. We 12:07:09
15 have no further questions. 12:07:12

16 THE WITNESS: Thank you. 12:07:13

17 MR. WHITE: And we don't have anything. 12:07:13

18 (Transcript orders discussed.) 12:07:15

19 COURT REPORTER: Thank you. That's all I 12:07:59
20 need. 12:08:00

21 (Off the record at 12:08 p.m.)
22

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:

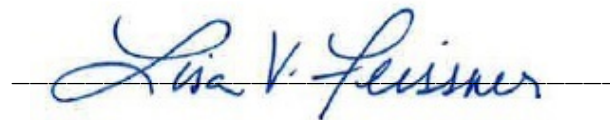
6
7 That DeFOREST McDUFF, Ph.D., the witness
8 whose deposition is hereinbefore set forth, was duly
9 sworn by me before the commencement of such
10 deposition, and that such deposition was taken
11 before me and is a true record of the testimony
12 given by such witness.

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 DeFOREST McDUFF, Ph.D., occurred at the offices of
20 GROOMBRIDGE, WU, BAUGHMAN & STONE LLP on FRIDAY,
21 JULY 19, 2024, commencing at 10:13 and concluding at
22 12:07.

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 22ND 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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