

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC., DR. REDDY'S LABORATORIES, INC.,
DR. REDDY'S LABORATORIES, LTD., SUN PHARMACEUTICAL
INDUSTRIES LTD., AND SUN PHARMACEUTICAL INDUSTRIES, INC.,

Petitioner,

v.

NOVO NORDISK A/S,

Patent Owner.

Case No. IPR2023-00724¹

Patent No. 10,335,462

**PETITIONER'S OBJECTIONS TO PATENT OWNER'S
DEMONSTRATIVE EXHIBITS**

¹ IPR2024-00009 (Dr. Reddy's Laboratories) and IPR2024-00107 (Sun Pharmaceutical Industries) have been joined with this proceeding.

As authorized by the Board’s August 14, 2024 order Setting Oral Argument (Paper 78), Petitioner objects to Patent Owner’s Demonstratives, filed on August 26, 2024, as follows:

Slide	Objection
27	<u>Contains new argument</u> : The title of this slide and third bullet point assert that the preamble of claim 1 requires tolerability as a matter of claim construction, which is a new argument that does not appear in any of Patent Owner’s Papers or supporting declarations, including the specific citations on this slide.
28	<u>Contains new argument</u> : The title of this slide and first bullet point assert that the preamble of claim 1 requires tolerability as a matter of claim construction, which is a new argument that does not appear in any of Patent Owner’s Papers or supporting declarations, including the specific citations on this slide.
29	<u>Contains new argument</u> : The title of this slide asserts that the preamble of claim 1 requires tolerability as a matter of claim construction, which is a new argument that does not appear in any of Patent Owner’s Papers or supporting declarations, including the specific citations on this slide.
34	<u>Contains new argument</u> : The second dash under the second bullet on

	this slide asserts that the preamble of claim 1 requires [REDACTED] as a matter of claim construction, which is a new argument that does not appear in any of Patent Owner's Papers or supporting declarations, including the specific citations on this slide.
60	<u>Contains new argument:</u> The third dash under the bullet point on this slide asserts that [REDACTED] [REDACTED] which is a new argument that does not appear in any of Patent Owner's Papers or supporting declarations, including the specific citations on this slide.
104	<u>Contains new argument:</u> The title of this slide and second bullet point assert that the preamble of claim 1 requires tolerability as a matter of claim construction, which is a new argument that does not appear in any of Patent Owner's Papers or supporting declarations, including the specific citations on this slide.
105	<u>Contains new argument:</u> The title of this slide and bullet point assert that the preamble of claim 1 requires tolerability as a matter of claim construction, which is a new argument that does not appear in any of Patent Owner's Papers or supporting declarations, including the specific citations on this slide.

106	<u>Contains new argument:</u> The title of this slide asserts that the preamble of claim 1 requires tolerability as a matter of claim construction, which is a new argument that does not appear in any of Patent Owner's Papers or supporting declarations, including the specific citations on this slide.
107	<u>Contains new argument:</u> The title of this slide and bullet point assert that the preamble of claim 1 requires tolerability as a matter of claim construction, which is a new argument that does not appear in any of Patent Owner's Papers or supporting declarations, including the specific citations on this slide.
115	<u>Contains new argument:</u> The arguments on this slide related to <i>Galderma</i> did not appear in any of Patent Owner's Papers, and Patent Owner modified the content of this slide approximately two days after the parties exchanged demonstratives.
202	<u>Contains new and improper attorney argument:</u> The third bullet on this slide is misleading because Patent Owner's experts did not opine on differences in kind or degree, including in the specific expert declarations that are cited, and instead the argument presented here is supported only by previously undisclosed attorney argument.
203	<u>Contains new and improper attorney argument:</u> The bullet on this

	slide is misleading because Patent Owner's experts did not opine on differences in kind or degree, and instead the argument presented here is supported only by previously undisclosed attorney argument.
204	<u>Contains new and improper attorney argument:</u> The bullet point and dashes on this slide are misleading because Patent Owner's experts did not opine on differences in kind or degree, and instead the arguments presented here are supported only by previously undisclosed attorney argument.

Consistent with the Board's order (Paper 78), the parties met and conferred in good faith, but were unable to resolve these disputes. As requested by the Board (Paper 78), copies of the objected-to slides are attached, and the specific portions of each respective slide to which Petitioner objects are discussed in the chart above.

Dated: August 27, 2024

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Respectfully submitted,

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APPENDIX

The Claimed “Method for Treating” T2D Requires Expectations of Both Efficacy and Tolerability

- Petitioner argues Dr. Jensen’s analysis of [REDACTED] is irrelevant to conception. Rep.4-5
- But Dr. Jensen’s described mental path to the invention is pertinent to how and when she conceived. SurRep.3
- And **the parties’ experts agree that “treating” requires an expectation of both tolerability and efficacy.**

Slides 6, 28-29; EX2010, ¶305; Inst.23; POR.10-11, 45; SurRep.2.;

1. A method for treating type 2 diabetes, comprising administering semaglutide once weekly in an amount of 1.0 mg to a subject in need thereof.

The Claimed “Method for Treating” T2D Requires Expectations of Both Efficacy and Tolerability (*cont'd*)

- But Petitioner **ignores** these agreed requirements of **tolerability** and **efficacy**, even though its own experts confirmed they are required.
 - Per Petitioner’s Dr. Jusko:

[I]f the patient **won’t accept treatment**, then **it’s not a treatment**.

EX2553 (Jusko Dep. Tr.), 14:7-15:4; SurRep.1-2

[T]reating diabetes **requires clinically meaningful change**.

EX2553 (Jusko Dep. Tr.), 41:3-15 (“statistically insignificant [HbA_{1c}] decrease” “[p]robably not” claimed “treating”); SurRep.1-2

[T]he goal is to have **as much efficacy without toxicity**.

EX2019 (Jusko Dep. Tr.), 128:6-16; SurRep.2

The Claimed “Method for Treating” T2D Requires Expectations of Both Efficacy and Tolerability (*cont'd*)

– And Per Petitioner’s Dr. Spiegel:

Q. So in your opinion, what is -- what does it mean to treat type 2 diabetes with semaglutide? What is required for it to be a treatment of type 2 diabetes??

A. **What’s required is that there be an acceptable safety and tolerability profile -- and this is not reflected in the patent, this is me, as a physician -- and that it be effective at a given dose and a given frequency of administration in lowering the hemoglobin A1c.**

EX2556 (Spiegel Dep. Tr.), 88:8-18; SurRep.1-2, 18

– PO’s Dr. Rosenstock confirmed the same.

See also EX2010 (Rosenstock Decl.), ¶¶305, 240-258; Pet.14-15 (“to **alleviate or reduce** [T2D] symptoms and complications...”); POR.45; SurRep.1-2

Until Dr. Jensen's Conception, Which Dose to Use [REDACTED]

- With the results of the 1821 Trial in hand, Dr. Jensen (and others at Novo) continued to [REDACTED].

EX2050 (Jensen Decl.), ¶¶14-16; POR.15; SurRep.3-5

- Petitioner argues that “others suggested th[e] idea” of “a once-weekly 1.0mg semaglutide dose to treat T2D.”

Rep.4, 8

- But Petitioner presented no evidence indicating Dr. Jensen “derived” or “reproduced” an **already-conceived invention**.

Rep.2-4, 6; SurRep.2-4

- Petitioner never even attempts to show anyone else previously conceived a **permanent** and **definite** idea of the **complete invention** with an expectation of [REDACTED], as the claims require.

Rep.2-4, 6; SurRep.4-5; Slides 22-23, 35-42

- Instead, **which dose—and whether 1.0mg should be used—to treat T2D** [REDACTED]

[REDACTED]; POR.14-16; SurRep.4-5

Petitioner's Efforts to Suggest That Others Conceived of the Invention Fail

- Petitioner has not shown any evidence that others conceived of the invention.

Slides 22-23, 34-42; SurRep.3-4

- Overcoming the presumption of correct inventorship requires clear and convincing evidence in AIA proceedings.

Incyte Corp. v. Concert Pharms., Inc., PGR2021-00006, Pap.70, 11-16 (Oct. 11, 2022);
Hess v. Advanced Cardiovascular Sys., Inc., 106 F.3d 976, 980 (Fed. Cir. 1997); SurRep.4-5 & n.3

- No evidence indicates Dr. Jensen “derived” or “reproduced” an already-conceived invention.

Rep.4 (citing *Solvay S.A. v. Honeywell Int’l*, 622 F.3d 1367, 1376-1379 (Fed. Cir. 2010)); SurRep.3-5

- [REDACTED]

Rep.2-4, 6; SurRep.3-5; Slides 22-23, 34-42

- No one except Dr. Jensen had, [REDACTED] leading to Jensen’s conception.

Compare, e.g., [REDACTED]

[REDACTED] see also EX1312 (Jensen Dep. Tr.), 71:6-8; Slides 43-47

- [REDACTED]

Rep.2-3; SurRep.4; Slides 43-47

Even If Criticality Required the Effects Be Claimed, “Treating” Does, Indeed, Require an Expectation of Efficacy and Tolerability

- To gain institution, Petitioner told the Board: “The [district court] agreed the patent’s claims are all about ‘intent’ and ‘purpose’ and not any specific level of efficacy, construing the preamble language to mean ‘the claimed administration *is for the purpose of* care and management of a patient Type 2 diabetes’ or ‘*is intended to* care for and manage a patient with Type 2 diabetes.”

Pap.7 (Petitioner’s Reply to POPR), 1-2 (emphasis original); Slides 6, 27-29

- Dr. Rosenstock confirmed that treating **requires tolerability** and **efficacy**:

Moreover, it still would have been unknown to POSITA whether any of the doses being tested (which did not even include 1.0mg) would have **tolerability**, **safety**, or **efficacy** issues that would have made them **unsuitable for use in treating type 2 diabetes as required by the claims** of the ’462 patent.

EX2010 (Rosenstock Decl.), ¶1305; POR.45

Even If Criticality Required the Effects Be Claimed, “Treating” Does, Indeed, Require an Expectation of Efficacy and Tolerability

- And Petitioner’s Dr. Jusko agrees treatment **requires tolerability**:

Q. Is it your understanding of claim 1 that a drug that’s entirely intolerable on a dosing schedule that’s entirely intolerable could meet the treatment requirement of the preamble?

A. **Well, the preamble calls for treating diabetes; it doesn’t specify the tolerance issue.**

Q. So **can you treat diabetes with an intolerable drug?**

A. **Well, you’re getting into the realm where a clinician would be needed to help answer that question. But in my view, if the patient won’t accept treatment, then it’s not a treatment.**

EX2553 (Jusko Reply Dep. Tr.), 14:7-15:4; SurRep.1-2

Even If Criticality Required the Effects Be Claimed, “Treating” Does, Indeed, Require an Expectation of Efficacy and Tolerability (*cont'd*)

- Dr. Jusko further testified treatment **requires *clinically meaningful improvement***.

SurRep.1-2

Q. Okay. But in terms of your understanding of what the claim construction of the preamble means, would claim 1 be met if administering the semaglutide as claimed resulted in a statistically insignificant decrease in HbA1c?

A. **Probably not.**

Q. And why is that?

A. **Statistical significance is often a very small change that may or may not correspond to clinical significance. But treating diabetes requires clinically meaningful change.**

EX2553 (Jusko Reply Dep. Tr.), 41:3-15; SurRep.1-2

Even If Criticality Required the Effects Be Claimed, “Treating” Does, Indeed, Require an Expectation of Efficacy and Tolerability (*cont'd*)

- Petitioner’s Dr. Spiegel also agrees treatment **requires efficacy** and **tolerability**.

SurRep.1-2

Q. So in your opinion, what is -- what does it mean to treat type 2 diabetes with semaglutide?
What is required for it to be a treatment of type 2 diabetes?

A. **What’s required is that there be an acceptable safety and tolerability profile -- and this is not reflected in the patent, this is me, as a physician -- and that it be effective at a given dose and a given frequency of administration in lowering the hemoglobin A1c.**

EX2556 (Spiegel Reply Dep. Tr.), 88:8-18; SurRep.1-2

Galderma Is Inapplicable—No Presumption Applies

- Petitioner cites *Galderma* to argue that obviousness here must be assumed and can only be rebutted by secondary indicia.

Galderma Lab'ys, L.P. v. Tolmar, Inc., 737 F.3d 731, 737-38 (Fed. Cir. 2013); Pet.38; Rep.19

- The claim here is directed to a **single dose** (1.0mg) – **not a range**.

POR.31; SurRep.20

- And a claimed “single, discrete point suggests a **difference** in how the invention operates at another discrete point.”

Fonterra Co-Operative Grp. Ltd. v. Arla Foods Amba, IPR2022-00661, Pap.15, 10-11 (Aug. 31, 2022); SurRep.20; see also POR.31

Petitioner Improperly Assumes That All Differences in Percentages Are Merely Differences in Degree

- “There is no specific fold-difference that defines what may, or may not, support a finding of nonobviousness.”

Amgen Inc. v. Sandoz Inc., 66 F.4th 952, 964 (Fed. Cir. 2023); SurRep.34

- The question of where to “draw [the] line between difference in degree . . . and difference in kind” is a “fact-specific” inquiry.

Amgen Inc. v. Sandoz Inc., 66 F.4th 952, 964 (Fed. Cir. 2023); SurRep.34

- Here, the unexpected results evidence PO presented shows differences in **kind** and not just differences in **degree**.

EX2054 (Goland Decl.), ¶¶61-83; EX2055 (Blaha Decl.), ¶¶34-33; EX2011 (Bakris Decl.), ¶¶44-63; EX1001 ('462 Patent), Fig. 5; EX2082 (SUSTAIN 10), 1, 6-7; POR.83-87; SurRep.34

- But Petitioner’s experts consistently failed to understand this legal principle.

EX2557 (Schwartzbard Dep. Tr.), 27:18-29:7; EX2554 (Coca Dep. Tr.), 118:6-119:4; EX2556 (Spiegel Dep. Tr.), 41:22-44:2; SurRep.34

The Differences Here Are Differences in Kind

- For example, the '462 Patent demonstrated there is a **30.8% greater weight loss** with 0.8mg semaglutide (3.4kg) than 1.8mg liraglutide (2.6kg)

EX1001 ('462 Patent), Fig.5; SurRep.34

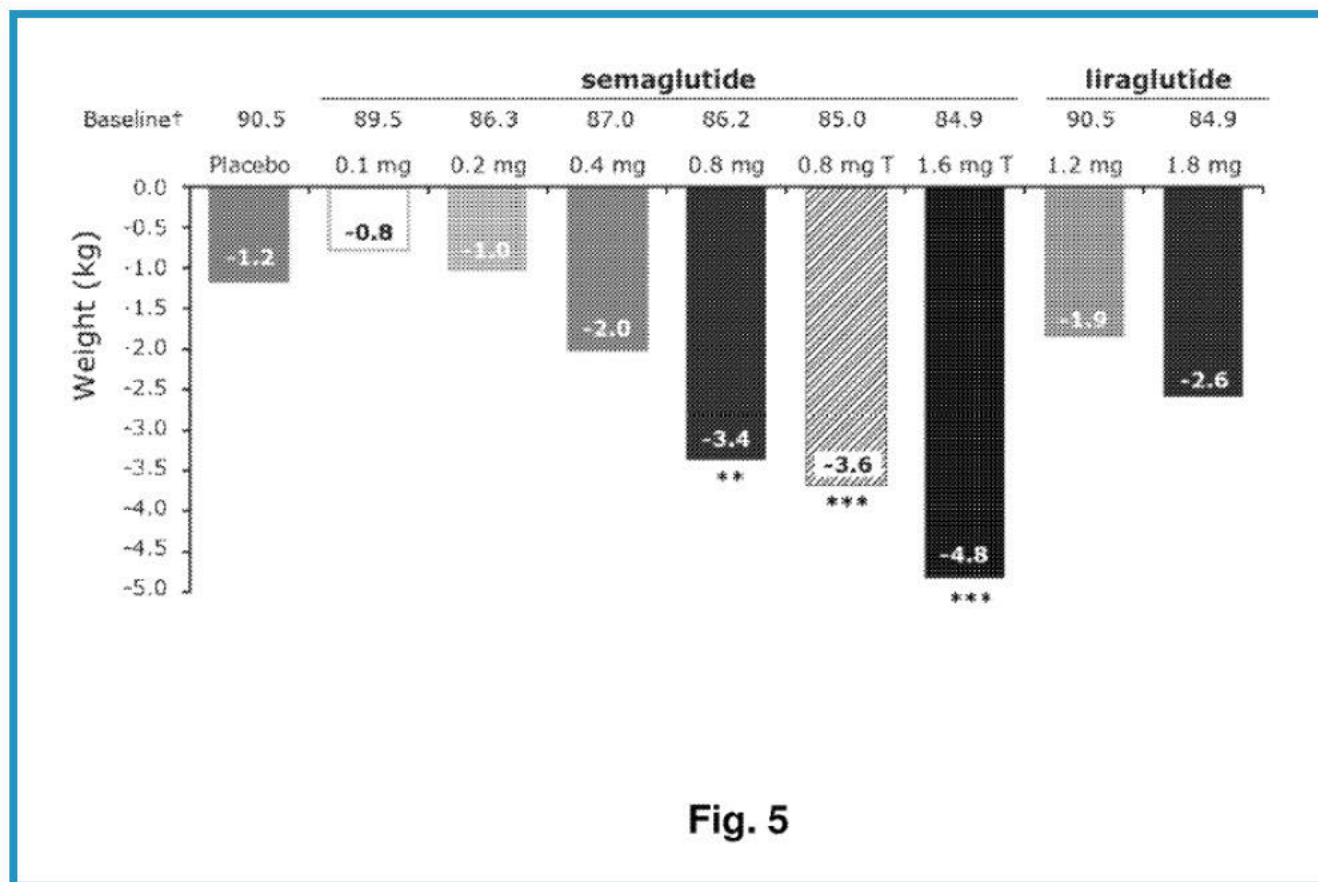


Fig. 5

The Differences Here Are Differences in Kind

- And the SUSTAIN 10 trial compared 1.0mg semaglutide against 1.2mg liraglutide over 30 weeks, again confirming a difference in kind:

EX2082 (SUSTAIN 10), 1, 6-7; SurRep.34

- **211% more patients hit 5% weight loss** (56% with semaglutide v. 18% for liraglutide).

EX2082 (SUSTAIN 10), 1, 6-7; SurRep.34

- **375% more patients hit 10% weight loss** (19% with semaglutide v. 4% for liraglutide).

EX2082 (SUSTAIN 10), 1, 6-7; SurRep.34

- **205% greater average weight loss** (5.8kg with semaglutide v. 1.9kg for liraglutide).

EX2082 (SUSTAIN 10), 1, 6-7; SurRep.34

- **70% greater reduction in HbA_{1c}** (1.7% reduction with semaglutide v. 1.0% for liraglutide).

EX2082 (SUSTAIN 10), 1, 6-7; SurRep.34

CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. § 42.6(e), I certify that I caused to be served a true and correct copy of the foregoing: PETITIONER'S OBJECTIONS TO PATENT OWNER'S DEMONSTRATIVE EXHIBITS by email to the electronic service addresses for Patent Owner and Petitioners in IPR2024-0009 and IPR2024-00107

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