

Filed: August 12, 2024

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.

IPR2023-00724¹

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

**PETITIONER'S OBJECTIONS TO PATENT OWNER'S
SUR-REPLY EVIDENCE**

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

Pursuant to 37 C.F.R. § 42.64(b)(1), Petitioner Mylan Pharmaceuticals Inc. (“Petitioner”) objects to the admissibility of the following exhibits filed by Patent Owner Novo Nordisk A/S (“Patent Owner”) with Patent Owner’s Sur-Reply in the above-captioned *inter partes* review.

Petitioner’s objections are timely under 37 C.F.R. § 42.64(b)(1) because they are being filed and served within five business days of service and filing of Patent Owner’s Sur-Reply on August 5, 2024.

In this paper, a reference to “FRE” means the Federal Rules of Evidence, a reference to “CFR” means the Code of Federal Regulations, and “’462 patent” means U.S. Patent No. 10,335,462. All objections under FRE 801-803 (hearsay) apply to the extent that Patent Owner relies on the exhibit identified in connection with that objection for the truth of the matter asserted therein.

Exhibit descriptions provided in this table are from Patent Owner’s exhibit list and are used for identification purposes only. The use of an exhibit description does not indicate that Petitioner agrees with that description or characterization of the document.

Petitioner objects to paragraphs in Patent Owner’s Sur-Reply that rely on exhibits objected to herein.

Exhibit	Patent Owner’s Description	Objection
EX2552	Transcript of July 11, 2024 Deposition of John Bantle, M.D.	A, B, C, D, E, F, I, N

Exhibit	Patent Owner's Description	Objection
EX2553	Transcript of July 12, 2024 Deposition of William J. Jusko, Ph.D.	A, B, C, D, E, F, I, N
EX2554	Transcript of July 16, 2024 Deposition of Steven Coca, M.D.	A, B, C, D, E, F, I, N
EX2555	Transcript of July 19, 2024 Deposition of DeForest McDuff	A, B, C, D, E, F, I, N
EX2556	Transcript of July 26, 2024 Deposition of Allen Spiegel, M.D.	A, B, C, D, E, F, I, N
EX2557	Transcript of July 9, 2024 Deposition of Arthur Z. Schwartzbard, M.D.	A, B, C, D, E, F, I, N
EX2558	February 26, 2010 DPComm Brief Summary Sheet (produced as NNOZEM-004442611) (Marked As Exhibit 9 at C. Jensen Deposition) [UNDER SEAL]	A, B, C, D, E, F, I, L, N, W
EX2601	T. Wilcox, A. Schwartzbard, et. al, Diabetic Agents, From Metformin to SGLT2 Inhibitors and GLP1 Receptor Agonists, JACC Focus Seminar, JACC Vol. 75 (2020) (Marked As Exhibit 2601 at Arthur Z. Schwartzbard Deposition)	A, B, C, D, E, F, I, N
EX2602	J. Newman, A. Schwartzbard, et. al, The Changing Landscape of Diabetes Therapy for Cardiovascular Risk Reduction, JACC State-of-the-Art Review, JACC Vol. 72 (2018) (Marked As Exhibit 2602 at Arthur Z. Schwartzbard Deposition)	A, B, C, D, E, F, I, N
EX2603	S. Coca et. al, Role of Intensive Glucose Control in Development of Renal End Points in Type 2 Diabetes Mellitus, Arch. Intern. Med. Vol. 172 (2012) (Marked As Exhibit 09/2603 at Steven Coca Deposition)	A, B, C, D, E, F, I, N
EX2604	V. Perkovic et. al., Effects of Semaglutide on Chronic Kidney Disease in Patients with Type 2 Diabetes, N. Engl. J. Med. (May 24, 2024) (Marked As Exhibit 11/2604 at Steven Coca Deposition)	A, B, C, D, E, F, I, N
EX2610	Trackdrugs.com Homepage (Marked As Exhibit 2610 at DeForest McDuff Deposition)	A, B, C, D, E, F, I, N

Exhibit	Patent Owner's Description	Objection
EX2650- EX2656	Multiple exhibits	A, B, C, D, E, F, I, O, V

Objection Key:

- A: FRE 801/802/803 (hearsay).
- B: FRE 401/402 (relevance) the document is not relevant to any issue in this IPR proceeding because the purported date of the document is after the filing date of the '462 patent.
- C: FRE 401/402 (relevance) the document is not relevant to any issue in the IPR proceeding.
- D: FRE 403 (confusing, waste of time) the document is not relevant to any issue in this IPR proceeding because the purported date of the document is after the filing date of the '462 patent.
- E: FRE 403 (cumulative).
- F: FRE 403 (confusing, waste of time) the document is not relevant to any issue in the IPR proceeding.
- G: FRE 702 (improper expert testimony) expert testimony that relies on the document is not based on sufficient facts or data and/or is not the product of reliable principles and methods.
- H: FRE 703 (bases of expert opinion) expert testimony that relies on the document is unreliable because the document is not of a type reasonably relied upon by experts in the field.
- I: FRE 106 (completeness) the document is incomplete and includes only a select portion of a larger document that in fairness should be considered along with this document, or the document is incomplete and should be considered along with other documents.
- J: FRE 701, 702 (improper expert testimony) improper expert testimony by a lay witness.
- K: FRE 1001-1003 (best evidence).
- L: FRE 403, 901 (improper compilation).
- M: Reserved.

- N: FRE 402 (relevance) the document is not relevant to any issue in the IPR Proceeding.
- O: Not cited in Patent Owner Response or Sur-Reply
- P: No exhibit filed.
- Q: Expert testimony fails to identify with particularity the underlying facts or data on which the opinion is based, violating 37 C.F.R. § 42.65(a).
- R: FRE 602 (lack of personal knowledge).
- S: FRE 702/703 to the extent that the expert declarant relies on an exhibit objected to under grounds G and/or H, the testimony is (i) not based on sufficient facts or data and/or is not the product of reliable principles and methods and/or is (ii) is unreliable because the exhibit is not of a type reasonably relied upon by experts in the field.
- T: FRE 1006 (improper summary).
- U: 37 C.F.R. § 42.65 (fails to provide underlying facts or data on which opinion is based).
- V: FRE 403 (confusing, waste of time, unfair prejudice) the document is in a different forum with a different claim construction standard and its use would unfairly prejudice Petitioner, waste time and confuse the issues.
- W: Insufficient corroboration of date of invention and/or reduction to practice.

Dated: August 12, 2024

Respectfully submitted,

/Brandon M. White/

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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 SUR-REPLY EVIDENCE** by email to the electronic service addresses for Patent Owner and Petitioners in IPR2024-0009 and IPR2024-00107

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