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., SUN PHARMACEUTICAL INDUSTRIES, INC., AND APOTEX INC.
Petitioners,

v.

NOVO NORDISK A/S,
Patent Owner.

Case IPR2023-00724[1]
Patent 10,335,462

PATENT OWNER'S MOTION TO EXPUNGE

[1] IPR2024-00009 (Dr. Reddy's Laboratories); IPR2024-00107 (Sun Pharmaceutical Industries); and IPR2024-00631 (Apotex Inc.) have been joined with this proceeding.

I. Introduction

Pursuant to the default protective order and 37 C.F.R. § 42.56, and in view of the Board's order dismissing the petition and terminating this proceeding, Pap.118, 4, Patent Owner Novo Nordisk A/S ("Novo") hereby moves to expunge confidential information in the record for this proceeding or, in the alternative, requests that the information be permanently retained as confidential. This request is unopposed.[2]

II. Applicable Legal Standard

After final judgment in a trial, 37 C.F.R. § 42.56 provides that "a party may file a motion to expunge confidential information from the record." The Trial Practice Guide similarly explains that a "party seeking to maintain the confidentiality of information… may file a motion to expunge the information from the record prior to the information becoming public." USPTO, *Consolidated Trial Practice Guide*, 22 (Nov. 2019).

The Board has held that a "'good cause' standard [] applies to motions to expunge confidential information under 37 C.F.R. § 42.56." *Panduit Corp. v. Corning Optical Commc'ns LLC*, IPR2016-01703, Pap.44, 4 (Aug. 26, 2020). While "[t]here is an expectation that information will be made public where the existence of the information is referred to in a decision to grant or deny a request to

[2] Novo is the only remaining party in this proceeding.

institute a review or is identified in a final written decision following a trial," this "rule balances the needs of the parties to submit confidential information with the public interest in maintaining a complete and understandable file history for public notice purposes." USPTO, *Consolidated Trial Practice Guide*, 22. Therefore, a party seeking expungement from the record must demonstrate "that any information sought to be expunged constitutes confidential information, and that [a party's] interest in expunging it outweighs the public's interest in maintaining a complete and understandable history of this *inter partes* review." *Atl. Gas Light Co. v. Bennett Regulator Guards, Inc.*, IPR2013-00453, Pap.97, 2 (Apr. 15, 2015). Where confidential information has not been and should not be publicly disclosed, and "the Board did not reference any purported confidential information in the Final Written Decisions, except in a general manner, and those decisions are not sealed," the Board has found "the public's interest in a complete and understandable record is not impaired by expunging the exhibits." *Panduit Corp.*, IPR2016-01703, Pap.44, 4 (citing *Celltrion, Inc. v. Genentech, Inc.*, IPR2016-01667, Pap.31, 3 (July 23, 2018)).

When, in contrast, the Board has declined to expunge documents—particularly Papers that "contain significant amounts of information that support the outcome of [the Board's] Decisions"—the Board has found it appropriate to "maintain as confidential and under seal the unredacted versions" of those

documents. *Baker Hughes Holdings, LLC v. LiquidPower Specialty Prods. Inc.*, IPR2016-00734, Pap.119, 6-7 (Oct. 10, 2023); *see also Unified Pats. LLC v. Monarch Networking Sols. LLC*, IPR2020-01708, Pap.63, 6 (July 26, 2022) (similar).

III. Good Cause Exists to Expunge or Maintain the Confidentiality of the Sealed Documents

Exhibits 2021-2036, 2038-2041, 2046-2048, 2050, 2051, 2056, 2300-2318, 2320-2334, 1308, 1311, 1312, 1314, 1323, 2555, and 2558, and Patent Owner Response (Pap.29), Petitioner's Reply (Pap.53), Patent Owner Sur-Reply (Pap.73), Petitioner's Oral Hearing Demonstratives (Exhibit 1334), Patent Owner's Oral Hearing Demonstratives (Pap.89), Patent Owner's Submission of Unresolved Objections to Petitioner's Demonstratives (Pap.90), and Petitioner's Objections to Patent Owner's Demonstrative Exhibits (Pap.94) were filed under seal because they contain Novo and third-party confidential information. Pursuant to the Trial Practice Guide, sensitive information was redacted from these documents where possible, and redacted versions of the papers and certain exhibits are available on the public docket. *See* Paps.30, 65, 74, 92, 93, 95; Exs. 2050, 2051, 2056, 2300, 1308, 1311, 1312, 1314, 1323, 2555. The present motion pertains only to the sealed copies of these documents.

During the proceeding, the Board **granted** Novo's motion to seal its Patent Owner Response and Exhibits 2021-2036, 2038-2041, 2046-2048, 2050, 2051, 2056, 2300-2318, 2320-2334, Novo's motion to seal its Patent Owner Sur-Reply and Exhibits 2555 and 2558, Novo's motion to seal its Patent Owner Oral Hearing Demonstratives and its Submission of Unresolved Objections to Petitioner's Demonstratives, and Novo's motion to seal its Request for Director Review, after finding good cause to do so. Pap.120, 3-5. The Board also stated that "the sponsoring party may file a motion to expunge these sealed documents from the official record. *See* 37 C.F.R. § 42.56." Pap.120, 6. The Board also granted Petitioner's motions to seal its Reply and Exhibits 1308, 1311, 1312, 1314, and 1323, as well as Petitioner's Oral Hearing Demonstratives (Exhibit 1334), and its Objections to Patent Owner's Demonstrative Exhibits, finding good cause to do so and stating that "the sponsoring party may file a motion to expunge that document from the official record." Pap.120, 6.

As detailed in the motions to seal, the confidential information contained in the above-discussed documents includes non-public research and development information in the form of proprietary clinical and scientific data concerning semaglutide, confidential information about drug development and regulatory approval strategies, and confidential business information, including proprietary financial information and marketing strategies. The confidential information also

includes confidential information in the form of third-party proprietary business and financial information provided to Novo Nordisk contingent upon and subject to confidentiality restrictions and the sealing of this information under the terms of the PTAB's default protective order. Pap.28; Pap.51; Pap.72; Pap.96; Pap.97 (Motions to Seal). That information remains confidential such that public disclosure would likely cause irreparable harm to Novo and the third party. As such, there is good cause to expunge such information now that this proceeding has concluded. Doing so would not affect the public interest, particularly since most of the record would remain publicly available. *See, e.g.*, *Samsung Elecs. Co. v. Nucurrent, Inc*., IPR2019-00861, Pap.85, 4-5 (Nov. 1, 2022) (finding good cause to expunge previously sealed material where doing so did not affect the public interest). And given that the Board did not rely on any of this material in its institution decision and did not issue a final written decision, the record of the proceeding would remain understandable even after the above referenced exhibits and papers are expunged. S*ee, e.g., Apple Inc. v. Firstface Co*., IPR2019-00612, Pap.30, 3 (Nov. 29, 2021) (finding good cause to expunge confidential material where "the record of the proceedings… remain[s] understandable in the absence of the redacted material"). Novo's interest in expunging the sealed documents or, alternatively, maintaining the documents as sealed, outweighs any potential justification for maintaining them as public. *Atl. Gas Light*, IPR2013-00453,

Pap.97, 2; *see also* Pap.119 at 3 (granting Motion to Expunge by joined Petitioner Apotex Inc.: "We find that the public has sufficient information from the public Institution Decision as well as the public, redacted versions of the confidential papers to understand sufficiently the record in this case").

A. Exhibits 2021-2036, 2038-2041, 2046-2048, 2050, 2051, 2056, 2300-2318, 2320-2334, and Patent Owner Response (Pap.29)

Portions of the Patent Owner Response cite and discuss Exhibits 2021-2036, 2038-2041, 2046-2048, 2050, 2051, 2056, 2300-2318, 2320-2334, each of which was designated by Novo as "Confidential" under the parties' agreed Protective Order (Exhibit 2079). All of these documents were filed under seal, and redacted versions of the Patent Owner Response and Exhibits 2050, 2051, 2056, and 2300 were concurrently filed. Pap.28 (Novo's Motion to Seal); Pap.120 (granting Novo's Motions to Seal). The confidential information in each document remains confidential to Novo and has not been disclosed to the public since Novo filed the motion to seal.

B. Exhibits 1308, 1311, 1312, 1314, 1323, and Petitioner's Reply (Pap.53)

Petitioner's Reply and Exhibits 1308, 1311, 1312, 1314, and 1323 were also filed under seal because certain portions of these documents likewise refer to the same confidential information that is contained in Exhibits 2021-2036, 2038-2041, 2046-2048, 2050, 2051, 2056, 2300-2318, 2320-2334. All of these documents

were filed under seal. Pap.28 (Novo's Motion to Seal); Pap.51 (Petitioner's Motion to Seal); Pap.120 (granting Novo's Motions to Seal). That information remains confidential and has not been disclosed to the public since Novo and Petitioner filed the motions to seal.

C. Exhibits 2555, 2558, and Patent Owner Sur-Reply (Pap.73)

The Patent Owner Sur-Reply and Exhibits 2555 and 2558 were also filed under seal because certain portions of the Patent Owner Sur-Reply likewise refer to the same confidential information that is contained in Exhibits 2021-2036, 2038-2041, 2046-2048, 2050, 2051, 2056, 2300-2318, 2320-2334, 1308, 1311, 1312, 1314, and 1323 as well as information contained in Exhibits 2555 and 2558, which were designated by Novo as "Confidential" under the parties' agreed Protective Order (Exhibit 2079). Each of these documents were filed under seal. Pap.28; Pap.51; Pap.72 (Motions to Seal); Pap.120 (granting Novo's Motions to Seal). That information remains confidential and has not been disclosed to the public since Novo filed the motion to seal.

D. Petitioner's Oral Hearing Demonstratives (Exhibit 1334), Patent Owner's Oral Hearing Demonstratives (Pap.89), Patent Owner's Submission of Unresolved Objections to Petitioner's Demonstratives (Pap.90), Petitioner's Objections to Patent Owner's Demonstrative Exhibits (Pap.94)

The oral hearing demonstratives and objections to the same were also filed under seal because certain portions refer to the same confidential information that

is contained in Exhibits 2022, 2024-2030, 2032, 2033, 2036, 2046, 2047, 2050, 2051, 2300, 2301, 2306, 2308, 2314, 2315, 2322, 2323, 2327, 2328, 2331, 2334 and Patent Owner's Response, Exhibits 1308, 1311, 1312, and Petitioner's Reply, and Exhibits 2555 and 2558, and Petitioner's Reply, each of which were designated by Novo as "Confidential" under the parties' agreed Protective Order (Exhibit 2079) or reference information designated as "Confidential." All of these documents were filed under seal. Pap.28; Pap.51; Pap.72; Pap.96; Pap.97 (Motions to Seal); Pap.120 (granting Novo's Motions to Seal). That information remains confidential and has not been disclosed to the public since Novo filed the motion to seal.

IV. Conclusion

For the reasons above, Novo respectfully requests that the Board protect its confidential information by expunging or, in the alternative, maintaining the confidentiality of Exhibits 2021-2036, 2038-2041, 2046-2048, 2050, 2051, 2056, 2300-2318, 2320-2334, 1308, 1311, 1312, 1314, 1323, 2555, and 2558, and Patent Owner Response (Pap.29), Petitioner's Reply (Pap.53), Patent Owner Sur-Reply (Pap.73), Petitioner's Oral Hearing Demonstratives (Exhibit 1334), Patent Owner's Oral Hearing Demonstratives (Pap.89), Patent Owner's Submission of Unresolved Objections to Petitioner's Demonstratives (Pap.90), and Petitioner's Objections to Patent Owner's Demonstrative Exhibits (Pap.94) pursuant to 37 C.F.R. § 42.56.

Respectfully submitted by: Dated: February 11, 2025

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CERTIFICATE OF PAGE COUNT

The undersigned certifies that the foregoing PATENT OWNER'S MOTION TO EXPUNGE complies with the 15-page limitation in 37 C.F.R. §42.24(a)(1)(v).

Dated: February 11, 2025

Respectfully Submitted,

By: /*Michael Milea*/

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