

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SUN PHARMACEUTICAL INDUSTRIES LTD.
and
SUN PHARMACEUTICAL INDUSTRIES, INC.,

Petitioners

v.

NOVO NORDISK A/S,
Patent Owner

Case IPR2024-00107
Patent 10,335,462

PATENT OWNER'S SUR-REPLY

LIST OF EXHIBITS

Exhibit	Description
EX2001	Excerpt of Defendants’ Initial Invalidity Contentions Regarding U.S. Patent Nos. 8,129,343; 8,536,122; 8,114,833; 8,920,383; 9,775,953; 9,457,154; and 10,335,462, <i>In re: Ozempic (Semaglutide) Patent Litigation</i> , No. 22-MD-03038-CFC (D. Del. Oct. 20, 2022)
EX2002	Petition for <i>Inter Partes</i> Review, <i>Mylan Pharms. Inc. v. Novo Nordisk A/S</i> , IPR2023-00724, Pap.1 (Mar. 16, 2023)
EX2003	Declaration of Sayem Osman
EX2004	Stipulation and Order Regarding Trial of the MPI Ozempic Litigation, <i>In re: Ozempic (Semaglutide) Patent Litigation</i> , No. 22-MD-03038-CFC, Dkt. 245 (D. Del. Oct. 31, 2023)
EX2005	Nov. 29, 2023 Email from E. Goldschlager to Counsel, re: IPR2023-00724 – Request for Conference Call
EX2006	Scheduling Order, <i>Novo Nordisk Inc. v. Rio Biopharms., Inc.</i> , No. 1:22-cv-00294-CFC, Dkt. 22 (D. Del. June 30, 2022)
EX2007	Excerpt of Transcript of Dec. 13, 2023 Claim Construction Hearing, <i>Novo Nordisk Inc. v. Mylan Pharmaceuticals Inc.</i> , No. 23-101-CFC (D. Del. Dec. 13, 2023)
EX2008	Claim Construction Order, <i>In re: Ozempic (Semaglutide) Patent Litigation</i> , No. 22-MD-03038-CFC, Dkt. 148 (D. Del. July 25, 2023)
EX2009	Joint Stipulation and Order Amending Scheduling Order, <i>In re: Ozempic (Semaglutide) Patent Litigation</i> , MDL No. 22-MD-03038-CFC, Dkt. 268 (D. Del. Dec. 1, 2023)
EX2010	Excerpt of Novo Nordisk’s Third Amended Disclosures to Defendants Sun Pharmaceutical Industries Ltd. and Sun Pharmaceutical Industries, Inc., <i>In re: Ozempic (Semaglutide) Patent Litigation</i> , No. 22-MD-03038-CFC (D. Del. July 28, 2023)
EX2011	U.S. Patent No. 8,114,833
EX2012	Summons in a Civil Action, Sun Pharmaceutical Industries, Inc., <i>Novo Nordisk Inc. v. Sun Pharmaceutical Indus. Ltd.</i> , No. 1:22-cv-00296-CFC, Dkt. 7 (D. Del. Mar. 7, 2022)
EX2013	Summons in a Civil Action, Sun Pharmaceutical Industries Ltd., <i>Novo Nordisk Inc. v. Sun Pharmaceutical Indus. Ltd.</i> , No. 1:22-cv-00296-CFC, Dkt. 8 (D. Del. Mar. 16, 2022)

Exhibit	Description
EX2014	Excerpt of Redacted Patent Owner's Response, <i>Mylan Pharms. Inc. v. Novo Nordisk A/S</i> , IPR2023-00724, Pap.30 (Jan. 17, 2023)
EX2015	Excerpt of Novo Nordisk's Initial Responses to Defendants' Initial Invalidity Contentions Regarding U.S. Patent Nos. 8,129,343; 8,536,122; 8,114,833; 8,920,383; 9,775,953; 9,457,154; and 10,335,462, <i>In re: Ozempic (Semaglutide) Patent Litigation</i> , No. 22-MD-03038-CFC (D. Del. Dec. 21, 2022) [REDACTED]
EX2016	Transfer Order, <i>In re: Ozempic (Semaglutide) Patent Litigation</i> , No. 22-MD-03038-CFC, Dkt. 1 (D. Del. Aug. 5, 2022)
EX2017	INTENTIONALLY OMITTED
EX2018	Excerpt of Defendants' Second Supplemental Invalidity Contentions Regarding U.S. Patent Nos. 8,129,343; 8,536,122; 8,114,833; 8,920,383; 9,775,953; 9,457,154; and 10,335,462, <i>In re: Ozempic (Semaglutide) Patent Litigation</i> , No. 22-MD-03038-CFC (D. Del. Jan. 12, 2024) [REDACTED]
EX2019	Novo Nordisk Production Letter, <i>In re: Ozempic (Semaglutide) Patent Litigation</i> , No. 22-MD-03038-CFC (D. Del. Oct. 17, 2023) [REDACTED]
EX2020	Compilation of Defendants' Production Letters, <i>In re: Ozempic (Semaglutide) Patent Litigation</i> , No. 22-MD-03038-CFC (D. Del.) [REDACTED]
EX2021	Compilation of Rule 30(b)(1) Deposition Notices, <i>In re: Ozempic (Semaglutide) Patent Litigation</i> , No. 22-MD-03038-CFC (D. Del.)
EX2022	Notice of Service for Defendants' Initial Invalidity Contentions, <i>In re: Ozempic (Semaglutide) Patent Litigation</i> , No. 22-MD-03038-CFC (D. Del. Oct. 20, 2022)
EX2023	Notice of Service for Defendants' Supplemental Invalidity Contentions, <i>In re: Ozempic (Semaglutide) Patent Litigation</i> , No. 22-MD-03038-CFC (D. Del. Nov. 6, 2023)
EX2024	Stipulation for Extension of Time, <i>In re: Ozempic (Semaglutide) Patent Litigation</i> , No. 22-MD-03038-CFC, Dkt. 309 (D. Del. Feb. 9, 2024)
EX2025	February 26, 2024 Email from C. Ferenc to M. Raymond, re: IPR2024-00107

Exhibit	Description
EX2026	Sun Pharmaceutical Industries Ltd.’s and Sun Pharmaceutical Industries Inc.’s Stipulation of Invalidity Contentions, <i>Novo Nordisk Inc. v. Rio Biopharmaceuticals Inc.</i> , No. 22-cv-00294-CFC, Dkt. 275 (D. Del. Nov. 6, 2023)
EX2027	Joint Stipulation and Order Extending Deadline for Certain Fact Discovery, <i>In re: Ozempic (Semaglutide) Patent Litigation</i> , No. 22-MD-03038-CFC, Dkt. 305 (D. Del.)
EX2028	Excerpt of Opening Expert Report of Dr. John Bantle Regarding Invalidity of U.S. Patent No. 10,335,462, <i>In re: Ozempic (Semaglutide) Patent Litigation</i> , No. 22-MD-03038-CFC (D. Del.)
EX2029	Excerpt of Opening Expert Report of William J. Jusko, Ph.D. Regarding Invalidity of U.S. Patent No. 10,335,462, <i>In re: Ozempic (Semaglutide) Patent Litigation</i> , No. 22-MD-03038-CFC (D. Del.)
EX2030	Excerpt of Opening Expert Report of Dr. Paul Dalby Regarding Invalidity of U.S. Patent No. 10,335,462, <i>In re: Ozempic (Semaglutide) Patent Litigation</i> , No. 22-MD-03038-CFC (D. Del.)

Petitioner’s “Reply” is largely unresponsive to PO’s *Fintiv* analysis in its POPR, and fails to show *Fintiv* does not support denial—including because Petitioner’s stipulation is **not** a true *Sotera* stipulation.

Factor 1. Petitioner does not dispute that it is highly unlikely the Delaware Litigation will be stayed. Indeed, Petitioner does not even argue it will request a stay, and does not dispute that the Court would disfavor staying the Delaware Litigation. This factor is not neutral: rather, it favors denial. POPR, 7-8.

Factor 2. Petitioner ignores that, even with a December 9, 2024 trial date, the FWD would have **no statutory deadline** after joinder. *Fintiv*, IPR2020-00019, Pap.11, 9; §316(a)(11); §42.100(c). Indeed, multiple cases with a joined party have been decided well over a year from institution. *See Amerigen Pharms. Ltd. v. Janssen Oncology, Inc.*, IPR2016-00286, Pap.86 (Jan. 17, 2018) (FWD 19 months after institution (Pap.14)); *West-Ward Pharms. Int’l Ltd. v. Novartis Pharms. Corp.*, IPR2017-01592, Pap.78, 2-3 (Dec. 31, 2018) (extending FWD by 6 months after joinder). Such delay would result in an FWD issuing **after** trial. This favors denial. *See also* POPR, 9-12.

Factor 3. Petitioner does not dispute the significant investment in the Delaware Litigation, which weighs heavily in favor of denial. *See* POPR, 13-17. Petitioner instead argues that certain challenged claims are not asserted in the litigation. But Petitioner ignores PO’s stipulation about assertion of non-overlapping claims in

litigation, and that, accordingly, ***there is no such issue here***. POPR, 23 n.9. Further, Petitioner's citation of *Samsung Bioepis Co. v. Regeneron Pharmaceuticals, Inc.*, IPR2023-00739, Pap.9, 57 (Oct. 20, 2023) is inapposite. Unlike here, that IPR involved little overlap in claims (only two of twelve challenged claims were asserted in the litigation), and ***a non-overlapping independent claim***. Moreover, Petitioner's assertion here that claims 2 and 6 are not at issue in the Delaware Litigation is simply incorrect given that there are asserted claims that depend from claims 2 and 6.

Factor 4. Petitioner's so-called "Sotera-type stipulation," by its own admission, is ***not*** a *Sotera* stipulation as addressed in the Director's *Fintiv* guidance. Pet'r's Rep., 2. Petitioner does not dispute the stipulation was filed by Petitioner ***as a joining party*** and thus does not ensure avoidance of overlap between the IPR and litigation here. *See USPTO Interim Procedure for Discretionary Denials in AIA Post-Grant Proceedings with Parallel District Court Litigation* at 7-8 (USPTO, June 21, 2022). Petitioner's citation to *BMW of North America LLC v. NorthStar Systems LLC*, IPR2023-01017, Paper 12 (Dec. 8, 2023) has no bearing because the petitioner in that case was not a joining party. Nor does Petitioner or its stipulation provide any reassurances that it will not argue that the estoppel against invalidity grounds that "reasonably could have [been] raised" under 35 U.S.C. § 315(e)(2) is inapplicable to Petitioner as a joining party based on *Network-1 Technologies, Inc. v. Hewlett-Packard Co.*, 981 F.3d 1015, 1026-28 (Fed. Cir. 2020). *See also* EX2026 ("This

stipulation is not intended, and should not be construed, to limit [Petitioner's] ability to assert invalidity... beyond the scope of the estoppel provisions set forth in [§ 315(e)(2)].”). And Petitioner shares invalidity experts (and, presumably, the experts' expenses) in litigation with parties who have not agreed to any estoppel. *See also* POPR, 21 n.8; EX2028, 10; EX2029, 9; EX2030, 6.

Factor 5. Petitioner argues Factor 5 “should only play a role where a Petitioner is unrelated to a defendant in a district court proceeding” in asserting this factor should be neutral. Pet'r's Rep., 3. But that is not what *Fintiv* says. IPR2020-00019, Pap.11, 14. Indeed, the Board's *Fintiv* institution decision found that, “[b]ecause the petitioner and the defendant in the parallel proceeding *are the same party*, this factor weighs in favor of discretionary denial.” *Fintiv*, IPR2020-00019, Pap.15, 15 (May 13, 2020). Here, too, Factor 5 weighs in favor of denial.

Factor 6. Petitioner cannot demonstrate “compelling merits” by arguing Mylan's petition was instituted. POPR, 24. Further, Petitioner continues to ignore PO's intent to swear behind prior art and argue objective indicia at trial. Petitioner also fails to address its unexplained delay in filing an IPR. *See* POPR, 24-25.

Dated: March 29, 2024

Respectfully submitted,

By: /Megan Raymond/
Megan Raymond

CERTIFICATE OF SERVICE

The undersigned hereby certifies that a copy of PATENT OWNER’S SUR-
REPLY has been served in its entirety on March 29, 2024, by causing the afore-
mentioned document to be electronically mailed to the following attorneys of rec-
ord for the Petitioner listed below.

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Dated: March 29, 2024

Respectfully submitted,

By: /Sayem Osman/
Sayem Osman