

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

DR. REDDY'S LABORATORIES, INC.
and
DR. REDDY'S LABORATORIES, LTD.,

Petitioners

v.

NOVO NORDISK A/S,
Patent Owner

Case IPR2024-00009
Patent 10,335,462

**PETITIONERS' REPLY
TO PATENT OWNER'S PRELIMINARY RESPONSE**

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 Litig.</i> , No. 22-MD-03038-CFC (D. Del. Oct. 20, 2022)
EX2002	Petition for Inter Partes 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 Litig.</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.)
EX2007	Excerpt of Transcript of Dec. 13, 2023 Claim Construction Hearing, <i>Novo Nordisk Inc. v. Mylan Pharms. Inc.</i> , No. 23-101-CFC (D. Del. Dec. 13, 2023)
EX2008	Claim Construction Order, <i>In re: Ozempic (Semaglutide) Patent Litig.</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 Litig.</i> , MDL No. 22-MD-03038-CFC, Dkt. 268 (D. Del. Dec. 1, 2023)
EX2010	Excerpt of Novo Nordisk’s Second Amended Disclosures to Dr. Reddy’s Laboratories Ltd. and Dr. Reddy’s Laboratories, Inc., <i>In re: Ozempic (Semaglutide) Patent Litig.</i> , No. 22-MD-03038-CFC (D. Del. July 28, 2023)
EX2011	U.S. Patent No. 8,114,833
EX2012	Waiver of Service of Summons for Dr. Reddy’s Laboratories, Inc., <i>Novo Nordisk Inc. v. Dr. Reddy’s Lab’ys Ltd.</i> , No. 1:22-cv-00298-CFC, Dkt. 6 (D. Del., Mar. 4, 2022)
EX2013	Waiver of Service of Summons for Dr. Reddy’s Laboratories Ltd., <i>Novo Nordisk Inc. v. Dr. Reddy’s Lab’ys Ltd.</i> , No. 1:22-cv-00298-CFC, Dkt. 7 (D. Del. Mar. 4, 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 Litig.</i> , No. 22-MD-03038-CFC (D. Del. Dec. 21, 2022)
EX2016	Transfer Order, <i>In re: Ozempic (Semaglutide) Patent Litig.</i> , No. 22-MD-03038-CFC, Dkt. 1 (D. Del. Aug. 5, 2022)
EX2017	INTENTIONALLY OMITTED
EX2018	Excerpt of Defendants' 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 Litig.</i> , No. 22-MD-03038-CFC (D. Del. Nov. 2, 2023)
EX2019	Novo Nordisk Production Letter, <i>In re: Ozempic (Semaglutide) Patent Litig.</i> , No. 22-MD-03038-CFC (D. Del. Oct. 17, 2023) [REDACTED]
EX2020	Compilation of Defendants' Production Letters, <i>In re: Ozempic (Semaglutide) Patent Litig.</i> , No. 22-MD-03038-CFC (D. Del.) [REDACTED]
EX2021	Compilation of Rule 30(b)(1) Deposition Notices, <i>In re: Ozempic (Semaglutide) Patent Litig.</i> , No. 22-MD-03038-CFC (D. Del.)
EX2022	Notice of Service for Defendants' Initial Invalidity Contentions, <i>In re: Ozempic (Semaglutide) Patent Litig.</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 Litig.</i> , No. 22-MD-03038-CFC (D. Del. Nov. 6, 2023).

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The Board should decline to exercise its discretion to deny institution under *Fintiv*, including because Petitioners now offer a *Sotera* stipulation. *See Director’s Interim Procedure for Discretionary Denials*, pp. 7-8 (June 21, 2022).

I. *Fintiv*/314(a) Factors

A. Factor 1: Whether a Stay Exists or Is Likely to Be Granted

Factor 1 “does not weigh for or against discretionary denial” when neither party has requested a stay, *Apple Inc. v. Fintiv, Inc.*, IPR2020-00019, Paper 15 at 12 (PTAB May 13, 2020) (informative), as is the circumstance here—this factor should therefore be found to be **neutral**.

B. Factor 2: Proximity of Trial Date

Factor 2 should be **neutral** when, as here (POPR, at 9–10), “the expected trial date and the due date of a final written decision will be around the same time.” *Bose Corp. v. Koss Corp.*, IPR2021-00297, Paper 16 at 12–13 (PTAB June 3, 2021). In any event, Patent Owner also concedes that the Delaware district court “might ‘move that [Delaware Litigation] trial date a little bit’ due to scheduling conflicts in September and October generally.” POPR, at 12 n.4 (citing EX2007, at 3–4 (104:16–105:18)). Such a move in the trial date—which would likely be **later**, (EX2007, at 4 (105:1–18) (suggesting a September trial would be too early because “my clerks are just coming onboard”))—tips this factor **against discretionary denial**. *Samsung Elecs. Co. v. Staton Techiya, LLC*, IPR2022-00243, Paper 15, at 9–10 (PTAB June 21, 2022).

As to Patent Owner’s assertions that joinder disrupts the statutory deadline for the FWD, Petitioners have already assured the Board (and Patent Owner)—both in its Motion for Joinder and in the filed Joint Stipulation (*see* Paper 12)—that Petitioners would maintain an understudy role and not “raise any new grounds” or “[new] argument,” so Patent Owner’s concerns about an unremitting delay in the insurance of the FWD are simply unfounded and speculative.

C. Factor 3: Investment in the Parallel Proceeding

Factor 3 **favours institution** because claims 2, 6, and 8–10 (which are challenged in the Petition) are not at issue in the district court litigation. *Samsung Bioepis Co. v. Regeneron Pharms., Inc.*, IPR2023-00739, Paper 9 at 57 (PTAB Oct. 20, 2023) (“[B]ecause certain of the challenged claims . . . are not expressly at issue in the district court litigation, *Fintiv* factor 3 favors institution.”).

D. Factor 4: Overlap Between Petition and Parallel Proceeding Issues

In the interest of efficiency, Petitioners stipulate that, if instituted, they will not pursue in the parallel district court proceeding the same grounds as in the Petition or any grounds that could have reasonably been raised therein. Given Director Vidal’s guidance on *Fintiv*, the Board should decline to exercise its discretion to deny institution. *See Director’s Interim Procedure for Discretionary Denials*, pp. 7-8 (June 21, 2022). Factor 4, therefore, **favours institution**.

E. Factor 5: Parallel Proceeding Party Identities

Factor 5 should only play a role where a Petitioner is unrelated to a defendant

in a district court proceeding. *See Fintiv*, IPR2020-00019, Paper 11 at 13–14 (PTAB Mar. 20, 2020). Accordingly, the Board should find this factor to be **neutral**.

F. Factor 6: Other Circumstances for Discretion, Including Merits

“[I]n circumstances where the Board determines that the other *Fintiv* factors 1–5 do not favor discretionary denial, the Board shall decline to discretionarily deny under *Fintiv* without reaching the compelling merits analysis.” *CommScope Techs. LLC v. Dali Wireless, Inc.*, IPR2022-01242, Paper No. 23 at 4–5 (PTAB Feb. 27, 2023). For at least this reason, the Board need not reach the question on Factor 6.

Even so, Petitioners offer compelling evidence of unpatentability: the Board instituted Mylan’s IPR on all grounds after considering the Patent Owner’s merits challenges and, furthermore, found material error by the patent examiner. *Mylan Pharms. Inc. v. Novo Nordisk A/S*, IPR2023-00724, Paper 10 at 15–16 (PTAB Oct. 4, 2023). This factor thus also **favors institution**.

II. The 35 U.S.C. § 315(b) Statutory Bar Does Not Apply to Joinder

As the Supreme Court recognized, “failure to satisfy §315(b)” does not “prevent [a petitioner] from participating on the merits” of an IPR because an otherwise time-barred “party can join a proceeding initiated by another petitioner.” *Thryv, Inc. v. Click-to-Call Techs., LP*, 140 S. Ct. 1367, 1374 (2020). Such is the case here. *See also VirnetX Inc. v. Mangrove Partners Master Fund Ltd.*, U.S., 23-315, cert. denied 2/20/24.

CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. § 42.6(e), I hereby certify that on this 21st day of February 2024, I caused to be served a true and correct copy of the foregoing by electronic delivery to Patent Owner's counsel of record:

J. Steven Baughman - steve.baughman@groombridgewu.com
Megan Raymond - megan.raymond@groombridgewu.com
Novo-Semaglutide-IPR@groombridgewu.com
GROOMBRIDGE, WU, BAUGHMAN & STONE LLP

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Respectfully Submitted,

/Jovial Wong/
Jovial Wong (lead counsel)
Reg. No. 60,115
Scott M Border (backup counsel)
Reg. No. 77,744
Sharon Lin McIntosh (backup counsel)
(*pro hac vice* to be submitted)
Winston & Strawn LLP
1901 L Street, N.W.
Washington, D.C. 20036
T: 202-282-5100
sborder@winston.com
jwong@winston.com
slin@winston.com