

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

PATENT OWNER'S FURTHER AUTHORIZED REPLY*

* Authorized by Pap.16 (Mar. 29, 2024). Emphases herein are added, and abbreviations/references are as in Paps.13 and 15.

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.)
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 Second Amended Disclosures to Dr. Reddy’s Laboratories Ltd. and Dr. Reddy’s Laboratories, 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	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 Litigation</i> , No. 22-MD-03038-CFC (D. Del. Dec. 21, 2022)
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' 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. Nov. 2, 2023)
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	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.)
EX2025	Excerpt of Opening Expert Report of William J. Jusko, Ph.D. Regarding Invalidity of U.S. Patent No. 10,335,462, <i>In re:</i>

Exhibit	Description
	<i>Ozempic (Semaglutide) Patent Litigation</i> , No. 22-MD-03038-CFC (D. Del.)
EX2026	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, effectively conceding its two prior stipulations failed to counter PO's *Fintiv* showing, proffers yet another “do-over”—its ***third*** incremental bite at the apple, attempting to find the least estoppel it might get away with. Petitioner has now experimented with ***three different, serial stipulations at PO's and the Board's expense***, using PO's arguments as a roadmap to determine the scope of incremental replacement stipulations, and wasting time and resources on briefing stipulations that were twice replaced. *See* Pap.2, 64; Pap.13, 17-23. Only after all extra briefing was finished and PO's Sur-Reply confirmed this “‘do-over’ stipulation... ha[d] the same inadequate impact as [the] original” (Pap.15, 2-3) did Petitioner propose its *third* stipulation with what the Board's recent Order notes was new wording: “additional language... agreeing [Petitioner] is estopped *to the same extent as the Petitioner in the original case [(Mylan)]* to which it seeks joinder...” Pap.16, 2.

Petitioner's ever-changing positions significantly prejudice PO, and the Petition should be denied under §314(a). ***First***, PO determined what substance to include in its POPR and to oppose only institution (rather than institution *and* joinder) in light of Petitioner's stated reliance on only *Sand Revolution*—allocating resources to *Fintiv* rather than, *e.g.*, additional substantive arguments based on Mylan's experts' deposition concessions, or seeking discovery of Petitioner's relationship with Mylan and the remaining litigation defendants. The full scope of that undisclosed relationship and resulting prejudice is only now becoming clearer: Petitioner used

three IPR experts different from Mylan's, suggesting it had no choice (*e.g.*, Pap.3, 2, 5 (“in the event that Mylan does not agree to allow DRL to retain [them]”)), but *Petitioner actually shares those same experts (and their declarations and presumably their cost) in litigation with both Mylan (in violation of the stipulation Mylan promised in its Petition, but never provided in litigation) and other parties who have not agreed to any estoppel.* See EX2024, 10; EX2025, 9; EX2026, 6. Cf. Pap.16, 2 (“Petitioner also stated that it would not present any invalidity arguments in [litigation] based on...§§102 or 103”); Guidance, 7-8 (*Sotera* policy enables Board “to review grounds that... district court litigation **will not resolve**” and “avoid[] inconsistent outcomes”). ***Second***, far from sparing PO “any additional burden” (Pap.3, 8), Petitioner has already compelled extended, wasted briefing: first of its inadequate *Sand Revolution* stipulation (Pap.13, 17-23); next, of its inadequate “joiner” stipulation (Pap.15, 1-3); and now of its newest change in position. Petitioner's serial gambit to try out lesser levels of estoppel constitutes harassing, burdensome, prejudicial gamesmanship meriting §314(a) denial (*see, e.g. Consolidated Trial Practice Guide*, 2 (aiming to “**streamlin[e] and converg[e]**... issues for decision [and] conduct proceedings in a timely, fair, and **efficient** manner”), 55-58), which should be granted for the reasons briefed here and earlier. Cf. *General Plastic Indus. Co., Ltd. v. Canon Kabushiki Kaisha*, IPR2016-01357, Pap. 19 (Sept. 6, 2017) (§II.B.4.i precedential) (considering, *inter alia*, harassment, “potential for abuse,”

“roadmap[ping],” “fundamental fairness,” “efficiency,” and “prejudice” in analyzing discretionary denial). And, while Petitioner’s first stipulation tracked Mylan’s in the IPR it seeks to join, Petitioner’s two subsequent stipulations have not. Thus, Petitioner has also disregarded its promise that, for joinder, “no additional briefing or discovery would be required, and no additional burdens would be placed on any party or the PTAB....” Pap.3, 5, 8, 3 (“will promote judicial efficiency... without prejudice to [PO]”).

Further, the *Fintiv* guidance does not require that a *Sotera* stipulation be considered regardless of when it is filed. Indeed, including for the reasons above, the new, prejudicial, stipulation should not be considered. Petitioner has identified no case in which a *third* stipulation filed *after* the sur-reply to the POPR was relied on to skirt *Fintiv*. And doing so here would encourage gamesmanship and ever-changing positions until institution from petitioners seeking advantage (and more unnecessary briefing). Institution should be denied based on *Fintiv*—including because of Petitioner’s chosen relationship with other litigation defendants (and despite the December 2024 trial date; see Pap.15, 1; *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 due to joinder)).

Respectfully submitted: /Megan Raymond/

April 3, 2024

CERTIFICATE OF SERVICE

The undersigned hereby certifies that a copy of NOVO NORDISK’S FURTHER AUTHORIZED REPLY AND EXHIBITS 2024-2026 have been served in their entirety on April 3, 2024, by causing the aforementioned documents to be electronically mailed to the following attorneys of record for the Petitioner listed below.

Petitioner’s Counsel of Record:

Lead Counsel:	Jovial Wong Reg. No. 60,115 Winston & Strawn LLP 1901 L Street NW Washington, DC 20036 Telephone: (202) 282-5867 jwong@winston.com By Electronic Mail
Backup Counsel:	Scott Border Reg. No. 77,744 Winston & Strawn LLP 1901 L Street NW Washington, DC 20036 Telephone: (202) 285-5054 sborder@winston.com Sharon Lin McIntosh (<i>pro hac vice</i> to be submitted) Winston & Strawn LLP 1901 L Street NW Washington, DC 20036 Telephone: (202) 285-5756 slin@winston.com By Electronic Mail

Dated: April 3, 2024

Respectfully submitted,

By: /Sayem Osman/
Sayem Osman