

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

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