

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC.,
Petitioner

v.

NOVO NORDISK A/S,
Patent Owner

Case IPR2023-00724
Patent 10,335,462

PATENT OWNER'S RESPONSE

PROTECTIVE ORDER MATERIAL

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LIST OF EXHIBITS

Exhibit	Description
EX2001	U.S. Patent No. 9,764,003 File History
EX2002	U.S. Patent No. 9,764,003
EX2003	Excerpt of Amended Joint Claim Construction Chart, <i>In re: Ozempic (Semaglutide) Patent Litigation</i> , No. 1:22-cv-01040-CFC, Dkt. 101 (D. Del. May 23, 2023)
EX2004	Miller, M., et al., “Low Viscosity Highly Concentrated Injectable Nonaqueous Suspensions of Lysozyme Microparticles,” <i>Langmuir</i> , Author Manuscript (2011), PMC 2011 (Feb 17)
EX2005	Knight, A., “Systematic Reviews of Animal Experiments Demonstrate Poor Contributions Toward Human Healthcare,” <i>Reviews on Recent Clinical Trials</i> , Vol.3, Issue 2, 89-96 (2008)
EX2006	Arrowsmith, J., “Phase II failures: 2008–2010,” <i>Nature Reviews, Drug Discovery</i> , Vol. 10 (May 2011)
EX2007	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. 1:22-cv-01040-CFC, (D. Del. Dec. 21, 2022)
EX2008	Ozempic®, Prescribing Information (October 2022)
EX2009	Declaration of Sayem Osman
EX2010	Declaration of Julio Rosenstock, M.D.
EX2011	Declaration of George L. Bakris, M.D.
EX2012	Rossing, P., et al., “The rationale, design and baseline data of FLOW, a kidney outcomes trial with once-weekly semaglutide in people with type 2 diabetes and chronic kidney disease,” <i>Nephrol Dial Transplant</i> , Vol.38, 2041-2051 (2023)
EX2013	Heerspink, H., et al., “Effects of Semaglutide on Albuminuria and Kidney Function in People with Overweight or Obesity With or Without Type 2 Diabetes: Exploratory Analysis from the STEP 1, 2 and 3 Trials,” <i>Diabetes Care</i> , Vol.46, Issue 4, 801-810 (2023)
EX2014	Weeda, E., et al., “Medication adherence to injectable glucagon-like peptide-1 (GLP-1) receptor agonists dosed once weekly vs once daily in patients with type 2 diabetes: A meta-analysis,” <i>Int J Clin Pract.</i> , Vol.75 (2021)

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EX2015	Shaman, A., et al., “Effect of the Glucagon-Like Peptide-1 Receptor Agonists Semaglutide and Liraglutide on Kidney Outcomes in Patients With Type 2 Diabetes: Pooled Analysis of SUSTAIN 6 and LEADER,” <i>Circulation</i> , Vol.145, 575-585 (2022)
EX2016	Mehdi, S., et al., “Glucagon-like peptide-1: a multi-faceted anti-inflammatory agent,” <i>Frontiers in Immunology</i> , Vol. 14 (2023)
EX2017	Novo Nordisk Company Announcement (October 10, 2023)
EX2018	Transcript of December 29, 2023 Deposition of John Bantle, M.D.
EX2019	Transcript of January 5, 2024 Deposition of William J. Jusko, Ph.D.
EX2020	World Trade Organization: Members and Observers, available at https://www.wto.org/english/thewto_e/whatis_e/tif_e/org6_e.htm (last visited January 15, 2024)
EX2021	Drug Product: Semaglutide C solution for injection, syringe, Pharmaceutical Development (produced as NN-OZEM-000158851) [UNDER SEAL]
EX2022	April 22, 2009 NN9535-1821 Key Results Meeting Presentation (produced as NN-OZEM-004470861) [UNDER SEAL]
EX2023	April 22, 2009 email from Lise Brondsted to Christine Jensen et al (produced as NN-OZEM-004470860) [UNDER SEAL]
EX2024	May 22, 2009 email from Milan Zdravkovic to Christine Jensen et al (produced as NN-OZEM-004449575) [UNDER SEAL]
EX2025	May 25, 2009 Selection of Doses for Phase 3 presentation (produced as NN-OZEM-004338784) [UNDER SEAL]
EX2026	March 5, 2010 email exchange between Daniel Jonker and Christine Jensen (produced as NN-OZEM-004442953) [UNDER SEAL]
EX2027	March 5, 2010 PK/PD Simulations presentation (produced as NN-OZEM-004442955) [UNDER SEAL]
EX2028	March 17, 2010 Novo Nordisk Diabetes Pipeline Advisory Board Meeting presentation (produced as NN-OZEM-000020275) [UNDER SEAL]
EX2029	May 25, 2010 email from Niklas Ohrner to Christine Jensen (produced as NN-OZEM-004443136) [UNDER SEAL]
EX2030	May 28, 2010 DPCComm presentation (produced as NN-OZEM-004443139) [UNDER SEAL]
EX2031	June 9, 2010 End of Phase 2 Meeting Minutes (produced as NN-OZEM-004338845) [UNDER SEAL]
EX2032	April 23, 2012 NN9535-3819 Key Result Meeting presentation (produced as NN-OZEM-004341616) [UNDER SEAL]

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EX2033	September 24, 2012 NN9535-3819 Clinical Trial Report (produced as NN-OZEM-000064989) [UNDER SEAL]
EX2034	September 19, 2011 NN9535-3819 Safety Committee Meeting (produced as NN-OZEM-004435305) [UNDER SEAL]
EX2035	September 18, 2011 email from Lisbeth Vesterg Jacobsen to Christine Jensen (produced as NN-OZEM-004435304) [UNDER SEAL]
EX2036	NN9535-3819 CTR Workflow (produced as NN-OZEM-004437994) [UNDER SEAL]
EX2037	--intentionally omitted--
EX2038	March 11, 2010 email from Anne Flint to Nilas Ohrner, copying Christine Jensen (produced as NN-OZEM-004442969) [UNDER SEAL]
EX2039	March 11, 2010 draft Semaglutide Dose selection for phase 3 presentation (produced as NN-OZEM-004442970) [UNDER SEAL]
EX2040	November 26, 2010 draft Clinical Trial Protocol for NN9535-3819 (produced as NN-OZEM-004434630) [UNDER SEAL]
EX2041	November 26, 2010 email from Anne Flint to Christine Jensen et al (produced as NN-OZEM-004434628) [UNDER SEAL]
EX2042	--intentionally omitted--
EX2043	--intentionally omitted--
EX2044	--intentionally omitted--
EX2045	--intentionally omitted--
EX2046	May 20, 2010 DPComm Summary Sheet (produced as NN-OZEM-004338873) [UNDER SEAL]
EX2047	May 28, 2010 DPComm Clipping (produced as NN-OZEM-004338872) [UNDER SEAL]
EX2048	Drug Product Semaglutide B, 1.34 mg/ml, Description and Composition of the Drug Product [UNDER SEAL]
EX2049	Declaration of Devraj Chakravarty
EX2050	Declaration of Christine B. Jensen, Ph.D. [UNDER SEAL AND REDACTED COPIES]
EX2051	Declaration of Anne Flint [UNDER SEAL AND REDACTED COPIES]
EX2052	Declaration of Chloe Jiang
EX2053	Declaration of Smita Agarwal
EX2054	Declaration of Robin S. Goland, M.D.
EX2055	Declaration of Michael J. Blaha, M.D.
EX2056	Declaration of Patrick J. Sinko, Ph.D. [UNDER SEAL AND REDACTED COPIES]

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EX2057	Declaration of Jenna DiCicco
EX2058	Declaration of Sayem Osman
EX2059	Declaration of Vanessa Costain
EX2060	Rosenstock, J., et al., “The Fate of Taspoglutide, a Weekly GLP-1 Receptor Agonist, Versus Twice-Daily Exenatide for Type 2 Diabetes,” <i>Diabetes Care</i> , Vol.36, 498-504 (March 2013)
EX2061	Nordqvist, C., “Experimental Diabetes Drug Taspoglutide Late-Stage Trials Suspended,” available at https://www.medicalnewstoday.com/articles/200893#1 (September 13, 2010)
EX2062	Rosenstock, J., et al., “Potential of Albiglutide, a Long-Acting GLP-1 Receptor Agonist, in Type 2 Diabetes,” <i>Diabetes Care</i> , Vol.32, Issue 10, 1880-1886 (October 2009)
EX2063	OPTUMRx, “Tanzeum® (albiglutide) – Drug Discontinuation,” available at https://professionals.optumrx.com/content/dam/optum3/professional-optumrx/news/rxnews/drug-recalls-shortages/drugwithdrawal_tanzeum_2017-0801.pdf (2017)
EX2064	Synapse, “Pegylated GLP-1 analogue (LY2428757) – (Eli Lilly & Co.),” available at https://synapse.patsnap.com/drug/482a547adeba4170ab23efa225fb966d (last updated December 27, 2023)
EX2065	Novo Nordisk, “Annual Report 2010” (February 1, 2011)
EX2066	Kim, K., et al., “Differences in Drug Pharmacokinetics Between East Asians and Caucasians and the Role of Genetic Polymorphisms,” <i>J Clin Pharmacol</i> , Vol.44, 1083-1105 (2004)
EX2067	Evaluation and Licensing Division, Pharmaceutical and Food Safety Bureau, Ministry of Health, Labour and Welfare, “Report on the Deliberation Results,” available at https://www.pmda.go.jp/files/000153180.pdf (December 3, 2009)
EX2068	Victoza® Prescribing Information (January 2010)
EX2069	Ozempic® Prescribing Information (September 2023)
EX2070	NCT03144271, “Dose Escalation of Single Subcutaneous Doses of NNC 0113-0217 to Assess Safety, Tolerability, Pharmacokinetics and Pharmacodynamics in Healthy Male Subjects,” available at https://clinicaltrials.gov/study/NCT03144271 (last visited December 28, 2023)

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