

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC., DR. REDDY'S LABORATORIES,
INC., DR. REDDY'S LABORATORIES, LTD.,
SUN PHARMACEUTICAL INDUSTRIES LTD.,
SUN PHARMACEUTICAL INDUSTRIES, INC., and APOTEX INC.,
Petitioner,

v.

NOVO NORDISK A/S,
Patent Owner.

IPR2023-00724¹
Patent 10,335,462 B2

Before JOHN G. NEW, SUSAN L. C. MITCHELL, and
ROBERT A. POLLOCK, *Administrative Patent Judges*.

MITCHELL, *Administrative Patent Judge*.

ORDER

Granting Patent Owner's Motion to Expunge Confidential Information
37 C.F.R. § 42.56

¹ IPR2024-00009 (Dr. Reddy's Laboratories), IPR2024-00107 (Sun Pharmaceutical Industries), and IPR2024-00631 (Apotex Inc.) have been joined with this proceeding.

I. Motion to Expunge

Novo Nordisk A/S (“Patent Owner”) moves to expunge certain confidential papers and exhibits in this proceeding, IPR2023-00724, that contain Patent Owner’s confidential business information. Paper 121, 1. Patent Owner represents that this request is unopposed as Patent Owner is the only remaining party in this proceeding. *Id.* at 1 & n.2.

Patent Owner requests that the documents in the following list be expunged.

Document	Description
Paper 29	Patent Owner Response
Paper 53	Petitioner’s Reply
Paper 73	Patent Owner’s Sur-Reply
Paper 89	Patent Owner’s Oral Hearing Demonstratives
Paper 90	Patent Owner’s Submission of Unresolved Objections to Petitioner’s Demonstratives
Paper 94	Petitioner’s Objections to Patent Owner’s Demonstrative Exhibits
Exhibit 1308	Reply Declaration of Deforest McDuff, Ph.D.
Exhibit 1311	Transcript of March 14, 2024 Deposition of Anne Flint, Ph.D.
Exhibit 1312	Transcript of March 22, 2024 Deposition of Christine B. Jensen, M.D., Ph.D.
Exhibit 1314	Transcript of April 24, 2024 Deposition of Christopher A. Vellturo, Ph.D.
Exhibit 1323	NN-OZEM-004426808
Exhibit 1334	Petitioner’s Oral Hearing Demonstratives
Exhibit 2021	Drug Product: Semaglutide C solution for injection, syringe, Pharmaceutical Development

Document	Description
Exhibit 2022	April 22, 2009 NN9535-1821 Key Results Meeting Presentation
Exhibit 2023	April 22, 2009 email from Lise Brondsted to Christine Jensen et al
Exhibit 2024	May 22, 2009 email from Milan Zdravkovic to Christine Jensen et al
Exhibit 2025	May 25, 2009 Selection of Doses for Phase 3 presentation
Exhibit 2026	March 5, 2010 email exchange between Daniel Jonker and Christine Jensen
Exhibit 2027	March 5, 2010 PK/PD Simulations presentation
Exhibit 2028	March 17, 2010 Novo Nordisk Diabetes Pipeline Advisory Board Meeting presentation
Exhibit 2029	May 25, 2010 email from Niklas Ohrner to Christine Jensen
Exhibit 2030	May 28, 2010 DPComm presentation
Exhibit 2031	June 9, 2010 End of Phase 2 Meeting Minutes
Exhibit 2032	April 23, 2012 NN9535-3819 Key Result Meeting presentation
Exhibit 2033	September 24, 2012 NN9535-3819 Clinical Trial Report
Exhibit 2034	September 19, 2011 NN9535-3819 Safety Committee Meeting
Exhibit 2035	September 18, 2011 email from Lisbeth Vesterg Jacobsen to Christine Jensen
Exhibit 2036	NN9535-3819 CTR Workflow
Exhibit 2038	March 11, 2010 email from Anne Flint to Niklas Ohrner, copying Christine Jensen
Exhibit 2039	March 11, 2010 draft Semaglutide Dose selection for Phase 3 presentation
Exhibit 2040	November 26, 2010 draft Clinical Trial Protocol for NN9535-3819
Exhibit 2041	November 26, 2010 email from Anne Flint to Christine Jensen et al

Document	Description
Exhibit 2046	May 20, 2010 DPComm Summary Sheet
Exhibit 2047	May 28, 2010 DPComm Clipping
Exhibit 2048	Drug Product Semaglutide B, 1.34 mg/ml, Description and Composition of the Drug Product
Exhibit 2050	Declaration of Christine B. Jensen, Ph.D.
Exhibit 2051	Declaration of Anne Flint
Exhibit 2056	Declaration of Patrick J. Sinko, Ph.D.
Exhibit 2300	Declaration of Christopher A. Vellturo, Ph.D.
Exhibit 2301	IQVIA Data
Exhibit 2302	February 27, 2020 Specifications for 2020 Ozempic [®] People Cover Wrap
Exhibit 2303	March 3, 2020 Specifications for the “Music Man Digital Exam Room Poster”
Exhibit 2304	July 30, 2021 internal specifications for the Ozempic [®] website with savings card details
Exhibit 2305	September 13, 2021 internal specifications for the Ozempic [®] website with savings card details
Exhibit 2306	January 30, 2018 Brand Strategy presentation
Exhibit 2307	January 12, 2018 Ozempic [®] Brand Presentation
Exhibit 2308	July 6, 2018 Product Development Plan, Ozempic [®] NN9535
Exhibit 2309	September 18, 2018 Semaglutide NNI Evidence Generation Plan – 2018-2021/25 presentation
Exhibit 2310	September 22, 2018 SC Semaglutide QW, US RWE Plan presentation
Exhibit 2311	June 13, 2017 Market Access – Track 6 presentation
Exhibit 2312	September 5, 2018 Novo Nordisk/Non-Insulin Market Weekly Performance Report spreadsheet
Exhibit 2313	November 5, 2019 Market Overview/GLP-1 Strategy presentation

Document	Description
Exhibit 2314	May 16, 2017 Semaglutide Ad Board Market Overview presentation
Exhibit 2315	November 5, 2019 Ozempic® US Launch Tracker presentation
Exhibit 2316	May 6, 2020 Integrated Insights Ecosystem, Wave 1 Quarterly Insights Report presentation
Exhibit 2317	June 2, 2021 Integrated Insights Ecosystem, 2021 Q1 Quarterly Insights Report presentation
Exhibit 2318	March 28, 2018 GfK RepInsight® spreadsheet
Exhibit 2320	September 12, 2018 GLP-1 ATU 3Q18, West Area Analysis presentation
Exhibit 2321	September 10, 2018 GLP-1 ATU 3Q18 presentation
Exhibit 2322	February 17, 2021 Integrated Insights Ecosystem, Wave 4 Quarterly Insights Report presentation
Exhibit 2323	February 26, 2019 Ozempic US Launch Tracker presentation
Exhibit 2324	May 2017 Brand Strategy 2018 GLP-1 Franchise presentation
Exhibit 2325	February 23, 2022 Quarterly Insights Report – Q4’ 2021, Diabetes Integrated Insights Ecosystem presentation
Exhibit 2326	November 16, 2021 Quarterly Insights Report – Q3’ 2021, Diabetes Integrated Insights Ecosystem presentation
Exhibit 2327	February 17, 2021 Integrated Insights Ecosystem, Wave 4 Quarterly Insights Report presentation
Exhibit 2328	August 8, 2021 specifications for detailing material
Exhibit 2329	January 4, 2021 CV Region New Year Kick-Off Meeting presentation
Exhibit 2330	November 11, 2020 Integrated Insights Ecosystem, Wave 3 Quarterly Report presentation
Exhibit 2331	May 6, 2020 Integrated Insights Ecosystem, Wave 1 Quarterly Report presentation
Exhibit 2332	May 2017 GLP-1 Franchise Patient Segmentation, Results & Recommendations presentation

Document	Description
Exhibit 2333	August 11, 2020 Integrated Insights Ecosystem, Wave 2 Quarterly Report presentation
Exhibit 2334	January 17, 2018 Pre-POA opening presentation
Exhibit 2555	Transcript of July 19, 2024 Deposition of DeForest McDuff
Exhibit 2558	February 26, 2010 DPComm Brief Summary Sheet

Paper 117, 3.

Patent Owner states:

[T]he confidential information contained in the above-discussed documents includes non-public research and development information in the form of proprietary clinical and scientific data concerning semaglutide, confidential information about drug development and regulatory approval strategies, and confidential business information, including proprietary financial information and marketing strategies. The confidential information also includes confidential information in the form of third-party proprietary business and financial information provided to Novo Nordisk contingent upon and subject to confidentiality restrictions and sealing of this information under the terms of the PTAB's default protective order.

Paper 121, 4–5. Patent Owner also asserts that where possible, sensitive information was redacted from these documents and these redacted documents are available on the public docket for this case. *Id.* at 3.

Patent Owner asserts that good cause exists for expungement of these papers and exhibits because these documents contain information as described above that “remains confidential such that public disclosure would likely cause irreparable harm to Novo and the third party.” Paper 121, 5. Patent Owner also asserts that “given that the Board did not rely on any of this material in its institution decision and did not issue a final written

decision, the record of the proceeding would remain understandable even after the above referenced exhibits and papers are expunged.” *Id.*

Patent Owner concludes that “there is good cause to expunge such information now that this proceeding has concluded. Doing so would not affect the public interest, particularly since most of the record would remain publicly available.” Paper 121, 5.

There is generally an expectation that information will be made public where the existence of the information is referred to in a decision to grant or deny a request to institute a review, or is identified in a final written decision following a trial. USPTO, *Consolidated Trial Practice Guide* (November 2019) at 21–22. A party seeking to maintain the confidentiality of information, however, may file a motion to expunge the information from the record prior to the information becoming public. *Id.* (see also 37 C.F.R. § 42.56).

After considering the Motion to Expunge, we grant Patent Owner’s Motions to Expunge. We find that the public has sufficient information from the public Institution Decision as well as the public, redacted versions of the confidential papers to understand sufficiently the record in this case.

IV. ORDER

Accordingly, it is hereby:

ORDERED that Patent Owner’s Motion to Expunge is *granted*;

FURTHER ORDERED that the documents in the table set forth above in this opinion, including Exhibits 2021–2036, 2038–2041, 2046–2048, 2050, 2051, 2056, 2300–2318, 2320–2334, 1308, 1311, 1312, 1314, 1323, 2555, and 2558, and Patent Owner Response (Paper 29), Petitioner’s Reply

(Paper 53), Patent Owner Sur-Reply (Paper 73), Petitioner's Oral Hearing Demonstratives (Exhibit 1334), Patent Owner's Oral Hearing Demonstratives (Paper 89), Patent Owner's Submission of Unresolved Objections to Petitioner's Demonstratives (Paper 90), and Petitioner's Objections to Patent Owner's Demonstrative Exhibits (Paper 94), be expunged from the record in this proceeding.

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