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Paper 16
Entered: May 28, 2024

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SUN PHARMACEUTICAL INDUSTRIES LTD. and
SUN PHARMACEUTICAL INDUSTRIES, INC.,
Petitioner,

v.

NOVO NORDISK A/S,
Patent Owner.

IPR2024-00107
Patent 10,335,462 B2

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

MITCHELL, *Administrative Patent Judge*.

DECISION
Granting Institution of *Inter Partes* Review
35 U.S.C. § 314

Granting Motion for Joinder
35 U.S.C. § 315(c); 37 C.F.R. § 42.122

I. INTRODUCTION

A. Background

Sun Pharmaceutical Industries Ltd. and Sun Pharmaceutical Industries Inc. ("Petitioner") filed a Petition requesting an *inter partes* review of claims 1–10 of U.S. Patent No. 10,335,462 B2 (Ex. 1001, "the '462 patent"). Paper 3 ("Pet."). Petitioner also filed a Motion for Joinder with the Petition seeking joinder with *Mylan Pharmaceuticals Inc. v. Novo Nordisk A/S*, IPR2023-00724 ("Mylan IPR"), which we have previously instituted on the same challenged claims of the '462 patent. Paper 2 ("Mot."); *see* IPR2023-00724, Paper 10 (PTAB Oct. 4, 2024) ("Mylan Dec.").

Patent Owner Novo Nordisk A/S ("Patent Owner") did not file an opposition to Petitioner's Motion for Joinder. *See* Paper 8 (Joint Stipulation Regarding Petitioners' Motion for Joinder"), 1. Patent Owner, however, filed a Preliminary Response requesting that we exercise our discretion to deny the Petition under 35 U.S.C. § 314(a) in light of the parallel district court proceeding and Petitioner's delay in filing this Petition requesting *inter partes* review. Paper 10, 1–2.

Petitioner filed an authorized Reply addressing whether discretionary denial is appropriate. Paper 11. Patent Owner filed an authorized Sur-Reply in response. Paper 12.

We further authorized Petitioner to file an updated *Sotera*[1] stipulation that it filed with the District Court in parallel litigation in which it agrees

[1] *See Sotera Wireless, Inc. v. Masimo Corp.*, IPR2020-01019, Paper 12 (PTAB Dec. 1, 2020) (precedential as to § II.A) (discussing the petitioner's broad stipulation to limit invalidity grounds in district court).

that it is estopped to the same extent as the petitioner in the original case to which it seeks joinder. *See* Exhibit 1099 (*Sotera* Stipulation). We also authorized Patent Owner an additional brief to address discretionary denial in view of Petitioner's *Sotera* stipulation, and authorized Petitioner a one-page response. *See* Exhibit 3001; Papers 14, 15, respectively.

We have authority to determine whether to institute an *inter partes* review under 35 U.S.C. § 314 and 37 C.F.R. § 42.4(a). To institute an *inter partes* review, we must determine that the information presented in the Petition shows "a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." 35 U.S.C. § 314(a).

For the reasons set forth below, we decline to exercise our discretion to deny the Petition under 35 U.S.C. § 314(a) because of Petitioner's *Sotera* stipulation and the postponement of the district court's trial date, and conclude that Petitioner has established a reasonable likelihood that it would prevail in showing the unpatentability of at least one of the challenged claims of the '462 patent. Therefore, we institute an *inter partes* review for claims 1–10 of the '462 patent on the same grounds instituted in the Mylan IPR, and we grant Petitioner's Motion for Joinder.

B. Related Proceedings

The parties identify the following consolidated litigation involving the '462 patent to which Petitioner is a defendant: (1) *Novo Nordisk Inc. and Novo Nordisk A/S v. Sun Pharmaceutical Industries Ltd. and Sun Pharmaceutical Industries, Inc.*, No. 1:22-cv-00296 (D. Del.) (transferred to MDL on August 5, 2022); (2) *In re Ozempic (Semaglutide) Patent*

Litigation, No. 22-md-3038-CFC (D. Del.) ("Delaware Litigation"); and (3) *Novo Nordisk Inc. and Novo Nordisk A/S v. Rio Biopharmaceuticals, Inc. et al.*, No. 1:22-cv-00294 (D. Del.). Pet 1–2; Paper 5, 1–2; Paper 7, 1. The parties also list the following litigations that involve the '462 patent: (1) *Novo Nordisk Inc. v. Aurobindo Pharma USA, Inc.*, No. 1:22-cv-00295 (D. Del.) (dismissed on March 28, 2022); (2) *Novo Nordisk Inc. v. Rio Biopharmaceuticals, Inc.*, No. 1:22-cv-00294 (D. Del.); (3) *Novo Nordisk A/S v. Sun Pharm. Indus. Ltd.*, No. 1:22-cv-00296 (D. Del.); (4) *Novo Nordisk Inc. v. Zydus Worldwide DMCC*, No. 1:22-cv-00297 (D. Del.); (5) *Novo Nordisk Inc. v. Mylan Pharms. Inc.*, No. 22-cv-01040-CFC (D. Del.) (6) *Novo Nordisk Inc. v. Dr. Reddy's Labs. Ltd.*, No. 1:22-cv-00298 (D. Del.); and (7) *Novo Nordisk Inc. v. Alvogen, Inc.*, No. 1:22-cv-00299 (D. Del.). Pet. 2; Paper 5, 1–2; Paper 7, 2.

The parties also identify the following *inter partes* review proceedings as a related matter involving the '462 patent: *Mylan Pharmaceuticals Inc. v. Novo Nordisk A/S*, IPR2023-00724 (PTAB) and *Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Labs., Ltd v. Novo Nordisk A/S*, IPR2024-00009, both of which are instituted. Pet. 2; Paper 5, 1; Paper 7, 3; *see* IPR2023-00724, Paper 10; IPR2024-00009, Paper 19. There is also one additional petition filed along with a motion for joinder to IPR2023-00724 that is pending decision on whether to institute trial: *Apotex Inc. v. Novo Nordisk A/S*, IPR2024-00631 (PTAB).

C. Asserted Grounds of Unpatentability

Petitioner asserts the following grounds of unpatentability, which are identical to the grounds on which we instituted trial in IPR2023-00724:

Claim(s) Challenged	35 U.S.C. §[2]	Reference(s)/Basis
1–3	102(a), (e)	WO421[3]
1–3	102(b)	Lovshin[4]
1–10	103(a)	WO421, '424 publication[5]
1–10	103(a)	WO537,[6] Lovshin
1–10	103(a)	NCT657,[7] NCT773,[8] '424 publication

Compare Pet. 4, *with* Mylan Dec. 6–7, 40.

[2] The Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011) ("AIA"), included revisions to 35 U.S.C. §§ 102 and 103 that became effective on March 16, 2013, after the filing of the applications to which the '462 patent claims priority. Therefore, we apply the pre-AIA versions of Sections 102 and 103.

[3] Thomas Klein et al., WO 2011/138421 A1, published November 10, 2011 (Ex. 1011, "WO421").

[4] Julie A. Lovshin and Daniel J. Drucker, *Incretin-based therapies for type 2 diabetes mellitus*, 5 NATURE REVIEWS/ENDOCRINOLOGY 262–269 (2009) (Ex. 1012, "Lovshin").

[5] Tina B. Pedersen et al., US 2007/0010424 A1, published Jan. 11, 2007 (Ex. 1016, "'424 publication").

[6] Jesper Lau et al., WO 2006/097537 A2, published Sept. 21, 2006 (Ex. 1015, "WO537").

[7] ClinicalTrials.gov, Clinical Trial No. NCT00696657, *A Randomised Controlled Clinical Trial in Type 2 Diabetes Comparing Semaglutide to Placebo and Liraglutide*, http://web.archive.org/web/20111020123620/https://clinicaltrials.gov/ct2/show/NCT00696657 (Ex. 1013, "NCT657").

[8] ClinicalTrials.gov, Clinical Trial No. NCT00851773, *Safety, Tolerability, and Profile of Action of Drug in the Body of NN9536 in Healthy Male Japanese and Caucasian Subjects*, https://web.archive.org/web/20090911011536/https://clinicaltrials.gov/ct2/show/NCT00851773 (Ex. 1014, "NCT773").

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