Trials@uspto.gov
571-272-7822

Paper 19
Entered: April 25, 2024

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

DR. REDDY'S LABORATORIES, INC. and
DR. REDDY'S LABORATORIES, LTD.,
Petitioner,

v.

NOVO NORDISK A/S,
Patent Owner.

IPR2024-00009
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

Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories, Ltd. ("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 2 ("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 3 ("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 12 (Joint Stipulation Regarding Petitioners' Motion for Joinder submitted "in lieu of [Patent Owner] filing an opposition to that motion"). Patent Owner, however, filed a Preliminary Response requesting that we exercise our discretion to deny the Petition under 35 U.S.C. §§ 314(a) and 315(c)[1] in light

[1] Patent Owner asserts that the Petition was not "properly filed" because it was filed more than one year after Petitioner was served with a complaint alleging infringement of the '462 patent. *See* Prelim. Resp. 24–25. Although acknowledging that the United States Court of Appeals for the Federal Circuit has taken an opposing view, Patent Owner raised this issue to preserve it in light of a petition for a writ of *certiorari* at the Supreme Court in which it was argued that such petitions are not properly filed. *Id*. (citing *VirnetX Inc. v. Mangrove Partners Master Fund, Ltd*., No. 23-315, Dkt. 1, at 11 (U.S. Sept. 20, 2024)). The petition for writ of *certiorari* in *VirnetX* has since been denied. *See id*., *cert. denied* Feb. 20, 2024.

of the parallel district court proceeding and Petitioner's delay in filing this Petition requesting *inter partes* review. Paper 13, 1.

Petitioner filed an authorized Reply addressing whether discretionary denial is appropriate. Paper 14. Patent Owner filed an authorized Sur-Reply in response. Paper 15.

After a conference call with the parties, we further authorized Petitioner to file a *Sotera*[2] stipulation in which it agrees that it is estopped to the same extent as the petitioner in the original case to which it seeks joinder, and the District Court Order changing the trial date in the parallel proceeding. *See* Exhibits 1098 (District Court's Order) and 1099 (*Sotera* Stipulation). We also authorized Patent Owner an additional brief to address discretionary denial in view of Petitioner's *Sotera* stipulation. *See* Paper 18.

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) or 315(c) 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

[2] *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).

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. v. Mylan Pharms. Inc.*, No. 22-cv-01040-CFC (D. Del.); (2) *In re Ozempic (Semaglutide) Patent Litigation*, No. 22-md-3038-CFC (D. Del.) ("Delaware Litigation"); and (3) *Novo Nordisk Inc. v. Mylan Pharms. Inc.*, No. 22-cv-00023 (N.D. W. Va.). Pet 1–2; Paper 6, 1 (noting Northern District of West Virginia case transferred to the District of Delaware); Paper 8, 1; Paper 10, 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. Dr. Reddy's Laby's Ltd.*, No. 1:22-cv-00298 (D. Del.); and (6) *Novo Nordisk Inc. v. Alvogen, Inc.*, No. 1:22-cv-00299 (D. Del.). Pet. 2; Paper 6, 2; Paper 8, 2; Paper 10, 1.

Patent Owner further identifies the following *inter partes* review proceeding as a related matter involving the '462 patent: *Mylan Pharmaceuticals Inc. v. Novo Nordisk A/S*, IPR2023-00724 (PTAB).

Paper 6, 1; Paper 8, 1; Paper 10, 1. There are also two additional petitions filed along with motions for joinder to IPR2023-00724 that are pending decisions on whether to institute trial: (1) *Sun Pharmaceutical Industries Ltd. v. Novo Nordisk A/S*, IPR2024-00107 (PTAB); and (2) *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. §[3]	Reference(s)/Basis
1–3	102(a), (e)	WO421[4]
1–3	102(b)	Lovshin[5]
1–10	103(a)	WO421, '424 publication[6]
1–10	103(a)	WO537,[7] Lovshin

[3] 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.
[4] Thomas Klein et al., WO 2011/138421 A1, published November 10, 2011 (Ex. 1011, "WO421").
[5] 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").
[6] Tina B. Pedersen et al., US 2007/0010424 A1, published Jan. 11, 2007 (Ex. 1016, "'424 publication").
[7] Jesper Lau et al., WO 2006/097537 A2, published Sept. 21, 2006 (Ex. 1015, "WO537").

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