

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

APOTEX INC.,
Petitioner,

v.

NOVO NORDISK A/S,
Patent Owner.

IPR2024-00631
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

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I. INTRODUCTION

A. Background

Apotex 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 1 (“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 4 (“Mot.”) (Public Version); *see* IPR2023-00724, Paper 10 (PTAB Oct. 4, 2024) (“Mylan Dec.”).

Patent Owner Novo Nordisk A/S (“Patent Owner”) filed an opposition to Petitioner’s Motion for Joinder, *see* Paper 13 (Public Version), and also 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 Mylan IPR and Petitioner’s delay in filing this Petition requesting *inter partes* review, *see* Paper 16, 1 (Public Version).

Petitioner filed an authorized Reply addressing whether discretionary denial is appropriate. Paper 18 (Public Version). Patent Owner filed an authorized Sur-Reply in response. Paper 21 (Parties and Board only).

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

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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 we waive the one-month time period for filing a motion for joinder for good cause shown, and we conclude that in its me-too Petition, Petitioner has established a reasonable likelihood that it would prevail in showing at trial the unpatentability of at least one of the challenged claims of the ’462 patent for the same reasons as set forth in the Mylan IPR. Therefore, we institute *inter partes* review of claims 1–10 of the ’462 patent on the same grounds instituted in the Mylan IPR. Additionally, we grant Petitioner’s Motion for Joinder.

B. Related Proceedings

The parties identify the following consolidated litigation involving the ’462 patent: (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.); (3) *Novo Nordisk Inc. v. Mylan Pharms. Inc.*, No. 22-cv-00023 (N.D.W. Va.); (4) *Novo Nordisk Inc. v. Aurobindo Pharma USA, Inc.*, No. 1:22-cv-00295 (D. Del.) (dismissed on March 28, 2022); (5) *Novo Nordisk Inc. v. Rio Biopharmaceuticals, Inc.*, No. 1:22-cv-00294 (D. Del.); (6) *Novo Nordisk A/S v. Sun Pharm. Indus. Ltd.*, No. 1:22-cv-00296 (D. Del.) (transferred to MDL on August 5, 2022); (7) *Novo Nordisk Inc. v. Zydus Worldwide DMCC*, No. 1:22-cv-00297 (D. Del.); (8) *Novo Nordisk Inc. v. Dr. Reddy’s Laby’s Ltd.*, No. 1:22-cv-00298 (D.

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Del.); and (9) *Novo Nordisk Inc. v. Alvogen, Inc.*, No. 1:22-cv-00299 (D. Del.) (dismissed on January 10, 2024). Pet. 2–3; Paper 7, 1–2.

The parties also identify the following *inter partes* review proceedings as a related matters involving the '462 patent: *Mylan Pharmaceuticals Inc. v. Novo Nordisk A/S*, IPR2023-00724 (PTAB), *Dr. Reddy's Laboratories, Inc. v. Novo Nordisk A/S*, IPR2024-00009, and *Sun Pharmaceutical Indus. Ltd. v. Novo Nordisk A/S*, Case No. IPR2024-00107, all of which have been instituted. Pet. 2; Paper 7, 1; *see* IPR2023-00724, Paper 10; IPR2024-00009, Paper 19; IPR2024-00107, Paper 16. IPR2024-00009 (Dr. Reddy's Labs.) and IPR2024-00107 (Sun Pharmaceutical Indus. Ltd) have both been joind to the Mylan IPR. *See* IPR2024-00009, Paper 19; IPR2024-00107.

Petitioner states that it “is not a party to any litigation relating to the '462 patent.” Pet. 66.

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:

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

Compare Pet. 5, with Mylan Dec. 6–7, 40; *see* Pet. 20–25 (describing asserted prior art status of asserted references).

¹ 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.

² Thomas Klein et al., WO 2011/138421 A1, published November 10, 2011 (Ex. 1011, “WO421”).

³ 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”).

⁴ Tina B. Pedersen et al., US 2007/0010424 A1, published Jan. 11, 2007 (Ex. 1016, “'424 publication”).

⁵ Jesper Lau et al., WO 2006/097537 A2, published Sept. 21, 2006 (Ex. 1015, “WO537”).

⁶ 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”).

⁷ 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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II. DISCRETIONARY DENIAL UNDER 35 U.S.C. § 314(a)

Under 35 U.S.C. § 314(a), institution of *inter partes* review is discretionary. *See Harmonic Inc. v. Avid Tech., Inc.*, 815 F.3d 1356, 1367 (Fed. Cir. 2016); *see also* 35 U.S.C. § 314(a). In *Apple Inc. v. Fintiv, Inc.*, IPR2020-00019, Paper 11 (PTAB Mar. 20, 2020) (precedential), the Board set forth six non-exclusive factors for determining “whether efficiency, fairness, and the merits support the exercise of authority to deny institution in view of an earlier trial date in the parallel proceeding.” *Id.* at 6. These factors are as follows:

1. whether the court granted a stay or evidence exists that one may be granted if a proceeding is instituted;
2. proximity of the court’s trial date to the Board’s projected statutory deadline for a final written decision;
3. investment in the parallel proceeding by the court and the parties;
4. overlap between issues raised in the petition and in the parallel proceeding;
5. whether the petitioner and the defendant in the parallel proceeding are the same party; and
6. other circumstances that impact the Board’s exercise of discretion, including the merits.

Id. at 5–6.

In evaluating these factors, we take a holistic view of whether efficiency and integrity of the system are best served by denying or instituting review. *Id.* at 6. The Director has also issued interim guidance to the Board on applying the factors. *See* Katherine K. Vidal, Interim Procedure for Discretionary Denials in AIA Post-Grant Proceedings with

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Parallel District Court Litigation (June 21, 2022) 9, *available at*:
https://www.uspto.gov/sites/default/files/documents/interim_proc_discretionary_denials_aia_parallel_district_court_litigation_memo_20220621_.pdf
 (“Director’s Guidance”).

As discussed in detail in Section IV, below, Petitioner did not timely file its Motion for Joinder within the one-month window after institution of the Mylan IPR. *See* 37 C.F.R. § 42.122(b) (“Any request for joinder must be filed, as a motion under § 42.22, no later than one month after the institution date of any *inter partes* review for which joinder is requested.”). Patent Owner asserts that Petitioner’s delay in filing its Petition asserting the same grounds and arguments as that brought in the instituted Mylan IPR supports its assertion that we should exercise our discretion to deny institution under 35 U.S.C. § 314(a) applying the factors set forth in *General Plastic Industries, Co. v. Canon Kabushiki Kaisha*, IPR2016-01357, Paper 19 (PTAB Sept. 6, 2017). *See* Prelim. Resp. 1–2 (“Apotex continued monitoring the Mylan IPR, and waited until March 1, 2024, some five months after the Mylan IPR’s institution, to file the instant copycat Petition along with an unauthorized, four-month-late, joinder motion.”). Because Patent Owner asserts that we should deny Petitioner’s untimely Motion for Joinder, Patent Owner’s discussion of the *General Plastics* factors presumes that if instituted, the instant proceeding would proceed on a parallel track to the Mylan IPR and not be joined to the Mylan IPR with Petitioner taking an understudy role. *See generally* Prelim. Resp. 3–26. Tellingly, Patent Owner states:

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Petitioner's untimely copycat petition would require the Board to duplicate its analysis of this extensive record, severely imposing upon the finite resources of the Board. That the Petition is a copycat is not relevant, as its joinder motion was untimely and Petitioner is not entitled to join, consolidate, or coordinate this IPR with the Mylan IPR. Petitioner's delay thus would involve a second separate proceeding were the Board to institute Apotex's Petition.

Prelim. Resp. 23 (citations omitted); *see, e.g., id.* at 8 ("Board may exercise its discretion to deny institution of Apotex's Petition *solely* on the basis that Apotex raises the same art and arguments as in the previously-instituted Mylan IPR"), *id.* at 16 (addressing Factor 2 of *General Plastics*, Patent Owner states: "Petitioner knew or should have known of most of the art in its Petition at least as of the time it learned of the '462 [patent] itself, and of all the art by the time it learned of the Mylan IPR."), *id.* at 18–19 ("Apotex will perpetually and improperly benefit (to PO's prejudice) from its own gamesmanship, and will have continued opportunities to roadmap its arguments based on the developments (and even the final written decision) in the Mylan IPR.").

Patent Owner also takes issue with Petitioner's failure to address Patent Owner's objective evidence of non-obviousness stating such failure supports denial of the Petition because Petitioner cannot show a reasonable likelihood of prevailing on its obviousness grounds without overcoming this evidence. *See* Prelim. Resp. 1, 26–29.

Petitioner responds that Patent Owner's Section 314(a) analysis is flawed because it "filed an IPR petition substantially similar to Mylan's so that it could serve as a silent understudy and minimize any impact on the

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pending Mylan IPR proceedings.” Paper 18, 1. Therefore, Petitioner asserts that as Mylan’s understudy, institution of the instant proceeding “would *not* burden the Board in view of the many conditions Apotex has agree to as part of assuming that role.” *Id.* at 3.

Petitioner provides four reasons why it did not need to address Patent Owner objective indicia of nonobviousness: (1) Objective indicia evidence was not relied upon in the institution of the Mylan IPR; (2) Petitioner seeks to become a silent understudy to Mylan, and Mylan had not yet addressed the indicia in its Reply when Petitioner filed its Petition; (3) Patent Owner itself did not raise objective indicia evidence in its Preliminary Response here; and (4) “[I]f the Board believes that Apotex must address those indicia, Apotex relies on the positions of Mylan and its experts, consistent with a silent understudy role.” Paper 18, 4.

As we find below in our analysis of Petitioner’s motion for joinder, Petitioner has provided good cause justifying waiver of the one-month after institution time period for requesting joinder. *See* 37 C.F.R. § 42.5(b); *see infra* Section IV. Also, as we set forth below, we are granting Petitioner’s motion for joinder under the conditions set forth by Petitioner as an understudy to Mylan mooted Patent Owner’s arguments here under 35 U.S.C. § 314(a) that assume this proceeding would go forward on a separate, but parallel, track to the Mylan IPR. *See infra* Section IV.

Therefore, we decline to exercise our discretion to deny the Petition Section 314(a).

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III. INSTITUTION OF *INTER PARTES* REVIEW

The Petition in this proceeding asserts the same grounds of unpatentability as the ones on which we instituted review in the Mylan IPR. *Compare* Pet. 5, with Mylan Dec. 6–7, 40. Here, Petitioner states:

This petition is substantively identical to Mylan’s petition filed in IPR2023-00724, except for arguments made with respect to discretionary denial under 35 U.S.C. § 314(a). For example, this Petition asserts the same unpatentability grounds of the ’462 patent upon which the Patent Trial and Appeal Board already instituted review in the Mylan IPR.

Pet. 1 (citing *Mylan Pharms. Inc. v. Novo Nordisk A/S*, IPR2023-00724, Paper No. 10 (PTAB Oct. 4, 2023)). Petitioner also states in support of its asserted ground of unpatentability:

Apotex submits the Declarations of Drs. Bantle, Jusko, and Dalby and relies on the exhibits identified in List of Exhibits, above. To preserve its right to rely on expert testimony in the event that the Mylan IPR settles, Apotex further relies on the accompanying Declarations of Dr. Judith Korner, M.D., Ph.D. (Ex. 1501), Dr. Mark J. Ratain, M.D. (Ex. 1503), and Dr. Hugh David Charles Smyth, Ph.D. (Ex. 1505), each of whom adopts the opinions set forth by Drs. Bantle, Jusko, and Dalby, respectively, in connection with the Mylan IPR.

Pet. 5.

In Patent Owner’s Preliminary Response, Patent Owner addresses whether we should exercise our discretion under 35 U.S.C. 314(a) to deny the Petition, and does not address the merits of the Petition at this stage of the proceeding. *See generally* Prelim. Resp.

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For the same reasons set forth in our institution decision in the Mylan IPR, we determine that Petitioner has shown a reasonable likelihood that at least one claim is unpatentable. *See Mylan IPR*, Paper 10, 17–29 (PTAB Oct. 4, 2023). We therefore institute trial as to all challenged claims on all grounds stated in the Petition.

IV. MOTION FOR JOINDER

Joinder for purposes of an *inter partes* review is governed by 35 U.S.C. § 315(c), which states:

If the Director institutes an inter partes review, the Director, in his or her discretion, may join as a party to that inter partes review any person who properly files a petition under section 311 that the Director, after receiving a preliminary response under section 313 or the expiration of the time for filing such a response, determines warrants the institution of an inter partes review under section 314.

See also 37 C.F.R. § 42.122 (describing Board’s authority for handling multiple proceedings and joinder).

As the moving party, Petitioner bears the burden of proving that it is entitled to the requested relief. 37 C.F.R. § 42.20(c). A motion for joinder should set forth the reasons joinder is appropriate, identify any new grounds of unpatentability asserted in the petition, and explain what impact (if any) joinder would have on the trial schedule for the existing review. *See Kyocera Corp. v. Softview LLC*, IPR2013-00004, Paper 15 at 4 (PTAB Apr. 24, 2013).

Petitioner did not timely file its Motion for Joinder within the one-month window after institution of the Mylan IPR, but states:

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Apotex files its joinder motion less than four months after the regulatory deadline for seeking joinder, *see* 37 C.F.R. § 42.122(b), in view of business considerations concerning Apotex's products, not due to lack of diligence nor for an improper purpose. In view of the efficiencies gained by joinder, Apotex's explanation for the timing of its filing, and the fact that the Board has not yet issued a joinder decision in the DRL and Sun IPR proceedings, the Board should waive the timing requirement for joinder and thus grant Apotex's motion for joinder.

Mot. 1–2. Petitioner also states that should we deem joinder inappropriate here, it seeks consolidation with the Mylan IPR as there is no commensurate timing requirement for consolidation. *Id.* at 2.

Finally, Petitioner analyzes each of the *Kyocera* factors set forth above. Mot. 5–9. In this analysis, Petitioner asserts that joinder is appropriate because it raises the same grounds as in the Mylan IPR, it has filed substantially identical supporting declarations, and it is willing to be a silent understudy to Mylan. *Id.* Petitioner asserts that in its silent understudy role to Mylan, its filings will be consolidated with Mylan's filings, unless a filing solely concerns issues that do not involve Mylan, it will not raise any new grounds or arguments not already raised by Mylan, and it will abide by 37 C.F.R. § 42.53 or any agreement between Patent Owner and Mylan concerning the taking of testimony. Mot. 9.

Patent Owner opposes Petitioner's motion to joinder, asserting the motion is inexcusably untimely. Paper 13, 1–8. Patent Owner asserts that "Petitioner filed its copycat petition and motion for joinder on March 1, 2024, almost four months after the deadline to move to join IPR2023-00724,

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and about a month and a half after the Patent Owner Response was filed in IPR2023-00724.” *Id.* at 1. Patent Owner also states that “Petitioner was free to file an IPR at any time, but chose (1) to file a copycat petition, and (2) to do so after the deadline for joinder, using as its sole excuse the unremarkable premise that delaying allowed it more certainty about its business plans.” Paper 9, 4 (Board and Parties Only). Patent Owner points out that Petitioner did not need to wait to file its Petition as there is no standing requirement, but *chose* to file past the joinder deadline to achieve more “business certainty” before filing. *Id.* at 5–6.

Petitioner responds that after prudently confirming its business plans in late January 2024, two months after the joinder deadline, it “quickly prepared its petition and this motion, retained 3 experts with appropriate expertise, ensured their alignment with Mylan’s experts’ positions, and assembled 3 declarations, in 4 weeks.” Paper 10, 2–3 (Board and Parties Only).

Under 37 C.F.R. § 42.5(b), we “may waive or suspend a requirement of [part 42 of the Board’s rules] and may place conditions on the waiver or suspension.” Here, we agree with Petitioner that it has shown sufficient reason for us to waive the one-month from institution joinder motion deadline. *See* 37 C.F.R. § 42.122(b). Petitioner waited until it had a sufficient business reason to file this Petition, and subsequently promptly filed its Petition and Motion for Joinder. Most critically, Petitioner raises no new unpatentability grounds, the trial schedule for the Mylan IPR need not be adjusted, and Petitioner agrees to serve in a silent understudy role.

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We determine that joinder with the Mylan IPR is appropriate under the circumstances. Accordingly, we grant Petitioner's Motion for Joinder.

V. CONCLUSION

For the foregoing reasons, we decline to exercise our discretion under 35 U.S.C. § 314(a) to deny the Petition and determine that the information presented in the Petition shows that there is a reasonable likelihood that Petitioner would prevail in challenging at least one claim of the '462 patent. At this stage in the proceeding, we have not made a final determination with respect to patentability of the challenged claims.

VI. ORDER

For the foregoing reasons, it is:

ORDERED that pursuant to 35 U.S.C. § 314(a), an *inter partes* review of claims 1–10 of the '462 patent is hereby instituted on the grounds set forth in the Petition;

FURTHER ORDERED that the Motion for Joinder with IPR2023-00724 is granted;

FURTHER ORDERED that Petitioner is joined as a party in IPR2023-00724, pursuant to 37 C.F.R. § 42.122, wherein Petitioner will maintain a secondary role in the proceeding, unless and until the current IPR2023-00724 petitioners cease to participate as a petitioner in the *inter partes* review;

FURTHER ORDERED that all future filings in the joined proceeding are to be made only in IPR2023-00724;

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FURTHER ORDERED that the case caption in IPR2023-00724 shall be changed to reflect the joinder in accordance with the below example; and

FURTHER ORDERED that a copy of this Decision shall be entered into the record of IPR2023-00724.

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC., DR. REDDY'S
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PHARMACEUTICAL INDUSTRIES LTD., SUN PHARMACEUTICAL
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⁸ IPR2024-00009 (Dr. Reddy's Laboratories); IPR2024-00107 (Sun Pharmaceutical Industries); and IPR2024-00631 (Apotex Inc.) have been joined with this proceeding.