

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”).

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 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”).

Patent Owner raises several arguments in favor of our exercise of discretion to deny this Petition under 35 U.S.C. 314(a). *See* Prelim. Resp. 7–25. Namely, Patent Owner asserts that Petitioner inappropriately delayed twenty months to file this Petition after Petitioner was sued for infringing the ’462 patent, “watching from the sidelines” while “Delaware Litigation claim construction has been completed, fact discovery has closed, and the district court has continued to move toward trial seven months from now.” Prelim. Resp. 1–2; *see id.* at 13–17 (further stating final invalidity contentions have been served and expert discovery is underway in the parallel district court proceeding). Patent Owner further states that “Petitioner’s choice to *delay* its own challenge before the Office—and its attendant request for joinder, *eliminating any final-written-decision deadline*—significantly increases the risk of inconsistent outcomes in close proximity in two different jurisdictions.” *Id.* at 4 (emphases in original).

In evaluating the *Fintiv* factors as set forth above, Patent Owner asserts that due to the advanced stage of the Delaware Litigation, it is unlikely to be stayed, the joined nature of this proceeding with the Mylan IPR renders the October 4, 2024 final written decision date a nullity, there is significant overlap between the issues raised in this Petition and those in the Delaware Litigation, and there are at least two defendants in the Delaware Litigation that are not subject to Petitioner’s *Sotera* stipulation here. Prelim. Resp. 7–23. Patent Owner concludes that the Petition does not present “compelling merits” especially in light of Patent Owner’s intent to swear

behind some of the asserted prior art and its reliance on objective indicia of non-obviousness. *Id.* at 24–25.

Petitioner responds that *Fintiv* Factors 1, 2, and 5 are neutral because neither party has asked for a stay, the expected trial date in the Delaware Litigation and the Mylan IPR are “around the same time,” and Factor 5 plays no role because Petitioner here is a defendant in the Delaware Litigation. Reply 1–3. Petitioner asserts that the remaining *Fintiv* factors favor institution because claims 2, 6, and 8–10 involved in this proceeding are not at issue in the Delaware Litigation, Petitioner’s *Sotera*-type stipulation filed in the parallel district court proceeding is “dispositive” of any *Fintiv* analysis in view of the Director’s Guidance, and the Board instituted Mylan’s *inter partes* review on the same grounds presented here. Reply 2–3.

Patent Owner responds that Petitioner’s stipulation set forth in the paragraph above does not qualify as a *Sotera* stipulation because it was “filed by Petitioner *as a joining party* and thus does not ensure avoidance of overlap between the IPR and litigation here.” Sur-Reply 2 (emphasis in original).

We granted Petitioner further authorization to file an updated stipulation as an exhibit in this proceeding that it filed with the District Court in the parallel proceeding. *See* Exhibit 3001. That stipulation provides as follows:

Sun hereby stipulates that if the Patent Trial and Appeal Board (PTAB) institutes IPR2024-00107, then Sun will agree to be bound by the estoppel provisions set forth in 35 U.S.C. § 315(e)(2) in this civil action as of the date of institution of the Petition. For the avoidance of doubt, Sun also stipulates that it is bound by the estoppel provisions set forth in 35 U.S.C. § 315(e)(2) in this civil action as of the date of the Institution

Decision as such provisions would apply to Petitioner Mylan Pharmaceutical, Inc. in the Mylan IPR.

Ex. 1099, 2.

Patent Owner filed a further authorized reply to address this stipulation. *See* Paper 14. Patent Owner asserts that this latest stipulation “should not be credited” because

Whether the Board considers Petitioner’s (“Sun’s”) latest stipulation presents two significant questions of Board practice and policy: (1) whether a purported *Sotera* stipulation should be treated as dispositive when Sun admits it ***may still pursue the stipulated grounds “behind the scenes” in district court***, and (2) whether the Board, despite its discretion, will consider Sun’s stipulation ***filed only 8 business days before institution is due***, especially when this is Sun’s *third* attempt, and Sun unfairly used the developments and briefing in a related IPR to roadmap, delay and decide how little it could offer.

Paper 14, 1.

Petitioner filed an authorized response stating that our recent decision in *Dr. Reddy’s Labs. Inc. et al. v. Novo Nordisk A/S*, IPR2024-00009, Paper No. 19, 9 (PTAB April 25, 2024) (“DRL Decision”), relying on the Director’s’s Guidance is dispositive. Paper 15, 1. Petitioner asserts that “[t]he operable facts in this case are now the same as those considered by the Board in the DRL Decision, and thus, the resolution should be the same.” *Id.*

The Director set forth in the Interim Procedure that “the PTAB will not discretionarily deny institution of an IPR or PGR in view of parallel district court litigation where a petitioner stipulates not to pursue in a parallel district court proceeding the same grounds as in the petition or any

grounds that could have reasonably been raised in the petition.” Interim Procedure, 7, 9. This guidance does not condition or otherwise qualify the effect of a *Sotera* stipulation on our exercise of discretion to deny the Petition based on any remaining defendants in the parallel litigation that are not subject to the stipulation or any alleged “behind the scenes” participation by Petitioner such as paying for experts, participating in expert reports or deposition preparation “in connection with any of the stipulated grounds.” *See* Paper 14, 1. Petitioner has filed such a stipulation. *See* Ex. 1099. Therefore, we will not exercise our discretion to deny the Petition.

We also find that with the change of the district court trial date to over two months after the original statutory due date for the Mylan IPR, the Mylan IPR should be completed before a trial in the district court begins. *See* Mylan IPR, Ex. 1098. This change in trial date, in addition to the lack of complete overlap in the claims asserted here and in the Delaware Litigation, provide further reason for us to refrain from exercising our discretion to deny the Petition under 35 U.S.C. § 314(a) regardless of remaining defendants in the Delaware Litigation that are not bound by any estoppel arising from the Mylan IPR.⁹

For the reasons set forth above, we decline to exercise our discretion to deny the Petition under 35 U.S.C. § 314(a).

⁹ Patent Owner stipulates that if we deny institution here, “and to the extent any claims challenged here are not asserted in the Delaware Litigation, it will not seek to assert those claims in the Delaware Litigation against this Petitioner.” Prelim. Resp. 23 n.9. This stipulation leaves Patent Owner free to assert all these challenged claims against other defendants in the Delaware Litigation, which does not promote the public interest in resolving patentability issues for those claims.

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. 4, with Mylan Dec. 6–7, 40. Here, Petitioner states:

[T]he Sun Petition is limited to the same grounds instituted in Mylan’s IPR2023-00724 petition. It also relies on the same prior art analysis and expert analysis submitted by Mylan. Indeed, the Petition raises grounds identical to those raised in the IPR2023-00724 petition and does not include any new grounds not raised in that petition.

Mot. 4. Petitioner also states:

In order to further simplify the proceeding, Sun will rely on the same declarants as Mylan, Dr. John Bantle, Dr. William J. Jusko, and Dr. Paul Dalby (collectively, the “Mylan Declarants”), should Mylan permit it. If Mylan allows Sun to use the Mylan Declarants, then Sun will withdraw the declarations of Dr. Melissa Weinberg, Dr. Craig Dyar, and Dr. Alekha K. Dash (the “Sun Declarants”) and rely solely on the declarations and testimonies of the Mylan Declarants.

Mot. 4.

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.

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. *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 parties review under section 314.

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 timely filed the Motion no later than one month after institution of the Mylan IPR. *See* Mot. 2–3; 37 C.F.R. § 42.122(b). As noted, the Petition in this case asserts the same unpatentability grounds on which we instituted review in the Mylan IPR. *See supra* Section III; Mot. 4–6. Petitioner also relies on the same prior art analysis and substantially identical declarant testimony to that submitted by Mylan. *See* Mot. 4–5. Petitioner states:

Further, the declarations of the Sun Declarants submitted in support of the present Petition present substantively identical

testimony to that of the Mylan Declarants, thus streamlining the issues for trial even if Mylan does not permit Sun to rely directly on the Mylan Declarants.

Mot. 5. If Mylan agrees that Petitioner may use the Mylan Declarants, Petitioner will withdraw the declarations of its declarants. Mot. 4. If Mylan does not agree to allow Petitioner to retain the Mylan Declarants, Petitioner asserts it “would agree to withdraw the Sun Declarants if the Mylan Declarants have already been deposed based on their declarations in the Mylan IPR and the deposition transcripts have been made of record,” and Petitioner would rely on those declarations and testimony of the Mylan Declarants. Mot. 6.

The Petition is substantively identical to the petition filed by Mylan. *See supra* Section III; Mot. 4. Thus, this *inter partes* review does not present any ground or matter not already at issue in the Mylan IPR.

If joinder is granted, Petitioner agrees to assume a “silent understudy” role in the Mylan IPR, and agrees that this role shall apply unless Mylan ceases to participate in the instituted IPR. Mot. 7. Petitioner also agrees that as a “silent understudy,” it will abide by the following conditions:

- (a) all filings by [Petitioner] in the joined proceeding be consolidated with the filings of Mylan, unless a filing solely concerns issues that do not involve Mylan;
- (b) Sun shall not be permitted to raise any new grounds not instituted by the Board in the Mylan IPR, or introduce any argument not already introduced by Mylan; and
- (c) With regard to taking of testimony, Sun will abide by 37 C.F.R. § 42.53 or any agreement between the Patent Owner and Mylan.

Mot. 8.

In lieu of filing an opposition to Petitioner's Motion for Joinder, Patent Owner filed a Joint Stipulation Regarding Petitioners' Motion for Joinder setting forth the parties' agreement as to the conduct of the Mylan proceeding if Petitioner is joined as a party. *See* Paper 8.

Based on our review of Petitioner's Motion for Joinder and the parties' stipulations as set forth in Paper 8, 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

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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;

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
LABORATORIES, INC., DR. REDDY'S LABORATORIES, LTD., SUN
PHARMACEUTICAL INDUSTRIES LTD., AND SUN
PHARMACEUTICAL INDUSTRIES, INC.,
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NOVO NORDISK A/S,
Patent Owner.

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¹⁰ IPR2024-00009 (Dr. Reddy's Laboratories) and IPR2024-00107 (Sun Pharmaceutical Industries) have been joined with this proceeding.