

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

APOTEX INC.,
Petitioner

v.

NOVO NORDISK A/S,
PATENT OWNER

CASE IPR2024-00631
U.S. PATENT NO. 10,335,462
ISSUED: JULY 2, 2019

TITLE:
USE OF LONG-ACTING GLP-1 PEPTIDES

**APOTEX'S MOTION FOR JOINDER UNDER
35 U.S.C. § 315(c) AND 37 C.F.R. §§ 42.22 AND 42.122(b)
TO *INTER PARTES* REVIEW OF IPR2023-00724**

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I. STATEMENT OF PRECISE RELIEF REQUESTED

Petitioner Apotex Inc. (“Apotex”) respectfully requests joinder to *Mylan Phams., Inc. v. Novo Nordisk, A/S*, IPR2023-00724 (the “Mylan IPR proceeding”), or alternatively, consolidation of this proceeding with that proceeding. Apotex files this motion concurrently with its petition for *inter partes* review (“IPR”) of U.S. Patent No. 10,335,462 (the “’462 patent”). That petition challenges the same claims of the same patent on the same unpatentability grounds supported by the same prior art, arguments, and evidence as Mylan’s petition.

Joinder is appropriate here pursuant to 35 U.S.C. § 315(c) and 37 C.F.R. § 42.122(b), because it will reduce duplicative filings and discovery, promoting quick and inexpensive resolution of the case. Apotex has filed a substantially identical petition to Mylan, Apotex’s experts have adopted the opinions set forth in Mylan’s declarations in their entirety, and Apotex is willing to be a silent understudy to Mylan. Notably, Novo Nordisk A/S (“Patent Owner”) does not oppose joinder of two other petitioners, Doctor Reddy’s Laboratories (“DRL”) and Sun Pharmaceuticals Industries, Ltd. (“Sun”).

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

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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.

Alternatively, if the Board does not waive the timing requirement for joinder, Apotex respectfully requests that the Board consolidate this IPR with Mylan's IPR pursuant to 35 U.S.C. § 315(d) and 37 C.F.R. § 42.122(a). Unlike joinder, there is no timing requirement for consolidation, and consolidation is appropriate for all the same reasons as joinder.

II. STATEMENT OF FACTS

A. Procedural History of Pending IPR Proceedings

On March 16, 2023, Mylan filed the first IPR petition challenging the '462 patent. *Mylan*, Paper No. 1, IPR2023-00724. On October 4, 2023, the Board issued its decision to institute *inter partes* review. *Mylan*, Paper No. 10, IPR2023-00724. DRL and Sun subsequently filed IPR petitions challenging the '462 patent. *Dr. Reddy's Lab 'ys v. Novo Nordisk A/S*, IPR2024-00009, Paper No. 2 (PTAB Oct. 20, 2023); *Sun Pharm. Indus. Ltd. v. Novo Nordisk A/S*, IPR2024-00107, Paper No. 3 (PTAB Nov. 2, 2023). DRL and Sun concurrently filed motions seeking joinder

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to Mylan’s IPR proceeding, expressing their willingness to be silent understudies to Mylan and explaining that their petitions were substantially identical to Mylan’s petition. *See DRL*, IPR2024-00009, Paper No. 3 (PTAB Oct. 20, 2023); *Sun*, IPR2024-00107, Paper No. 2 (PTAB Nov. 2, 2023). Patent Owner agreed not to oppose those motions.¹ *DRL*, IPR2024-00009, Paper No. 12 (PTAB Nov. 20, 2023); *Sun*, IPR2024-00107, Paper No. 8 (PTAB Nov. 28, 2023). The Board has not yet issued institution decisions as to DRL’s and Sun’s IPR petitions.

B. Apotex’s Development of a Generic Ozempic® Product and Decision to File an IPR Petition

The ’462 patent is directed to semaglutide. Ex.1001. Semaglutide is sold as Ozempic® in the form of an injectable pre-filled syringe. Ex. 1507 ¶ 1. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

¹ Patent Owner only opposes institution of DRL’s and Sun’s IPRs for reasons arising from those parties’ participation in co-pending district court litigation involving the ’462 patent. *DRL*, IPR2024-00009, Paper No. 13 (PTAB Jan. 26, 2024). Apotex, however, is not a party to that litigation.

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[REDACTED]

[REDACTED]

As part of that process, Apotex identified and retained its own experts to support its petition. Each of Apotex’s experts adopted *in toto* the opinions set forth in the respective declarations submitted by Mylan’s experts. Ex. 1501 ¶ 1; Ex. 1503 ¶ 1; Ex. 1505 ¶ 1. As such, Apotex’s IPR petition and three underlying expert declarations are substantially identical to Mylan’s petition and expert declarations, respectively.

III. LEGAL STANDARDS FOR JOINDER

The Board’s decision to permit joinder to a previously instituted IPR proceeding is a discretionary one. 35 U.S.C. § 315(c). In rendering that decision, the Board considers: (1) the reasons why joinder is appropriate, (2) whether the new petition presents new unpatentability grounds, (3) any impact on the trial schedule for the existing IPR, and (4) how briefing or discovery may be simplified (collectively, the “*Kyocera* factors”). *Kyocera Corp. v. Softview LLC*, IPR2013-

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00004, Paper No. 15 at 4 (PTAB Apr. 24, 2013); *see also, e.g., Hyundai Motor Co. v. Am. Vehicular Sci. LLC*, IPR2014-01543, Paper No. 11 at 3 (PTAB Oct. 24, 2014); *Macronix Int’l Co. v. Spansion LLC*, IPR2014-00898, Paper No. 15 at 4 (PTAB Aug. 13, 2014).

Under 37 C.F.R. § 42.122(b), a petitioner may request joinder to a previously instituted IPR proceeding “no later than one month after the institution date” of that proceeding. Nonetheless, the Board may waive or suspend this rule, 37 C.F.R. § 42.5(b), and has done so on at least two occasions, *GlobalFoundries U.S. Inc. v. Godo Kaisha IP Bridge 1*, IPR2017-00925, Paper No. 13 at 8 (PTAB June 9, 2017); *Sony Corp. of Am. v. Network-1 Security Sols.*, IPR2013-00495, Paper No. 13 at 9 (PTAB Sept. 16, 2013).

IV. STATEMENT OF REASONS FOR RELIEF REQUESTED

A. Each of the *Kyocera* Factors Weighs in Favor of Joinder

1. Joinder Is Appropriate

Joinder of Apotex to Mylan’s IPR proceeding is appropriate here. Joinder will reduce duplicative filings and discovery, promoting quick and inexpensive resolution of the case for the benefit of Board, Patent Owner, and Apotex. That is because Apotex (1) has filed a substantially identical petition to Mylan, such that the unpatentability grounds raised in its petition are the same as those in Mylan’s

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petition, (2) has filed substantially identical supporting declarations to Mylan, with its experts adopting the opinions set forth in Mylan's declarations in their entirety, and (3) is willing to be a silent understudy to Mylan. *See* §§ IV.A.2-4, *infra*.

Further, Patent Owner's agreement not to oppose joinder of DRL and Sun to Mylan's IPR proceeding shows that joinder is appropriate in circumstances such as DRL's and Sun's. *DRL*, IPR2024-00009, Paper No. 12; *Sun*, IPR2024-00107, Paper No. 8. And, apart from filing its motion outside the 1-month window, Apotex is almost identically situated to DRL and Sun given its substantively identical petition and expert declarations and willingness to serve as a silent understudy. *See DRL*, IPR2024-00009, Paper No. 3; *Sun*, IPR2024-00107, Paper No. 2.

For the foregoing reasons, this factor weighs in favor of joinder.

2. Apotex's Petition Presents No New Unpatentability Grounds

Apotex's petition presents identical grounds, prior art, challenged claims, evidence, and unpatentability arguments as Mylan's petition.

Further, Apotex's expert testimony is substantially identical to Mylan's expert testimony. If Mylan allows, Apotex will rely on Mylan's declarants and withdraw its own declarants. Even if Mylan does not allow that, if Mylan's experts' declarations and deposition transcripts become publicly available, Apotex

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will rely on the publicly available declarations and transcripts and withdraw its own declarations. And even if Apotex were compelled to rely on its own declarants, Apotex's expert declarations are substantially identical to Mylan's expert declarations. So there would be little impact on the case if Apotex must rely on its own experts' declarations. *See, e.g., Sawai USA, Inc. v. Biogen MA Inc.*, IPR2019-00789, Paper No. 17 at 19-21 (PTAB Sept. 12, 2019) (granting joinder, reasoning that the petitions had "no substantial difference" and new petitioner had its own expert declarations but agreed to withdraw them); *SAP Am. Inc. v. Clouding IP, LLC*, IPR2014-00306, Paper No. 13, at 4 (PTAB May 19, 2014) (granting joinder where petitioner agreed to same condition).

For the foregoing reasons, this factor weighs in favor of joinder.

3. Joinder Will Not Impact the Lead Case's Schedule

Joinder will not affect the lead case's schedule. Apotex's petition has no new unpatentability grounds, so no additional briefing or discovery is necessary. Further, Apotex will adhere to the deadlines set in the Mylan IPR proceeding. Moreover, Apotex is willing to be a silent understudy to Mylan, as discussed below. For the foregoing reasons, this factor weighs in favor of joinder.

4. Briefing and Discovery May Be Simplified

To simplify briefing and discovery, Apotex is willing to be a silent understudy to Mylan, meaning that the following conditions will apply if joinder is granted and Mylan remains an active party:

(1) Apotex's filings will be consolidated with Mylan's filings, unless a filing solely concerns issues that do not involve Mylan;

(2) Apotex will not raise any new grounds or arguments not already raised by Mylan; and

(3) Apotex will abide by 37 C.F.R. § 42.53 or any agreement between Patent Owner and Mylan concerning taking of testimony. *See Mylan Pharms. Inc. v. Novartis AG*, IPR2015-00268, Paper No. 17 at 5-6 (PTAB Apr. 10, 2015) (granting joinder, holding that same proposed conditions “are consistent with the ‘understudy’ role that Petitioner agrees to assume, as well as Petitioner’s assertion that its presence would not require introducing any additional arguments, briefing, or discovery.”); *Sony Corp. v. Memory Integrity, LLC*, IPR2015-01353, Paper No. 11 at 6-7 (PTAB Oct. 15, 2015) (granting joinder where petitioner agreed to same conditions). Accordingly, this factor also weighs in favor of joinder.

For the foregoing reasons, each of the *Kyocera* factors weigh in favor of joinder and therefore the Board should join Apotex to Mylan’s IPR proceeding.

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B. The Board Should Waive the Joinder Timing Requirement

The Board should waive the joinder timing requirement. As an initial matter, the reasons discussed above as to why joinder is appropriate weigh heavily in favor of waiving the requirement. *See* § IV.A.1, *supra*; *GlobalFoundries*, IPR2017-00925, Paper No. 13 at 7-8 (waiving requirement, reasoning in part that new petition raised no new unpatentability grounds, trial schedule would not need to be adjusted, and petitioner agreed to serve as a silent understudy); *Sony*, IPR2013-00495, Paper No. 13 at 9 (same).

Moreover, the timing of Apotex's filing was not due to lack of diligence or some improper purpose. Rather Apotex filed now due to business considerations relating to its development of a generic Ozempic[®] product and, upon achieving heightened confidence that it would develop a product, acted diligently in preparing its petition, declarations, and the present motion. *See* § II, *supra*.

It should also be noted that Apotex's decision to file now, rather than earlier, has not impacted the proceedings thus far, as the Board has not yet addressed DRL's or Sun's joinder motions. Nor would joinder impact the proceedings going forward, given that Apotex would serve as a silent understudy to Mylan.

For these reasons, the joinder timing requirement should be waived.

V. ALTERNATIVELY, THE BOARD SHOULD CONSOLIDATE THIS IPR PROCEEDING WITH MYLAN’S IPR PROCEEDING

If the Board does not waive the timing requirement for joinder to Mylan’s IPR proceeding, it should instead consolidate this IPR proceeding with Mylan’s IPR proceeding. The Board may consolidate one IPR proceeding with another proceeding before it, 35 U.S.C. § 315(d); 37 C.F.R. § 42.122(a), and the Board’s rules do not limit the timing of a consolidation motion, 37 C.F.R. § 42.122(a) (setting no timing requirement for a consolidation motion).

Consolidation is appropriate for the same reasons as joinder, namely that consolidation will reduce duplicative filings and discovery, promoting quick and inexpensive resolution of these issues for the benefit of Board, Patent Owner, and Apotex. *See* § IV.A.1. That is because Apotex has filed a substantially identical petition to Mylan with the same unpatentability grounds, its experts have adopted the opinions set forth in Mylan’s declarations in their entirety, and it is willing to be a silent understudy to Mylan. *Sony Elecs. Inc. v. Jawbone Innovations, LLC*, IPR2023-01110, Paper No. 12 at 2-3 (PTAB Feb. 9, 2024) (granting consolidation where petitions were “substantially identical” and one petitioner agreed to be an understudy, reasoning that consolidation would “secure a just, speedy, and inexpensive resolution to the proceedings” and promote efficiency); *ZTE (USA)*

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Inc. v. Evolved Wireless LLC, IPR2016-01277, Paper No. 8 (PTAB Dec. 21, 2016)
(granting consolidation where petitions were “identical in substance”).

VI. CONCLUSION

For the foregoing reasons, Apotex respectfully requests that the Board join Apotex to Mylan’s proceeding, or alternatively, consolidate the two proceedings.

Dated: March 1, 2024

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CERTIFICATE OF SERVICE

The undersigned certifies that, in accordance with 37 C.F.R. § 42.6(e) and 37 C.F.R. § 42.105, and with Patent Owner's consent, electronic service of APOTEX'S MOTION FOR JOINDER UNDER 35 U.S.C. § 315(c) AND 37 C.F.R. §§ 42.22 AND 42.122(b) TO *INTER PARTES* REVIEW OF IPR2023-00724 was made on Patent Owner to the following email addresses:

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