

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

APOTEX INC.,
Petitioner
v.
IPSEN BIOPHARM LTD.,
Patent Owner

Case IPR2025-01531
U.S. Patent No. 11,344,552
Issued: May 31, 2022

Title: Methods for Treating Metastatic Pancreatic Cancer Using Combination
Therapies Comprising Liposomal Irinotecan and Oxaliplatin

**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 IPR2025-00505**

I. STATEMENT OF PRECISE RELIEF REQUESTED

Petitioner Apotex Inc. (“Apotex”) respectfully requests joinder to *CSPC Pharmaceutical Group Limited et al. v. Ipsen Biopharm Ltd.*, IPR2025-00505 (the “CSPC IPR proceeding”). Apotex files this motion concurrently with its petition for *inter partes* review (“IPR”) of U.S. Patent No. 11,344,552 (the “’552 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 CSPC’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 CSPC, Apotex’s expert has adopted the opinions set forth in CSPC’s declaration in their entirety, and Apotex is willing to be a silent understudy to CSPC.

Apotex files this joinder motion within the one-month deadline following institution. *See* 37 C.F.R. § 42.122(b). The Board instituted the CSPC IPR proceeding on August 14, 2025, making the deadline for joinder September 15, 2025. This motion is timely filed.

On December 20, 2024, Patent Owner filed a complaint against Conjupro Biotherapeutics, Inc. (“CBI”) in the U.S. District Court for the District of New Jersey, Case No. 1:25-cv-13647, asserting infringement of the ’552 patent. *Ipsen Biopharm Ltd. v. Conjupro Biotherapeutics, Inc.*, No. 1:25-cv-13647 (D.N.J. filed Dec. 20, 2024). Apotex is not a party to that litigation. Approximately one year later on January 17, 2025, CBI, CSPC Pharmaceutical Group Limited, and CSPC Ouyi Pharmaceutical Co., Ltd. and (collectively “CSPC”) filed the first IPR petition challenging the ’552 patent. *CSPC*, Paper No. 1, IPR2025-00505.

On July 16, 2025, the Acting Director ruled on discretionary denial issues, determining that discretionary denial was not appropriate despite the pending litigation. *CSPC*, Paper No. 11, IPR2025-00505. On August 14, 2025, the Board issued its decision to institute *inter partes* review. *CSPC*, Paper No. 13, IPR2025-00505.

As part of preparing its IPR petition, Apotex identified and retained Robert Dreicer, M.D., M.S., MACP, FASCO, to support its petition. Dr. Dreicer has adopted *in toto* the opinions set forth in the declaration submitted by CSPC’s expert, Dr. Mark Ratain. Ex. 1501 ¶ 2. As such, Apotex’s IPR petition and underlying expert declaration are substantially identical to CSPC’s petition and expert declaration, respectively.

II. 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*, IPR2013-00004, 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. Here, Apotex’s motion is timely filed within the one-month deadline.

III. STATEMENT OF REASONS FOR RELIEF REQUESTED

A. Joinder Is Appropriate

Joinder of Apotex to CSPC’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 the Board, Patent Owner, and Apotex. That is because Apotex (1) has filed a substantially identical petition to CSPC, such that

the unpatentability grounds raised in its petition are the same as those in CSPC's petition, (2) has filed a substantially identical supporting declaration to CSPC, with its expert adopting the opinions set forth in CSPC's declaration in their entirety, and (3) is willing to be a silent understudy to CSPC. *See* §§ IV.A-D, *infra*.

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

B. Apotex's Petition Presents No New Unpatentability Grounds

Apotex's petition presents identical grounds, prior art, challenged claims, evidence, and unpatentability arguments as CSPC's petition. Specifically, Apotex challenges Claims 1-15 of the '552 patent based on the same obviousness grounds asserted by CSPC.

Further, Apotex's expert testimony is substantially identical to CSPC's expert testimony. If CSPC allows, Apotex will rely on CSPC's declarant and withdraw its own declarant. Even if CSPC does not allow that, if CSPC's expert's declaration and deposition transcript become publicly available, Apotex will rely on the publicly available declaration and transcript and withdraw its own declaration. And even if Apotex were compelled to rely on its own declarant, Apotex's expert declaration is substantially identical to CSPC's expert declaration. So there would be little impact on the case if Apotex must rely on its own expert's declaration. *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 declaration but agreed to withdraw it); *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.

C. 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 CSPC IPR proceeding, which according to the Scheduling Order (Paper No. 14) includes Patent Owner’s Response due November 10, 2025, Petitioner’s Reply due February 2, 2026, and oral argument (if requested) on May 19, 2026. Moreover, Apotex is willing to be a silent understudy to CSPC, as discussed below. For the foregoing reasons, this factor weighs in favor of joinder.

D. Briefing and Discovery May Be Simplified

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

- Apotex’s filings will be consolidated with CSPC’s filings, unless a filing solely concerns issues that do not involve CSPC;

- Apotex will not raise any new grounds or arguments not already raised by CSPC; and
- Apotex will abide by 37 C.F.R. § 42.53 or any agreement between Patent Owner and CSPC concerning taking of testimony.

See, e.g., Intel Corp. v. Alacritech, Inc., IPR2017-01409, Paper No. 10 at 3-4 (PTAB Oct. 4, 2017) (granting joinder where petitioner agreed to understudy role and consolidated filings); *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 CSPC's IPR proceeding.

IV. CONCLUSION

For the foregoing reasons, Apotex respectfully requests that the Board join Apotex to CSPC's proceeding.

Dated: September 12, 2025
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CERTIFICATE OF SERVICE

I hereby certify that on September 12, 2025, I caused a true and correct copy of the foregoing Motion for Joinder to be served by Federal Express on the Patent Owner at the following correspondence address of record as listed on the USPTO's Patent Center website:

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