

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

APOTEX, INC.,
Petitioner,

v.

IPSEN BIOPHARM LTD.,
Patent Owner.

Case No. IPR2025-01531
U.S. Patent No. 11,344,552

**PATENT OWNER'S OPPOSITION TO 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**

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I. STATEMENT OF THE PRECISE RELIEF REQUESTED

Ipsen Biopharm Ltd. (“Ipsen”) respectfully submits this Opposition to Apotex Inc.’s (“Apotex”) Motion for Joinder with the *inter partes* review of U.S. Patent No. 11,344,552 (“the ’552 patent”) filed by CSPC Pharmaceutical Group Limited, CSPC Ouyi Pharmaceutical Co., Ltd., and Conjupro Biotherapeutics Inc. (collectively, “CSPC”) instituted on August 14, 2025 (the “CSPC IPR”). Ipsen opposes Apotex’s motion to the extent that Apotex seeks to introduce new arguments and/or evidence, namely through its expert Dr. Dreicer.

Joinder is inappropriate to the extent that it would unduly burden and prejudice Ipsen under the current CSPC IPR schedule. Despite Apotex’s claim that it will be a “silent understudy” to CSPC, Apotex’s petition and expert declaration explicitly reserve the right to present new argument and evidence. Apotex’s petition relies on a declaration from an entirely new expert who reserves the right to present new argument. As such, Apotex has expressly left the door open to new and different arguments against patentability, which would unduly burden and prejudice Ipsen in defending the ’552 patent.

To the extent that Apotex intends to rely on a different expert from CSPC and/or not rely entirely on CSPC’s arguments and evidence moving forward in the CSPC IPR, Apotex’s motion for joinder should be denied.

II. STATEMENT OF MATERIAL FACTS

1. On January 17, 2025, CSPC filed its CSPC IPR Petition accompanied by an expert declaration by Mark J. Ratain. *See* IPR2025-00505, Paper 1; Ex. 1002. In his declaration, Dr. Ratain explicitly: “reserve[s] the right to address any secondary considerations put forth by Patent Owner (including but not limited to unexpected results) in any later response to this declaration or the petition it accompanies” (IPR2025-00505, Ex. 1002 at 10); “reserve[s] the right to supplement this declaration” “[t]o the extent Patent Owner asserts that the claims of the ’552 patent are entitled to an earlier priority or invention date” (*id.* at 14-15); “reserve[s] the right to supplement my Declaration should any claim terms be given different constructions” (*id.* at 15); and “reserve[s] the right to address any secondary considerations set forth by Patent Owner in any later response to this declaration or the petition it accompanies” (*id.* at 108).

2. On May 23, 2025, Patent Owner filed its Preliminary Response. *See* Paper 9. Claim construction arguments and objective indicia (secondary considerations) of nonobviousness were included in the Preliminary Response. *See id.* at 6-13, 46-51.

3. On June 23, 2025, CSPC filed its Petitioners’ Response to Patent Owner’s Request for Discretionary Denial of Institution, accompanied by a Supplemental

Expert Declaration by Mark J. Ratain. *See* IPR2025-00505, Paper 10; Ex. 1200. In this Supplemental Declaration, Dr. Ratain provides additional opinions. *See id.*

4. On August 14, 2025, the Board instituted the CSPC IPR. *See* IPR2025-00505, Decision Instituting IPR, Paper 13. At issue in the CSPC IPR are claims 1-15 based on obviousness over the prior art. In the Institution Decision, the Board addressed the construction of the terms “treat” and “treating.” *See id.* at 9-14.

5. The CSPC IPR is in the trial phase, with Ipsen’s Patent Owner Response due November 10, 2025. Dr. Ratain’s deposition has been scheduled for October 24, 2025. CSPC’s Reply to Ipsen’s Patent Owner Response will be due February 2, 2026, wherein it will have the opportunity to “respond to arguments raised in the ... patent owner response,” including potentially submitting a supplemental expert declaration. *See* 37 C.F.R. § 42.23(b).

6. On September 12, 2025, Apotex filed a Petition for *inter partes* review along with the instant motion for joinder. *See* Paper Nos. 1, 3.

7. Along with its Petition, Apotex also filed on September 12, 2025 an expert declaration from an entirely new expert—Dr. Robert Dreicer. *See* Ex. 1501. In his Declaration, Dr. Dreicer explicitly: “reserve[s] the right to address any secondary considerations put forth by Patent Owner (including but not limited to unexpected results) in any later response to this declaration or the petition it accompanies” (*id.* at 8-9); “reserve[s] the right to supplement this declaration” “[t]o the extent Patent

Owner asserts that the claims of the '552 patent are entitled to an earlier priority or invention date” (*id.* at 13); “reserve[s] the right to supplement my Declaration should any claim terms be given different constructions” (*id.*); and “reserve[s] the right to address any secondary considerations set forth by Patent Owner in any later response to this declaration or the petition it accompanies” (*id.* at 109). Dr. Dreicer notes that, in the CSPC IPR, CSPC submitted a declaration of Dr. Ratain (citing Dr. Ratain’s January 17, 2025 declaration, IPR2025-00505, Ex. 1002), and he states that he has “reviewed and considered Dr. Ratain’s declaration,” “agree[s] with Dr. Ratain’s opinions set forth in his declaration,” and has “adopted them.” Ex. 1501 at 1.

8. Dr. Dreicer does not address Dr. Ratain’s Supplemental Expert Declaration filed June 23, 2025 (IPR2025-00505, Ex. 1200), nor does he state that he adopts any opinions set forth therein. *See id.* Dr. Dreicer also does not mention CSPC’s opportunity to submit a reply to the forthcoming Patent Owner Response, wherein CSPC will have the opportunity to submit an additional declaration by Dr. Ratain, nor does Dr. Dreicer agree to adopt any opinions Dr. Ratain or CSPC may set forth therein. *See id.*

9. In its motion for joinder, Apotex stated that “[i]f CSPC allows, Apotex will rely on CSPC’s declarant and withdraw its own declarant,” and “[e]ven 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.” Paper 3 at 5. Nevertheless, Apotex filed Dr. Dreicer’s Declaration in this IPR and has not withdrawn it. *See id.*

III. JOINDER IS NOT APPROPRIATE

A. Legal Standard

The decision to grant joinder is discretionary and not a matter of right. 35 U.S.C. § 315(c); 37 C.F.R. § 42.122; *Unified Pats., Inc. v. Personalweb Techs., LLC et al.*, 2014 WL 4412491, IPR2014-00702, Paper 12 at 4 (P.T.A.B. July 24, 2014) (denying joinder despite Petitioner’s assertion that the proceedings had nearly identical petitions and noting that joinder is discretionary, not automatic). The petitioner seeking joinder bears the burden of demonstrating it is entitled to joinder. 37 C.F.R. § 42.20(c). “[J]oinder is not automatic, particularly given the need to complete proceedings in a just, speedy, and inexpensive manner.” *Unified Pats.*, 2014 WL 4412491, IPR2014-00702, Paper 12 at 4.

The Board should determine whether to grant joinder on a “case-by-case basis, taking into account the particular facts of each case.” *Harmonix Music Sys., Inc. et al. v. Princeton Digit. Image Corp.*, 2015 WL 3507762, IPR2015-00271, Paper 15 at 3 (P.T.A.B. June 2, 2015).

In deciding whether to exercise its discretion to permit joinder, the Board should consider several factors, including: (1) the reasons why joinder is appropriate; (2) whether the new petition presents any new grounds for unpatentability; (3) what

impact, if any, joinder would have on the IPR schedule for the existing review; and (4) how briefing and discovery may be simplified. *See Kyocera Corp. v. Softview LLC*, 2013 WL 5947698, at *2, IPR2013-00004, Paper 15 at 4 (P.T.A.B. Apr. 24, 2013).

B. Apotex Fails to Establish That Joinder Is Warranted

1. Apotex Has Expressly Reserved Its Opportunity to Present New Arguments and Evidence

Joinder with CSPC's IPR is not appropriate because Apotex's Petition opens the door for potential new and different arguments against patentability. Along with its Petition, Apotex submitted an Expert Declaration of Robert Dreicer. Ex. 1501. Apotex alleges in its motion for joinder that "Dr. Dreicer has adopted *in toto* the opinions set forth in the declaration submitted by CSPC's expert, Dr. Mark Ratain," and, "[a]s such, Apotex's IPR petition and underlying expert declaration are substantially identical to CSPC's petition and expert declaration, respectively." Paper 3 at 3. However, Dr. Dreicer failed to address two issues related to Dr. Ratain's opinions. First, Dr. Dreicer ignores the fact that Dr. Ratain, in his declaration, reserved his right to make future arguments—Dr. Dreicer has not addressed whether he will adopt such arguments. Second, Dr. Dreicer does not address Dr. Ratain's opinions set forth in his June 23, 2025 Supplemental Declaration, or in his potential forthcoming declaration accompanying CSPC's reply

to Patent Owner Response—Dr. Dreicer similarly has not addressed whether he will adopt such arguments.

Further, in his Expert Declaration, Dr. Dreicer explicitly “reserve[s] the right to address any secondary considerations put forth by Patent Owner (including but not limited to unexpected results) in any later response to this declaration or the petition it accompanies” (*see* Ex. 1501 at 8-9, 109), and explicitly “reserve[ed] the right to supplement [his] Declaration should any claim terms be given different constructions” (*id.* at 13). But both of these predicate conditions have already occurred: Ipsen asserted secondary considerations of non-obviousness in its Patent Owner Preliminary Response in the CSPC IPR, including unexpected results (*see* IPR2025-00505, Paper 9 at 46-51); and the Board construed the claim terms “treat” and “treating” against Dr. Ratain’s opinions in the CSPC IPR Institution Decision (*see* IPR2025-00505, Paper 13 at 13-14). Dr. Dreicer had the opportunity to address these issues but instead open-endedly “reserved the right” to opine on them at some future time.

Finally, Apotex stated that, “[i]f CSPC allows, Apotex will rely on CSPC’s declarant and withdraw its own declarant,” and, “[e]ven 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.” Paper 3 at 5. Thus, regardless of the scenario, Apotex claims

it will withdraw Dr. Dreicer's declaration, yet nevertheless submitted his declaration and has not withdrawn it. *See id.*

The two proceedings are therefore materially different, and joinder is not appropriate. *See* 37 C.F.R. § 42.1(b).

2. Joinder Would Unduly Burden Ipsen and Negatively Impact the IPR

The “rules for joinder[] must be construed to secure the just, speedy, and inexpensive resolution of every proceeding.” *Microsoft Corp. v. Biscotti Inc.*, 2015 WL 6449520, IPR2015-01054, at *3, Paper 10 at 8 (P.T.A.B. Oct. 22, 2015) (citing 37 C.F.R. § 42.1(b)). Joinder would adversely impact the IPR schedule because, as explained above, Apotex's Petition opens the door for new and different arguments against patentability. It presents new issues for the Board to address, and to which Ipsen must respond.

Because Apotex's Petition relies on a different expert's declaration, Ipsen would need to take at least one additional expert deposition if there is a joined proceeding. Despite its claims that, “[i]f CSPC allows, Apotex will rely on CSPC's declarant and withdraw its own declarant,” and, “[e]ven 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” (Paper 3 at 5), Apotex filed Dr. Dreicer's Declaration in this IPR and has not withdrawn it. If there is a joined proceeding, these new issues and

additional discovery would negatively affect the CSPC IPR schedule and possibly prevent the PTAB from issuing a final written decision within one year from institution. While the PTAB may extend the trial for an additional six months in the case of joinder (37 C.F.R. § 42.100(c)), the resulting delay and added expense would be prejudicial to Ipsen.

Accordingly, joinder with the CSPC IPR would unduly burden Ipsen and negatively impact the IPR schedule.

IV. CONCLUSION

For the foregoing reasons, Apotex's motion for joinder should be denied.

Date: October 10, 2025

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CERTIFICATE OF LENGTH (37 C.F.R. § 42.24(D))

The undersigned hereby certifies that, according to the word-processing system used to prepare the foregoing document, this document has 9 pages and thus complies with the applicable page limit.

Date: October 10, 2025

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CERTIFICATE OF SERVICE (37 C.F.R. § 42.6(E))

The undersigned hereby certifies that on October 10, 2025 copies of the foregoing document and supporting exhibits were served upon the following parties via electronic mail, with a copy to irinotecan@steptoe.com:

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