

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 REPLY TO PATENT OWNER'S
OPPOSITION TO APOTEX'S MOTION FOR JOINDER**

Apotex replies to Ipsen's opposition to Apotex's motion for joinder. *See* Paper Nos. 3, 7. Ipsen does not meaningfully contest the core facts supporting joinder and instead raises speculative concerns that Apotex may be able to introduce new arguments through its expert. Those concerns may soon be moot, and, in any event, are misplaced. Apotex has committed to withdraw its expert declaration upon availability of the deposition transcript of CSPC's expert, which Ipsen has indicated is imminent. Moreover, Apotex has already committed not to raise new arguments in its silent understudy role—a commitment that extends to its expert. Further, its petition and supporting materials mirror those of CSPC. Under well-established Board precedent, joinder is appropriate in these circumstances. Notably, Ipsen cites no precedent to the contrary.

THE ENTIRE JOINDER DISPUTE MAY BE MOOT

To begin, the entire joinder dispute may be moot. Ipsen's sole point of contention appears to be the declaration of Apotex's expert, Dr. Dreicer, and new arguments that may purportedly arise from it. Opp. 1. But Apotex will withdraw the declaration if the deposition transcript of CSPC's expert, Dr. Ratain, becomes available. Notably, Ipsen has represented that Dr. Ratain's deposition was scheduled for October 24, 2025 and its Patent Owner Response is due November 10, 2025, the same day that this reply is due. Opp. 3.

JOINDER IS APPROPRIATE

In any event, Ipsen does **not** dispute the key facts demonstrating that joinder is appropriate: Apotex (1) filed a substantially identical petition to CSPC's, (2) filed a supporting declaration that mirrors CSPC's, and (3) has committed to serve as a silent understudy to CSPC. *See* Mot. 4-5. The Board routinely grants joinder in such circumstances. *See, e.g., Feit Elec. Co., Inc v. CAO Lighting, Inc.*, IPR2023-00129, Paper No. 14 at 6-8 (May 12, 2023); *Everlight Elecs. Co., Ltd. v. Document Sec. Sys., Inc.*, IPR2018-01260, Paper No. 12 at 6-8 (Nov. 14, 2018); *Celltrion, Inc. v. Genentech, Inc.*, IPR2018-01019, Paper No. 11 at 14-15 (Oct. 30, 2018).

Yet Ipsen confusingly asserts that “Apotex’s Petition opens the door for potential new and different arguments.” Opp. 6. But that potential does not exist under the circumstances pertinent to the joinder analysis—if the Board grants joinder and the lead petitioner remains an active party. *See, e.g., Feit*, IPR2023-00129, Paper No. 14 at 6-8 (accepting petitioner’s representations as to understudy role if joinder is granted and lead petitioner remains an active party); *Everlight*, IPR2018-01260, Paper No. 12 at 6-8 (same); *Celltrion*, IPR2018-01019, Paper No. 11 at 14-15 (same). Under those circumstances, Apotex has committed to serve as a silent understudy to CSPC and **not** raise different arguments. Mot. 6-7. Indeed, Ipsen offers no citation to the petition itself to support its assertion. Opp. 6.

Instead, Ipsen relies solely upon Dr. Dreicer's declaration to suggest that Apotex may make different arguments. *Id.* at 6-7. Ipsen points to Dr. Dreicer's purported failures to address Dr. Ratain's reservation of rights in his initial declaration, potential future declarations, and supplemental declaration. *Id.* But Dr. Dreicer need not have addressed any of those. Dr. Dreicer need only have mirrored Dr. Ratain's declaration supporting CSPC's petition, which is what Dr. Dreicer did. Mot. 5-6.

As for Dr. Ratain's potential future arguments and declarations, Ipsen's concerns are speculative. It is unknown whether Dr. Ratain will even offer future opinions, let alone what the content of those opinions might be. It would be unfair and illogical to require Dr. Dreicer to address hypothetical opinions he cannot review and may or may not agree with. Indeed, Ipsen cites no authority requiring him to do so. In any event, if Dr. Ratain offers additional opinions, Dr. Dreicer cannot offer *any* opinions—different or otherwise—while Apotex serves as a silent understudy. Mot. 6-7. Dr. Dreicer's opinions serve as a backup, relevant only if Apotex cannot rely on Dr. Ratain's opinions. *Id.* at 4; *Feit*, IPR2023-00129, Paper No. 14 at 7-8 (explaining that differences between the opinions of joining petitioner's expert and lead petitioner's expert "have no relevance" if petitioner does not rely on its own expert).

As for Dr. Ratain's supplemental declaration, it supported Ipsen's discretionary denial response in the CSPC proceeding. IPR2025-00505, Ex. 1200. But the discretionary denial phase of that proceeding is separate from this proceeding. Here, Ipsen has **not** filed such briefing, and it is unclear if Ipsen will do so or what the briefing's contents might be. It would thus be unreasonable to require Dr. Dreicer to preemptively respond to this briefing. Again, Ipsen cites no authority requiring him to do so. In any event, discretionary denial will be resolved before joinder. So discretionary denial arguments are immaterial to the joinder analysis. The pertinent arguments, those on the merits, will be the same between Apotex and CSPC. Mot. 5-6.

Ipsen further points to Dr. Dreicer's reservation of rights. Opp. 6-7. But Dr. Dreicer has not exercised those rights and cannot do so in a manner inconsistent with Apotex's silent understudy role, so they do not provide a basis for him to make different arguments.

Ipsen next appears to criticize Apotex for not withdrawing Dr. Dreicer's declaration, suggesting that Apotex's conditions for withdrawal have been met. Opp. 7-8. But those conditions have not been met. Apotex proposed withdrawal (1) if CSPC permits reliance upon Dr. Ratain or (2) if Dr. Ratain's declaration **and** deposition transcript become available. Mot 5. CSPC has not granted permission.

And while Dr. Ratain's declaration is available, his transcript is not. Of course, if the transcript becomes available, Apotex will withdraw its declaration. *Id.*

Ipsen finally asserts that Dr. Dreicer's potential new arguments would adversely affect the schedule and unduly burden Ipsen, including by necessitating an additional deposition. Opp. 8-9. But, as discussed above, Dr. Dreicer's declaration is merely a backup if Apotex cannot rely on Dr. Ratain's declaration. So Dr. Dreicer's declaration will not impact the schedule, burden Ipsen, or necessitate an additional deposition. *See Feit*, IPR2023-00129, Paper No. 14 at 7-8.

For these reasons, and those set forth in Apotex's motion, Apotex respectfully requests joinder.

RESPONSE TO IPSEN’S STATEMENT OF MATERIAL FACTS

Ipsen presented a statement of material facts in its opposition. Opp. 2-5.

Pursuant to 37 CFR §§ 42.23(a) and 42.24(c), Apotex responds to Ipsen’s statement of material facts as follows.

MATERIAL FACT NO. 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).

RESPONSE TO MATERIAL FACT NO. 1:

Admitted.

MATERIAL FACT NO. 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.

RESPONSE TO MATERIAL FACT NO. 2:

Admitted.

MATERIAL FACT NO. 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.*

RESPONSE TO MATERIAL FACT NO. 3:

Admitted.

MATERIAL FACT NO. 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.

RESPONSE TO MATERIAL FACT NO. 4:

Admitted.

MATERIAL FACT NO. 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).

RESPONSE TO MATERIAL FACT NO. 5:

Admitted that the CSPC IPR is in the trial phase. Otherwise, cannot be admitted or denied, as Apotex lacks knowledge of future filings in the CSPC IPR.

MATERIAL FACT NO. 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.

RESPONSE TO MATERIAL FACT NO. 6:

Admitted.

MATERIAL FACT NO. 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.

RESPONSE TO MATERIAL FACT NO. 7:

Admitted that along with its Petition, Apotex filed on September 12, 2025 an expert declaration from Dr. Robert Dreicer and that Dr. Dreicer's declaration contains the statements set forth in this paragraph. Otherwise denied.

MATERIAL FACT NO. 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.*

RESPONSE TO MATERIAL FACT NO. 8:

Admitted that 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. Further admitted that Dr. Dreicer does not mention a possible Patent Owner Response or possible additional declaration by Dr. Ratain. Otherwise, cannot be admitted or denied, as Apotex lacks knowledge of future filings in the CSPC IPR.

MATERIAL FACT NO. 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.*

RESPONSE TO MATERIAL FACT NO. 9:

Denied to the extent that Ipsen implies Apotex should have withdrawn Dr. Dreicer’s Declaration, as a deposition transcript of Dr. Ratain has not become publicly available. Otherwise admitted.

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CERTIFICATE OF SERVICE

I hereby certify that on November 10, 2025, I caused a true and correct copy of the foregoing APOTEX'S REPLY TO PATENT OWNER'S OPPOSITION TO PETITIONER'S MOTION FOR JOINDER to be served by electronic mail at the following addresses:

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