

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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SUN PHARMACEUTICAL INDUSTRIES, LTD., SUN PHARMA  
GLOBAL FZE and AMNEAL PHARMACEUTICALS LLC,  
Petitioner,

v.

ASTRAZENECA AB,  
Patent Owner.

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Case IPR2016-01104  
Patent RE44,186 E

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Before MICHAEL P. TIERNEY, RAMA G. ELLURU, and  
CHRISTOPHER G. PAULRAJ, *Administrative Patent Judges*.

ELLURU, *Administrative Patent Judge*.

DECISION  
Instituting Inter Partes Review  
37 C.F.R. § 42.108  
Grant of Motion for Joinder  
37 C.F.R. § 42.122(b)

Petitioner, Sun Pharmaceutical Industries, Ltd., Sun Pharma Global FZE and Amneal Pharmaceuticals LLC (collectively “Sun/Amneal”), filed a Petition requesting *inter partes* review of claims 1, 2, 4, 6–22, 25–30, 32–37, and 39–42 (the “challenged claims”) of U.S. Patent No. RE44,186 E (Ex. 1001, “the ’186 patent”) (Paper 3, “Pet.”). Concurrently with its Petition, Sun/Amneal filed a Motion for Joinder (Paper 4, “Mot.”), seeking to consolidate this case, under 35 U.S.C. § 315(c), with the *inter partes* review in *Mylan Pharms., Inc. v. AstraZeneca AB, LLC*, Case IPR2015-01340 (“the Mylan IPR” and Petitioner “Mylan”), which was instituted on May 2, 2016. *See* IPR2015-01340 (Paper 16, 34–35) (rehearing decision instituting review of claims 1, 2, 4, 6–22, 25–30, 32–37, and 39–42 of the ’186 patent).

Patent Owner AstraZeneca AB (“AstraZeneca”) filed a Preliminary Response in the present proceeding (Paper 17), and an opposition to Sun’s Motion for Joinder (Paper 12 (“Opp.”)).

For the reasons set forth below, we conclude that Sun/Amneal has shown that the Petition warrants institution of *inter partes* review of claims 1, 2, 4, 6–22, 25–30, 32–37, and 39–42 of the ’186 patent. This conclusion is consistent with our institution decision in the Mylan IPR. *See* IPR2015-01340, Paper 16, 34–35. Further, we grant Sun/Amneal’s Motion for Joinder and exercise our discretion to join Sun as a Petitioner to the Mylan IPR. We further terminate the present proceeding, IPR2016-01104.

#### I. PETITION FOR *INTER PARTES* REVIEW

Sun/Amneal indicates that the ’186 patent is the subject of numerous district court cases filed in the U.S. District Court for the District of Delaware. Pet. 18; Paper 11, 1. In addition, the ’186 patent is the subject of

pending *inter partes* review proceedings, including IPR2016-01029, IPR2016-01117, and IPR2016-01122. Pet. 18; Paper 11, 1–2. The ’186 patent also was the subject of the Mylan IPR, as noted above.

In the Mylan IPR, we instituted *inter partes* review of claims 1, 2, 4, 6–22, 25–30, 32–37, and 39–42 of the ’186 patent on the same grounds of unpatentability asserted in the present Petition. Pet 19–20; Mot. 6; IPR2015-01340, Paper 16, 34–35.

Sun/Amneal supports its assertions with the same evidence and arguments proffered in the Mylan IPR. Pet. 25–63. Sun/Amneal notes that “[t]he Petition that accompanies the present Motion for Joinder is substantially identical to the instituted Mylan IPR Petition, and the accompanying evidence is the same as that relied upon in the Mylan IPR Petition and Petitioner’s Reply to the Patent Owner Response.” Mot. 7.

We incorporate our analysis from our institution decision in the Mylan IPR. IPR2015-01340, Paper 16, 6–32, 34–35. For the same reasons, we determine that Sun/Amneal has demonstrated a reasonable likelihood that it will prevail with respect to its challenge to claims 1, 2, 4, 6–22, 25–30, 32–37, and 39–42 of the ’161 patent on the asserted grounds.

## II. MOTION FOR JOINDER

In the Motion for Joinder, Sun/Amneal seeks joinder with the *inter partes* review in the Mylan IPR. Mot. 1–2. Sun/Amneal filed the present Motion on June 1, 2016, within one month of our decision instituting *inter partes* review in IPR2015-01340, which issued on May 2, 2016. *See* IPR2015-01340, Paper 16; Mot. Therefore, the Motion is timely under 37 C.F.R. § 42.122(b). *See* 37 C.F.R. § 42.122(b) (“Any request for joinder

must be filed, as a motion under § 42.22, no later than one month after the institution date of any inter partes review for which joinder is requested.”).

The Board, acting on behalf of the Director, has the discretion to join a party to a pending *inter partes* review where the conditions of 35 U.S.C. § 315(c) are met. *See* 35 U.S.C. § 315(c); *see also* 37 C.F.R. § 42.4(a) (“The Board institutes the trial on behalf of the Director.”). Specifically, 35 U.S.C. § 315(c) provides:

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 partes review under section 314.

As noted above, we have instituted *inter partes* review of claims 1, 2, 4, 6–22, 25–30, 32–37, and 39–42 of the ’186 patent in the Mylan IPR. *See generally* IPR2015-01340, Paper 16. In addition, we determined above that Sun/Amneal has filed a Petition that warrants institution of *inter partes* review of the same claims. Accordingly, the conditions of 35 U.S.C. § 315(c) are satisfied, and we must consider whether to exercise our discretion to join Sun/Amneal as a Petitioner to the Mylan IPR.

In its Motion for Joinder, Sun/Amneal asserts that:

AstraZeneca has asserted the ’186 patent against Petitioner in concurrent district court litigation, and Petitioner is in the same consolidated suit as Mylan (*AstraZeneca AB v. Aurobinda Pharma, Ltd. et al.*, 1:14-cv-00664 (D. Del.)). As such, allowing Petitioner to participate in the Mylan IPR may allow Petitioner and AstraZeneca to resolve the underlying litigation between the parties in a cost-effective, expeditious manner even if Mylan

seeks to terminate its participation in the Mylan IPR based on settlement or other factors.

Mot. 9. As such, allowing Sun/Amneal to participate in the Mylan IPR may allow Sun/Amneal and AstraZeneca to resolve the underlying litigation between the parties in a cost-effective, expeditious manner even if Mylan seeks to terminate its participation in the Mylan IPR based on settlement or other factors.

Upon authorization, the parties filed a joint stipulation explaining the agreement between Petitioners Mylan and Sun/Amneal, and other petitioners which have moved to join the Mylan IPR, with respect to the level of cooperation that will be maintained should joinder be granted. Paper 16. Pursuant to the stipulation, Sun/Amneal agrees with Mylan “to share the use and, after joinder, the *pro rata* costs of Mylan’s experts in this IPR proceeding in exchange for continuing access to the experts in the event that Mylan no longer participates in the review.” *Id.* at 1–2. Further, as long as Mylan remains a party in the Mylan IPR, Sun/Amneal agrees to “coordinate any communications with Mylan’s experts through Mylan; not produce their own testifying witness; and not file substantive papers (except for those associated with Board-approved motions that do not affect Mylan or Mylan’s position).” *Id.* at 2. Sun/Amneal also agrees to confer and cooperate with Mylan on the consolidated filings, and that as long as Mylan remains a party in the Mylan IPR, Mylan will make all final decisions, will retain responsibility for oral argument (including telephone hearings and appeals) and Sun/Amneal will not receive separate time and will not separately argue during oral argument, including during telephone hearings and appeals, except when addressing “Board-approved motions that do not



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