

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

WOCKHARDT BIO AG
Petitioner,

v.

ASTRAZENECA AB,
Patent Owner.

Case IPR2016-01029
Patent RE44,186 E

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

ELLURU, *Administrative Patent Judge*.

REPLACEMENT DECISION¹

Grant of Motion for Joinder

37 C.F.R. § 42.108

37 C.F.R. § 42.222

¹ This “replacement” decision is issued to only correct typographical errors in the original decision (IPR2015-01340, Papers 32 and 33; IPR2016-01029, Paper 15), e.g., with respect to party names and case number cites.

Petitioner, Wockhardt Bio AG (“Wockhardt”), 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 1, “Pet.”). Concurrently with its Petition, Wockhardt filed a Motion for Joinder (Paper 3, “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”) did not file a preliminary response in the present proceeding, but opposes Wockhardt’s Motion for Joinder. Paper 8 (“Opp.”).

For the reasons set forth below, we conclude that Wockhardt 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 Wockhardt’s Motion for Joinder and exercise our discretion to join Wockhardt as a Petitioner to the Mylan IPR. We further terminate the present proceeding, IPR2016-01209.

I. PETITION FOR *INTER PARTES* REVIEW

Wockhardt 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. 16–17. In addition, the ’186 patent is the subject of pending

inter partes review proceedings, including IPR2016-01122, IPR2016-01104, and IPR2016-01117. 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, reproduced below.

IPR2015–01340, Pet 17; Mot. 5–6; IPR2015-01340, Paper 16, 34–35.

Ground	Claims	Description
1	1, 2, 4, 6-11, 25-28, 32-35, 39 and 40	Obvious under 35 U.S.C. § 103 over Ashworth, Villhauer, Raag and Hanessian
2	12-16, 29, 30, 36, 37, 41 and 42	Obvious under § 103 over Ashworth, Villhauer, Raag, Hanessian, Bachovchin and Glucophage® Label
3	12, 17, 18, 22	Obvious under § 103 over Ashworth, Villhauer, Raag, Hanessian, Bachovchin and Xenical® Label
4	12, 19, 20, 21	Obvious under § 103 over Ashworth, Villhauer, Raag, Hanessian, Bachovchin and Mevacor® Label

Pet. 17.

Wockhardt supports its assertions with the same evidence and arguments proffered in the Mylan IPR. Pet. 23–57. Wockhardt notes that “Wockhardt’s Petition that accompanies the present Motion for Joinder and accompanying evidence are the same as the instituted Mylan IPR Petition and Petitioner’s Reply to the Patent Owner Response, aside from procedural sections that, for example, identify Wockhardt, any real parties in interest, and its standing, etc.” Mot. 6.

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 Wockhardt 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, Wockhardt seeks joinder with the *inter partes* review in the Mylan IPR. Mot. 1–2. Wockhardt filed the present Motion on May 11, 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 Wockhardt 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 Wockhardt as a Petitioner to the Mylan IPR.

In its Motion for Joinder, Wockhardt asserts that:

[A]llowing Wockhardt to participate in the Mylan IPR will allow Wockhardt and AstraZeneca to resolve the underlying litigation between the parties in a cost effective, expeditious manner should Mylan seek to terminate its participation in the Mylan IPR based on settlement or other factors.

Mot. 8–9.

Upon authorization, Wockhardt and AstraZeneca filed a joint stipulation explaining the agreement between Petitioners Mylan and Wockhardt, 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 13. Pursuant to the stipulation, Wockhardt 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, Wockhardt 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.* Wockhardt also

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