Trials@uspto.gov
Tel: 571-272-7822

IPR2016-01122, Paper 14
IPR2015-01340, Paper 34
Entered: September 23, 2016

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

TEVA PHARMACEUTICALS USA, INC.,
Petitioner,

v.

ASTRAZENECA AB,
Patent Owner.

Case IPR2016-01122
Patent RE44,186

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

ELLURU, *Administrative Patent Judge*.

DECISION
Grant of Motion for Joinder
37 C.F.R. § 42.208
37 C.F.R. § 42.222

Petitioner, Teva Pharmaceuticals, USA, Inc. ("Teva"), filed a Petition requesting *inter part*es 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 (Ex. 1001, "the '186 patent") (Paper 1, "Pet."). Concurrently with its Petition, Teva 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") waived filing a preliminary response. Paper 13. AstraZeneca initially opposed Teva's Motion for Joinder (Paper 10), but subsequently withdrew its opposition to the Motion for Joinder (Paper 13).

For the reasons set forth below, we conclude that Teva 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 Teva's Motion for Joinder and exercise our discretion to join Teva as a Petitioner to the Mylan IPR. We further terminate the present proceeding, IPR206-01122.

I. PETITION FOR *INTER PARTES* REVIEW

Teva 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. In addition, the '186 patent is the subject of pending *inter partes* review proceedings, including IPR2016-01029, 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. Pet 19; *see also* Mot. 5–6; and 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. 19.

Teva supports its assertions with the same evidence and arguments proffered in the Mylan IPR. Pet. 24–60. Teva notes that "[i]n this case, joinder will not affect the Board's ability to issue the decision within [the] required one-year timeframe because the Petition filed in the present Teva IPR is substantially identical to the Mylan IPR." Mot. 8.

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 Teva 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, Teva seeks joinder with the *inter partes* review in the Mylan IPR. Mot. 1. Teva filed the present Motion on May 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; *see also* Mot 2. 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* IPR2015-01209, Paper 16. In addition, we determined above that Teva 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 Teva as a Petitioner to the Mylan IPR.

In its Motion for Joinder, Teva asserts that:

> Joinder is also warranted in order to permit Teva to protect its interests related to the validity and interpretation of the '186 patent claims, and Teva could be prejudiced if it is not permitted to participate in the Mylan IPR. For example, allowing a joined *inter partes* review would avoid potential inconsistency and avoid prejudice to Teva in the event that Mylan and AstraZeneca reach a resolution.

Mot. 11–12.

Upon authorization, Teva and AstraZeneca filed a Joint Stipulation explaining the agreement between Petitioners Mylan and Teva with respect to the level of cooperation that will be maintained should joinder be granted. Paper 12. Pursuant to the stipulation, Teva agrees with Mylan "to share the use of Mylan's experts with Mylan, the 'Lead Petitioner,' and all joined petitioners in this IPR proceeding." *Id*. at 1. Further, as long as Mylan remains a party in the Mylan IPR, Teva 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*. Teva also agrees to confer and cooperate with Mylan, and all joined petitioners, 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 Teva 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 affect Mylan or Mylan's position." *Id*. at 1, 2. In addition, Teva agrees to coordinate the discovery and testimony relating to witnesses with Mylan,

and that as long as Mylan remains a party in the Mylan IPR, Mylan will make all final decisions, and Teva will not separately file or serve objections or discovery requests, will not receive separate cross examination or redirect time, will not separately cross examine or redirect any witness, and stipulates that cross examinations will occur within the timeframe normally allotted to one party without a need for extensions in light of joinder. *Id*. at 2. Further, if Mylan is no longer a party to the Mylan IPR, Teva agrees to "meet and confer with the remaining joined parties, if any, to select a new Lead Petitioner," and that any such "Lead Petitioner will effectively take Mylan place in this proceeding and Teva will continue to be bound." *Id*. at 2–3.

AstraZeneca stipulated that if joinder is granted "it will not request any additional level of cooperation other than that specified in the previous section." *Id*. at 3. In addition, as noted above, AstraZeneca withdrew its opposition to the Motion for Joinder. Paper 13.

Because Teva has satisfied the requirements of § 315(c), we grant Teva's Motion for Joinder and exercise our discretion to join Teva as a Petitioner to the already existing Mylan IPR. We further terminate the present proceeding.

As a Petitioner in the Mylan IPR, Teva shall adhere to the existing schedule in the Mylan IPR and abide by the Joint Stipulation with respect to consolidated filings, and discovery and testimony. Paper 12. More specifically, all filings by Teva in the Mylan IPR shall be consolidated with the filings of the other Mylan IPR Petitioner(s), unless the filing involves an issue unique to Teva or states a point of disagreement related to the consolidated filing. In such circumstances, Teva shall seek authorization

from the Board to file a separate paper. The page limits set forth in 37 C.F.R. § 42.24 will apply to all consolidated filings.

Teva is bound by any discovery agreements, including deposition arrangements, between AstraZeneca and Mylan, and shall not seek any discovery beyond that sought by Mylan. AstraZeneca shall not be required to provide any additional discovery or deposition time as a result of joinder.

The Board expects Mylan and Teva to resolve any disputes between them and to contact the Board only if such matters cannot be resolved.

IV. ORDER

Accordingly, it is

ORDERED that Teva's Motion for Joinder is *granted*;

FURTHER ORDERED that Teva is joined as a Petitioner in IPR2015-01340;

FURTHER ORDERED that the instant proceeding, IPR2016-01122, is terminated under 37 C.F.R. § 42.72, and all further filings shall be made only in IPR2015-01340;

FURTHER ORDERED that the asserted grounds of unpatentability on which a trial was instituted in IPR2015-01340 are unchanged;

FURTHER ORDERED that the current Scheduling Order for IPR2015-01340 shall continue to govern IPR2015-01340;

FURTHER ORDERED that Teva shall adhere to the existing schedule in the Mylan IPR, IPR2015-01340;

FURTHER ORDERED that Teva shall abide by the Joint Stipulation with respect to consolidated filings, and discovery and testimony (Paper 12);

FURTHER ORDERED that all filings by Teva in the Mylan IPR shall be consolidated with the filings of the other Mylan IPR Petitioner(s), unless the filing involves an issue unique to Teva or states a point of disagreement related to the consolidated filing. In such circumstances, Teva shall seek authorization from the Board to file a separate paper;

FURTHER ORDERED that all page limits set forth in 37 C.F.R. § 42.24 will apply to all consolidated filings;

FURTHER ORDERED that Teva shall be bound by any discovery agreements, including deposition arrangements, between AstraZeneca and Mylan, and shall not seek any discovery beyond that sought by Mylan;

FURTHER ORDERED that AstraZeneca shall not be required to provide any additional discovery or deposition time as a result of joinder;

FURTHER ORDERED that Mylan and Teva shall resolve any disputes between them and to contact the Board only if such matters cannot be resolved;

FURTHER ORDERED that the case caption in IPR2015-01340 shall be changed to reflect the joinder of Teva as a Petitioner in accordance with the attached example; and

FURTHER ORDERED that a copy of this Decision be entered into the file of IPR2015-01340.

FOR PETITIONER MYLAN:
Steven Parmelee
sparmelee@wsgr.com
Richard Torczon
rtorczon@wsgr.com

FOR PETITIONER WOCKHARDT:
Patrick Gallagher
pcgallagher@duanemorris.com

FOR PETITIONER TEVA:
Gary Speier
gspeier@carlsoncaspers.com

Iain McIntyre
IMcIntyre@carlsoncaspers.com

FOR PATENT OWNER:
Charles Lipsey
Charles.lipsey@finnegan.com
David Weingarten
David.weingarten@finnegan.com
Eric Grondahl
egrondahl@mccarter.com
John Livingstone
Jonh.livingstone@finnegan.com
Anthony Hartmann
Anthony.hartmann@finnegan.com

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC.,
WOCKHARDT BIO AG, and TEVA PHARMACEUTICALS USA, INC.,
Petitioner,

v.

ASTRAZENECA AB
Patent Owner.

Case IPR2015-01340[1][2]
Patent RE44,186 E

---

[1] Petitioner Wockhardt from IPR2016-01209 has been joined as a Petitioner to this proceeding.
[2] Petitioner Teva from IPR2016-01122 has been joined as Petitioner to this proceeding.