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

IPR2016-01117, Paper 12
IPR2015-01340, Paper 39
Entered: October 21, 2016

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AUROBINDO PHARMA U.S.A. INC.,
Petitioner,

v.

ASTRAZENECA AB,
Patent Owner.

Case IPR2016-01117
Patent RE44,186 E

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. § 42.108
37 C.F.R. § 42.222

Petitioner, Aurobindo Pharma USA, Inc. ("Aurobindo"), 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 E (Ex. 1001, "the '186 patent") (Paper 1, "Pet."). Concurrently with its Petition, Aurobindo 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") filed a preliminary response in the present proceeding (Paper 11), and an Oppsotion to Aurobindo's Motion for Joinder. Paper 8 ("Opp.").

For the reasons set forth below, we conclude that Aurobindo 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 Aurobindo's Motion for Joinder and exercise our discretion to join Aurobindo as a Petitioner to the Mylan IPR. We further terminate the present proceeding, IPR2016-01117.

I. PETITION FOR *INTER PARTES* REVIEW

Aurobindo 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. 17. In addition, the '186 patent is the subject of pending

inter partes review proceedings, including IPR2016-1029, IPR2016-01122, and IPR2016-01104. 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 18; Mot. 6–7; IPR2015-01340, Paper 16, 34–35.

Ground	35 U.S.C. Section (pre-3/16/2013)	Claims	Index of References
1	103(a)	1, 2, 4, 6-11, 25-28, 32-35, 39, and 40	Ashworth, Villhauer, Raag and Hanessian
2	103(a)	12-16, 29, 30, 36, 37, 41 and 42	Ashworth, Villhauer, Raag, Hanessian, Bachovchin, and Glucophage® Label
3	103(a)	12, 17, 18, and 22	Ashworth, Villhauer, Raag, Hanessian, Bachovchin, and Xenical® Label
4	103(a)	12, 19, 20, and 21	Ashworth, Villhauer, Raag, Hanessian, Bachovchin, and Mevacor® Label

Pet. 18.

Aurobindo supports its assertions with the same evidence and arguments proffered in the Mylan IPR. Pet. 24–69. Aurobindo notes that its "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 Aurobindo, any real parties in interest, and its standing." Mot. 7. Aurobindo also asserts that it "challenges the same '186 patent claims based on the same arguments, evidence, and ground of unpatentability on which the Board instituted review in the Mylan IPR." *Id*.

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 Aurobindo 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 '186 patent on the asserted grounds.

II. MOTION FOR JOINDER

In the Motion for Joinder, Aurobindo seeks joinder with the *inter partes* review in the Mylan IPR. Mot. 1–2. Aurobindo filed the present Motion on June 2, 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 Aurobindo 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 Aurobindo as a Petitioner to the Mylan IPR.

In its Motion for Joinder, Aurobindo asserts that:

> [A]llowing Aurobindo to participate in the Mylan IPR will allow Aurobindo 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. 9.

Upon authorization, Aurobindo and AstraZeneca filed a joint stipulation explaining the agreement between Petitioners Mylan and Aurobindo, and any other petitioners joined to the Mylan IPR, with respect to the level of cooperation that will be maintained should joinder be granted. Paper 10. Pursuant to the stipulation, Aurobindo agrees "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 is a party to the proceeding, Aurobindo will "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 1. Aurobindo 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 and will retain responsibility for oral argument (including telephone hearings and appeals)." *Id*. at 2. Aurobindo further agrees that "Aurobindo will not seek or receive separate time and will not separately argue during oral argument, including telephone hearings and appeals, except when addressing Board-approved motions that do not affect Mylan or Mylan's position." *Id*. In addition, Aurobindo agrees to coordinate the discovery and testimony relating to witnesses with Mylan, and all joined petitioners, and that as long as Mylan remains a party in the Mylan IPR, Mylan will make all final decisions, and Aurobindo 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*.

Lastly, Aurobindo agrees that if Mylan is no longer a party to the Mylan IPR, "Aurobindo shall meet and confer with the remaining joined parties, if any, to select a new Lead Petitioner," and that "[a]ny such new Lead Petitioner will effectively take Mylan's place in this proceeding and Aurobindo will continue to be bound" to the present agreement. *Id*. at 3.

AstraZeneca advised Aurobindo that it maintains that joinder is not proper for the reasons provided in its opposition to the motion for joinder. *Id*. at 3. However, if joinder is granted, AstraZeneca does not request any additional level of cooperation other than that specified in the joint stipulation. *Id*.

AstraZeneca opposes joinder, contending that "[j]oinder will complicate the Mylan IPR because Aurobindo and Mylan are not working together." Opp. 4. For example, AstraZeneca asserts that "Aurobindo and Mylan are direct competitors with independent agendas that are advancing different substantive positions in the district court litigation with different lead compound theories, different prior art, and different expert witnesses." Opp. 4–5. This argument does not persuade us from granting joinder because the joint stipulation filed subsequent to AstraZeneca's opposition explains the level of cooperation that will exist between Aurobindo and Mylan should joinder be granted. The level of cooperation agreed to between Mylan and Aurobindo addresses AstraZeneca's concerns about Aurobindo proffering different arguments and evidence. AstraZeneca's opposition further requests that safeguards be imposed should Aurobindo's motion for joinder be granted. Opp. 10–11. Pursuant to the subsequent joint stipulation, however, AstraZeneca asserts that "[i]f joinder is granted, AstraZeneca advises that it does not request any additional level of cooperation other than that specified in the previous section." Paper 10, 3. Thus, we determine that AstraZeneca's requested safeguards have been agreed to by Petitioners Mylan and Aurobindo.

AstraZeneca further contends that joinder will not enhance efficiencies, because Aurobindo's petition "has no independent right to seek an IPR" given its petition is time-barred pursuant to 35 U.S.C. § 315(b). Opp. 7–8. Section 315(b) states:

> An inter partes review may not be instituted if the petition requesting the proceeding is filed more than 1 year after the date on which the petitioner, real party in interest, or privy of the petitioner is served with a complaint alleging infringement of the patent. The time limitation set forth in the preceding sentence shall not apply to a request for joinder under subsection (c).

AstraZeneca argues that "[t]he last sentence of § 315(b) provides an exception to the one-year bar only for a request for joinder, not for a petition for IPR." Opp. 9. According to AstraZeneca, the one-year time bar applies to "all petitions, even in the joinder context," and that § 315(c) does not "provide a backdoor for time-barred petitions to be effectively instituted through joinder." Opp. 9. In support, AstraZeneca asserts that § 315(c) "requires compliance with § 311, which in turn requires compliance with the other provisions of Title 35, Chapter 31 of the U.S. Code, including the timeliness provisions." Opp. 10.

AstraZeneca's argument does not persuade us from granting joinder. The Office has implemented a regulation that implements § 315(b)'s one-year deadline. *See* 37 C.F.R. § 42.101(b). Our regulations also address the exception created by the second sentence of § 315(b); they provide that the one-year time limit "shall not apply when the petition is accompanied by a request for joinder." 37 C.F.R. § 42.122(b). *See Achates Reference Publ'g, Inc. v. Apple Inc.*, 803 F.3d 652, 657 (Fed. Cir. 2015) (the second sentence of § 315(b) "means that *an otherwise time-barred party* may nonetheless

participate in an *inter partes* review proceeding if another party files a proper petition.") (citing 35 U.S.C. § 315(c) (emphasis added)). Thus, we determine that the second sentence of § 315(b) does not preclude us from joining Aurobindo as a Petitioner to the Mylan IPR.

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

As a Petitioner in the Mylan IPR, Aurobindo 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 10. More specifically, all filings by Aurobindo 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 Aurobindo or states a point of disagreement related to the consolidated filing. In such circumstances, Aurobindo 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.

Aurobindo 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 Aurobindo to resolve any disputes between them and to contact the Board only if such matters cannot be resolved.

III. ORDER

Accordingly, it is

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

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

FURTHER ORDERED that the instant proceeding, IPR2016-01117, 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 Aurobindo shall adhere to the existing schedule in the Mylan IPR IPR2015-01340;

FURTHER ORDERED that Aurobindo shall abide by the joint stipulation with respect to consolidated filings, and discovery and testimony (Paper 10);

FURTHER ORDERED that all filings by Aurobindo 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 Aurobindo or states a point of disagreement related to the consolidated filing. In such

circumstances, Aurobindo 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 Aurobindo 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 Aurobindo 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 Aurobindo 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 AUROBINDO:

Sailesh K. Patel
SPatel@schiffhardin.com
George Yu
gyu@schiffhardin.com

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, TEVA PHARMACEUTICALS USA, INC., and AUROBINDO PHARMA U.S.A., INC.
Petitioner,

v.

ASTRAZENECA AB
Patent Owner.

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

---

[1] Petitioner Wockhardt from IPR2016-01209, Petitioner Teva from IPR2016-01122, and Petitioner Aurobindo from IPR2016-01117 have each been joined as Petitioners to this proceeding.