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

Paper 30
Entered: September 19, 2016

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ARGENTUM PHARMACEUTICALS LLC,
Petitioner,

v.

JANSSEN ONCOLOGY, INC.,
Patent Owner.

Case IPR2016-01317
Patent 8,822,438 B2

Before LORA M. GREEN, RAMA G. ELLURU, and KRISTINA M. KALAN, *Administrative Patent Judges*.

KALAN, *Administrative Patent Judge*.

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

Argentum Pharmaceuticals LLC ("Argentum") filed a Petition (Paper 2, "Pet.") requesting *inter partes* review of claims 1–20 (the "challenged claims") of U.S. Patent No. 8,822,438 B2 (Ex. 1001, "the '438 patent") pursuant to 35 U.S.C. §§ 311–319. Concurrently with its Petition, Argentum filed a Motion for Joinder (Paper 3, "Mot."), seeking to join this case, under 35 U.S.C. § 315(c), with the *inter partes* review in *Amerigen Pharmaceuticals, Ltd. v. Janssen Oncology, Inc.*, Case IPR2016-00286 ("the Amerigen IPR" and Petitioner "Amerigen"), which was instituted on May 31, 2016. *See* IPR2016-00286, slip op. at 19 (PTAB May 31, 2016) (Paper 14) (decision instituting review of claims 1–20 of the '438 patent).

Patent Owner, Janssen Oncology, Inc. ("Janssen"), filed a Response to the Motion for Joinder (Paper 7, "Resp.") and a Waiver of Preliminary Response (Paper 8, "Waiver").

For the reasons set forth below, we conclude that Argentum has shown that its Petition warrants institution of *inter partes* review of claims 1–20 of the '438 patent. This conclusion is consistent with our institution decision in the Amerigen IPR. *See* IPR2016-00286, Paper 14, 19. Thus, we institute *inter partes* review, grant Argentum's Motion for Joinder, and exercise our discretion to join Argentum as a Petitioner to the Amerigen IPR. We further terminate the present proceeding, IPR2016-01317.

I. PETITION FOR *INTER PARTES* REVIEW

The parties indicate that the '438 patent is being asserted in a number of district court proceedings. Pet. 1–2; Paper 5, 2–3. In addition, the '438 patent is the subject of pending *inter partes* review proceedings, including the Amerigen IPR, as noted above, which has been instituted, and IPR2016-01332 and IPR2016-01582, which are pending. Patent Owner also states

that the '438 patent "was the subject of *ex parte* reexamination request No. 90/020,096," but "will not be granted a filing date for failure to comply with the requirements of 37 C.F.R. § 1.501(a)." Paper 5, 2.

In the Amerigen IPR, we instituted *inter partes* review of claims 1–20 of the '438 patent on the same grounds of unpatentability asserted in the present Petition:

References	Basis	Claims Challenged
O'Donnell[1] and Gerber[2]	§ 103	1–20
Barrie[3] and Gerber	§ 103	1–4 and 6–11

Pet 4; Mot. 4; IPR2016-00286, Paper 14, 19.

Argentum supports its assertions with substantially the same evidence and arguments proffered by Amerigen in the Amerigen IPR. Pet. 18–60. The only exception is the declaration of Argentum's expert, Dr. Devalingam Mahalingam (Ex. 1073), which we discuss below. Argentum represents that joinder with the Amerigen IPR is appropriate because Argentum's Petition

> is limited to the same grounds instituted in the IPR2016-00286 petition. It also relies on the same prior art analysis and expert testimony submitted by Amerigen. Indeed, the Petition is nearly identical with respect to the grounds raised in the

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[1] O'Donnell, A. et al., *Hormonal impact of the 17α-hydroxylase/ $C_{17,20}$-lyase inhibitor abiraterone acetate (CB7630) in patients with prostate cancer*, British Journal of Cancer 90:2317–2325 (2004) ("O'Donnell") (Ex. 1003).
[2] Gerber, G.S. & Chodak, G.W., *Prostate specific antigen for assessing response to ketoconazole and prednisone in patients with hormone refractory metastatic cancer*, J. Urol. 144:1177–79 (1990) ("Gerber") (Ex. 1004).
[3] U.S. Patent No. 5,604,213 to Barrie, issued February 18, 1997 ("Barrie") (Ex. 1005).

> IPR2016-00286 petition, and does not include any grounds not raised in that petition.

Mot. 4.

We incorporate our analysis from our institution decision in the Amerigen IPR. IPR2016-00286, Paper 14, 4–15. For the same reasons, we determine that Argentum has demonstrated a reasonable likelihood that it will prevail with respect to its challenge to claims 1–20 of the '438 patent on the asserted grounds. In view of the identical challenges in the Petition and Patent Owner's waiver of its Preliminary Response, we institute an *inter partes* review in this proceeding on the same grounds as those on which we instituted trial in IPR2016-00286. We do not institute an *inter partes* review on any other grounds.

II. MOTION FOR JOINDER

In the Motion for Joinder, Argentum seeks joinder "of the concurrently filed Petition with a pending *inter partes* review filed by Amerigen." Mot. 1. Argentum filed the present Motion on June 29, 2016, within one month of our decision instituting *inter partes* review in IPR2016-00286, which issued on May 31, 2016. *See* IPR2016-00286, Paper 14; 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 the moving party, Argentum bears the burden of proving that it is entitled to the requested relief. 37 C.F.R. § 42.20(c). A motion for joinder should (1) set forth reasons why joinder is appropriate; (2) identify any new grounds of unpatentability asserted in the petition; (3) explain what impact (if any) joinder would have on the trial schedule for the existing review; and (4) address specifically how briefing and discovery may be simplified. *See Kyocera Corp. v. Softview LLC*, Case IPR2013-00004, slip op. at 4 (PTAB Apr. 24, 2013) (Paper 15).

As noted above, we have instituted *inter partes* review of claims 1–20 of the '438 patent in the Amerigen IPR. *See generally* IPR2016–00286, Paper 14. In addition, we determine above that Argentum 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 Argentum as a Petitioner to the Amerigen IPR.

In its Motion for Joinder, Argentum asserts that joinder is appropriate "because it will promote efficient and consistent resolution of the validity of a single patent and will not prejudice any of the parties to the Amerigen IPR." Mot. 2. Argentum represents that (1) joinder is appropriate; (2) no new grounds are presented; (3) joinder will not negatively impact the Amerigen IPR trial schedule; and (4) discovery and briefing can be

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