

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC.,
Petitioner,

v.

JANSSEN ONCOLOGY, INC.,
Patent Owner.

Case IPR2016-01332
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 Denial of Motion for Joinder

37 C.F.R. § 42.108

37 C.F.R. § 42.122(b)

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Mylan Pharmaceuticals Inc. (“Mylan”) filed a Petition (Paper 1, “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, Mylan 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* Case 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 an Opposition to the Motion for Joinder (Paper 9, “Opp.”) and Mylan filed a Reply to Janssen’s Opposition (Paper 10, “Reply”). Janssen also filed a Preliminary Response to the Petition (Paper 14, “Prelim. Resp.”).

For the reasons set forth below, we conclude that Mylan 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 an *inter partes* review. We, however, do not grant Mylan’s Motion for Joinder.

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 7, 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; IPR2016-01317 (*Argentum Pharmaceuticals LLC v. Janssen Oncology, Inc.*), which was joined with the Amerigen IPR on September 19, 2016 (IPR2016-01317,

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Paper 9); and IPR2016-01582, which is pending. Janssen 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 7, 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 3; Mot. 2; IPR2016-00286, Paper 14, 19.

Mylan supports its assertions in its Petition with substantially the same art and arguments proffered by Amerigen in the Amerigen IPR. Pet. 4–61. Mylan states that "the proposed grounds for instituting *inter partes* review in the Mylan IPR are identical to the ones on which the Amerigen IPR was instituted." Mot. 6. The exceptions to the similarities between the present Petition and the petition in the Amerigen IPR are: the declaration of Mylan's declarant, Marc B. Garnick, M.D. (Ex. 1002), the declaration of

¹ O'Donnell, A. et al., *Hormonal impact of the 17 α -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).

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Mylan's declarant Ivan T. Hoffman (Ex. 1017);⁴ and the inclusion of Exhibits 1068–1080.⁵

Additionally, Mylan notes that it would not be time-barred from filing the present Petition without a corresponding motion for joinder. Mot. 6; 35 U.S.C. § 315(b).

Janssen responds that, because “Mylan's petition is merely a repetition of Amerigen's first petition and Argentum's second petition, it does nothing more than drain the Board's resources with no added value.” Prelim Resp. 2. Janssen requests that the Board exercise its discretion and deny institution pursuant to 35 U.S.C. § 325(d). *Id.*

We have discretion under 35 U.S.C. § 325(d) to reject a petition when the same or substantially the same prior art or arguments were presented previously to the Office. The relevant portions of that statute are reproduced below:

In determining whether to institute or order a proceeding under this chapter, chapter 30, or chapter 31, the Director may take into account whether, and reject the petition or request because, the same or substantially the same prior art or arguments previously were presented to the Office.

35 U.S.C. § 325(d). In exercising our discretion under § 325(d), we take into account numerous factors, including the facts of each case, and the

⁴ Amerigen relied on the declarations of Dr. Scott R. Serels, M.D. (IPR2016-00286, Ex. 1002) and DeForest McDuff, Ph.D. (IPR2016-00286, Ex. 1017) in support of its assertions and arguments.

⁵ Janssen also notes in its Opposition that “Mylan appears to withdraw, and does not appear to rely, on original Exhibits 1002, 1017, 1037, 1038, 1042–44, 1052, 1056, 1058–1063, and 1067 that were submitted in the Amerigen IPR.” Opp. 6 n.3.

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burden on the parties and the Board. *See Conopco, Inc. v. Proctor & Gamble Co.*, Case IPR2014-00506, slip op. at 4, 6 (PTAB Dec. 10, 2014) (Paper 25) (Informative), slip op. at 6 (PTAB July 7, 2014) (Paper 17), *cited in NVIDIA Corp. v. Samsung Elec. Co.*, Case IPR2016-00134, slip op. at 6–7 (PTAB May 4, 2016) (Paper 9); *see also* Amendments to the Rules of Practice for Trials Before the Patent Trial and Appeal Board, 77 Fed. Reg. 18750, 18759 (Apr. 1, 2016) (“[T]he current rules provide sufficient flexibility to address the unique factual scenarios presented to handle efficiently and fairly related proceedings before the Office on a case-by-case basis, and that the Office will continue to take into account the interests of justice and fairness to both petitioners and patent owners where multiple proceedings involving the same patent claims are before the Office.”).

Having reviewed the Petition and Janssen’s Preliminary Response, we incorporate our analysis from our institution decision in the Amerigen IPR. IPR2016-00286, Paper 14, 4–15. For the same reasons given in the institution decision in the Amerigen IPR, we determine that Mylan has demonstrated a reasonable likelihood that it would prevail with respect to its challenge to claims 1–20 of the ’438 patent on the asserted grounds.

Although we have discretion to reject a petition when the same or substantially the same prior art or arguments previously were presented to the Office (35 U.S.C. § 325(d)), we decline to exercise that discretion here. Mylan brings the same challenges brought by Amerigen and Argentum, but supports them with additional evidence and with two different declarations from two different declarants. The depositions of those declarants, as well as the additional evidence presented by Mylan, may affect the course of this trial relative to the course of the trial in IPR2016-00286. For example,

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