

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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Janssen states that Mylan's "new testimony would force Janssen to engage in discovery and briefing not currently contemplated" in the Amerigen IPR. Opp. 6–7.

Moreover, it appears that this case will involve arguments concerning objective indicia of non-obviousness, which involves a fact-specific analysis that often turns on evidence presented during trial. Pet. 51–61. A patent owner generally presents arguments based on objective indicia in response to a petitioner's allegations of obviousness. Here, Mylan preemptively presented arguments directed to objective indicia. *Id.* Janssen presented arguments directed to objective indicia in its Preliminary Response in the Amerigen IPR (IPR2016-00286, Paper 12, 46–52), but has not presented the same arguments in the Preliminary Response in this case. As such, the objective indicia arguments possibly differ between the Amerigen IPR and the present case. Because evidence directed to objective indicia typically develops during trial, we cannot assume, at this stage, that the arguments to be made during the course of the trial are the same or similar to those made in IPR2016-00286.

Other than these differences, however, both the instant Petition and the petition in the Amerigen IPR assert substantially the same two challenges to patentability. Thus, given this substantial similarity in proceedings, we do not perceive that either Janssen or the Board will be overwhelmed with an unreasonable number of challenges to patentability.

While we recognize Janssen's concern with respect to the need to defend its patent in multiple *inter partes* review proceedings, the present Petition was timely filed within the one year time set by Congress in 35

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U.S.C. § 315(b).⁶ The time elapsed between the filing of Amerigen’s petition in IPR2016-00286 and the filing of Mylan’s Petition in this case was approximately six months, which is not excessive for purposes of institution.

Unlike other cases in which we have exercised our discretion under § 325(d) to deny institution of a follow-on petition, based on the particular facts of this case, we are not presented with a second bite at the apple by an identical petitioner. In addition, Mylan does not seek to cure any problems of the petition in IPR2016-00286 with the filing of the present Petition. Also, we have not decided the outcome in IPR2016-00286.

In view of the challenges in the Petition, and having considered Janssen’s arguments in the Patent Owner 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. We decline to exercise our discretion under 35 U.S.C. § 325(d) to reject the Petition.

II. MOTION FOR JOINDER

In the Motion for Joinder, Mylan seeks joinder “of the above-captioned *inter partes* review (hereinafter ‘Mylan IPR’) with the pending *inter partes* review concerning the same patent and the same grounds of invalidity in” the Amerigen IPR. Mot. 1. Mylan filed the present Motion on June 30, 2016, within one month of our decision instituting *inter partes* review in IPR2016-00286, which issued on May 31, 2016. *See* IPR2016-

⁶ 35 U.S.C. § 315(b) states, in part, that “[a]n *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 . . . is served with a complaint alleging infringement of the patent.”

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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.

Joinder may be authorized when warranted, but the decision to grant joinder is discretionary. 35 U.S.C. § 315(c); 37 C.F.R. § 42.122(b).

As the moving party, Mylan 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; and (3) explain what impact (if any) joinder would have on the trial schedule for the existing review. *See* Frequently Asked Question H5, <https://www.uspto.gov/patents-application-process/patent-trial-and-appeal-board/ptab-e2e-frequently-asked-questions> (last visited January 3, 2017). Patent trial regulations, including the rules for joinder, must be construed to secure the just, speedy, and inexpensive resolution of every proceeding. 37 C.F.R. § 42.1(b).

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 Mylan 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 Mylan as a Petitioner to the Amerigen IPR.

In its Motion for Joinder, Mylan 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. 1. Mylan represents that joinder with the Amerigen IPR is appropriate because the grounds proposed in the present Petition are “the same grounds of invalidity on which the Board instituted the Amerigen IPR.” Mot. 3. Mylan further argues that (a) joinder will not impact the Board’s ability to complete the review in a timely manner; (b) joinder will promote efficiency by consolidating issues, avoiding duplicate efforts, and preventing inconsistencies; (3) joinder will not prejudice Janssen or Amerigen. Mot. 4–6.

Janssen filed an Opposition to Mylan’s Motion for Joinder, stating that “the Board should deny Mylan’s motion because it introduces new exhibits, including two new expert declarations” and because “Mylan also fails to specify how its petition differs from Amerigen’s petition and it cites no Board decisions to support what it seeks to do here.” Opp. 1. Specifically, Janssen argues that (a) Mylan’s Petition introduces new evidence and testimony that would prejudice Janssen by unduly complicating the Amerigen IPR if joinder is allowed; (b) Mylan’s Motion

for Joinder fails to specify how its Petition differs from Amerigen’s petition and how briefing and discovery may be simplified; and (c) Mylan cites no Board decision granting joinder where a petitioner requesting joinder sought to rely on expert testimony from a different expert. Opp. 6–11.

In its Reply, Mylan asserts that the Board should grant joinder, because its new exhibits, apart from the two expert declarations, “simply complete the record.” Reply 3. Regarding its expert declarations, Mylan argues that “taking a single deposition” does not present the type of prejudicial burden that counsels in favor of denying joinder.⁷ *Id.* at 2. Mylan relies on *Torrent Pharms. Ltd. v. Novartis AG*, Case IPR2014-00784, in support of its assertion that related discovery would not be an undue burden. *Id.* at 3–4.

In view of the circumstances of this case, we are not persuaded that Mylan has established sufficiently that joinder to the Amerigen IPR is warranted. Granting joinder in view of Mylan’s two different declarations and new evidence would add an additional dimension to the substantive issues in the Amerigen IPR, and thus would be more significant than Mylan suggests. Although the parties have conferred and cooperated on certain matters in this proceeding, their inability to agree on several critical issues in connection with facilitating joinder further differentiates this case from other

⁷ Janssen states that Mylan “has represented to Janssen off the record that it is willing to withdraw the Hofmann Declaration to rely solely on the McDuff Declaration,” but that “Mylan is not willing to withdraw the Garnick Declaration to rely solely on the Serels Declaration.” Opp. 3 n.2. Off-the-record representations notwithstanding, we have before us in this case two declarations from two different declarants on Mylan’s behalf.

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cases in which the parties have cooperated and in which we have granted joinder.

Additionally, granting joinder would add significant procedural complications and delay to the progress of the Amerigen IPR. In the Amerigen IPR, Janssen has filed its Response, and the date for the oral hearing is only a few weeks away. Granting joinder would require adjusting the schedule to allow Janssen discovery regarding the different declarants' testimony and the additional evidence associated with the present Petition. Mylan's Motion for Joinder does not offer a practical way to accommodate the additional discovery without inconveniencing all involved or delaying the due dates in the Amerigen IPR.

In view of the facts and circumstances of this case, Mylan, as movant, has not met its burden to show why joinder is appropriate, consistent with the goal of securing the just, speedy, and inexpensive resolution of every proceeding. Based on the record before us, and for the reasons given above, we institute an *inter partes* review in IPR2016-01332. However, we decline to exercise our discretion to join Mylan as a Petitioner to the Amerigen IPR. In view of the timeline of the Amerigen IPR, and in view of the number of common issues between the cases, we implement a condensed schedule in the present case to allow for resolution of these two cases involving the '438 patent in relative proximity to each other.

IV. ORDER

Accordingly, it is

ORDERED that trial is instituted in IPR2016-01332 as to claims 1–20 of the '438 patent on the following grounds only:

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Claims 1–20 as obvious under 35 U.S.C. § 103 over O’Donnell and Gerber;

Claims 1–4 and 6–11 as obvious under 35 U.S.C. § 103 over Barrie and Gerber;

FURTHER ORDERED that no grounds other than the ones specifically granted above are authorized for *inter partes* review as to the claims of the ’438 patent;

FURTHER ORDERED that pursuant to 35 U.S.C. § 314(c) and 37 C.F.R. § 42.4, notice is given of the institution of a trial commencing on the entry date of this Decision; and

FURTHER ORDERED that Mylan’s Motion for Joinder is *denied*.

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FOR PETITIONER:

Brandon M. White

bmwhite@perkinscoie.com

Crystal Canterbury

ccanterbury@perkinscoie.com

FOR PATENT OWNER:

Dianne Elderkin

delderkin@akingump.com

Barbara Mullin

bmullin@akingump.com

Ruben Munoz

rmunoz@akingump.com