

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC.,
Petitioners

v.

JANSSEN ONCOLOGY, INC.,
Patent Owner

Inter Partes Review No. IPR2016-01332

U.S. Patent No. 8,822,438

**MOTION FOR JOINDER PURSUANT TO
35 U.S.C. § 315(c) AND 37 C.F.R. § 42.122(b)**

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I. STATEMENT OF THE PRECISE RELIEF REQUESTED

Petitioners Mylan Pharmaceuticals Inc. (“Mylan,” or “Petitioner”) respectfully request joinder pursuant to 35 U.S.C. § 315(c) and 37 C.F.R. § 42.122(b) 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 *Amerigen Pharmaceuticals Limited v. Janssen Oncology, Inc.*, Case No. IPR2016-00286 (“Amerigen IPR”), which was instituted on May 31, 2016. 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.

This Motion for Joinder is timely under 37 C.F.R. §§ 42.22 and 42.122(b), as it is submitted within one month of May 31, 2016, the date on which the Board instituted the Amerigen IPR.

II. STATEMENT OF MATERIAL FACTS

1. Petitioners are not aware of any reexamination certificates or pending prosecution concerning U.S. Patent No. 8,822,438 (“the ’438 patent”), which is the subject of both the Amerigen IPR and the Mylan IPR. The following litigations or *inter partes* reviews relate to the ’438 patent are pending:

- *Amerigen Pharms. Ltd. v. Janssen Oncology, Inc.*, IPR2016-00286 (P.T.A.B.);

- *Argentum Pharms. LLC v. Janssen Oncology, Inc.*, IPR2016-01317 (P.T.A.B.);
- *BTG Int’l Ltd. v. Actavis Labs. FL, Inc.*, No. 15-cv-5909-KM-JBC (D.N.J.);
- *BTG Int’l Ltd. v. Amerigen Pharms., Inc.*, No. 16-cv-02449-KM-JBC (D.N.J.);
- *Janssen Biotech, Inc. v. Mylan Pharms. Inc.*, No. 15-cv-00130-IMK (N.D.W. Va.); and
- *BTG Int’l Ltd. v. Glenmark Pharms. Inc., USA*, No. 16-cv-03743-KM-JBC (D.N.J.).

2. Amerigen Pharmaceuticals Limited (“Amerigen”) filed its petition for *inter partes* review of the ’438 patent on December 4, 2015. IPR2016-00286, Paper 1.

3. The Amerigen IPR included the following two grounds for challenging the validity of the ’438 patent:

Ground 1: Claims 1-20 were unpatentable as obvious over O’Donnell in view of Gerber; and

Ground 2: Claims 1-4 and 6-11 were unpatentable as obvious over U.S. Patent No. 5,604,213 in view of Gerber.

See IPR2016-00286, Paper 1.

4. The Board instituted the Amerigen IPR on May 31, 2016, on both grounds. *See* IPR2016-00286, Paper 14.

5. The Petition filed in the present Mylan IPR includes only the two grounds on which the Amerigen IPR was instituted.

6. The grounds proposed in the present Mylan IPR are, therefore, the same grounds of invalidity on which the Board instituted the Amerigen IPR.

III. STATEMENT OF REASONS FOR RELIEF REQUESTED

The Leahy-Smith America Invents Act (AIA) permits joinder of *inter partes* review proceedings. The statutory provision governing joinder of *inter partes* review proceedings is 35 U.S.C. § 315(c), which reads as follows:

(c) JOINDER.--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.

In exercising its discretion to grant joinder, the Board considers the impact of substantive and procedural issues on the proceedings, as well as other considerations, while being “mindful that patent trial regulations, including the rules for joinder, must be construed to secure the just, speedy, and inexpensive resolution of every proceeding.” *See Dell, Inc. v. Network-1 Security Solns., Inc.*,

Case IPR2013-00385, Paper No. 17 (July 29, 2013) at 3. The Board should consider “the policy preference for joining a party that does not present new issues that might complicate or delay an existing proceeding.” *Id.* at 10. Under this framework, joinder of the present Mylan IPR with the Amerigen IPR is appropriate.

“A motion for joinder should: (1) set forth the 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.” *Id.* at 4. Each of these is addressed fully below.

A. Joinder will not impact the Board’s ability to complete the review in a timely manner

Joinder in this case will not impact the Board’s ability to complete its review in a timely manner. 35 U.S.C. § 316(a)(11) and associated rule 37 C.F.R. § 42.100(c) provide that *inter partes* review proceedings should be completed and the Board’s final decision issued within one year of institution of the review. In this case, joinder will not affect the Board’s ability to issue the decision within this required one-year timeframe because the Petition filed in the present Mylan IPR contains the identical grounds on which the Amerigen IPR was instituted.

In addition, Mylan respectfully proposes procedures to simplify any further briefing and discovery, which will minimize any potential impact on the schedule

or the volume of materials to be submitted to the Board. Given that both of the petitioners—Mylan and Amerigen— will be addressing the identical grounds for challenging the claims at issue, the Board may adopt procedures similar to those adopted in *Dell, Inc. v. Network-1 Security Solns., Inc.*, IPR2013-00385 and *Motorola Mobility LLC v. SoftView LLC*, IPR2013-00256. In those cases, the Board ordered the petitioners to file consolidated filings, for which the first petitioner was responsible, and allowed the new petitioner to file seven additional pages with corresponding additional responsive pages allowed to the Patent Owner. IPR2013-00385, Paper 17 at 8; IPR2013-00256, Paper 10 at 8-9. This procedure would minimize any complication or delay caused by joinder, as the Board recognized in those cases. As in Cases IPR2013-00385 and IPR2013-00256, the Petitioners in this case can work together to manage the questioning at depositions and presentations at the hearing to avoid redundancy. IPR2013-00385, Paper 17 at 9; IPR2013-00256, Paper 10 at 9-10. Additionally, while the Petitioner in the Mylan IPR and the Petitioner in the Amerigen IPR have relied upon testimony from separate experts in their respective petitions, the conclusions and underlying reasoning of the experts are congruent, and therefore present no additional burden on the part of the Patent Owners to address.

B. Joinder will promote efficiency by consolidating issues, avoiding duplicate efforts, and preventing inconsistencies

It is noted that Mylan would not be time barred from filing the present Petition without a corresponding motion for joinder. However, determining the same validity questions concerning the '438 patent in separate concurrent proceedings would duplicate efforts, and create a risk of inconsistent results and piecemeal review. Proceeding with a consolidated *inter partes* review would avoid inefficiency and potential inconsistency and would result in a final written decision without any delay.

C. Joinder will not prejudice Patent Owners or Amerigen

Permitting joinder will not prejudice the Patent Owner or Amerigen. As noted above, the proposed grounds for instituting *inter partes* review in the Mylan IPR are identical to the ones on which the Amerigen IPR was instituted. Moreover, joinder will not affect the timing of the Amerigen IPR, and any extension to the schedule that may be required is permitted by law and the applicable rules. 35 U.S.C. § 316(a)(1); 37 C.F.R. § 42.100(c). In fact, joinder is likely more convenient and efficient for the Patent Owners by providing a single trial on the '438 patent. By allowing all grounds of invalidity to be addressed in a single proceeding, the interests of all parties and the Board will be well served.

IV. CONCLUSION

For the foregoing reasons, Mylan respectfully requests that its Petition for *inter partes* review of U.S. Patent No. 8,822,438 be instituted and that the proceeding be joined with *Amerigen Pharmaceuticals Limited v. Janssen Oncology, Inc.*, Case No. IPR2016-00286.

June 30, 2016

Respectfully submitted,

/Brandon M. White/

Brandon M. White, Esq.
Reg. No. 52,354
Perkins Coie LLP
700 Thirteenth Street, N.W.
Suite 600
Washington, DC 20005-3960
bmwhite@perkinscoie.com
Tel: 202-654-6206
Fax: 202-654-9681

*Counsel for Petitioner
Mylan Pharmaceuticals Inc.*

CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. § 42.6(e), I certify that I caused to be served a true and correct copy of the foregoing: MOTION FOR JOINDER PURSUANT TO 35 U.S.C. § 315(c) AND 37 C.F.R. § 42.122(b) by Federal Express Next Business Day Delivery on this day on the Patent Owner's correspondence address of record for the subject patent as follows:

Janssen Oncology, Inc.
10990 Wilshire Blvd., Suite 1200
Los Angeles, CA 90024

Johnson & Johnson,
Attn: Joseph F. Shirtz
One Johnson & Johnson Plaza
New Brunswick, NJ 08933-7003

and by email to the service addresses for Patent Owner listed in Paper No. 13 in IPR2016-00286:

JANS-ZYTIGA@akingump.com and
ZytigaIPRTeam@sidley.com

Dated: June 30, 2016

/Brandon M. White/
Brandon M. White
Reg. No. 52,354

Counsel for Petitioner Mylan Pharmaceuticals Inc.