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

Paper 19
Entered: April 12, 2017

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ACTAVIS LABORATORIES FL, INC., AMNEAL PHARMACEUTICALS LLC, AMNEAL PHARMACEUTICALS OF NEW YORK, LLC, DR. REDDY'S LABORATORIES, INC., DR. REDDY'S LABORATORIES, LTD., SUN PHARMACEUTICALS INDUSTRIES, LTD., SUN PHARMACEUTICALS INDUSTRIES, INC., TEVA PHARMACEUTICALS USA, INC., WEST-WARD PHARMACEUTICAL CORP., and HIKMA PHARMACEUTICALS, LLC,
Petitioner,

v.

JANSSEN ONCOLOGY, INC.,
Patent Owner.

Case IPR2017-00853
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)

Petitioners, Actavis Laboratories FL, Inc., Amneal Pharmaceuticals LLC, Amneal Pharmaceuticals of New York, LLC, Dr. Reddy's Laboratories, Inc., Dr. Reddy's Laboratories, Ltd., Sun Pharmaceuticals Industries, Ltd., Sun Pharmaceuticals Industries, Inc., Teva Pharmaceuticals USA, Inc., West-Ward Pharmaceutical Corp., and Hikma Pharmaceuticals, LLC (collectively, the "Actavis Petitioners") filed a Petition (Paper 8, "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. §§ 311–19. Concurrently with the Petition, the Actavis Petitioners filed a Motion for Joinder (Paper 9, "Mot."), seeking to join this case, under 35 U.S.C. § 315(c), with the *inter partes* review in *Mylan Pharmaceuticals Inc., v. Janssen Oncology, Inc.*, Case IPR2016-01332 ("the Mylan IPR" and Petitioner "Mylan"), which was instituted on January 10, 2017. *See* IPR2016-01332, slip op. at 11–12 (PTAB January 10, 2017) (Paper 21) (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 15, "Opp."), to which Petitioner filed a Reply (Paper 17, "Reply"). Janssen also filed a Waiver of Preliminary Response (Paper 18, "Waiver").

For the reasons set forth below, we conclude that the Actavis Petitioners have shown that their 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 Mylan IPR. *See* IPR2016-01332, Paper 21, 11–12. Thus, we institute *inter partes* review, grant the Actavis Petitioners' Motion for Joinder, and exercise our discretion to join the Actavis

Petitioners as Petitioners to the Mylan IPR. We further terminate the present proceeding, IPR2017-00853.

I. PETITION FOR *INTER PARTES* REVIEW

The parties indicate that the '438 patent is being asserted in a number of district court proceedings. Pet. 2–3; Paper 10, 2–4. In addition, the '438 patent is the subject of pending *inter partes* review proceedings, including the Mylan IPR, as noted above, which has been instituted, and IPR2016-00286 and IPR2016-01582, which also have been instituted. 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 10, 2.

In the Mylan 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[4]

[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*, 90 British Journal of Cancer 2317–25 (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).

[4] In the Petition, the Actavis Petitioners identify "Ground 2" as challenging "Claims 1–4 and 5–11." Pet. 4. In the body of the Petition, however, the

Pet 4; Mot. 4; IPR2016-01332, Paper 21, 11–12.

The Actavis Petitioners support their assertions with substantially the same evidence and arguments proffered by Mylan in the Mylan IPR. Pet. 20–61. The Actavis Petitioners represent that joinder with the Mylan IPR is appropriate because the "grounds proposed in the present Petition are [] the same grounds of invalidity on which the Board instituted the Mylan IPR, and the Petition does not contain any additional arguments or evidence in support of the invalidity of claims 1–20 of the '438 patent." Mot. 4.

In response to an exchange of correspondence with the Board, Janssen filed a Waiver of Preliminary Response on March 23, 2017, stating that Janssen "elects to waive its Patent Owner Preliminary Response to the Petition filed in the above-captioned proceeding (IPR2017-00853)." Waiver 1. Janssen emphasizes, however, that "no adverse inference should be taken by this election" and that "this election should not be deemed a waiver or admission on the part of Janssen of any material presented in the Petition." *Id.*

We incorporate our analysis from our institution decision in the Mylan IPR. IPR2016-01332, Paper 21, 2–11. For the same reasons, we determine that the Actavis Petitioners have demonstrated a reasonable likelihood that they will prevail with respect to their challenge to claims 1–20 of the '438 patent on the asserted grounds. In view of the identical challenges in the

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Actavis Petitioners only argue that that claim 5 is obvious over O'Donnell in view of Gerber, and do not argue that claim 5 is obvious over Barrie and Gerber. Pet. 44. Given this latter argument, and given the Actavis Petitioners' representations that the arguments and Grounds are identical to those in the Mylan IPR (Mot. 6), we understand the Actavis Petitioners' Ground 2 to be limited to claims 1–4 and 6–11.

Petition and in view of Janssen'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 IPR2016-01332. We do not institute an *inter partes* review on any other grounds.

II. MOTION FOR JOINDER

In the Motion for Joinder, the Actavis Petitioners seek joinder of their Petition with "a previously instituted and currently pending IPR" filed by Mylan, i.e., the Mylan IPR. Mot. 1. The Actavis Petitioners filed the present Motion on February 8, 2017, within one month of our decision instituting *inter partes* review in IPR2016-01332, which issued on January 10, 2017. *See* IPR2016-01332, Paper 21; 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.

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