

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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AMNEAL PHARMACEUTICALS LLC,  
Petitioner,

v.

YEDA RESEARCH AND DEVELOPMENT CO. LTD.,  
Patent Owner.

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Case IPR2015-01976  
Patent 8,232,250 B2

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Before SHERIDAN K. SNEDDEN, ZHENYU YANG, and  
TINA E. HULSE, *Administrative Patent Judges*.

YANG, *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)*

## I. INTRODUCTION

On August 25, 2015, we instituted trial in *Mylan Pharmaceuticals Inc. v. Yeda Research & Development Co. Ltd.*, IPR2015-00643, to review whether claims 1–20 of U.S. Patent No. 8,232,250 B2 (“the ’250 patent”) would have been obvious over (1) the combination of Pinchasi and 1996 SBOA, or (2) the combination of Pinchasi and Flechter. IPR2015-00643, Paper 13. On September 25, 2015, Amneal Pharmaceuticals LLC (“Petitioner”) filed a Petition, seeking an *inter partes* review of claims 1–20 of the ’250 patent. Paper 1 (“Pet.”). Along with the Petition, Petitioner also filed a Motion for Joinder to join this proceeding with IPR2015-00643. Paper 3 (“Mot.”). During a conference call held on November 19, 2015, Yeda Research and Development Co. Ltd. (“Patent Owner”) stated that it does not oppose the joinder motion. Paper 7, 2. At the parties’ request, we deemed the Patent Owner’s Preliminary Response filed in IPR2015-00643 as timely filed and served in the present case. Paper 8, 3.

As explained further below, we institute trial on the same grounds as instituted in IPR2015-00643 and grant Petitioner’s Motion for Joinder.

## II. DISCUSSION

In IPR2015-00643, Mylan Pharmaceuticals Inc. (“Mylan”) challenged claims 1–20 of the ’250 patent on the following four grounds:

Claims	Basis	Reference(s)
1–13, 19, 20	§ 102(b)	Pinchasi <sup>1</sup>
1–20	§ 103	Pinchasi
1–20	§ 103	Pinchasi and the 1996 SBOA <sup>2</sup>
1–20	§ 103	Pinchasi and Flechter <sup>3</sup>

<sup>1</sup> Pinchasi, WO 2007/081975 A2, published July 19, 2007 (Ex. 1005).

<sup>2</sup> Summary Basis of Approval for the New Drug Application for 20 mg daily Copaxone ® (NDA #20-622) (Ex. 1007).

We instituted trial in IPR2015-00643 on two grounds: (1) obviousness over Pinchasi and 1996 SBOA; and (2) obviousness over Pinchasi and Flechter. IPR2015-00643, Paper 13, 17.

The Petition in this case is substantively identical to the one in IPR2015-00643. *Compare* IPR2015-00643, Paper 2 *with* IPR2015-01976, Paper 1. For the same reasons stated in our Decision on Institution in IPR2015-00643, we institute trial in this proceeding on the same two grounds. *See* IPR2015-00643, Paper 13.

Having determined that institution is appropriate, we now turn to Petitioner's Motion for Joinder. Based on authority delegated to us by the Director, we have discretion to join an *inter partes* review to a previously instituted *inter partes* review. 35 U.S.C. § 315(c). Section 315(c) provides, in relevant part, that “[i]f 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.” *Id.* When determining whether to grant a motion for joinder we consider factors such as timing and impact of joinder on the trial schedule, cost, discovery, and potential simplification of briefing. *Kyocera Corp. v. SoftView, LLC*, Case IPR2013-00004, slip op. at 4 (PTAB Apr. 24, 2013) (Paper 15).

Under the circumstances of this case, we determine that joinder is appropriate. Petitioner filed the Petition and Motion for Joinder in the present proceeding on September 25, 2015, within one month after we instituted trial in IPR2015-00643. *See* 37 C.F.R. § 42.122(b). Petitioner represents that the Petition in this case and the one in IPR2015-00643 include “identical grounds, analysis, and exhibits,” and rely on the same expert declarations. Mot. 5. Petitioner agrees

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<sup>3</sup> S. Flechter et al., *Copolymer 1 (Glatiramer Acetate) in Relapsing Forms of Multiple Sclerosis: Open Multicenter Study of Alternate-Day Administration*, 25 CLINICAL NEUROPHARM. 11–15 (2002) (Ex. 1008).

to consolidated filings and discovery with Mylan, and agrees not to be permitted any separate arguments. *Id.* at 6. Petitioner raises no new grounds of unpatentability from IPR2015-00643. *Id.* at 7. In addition, Petitioner contends that there will be no impact on the trial schedule of IPR2015-00643. *Id.* Patent Owner confirmed during the November 19, 2015, conference call that it does not oppose Petitioner's Motion for Joinder. Paper 7, 2.

In view of the foregoing, we find that joinder based upon the conditions stated by Petitioner in its Motion for Joinder will have little or no impact on the timing, cost, or presentation of the trial on the instituted ground. Discovery and briefing will be simplified if the proceedings are joined. Thus, there being no opposition to Petitioner's Motion for Joinder from any of the parties, the Motion for Joinder is *granted*.

### III. ORDER

Accordingly, it is

ORDERED that trial is instituted in IPR2015-01976 on the following grounds:

1. Claims 1–20 as obvious over Pinchasi and 1996 SBOA; and
2. Claims 1–20 as obvious over Pinchasi and Flechter;

FURTHER ORDERED that Petitioner's Motion for Joinder with IPR2015-00643 is *granted*;

FURTHER ORDERED that IPR2015-01976 is terminated and joined to IPR2015-00643, pursuant to 37 C.F.R. §§ 42.72, 42.122, based on the conditions stated in Petitioner's Motion for Joinder (Paper 3), as discussed above;

FURTHER ORDERED that the Scheduling Order in place for IPR2015-00643 shall govern the joined proceedings;

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FURTHER ORDERED that all future filings in the joined proceeding are to be made only in IPR2015-00643;

FURTHER ORDERED that the case caption in IPR2015-00643 for all further submissions shall be changed to add Amneal as a named Petitioner after Mylan, and to indicate by footnote the joinder of IPR2015-01976 to that proceeding, as indicated in the attached form of caption;

FURTHER ORDERED that the parties shall file an updated Protective Order to reflect the addition of Amneal as a named Petitioner; and

FURTHER ORDERED that a copy of this Decision shall be entered into the record of IPR2015-00643.

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