

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 IPR2015-01980  
Patent 8,399,413 B2

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

HULSE, *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

Amneal Pharmaceuticals LLC (“Amneal”) filed a Petition, seeking an *inter partes* review of claims 1–20 of U.S. Patent No. 8,399,413 B2 (“the ’413 patent,” Ex. 1001). Paper 1 (“Pet”). Along with the Petition, Amneal filed a Motion for Joinder to join this proceeding with *Mylan Pharmaceuticals Inc. v. Yeda Research & Development Co. Ltd.*, IPR2015-00644. Paper 3 (“Mot”). Amneal filed the Petition and Motion for Joinder in the present proceeding on September 25, 2015, within one month after we instituted trial in IPR2015-00644. 37 C.F.R. § 42.122(b). On December 7, 2015, the parties requested that we deem the Patent Owner Preliminary Response filed in IPR2015-00644 as filed and served in the present case. The panel granted the parties’ request. Paper 8.

As explained further below, we institute trial on the same grounds as instituted in IPR2015-00644 and grant Amneal’s Motion for Joinder.

## II. DISCUSSION

In IPR2015-00644, Mylan Pharmaceuticals Inc. (“Mylan”) challenged claims 1–20 of the ’413 patent on the following four grounds:

References	Basis	Claims challenged
Pinchasi <sup>1</sup>	§ 102	1–6 and 8–20
Pinchasi	§ 103	1–20
Pinchasi and the 1996 SBOA <sup>2</sup>	§ 103	1–20

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

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

References	Basis	Claims challenged
Pinchasi and Flechter <sup>3</sup>	§ 103	1–20

After considering the Petition and the Patent Owner Preliminary Response, we instituted trial in IPR2015-00644 on two grounds: (1) obviousness over Pinchasi and 1996 SBOA; and (2) obviousness over Pinchasi and Flechter. IPR2015-00644, Paper 14, 15–16.

Amneal’s Petition is substantively identical to Mylan’s Petition, challenging the same claims based on the same art and the same grounds. *Compare* IPR2015-00644, Paper 2 *with* IPR2015-01980, Paper 1. For the same reasons stated in our Decision on Institution in IPR2015-00644, we institute trial in this proceeding on the same two grounds. *See* IPR2015-00644, Paper 14.

Having determined that institution is appropriate, we now turn to Amneal’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,

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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).

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. As Amneal notes, the Petition in IPR2015-00644 is substantively identical to the grounds, analysis, exhibits, and expert declaration relied on in the instant proceeding. Mot. 5. Amneal has also agreed to consolidated filings and discovery with Mylan, and has agreed not “to be permitted any arguments separate from those advanced by Amneal and Mylan in the consolidated filings.” *Id.* at 6. Amneal raises no new grounds of unpatentability from IPR2015-00644. *Id.* at 7. And Amneal contends that there will be no impact on the trial schedule of IPR2015-00644. *Id.* As confirmed during the conference call held November 19, 2015, Patent Owner does not oppose Amneal’s Motion for Joinder. Paper 7, 2.

In view of the foregoing, we find that joinder based upon the conditions stated in Amneal’s Motion for Joinder will have little or no impact on the timing, cost, or presentation of the trial on the instituted grounds. Moreover, discovery and briefing will be simplified if the proceedings are joined. Thus, without opposition to the Motion for Joinder from any of the parties, the Motion is *granted*.

### III. ORDER

Accordingly, it is

ORDERED that trial is instituted in IPR2015-01980 on the following grounds:

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

B. Claims 1–20 as obvious over Pinchasi and Flechter;

FURTHER ORDERED that Amneal’s Motion for Joinder with IPR2015-00644 is *granted*;

FURTHER ORDERED that IPR2015-01980 is terminated and joined to IPR2015-00644, pursuant to 37 C.F.R. §§ 42.72, 42.122, based on the conditions stated in Amneal’s Motion for Joinder (Paper 3), as discussed above;

FURTHER ORDERED that the Scheduling Order in place for IPR2015-00644 shall govern the joined proceedings;

FURTHER ORDERED that all future filings in the joined proceeding are to be made only in IPR2015-00644;

FURTHER ORDERED that the case caption in IPR2015-00644 for all further submissions shall be changed to add Amneal as a named Petitioner after Mylan, and to indicate by footnote the joinder of IPR2015-01980 to that proceeding, as indicated in the attached sample case 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 IPR2015-00644.

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