

UNITED STATES PATENT AND TRADEMARK OFFICE

---

BEFORE THE PATENT TRIAL AND APPEAL BOARD

---

AMNEAL PHARMACEUTICALS LLC,  
Petitioner,

v.

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

---

Case IPR2015-01980  
Patent 8,399,413 B2

---

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

---

<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,

---

<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.

# Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

## Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

## Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

## Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

## API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

## LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

## FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

## E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.