Trials@uspto.gov
571-272-7822

Paper 13
Entered: February 4, 2015

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AMNEAL PHARMACEUTICALS, LLC,
Petitioner,

v.

ENDO PHARMACEUTICALS INC.,
Patent Owner.

Case IPR2014-01365
Patent 8,329,216 B2

Before TONI R. SCHEINER, FRANCISCO C. PRATS, and JACQUELINE WRIGHT BONILLA, *Administrative Patent Judges*.

BONILLA, *Administrative Patent Judge.*

DECISION
Granting Petitioner's Motion for Joinder *In-Part*,
and Instituting *Inter Partes* Review
37 C.F.R. §§ 42.108, 42.122

I. INTRODUCTION

Amneal Pharmaceuticals, LLC, ("Petitioner") filed a Petition requesting *inter partes* review of claims 5, 16, 44, 46, 47, and 72–82 of U.S. Patent No. 8,329,216 ("the '216 patent"). Paper 2 ("Pet.," "current Petition," or "Second Petition"). On the same day, Petitioner also filed a Motion for Joinder, requesting joinder of the Petition with a related and instituted proceeding, IPR2014-00360. Paper 3 ("Joinder Motion"), 1–2. Petitioner filed its Joinder Motion within one month after institution of a trial in IPR2014-00360, as required by 37 C.F.R. § 42.122(b). Endo Pharmaceuticals Inc. ("Patent Owner") filed an Opposition to Petitioner's Motion for Joinder (Paper 8, "Opp. to Joinder"), and Petitioner filed a Reply to Opposition to Motion for Joinder (Paper 10, "Reply to Opp. to Joinder"). Thereafter, Patent Owner filed a Preliminary Response (Paper 12, "Prelim. Resp."). We have jurisdiction under 35 U.S.C. § 314.

For the reasons that follow, we grant Petitioner's Motion for Joinder in relation to a ground in the current Petition regarding claims 44 and 47, but not in relation to any grounds regarding claims 5, 16, 46, and 72–82. In addition, we are persuaded that Petitioner has demonstrated that there is a reasonable likelihood that it would prevail with respect to claims 44 and 47 of the '216 patent, and we grant the Petition as to those claims.

II. BACKGROUND REGARDING JOINDER

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.

Section 315(b) of the statute normally bars institution of *inter partes* review when the petition is filed more than one year after the petitioner (or petitioner's real party in interest or privy) is served with a complaint alleging infringement of the patent. 35 U.S.C. § 315(b); 37 C.F.R. § 42.101(b). That one-year time bar, however, does not apply to a request for joinder. 35 U.S.C. § 315(b) (final sentence); 37 C.F.R. § 42.122(b). This is an important consideration here because Petitioner was served with a complaint asserting infringement of the '216 patent more than one year before filing the Petition in this proceeding.[1] Thus, absent joinder of Petitioner in this proceeding as a party to IPR2014-00360, institution based on the current Petition is barred.

Joinder may be authorized when warranted, but the decision to grant joinder is discretionary. 35 U.S.C. § 315(c); 37 C.F.R. § 42.122(b). When exercising that discretion, the Board is mindful that patent trial regulations, including the rules for joinder, must be construed to secure the just, speedy, and inexpensive resolution of every proceeding. 37 C.F.R. § 42.1(b).[2]

---

[1] Petitioner was served with a complaint alleging infringement of the '216 patent on January 17, 2013, triggering a § 315(b) bar date of January 17, 2014. IPR2014-00360, Paper 15, 6, 9–10. Petitioner filed its Petition in the instant proceeding on August 22, 2014.

[2] 35 U.S.C. § 316(b) ("In prescribing regulations under this section, the Director

III. ANALYSIS ON JOINDER

Petitioner filed its Second Petition approximately one month after institution in IPR2014-00360. Thus, this case represents a "second bite at the apple" for Petitioner, who has received the benefit of seeing our Institution Decision in the prior case involving the same parties and patent. *See* IPR2014-00360, Paper 16 ("Institution Decision," dated July 25, 2014). This "second bite at the apple" situation is particularly noteworthy in view of the § 315(b) bar at issue here.

We observe that in its Opposition to Petitioner's Motion for Joinder, Patent Owner points us to a Decision Denying a Motion for Joinder by a different Board panel in *Target Corp. v. Destination Maternity Corp.*, Case IPR2014-00508 (PTAB Sept. 25, 2014) (Paper 18) ("*Target* Decision"). Opp. to Joinder 5–10. We are aware of the *Target* Decision, and respect our colleagues' well-reasoned position in the majority opinion in that case. We also recognize, however, as evident from *Target* Decision itself, that reasonable minds can differ on an interpretation of 35 U.S.C. § 315 as it relates to joining a party to an earlier proceeding in which the party is already a participant.[3]

---

shall consider the effect of any such regulation on the economy, the integrity of the patent system, the efficient administration of the Office, and the ability of the Office to timely complete proceedings instituted under this chapter.").

[3] *See Target Corp. v. Destination Maternity Corp.*, Case IPR2014-00508 (PTAB Sept. 25, 2014) (Paper 18); *see also*, *e.g.*, *Ariosa Diagnostics v. Isis Innovation Ltd.*, Case IPR2012-00022, slip op. at 18–22 (PTAB Sept. 2, 2014) (Paper 166); *Ariosa Diagnostics v. Isis Innovation Ltd.*, Case IPR2013-00250 (PTAB Sept. 3, 2013) (Paper 25) (designated Paper 24). In *Target*, a Motion for Rehearing of the Decision Denying Petitioner's Motion of Joinder is currently pending. *Target*, Case IPR2014-00508 (Papers 18–25).

In view of the reasonable difference of opinion, as well as the existence of other Board cases allowing joinder of Petitions filed by a same party, we interpret § 315(c) as granting us discretion to allow joinder under the circumstances of this case. That said, when a § 315(b) bar would apply absent joinder, we hesitate to allow a petitioner a second bite one month after institution in a first case, at the expense of scheduling constraints for everyone, as well as additional costs (and potential prejudice) to Patent Owner, absent a good reason for doing so.

In this proceeding, in relation to the current Petition, Petitioner moves for joinder with IPR2014-00360. Joinder Motion 1–2. We instituted a trial in IPR2014-00360 on July 25, 2014, and denied a Request for Rehearing of our Institution Decision on September 16, 2014; Patent Owner subsequently filed a Response and Contingent Motion to Amend on October 27, 2014. IPR2014-00360, Institution Decision, Papers 21, 29, 31, 32.

The current Petition raises three grounds in relation to challenged claims 5, 16, 44, 46, 47, and 72–82 of the '216 patent, as indicated below.

	References	Challenged Claims
1	Oshlack (Ex. 1007)[4] and Handbook of Dissolution Testing ("the Handbook") (Ex. 1008)[5]	5, 16, 44, 46, and 47

[4] Oshlack et al., U.S. Patent No. 5,958,452, "Extruded Orally Administrable Opioid Formulations," filed Apr. 10, 1997, issued Sept. 28, 1999.

[5] Hanson, HANDBOOK OF DISSOLUTION TESTING, v–xii, 1–13, 26–53, 69–91, 111–123 (2d ed. 1991).

DOCKET ALARM

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.