Paper No. 17
Filed: March 17, 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

Petitioners

v.

JANSSEN ONCOLOGY, INC.,

Patent Owner

U.S. Patent No. 8,822,438 to Auerbach et al.

Inter Partes Review IPR2017-00853

REPLY IN SUPPORT OF PETITIONERS' MOTION FOR JOINDER WITH RELATED INSTITUTED *INTER PARTES* REVIEW OF U.S. PATENT NO. 8,822,438 PURSUANT TO 35 U.S.C. § 315(c), 37 C.F.R. 42.22 AND 42.112(b)

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Page(s)

Cases

Statutes

Other Authorities

Far from being the "gang tackling" of the '438 patent alleged by Patent Owner, the Petitioners' request for joinder to the trial instituted in *Mylan Pharmaceuticals Inc., v. Janssen Oncology, Inc.*, IPR2015-01332 ("Mylan IPR") is expressly permitted and encouraged by both 37 C.F.R. § 42.122(b) and relevant prior Board decisions. Petitioners have taken all necessary steps to ensure that their request will neither disrupt ongoing proceedings nor prejudice Patent Owner. For at least the following reasons, the Board should institute Petitioners' IPR and join it to the Mylan IPR.

I. Petitioners' joinder request is timely.

Petitioner's IPR is timely pursuant to 37 C.F.R. § 42.122(b) because the Petition was filed within one month of the Mylan IPR's institution. *See* 37 C.F.R. § 42.122(b) ("The time period set forth in § 42.101(b) shall not apply when the petition is accompanied by a request for joinder."). Section 42.122(b) is agnostic to district court-related time bars, and joinder is liberally granted under this regulation. *See Wockhardt Bio AG v. AstraZeneca AB*, IPR2016-01029, Paper 15 (P.T.A.B., Aug. 23, 2016) (granting joinder irrespective of the one-year time bar); *see also Achates Reference Publishing, Inc. v. Apple, Inc.* 803 F.3d 652, 657 (Fed. Cir. 2015) ("[A]n otherwise time-barred party may nonetheless participate in an *inter partes* review proceeding if another party files a proper petition."). Thus, the law is clear that

Petitioners' Motion for Joinder is timely, and Patent Owner's argument to the contrary runs afoul of statute, regulations, and the related case law.

Patent Owner characterizes this Petition as a "gang tackling" of the '438 patent and argues that Petitioners are "manipulating the IPR process" by requesting joinder. Patent Owner's Opposition at 7. This is not the case. As stated throughout this Reply and opening Motion for Joinder, Petitioners have agreed to play a secondary role in the Mylan IPR. *See, e.g.*, Petitioners' Motion for Joinder, Paper 9 at 8. There are no new experts or arguments in Petitioners' Petition. And Petitioners have agreed to be bound by all proceedings that have already occurred in the Mylan IPR. There will be no prejudice to Patent Owner because it can continue to defend against the Mylan IPR just as it would before joinder while still allowing Petitioners to take part in an "efficient, streamlined, and cost-effective alternative to district court litigation." Patent Owner's Opposition at 7.

Patent Owner argues that, because Petitioners' ability to independently file a petition is time-barred, Petitioners' joinder request should be denied because there would otherwise "be no parallel proceeding and no threat of duplicative briefs, expert discovery, or trial testimony." Patent Owner's Opposition at 9. But this argument has already been rejected by other boards. For example, in *Wockhardt Bio AG v. AstraZeneca AB*, petitioner filed a petition and motion for joinder over a year after it was served in the district court. *Wockhardt*, paper 15 at p. 7. Patent owner

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.