

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

RANBAXY LABORATORIES LTD. and RANBAXY INC.,
Petitioners,

v.

ADAMAS PHARMACEUTICALS, INC.,
Patent Owner.

Case IPR2015-00410
Patent No. 8,362,085

**PATENT OWNER'S PRELIMINARY RESPONSE
PURSUANT TO 37 C.F.R. § 42.107**

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I. INTRODUCTION

The Board should not institute *inter partes* review of U.S. Patent No. 8,362,085 (the “’085 patent”) because petitioners – Ranbaxy Laboratories Ltd. (“Ranbaxy Labs”) and Ranbaxy Inc. (collectively, “Petitioners”) – filed a fatally flawed Petition. Specifically, Petitioners failed to name all real parties-in-interest, and their belated correction of this defect is futile under 35 U.S.C. § 315(b). Accordingly, institution of *inter partes* review should be denied.

II. THE PETITION FAILED TO NAME ALL REAL PARTIES-IN-INTEREST

Petitioners did not identify all real parties-in-interest in their Petition as required by 35 U.S.C. § 312(a)(2) and 37 C.F.R. § 42.8(b)(1). Specifically, the Petition did not identify Sun Pharmaceutical Industries Ltd. (“Sun Pharma”) as a real party-in-interest, despite the fact that Ranbaxy Labs was acting as a proxy for Sun Pharma and subject to its direct control at the time the Petition was filed. Notably, at the time Petition was filed, both Sun Pharma and Ranbaxy were in infringement litigation regarding the ‘085 patent.

Sun Pharma recently completed its acquisition of petitioner Ranbaxy Labs, which is now defunct. Ex. 2001 p. 1 (“Ranbaxy will be delisted”). On April 8, 2015, Petitioners served updated Mandatory Notices, identifying for the first time Sun Pharma as a real party-in-interest. Paper 15 p. 2.

Unmentioned in Petitioners' updated Mandatory Notices, however, is the fact that at the time the Petition was filed on December 17, 2014, the legal relationship between Ranbaxy Labs and Sun Pharma was governed by an agreement between them titled Scheme of Arrangement (the "Scheme"). *See* Ex. 2002. The Scheme created an explicit agency relationship between the entities, designating Ranbaxy Labs as the agent of Sun Pharma from April 1, 2014 to March 25, 2015 (the "standstill" period).

The Petition was filed on December 17, 2014, which was during the standstill period of the Scheme, when Ranbaxy Labs was expressly designated by the Scheme as acting "for and on behalf of and as an agent for [Sun Pharma]." *Id.* p. 15. Accordingly, as provided by the Scheme, Ranbaxy Labs filed the petition for *inter partes* review on behalf of Sun Pharma. Petitioners, however, failed to identify Sun Pharma as a real party-in-interest.

Petitioners' failure to identify Sun Pharma as a real party-in-interest in its Petition is fatal. Petitioners' belated identification of Sun Pharma as a real party-in-interest cannot change that outcome. Specifically, Petitioners' belated identification of Sun Pharma as a real party-in-interest is futile given the pre-existing litigation regarding the '085 patent. The earliest filing date that can be accorded to the Petition is the date of the correction of the real parties-in-interest, April 8, 2015. *See* Paper 15. That is more than one year after Sun Pharma – which

is now seeking to act as a petitioner and is undisputedly a real party-in-interest – was constructively served and waived formal service of a complaint alleging infringement of the '085 patent. *See* Ex. 2003; *see also* 35 U.S.C. § 315(b) (including service against a real party-in-interest or privy); Fed. R. Civ. P. 4(d)(4) (“When the plaintiff files a waiver, proof of service is not required and these rules apply as if a summons and complaint had been served at the time of filing the waiver.”); *Motorola Mobility LLC v. Arnouse*, Case IPR2013-00010, slip op. at 6 (PTAB Jan. 30, 2013) (Paper 20) (holding that “in the situation where the petitioner waives service of a summons, the one-year time period begins on the date on which such a waiver is filed”).

A. FACTUAL BACKGROUND

Both Ranbaxy Labs and Sun Pharma are defendants in patent infringement litigation in which, *inter alia*, the '085 patent has been asserted by patent owner Adamas Pharmaceuticals, Inc. and its exclusive licensee, Forest Laboratories. In that litigation, Sun Pharma was provided with a copy of the Complaint and requested to waive service on February 10, 2014. Ex. 2004. Sun Pharma promptly agreed to waive service, and that waiver was filed with the U.S. District Court for the District of Delaware on February 17, 2014. Ex. 2003.

On April 6, 2014, Ranbaxy Labs and Sun Pharma publicly announced that they had entered into final agreements under which Sun Pharma would acquire

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