

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

DR. REDDY'S LABORATORIES, LTD. AND DR. REDDY'S
LABORATORIES, INC.,
Petitioners

v.

INDIVIOR UK LIMITED,
Patent Owner

Case: IPR2016-01113

Patent 8,475,832

**PATENT OWNER INDIVIOR UK LIMITED'S
MOTION FOR ADDITIONAL DISCOVERY¹**

¹ Corresponding motions are being filed in IPR2016-01111 and IPR2016-01112.

EXHIBIT LIST

Exhibit	Description
2001	Redline comparison of Teva IPR2016-00280 Petition and Dr. Reddy's IPR2016-01113 Petition
2002	Redline comparison of Teva IPR2016-00280 Declaration of Dr. Das and Dr. Reddy's IPR2016-01113 Declaration of Dr. Celik
2003	<i>Dr. Reddy's to acquire product portfolio from TEVA for US Market</i> , Press Release, Dr. Reddy's Laboratories Ltd., June 11, 2016
2004	Email from Dr. Reddy's counsel summarizing meet and confer teleconference conducted July 6, 2016
2005	Teva/Allergan Divestiture Products Table, Docket No. C-4589 (F.T.C. July 27, 2016)
2006	<i>FTC Requires Teva to Divest Over 75 Generic Drugs to Settle Competition Concerns Related to its Acquisition of Allergan's Generic Business</i> , Press Release, Federal Trade Commission (July 27, 2016), https://www.ftc.gov/news-events/press-releases/2016/07/ftc-requires-teva-divest-over-75-generic-drugs-rival-firms-settle
2007	PTAB Telephonic Conference Transcript, IPR2016-01111, IPR2016-01112, IPR2016-01113 (August 1, 2016)
2008	Carl O'Donnell, <i>Teva Pharm finalizing asset sales to clear Allergan deal - source</i> , Reuters (May 5, 2016), http://www.reuters.com/article/allergan-ma-teva-pharm-ind-assets-idUSL2N1820VD

Pursuant to the Board's Order (Paper 8), Patent Owner moves under 37 C.F.R. § 42.51(b)(2) for additional discovery related to entities in privity with Petitioners Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. ("Petitioner" or "Dr. Reddy's").

I. INTRODUCTION

Teva Pharmaceuticals USA, Inc. ("Teva") filed two Abbreviated New Drug Applications ("ANDAs") with the FDA to market generic versions of Suboxone® Film, a branded drug for the treatment of opioid addiction covered by numerous patents. After Patent Owner sued Teva for infringement under the Hatch-Waxman Act, Teva filed several petitions for *inter partes* review ("IPR") challenging three patents covering Suboxone® Film. The Board denied institution for several reasons, including because Teva did not file two of its petitions within the one-year time bar under 35 U.S.C. § 315(b).

Eight days after the Board determined that Teva's petitions were time-barred, Dr. Reddy's—a drug company that was not a defendant in the underlying lawsuit and that had not filed its own ANDAs pertaining to Suboxone® Film—filed IPR petitions that are substantially identical to the failed Teva petitions. Shortly after filing the petitions, Dr. Reddy's announced that it had entered into an agreement with Teva to acquire a number of ANDAs for \$350 million. Patent Owner has since learned that the acquired ANDAs include the Suboxone® Film

ANDAs. Litigation counsel for Patent Owner has also learned from litigation counsel for Teva that Dr. Reddy's will likely be moving to substitute itself for Teva in the ongoing litigation, and that Dr. Reddy's will provide more information once the acquisition is completed within a few days.

Accordingly, the information available without discovery suggests that Teva, as a predecessor in interest to the Suboxone® Film ANDAs, is in privity with Petitioner. *See Taylor v. Sturgell*, 553 U.S. 880, 892–93 (2008) (legal relationships, such as those between “preceding and succeeding owners of property” or between “assignee and assignor,” can support nonparty preclusion due to privity). Patent Owner brings this motion to obtain further discovery regarding privity as the question of “[w]hether a party who is not a named participant in a given proceeding nonetheless constitutes a . . . ‘privy’ to that proceeding *is a highly fact-dependent question.*” Office Patent Trial Practice Guide, 77 Fed. Reg. 48,756, 48,759 (Aug. 14, 2012) (emphasis added) (hereinafter “Trial Guide”).

In an attempt to avoid discovery, Petitioner espouses a narrow concept of privity that is contrary to both Congressional and Board guidance. Were Petitioner's notion of privity to become law, it would enable *any* accused infringer to circumvent the statutory time limit in § 315(b) after failing to timely file an IPR petition by selling its accused asset to a third party, which would then be able to take over the infringement litigation and file an otherwise time-barred IPR petition.

Petitioner's approach unlawfully contravenes the purpose of the one-year deadline of § 315(b), which "helps to ensure that *inter partes* review provides a quick and cost effective alternative to litigation, and is not used as a tool for harassment or litigation gamesmanship." *Johnson Health Tech Co. v. Icon Health & Fitness, Inc.*, IPR2014-01242, 2015 WL 996358, at *2 (Feb. 11, 2015) (citing H.R. REP. NO. 112-98, at 48, *as reprinted in* 2011 U.S.C.C.A.N. at 78). To prevent abuse of the IPR process by efforts at gamesmanship, this Board should permit the discovery requested in this motion to ensure appropriate resolution of this highly fact-dependent privity issue.

II. FACTUAL BACKGROUND

The three patents challenged by Petitioner in these proceedings (IPR2016-01111, -01112 and -01113), the '514, '150 and '832 Patents, respectively, are all listed in the FDA's Orange Book for Suboxone® Film, a treatment for opioid dependence that is the first sublingual pharmaceutical film ever approved by the FDA. MonoSol Rx, LLC ("MonoSol") owns the '514 and '150 patents, and Indivior UK Limited ("Indivior") owns the '832 patent (these three patents will be collectively referred to as the "Suboxone® Film Patents"). The Suboxone® Film Patents have been asserted in Hatch-Waxman litigation against several defendants, including Teva, related to potential generic versions of Suboxone® Film. *See, e.g., Reckitt Benckiser Pharmaceuticals Inc. et al. v. Teva Pharmaceuticals USA, Inc.*,

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