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Paper 9 (IPR2016-01111)
Paper 9 (IPR2016-01112)
Entered: September 1, 2016

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

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

Petitioner,

v.

MONOSOL RX, LLC,

Patent Owner.

Case IPR2016-01111 (Patent 8,603,514 B2)
Case IPR2016-01112 (Patent 8,017,150 B2)

Before ERICA A. FRANKLIN, TINA E. HULSE, and CHRISTOPHER G. PAULRAJ, *Administrative Patent Judges.*

FRANKLIN, *Administrative Patent Judge.*

DECISION
Denying Patent Owner's Motions for Additional Discovery
37 C.F.R. § 42.51(b)(2)

I. INTRODUCTION

With authorization of the Board, Paper 6,[1] MonoSol RX, LLC ("Patent Owner") filed a motion for additional discovery in each captioned proceeding relating to the issue of privity between Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. (collectively, "Petitioner") and Teva Pharmaceuticals USA, Inc. ("Teva"). Paper 7 ("Mot." or "Motion"). Previously, Teva filed Petitions directed to the same patents and challenging the same claims as in the instant Petitions. *See* Case IPR2016-00281, Paper 1 and Case IPR2016-00282, Paper 1. Those Teva Petitions were denied because we determined that Teva did not file its Petitions within one year from the time it was served with a complaint in district court by Patent Owner. Case IPR2016-00281, Paper 21; Case IPR2016-00282, Paper 19; 35 U.S.C. § 315(b). In addition, Teva previously filed a Petition directed to a related patent, owned by a different entity, Indivior UK Limited, and involving substantially similar subject matter. *See* Case IPR2016-00280, Paper 1. The Petition in IPR2016-00280 was denied primarily because Teva failed to make a threshold showing that certain references, critical to the grounds asserted, were sufficiently publicly accessible to qualify as "printed publications" under 35 U.S.C. § 102(b). *See* Case IPR2016-00280, Paper 23.

In its Motions now, Patent Owner seeks to serve four Requests for Production of documents relating to agreements and communications between Petitioner and Teva concerning Petitioner's acquisition from Teva

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[1] Papers and Exhibits cited in this decision are numbered the same in each proceeding.

of a portfolio of Abbreviated New Drug Applications ("ANDAs") for buprenorphine HCl/naloxone HCl oral film, i.e., a generic version of Suboxone® Film. Mot. 6, Appendix. Petitioner opposes the Motion. Paper 8 ("Opp." or "Opposition"). For the reasons that follow, we deny Patent Owner's Motion.

II. ANALYSIS

A party seeking discovery beyond what is expressly permitted by our rules must establish that such additional discovery is "necessary in the interest of justice." 35 U.S.C. § 316(a)(5); *see also* 37 C.F.R. § 42.51(b)(2) ("The moving party must show that such additional discovery is in the interest of justice."). Discovery in an *inter partes* review proceeding is more limited than in district court patent litigation, as Congress intended our proceedings to provide a more efficient and cost-effective alternative to such litigation. H. Rep. No. 112-98 at 45–48 (2011). Thus, we take a conservative approach to granting additional discovery. 154 Cong. Rec. S9988-89 (daily ed. Sept. 27, 2008) (statement of Sen. Kyl).

The Board has identified five factors (the "*Garmin* factors") to be considered in determining whether additional discovery is in the interest of justice. *See Garmin Int'l, Inc. v. Cuozzo Speed Techs. LLC*, Case IPR2012-00001, slip op. at 6–7 (PTAB Mar. 5, 2013) (Paper 26) (precedential) ("*Garmin*"). In particular, the first *Garmin* factor requires essentially that the party seeking additional discovery establish that it already is in possession of a threshold amount of evidence or reasoning tending to show beyond speculation that something useful will be uncovered. *Garmin* at 7.

In support of its assertion that its Requests for Production will uncover documents favorable to its position, Patent Owner offers the

following as evidence tending to show beyond speculation that "Teva, as a predecessor in interest of the Suboxone® Film ANDAs, is in privity with Petitioner," and therefore, like Teva, is now time-barred under § 315(b). Mot. 2. In particular, Patent Owner notes that Teva filed two ANDAs to market generic versions of Suboxone® Film. *Id*. at 1. Patent Owner asserts also that Teva's denied Petitions were directed to patents covering Suboxone® Film. *Id*. Moreover, according to Patent Owner, the present Petitions, as well as the concurrently filed Petition in IPR2016-01113, with few exceptions, are virtually identical to Teva's Petitions in IPR2016-00280, IPR2016-00281, and IPR2016-00282. *Id*. at 4.

Patent Owner asserts also that after filing the Petitions in IPR2016-01111, 01112, and 01113, Petitioner issued a press release announcing that it had entered into an agreement to acquire a number of Teva's ANDAs. Patent Owner represents that it "has since learned that the acquired ANDA's include the Suboxone® Film ANDAs." *Id*. at 1–2. Patent Owner further represents that it has been informed that Petitioner will likely be moving to substitute itself for Teva in ongoing district court litigation. *Id*. at 2.

In an effort to determine the "timing and nature" of the agreement, Patent Owner initiated a telephone conference on July 6, 2016, with Petitioner. *Id*. at 5. Patent Owner asserts that Petitioner's counsel was unwilling to answer questions during the conference regarding the ANDAs to be transferred by the agreement. *Id*. Thereafter, Patent Owner "propounded specific written requests to Petitioner on July 14, 2016," but asserts that "Petitioner has refused to provide the requested discovery." *Id*.

Patent Owner contends that "Petitioner is likely in possession of documents, such as draft agreements and communications with Teva, that

will provide important evidence regarding whether there is a privity relationship between Teva and Petitioner." Mot. 9–10. According to Patent Owner, Petitioner "notably has not denied the existence of draft agreements or communications." *Id*. at 10.

Patent Owner's Requests for Production are set forth in an Appendix to its Motion. Patent Owner's first proposed Request for Production is directed to the "definitive agreement" between Petitioner and Teva referenced in Petitioner's June 11, 2016 press release ("the Agreement"), along with "any term sheets or letter of intent related to the Agreement, and any common interest or other related agreements." Mot. Appendix 1. The second proposed Request for Production is directed to correspondence or communications related to the Agreement or other agreements or term sheets related to the Agreement, or the Suboxone® Film-related ANDAs. *Id*. The third proposed Request for Production is directed to correspondence or communications between Teva or its counsel and Petitioner or its counsel regarding either Teva's or Petitioner's Petitions for *inter partes* review. *Id*. Finally, the fourth proposed Request for Production is directed to documents "sufficient to show the date on or about which Teva and Petitioner initiated discussions relating to the Suboxone® Film-related ANDAs." *Id*.

In its Opposition, Petitioner has provided responses to each of Patent Owner's Requests for Production. Opp. 17–18 (Appendix). In response to the first request, Petitioner initially "objects to the use of 'related to' in this request as vague." Opp. 17. Nevertheless, Petitioner represents that:

> No "definitive agreement," common interest agreements or drafts thereof or other agreements related to the 'definitive agreement' or drafts thereof *executed on or before May 31, 2016*

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