UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

DR. REDDY'S LABORATORIES S.A. and
DR. REDDY'S LABORATORIES, INC.,
Petitioner

v.

MONOSOL RX, LLC,
Patent Owner

Case IPR2017-01582
Patent 8,603,514

PATENT OWNER PRELIMINARY RESPONSE

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EXHIBIT LIST

Exhibit No.	Description
2001	Reckitt Benckiser v. Watson Trial Opinion
2002	Redline comparison of Teva Petition and Dr. Reddy's Petition
2003	Redline comparison of Dr. Panyam's and Dr. Celik's declarations
2004	Reckitt Benckiser v. Dr. Reddy's Laboratories Trial Opinion, C.A. 1:14-cv-01451, D.I. 312

Patent Owner MonoSol Rx, LLC ("PO") respectfully submits this Patent Owner Preliminary Response to the Petition seeking *inter partes* review of U.S. Patent No. 8,603,514 ("the '514 Patent") filed by Dr. Reddy's Laboratories S.A. and Dr. Reddy's Laboratories, Inc. (collectively "Petitioner") alleging that Claims 1–3, 9, 15, 62–65, 69–73, and 75 of the '514 Patent ("the Challenged Claims") are unpatentable. The Petition is one of five IPR petitions filed against the '514 patent, and one of eleven overall challenges to the patent over the past four years. Patent Owner's Preliminary Response is timely under 35 U.S.C. § 313 and 37 C.F.R. § 42.107 because it is filed within three months of the Notice of Filing Date. Paper 4 at 2. PO submits that the Petition (1) is time-barred under 35 U.S.C. § 315(b) and 37 C.F.R. § 42.101(b), (2) fails to establish that any of the Challenged Claims is unpatentable, and (3) should be denied using the Board's discretion under 35 U.S.C. §§ 314(a) and 325(d).

I. INTRODUCTION

The '514 Patent is directed to pharmaceutical films and is listed in FDA's Orange Book for Suboxone® Film, a treatment for opioid dependence and the first sublingual film ever approved by FDA. Prior to the '514 Patent, it was widely acknowledged that it was difficult to manufacture pharmaceutical films in a manner that kept an active drug ingredient substantially uniformly distributed throughout the film matrix during casting and drying, *i.e.*, drug content uniformity

or "DCU." The inventors of the '514 Patent discovered an elegant solution to the DCU problem—controlling, among other things the viscosity of the wet matrix of a cast film and various drying parameters, *e.g.*, air flow, in order to prevent active particles from migrating from one unit dose to the next and agglomerating before the film was sufficiently dried to lock them in a substantially uniform distribution. While the Claims do not use the phrase, drug content uniformity is shorthand for the heart of the invention maintaining drug content uniformity throughout the manufacturing process such that "the uniformity subsequent to casting and drying of the matrix is measured by substantially equally sized individual unit doses which do not vary by more than 10% of said desired amount of said at least one active." Ex. 1001, '514 Patent at 67:53–56 (Claim 1), 74:6–9 (Claim 62).

The '514 Patent has been the subject of multiple validity attacks in both district court and at the PTAB—even withstanding attacks by this same Petitioner. For this reason alone, the Board should exercise its discretion under 35 U.S.C. §§ 314(a) and 325(d) to deny the petition. Indeed, Petitioner and the predecessor of Petitioner's ANDA for a generic version of Suboxone® Sublingual Film—Teva Pharmaceuticals—have twice filed petitions for *inter partes* review of the '514 Patent. The Board denied institution in both proceedings, finding that Teva's petition was time-barred (IPR2016-00281, Paper 21 at 13-14) and that Petitioner failed to establish a reasonable likelihood any challenged claim was unpatentable

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