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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 B2

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

FRANKLIN, *Administrative Patent Judge*.

DECISION
Dismissing Motion for Joinder
Denying Institution of *Inter Partes* Review
37 C.F.R. §§ 42.108, 42.122

I. INTRODUCTION

On June 12, 2017, Dr. Reddy's Laboratories S.A. and Dr. Reddy's Laboratories, Inc. (collectively, "Petitioner") filed a Petition for an *inter partes* review of claims 1–3, 9, 15, 62–65, 69–73, and 75 of U.S. Patent 8,603,514 B2 (Ex. 1001, "the '514 patent"). Paper 2 ("Pet."). Petitioner concurrently and timely filed a Motion for Joinder (Paper 3, "Mot.") seeking to be joined to *Mylan Technologies, Inc. v. MonoSol Rx, LLC*, Case No. IPR2017-00200 (the "Mylan IPR"). Monosol Rx, LLC ("Patent Owner") filed an Opposition to the Motion for Joinder (Paper 7) to which Petitioner filed a Reply (Paper 8). Patent Owner timely filed a Patent Owner Preliminary Response (Paper 9, "Prelim. Resp.") on September 18, 2017.

We have authority under 35 U.S.C. § 314 to determine whether to institute an *inter partes* review. 35 U.S.C. § 314(b); *see also* 37 C.F.R. § 42.4(a). For the reasons provided below, we *dismiss* the Motion for Joinder and *deny* the Petition.

A. Related Proceedings

Petitioner and Patent Owner identify a number of prior and pending district court proceedings involving the '514 patent, including at least one involving Dr. Reddy's Laboratories S.A. and Dr. Reddy's Laboratories, Inc. Pet. 21–23; Paper 6, 2–4. Both parties also identify two prior petitions challenging claims of the '514 patent: IPR2016-00281 (institution denied; Paper 21) and IPR2016-01111 (filed by Dr. Reddy's Laboratories S.A. and Dr. Reddy's Laboratories, Inc.; institution and rehearing denied; Papers 14, 16).

The '514 patent is also the subject of the Mylan IPR. In that case, we instituted trial on May 12, 2017 (IPR2017-00200, Paper 8), but terminated it

on October 6, 2017, because the involved parties settled their dispute (IPR2017-00200, Paper 23).

B. The '514 Patent

The '514 patent relates to rapidly dissolving films for delivering orally administered active ingredients. Ex. 1001, 1:43–44. The films comprise a polymer component and active ingredients as taste-masked coated particles uniformly distributed throughout the film. *Id*. at 1:44–47. The Specification explains that some film-forming techniques suffer from aggregation or conglomeration of particles, resulting in a random distribution of film components and any actives present in a non-uniform manner. *Id*. at 2:7–28, 60–62. Non-uniform film "necessarily prevents accurate dosing." *Id*. at 2:51–52. The Specification explains also that such films would not likely meet standards set by the U.S. Federal Drug Administration ("FDA") for an acceptable amount of variation in dosage forms. *Id*. at 2:38–42. According to the Specification, "as required by various world regulatory authorities, dosage forms may not vary more than 10% in the amount of active present." *Id*. at 2:42–45.

The Specification describes the instant invention as providing "rapid-dissolve film products for drug delivery whereby the active agents are taste-masked or controlled-release coated particles uniformly distributed throughout the film," wherein the uniform film may be "divided into equally sized dosage units having substantially equal amounts of each compositional component present." *Id*. at 4:27–33. The invention is described as particularly advantageous for the pharmaceutical industry because it permits "large area films to be initially formed, and subsequently cut into individual dosage units without concern for whether each unit is compositionally

equal" and "contain the proper predetermined amount of drug." *Id*. at 4:33–42.

C. Illustrative Claim

Independent claim 1 of the '514 patent is illustrative and reproduced below:

> 1. A drug delivery composition comprising:
> (i) a cast film comprising a flowable water-soluble or water swellable film-forming matrix comprising one or more substantially water soluble or water swellable polymers; and a desired amount of at least one active;
> wherein said matrix has a viscosity sufficient to aid in substantially maintaining non-self-aggregating uniformity of the active in the matrix;
> (ii) a particulate active substantially uniformly stationed in the matrix; and
> (iii) a taste-masking agent coated or intimately associated with said particulate to provide taste-masking of the active;
> wherein the combined particulate and taste-masking agent have a particle size of 200 microns or less and said flowable water-soluble or water swellable film-forming matrix is capable of being dried without loss of substantial uniformity in the stationing of said particulate active therein; and
> wherein 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, 67:34–56.

D. Asserted Ground of Unpatentability

Petitioner challenges the patentability of claims 1–3, 9, 15, 62–65, 69–73, and 75 of the '514 patent as obvious under 35 U.S.C. § 103(a) over Ilango[1] and Chen[2].

Petitioner also relies on the Declaration of Bozena Michniak-Kohn, Ph.D. (Ex. 1002).

II. ANALYSIS

A. The Motion for Joinder is Moot

Petitioner seeks joinder with the Mylan IPR. Mot. 1. The Mylan IPR has been terminated based on a settlement between the parties. *See* IPR2017-00200, Paper 23. Thus, there is no longer a pending proceeding for Petitioner to join. Accordingly, we *dismiss* the Motion for Joinder as moot.

B. The Petition Is Time-Barred Under 35 U.S.C. § 315(b)

Section 315(b) bars institution of *inter partes* review when the petition is filed more than one year after the petitioner is served with a complaint alleging infringement of the patent. 35 U.S.C. § 315(b). The one-year time bar, however, does not apply to a request for joinder. *Id*. The decision whether to grant joinder is discretionary. *Id*. at § 315(c).

Petitioner admits that a complaint alleging infringement of the '514 patent was filed more than one year before it filed its Petition. Mot. 1–2 (explaining that a complaint alleging infringement of the '514 patent against Teva Pharmaceuticals USA, Inc. ("Teva") was filed on December 2, 2014 in

[1] R. Ilango et al., *In-Vitro studies on Buccal strips of Glibenclamide using Chitosan*, 59 INDIAN J. PHARM. SCI. 232–35 (1997). Ex. 1005 ("Ilango").
[2] Patent Application Publication No. WO 00/42992 by Li-Lan Chen et al., published July27, 2000. Ex. 1006 ("Chen").

district court). Patent Owner notes that Teva was served with the complaint on December 3, 2014, and that, by court order, on September 22, 2016, Dr. Reddy's Laboratories S.A. and Dr. Reddy's Laboratories, Inc. were substituted as defendants in place of Teva and, therefore, "stepped into the shoes of Teva, including service of its complaint for infringement of the '514 Patent on December 3, 2014." Paper 9, 6–7. Despite the late filing, Petitioner asserts as its grounds for standing that "under 37 C.F.R. § 42.104(a), if the simultaneous motion for joinder is granted, the '514 patent is available for *inter partes* review, and Petitioners are not barred or estopped from requesting inter partes review of the '514 patent on the grounds identified." Pet. 21.

As discussed above, Petitioner's Motion for Joinder is dismissed as moot because there is no instituted *inter partes* review for Petitioner to join. Thus, the Petition is statutorily barred, and no *inter partes* review may be instituted. 35 U.S.C. § 315(b).

ORDER

Accordingly, it is

ORDERED that the Motion for Joinder is *dismissed*; and

FURTHER ORDERED that the Petition for *inter partes* review of claims 1–3, 9, 15, 62–65, 69–73, and 75 of the '514 patent is *denied*.

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