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Paper 14
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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

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

FRANKLIN, *Administrative Patent Judge.*

DECISION
Denying Institution of *Inter Partes* Review
37 C.F.R. § 42.108

I. INTRODUCTION

Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. (collectively, "Petitioner") filed a Petition to institute an *inter partes* review of claims 1–3, 9, 15, 62–65, 69–73, and 75 of U.S. Patent No. 8,603,514 B2[1] (Ex. 1001, "the '514 patent"). Paper 1 ("Pet."). MonoSol RX, LLC ("Patent Owner") filed a Preliminary Response to the Petition. Paper 10 ("Prelim. Resp.").

We have jurisdiction under 35 U.S.C. § 314, which provides that an *inter partes* review may not be instituted "unless . . . there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." 35 U.S.C. § 314(a).

Upon considering the Petition and Preliminary Response, we determine that the Petitioner has not demonstrated a reasonable likelihood that it would prevail in showing the unpatentability of at least one of the challenged claims. Accordingly, we decline to institute an *inter partes* review of any challenged claim.

A. Related Proceedings

Petitioner and Patent Owner identify a number of district court proceedings that "may affect or be affected by a decision in the proceeding." Pet. 8–9; Paper 4, 2–3. In particular, both parties identify *Reckitt Benckiser Pharmaceuticals Inc. v. Watson Laboratories, Inc. et al.*, C.A. No.1:13-CV-01674-RGA (D. Del.) and *Reckitt Benckiser Pharmaceuticals Inc. v. Par Pharmaceutical, Inc. et al.*, C.A. No.1:14-CV-00422-RGA (D. Del.),

[1] Issued to Robert K. Yang et al., Dec. 10, 2013.

wherein each case included MonoSol Rx among the plaintiffs and for which a consolidated trial opinion addressing the '514 patent was issued on June 3, 2016. Ex. 2009.

B. The '514 Patent (Ex. 1001)

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 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; (emphasis added to identify dispositive limitation).

D. The Cited References and Declaration

Petitioner relies upon the following references:

Bess	US Patent No. 7,067,116, issued Jun. 27, 2006	Ex. 1004
Chen	Patent Application Publication No. WO 00/42992, published Jul. 27, 2000	Ex. 1005
Cremer	Patent Application Publication No. CA 2,274,910 A1, issued Jun 25, 1998	Ex. 1006

Petitioner relies also upon the Declaration of Metin Çelik, Ph.D. (Ex. 1003).

E. The Asserted Grounds of Unpatentability

Petitioner challenges the patentability of claims 1–3, 9, 15, 62–65, 69–73, and 75 of the '514 patent on the following grounds (Pet. 12):

Claims Challenged	Basis	References
1–3, 9, 15, 62–65, 69–73, and 75	§ 103	Bess and Chen
1–3, 9, 15, 62–65, 69–73, and 75	§ 103	Chen and Cremer

II. ANALYSIS

A. Claim Construction

In an *inter partes* review, the Board interprets claim terms in an unexpired patent according to the broadest reasonable construction in light of the specification of the patent in which they appear. 37 C.F.R. § 42.100(b); *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2142 (2016) (affirming applicability of broadest reasonable construction standard to *inter partes* review proceedings). Under that standard, and absent any special definitions, we give claim terms their ordinary and customary meaning, as

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