

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 IPR2016-01112
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 Petitioner's Request for Rehearing
37 C.F.R. § 42.71

I. INTRODUCTION

Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. (collectively, "Petitioner") request a rehearing of the Decision Denying Institution, entered on December 5, 2016 (Paper 14, "Dec."). Paper 15 ("Reh'g Req."). As background, Petitioner filed a Petition to institute an *inter partes* review of claims 1, 3–10, and 12–18 of U.S. Patent No. 8,017,150 B2¹ (Ex. 1001, "the '150 patent"). Paper 1 ("Pet."). In the Petition, Petitioner raised the following challenges to the claims:

Claims Challenged	Basis	Reference(s)
1, 3–10, 12–18	§ 103	Chen, ² Schiraldi, ³ and Chen II ⁴
1, 4–5, 8, 10, 12–14, and 17	§ 103	Schiraldi and Verma ⁵
6–7, 9, 15–16, 18	§ 103	Schiraldi, Verma, and Khan ⁶
1, 4–10, and 13–18	§ 103	Yang ⁷

¹ Issued to Robert K. Yang et al., Sept. 13, 2011.

² Patent Application Publication No. WO 00/42992, published Jul. 27, 2000 (Ex. 1021) ("Chen").

³ US Patent No. 4,713,243 issued to Michael T. Schiraldi et al., Dec. 15, 1987 (Ex. 1004) ("Schiraldi").

⁴ Patent Application Publication No. US 2002/0147201 A1, issued Oct. 10, 2002 (Ex. 1049) ("Chen II").

⁵ US Patent No. 6,322,811 issued to Surendra Kumar Verma et al., Nov. 27, 2001 (Ex. 1005) ("Verma").

⁶ US Patent No. 5,656,296 issued to Sadath U. Khan et al, Aug. 12, 1997 (Ex. 1046) ("Khan").

⁷ Patent Application Publication No. US 2005/0037055 A1, published Feb. 17, 2005 (Ex. 1006) ("Yang").

Petitioner also relied upon the Declaration of Russell J. Mumper, Ph.D. (Ex. 1003). MonoSol RX, LLC (“Patent Owner”) filed a Preliminary Response to the Petition. Paper 10 (“Prelim. Resp.”).

Upon considering the Petition, Preliminary Response, and evidence of record, we determined that Petitioner failed to demonstrate a reasonable likelihood of prevailing in showing the unpatentability of the challenged claims. Dec. 1. In the Rehearing Request, Petitioner seeks reconsideration of our Decision only with respect to its contention that claims 1, 3–10, and 12–18 would have been obvious over the combination of Chen, Schiraldi, and Chen II. Reh’g Req. 1.

II. ANALYSIS

“When rehearing a decision on petition, a panel will review the decision for an abuse of discretion.” 37 C.F.R. § 42.71(c). “The burden of showing a decision should be modified lies with the party challenging the decision. The request must specifically identify all matters the party believes the Board misapprehended or overlooked, and the place where each matter was previously addressed in a motion, an opposition, or a reply.” *Id.* § 42.71(d). Because Petitioner has not met that burden, as discussed below, the Rehearing Request is *denied*.

Petitioner asserts that “the Board overlooked key testimony of Petitioners’ expert, Dr. Russell J. Mumper, Ph.D.” Reh’g Req. 2. In particular, Petitioner asserts that the Board erroneously found that Dr. Mumper’s “opinion does not address a skilled artisan’s motivation, ability, or reasonable expectation of successfully achieving a film comprising the specific ranges and portions of low and high molecular weight polyethylene oxides required by the claims.” *Id.* at 1–2 (quoting Dec. 11). According to

Petitioner, Dr. Mumper addressed those issues at paragraphs 148–154 of his declaration. Reh’g Req. 6 (citing Ex. 1003 ¶¶ 148–154). Further, Petitioner asserts that those paragraphs were referenced in the Petition. *Id.* (citing Pet. 30). The remainder of the rehearing request discusses the testimony of Dr. Mumper in those paragraphs of his declaration. Reh’g Req. 6–9.

We begin by noting that the contents of Dr. Mumper’s testimony relied upon and discussed by the Petitioner in the Rehearing Request was not discussed in the Petition. Indeed, in the Rehearing Request, Petitioner confirms that its discussion of how the prior art “would have particularly motivated a person of ordinary skill to test different ratios of polyethylene oxides, and thereby arrive at the claimed [invention]” is found at pages 32–33 of the Petition. Reh’g Req. 3 (citing Pet. 32–33). That portion of the Petition does not reference paragraphs 148–151 of Dr. Mumper’s declaration, or describe the contents thereof now relied upon by Petitioner. Pet. 32–33. Rather, as discussed in the Decision, that portion of Petitioner’s argument references paragraph 30 of Dr. Mumper’s declaration. Dec. 11, *see also* Pet. 33 (citing Ex. 1003 ¶ 30). Further, we explained in the Decision why that portion of the declaration did not support Petitioner’s contention. Specifically, we stated:

The portions of Dr. Mumper’s declaration cited by Petitioner do not provide any further support for Petitioner’s position. We note that Dr. Mumper does not explain why the polyethylene oxides molecular weights limitation would have been obvious to a person of ordinary skill over the combined teachings of the prior art. Instead, Dr. Mumper opines only that the skilled artisan “would be highly motivated to vary the amounts of the low and high molecular weight polyethylene oxide to achieve the desired effects including, but not limited to drug solubility, mucoadhesion and drug release rate.” Ex. 1003

¶ 30. That opinion does not address a skilled artisan's motivation, ability, or reasonable expectation of successfully achieving a film comprising the specific ranges and proportion of low and high molecular weight polyethylene oxides required by the claims. *See In re Fine*, 837 F.2d at 1074 (a showing of obviousness must be supported by evidence, as shown by some objective teaching in the prior art or by knowledge generally available to one of ordinary skill in the art that would have led that individual to combine the relevant teachings of the references to arrive at the claimed invention).

Dec. 11.

Petitioner's assertion in the Rehearing Request that paragraphs 148–151 of Mr. Mumper's declaration were referenced in a different portion of the Petition is unavailing, as that reference was only provided to support Petitioner's contention that the prior art teaches a specific element of the challenged claims. Reh'g Req. 6 (citing Pet. 30). The Petition states:

As of the earliest possible priority date (2003) of the '150 patent, the prior art taught the major elements of the challenged claims:

- **Mucoadhesive films.** (Ex. 1003, Mumper Decl. at ¶¶ 102-126, 131-132, 141-156.) Schiraldi, for example, described mucosally-adhesive, thin-film delivery systems that could provide controlled-release medications within the oral cavity of a patient. (Ex. 1004, Schiraldi at Abstract, 2:56-60; Ex. 1003, Mumper Decl. ¶¶ 119-126, 131.) Chen also described mucosally adhesive films containing a pharmaceutical agent. (Ex. 1021, Chen at 3:30-32). A film made according to Schiraldi's teachings is "so thin and flexible when wet as to be unobtrusive to the patient when properly positioned and placed in the patients [sic] mouth." (Ex. 1004, Schiraldi at 9:52-55, claim 2.)

As seen, that portion of the Petition citing to paragraphs 141–156 of Dr. Mumper's declaration is not in connection with any discussion regarding the alleged motivation, skill in the art, or a reasonable expectation of success in

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