

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 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 1–3, 9, 15, 62–65, 69–73, and 75 of U.S. Patent No. 8,603,514 B2¹ (Ex. 1001, "the '514 patent"). Paper 1 ("Pet."). In the Petition, Petitioner raised the following challenges to the claims:

Claims Challenged	Basis	References
1–3, 9, 15, 62–65, 69–73, and 75	§ 103	Bess ² and Chen ³
1–3, 9, 15, 62–65, 69–73, and 75	§ 103	Chen and Cremer ⁴

Petitioner also relied upon the Declaration of Metin Çelik, 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 that determination. Reh'g Req. 1.

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

² US Patent No. 7,067,116, issued Jun. 27, 2006 (Ex. 1004) ("Bess").

³ Patent Application Publication No. WO 00/42992, published Jul. 27, 2000 (Ex. 1005) ("Chen").

⁴ Patent Application Publication No. CA 2,274,910 A1, issued Jun 25, 1998 (Ex. 1006) ("Cremer").

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 its burden, as discussed below, the Rehearing Request is *denied*.

At issue in the Rehearing Request is a decision rendered in Appeal 2014-000547, an *inter partes* reexamination of U.S. Patent 7,824,588 B2 (“the ’588 patent”), referred to as “the ’588 patent decision” (Ex. 1038). Petitioner asserts that the “Board overlooked very specific evidence provided in the ’588 patent decision, which resulted in misapprehending the applicability of the collateral estoppel issue.” Reh’g Req. 3. According to Petitioner, the dispositive claim limitation identified in the Decision was previously decided in the ’588 patent decision, i.e., that the individual unit dose does “not vary by more than 10” of said desired amount of said at least one active. *Id.* (citing Dec. 4). Petitioner asserts also that the Board overlooked the “previous finding of inherency as it relates to Chen for the very same issue” in the ’588 patent decision. *Id.* at 11.

We disagree with Petitioner’s assertion that the Decision overlooks Petitioner’s arguments relying upon the ’588 patent decision. The Decision specifically addresses those arguments. Dec. 16–17. In that discussion, we explain the following:

In the '588 patent decision, because Patent Owner did not argue any claims separately, the Board resolved the issue of whether Chen met the uniformity requirement based on independent claim 1 of the '588 patent. Ex. 1038, 12. Unlike independent claims 1 and 62 of the challenged patent, claim 1 of the '588 patent, as amended, required only “substantially uniform content of therapeutic active composition per unit of film.” Ex. 1038, 4. Thus, the '588 patent decision did not resolve the issue of whether Chen met the 10% variation limit required by the challenged patents. Consequently, Petitioner has not shown that the instant situation meets the requirements for applying collateral estoppel, i.e., issue preclusion, because the issue presented in the '588 patent decision is not identical to the issue presented here, and resolution of the issue presented in this case was not essential to the final judgment in the '588 patent decision. *See In re Freeman*, 30 F.3d 1459, 1465 (Fed. Cir. 1994) (setting forth the four requirements for issue preclusion).

*Id.*⁵ Thus, we were not persuaded by Petitioner’s argument because Petitioner failed to establish, at least, that the issue addressed in the Decision is *identical* to one decided in the first action and that the issue was *actually litigated* in the first action. *See Freeman*, 30 F.3d at 1465. Because that matter was addressed in the Decision, Petitioner has not established that we overlooked it.

⁵ Petitioner inappropriately uses its Rehearing Request to take issue with a footnote here in the Decision noting that a “district court has issued a decision addressing the disclosures of Chen and Bess with respect to the '514 patent” and that “our findings are consistent with those set forth in that decision.” Reh’g Req. 11 (quoting Dec. 17 n.3.), 13. To the extent that Petitioner suggests that note means that the Decision relies, in any way, upon the district court findings, that contention is unfounded. The basis for the Decision is set forth expressly in the body of the “Analysis” section. *See* Dec. 5–19.

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Also at issue in the Rehearing Request is the Patent Owner's reference to "findings provided in IPR2015-00165, IPR2015-00167, IPR2015-00168, and IPR2015-00169." Reh'g Request 12. According to Petitioner, because those decisions were not "formally entered as exhibits . . . all arguments in reliance on these prior IPR proceedings should have carried no evidentiary weight in deciding this Petition." *Id.* We note that Petitioner did not request authorization from the Board to file a reply to the Preliminary Response to raise that argument. Presenting that issue for the first time in a Rehearing Request is inappropriate. A rehearing request provides a party with an opportunity to identify a *previously raised matter* that the party believes the Board misapprehended or overlooked. *See* 37 C.F.R. § 42.71(d). Here, Petitioner has not done so.

For the foregoing reasons, we conclude that Petitioner has not shown that the Board abused its discretion in denying institution of the challenged claim. *See* 37 C.F.R. § 42.71(d).

III. ORDER

In consideration of the foregoing, it is hereby ordered that the Petitioner's Rehearing Request is *denied*.

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