

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

LUPIN LTD. AND LUPIN PHARMACEUTICALS INC.,
Petitioner,

v.

POZEN INC.,
Patent Owner.

Case IPR2015-01774
Patent 8,852,636 B2

Before JACQUELINE WRIGHT BONILLA, *Vice Chief Administrative Patent Judge*, TONI R. SCHEINER, and LORA M. GREEN, *Administrative Patent Judges*.

SCHEINER, *Administrative Patent Judge*.

DECISION
Denying Petitioner's Request for Rehearing
37 C.F.R. § 42.71

I. INTRODUCTION

In denying institution of an *inter partes* review in this case, we determined that Petitioner had not established a reasonable likelihood that it would prevail in showing the unpatentability of challenged claims 1–6 and 13–15 of U.S. Patent 8,852,636 B2 (Ex. 1001, “the ’636 patent”) on any of the five grounds advanced in the Petition (Paper 4, “Pet.”). Paper 15 (“Decision” or “Dec.”). Subsequently, Lupin Ltd. and Lupin Pharmaceuticals Inc. (collectively “Petitioner”) filed a Request for Rehearing (Paper 16, “Reh’g Req.” or “Request”) asking us to reconsider our Decision denying an *inter partes* review on two of the grounds advanced in the Petition: (1) whether claims 1–6 and 13–15 are unpatentable under 35 U.S.C. § 103(a) over Chen¹ and Gimet;² and (2) whether claims 1–6 and 13–15 are unpatentable under 35 U.S.C. § 103(a) over Gimet, Chandramouli,³ and Phillips.⁴

We deny Petitioner’s Request for Rehearing for the reasons set forth below.

¹ U.S. Patent No. 6,544,556 B1, issued April 8, 2003 to Chen et al. (“Chen”) (Ex. 1004).

² U.S. Patent No. 5,698,225, issued December 16, 1997 to Gimet et al. (“Gimet”) (Ex. 1007).

³ Jane C. Chandramouli & Keith G. Tolman, *Prevention and Management of NSAID-Induced Gastropathy*, 8 J. PHARM. CARE PAIN & SYMPTOM CONTROL 27–40 (2000) (“Chandramouli”) (Ex. 1011).

⁴ PCT Int’l Patent Appl. WO 00/26185, published May 11, 2000, by Phillips (“Phillips”) (Ex. 1012).

II. STANDARD OF REVIEW

When reconsidering a decision on institution, the Board reviews the decision for an abuse of discretion. *See* 37 C.F.R. § 42.71(c). An abuse of discretion occurs if a decision is based on an erroneous interpretation of law, if a factual is not supported by substantial evidence, or if the decision represents an unreasonable judgment in weighing relevant factors. *See Star Fruits S.N.C. v. United States*, 393 F.3d 1277, 1281 (Fed. Cir. 2005); *Arnold P'ship v. Dudas*, 362 F.3d 1338, 1340 (Fed. Cir. 2004); *In re Gartside*, 203 F.3d 1305, 1315–16 (Fed. Cir. 2000). “The burden of showing that a decision should be modified lies with the party challenging the decision.” Office Patent Trial Practice Guide, 77 Fed. Reg. 48,756, 48,768 (Aug. 14, 2012). In its request for rehearing, the dissatisfied party must, in relevant part, “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.” 37 C.F.R. § 42.71(d); Office Patent Trial Practice Guide, 77 Fed. Reg. at 48,768. We address Petitioner’s arguments with these principles in mind.

III. ANALYSIS

A. Claims 1–6 and 13–15—Asserted Obviousness over Chen (Ex. 1004) and Gimet (Ex. 1007)

In relation to this ground, Petitioner asserts that we erred when we “dismiss[ed] Dr. Banakar’s testimony as a ‘conclusory statement.’” Reh’g Req. 5. This is in reference to our statement in the Decision that

“conclusory statements by Petitioner and Dr. Banakar do not explain sufficiently, nor provide adequate support as to why one of ordinary skill in the art would have done the opposite of what Chen teaches in order to address the issue of PPI stability at lower pHs.” Dec. 16 (citing Ex. 1004, 8:17–40, 12:4–32). We remain persuaded, however, that neither the Petition nor Petitioner’s Declarant adequately addresses that point, that is, why the ordinary artisan would have done the opposite of what Chen teaches in order to address the issue of PPI stability at lower a pH. Petitioner’s arguments in its Request, which do not explain where the Petitioner and Petitioner’s Declarant address Chen, do not persuade us otherwise. Reh’g Req. 5–7.

In addition, Petitioner argues that we misunderstood the teachings of the Pilbrant⁵ reference. Reh’g Req. 7. Petitioner asserts that our “analysis is contrary to the educational background and experience of a POSA for the [’636] patent” because “it dismissed Pilbrant based on a single phrase in the publication” (*id.*), and “overlooked all data disclosed in the publication” (*id.* at 8). However, we considered Pilbrant in its entirety in reaching our Decision. *See* Dec. 16–18, 21, 24 (citing Ex. 1008, 113–114, 116–117). We are not persuaded that we erred in denying an *inter partes* review of challenged claims in view of arguments by Petitioner we have considered already. *Id.* (discussing Pet. 15, 18).

⁵ Å. Pilbrant & C. Cederberg, *Development of an Oral Formulation of Omeprazole*, 20 SCAND. J. GASTROENTEROL. 113–120 (1985) (“Pilbrant”) (Ex. 1008).

*B. Claims 1–6 and 13–15—Asserted Obviousness over
Gimet, Chandramouli, and Phillips*

In relation to this ground, Petitioner asserts that “the Board read [Phillips] to teach [that] ‘a sodium bicarbonate solution is capable of dissolving an enteric coating,’ but “[t]his reliance is clear error because the cited statement of [Phillips] has no bearing on the obvious analysis.” Reh’g Req. 11. Petitioner argues that “[t]he cited passage in [Phillips] reads: ‘The coated omeprazole particles are mixed with a sodium bicarbonate (NaHCO₃) *solution* which dissolves the enteric coating . . .’” but “the disclosure provides no suggestion that a solid salt form will impact the enteric coating.” *Id.* at 11–13 (citing Ex. 1012, 19:19–23).

Because Petitioner does not indicate in its Request where it raised an argument regarding the teachings on page 19 of Phillips, Petitioner does not show adequately that our Decision should be modified based on such an argument now, or that we misapprehended or overlooked an argument by Petitioner in this regard. *See* 37 C.F.R. § 42.71(d).

IV. CONCLUSION

We have considered Petitioner’s Request for Rehearing, but are not persuaded that we abused our discretion in denying an *inter partes* review claims 1–6 and 13–15.

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