

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

LUPIN LIMITED and LUPIN PHARMACEUTICALS INC.,
Petitioner,

v.

iCEUTICA PTY LTD.,
Patent Owner.

Case IPR2016-00399
Patent 9,017,721 B2

Before TONI R. SCHEINER, SHERIDAN K. SNEDDEN, and
ZHENYU YANG, *Administrative Patent Judges*.

YANG, *Administrative Patent Judge*.

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

INTRODUCTION

Lupin Limited and Lupin Pharmaceuticals, Inc. (collectively “Petitioner”) filed a Petition for an *inter partes* review of claims 1–24 of U.S. Patent No. 9,017,721 B2 (Ex. 1001, “the ’721 patent”). Paper 1 (“Pet.”). iCeutica Pty Ltd. (“Patent Owner”) filed a Preliminary Response. Paper 8 (“Prelim. Resp.”). We review the Petition under 35 U.S.C. § 314.

Based on this record, we determine Petitioner has not established a reasonable likelihood that it would prevail in showing the unpatentability of at least one challenged claim. *See* 35 U.S.C. § 314(a). Therefore, we deny the Petition for an *inter partes* review.

Related Proceedings

According to the parties, Patent Owner previously asserted the ’721 patent against Petitioner in *iCeutica Pty Ltd. v. Lupin Limited*, No. 1:14-cv-01515 (D. Del.). Pet. 1; Paper 5, 3.

Petitioner also concurrently filed a petition in IPR2016-00397, seeking an *inter partes* review of U.S. Patent No. 8,999,387 B2, a patent in the same family as the ’721 patent. Pet. 1–2; Paper 5, 3.

The ’721 Patent

The ’721 patent relates to methods for producing particles of diclofenac using dry milling processes and methods for treating pain using a therapeutically effective amount of diclofenac in particulate form. Ex. 1001, Abstract, 1:18–24.

The ’721 patent discloses that diclofenac, a pain medication, “is a poorly water soluble drug so dissolution and absor[p]tion to the body is slow.” *Id.* at 3:7–11. At the time of the ’721 patent invention, it was known

that decreasing particle size increases the surface area of a particulate drug, which in turn increases the rate of its dissolution. *Id.* at 1:45–47. According to the '721 patent, then-existing dry milling techniques used to reduce particle size, however, have various drawbacks. *Id.* at 1:53–61, 2:66–67. The '721 patent purportedly discloses a milling process that overcomes such problems. *Id.* at 2:67–3:4. Diclofenac made by this process has improved dissolution and faster absorption, which result in a more rapid onset of the therapeutic effect. *Id.* at 3:11–17.

Illustrative Claims

Among the challenged claims, claims 1 and 8 are independent. Claim 1 is representative and is reproduced below:

1. A solid oral unit dose of a pharmaceutical composition containing 18 mg of diclofenac acid, wherein the diclofenac acid has a median particle size, on a volume average basis, of less than 1000 nm and greater than 25 nm, wherein the unit dose, when tested in vitro by USP Apparatus I (Basket) method of U.S. Pharmacopoeia at 100 rpm, at 37° C. in 900 ml of 0.05% sodium lauryl sulfate in citric acid solution buffered to pH 5.75, has a dissolution rate of diclofenac acid such that at least 94%, by weight, is released by 75 minutes.

Claim 8 is similar to claim 1, except it recites “a pharmaceutical composition containing 35 mg of diclofenac acid,” and the unit dose “has a dissolution rate of diclofenac acid such that at least 95%, by weight, is released by 75 minutes.”

Asserted Grounds of Unpatentability

Petitioner asserts the following grounds, each of which challenges the patentability of claims 1–24:

Basis	References
§ 103	Meiser ¹ and Norvatis Package Insert ²
§ 103	Meiser, Norvatis Package Insert, USP, ³ and Chuasuwan ⁴
§ 103	Meiser, Norvatis Package Insert, USP, Chuasuwan, and Reiner ⁵

In support of its patentability challenge, Petitioner relies on the Declaration of Dr. Mansoor M. Amiji. Ex. 1002.

ANALYSIS

Claim Construction

In an *inter partes* review, the Board interprets a claim term in an unexpired patent according to its broadest reasonable construction in light of the specification of the patent in which it appears. 37 C.F.R. § 42.100(b); *Cuozzo Speed Techs., LLC v. Lee*, No. 15-446, 2016 WL 3369425 (U.S. June 20, 2016).

Claim terms need only be construed to the extent necessary to resolve the controversy. *Wellman, Inc. v. Eastman Chem. Co.*, 642 F.3d 1355, 1361 (Fed. Cir. 2011). On this record and for purposes of this Decision, we see no need to construe any term expressly.

¹ Meiser et al., *International Pub. No.* WO2008/000042, published on January 3, 2008 (Ex. 1005, “Meiser”).

² Novartis Package Insert for Cataflam®, Voltaren®, and Voltaren®-XR, dated May 2000 (Ex. 1006, “Norvatis Package Insert”).

³ United States Pharmacopeia 30, Sections <711> and <1092>, dated May 2007 (Exs. 1007, 1008, collectively “USP”).

⁴ Chuasuwan et al., *Biowaiver Monographs for Immediate Release Solid Oral Dosage Forms Diclofenac Sodium and Diclofenac Potassium*, 98 J. PHARM. SCIS. 1206–19 (2009) (Ex. 1009, “Chuasuwan”).

⁵ Reiner et al., *International Pub. No.* WO2006/133954, published on December 21, 2006 (Ex. 1010, “Reiner”).

Obviousness over Meiser and Norvatis Package Insert

Petitioner contends that the combination of Meiser and the Norvatis Package Insert renders claims 1–24 obvious. Pet. 36–47. Based on the record before us, and for at least the following reasons, we determine Petitioner has not established a reasonable likelihood that it would prevail in this assertion.

Petitioner asserts that the combination of Meiser and Norvatis Package Insert teaches or suggests all limitations of the asserted claims. Specifically, Petitioner refers to Norvatis Package Insert for teaching tablets of diclofenac, in the form of 25 mg, 50 mg, and 75 mg diclofenac sodium. *Id.* at 38–39; Ex. 1006, 2. According to Petitioner, diclofenac, like other non-steroidal anti-inflammatory drugs (NSAIDs), has been associated with some side effects. Pet. 4–5 (citing Ex. 1009, 1208). Petitioner argues, “one of ordinary skill knew at the time of the ’721 patent that reducing the required dose of NSAIDs, such as diclofenac, would reduce the known negative side-effects of NSAIDs.” *Id.* at 5.

Petitioner then refers to Meiser where it teaches improving the solubility of diclofenac acid by dry milling to obtain nanoparticles. *Id.* at 9 (citing Ex. 1005, 6–7, 27–28). Petitioner points out that compounds in nonparticulate form “exhibit advantages over conventional compounds by way of, for example, more rapid therapeutic action or lower dose.” *Id.* at 39 (citing Ex. 1005, 7).

Petitioner concludes an ordinary artisan “would have been motivated to combine the prior art dosages in the Novartis Package Insert with the teachings of Meiser to develop a formulation containing a dosage lower than

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