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Paper No. 9
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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 IPR2016-00397
Patent 8,999,387 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

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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. 8,999,387 B2 (Ex. 1001, "the '387 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 '387 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 IPR2016-00399, seeking an *inter partes* review of U.S. Patent No. 9,017,721 B2, a patent in the same family as the '387 patent. Pet. 1–2; Paper 5, 3.

The '387 Patent

The '387 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, 1:16–22.

The '387 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 3:6–10. At the time of the '387 patent invention, it was known

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that decreasing particle size increases the surface area of a particulate drug, which in turn increases the rate of its dissolution. *Id.* at 1:43–45. According to the '387 patent, then-existing dry milling techniques used to reduce particle size, however, have various drawbacks. *Id.* at 1:49–59, 2:65–66. The '387 patent purportedly discloses a milling process that overcomes such problems. *Id.* at 2:66–3:3. Diclofenac made by this process has improved dissolution and faster absorption, which result in a more rapid onset of the therapeutic effect. *Id.* at 3:9–13.

Illustrative Claims

Among the challenged claims, claims 1 and 11 are independent. They are reproduced below:

> 1. A method for treating pain comprising administering 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 37º 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.
>
> 11. A method for treating pain comprising administering a solid oral unit dose of a pharmaceutical composition containing 35 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 37º 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 95%, by weight, is released by 75 minutes.

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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).

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[1] Meiser et al., International Pub. No. WO2008/000042, published 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 December 21, 2006 (Ex. 1010, "Reiner").

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Petitioner contends that the "wherein . . . when tested" clause recited in each independent claim, i.e., "wherein the unit dose, when tested in vitro by USP Apparatus I (Basket) method of U.S. Pharmacopoeia at 100 rpm, at 37º 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% [/95%], by weight, is released by 75 minutes," deserves no patentable weight. Pet. 32–36. Patent Owner disagrees, arguing that the clause is entitled to patentable weight. Prelim. Resp. 17–28.

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.

Prior Art Disclosures

Meiser teaches improving the solubility of diclofenac acid by dry milling to obtain nanoparticles. Ex. 1005, 68–69, 71–72. According to Meiser, drugs in nanoparticulate form have advantages over conventional compounds, including more rapid therapeutic action and achieving a given therapeutic effect with a lower dose. *Id.* at 7.

Norvatis Package Insert teaches tablets of diclofenac, in the form of sodium or potassium salt, for treating pain. Ex. 1006, 2.

USP teaches performing the dissolution procedure in Apparatus 1 at 37ºC. Ex. 1007, 278, 282; Ex. 1008, 581. It suggests the agitation speed, volume, surfactants, pH range, and time points for measuring the dissolution. Ex. 1008, 580–81.

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