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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

INNOPHARMA LICENSING, INC., INNOPHARMA LICENSING LLC,
INNOPHARMA INC., INNOPHARMA LLC,
MYLAN PHARMACEUTICALS INC., MYLAN INC.,
LUPIN LTD., and LUPIN PHARMACEUTICALS, INC.,
Petitioner,

v.

SENJU PHARMACEUTICAL CO., LTD., BAUSCH & LOMB, INC., and
BAUSCH & LOMB PHARMA HOLDINGS CORP.,
Patent Owner.

Case IPR2015-00903[1]
Patent 8,129,431 B2

Before FRANCISCO C. PRATS, ERICA A. FRANKLIN, and
GRACE KARAFFA OBERMANN, *Administrative Patent Judges.*

OBERMANN, *Administrative Patent Judge.*

FINAL WRITTEN DECISION
35 U.S.C. § 318 and 37 C.F.R. § 42.73

[1] IPR2015-01871 has been joined with this proceeding. Specifically, in an Institution Decision dated January 25, 2016, we joined Lupin Ltd. and Lupin Pharmaceuticals, Inc., as parties to this proceeding. Paper 37.

I. INTRODUCTION

This is a Final Written Decision in an *inter partes* review challenging the patentability of claims 1–22 ("the challenged claims") of U.S. Patent No. 8,129,431 B2 (Ex. 1001, "the '431 patent"). We have jurisdiction under 35 U.S.C. § 6(c). For reasons that follow, we determine that Petitioner fails to show by a preponderance of evidence that claims 1–22 are unpatentable. We also address the parties' Motions to Exclude.

A. Procedural History

The Petition (Paper 2, "Pet.") for *inter partes* review was filed pursuant to 35 U.S.C. § 311. We instituted trial on two grounds of unpatentability stated in the Petition:

(1) Whether the subject matter of claims 1–5, 7–14, and 18–19 would have been obvious under 35 U.S.C. § 103 based on the combined disclosures of Ogawa[2] and Sallmann[3]; and

(2) Whether the subject matter of claims 6, 15–17, and 20–22 would have been obvious over Ogawa, Sallmann, and Fu[4]. Paper 15 ("Dec.").

Patent Owner filed a Response (Paper 32, "Resp.") and Petitioner filed a Reply (Paper 49, "Reply").[5] The parties' fully briefed Motions to

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[2] U.S. Patent No. 4,910,225, issued Mar. 20, 1990 (Ex. 1004, "Ogawa").

[3] U.S. Patent No. 6,107,343, issued Aug. 22, 2000 (Ex. 1009, "Sallmann").

[4] Austrl. Patent Application No. AU-B-22042/88, issued Mar. 16, 1989 (Ex. 1011, "Fu").

[5] To the extent that we rely on information in papers and exhibits for which confidentiality is claimed, we determine that the general nature of the discussions of such information herein does not require that this Decision be

Exclude also are pending. Papers 56, 59 (Motions to Exclude); Papers 64, 66 (Oppositions to Motions to Exclude); Papers 69, 70 (Replies to Motions to Exclude). The record includes a transcript of a consolidated final oral hearing conducted on April 19, 2016, in this proceeding and related proceeding IPR2015-00902 ("IPR 902"). Paper 75 ("Tr.").

B. Related Proceedings

Petitioner identifies eight district court actions involving the '431 patent, including two that involve Petitioner as a defendant. Pet. 11–12; *see Senju Pharmaceutical Co. v. Lupin, Ltd*., No. 1:14-CV-00667-MAS-LHG (D.N.J. filed Jan. 31, 2014); *Senju Pharmaceutical Co. v. InnoPharma Licensing, Inc.*, C.A. No. 1:14-CV-06893-JBS-KMW (D.N.J. filed Nov. 3, 2014). Concurrently herewith, we issue a final written decision in IPR 902, which involves the same parties and is directed to U.S. Patent No. 8,669,290 ("the '290 patent"). The '290 patent claims priority to the '431 patent.

C. The '431 Patent (Ex. 1001)

The '431 patent is titled "Aqueous Liquid Preparation Containing 2-Amino-3-(4-Bromobenzoyl) Phenylacetic Acid." Ex. 1001, Title. The claimed invention relates to an aqueous liquid preparation consisting essentially of two components: (1) bromfenac (or its salts and hydrates);

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treated as confidential. The parties are reminded that confidential information that is subject to a protective order ordinarily becomes public 45 days after final judgment in a trial. Office Patent Trial Practice Guide, 77 Fed. Reg. 48,756, 48,761 (Aug. 14, 2012). Further, there is an expectation that information will be made public where the existence of the information is identified in a final written decision. *Id*. We provided the parties advance notice "that information subject to a protective order will become public if identified in a final written decision in this proceeding." Paper 77, 4.

and (2) tyloxapol. *Id*. at 11:66–12:10 (independent claim 1). Bromfenac is a non-steroidal anti-inflammatory drug ("NSAID"). *Id*. at 1:24–40. Tyloxapol is added to the claimed formulation "to stabilize an aqueous liquid preparation of" the bromfenac component "and inhibit decrease in preservative effect of" quaternary ammonium compounds in the formulation. *Id*. at 2:4–11. The preparation is useful for ophthalmic administration, for example, in an eye drop to treat blepharitis, conjunctivitis, scleritis, or postoperative inflammation. *Id*., Abstract, 12:5–6. Claim 1 specifies that a quaternary ammonium compound, specifically, benzalkonium chloride ("BAC"), may be included in the liquid preparation. *Id*. at 12:8–9.

An object of the invention is to provide an aqueous liquid preparation of bromfenac that "is stable within a pH range giving no irritation to eyes" when preserved with a quaternary ammonium compound, such as benzalkonium chloride ("BAC"). *Id*. at 2:15–22. The inventors claim to have discovered that the addition of an alkyl aryl polyether alcohol type polymer, such as tyloxapol, provides the sought-after stability, giving no irritation to the eyes. *Id*. at 2:35–49. Specifically, tyloxapol both inhibits the change or degradation of bromfenac "over time" and also inhibits "deterioration in the preservative effect" when a preservative is included in the formulation. *Id*. The inventors describe tyloxapol as "a non-ionic surfactant." *Id*. at 4:37–39.

D. Illustrative Claim

Claim 1, reproduced below, is illustrative of the subject matter.

> 1. An aqueous liquid preparation consisting essentially of the following two components, wherein the first component is 2-amino-3-(4-bromobenzoyl)phenylaceticacid or a

> pharmacologically acceptable salt thereof or a hydrate thereof, wherein the hydrate is at least one selected from a 1/2 hydrate, 1 hydrate, and 3/2 hydrate and the second component is tyloxapol, wherein said liquid preparation is formulated for ophthalmic administration, and wherein when a quaternary ammonium compound is included in said liquid reparation, the quaternary ammonium compound is benzalkonium chloride.

Ex. 1001, 11:66–12:10.

E. Declaration Testimony

The Petition is supported by the Declaration of Dr. Paul A. Laskar. Ex. 1003.

The Response is supported by the Declaration of Dr. Robert O. Williams, III (Ex. 2082), the Declaration of Mr. Shirou Sawa (Ex. 2098); the Declaration of Dr. Stephen G. Davies (Ex. 2105), the Declaration of Dr. William B. Trattler (Ex. 2116), and the Declaration of Mr. John C. Jarosz (Ex. 2130).

The Reply is supported by the Reply Declaration of Dr. Paul A. Laskar (Ex. 1104) and the Declaration of Mr. Ivan T. Hofmann (Ex. 1150).

II. ANALYSIS

A. Claim Construction

In an *inter partes* review, claim terms in an unexpired patent are interpreted according to their broadest reasonable construction in light of the specification of the patent in which they appear. *See Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2144-46 (2016) (upholding the use of the broadest reasonable interpretation standard); 37 C.F.R. § 42.100(b). Claim terms generally are given their ordinary and customary meaning, as

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