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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., and MYLAN INC.,
Petitioner,

v.

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

Case IPR2015-00902
Patent 8,669,290 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

I. INTRODUCTION

This is a Final Written Decision in an *inter partes* review challenging the patentability of claims 1–30 ("the challenged claims") of U.S. Patent No. 8,669,290 B2 (Ex. 1001, "the '290 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 1–30 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 a single ground of unpatentability stated in the Petition: Whether the subject matter of claims 1–30 would have been obvious under 35 U.S.C. § 103 based on the combined disclosures of Ogawa[1] and Sallmann[2]. Paper 17 ("Dec.").

Patent Owner filed a Response (Paper 32, "Resp.") and Petitioner filed a Reply (Paper 54, "Reply").[3] The parties' fully briefed Motions to

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

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

[3] 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 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 85, 4.

Exclude also are pending. Papers 62, 65 (Motions to Exclude); Papers 70, 74 (Oppositions to Motions to Exclude); Papers 77, 78 (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 IPR2015-00903 ("IPR 903"). Paper 83 ("Tr.").

B. Related Proceedings

Petitioner identifies eight district court actions involving the '290 patent, including one that involves Petitioner as a defendant. Pet. 11–13; *see Senju Pharmaceutical Co. v. InnoPharma Licensing, Inc.*, No. 1:14-CV-06893-JBS-KMW (D.N.J. filed Nov. 3, 2014). Concurrently herewith, we issue a final written decision in IPR 903, which involves the same parties and is directed to U.S. Patent No. 8,129,431 B2 ("the '431 patent"). The '290 patent claims priority to the '431 patent.

C. The '290 Patent (Ex. 1001)

The '290 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 comprising two components: (1) bromfenac (or its salts and hydrates); and (2) tyloxapol. *Id.* at 12:2–13 (independent claim 1). Bromfenac is a non-steroidal anti-inflammatory drug ("NSAID"). *Id.* at 1:26–49. Tyloxapol is present in the preparation "in an amount sufficient to stabilize" the bromfenac component. *Id.* at 12:10–11. The preparation is useful for ophthalmic administration, for example, in an eye drop to treat blepharitis, conjunctivitis, scleritis, or postoperative inflammation. *Id.*, Abstract, 12:12.

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 2:16–23. 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. A stable aqueous liquid preparation comprising: (a) a first component; and (b) a second component; wherein the first component is 2-amino-3-(4-bromobenzoyl)phenylacetic acid 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; the first component is the sole pharmaceutical active ingredient contained in the preparation; the second component is tyloxapol and is present in said liquid preparation in an amount sufficient to stabilize said first component; and wherein said stable liquid preparation is formulated for ophthalmic administration.

Ex. 1001, 12:2–13.

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 understood by one of ordinary skill in the art in the context of the entire disclosure. *In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007). If an inventor acts as his or her own lexicographer, the definition must be set forth in the specification with reasonable clarity, deliberateness, and precision. *Renishaw PLC v. Marposs Societa' per Azioni*, 158 F.3d 1243, 1249 (Fed. Cir. 1998). The construction that stays true to the claim language, and most naturally aligns with the inventor's description, is likely the correct interpretation. *Id.* at 1250.

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