Trials@uspto.gov
571-272-7822

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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*.

DECISION
Instituting *Inter Partes* Review
37 C.F.R. § 42.108

I. BACKGROUND

On March 19, 2015, Petitioner filed a request for an *inter partes* review of claims 1–30 of U.S. Patent No. 8,669,290 B2 (Ex. 1001, "the '290 patent"). Paper 2 ("Pet."). Patent Owner filed a Preliminary Response.

Paper 13 ("Prelim. Resp."). Also on March 19, 2015, Petitioner filed a Motion for Joinder (Paper 3) of this case with *Metrics, Inc. v. Senju Pharmaceutical Co., Ltd.*, IPR2014-01043. We address the Motion for Joinder in an Order filed concurrently herewith.

We have jurisdiction under 35 U.S.C. § 314(a), which provides that an *inter partes* review may be instituted upon a showing of "a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." Petitioner makes that showing with respect to claims 1–30; therefore, we institute review as to those claims.

Our findings of fact and conclusions of law are based on the record developed thus far, prior to Patent Owner's Response. This is not a final decision as to the patentability of any challenged claim. If a final decision is issued in this case, it will be based on the full record developed during trial.

A. 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.*, C.A. No. 1:14-CV-06893-JBS-KMW (D.N.J. filed Nov. 3, 2014).

Concurrently herewith, we issue a decision to institute in IPR2015-00903, involving the same parties and directed to U.S. Patent No. 8,129,431 B2 (the '431 patent). The '290 patent claims priority to the '431 patent.

B. The '290 Patent (Ex. 1001)

The '290 patent relates to an aqueous liquid preparation comprising two components: (1) bromfenac (or its salts and hydrates); and (2) tyloxapol. Ex. 1001, 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. *Id*. at 12:10–11. The preparation is useful for ophthalmic administration, such as an eye drop to treat blepharitis, conjunctivitis, scleritis, and 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 2:16–24. The inventors claim to have discovered that 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. The inventors acknowledge that tyloxapol "is a non-ionic surfactant." *Id*. at 4:37–39.

C. Illustrative Claim

Petitioner seeks *inter partes* review of claims 1–30 of the '290 patent. Independent 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.

D. The Applied Prior Art

Petitioner relies upon the following prior art references:

Ogawa *et al*., U.S. Patent No. 4,910,225, issued Mar. 20, 1990 (Ex. 1004) ("Ogawa").

Sallmann *et al.*, U.S. Patent No. 6,107,343, issued Aug. 22, 2000 (Ex. 1009) ("Sallmann").

E. The Asserted Grounds of Unpatentability

Petitioner challenges the patentability of claims 1–30 of the '290 patent on a single ground, specifically, unpatentability over Ogawa and Sallmann under 35 U.S.C. § 103. Pet. 18. Petitioner relies on a declaration of Dr. Paul A. Laskar. Ex. 1003.[1]

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. 37 C.F.R. § 42.100(b); *In re Cuozzo Speed Techs., LLC*, No. 2014–1301, 2015 WL 4097949, at *5–*8 (Fed. Cir. July 8, 2015). Claim terms 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

[1] Dr. Laskar has a Ph.D. in Pharmaceutical Sciences and is the founder of a pharmaceutical development consulting firm focused on development and evaluation of pharmaceuticals, including ophthalmic products. Ex. 1003 ¶¶ 14–15, 19. Dr. Laskar has significant experience in the development and assessment of ophthalmic preparations. Ex. 1003 ¶¶ 16, 18. He appears on this record to have the requisite familiarity with ophthalmic preparations to opine on the views of a hypothetical person of ordinary skill in the art at the time of the invention. *See id*. at ¶¶ 12–19. At this stage of the proceeding, we find his testimony credible and persuasive.

(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.

Neither Petitioner nor Patent Owner proposes a specific claim construction for any claim term. Pet. 16; Prelim. Resp. 14. At this stage of the proceeding, we determine that the claim terms are clear on their face, and none is specially defined in the written description of the '290 patent. No claim term requires express construction for the purposes of this decision.

B. The Applied Prior Art

We next turn to the prior art references applied in the Petition and, in particular, to what those references would have conveyed to an ordinary artisan about the state of the art at the time of the invention of the '290 patent. At this stage of the proceeding, we consider the applied prior art as representative of the level of ordinary skill in the art. We discuss facts as presented thus far in the record. Any inferences or conclusions drawn from those facts are neither final nor dispositive of any issue.

i. Ogawa (Ex. 1004)

Ogawa's Example 6 discloses a stable aqueous liquid preparation, formulated for ophthalmic administration, which comprises bromfenac, as the sole pharmaceutical active ingredient, and polysorbate 80. Ex 1004, 10:5–18, 49–57 (for stable aqueous liquid preparation); 10:5–9 (for bromfenac, as sole pharmaceutical active ingredient, and polysorbate 80); 14:45–50 (Table 11, reporting 100% stability for the Example 6

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