Trials@uspto.gov
571-272-7822

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

METRICS, INC., MAYNE PHARMA, and JOHNSON MATTHEY, INC.,
Petitioner,

v.

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

Case IPR2014-01041
Patent 8,129,431 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

Petitioner requests an *inter partes* review of claims 1–22 of U.S. Patent No. 8,129,431 B2 (Ex. 1001, "the '431 patent"). Paper 9 ("Pet."). Patent Owner filed a Preliminary Response. Paper 13 ("Prelim. Resp.").

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 1–22; therefore, we institute review as to those claims.

We authorized, and the parties filed, additional briefing on the issue whether the Petition identifies all real parties-in-interest as required by 35 U.S.C. § 312(a)(2). Paper 15 ("Pet. Opp."); Paper 17 ("PO Reply").

Our findings of fact and conclusions of law, including those relating to the Petition's identification of all real parties-in-interest, 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. Our final decision will be based on the full record developed during trial.

A. Related Proceedings

The '431 patent is the subject of two district court actions. *Senju Pharmaceutical Co. v. Lupin, Ltd.*, C.A. No. 1:14-CV-00667-MAS-LHG (D.N.J.); *Senju Pharmaceutical Co. v. Metrics, Inc*, C.A. No. 1:14-cv-03962-JBS-KMW (D.N.J.); *see* Pet. 12.

Concurrently herewith, we issue a decision to institute in IPR2014-01043, involving the same parties and directed to U.S. Patent No. 8,669,290 B2, which claims priority to the '431 patent.

B. The '431 Patent

The '431 patent relates to an aqueous liquid preparation consisting essentially of two components: (1) bromfenac (or its salts and hydrates); and (2) tyloxapol. Ex. 1001, 11:66–12:10 (independent claim 1). Bromfenac is a non-steroidal anti-inflammatory drug ("NSAID") and tyloxapol serves as a non-ionic surfactant, or stabilizer, in the preparation

recited in the challenged claims. *Id*. at 1:24–47, 2:34–49, 4:37–41. The '431 patent discloses a preparation useful for ophthalmic administration, such as an eye drop to treat blepharitis, conjunctivitis, scleritis, and postoperative inflammation. Ex. 1001, Abstract. The '431 patent discloses that the preparation also is useful as a nasal drop for treatment of allergic rhinitis and inflammatory rhinitis. *Id*.

According to the '431 patent, 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 2:14–22. Petitioner contends, and Patent Owner does not contest at this stage of the proceeding, that NSAIDs were known to interact with BAC to form insoluble complexes, which reduce the stability of the ophthalmic preparation, by rendering the preservative (BAC) less available to serve its function. Pet. 23 (citing Ex. 1003 ¶ 31). 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. Ex. 1001, 2:35–49.

C. Illustrative Claim

Petitioner seeks *inter partes* review of claims 1–22 of the '431 patent. Independent claim 1 is illustrative of the subject matter and is reproduced below.

> 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 preparation, the quaternary ammonium compound is benzalkonium chloride.

Ex. 1001, 11:66–12:10.

D. Prior Art Relied Upon

Petitioner relies upon the following prior art references:

Owaga, U.S. Patent No. 4,910,225, issued Mar. 20, 1990 (Ex. 1004) ("Owaga").

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

Fu, AU-B-22042/88, issued Mar. 16, 1989 (Ex. 1011 ("Fu").

E. The Asserted Grounds of Unpatentability

Petitioner challenges the patentability of claims 1–22 of the '431patent on the grounds set forth in the chart below. *See* Pet. 18–19, 43–46.[1] Petitioner also relies on a declaration of Dr. Uday B. Kompella. Ex. 1003.[2]

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[1] Petitioner's identification of challenged claims in its chart of grounds (Pet. 18–19) differs from the arguments presented in support of the challenges (*see* Pet. 43–46). We identify the challenged claims based on the arguments presented in the Petition.

[2] Dr. Kompella has a Ph.D. in Pharmaceutical Sciences and has significant experience, as a tenured professor, researcher, and author, in the field of ophthalmology and ophthalmic preparations. Ex. 1003 ¶¶ 12–17. 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

References	Basis	Claims Challenged
Owaga and Sallmann	§ 103	1–5, 7–14, and 18–19
Owaga, Sallmann, and Fu	§ 103	6, 15–17, and 20–22

II. ANALYSIS

A. Threshold Issues Under 35 U.S.C. §§ 312 (a)(2), 315(a)(1)

We first address two threshold issues raised by Patent Owner: (1) whether the Petition identifies all real parties-in-interest, as required under 35 U.S.C. § 312(a)(2); and (2) whether Petitioner is barred from pursuing an *inter partes* review under 35 U.S.C. § 315(a)(1).

i. Real Parties-in-Interest under 35 U.S.C. § 312(a)(2)

Patent Owner contends that the filing date of the Petition should be vacated because the Petition does not identify all real parties-in-interest, as required by 35 U.S.C. § 312(a)(2). Prelim. Resp. 14–20. The gravity of that contention, and its potential ramifications, prompted us to authorize further briefing on the issue. We may consider a petition for *inter partes* review only if it identifies all real parties-in-interest. 35 U.S.C. § 312(a)(2).

Patent Owner argues that Coastal Pharmaceuticals, Inc. ("Coastal") is an unidentified real party-in-interest in this proceeding. Prelim. Resp. 1. On that point, Patent Owner contends that Coastal filed, "on [Petitioner's] behalf," a certification with the U.S. Food and Drug Administration ("FDA") pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV certification"). *Id*. Patent Owner states that Petitioner's "arguments in the

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in the art at the time of the invention. *See id*. At this stage of the proceeding, we find his testimony credible and persuasive.

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