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Paper 9
Entered: October 27, 2015

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

LUPIN LTD. and LUPIN PHARMACEUTICALS INC.,
Petitioner,

v.

SENJU PHARMACEUTICAL CO., LTD.,
Patent Owner.

Case IPR2015-01100
Patent 8,927,606 B1

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

FRANKLIN, *Administrative Patent Judge.*

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

I. INTRODUCTION

Lupin Ltd. and Lupin Pharmaceuticals Inc. (collectively, "Petitioner") filed a Petition requesting an *inter partes* review of claims 1–30 of U.S. Patent No. 8,927,606 B1 (Ex. 1004, "the '606 patent"). Paper 1 ("Petition" or "Pet."). Senju Pharmaceutical Co., Ltd. ("Patent Owner") filed a Preliminary Response to the Petition. Paper 8 ("Prelim. Resp.").

We have jurisdiction under 35 U.S.C. § 314, which provides that an *inter partes* review may not be instituted "unless . . . there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." 35 U.S.C. § 314(a). Upon considering the Petition and Preliminary Response, we determine that Petitioner has shown a reasonable likelihood that it would prevail in showing the unpatentability of claims 1–30. Accordingly, we institute an *inter partes* review of those claims.

A. Related Proceedings

Petitioner and Patent Owner identify a number of related district court proceedings involving the '606 patent, including one that involves both parties in this proceeding: *Senju Pharmaceutical Co., Ltd., et al. v. Lupin, Ltd.et al.*, C.A. No. 1:15-cv-00335-JBS-KMW (D.N.J). Pet. 2–3; Paper 5, 2–3.

The parties identify also *inter partes* proceedings involving two patents to which the '606 patent claims priority. Pet. 3; Paper 5, 3. An *inter partes* review of claims of U.S. Patent No. 8,669,290 B2 was instituted in *Metrics, Inc. v. Senju Pharmaceutical Co., Ltd.*, IPR2014-01043 (trial terminated after settlement, IPR2014-01043, Paper 39) and in *InnoPharma Licensing Inc. v. Senju Pharmaceutical Co., Ltd.*, IPR2015-00902 (trial in

progress). An *inter partes* review of claims of U.S. Patent No. 8,129,431 was instituted in *Metrics, Inc. v. Senju Pharmaceutical Co., Ltd.*, IPR2014-01041 (trial terminated after settlement, IPR2014-01041, Paper 39) and in *InnoPharma Licensing Inc. v. Senju Pharmaceutical Co., Ltd.*, IPR2015-00903 (trial in progress).

Additionally, Petitioners have filed petitions requesting *inter partes* review of claims of U.S. Patent 8,754,131 and U.S. Patent 8,871,813, to which the '606 patent claims priority. Pet. 3; Paper 5, 3.

B. The '606 Patent (Ex. 1004)

The '606 patent relates to methods for treating an inflammatory disease of an eye by administering to the eye a stable aqueous liquid ophthalmic preparation comprising: (a) 2-amino-3-(4-bromobenzoyl) phenylacetic acid, or a pharmacologically acceptable salt or a hydrate thereof, also known by its generic name, "bromfenac"; and (b) tyloxapol. Ex. 1004, 1:7–31; 2:26–28.

The Specification explains that, prior to the invention, bromfenac was known as a non-steroidal anti-inflammatory agent ("NSAID") effective against inflammatory diseases of the anterior and posterior segments of the eye, such as blepharitis, conjunctivitis, scleritis, and postoperative inflammation. *Id*. at 1:33–38. According to the Specification, the inventors of the '606 patent found that by adding an alkyl aryl polyether alcohol type polymer, such as tyloxapol, which is an non-ionic surfactant, to an aqueous liquid preparation of bromfenac, the preparation "becomes stable within a pH range giving no irritation to eyes, and change of the [bromfenac] . . . over time can be inhibited, and furthermore, when the aqueous solution contains a

preservative, deterioration in the preservative effect of said preservative can be inhibited for a long period of time." *Id*. at 2:26–38; 4:21–22.

Experimental Example 1 of the '606 patent compares the stability of bromfenac-containing ophthalmic solutions comprising 0.15 w/v% tyloxapol, 0.02 w/v% tyloxapol, 0.15 w/v% polysorbate 80, or 0.15 w/v% polyoxyl 40 stearate. *See id.* at 6:46–7:22. The stability of each preparation was tested under conditions of pH 7.0 at 60° C for 4 weeks. *Id*. at 7:12–14. The results of the comparison are shown in Table 1, reproduced below:

TABLE 1

Component	Comparison Example 1	A-01	A-02	A-03
Sodium 2-amino-3-(4-bromobenzoyl) phenylacetate	0.1 g	0.1 g	0.1 g	0.1 g
Boric acid	1.5 g	1.5 g	1.5 g	1.5 g
Benzalkonium chloride	0.005 g	0.005 g	0.005 g	0.005 g
Polysorbate 80	0.15 g	—	—	—
Polyoxyl 40 stearate	—	0.15 g	—	—
Tyloxapol	—	—	0.15 g	0.02 g
Sterile purified water	q.s.	q.s.	q.s.	q.s

TABLE 1-continued

Component	Comparison Example 1	A-01	A-02	A-03
Total volume	100 mL	100 mL	100 mL	100 mL
pH	7.0	7.0	7.0	7.0
Remaining rate (%) at 60° C. after 4 weeks	51.3	63.7	73.8	89.6

Id. at 6:55–7:9, Table 1. As seen in Table 1, the bromfenac activity remaining in each of the tyloxapol-containing preparations (73.8% for the 0.15 w/v% tyloxapol-containing preparation and 89.6% for the 0.02 w/v% tyloxapol-containing preparation) was greater than the remaining activity in

either the polysorbate 80-containing preparation (51.3%) or the polyoxyl 40 stearate-containing preparation (63.7%). *Id.*

C. Illustrative Claims

Claims 1, 9, and 11 of the '606 patent are illustrative and reproduced below:

> 1. A method for treating an inflammatory disease of an eye, the method comprising administering to said eye a stable aqueous liquid preparation that comprises: (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; wherein said stable liquid preparation is formulated for ophthalmic administration; and wherein said liquid preparation is administered to said eye at a dose and a frequency effective to treat said inflammatory disease.
>
> 9. The method according to claim 1; wherein the stable aqueous liquid preparation consists essentially of:
> (a) 2-amino-3-(4-bromobenzoyl)phenylacetic acid sodium salt,
> [(b) tyloxapol, (c) boric acid,] (d) sodium tetraborate, (e) EDTA sodium salt, (f) benzalkonium chloride, (g) polyvinyl-pyrrolidone, and (h) sodium sulfite, wherein said liquid preparation is formulated for ophthalmic administration, wherein the concentration of the 2-amino-3-(4-bromobenzoyl) phenylacetic acid sodium salt is from about 0.02 w/v % to about 0.1 w/v %.

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