

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 a 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) polyvinylpyrrolidone, 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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