

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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LUPIN LTD. and LUPIN PHARMACEUTICALS INC.,  
Petitioner,

v.

SENJU PHARMACEUTICAL CO., LTD.,  
Patent Owner.

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Case IPR2015-01105  
Patent 8,871,813 B2

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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 1–27 of U.S. Patent No. 8,871,813 B2 (Ex. 1003, “the ’813 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 1–27. 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 ’813 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; Paper 5, 3.

The parties identify also two related *inter partes* proceedings. Pet. 3; Paper 5, 3. An *inter partes* review of claims of U.S. Patent No. 8,669,290 B2 (“the ’290 patent”) 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). The ’813 patent claims priority to the ’290 patent. An *inter partes* review of claims of

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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, the parent of the '813 patent, and U.S. Patent 8,927,606, which claims priority to the application that issues as the '813 patent. Pet. 3; Paper 5, 3.

*B. The '813 Patent (Ex. 1003)*

The '813 patent relates to 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. 1003, 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 '813 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 2:24–37; 4:13–15.

Experimental Example 1 of the '813 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 6:44–7:5. The stability of each preparation was tested under conditions of pH 7.0 at 60° C for 4 weeks. *Id.* at 6:62–64. 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.
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 6:43–60, 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 and 7 of the '813 patent are illustrative and reproduced below:

1. A stable aqueous liquid preparation consisting essentially of: (a) a first component; (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; (c) boric acid; (d) sodium tetraborate; and (e) water; 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 and is present in the preparation at a concentration from about 0.05 w/v % to about 0.2 w/v %; 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.

7. A stable aqueous liquid preparation consisting essentially of: (a) a first component; (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; (c) boric acid; (d) sodium tetraborate; and (e) water; 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 and is present in the preparation at a concentration from about 0.05 w/v % to about 0.2 w/v %; the second component is tyloxapol; wherein said stable liquid preparation is formulated for ophthalmic administration; and wherein the stable aqueous liquid preparation is characterized in that greater than about 90% of the original amount of the first component remains in the preparation after storage at about 60° C. for 4 weeks.

Ex. 1004, 11:30–43; 11:64–12:15.

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