

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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LUPIN LTD., LUPIN PHARMACEUTICALS INC., INNOPHARMA  
LICENSING, INC., INNOPHARMA LICENSING LLC, INNOPHARMA  
INC., INNOPHARMA LLC, MYLAN PHARMACEUTICALS INC., and  
MYLAN INC.,

Petitioners,

v.

SENJU PHARMACEUTICAL CO., LTD.,

Patent Owner.

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Case IPR2015-01100<sup>1</sup>  
Patent 8,927,606 B1

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

FRANKLIN, *Administrative Patent Judge*.

FINAL WRITTEN DECISION  
35 U.S.C. § 318(a) and 37 C.F.R. § 42.73

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<sup>1</sup> IPR2016-00091 has been joined with this proceeding.

## I. INTRODUCTION

Lupin Ltd. and Lupin Pharmaceuticals Inc. (collectively, “Lupin”) 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.”).

On October 27, 2015, we instituted an *inter partes* review of claims 1–30 of the ’606 patent. Paper 9 (“Dec. Inst.”). Patent Owner filed a Patent Owner Response to the Petition. Paper 23 (Board Only), Paper 24 (Parties and Board Only), Paper 25 (Public), (collectively, “PO Resp.”).

On February 25, 2016, we instituted an *inter partes* review in IPR2016-00091 and granted the motion for joinder with IPR2015-01100, adding InnoPharma Licensing, Inc., InnoPharma Licensing LLC, InnoPharma Inc., InnoPharma LLC, Mylan Pharmaceuticals, and Mylan Inc. to the Lupin petitioner (collectively “Petitioners”). Paper 22. Petitioners filed a Reply to the Patent Owner Response. Paper 35 (Public), Paper 37 (Parties and Board Only), (collectively, “Reply”).

Both parties filed a Motion to Exclude Evidence. Paper 44 (“Pet. Mot.”) and Paper 46 (“PO Mot.”). Each party filed an Opposition to the other party’s Motion to Exclude Evidence. Paper 49 (“PO Opp.”); Paper 51 (“Pet. Opp.”). Each party filed also a Reply to the other party’s Opposition to the Motion to Exclude Evidence. Paper 55 (“Pet. Reply Opp.”); Paper 56 (“PO Reply Opp.”).

Patent Owner filed a Motion for Observation Regarding Cross Examination of Reply Witnesses, Paper 47, and Petitioners filed a Response to that motion, Paper 52.

On June 9, 2016, the parties presented arguments at an oral hearing. The hearing transcript has been entered in the record. Paper 63 (“Tr.”).

The Board has jurisdiction under 35 U.S.C. § 6(b). In this Final Written Decision, issued pursuant to 35 U.S. C. § 318(a) and 37 C.F.R. § 42.73, Petitioners have not proved by a preponderance of the evidence that claims 1–30 of the ’606 patent are unpatentable.

Petitioners’ Motion to Exclude Evidence is *dismissed* as moot. Patent Owner’s Motion to Exclude Evidence is *denied-in-part* and *dismissed-in-part* as moot.

#### A. *Related Proceedings*

Petitioners 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 (claims 1–30 of the ’290 patent were held not to have been shown to be unpatentable in a Final Written Decision, IPR2015-00902, Paper 90). 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.*

IPR2015-01100  
Patent 8,927,606 B1

*Senju Pharmaceutical Co., Ltd.*, IPR2015-00903 (claims 1–22 of the ’431 patent were held not to have been shown to be unpatentable in a Final Written Decision, IPR2015-00903, Paper 83).

Additionally, an *inter partes* review was instituted for claims of U.S. Patent 8,754,131 (IPR2015-01097), U.S. Patent 8,669,290 (IPR2015-01099), and Final Written Decisions have been entered determining that the challenged claims of those patents have not been shown to be unpatentable. Also, an *inter partes* review was instituted for claims 1–27 of U.S. Patent 8,871,813 (IPR2015-01105) and a Final Written Decision in that case is entered concurrently herewith determining that the challenged claims have not been shown to be unpatentable.

*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%

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