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Paper 14
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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

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.

Case IPR2015-01105[1]
Patent 8,871,813 B2

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

[1] IPR2016-00090 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 1–27 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.").

On October 27, 2015, we instituted an *inter partes* review of claims 1–27 of the '813 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 IPR2016-00090 and granted the motion for joinder with IPR2015-01105, 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 1–27 of the '813 patent are unpatentable.

Petitioners' Motion to Exclude Evidence is *dismisse*d as moot. Patent Owner's Motion to Exclude Evidence is *denied-in-par*t and *dismissed-in-part* as moot.

A. Related Proceedings

Petitioners 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 (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). The '813 patent claims priority to the '290 patent. 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 (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 1–30 of U.S. Patent 8,927,606 (IPR2015-01100) 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 ’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 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 2:24–37, 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.*

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