

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 IPR2015-01097
Patent 8,754,131 B2

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

PRATS, *Administrative Patent Judge*.

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

I. INTRODUCTION

A. *Statement of the Case*

Lupin Ltd. and Lupin Pharmaceuticals, Inc. (collectively,
“Petitioner”) filed a Petition (Paper 1, “Pet.”) requesting an *inter partes*
review of claims 1–30 of U.S. Patent No. 8,754,131 B2 (Ex. 1002, “the ’131

patent”). Senju Pharmaceutical Co., Ltd. (“Patent Owner”) filed a Preliminary Response. Paper 8 (“Prelim. Resp.”).

We have jurisdiction under 35 U.S.C. § 314(a), which provides that an *inter partes* review may be instituted only if “the information presented in the [Petition and Preliminary Response] . . . shows that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition.”

Having considered the Petition and Preliminary Response, we determine, for the reasons discussed, that Petitioner has established a reasonable likelihood that it would prevail in its challenge to claims 1–30 of the ’131 patent. Accordingly, we institute an *inter partes* review of those claims.

B. Related Proceedings

Petitioner identifies eight district court proceedings involving the ’131 patent, including one that involves Petitioner as a defendant. Pet. 2–3; *see Senju Pharmaceutical Co. v. Lupin Ltd. et al.*, C.A. No. 1:14-CV-05144-JBS-KMW (D.N.J.).

Petitioner also identifies *inter partes* proceedings involving two patents to which the ’131 patent claims priority. Pet. 3. Specifically, the claims of U.S. Patent No. 8,669,290 B2 (“the ’290 patent”) were challenged in *Metrics, Inc. v. Senju Pharmaceutical Co., Ltd.*, IPR2014-01043, and *InnoPharma Licensing Inc. v. Senju Pharmaceutical Co., Ltd.*, IPR2015-00902. *Metrics v. Senju*, IPR2014-01043, was terminated after settlement. IPR2014-01043, Paper 39. Trial was instituted in *InnoPharma v. Senju*, IPR2015-00902, and the proceeding remains pending. IPR2015-00902, Paper 17.

IPR2015-01097
Patent 8,754,131 B2

The claims of U.S. Patent No. 8,129,431 B2 (“the ’431 patent”), to which the ’131 patent also claims priority, were challenged in *Metrics, Inc. v. Senju Pharmaceutical Co., Ltd.*, IPR2014-01041, and *InnoPharma Licensing Inc. v. Senju Pharmaceutical Co., Ltd.*, IPR2015-00903. *Metrics v. Senju*, IPR2014-01041, was terminated after settlement. IPR2014-01041, Paper 39. Trial was instituted in *InnoPharma v. Senju*, IPR2015-00903, and the proceeding remains pending. IPR2015-00903, Paper 15.

Petitioner filed, concurrently with the Petition under consideration herein, petitions challenging the claims of the ’290 patent mentioned above (IPR2015-01099), the claims of U.S. Patent No. 8,871,813 B2 (“the ’813 patent;” IPR2015-01105), and the claims of U.S. Patent No. 8,927,606 B1 (“the ’606 patent;” IPR2015-01100). Pet. 3–4. The ’813 and ’606 patents claim priority to the ’131 patent. *Id.*

Concurrently herewith, we issue decisions to institute trial in each of IPR2015-01099, IPR2015-01100, and IPR2015-01105.

C. Proposed Grounds of Unpatentability

Petitioner advances the following two grounds of unpatentability (Pet. 12):

Reference[s]	Statutory Basis	Challenged Claims
Ogawa ¹ and Fu ²	35 U.S.C. § 103(a)	1–30

¹ Ogawa et al., U.S. Patent No. 4,910,225 (issued Mar. 20, 1990) (“Ogawa,” Ex. 1010).

² Fu et al., EP 0 306 984 A1 (published March 15, 1989) (“Fu,” Ex. 1014).

Reference[s]	Statutory Basis	Challenged Claims
Sallmann ³ and Ogawa	35 U.S.C. § 103(a)	1–30

Petitioner supports its challenge with a Declaration by M. Jayne Lawrence, Ph.D. (“Lawrence Decl.”) (Ex. 1005).

D. The ’131 Patent (Ex. 1002)

The ’131 patent relates to an aqueous liquid preparation that includes two components: (1) 2-amino-3-(4-bromobenzoyl)phenylacetic acid (or its salts and hydrates), generically named “bromfenac”; and (2) tyloxapol.

Ex. 1002, 2:45–59; *id.* at 1:20–22.

The ’131 patent discloses that bromfenac was known in the prior art as a non-steroidal anti-inflammatory drug (“NSAID”) used in eye drops to treat inflammatory disorders of the eye, including blepharitis, conjunctivitis, scleritis, as well as postoperative inflammation. *Id.* at 1:35–44.

The ’131 patent discloses that alkyl aryl polyether polymers, which are non-ionic surfactants, and which include tyloxapol, may be used to stabilize bromfenac-containing ophthalmic solutions. *Id.* at 4:36–5:15. In particular, the ’131 patent discloses that when tyloxapol is added to a bromfenac-containing aqueous ophthalmic solution, the solution “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 2:37–42.

³ Sallmann et al., U.S. Patent No. 5,891,913 (issued Apr. 6, 1999) (“Sallmann,” Ex. 1021).

Experimental Example 1 of the '131 patent compares the stability of pH 7.0 bromfenac-containing ophthalmic solutions that included 0.15 w/v% and 0.02 w/v% tyloxapol, to solutions containing 0.15 w/v% of the surfactants polysorbate 80 and polyoxyl 40 stearate. *See id.* at 7:1–67. 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 7:35–53. As seen in Table 1, after 4 weeks at 60° C, the bromfenac activity remaining in the polysorbate 80-containing solution was 51.3%, and the remaining bromfenac activity in the polyoxyl 40 stearate solution was 63.7%, whereas the remaining activity in the tyloxapol solutions was 73.8% (0.15 w/v% tyloxapol) and 89.6% (0.02 w/v% tyloxapol). *Id.*

Claims 1 and 6 of the '131 patent illustrate the challenged subject matter and read as follows (paraphrasing added):

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