Trials@uspto.gov
571-272-7822

Paper 9
Entered: October 27, 2015

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.

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 (paragraphing added):

DOCKET ALARM

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts

Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research

With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips

Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS
Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS
Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS
Sync your system to PACER to automate legal marketing.