Trials@uspto.gov
571-272-7822

Paper No. 69
Date Entered: September 12, 2016

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

LUPIN LTD. and LUPIN PHARMACEUTICALS INC.,
Petitioners,

v.

SENJU PHARMACEUTICAL CO., LTD.,
Patent Owner.

Case IPR2015-01099
Patent 8,669,290 B2

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

PRATS, *Administrative Patent Judge*.

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

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. 8,669,290 B2 (Ex. 1001, "the '290 patent"). Senju Pharmaceutical Co., Ltd. ("Patent Owner") filed a Preliminary Response. Paper 8 ("Prelim. Resp.").

Upon review of those papers and cited information, we instituted trial as to claims 1–30 of the '290 patent in relation to a single ground of unpatentability: obviousness over Sallmann[1] and Ogawa[2] under 35 U.S.C. § 103(a). Paper 9, 21–22 ("Decision to Institute," or "Dec.").

Thereafter, Patent Owner filed a Response (Paper 24; "PO Resp."), and Petitioner filed a Reply (Paper 32, "Reply").[3]

Both parties filed Motions to Exclude Evidence. Paper 43 ("Pet. Mot. to Exclude") and Paper 45 ("PO Mot. to Exclude").

---

[1] Sallmann et al., U.S. Patent No. 5,891,913 (issued Apr. 6, 1999) ("Sallmann," Ex. 1021).

[2] Ogawa et al., U.S. Patent No. 4,910,225 (issued Mar. 20, 1990) ("Ogawa," Ex. 1010).

[3] To the extent that we rely on information in papers and exhibits for which confidentiality is claimed, we determine that the general nature of the discussions of such information herein does not require that this Decision be treated as confidential. The parties are reminded that confidential information that is subject to a protective order ordinarily becomes public 45 days after final judgment in a trial. Office Patent Trial Practice Guide, 77 Fed. Reg. 48,756, 48,761 (Aug. 14, 2012). Further, there is an expectation that information will be made public where the existence of the information is identified in a final written decision. *Id*.

Each party filed an Opposition to the other party's Motion to Exclude Evidence. Paper 50 ("Pet. Opp."); Paper 48 ("PO Opp."). Each party filed also a Reply to the other party's Opposition to the Motion to Exclude Evidence. Paper 54 ("Pet. Reply Opp."); Paper 55 ("PO Reply Opp.").

Patent Owner filed a Motion for Observation Regarding Cross Examination of Reply Witnesses (Paper 46; "PO Mot. Observ."), and Petitioner filed a Response to that motion (Paper 51; "Pet. Resp. Observ.").

An oral hearing was held on June 9, 2016, and the hearing transcript has been entered in the record. Paper 62 ("Tr.").

We have jurisdiction under 35 U.S.C. § 6(b). This Final Written Decision is entered pursuant to 35 U.S.C. § 318(a).

"In an inter partes review instituted under this chapter, the petitioner shall have the burden of proving a proposition of unpatentability by a preponderance of the evidence." 35 U.S.C. § 316(e).

We conclude that Petitioner has not proved by a preponderance of the evidence that claims 1–30 of the '290 patent are unpatentable for obviousness over Sallmann and Ogawa under 35 U.S.C. § 103(a).

Petitioner's 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.

B. Related Proceedings

Petitioner identifies eight district court proceedings involving the '290 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-4149-JBS-KMW (D.N.J.).

Petitioner identifies two *inter partes* proceedings involving the '290 patent. Pet. 3. Specifically, the claims of 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. In *InnoPharma v. Senju*, Case IPR2015-00902, claims 1–30 of the '290 patent were held not to have been shown to be unpatentable. IPR2015-00902, Paper 90.

The claims of U.S. Patent No. 8,129,431 B2 ("the '431 patent"), to which the '290 patent 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. Pet. 3. *Metrics v. Senju,* IPR2014-01041, was terminated after settlement. IPR2014-01041, Paper 39. In *InnoPharma v. Senju*, Case IPR2015-00903, claims 1–22 of the '431 patent were held not to have been shown to be unpatentable. IPR2015-00903, Paper 83.

Petitioner filed, concurrently with the Petition under consideration herein, petitions challenging the claims of U.S. Patent No 8,754,131 B2 ("the '131 patent, IPR2015-01097), 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 '131, '813, and '606 patents claim priority to the '290 patent. *Id.*

Decisions in IPR2015-01097, IPR2015-01100, and IPR2015-01105 are issued concurrently herewith.

C. The '290 Patent (Ex. 1001)

The '290 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. 1001, 1:25–27; *id.* at 2:50–64.

The '290 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 1:25–49.

The '290 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 4:37–5–15. In particular, the '290 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 2:42–47.

Experimental Example 1 of the '290 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 7:6–8:2. The results of the comparison are shown in Table 1, reproduced below:

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.