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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 IPR2015-01099
Patent 8,669,290 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. 8,669,290 B2 (Ex. 1001, "the '290

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 '290 patent. Accordingly, we institute an *inter partes* review of those claims.

*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. 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 '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. 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 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.*

Concurrently herewith, we issue decisions to institute trial in each of IPR2015-01097, IPR2015-01100, and IPR2015-01105.

*C. Proposed Grounds of Unpatentability*

Petitioner advances the following two grounds of unpatentability (Pet. 11):

| **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 '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, 2:50–64; *id.* at 1:25–27.

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.

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

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:

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 7:39–54. 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 7 of the ’290 patent illustrate the challenged subject matter and read as follows (paragraphing added):

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