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Paper No. 14
Date Entered: September 12, 2016

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 IPR2015-01097[1]
Patent 8,754,131 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

[1] Case IPR2016-00089 has been joined with this proceeding.

I. INTRODUCTION

A. Statement of the Case

Lupin Ltd. and Lupin Pharmaceuticals, Inc. (collectively, "Lupin") 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.").

Upon review of those papers and cited information, we instituted trial as to claims 1–30 of the '131 patent in relation to a single ground of unpatentability: obviousness over Sallmann[2] and Ogawa[3] under 35 U.S.C. § 103(a). Paper 9, 21–22 ("Decision to Institute," or "Dec.").

After the Decision to Institute, InnoPharma Licensing, Inc., InnoPharma Licensing LLC, InnoPharma Inc., InnoPharma LLC, Mylan Pharmaceuticals Inc., and Mylan Inc. ("InnoPharma and Mylan"), timely filed a separate petition to institute an *inter partes* review of claims 1–30 of the '131 patent, the petition including an obviousness ground relying on the same combination of prior art for which trial was instituted in this proceeding. *InnoPharma Licensing, Inc. v. Senju Pharmaceutical Co., Ltd.*, Case IPR2016-00089, Paper 1. At the same time, InnoPharma and Mylan filed a Motion for Joinder with the instituted case. *Id.*, Paper 3. Patent Owner filed a Preliminary Response and an Opposition to the Motion for Joinder. *Id.*, Papers 10, 11.

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[2] Sallmann et al., U.S. Patent No. 5,891,913 (issued Apr. 6, 1999) ("Sallmann," Ex. 1021).
[3] Ogawa et al., U.S. Patent No. 4,910,225 (issued Mar. 20, 1990) ("Ogawa," Ex. 1010).

We instituted *inter partes* review of claims 1–30 of the '131 patent in IPR2016-00089, granted the Motion for Joinder, and terminated IPR2016-00089. *Id.*, Paper 17. Therefore, in the instant *inter partes* review, Lupin, InnoPharma, and Mylan are, collectively, the "Petitioner."

Thereafter, Patent Owner filed a Response (Paper 25; "PO Resp."), and Petitioner filed a Reply (Paper 35, "Reply").[4]

Both parties filed Motions to Exclude Evidence. Paper 45 ("Pet. Mot. to Exclude") and Paper 46 ("PO Mot. to Exclude").

Each party filed an Opposition to the other party's Motion to Exclude Evidence. Paper 51 ("Pet. Opp."); Paper 49 ("PO 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; "PO Mot. Observ.") and Petitioner filed a Response to that motion (Paper 52; "Resp. Observ.").

An oral hearing was held on June 9, 2016, and the hearing transcript has been entered in the record. Paper 63 ("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).

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[4] 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*.

"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 '131 patent are unpatentable for obviousness over Sallmann and Ogawa under 35 U.S.C. § 103(a).

Petitioner's Motion to Exclude Evidence is *dismissed* as moot. Patent Owner's Motion to Exclude Evidence is *denied-in-part* and *dismissed-in-part* as moot.

B. Related Proceedings

Petitioner identifies eight district court proceedings involving the '131 patent. Pet. 2–3; *see Senju Pharmaceutical Co. v. Lupin Ltd. et al.*, C.A. No. 1:14-CV-05144-JBS-KMW (D.N.J.); *Senju Pharmaceutical Co v. InnoPharma Licensing, Inc. et al.*, C.A. No. 1:14-cv-06893-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. 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 '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. 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 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.*

Decisions in IPR2015-01099, IPR2015-01100, and IPR2015-01105 are issued concurrently herewith.

C. 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

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