Paper 13

Tel: 571-272-7822 Entered: January 25, 2016

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 IPR2015-01871 Patent 8,129,431

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

OBERMANN, Administrative Patent Judge.

DECISION

Instituting *Inter Partes* Review and Granting Petitioner's Motion for Joinder 37 C.F.R. § 42.108 37 C.F.R. § 42.122(b)

Petitioner ("Lupin") filed a petition (Paper 2, "Pet.") requesting an *inter* partes review of claims 1–22 of U.S. Patent No. 8,129,431 (Ex. 1001, "the '431 patent"). Patent Owner ("Senju") waived filing a preliminary response. Paper 11. With the petition, Lupin filed a motion (Paper 3, "Mot.") requesting joinder of the instant proceeding with IPR2015-00903 ("IPR 903"). Lupin's petition asserts the same grounds, directed to the same patent claims, as those set for trial in IPR 903, which was initiated by a different entity ("InnoPharma"). IPR 903, Paper 15, ("903 Dec."). Senju opposes Lupin's motion for joinder. Paper 7, ("Opp.").

During a telephone conference with the Board held November 17, 2015, Senju, Lupin, and InnoPharma clarified their respective positions relating to the petition and motion. Paper 10, ("Order"). In the event of joinder, Lupin agreed to proceed based solely on the arguments and evidence presented by InnoPharma in IPR 903. *Id.* at 4. Lupin also consented to being added to the case caption of IPR 903 as a petitioner, "without any active participation or involvement that is separate from InnoPharma, unless authorized by the Board upon a request pertaining to an issue unique to Lupin alone." *Id.* InnoPharma agreed to permit Lupin to rely on the declaration of InnoPharma's witness. *Id.* at 3. Senju continued to oppose Lupin's request for joinder. *Id.* at 4.

Institution of Inter Partes Review

We first address whether Lupin's petition warrants review; only then do we address whether joinder is appropriate. *See* 35 U.S.C. § 315 (c) (joinder provision, relating to *inter partes* reviews, requires, as an initial matter, a determination that the petition accompanying the joinder motion warrants institution of review). We have jurisdiction under 35 U.S.C. § 314, which provides that an *inter partes* review may be authorized only if "the information presented in the petition . . . and any [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." 35 U.S.C. § 314(a).

For reasons that follow, we are persuaded that Lupin's petition warrants institution of an *inter partes* review, for the same reasons stated in our decision instituting review in IPR 903. Lupin's petition challenges the same patent claims, on the same grounds, as those set for trial in IPR 903. Pet. 20; 903 Dec. 19. The argument and evidence presented in Lupin's petition, and the argument and evidence presented in InnoPharma's petition, are essentially identical in substance. *See generally* Pet.; IPR 903, Paper 2 ("903 Pet."). For example, although Lupin's petition is supported by the declaration of a different witness, Lupin's witness in the instant proceeding provides essentially identical testimony as that supplied by InnoPharma's witness in IPR 903. *Compare* Ex. 1054 (Declaration of Dr. M. Jayne Lawrence) *with* IPR 903, Ex. 1003 (Declaration of Dr. Paul A. Laskar).

In IPR 903, we have already determined that the argument and evidence presented in InnoPharma's petition warrants institution of an *inter partes* review. 903 Dec. 19. Given that Lupin presents substantively identical arguments and evidence as that raised by InnoPharma in IPR 903, we determine that Lupin's petition demonstrates a reasonable likelihood of prevailing with respect to at least one claim of the '431 patent. In particular, for the reasons stated in our decision instituting review in IPR 903, Lupin is reasonably likely to show that (1) claims 1–5, 7–14, and 18–19 are unpatentable as obvious over Ogawa and Sallman; and (2)

claims 6, 15–17, and 20–22 are unpatentable as obvious over Ogawa, Sallmann, and Fu. Id. at 4–19.

Grant of the Motion for Joinder

Lupin and InnoPharma "relied upon testimony from separate experts" in their respective petitions. Mot. 6. However, "in order to further simplify the proceeding, Lupin will rely on the same expert as InnoPharma" in any consolidated proceeding, "should InnoPharma permit it." *Id.* at 7. In that regard, during the telephone conference held on November 17, 2015, these facts became apparent: InnoPharma and Lupin have reached an agreement, regarding their respective roles and the content of the evidence, should the Board join this proceeding with IPR 903. In particular, InnoPharma agrees to permit Lupin to rely on the declaration of InnoPharma's witness, Dr. Laskar, filed in support of InnoPharma's petition in IPR 903. Lupin agrees to accept a back-seat role as an "understudy" in any joined proceeding, without any right to separate briefing or discovery in IPR 903. Order 3–4.

To the extent that Lupin's petition in this proceeding differs from the petition that InnoPharma filed in IPR 903, Lupin agrees to withdraw all additional arguments, as well as its supporting declaration of Dr. Lawrence, and proceed in IPR 903 based on the arguments and evidence provided by InnoPharma in IPR 903. Lupin agrees to assume a primary role in IPR 903 only if InnoPharma

¹ Ogawa *et al.*, U.S. Patent No. 4,910,225, issued Mar. 20, 1990 (Ex. 1004) ("Ogawa").

² Sallmann *et al.*, U.S. Patent No. 6,107,343, issued Aug. 22, 2000 (Ex. 1009) ("Sallmann").

³ Fu, Austl. Patent Application No. AU-B-22042/88, published Mar. 16, 1989 (Ex. 1011) ("Fu").

ceases to participate in IPR 903. In other words, Lupin requests permission to be added to the case caption as a petitioner in IPR 903, without any active participation or involvement that is separate from InnoPharma, unless authorized by the Board upon a request pertaining to an issue unique to Lupin alone. *Id.* at 4.

The Board several times requested counsel for Senju to address what burden, if any, Senju would bear, should joinder be granted on the above terms agreed to between InnoPharma and Lupin. Counsel for Senju advocated that consolidation of ten reviews (including IPR 903, any review instituted in the instant proceeding, and eight other reviews identified during the telephone conference) would foster consistency and efficiency, while opposing consolidation of this proceeding and IPR 903; averred that extending the statutory due date of a final decision in IPR 903, so that the ten reviews can be decided simultaneously, would permit the parties to focus on a trial presently set for April, 2016, in co-pending district court litigation that involves issues similar to those presented here; and argued that the ability of Lupin to request Board pre-authorization to provide separate argument or evidence in IPR 903, on issues unique to Lupin alone, is vague and presents uncertainties that may burden Senju. *Id.* None of those arguments, presented during the telephone conference, persuades us that any prejudice to Senju outweighs the interests of economy and speed that will be facilitated by granting Lupin's request for joinder.

Senju argued also, during the conference and in its written opposition, that Lupin "sat by and watched while other companies initiated IPRs challenging the '431 patent." Opp. 1. Our authorizing statute, however, sets forth the conditions under which a delay in filing a petition for an *inter partes* review will preclude a petitioner from seeking relief in our forum—and Senju does not establish sufficiently that those conditions are present in this case. *See* 35 U.S.C.

§ 315(b) (an IPR may not be filed if the petition requesting the proceeding is filed more than one year after the date on which the petitioner, real party in interest, or privy of the petition is served with a complaint alleging infringement of the patent). Under the circumstances, Senju fails to demonstrate an undue delay that justifies our denial of Lupin's petition or motion.

Senju also avers in the written opposition that, "[u]nlike many parties that have sought to prevent the undue procedural and substantive prejudice associated with joinder by agreeing to schedule extensions and procedural safeguards, Lupin does not agree to subordinate itself, even though that is in line with common Board practice." Opp. 3. Lupin's subsequent representations to the Board, during the telephone conference of November 17, 2015, obviate those objections.

Specifically, Lupin expressly agrees to "subordinate itself," *id.*, to "a back-seat role as an 'understudy' in any consolidated proceeding, without any right to separate briefing or discovery in IPR 903." Order 3–4. Lupin's representations during the telephone conference effectively overcome Senju's objections to joinder.

For example, Senju alleges that joinder will negatively affect the Board's ability to timely complete review, given that Lupin's petition "presents significant new substantive issues." Opp. 7. Senju's concern that Lupin presents "new claim construction positions and new evidence, including a new declaration," *id.*, is substantially removed by Lupin's subsequent agreement to forgo its own arguments and evidence and allow IPR2015-00903 to proceed based on InnoPharma's arguments and evidence alone. Order 3–4.

We have considered also the other arguments presented by Senju, but none persuades us that joinder is inappropriate in this case, given the concessions made by Lupin during the telephone conference of November 17, 2015. Opp. 7–15; Order 3–4. The interests of efficiency and speed in the resolution of this

proceeding outweigh the considerations raised by Senju in opposition to Lupin's request for joinder. Under the circumstances, we conclude that Lupin has demonstrated persuasively that it is entitled to the requested relief. 37 C.F.R. § 42.20(c).

It is

ORDERED that Lupin's challenge to claims 1–22 is instituted; FURTHER ORDERED that Lupin's motion for joinder is granted; FURTHER ORDERED that this proceeding is joined with IPR2015-00903;

FURTHER ORDEED that the grounds on which IPR2015-00903 was instituted are unchanged, and no other grounds are instituted;

FURTHER ORDERED that the Scheduling Order in place for IPR2015-00903 shall govern the proceeding;

FURTHER ORDERED that, throughout IPR2015-00903, any paper, except for a motion that does not involve the other party, shall be filed by InnoPharma, as a single, consolidated filing on behalf of InnoPharma and Lupin, and InnoPharma will identify each such filing as a consolidated filing;

FURTHER ORDERED that IPR2015-00903 will proceed without any active participation or involvement by Lupin that is separate from InnoPharma, unless authorized by the Board upon a request pertaining to an issue unique to Lupin alone;

FURTHER ORDERED that except as otherwise agreed by counsel,
InnoPharma will conduct cross-examination and other discovery on behalf of
InnoPharma and Lupin, and that Senju is not required to provide separate
discovery responses or additional deposition time as a result of the consolidation;

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FURTHER ORDERED that IPR2015-01871 is terminated under 37 C.F.R. § 42.72, and all further filings are to be made in IPR2015-00903;

FURTHER ORDERED that a copy of this Decision will be entered into the record of IPR2015-01871 and IPR2015-00903; and

FURTHER ORDERED that the case caption in IPR2015-00903 shall be changed to reflect joinder with this proceeding in accordance with the attached example.

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

INNOPHARMA LICENSING, INC., INNOPHARMA LICENSING LLC, INNOPHARMA INC., INNOPHARMA LLC, MYLAN PHARMACEUTICALS INC., MYLAN INC., LUPIN LTD., and LUPIN PHARMACEUTICALS INC., Petitioner,

v.

SENJU PHARMACEUTICAL CO., LTD., BAUSCH & LOMB, INC., and BAUSCH & LOMB PHARMA HOLDINGS CORP., Patent Owner.

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⁴ IPR2015-01871 has been joined with this proceeding.