Trials@uspto.gov
571-272-7822

Paper 13
Date: February 25, 2016

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

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

v.

SENJU PHARMACEUTICAL CO., LTD.,
Patent Owner.

Case IPR2016-00089
Patent 8,754,131 B2

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

OBERMANN, *Administrative Patent Judge*.

DECISION
Institution of *Inter Partes* Review and Grant of Motion for Joinder
37 C.F.R. § 42.108; 37 C.F.R. § 42.122(b)

I. INTRODUCTION

InnoPharma Licensing, Inc., InnoPharma Licensing LLC, InnoPharma Inc., InnoPharma LLC, Mylan Pharmaceuticals Inc., and Mylan Inc. (collectively, "Petitioner" or "InnoPharma") timely filed a Petition requesting an *inter partes* review of claims 1–30 of U.S. Patent No. 8,754,131 B2 (Ex. 1001, "the '131 patent"). Paper 2 ("Pet."). Petitioner also timely filed a Motion for Joinder to join this proceeding with *Lupin Ltd. et al. v. Senju Pharmaceutical Co., Ltd.*, Case IPR2015-01097 (the "*Lupin* IPR") which was instituted on October 27, 2015. Paper 3 ("Mot.").

Senju Pharmaceutical Co., Ltd. ("Patent Owner") filed a Preliminary Response to the Petition. Paper 10 ("Prelim. Resp."). By Order we modified the Patent Owner's time for filing an Opposition to the Motion for Joinder to coincide with the due date for the Preliminary Response. Paper 9. With that authorization, Patent Owner filed an Opposition to Petitioner's Motion for Joinder on the same date that it filed the Preliminary Response. Paper 11 ("Opp.").

For the reasons set forth below, we (1) institute an *inter partes* review based on the same grounds as instituted in the *Lupin* IPR, and (2) grant InnoPharma's Motion for Joinder, subject to the conditions detailed herein.

II. INSTITUTION OF *INTER PARTES* REVIEW

In the *Lupin* IPR, we instituted trial on the following ground: Claims 1–30 of the '131 patent under 35 U.S.C. § 103(a) as obvious over Sallmann (U.S. Patent No. 5,891,913, issued Apr. 6, 1999) ("the '913 patent") and Ogawa (U.S. Patent No. 4,910,225, issued Mar. 20, 1990). *Lupin* IPR, Paper 9, 22.

InnoPharma's Petition is substantially identical to the petition in the *Lupin* IPR, with respect to the ground challenging claims 1–30 as obvious over Sallmann[1] and Ogawa. InnoPharma's Petition includes additional grounds not authorized in the *inter partes* review instituted the *Lupin* IPR. By email correspondence to the Board, dated February 4, 2016, InnoPharma stated that "in the interests of facilitating joinder, InnoPharma will agree to proceed in [] IPR2015-01105 based only upon the arguments and evidence advanced by Lupin in its earlier-filed actions and accept[s] a back-seat, 'understudy' role in [the] joined proceedings." Ex. 3001. In other words, InnoPharma confirmed that it seeks institution only as to the single ground of unpatentability that corresponds to the ground authorized by the Board in the *Lupin* IPR.

Further, InnoPharma's Petition is supported by the declaration of a different witness than in the *Lupin* IPR. Both declarants, however, provide essentially the same testimony regarding the ground challenging claims 1–30 as obvious over Sallmann and Ogawa. *Compare* Ex. 1003 (Declaration of Dr. Paul A. Laskar) *with* the *Lupin* IPR, Ex. 1005 (Declaration of Dr. M. Jayne Lawrence).

In the Preliminary Response, Patent Owner acknowledges that InnoPharma's Petition "relies on the same references and the same or substantially the same arguments as the Lupin petition." Prelim. Resp. 1. Rather than addressing those arguments, Patent Owner requests that we

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[1] The Sallmann reference (Ex. 1009) applied in InnoPharma's Petition is U.S. Patent No. 6,107,343, which issued Aug. 22, 2000, from a divisional application of the parent application that issued as the '913 patent. Due to that relationship, the Sallmann references have identical disclosures.

exercise our discretion to deny InnoPharma's Petition pursuant to 35 U.S.C. § 325(d) and 37 C.F.R. § 42.208(b).[2] *Id*. In support of that request, Patent Owner asserts that InnoPharma "has not only intentionally delayed in filing its piecemeal IPRs, but also unduly procrastinated to potentially resolve the joinder issue." *Id*. According to Patent Owner, granting the Petition would be unfair. *Id*. Patent Owner, however, has not persuasively supported those assertions or shown that the Petition was untimely filed. *See id*. at 1–11.

When a petition for *inter partes* review challenges the same patent raised in a proceeding already before us, our decision whether to institute a trial is guided by 35 U.S.C. §§ 315(d) and 325(d). Section 315(d) states:

> during the pendency of an inter partes review, if another proceeding or matter involving the patent is before the Office, the Director may determine the manner in which the inter partes review or other proceeding or matter may proceed, including providing for stay, transfer, consolidation, or termination of any such matter or proceeding.

Section 325(d) has similar language and further explains:

> In determining whether to institute or order a proceeding under this chapter, chapter 30, or chapter 31,[3] the Director may take into account whether, and reject the petition or request because,

[2] We interpret Patent Owner's argument as seeking application of 37 C.F.R. § 42.108(b), which applies to *inter partes* reviews, rather than 37 C.F.R. § 42.208(b), which applies to post-grant reviews.

[3] Chapter 31 of the Patent Act covers *inter partes* review proceedings. Thus, although § 325(d) appears in Chapter 32, which is directed to post-grant reviews, it is applicable to *inter partes* reviews.

> the same or substantially the same prior art or arguments previously were presented to the Office.

Having considered the Petition, InnoPharma's modification of the grounds to be considered in the Petition, Ex. 3001, and Patent Owner's Preliminary Response, we determine that, under the current circumstances, it is appropriate to exercise our discretion to institute an *inter partes* review of the challenged claims based upon the same ground authorized and for the same reasons discussed in our Institution Decision in the *Lupin* IPR. *See Lupin* IPR, Paper 9. We find that proceeding in this manner is equitable for the parties.

III. JOINDER OF *INTER PARTES* REVIEWS

An *inter partes* review may be joined with another *inter partes* review, subject to the provisions 35 U.S.C. § 315(c), which governs joinder of *inter partes* review proceedings:

> (c) JOINDER. — If the Director institutes an inter partes review, the Director, in his or her discretion, may join as a party to that inter partes review any person who properly files a petition under section 311 that the Director, after receiving a preliminary response under section 313 or the expiration of the time for filing such a response, determines warrants the institution of an inter partes review under section 314.

As the moving party, Petitioner bears the burden of proving that it is entitled to the requested relief. 37 C.F.R. § 42.20(c). A motion for joinder should: set forth the reasons joinder is appropriate; identify any new grounds of unpatentability asserted in the petition; and explain what impact (if any) joinder would have on the trial schedule for the existing review. *See Kyocera Corp. v. Softview, LLC,* Case IPR2013-00004, slip op. at 4 (PTAB

Apr. 24, 2013) (Paper 15); *see also,* "Frequently Asked Questions H5," http://www.uspto.gov/ip/boards/bpai/prps.jsp.

Petitioner timely filed its Joinder Motion within one month of the institution of the *Lupin* IPR, as required by 37 C.F.R. § 42.122(b).

As discussed in the Institution Decision, *supra*, InnoPharma sent an e-mail correspondence to the Board on February 4, 2016, offering certain concessions "in the interest of facilitating joinder." Ex. 3001. Specifically, InnoPharma stated the following:

> InnoPharma will agree to proceed in IPR2015-01097, IPR2015-01100, and IPR2015-01105 based only upon the arguments and evidence advanced by Lupin in its earlier-filed actions and accept a back-seat, "understudy" role in those joined proceedings, without any right to separate or additional briefing or discovery, unless authorized by the Board upon a request to address an issue that is unique to InnoPharma. Only if Lupin drops out of the proceedings for any reason, will InnoPharma cease its understudy role. The conditions are the same as to what Lupin agreed to in connection with its corresponding motion for joinder to join InnoPharma's IPR (IPR2015-00903), which the Board granted. *See, e.g.*, IPR2015-0187 (Paper 13). Moreover, InnoPharma has contacted Lupin, and Lupin has agreed to permit InnoPharma to rely upon its declarant (Dr. Lawrence) in the joined proceedings.

Ex. 3001.

In its Opposition, Patent Owner asserts that joinder would "unduly prejudice Senju with piecemeal filings of IPRs designed by InnoPharma to harass Senju." Opp. 1. In particular, Patent Owner asserts that "joinder here will affect the procedure, and scheduling of the Lupin IPR. Joinder also would unduly complicate the case and the issues and, given the June hearing date, would unduly prejudice Senju and Lupin." *Id*. at 10.

We disagree with Patent Owner. As InnoPharma has agreed to "accept a back-seat, 'understudy' role" in a joined proceeding, joinder would essentially only add InnoPharma as a petitioner in the *Lupin* IPR. InnoPharma has acknowledged that its role in a joined proceeding would not "entitle it to any right" to separate or additional briefing or discovery, as long as Lupin remains a party to the proceeding. In the event that Lupin settles with Patent Owner, or otherwise does not continue as the petitioner in the *Lupin* IPR, InnoPharma may take on an active role as the petitioner. Whether or not Lupin remains the petitioner in the *Lupin* IPR, InnoPharma has agreed to proceed only upon the ground authorized in the *Lupin* IPR and to rely only upon Lupin's declarant, Dr. Lawrence. Moreover, joinder would not affect the schedule in the *Lupin* IPR. Thus, we do not find that Patent Owner has established persuasively that joinder would unduly complicate any aspect of the case or unduly prejudice the parties.

Having considered the motion for joinder, InnoPharma's email correspondence, and the opposition to the motion for joinder, we determine that InnoPharma has established persuasively that joinder is appropriate and will have little to no impact on the timing, cost, or presentation of the trial on the instituted ground. Thus, in consideration of the foregoing, and in the manner set forth in the following Order, the Motion for Joinder is *granted*.

IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that trial is instituted in IPR2016-00089 on the following ground:

Claims 1–30 of the '131 patent under 35 U.S.C. § 103(a) as obvious over Sallmann and Ogawa;

FURTHER ORDERED that InnoPharma's Motion for Joinder with IPR2015-01097 is *granted*;

FURTHER ORDERED that IPR2016-00089 is terminated and joined with IPR2015-01097, pursuant to 37 C.F.R. §§ 42.72, 42.122, and based on the conditions stated in the Motion for Joinder, as modified by the Exhibit 3001, and further clarified in this Decision;

FURTHER ORDERED that the Scheduling Order in place for IPR2015-01097 shall govern the joined proceeding;

FURTHER ORDERED that all future filings in the joined proceeding are to be made only in IPR2015-01097;

FURTHER ORDERED that the case caption in IPR2015-01097 for all further submissions shall be changed to add InnoPharma as a named Petitioner after the Lupin Petitioner, and to indicate by footnote the joinder of IPR2016-00089 to that proceeding, as indicated in the attached sample case caption; and

FURTHER ORDERED that a copy of this Decision shall be entered into the record of IPR2015-01097.

FOR PETITIONER INNOPHARMA:

Jitendra Malik
Hidetada James Abe
Lance Soderstrom
ALSTON & BIRD LLP
jitty.malik@alston.com
james.abe@alston.com
lance.soderstrom@alston.com

FOR PETITIONER LUPIN (IPR2015-01097):

Deborah H. Yellin
Jonathan Lindsay
CROWELL & MORING LLP
DYellin@Crowell.com
JLindsay@Crowell.com

PATENT OWNER SENJU:

Bryan C. Diner
Justin J. Hasford
Joshua L. Goldberg
FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, LLP
Bryan.Diner@finnegan.com
Justin.Hasford@finnegan.com
Joshua.Goldberg@finnegan.com

Sample Case Caption

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v.

SENJU PHARMACEUTICAL CO., LTD.,
Patent Owner.

Case IPR2015-01097[1]
Patent 8,754,131 B2

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