

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 IPR2016-00090 (Patent 8,871,813)

PATENT OWNER'S OPPOSITION TO MOTION FOR JOINDER

I. PRELIMINARY STATEMENT OF RELIEF REQUESTED

Patent Owner Senju opposes the motion for joinder submitted on November 2, 2015, by the InnoPharma petitioners (“InnoPharma”) concurrently with its corresponding IPR petition on USP 8,871,813. *InnoPharma Licensing, Inc. v. Senju Pharm. Co., Ltd.*, IPR2015-00090 at Paper 3. The ’813 patent represents one of five patents-in-suit between Senju and InnoPharma, as well as Lupin in parallel District Court proceedings, of which the Board is well aware. The ’813 patent was issued before InnoPharma was sued in District Court by Senju *et al.* and long before InnoPharma filed two other IPRs on two other patents-in-suit. *See* IPR2015-00902; IPR2015-00903. Allowing InnoPharma to join Lupin’s instituted IPR2015-01105 on the ’813 patent (“the Lupin IPR”) would unduly prejudice Senju with piecemeal filings of IPRs designed by InnoPharma to harass Senju. This is particularly true given that InnoPharma has deliberately delayed and staggered its filing of this and two other IPRs, IPR2015-00089 and IPR2015-00091, and has also dragged its feet in pursuing a potential resolution on the joinder issue to the point where it no longer makes sense to join them. In fairness, InnoPharma’s petition should independently go forward or not based the Board’s consideration of that petition in light of Senju’s Preliminary Response. Indeed, joining InnoPharma would not only prejudice Senju, but also condone InnoPharma’s intentional gaming of the system solely to harass Senju.

InnoPharma will argue that it just recently submitted, after almost three months of delay and at the eleventh hour, an email to the Board agreeing to “accept a back-seat, ‘understudy’ role in the joined proceedings.” (Ex. 2007.) But InnoPharma has not actually implemented what it says it agrees to do. Moreover, the lack of specificity in InnoPharma’s “back-seat role” email just creates more questions than it answers, including additional pages for briefing, procedures for conducting depositions, or contingencies in the event of settlement by Lupin. For example, InnoPharma says that it will cease to take a back-seat role should Lupin drop out of the proceedings. What InnoPharma does not address is, if that contingency were to occur, whether InnoPharma would go forward with Lupin’s position and Lupin’s expert or instead seek to resurrect its own positions and its expert who opined on those positions. Shortly before InnoPharma sent its belated “back-seat role” email to the Board, Senju specifically asked InnoPharma to provide its basis for reaching a potential resolution on joinder. InnoPharma ignored Senju’s request and sent its “back-seat role” email to the Board instead.

At this late stage of this phase of the proceeding, InnoPharma’s gamemanship just further prejudices Senju from focusing on the tasks at hand, including preparing for depositions of Lupin’s expert and filing a Patent Owner’s Response in IPR2015-01105, as well as preparing for the upcoming trial in the District Court proceeding. Senju therefore respectfully requests that InnoPharma’s

motion for joinder be denied and that this proceeding independently move to the Board's combined consideration of InnoPharma's petition and Senju's Preliminary Response on the question of institution.

II. BACKGROUND

In November 2014, Senju sued InnoPharma for infringement of the '813 patent; InnoPharma filed its Answer on January 23, 2015. (Ex. 2002; Ex. 2003.) The '813 patent claims, among other things, formulations of bromfenac for ophthalmic administration, sold under the name Prolensa[®], specifically for treatment of pain and inflammation in patients undergoing cataract surgery. (Ex. 2002 at ¶¶ 18-20.) The '813 patent is related to four other patents also directed to formulation of bromfenac—all five of which are involved in IPR proceedings. In March 2015, InnoPharma filed two IPRs against Senju's U.S. Patent No. 8,129,431 (IPR2015-00903) and Senju's U.S. Patent No. 8,669,290 (IPR2015-00902). Lupin later filed for review of the '431 patent (IPR2015-01871, which is now joined with the -00902 proceeding) and the '290 patent (IPR2015-01099).

A. InnoPharma's IPR challenges of Senju's related patents are a piecemeal approach designed to harass Senju.

After filing its first two petitions, InnoPharma sat by and watched while its competitor Lupin initiated an IPR challenging the '813 patent ("the Lupin IPR") on two grounds. IPR2015-01105, Paper 1 (filed April 23, 2015). Lupin also filed challenges against two other members of this patent family, U.S. Patent No.

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8,754,131 (subject of the Lupin’s IPR2015-01097) and U.S. Patent No. 8,927,606 (subject of Lupin’s IPR2015-01100). The Board instituted the Lupin IPR on October 27, 2015, on a single ground of unpatentability. IPR2015-01105, Paper 9 at 16.

But InnoPharma waited in the wings nearly a full year, until after the Lupin IPR was instituted, to initiate its own IPR challenging the ’813 patent (“the InnoPharma IPR”) and request joinder with the Lupin IPR.¹ IPR2016-00090, Paper 3. Despite having access to the Board’s Institution Decision in the Lupin IPR, InnoPharma did not file a “copycat” petition, as petitioners often do in connection with a request for joinder with an instituted petition. Instead, InnoPharma relied on three grounds that were worded differently than Lupin’s two grounds, but in fact relied on the same prior art. InnoPharma also complicated matters by relying on a different expert, Dr. Paul Laskar.

B. InnoPharma made overtures toward working on a plan to join the Lupin IPR, but did not follow the Board’s advice from December 11.

Shortly after InnoPharma filed its motion for joinder, the parties discussed a consolidated schedule including potential schedule extensions to accommodate the newly-filed, second round of InnoPharma IPRs. But, in the December 9, 2015, email from the Board and in the Board’s December 11 Conference Call with the

¹ InnoPharma also filed IPRs challenging the ’131 patent and the ’606 patent.

parties, the Board indicated that it was not inclined to change the June 2016 hearing date for the Lupin IPR and expected that, if this proceeding and the Lupin IPR were joined, then the parties would contend with an “abbreviated discovery schedule.” (Ex. 2001 at 16:17-17:3; *see also* Ex. 2004.)

In view of the Board’s disinclination to move the June hearing in the Lupin IPR, the December 11 Conference Call included extensive discussion of how InnoPharma might streamline its petition to join the InnoPharma IPR to the Lupin IPR with as little disruption as possible. At the time, it was almost two months until Senju’s Patent Owner Response was due in the Lupin IPR. *See* IPR2015-01105, Paper 12. On the December 11 call, the Board and counsel for InnoPharma discussed whether InnoPharma would be willing to drop the additional grounds in InnoPharma’s petition (a proposal that counsel for InnoPharma had yet to discuss with his client at the time) and the feasibility of InnoPharma’s continued reliance on Dr. Laskar in a potentially joined proceeding. (Ex. 2001 at 12-13, 16, 19-21.) While no agreement was reached, the Board suggested that to join the proceedings, InnoPharma would need to modify its Petition to clarify the ground(s) at issue and to change its supporting expert declaration accordingly. (*Id.* at 19:5-22.) Specifically, the Board noted clarity of the record was paramount. (*Id.* at 22:13-19.) In closing, the Board encouraged the parties to meet and confer and return to the Board with a concrete proposal, and extended Senju’s deadline for filing its

Opposition to Joinder as a result. (*Id.* at 30:1-9.)

C. For nearly three months, InnoPharma dragged its feet before finally informing the Board at the eleventh hour that InnoPharma “will agree” to a back-seat role, but without sufficient details.

It was some time until Senju heard from InnoPharma again. Several weeks passed, and on December 29, 2015, Senju actually inquired about whether InnoPharma had made a decision about dropping the additional grounds, in view of the approaching February 1 Patent Owner’s Response deadline in the Lupin IPR. (Ex. 2006 at 5.) More than two weeks later on January 13, InnoPharma finally responded that it was now “prepared to drop” additional Grounds 2 and 3, but still wished to rely on Dr. Laskar. (Ex. 2006 at 4-5.) In view of the deadline for the Patent Owner’s Response (which by then had been extended to February 8, 2015, due to the late availability of Lupin’s expert for cross examination), Senju responded that same day that too much time had passed for InnoPharma to file its substitute petition and realign the Laskar declaration, for the Board to institute and join the proceedings, and for Senju to depose Dr. Laskar and respond to Dr. Laskar’s arguments in its Patent Owner response, then due in less than one month. (Ex. 2006 at 4.) As a result, Senju stated that it would only be possible to join the Lupin and InnoPharma IPRs if InnoPharma would agree to no longer rely on Dr. Laskar and take a secondary role to Lupin in the joined proceedings. (Ex. 2006 at 4.) The parties continued to discuss this matter by phone on January 21 and by

email on January 25 and 26, with Senju maintaining its position that time was short. (Ex. 2006 at 1-3.) On January 26, Senju reiterated its position that unless the issue was fully resolved by February 9 (the due date of this paper), Senju would oppose joinder. (*Id.*) On February 1, InnoPharma appeared to have made no progress toward a concrete plan and again requested clarification of Senju's position "before our discussions with our client." (*Id.* at 1-2.) In response, Senju requested clarification about InnoPharma's specific proposal to the Board on joinder, noting that the burden for establishing the appropriateness of joinder rested with InnoPharma, not Senju. (*Id.* at 1.) Rather than respond to Senju, InnoPharma ignored Senju's request and, on February 4, sent its "back-seat role" email to the Board. (Ex. 2007.) In that email, InnoPharma stated that it "will agree" to "accept a back-seat, 'understudy' role in the joined proceedings." (Ex. 2007 at 1-2.) But InnoPharma's email contained few other details about how and when this "back-seat" plan could come to fruition. (*Id.*)

Meanwhile, the Lupin IPR has proceeded at full steam. Senju is preparing to cross examine Lupin's expert in one week. February 25 is the deadline for Senju to file its Patent Owner Response in the Lupin IPR and then Lupin will have the option to depose Senju's declarants. Moreover, expert discovery continues in the related District Court proceedings, which are scheduled for trial in less than two months on April 4, 2016.

III. THE BOARD SHOULD DENY JOINDER

A. Petitioner bears the burden of establishing that joinder is appropriate.

The America Invents Act permits the Board in its discretion to join multiple IPR proceedings only in certain circumstances. 35 U.S.C. § 315(c); 37 C.F.R.

§ 42.122. A party must request joinder by motion within a month of institution, and the movant bears the burden of establishing that joinder is appropriate. *See id.*; 37 C.F.R. § 42.20(c). A Motion for Joinder must:

- (1) set forth the reasons why joinder is appropriate;
- (2) identify any new grounds of unpatentability asserted in the petition;
- (3) explain what impact (if any) joinder would have on the trial schedule for the existing review; and
- (4) address specifically how briefing and discovery may be simplified.

See Sony Corp. of Am. v. Network-1 Sec. Solutions, Inc., IPR2013-00386, Paper 16 at 4 (July 29, 2013).

The Board determines each joinder request individually, in light of the equities, the facts, and the procedural and substantive issues, including, for example, new claim construction positions. A petitioner seeking joinder has the burden to “explain adequately the impact of those new substantive issues on the patent owner, other petitioners, and the trial schedule of [the earlier IPR].” *NetApp, Inc. v. PersonalWeb Techs., LLC*, IPR2013-00319, Paper 18 at 6 (July 22, 2013).

As discussed below, InnoPharma has not met this burden.

B. Joinder is not appropriate here, because InnoPharma has not set forth a concrete plan for joining the Lupin IPR, and doing so at this late date would unduly prejudice both Lupin and Senju.

At the outset, InnoPharma has not made this process easy by filing a “copycat” petition, as is often done by those wishing to join an instituted IPR. Instead, InnoPharma has created additional work for Senju, Lupin, and the Board by filing a redundant petition and in failing in a timely fashion to devise any detailed plan to align the InnoPharma petition to join it into the on-going Lupin IPR.

Moreover, to complicate matters, InnoPharma indicated some potential willingness to align its petition with the Lupin IPR to facilitate joinder, but actually wasted valuable time—almost three months from early November to present—in finally making its request to the Board. (Ex. 2007.) And when that request was made, it was in a brief email submitted only days before Senju’s papers were due and raised yet more questions. InnoPharma has still not set forth a concrete plan for joining the Lupin IPR or the details for implementing such a plan, as such as additional pages for briefing, procedures for conducting cross examinations, or contingencies in the event of settlement by Lupin. For instance, the parties to the Lupin IPRs have already agreed to limit cross examinations of all declarants to seven hours, and such cross examinations will involve IPR2015-01097, -01099,

and -01100. InnoPharma has provided no specific plan how it would also participate in such cross examinations without prejudicing all involved.

It is InnoPharma's burden—not Senju's or any other party's—to show in a timely manner than joinder is appropriate. As noted above, the Board has indicated that it is not inclined to move the June hearing date and so time to resolve all of these issues is short. (Ex. 2001 at 16-17; *see also* Ex. 2004). Discovery and briefing are well underway in the Lupin IPR. As a result, InnoPharma's February 4 email was too little, too late, and InnoPharma should not be rewarded for its delay with joinder in the Lupin IPR—instead InnoPharma's petition should be considered separately on its own merit for institution.

IV. CONCLUSION

As discussed above, 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. It would also effectively condone InnoPharma's piecemeal filing approach and reward it for sitting on its hands until the last possible moment to file its redundant IPR petition. Accordingly, Senju requests denial of IPR joinder with the Lupin '813 IPR and that InnoPharma's petition should go forward or not based the Board's consideration of that petition in light of Senju's Preliminary Response.

Date: February 9, 2016

Respectfully submitted,

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that a copy of the foregoing **PATENT OWNER'S OPPOSITION TO MOTION FOR JOINDER** was served on February 9, 2016, via email directed to counsel of record for the Petitioner at the following:

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