

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 PRELIMINARY RESPONSE

I. PRELIMINARY STATEMENT OF RELIEF REQUESTED

The petition filed by the InnoPharma petitioners (“InnoPharma”) continues to attack the patentability of U.S. Patent No. 8,871,813 by retreading ground already covered by the Lupin petitioners (“Lupin”) in the IPR2015-01105 proceeding. InnoPharma waited until the last possible moment, after the institution of the Lupin IPR, to file its redundant petition. As explained herein, the InnoPharma petition relies on the same references and the same or substantially the same arguments as the Lupin petition. Congress created the IPR system to provide faster and less costly alternatives to civil litigation to challenge patents, not to multiply disputes or to promote harassment of patent owners. In these circumstances, often the later filing petitioner requests joinder with the earlier proceeding. As explained in Senju’s Opposition to InnoPharma’s motion for joinder, although InnoPharma filed a petition that is substantially the same as the Lupin petition and ostensibly wishes to join the Lupin IPR, it has not only intentionally delayed in filing its piecemeal IPRs, but also unduly procrastinated to potentially resolve the joinder issue. To permit InnoPharma to benefit from its inaction, by instituting the redundant InnoPharma petition, represents a misuse of the IPR system and would be unfair to Senju and burdensome to the Board. Senju thus requests that the Board exercise its § 325(d) power and discretion under 37 C.F.R. § 42.208(b) to deny the InnoPharma petition.

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.)

A. InnoPharma waited until the last possible moment to file its redundant petition.

After responding to Senju's complaint, InnoPharma sat by and watched while its competitor Lupin initiated an IPR challenging the '813 patent. On April 23, 2015, Lupin initiated IPR2015-01105 challenging the '813 patent ("the Lupin IPR"). IPR2015-01105, Paper 1. The Board instituted the Lupin IPR on October 27, 2015, on a single ground of unpatentability, namely obviousness over Sallmann and Ogawa. IPR2015-01105, Paper 9 at 16.

InnoPharma waited until after the Lupin IPR was instituted, nearly a full year, to initiate its own IPR challenging the '813 patent ("the InnoPharma IPR") and request joinder with the Lupin IPR. *InnoPharma Licensing, Inc. v. Senju Pharm. Co., Ltd.*, IPR2016-00090, Paper 3.

B. As InnoPharma readily admits, the InnoPharma petition relies on the same references and substantially the same arguments as the Lupin IPR.

Despite having access to the Board's Institution Decision in the Lupin IPR, InnoPharma did not pattern its first ground after the sole ground instituted by the Board in the Lupin IPR to facilitate joinder, but rather it attempted a second bite at the apple and reformulated the arguments presented by Lupin in the Lupin IPR into three "new" grounds. Nonetheless, as explained herein, the two petitions are the same or substantially the same.

1. The InnoPharma and Lupin petitions rely on the same prior art.

First and foremost, InnoPharma's arguments rely on the *same prior art references* as the Lupin IPR. InnoPharma admits this in its motion for joinder. IPR2016-00090, Paper 3 at 5 n.1. InnoPharma's three grounds, all based on §103 arguments, involve combinations of Ogawa (Ex. 1004), Sallmann (Ex. 1009), Fu (Ex. 1011), and Yasueda (Ex. 1012). IPR2016-00090, Paper 2 at 10. The first three references, Ogawa, Sallmann, and Fu, collectively formed the basis of both of Lupin's grounds of invalidity in the Lupin IPR. IPR2015-01105, Paper 1 at 11. Moreover, Lupin also relied on Yasueda as part of the state-of-the-art discussion to support its contention that polysorbate 80 could be substituted for tyloxapol in ophthalmic formulations. IPR2015-01105, Paper 1 at 10. Importantly, this is the

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very same reason that InnoPharma relies on Yasueda in its Ground 3. *See*

IPR2016-00090, Paper 2 at 47-50.

2. InnoPharma offers no new claim construction, relies on the same art for its state-of-the-art, and relies on the same arguments contesting objective indicia of non-obviousness.

Further mimicking Lupin, InnoPharma did not offer any new claim constructions, relying completely on the Board's decision in the Lupin IPR Institution Decision that no express construction was necessary for any term. IPR2016-00090, Paper 2 at 7. As to its state-of-the-art discussion, InnoPharma relies on nearly all the same references as Lupin, but with different exhibit numbers:

InnoPharma's Exhibits IPR2016-00090	Lupin's Exhibits IPR2016-01105
Ex. 1005 (Desai <i>et al.</i> , USP 5,603,929)	Ex. 1012
Ex. 1017 (Kapin, WO 2002/13804)	Ex. 1036
Ex. 1002 (Hara paper)	Ex. 1006
Ex. 1010 (Guttman paper)	Ex. 1042
Ex. 1030 (Prince paper)	Ex. 1057
Ex. 1006 (Desai <i>et al.</i> , USP 5,558,876)	Ex. 1013
Ex. 1022 (Bergamini paper)	Ex. 1039
Ex. 1035 (Wong, WO 94/15597)	Ex. 1027

As to objective indicia of non-obviousness, InnoPharma, offers the same arguments as Lupin in contesting Senju's ability to establish unexpected results

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regarding tyloxapol's stabilizing effects; long-felt, but unmet, need; copying; and commercial success. *Compare* IPR2016-00090, Paper 2 at 54-60 *with* IPR2015-01105, Paper 1 at 55-59. InnoPharma brings nothing new to the table on any of these issues.

3. InnoPharma's grounds of unpatentability are the same or substantially the same as those presented by Lupin.

In connection with the Lupin IPR, the Board has already considered all of the references and arguments presented by InnoPharma in its petition. After relying on the same main references and nearly identical state-of-the-art references, proposing no new claim construction, and making similar arguments regarding the alleged lack of objective indicia of non-obviousness, InnoPharma sets forth substantially the same arguments, albeit spread over three grounds of unpatentability, rather than only two, as Lupin did in its petition. As a result, the Board should use its discretion to end this serial challenge to the '813 patent as redundant.

a. InnoPharma's Ground 1 is the same as Lupin's Instituted Ground 2.

In its Ground 1, InnoPharma argues that claims 1-27 of the '813 are unpatentable under 35 U.S.C. § 103(a) over Ogawa and Sallmann. InnoPharma's Ground 1 is identical to Lupin's Ground 2, which the Board instituted. The order of the references makes no difference. *See* IPR2014-01041, Paper 19 at 19 (citing

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In re Bush, 296 F.2d 491, 496 (CCPA 1961) for the proposition that “[T]o term one reference primary and the other secondary’ is a distinction ‘of little consequence, and []basing arguments on’ such distinctions is an attempt ‘to make a mountain out of a mole-hill.’”).

In its petition, Lupin argues that Sallmann discloses ophthalmic solutions for treating inflammatory conditions of the eye with the NSAID diclofenac in a solution with tyloxapol as the solubilizer and BAC as the preservative. IPR2015-01105, Paper 1 at 34-35. Lupin further argues that Ogawa describes formulations for ophthalmic solutions containing bromfenac and polysorbate 80. *Id.* at 35. Relying on a “swapping” theory, Lupin concludes that: “[i]t would have been obvious to a [person of ordinary skill in the art (POSA)] to substitute bromfenac for diclofenac in [Sallmann], at least in view of the disclosure of [Ogawa]” and “the POSA would have been motivated to substitute tyloxapol [disclosed in Sallmann] for polysorbate 80 [disclosed in Ogawa].” *Id.* at 37. Likewise, InnoPharma makes the same “swapping” argument. The core of InnoPharma’s argument is that “it would have been obvious to substitute tyloxapol from Sallmann’s Example 2 for polysorbate 80 in Ogawa’s Example 6,” IPR2016-00090, Paper 2 at 19, and “to try to prepare a bromfenac ophthalmic formulation containing tyloxapol,” *id.* at 22. Even InnoPharma admits its Ground 1 is

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“essentially the same” as the instituted ground in the Lupin IPR. IPR2016-00090, Paper 3 at 5. The Board need not review this ground as it is redundant.

b. InnoPharma’s Ground 3 is substantially the same as Lupin’s Instituted Ground 2

InnoPharma’s ground 3 also covers substantially the same arguments as Lupin’s ground 2. Both grounds center on Ogawa, Sallmann, and Yasueda. Lupin discussed Yasueda in its state-of-the-art section, alleging that Yaseuda discloses “tyloxapol was better than polysorbate 80 at solubilizing” in an ophthalmic solution. IPR2015-01105, Paper 1 at 10. InnoPharma merely promotes Yasueda from the state-of-the-art to a secondary reference, arguing that Yasueda “further substantiate[s]” replacing polysorbate 80 with tyloxapol. IPR2016-00090, Paper 2 at 47-48, 50. InnoPharma uses Yasueda in the same way that Lupin did. In its analysis of the ground involving Ogawa and Sallmann, on which the Board later instituted IPR proceedings, the Board specifically discussed the disclosure of Yasueda. IPR2015-01105, Paper 9 at 10. As result, InnoPharma’s Ground 3 does not warrant fresh review by the Board.

c. InnoPharma’s Ground 2 is substantially the same as Lupin’s Non-Instituted Ground 1

In its second ground, InnoPharma relies on Ogawa, Sallmann, and Fu, which is substantially the same as Lupin’s ground 1, which relies on Ogawa and Fu. The Board considered Lupin’s ground 1, but declined to institute on it. Like Lupin,

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InnoPharma relies on Fu and its purported disclosure of greater stability for ethoxylated octylphenols, of which it alleges tyloxapol is one, as further motivation for a proposed modification of Ogawa and Sallmann that involved replacing polysorbate 80 with tyloxapol. *Compare* IPR2016-00090, Paper 2 at 43 *with* IPR2015-01105, Paper 1 at 17-18. In this case, InnoPharma's addition of Sallmann does not change that InnoPharma's Ground 2 is substantially the same as a ground already considered by the Board.

In sum, in the Lupin IPR, the Board had before it Ogawa, Sallmann, Fu, and Yasueda, as well as the common state-of-the-art references listed above, as part of its evaluation of Lupin's grounds of unpatentability. IPR2015-01105, Paper 9. As a result, the Board has already considered all of the references and arguments presented by InnoPharma in its petition and should use its discretion to end this serial challenge to the '813 patent.

III. THE PETITION SHOULD BE DENIED BECAUSE IT REPRESENTS A MISUSE OF THE IPR PROCESS

This petition, one part of a delayed and constant attack on Senju's patents by various petitioners, constitutes litigation gamesmanship rather than usage of IPR for its intended purpose—speedier and more efficient resolution of legitimate defenses. The Board should use its statutory authority to deny petitions like these to prevent misuse.

A. The Board has the discretionary power to deny this petition.

Congress created IPR to “provide faster [and] less costly alternatives to civil litigation to challenge patents”—not to multiply disputes or to promote litigation gamesmanship. (Ex. 2008 at 17.) Further, the bill was designed to “significantly reduce the ability to use post-grant procedures for abusive serial challenges to patents.” (*Id.*) Before the Judiciary Committee of the House of Representatives, Hon. Paul Michel (Ret.), former Chief Judge of the Court of Appeals for the Federal Circuit expressed frustration with the delay in then-current post-issuance PTO proceedings (*e.g.*, *ex parte* reexamination and *inter partes* reexamination) and the need for measures to guard against serial attacks in any new system. “So strong safeguards are needed, a threshold, a clear burden of proof, estoppel effects, and a ban on serial attacks on the same patent are examples of those safeguards.” (Ex. 2009 at 8-9.) When a bill was introduced to try and expand the timing of filing an IPR until after the Markman hearing, Committee Chairman Lamar Smith strongly opposed the amendment, stating: “The *inter partes* proceeding in H.R. 1249 has been carefully written to balance the need to encourage its use while at [the] same time preventing the serial harassment of patent holders.” (Ex. 2010 at 72.)

With this in mind, Congress created a structure aimed at preventing serial filings. The AIA contains numerous provisions evidencing such intent—barring review by those who have already filed declaratory judgment actions, providing for

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stays of civil actions, creating estoppel for petitioners, providing for joinder of interested parties, and, critically, providing broad discretion to the Board to decline institution where “the same or substantially the same prior art or arguments previously were presented to the Office.” 35 U.S.C. § 325(d). Moreover, the statute makes institution discretionary. *See* 35 U.S.C. § 324(a). And recently, the PTO recognized Congress’s requirement that, in addition to the one-year time bar, the AIA required the USPTO to establish regulations “to protect [Patent Owners] from harassment,” including “any . . . improper use of the proceeding.” (Ex. 2011 at 33.) Further, the “Director may take into account whether the same or substantially [the] same prior art or arguments previously were presented to the PTO and may reject the petition on that basis.” (*Id.*)

The PTO must use its regulations to combat the litigation gamesmanship exhibited here where InnoPharma has intentionally delayed filings to craft a petition based on events in other IPRs, timed filings to attempt to cause scheduling difficulties by creating additional rounds of cross examinations, and used this forum to seek multiple bites at the apple for additional arguments after other petitioners have already presented substantially the same arguments. In addition to its § 325(d) powers, the Board has broad discretion to “deny some or all grounds” 37 C.F.R. § 42.208(b). The Board should exercise that discretion here.

B. The Board has already considered the references and arguments in InnoPharma's petition and should decline institution under § 325(d).

Without joinder, InnoPharma's petition represents nothing more than a serial attack on the '813 patent, because InnoPharma's petition relies on the *same prior art* and *the same or substantially the same arguments* as those the Board already considered in the Lupin IPR. Even though InnoPharma filed its petition just prior to the one-year bar, this action alone should not insulate it and its redundant arguments from the Board's discretion. The Board should decline to reconsider references and arguments that it already fully considered.

IV. CONCLUSION

For the reasons discussed above, the Board should use its § 325(d) powers and discretion under 37 C.F.R. § 42.208(b), to deny the InnoPharma petition on two independent grounds: (1) because the InnoPharma's arguments have been presented to the Board before in IPR proceedings already instituted and (2) because the Board should not condone InnoPharma's misuse of IPR as a vehicle for litigation gamesmanship and harassment.

Respectfully submitted,

Date: February 9, 2015

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CERTIFICATE OF SERVICE

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

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