

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 IPR2016-00091 (Patent 8,927,606)

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. 8,927,606 by retreading ground already covered by the Lupin petitioners (“Lupin”) in the IPR2015-01100 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 May 2015, Senju sued InnoPharma for infringement of the '606 patent; InnoPharma filed its Answer on August 17, 2015. (Ex. 2002; Ex. 2003.) The district court case involving the '606 patent was consolidated with the then-ongoing litigation between Senju and InnoPharma involving the '813 and '131 patents, among others. (Ex. 2005.) The '606 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 ¶¶ 23-25.)

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

On April 23, 2015, Lupin initiated IPR2015-01105 challenging the '606 patent (“the Lupin IPR”). IPR2015-01105, Paper 1. But, InnoPharma sat by and watched while its competitor Lupin challenged the '606 patent. The Board instituted the Lupin IPR on October 27, 2015, on a single ground of unpatentability, namely obviousness over Sallmann and Ogawa. IPR2015-01100, Paper 9 at 17.

InnoPharma waited until after the Lupin IPR was instituted to initiate its own IPR challenging the '606 patent (“the InnoPharma IPR”) and request joinder with the Lupin IPR. *InnoPharma Licensing, Inc. v. Senju Pharm. Co., Ltd.*, IPR2016-00091, 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. IPR2016-00091, 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). IPR2016-00091, Paper 2 at 11. The first three references, Ogawa, Sallmann, and Fu, collectively formed the basis of both of Lupin’s grounds of invalidity in the Lupin IPR. IPR2015-01100, 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. IPR2015-01100, 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*

IPR2016-00091, Paper 2 at 48-50.

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. IPR2016-00091, 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 IPR2016-00091 | Lupin's Exhibits IPR2016-01100 |
|--|---|
| 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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