

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

LUPIN LTD., and LUPIN PHARMACEUTICALS INC.
Petitioners

v.

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

IPR2015-01099 (US Patent No. 8,669,290)

PETITIONERS' MOTION TO EXPUNGE

I. Introduction

Pursuant to 37 C.F.R. § 42.56, Petitioner Lupin submits this motion to expunge the previously-sealed versions of: (1) Exhibit 2109 and (2) Exhibit 2082. Pursuant to the Board’s Order on September 15, 2016 (Paper 70), Petitioner is authorized to file a motion to expunge confidential information from the records within 35 days of the entry of the Final Written Decision.¹ Patent Owner does not oppose this motion.

II. Legal Standard

“After denial of a petition to institute a trial or after final judgment in a trial, a party may file a motion to expunge confidential information from the record.” 37 C.F.R. § 42.56. Under the rules, “information will be made public where the existence of the information is referred to in a decision to grant or deny a request to institute review or is identified in a final written decision following a trial.” Trial Practice Guide, 77 Fed. Reg. at 48,761. Conversely, where confidential information is not relied on by the Board, that information will generally be expunged. *Volkswagen Grp. of Am. v. Emerachem Holdings, LLC*, IPR2014-01556, Paper No. 61, at 2 (expunging confidential papers where “our consideration of the Subject Papers and Exhibits was not necessary for our determination of

¹ Sealed copies of Exhibit 2109 and Exhibit 2082 appear to have been already expunged by the Board, however, in an abundance of caution Petitioner hereby moves to expunge Exhibit 2109 and Exhibit 2082.

whether the challenged claims of the '911 patent were patentable.”). In other *inter partes* review proceedings, the Board has held that confidential research, development, or commercial information should remain under seal. *See Otter Products, LLC, Petr.*, IPR2014-01464, Paper No. 28, pp. 2-4 (PTAB Aug. 27, 2015); *Greene’s Energy Grp., LLC, Inc. v. Oil States Energy Svcs., LLC*, IPR2014-00216, Paper 27, at 5 (PTAB Sept. 23, 2014); *Gnosis, et al. v. South Alabama Med. Science Found.*, IPR2013-00117, Paper 39, at 2 (PTAB Oct. 31, 2013); *Unified Patents Inc. v. Dragon Intellectual Property, LLC*, IPR2014-01252, Paper 40, at 7 (PTAB Feb. 27, 2015); *Microsoft Corp. v. SurfCast, Inc.*, IPR2013-00292, Paper 58, at 4 (PTAB Apr. 24, 2014). In *Greene’s Energy Group*, the Board held that portions of an exhibit containing confidential financial information should remain under seal where the proposed redactions were reasonable and the thrust of the underlying argument or evidence was clearly discernible from the redacted versions. *Greene’s Energy Grp.*, IPR2014-00216, Paper 27, at 5. Moreover, in *Otter Products*, the Board held that it was appropriate to expunge select exhibits in support of redacted papers where the public release of such exhibits “has not been published or other made available to the public,” and where public disclosure of the exhibits “would be commercially harmful.” *Otter Products*, IPR2014-01464, Paper No. 28, at 4. Public disclosure of the information that the parties seek to have expunged would be commercially harmful as explained further below.

Further, such information is unnecessary to understand the thrust of the Board's final written decision.

III. Confidential Documents that Should be Expunged from the Record

Lupin moves to expunge the sealed versions of (1) Exhibit 2109 that contains Lupin's Abbreviated New Drug Application ("ANDA") and (2) Exhibit 2082 (Declaration of Robert O. Williams, III, Ph.D.) that cite to or substantially describe the confidential information in Exhibit 2109. Because public disclosure of the contents of these documents, or descriptions of those contents, would disclose confidential business information in a highly competitive market, Petitioner requests that the sealed versions of Exhibit 2109 and Exhibit 2082 be expunged. This information has not been published and is not publicly available.

A. Exhibit 2109

As explained in Petitioner's motion to seal (Paper 63) the sealed version of Exhibit 2109 is Lupin's ANDA, which was filed confidentially with the FDA in order to obtain FDA approval to market Lupin's generic pharmaceutical product. The information the parties seek to seal contains Lupin's highly sensitive, confidential development information and technical, business information. Lupin's product has not yet been marketed and remains confidential.

This exhibit is not cited or discussed in the Board's Final Written Decision (Paper 69), therefore, the public can understand the thrust of the Board's decision

without resorting to the information contained in Exhibit 2109. If Lupin's confidential information is made public, Lupin's competitors could exploit its confidential information and gain an unfair competitive advantage over Lupin. Accordingly, Petitioner requests that Exhibit 2109 be expunged.

B. Exhibit 2082

As explained in Petitioner's motion to seal (Paper 63), the Williams Declaration (Exhibit 2082) describes the confidential information contained in the ANDA (Exhibit 2109) in connection with secondary considerations of nonobviousness. In particular, paragraph 201 cites to Exhibit 2109, and the chart at paragraph 234 shows the generic bromfenac product components described in Exhibit 2109, and the Final Written Decision (Paper 69) does not cite or rely on paragraphs 201 or 234 of Exhibit 2082. If Lupin's confidential information is made public, Lupin's competitors could exploit its confidential information and gain an unfair competitive advantage over Lupin. A redacted copy of Exhibit 2082 has been filed and will remain in the record, so expunging the aforementioned confidential information will not impede public understanding of the underlying arguments and evidence. Accordingly, Petitioner requests that the sealed copy of Exhibit 2082 be expunged.

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