

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

LUPIN LTD. and LUPIN PHARMACEUTICALS INC.,
Petitioner,

v.

SENJU PHARMACEUTICAL CO., LTD.,
Patent Owner.

Case IPR2015-01099
Patent 8,699,290 B2

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

OBERMANN, *Administrative Patent Judge*.

ORDER

Granting Petitioner's Motion to Seal and
Granting Petitioner's Motion to Enter Default Protective Order
37 C.F.R. §§ 42.14 and 42.54

In an Order dated June 21, 2016, the Board denied Patent Owner's request to enter a Stipulated Protective Order. Paper 61. That same day, the Board denied without prejudice all pending motions to seal documents. Papers 57–61. We entered a Final Written Decision on September 12, 2016. Paper 69.

On July 29, 2016, Petitioner filed a combined Motion to Seal and Motion to Enter Default Protective Order. Paper 63 (“Motion” or “Mot.”). This Order addresses that Motion.

Granting Motion to Seal

Petitioner seeks to seal Exhibit 2109, described as “Lupin’s ANDA [Abbreviated New Drug Application], which was filed confidentially with the FDA [Food and Drug Administration] in order to obtain FDA approval to market Lupin’s generic pharmaceutical product.” Mot. 5. Petitioner states that Exhibit 2109 “contains Lupin’s highly sensitive, confidential development information and technical, business information.” *Id.* Petitioner further states that if the asserted “confidential information is made public, Lupin’s competitors could exploit its confidential information and gain an unfair competitive advantage over Lupin.” *Id.* Petitioner further identifies Exhibit 2109 as “an excerpt of the much larger Lupin ANDA,” arguing that “redaction of this excerpt would not be practical.” *Id.* Petitioner, thus, requests “that Exhibit 2109 be sealed in its entirety.” *Id.*

Petitioner also seeks to seal portions of a declaration of Dr. Robert O. Williams, III (Ex. 2082). *Id.* Specifically, Petitioner seeks to seal paragraphs 201 and 234, which are alleged to describe “the confidential information contained in the ANDA in connection with secondary

considerations of non-obviousness.” *Id.* Petitioner states that, in particular, paragraph 234 “shows the generic bromfenac product components described in Exhibit 2109,” discussed above. *Id.*

In addition, Petitioner moves to seal page 50 of Patent Owner’s Response (Paper 24) because “the third sentence of the paragraph beginning on page 50” discusses “Lupin’s ANDA product and cites to paragraph 201 of [Exhibit 2082].” Mot. 6. Petitioner avers that sealing is necessary to protect “confidential business terms in a highly competitive market.” *Id.*

We previously denied a joint motion to seal these same documents. Paper 58, 3. We denied that prior request because a protective order had not been entered, and the parties had not proposed an adequate proposed protective order. *Id.* We determined, however, that “the parties have established that” the materials sought to be sealed “represent or contain confidential information.” *Id.*

As explained below, our prior concerns about the lack of an adequate protective order have been addressed. Specifically, upon Petitioner’s unopposed request, we enter a suitable protective order in this proceeding. Accordingly, based on our prior determination that the parties have established good cause for sealing the documents that are the subject of the instant request, we *grant* Petitioner’s request to seal Exhibit 2109 in its entirety, portions of Exhibit 2082 (namely, paragraph 201 and 234), and page 50 of Patent Owner’s Response.

Granting Motion to Enter Default Protective Order

Previously, the Board determined that a proposed Stipulated Protective Order jointly submitted by the parties was “not in an adequate

form for entry.” Paper 61, 3. In the instant Motion, Petitioner requests “entry of the Default Protective Order.” Mot. 3. Petitioner states that “Patent Owner does not oppose” the request. *Id.* Accordingly, we grant Petitioner’s request for entry of the Board’s Default Protective Order, which shall apply to confidential information filed in this proceeding. The parties are directed to enter a copy of the Board’s Default Protective Order as an exhibit in this proceeding within five (5) business days.

Requiring a Joint Stipulation and Counsel Certification

Within thirty five (35) days after entry of the Final Written Decision, Patent Owner and Petitioner shall file a Joint Stipulation that identifies with particularity the exact portions (by page or paragraph number) of all sealed papers and exhibits that are cited in the Final Written Decision. The Joint Stipulation shall include a Counsel Certification attesting to the accuracy and completeness of the Joint Stipulation, including a statement verifying that the exact portion of each paper and exhibit cited in the Final Written Decision is identified (by page or paragraph number) in the Joint Stipulation.

We specifically provided the parties advance notice “that information subject to a protective order will become public if identified in a final written decision in this proceeding.” Paper 61, 4. Further, the Rules of Practice for Trial Before the Patent Trial and Appeal Board (“Rules of Practice”) provide that:

Confidential information that is subject to a protective order ordinarily will become public 45 days after denial of a petition to institute a trial or 45 days after final judgment in a trial. *There is an expectation that 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 a review or is identified in a final*

written decision following a trial. A party seeking to maintain the confidentiality of information, however, may file a motion to expunge the information from the record prior to the information becoming public.

77 Fed. Reg. 48756, 48761, Section I.E.6. (Aug. 14, 2012) (emphasis added). There is a presumption, therefore, that any confidential information cited in the Final Written Decision shall become public forty five (45) days after entry of the Final Written Decision.

A strong public interest favors maintaining a complete and understandable record of the patent history, including the factual basis for the Board's findings and the intelligibility of the Final Written Decision. By placing confidential information before the Board, Petitioner accepted the risk that the information will become public if relied upon in the Final Written Decision. Rules of Practice, 77 Fed. Reg. 48756, 48761, Section I.E.6. (Aug. 14, 2012) ("There is an expectation that information will be made public where the existence of the information . . . is identified in a final written decision following a trial.").

Accordingly, all papers and exhibits identified in the Joint Stipulation shall be unsealed and made publicly available forty five (45) days after entry of the Final Written Decision, unless a revised public version of the paper or exhibit, conforming to the following requirements, is filed no later than thirty five (35) days (that is, ten days prior to the date set for unsealing) after entry of the Final Written Decision. Specifically, a party may prevent the unsealing of any paper or exhibit identified in the Joint Stipulation by filing, no later than thirty five (35) days after entry of the Final Written Decision, a revised public version of the paper or exhibit in which each page or paragraph cited in the Final Written Decision is left unredacted. Material

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