

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 8,669,290 B2

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

FRANKLIN, *Administrative Patent Judge*.

DECISION

*Denying Patent Owner's Motion to Seal and Denying Entry of
the Proposed Stipulated Protective Order
37 C.F.R. §§ 42.14 and 42.54*

I. INTRODUCTION

Patent Owner filed a combined Motion to Seal and Motion to Enter Stipulated Protective Order. Paper 25 (“Mot.”). Patent Owner seeks to seal the following exhibits and papers: the entirety of excerpts from Patent Owner’s New Drug Application (“NDA”) (Exs. 2096, 2102, 2103, 2110, 2251, and 2291–2293); three presentations related to Patent Owner’s research and development of the patented formulation (Exs. 2220, 2226, and 2296); testimony related to the market share of Patent Owner’s product in a related district court case (Ex. 2258); testing reports and materials documenting the testing methods of third-party test companies (Exs. 2267–2278, 2286, 2294); the transcripts of the testimony in related Cases IPR2015-00902 and -00903 of Dr. Paul Laskar (Ex. 2114) and Dr. Jayne Lawrence (Ex. 2316), portions of Patent Owner’s Response (Papers 22 and 23); and portions of the declarations of Drs. Adam C. Myers (Ex. 2126), Daryl S. Paulson (Ex. 2128), Robert O. Williams (Ex. 2082), Stephen G. Davies (Ex. 2105), William B. Trattler (Ex. 2116), and John C. Jarosz (Ex. 2130) that cite or substantially describe the above categories of documents sought to be sealed. Mot. 1. Patent Owner asserts that Petitioner does not oppose the motion. *Id.* at 2.

The Stipulated Protective Order (“proposed order”) differs from the Board’s default protective order set forth in the Office Patent Trial Practice Guide (“Trial Practice Guide”), 77 Fed. Reg. 48,756, 48,771 (Aug. 14, 2012) in a number of ways, such as including two additional categories of confidential information, i.e., “PROTECTIVE ORDER MATERIAL – BOARD’S EYES ONLY” and “PROTECTIVE ORDER MATERIAL – FED R. EVID 615.” Mot. 1, App’x A at 2; *see* Paper 32 (redlined version of

the proposed order showing modifications to the Board’s default protective order).

For the reasons described in the following discussion, we *deny* the Motion to Seal and we *deny* entry of the proposed order without prejudice.

II. DISCUSSION

A. Proposed Order

When a party seeks entry of a protective order that differs from the default protective order set forth in the Trial Practice Guide, it is essential that the modifications made and the effect of those modifications are clear. Based upon our review, the proposed order is not in an adequate form for entry. In particular, the proposed order recites variations of the term “party” with apparently different meanings. In some instances the term refers to either Petitioner or Patent Owner. For example, the proposed order states “Nothing in this Order prevents any Party from challenging a confidentiality designation to any Exhibit by raising the matter with the Board.” *Id.* at 5 n.2. In other instances, the term is defined in a manner that apparently excludes the Petitioner in the captioned cases, i.e., “(A) Parties. Persons who are owners of a patent involved in the proceeding and other persons who are identified as a real party-in-interest in any Related Proceeding.” *Id.* at 4, 6. Those inconsistencies create an ambiguity in the proposed order that prevents us from entering it.

Further, the proposed order includes a category of confidential information that may be marked as “PROTECTIVE ORDER MATERIAL – FED R. EVID. 615.” It is unclear whether that category of confidential information is necessary at this stage in the proceeding because the discovery phase has concluded. If the parties determine that such category is

still necessary, that need should be explained. Also, the proposed order states that such disclosures shall not occur “until after such time as the Board has lifted the Rule on Witnesses under Fed. R. Evid. 615” *Id.* at 3. We do not contemplate, however, “lift[ing] the Rule on Witnesses.” Rather, the proposed order should describe sufficiently when and/or under what circumstances the disclosure restriction shall expire, if that is the intent of the parties, without requiring an additional order by the panel. Similarly, after an expiration of the Fed. R. Evid. 615 disclosure restriction, any request to disclose such material to an expert should not be made contingent “upon the formal request of any Party to the Board or upon a joint request by the Parties to the Board’s administrative staff.” *See id.* at 4. Such requests, if required, should be directed to the party from whom the disclosure is sought.

Additionally, rather than reciting that nothing in the proposed order “shall amend or alter the Stipulated Discovery Confidentiality Order” filed in the cited district court litigation, we recommend that provision state, more precisely, that the proposed order shall apply only to the captioned proceedings.

The parties are reminded that information subject to a protective order will become public if identified in a final written decision in this proceeding, and that a motion to expunge the information will not necessarily prevail over the public interest in maintaining a complete and understandable file history. *See Office Patent Trial Practice Guide, 77 Fed. Reg. 48,756, 48,761 (Aug. 14, 2012).*

B. Motion to Seal

“There is a strong public policy for making all information filed in a quasi-judicial administrative proceeding open to the public, especially in an *inter partes* review which determines the patentability of claims in an issued patent and therefore affects the rights of the public.” *Garmin Int’l v. Cuozzo Speed Techs., LLC*, IPR2012-00001, slip op. at 1–2 (PTAB Mar. 14, 2013) (Paper 34). A motion to seal may be granted for good cause. 37 C.F.R. § 42.54. The moving party bears the burden of showing that there is good cause for the relief requested, including why the information is appropriate to be filed under seal. 37 C.F.R. §§ 42.20, 42.54. The Office Patent Trial Practice Guide notes that 37 C.F.R. § 42.54 identifies confidential information in a manner consistent with Federal Rule of Civil Procedure 26(c)(1)(G), which provides for protective orders for trade secret or other confidential research, development, or commercial information. 77 Fed. Reg. at 48,760. Until a motion to seal is decided, documents filed with the motion shall be sealed provisionally. 37 C.F.R. § 42.14.

Patent Owner requests that we seal four categories of exhibits and portions of its Patent Owner Response and supporting declarations citing or describing those exhibits. Mot. 7.

As discussed, we have *denied* entry of the proposed order without prejudice. Thus, the motion to seal is also *denied* without prejudice, as it is based upon an unacceptable protective order. Under the circumstances, we exercise our discretion to maintain the papers and exhibits cited by Patent Owner under a provisional seal, in the manner requested, through July 31, 2016, to (a) permit Patent Owner and Petitioner to resolve the issues that we have identified regarding the proposed order in an amended proposed order,

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