Paper 58 Entered: June 21, 2016

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

LUPIN LTD., LUPIN PHARMACEUTICALS INC., INNOPHARMA LICENSING, INC., INNOPHARMA LICENSING LLC, INNOPHARMA INC., INNOPHARMA LLC, MYLAN PHARMACEUTICALS INC., and MYLAN INC.,

Petitioners,

v.

SENJU PHARMACEUTICAL CO., LTD.,

Patent Owner.

Case IPR2015-01097 (Patent 8,754,131 B2)¹ Case IPR2015-01100 (Patent 8,927,606 B1)² Case IPR2015-01105 (Patent 8,871,813 B2)³

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

FRANKLIN, Administrative Patent Judge.

DECISION⁴

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

⁴ This Decision relates to and shall be filed in each referenced case.



¹ Case IPR2016-00089 has been joined with this proceeding.

² Case IPR2016-00091 has been joined with this proceeding.

³ Case IPR2016-00090 has been joined with this proceeding.

I. INTRODUCTION

In each of the captioned proceedings, Patent Owner filed a combined Motion to Seal and Motion to Enter Stipulated Protective Order. Paper 26⁵ ("Mot."). Thereafter, Petitioners and Patent Owner jointly filed, in each proceeding, an Amended Proposed Stipulated Protective Order ("proposed order"), Paper 29, to add the joined Petitioners InnoPharma Licensing, Inc., InnoPharma Licensing LLC, InnoPharma Inc., and InnoPharma LLC to the caption, *see* Paper 26, 15 n.2 (explaining that the Stipulated Protective Order would be refiled after joinder). This Decision addresses Patent Owner's Motion to Seal (Paper 26) and the jointly filed proposed order (Paper 29).

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.

⁵ In this Decision, we reference only citations to exemplary papers filed in IPR2015-01100. Exhibit numbers are the same in each captioned proceeding.



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 Amended Proposed 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.



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