

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC. and AMNEAL
PHARMACEUTICALS LLC,
Petitioner

v.

YEDA RESEARCH & DEVELOPMENT CO. LTD.,
Patent Owner

Case No. IPR2015-00644
Patent 8,399,413

PATENT OWNER'S MOTION TO EXPUNGE CONFIDENTIAL EXHIBITS

I. INTRODUCTION

Pursuant to 37 C.F.R. § 42.56, Patent Owner Yeda Research & Development Co., Ltd., (“Patent Owner” or “Yeda”) respectfully submits this Motion to Expunge Exhibits 2108-2114, 2120-2122, and the Grabowski Declaration (Exhibit 2133) (“the Confidential Exhibits”) from the record. These exhibits contain confidential information of a third party, IMS Health Inc. (“IMS Health”).

According to the Office Patent Trial Practice Guide, 77 Fed. Reg. 48756 (Aug. 14, 2012) (“Trial Practice Guide”), confidential information that is subject to a protective order ordinarily would become public 45 days after final judgment in a trial. Trial Practice Guide at 48760-61. A party seeking to maintain the confidentiality of information may file a motion to expunge the information from the record prior to the information becoming public. *Id.*; 37 C.F.R. § 42.56. In this case, 45 days after final judgment falls on Saturday, October 8, 2016, and so the confidential information would ordinarily become public on Monday, October 10, 2016. Since Monday, October 10, 2016, is Columbus Day, a Federal Holiday, the confidential information in this case is scheduled to become public on Tuesday, October 11, 2016. Because the Confidential Exhibits contain confidential information, Patent Owner respectfully requests that the Board rule on this motion prior to the Confidential Exhibits becoming a part of the public record in this case.

Alternatively, Patent Owner requests that the Board issue an interim order delaying the public release of the Confidential Exhibits until such time that the Board can rule on Patent Owner's Motion to Expunge.

II. PROCEDURAL BACKGROUND

On November 20, 2015, Patent Owner and Petitioner in this proceeding jointly requested that the Board enter the Board's Default Protective Order. (Paper 25.) On that same day, Patent Owner moved to seal portions of Exhibits 2108-2114, 2120-2122, and 2133, which all contain trade secrets and confidential business information of a non-party, IMS Health. (Paper 26, "Motion to Seal.") On February 12, 2016, the Board ordered that the Default Protective Order be entered in this case (paper 52), and also granted Patent Owner's motion to seal the Confidential Exhibits (paper 53, "Decision"), finding that Patent Owner had shown good cause for sealing the redacted portions of those declarations. Redacted versions of the Confidential Exhibits are publically available on the docket.

III. APPLICABLE LEGAL STANDARDS

Pursuant to 35 U.S.C. § 316(a)(7), "confidential information" is protected from disclosure. 35 U.S.C. § 316(a)(7) ("The Director shall prescribe regulations...providing for protective orders governing the exchange and submission of confidential information."). Confidential information should be

defined in a manner consistent with Fed. R. Civ. P. 26(c)(1)(G). Trial Practice Guide at 48760.

Granting a motion to seal confidential information requires a showing of “good cause.” 37 C.F.R. § 42.54. The same standard applies to a motion to expunge “confidential information” under 37 C.F.R. § 42.56 after final judgment in a trial. *RPX Corp. v. Virnetx Inc.*, IPR2014-00171, Paper 62 at 3 (PTAB Sept. 9, 2014). The movant generally has the burden of showing entitlement to the requested relief. 37 C.F.R. § 42.20(c); *RPX Corp* at 3.

IV. GOOD CAUSE EXISTS TO EXPUNGE THE CONFIDENTIAL EXHIBITS FROM THE RECORD

The Board already agreed that there is good cause for the confidential information to be sealed. As Patent Owner stated in its Motion to Seal and as the Board agreed in its Decision granting that motion, the Confidential Exhibits “include proprietary data provided by IMS Health, a third party, concerning sales, prescriptions, and promotional spending concerning Copaxone® 40 mg/mL.” Decision at 2, citing Motion to Seal at 2. Further, “IMS Health represents that IMS data retains its value to IMS only when access to the data is restricted. IMS also represents that it owes contractual duties of confidentiality to its sources.” *Id.* Moreover, “interested members of the public can obtain the data in question directly from IMS Health (with any appropriate fee).” *Id.*

According to the Practice Trial Guide, the rule regarding lifting the seal from any exhibits that had been filed under seal in an IPR “balances the needs of the parties to submit confidential information with the public interest in maintaining a complete and understandable file history for public notice purposes.” Trial Practice Guide at 48761. In this case, disclosure of the information in the Confidential Exhibits would detrimentally impact a non-party to this proceeding, which is contractually obligated to maintain the confidentiality of its data, and which sells its data to interested members of the public for an appropriate fee. As the Board noted in its Decision, any interested member of the public may access the sealed information directly from IMS, for an appropriate fee. Thus, the public interest in maintaining a complete and understandable file history may therefore be met in this case without the filed documents becoming public and the attendant negative impact to a non-party.

Further, the Board’s Final Written Decision incorporates only a single number that is redacted from the entirety of the public versions of the Confidential Documents. Final Written Decision, Paper 86 at 28. This number is therefore now part of the public record. The remainder of the redacted material was not incorporated into the Board’s Final Written Decision and its publication is therefore not necessary to meet the public interest in maintaining a complete and

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