UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

HOPEWELL PHARMA VENTURES, INC.,
Petitioner,

v.

MERCK SERONO SA,
Patent Owner.

Case IPR2023-00480

U.S. Patent 7,713,947

PATENT OWNER'S UNOPPOSED MOTION TO SEAL AND FOR ENTRY OF DEFAULT PROTECTIVE ORDER

I. INTRODUCTION

Under 37 C.F.R. §§ 42.54 and 42.14, Patent Owner, Merck Serono SA, hereby moves to seal Exhibits 2048, 2049, and 2050 submitted with the Patent Owner's Response on December 21, 2023. Good cause to seal these documents exists because they include highly confidential, competitively sensitive information of Patent Owner, which Patent Owner designated as "PROTECTIVE ORDER MATERIAL." Patent Owner further moves for entry of the Board's Default Protective Order. Petitioner, Hopewell Pharma, Ventures, Inc., does not oppose Patent Owner's Motion to Seal and has consented to the Board's Default Protective Order.

II. AUTHORIZATION FOR THIS MOTION

Prior Board authorization is not required for "motions where it is impractical for a party to seek prior Board authorization." Consolidated Trial Practice Guide (Nov. 20, 2019) (the "Consolidated Trial Practice Guide"), p. 37. "Motions where it is not practical to seek prior Board authorization include motions to seal. . . ." *Id.*

III. CERTIFICATION OF CONFERENCE

Under 37 C.F.R. § 42.54, Patent Owner, through the undersigned, hereby certifies that it has conferred with Petitioner through counsel on

November 22 and 27, 2023 and December 19, 2023 in good faith regarding this motion. Petitioner does not oppose Patent Owner's Motion to Seal and has agreed to entry of the Default Protective Order.

IV. GOOD CAUSE EXISTS FOR SEALING EXHIBITS 2048, 2049, AND 2050

The Board may issue protective orders for good cause to protect a party from disclosing confidential information. Consolidated Trial Practice Guide, pp. 19-20; 37 C.F.R. § 42.54. In deciding whether to grant a motion to seal, the Board must find "good cause," and must "strike a balance between the public's interest in maintaining a complete and understandable file history and the parties' interest in protecting truly sensitive information." *Garmin International, Inc. et al. v. Cuozzo Speed Technologies LLC*, IPR2012-00001, Paper 36 at 4 (P.T.A.B. April 5, 2013). "Confidential Information" is identified in a manner consistent with Fed. R. Civ. P. 26(c)(1)(G), "which provides for protective orders for trade secret or other confidential research, development, or commercial information." *Id*.

Good cause for sealing material can be established by demonstrating that the balance of the following considerations favors sealing the material: whether (1) the information sought to be sealed is truly confidential, (2) a concrete harm would result upon public disclosure, (3) there exists a genuine

need to rely in the trial on the specific information sought to be sealed, and (4), on balance, an interest in maintaining confidentiality outweighs the strong public interest in having an open record. *See Argentum Pharms. LLC v. Alcon Research, Ltd*., IPR2017-01053, Paper 27 at 4 (P.T.A.B. January 19, 2018).

Exhibits 2048 (the "IVAX-Serono Agreement"), 2049 ("December 17, 2003, Briefing Document"), and 2050 ("August 27, 2003, Meeting Minutes") contain confidential research, development, or business information designated as "PROTECTIVE ORDER MATERIAL" under the Default Protective Order that was agreed-upon by the parties. The balance of the *Argentum* factors favors sealing Exhibits 2048, 2049, and 2050.

a. Exhibits 2048, 2049, and 2050 Contain Confidential Information

The information Patent Owner seeks to seal in Exhibits 2048, 2049, and 2050 is "truly confidential." *See* Fed. R. Civ. P. 26(c)(1)(G). Exhibits 2048, 2049, and 2050 contain confidential technical information regarding drug development and/or financial and business information of Patent Owner and non-parties to this proceeding. The information contained in Exhibits 2048, 2049, and 2050 is subject to non-party confidentiality obligations (*e.g.*, with development partners and Patent Owner's affiliate) or would cause

competitive business harm to Patent Owner if publicly disclosed.

First, the IVAX-Serono Agreement (EX 2048) is a true and redacted[1] copy of the highly confidential joint development and license agreement between Ares Trading S.A., an affiliate of Patent Owner, and IVAX International GmBH ("IVAX")[2] dated October 16, 2002. The IVAX-Serono Agreement contains Patent Owner's and non-party Ares Trading S.A. and IVAX's highly confidential commercial terms concerning the joint research and development obligations for investigational cladribine oral formulations, dosing regimens, and clinical studies that have not been made publicly available. *See* Ex. 2048. Moreover, the IVAX-Serono Agreement contains confidentiality provisions requiring Ares Trading S.A. and its affiliate, Patent Owner, to maintain the confidentiality of the agreement terms. To the best of

[1] Ex. 2048 contains minimal redactions of specific monetary values which are highly sensitive to Patent Owner, its non-party affiliate Ares Trading S.A., and non-party IVAX, which are not relevant to any issue in dispute in this proceeding.

[2] In January 2006, IVAX became part of Teva Pharmaceutical Industries Ltd. ("Teva") through the acquisition of IVAX Corporation by Teva. References to IVAX also refer to Teva as its successor.

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