UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

TWI PHARMACEUTICALS, INC.,
Petitioner,

v.

MERCK SERONO SA,
Patent Owner.

Case IPR2023-00050

U.S. Patent 8,377,903

PATENT OWNER'S REPLY TO PETITIONER'S OPPOSITION TO PATENT OWNER'S MOTION TO SEAL AND FOR ENTRY OF DEFAULT PROTECTIVE ORDER

I. Introduction

Patent Owner satisfied its burden to establish that the contents of Exhibits 2048-2050 are "truly confidential." Moreover, good cause exists to protect and seal that material. The Motion to Seal should be granted.

II. There is Good Cause to Seal the JRA (Exhibit 2048), Briefing Document (Exhibit 2049), and Internal Business Notes (Exhibit 2050)

Good cause to seal material is determined on the balance of four factors. Paper 26 (Patent Owner's Motion to Seal) at 3-4. Petitioner's opposition challenges only one: whether the sealed material is "truly confidential." But Patent Owner satisfied this factor by explaining that these documents contain confidential technical, financial, and commercial information. *See id*. at 4-10.

The documents Petitioner seeks to unseal relate to its challenge under §102(e) and help to establish the disclosure set out in the Bodor reference on which Petitioner relies is not "by another." These materials are not publicly available and contain sensitive business, licensing, commercial, and research and development information of Patent Owner, Patent Owner's predecessor, and third parties. *See* Paper 26 at 3-8. These types of documents are routinely considered confidential and sealed. *See, e.g., Mylan Lab'ys Ltd. v. Aventis Pharm. S.A.*, IPR2016-00712, Paper 35 at 3 (granting motions to seal exhibits containing market analyses and meeting minutes related to regulatory plans and clinical trials); *Associated British Foods PLC et al. v. Cornell Rsch. Found*., IPR2019-00577, Paper 129 at 3-4

(granting motion to seal "grant applications, a record of invention, and license agreements"); *Celltrion, Inc. v. Genentech, Inc.*, IPR2016-01667, Paper 20 at 3 (granting motion to seal exhibits including "'non-public research and development information in the form of proprietary clinical and scientific data concerning [the drug product], and confidential information about drug development and regulatory approval strategies.'").

Turning first to the confidential Joint Research Agreement ("JRA") in Exhibit 2048, that document establishes the relationship between Patent Owner's predecessor and third parties that led to the disclosure upon which Petitioner relies. On its face, the JRA establishes why it is appropriately sealed in this proceeding: It explicitly states that the parties can neither disclose the JRA nor its performance without permission. *See* Exhibit 2048 at 29. It further demands that the involvement of certain entities may not be disclosed. *Id*. The JRA further includes confidential information related to commercial business information (e.g., research and development information, financial data, and licensing terms and practices) that could have significant value to competitors of both Patent Owner and third parties to the agreement. Good cause therefore exists to seal this material. The Board has granted motions to seal similar agreements on similar grounds. *See, e.g., Westinghouse Air Brake Techs. Corp. v. Siemens Mobility, Inc.*, IPR2017-01669, Paper 60.

Next, turning to Exhibits 2049 and 2050, these documents were created pursuant to the performance outlined in the confidential JRA. Contrary to Petitioner's argument, the JRA expressly contemplates treating documents like Exhibits 2049 and 2050, which trigger the contractual obligation, as confidential information. *See* Exhibit 2048 at 3 (stating that one of two categories of confidential material include "any information that, by the nature of the information or the circumstances surrounding its disclosure, ought, in good faith, to be treated as confidential."). Because these documents concern research and development efforts, marketing plans, regulatory plans, and licensing practices of third parties and of Patent Owner's predecessor, they satisfy the JRA's confidential information definition. Specifically, Exhibit 2049 is a draft of a document for confidential submission before the Swedish Medical Products Authority. The contents include confidential business information and research and development information of both Patent Owner's predecessor and third parties. These categories of confidential information should be sealed. *See Activision Blizzard, Inc. et al. v. Acceleration Bay, LLC*, IPR2015-01951, Paper 108 at 3-4 (granting motion to seal "confidential information regarding internal research and development efforts of a third party" and "licensing practices of a third party").

Exhibit 2050 is a copy of internal meeting notes that discuss business-sensitive marketing plans, research and development plans, and regulatory

strategy. Such information is generally understood to be confidential and known to potentially cause harm by its disclosure. The Board has withheld similar confidential information from public disclosure before. *See, e.g.*, *Mylan*, IPR2016-00712, Paper 35 at 3 (granting motion to seal business notes related to confidential FDA submissions, marketing plans, and regulatory strategy); *British Foods*, IPR2019-00577, Paper 129 at 3-4 (same). Accordingly, good cause exists to seal the confidential information in all three documents.

III. Reference in Patent Owner Response Does Not Extinguish the Documents' Entire Confidentiality

Beyond pointing to the material cited in the Patent Owner Response ("POR"), Petitioner does not point to any specific material that is public. That is because there is none. Patent Owner acknowledges that its POR quotes and references a handful of sentences out of numerous pages of the challenged Exhibits. But such quotes and references do not extinguish the documents' confidentiality—and certainly should not result in public disclosure of the confidential documents' ***entire*** contents. Exhibit 2048-2050 are referenced in the POR in conjunction with other unsealed and public exhibits. *See* Paper 27 (POR) at 12-15. The POR introduces the existence of these confidential documents and points to precise instances where they help establish Patent Owner's predecessor's involvement in the disclosure found in Petitioner's Bodor reference. *See id*. The

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