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Paper 25
Date: January 8, 2024

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SAMSUNG BIOEPIS CO., LTD.,
Petitioner,

v.

REGENERON PHARMACEUTICALS, INC.,
Patent Owner.

IPR2023-00884
Patent 11,253,572 B2

Before SUSAN L. C. MITCHELL, ROBERT A. POLLOCK, and RYAN H. FLAX, *Administrative Patent Judges*.

FLAX, *Administrative Patent Judge*.

ORDER

Granting Parties Motions to File Documents Under Seal and for Protective Order
U.S.C. § 316; 37 C.F.R. §§ 42.14, 42.54

I. INTRODUCTION

On August 25, 2023, Patent Owner filed a Motion to File Confidential Documents under Seal (Paper 7, "Patent Owner's Motion to Seal") and a Motion for Protective Order (Paper 8). Patent Owner's Motion to Seal seeks to seal the following exhibits filed with Patent Owner's Preliminary Response: Exhibits 2001, 2013, 2015, 2018, 2019, 2036, 2037, 2038, 2039, 2040, 2041, 2043, and 2048. Paper 7 at 1. The Motion for Protective Order seeks entry of the Board's Default Protective Order (submitted as Ex. 2059). Paper 8 at 1. On September 18, 2023, Petitioner filed a Motion to Seal as well, seeking to seal portions of its Reply that disclose, analyze, and discuss Exhibits 2015, 2018, 2019, 2019, 2039, 2040, and 2043. Paper 11.

For the reasons below, the Motions are *granted*, and the Protective Order is entered.

II. MOTIONS TO SEAL

Under 37 C.F.R. § 42.14, the default rule is that all papers filed in such proceedings are available to the public. Only "confidential information" is subject to protection against public disclosure. 35 U.S.C. § 326(a)(7); 37 C.F.R. § 42.55. The Board also observes a strong policy in favor of making all information filed in *inter partes* review proceedings open to the public. *See Argentum Pharms. LLC v. Alcon Research, Ltd.*, IPR2017-01053, Paper 27, 3–4 (PTAB Jan. 19, 2018) (informative). "Redactions to documents filed in [a] proceeding should be limited to the minimum amount necessary to protect confidential information, and the thrust of the underlying argument or evidence must be clearly discernible from the redacted versions." CTPG 91. The moving party bears the burden of showing that the relief requested should be granted. 37 C.F.R. § 42.20(c).

The standard for granting a party's requested relief is "good cause." *Id.* § 42.54(a).

A. PATENT OWNER'S MOTION TO SEAL

Patent Owner's Motion to Seal seeks to seal Exhibits 2001, 2013, 2015, 2018, 2019, 2036, 2037, 2038, 2039, 2040, 2041, 2043, and 2048. Paper 7 at 1–7. For reasons that follow, we determine that the Motion to Seal demonstrates "good cause" for sealing these Exhibits. 37 C.F.R. § 42.54(a). As noted, Petitioner does not oppose the Motion. Accordingly, the Motion is *granted*.

1. Exhibit 2001

Patent Owner states that "Dr. Richard Manning relies on a range of confidential information in his declaration," Exhibit 2001, "including:

> (1) "Confidential financial information drawn from Patent Owner's internal business records";
>
> (2) "Confidential marketing plans and information prepared and compiled by Patent Owner";
>
> (3) "Confidential market metrics and projections . . . compiled and provided by third party data provider[s] Vestrum Health . . . and IQVIA"; and
>
> (4) "Confidential information obtained from the American Society of Retina Specialists (ASRS)."

Paper 7 at 2–4.

Patent Owner asserts that the "confidential financial information" "is not publicly available," "is completely sensitive," and "[i]ts inclusion in the public docket would cause commercial harm to Patent Owner." *Id.* at 3. Patent Owner asserts that the "confidential marketing plans and information" "is not publicly, and public release of this information could benefit Patent Owner's competitors and thereby cause competitive harm to Patent Owner." *Id.* Patent Owner asserts that the "confidential market metrics and

projections" contain information that is not publicly available and would cause competitive harm to Patent Owner, Vestrum, and IQVIA if disclosed on the public docket. *Id.* at 3–4. And, Patent Owner asserts that the "confidential information obtained from . . . ASRS" are documents that "include restrictions on their publication," and the information "is not publicly available and may cause competitive harm to ASRS if disclosed on the public docket." *Id.* at 4. Patent Owner also states that it "moves to seal the specific portions of Dr. Manning's declaration that reveal this confidential information," and "[p]ursuant to Paragraph 5(A)(ii) of the Board's default protective order, Ex.2059, a redacted copy of Dr. Manning's declaration is being filed publicly with the same exhibit number." *Id.* (citing Ex. 2059).

2. Exhibits 2013, 2036, 2037, 2038, 2039, 2040, and 2041

Patent Owner asserts that "Exhibits 2013, 2036, 2039, 2040, and 2041 are Patent Owner's internal memoranda, notes, and other planning documents . . . related to Regeneron's development of aflibercept, and in particular to the design of aflibercept clinical trials," which "reveal non-public aspects of Patent Owner's strategic decision making in the development of Eylea®, including its commercial and regulatory strategies," where "[p]ublic release of these details could cause competitive harm to Patent Owner by giving its competitors knowledge of its clinical research operations." Paper 7 at 5. Patent Owner similarly asserts that "Exhibits 2037 and 2038 are Patent Owner's internal summaries of the status of planned, ongoing, and completed clinical trials and planned regulatory submissions," which "reveal non-public details of Patent Owner's clinical development for Eylea® and aspects of Patent Owner's regulatory and

commercial strategies," where "[p]ublic release of these details could cause competitive harm to Patent Owner by giving its competitors knowledge of its clinical research operations." *Id.*

3. Exhibits 2015, 2019, and 2043

Patent Owner asserts that "Exhibits 2015, 2019, and 2043 are Patent Owner's internal summaries of its DA VINCI and VIEW clinical trial results," which "reveal non-public data and data analysis," where "[p]ublic release of these details could cause competitive harm to Patent Owner." Paper 7 at 6. According to Patent Owner, "these exhibits report patient-level demographic information as well as details of these patients' adverse events and treatment outcomes," the disclosure of which "would compromise the confidentiality of the clinical trial subjects." *Id.* Patent Owner states that it "moves to seal the specific portions of these exhibits that reveal unpublished data and data analysis," and that "a redacted copy of these exhibits is being filed publicly with the same exhibit number." *Id.*

4. Exhibits 2018 and 2048

Patent Owner asserts that "Exhibit 2018 is a detailed report of Patent Owner's DA VINCI clinical trial results," which "reveals non-public details of the protocol, results, and data analysis," the public release of which "could cause competitive harm to Patent Owner." According to Patent Owner, "these exhibits report patient-level demographic information as well as details of these patients' adverse events and treatment," the disclosure of which "would compromise the confidentiality of the clinical trial subjects." Paper 7 at 6–7. Patent Owner also asserts that "Exhibit 2048 is a detailed clinical trial protocol for the DA VINCI trial," which "reveals non-public details about Patent Owner's clinical trial protocol, data analysis, and the product used in the clinical trial, and it implicates Patent Owner's

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