UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SAMSUNG BIOEPIS CO., LTD.,
Petitioner,

v.

REGENERON PHARMACEUTICALS, INC.,
Patent Owner.

Patent No. 11,253,572

Inter Partes Review No. IPR2023-00884

MOTION TO FILE CONFIDENTIAL DOCUMENTS UNDER SEAL PURSUANT TO 37 C.F.R. §§ 42.14 AND 42.54

Pursuant to 35 U.S.C. § 316(a)(1) and 37 C.F.R. §§ 42.14 and 42.54, Patent Owner Regeneron Pharmaceuticals, Inc. moves to seal the following exhibits filed concurrently with Patent Owner's Preliminary Response:

Exhibit	Description
2001	Expert Declaration of Richard Manning, Ph.D., Mylan Pharms. Inc. v. Regeneron Pharms., Inc., IPR2021-00881, Ex. No. 2052 (Feb. 11, 2022)
2013	Regeneron, *Clinical Study Concept - Ophthalmology-Diabetic Macular Edema-Phase 2-IVT-VGFT-OD-0706* (updated May 19, 2008)
2015	DA VINCI – DME And VEGF Trap-Eye: Investigation of Clinical Impact: One Year Data (Dec. 8, 2010) (attachment to Ex.2024)
2018	Regeneron Pharmaceuticals, Inc., *VGFT-OD-0706 Week 24 Topline Results* (Feb. 1, 2010) (attachment to Ex.2017)
2019	DRAFT – DA VINCI – 6-Month Primary Endpoint (Feb. 1, 2010) (attachment to Ex.2017)
2036	DME Target Product Profile - VEGF Trap-Eye (Sept. 26, 2007)
2037	Clinical Development & Regulatory Affairs Weekly Update (Oct. 29, 2010)
2038	Clinical Development & Regulatory Affairs Weekly Update (Dec. 3, 2010)
2039	Email from George Yancopoulos re DME PLANS & FDA meeting pre-discussion (Jan. 9, 2008)
2040	MEMO re Guidance From Bayer/ REGN Sr. Management Regarding Additional Indications in Ophthalmology from George Yancopoulos to Bayer/REGN Joint Development Group (Mar. 28, 2008)
2041	Action Items by GD Yancopoulos - Bayer/REGN JSC (Feb. 15, 2008)
2043	Vascular Endothelial Growth Factor (VEGF): Investigation of Efficacy and Safety in Wet Age-Related Macular Degeneration (AMD)—VIEW 1 + VIEW 2: 1-Year Results (Nov. 20, 2010) (Attachment to Ex.2042)
2048	Regeneron Pharmaceuticals, Inc., *A Double-Masked, Randomized, Controlled Study of the Safety, Tolerability and Biological Effect of Repeated Intravitreal Administration of VEGF Trap-Eye in Patients with Diabetic Macular Edema (DME)* (Issued Jan. 28, 2009)

I. DOCUMENTS TO BE SEALED AND REASONS FOR SEALING

The standard governing the Board's determination of whether to grant a motion to seal is "good cause." *Garmin Int'l, Inc. v. Cuozzo Speed Techs. LLC*, IPR2012-00001, Paper 36 at 4 (April 5, 2013) (quoting 37 C.F.R. § 42.54). The Board aims to "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." *Id.*

The documents, exhibits, and portions of exhibits that Patent Owner seeks to file under seal fall into three general categories, each of which meets the "good cause" standard to be maintained in the docket under seal and available only to the parties and Board. In each instance, the material is either the confidential information of a third party, or else consists of confidential business information that would cause competitive harm to Patent Owner were it to be disclosed publicly.

A. Declaration Including Confidential Market and Pricing Information

Exhibit 2001 is a declaration of Dr. Richard Manning, an expert witness retained by Patent Owner who addressed the commercial success of Eylea® in a related proceeding, IPR2021-00881. Dr. Manning relies on a range of confidential information in his declaration, including the following:

- Confidential financial information drawn from Patent Owner's internal business records, which contain information such as profits and costs associated with Patent Owner's activities in connection with Eylea®. This confidential business information is not publicly available and is competitively sensitive. Its inclusion in the public docket would cause commercial harm to Patent Owner.
- Confidential marketing plans and information prepared and compiled by Patent Owner. These documents include and/or reference Patent Owner's marketing plans and its Awareness Trial and Usage ("ATU") market research for Eylea®. This information is not publicly, and public release of this information could benefit Patent Owner's competitors and thereby cause competitive harm to Patent Owner.
- Confidential market metrics and projections that are compiled and provided by third party data provider Vestrum Health ("Vestrum"). These documents include data analysis related to Patent Owner's activities in connection with Eylea®. The information contained in these exhibits is not publicly available and would cause competitive harm to Patent Owner and Vestrum if disclosed on the public docket. Patent Owner agreed with Vestrum to maintain the confidentiality this information.

- Confidential market metrics and projections that are compiled and provided by third party data provider, IQVIA. These documents include data analysis related to Patent Owner's activities in connection with Eylea®. The information contained in these exhibits is not publicly available and would cause competitive harm to Patent Owner and IQVIA if disclosed on the public docket. Patent Owner agreed with IQVIA to maintain the confidentiality of this information.
- Confidential information obtained from the American Society of Retina Specialists (ASRS). These documents include compiled survey information from ASRS member retina specialists. Only members of ASRS have access to this information, and the documents themselves include restrictions on their publication. The information contained in these exhibits is not publicly available and may cause competitive harm to ASRS if disclosed on the public docket.

Patent Owner moves to seal the specific portions of Dr. Manning's declaration that reveal this confidential information. Pursuant 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.

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