

**UNITED STATES PATENT AND TRADEMARK OFFICE**

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**BEFORE THE PATENT TRIAL AND APPEAL BOARD**

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SAMSUNG BIOEPIS CO., LTD.,  
Petitioner,

v.

REGENERON PHARMACEUTICALS, INC.,  
Patent Owner.

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Case IPR2023-00884

U.S. Patent No. 11,253,572

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**PETITIONER'S MOTION TO SEAL**

Pursuant to 37 C.F.R. §§ 42.14 and 42.54 and the Patent Trial and Appeal Board Consolidated Trial Practice Guide November 2019, Petitioner Samsung Bioepis Co., Ltd. (“Petitioner” or “Samsung”) respectfully submits this Motion to Seal concurrently with Petitioner’s Reply to Patent Owner Preliminary Response (“Reply”). Specifically, based on Patent Owner’s representations that a number of its exhibits are confidential (*See*, Paper 7, Patent Owner’s Motion to File Confidential Documents Under Seal), Samsung seeks to seal portions of its Reply disclosing and analyzing the substance of those exhibits submitted by Patent Owner.

#### **I. GOOD CAUSE EXISTS TO SEAL**

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 portions of the Reply Petitioner seeks to file under seal discuss Patent Owner’s exhibits that, according to Patent Owner, allegedly contain confidential business information that would cause competitive harm to Patent Owner were it to be disclosed publicly. Paper 7, 2-7. Based on Patent Owner’s representations, “good cause” exists to maintain the portions of the Reply discussing Patent Owner’s

allegedly confidential exhibits under seal and available only to the parties and Board. Pursuant to Paragraph 5(A)(ii) of the Board's default protective order (Ex. 2059), a redacted copy of Petitioner's Reply is being filed publicly.

**A. Petitioner's Reply Discusses Exhibits Patent Owner Has Designated Confidential**

Certain portions of Petitioner's Reply discuss the substance of Exhibits 2015, 2018, 2019, 2039, 2040, and 2043, previously submitted by the Patent Owner under seal in this proceeding. *See*, Reply, 4-10; Paper 7. According to Patent Owner, Exhibits 2015, 2019, and 2043 are Patent Owner's internal summaries of its DA VINCI and VIEW clinical trial results; Exhibit 2018 is a detailed report of Patent Owner's DA VINCI clinical trial results; and Exhibits 2039-2040 are Patent Owner's internal memoranda, notes, and other planning documents from 2008 related to Patent Owner's development of aflibercept, and in particular to the design of aflibercept clinical trials. *Id.*, 2-7.

In its motion to seal, Patent Owner argues that these documents include non-public confidential internal memoranda, notes, and other planning documents concerning Patent Owner's design of aflibercept clinical trials as well as Patent Owner's strategic decision making in the development of Eylea®, including its

commercial and regulatory strategies. *Id.*<sup>1</sup> According to Patent Owner, public release of the details in these exhibits could cause competitive harm to Patent Owner by giving its competitors knowledge of its clinical research operations. *Id.* For purposes of the instant Motion to Seal only, Petitioner does not object to the confidentiality of Patent Owner’s exhibits referenced in the Reply. On that basis, the Board should grant this Motion to Seal.

## II. CERTIFICATION

Pursuant to 37 CFR § 42.54, Petitioner certifies that it has conferred with Patent Owner regarding this motion to seal. Patent Owner does not object to the motion.

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<sup>1</sup> Patent Owner further notes that in the district court litigation between Patent Owner and Mylan, Patent Owner produced these documents with a designation of “CONFIDENTIAL” as defined by the protective order in that case.

DATED: September 18, 2023

Respectfully submitted,

By /Raymond N. Nimrod/

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