

**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., CELLTRION, INC.,  
and BIOCON BIOLOGICS INC.,  
Petitioners,

v.

REGENERON PHARMACEUTICALS, INC.,  
Patent Owner.

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Case IPR2023-00884<sup>1</sup>

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

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

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<sup>1</sup> IPR2024-00260 and IPR2024-00298 are joined with IPR2023-00884.

Pursuant to 35 U.S.C. § 316(a)(1) and 37 C.F.R. §§ 42.14, Petitioner Samsung Bioepis, Co., Ltd. moves to seal Exhibits 1080, 1082, and 1083, along with the specific portions of the Petitioner’s Reply that reveal confidential information in Exhibits 1080, 1082, 1083, 2067, 2069, and 2073. Pursuant to the Protective Order entered in this proceeding (Paper 25) and the Amended Protective Order which Petitioner and Patent Owner have agreed to abide by until entered (Paper 60), Petitioner must “maintain the confidentiality” of material that has been marked or designated as “Protective Material” in this proceeding. Accordingly, Petitioner moves to seal the following exhibits which Patent Owner has designated “Protective Material” and references of such confidential information in its Reply:

<b>Exhibit</b>	<b>Description</b>
1080	Deposition Transcript of George D. Yancopoulos, M.D., Ph.D. (April 12, 2024) in IPR2023-00884
1082	Deposition Transcript of Karen Chu (April 11, 2024)
1083	RGN-EYLEA-MYLAN-00526220 to RGN-EYLEA-MYLAN-00526223

## **I. GOOD CAUSE EXISTS FOR SEALING**

The standard governing the Board’s determination of whether to grant a motion to seal is “good cause.” *Arctic Cat, Inc. v. Polaris Indus. Inc.*, No. IPR2017-00433, 2018 WL 1145910, at \*1 (P.T.A.B. Feb. 27, 2018) (quoting 37 C.F.R. § 42.54). “The moving party bears the burden of showing that the relief requested

should be granted, and establishing that information sought to be sealed is confidential information.” *Askeladden LLC v. Verify Smart Corp.*, No. IPR2017-00726, 2017 WL 4763581, at \*1 (P.T.A.B. Oct. 18, 2017).

The documents, exhibits, and portions of the Reply that Petitioner seeks to file under seal, according to Patent Owner, contain confidential information of Regeneron. *See* Papers 34; 60. Based on Patent Owner’s representations, the “good cause” standard is met, as in each instance, the material is the confidential information of Patent Owner. *See Id.* Pursuant to Paragraph 5(A)(ii) of the Board’s default protective order, a redacted copy of the Petitioner’s Reply is being filed publicly.

**A. Documents to Be Sealed**

Exhibits 1080 and 1082 are the transcripts of Dr. Yancopoulos and Ms. Chu from this proceeding, IPR2023-00884. Dr. Yancopolos and Ms. Chu were both involved in the development of Eylea. Counsel for Patent Owner designated both transcripts as “Confidential Under the Protective Order.” Ex. 1080 at 254:8-12; Ex. 1082 at 247:22-248:3. Petitioner understands these transcripts contain discussion related to Regeneron’s clinical development processes and strategic decision making and that Patent Owner considers this subject matter commercially sensitive information that would cause competitive harm if publicly disclosed. *See* Paper 34 at 5-7.

Exhibit 1083 is email correspondence between George Yancopoulos and other Regeneron employees regarding the design of the studies for VEGF-Trap-Eye (i.e., aflibercept). The exhibit was marked “Confidential Protective Order Material” by Patent Owner. Petitioner understands this material contains discussion related to Regeneron’s clinical development processes and strategic decision making and that Patent Owner considers such materials commercially sensitive information that would cause competitive harm if publicly disclosed. *See* Paper 34 at 5-7.

Petitioner relies on and discusses the confidential contents of the above-mentioned exhibits within its Reply. Petitioner also relies on and discusses Patent Owner’s Exhibits 2067, 2069, and 2073, these Exhibits are the subject of Patent Owner’s pending Motion to Seal and marked “Confidential Material – Subject to Protective Order”. Paper 34. In this paper, Petitioner identifies Ex 2069 and Ex 2073 as internal correspondence from 2006-2007 related to the development of aflibercept, and in particular to the design of aflibercept clinical trials. *Id.* at 5-6. Patent Owner states release of these details could cause competitive harm to Patent Owner. *Id.* Patent Owner identifies Exhibit 2073 as containing detailed internal results on Patent Owner’s CLEAR-IT-2 clinical trial. *Id.* at 6-7. Patent Owner states release of these details could cause competitive harm to Patent Owner. *Id.*

Accordingly, Petitioner moves to seal Exhibits 1080, 1082, and 1083, along with the specific portions of the Petitioner's Reply that reveal confidential information in Exhibits 1080, 1082, 1083, 2067, 2069, and 2073.

DATED: June 10, 2024

Respectfully submitted,

By /Raymond N. Nimrod/

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