

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SAMSUNG BIOEPIS CO., LTD., CELLTRION INC.,
and BIOCON BIOLOGICS INC.,
Petitioners,

v.

REGENERON PHARMACEUTICALS, INC.,
Patent Owner.

Patent No. 11,253,572

Inter Partes Review No. IPR2023-00884¹

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

¹ 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 and 42.54, Patent Owner Regeneron Pharmaceuticals, Inc. moves to seal the following exhibits and references to confidential information within these exhibits and in the Patent Owner's Response:

Exhibit	Description
2063	Declaration of George Yancopoulos
2064	Declaration of Karen Chu
2067	Expert Declaration of Richard Manning, PhD and Attachments C-1 through Y-4
2069	Regeneron, "Bayer Alliance Internal Kick-Off Meeting," 11/2006
2070	Regeneron, Email from Terifay to Yancopoulos et. al, 3/22/2007 with attached slides
2072	Regeneron, CLEAR-IT-2 results, sent by Powchik to Yancopoulos 3/22/2007
2073	Regeneron, CLEAR-IT-2 results and analysis, sent by Yancopoulos to Schleifer 3/22/2007
2075	Regeneron, Email from Yancopoulos to Jody, 4/2007
2076	Regeneron, VIEW Protocol, 5/2007
2092	Metadata Exhibit
2141	American Society of Retina Specialists, "2015 Preferences and Trends (PAT) Survey," c. 2015
2142	American Society of Retina Specialists, "2016 Preferences and Trends (PAT) Survey," c. 2016
2143	Regeneron, "DME Market Assessment," 8/2014
2144	Regeneron, "Q2 2020 Performance Update Wet AMD, DME, MEfRVO & DR w/out DME," 7/2020
2147	American Society of Retina Specialists, "2009 Preferences and Trends Membership Survey," c. 2009
2162	Regeneron, "DME Market Assessment Q1 2015," 4/2015

Exhibit	Description
2163	Regeneron, "DME Market Assessment Q1 2016," 4/2016
2164	Regeneron, "DME Market Assessment Q1 2017," 5/2017
2165	Regeneron, "DME Market Assessment Q1 2018," 5/2018
2166	Regeneron, "DME Market Assessment Q2 2015," 8/2015
2167	Regeneron, "DME Market Assessment Q2 2016," 8/2016
2168	Regeneron, "DME Market Assessment Q2 2017," 7/2017
2169	Regeneron, "DME Market Assessment Q2 2018," 7/2018
2170	Regeneron, "DME Market Assessment Q3 2015," 11/2015
2171	Regeneron, "DME Market Assessment Q3 2016," 10/2016
2172	Regeneron, "DME Market Assessment Q3 2017," 10/2017
2173	Regeneron, "DME Market Assessment Q4 2014," 1/2015
2174	Regeneron, "DME Market Assessment Q4 2015," 2/2016
2175	Regeneron, "DME Market Assessment Q4 2016," 1/2017
2176	Regeneron, "DME Market Assessment Q4 2017," 2/2018
2177	Regeneron, "DME Market Assessment Wave 3, Q3 2014
2178	Regeneron, "DME Market Assessment, Benchmark Wave," 11/8/2013
2179	Regeneron, "Physician ATU: Q1 2015," 4/2015
2180	Regeneron, "Physician ATU: Q2 2015," 7/2015
2181	Regeneron, "Physician ATU: Q3 2014," 11/2014

Exhibit	Description
2182	Regeneron, "Physician ATU: Q3 2015," 11/2015
2183	Regeneron, "Physician ATU: Q4 2014," 1/2015
2184	Regeneron, "Physician ATU: Q4 2015," 1/2016
2185	Regeneron, "Physician ATU: Wave 2," 2/2013
2186	Regeneron, "Physician ATU: Wave 4," 8/6/2013
2187	Regeneron, "Physician ATU: Wave 5," 11/2013
2188	Regeneron, "Physician ATU: Wave 6," 1/2014
2189	Regeneron, "Physician ATU: Wave 7," 4/2014
2190	Regeneron, "Physician ATU: Wave 8," 8/2014
2191	Regeneron, "Q1 2019 Performance Update Wet AMD, DME, & MEfRVO," 5/2019
2192	Regeneron, "Q1 2020 Performance Update Wet AMD, DME, MEfRVO & DR w/out DME," 4/2020
2193	Regeneron, "Q2 2019 Performance Update Wet AMD, DME, MEfRVO & DR w/out DME," 8/2019
2194	Regeneron, "Q3 2018 Performance Update Wet AMD, DME, & MEfRVO," 11/2018
2195	Regeneron, "Q3 2019 Performance Update Wet AMD, DME, MEfRVO & DR w/out DME," 11/2019
2196	Regeneron, "Q3 2020 Performance Update Wet AMD, DME, MEfRVO & DR w/out DME," 11/2020
2197	Regeneron, "Q4 2018 Performance Update Wet AMD, DME, & MEfRVO," 2/2019
2198	Regeneron, "Q4 2019 Performance Update Wet AMD, DME, & MEfRVO," 1/2020
2199	Regeneron, "Q4 2020 Performance Update Wet AMD, DME, MEfRVO & DR w/out DME," 1/29/2021
2214	Regeneron, "US Eylea P&L LTD," 12/2021

Exhibit	Description
2215	Regeneron, "Wet AMD Physician ATU: Q1 2016," 4/2016
2216	Regeneron, "Wet AMD Physician ATU: Q1 2017," 4/2017
2217	Regeneron, "Wet AMD Physician ATU: Q1 2018," 5/2018
2218	Regeneron, "Wet AMD Physician ATU: Q2 2016," 8/2016
2219	Regeneron, "Wet AMD Physician ATU: Q2 2017," 7/2017
2220	Regeneron, "Wet AMD Physician ATU: Q2 2018," 7/2018
2221	Regeneron, "Wet AMD Physician ATU: Q3 2016," 10/2016
2222	Regeneron, "Wet AMD Physician ATU: Q3 2017," 10/2017
2223	Regeneron, "Wet AMD Physician ATU: Q4 2016," 1/2016
2224	Regeneron, "Wet AMD Physician ATU: Q4 2017," 1/2018
2225	Regeneron, "Wave 1 2021 Performance Update Wet AMD, DME, MEfRVO, and DR w/out DME," 9/2021
2232	Regeneron, Eylea Gross & Net Sales P&L YTD, c.2021
2238	Vestrum, Anti-VEGF Category Sales Shares, c. 2/2022

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." *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 exhibits that Patent Owner seeks to file under seal meet the “good cause” standard. In each instance, the material is either the confidential information of a third party, or else contains confidential business information or confidential analyses that could cause competitive harm to Patent Owner if disclosed publicly. Pursuant to Paragraph 5(A)(ii) of the Board’s default protective order, redacted copies of the Patent Owner Response and exhibits 2063, 2064, 2067, 2070, 2092, 2214, and 2232 are being filed publicly.

A. Confidential Commercial and Financial Documents of Patent Owner

Exhibits 2143, 2144, 2162–2199, 2214–2225, and 2232 contain Patent Owner’s confidential financial and sales information and confidential surveys and analyses. The information contained in these exhibits is not publicly available and would cause competitive harm to Patent Owner if disclosed on the public docket. Public release of these documents and information could benefit Patent Owner’s competitors and would therefore cause competitive harm to Patent Owner.

B. Patent Owner’s Clinical Development Processes and Strategic Decision Making

Exhibits 2069, 2070, 2073, and 2075 contain Patent Owner’s internal correspondence and presentations from 2006-2007 related to Regeneron’s

development of aflibercept, and in particular to the design of aflibercept clinical trials. These documents reveal non-public aspects of Patent Owner's strategic decision making in the development of Eylea®, including its commercial and regulatory strategies. Public release of these details could cause competitive harm to Patent Owner by giving its competitors knowledge of its clinical research operations. Patent Owner produced many of these documents in its district court litigation against Mylan and Biocon, and designated them "CONFIDENTIAL" as defined by the protective order in that case.

Exhibit 2092 contains the first pages of confidential documents relating to Regeneron's development of aflibercept. This document also reveals non-public aspects of Patent Owner's strategic decision making, and public release could cause competitive harm to Patent Owner. Patent Owner produced many of these documents in its district court litigation against Mylan and Biocon, and designated them "CONFIDENTIAL" as defined by the protective order in that case.

C. Patent Owner's Confidential Clinical Trial Protocols and Results

Exhibits 2072 and 2073 contain detailed internal results of Patent Owner's CLEAR-IT-2 clinical trial results. They reveal details of the trial protocol, results, and data analysis that have not been made public. Public release of these details could cause competitive harm to Patent Owner.

Exhibit 2076 is a detailed clinical trial protocol for the VIEW trial. It 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 commercial and regulatory strategies. Public release of these details could cause competitive harm to Patent Owner by giving its competitors knowledge of its clinical research operations. As reflected on the first page, this document was designated as confidential to the Institutional Review Board and those involved in the conduct of the clinical trial.

D. Other Confidential Commercial and Financial Documents

Exhibit 2238 contains confidential financial information that is 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.

Exhibits 2141, 2142, and 2147 contain 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 if disclosed on

the public docket.

E. Briefing and Declarations Including or Describing Confidential Information

The Patent Owner Response relies on Exhibit 2067, which is the Expert Declaration of Richard Manning, PhD (“Manning Declaration”). Dr. Manning is an expert economist retained by Patent Owner who opines on commercial success. Dr. Manning relies on Patent Owner’s confidential information in his declaration, and the confidential exhibits described above. Attachments C-1 through Y-4 contain either confidential information from the exhibits below or confidential non-public analyses. Patent Owner moves to seal the specific portions of the Patent Owner Response and Manning Declaration that reveal this confidential information.

The Patent Owner Response also relies on Exhibits 2064 and 2063, which are the Declaration of Dr. George Yancopoulos and the Declaration of Karen Chu. These declarations discuss non-public aspects of Patent Owner’s strategic decision making in the development of Eylea® as well as details of the clinical trial protocols, results, and data analysis that have not been made public. They discuss contents of the confidential exhibits described above. Patent Owner moves to seal the specific portions of the Patent Owner Response, Yancopoulos Declaration, and Chu Declaration that reveal this confidential information.

II. PROTECTIVE ORDER

Regeneron filed an unopposed Motion for Protective Order requesting entry of the Board's default protective order, Ex.2059, on August 25, 2023. *See* Paper 8. The Protective Order was entered on January 8, 2024. *See* Paper 25.

III. CERTIFICATION

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

Dated: February 23, 2024

Respectfully submitted,

By /Adam R. Brausa/
Adam R. Brausa, Reg. No. 60,287
MORRISON & FOERSTER LLP
425 Market Street
San Francisco, California 94105
Tel: (415) 268-6053
ABrausa@mofo.com

Counsel for Patent Owner

Certificate of Service (37 C.F.R. § 42.6(e)(4))

I hereby certify that the attached MOTION TO FILE CONFIDENTIAL DOCUMENTS UNDER SEAL PURSUANT TO 37 C.F.R. §§ 42.14 AND 42.54 was served as of the below date on the Petitioners via e-mail (by agreement) to the following counsel of record:

Raymond N. Nimrod (Reg. No. 31,987)
Matthew A. Traupman (Reg. No. 50,832)
Elliot Choi (*pro hac vice*)
Zachariah Summers (*pro hac vice*)
Sarah Cork (*pro hac vice* to be applied for)
Landon Andrew Smith (Reg. No. 79,248)
QUINN EMANUEL URQUHART
& SULLIVAN, LLP
51 Madison Ave., 22nd Floor
New York, NY 10010
General Tel: (212) 849-7000
Direct Tel: (212) 849-7322
Fax: (212) 849-7100
raynimrod@quinnemanuel.com
matthewtraupman@quinnemanuel.com
elliotchoi@quinnemanuel.com
zachsummers@quinnemanuel.com
landonsmith@quinnemanuel.com
qe-samsungbioepis@quinnemanuel.com

Paul J. Molino (Reg. No. 45,350)
William A. Rakoczy (*pro hac vice* to be filed)
Deanne M. Mazzochi (Reg. No. 50,158)
Heinz J. Salmen (*pro hac vice* to be filed)
Jeff A. Marx (Reg. No. 56,977)
Eric R. Hunt (*pro hac vice* to be filed)
Neil B. McLaughlin (Reg. No. 70,810)
Lauren M. Lesko (*pro hac vice* to be filed)

L. Scott Beall (Reg. No. 52,601)
Thomas H. Ehrich (Reg. No. 67,122)
Steven J. Birkos (Reg. No. 65,300)
Jake R. Ritthamel (*pro hac vice* to be filed)
Rakoczy Molino Mazzochi Siwik LLP
6 West Hubbard Street
Chicago, IL 60654
MYL_REG_IPR@rmmslegal.com

Lora Green (Reg. No. 43,541)
Yahn-Lin Chu (Reg. No. 75,946)
Robert Cerwinski (to be admitted *pro hac vice*, pending)
Aviv Zalcenstein (to be admitted *pro hac vice*, pending)
Brigid Morris (to be admitted *pro hac vice*, pending)
Gemini Law LLP
40 W 24th Street, Suite 6N
New York, NY 10010
Tel.: 917-915-8832
Email: lgreen@geminilaw.com
Email: fchu@geminilaw.com
Email: rcerwinski@geminilaw.com
Email: azalcenstein@geminilaw.com
Email: bmorris@geminilaw.com

Dated: February 23, 2024

/Adam R. Brausa/
Adam R. Brausa, Reg. No. 60,287