

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

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

Petitioner,

v.

REGENERON PHARMACEUTICALS, INC.,
Patent Owner.

Patent No. 11,253,572

Inter Partes Review No. IPR2023-00884¹

**PATENT OWNER'S MOTION TO EXPUNGE
PURSUANT TO 37 C.F.R. § 42.56**

¹ IPR2024-00260 and IPR2024-00298 are joined with IPR2023-00884.

I. INTRODUCTION

Pursuant to the Trial Practice Guide and 37 C.F.R. § 42.56, Patent Owner Regeneron Pharmaceuticals, Inc. (“Regeneron”) requests that the Board expunge certain confidential Papers and Exhibits from the record. After Regeneron identified the exhibits it intended to expunge, Petitioner Samsung Bioepis Co., Ltd. (“Samsung”) indicated that it “may be able to agree not to oppose Regeneron’s motion” if Regeneron agreed to provide redacted, public versions of Exs. 1080 and 1082 in IPR2023-00884 and Ex. 2043 in the IPR2023-00739. Redacted versions of those exhibits are being filed concurrently with this Motion.

For the reasons set forth below, Regeneron respectfully requests that the following documents currently under seal be expunged from the record, as these documents contain Regeneron’s highly confidential business information:

Document	Description
2024-02-23 (Paper 35)	Patent Owner’s Response
2024-06-10 (Paper 64)	Petitioner’s Reply
Ex. 1080	Yancopoulos 572 IPR Tr.
Ex. 1082	Chu 572 IPR Tr.
Ex. 1083	RGN-EYLEA-MYLAN-00526220
Ex. 2001	Expert Declaration of Richard Manning, Ph.D., Mylan Pharms. Inc. v. Regeneron Pharms., Inc., IPR2021-00881, Ex. No. 2052 (Feb. 11, 2022)

Document	Description
Ex. 2013	Regeneron, <i>Clinical Study Concept - Ophthalmology-Diabetic Macular Edema-Phase 2-IVT-VGFT-OD-0706</i> (updated May 19, 2008)
Ex. 2015	DA VINCI – DME And VEGF Trap-Eye: Investigation of Clinical Impact: One Year Data (Dec. 8, 2010) (attachment to Ex.2024)
Ex. 2018	Regeneron Pharmaceuticals, Inc., <i>VGFT-OD-0706 Week 24 Topline Results</i> (Feb. 1, 2010) (attachment to Ex.2017)
Ex. 2019	DRAFT – DA VINCI – 6-Month Primary Endpoint (Feb. 1, 2010) (attachment to Ex.2017)
Ex. 2036	DME Target Product Profile - VEGF Trap-Eye (Sept. 26, 2007)
Ex. 2037	Clinical Development & Regulatory Affairs Weekly Update (Oct. 29, 2010)
Ex. 2038	Clinical Development & Regulatory Affairs Weekly Update (Dec. 3, 2010)
Ex. 2039	Email from George Yancopoulos re DME PLANS & FDA meeting pre-discussion (Jan. 9, 2008)
Ex. 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)
Ex. 2041	Action Items by GD Yancopoulos - Bayer/REGN JSC (Feb. 15, 2008)
Ex. 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)
Ex. 2048	Regeneron Pharmaceuticals, Inc., <i>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)</i> (Issued Jan. 28, 2009)
Ex. 2063	Declaration of George Yancopoulos
Ex. 2064	Declaration of Karen Chu
Ex. 2067	Expert Declaration of Richard Manning, PhD and Attachments C-1 through Y-4

Document	Description
Ex. 2069	Regeneron, "Bayer Alliance Internal Kick-Off Meeting," 11/2006
Ex. 2070	Regeneron, Email from Terifay to Yancopoulos et. al, 3/22/2007 with attached slides
Ex. 2072	Regeneron, CLEAR-IT-2 results, sent by Powchik to Yancopoulos 3/22/2007
Ex. 2073	Regeneron, CLEAR-IT-2 results and analysis, sent by Yancopoulos to Schleifer 3/22/2007
Ex. 2075	Regeneron, Email from Yancopoulos to Jody, 4/2007
Ex. 2076	Regeneron, VIEW Protocol, 5/2007
Ex. 2092	Metadata Exhibit
Ex. 2141	American Society of Retina Specialists, "2015 Preferences and Trends (PAT) Survey," c. 2015
Ex. 2142	American Society of Retina Specialists, "2016 Preferences and Trends (PAT) Survey," c. 2016
Ex. 2143	Regeneron, "DME Market Assessment," 8/2014
Ex. 2144	Regeneron, "Q2 2020 Performance Update Wet AMD, DME, MEfRVO & DR w/out DME," 7/2020
Ex. 2147	American Society of Retina Specialists, "2009 Preferences and Trends Membership Survey," c. 2009
Ex. 2162	Regeneron, "DME Market Assessment Q1 2015," 4/2015
Ex. 2163	Regeneron, "DME Market Assessment Q1 2016," 4/2016
Ex. 2164	Regeneron, "DME Market Assessment Q1 2017," 5/2017
Ex. 2165	Regeneron, "DME Market Assessment Q1 2018," 5/2018
Ex. 2166	Regeneron, "DME Market Assessment Q2 2015," 8/2015
Ex. 2167	Regeneron, "DME Market Assessment Q2 2016," 8/2016
Ex. 2168	Regeneron, "DME Market Assessment Q2 2017," 7/2017
Ex. 2169	Regeneron, "DME Market Assessment Q2 2018," 7/2018

Document	Description
Ex. 2170	Regeneron, "DME Market Assessment Q3 2015," 11/2015
Ex. 2171	Regeneron, "DME Market Assessment Q3 2016," 10/2016
Ex. 2172	Regeneron, "DME Market Assessment Q3 2017," 10/2017
Ex. 2173	Regeneron, "DME Market Assessment Q4 2014," 1/2015
Ex. 2174	Regeneron, "DME Market Assessment Q4 2015," 2/2016
Ex. 2175	Regeneron, "DME Market Assessment Q4 2016," 1/2017
Ex. 2176	Regeneron, "DME Market Assessment Q4 2017," 2/2018
Ex. 2177	Regeneron, "DME Market Assessment Wave 3, Q3 2014
Ex. 2178	Regeneron, "DME Market Assessment, Benchmark Wave," 11/8/2013
Ex. 2179	Regeneron, "Physician ATU: Q1 2015," 4/2015
Ex. 2180	Regeneron, "Physician ATU: Q2 2015," 7/2015
Ex. 2181	Regeneron, "Physician ATU: Q3 2014," 11/2014
Ex. 2182	Regeneron, "Physician ATU: Q3 2015," 11/2015
Ex. 2183	Regeneron, "Physician ATU: Q4 2014," 1/2015
Ex. 2184	Regeneron, "Physician ATU: Q4 2015," 1/2016
Ex. 2185	Regeneron, "Physician ATU: Wave 2," 2/2013
Ex. 2186	Regeneron, "Physician ATU: Wave 4," 8/6/2013
Ex. 2187	Regeneron, "Physician ATU: Wave 5," 11/2013
Ex. 2188	Regeneron, "Physician ATU: Wave 6," 1/2014

Document	Description
Ex. 2189	Regeneron, "Physician ATU: Wave 7," 4/2014
Ex. 2190	Regeneron, "Physician ATU: Wave 8," 8/2014
Ex. 2191	Regeneron, "Q1 2019 Performance Update Wet AMD, DME, & MEfRVO," 5/2019
Ex. 2192	Regeneron, "Q1 2020 Performance Update Wet AMD, DME, MEfRVO & DR w/out DME," 4/2020
Ex. 2193	Regeneron, "Q2 2019 Performance Update Wet AMD, DME, MEfRVO & DR w/out DME," 8/2019
Ex. 2194	Regeneron, "Q3 2018 Performance Update Wet AMD, DME, & MEfRVO," 11/2018
Ex. 2195	Regeneron, "Q3 2019 Performance Update Wet AMD, DME, MEfRVO & DR w/out DME," 11/2019
Ex. 2196	Regeneron, "Q3 2020 Performance Update Wet AMD, DME, MEfRVO & DR w/out DME," 11/2020
Ex. 2197	Regeneron, "Q4 2018 Performance Update Wet AMD, DME, & MEfRVO," 2/2019
Ex. 2198	Regeneron, "Q4 2019 Performance Update Wet AMD, DME, & MEfRVO," 1/2020
Ex. 2199	Regeneron, "Q4 2020 Performance Update Wet AMD, DME, MEfRVO & DR w/out DME," 1/29/2021
Ex. 2214	Regeneron, "US Eylea P&L LTD," 12/2021
Ex. 2215	Regeneron, "Wet AMD Physician ATU: Q1 2016," 4/2016
Ex. 2216	Regeneron, "Wet AMD Physician ATU: Q1 2017," 4/2017
Ex. 2217	Regeneron, "Wet AMD Physician ATU: Q1 2018," 5/2018
Ex. 2218	Regeneron, "Wet AMD Physician ATU: Q2 2016," 8/2016
Ex. 2219	Regeneron, "Wet AMD Physician ATU: Q2 2017," 7/2017
Ex. 2220	Regeneron, "Wet AMD Physician ATU: Q2 2018," 7/2018
Ex. 2221	Regeneron, "Wet AMD Physician ATU: Q3 2016," 10/2016

Document	Description
Ex. 2222	Regeneron, "Wet AMD Physician ATU: Q3 2017," 10/2017
Ex. 2223	Regeneron, "Wet AMD Physician ATU: Q4 2016," 1/2016
Ex. 2224	Regeneron, "Wet AMD Physician ATU: Q4 2017," 1/2018
Ex. 2225	Regeneron, "Wave 1 2021 Performance Update Wet AMD, DME, MEfRVO, and DR w/out DME," 9/2021
Ex. 2232	Regeneron, Eylea Gross & Net Sales P&L YTD, c.2021
Ex. 2238	Vestrum, Anti-VEGF Category Sales Shares, c. 2/2022

II. APPLICABLE STANDARD FOR EXPUNGEMENT

Ordinarily, confidential information subject to a Protective Order that is submitted in PTAB proceedings becomes public 45 days after final judgment. 77 Fed. Reg. 48,756, 48,761 (Aug. 14, 2012). A party may preserve the confidentiality of such information by filing a motion to expunge under 37 C.F.R. § 42.56, which “balances the needs of the parties to submit confidential information with the public interest in maintaining a complete and understandable file history for public notice purposes.” *Id.* A party seeking expungement of its papers or exhibits from the record must show good cause by demonstrating “that any information sought to be expunged constitutes confidential information, and that [the party’s] interest in expunging it outweighs the public’s interest in maintaining a complete and understandable history of this *inter partes* review.” *Atlanta Gas Light Co. v. Bennett Regulator Guards, Inc.*, IPR2013-00453, Paper

97 at 2 (P.T.A.B. Apr. 15, 2015).

“The Board has held [that] th[e] rule controlling the expungement of confidential information is subject to the same ‘good cause’ standard for granting a motion to seal under 37 C.F.R. § 42.54.” *Corning Optical Commc’ns RF, LLC v. PPC Broadband, Inc.*, IPR2013-00346, Paper 94 at 3 (Oct. 2, 2018) (internal citations omitted). For example, the Board has found good cause to expunge previously sealed material where doing so does not impact the public’s interest because, for example, publicly available redacted versions are retained in the record. *See, e.g., Samsung Elecs. Co. v. Nucurrent, Inc.*, IPR2019-00861, Paper 85 at 4-5 (Nov. 1, 2022). The Board has expunged confidential material if “the record of the proceedings and Final Written Decisions remain understandable in the absence of the redacted material.” *See, e.g., Apple Inc. v. Firstface Co.*, IPR2019-00612, Paper 30 at 3 (Nov. 29, 2021).

Additionally, the Board has generally expunged confidential information that it does not rely upon. *See, e.g., FireKing Security Prods., LLC v. Ellenby Techs., Inc.*, IPR2021-00531, Paper 24 at 4 (Feb. 17, 2022) (expunging papers and exhibits “not relied on” in the decision granting institution or “this Order terminating the proceeding” due to the parties’ settlement). The same principle applies even if the exhibit or paper is cited by the Board, where the specific confidential information is not substantively discussed or relied on by the Board

even if the exhibit or paper is cited. *See, e.g., Red Diamond, Inc. v. Southern Visions, LLP*, IPR2020-00001, Paper 41 at 4 (Jan. 14, 2022) (expunging the confidential exhibit where the Final Written Decision “did not rely on the specific confidential information contained” in the paragraph of the confidential exhibit cited by the Board).

III. GOOD CAUSE EXISTS FOR EXPUNGING THE REQUESTED MATERIALS

Good cause exists for expunging the exhibits listed above because the Board did not rely on the confidential information in any exhibits that Regeneron now seeks to expunge in its judgement (Granting Adverse Judgment after Institution of Trial, pursuant to 37 C.F.R. § 42.73(b)). For the handful of exhibits the Board did rely on in its Decision Granting Institution (Paper 13), the Board has already acknowledged that Regeneron has “good cause” to seal those exhibits by granting Regeneron’s Motion to Seal. (Paper 25.) The same good cause warrants expungement for the reasons discussed in further detail below.

A. Procedural Background

On April 27, 2023, Samsung petitioned for inter partes review of claims 1-30 of U.S. Patent No. 11,253,572, owned by Regeneron. (Paper 2.) Regeneron filed its Patent Owner’s Preliminary Response on August 25, 2023, along with Exhibits 2001, 2013, 2015, 2018-2019, 2036-2041, 2043, and 2048, as well as an unopposed Motion to Seal describing the confidential information in these exhibits

at a high level, sufficient to demonstrate good cause for sealing. (Papers 6 and 7.) The Board instituted review on November 17, 2023. (Paper 13.) The Board granted Regeneron's Motion to Seal its confidential information on January 8, 2024. (Paper 25.)

On February 23, 2024, Regeneron submitted a Patent Owner Response (Paper 35, Redacted—Paper 36) along with certain confidential exhibits, including Exhibits 2063-2064, 2067, 2069-2070, 2072-2073, 2075-2076, 2092, 2141-2144, 2147, 2162-2199, 2214-2225, 2232, and 2238. Regeneron also submitted an unopposed Motion to Seal the confidential exhibits under the terms of the default Protective Order. (Paper 34.) Regeneron's Motion to Seal describes the information included in the confidential exhibits at a high level, sufficient to demonstrate good cause for sealing.

On June 10, 2024, Samsung filed a Reply to Patent Owner's Response. (Paper 64, Redacted—Paper 63.) Samsung also submitted an unopposed Motion to Seal for Exhibits 1080, 1082, and 1083 (which include Regeneron confidential information), as well as portion of its Reply disclosing Regeneron's confidential information. (Paper 62.) On July 10, 2024, Regeneron disclaimed all claims—claims 1-30—in an email to the Board. On July 23, 2024, the Board entered adverse judgment against Regeneron. (Paper 69.) The Board did not rely on any confidential Papers or Exhibits that Regeneron now seeks to expunge in its entry of

that judgment.

B. Publishing the Confidential Papers and Exhibits Does Not Serve the Public Interest

The public interest is not advanced by publishing confidential Papers 35 and 64 and Exhibits 1080, 1082, 1083, 2001, 2013, 2015, 2018-2019, 2036-2041, 2043, 2048, 2063-2064, 2067, 2069-2070, 2072-2073, 2075-2076, 2092, 2141-2144, 2147, 2162-2199, 2214-2225, 2232, and 2238.

First, the Board has already acknowledged the confidential nature of Regeneron's materials. The Board granted Regeneron's first Motion to Seal (Paper 7), recognizing that Regeneron had "good cause" to seal Exhibits 2001, 2013, 2015, 2018-2019, 2036-2041, 2043, and 2048. (Paper 25, 6.) The Board further granted Regeneron's Motion for Protective Order (Paper 8), finding "good cause" exists for Regeneron's non-public, confidential information. (Paper 25, 7.) The "good cause" the Board already found is the same for a motion to expunge. *Corning Optical Commc'ns RF, LLC v. PPC Broadband, Inc.*, IPR2013-00346, Paper 94 at 3 (Oct. 2, 2018) (internal citations omitted).

Second, the parties filed redacted, public versions of Papers 35 and 64 as Papers 36 and 63, respectively. Regeneron has also previously provided redacted versions of Exhibits 2001, 2015, 2019, 2043, 2063-2064, 2067, 2070, 2092, 2214, and 2232. With this Motion, Regeneron additionally provides redacted versions of Exhibits 1080, 1082, 2018 and 2039-2041. The remaining confidential exhibits

Regeneron seeks to expunge are not relied upon in the Board's Decision Granting Institution or its final judgment and include sensitive information relating to Regeneron's products and finances. Filing redacted versions of these documents would not be feasible or beneficial to the public because almost the entirety of each document constitutes Regeneron confidential information.

Third, Regeneron provided a high-level description of the confidential information contained in those Papers and Exhibits sufficient for the public to understand the general subject matter of these materials. As set forth in Regeneron's Motions to Seal (Papers 7 and 34), these materials contain Regeneron's confidential, sensitive commercial information, including closely held information, related to core business, business operations, and business strategy.

For example, Exhibits 2143-2144, 2162-2199, 2214-2225, and 2232 are Regeneron confidential analyses relating to the market for its products. These exhibits contain details related to Regeneron's finances and sales information. These analyses are not publicly available, and disclosing these exhibits on the public docket could cause Regeneron competitive harm by allowing Regeneron's competitors to gain an unfair informational advantage.

Additionally, Exhibits 2015, 2018-2019, 2043, 2048, 2072-2073, and 2076 contain detailed, confidential information relating to Regeneron's clinical trials and results. These exhibits disclose Regeneron's internal notes and summaries of

clinical trials, non-public results and data analyses from the trials, and detailed clinical trial protocols. Public disclosure of these exhibits could cause competitive harm to Regeneron by giving competitors knowledge of Regeneron's internal analyses and protocols.

Exhibits 1083, 2013, 2036-2041, 2069-2070, 2073, 2075, and 2092 contain confidential information regarding Regeneron's clinical development decisions and strategies. These exhibits disclose decisions from the development of Eylea®, the design of its clinical trials, and plans for future regulatory submissions. These materials were subject to a protective order in related litigation with Mylan, and again, public disclosure of these sensitive materials would put Regeneron at a competitive disadvantage.

Exhibits 2141-2142, 2147, and 2238 contain confidential information obtained from third parties. Exhibit 2238 contains confidential financial information compiled and provided by a third-party data provider, Vestrum Health ("Vestrum"), including data analysis related to Patent Owner's activities in connection with Eylea®. Exhibits 2141-2142 and 2147 contain survey results from retina specialists compiled by the American Society of Retina Specialists ("ASRS"). These surveys are not publicly available and have restrictions on their publication. Public disclosure of these exhibits could cause competitive harm to Regeneron, Vestrum, and members of ASRS.

Exhibits 1080 and 1082 are depositions of Drs. George Yancopoulos and Karen Chu, and Exhibits 2001, 2063, 2064, and 2067 are declarations from Drs. Richard Manning, George Yancopoulos, and Karen Chu, all of which rely on the confidential information disclosed in the exhibits discussed above. Dr. Manning's declarations contain confidential information regarding Regeneron's costs and profits of Eylea®, marketing plans and projections compiled by Regeneron and third parties, and non-public analyses in Dr. Manning's attachments. Drs. Yancopoulos and Chu's depositions and declarations contain confidential information relating to Regeneron's strategic decisions in the development of Eylea®, Regeneron's clinical trials and results, and non-public data analyses.

Fourth, the Board did not rely on the confidential information in the Papers or Exhibits listed above in rendering its final judgment. The Board did not issue a Final Written Decision in this proceeding; instead, the Board entered adverse judgment following Regeneron's disclaimer of all claims. (Paper 69.) This judgment did not cite nor depend on any Paper or Exhibit Regeneron seeks to expunge. Therefore, the public interest in Regeneron's confidential Papers and Exhibits is minimal because it is not necessary to understand the proceeding, particularly where all claims of the '572 patent have been disclaimed. Accordingly, expunging the confidential documents does not inhibit the "public's interest in maintaining a complete and understandable history of this inter partes

review.” *Atlanta Gas Light Co. v. Bennett Regulator Guards, Inc.*, IPR2013-00453, Paper 97 at 2 (P.T.A.B. Apr. 15, 2015).

IV. CONCLUSION

For the reasons set forth above, good cause exists for expungement. Accordingly, pursuant to 37 C.F.R § 42.56, Regeneron respectfully requests the Board expunge confidential Papers 35 and 64 and Exhibits 1080, 1082, 1083, 2001, 2013, 2015, 2018-2019, 2036-2041, 2043, 2048, 2063-2064, 2067, 2069-2070, 2072-2073, 2075-2076, 2092, 2141-2144, 2147, 2162-2199, 2214-2225, 2232, and 2238 from the record.

Dated: September 4, 2024

Respectfully submitted,

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

I hereby certify that the attached PATENT OWNER'S MOTION TO
EXPUNGE PURSUANT TO 37 C.F.R. § 42.56 was served on the below date on
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