UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC., CELLTRION, INC., and APOTEX, INC.,
Petitioners

v.

REGENERON PHARMACEUTICALS, INC.
Patent Owner

Case IPR2021-00881[1]
Patent 9,254,338 B2

CORRECTED PATENT OWNER'S MOTION TO SEAL

[1] IPR2022-00258 and IPR2022-00298 have been joined with this proceeding.

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 documents:

- Ex. 2048 (Expert Declaration of Dr. Lucian V. Del Priore, M.D., Ph.D.);
- Ex. 2049 (Expert Declaration of Dr. Alexander M. Klibanov, Ph.D.);
- Ex. 2052 (Expert Declaration of Richard Manning, Ph.D.);
- Ex. 2059 (Regeneron Sample Analysis Report: PK06005-9-SA-01V1 (2006));
- Ex. 2060 (Regeneron Pharmaceuticals Protocol VGFT-OD-0605, Table 14.2.3/2a Summary of Proportion of Vision Loss from Baseline to Week 96, Last Observations Carried Forward (Full Analysis Set));
- Ex. 2073 (Zaltrap non-comparability issue: Regeneron Sanofi Analytical Investigation Workshop (March 14, 2014));
- Ex. 2096 (Clinical Study Agreement Between Vitreoretinal Consultants and Regeneron Pharmaceuticals, Inc. (July 31, 2007));
- Ex. 2128 (VGFT-OD-0605 (VIEW 1 Trial) Protocol Signature Page);
- Ex. 2138 (Regeneron, “Physician ATU: Wave 2,” 2/2013);
- Ex. 2140 (Regeneron, “Physician ATU: Wave 5,” 11/2013);
- Ex. 2163 (Regeneron, “Physician ATU: Wave 4,” 8/6/2013);

- Ex. 2169 (Regeneron, "Eylea Sample Disbursement 2013 to 2021," c. 2021);
- Ex. 2170 (Regeneron, "US Eylea P&L LTD," 12/2021);
- Ex. 2176 (Regeneron, “Q4 2020 Performance Update Wet AMD, DME, MEfRVO & DR w/out DME,” 1/29/2021);
- Ex. 2197 (Regeneron, “Physician ATU – Benchmark Wave,” 9/15/2011);
- Ex. 2200 (Regeneron, “U.S. Eylea Historical Brand P&L”);
- Ex. 2205 (Regeneron, “DME Market Assessment,” 8/2014);
- Ex. 2208 (Regeneron, “Eylea MD ATU – Wave 2 Final Questionnaire,” 12/19/2012);
- Ex. 2218 (Regeneron, “Eylea (aflibercept) Injection: Components of Reimbursement,” c. 2015);
- Ex. 2229 (Regeneron, WAC Pricing File, 5/2021);
- Ex. 2243 (American Society of Retina Specialists, “Preferences and Trends (PAT) Survey,” 2016);
- Ex. 2244 (American Society of Retina Specialists, “Preferences and Trends (PAT) Survey,” 2015);
- Ex. 2250 (American Society of Retina Specialists, “Preferences and Trends (PAT) Survey,” 2014);

- Ex. 2259 (American Society of Retina Specialists, "Preferences and Trends Membership Survey," 2009);
- Ex. 2263 (Regeneron, Eylea Sales Summary, c.2020);
- Ex. 2272 (Regeneron, "Eylea Q2 2021 Performance," 8/2/2021);
- Ex. 2273 (Vestrum, Anti-VEGF Category Sales Shares, c. 2/2022);
- Ex. 2274 (Regeneron, "Eylea Wet AMD Line of Therapy Insights," 4/2020);
- Ex. 2275 (Regeneron, "Vestrum Anti-VEGF Market Share Adjustment Overview," 5/10/2019);
- Ex. 2276 (Regeneron, "Eylea Q2 2020 Performance (Vestrum Projection Data)," 8/4/2020);
- Ex. 2277 (Regeneron, "Marketing Planning Process," 9/2011);
- Ex. 2278 (Regeneron, "Wave 1 2021 Performance Update Wet AMD, DME, MEfRVO, and DR w/out DME," 9/2021);
- Ex. 2285 (Regeneron, Eylea Gross & Net Sales P&L YTD, c.2021); and
- Paper No. 40 (Patent Owner's Response in IPR2021-00881).

These exhibits and documents were filed concurrently with Patent Owner's Response. Petitioner indicated that it did not oppose this Motion.

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*, Case 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 six 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 who has permitted its use in this proceeding subject to a protective order, or else consists of confidential business information that would cause competitive harm to Patent Owner were it to be disclosed publicly.

A. Confidential Partner Technical Documents

Exhibit 2073 is a presentation that was produced by Regeneron's partner, Sanofi. It describes internal aflibercept manufacturing studies performed by Sanofi and contains data and results from those studies. The information contained in this exhibit is not publicly available and would cause competitive harm to Regeneron and Sanofi if disclosed on the public docket. Sanofi has consented to its use in this

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