UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SAMSUNG BIOEPIS CO., LTD.,
Petitioner,

v.

REGENERON PHARMACEUTICALS, INC.,
Patent Owner.

Case: IPR2025-00176
U.S. Patent No. 11,084,865

PATENT OWNER'S SUPPLEMENTAL MANDATORY NOTICES

Pursuant to 37 C.F.R. § 42.8, Patent Owner Regeneron Pharmaceuticals, Inc. respectfully submits the following supplemental mandatory notices.

I. REAL PARTY IN INTEREST

The real party-in-interest is the patent owner, Regeneron Pharmaceuticals, Inc. ("Regeneron").

II. RELATED MATTERS

A. District Court Litigation

Over the past two years, Regeneron has been engaged in patent litigation pursuant to the Biologics Price Competition and Innovation Act ("BPCIA") against multiple companies, including Petitioner, seeking to make biosimilar versions of Regeneron's product Eylea®. In each case, Regeneron asserted U.S. Patent No. 11,084,865 (the "'865 patent") that is the subject of this IPR. The '865 patent is directed to ophthalmic formulations of the fusion protein aflibercept, the active ingredient in Eylea.

Regeneron first asserted the '865 patent against Mylan Pharmaceuticals Inc. ("Mylan") in the Northern District of West Virginia, *Regeneron Pharmaceuticals, Inc. v. Mylan Pharmaceuticals Inc.*, No. 1:22-cv-61 (N.D.W. Va.). Last fall, Regeneron also asserted the '865 patent against Petitioner Samsung Bioepis Co., Ltd., *Regeneron Pharmaceuticals, Inc. v. Samsung Bioepis Co., Ltd.*, Nos. 1:23-cv-94, 1:23-cv-106 (N.D.W. Va.), along with Formycon AG ("Formycon"), *Regeneron Pharmaceuticals, Inc. v. Formycon AG*, No. 1:23-cv-97 (N.D.W. Va.),

and Celltrion, Inc. ("Celltrion"), *Regeneron Pharmaceuticals, Inc. v. Celltrion, Inc.*, Nos. 1:23-cv-89, 1:24-cv-53 (N.D.W. Va.), in the same court. Regeneron later brought suit against Amgen Inc. in the Central District of California, *Regeneron Pharmaceuticals, Inc. v. Amgen Inc.*, No. 2:24-cv-264 (C.D. Cal.), and against Sandoz Inc. in the District of New Jersey, *Regeneron Pharmaceuticals, Inc. v. Sandoz Inc.*, No. 3:24-cv-876 (D.N.J.), again asserting the '865 patent. The U.S. Judicial Panel on Multidistrict Litigation instituted a multidistrict litigation incorporating the aforementioned actions in the Northern District of West Virginia, *In re Aflibercept Pat. Litig.*, No. 1:24-md-3103 (N.D.W. Va.); *see Regeneron Pharm., Inc. v. Amgen, Inc.*, 24-cv-39 (N.D.W. Va.); *Regeneron Pharm., Inc. v. Sandoz, Inc.*, No. 24-cv-85 (N.D.W. Va.).

In the first case against Mylan, the district court held a two-week bench trial on the infringement and validity of the '865 patent (among others) and held that the asserted claims (4, 7, 9, 11, and 14-17) of the '865 patent were infringed and not invalid for anticipation, obviousness, indefiniteness, lack of written description, or nonenablement. *Regeneron Pharm., Inc. v. Mylan Pharm. Inc.*, 714 F. Supp. 3d 652 (N.D.W. Va. 2024). Mylan appealed. Briefing in the appeal has concluded, and the parties are awaiting argument. *Regeneron Pharm., Inc. v. Mylan Pharm. Inc.*, No. 24-2002 (Fed. Cir.).

In Regeneron's case against Petitioner, Regeneron moved for a preliminary injunction against Petitioner based on the '865 patent. Earlier this year, the district court granted the preliminary injunction and concluded that Regeneron was likely to succeed on infringement and validity of the '865 patent. *In re Aflibercept Pat. Litig.*, 2024 WL 3422971 (N.D.W. Va. June 24, 2024). Petitioner appealed, and the Federal Circuit heard argument on December 5, 2024. *Regeneron Pharm., Inc. v. Mylan Pharm. Inc.*, Nos. 24-1965, 24-1966, 24-2082, 24-2083 (Fed. Cir.). Regeneron also moved for preliminary injunctions against Formycon and Celltrion based on the '865 patent, and the district court granted preliminary injunctions against both defendants. *In re Aflibercept Pat. Litig.*, 2024 WL 3423047 (N.D.W. Va. July 9, 2024); *In re Aflibercept Pat. Litig.*, 1:24-md-3103, Dkt. 248 (N.D.W. Va. July 9, 2024). Formycon and Celltrion both appealed. Formycon's appeal was heard alongside Petitioner's appeal on December 5. *Regeneron Pharm., Inc. v. Mylan Pharm. Inc.*, Nos. 24-2009, 24-2019, 24-2156 (Fed. Cir.). Briefing has concluded in Celltrion's appeal, which is awaiting argument. *Regeneron Pharm., Inc. v. Mylan Pharm. Inc.*, Nos. 24-2058, 24-2147 (Fed. Cir.).

Regeneron also moved for a preliminary injunction in the Amgen case based on the '865 patent. The district court denied a preliminary injunction because it found that Regeneron was not likely to succeed on infringement. *In re Aflibercept Pat. Litig.*, No. 24-md-03103, Dkt. 352 (N.D.W. Va. Oct. 1, 2024). Regeneron

appealed. The appeal is fully briefed and argument is scheduled for January 9, 2024. *Regeneron Pharm., Inc. v. Mylan Pharm. Inc.*, No. 24-2351 (Fed. Cir.).

The above-listed cases may affect or be affected by a decision in the present *inter partes* review of the ’865 patent.

B. Administrative Matters

Formycon has filed a “copycat” petition for *inter partes* review of the ’865 patent, which Formycon purports to be substantially identical to the Petition here. *See* IPR2025-00233. Formycon’s petition for *inter partes* review may affect or be affected by a decision in the present *inter partes* review of the ’865 patent. The ’865 patent has not been the subject of any other *inter partes* review or *ex parte* or *inter partes* reexamination.

U.S. Patent No. 10,464,992 (the “’992 patent”) is related to the ’865 patent and was challenged in three *inter partes* reviews: *Chengdu Kanghong Biotechnology Co., Ltd. v. Regeneron Pharm., Inc.*, IPR2021-00402 (P.T.A.B.); *Celltrion, Inc. v. Regeneron Pharm., Inc.*, IPR2023-00462 (P.T.A.B.); and *Samsung Bioepis Co., Ltd. v. Regeneron Pharm., Inc.*, IPR2023-01312 (P.T.A.B.). The ’992 patent was also the subject of an *ex parte* reexamination, No. 90/014,448. The parties agreed to terminate IPR2021-00402. The Board instituted *inter partes* review in IPR2023-00462 and joined Samsung Bioepis Co., Ltd. Regeneron subsequently disclaimed all claims of the ’992 patent, and the Board terminated

inter partes review. IPR2023-00462, Paper 37. Regeneron does not concede that any of these matters would affect or be affected by the present *inter partes* review.

The following patents and applications claim, or may claim, the benefit of priority of the filing date of the '865 patent: Application Nos. 18/344,786, 18/924,707.

III. LEAD AND BACKUP COUNSEL

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An Updated Power of Attorney is being filed concurrently with these Supplemental Mandatory Notices.

IV. SERVICE INFORMATION

Patent Owner consents to electronic service of all documents at the email addresses Eylea@wc.com and GRP-PW-EYLEA-Biosimilars@paulweiss.com.

Dated: December 31, 2024

Respectfully submitted,

By: /David I. Berl/
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CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. § 42.6(e), the undersigned hereby certifies that a true and correct copy of the foregoing Mandatory Notices and Power of Attorney was served on December 31, 2024, by delivering copies via electronic mail on the following counsel of record for the Petitioner:

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Dated: December 31, 2024

By: /David I. Berl/
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