

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ALVOTECH USA INC. AND ALVOTECH HF,
Petitioners,

v.

REGENERON PHARMACEUTICALS, INC.,
Patent Owner.

Case: PGR2025-00085
U.S. Patent No. 12,168,036

PATENT OWNER'S MANDATORY NOTICES

Pursuant to 37 C.F.R. § 42.8, Patent Owner Regeneron Pharmaceuticals, Inc. respectfully submits the following 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 and Federal Circuit Litigation

Regeneron invented, developed, and markets two products containing the fusion protein aflibercept—Eylea[®] and Eylea HD[®]. The patent challenged in this proceeding is Regeneron’s U.S. Patent No. 12,168,036 (the “’036 patent”), which relates to higher-dose formulations of aflibercept—including the Eylea HD[®] formulation comprising 8 mg of aflibercept—and their use for treating angiogenic eye disorders. With respect to Regeneron’s Eylea[®] product, which comprises 2 mg aflibercept, Regeneron has been engaged for roughly three years in consolidated multidistrict patent litigation against multiple companies seeking to market biosimilar versions of Eylea[®]. Regeneron has asserted against each biosimilar manufacturer U.S. Patent No. 11,084,865 (the “’865 patent”), directed to ophthalmic formulations of aflibercept. *Regeneron Pharm., Inc. v. Mylan Pharm. Inc.*, No. 1:22-cv-61 (N.D.W. Va.); *Regeneron Pharm., Inc. v. Samsung Bioepis Co., Ltd.*, Nos. 1:23-cv-94, 1:23-cv-106 (N.D.W. Va.); *Regeneron Pharm., Inc. v. Formycon AG*,

No. 1:23-cv-97 (N.D.W. Va.); *Regeneron Pharm., Inc. v. Celltrion, Inc.*, Nos. 1:23-cv-89, 1:24-cv-53 (N.D.W. Va.); *Regeneron Pharm., Inc. v. Amgen Inc.*, No. 2:24-cv-264 (C.D. Cal.); *Regeneron Pharm., Inc. v. Sandoz Inc.*, No. 3:24-cv-8760 (D.N.J.); *In re Aflibercept Pat. Litig.*, No. 1:24-md-3103 (N.D.W. Va.); *Regeneron Pharm., Inc. v. Amgen Inc.*, No. 1:24-cv-39 (N.D.W. Va.); *Regeneron Pharm., Inc. v. Sandoz Inc.*, No. 1:24-cv-85 (N.D.W. Va.); *Regeneron Pharm., Inc. v. Mylan Pharm. Inc.*, No. 24-2002 (Fed. Cir.); *Regeneron Pharm., Inc. v. Mylan Pharm. Inc.*, Nos. 24-1965 & 24-1966 (Fed. Cir.); *Regeneron Pharm., Inc. v. Mylan Pharm. Inc.*, No. 24-2009 (Fed. Cir.); *Regeneron Pharm., Inc. v. Mylan Pharm. Inc.*, No. 24-2058 (Fed. Cir.); *Regeneron Pharm., Inc. v. Mylan Pharm. Inc.*, No. 24-2351 (Fed. Cir.). In other consolidated cases, Regeneron has asserted a patent related to the '865 patent that likewise is directed to ophthalmic formulations of aflibercept, U.S. Patent No. 12,331,099. *Regeneron Pharm., Inc. v. Amgen Inc.*, No. 2:25-cv-5499 (C.D. Cal.); *Regeneron Pharm., Inc. v. Amgen Inc.*, No. 1:25-cv-74 (N.D.W. Va.).

In the same consolidated multidistrict litigation, Regeneron also has asserted U.S. Patent No. 11,103,552 (the "'552 patent"), which is the parent patent of the '036 patent at issue in this post-grant review proceeding. *Regeneron Pharm., Inc. v. Samsung Bioepis Co., Ltd.*, No. 1:23-cv-106 (N.D.W. Va.). Although the '552 patent, like the '036 patent, relates to higher-dose aflibercept formulations, Regeneron asserted it pursuant to the parties' exchanges under the Biologics Price

Competition and Innovation Act. *See* 42 U.S.C. § 262.

Regeneron does not concede that the above-listed cases would affect or be affected by a decision in the present post-grant review of the '036 patent.

B. Administrative Matters

The '865 patent and Regeneron's related U.S. Patent No. 10,464,992 have been challenged in *inter partes* reviews and *ex parte* reexaminations. *Samsung Bioepis Co., Ltd. v. Regeneron Pharm., Inc.*, IPR2025-00176 (P.T.A.B.) ('865 patent, institution denied); *Formycon AG v. Regeneron Pharm., Inc.*, IPR2025-00233 (P.T.A.B.) ('865 patent, institution denied); *Celltrion, Inc. v. Regeneron Pharm., Inc.*, IPR2025-00456 (P.T.A.B.) ('865 patent, institution denied); *Fresenius Kabi SwissBioSim GmbH v. Regeneron Pharm., Inc.*, IPR2025-01269 (P.T.A.B.) ('865 patent, pending); *Chengdu Kanghong Biotechnology Co., Ltd. v. Regeneron Pharm., Inc.*, IPR2021-00402 (P.T.A.B.) ('992 patent, dismissed before decision on institution); *Celltrion, Inc. v. Regeneron Pharm., Inc.*, IPR2023-00462 (P.T.A.B.) ('992 patent, instituted and terminated upon patent disclaimer); *Samsung Bioepis Co., Ltd. v. Regeneron Pharm., Inc.*, IPR2023-01312 (P.T.A.B.) ('992 patent, instituted and terminated upon patent disclaimer); *Ex Parte* Reexamination No. 90/014,448 ('992 patent, instituted and terminated upon patent disclaimer). Regeneron does not concede that any of these matters would affect or be affected by the present post-grant review.

The following patents and applications claim, or may claim, the benefit of priority of the filing date of the '036 patent: The '552 patent, Application No. 18/367,444, and Application No. 18/984,981.

III. LEAD AND BACKUP COUNSEL

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A Power of Attorney is filed concurrently with these Mandatory Notices.

IV. SERVICE INFORMATION

Patent Owner consents to electronic service of all documents at the email address Eylea@wc.com.

Dated: April 1, 2026

Respectfully submitted,

PGR2025-00085

U.S. Patent No. 12,168,036

By: /David I. Berl/
David I. Berl
Reg. No. 72,751

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 April 1, 2026, by delivering copies via electronic mail on the following counsel of record for the Petitioner:

PGR46514-0017PS1@fr.com

Dated: April 1, 2026

By: /David I. Berl/
David I. Berl
Reg. No. 72,751