

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

FRESENIUS KABI SWISSBIOSIM GMBH,
Petitioner,

v.

REGENERON PHARMACEUTICALS, INC.,
Patent Owner.

Case: IPR2025-01269
U.S. Patent No. 10,828,345

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 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 seeking to make biosimilar versions of Regeneron’s product Eylea®. Regeneron has asserted U.S. Patent No. 10,828,345 (the “’345 patent”) against Amgen Inc. (“Amgen”) and Sandoz Inc. (“Sandoz”). *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.). The U.S. Judicial Panel on Multidistrict Litigation instituted a multidistrict litigation incorporating the Amgen and Sandoz litigations with several others Regeneron had filed 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.*, No. 1:24-cv-39 (N.D.W. Va.); *Regeneron Pharm., Inc. v. Sandoz Inc.*, No. 1:24-cv-85 (N.D.W. Va.).

The above-listed cases may affect or be affected by a decision in the present

inter partes review of the '345 patent.

B. Administrative Matters

Chengdu Kanghong Biotechnology Co., Ltd., filed a petition for post-grant review of the '345 patent. PGR2021-00035. The parties agreed to terminate that proceeding. PGR2021-00035, Paper 8. The '345 patent has not been the subject of any other *inter partes* review or *ex parte* or *inter partes* reexamination.

U.S. Patent Nos. 9,254,338 (the "'338 patent"), 9,669,069 (the "'069 patent"), 10,130,681 (the "'681 patent"), 10,888,601 (the "'601 patent"), 10,857,205 (the "'205 patent"), and 11,253,572 (the "'572 patent") are related to the '345 patent. The '338 patent was challenged in three *inter partes* reviews, IPR2022-00258; IPR2022-00298; IPR2021-00881, and the challenged claims were found unpatentable by the Board, IPR2021-00881, Paper 94. The '069 patent was challenged in three *inter partes* reviews, IPR2022-00257; IPR2022-00301; IPR2021-00880, and the challenged claims were found unpatentable by the Board, IPR2021-00880, Paper 89. The '681 patent was challenged in three *inter partes* reviews, IPR2023-00532; IPR2023-00442; IPR2022-01225, and the challenged claims were found unpatentable by the Board, IPR2022-01225, Paper 96. The '601 patent was challenged in five *inter partes* reviews, IPR2024-00201; IPR2023-00739; IPR2023-00566; IPR2023-00533; IPR2022-01226, and the challenged claims were found unpatentable by the Board, IPR2022-01226, Paper 101. The '205

patent was challenged in one *inter partes* review, and the Board denied institution after Regeneron filed a statutory disclaimer, disclaiming all claims of the '205 patent. IPR2023-00099, Paper 10. The '572 patent was challenged in four *inter partes* reviews, IPR2024-00298; IPR2024-00260; IPR2023-00884; IPR2022-01524, and while the Board denied institution in one, IPR2022-01524, Paper 9, in the other three proceedings, the Board granted Regeneron's request for adverse judgment following its disclaimer of the challenged claims, IPR2023-00884, Paper 69. 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 '345 patent: the '601 patent, the '511 patent, the '572 patent; U.S. Patent Nos. 11,559,564; 11,730,794; 11,975,045; 12,268,730; and 11,707,506; and Application No. 19/027,212.

III. LEAD AND BACKUP COUNSEL

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A Power of Attorney is being 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: August 4, 2025

Respectfully submitted,

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 August 4, 2025, by delivering copies via electronic mail on the following counsel of record for the Petitioner:

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