

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AMNEAL PHARMACEUTICALS, INC. AND KASHIV BIOSCIENCES,

Petitioners,

v.

GENENTECH, INC. AND NOVARTIS PHARMACEUTICALS CORP.,

Patent Owners.

Case: IPR2026-00260

U.S. Patent No. 12,030,959

PATENT OWNERS' MANDATORY NOTICES

Pursuant to 37 C.F.R. § 42.8, Patent Owners Genentech, Inc. and Novartis Pharmaceuticals Corp. respectfully submit the following mandatory notices.

I. REAL PARTY IN INTEREST

The real parties-in-interest are the patent owners, Genentech, Inc. (“Genentech”) and Novartis Pharmaceuticals Corp. (“Novartis”).

II. RELATED MATTERS

The patent challenged in this proceeding, U.S. Patent No. 12,030,959 (the “’959 patent”), relates to Genentech’s Xolair® (omalizumab) product marketed pursuant to BLA No. 103976.

The ’959 patent is related to issued patent U.S. Patent No. 12,492,265 and pending United States patent application Nos. 18/762543, 19/331943, and 19/331731, which may be affected by a decision in this proceeding.

Genentech and Novartis have notified Kashiv pursuant to 42 U.S.C. § 262(l)(3)(A) that marketing of its proposed omalizumab biosimilar will infringe the ’959 patent and, pursuant to the statutory process created by the Biosimilar Price Competition and Innovation Act, district court litigation concerning this allegation will commence during this proceeding.

Genentech is not aware of any other judicial or administrative matters that would affect, or be affected by, a decision in this proceeding.

III. LEAD AND BACKUP COUNSEL

Lead Counsel
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Backup Counsel	
Richard Hildreth III (Reg. No. 80,415) Williams & Connolly LLP 680 Maine Avenue SW Washington, DC 20024 (202) 434-5373 rhildreth@wc.com	All attorneys at Williams & Connolly LLP for whom a motion to appear <i>pro hac vice</i> is filed

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:

Xolair@wc.com.

Dated: June 16, 2026

Respectfully submitted,

By: /Thomas S. Fletcher/

Thomas S. Fletcher

Reg. No. 72,383

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 June 16, 2026, by delivering copies via electronic mail on the following counsel of record for the Petitioner:

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Dated: June 16, 2026

Respectfully submitted,

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