

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

REGENERON PHARMACEUTICALS, INC.,
Petitioner,

v.

NOVARTIS PHARMA AG,
NOVARTIS TECHNOLOGY LLC,
NOVARTIS PHARMACEUTICALS CORPORATION,
Patent Owner.

Case IPR2021-00816
U.S. Patent No. 9,220,631 B2

**PETITIONER'S UPDATED MANDATORY NOTICES
PURSUANT TO 37 C.F.R. § 42.8**

Petitioner Regeneron Pharmaceuticals, Inc. hereby submits its updated mandatory notices pursuant to 37 C.F.R. § 42.8(a)(3).

A. Real Party-In-Interest (37 C.F.R. § 42.8(b)(1)) - Unchanged

The real party-in-interest is Regeneron Pharmaceuticals, Inc.

B. Related Matters (37 C.F.R. § 42.8(b)(2)) – Updated

On June 19, 2020, Novartis Pharma AG, Novartis Pharmaceuticals Corporation, and Novartis Technology LLC (collectively, “Novartis”) filed a complaint at the International Trade Commission (“ITC”) alleging that Regeneron infringes claims 1-6 and 11-26 of the ’631 Patent, and that a domestic industry exists with respect to certain claims. On April 8, 2021, Novartis filed a motion to terminate the ITC Investigation on the basis of withdrawal of the complaint. On April 8, 2021, the Administrative Law Judge issued an initial determination terminating the ITC Investigation. On May 3, 2021, the ITC issued a notice formally terminating the ITC investigation.

On June 19, 2020, Novartis filed a complaint in the United States District Court for the Northern District of New York (N.D.N.Y. 1:20-cv-00690-TJM-CFH) alleging that Petitioner infringes at least claim 1 of the ’631 Patent. That case was stayed pursuant to 28 U.S.C. § 1659 on July 30, 2020. On June 14, 2021, the Court lifted the stay. On November 4, 2021, Case No. 1:20-cv-00690-TJM-CFH was

reassigned within the Northern District of New York, where it remains pending as Case No. 1:20-cv-00690-DNH-CFH.

On July 16, 2020, Regeneron filed IPR2020-01317 and IPR2020-01318 challenging claims 1-26 of the '631 Patent. On December 2, 2020, Regeneron filed a motion to terminate IPR2020-01318 and the Board issued a determination terminating the proceeding on December 7, 2020. On January 15, 2021, the Board exercised its discretion under 35 U.S.C. § 314(a) and denied institution of IPR2020-01317 based on the co-pending ITC Investigation.

On July 17, 2020, Regeneron filed a complaint in the United States District Court for the Southern District of New York against Novartis and Vetter Pharma International GmbH (“Vetter”) (S.D.N.Y. 1:20-cv-00502-AJN) seeking judgment that (i) Novartis’s and Vetter’s conduct violates Section 1 of the Sherman Act, 15 U.S.C. § 1; (ii) Novartis’s conduct violates Section 2 of the Sherman Act, 15 U.S.C. § 2; and (iii) the '631 Patent be declared unenforceable. On September 21, 2021, the Southern District of New York transferred Case No. 1:20-cv-00502-AJN to the Northern District of New York. Case No. 1:21-cv-01066-DNH-CFH (NDNY). On January 31, 2022, the Court granted Novartis’s and Vetter’s motion to dismiss Regeneron’s complaint.

C. Lead and Back-Up Counsel and Service Information (37 C.F.R. § 42.8(b)(3)-(4)) - Unchanged

Petitioner identifies the following lead and back-up counsel and service information:

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