

**UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, D.C.**

In the Matter of

**CERTAIN PRE-FILLED SYRINGES FOR
INTRAVITREAL INJECTION AND
COMPONENTS THEREOF**

Investigation No. 337-TA-1207

**NOTICE OF COMMISSION DETERMINATION TO REVIEW AN INITIAL
DETERMINATION GRANTING SUMMARY DETERMINATION AND ON REVIEW TO
VACATE AS MOOT; NOTICE OF COMMISSION DETERMINATION NOT TO REVIEW AN
INITIAL DETERMINATION TERMINATING THE INVESTIGATION IN ITS ENTIRETY
BASED ON A WITHDRAWAL OF THE COMPLAINT; TERMINATION OF THE
INVESTIGATION**

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission (“Commission”) has determined to review an initial determination (“ID”) (Order No. 31) granting summary determination of infringement and of domestic industry, and on review, to vacate that ID as moot, and not to review a second ID (Order No. 33) terminating the investigation based on a withdrawal of the complaint. The investigation is terminated.

FOR FURTHER INFORMATION CONTACT: Robert Needham, Office of the General Counsel, U.S. International Trade Commission, 500 E Street, S.W., Washington, D.C. 20436, telephone (202) 708-5468. Copies of non-confidential documents filed in connection with this investigation may be viewed on the Commission’s electronic docket (EDIS) at <https://edis.usitc.gov>. For help accessing EDIS, please email EDIS3Help@usitc.gov. General information concerning the Commission may also be obtained by accessing its Internet server at <https://www.usitc.gov>. Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission’s TDD terminal on (202) 205-1810.

SUPPLEMENTARY INFORMATION: On July 27, 2020, the Commission instituted this investigation based on a complaint filed by Novartis Pharma AG, Novartis Pharmaceuticals Corporation, and Novartis Technology LLC (collectively, “Novartis”). 85 FR 45227-28. The complaint alleges violations of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, based on the importation into the United States, sale for importation, or sale in the United States after importation of certain pre-filled syringes for intravitreal injections and components thereof that infringe one or more of claims 1-6 and 11-26 of U.S. Patent No. 9,220,631 (“the ’631 patent”). *Id.* The complaint also alleges the existence of a domestic industry. *Id.* The notice of investigation names Regeneron Pharmaceuticals Inc. of Tarrytown, New York (“Regeneron”) as the sole respondent and the Office of Unfair Import Investigations (“OUII”) as a party. *Id.* at 45228.

On February 18, 2021, Novartis filed a motion for summary determination that Regeneron directly infringes the '631 patent and that Novartis satisfied the domestic industry requirement. On March 1, 2021, OUII filed a response in support of the motion, and Regeneron filed a response opposing Novartis's argument that it satisfied the economic prong of the domestic industry requirement.

On April 2, 2021, the presiding administrative law judge ("ALJ") issued the first ID (Order No. 31), granting summary determination of infringement and domestic industry. No petitions for review of the ID were received.

On April 8, 2021, Novartis filed an unopposed motion to terminate the investigation in its entirety based on its withdrawal of the complaint. The motion indicated that Regeneron and OUII did not oppose the motion, and Regeneron did not file a response to the motion. OUII filed a response in support of the motion. The motion to terminate the investigation was filed before the deadline to petition for review of Order No. 31 had passed. *See* 19 CFR 210.43(a).

On April 8, 2021, the ALJ issued the second ID (Order No. 33), granting the motion and terminating the investigation. Order No. 33 was issued before the deadline to petition for review of Order No. 31 had passed. No petitions for review of the second ID were filed.

The Commission has determined to review the first ID, Order No. 31, in its entirety, and on review, to vacate that ID as moot because the summary determination issues became moot in light of Novartis's motion to withdraw its complaint and terminate the investigation. Vice Chair Stayin and Commissioner Johanson do not join the Commission's decision to review and vacate Order No. 31. In the absence of a request from any party to review or vacate the Order, or any other grounds for review set forth in 19 CFR 210.44, they would not review Order No. 31.

The Commission has further determined not to review the second ID, Order No. 33, terminating the investigation. The investigation is hereby terminated in its entirety.

The Commission vote for this determination took place on May 3, 2021.

The authority for the Commission's determination is contained in Section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in Part 210 of the Commission's Rules of Practice and Procedure (19 CFR Part 210).

By order of the Commission.



Lisa R. Barton
Secretary to the Commission

Issued: May 3, 2021