7020-02

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337-TA-1207]

Certain Pre-Filled Syringes for Intravitreal Injection and Components Thereof; Institution of Investigation

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that a complaint was filed with the U.S. International Trade Commission on June 19, 2020, under section 337 of the Tariff Act of 1930, as amended, on behalf of Novartis Pharma AG of Switzerland; Novartis Pharmaceuticals Corporation of East Hanover, New Jersey; and Novartis Technology LLC of East Hanover, New Jersey. A letter supplementing the complaint was filed on July 10, 2020. The complaint alleges violations of section 337 based upon the importation into the United States, the sale for importation, and the sale within the United States after importation of certain pre-filled syringes for intravitreal injection and components thereof by reason of infringement of certain claims of U.S. Patent No. 9,220,631 ("the '631 patent"). The complaint further alleges that an industry in the United States exists or is in the process of being established as required by the applicable Federal Statute. The complainants request that the Commission institute an investigation and, after the investigation, issue a limited exclusion order and a cease and desist order.

ADDRESSES: The complaint, except for any confidential information contained therein, may be viewed on the Commission's electronic docket (EDIS) at https://edis.usitc.gov. For help accessing EDIS, please email EDIS3Help@usitc.gov. Hearing impaired individuals are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205-1810. Persons with mobility impairments who will need special assistance in

gaining access to the Commission should contact the Office of the Secretary at (202) 205-2000. General information concerning the Commission may also be obtained by accessing its internet server at https://www.usitc.gov.

FOR FURTHER INFORMATION CONTACT: Pathenia M. Proctor, The Office of Unfair Import Investigations, U.S. International Trade Commission, telephone (202) 205-2560.

SUPPLEMENTARY INFORMATION:

Authority: The authority for institution of this investigation is contained in section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, and in § 210.10 of the Commission's Rules of Practice and Procedure, 19 CFR 210.10 (2020).

Scope of Investigation: Having considered the complaint, the U.S. International Trade Commission, on July 21, 2020, 2020, **ORDERED THAT** –

(1) Pursuant to subsection (b) of section 337 of the Tariff Act of 1930, as amended, an investigation be instituted to determine whether there is a violation of subsection (a)(1)(B) of section 337 in the importation into the United States, the sale for importation, or the sale within the United States after importation of certain products identified in paragraph (2) by reason of infringement of one or more of claims 1–6 and 11–26 of the '631 patent, and whether an industry in the United States exists as required by subsection (a)(2) of section 337;

(2) Pursuant to § 210.10(b)(1) of the Commission's Rules of Practice and Procedure, 19 CFR 210.10(b)(1), the plain language description of the accused products or category of accused products, which defines the scope of the investigation, is "syringes that are pre-filled with ophthalmic medication, and components of such syringes, including barrels, plungers, and stoppers";

(3) Pursuant to Commission Rule § 210.50(b)(1), 19 CFR 210.50(b)(1), the presiding administrative law judge shall take evidence or other information and hear arguments from the parties or other interested persons with respect to the public interest in this investigation, as appropriate, and provide the Commission with findings of fact and a recommended determination on this issue, which shall be limited to the statutory public interest factors set forth in 19 U.S.C. 1337(d)(1), (f)(1), (g)(1);

(4) For the purpose of the investigation so instituted, the following are hereby named as parties upon which this notice of investigation shall be served:

(a) The complainants are:

Novartis Pharma AG

Forum 1

Novartis Campus

CH-4056 Basel

Switzerland

Novartis Pharmaceuticals Corporation
One Health Plaza

East Hanover, New Jersey, 07936

Novartis Technology LLC

One Health Plaza

East Hanover, New Jersey, 07936

(b) The respondent is the following entity alleged to be in violation of section 337, and is the party upon which the complaint is to be served:

Regeneron Pharmaceuticals, Inc.

77 Old Saw Mill River Road

Tarrytown, New York 10591

(c) The Office of Unfair Import Investigations, U.S. International Trade Commission, 500 E Street, S.W., Suite 401, Washington, D.C. 20436; and

(5) For the investigation so instituted, the Chief Administrative Law Judge, U.S. International Trade Commission, shall designate the presiding Administrative Law Judge.

Responses to the complaint and the notice of investigation must be submitted by the named respondent in accordance with § 210.13 of the Commission's Rules of Practice and Procedure, 19 CFR 210.13. Pursuant to 19 CFR 201.16(e) and 210.13(a), as amended in 85 FR 15798 (March 19, 2020), such responses will be considered by the Commission if received not later than 20 days after the date of service by the complainants of the complaint and the notice of investigation. Extensions of time for submitting responses to the complaint and the notice of investigation will not be granted unless good cause therefor is shown.

Failure of the respondent to file a timely response to each allegation in the complaint and in this notice may be deemed to constitute a waiver of the right to appear and contest the allegations of the complaint and this notice, and to authorize the administrative law judge and the Commission, without further notice to the respondent, to find the facts to be as alleged in the complaint and this notice and to enter an initial determination and a final determination containing such findings, and may result in the issuance of an exclusion order or a cease and desist order or both directed against the respondent.

By order of the Commission.

Lisa Barton,
Secretary to the Commission.

Issued: July 21, 2020.

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