

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

In the Matter of

**CERTAIN ADALIMUMAB, PROCESSES
FOR MANUFACTURING OR
RELATING TO SAME, AND
PRODUCTS CONTAINING SAME**

Inv. No. 337-TA-1296

NOTICE OF INSTITUTION OF INVESTIGATION

Institution of Investigation Pursuant to 19 U.S.C. 1337

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 December 17, 2021, under section 337 of the Tariff Act of 1930, as amended, on behalf of AbbVie Inc. of Chicago, Illinois; AbbVie Biotechnology Ltd. of Bermuda; and AbbVie Operations Singapore Pte. Ltd. of Singapore. A supplement to the complaint was filed on January 4, 2022. The complaint, as supplemented, alleges violations of section 337 based upon the importation into the United States and the sale of certain adalimumab, processes for manufacturing or relating to same, and products containing same by reason of the misappropriation of trade secrets and tortious interference with contractual relations, the threat or effect of which is to destroy or substantially injure an industry in the United States.

The complainant requests that the Commission institute an investigation and, after the investigation, issue a limited exclusion order and cease and desist orders.

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 section 210.10 of the Commission’s Rules of Practice and Procedure, 19 C.F.R. 210.10 (2021).

SCOPE OF INVESTIGATION: Having considered the complaint, the U.S. International Trade Commission, on January 25, 2022, 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)(A) of section 337 in the importation into the United States or in the sale of certain products identified in paragraph (2) by reason of the misappropriation of trade secrets and tortious interference with contractual relations, the threat or effect of which is to destroy or substantially injure an industry in the United States;

(2) Pursuant to section 210.10(b)(1) of the Commission’s Rules of Practice and Procedure, 19 C.F.R. 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 “adalimumab (drug substance and drug product), vials, prefilled syringes, autoinjectors or other presentations containing same, and the methods of manufacturing and processes for making the same”;

(3) 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:

AbbVie Inc.
1 North Waukegan Rd.
North Chicago, IL 60064

AbbVie Biotechnology Ltd
Harbour Fiduciary Services Limited
Thistle House
4 Burnaby Street
Hamilton HM11
Bermuda

AbbVie Operations Singapore Pte. Ltd.
23 Tuas South Avenue 6
Singapore 637022

(b) The respondents are the following entities alleged to be in violation of section 337, and are the parties upon which the complaint is to be served:

Alvotech hf.
Sæmundargata 15-19
101 Reykjavik
Iceland

Alvotech Germany GmbH
Karl-Heinz-Beckurts-Str. 13
52428, Jülich, Nordrhein-Westfalen
Germany

Alvotech Swiss AG
Thurgauerstrasse 54 Zürich
8050 Switzerland

Alvotech USA Inc.
1201 Wilson Blvd Ste 2130
Arlington, VA, 22209

Ivers-Lee AG
Kirchbergstrasse 160
Burgdorf, Bern
3400 Switzerland

Teva Pharmaceutical Industries Ltd.
5 Basel Street
Petach Tikva
49131 Israel

Teva Pharmaceuticals USA Inc.
1090 Horsham Road
North Wales, PA 19454

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

(4) 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 respondents in accordance with section 210.13 of the Commission's Rules of Practice and Procedure, 19 C.F.R. 210.13. Pursuant to 19 C.F.R. 201.16(e) and 210.13(a), as amended in 85 Fed. Reg. 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 a/the respondents 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.

A handwritten signature in black ink, appearing to read 'L.R. Barton', enclosed within a large, loopy oval shape.

Lisa R. Barton
Secretary to the Commission

Issued: January 26, 2022