

UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, D.C.

In the Matter of

**CERTAIN RECOMBINANT FACTOR
VIII PRODUCTS**

Investigation No. 337-TA-956

**NOTICE OF COMMISSION DETERMINATION NOT TO REVIEW
AN INITIAL DETERMINATION GRANTING AN UNOPPOSED MOTION TO
AMEND THE COMPLAINT AND NOTICE OF INVESTIGATION**

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has determined not to review an initial determination (“ID”) (Order No. 10) granting an unopposed motion to add as complainants Baxalta, Inc. of Deerfield, Illinois; Baxalta US Inc. of Deerfield, Illinois; and Baxalta GmbH of Glattpark, Switzerland.

FOR FURTHER INFORMATION CONTACT: Lucy Grace D. Noyola, Office of the General Counsel, U.S. International Trade Commission, 500 E Street, S.W., Washington, D.C. 20436, telephone 202-205-3438. Copies of non-confidential documents filed in connection with this investigation are or will be available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street, S.W., Washington, D.C. 20436, telephone 202-205-2000. General information concerning the Commission may also be obtained by accessing its Internet server (<http://www.usitc.gov>). The public record for this investigation may be viewed on the Commission’s electronic docket (EDIS) at <http://edis.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: The Commission instituted this investigation on May 22, 2015, based on a complaint filed by Baxter International Inc. of Deerfield, Illinois; Baxter Healthcare Corporation of Deerfield, Illinois; and Baxter Healthcare SA of Glattpark, Switzerland (“Baxter”). 80 *Fed. Reg.* 29745 (May 22, 2015). The complaint alleges violations of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337, in the importation into the United States, the sale for importation, and the sale within the United States after importation of certain recombinant factor VIII products by reason of infringement of certain claims of U.S. Patent Nos. 6,100,061; 6,936,441; and 8,084,252. *Id.* The notice of investigation named Novo Nordisk A/S of Bagsvaerd, Denmark and Novo Nordisk Inc. of Plainsboro, New Jersey (“Novo Nordisk”) as respondents. *Id.* at 29746. The Office of Unfair Import Investigations (“OUII”) also was named as a party to the investigation. *Id.*

On September 3, 2015, Baxter filed a motion to amend the complaint and notice of investigation to add Baxalta, Inc., Baxalta US Inc., and Baxalta GmbH (“the Baxalta entities”) as complainants. Neither Novo Nordisk nor OUII opposed the motion.

On September 16, 2015, the presiding administrative law judge (“ALJ”) issued an ID, Order No. 10, granting the motion to amend the complaint and notice of investigation. The ALJ found good cause for the amendment. The ALJ found the amendment would not prejudice the parties because (1) they have been aware of a corporate transition involving Baxter and the Baxalta entities since the service of the complaint and the notice of investigation and (2) Baxter has been responding to discovery requests as though they were directed to Baxter and the Baxalta entities and will continue to do so. The ALJ found that having the correct parties in the investigation would simplify and streamline the discovery process. No petitions for review of the ID were filed.

The Commission has determined not to review the subject ID.

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 C.F.R. Part 210).

By order of the Commission.

A handwritten signature in black ink, appearing to read 'Lisa R. Barton', with a stylized flourish at the end.

Lisa R. Barton
Secretary to the Commission

Issued: October 8, 2015