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 TO EXTEND THE TARGET DATE FOR COMPLETION OF THE INVESTIGATION

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has determined to extend the target date for the completion of this investigation to October 27, 2016.

FOR FURTHER INFORMATION, CONTACT: Ron Traud, Office of the General Counsel, U.S. International Trade Commission, 500 E Street, S.W., Washington, D.C. 20436, (202) 205-3427. 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, (202) 205-2000. General information concerning the Commission may also be obtained at *https://www.usitc.gov*. The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov*. Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal at (202) 205-1810.

SUPPLEMENTARY INFORMATION: On May 22, 2015, the Commission instituted this investigation pursuant to Section 337 of the Tariff Act of 1930, as amended, based on a complaint filed by Baxter Healthcare Corporation and Baxter Healthcare SA, both of Deerfield, Illinois. 80 *Fed. Reg.* 29745 (May 22, 2015). Baxalta Inc., Baxalta US Inc., and Baxalta GmbH were added as complainants after the filing of the complaint. 80 *Fed. Reg.* 62569 (Oct. 16, 2015). (The complainants are collectively referred to as "Baxter.") The Commission sought to determine whether there is a violation of Section 337(a)(1)(B) in the importation into the United States, the sale for importation into the United States, or the sale within the United States after importation of certain recombinant factor VIII products by reason of infringement of any of claims 19–21, 36, 37, and 39 of U.S. Patent No. 6,100,061 ("the '061 patent"); claims 20 and 21 of U.S. Patent No. 6,936,441 ("the '441 patent"); and claims 1, 5, 8, 10, 14, and 18 of U.S. Patent No. 8,084,252 ("the '252 patent"). *Id.* at 29746. The Commission directed the ALJ to make findings of fact and provide a recommended determination with respect to the statutory public interest factors set forth in 19 U.S.C. § 1337(d)(1), (f)(1), and (g)(1). *Id.* The notice of

investigation named as respondents Novo Nordisk A/S of Bagsvaerd, Denmark, and Novo Nordisk Inc., of Plainsboro, NJ (collectively, "Novo Nordisk"). *Id.* The Office of Unfair Import Investigations ("OUII") is also a party to this investigation. *Id.*

On September 17, 2015, the ALJ issued Order No. 11, which construes the terms "protein-free conditions" and "protein-free medium" in the asserted claims of the '061 and '252 patents. On December 4, 2015, Novo Nordisk moved for reconsideration. On January 7, 2016, the ALJ issued Order No. 25, which grants the motion, but reaffirms the previous claim constructions. On January 11, 2016, Baxter filed a motion requesting a summary determination that the accused products infringe claims 19 and 20 of the '061 patent. On February 26, 2016, the ALJ issued an initial determination ("ID") (Order No. 30), which grants the motion. On February 29, 2016, Novo Nordisk filed a petition requesting that the Commission review Order Nos. 11, 25, and 30. On March 29, 2016, the Commission determined to defer its decision on whether to review those order until the date on which the Commission determines whether to review the ALJ's final ID ("Final ID"). Notice of Comm'n Determination to Extend the Date for Determining Whether to Review a Non-Final Initial Determination Granting Complainants' Motion for Summary Determination that the Accused Products Infringe U.S. Patent No. 6,100,061 (Mar. 29, 2016).

On May 27, 2016, the ALJ issued the Final ID, which finds no violation of Section 337 as to any remaining asserted patent, and on June 3, 2016, the ALJ issued the Recommended Determination on Remedy, Bonding, and the Public Interest, which contingently recommends both a limited exclusion order and cease and desist orders. On June 13, 2016, Baxter, Novo Nordisk, and OUII filed petitions for review of the Final ID, and the parties thereafter filed responses to the petitions. On July 29, 2016, the Commission determined to review certain petitioned issues and requested briefing from the parties on one issue under review and on remedy, the public interest, and bonding. 81 *Fed. Reg.* 51463 (Aug. 4, 2016).

In view of the private parties' September 12, 2016, Joint Motion to Terminate the Investigation Based on a Settlement Agreement, the Commission is extending the target date for the completion of this investigation to October 27, 2016.

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.

Lisa R. Barton
Secretary to the Commission

Issued: September 15, 2016