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 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

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 date on which it determines whether to review a non-final initial determination (the subject ID) (Order No. 30) to the date on which it determines whether to review the final initial determination in the investigation.

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, telephone (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, telephone (202) 205-2000. General information concerning the Commission may also be obtained by accessing its Internet server at 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: On May 22, 2015, the Commission instituted this investigation 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. 80 Fed. Reg. 29745-46 (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 (the '061patent), 6,936,441 (the '441 patent), and 8,084,252 (the '252 patent). *Id.* The notice of investigation named as respondents Novo Nordisk A/S of Bagsvaerd, Denmark and

Novo Nordisk Inc. of Plainsboro, New Jersey (collectively, "Respondents"). *Id.* at 29746. The Office of Unfair Import Investigations (OUII) also was named as a party to the investigation. *Id.* On October 8, 2015, the Commission amended the complaint and notice of investigation to add Baxalta, Inc. of Deerfield, Illinois; Baxalta US Inc. of Deerfield, Illinois; and Baxalta GmbH of Glattpark, Switzerland as complainants. 80 Fed. Reg. 62569-70 (Oct. 16, 2015). Hereinafter, Baxalta, Inc., Baxalta US Inc., Baxalta GmbH, Baxter International Inc., Baxter Healthcare Corporation, and Baxter Healthcare SA are referred to as "Complainants."

On January 5, 2016, the investigation was terminated as to all asserted claims of the '061 patent except for claims 19 and 20, all asserted claims of the '441 patent, and certain asserted claims of the '252 patent. Notice of Commission Determination Not to Review an Initial Determination Granting a Motion for Partial Termination of the Investigation with Respect to Certain Claims.

On September 17, 2015, the ALJ issued Order No. 11 construing the terms "protein-free conditions" and "protein-free medium." On December 4, 2015, Respondents moved for reconsideration. On January 7, 2016, the ALJ issued Order No. 25 granting the motion and reaffirming the previous constructions. On January 11, 2016, Complainants 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 the subject ID (Order No. 30) granting the motion. The ALJ reasoned that, under the construction of "protein-free conditions" and "protein-free medium" of Order No. 25, there was no genuine issue of material fact in dispute regarding whether the accused products infringe the asserted claims of the '061 patent.

On February 29, 2016, Respondents filed a petition requesting that the Commission review the subject ID and Order Nos. 11 and 25. On March 7, 2016, Complainants and the OUII filed responses to the petition.

Having examined the record of this investigation, including the subject ID and the submissions of the parties, the Commission has determined to defer its decision on whether to review the subject ID until the date on which it determines whether to review the final initial determination in this investigation.

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: March 29, 2016