



## INTERNATIONAL TRADE COMMISSION

[Investigation No. 337-TA-956]

### Certain Recombinant Factor VIII Products

#### Notice of Commission Determination to Grant a Joint Motion to Terminate the

#### Investigation on the Basis of a Settlement Agreement; Termination 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 grant a joint motion to terminate the above-captioned investigation based on a settlement agreement.

**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 docketing system (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”). 80 *Fed. Reg.* 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 December 8, 2015, Baxter moved for partial termination of this investigation based on the withdrawal of claims 21, 36, 37, and 39 of the ’061 patent; claims 1 and 10 of the ’252 patent; and claims 20 and 21 of the ’441 patent. That motion was granted, leaving only claims 19 and 20 of the ’061 and claims 5, 8, 14, and 18 of the ’252 patent at issue. Order No. 23 (Dec. 10, 2016), *unreviewed*, Notice of Commission Determination Not to Review an Initial Determination Granting a Motion for Partial Termination of the Investigation with Respect to Certain Claims (Jan. 5, 2016).

On February 26, 2016, the ALJ issued an initial determination (“the Summary ID”) (Order No. 30), which concluded that Novo Nordisk infringed the ’061 patent. Novo Nordisk

filed a petition requesting that the Commission review the Summary ID and related claim construction orders. The Commission determined to defer its decision on whether to review those orders until the date on which the Commission determines whether to review the ALJ's final ID ("the 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 found no violation of Section 337 as to either remaining asserted patent. 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 a cease and desist order. The parties each petitioned for review of the Final ID. The Commission determined to review (1) the Summary ID's conclusion that the '061 patent is infringed (and the underlying claim constructions); (2) the Final ID's conclusion that the asserted claims of the '061 patent are anticipated and obvious; and (3) the Final ID's conclusion that the economic prong of the domestic industry is not met as to both remaining patents. 81 *Fed. Reg.* 51463, 51464 (Aug. 4, 2016). The Commission requested briefing on one issue under review and on remedy, the public interest, and bonding. *Id.* at 51464–65.

On September 12, 2016, the private parties filed a Joint Motion to Terminate the Investigation Based on a Settlement Agreement ("the Motion") and a confidential and a public version of the settlement agreement. On September 14, 2016, OUII filed a response supporting the Motion.

The Commission has determined that the Motion complies with the requirements of section 210.21(b)(1) of the Commission's Rules of Practice and Procedure (19 C.F.R. §

210.21(b)(1)), and that there are no extraordinary circumstances that would prevent the requested termination. The Commission also finds that granting the Motion would not be contrary to the public interest pursuant to section 210.50(b)(2) of the Commission's Rules of Practice and Procedure (19 C.F.R. § 210.50(b)(2)). Accordingly, the Commission hereby grants the Motion. This investigation is terminated.

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.

Issued: September 28, 2016

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[FR Doc. 2016-23864 Filed: 10/3/2016 8:45 am; Publication Date: 10/4/2016]