## INTERNATIONAL TRADE COMMISSION

**[Investigation No. 337–TA–956]**

## Certain Recombinant Factor VIII Products; Determination To Review In Part a Final Initial Determination Finding No Violation of Section 337 and a Summary Determination; Schedule for Filing Written Submissions on One Issue Under Review and on Remedy, the Public Interest, and Bonding

**AGENCY:** U.S. International Trade Commission.

**ACTION:** Notice.

**SUMMARY:** Notice is hereby given that the U.S. International Trade Commission has determined to review in part (1) the final initial determination (''FID'') issued by the presiding administrative law judge (''ALJ'') on May 27, 2016, finding no violation of section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337); and (2) the initial determination issued on February 26, 2016, granting a summary determination of infringement of U.S. Patent No. 6,100,061 (the ''Summary ID'') (Order No. 30). On review, the Commission has determined to reverse the FID's finding that the economic prong of the domestic industry was not met for either asserted patent. Other issues remain on review.

**FOR FURTHER INFORMATION CONTACT:** Ron Traud, Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW., Washington, DC 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 SW., Washington, DC 20436, (202) 205–2000. General information concerning the Commission may also be obtained at *http://www.usitc.gov.* The public record for this investigation may be viewed on the Commission's electronic docketing system (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 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 FR 29745 (May 22, 2015). Baxalta Inc., Baxalta US Inc., and Baxalta GmbH were added as complainants after the filing of the complaint. 80 FR 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 FR 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. 6, 2016).

On September 17, 2015, the ALJ issued Order No. 11, which construed the terms ''protein-free conditions'' and ''protein-free medium'' in the asserted claims of each asserted patent. On December 4, 2015, Novo Nordisk moved for reconsideration. On January 7, 2016, the ALJ issued Order No. 25, which granted the motion and reaffirmed her 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 granted 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 orders until the date on which the Commission determines whether to review the ALJ's final ID (FID). 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 FID, which found no violation of section 337 as to either remaining asserted patent. Regarding the '061 patent, the ALJ concluded (1) claims 19 and 20 are invalid as anticipated under 35 U.S.C. 102(g) and obvious under 35 U.S.C. 103; (2) the economic prong of the domestic industry requirement is not met; and (3) the technical prong of the domestic industry requirement is met by Baxter's Advate product. Regarding the '252 patent, the ALJ concluded (1) Novo Nordisk has not established the invalidity of any asserted claim; (2) Baxter failed to establish the economic prong of the domestic industry requirement; (3) the technical prong of the domestic industry requirement is met by Advate; and (4) Novo Nordisk's Novoeight is made by a process that infringes claims 5, 8, 14, and 18.

On June 3, 2016, the ALJ issued her Recommended Determination on Remedy, Bonding, and the Public Interest, which contingently recommends both a limited exclusion order (''LEO'') and cease and desist orders (''CDOs''). If the Commission finds a Section 337 violation, the ALJ recommended that an LEO should be issued that excludes recombinant factor VIII products manufactured by processes that infringe the asserted claims. The ALJ further recommended that the LEO should not extend to products imported to support clinical trials in the United States and that Novo Nordisk should be required to certify to U.S. Customs and Border Protection that any imported Novoeight will be used solely for such trials. The ALJ additionally recommended that the LEO provide for a grace period of 60 days from the end of the Presidential review period before the LEO is enforced. Furthermore, the ALJ recommend that a CDO containing the above exception and grace period be directed to each respondent. The ALJ also recommended that no bond should be required during the Presidential review period.

On June 13, 2016, Baxter and OUII filed petitions for review of the FID, and Novo Nordisk filed a contingent petition for review. OUII and Baxter each

petitioned for review of the ALJ's determination that Baxter did not meet the economic prong of the domestic industry requirement. Baxter additionally petitioned for review of the FID's conclusions that the asserted claims of the '061 patent are anticipated and rendered obvious. Novo Nordisk's contingent petition challenged the ALJ's construction of ''protein-free'' in the asserted patents; the ALJ's construction of ''selective pressure for the selective marker'' in the '252 patent; and the ALJ's conclusion that Novo Nordisk infringes the '061 and '252 patents. On June 21, 2016, the parties filed responses to the petitions. On July 5, 2016, Novo Nordisk filed its Statement on the Public Interest, and on July 6, 2016, Baxter did the same. Members of the public filed comments on the public interest on June 27 and 28, 2016.

Having examined the record of this investigation, including the FID and Order Nos. 11, 25, and 30; the petitions for review; and the responses thereto; the Commission has determined to review the FID in part and Orders Nos. 11, 25, and 30. Specifically, the Commission has determined to review the construction of ''protein-free medium'' and ''protein-free conditions'' in Orders No. 11 and 25 and the ID granting summary determination of infringement of the asserted claims of the '061 patent in Order No. 30. The Commission has also determined to review the ALJ's conclusion in the FID that the asserted claims of the '061 patent are anticipated and obvious. The Commission has determined to review and, on review, to reverse the ALJ's determination in the FID that the economic prong of the domestic industry requirement is not met as to the '061 and '252 patents. The Commission has determined not to review the ALJ's conclusion in the FID that the '252 patent is infringed.

The parties are requested to brief their positions regarding the FID's determination that the '061 patent is anticipated, the relevant applicable law, and the evidentiary record. In connection with its review, the Commission is particularly interested in a response to the following:

The Federal Circuit has distinguished printed publication prior art from prior use/on sale prior art for purposes of the enablement requirement of 35 U.S.C. 102 and 103. *See In re Epstein*, 32 F.3d 1559, 1567–68 (Fed. Cir. 1994). Does this distinction have implications for enablement for prior inventions under 35 U.S.C. 102(g)?

In connection with the final disposition of this investigation, the Commission may (1) issue an order that could result in the exclusion of the subject articles from entry into the United States, and/or (2) issue one or more cease and desist orders that could result in the respondent being required to cease and desist from engaging in unfair acts in the importation and sale of such articles. Accordingly, the Commission is interested in receiving written submissions that address the form of remedy, if any, that should be ordered. If a party seeks exclusion of an article from entry into the United States for purposes other than entry for consumption, the party should so indicate and provide information establishing that activity involving other types of entry either are adversely affecting it or likely to do so. For background, see *Certain Devices for Connecting Computers via Telephone Lines*, Inv. No. 337–TA–360, USITC Pub. No. 2843 (December 1994) (Commission Opinion).

If the Commission contemplates some form of remedy, it must consider the effects of that remedy upon the public interest. The factors the Commission will consider include the effect that an exclusion order and/or cease and desist orders would have on (1) the public health and welfare, (2) competitive conditions in the U.S. economy, (3) U.S. production of articles that are like or directly competitive with those that are subject to investigation, and (4) U.S. consumers. The Commission is, therefore, interested in receiving written submissions that address the aforementioned public interest factors in the context of this investigation.

The parties and the public are requested to brief their positions regarding the public interest. The Commission is especially interested in public comments from hemophilia A patients and medical professionals with experience in treating hemophilia A patients. The Commission is particularly interested in responses to the following:

(1) What criteria are appropriate to assess the scope of alternative medications to Novoeight that are on the market and that are available to new or existing hemophilia A patients? For example, given the increased safety of third generation hemophilia A medicines, should the relevant scope be limited to third generation (or higher) medications? Should the relevant scope be limited to those alternative medications suitable for patients of all ages and suitable for prophylaxis treatment? Applying these criteria, please identify all available medications that are suitable alternatives to Novoeight.

(2) What is the likelihood that a patient currently using Novoeight and who has insurance coverage for Novoeight will also have insurance coverage for a comparable medication that has similar therapeutic efficacy for that patient?

(3) What costs will patients incur in the process of switching from Novoeight to a comparable alternative? For example, does insurance typically cover (and to what extent does insurance cover) consultations with medical professionals associated with the switching process? Do the associated consultations often take place at one of the approximately 141 federally funded Hemophilia Treatment Centers (''HTCs'')? If so, do patients commonly incur significant expenses in traveling to those HTCs?

(4) What are the therapeutic and safety advantages, if any, of choosing to use Novoeight over Advate and/or other competing medications available in the U.S.?

(5) Do some patients have better therapeutic outcomes with Novoeight than other alternatives? If so, what would the risks be of requiring a patient to switch from Novoeight to a medicine that is less effective for a given patient? Could the risk of switching to a less effective treatment include serious health risks or death?

(6) How should the Commission take into account hemophilia A patients' well-documented fear of developing an inhibitor upon switching hemophilia A medications, given the potentially serious consequences of developing an inhibitor, regardless of the likelihood of developing an inhibitor?

(7) How much weight should the Commission give the fact that Novoeight can be used by a patient for a longer period after reconstitution, and that it has a longer shelf life, than some other medications? For example, how much weight should the Commission give to the fact that some patients may have structured their lives around this increased convenience and flexibility?

(8) Is the ALJ's recommendation that any remedial order should be delayed for sixty days necessary and/or sufficient to allow all individuals who are currently using Novoeight to transition to a different medicine? For example,

(a) How much time is typically needed to establish the viability of a suitable alternative medicine for a particular patient?

(b) How should the Commission consider that some hemophilia A patients may need additional time to switch because (1) those patients have upcoming scheduled surgeries, and/or (2) those patients started using Novoeight near the time of the issuance

of any remedial order and should not change hemophilia medications within fifty days?

(c) If patients need to travel to and schedule appointments at HTCs, is the sixty day grace period sufficient?

(d) If all patients currently using Novoeight need to begin seeking alternative treatments at the same time, is the availability of medical professionals qualified to treat hemophilia A sufficient to meet that spike in demand such that all patients can find alternative treatments within a sixty day time frame?

(e) If the Commission were to limit a remedy so that patients who cannot find an alternative medicine within sixty days (or other time period), despite reasonable efforts, can continue to obtain Novoeight, how could the Commission do so without placing any or only a minimal burden on patients or medical professionals and still guarantee access to Novoeight by those patients? Could such a limit on the remedy be crafted so that the parties, Customs and Border Protection (''CBP''), U.S. distributors and vendors, doctors, and patients can maintain reliable supplies of Novoeight for patients in need?

(9) If the Commission were to tailor any remedial order to allow current users to continue to reliably obtain Novoeight, how could the Commission draft such an exception? Could such an exception be crafted so that the parties, CBP, U.S. distributors and vendors, the appropriate decisionmakers, doctors or other prescribers, and patients can maintain reliable supplies of Novoeight for patients in need while providing no or only a minimal burden on medical professionals and patients?

(10) If the Commission were to issue a remedial order, to what extent should the Commission craft the remedy so that individuals who are seeking treatment for hemophilia A for the first time and for whom relevant alternative medications are not suitable could access Novoeight? For example,

(a) If such modification is appropriate, how could it be accomplished?

(b) What standards should a physician or other decisionmaker use to determine whether such medicines are suitable for the patient?

(c) Could such a limit on the remedy be crafted so that the parties, CBP, U.S. distributors and vendors, the appropriate decisionmakers, doctors or other prescribers, and patients can maintain reliable supplies of Novoeight for patients in need while providing no or only a minimal burden on medical professionals and patients?

If the Commission orders some form of remedy, the U.S. Trade Representative, as delegated by the President, has 60 days to approve or disapprove the Commission's action. *See* Presidential Memorandum of July 21, 2005. 70 FR 43251 (July 26, 2005). During this period, the subject articles would be entitled to enter the United States under bond, in an amount determined by the Commission and prescribed by the Secretary of the Treasury. The Commission is, therefore, interested in receiving submissions concerning the amount of the bond that should be imposed if a remedy is ordered.

*Written Submissions:* The parties to the investigation are requested to file written submissions responding to the above question regarding anticipation under 35 U.S.C. 102(g) of the asserted claims of the '061 patent. Parties to the investigation, interested government agencies, and the public are encouraged to file written submissions on the issues of remedy, the public interest, and bonding; and such submissions should address the recommended determination by the ALJ on remedy, public interest, and bonding, and the questions posed above. Complainants are requested to submit proposed remedial orders for the Commission's consideration. Complainants and OUII are also requested to state the date that the subject patents expire and the HTSUS numbers under which the accused products are imported. Complainants are further requested to supply the names of known importers of the products at issue in this investigation. The written submissions and proposed remedial orders must be filed no later than close of business on August 19, 2016. Reply submissions must be filed no later than the close of business on August 26, 2016. No further submissions will be permitted unless otherwise ordered by the Commission.

Persons filing written submissions must file the original document electronically on or before the deadlines stated above and submit eight true paper copies to the Office of the Secretary by noon the next day pursuant to section 210.4(f) of the Commission's Rules of Practice and Procedure (19 CFR 210.4(f)). Submissions should refer to the investigation number (''Inv. No. 337–TA–956'') in a prominent place on the cover page and/or the first page. (*See* Handbook for Electronic Filing Procedures, *http://www.usitc.gov/secretary/fed_reg_notices/rules/handbook_on_electronic_filing.pdf*). Persons with questions regarding filing should contact the Secretary (202–205–2000).

Any person desiring to submit a document to the Commission in confidence must request confidential treatment. All such requests should be directed to the Secretary to the Commission and must include a full statement of the reasons why the Commission should grant such treatment. *See* 19 CFR 201.6. Documents for which confidential treatment by the Commission is properly sought will be treated accordingly. All information, including confidential business information and documents for which confidential treatment is properly sought, submitted to the Commission for purposes of this Investigation may be disclosed to and used: (i) By the Commission, its employees and Offices, and contract personnel (a) for developing or maintaining the records of this or a related proceeding, or (b) in internal investigations, audits, reviews, and evaluations relating to the programs, personnel, and operations of the Commission including under 5 U.S.C. Appendix 3; or (ii) by U.S. government employees and contract personnel, solely for cybersecurity purposes. All nonconfidential written submissions will be available for public inspection at the Office of the Secretary and on EDIS.

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.

Issued: July 29, 2016.

**Katherine M. Hiner,**

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[FR Doc. 2016–18464 Filed 8–3–16; 8:45 am]

**BILLING CODE 7020–02–P**

## DEPARTMENT OF JUSTICE

### Antitrust Division

### United States v. Anheuser-Busch InBev SA/NV et al.; Proposed Final Judgment and Competitive Impact Statement

Notice is hereby given pursuant to the Antitrust Procedures and Penalties Act, 15 U.S.C. 16(b)–(h), that a proposed Final Judgment, Stipulation, and Competitive Impact Statement have been filed with the United States District Court for the District of Columbia in *United States of America* v. *Anheuser Busch InBev SA/NV et al.,* Civil Action No. 1:16–cv–01483. On July 20, 2016, the United States filed a