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April 16, 2015

DOCKET NUMBER 3065

Office of the Secretary
Int'l Trade Commission

VIA HAND DELIVERY

The Honorable Lisa R. Barton
Secretary
U.S. International Trade Commission
500 E Street, S.W.
Washington, DC 20436

Re: *Certain Recombinant Factor VIII Products;* Inv. No. 337-TA-_____

Dear Secretary Barton:

Enclosed for filing on behalf of Complainant Baxter International Inc., Baxter Healthcare Corporation and Baxter Healthcare SA (collectively "Baxter" or "Complainants") against the proposed Respondents Novo Nordisk A/S and Novo Nordisk Inc. (collectively, the "Proposed Respondents") are documents in support of Baxter's request that the Commission commence an investigation pursuant to Section 337 of the Tariff Act of 1930, as amended. A request for confidential treatment of Confidential Exhibits 11C, 13C, 14C, 31C, 32C, 39C and 41C – 51C is included with this letter.

Accordingly, Complainant submits the following documents for filing:

1. An original and eight (8) copies of the verified Non-Confidential Complaint and the Public Interest Statement, one (1) CD of the accompanying Non-Confidential exhibits and one (1) CD with Confidential Exhibits 11C, 13C, 14C, 31C, 32C, 39C and 41C – 51C. (19 C.F.R. §§ 201.6(c), 210.4(f)(2), 210.8(a)(1)(i), and 210.8(b));

2. Two (2) additional copies of both the verified Non-Confidential Complaint and the Public Interest Statement and two (2) CDs of the Non-Confidential exhibits, one (1) of each for service upon each of the Proposed Respondents. (19 C.F.R. §§ 210.8(a)(1)(iii) and 210.11(a));

3. Two (2) CDs of Confidential Exhibits 11C, 13C, 14C, 31C, 32C, 39C and 41C – 51C, one (1) of each for service upon each of the Proposed Respondents. (19 C.F.R. §§ 210.8(a)(1)(iii) and 210.11(a));

4. One (1) additional copy of the verified Non-Confidential Complaint for service upon the Embassy of Denmark (19 C.F.R. §§ 210.8(a)(1)(iv) and 210.11(a)(1)(ii));

5. The original certified copies of United States Patent No. 6,100,061 ("the '061 patent"); United States Patent No. 6,936,441 ("the '441 patent"); and United States Patent No. 8,084,252 ("the '252 patent") (collectively, the "Asserted Patents"); and a copy of the patents on CD, cited in the Complaint as Exhibits 1-3. (19 C.F.R. §§ 210.8(a)(1)(iii), 210.12(a)(9)(i));

6. The original certified copies of the assignments for the Asserted Patents and copies of the assignments for the patents on CD, cited in the Complaint as Exhibits 5-7. (19 C.F.R. §§ 210.8(a)(1)(iii) and 210.12(a)(9)(ii));

7. Uncertified copies of the prosecution histories of the Asserted Patents included in the Complaint as Appendices A, B and C to the Complaint, and three (3) additional copies of each on separate CDs, for which certified copies will be provided when received from the USPTO. (19 C.F.R. § 210.12(c)(1));

8. Four (4) copies on separate CDs of patent and technical reference documents identified in each of the prosecution histories of the Asserted Patents, included in the Complaint as Appendices D, E and F to the Complaint. (19 C.F.R. §210.12(c)(2)).

In accordance with Commission Rules 201.6 and 210.5, 19 C.F.R. §§ 201.06 and 210.5, Baxter requests confidential treatment of the business information contained in Confidential Exhibits 11C, 13C, 14C, 31C, 32C, 39C and 41C – 51C. A certification is provided below pursuant to 19 C.F.R. §§ 201.06 and 210.5 requesting confidential treatment of Confidential Exhibits 11C, 13C, 14C, 31C, 32C, 39C and 41C – 51C.

The information for which confidential treatment is sought is proprietary commercial information not otherwise publicly available. Specifically, Confidential Exhibit 11C is a declaration that discusses proprietary and confidential business information regarding Baxter's investments in its domestic industry. Confidential Exhibits 13C and 14C are domestic industry claim charts, the information of which is proprietary to Baxter. Confidential Exhibit 31C is a competitive intelligence report, the information of which is proprietary to Baxter. Confidential Exhibit 32C is a sales spreadsheet, the information of which is proprietary to Baxter. Confidential Exhibits 39C, 41C – 43C and 45C – 51C are agreements among certain Baxter entities containing proprietary information pertinent to Baxter's operations. Exhibit 44C is an article of incorporation containing proprietary information pertinent to Baxter's operations.

The information described above qualifies as confidential business information pursuant to Commission Rule 201.6 because:

a. it is not available to the public;

b. unauthorized disclosure of such information could cause substantial harm to the competitive position of Baxter; and

c. its disclosure could impair the Commission's ability to obtain information necessary to perform its statutory function.

Thank you for your attention to this matter. Please contact me if you have any questions.

Respectfully submitted,

Tom M. Schaumberg

TMS:jep
Enclosures
BAXTER

UNITED STATES INTERNATIONAL TRADE COMMISSION
WASHINGTON, D.C.

In the Matter of	
CERTAIN RECOMBINANT FACTOR VIII PRODUCTS	**Investigation No. _____**

COMPLAINANTS' STATEMENT REGARDING THE PUBLIC INTEREST

Complainants Baxter International Inc., Baxter Healthcare Corporation and Baxter Healthcare SA (collectively, "Baxter") hereby submit this Statement Regarding the Public Interest in compliance with 19 C.F.R. § 210.8(b). As discussed more fully below, Baxter submits that the issuance of the relief requested in the concurrently-filed Complaint, including an exclusion order and cease and desist orders covering the accused recombinant factor VIII products, will not adversely impact the public health, safety, or welfare conditions in the United States, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, or United States consumers.

Baxter and several other suppliers have supplied and can continue to supply products to satisfy U.S. demand for recombinant factor VIII products. Specifically, recombinant factor VIII products currently available in the United States include Advate® (Baxter), Recombinate (Baxter), Kogenate® FS (Bayer), Helixate® FS (CSL Behring), and Xyntha® (Pfizer/Wyeth). Thus, the unavailability of proposed Respondents' recombinant factor VIII products would not implicate any public health, safety or welfare concerns, because consumers would not face any potential shortage of like or competitive products in the United States. Indeed, Respondents' infringing products have just begun to enter the U.S. market and, thus, exclusion of these products from the U.S. market for the remaining life of the patents at issue (which expire in 2018) would simply maintain the status quo, namely a market that is well-supplied from several

sources with recombinant factor VIII products. Thus, the requested Investigation does not present an instance where a compelling public interest might supersede entry of remedial orders in the event a violation of Section 337 is found.

Baxter therefore submits that this is not a case where the Commission, the parties, and the public should be required to undergo the time and expense of discovery into public interest issues, the presentation of evidence on the public interest before the ALJ, and the issuance of a Recommended Determination by the ALJ on the public interest.

I. Use of articles potentially subject to remedial orders in the United States.

Respondents' products potentially subject to remedial orders in the proposed Investigation are recombinant factor VIII products (referred to herein as "Novoeight" or "Accused Products") that are used in the management of hemophilia A by health-care professionals in a hospital, clinic or other medical facility to treat patients, and for home use, e.g., self-infusion by a patient. Respondents have stated that Novoeight will be introduced in the United States by mid-April 2015.[1] *See* Complaint ¶ 14; Complaint Exhibit 18 at 2-3; *see also* Complaint Exhibit 22 at 38; Complaint Exhibit 19 at ¶ 16.

II. There are no public health, safety, or welfare concerns in the United States relating to the potential remedial orders.

Excluding Respondents' Accused Products from importation into the United States would not implicate any public health, safety, or welfare concerns. As noted above, Respondents' Accused Products, first being introduced for sale in the United States in April 2015, have not yet established a presence in the United States market. Currently there are several recombinant factor VIII products available in the U.S. market, including those manufactured by Baxter,

[1] *See* http://press.novonordisk-us.com/2015-03-26-Novo-Nordisk-to-Launch-Novoeight-in-the-United-States-for-People-With-Hemophilia-A ("Novo Nordisk plans to make Novoeight® available by mid-April 2015" in the United States).

Bayer, CSL Behring, and Pfizer/Wyeth. These manufacturers are currently supplying the market in the absence of the Accused Products and can continue to do so in the future. Furthermore, Novoeight is not a "game changing" medication. The Accused Products have been described as being akin to a "me-too" entry to the market that are "not very differentiated from the [already] marketed products."[2]

By introducing Novoeight into the United States, Respondents "bolster [their own] portfolio" but nevertheless are expanding into an "increasingly crowded hemophilia A market."[3] There are numerous medicines available to replace clotting factor (factor VIII or antihemophilic factor) that is missing in people with hemophilia A. Accordingly, there are no public health, safety, or welfare considerations that caution against excluding Respondents' Accused Products.

III. Articles which could replace the subject articles if they were to be excluded from the United States.

The Accused Products in this investigation are a recombinant factor VIII product that is just beginning to enter the U.S. market. As noted above, there are several recombinant factor VIII products with which the Accused Products intend to compete that are available for treatment of hemophilia A. Baxter and the other manufacturers of currently available recombinant factor VIII products adequately supply the market and have done so for many years. Accordingly, Baxter's Advate® or the recombinant factor VIII products of other manufacturers could easily replace the Accused Products if the Accused Products were introduced and then later excluded from the United States.

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[2] *See* http://www.academia.edu/8189123/Index_00; *see also* http:// analysisreport. morningstar.com/stock/research?t=BAX&region=USA&culture=en-US&productcode=MLE ("Novo Nordisk could launch a me-too Advate in 2015").

[3] *See* http://healthcare.globaldata.com/resources/expert-insights/pharmaceuticals/novo-nordisk-faces-challenges-in-expanding-its-franchise-into-the-hemophilia-a-market-following-fda-approval-of-novoeight.

IV. The domestic factor VIII market can be satisfied by existing products.

Recombinant factor VIII products currently available in the United States include Advate® (Baxter), Recombinate (Baxter), Kogenate® FS (Bayer), Helixate® FS (CSL Behring), and Xyntha® (Pfizer/Wyeth). There is no reason to hold an evidentiary hearing to establish that the exclusion of Respondents' Accused Products would not result in any adverse impact to this already well-supplied market.

V. The requested remedial orders will not have a significant negative impact on consumers in the United States.

As explained above, given that the Accused Products have not established a presence in the U.S. market, the issuance of the requested exclusion and cease and desist orders for the remaining life of the patents will merely maintain the status quo and will have no meaningful adverse impact on U.S. consumers.

Moreover, the public interest favors the protection of intellectual property rights in the United States. *Certain Two-Handle Centerset Faucets & Escutcheons, & Components Thereof*, Inv. No. 337-TA-422, Comm'n Op. at 9 (June 19, 2000); *Certain Hardware Logic Emulation Sys. & Components Thereof*, Inv. No. 337-TA-383, Comm'n Op. at 8-9 (Oct. 15, 1996). The issuance of the requested relief here—excluding Respondents' infringing products—would serve the public interest by protecting Baxter's intellectual property rights. The patents at issue expire in 2018. Respondents should not be permitted to enter the U.S. market with an infringing product with approximately three years remaining in the asserted patents' life and contend that such infringement should be excused due to "public interest" concerns.

VI. Conclusion.

Issuing a permanent exclusion order and cease and desist orders against Respondents' infringing products will not negatively affect the public health, safety or welfare in the United

States, competitive conditions in the United States economy, the production of like or competitive articles in the United States, and the availability of such products to consumers. Availability of the accused recombinant factor VIII products is not essential to public health and safety because, among other things, they represent a new entrant to a well-supplied field and do not contain any unique health- or safety-related features. Accordingly, there are no public interest concerns preventing the issuance of a permanent exclusion order and cease and desist orders or that would necessitate discovery, presentation of evidence, and a Recommended Determination on the public interest by the ALJ.

Dated: April 16, 2015

Respectfully submitted,

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UNITED STATES INTERNATIONAL TRADE COMMISSION
WASHINGTON, D.C.

In the Matter of	
CERTAIN RECOMBINANT FACTOR VIII PRODUCTS	**Investigation No. _____**

COMPLAINT OF BAXTER INTERNATIONAL INC., BAXTER HEALTHCARE CORPORATION, AND BAXTER HEALTHCARE SA UNDER SECTION 337 OF THE TARIFF ACT OF 1930, AS AMENDED

COMPLAINANTS

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PROPOSED RESPONDENTS

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TABLE OF SUPPORTING MATERIALS

EXHIBITS

Exhibit No.	Description
1.	Certified Copy of U.S. Patent No. 6,100,061
2.	Certified Copy of U.S. Patent No. 6,936,441
3.	Certified Copy of U.S. Patent No. 8,084,252
4.	List of Foreign Counterparts to the Asserted Patents
5.	Certified Copy of the PTO Assignment records for U.S. Patent No. 6,100,061 as of March 31, 2015
6.	Certified Copy of the PTO Assignment records for U.S. Patent No. 6,936,441 as March 30, 2015
7.	Certified Copy of the PTO Assignment records for U.S. Patent No. 8,084,252 as March 30, 2015
8.	Infringement Claim Charts for U.S. Patent No. 6,100,061 for claims 19 and 36
9.	Infringement Claim Charts for U.S. Patent No. 6,936,441 for claim 20
10.	Infringement Claim Charts for U.S. Patent No. 8,084,252 for claims 1, 5, and 8
11C.	**[CONFIDENTIAL]** Declaration of David Ackerson re Domestic Industry
12.	Domestic Industry Claim Chart for U.S. Patent No. 6,100,061 for claims 19 and 36
13C.	**[CONFIDENTIAL]** Domestic Industry Claim Chart for U.S. Patent No. 6,936,441 for claim 20
14C.	**[CONFIDENTIAL]** Domestic Industry Claim Chart for U.S. Patent No. 8,084,252 for claims 1, 5, and 8
15.	Baxter International Inc. Form 10-K (Dec. 31, 2014)
16.	Baxter's BioScience Business Information Sheet
17.	Ewenstein, Bruce, M.D., Ph.D., and Valentino, Leonard A., M.D., *Envisioning a World Without Bleeds: Making a Real Impact on the Lifetime Burden of Bleeds for People Living with Hemophilia* (Apr. 16, 2014)
18.	Novo Nordisk Inc. News Release, *Novo Nordisk to Launch Novoeight® in the United States for People with Hemophilia A* (Mar. 26, 2015)
19.	Complaint filed in *Novo Nordisk Inc. v. Baxter Healthcare Corp. et al.*, Case No. 15-cv-02157-PGS-LHG (D.N.J.) (Mar. 26, 2015)
20.	Letter from FDA to Novo Nordisk Inc. regarding Biologics License Application for Novoeight® (Oct. 15, 2013)
21.	Novoeight® Highlights of Prescribing Information (Sept. 2014)
22.	Novo Nordisk Inc. Annual Report (2014)
23.	Letter from Baxter Healthcare Corp. to Novo Nordisk Inc. (Mar. 23, 2015)
24.	Letter from Novo Nordisk Inc. to Baxter Healthcare Corp. (Mar. 26, 2015)
25.	Website Printout from http://www.advate.com/efficacy/experience.html
26.	Pictures of Baxter's Advate® products
27.	Website Printout: http://www.baxter.com.sg/press_room/press_releases /2006/01-31-06-advate_billion.html
28.	Website Printout from http://www.novoeight.com/what-is-novoeight/HighStandards.html

29.	Website Printout from http://www.novoeight.com/talk-with-us.html
30.	Website Printout from http://www.novoeight.com/
31C.	**[CONFIDENTIAL]** Report dated Dec. 22, 2014
32C.	**[CONFIDENTIAL]** Spreadsheet dated 2013
33.	Picture of Respondent's Novoeight® products
34.	HyClone™ CDM4CHO Media, Liquid Specifications
35.	Website Printout from https://us.vwr.com/store/catalog/product.jsp?product_id=9092318.
36.	English Translation of European Patent Office Decision
37.	Corporate Name Change filed on January 1, 2014
38.	Filing of the Corporate Name Change document with the PTO (April 16, 2015)
39C.	**[CONFIDENTIAL]** Agreement dated April 15, 2015
40.	Assignment Agreement (April 15, 2015)
41C.	**[CONFIDENTIAL]** Agreement dated December 21, 2000
42C.	**[CONFIDENTIAL]** Agreement dated January 1, 2001
43C.	**[CONFIDENTIAL]** Agreement dated April 11, 2003
44C.	**[CONFIDENTIAL]** Articles of Incorporation (May 3, 2003)
45C.	**[CONFIDENTIAL]** Agreement dated January 1, 2008
46C.	**[CONFIDENTIAL]** Agreement dated January 1, 2008
47C.	**[CONFIDENTIAL]** Amended Agreement dated January 5, 2009
48C.	**[CONFIDENTIAL]** Letter of Understanding (July 3, 2009)
49C.	**[CONFIDENTIAL]** Agreement dated December 18, 2013
50C.	**[CONFIDENTIAL]** Agreement dated December 18, 2013
51C.	**[CONFIDENTIAL]** Agreement dated December 18, 2013
52	Novoeight® Trade Unit Product Information
53	Novoeight® Patient Brochure
54	Filing of the Assignment Agreement with the PTO (April 16, 2015)

APPENDICES

Appendix No.	Description
A.	Prosecution History of U.S. Patent No. 6,100,061
B.	Prosecution History of U.S. Patent No. 6,936,441
C.	Prosecution History of U.S. Patent No. 8,084,252
D.	Technical references cited in the Prosecution History of U.S. Patent No 6,100,061
E.	Technical references cited in the Prosecution History of U.S. Patent No 6,936,441
F.	Technical references cited in the Prosecution History of U.S. Patent No 8,084,252

TABLE OF CONTENTS

I. INTRODUCTION

1. This Complaint is filed by Baxter International Inc., Baxter Healthcare Corporation, and Baxter Healthcare SA (collectively, "Baxter" or "Complainants") under Section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337, based on the unlawful importation into the United States, the sale for importation into the United States, and the sale or imminent sale within the United States after importation, by the proposed Respondents, of recombinant factor VIII products that infringe at least claims 19, 20, 21, 36, 37, and 39 of U.S. Patent No. 6,100,061; claims 20 and 21 of U.S. Patent No. 6,936,441; and claims 1, 5, 8, 10, 14, and 18 of U.S. Patent No. 8,084,252 (collectively, the "Asserted Patents") either literally or under the doctrine of equivalents.

2. Baxter is one of the world's leading manufacturers of medical products, including products used in the treatment of hemophilia. Hemophilia is a bleeding disorder caused by the lack or insufficiency of circulatory clotting factors that makes it difficult or impossible for a patient's blood to clot. Baxter has more than 60 years of experience in hemophilia treatment and product development and is a leading innovator in the field.

3. Baxter has developed a number of innovative treatments for hemophilia patients, including replacing a missing or defective blood-clotting protein known as factor VIII to control and prevent bleeding episodes in patients with hemophilia A, which is a hereditary bleeding disorder caused by a deficiency of clotting factor VIII. Initially, the replacement factor VIII protein was derived from human blood, but, because of the rise in blood-borne viruses, it has been largely replaced among more recently diagnosed patients with laboratory-produced proteins referred to as recombinant factor VIII.

4. Baxter introduced the first synthetically manufactured recombinant factor VIII product, Recombinate, in 1992. Recombinate was a breakthrough product that dramatically

decreased the risk of blood-borne pathogen transmission, such as transmission of HIV and hepatitis B and C. Throughout the 1990s, Baxter continued to innovate with respect to its recombinant factor VIII products. As part of that innovation, Baxter developed and patented novel methods of synthesizing recombinant proteins, including recombinant factor VIII, in serum- and protein-free environments. Many of those innovations are protected by the Asserted Patents. As a result of these innovations, in 2003, Baxter introduced Advate®, which was the first factor VIII product to be completely free of blood-based additives and which is made by the novel processes protected by the Asserted Patents.

5. Novo Nordisk A/S and Novo Nordisk Inc. (collectively, "Respondents"), upon information and belief, manufacture, import, and have sold or imminently will sell after importation into the United States a recombinant factor VIII treatment for hemophilia A known as turoctocog alfa and marketed under the name "Novoeight®" (referred to herein as "Novoeight®" or "Accused Products"). The Accused Products are manufactured by processes that were developed by Baxter and are protected by patents issued to and owned by Baxter to which Respondents are not licensed.

6. A domestic industry, as required by 19 U.S.C. §§ 1337(a)(2) and (3), exists in the United States relating to Baxter's recombinant factor VIII products marketed under the name Advate®.

7. Baxter seeks a limited exclusion order under 19 U.S.C. § 1337(d) barring from entry into the United States infringing recombinant factor VIII products manufactured or sold by or on behalf of Respondents. Baxter further seeks cease-and-desist orders under 19 U.S.C. § 1337(f) prohibiting each of the Respondents from marketing, distributing, selling, offering for

sale, warehousing inventory for distribution, or otherwise transferring or bringing into the United States infringing recombinant factor VIII products.

II. COMPLAINANTS

8. Complainants Baxter International Inc. and Baxter Healthcare Corporation are corporations organized and existing under the laws of Delaware, having their principal place of business at One Baxter Parkway, Deerfield, Illinois.[1] Baxter Healthcare SA is a corporation existing under the laws of Switzerland, having its principal place of business at Thurgauerstrasse 130, Glattpark (Opfikon), Switzerland. Baxter Healthcare Corporation and Baxter Healthcare SA are wholly-owned subsidiaries of Baxter International Inc.

9. As a global healthcare company, Baxter applies a unique combination of expertise in medical devices, pharmaceuticals, and biotechnology to create products that advance patient care in the United States and worldwide. (*See* Ex. 15 at 1, 21-22, 28-30.) Baxter designs, develops, manufactures, markets, and supports various medical products, including novel recombinant factor VIII products that lead the market in the treatment of hemophilia A. (*Id.*)

10. As a result of its continued commitment to scientific innovation, Baxter has remained at the forefront of the medical device, pharmaceutical, and biotechnology fields. Baxter is the market leader in the treatment of hemophilia A and also has the broadest portfolio of hemophilia treatments in the industry. (*See* Ex. 16; Ex. 27.) Baxter is focused on optimizing hemophilia care and improving the lives of patients living with bleeding disorders. (*See* Ex. 17 at 2-4.)

[1] Baxter currently operates in two segments: BioScience and Medical Products. In March 2014, Baxter announced the spin-off by mid-2015 of the BioScience division, which will become Baxalta Incorporated ("Baxalta").

11. Baxter's innovative recombinant factor VIII treatments for hemophilia A sold under the name Advate® are manufactured by processes that are protected by the Asserted Patents. (*See* Exs. 12, 13C, 14C.) Baxter has substantial operations devoted to Advate® in the United States, which include manufacturing and product support. (*See* Ex. 11C at ¶¶ 5-7, 9-17.) Further, with respect to Advate®, Baxter has made significant investments in the United States in facilities, equipment, labor, and capital, as well as product support and patient and community education and advocacy. (*Id.* at ¶¶ 10-17.)

III. THE PROPOSED RESPONDENTS

12. On information and belief, Respondents design, develop, manufacture, import into the United States, and have sold or will imminently sell after importation into the United States the Accused Products, which are known as turoctocog alfa and which Respondents market and sell under the name Novoeight®. (*See* Ex. 18 at 2-3; Ex. 19 at ¶¶ 16, 22.) On information and belief, the process that Respondents use to manufacture Novoeight® infringes the Asserted Patents in violation of Section 337, as detailed below.

13. On information and belief, Novo Nordisk A/S is a corporation organized and existing under the laws of Denmark, having its principal place of business at Novo Allé, 2880 Bagsværd, Denmark. Novo Nordisk Inc. is a corporation organized and existing under the laws of New Jersey, having its principal place of business at Route 800 Scudders Mill Road, Plainsboro, New Jersey 08536. (Ex. 19 at ¶ 3.) On information and belief, Novo Nordisk Inc. is a wholly-owned subsidiary of Novo Nordisk A/S.

14. On October 15, 2013, the Food and Drug Administration ("FDA") approved Novo Nordisk Inc.'s Biologics License Application ("BLA") for Novoeight®. (Ex. 19 at ¶ 16; Ex. 20.) Novo Nordisk A/S plans to manufacture, package, and label Novoeight® in Denmark before importation into the United States for sale. (*See* Ex. 19 at ¶ 18; *see also* Ex. 20 at 1; Ex.

21 at 5.) On information and belief, Respondents have imported and will import Novoeight® into the United States where Novo Nordisk Inc. will sell Novoeight®. Respondents have announced plans to begin selling Novoeight® after importation into the United States by mid-April 2015. (Ex. 18 at 2-3; *see also* Ex. 22 at 38; Ex. 19 at ¶ 16.) On information and belief, Novoeight® has already been imported and is stored in warehouses in the United States. Novoeight® will directly compete with Baxter's recombinant factor VIII treatments, including Advate®, for treatment of hemophilia A in the United States. (Ex. 19 at ¶ 2.)

15. On March 23, 2015, Baxter sent a letter informing Novo Nordisk Inc. that the process it uses to manufacture Novoeight® may infringe Baxter's patents, including U.S. Patent No. 6,100,061. (Ex. 23 at 1.) Baxter acknowledged that "certain aspects of [Novo Nordisk's] manufacturing processes are not publicly disclosed and could include information that demonstrates that Novo Nordisk's process for making Factor VIII does not infringe Baxter's Factor VIII Portfolio." (*Id.*) To that end, Baxter offered Novo Nordisk Inc. the opportunity to disclose information to Baxter's outside counsel showing that Respondents' processes were, in fact, non-infringing, including the Chemical, Manufacturing, and Controls information from Respondents' FDA-approved Biologics Licensing Application. (*Id.* at 1-2.) Baxter also asked that Novo Nordisk Inc. delay the planned mid-April launch of Novoeight®. (*Id.* at 2.)

16. Novo Nordisk Inc. wrote in a response letter to Baxter that Novoeight® "will be available in the United States starting in April" and expressly declined to delay its launch. (Ex. 24 at 1.) Novo Nordisk Inc. also failed to provide any of the requested information. Instead, on the same day it sent its letter to Baxter, Novo Nordisk Inc. filed an action in the United States District Court for the District of New Jersey seeking a declaratory judgment that the claims of the Asserted Patents, as well as other of Baxter's patents, are invalid and not infringed. (Ex. 19.)

In its letter, Novo Nordisk Inc. claimed that it did not infringe the Asserted Patents because "the medium used for multiplying CHO cell clones in the manufacture of Novoeight® (a commercially available product called HyClone™ CDM4CHO) is not protein free." (Ex. 24 at 1.) Novo Nordisk Inc.'s statement, however, is contrary to HyClone™'s specifications, which state that its medium is, in fact, protein free. (*See, e.g.*, Exs. 34 and 35.)

IV. THE TECHNOLOGY AND PLAIN ENGLISH STATEMENT OF THE PRODUCTS AT ISSUE

17. The technology at issue relates to novel processes for the manufacture of recombinant proteins in a serum- and protein-free environment, including recombinant factor VIII products, used by medical providers to treat patients with hemophilia A.

A. Hemophilia A and Development of Therapies

18. Hemophilia is a bleeding disorder caused by lack or insufficiency of circulatory clotting factors that make it difficult or impossible for a patient's blood to clot. Hemophilia leads to severely increased risks of prolonged bleeding from common injuries and internal bleeding in the joints, muscles, digestive tract, and brain that, without treatment, can cause stiffness, pain, and severe joint damage.

19. Patients with hemophilia A suffer from a lack or deficiency of factor VIII, which is an essential blood-clotting protein. Factor VIII circulates in the bloodstream in an inactive form until an injury that damages blood vessels occurs. In response to the injury, factor VIII is activated, and the activated factor VIII interacts with other coagulation factors, setting off a chain reaction that forms a blood clot. Patients suffering from hemophilia A lack or have insufficient amounts of factor VIII and have difficulty forming or cannot form blood clots.

20. Treatments for hemophilia A provide the necessary factor VIII so that blood can clot properly. The first factor VIII treatments were introduced in the 1960s and were plasma-

derived concentrates. Plasma-derived factor VIII is made from human blood by separating factor VIII from the other parts of the blood's plasma. Although the early plasma-derived products were effective for clotting, they presented significant risks of blood-borne pathogen transmission, such as transmission of HIV and hepatitis B and C.

21. In 1992, Baxter introduced Recombinate, the first synthetically, recombinantly manufactured factor VIII product. (Ex. 25 at 2.) Although Recombinate was synthetically manufactured, it still required the addition of plasma-derived proteins at several steps during processing and in the final formulation. (*Id.*) Baxter continued to innovate, and, in the late 1990s, it introduced a second-generation Recombinate product, the final formulation of which was free of plasma-derived proteins. (*Id.*) Even in this second-generation product, however, plasma proteins were still used in the cell-growth phase of the process. (*Id.*)

B. Baxter's Development of Advate®

22. In 2003, after further innovation, Baxter introduced its third generation of recombinant factor VIII products—Advate®. (Ex. 25 at 2.) Advate® was Baxter's first recombinant factor VIII treatment to be made under serum- and protein-free conditions as claimed in the Asserted Patents. Advate®'s recombinant factor VIII proteins are synthesized by a genetically engineered Chinese Hamster Ovary ("CHO") cell line. In culture, the CHO cell line secretes recombinant factor VIII into a cell culture medium that is serum- and protein-free. The recombinant factor VIII is purified from the culture medium using a series of chromatography columns. Advate® is formulated as a sterile, non-pyrogenic, white to off-white powder for intravenous injection.

23. Baxter is the leading provider of recombinant factor VIII products in the United States and worldwide. Pictures of Baxter's Advate® products are provided at Exhibit 26.[2]

24. Baxter owns a number of patents relating to novel methods for production of recombinant proteins in serum- and protein-free environments, such as recombinant factor VIII, including the Asserted Patents, which are described below in Section V.

25. On information and belief, Novoeight® is a recombinant factor VIII product made using Baxter's patented processes. (*See* Exs. 21 and 28.) On information and belief, Novoeight® is sold and imported into the United States by or on behalf of Respondents, and Respondents plan to market and sell Novoeight® after importation in mid-April 2015. (Ex. 18 at 2-3; Ex. 19 at ¶¶ 16, 22.) In their newly released launch materials, Respondents tout the fact that "[n]o additives of human or animal origin are used in the cell culture, purification and formulation of Novoeight." (Ex. 21 at 3; *see also* Ex. 28.) This feature is derived from Baxter's patented processes, including those protected by the Asserted Patents. (*See* Exs. 8-10.)

26. A picture of Respondents' Novoeight® products is provided at Exhibit 33.

V. THE ASSERTED PATENTS AND NONTECHNICAL DESCRIPTIONS OF THE INVENTIONS

27. Certified copies of the Asserted Patents are included at Exhibits 1-3. Certified copies of the assignment records for each of the Asserted Patents as of March 2015 are included at Exhibits 5-7.[3]

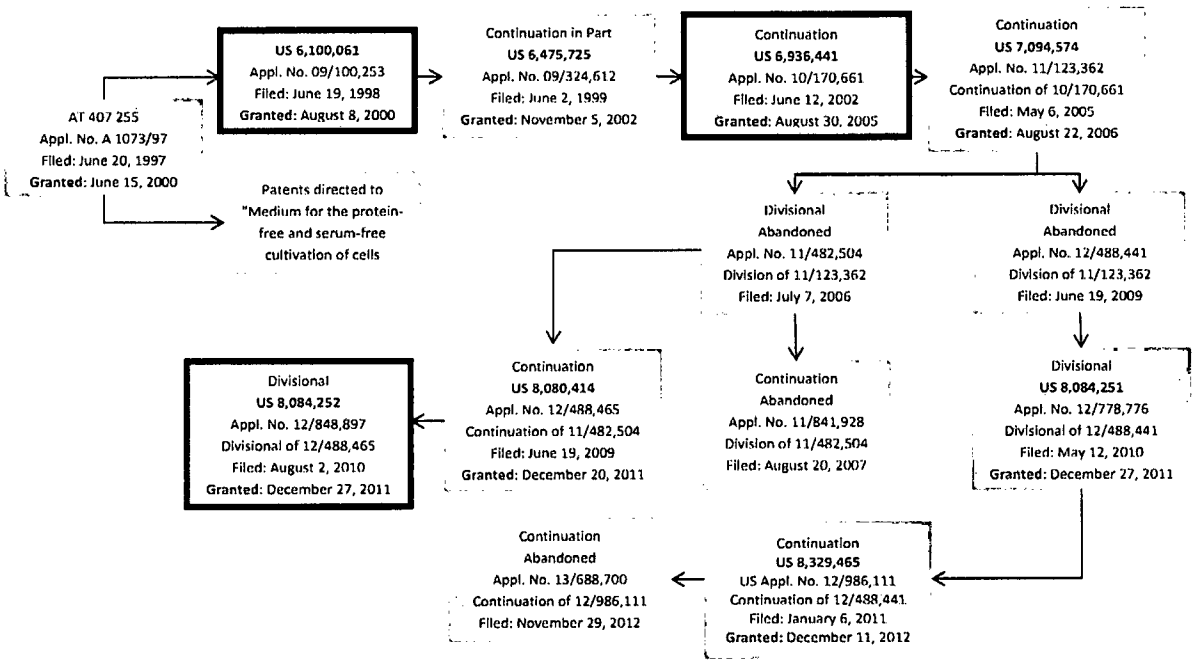
28. The Asserted Patents are members of a patent family resulting from, among other things, the inventors' efforts to develop innovative methods for the production of recombinant

[2] Due to the nature of the product, Baxter is not submitting a physical sample of its Advate® products with the Complaint.

[3] Baxter has ordered updated assignment records from the PTO and will produce them to the ITC upon receipt.

cell clones, including CHO clones used for the production of factor VIII, that are stable in serum- and protein-free medium.

29. The patent family from which the Asserted Patents issued is depicted below. Asserted Patents are outlined in black boxes.



30. Pursuant to Commission Rule 210.12(c), four copies of the prosecution histories of each of the Asserted Patents have been submitted with this Complaint as Appendices A-C.[4] Pursuant to Commission Rule 210.12(c), the cited references for each of the Asserted Patents also have been submitted with this Complaint as Appendices D-F.

[4] Baxter has ordered certified copies of the prosecution history of each Asserted Patent and will provided them to the ITC upon receipt.

A. Nontechnical Description of U.S. Patent No. 6,100,061[5]

31. United States Patent No. 6,100,061 ("the '061 Patent"), entitled "Recombinant Cell Clone Having Increased Stability In Serum- And Protein-Free Medium And A Method Of Recovering The Stable Cell Clone And The Production Of Recombinant Proteins By Using A Stable Cell Clone," issued on August 8, 2000, to inventors Manfred Reiter, Wolfgang Mundt, and Friedrich Dorner. The '061 Patent issued from U.S. Patent App. Ser. No. 09/100,253, filed on June 19, 1998. The '061 Patent claims priority to a foreign application with application serial number 1073/97, filed in Austria on June 20, 1997.

32. The inventors assigned their rights in the application leading to the '061 Patent to Immuno Aktiengesellschaft on July 22, 1998. (*See* Ex. 5.) Immuno Aktiengesellschaft subsequently underwent a series of name changes and ultimately, on January 9, 2008, became known as Baxter Innovations GmbH. (*See* Ex. 37.) The renaming assignment was recorded at the PTO on April 16, 2015. (*See* Ex. 38.) Subsequent to the inventors' assignment, Baxter and its wholly owned subsidiaries executed certain agreements relating to, among other things, the technologies described in the Asserted Patents, as more fully described in Section V.E. below. On April 15, 2015, Baxter Innovations GmbH assigned all right, title, and interest in the '061 Patent to Baxter International Inc. and Baxter Healthcare SA. (*See* Ex. 40.) That assignment was recorded with the PTO on April 16, 2015.[6] (*See* Ex. 54.)

33. The '061 Patent contains 44 claims, including 10 independent claims and 34 dependent claims. Baxter asserts that Respondents infringe, either directly or under the doctrine

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[5] These descriptions and any other nontechnical descriptions within this Complaint are for illustrative purposes only. Nothing contained within this Complaint is intended to express, either implicitly or explicitly, any position regarding the proper construction or scope of any claim of the Asserted Patents.

[6] Baxter has requested an updated copy of the assignment record from the PTO and will provide them to the ITC upon receipt.

of equivalents, at least claims 19, 20, 21, 36, 37, and 39 of the '061 Patent, by the importation, sale for importation, and sale, imminent sale, or use after importation of Novoeight®, which is made, produced, or processed by means of the methods claimed therein.

34. The '061 Patent is directed to, among other things, a novel method for producing recombinant proteins, including recombinant factor VIII, under serum- and protein-free conditions.

B. Nontechnical Description of U.S. Patent No. 6,936,441

35. United States Patent No. 6,936,441 ("the '441 Patent"), entitled "Recombinant Cell Clones Having Increased Stability And Methods Of Making And Using The Same," issued on August 30, 2005, to inventors Manfred Reiter, Wolfgang Mundt, and Friedrich Dorner. The '441 Patent claims priority ultimately to the application for the '061 Patent and foreign priority to an application with serial number 1073/97, filed in Austria on June 20, 1997.

36. The inventors assigned their rights in the application leading to the '441 Patent to Baxter Aktiengesellschaft on August 31, 1999. (*See* Ex. 6 at 1-5.) Baxter Aktiengesellschaft subsequently underwent a series of name changes and ultimately, on January 9, 2008, became known as Baxter Innovations GmbH. (*See id.* at 6-10.) Subsequent to the inventors' assignment, Baxter and its wholly owned subsidiaries executed certain agreements relating to, among other things, the technologies described in the Asserted Patents, as more fully described in Section V.E. below. On April 15, 2015, Baxter Innovations GmbH assigned all right, title, and interest in the '441 Patent to Baxter International Inc. and Baxter Healthcare SA. (*See* Ex. 40.) That assignment was recorded with the PTO on April 16, 2015.[7] (*See* Ex. 54.)

[7] Baxter has requested an updated copy of the assignment record from the PTO and will provide them to the ITC upon receipt.

37. The '441 Patent contains 27 claims, including 4 independent claims and 23 dependent claims. Baxter asserts that Respondents infringe, either directly or under the doctrine of equivalents, at least claims 20 and 21 of the '441 Patent, by the importation, sale for importation, and sale, imminent sale, or use after importation of Novoeight®, which is made, produced, or processed by means of the methods claimed therein.

38. The '441 Patent is directed to, among other things, a novel method for producing a recombinant product, including recombinant factor VIII, under serum- and protein-free conditions.

C. Nontechnical Description of U.S. Patent No. 8,084,252

39. United States Patent No. 8,084,252 ("the '252 Patent"), entitled "Recombinant Cell Clones Having Increased Stability And Methods Of Making And Using The Same," issued on December 27, 2011, to inventors Manfred Reiter, Wolfgang Mundt, and Friedrich Dorner. The '252 Patent issued from U.S. Patent App. Ser. No. 12/848,897, filed on August 2, 2010. The '252 Patent claims priority ultimately to the application for the '061 Patent and foreign priority to an application with serial number 1073/97, filed in Austria on June 20, 1997.

40. The inventors assigned their rights in the application leading to the '252 Patent to Baxter Aktiengesellschaft on August 31, 1999. (*See* Ex. 7 at 1-5.) Baxter Aktiengesellschaft subsequently underwent a series of name changes and ultimately, on January 9, 2008, became known as Baxter Innovations GmbH. (*See id.* at 6-10.) Subsequent to the inventors' assignment, Baxter and its wholly owned subsidiaries executed certain agreements relating to, among other things, the technologies described in the Asserted Patents, as more fully described in Section V.E. below. On April 15, 2015, Baxter Innovations GmbH assigned all right, title, and interest in

the '252 Patent to Baxter International Inc. and Baxter Healthcare SA. (*See* Ex. 40.) That assignment was recorded with the PTO on April 16, 2015.[8] (*See* Ex. 54.)

41. The '252 Patent contains 21 claims, including 3 independent claims and 18 dependent claims. Baxter asserts that Respondents infringe, either directly or under the doctrine of equivalents, at least claims 1, 5, 8, 10, 14, and 18 of the '252 Patent, by the importation, sale for importation, and sale, imminent sale, or use after importation of Novoeight®, which is made, produced, or processed by means of the methods claimed therein.

42. The '252 Patent is directed to, among other things, a novel method for producing a recombinant product, including recombinant factor VIII, under serum- and protein-free conditions.

D. Foreign Counterparts

43. A list of foreign counterpart patents and applications to the Asserted Patents is included with this Complaint at Exhibit 4. Baxter owns all right, title, and interest in and to each of these foreign counterpart patents and foreign counterpart applications. Baxter is not aware of any other foreign counterpart patents or foreign counterpart applications corresponding to the Asserted Patents that have issued, are pending, or have been denied, abandoned, or withdrawn.

E. Licenses & Agreements

44. Baxter and its wholly owned subsidiaries have executed certain agreements relating to the Asserted Patents. Those agreements are set forth in Exhibits 41C-51C. On April 15, 2015, Baxter Innovations GmbH's full right, title, and interest in each of the Asserted Patents was confirmed through the execution of a Global Assignment Agreement. (*See* Ex. 39C.) Baxter Innovations GmbH subsequently assigned all right, title, and interest in each of the Asserted

[8] Baxter has requested an updated copy of the assignment record from the PTO and will provide them to the ITC upon receipt.

Patents to Baxter International Inc. and Baxter Healthcare SA in an Assignment Agreement dated April 15, 2015. (*See* Ex. 40.)

45. Baxter is not aware of any third-party entities licensed under the Asserted Patents or third-party entities that have received from Baxter a covenant not to assert with respect to the Asserted Patents.

VI. UNLAWFUL AND UNFAIR ACTS OF RESPONDENTS—PATENT INFRINGEMENT

46. On information and belief, Respondents have engaged in unlawful and unfair acts, including the importation into the United States, sale for importation into the United States, or sale or imminent sale within the United States after importation of the Accused Products. On information and belief, Respondents have imported and plan to import into the United States and market and sell the Accused Products as early as mid-April 2015. The process by which the Accused Products are manufactured infringes one or more of the following claims, either literally or under the doctrine of equivalents:

Patent Number	Asserted Claims
'061 Patent	19, 20, 21, 36, 37, 39
'441 Patent	20, 21
'252 Patent	1, 5, 8, 10, 14, 18

A. Infringement of the Asserted Patents

47. On information and belief, Respondents are currently importing into the United States the Accused Products, which are recombinant factor VIII products for the treatment of hemophilia A.

48. On information and belief, Respondents have sold or will imminently sell in the United States after importation the Accused Products, which are recombinant factor VIII products for treatment of hemophilia A.

49. On information and belief, the Accused Products are made abroad by means of a process covered by one or more process claim of the Asserted Patents.

50. On information and belief, Respondents' manufacture of the Accused Products directly infringes at least the following claims: claims 19, 20, 21, 36, 37, and 39 of the '061 Patent; claims 20 and 21 of the '441 Patent; and claims 1, 5, 8, 10, 14, and 18 of the '252 Patent. Exemplary claim charts comparing the independent, asserted claims of the Asserted Patents to Respondents' process for manufacturing the Accused Products are attached as Exhibits 8-10. Further discovery may reveal that additional claims of the Asserted Patents are infringed by the manufacture of the Accused Products.

51. A photograph of the Accused Products is provided at Exhibit 33.[9]

VII. SPECIFIC INSTANCES OF UNFAIR IMPORTATION AND SALE

52. On information and belief, respondent, Novo Nordisk A/S, manufactures recombinant factor VIII products, including Novoeight® in Denmark. (Ex. 19 at ¶¶ 16, 18, 22; Ex. 20 at 1.)

53. On information and belief, Respondents have imported and are importing into the United States products containing recombinant factor VIII, including the Accused Products, manufactured in Denmark according to the processes protected by the Asserted Patents, including for sale or imminent sale. On information and belief, the Accused Products are currently stored in warehouses in the United States.

54. Respondents received FDA approval to manufacture, market, and sell Novoeight® in the United States in 2013. (Ex. 20 at 1.)

[9] Due to the nature of the product, Baxter is not submitting a physical sample of the Accused Products with the Complaint.

55. Respondents have announced that they will begin selling Novoeight® in direct competition with Baxter in the United States by mid-April 2015. (Ex. 19 at ¶¶ 2, 16, 22; Ex. 18 at 2-3; Ex. 22 at 38.) In a March 26, 2015, press release, Novo Nordisk Inc. stated that it "will launch Novoeight®. . . in the United States" and "plans to make Novoeight® available by mid-April 2015." (Ex. 18 at 2.) Similarly, in a letter to Baxter declining to delay Novoeight®'s mid-April launch, Novo Nordisk Inc. wrote that Novoeight® "will be available in the United States starting in April." (Ex. 24 at 1.)

56. In addition, in anticipation of releasing Novoeight® in the United States, Respondents have been and are making meaningful preparations to market and sell Novoeight® in the United States, including launching the Novoeight® website (http://novoeight.com/), marketing to patients and healthcare providers, and engaging hemophilia community specialists across the United States. (Ex. 29 at 1-2; Ex. 30; Ex. 18 at 2-3; Ex. 52; Ex. 53.) The Novoeight® website, which is directed to both patients and healthcare providers, provides product information on Novoeight®, including brochures, "Demo Kits," and videos demonstrating Novoeight® reconstitution. (*See e.g.* Exs. 29-30.) The website also offers consultations with Novo Nordisk Hemophilia Sales Managers and assistance in seeking financial aid for patients. (*See e.g.* Ex. 29.) Furthermore, on information and belief, the Accused Products are available for order by calling 1-844-303-4448. (*See* Ex. 52 at 2.)

57. Respondents' marketing efforts in the United States include attending trade shows, such as the 2014 American Society of Hematology ("ASH") Conference in San Francisco. (Ex. 31C at 5-6.) At the ASH Conference, Respondents provided presentations concerning Novoeight® product safety and efficacy and confirmed the Novoeight® launch in April 2015. (*Id.*) On information and belief, the Respondents also had a strong promotional

presence at a large patient meeting the last weekend in March 2015, including sales representative discussions with patients that focused on the benefits of the Novoeight® brand.

VIII. HARMONIZED TARIFF SCHEDULE ITEM NUMBERS

58. On information and belief, the Harmonized Tariff Schedule ("HTS") of the United States item numbers under which the Accused Products have been imported into the United States may include at least the following HTS numbers: 3002.10.02 (Antisera, other blood fractions and modified immunological products, whether or not obtained by means of biotechnological processes); and 3504.00.50 (Peptones and their derivatives; other protein substances and their derivatives, not elsewhere specified or included; hide powder, whether or not chromed). The identified HTS numbers are intended for illustration only and are not exhaustive of the products accused of infringement in this Complaint. The HTS numbers are not intended to limit the scope of the Investigation.

IX. RELATED LITIGATION

59. On March 26, 2015, Novo Nordisk Inc. filed a declaratory judgment action in the United States District Court for the District of New Jersey seeking declaratory judgment of non-infringement and invalidity of the claims of the Asserted Patents as well as other of Baxter's patents. (*See* Ex. 19.)

60. Additionally, several entities, including Novo Nordisk A/S, filed an opposition to European Patent No. 1 200 561 (the "'561 EP Patent"). Although the '561 EP Patent is not related by family to any of the Asserted Patents, it does describe the culturing of cells using serum- and protein-free media and identifies the same inventors. The Opposition Division issued a decision to revoke the '561 EP Patent on largely procedural grounds on October 22, 2010. (Ex. 36 at 38.) Baxter Aktiengesellschaft appealed that decision on December 16, 2010, and the appeal is pending. The '561 EP Patent remains in force during the pendency of the appeal. There

is no other court or agency litigation, foreign or domestic, involving the unfair methods of competition and unfair acts alleged herein, or the subject matter thereof.

X. THE DOMESTIC INDUSTRY

61. A domestic industry exists in the United States relating to Advate® based on Baxter's significant investments in plant, equipment, labor, and capital and in product and customer support.

62. Baxter makes extensive use of the inventions claimed in the Asserted Patents in its recombinant protein products, including its recombinant factor VIII product Advate®, and has made and continues to make significant domestic investments in these products, as set forth more fully in the accompanying Declaration of David Ackerson, attached at Exhibit 11C. For example, Baxter manufactures and sells, in the United States, its Advate® recombinant factor VIII products. Advate® leads the market in sales for recombinant factor VIII products. (Ex. 32C.) As set forth in greater detail below, Advate® is manufactured by processes that practice at least one claim of each of the Asserted Patents. Baxter's domestic investments and activities relating to Advate® are continuing and ongoing.

A. Baxter's Advate® Products

63. Baxter is a global healthcare company engaged in the business of developing, manufacturing, and marketing products in the medical device, pharmaceutical, and biotechnology arenas that save and sustain the lives of patients with various disease states and medical conditions. Baxter's products are used in all facets of healthcare, including hospitals, rehabilitation centers, doctors' offices, clinical laboratories, and by patients in an outpatient setting.

64. At the time of filing of this Complaint, Baxter has two operating segments: BioScience and Medical Products. In March 2014, Baxter announced that it would spin off its

BioScience business into a stand-alone company that will become Baxalta. Baxter expects that the spin-off will be complete by mid-2015. Baxter's factor VIII products, including Advate®, will become part of Baxalta's product portfolio.

65. Among Baxter's many areas of focus has been its devotion to developing, manufacturing, and providing the marketplace with life-saving and life-improving products for the treatment of hemophilia. Baxter has more than 60 years of experience with hemophilia products and has the broadest portfolio of hemophilia treatments in the industry. Among those are Baxter's innovative recombinant factor VIII Advate® products, which lead the market in the United States and worldwide in the treatment of hemophilia A.

B. Baxter's Advate® Products are Protected by the Asserted Patents

66. Baxter owns the rights to an extensive portfolio of intellectual property covering the novel manufacturing processes used to make its Advate® products. Among the patents in Baxter's portfolio are the Asserted Patents.

67. Baxter practices at least claims 19-21, 36, 37, and 39 of the '061 Patent, claims 20 and 21 of the '441 Patent, and claims 1, 5, 8, 10, 14 and 18 of the '252 Patent in its manufacture of Advate® products. Exemplary claim charts comparing the processes by which Advate® is manufactured to claims 19 and 36 of the '061 Patent, claim 20 of the '441 Patent, and claims 1, 5, and 8 of the '252 Patent are set forth in Exhibits 12, 13C, and 14C. As shown therein, Baxter continues to practice each of the Asserted Patents and devotes considerable investment and expenditures in its domestic industries for the Asserted Patents to this date.

C. Baxter Has a Domestic Industry With Respect to Its Advate® Products

68. Baxter has a 60-year history of providing critical and innovative treatments to patients suffering from hemophilia, including its recombinant factor VIII treatments. In particular, Baxter has invested significant resources in developing, manufacturing, and selling

Advate®. Baxter introduced Advate® in 2003. As discussed above, Advate® was the first recombinant factor VIII product to be manufactured without the introduction of plasma-derived proteins in either the cell culture medium or the final formulation, which completely eliminates the risk of transmission of blood-borne pathogens to the patient. Advate® leads the market in sales for recombinant factor VIII products. (Ex. 32C.)

69. Baxter has been manufacturing Advate®, in part, at its Thousand Oaks, California facility since at least 2009. (*See* Ex. 11C at ¶¶ 6-7, 9, 11.) Advate® is made via a recombinant cell culture manufacturing process, which is described in further detail in the Declaration of David Ackerson, attached as Exhibit 11C. (*Id.*)

70. In bringing Advate® to market, Baxter made and continues to make significant investments in plants and equipment and labor and capital. (*See id.* at ¶¶ 11-17.) For example, Baxter has nearly completed construction on a new U.S. facility, which Baxter expects will be usable as early as April 2015. (*See id.* at ¶ 8.) Baxter's U.S.-based personnel and resources are involved in the manufacture, packaging, and post-sale support for Baxter's Advate® products. (*See id.* at ¶¶ 5-7, 9-17.) Baxter's U.S.-based personnel are also involved in efforts to educate and support patients using Advate® as well as the broader hemophilia community. (*See id.* at ¶ 10.)

XI. RELIEF REQUESTED

71. WHEREFORE, by reason of the foregoing, Baxter respectfully requests that the United States International Trade Commission:

a) Institute an immediate investigation, pursuant to Section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337, with respect to violations of 19 U.S.C. §337(a)(1)(B)(i) based upon the importation, sale for importation, and sale after importation, into the United States, of Respondents' recombinant factor VIII products made by or on behalf of

Respondents that infringe one or more asserted claims of Complainants' '061, '441, and '252 Patents.

b) Schedule and conduct a hearing pursuant to 19 U.S.C. § 1337 for the purposes of (i) receiving evidence and hearing argument concerning whether there has been a violation of 19 U.S.C. § 1337, and (ii) following the hearing, determining that there has been a violation of 19 U.S.C. § 1337.

c) Issue a limited exclusion order, pursuant to 19 U.S.C. § 1337(d)(1), barring from entry into the United States all recombinant factor VIII products made by or on behalf of Respondents that infringe one or more asserted claims of Complainants' '061, '441, and '252 Patents.

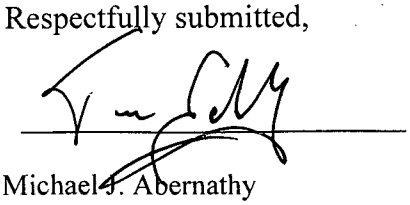
d) Issue cease-and-desist orders, pursuant to 19 U.S.C. § 1337(f), prohibiting Respondents, and others acting on their behalf, from importing, marketing, advertising, demonstrating, warehousing inventory for distribution, distributing, offering for sale, selling, licensing, using, or transferring outside the United States for sale in the United States any recombinant factor VIII products that infringe one or more asserted claims of Complainants' '061, '441, and '252 Patents.

e) Impose a bond, pursuant to 19 U.S.C. § 1337(j), upon importation of any recombinant factor VIII products that infringe one or more asserted claims of Complainants' '061, '441, and '252 Patents during any Presidential Review; and

f) Grant such other and further relief as the Commission deems just and proper based on the facts determined by the investigation and the authority of the Commission.

Dated: April 16, 2015

Respectfully submitted,



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Counsel for Complainants Baxter International Inc., Baxter Healthcare Corporation, and Baxter Healthcare SA

VERIFICATION OF COMPLAINT

I, Shannon M. Resetich, declare, in accordance with 19 C.F.R. §210.12(a), under penalty of perjury, that the following statements are true:

1. I am currently the Business Head for U.S. Hemophilia at Baxter Healthcare Corporation. I am duly authorized by Complainants Baxter International Inc., Baxter Healthcare Corporation, and Baxter Healthcare SA to verify the foregoing Complaint.

2. I have read the Complaint and am aware of its contents.

3. The Complaint is not being filed for any improper purpose, such as to harass or to cause unnecessary delay or needless increase in the cost of litigation.

4. To the best of my knowledge, information, and belief, formed after a reasonable inquiry, the claims and other legal contentions set forth in the Complaint are warranted by existing law or by a good-faith, nonfrivolous argument for extension, modification, or reversal of existing law, or by the establishment of new law.

5. To the best of my knowledge, information, and belief, formed after a reasonable inquiry, the allegations of the Complaint are well grounded in fact and have evidentiary support, or, where specifically identified, are likely to have evidentiary support after a reasonable opportunity for further investigation or discovery.

Executed April 16, 2015

Shannon Resetich