FOSTER MURPHY ALTMAN & NICKEL

David F. Nickel
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July 7, 2017

VIA HAND DELIVERY

The Honorable Lisa R. Barton
Secretary
U.S. International Trade Commission
500 E Street, SW
Washington, D.C. 20436

Re: *Certain Recombinant Factor IX Products,* Inv. No. 337-TA-

Dear Secretary Barton:

Enclosed for filing on behalf of Complainants Bioverativ Inc., Bioverativ Therapeutics Inc., and Bioverativ U.S. LLC ("Bioverativ" or "Complainants") are documents in support of Bioverativ's request that the Commission commence an investigation pursuant to Section 337 of the Tariff Act of 1930, as amended. Pursuant to the Commission Rules of Practice and Procedure, a request for confidential treatment of Confidential Exhibit No. 11C is also included with this submission.

Bioverative submits the following documents for filing:

1. An unbound original and eight (8) copies of Bioverativ's non-confidential verified Complaint and the Statement of Public Interest; and (1) copy of the accompanying non-Confidential Exhibits in electronic form (on a CD), with (1) copy of Confidential Exhibit No. 11C in electronic form (on a CD) segregated from the other material submitted (Commission Rules 201.6(c), 210.4(f)(3)(i) and 210.8(a));

2. Certified copies of United States Patent Nos. 9,623,091 ("the '091 patent"); 9,629,903 ("the '903 patent") and 9,670,475 ("the '475 patent") referenced in the Complaint as Exhibits 1-3, respectively (Commission Rule 210.12(a)(9)(i));

3. Certified copies of the assignment histories for the asserted patents, referenced in the Complaint as Exhibits 5-7, respectively (Commission Rule 210.12(a)(9)(ii));

4. A certified copy of the prosecution history of the '091 patent (Appendix A), a certified copy of the prosecution history of the '903 patent (Appendix B), a certified copy of the '475 patent (Appendix C) and four (4) additional copies of each in electronic form (on a CD) (Commission Rule 210.12(c)(i));

5. Four (4) copies in electronic form (on CD) of each patent and technical reference mentioned in the prosecution histories of the asserted patents, referenced in the Complaint as Appendices D, E and F (Commission Rule 210.12(c)(2));

6. Three (3) additional copies of the verified non-confidential Complaint, including all accompanying non-confidential Exhibits in electronic form (on a CD), for service upon each Proposed Respondent (Commission Rules 210.4(f)(3)(i), 210.8(a) and 210.11(a));

7. Three (3) additional copies of Confidential Exhibit No. 11C in electronic form (on a CD) for service upon a representative of each Proposed Respondent who has properly subscribed to the protective order in this matter (Commission Rules 210.4(f)(3)(i), 210.8(a) and 210.11(a));

8. Two (2) additional copies of the non-confidential Complaint for service upon each Embassy (Commission Rules 210.8(a)(1)(iv) and 210.11(a)(1)); and

9. A letter and certification pursuant to Commission Rules 201.6(b) and 210.5(d) requesting confidential treatment of information appearing in Confidential Exhibit No. 11C.

Thank you for your assistance in this matter. Please contact me if you have any questions.

Respectfully submitted,

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500 E Street, SW
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Re: *Certain Recombinant Factor IX Products,*
Inv. No. 337-TA-

Dear Secretary Barton:

Foster, Murphy, Altman & Nickel, PC represents Complainants Bioverativ Inc., Bioverativ Therapeutics Inc., and Bioverativ U.S. LLC ("Bioverativ") in connection with a complaint filed pursuant to Section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337.

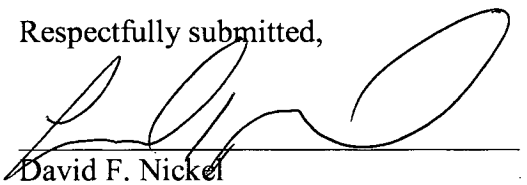
Pursuant to Commission Rules 201.6 and 210.5, 19 C.F.R. §§ 201.6 and 210.5, Bioverativ respectfully requests confidential treatment of the business information contained in Confidential Exhibit 11C. This exhibit contains confidential business information pursuant to 19 C.F.R. § 201.6 because it discloses proprietary commercial information, proprietary commercial relationships, proprietary business information, and/or proprietary business relationships that is not otherwise publicly available.

Specifically, Confidential Exhibit 11C qualifies as confidential business information pursuant to 19 C.F.R. § 201.6 because this confidential exhibit contains confidential proprietary commercial information relating to Bioverativ's investments relating to the domestic development, manufacture, packaging, sale, and support of Alprolix®. The disclosure of this information would result in substantial harm to the competitive position of Bioverativ and also would impair the Commission's ability in the future to obtain such types of information in performance of its statutory function.

I certify that substantially identical information is not reasonably available to the public.

Thank you for your assistance in this matter. Please contact me if you have any questions.

Respectfully submitted,



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Counsel to Complainants Bioverativ Inc., Bioverativ Therapeutics Inc., and Bioverativ U.S. LLC

UNITED STATES INTERNATIONAL TRADE COMMISSION
WASHINGTON, D.C.

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

COMPLAINANTS' STATEMENT REGARDING THE PUBLIC INTEREST

Complainants Bioverativ Inc., Bioverativ Therapeutics Inc., and Bioverativ U.S. LLC (collectively "Bioverativ") hereby respectfully submit this Statement Regarding the Public Interest in compliance with 19 C.F.R. § 210.8(b). Bioverativ 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 IX 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. The issuance of the requested relief would serve the public interest by protecting Bioverativ's intellectual property rights.

Bioverativ manufactures its patented Alprolix® products in the United States and has the ability to replace the Accused Products should exclusion and cease and desist orders issue. Moreover, several other non-infringing suppliers have supplied and can continue to supply products to satisfy U.S. demand for recombinant Factor IX products. Specifically, recombinant Factor IX products currently available in the United States include Alprolix® (Bioverativ), BeneFix® (Pfizer), Ixinity® (Aptevo), and Rixubis® (Shire). The unavailability of proposed Respondents' recombinant Factor IX products, manufactured in Germany, 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. *See Certain Recombinant Factor*

VIII Products, Inv. No. 337-TA-956, Recommended Determination at 11 (June 3, 2016) (recommending exclusion and cease-and-desist orders where "[t]he evidence indicates there is no shortage of competing products on the U.S. market. Several different recombinant and non-recombinant factor VIII products currently are available ...."). The requested Investigation therefore does not present an instance where a compelling public interest might supersede entry of remedial orders when a violation of Section 337 is found.

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 IX products (referred to herein as "Idelvion®" or "Accused Products") that are used in the management of hemophilia B by healthcare professionals in a hospital, clinic, or other medical facility to treat patients, and for home use, *e.g.*, self-infusion by a patient. Idelvion® was approved for use in the United States in March 2016[1] and is currently sold for use in the United States. *See* Exs. 18, 19, 21, 24 to Compl.

II. THERE ARE NO PUBLIC HEALTH, SAFETY, OR WELFARE CONCERNS IN THE UNITED STATES RELATING TO THE POTENTIAL REMEDIAL ORDERS

The exclusion of Respondents' Accused Products from importation into the United States would not implicate any public health, safety, or welfare concerns. Respondents' Accused Products were first introduced for sale in the United States after March 2016. In addition to the availability of Bioverativ's Alprolix® products, there are several other recombinant Factor IX products available in the U.S. market, including those manufactured by or on behalf of Pfizer, Shire, and Aptevo. Until early last year, these manufacturers fully supplied the market in the

[1] *See* https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm489266.htm.

absence of the Accused Products and can continue to do so in the future. According to the World Federation of Hemophilia's 2015 Survey, approximately 4,400 people in the United States live with hemophilia B.

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 recombinant Factor IX products that entered the U.S. market in March 2016. As noted above, there are numerous safe, FDA-approved, and non-infringing recombinant Factor IX products with which the Accused Products compete that are available for treatment of hemophilia B. Bioverativ and other manufacturers of currently available recombinant Factor IX products can adequately supply the market and have done so for years. Bioverativ's Alprolix® or the recombinant Factor IX products of other manufacturers could readily replace the Accused Products if they are excluded from the United States. *See Certain Recombinant Factor VIII Products*, Inv. No. 337-TA-956, Recommended Determination at 7-11 (June 3, 2016).

IV. THE DOMESTIC FACTOR IX MARKET CAN BE SATISFIED BY EXISTING PRODUCTS

Non-infringing recombinant Factor IX products currently available in the United States include Alprolix® (Bioverativ), BeneFix® (Pfizer), Ixinity® (Aptevo), and Rixubis® (Shire). Thus, 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 IMPACT ON CONSUMERS IN THE UNITED STATES

As explained above, in light of the numerous other safe, approved, and non-infringing recombinant Factor IX alternatives available in the United States market, the issuance of the

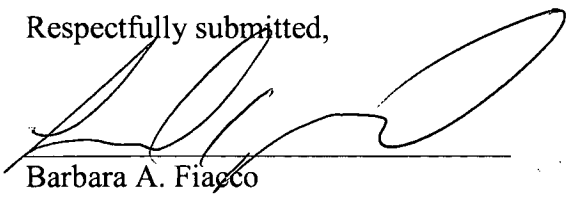
requested exclusion and cease-and-desist orders for the remaining life of the patents will have no meaningful adverse impact on customers in the United States.

Moreover, the public interest favors the protection of intellectual property rights in the United States. *Certain Two-Handle Centerset Faucets & Escucheons, & Components Thereof*, Inv. No. 337-TA-422, Comm'n Op. at 9 (July 21, 2000); *Certain Recombinant Factor VIII Products*, Inv. No. 337-TA-956, Recommended Determination at 7-11 (June 3, 2016). The issuance of the requested relief—excluding Respondents' infringing products—would serve the public interest by protecting Bioverativ's intellectual property rights.

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 Respondents' infringing recombinant Factor IX products is not essential to the public health and safety because, among other things, they represent a recent entrant into a well-supplied field. 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.

Respectfully submitted,



Dated: July 7, 2017

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Counsel for Complainants Bioverativ Inc., Bioverativ Therapeutics Inc., and Bioverativ U.S. LLC

UNITED STATES INTERNATIONAL TRADE COMMISSION
WASHINGTON, D.C.

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

COMPLAINT OF BIOVERATIV INC., BIOVERATIV THERAPEUTICS INC., AND BIOVERATIV U.S. LLC UNDER SECTION 337 OF THE TARIFF ACT OF 1930, AS AMENDED

COMPLAINANTS

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PROPOSED RESPONDENTS

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+41 31 344 44 44

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TABLE OF SUPPORTING MATERIALS

EXHIBITS

Exhibit No.	Description
1.	Certified Copy of U.S. Patent No. 9,623,091
2.	Certified Copy of U.S. Patent No. 9,629,903
3.	Certified Copy of U.S. Patent No. 9,670,475
4.	List of Foreign Counterparts to the Asserted Patents
5.	Certified Copy of the PTO Assignment records for U.S. Patent No. 9,623,091
6.	Certified Copy of the PTO Assignment records for U.S. Patent No. 9,629,903
7.	Certified Copy of the PTO Assignment records for U.S. Patent No. 9,670,475
8.	Infringement Claim Chart for U.S. Patent No. 9,623,091 for claim 1
9.	Infringement Claim Chart for U.S. Patent No. 9,629,903 for claim 1
10.	Infringement Claim Chart for U.S. Patent No. 9,670,475 for claim 1
11C.	Confidential Declaration of Nicole Murphy regarding Domestic Industry
12.	Domestic Industry Claim Chart for U.S. Patent No. 9,623,091 for claim 1
13.	Domestic Industry Claim Chart for U.S. Patent No. 9,629,903 for claim 1
14.	Domestic Industry Claim Chart for U.S. Patent No. 9,670,475 for claim 1
15.	Picture of Accused Product
16.	Picture of Domestic Product
17.	Alprolix® FDA Approval Letter
18.	Idelvion® FDA Approval Letter
19.	Idelvion® Label
20.	Idelvion® Summary Basis for Regulatory Action
21.	Idelvion® Homepage
22.	CSL Behring Worldwide Locations Website
23.	CSL Behring Corporate Brochure
24.	CSL Behring Press Release dated March 21, 2016
25.	Alprolix® Label
26.	Y. Zhang et al., *Population pharmacokinetics of a new long-acting recombinant coagulation factor IX albumin fusion protein for patients with severe hemophilia B*, 14 J. Thrombosis & Haemostasis 2132 (2016)
27.	Jerry Powell et al., *Switching to recombinant factor IX Fc fusion protein prophylaxis results in fewer infusions, decreased factor IX consumption and lower bleeding rates*, British J. of Haematology (2014)
28.	Chris Guelcher et al., *Extended-Interval Dosing with rFIXFc Is Associated with Low Bleeding Rates and a Reduction in Weekly Factor Use*, Nat'l Hemophilia Found., CR23 (Sept. 18-20, 2014)
29.	Jonathan M. Ducore et al., *Alprolix (recombinant Factor IX Fc fusion protein): extended half-life product for the prophylaxis and treatment of hemophilia B*, 7(5) Expert Rev. Hematology 559 (2014)

APPENDICES

Appendix No.	Description
A.	Certified Copy of Prosecution History of U.S. Patent No. 9,623,091
B.	Certified Copy of Prosecution History of U.S. Patent No. 9,629,903
C.	Certified Copy of Prosecution History of U.S. Patent No. 9,670,475
D.	Technical References Cited in the Prosecution History of U.S. Patent No. 9,623,091
E.	Technical References Cited in the Prosecution History of U.S. Patent No. 9,629,903
F.	Technical References Cited in the Prosecution History of U.S. Patent No. 9,670,475

TABLE OF CONTENTS

I. INTRODUCTION

1. This Complaint is filed by Bioverativ Inc., Bioverativ Therapeutics Inc., and Bioverativ U.S. LLC (collectively, "Bioverativ" or "Complainants") under Section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337, to block Respondents' unlawful attempt to reap the rewards of Bioverativ's innovation in the treatment of hemophilia B. Complainants and their predecessors invested in more than a decade of scientific research and development, including extensive and costly clinical trials in the United States and abroad, to develop a new therapy to improve the lives of people suffering from the pain, joint damage, and life-threatening hemorrhages associated with this genetic blood-clotting disorder.

2. The success of Complainants' innovation and investment was realized in 2014, when the FDA approved Bioverativ's Alprolix®, the first FDA-approved recombinant, clotting factor therapy offering prolonged circulation in the body. Before Alprolix®, people with hemophilia B wanting to protect against bleeding episodes had to be infused with replacement Factor IX two to three times per week. Alprolix®'s prolonged half-life allows extended protection with less frequent prophylactic infusions than could be offered by prior treatments. This reduction in the burden of treatment has improved the lives of those with hemophilia B while maintaining efficacy in controlling and reducing the frequency of bleeding episodes.

3. Respondents' unlawful conduct includes the importation into the United States, the sale for importation into the United States, and/or the sale within the United States after importation, of recombinant Factor IX products that infringe at least claims 1-2, 4-19, 24-25, 29, and 34 of United States Patent No. 9,670,475 (the "'475 patent"); at least claims 1-7, 11-16, 18, 19, 21, and 23-27 of United States Patent No. 9,623,091 (the "'091 patent"); and at least claims 1-10, 13-15, and 17-28 of United States Patent No. 9,629,903 (the "'903 patent") (collectively,

the "Asserted Patents") either literally or under the doctrine of equivalents. Bioverativ Therapeutics Inc. owns the entire right, title, and interest in and to the Asserted Patents by assignment.

4. Complainants' Alprolix® [Coagulation Factor IX (Recombinant), Fc Fusion Protein] is a novel biological molecule created by fusing Factor IX to the Fc portion of immunoglobulin G subclass 1, or IgG_1 (a protein commonly found in the body). The fusion of the Factor IX with the Fc fragment results in a protein that is designed to extend the half-life of Factor IX, by using a naturally occurring mechanism called the FcRn recycling pathway to delay the breakdown of the protein in circulation and thereby make the product last longer in a person's blood than traditional factor therapies. Alprolix® is indicated for the control and prevention of bleeding episodes, perioperative (surgical) management, and routine prophylaxis in adults and children with hemophilia B. Alprolix®, when administered according to its label, practices inventions claimed in the '475, '091, and '903 patents, which are directed to novel methods of treating hemophilia B patients by administering a chimeric Factor IX polypeptide comprising Factor IX and an FcRn binding partner, including albumin.

5. Two years after the FDA approved Bioverativ's Alprolix®, Respondents obtained FDA approval for their copycat therapy under the name Idelvion® [Coagulation Factor IX (Recombinant), Albumin Fusion Protein] (the "Accused Products"). Like Alprolix®, Idelvion® is a recombinant Factor IX treatment for hemophilia B. Idelvion®'s Factor IX molecule is fused to albumin (as claimed in the Asserted Patents), which uses the same recycling pathway as Alprolix®. The administration of the Accused Products to people with hemophilia B in accordance with the Idelvion® label infringes the Asserted Patents.

6. Respondents' activities, including the sale for importation into the United States, the importation into the United States, and/or the sale within the United States after importation of the Accused Products, are unlawful under 19 U.S.C. § 1337(a)(1)(B)(i) because they constitute infringement of the Asserted Patents.

7. A domestic industry, as required by 19 U.S.C. § 1337(a)(2) and (3), exists in the United States relating to Complainants' Recombinant Factor IX products marketed under the name Alprolix®. *See* Ex. 11C.

8. Complainants seek a limited exclusion order under 19 U.S.C. § 1337(d) to prevent widespread infringement, throughout the United States, of patents that the United States Patent and Trademark Office awarded to Complainants to recognize and reward innovation that is benefitting the lives of individuals living with hemophilia B. The requested order would bar from entry into the United States infringing recombinant Factor IX products manufactured or sold by or on behalf of Respondents, their subsidiaries, related companies, distributors, and/or agents. Complainants further seek cease-and-desist orders under 19 U.S.C. § 1337(f) prohibiting each of the Respondents, their subsidiaries, related companies, distributors, and/or agents from marketing, distributing, selling, offering for sale, supporting, warehousing inventory for distribution, or otherwise transferring or bringing into the United States infringing recombinant Factor IX products.

II. COMPLAINANTS

9. Complainant Bioverativ Inc. is a Delaware corporation with its principal place of business at 225 Second Avenue, Waltham, Massachusetts.

10. Complainant Bioverativ Therapeutics Inc. is a Delaware corporation with its principal place of business at 225 Second Avenue, Waltham, Massachusetts.

11. Complainant Bioverativ U.S. LLC is a Delaware corporation with its principal place of business at 225 Second Avenue, Waltham, Massachusetts.

12. Complainants are related biotechnology companies focused on the discovery, research, development, and commercialization of innovative therapies for the treatment of hemophilia and other rare blood disorders. Bioverativ Inc. was formed on August 4, 2016 to hold the hemophilia business of Biogen Inc. ("Biogen"). Bioverativ Inc. separated from Biogen on February 1, 2017. Bioverativ Therapeutics Inc. was formerly called Biogen Hemophilia Inc. and was a wholly owned subsidiary of Biogen. It is now a wholly owned subsidiary of Bioverativ Inc. Bioverativ U.S. LLC is a wholly owned subsidiary of Bioverativ Therapeutics Inc. Bioverativ U.S. LLC controls the distribution of product to specialty distributors, specialty pharmacies, hemophilia treatment centers (HTC), payors, and the like, and employs the existing sales force supporting Alprolix®.

13. Complainants collectively have made, market, and sell two extended half-life clotting-factor therapies, Alprolix® [Coagulation Factor IX (Recombinant), Fc Fusion Protein], for the treatment of hemophilia B, and Eloctate® [Antihemophilic Factor (Recombinant), Fc Fusion Protein], for the treatment of hemophilia A. This case concerns only Alprolix®, for treatment of hemophilia B, and Alprolix® is the Domestic Industry product for purposes of this Complaint.

14. Complainants have multiple programs intended to support their marketed products and an innovative product pipeline devoted to the creation and delivery of new therapies to transform the lives of people with hemophilia and other rare blood disorders. Complainants' research activities relating to their marketed products include ongoing and planned post-marketing studies investigating the potential of Fc fusion technology to improve long-term joint

health, immunogenicity, and immune tolerance induction in hemophilia patients who develop inhibitors.

15. Complainants' research activities relating to new products are focused on drug discovery and preclinical programs for, among other things, a next generation recombinant Factor IX replacement product subcutaneously administered with the objective of achieving once weekly or less frequent dosing; a combination of Factor VIII-Fc fusion protein with part of Von Willebrand Factor with the objective of achieving once weekly or less frequent dosing by intravenous administration; and a non-factor bi-specific antibody for the treatment of patients with hemophilia A with inhibitors as well as for the general hemophilia A population. Bioverativ is also working to develop gene therapies for both hemophilia A and B, and has ongoing research programs relating to sickle cell disease and beta-thalassemia. Bioverativ's commitment to these rare diseases extends beyond the products it sells, and includes the donation, with a collaboration partner, of up to one billion international units (IUs) of clotting factor for humanitarian use, with up to 500 million IUs to be donated to the World Federation of Hemophilia over a five-year period. Bioverativ also provides funding for the world's largest genetic hemophilia repository in order to gain greater knowledge about the disorder.

16. Complainants' innovative Factor IX treatments for hemophilia B sold under the name Alprolix® are protected by the Asserted Patents. *See* Exs. 12-14. Complainants and their contract manufacturer have substantial operations devoted to Alprolix® in the United States, which include manufacturing and product support. *See* Ex. 11C. Further, Complainants and their contract manufacturer have invested hundreds of millions of dollars in the United States in facilities, equipment, labor, and capital, as well as product support and patient and community advocacy dedicated to Alprolix®. *Id.*

III. THE PROPOSED RESPONDENTS

17. On information and belief, Respondents designed, developed, manufacture, sell for importation, import into the United States, and/or sell after importation into the United States the Accused Products, which are known as Coagulation Factor IX (Recombinant), Albumin Fusion Protein. Respondents market and sell the Accused Products under the name Idelvion®. Through such acts, Respondents infringe the Asserted Patents in violation of Section 337, as detailed below.

18. On information and belief, Respondent CSL Behring LLC is a Delaware corporation having its principal place of business at 1020 First Avenue, PO Box 61501, King of Prussia, Pennsylvania.

19. On information and belief, Respondent CSL Behring GmbH is a German company with its principal place of business at Emil-von-Behring-Strasse 76, Marburg, Hessen 35041 Germany.

20. On information and belief, Respondent CSL Behring Recombinant Facility AG is a Swiss company with its principal place of business at Wankdorfstrasse 10, Bern, Bern 3014 Switzerland.

21. On information and belief, Respondents are wholly owned subsidiaries of CSL Limited, an Australian company.

22. On March 4, 2016, two years after approval of Complainants' Alprolix® as a treatment for hemophilia B, the FDA approved CSL Behring Recombinant Facility AG's Biologics License Application ("BLA") for Idelvion®. Exs. 18, 24.

23. CSL Behring GmbH manufactures Idelvion® in Germany for CSL Behring Recombinant Facility AG, the Idelvion® BLA holder, before importation into the United States.

Ex. 19. On information and belief, Respondents sell for importation and/or import Idelvion® into the United States, where CSL Behring LLC sells Idelvion® after importation. *Id.*

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

24. The technology at issue relates generally to the control and prevention of bleeding episodes, perioperative (surgical) management, and routine prophylaxis in adults and children with hemophilia B. In particular, the technology involves novel methods of treating patients with hemophilia B by administering a chimeric Factor IX polypeptide comprising Factor IX and an FcRn binding partner (*e.g.,* Fc or albumin). Fc is a portion of a common protein in the body. Fusing Fc to Factor IX results in a longer active half-life for the Factor IX molecule. Pursuant to Commission Rule 210.12(a)(12), the Accused Products are certain Factor IX hemophilia products, including intermediates, manufactured by or for, and/or sold by or for Respondents that, without permission, practice Bioverativ's patented methods as described and claimed in the Asserted Patents.

A. Hemophilia B

25. Hemophilia B is a rare, X-linked genetic disorder that impairs the ability of a person's blood to clot due to reduced levels of Factor IX activity. This impairment can lead to recurrent and extended bleeding episodes that may cause pain, irreversible joint damage, and life-threatening hemorrhages.

26. In its Annual Global Survey 2015, the World Federation of Hemophilia estimated that nearly 30,000 people worldwide, including approximately 4,400 people in the United States, have hemophilia B.

27. Hemophilia B is usually diagnosed at birth or at a very young age, and predominantly affects males. An individual's hemophilia is classified as mild, moderate, or severe, based on the

level of Factor IX activity in the blood. Although hemophilia care varies widely across the globe, in the United States a majority of patients receive care from specialized hemophilia treatment centers.

28. Hemophilia B is treated by infusing the missing clotting Factor IX directly into the patient's bloodstream. Therapies can be administered either on a schedule to help prevent or reduce bleeding episodes (prophylaxis) or as needed to control bleeding when it occurs (on-demand). Over time, regimens have shifted from on-demand treatment to routine prophylaxis due to observed improvements in long-term clinical outcomes, such as with respect to joint damage.

29. Before the era of prophylaxis, the repeated spontaneous bleeds into joints and soft tissues led to severe complications in people with hemophilia, including joint damage and arthopathy that required surgical intervention, and resulted in limited mobility and significant negative impact to quality of life. With the advent of plasma-derived, highly purified factor preparations and a recombinant Factor IX product in the late 1990s, people in the developed world can now maintain prophylactic regimens that enable them to live much more active and normal lives, but with a significant burden of treatment. Prophylaxis requires intravenous infusions of conventional Factor IX products ranging from 2 to 3 times per week.

30. While plasma-derived products have been available since the 1970s, and the first recombinant Factor IX product has been available since the late 1990s, there had not been any advances in technology to extend the half-life of Factor IX and enable less frequent dosing until the approval and launch of Complainants' Alprolix®.

B. Alprolix®

31. Alprolix® is the first FDA-approved recombinant, clotting factor therapy with prolonged circulation in the body. It is indicated for use in adults and children for the control and prevention of bleeding episodes, perioperative (surgical) management, and routine prophylaxis in adults and children with hemophilia B.

32. Alprolix® is a novel biological molecule created by fusing Factor IX to the Fc portion of immunoglobulin G subclass 1, or IgG_1 (a protein commonly found in the body). The fusion of the Factor IX with the Fc protein fragment results in a protein that extends the half-life of Factor IX by using a naturally occurring mechanism called the FcRn recycling pathway to delay the breakdown of the protein. Prophylactic infusions of Alprolix® temporarily replace clotting factor necessary to control bleeding and help protect against new bleeding episodes.

33. The FDA approved Alprolix® in March 2014. Ex. 17.[1] Alprolix® was the first hemophilia therapy to demonstrate prolonged circulation in the body, which was shown in adults and children with hemophilia B to extend the time between prophylactic infusions.

34. Alprolix® is available as a lyophilized powder in single-use vials containing nominally 250, 500, 1000, 2000, 3000, and 4000 IU. It is reconstituted in solution and administered by intravenous infusion. Images of the packaging of Alprolix® are provided at Exhibit 16.[2]

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[1] https://www.fda.gov/BiologicsBloodVaccines/BloodBloodProducts/ApprovedProducts/LicensedProductsBLAs/FractionatedPlasmaProducts/ucm391050.htm.

[2] Due to the nature of the products, Complainants are not submitting physical samples of Alprolix® or Idelvion®.

35. The recommended starting prophylaxis regimens for Alprolix® are either 50 IU/kg once weekly or 100 IU/kg once every 10 days. The treating healthcare provider may adjust the dosing interval to a 14-day regimen based on a person's individual response. In the pivotal clinical study, more than half of study subjects in the fixed-dose arm adjusted to a dosing interval of 14 days or more. In other words, over half of the patients could reduce their treatments to once every two weeks.

36. The groundbreaking Fc-fusion technology employed in Alprolix® was developed by Syntonix Pharmaceuticals, Inc. ("Syntonix"), also based in Waltham, Massachusetts, which Biogen acquired in January 2007. Syntonix was a biopharmaceutical company formed in 1999 to focus on discovering and developing new long-acting therapeutic products to improve treatment regimens for chronic diseases using Fc-fusion technology. Syntonix began its investment in its Factor IX research in 2000. At the time of Syntonix's acquisition by Biogen, Syntonix's lead product was its proprietary Factor IX-Fc for the treatment of hemophilia B, which became Alprolix®. The Phase1/2a trial was initiated in April 2008. In January 2010, Biogen began enrolling patients in the Phase 3 registrational trial of Alprolix®. After more than a decade of research and development and years of clinical trials conducted by Syntonix and Biogen, Biogen obtained FDA approval of Alprolix® for treatment of hemophilia B on March 28, 2014. Ex. 17.

37. When it separated from Biogen, Bioverativ Inc. entered into a manufacturing and supply agreement with Biogen, by which Biogen agreed, among other things, to manufacture and supply, exclusively for Bioverativ, Alprolix® drug substance. Biogen also agreed to supply Alprolix® drug product and finished goods. Attachment A to Ex. 11C. Biogen has been and continues to be the sole manufacturer of Alprolix® drug substance.

38. Biogen currently holds the BLA approved by the FDA for Alprolix®. Biogen is in the process of effecting the transfer of the Alprolix® BLA to Bioverativ. Bioverativ has taken steps to obtain a Department of Health and Human Services United States License Number, certain state authorizations, and other federal and state regulatory authorizations. In the interim, pursuant to agreements between Biogen and Bioverativ, Biogen currently performs distribution services on behalf of Bioverativ in the United States. After completion of the transfer of the Alprolix® BLA to Bioverativ, Biogen will continue to manufacture Alprolix® drug substance in the United States under contract with Bioverativ.

39. Bioverativ has its own direct sales force for Alprolix®. In the United States, a third party warehouses and ships all of the Alprolix® supply through distributors, distribution centers, and specialty pharmacies.

40. Bioverativ receives all revenues from the sales of Alprolix®.

C. Idelvion®

41. In March 2016, two years after the FDA approved Bioverativ's Alprolix®, CSL Behring Recombinant Facility AG obtained FDA approval for Idelvion®, the Accused Products. Exs. 18, 24. Idelvion® is indicated for use in children and adults with hemophilia B for on-demand treatment and control of bleeding episodes, perioperative management of bleeding, and routine prophylaxis to reduce the frequency of bleeding episodes. Ex. 19.

42. Idelvion® is available as a lyophilized powder in single-use vials containing nominally 250, 500, 1000, and 2000 IU. It is reconstituted in solution and administered by intravenous infusion. *Id.*

43. According to its U.S. label, Idelvion® is manufactured by CSL Behring GmbH in Marburg, Germany for CSL Recombinant Facility AG in Bern, Switzerland and distributed by CSL Behring LLC in Kankakee, Illinois. *Id.*

44. The recombinant Factor IX molecule in Idelvion® is fused to albumin, which uses the same Fc recycling pathway as Alprolix® for half-life extension. The administration of the Accused Products to patients in accordance with the Idelvion® label infringes the Asserted Patents.

V. THE ASSERTED PATENTS AND NON-TECHNICAL DESCRIPTIONS OF THE INVENTIONS[3]

45. Certified copies of the Asserted Patents are included at Exhibits 1-3. Certified copies of the assignment records for each of the Asserted Patents are included as Exhibits 5-7.

46. The Asserted Patents are members of a patent family resulting from, among other things, the inventors' conception of new and innovative methods for treating hemophilia B using Fc fusion technology.

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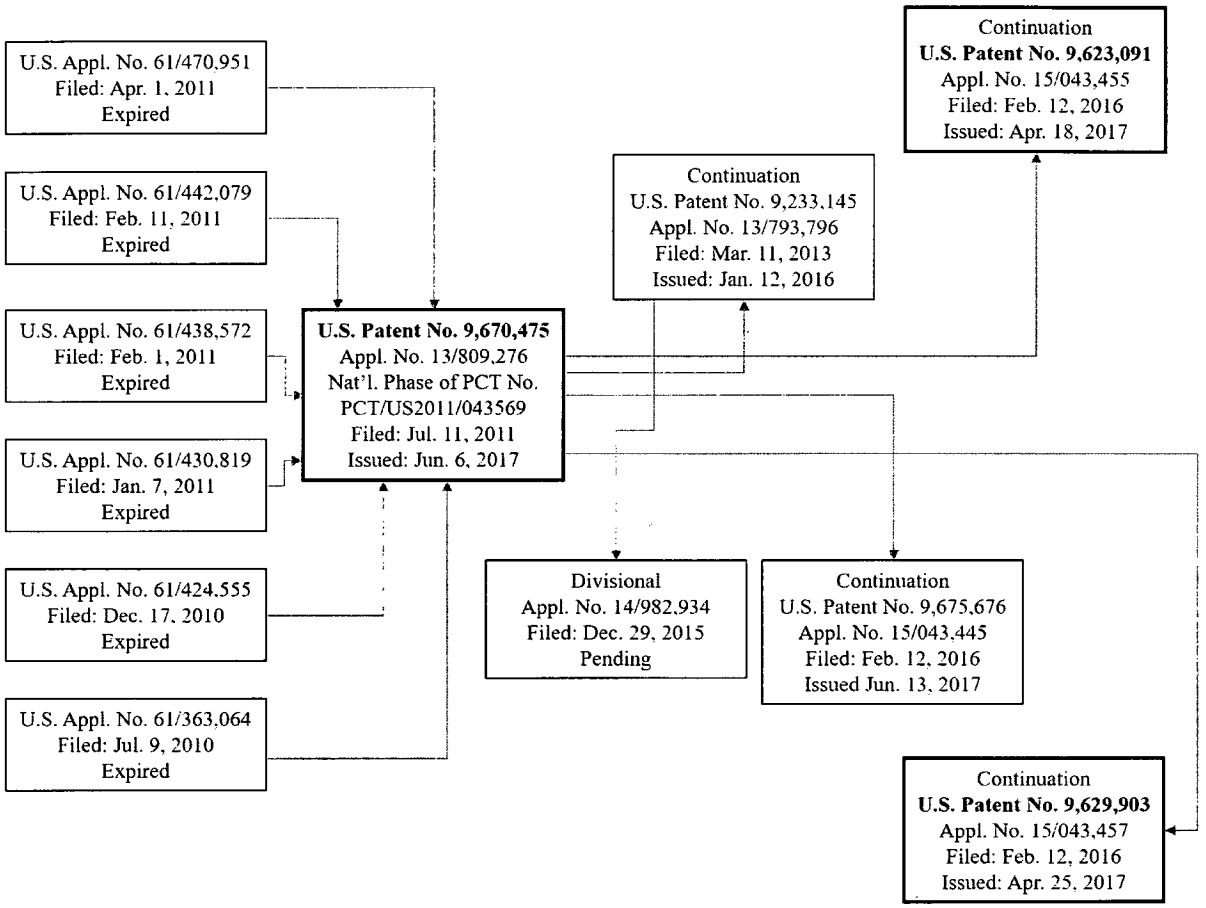
[3] These descriptions and any other non-technical descriptions within this Complaint are for illustrative purposes only. Nothing contained within this Complaint is intended to express, either implicitly or explicitly, any position regarding the proper construction or scope of any claim of the Asserted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

47. The U.S. patent family from which the Asserted Patents issued is depicted below.



48. Pursuant to Commission Rule 210.12(c)(1), one certified copy and three additional copies of the prosecution history of each of the Asserted Patents have been submitted with this Complaint as Appendices A-C. Pursuant to Commission Rule 210.12(c)(2), four copies of the references cited for each of the Asserted Patents also have been submitted with this Complaint as Appendices D-F.

A. Non-technical Description of U.S. Patent No. 9,670,475

49. United States Patent No. 9,670,475 (the "'475 patent"), entitled "Factor IX Polypeptides and Methods of Use Thereof," issued on June 6, 2017 to inventors Glenn Pierce,

Samantha Truex, Robert T. Peters, and Haiyan Jiang. The '475 patent issued from U.S. Patent App. Ser. No. 13/809,276, filed on July 11, 2011. The '475 patent claims priority to April 1, 2011.

50. The inventors assigned their rights in a PCT application leading to the '475 patent to Biogen Idec Hemophilia Inc. in December 2011 and January 2012. Ex. 7. The assignment was recorded at the United States Patent and Trademark Office ("PTO") on March 13, 2012. The inventors executed an assignment of their rights in a U.S. application leading to the '475 patent to Biogen Idec Hemophilia Inc. in April 2013. The assignment was recorded at the PTO on May 10, 2013. Biogen Idec Hemophilia Inc. changed its name to Biogen Hemophilia Inc. in March 2015. The renaming document was recorded at the PTO on April 30, 2015. Biogen Hemophilia Inc. changed its address in 2015. The change in address was recorded at the PTO on July 2, 2015. Biogen Hemophilia Inc. changed its name to Bioverativ Therapeutics Inc. in September 2016. The renaming document was recorded at the PTO on February 16, 2017.

51. The '475 patent contains 34 claims, including 1 independent claim and 33 dependent claims. Complainants assert that Respondents indirectly infringe, either literally or under the doctrine of equivalents, at least claims 1-2, 4-19, 24-25, 29, and 34 of the '475 patent, by importation, sale for importation, and/or sale or use after importation of Idelvion® which, when administered according to its label, practices the claimed methods.

52. The '475 patent is directed to, among other things, methods of controlling a bleeding episode in a human subject by administering multiple doses of about 25 IU/kg to about 50 IU/kg of a chimeric Factor IX polypeptide comprising Factor IX and an FcRn binding partner (*e.g.*, Fc or albumin) at a dosing interval of about 7 days between two doses in order to maintain the plasma Factor IX activity of the subject above 1 IU/dL during the dosing interval.

B. Non-technical Description of U.S. Patent No. 9,623,091

53. United States Patent No. 9,623,091 (the "'091 patent"), entitled "Factor IX Polypeptides and Methods of Use Thereof," issued on April 18, 2017 to inventors Glenn Pierce, Samantha Truex, Robert T. Peters, and Haiyan Jiang. The '091 patent issued from U.S. Patent App. Ser. No. 15/043,455, filed on February 12, 2016. The '091 patent claims priority to April 1, 2011.

54. The inventors assigned their rights in an application leading to the '091 patent to Biogen Idec Hemophilia Inc. in April 2013. Ex. 5. The assignment was recorded at the PTO on February 26, 2016. Biogen Idec Hemophilia Inc. changed its name to Biogen Hemophilia Inc. in March 2015. The renaming document was recorded at the PTO on February 24, 2016. Biogen Hemophilia Inc. changed its name to Bioverativ Therapeutics Inc. in September 2016. The renaming document was recorded at the PTO on February 16, 2017.

55. The '091 patent contains 28 claims, including 1 independent claim and 27 dependent claims. Complainants assert that Respondents indirectly infringe, either literally or under the doctrine of equivalents, at least claims 1-7, 11-16, 18, 19, 21, and 23-27 of the '091 patent, by importation, sale for importation, and/or sale or use after importation of Idelvion® which, when administered according its label, practices the claimed methods.

56. The '091 patent is directed to, among other things, methods of treating hemophilia B in a human subject by intravenously administering multiple doses of about 50 IU/kg to about 100 IU/kg of a chimeric Factor IX polypeptide comprising Factor IX and an FcRn binding partner (*e.g.*, Fc or albumin) at a dosing interval of about 10 days to about 14 days between two doses in order to maintain the plasma Factor IX activity of the subject above 1 IU/dL and reduce the frequency of spontaneous bleeding.

C. Non-technical Description of U.S. Patent No. 9,629,903

57. United States Patent No. 9,629,903 (the "'903 patent"), entitled "Factor IX Polypeptides and Methods of Use Thereof," issued on April 25, 2017 to inventors Glenn Pierce, Samantha Truex, Robert T. Peters, and Haiyan Jiang. The '903 patent issued from U.S. Patent App. Ser. No. 15/043,457, filed on February 12, 2016. The '903 patent claims priority to April 1, 2011.

58. The inventors assigned their rights in an application leading to the '903 patent to Biogen Idec Hemophilia Inc. in April 2013. Ex. 6. The assignment was recorded at the PTO on February 26, 2016. Biogen Idec Hemophilia Inc. changed its name to Biogen Hemophilia Inc. in March 2015. The renaming document was recorded at the PTO on February 24, 2016. Biogen Hemophilia Inc. changed its name to Bioverativ Therapeutics Inc. in September 2016. The renaming document was recorded at the PTO on February 16, 2017.

59. The '903 patent contains 29 claims, including 1 independent claim and 28 dependent claims. Complainants assert that Respondents indirectly infringe, either literally or under the doctrine of equivalents, at least claims 1-10, 13-15, and 17-28 of the '903 patent, by importation, sale for importation, and/or sale or use after importation of Idelvion® which, when administered according it its label, practices the claimed methods.

60. The '903 patent is directed to, among other things, methods of treating hemophilia B in a human subject by intravenously administering multiple doses of about 50 IU/kg to about 100 IU/kg of a chimeric Factor IX polypeptide comprising Factor IX and an FcRn binding partner (*e.g.*, Fc or albumin) at a dosing interval of about 10 days to about 14 days between two doses in order to maintain a trough level of plasma Factor IX activity of at least 3 IU/dL after six days and reduce the frequency of spontaneous bleeding.

D. Foreign Counterparts

61. A list of foreign counterpart patents and applications to the Asserted Patents is included with this Complaint at Exhibit 4. Bioverativ Therapeutics Inc. owns all right, title, and interest in and to each of these foreign counterpart patents and foreign counterpart applications. As of the filing of this Complaint, Complainants are 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

62. Complainants have not executed any agreements relating to the Asserted Patents, other than the assignments recorded at the PTO and listed above.

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

VI. UNLAWFUL AND UNFAIR ACTS BY RESPONDENTS—PATENT INFRINGEMENT

64. Respondents have engaged in unlawful and unfair acts, including the importation into the United States, sale for importation into the United States, and/or sale within the United States after importation of the Accused Products. When administered according to its label, the Accused Products infringe one or more of the following claims, either literally or under the doctrine of equivalents (independent claims bolded):

Patent Number	**Asserted Claims**
'475 patent	**1**-2, 4-19, 24-25, 29, and 34
'091 patent	**1**-7, 11-16, 18, 19, 21, and 23-27
'903 patent	**1**-10, 13-15, and 17-28

A. Infringement of the Asserted Patents

65. On information and belief, Respondents manufacture for import into the United States, import into the United States, and/or sell after importation into the United States the Accused Products, which are recombinant Factor IX products for the treatment of hemophilia B.

66. Respondents have induced and continue to actively induce infringement of the Asserted Patents under 35 U.S.C. § 271(b). At least by the date of service of this Complaint, Respondents know of the Asserted Patents, and that their conduct and communications induce users of Idelvion® to directly infringe the Asserted Patents. For instance, by means of the Idelvion® label provided by Respondents and through other communications, Respondents instruct, direct, and encourage users of Idelvion® and others with respect to the use of Idelvion® with the knowledge that such use according to the label infringes the Asserted Patents, intending that physicians and/or health care providers in the United States perform the directly infringing activities. On information and belief, such conduct by Respondents was intended to cause, and actually resulted in, direct infringement in the United States.

67. Respondents have contributorily infringed, and continue to contributorily infringe, the Asserted Patents under 35 U.S.C. § 271(c), by selling and/or offering for sale in the United States, and/or importing into the United States Idelvion®, which is a material part of the invention of the Asserted Patents, knowing that Idelvion® is especially made or adapted to infringe the Asserted Patents, and is not a staple article or commodity of commerce suitable for substantial non-infringing use. Idelvion®, when administered by physicians and/or health care providers in the United States according to the label provided by Respondents, practices one or

more of the Asserted Patents. On information and belief, such conduct by Respondents was intended to cause, and actually resulted in, direct infringement in the United States.

68. Exemplary claim charts comparing the independent, asserted claims of the Asserted Patents to the Accused Products are attached as Exhibits 8-10. Further discovery may reveal that additional claims of the Asserted Patents are infringed by the Accused Products.

69. Images of the packaging of the Accused Products are provided at Exhibit 15.

VII. SPECIFIC INSTANCES OF UNFAIR IMPORTATION AND SALE

70. According to the Idelvion® web site, Idelvion® is manufactured by CSL Behring GmbH, a German company, and distributed by CSL Behring LLC. Ex. 21.[4]

71. According to Respondents' website, they have manufacturing facilities in Bern, Switzerland; Marburg, Germany; Broadmeadows, Australia; and Kankakee, Illinois. Ex. 22.[5]

72. On information and belief, Idelvion® is manufactured in Marburg, Germany by Respondent CSL Behring GmbH.

73. Respondents describe the "core products" produced at Marburg, Germany as including "plasma-derived and recombinant coagulation factors." Ex. 23 at 11.[6]

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[4] http://www.idelvion.com/.

[5] http://www.cslbehring.com/about/worldwide-locations.htm#Manufacturing.

[6] http://www.cslbehring.com/docs/993/720/CSL-Corporate-Brochure.pdf.

74. The U.S. Food and Drug Administration BLA (Biologics License Application) Approval Letter for Idelvion® authorizes its manufacture in Marburg, Germany. The letter states that:

> The bulk drug substance, final formulated product and diluent sterile Water for Injection will be manufactured, filled, labeled and packaged at CSL Behring GmbH, Emil-von-Behring-Strasse 76 D-35041 Marburg, Germany.

Ex. 18.[7]

75. In addition, the FDA Summary Basis for Regulatory Action states:

> The manufacture of IDELVION is divided into [] main stages (see Figure 2) conducted at two FDA-licensed manufacturing facilities. Production of unprocessed bulk and Bulk Drug Intermediate (BDI) takes place at contract manufacturer [], and production of Bulk Drug Substance (BDS) and Final Drug Product (FDP) are conducted by CSLB's subsidiary CSL Behring GmbH in Marburg, Germany.

Ex. 20.[8]

76. Likewise, the Prescribing Information for Idelvion® states that Idelvion® is manufactured by CSL Behring GmbH, 35041 Marburg, Germany, for CSL Behring Recombinant Facility AG, Bern 22, Switzerland 3000, and distributed by CSL Behring LLC Kankakee, IL 60901 USA. Ex. 19.

77. At least since March 21, 2016, Idelvion® has been sold after importation into the United States by or for Respondents. *See* Ex. 24 ("Idelvion® for Hemophilia B Now Available in the U.S."); Ex. 21 (Respondents' Idelvion® website offering a "free trial of Idelvion" and "intended for US residents only").

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[7] https://www.fda.gov/downloads/BiologicsBloodVaccines/BloodBloodProducts/ApprovedProducts/LicensedProductsBLAs/FractionatedPlasmaProducts/UCM489313.pdf.

[8] https://www.fda.gov/downloads/BiologicsBloodVaccines/BloodBloodProducts/ApprovedProducts/LicensedProductsBLAs/FractionatedPlasmaProducts/UCM491636.pdf.

VIII. HARMONIZED TARIFF SCHEDULE ITEM NUMBERS

78. 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: 3002.15.0000 and 3002.10.0290. 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

79. A complaint alleging infringement of the Asserted Patents by Respondents is pending in the United States District Court for the District of Delaware, captioned *Bioverativ Inc. et al. v. CSL Behring LLC et al.*, civil action number 17-914, filed on July 7, 2017. There is not currently nor has there been any 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

80. A domestic industry exists in the United States based on Complainants' significant investments in plant, equipment, labor, and capital dedicated to the domestic development, manufacture, packaging, sale, and support of Alprolix®.

81. Complainants make extensive use of the inventions claimed in the Asserted Patents in their Alprolix® recombinant Factor IX therapy. Further, Complainants and their contract manufacturer have made and continue to make significant domestic investments in these products, as set forth more fully in the accompanying Declaration of Nicole C. Murphy attached at Exhibit 11C. For example, Biogen, Complainant's contract manufacturer, performs all of the manufacturing steps for producing the Alprolix® bulk drug substance, which practices the

Asserted Patents when used in accordance with the Alprolix® label, in the United States. These domestic investments and activities relating to Alprolix® are continuing and ongoing.

A. Complainants' Alprolix® Products

82. As discussed above, Complainants' Alprolix® products are the first recombinant, clotting Factor IX therapies with an extended half-life resulting in prolonged circulation in the body and is indicated for the control and prevention of bleeding episodes, perioperative (surgical) management, and routine prophylaxis in adults and children with hemophilia B.

83. As discussed above, Complainants are related biotechnology companies focused on the discovery, research, development, manufacture, and commercialization of innovative therapies for the treatment of hemophilia and other blood disorders, including Alprolix®. Complainants employ about 275 people in the United States, which is about 78% of their total workforce.

84. As discussed above, the Fc-fusion technology employed in Alprolix® was invented at Syntonix, based in Waltham, Massachusetts, which Biogen acquired in January 2007. Syntonix, and then Biogen, developed Alprolix® in the United States over many years, committing substantial resources to making this treatment available to the public. Biogen received FDA approval to market Alprolix® in the United States on March 28, 2014 and began to sell it in the United States in May 2014. Bioverativ Inc. was formed on August 4, 2016 to hold the hemophilia business of Biogen and then spun off as an independent company on February 1, 2017. Bioverativ Therapeutics Inc. is a wholly owned subsidiary of Bioverativ Inc.

85. Alprolix® is made via a complex recombinant cell culture manufacturing process. This begins with the manufacture of the drug substance. The drug substance is then used to

create the drug product. The drug product is labeled and then kitted to become the finished product.

86. Biogen has been manufacturing, and will continue to manufacture, Alprolix® drug substance at its Research Triangle Park, North Carolina ("RTP") facility, which it owns, since 2010.

87. The manufacturing process for bulk drug substance includes protein production, purification, and viral clearance. Manufacture and supply of drug product, which includes fill finish, labeling, and packaging, are provided primarily through third-party contract manufacturing and third-party logistics organizations.

B. Complainants' Alprolix® Products are Protected by the Asserted Patents

88. As discussed above, Bioverativ Therapeutics Inc. owns the rights to the Asserted Patents.

89. Use of the Alprolix® products in accordance with their label practices at least claims 1-23, 26, 29-33 of the '475 patent; claims 1, 2, 5-11, 16, 17, 20, 24, and 28 of the '091 patent; and claims 1, 4, 6, 7, 11, 12, 21, 22, 24, and 25 of the '903 patent. Exemplary claim charts comparing the Alprolix® products to claim 1 of the '475 patent, claim 1 of the '091 patent, and claim 1 of the '903 patent are set forth in Exhibits 12-14. As shown therein, Complainants continue to practice each of the Asserted Patents.

C. A Domestic Industry Exists with Respect to Complainants' Alprolix® Products

90. Complainants and their contract manufacturer have invested significant resources in developing, manufacturing, and selling Alprolix® drug substance. Ex. 11C.

91. Biogen's manufacturing activities in producing Alprolix® drug substance at its RTP facility represents a significant investment in plant and equipment and a significant investment of labor and capital in the United States.

92. Complainants, their contract manufacturer, and third-party logistics providers employ U.S.-based personnel and resources in the manufacture, packaging, sale, and post-sale support for Complainants' Alprolix® products. Complainants' U.S.-based personnel are also involved in post-approval clinical studies and efforts to educate and support the medical community, patients using Alprolix®, and the broader hemophilia community. These activities represent a significant investment in plant, equipment, labor, and capital in the United States.

XI. RELIEF REQUESTED

93. WHEREFORE, by reason of the foregoing, Complainants respectfully request 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. § 1337(a)(1)(B)(i) based on the importation, sale for importation, and sale after importation, into the United States, of Respondents' recombinant Factor IX products made by or on behalf of Respondents that infringe one or more asserted claims of the '475, '091, and '903 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;

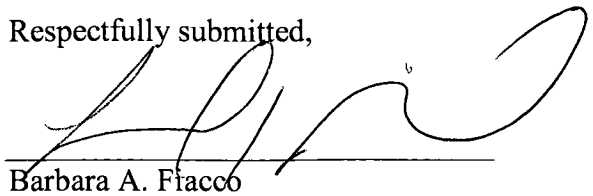
c. Issue a limited exclusion order, pursuant to 19 U.S.C. § 1337(d)(1), barring from entry into the United States all recombinant Factor IX products made by or on behalf of Respondents that infringe one or more asserted claims of the '475, '091, and '903 patents;

d. Issue cease-and-desist orders, pursuant to 19 U.S.C. § 1337(f), prohibiting each of the Respondents, their subsidiaries, related companies, distributors, and/or agents from marketing, distributing, selling, offering for sale, supporting, warehousing inventory for distribution, or otherwise transferring or bringing into the United States any recombinant Factor IX products that infringe one or more asserted claims of the '475, '091, and '903 patents;

e. Impose a bond, pursuant to 19 U.S.C. § 1337(j), upon importation of any recombinant Factor IX products that infringe one or more asserted claims of the '475, '091, and '903 patents during the 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 authority of the Commission.

Respectfully submitted,



Dated: July 7, 2017

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Counsel for Complainants Bioverativ Inc., Bioverativ Therapeutics Inc., and Bioverativ U.S. LLC

VERIFICATION OF COMPLAINT

I, Nicole C. Murphy, declare, in accordance with 19 C.F.R. § 210.12(a), under penalty of perjury, the following are true:

1. I am currently Vice President, Technical Operations at Bioverativ Inc. I am duly authorized by Complainants to verify the foregoing Complaint.

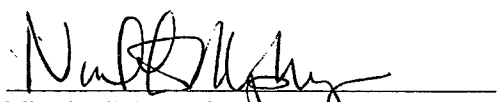
2. I have read the Complaint and am aware of its contents.

3. The Complaint is not being filed for any improper purpose, such as to harass or to cause unnecessary delay or needless increase of 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, non-frivolous 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 on July 6, 2017



Nicole C. Murphy
Bioverativ Inc.