IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BIOVERATIV INC., BIOVERATIV THERAPEUTICS INC., and BIOVERATIV U.S. LLC,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
CSL BEHRING LLC, CSL BEHRING GMBH, and CSL BEHRING RECOMBINANT FACILITY AG,	)	JURY TRIAL DEMANDED
Defendants.	)	

COMPLAINT

Plaintiffs Bioverativ Inc., Bioverativ Therapeutics Inc., and Bioverativ U.S. LLC (collectively, "Bioverativ" or "Plaintiffs") file this Complaint against Defendants CSL Behring LLC, CSL Behring GmbH, and CSL Behring Recombinant Facility AG (collectively, "CSL Behring" or "Defendants"). In support of their claims, Plaintiffs allege as follows:

Nature of the Action

1. This is a civil action for infringement of United States Patent No. 9,670,475 (the "'475 patent"); United States Patent No. 9,623,091 (the "'091 patent"); and United States Patent No. 9,629,903 (the "'903 patent") (collectively, the "Asserted Patents"), under the Patent Act, 35 U.S.C. § 1 et seq.

Parties

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

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

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

5. Plaintiffs 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.

6. On information and belief, CSL Behring LLC is a Delaware corporation having its principal place of business at 1020 First Avenue, P.O. Box 61501, King of Prussia, Pennsylvania. CSL Behring LLC may be served via its registered agent, The Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, Delaware.

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

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

9. On information and belief, Defendants are all wholly owned subsidiaries of CSL Limited, an Australian company.

Jurisdiction and Venue

10. This Court has subject matter jurisdiction over this action under 28 U.S.C. §§ 1331 and 1338(a).

11. This Court has personal jurisdiction over CSL Behring LLC because it is incorporated in Delaware, knowingly transacts business in Delaware and, on information and belief, has engaged in, and made meaningful preparations to engage in, infringing conduct in Delaware.

12. On information and belief, this Court may exercise personal jurisdiction over CSL Behring GmbH and CSL Behring Recombinant Facility AG because of their contacts with this forum, including their regularly and intentionally doing business here and/or committing acts giving rise to this lawsuit here. Alternatively, on information and belief, this Court may exercise personal jurisdiction over CSL Behring GmbH and CSL Behring Recombinant Facility AG under Federal Rule of Civil Procedure 4(k)(2).

13. Venue is proper in this district pursuant to 28 U.S.C. § 1400(b) with respect to CSL Behring LLC because it resides in this district.

14. Venue is proper in this district pursuant to at least 28 U.S.C. § 1391(b) and (c) with respect to CSL Behring GmbH and CSL Behring Recombinant Facility AG.

Hemophilia B

15. 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.

16. 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.

17. 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.

18. 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.

19. 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.

20. 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 Bioverativ's Alprolix®.

Alprolix®

21. 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.

22. 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.

23. Biogen obtained FDA approval of Alprolix® for treatment of hemophilia B on March 28, 2014. 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.

24. When it separated from Biogen, Bioverativ 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. Biogen has been and continues to be the sole manufacturer of Alprolix® drug substance.

25. Biogen currently holds the BLA (Biologics License Application) approved by the FDA for Alprolix®. Biogen is in the process of effecting the transfer of the Alprolix® BLA to Bioverativ. In the interim, pursuant to agreements between Biogen and Bioverativ, Biogen currently performs distribution services on behalf of Bioverativ in the United States.

26. Bioverativ has its own direct sales force for Alprolix®.

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

Idelvion®

28. In March 2016, two years after the FDA approved Bioverativ's Alprolix®, CSL Behring Recombinant Facility AG obtained FDA approval for Idelvion® [Coagulation Factor IX (Recombinant), Albumin Fusion Protein]. 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. A true and correct copy of the Idelvion® label is attached as Exhibit A.

29. 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 Idelvion® to patients in accordance with the Idelvion® label infringes the Asserted Patents.

30. On information and belief, CSL Behring GmbH manufactures Idelvion® in Germany for CSL Behring Recombinant Facility AG, the Idelvion® BLA holder, before importation into the United States. On information and belief, Defendants sell for importation and/or import Idelvion® into the United States, where CSL Behring LLC sells Idelvion® after importation.

Patents-in-Suit

31. 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. Bioverativ Therapeutics Inc. owns by assignment the entire right, title, and interest in and to the ’475 patent. A true and correct copy of the ’475 patent is attached as Exhibit B.

32. 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. Bioverativ Therapeutics Inc. owns by assignment the entire right, title, and interest in and to the ’091 patent. A true and correct copy of the ’091 patent is attached as Exhibit C.

33. 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. Bioverativ Therapeutics Inc. owns by assignment the entire right, title, and interest in and to the ’903 patent. A true and correct copy of the ’903 patent is attached as Exhibit D.

Count I: Infringement of U.S. Patent No. 9,670,475

34. Plaintiffs repeat and reallege the allegations set forth in paragraphs 1 through 33 above as though fully set forth herein.

35. On information and belief, Defendants have induced and continue to actively induce infringement of at least claims 1-2, 4-19, 24-25, 29, and 34 of the ’475 patent under 35 U.S.C. § 271(b). At least by the date of service of this Complaint, Defendants know of the ’475 patent, and that their conduct and communications induce users of Idelvion® to directly

infringe the ’475 patent. For instance, by means of the Idelvion® label provided by Defendants and through other communications, Defendants 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 ’475 patent, intending that physicians and/or health care providers in the United States perform the directly infringing activities. On information and belief, such conduct by Defendants was intended to cause, and actually resulted in, direct infringement in the United States.

36. On information and belief, Defendants have contributorily infringed, and continue to contributorily infringe, at least claims 1-2, 4-19, 24-25, 29, and 34 of the ’475 patent 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 ’475 patent, knowing that Idelvion® is especially made or adapted to infringe the ’475 patent, 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 according to the label provided by Defendants, practices one or more of the asserted claims of the ’457 patent. On information and belief, such conduct by Defendants was intended to cause, and actually resulted in, direct infringement by physicians and/or health care providers in the United States.

37. The ’475 patent has one independent claim, claim 1, which recites:

> A method of controlling a bleeding episode in a human subject in need thereof, comprising administering to the subject multiple doses of about 25 IU/kg to about 50 IU/kg of a chimeric Factor IX (“FIX”) polypeptide comprising FIX and an FcRn binder partner (“FcRn BP”) at a dosing interval of about 7 days between two doses, wherein the FcRn BP comprises Fc or albumin and wherein the subject exhibits the plasma FIX activity above 1 IU/dL during the dosing interval.

38. Idelvion® is a chimeric Factor IX polypeptide comprising Factor IX and the FcRn binding partner albumin. Ex. A at Section 11, Description.

39. Idelvion® is indicated for controlling bleeding episodes in humans. *Id*. at Section 1, Indications and Usage.

40. The Idelvion® label recommends that patients at or over the age of twelve receive 25-40 IU/kg of Idelvion® every seven days and that prescribing physicians adjust the dosing regimen based on individual response. *Id.* at Section 2.1, Dosage.

41. The Idelvion® label recommends that patients under the age of twelve receive 40-55 IU/kg of Idelvion® every seven days and that prescribing physicians adjust the dosing regimen based on individual response. *Id.*

42. On information and belief, patients receiving doses of about 25 IU/kg to about 50 IU/kg of Idelvion® at a dosing interval of about seven days between two doses exhibit plasma Factor IX activity above 1 IU/dL during the dosing interval.

43. Plaintiffs have suffered damages as a result of Defendants' infringement of the '475 patent and will continue to suffer damages as long as those infringing activities continue.

44. Plaintiffs have been and will continue to be irreparably harmed by Defendants' infringement of the '475 patent unless and until such infringement is enjoined by this Court.

45. On information and belief, Defendants' infringement has been and continues to be willful. Since having knowledge of the '475 patent, Defendants knew or should know that their actions infringe the '475 patent.

Count II: Infringement of U.S. Patent No. 9,623,091

46. Plaintiffs repeat and reallege the allegations set forth in paragraphs 1 through 45 above as though fully set forth herein.

47. On information and belief, Defendants have induced and continue to actively induce infringement of at least claims 1-7, 11-16, 18, 19, 21, and 23-27 of the '091 patent under

35 U.S.C. § 271(b). At least by the date of service of this Complaint, Defendants know of the '091 patent, and that their conduct and communications induce users of Idelvion® to directly infringe '091 patent. For instance, by means of the Idelvion® label provided by Defendants and through other communications, Defendants 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 '091 patent, intending that physicians and/or health care providers in the United States perform the directly infringing activities. On information and belief, such conduct by Defendants was intended to cause, and actually resulted in, direct infringement in the United States.

48. On information and belief, Defendants have contributorily infringed, and continue to contributorily infringe, at least claims 1-7, 11-16, 18, 19, 21, and 23-27 of the '091 patent 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 '091 patent, knowing that Idelvion® is especially made or adapted to infringe the '091 patent, 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 according to the label provided by Defendants, practices one or more of the asserted claims of the '091 patent. On information and belief, such conduct by Defendants was intended to cause, and actually resulted in, direct infringement by physicians and/or health care providers in the United States.

49. The '091 patent has one independent claim, claim 1, which recites:

> A method of treating hemophilia B in a human subject in need thereof comprising intravenously administering to the subject multiple doses of about 50 IU/kg to about 100 IU/kg of a chimeric factor IX ("FIX") polypeptide comprising FIX and an FcRn binding partner ("FcRn BP") at a dosing interval of about 10 days to about 14 days between two doses, wherein the FcRn BP comprises Fc or albumin, wherein the administration maintains the plasma FIX activity of the subject above

1 IU/dL between the dosing interval, and wherein the administration treats the human subject by reducing the frequency of spontaneous bleeding.

50. Idelvion® is a chimeric Factor IX polypeptide comprising Factor IX and the FcRn binding partner albumin. Ex. A at Section 11, Description.

51. Idelvion® is indicated for treating humans with hemophilia B by reducing the frequency of spontaneous bleeding. *Id*. at Section 1, Indications and Usage.

52. Idelvion® is administered intravenously. *Id*. at Section 2.3, Administration.

53. The Idelvion® label recommends that patients at or over the age of twelve may receive 50-75 IU/kg of Idelvion® at a dosing internal of 14 days and that prescribing physicians adjust the dosing regimen based on individual response. *Id.* at Section 2.1, Dosage.

54. On information and belief, administering multiple doses of about 50 IU/kg to about 100 IU/kg of Idelvion® at a dosing interval of about 10 days to about 14 days between two doses maintains the plasma Factor IX activity of the patient above 1 IU/dL between the dosing interval and reduces the frequency of spontaneous bleeding.

55. Plaintiffs have suffered damages as a result of Defendants' infringement of the '091 patent and will continue to suffer damages as long as those infringing activities continue.

56. Plaintiffs have been and will continue to be irreparably harmed by Defendants' infringement of the '091 patent unless and until such infringement is enjoined by this Court.

57. On information and belief, Defendants' infringement has been and continues to be willful. Since having knowledge of the '091 patent, Defendants knew or should know that their actions infringe the '091 patent.

Count III: Infringement of U.S. Patent No. 9,629,903

58. Plaintiffs repeat and reallege the allegations set forth in paragraphs 1 through 57 above as though fully set forth herein.

59. On information and belief, Defendants have induced and continue to actively induce infringement of at least claims 1-10, 13-15, and 17-28 of the '903 patent under 35 U.S.C. § 271(b). At least by the date of service of this Complaint, Defendants know of the '903 patent, and that their conduct and communications induce users of Idelvion® to directly infringe the '903 patent. For instance, by means of the Idelvion® label provided by Defendants and through other communications, Defendants 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 '903 patent, intending that physicians and/or health care providers in the United States perform the directly infringing activities. On information and belief, such conduct by Defendants was intended to cause, and actually resulted in, direct infringement in the United States.

60. On information and belief, Defendants have contributorily infringed, and continue to contributorily infringe, at least claims 1-10, 13-15, and 17-28 of the '903 patent 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 '903 patent, knowing that Idelvion® is especially made or adapted to infringe the '903 patent, 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 according to the label provided by Defendants, practices one or more of the asserted claims of the '903 patent. On information and belief, such conduct by Defendants was intended to cause, and actually resulted in, direct infringement by physicians and/or health care providers in the United States.

61. The '903 patent has one independent claim, claim 1, which recites:

> A method of treating hemophilia B in a human subject in need thereof, comprising intravenously administering to the subject multiple doses of about

> 50 IU/kg to about 100 IU/kg of a chimeric Factor IX ("FIX") polypeptide comprising FIX and an FcRn binding partner ("FcRn BP") at a dosing interval of about 10 days to about 14 days between two doses, wherein the FcRn BP comprises Fc or albumin, wherein the trough level of the plasma FIX activity after each administration is at least 3 IU/dL after six days, and wherein the administration treats the human subject by reducing the frequency of spontaneous bleeding.

62. Idelvion® is a chimeric Factor IX polypeptide comprising Factor IX and the FcRn binding partner albumin. Ex. A at Section 11, Description.

63. Idelvion® is indicated for treating humans with hemophilia B by reducing the frequency of spontaneous bleeding. *Id*. at Section 1, Indications and Usage.

64. Idelvion® is administered intravenously. *Id*. at Section 2.3, Administration.

65. The Idelvion® label recommends that patients over the age of twelve may receive 50-75 IU/kg of Idelvion® at a dosing internal of 14 days and that prescribing physicians adjust the dosing regimen based on individual response. *Id.* at Section 2.1, Dosage.

66. On information and belief, when multiple doses of about 50 IU/kg to about 100 IU/kg of Idelvion® are administered to patients at a dosing interval of about 10 days to about 14 days between two doses, the trough level of plasma Factor IX activity after each administration is at least 3 IU/dL after six days, and the frequency of spontaneous bleeding is reduced.

67. Plaintiffs have suffered damages as a result of Defendants' infringement of the '903 patent and will continue to suffer damages as long as those infringing activities continue.

68. Plaintiffs have been and will continue to be irreparably harmed by Defendants' infringement of the '903 patent unless and until such infringement is enjoined by this Court.

69. On information and belief, Defendants' infringement has been and continues to be willful. Since having knowledge of the '903 patent, Defendants knew or should know that their actions infringe the '903 patent.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that the Court:

A. Enter judgment that Defendants have infringed the '475, '091, and '903 patents;

B. Enter judgment that Defendants' infringement of the '475, '091, and '903 patents is willful;

C. Enter an injunction enjoining Defendants, their officers, directors, servants, managers, employees, agents, attorneys, successors and assignees, and all persons in active concert or participation with any of them, from further acts of infringement of the '475, '091, '903 patents, under 35 U.S.C. § 283;

D. Award damages adequate to compensate Plaintiffs for Defendants' infringement, including increased damages up to three times the amount found or assessed, together with pre-judgment and post-judgment interest and costs, under 35 U.S.C. § 284;

E. Enter judgment that this case is exceptional and award Plaintiffs their reasonable attorneys' fees, costs, and expenses, under 35 U.S.C. § 285; and

F. Award such other and further relief as this Court may deem just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

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