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 LEGNAU 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 Legnau 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. 10,548,954 (the "'954 Patent"); United States Patent No. 10,561,714 (the "'714 Patent"); and United States Patent No. 10,568,943 (the "'943 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 Lengnau 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 Lengnau 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 CSL Behring Lengnau 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 Lengnau 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. Bioverativ holds the BLA (Biologics License Application) approved by the FDA for Alprolix®.

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] and began sales and active promotion of the product in the United States for the prophylactic treatment of Hemophilia B. 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 dated March 2016 is attached as Exhibit A. A true and correct copy of the Idelvion® label issued dated October 2019 is attached as Exhibit B.

29. On information and belief, there are no substantive differences between the March 2016 and October 2019 versions of the Idelvion® label with respect to the Asserted Patents.

30. On information and belief, any revisions between the March 2016 and October 2019 versions of the Idelvion® label have not altered the Dosage and Administration information and doctors have prescribed, and continue to prescribe, and patients have used, and continue to use, Idelvion® prophylactically in a manner consistent with the label since at least April 18, 2017.

31. 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.

32. 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

33. The ’954 Patent, entitled “Factor IX Polypeptides and Methods of Use Thereof,” issued on February 4, 2020 to inventors Glenn Pierce, Samantha Truex, Robert T. Peters, and Hayian Jiang. Bioverativ Therapeutics Inc. owns by assignment the entire right, title, and interest in and to the ’954 Patent. A true and correct copy of the ’954 Patent is attached as Exhibit C.

34. The ’954 Patent issued from U.S. Application No. 16/271,689 (the “’689 Application”). On June 27, 2019, the ’689 Application published as U.S. Publication No. 2019/0192641 (the “’641 Published Application”).

35. On information and belief, Defendants were actively monitoring Bioverativ’s patent applications and had actual notice of the ’641 Published Application at the time of publication.

36. The invention as claimed in the ’954 Patent is substantially identical to the invention as claimed in the ’641 Published Application.

37. The ’714 Patent, entitled “Factor IX Polypeptides and Methods of Use Thereof,” issued on February 18, 2020 to inventors Glenn Pierce, Samantha Truex, Robert T. Peters, and Hayian Jiang. Bioverativ Therapeutics Inc. owns by assignment the entire right, title, and interest in and to the ’714 Patent. A true and correct copy of the ’714 Patent is attached as Exhibit D.

38. The ’714 Patent issued from U.S. Application No. 15/890,284 (the “’284 application”). On August 16, 2018, the ’284 application published as U.S. Publication No. 2018/0228878 (the “’878 Published Application”).

39. On information and belief, Defendants were actively monitoring Bioverativ’s patent applications and had actual notice of the ’878 Published Application at the time of publication.

40. The ’943 Patent, entitled “Factor IX Polypeptides and Methods of Use Thereof,” issued on February 25, 2020 to inventors Glenn Pierce, Samantha Truex, Robert T. Peters, and Hayian Jiang. Bioverativ Therapeutics Inc. owns by assignment the entire right, title, and interest in and to the ’943 Patent. A true and correct copy of the ’943 Patent is attached as Exhibit E.

41. The ’943 Patent issued from U.S. Patent Application No. 16/271,686 (the “’686 Application”). On June 27, 2019, the ’686 Application published as U.S. Publication No. 2019/0192640 (the “’640 Published Application”).

42. On information and belief, Defendants were actively monitoring Bioverativ’s patent applications and had actual notice of the ’640 Published Application at the time of publication.

43. The invention as claimed in the ’943 Patent is substantially identical to the invention as claimed in the ’640 Published Application.

Count I: Infringement of U.S. Patent No. 10,548,954

44. Plaintiffs repeat and reallege the allegations set forth in paragraphs 1 through 43 above as though fully set forth herein.

45. On information and belief, Defendants have induced and continue to actively induce infringement of at least claims 1 and 9 of the '954 patent under 35 U.S.C. § 271(b). Defendants know of the '954 patent, and that their conduct and communications induce users of Idelvion® to directly infringe the '954 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 '954 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.

46. The '954 patent has two independent claims, claim 1 and 9. Claim 1 recites:

> A method of treating hemophilia B comprising intravenously administering to a human subject in need thereof multiple doses of about 50 IU/kg to about 100 IU/kg of a chimeric factor IX ("FIX") polypeptide comprising human FIX having an amino acid sequence identical to amino acids 1 to 415 of SEQ ID NO:2 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 is human albumin, wherein the administration treats the human subject by reducing the frequency of spontaneous bleeding.

47. Claim 9 of the '954 patent recites:

> A method of treating hemophilia B comprising intravenously administering to a human subject in need thereof multiple doses of about 50 IU/kg to about 100 IU/kg of a chimeric factor IX ("FIX") polypeptide comprising human FIX having an amino acid sequence identical to amino acids 1 to 415 of SEQ ID NO:2 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 is human albumin, wherein the administration treats the human subject by reducing the severity of a bleeding episode.

48. Idelvion® is a chimeric factor IX polypeptide comprising an amino acid sequence identical to amino acids 1 to 415 of SEQ ID NO:2 and an FcRn binding partner ("FcRn BP"), where the FcRn BP comprises human albumin. Ex. B at Section 11, Description.

49. Idelvion® is indicated for treating humans with hemophilia B. *Id*. at Section 1, Indications and Usage.

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

51. 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.

52. 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 reduces the frequency of spontaneous bleeding.

53. 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 reduces the severity of a bleeding episode.

54. Plaintiffs have suffered damages as a result of Defendants' infringement of the '954 patent and will continue to suffer damages as long as those infringing activities continue.

55. On information and belief, Defendants' infringement has been and continues to be willful. Since having knowledge of the '954 patent, Defendants knew or should know that their actions infringe the '954 patent.

Count II: Infringement of U.S. Patent No. 10,561,714

56. Plaintiffs repeat and reallege the allegations set forth in paragraphs 1 through 55 above as though fully set forth herein.

57. On information and belief, Defendants have induced and continue to actively induce infringement of at least claim 1 of the '714 patent under 35 U.S.C. § 271(b). Defendants know of the '714 patent, and that their conduct and communications induce users of Idelvion®

to directly infringe the '714 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 '714 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.

58. The '714 patent has one independent claim, claim 1, which recites:

> A method of treating hemophilia B, comprising intravenously administering to a human subject in need thereof multiple doses of about 50 IU/kg to about 100 IU/kg of a chimeric Factor IX (FIX) polypeptide comprising human FIX having an amino acid sequence identical to amino acids 1 to 415 of SEQ ID N0:2 and a FcRn binding partner (FcRn BP) at a dosing interval of 7 days between two doses, wherein the FcRn BP is human albumin, and wherein the administration treats the human subject by reducing the frequency of spontaneous bleeding.

59. Idelvion® is a chimeric Factor IX polypeptide comprising an amino acid sequence identical to amino acids 1 to 415 of SEQ ID NO:2 and an FcRn binding partner ("FcRn BP"), where the FcRn BP comprises human albumin. Ex. B at Section 11, Description.

60. Idelvion® is indicated for treating hemophilia B. *Id*. at Section 1, Indications and Usage.

61. 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.

62. 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.*

63. 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 seven days between two doses reduces the frequency of spontaneous bleeding.

64. On information and belief, at least a portion of the time when prescribing physicians adjust the dosing regimen based on individual response, the prescribing physicians adjust the dosing regimen to about 50 IU/kg to about 100 IU/kg of Idelvion® at a dosing interval of about seven days between two doses.

65. Plaintiffs have suffered damages as a result of Defendants' infringement of the '714 patent and will continue to suffer damages as long as those infringing activities continue.

66. On information and belief, Defendants' infringement has been and continues to be willful. Since having knowledge of the '714 patent, Defendants knew or should know that their actions infringe the '714 patent.

Count III: Infringement of U.S. Patent No. 10,568,943

67. Plaintiffs repeat and reallege the allegations set forth in paragraphs 1 through 66 above as though fully set forth herein.

68. On information and belief, Defendants have induced and continue to actively induce infringement of at least claims 1 and 10 of the '943 Patent under 35 U.S.C. § 271(b). Defendants know of the '943 Patent, and that their conduct and communications induce users of Idelvion® to directly infringe the '943 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 '943 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.

69. The '943 Patent has two independent claims, claims 1 and 10. Claim 1 recites:

> A method of reducing the frequency of spontaneous bleeding, comprising intravenously administering to a human hemophilia B subject in need thereof multiple doses of about 25 IU/kg to about 50 IU/kg of a chimeric Factor IX ("FIX") polypeptide comprising human FIX having an amino acid sequence identical to amino acids 1 to 415 of SEQ ID N0:2 and an FcRn binding partner ("FcRn BP") at a dosing interval of about 7 days between two doses, wherein the FcRn BP is human albumin.

70. Claim 10 recites:

> A method of reducing the severity of a bleeding episode, comprising intravenously administering to a human hemophilia B subject in need thereof multiple doses of about 25 IU/kg to about 50 IU/kg of a chimeric Factor IX ("FIX") polypeptide comprising human FIX having an amino acid sequence identical to amino acids 1 to 415 of SEQ ID N0:2 and an FcRn binding partner ("FcRn BP") at a dosing interval of about 7 days between two doses, wherein the FcRn BP is human albumin.

71. Idelvion® is a chimeric Factor IX polypeptide comprising an amino acid sequence identical to amino acids 1 to 415 of SEQ ID NO:2 and an FcRn binding partner ("FcRn BP"), where the FcRn BP comprises human albumin. Ex. B at Section 11, Description.

72. Idelvion® is indicated for reducing the frequency of spontaneous bleeding. *Id*. at Section 1, Indications and Usage.

73. 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.

74. 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.*

75. On information and belief, administering multiple doses of about 25 IU/kg to about 50 IU/kg of Idelvion® at a dosing interval of about seven days between two doses reduces the frequency of spontaneous bleeding.

76. On information and belief, administering multiple doses of about 25 IU/kg to about 50 IU/kg of Idelvion® at a dosing interval of about seven days between two doses reduces the severity of a bleeding episode.

77. Plaintiffs have suffered damages as a result of Defendants' infringement of the '943 Patent and will continue to suffer damages as long as those infringing activities continue.

78. On information and belief, Defendants' infringement has been and continues to be willful. Since having knowledge of the '943 Patent, Defendants knew or should know that their actions infringe the '943 Patent.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that the Court:

A. Enter judgment that Defendants have infringed the'954, '714, and '943 Patents;

B. Enter judgment that Defendants' infringement of the'954, '714, and '943 Patents is willful;

C. 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 and 154(d);

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

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

DEMAND FOR JURY TRIAL

Plaintiffs hereby demand a trial by jury as to all issues so triable.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Jeremy A. Tigan

Thomas C. Grimm (#1098)
Jeremy A. Tigan (#5239)
1201 N. Market Street
P.O. Box 1347
Wilmington, DE 19899-1347
(302) 658-9200
tgrimm@mnat.com
jtigan@mnat.com

Attorneys for Plaintiffs Bioverativ Inc., Bioverativ Therapeutics Inc., and Bioverativ U.S. LLC

OF COUNSEL:

Paul H. Berghoff
Alison J. Baldwin
James C. Gumina
Sarah E. Fendrick, Ph.D.
James L. Lovsin
Nicole E. Grimm
Nathaniel P. Chongsiriwatana, Ph.D.
Daniel F. Gelwicks
McDONNELL BOEHNEN HULBERT & BERGHOFF LLP
300 South Wacker Drive
Chicago, IL 60606
(312) 913-0001

March 4, 2020