IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT NEW YORK

CSL LIMITED and ZENYTH THERAPEUTICS LIMITED,

Plaintiffs,

vs.

CREATIVE BIOLABS INC. and CD BIOSCIENCES INC.,

Defendants.

Civil Action No.: 18-cv-2684

JURY TRIAL DEMANDED

COMPLAINT

Plaintiffs CSL Limited ("CSL") and its subsidiary Zenyth Therapeutics Limited ("Zenyth") (collectively, "Plaintiffs") bring this action against defendants Creative Biolabs Inc. and CD Biosciences Inc. (collectively, "Defendants") and allege as follows:

INTRODUCTION

1. This is an action under federal patent and trademark law, as well as New York statutes and common law, to stop defendants from selling blatant knock-offs of antibodies created by CSL, a global leader in the research, development and commercialization of biotherapies that save and improve the lives of patients with chronic disease.

2. Defendants have used CSL's patent-protected information to illegally duplicate CSL's antibodies in development, and are selling them to the public as CSL products, when in fact they are not. Defendants' illegal actions willfully infringe CSL's patents and trademarks, and threaten to create irreparable injury to CSL. More importantly, defendants' sale of fake "CSL" antibodies of suspect and unknown quality not only threaten irreparable injury to CSL and its brand, but also threaten public safety if a physician or researcher used these fake

antibodies for investigative use. Simply put, Plaintiffs ask the Court to stop Defendants' actions now, and to order Defendants to pay CSL for the damages the Defendants have caused.

THE PARTIES

3. Plaintiff CSL is headquartered at 45 Poplar Rd, Parkville, Victoria 3052, Australia.

4. Plaintiff Zenyth, a wholly owned subsidiary of CSL, is located at 45 Poplar Rd, Parkville, Victoria 3035, Australia.

5. On information and belief, Defendant Creative Biolabs Inc. is a domestic corporation, organized and existing under the laws of New York since 2015, with a principal place of business at 45-1 Ramsey Rd, Shirley, NY 11967.

6. On information and belief, Defendant CD Biosciences Inc. is a domestic corporation, organized and existing under the laws of New York since 2009, with a principal place of business at 45-16 Ramsey Rd, Shirley, NY 11967.

7. On information and belief, Defendant CD Biosciences Inc. operates under numerous assumed names and is the corporate parent of Defendant Creative Biolabs, Inc.

JURISDICTION AND VENUE

8. This action for patent and trademark infringement arises under 35 U.S.C. § 271 and 15 U.S.C. §§ 1114 and 1125, respectively.

9. This Court has federal question jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331 and 1338(a) because this is a civil action arising under the Patent Act and the Lanham Act.

10. This Court has original jurisdiction over Plaintiffs' New York State statutory and common law claims under 28 U.S.C. §§ 1332 and 1338(b), as well as supplemental jurisdiction under 28 U.S.C. § 1367.

11. This Court has general jurisdiction over Defendants Creative Biolabs Inc. and CD Biosciences Inc. because both are incorporated in the State of New York.

12. Venue is proper in this District under both 28 U.S.C. §§ 1391(b)–(c) and 1400(b) because Defendants reside in this District and, alternatively, have committed acts of infringement and have a regular and established place of business in this District.

BACKGROUND

CSL – Global Biotherapy Industry Leader

13. CSL was established over a century ago in Australia to provide lifesaving medicines to a nation isolated by World War I. Since that time, CSL has become a global biopharmaceutical company focused on improving and saving lives though the research and development of innovative therapies. CSL's reach is global, with more than 17,000 employees in over 30 countries and major facilities in the United States, Australia, and Europe. The global headquarters of its primary subsidiary CSL Behring is located outside Philadelphia.

14. CSL is a leader in the research, development and commercialization of biotherapies that save and improve the lives of patients with chronic disease such as hemophilia, autoimmune diseases, and other life-threatening illnesses.

15. For example, CSL, through its subsidiary CSL Behring, offers one of the world's most comprehensive portfolios of safe, high quality, technically advanced immunoglobulin products derived from human plasma, which are designed to boost a patient's own immune system. The current immunoglobulin market is over $10 billion total worldwide,

and used by thousands to treat chronic disease. CSL, through its subsidiary CSL Plasma, has collection centers throughout the United States and abroad to collect human plasma in order to produce its immunoglobulin and other therapies. There are ten CSL plasma collection centers in New York.

16. CSL also is a market leader in researching and developing new potential therapies. For example, CSL has spent hundreds of millions of dollars to develop several monoclonal antibodies, potentially for the targeted treatment of leukemia, diabetes, asthma, rheumatoid arthritis, and other diseases. These new potential therapies are not yet approved for use by the FDA; rather, CSL is conducting research and development in accordance with FDA guidelines, including animal research and clinical trials throughout the world, to ensure these therapeutic antibodies are both safe and effective for the intended treatment.

CSL's Patents

17. Because of the substantial expertise and investment of time, effort, and financial resources required to develop potential therapeutic antibodies, CSL has sought and secured patents for its antibodies.

18. Zenyth, CSL's wholly owned subsidiary, also holds a portfolio of patents to antibodies developed through its own research and development efforts.

19. On November 24, 2015, the United States Patent and Trademark Office ("USPTO") duly issued U.S. Patent No. 9,193,793 (the "'793 patent"), titled "Antibodies Against G-CSFR and Uses Thereof." CSL is the owner by assignment of all right, title, and interest in and to the '793 patent. A true and correct copy of the '793 patent is attached as Exhibit 1.

20. On April 14, 2009, the USPTO duly issued U.S. Patent No. 7,517,524 (the "'524 patent"), titled "Immunoreactive Molecules." Zenyth is the owner by assignment of all right, title, and interest in and to the '524 patent. A true and correct copy of the '524 patent is attached as Exhibit 2.

21. On September 2, 2014, the USPTO duly issued U.S. Patent No. 8,822,644 (the "'644 patent), titled "Method of Treating Cancer Comprising a VEGF-B Antagonist." Zenyth is the owner by assignment of all right, title, and interest in and to the '644 patent. A true and correct copy of the '644 patent is attached as Exhibit 3.

22. On October 29, 2013, the USPTO duly issued U.S. Patent No. 8,569,461 (the "'461 patent"), titled "Humanized Anti-Interleukin 3 Receptor Alpha Chain Antibodies." CSL is the owner by assignment of all right, title, and interest in and to the '461 patent. A true and correct copy of the '461 patent is attached at Exhibit 4.

23. On May 17, 2016, the USPTO duly issued U.S. Patent No. 9,340,618 (the "'618 patent"), titled "IL-11R Binding Proteins." CSL is the owner by assignment of all right, title, and interest in and to the '618 patent. A true and correct copy of the '618 patent is attached as Exhibit 5.

CSL's Trademarks

24. As noted above, CSL is a highly regarded biopharmaceutical company that offers one of the world's most comprehensive portfolios of technically advanced immunoglobulin products, which are designed to boost a patient's own immune system.

25. To protect CSL's reputation and the millions of dollars invested in its innovative products, CSL developed its trade name and trademarks.

26. CSL currently has federal registrations for the mark CSL® (collectively referred to as the "CSL Registered Marks"), including U.S. Trademark Registration No. 3,340,255 for use in connection with printed matter and publications featuring, among other things, pharmaceutical products, registered on November 20, 2007. A true and correct copy of this registration is attached hereto as Exhibit 6.

27. CSL also owns common law trademark and trade name rights throughout the United States for CSL by virtue of it continuous use of those Marks in interstate commerce in such a way that the public understands CSL to designate CSL as a house brand and trade name. Through CSL's use of the CSL Mark, the public perceives the CSL Mark as an indicator of CSL and its products and services. The CSL Mark is referred to, together with the CSL Registered Marks, as the "CSL Marks."

28. The CSL Marks symbolize the longstanding goodwill and value belonging exclusively to CSL. CSL has continuously used the CSL Marks on its website, in its social media postings, agreements with third parties and patients, press releases, financial statements and communications with Wall Street.

Defendants Are Biotech Pirates

29. Although marketing themselves as "biotechnology pioneers" and "independent technology companies," Defendants are engaged in the unauthorized manufacture, use, offer for sale, and sale of antibodies protected by the intellectual property of others, including CSL's patented antibodies, to customers in the United States and around the world.

30. On information and belief, from an office in Shirley, New York, and with a handful of employees, CD Biosciences Inc. conducts its business through a dizzying array of names such as Creative Biolabs Inc., Creative Biomart Inc., Creative Diagnostics, Inc., Creative

Dynamics, Inc. (which operates under the trade name Creative Biolabs), Creative Bioarray and Creative Enzymes (which are identified as divisions of Creative Dynamics, Inc.), CD Genomics, CD Bioparticles, Creative Peptides, BOC Sciences, and Profacgen.

31. On information and belief, Creative Biolabs Inc. is the alter ego of CD Biosciences Inc. as evidenced by the fact that Creative Biolabs Inc.'s website "creativebiolabs.net" is registered to Mr. Donghai Chen, the president of CD Biosciences, Inc.

32. Defendants, through their website www.creativebiolabs.net (and through www.creative-biolabs.com), offer for sale and sell a large array of customized antibodies.

33. Indeed, in a December 28, 2016 press release, Creative Biolabs, Inc. boasted of having "released thousands of therapeutic antibodies for research use." Creative Biolabs' press release, dated December 28, 2016, a true and correct copy is attached as Exhibit 7.

34. In addition to knocking-off CSL's products, Defendants make a habit of flagrantly disregarding the intellectual property of others, as evidenced by Defendants' offer for sale of Eli Lilly and Company's patented therapeutic antibody (ERBITUX®) and Amgen Inc.'s patented therapeutic antibody (VECTIBIX®) using their trademarked names. True and correct copies of Creative Biolabs' Product Information for ERBITUX and VECTIBIX are attached as Exhibits 8 and 9, respectively.

35. On information and belief, Defendants use information pirated from published patent disclosures to manufacture their infringing products.

36. Defendants attempt to pass off their products as those of an innovator by using the publically available product identifiers used by the actual innovator to promote their own products.

37. Defendants do not provide information regarding the quality of their products or manufacturing processes. However, based on information and belief, Defendants' products are not made to the same exacting specifications and process as CSL's products. Accordingly, the sale of Defendants' products potentially presents a real public health hazard, particularly if Defendants' products are confused with the CSL products that have been manufactured for clinical trials.

CSL's Therapeutic Antibodies In Development and Defendants' Knock-Off Antibodies

38. CSL and its partners have developed a number of antibodies to potentially treat various conditions.

39. Antibodies are proteins that are naturally produced as part of the body's immune response to foreign substances (e.g., bacteria, viruses, fungi, and pollen).

40. A substance that triggers the body's immune response is known as an antigen. The term "antigen" is also used to designate the target molecule to which antibodies bind. Though the general structure of all antibodies is very similar, the portions of the antibody that bind to the antigen are extremely variable, allowing millions of antibodies with different antigen-binding sites to exist.

41. Just as each lock has a unique corresponding key that opens it, each antibody recognizes a region unique to a specific antigen ("epitope") and binds to it with a high degree of specificity.

42. Advances in antibody engineering, including the use of recombinant DNA technology, have made it possible to generate antibodies against specific proteins that are implicated in the onset or advancement of a particular disease. The protein of interest includes the antigen or target molecule against which particular antibodies are generated. Scientists use

antibody engineering to produce antibodies in the laboratory beyond those that are naturally produced by the body (so-called "recombinant antibodies"). Scientists routinely refer to an antibody that binds to a specific protein (e.g., Protein X) as an anti-Protein X antibody or, simply, as a Protein-X antibody.

43. The binding of some of these engineered antibodies to their target proteins may serve to neutralize the activity of those proteins or even trigger an immune response leading to the destruction of the cells displaying the target proteins, thereby arresting or reversing the progress of the targeted disease.

44. CSL identifies antibodies in their development stage using the CSL### designation in its publically available investor briefings on research and development, various other publically available corporate documents, scientific publications, and in press releases. For example, CSL provides an annual investor briefing that highlights CSL's research and development efforts. *See e.g.*, CSL's Investor R&D Briefing, dated December 1, 2016, and CSL's R&D Investor Briefing, dated December 5, 2017, true and correct copies are attached as Exhibits 10 and 11, respectively. In these briefings, CSL provides an update of some of its products in development, including some of those being knocked-off by defendants, such as CSL324, CSL346, and CSL362. *See, e.g.*, Exhibit 10 at 8-10, 22–24, 28–29; Exhibit 11 at 8, 11–12, 22, 25–28. Similarly, CSL has issued press releases that refer to its products in development, such as CSL324 and CS346. *See, e.g.*, Press Releases, dated December 1, 2016 and February 10, 2017, true and correct copies are attached as Exhibits 12 and 13, respectively. CSL has also used the CSL### designation in scientific publications. *See, e.g.,* Scalzo-Inguanti, K., *et al.*, CSL324, A Humanised Anti-G-CSFR Antibody, Can Inhibit Neutrophil Migration While Not Impaction on Neutrophil Number or Effector Functions, 70 *Cytokine* 1, 68 (2014), a

true and correct copy is attached at Exhibit 14. By using the CSL### designation, CSL is telling the investment and scientific communities that such antibodies are being developed by CSL. In turn, the investment and scientific communities perceive the CSL### designation as an indicator of products being developed by CSL, along with any goodwill associated with the CSL Mark.

CSL Antibody CSL324

45. CSL has developed a recombinant antibody that binds to the receptor for human granulocyte-colony stimulating factor ("human G-CSFR" also known as "human CSF3R") and neutralizes the signaling that would result from the binding of human granulocyte-colony stimulating factor ("G-CSF") to human G-CSFR. This anti-human G-CSFR antibody (or anti-human CSF3R antibody) has been designated by CSL as CSL324.

46. CSL has completed a Phase I clinical trial with CSL324 as a potential therapy for patients suffering from inflammatory conditions, for example rheumatoid arthritis, and has identified CSL324 as its human G-CSFR antibody in its public documents. Exhibit 11 at 8, 12, 22, 26, and 32.

47. CSL does not currently sell CSL324, or make it available to the public except via rigorously monitored clinical trials that are conducted in accordance with FDA guidelines. However, as required by statute, the '793 patent provides all of the information necessary to create a G-CSFR antibody that would infringe the '793 patent.

Defendants' Knock-Off Antibodies of CSL324

48. On their website www.creativebiolabs.net, Defendants promote and offer to sell the following antibodies that infringe the '793 patent, including two that are identified as ***CSL's own CSL324 product***:

a. "Anti-Human CSF3 Therapeutic Antibody (CSL324)" (catalog no. TAB-190CL),

b. "Anti-Human CSF3R Therapeutic Antibody" (catalog no. TAB-191CL), and

c. "Afuco™ Anti-Human CSF3 ADCC Theraputic Antibody (CSL324), ADCC Enhanced" (catalog no. AFC-180CL).

49. On information and belief, Defendants use the information in the '793 patent to manufacture antibodies that infringe the '793 patent.

50. On information and belief, TAB-190CL, TAB-191CL, and AFC-180CL infringe at least claims 1, 20 and 21 of the '793 patent.

51. Claim 1 of the '793 patent encompasses a protein comprising an antigen binding site of an antibody that (i) binds to human G-CSFR, (ii) neutralizes G-CSF signaling, (iii) has certain binding properties, and (iv) comprises certain amino acid sequences at its binding site. Exhibit 1 at claim 1.

52. Claims 20 and 21 of the '793 patent more particularly recite the amino acid sequences at the binding site of the claimed antibody. *Id.*at claims 20 and 21.

53. Defendants identify each of TAB-190CL, TAB-191CL, and AFC-180CL as "a fully human antibody that binds to the G-CSFR, and neutralizes the activity of G-CSF." Creative Biolabs' Product Information for TAB-190CL, TAB-191CL, and AFC-180CL, true and correct copies are attached as Exhibits 15, 16, and 17, respectively.

54. The description for these antibodies as supplied by Defendants in the "Product Overview" copies verbatim the description of the CSL324 antibody as provided in the publically-available publication of a CSL-sponsored study by *Scalzo-Inguanti et al*. *Compare* Exhibit 14 *to* Exhibits 15–17.

55. Regarding TAB-190CL and AFC-180CL, Defendants expressly identify these antibodies as "CSL324." Exhibits 15 and 17.

56. CSL324 falls within the scope of at least claims 1, 20, and 21 of the '793 patent.

57. By identifying TAB-190CL and AFC-180CL as "CSL324," Defendants are representing that TAB-190CL and AFC-180CL have the same binding site and binding properties as CSL324, including those recited in claims 1, 20, and 21 of the '793 patent.

58. Based on the antibody description for TAB-190CL and AFC-180CL, and Defendants' use of "CSL324," TAB-190CL and AFC-180CL infringe at least claims 1, 20, and 21 of the '793 patent.

59. Defendants are using the "CSL" mark in connection with TAB-190CL and AFC-180CL without CSL's authorization, and thus are violating CSL's trademark rights.

60. Regarding TAB-191CL, CSL obtained this antibody from Creative Biolabs, Inc.

61. CSL tested TAB-191CL and determined that the key amino acid sequences of the antigen-binding site (so-called complementarity-determining regions or CDRs) of TAB-191CL are identical to CDRs of CSL324, and that TAB-191CL has the same binding properties as CSL324.

62. Because TAB-191CL's antigen-binding site has the same key amino acid sequences as CSL324 and the same binding properties as CSL324, TAB-191CL infringes at least claims 1, 20, and 21 of the '793 patent.

CSL Antibody CSL346

63. CSL has developed a recombinant antibody that binds to human vascular endothelial growth factor-B ("human VEGF-B") and disrupts the binding of human VEGF-B to

its receptor ("VEGF-R1"). This anti-human VEGF-B antibody has been designated by CSL as CSL346.

64. CSL has entered Phase I clinical trials with CSL346 as a potential therapy for diabetes and diabetic complications, and has identified CSL346 as its human VEGF-B antibody in its public documents. Exhibit 11 at 11, 12, 22, 28, 32, and 35.

65. CSL does not currently sell CSL346, or make it available to the public except via rigorously monitored clinical trials that are conducted under FDA guidelines. However, as required by statute, the '524 and '644 patents provide all of the information necessary to create a human VEGF-B antibody as claimed in the patents.

Defendants' Knock-Off Antibodies of CSL346

66. On their website www.creativebiolabs.net, Defendants promote and offer to sell the following antibodies that infringe the '524 and '644 patents and that are identified as ***CSL's own CSL346 product***:

a. "Anti-Human VEGFB Therapeutic Antibody (CSL346)" (catalog no. TAB-660CL), and

b. "Afuco™ Anti-Human VEGFB ADCC Therapeutic Antibody" (CSL346), ADCC Enhanced" (catalog no. AFC-634CL).

67. On information and belief, Defendants use the information in the '524 and '644 patents to manufacture antibodies that infringe the '524 and '644 patents.

68. On information and belief, TAB-660CL and AFC-634CL infringe at least claim 3 of the '524 patent and claim 1 of the '644 patent.

69. Claim 3 of the '524 patent encompasses a monoclonal antibody or fragment that (i) binds to human VEGF-B, (ii) antagonizes the binding between human VEGF-B and VEGF-R1, and (ii) is the humanized form of antibody 2H10 produced by a hybridoma deposited at the American Type Culture Collection (ATCC) as PTA-6889. Exhibit 2 at claim 3.

70. Claim 1 of the ’644 patent encompasses an anti-VEGF-B antibody that (i) inhibits binding of VEGF-B to VEGFR-1, (ii) binds with a certain affinity to VEGF-B, and (iii) has the same binding site sequence as 2H10. Exhibit 3 at claim 1.

71. Defendants identify TAB-660CL and AFC-634CL as humanized monoclonal antibodies to VEGF-B that antagonize VEGF-B. Creative Biolabs’ Product Information for TAB-660CL and AFC-634CL, true and correct copies are attached as Exhibits 18 and 19, respectively.

72. Defendants expressly identify TAB-660CL and AFC-634CL as “CSL346.” *Id.*

73. CSL346 falls within the scope of at least claim 3 of the ’524 patent and claim 1 of the ’644 patent.

74. By identifying TAB-660CL and AFC-634CL as “CSL346,” Defendants are representing that these antibodies have the same properties as CSL346, including those recited in claim 3 of the ’524 patent and claim 1 of the ’644 patent.

75. Based on the antibody descriptions of TAB-660CL and AFC-634CL and Defendants’ use of “CSL346,” these antibodies infringe at least claim 3 of the ’524 patent and claim 1 of the ’644 patent.

76. Defendants are using the “CSL” mark in conjunction with TAB-660CL and AFC-634CL, without CSL’s authorization, and thus are violating CSL’s trademark rights.

CSL Antibody CSL360

77. CSL has developed a recombinant antibody (CSL360) that binds to the human interleukin-3 receptor α-chain (“human IL-3Rα” also known as “human IL-3RA”). This anti-human IL-3RA antibody has been designated by CSL as CSL360.

78. CSL developed CSL360 as a potential targeted anti-cancer agent for conditions such as acute myeloid leukemia and lymphoma.

79. CSL does not currently sell CSL360, or make it available to the public. However, as required by statute, the '461 patent provides all of the information necessary to create a human IL-3Rα antibody as claimed in the patent.

Defendants' Knock-Off Antibodies of CSL360

80. On their website www.creativebiolabs.net, Defendants promote and offer to sell the following antibodies that are identified as ***CSL's own CSL360 product***:

a. "Anti-Human IL3RA Therapeutic Antibody (CSL360)" (catalog no. TAB-431CL), and

b. "Afuco™ Anti-Human IL3RA ADCC Therapeutic Antibody (CSL360), ADCC Enhanced" (catalog no. AFC-414CL).

81. Defendants identify these antibodies as monoclonal antibodies to human IL-3Rα that are used to target cells implicated in acute myeloid leukemia. Creative Biolabs' Product Information for TAB-431CL and AFC-414CL, true and correct copies are attached as Exhibits 20 and 21.

82. Defendants expressly identify these antibodies as "CSL360." *Id.*

83. Defendants are using the "CSL" mark in conjunction with TAB-431CL and AFC-414CL, without CSL's authorization, and thus are violating CSL's trademark rights.

CSL Antibody CSL362

84. CSL has developed another recombinant antibody that binds IL-3RA. This anti-human IL-3RA antibody has been designated by CSL as CSL362.

85. CSL362 is a potential therapy for a number of conditions, including acute myeloid leukemia and lymphoma.

86. CSL has identified CSL362 as its IL-3Rα antibody in its public documents. *See e.g.*, Exhibit 11 at 8 and 11.

87. CSL does not currently sell CSL362, or make it available to the public except via rigorously monitored clinical trials that are conducted under FDA guidelines.

Defendants' Knock-Off Antibodies of CSL362

88. On their website www.creativebiolabs.net, Defendants promote and offer to sell the following antibodies or antibody fragments that are identified as ***CSL's own CSL362 product***:

a. Recombinant Mouse Anti-IL3RA Antibody (CSL362)" (catalog no. PABZ-159), and

b. "Recombinant Mouse Anti-1L3R Antibody (CSL362)" (catalog no. PABL-617).

c. "Recombinant Mouse Anti-IL3RA Antibody Fab Fragment (CSL362)" (catalog no. PFBZ-159),

d. "Recombinant Mouse Anti-IL3RA Antibody scFV Fragment (CSL362)" (catalog no. PSBZ-159),

e. "Recombinant Mouse Anti-IL3R Antibody Fab Fragment (CSL362)" (catalog no. PFBL-612), and

f. "Recombinant Mouse Anti-1L3R Antibody scFV Fragment (CSL362)" (catalog no. PSBL-612).

89. On information and belief, Defendants use the information in the '461 patent to manufacture antibodies that infringe the '461 patent.

90. On information and belief, PABZ-159 and PABL-617 infringe at least claim 1 of the '461 patent.

91. Claim 1 of the '461 patent encompasses an isolated or recombinant antibody that is capable of specifically binding to human IL-3Rα and comprises certain amino acid sequences. Exhibit 4 at claim 1.

92. Defendants identify these antibodies and antibody fragments as capable of binding to human IL-3Rα. Creative Biolabs' Product Information for PABZ-159 and PABL-617, true and correct copies are attached as Exhibits 22 and 23, respectively.

93. Defendants expressly identify PABZ-159 and PABL-617 as "CSL362." *Id.*

94. CSL362 falls within the scope of at least claim 1 of the '461 patent.

95. By identifying PABZ-159 and PABL-617 as "CSL362," Defendants are representing that these antibodies have the same properties as CSL362, including those recited in claim 1 of the '461 patent.

96. Based on the antibody descriptions of PABZ-159 and PABL-617 and Defendants' use of "CSL362," these antibodies infringe at least claim 1 of the '461 patent.

97. Defendants also expressly identify PFBZ-159, PSBZ-159, PFBL-612, and PSBL-612 as "CSL362." Creative Biolabs' Product Information for PFBZ-159, PSBZ-159, PFBL-612, and PSBL-612, true and correct copies are attached as Exhibits 24, 25, 26, and 27, respectively.

98. Defendants are using the "CSL" mark in conjunction with PABZ-159, PABL-617, PFBZ-159, PSBZ-159, PFBL-612, and PSBL-612, without CSL's authorization, and thus are violating CSL's trademark rights.

CSL Antibody 8E2

99. CSL has developed a recombinant antibody that binds to the human interleukin-11 receptor α ("human IL-11Rα" also known as "human IL-11RA"). This anti-human IL-11Rα antibody has been designated by CSL as 8E2.

100. CSL has entered the pre-clinical development phase with 8E2 as a potential therapy for diseases such as gastric and colon cancers, and has described 8E2 in the '618 patent.

101. CSL does not currently sell 8E2, or make it available to the public. However, as required by statute, the '618 patent provides all the information necessary to create an IL-11Rα antibody as claimed in the patent.

Defendants' Knock-Off Antibodies of 8E2

102. On their website www.creativebiolabs.net, Defendants promote and offer to sell the following antibody and antibody fragments that infringe the '618 patent and are identified as ***CSL's own 8E2 product***:

a. "Anti-Human IL-11RA Therapeutic Antibody (8E2)" (catalog no. TAB-062ZJ),

b. "Anti-Human IL-11RA Therapeutic Antibody FabFragment (8E2)" (catalog no. TAB-062ZJ-F(E)), and

c. "Anti-Human IL-11RA Therapeutic Antibody scFV Fragment (8E2)" (catalog no. TAB-062ZJ-S(P)).

103. On information and belief, Defendants use the information in the '618 patent to manufacture antibodies which infringe the '618 patent.

104. On information and belief, TAB-062ZJ, TAB-062ZJ-F(E), and TAB-062ZJ-S(P) infringe at least claims 1 and 5 of the '618 patent.

105. Claim 1 of the '618 patent encompasses an antibody binding domain of an antibody that (i) binds to human IL-11Rα, (ii) neutralizes IL-11 signaling, (iii) binds to a particular domain of human IL-11Rα, and (iv) comprises certain amino acid sequences at its binding site. Exhibit 5 at claim 1.

106. Claim 5 of the ’618 patent more particularly recites the amino acid sequences at the binding site. *Id.*at claim 5.

107. Defendants identify TAB-062ZJ, TAB-062ZJ-F(E), and TAB-062ZJ-S(P) as recombinant antibodies or fragments to human IL-11Rα. Creative Biolabs’ Product Introduction for TAB-062ZJ, TAB-062ZJ-F(E), and TAB-062ZJ-S(P), true and correct copies are attached as Exhibits 28, 29, and 30, respectively.

108. Defendants expressly identify TAB-062ZJ, TAB-062ZJ-F(E), and TAB-062ZJ-S(P) as “8E2.” *Id*.

109. 8E2 falls within the scope of at least claims 1 and 5 of the ’618 patent.

110. By identifying TAB-062ZJ, TAB-062ZJ-F(E), and TAB-062ZJ-S(P) as “8E2,” Defendants are representing that these antibodies have the same properties as 8E2, including those recited in claims 1 and 5 of the ’618 patent.

111. Based on the antibody descriptions for TAB-062ZJ, TAB-062ZJ-F(E), and TAB-062ZJ-S(P) and Defendants’ use of “8E2”, these antibodies infringe at least claim 1 and 5 of the ’618 patent.

COUNT I

Infringement of U.S. Patent No. 9,193,793

112. Plaintiffs re-allege and incorporate by reference the allegations contained in paragraphs 1–111 above as relevant to this Count.

113. Defendants have directly infringed and continue to infringe, literally or under the doctrine of equivalents, at least claims 1, 20, and 21 of the ’793 patent by making, using, offering for sale, selling in the United States and/or importing into the United States the following antibodies, including two that are identified as ***CSL’s own CSL324 product***:

a. "Anti-Human CSF3 Therapeutic Antibody (CSL324)" (catalog no. TAB-190CL),

b. "Anti-Human CSF3R Therapeutic Antibody" (catalog no. TAB-191CL), and

c. "Afuco™ Anti-Human CSF3 ADCC Theraputic Antibody (CSL324), ADCC Enhanced" (catalog no. AFC-180CL).

114. Defendants' past and continued infringement of the '793 patent has damaged and continues to damage Plaintiffs.

115. Defendants' past and continuing infringement of the '793 patent has irreparably harmed Plaintiffs, and Defendants' infringement will continue unless enjoined by this Court pursuant to 35 U.S.C. § 283.

116. Upon information and belief, such infringement of the '793 patent has been, and will continue to be, willful making this an exceptional case and entitling Plaintiffs to increased damages and reasonable attorneys' fees pursuant to 35 U.S.C. §§ 284 and 285.

COUNT II

Infringement of U.S. Patent No. 7,517,524

117. Plaintiffs re-allege and incorporate by reference the allegations contained in paragraphs 1–116 above as relevant to this Count.

118. Defendants have directly infringed and continue to infringe, literally or under the doctrine of equivalents, at least claim 3 of the '524 patent by making, using, offering for sale, selling in the United States and/or importing into the United States the following antibodies that are identified as ***CSL's own CSL346 product***:

a. "Anti-Human VEGFB Therapeutic Antibody (CSL346)" (catalog no. TAB-660CL), and

b. "Afuco™ Anti-Human VEGFB ADCC Therapeutic Antibody (CSL346), ADCC Enhanced" (catalog no. AFC-634CL).

119. Defendants' past and continued infringement of the '524 patent has damaged and continues to damage Plaintiffs.

120. Defendants' past and continuing infringement of the '524 patent has irreparably harmed Plaintiffs, and Defendants' infringement will continue unless enjoined by this Court pursuant to 35 U.S.C. § 283.

121. Upon information and belief, such infringement of the '524 patent has been, and will continue to be, willful making this an exceptional case and entitling Plaintiffs to increased damages and reasonable attorneys' fees pursuant to 35 U.S.C. §§ 284 and 285.

COUNT III

Infringement of U.S. Patent No. 8,822,644

122. Plaintiffs re-allege and incorporate by reference the allegations contained in paragraphs 1–121 above as relevant to this Count.

123. Defendants have directly infringed and continue to infringe, literally or under the doctrine of equivalents, at least claim 1 of the '644 patent by making, using, offering for sale, selling in the United States and/or importing into the United States the following antibodies that are identified as ***CSL's own CSL346 product***:

a. "Anti-Human VEGFB Therapeutic Antibody (CSL346)" (catalog no. TAB-660CL), and

b. "Afuco™ Anti-Human VEGFB ADCC Therapeutic Antibody (CSL346), ADCC Enhanced" (catalog no. AFC-634CL).

124. Defendants' past and continued infringement of the '644 patent has damaged and continues to damage Plaintiffs.

125. Defendants' past and continuing infringement of the '644 patent has irreparably harmed Plaintiffs, and Defendants' infringement will continue unless enjoined by this Court pursuant to 35 U.S.C. § 283.

126. Upon information and belief, such infringement of the ’644 patent has been, and will continue to be, willful making this an exceptional case and entitling Plaintiffs to increased damages and reasonable attorneys’ fees pursuant to 35 U.S.C. §§ 284 and 285.

COUNT IV

Infringement of U.S. Patent No. 8,569,461

127. Plaintiffs re-allege and incorporate by reference the allegations contained in paragraphs 1–126 above as relevant to this Count.

128. Defendants have directly infringed and continue to infringe, literally or under the doctrine of equivalents, at least claim 1 of the ’461 patent patent by making, using, offering for sale, selling in the United States and/or importing into the United States the following antibodies, including two that are identified as ***CSL’s own CSL362 product***:

a. Recombinant Mouse Anti-IL3RA Antibody (CSL362)” (catalog no. PABZ-159), and

b. “Recombinant Mouse Anti-1L3R Antibody (CSL362)” (catalog no. PABL-617).

129. Defendants’ past and continued infringement of the ’461 patent has damaged and continues to damage Plaintiffs.

130. Defendants’ past and continuing infringement of the ’461 patent has irreparably harmed Plaintiffs, and Defendants’ infringement will continue unless enjoined by this Court pursuant to 35 U.S.C. § 283.

131. Upon information and belief, such infringement of the ’461 patent has been, and will continue to be, willful making this an exceptional case and entitling Plaintiffs to increased damages and reasonable attorneys’ fees pursuant to 35 U.S.C. §§ 284 and 285.

COUNT V

Infringement of U.S. Patent No. 9,340,618

132. Plaintiffs re-allege and incorporate by reference the allegations contained in paragraphs 1–131 above as relevant to this Count.

133. Defendants have directly infringed and continue to infringe, literally or under the doctrine of equivalents, at least claim 1 of the ’618 patent by making, using, offering for sale, selling in the United States and/or importing into the United States the following antibody and antibody fragments that are identified as ***CSL’s own 8E2 product***:

a. “Anti-Human IL-11RA Therapeutic Antibody (8E2)” (catalog no. TAB-062ZJ),

b. “Anti-Human IL-11RA Therapeutic Antibody Fab Fragment (8E2)” (catalog no. TAB-062ZJ-F(E)), and

c. “Anti-Human IL-11RA Therapeutic Antibody scFV Fragment (8E2)” (catalog no. TAB-062ZJ-S(P)).

134. Defendants’ past and continued infringement of the ’628 patent has damaged and continues to damage Plaintiffs.

135. Defendants’ past and continuing infringement of the ’618 patent has irreparably harmed Plaintiffs, and Defendants’ infringement will continue unless enjoined by this Court pursuant to 35 U.S.C. § 283.

136. Upon information and belief, such infringement of the ’618 patent has been, and will continue to be, willful making this an exceptional case and entitling Plaintiffs to increased damages and reasonable attorneys’ fees pursuant to 35 U.S.C. §§ 284 and 285.

COUNT VI

Federal Trademark Infringement (15 U.S.C. § 1114(1))

137. Plaintiffs re-allege and incorporate by reference the allegations contained in paragraphs 1–136 above as relevant to this Count.

138. The CSL Registered Trademarks are valid, federally registered trademarks. CSL is the owner of the CSL Registered Trademarks.

139. Upon information and belief, Defendants, without consent of CSL, used and are using in commerce the CSL Registered Marks and/or a reproduction, counterfeit, copy, or colorable imitation of the CSL Registered Marks in connection with the sale, offering for sale, packaging, distribution, and/or advertising of goods in connection with which such use that is likely to cause confusion, cause mistake, or deceive. Defendants' actions constitute willful infringement of CSL's exclusive rights in the CSL Registered Marks.

140. As a result of Defendants' infringing activities, CSL has suffered and will continue to suffer irreparable harm. Unless Defendants are restrained from further infringement, CSL will continue to be irreparably harmed, and CSL has no adequate remedy at law that will compensate for the continued and irreparable harm it will suffer if Defendants' acts are allowed to continue.

141. As a result of Defendants' activities, CSL has also suffered damages in an amount to be proved at trial.

COUNT VII

Federal False Description and Designation of Origin (15 U.S.C. § 1125)

142. Plaintiffs re-allege and incorporate by reference the allegations contained in paragraphs 1–141 above as relevant to this Count.

143. The CSL Marks serve to identify products bearing that mark as originating from CSL.

144. Defendants used and are using in commerce, in connection with counterfeit CSL products, the CSL Marks. This use is likely to cause confusion, or to cause mistake, or to deceive as to the origin, sponsorship, or approval of Defendants' goods, and/or misrepresents the nature, characteristics, qualities, or geographic origin of Defendants' goods.

145. Defendants' use of the CSL Marks has deceived or is likely to deceive the purchasing public and is likely to influence purchasing decisions of consumers and retailers.

146. Defendants' actions constitute willful infringement of CSL's exclusive rights in the CSL Marks.

147. As a result of Defendants' infringing activities, CSL has suffered and will continue to suffer irreparable harm. Unless Defendants are restrained from further infringement, CSL will continue to be irreparably harmed, and CSL has no adequate remedy at law that will compensate for the continued and irreparable harm it will suffer if Defendants' acts are allowed to continue.

148. As a result of Defendants' activities, CSL has also suffered damages in an amount to be proved at trial.

COUNT VIII

New York Deceptive Business Practices

149. Plaintiffs re-allege and incorporate by reference the allegations contained in paragraphs 1–148 above as relevant to this Count.

150. In violation of New York General Business Law § 349, Defendants are selling, offering for sale and/or distributing counterfeit products unlawfully bearing the CSL Marks.

151. As a result of Defendants' infringing activities, CSL has suffered and will continue to suffer irreparable harm. Unless Defendants are restrained from further infringement, CSL will continue to be irreparably harmed, and CSL has no adequate remedy at law that will compensate for the continued and irreparable harm it will suffer if Defendants' acts are allowed to continue.

152. As a result of Defendants' activities, CSL has also suffered damages in an amount to be proved at trial.

COUNT IX

Common Law Trademark Infringement

153. Plaintiffs re-allege and incorporate by reference the allegations contained in paragraphs 1–152 above as relevant to this Count.

154. The aforesaid acts of Defendants constitute use of a designation that is likely to cause confusion as to the source, sponsorship, endorsement, or affiliation of the counterfeit CSL products.

155. The aforesaid acts of Defendants constitute trademark infringement in violation of the common law of the State of New York.

156. Defendants are directly liable for such false designation and trademark infringement.

157. Defendants' use of the CSL Marks has deceived or is likely to deceive the purchasing public and is likely to influence purchasing decisions of consumers and retailers.

158. Defendants' actions constitute willful infringement of CSL's exclusive rights in the CSL Marks.

159. As a result of Defendants' infringing activities, CSL has suffered and will continue to suffer irreparable harm. Unless Defendants are restrained from further infringement, CSL will continue to be irreparably harmed, and CSL has no adequate remedy at law that will compensate for the continued and irreparable harm it will suffer if Defendants' acts are allowed to continue.

160. As a result of Defendants' activities, CSL has also suffered damages in an amount to be proved at trial.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that this Court enter judgment against Defendants, granting Plaintiffs the following relief:

A. A judgment holding Defendants liable for direct infringement of U.S. Patent Nos. 9,193,793; 7,517,524; 8,822,644; 8,569,461; and 9,340,618 (collectively, the "CSL patents");

B. Damages resulting from Defendants' infringement of the CSL patents in an amount to be proved at trial, but no less than a reasonable royalty, together with pre-judgment and post-judgment interest;

C. A permanent injunction against Defendants, under 35 U.S.C. § 283, prohibiting Defendants and any individual or entity acting on their behalf from infringing the CSL patents;

D. A judgment holding this to be an exceptional case and awarding Plaintiffs increased damages pursuant to 35 U.S.C. § 284 and their attorneys' fees and costs pursuant to 35 U.S.C. § 285;

E. A judgment holding that Defendants have infringed the CSL Marks in violation of 15 U.S.C. §§ 1114 and 1125 and engaged in deceptive trade practices in violation of New York Gen. Bus. Law 349;

F. Statutory or actual damages in an amount to be ascertained at trial and costs and attorneys' fees;

G. A permanent injunction against Defendants, prohibiting Defendants and any individual or entity acting on their behalf from using any of the CSL Marks or any marks confusingly similar thereto in connection with the manufacture, sale, offer for sale, distribution, advertisement, or any other use; and

H. Such other and further relief as the Court deems just and equitable.

Dated: May 7, 2018

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