

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

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SBI BIOTECH CO., LTD, :
Plaintiff, : INDEX NO. _____
v. : **DEMAND FOR JURY TRIAL**
CREATIVE BIOLABS, INC., :
Defendant. :
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COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff SBI Biotech Co., Ltd (“SBI” or “Plaintiff”), by its attorneys, for its complaint against Defendant Creative Biolabs, Inc. (“Creative Biolabs” or “Defendant”) alleges as follows:

INTRODUCTION

1. Plaintiff SBI bring this action under federal patent law against Defendant Creative Biolabs for unlawfully making, using, selling, offering to sell, importing copies, and/or inducing infringement of SBI’s patented anti-PLD4 monoclonal antibodies.

2. SBI is the owner and assignee of U.S. Patent Nos. 9,944,715 (the “715 Patent”) and 10,336,834 (the “834 Patent”) (collectively, the “SBI Patents”).

3. Creative Biolabs is unlawfully making and marketing SBI’s patented antibodies for sale on its website providing unique identifiers, which are identical to the hybridoma clone numbers disclosed and claimed in the SBI Patents; thus, Creative Biolabs, on information and belief, would have directly copied the amino acid and/or nucleotide sequence from the SBI Patents in order to make it’s infringing anti-PLD4 antibodies, or antigen-binding fragments thereof (collectively, the “Anti-PLD4 Antibody Products”).

4. Creative Biolabs has a history of willfully disregarding intellectual property rights. At least four other lawsuits have been filed in the last three years with strikingly similar claims of willful patent infringement. In each complaint, Creative Biolabs was accused of making and marketing an infringing antibody product using either the plaintiff's internal reference number, or the plaintiff's trademark, or both. Filed complaints have accused Creative Biolabs of "brazenly copying" parties' patented antibodies.

5. Such actions show that Creative Biolabs' infringement is knowing and willful. SBI respectfully asks this Court to enjoin Creative Biolabs' actions and to order Creative Biolabs to pay SBI for the willful damages it has caused plus the attorneys' fees and costs SBI has incurred to force Creative Biolabs to respect SBI's intellectual property and the law.

NATURE OF THIS ACTION

6. This is a civil action arising out of Creative Biolabs' patent infringement in violation of the patent laws of the United States, including 35 U.S.C. §§ 271 and 281-285.

PARTIES

7. SBI is a company organized under Japanese law with its principal location at Izumi Garden Tower 15F, 1-6-1 Roppongi, Minato-ku Tokyo, 106-6015 Japan. SBI is engaged in the research and development of innovative new drugs for intractable diseases, such as cancer and autoimmune diseases.

8. On information and belief, Creative Biolabs is a privately-held corporation organized and existing under the laws of New York with a principal place of business at 45-1 Ramsey Road, Shirley, NY 11967.

JURISDICTION AND VENUE

9. This action arises under the patent laws of the United States, 35 U.S.C. § 100 *et seq.*, and this Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331 and 1338(a).

10. This Court has personal jurisdiction over Creative Biolabs because, among other things, Creative Biolabs is a corporation formed under the laws of the State of New York and has registered to do business in the State of New York. Creative Biolabs has further consented to jurisdiction in New York in past infringement lawsuits filed against it.

11. Venue is proper in this District under both 28 U.S.C. § 1391 and 28 U.S.C. § 1400 because Creative Biolabs resides in this District and, alternatively, has committed acts of infringement and has a regular and established place of business in this District.

BACKGROUND FACTS

12. Antibodies are proteins produced by the immune system in response to a foreign substance. The antibody recognizes a unique part of the foreign substance, called an antigen, and binds to it with a high degree of specificity. The term “monoclonal antibodies” refers to a substantially homogeneous population of antibodies. Typically, scientists initially engineer monoclonal antibodies by cloning a unique parent cell-line that will produce the desired antibody. The antibody and/or the unique parent cell-line can further be sequenced to determine the antibody’s amino acid sequence or the cell’s unique genetic nucleotide sequence. Scientists will then use the amino acid sequence or nucleotide sequence information to make copies of the desired monoclonal antibody or to produce antigen-binding fragments thereof.

A. THE ASSERTED PATENTS

13. On April 17, 2018, the United States Patent and Trademark Office (USPTO) duly and lawfully issued U.S. Patent No. 9,944,715, entitled “Anti-Phospholipase D4 Antibody.” By

way of assignment, SBI holds all rights, title, and interest in and to the ‘715 Patent. A true and correct copy of the ‘715 Patent is attached hereto as Exhibit 1.

14. On July 2, 2019, the USPTO duly and lawfully issued U.S. Patent No. 10,336,834, entitled “Methods of Using Anti-Phospholipase D4 Antibody.” By way of assignment, SBI holds all rights, title, and interest in and to the ‘834 Patent. A true and correct copy of the ‘834 Patent is attached hereto as Exhibit 2.

15. Among other things, the SBI Patents cover certain monoclonal antibodies, or antigen-binding fragments thereof, which bind to the human phospholipase D4 (PLD4) protein, and their uses for suppressing an activity of a plasmacytoid dendritic cell in a living organism.

16. The SBI Patents disclose a number of anti-PLD4 antibodies, or their antigen-binding fragments thereof, both by hybridoma clone number (and deposit Accession No.) and further by Seq. ID No., including hybridomas 3B4, 5B7, 8C11, 10C3, 13D4 and 13H11.

B. CREATIVE BIOLABS’ INFRINGING ANTI-PLD4 ANTIBODIES

17. On information and belief, Creative Biolabs markets and sells the Anti-PLD4 Antibody Products it manufactures through its websites, <https://www.creativebiolabs.net> and <https://www.antibody-creativebiolabs.com> (collectively, the “Website”). The home page for the [creativebiolabs.net](https://www.creativebiolabs.net) website, for example, provides a search bar by which a user can search for an antibody based on “product,” “gene” or “key word.” as shown in Exhibit 3.¹

18. Using this search function, a search of the keyword “PLD4” produces antibodies or their antigen-binding fragments that include the word “PLD4” in their designated name that plainly infringe SBI Patents, as further pled, *infra*. Specifically, the following antibodies or fragments

¹ <https://www.creativebiolabs.net>

thereof listed for sale on Creative Biolabs' website match the hybridoma clone numbers identified in the SBI Patents. *See, e.g.:*

- Anti-Human PLD4 Therapeutic Antibody (3B4)(CAT#: TAB-1034CL)²
- Anti-Human PLD4 Therapeutic Antibody (5B7)(CAT#: TAB-1035CL)³
- Anti-Human PLD4 Therapeutic Antibody (8C11)(CAT#: TAB-1036CL)⁴
- Anti-Human PLD4 Therapeutic Antibody (10C3)(CAT#: TAB-1037CL)⁵
- Anti-Human PLD4 Therapeutic Antibody (13D4)(CAT#: TAB-1038CL)⁶
- Anti-Human PLD4 Therapeutic Antibody (13H11)(CAT#: TAB-1039CL)⁷

19. By clicking on any one of these search results, the user is redirected to a page that states that the antibody "is available from Creative Biolabs." For example, by clicking on <https://www.creativebiolabs.net/Anti-PLD4-Therapeutic-Antibody-27722.htm>, the user is redirected to a page where the user may purchase various quantities of the 13D4 monoclonal anti-PLD4 antibody. In this particular example, Figure 2 on the website is identical to a portion of Fig. 11 in the '715 Patent.

20. On information and belief, the Anti-PLD4 Antibody Products identified as 3B4, 5B7, 8C11, 10C3, 13D4 and 13H11, or their antigen-binding fragments thereof, infringe at least

² <https://www.creativebiolabs.net/Anti-PLD4-Therapeutic-Antibody-27718.htm>. An example of an antigen-binding fragment of 3B4 may be found at <https://www.creativebiolabs.net/Anti-PLD4-scFv-29372.htm>.

³ <https://www.creativebiolabs.net/Anti-PLD4-Therapeutic-Antibody-27719.htm>. An example of an antigen-binding fragment of 5B7 may be found at <https://www.creativebiolabs.net/Anti-PLD4-Fab-31027.htm>.

⁴ <https://www.creativebiolabs.net/Anti-PLD4-Therapeutic-Antibody-27720.htm>. An example of an antigen-binding fragment of 8C11 may be found at <https://www.creativebiolabs.net/Anti-PLD4-scFv-29374.htm>.

⁵ <https://www.creativebiolabs.net/Anti-PLD4-Therapeutic-Antibody-27721.htm>. An example of an antigen-binding fragment of 10C3 may be found at <https://www.creativebiolabs.net/Anti-PLD4-Fab-31029.htm>.

⁶ <https://www.creativebiolabs.net/Anti-PLD4-Therapeutic-Antibody-27722.htm>. An example of an antigen-binding fragment of 13D4 may be found at <https://www.creativebiolabs.net/Anti-PLD4-scFv-29376.htm>.

⁷ <https://www.creativebiolabs.net/Anti-PLD4-Therapeutic-Antibody-27723.htm>. An example of an antigen-binding fragment of 13H11 may be found at <https://www.creativebiolabs.net/Anti-PLD4-Fab-31031.htm>.

one claim of the SBI Patents because the identified 3B4, 5B7, 8C11, 10C3, 13D4 and 13H11 antibodies, or antigen-binding fragment thereof, bind to the human PLD4 protein, and the clone identifiers provided on the Creative Biolabs website are identical to the unique hybridoma clone numbers disclosed and claimed in the SBI Patents.

21. SBI has been injured by Creative Biolabs' infringement of the SBI Patents and will suffer irreparable harm unless Creative Biolabs is enjoined from infringing the SBI Patents

C. CREATIVE BIOLABS' INFRINGEMENT IS WILLFUL

22. On information and belief, Creative Biolabs is aware or should be aware that its conduct described above infringes the SBI Patents from the date upon which it began infringing the SBI Patents. In order to make, use or sell its Anti-PLD4 Antibody Products, Creative Biolabs would have needed to obtain either the amino acid or nucleotide sequence of SBI's patented anti-PLD4 antibodies. On information and belief, these sequences are only available to the public through the specification of the SBI Patents or its prior application's publication. On information and belief, Creative Biolabs would necessarily have had to review the SBI Patents or its prior application in order to obtain the amino acid or nucleotide sequence to make the Anti-PLD4 Antibody Products, which it offers for sale on its Website. For example, Creative Biolabs copied portions of Figure 11 of the '715 Patent into its website pages for each of the SBI Patents' antibodies. Creative Biolabs' deliberate copying of SBI's proprietary inventions directly from the SBI Patents or their prior publications exemplifies willful behavior.

23. Further supporting that Creative Biolabs' infringement has been willful, within the last three years Creative Biolabs has been sued for patent infringement on at least four occasions that have strikingly similar fact patterns to the present dispute, confirming a pattern and practice by Creative Biolabs to pirate antibodies for its own gain in complete disregard of existing patent rights.

24. For example, in 2018, CSL Limited (“CSL”) and its subsidiary Zenyth Therapeutics Limited (“Zenyth”) sued Creative Biolabs and its believed aliases for illegally duplicating CSL’s antibodies and infringing CSL’s patents and trademarks. *See CSL Ltd et al. v. Creative Biolabs Inc. et al.*, Civ. No. 18-CV-2684 (E.D.N.Y. 2018). In their complaint, CSL and Zenyth characterized Creative Biolabs as “Biotech Pirates,” alleging that it has “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.” *Id.* at 20 (ECF No. 1). “In addition to knocking-off CSL’s products,” the complaint alleges, “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.” *Id.* at 34.

25. In early 2020, Biogen Inc. and the University of Zurich filed a similar complaint for patent and trademark infringement against Creative Biolabs for “brazenly copying . . . Biogen’s patented antibody aducanumab, including identification of the antibody using Biogen’s propriety designation BIIB037.” *See Biogen Inc. et al., v. Creative Biolabs Inc.*, Civ. No. 20-CV-10543 (D.Mass. 2020). Complaint at 35-36 (ECF No. 1).

26. In July 2020, Adienne Pharma & Biotech S.A. filed a similar complaint for patent infringement against Creative Biolabs “to stop defendant Creative Biolabs from selling a knock-off version of [its] patented monoclonal antibody.” *See Adienne Pharma & Biotech S.A. v. Creative Biolabs Inc.*, Civ. No. 2:20-CV-02950. Compl. 1 (ECF No. 1). The complaint accused Creative Biolabs of “illegally copy[ing] ADIENNE’s antibody, and [] willfully infringing ADIENNE’s patent by offering them for sale to the public.” *Id.*

27. In December 2020, The University of Southern Denmark also filed a similar complaint for patent infringement against Creative Biolabs for making, using, selling, offering to sell, and/or importing copies of The University's patented monoclonal antibody, HG-HYB 7-5. *See The University of Southern Denmark v. Creative Biolabs, Inc.*, Civ. No. 2:20-CV-5943, Complaint at 1 (ECF 1).

28. Given Creative Biolabs' pattern of misconduct and culture of copying, and the fact that Creative Biolabs directly copied from the SBI Patents the amino acid and/or nucleotide sequence of its anti-PLD4 antibodies, or antigen-binding fragments thereof, Creative Biolabs' infringement has always been and continues to be willful, wanton, malicious, bad-faith, deliberate, consciously wrongful and flagrant (*i.e.* characteristic of a pirate).

COUNT I: INFRINGEMENT OF U.S. PATENT NO. 9,944,715

29. Plaintiff repeats and re-alleges paragraphs 1-28 as if fully set forth therein.

30. Creative Biolabs has infringed and continues to infringe, literally or by the doctrine of equivalents, one or more claims of the '715 Patent, including but not limited to claim 1, under 35 U.S.C. § 271(a) by making, offering to sell, importing, and/or selling infringing Anti-PLD4 Antibody Products in and into the United States.

31. Creative Biolabs' infringement of the '715 Patent has damaged, and continues to damage, SBI in an amount yet to be determined, of at least a reasonable royalty and/or lost profits that SBI would have made but for Creative Biolabs' infringing acts as provided by 35 U.S.C. § 284.

32. SBI will suffer irreparable harm unless Creative Biolabs is enjoined from infringing the '715 Patent.

33. Such infringement of the '715 Patent has been, and will continue to be, willful, making this an exceptional case and entitling SBI to increased damages and reasonable attorneys' fees pursuant to 35 U.S.C. §§ 284 and 285.

COUNT II: INFRINGEMENT OF U.S. PATENT NO. 10,336,834

34. Plaintiff repeats and re-alleges paragraphs 1-28 as if fully set forth therein.

35. Creative Biolabs has infringed and continues to infringe, literally or by the doctrine of equivalents, one or more claims of the '834 Patent, including but not limited to claim 1, under 35 U.S.C. § 271(a) by using the infringing Anti-PLD4 Antibody Products in the '834 Patent's claimed methods.

36. Further, Creative Biolabs has infringed under 35 U.S.C. § 271(b) by selling and offering for sale in the United States the Anti-PLD4 Antibody Products and instructing end-users through instructional materials, product manuals, and technical materials, disseminating promotional/marketing materials that describe the workflows and use of those tests, and otherwise instructing end-users to use the Anti-PLD4 Antibody Products to infringe at least one claim of the '834 Patent. At least as of the date hereof, Creative Biolabs sells and distributes the Anti-PLD4 Antibody Products with the knowledge and specific intent that these instructions will cause end-users to infringe at least one claim of the '834 Patent, and therefore Creative Biolabs induces end-users to use the Anti-PLD4 Antibody Products in methods that directly infringe at least one claim of the '834 Patent.

37. Creative Biolabs' infringement of the '834 Patent has damaged, and continues to damage, SBI in an amount yet to be determined, of at least a reasonable royalty and/or lost profits that SBI would have made but for Creative Biolabs' infringing acts as provided by 35 U.S.C. § 284.

38. SBI will suffer irreparable harm unless Creative Biolabs is enjoined from infringing the '834 Patent.

39. Such infringement of the '834 Patent has been, and will continue to be, willful, making this an exceptional case and entitling Plaintiff to increased damages and reasonable attorneys' fees pursuant to 35 U.S.C. §§ 284 and 285.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff requests entry of judgment against Creative Biolabs as follows:

A. A judgment that Creative Biolabs has infringed one or more claims of U.S. Patent Nos. 9,944,715 and 10,336,834 in violation of 35 U.S.C. § 271;

B. An order permanently enjoining Creative Biolabs, its officers, directors, employees, agents, and all persons acting in concert with them, from infringing U.S. Patent Nos. 9,944,715 and 10,336,834;

C. An award of damages for infringement of the U.S. Patent Nos. 9,944,715 and 10,336,834 with prejudgment interest and costs, including all legal and professional expenses incurred in or that derive from the events detailed in this complaint, said damages to be trebled by reason of the intentional and willful nature of Creative Biolabs' infringement, as provided by 35 U.S.C. § 284; and

D. A determination that this case is "exceptional" under 35 U.S.C. § 285 and an award of Plaintiff's reasonable attorneys' fees.

