

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BIO-RAD LABORATORIES, INC. and THE)
UNIVERSITY OF CHICAGO,)
)
Plaintiffs,)
) C.A. No. _____
v.)
) **DEMAND FOR JURY TRIAL**
DROPWORKS, INC.)
Defendant.)
)
)
)

COMPLAINT

Bio-Rad Laboratories, Inc. (“Bio-Rad”) and the University of Chicago (collectively, “Plaintiffs”) hereby allege for their Complaint against Defendant Dropworks, Inc. (“Dropworks” or “Defendant”), on personal knowledge as to their own actions and on information and belief as to the actions of others, as follows:

NATURE OF THE ACTION

1. This is an action alleging patent infringement arising under the United States Patent Act 35 U.S.C. §§1 et seq., including 35 U.S.C. § 271, and under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

2. Plaintiffs bring this action to halt Dropworks’s activities that directly and indirectly infringe Plaintiffs’ rights under the Patent Laws of the United States 35 U.S.C. § 1, *et. seq.*, which arise under U.S. Patent Nos. 8,304,193 (“’193 Patent”) and 9,127,310 (“’310 Patent”) (collectively, the “Asserted Patents”).

THE PARTIES

3. Bio-Rad is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 1000 Alfred Nobel Drive, Hercules, California

94547. Bio-Rad is the exclusive licensee of the '193 Patent and the patent owner of the '310 Patent.

4. The University of Chicago is a research university incorporated as an Illinois not-for-profit corporation, with its principal place of business at 5801 S. Ellis Avenue, Chicago, Illinois 60637. The University is the patent owner and licensor of the '193 Patent.

5. Dropworks is a company organized and existing under the laws of Delaware, with its principal place of business at 2560 55th Street, Suite 100, Boulder, Colorado 80301.

JURISDICTION AND VENUE

6. This action for patent infringement arises under the patent laws of the United States, Title 35 of the United States Code.

7. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a).

8. This Court has personal jurisdiction over Dropworks because Dropworks is incorporated in Delaware. Dropworks has purposefully availed itself of the benefits and protections of Delaware state law by incorporating under Delaware law.

9. Venue is proper in this District under 28 U.S.C. §§ 1391(b) and (c), and 1400(b) because Dropworks is a Delaware corporation, and Delaware is a convenient forum for resolution of the parties' disputes set forth herein.

BACKGROUND

10. Since its founding, Bio-Rad has led the transformation in disease research by making innovative tools using its proprietary technologies that simplify complex genetic analysis. In particular, as relevant to this proceeding, Bio-Rad has pioneered the introduction of droplet digital PCR ("ddPCR"), a method for performing digital PCR that is based on water-oil emulsion

droplet technology. During this process, droplets are formed in a water-oil emulsion to form the partitions that separate the template DNA molecules. The droplets serve essentially the same function as individual test tubes or wells in a plate in which the PCR reaction takes place, albeit in a much smaller format. The massive sample partitioning is a key aspect of the ddPCR technique. The ddPCR technique is capable of partitioning nucleic acid samples into thousands of droplets that may be on the order of nanoliters in volume, and PCR amplification is carried out within each droplet. In addition to offering unparalleled sensitivity, this technique has a smaller sample requirement than other commercially available digital PCR systems, reducing cost and preserving precious samples.

11. Dropworks was incorporated in the State of Delaware on June 16, 2016. Dropworks has been developing a product that performs ddPCR. According to Dropworks' website and other public information, this product is built upon the core technology of forming an emulsion of droplets containing nucleic acids and other reagents for PCR. In particular, this product flows samples through microchannels and partitions the samples into droplets dispersed in an immiscible fluid. The product then adjusts the thermal conditions of the droplet-based emulsion to amplify targeted regions of nucleic acid. The product then detects and quantifies up to four different genetic targets via optical means that measure light emitted from the amplified targets. Each of these steps occurs within a single device. On information and belief, the design of this product is substantially fixed with respect to these steps. Dropworks currently refers to this product as its Continuum Digital Assay Platform.

12. On information and belief, Dropworks tests and uses the Continuum Digital Assay Platform in connection with its internal work towards development and commercialization of the Continuum Digital Assay Platform.

13. Dropworks has made, and will continue to make, substantial preparation in the United States to manufacture, sell, offer to sell, import into the United States, and otherwise provide its Continuum Digital Assay Platform and accompanying chemical reagents to potential customers for their use.

14. On information and belief, Dropworks plans to launch its Continuum Digital Assay Platform for public sale and use. Dropworks has actively engaged in marketing its Continuum Digital Assay Platform in preparation for the commercial launch. For example, (1) Dropworks's website (dropworks.com) provides detailed images and specifications of the Continuum Digital Assay Platform and touts its alleged benefits over digital PCR approaches (*see* Exhibit I); (2) Dropworks has demonstrated and/or provided product information about its Continuum Digital Assay Platform at industry meetings, including the ASHG 2019 Annual Meeting and the ABRF 2020 Annual Meeting (*see* Exhibits J-N); (3) Dropworks maintains and actively updates social media sites, such as Twitter and LinkedIn, with information about its Continuum Digital Assay Platform (*see* Exhibits O-P); and (4) Dropworks has been expanding its marketing and sales resources, including by recently hiring a Director of Marketing (*see* Exhibit Q).

15. Additionally, Dropworks has been in contact with potential customers about offers to sell its Continuum Digital Assay Platform and plans to provide these potential customers with its Continuum Digital Assay Platform and accompanying chemical reagents imminently.

16. Dropworks directly infringes the '193 Patent and '310 Patent through the testing and use of its Continuum Digital Assay Platform. Additionally, there is a substantial controversy of sufficient immediacy and reality regarding whether Dropworks will indirectly infringe the '193 Patent and the '310 Patent.

COUNT I
(Direct Infringement of U.S. Patent No. 8,304,193)

17. Plaintiffs re-allege and incorporate by reference the allegations contained in paragraphs 1 through 16 above as relevant to this count.

18. On November 6, 2012, the United States Patent and Trademark Office duly and legally issued U.S. Patent No. 8,304,193 B2 (“’193 Patent”), entitled “Method for Conducting an Autocatalytic Reaction in Plugs in a Microfluidic System.” A copy of the ’193 Patent is attached as Exhibit A.

19. Rustem F. Ismagilov, Joshua David Tice, Cory John Gerdts, and Bo Zheng, are the sole and true inventors of the ’193 Patent. By operation of law and as a result of written assignment agreements, the University of Chicago obtained the entire right, title and interest to and in the ’193 Patent.

20. Pursuant to license agreements Bio-Rad entered into with the University of Chicago, Bio-Rad obtained an exclusive license to the ’193 Patent in the field of microfluidic systems, kits and chips.

21. Dropworks has infringed and continues to infringe one or more claims of the ’193 Patent pursuant to 35 U.S.C. § 271(a), literally or under the doctrine of equivalents, by making and/or using in the United States without authority, digital droplet PCR products, devices, systems, and/or components of systems that include the claimed method for conducting an autocatalytic reaction in plugs in a microfluidic system, including, but not limited to, Dropworks’s Continuum Digital Assay Platform.

22. To demonstrate how Dropworks infringes claim 1 of the ’193 Patent, attached is a preliminary and exemplary claim chart. Exhibit C. This chart is not intended to limit Plaintiffs’ rights to modify this chart or any other claim chart or allege that other activities of Dropworks

infringe the identified claims or any other claims of the '193 Patent or any other patents. This chart is hereby incorporated by reference in its entirety. Each claim element that is charted shall be considered an allegation within the meaning of the Federal Rules of Civil Procedure and therefore a response to each allegation is required.

23. Dropworks has had knowledge of the '193 Patent at least as early as August 20, 2019 when it cited the '193 Patent in an IDS filed in United States Patent Application Serial No. 16/413,416, entitled "Systems and Methods Related to Continuous Flow Droplet Reaction." A copy of the IDS is attached as Exhibit G. Dropworks also cited the '193 Patent in a January 2, 2020 IDS filed in United States Patent Application Serial No. 16/372,290, entitled "Systems and Methods for Serial Flow Emulsion Processes." A copy of the IDS is attached as Exhibit H. In addition, Dropworks has had knowledge of and notice of the '193 Patent and its infringement since at least, and through, the filing and service of the Complaint and despite this knowledge continues to commit the aforementioned infringing acts.

24. Moreover, upon information and belief, Dropworks monitors the intellectual property portfolios of companies engaged in the development of products based on microfluidic droplet technology, including companies engaged in the development of droplet-based PCR technology. On information and belief, one such company Dropworks monitors is Bio-Rad. By virtue of its monitoring of Bio-Rad's patent portfolio, Dropworks has become aware of the '193 Patent and the fact that it infringes. Despite this knowledge, Dropworks continues to commit the aforementioned infringing acts.

25. Dropworks's infringement of the '193 Patent has injured Bio-Rad and the University of Chicago in their business and property rights. Bio-Rad and the University of Chicago

are entitled to recover monetary damages for such injuries pursuant to 35 U.S.C. § 284 in an amount to be determined at trial.

26. Dropworks's infringement of the '193 Patent has caused irreparable harm to Bio-Rad and the University of Chicago and will continue to cause such harm unless and until Dropworks's infringing activities are enjoined by this Court.

27. Upon information and belief, Dropworks's infringement of the '193 Patent has been and is deliberate and willful, entitling Bio-Rad and the University of Chicago to increased damages under 35 U.S.C. § 284 and to attorney's fees and costs incurred in prosecuting this action under 35 U.S.C. § 285. Dropworks has cited the '193 Patent in its publicly available patent applications, which indicates Dropworks had actual knowledge of the '193 Patent. Dropworks has infringed and continues to infringe the '193 Patent despite an objectively high likelihood that its actions constitute infringement.

COUNT II
(Declaratory Judgment of Indirect Infringement of the '193 Patent)

28. Plaintiffs re-allege and incorporate by reference the allegations contained in paragraphs 1 through 27 above as relevant to this count.

29. This count arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

30. Dropworks has had knowledge of the '193 Patent at least as early as August 20, 2019.

31. On information and belief, Dropworks has contacted third-parties, including at least one of Bio-Rad's customers, with the specific intent to provide them with Dropworks's Continuum Digital Assay Platform and accompanying chemical reagents for their use and testing. The claim chart attached hereto as Exhibit C demonstrates how such use and testing by these third-parties will directly infringe the '193 Patent.

32. On information and belief, the design of the Continuum Digital Assay Platform is substantially fixed at least with respect to the features and performance of steps identified in Exhibit C. *See also* Exhibit I.

33. On information and belief, Dropworks plans to provide its Continuum Digital Assay Platform to these third-parties imminently.

34. By actively engaging in marketing efforts and contacting the aforementioned third-parties to provide them with its Continuum Digital Assay Platform and accompanying chemical reagents with the knowledge that using the Continuum Digital Assay Platform with the accompanying chemical reagents infringes the '193 Patent, Dropworks has actively engaged in present activity and/or taken concrete steps to induce the infringement of the '193 Patent pursuant to 35 U.S.C. § 271(b).

35. Likewise, by actively engaging in marketing efforts and contacting the aforementioned third-parties to provide them with its Continuum Digital Assay Platform and accompanying chemical reagents with the knowledge that the Continuum Digital Assay Platform or accompanying chemical reagents (1) constitutes a material part of the inventions of the '193 Patent, (2) is especially made or adapted to infringe the '193 Patent, (3) and is not a staple article or commodity of commerce suitable for non-infringing use, Dropworks has actively engaged in present activity and/or taken concrete steps to contribute to the infringement of the '193 Patent pursuant to 35 U.S.C. § 271(c).

36. By virtue of Dropworks's activities, there is an actual case or controversy such that the Court may entertain Bio-Rad and the University of Chicago's request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

37. Bio-Rad and the University of Chicago are entitled to a declaratory judgment that Dropworks will be liable for induced infringement and contributory infringement.

COUNT III
(Direct Infringement of U.S. Patent No. 9,127,310)

38. Plaintiffs re-allege and incorporate by reference the allegations contained in paragraphs 1 through 37 above as relevant to this count.

39. On September 8, 2015, the United States Patent and Trademark Office duly and legally issued U.S. Patent No. 9,127,310 (“’310 Patent”), entitled “Digital Analyte Analysis.” A copy of the ’310 Patent is attached to the Complaint as Exhibit B.

40. Jonathan William Larson, Qun Zhong, and Darren R. Link, are the sole and true inventors of the ’310 Patent. By operation of law and as a result of written assignment agreements, Bio-Rad obtained the entire right, title and interest to and in the ’310 Patent.

41. On information and belief, Dropworks has infringed and continues to infringe one or more claims of the ’310 Patent pursuant to 35 U.S.C. § 271(a), literally or under the doctrine of equivalents, by making and/or using in the United States without authority, digital droplet PCR products, devices, systems, and/or components of systems that include the claimed method for detecting target sequences from a sample, including, but not limited to, Dropworks’s Continuum Digital Assay Platform.

42. To demonstrate how Dropworks infringes claim 1 of the ’310 Patent, attached is a preliminary and exemplary claim chart. Exhibit D. This chart is not intended to limit Plaintiffs’ rights to modify this chart or any other claim chart or allege that other activities of Dropworks infringe the identified claims or any other claims of the ’310 Patent or any other patents. This chart is hereby incorporated by reference in its entirety. Each claim element that is charted shall

be considered an allegation within the meaning of the Federal Rules of Civil Procedure and therefore a response to each allegation is required.

43. Dropworks has had knowledge of the '310 Patent at least as early as August 20, 2019 when it cited the '310 Patent in an IDS filed in United States Patent Application Serial No. 16/413,416, entitled "Systems and Methods Related to Continuous Flow Droplet Reaction." A copy of the IDS is attached as Exhibit G. Dropworks also cited the '310 Patent in a January 2, 2020 IDS filed in United States Patent Application Serial No. 16/372,290, entitled "Systems and Methods for Serial Flow Emulsion Processes." A copy of the IDS is attached as Exhibit H. In addition, Dropworks has had knowledge of and notice of the '310 Patent and its infringement since at least, and through, the filing and service of the Complaint and despite this knowledge continues to commit the aforementioned infringing acts.

44. Moreover, upon information and belief, Dropworks monitors the intellectual property portfolios of companies engaged in the development of products based on microfluidic droplet technology, including companies engaged in the development of droplet-based PCR technology. On information and belief, one such company Dropworks monitors is Bio-Rad. By virtue of its monitoring of Bio-Rad's patent portfolio, Dropworks has become aware of the '310 Patent and the fact that it infringes. Despite this knowledge, Dropworks continues to commit the aforementioned infringing acts.

45. Dropworks's infringement of the '310 Patent has injured Bio-Rad in its business and property rights. Bio-Rad is entitled to recover monetary damages for such injuries pursuant to 35 U.S.C. § 284 in an amount to be determined at trial.

46. Dropworks's infringement of the '310 Patent has caused irreparable harm to Bio-Rad and will continue to cause such harm unless and until Dropworks's infringing activities are enjoined by this Court.

47. Upon information and belief, Dropworks's infringement of the '310 Patent has been and is deliberate and willful, entitling Bio-Rad to increased damages under 35 U.S.C. § 284 and to attorney's fees and costs incurred in prosecuting this action under 35 U.S.C. § 285. Dropworks has cited the '310 Patent in its publicly available patent applications, which indicates Dropworks had actual knowledge of the '310 Patent. Dropworks has infringed and continues to infringe the '310 Patent despite an objectively high likelihood that its actions constitute infringement.

COUNT IV
(Declaratory Judgment of Indirect Infringement of the '310 Patent)

48. Plaintiffs re-allege and incorporate by reference the allegations contained in paragraphs 1 through 47 above as relevant to this count.

49. This count arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

50. Dropworks has had knowledge of the '310 Patent at least as early as August 20, 2019.

51. On information and belief, Dropworks has contacted third-parties, including at least one of Bio-Rad's customers, with the specific intent to provide them with Dropworks's Continuum Digital Assay Platform and accompanying chemical reagents for their use and testing. The claim chart attached hereto as Exhibit D demonstrates how such use and testing by these third-parties will directly infringe the '310 Patent.

52. On information and belief, the design of the Continuum Digital Assay Platform is substantially fixed at least with respect to the features and performance of steps identified in Exhibit D. *See also* Exhibit I.

53. On information and belief, Dropworks plans to provide its Continuum Digital Assay Platform to these third-parties imminently.

54. By actively engaging in marketing efforts and contacting the aforementioned third-parties to provide them with its Continuum Digital Assay Platform and accompanying chemical reagents with the knowledge that using the Continuum Digital Assay Platform with the accompanying chemical reagents infringes the '310 Patent, Dropworks has actively engaged in present activity and/or taken concrete steps to induce the infringement of the '310 Patent pursuant to 35 U.S.C. § 271(b).

55. Likewise, by actively engaging in marketing efforts and contacting the aforementioned third-parties to provide them with its Continuum Digital Assay Platform and accompanying chemical reagents with the knowledge that the Continuum Digital Assay Platform or accompanying chemical reagents (1) constitutes a material part of the inventions of the '310 Patent, (2) is especially made or adapted to infringe the '310 Patent, (3) and is not a staple article or commodity of commerce suitable for non-infringing use, Dropworks has actively engaged in present activity and/or taken concrete steps to contribute to the infringement of the '310 Patent pursuant to 35 U.S.C. § 271(c).

56. By virtue of Dropworks's activities, there is an actual case or controversy such that the Court may entertain Bio-Rad's request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

57. Bio-Rad is entitled to a declaratory judgment that Dropworks will be liable for induced infringement and contributory infringement.

PRAYER FOR RELIEF

WHEREFORE, Bio-Rad and the University of Chicago pray for relief with respect to the '193 Patent as follows:

A. Declaration and judgment that Dropworks's present and/or future activity constitutes infringement of the '193 Patent directly, by inducement, as contributory infringement, and/or otherwise;

B. An order permanently enjoining Dropworks from engaging in activities that directly or indirectly infringe the '193 Patent;

C. An award of damages pursuant to 35 U.S.C. § 284;

D. An award to Bio-Rad and the University of Chicago of their costs and reasonable expenses to the fullest extent permitted by law and pre- and post-judgment interest;

E. A declaration that this case is exceptional pursuant to 35 U.S.C. § 285, and an award of attorney's fees and costs; and

F. An award of such other and further relief as the Court may deem just and proper.

WHEREFORE, Bio-Rad individually prays for relief with respect to the '310 Patent as follows:

A. Declaration and judgment that Dropworks's present and/or future activity constitutes infringement of the '310 Patent directly, by inducement, as contributory infringement, and/or otherwise;

B. An order permanently enjoining Dropworks from engaging in activities that directly or indirectly infringe the '310 Patent;

C. An award of damages pursuant to 35 U.S.C. § 284;

D. An award to Bio-Rad of its costs and reasonable expenses to the fullest extent permitted by law and pre- and post-judgment interest;

E. A declaration that this case is exceptional pursuant to 35 U.S.C. § 285, and an award of attorney's fees and costs; and

F. An award of such other and further relief as the Court may deem just and proper.

DEMAND FOR JURY TRIAL

Pursuant to Federal Rule of Civil Procedure 38(b), Plaintiffs hereby demand a trial by jury on all issues so triable.

Dated: April 14, 2020

Respectfully submitted,

Of Counsel:

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