IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

BIO-RAD LABORATORIES, INC.,)	
)	
Plaintiff,)	
)	
v.)	C.A. No
)	
THERMO FISHER SCIENTIFIC INC.,)	JURY TRIAL DEMANDED
)	
Defendant.)	

COMPLAINT FOR PATENT INFRINGEMENT

Bio-Rad Laboratories, Inc. ("Bio-Rad"), for its complaint against Thermo Fisher Scientific Inc. ("TFS"), avers as follows:

THE PARTIES

- 1. Bio-Rad is a corporation organized and existing under the laws of the State of Delaware, having a place of business at 1000 Alfred Nobel Drive, Hercules, California 94547.
- 2. TFS is, on information and belief, a Delaware corporation having a place of business at 81 Wyman Street, Waltham, Massachusetts 02451.

JURISDICTION AND VENUE

- 3. This is an action for patent infringement arising under the patent laws of the United States, Title 35 of the United States Code.
- 4. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338.
- 5. This Court has personal jurisdiction over TFS because, on information and belief, TFS is a Delaware corporation and transacts business in this judicial district. In addition, on information and belief, TFS is registered to conduct business within the State of Delaware and

maintains as a registered agent, Capital Services, Inc., 1675 S. State Street, Suite B, Dover, DE 19901.

- 6. This Court further has personal jurisdiction over TFS because TFS has committed, or aided, abetted, contributed, and/or participated in the commission of tortious acts of patent infringement that have led to foreseeable harm and injury to Bio-Rad, which is a corporation organized and existing under the laws of the State of Delaware.
 - 7. Venue is proper pursuant to 28 U.S.C. §§ 1391 and 1400.

THE PATENT-IN-SUIT

8. On April 18, 2017, the U.S. Patent and Trademark Office duly and lawfully issued U.S. Patent No. 9,623,414 ("the 414 Patent"), entitled "Localized Temperature Control for Spatial Arrays of Reaction Media," naming Jeff Ceremony *et al.* as the inventors. The 414 Patent is in force. Bio-Rad is the lawful owner of all right, title and interest in the 414 Patent and has the right to sue and to recover for past infringement of the 414 Patent. A copy of the 414 Patent is attached as Exhibit A.

BACKGROUND

- 9. Bio-Rad manufactures a broad range of products for the life science research and clinical diagnostic markets. Bio-Rad distributes its products to research, industry, and clinical laboratories around the world.
- 10. Bio-Rad designs, develops, makes, and sells polymerase chain reaction ("PCR") systems, including real-time PCR systems. In real-time PCR, target DNA molecules are amplified by PCR and monitored in real-time using, for example, fluorescent dyes that become associated with the DNA. Amplification of DNA using PCR can result in generation of thousands to millions of copies of a target DNA sequence from only one or a few copies. Amplification can be accomplished within the PCR system by placing sample tubes containing

DNA to be amplified into wells of a "thermal block," and raising and lowering the temperature of the block. As DNA in a sample is amplified during real-time PCR, an increase in fluorescence intensity can be measured. Bio-Rad sells PCR systems under its brand names CFX96 Touch™, CFX96 Touch™ Deep Well, CFX384 Touch™, and CFX Connect™. Each of these systems comprises a thermal block configuration that falls within the scope of claims of the 414 Patent.

11. TFS makes, uses, sells, and offers for sale in the United States PCR systems, including the QuantStudio[™] 3 and QuantStudio[™] 5 real-time PCR Systems, the ProFlex[™] PCR system, the Veriti® thermal cycler, and the StepOnePlus[™] PCR system (together, the "TFS PCR Systems").

INFRINGEMENT OF THE 414 PATENT

- 12. Plaintiff realleges and incorporates by reference each of the allegations set forth in Paragraphs 1-11.
- 13. TFS has infringed at least claims 1, 6 and 7 of the 414 Patent by making, using, selling, and offering to sell PCR systems, including at least the TFS PCR Systems, without authority or license from Bio-Rad.
- 14. Claim 1 of the 414 Patent is directed to an apparatus for performing polymerase chain reactions in a plurality of samples. Claim 1 recites that the apparatus comprises: (1) a plurality of thermally conductive sample blocks for polymerase chain reactions, arranged in a fixed horizontal array, wherein each sample block comprises a plurality of sample wells and is configured to retain a plurality of samples; (2) a plurality of independently controlled thermoelectric modules configured to cycle the temperatures of the sample blocks for polymerase chain reactions, a thermoelectric module positioned underneath each said sample block; (3) a layer of thermally conductive material between each sample block and each

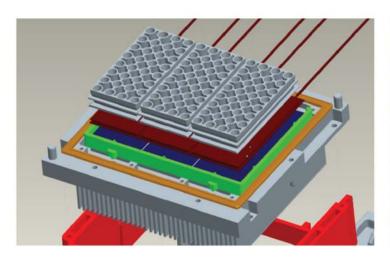
thermoelectric module; and (4) a solid barrier of thermally insulating material positioned between each pair of adjacent sample blocks.

- 15. A document entitled "QuantStudio 3 and QuantStudio 5 Real-Time PCR Systems" ("QuantStudio™ Guide") is provided on TFS's website. A copy of this document, accessed on April 19, 2017 from https://tools.thermofisher.com/content/sfs/manuals/ MAN0010407_QuantStudio3_5_InstallUseMaint_UG.pdf, is attached as Exhibit B. The QuantStudio™ Guide bears a copyright notice of 2015. On information and belief, the QuantStudio™ Guide describes certain features and applications of the QuantStudio 3 and QuantStudio 5 systems made, used, and sold by TFS.
- 16. A document entitled "ProFlexTM PCR System User Guide" ("ProFlexTM Guide") is provided on TFS's website. A copy of this document, accessed on April 19, 2017 from https://tools.thermofisher.com/content/sfs/manuals/MAN0007697.pdf, is attached as <u>Exhibit C</u>. The ProFlexTM Guide bears a copyright notice of 2016. On information and belief, the ProFlexTM Guide describes certain features and applications of the ProFlexTM system made, used, and sold by TFS.
- 17. A document entitled "Applied Biosystems VeritiTM Thermal Cycler User Guide" ("VeritiTM Guide") is provided on TFS's website (upon information and belief, TFS became owner of all Applied Biosystems products upon its 2014 acquisition of Life Technologies Corporation). A copy of this document, accessed on April 19, 2017 from https://tools.thermofisher.com/content/sfs/manuals/cms_042832.pdf, is attached as Exhibit D. The VeritiTM Guide bears a copyright notice of 2010. On information and belief, the VeritiTM Guide describes certain features and applications of the VeritiTM thermal cycler made, used, and sold by TFS.

- 18. A document entitled "StepOne and StepOnePlus Real-Time PCR Systems" ("StepOnePlus™ Brochure") is provided on TFS's website. A copy of this document, accessed on April 19, 2017 from https://tools.thermofisher.com/content/sfs/brochures/cms_042763.pdf, is attached as Exhibit E. The StepOnePlus™ Brochure bears a copyright notice of 2016. On information and belief, the StepOnePlus™ Brochure describes certain features and applications of the StepOnePlus™ system made, used, and sold by TFS.
- 19. Each of the TFS PCR Systems contain "VeriFlexTM blocks." Exhibit B, pp. 10, 13; Exhibit C, pp. 7, 73; Exhibit D, pp. 1.2, 3.16; Exhibit E, pp. 3, 7. A document describing the structure and operation of the VeriFlexTM block, entitled "VeriFlex temperature control technology for thermal cycling," is available on TFS's website¹ ("VeriFlexTM Application Note") and attached as Exhibit F.
- 20. Images of the VeriFlexTM block configuration are shown below. The image on the left, copied from the second page of Exhibit F, depicts "VeriFlex technology construction." Three metal blocks (shown in gray) are positioned above three heating/cooling elements (red). The image on the right, copied from page 7 of Exhibit E, depicts a 96-well VeriFlexTM block. Here, "six independently controllable peltier blocks" are shown. Exhibit E, p. 7. Each image depicts a plurality of independently controllable blocks that contain a plurality of wells for holding samples arranged in a horizontal array. Therefore, the VeriFlexTM blocks used in the TFS PCR Systems satisfy the first element of claim 1 of the 414 Patent.

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Accessed from https://www.thermofisher.com/content/dam/LifeTech/global/life-sciences/PCR/pdfs/App-note-Temperature-control-VeriFlex-vs-Gradient-Global-FHR.pdf on April 19, 2017.





- 21. According to the VeriFlexTM Application Note "[t]hermal cyclers that use VeriFlex technology are constructed with 3 or more separate heating/cooling elements below each of the 3 or more segmented metal blocks…" Exhibit F, p. 2. This feature of the VeriFlexTM blocks used in the TFS PCR Systems satisfies the second element of claim 1 of the 414 Patent.
- 22. The VeriFlex[™] blocks used in the TFS PCR Systems comprise a layer of thermally conductive material between each sample block and each heating/cooling element. Pictured below is a VeriFlex[™] block system taken from one of TFS's Veriti® thermal cyclers. One of the six metal blocks (the rightmost one) has been removed. Upon information and belief, the white substance present below the block and above the heating/cooling element (*i.e.*, between the block and heating/cooling element) is a thermally conductive material. Thus, the VeriFlex[™] blocks used in the TFS PCR Systems satisfy the third element of claim 1 of the 414 Patent.



- 23. The VeriFlexTM Application Note also states that each "block is physically isolated using heat insulator material to minimize temperature interference among adjacent [] blocks." Exhibit F, p. 4. This feature of the VeriFlexTM blocks used in the TFS PCR Systems satisfies the fourth element of claim 1 of the 414 Patent.
- 24. Based on the foregoing, the VeriFlex[™] blocks used in the TFS PCR Systems literally satisfy each feature of claim 1 of the 414 Patent. Therefore, claim 1 of the 414 Patent is infringed by the TFS PCR Systems.
- 25. Claim 6 of the 414 Patent depends from claim 1, and recites that the fixed horizontal array of thermally conductive sample blocks is a two-dimensional array. As shown in the images above, the VeriFlexTM blocks used in the TFS PCR Systems are arranged in a two-dimensional array. Thus, the TFS PCR Systems literally infringe claim 6 of the 414 Patent.

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26. Claim 7 of the 414 Patent depends from claim 1, and recites that the plurality of sample wells of each sample block is configured to receive a sample plate or portion thereof.

The VeriFlexTM blocks used in each of the TFS PCR Systems are configured to receive a sample plate or portion of one. Exhibit B, pp. 13, 36; Exhibit C, pp. 36-40; Exhibit D, Appendix B; Exhibit E, p. 11. Accordingly, the TFS PCR Systems literally infringe claim 7 of the 414 Patent.

REQUEST FOR RELIEF

WHEREFORE, Bio-Rad respectfully requests that this Court:

- a. adjudge that TFS has infringed one or more claims of the 414 Patent, and that the manufacture, use, sale, offer for sale, and/or importation of TFS's QuantStudio™ 3 and QuantStudio™ 5 real-time PCR Systems, ProFlex™ PCR system, Veriti® thermal cycler, and StepOnePlus™ PCR system, infringe one or more claims of the 414 Patent;
- b. permanently enjoin TFS, its officers, agents, servants, and employees, and those in active concert or participation with any of them, from infringing the 414 Patent;
 - c. award Bio-Rad compensatory damages for TFS's infringement of the 414 Patent;
 - d. declare this to be an exceptional case under 35 U.S.C. § 285;
- e. award Bio-Rad its attorney fees and costs incurred in prosecuting this action, together with pre-judgment and post-judgment interest; and
 - f. grant Bio-Rad such other and further relief as this Court deems just and proper.

JURY DEMAND

Bio-Rad hereby respectfully requests a trial by jury of all issues so triable, pursuant to Rule 38, Fed. R. Civ. P.

ASHBY & GEDDES

/s/ Andrew C. Mayo

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April 25, 2017