PUBLIC VERSION

UNITED STATES INTERNATIONAL TRADE COMMISSION

Washington, D.C.

In the Matter of	
CERTAIN MICROFLUIDIC SYSTEMS AND COMPONENTS THEREOF AND PRODUCTS CONTAINING SAME	**Inv. No. 337-TA-1100**

ORDER NO. 35: DENYING RESPONDENT'S MOTION FOR SUMMARY DETERMINATION OF NON-INFRINGEMENT

(March 5, 2019)

On November 16, 2018, Respondent Bio-Rad Laboratories, Inc. ("Bio-Rad") filed a motion for summary determination that its products do not infringe the asserted claims of U.S. Patent Nos. 9,856,530 (the "'530 patent") and 9,644,204 (the "'204 patent") (Motion Docket No. 1100-021). Complainant 10X Genomics, Inc. ("10X") filed a response in opposition on November 28, 2018. The Commission Investigative Staff ("Staff") also filed a response in opposition on November 28, 2018. Bio-Rad filed a reply brief on December 3, 2018.

I. BACKGROUND

The '530 patent and the '204 patent are two of the four patents asserted in this investigation. *See* Notice of Investigation (Feb. 12, 2018). 10X asserts that Bio-Rad infringes claims 1, 4, 11, 14, 19, 26, and 28 of the '530 patent and claims 27, 29, 31, and 33 of the '204 patent. Order No. 27 at 2 n. 3 (Dec. 10, 2018).

A. '530 Patent

All of the asserted claims of the '530 patent depend directly or indirectly from claim 1, which recites:

A method for nucleic acid preparation or analysis, comprising:

(a) providing:

(i) at least 1,000 gel beads;

(ii) releasably attached to each of said at least 1,000 gel beads, at least 1,000 barcode molecules comprising identical barcode sequences that are distinct from barcode sequences of at least 1,000 barcode molecules releasably attached to any other gel bead of said at least 1,000 gel beads; and

(iii) a plurality of cells each comprising a plurality of polynucleotide molecules;

(b) generating a plurality of droplets, wherein at least 1,000 droplets of said plurality of droplets each comprise:

(i) a single gel bead from said at least 1,000 gel beads; and

(ii) a single cell from said plurality of cells; and

(c) in each of said at least 1,000 droplets, using said plurality of polynucleotide molecules from said single cell and barcode molecules of said at least 1,000 barcode molecules from said single gel bead to generate a plurality of barcoded polynucleotide molecules,

wherein said barcode molecules become detached from said gel bead.

'530 patent, col. 47:58-67, col. 48:57-col. 49:4. As stated in the *Markman* order, this claim is directed to a three-step method. Order No. 22 at 45 (Oct. 31, 2018). The first step requires "providing" at least 1,000 gel beads and "a plurality of cells." '530 patent, col. 47:60-67 & col. 48:58-64. Barcode molecules are attached to each of the gel beads and each of the cells contains polynucleotides. *Id.* The second step requires generating "a plurality of droplets, wherein at least 1,000 droplets of said plurality of droplets each" have "a single gel bead from said plurality of cells" and "a single cell from said plurality of cells." *Id.*, col. 48:60-64. The third step requires using the polynucleotide molecules and barcode molecules to form "a plurality of barcoded polynucleotide molecules" "in each of said 1,000 droplets." *Id.*, col. 48:65-col. 49:4.

The *Markman* order rejected Bio-Rad's proposed construction of this claim requiring that the method be performed "in one experiment," but clarified that the claim requires that all of the

"at least 1,000 droplets" in the second step be generated before the third step of the claim is performed on any of "said at least 1,000 droplets." Order No. 22 at 48-49.

B. '204 Patent

The asserted claims of the '204 patent depend from independent claims 1, 23, and 25. Claim 1 recites a "composition comprising a plurality of capsules, said capsules situated within droplets in an emulsion," claim 23 recites a device comprising a capsule, and claim 25 recites a method comprising a step of "providing a plurality of" capsules. '204 patent, col. 44:42-48, col. 45:51-58, col. 46:3-12. Each of these claims requires that the claimed capsules "are configured to release their contents into said droplets upon the application of a stimulus," and that "said stimulus is selected from the group consisting of a change in pH, a change in ion concentration, reduction of disulfide bonds, and combinations thereof." *Id.*

II. LEGAL STANDARDS

In section 337 investigations, Commission Rule 210.18 governs motions for summary determination:

> The determination sought by the moving party shall be rendered if pleadings and any depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a summary determination as a matter of law.

19 C.F.R. § 210.18(b). By analogy to Fed. R. Civ. P. 56 (a), in deciding whether to grant summary determination, the evidence "must be viewed in the light most favorable to the party opposing the motion . . . with doubts resolved in favor of the nonmovant." *Crown Operations Int'l, Ltd. v. Solutia, Inc.*, 289 F.3d 1367, 1375 (Fed. Cir. 2002) (citations omitted); *see also Xerox Corp. v. 3Com Corp.*, 267 F.3d 1361, 1364 (Fed. Cir. 2001) ("When ruling on a motion for summary judgment, all of the nonmovant's evidence is to be credited, and all justifiable

inferences are to be drawn in the nonmovant's favor."). The court should "assure itself that there is no reasonable version of the facts, on the summary judgment record, whereby the nonmovant could prevail, recognizing that the purpose of summary judgment is not to deprive a litigant of a fair hearing, but to avoid an unnecessary trial." *EMI Group N. Am., Inc. v. Intel Corp.*, 157 F.3d 887, 891 (Fed. Cir. 1998) (citations omitted). "In other words, '[s]ummary judgment is authorized when it is quite clear what the truth is' . . . and the law requires judgment in favor of the movant based upon facts not in genuine dispute." *Paragon Podiatry Lab., Inc. v. KLM Labs., Inc.*, 984 F.2d 1182, 1185 (Fed. Cir. 1993) (citations omitted).

III. DISCUSSION

Bio-Rad contends that the accused products do not infringe the asserted claims of the '530 patent and the '204 patent, relying on the analysis of its expert, Michael L. Metzker.

A. Accused Products

The accused products are Bio-Rad's ddSEQ products and components used as part of Bio-Rad's Single-Cell Sequencing Solution. *See* Complaint ¶ 24. Bio-Rad's process generates droplets that each contain a single cell and a single gel bead. Motion Memo. at 6-8. [redacted]. *Id.* at 8-9; 10X Opp. at 7-8. The droplets also contain enzymes and reagents that facilitate cell lysis and the release of certain molecules from the gel beads. *Id.* at 9-10; Opp. at 19-23.

B. Infringement of the '530 patent

Bio-Rad submits that the accused products do not infringe the '530 patent because [redacted].

Motion Memo. at 12-15. Bio-Rad contends that it is undisputed that [redacted]. Reply at 8-10.

10X disputes Bio-Rad's description of the accused process, citing to Bio-Rad documents describing the subsequent step of placing the droplets in a thermal cycler that incubates the droplets at high temperatures. 10X Opp. at 5-12. According to 10X's expert Atul Butte, [redacted]. *Id.* 10X further disputes the veracity of Dr. Metzger's opinion [redacted], arguing that this at least creates a dispute of material fact. *Id.* at 12-13. In addition, 10X argues that Bio-Rad's motion is legally incorrect, because the presence of added steps in an accused method does not preclude infringement, and the steps of a method can satisfy the required order as long as the subsequent step is completed after the completion of the previous step. *Id.* at 13-19 (citing *Northern Telecom, Inc. v. Datapoint Corp.*, 908 F.2d 931, 945 (Fed. Cir. 1990) ("The addition of features does not avoid infringement, if all the elements of the patent claims have been adopted.")).

The motion is denied with respect to the '530 patent because Bio-Rad's arguments are premised on an incorrect interpretation of the claim language and a misreading of the *Markman* order. The issue addressed in the *Markman* order was whether the steps of the claim could be repeated multiple times to satisfy the "at least 1,000 droplets" limitation. *See* Order No. 22 at

46-51. I found that the claims would not cover such a repeated process, requiring that the "at least 1,000 droplets" be generated in the second step before the "plurality of barcoded polynucleotide molecules" are generated in the third step. *Id.* at 48-51. Bio-Rad reads the claims to require "that all 1,000 droplets form before any barcoding begins," Reply at 8, but no such limitation was contemplated in the *Markman* order. The claim language merely requires that any accused step of generating a plurality of barcoded molecules occurs after the at least 1,000 droplets are generated. 10X has identified [redacted] the accused third step, which indisputably occurs after at least 1,000 droplets are generated. This is consistent with the claimed order of steps, regardless of what reactions may occur during the second step while the droplets are generated.

The facts regarding the accused process are similar to *Kaneka Corp. v. Xiamen Kingdomway Group Co.*, where the Federal Circuit reversed a non-infringement finding based on "passive oxidation" that occurred prior to a claimed oxidation step. 790 F.3d 1298, 1306, (Fed. Cir. 2015) ("We disagree that the claimed order excludes passive oxidation during other process steps. The claims' preamble term 'comprises' indicates that additional oxidation steps or results are not excluded. Requiring active oxidation during the oxidation step preserves the claimed order, but does not exclude passive oxidation during other steps.") (citations omitted). Here, the generation of barcoded molecules at room temperature does not preclude a finding of infringement based on a subsequent step of generating barcoded molecules in a thermal cycler. Bio-Rad's motion relies on an incorrect interpretation of the asserted claims, and accordingly, summary determination is denied with respect to the '530 patent.

C. Infringement of the '204 patent

In the accused products, the droplets contain [redacted]. *Id.* at 9-10; Opp. at 19-23. The '204 patent requires that this release occur upon the application of a stimulus that "is selected from the group consisting of a change in pH, a change in ion concentration, reduction of disulfide bonds, and combinations thereof." '204 patent, claims 1, 23, and 25. Bio-Rad submits that the accused products do not infringe the '204 patent [redacted]. Motion Memo. at 15-19.

10X maintains that Bio-Rad infringes this limitation, relying on Dr. Butte's identification [redacted]. 10X Opp. at 20-23. According to Dr. Butte, this is "a change in ion concentration" that infringes the asserted claims of the '204 patent. *Id.* 10X further alleges infringement under the doctrine of equivalents based on Dr. Butte's opinion that the "[redacted]" in the accused products is equivalent to the claimed "reduction of disulfide bonds" under a function-way-result analysis. 10X Opp. at 30-34.

Bio-Rad argues that there is insufficient evidence in the record to support 10X's infringement allegations, because no discovery was obtained from the manufacturer of [redacted]. Reply at 15-17. In the absence of this third-party discovery, Dr. Butte relies on deposition testimony from a Bio-Rad scientist, Jeremy Agresti. Motion Ex. 5, Butte Expert Report, Appendix B ¶¶ 60-61. Bio-Rad argues that Dr. Agresti's testimony regarding [redacted] is unreliable, however, because he admitted at his deposition that "[redacted]." Motion Ex. 14, Agresti Dep. Tr. at 423. Dr. Agresti also testified, however, [redacted]

[redacted] *Id.* at 422-25. Although I agree with Bio-Rad that Dr. Agresti's testimony is not the best evidence that 10X could have relied upon to prove infringement, this evidence must be viewed in the light most favorable to 10X on summary determination. A reasonable inference can be drawn from Dr. Agresti's testimony [redacted], and this is the basis for 10X's infringement allegations. 10X Opp. at 20-23. I agree with Staff that there is a genuine dispute of material fact [redacted], Staff Opp. at 7-8, and accordingly, summary determination on literal infringement is denied.

Bio-Rad further argues that summary determination of non-infringement is warranted with respect to the doctrine of equivalents. Motion Memo. at 18-19. Bio-Rad submits that the claim language enumerating a *Markush* group "consisting of" three options "creates a very strong presumption that that claim element is closed and therefore excludes any elements, steps or ingredients not specified in the claim." *Multilayer Stretch Cling Film Holdings, Inc. v. Berry Plastics Corp.*, 831 F.3d 1350, 1357 (Fed. Cir. 2016). (internal quotations removed). This does not, however, preclude a finding of infringement under the doctrine of equivalents. *See Vehicular Techs. Corp. v. Titan Wheel Int'l, Inc.*, 212 F.3d 1377, 1383 (Fed. Cir. 2000) ("[T]he drafter's choice of the phrase 'consisting of' does not foreclose infringement under the doctrine of equivalents."). Accordingly, although there is a presumption that weighs against this theory, 10X is not legally barred from pursuing infringement under the doctrine of equivalents.

Bio-Rad argues that 10X's doctrine of equivalents allegations rely on "conclusory conjecture," Motion Memo. at 18, but Dr. Butte's expert report provides several factual bases for his opinion [redacted]. Motion Ex. 5, Butte Expert Report, Appendix B ¶¶ 69-75. In particular, Dr. Butte explains that [redacted]. *Id.* ¶ 71. Dr. Butte cites a patent publication that describes uracil as a "trigger residue" that renders a nucleic acid more susceptible to cleavage. *Id.* He further offers his opinion that a reduction of disulfide bonds can be [redacted]. *Id.* Bio-Rad argues that there are no similarities between a "[redacted]" and a "[redacted]," relying on the opinions of Dr. Metzger. Motion Ex. 9, Metgzer Expert Report ¶ 146. This does not directly refute 10X's contentions, however, which rely on similarities between [redacted] and the reduction of disulfide bonds recited in the claim.

Bio-Rad submits that finding [redacted] to be equivalent to a reduction of disulfide bonds would vitiate the limitation reciting three specific stimuli, Motion Memo. at 19, but the record on summary determination is insufficient to make such a finding. The Federal Circuit has held that in a doctrine of equivalents analysis, a court must consider "the totality of the circumstances of each case and determine whether the alleged equivalent can be fairly characterized as an insubstantial change from the claimed subject matter without rendering the pertinent limitation meaningless." *Freedman Seating Co. v. Am. Seating Co.*, 420 F.3d 1350, 1359 (Fed. Cir. 2005). Bio-Rad's motion fails to address the "totality of the circumstances," however, only offering conclusory arguments regarding the differences [redacted]

[redacted]. *See* Motion Memo. at 19 ("[redacted]."). Although the Federal Circuit has held that claim vitiation is a question of law, the cases cited by Bio-Rad rely on context from the asserted patents to make such a determination. *See* Reply at 19-20. For example, in *Trading Techs. Int'l, Inc. v. eSpeed, Inc.*, the Federal Circuit cited a portion of the specification placing the disputed limitation "at the heart of the advantages of the patented invention over prior art." 595 F.3d 1340, 1356 (Fed. Cir. 2010). Bio-Rad does not explain the context of the claim language specifying three stimuli and does not address Dr. Butte's testimony identifying similarities between [redacted] and the claimed reduction of disulfide bonds. On this record, Bio-Rad has failed to carry its burden to show that the "totality of circumstances" warrants summary determination with respect to the doctrine of equivalents.

IV. CONCLUSION

Accordingly, Motion Docket No. 1100-021 is DENIED.

This order is being issued with a confidential designation, and pursuant to Ground Rule 1.10, each party shall submit to the Administrative Law Judge a statement as to whether or not it seeks to have any portion of this order deleted from the public version within seven (7) days. *See* 19 C.F.R. § 210.5(f). The parties' submissions under this subsection need not be filed with the Commission Secretary but shall be submitted by paper copy to the Administrative Law Judge and by e-mail to the Administrative Law Judge's attorney advisor.

A party seeking to have a portion of the order deleted from the public version thereof must attach to its submission a copy of the order with red brackets indicating the portion(s) asserted to contain confidential business information. Redactions should be limited to avoid

depriving the public of the basis for understanding the result and reasoning underlying the decision. Parties who submit excessive redactions may be required to provide an additional written statement, supported by declarations from individuals with personal knowledge, justifying each proposed redaction and specifically explaining why the information sought to be redacted meets the definition for confidential business information set forth in Commission Rule 201.6(a). 19 C.F.R. § 201.6(a).

SO ORDERED.

Dee Lord
Administrative Law Judge

CERTAIN MICROFLUIDIC SYSTEMS AND COMPONENTS THEREOF AND PRODUCTS CONTAINING SAME

Inv. No. 337-TA-1100

PUBLIC CERTIFICATE OF SERVICE

I, Lisa R. Barton, hereby certify that the attached **ORDER** has been served by hand upon the Commission Investigative Attorney, **Monica Bhattacharyya, Esq.**, and the following parties as indicated, on **March 29, 2019.**

Lisa R. Barton, Secretary
U.S. International Trade Commission
500 E Street, SW, Room 112
Washington, DC 20436

On Behalf of Complainants 10X Genomics, Inc.:

Paul T. Ehrlich, Esq.
TENSEGRITY LAW GROUP LLP
555 Twin Dolphin Dr., Suite 650
Redwood Shores, CA 94061

- ☐ Via Hand Delivery
- ☐ Via Express Delivery
- ☑ Via First Class Mail
- ☐ Other:_____

On Behalf of Respondents Bio-Rad Laboratories, Inc.:

S. Alex Lasher, Esq.
QUINN EMANUEL URQUHART & SULLIVAN, LLP
1300 I Street NW, Suite 900
Washington, DC 20005

- ☐ Via Hand Delivery
- ☐ Via Express Delivery
- ☑ Via First Class Mail
- ☐ Other:_____