PUBLIC VERSION

UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, D.C.

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

NOTICE OF A COMMISSION DETERMINATION TO REVIEW IN PART A FINAL INITIAL DETERMINATION FINDING A VIOLATION OF SECTION 337 AND TO EXTEND THE TARGET DATE; SCHEDULE FOR FILING WRITTEN SUBMISSIONS

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has determined to review in part the Administrative Law Judge's ("ALJ") final initial determination ("ID"), issued on July 12, 2019, finding a violation of section 337 in the above-referenced investigation and to extend the target date for completion of the above-referenced investigation to December 19, 2019. The Commission requests briefing from the parties on certain issues under review, as indicated in this notice.

FOR FURTHER INFORMATION CONTACT: Benjamin S. Richards, Esq., Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 708-5453. Copies of non-confidential documents filed in connection with this investigation are or will be available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 205-2000. General information concerning the Commission may also be obtained by accessing its Internet server at *https://www.usitc.gov*. The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov*. Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205-1810.

SUPPLEMENTARY INFORMATION: On February 21, 2018, the Commission instituted this investigation based on a complaint filed by 10X Genomics, Inc. of Pleasanton, CA. 83 FR 7491 (Feb. 21, 2018). The complaint alleges violations of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, in the importation into the United States, the sale for importation, or the sale within the United States after importation of certain microfluidic systems and components thereof and products containing same by reason of infringement of one or more claims of U.S. Patent Nos. 9,644,204 ("the '204 patent"); 9,689,024 ("the '024 patent");

9,695,468 ("the '468 patent"); and 9,856,530 ("the '530 patent"). *Id.* The Commission's notice of investigation named as the sole respondent Bio-Rad Laboratories, Inc. of Hercules, CA. *Id.* The Office of Unfair Import Investigations ("OUII") is participating in this investigation. *Id.*

On July 12, 2019, the ALJ issued the final ID. The ID found a violation of section 337 by virtue of Bio-Rad's indirect infringement of the '024, the '468, and the '530 patents. The ID found that 10X had not established a violation with respect to the '204 patent. The ID also found that Bio-Rad failed to establish invalidity of any of the asserted claims of any patent. The ID further found that the domestic industry requirement was satisfied for each of the asserted patents. Finally, the ID found that Bio-Rad had not carried its burden with respect to various additional affirmative defenses, including improper inventorship and ownership.

On July 25, 2019, the ALJ issued her recommended determination on remedy and bonding. The ALJ recommended, upon a finding of violation, that the Commission issue a limited exclusion order, issue a cease and desist order, and impose a bond in the amount of twenty-five percent of the entered value of any covered products imported during the period of Presidential review.

On July 29, 2019, 10X, Bio-Rad, and OUII submitted petitions seeking review of the ID. On August 6, 2019, 10X, Bio-Rad, and OUII submitted responses to the others' petitions. On August 26, 2019, 10X and Bio-Rad submitted comments on the public interest pursuant to Commission Rule 210.50(a)(4).

Having examined the record of this investigation, including the ID, the petitions for review, and the responses thereto, the Commission has determined to review the ID with respect to (1) all findings related to a violation based on the '024 patent; (2) all findings related to a violation based on the '468 patent; (3) noninfringement of the '204 patent; (4) all findings related to a violation based on the '530 patent; (5) Bio-Rad's inventorship and ownership defenses; and (6) a typographical error on page 91. The Commission has determined not to review the remainder of the ID.

The Commission has further determined to extend the target date in this investigation to December 19, 2019.

The parties are requested to brief their positions on only the following issues under review with reference to the applicable law and the evidentiary record:

1. With respect to Bio-Rad's ownership defense, would Drs. Hindson and Saxanov be considered inventors of the asserted patents based only on the "ideas" they developed at QuantaLife/Bio-Rad? Your response should address how, if at all, those "ideas" correspond to the particular inventions claimed in the asserted patents.

2. Was the ALJ correct to focus on the "inventive concept" of the asserted patents in determining whether Bio-Rad has ownership rights in the asserted patents? If not, what is the correct focus?

3. The ID construed the term "amplification" in the '024 and '468 patent claims to mean "increasing the number of copies of the target sequence to be detected, including by reverse transcription." Explain whether the ID's construction is supported by the Application No. PCT/US 99/01705 ("the '705 application"), U.S. Patent Application Publication No. 2011/0053798 ("the '798 application"), or the specifications of the '024 and '468 patents. Please cite and explain each section that supports or detracts from this construction as well as any expert testimony that interprets those sections.

4. If the Commission determined to construe "amplification" to exclude reverse transcription, consistent with OUII's petition, what effect, if any, would that have on the ID's finding of infringement of the asserted claims of the '024 and '468 patents?

5. In its response to OUII's petition on the construction of "amplification," Bio-Rad argues that, if the ID's construction of "amplification" is modified to exclude reverse transcription, then the ID's infringement findings with respect to the '024 patent should be reversed. Bio-Rad's argument focuses particularly on whether amplification occurs in a droplet. Explain how, if at all, modifying the ID's construction of "amplification" to exclude reverse transcription could give rise to a noninfringement finding based on the location where amplification occurs.

6. Has Bio-Rad waived its noninfringement argument for the '024 patent based on the location where amplification occurs, as described in question 5, by failing to raise the argument in its petition for review? If you contend that the argument is not waived, provide citations to where this issue was raised in Bio-Rad's prehearing brief, posthearing brief, and petition for review.

7. Does the evidence of record support the conclusion that [[ ]] in the context of the products accused of infringing the '204 patent?

8. Claim 1 of the '530 patent includes the clause "wherein said barcode molecules become detached from said gel bead." Is this clause part of step (c) of the claimed method such that barcode molecules must become detached from the gel bead during that step, or does the clause modify the entire method such that the barcode molecules may become detached during any step of the method? Address the significance of the separate indentation of the "wherein" clause and the punctuation setting it off from the rest of the claim.

9. If claim 1 of the '530 patent is construed such that the barcode molecules must become detached from the gel bead during step (c) of the claimed method, does a preponderance of the evidence show that Bio-Rad's accused products and/or 10X's domestic industry products practice step (c) of claim 1? Please identify all evidence supporting your position.

10. Did any party argue in its pre- or post-hearing briefing that the ALJ's construction of claim 1 of the '530 patent, as laid out in orders 22 and 35, was indefinite? If they did, identify where in the briefing those arguments were made.

The parties are not to brief other issues on review, which are adequately presented in the parties' existing filings.

In connection with the final disposition of this investigation, the Commission may issue: (1) an exclusion order that could result in the exclusion of the subject articles from entry into the United States, and/or (2) a cease-and-desist order that could result in the respondent being required to cease and desist from engaging in unfair acts in the importation and sale of such articles. Accordingly, the Commission is interested in receiving written submissions that address the form of remedy, if any, that should be ordered. If a party seeks exclusion of an article from entry into the United States for purposes other than entry for consumption, the party should so indicate and provide information establishing that activities involving other types of entry either are adversely affecting it or likely to do so. For background, *see Certain Devices for Connecting Computers via Telephone Lines*, Inv. No. 337-TA-360, USITC Pub. No. 2843, Comm'n Op. at 7-10 (Dec. 1994).

If the Commission contemplates some form of remedy, it must consider the effects of that remedy upon the public interest. The factors the Commission will consider include the effect that an exclusion order and/or cease and desist orders would have on (1) the public health and welfare, (2) competitive conditions in the U.S. economy, (3) U.S. production of articles that are like or directly competitive with those that are subject to investigation, and (4) U.S. consumers. The Commission is therefore interested in receiving written submissions that address the aforementioned public interest factors in the context of this investigation.

If the Commission orders some form of remedy, the U.S. Trade Representative, as delegated by the President, has 60 days to approve or disapprove the Commission's action. *See* Presidential Memorandum of July 21, 2005, 70 FR 43251 (July 26, 2005). During this period, the subject articles would be entitled to enter the United States under bond, in an amount determined by the Commission and prescribed by the Secretary of the Treasury. The Commission is therefore interested in receiving submissions concerning the amount of the bond that should be imposed if a remedy is ordered.

WRITTEN SUBMISSIONS: The parties to this investigation are requested to file written submissions on the issues identified in this Notice and on the issues of remedy, the public interest, and bonding. Complainant and OUII are requested to submit proposed remedial orders

for the Commission's consideration. Complainant is also requested to state the date that the patents expire and the HTSUS numbers under which the accused products are imported. Complainant is further requested to supply the names of known importers of the Respondent's products at issue in this investigation.

The parties' written submissions and proposed remedial orders must be filed no later than the close of business on October 31, 2019. Reply submissions must be filed no later than the close of business on November 7, 2019. Opening submissions are limited to 75 pages. Reply submissions are limited to 60 pages. Such submissions should address the ALJ's recommended determination on remedy and bonding. Interested government agencies and any other interested parties are also encouraged to file written submissions on the issues of remedy, the public interest, and bonding. Third-party submissions should be filed no later than the close of business on October 31, 2019, 2019. No further submissions on any of these issues will be permitted unless otherwise ordered by the Commission.

Persons filing written submissions must file the original document electronically on or before the deadlines stated above and submit eight true paper copies to the Office of the Secretary pursuant to Section 210.4(f) of the Commission's Rules of Practice and Procedure (19 CFR 210.4(f)). Submissions should refer to the investigation number ("Inv. No. 337-TA-1100") in a prominent place on the cover page and/or the first page. (*See* Handbook on Filing Procedures, *https://www.usitc.gov/documents/handbook_on_filing_procedures.pdf*). Persons with questions regarding filing should contact the Secretary at (202) 205-2000.

Any person desiring to submit a document to the Commission in confidence must request confidential treatment unless the information has already been granted such treatment during the proceedings. All such requests should be directed to the Secretary of the Commission and must include a full statement of the reasons why the Commission should grant such treatment. *See* 19 CFR 210.6. Documents for which confidential treatment by the Commission is sought will be treated accordingly. A redacted non-confidential version of the document must also be filed simultaneously with any confidential filing. All information, including confidential business information and documents for which confidential treatment is properly sought, submitted to the Commission for purposes of this Investigation may be disclosed to and used: (i) by the Commission, its employees and Offices, and contract personnel (a) for developing or maintaining the records of this or a related proceeding, or (b) in internal investigations, audits, reviews, and evaluations relating to the programs, personnel, and operations of the Commission including under 5 U.S.C. Appendix 3; or (ii) by U.S. government employees and contract personnel[1], solely for cybersecurity purposes. All non-confidential written submissions will be available for public inspection at the Office of the Secretary and on EDIS

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in part 210 of the Commission's Rules of

[1] All contract personnel will sign appropriate nondisclosure agreements.

Practice and Procedure (19 CFR 210).

By order of the Commission.

Lisa R. Barton
Secretary to the Commission

Issued: October 17, 2019