

**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

LIMITED EXCLUSION ORDER

The Commission has determined that there is a violation of section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), in the unlawful importation, sale for importation, and/or sale within the United States after importation by Bio-Rad Laboratories, Inc. of Hercules, California (“Bio-Rad” or “Respondent”) of certain microfluidic systems and components thereof and products containing same that infringe one or more of claims 1, 5, 17, 19, and 22 of U.S. Patent No. 9,689,024 (“the ’024 patent”); claims 1, 6, 7, 9, and 21 of U.S. Patent No. 9,695,468 (“the ’468 patent”); and claims 1, 4, 11, 14, 19, 26, and 28 of U.S. Patent No. 9,856,530 (“the ’530 patent”).

Having reviewed the record of this investigation, including the written submissions of the parties, the Commission has made its determination on the issues of remedy, the public interest, and bonding. The Commission has determined that the appropriate form of relief includes a limited exclusion order prohibiting the unlicensed entry of covered microfluidic systems and components thereof and products containing same manufactured by or on behalf of, or imported by or on behalf of, Respondent or any of its affiliated companies, parents, subsidiaries, or other

related business entities, or its successors or assigns. This Exclusion Order does not apply to microfluidic consumables¹ imported into the United States for use by researchers who are using such consumables in the United States as of the date of issuance of this Order, and who have a documented need to continue receiving the consumables for a specific current ongoing research project for which that need cannot be met by any alternative product.

The Commission has also determined that the public interest factors enumerated in 19 U.S.C. § 1337(d)(1) do not preclude the issuance of this limited exclusion order. Finally, the Commission has determined that the bond during the Presidential review period shall be in the amount of twenty-five (25) percent of the entered value for all covered products.

Accordingly, the Commission hereby **ORDERS** that:

1. Microfluidic systems and components thereof and products containing same that infringe one or more of claims 1, 5, 17, 19, and 22 of the '024 patent; claims 1, 6, 7, 9, and 21 of the '468 patent; and claims 1, 4, 11, 14, 19, 26, and 28 of the '530 patent, and that are manufactured by or on behalf of, or imported by or on behalf of, Respondent or any of its affiliated companies, parents, subsidiaries, or other related business entities, or their successors or assigns ("covered products"), are excluded from entry for consumption into the United States, entry for consumption from a foreign trade zone, or withdrawal from a warehouse for consumption, for the remaining terms of the patents, except under license of the patent owner or as provided by law.

¹ "Consumable" means any otherwise covered Bio-Rad part or material that is purchased for use with Bio-Rad's droplet generation instruments and which is consumed during the use of those instruments. For example, Bio-Rad's microfluidic chips are consumables.

2. The provisions of this Order shall not apply to covered consumables imported into the United States for use by researchers who are using such consumables in the United States as of the date of issuance of this Order, and who have a documented need² to continue receiving the consumables for a specific current ongoing research project for which that need cannot be met by any alternative product. The provisions of this Order shall also not apply to service or repair articles imported for use in servicing or repairing microfluidic systems that were imported as of the date of this Order and are under a warranty that existed as of the date of this Order, if such servicing or repairing is provided for in terms of the warranty.
3. Notwithstanding paragraph 1 of this Order, the covered products are entitled to entry into the United States for consumption, entry for consumption from a foreign-trade zone, or withdrawal from a warehouse for consumption under bond in the amount of twenty-five (25) percent of the entered value of such articles pursuant to subsection (j) of Section 337 (19 U.S.C. § 1337(j)) and the Presidential Memorandum for the United States Trade Representative of July 21, 2005 (70 Fed. Reg. 43,251), from the day after this Order is received by the United States Trade Representative until such time as the United States Trade Representative notifies the Commission that this Order is approved or disapproved but, in any event, not later than sixty (60) days after the date of receipt of this Order. All entries of covered products made pursuant to this paragraph are to be reported to U.S. Customs and Border Protection (“CBP”), in

² This “documented need” is to be satisfied by the questionnaire attached to this Order, as discussed at pages 84–86 of the Commission Opinion issued in this investigation on the date of this Order. Bio-Rad is not required to maintain the individual researchers’ records supporting the questionnaire. Commission Opinion, at 85–86.

advance of the date of the entry, pursuant to procedures CBP establishes.

4. At the discretion of CBP and pursuant to procedures that it establishes, persons seeking to import microfluidic systems and components thereof and products containing same that are potentially subject to this Order may be required to certify that they are familiar with the terms of this Order, that they have made appropriate inquiry, and thereupon state that, to the best of their knowledge and belief, the products being imported are not excluded from entry under paragraph 1 of this Order. At its discretion, CBP may require persons who have provided the certification described in this paragraph to furnish such records or analyses as are necessary to substantiate the certification.
5. In accordance with 19 U.S.C. § 1337(1), the provisions of this Order shall not apply to covered products that are imported by and for the use of the United States, or imported for, and to be used for, the United States with the authorization or consent of the Government.
6. The Commission may modify this Order in accordance with the procedures described in Rule 210.76 of the Commission's Rules of Practice and Procedure (19 C.F.R. § 210.76).
7. The Secretary shall serve copies of this Order upon each party of record in this

Investigation and upon CBP.

8. Notice of this Order shall be published in the *Federal Register*.

By order of the Commission.

A handwritten signature in black ink, appearing to read "Lisa R. Barton". The signature is stylized and cursive.

Lisa R. Barton
Secretary to the Commission

Issued: February 12, 2020

ATTACHMENT

Name: _____

Institution: _____

If you were conducting research using Bio-Rad's ddSEQ consumables as of February 12, 2020, in the United States and you need to continue to receive the ddSEQ consumables for that research, answer the following questions:

1. What is the subject matter of your research that uses Bio-Rad's ddSEQ system and consumables?
2. On what date (mm/dd/yyyy) did your research using these Bio-Rad systems begin?
3. What is the expected completion date (mm/dd/yyyy) of your research that uses these Bio-Rad systems?
4. What other competing products did you consider for your research, and why did you reject these products?

I certify that all information provided as part of this questionnaire is accurate and complete to the best of my knowledge. I am aware that U.S. law (including, but not limited to, 18 U.S.C. § 1001) imposes criminal sanctions on individuals who knowingly and willfully make material false statements to the U.S. Government.

I acknowledge that I am to maintain records supporting the above declarations and am not to provide those supporting records to Bio-Rad. If the facts change concerning my research, which began on or before February 12, 2020, I understand that I am to provide an updated questionnaire response to Bio-Rad.

Date: _____

Signature: _____

Additional Bio-Rad comments [to be completed by Bio-Rad]:

I certify that all information provided as part of this questionnaire is accurate and complete to the best of my knowledge. I am aware that U.S. law (including, but not limited to, 18 U.S.C. 1001) imposes criminal sanctions on individuals who knowingly and willfully make material false statements to the U.S. Government.

Date: _____

Signature: _____

**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 **COMMISSION ORDER** has been served by hand upon the Commission Investigative Attorney, **Monica Bhattacharyya, Esq.**, and the following parties as indicated, on **February 12, 2020**.



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
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
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: _____

**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

CEASE AND DESIST ORDER

IT IS HEREBY ORDERED THAT Bio-Rad Laboratories, Inc. of Hercules, California cease and desist from conducting any of the following activities in the United States: importing, selling, marketing, advertising, distributing, transferring (except for exportation), and soliciting U.S. agents or distributors for, or aiding and abetting other entities in the importation, sale for importation, sale after importation, transfer (except for exportation), or distribution of microfluidic systems and components thereof and products containing same covered by one or more of claims 1, 5, 17, 19, and 22 of U.S. Patent No. 9,689,024 (“the ’024 patent”); claims 1, 6, 7, 9, and 21 of U.S. Patent No. 9,695,468 (“the ’468 patent”); and claims 1, 4, 11, 14, 19, 26, and 28 of U.S. Patent No. 9,856,530 (“the ’530 patent”) in violation of Section 337 of the Tariff Act of 1930, as amended (19 U.S.C. § 1337).

**I.
Definitions**

As used in this order:

- (A) “Commission” shall mean the United States International Trade Commission.
- (B) “Complainant” shall mean 10X Genomics, Inc. of Pleasanton, California.

- (C) “Respondent” shall mean Bio-Rad Laboratories, Inc., of Hercules, California.
- (D) “Person” shall mean an individual, or any non-governmental partnership, firm, association, corporation, or other legal or business entity other than Respondent or its majority owned or controlled subsidiaries, successors, or assigns.
- (E) “United States” shall mean the fifty States, the District of Columbia, and Puerto Rico.
- (F) The terms “import” and “importation” refer to importation for entry for consumption under the Customs laws of the United States.
- (G) The term “covered products” shall mean microfluidic systems and components thereof and products containing same that infringe one or more of claims 1, 5, 17, 19, and 22 of the ’024 patent; claims 1, 6, 7, 9, and 21 of the ’468 patent; and claims 1, 4, 11, 14, 19, 26, and 28 of the ’530 patent.¹ “Covered products” shall not include articles for which a provision of law or license avoids liability for infringement of all asserted claims of the Asserted Patents.
- (H) The term “consumable” means any otherwise covered Bio-Rad part or material that is purchased for use with Bio-Rad’s droplet generation instruments and which is consumed during the use of those instruments. For example, Bio-Rad’s microfluidic chips are consumables.

II. Applicability

The provisions of this Cease and Desist Order shall apply to Respondent and to any of its principals, stockholders, officers, directors, employees, agents, distributors, controlled (whether

¹ For purposes of this Order, “covered products” includes products for which associated conduct and/or inventory is permitted based on a documented need.

by stock ownership or otherwise) and majority-owned business entities, successors, and assigns, and to each of them, insofar as they are engaging in conduct prohibited by section III, *infra*, for, with, or otherwise on behalf of, Respondent.

III. Conduct Prohibited

The following conduct of Respondent in the United States is prohibited by this Order. For the remaining term of one of the '024, '468, and '530 patents, Respondent shall not:

- (A) import, sell for importation into the United States, or sell after importation covered products;
- (B) market, distribute, offer to sell, or otherwise transfer (except for exportation) in the United States imported covered products;
- (C) advertise imported covered products;
- (D) solicit U.S. agents or distributors for imported covered products; or
- (E) aid or abet other entities in the importation, sale for importation, sale after importation, transfer, or distribution of imported covered products.

IV. Conduct Permitted

Notwithstanding any other provision of this Order, specific conduct otherwise prohibited by the terms of this order shall be permitted if: (1) in a written instrument, the owner of the '024, '468, and '530 patents licenses or authorizes such specific conduct; (2) the conduct is limited to service or repair articles imported for use in servicing or repairing microfluidic systems that were imported as of the date of this Order and are under a warranty that existed as of the date of this Order, if such servicing or repairing is provided for in terms of the warranty; or (3) such specific conduct is related to the importation or sale of covered products by or for the United States. This Order does not prohibit the importation or sale of covered microfluidic consumables for use by

researchers who are using such consumables in the United States as of the date of the issuance of this Order, and who have a documented need² to continue receiving the consumables for a specific current ongoing research project for which that need cannot be met by any alternative product.

V. Reporting

For purposes of this requirement, the reporting periods shall commence on the first day of each calendar month and shall end on the last day of each calendar month. The first report required under this section shall cover the period from the date of issuance of this order through the last day of that calendar month.

Within five (5) days of the last day of each month's reporting period, Respondent shall report to the Commission: (a) the quantity in units and the value in dollars of covered products that it has (i) imported and/or (ii) sold in the United States after importation during the reporting period, (b) the quantity in units and the value in dollars of covered products imported and/or sold for use in each research project for which there is a documented need pursuant to Section IV and the identity of each such purchaser, (c) questionnaires³ from each such purchaser supporting the documented need pursuant to Section IV, and (d) the quantity in units and value in dollars of reported covered products that remain in inventory in the United States at the end of the reporting period.

When filing written submissions, Respondent must file the original document

² This "documented need" is to be satisfied by the questionnaire attached to this Order, as discussed at pages 84–86 of the Commission Opinion issued in this investigation on the date of this Order. Bio-Rad is not required to maintain the individual researchers' records supporting the questionnaire. Commission Opinion, at 85–86.

³ See Footnote 2.

electronically on or before the deadlines stated above and submit eight (8) true paper copies to the Office of the Secretary by noon the next day pursuant to section 210.4(f) of the Commission's Rules of Practice and Procedure (19 C.F.R. § 210.4(f)). Submissions should refer to the investigation number ("Inv. No. 337-TA-1100") in a prominent place on the cover pages and/or the first page. (See Handbook for Electronic Filing Procedures, https://www.usitc.gov/documents/handbook_on_filing_procedures.pdf). Persons with questions regarding filing should contact the Office of the Secretary (202-205-2000). If Respondent desires to submit a document to the Commission in confidence, it must file the original and a public version of the original with the Office of the Secretary and must serve a copy of the confidential version on Complainant's counsel.⁴

Any failure to make the required report or the filing of any false or inaccurate report shall constitute a violation of this Order, and the submission of a false or inaccurate report may be referred to the U.S. Department of Justice as a possible criminal violation of 18 U.S.C. § 1001.

VI. Recordkeeping and Inspection

(A) For the purpose of securing compliance with this Order, Respondent shall retain any and all records relating to the sale, offer for sale, marketing, or distribution in the United States of covered products, made and received in the usual and ordinary course of business (including documents related to the documented need to continue receiving consumables for a specific current ongoing research project provided in Section IV), whether in detail or in summary form, for a period of three (3) years

⁴ Complainant must file a letter with the Secretary identifying the attorney to receive reports associated with this order. The designated attorney must be on the protective order entered in the investigation.

from the close of the fiscal year to which they pertain.

- (B) For the purposes of determining or securing compliance with this Order and for no other purpose, subject to any privilege recognized by the federal courts of the United States, and upon reasonable written notice by the Commission or its staff, duly authorized representatives of the Commission shall be permitted access and the right to inspect and copy, in Respondent's principal office during office hours, and in the presence of counsel or other representatives if Respondent so chooses, all books, ledgers, accounts, correspondence, memoranda, and other records and documents, in detail and in summary form, that must be retained under subparagraph VI(A) of this Order.

VII.

Service of Cease and Desist Order

Respondent is ordered and directed to:

- (A) Serve, within fifteen days after the effective date of this Order, a copy of this Order upon each of its respective officers, directors, managing agents, agents, and employees who have any responsibility for the importation, marketing, distribution, sale of imported covered products in the United States;
- (B) Serve, within fifteen days after the succession of any persons referred to in subparagraph VII(A) of this order, a copy of the order upon each successor; and
- (C) Maintain such records as will show the name, title, and address of each person upon whom the order has been served, as described in subparagraphs VII(A) and VII(B) of this order, together with the date on which service was made.

The obligations set forth in subparagraphs VII(B) and VII(C) shall remain in effect until the expiration dates of the '024, '468, and '530 patents.

VIII.
Confidentiality

Any request for confidential treatment of information obtained by the Commission pursuant to section V–VI of this order should be made in accordance with section 201.6 of the Commission’s Rules of Practice and Procedure (19 C.F.R. § 201.6). For all reports for which confidential treatment is sought, Respondent must provide a public version of such report with confidential information redacted.

IX.
Enforcement

Violation of this order may result in any of the actions specified in section 210.75 of the Commission’s Rules of Practice and Procedure (19 C.F.R. § 210.75), including an action for civil penalties under section 337(f) of the Tariff Act of 1930 (19 U.S.C. § 1337(f)), as well as any other action that the Commission deems appropriate. In determining whether Respondent is in violation of this order, the Commission may infer facts adverse to Respondent if it fails to provide adequate or timely information.

X.
Modification

The Commission may amend this order on its own motion or in accordance with the procedure described in section 210.76 of the Commission’s Rules of Practice and Procedure (19 C.F.R. § 210.76).

XI.
Bonding

The conduct prohibited by Section III of this Order may be continued during the sixty-day period in which this Order is under review by the United States Trade Representative, as delegated by the President (70 Fed. Reg. 43,251 (Jul. 21, 2005)) subject to the Respondent’s posting of a bond in the amount of twenty-five (25) percent of the entered value of the covered

products. This bond provision does not apply to conduct that is otherwise permitted by section IV of this order. Covered products imported on or after the date of issuance of this order are subject to the entry bond set forth in the exclusion order issued by the Commission, and are not subject to this bond provision.

The bond is to be posted in accordance with the procedures established by the Commission for the posting of bonds by complainants in connection with the issuance of temporary exclusion orders. *See* 19 C.F.R. § 210.68. The bond and any accompanying documentation are to be provided to and approved by the Commission prior to the commencement of conduct that is otherwise prohibited by section III of this Order. Upon the Secretary's acceptance of the bond, (a) the Secretary will serve an acceptance letter on all parties, and (b) Respondent must serve a copy of the bond and any accompanying documentation on Complainant's counsel.⁵

The bond is to be forfeited in the event that the United States Trade Representative approves this Order (or does not disapprove it within the review period), unless the U.S. Court of Appeals for the Federal Circuit, in a final judgment, reverses any Commission final determination and order as to Respondent on appeal, or unless Respondent exports or destroys the products subject to this bond and provides certification to that effect that is satisfactory to the Commission.

⁵ *See* Footnote 4.

The bond is to be released in the event the United States Trade Representative disapproves this order and no subsequent order is issued by the Commission and approved (or not disapproved) by the United States Trade Representative, upon service on Respondent of an order issued by the Commission based upon application therefore made by Respondent to the Commission.

By order of the Commission.

A handwritten signature in black ink, appearing to read "Lisa R. Barton".

Lisa R. Barton
Secretary to the Commission

Issued: February 12, 2020

ATTACHMENT

Name: _____

Institution: _____

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2. On what date (mm/dd/yyyy) did your research using these Bio-Rad systems begin?

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4. What other competing products did you consider for your research, and why did you reject these products?

I certify that all information provided as part of this questionnaire is accurate and complete to the best of my knowledge. I am aware that U.S. law (including, but not limited to, 18 U.S.C. 1001) imposes criminal sanctions on individuals who knowingly and willfully make material false statements to the U.S. Government.

I acknowledge that I am to maintain records supporting the above declarations and am not to provide those supporting records to Bio-Rad. If the facts change concerning my research, which began on or before February 12, 2020, I understand that I am to provide an updated questionnaire response to Bio-Rad.

Date: _____

Signature: _____

Additional Bio-Rad comments [to be completed by Bio-Rad]:

I certify that all information provided as part of this questionnaire is accurate and complete to the best of my knowledge. I am aware that U.S. law (including, but not limited to, 18 U.S.C. 1001) imposes criminal sanctions on individuals who knowingly and willfully make material false statements to the U.S. Government.

Date: _____

Signature: _____

**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 **COMMISSION ORDER** has been served by hand upon the Commission Investigative Attorney, **Monica Bhattacharyya, Esq.**, and the following parties as indicated, on **February 12, 2020**.



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
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
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: _____