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 THE COMMISSION'S FINAL DETERMINATION FINDING A VIOLATION OF SECTION 337; ISSUANCE OF A LIMITED EXCLUSION ORDER AND CEASE AND DESIST ORDER; AND TERMINATION OF THE INVESTIGATION.

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has determined that there is a violation of 19 U.S.C. 1337, as amended ("section 337"), in the above-captioned investigation. The Commission has further determined to issue a limited exclusion order and cease and desist order and to set a bond rate on the entered value of covered products imported during the period of Presidential review.

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 Fed. Reg. 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 administrative law judge ("ALJ") issued the final initial determination ("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).

On October 17, 2019, the Commission issued a notice indicating its determination 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 same notice also requested briefing from the parties on certain of those issues, and on remedy, bonding, and the public interest. The notice also included an extension of the target date to December 19, 2019.

The parties filed their initial responses to the Commission's questions on October 31, 2019, and their replies on November 7, 2019.

Upon review of the parties' submissions, the ID, RD, and evidence of record, the Commission has determined that Bio-Rad violated section 337 by reason of infringement of asserted 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. The Commission found no violation with respect to the '240 patent. The Commission has further determined to issue a limited exclusion order prohibiting further importation of Bio-Rad's infringing microfluidic systems and a cease and desist order against Bio-Rad. The Commission will set a bond of twenty-five percent of entered value on Bio-Rad's infringing microfluidic systems imported during the period of Presidential review.

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 Practice and Procedure (19 CFR 210).

By order of the Commission.

Lisa R. Barton
Secretary to the Commission

Issued: February 12, 2020

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 **NOTICE** 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**

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 consumables[1] 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 need[2] 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.

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 need[2] 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) questionnaires[3] 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

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[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.

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:_____

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

COMMISSION OPINION

PUBLIC VERSION

PUBLIC VERSION

I. INTRODUCTION

On October 17, 2019, the Commission determined to review portions of the Administrative Law Judge's ("ALJ") final initial determination, which issued on July 12, 2019. 84 Fed. Reg. 56835 (Oct. 23, 2019). On review, the Commission has determined that respondent Bio-Rad Laboratories, Inc. of Hercules, CA ("Bio-Rad" or "Respondent") violated section 337 of the Tariff Act of 1930, 19 U.S.C. § 1337, as amended ("Section 337"), by way of infringement of certain claims of U.S. Patent No. 9,689,024 ("the '024 patent"), U.S. Patent No. 9,695,468 ("the '468 patent"), and U.S. Patent No. 9,856,530 ("the '530 patent"). The Commission has also determined that there is no violation with respect to U.S. Patent No. 9,644,204 ("the '204 patent"). The Commission has determined to issue a limited exclusion order ("LEO") and a cease and desist order ("CDO") against Bio-Rad. The Commission has further determined that during the period of Presidential review, a bond in the amount of twenty-five (25) percent of entered value shall be applied to Bio-Rad's covered products.

II. BACKGROUND

A. Procedural History

On February 21, 2018, the Commission instituted this investigation based on a complaint filed by 10X Genomics, Inc. of Pleasanton, California ("10X" or "Complainant"). 83 Fed. Reg. 7491 (Feb. 21, 2018). The complaint, as supplemented, alleges violations of Section 337, 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 the '204 patent; the '024 patent; the '468 patent; and the '530 patent. *Id.* The Commission's notice of investigation named Bio-Rad as the sole respondent. *Id.* The Office of Unfair Import Investigations ("OUII") participated in this investigation. *Id.*

The ALJ granted 10X's unopposed motion for summary determination that it has satisfied the economic prong of the domestic industry requirement. Order No. 19 at 5 (Oct. 5, 2018), *unreviewed*, Notice (Nov. 6, 2018). The ALJ also terminated the investigation with respect to several patent claims. Order No. 26 at 2 (Nov. 30, 2018), *unreviewed*, Notice (Dec. 20, 2018); Order No. 27 at 2 (Dec. 10, 2018), *unreviewed*, Notice (Dec. 21, 2018).

From March 25 to 29, 2019, an evidentiary hearing was held in this investigation. At the hearing, 10X asserted the following claims against Bio-Rad:

Patent	Asserted Claims
'024 Patent	Claims 1, 5, 17, 19, 22
'204 Patent	Claims 27, 29, 31, 33
'468 Patent	Claims 1, 6, 7, 9, 21
'530 Patent	Claims 1, 4, 11, 14, 19, 26, 28

See ID at 16–17, 58, 70, 89; *see also* 10X Posthearing Br. at 4.

On July 12, 2019, the ALJ issued her final initial determination ("ID") on violation. The ID found that Bio-Rad imported into the United States, sold for importation, or sold within the United States after importation "the accused microfluidic systems and components thereof and products containing same." ID at 154. The ID found that Bio-Rad indirectly infringed all of the remaining asserted claims of the '024, '468, and '530 patents, but that 10X had not established that Bio-Rad infringed any asserted claims of the '204 patent. *Id.* The ID found that Bio-Rad failed to establish invalidity of any of the asserted claims of any patent. *Id.* The ID found that the domestic industry requirement was satisfied for each of the asserted patents. *Id.* at 154–55. Finally, the ID found that Bio-Rad had not carried its burden with respect to various additional affirmative defenses, including improper inventorship and ownership. *Id.* at 155. Thus, the ID concluded that Bio-Rad violated Section 337 with respect to the '024, '468, and '530 patents, but not with respect to the '204 patent. *Id.* at 154.

On July 25, 2019, the ALJ issued her recommended determination on remedy and bonding ("RD"). The RD recommended issuance of a limited exclusion order upon a finding of violation, without a certification provision. RD at 1–2. The RD further recommended issuance of a cease and desist order. *Id.* at 2–3. The RD also recommended imposition of a bond of twenty-five (25) percent of the entered value of any covered products during the Presidential review period. *Id.* at 3–5. On July 29, 2019, 10X, Bio-Rad, and OUII submitted petitions seeking review of the ID.[1] On August 6, 2019, 10X, Bio-Rad, and OUII submitted responses to the others' petitions.[2]

On October 17, 2019, the Commission issued a notice of its determination to review the ID in part. Particularly, the Commission 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.

84 Fed. Reg. 56835. The Commission also requested briefing on multiple issues. *Id.*

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[1] Complainant 10X Genomics, Inc.'s Petition for Review of the Initial Determination (July 29, 2019) ("10X Pet."); Respondent Bio-Rad Laboratories, Inc.'s Petition for Review of the Initial Determination on Violation of Section 337 (July 30, 2019) ("Bio-Rad Pet."); Petition of the Office of Unfair Import Investigations for Review of the Initial Determination on Violation of Section 337 (July 29, 2019) ("OUII Pet.").

[2] Complainant 10X Genomics, Inc.'s Response to Respondent Bio-Rad Laboratories, Inc.'s Petition for Review of the Initial Determination on Violation of Section 337 (Aug. 6, 2019) ("10X Resp. to Bio-Rad Pet."); Complainant 10X Genomics, Inc.'s Response to Petition of the Office of Unfair Import Investigations Petition for Review of the Initial Determination on Violation of Section 337 (Aug. 6, 2019) ("10X Resp. to OUII Pet."); Respondent Bio-Rad Laboratories, Inc.'s Combined Response to 10X's and the Office of Unfair Import Investigations' Petitions for Review of the Initial Determination (Aug. 6, 2019) ("Bio-Rad Resp. to Pets."); The Office of Unfair Import Investigations' Combined Response to Petitions for Review of the Initial Determination on Violation of Section 337 (Aug. 6, 2019) ("OUII Resp. to Pets.").

On October 31, 2019, the parties filed their respective responses to the Commission's questions on review.[3] On November 7, 2019, the parties filed their respective replies.[4]

B. Overview of the Technology

The technology at issue in this investigation relates to methods of preparing deoxyribonucleic acid ("DNA") and ribonucleic acid ("RNA") samples for genetic sequencing and analysis. Particularly, the technology seeks to preserve certain information about nucleic acid segments that would otherwise be lost during sequencing, *e.g.*, whether two nucleic acid segments originated from the same source. This is accomplished by tagging nucleic acid segments, prior to sequencing, with oligonucleotide "barcodes."[5] These barcodes allow researchers to later identify nucleic acid segments that originated from a common sample. The barcoding process involves partitioning nucleic acids from a sample into droplets along with single gel beads to which oligonucleotide barcodes are attached. The barcodes are released from the gel beads and combined with the nucleic acids. At that point, the nucleic acids in each droplet bear a unique barcode. Those nucleic acids can then be pooled and sequenced, and it will still be possible to associate nucleic acid segments from a common droplet. The partitioning of nucleic acids and gel beads

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[3] Complainant 10X Genomics, Inc.'s Opening Written Submission Regarding the Commission's October 17, 2019 Notice (Oct. 31, 2019) ("10X Resp. to Qs."); Respondent Bio-Rad Laboratories, Inc.'s Opening Submission Responding to the Commission's Notice Dated October 17, 2019 (Oct. 31, 2019) ("Bio-Rad Resp. to Qs."); The Office of Unfair Import Investigations' Responses to the Commission's October 17, 2019 Questions (Oct. 31, 2019) ("OUII Resp. to Qs.").

[4] Complainant 10X Genomics, Inc.'s Reply Written Submission Regarding the Commission's October 17, 2019 Notice (Nov. 7, 2019) ("10X Reply"); Respondent Bio-Rad Laboratories, Inc.'s Combined Reply to 10X's and the Office of Unfair Import Investigations' Response to the Commission Notice Dated October 17, 2019 (Nov. 7, 2019) ("Bio-Rad Reply"); The Office of Unfair Import Investigations' Reply to the Private Parties' Responses to the Commission's October 17, 2019 Questions (Nov. 7, 2019) ("OUII Reply").

[5] A "barcode" is a short DNA sequence of 3–12 DNA bases. *See* Bio-Rad Prehearing Br. at 8.

into droplets is accomplished with microfluidic systems that rely on small channels to combine streams of nucleic acids and gel beads into droplets. The asserted claims that remain in this investigation are directed to various aspects of this barcoding process.

C. Products at Issue

The accused products are components and assays of Bio-Rad's ddSEQ system, which includes ddSEQ version 1 and version 2. ID at 3. The ID explained that the ddSEQ v1 products include Bio-Rad's ddSEQ v1 Cartridge, ddSEQ v1 Single-Cell Isolator, ddSEQ Cartridge Holder, and consumables and assays used with and/or as part of Bio-Rad's ddSEQ v1 system, including the SureCell WTA 3' v1 assay. *Id.* (citing CX-0004C (Butte DWS) at Q/A 54; RX-0665C (Metzker RWS) at Q/A 29). The ddSEQ v2 products include [redacted], scATACseq, [redacted]. *Id.* 10X provided the following image of the ddSEQ v1 Single-Cell Isolator and WTA 3' library prep kit products:

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See CX-1485C (product launch announcement); CDX-2 at 22 (reproducing CX-1485C).

The domestic industry products are 10X's GemCode™ and Chromium™ product lines. *Id.* at 3. The ID explained that these products were developed by 10X based on its GEM ("Gel bead in Emulsion") architecture, and the first GemCode™ product was sold in 2015. *Id.* (citing CX-0003C at Q/A 47-52). The domestic industry products include both single-cell and linked-read applications, including the Chromium™ Single Cell 3' Solution, Chromium™ Single Cell V(D)J Solution, and GemCode™ Single Cell platform, and the Chromium™ Genome Solution, Chromium™ Exome Solution, Chromium™ de nova Assembly Solution, and GemCode™ Long Read platform. *Id.* 10X provided the following image of its domestic industry products:

See CDX-2 at 80 (reproducing images from 10X's website).

III. THE '024 PATENT

The Commission determined to review all of the ID's findings related to the '024 patent. 84 Fed. Reg. 56835. On review, the Commission has determined to affirm with modified reasoning the ID's finding that Bio-Rad has violated section 337 based on infringement of the '024 patent. Specifically, the Commission finds that Bio-Rad failed to raise the location of amplification as a basis for noninfringement in its petition for review and has therefore abandoned that argument. The Commission further finds that the '024 patent is infringed regardless of whether the claim term "amplification" encompasses reverse transcription, and therefore the Commission need not resolve that dispute as it will not have a material effect on the outcome of this investigation. Concerning invalidity, the Commission affirms the ID's finding that Bio-Rad has not established that any of the asserted claims are invalid under modified reasoning. The Commission adopts the remainder of the ID's findings with respect to the '024 patent to the extent they are not inconsistent with this opinion.

For reference, claim 1 of the '024 patent follows:

1. A method for sample preparation, comprising:

    a) providing a droplet comprising ***a porous gel bead*** and a target nucleic acid analyte, wherein said porous gel bead comprises at least 1,000,000 oligonucleotide molecules comprising barcode sequences, wherein said oligonucleotide molecules are releasably attached to said porous gel bead, wherein said barcode sequences are the same sequence for said oligonucleotide molecules;

    b) applying a stimulus to said porous gel bead to release said oligonucleotide molecules from said porous gel bead into said droplet, wherein upon release from said porous gel bead, a given oligonucleotide molecule from said oligonucleotide molecules attaches to said target nucleic acid analyte; and

    c) subjecting said given oligonucleotide molecule attached to said target nucleic acid analyte to nucleic acid ***amplification*** to yield a barcoded target nucleic acid analyte.

'024 patent at cl. 1 (emphasis added on contested terms).

A. Construction of "Amplification" and the Effect on Infringement

OUII petitioned for review of the ALJ's construction of the term "nucleic acid amplification," which appears in asserted claim 1 of the '024 patent and asserted claim 21 of the '468 patent. *See* OUII Pet. at 18–26. Specifically, OUII asserted that the *Markman* order erred by construing "nucleic acid amplification" such that "creation of a single complementary copy through reverse transcription constitutes 'amplification.'" *Id.* at 20. However, OUII also acknowledged that whether "amplification" should be construed to encompass reverse transcription may be immaterial to the ID's ultimate conclusion that Bio-Rad violated section 337 based on infringement of the '024 patent. *See id.* at 19 ("[T]his issue may not be material since, under the proper construction, the ID's ultimate violation holdings on [the '024 and '468] patents are correct."). OUII elaborated that "10X provided evidence of infringement and the technical prong under both the broader construction adopted by the Court, as well as the narrower

construction supported by OUII," and noted that "the ID appeared to rely on 10X's evidence under both constructions, although the ID focused at times on reverse transcription." *Id.* at 25.

10X disagreed with OUII's assertion that the *Markman* order misconstrued "nucleic acid amplification," 10X Resp. to OUII Pet. at 7–13, but agreed that "under either the ALJ's or Staff's proposed construction of 'amplification,' the findings of violation for the ['']024 and ['']468 Patents are correct and should stand." *Id.* at 13. Particularly, 10X asserted that because no party challenged the ID's infringement findings based on the construction of "amplification," "[OUII]'s challenge to one aspect of the claim construction will have no material effect and any error would be harmless." *Id.*

Bio-Rad did not petition for review of the *Markman* order's construction of "nucleic acid amplification." *See generally* Bio-Rad Pet. Bio-Rad did petition for review of the ID's finding that the asserted claims of the '024 and '468 patents were infringed, but the arguments Bio-Rad advanced in support of that aspect of its petition were based on entirely different limitations in the claims. *See* Bio-Rad Pet. at 6–9, 27–33, 66–73. In its response to OUII's petition, however, Bio-Rad agreed with OUII that the *Markman* order misconstrued "amplification" to encompass reverse transcription. *See* Bio-Rad Resp. to Pets. at 35–38.

Notwithstanding the fact that Bio-Rad did not petition for review of the construction of "nucleic acid amplification," it argued for the first time in its response to OUII's petition that its products do not infringe the '024 patent "under the correct construction of the 'amplification' terms." Bio-Rad Resp. to Pets. at 38. The noninfringement argument Bio-Rad laid out in support of that assertion did not relate to whether "nucleic acid amplification" encompassed reverse transcription, however. *See id.* at 38–40 (no discussion of reverse transcription). Rather, Bio-Rad argued that "claim 1 of the '024 Patent requires that amplification occur in the droplet," and that

the evidence does not show that amplification occurs in a droplet in Bio-Rad's products. *Id.* at 39. In making that argument, Bio-Rad revived a dispute decided in the *Markman* order — whether amplification must occur in a droplet — for which no party sought review. *See* Order No. 22 at 44–45 (rejecting the same Bio-Rad argument and finding that "[t]he requirement that the 'said given oligonucleotide molecule attached to said target nucleic acid analyte' be created in a droplet in the second step does not mean that it has to remain in the droplet for all subsequent steps").

Given the disagreement over the materiality of the construction of "amplification" as set forth in OUII's petition for review, and the apparent disconnect between Bio-Rad's noninfringement argument and the question of whether "amplification" encompasses reverse transcription, the Commission sought briefing from the parties addressing those issues. 84 Fed. Reg. 56836. 10X and OUII both responded that modifying the construction of "amplification" to exclude reverse transcription would have no effect on the ID's infringement findings because the evidence of record shows other multiple types of amplification in the accused products, including polymerase chain reaction ("PCR"), which would meet the definition of "amplification" even if that term did not encompass reverse transcription. 10X Resp. to Qs. at 21–23; OUII Resp. to Qs. at 13. Further, both 10X and OUII responded that whether "amplification" must occur in a droplet and whether "amplification" encompasses reverse transcription are distinct issues and therefore modifying the ID's construction of "amplification" to exclude reverse transcription would not give rise to a noninfringement finding based on the location where amplification occurs. *See* 10X Resp. to Qs. at 23–24; OUII Resp. to Qs. at 14. Accordingly, both 10X and OUII responded that Bio-Rad waived its noninfringement argument based on whether amplification must occur in a droplet. 10X Resp. to Qs. at 26–27; OUII Resp. to Qs. at 14–15.

Bio-Rad responded that "[i]f amplification does not include reverse transcription, than [sic] all but Bio-Rad's scATACseq products do not infringe Claim 1 of the '024 Patent or Claim 21 of the '468 Patent," because reverse transcription is the only amplification reaction that occurs in a droplet in Bio-Rad's products. *See* Bio-Rad Resp. to Qs. at 28. We note that, by taking this position, Bio-Rad expanded its previous noninfringement argument, which was limited to the '024 patent. *See* Bio-Rad Resp. to Pets. at 38. Bio-Rad's briefing in support of its position also included a new argument not previously made in its petition or in response to the other parties' petitions. Particularly, Bio-Rad argued that the "said target nucleic acid analyte" in claim 1 of the '024 patent and claim 21 of the '468 patent must be messenger RNA ("mRNA"), but that in proving infringement 10X relied on complementary DNA ("cDNA") to establish amplification of nucleic acids outside a droplet. *See* Bio-Rad Resp. to Qs. at 29–31.

Concerning waiver, Bio-Rad responded that OUII's petition preserved its noninfringement argument. The crux of Bio-Rad's position in this regard appears to be that by challenging one aspect of the *Markman* order's construction of "amplification" — whether "amplification" encompasses reverse transcription — OUII's petition opened the door for Bio-Rad (or 10X) to challenge other aspects of that construction in its response to OUII's petition. *See id.* at 31–33. Bio-Rad also argued that the ID only relied on reverse transcription as the basis for its infringement finding, and therefore, Bio-Rad was not required to specifically petition for review of whether its products are infringing based on amplification outside the droplet. *See id.* at 33–34. Bio-Rad then submitted that "[i]f the Commission determines that 'amplification' can occur outside of the droplet, the Commission should remand to the ALJ to make specific findings on infringement under that construction." *Id.* at 34. Notably, notwithstanding the Commission's request for "citations to where this [amplification location] issue was raised in Bio-Rad's prehearing brief,

posthearing brief, and petition for review," 84 Fed. Reg. 56836, Bio-Rad provides none in its response to the Commission's waiver question. *See* Bio-Rad Resp. to Qs. at 31–34.

The dispute regarding whether the term "nucleic acid amplification" encompasses reverse transcription is immaterial to any issue in the investigation, and thus the Commission need not resolve that dispute. As the Federal Circuit has explained, "only those terms need be construed that are in controversy, and only to the extent necessary to resolve the controversy." *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999). The Commission need not resolve issues of claim construction that are not material to any issue in this investigation. *See Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co. Matal*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) ("[W]e need not construe the claim preambles here where the construction is not material to the [obviousness] dispute." (alteration in original) (internal quotation marks omitted)); *EmeraChem Holdings, LLC v. Volkswagen Grp. of Am., Inc.*, 714 F. App'x 995, 997 (Fed. Cir. 2017) (unpublished) (declining to decide claim construction dispute "because the prior art would anticipate the '558 patent claims regardless of which construction we apply.").

The dispute over whether "amplification" should encompass reverse transcription is immaterial because, as noted in the ID, 10X pointed to four different reactions in the accused products to satisfy the "amplification" limitation of claim 1 of the '024 patent. *See* ID at 25–26 ("[Dr. Butte] further explains that barcoded cDNA strands are generated from the oligonucleotide molecules through several different processes, which 10X identifies in its brief as four types of amplification."). One of the processes identified is PCR, which is explicitly listed as an amplification reaction in the '024 patent. *See* '024 patent at 25:25–28 ("[O]ligonucleotide primers containing bar code sequences may be used in amplification reactions (e.g., PCR, qPCR, reverse-transcriptase PCR, digital PCR, etc.) of the DNA template analytes, thereby producing tagged

analytes."). Even Bio-Rad has acknowledged that PCR is a type of amplification reaction. *See* Bio-Rad Initial Claim Construction Br. at 16 (listing evidence where PCR is described as an amplification reaction). While 10X argued in its pre- and post-hearing briefs that PCR in the accused products satisfied the "amplification" limitation in claim 1 of the '024 patent, Bio-Rad did not address whether the PCR relied on by 10X satisfied the "nucleic acid amplification" limitation. *Compare* 10X Prehearing Br. at 33–35; 10X Initial Posthearing Br. at 24–26 *with* Bio-Rad Posthearing Br. at 62–63 (disputing infringement of "amplification" limitation without addressing PCR) *and* Bio-Rad Posthearing Reply at 12 (same). Instead, Bio-Rad limited itself to arguing that "the oligonucleotide molecule containing the barcode that attaches to the target nucleic acid analyte (mRNA) acts as a primer during the reverse transcription reaction," and because "this portion of the oligonucleotide molecule is not amplified in reverse transcription," 10X could not show that the accused products satisfy the "amplification" limitation. Bio-Rad Posthearing Br. at 62–63; *see also* Bio-Rad Posthearing Reply Br. at 12; Bio-Rad Prehearing Br. at 65–68. Bio-Rad never challenged 10X's assertion that the "amplification" limitation is satisfied by PCR. *See generally* 10X Initial Posthearing Br. at 24–26.

Given Bio-Rad's failure to present evidence or argument disputing 10X's evidence and argument that the "amplification" limitation is satisfied by PCR in the accused products, the Commission affirms the ID's finding that the accused products practice the "amplification" limitation. A preponderance of the evidence supports that finding under the broad construction applied in the ID, as well as under a narrow construction that excludes reverse transcription from the definition of "amplification." Accordingly, whether "amplification" should be construed to encompass reverse transcription is not material to any issue in this investigation; the Commission

need not resolve that question and takes no position on it. The Commission affirms the remainder of the ID's infringement findings with respect to the '024 patent.[6]

With respect to the argument regarding whether amplification must occur in a droplet, which Bio-Rad raised as a basis for noninfringement in its response to OUII's petition, Bio-Rad abandoned that argument and waived it by failing to raise it in its petition for review. Commission Rule 210.43(b)(2) states that "[a]ny issue not raised in a petition for review will be deemed to have been abandoned by the petitioning party and may be disregarded by the Commission in reviewing the initial determination . . . and any argument not relied on in a petition for review will be deemed to have been abandoned and may be disregarded by the Commission." 19 C.F.R. § 210.43(b)(2). Further, the ALJ's Ground Rule 8.2 states that "[a]ny contentions not set forth in detail as required herein shall be deemed abandoned or withdrawn, except for contentions of which a party is not aware and could not be aware in the exercise of reasonable diligence at the time of filing the pre-trial brief," while Ground Rule 11.1 states that issues not raised in post-trial briefs "shall be deemed waived." *See* Order No. 2 (Ground Rules). During the *Markman* process, the ALJ resolved three distinct disputes with respect to the meaning of "amplification" in the asserted patents. *See* Order No. 22 at 31–45. Whether "amplification" encompassed reverse transcription was one dispute; whether amplification must occur in a droplet was another. *Compare id.* at 31–41 *with id.* at 42–

[6] The Commission notes that Bio-Rad did not assert in response to OUII's petition that the ID's domestic industry findings would be affected by construing "amplification" to exclude reverse transcription. *See* Bio-Rad Resp. to Pets. at 34–40. To avoid confusion, however, the Commission finds that the ID's determination that 10X satisfies the domestic industry requirement is supported by a preponderance of the evidence regardless of whether "amplification" encompasses reverse transcription. This is because, as with the accused products, 10X presented unrebutted evidence that PCR in the domestic industry products satisfies the "amplification" limitation of claim 1 of the '024 patent. *See* 10X Posthearing Br. at 39 (citing CX-0004C at Q/A 278-279; CX-0481 at 11; CX-0542 at 1; CX-0579 at 1–2; CX-0578 at 15, 53). Accordingly, the Commission also affirms the ID's finding that 10X satisfied the domestic industry requirement with respect to the '024 patent.

45. The *Markman* order resolved both disputes — "amplification" is broad enough to include reverse transcription and "amplification" need not occur only in a droplet. *See* Order 22 at 32–41, 44–45.

OUII petitioned for review of the *Markman* order's conclusion on the reverse transcription issue, *see* OUII Pet. at 18–26, but no party petitioned for review of the *Markman* order's conclusion on the location of amplification issue. Bio-Rad contends that it was entitled to raise the issue in its response to OUII's petition because OUII's petition put the construction of "amplification" at issue. *See* Bio-Rad Resp. to Qs. at 31–33. That line of reasoning, if accepted, necessarily implies that by petitioning for review of one of the three issues regarding the construction of "amplification," OUII opened the door to review the other two issues as well, even though *no party petitioned for review of those issues*. Commission Rule 210.43(b)(2) provides that "[a]ny issue not raised" and "any argument not relied on" in a petition for review will be deemed abandoned. Such is the case with Bio-Rad's belated challenge to the *Markman* order's resolution of whether "amplification" must occur in a droplet. By withholding that argument until its response to OUII's petition, Bio-Rad precluded 10X and OUII from responding to that argument in their own petition responses. There would be obvious prejudice to both if the Commission declined to enforce Rule 210.43(b)(2).

Finally, the Commission notes that the noninfringement argument Bio-Rad advances in its response to the Commission's questions bears little resemblance to the argument it raised in its response to OUII's petition. Indeed, the new argument raised in Bio-Rad's response to the Commission's questions strongly suggests that even Bio-Rad understands that the noninfringement argument it raised in its response to OUII's petition is unrelated to the reverse transcription issue. For example, Bio-Rad's argument in its response to OUII's petition relied on

evidence from the *Markman* phase of this investigation to ultimately argue that "[t]he structure of claim 1 of the '024 Patent requires that amplification occur in the droplet. But 10X has presented no evidence that amplification in the Bio-Rad Accused Products (*i.e.*, PCR) occurs in the droplet and, in fact, there is evidence that this step takes place after the droplets are broken." Bio-Rad Resp. to Pets. at 39–40. The success of that argument is contingent on a claim construction that requires amplification to occur in a droplet such that the PCR in Bio-Rad's products will not read on the "amplification" limitation. As noted, Bio-Rad abandoned this argument by failing to include it in its petition for review.

By contrast, in its responses to the Commission's questions, Bio-Rad shifted its focus away from claim construction. Instead, Bio-Rad argued that the subject of the "nucleic acid amplification" limitation — "said given oligonucleotide molecule attached to said target nucleic acid analyte" — "only exists in the droplet," in Bio-Rad's products. Bio-Rad Resp. to Qs. at 29 (internal quotations omitted). That argument relies on the assumption that the target nucleic acid analyte is mRNA. *See id.* at 29–30. The argument fails to address, however, the fact that 10X did not rely solely on amplification of mRNA to satisfy the "amplification" limitation. In two of the four types of amplification 10X relied on, cDNA is the target nucleic acid analyte in both steps (b) and (c) of claim 1 of the '024 patent. *See* 10X Posthearing Br. at 24–25. As previously noted, Bio-Rad's posthearing briefing and evidence only addressed 10X's infringement allegations that relied on reverse transcription as the amplification reaction. Bio-Rad did not present evidence or argument to counter 10X's evidence and arguments that the amplification reaction is satisfied by PCR. Accordingly, the Commission finds that Bio-Rad's most recent noninfringement argument does not change the fact that a preponderance of the evidence shows that the amplification step of claim 1 of the '024 patent is satisfied regardless of whether "amplification" encompasses reverse

transcription. Moreover, because Bio-Rad raised this argument for the first time before the Commission, it is also waived. *See* 19 C.F.R. § 210.43(b)(2).

The Commission notes that Bio-Rad's response to OUII's petition for review did not argue that modifying the construction of "amplification" to exclude reverse transcription would alter the ID's conclusion that 10X satisfied the domestic industry requirement for any asserted patent, or the ID's conclusion that the '468 patent is infringed. *See* BioRad Resp. to Pets. at 39–40. Moreover, as OUII noted in its petition, 10X presented, and the ID identified, similar evidence showing amplification through PCR in the context of the domestic industry products and infringement of the '468 patent. *See* OUII Pet. at 25–26; ID at 32, 63, 66. Accordingly, the Commission also finds that whether "amplification" encompasses reverse transcription is immaterial to those issues as well.

B. Validity: Disclosure of "Porous Gel Beads" in the Prior Art

Bio-Rad petitioned for review of the ID's finding that the asserted claims of the '024 patent were not invalid as anticipated or obvious. Bio-Rad Pet. at 10–26. Like the ID, Bio-Rad's petition focused on two limitations in the asserted claims: (1) porous gel beads and (2) releasable attachment of barcodes to those gel beads. *See id.* In Bio-Rad's view, those limitations are anticipated or rendered obvious by U.S. Patent No. 9,347,059 (JX-0031, "the '059 patent") and/or U.S. Patent No. 9,902,950 (RX-0462, "the Church patent"). *See id.* On review, the Commission has determined to affirm the ID's finding that the asserted claims of the '024 patent are not invalid as anticipated or obvious with supplemented reasoning concerning the disclosure of "porous gel beads" in the prior art.

First, Bio-Rad asserted that the ID erred by relying on (1) the '059 patent's description of certain beads as "coated" and (2) the testimony of the inventor of the '059 patent that he believed he disclosed solid beads in the '059 patent to conclude that the beads were solid as opposed to

porous. *See* Bio-Rad Pet. at 10–11. However, even if those assertions of error are true, they would not provide a basis to find an affirmative disclosure of porous gel beads in the '059 patent. Bio-Rad's arguments are limited to criticizing evidence the ID relied on to support the conclusion that the antibody-linked beads are solid, *i.e.*, not porous. At best, Bio-Rad's arguments may lead to the conclusion that the composition of the antibody-linked beads is not disclosed in the '059 patent. However, Bio-Rad's arguments do not show, by clear and convincing evidence, that the antibody-linked beads of the '059 patent are disclosed as being porous.

Second, with respect to Bio-Rad's reliance on the Roche 454 sequencing technique listed in the specification of the '059 patent as disclosing the "porous gel bead" limitation, the Commission notes that neither the '059 patent itself, nor the publication by Margulies, *et al.*, cited in the '059 patent in connection with the Roche 454 sequencing technique, disclose the use of Sepharose beads with the technique. Both the '059 patent and the Margulies paper are in evidence, but neither mentions Sepharose beads. *See* JX-0031 ('059 patent); CX-1940 (Margulies, *et al.*). Rather than acknowledge this lack of disclosure, Bio-Rad represented in its petition that "[t]he undisputed testimony from 10X's expert Dr. Dear is that Margulies describes the 454 beads as being Sepharose." Bio-Rad Pet. at 11 (citing Tr. at 869:21–870:4; JX-31 at 26:52–54). However, the evidence Bio-Rad cites does not support its representation. The cited portion of Dr. Dear's evidentiary hearing testimony follows:

> Q. Now the 454, beads, those are Sepharose beads; correct?
>
> A. You mean the 454 sequencing beads?
>
> Q. That's correct.
>
> A. Yes, I believe — *at the time 454 was published, I believe they used Sepharose beads*. That's the Margulies paper. Whether they did since in their commercial instruments, I don't know. But in the Margulies paper, I believe they are Sepharose — Sepharose beads.

Tr. at 869:21–870:4 (emphasis added). Dr. Dear did not testify that the Margulies paper describes the 454 beads as being Sepharose beads. *See id.* He testified that he believed Sepharose beads were used with the technique at the time Margulies was published. *See id.* The fact that one of the expert witnesses in this investigation had a belief as to the particular type of bead used with the Roche 454 sequencing technique by the authors of the Margulies paper does not lead to the conclusion that the paper discloses the composition of those beads. Indeed, one need only review the Margulies paper, which is in evidence, to see that Margulies does not discuss Sepharose beads. *See generally* CX-1940. Moreover, Dr. Dear's testimony falls short of establishing that persons of ordinary skill in the art would understand Margulies to disclose the use of Sepharose beads. *Cf. Akamai Techs., Inc. v. Cable & Wireless Internet Servs., Inc.*, 344 F.3d 1186, 1192 (Fed. Cir. 2003) ("[T]he dispositive question regarding anticipation is whether one skilled in the art would reasonably understand or infer from the prior art reference's teaching that every claim [limitation] was disclosed in that single reference."); *Rosco v. Mirror Lite,* 304 F.3d 1373, 1380 (Fed. Cir. 2002) ("[I]f an element is not expressly disclosed in a prior art reference, the reference will still be deemed to anticipate a subsequent claim if the missing element is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill." (internal quotation marks omitted)). In addition, his testimony does not indicate that Sepharose beads must necessarily or inevitably be used with the Roche 454 technique, which would be required to show inherent disclosure. *See Akamai Techs., Inc.*, 344 F.3d at 1192 ("A claim limitation is inherent in the prior art if it is necessarily present in the prior art, not merely probably or possibly present.").

The portion of the '059 patent on which Bio-Rad relies is also inapposite to its position. The cited portion of that patent merely provides that "[i]n some embodiments, the next generation

sequencing technique is 454 sequencing (Roche) (see e.g., Margulies, M et al. (2005) *Nature* 437: 376-380)." JX-31 at 26:52–54. That statement does not support the conclusion that the Margulies publication discloses the use of Sepharose beads with the Roche 454 sequencing technique. *See id.*

Finally, the Commission notes, as did OUII, that the Roche 454 technique is a sequencing technique as opposed to the sample preparation technique that is the subject of the asserted claims. *See* OUII Resp. to Pets. at 7 (citing CX-1827C at Q/A 108–109). The ID makes that point explicitly in its discussion of the releasable attachment limitation, *see* ID at 37 (citing CX-1827C at Q/A 87, 108), but the Commission reiterates it here because it is equally applicable to the "porous gel bead" limitation. Thus, nothing in the '059 patent or the Margulies paper discloses the porous gel beads of the asserted claims. Accordingly, neither reference anticipates the asserted claims of the '024 patent, all of which include limitations drawn to porous gel beads. Similarly, neither reference can supply that limitation as part of a combination of prior art references to show that the asserted claims are obvious.

Consistent with the supplemented reasoning above, the Commission affirms the ID's finding that the porous gel bead limitation is not disclosed in the prior art. The Commission further affirms the remainder of the ID's findings with respect to the validity of the '024 patent to the extent they are not inconsistent with the reasoning herein. Those findings include that the prior art, including the Church patent, does not disclose porous gel beads with "releasably attached" oligonucleotide molecules, and that the asserted claims are not rendered obvious by a combination of prior art. Accordingly, the Commission affirms the ID's finding that no asserted claim of the '024 patent is invalid.

IV. THE '468 PATENT

The Commission determined to review all of the ID's findings related to a violation of section 337 based on the '468 patent. 84 Fed. Reg. 56835. On review, the Commission has determined to affirm with modified reasoning the ID's finding that Bio-Rad has violated section 337 based on infringement of the '468 patent. The Commission also affirms with modified reasoning the ID's findings that 10X satisfies the domestic industry requirement with respect to the '468 patent and that no asserted claim of the '468 patent is invalid. The Commission adopts the remainder of the ID's findings with respect to the '468 patent to the extent they are not inconsistent with this opinion.

For reference, claims 1 and 21 of the '468 patent follow:

> 1. A method for droplet generation, comprising:
>
> (a) providing at least 1,000,000 oligonucleotide molecules comprising barcode sequences, wherein said barcode sequences are the same sequence for said at least 1,000,000 oligonucleotide molecules, wherein said at least 1,000,000 oligonucleotide molecules are ***releasably attached*** to a bead, wherein said bead is porous;
>
> (b) ***combining said at least 1,000,000 oligonucleotide molecules and a sample comprising a nucleic acid analyte each in an aqueous phase at a first junction of two or more channels of a microfluidic device to form an aqueous mixture comprising said at least 1,000,000 oligonucleotide molecules attached to said bead and said sample***; and
>
> (c) ***generating a droplet comprising said at least 1,000,000 oligonucleotide molecules attached to said bead and said sample comprising said nucleic acid analyte by contacting said aqueous mixture with an immiscible continuous phase at a second junction of two or more channels of said microfluidic device***.
>
> * * *
>
> 21. The method of claim **1,** wherein subsequent to generating said droplet in (c), a given oligonucleotide molecule of said at least 1,000,000 oligonucleotide molecules attaches to said nucleic acid analyte, and wherein said given oligonucleotide molecule attached to said given nucleic acid analyte is subjected to ***nucleic acid amplification*** to yield a barcoded nucleic acid analyte.

'468 patent at cls. 1, 21 (emphasis added on contested limitations).

A. Construction of "Amplification" and the Effect on Infringement and Domestic Industry

As noted in the context of the '024 patent, the Commission has determined to take no position on whether "amplification" encompasses reverse transcription. As with the '024 patent, that issue is immaterial to the issue of whether Bio-Rad infringes the '468 patent and 10X satisfies the domestic industry requirement for the '468 Patent because a preponderance of the evidence shows that that "amplification" limitation is satisfied by PCR in the accused and domestic industry products even under a narrower construction of "amplification" than the one employed by the ID. *See* discussion *supra* Section III.A. Accordingly, the Commission affirms the ID's findings that the '468 patent is infringed and that 10X satisfies the domestic industry requirement for the '468 patent. *See* ID at 58–66. A preponderance of the evidence supports this finding under the construction the ID applied, as well as under a narrower construction that would exclude reverse transcription from the definition of "amplification."

B. Validity

Bio-Rad petitioned for review of the ID's finding that none of the asserted claims of the '468 patent are invalid as anticipated or obvious based on the '059 patent. *See* Bio-Rad Pet. at 33–38 The ID's finding is based on three principal findings: (1) that the "releasably attached" limitation of the asserted claims is not disclosed in the prior art; (2) that the "combining" step of the asserted claims is not disclosed in the prior art; and (3) that the "generating a droplet" limitation of the asserted claims is not disclosed in the prior art. *See* ID at 66–70. The ID also found that secondary considerations weighed against finding any of the asserted claims obvious. *See id.* at 70.

On review, the Commission has determined to affirm the ID's finding that the asserted claims of the '468 patent are not invalid, but under modified reasoning. Particularly, the Commission affirms the ID's finding that the "releasably attached" limitation in (1) above is not disclosed in the prior art and the ID's finding that secondary considerations weigh against finding the asserted claims obvious and adopts those findings in whole. *See* ID at 66, 70. Those findings, including particularly the absence of the "releasably attached" limitation from the prior art, are sufficient to support the ID's finding that the asserted claims are not invalid as anticipated or obvious by the prior art. The Commission has determined to take no position on whether the "combining" and "generating a droplet" limitations in (2) and (3) above are disclosed by the '059 patent.

V. THE '204 PATENT

The ID found that 10X failed to establish that Bio-Rad's accused products infringe any asserted claim of the '204 patent. *See* ID at 77. The ID's noninfringement finding follows from two subsidiary findings: (1) the ID found that Bio-Rad's accused products do not meet a Markush group limitation that defines the type of stimulus used to cause a capsule to release its contents; and (2) the ID found that 10X could not rely on the doctrine of equivalents to satisfy the Markush group limitation. 10X petitioned for review of the ID's noninfringement finding by challenging both findings. *See* 10X Pet. at 9–18. The Commission has determined to affirm with supplemented reasoning the ID's finding that none of the asserted claims of the '204 patent are infringed. The Commission adopts the ID's findings to the extent they are not inconsistent with this opinion.

For reference, claims 1 and 27 of the '204 patent follow:

> 1. A composition comprising a plurality of capsules, said capsules situated within droplets in an emulsion, wherein said capsules are configured to release their contents into said droplets upon the application of a stimulus to provide said contents in said droplets in said emulsion, wherein 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.***
>
> * * *
>
> 27. The composition of claim 1, wherein said contents comprise at least 10,000 barcoded oligonucleotides releasably attached to each of said capsules.

'204 patent at cls. 1, 27 (emphasis added on contested Markush group).

A. Literal Infringement

The salient issue addressed in 10X's petition is the ID's determination that Bio-Rad's products "do not literally infringe the asserted claims because they do not have a stimulus 'selected from the group consisting of a change in pH, a change in ion concentration, reduction of disulfide bonds, and combinations thereof.'" ID at 73. The crux of the ID's decision with respect to this limitation is that the stimulus that causes barcode molecules to be released in Bio-Rad's products are [redacted]. *See id.* at 74. [redacted] are not listed among the stimulus choices in the Markush group (a change in pH, a change in ion concentration, reduction of disulfide bonds, and combinations thereof) and, therefore, Bio-Rad's products do not practice this limitation, which is incorporated into every asserted claim of the '204 patent. *See id.*

In concluding that Bio-Rad's products do not satisfy the Markush group limitation, the ID rejected several arguments from 10X. First, the ID rejected 10X's reliance on an [redacted] as the stimulus responsible for causing barcode molecules to be released from the gel beads in Bio-Rad's products. *See id.* at 74–78. The ID explained that the evidence of record did not show that an [redacted] alone would cause the release of barcode

molecules from gel beads. *See id.* at 75 ("[T]here is no evidence that the [redacted] by themselves would have any effect on the attached barcode molecules or the gel bead."). Rather, at best, 10X's evidence showed that barcode release is caused by [redacted] *See id.* ("Thus, as understood by [10X's expert,] Dr. Butte, the stimulus that causes the release of the barcode molecules from the gel bead in the accused products is the [redacted]"). Relying on the closed transition phrase "consisting of" in the Markush group, however, the ID interpreted the group to exclude additional unrecited elements, in this case, the [redacted]. *See id.* at 75–77. Thus, the ID determined that the stimulus limitation of the asserted claims could not be satisfied by the combination of an [redacted] and provision of [redacted] in Bio-Rad's products. *See id.* at 78.

The ID also rejected reliance on the [redacted] alone as the claimed stimulus. *See* ID at 77. Further to that finding, the ID noted that "there is no evidence that changing the [redacted] without the [redacted] will cause the release of barcode molecules from the gel beads." *Id.* The ID also pointed to a portion of 10X's posthearing brief that acknowledges the role of [redacted] in releasing the barcode molecules. *See id.* (citing 10X Posthearing Br. at 181–182). Regarding 10X's assertion that only the [redacted] is the claimed stimulus, the ID characterized that assertion as "unsupported attorney argument that is contradicted by the testimony of [10X's] own expert." *Id.* at 78 (citing Tr. (Butte) at 474:18-21). For these reasons, the ID found that "the accused products do not literally infringe the asserted claims." *Id.*

10X's primary argument is that an [redacted] is the claimed stimulus, and that the actions of [redacted] is the mechanism through which release is effectuated. *See* 10X

Pet. at 9–10 [redacted] is the start of a chain reaction: the [redacted]; and the contents of the capsule are released as a result. This [redacted] is applied as the trigger of a series of events leading to the release of the contents of the capsule and meets the claimed stimulus within the Markush group consisting of a change in pH, a change in ion concentration, reduction of disulfide bonds, and combinations thereof."). Relying on this premise, 10X attacks the ID from several directions, including arguing that the ID erroneously construed the claim such that the stimulus must "effectuate by itself the release of the contents without any facilitating or intermediate steps," 10X Pet. at 10, and that the ID erred by failing to give due weight to the fact that 10X stated in its various infringement contentions that only the [redacted] is the claimed stimulus, *id.* at 12–14.

None of 10X's arguments show that the ID erred in finding no literal infringement by Bio-Rad's products. First, as the ID noted, there is a pronounced lack of evidence supporting 10X's argument. For example, 10X's own expert *never* testified that an [redacted] alone was the stimulus recited in the asserted claims. Rather, Dr. Butte consistently testified that the stimulus was the [redacted]. For example, Dr. Butte testified as follows:

> Q: Sure. You're not claiming that the [redacted] is one of the claimed stimuli that's mentioned in claim 1 of the '204 patent; correct?
>
> A: It's [redacted]
>
> * * *
>
> Q: Right. But it's not the [redacted] itself; right?

A: It's not the [redacted] itself. It's the combination with the [redacted] specifically.

* * *

Q: Now, it's your view that the stimulus in the accused products is the [redacted] correct?

A: That is correct.

Tr. 371:14–18, 371:19–23, 432:13–16. Moreover, while 10X argues that the [redacted], *see* 10X Pet. at 9, its primary support for that contention is a section of equivocal corporate deposition testimony from a Bio-Rad witness who testified repeatedly that he was unsure of the purpose of [redacted] in Bio-Rad's process. *See, e.g.*, CX-0009C at 425:7–22 ("There are – there is [redacted] in that reaction. But it's required for a lot of DNA modifying enzymes. So I don't – I don't know. It's – it's not uncommon for an enzyme to bind a cofactor and – and not require additional – addition of a cofactor to – to be active. So I don't know if that – I don't know if the [redacted] that we add is – is necessary for the [redacted]."). Further still, Bio-Rad and OUII point to evidence suggesting that the [redacted] in Bio-Rad's products is unrelated to the action of the [redacted], which would directly refute 10X's argument that the [redacted]. *See* OUII Resp. to Pets. at 22; Bio-Rad Resp. to Pets. at 9–15; *see also* Tr. at 376:19–377:7, 377:11–379:4, 381:5–382:9, 383:18–384:16, 533:12–19, 564:15–565:9; JX-0050C at 56; JX-0132 at 65; RX-503C at Q/A 60–64; RX-537 at 5, RX-665C at Q/A 52, 59–65 (evidence relied on by OUII and Bio-Rad).

Second, 10X's argument that the ALJ misinterpreted its contentions about the accused stimulus is largely immaterial. *See* 10X Pet. at 12–14. Regardless of whether 10X asserted in its

briefs that only [redacted] is the claimed stimulus, the fact remains that there is little, if any, evidence to support that contention. That is, 10X's infringement argument did not fail because the ID misunderstood its contentions; it failed because those contentions do not show infringement by a preponderance of the evidence.

Finally, 10X's reliance on the word "comprising" in the preamble of the claims to argue that the presence of [redacted] in the accused products does not defeat infringement is at odds with the most analogous cases addressing the issue. Here, each of the independent claims begins with a preamble such as, "A composition comprising . . . ," '024 patent at cl. 1, "A device comprising . . . ," *id.* at cl. 23, or "A method comprising . . . ," *id.* at cl. 25. 10X relies on the word "comprising" in each to argue that the claims are open to additional unrecited elements. 10X Pet. at 11 (citing *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 811 (Fed. Cir. 1999); *Northern Telecom, Inc. v. Datapoint Corp.*, 908 F.2d 931, 945 (Fed. Cir. 1990)). Based on that uncontroversial legal principle, 10X argues that "[redacted] is no different than any other *unaccused* component of the buffer that plays a role in creating the right operating environment such that the [redacted] results in release of contents." 10X Pet. at 11 (emphasis in original).

10X's argument misapprehends the ID's reasoning and fails to acknowledge the rest of the claim language. First, the ID did not find that the mere presence of [redacted] in the accused products defeated infringement. The ID found that 10X's own expert admitted that [redacted] alone did not stimulate the release of barcodes as required by the claims, but rather the [redacted] were an essential component of the stimulus. *See* ID at 75. Second, each claim uses the phrase "said stimulus is selected from the group *consisting of* . . ." in the limitation at issue. '204 patent at cls. 1, 23, 25 (emphasis added). The transitional phrase "consisting of" indicates a closed

group of elements, including only "a change in pH, a change in ion concentration, reduction of disulfide bonds, and combinations thereof." *Id.* Because the evidence shows that [redacted] are all or part of the stimulus that caused the release of barcodes, this limitation is not met. The presence of the word "comprising" in the preamble of each claim does not negate the closed nature of the Markush group defining the set of stimuli that will read on the claim. Indeed, the cases the ID relied on to support its interpretation of the Markush group as a closed set of options dealt with exactly such claims — introduced by an open preamble with "comprising," but including a closed Markush group signaled with "consisting of." *See Multilayer Stretch Cling Film Holdings, Inc. v Berry Plastics Corp.,* 831 F.3d 1350, 1358 (Fed. Cir. 2016) (analyzing claims with "comprising" in the preamble followed by an element reciting, "selected from the group consisting of"); *Abbott Labs. v. Baxter Pharm. Prod., Inc.*, 334 F.3d 1274, 1276 (Fed. Cir. 2003) (same); *see also* ID at 74 (citing *Multilayer* and *Abbott*).

Under 10X's interpretation of the claim, the Markush group limitation would effectively become an open limitation, allowing any number of additional unrecited stimuli as long as one of the recited stimuli also had some connection to causing the capsules to release their contents. 10X cites no precedent interpreting a Markush group that introduces its elements with the signal "consisting of" in that way. To the contrary, precedent uniformly treats Markush groups using the signal "consisting of" as closed, excluding other unrecited elements absent explicit language in the claim permitting as much. *See Multilayer,* 831 F.3d at 1358; *Abbott Labs.*, 334 F.3d at 1276. Given the Federal Circuit's binding precedent, the Commission affirms the ID's reasoning that the Bio-Rad products do not infringe because the [redacted] are part of the stimulus that releases barcodes in the accused products, but the Markush group recited in the asserted claims does not encompass the [redacted]. We adopt those findings.

The Commission notes that the ID reached its conclusion without resolving the disputed issue of whether an [redacted] in the accused products. In response to the Commission's request for briefing, 10X argued that the [redacted] *See* 10X Resp. to Qs. at 28–35. In support of that argument, 10X argued that (1) [redacted]. *See id.* at 33–35. This facet of 10X's argument relied on a publication by Melamede, *et al.*, listed on the face of the [redacted] product insert.[7] *See* JX-0050C at 56; CX-1965. Particularly, 10X asserted that "Figure 6C of Melamede plots the activity of Endo VIII [redacted]. *Id.* at 34; *see also id.* at 35.

[7] The [redacted] product insert lists five articles and one U.S. Patent on its face. JX-0050C at 56. 10X relies on one of those references — Melamede, R.J., Hatahet, Z., Kow, Y.W., Ide, H. and Wallace, S.S. (1994) *Biochemistry* 33, 1255–1264 (hereinafter "Melamede") (CX-1965) — to support its argument that an [redacted] activity. Bio-Rad relies on the U.S. Patent — U.S. Patent No. 7,435,572, "Methods and Compositions for DNA Manipulation," issued to Jurate Bitinaite on October 14, 2008 (hereinafter "the '572 patent") (JX-0132) — and one of the articles — Lindhal, T., Ljungquist, S., Siegert, W., Nyberg, B. and Sperens, B. (1977) *J. Biol. Chem.* 252, 3286–3294 (hereinafter "Lindhal") (RX-0537) — to support its counter-argument that an [redacted].

10X also relies on the testimony of a Bio-Rad employee, Dr. Agresti, who provided corporate deposition testimony on behalf of Bio-Rad, and also testified at the evidentiary hearing. *See id.* at 36. Specifically, 10X notes that "Dr. Agresti provided corporate deposition testimony that [redacted], but that he did not recall which of the [redacted] required it." *Id.* In 10X's view, Dr. Agresti's deposition testimony supports its argument that "the activity [of] [sic] [redacted]." *Id.* 10X further noted that Dr. Agresti testified at the evidentiary hearing that he did not believe [redacted], but 10X characterizes that testimony as contradictory to his deposition testimony. 10X also argued that the bases of Dr. Agresti's hearing testimony — a publication by Lindhal, RX-0537, and U.S. Patent No. 7,435,572, JX-0132, both of which appear on the [redacted] product insert — were cherry-picked for him by Bio-Rad's counsel, and that neither are reliable because they concern [redacted] activity under conditions that are materially different from those found in the accused products. *See id.* at 36–40. Based on these arguments, 10X submits that a "preponderance of evidence therefore shows that an [redacted], meeting the relevant language of Claim 1 of the 204 Patent." *Id.* at 41.

Bio-Rad argued in its response that any [redacted] in the workflow of its products does not [redacted]. *See* Bio-Rad Resp. to Qs. at 34–35. Bio-Rad does not appear to dispute that [redacted] to the ddSEQ system, but submits that the purpose of that addition is to [redacted]). *See id.* at 37 ("On the contrary, the evidence shows that Bio-Rad [redacted],

[redacted].”). Bio-Rad argued that the [redacted] is already 100% active without any [redacted]. *See id.* at 35–37.

The strongest part of Bio-Rad’s counter-argument is that 10X’s cited evidence purporting to show a relationship between [redacted] is inapposite because of material differences in the conditions surrounding the experiments in the cited article and the conditions present in Bio-Rad’s products. *See id.* at 41–43. For example, Bio-Rad points out that while 10X relies heavily on Melamede, that article “tested the activity of Endonuclease VIII ***on DNA containing thymine glycols***.” Bio-Rad Resp. to Qs. at 42 (emphasis in original). Moreover, Bio-Rad submits that “Melamede expressly states that Endonuclease VIII [redacted]” *Id.* (citing CX-1965.00008). Thus, Bio-Rad argues that 10X is relying on information about [redacted] activity that is insufficiently related to the behavior of the [redacted] in the accused products. *See id.* at 41–43 (“10X does not even attempt to demonstrate that the context of Melamede has any relevance to the context of the Bio-Rad Accused Products”).

Bio-Rad also argued that 10X’s calculations of the amount of [redacted] to Bio-Rad’s products are unsupported attorney argument, and are also contradicted by witness testimony in the record. Bio-Rad Resp. to Qs. at 43–44 (citing Greiner Tr. 539:16-541:15). The point of that argument, presumably, is to further undermine any reliance on Melamede by arguing that the concentrations of [redacted] investigated in Melamede are not similar to the concentrations present in Bio-Rad’s products.

Finally, Bio-Rad pointed to the Lindhal article and the ’572 patent referenced on the [redacted] product insert as evidence that the [redacted] are either unaffected or inhibited by the [redacted]. *See id.* at 44–46; *see also* Bio-Rad Resp. to Pets. at 12–15.

Particularly, Bio-Rad argued that "according to Lindahl, UDG, [redacted]," Bio-Rad Resp. to Qs. at 44, and that "the '572 Patent describes the [redacted] and confirms that [redacted]," *id.* at 44–45.

OUII's response was in substantial alignment with Bio-Rad's. OUII Resp. to Qs. at 15–19. OUII reiterated the evidence it pointed to in its petition for review to show that the [redacted] used in the Bio-Rad products are active without any [redacted], that the [redacted], and that the purpose of the [redacted] present in the Bio-Rad products is to [redacted]. *See id.* at 15–18. With respect to the Melamede article, OUII takes the position that the experiments reported therein are insufficiently related to the accused products to conclude that an [redacted]. *See id.* at 18. OUII was also critical of the absence of expert testimony supporting 10X's interpretation of Melamede. *Id.*

There is no dispute that Bio-Rad's processes involve an [redacted]. There is, however, a lack of reliable evidence as to the effect, if any, that [redacted]. This is because the parties failed to show that the articles and references upon which they rely analyzed [redacted] activity in conditions that are the same or similar to those in the accused products. 10X has the burden of proving infringement by a preponderance of the evidence; the evidence does not establish that Melamede's reported relationship between [redacted] and Endo VIII's activity in nicking thymine glycols is probative of the relationship between [redacted]

[redacted] in the accused products to release barcodes. *See* Bio-Rad Reply at 35–37 (discussing evidence supporting the distinction between [redacted] in the accused products and Endonuclease VIII nicking thymine glycol). Dr. Agresti's deposition testimony is hardly persuasive on the effect of [redacted] in the accused products. When viewed in whole, the relevant portion of Dr. Agresti's deposition transcript demonstrates that Dr. Agresti did not know at the time whether the [redacted] was necessary for the [redacted] to work. *See* CX-0009C at 422:20–429:15.

Even if 10X's argument is accepted as true, it would not show that an [redacted] is the "trigger of a series of events leading to the release of" barcodes from the beads in the accused products. *Cf.* 10X Pet. at 10 (arguing that an [redacted]). According to 10X, prior to any [redacted] in the accused products, *see* 10X Pet. at 35 ("According to Melamede, that [redacted] Thus, even under 10X's theory, an [redacted] does not "trigger" the release of barcodes from beads in the accused products. The [redacted] is already active, and the presence of [redacted] only improves its activity. 10X fails to explain how that [redacted] reads onto the '204 patent's claim language requiring capsules "configured to release their contents . . . upon the application of a stimulus." *See, e.g.*, '204 patent at cl. 1. Under 10X's theory, the [redacted] will stimulate the capsules in Bio-Rad's products to release barcodes regardless of whether [redacted] is added, albeit possibly at a slower rate. Accordingly, even under its own theory of how [redacted] in the accused products, 10X

has not shown that an [redacted] is the stimulus that causes the capsules in Bio-Rad's products to release their barcodes.

In conclusion, the Commission affirms the ID's finding that 10X failed to show that the asserted claims of the '204 patent are literally infringed by the accused products.

B. Doctrine of Equivalents

Before the ALJ, 10X argued in the alternative that the Markush group limitation was satisfied by the [redacted] in the presence of a change in [redacted] ion concentration as an equivalent to the recited "reduction in disulfide bonds" element. *See* ID at 78. The ID rejected this argument, finding that 10X was estopped from relying on the doctrine of equivalents ("DOE") to satisfy this limitation. The ID's finding in that regard has two facets: (1) there is a presumption that 10X is estopped from relying on DOE based on its amendments during prosecution, *see id.* at 82; and (2) 10X had not established that its narrowing amendment was tangential to the alleged equivalent (which would overcome the presumption against DOE), *see id.* at 85.

10X petitioned for review of the ID's finding that it is estopped from relying on DOE to satisfy this element of the asserted claims. 10X does not dispute the ID's finding that a presumption of estoppel is proper, but rather faults the ID for misunderstanding what evidence was in the record.[8] 10X Pet. at 16. Particularly, 10X faults the ID's statement that "the record **is devoid of any evidence concerning Trnovsky's teachings**." *Id.* (quoting ID at 84 (emphasis 10X's)).

[8] 10X spends several pages of its petition reciting the "procedural history of Staff's [prosecution history estoppel] argument" to show "the improper burden the ID imposes on 10X." 10X, however, does not explain how the procedural history of the issue supports modifying or reversing the ID, and we find such argument meritless in any event. 10X's chief complaint appears to be that Bio-Rad raised but abandoned a similar argument, while OUII raised the argument for the first time in its prehearing brief. Presumably, 10X's implication is that it did not receive a fair opportunity to prepare evidence in response to OUII's argument. If that is the case, 10X's recourse was to seek relief from the ALJ.

10X argues this statement is clear error because Trnovsky itself is in the record, as is testimony from 10X's expert, Dr. Butte. *Id.* at 16–17.

As explained in the ID, "[d]uring the prosecution of the '204 patent, application claims 1, 78, and 110 matured into issued claims 1, 23, and 25, respectively." ID at 79 (citing JX-0009 at 13630). As originally filed, application claims 1 and 78 required a capsule(s) "configured to release their contents . . . upon the application of a stimulus," but did not require that the stimulus be selected from a particular group of stimuli. *Id.* (quoting JX-0009 at 80 (application claim 1); JX-0009 at 85 (application claim 78) (requiring a capsule "configured to release its contents into said droplets upon the application of a stimulus"). Similarly, application claim 110 required a step of "providing a stimulus to cause said capsules to release their contents into said droplets," without requiring the stimulus be selected from a group of stimuli. *Id.* (citing JX-0009 at 87).

The ID further explains that while "application claim 1 did not limit the stimulus to a group of stimuli, two of its dependent claims [(application claims 19 and 21)] did." ID at 80. Application claim 19 required the stimulus to be "selected from the group consisting of a chemical stimulus, a bulk stimulus, a biological stimulus, a light stimulus, a thermal stimulus, a magnetic stimulus, and combinations thereof," while application claim 21 required the stimulus to be "selected from the group consisting of a change in pH, a change in ion concentration, reduction of disulfide bonds, and combinations thereof." JX-0009 at 81.

A brief description of the prosecution history is helpful before addressing 10X's argument. In an office action issued on January 29, 2016, the examiner rejected all of the pending claims as anticipated in view of several prior art references. *Id.* at 9770–9781. Application claim 1 was found to be anticipated by seven references: (1) U.S. Patent Publication No. 2005/007951 to Berka et al. ("Berka"), (2) U.S. Patent Publication No. 2015/0079510 to Church et al. ("Church"), (3)

U.S. Patent Publication No. 2014.0227706 to Kato et al. ("Kato"), (4) U.S. Patent Publication No. 2003/0207260 to Trnovsky et al. ("Trnovsky"), (5) U.S. Patent Publication No. 2013/0189700 to So et al. ("So"); (6) U.S. Patent Publication No. 2004/0258701 to Dominowski et al. ("Dominowski"); and (7) U.S. Patent Publication No. 2009/0025277 to Takanashi ("Takanashi"). *Id.* at 9777–9780. Application claim 19 was rejected as anticipated by five references: (1) Berka, (2) Trnovsky, (3) So, (4) Dominowski, and (5) Takanashi. *Id.* Application claims 78 and 110 were rejected as being anticipated by Berka. *Id.* Application claim 21 was rejected as being anticipated by Kato. *Id.*

On April 28, 2016, the applicants responded to the rejections by, *inter alia*, cancelling application claims 19 and 21 and amending application claims 1, 78, and 110. As amended, application claims 1, 78, and 110 incorporated application claim 21's limitation requiring that the stimulus be "selected from the group consisting of a change in pH, a change in ion concentration, reduction of disulfide bonds, and combinations thereof." *Id.* at 10009; *see also id.* at 10000, 10002, 10003. With this amendment, the applicants argued that the amended application claims were allowable over the cited prior art with the exception of Kato. *Id.* at 10009 ("Initially, as Claim 21 was rejected only over Kato, Applicant understands that the Office acknowledges that none of Berka, Church, Trnovsky, So, Dominowski and Takanashi teach or disclose 'wherein 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,' as recited in claims 1, 31, 78, 89, 110 and 118."). With regard to Kato, the applicants argued that "Kato does not teach or disclose, 'wherein said capsules are configured to release their contents into said droplets upon the application of a stimulus,' as recited in Claim l." *Id.* at 10010. The applicants also argued that Kato did not qualify as prior art. *Id.*

On August 5, 2016, the examiner rejected the amended claims in view of a new set of prior art references and noted that the previous rejections had been rendered moot in view of the new grounds of rejection. *Id.* at 10074. The examiner also "noted that the 102(b) rejection of Claims 1 and 21 over Kato has been withdrawn in light of the applicant's persuasive arguments." *Id.* In response to the new rejections, the applicants further amended application claims 1, 78, and 110 to require that the capsule or capsules "provide said contents in said droplets in said emulsion" upon the application of a stimulus. *Id.* at 10118, 10120–21. The application claims as amended were allowed. *Id.* at 13617.

The Commission finds that 10X is correct that Trnovsky is in the record, and thus the ID was wrong to state that there is no record evidence of Trnovsky's teachings. Trnovsky is exhibit JX-0030, and was admitted on March 25, 2019. Tr. at 480. The ID apparently interpreted the statement in 10X's posthearing reply brief that "Staff [] did not introduce the underlying references, and the evidence of record is that they do *not* disclose [redacted] with a change in ion concentration," to mean that the Trnovsky was not introduced at all, when apparently 10X only meant that OUII did not introduce Trnovsky as an exhibit. CRB at 85; *see also* ID at 84 (citing same). Because the ID's statement concerning Trnovsky's admission is incorrect, the Commission reverses that limited portion of the ID's reasoning. However, notwithstanding that correction, 10X still has not shown why it is entitled to rely on DOE based on correction of this error.

The crux of 10X's tangential relationship argument is that Trnovsky did not disclose the combination of an enzyme with a change in ion concentration as the stimulus to cause a capsule to release its contents. 10X Pet. at 17 (quoting CX-0004C (Butte WS) at Q/A 331). Rather, the reference only disclosed the use of a specific enzyme (agarase) on its own. *See id.* Thus, 10X

argued that the amendment to overcome Trnovsky only surrendered the use of enzymes that did not work in combination with a change in pH, a change in ion concentration, or a reduction of disulfide bonds. *See id.* Thus, according to 10X, the combination of an enzyme *with* a change in pH, a change in ion concentration, or a reduction of disulfide bonds continued to be covered by the claims. *See id.*

The Commission finds that the legal support for 10X's tangential relation argument is lacking. Particularly, 10X's argument implicitly relies on the premise that the tangential relation exception to prosecution history estoppel applies if the prior art does not contain the asserted equivalents. This is incorrect. As explained by the Federal Circuit, while "[a]n amendment made to avoid prior art that contains the equivalent is not tangential," ***"[i]t does not follow [] that equivalents not within the prior art must be tangential to the amendment***." *Integrated Tech. Corp. v. Rudolph Techs., Inc.*, 734 F.3d 1352, 1358 (Fed. Cir. 2013) (emphasis added) (internal citations and quotation marks omitted). Indeed, an applicant may surrender by amendment more than what was required to overcome the prior art, and yet, the applicant cannot reclaim that excess via the DOE. *See Southwall Techs., Inc. v. Cardinal IG Co.*, 54 F.3d 1570, 1581 (Fed. Cir. 1995) ("[T]he limits imposed by prosecution history estoppel on the permissible range of equivalents can be broader than those imposed by the prior art.").

What 10X must show to rely on the tangential relation exception to prosecution history estoppel is that the reason for the applicant's "narrowing amendment was peripheral, or not directly relevant, to the alleged equivalent." *Integrated Tech. Corp. v. Rudolph Techs., Inc.*, 734 F.3d 1352, 1358 (Fed. Cir. 2013) (quoting *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.,* 344 F.3d 1359, 1369 (Fed. Cir. 2003) (en banc)). In other words, 10X must show that the reason the applicant amended the Markush group limitation to recite a change in pH, a change in ion

concentration, or a reduction of disulfide bonds was peripheral, or not directly relevant, to its alleged equivalent, *i.e.*, the action of [redacted]. That showing should "focus[] on the patentee's objectively apparent reason for the narrowing amendment, which should be discernible from the prosecution history record." *Integrated Tech. Corp.*, 734 F.3d at 1358 (internal quotation marks omitted) (quoting *Festo*, 344 F.3d at 1369).

Here, 10X has not made the required showing. Rather, 10X relies on the following testimony from its expert, Dr. Butte:

> Trnovsky did not describe [redacted] generally, but digestion with a specific enzyme: agarase (which Bio-Rad incorrectly quoted as agarose). JX-0030.00010 ([0009]). Trnovsky was overcome by the amendment because Trnovsky has no description, either in paragraph 9 or 102, which were cited by the examiner, see JX-0009.09778, of the use of agarase with a change in a change in pH, a change in ion concentration, or a reduction of disulfide bonds. One of ordinary skill in the art would understand that the amended claims no longer covered enzymes such as agarase that did not work with a change in a change in pH, a change in ion concentration, or a reduction of disulfide bonds. *However, one of ordinary skill would also understand that the claims continue to cover the use of enzymes with change in a change in pH, a change in ion concentration, or a reduction of disulfide bonds.*

10X Pet. at 17 (quoting CX-0004C at Q/A 331) (emphasis added). Even assuming that this testimony is uncontested, as 10X claims it is, it does not show that the tangential relation exception applies. Here, Dr. Butte merely testifies that the reference "Trnovsky has no description, either in paragraph 9 or 102, which were cited by the examiner, see JX-0009.09778, of the use of agarase with a change in a change in pH, a change in ion concentration, or a reduction of disulfide bonds." *Id.* But, as explained above, "[i]t does not follow [] that equivalents not within the prior art must be tangential to the amendment." *Integrated Tech. Corp. v. Rudolph Techs., Inc.*, 734 F.3d 1352, 1358 (Fed. Cir. 2013) (internal citations and quotation marks omitted).

The applicant's amendment drastically reduced the universe of stimuli covered by the Markush group to overcome an anticipation rejection based on references, such as Trnovsky, that

disclosed stimuli covered by the applicant's original, broader claims. That reason is neither peripheral nor irrelevant to 10X's alleged equivalent, which would replace a reduction in disulfide bonds with the action of [redacted] in the presence of an [redacted] ions. The action of [redacted] would have been included within the scope of the applicant's original claims, but also would have been anticipated by the disclosure of Trnovsky concerning agarase, both [redacted] and agarase enzymes being within the original Markush group consisting of a chemical stimulus, a bulk stimulus, and a biological stimulus. The applicant's amendment surrendered both enzymes by narrowing the universe of claimed stimuli drastically. Though 10X now tries to create space between the amendment's rationale and its claimed equivalent by relying on [redacted] in combination with an [redacted], it points to nothing "objectively apparent" in the prosecution history to show that the rationale for its amendment was irrelevant to enzymes in combination with an increase in ion concentrations. Particularly, Dr. Butte's testimony to that effect is wholly conclusory, and not part of the prosecution history. *See Integrated Tech. Corp.*, 734 F.3d at 1358 ("The tangential relation inquiry 'focuses on the patentee's objectively apparent reason for the narrowing amendment,' which 'should be discernible from the prosecution history record.'" (quoting *Festo*, 344 F.3d at 1369)).

At bottom, 10X's tangential relation argument against prosecution history estoppel lacks legal and evidentiary support. The ID was correct to discount it. However, the ID erroneously stated that Trnovsky is not in evidence, and that the record is devoid of evidence concerning its teachings. Accordingly, the Commission affirms the ID's finding that 10X is estopped from relying on the doctrine of equivalents to show infringement, *see* ID at 78 (finding that 10X "is precluded from relying on the DOE to satisfy the Markush group limitation."), but with the

correction that Trnovsky is in evidence and with the additional reasoning laid out above. *See* discussion *supra* pp. 35–41.

VI. THE '530 PATENT

The Commission previously determined to review all of the ID's findings related to a violation of section 337 based on the '530 patent. 84 Fed. Reg. 56835. On review, the Commission has determined to affirm with modified reasoning the ID's finding that Bio-Rad has violated section 337 based on infringement of the '530 patent. The Commission also affirms with modified reasoning the ID's finding that 10X satisfies the domestic industry requirement with respect to the '530 patent. The Commission has determined to take no position on whether Bio-Rad contributorily infringes the '530 patent. The Commission also finds that Bio-Rad abandoned the indefiniteness argument raised for the first time in its petition for review of the ID, but that even if not abandoned, the argument would fail. The Commission adopts the remainder of the ID's findings with respect to the '530 patent to the extent they are not inconsistent with this opinion.

A. Background

Of the asserted claims — claims 1, 4, 11, 14, 19, 26, 28 — claim 1 is the sole independent claim, and the bulk of the disputes with respect to the '530 patent involve the limitations recited in claim 1. All of the other asserted claims depend, both directly and indirectly, from independent claim 1. Claim 1 reads as follows:

> 1. 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 at cl. 1 (emphasis added on contested limitations; indentation from "wherein said barcode molecules become detached from said gel bead" paragraph maintained from admitted joint exhibit, JX-7).

In construing claim 1, the *Markman* order rejected proposed constructions from OUII and Bio-Rad that would limit the claim by requiring that the 1,000 droplets be provided in a single experiment (Bio-Rad's proposal) or by requiring that the plurality of cells come from a common sample (OUII's proposal). *See* Order No. 22 at 46 (*Markman* Order) at 46–48. The *Markman* order also rejected 10X's argument that multiple runs of the method could be combined to reach the 1,000-droplet threshold in step (b). *See id.* at 50–51. Ultimately, the *Markman* order concluded that "claim 1 requires that the step of generating 'at least 1,000 droplets' be completed before the third step of forming a 'plurality of barcoded polynucleotide molecules' is performed in any of the droplets." *Id.* at 51.

Thereafter, on March 5, 2019, the ALJ issued Order No. 35, which denied Bio-Rad's motion for summary determination of non-infringement with respect to the '530 patent, among others things. In its motion, Bio-Rad had argued that its products did not infringe because, in them, barcoding began before all of the at least 1,000 droplets were formed. *See* Order No. 35 at 4–5.

Order No. 35 rejected Bio-Rad's argument on the basis that the *Markman* order did not interpret claim 1 such that "all 1,000 droplets form before any barcoding begins." *Id.* at 6 (internal quotation marks omitted). Rather, "[t]he 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." *Id.* Order No. 35 then further explained that even if Bio-Rad's assertion were true that some barcoded molecules were formed at room temperature before the at least 1,000 droplets were generated, that would "not preclude a finding of infringement based on a subsequent step of generating barcoded molecules in a thermal cycler." *Id.* The crux of Order No. 35's reasoning is that some barcoding may occur during the droplet generation claimed in step (b) without precluding the possibility that after 1,000 droplets are generated in step (b) additional barcoding may occur that will satisfy step (c) of claim 1. *See id.* (citing *Kaneka Corp. v. Xiamen Kingdomway Group Co.*, 790 F.3d 1298, 1306, (Fed. Cir. 2015)).

The final ID reiterated and applied the claim constructions for the '530 patent from Order Nos. 22 and 35, discussed above. ID at 91.

B. "wherein said barcode molecules become detached from said gel bead."

Bio-Rad petitioned for review of the ID's findings of infringement and domestic industry with respect to the '530 patent. Among the arguments raised in Bio-Rad's petition is that neither the accused products nor the domestic industry products practice the final clause of step (c) of claim 1, which reads: ". . . wherein said barcode molecules become detached from said gel bead." '530 patent at cl. 1. Bio-Rad's arguments rely on the premise that this "wherein" clause is part of step (c), and thus subject to the ID's requirement that step (c) occur after at least 1,000 droplets are generated in step (b). In other words, barcode detachment must occur after at least 1,000 droplets are generated. There is no question that barcode detachment occurs in the accused and

domestic industry products; thus, the salient dispute raised by Bio-Rad's petition is the timing of barcode detachment.

Step (c) of claim 1, as it appears in the '530 patent, sets off the "wherein" clause with separate indentation from the other limitations of step (c). *See* '530 patent at cl. 1.[9] At the same time, the wherein clause is separated from the other clauses of step (c) with only a comma, where elsewhere in the claim separate steps are set off with semi-colons. Because the unusual indentation of the "wherein" clause raises some ambiguity as to whether that clause is part of step (c) — and thus subject to the timing requirement at the heart of Bio-Rad's argument — the Commission sought briefing from the parties on whether the "wherein" clause is included within step (c). The parties all agreed in response that the "wherein" clause is part of step (c) of the method claimed in claim 1. The Commission agrees, and therefore affirms the ID's finding that the third step of the

[9] Images from the '530 patent follow:

What is claimed is:

1. 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

* * *

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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.

2. The method of claim **1**, wherein, prior to (c), said

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15. The method of claim **1**, wherein, in (a), said at least 1,000 gel beads are a subset of a plurality of gel beads.

16. The method of claim **15**, wherein said plurality of gel beads comprises at least 10,000 gel beads.

17. The method of claim **1**, wherein said at least 1,000

'530 patent at cl. 1 (highlighting added on disputed clause).

claimed process "requires that the 'barcode molecules become detached from said gel bead.'" ID at 98. Accordingly, because the "wherein" clause is part of step (c), the barcode detachment required by that clause must occur after at least 1,000 droplets have been generated in step (b). The parties dispute whether the accused and domestic industry products practice the "wherein" clause so construed.

10X argued that a "preponderance of evidence shows that Bio-Rad's accused products and 10X's domestic industry products practice step (c) of Claim 1 of the ']530 Patent if the Commission finds that the barcode molecules must become detached from the gel bead during that step." 10X Resp. to Qs. at 46. Concerning the accused Bio-Rad products, 10X pointed to evidence showing that [redacted], *i.e.*, the barcodes are released during step (c). *See id.* at 46–48.

Concerning its own domestic industry products, 10X argued that "[o]n the thermal cycler in 10X's single-cell products, barcode detachment occurs and those barcodes are used to form barcoded cDNAs." *Id.* at 49. 10X further argued that "[t]he entire droplet formation process takes only several minutes, whereas 10X's technical fact witness explained upon cross-examination that the gel bead with attached barcodes persists after droplet formation." *Id.* at 50 (citing Schnall-Levin, Tr. at 224:18-23). In making that point, 10X implicitly argues that barcode release does not happen instantaneously in its products such that at least 1,000 droplets can be formed and transferred to a thermal cycler before the barcodes are released in those droplets.

By contrast, Bio-Rad argued that neither the accused nor domestic industry products satisfy the "wherein said barcode molecules become detached from said gel bead" limitation of claim 1 because in both sets of the products the barcodes become detached before a collection of at least 1,000 droplets can be generated. *See* Bio-Rad Resp. to Qs. at 54. With respect to the domestic

industry products, Bio-Rad pointed to evidence showing that [redacted] dissolves the gel beads and thus releases the barcodes immediately after droplet formation and prior to incubation on the thermal cycler. *See id.* at 58–64. Because the barcodes are released immediately after barcode formation, Bio-Rad argued that the domestic industry products do not release barcodes after at least 1,000 droplets have been formed, as required by step (b) of claim 1. Thus, Bio-Rad argued that the domestic industry products do not practice the "wherein" clause during step (c), because there is never a collection of at least 1,000 droplets in which gel beads release their barcodes. Bio-Rad also pointed out that the evidence cited in the ID to support the conclusion that barcodes are detached during incubation (and thus as part of step (c)), does not actually support that conclusion. *See id.* at 59–60. Bio-Rad further pointed to portions of the user manual cited by the ID that actually tend to show that barcodes are released prior to incubation on the thermal cycler. *Id.* at 60 (citing CX-0481 at 11).

With respect to its accused products, the crux of Bio-Rad's argument is that the [redacted]. *See id.* at 65–66. Bio-Rad disputed the ID's finding that the purpose of heating the droplets in the accused products on a thermal cycler[10] — a process that occurs after droplet formation — is to activate the [redacted]. *See id.* at 66. Bio-Rad argued that the ID incorrectly described the product label for [redacted] as describing a reaction temperature and time when the label only actually specifies a temperature. *See id.* Bio-Rad also disputed that many of its own documents cited by

[10] A thermal cycler, also known as a thermocycler, is a laboratory instrument that can be used to raise and lower the temperature of a sample in discrete, pre-programmed steps. *See* CX-0481 at 26 (10X Chromium™ Single Cell 3' Reagent Kits v2 User Guide describing three-step incubation procedure on a thermal cycler); *see also id.* at 9 (listing recommended thermal cyclers).

the ID show that [redacted]. *See id.* at 66–67. Bio-Rad also argued that the ID erred in concluding that even if the [redacted]. *See id.* at 67–68. Finally, Bio-Rad argued that the weight of expert and fact witness testimony presented supported the conclusion that the [redacted]. *See id.* at 68–70.

OUII argued, like 10X, that the ID's finding that the accused products infringe should stand under its position on the relationship between the "wherein" clause and step (c) of claim 1. OUII Resp. to Qs. at 22. OUII pointed to evidence showing that the purpose of incubating the accused products on a thermal cycler at 37°C is to [redacted]. *Id.* at 22–24. OUII thus concluded that a preponderance of the evidence shows that the accused products practice step (c) of the claimed method, including the [redacted].

OUII agreed with Bio-Rad, however, that a preponderance of the evidence does not support the conclusion that the domestic industry products practice step (c) of claim 1. Like Bio-Rad, OUII pointed to documentation produced by 10X that indicates that the gel beads in the droplets dissolve "immediately" upon droplet generation, thus releasing barcode molecules, before droplets are placed on the thermal cycler. *See id.* at 24–25 (citing CX-423C at 15; CX-0004C at Q/A 242, 260; CX-540 at 5:48–6:08).

On review, the Commission has determined to affirm, with modified reasoning, the ID's conclusion that the accused products infringe the asserted claims of the '530 patent, and affirm, with modified reasoning, the ID's conclusion that the domestic industry products practice claim 1.

1. Accused Products

With respect to the accused products, there is ample evidence to show that barcode cleavage happens on the thermal cycler when the samples are heated at 37°C for 30 minutes. This evidence comes in the form of (1) a declaration submitted by a Bio-Rad scientist during prosecution of a Bio-Rad patent, *see* JX-0171 at 328–29 (Declaration from Bio-Rad scientist Andrew Kohlway) ("The data was generated using the protocol from the Illumina-Biorad SureCell WTA 3' Library Prep kit . . . *Droplets were incubated at 37° for 30 minutes to allow the cleaving agent to cleave the dT oligonucleotides off the bead.* Next droplets were incubated at 50°C for 1 hour to allow cellular RNA to be reverse transcribed using dT oligonucleotide primers.") (emphasis added), and (2) Bio-Rad's own expert's testimony, *see* RX-665C at Q/A 41 ("Then another step is carried out to make sure that the [redacted] and reverse transcription reactions, which took place [redacted]. In this step, the tube with the emulsion is placed into a thermocycler that is programmed to operate at two temperatures, [redacted]. First, the thermocycler operates at 37°C (basically our body temperature) for 30 minutes [redacted].

Bio-Rad's counter arguments are unpersuasive. Bio-Rad simply lacks evidentiary support for its position that "the barcode molecules [redacted]" Bio-Rad Resp. to Qs. at 65. Bio-Rad relies heavily on the testimony of its own expert, Dr. Michael Metzker, and one of its own employees, Dr. Douglas Greiner, who testify not only that [redacted]. *See* RX-665C at Q/A 97, 102, 107; RX-507C at Q/A 65; RX-727C at Q/A 8–11, 17–20. However, as noted in the ID, Dr. Metzker's testimony stands only for the

proposition that [redacted]. *See* RX-665C at Q/A 97, 102, 107; ID at 101. That testimony does not contradict the ID's ultimate finding that the [redacted].

Dr. Greiner's initial testimony is similar, establishing only that [redacted]. *See* RX-507C at Q/A 65. Dr. Greiner's rebuttal testimony goes further and, if accepted, would establish that both [redacted]. *See* RX-727C at Q/A 8–11, 17–20. Even this rebuttal testimony, however, stops short of establishing error in the ID's finding that the [redacted]. The claimed process does not include a negative limitation precluding any [redacted] or barcoding from occurring immediately upon droplet formation. The process requires only that [redacted] and barcoding occur in at least 1,000 droplets after those droplets are generated. *See* '503 patent at cl. 1.

Moreover, Dr. Greiner's rebuttal testimony relies on the assumption that the [redacted] is active at room temperature, which is contradicted by the [redacted]. *Compare* RX-727C at Q/A 11 ("Based on my own experience, I know that enzymes generally are active at room temperature, 25°C. Also, the scientific literature shows that the [redacted]") *with* JX-0050C at 56 ("[redacted] (emphasis added)). Similarly, Dr. Greiner's testimony that [redacted] is contradicted by Bio-Rad's own reference guide, which explains that reverse transcription occurs on the thermal cycler. *Compare* RX-727C at Q/A 18 ("[redacted]

[redacted].") *with* JX-0034 at 25 ("This step reverse transcribes samples on a thermal cycler.").

Order No. 35 specifically rejected Bio-Rad's interpretation of claim 1 wherein all droplet formation must be complete before *any* barcode release and barcoding began. *See* Order 35 at 6. Under such a construction, Bio-Rad might have a stronger argument that some limited amount of barcode release and barcoding occurs before 1,000 droplets have been generated. Thus, Bio-Rad's arguments are most persuasive when viewed through the lens of a claim construction that was never adopted. While Bio-Rad now tries to adjust its argument to fit the ID's claim construction — which *does not* require *all* droplet generation to be complete before any barcodes are released — the two are an imperfect match, which leads to Bio-Rad's failure on this issue.

At bottom, the dispute here is a factual one about the operation of Bio-Rad's products. The ID considered this dispute, including the testimonial evidence from Bio-Rad's expert, and concluded that "10X has shown by the preponderance of the evidence that at least the bulk of the following processes occur while the droplets are being heated on the thermal cycler: (1) the [redacted] release the barcode molecules from the gel bead and (2) the reverse transcription of barcoded cDNA from mRNA and barcode molecules." ID at 102. The Commission has determined to affirm that ultimate finding under the modified reasoning given above.[11]

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[11] The ID misstates a piece of evidence on which it relies to reach that conclusion. Particularly, the ID describes exhibit JX-0050C at 56, which is a picture of the [redacted] product label, as "[redacted]" ID at 100. However, the label reproduced on the exhibit does not state that incubation should occur for 30 minutes. Instead, it states as follows: "[redacted]" JX-0050C at 56.

Bio-Rad pointed out this discrepancy in its petition for review, *see* Bio-Rad Pet. at 61, and neither OUII nor 10X disputed the point. To the contrary, 10X's response to Bio-Rad's petition is carefully worded to avoid misrepresenting the [redacted] product label. *See* 10X Resp. to Bio-Rad Pet. at 65 ("The ALJ relied upon Bio-Rad's documentation that shows the RT program at the thermal cycler contains a step of incubating the droplets at 37°C for 30 minutes, which

2. Domestic Industry Products

Turning to the domestic industry products, although the ID found that "[w]hile the droplets are being heated on the thermal cycler, the barcode molecules are released from the gel bead through the application of [redacted], which dissolves the disulfide bonds holding the barcode molecules to the gel beads," the exhibits that were cited to support that statement do not, on their face, support it. ID at 115 (citing CX-0481.0 at 11; CX-0004C (Butte DWS) at Q/A 481). Page 11 of CX-0481 (10X's Single Cell 3' Reagent Kits v2 User Guide) says nothing about barcode molecules being released from a gel bead during incubation on a thermal cycler. CX-0481 at 11. Rather, that exhibit describes incubation as occurring *after* dissolution of the gel bead delivering the barcodes. *See id.* That evidence does not address whether barcodes are released in the domestic industry products after at least 1,000 droplets have been generated as required by step (b) of the asserted claims.

Further, Q/A 481 of CX-0004C, Dr. Butte's witness statement, relates to infringement by Bio-Rad's accused products, not 10X's domestic industry products. CX-0004C at Q/A 481. Though no party petitioned for correction, this citation in the ID appears to be an inadvertent error. However, even assuming that the citation is an oversight, the portions of Dr. Butte's witness statement that *are* directed to domestic industry still do not support the conclusion that barcodes are released on the thermal cycler. *See id.* at Q/A 580–81.[12]

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matches the reaction *temperature* for [redacted] as shown in [redacted] product label." (emphasis added)). Accordingly, the Commission has determined to modify the sentence starting on the seventh line of page 100 of the ID to read [redacted]. Notwithstanding this modification, the Commission nonetheless agrees with and affirms the ID's conclusion that the accused products practice step (c) of claim 1.

[12] The parties addressed waiver at length in their responses to the Commission's request for briefing on whether the domestic industry products practice the "wherein" clause limitation of step

Nevertheless, the Commission has determined that, more likely than not, barcodes are still being released in the domestic industry products after at least 1,000 droplets have been generated, thus satisfying step (c) in combination with the ID's finding that barcoding of the polynucleotide molecules occurs on the thermal cycler in the domestic industry products. *See* ID at 115–16; *see also* CX-0481 at 11; CX-0004C at Q/A 576–78. Particularly, while evidence identified by Bio-Rad and OUII does establish that some of 10X's promotional materials explain that the gel bead dissolves "immediately" after droplet generation, *see* CX-423C at 15; CX-540 at 5:48–6:08; RX-665C at Q/A 116, counter-evidence identified by 10X shows that while the process may begin immediately, gel bead dissolution is not instantaneous, and that when at least the last 1,000 droplets are formed in the domestic industry products, dissolution of the gel beads in those droplets will not yet have occurred, but will occur shortly thereafter. *See* CX-0076C at 36; CX-0116C at 27; *see also* 10X Reply at 50–53 (citing same).

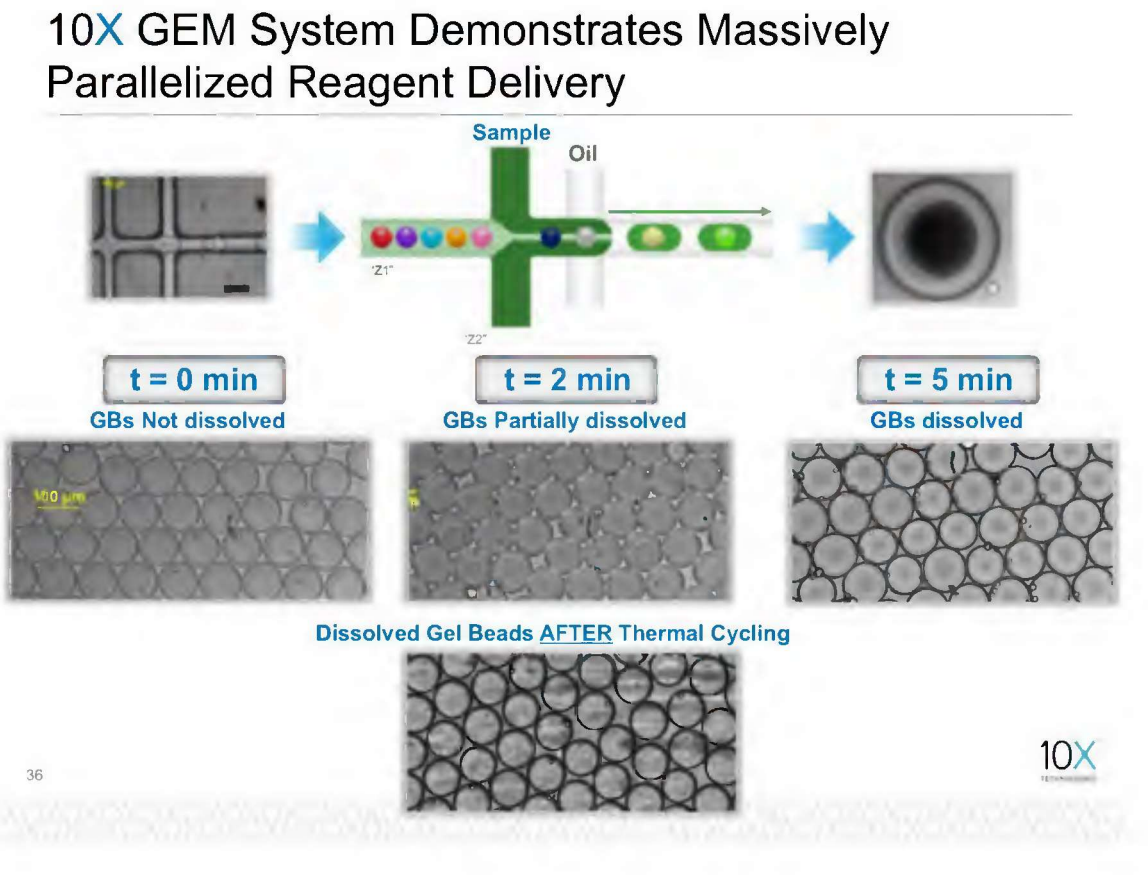
10X's counter-evidence establishes two main points in support of its position. First, it establishes that, if used according to 10X's recommendations, 17,000 cells are loaded into each of eight reaction lanes on a 10X chip, which results in recovery of about 8,000 droplets each with one gel bead and one cell. *See* CX-0004C at Q/A 570; CX-0481 at 15; *see also* 10X Reply at 50 (citing same). Because a typical run of droplet formation lasts approximately 6.5 minutes, more than 1,000 droplets are generated just in the last minute of the droplet formation process. *See* CX-0481 at 13, 23 (describing ~6.5 minute run time); 10X Reply at 51–52 ("Taking the example described above of loading a small number of cells per channel to generate 8,000 good droplets over a six

(c). *See* 10X Reply at 39; OUII Resp. to Qs. at 24, 24 n.12; OUII Reply at 19 n.14; Bio-Rad Resp. to Qs. at 54 n.9; Bio-Rad Reply at 48–50. The parties fail to acknowledge that the Commission enjoys *sua sponte* authority to review any aspect of an ID. *See* 19 C.F.R. § 210.44. Here, where the evidence cited by the ID does not support the ID's finding, such *sua sponte* review is appropriate.

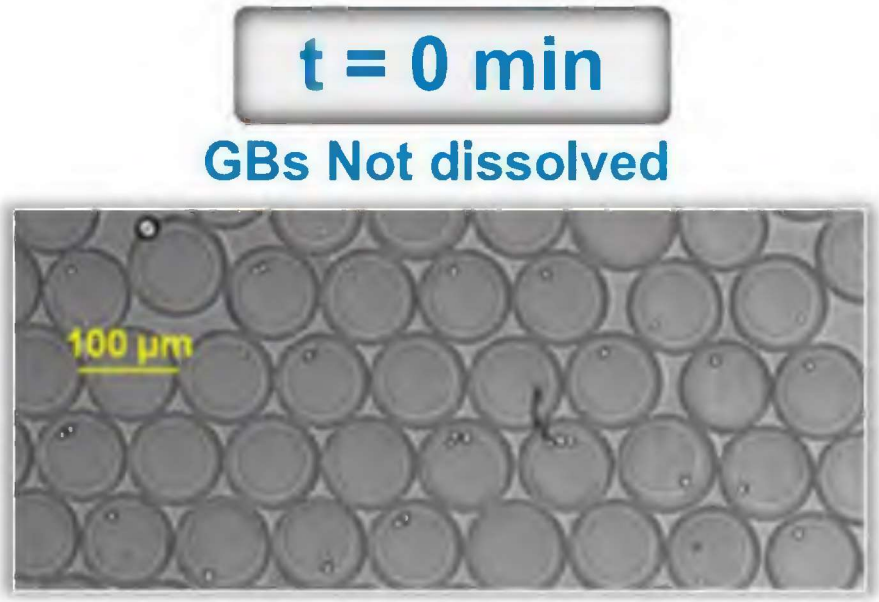
minute run (*see* CX-0477.00002) means that at least 1,000 good droplets are generated in the last minute alone of droplet formation." (footnote omitted)). The crucial question then is whether those droplets generated in the last minute still contain gel beads with attached barcodes. If they do, then the release of those barcodes will satisfy the "wherein" clause of step (c) of the claimed method. If, however, the gel beads dissolve instantaneously as each droplet is formed, the "wherein" clause of step (c) would not be satisfied because, per the construction of this claim, step (c) must occur after at least 1,000 droplets have been generated in step (b).[13]

The second point established by 10X's counter-evidence addresses that crucial question. The evidence shows that the gel beads in 10X's domestic industry products are only partially dissolved two (2) minutes after droplet formation. *See* CX-0076C at 36; CX-0116C at 27; *see also* 10X Reply at 52 (citing same). The following slide, which appears in two of 10X's investment presentations admitted into evidence, is illustrative:

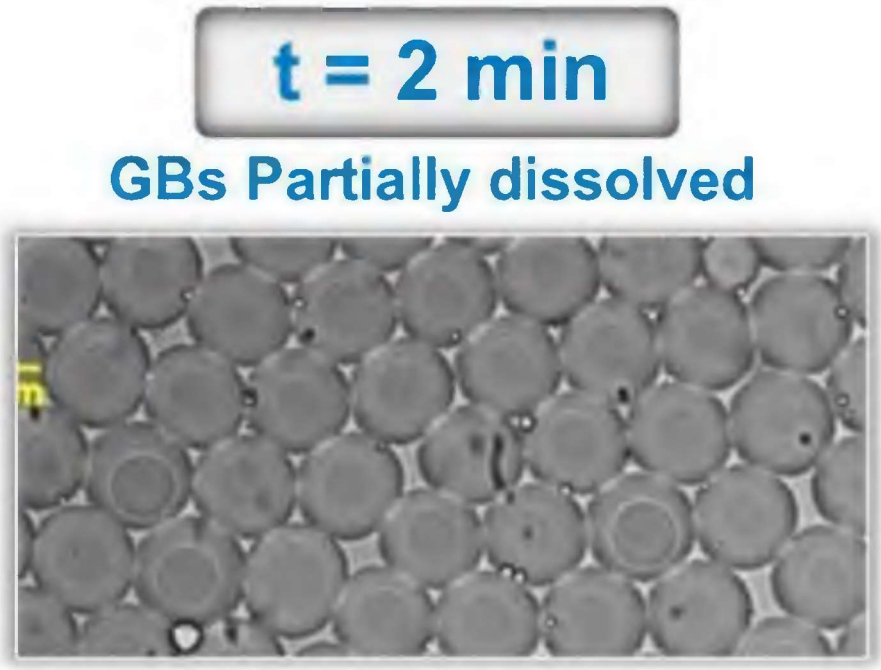
[13] The claim requires that a generated droplet must contain within it both a single gel bead with barcodes attached and a single cell made up of polynucleotide molecules. *See* '530 patent at cl. 1 (steps (a) and (b)). Inside the droplet, barcodes are released from the gel bead and then combine with the polynucleotide molecules to form barcoded polynucleotide molecules. *See id.* (step (c)). There is no dispute that all of this occurs in each droplet generated in the domestic industry products. *See, e.g.*, Bio-Rad Pet. at 63 (acknowledging formation of barcoded polynucleotide molecules in droplets in the domestic industry products). The dispute between the parties is over the timing of this process. *See, e.g.*, *id.* at 63–65.



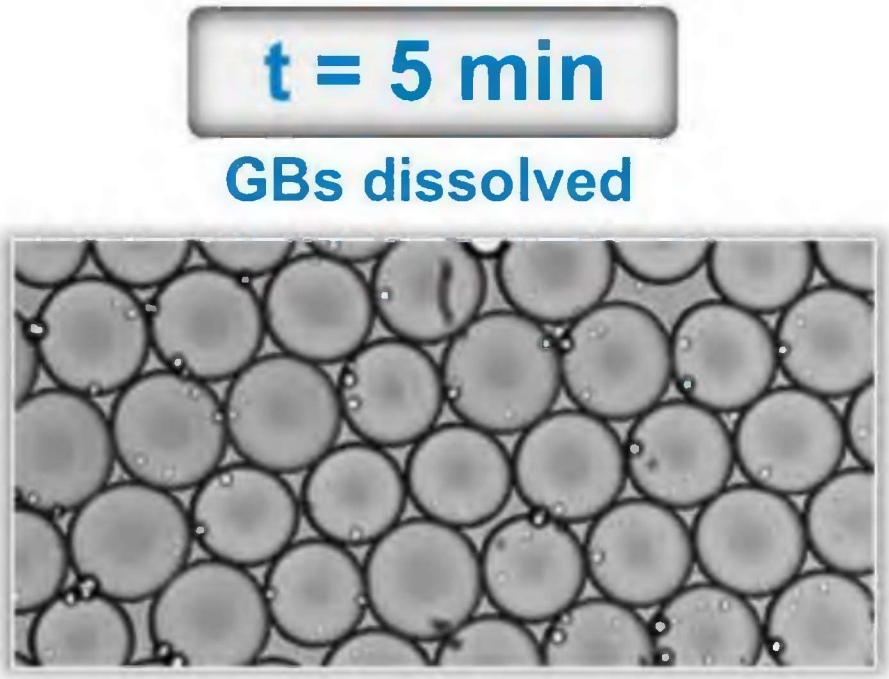
CX-0076C at 36; *see also* CX-0116C at 27 (same image in black and white). The image on the left of the middle row shows that immediately after droplet formation (t=0 min), the gel beads inside the droplet have a defined, circular boundary:



Id.; *see also id.* at 23 (illustrating components of droplet containing a gel bead). At two (2) minutes after droplet formation (t=2 min), the image in the center of the middle row shows gel beads with a blurred boundary, which are described as "partially dissolved":



See CX-0076C at 36. And, at five (5) minutes after droplet formation (t=5 min), the image on the right of the middle row shows droplets with no visible boundary around a gel bead, which are described as "dissolved":



See id. Accordingly, the Commission agrees that "whatever 'immediately' means in 10X's promotional literature, it does not mean that [redacted] dissolves the gel beads so fast that fewer than 1,000 of them still have barcodes attached after the completion of droplet formation." 10X Reply at 52.

The Commission also agrees that this evidence adequately addresses OUII's and Bio-Rad's argument that the use of the word "immediately" in 10X's promotional material means that all barcodes were released instantaneously after droplet formation. 10X's evidence is also consistent with the testimony of Dr. Schnall-Levin, who testified on cross-examination that the gel bead does not disappear instantaneously after droplet formation:

Q. When you take the first droplet, the cell and bead disappear immediately; right?

A. No, I don't think so.

Tr. at 224:18–23. Accordingly, the Commission has determined to affirm under modified reasoning the ID's finding that 10X satisfied the domestic industry requirement with respect to the '530 patent.

C. Infringement of Dependent Claim 26

Dependent claim 26 requires that the gel beads have at least 1,000,000 barcode molecules. '530 patent at cl. 26 ("26. The method of claim 1, wherein said at least 1,000 barcode molecules are at least 1,000,000 barcode molecules."). The ID found that "the WTA 3' v1, [redacted] and scATAC-seq assays infringe claim 26." ID at 105.

10X and OUII both petitioned for review of the ID's finding that dependent claim 26 of the '530 patent is infringed by the accused products. *See* 10X Pet. at 19; OUII Pet. at 17. Particularly, both argued that the ID inadvertently omitted the [redacted] from the list of infringing assays for claim 26. *See* 10X Pet. at 19; OUII Pet. at 17. Bio-Rad did not dispute 10X and OUII's position in its response to their petitions for review. *See generally* Bio-Rad Resp. to Pets.

Upon review of the ID, we agree with 10X and OUII that the omission of the [redacted] in the portion of the ID listing the assays that infringe dependent claim 26 of the '530 patent is the result of a clerical error and should be corrected. *Cf.* ID at 105. Where the ID excluded an assay from its infringement findings, it did so explicitly and with an explanation, as in the case of claim 4. *See id.* at 103. However, in the ID's analysis of claim 26, there is no discussion of the [redacted] specifically. *See id.* at 105. Moreover, the record shows that 10X timely submitted evidence to establish infringement of claim 26 with respect to all four assays. CX-

0004C at Q/A 554–556. Accordingly, the Commission has determined to modify the ID's findings to include the [redacted] among the assays that infringe claim 26.

D. Contributory Infringement

OUII petitioned for review of the ID's finding that "10X has failed to show that using the scATAC-seq assay with isolated nuclei is not a substantial non-infringing use of the ddSEQ vl products," ID at 112, which defeated 10X's allegations of contributory infringement with respect to the '530 patent. *See* OUII Pet. at 17–18. In OUII's view, the finding should be reversed because "as of the time of the hearing, the record evidence showed a lack of substantial, non-infringing uses for the ddSEQ v1 products under the '530 patent." *Id.* at 18. OUII noted, however, that even if the ID's finding was reversed, the ID's ultimate finding of violation would not be affected because the ID found that Bio-Rad induced infringement of the '530 patent. 10X summarily joined OUII on this issue in its response to OUII's petition for review. *See* 10X Resp. to OUII Pet. at 7. Bio-Rad did not respond to OUII's petition on this issue. *See generally* Bio-Rad Resp. to Pets.

The Commission has determined to take no position on whether 10X has established contributory infringement with respect to the '530 patent. The Commission affirms the remainder of the ID's findings with respect to indirect infringement of the '530 patent, including specifically its finding that Bio-Rad induced infringement of the '530 patent.

E. Indefiniteness

The Commission asked the parties to brief whether "any party argue[d] 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." Notice at 4. No party contended in response that indefiniteness was briefed in either pre- or post-hearing briefing. Bio-Rad and OUII, nonetheless, argued that Bio-Rad's indefiniteness argument is not waived. Notably, Bio-Rad and OUII adopted different rationales for why waiver does not apply.

OUII pointed back to Bio-Rad's briefing during the *Markman* stage of the hearing, where Bio-Rad argued that claim 1 of the '530 patent was indefinite. *See* OUII Resp. to Qs. at 26. The *Markman* order rejected that indefiniteness argument on the basis that Bio-Rad had conflated breadth with indefiniteness. *See* Order No. No. 22 at 46. OUII submitted that because the "*Markman* Order rejected Bio-Rad's indefiniteness arguments in view of the 'clear and readily understood' meaning of the disputed terms," it also "implicitly h[eld] that the Order's own construction did not render the claim indefinite." *Id.* OUII further submitted that an instruction in the *Markman* order directing the parties' subsequent briefing to apply the *Markman* order's constructions "presumably limit[ed] the parties to challenging the ordered constructions in petitions for review." *Id.* (citing Order No. 22 at 52 ("Hereafter, discovery and briefing in this Investigation shall be governed by the construction of the claim terms in this Order.").

Bio-Rad did not point to its *Markman* stage indefiniteness argument to avoid waiver. Instead, Bio-Rad argued it was precluded from raising its indefiniteness argument by the timing of Order Nos. 22 and 35. Bio-Rad Resp. to Qs. at 70–71. Expanding on that idea, Bio-Rad explained that it "believed that, as a result of the limitations imposed on the claimed method in the *Markman* Order, in particular, the requirement that step (b) of the method be completed in all 1,000 droplets before step (c) was performed on any of the droplets, a requirement the judge identified in finding the claim definite, it no longer had a basis to argue indefiniteness in its Prehearing Brief, as it had previously argued during claim construction." *Id.* at 71. Bio-Rad appears to have argued though that Order No. 35, which clarified the construction of claim 1 given in the *Markman* Order, either gave rise to a new basis for arguing indefiniteness or revived its prior basis. *See id.* at 72. Bio-Rad's briefing also suggested that the language of the *Markman* Order directing the parties to

apply the constructions therein precluded it from raising its indefiniteness arguments. Bio-Rad Reply at 53.

On review, the Commission has determined that the indefiniteness challenge raised by Bio-Rad in its petition for review is new, could have been presented before the ALJ, was not presented before the ALJ, and therefore is waived. *See* Ground Rule 11.1.

If OUII were correct that Bio-Rad's indefiniteness arguments before the ALJ during the *Markman* phase of the investigation preserved the indefiniteness arguments in its petition, Bio-Rad would, presumably, be limited to challenging the *Markman* Order's resolution of Bio-Rad's indefiniteness argument. Bio-Rad's petition is, however, silent on the reasoning given in the *Markman* Order rejecting Bio-Rad's indefiniteness argument at the time. *See* Bio-Rad Pet. at 48–55. The *Markman* order explained that:

> Bio-Rad asserts that the terms "providing," "plurality of cells," and "at least 1,000 droplets" render the claim indefinite because the claim "calls for the generation of 1,000 droplets containing specific material but does not describe how or under what circumstances those droplets are formed." RRB at 23. In making this argument, Bio-Rad confuses breadth with indefiniteness. Breadth does not render a claim indefinite. *BASF Corp. v. Johnson Matthey Inc.*, 875 F.3d 1360, 1367 (Fed. Cir. 2017 ("[B]readth is not indefiniteness.") (quoting *SmithKline Beecham Corp. v. Apotex Corp.*, 403 F.3d 1331, 1341 (Fed. Cir. 2005)) (internal quotation marks omitted); Manual of Patent Examining Procedure § 2173.02 ("A broad claim is not indefinite merely because it encompasses a wide scope of subject matter provided the scope is clearly defined"). Standing alone and in the context of the claim, the claim terms identified by Bio-Rad are clear and readily understood "even to lay judges." *Phillips*, 415 F.3d at 1314. Based on the foregoing, I find that Bio-Rad has not shown that claim 1 is indefinite.

Order No. 22 at 46. Bio-Rad's petition did not address the *Markman* Order's conclusion that Bio-Rad mistook breadth for indefiniteness. Instead, Bio-Rad's petition argued that "[t]he ID construction renders the claim indefinite both because it permits aggregation of multiple runs and because it eliminates the requirement that the method steps be performed in a specific order." Bio-Rad Pet. at 48. Moreover, Bio-Rad's petition made clear that the indefiniteness argument raised

therein is based on the construction applied in the ID, which, in Bio-Rad's view, is consistent with the clarified construction of Order No. 35, but not with the construction in the *Markman* Order. *See* Bio-Rad Pet. at 48 ("*The ID construction renders the claim indefinite* both because it permits aggregation of multiple runs and because it eliminates the requirement that the method steps be performed in a specific order." (emphasis added)). Bio-Rad's focus on the clarified construction of Order No. 35 suggests that Bio-Rad itself does not view its *Markman* indefiniteness argument and its petition indefiniteness argument as one and the same. Moreover, Bio-Rad's focus on the timing of Order No. 35, *i.e.*, that it was issued after Bio-Rad submitted its prehearing brief, as a reason it could not raise its indefiniteness argument at the hearing or in post-hearing briefing further supports the conclusion that the indefiniteness argument in the petition is distinct from the one raised before the ALJ. If not, the timing of Order No. 35 would be irrelevant, as Bio-Rad would have already had the opportunity to raise its indefiniteness argument during the *Markman* proceeding. Put differently, by arguing unfairness in the timing of Order No. 35 to support raising indefiniteness on review, Bio-Rad effectively undercut any argument that its petition's indefiniteness argument was preserved by its *Markman* indefiniteness argument.

Moreover, the indefiniteness argument in Bio-Rad's petition included new arguments that it did not raise in its *Markman* briefing. During the *Markman* process, Bio-Rad relied exclusively on the fact that the claims did not specify whether the droplets had to be generated in a single experiment or in multiple experiments. Bio-Rad Opening Markman Br. at 31 ("Nothing in the intrinsic evidence clarifies how or when the claimed 1,000 droplets each containing a gel bead and a cell should be generated. For example, the droplets could be generated in one experiment or in multiple experiments."). By contrast, the indefiniteness argument in Bio-Rad's petition is based on the theories that "numerical limitations in method claims must be met in each run of the method,

and cannot be met through aggregation of multiple runs," Bio-Rad Pet. at 48, and "[i]f the '530 Patent encompasses a continuous process, the '530 Patent is indefinite because the plain language of the claims does not inform a person of skill in the art with reasonable certainty about the scope of the claimed method." *Id.* at 54–55. Even assuming that the multiple experiment argument of the *Markman* brief and the aggregation argument of the petition are the same — an assumption which is not clearly justified — the continuous-process argument is still a new theory of indefiniteness that was never presented to the ALJ.

In a similar vein, the indefiniteness argument in Bio-Rad's petition relies on new evidence that was never presented to the ALJ in connection with indefiniteness. Particularly, Bio-Rad relies on deposition testimony from one of the inventors of the '530 patent and a 10X executive (Dr. Michael Schnall-Levin) to support its petition's indefiniteness argument. *See* Bio-Rad Pet. at 52. Bio-Rad did not rely on testimony from Dr. Schnall-Levin in its *Markman* briefing.

At bottom, the indefiniteness argument raised in Bio-Rad's petition is a new argument that was never raised before the ALJ. The Commission does not agree with OUII that the instruction in Order No. 22 requiring the parties to apply the constructions therein precluded the parties from asserting the indefiniteness of those claims as construed. A more reasonable reading of that statement is that the parties should not present multiple analyses based on different claim constructions going forward in the case.

Bio-Rad's argument that it has not waived its petition's indefiniteness arguments because the timing of Order No. 35 prevented it from raising the argument at the hearing or in its briefing is not persuasive. First, the argument is premised on Bio-Rad's belief that Order No. 35 reversed the construction of claim 1 given in Order No. 22. The Commission does not agree, however, that the two orders are inconsistent with each other. Rather, Bio-Rad interpreted Order No. 22 in a

way that was not correct — it interpreted the order such that any barcoding that occurred prior to the completion of droplet formation would defeat infringement — and Order No. 35 pointed out as much in denying Bio-Rad's motion for summary determination of no infringement. Bio-Rad's misinterpretation of Order No. 22 cannot be a reason to excuse its failure to argue indefiniteness before the ALJ.

However, even if Order No. 35 *had* materially altered the construction of claim 1 of the '530 patent, Bio-Rad's late indefiniteness argument would still be waived. This is because Bio-Rad could have sought relief from the ALJ, but did not. For example, Bio-Rad could have asked the ALJ for leave to amend its prehearing filings on the basis that Order No. 35 provided a new construction that it could not possibly have addressed in those filings. But Bio-Rad did not seek such leave. Instead, it waited until after the ID issued to argue that the clarification given in Order No. 35 rendered claim 1 indefinite. That course of action prevented 10X and OUII from developing testimony or introducing evidence to rebut that argument, and prevented the ALJ from considering the argument. While Bio-Rad argues repeatedly that it was "denied the opportunity" to argue that the ALJ's construction of claim 1 was indefinite, there is no support for that statement. Bio-Rad Reply at 53. Particularly, it is not clear why Order No. 22's statement that "[h]ereafter, discovery and briefing in this Investigation shall be governed by the construction of the claim terms in this Order," would preclude Bio-Rad from arguing that claim 1 was indefinite. If Bio-Rad had sought leave to raise its indefiniteness argument at the hearing after receiving Order No. 35, and if the ALJ denied that request, Bio-Rad would be on much stronger ground to argue that it was not permitted to make its indefiniteness argument. That is not what happened though. Bio-Rad simply did not argue that claim 1 as construed was indefinite until after the ID issued. That is waiver.

In the alternative, even if there were no waiver, Bio-Rad has not shown by clear and convincing evidence that claim 1 of the '530 patent is indefinite. *See BASF Corp. v. Johnson Matthey Inc.*, 875 F.3d 1360, 1365 (Fed. Cir. 2017) (explaining that the defendant has "the burden of proving indefiniteness by clear and convincing evidence."). Concerning the argument it made at the *Markman* phase of the investigation, the Commission agrees with the ALJ's reasoning in Order No. 22 that Bio-Rad's arguments conflated broad claims with indefinite ones. The fact that the claim does not limit droplet generation to one particular mode, *i.e.*, in a single experiment, or from a single sample, or in one run, etc., simply means the claim is broad and all of those modes are covered. Bio-Rad cannot manufacture uncertainty in the claim by arguing that only one mode can be claimed and then arguing that the claims fail to specify the particular mode.

Bio-Rad's petition-stage indefiniteness argument fails for multiple reasons. First, the argument is based on Bio-Rad's continued misinterpretation of the ID's construction of the claim. Bio-Rad argued that the ID's construction of claim 1 allows aggregation of multiple runs to meet the numerical limitations therein. Explaining that assertion, Bio-Rad argued that because its chips each have four lanes, processing droplets on one chip is actually four different experimental runs. Because the ID found that a chip generates approximately 1,200 droplets, Bio-Rad argued that the ID relied on the aggregation of four different runs that each generate about 300 droplets to find infringement. *See* Bio-Rad Pet. at 49. Bio-Rad relies on *Applera Corp. v. Illumina, Inc.*, 375 Fed. App'x. 12, 20-21 (Fed. Cir. 2010), and *In re Varma*, 816 F.3d 1352, 1362–64 (Fed. Cir. 2016), for the proposition that aggregation is not permitted.

The Commission disagrees with Bio-Rad's aggregation argument because nothing in the claim indicates that the method must be confined to a single lane on a chip. *See* '530 patent at cl. 1. To the contrary, the specification clearly contemplates that different machinery used together

can practice the invention. *See* '530 patent at 10:1–18 (describing use of a device with microwell chambers to practice the method). Further, the concerns animating *In re Varma* and *Applera* are not present here. The portion of *In re Varma* relied on by Bio-Rad simply stands for the proposition that where a claim recites an object that performs two functions, the claim is not practiced by two objects that each perform one of the functions. *In re Varma*, 816 F.3d at 1363 ("For a dog owner to have 'a dog that rolls over and fetches sticks,' it does not suffice that he have two dogs, each able to perform just one of the tasks."). That issue is not present here where the claims do not include a requirement that a single lane on the chip generate at least 1,000 droplets.

Applera is no more on point. There, the claim at issue, in simple terms, covered a three-step process where the third step was to repeat the first two. *Applera*, 375 Fed. App'x at 20. The patentee advanced a construction that would allow one to skip the second step of the process for some repetitions of the process. The Federal Circuit agreed with the district court that such a construction was incorrect because it abrogated the second step of the process. *Id.* at 20–21. Thus, neither *Applera* nor *In re Varma* stand for a broad prohibition on aggregation as Bio-Rad contends. The Commission further notes that neither of those cases addresses indefiniteness based on aggregation.

Separate from *Applera* and *In re Varma*, Bio-Rad argued that if aggregation is permitted, claim 1 is indefinite because "there is no starting point and no endpoint that defines any particular method cycle" and "[a]ny number of droplets containing a single bead and a single cell, with reagents for barcoding, can be generated at any time over the course of any number of runs, on any number of independent droplet generators." Bio-Rad Pet. at 50. Bio-Rad then argued that "[a]s long as, at some point, it is determined that at least 1,000 productive droplets were generated where barcoding occurred, the limitations of the claim are met," and submits that such a claim is

in conflict with *Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898 (2014). Bio-Rad relied on *Dow Chemical Co. v. Nova Chemicals Corp.*, 803 F.3d 620 (Fed. Cir. 2015), and *Icon Health & Fitness, Inc. v. Polar Electric Oy*, 656 Fed. Appx. 1008 (Fed. Cir. 2016), as analogous situations where indefiniteness was found. Bio-Rad at 50. Bio-Rad also argued that deposition testimony from 10X's expert and an inventor of the '530 patent indicates that claim 1 has no objective boundaries. Bio-Rad Pet. at 51.

First, Bio-Rad's assertions that claim 1 has no starting point or end point under the ID's constructions are baseless. Claim 1 has three steps: (a) a "providing" step in which raw materials are provided; (b) a "generating" step in which those raw materials are used to generate droplets; and (c) a barcoding step where barcoded polynucleotides are generated in at least 1,000 droplets. '530 patent at claim 1. The claimed method starts at the providing step and ends after barcoding has occurred in at least 1,000 droplets. *Id.* Bio-Rad's argument attempts to manufacture uncertainty in an otherwise straightforward three-step claim by focusing on limitations that are not present in the claim — for example, that droplets must be generated in a single "run," or that they must be generated only in a single droplet generator, or only in droplet generators that are not independent. *Cf.* Bio-Rad Pet. 50. Bio-Rad's indefiniteness argument is not directed at claim 1 of the '530 patent; it is directed at a claim of its own making, *i.e.*, a strawman.

The cases Bio-Rad relies on bear little resemblance to the facts in this investigation and are of little relevance. *Dow* dealt with the claim phrase "slope of strain hardening coefficient greater than or equal to 1.3," which the facts in that case showed could be calculated four different ways — each with different results. *Dow Chemical Co.*, 803 F.3d at 631–634. This investigation does not present that scenario, nor even an analogous scenario. *Icon Fitness* found a claim indefinite where the evidence of record showed that the terms "in-band" and "out-of-band" were relative

terms that only have meaning in the context of a defined reference. *Icon Health & Fitness, Inc.*, 656 Fed. App'x at 1016. Here again, that scenario is not presented in this investigation. And, with respect to *Nautilus*, a case that dealt with the meaning of the phrase "spaced relationship" in exercise equipment, *see Nautilus*, 572 U.S. at 903–906, but which is legally significant for striking down the Federal Circuit's prior formulations of the test for indefiniteness, *see id.* at 901, Bio-Rad relies on the case for broad assertions unrelated to the facts of *Nautilus*. This includes the assertion that "the fact that the ALJ issued and applied two conflicting constructions over the course of the investigation supports the indefiniteness of the '530 Patent claims," Bio-Rad Pet. at 38–39 (citing *Nautilus*), and that open ended claims "violate[] the strictures of *Nautilus*," *id.* at 50. Yet, Bio-Rad's reliance on *Nautilus* is little more than a collection of unsupported assertions that the ID's construction of claim 1 somehow conflicts with the reasonable certainty standard for indefiniteness laid out in *Nautilus.* Merely identifying the case that lays out the standard for indefiniteness and then asserting that the standard is met, or not met, is not clear and convincing evidence of invalidity, which is what is required.

The expert testimony Bio-Rad relies on does not meet its burden either. *See* Bio-Rad Pet. at 51. The citations from the transcript of Dr. Butte's deposition show the attorney and Dr. Butte having a lengthy discussion about what is and is not a "common process," with Dr. Butte giving, admittedly, widely varying answers. *See* JX-157 at 123:13–137:3. Bio-Rad relied on this testimony to argue that whether aggregation is permitted depends on the vagaries of a person's opinion, thus rendering claim 1 indefinite. *See* Bio-Rad Pet. at 51–52. This entire line of reasoning is tainted however by the fact that, again, there is no limitation in the claim requiring droplet generation to occur on a single machine, in a single experiment, as part of a single "run," from a single "sample," or as part of a "common process." *See generally* '530 patent at cl. 1. An expert's

extrinsic testimony on a limitation that is not present in the claims is not probative evidence of indefiniteness. For that reason, we also find Bio-Rad's reliance on *Interval Licensing LLC v. AOL, Inc.*, 766 F.3d 1364, 1371 (Fed. Cir. 2014), which found the term "unobtrusive manner" depended on a person's subjective opinion and therefore rendered the claim in which it appeared indefinite, to be inapposite. *See* Bio-Rad Pet. at 51–52. *Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 789 F.3d 1335, 1345 (Fed. Cir. 2015), which Bio-Rad also relies on in connection with Dr. Butte's testimony, is also unhelpful as the indefiniteness issue in *Teva* is essentially identical to the one in *Dow*. *See* Bio-Rad Pet. at 52.

Bio-Rad's reliance on Dr. Schnall-Levin's deposition testimony is no more probative. *See id.* (citing RX-413C at 285:19–24). Bio-Rad asked Dr. Schnall-Levin if the patent provided directions of how many cells to run per chip in claim 1, and Dr. Schnall-Levin answered that there were no instructions on cells per chip. *See id.* This testimony does not show that a person of ordinary skill in the art would not understand the boundaries of the three-step process laid out in claim 1 of the '530 patent. It simply shows that Bio-Rad can concoct a limitation that is not present in the claim, ask if the patent describes that limitation, and then get an answer in the negative. This is manufactured uncertainty — not indefiniteness.

As to Bio-Rad's continuous-process indefiniteness argument, Bio-Rad Pet. at 53–55, the argument fails because it is based on a faulty premise: that the ID's construction does not require the steps to be performed in order. *Id.* at 54. That is not the case. The ID, as well as Order Nos. 35 and 22, all require step (b) to be completed before step (c). Thus, the ID does not permit an assembly-line style process where step (c) is completed on a droplet as soon as it is generated in step (b). Bio-Rad, however, appears to mean something different when it refers to performing the steps of the claim in order. In Bio-Rad's view, no barcoding can occur in any droplet before at

least 1,000 droplets are generated in step (b). This is something more than simply requiring the steps be performed in order. What Bio-Rad seeks is to include a new negative limitation in claim 1 that excludes any barcoding from occurring before at least 1,000 droplets have been generated. This was the issue that was clarified in Order No. 35, and the basis of Bio-Rad's unsuccessful motion for summary determination of noninfringement.

Claim 1, however, is an open-ended claim, and thus other non-recited activity may occur that will not defeat infringement. Here, as 1,000 droplets are generated in step (b), there may be some barcoding happening as soon as each droplet is generated. This will not preclude the process from reading on step (c) though if, after 1,000 droplets are generated, barcodes are released in those droplets and a plurality of polynucleotides are barcoded. The fact that barcoding of other polynucleotides also happened before 1,000 droplets were generated is irrelevant. Bio-Rad incorrectly characterizes the ALJ's observation to that effect as permitting a continuous process. The ALJ correctly determined that extraneous unrecited activity will not defeat infringement of a claim drafted in open language.

Finally, we note that Bio-Rad offers no real reasoning why construing claim 1 to encompass a continuous process would render it indefinite. Bio-Rad simply parrots the reasonable certainty language of *Nautilus*. Bio-Rad Pet. at 54–55.

For all these reasons, the Commission finds that Bio-Rad waived the indefiniteness arguments raised in its petition for review, but even if not waived, those arguments and the evidence presented therein would fail to establish that claim 1 is indefinite by clear and convincing evidence.

VII. INVENTORSHIP

The Commission determined to review the ID's findings with respect to Bio-Rad's inventorship defense. *See* Notice at 2. On review, the Commission has determined to take no

position on whether Dr. Heredia should have been named as a joint inventor of the '204 patent. The Commission affirms the ID's findings with respect to Bio-Rad's inventorship defense for the other three patents. Because the Commission has affirmed the ID's finding of noninfringement with respect to the '204 patent, the Commission's determination to take no position on Bio-Rad's inventorship defense with respect to the '204 patent does not affect the ID's ultimate finding of no violation with respect to the '204 patent.

VIII. OWNERSHIP

The ID rejected Bio-Rad's claim that it had an ownership interest in each of the asserted patents based on work done by Drs. Hindson and Saxonov during their time at QuantaLife/Bio-Rad. *See* ID at 136–152. The ID began by explaining that inventorship and ownership are distinct issues, and that while federal patent law governs inventorship, ownership is a question of state contract law. *Id.* at 136–141. The ID noted with disapproval that the parties conflated the two issues in their briefing. *See id.* at 141. The ID went on to explain that the crux of the dispute with respect to Bio-Rad's ownership defense involves defining the "inventive concept" in the asserted patents. *See id.* The ID rejected Bio-Rad's approach to that issue, explaining that Bio-Rad "briefed the matter as if it owned a share of the patents because it could trace some elements of the asserted patents to work done at Quanta/Life and Bio-Rad." *Id.* The ID explained that while Bio-Rad "owns many ideas conceived by Drs. Hindson and Saxonov, [] it does not own the idea for the specific arrangement of elements claimed in the asserted patents . . . because there is insufficient evidence that that idea was conceived-during the period of employment." *Id.* at 142.

Concerning the pertinent contract language, the ID noted that "[n]o provision of any of the applicable contracts governs future inventions that are based on or developed from work done during employment." *Id.* at 144. Based on this observation, the ID found Bio-Rad's interpretation of the contract to be unreasonable because it "read out the plain meaning of the durational

limitation in the pertinent contracts, and in its place suggest[ed] an interpretation of the contracts in which inventions developed by the employee after his employment belong to the company if they are related to ideas conceived during employment." *Id.* at 145. The ID went on to reject Bio-Rad's theory that it is entitled to a pro-rata undivided co-ownership interest in the asserted patents based on Drs. Hindson and Saxonov's discovery of ideas that are related to the invention in the asserted patents, as opposed to their actual discovery of the invention. *See id.*

The ID next considered whether Bio-Rad had presented evidence showing that the inventive idea embodied in the asserted patents was conceived at QuantaLife/Bio-Rad. The ID concluded that Bio-Rad presented no direct evidence of such conception. *See id.* As for circumstantial evidence, the ID determined that the relatively short time between when Drs. Hindson and Saxonov left Bio-Rad and when they filed their first provisional patent application did not, on its own, establish conception by Drs. Hindson and Saxonov at Bio-Rad. *Id.* at 146.[14] The ID also rejected several challenges to Dr. Hindson's credibility. *Id.* at 147–48.

Next, the ID rejected Bio-Rad's argument that certain concepts disclosed by Drs. Hindson and Saxonov at Bio-Rad can be traced to the asserted patents such that conception at Bio-Rad should be implied. *Id.* at 149. In rejecting this argument, the ID credited testimony from Dr. Saxonov that the ideas formed at Bio-Rad were only directions for further research, as opposed to ideas that would work. *See id.* at 149–150. The ID also rejected a similar argument based on the '059 patent's disclosure of certain numerical ranges, *see id.* at 150, and based on lab notebooks offered by 10X. *See id.* at 150–51. The ID concluded as follows: "In sum, the evidence before me is insufficient to permit the conclusion that, more likely than not, the work Drs. Hindson and

[14] The ID noted that Drs. Hindson and Saxonov left Bio-Rad in April 2012 and founded 10X several months later. ID at 146. In August 2012, Drs. Hindson and Saxonov filed their first provisional patent application at 10X. *Id.*

Saxonov did at QuantaLife and Bio-Rad led them to conceive the idea described in the 10X patents while they were still under contract." *Id.* at 151. Accordingly, the ID found that Bio-Rad "failed to establish ownership of the asserted patents." *Id.*

The ownership dispute in this investigation revolves around Drs. Hindson and Saxonov's employment contracts with QuantaLife and Bio-Rad. The relevant portions of the QuantaLife contracts contain identical language, as follows:

RX-0623C (Hindson-QuantaLife contract) at ¶ 2; RX-0624C (Saxonov-QuantaLife contract) at ¶ 2; *see also* ID at 143–44 (quoting same). The relevant portions of the Bio-Rad contracts also contain identical language, as follows:

[redacted]

RX-0619C (Hindson-Bio-Rad employment agreement) at ¶¶ 3, 6; RX-0620C (Saxonov-Bio-Rad employment agreement) at ¶¶ 3, 6; *see also* ID at 144 (quoting same).

The Commission finds that Bio-Rad has failed to show that the "ideas" developed by Drs. Hindson and Saxonov at QuantaLife/Bio-Rad would entitle them to an ownership interest in the asserted patents. This follows for several reasons. First, in its response to the Commission's questions, Bio-Rad only attempted to map the ideas developed at QuantaLife/Bio-Rad onto a single claim: claim 1 of the '468 patent. *See* Bio-Rad Resp. to Qs. at 4–12. Bio-Rad summarily asserted that the "'468 Patent is representative of the claims of the four 10X Patents," *id.* at 5, but did not attempt to show a direct correspondence between the "ideas" developed at QuantaLife/Bio-Rad and the particular limitations of any claim of the '024, '204, and '530 patents.[15] Instead, Bio-Rad argued that all four asserted patents have the same "fundamental architecture," and thus its mapping of ideas onto the limitations of claim 1 of the '468 patent should entitle it to an ownership interest in the other asserted patents as well. *See id.* at 12–14. Thus, at best, Bio-Rad's showing of ownership under its theory would be limited to the '468 patent.

Second, Bio-Rad was only able to map the "ideas" it relies on to claim 1 of the '468 patent because it substituted generic descriptions in place of the specific limitations of that claim. For example, Bio-Rad argued that Dr. Hindson "came up with ideas at QuantaLife about [redacted]

[15] Among other "ideas," Bio-Rad argued that Drs. Hindson and Saxonov conceived of the idea to use porous gel beads as a reagent delivery system while at QuantaLife. *See* Bio-Rad Resp. to Qs. at 10. However, Order No. 43 precluded Bio-Rad from arguing that the idea for porous gel beads was conceived at QuantaLife/Bio-Rad. Bio-Rad did not petition for review of that order, nor has the Commission determined to review that order *sua sponte*. Accordingly, Bio-Rad may not now argue that it is entitled to an ownership interest in the asserted patents because the idea of using porous gel beads was developed at QuantaLife.

[redacted] and that "[t]he use of droplets to partition sample (and achieve a single cell per partition) is fundamental to claim 1 of the '468 Patent." Bio-Rad Resp. to Qs. at 5. But claim 1 of the '468 patent recites a method for droplet generation with three steps, each of which has a number of specific internal limitations; it does not broadly claim the use of droplets to partition a sample. *See* '468 patent at cl. 1. That disconnect undercuts Bio-Rad's theory of ownership based on Drs. Hindson and Saxonov's prior "ideas."

In the same vein, the Commission also notes that the "ideas" Bio-Rad identified relate to different architectures and applications than those central to the asserted patents. *See* CX-0001C (Hindson WS) at Q/A 79–107 (discussing 10X's development of its GEMs and their attributes); *see also* ID at 142 ("the inventive idea is a specific arrangement of elements which, when combined, works to achieve a desired goal."). This follows from the fact that the "ideas" relied on by Bio-Rad were developed in connection with the droplet-in-droplet architecture described in the '059 patent. *See, e.g.*, Bio-Rad Pet. at 84, 87 (citing lab notebook (RX-127C at 95, 97) and [redacted], to support ownership claim based on "ideas" developed at QuantaLife). The asserted patents, however, do not use a droplet-in-droplet approach, as the '059 patent did (Dr. Saxonov is the named inventor of the '059 patent, and he assigned the patent to Bio-Rad). *See* Tr. (Metzker) at 656–657; CX-1829C (Saxonov WS) at Q/A 28–32 (discussing the droplet-in-droplet concept for barcoding before sequencing and its disclosure in the '059 patent); CX-1827C (Dear WS) at Q/A 40. Rather, the asserted patents, in contrast, require features such as the release of the barcodes from the bead into the droplet in the '024 patent, a particular microfluidic arrangement for generating droplets with the beads in the '468 patent, and a large diversity of beads for use in

generating droplets with single cells in the '530 patent. *See* CX-1827C (Dear WS) at Q/A 40; *see also* ID at 33–40 (finding that the '024 patent was novel and not obvious vis-à-vis the '059 patent and Church (RX-0462)). As such, the asserted patents are based on a different architecture involving beads or capsules that release key reactants. *See* CX-1828C (Hindson WS) at Q/A 24–34 (describing how 10X invented its GEM architecture "from scratch . . . because there was no such architecture at QuantaLife."). Thus, the inventions claimed in the asserted patents are fundamentally different from the prior work conducted at QuantaLife/Bio-Rad.

Third, even under Bio-Rad's theory that it owns a share of the patents based on joint inventorship principles, *see, e.g.*, Bio-Rad Pet. at 77–80, Bio-Rad has not shown that the "ideas" it relies on to build its joint inventorship argument are distinct from the prior art. Indeed, many of these "ideas" are embodied in the '059 patent — a patent naming Dr. Saxonov as an inventor that *was* assigned to Bio-Rad because the underlying invention was developed during his employment at Bio-Rad — which make those ideas part of the prior art. *See* '059 patent (JX-0031) at 1:26–55. But merely explaining the prior art is not sufficient to render someone a joint inventor. *See Fina Oil & Chem. Co. v. Ewen*, 123 F.3d 1466, 1473 (Fed. Cir. 1997) ("[A] person will not be a co-inventor if he or she does no more than explain to the real inventors concepts that are well known and the current state of the art."). No part of Drs. Hindson and Saxonov's employment agreements preclude them from building on ideas in the prior art. Moreover, the existence of the '059 patent demonstrates that Bio-Rad received the benefit of its bargain with respect to the employment agreements. For the ideas that were conceived at QuantaLife or Bio-Rad, Dr. Saxonov did assign his rights. *See* '059 patent (JX-0031) at Cover ("Assignee: Bio-Rad Laboratories, Inc."). Bio-Rad overreaches insomuch as it now attempts to extend its rights to inventions conceived outside the term of Drs. Hindson and Saxonov's employment agreements. *Cf. Israel Bio-Eng'g Project v.*

Amgen, Inc., 475 F.3d 1256, 1267 (Fed. Cir. 2007) (in a case involving an Israeli contract, the Federal Circuit concluded that the plaintiff "was not entitled to further assignments of any other newly developed inventions, even when these inventions built on proprietary information developed during the [contractual] R & D process," which concluded in December 1987); *see also* ID at 148–49 n.29 (reasoning that if Hindson and Saxonov's prior, generic work [redacted] were sufficient to trigger ownership rights, "the contracts' [redacted] would be nullities."); *Dawson v. Dawson*, 710 F.3d 1347, 1353–56 (Fed. Cir. 2013) (concluding that, along with other evidence, a preliminary statement about a potential use was insufficient to establish that an inventor conceived the claimed invention while employed by his former employer). Accordingly, for the reasons provided above, the Commission finds that Bio-Rad has failed to show that the "ideas" Bio-Rad relies on entitle it to an ownership interest in the asserted patent.

Concerning the ID's use of the phrase "inventive concept," the Commission notes that the phrase has some history in patent law and its use in the ID may invite confusion, as evidenced by Bio-Rad's brief. *See, e.g.,* Bio-Rad Ans. at 16 ("The ALJ's analysis was incorrect because it treated the ownership question as requiring proof of a singular eureka moment at a specific point in time when everything was finalized and established to work."). Particularly, "inventive concept" may imply similarity to the pre-1952 patent law's requirement for a "flash of genius," *compare Cuno Eng'g Corp. v. Automatic Devices Corp.*, 314 U.S. 84, 91 (1941) (requiring an invention to "reveal the flash of creative genius not merely the skill of the calling.") *with* Pub. L. 82-593, § 103, July 19, 1952, 66 Stat. 798 (Patent Act of 1952) ("Patentability shall not be negatived by the manner in which the invention was made."), or it may suggest the search for an "inventive concept" in step 2 of an *Alice* patent-eligibility analysis. *See Alice Corp. Pty. v. CLS*

Bank Int'l, 573 U.S. 208, 217 (2014) ("We have described step two of this analysis as a search for an 'inventive concept.'").

Upon review of the ID, the Commission has determined to clarify that the ID's use of the phrase "inventive concept" is synonymous with "the specific arrangement of elements claimed in the asserted patents." ID at 142; *see also id.* ("[T]he invention claimed in the asserted patents is complex and consists of many elements. CX-0001C (Hindson WS) at Q/A 88. The inventive idea, which emerged from many other ideas (some of which clearly were in the prior art), is to combine these elements in a process resulting in what 10X calls the GEM ('gel bead in emulsion') architecture. As confirmed by both parties, **the inventive idea is a specific arrangement of elements which, when combined, works to achieve a desired goal**."). Bio-Rad's position that the use of the phrase "inventive concept" in the ID is indicative of a search for a singular eureka moment conflicts with the ID's explanation that the inventive concept is the combination and specific arrangement of elements laid out in the claims of the asserted patents. The Commission finds no error in the ID's focus on the inventions as laid out in the claims in its analysis of Bio-Rad's ownership defense.

Consistent with the reasoning above, the Commission affirms with supplemented reasoning the ID's finding that Bio-Rad has not shown that it is entitled to an ownership interest in any of the asserted patents.

IX. CLERICAL ERROR

10X's petition for review included a request to correct two clerical errors in the ID. *See* 10X Pet. at 18–19. One of the errors appears on page 91 of the ID, and the other on page 105. *See id.* at 19. The error on page 105 relates to the same absence of an accused assay in the ID's infringement findings for dependent claim 26 of the '530, which has already been addressed *supra* in this opinion. Concerning the error on page 91, 10X explained that "[t]he ID states on page 91

that '[i]n Order No. 35, this claim construction was further clarified so that it does preclude the generation of some barcoded molecules before the start of the claimed third step,' which should have stated 'so that it does *not* preclude the generation of some barcoded molecules before the start of the claimed third step.'" *Id.* OUII agreed that the omission of the word "not" was an oversight. *See* OUII Resp. to Pets. at 44–45. Bio-Rad did not directly respond to 10X's assertion that the omission of the word "not" was a clerical error. *See generally* Bio-Rad Resp. to Pets. Instead, through its own petition, Bio-Rad pointed to the absence of the word "not" as evidence of "contradictory statements" by the ALJ for the purpose of bolstering its argument that the ALJ adopted two contradictory claim constructions for the '530 patent in Order No. 22 and Order No. 35. *See* Bio-Rad Pet. at 46, n.7.

Upon review of Order No. 35, the Commission agrees with 10X and OUII that the omission of the word "not" on page 91 of the ID is a simple clerical error. *Cf.* Order No. 35 ("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."). Bio-Rad's attempt to frame that error as evidence of contradictory statements by the ALJ is not persuasive. Accordingly, the last sentence of the first full paragraph on page 91 of the ID is modified to read: "In Order No. 35, this claim construction was further clarified so that it does *not* preclude the generation of some barcoded molecules before the start of the claimed third step."

X. REMEDY

The RD recommended that the Commission issue an LEO and CDO directed to Bio-Rad. There was no dispute among the parties that an LEO would be the appropriate remedy. *See* RD at 1. The RD also explained that while Bio-Rad "suggest[ed]" that the LEO should include a

certification provision, "there is no evidence in the record that a certification provision will be necessary to distinguish between infringing and non-infringing products," and on that basis declined to recommend the inclusion of a certification provision. *Id.* at 2.

With respect to the CDO, the RD found that Bio-Rad maintains a commercially significant domestic inventory of ddSEQ products and on that basis recommended that the Commission issue a CDO directed to Bio-Rad.[16] *See id.* at 2–3. Specifically, the RD found that Bio-Rad had inventory of ddSEQ Single-Cell Isolators and ddSEQ-M cartridges in California. *See id.* at 2. The RD found these inventories to be significant because the number of units in inventory exceeded the number of such units Bio-Rad actually sold between 2017 and 2018. *See id.* While there was a dispute regarding whether some number of the cartridges should be discounted because they were for testing purposes, the RD agreed with 10X's expert, Dr. Vander Veen, that the inventory of cartridges would be significant even if the test cartridges were not considered. *See id.* at 2–3.

A. Limited Exclusion Order

Section 337(d)(1) provides that "[i]f the Commission determines, as a result of an investigation under this section, that there is a violation of this section, it shall direct that the articles concerned, imported by any person violating the provision of this section, be excluded from entry into the United States, unless, after considering the [public interest], it finds that such articles should not be excluded from entry." 19 U.S.C. § 1337(d)(1). The Commission has "broad discretion in selecting the form, scope, and extent of the remedy." *Viscofan, S.A. v. US. Int'l*

[16] As explained in *Certain Road Construction Machines and Components Thereof*, "[t]he Commission generally issues cease and desist orders with respect to the imported infringing products when 'respondents maintain commercially significant inventories in the United States or have significant domestic operations that could undercut the remedy provided by an exclusion order.'" Inv. No. 337-TA-1088, Comm'n Op. at 51 (June 27, 2019) (quoting *Certain Table Saws Incorporating Active Injury Mitigation Technology and Components Thereof*, Inv. No. 337-TA-965, Comm'n Op. at 4 (Jan. 27, 2017)).

Trade Comm'n, 787 F.2d 544, 548 (Fed. Cir. 1986). Thus, the Commission may issue an LEO excluding the goods of the person(s) found in violation.

Here, all parties agree that an LEO is appropriate in this investigation should the Commission affirm the ID's finding of a violation, and we agree that an LEO is appropriate here. There are, however, questions about the scope of that LEO and the exemptions it should contain. The questions concern: (1) whether the LEO should include an exemption for all ddSEQ v2 products ("v2 product exemption"); (2) whether the LEO should include exemptions for any product used for warranty, repair, or service purposes, and/or for consumables for existing deployments of Bio-Rad's ddSEQ v1 products ("existing use exemptions"); (3) whether the LEO should include an exemption for internal research and development testing by Bio-Rad ("internal research and development exemption"); and (4) whether a certification of noninfringement provision should be included in the LEO ("certification provision").[17] The parties disagree on questions (1), (3) and (4) but agree that the LEO should include existing use exemptions.

1. v2 Product Exemption

The most significant disagreement between the parties is whether the LEO should explicitly exempt the ddSEQ v2 products because the ID found that 10X did not establish indirect infringement of those products. Bio-Rad seeks an exemption for its ddSEQ v2 products on the

[17] 10X also includes a section explaining that Bio-Rad has admitted "that the scATAC-seq assay is now commercially available and has been used by its customers in the United States," and therefore "Bio-Rad now also contributorily infringes 10X's Asserted Patents through sales of the scATAC-seq assay and induces infringement of others' uses of its scATAC-seq assay." 10X Resp. to Qs. at 55–56. The purpose of 10X's briefing on this point is far from clear, but it appears that 10X is asking the Commission to expand the indirect infringement findings in the ID to include the scATAC-seq assay, though it fails to explicitly make that request. To the extent 10X intends to request a Commission ruling as to whether the scATAC-seq assay indirectly infringes, the Commission's Rules provide procedures for obtaining such as ruling through a request for an advisory opinion or a petition for modification of the remedial orders. *See* 19 C.F.R §§ 210.76, 210.79.

basis that the ID found no indirect infringement due to the fact that the products were not available for commercial sale and had not yet been used in the United States, which necessarily precluded a finding of indirect infringement due to an underlying lack of direct infringement. *See* Bio-Rad Resp. to Qs. at 72–73. 10X counters that the ID nonetheless found the v2 products to be infringing, just like the v1 products, and that the Commission's longstanding practice has been to direct its exclusion orders broadly to articles that infringe, whether those articles currently exist or if they are manufactured and imported in the future. *See* 10X Reply at 58–59. OUII's position is that the v2 products should not be exempted because the ID did not foreclose the possibility that the importation of the v2 products would constitute a violation of section 337 if the requirements for indirect infringement are later met. *See* OUII Reply at 22. OUII does, however, recommend including a certification provision in the LEO allowing Bio-Rad to certify that either the v1 or v2 products are imported for use in a noninfringing manner. *See id.* at 22–23.

The ID uses a two-step approach to its infringement analysis. First, for each asserted patent, the ID determines whether the accused products practice the limitations of the asserted claims of that patent. Those determinations revolve around an analysis of how the microfluidic chips and instruments operate when used with the assays specific to those chips, *i.e.*, the v1 chips with the WTA 3' v1 assay, and the v2 chips with the [redacted], scATAC-seq,[18] [redacted] *See* ID at 3 (listing assays for the v1 and v2 ddSEQ systems). For the '024 and '468 patents, the ID found that the v1 and v2 systems/processes infringe all of the claims asserted from those patents. *See id.* at 27, 62–63. For the '530 patent, only the WTA 3' v1 [redacted] scATAC-seq, and [redacted] assays were accused. *See id.* at 91. The ID found that all of those

[18] The ID also includes a finding that shows that the scATAC-seq assay can be used with a v1 cartridge. *See* ID at 96 ("If the scATAC-seq assay is performed using the ddSEQ vl cartridge, each lane is capable of generating 500 droplets with a cell and gel bead.").

accused products infringe independent claim 1 of the '530 patent. *See id.* at 102–103. For the dependent claims of the '530 patent, the ID found infringement with respect to all of the asserted dependent claims and all of the accused products except in two instances. The ID explicitly found that the scATAC-seq assay does not infringe claim 4, and the ID omitted [redacted] from the list of assays that infringe claim 26. *See id.* at 103, 104. As explained above, the omission of the [redacted] assay from the claim 26 findings is an inadvertent error that the Commission has corrected on review. Accordingly, for the '530 patent, there is a single accused assay — scATAC-seq — that does not infringe one particular asserted dependent claim: dependent claim 4.

The second step in the ID's analysis was the determination of whether Bio-Rad induced or contributed to the infringement of any of the asserted claims. Of particular importance here, for each of the '024, '468, and '530 patents, the ID first considered whether there was an underlying act of direct infringement that could support a finding of indirect infringement. For each of the '024, '468, and '530 patents, the ID found that an act of direct infringement had occurred with respect to the v1 products but not the v2 products. The failure as to the v2 products was based on the fact that 10X could not show actual use of the v2 products in the United States by entities other than Bio-Rad at the time of the hearing. *See* ID at 28–29, 64, 105–108. Because the ID found no act of direct infringement with respect to the v2 products, it did not make findings about whether Bio-Rad induced infringement with the v2 products, or if the v2 products have a substantial noninfringing use.

Upon review of the parties' submissions, the Commission has determined not to adopt an exemption for the v2 products. The Commission's established practice is to direct its remedial orders to articles that infringe, as opposed to specific product model numbers. *See Certain Hardware Logic Emulation Systems and Components Thereof*, Inv. No. 337-TA-383, USTIC Pub.

3089 (Mar. 1998), Comm'n Op. on Remedy, the Public Interest, and Bonding at 16 ("The limited exclusion order is not limited to the specific models of emulation system found by the Commission to infringe, as urged by respondents. As the ALJ noted, the Commission's long-standing practice is to direct its remedial orders to all products covered by the patent claims as to which a violation has been found, rather than limiting its orders to only those specific models selected for the infringement analysis. As the IAs noted, while individual models may be evaluated to determine importation and infringement, the Commission's jurisdiction extends to all models of infringing products that are imported at the time of the Commission's determination and to all such products that will be imported during the life of the remedial orders.").

2. Existing Use Exemptions

There is broad agreement among the parties that certain exemptions to the LEO *are* appropriate. These consist of an exemption for customers who currently have access to ddSEQ equipment to continue to purchase repair parts and warranty replacements as well as consumables. *See* 10X Resp. to Qs. at 59–60; Bio-Rad Resp. to Qs. at 73–74; OUII Reply at 23. These exemptions will allow the work of researchers already using Bio-Rad's products to continue. Consistent with the existing use exemption adopted in the LEO and CDO issued in *Certain Microfluidic Devices*, Inv. No. 337-TA-1068 ("the 1068 investigation"),[19] researchers seeking to

[19] In the 1068 investigation, Bio-Rad was the complainant and 10X was the respondent. *See* 82 Fed. Reg. 42115 (Sep. 6, 2017). The Commission found that 10X had violated section 337 through the importation of microfluidic devices that infringed Bio-Rad's patents. *Certain Microfluidic Devices*, Inv. No. 337-TA-1068, Comm'n Op. at 1 (Jan. 10, 2020) (public version). Due to substantial public interest concerns and supporting record evidence, particularly with respect to the public health and welfare, the Commission tailored its remedial orders in the 1068 investigation to exempt otherwise covered microfluidic devices, provided that scientists and medical researchers using those devices established that they had a documented need to continue receiving the devices to continue ongoing research and that no alternative product could be substituted for the covered microfluidic device. *See id.* at 46.

receive ddSEQ consumables under that provision must provide Bio-Rad with a documented need to continue receiving those consumables for an identified current ongoing research project for which that need cannot be met by any alternative product. With respect to warranty and repair parts, the orders also exempt 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.

The Commission's remedial orders include as attachments questionnaires that Bio-Rad is to provide to its customers for purposes of obtaining infringing ddSEQ consumables after the effective date of the Commission's orders. Bio-Rad may provide a modified version of that questionnaire to its customers, but whatever documentation it uses must request from its customers at least the information requested in the attached questionnaires using the verbiage as it appears in the questionnaires. A completed questionnaire (or its modified equivalent) establishes a "documented need" to qualify for the exemption, as that phrase is used in this opinion. The questionnaires request, *inter alia*, a researcher to identify the date the research for which he or she is using the ddSEQ system began and to state whether other products could meet his or her research needs. The questionnaires also require both Bio-Rad and its customers to certify their statements and to acknowledge 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. To qualify for the exemption, the researcher must attest in the questionnaire that the research using the ddSEQ system began prior to the date of issuance of these remedial orders, and also attest that other products cannot meet his or her research needs. In addition, researchers who avail themselves of this exemption are required to maintain records to support

their declarations in case an audit is carried out or such records are required for any future enforcement proceeding. These accompanying records are not to be provided to Bio-Rad.

United States Customs and Border Protection ("CBP") may choose to require Bio-Rad to furnish the relevant completed questionnaires for each entry that is claimed to be exempted. *See* LEO, at ¶¶ 2–3. CBP may require that the questionnaires be submitted in advance of the date of entry of the ddSEQ consumables and pursuant to procedures that CBP establishes. The recordkeeping provision of the CDO requires Bio-Rad to retain such questionnaires, and the reporting provision requires Bio-Rad to report such records. *See* CDO, at §§ V, VI.

Consistent with the 1068 investigation, the CDO in this investigation requires Bio-Rad to provide a detailed accounting showing that the consumables imported and/or sold in the United States after importation (including sales of any infringing domestic inventory existing at the time of the Commission's decision) are being sent to only those identified customers and that consumables are not being stockpiled, sent to unauthorized customers, or used for research projects other than those identified. *See* CDO at § V. That accounting must be supported by documentation (including the questionnaires) referencing all relevant information, including the number of consumables imported and/or sold and the identity of the customers, their exempted research project(s), and the projected completion date of such projects. The reporting provision requires monthly, rather than the Commission's standard annual, reports.

3. Internal Research and Development Exemption

Bio-Rad also seeks an exemption for its internal research and development testing by Bio-Rad; 10X has not acquiesced to that exemption. *See* Bio-Rad Resp. to Qs. at 74; 10X Reply at 57. Bio-Rad makes two arguments in favor of such an exemption. The first is that the Commission has incorporated such exemptions before. *Id.* (citing *Certain Devices for Connecting Computers*

via Tel. Lines, Inv. No. 337-TA-360, Comm'n Op. at 7–10 (Nov. 18, 1994) ("A complainant that seeks exclusion of other types of entry [other than for consumption] should present evidence that activities by respondents involving other types of entry either are adversely affecting it or are likely to do so."); *Certain Magnetic Data Storage Tapes and Cartridges Containing the Same*, Inv. No. 337-TA-1012, Comm'n Op. at 128–133 (Apr. 2, 2018) ("*Magnetic Storage Tapes*") (exempting infringing products used for U.S.-based compliance testing that was necessary for foreign sales)). The second argument is that because the asserted claims for which a violation was found are method claims, Bio-Rad's own use of its products cannot be a violation of Section 337. *See* Bio-Rad Reply at 55 (citing *Electronic Devices with Image Processing Systems, Components Thereof, and Associated Software*, Inv. No. 337-TA-724, Comm'n Op at 18-20 (Dec. 1, 2011)). 10X opposes this exemption on the basis that Bio-Rad waived it by failing to ask for it in briefing before the ALJ, and that the cases relied on by Bio-Rad are factually distinguishable from this investigation. *See* 10X Reply at 57–58. OUII also opposes an exemption for internal development and testing purposes. *See* OUII Reply at 23.

The Commission has determined not to include an exemption for internal development and testing. Neither of the cases Bio-Rad cited in its initial response to the Commission's questions stand for the proposition that an "entry for consumption" excludes research and development uses. Further, Bio-Rad has not established an evidentiary basis to support a need for this exemption in contrast to the respondent in *Magnetic Storage Tapes*. *See* Comm'n Op. at 132 (finding that denial of an exemption for compliance verification testing would amount to a "world-wide" prohibition against Sony's products, since verification testing in the United States appears to be necessary even for foreign sales of Sony's LTO-7 products). Bio-Rad's request that it be allowed to continue importing infringing products for research and development purposes finds no precedent as a matter of patent law or section 337. As the Federal Circuit has recognized, there "is no fair use or