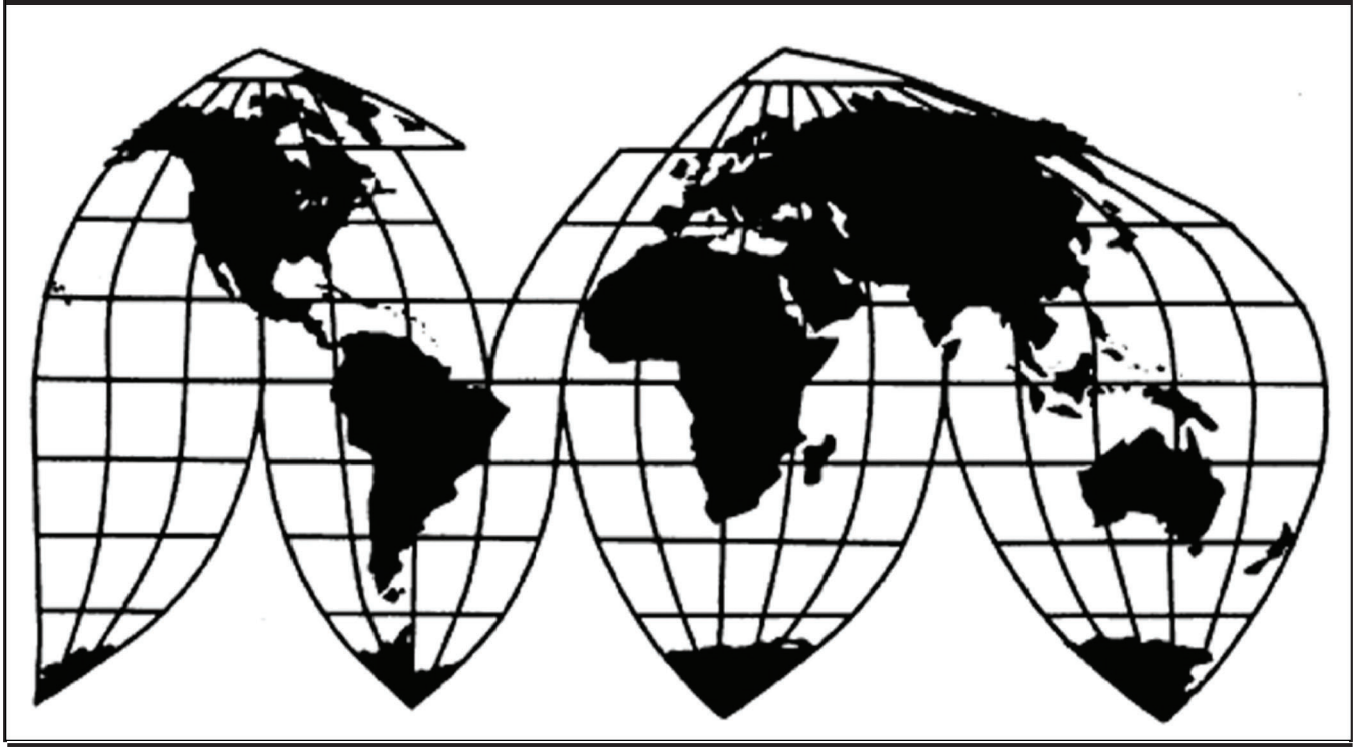
In the Matter of

CERTAIN MICROFLUIDIC DEVICES

Investigation No. 337-TA-1068

Publication 5245 **February 2022**

U.S. International Trade Commission



Washington, DC 20436

U.S. International Trade Commission

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U.S. International Trade Commission

Washington, DC 20436
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In the Matter of

CERTAIN MICROFLUIDIC DEVICES

Investigation No. 337-TA-1068

Publication 5245

February 2022

UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, D.C.

In the Matter of **CERTAIN MICROFLUIDIC DEVICES**	**Investigation No. 337-TA-1068** **(Rescission)**

NOTICE OF THE COMMISSION'S DETERMINATION TO INSTITUTE A RESCISSION PROCEEDING; TO RESCIND PERMANENTLY A LIMITED EXCLUSION ORDER AND A CEASE AND DESIST ORDER; TERMINATION OF RESCISSION PROCEEDING

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has determined to institute a rescission proceeding and rescind the remedial orders issued in the underlying investigation. The rescission proceeding is terminated.

FOR FURTHER INFORMATION CONTACT: Ronald A. Traud, Esq., Office of the General Counsel, U.S. International Trade Commission, 500 E Street S.W., Washington, D.C. 20436, telephone (202) 205-3427. Copies of non-confidential documents filed in connection with this investigation may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov*. For help accessing EDIS, please email EDIS3Help@usitc.gov. General information concerning the Commission may also be obtained by accessing its Internet server at *https://www.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 September 6, 2017, the Commission instituted this investigation based on a complaint filed by Bio-Rad Laboratories, Inc. of Hercules, CA; and Lawrence Livermore National Security, LLC of Livermore, CA (collectively, "Bio-Rad"). 82 FR 42115 (Sept. 6, 2017). The complaint alleged violations of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337 ("section 337"), based upon the importation into the United States, the sale for importation, or the sale within the United States after importation of certain microfluidic devices by reason of infringement certain claims of U.S. Patent Nos. 9,500,664 ("the '664 patent"); 9,089,844 ("the '844 patent"); 9,636,682 ("the '682 patent"); 9,649,635 ("the '635 patent"); and 9,126,160 ("the '160 patent"). *Id.* The Commission's Notice of Investigation named as the sole respondent 10X Genomics, Inc. of Pleasanton, CA ("10X"). *Id.* The Office of Unfair Import Investigations ("OUII") was also named as a party to this

investigation. *Id.* The Commission subsequently terminated the investigation as to the '844 patent. Order No. 19 (Mar. 6, 2018); *unreviewed by* Notice (Apr. 16, 2018).

On September 20, 2018, the presiding administrative law judge issued the final initial determination ("ID"). The ID found a violation of section 337 by virtue of 10X's infringement of the '664, '682, and '635 patents. The ID found that 10X had not established a violation with respect to the '160 patent. On December 4, 2018, the Commission determined to review various findings in the ID. 83 FR 63672 (Dec. 11, 2018).

On December 18, 2019, the Commission found a violation of section 337 with respect to the '664, '682, and '635 patents. 84 FR 70999 (Dec. 26, 2019). The Commission also found no violation of section 337 with respect to the '160 patent. *Id.* Having found a violation of section 337, and upon consideration of the statutory public interest factors, the Commission determined to issue a limited exclusion order ("LEO") prohibiting further importation of 10X's infringing microfluidic devices and a cease and desist order ("CDO") against 10X. *Id*. On May 28, 2021, in an appeal initiated by Bio-Rad, the U.S. Court of Appeals for the Federal Circuit affirmed the Commission's final determination. *Bio-Rad Labs., Inc. v. Int'l Trade Comm'n*, 998 F.3d 1320 (Fed. Cir. 2021).

On July 26, 2021, Bio-Rad and 10X entered into a settlement agreement that resolved the disputes concerning the subject matter of this investigation. Thereafter, on July 28, 2021, Bio-Rad and 10X jointly petitioned for rescission of the Commission's remedial orders under section 337(k) (19 U.S.C. 1337(k)) and Commission Rule 210.76(a) (19 C.F.R. 210.76(a)). On August 6, 2021, OUII filed a response in support of the rescission petition.

The Commission has determined that the petition complies with Commission rules, *see* 19 CFR 210.76(a)(3), and that there are no extraordinary reasons to deny rescission of the remedial orders. Accordingly, the Commission has determined to institute a rescission proceeding and to permanently rescind the LEO and the CDOs. The rescission proceeding is hereby terminated.

The Commission's vote on this determination took place on August 25, 2021.

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: August 25, 2021

PUBLIC CERTIFICATE OF SERVICE

I, Lisa R. Barton, hereby certify that the attached **NOTICE** has been served via EDIS upon the Commission Investigative Attorney, **Thomas Chen, Esq.**, and the following parties as indicated, on **August 25, 2021**.

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

On Behalf of Complainants Bio-Rad Laboratories, Inc. and Lawrence Livermore National Security, LLC:

S. Alex Lasher, Esq.
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On Behalf of Respondent 10X Genomics, Inc.:

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UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, D.C.

In the Matter of **CERTAIN MICROFLUIDIC DEVICES**	**Investigation No. 337-TA-1068** **(Rescission)**

COMMISSION ORDER

On September 6, 2017, the Commission instituted this investigation based on a complaint filed by Bio-Rad Laboratories, Inc. of Hercules, CA; and Lawrence Livermore National Security, LLC of Livermore, CA (collectively, "Bio-Rad"). 82 Fed. Reg. 42115 (Sept. 6, 2017). The complaint alleged violations of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337 ("section 337"), based upon the importation into the United States, the sale for importation, or the sale within the United States after importation of certain microfluidic devices by reason of infringement certain claims of U.S. Patent Nos. 9,500,664 ("the '664 patent"); 9,089,844 ("the '844 patent"); 9,636,682 ("the '682 patent"); 9,649,635 ("the '635 patent"); and 9,126,160 ("the '160 patent"). *Id.* The Commission's Notice of Investigation named as the sole respondent 10X Genomics, Inc. of Pleasanton, CA ("10X"). *Id.* The Office of Unfair Import Investigations ("OUII") was also named as a party to this investigation. *Id.* The Commission subsequently terminated the investigation as to the '844 patent. Order No. 19 (Mar. 6, 2018); *unreviewed by* Notice (Apr. 16, 2018).

On September 20, 2018, the presiding administrative law judge issued the final initial determination ("ID"). The ID found a violation of section 337 by virtue of 10X's infringement

of the ’664, ’682, and ’635 patents. The ID found that 10X had not established a violation with respect to the ’160 patent. On December 4, 2018, the Commission determined to review various findings in the ID. 83 Fed. Reg. 63672 (Dec. 11, 2018).

On December 18, 2019, the Commission found a violation of section 337 with respect to the ’664, ’682, and ’635 patents. 84 Fed. Reg. 70999 (Dec. 26, 2019). The Commission also found no violation of section 337 with respect to the ’160 patent. *Id.* Having found a violation of section 337, and upon consideration of the statutory public interest factors, the Commission determined to issue a limited exclusion order (“LEO”) prohibiting further importation of 10X’s infringing microfluidic devices and a cease and desist order (“CDO”) against 10X. *Id*. On May 28, 2021, in an appeal initiated by Bio-Rad, the U.S. Court of Appeals for the Federal Circuit issued a decision affirming the Commission’s final determination. *Bio-Rad Labs., Inc. v. Int’l Trade Comm’n*, 998 F.3d 1320 (Fed. Cir. 2021).

On July 26, 2021, Bio-Rad and 10X entered into a settlement agreement that resolved the disputes concerning the subject matter of this investigation. Thereafter, on July 28, 2021, Bio-Rad and 10X jointly petitioned for rescission of the Commission’s remedial orders under section 337(k) (19 U.S.C. 1337(k)) and Commission Rule 210.76(a) (19 C.F.R. 210.76(a)). On August 6, 2021, OUII filed a response in support of the rescission petition.

Having reviewed Bio-Rad and 10X’s petition and OUII’s response in support thereof, and in view of the settlement agreement between Bio-Rad and 10X attached to that petition, the Commission finds that the conditions that led to the exclusion of 10X’s products no longer exist. Accordingly, the Commission has determined to grant the petition and rescind the remedial orders in this investigation. *See* 19 U.S.C. § 1337(k); 19 C.F.R. § 210.76.

It is hereby ORDERED that:

(1) Pursuant to 19 U.S.C. § 1337(k) and 19 C.F.R. § 210.76, the remedial orders are RESCINDED.

(2) The Secretary shall serve a copy of this Order on the Secretary of the Treasury and all parties of record and shall publish notice thereof in the Federal Register.

By order of the Commission.

Lisa R. Barton
Secretary to the Commission

Issued: August 25, 2021

PUBLIC CERTIFICATE OF SERVICE

I, Lisa R. Barton, hereby certify that the attached **ORDER, COMMISION** has been served via EDIS upon the Commission Investigative Attorney, **Thomas Chen, Esq.**, and the following parties as indicated, on **August 25, 2021**.

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

On Behalf of Complainants Bio-Rad Laboratories, Inc. and Lawrence Livermore National Security, LLC:

S. Alex Lasher, Esq.
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On Behalf of Respondent 10X Genomics, Inc.:

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UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, D.C.

In the Matter of	
CERTAIN MICROFLUIDIC DEVICES	**Investigation No. 337-TA-1068**

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

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission ("Commission") has found a violation of section 337 in the above-captioned investigation. The Commission has determined to issue tailored remedial orders that permit researchers to continue their work in ongoing research projects using the infringing microfluidic devices as explained in the accompanying opinion. These remedial orders include: (1) a limited exclusion order ("LEO") prohibiting the unlicensed entry of infringing microfluidic devices covered by certain claims of U.S. Patent Nos. 9,500,664 ("the '664 patent"); 9,636,682 ("the '682 patent"); and 9,649,635 ("the '635 patent") that are manufactured abroad for or on behalf of, or imported by or on behalf of 10X Genomics, Inc. of Pleasanton, California ("10X") or any of its affiliated companies, parents, subsidiaries, or other related business entities, or its successors or assigns; and (2) a cease and desist order ("CDO") directed against 10X and its affiliated companies, parents, subsidiaries, or other related business entities, or its successors or assigns.

This investigation is terminated.

FOR FURTHER INFORMATION CONTACT: Ron Traud, Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436, telephone 202-205-3427. 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, telephone 202-205-1810.

SUPPLEMENTARY INFORMATION: On September 6, 2017, the Commission instituted this investigation based on a complaint filed by Bio-Rad Laboratories, Inc. of Hercules, California; and Lawrence Livermore National Security, LLC of Livermore, California. 82 FR 42115 (Sept.

6, 2017). The complaint (and supplement thereto) alleges violations of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337 ("section 337") based upon the importation into the United States, the sale for importation, or the sale within the United States after importation of certain microfluidic devices by reason of infringement of one or more claims of the '664 patent, the '682 patent, the '635 patent, and U.S. Patent Nos. 9,089,844 ("the '844 patent") and 9,126,160 ("the '160 patent). *Id.* The Commission's notice of investigation named as the sole respondent 10X. *Id.* The Office of Unfair Import Investigations was also named as a party to this investigation. *Id.*

Prior to the issuance of the final initial determination ("ID") by the presiding administrative law judge (the "ALJ"), the investigation was terminated as to the '844 patent in its entirety and as to certain claims of the '160, '664, '682, and '635 patents. *See* Order No. 12, *unreviewed*, Notice (Mar. 6, 2018); Order No. 16, *unreviewed*, Notice (Mar. 26, 2018); Order No. 19, *unreviewed*, Notice (Apr. 16, 2018); Order No. 29, *unreviewed*, Notice (June 1, 2018). The ALJ's final ID addressed the following claims: (i) claim 20 of the '160 patent; (ii) claims 1, 2, 14, and 15 of the '664 patent; (iii) claims 14, 16, and 17 of the '682 patent; and (iv) claims 1, 13, 14, 16, and 21 of the '635 patent.

On September 20, 2018, the ALJ issued the final ID, which finds 10X in violation of section 337 as to the remaining asserted claims of the '664, '682 patent, and '635 patents. On September 28, 2018, the ALJ issued her recommendations on remedy, bond, and the public interest. The ALJ recommended that the Commission issue a limited exclusion order directed to 10X's infringing products and a cease and desist order directed to 10X. The ALJ also recommended a bond of 100 percent of entered value during the period of Presidential review. *See* 19 U.S.C. 1337(j)(3).

The private parties petitioned for the Commission to review certain of the ALJ's determinations. On December 4, 2018, after considering the parties' petitions and responses thereto, the Commission determined to review the following issues:

(1) Whether 10X indirectly infringes the '682 and '635 patents;

(2) Whether 10X's Chip GB infringes claims 1 and 14 of the '664 patent; and

(3) Whether 10X's Chip SE infringes claim 20 of the '160 patent and claim 1 of the '664 patent.

83 FR 63672 (Dec. 11, 2018). The Commission thereafter requested briefing only on remedy, the public interest, and bonding.

On June 10, 2019, the Commission requested supplemental briefing on the public interest. 84 FR 27802 (June 14, 2019); 84 FR 31912 (July 3, 2019) (modifying briefing schedule). Thereafter, the parties, members of the public, and a government agency submitted public interest briefing.

On review, and consistent with the simultaneously-issued Commission opinion, the Commission has determined to affirm with modification the final ID's finding of a violation of

section 337 with respect to claims 1, 2, 14, and 15 of the '664 patent, claims 14, 16, and 17 of the '682 patent, and claims 1, 13, 14, 16, and 21 of the '635 patent.

The Commission has further determined that the public interest factors enumerated in subsections (d)(l) and (f)(1) (19 U.S.C. 1337(d)(l), (f)(1)) do not preclude issuance of the above-referenced remedial orders. However, the Commission has determined to tailor the LEO and CDO to allow research studies using the infringing articles at issue as of the date of issuance of the remedial orders to continue to use those infringing articles.

The Commission has determined to impose a bond of three (3) percent of entered value of the covered products during the period of Presidential review (19 U.S.C. 1337(j)).

This investigation is terminated.

This action is taken under the authority of 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 part 210).

By order of the Commission.

Lisa R. Barton
Secretary to the Commission

Issued: December 18, 2019

PUBLIC CERTIFICATE OF SERVICE

I, Lisa R. Barton, hereby certify that the attached **NOTICE** has been served by hand upon the Commission Investigative Attorney, **Whitney Winston, Esq.**, and the following parties as indicated, on **December 18, 2019**.

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

On Behalf of Complainants Bio-Rad Laboratories, Inc. and Lawrence Livermore National Security, LLC:

Jeffrey Gerchick, Esq.
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On Behalf of Respondent 10X Genomics, Inc.:

Nicholas Groombridge, Esq.
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New York, NY 10019

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UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, D.C.

In the Matter of **CERTAIN MICROFLUIDIC DEVICES**	**Investigation No. 337-TA-1068**

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 respondent 10X Genomics, Inc. of Pleasanton, California ("10X" or "Respondent") of certain microfluidic devices by reason of infringement of: (1) one or more of claims 1, 2, 14, and 15 of U.S. Patent No. 9,500,664 ("the '664 patent"); (2) one or more of claims 14, 16, and 17 of U.S. Patent No. 9,636,682 ("the '682 patent"); or (3) one or more of claims 1, 13, 14, 16, and 21 of U.S. Patent No. 9,649,635 ("the '635 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 devices 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. This Exclusion Order does not apply to covered microfluidic devices imported into the United States for use by researchers who are using such devices in the United States as of the

date of issuance of this Order, and who have a documented need to continue receiving the devices for a specific current ongoing research project for which that need cannot be met by any alternative product, including the Next GEM Chip.

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 three (3) percent of the entered value for all covered products.

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

1. Microfluidic devices that infringe one or more of claims 1, 2, 14, and 15 of the '664 patent; claims 14, 16, and 17 of the '682 patent; and claims 1, 13, 14, 16, and 21 of the '635 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.
2. The provisions of this Order shall not apply to covered products imported into the United States for use by researchers who are using such devices in the United States as of the date of issuance of this Order, and who have a documented need[1] to continue

[1] This "documented need" is to be satisfied by the questionnaire attached to this Order, as discussed at pages 25–27 and 46–47 of the Commission Opinion issued in this investigation on the date of this Order. 10X is not required to maintain the individual researchers' records supporting the questionnaire. Commission Opinion, at 47.

receiving the devices 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 certain microfluidic devices found to be non-infringing as detailed in the Administrative Law Judge's final initial determination dated September 20, 2018, at pages 82–85, and as modified and affirmed by the Commission Opinion issued in this investigation on the date of this Order, at pages 17–22.

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 three (3) 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 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 devices 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 or 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: December 18, 2019

ATTACHMENT

Name: _____

Institution: _____

If you were conducting research using 10X's GEM chips (as opposed to 10X's Next GEM chips) as of December 18, 2019, in the United States and you need to continue to receive the GEM chips for that research, answer the following questions:

1. What is the subject matter of your research that uses 10X's Chromium products and GEM chips?

2. On what date (mm/dd/yyyy) did your research using these 10X products begin?

3. What is the expected completion date (mm/dd/yyyy) of your research that uses these 10X products?

4. Which type of 10X product do you use (*e.g.*, Single Cell RNA-Seq, Single Cell V(D)J, Single Cell ATAC, Single Cell CNV, Linked-Reads)?

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

6. Can you use Next GEM chips for your research? If no, why not, and if yes, why have you not transitioned to 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 10X. If the facts change concerning my research, which began on or before December 18, 2019, I understand that I am to provide an updated questionnaire response to 10X.

Date: _____ Signature: _____

Additional 10X comments [to be completed by 10X]:

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: _____

PUBLIC CERTIFICATE OF SERVICE

I, Lisa R. Barton, hereby certify that the attached **ORDER** has been served by hand upon the Commission Investigative Attorney, **Whitney Winston, Esq.**, and the following parties as indicated, on **December 18, 2019**.

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

On Behalf of Complainants Bio-Rad Laboratories, Inc. and Lawrence Livermore National Security, LLC:

Jeffrey Gerchick, Esq.
QUINN EMANUEL URQUHART & SULLIVAN LLP
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On Behalf of Respondent 10X Genomics, Inc.:

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UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, D.C.

In the Matter of **CERTAIN MICROFLUIDIC DEVICES**	**Investigation No. 337-TA-1068**

CEASE AND DESIST ORDER

IT IS HEREBY ORDERED THAT 10X Genomics, Inc., of Pleasanton, 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 devices covered by one or more of claims 1, 2, 14, and 15 of U.S. Patent No. 9,500,664 ("the '664 patent"); claims 14, 16, and 17 of U.S. Patent No. 9,636,682 ("the '682 patent"); and claims 1, 13, 14, 16, and 21 of U.S. Patent No. 9,649,635 ("the '635 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 Bio-Rad Laboratories, Inc., of Hercules, California.

(C) "Respondent" shall mean 10X Genomics, Inc., of Pleasanton, 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 devices that infringe one or more of claims 1, 2, 14, and 15 of the '664 patent; claims 14, 16, and 17 of the '682 patent; and claims 1, 13, 14, 16, and 21 of the '635 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. "Covered products" shall also not include certain microfluidic devices found to be non-infringing as detailed in the Administrative Law Judge's final initial determination dated September 20, 2018, at pages 82–85, and as modified and affirmed by the Commission Opinion issued in this investigation on the date of this Order, at pages 17–22.

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 by stock ownership or otherwise) and majority-owned business entities, successors, and assigns,

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

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 the relevant one of the '664, '682, and '635 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 '664, '682, and '635 patents licenses or authorizes such specific conduct, or (2) 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 devices for use by researchers who are using such devices 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 devices for a specific current ongoing

[2] This "documented need" is to be satisfied by the questionnaire attached to this Order, as discussed at pages 25–28 and 46–47 of the Commission Opinion issued in this investigation on

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, and (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 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-1068") in a prominent place on the cover pages

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the date of this Order. 10X is not required to maintain the individual researchers' records supporting the questionnaire. Commission Opinion, at 47.

[3] *See* Footnote 2.

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 devices 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 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

[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.

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 '664, '682, and '635 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 three (3) 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

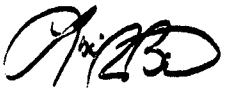
Commission for the posting of bonds by complainants in connection with the issuance of temporary exclusion orders. *See* 19 C.F.R. § 210.68. The bond and any accompanying documentation are to be provided to and approved by the Commission prior to the commencement of conduct that is otherwise prohibited 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: December 18, 2019

ATTACHMENT

Name: _____

Institution: _____

If you were conducting research using 10X's GEM chips (as opposed to 10X's Next GEM chips) as of December 18, 2019, in the United States and you need to continue to receive the GEM chips for that research, answer the following questions:

1. What is the subject matter of your research that uses 10X's Chromium products and GEM chips?

2. On what date (mm/dd/yyyy) did your research using these 10X products begin?

3. What is the expected completion date (mm/dd/yyyy) of your research that uses these 10X products?

4. Which type of 10X products do you use (*e.g.*, Single Cell RNA-Seq, Single Cell V(D)J, Single Cell ATAC, Single Cell CNV, Linked-Reads)?

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

6. Can you use Next GEM chips for your research? If no, why not, and if yes, why have you not transitioned to 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 10X. If the facts change concerning my research, which began on or before December 18, 2019, I understand that I am to provide an updated questionnaire response to 10X.

Date: _____ Signature: _____

Additional 10X comments [to be completed by 10X]:

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: _____

PUBLIC CERTIFICATE OF SERVICE

I, Lisa R. Barton, hereby certify that the attached **ORDER** has been served by hand upon the Commission Investigative Attorney, **Whitney Winston, Esq.**, and the following parties as indicated, on **December 18, 2019**.

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

On Behalf of Complainants Bio-Rad Laboratories, Inc. and Lawrence Livermore National Security, LLC:

Jeffrey Gerchick, Esq.
QUINN EMANUEL URQUHART & SULLIVAN LLP
1300 I Street NW, Suite 900
Washington, DC 20005

☐ Via Hand Delivery
☒ Via Express Delivery
☐ Via First Class Mail
☐ Other:_____

On Behalf of Respondent 10X Genomics, Inc.:

Nicholas Groombridge, Esq.
PAUL, WEISS, RIFKIND, WHARTON & GARRISON LLP
1285 Avenue of the Americas
New York, NY 10019

☐ 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 DEVICES**	**Investigation No. 337-TA-1068**

COMMISSION OPINION
[REVISED]

This investigation is before the Commission for a final determination on the issues under review, and for a determination on remedy, the public interest, and bonding. The Commission has determined to affirm with modifications the finding of the final initial determination ("ID") that respondent 10X Genomics, Inc. of Pleasanton, California ("10X") has violated section 337 of the Tariff Act of 1930, as amended (19 U.S.C. § 1337) ("section 337"), in connection with certain claims of U.S. Patent Nos. 9,500,664 ("the '664 patent"); 9,636,682 ("the '682 patent"), and 9,649,635 ("the '635 patent"), but has not violated section 337 in connection with the asserted claim of U.S. Patent No. 9,126,160 ("the '160 patent"). The Commission adopts the final ID to the extent that it does not conflict with this opinion.

Having found a violation of section 337 in this investigation by 10X, the Commission has determined, based on the record in this investigation, that the appropriate remedy under the facts here is a limited exclusion order ("LEO") and a cease and desist order ("CDO") that are tailored to mitigate potential adverse effects on the public interest. This investigation is terminated.

I. BACKGROUND

A. Procedural History

1. Institution

On September 6, 2017, the Commission instituted this investigation based on a complaint filed by Bio-Rad Laboratories, Inc. of Hercules, California ("Bio-Rad"); and Lawrence Livermore National Security, LLC of Livermore, California ("LLNS," and collectively with Bio-Rad, "Complainants"). 82 *Fed. Reg.* 42115 (Sept. 6, 2017). The complaint (and supplement thereto) allege violations of section 337 based upon the importation into the United States, the sale for importation, or the sale within the United States after importation of certain microfluidic devices by reason of infringement of one or more claims of the '664 patent, the '682 patent, the '635 patent, the '160 patent, and U.S. Patent No. 9,089,844 ("the '844 patent"). *Id.* The Commission's notice of investigation names 10X as the sole respondent. *Id.* The Office of Unfair Import Investigations ("OUII") was also named as a party in this investigation. *Id.*

2. Pre-Final ID Procedural History

On January 17, 2018, Complainants filed a motion for summary determination that assignor estoppel precluded 10X from challenging the validity of the asserted patents. On March 15, 2018, the administrative law judge ("ALJ") issued an ID granting that motion. Order No. 15 (Mar. 15, 2018). On April 9, 2018, the Commission declined to review that ID. Notice (Apr. 9, 2018).

On April 4, 2018, the ALJ issued a *Markman* Order adopting the claim constructions on which the parties agreed and construing the claim terms in dispute. Order No. 20 (Apr. 4, 2018).

Prior to the issuance of the final ID by the ALJ, the investigation terminated as to the '844 patent in its entirety and as to certain claims of the '160, '664, '682, and '635 patents. *See* Order No. 12, *unreviewed*, Notice (Mar. 6, 2018); Order No. 16, *unreviewed*, Notice (Mar. 26, 2018); Order No. 19, *unreviewed*, Notice (Apr. 16, 2018); Order No. 29, *unreviewed*, Notice (June 1, 2018). Thus, the ALJ's final ID addresses the following claims: (i) claim 20 of the '160 patent; (ii) claims 1, 2, 14, and 15 of the '664 patent; (iii) claims 14, 16, and 17 of the '682 patent; and (iv) claims 1, 13, 14, 16, and 21 of the '635 patent.

3. The Final ID and the RD

On September 20, 2018, the ALJ issued the final ID, which finds 10X in violation of section 337 as to the '664, '682, and '635 patents, but not as to the '160 patent. A summary of the final ID's findings is provided in the table below:

Accused Products[1]	Patent	Claims	Initial Determination
GEM Chips and Next GEM Chips[2]	'160 Patent	20	***No violation***: Claim 20 is not invalid, but is also not infringed by the GEM Chips or Next GEM Chips.
GEM Chips, Next GEM Chips, and Chip GB	'664 Patent	1, 2, 14, and 15	***Violation***: Claims 1, 2, 14, and 15 are not invalid and are infringed by the GEM Chips, but not by the Next GEM Chips or Chip GB.
GEM Chips	'682 Patent	14, 16, and 17	***Violation***: Claims 14, 16, and 17 are not invalid and are infringed by the GEM Chips when used with the Chromium Controllers.
GEM Chips	'635 Patent	1, 13, 14, 16, and 21	***Violation***: Claims 1, 13, 14, 16 and 21 are not invalid and are infringed by the GEM Chips when used with the Chromium Controllers.
Domestic Industry Products	All Asserted Patents		***Satisfied***: Complainants' domestic R&D activities with respect to their domestic industry products satisfy the domestic industry requirement set forth in 19 U.S.C. § 1337(a)(3)(A), (B), and (C).

ID at 2–3, 146–47.

On September 28, 2018, the ALJ issued her recommendations on remedy, bonding, and the public interest[3] (the "RD"). The RD recommends issuance of an LEO with a certification

[1] The accused products are described in more detail below.

[2] The final ID refers to the Next GEM Chip as the "Chip SE."

[3] In the notice of investigation, the Commission directed that the ALJ "take evidence or other information and hear arguments from the parties and other interested persons with respect to the public interest in this investigation, as appropriate, and provide the Commission with findings of facts and a recommended determination on this issue." 82 *Fed. Reg.* at 42115.

Footnote continued on following page.

provision directed to 10X's infringing products,[4] and of a CDO directed to 10X's U.S. activities in connection with the infringing products. RD at 31, 41. The RD also recommends that the Commission set a bond in the amount of 100 percent of entered value for infringing products imported during the period of Presidential review. RD at 33. Based on the record available at the time, the RD further finds that the statutory public interest factors do not preclude the issuance or require the tailoring of the requested remedy. RD at 4–5.

After the RD issued, the Commission requested statements from the public on the public interest issues raised by the recommended relief in the RD. 83 *Fed. Reg.* 50409 (Oct. 5, 2018).[5]

4. Commission Review of the Final ID

On October 3, 2018, Complainants and 10X each filed petitions for review of the final ID. On December 4, 2018, the Commission determined to review the final ID in part. 83 *Fed. Reg.* 63672, 63673 (Dec. 11, 2018). Specifically, the Commission determined to review the following issues:

(1) Whether 10X indirectly infringes the '682 and '635 patents;

(2) Whether 10X's Chip GB infringes claims 1 and 14 of the '664 patent; and

(3) Whether 10X's Chip SE infringes claim 20 of the '160 patent and claim 1 of the '664 patent.

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[4] The certification provision would allow 10X to "certify its non-infringing microfluidic chips pursuant to the procedures to be specified by the U.S. Customs and Border Protection." RD at 33 (internal quotations omitted).

[5] The Commission received three responses to this particular request: Letter from Dr. Akira Watanabe, Kyoto University (Oct. 26, 2018); Letter from Dr. Michael Hunkapiller, Pacific Biosciences (Oct. 26, 2018); Letter from Kathy Ordonez, Pacific Biosciences (Oct. 26, 2018).

Footnote continued on following page.

Id. The Commission did not request briefing on the issues under review, but did request briefing on remedy, the public interest, and bonding from the parties to the investigation, interested government agencies, and any other interested parties, including the public. *Id.*

On December 17, 2018, the parties filed their written submissions on remedy, public interest, and bonding,[6] and on January 30, 2019, Complainants and 10X filed their reply submissions.[7] OUII did not file a reply submission.

10X's reply submission included for the first time correspondence authored by medical researchers and a medical research institution. These correspondences stated that important research relevant to the public health and welfare would be negatively impacted, either temporarily or permanently, if researchers were to lose access to 10X's products. 10X Br. (Reply), Ex. 7, Ex. 8.[8] The correspondence generally asserted that 10X's Chromium products

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[6] Complainants' Submission on Remedy, Public Interest and Bond (Dec. 17, 2018) ("Compls. Br."); Respondent 10X Genomics, Inc.'s Written Submission Pursuant to Commission's December 4, 2018 Notice (Dec. 17, 2018) ("10X Br."); Written Submission of the Office of Unfair Import Investigations on Remedy, the Public Interest, and Bonding (Dec. 17, 2018) ("OUII Br.").

[7] Complainants' Reply Submission on Remedy, Public Interest and Bond (Jan. 30, 2019) ("Compls. Br. (Reply)"); Respondent 10X Genomics, Inc.'s Response to Written Submissions Pursuant to Commission's December 4, 2018 Notice (Jan. 30, 2019) ("10X Br. (Reply)").

[8] Exhibit 7 is a declaration of Randy Wu, 10X's Senior Director of Intellectual Property and Litigation. Exhibit 7 includes thirteen letters from medical researchers, Exhibits A–M. 10X previously filed Exhibit 7 with the Delaware District Court to oppose an injunction that would affect 10X products. *Bio-Rad Labs. Inc. v. 10X Genomics, Inc.*, No. 15-CV-152-RGA (D. Del.), D.I. 545 (Jan. 28, 2019).

Exhibit 8, cited herein as the "Broad Institute Mem.," is an *Amicus Curiae* Memorandum drafted by the Broad Institute. The Broad Institute is associated with MIT and Harvard and "was launched in 2004 to improve human health by using genomics to advance our understanding of the biology and treatment of human disease, and to help lay the groundwork for a new generation of therapies." https://www.broadinstitute.org/about-us (last visited Sept. 13, 2019); *see also* 10X Br. (Reply), Ex. 8 (Broad Institute Mem.), at 1. The Broad Institute

Footnote continued on following page.

enable certain research that competing products do not, and that switching to a competitor's system mid-study would cause major research setbacks. *Id.* The latter of these arguments was not previously presented to the ALJ or to the Commission. Because 10X did not submit these third party comments until its reply submission, the parties and the public did not have an opportunity to provide rebuttal responses.

On June 10, 2019, the Commission requested supplemental public interest briefing to allow the parties, interested members of the public, and interested government agencies to respond to the evidence submitted by 10X in its reply submission, and to allow further submissions on the public interest. 84 *Fed. Reg.* 27802 (June 14, 2019); *see also* 84 *Fed. Reg.* 31912 (July 3, 2019) (modifying briefing schedule). The Commission requested more detailed information regarding the concerns brought to light by the researchers' correspondences and the feasibility of tailoring any remedy to mitigate identified public interest concerns. 84 *Fed. Reg.* at 27802–03.

On June 24, 2019, the parties submitted their opening supplemental submissions,[9] and on July 15, 2019, the parties filed their reply supplemental submissions.[10] The *Eunice Shriver*

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previously filed its memorandum in the Delaware action. *Bio-Rad Labs.*, No. 15-CV-152-RGA, D.I. 534 (Jan. 24, 2019). The Broad Institute Memorandum declares that it does not support any party, but instead wishes to inform the court of the harm that an injunction would cause to the public interest. 10X Br. (Reply), Ex. 8, at 1–2.

[9] Complainants' Opening Supplemental Submission on Public Interest (June 24, 2019) ("Compls. Supp. Sub."); Respondent 10X Genomics, Inc.'s Written Submission Pursuant to Commission's June 10, 2019 Notice (June 24, 2019) ("10X Supp. Sub."); Supplemental Submission of the Office of Unfair Import Investigations on the Public Interest (June 24, 2019) ("OUII Supp. Sub.").

[10] Complainants' Reply Supplemental Submission on Public Interest (July 15, 2019) ("Compls. Supp. Sub. (Reply)"); Respondent 10x Genomics, Inc.'s Reply Supplemental Written Submission on Public Interest Issues (July 15, 2019) ("10X Supp. Sub. (Reply)"); Reply of the

Footnote continued on following page.

Kennedy National Institute of Child Health and Development ("NICHD") and several members of the public also filed submissions in response to the Commission's June 2019 notice.[11]

B. The Private Parties

1. Complainant Bio-Rad Laboratories, Inc.

Bio-Rad is a Delaware corporation with a principal place of business in Hercules, California that develops products and services to identify, separate, purify, and analyze chemical and biological materials. Final ID at 9–10; Compl. at ¶ 7; Tr. at 85:21–22, 86:10–13, 87:3–17; JX-0144.0134. Bio-Rad is the sole owner of the '644, '682, and '635 patents. *E.g.*, Compl. at ¶¶ 1, 40, 46, 49; Final ID at 10.

2. Complainant Lawrence Livermore National Security, LLC

LLNS is a Delaware corporation having a place of business in Livermore, California. Compl. at ¶¶ 1, 40, 46, 49; Final ID at 10. LLNS and Bio-Rad each own an undivided 50 percent joint interest in the '160 patent. Compl. at ¶ 52; Compl. at Exs. 10A–D; Final ID at 10–11. LLNS has no interest in any of the other asserted patents. *Id.* The Commission has found no section 337 violation as to the '160 patent.

Office of Unfair Import Investigations to the Written Submissions of the Private Parties Pursuant to the Commission's June 10, 2019 Notice (July 15, 2019) ("OUII Supp. Sub. (Reply)").

[11] Letter from Constantine Stratakis, M.D., Scientific Director of the *Eunice Kennedy Shriver* National Institute of Child Health and Development (July 1, 2019) ("NICHD Submission"); Letter from Dr. Kenneth Beckman, University of Minnesota (July 1, 2019) ("Beckman Submission"); Letter from Dr. Jason Bielas, Fred Hutchinson Cancer Research Center (July 2, 2019); Letter from Dr. John Carpten, University of Southern California (July 1, 2019); Letter from Dr. Calvin Kuo, Stanford University (July 1, 2019); Letter from Dr. Aldons Lusis, University of California, Los Angeles (July 1, 2019); Letter from Dr. Gregory Gibson, Georgia Institute of Technology (June 29, 2019).

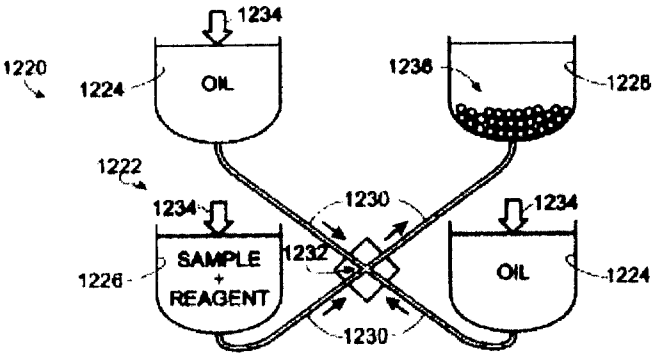
3. Respondent 10X Genomics, Inc.

10X is a Delaware corporation that has a principal place of business in Pleasanton, California. Resp. at ¶ 29; Final ID at 11. 10X is a genomic technology company that designs and sells solutions for sample partitioning, barcoding, and sequencing preparation, which can be used for DNA sequencing or other genomic applications. Tr. at 927:22–24, 928:16–929:1; Final ID at 11. 10X is responsible for importing the accused microfluidic chip products and selling those products in the United States after importation. *See* Tr. at 562:16–25, 975:18–19, 1047:7–13, 1264:15–25; RX-1550C; Final ID at 11.

C. The Patents at Issue

1. U.S. Patent No. 9,126,160

The '160 patent, titled "System for Forming an Array of Emulsions," issued on September 8, 2015. JX-0001 at cover page. The '160 patent generally relates to forming an array of emulsions on a microfluidic plate. JX-0001 at Abstract, 1:46–57. The plate includes an array of emulsion production units, each configured to produce a separate emulsion and including a set of wells interconnected by channels that intersect to form a site for droplet generation. *Id.* Each set of wells includes: (i) at least one first input well to receive a continuous phase; (ii) a second input well to receive a dispersed phase; and (iii) an output well configured to receive from the site of droplet generation an emulsion of droplets of the dispersed phase disposed in the continuous phase. *Id.* A representative figure of the disclosed embodiments is reproduced below.



2. U.S. Patent No. 9,500,664

The '664 patent, titled "Droplet Generation for Droplet-Based Assays," issued on November 22, 2016. JX-0002 at cover page. Like the '160 patent, the '664 patent generally relates to forming emulsions on a microfluidic plate. JX-0002 at Abstract, 2:31–42. The disclosed droplet generation components are configured to form sample-containing droplets by merging aqueous, sample-containing fluid with a background emulsion fluid such as oil, to form an emulsion of sample-containing droplets suspended in the background fluid. *Id.* As described in the '160 and '664 patents, these fluids are contained in wells that are interconnected by channels that intersect at a droplet generation region. *Id.* at 19:59–20:10.

3. U.S. Patent No. 9,636,682

The '682 patent, titled "System for Generating Droplets—Instruments and Cassette," issued on May 2, 2017. JX-0004 at cover page. The '682 patent discloses a holder or cassette that receives a microfluidic plate and an instrument configured to receive the plate and the holder/cassette. JX-0004 at Abstract, 3:39–55. The instrument also drives: (1) sample-containing fluid from the sample well to the droplet-generation region via the first channel; (2) continuous-phase fluid from the continuous-phase well to the droplet-generation region via

the second channel; and (3) sample-containing droplets from the droplet-generation region to the droplet well via the third channel. *Id.*

4. U.S. Patent No. 9,649,635

The '635 patent, titled "System for Generating Droplets with Push-Back to Remove Oil," issued on May 16, 2017. JX-0005 at cover page. Like the '682 patent, the '635 patent discloses a holder or cassette that receives a microfluidic plate, and an instrument configured to receive the plate and holder/cassette. JX-0005 at Abstract, 3:35–50. The instrument described in the '635 patent is configured to create: (i) a first pressure differential to produce an emulsion collected in the droplet well; and (ii) a second pressure differential to decrease a volume fraction of continuous-phase fluid in the emulsion after the emulsion has been collected in the droplet well by selectively driving continuous-phase fluid relative to sample-containing droplets from the droplet well, which results in a more droplet-concentrated emulsion. *Id.* at Abstract; Tr. at 515:5–19.

D. The Products at Issue

1. The Accused Products

The 10X products subject to this investigation are certain imported 10X microfluidic "chips." *See* Final ID at 30; CX-0612C at 72:4–19; Tr. at 1264:9–25, 956:20–957:23, 362:14–363:15. Specifically, the accused products include 10X's GEM-Q and GEM-U Chips (collectively, the "GEM Chips"), the Next GEM Chip (sometimes called the Chip Step Emulsification, or "Chip SE"), and the Chip GB. The accused GEM Chips or Next GEM Chips are required for use in a system that includes a domestically manufactured 10X Chromium Controller or Chromium Single Cell Controller (collectively, the "Chromium Controllers"). Tr. at 1052:6–1052:11. The system allows researchers to isolate cell samples (*e.g.*, human cells obtained from a biopsy) so that the cell samples can be subsequently used by researchers in

various forms of analysis, such as genetic sequencing. Final ID at 30 (citing, *e.g.*, Tr. at 954:2–25). Chips of other systems are not interchangeable with 10X chips and cannot be used with 10X's system. *See* RD at 7 (citing Tr. at 1052:6–11; 10X Post-Hrg. Br. (Reply) at 81–82).

10X divides its product offerings into various "solutions." RD at 9 (citing 10X Post-Hrg Br. (Reply) at 44–47); 10X Br. (Reply) at 1–3. 10X's "Single-Cell Gene Expression Solution" (also called "Single Cell RNA-Seq" or "Single Cell 3' Gene Expression") uses either the Chromium or Chromium Single Cell Controller with 10X's GEM-U Chip and gel beads made using the Chip GB (discussed below). Tr. at 1046:16–1049:2, 1028:1–5; CX-0568C at 34:13–21. "This solution is used by the Human Cell Atlas consortium, which 'involves hundreds of labs from across different countries that are trying to map out all of the different cell types out of the trillions of cells that are present in the human body.'" RD at 10 (citing Tr. at 1046:16–1049:2, 1028:1–5; CX-0568C at 34:13–21).

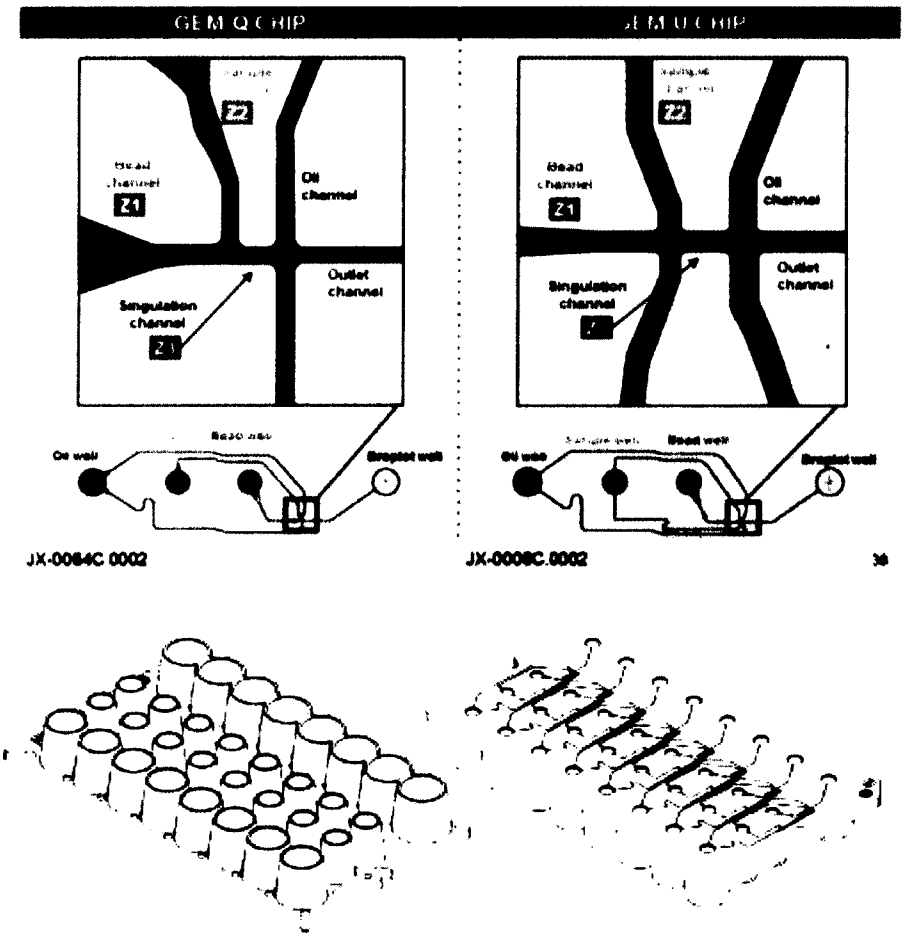
10X's "Single-Cell V(D)J Solution" (also called "Single Cell Immune Profiling") also uses either the Chromium or Chromium Single Cell Controller with 10X's GEM-U Chip and gel beads made using the Chip GB. Tr. at 1046:16–19, 1053:16–1054:19, 1028:1–5; CX-0568C at 34:13–21. "This solution allows mapping of T-cell or B-cell receptors on a single-cell level that allows researchers to understand at a molecular level what a given immune cell is going to target and uses that to map out the gene expression from the cell and understand the attack or non-attack state of the cell." RD at 10–11 (citing Tr. at 1046:16–19, 1053:16–1054:19, 1028:1–5; CX-0568C at 34:13–21) (internal quotations omitted). The Single-Cell V(D)J Solution is reportedly valuable to research in immunology and immuno-oncology (the use of the immune system to fight cancer). Tr. at 1053:16–1054:19.

10X's "Single Cell ATAC Solution" is used to "study the epigenetic state of a cell, *i.e.*, how the genome is modified to influence what genes are turned on," and "enables researcher[s] to understand the epigenetic state of tens of thousands of cells at once." 10X Br. (Reply) at 3.

10X's "Single Cell CNV Solution" (also called "Single Cell DNA-seq") is used to "measure mutations across the genome from thousands to tens of thousands of cells," and "is targeted specifically for cancer research." 10X Br. (Reply) at 3.

10X's "Linked Read Solution" uses the Chromium Controller with 10X's GEM-Q Chip and gel beads made using the Chip GB. RD at 9 (citing Tr. at 1046:7–1047:15, 1028:1–5; CX-0568C at 34:13–21). The Linked-Read Solution allows "sequencing of the entire genome or exome, and phasing or haplotyping that information to determine if a mutation is on the set of chromosomes from the mother or the father." 10X Post-Hrg. Br. (Reply) at 88 (citing Tr. at 1046:7–1047:15). Because the Linked Read Solution "avoid[s] the loss of long-range information, it is extremely valuable in a number of research areas, including cancer and genetic diseases." Tr. at 1061:22–1062:21. In contrast to 10X's other products, the Linked-Read Solution is not a "single cell" solution.

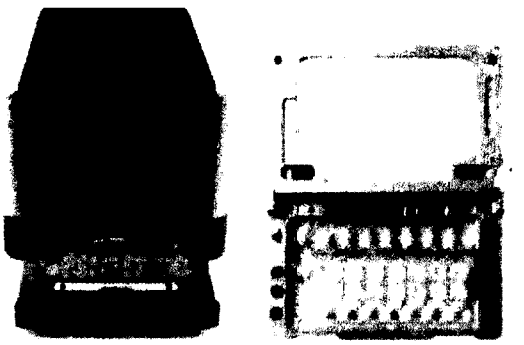
Schematics of the GEM Chips are reproduced below.



RDX-0004C.0011 (citing JX-0064C; JX-0008C).

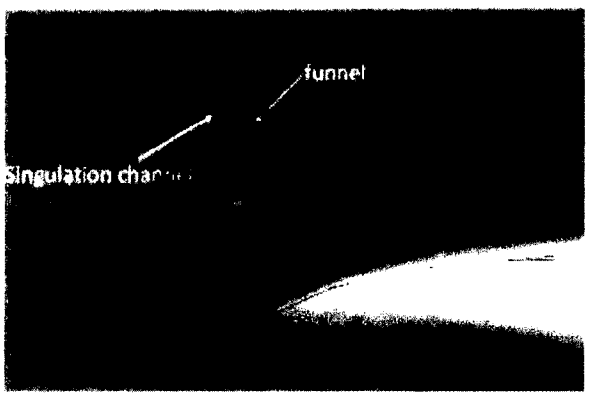
To function with the Chromium Controllers, the GEM Chips require what 10X calls a "backpack," which mounts onto a side of the chip. CX-0616C at 101:7–102:13. An

EEPROM[12] is adhered to the backpack. *Id.* Photographs of a controller and a holder in which the chips are inserted are reproduced below.



CDX-0005C.0016.

The Next GEM Chip is a different design than the GEM Chips. Final ID at 32 (citing Tr. at 973:20–974:3, 974:10-25, 975:18–976:10, 978:4–979:24). A schematic of the Next GEM Chip is shown below.



RX-0261C.0002. When the investigation was before the ALJ, the Next GEM Chip was not yet commercially available. Tr. at 975:22–976:10. According to testimony in the investigation, 10X began developing the Next GEM Chip "after being in litigation with Bio-Rad several

[12] An EEPROM is a programmable and reprogrammable electronic memory chip used to specify the control of the instrument.

times" and in order "to have a completely different design . . . for how droplets are formed." Tr. at 974:10–23. 10X has begun selling the Next GEM Chips. 10X Supp. Sub. at 5–6; *id.* at Ex. 1, ¶¶ 5–11. According to 10X, it is "introducing the Next GEM [C]hip to its customers on a measured and progressive basis," and the Next GEM Chip is available for nearly all of its research applications. *Id.* Next GEM versions are available for the Single-Cell Gene Expression Solution, Single-Cell V(D)J Solution, and Single Cell ATAC Solution, but not for the Linked Read Solution or Single Cell CNV Solution. 10X Supp. Sub. at 11.

Also subject to this investigation is the Chip GB, which 10X uses in its own business to prepare and manufacture gel beads. Final ID at 31–32 (citing CX-0408C at 0007, 0011; Tr. at 521:10–15, 1155:18–22, 1204:7–10; RPX-0022C; RPX-0023C). These gel beads are sold to customers as part of a kit and used in the gel bead wells of the GEM Chips as a reagent in sample preparation. Final ID at 32 (citing CX-0408C at 0007, 0011; Tr. at 1155:18–22, 1204:7–10). As noted above, these Chip GB products have been found non-infringing.

Finally, on the issue of contributory infringement, there are two products that 10X asserts can be used with the GEM Chip to create a substantial non-infringing use for the GEM Chip: (1) the Chip PB System and (2) the System NH.[13] Final ID at 32–33; RDX-0004C.0006; Tr. at 1155:25–1156:11. These designs are modifications to the Chromium system. Final ID at 32–33; RDX-0004C.0006, -0059, -0062; Tr. at 1155:25–1156:11. 10X argues that the use of the Chip PB System [ ] required by the asserted claims of the '635 patent. *See* 10X Post-Hrg. Br. at 78–80. Similarly, 10X argues that the use of the System

[13] [ ] ID at 32. [ ] *Id.* The final ID refers to the Chip PB System and the System NH collectively as the "Alleged Design Arounds." *Id.* at 33.

NH with the GEM Chip [ ] required by the asserted claims of the '682 patent. *See id.* at 73–75; Final ID at 33; RDX-0004C.0006; Tr. at 1155:25–1156:11. The ID concludes that these designs are not themselves accused products, but instead are considered for whether they provide substantial non-infringing uses that may negate a finding of contributory infringement of the '682 and '635 patents. Final ID at 33; *also id.* at 135–38 (discussing only the System NH).

The asserted claims are directed to either the chips themselves (the '160 and '664 patents) or to the combination of the chip and other components of a system (the '682 and '635 patents).

2. The Domestic Industry Products

The domestic industry products include: (1) Bio-Rad's DG8 Chip used with its QX100 and QX200 instruments; and (2) Bio-Rad's DG32 Chip, which consists of 4 DG8 Chips in a holder, and is used with the Bio-Rad AutoDG instrument. Final ID at 33–34; Compls. Post-Hrg. Br. at 7.

II. ISSUES UNDER REVIEW

A. Whether 10X Indirectly Infringes the '682 and '635 Patents

Complainants assert a violation of section 337 by 10X for the '682 and '635 patents based on indirect infringement. *See* Final ID at 87, 98, 116. The asserted claims of those patents recite a "system" for generating droplets using a certain claimed device for applying pressure. Under Complainants' theory, when the GEM chips are combined with Chromium Controllers by 10X's customers, the combination reads directly onto the claims of the '682 and '635 patents, and 10X induces and contributes to that infringement by importing and selling the GEM Chips. *E.g.*, Compls. Post-Hrg. Br. at 21, 27, 29–31. The Commission determined to review the final ID's findings related to indirect infringement of the '682 and '635 patents. 83

Fed. Reg. at 63673. On review, the Commission affirms, with modifications, the final ID's conclusion that 10X indirectly infringes those patents. The Commission adopts the findings and conclusions in the final ID except as noted below.

1. Knowledge of the '682 and '635 Patents Prior to Their Issuance

The Commission does not adopt the final ID to the extent that it finds that 10X had knowledge of the '682 and '635 patents prior to their issuance. *See* Final ID at 119. However, the final ID correctly finds that both the direct and circumstantial evidence admitted into the record establish that 10X had knowledge of the '682 and '635 patents at least by the filing of the complaint on July 31, 2017. *See id.* at 117–19.

2. Relevance of Absence of Advice from Counsel to Indirect Infringement

The Commission does not adopt and takes no position on the final ID's finding concerning 10X's failure to present evidence of obtaining advice of counsel as to indirect infringement. *See* Final ID at 127–28. The final ID's undisturbed findings of fact support a determination that 10X had the requisite mental state for both induced and contributory infringement, regardless of whether the absence of advice from counsel was considered. *See id.* at 117–28.

3. Finding of Waiver of 10X's Argument the Asserted Claims of the '682 and '685 Patents are Not Directly Infringed

The Commission does not adopt the final ID's finding that 10X waived its argument that the asserted claims of the '682 and '635 patents are not directly infringed. *See* Final ID at 87, 90, 92, 95, 96, 100, 101, 104–113.

4. Contributory Infringement and 10X's Chip PB System

The final ID does not address one of 10X's arguments that the GEM Chip has a substantial non-infringing use that precludes liability for contributory infringement. *See* 10X

Post-Hrg. Br. at 78–80. According to 10X's argument, when the GEM Chip is used with the Chip PB System, that system [ ] required by the asserted claims of the '635 patent, and the use of the GEM Chip with the Chip PB is a substantial non-infringing use. *See id.* However, the final ID properly finds 10X's similar arguments for the System NH unpersuasive. *See* Final ID at 135–36. For example, the final ID finds that the use of the GEM Chips with the System NH cannot be a "substantial non-infringing use" because the System NH is a hypothetical system that is not yet available to 10X's customers. *Id.* The Commission has determined that 10X's argument regarding the Chip PB System is unpersuasive for the same reasons. *See Certain Network Devices, Related Software & Components Thereof(II),* Inv. No. 337-TA-945, Comm'n Op., 2017 WL 3614521, at *11 (June 1, 2017) ("To determine whether a use is substantial, an ALJ may evaluate 'the use's frequency. . . .'" (quoting *i4i Ltd. P'ship v. Microsoft Corp.*, 598 F.3d 831, 851 (Fed. Cir. 2010))); Final ID at 135–36. Like the System NH, the record shows that the Chip PB System is merely hypothetical. 10X has failed to provide any evidence that the Chip PB System has been actually used anywhere or is available to customers. Tr. at 984:1–2 ("Q. And *could you* implement that if you wished to? A. Yes." (emphasis added)); *see also* final ID at 135 (discussing the System NH). 10X's petition acknowledges that the Chip PB System has not yet been implemented—"With respect to actual use, 10X *is prepared to implement* [the Chip PB System] to replace the current system." 10X Pet. at 85 (emphasis added). Accordingly, 10X's argument regarding the Chip PB System fails for the same reasons as its argument concerning the System NH.

B. Whether 10X's Chip GB Infringes Claims 1 and 14 of the '664 Patent

The Commission determined to review the final ID's finding that 10X's Chip GB does not infringe claims 1 and 14 of the '664 patent. 83 *Fed. Reg.* at 63673. On review, the

Commission affirms the ID's conclusion and adopts the ID, except for the reasoning found in the first full paragraph on page 84 of the final ID.

C. Whether 10X's Next GEM Chip Infringes Claim 20 of the '160 Patent and Claim 1 of the '664 Patent

The Commission determined to review the final ID's finding that 10X's Next GEM Chip does not infringe claims 20 of the '160 patent and claim 1 of the '664 patent. 83 *Fed. Reg.* at 63673. On review, the Commission adopts the final ID and supplements it with the following additional reasoning.

Complainants theorize that, without changing any structure, but simply altering the placement of the fluids in the chip from their intended locations, that the chips can be used to generate emulsions in a way that literally infringes the claims. The Commission finds that Complainants have failed to meet their burden of proof. For example, the claims require the ability to form droplets, (*e.g.*, *Markman Order*, App, A, Chart No. 1 at 12), and Complainants have not shown that this claim limitation is met. The hypothetical misuse that Dr. Anna, Complainants' expert witness, proposed is contrary to the product's design. *See* Tr. at 1155:5–24; RDX-0004C.0040–.0044; JX-0083C; CX-0403. Moreover, the evidence shows that chip design is important for droplet generation—Dr. Gale, Complainants' expert, testified that a "network of wells in combination with a cross-shaped or cruciform channel junction" is not sufficient to generate droplets. Tr. at 455:23–456:1. Droplet generation depends on, for example, precise channel dimensions and pressure. Tr. at 454:18–23, 693:17–22. Complainants have failed to establish that the channel dimensions are capable of generating droplets under their theory of infringement.

Complainants cite the testimony of 10X's expert, Dr. Santiago, to allege that droplets would be formed, albeit, as Complainants concede, only after experimentation. Compls. Post-

Hrg. Br. at 11, 21–22 (citing Tr. at 1244:8–1245:1). However, Dr. Santiago testified only that it may be *theoretically* possible to generate droplets. Tr. at 1244:21–1245:1. Thus, given that the precise design parameters of a chip contribute to droplet generation, that the Next GEM Chip was designed for a purpose other than droplet generation at a channel junction, and that Complainants rely solely on a hypothetical misuse of the Next GEM Chip, Complainants have not met their burden of showing that the Next GEM Chip directly infringes claim 20 of the '160 patent or claim 1 of the '664 patent.

Lastly, Complainants argued for the first time in their reply post-hearing brief, without citing any evidence, that the Next GEM Chip was not imported and is not able to be adjudicated at this time. Compls. Post-Hrg. Br. (Reply) at 14–15. This followed extensive arguments in their opening brief that the Next GEM Chip is infringing. Compls. Post-Hrg. Br. at 11–14, 16–17, 21–24, 26, 28–29. The Commission finds that Complainants waived their argument by not presenting it in their opening brief. *See* ALJ's Ground Rule 10.1. Regardless, Complainants' argument is without merit. Record evidence supports the final ID's finding that the Next GEM Chip had been imported and was made available to Complainants to analyze. Tr. at 973:20–974:3, 974:10–25, 975:18–976:10, 978:4–979:24, 562:16–25, 679:11–680:21; RX-1550C; RX-1197C; RX-0261C. Moreover, it appears, based on Complainants' infringement allegations, that no additional discovery was needed. *See* Compls. Post-Hrg. Br. at 11–14, 16–17, 21–24, 26, 28–29; Compls. Pet. at 23–25. Furthermore, a critical design feature, droplet generation over a step or edge, was fixed. Tr. at 974:4–25. Although the imported prototypes of Next GEM Chip were not final commercial products, the step emulsification design was sufficiently fixed such that an infringement determination could be made. *See, e.g.*, *Certain Multiple Mode Outdoor Grills and Parts Thereof*, Inv. No. 337-TA-895, Comm'n Op. at 16–17 (finding

redesigned products to be properly at issue where the design was sufficiently fixed to make an infringement determination).

D. Conclusion

Based on the preceding discussion, the Commission finds that Complainants have demonstrated a section 337 violation by 10X's imported GEM Chips that infringe the asserted claims of the '664, '682, and '635 patents. The Commission further finds that Complainants have not demonstrated a section 337 violation as to the Chip GB or Next GEM Chip.

III. REMEDY AND THE PUBLIC INTEREST

A. REMEDY

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. U.S. Int'l Trade Comm'n*, 787 F.2d 544, 548 (Fed. Cir. 1986). The Commission may issue an LEO excluding the goods of the person(s) found in violation, or, if certain criteria are met, a general exclusion order against all infringing goods regardless of the source.

Section 337 provides that in addition to, or in lieu of, the issuance of an exclusion order, the Commission may issue a CDO as a remedy for violation of section 337. *See* 19 U.S.C. § 1337(f)(1). CDOs are generally issued when, with respect to the imported infringing products, respondents maintain commercially significant inventories in the United States or have significant domestic operations that could undercut the remedy provided by an exclusion

order.[14] *See, e.g., Certain Table Saws Incorporating Active Injury Mitigation Technology & Components Thereof* ("*Table Saws*"), Inv. No. 337-TA-965, Comm'n Op. at 4–6 (Feb. 1, 2017); *Certain Protective Cases & Components Thereof, Inv.* No. 337-TA-780, USITC Pub. No. 4405, Comm'n Op. at 28 (Nov. 19, 2012) (citing *Certain Laser Bar Code Scanners & Scan Engines, Components Thereof & Prods. Containing Same*, Inv. No. 337-TA-551, Comm'n Op. at 22 (June 24, 2007)). Complainants bear the burden on this issue. "A complainant seeking a cease and desist order must demonstrate, based on the record, that this remedy is necessary to address the violation found in the investigation so as to not undercut the relief provided by the exclusion order." *Table Saws*, Comm'n Op. at 5 (citing *Certain Integrated Repeaters, Switches, Transceivers, & Prods. Containing Same*, Inv. No. 337-TA-435, USITC Pub. No. 3547 (Oct. 2002), Comm'n Op. at 27 (Aug. 16, 2002); *see also* H.R. REP. No. 100-40, at 160 (1987)).

1. The Scope of the Commission Record on Remedy and the Public Interest

To ensure the completeness of the Commission record on public interest, the Commission notified third parties who had previously authored public interest comments of the Commission's June 2019 notice seeking further public interest briefing. In that regard, counsel for the Commission notified those researchers and certain government agencies of the notice. In their reply supplemental submission, Complainants allege that these notifications were

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[14] When the presence of infringing domestic inventory or domestic operations is asserted as the basis for a CDO under section 337(f)(1), Commissioner Schmidtlein does not adopt the view that the inventory or domestic operations needs to be "commercially significant" in order to issue the CDO. *See, e.g., Certain Magnetic Tape Cartridges and Components Thereof*, Inv. No. 337-TA-1058, Comm'n Op. at 65, n.24 (Mar. 25, 2019); *Table Saws*, Comm'n Op. at 6–7, n.2. In Commissioner Schmidtlein's view, the presence of some infringing domestic inventory or domestic operations, regardless of its commercial significance, provides a basis to issue a CDO. *Table Saws*, Comm'n Op. at 6–7, n.2.

Footnote continued on following page.

prohibited ex parte communications. Compls. Supp. Sub. (Reply) at 4, n.2 (citing 5 U.S.C. § 557(d)(1)(B)). Complainants request that the Commission place those communications on the public record and not consider the submissions received from contacted persons and government agencies after the communications occurred. *Id.* In the interest of transparency, the Commission has placed the communications on EDIS.[15] The Commission has determined to consider the NICHD Submission in accordance with its statutory consultation authority. *See* 19 U.S.C. § 1337(b)(2) (authorizing consultation with the Department of Health and Human Services[16]); *id.* § 1334 (same). Out of an abundance of caution, the Commission has chosen not to rely on the June and July 2019 Bielas, Carpten, Kuo, Lusis, and Gibson submissions[17] in its

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[15] The communications are as follows: Email to Wolinetz, Jorgensen, Science Policy NIH (EDIS Doc. No. 698759); Email to Glavez and Li (EDIS Doc. No. 698760); Email to Snyder EDIS Doc. No. 698762); Email to NIAID NIH EDIS Doc. No. 698763); Email to Kuo (EDIS Doc. No. 698764); Email to Sebra (EDIS Doc. No. 698765); Email to Gibson (EDIS Doc. No. 698766); Email to NICHD NIH (EDIS Doc. No. 698767); Email to Robinson NIH (EDIS Doc. No. 698768); Email to Pe'er (EDIS Doc. No. 698769); Email to Lusis (EDIS Doc. Nos. 698770 (public), 697771 (confidential)); Email to Bielas (EDIS Doc. Nos. 698772 (public), 698774 (confidential)); Email to Guerrero (EDIS Doc. No. 698773); Email to Dr. Kean (EDIS Doc. No. 698776); Email to Dr. Carpten (EDIS Doc. No. 698777); Email to Dr. Weissman (EDIS Doc. No. 698778); Email to Dr. Liu (EDIS Doc. No. 698779)

[16] As one of the National Institutes of Health, the NICHD is part of the Department of Health and Human Services.

[17] As stated above, those submissions are Letter from Dr. Jason Bielas, Fred Hutchinson Cancer Research Center (July 2, 2019) (EDIS Doc. Nos. 679921, 679922); Letter from Dr. John Carpten, University of Southern California (July 1, 2019) (EDIS Doc. Nos. 679867, 679865); Letter from Dr. Calvin Kuo, Stanford University (July 1, 2019) (EDIS Doc. Nos. 679799, 679797); Letter from Dr. Aldons Lusis, University of California, Los Angeles (July 1, 2019) (EDIS Doc. No. 679796); and Letter from Dr. Gregory Gibson, Georgia Institute of Technology (June 29, 2019) (EDIS Doc. No. 679778). The Commission has considered the letters authored by Drs. Bielas, Carpten, Kuo, Lusis, and Gibson submitted by 10X in its Respondent 10X Genomics, Inc.'s Response to Written Submissions Pursuant to Commission's December 4, 2018 Notice.

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final determination on remedy and the public interest. As elaborated below, the Commission finds that there is compelling and persuasive evidence on the record, outside of the June and July 2019 Bielas, Carpten, Kuo, Lusis, and Gibson submissions, that the potential effect of the remedial orders on the public health and welfare requires tailoring the remedies in this investigation to exempt imports of infringing microfluidic devices for certain research from the remedies, as set forth below.[18] Further, even if the June and July 2019 Bielas, Carpten, Kuo, Lusis, and Gibson submissions were considered by the Commission, it would not result in the denial of any Commission relief in this investigation.[19]

2. Limited Exclusion Order

The Commission has determined that the appropriate remedy is an LEO that bars the importation of infringing GEM Chips, subject to an exemption for continued importation for existing research projects with a documented need to ameliorate significant public interest concerns discussed below. The LEO exempts from its scope the importation of certain microfluidic devices for use by researchers who have been using such devices in the United States as of the date of the issuance of the LEO, and who have provided 10X a documented need to continue receiving the devices for an identified current ongoing research project for which that need cannot be met by any alternative product, including the Next GEM Chip.[20] Customs and Border Protection has declared that such an exemption is administrable.

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[18] Evidence outside of those submissions, as discussed below, indicates the problems inherent in using other products in place of the infringing chips for existing research projects.

[19] As discussed below, evidence outside of those submissions concerns the availability of substitute products that can be used in place of the infringing chips for new research projects.

[20] As also explained in Section III.B below, attached to the LEO and CDO issued today is a questionnaire to be provided to and completed by 10X customers that seek to use the

Footnote continued on following page.

10X requested that any LEO include a standard certification provision. *See* RD at 32. OUII did not object to that provision, and Complainants chose not to address this issue. *Id.* The Commission finds that this certification is appropriate under the facts described in the RD. In addition to certification according to the standard provision, 10X may certify that the microfluidic devices are being imported for use by researchers who have been using such devices in the United States as of the date of the issuance of the LEO, and who have provided 10X a documented need to continue receiving the devices for an identified current ongoing research project for which that need cannot be met by any alternative product, including the Next GEM Chip.

10X requested that the LEO explicitly pertain only to the model numbers of the articles, microfluidic chips, found to infringe. *See* RD at 31. The Commission rejects that request as contrary to Commission practice. *See, e.g., Hardware Logic Emulation Sys. & Components Thereof*, Inv. No. 337-TA-383, Comm'n Op., at 22–23 (Dec. 10, 1997); *see also* RD at 32.

10X also requested that any exclusion order specifically exempt from its scope "the Chip SE and any chips using step emulsifications that 10X develops in the future." 10X Br. at 25:

> exemption. 10X 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. That questionnaire is required to be maintained by 10X and to be available for inspection pursuant to the terms of the CDO and LEO. *See* CDO, ¶ VI. Researchers who wish to benefit from this exemption are required to maintain records to support their responses in the questionnaire in case an audit is carried out or such records are required for any future enforcement proceeding. These supporting records are not to be provided to 10X. Researchers who wish to benefit from this exemption are further required to acknowledge in the questionnaire 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.

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see also 10X Br. (Reply) at 35–36. Consistent with Commission practice, the LEO exempts from its scope the Chip SE (also called the Next GEM Chip) and the Chip GB because those products were adjudicated and found to be non-infringing. *See Certain Robotic Vacuum Cleaning Devices & Components Thereof such as Spare Parts*, Inv. No. 337-TA-1057, Comm'n Op. at 55–56 (Nov. 30, 2018) ("*Robotic Vacuum Cleaning Devices*").[21]

3. Cease and Desist Order

The Commission has determined to issue a tailored CDO directed to 10X's U.S. activities related to the infringing GEM Chips. The RD found, and 10X does not dispute, that it maintains a commercially significant inventory of the GEM Chips.[22] RD at 41–42. To ensure that sale of this inventory is not used to undercut the relief provided by the exclusion order, we find that a CDO directed to 10X's U.S. activities relating to the infringing GEM Chips is appropriate.

10X asserted that the CDO should not apply to the Next GEM Chip and the Chip GB because those products were found to be non-infringing. 10X Br. (Reply) at 35–36. The Commission agrees; an exemption for products found to be non-infringing is consistent with Commission practice. *See Robotic Vacuum Cleaning Devices*, Comm'n Op. at 55–56. Further, like the LEO discussed above, the CDO exempts from its scope the importation of certain

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[21] To the extent 10X seeks to import new models of chips in the future, it can obtain a determination as to whether the new product is within the scope of the remedial orders under the Commission's procedures for advisory opinion and modification proceedings under Commission Rule 210.76 and 210.79. 10X may also consider requesting a ruling from U.S. Customs and Border Protection pursuant to 19 C.F.R. Part 177.

[22] Commissioner Schmidtlein supports issuance of the CDO in this investigation for reasons similar to those offered by her in previous investigations. Specifically, she finds that the presence of some infringing domestic inventory, regardless of the commercial significance, provides a basis to issue the CDO.

microfluidic devices for use by researchers who have been using such devices in the United States as of the date of the issuance of the CDO, and who have provided 10X a documented need to continue receiving the devices for an identified current ongoing research project for which that need cannot be met by any alternative product, including the Next GEM Chip.

B. The Public Interest

Section 337 requires the Commission, upon finding a violation of section 337, to issue an LEO "unless, after considering the effect of such exclusion upon the public health and welfare, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, and United States consumers, it finds that such articles should not be excluded from entry." 19 U.S.C. § 1337(d)(1). Similarly, the Commission must consider these public interest factors before issuing a CDO. 19 U.S.C. § 1337(f)(1).

Under appropriate facts and circumstances, the Commission may determine that no remedy should issue because of the adverse impacts on the public interest.[23] Moreover, when the circumstances of a particular investigation require, the Commission has tailored its relief in light of the statutory public interest factors. For example, the Commission has exempted service parts, grandfathered certain infringing products, and delayed the imposition of remedies to allow affected third party consumers to transition to non-infringing products. *E.g.*, *Certain Road Milling Machines & Components Thereof*, Inv. No. 337-TA-1067, Comm'n Op. at 32–33

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[23] The investigations in which the Commission denied remedies based upon the public interest are: *Certain Fluidized Supporting Apparatus and Components*, Inv. No. 337-TA-182/188 (Oct. 1984) (declining relief because the accused beds were sold, rented and leased to hospitals for the treatment of burn patients) ("*Fluidized Supporting Apparatus*"); *Certain Inclined Field Acceleration Tubes*, Inv. No. 337-TA-67 (Dec. 1980) (declining relief because of likely effects on important scientific research) ("*Acceleration Tubes*"); and *Certain Automatic Crankpin Grinders*, Inv. No. 337-TA-60 (Dec. 1979) (declining relief due to countervailing national energy policies) ("*Crankpin Grinders*").

(July 18, 2019) (exempting service parts) ("*Road Milling Machines*"); *Certain Baseband Processor Chips & Chipsets, Transmitter, & Receiver (Radio) Chips, Power Control Chips, & Prods. Containing Same, Including Cellular Tel. Handsets*, 337-TA-543, USITC Pub. No. 4258, Comm'n Op. at 150–51 (Oct. 2011) (grandfathering certain products) ("*Baseband Processor Chips*"); *Certain Personal Data & Mobile Comm'n Devices & Related Software*, 337-TA-710, USITC Pub. No. 4331, Comm'n Op., at 72–73, 80–81 (June 2012) (delaying imposition of remedy) ("*Personal Data & Mobile Comm'n Devices*").

The statute does not place the burden on any party to an investigation of proving that a public interest concern precludes a remedy or requires tailoring of a remedy.[24] Indeed, the statute requires the Commission to consider and make findings on the public interest in every case in which a violation is found regardless of the quality or quantity of public interest information supplied by the parties. 19 U.S.C. § 1337(d)(1), (f)(1).[25] Thus the Commission publishes a notice inviting the parties as well as interested members of the public and interested government agencies to gather and present evidence on the public interest at multiple junctures in the proceeding. 19 U.S.C. § 1337(d)(1), (f)(1). Where, as here, information has been submitted at the outset of the investigation indicating that there may be serious public interest concerns, the Commission has delegated the issue to the ALJ pursuant to Rule 210.50(b)(1) for the development of a fulsome evidentiary record on the public interest, especially direct

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[24] The RD incorrectly places the burden on the respondent. *See, e.g.*, RD at 4.

[25] The Commission has a statutory duty to consider the public interest. *See, e.g.*, 19 U.S.C. § 1337 (d)(1), (f)(1); *see also* S. REP. No. 93-1298, at 197 ("The Committee believes that the public health and welfare and the assurance of competitive conditions in the United States economy must be the overriding considerations in the administration of this statute.").

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evidence from the third parties in the United States that are likely to be impacted. The parties, however, did not offer into the evidentiary record before the ALJ any information or evidence from any third party, such as researchers, medical schools or universities, cancer research institutes, and the like pertaining to the potential effect of remedial orders on their scientific and medical research.[26] On a record lacking this third party evidence, the ALJ recommended that the Commission issue both an LEO and CDO, without delay or modification to accommodate any public interest concern. *See, e.g.,* RD at 4, 5 n.4.

After considering the public interest evidence and arguments, as required by section 337, the Commission has concluded that the potential effect of the remedial orders on the public health and welfare requires that the Commission tailor its remedy to allow continued importation and use of the infringing GEM Chips by researchers who have been using such devices in the United States as of the date of the issuance of the remedial orders, and who have

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[26] The Commission's notice of investigation required the parties to develop the evidentiary record before the ALJ to include public interest evidence and information from potentially impacted third parties. *See* 82 *Fed. Reg.* at 42115 (requiring the ALJ to "take *evidence or other information and hear arguments from* the parties and *other interested persons with respect to the public interest* in this investigation ....") (emphasis added). The Commission considers the development of the evidentiary record on the public interest pursuant to delegation under Rule 210.50(b)(1) as a serious matter. To develop a robust record on the public interest, Rule 210.50(b)(1) recognizes that testing information and evidence, including from third parties, within the adversarial process conducted by the ALJ ensures reliable findings of fact, within a fair proceeding governed by the APA, with its attendant due process protections. Accordingly, although the Commission is required to consider the public interest before issuing a remedy in every case in which it finds a violation, where public interest is delegated to the ALJ, it is important, even if not technically required, that all parties to the proceeding—complainant, respondent, and OUII—seek factual information and statements from knowledgeable sources, including interested third parties, during fact discovery, and present this information and evidence subject to cross-examination and rebuttal at the hearing so that the ALJ's RD will provide a complete and reliable factual record on the statutory public interest considerations.

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provided 10X a documented need to continue receiving the devices for an identified current ongoing research project for which that need cannot be met by any alternative product, including the Next GEM Chip.

1. Public Health and Welfare

Basic scientific research is "precisely the kind of activity intended by Congress to be included when it required the Commission to consider the effect of a remedy on the public health and welfare." *Acceleration Tubes*, Comm'n Op. at 22. Here, the evidence indicates that 10X's technology is used in certain medical and scientific research. *E.g.*, 10X Br. (Reply), Ex. 8, at 11–15. Specifically, the evidence presented to the Commission establishes that 10X's Chromium technology platform enables the following research:[27]

1. Development of "single-cell approaches to study development, immunology and cancer, with a focus on tumor-immune interactions and the spread of cancer." 10X Br. (Reply), Ex. 7, Ex. A, at 1.[28]

2. "[P]rofiling of primary human blood cells" for "studying the genetic basis of autoimmune disease and of cancer immunotherapy." *Id.* at Ex. 7, Ex. B, at 1.[29]

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[27] The evidence discussed here was provided to the Commission in connection with: (1) Exhibit 7 (Wu Declaration) of Respondent 10X Genomics, Inc.'s Response to Written Submissions Pursuant to Commission's December 4, 2018 Notice, which includes correspondences from several researchers attached as Exhibits A–M to the Wu Declaration; (2) Exhibit 2 of Respondent 10X Genomics, Inc.'s Written Submission Pursuant to Commission's June 10, 2019 Notice, which is another declaration of Randy Wu, which includes questionnaire responses from several researchers, attached as Exhibits B–F to the declaration; and (3) the NICHD Submission.

[28] Exhibit A, cited herein as "Pe'er Letter," is a submission from Dr. Dana Pe'er, Chair of the Computational and Systems Biology Program at Memorial Sloan Kettering Cancer Center.

[29] Exhibit B, cited herein as "Gibson Letter," is a submission from Dr. Greg Gibson, a cancer researcher and Professor and Director at the Center for Integrative Genomics at the Georgia Institute of Technology.

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3. "[D]etermin[ing] how heterogeneous populations of tumor cells may lead to previously identified molecular subtypes of pancreatic cancer which dictate response to therapy." *Id.* at Ex. 7, Ex. C, at 1.[30]

4. "[A]pplying genomics, transcriptomics, and other systems-wide analysis to establish new and effective treatment for pediatric patients" for ailments such as inflammatory bowel disease and graft-versus host disease, the "deadliest complication associated with [pediatric] bone marrow transplants." *Id.* at Ex. 7, Ex. D, at 1.[31]

5. "Interrogat[ing] the genomes, epigenomes and transcriptomes of tumors to identify targetable events for select therapeutics that might be specific to small populations of cells within a tumor or cancer." *Id.* at Ex. 7, Ex. E, at 1[32]; *see also* 10X Supp. Sub., Ex. 2, Ex. E, at 1 (Carpten Questionnaire).

6. "[E]xploring how cells ensure that proteins fold into their correct shape, as well as the role of protein misfolding in disease and normal physiology." 10X Br. (Reply), Ex. 7, Ex. F, at 1.[33]

7. "[E]lucidat[ing] the fundamental and clinical implications of nuclear and mitochondrial DNA mutations in the pathogenesis of cancer and age-related disease." *Id.* at Ex. 7, Ex. G, at 1[34]; *see also* 10X Supp. Sub., Ex. 2, Ex. F, at 1 (Bielas Questionnaire).

8. "[A]pplying genomics, transcriptomics, and other systems-wide analysis to analyze stem cell biology and cancer therapeutics," research that has the "potential to generate stem cells that can be transplanted for treatment of diseases such as inflammatory bowel

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[30] Exhibit C, cited herein as "Guerrero Letter," is a submission from Dr. Paola A. Guerrero, a scientific manager at The University of Texas MD Anderson Cancer Center.

[31] Exhibit D, cited herein as "Kean Letter," is a submission from Dr. Leslie S. Kean, who is a cancer researcher and professor at Harvard Medical School.

[32] Exhibit E, cited herein as "Carpten Letter," is a submission from Dr. John D. Carpten, Professor and Chair at the Keck School of Medicine at the University of Southern California.

[33] Exhibit F, cited herein as "Weissman Letter," is a submission from Dr. Weissman, who is a genomics researcher and professor at the University of California San Francisco Cellular Molecular Pharmacology UCSF School of Medicine.

[34] Exhibit G, cited herein as "Bielas Letter," is a submission from Dr. Jason H. Bielas, a Full Member in the Translational Research Program at Fred Hutchinson Cancer Research Center.

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disease or cystic fibrosis." 10X Br. (Reply), Ex. 7, Ex. H, at 1[35]; *see also* 10X Supp. Sub., Ex. 2, Ex. B, at 1 (Kuo Questionnaire).

9. "[I]nvestigat[ing] the tumor microenvironment changes under different steroid application conditions," and "generat[ing] useful insights" in "cancer and immune cells." 10X Br. (Reply), Ex. 7, Ex. I, at 1.[36]

10. "[C]onducting multiple studies that are leading to new discoveries about cancer and providing us with candidate[s] for new types of treatments for patients." *Id.* at Ex. 7, Ex. J, at 1.[37]

11. "[U]nderstanding how genes are regulated" in order to "uncover the underlying dysfunction in human disease." *Id.* at Ex. 7, Ex. K, at 1.[38]

12. "[U]nderstand[ing], among other things, tumor heterogeneity in a variety of different cancer types and embryonic development at a single cell resolution." *Id.* at Ex. 7, Ex. L, at 1.[39]

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[35] Exhibit H, cited herein as "Kuo Letter," is a submission from Dr. Calvin Kuo, the Maureen Lyles D'Ambrogio, Professor of Medicine and Vice Chair of the Department of Medicine at the Stanford University School of Medicine.

[36] Exhibit I, cited herein as "Liu Letter," is a submission from Dr. Xiaole Shirley Liu, Professor of Biostatistics at the Harvard School of Public Health and Co-Director of the Center for Functional Cancer Epigenetics at the Dana-Farber Cancer Institute.

[37] Exhibit J, cited herein as "Ji Letter," is a submission from Dr. Hanlee P. Ji, an Associate Professor at Stanford University who leads a biomedical research team.

[38] Exhibit K, cited herein as "Snyder Letter," is a submission from Dr. Michael Snyder, the Stanford B. Ascherman Professor and Chair of Genetics and Director of Genomics and Personalized Medicine at Stanford University School of Medicine.

[39] Exhibit L, cited herein as "Sebra Letter," is a submission from Dr. Robert P. Sebra, Associate Professor at the Icahn School of Medicine at Mt. Sinai and Director of Technology Development and the Genomics Core Facility for the Icahn Institute for Data Science and Genomic Technology.

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13. "[S]tudy[ing] the genetic basis of cardiovascular and metabolic diseases in human populations and in experimental models." *Id.* at Ex. 7, Ex. M, at 1.[40]

14. "[U]nderstanding mechanisms underlying nonalcoholic fatty liver disease and atherosclerosis." 10X Supp. Sub., Ex. 2, Ex. C, at 1 (Lusis Questionnaire).

15. "[A]dvanc[ing] our understanding of gene expression in individual brain cells" and performing "research and studies on biomarkers for pregnancy complications." NICHD Submission, at 1–2.

Much of the research identified above relates to cancer. According to the Centers for Disease Control and Prevention ("CDC"), cancer is the second leading cause of death in the United States.[41] Moreover, some of the research relates to cardiovascular disease research, 10X Br. (Reply), Ex. 7, Ex. M, at 1 (Lusis Letter), and according to the CDC, heart disease is the leading cause of death in the United States.[42] We also note that some of the above-identified research is funded by the government. *See Acceleration Tubes*, Comm'n Op. at 23–25 (considering government support for nuclear structure physics in determining the importance of a public interest). For example, the NICHD uses its resources to perform medical research using 10X's Chromium system and also funds extramural research that uses 10X technology. NICHD Submission, at 1–2. Furthermore, many researchers have declared that they have received government grants for 10X system-enabled research and that 10X's platform is needed

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[40] Exhibit M, cited herein as "Lusis Letter," is a submission from Dr. Aldons Luis, Professor of Human Genetics and Medicine at the University of California, Los Angeles.

[41] *See* Leading Causes of Death, Centers for Disease Control and Prevention, https://www.cdc.gov/nchs/fastats/leading-causes-of-death.htm (last visited Sept. 12, 2019); *see also* Cancer Statistics, National Cancer Institute, https://www.cancer.gov/about-cancer/understanding/statistics (last visited Sept. 12, 2019).

[42] *Id.*

Footnote continued on following page.

for their research.[43] While Complainants and 10X dispute the exact amount of federal funding provided for 10X platform-enabled research, it is undisputed that some such research is funded by the government. *See* Compls. Supp. Sub. (Reply) at 19–20.

a. Availability of Alternative Products for New Studies

10X has repeatedly represented that its non-infringing Next GEM Chip can replace the infringing GEM Chips. *E.g.*, 10X Post-Hrg. Br. at 37, 43. 10X does not dispute that the Next GEM Chip is designed for use with existing instruments and existing reagents. *See* 10X Br. (Reply) at 33–35; *see also* CX-616C at 278:9–17. 10X's project lead on Next GEM Chip development, Dr. Hindson,[44] testified that the Next GEM Chip "can get equivalent performance" when compared to the infringing GEM Chips. Tr. at 977:2–4. Dr. Hindson further elaborated that, with the Next GEM Chip, "[w]e get the equivalent data. When you look at the key metrics, they basically overlay right on top of one another." *Id.* at 977:6–8. 10X has indicated that the Next GEM Chip has been available since May 2019 for most applications for which the GEM Chips are available, and 10X currently has the production capacity to "onboard[ ] new customers with the Next GEM [C]hip, and is beginning to sell the Next GEM [C]hip to existing customers who will use the Next GEM [C]hip to begin a new series of

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[43] *See e.g.*, 10X Br. (Reply), Ex. 7, Ex. A, at 1–2 (Pe'er Letter) (declaring that "[d]ata collected with the 10X Genomics platform served as preliminary data" for a $13.4 million grant from the National Cancer Institute, and losing access to 10X's platform would be "catastrophic" to that ongoing research); *id.* at Ex. 7., Ex. K, at 1 (Snyder Letter) (declaring that 10X's "platform is essential for our $13 M NIH[43]-sponsored PreCancer Atlas grant"); Beckman Submission, at 1; 10X Supp. Sub., Ex. 2, Ex. B, at 1 (Kuo Questionnaire); *id.* at Ex. 2, Ex. C, at 1 (Lusis Questionnaire); *id.* at Ex. 2, Ex. D, at 1 (Beckman Questionnaire); *id.* at Ex. 2, Ex. F, at 1–2 (Bielas Questionnaire).

[44] Dr. Hindson is also an inventor on the asserted patents; he left Bio-Rad to co-found 10X. Tr. at 906:12–14.

experiments." 10X Supp. Sub. (Reply) at 5–6. Thus, 10X has an available redesign for the infringing GEM Chips that, for new research, customers who prefer or require use of the Chromium system may use.

10X argues that the Next GEM Chip is not an adequate substitute because it is not yet available for two of its products, the Single Cell CNV product and the Linked-Read product. 10X Supp. Sub. at 5–6, 14–15. However, these two products are [ ]. *See* 10X Supp. Sub., Ex. 3. For example, between December 1, 2018, and June 13, 2019, by quantity, Linked-Read products accounted for [ ], while the Single Cell CNV product accounted for [ ]. *See* 10X Supp. Sub., Ex. 3. There is evidence that 10X's Linked-Read product has not been adopted to a significant extent by researchers in the field of next generation sequencing. *See* Pachter Decl. ¶ 53 (July 15, 2019). Moreover, [ ]. *E.g.*, 10X Supp. Sub. (Reply) at 5–6. Importantly, the vast majority of information submitted by researchers in this investigation refer to the applications for which the Next GEM Chip is commercially available, in particular the Single Cell RNA-Seq, the Single Cell V(D)J, and the Single Cell ATAC products.[45] Given what the record shows in terms of adoption of these applications, it is reasonable to expect that new research will similarly focus on these applications, and for these applications, the Next GEM chip is now available. Since changing chips mid-study is not an

[45] *See, e.g.*, 10X Br. (Reply) at Ex. 7, Ex. C, at 1 (Guerrero Letter); *id.* at Ex. 7, Ex. D, at 1 (Kean Letter); *id.* at Ex. 7, Ex. E, at 1 (Carpten Letter); *id.* at Ex. 7, Ex. F, at 2 (Weissman Letter); *id.* at Ex. 7, Ex. H, at 1 (Kuo); *id.* at Ex. 7, Ex. I, at 1 (Liu Letter).

issue for new research projects, the concerns discussed below regarding use of Next GEM Chips in ongoing research is not present for new research studies.

The record also does not provide concrete evidence of likely new research projects that may require the use of infringing products for which the Next GEM Chip may not be available in the United States. As opposed to the specific information from researchers regarding ongoing research, statements on new research were more general and vague.

Also, evidence shows that there are other platforms that can be used instead of 10X's for at least some types of new research projects. *See, e.g.*, RD at 14–16; Pachter Decl. (June 24, 2019), Ex. 1, at Abstract ("We performed a multi-center study comparing 13 commonly used single-cell and single-nucleus RNA-seq protocols using a highly heterogeneous reference sample resource."); *id.* at Ex. 4, at 3 ("Each [Human Tumor Atlas Network Team] is using different single-cell technologies, but their end-goal is the same: to map the location of and understand the role of each type of cell in a tumor."); *id.* at Ex. 5, at 27 ("Most recently, innovations in DNA-based cellular barcoding using primer-coated microparticles have been combined with droplet microfluidics (Drop-Seq, InDrop) or nanowell arrays (Seq-Well, CytoSeq) to scale single-cell profiling to hundreds of thousands of cells at once.") (footnotes omitted)); *id.* at Ex. 18, at 15, Table 2; *id.* at Ex. 34.

In sum, the evidence does not support a finding that remedial orders covering GEM Chips for use in new studies would adversely affect the public health and welfare. 10X's Chromium system used with the redesigned Next GEM Chip and 10X's competitors' systems are alternatives to 10X's Chromium system used with the GEM Chips for new studies.

b. Inability to Switch from GEM Chips Mid-Study to Next GEM Chip or Alternative Sources

The information on the record from third party researchers who currently use the 10X Chromium system shows a consistent concern that switching technologies or platforms mid-study away from the 10X system would compromise their research results and disrupt important medical and genealogical studies. For example, as to the 10X system, Dr. Kean declared

> We have already invested >$1,500,000 in generating data on [our] first 51 patients. If I were forced to transition to another technology for this work, there is a good chance that this initial investment would be wasted. Finally, in the worst-case scenario in which I am forced to use a new product, I would need at least 12 months to transition my research to that new platform (if a suitable product existed), and would likely have to enroll many additional patients on-study, which would be a significant detriment to the goals of this work, which include rapid dissemination of our results to the patient community.

10X Br. (Reply) at Ex. 7, Ex. D, at 1–2 (Kean Letter).[46] In addition, the evidence indicates that researchers view reliable scientific results to require consistency across experimentation, particularly the use of a single platform or technology.[47]

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[46] *See also id.* at Ex. 7, Ex. C, at 1 (Guerrero Letter) (declaring, "[I]n the worst case scenario in which I am forced to use a new product, I would need months to transition my research to a new product."); *id.* at Ex. 7, Ex. E, at 1 (Carpten Letter) (declaring that he would "need months to transition my research to a new product"); *id.* at Ex. 7, Ex. F, at 1 (Weissman Letter) (declaring that switching to a "new single cell system . . . would do great harm to my research"); *id.* at Ex. 7, Ex. H, at 2 (Kuo Letter) (declaring that switching to a new technology would severely compromise his research efforts); *id.* at Ex. 7, Ex. K, at 1 (Snyder Letter); *id.* at Ex. 7, Ex, L, at 1 (Sebra Letter); 10X Supp. Sub. at Ex. 2, Ex. F, at 2 (Bielas Questionnaire); *id.* at Ex. 2, Ex. B, at 1–2 (Kuo Questionnaire); *id.* at Ex. 2, Ex. D, at 1 (Beckman Questionnaire); *id.* at Ex. 2, Ex. E, at 1–2 (Carpten Questionnaire).

[47] For example, Dr. Pe'er declared, "Even a new and greatly improved product would involve many months of setup, and switching technologies is completely incompatible with most ongoing projects. New technologies typically require substantial time investments to separate biological signal from technological [artifacts] and result in significant data loss at instantiation [sic]." *Id.* at Ex. 7, Ex. A, at 2 (Pe'er Letter); *see also* 10X Supp. Sub. at Ex. 2, Ex. F, at 2 (Bielas Questionnaire) ("[S]cientific rigor demands that consistency across

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As discussed above, use of 10X's system requires the use of 10X GEM or Next GEM Chips; chips of competitors' systems are not interchangeable with 10X chips. Thus, loss of access to 10X chips would mean that researchers lose access to the 10X platform, with the resultant impacts on ongoing research discussed above.

Although the Next GEM Chip is available for the applications of the 10X system most frequently cited by third party researchers as used in their ongoing research, the record evidence here supports the conclusion that the adverse effects generally associated with changing from the 10X Chromium system to a different technology or platform mid-study also extends to switching from the GEM Chip to the Next GEM Chip for ongoing research studies.

Dr. Michael Schnall-Levin, 10X's VP for Product, R&D and Strategy, testified that "performing an immediate switch over to the Next GEM [C]hip for all of 10X's customers would be highly disruptive to customers who are performing ongoing research projects using GEM Chips." *See* 10X Supp. Sub Ex. 1, at ¶ 12 (Schnall-Levin Decl.). Dr. Schnall-Levin identifies the disruptions from switching to the Next GEM Chips for ongoing research as resulting from the following: "(1) the loss of precious biological sample; (2) the loss of experimental consistency; and (3) the loss of research funds invested into prior experiments."

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experiments be maintained, if meaningful conclusions are to be drawn from the data."); *id.* at Ex. 2, Ex. C, at 1 ("We have already accumulated a great deal of data with 10x and it would be difficult to combine with a separate technology."). Dr. Pe'er adds:

> The immediate effect of an injunction [in the Delaware district court case] would be to bring great harm to dozens of ongoing projects at [Memorial Sloan Kettering Cancer Center] involving dozens of rare selected patient samples, millions of federal grant dollars, and many years of work by postdoctoral trainees. It would impede the budding careers of young scientists.

10X Br. (Reply), Ex. 7, Ex. A, at 2.

Id. Complainants do not dispute, rebut, or even address Dr. Schnall-Levin's specific assertions concerning the identified difficulties in switching from the GEM Chip to the Next GEM Chip. Compls. Supp. Sub. (Reply) at 21. Instead, Complainants aim their criticism at another statement in the declaration relating to switching *systems*, not *chips*, and even then their critique is limited to noting that "Dr. Schnall-Levin can only say that it is *possible* changing to a different system *can* compromise the ability to draw reliable conclusions." *Id.* (emphasis in original).

The NICHD Submission supports Dr. Schnall-Levin's testimony. In its submission, NICHD explains that various labs within NICHD use the Chromium system with the GEM Chips Types A, B and E. *See* NICHD Submission at 1. For example, the intramural NICHD Unit on Cellular and Molecular Development routinely uses the 10X Genomics Controller for both scRNAseq and scATACseq reactions on embryonic and mature neurons. These data are being used for analyzing multiple ongoing projects, which will ultimately result in publications on their findings. *Id.* at 2. This group also collaborates with NICHD's Section on Cellular and Synaptic Physiology and the National Institute on Mental Health to perform seRNAseq on various neuronal populations. The NICHD explains that "[a]ny disruption in obtaining GEM chips for carrying out these assays will be extremely problematic for current and future experiments (as well as ongoing and future collaborations)." *Id.* at 2. NICHD states: "Forcing U.S. scientists to pursue alternative avenues for single cell sequencing would create an undue burden on research efforts, requiring re-initiation of their research using a new platform and

potentially requiring recollection of samples, thus delaying research results and imposing additional costs." *Id.* at 1.[48]

The Broad Institute's views are consistent with the evidence from the NICHD and Dr. Schnall-Levin regarding difficulties in switching from the GEM Chip to the Next GEM Chip for ongoing projects. 10X Br. (Reply), Ex. 8, at 15–16 (Broad Institute Mem.). The Broad Institute declares

> For ongoing projects with existing data, there needs to be the ability to continue use of the same instruments, *i.e.*, 10X instruments, and reagents with optimized protocols specific thereto by Broad and others in order to retain the value of the existing data, results obtained as to other instruments and other reagents will likely not be able to be readily comparable. To require that Broad and others switch to other instruments immediately and in the middle of projects means that that previous research work on those projects likely will need to be discarded and the work redone on new instruments and with new reagents after time taken to learn and optimize protocols specific for the new instruments and new reagents in order to have the needed consistency. And, during this period of changeover and re-optimization, precious biological samples (especially from humans) may be lost as they will not be able to be timely used.

Id. at 15. The Broad Institute adds that "even if the project is such that the work can be re-done, Broad and other research institutions have no means to recover the monetary costs of re-doing research work." *Id.* at 16.

The Commission finds the above evidence to be credible, authoritative, and persuasive. *See, e.g.*, 10X Supp. Sub. (Reply) at 16–23 (presenting credentials); 10X Br. (Reply), Ex. 7, at

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[48] As to the NICHD, Complainants argue that, "[t]o the extent the infringing products are being imported by, or being used for the U.S. Government, they would be exempt from exclusion." Compls. Supp. Sub. (Reply) at 6, n.3 (citing 19 U.S.C. § 1337(l)). Complainants are correct. However, NICHD's submission supports the testimony of Dr. Schnall-Levin that requiring medical researchers to switch from GEM chips to the Next GEM Chip in ongoing research would be highly disruptive to that research.

1–5 (presenting credentials). We find no basis to credit Complainants' attacks on the third party researchers' and institutions' trustworthiness and credibility (*e.g.*, Compls. Supp. Sub. at 6–41; Compls. Supp. Sub. (Reply) at 5–18). Nor have Complainants explained why the third party evidence should be afforded little weight based on alleged bias of the kind discussed in *Flash Memories*. Compls. Supp. Sub. at 7 (citing *Certain Flash Memory Circuits & Prods. Containing Same*, Inv. No. 337-TA-382, Comm'n Op., 1997 WL 817778 at *15 (Jan. 1, 1997). Unlike in *Flash Memories,* none of the third parties are 10X corporate officers.

Complainants attack the third party researchers' letters to the Commission as failing to provide specific information about "available substitutes for 10X's products" and not stating reasons for why 10X products are important to their identified areas of research. Compls. Supp. Sub. at 11–12 (citing *Certain Magnetic Data Storage Tapes & Cartridges Containing the Same*, Inv. No. 337-TA-1012, Comm'n Op. at 136–37 (Apr. 2, 2018)). However, *Magnetic Data Storage Tapes* is distinguishable. In that investigation, complainant Sony asserted that its "LTO-7 customers include[d] . . . hospitals and pharmaceutical companies." *Magnetic Data Storage Tapes*, Comm'n Op. at 136. As to the hospitals, Sony failed to tie its public interest argument to public health and welfare aspects of those companies' operations. *Id.* at 136–37. Moreover, it was unclear how the pharmaceutical companies "utilize the accused LTO-7 tape products in any context that might impact the public health and welfare." *Id.* Here, the third party evidence shows how the 10X platform directly relates to the public health and welfare through its relationship to medical and scientific research. More importantly, as discussed above, record evidence directly ties the difficulties in switching mid-study from the infringing GEM Chip to alternative technologies (including the Next GEM Chip) to adverse impacts on medical and scientific research.

Complainants argue that requiring researchers to switch from the GEM Chips mid-study raises no significant public health and welfare concerns because researchers can combine results using different instrumentation of the type at issue. *E.g.*, Compls. Supp. Sub. at 22–23. They argue that doing so is routine and easily accomplished, relying primarily on the declarations of its expert, Dr. Pachter. *E.g.*, *id.* Dr. Pachter, in turn, bases his opinion on two recent scientific journal articles.[49]

Complainants overstate the conclusions that may be drawn from the two articles, and fail to show that combining results from different instrumentation has become "routine." The fact that researchers are working on ways to integrate data as described in the articles indicates that this is still an area of active research. Furthermore, the articles relate to, at most, a subset of the research at issue.[50] We also note that the Nature Biotechnology Article, in particular, notes its limitations.

> Lastly, we note many challenges that future methods will address in extending this work. Although our procedure can jointly analyze multiple data sets with overlapping and non-overlapping populations, future data sets *that consist of tens to hundreds of batches with dramatically varying sizes and non-overlapping populations will likely require new methods*. We also note that examples in this manuscript,

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[49] *See* Compls. Supp. Sub., Ex. 25 (Andrew Butler, et al., *Integrated single-cell transcriptomic data across different conditions, technologies, and species*, 36 NATURE BIOTECHNOLOGY 411 (2018)) (the "Nature Biotechnology Article"); Compls. Supp. Sub. (Reply), Ex. 153 (Nikolas Barkas, et al., *Joint analysis of heterogeneous single-cell RNA-seq dataset collections*, 16 NATURE METHODS 695 (2019)) (the "Nature Methods Articles").

[50] *Compare* Nature Biotechnology Article, Compls. Supp. Sub., Ex. 25; Nature Methods Article, Compls. Supp. Sub. (Reply), Ex. 153, *with* 10X Br. (Reply), Ex. 7, Ex. A–M; NICHD Submission. The Nature Methods Article, for example, relates to "identifying *recurrent* cell subpopulations in . . . heterogeneous collections." Nature Methods Article, Compls. Supp. Sub. (Reply), Ex. 153, p. 1. The Nature Biotechnology Article relates to "identifying subpopulations of cells that are present across multiple data sets." Nature Biotechnology Article, Compls. Supp. Sub., Ex. 25, p. 411.

Footnote continued on following page.

> including data sets with tens of thousands of cells, run in less than half an hour on a standard laptop computer, *but new data sets extending to millions of cells may require advanced computation, subsampling, or newly optimized techniques for integration.*

Nature Biotechnology Article, Compls. Supp. Sub., Ex. 25, p. 419 (emphasis added). Moreover, Complainants' arguments based on these articles are also contradicted by the evidence contained in the researcher correspondences, which state that switching platforms mid-study has detrimental impacts on scientific research.[51]

Complainants argue that 10X's position is inconsistent because it recently required customers to switch from their v2 reagents to their newer v3 reagent kits. *E.g.*, Compls. Supp. Sub. at 39–40. However, customers whose research was affected either did not make the switch or found that the reagent change does not have the magnitude of impact compared to a switch to a different chip design. *See* 10X Br. (Reply), Ex. 7, Ex. A, at 2 (Pe'er Letter).

Complainants also argue that tailored relief is unnecessary because the accused products relate to a preparatory step for research experiments, and not for the actual genetic sequencing. *E.g.*, Compls. Br. at 9. However, the evidence shows that that preparatory step is nonetheless essential for conducting the important research at issue. *E.g.*, 10X Br. (Reply), Ex. 7, Ex. F, at 2 (Weissman Letter) ("The 10[X] genomic single cell RNA-seq has proven to be an essential and irreplaceable component of the Perturb-seq nad molecular recorder approaches.").

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[51] *See, e.g.,* 10X Br. (Reply) at Ex. 7, Ex. A, at 2 (Pe'er Letter); *id.* at Ex. 7, Ex. C, at 1 (Guerrero Letter); *id.* at Ex. 7, Ex. D, at 1–2 (Kean Letter); *id.* at Ex. 7, Ex. E, at 1 (Carpten Letter); *id.* at Ex. 7, Ex. F, at 1 (Weissman Letter); *id.* at Ex. 7, Ex. H, at 2 (Kuo Letter); *id.* at Ex. 7, Ex. K, at 1 (Snyder Letter); *id.* at Ex. 7, Ex, L, at 1 (Sebra Letter); 10X Supp. Sub. at Ex. 2, Ex. F, at 2 (Bielas Questionnaire); *id.* at Ex. 2, Ex. B, at 1–2 (Kuo Questionnaire); *id.* at Ex. 2, Ex. D, at 1 (Beckman Questionnaire); *id.* at Ex. 2, Ex. E, at 1–2 (Carpten Questionnaire).

Footnote continued on following page.

In sum, the evidence shows that switching from the GEM Chips to the Next GEM Chip or another technology mid-study would disrupt important medical research, result in research studies that have questionable conclusions, and result in loss of data and wasted time, money, and effort. Reliable conclusions are the primary purpose of those costly and often government-funded research endeavors.[52] To remedy that issue, researchers would need to redo experiments using substitute equipment and consumables.[53] In some cases, samples may not be available, or financial resources may not exist, so that research would never be performed.[54] In nearly all cases, researchers would face, at the very least, delays and wasted expense. Those delays may compromise the availability of medical treatments for patients, such as cancer patients. *E.g.*, 10X Br. (Reply), Ex. 7, Ex. A at 3 (Pe'er Letter); *see also id.* at Ex. 7, Ex. G at 1 (Bielas Letter) ("I do hope, however, that the impact of a possible injunction on our research, and thus lives of our patients will be taken into consideration."). Although there is a significant public interest in protecting and enforcing intellectual property rights, *see, e.g.*, *Certain Two-Handle Centerset*

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[52] *E.g.*, NICHD Submission, at 1–2; 10X Br. (Reply), Ex. 7, Ex. A, at 1–2 (Pe'er Letter); *id.* at Ex. 7., Ex. K, at 1 (Snyder Letter); Beckman Submission, at 1 (discussing government grants); 10X Supp. Sub., Ex. 2, Ex. B, at 1 (Kuo Questionnaire); *id.* at Ex. 2, Ex. C, at 1 (Lusis Questionnaire); Ex. 2, Ex. D, at 1 (Beckman Questionnaire); Ex. 2, Ex. F, at 1–2 (Bielas Questionnaire).

[53] *See, e.g.*, 10X Br. (Reply), Ex. 7, Ex. A, at 2 (Pe'er Letter); *id.* at Ex. 7, Ex. D, at 1–2 (Kean Letter); *id.* at Ex. 7, Ex. L (Sebra Letter); 10X Br. (Reply), Ex. 8, at 15–16 (Broad Institute Mem.).

[54] 10X Br. (Reply), Ex. 7, Ex. A, at 2 (Pe'er Letter); *id.* at Ex. 7, Ex. B, at 1 (Gibson Letter); *id.* at Ex. 7, Ex. C, at 1 (Guerrero Letter); *id.* at Ex. 7, Ex. D, at 1 (Kean Letter); *id.* at Ex. 7, Ex. E (Carpten Letter); *id.* at Ex. 7, Ex. F, at 2 (Weissman Letter); *id.* at Ex. 7, Ex. H, at 1 (Kuo Letter); *id.* at Ex. 7, Ex. I (Liu Letter); Ex. 7, Ex. J (Ji Letter); *id.* at Ex. 7, Ex. K (Snyder Letter); *id.* at Ex. 7, Ex. L (Sebra Letter); NICHD Submission, at 1; Beckman Submission, at 1; 10X Supp. Sub., Ex. 2, Ex. B, at 1–2 (Kuo Questionnaire); *id.* at Ex. 2, Ex. D, at 1 (Beckman Questionnaire).

Faucets & Escutcheons & Components Thereof, Inv. No. 337-TA-422, Comm'n Op. at 9 (July 21, 2000), the countervailing public interest concerns demonstrated on this record are compelling. The tailored remedy issued by the Commission, as discussed further above and below, will ameliorate these concerns that pertain to ongoing research using the infringing GEM Chips. This tailoring will allow researchers to continue to receive and use the infringing GEM Chips if the facts show that switching to the Next GEM Chip (or a competitor's system) mid-study would harm their specific current ongoing research project.

Thus, the Commission has determined to issue an LEO (discussed in more detail above) that does not apply to covered microfluidic devices imported into the United States for use by researchers who have been using such devices in the United States as of the date of the issuance of the LEO, and who have provided 10X a documented need to continue receiving the devices for an identified current ongoing research project for which that need cannot be met by any alternative product, including the Next GEM Chip. The Commission has also determined to issue a CDO (discussed in more detail above) that contains the same exemption.

The Commission's remedial orders include as attachments questionnaires that 10X is to provide to its customers for purposes of obtaining infringing GEM Chips after the effective date of the Commission's orders. 10X 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. The questionnaires request, *inter alia*, a researcher to identify the date the research for which he or she is using the GEM Chips began and to state whether other products, including the Next GEM Chips, could meet his or her research needs. The questionnaires also require both 10X and its customers to certify as to the veracity of their statements and to

acknowledge their understanding of the consequences of being untruthful. To qualify for the exemption, the researcher must attest in the questionnaire that the research using the GEM Chips began prior to the date of issuance of these remedial orders, and also attest that other products, including the Next GEM Chips, 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 10X.

Customs and Border Protection may choose to require 10X 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 GEM Chips and pursuant to procedures that CBP establishes. The recordkeeping provision of the CDO requires 10X to retain such questionnaires, and the reporting provision requires 10X to report such records. *See* CDO, at §§ V, VI.

Complainants argue that this public interest carve out "provides no reasonable way to police how the chips are used." Compls. Supp. Sub. (Reply) at 43. However, if Complainants choose and doing so is warranted, Complainants may file a complaint for an enforcement proceeding pursuant to 19 C.F.R. § 210.75. *See also* 19 U.S.C. § 1337(f). Furthermore, at Complainants' request, the CDO's reporting provision reduces the discovery burden of an enforcement proceeding against 10X. *See* CDO, at § V. That provision requires 10X to provide detailed accounting showing that the chips 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 chips are not being stockpiled, sent to unauthorized customers, or used for research projects other than those

identified. That accounting must be supported by documentation (including the questionnaires) referencing all relevant information, including the number of chips imported and/or sold and the identity of the customers, their exempted research project(s), and the projected completion date of such projects. Moreover, to the same end, and also at Complainants' request, the reporting provision requires monthly, rather than the Commission's standard annual, reports. *See id.*

2. The Other Public Interest Factors

In addition to the public health and welfare, the Commission is also required to consider "the competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, and United States consumers." 19 U.S.C. § 1337 (d)(1), (f)(1). The Commission has considered the impact of the orders on those considerations, as well as on the public health and welfare. Here, the competitive conditions in the United States economy and United States consumers factors are subsumed by the public health and welfare as they present the same issues for researchers who have begun studies using the GEM Chips. And, even assuming a remedial order would affect the production of like or directly competitive articles in the United States, the effect, if any, would be nominal and not require denying or further tailoring a remedy. As discussed above, for ongoing research projects, the record shows that competitors' products cannot be substituted for 10X products mid-study. *See* RD at 27–28.

IV. BONDING

If the Commission enters an exclusion order, a respondent may continue to import and sell its products during the 60-day period of Presidential review under a bond in an amount determined by the Commission to be "sufficient to protect the complainant from any injury." 19 U.S.C. § 1337(j)(3); *see also* 19 CFR 210.50(a)(3). When reliable price information is available in the record, the Commission has often set the bond in an amount that would

eliminate the price differential between the domestic product and the imported, infringing product. *See Certain Microsphere Adhesives, Processes for Making Same, & Prods. Containing Same, Including Self-stick Repositionable Notes,* Inv. No. 337-TA-366, USITC Pub. No. 2949, Comm'n Op. at 24 (Jan. 16, 1996). The Commission also has used a reasonable royalty rate to set the bond amount where a reasonable royalty rate could be ascertained from the evidence in the record. *See, e.g., Certain Audio Digital-to-Analog Converters & Prods. Containing Same,* Inv. No. 337-TA-499, Comm'n Op. at 25 (Mar. 3, 2005). Where the record establishes that the calculation of a price differential is impractical or there is insufficient evidence in the record to determine a reasonable royalty, the Commission has imposed a 100 percent bond. *See, e.g., Certain Liquid Crystal Display Modules, Prods. Containing Same, & Methods Using the Same*, Inv. No. 337-TA-634, Comm'n Op. at 6–7 (Nov. 24, 2009) ("*Liquid Crystal Display Modules*"). The complainant, however, bears the burden of establishing the need for a bond. *Certain Rubber Antidegradants, Components Thereof, & Prods. Containing Same*, Inv. No. 337-TA-533, USITC Pub. No. 3975, Comm'n Op. at 40 (July 21, 2006) ("*Rubber Antidegradants*").

The Commission has determined to set a bond during the period of Presidential review at the reasonable royalty rate—3 percent of the entered value of the infringing chips. *See Audio Digital-to-Analog Converters,* Comm'n Op. at 25 (setting bond at the reasonable royalty rate when such rate can be ascertained from the record). First, Complainants have shown that bond is warranted.[55] *See Rubber Antidegradants*, Comm'n Op. at 40 (requiring the complainant to

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[55] Commissioner Schmidtlein agrees with the majority that Complainants have established that a bond is warranted. She, however, disagrees with the decision to impose a three percent bond rate since the ALJ's findings show that the three percent royalty rate advanced

Footnote continued on following page.

establish the need for bond). 10X argues that Bio-Rad will not lose any sales because Bio-Rad does not compete with it in its market segments and the parties' chips are not interchangeable. 10X Br. at 29. While we recognize that the 10X and Bio-Rad chips are not interchangeable, Bio-Rad and 10X both make microfluidic devices for next generation sequencing as do a number of other companies. RD at 12–22 (discussing competition in the next generation sequencing market). There may be researchers undertaking new studies who view themselves as having a choice between Bio-Rad's and 10X's products to meet their needs. Moreover, the record shows that 10X views itself to be in competition with Bio-Rad, and that it used a discounting strategy to avoid losing sales to Bio-Rad. *See, e.g.*, JX-0040C.0007; JX-0041C;

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by 10X's expert Dr. Sullivan as the basis for the three percent bond is predicated on a flawed analysis. Specifically, the ALJ found that Complainants on cross examination undermined Dr. Sullivan's specific analysis of royalty-bearing licenses, including findings that Dr. Sullivan "reached this opinion by excluding license agreements with high royalty rates from his analysis," "analyz[ed] only licenses between non-competitors," and "declin[ed] to adjust any license's royalty rate to account for other consideration exchanged for the license." RD at 40. Thus, the ALJ determined that Complainants successfully impeached Dr. Sullivan's testimony related to the three percent calculation. *Id.* Commissioner Schmidtlein sees no reason to doubt this determination made by the ALJ who witnessed the cross examination. The ALJ offered a second rational supporting 100 percent bond—*i.e.*, the three percent rate would not account for any injury due to 10X's sales of its instruments that use the infringing chips. Commissioner Schmidtlein does not see a need to address this second rationale in light of the ALJ's determination that the three percent calculation is flawed.

Instead, Commission Schmidtlein supports granting the 100 percent bond rate requested by the Complainants and recommended by the ALJ. Where the record establishes that the calculation of a price differential is impractical or there is insufficient evidence in the record to determine a reasonable royalty, the Commission has typically imposed a 100 percent bond. *See, e.g.*, *Liquid Crystal Display Modules*, Comm'n Op. at 6–7. Commissioner Schmidtlein finds that the record does not establish a reliable reasonable royalty rate and she also observes that the ALJ found that the parties agreed that calculating a bond rate based on a price comparison between the domestic industry product and the infringing product was not appropriate in this case. *See* RD at 35, 41. Under these circumstances, Commissioner Schmidtlein supports granting Complainants' request for a bond rate of 100 percent of the entered value of the imported infringing chips.

CX-0629C at 79:19–25, 131:12–17; CX-0568C at 236:1–7; JX-0048C.0004–9; JX-0038C; Tr. 307:17–308:18 (Mulhern). Accordingly, a bond during the Presidential review period is necessary to protect Bio-Rad from injury. *See* 19 U.S.C. § 1337(j)(3); 19 C.F.R. § 210.50(a)(3).

The parties dispute whether bond should be set at 3 percent or 100 percent of the entered value of the chips. The Commission finds that 3 percent of entered value is a reasonable royalty rate based on the unrebutted testimony of 10X's expert, Dr. Ryan Sullivan. *See* RD at 35. As the RD notes, Dr. Sullivan opined that a 3 percent royalty was appropriate after reviewing several licensing agreements that "all relate to microfluidic systems or droplet generation," which collectively demonstrate [

]. RD at 35 (citing Tr. at 1278:10–15). Dr. Sullivan specifically relied on a licensing agreement [

] and in which the royalty rate was 3 percent of "net revenues." *Id.* (citing Tr. at 1279:14–15). Despite these findings, however, the RD finds that none of the parties explained how the 3 percent royalty rate could be applied to the value of the 10X GEM Chips as imported in order to compensate for Complainants' injury by reason of 10X's continued sales of its products. *Id.* at 36.

Because 10X sells to its customers Chromium instruments and kits that contain consumables such as infringing chips, gel beads, and reagents, the RD finds that imposing a 3 percent bond only on the entered value of the GEM Chips may underestimate the potential injury to complainants by reason of these continued sales. *Id.* at 36–41.

The RD focuses on the manner in which 10X markets and sells its products in order to compete against Bio-Rad even if in some research using Bio-Rad's products could not be substituted for 10X's products. RD at 37–38 (declaring that "the potential harm to

Complainants [from] Respondent's importation of chips during the Presidential Review Period is inextricably linked to Respondent's sales of Chromium™ instruments and subsequent repeat sales of kits that do not interoperate with competing products."). Thus, although the RD concludes that Complainants may be harmed by the sale of Chromium instruments and kits containing consumables besides the GEM Chips, these products are beyond the scope of this investigation. The Chromium instruments and other consumables in the kits are not microfluidic devices, and they are not imported into the United States. Accordingly, the Commission has determined to set bond at the reasonable royalty rate of 3 percent of the entered value of infringing chips.

Complainants do not dispute that the bond applicable to imports of infringing GEM chips during the Presidential review period may be based on a reasonable royalty that is established using Bio-Rad's own license agreements and those of 10X that were produced in discovery in this investigation. *See* Compls. Br. at 4–6; Compls. Br. (Reply) at 7–9. Complainants likewise do not contest that [ ] to compensate for the use of the technology claimed in one of the patents asserted in this investigation. Tr. at 1291:23–1292:6. Complainants' argument as to the use of a bond based on reasonable royalties is that the RD found that some aspects of Dr. Sullivan's analysis were flawed. *See* Compls. Br. at 4–6; Compls. Br. (Reply) at 7–9. While the ALJ stated that Dr. Sullivan's testimony was impeached to some extent (RD at 40), the ALJ does not explain the extent of the impeachment, and a review of the transcript does not clarify the specific testimony impeached. On the other hand, the ALJ specifically recognized Dr. Sullivan's more than 25 years' experience of providing professional economic services and found that Dr. Sullivan's testimony of a three percent reasonable royalty rate was unrebutted. RD 35, 35 n.29. The

Commission notes that a three percent reasonable royalty rate was the *only* reasonable royalty rate presented to the ALJ, and it appears that the ALJ would have recommended that reasonable rate but for her consideration of Chromium instruments and kits, which we have rejected as explained above. Moreover, Complainants did not offer their own expert opinion as to the license agreements or royalty rates in the record (Tr. at 1291:19–22), or attempt to rebut Dr. Sullivan's opinion as to licensing royalties that are appropriate for the articles at issue in this investigation. Where a complainant has shown, based on the record, that the calculation of a price differential is impractical or there is insufficient evidence in the record to determine a reasonable royalty, the Commission has imposed a 100 percent bond. *See, e.g.*, *Certain Liquid Crystal Display Modules*, Comm'n Op. at 6–7. Here, all parties agree that price comparisons are not appropriate for the products involved in this case. RD at 35. However, the record in this investigation contains ample evidence of the licensing royalties to which Bio-Rad and 10X have agreed to compensate for third party use of their technologies. Given the fulsome record of multiple Bio-Rad and 10X license agreements that show these parties' willingness to accept royalties, and the specific royalty rates that the parties themselves have set for the use of their technologies, Complainants have failed to establish that the evidence here is insufficient to determine a bond based on a reasonable royalty rate. Accordingly, the Commission has determined to set bond at the reasonable royalty rate of three percent of the entered value of infringing chips.

V. CONCLUSION

In sum, the Commission finds that Complainants have demonstrated a violation of section 337 based on 10X's importation of the GEM Chips with respect to the asserted claims of the '664, '682, and '635 patents. After considering the record evidence and arguments concerning the public interest, as required by section 337, the Commission has concluded that

the appropriate remedy includes a tailored LEO and CDO that permits researchers to continue receiving the infringing GEM Chips for an identified ongoing research project in the United States for which that need cannot be met by any alternative product, including the Next GEM Chip. The Commission has also determined to set a bond during the period of Presidential review at 3 percent of the entered value of the infringing chips. This investigation is terminated.

By order of the Commission.

Lisa R. Barton
Secretary to the Commission

Issued: January 10, 2020

PUBLIC CERTIFICATE OF SERVICE

I, Lisa R. Barton, hereby certify that the attached **COMMISSION OPINION [REVISED]** has been served by hand upon the Commission Investigative Attorney, **Whitney Winston, Esq.**, and the following parties as indicated, on **January 10, 2020**.

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

On Behalf of Complainants Bio-Rad Laboratories, Inc. and Lawrence Livermore National Security, LLC:

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UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, D.C.

In the Matter of CERTAIN MICROFLUIDIC DEVICES	Investigation No. 337-TA-1068

NOTICE OF COMMISSION DETERMINATION TO REVIEW IN PART A FINAL INITIAL DETERMINATION FINDING A VIOLATION OF SECTION 337; SCHEDULE FOR FILING WRITTEN SUBMISSIONS ON THE ISSUES UNDER REVIEW AND ON REMEDY, THE PUBLIC INTEREST, AND BONDING; EXTENSION OF TARGET DATE

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission (the "Commission") has determined to review in part the final initial determination (the "ID") issued by the presiding administrative law judge ("ALJ") on September 20, 2018, finding a violation of section 337 of the Tariff Act of 1930, as amended, in connection with certain asserted patents. The Commission has also determined to extend the target date for the completion of this investigation to February 11, 2019.

FOR FURTHER INFORMATION CONTACT: Ron Traud, Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436, telephone 202-205-3427. 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, telephone 202-205-1810.

SUPPLEMENTARY INFORMATION: On September 6, 2017, the Commission instituted this investigation based on a complaint filed by Bio-Rad Laboratories, Inc. of Hercules, CA; and Lawrence Livermore National Security, LLC of Livermore, CA (collectively, "complainants"). 82 FR 42115 (Sept. 6, 2017). The complaint (and supplement thereto) alleges violations of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337 ("section 337") based upon the importation into the United States, the sale for importation, or the sale within the United States after importation of certain microfluidic devices by reason of infringement of one or more of claims 1-12 and 14-16 of U.S. Patent No. 9,500,664 ("the '664 patent"); claims 1-15 of U.S. Patent No. 9,089,844 ("the '844 patent"); claims 1-21 of U.S. Patent No. 9,636,682 ("the '682

patent"); claims 1-27 of U.S. Patent No. 9,649,635 ("the '635 patent"); and claims 1, 2, 4-8, and 14-21 of U.S. Patent No. 9,126,160 ("the '160 patent). *Id.* The Commission's notice of investigation named as the sole respondent 10X Genomics, Inc. of Pleasanton, CA ("10X"). *Id.* The Office of Unfair Import Investigations was also named as a party to this investigation. *Id.*

On March 6, 2018, the Commission terminated the investigation as to claims 14-17 of the '160 patent; claim 3 of the '664 patent; claims 2, 8, 11, and 14–15 of the '844 patent; claims 2–3 of the '682 patent; and claims 2–4, 9–10, 15, 22, and 27 of the '635 patent. *See* Order No. 12, *unreviewed*, Notice of Commission Determination Not to Review an Initial Determination (Order No. 12) Partially Terminating the Investigation as to Certain Patent Claims (March 6, 2018). On March 26, 2018, the Commission terminated the investigation as to claims 1 and 18 of the '160 patent; claims 6, 7, 9, and 13 of the '844 patent; claims 4 and 13 of the '682 patent; and claims 5 and 17 of the '635 patent. *See* Order No. 16, *unreviewed*, Notice of Commission Determination Not to Review an ID (Order No. 16) Partially Terminating the Investigation as to Certain Patent Claims (March 26, 2018). On April 16, 2018, the Commission terminated the investigation as to claims 2, 6, 7, and 19 of the '160 patent; claims 5–7, 10, and 12 of the '664 patent; claims 1, 3–5, 10, and 12 of the '844 patent; claims 5–6, 8, 10–12, 15, and 20–21 of the '682 patent; and claims 6–8, 11–12, 18–20, and 23–26 of the '635 patent. *See* Order No. 19, *unreviewed*, Notice of Commission Determination Not to Review an Initial Determination (Order No. 19) Partially Terminating the Investigation as to U.S. Patent No. 9,089,844 and Other Asserted Patent Claims (Apr. 16, 2018).

On September 20, 2018, the ALJ issued the ID, which finds 10X in violation of section 337 as to the '664 patent, the '682 patent, and the '635 patent. On September 28, 2018, the ALJ issued her recommendations on remedy, bond, and the public interest. The ALJ recommended that the Commission issue a limited exclusion order directed to 10X's infringing products and a cease and desist order directed to 10X. The ALJ also recommended a bond of 100 percent of entered value during the Presidential review period. *See* 19 U.S.C. 1337(j)(3).

On October 3, 2018, Complainants and 10X each filed petitions for review. OUII did not file a petition for review. On October 11, 2018, the Complainants, 10X, and OUII filed responses to those petitions.

Having examined the record in this investigation, including the ID, the petitions for review, and the responses thereto, the Commission has determined to review the ID in part. In particular, the Commission has determined to review the following:

(1) Whether 10X indirectly infringes the '682 and '635 patents.

(2) Whether 10X's Chip GB infringes claims 1 and 14 of the '664 patent.

(3) Whether 10X's Chip SE infringes claim 20 of the '160 patent and claim 1 of the '664 patent.

As the petitions and responses thereto have adequately addressed these issues, the Commission does not request any briefing on these issues. The Commission has determined to not review the remainder of the ID.

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

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

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

WRITTEN SUBMISSIONS: Parties to the investigation, interested government agencies, and any other interested parties are encouraged to file written submissions on the issues of remedy, the public interest, and bonding. Such submissions should address the recommended determination by the ALJ on remedy and bonding. Complainants and OUII are requested to submit proposed remedial orders for the Commission's consideration. Complainants are also requested to state the date that the patents expire and the HTSUS numbers under which the accused products are imported. Complainants are further requested to supply the names of known importers of the products at issue in this investigation. The written submissions and proposed remedial orders must be filed no later than close of business on December 17, 2018. Reply submissions must be filed no later than the close of business on December 24, 2018. Such submissions should address the ALJ's recommended determinations on remedy and bonding and the public interest. No further submissions on any of these issues will be permitted unless otherwise ordered by the Commission.

Persons filing written submissions must file the original document electronically on or before the deadlines stated above and submit eight true paper copies to the Office of the Secretary by noon the next day pursuant to section 210.4(f) of the Commission's Rules of Practice and Procedure (19 CFR 210.4(f)). Submissions should refer to the investigation number ("Inv. No. 337-TA-1068") in a prominent place on the cover page and/or the first page. (*See*

Handbook for Electronic Filing Procedures, *https://www.usitc.gov/ secretary/fed_reg_notices/rules/ handbook_on_electronic_filing.pdf*). Persons with questions regarding filing should contact the Secretary (202-205-2000).

Any person desiring to submit a document to the Commission in confidence must request confidential treatment. All such requests should be directed to the Secretary to the Commission and must include a full statement of the reasons why the Commission should grant such treatment. *See* 19 CFR 201.6. Documents for which confidential treatment by the Commission is properly sought will be treated accordingly. All information, including confidential business information and documents for which confidential treatment is properly sought, submitted to the Commission for purposes of this Investigation may be disclosed to and used: (i) By the Commission, its employees and Offices, and contract personnel (a) for developing or maintaining the records of this or a related proceeding, or (b) in internal investigations, audits, reviews, and evaluations relating to the programs, personnel, and operations of the Commission including under 5 U.S.C. Appendix 3; or (ii) by U.S. government employees and contract personnel, solely for cybersecurity purposes (all contract personnel will sign appropriate nondisclosure agreements). All nonconfidential written submissions will be available for public inspection at the Office of the Secretary and on EDIS.

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

By order of the Commission.

Lisa R. Barton
Secretary to the Commission

Issued: December 4, 2018

PUBLIC CERTIFICATE OF SERVICE

I, Lisa R. Barton, hereby certify that the attached **NOTICE** has been served by hand upon the Commission Investigative Attorney, **Whitney Winston, Esq.**, and the following parties as indicated, on **December 4, 2018**.

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

On Behalf of Complainants Bio-Rad Laboratories, Inc. and Lawrence Livermore National Security, LLC:

Jeffrey Gerchick
QUINN EMANUEL URQUHART & SULLIVAN LLP
1300 I Street NW, Suite 900
Washington, DC 20005

☐ Via Hand Delivery
☐ Via Express Delivery
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☐ Other:_____

On Behalf of Respondents 10X Genomics, Inc.:

Nicholas Groombridge
PAUL, WEISS, RIFKIND, WHARTON & GARRISON LLP
1285 Avenue of the Americas
New York, NY 10019

☐ 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	**Inv. No. 337-TA-1068**
CERTAIN MICROFLUIDIC DEVICES	

ORDER NO. 36: ERRATA TO INITIAL DETERMINATION ON VIOLATION OF SECTION 337 AND RECOMMENDED DETERMINATION ON REMEDY AND BOND

(September 27, 2018)

The Initial Determination ("ID") for this Investigation was issued on September 20, 2018. (*See* ID, Doc. ID No. 656331 (Sept. 20, 2018).). After the ID issued, it was discovered that typographical edits, due to technical difficulties or editing errors, were omitted from or should have been omitted from the ID.

Page No.	Original Text	Corrected Text
69-70	Complainants have proven that the GEM Chips, the Chip GB, and the Chip SE ("Accused 664 Products") directly infringe claims 1, 2, 14, and 15 of the '664 patent.	Complainants have proven that the GEM Chips directly infringe claims 1, 2, 14, and 15 of the '664 patent.
71	Accordingly, Complainants have met their burden and proven that the Accused 664 Products infringe claims 1, 2, 14, and 15 of the '664 patent.	Accordingly, Complainants have met their burden and proven that the GEM Chips infringe claims 1, 2, 14, and 15 of the '664 patent.
146	Complainants have proven by a preponderance of evidence that the Accused Products infringe asserted claims 14, 16, and 17 of U.S. Patent No. 9,636,682.	Complainants have proven by a preponderance of evidence that certain of the Accused Products infringe asserted claims 14, 16, and 17 of U.S. Patent No. 9,636,682.

Page No.	Original Text	Corrected Text
146	Complainants have proven by a preponderance of evidence that the Accused Products infringe asserted claims 1, 13, 14, 16, and 21 of U.S. Patent No. 9,649,635.	Complainants have proven by a preponderance of evidence that certain of the Accused Products infringe asserted claims 1, 13, 14, 16, and 21 of U.S. Patent No. 9,649,635.

The modifications do not impact the analyses or findings set forth in the text of the ID. Moreover, the corrections do not adversely affect any of the parties in this Investigation because the analyses were clear in context.

Within eight (8) business days of the date of this document, each party shall submit to the Office of the Administrative Law Judges a statement as to whether or not[1] it seeks to have any confidential portion of this document deleted from the public version. Any party seeking redactions to the public version must submit to this office two (2) copies of a proposed public version of this document pursuant to Ground Rule 1.11 with red brackets clearly indicating any portion asserted to contain confidential business information.

After the parties have submitted any proposed redactions, and those proposed redactions, if any, have been reviewed, any unredacted corrections contained in this Erratum document will be incorporated into the public version of the ID.

SO ORDERED.

MaryJoan McNamara
Administrative Law Judge

[1] This means that parties that do not seek to have any portion redacted are still required to submit a statement to this effect.

PUBLIC CERTIFICATE OF SERVICE

I, Lisa R. Barton, hereby certify that the attached **INITIAL DETERMINATION** has been served by hand upon the Commission Investigative Attorney, **Whitney Winston, Esq.**, and the following parties as indicated, on **October 29, 2018**.

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

On Behalf of Complainants Bio-Rad Laboratories, Inc. and Lawrence Livermore National Security, LLC:

Jeffrey Gerchick, Esq.
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Respondent 10X Genomics, Inc.:

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Public Version

UNITED STATES INTERNATIONAL TRADE COMMISSION

Washington, D.C.

In the Matter of **CERTAIN MICROFLUIDIC DEVICES**	**Inv. No. 337-TA-1068**

ANALYSES AND FINDINGS WITH RESPECT TO THE PUBLIC INTEREST, AND RECOMMENDED DETERMINATION ON REMEDY AND BOND

Administrative Law Judge MaryJoan McNamara

(September 28, 2018)

Pursuant to Commission Rule 210.42(a)(1)(ii), this document contains my analyses and findings with respect to the public interest and my recommended determination on remedy and bond ("Recommended Determination"). 19 C.F.R. § 210.42(a)(1)(ii).[1]

I. PUBLIC INTEREST

A. Legal Standard

Section 337 mandates consideration of the effect of an exclusion order on the: (1) public health and welfare; (2) competitive conditions in the U.S. economy; (3) U.S. production of articles that are like or directly competitive with the articles subject to the investigation; and (4) U.S. consumers. 19 U.S.C. § 1337(d)(l). In general, relief for a violation under section 337 should be denied only when the adverse effect on the public interest outweighs the interest in protecting the patent holder. *Certain Battery-Powered Ride-On Toy Vehicles*, Inv. No. 337-TA-

[1] On September 20, 2018, I issued the Final Initial Determination ("ID") in this Investigation, finding that Respondent 10X Genomics, Inc. has violated subsection (b) 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 devices.

314, Comm'n Op., 0091 WL 11732578, at *8-9 (Apr. 1991). Instances of the denial of relief are rare in the history of the Commission.

B. The Commission Directed that Evidence Be Taken on Public Interest Considerations

In the Notice of Investigation ("NOI"), the Commission directed the administrative law judge ("ALJ") to "take evidence or other information and hear arguments from the parties and other interested persons with respect to the Public Interest in this investigation, as appropriate, and provide the Commission with findings of fact and a recommended determination on this issue[.]" 82 Fed. Reg. 42115 (Sept. 6, 2017).

The four (4) factors that are part of the Section 337 public interest considerations are referred to as the "public interest" analysis. *See, e.g.*, Commission Rule § 210.50(a)(2), (4). In this Investigation, Respondent 10X Genomics, Inc. ("Respondent") has the burden of proving that remedial relief should be precluded in whole or in part based upon the public interest factors. *Certain Light-Emitting Diodes and Prods. Containing Same*, Inv. No. 337-TA-512, Comm'n Op. at 10 (Apr. 14, 2008)). Respondent has argued that any recommended remedial orders[2] in this Investigation should be precluded because of their potential damaging effects on the public interest. (RBr. at 86.).

In the alternative, Respondent has requested that, at a minimum, the Commission modify any remedial orders to allow the Respondent to continue its importation of "infringing microfluidic devices solely for the use on the existing installed base of Chromium™ instruments." (SRBr. at 27; RRBr. at 49 (referencing Staff's position).). On this issue,

[2] In its briefing of the public interest factors, Respondent typically referred to "remedial orders" collectively, without differentiating between different types of remedial orders and the potential individual effects of each type of remedial order on the public interest. (*See, e.g.*, RBr. at 86.).

Respondent and Commission Investigative Staff ("Staff") have agreed. (SRBr. at 27.).

Respondent then refined this request and argued in the alternative that any remedial orders should permit importation of microfluidic devices used for Respondent's "Single-Cell V(D)J Solution."[3] (RRBr. at 49.). On this issue, in its Initial Post-Hearing Brief, Staff supported Respondent, stating that "there does not appear to be any competing solution" for Respondent's "Single-Cell V(D)J Solution." (SBr. at 60.). However, Staff appears to have changed its position in its Reply Post-Hearing Brief, explaining "[t]he Staff agrees" with Complainants that "Respondent has not shown that any specific research will be materially affected should the requested remedial orders issue." (SRBr. at 26.). Staff's changed position did not influence or change Respondent's request for either preclusion or modified orders with respect to only Respondent's "Single-Cell V(D)J Solution." (RRBr. at 49.).

In its Pre- and Post-Hearing Briefs, Complainants Bio-Rad Laboratories, Inc. and Lawrence Livermore National Security, LLC (collectively, "Complainants" and with Staff and Respondent, "the Parties") consistently argued that public interest factors do not favor Respondent's position. (CPBr. at 86; CBr. at 84.). As Complainants stated, "[a]n order excluding Respondent's infringing products would protect a domestic industry from Respondent's encroachment of intellectual property rights and would leave consumers of Respondent's products free to choose offerings from—in Respondent's words—'a number of companies that have different products in next-gen sequencing.'" (CRBr. at 33.).

Against this backdrop, Respondent conceded that the public interest analysis requires an examination of the purportedly indispensable role of Respondent's Accused Products in the

[3] "V(D)J stands for variable, joining, and diversity. And this refers to recombination of sequences from specific T-cell receptors that then allow the immune system to operate." (Tr. (Pachter) at 803:3-6.).

marketplace. (RBr. at 93 ("the test is not whether there may be some applications where competing solutions might perform comparably to Respondent's, but rather whether there are applications that can only be performed using Respondent's system"); RRBr. at 41.).

The inquiry's focus is whether the exclusion of Respondent's Accused Chips would not only deprive the marketplace of a competing good, but would deprive the market of a unique good whose absence from the marketplace would cause the public undue harm and thereby justify the non-enforcement of intellectual property rights by the Commission. *See Certain Table Saws Incorporating Active Injury Mitigation Tech. and Components Thereof*, Inv. No. 337-TA-965, Comm'n Op., 2017 WL 1476193, *4 (Feb. 1, 2017) ("the appropriate standard is not that no remedy should issue if every consumer cannot obtain the exact device desired that was found to infringe."); *Certain Inclined-Field Acceleration Tubes & Components Thereof* ("*Acceleration Tubes*"), Inv. No. 337-TA-67, Comm'n Op. at 29 (Dec. 29, 1980) ("The issue here is not, however, which [products] perform better in a given application, but whether the superior performance at lower cost of the [accused products] in some applications justifies overriding the patent owner's rights.").).

Respondent has not met its burden of proof. *Certain Light-Emitting Diodes and Prods. Containing Same*, Inv. No. 337-TA-512, Comm'n Op. at 10 (Apr. 14, 2008) (respondent has the burden of proving that the recommended remedial relief should be precluded in whole or part based on public interest factors). For each supposed "specific and concrete example[] of 10X-enabled research for which there are no substitutes," Complainants offered evidence of substitutes. (CBr. at 87-95; CRBr. at 35-40; RRBr. at 42.). Notably, in the research-oriented NGS industry comprised largely of laboratories and academic consortia, Respondent offered no third-party evidence of how Complainants' requested remedial relief would affect the progress of

scientific research in the NGS industry. Instead, as Complainants noted, Respondent based its public interest case "on self-serving testimony from Respondent's employees, officers and a board member." (CRBr. at 33.).[4]

Based upon the weight of the evidence in keeping with the analysis of the public interest factors, this decision recommends that the Commission enforce any recommended orders without delay or modification. On balance, three (3) public interest factors in favor of enforcing the orders and protecting intellectual property outweigh one (1) factor that only slightly weighs in Respondent's favor. Based upon the admitted evidence, enforcement of remedial orders would likely have an indeterminate and, more likely than not, a minimal, adverse effect on the public interest based upon what was known and provided during the evidentiary hearing ("Hearing").

C. Respondent's Presence in the NGS Marketplace

Respondent is a relatively small player in the NGS industry. (CX-0568C (Michael Schnall-Levin Dep. Tr.)[5] at 56:3-57:10.). Respondent's own Chief Executive Officer ("CEO"), Dr. Serge Saxonov, [redacted] (CX-0129C.). Respondent had global sales of $27 million in 2016 and $70 million in 2017. (JX-0036C; CDX-0002.0003.). Respondent's sales represented approximately [redacted]

[4] Neither Complainants nor Respondent obtained statements, let alone testimony, from other marketplace participants to address the potential effects of public interest factors on the NGS industry.

[5] When he testified during the Hearing on May 10, 2018, Dr. Michael Schnall-Levin was the Vice President of Product Research & Development ("R&D") and Strategy at 10X. (Tr. Schnall-Levin) at 1044:7-8.). Respondent identified Dr. Schnall-Levin as a fact witness to testify about matters relating to public interest, including the marketing, advertising, and price of Respondent's products and other products. (RPSt. at 3.).

respectively of global NGS revenues in each of 2016 and 2017. (Tr. (Carla Mulhern)[6] at 280:15-281:3; JX-0036C; CX-0522C; CDX-0002.3.). By the end of 2017, [redacted] of Respondent's Chromium™ instruments were being operated in the United States. (JX-0036C.0004, -0005.).

1. Respondent's Accused Chips and Other Products

Respondent sells two (2) instruments for making sample-containing droplets: a Chromium™ Controller and a Chromium™ Single Cell Controller (collectively, "Chromium™ Controllers"). (Tr. (Schnall-Levin) at 1051:25-1052:5; Tr. (Benjamin Hindson)[7] at 954:2-25; CX-0568C (Schnall-Levin Dep. Tr.) at 34:13-21.). Respondent manufactures and assembles its [redacted]. (Tr. (Schnall-Levin) at 1052:6-11.). Respondent sells not only Chromium™ Controllers, but kits that contain "consumables" for making the microfluidic droplets, such as enzymatic reagents, chips (the only products accused of infringement in this Investigation), and gel beads. (*Id.* at 1052:16-21.). According to Dr. Schnall-Levin, "every time you want to run a new experiment, you purchase a new set of reagents and consumables for that." (*Id.* at 1052:16-21.).

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[6] Complainants called Ms. Carla Mulhern to testify as an expert witness on Monday, May 7, 2018, and Tuesday, May 8, 2018, with respect to "the economics of Bio-Rad's domestic industry, the appropriate remedy and/or bond rate should the Commission find a violation of Section 337, and the effect on the public interest should the Commission issue remedial orders against Respondent and the accused products in this investigation[.]" (CPSt. at 2.). Ms. Mulhern is a partner in the Washington, D.C. office of Analysis Group, Incorporated. (Tr. (Mulhern) at 270:17-22.). Ms. Mulhern is an economist who "specializes in the application of economic principles to issues arising in litigation," including "the valuation of intellectual property or the analysis of damages" and "economic issues that arise in Section 337 cases at the ITC." (*Id.* at 270:23-271:7).

[7] When he testified during the Hearing on May 10, 2018, Dr. Benjamin Hindson was a co-founder, Chief Scientific Officer, and President of 10X. (Tr. (Hindson) at 906:12-14.). Respondent identified Dr. Hindson as a fact witness to provide testimony on matters relating to 10X, including the company, its history, and its products; QuantaLife's products; the Asserted Patents, including any purported invention(s) disclosed therein; claim construction, including the state of the prior art; non-infringement; and the prior proceedings between 10X and Bio-Rad. (RPSt. at 2-3.).

Respondent imports its Accused Chips that work with its Chromium™ Controllers. Respondent imports the Accused Chips for approximately [redacted] each; [redacted]. (CX-0612C (Paul Wyatt Dep. Tr.)[8] at 72:4-19; Tr. (Juan Santiago)[9] at 1264:9-25; Tr. (Hindson) at 956:20-957:23; Tr. (Mulhern) at 362:14-363:15.). Respondent assembles the Accused Chips into kits [redacted] and sells the kits to customers worldwide. (Tr. (Hindson) at 956:25-957:20; Tr. (Lior Pachter)[10] at 884:22-885:19.). Respondent's Chromium™ Controllers cannot be used without the Accused Chips for making droplets, including the GEM Chips and the "redesigned" Chip SE. (Tr. (Schnall-Levin) at 1052:6-11.). Respondent's Chromium™ Controllers also cannot be used without certain gel beads [redacted]. (*Id.*). It appears that Respondent's Accused Chips and Chromium™ Controllers are not interchangeable with other NGS systems. (RBr. at 81-82 (stating that "Bio-Rad's ddSEQ chips cannot be used in 10X's Chromium controllers, and 10X's

[8] At the time of his deposition on January 20, 2018, Mr. Paul Wyatt was the Vice President of Operations at 10X. (CX-0612C (Wyatt Dep. Tr.) at 7:3-7, 9:7-14.). His responsibilities included overseeing process development, manufacturing function, quality assurance facilities, and systems engineering. (*Id.*). Respondent identified Mr. Wyatt as a fact witness to provide testimony with regard to matters relating to 10X, including the company, its history, and its products. (RPSt. at 4.).

[9] When he testified during the Hearing on May 11, 2018, Dr. Juan Santiago was a Professor of mechanical engineering at Stanford University. (Tr. (Santiago) at 1148:13-14, 1149:8-13.). Respondent identified Dr. Santiago as an expert to testify about the background of microfluidic technology and matters relating to the Asserted Patents, the Accused Products, the DI Products, claim construction, and non-infringement of the Asserted Patents. (RPSt. at 4.).

[10] Complainants called Dr. Lior Pachter to testify as an expert witness on Wednesday, May 9, 2018, with respect to "technical issues relevant to the public interest, in particular, available alternatives to Respondent's products, including those manufactured by Bio-Rad, and the effect on the public interest should the Commission issue remedial orders against Respondent and the accused products in this investigation." (CPSt. at 2.). As the Bren Professor of Computational Biology at Caltech, Dr. Pachter conducts research in the area of single cell genomics and, in particular, the molecular biology of single cells. (Tr. (Pachter) at 756:6-20.).

GEM-Q and GEM-U Chips cannot be used in Bio-Rad's ddSEQ controller") (citing Tr. (Schnall-Levin) at 1052:6-11; Tr. (Mulhern) at 317:23-318:17).).

Respondent's Chromium™ Controllers do not perform genetic sequencing. (Tr. (Pachter) at 776:4-22; CX-0568 (Schnall-Levin Dep. Tr.) at 98:2-15; CDX-0007.0007.). Instead, Respondent's Chromium™ Controllers and kits operate together to prepare droplets containing genetic samples for subsequent analyses to be used in other, third-party sequencing instruments. (CX-0568C (Schnall-Levin Dep. Tr.) at 98:2-15; Tr. (Pachter) at 776:4-22.).

Respondent's Chromium™ Controllers, much like competing NGS products, are expensive. According to Dr. Ryan Sullivan,[11] one of Respondent's experts on its product offerings and their price points and positions in the product market, "Respondent's customers have invested in a Chromium™ Controller or a Chromium™ Single Cell Controller, which have list prices of $125,000.00 and $75,000.00 respectively." (RBr. at 99 (citing Tr. (Sullivan) at 1270:6-1271:6); *see also* Tr. (Schnall-Levin) at 1051:23-1052:5, 1077:13-21; Tr. (Mulhern) at 311:10-312:25, 330:5-331:15; RDX-0005C.0006.).

Researchers typically access NGS technologies, including substitutes for Respondent's Accused Chips and Chromium™ Controllers, through "core facilities" and genomics [12]consortia. (Tr. (Pachter) at 769:25-770:15.). Core facilities are centralized hubs for researchers to conduct experiments using a variety of instrumentation. (*Id.* at 772:8-13.). Core facilities "try to work in

[11] Respondent called Dr. Ryan Sullivan to testify as an expert witness on Friday, May 11, 2018, with respect to "[m]atters relating to the calculation of bond, including any price differential between 10X's products and Bio-Rad's products and comparable licensing." (RPSt. at 4.). Dr. Sullivan has provided professional economic services for more than 25 years. (Tr. (Sullivan) at 1266:21-24.). At the time of the Hearing, Dr. Sullivan was CEO of Intensity Corporation. (*Id.* at 1267:8-11.).

[12] Genomics is a discipline in genetics that applies recombinant DNA, DNA sequencing methods, and bioinformatics to sequence, assemble, and analyze the function and structure of genomes (the complete set of DNA within a single cell of an organism).

some redundancy" in their equipment in the event that certain, specific instruments are broken or otherwise unavailable. (*Id.* at 772:14-773:7.). Dr. Schnall-Levin and Ms. Mulhern corroborated each other's testimony that researchers often use multiple NGS products, and sometimes interchangeably, including those offered by other companies, such as Illumina, Oxford Nanopore, Pacific Biosciences, DoveTail, and Ion Torrent. (Tr. (Mulhern) at 301:13-302:13; CX-0518.0007, -0008; CX-0568C (Schnall-Levin Dep. Tr.) at 195:9-196:14.).

2. Respondent's "Solutions" in the NGS Marketplace

Respondent divided its product offerings into three (3) "solutions" for the purposes of assessing and describing its competition and to support its analysis whether any recommended remedial orders, and specifically a limited exclusion order, would deprive consumers of specific research applications that would harm the public interest. (RRBr. at 44-47.). An important clarification is that each of Respondent's "solutions" is applied in research and not in what would be described as clinical settings. (Tr. (Pachter) at 764:13-24, 769:25-774:5; CDX-0002C.0005).

A cornerstone of Respondent's public interest argument is that Respondent is pioneering new markets and new applications that currently lack viable substitutes for Respondent's "solutions." (RRBr. at 49 (citing Tr. (Schnall-Levin) at 1081:11-1082:10).).

a) Respondent's "Linked Read Solution" for the "Long Range" Market Segment

Respondent's "Linked Read Solution" uses the Chromium™ Controller with Respondent's GEM-Q Chip and [redacted]. (Tr. (Schnall-Levin) at 1046:7-1047:15; *see also* Tr. (Hindson) at 1028:1-5; CX-0568C (Schnall-Levin Dep. Tr.) at 34:13-21.). This solution specifically allows the "sequencing of the entire

genome or exome, and phasing or haplotyping that information to determine if a mutation is on the set of chromosomes from the mother or the father." (RBr. at 88 (citing Tr. (Schnall-Levin) at 1046:7-1047:15).). In what Respondent described as its "long range" market segment for this solution,[13] Respondent's market penetration is [redacted]. (Tr. (Mulhern) at 298:21-299:7; *accord* CX-0568C (Schnall-Levin Dep. Tr.) at 60:2-10.).

b) Respondent's "Single-Cell" Solutions for the "Single Cell RNA-Seq Transcriptome" Market Segment

Respondent's "Single-Cell Gene Expression Solution" uses either the Chromium™ or Chromium™ Single Cell Controller with Respondent's GEM-U Chip and [redacted]. (Tr. (Schnall-Levin) at 1046:16-1049:2; *see also* Tr. (Hindson) at 1028:1-5; CX-0568C (Schnall-Levin Dep. Tr.) at 34:13-21.). This solution is used by the Human Cell Atlas consortium, which "involves hundreds of labs from across different countries that are trying to map out all of the different cell types out of the trillions of cells that are present in the human body." (*Id.*).

Respondent's "Single-Cell V(D)J Solution" also uses either the Chromium™ or Chromium™ Single Cell Controller with Respondent's GEM-U Chip and [redacted]. (Tr. (Schnall-Levin) at 1046:16-19, 1053:16-1054:19; *see also* Tr. (Hindson) at 1028:1-5; CX-0568C (Schnall-Levin Dep. Tr.) at 34:13-21.). This solution allows "mapping of T-cell or B-cell receptors on a single-cell level that allows

[13] Dr. Schnall-Levin explained that "long-range sequencing" is "sequencing that gets you information that's, you know, larger than what you would get with next-generation sequencing, which is on the order of kind of low hundreds of base pairs of information" and that "the ultimate idea is to get you information that you lose when you only read these 300, say, base SNPs. So things like structural variation, how the mutations are arranged on, you know, chromosomes relative to each other . . . ." (CX-0568C (Schnall-Levin Dep. Tr.) at 81:24-82:12.).

researchers to understand at a molecular level what a given immune cell is going to target and uses that to map out the gene expression from the cell and understand the attack or non-attack state of the cell." (*Id.*).

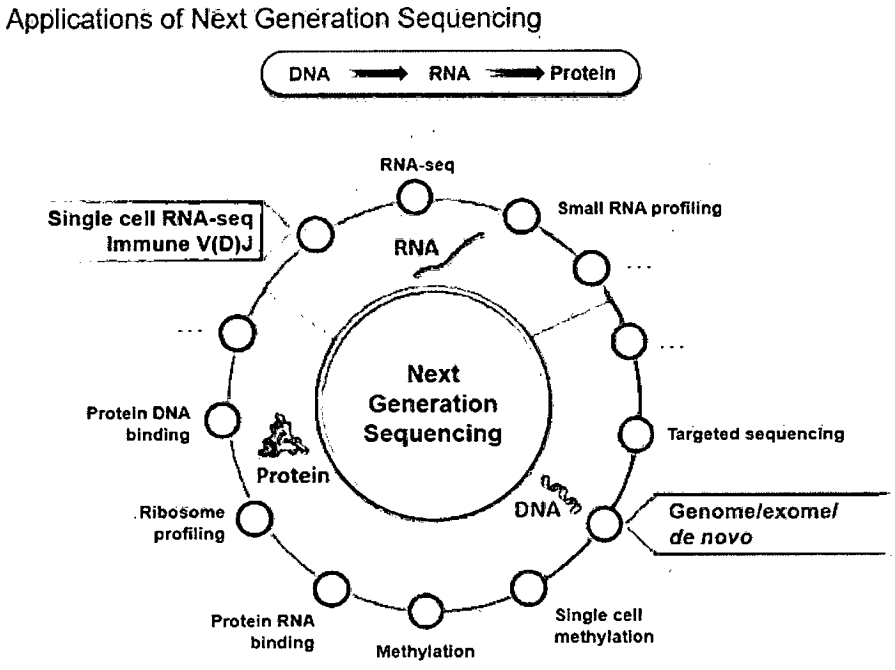
Respondent's "Single-Cell Gene Expression Solution" and "Single-Cell V(D)J Solution" appear to occupy the "single cell RNA-Seq transcriptome" market segment. (Tr. (Mulhern) at 300:10-301:7; JX-0149; CX-0568C (Schnall-Levin Dep. Tr.) at 56:3-57:10.). Respondent's penetration in this market segment is approximately [redacted]. (*Id.*).

As explained below, in general, it appears that Respondent's "solutions" have significant competition. (JX-0148C; JX-0048C; Tr. (Pachter) at 777:17-23, 779:19-24, 780:8-13, 780:22-781:4, 787:21-788:9, 803:10-14; CDX-0007.0007, 14; Tr. (John Stuelpnagel)[14] at 1309:24-1311:22.).

Figure No. 1, below, depicts NGS and the different types of research that is involved, including what most consumers may be familiar with, i.e., DNA sequencing.

[14] When he testified during the Hearing on May 11, 2018, Dr. John Stuelpnagel was the Chairman of 10X. (Tr. (Stuelpnagel) at 1293:9-11.). Respondent identified Dr. Stuelpnagel as a fact witness to testify about matters relating to 10X, including the company, its history, and its products. (RPSt. at 4.).

Figure No. 1: Complainants' Depiction of the NGS Marketplace Highlighting Application Areas Targeted by Respondent (in Red ("Single-Cell Gene Expression Solution" and "Single-Cell V(D)J Solution") and in Blue ("Linked Read Solution"))



(CDX-0007.0003 (introduced during Dr. Pachter's testimony).).

3. There Is Competition in Respondent's "Long Range" Market Segment

With respect to Respondent's "Linked Read Solution," Complainants identified some of Respondent's competitors from Respondent's own documents that include at least: Pacific Biosciences, Oxford Nanopore, Illumina, DoveTail Genomics, and BGI. They appear to be competitors for Respondent's whole genome, whole exome, and *de novo* products. (JX-0148C; CX-0135C.0008; CX-0568C (Schnall-Levin Dep. Tr.) at 181:2-182:19, 186:3-4, 192:5-15, 239-240; Tr. (Pachter) at 774:6-20, 777:17-778:5, 779:19-24, 780:8-13, 780:22-781:4.). A chart of Respondent's competitors engaged in the same type of research, according to Complainants, is provided in Figure Nos. 2 and 3, below.

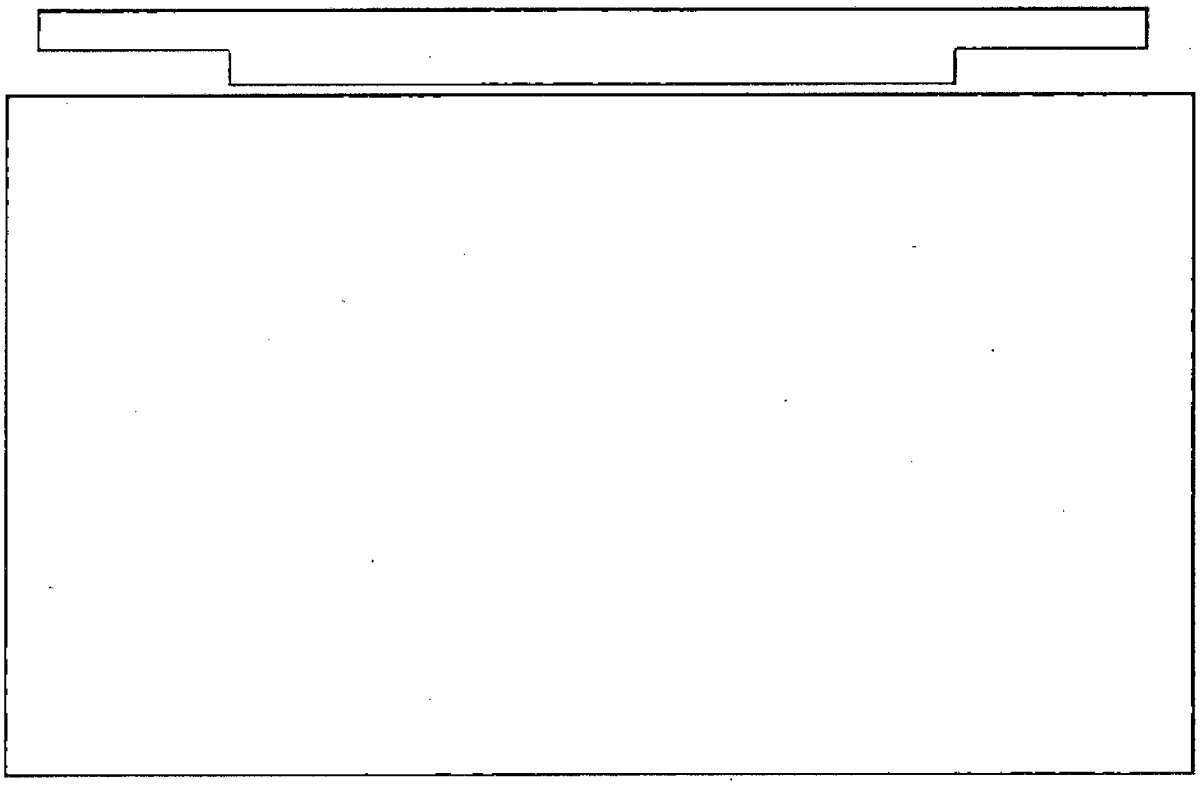
In rebuttal, Respondent critiqued Pacific Bioscience's and Oxford Nanopore's products as being less desirable than its own, or for having "higher error rates and lower cell throughput." (RBr. at 93 (citing Tr. (Schnall-Levin) at 1062:22-1063:25, 1131:21-1132:5; RX-0148C.0003, -0004; CX-0131.0055; CX-0568C (Schnall-Levin Dep. Tr.) at 209:21-210:25).). Similarly, Respondent distinguished Illumina, DoveTail, and BGI for lacking features such as "structural variance, haplotype phasing, or sequence difficult regions of the genome." (Tr. (Schnall-Levin) at 1064:1-9, 1065:9-22; CX-0131.0052; RRBr. at 45.). In other words, Respondent argued that while it has other competitors for its "Linked Read Solution," the inferior quality of the products, or their lack of certain features that Respondent's products offer limits the significance of Respondent's nominal competitors as true competitors.

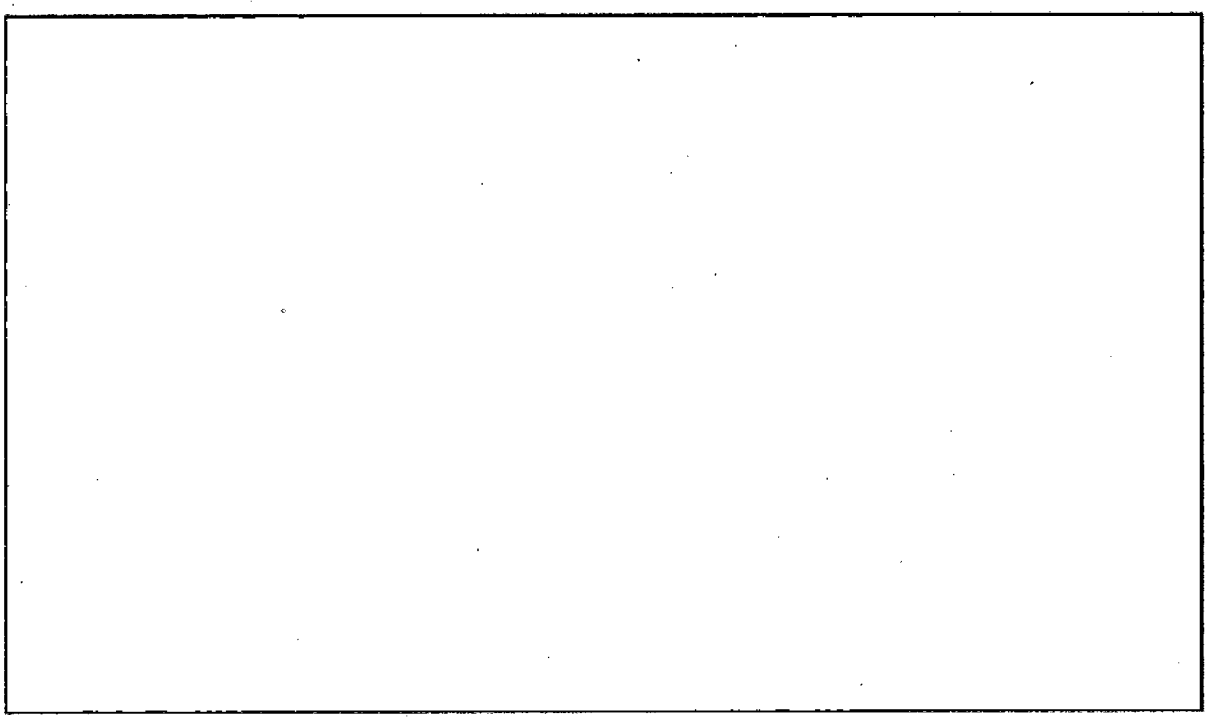
However, Respondent identified only one research application that was purportedly not possible without Respondent's "Linked Read Solution": Dr. Lo's non-invasive prenatal testing. (Tr. (Schnall-Levin) at 1045:12-1046:19, 1086:20-1088:9; RBr. at 88.). Yet, Dr. Schnall-Levin appeared to concede that one of Pacific Biosciences' products would suffice as a substitute for Respondent's "Linked Read Solution" in non-invasive prenatal testing, but with some performance limitations which he did not specifically describe. (Tr. (Schnall-Levin) at 1088:15-1089:4.). As Dr. Schnall-Levin testified: "you look at the actual performance, there's an enormous difference." (*Id.*). Moreover, as Dr. Schnall-Levin noted, Dr. Lo's research appears to occur only in China, with potential clinical applications directed to the Chinese marketplace, not the United States. (*Id.*). In other words, according to Complainants, there would be no impact on public interest in the U.S. if Respondent's "Linked Read Solution" were unavailable for the type of pre-natal application that appears to be in use only in China.

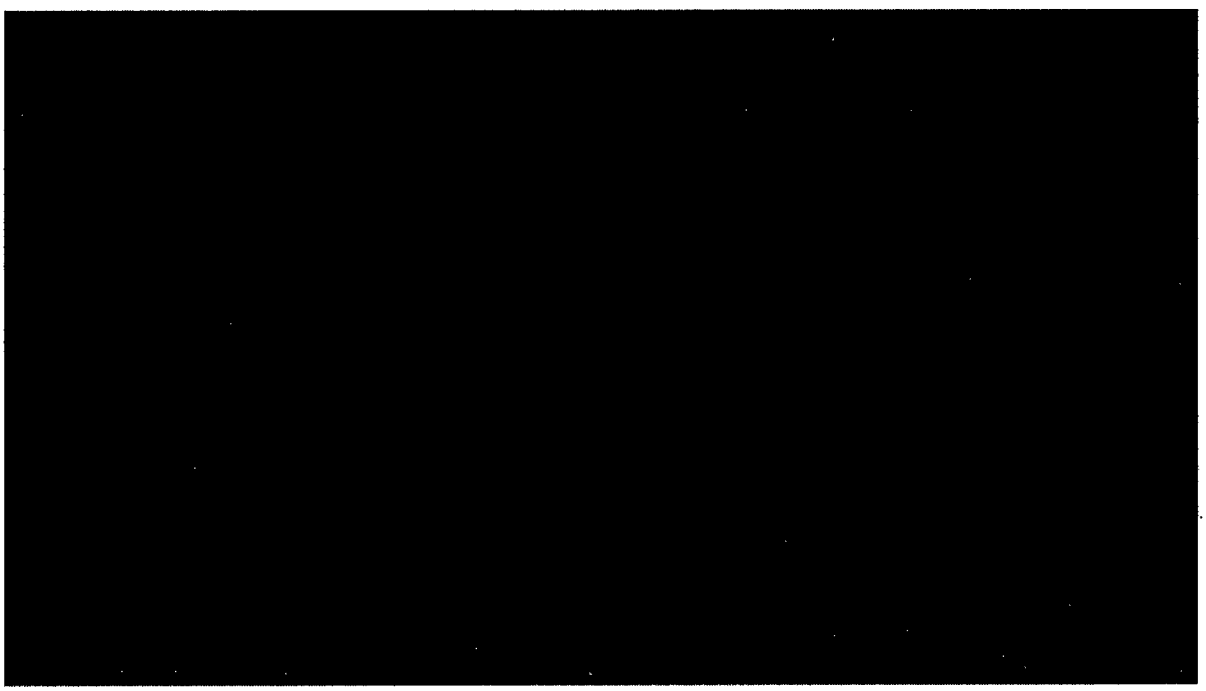
Figure No. 2: Complainants' Depiction of Competition in the "Long Range" Market Segment for Respondent's "Linked Read Solution"

DNA					
	Applications				
	Whole genome	Whole exome	*De novo*	Phasing	Methylation
Illumina	+	+	+	+	+
Oxford Nanopore	✓	✓	✓	✓	✓
Pacific Biosciences	✓	✓	✓	✓	✓
Hi-C (DoveTail)	✓	✓	✓	✓	
10X Chromium	✓	✓	✓	✓	
Bio-Rad DropPhase				✓ (targeted)	

(CDX-0007.0008 (introduced during testimony of Dr. Pachter).).







(JX-0148C.0003 to-0006 (dated 2016).).

4. There Is Competition in Respondent's "Single Cell RNA-Seq Transcriptome" Market Segment

With respect to the "single cell RNA-Seq transcriptome" market segment, in [redacted], Complainants and Illumina, in support of Respondent's assertion that it offers unique products in this market segment, provided a [redacted]. (JX-0023C). The presentation states: [redacted] (*Id.*). This assessment comports with an undated presentation that appears to be from 2017 or before, entitled [redacted] The same presentation predicts the [redacted] (JX-0041C.0005.).

Consistent with this prediction, in a presentation entitled [redacted]. (JX-48C.0005 ([redacted]).).

a) Within the "Single Cell RNA-Seq Transcriptome" Market Segment, There Is Competition for Respondent's "Single-Cell Gene Expression Solution"

With respect to Respondent's "Single-Cell Gene Expression Solution," Complainants

[15] 2H18 stands for the second half of 2018. (Tr. (Tumolo) at 157:21-23.).

cited one of Respondent's documents that: "[a] number of companies, including Complainants, have single cell RNA-Seq whole transcriptome sample preparation products that directly compete with, are often superior to, and can substitute for the accused Respondent single cell RNA-Seq whole transcriptome sample preparation products." (CBr. at 90 (citing Tr. (Pachter) at 787:21-788:9, 789:18-780:2; Tr. (Mulhern) at 299:8-14, 332:13-333:15; CDX-0007.0014; CX-0568C (Schnall-Levin Dep. Tr.) at 55:13-58:12; JX-0048C).). Column 1 of Figure No. 4 below shows "whole transcriptome" products that, according to Complainants, compete with Respondent's "Single-Cell Gene Expression Solution."

Specifically, with regard to Respondent's example of the Human Cell Atlas consortium for which Respondent is a "preferred partner,"[16] Dr. Pachter testified in a conclusory fashion that "researchers already have access to different technologies," and that he "do[esn't] think their work would be stopped if the Respondent was taken off the market." (Tr. (Pachter) at 827:2-828:3; Tr. (Schnall-Levin) at 1047:14-1051:22.).

Respondent rebutted Dr. Pachter's statement, in keeping with its general critique that its competitors provide lower quality products than Respondent does, by describing competing products as "a low-throughput technology," having a "high doublet rate," presenting a "cell size limit and cumbersome workflow." (RRBr. at 45-47.). According to Respondent, its "tremendous success" is attributable to the "quality of its data" and "its gel beads, barcodes, and visualization and analysis software," which "really speeds up their research." (*Id.* (citing Tr. (Schnall-Levin) at 1059:2-1061:6, 1084:16-25; JX-0036C; JX-0024C).).

Respondent cited a specific example of a Human Cell Atlas dataset of 500,000 cells that

[16] Although Respondent is a "preferred partner," consortium members are free to use NGS products from other companies. (RBr. at 89.).

purportedly ***requires*** the use of Respondent's "Single-Cell Gene Expression Solution" because it "measure[s] many different cells at once and so it makes a study like that practical." (Tr. (Schnall-Levin) at 1048:16-1051:7; RDX-0010.). According to Dr. Schnall-Levin, due to its scale, a dataset of 500,000 cells "could not realistically be studied using the SmartSEQ technology discussed by Dr. Pachter." (*Id.*).

There is some evidence on three (3) existing "Human Cell Atlas Previous Datasets," including the above-mentioned 500,000 cell dataset, but it is unclear where each dataset was formulated or where it is used predominantly. (*See* CX-0871.). What is known (and unrebutted) is that most of the Human Cell Atlas research is conducted *outside* the U.S. (Tr. (Pachter) at 877:2-9 (emphasis added).). It is also unrebutted that the other two Human Cell Atlas datasets are much smaller than the 500,000-cell dataset. (*See* CX-0871.). They contain approximately 10,000 and 6,000 cells, respectively, and one was created using SmartSEQ technology, which competes with Respondent's "Single-Cell Gene Expression Solution." (*Id.*; Tr. (Pachter) at 827:2-828:3.). Therefore, the weight of the evidence, including CX-0871 and Dr. Pachter's testimony, undermine Dr. Schnall-Levin's claim that without the Respondent's "Single-Cell Gene Expression Solution" and, specifically, its ability handle large datasets, work on the Human Cell Atlas "would be severely disrupted." (*Id.* at 1051:8–11.).

Figure No. 4: Complainants' Depiction of Competition for Respondent's "Single-Cell Gene Expression Solution" and "Single-Cell V(D)J Solution"

Single Cell RNA-seq		
	Whole Transcriptome	V(D)J
10X Chromium 3'	✓	✓
Fluidigm	✓	✓
Drop-seq (Dolomite)	✓	✓
Smart-seq (Clontech)	✓	
Bio-Rad ddSeq	✓	
inDrop (1CellBio)	✓	

(CDX-0007.0014 (introduced during testimony of Dr. Pachter).).

b) Within the "Single Cell RNA-Seq Transcriptome" Market Segment, There Is Competition for Respondent's "Single-Cell V(D)J Solution"

Another of Respondent's solutions, that is the "Single-Cell V(D)J Solution," is new and not yet established in the field. Dr. Pachter testified that he was not aware of "any papers that have been published reporting the use of Respondent's single cell V(D)J technology" because "analysis of [V(D)J] at the single cell level is very new. . . . I don't think it's clear what really the value will be and what one will learn from that." (Tr. (Pachter) at 803:19-804:11.). However, Dr. Pachter agreed that "single cell RNA sequencing research is important and transformative" and that "V(D)J at the single cell level" is "interesting." (*Id.* at 804:5, 889:11–13.).

Complainants asserted, again by citing Dr. Pachter's conclusory testimony, that "there are already competing single cell RNA-Seq V(D)J products, such as those of Fluidigm and Dolomite (Drop-seq), which can substitute for the 10X product." (CBr. at 94 (citing Tr. (Pachter) at

803:10-14).). Rebutting Dr. Pachter's testimony with respect to Dolomite (Drop-seq), Dr. Schnall-Levin stated that he had not seen any V(D)J-type "single-cell paired receptor work on Drop-seq at all," leaving unrebutted Dr. Pachter's testimony with respect to Fluidigm competing with Respondent's "Single-Cell V(D)J Solution." (CX-0568C (Schnall-Levin Dep. Tr.) at 45:14-17, 45:22-46:11, 290:9-292:18.). Respondent also challenged the desirability of products that compete with its "Single-Cell V(D)J Solution," including offering "evidence showing performance issues with" Fluidigm and Dolomite. (RRBr. at 47.).

During his Hearing testimony, Dr. Schnall-Levin discussed at least one application that purportedly uses and requires Respondent's "Single-Cell V(D)J Solution," that is the work of Dr. Aude Chapuis,[17] a medical researcher at the Fred Hutchinson Cancer Research Center in Seattle.[18] (Tr. (Schnall-Levin) at 1053:16-1054:5.). Dr. Schnall-Levin explained in conclusory fashion that "there really is no alternative that provides what she's using the single cell V(D)J product for[.]" (*Id.* at 1054:6-19.).

While Respondent's expert, Dr. Schnall-Levin, emphasized the importance of Respondent's "Single-Cell V(D)J Solution" in cancer research, Complainants' expert, Dr. Pachter, provided examples of competing products that also are used in cancer research. His general observation, without specifically addressing Dr. Chapuis' research, was that

[17] Respondent did not offer a declaration or any other form of testimony from Dr. Chapuis about her use of Respondent's "Single-Cell V(D)J Solution." Consequently, there is no information whether Dr. Chapuis could substitute other products for Respondent's for any reason, whether because of price or the uniqueness of Respondent's product.

[18] Accordingly to Dr. Schnall-Levin, Dr. Aude Chapuis profiles "the immune cells that infiltrate tumors" with the goal of "understand [ing] the naturally occurring immune cells that will be attacking a tumor," "us[ing] that understanding to reengineer synthetic immune cells that would go on to do a better job attacking a tumor," and "eventually us[ing] that as a form of immunotherapy to treat cancers." (Tr. (Schnall-Levin) at 1053:19-154:5.).

Respondent's "Single-Cell V(D)J Solution" was largely undistinguishable from other similar products, and that none of the features of Respondent's "Single-Cell V(D)J Solution" were essential for cancer research. (Tr. (Pachter) at 802:18-807:22.). The Parties' experts were clearly at odds. However, beyond the clearly important work of Dr. Chapuis at the Fred Hutchinson Cancer Research Center, Respondent named no other research center or project whose work could not be performed without Respondent's "Single-Cell V(D)J Solution." Respondent did not even demonstrate that its own product was the only product that Dr. Chapuis could use in her research.

D. Public Interest Factors Weigh in Favor of Full Implementation of the Recommended Remedial Orders

1. Public Health and Welfare Considerations Favor Full Implementation of the Recommended Remedial Orders

It appears that only one technology application of Respondent's products, the "Single-Cell V(D)J Solution" that Dr. Chapuis uses at the Fred Hutchinson Cancer Research Center in Seattle, might cease in the U.S. because of the recommended remedial orders. (Tr. (Schnall-Levin) at 1053:16-1054:5.). While Complainants presented Dr. Pachter's testimonial observation that a Fluidigm product could substitute for Respondent's "Single-Cell V(D)J Solution," neither Complainants nor Respondent offered any explanation or evidence whether the Fluidigm product was an adequate substitute for Respondent's "Single-Cell V(D)J Solution," or even whether Dr. Chapius would consider using Fluidigm. (Tr. (Pachter) at 803:10-14.). As noted previously, without direct testimony from Dr. Chapius, the true impact of a remedial order that would preclude Respondent's "Single-Cell V(D)J Solution" from Dr. Chapius' research cannot be evaluated.

Respondent argued generally, with little explicit and no direct evidence, that the

recommended remedial orders would cause Respondent's customers in the U.S. to experience setbacks in terms of loss of data or samples. (RBr. at 99.). It may be true that this would happen if researchers tailor their workflows based upon their chosen NGS technologies, as Dr. Schnall-Levin suggested. (*See* Tr. (Schnall-Levin) at 1046:16-25, 1054:6-19.). However, the NGS industry is research-based, not clinically-oriented. The NGS industry is apparently highly competitive in terms of potential product substitution. (*See* Tr. (Pachter) at 764:13-24, 769:25-774:5; CDX-0002C.0005.). Moreover, V(D)J technology, and applications that use that technology, are still considered to be new, dynamic, and uncertain in terms of research value. (Tr. (Pachter) at 803:23-804:11.).

Consequently, to find in Respondent's favor on this public interest factor is speculative at best. Even if Respondent has a [redacted] share in one market segment, there is insufficient evidence to calculate the impact of the exclusion of Respondent's Accused Chips on U.S.-based research. There is ***no*** *e*vidence that the loss of Respondent's Accused Chips will impact clinical applications. Therefore, Respondent has not met its burden to prove that the public health and welfare factor favors the preclusion, curtailment, or delay of the implementation of any remedial orders. For the reasons articulated above, public health and welfare considerations favor the implementation of any recommended remedial orders without reservation.

2. Competitive Conditions in U.S. Economy Favor Full Imposition of the Recommended Remedial Orders

There is little evidence, let alone compelling evidence, that remedial orders would cause a loss of competition in the NGS industry. As an initial matter, Complainants inappropriately framed their "competitive conditions" analysis in terms of the NGS industry as a whole. (CBr. at 84-84.). This made it easy for Complainants to argue, if Ms. Mulhern's figures are correct, that

Respondent's sales account for [redacted]. (Tr. (Mulhern) at 280:15-281:3; JX-0036C; CX-0522C; CDX-0002.0003.).

However, even given limited public interest evidence in the record, it is clear that the NGS industry has a number of market segments. The salient inquiry for this factor, notwithstanding Respondent's relatively small overall NGS market share, is whether remedial orders that would remove Respondent's products from the NGS market segments in which they compete would adversely affect "competitive conditions" within the U.S. economy. As mentioned above, the two (2) market segments at issue are "long range" and "single cell RNA-Seq transcriptome." (CX-0568C (Schnall-Levin Dep. Tr.) at 94:23-96:19, 98:2-15.). According to unrebutted testimony, Respondent's penetration in the "long range" segment is [redacted]. (Tr. (Mulhern) at 298:21-299:7; CX-0568C (Schnall-Levin Dep. Tr.) at 60:2-10.). Again, based upon unrebutted testimony, in the "single cell RNA-Seq transcriptome" segment, Respondent's penetration is approximately [redacted]. (Tr. (Mulhern) at 300:10-301:7; JX-0149; CX-0568C (Schnall-Levin Dep. Tr.) at 56:3-57:10.).

Respondent has significant market share in each of the two (2) referenced market segments. However, as depicted above in Figure Nos. 2, 3, and 4, Respondent also has competitors in each segment. (CDX-0007.0008, -0014; JX-0148C.0003 to -0006; JX-0048C.0005); *Digital Media Devices*, Comm'n Op. at 120 ("consideration is given to whether there are reasonable substitutes for the devices subject to the exclusion order in terms of features, price points, and other pertinent factors"). That said, it is not clear from the evidentiary record whether and how quickly the removal of Respondent's products from these market segments could be absorbed by its nominal competitors.

While competition for Respondent's "Linked Read Solution" and "Single-Cell Gene

Expression Solution" appears somewhat robust, that is not necessarily the case for Respondent's "Single-Cell V(D)J Solution." Dr. Schnall-Levin testified that he had not seen any V(D)J-type "single-cell paired receptor work on Drop-seq at all," suggesting that any remedial orders might leave Fluidigm as the only product provider in the V(D)J category. (CX-0568C (Schnall-Levin Dep. Tr.) at 45:14-17, 45:22-46:11, 290:9-292:18.).

However, Respondent's internal documents tell a different story. In a presentation from 2017 (or earlier), Respondent asserted that within [redacted] (JX-0041C.0005.). As Dr. Pachter testified, the NGS industry is highly competitive, and the V(D)J space in particular is new, dynamic, and uncertain in terms of research value. (Tr. (Pachter) at 803:23-804:11.). While this testimony may be speculative, even [redacted].

Because direct evidence of possible adverse impacts of remedial orders on competition is fairly minimal, and because it appears that Respondent has many nominal competitors in the general NGS market, Respondent failed to meet its burden to prove that competitive conditions in U.S. economy weigh against the full implementation of the recommended remedial orders.

3. U.S. Production of the Same Products, or Products that Would Be Considered To Be "Like" Products, Favor Respondent's Requested Curtailment of the Recommended Remedial Orders

Unlike the first two (2) public interest factors, the third factor weighs in favor of providing the remedial relief Respondent sought. Respondent manufactures and assembles all of its Chromium™ Controllers and kits [redacted]. (Tr. (Schnall-Levin) at 1052:6-11.).

Respondent imports its Accused Chips for approximately [redacted] each. (CX-0612C (Wyatt Dep. Tr.) at 72:4-19). Respondent assembles its Accused Chips into kits [redacted], which are then sold to customers worldwide. (Tr. (Hindson) at 956:25-957:20; Tr. (Pachter) at 884:22-885:19.). Respondent's Chromium™ Controller and Chromium™ Single Cell Controller cannot be used without the accused, imported GEM-Q or GEM-U Chips, or the Chip SE. (Tr. (Hindson) at 1052:6–11.). The same is true [redacted]. (*Id.*).

Ms. Mulhern, Complainants' economic expert, testified that Respondent's lost sales occasioned by the recommended remedial orders would simply and easily shift sales to competitors with United States production facilities. (Tr. (Mulhern) at 304:3-305:22.). She intimated that neither United States-based research nor clinical applications would adversely suffer from a substitution of products competitive with those sold by Respondent. (*Id.*). However, Ms. Mulhern's testimony was general. She did not "speak to the scientific interchangeability" of the products at issue. (Tr. (Mulhern) at 367:9-369:6.). In other words, because she had no information on the specific usage of Respondent's products and competing products in specific market segments, her opinion was unsupported by facts.

Moreover, some evidence suggests the Ms. Mulhern's observation may be incorrect. Respondent made a persuasive showing that excluding its accused GEM Chips, Chip SE, and Chip GB from importation would curtail Respondent's sales of Chromium™ Controllers and kits, which in turn would drive down U.S. production. (RBr. at 90, 92; RRBr. at 48.). Importantly, Respondent's Accused Chips are the only components of Respondent's systems not [redacted]. (Tr. (Santiago) at 1264:9-25; Tr. (Hindson) at 956:20-957:23; Tr. (Mulhern) at 362:14-363:15).

In rebuttal, Complainants have not provided compelling, let alone any specific, discrete, evidence to prove that a resulting increase in sales to Respondent's competitors would necessarily leave domestic production unaffected. There is evidence that Respondent's competitors have manufacturing facilities in the United States, but there is ***no*** evidence whether Respondent's competitors manufacture their microfluidic ***instruments*** in the United States. (Tr. (Mulhern) at 305:9-22.).

For example, on cross-examination, Ms. Mulhern did not provide information on where Complainants' ddSEQ instrument is made, stating only that Complainants manufacture their AutoDG droplet generator and [redacted] reagents used with Complainants' ddPCR and ddSEQ sample preparation systems in Hercules, California. (Tr. (Mulhern) at 303:20-304:14, 364:13-366:2.). Ms. Mulhern also asserted that, based on publicly available information, Pacific Biosciences "currently manufacture[s] critical reagents in-house" in Menlo Park, California. (*Id.* at 305:9-22.). Additionally she asserted, without specifics, that Illumina has several U.S. manufacturing facilities in the U.S. (*Id.*).

Yet, this information is incomplete. Neither party has identified a single competitor of Respondent that, [redacted]. Consequently, the weight of the evidence suggests that the recommended remedial orders would cause U.S. instrument manufacturing to decline slightly because of the loss of the manufacture of [redacted] and that such a loss would not necessarily shift to a competing facility manufacturing instruments in the United States.

In short, although the impact of the recommended remedial orders on U.S. production is not entirely clear from the record, the weight of the evidence suggests that U.S. production

would decrease at least slightly, and not remain the same, due to the recommended remedial orders.

Thus, for the reasons articulated above, Respondent has done just enough to satisfy its burden that a consideration of U.S. production of the same or like products favors preclusion or modification of the remedial orders.

4. Effects on U.S. Consumers Favor Full Imposition of the Recommended Remedial Orders

For this public interest factor, Respondent related its "new market, new applications" argument to the impact on individual U.S. consumers. Respondent asserted that it "would be against the public interest to deny researchers the benefits arising from [] non-infringing features" of its accused products, such as "a carefully designed singulation channel" and "super-Poisson loading contribut[ing] to Respondent's superior cell capture and doublet rates[.]" (RBr. at 97-98.). As Dr. Stuelpnagel, Respondent's Chairman, testified with respect to the presence of identifiable competitors for Respondent's "solutions," "I don't think they're adequate replacements for what we do because what we do is so much better on every dimension of quality, we exceed every one of those competitors." (Tr. (Stuelpnagel) at 1293:11, 1300:7-16.). However, Dr. Stuelpnagel's statements were somewhat conflicting because he acknowledged that he is "not an expert in the field of the art for droplets" and that the "subtleties of the technologies are beyond [his] knowledge." (*Id.* at 1318:13-21.).

What is apparent from the evidentiary record is that across Respondent's product lines, competition exists. According to testimony from Ms. Mulhern, Dr. Pachter, and Dr. Schnall-Levin, researchers appear to use multiple NGS products, including Respondent's products and offerings from Illumina, Oxford Nanopore, Pacific Biosciences, DoveTail, and Ion Torrent. (Tr.

(Mulhern) at 301:13-302:13; CX-0518.0007, -0008; CX-0568C (Schnall-Levin Dep. Tr.) at 195:9-196:14.).

In the NGS industry, including in market segments targeted by Respondent, Respondent's significant market penetration in combination with documentary and testimonial evidence of direct competition for Respondent's "solutions" as discussed above, attest to a consumer experience free from any purported reliance on Respondent's products and their "non-infringing" features. Against this backdrop, any inconvenience occasioned by requiring researchers to proceed without access to Respondent's products is not a sufficient justification to curtail Complainants' intellectual property rights. *Certain Personal Data & Mobile Comm'ns Devices & Related Software,* Inv. No. 337-TA-710, Comm'n Op., 2011 WL 12488979, at *69 (Dec. 29, 2011) ("[T]he mere constriction of choice cannot be a sufficient basis for denying the issuance of an exclusion order.").

Respondent's reliance on the Commission's opinion in *Acceleration Tubes* is misplaced. Inv. No. 337-TA-67, Comm'n Op. at 21. In that Investigation, the Commission deemed an exclusion order inappropriate where its issuance prevented "the continued availability of tubes *essential* to [nuclear physics] research programs." *Id.* at 30 (emphasis added). By contrast, here the evidence suggests that Respondent's product offerings are not necessarily essential to NGS research programs. Respondent provided limited evidence that its "Single-Cell V(D)J Solution" might be essential to Dr. Chapuis' cancer research at the Fred Hutchinson Cancer Research Center in Seattle. However, with no direct evidence from Dr. Chapuis, any testimony from anyone else is largely speculative and unsupported. Moreover, as Dr. Pachter testified, and as even Respondent acknowledged, the research using V(D)J technology is new, dynamic, and uncertain in terms of research value, distinguishing V(D)J from nuclear physics research

programs of the 1980s. (Tr. (Pachter) at 803:23-804:11.).

For the reasons articulated above, Respondent has failed to meet its burden that a consideration of effects on U.S. consumers weighs against implementation of remedial orders. In sum, based on the evidentiary analysis, it is recommended that the public interest factors weigh in favor of the imposition of the recommended remedial orders without preclusion or modification.

II. RECOMMENDATION ON REMEDY AND BOND

This decision recommends: (1) a limited exclusion order directed to Respondent 10X Genomic, Inc.'s ("Respondent") microfluidic chips[19] that infringe one or more of asserted claims 1, 2, 14 and 15 of U.S. Patent No. 9,500,664 ("the '664 patent"), asserted claims 14, 16 and 17 of U.S. Patent No. 9,636,682 ("the '682 patent"), and asserted claims 1, 13, 14, 16 and 21 of U.S. Patent No. 9,649,635 ("the '635 patent") (collectively, "the Asserted Claims of the Asserted Patents"); (2) a cease and desist order directed to Respondent's microfluidic chips that infringe one or more of the Asserted Claims of the Asserted Patents; and (3) a bond rate during the Presidential Review Period set to 100% of entered value for Respondent's microfluidic chips that infringe one or more of the Asserted Claims of the Asserted Patents.

A. Legal Standard

Pursuant to Commission Rule 210.42, an ALJ must issue a recommended determination on: (i) an appropriate remedy if the Commission finds a violation of Section 337, and (ii) an

[19] Complainants accused the following microfluidic chips of infringing one or more of the Asserted Claims of the Asserted Patents: (1) Chromium™ Genome Chip ("GEM-Q Chip"); (2) Chromium™ Single Cell A Chip ("GEM-U Chip," and with GEM-Q Chip, the "GEM Chips"); (3) [redacted] ("Chip GB"); and (4) [redacted] ("Chip SE"). (*See, e.g.*, Initial Determination at 30.). It is a finding of the ID that the GEM Chips infringe one or more of the Asserted Claims of the Asserted Patents.

amount, if any, of the bond to be posted. 19 C.F.R. § 210.42(a)(1)(ii). When a Section 337 violation has been found, as has been found in this Investigation, "the Commission has the authority to enter an exclusion order, a cease and desist order, or both." *Certain Flash Memory Circuits and Prods. Containing the Same*, Inv. No. 337-TA-382, Comm'n Opinion on the Issues Under Review and on Remedy, the Public Interest and Bonding, at 26 (June 9, 1997).

Upon a finding of infringement, 19 U.S.C. § 1337(d) provides for a Limited Exclusion Order ("LEO"), directed to the products of named respondents, excluding any articles that infringe one or more claims of the asserted patents. 19 U.S.C. § 1337(d). A Cease and Desist Order ("CDO") is also appropriate where the evidence demonstrates the presence of commercially significant inventory in the United States. 19 U.S.C. § 1337(f); *see also Certain Crystalline Cefadroxil Monohydrate*, Inv. No. 337-TA-293, Comm'n Opinion, USITC Pub. No. 2391, 1991 WL 790061 at *30-32 (June 1991). Infringing articles may enter upon the payment of a bond during the sixty-day Presidential Review Period. 19 U.S.C. § 1337(j)(3). The bond is to be set at a level sufficient to "offset any competitive advantage resulting from the unfair method of competition or unfair act enjoyed by persons benefiting from the importation." *Certain Dynamic Random Access Memories, Components Thereof and Prods. Containing Same*, Inv. No. 337- TA-242, Comm'n Opinion, 1987 WL 450856 at 37 (Sept. 21, 1987).

B. A Limited Exclusion Order with a Certification Provision Is Warranted

In the event of a finding of violation of Section 337, Complainants have requested that the Commission issue a LEO prohibiting Respondent from importing, selling for importation, or selling after importation any infringing articles. (CBr. at 81.). Respondent contended that any remedial order should explicitly pertain only to model numbers of the articles, microfluidic chips, found to infringe. (RRBr. at 38.). Staff and Complainants disagreed. (SBr. at 55; CBr. at

81.).

Staff argued that tailoring a LEO only to model numbers of infringing chips is "contrary to Commission practice." (SBr. at 55-56.). According to Staff, such a LEO would "be subject to circumvention," as an importer "could simply create a new product, changing non-functional aspects of the infringing product so as to circumvent the exclusion order." (*Id.*).

Staff and Complainants are correct. "Commission practice is to direct remedial orders to all products 'covered by' the asserted claims as to which a violation has been found, not to limit the orders to . . . specific models." *Certain Mobile Tel. Handsets, Wireless Commc'n Devices, & Components Thereof* ("*Certain Handsets*"), Inv. No. 337-TA-578, Recommended Determination, 2010 WL 1436458, at *139 (Dec. 12, 2007). Respondent provided no specific justification for deviating from Commission practice. Instead, Respondent offered a string citation in its Post-Hearing Reply Brief to Commission opinions pertaining to tailored LEOs. (RRBr. at 38.). Respondent implied, without any explanation or analysis, that the evidentiary records presented in the referenced Commission opinions resemble the evidentiary record here with regard to a tailored LEO. Whether, or the extent to which, that is true is unclear. Thus, Respondent has failed to demonstrate that a deviation from standard Commission practice is warranted.

Respondent also requested "to certify the noninfringing products as entitled to entry pursuant to the procedures to be specified by the U.S. Customs and Border Protection." (RBr. at 81; RRBr. at 39.). Staff concluded that it "would not object to including a certification provision in any recommended relief." (SBr. at 56.). Complainants elected not to address this issue and instead highlighted generally the purported lack of "any defensible justification for undermining the relief with a 'carve-out' to the remedial orders." (CRBr. at 21.).

On this issue, Staff and Respondent prevail. A LEO with a certification provision is appropriate because whether Respondent's chips infringe one or more of the Asserted Claims of the Asserted Patents is not readily apparent by inspection. *Certain Digital Televisions & Certain Prods. Containing Same & Methods of Using Same*, Inv. No. 337-TA-617, Comm'n Op. at 11 (Apr. 23, 2009) ("Certification provisions are necessary to minimize the possibility that non-infringing products will be excluded from entry into the United States when CBP is unable to easily determine by inspection whether an imported product violates a particular exclusion order.").

As indicated by the prefix "micro" in "microfluidic" devices, differentiating between Respondent's infringing and non-infringing chips is not a trivial matter. As Dr. Santiago, Respondent's expert on the background of microfluidic technology, testified during the Hearing: "[s]o many of these chips across companies look very similar. They're sort of microchannels . . . something like a human hair in diameter. And sometimes smaller. Because of this, they're very difficult to see with a naked eye. So for example, a good way to do it is with a microscope." (Tr. (Santiago) at 1165:18-25.). Therefore, it is recommended that a LEO issue with a provision requiring Respondent to certify its non-infringing microfluidic chips "pursuant to the procedures to be specified by the U.S. Customs and Border Protection."

C. Respondent's Sales of GEM Chips During the Presidential Review Period Warrant a 100% Bond Applied to the Entered Value of the Accused Chips

Complainants requested that the Commission impose a 100% bond rate during the Presidential Review Period. (CBr. at 32.). In rebuttal, Respondent asserted that "the bond rate should be set at no more than 3%," based on a reasonable royalty analysis. (RBr. at 85.). Similarly, Staff recommended basing the bond determination on royalty rates revealed by

"comparable licenses in the industry" and "that royalty be set at 3% of entered value during the Presidential review period." (SBr. at 59.).

The Commission frequently sets the bond rate based on the difference in sales prices between patented domestic products and infringing products. *See, e.g., Certain Microsphere Adhesives, Process for Making Same, and Prods. Containing Same, Including Self-Stick Repositionable Notes*, Inv. No. 337-TA-366, USITC Pub. No. 3949, Comm'n Op. at 24 (Jan. 1996). In other instances where a direct comparison between a patentee's product and the accused product is not possible, the Commission has set the bond at a reasonable royalty rate. *See, e.g., Certain Integrated Circuit Telecommunication Chips and Prods. Containing Same, Including Dialing Apparatus*, Inv. No. 337-TA-337, Comm'n Op. at 41-43 (Aug. 3, 1993). However, Commission precedent allows for a 100 percent bond when it is not practical or possible to set the bond based on price differential. *Certain Voltage Regulators, Components Thereof and Prods. Containing Same*, Inv. No. 337-TA-564, Comm'n Op. at 79 (Public Version Oct. 19, 2007). The purpose of the bond is to protect the complainant from any injury. 19 U.S.C. § 1337(j)(3); 19 C.F.R. §§ 210.42(a)(1)(ii), 210.50(a)(3).

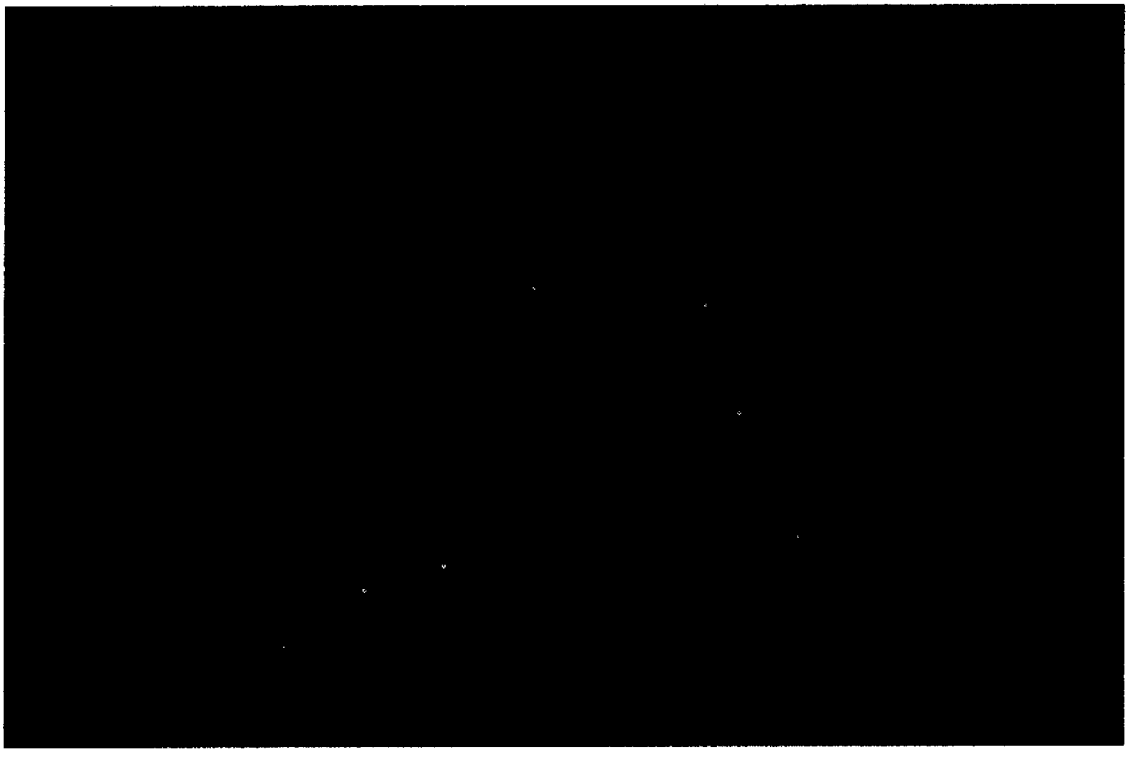
Complainants bear the burden of establishing the need for a bond, including the amount of bond. *See, e.g., Certain Rubber Antidegradants, Components Thereof & Prods. Containing Same*, USITC Pub. No. 3975, Inv. No. 337-TA-533, Comm'n Op. at 40 (April 2008); *Certain Coenzyme Q10 Prods. and Methods of Making Same*, Inv. No. 337-TA-790, Initial and Recommended Determination (Sept. 27, 2012) (recommending Commission not impose a bond because complainant failed in its burden to demonstrate the appropriate bond amount); *Certain Mobile Tels. and Wireless Commc'n Devices Featuring Dig. Cameras, and Components Thereof*, Inv. No. 337-TA-703, Recommended Determination (Jan. 24, 2011) (recommending no bond

because complainant did not meet its burden in providing evidence on the necessity of a bond); *Certain Liquid Crystal Display Devices and Prods. Containing the Same*, Inv. No. 337-TA-631, Comm'n Op. at 27-28 (July 14, 2009) (setting zero bond because complainant "simply claimed that it was impossible to conduct a price differential analysis" and "should not benefit from a lack of any effort to identify" relevant pricing information, particularly that which is in its possession).).

The Parties appear to agree that comparing prices of Complainants' protected domestic industry microfluidic chips and Respondent's infringing microfluidic chips is not appropriate for calculating a bond rate. (CRBr. at 33; SBr. at 58; RBr. at 81-86.). Staff and Respondent appear amenable to setting the bond based on a reasonable royalty rate. (RBr. at 85-86 ("any bond rate during the 60-day Presidential Review Period should be no more than 3%"); SBr. at 25 ("bond be set at 3% of entered value of infringing articles during the Presidential review period").). Dr. Ryan Sullivan,[20] Respondent's expert on the calculation of a bond, provided unrebutted testimony that a 3% bond rate was appropriate. (Tr. (Sullivan) at 1268:21-22.). He provided this opinion after reviewing several licensing agreements that "all relate to microfluidic systems or droplet generation," which collectively demonstrate [redacted] as depicted below in Figure No. 5. (*Id.* at 1278:10-15.). Specifically, Dr. Sullivan relied on a licensing agreement between [redacted] (depicted on far right of Figure No. 5) "relating to droplet generation technology" and in which the royalty rate was 3% of "net revenues." (*Id.* at 1279:14-15.).

[20] Respondent called Dr. Ryan Sullivan to testify as an expert witness on Friday, May 11, 2018, with respect to "[m]atters relating to the calculation of bond, including any price differential between 10X's products and Bio-Rad's products and comparable licensing." (RPSt. at 4.). Dr. Sullivan has provided professional economic services for more than 25 years. (Tr. (Sullivan) at 1266:21-24.). At the time of the Hearing, Dr. Sullivan was CEO of Intensity Corporation. (*Id.* at 1267:8-11.).

Figure No. 5: Respondent's Depiction of Royalty Rates in "Microfluidic Systems or Droplet Generation" Licensing Agreements Analyzed by Dr. Sullivan



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(RDX-0005C.0007 (introduced during the testimony of Dr. Sullivan).).

However, except for Staff, the Parties are silent on how to apply the bond rate to protect Complainants from injury. Staff "recommends that bond be set at 3% of entered value of infringing articles[.]" (SRBr. at 25.). By "infringing articles," Staff presumably refers to Respondent's microfluidic chips, which are valued at approximately [redacted] per chip. (CX-0612C (Wyatt Dep. Tr.) at 72:4–19; Tr. (Santiago) at 1264:9-25; Tr. (Hindson) at 956:20-957:23; Tr. (Mulhern) at 362:14-363:15.). However, Respondent does not sell microfluidic chips. Instead, it sells Chromium™ instruments that require Respondent's proprietary microfluidic chips to

operate (either directly for the GEM Chips and the Chip SE or indirectly for the [redacted]). (*See, e.g.*, Tr. (Schnall-Levin) at 1051:25-1052:21; Tr. (Hindson) at 954:2–25; CX-0568C (Schnall-Levin Dep. Tr.) at 34:13-21.). Respondent also sells kits that contain "consumables" such as infringing chips, gel beads, and reagents. (*See, e.g.*, RBr. at 81-82 (stating that "Bio-Rad's ddSEQ chips cannot be used in 10X's Chromium controllers, and 10X's GEM-Q and GEM-U Chips cannot be used in Bio-Rad's ddSEQ controller") (citing Tr. (Schnall-Levin) at 1052:6-11;Tr. (Mulhern) at 317:23-318:17).).

Imposing a royalty rate of 3% on only the entered value of Respondent's microfluidic chips could markedly underestimate the potential injury to Complainants posed by the continued importation of Respondent's infringing chips during the Presidential Review Period. This is because Chromium™ instruments and kits, not standalone chips, are the items that Respondent actually offers to customers to achieve sales victories over Complainants in head-to-head competition[21] and that Respondent also uses to leverage a first-mover advantage and accumulate early market share in emerging market segments.[22]

Moreover, the potential harm to Complainants of Respondent's importation of chips during the Presidential Review Period is inextricably linked to Respondent's sales of Chromium™ instruments and subsequent repeat sales of kits that do not interoperate with

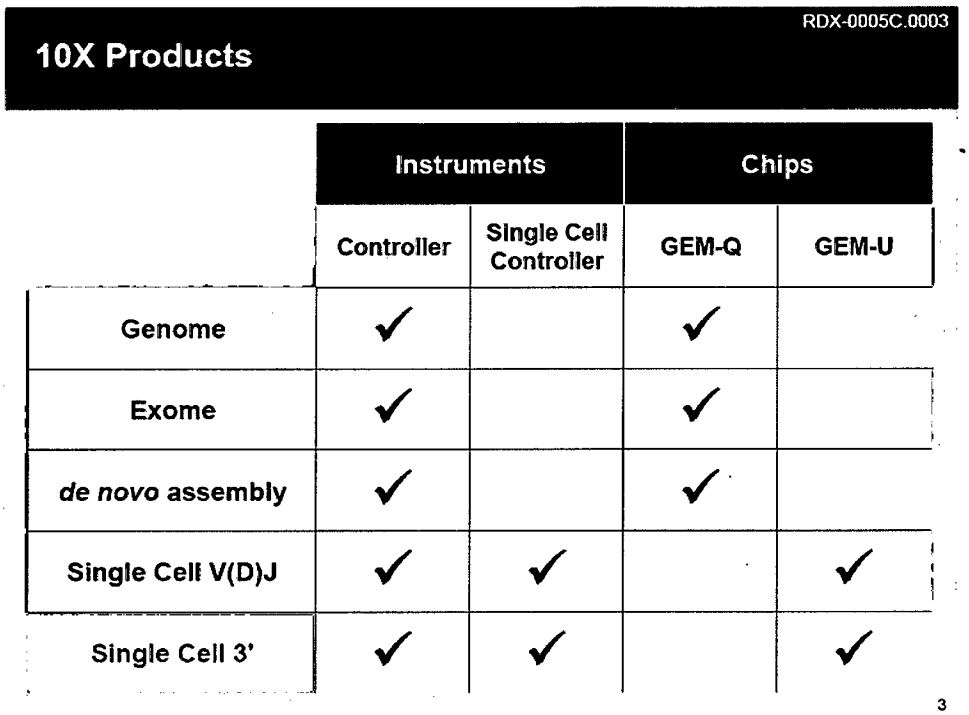
[21] Complainants cited two [redacted] (Tr. (Mulhern) at 307:17-308:18.).

[22] Respondent is purportedly pioneering new markets and new applications that currently lack viable substitutes for Respondent's "solutions." (RRBr. at 49 (citing Tr. (Schnall-Levin) at 1081:11-1082:10).). In "Single Cell Genomics," Respondent considers itself the market leader but nevertheless strives to [redacted] (JX-0041C.0005.).

competing products, as depicted below in Figure No. 6. (Tr. (Schnall-Levin) at 1052:16-21 ("every time you want to run a new experiment, you purchase a new set of reagents and consumables for that.").). The combination of these two factors makes it hard to ameliorate Complainants' potential injury by isolating Respondent's imported chips from the business environment in which they operate and imposing a small royalty on their entered value.[23]

[23] Moreover, in their respective remedy and bond, and public interest, analyses, Complainants and Respondent each alleged significant price discounting by the other Private Party. (*See, e.g.*, Tr. (Pachter) at 880:14-881:12 [redacted]; RX-1675C [redacted].). This evidence reveals is that, in a highly competitive NGS marketplace, competitors discount products to make sales. That is not remarkable. In light of the discussion supra, in the Remedy and Bond section, presenting inherent difficulties associated with pricing comparisons of Complainants' and Respondent's NGS products, evidence of price discounts, without more, is largely inconsequential to the public interest analysis. This is particularly true where, as here, price discount evidence is spotty, anecdotal, and often speculative with respect to relevance to a particular public interest factor. (*See, e.g.*, RBr. at 96 [redacted].).

Figure No. 6: Respondent's Depiction of the Integrated Nature of Its Chromium™ Instruments and GEM Chips, Broken Down by Respondent's "Solutions"



(RDX-0005C.0007 (introduced during the testimony of Dr. Sullivan).).

Basing the bond calculation on a royalty rate applied to the entered value of Respondent's microfluidic chips would also conflict to some extent with Dr. Sullivan's testimony. The royalty calculation set forth in the licensing agreement between [redacted], upon which Dr. Sullivan relied, requires a royalty payment of [redacted][24] (RX-0543C at 12.). Yet, it appears

[24] "'Net Revenues' means the gross amount billed or invoiced by Licensee, its Affiliates and Sublicensees (in each case the 'Invoicing Entity'), on all sales of Licensed Products and Licensed Services less: (a) credits for claims, allowances, or returned goods; (b) any charges for insurance, freight, and other transportation costs directly related to the delivery of Licensed Products; (c) any tax, tariff, or governmental charge levied on the sales of a Licensed Product or performance of a Licensed Service (but excluding what are commonly known as value-added taxes, franchise taxes, gross receipts taxes, income taxes or similar government charges) home by the seller thereof; and (d) any import or export duties or

that Respondent's imported chips are not products or services. Instead, Respondent's "products" are Chromium™ instruments and kits. Consequently, it is incongruous here to apply a 3% bond rate to the "entered value" of not a product, but a product component, based in large part on a royalty applied by the [redacted] to "Net Revenues" of "Licensed Products."

The weight of the evidence demonstrates that a 100% bond rate applied to the entered value of Respondent's microfluidic chips is appropriate here. *Certain Electronic Paper Towel Dispensing Devices & Components Thereof*, 337-TA-718, Recommended Determination, at 11 (Jul. 12, 2011) ("[W]here variations in pricing make price comparisons complicated and difficult, the Commission typically has set a 100 percent bond.") (citing *Certain Microsphere Adhesives, Process for Making Same, and Products Containing Same, Including Self-Stick Repositionable Notes*, Inv. No. 337-TA-366, Comm'n Op. at 24 (Jan. 16, 1996)).

While Staff and Respondent have proposed a bond rate based on a royalty percentage derived from purportedly comparable licensing agreements, they have done so without addressing whether it is appropriate to apply the royalty rate to the entered value of chips not sold as separate products in the United States. Similarly, Complainants have succeeded to some extent in impeaching Dr. Sullivan's testimony insofar as he "reached this opinion by excluding license agreements with high royalty rates from his analysis," "analyz[ed] only licenses between non-competitors," and "declin[ed] to adjust any license's royalty rate to account for other consideration exchanged for the license." (Tr. (Sullivan) at 1287:17-24, 1288:4-1289:15, 1289:16-1291:2.).

While Complainants have struggled to justify their bond request based on Respondent's

[redacted]
(RX-0543C.0004.).

alleged "price-per-cell" pricing,[25] they have successfully demonstrated that treating Respondent's Accused Chips in isolation as something they are not, that is, as traditional standalone products, undermines the bond's purpose to protect the Complainants from injury during the Presidential Review Period. This is particularly true in the context of a competitive marketplace with integrated, proprietary product offerings. Here, where product pricing and licensing comparisons have failed to illuminate an appropriate bond rate, and where Complainants have revealed Respondent's aggressive pricing strategies and desire to capture market share in new market segments, Complainants have carried their burden of proof that a 100% bond rate is warranted.

D. A Cease and Desist Order Is Warranted

Complainants requested that a CDO issue against all of Respondent's Accused Chips maintained as inventory in the United States. Respondent did not dispute Complainants' evidence that Respondent maintains in the United States commercially significant inventories of GEM Q and GEM U chips. (RBr. at 81.). However, Respondent requested a tailored CDO that excludes the Chip SE and Chip GB because "Complainants have not demonstrated a

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[25] Evaluating Complainants' and Respondent's products on a "price-per-cell" basis is too speculative to garner much evidentiary weight. According to Complainants, Respondent [redacted] (CBr. at 83-84.). Respondent asserted [redacted] (RBr. at 85 (citing Tr. (Mulhern) at 322:6-326:21; Tr. (Sullivan) at 1276:7-1277:14; RX-0547C.0002).). Respondent also noted that Complainants "price-per-cell" calculation fails to reflect reagent and instrument costs. (*Id.*). Staff clarified the speculative nature of Complainants' "price-per-cell" argument by explaining that "accused products . . . are not sold on a per cell basis . . . [and] are actually more expensive than Bio-Rad's." (SBr. at 58.). Importantly, according to Staff, "[w]hile some customers may ultimately achieve lower costs using 10X's more efficient solution, it would depend in large part on how a particular customer used the system." (*Id.*).

commercially significant inventory of the Chip SE and Chip GB." (*Id.*).

Staff opposed Respondent's request for a tailored CDO, explaining without citation to authority that "Respondent 10X has not shown any basis for the Commission to depart from its standard practice of issuing remedial orders covering all infringing products." (SRBr. at 24.).

As explained above, Respondent sells its Accused Chips in kits, not as standalone products. As of January 2018, Respondent reported inventories of finished goods with [redacted], representing between [redacted] months of inventory. (JX-0036C; CX-0190C; CX-0612C.). This is consistent with Mr. Watt's testimony that Respondent maintains [redacted] (CX-0612C (Wyatt) 71:3-15; Mulhern Tr. 315:2-15; CDX-0002C.8.). Respondent's finished goods inventory, valued at 4Q 2017 average selling prices, is valued at [redacted].[26] (*Id.*).

As for Chip SE and Chip GB, according to Respondent, only [redacted] of the Chip SE have been imported into the United States over the past year. (RBr. at 37; Tr. (Hindson) at 975:16-21.). It appears that the evidentiary record lacks an accounting of Respondent's inventory in the United States of Chip GB.

A CDO is appropriate here because the evidence proves that Respondent maintains a commercially significant inventory of GEM Chips in the United States. "Commission practice is to direct remedial orders to all products 'covered by' the asserted claims as to which a violation has been found, not to limit the orders to . . . specific models." *Certain Handsets*, 2010 WL

[26] The evidence also proves that [redacted] of the Chromium Single Cell A Chip kits (depending on whether they are included in a 16 reaction or 48 reaction SKU)." (CBr. at 82 (citing CX-0190C.0003).). Applying a purchase cost of [redacted] per chip, the value of the [redacted] chips in intermediate and raw materials inventory is [redacted]. (CX-0612C (Wyatt) 71:16-73:1; CX-0190C.0003; JX-0036C.).

1436458, at *139. Respondent has failed to demonstrate by application of legal authority to the facts presented in this Investigation, that a deviation from standard Commission practice is warranted. Thus, a conventional CDO is recommended here.

Within fourteen (14) days of the date of this document, the Parties shall submit to the Office of Administrative Law Judges a joint statement regarding whether or not they seek to have any portion of this document deleted from the public version. The Parties' submission shall be made by hard copy and must include a copy of this ID with yellow highlighting, with or without red brackets, indicating any portion asserted to contain CBI to be deleted from the public version. The Parties' submission shall also include a chart that: (i) contains the page number of each proposed redaction; and (ii) states (next to each page number) every sentence or phrase, listed separately, that the party proposes be redacted; and (iii) for each such sentence or phrase that the party proposes be redacted, a citation to case law with an explanation as to why each proposed redaction constitutes CBI consistent with case law. Any proposed redaction that is not explained may not be redacted after a review. The Parties' submission concerning the public version of this document need not be filed with the Commission Secretary.

SO ORDERED.

MaryJoan McNamara
Administrative Law Judge

PUBLIC CERTIFICATE OF SERVICE

I, Lisa R. Barton, hereby certify that the attached **INITIAL DETERMINATION** has been served by hand upon the Commission Investigative Attorney, **Whitney Winston, Esq.**, and the following parties as indicated, on **October 16, 2018**.

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

On Behalf of Complainants Bio-Rad Laboratories, Inc. and Lawrence Livermore National Security, LLC:

Jeffrey Gerchick, Esq.
QUINN EMANUEL URQUHART & SULLIVAN LLP
1300 I Street, NW, Suite 900
Washington, DC 20005

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

Respondent 10X Genomics, Inc.:

Nicholas Groombridge, Esq.
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1285 Avenue of the Americas
New York, NY 10019

- ☐ 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	**Inv. No. 337-TA-1068**
CERTAIN MICROFLUIDIC DEVICES	

INITIAL DETERMINATION ON VIOLATION OF SECTION 337

Administrative Law Judge MaryJoan McNamara

(September 20, 2018)

Appearances:

For the Complainants Bio-Rad Laboratories, Inc. and Lawrence Livermore National Security, LLC:

Jeffrey Gerchick, Esq. and S. Alex Lasher, Esq. of Quinn Emanuel Urqhart & Sullivan, LLP, Washington, DC.

David Bilsker, Esq. of Quinn Emanuel Urqhart & Sullivan, LLP, San Francisco, CA.

Kevin P.B. Johnson, Esq. of Quinn Emanuel Urqhart & Sullivan, LLP, Redwood Shores, CA.

Sky Adams, Esq. of Quinn Emanuel Urqhart & Sullivan, LLP, New York, NY.

For the Respondent 10X Genomics, Inc.:

Nicholas Groombridge, Esq.; Jennifer H. Wu, Esq.; Josephine Young, Esq.; Jennifer Rea Deneault, Esq.; and Simone Park, Esq. of Paul, Weiss, Rifkind, Wharton & Garrison LLP, New York, NY.

David J. Ball, Jr., Esq. and F. Raymond, Esq. of Paul, Weiss, Rifkind, Wharton & Garrison LLP, Washington, DC.

For the Commission Investigative Staff:

Margaret D. McDonald, Esq., Director; Anne Goalwin, Esq., Supervisory Attorney; and R. Whitney Winston, Esq., Investigative Attorney, of the Office of Unfair Import Investigations, U.S. International Trade Commission, Washington, D.C.

SELECTED SUMMARY FINDINGS

Pursuant to the Notice of Investigation, 82 Fed. Reg. 42115, dated September 6, 2017, this is the Initial Determination ("ID") of the Investigation in the Matter of Certain Microfluidic Devices, United States International Trade Commission Investigation No. 337-TA-1068. *See* 19 C.F.R. § 210.42(a).

It is a finding of this ID that Bio-Rad Laboratories, Inc. and Lawrence Livermore National Security, LLC (collectively, "Complainants") have proven by a preponderance of evidence that Respondent 10X Genomics, Inc. ("Respondent") has violated subsection (b) of Section 337 of the Tariff Act of 1930, in the importation into the United States, the sale for importation, or the sale within the United States after importation of certain microfluidic devices.

It is a finding of this ID that Respondent has not infringed asserted claim 20 of U.S. Patent No. 9,126,160 ("the '160 patent").

It is a finding of this ID that Respondent has infringed asserted claims 1, 2, 14, and 15 of U.S. Patent No. 9,500,664 ("the '664 patent").

It is a finding of this ID that Respondent has infringed asserted claims 14, 16, and 17 of U.S. Patent No. 9,636,682 ("the '682 patent").

It is a finding of this ID that Respondent has infringed asserted claims 1, 13, 14, 16, and 21 of U.S. Patent No. 9,649,635 ("the '635 patent").

It is a finding of this ID that one or more of Complainants' domestic industry products have satisfied the technical industry prong of the domestic industry requirement for the '160, '664, '682, and '635 patents. It is also a finding of this ID that Complainants have satisfied the economic prong of the domestic industry requirement under Section 337(a)(3)(A), (B), and (C).

A recommendation on remedy and bond will be forthcoming together with findings of

fact and an analysis of the effects of the public interest factors on the issue of remedy pursuant to 19 C.F.R. §§ 210.42(a)(1)(ii)(A), (B), and (C).

TABLE OF CONTENTS

ABBREVIATIONS

The following shorthand references to the parties and related U.S. agencies are used in this Initial Determination:

Complainants or Bio-Rad	Complainants Bio-Rad Laboratories, Inc. and Lawrence Livermore National Security, LLC, collectively
Respondent or 10X	Respondent 10X Genomics, Inc.
Staff	Commission Investigative Staff, Office of Unfair Import Investigations
CBP	U.S. Customs and Border Protection
PTO	U.S. Patent and Trademark Office
PTAB	Patent Trial and Appeal Board of the PTO

The following abbreviations for pleadings, exhibits, briefs, transcripts, and Orders are used in this Initial Determination:

Compl.	Complaint
Resp.	Response of Respondent 10X Genomics, Inc. to the Notice of Investigation and Complaint Under Section 337 of the Tariff Act of 1930, as Amended
CX	Complainants' exhibit
CDX	Complainants' demonstrative exhibit
CPX	Complainants' physical exhibit
CPBr.	Complainants' Pre-Hearing Brief
CBr.	Complainants' Initial Post-Hearing Brief[1]
CRBr.	Complainants' Post-Hearing Reply Brief

[1] This is Complainants' Corrected Initial Post-Hearing Brief.

CPSt.	Complainants' Pre-Hearing Statement
JX	Joint exhibit
RX	Respondent's exhibit
RDX	Respondent's demonstrative exhibit
RPX	Respondent's physical exhibit
RPBr.	Respondent's Pre-Hearing Brief
RBr.	Respondent's Initial Post-Hearing Brief
RRBr.	Respondent's Post-Hearing Reply Brief
RPSt.	Respondent's Pre-Hearing Statement
SPBr.	Commission Investigative Staff's Pre-Hearing Brief
SBr.	Commission Investigative Staff's Initial Post-Hearing Brief
SRBr.	Commission Investigative Staff's Post-Hearing Reply Brief
SPSt.	Commission Investigative Staff's Pre-Hearing Statement
SX	Commission Investigative Staff's exhibit
Tr.	Evidentiary hearing transcript
Dep. Tr.	Deposition transcript
COMBr.	Complainants' Opening *Markman* Brief
CRMBr.	Complainants' *Markman* Reply Brief
ROMBr.	Respondent's Opening *Markman* Brief
RRMBr.	Respondent's *Markman* Reply Brief
SMBr.	Commission Investigative Staff's *Markman* Brief
***Markman* Order**	Order No. 20 (Apr. 4, 2018)

The following abbreviations for technical terms are used in this Initial Determination:

Chip GB	[redacted]
Chip PB	[redacted]
Chip SE	[redacted]
ddPCR	Droplet digital PCR
GEM-Q Chip	Chromium™ Genome Chip
GEM-U Chip	Chromium™ Single Cell A Chip
GEM Chips	GEM-Q Chip and GEM-U Chip, collectively
NGS	Next-generation sequencing
PCR	Polymerase chain reaction
System NH	[redacted]

The following shorthand references to certain products and patents at issue are used in this Initial Determination:

'160 patent	U.S. Patent No. 9,126,160
'664 patent	U.S. Patent No. 9,500,664
'682 patent	U.S. Patent No. 9,636,682
'635 patent	U.S. Patent No. 9,649,635
Asserted Patents	'160, '664, '682, and '635 patents, collectively
Accused Products	GEM Chips, Chip GB, and Chip SE, collectively
Accused 160 Products	GEM Chips and Chip SE, collectively

Accused 664 Products	GEM Chips, Chip GB, and Chip SE, collectively
Accused 682 Products	GEM Chips
Accused 635 Products	GEM Chips
Chromium™ Controllers	Chromium™ Controller and the Chromium™ Single Cell Controller, collectively
DI Products	DG8 Chip and DG8 Chip, collectively

I. INITIAL DETERMINATION ON VIOLATION OF SECTION 337, AND RECOMMENDED DETERMINATION ON REMEDY AND BOND

A. Technology Comment

Polymerase Chain Reaction ("PCR") is a method of amplifying genetic material such as DNA to produce multiple copies of the starting DNA so that a sufficient amount of material will exist for analysis. Traditional PCR involved precisely cycling the temperature of the genetic material between hot and cold set points to denature the double strands and allow new copies of the material to be formed.

Although this was a powerful tool, traditional PCR had a number of limitations, one of the most critical was the need for large sample sizes. Additionally, only a single measurement from the sample indicated whether a target was present or not. Traditional PCR also required additional samples or "standards" to be analyzed each time PCR was performed in order to quantify the starting amount of the target molecule.

Newer approaches to PCR included digital PCR ("dPCR"), which allowed more precise quantification of the target sequences present in the original sample. Early forms of dPCR required dividing the starting sample into multiple wells through a series of dilutions performed by repeatedly pipetting the sample to achieve very dilute samples that contained either a single molecule or no molecule. Once this level of dilution was achieved, PCR was performed on the diluted sample. The resulting amplification products and "empty" wells are then evaluated using statistics to quantify the nucleic acid concentration of the target. Because dPCR is an absolute measurement, no standards are needed to quantify starting amounts.

While dPCR was an improvement over prior forms of PCR, first generation dPCR also had its share of drawbacks. Performing serial dilutions is laborious and prone to errors.

Moreover, because of the time it took to execute, first generation dPCR was not particularly well-suited to large scale applications.

The technology at issue in this Investigation, digital droplet PCR ("ddPCR"), allows genetic material to be amplified and precisely quantified in small droplets. Specifically, a droplet generator produces very small aqueous droplets from a sample containing genetic material and reagents. The droplets are formed on plastic chips that contain interconnected microfluidic channels. Aqueous sample travels through one channel on the chip while oil flows through the other channels. Because the oil and water do not mix, the oil pinches off individual aqueous droplets that are surrounded by oil. Emulsification can create thousands of aqueous droplets, each of which acts as a separate, miniature test tube in which reactions can occur. The droplets can then be run through a droplet reader, which can determine with a high degree of accuracy the amount of a genetic material in the original sample.

B. Summary of Findings

A summary of findings in this decision are reflected in Table No. 1, below.

Table No. 1: Summary of Findings

Product	Patent	Claims	Determination
Accused 160 Products	'160 patent	20	*No violation*: Claim 20 is valid but not infringed by the Accused 160 Products.
Accused 664 Products	'664 patent	1, 2, 14, and 15	***Violation (claims 1, 2, 14, and 15)***: Claims 1, 2, 14, and 15 are valid and infringed by the GEM Chips.

Product	Patent	Claims	Determination
Accused 682 Products	'682 patent	14, 16, and 17	***Violation (claims 14, 16, and 17)***: Claims 14, 16, and 17 are valid and infringed by the Accused 682 Products when used with the Chromium™ Controllers.
Accused 635 Products	'635 patent	1, 13, 14, 16, and 21	***Violation (claims 1, 13, 14, 16, and 21)***: Claims 1, 13, 14, 16 and 21 are valid and infringed by the Accused 635 Products when used with the Chromium™ Controllers.
DI Products	All Asserted Patents		***Satisfied***. Complainants' domestic R&D activities with respect to their DI Products satisfy the domestic industry requirement set forth in 19 U.S.C. § 337(a)(3)(A), (B), and (C).

II. BACKGROUND

A. Institution and Selected Procedural History

On July 31, 2017, Bio-Rad Laboratories, Inc. and Lawrence Livermore National Security, LLC filed a complaint ("Complaint") under Section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337, alleging infringement of certain claims of U.S. Patent No. 9,126,160 (JX-

0001, hereafter "the '160 patent"); U.S. Patent No. 9,500,664 (JX-0002, hereafter "the '664 patent"); U.S. Patent No. 9,636,682 (JX-0004, hereafter "the '682 patent); U.S. Patent No. 9,649,635 (JX-0005, hereafter "the '635 patent); and U.S. Patent No. 9,089,844 (hereafter "the '844 patent). (*See, e.g.*, Compl. at ¶¶ 1, 40-54; Doc. ID No. 618543 (July 31, 2017).).

The Commission instituted this Investigation pursuant to subsection (b) of Section 337 of the Tariff Act of 1930, as amended, to determine:

> whether there is a violation of subsection (a)(1)(B) 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 devices by reasons of infringement of one or more of claims 1-12 and 14-16 of the '664 patent; claims 1-15 of the '844 patent; claims 1-21 of the '682 patent; claims 1-27 of the '635 patent; and claims 1, 2, 4-8, and 14-21 of the '160 patent; and whether an industry in the United States exists as required by subsection (a)(2) of section 337[.]

82 Fed. Reg. 42116 (Sept. 6, 2017).

The Notice of Investigation ("NOI") names as complainants: Bio-Rad Laboratories, Inc. of Hercules, California, and Lawrence Livermore National Security, LLC of Livermore, California ("Complainants"). *Id.* The NOI names as respondent: 10X Genomics, Inc. of Pleasanton, California ("Respondent," and with Complainants, the "Private Parties"). *Id.* Commission Investigative Staff of the Office of Unfair Import Investigations ("Staff," and with the Private Parties, the "Parties") is also named as a party. *Id.*

On September 19, 2017, Respondent filed a response to the Complaint and NOI ("Response"). (Doc. ID No. 623425 (Sept. 19, 2017).). In the Response, Respondent identified four (4) affirmative defenses ("Respondent's Affirmative Defenses"). (Resp. at 19-21.).

As the result of a series of Initial Determinations ("ID") granting Complainants' partial terminations of this Investigation against Respondent with respect to certain asserted claims and the asserted '844 patent in its entirety, the claims remaining that are the subject of this decision

are: (i) claim 20 of the '160 patent; (ii) claims 1, 2, 14, and 15 of the '664 patent; (iii) claims 14, 16, and 17 of the '682 patent; and (iv) claims 1, 13, 14, 16, and 21 of the '635 patent.[2]

On January 17, 2018, Complainants filed a motion for summary determination, and a memorandum in support, that the doctrine of assignor estoppel precluded Respondent from challenging the validity of the Asserted Patents.[3] (Motion Docket No. 1068-003 (Jan. 17, 2018).). On March 5, 2018, an ID issued granting Complainants' motion. (Order. No. 15 (Mar. 5, 2018).). On March 13, 2013, Respondent filed a petition for review of the ID. (Doc. ID No. 638869 (Mar. 13, 2018).). Complainants and Staff filed responses to Respondent's petition on March 20, 2018 and March 23, 2018, respectively. (Doc. ID Nos. 639492 (Mar. 20, 2018), 639824 (Mar. 23, 2018).). On April 9, 2018, the Commission issued a notice in which it declined to review the ID.[4] (Doc. ID No. 641398 (Apr. 9, 2018).).

On January 24, 2018, the Private Parties filed a joint *Markman* hearing proposal. (Doc. ID No. 634538 (Jan. 24, 2018).). The Private Parties agreed that a *Markman* hearing was not necessary unless one were to occur in conjunction with the evidentiary hearing ("Hearing"). (*Id.* at 1.). No *Markman* hearing was held in this Investigation. (*See* Order No. 7 (Jan. 25, 2018).). On April 4, 2018, a *Markman* Order issued adopting the claim terms on which the Parties agreed

[2] These ID's are Order Nos. 12 (Feb. 14, 2018), 16 (Mar. 8, 2018), 19 (Mar. 16, 2018), and 29 (May 10, 2018), which the Commission determined not to review. (Doc. ID Nos. 638012 (Mar. 6, 2018), 639962 (Mar. 26, 2018), 642114 (Apr. 16, 2018), 646574 (June 1, 2018).).

[3] Complainants submitted with the motion and memorandum a statement of material facts. (Motion Docket No. 1068-003 (Jan. 17, 2018).).

[4] On May 14, 2018, three (3) days after the close of the Hearing, Respondent submitted a proffer by motion ("Motion Proffer") of the evidence Respondent claimed it would have submitted into the record had it been permitted to proceed with its invalidity defense that was precluded by Order No. 15. (Motion Docket No. 1068-015 (May 14, 2018).). Respondent's Motion Proffer was denied. (Order No. 31 (May 24, 2018).).

and construing the claim terms in dispute. (Order No. 20 ("*Markman* Order") (Apr. 4, 2018).).

Complainants filed five (5) motions *in limine* ("MILs"). (Motion Docket Nos. 1068-016 to -020 (Apr. 2, 2018).). Respondent filed three (3) MILs in one combined motion. (Motion Docket No. 1068-021 (Apr. 2, 2018). Staff filed three (3) High Priority Objections ("HPOs"). (Doc. ID No. 640657 (Apr. 2, 2018).).

The Parties' MILs and HPOs, and the rulings on these motions/objections, are summarized in Table Nos. 2, 3, and 4, below.

Table No. 2: Complainants' MILs

MIL No.	Issue	Ruling
MIL No. 1 (Motion Docket No. 1068-016)	Complainants' MIL to Preclude Expert Testimony from Fact Witnesses Drs. Benjamin Hindson, Donald Masquelier, and Kevin Ness Regarding at Least Infringement and/or Claim Construction	Granted. (Order No. 24 (Apr. 23, 2018) at 2.). "Respondent legitimately may question Drs. Hindson, Masquelier and Ness about the history and background to the Asserted Patents for which they are named inventers. They may not offer opinion with respect to claim construction, infringement, and non-infringement *per se*. They may offer testimony on their state of mind with respect to their inventions, but they may not stray into ultimate conclusions of law or fact with respect to "intent." Since Respondent has already assured that it "will not elicit expert testimony from them," i.e., the three (3) witnesses, it appears that the Respondent is mindful that it will need to ask questions that will elicit only that information that is factual and that does not stray into opinion, or that masks as fact but which is opinion. Explicitly, none of the inventors may discuss claim terms and what they intended claim terms in the Asserted Patents to mean." (*Id.* at 3-4.).

MIL No.	Issue	Ruling
MIL No. 2 (Motion Docket No. 1068-017)	Complainants' MIL to Strike 10X's Licensing Defense and to Preclude Respondent from Offering Evidence Relating to Its Licensing Defense or from Relying on Its Licensing Defense	Granted. (*Id.* at 4.). "Complainants and Staff demonstrated with facts and law that Respondent failed to include licensing as a defense in response to the complaint consistent with Commission pleading Rules. Respondent may not argue the licensing issue in its Post-Hearing Brief. It waived that right under Ground Rule 7.2." (*Id.* at 6.).
MIL No. 3 (Motion Docket No. 1068-018)	Complainants' MIL to Strike the Expert Reports of Dr. Santiago and to Preclude Respondent from Offering Evidence Relating to the Late-Disclosed	Denied. (*Id.* at 7.).
MIL No. 4 (Motion Docket No. 1068-019)	Complainants' MIL to Strike and to Preclude Respondent from Offering Evidence Regarding Invalidity and/or Claim Construction Not Presented During the *Markman* Process	Moot in light of Order No. 15 and the *Markman* Order. (*Id.* at 9.).
MIL No. 5 (Motion Docket No. 1068-020)	Complainants' MIL to Preclude Respondent from Offering Evidence from John Stuelpnagel, Serge Saxonov, and Kevin Ness	Granted in-part, denied in-part. (*Id.* at 10.). "[B]oth Drs. Saxonov and Dr. Stuelpnagel will be permitted to testify but only to the documentary information that was already provided. Neither will be permitted to testify to infringement, invalidity, or claim construction." (*Id.* at 12.). Dr. Ness was not permitted to testify during the Hearing. (*Id.*).

Table No. 3: Respondent's MILs

MIL No.	Issue	Ruling
MIL No. 1 (Motion Docket No. 1068-021)	Respondent's MIL that Each of the Additional 10X Chip Designs (Including but Not Limited to 10X Chip SE) Are Admissible in Evidence	Granted in-part. (Order No. 25 (Apr. 24, 2018).). "[T]he evidence with respect to the [redacted] may be discussed during the Hearing."[5] (*Id.* at 3-4.).
MIL No. 2 (Motion Docket No. 1068-021)	Respondent's MIL to Preclude Complainants from Presenting Argument and Evidence in Support of a Bond Rate (Other than of 1.25%)	Denied. (*Id.* at 4.).
MIL No. 3 (Motion Docket No. 1068-021)	Respondent's MIL to Preclude Complainants from Offering Arguments or Evidence on Infringement or Substantial Non-Infringing Uses of the [redacted]	Denied. (*Id.* at 6.).

Table No. 4: Staff's HPOs

HPO No.	Issue	Ruling
HPO No. 1 (Doc. ID No. 640657)	HPO to Exclude from Evidence Exhibits that Consist of Complainants' and Respondent's Expert Reports and Expert Rebuttal Reports	Granted. (Order No. 23 at 1 (Apr. 19, 2018).). "However, Staff's HPO No. 1 may be moot since the Private Parties have advised Staff they will not be seeking to admit expert reports into evidence. . . . However, the expert report exhibits

[5] These [redacted] are the products that were not accused in the Complaint, [redacted] (Order No. 25 at 2.). These products include the 10X Chip SE, 10X Chip PB, 10X Chip GB, the 10X Chip NH, and the 10X System NH-PF [redacted]. (*See* Section V.A, *infra*, discussing the Accused Products.).

HPO No.	Issue	Ruling
		identified, and any portions thereof, may be used for cross-examination and impeachment purposes and any other purposes permitted under Commission Rules." (*Id.*).
HPO No. 2 (Doc. ID No. 640657)	HPO to Exclude from Evidence Exhibits that Consist of the Private Parties' Discovery Responses	Granted. (*Id.* at 2.). "However, to the extent the identified documents contain or constitute admissions by a party, they may be admissible as evidence subject to other appropriate objections. Moreover, as Staff notes, the interrogatory responses may not be used *per se* as contentions or argument. However, discovery responses may be used for cross-examination and impeachment and for any other purposes specified in Commission Rules, subject to other appropriate substantive objections during the Hearing." (*Id.*).
HPO No. 3 (Doc. ID No. 640657)	HPO to Exclude from Evidence Deposition Transcripts Identified as Complainants' Exhibits, Deposition and Arbitration Transcripts as Respondent's Exhibits, and Deposition Transcripts from Another Proceeding	Granted. (*Id.*). "However, Staff's HPO No. 3 may be moot since Staff states that the Private Parties have confirmed that they will not seek to ask for admission into evidence deposition testimony that falls outside the scope of Commission Rule 210.28(h)." (*Id.*).

The Hearing was held from May 7, 2018 through May 11, 2018.

B. The Parties

1. Complainant Bio-Rad Laboratories, Inc.

Complainant Bio-Rad Laboratories, Inc. ("Bio-Rad") is a Delaware corporation having a

principal place of business in Hercules, California. (Compl. at ¶ 7; Tr. (Annette Tumolo)[6] at 85:21-22, 86:10-13; JX-0144.0134.). Founded in 1952, Bio-Rad develops products and services to identify, separate, purify, and analyze chemical and biological materials. (Compl. at ¶ 7; Tr. (Tumolo) at 87:3-17 ("The products we make help people separate, measure, analyze biomolecules like protein cells or DNA.").).

Bio-Rad is the sole owner of the '644, '682, and '635 patents. (*See* Compl. at ¶¶ 1, 40, 46, 49; *id.* at Exs. 6, 8, 9; JX-0144.0134 to -0138 (Assignment of the '664 patent); JX-0121.0273 to -0278 (Assignment of the '682 patent); JX-0120.0245 to -0250 (Assignment of the '635 patent).

2. Complainant Lawrence Livermore National Security, LLC

Complainant Lawrence Livermore National Security, LLC ("LLNS") is a Delaware corporation having a place of business in Livermore, California. (Compl. at ¶¶ 3, 11; Tr. (Tumolo) at 101:15-19.). LLNS operates Lawrence Livermore National Laboratory ("LLNL"), a federal research facility established in 1952. (*See* Compl. at ¶ 11; Tr. (Tomolo) at 101:15-19.). LLNL develops and applies science, technology, and engineering aimed at improving the nation's defense, reducing the global threat from terrorism and weapons of mass destruction, and addressing scientific issues of national importance. (Compl. at ¶ 11.).

LLNS and Bio-Rad each own an undivided 50% joint interest in the '160 patent. (Compl. at ¶ 52; Compl. at Exs. 10A-D; Tr. (Tumolo) at 102:3-103:2; JX-0111.0002-0013

[6] When she testified during the Hearing on May 7, 2018, Ms. Annette Tumulo was the President of the Bio-Rad's Life Science Group. (Tr. (Tumulo) at 85:10-12.). Complainants identified Ms. Tumulo as a fact witness to testify about the organization and operations of Bio-Rad's Life Science Group and the Life Science Group's involvement in the development of microfluidic technology and sequencing preparations. (CPSt. at 3.).

(Assignment of the '160 patent from the inventors to QuantaLife, Inc. ("QuantaLife")).[7]).

3. Respondent 10X Genomics, Inc.

Respondent 10X Genomics Inc. ("10X") is a Delaware corporation that has a principal place of business in Pleasanton, California. (Resp. at ¶ 29.). 10X is a genomic technology company that designs and sells solutions for sample partitioning, barcoding, and sequencing preparation, which can be used with existing sequencers. (Tr. (Benjamin Hindson)[8] at 927:22-24, 928:16-929:1.). 10X is responsible for importing the accused microfluidic chip products and selling those products in the United States after importation. (*See* Tr. (Michael Schnall-Levin)[9] at 1047:7-13; Tr. (Hindson) at 975:18-19; Tr. (Juan Santiago)[10] at 1264:15-25; Tr. (Shelley Anna)[11] at 562:16-25; RX-1550C (email confirming tracking numbers of Chip SE).).

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[7] QuantaLife was founded by Drs. Bill Colston and Benjamin Hindson. (Tr. (Hindson) at 913:4-16; *see also* Section XI.B.3, *infra*.). Bio-Rad acquired QuantaLife in 2011. (*See, e.g.*, CX-0529 (Bio-Rad Press Release: "Bio-Rad Acquires QuantaLife and Digital PCR Technology").).

[8] When he testified during the Hearing on May 10, 2018, Dr. Benjamin Hindson was a co-founder, Chief Scientific Officer, and President of 10X. (Tr. (Hindson) at 906:12-14.). Respondent identified Dr. Hindson as a fact witness to provide testimony on matters relating to 10X, including the company, its history, and its products; QuantaLife's products; the Asserted Patents, including any purported invention(s) disclosed therein; claim construction, including the state of the prior art; non-infringement; and the prior proceedings between 10X and Bio-Rad. (RPSt. at 2-3.).

[9] When he testified during the Hearing on May 10, 2018, Dr. Michael Schnall-Levin was the Vice President of Product Research & Development ("R&D") and Strategy at 10X. (Tr. Schnall-Levin) at 1044:7-8.). Respondent identified Dr. Schnall-Levin as a fact witness to testify about matters relating to public interest, including the marketing, advertising, and price of 10X's products and other products. (RPSt. at 3.).

[10] When he testified during the Hearing on May 11, 2018, Dr. Juan Santiago was a Professor of mechanical engineering at Stanford University. (Tr. (Santiago) at 1148:13-14, 1149:8-13.). Respondent identified Dr. Santiago as an expert to testify about the background of microfluidic technology and matters relating to the Asserted Patents, the Accused Products, the DI Products, claim construction, and non-infringement of the Asserted Patents. (RPSt. at 4.).

[11] When she testified during the Hearing on May 8-9, 2018, Dr. Shelley Anna was a Professor in the Department of Chemical Engineering at Carnegie Mellon University. (CPSt. at Ex. 1.). Complainants

III. JURISDICTION, IMPORTATION, AND STANDING

A. The Commission Has Jurisdiction

To have the authority to decide a case, a court or agency must have both subject matter jurisdiction and jurisdiction over either the parties or the property involved. *See Certain Steel Rod Treating Apparatus and Components Thereof*, Inv. No. 337-TA-97, Comm'n Op., 215 U.S.P.Q. 229, 231 (U.S.I.T.C. 1981). For the reasons discussed below, the facts support a finding that the Commission has jurisdiction over this Investigation.

1. Subject Matter Jurisdiction

The Commission has subject matter jurisdiction over this Investigation because Complainants alleged that Respondent has violated 19 U.S.C. §1337(a)(1)(B). *See Amgen v. U. S. Int'l Trade*, 902 F.2d 1532, 1536 (Fed. Cir. 1990). Since the inception of this Investigation, Respondent did not contest the Commission's subject matter jurisdiction. (*See* RPBr. at 16; RBr. at 13; SBr. at 16.).

2. Personal Jurisdiction

Respondent appeared and responded to the Complaint and NOI, and participated in discovery and the Hearing. The Commission has personal jurisdiction over the Respondent, which Respondent did not contest. *See, e.g., Certain Windshield Wiper Devices and Components Thereof*, Inv. No. 337-TA-881, ID at 5 (May 8, 2014) (unreviewed in relevant-part) (Doc. ID No. 534255). (*See* RPBr. at 16; RBr. at 13; SBr. at 16.).

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identified Dr. Anna as an expert to testify about the technical background and state of the art relevant to the asserted claims of the Asserted Patents; the interpretation and scope of the asserted claims of the Asserted Patents; the design, development, and operation of Bio-Rad's DI Products and Respondent's Accused Products; infringement of the asserted claims by Respondent; and whether Bio-Rad's DI Products practice the Asserted Patents.

3. *In Rem* Jurisdiction

Section 337(a)(1)(B) applies to the "[t]he importation into the United States, the sale for importation, or the sale within the United States after importation" of articles that infringe a valid and enforceable United States patent." 19 U.S.C. § 1337(a)(1)(B). A single instance of importation is sufficient to satisfy the importation requirement of Section 337. *Certain Optical Disc Drives, Components Thereof, and Prods. Containing the Same*, Inv. No. 337-TA-897, Order No. 101 at 3 (Sept. 22, 2014) (citations omitted) (Doc. ID No. 543438).

Since the inception of this Investigation, Respondent has not disputed that it has sold for importation, has imported into the United States, and/or has sold within the United States after importation, within the meaning of 19 U.S.C. § 1337(a)(1)(B), the Accused Products. (*See* RPBr. at 16; RBr. at 13-4; SBr. at 16.). Specifically, Respondent acknowledged that it imports at least one unit of each of the accused GEM-Q and GEM-U Chips ("GEM Chips"), 10X Chip SE ("Chip SE"), and 10X Chip GB ("Chip GB"). (Tr. (Schnall-Levin) at 1047:7–13; Tr. (Hindson) at 975:18-19; CX-0190C.0003; Tr. (Anna) at 681:20-682:3.).

Thus, evidence admitted in this Investigation establishes that the Commission has *in rem* jurisdiction over the Accused Products. *See, e.g.*, *Wiper Devices*, Inv. No. 337-TA-881, Initial Determination at 5 (*in rem* jurisdiction exists when importation requirement is satisfied).

B. Complainants Have Standing in the Commission

Jurisdiction also requires standing. *See SiRF Technology, Inc. v. Int'l Trade Comm'n*, 601 F.3d 1319, 1326 (Fed. Cir. 2016) (standing to bring an infringement suit is the same under Commission Rules as it would be in a Federal District Court case); *Certain Optical Disc Drives, Components Thereof and Prods. Containing Same*, Inv. No. 337-TA897, Opinion Remanding the Investigation at 4 (Jan. 7, 2015). Commission Rule 210.12 requires that intellectual-property

based complaints filed by a private complainant "include a showing that at least one complainant is the exclusive license of the subject intellectual property." 19 C.F.R. § 210.12(a)(7).

Complainants have standing to bring suit for infringement under Section 337 because Bio-Rad is the sole owner of the '644, '682, and '635 patents, and together with LLNS, is the co-owner of the '160 patent. (Complaint at ¶¶ 1, 40, 46, 49, 52; *id.* at Exs. 6, 8, 9, 10A-D; JX-0144.0134-0138 (Assignment of the '664 patent); JX-0121.0273-0278 (Assignment of the '682 patent); JX-0120.0245-0250 (Assignment of the '635 patent); JX-0111.0002-0013 (Assignment of the '160 patent from the inventors to QuantaLife).).

IV. THE ASSERTED PATENTS

A. Overview of the Technology

The technology claimed in the Asserted Patents relates to a device ('160 and '664 patents) and instrument ('682 and '635 patents) for forming droplets, which are small volumes of liquid encapsulated by an immiscible fluid,[12] in order to perform droplet-based assays for use in biomedical applications. (*See* JX-0001 at 1:30-42, 11:50-52; Tr. (Gale) at 380:5-10, 383:14-17.).

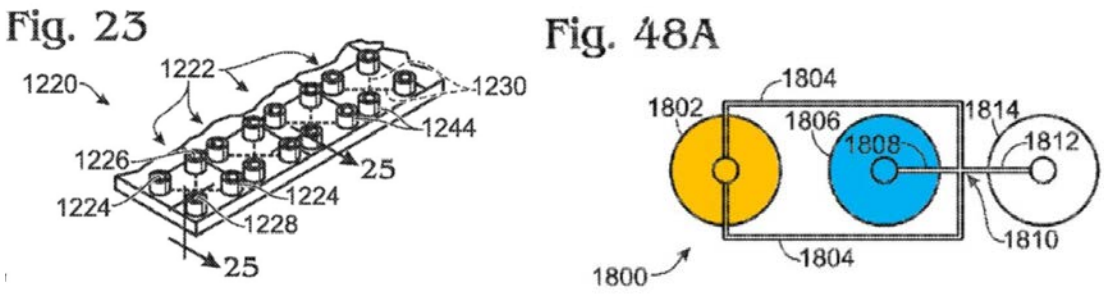
The '160 patent defines assays as "procedures for determining the presence, quantity, activity, and/or other properties or characteristics of components in a sample." (*See, e.g.*, JX-0001 at 1:30-32.). Rather than testing large volumes, sample fluid can be partitioned into small droplets suspended in an immiscible background fluid that then forms an emulsion. (*See id.* at 9:35-43.). "In this way, complex samples may be converted into a plurality of simpler, more easily analyzed samples, with concomitant reductions in background and assay times." (*Id.* at

[12] Immiscible fluids are fluids that "do not mix to attain homogeneity." (JX-0001 at 10:11-21; *see also* Tr. (Gale) at 377:16-23 ("two fluids that do not mix").

9:35-38.).

The device claimed in the Asserted Patents is commonly referred to as a chip, microfluidic chip, or plate.[13] (Tr. (Gale) at 375:18-22.). The chip or plate has a "well" to hold: (i) a dispersed phase such as sample and water (shown in Figure 48A, in blue below); (ii) a continuous phase fluid such as oil (shown in Figure 48A, in yellow below); and (iii) droplets that are formed when the oil and the water come together (shown in Fig. 48A of Figure No. 1, in white below). (*Id.* at 380:23-381:5, 376:20-377:8, 418:1-420:11; Tr. (Anna) at 592:23-593:10, 631:14-632:16, 648:7-649:10.).

Figure No. 1: Figures from the '160 Patent Showing Plate with Wells



(JX-0001 at Figs. 23, 48A.).

The chips or plates (*see, e.g.*, Fig. 23 and 48A of Figure No. 1, above) also include microfluidic channels for fluid to travel so that the oil (continuous phase fluid) and water (dispersed phase fluid) phases can intersect to form "droplets," as shown in the image in Figure No. 3, below.

[13] Complainants' expert, Dr. Gale, described microfluidics as "the science and engineering that revolves around channels that are less than one millimeter across." (Tr. (Gale) at 375:25-376:5.).

Figure No. 2: Figure 9 from the '664 Patent Showing Plate with Microfluidic Channels

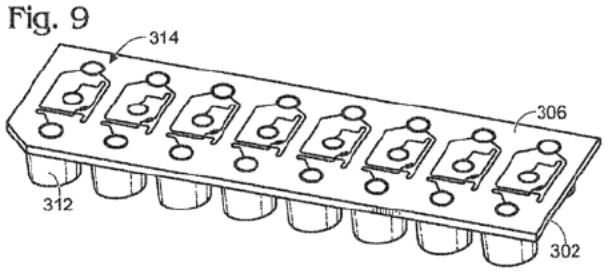
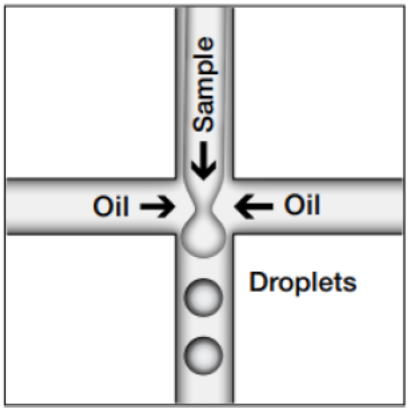


Figure No. 3: Images Showing Droplet Formation



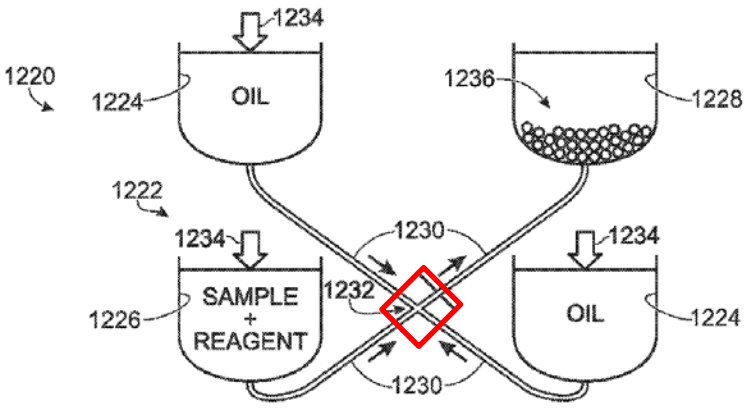
(CPBr. at 3.).

(CX-0373C.).

In order to generate a droplet, the dispersed phase must be "pushed" or "forced" into the continuous phase. (Tr. (Gale) at 379:4-12.). The Asserted Patents refer to the droplet generation site as either a "channel junction" ('160 patent) or "droplet generation region" **1232** ('664, '682, and '635 patents), shown below in the red box in Figure 24 from the '160 patent, Figure No. 4,

below:

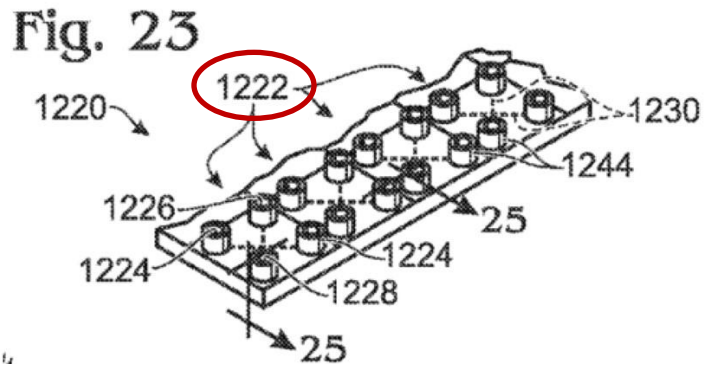
Figure No. 4: Figure of the '160 Patent Depicting Channel Junction



(JX-0001 at Fig. 24.).

A collection of droplets is an "emulsion." (Tr. (Gale) at 378:25-379:3; JX-0001 at 10:11-24.). As is reflected in Figure No. 5, below, each chip can contain an array of emulsion production units **1222**, which can each produce a separate emulsion. (Tr. (Gale) at 380:8-10, 14-16, 380:23-381:5.).

Figure No. 5: Figure 23 of the '160 Patent Depicting Multiple Emulsion Production Units

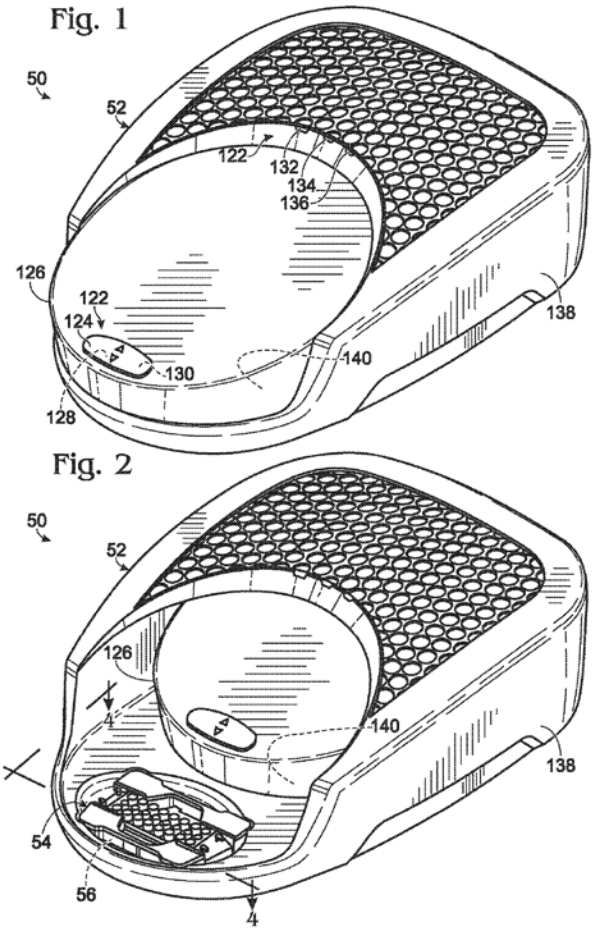


(JX-0001 at Fig. 23.).

The instrument claimed in the Asserted Patents is described as an "emulsification engine or apparatus" that includes a holder and a chip or plate that is inserted in the holder. (JX-0004 at

7:1-9; Tr. (Gale) at 383:14-17.). The instrument applies pressure on the wells of the chip/plate so that the dispersed and continuous phase fluids move through the chip/plate and produce the emulsion. (Tr. (Gale) at 384:5-10.).

Figure No. 6: Figures from the '682 Patent Depicting the Instrument in Open and Closed Configurations



(JX-0004 at Figs. 1, 2.).

B. U.S. Patent No. 9,126,160 ("the '160 Patent")

1. Overview of the '160 Patent

The '160 patent, titled "System for Forming an Array of Emulsions," was filed on December 8, 2010, as U.S. Patent Application Serial No. 12/963,523 ("the '523 application").

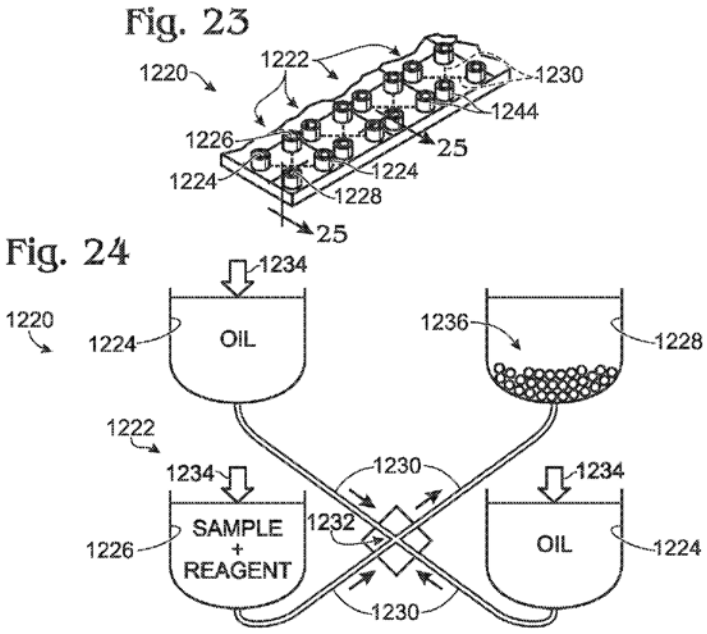
(JX-0001 at (21), (22), (54).). The '523 application issued as the '160 patent on September 8, 2015, and names Kevin D. Ness, Benjamin J. Hindson, Billy W. Colston, Jr., and Donald A. Masquelier as the inventors. (*Id.* at (10), (45), (75).). The '523 application is a continuation of U.S. Patent Application Serial No. 12/586,626, filed on September 23, 2009. (*Id.* at (63).). The '160 patent claims priority to U.S. Provisional Application Serial Nos. 61/194,043, filed on September 23, 2008; 61/206,975, filed on February 5, 2009; 61/271,538, filed on July 21, 2009; 61/275,731, filed on September 1, 2009; 61/277,200, filed on September 21, 2009; 61/277,203, filed on September 21, 2009; 61/277,204, filed on September 21, 2009; 61/277,216, filed on September 21, 2009; 61/277,249, filed on September 21, 2009; and 61/277,270, filed on September 22, 2009. (*Id.* at (60).).

Bio-Rad is the named assignee on the face of the '160 patent. (JX-0001 at (73).). However, LLNS and Bio-Rad each own an undivided 50% joint interest in the '160 patent. (Compl. at ¶ 52; Compl. at Exs. 10A-D.).

The '160 patent generally relates to the formation of an array of emulsions on a microfluidic plate. (JX-0001 at Abstract, 1:46-57.). The plate includes an array of emulsion production units each configured to produce a separate emulsion and each including a set of wells interconnected by channels that intersect to form a site for droplet generation. (*Id.*). Each set of wells may include: (i) at least one first input well to receive a continuous phase; (ii) a second input well to receive a dispersed phase; and (iii) an output well configured to receive from the site of droplet generation an emulsion of droplets of the dispersed phase disposed in the continuous phase. (*Id.*).

An embodiment of a droplet generator is shown below in Figures 23 and 24 of the '160 patent, as depicted in Figure No. 7, below.

Figure No. 7: Figures 23 and 24 of the '160 Patent Depicting the Droplet Generator



(*Id.* at Figs. 23, 24.).

In this four-well embodiment, pressure is applied to the sample and reagent well **1226** and to oil wells **1224** to drive fluid flow to a channel junction or intersection **1232**. (*See id.* at 35:24-55.). This forms an emulsion in the output well **1228**. (*See id.*).

2. Asserted Claim of the '160 Patent

Remaining asserted claim 20 of the '160 patent is recited below.[14] It is an apparatus claim directed to a system for forming an array of emulsions in parallel.

> **20.** A system for forming an array of emulsions in parallel, comprising:
>
> a plate having an upper member attached to a lower member to form an array of emulsion production units each configured to produce a separate emulsion,
>
> each unit including a set of wells interconnected by a set of channels

[14] Bolded patent claim number indicates an independent claim.

forming a channel junction,

each channel being bounded circumferentially,

each set of wells including at least one first input well to receive a continuous phase, a second input well to receive a dispersed phase, and an output well;

wherein the set of channels includes at least two input channels extending separately from the input wells to the channel junction, at which droplets of the dispersed phase are generated in the continuous phase, and an output channel extending from the channel junction to the output well, in which an emulsion is collected,

and wherein the lower member has an upper surface that is flat and that abuts a lower surface of the upper member to form a bottom wall of openings formed in the lower surface and corresponding to the wells and the channels of each unit.

(JX-0001 at 163:15-20-164:16.).

C. U.S. Patent No. 9,500,664 ("the '664 Patent")

1. Overview of the '664 Patent

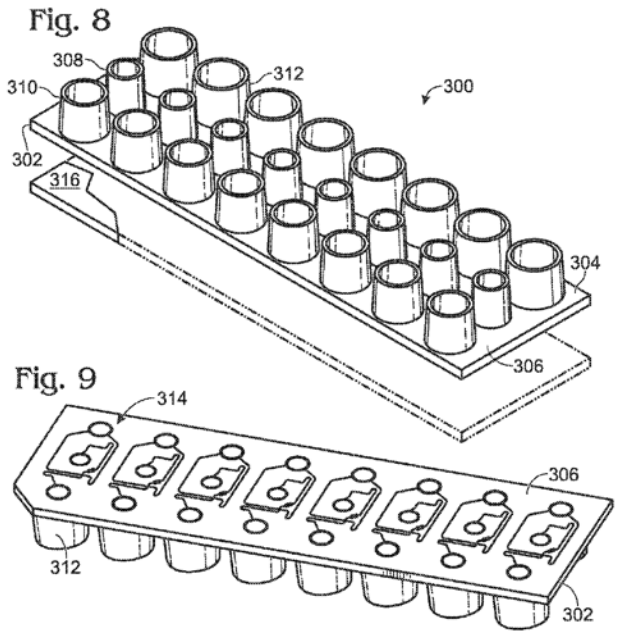
The '664 patent, titled "Droplet Generation for Droplet-Based Assays," was filed on December 20, 2011, as U.S. Patent Application Serial No. 13/341,669 ("the '669 application"). (JX-0002 at (21), (22), (54).). The '669 application issued as the '664 patent on November 22, 2016, and names Kevin D. Ness, Christopher F. Kelly, and Donald A. Masquelier as the inventors. (*Id.* at (10), (45), (75).). The '669 application is a continuation of PCT Application Serial No. PCT/US/2011/03101, filed March 25, 2011, which claims priority to U.S. Provisional Application Serial No. 61/341,218, filed on March 25, 2010. (*Id.* at (60), (63).). Bio-Rad is the assignee and owner of the '664 patent. (JX-0144.0134-0138 (Assignment of the '664 patent); *see also* JX-0002 at (73).).

Like the '160 patent, the '664 patent generally relates to the formation of emulsions on a microfluidic plate. (JX-0002 at Abstract, 2:31-42.). The disclosed droplet generation

components are configured to form sample-containing droplets by merging aqueous, sample-containing fluid with a background emulsion fluid such as oil, to form an emulsion of sample-containing droplets suspended in the background fluid. (*Id.*). As described in the '160 and '664 patents, these fluids are contained in wells that are interconnected by channels that intersect at a droplet generation region. (*Id.* at 19:59-20:10.).

An embodiment of a droplet generator is shown below in Figures 8 and 9 of the '664 patent and depicted in Figure No. 8, below.

Figure No. 8: Figures 8 and 9 of the '664 Patent Depicting the Droplet Generator

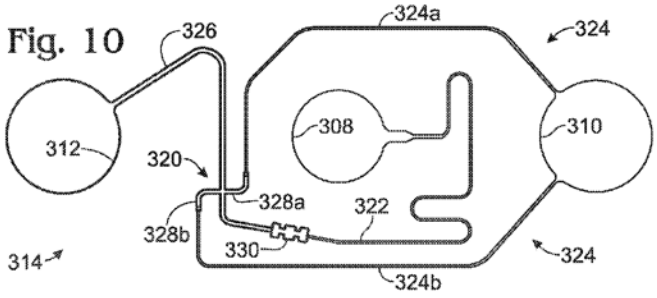


(*Id.* at Figs. 8, 9.).

In the Figure No. 8 (above) embodiment, and as shown in more detail below in Figure No. 9, the channel network **314** defines a droplet generation region **320**, which is configured to generate sample-containing droplets suspended in the background fluid. (*Id.* at 19:59-20:6.). More specifically, droplet generation region **320** is defined by the intersection of a first channel

322, a second channel **324**, and a third channel **326**. (*Id.*). First channel **322** is configured to transport sample-containing fluid from sample well 308 to droplet generation region **320**, second channel **324** is configured to transport background fluid from background fluid well 310 to droplet generation region **320**, and third channel **326** is configured to transport sample-containing droplets from droplet generation region **320** to droplet well **312**. (*Id.*).

Figure No. 9: Figure 10 of the '664 Patent Showing a Channel Network



(*Id.* at Fig. 10.).

2. Asserted Claims of the '664 Patent

Remaining asserted claims 1, 2, 14, and 15 of the '664 patent are recited below.[15] They are apparatus claims directed to systems for forming a plurality of sample-containing droplets suspended in a background fluid, and method claims for manufacturing a droplet generation system.

> **1.** A system for forming a plurality of sample-containing droplets suspended in a background fluid, comprising:
>
> a substrate having a bottom surface and a top surface;
>
> a sample well, a background fluid well, and a droplet well each having an upper region protruding from the top surface of the substrate;
>
> a network of channels formed in the bottom surface of the substrate and fluidically interconnecting the sample well, the background fluid well, and the

[15] Bolded patent claim numbers indicate independent claims.

droplet well;

and a droplet generation region defined by the network of channels and configured to generate sample-containing droplets suspended in the background fluid;

wherein the droplet generation region is defined by the intersection of a first channel, a second channel, and a third channel;

wherein the first channel is configured to transport sample-containing fluid from the sample well to the droplet generation region, the second channel is configured to transport background fluid from the background fluid well to the droplet generation region, and the third channel is configured to transport sample-containing droplets from the droplet generation region to the droplet well;

and wherein the substrate and the upper region of each well are injection molded as a single piece.

2. The system of claim 1, wherein the first channel includes an air trap configured to prevent sample-containing fluid from being inadvertently drawn through the first channel by capillary action.

14. A method of manufacturing a droplet generation system, comprising:

(i) forming a substrate having a bottom surface and a top surface;

(ii) forming a sample well;

(iii) forming a background fluid well;

(iv) forming a droplet well; and

(v) forming a droplet generation region defined by the intersection of a first channel fluidically connected with the sample well, a second channel fluidically connected with the background fluid well, and a third channel fluidically connected with the droplet outlet region

wherein the substrate, an upper region of the sample well, an upper region of the background fluid well, and an upper region of the droplet well are injection molded as a single piece;

wherein the upper region of each well protrudes from the top surface of the substrate; and wherein the first channel, the second channel, and the third channel are formed in the bottom surface of the substrate.

15. The method of claim 14, further comprising attaching a sealing

> member to the bottom surface of the substrate to form a substantially fluid tight seal and a bottom wall for each of the channels and each of the wells.

(JX-0002 at 44:55-44:18, 45:18-46:23.).

D. U.S. Patent No. 9,636,682 ("the 682 Patent")

1. Overview of the '682 Patent

The '682 patent, titled "System for Generating Droplets—Instruments and Cassette," was filed on November 14, 2016, as U.S. Patent Application Serial No. 15/351,335 ("the '335 application"). (JX-0004 at (21), (22), (54).). The '335 application issued as the '682 patent on May 2, 2017, and names Amy L. Hiddessen, Kevin D. Ness, Benjamin J. Hindson, and Donald A. Masquelier as the inventors. (*Id.* at (10), (45), (75).). The '335 application is a continuation of U.S. Patent Application Serial No. 14/159,410,[16] filed on January 20, 2014, which is a continuation-in-part ("CIP") of U.S. Patent Application Serial No. 13/287,120,[17] filed on November 1, 2011. (*Id.* at (63).). The '682 patent claims priority to U.S. Provisional Application Serial Nos. 61/409,106, filed on November 1, 2010, 61/409,473, filed on November 2, 2010, and 61/410,769, filed on November 5, 2010. (*Id.* at (60).). Bio-Rad is the assignee and owner of the '682 patent. (JX-0121.0273 to -0278 (Assignment of the '682 patent); *see also* JX-0004 at (73).).

The '682 patent discloses a holder or cassette that receives a microfluidic plate, and an instrument configured to receive the plate and the holder/cassette and to drive sample-containing fluid from the sample well to the droplet-generation region via the first channel, continuous-

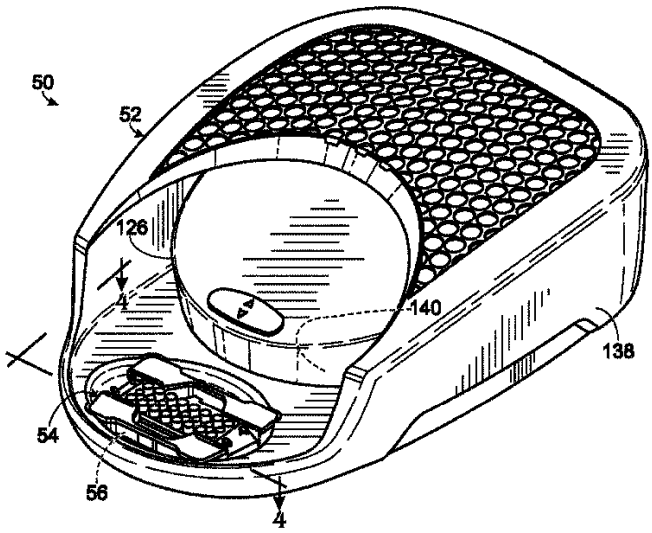
[16] This application issued as U.S. Patent No. 9,492,797. (JX-0004 at (63).).

[17] This application issued as U.S. Patent No. 9,089,844, which was asserted in the Complaint, but subsequently terminated from this Investigation. (JX-0004 at (63); Compl. at ¶ 1; Order Nos. 12 (Feb. 14, 2018), 16 (Mar. 8, 2018), 19 (Mar. 16, 2018).).

phase fluid from the continuous-phase well to the droplet-generation region via the second channel, and sample-containing droplets from the droplet-generation region to the droplet well via the third channel. (JX-0004 at Abstract, 3:39-55.).

An embodiment of the instrument **52** with cassette **54** is shown below in Figure 1 of the '682 patent, as depicted in Figure No. 10, below.

Figure No. 10: Figure 1 from the '682 Patent Showing Instrument and Cassette



(*Id.* at Fig. 1.).

The instrument is equipped with a fluidics assembly, which may include at least one pressure source, and a drive assembly, which may include one or more motors. (*Id.* at 7:1-39, 8:13-35.).

2. Asserted Claims of the '682 Patent

Remaining asserted claims 14, 16, and 17 of the '682 patent are recited below.[18] They are apparatus claims directed to systems for generating droplets.

[18] Bolded patent claim numbers indicate independent claims.

> **14.** A system for generating droplets, comprising:
>
> a device including a row of sample wells each configured to receive sample-containing fluid, a row of continuous-phase wells each configured to receive continuous-phase fluid, and a row of droplet wells, the device also including a corresponding channel network for each sample well, the channel network including a droplet-generation region and fluidically connecting the sample well to one of the continuous-phase wells and one of the droplet wells;
>
> a holder for the device; a gasket configured to be attached directly to the holder, such that the gasket extends over each sample well, each continuous-phase well, and each droplet well; and an instrument configured to
>
> (a) receive an assembly including the device, the holder, and the gasket,
>
> (b) engage the gasket with a manifold, and
>
> (c) apply positive pressure and/or negative pressure to the device via the manifold, such that sample-containing fluid flows from each sample well to the corresponding droplet-generation region, continuous-phase fluid flows from each continuous-phase well to the corresponding droplet-generation region, and sample-containing droplets flow from each droplet-generation region to the corresponding droplet well.
>
> 16. The system of claim 14, wherein the gasket defines a plurality of apertures, and wherein the holder has a plurality of projections configured to be received in the plurality of apertures to directly attach the gasket to the holder.
>
> 17. The system of claim 14, wherein the device has a planar base portion and a plurality of tubular protrusions that project upwardly from the planar base portion, and wherein the device is configured to be captured in the holder via the planar base portion.

(JX-0004 at 34:20-45, 34:50-58.).

E. U.S. Patent No. 9,649,635 ("the '635 Patent")

1. Overview of the '635 Patent

The '635 patent, titled "System for Generating Droplets with Push-Back to Remove Oil," was filed on November 14, 2016, as U.S. Patent Application Serial No. 15/351,331 ("the '331 application"). (JX-0005 at (21), (22), (54).). The '331 application issued as the '635 patent on May 16, 2017, and names Amy L. Hiddessen, Kevin D. Ness, Benjamin J. Hindson, Donald A. Masquelier, and Erin R. Chia as the inventors. (*Id.* at (10), (45), (75).). The '331 application is a

continuation of the same application and CIP as the ’335 application, which issued as the ’682 patent. (*Id.* at (63).). The ’635 patent also claims priority to the same provisional applications as the ’335 application. (*Id.* at (60).). Bio-Rad is the assignee and owner of the ’635 patent. (JX-0120.0245-0250 (Assignment of the ’635 patent); *see also* JX-0005 at (73).).

Like the ’682 patent, the ’635 patent discloses a holder or cassette that receives a microfluidic plate, and an instrument configured to receive the plate and holder/cassette. (JX-0005 at Abstract, 3:35-50.). The instrument described in the ’635 patent is configured to create: (i) a first pressure differential to produce an emulsion collected in the droplet well; and (ii) a second pressure differential to decrease a volume fraction of continuous-phase fluid in the emulsion, after the emulsion has been collected in the droplet well, by selectively driving continuous-phase fluid, relative to sample-containing droplets, from the droplet well, which results in a more droplet-concentrated emulsion. (*Id.* at Abstract; Tr. (Anna) at 515:5-19.).

2. Asserted Claims of the ’635 Patent

Remaining asserted claims 1, 13, 14, 16, and 21 of the ’635 patent are recited below.[19] They are apparatus claims directed to systems for forming and concentrating emulsions.

> **1.** A system to form and concentrate an emulsion, comprising:
>
> a device including a sample well configured to receive sample-containing fluid, a continuous-phase well configured to receive continuous-phase fluid, and a droplet well,
>
> the device also including a channel network having a first channel, a second channel, and third channel that meet one another in a droplet-generation region;
>
> and an instrument configured to operatively receive the device and to create
>
> (a) a first pressure differential to drive sample-containing fluid from the sample well to the droplet-generation region via the first channel,

[19] Bolded patent claim numbers indicate independent claims.

continuous-phase fluid from the continuous-phase well to the droplet-generation region via the second channel, and sample-containing droplets from the droplet-generation region to the droplet well via the third channel, such that the droplet well collects an emulsion including sample-containing droplets disposed in continuous-phase fluid, and

(b) a second pressure differential to decrease a volume fraction of continuous-phase fluid in the emulsion, after the emulsion has been collected in the droplet well, by selectively driving continuous-phase fluid, relative to sample-containing droplets, from the droplet well via the third channel.

13. The system of claim 1, wherein the instrument is configured to create the first pressure differential followed by the second pressure differential without user intervention.

14. The system of claim 13, wherein the instrument is configured (a) to operate a valve to eliminate the first pressure differential and (b) to create the second pressure differential after eliminating the first pressure differential, without user intervention.

16. A system to form and concentrate emulsions, comprising:

a device including a row of sample wells each configured to receive sample-containing fluid, a row of continuous-phase wells each configured to receive continuous-phase fluid, a row of droplet wells, and a plurality of separate channel networks,

each sample well being fluidically connected to one of the continuous-phase wells and one of the droplet wells via one of the channel networks,

each channel network having a first channel, a second channel, and a third channel that meet one another in a droplet-generation region;

a gasket configured to operatively engage at least one of the rows of wells;

and an instrument including a manifold, the instrument being configured to operatively engage the gasket with the manifold such that the manifold is sealed to each well of the at least one rows of wells, and to create via the manifold

(a) a first pressure differential to drive sample-containing fluid from each sample well and continuous-phase fluid from each continuous-phase well, such that sample-containing droplets are formed in the droplet-generation region of each channel network and travel via the third channel of the channel network to one of the droplet wells for collection as an emulsion including sample-containing droplets disposed in continuous-phase fluid, and

(b) a second pressure differential to decrease a volume fraction of continuous-phase fluid in each emulsion, after the emulsion has been collected in the one droplet well, by selectively driving continuous-phase fluid, relative to sample-containing droplets, from the one droplet well via the third channel.

21. The system of claim 16, wherein the instrument is configured to create the first pressure differential followed by the second pressure differential, without user intervention.

(JX-0005 at 33:29-55, 34:37-44, 34:52-35:18.).

V. THE PRODUCTS AT ISSUE.

A. Respondent's Accused Products

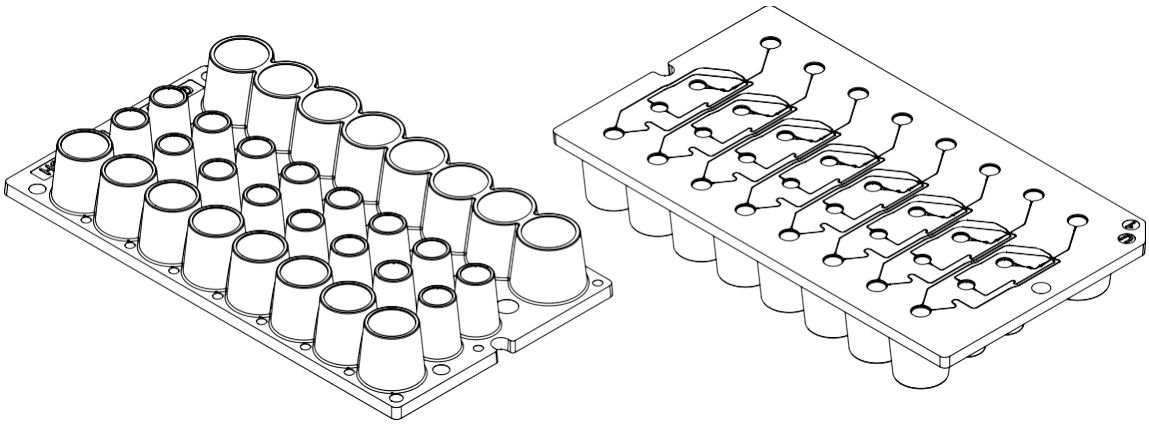
In the Complaint, Complainants accused "microfluidic chips designed for use in 10X's GemCode and Chromium sequencing platforms" of infringing, *inter alia*, claim 20 of the '160 patent; claims 1, 2, 14 and 15 of the '664 patent; claims 14, 16 and 17 of the '682 patent; and claims 1, 13, 14, 16 and 21 of the '635 patent. (Compl. at ¶ 32; *see also* CBr. at 1.). Complainants' experts specified that the Accused Products include the: (1) Chromium™ Genome Chip ("GEM-Q Chip"); (2) Chromium™ Single Cell A Chip ("GEM-U Chip," and with GEM-Q Chip, the "GEM Chips");[20] (3) [redacted] ("Chip GB"); and (4) [redacted] ("Chip SE"). (*See* Tr. (Gale) at 385:3-15; Tr. (Anna) at 511:14-17.).

The GEM Chips are used with the Chromium™ Controller and the Chromium™ Single Cell Controller (collectively, "Chromium™ Controllers," and with GEM Chips, the "Accused Products"), both of which contain different firmware but are otherwise the same, to prepare sample-containing droplets for DNA sequencing or other analysis. (Tr. (Schnall-Levin) at 1051:25-1052:5; Tr. (Hindson) at 954:2–25; CX-0568C (Schnall-Levin Dep. Tr.) at 34:13-21;

[20] GEM is an acronym for "Gel-Bead-In-Emulsions." (CX-0197.0011; CX-0353.0002; Tr. (Schnall-Levin) at 1016:15-19.).

Tr. (Anna) at 645:1-14; CX-0197.0011 (Chromium Single Cell 3' Reagent Kits v2 User Guide).). A schematic drawing of Respondent's GEM-U Chip is shown below in Figure No. 11.

Figure No. 11: Schematic Drawing of the GEM-U Chip



(JX-0008C (10X Schematic GEM-U Single Cell, Version 2.24).).

Below in Figure No. 12 is a photograph of the Chromium™ Controller and the holder into which the GEM Chips are placed.

Figure No. 12: Chromium™ Controller and Holder

(CDX-0005C.0016 (citations omitted).).

The Chip GB is a microfluidic device Respondent uses [redacted]. (*See* CX-0408C at 0007, 0011; Tr. (Santiago) at 1155:18-22, 1204:7-

10; Tr. (Anna) at 521:10-15; RPX-0022C; RPX-0023C.). [redacted]. (*See, e.g.*, CX-0408C at 0007, 0011; Tr. (Santiago) at 1155:18-22, 1204:7-10.).

Respondent has also imported [redacted], the Chip SE, [redacted]. (*See* Tr. (Hindson) at 973:20-974:3, 974:10-25, 975:18-976:10, 978:4-979:24; Tr. (Anna) at 562:16-25, 679:11-680:21; RX-1550C (Email Confirming Tracking Numbers of Chip SE); RX-1197C ([redacted]); RX-0261C (Chip SE Design). A depiction of the [redacted] of the Chip SE is shown below in Figure No. 13.

[redacted]

(RX-0261C.0002 (Chip SE Design).).

In addition to the GEM Chips, the Chip GB, and the Chip SE, Respondent argued that the following additional product designs are at issue in this investigation: (1) Chip PB [redacted] System; and (2) System NH [redacted]. (RDX-0004C.0006; Tr. (Santiago) at 1155:25-1156:11.). [redacted]

. (*See* RDX-0004C.0006, -0059, -0062; Tr. (Santiago) at 1155:25-1156:11.).

The Chip PB . (*See* RDX-0004C.0006; Tr. (Santiago) at 1155:25-1156:11.). The System NH . (*See* RDX-0004C.0006; Tr. (Santiago) at 1155:25-1156:11.).

Complainants did not raise any infringement contentions against the Chip PB and System NH in their Pre-Hearing or Initial Post-Hearing Brief.[22] Respondent also did not raise any non-infringement arguments with respect to the Chip PB and System NH in its Initial Post-Hearing Brief. Thus, these Alleged Design Arounds are not considered to be an Accused Product in this Investigation and they are not subject to the recommended LEO. Moreover, Respondent waived any argument with regard to these Alleged Design Arounds under Ground Rule 10.1.

B. Complainants' DI Products

Complainants and Respondent stipulated that Complainants have satisfied the technical prong of the domestic industry requirement. (CBr. at 7; CX-0832C (Stipulation Regarding the Economic Prong of the DI Requirement); CX-0838C (Stipulation Regarding the Technical Prong of the DI Requirement for Certain DI Products).).

The DI Products consist of: (1) Bio-Rad's DG8 Chip used with its QX100 and QX200

[21] Dr. Santiago described EEPROM firmware as "basically a piece of hardware that include coding information. (Tr. (Santiago) at 1208:14-21.).
[22] Staff did not discuss these devices in its Pre-Hearing or Initial Post-Hearing Briefs.

instruments; and (2) Bio-Rad's DG32 Chip, which consists of 4 DG8 Chips in a holder, and is used with the Bio-Rad AutoDG instrument.[23] (CBr. at 7.).

Respondent stipulated that each of Complainants' DI Products practices the asserted claims of the Asserted Patents. (CX-0838C.).

VI. PERSON OF ORDINARY SKILL IN THE ART

A. Legal Standard: Level of Ordinary Skill in the Art

The relevant time for assessing the level of ordinary skill in the art is the effective filing date of the patent. *Phillips v, AWH Corp.*, 415 F.3d 1303, 1313 (Fed. Cir. 2005) (en banc) ("We have made clear, moreover, that the ordinary and customary meaning of a claim term is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application.").

Factors to consider in determining the level of ordinary skill in the art include: (1) the educational level of the inventor; (2) the type of problems encountered in the art; (3) the prior art solutions to those problems; (4) the rapidity with which innovations are made; (5) the sophistication of the technology; and (6) the educational level of active workers in the field. *See Envtl. Designs, Ltd. v. Union Oil Co. of Cal.*, 713 F.2d 693, 696 (Fed. Cir. 1983). "These factors are not exhaustive but are merely a guide to determining the level of ordinary skill in the art." *Daiichi Sankyo Co., Ltd. v. Apotex, Inc.*, 501 F.3d 1254, 1256 (Fed. Cir. 2007).

[23] In their Pre-Hearing Brief, Complainants also relied upon the Bio-Rad ddSEQ Single Cell Isolator to satisfy the technical prong of the DI requirement in addition to the D8 and D32 Chips. (CPBr. at 8-9.). However, Complainants' experts, Dr. Gale and Dr. Anna, did not offer any opinions during the Hearing with regard to whether the ddSEQ Chip practices any claim of the Asserted Patents. (*See, e.g.*, CDX-0006.0005 (Summary of Dr. Anna's Opinions); Tr. (Anna) at 510:23-511:13; CDX-0005.0102 (Summary of Dr. Gale's Opinions); Tr. (Gale) at 448:10-22.). Moreover, this product was not included in Complainants' Initial Post-Hearing Brief. (CBr. at 7.). Thus, any argument with regard to this product has been waived under Ground Rule 10.1.

B. Definition of Person of Ordinary Skill in the Art

The Parties disagreed over the qualifications of a person of ordinary skill in the art for the Asserted Patents, but did not explicate the reasons for the disagreement. (COMBr. at 12; ROMBr. at 17; SMBr. at 21.). In arguing for their proposed constructions of disputed terms, the Parties focused on the intrinsic evidence. However, the Parties did not assert in any of their filed documents that this definition was necessary or dispositive for construction of the disputed claim terms. (*Id.*). Thus, the *Markman* Order did not provide a definition for a person of ordinary skill in the art. (*Markman* Order at 13.).

A person of ordinary skill in the field of microfluidic devices and methods of using such devices would have had knowledge of the scientific literature concerning microfluidic devices and the methods of using such devices at the time of the invention. Moreover, a person of ordinary skill in the art would have had knowledge of strategies for performing chemical and biological analysis in microfluidic devices. Thus, as Staff and Respondent proposed, a person of ordinary skill would have had a Ph.D. in chemical engineering, mechanical engineering, biomedical engineering, fluid dynamics, or a related discipline, with two years of experience in the field of microfluidic devices. (SBr. at 18, 27, 35; RBr. at 15, 46, 67, 76; RDX-0004C.0007; Tr. (Santiago) at 1157:3-17.). Additional training or work experience could substitute for formal education. (*See* RDX-0004C.0007; Tr. (Santiago) at 1157:3-17.).

VII. U.S. PATENT NO. 9,126,160

A. Claim Construction

1. Legal Standard[24]

Claim construction begins with the plain language of the claims themselves. Claims should be given their ordinary and customary meaning as understood by a person of ordinary skill in the art, viewing the claim terms in the context of the entire patent. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312-13 (Fed. Cir. 2005), *cert. denied*, 546 U.S. 1170 (2006). In some cases, the plain and ordinary meaning of the claim language is readily apparent and claim construction will involve little more that "the application of the widely accepted meaning of commonly understood words." *Id.* at 1314. In other cases, claim terms have a specialized meaning and it is necessary to determine what a person of ordinary skill in the art would have understood the disputed claim language to mean by analyzing "the words of the claims themselves, the remainder of the specification, the prosecution history, and extrinsic evidence concerning relevant scientific principles, as well as the meaning of technical terms, and the state of the art." *Id.* (quoting *Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc.*, 381 F.3d 1111, 1116 (Fed. Cir. 2004)).

The claims themselves provide substantial guidance as to the meaning of disputed claim language. *Id.* "[T]he context in which a term is used in the asserted claim can be highly instructive." *Id.* Likewise, other claims of the patent at issue, "both asserted and unasserted, can also be valuable sources of enlightenment as to the meaning of a claim term." *Id.* (citation omitted).

[24] The claim constructions for the agreed upon and disputed claim terms are listed in Sections VII.A, VIII.A, IX.A, and X.A, *infra*.

With respect to claim preambles, a preamble may limit a claimed invention if it: (i) recites essential structure or steps; or (ii) is "necessary to give life, meaning, and vitality" to the claim. *Eaton Corp. v. Rockwell Int'l Corp.*, 323 F.3d 1332, 1339 (Fed. Cir. 2003) (citations omitted). The Federal Circuit has explained that a "claim preamble has the import that the claim as a whole suggests for it. In other words, when the claim drafter chooses to use both the preamble and the body to define the subject matter of the claimed invention, the invention so defined, and not some other, is the one the patent protects." *Id.* (quoting *Bell Commc'ns Research, Inc. v. Vitalink Commc'ns Corp.*, 55 F.3d 615, 620 (Fed. Cir. 1995)). When used in a patent preamble, the term "comprising" is well understood to mean "including but not limited to," and thus, the claim is open-ended. *CIAS, Inc. v. Alliance Gaming Corp.*, 504 F.3d 1356, 1360 (Fed. Cir. 2007). The patent term "comprising" permits the inclusion of other unrecited steps, elements, or materials in addition to those elements or components specified in the claims. *Id.*

In cases in which the meaning of a disputed claim term in the context of the patent's claims remains uncertain, the specification is the "single best guide to the meaning of a disputed term." *Phillips*, 415 F.3d at 1321. Moreover, "[t]he construction that stays true to the claim language and most naturally aligns with the patent's description of the invention will be, in the end, the correct construction." *Id.* at 1316. As a general rule, however, the particular examples or embodiments discussed in the specification are not to be read into the claims as limitations. *Id.* at 1323.

The prosecution history may also explain the meaning of claim language, although "it often lacks the clarity of the specification and thus is less useful for claim construction purposes." *Id.* at 1317. The prosecution history consists of the complete record of the patent

examination proceedings before the U.S. Patent and Trademark Office ("PTO"), including cited prior art. *Id.* It may reveal "how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be." *Id.*

If the intrinsic evidence is insufficient to establish the clear meaning of a claim, a court may resort to an examination of the extrinsic evidence.[25] *Zodiac Pool Care, Inc. v. Hoffinger Indus., Inc.*, 206 F.3d 1408, 1414 (Fed. Cir. 2000). Extrinsic evidence may shed light on the relevant art, and "consists of all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises." *Phillips*, 415 F.3d at 1317. In evaluating expert testimony, a court should disregard any expert testimony that is conclusory or "clearly at odds with the claim construction mandated by the claims themselves, the written description, and the prosecution history, in other words, with the written record of the patent." *Id.* at 1318. Expert testimony is only of assistance if, with respect to the disputed claim language, it identifies what the accepted meaning in the field would be to one skilled in the art. *Symantec Corp. v. Comput. Assocs. Int'l, Inc.*, 522 F.3d 1279, 1289 n.3., 1290-91 (Fed. Cir. 2008). Testimony that recites how each expert would construe the term should be accorded little or no weight. *Id.* Extrinsic evidence is inherently "less reliable" than intrinsic evidence, and "is unlikely to result in a reliable interpretation of patent claim scope unless considered in the context of the intrinsic evidence." *Phillips*, 415 F.3d at 1318-19.

[25] "In those cases where the public record unambiguously describes the scope of the patented invention, reliance on any extrinsic evidence is improper." *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1583 (Fed. Cir. 1996).

2. Relevant Claim Terms

The following constructions of the claim terms recited in the asserted claim of the '160 patent have been agreed upon by the Parties and adopted by this Court. (*See Markman* Order, App. A at Chart No. 2.).

Table No. 5: Constructions of Agreed Upon Claim Terms Relevant to the '160 Patent

Claim Term	Adopted Construction
"channel"	an elongate passage for fluid travel
"dispersed phase"	an aqueous phase or other fluid that is immiscible with the continuous phase
at least two input channels extending separately from the input wells to the channel junction, at which droplets of the dispersed phase are generated in the continuous phase	at least two input channels extending separately from the input wells to the channel junction, at which droplets of the dispersed phase are generated in the continuous phase

The following construction of the disputed claim term was construed by this Court.[26] (*Markman* Order, App. A at Chart No. 1.).

Table No. 6: Construction of the Disputed Claim Term Relevant to the '160 Patent

Claim Term	Adopted Construction
"channel junction"	the intersection of (1) a sample- containing dispersed phase fluid inlet channel, (2) a continuous phase fluid inlet channel, and (3) a droplet outlet channel

[26] The Parties disputed the meaning of additional claim terms recited in claims that have been terminated from this Investigation. Those terms are not included in Table No. 6.

B. Legal Standard: Direct Infringement

"Determination of infringement is a two-step process which consists of determining the scope of the asserted claim (claim construction) and then comparing the accused product . . . to the claim as construed." *Certain Sucralose, Sweeteners Containing Sucralose, and Related Intermediate Compounds Thereof*, Inv. No. 337-TA-604, Comm'n Op. at 36 (U.S.I.T.C., April 28, 2009) (citing *Litton Sys., Inc. v. Honeywell, Inc*., 140 F.3d 1449, 1454 (Fed. Cir. 1998)).

1. Literal Infringement

An accused device literally infringes a patent claim if it contains each limitation recited in the claim exactly. *Litton*, 140 F.3d at 1454. Each patent claim element or limitation is considered material and essential. *London v. Carson Pirie Scott & Co.*, 946 F.2d 1534, 1538 (Fed. Cir. 1991). In a Section 337 investigation, the complainant bears the burden of proving infringement of the asserted patent claims by a preponderance of the evidence. *Enercon GmbH v. Int'l Trade Comm'n*, 151 F.3d 1376, 1384 (Fed. Cir. 1998). If any claim limitation is absent, there is no literal infringement of that claim as a matter of law. *Bayer AG v. Elan Pharm. Research Corp.*, 212 F.3d 1241, 1247 (Fed. Cir. 2000).

C. Infringement Overview

Complainants alleged that the GEM Chips and the Chip SE ("Accused 160 Products") contain each limitation and directly infringe claim 20 of the '160 patent. (CBr. at 10-17.). *Litton*, 140 F.3d at 1454.

With respect to the GEM Chips, Respondent's expert, Dr. Santiago, testified that these products do not satisfy the following two (2) limitations of the asserted claim: (1) "each unit including a set of wells interconnected by a set of channels forming a channel junction"; and (2)

"wherein the set of channels includes at least two input channels extending separately from the input wells to the channel junction." (Tr. (Santiago) at 1184:2-8; RDX-0004C.0021.).

In this case, record evidence clearly establishes that the GEM Chips have a "channel junction" where droplets are formed, and that this junction is located at the intersection of input channels and an output channel. (*See* Tr. (Santiago) at 1255:23-1256:8; RDX-0004C.0011.). In the GEM Chips, droplets are formed at the junction of what Respondent has labeled the singulation channel, the oil channel, and the outlet channel, shown in the red box in Figure No. 14, below. (*See id.*).

(CDX-0004C.0037; CDX-0005C.53.).

The critical issue about which the Parties disagreed is whether the input channel (indicated by the green arrows in Figure No. 14 above) carrying fluid from the second input well (i.e., the sample well) extends all the way from the second input well to the channel junction in a single channel, as claim 20 requires, or whether sample fluid moves through multiple channels to reach the channel junction.

For the reasons discussed below, Complainants failed to prove by a preponderance of evidence that the GEM Chips include "a set of channels" with "at least two input channels ***extending*** separately ***from*** the input wells ***to*** the channel junction," literally or under the doctrine of equivalents ("DOE"). Evidence accepted in this Investigation demonstrates that the sample fluid moves through the sample channel and the singulation channel before reaching the channel junction. Thus, the input channel from the sample well does not extend "from the input wells to the channel junction."

With regard to the Chip SE, Complainants maintained that the chip literally infringes claim 20 because it is "can be configured" to be used in an infringing and is thus "reasonably capable" of performing the limitations recited by the claim. As discussed in more detail below, Complainants' infringement arguments are based on a hypothetical use of the Chip SE.

Respondent's argument, supported by persuasive evidence from Dr. Santiago, supports a finding that when the Chip SE is used as Respondent intends, the Chip SE does not have the claimed oil well, oil channel, channel junction, outlet channel, and outlet well. (Tr. (Santiago) at 1155:5-24.). Moreover, because claim 20 recites structural, and not merely functional, limitations, it is not enough for Complainants to prove that the accused chip is "reasonably capable" of being used in the infringing manner.

Accordingly, Complainants have not met their burden and proven that the Accused 160 Products infringe claim 20 of the '160 patent.

D. The Accused 160 Products Do Not Directly Infringe Claim 20 of the '160 Patent

1. The GEM Chips Do Not Infringe Claim 20 Literally or Under the Doctrine of Equivalents

a) "A system for forming an array of emulsions in parallel, comprising"

Complainants produced compelling evidence and argument that the GEM Chips meet the preamble. (Tr. (Gale) at 393:18-24, 395:11-14.). Complainants presented compelling evidence that each GEM Chip includes multiple systems, or "an array," for forming a plurality of sample-containing droplets suspended in a background fluid where each system comprises a sample well, oil well, bead well, and outlet well that are connected by microfluidic channels, which is reflected below in Figure No. 15. (Tr. (Gale) at 393:25-394:24, 395:5-10; CPX-0003C; CPX-0004C; JX-0008C; JX-0064C; CDX-0005.0026, -0027.).

Figure No. 15: Schematic Drawings of the GEM Chips Showing an Array

Moreover, videos, Respondent 10X documents, and corporate testimony from Respondent 10X confirmed that each system generates sample-containing droplets at the intersection of the aqueous phase channel and oil channel. (Tr. (Gale) at 388:22-389:22; 393:25-395:4; CX-0376C; CX-0612C (Paul Wyatt Dep. Tr.)[27] at 37:25-38:10-20.). During his deposition, 10X's Director of Microfluidics, Rajiv Bharadwaj,[28] testified that each GEM Chip has "eight layouts" or systems that each produces droplets. (CX-0616C (Bharadwaj Dep. Tr.) at 43:3-12.).

Respondent did not rebut this evidence in its Pre-Hearing or Initial Post-Hearing Briefs.

[27] At the time of his deposition on January 20, 2018, Mr. Paul Wyatt was the Vice President of Operations at 10X. (CX-0612C (Wyatt Dep. Tr.) at 7:3-7, 9:7-14.). His responsibilities included overseeing process development, manufacturing function, quality assurance facilities, and systems engineering. (*Id.*). Respondent identified Mr. Wyatt as a fact witness to provide testimony with regard to matters relating to 10X, including the company, its history, and its products. (RPSt. at 4.).

[28] At the time of his depositions on November 17, 2017 and January 31, 2018, Rajiv Bharadwaj was Director of Microfluidics at 10X. (CDX-0006.0061; CX-0199C (Bharadwaj Dep. Tr.); CX-0616C (Bharadwaj Dep. Tr.).). 10X identified Mr./Dr. Bharadwaj as a fact witness to testify about matters relating to 10X's products, including research and development ("R&D") and design of 10X's products, microfluidic technology, claim construction, including the state of the prior art, and non-infringement. (RPSt. at 2.).

Thus, Respondent has waived argument on this issue under Ground Rules 7.2 and 10.1.

Alternatively, Complainants have proven by a preponderance of evidence that the GEM Chips meet the preamble of claim 20 of the ’160 patent.

b) “a plate having an upper member attached to a lower member to form an array of emulsion production units each configured to produce a separate emulsion”

Complainants alleged, and Respondent did not dispute, that the GEM Chips meet this limitation of claim 20. (Tr. (Gale) at 395:15-24, 398:2-5.). Persuasive evidence adduced in this Investigation reflects that each GEM Chip is a plate or chip having an upper member attached to the lower member (i.e., film) and an array of eight emulsion production units that each produce separate emulsions, which Respondent’s fact witness, Mr. Wyatt, confirmed. (Tr. (Gale) at 395:25-398:1; CPX-0003C; CPX-0004C; JX-0008C; JX-0064C; CDX-0005.0031 to -0033; CX-0612C (Wyatt Dep. Tr.) at 26:2-9.).

Respondent did not rebut this evidence in its Pre-Hearing or Initial Post-Hearing Briefs. Thus, any argument on this issue is waived under Ground Rules 7.2 and 10.1.

Alternatively, Complainants have proven by a preponderance of evidence that the GEM Chips meet this limitation of claim 20 of the ’160 patent.

c) “each unit including a set of wells interconnected by a set of channels forming a channel junction”

Complainants alleged that the GEM Chips meet this limitation of claim 20. (Tr. (Gale) at 398:6-10, 402:5-8.). Respondent did not dispute that the GEM Chips have “a set of wells interconnected by a set of channels.” As Complainants asserted, the physical chips and 10X schematics indicate that each GEM Chip includes a network of microfluidic channels in the bottom surface of the chip connecting each set of wells, which is reflected in Figure No. 16

below. (Tr. (Gale) at 399:16-400:4; CPX-0003C; CPX-0004C; JX-0008C; JX-0064C; CDX-0005.0037.).

Figure No. 16: Schematic Drawings Showing Interconnected Wells of the GEM Chips

(CDX.0005C.0037.).

Respondent's expert, Dr. Santiago, testified that the GEM Chips do not include the claimed "channel junction," which was construed to mean "the intersection of (1) a sample-containing dispersed phase fluid inlet channel, (2) a continuous phase fluid inlet channel, and (3) a droplet outlet channel." (Tr. (Santiago) at 1184:2-8; RDX-0004C.0021; *Markman* Order, App. A at Chart No. 1.). Specifically, Dr. Santiago offered his opinion that the singulation channel that intersects with the continuous phase (oil) inlet channel and the droplet outlet channel is not a "sample-containing dispersed phase fluid inlet channel" because it contains a mixture (Z3) that is different from the fluid from the sample well (Z2). (Tr. (Santiago) at 1184:18-1185:3, 1191:6-18.). In other words, according to Dr. Santiago, at the junction where the droplets are formed, i.e., at the intersection of the singulation, oil and outlet channels, because the Z3 fluid (shown in Figure No. 17, in purple below) is not purely the Z2 fluid from the sample well but a mixture of the Z1 and Z2 fluids from the bead well and the sample well, the singulation channel is not the "sample-containing dispersed phase fluid inlet channel" and this junction is not the claimed

"channel junction." (Tr. (Santiago) at 1184:18-1185:3, 1191:6-18.).

Figure No. 17: Singulation Channel in the GEM Chips

(RDX-0004C.0011 (citing JX-0064C; JX-0008C).).

Dr. Santiago's testimony is unavailing for the following reasons. As an initial matter, Dr. Santiago did not dispute that droplets are formed at the intersection of the singulation channel, the oil channel, and the outlet channel of the GEM Chips. (*See* Tr. (Santiago) at 1255:23-1256:8; RDX-0004C.0011; SBr. at 20-21.). Additionally, Dr. Santiago did not dispute that these droplets are comprised of sample-containing dispersed phase fluid that travels down the outlet channel to the outlet well where the sample-containing droplets are collected:

> Q. You would agree with me that there is -- in the outlet channel, there is a dispersed -- a sample containing dispersed phase fluid; correct?
>
> A. Yes. ***The sample is part of the mixture inside the droplets, I agree with that.***
>
> Q. There's a sample-containing dispersed phase fluid in the outlet channel; correct?

A. ***Sample is part of the mixture in the droplets, yes, correct***.

(Tr. (Santiago) at 1223:15-23 (emphases added); *see also id.* at 1225:18-1226:15; CDX-0203.0002.).

This is consistent with Dr. Santiago's testimony with respect to the Z3 mixture contained in the singulation channel shown in Figure Nos. 18 and 19 below. As Dr. Santiago testified, the fluid in the singulation channel shown in Figure Nos. 18 and 19 include ***sample*** from the sample well (small white dots in Figure Nos. 18 and 19) as well as beads from the bead well (colored larger dots in Figure Nos. 18 and 19).[29]

Figure No. 18: 10X Illustration Showing the Contents of the Singulation Channel

[29] In his testimony below, Dr. Santiago went to great lengths to distinguish a sample-containing "fluid" from a "suspension" that includes beads. (*See also* Tr. (Santiago) at 1161:10-1163:19.). Dr. Santiago's view was that the beads are not a fluid phase but cross-linked polymers that do not "deform[] continuously under shear stress." (*Id.* at 1162:8-23, 1163:11.). This line of argument is a red herring. The pertinent issue is whether the singulation channel holds sample-containing dispersed fluid from the sample well. Whether the singulation channel also holds a bead "suspension" that may or may not be a "fluid phase" is immaterial.

(CDX-0189.0003 (excerpt from ROMBr. at 10).)

Q. So in CX-189, which is the figure on the right-hand side of the screen, there are two vertical channels coming in on the left-hand side. Do you see those?

A. Yes.

Q. And those are colored in green with some white dots?

A. That's right.

Q. ***And that's material coming from the sample channel; correct?***

A. ***That's what was meant to be depicted there, yes.***

Q. And on to the left of those vertical lines, there is a channel which is carrying beads and fluid; correct?

A. It's carrying beads in a mixture.

Q. A mixture, there's fluid in there; correct?

A. The fluid is part of the suspension, yes.

Q. And when those two meet, what is depicted in this figure CX-189 is that the beads are traveling down the center of the singulation channel; correct?

A. Yes.

Q. ***And you see the fluid from the sample well towards the sidewalls of the singulation channel; correct?***

A. ***I see that that's what the cartoon shows.***

(Tr. (Santiago) at 1218:17-1219:15 (emphases added); CDX-0189.0003.).

(CX-0815C.0004.).

Q. Let's turn to CX-815 (as shown in Figure 19, above). And can we blow up CX-815, please. Dr. Santiago, this is a figure you're familiar with; correct? You remember drawing these lines at your deposition?

A. Yes, I do.

Q. So this again is a depiction of on the left-hand side of this figure CX-815C, we have beads coming in; correct?

A. Beads are depicted coming in, yes.

Q. And they're colored red, purple, blue, mustard, purple again?

A. Yes.

Q. And there's a fluid surrounding them that's colored in light blue; correct?

A. A mixture, a solution, yes.

Q. A solution is a fluid; correct?

A. No.

Q. There's no fluid in this channel?

A. There is fluid in that channel.

Q. And we also have coming in something two channels that are kind of arrow meeting like a point colored in green. Do you see those?

A. I do.

Q. And it says, "cell suspension." Do you see that?

A. Yes.

Q. And those are -- there's a fluid in there colored in green. Do you see that?

A. There's a mixture. I think it depicts a solution. A solution is a solvent and solutes.

Q. It's fluid; correct? There's fluid in there?

A. Is solvent is a fluid.

Q. And that's depicted in green; correct?

A. Yes.

Q. With white beads or white cells?

A. That's what's meant, yeah, in the cartoon. Yes.

Q. And this is a document from 10X; correct?

A. Yes, as far as I know. Yes.

Q. ***And what this shows is when the bead solution comes into contact with the cell solution, after that meeting point which is right here, correct, and I don't know how to say that in words, but they come together, correct, the bead solution comes together with the cell suspension -- solution; correct?***

A. ***At the first junction, yes.***

Q. ***And after they come together what's depicted in this cartoon is that the sample solution flows towards the sidewalls and the bead solution flows towards the middle; correct? That's what's shown here?***

A. ***That's what's attempted to be shown there, yes.***

* * *

Q. And it's fair to say, isn't it, that the material, the fluid from the sample well makes its way into the singulation channel; correct?

A. ***You said both material -- so the material from the sample well makes it to the singulation channel, yes.***

Q. That would include the fluid; correct?

A. Yes. It's part of the mixture.

(Tr. (Santiago) at 1219:22-1221:21, 1232:19-25 (emphases added); CX-0815C.0004.).

10X's employee, Rajiv Bharadwaj, corroborated Dr. Gale's testimony that the Z3 fluid includes sample fluid (Z2). (CX-0616C (Bharadwaj Dep. Tr.) at 173:1-14 ("Q. Okay. And you are talking about the place where the sample meets the beads? A. Yes. So I'm referring to the first channel intersection where the Z2 and the Z1 fluids meet . . . along with the bead and the cell. . . . And then they form a mixture. Right? And that mixture goes through the singulation channel. And the fluid in the singulation channel -- let's call it Z3, which is a mixture of the Z2 and Z1 fluids. So that's how I think about it."); *see also* Tr. (Gale) at 481:13-25.).

Respondent argued at length that because the bead channel, the sample channel, and the singulation channel each carry a "very different composition," the singulation channel is different from the sample channel. (Tr. (Santiago) at 1253:22–1255:6.). Respondent's focus on the exact composition of the fluid in the singulation misses the point. (RBr. at 20, 22.). As Complainants' expert, Dr. Gale, observed, the singulation channel contains sample-containing dispersed phase fluid that originated in the sample well. (Tr. (Gale) at 407:20-408:19, 409:9-25.). The adopted construction requires nothing more to establish a "channel junction," that is, a physical structure. Additionally, courts have consistently found that claims using "comprising" as a transitional term do not exclude the presence in the accused apparatus of additional elements that are not explicitly recited. *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 811 (Fed. Cir. 1999) ("['Comprising'] is generally understood to signify that the claims do not exclude the presence in the accused apparatus or method of factors in addition to those explicitly recited"); *see also Lee v. Mike's Novelties, Inc.*, 543 F. App'x 1010, 1014 (Fed. Cir. 2013); *Certain Microelectromechanical Sys. (Mems Devices) & Prod. Containing the Same*, Inv. No.

337-TA-876, Order No. 53, 2014 WL 507477, at *6 (Jan. 29, 2014). As Dr. Santiago acknowledged, the fluid that flows in the singulation channel contains sample-containing dispersed phase fluid from the sample well. (Tr. (Santiago) at 1221:10-21.). The addition of reagents, including beads, to the fluid does not alter the undisputed fact that sample-containing fluid is present in the singulation channel.

Moreover, Respondent's argument limiting the sample inlet channel to one that contains ***only*** fluid received directly from the sample well is an improper attempt to re-argue the claim construction for "channel junction. The *Markman* Order does not define a sample channel as a channel carrying sample-containing dispersed phase fluid received directly from the sample well. To the contrary, the *Markman* Order found Respondent's proposed construction that the channel must receive fluid ***from*** the well as inappropriately narrowing and departing from the plain and ordinary meaning of the claim language. (*Markman* Order, App. A, Chart No. 1 at 5.).

Additionally, for the first time in its Initial Post-Hearing Brief, Respondent asserted that the GEM-U Chip infringes ***sometimes*** because the "singulation channel does not contain any sample the majority of the time." (RBr. at 29.). Specifically, Respondent asserted that the GEM-U Chip infringes "less than 10% of the time" when the singulation channel contains sample. (*Id.*). This non-infringement argument is without merit. First, Respondent did not raise this argument in its Pre-Hearing Brief and thus waived it under Ground Rule 7.2. Additionally, Respondent did not argue any specific percentages applied (which is vague, in any case). Second, the Federal Circuit has held "[i]t is well settled that an accused device that 'sometimes, but not always, embodies a claim[] nonetheless infringes.'" *Broadcom Corp. v. Emulex Corp.*, 732 F.3d 1325, 1333 (Fed. Cir. 2013) (internal citation omitted).

For these reasons, Complainants have proven by a preponderance of evidence that the

GEM Chips meet this limitation of claim 20 of the ’160 patent.

d) “each channel being bounded circumferentially”

Complainants proved through persuasive evidence that the GEM Chips meet this limitation of claim 20. (Tr. (Gale) at 402:9-15.). The physical chips and 10X schematics show that each GEM Chip includes a network of microfluidic channels in the bottom surface of the chip that are circumferentially bound by a sealing layer. (Tr. (Gale) at 402:16-25, 403:21-24; CPX-0003C; CPX-0004C; JX-0008C; JX-0064C; CDX-0005.0040.). Relying upon documents, Mr. Wyatt’s testified that the channels in each GEM Chip are bound circumferentially so that fluid does not fall out. (CX-0612C (Wyatt) at 26:2-24 (“Q. And what is the purpose of the laminate? A. The laminate purpose is to enclose the . . . channels on the chips and basically make those what they call tubular or, you know, make them a fluidic channel. Q. Circumferentially bounded, would that be a fair characterization of what that film does? A. Yes, yes. Q. So it circumferentially bounds the channels in the . . . chip? A. Yes.”); *see also* Tr. (Gale) at 403:1-20; JX-0008C; JX-0064C; CDX-0005.0040.).

Because Respondent did not dispute or rebut this evidence in its Pre-Hearing or Initial Post-Hearing Briefs, Respondent has waived argument on this issue under Ground Rules 7.2 and 10.1.

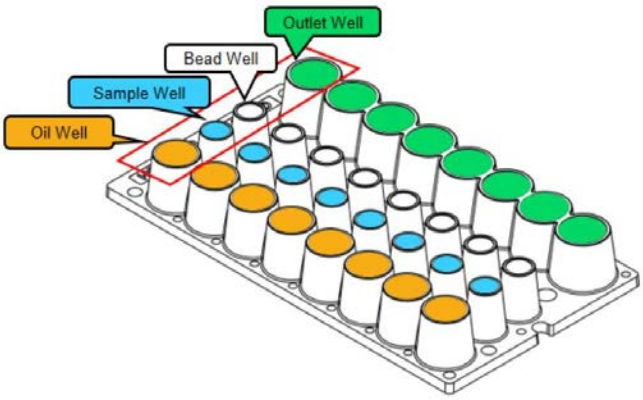
Based upon persuasive evidence, Complainants have proven by a preponderance of evidence that the GEM Chips meet this limitation of claim 20 of the ’160 patent.

e) “each set of wells including at least one first input well to receive a continuous phase, a second input well to receive a dispersed phase, and an output well”

Complainants have proven that the GEM Chips meet this limitation of claim 20. (Tr. (Gale) at 403:25-404:5, 405:9-13, 406:3-8.). Specifically, Complainants presented compelling

evidence that each GEM Chip is a substrate or chip having eight emulsion formation units, with each unit having an input well to receive continuous phase fluid (Tr. (Gale) at 404:6-405:4; CDX-0005.0043), a second input well to receive dispersed phase fluid (Tr. (Gale) at 405:14-23; CDX-0005.0046), and an output well to collect droplets (Tr. (Gale) at 406:9-21; CDX-0005.0049; CPX-0003C; CPX-0004C; JX-0008C; JX-0064C.).

Figure No. 20: Schematic Drawing Showing Set of Wells



(CDX-0005C.0043.).

Respondent did not rebut this evidence in its Pre-Hearing or Initial Post-Hearing Briefs. Thus, Respondent has waived argument on this issue under Ground Rules 7.2 and 10.1.

For the foregoing reasons, Complainants have proven by a preponderance of evidence that the GEM Chips meet this limitation of claim 20 of the ’160 patent.

f) “wherein the set of channels includes at least two input channels extending separately from the input wells to the channel junction, at which droplets of the dispersed phase are generated in the continuous phase, and an output channel extending from the channel junction to the output well, in which an emulsion is collected”

i. No Literal Infringement

Complainants alleged that the GEM Chips literally meet this limitation of claim 20. (Tr.

(Gale) at 407:1-408:19.). Dr. Gale, one of Complainants' experts offered an unsupported opinion that at the intersection of channels at which droplets are formed (shown in the red box in Figure No. 21 below), one of the inlet channels contains continuous phase fluid (oil) (indicated by the yellow arrows in Figure No. 21 below), the other inlet channel contains dispersed phase with sample (indicated by the blue arrow in Figure No. 21 below), and that the channel with dispersed phase contains sample that originated from the sample well (via the sample channels) (indicated by the green arrows in Figure No. 21 below). (*Id.* at 407:20-408:5, 409:9-20, 408:11-25; JX-0008C; JX-0064C; CDX-0005.0054.).

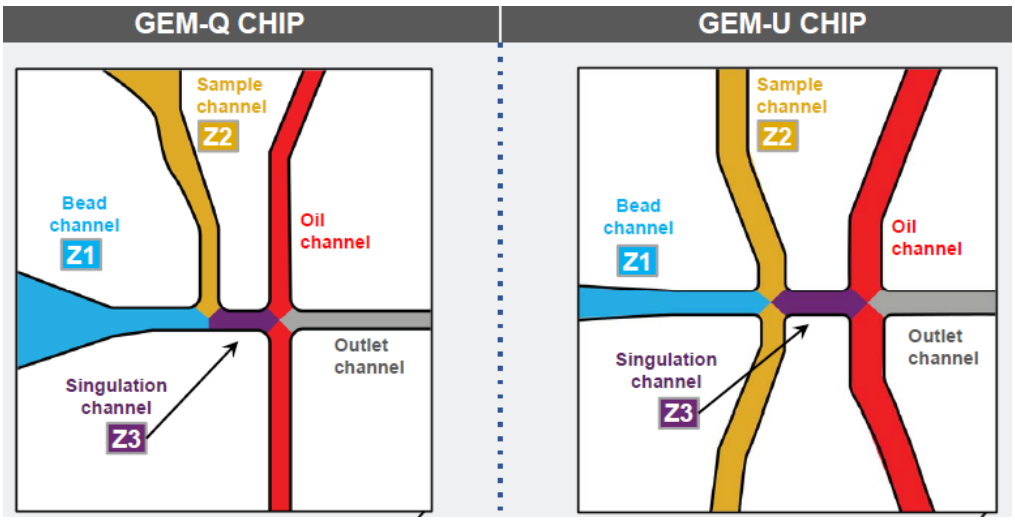
Figure No. 21: Schematic Drawing Showing the Channels and Channel Junction

(CDX-0005C.0054 (citing JX-0008C; JX-0064C).).

Dr. Gale's opinion is not persuasive. As Staff and Respondent argued, the GEM Chips do not meet this limitation because they do not have an input channel carrying fluid ***from*** the

second input well (i.e., the sample well) that extends all the way from the second input well ***to*** the channel junction in a single channel, as claim 20 requires. (SBr. at 24; RRBr. at 4-5.). As shown in Figure No. 22 below, the sample-containing fluid channel intersects with the bead channel, and fluid containing a combination of sample and beads travels down the singulation channel, a new channel, before arriving at the channel junction, where the droplets are formed.

Figure No. 22: Drawing of the GEM Chips Showing Multiple Channels



(RDX-0004C.0011.).

The ’160 patent defines the term “channel” as “an elongate passage for fluid travel.” (*See* JX-0001 at 17:61.). Although this definition does not exclude passages with two inlets (where fluid enters a channel), it does not necessarily support a finding that multiple passages leading to the multiple inlets (i.e., channels containing Z2 and Z3 in Figure No. 22 above) are part of the same channel. The specification of the ’160 patent is consistent with Respondent’s argument and Dr. Santiago’s testimony that the singulation channel is a separate channel having two inlets and one outlet. (*See* Tr. (Santiago) at 1255:7-22.).

Thus, in the GEM Chips, while the singulation channel does carry sample fluid to the

channel junction, the evidence demonstrates and supports a finding that the sample well does not extend from the sample well to the channel junction. (*See* JX-0064C.0002 (GEM-Q); JX-0008C.0001 (GEM-U).). Rather, the sample fluid from the sample well travels through ***multiple*** channels (i.e., sample channel and singulation channel) before reaching the channel junction. Accordingly, the GEM Chips do not have a channel that extends all the way from the sample well to the channel junction, as required by the claims. *Bayer*, 212 F.3d at 1247.

For the reasons discussed above, Complainants have not proven by a preponderance of evidence that the GEM Chips meet this limitation of claim 20 of the '160 patent.

ii. No Infringement Under the Doctrine of Equivalents

Complainants argued that "[e]ven if the addition of the gel bead reagent in dispersed phase to the sample containing fluid creates a new channel (the so-called 'singulation channel' in 10X parlance) and literal infringement is not found," the GEM Chips still infringes under the doctrine of equivalents. (CBr. at 16; Tr. (Gale) at 413:21-25; CDX-0005.0056.).

The Supreme Court has described the essential inquiry of the doctrine of equivalents analysis in terms of whether the accused product or process contains elements identical or equivalent to each claimed element of the patented invention. *Warner-Jenkinson Co., Inc. v. Hilton Davis Chemical Co.*, 520 U.S. 17, 40 (1997). According to the Federal Circuit:

> Infringement under the doctrine of equivalents may be found when the accused device contains an "insubstantial" change from the claimed invention. Whether equivalency exists may be determined based on the "insubstantial differences" test or based on the "triple identity" test, namely, whether the element of the accused device "performs substantially the same function in substantially the same way to obtain the same result." The essential inquiry is whether "the accused products or process contain elements identical or equivalent to each claimed element of the patented invention[.]"

TIP Sys., LLC v. Phillips & Brooks/Gladwin, Inc., 529 F.3d 1364, 1376-77 (Fed. Cir. 2008)

(citations omitted); *Cephalon, Inc. v. Watson Pharms., Inc.*, 707 F.3d 1330, 1341 (Fed. Cir. 2013).

Dr. Gale testified that the passages Respondent identified as the sample channel and the singulation channel are passages for fluid travel that together perform the same function in the same way to achieve the same result. (*See* Tr. (Gale) at 412:8-413:25.). Dr. Gale's testimony is not persuasive for a number of reasons.

To begin with, the limitation discussed in this Section recites "at least two input channels extending separately from the input wells to the channel junction." (JX-0001 at 164:6-11.). As Staff noted, although the GEM Chips achieve a similar result, "they do so in different ways using structural arrangements that are substantially different than the claimed invention." (SBr. at 25.). Respondent's expert, Dr. Santiago, explained that:

> [T]he two input channels that it's describing in the claim is the sample channel from the sample well, and the oil channel from the oil input well. . . . That sample channel has to travel or extend separately from the input well to the channel junction. So a channel as in the 10X chip, which before arriving at the junction goes through a first junction and combines material with another reagent, I don't consider that extending separately."

(Tr. (Santiago) at 1252:20-1253:21.).

Additionally, as Respondent argued, Complainants' description of and position on the structure would vitiate the structural limitation of a channel that extends from the sample well to the alleged channel junction. (RRBr. at 9.). The Federal Circuit has held that a claim to a direct connection is not equivalent to an indirect connection in the accused products, where the equivalent theory would entirely vitiate a particular claim element, as would be the case here. *See Searfoss v. Pioneer Consol. Corp.*, 374 F.3d 1142, 1151 (Fed. Cir. 2004); *Warner-Jenkinson*, 520 U.S. at 29 ("[i]t is important to ensure that the application of the doctrine [of equivalents],

even as to an individual element, is not allowed such broad play as to effectively eliminate that element in its entirety"); *Dolly, Inc. v. Spalding & Evenflo Cos.*, 16 F.3d 394, 400 (Fed. Cir. 1994) ("[T]he concept of equivalency cannot embrace a structure that is specifically excluded from the scope of the claims.").

Moreover, as Respondent and Staff pointed out correctly, we find, the "extending" language constitutes a clear, structural element, which a "skilled patent drafter" would have foreseen as limiting the potential of requiring the channel to extend from the well to the junction. (SBr. at 22; RRBr. at 4; Tr. (Santiago) at 1252:20-1253:21 ("Q. What is the structural limitation? A. So the two input channels that it's describing in the claim is the sample channel from the sample well, and the oil channel from the oil input well, and the way I've interpreted this is that sample channel has to travel or extend separately from the input well to the channel junction. So a channel as in the 10X chip, which before arriving at the junction goes through a first junction and combines material with another reagent, I don't consider that extending separately.").). *See Sage Prods., Inc. v. Devon Indus., Inc.*, 126 F.3d 1420, 1424 (Fed. Cir. 1997).

As in *Sage Products*, "[n]o subtlety of language or complexity of the technology, nor any subsequent change in the state of the art, such as later-developed technology, obfuscated the significance of this limitation at the time of its incorporation into the claim." *Id.* at 1425-26. "Because the patent contains clear structural limitations, the public has a right to rely on those limits in conducting its business activities. This court will not effectively remove such a limitation under a doctrine designed to prevent 'fraud on a patent.'" *Id.*

For the foregoing reasons, Complainants have not proven by a preponderance of evidence that the GEM Chips satisfy the "extending . . . from the input wells" limitation of claim 20 under

the doctrine of equivalents.

g) "wherein the lower member has an upper surface that is flat and that abuts a lower surface of the upper member to form a bottom wall of openings formed in the lower surface and corresponding to the wells and the channels of each unit"

Complainants have proven that the GEM Chips meet this limitation of claim 20. (Tr. (Gale) at 414:1-9.). Documentary evidence supports a finding that the GEM Chips have a lower member or film that has a flat upper surface, and this film is attached to the lower surface or bottom of the upper member. (*Id.* at 414:15-415:6; JX-0008C; JX-0064C; CDX-0005.0059.). 10X's VP of Operations, Mr. Wyatt, confirmed Dr. Gale's opinion that this film forms the bottom surface of the wells and channels in the chip. (CX-0612C (Wyatt Dep. Tr.) at 26:2-9; Tr. (Gale) at 414:15-416:5; CDX-0005.0060, -0061.).

Respondent did not rebut this evidence in its Pre-Hearing or Initial Post-Hearing Briefs. Thus, Respondent waived argument on this issue under Ground Rules 7.2 and 10.1.

For these reasons, the GEM Chips meet this limitation of claim 20 of the '160 patent.

2. The Chip SE Does Not Literally Infringe Claim 20

Complainants alleged and Dr. Ana testified, that the Chip SE literally infringes claim 20 of the '160 patent. (Tr. (Anna) at 635:9-15.). However, the Chip SE is a different design than the design that the '160 patent describes. (Tr. (Santiago) at 1155:5-24; RDX-0004C.0040 to -0044.). Documentary evidence admitted during the Hearing reflects that

(RDX-0004C.0043 (citing JX-0083C; RX-0261C).).

Based on the technical evidence and his analysis of the Chip SE, Respondent's expert, Dr. Santiago, provided persuasive testimony that because the Chip SE does not

(Tr. (Santiago) at 1155:5-24 (emphasis added); CPX-0005C; JX-0083C; RX-0261C; RX-1197C.).

(*Id.* at 1195:9-1196:14 (emphases added).).

(RX-0261C.0001.).

The schematic drawing shown in Figure No. 24 above supports Dr. Santiago's testimony that . (Tr. (Anna) at 680:12-14.).

Thus, the Chip SE fails to satisfy the following limitations: (i) "a set of wells interconnected by a set of channels forming a channel junction"; (ii) "at least one first input well to receive a continuous phase"; (iii) "at least two input channels extending separately from the input wells to the channel junction, at which droplets of the dispersed phase are generated in the continuous phase"; and (iv) "an output channel extending from the channel junction to the output well, in which an emulsion is collected."

Based on Dr. Anna's testimony, Complainants contended that the Chip SE "can be configured" to meet the claimed limitations. Complainants also argued that it is sufficient that

the Chip SE is "reasonably capable" of performing the claimed limitations to infringe. (CBr. at 9.).

(Tr. (Anna) at 617:7-20.).

(RDX-0004C.0048 (citing JX-0083C).).

According to Dr. Anna, if

[redacted]. (Tr. (Anna) at 617:21-618:20, 618:23-619:7; JX-0083C.).

However, as Respondent and Staff argued and as shown above in Figure No. 25, the hypothetical use Dr. Anna proposed (Figure No. 25 on the right) is contrary to the product's design (Figure No. 25 on the left). (*See* Tr. (Santiago) at 1155:5-24; RDX-0004C.0040 to -0044; JX-0083C; CX-0403.).

Moreover, the case law on which Complainants relied does not apply here. Certain courts have found in cases involving ***functional*** claimed limitations, that is, claims merely reciting the ***capability*** to perform a function, a complainant is not required to show that the accused product is "actually used" in the infringing way. *Ericsson, Inc. v. D-Link Sys., Inc.*, 773 F.3d 1201, 1217 (Fed. Cir. 2014) (holding that because the language in the asserted claims recite capability, the accused products "only need to have components that are reasonably capable" of performing the function); *Revolution Eyewear, Inc. v. Aspex Eyewear, Inc.*, 563 F.3d 1358, 1370 (Fed. Cir. 2009) (finding that because the asserted claim only required "'***capable of engaging***'" magnetic members from the top," and did not require a structure, "[i]t is irrelevant that Revolution's auxiliary frames . . . are not actually used" in the infringing manner) (emphasis added); *Versata Software, Inc. v. SAP America, Inc.*, 717 F.3d 1255, 1259 (asserted claims recited "'computer readable program code ***configured to cause a computer to' perform a set of claimed operations***" and "'computer program instructions ***capable of" retrieving 'pricing information'***") (emphasis added); *Silicon Graphics, Inc. v. ATI Tech., Inc.*, 607 F.3d 784, 794-95

(Fed. Cir. 2010) ("[T]his court has held that an apparatus claim directed to a computer that is claimed in ***functional*** terms is nonetheless infringed so long as the product is designed in such a way as to enable a user of that product to utilize the function . . . without having to modify the product.") (emphasis added); *Finjan, Inc. v. Secure Computing Corp.*, 626 F.3d 1197, 1204 (Fed. Cir. 2010) ("we have held that, to infringe a claim that recites ***capability*** and not actual operation, an accused device 'need only be capable of operating' in the described mode") (emphasis added) (citing *Intel Corp. v. U.S. Int'l Trade Com'n*, 946 F.2d 821, 832 (Fed. Cir. 1991)).

Unlike the cases to which Complainants cited, and as reflected above, the limitations recited in claim 20 are clearly ***structural***, not functional. Claim 20 recites chips having three (3) wells, including an oil well, i.e., a "first input well to receive a continuous phase," a droplet outwell, i.e., "an output well," and "an output channel extending from the channel junction to the output well." (JX-0001 at 163:15-164:15.). Claim 20 also sets forth chips having a particular architecture connecting those wells. (*Id.*). In addition, the specification of the '160 patent discloses examples where the "configuration" is directed to channel architecture and not to function, or even where fluids are placed. (*Id.* at 29:9–11 ("the droplet generator is ***structured*** as a cross, but any other ***configuration*** may be suitable" (emphasis added)), 35:41-55, 37:45–51, 64:60–67:8.).

The Federal Circuit has held repeatedly that "[u]nless the claim language ***only*** requires the capacity to perform a particular claim element, we have held that ***it is not enough to simply show that a product is capable of infringement***; the patent owner must show evidence of specific instances of direct infringement." *Fujitsu Ltd. v. Netgear Inc.*, 620 F.3d 1321, 1329 (Fed. Cir. 2010) (emphases added); *see also Ball Aerosol & Specialty Container, Inc. v. Ltd.*

Brands, Inc., 555 F.3d 984, 994 (Fed. Cir. 2009) (noting that the "reasonably capable" test applies "only to claim language that specifies that the claim is drawn to capability"); *ACCO Brands, Inc. v. ABA Locks Mfrs. Co.*, 501 F.3d 1307, 1313 (Fed. Cir. 2007).

The law is clear that for claims that require a specific configuration, i.e., structure, as is the case here, "infringement requires 'specific instances of direct infringement or that the accused device necessarily infringes the patent in suit.'" *Ball Aerosol*, 555 F.3d at 995.

Accordingly, for these reasons, Complainants have failed to prove by a preponderance of evidence that the Chip SE literally infringes claim 20 of the '160 patent.

VIII. U.S. PATENT NO. 9,500,664

A. Relevant Claim Terms

The following constructions of the claim terms recited in the asserted claims of the '664 patent have been agreed upon by the Parties and adopted by this Court. (*See Markman* Order, App. A at Chart No. 2.).

Table No. 7: Constructions of Agreed Upon Claim Terms Relevant to the '664 Patent

Claim Term	Construction
"channel"	an elongate passage for fluid travel
"sample"	a compound, composition, and/or mixture of interest, from any suitable source(s)
"a network of channels / a channel network"	an interconnected arrangement of channels
"wherein the first channel is configured to transport sample-containing fluid from the sample well to the droplet generation region"	wherein the first channel is configured to transport sample-containing fluid from the sample well to the droplet generation region
"transporting sample-containing fluid through a first channel, from the sample well to a droplet generation region"	transporting sample-containing fluid through a first channel, from the sample well to a droplet generation region

Claim Term	Construction
"a network of channels . . . fluidically interconnecting the sample well, the background fluid well, and the droplet well"	a network of channels. . . fluidically interconnecting the sample well, the background fluid well, and the droplet well

The following constructions of the disputed claim terms were construed by this Court.[30] (*Markman* Order, App. A at Chart No. 1.).

Table No. 8: Construction of the Disputed Claim Terms Relevant to the '664 Patent

Claim Term	Construction
"droplet generation region"	the intersection of (1) a sample- containing dispersed phase fluid inlet channel, (2) a continuous phase fluid inlet channel, and (3) a droplet outlet channel
"a droplet generation region defined by the network of channels and configured to generate sample-containing droplets suspended in the background fluid"	a droplet generation region defined by the network of channels and configured to generate sample-containing droplets suspended in the background fluid
"forming a droplet generation region defined by the intersection of a first channel fluidically connected with the sample well, a second channel fluidically connected with the background fluid well, and a third channel fluidically connected with the droplet outlet region"	forming a droplet generation region defined by the intersection of a first channel fluidically connected with the sample well, a second channel fluidically connected with the background fluid well, and a third channel fluidically connected with the droplet outlet region

B. Infringement Overview

Complainants have proven that the GEM Chips, the Chip GB, and the Chip SE

[30] The Parties disputed the meaning of additional claim terms recited in claims that have been terminated from this Investigation. Those terms are not included in Table No. 8.

("Accused 664 Products") directly infringe claims 1, 2, 14, and 15 of the '664 patent.[31] (CBr. at 20-29.). *Litton*, 140 F.3d at 1454.

With respect to the GEM Chips, Respondent's expert, Dr. Santiago, opined that for the same reasons explicated with regard to claim 20 of the '160 patent, the GEM Chips do not satisfy the following two limitations of claim 1: (i) "a first channel . . . configured to transport sample-containing fluid from the sample well to the droplet generation region"; and (ii) a "droplet generation region." (Tr. (Santiago) at 1184:2-8; RDX-0004C.0021.).

According to Dr. Santiago, the "droplet generation region" is at the junction of the ***singulation*** channel, the oil channel, and the outlet channel, and that the singulation channel is not the claimed "first channel" the singulation channel does not "transport sample-containing fluid from the sample well ***to*** the droplet generation region." (*See* Tr. (Santiago) at 1255:23-1256:8; RDX-0004C.0011.).

. Respondent waived future argument on this issue under Ground Rule 7.2.[32]

With regard to the Chip GB, because it

(RDX-0004C.0049 to -0057; Tr. (Santiago) at 1203:19-1206:18.).

Complainants' infringement arguments with respect to the Chip SE arguments are based

[31] In its Pre-Hearing Brief, Complainants argued that Respondent induces infringement of claim 14 of the '644 patent. (CPBr. at 37.). Complainants did not address this argument in their Initial Post-Hearing Brief. 19-36.). Thus, Complainants waive argument on this issue under Ground Rule 10.1.

[32] *See also* Order No. 35 (Sept. 20, 2018) granting in-part Respondent's motion to strike Complainants' new direct infringement argument under 35 U.S.C. § 271(g) in Complainants' Reply Post-Hearing Brief.

on a hypothetical use of the Chip SE. (Tr. (Hindson) at 974:17–974:23.). The evidence presented in this Investigation indicates that when used as Respondent intended, the Chip SE does not have the claimed oil well, [redacted]. (*See, e.g.*, Tr. (Anna) at 635:16–24.). Additionally, the asserted claims recite structural, and not merely functional, limitations. As discussed in Section VII.D.2, *supra*, it is not enough to prove that the accused chip is "reasonably capable" of being used in the infringing manner.

Accordingly, Complainants have met their burden and proven that the Accused 664 Products infringe claims 1, 2, 14, and 15 of the '664 patent.

C. Certain of the Accused 664 Products Directly Infringe Claims 1, 2, 14, and 15 of the '664 Patent

1. The GEM Chips Infringe Claims 1 and 14 of the '664 Patent

a) "A system for forming a plurality of sample-containing droplets suspended in a background fluid, comprising" (Claim 1) / "A method of manufacturing a droplet generation system, comprising" (Claim 14)

Complainants have proven that the GEM Chips meet the preambles of claims 1 and 14. (Tr. (Anna) at 528:1-13, 560:1-7.). Based on Dr. Anna's testimony, an examination of the physical exhibits of the accused chips, and schematic drawings, Complainants provided persuasive documentary and testimonial evidence that each GEM Chip includes a system for forming a plurality of sample containing droplets suspended in a background fluid comprising a sample well, oil well, bead well, and outlet well that are connected by microfluidic channels. (*Id.* at 528:23-530:4, 530:5-532:2, 560:1-22; CPX-0003C; CPX-0004C; JX-0008C; JX-0064C; CDX-0006.0027 to -0031.). This evidence also demonstrates that in each system, sample-containing droplets suspended in a background fluid are formed at the intersection of the sample channel, oil channel, and outlet channel of the GEM chips. (Tr. 529:20-530:4, 532:3-25; CDX-

0006.0030 to -0031.). Moreover, videos, 10X documents, and corporate testimony from 10X confirm that each system generates sample-containing droplets at this intersection. (Tr. (Anna) at 533:1-7, 534:3-536:19, 560:11-22; CDX-0006.0032 to -0036, -0065; CX-0376C; CX-0375C.0009; CDX-0189.0003; CX-0612C (Wyatt Dep. Tr.) at 37:25-38:10, 38:11-20; CX-0616C (Bharadwaj Dep. Tr.) at 43:3-12; Tr. (Santiago) at 1223:15-23, 1225:18-1226:15; CDX-0203.0002.).

Respondent did not offer arguments that rebutted either Dr. Anna's testimony or the documents that Complainants presented in its Pre-Hearing or Initial Post-Hearing Briefs. Thus, Respondent waived any future argument on this issue under Ground Rules 7.2 and 10.1.

Complainants have proven by a preponderance of evidence that the GEM Chips meet the preambles of claims 1 and 14 of the '664 patent.

b) "a substrate having a bottom surface and a top surface; a sample well, a background fluid well, and a droplet well each having an upper region protruding from the top surface of the substrate" (Claim 1) / "(i) forming a substrate having a bottom surface and a top surface; (ii) forming a sample well; (iii) forming a background fluid well; (iv) forming a droplet well" (Claim 14) / "wherein the upper region of each well protrudes from the top surface of the substrate" (Claim 14)

Complainants have proven that the GEM Chips meet these limitations of claims 1 and 14. (Tr. (Anna) at 536:20-538:8, 563:7-12.). Complainants presented compelling, unrebutted evidence that each GEM Chip is a substrate or chip having a bottom surface with the channels embedded in it and a top surface with wells protruding up. (*Id.* at 536:20-538:8, 563:7-12, 563:13-22; CPX-0003C; CPX-0004C; JX-0008C; JX-0064C; CDX-0006.0038, -0072; *see also* Fig. No 11, *supra*.). Additionally, Dr. Anna testified and used documents to demonstrate that each GEM Chip includes eight emulsion formation units and each unit has a sample well,

background fluid well, and a droplet well protruding from the top surface. (Tr. (Anna) at 536:20-538:8, 563:13-22; CPX-0003C; CPX-0004C; JX-0008C; JX-0064C; CDX-0006.0038, -0072.).

Respondent did not marshal arguments or even rebut Complainants' evidence with contrary evidence in its Pre-Hearing or Initial Post-Hearing Briefs. Thus, Respondent has waived any future argument on this issue under Ground Rules 7.2 and 10.1.

For the foregoing reasons, Complainants have proven by a preponderance of evidence that the GEM Chips meet these limitations of claims 1 and 14 of the '664 patent.

c) "a network of channels formed in the bottom surface of the substrate and fluidically interconnecting the sample well, the background fluid well, and the droplet well" (Claim 1) / "wherein the first channel, the second channel, and the third channel are formed in the bottom surface of the substrate" (Claim 14)

Complainants have proven that the GEM Chips meet these limitations of claims 1 and 14. (Tr. (Anna) at 536:20-538:8, 569:18-21.). Dr. Anna demonstrated persuasively, and it is a finding of this decision that each GEM Chip includes a network of microfluidic channels in the bottom surface of the chip. (*Id.* at 536:20-538:8, 569:18-570:17; CPX-0003C; CPX-0004C; JX-0008C; JX-0064C; CDX-0006.0039, -0083.).

As Dr. Anna demonstrated without any contradictory arguments or evidence, each network of channels fluidically interconnects a sample well, background fluid well, and a droplet well. (Tr. (Anna) at 532:3-25, 537:17-23, 538:16-539:2; CPX-0003C; CPX-0004C; JX-0008C; JX-0064C; CDX-0006.0039 to -0040.). Dr. Anna also offered her support opinion that the wells in the Gem Chips are fluidically interconnected by the microfluidic channels because there are unobstructed passageways for fluid to travel between each of the wells. Instead of rebutting Dr.

Anna's explanation, Respondent's fact witness, Mr. Wyatt confirmed that Dr. Anna's explanation is correct. (Tr. (Anna) at 539:3-20; CDX-0006.0040 to -0042; CX-0612C (Wyatt Dep. Tr.) at 25:20-26.1.).

For example, as Dr. Anna demonstrated, if the right amount of pressure is applied, sample fluid could flow from the sample well to the background fluid well, and from the sample well to the droplet well. (Tr. (Anna) at 539:7-20; CDX-0006.0040.).

Respondent did not present evidence that was contrary to Complainants' and did not rebut Complainants' arguments in its Pre-Hearing or Initial Post-Hearing Briefs. Thus, Respondent waived any future argument on this issue under Ground Rules 7.2 and 10.1.

For the foregoing reasons, Complainants have proven by a preponderance of evidence that the GEM Chips meet these limitations of claims 1 and 14 of the '664 patent.

d) "a droplet generation region defined by the network of channels and configured to generate sample-containing droplets suspended in the background fluid; wherein the droplet generation region is defined by the intersection of a first channel, a second channel, and a third channel" (Claim 1) / "(v) forming a droplet generation region defined by the intersection of a first channel fluidically connected with the sample well, a second channel fluidically connected with the background fluid well, and a third channel fluidically connected with the droplet outlet region" (Claim 14)

Complainants presented compelling testimonial and documentary evidence through Dr. Anna that the GEM Chips meet these limitations of claims 1 and 14. (Tr. (Anna) at 541:7-17, 548:13-16, 564:5-14.).

Respondent contended through Dr. Santiago that the GEM Chips do not have the claimed "droplet generation region" for the same reasons they do not have the "channel junction" recited

in claim 20 of the '160 patent.[33] (Tr. (Santiago) at 1190:16-1191:5; RBr. at 46.).

As discussed in Section VII.D.1(c) with regard to the "channel junction" limitation of claim 20 of the '160 patent, Dr. Santiago testified that the singulation channel that intersects with the continuous phase (oil) inlet channel and the droplet outlet channel is not a "sample-containing dispersed phase fluid inlet channel" because it contains a mixture (Z3) that is different from the fluid from the sample well (Z2), and thus cannot be the "channel junction." (Tr. (Santiago) at 1184:18-1185:3, 1191:6-18.).

However, as discussed in Section VII.D.1(c), Complainants presented supported, persuasive evidence that the GEM Chips include the claimed "droplet generation region." As desecribed in Section VII.D.1(c), droplets are formed at the intersection of the singulation channel, the oil channel, and the output channel. (*See* Tr. (Gale) at 420:12-423:15; CDX-0005.0092 to -0095; JX-0064C.0002; JX-0008C.0001.). The singulation channel carries a mixture of sample-containing dispersed phase fluid that originated from the sample well (Z2) and the beads from the bead well (Z2). (*See* Section VII.D.1(c), *supra*; Tr. (Gale) at 407:20-408:19, 409:9-25; Tr. (Santiago) at 1223:15-23, 1225:2-7, 1225:18-1226:15; CDX-0203.0002; CX-0616C (Bharadwaj Dep. Tr.) at 173:1-14.). The fact that the singulation channel contains reagents, including beads, in addition to sample-containing fluid, does not diminish the point that the singulation channel carries sample-containing dispersed phase fluid. (Tr. (Gale) at 407:20-408:19, 409:9-25.).

[33] The terms "droplet generation region" and "channel junction" were both construed to mean "the intersection of (1) a sample-containing dispersed phase fluid inlet channel, (2) a continuous phase fluid inlet channel, and (3) a droplet outlet channel." (*See* Table No. 8, *supra*.).

Figure No. 26: Singulation Channel in the GEM Chips

(RDX-0004C.0011 (citing JX-0064C; JX-0008C).).

Accordingly, Complainants have proven by a preponderance of evidence that the GEM Chips include the claimed "droplet generation region" and meet these limitations of claims 1 and 14 of the '664 patent.

e) "wherein the first channel is configured to transport sample-containing fluid from the sample well to the droplet generation region, the second channel is configured to transport background fluid from the background fluid well to the droplet generation region, and the third channel is configured to transport sample-containing droplets from the droplet generation region to the droplet well" (Claim 1)

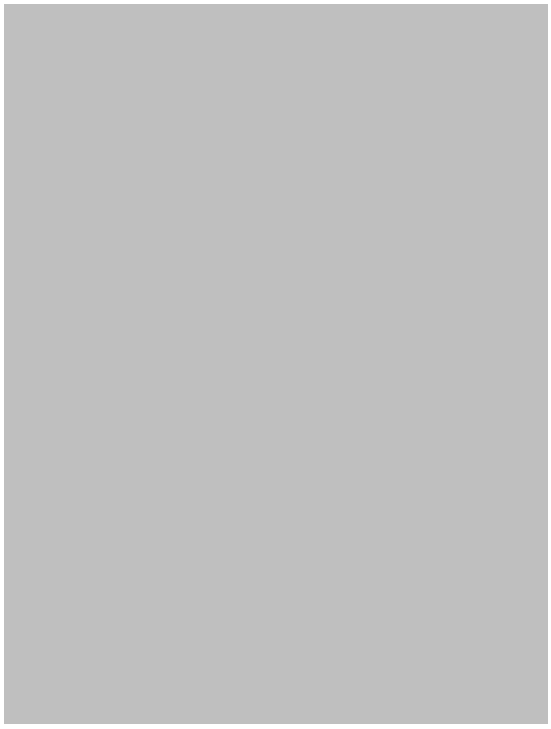
Complainants argued through Dr. Anna's testimony and persusaive documentation that the GEM Chips meet these limitations of claim 1. (Tr. (Anna) at 548:17-549:6, 553:20-24.). Respondent disputed Complainants' argument and Dr. Anna's testimony by contending through

its own expert, Dr. Santiago, that the GEM Chips do not have a "first channel . . . configured to transport sample-containing fluid from the sample well to the droplet gneration region" for the same reasons they do not include "input channels extending separately from the input wells to the channel junction" recited in claim 20 of the '160 patent. (Tr. (Santiago) at 1190:16-1191:5; RBr. at 46.).

As noted in the *Markman* Order, the limitation of claim 1 of the'664 patent requires a channel "***extending*** . . . ***from*** the input wells ***to*** the channel junction." (JX-0001 at 164:6-8 (emphases added).). It is less stringent than the "extending from" language of claim 20 of the '160 patent. (*Markman* Order, App. A, Chart No. 1 at 9-11.).

The 10X schematics show that each GEM Chip includes channels that are configured to transport fluid from the wells to the droplet generation region, where the droplets are formed. (Tr. (Anna) at 549:7-550:12; JX-0008C; JX-0064C.). As is reflected below in Figure No. 27 from demonstrative exhibits that Dr. Anna provided and explained in her testimony, a first channel, shown in blue, is configured to transport sample-containing dispersed phase fluid from the sample well to the droplet generation region. (Tr. (Anna) at 549:8-550:12, 551:11-552:14; CDX-0006.0052; CDX-0009; JX-0008C; JX-0064C.). Dr. Anna also described through opinion testimony that a second channel, shown in orange, is configured to transport background fluid (oil) from the background fluid well to the droplet generation region. (*Id.*). Lastly, Dr. Anna testified that a third channel, shown in green, is configured to transport sample-containing droplets from the droplet generation region to the outlet well. (*Id.*).

Figure No. 27: Demonstratives Based on Schematic Drawings Showing First, Second, and Third Channels and Droplet Generation Region



(CDX-0006.0052 (citing JX-0008C).).

Dr. Anna's testimony that the singulation well is configured to transport sample-containing dispersed phase fluid from the sample well to the droplet generation region was corroborated by 10X's VP of Operations, Mr. Wyatt, and its Director of Microfluidics, Rajiv Bharadwaj. (Tr. (Anna) at 552:16-553:19; CX-0612C (Wyatt Dep. Tr.) at 36:5-12 ("Q. Well, you know that the sample from the sample well made its way tto the singulation channel, right? A. Yes. Q. So that -- and we know that the singulation channel is connected to the sample well

for the sample to get there, right? A. Yes."), 36:25-37:8 ("Q. But you are comfortable saying that there's a path . . . between the sample well and the singulation channel that allows the sample to flow to the singulation channel? A. Yes. Q. That path is some passage, passageway? A. Yes."); CX-0616C (Bharadwaj Dep. Tr.) at 18:8-20 ("Q: So you're defining singulation channel as a channel that carries gel beads and reagents? A. Uh-huh. Q. Okay. A. And also the customer sample. Q. And the customer sample. A. Uh-huh. Q. Okay. So a channel that contains gel beads, reagents and the customer sample is a singulation channel? A. And the important part was that it is used to seaprate the gel beads, hence the name singulation."); CDX-0006.0053.).

For the reasons discussed above, Complainants have proven by a preponderance of evidence that the GEM Chips include the claimed "first channel" and meet these limitations of claim 1 of the '664 patent.

f) "wherein the substrate and the upper region of each well are injection molded as a single piece" (Claim 1) / "wherein the substrate, an upper region of the sample well, an upper region of the background fluid well, and an upper region of the droplet well are injection molded as a single piece" (Claim 14)

Complainants have proven that the GEM Chips meet these limitations of claims 1 and 14. (Tr. (Anna) at 553:25-554:5, 568:11-19.). According to Dr. Anna's unrebutted testimony and the documents she cited, each substrate or chip has an upper region of wells, appears to be constructed of a single piece, and has marks on it that are typical of injection molded pieces. (Tr. (Anna) at 555:14-556:3, 555:14-556:3; CPX-0003C; CPX-0004C.). [redacted]. (CX-0612C (Wyatt Dep. Tr.) at 23:14-21, 24:18-22; CDX-0006.0056, -0057; Tr. (Anna) at 554:10-555:13, 569:5-17.).

Respondent did not rebut either Dr. Anna's or Mr. Wyatt's testimony or make alternative

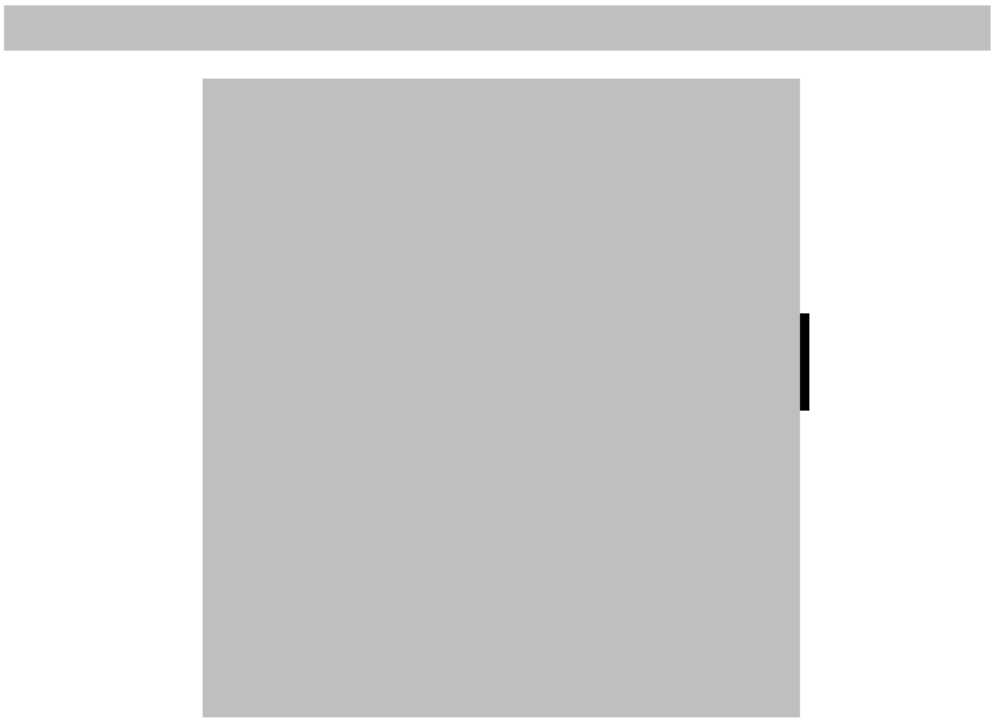
arguments in its Pre-Hearing or Initial Post-Hearing Briefs. Respondent waived any future argument on this issue under Ground Rules 7.2 and 10.1.

For the foregoing reasons, Complainants have proven by a preponderance of evidence that the GEM Chips meet these limitations of claims 1 and 14 of the ’664 patent.

2. The GEM-Q Chip Infringes Claim 2 of the ’664 Patent

a) “The system of claim 1, wherein the first channel includes an air trap configured to prevent sample-containing fluid from being inadvertently drawn through the first channel by capillary action.”

Complainants have proven that the GEM-Q Chip meets the additional limitation recited in claim 2. (Tr. (Anna) at 556:13-18, 557:10-13, 559:17-20.). Complainants presented through Dr. Anna’s explanation of the GEM-Q chip and how it is structured and it functions that the GEM-Q Chip includes a region on the sample channel with posts, which can be seen in the schematic drawing of Figure 28, below. (Tr. (Anna) at 557:14-558:16; JX-0064C.0002; CDX-0006.0060.).



(CDX-0006.0060 (citing JX-0064C).).

As Dr. Anna described, when sample-containing fluid flows down the channel (red arrow above) due to wicking or capillary action, the sample-containing fluid . (Tr. (Anna) at 558:10-16.). Rajiv Bharadwaj, 10X's Director of Microfluidics, . (CX-0616C (Bharadwaj Dep. Tr.) at 56:16-57:24, 60:15-62:22; Tr. (Anna) at 558:17-559:16; CDX-0006.0061.).

Respondent did not rebut either Complainants' drawings or Dr. Anna's and Rajiv Bharadwaj's testimony with evidence or even rebuttal argument of its own in its Pre-Hearing or Initial Post-Hearing Briefs. Thus, Respondent has waived future argument on this issue under Ground Rules 7.2 and 10.1.

For the foregoing reasons, Complainants have proven by a preponderance of evidence that the GEM Chips meet the additional limitation recited in claim 2 of the '664 patent.

3. The GEM Chips Infringe Claim 15 of the '664 Patent

a) "The method of claim 14, further comprising attaching a sealing member to the bottom surface of the substrate to form a substantially fluid tight seal and a bottom wall for each of the channels and each of the wells."

Complainants provided compelling evidence through Dr. Anna's testimony and documents that the GEM Chips meet the additional limitation recited in claim 15. (Tr. (Anna) at 571:12-21.). According to Dr. Anna's testimony and documents to which she cited, channels exist in the bottom surface of the Accuse 664 Products. Based on the evidence presented in this Investigation, Dr. Anna opined that there is a thin film on the bottom surface of the substrate that seals the channels and prevents the fluid from falling out. (Tr. (Anna) at 571:25-572:11, 572:12-573:23; CPX-0003C; CPX-0004C; CX-0052C.0005 to -0006; CDX-0006.0086 to -0087.).

Respondent did not rebut either Dr. Anna's testimony or the documents describing why the Accused 664 Products meet the referenced claim limitation in its Pre-Hearing or Initial Post-Hearing Briefs. Thus, Respondent has waived argument on this issue under Ground Rules 7.2 and 10.1.

For the foregoing reasons, Complainants have proven by a preponderance of evidence that the GEM Chips meet the additional limitation recited in claim 15 of the '664 patent.

4. The Chip GB Does Not Infringe Claims 1 or 14 of the '664 Patent

Complainants failed to prove that the Chip GB directly infringes claims 1 and 14 of the '664 patent. Dr. Anna testified that [redacted] (Tr. (Anna) at 593:16-594:25; *Markman* Order, App. A, Chart No. 2 at 2.). Specifically, Dr. Anna explained that the Chip GB [redacted]

[redacted] (*Id.* at 593:16-594:25.). Dr. Anna's testimony is not persuasive for the following reasons.

Respondent argued that the Chip GB does not infringe [redacted] (RBr. at 47.).

However, Dr. Hindson provided credible testimony that [redacted] (Tr. (Anna) at 717:4-6 (emphasis added).).

Dr. Hindson's testimony is consistent with the distinction the '664 patent makes between a "sample" and a "reagent." Namely, as part of the definition of a "sample," the '664 patent specification identifies clinical samples such as blood and plasma, and research samples such as culturued cells or bacteria. (JX-0002 at 8:35-67.). The '664 patent defines a "reagent" as "a compound, set of compounds, and/or composition that is ***combined with a sample*** in order to

perform a particular test(s) on the sample." (*Id.* at 9:19-37 (emphasis added).). Here, [redacted].

Additionally, Respondent's fact witnesses, Drs. Hindson and Schnall-Levin, testified that [redacted] (RDX-0004C.0049 to -0057; Tr. (Santiago) at 1203:19-1208:3.).

For the foregoing reasons, Complainants have failed to prove by a preponderance of evidence that the Chip GB infringes any of the asserted claims of the '664 patent.

5. The Chip SE Does Not Infringe Claim 1 of the '664 Patent

Complainants asserted from the outset of the Investigation that the Chip SE infringes claim 1 for the same reasons it infringes claim 20 of the '160 patent, that is, that the Chip SE "can be configured" in such a way as to infringe this claim. (CBr. at 20-29). However, Complainants have not met their burden of proof. For the reasons discussed in Section VII.D.2

with respect to claim 20 of the ’160 patent, the Chip SE does not infringe claim 1 of the ’664 patent.

To reiterate, Dr. Santiago’s testimony and documents Respondent produced demonstrate that when the Chip SE is used as Respondent intends,

Moreover, Complainants’ argument that the Chip SE is “reasonbly capable” of being used in a manner that infringes is sufficient for a finding of infringement is contrary to current precedent. (*See* Section VII.D.2; *Fujitsu*, 620 F.3d at 1329 (“Unless the claim language ***only*** requires the capacity to perform a particular claim element, we have held that ***it is not enough to simply show that a product is capable of infringement***; the patent owner must show evidence of specific instances of direct infringement.”) (emphases added); *see also Ball Aerosol*, 555 F.3d at 994; *ACCO Brands*, 501 F.3d at 1313.

For the reasons discussed above, Complainants failed to prove by a preponderance of evidence that the Chip SE infringes claim 1 of the ’664 patent.

IX. U.S. PATENT NO. 9,636,682

A. Relevant Claim Terms

The following constructions of the claim terms recited in the asserted claims of the ’682 patent have been agreed upon by the Parties and adopted by this Court. (*Markman* Order, App. A at Chart No. 2.).

Table No. 9: Constructions of Agreed Upon Claim Terms Relevant to the '682 Patent

Claim Term	Construction
"channel"	an elongate passage for fluid travel
"sample"	a compound, composition, and/or mixture of interest, from any suitable source(s)
"a corresponding channel network for each sample well, the channel network including a droplet-generation region and fluidically connecting the sample well to one of the continuous-phase wells and one of the droplet wells"	a corresponding channel network for each sample well, the channel network including a droplet-generation region and fluidically connecting the sample well to one of the continuous-phase wells and one of the droplet wells
"such that sample-containing fluid flows from each sample well to the corresponding droplet-generation region"	such that sample-containing fluid flows from each sample well to the corresponding droplet-generation region

The following construction of the disputed claim term was construed by this Court.[34] (*Markman* Order, App. A at Chart No. 1.).

Table No. 10: Construction of the Disputed Claim Term Relevant to the '682 Patent

Claim Term	Adopted Construction
"droplet-generation region"	the intersection of (1) a sample- containing dispersed phase fluid inlet channel, (2) a continuous phase fluid inlet channel, and (3) a droplet outlet channel

B. Infringement Overview

Complainants have argued that when used with the Chromium™ Controllers, the

[34] The Parties disputed the meaning of additional claim terms recited in claims that have been terminated from this Investigation. Those other disputed, terminated terms are not included in Table No. 10.

Accused 682 Products directly infringe claims 14, 16, and 17 of the ’682 patent. (CBr. at 39-43.). *Litton*, 140 F.3d at 1454.

In its Pre-Hearing Brief, Respondent contested that the GEM Chips do not have a “droplet generation region” or a “first channel” that carries sample-containing fluid. (RPBr. at 81-82.). Because Respondent did not make these arguments in its Initial Post-Hearing Brief, Respondent has waived future argument on this issue under Ground Rule 10.1.

Complainants have also argued and proven that Respondent indirectly infringes the asserted claims of the ’682 patent by contributing to and inducing infringement. (*Id.* at 43-56.). For the reasons discussed below, Complainants have proven that Respondent indirectly infringes the asserted claims by inducing its customers to use the accused microfluidic devices with the Chromium™ Controllers by providing instruction manuals and guides directing customers to use the GEM Chips to generate emulsions. *See, e.g.*, *i4i Ltd. P’ship v. Microsoft Corp.*, 598 F.3d 831, 852 (Fed. Cir. 2010), *aff’d on other grounds*, 564 U.S. 91 (2011); *Certain Semiconductor Chips and Prods. Containing Same*, Inv. No. 337-TA-753, Comm’n Op. at 41-42 (July 31, 2012) (“*Certain Semiconductor Chips*”). Technical documents and brochures also reflect that the GEM Chips are a material component of the overall system. (CX-0375C.0009; CX-0353.0003; *see also* CDX-0005.0099.). The GEM Chips are not a stable article or commodity of commerce having substantial noninfringing uses. (Tr. (Gale) at 433-6-17.).

Accordingly, Complainants have met their burden and proven that the Accused 682 Products when used with the Chromium™ Controllers directly and indirectly infringe claims 14, 16, and 17 of the ’682 patent.

C. The Use of the Accused 682 Products with the Chromium™ Controllers Directly Infringes Claims 14, 16 and 17 of the '682 Patent[35]

1. The Use of the Accused 682 Products with the Chromium™ Controllers Infringes Claim 14 of the '682 Patent

a) "A system for generating droplets, comprising"

Complainants has proven that when used with the Chromium™ Controllers, the Accused 682 Products meet the preamble of claim 14. (Tr. (Gale) at 417:8-11.). Complainants provided convincing testimony through Dr. Gale, as well as through documents he explained, that confirm that each GEM Chip includes wells and microfluidic channels. (*Id.* at 393:25-394:24, 395:5-10, 417:12-21; CPX-0003C; CPX-0004C; JX-0008C; JX-0064C; CX-0197.0023, -0052; CDX-0005.0064.). In each GEM Chip, sample-containing droplets are formed at the intersection of the sample channel, oil channel, and outlet channel. (Tr. (Gale) at 394:14-24, 417:12-21, 388:22-389:22; CX-0376C; CX-0612C (Wyatt Dep. Tr.) at 37:25-38:10, 38:11-20; CX-0616C (Bharadwaj Dep. Tr.) at 43:3-12.).

Respondent did not rebut either Dr. Gale's or Mr. Wyatt's testimony, or the documents that Complainants produced either with countervailing testimony, documents or argument in its Pre-Hearing or Initial Post-Hearing Briefs. Therefore, Respondent has waived any future argument on this issue under Ground Rules 7.2 and 10.1.

For the foregoing reasons, Complainants have proven by a preponderance of evidence that the Accused 682 Products when used with the Chromium™ Controllers meet the preamble of claim 14 of the '682 patent.

[35] The asserted claims do not cover the accused GEM Chips alone, as they are imported. (Tr. (Gale) at 416:21-435:19, 447:14-448:22; CDX-0005.0063 to -0101.). To satisfy the limitations of the asserted claims of the '682 patent, it is necessary to use the GEM Chips with the Chromium™ Controllers. The analysis of infringement below pertains to direct infringement for purposes of indirect infringement. The indirect infringement analysis is discussed in Section XI, *infra*.

b) "a device including a row of sample wells each configured to receive sample-containing fluid, a row of continuous-phase wells each configured to receive continuous-phase fluid, and a row of droplet wells"

Complainants argued and produced compelling documentary and testimonial evidence through Dr. Gale that the Accused 682 Products meet this limitation of claim 14. (Tr. (Gale) at 418:1-5, 418:22-419:2, 419:18-22.). Dr. Gale's testimony and his description of the GEM Chip establish factually that each GEM Chip is a substrate or chip having rows of sample wells, continuous phase wells and droplets wells. (*Id.* at 418:6-21, 419:3-17, 419:23-420:8; CPX-0003C; CPX-0004C; JX-0008C; JX-0064C; CDX-0005.0067, -0070, -0073.).

Respondent did not rebut Dr. Gale's testimony or Complainants' documentary evidence in its Pre-Hearing or Initial Post-Hearing Briefs. Therefore, Respondent has waived future argument on this issue under Ground Rules 7.2 and 10.1.

For the foregoing reasons, Complainants have proven by a preponderance of evidence that the Accused 682 Products meet this limitation of claim 14 of the '682 patent.

c) "the device also including a corresponding channel network for each sample well, the channel network including a droplet-generation region and fluidically connecting the sample well to one of the continuous-phase wells and one of the droplet wells"

Complainants argued that the Accused 682 Products meet this limitation of claim 14. (Tr. (Gale) at 420:12-21.). As is explained, and has been established as a fact in Section VII.D.1(c), the GEM Chips include the claimed "droplet generation region." As Dr. Gale explained, and as supported by documents, droplets are formed at the intersection of the singulation channel, the oil channel, and the output channel. (*See* Tr. (Gale) at 420:12-423:15; CDX-0005.0092 to -0095; JX-0064C.0002; JX-0008C.0001.). The singulation channel carries a mixture of sample-containing dispersed phase fluid that originated from the sample well (Z2)

and the beads from the bead well (Z2). (*See* Section VII.D.1(c), *supra*; Tr. (Gale) at 407:20-408:19, 409:9-25; Tr. (Santiago) at 1223:15-23, 1225:2-7, 1225:18-1226:15; CDX-0203.0002; CX-0616C (Bharadwaj Dep. Tr.) at 173:1-14.).

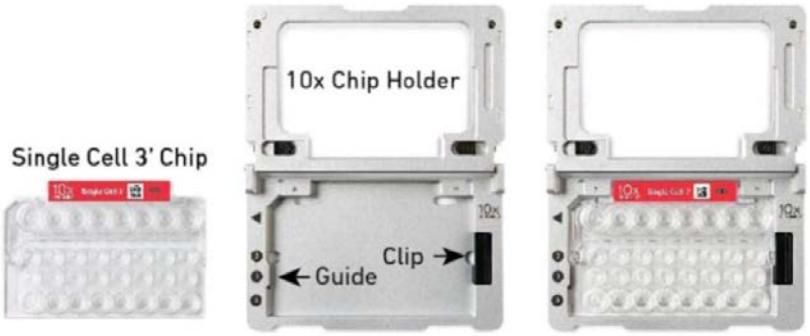
In its Pre-Hearing Brief, Respondent argued that the GEM Chips do not have a "droplet generation region" for the same reasons that they do not have the "channel junction" claimed in claim 20 of the '160 patent. (RPBr. at 81-82.). However, Respondent did not make even this argument in its Initial Post-Hearing Brief. (RBr. at 67.). Respondent offered no evidence that rebutted Complainants' testimonial or documentary evidence. Therefore, Respondent has waived future argument on this issue under Ground Rule 10.1.

For the foregoing reasons, Complainants have proven by a preponderance of evidence that the Accused 682 Products meet this limitation of claim 14 of the '682 patent.

d) "a holder for the device"

Complainants presented compelling documentary evidence and established through Dr. Gale's testimony that when used with the Chromium™ Controllers, the Accused 682 Products meet this limitation of claim 14. (Tr. (Gale) at 423:16-18.). Complainants provided evidence confirming that a "holder" (regardless of its structure or shape) is used with the GEM Chips. (Tr. (Gale) at 423:19-424:5; CX-0197.0052; CPX-0003C; CPX-0004C; RPX-0019C; RPX-0020C; CDX-0005.0080.). An image of 10X's GEM Chip holder is depicted in Figure 29.

Figure No. 29: Image of GEM Chip Holder



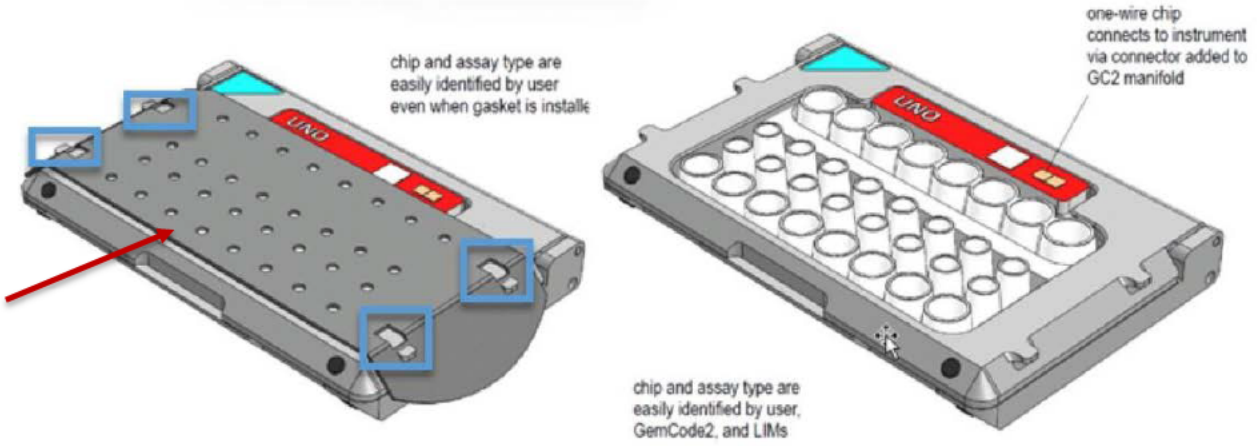
(CDX-0005C.0080 (citing CX-0197.0052).).

For the foregoing reasons, Complainants have proven by a preponderance of evidence that the Accused 682 Products when used with the Chromium™ Controllers meet this limitation of claim 14 of the '682 patent.

e) "a gasket configured to be attached directly to the holder, such that the gasket extends over each sample well, each continuous-phase well, and each droplet well"

Complainants provided both compelling testimony through Dr. Gale and through documents that when used with the Chromium™ Controllers, the Accused 682 Products meet these limitations of claim 14. (Tr. (Gale) at 424:10-16.). As Dr. Gale testified, and as is demonstrably evident through the pictures of the Respondent's GEM Chip used in conjunction with the holder it uses, the GEM Chips when used with the gasket and holder, have each of these limitations. (*Id.* at 424:17-425:24; CX-0007C.0031; CX-0197.0023; CPX-0003C; CPX-0004C; RPX-0013C; RPX-0019C; RPX-0020C; CDX-0005C.0083 to -0084.). Figure No. 30, below depicts a holder with a gasket, and the microfluidic device. The gasket is shown by the red arrow in Figure No. 30.

Figure No. 30: Drawing of Gasket



(CDX-0005C.0083 (citing CX-0007C.0031).).

Respondent did not rebut this evidence in its Pre-Hearing or Initial Post-Hearing Briefs. Therefore, Respondent waived future argument on this issue under Ground Rules 7.2 and 10.1.

For the foregoing reasons, Complainants have proven by a preponderance of evidence that the Accused 682 Products when used with the Chromium™ Controllers meet these limitations of claim 14 of the '682 patent.

f) "an instrument configured to (a) receive an assembly including the device, the holder, and the gasket, (b) engage the gasket with a manifold, and (c) apply positive pressure and/or negative pressure to the device via the manifold, such that sample-containing fluid flows from each sample well to the corresponding droplet-generation region, continuous-phase fluid flows from each continuous-phase well to the corresponding droplet-generation region, and sample-containing droplets flow from each droplet-generation region to the corresponding droplet well"

Complainants argued compellingly through Dr. Gale and with documentary evidence that when used with the Chromium™ Controllers, the Accused 682 Products meet this limitation of claim 14. (Tr. (Gale) at 426:4-21, 429:9-12.). Documents describe how the Chromium™

Controllers receive the GEM Chips after they are placed on the holder with a gasket stretched over the top of the wells. (*Id.* at 426:22-427:21; CX-0197.0023; CDX-0005.0087.). Although it cannot be seen clearly in Figure No. 31, below, the microfluidic device is inserted in the bottom (the tray-like device) on the left.

Figure No. 31: Images of Chromium™ Controller

(CDX-0005C.0087 (citing CX-0197.0023).).

10X documents also show that during operation, [redacted]. (Tr. (Gale) at 426:22-428:12; CX-0007C.0069; CDX-0005.0088.). Additionally, 10X's employee, Rajiv Bharadwaj testified that after a GEM Chip is inserted into a tray in the Chromium™ Controllers, [redacted]. (CX-199C (Bharadwaj) at 46:7-13, 43:1-18; *see also* Tr. (Gale) at 428:13-429:8; CDX-0005.0089.).

As Complainants noted, this limitation does not require the microfluidic connectivity between the input wells and droplet generation region to be configured in a specific way. The claim element only requires pressure that causes fluid to flow from the input wells to the droplet generation region, and for droplets to flow from the droplet generation region to the droplet well. (Tr. (Gale) at 428:13-429:8, 426:22-429:8.). Respondent's expert, Dr. Santiago, and 10X's VP of Operations, Mr. Wyatt, testified that the singulation channel is fluidically connected to the sample well. (Tr. (Santiago) at 1230:25-1232:18; CX-0612C (Wyatt Dep. Tr.) at 36:5-12, 36:25-37:8.). Similarly, the Parties did not dispute that fluid from the sample well (Z2) travels from the sample well to the singulation channel. (Tr. (Santiago) at 1218:17-1219:15, 1232:19-25; CX-0616C (Bharadwaj Dep. Tr.) at 172:18-173:14.). The Parties agreed that the two aqueous based fluids in the singulation channel, one from the bead well and one from sample well, both travel in the singulation channel [redacted] to the droplet generation region. (Tr. (Gale) at 481:13-25.).

Respondent's own drawings, as described by its expert, Dr. Santiago, reflect that the bead solution travels down the center of the singulation channel and the sample fluid travels towards the sidewalls of the singulation channel. (Tr. (Santiago) at 1218:17-1219:2, 1219:7-15, 1219:22-1221:21; CX-0815C.0004; CDX-0189.). Dr. Santiago testified, consistent with his claim construction Declaration, that the droplets formed at the intersection of the singulation channel and the oil channel contain sample-containing dispersed phase fluid. (Tr. (Santiago) at 1223:15-23, 1224:21-1225:7, 1225:18-1226:15, 1227:5-13; CDX-0203.0002.). In other words, Dr. Santiago agreed that applying pressure using the Chromium™ Controllers to the GEM Chips causes fluid to flow from the sample well to the droplet generation region to form sample-containing droplets.

For the foregoing reasons, Complainants have proven by a preponderance of evidence that the Accused 682 Products when used with the Chromium™ Controllers meet this limitation of claim 14 of the ’682 patent.

2. The Use of the Accused 682 Products with the Chromium™ Controllers Infringes Claim 16 of the ’682 Patent

a) “The system of claim 14, wherein the gasket defines a plurality of apertures, and wherein the holder has a plurality of projections configured to be received in the plurality of apertures to directly attach the gasket to the holder.”

Complainants presented compelling testimony through Dr. Gale, and through documents, that when used with the Chromium™ Controllers, the Accused 682 Products meet the additional limitations recited in claim 16. (Tr. (Gale) at 429:21-430:4.). As Complainants’ demonstrated pictorially and with explanation, when used with gasket and holder of the Chromium™ Controllers, Respondent’s GEM Chips directly infringe this claim limitation language. (Tr. (Gale) at 430:5-18; CPX-0003C; CPX-0004C; RPX-0013C; RPX-0019C; RPX-0020C; CX-0007C.0031; CDX-0005.0092.).

Respondent did not refute Complainants’ evidence with either countervailing evidence or argument in its Pre-Hearing or Initial Post-Hearing Briefs. Therefore, Respondent has waived future argument on this issue under Ground Rules 7.2 and 10.1.

For the foregoing reasons, Complainants have proven by a preponderance of evidence that the Accused 682 Products when used with the Chromium™ Controllers meet the additional limitations recited in claim 16 of the ’682 patent.

3. The Use of the Accused 682 Products with the Chromium™ Controllers Infringes Claim 17 of the '682 Patent

a) "The system of claim 14, wherein the device has a planar base portion and a plurality of tubular protrusions that project upwardly from the planar base portion, and wherein the device is configured to be captured in the holder via the planar base portion."

Complainants provided compelling evidence through Dr. Gale and with documents that when used with the Chromium™ Controllers, the Accused 682 Products meet the additional limitation recited in claim 17. (Tr. (Gale) at 431:2-11.). As Dr. Gale described, Respondent's GEM Chip has a flat portion at the bottom of the chip and plurality of tubular protrusion (wells) projecting up from this flat portion of the chip. (*Id.* at 431:12-432:7; CPX-0003C; CPX-0004C; RPX-0019C; RPX-0020C; JX-0008C; JX-0064C; CX-0197.0052.). Dr. Gale also explained that based on Respondent's documents and demonstratives, the bottom portion of each GEM Chip is configured to be held in a holder. (Tr. (Gale) at 431:12-432:7; CPX-0003C; CPX-0004C; RPX-0019C; RPX-0020C; JX-0008C; JX-0064C; CX-0197.0052.).

Respondent did not rebut Dr. Gale's testimony of how its GEM Chips are configured, or how they work structurally with Respondent's Chromium™ Controllers in its Pre-Hearing or Initial Post-Hearing Briefs. Thus, Respondent waived future argument on this issue under Ground Rules 7.2 and 10.1.

For the foregoing reasons, Complainants have proven by a preponderance of evidence that the Accused 682 Products when used with the Chromium™ Controllers meet the referenced, additional limitation recited in claim 17 of the '682 patent.

X. U.S. PATENT NO. 9,649,635

A. Relevant Claim Terms

The following constructions of the claim terms recited in the asserted claims of the '635

patent have been agreed upon by the Parties and adopted by this Court. (*Markman* Order, App. A at Chart No. 2.).

Table No. 11: Constructions of Agreed Upon Claim Terms Relevant to the '635 Patent

Claim Term	Construction
"channel"	an elongate passage for fluid travel
"sample"	a compound, composition, and/or mixture of interest, from any suitable source(s)
"a network of channels / a channel network"	an interconnected arrangement of channels
"a first pressure differential to drive sample-containing fluid from the sample well to the droplet-generation region via the first channel"	a first pressure differential to drive sample-containing fluid from the sample well to the droplet generation region via the first channel
"a plurality of separate channel networks, each sample well being fluidically connected to one of the continuous-phase wells and one of the droplet wells via one of the channel networks, each channel network having a first channel, a second channel, and a third channel that meet one another in a droplet-generation region"	a plurality of separate channel networks, each sample well being fluidically connected to one of the continuous-phase wells and one of the droplet wells via one of the channel networks, each channel network having a first channel, a second channel, and a third channel that meet one another in a droplet-generation region
"a first pressure differential to drive sample-containing fluid from each sample well and continuous-phase fluid from each continuous-phase well, such that sample-containing droplets are formed in the droplet-generation region"	a first pressure differential to drive sample-containing fluid from each sample well and continuous-phase fluid from each continuous-phase well, such that sample-containing droplets are formed in the droplet-generation region

The following construction of the disputed claim term was construed by this Court.[36]

[36] The Parties disputed the meaning of additional claim terms recited in claims that have been terminated from this Investigation. Those disputed, terminated terms are not included in Table No. 12.

(*Markman* Order, App. A at Chart No. 1.).

Table No. 12: Construction of the Disputed Claim Term Relevant to the '635 Patent

Claim Term	Adopted Construction
"droplet-generation region"	the intersection of (1) a sample- containing dispersed phase fluid inlet channel, (2) a continuous phase fluid inlet channel, and (3) a droplet outlet channel

B. Infringement Overview

Complainants presented compelling evidence and proved that when used with the Chromium™ Controllers, the Accused 635 Products directly infringe every asserted claim, that is claims 1, 13, 14, 16, and 21 of the '635 patent. (CBr. at 58-68.). *Litton*, 140 F.3d at 1454.

Respondent only argued that the GEM Chips do not have a "droplet generation region" and a "first channel" that carries sample-containing fluid. (RBr. at 76-77.). The evidence did not support Respondent's argument.

Complainants have also proven compellingly, based on facts discussed below, that Respondent indirectly infringes the asserted claims of the '635 patent by inducing its customers to use the accused microfluidic devices with the Chromium™ Controllers by providing instruction manuals and guides directing customers to use the GEM Chips to generate emulsions. (CBr. at 68-73.). *See, e.g.*, *i4i Ltd. P'ship*, 598 F.3d at 852; *Certain Semiconductor Chips*, Inv. No. 337-TA-753, Comm'n Op. at 41-42. Additionally, Complainants compellingly demonstrated that the GEM Chips are a material component of the overall system with Respondent's Chromium™ Controllers, and are not, by themselves, stable articles or commodities of commerce that have substantial non-infringing uses.

C. The Use of the Accused 635 Products with the Chromium™ Controllers Directly Infringes Claims 1, 13, 14, 16, and 21 of the '635 Patent[37]

1. The Use of the Accused 635 Products with the Chromium™ Controllers Infringes Claim 1 of the '635 Patent

a) "A system to form and concentrate an emulsion, comprising"

Complainants argued and produced compelling evidence that when used with the Chromium™ Controllers, the Accused 635 Products meet the preamble of claim 1. (Tr. (Anna) at 641:9-642:2.). Dr. Anna explained, using demonstratives and other documents, that Respondent's GEM Chip includes a system for forming a plurality of sample containing droplets suspended in a background fluid comprising a sample well, oil well, bead well, and outlet well that are connected by microfluidic channels. (*Id.* at 528:23-530:4; 530:20-532:2, 642:3-22; CPX-0003C; CPX-0004C; JX-0008C; JX-0064C; CDX-0006.0027 to -0031, -0182.).

As Dr. Anna described and demonstrated, in each system, sample-containing droplets suspended in a background fluid are formed at the intersection of a sample channel, an oil channel, and an outlet channel in the GEM Chips. (Tr. (Anna) at 529:20-530:4, 532:3-25, 533:1-7, 534:3-12, 534:18-536:19, 642:3-22; CX-376C; CX-375C.0009; CDX-189; *accord,* CX-0612C (Wyatt Dep. Tr.) at 37:25-38:-20; CDX-0006.0030 to -0031, -0182.). Moreover, each GEM Chip has "eight layouts" or systems that each produces droplets. (CX-0616C (Bharadwaj Dep. Tr.) at 43:3-12.).

Dr. Anna explained, following emulsion formation, a sample containing droplets suspended in a background fluid is concentrated by applying positive pressure to the outlet wells

[37] The asserted claims do not cover the accused GEM Chips alone, as they are imported. (Tr. (Anna) at 510:23-511:13, 641:4-676:17; CDX-0006C.0005, 0179 to -0238.). To satisfy the limitations of the asserted claims of the '682 patent, it is necessary to use the GEM Chips with the Chromium™ Controllers. The analysis of infringement below pertains to a showing of direct infringement for purposes of indirect infringement. The indirect infringement analysis is discussed in Section XI, *infra*.

which concentrates the emulsion, and is called the "push back" step. (Tr. (Anna) at 642:23-644:6; JX-0006C.0002; CX-0199C (Bharadwaj Dep. Tr.) at 92:18-93:7; CDX-0006.0184 to -0185.).

Respondent did not provide any countervailing testimony or argument in its Pre-Hearing or Initial Post-Hearing Briefs. Thus, Respondent waived future argument on this issue under Ground Rules 7.2 and 10.1.

For the reasons discussed above, Complainants have proven by a preponderance of evidence that the Accused 635 Products when used with the Chromium™ Controllers meet the preamble of claim 1 of the '635 patent.

b) "a device including a sample well configured to receive sample-containing fluid, a continuous-phase well configured to receive continuous-phase fluid, and a droplet well"

Complainants produced compelling evidence and argument that the Accused 635 Products meet the referenced limitation of claim 1. (Tr. (Anna) at 648:12-19.). As Dr. Anna described, each GEM Chip is a substrate or chip having a bottom surface with the channels embedded in it and a top surface with wells protruding up. (*Id.* at 536:20-538:8, 648:20-649:6; CPX-0003C; CPX-0004C; JX-0008C; JX-0064C; CDX-0006.0038, -0190.). Also as a matter of fact, each GEM Chip includes eight emulsion formation units and each unit has a well for receiving sample-contain fluid, continuous-phase well for receiving continuous-phase fluid, and a droplet well. (*See, e.g.*, CPX-0003C; CPX-0004C; JX-0008C; JX-0064C; CDX-0006.0038, -0190.).

Respondent offered neither countervailing nor documentary or testimonial evidence to refute Complainants' evidence in its Pre-Hearing or Initial Post-Hearing Briefs. Respondent waived future argument on this issue under Ground Rules 7.2 and 10.1.

Complainants have proven by a preponderance of evidence that the Accused 635 Products meet this limitation of claim 1 of the ’635 patent.

c) “the device also including a channel network having a first channel, a second channel, and third channel that meet one another in a droplet-generation region”

Complainants provided compelling testimonial and documentary evidence that the Accused 635 Products meet the referenced limitation of claim 1. (Tr. (Anna) at 649:11-18.). In its Pre-Hearing Brief, Respondent contended, relying on Dr. Santiago’s deposition testimony, that Respondent’s GEM Chips do not have the claimed “droplet generation region” for the same reasons they do not have the “channel junction” recited in claim 20 of the ’160 patent. According to Respondent, the singulation channel that intersects with the oil channel does not contain same fluid as in the sample well. (Tr. (Santiago) at 1190:16-1191:5; RPBr. at 86.). However, Respondent did not include this argument in its Initial Post-Hearing Brief or even cite to Dr. Santiago’s pre-hearing testimony. (RBr. at 76.). Respondent has waived future argument of this issue under Ground Rule 10.1.

Even if Respondent has not waived its argument, Respondent’s argument is, nonetheless, incorrect. Aa described in Section VII.D.1(c), the GEM Chips include the claimed “droplet generation region.” As Dr. Gale described, droplets are generated at the intersection of the singulation, oil, and output channels. (*See* Tr. (Gale) at 420:12-423:15; CDX-0005.0092 to -0095; JX-0064C.0002; JX-0008C.0001.). Neither the Parties’ experts nor their fact witnesses disputed that the singulation channel carries a combination of sample-containing dispersed phase fluid that originated from the sample well and the beads from the bead well. (*See* Section VII.D.1(c), *supra*; Tr. (Gale) at 407:20-408:19, 409:9-25; *accord* Tr. (Santiago) at 1223:15-23, 1225:2-7, 1225:18-1226:15; CDX-0203.0002; CX-0616C (Bharadwaj Dep. Tr.) at 173:1-14.).

That the singulation channel contains reagents, including beads, in addition to sample-containing fluid, does not change the fact that the singulation channel carries sample-containing dispersed phase fluid. In this instance, the facts do not lend themselves to different or conflicting outcomes.

For the foregoing reasons, Complainants have proven by a preponderance of evidence that the Accused 635 Products meet this limitation of claim 1 of the '635 patent.

d) "an instrument configured to operatively receive the device and to create (a) a first pressure differential to drive sample-containing fluid from the sample well to the droplet-generation region via the first channel, continuous-phase fluid from the continuous-phase well to the droplet-generation region via the second channel, and sample-containing droplets from the droplet-generation region to the droplet well via the third channel, such that the droplet well collects an emulsion including sample-containing droplets disposed in continuous-phase fluid"

Complainants provided compelling and convincing evidence through Dr. Anna, and with Respondent's own documents, that when used with the Chromium™ Controllers, the Accused 635 Products meet this limitation of claim 1. (Tr. (Anna) at 657:11-17.). As Dr. Anna explained using Respondent's technical documents, Respondent's Chromium™ Controllers include a tray that holds Respondent's GEM Chips, and that the GEM Chips are operatively received by and acted on by the Chromium™ Controllers. (Tr. (Anna) at 651:22-652:22; CX-0354.0025; CDX-0006.0196.).

Moreover, Dr. Anna testified that during operation, the Chromium™ Controllers apply a first pressure differential to the GEM Chips that drives fluid along the channels from each input well to the droplet generation region. The same pressure then drives droplets from the droplet generation region to the outlet well. (Tr. (Anna) at 653:22-654:4, 656:2-657:10; JX-0008C; JX-

0064C; CDX-0006.0199.). As reflected in Respondent's schematic drawings in Figure No. 32, below, sample-containing dispersed phase fluid is driven from the sample well to the droplet generation region via a first channel that is shown in blue. Background fluid (oil) is then driven from the background fluid well to the droplet generation region via a second channel shown in orange. Sample-containing droplets are driven from the droplet generation region to the droplet well via a third channel shown in green. (Tr. (Anna) at 656:2-657:10.).

Figure No. 32: Schematic Drawing Showing Droplet Generation Region

(CDX-0006.0199 (citing JX-0008C).).

In its Pre-Hearing Brief, Respondent contended that the GEM Chips do not have the claimed "first channel" because the singulation channel, and not the channel from the sample well, delivers sample-containing fluid to the droplet generation region. (RPBr. at 86-87.).

However, Respondent did not include this argument (and provided no countervailing evidence to that which Complainants provided) in its Initial Post-Hearing Brief. (RBr. at 76.). Respondent waived future argument on this issue under Ground Rule 10.1.

In any case, even if Respondent has not waived its argument, it is wrong based on the factual discription of the Chromium™ Controllers' practice of the relevant claim language. As described in Section VII.D.1(c), and has been determined as a matter of fact, Respondent's GEM Chip includes a claimed "first channel" carrying sample-containing fluid. Moreover, Complainants' proved factually that the Chromium™ Controllers apply a first pressure differential that drives sample-containing dispersed phase fluid from the sample well to the droplet generation region via the singulation channel, that is, sample fluid from the sample well travels via the singulation channel to the droplet generation region. (Tr. (Anna) at 653:22-655:1, 656:2-657:10; JX-0006C.0002; JX-0008C; JX-0064C; CX-0006C.0048; CDX-0006.0197 to -0199.).

Moreover, as Dr. Anna and Dr. Santiago both testified, the droplets formed at the intersection of the singulation channel and the oil channel contain sample-containing dispersed phase fluid. (Tr. (Santiago) at 1223:15-23, 1224:21-1225:7, 1225:18-1226:15, 1227:5-13; CDX-0203.0002.). Because the singulation channel is the only source for the sample-containing dispersed phase fluid, the sample-containing dispersed phase fluid travels via the singulation channel to the droplet generation region. (Tr. (Santiago) at 1223:15-23, 1224:21-1225:7, 1225:18-1226:15, 1227:5-13; CDX- 0203.0002.).

Without any viable counter-argument or countervailing facts from Respondent, Complainants have proven by a preponderance of evidence that the Accused 635 Products when used with the Chromium™ Controllers meet this limitation of claim 1 of the '635 patent.

e) "(b) a second pressure differential to decrease a volume fraction of continuous-phase fluid in the emulsion, after the emulsion has been collected in the droplet well, by selectively driving continuous-phase fluid, relative to sample-containing droplets, from the droplet well via the third channel"

Complainants presented compelling testimony through Dr. Anna and through documents, that when used with the Chromium™ Controllers, the Accused 635 Products meet this limitation of claim 1. (Tr. (Anna) at 657:22-658:14.). Dr. Anna explained that the Chromium™ Controllers create a second pressure differential following droplet formation, and apply positive pressure to the outlet wells of the GEM chips. (*Id.* at 658:15-20.).

Respondent's technical documents support Dr. Anna's explanation and confirm that the [redacted] (*Id.* at 658:21-659:5; JX-0006C.0002; CDX-0006.0202.). Rajiv Bharadwaj also corroborated Dr. Anna's explanation of [redacted]. (CX-0199C (Bharadwaj Dep. Tr.) at 92:18-93:7; CDX-0006.0203; Tr. (Anna) at 659:6-21.).

Respondent did not rebut this evidence in its Pre-Hearing or Initial Post-Hearing Briefs. Respondent has waived future argument on this issue under Ground Rules 7.2 and 10.1.

For the foregoing reasons, Complainants have proven by a preponderance of evidence that the Accused 635 Products when used with the Chromium™ Controllers meet this limitation of claim 1 of the '635 patent.

2. The Use of the Accused 635 Products with the Chromium™ Controllers Infringes Claim 16 of the '635 Patent

a) "A system to form and concentrate emulsions, comprising"

Complainants presented compelling evidence through Dr. Anna's testimony and

documents that when used with the Chromium™ Controllers, the Accused 635 Products meet the preamble of claim 16. (Tr. (Anna) at 664:11-14.). For the reasons discussed in Section IX.C.1(a) with respect to the preamble of claim 1 of the '682 patent, it is a finding of this decision that each GEM Chip used in conjunction with the Chromium™ Controllers includes a system for forming a plurality of sample-containing droplets at the intersection of the sample channel, oil channel, and outlet channel. (*See* Section IX.C.1(a); Tr. (Anna) at 528:23-530:4; 530:20-532:2, 532:3-25, 533:1-7, 534:3-12, 534:18-536:19, 663:10-664:10; CPX-0003C; CPX-0004C; JX-0008C; JX-0064C; CDX-0006.0027 to -0031, 0182, -0213; CX-0376C; CX-0375C.0009; CDX-0189; CX-0612C (Wyatt Dep. Tr.) at 37:25-38:20.).

After the emulsion is formed, the Chromium™ Controllers concentrate the droplets by applying positive pressure to the outlet wells, i.e., the "push back" step. (Tr. (Anna) at 642:23-643:17, 663:10-664:10; 643:18-644:6, 663:10-664:10; JX-0006C.0002; CDX-0006.0184, -0184, -0213; CX-0199C (Bharadwaj Dep. Tr.) at 92:18-93:7.).

Respondent did not refute any of Complainants' documentary or testamentary evidence in its Pre-Hearing or Initial Post-Hearing Briefs. Thus, Respondent has waived future argument on this under Ground Rules 7.2 and 10.1.

For the foregoing reasons, Complainants have proven by a preponderance of evidence that the Accused 635 Products when used with the Chromium™ Controllers meet the preamble of claim 16 of the '635 patent.

b) "a device including a row of sample wells each configured to receive sample-containing fluid, a row of continuous-phase wells each configured to receive continuous-phase fluid, a row of droplet wells"

Complainants presented compelling testimony through Dr. Anna and through documents,

that the Accused 635 Products meet this limitation of claim 16. (Tr. (Anna) at 664:15-24.). Through Dr. Anna's coherent and compelling testimony, and with documents, Complainants proved as a matter of material fact that each GEM Chip includes four rows of wells. One row of wells is configured to receive a sample-containing fluid (sample well); one row of wells is configured to receive continuous-phase fluid (oil well); a third row of wells is configured to receive beads (bead well); and a fourth row of wells configured to receive sample-containing droplets (output well). (Tr. (Anna) at 536:20-538:8, 664:25-665:14; CPX-0003C; CPX-0004C; JX-0008C; JX-0064C; CDX-0006.0038, -0216.).

Respondent did not rebut this evidence in its Pre-Hearing or Initial Post-Hearing Briefs. Respondent waived future argument on this issue under Ground Rules 7.2 and 10.1.

For the foregoing reasons, Complainants have proven by a preponderance of evidence that the Accused 635 Products meet this limitation of claim 16 of the '635 patent.

c) "a plurality of separate channel networks, each sample well being fluidically connected to one of the continuous-phase wells and one of the droplet wells via one of the channel networks, each channel network having a first channel, a second channel, and a third channel that meet one another in a droplet-generation region"

Complainants presented compelling testimony through Dr. Anna and through documents, that the Accused 635 Products meet these limitations of claim 16. (Tr. (Anna) at 665:20-666:5.). Factually, Complainants established that each Respondent's GEM Chip includes eight (8) separate channel networks in the bottom surface of the chip. (Tr. (Anna) at 666:6-25; CPX-0003C; CPX-0004C; JX-0008C; JX-0064C.). Complainants also proved factually that each channel network fluidically connects a sample well, background fluid well, and a droplet well. (Tr. (Anna) at 667:1-18; JX-0008C; CDX-0006.0219.). The wells are fluidically connected by

the microfluidic channels because the passageway for fluid to travel is unobstructed between each of the wells. (Tr. (Anna) at 666:6-17; CDX-0006.0219.).

In its Pre-Hearing Brief, Respondent contended that the GEM Chips do not have the claimed "droplet junction region" because the droplets are formed at the intersection of the singulation channel, oil channel, and output channel. (RPBr. at 86, 89.). Respondent did not include this contention in its Initial Post-Hearing Brief or cite to any testimonial or documentary evidence that would refute Complainants' evidence. (RBr. at 76-77.). Thus, Respondent waived future argument on this issue under Ground Rule 10.1.

However, regardless of whether or not Respondent waived its argument, its argument is nevertheless incorrect. As is described, and as is found as fact in Section VII.D.1(c), the GEM Chips include the claimed "droplet generation region." As Dr. Anna explained, the GEM Chips have a droplet generation region at the intersection of a first channel (transporting fluid from the sample well), a second channel (transporting oil from the oil well), and a third channel (transporting droplets from the droplet generation region to the droplet well). (*See* Tr. (Anna) at 649:11-651:20; CDX-0006C.0192 to -0194; JX-0064C.0002; JX-0008C.0001.).

Respondent did not contest that the GEM Chips include "a plurality of separate channel networks, each sample well being fluidically connected to one of the continuous-phase wells and one of the droplet wells via one of the channel networks" in its Pre-Hearing or Initial Post-Hearing Briefs. Respondent waived future argument on this issue under Ground Rules 7.2 and 10.1.

For the foregoing reasons, Complainants have proven by a preponderance of evidence that the Accused 635 Products meet these limitations of claim 16 of the '635 patent.

d) "a gasket configured to operatively engage at least one of the rows of wells"

Complainants presented compelling testimony through Dr. Anna and through documents, that when used with the Chromium™ Controllers, the Accused 635 Products meet this limitation of claim 16. (Tr. (Anna) at 667:23-668:2.). As Dr. Anna confirmed through her explanation of how the Chromium™ Controllers operate, the Chromium™ Controllers have a gasket that goes over the top surface of the wells of the GEM Chips. (*Id.* at 668:3-25; CPX-0003C; CPX-0004C; RPX-0013C.). When pressure is applied , the gasket is configured to operatively engage at least one of the row of wells on the GEM Chips. (Tr. (Anna) at 668:3-25; CX-0354.0025; CDX-0006.0222.).

Respondent did not rebut this evidence in its Pre-Hearing or Initial Post-Hearing Briefs. Respondent has waived future argument on this issue under Ground Rules 7.2 and 10.1.

For the foregoing reasons, Complainants have proven by a preponderance of evidence that the Accused 635 Products when used with the Chromium™ Controllers meet this limitation of claim 16 of the '635 patent.

e) "an instrument including a manifold"

Complainants presented compelling testimony through Dr. Anna and through documents, that when used with the Chromium™ Controllers, the Accused 635 Products meet this limitation of claim 16. (Tr. (Anna) at 669:11-21, 670:13-16.). The unrebutted testimonial and documentary evidence supports a factual finding that . (*Id.* at 669:11-670:16; JX-0006C.0002; CDX-0006.0225.).

Respondent did not refute Complainants' argument with countervailing evidence or

argument in its Pre-Hearing or Initial Post-Hearing Briefs. Thus, Respondent has waived future argument on this issue under Ground Rules 7.2 and 10.1.

For the foregoing reasons, Complainants have proven by a preponderance of evidence that the Accused 635 Products when used with the Chromium™ Controllers meet this limitation of claim 16 of the '635 patent.

f) "the instrument being configured to operatively engage the gasket with the manifold such that the manifold is sealed to each well of the at least one rows of wells, and to create via the manifold (a) a first pressure differential to drive sample-containing fluid from each sample well and continuous-phase fluid from each continuous-phase well, such that sample-containing droplets are formed in the droplet-generation region of each channel network and travel via the third channel of the channel network to one of the droplet wells for collection as an emulsion including sample-containing droplets disposed in continuous-phase fluid"

Complainants presented compelling testimony through Dr. Anna and through documents, that when used with the gasket of the Chromium™ Controllers, the Accused 635 Products meet this limitation of claim 16. (Tr. (Anna) at 670:17-671:16.). 10X documents reflect as a matter of fact that the Chromium™ Controllers [redacted] (Tr. (Anna) at 670:17-671:16, 672:5-673:14; CX-0007C.0069; JX-0006C.0001; CDX-0006.0228, -0229.).

Additionally, as discussed in Section X.C.1(d) with respect to claim 1 of the '635 patent, Complainants proved through Dr. Anna's undisputed testimony and using Respondent's documents, that during operation, the Chromium™ Controllers apply a first pressure differential to the GEM Chips that drives fluid from each input well to the droplet generation region, and then drives droplets from the droplet generation region to the outlet well. (Tr. (Anna) at 653:22-

654:4, 656:2-657:10, 673:15-674:7; JX-0006C.0002; CX-0006C.0048; CDX-0006.0230.). Sample-containing dispersed phase fluid is driven from the sample well to the droplet generation region via the sample channel and singulation, i.e., a "first channel.Background fluid (oil) is driven from the background fluid well to the droplet generation region via the oil channel, i.e., a "second channel." Sample-containing droplets are driven from the droplet generation region to the droplet well via the output channel, i.e., a "third channel." (Tr. (Anna) at 656:2-657:10.). The claim limitation element at issue only requires that a first pressure drives the fluid from the input wells to the droplet generation region. No particular path is specified.

Respondent did not refute or provide countervailing evidence or facts in its Pre-Hearing or Initial Post-Hearing Briefs. Respondent has waived future argument on this issue under Ground Rules 7.2 and 10.1.

For the foregoing reasons, Complainants have proven by a preponderance of evidence that the Accused 635 Products when used with the Chromium™ Controllers meet this limitation of claim 16 of the '635 patent.

g) "(b) a second pressure differential to decrease a volume fraction of continuous-phase fluid in each emulsion, after the emulsion has been collected in the one droplet well, by selectively driving continuous-phase fluid, relative to sample-containing droplets, from the one droplet well via the third channel"

Complainants presented compelling testimony through Dr. Anna and through documents, that when used with the Chromium™ Controllers, the Accused 635 Products meet this limitation of claim 16. (Tr. (Anna) at 674:8-16.). Dr. Anna has established as fact that the

(Tr. (Anna) at 658:15-659:21, 674:17-675:5; CX-0199C (Bharadwaj Dep. Tr.) at 92:18-93:7; JX-0006C.0002; CDX-0006.0202, -0203, -0234.).

Respondent did not dispute with either argument or evidence Complainants' position in its Pre-Hearing or Initial Post-Hearing Briefs. Thus, Respondent has waived future argument on this issue under Ground Rules 7.2 and 10.1.

For the foregoing reasons, Complainants have proven by a preponderance of evidence that the Accused 635 Products when used with the Chromium™ Controllers meet this limitation of claim 16 of the '635 patent.

1. The Use of the Accused 635 Products with the Chromium™ Controllers Infringes Claims 13, 14, and 21 of the '635 Patent

a) "The system of claim 1, wherein the instrument is configured to create the first pressure differential followed by the second pressure differential without user intervention." (Claim 13) / "The system of claim 13, wherein the instrument is configured (a) to operate a valve to eliminate the first pressure differential and (b) to create the second pressure differential after eliminating the first pressure differential, without user intervention." (Claim 14) / "The system of claim 16, wherein the instrument is configured to create the first pressure differential followed by the second pressure differential, without user intervention." (Claim 21)

Complainants presented compelling testimony through Dr. Anna and through documents, that when the Chromium™ Controllers the Accused 635 Products meet the additional limitations recited in claims 13, 14, and 21. (Tr. (Anna) at 661:14-17.). Dr. Anna described how the GEM Chips and the Chromium™ Controllers operate and confirmed that droplets are created without ***any user interaction***. (Tr. (Anna) at 660:4-25. 661:1-13, 675:21-676:13; JX-0006C.0002; CDX-0006.0206, -0234.). The same evidence also reflects that the Chromium™ Controllers (Tr. (Anna) at 662:2-663:4; JX-0006C.0002; CDX-

0006.0209.). This is a factual finding of this decision, which is unrefuted.

Respondent did not rebut this evidence in its Pre-Hearing or Initial Post-Hearing Briefs. Respondent has waived future argument on this issue under Ground Rules 7.2 and 10.1.

For the foregoing reasons, Complainants have proven by a preponderance of evidence that the Accused 635 Products when used with the Chromium™ Controllers meet the additional limitations recited in claims 13, 14, and 21 of the '635 patent.

XI. INDIRECT INFRINGEMENT

A. Legal Standard: Indirect Infringement

1. Induced Infringement

"Whoever actively induces infringement of a patent shall be liable as an infringer." 35 U.S.C. § 271(b). A patentee asserting a claim of inducement must show: (i) that there has been direct infringement;[38] and (ii) that the alleged infringer "knowingly induced infringement and possessed specific intent to encourage another's infringement." *Minnesota Mining & Mfg. Co. v. Chemque, Inc.*, 303 F.3d 1294, 1304-05 (Fed. Cir. 2002). With respect to the direct infringement requirement, the patentee "must either point to specific instances of direct infringement or show that the accused device necessarily infringes the patent in suit." [39] *ACCO Brands, Inc. v. ABA Locks Mfrs. Co., Ltd.*, 501 F.3d 1307, 1313 (Fed. Cir. 2007) (citation omitted). This requirement may be shown by circumstantial evidence. *Vita-Mix Corp. v. Basic Holding, Inc.*, 581 F.3d 1317, 1326 (Fed. Cir. 2009). "[A] finding of infringement can rest on as little as one instance of the claimed method being performed during the pertinent time period." *Lucent Techs., Inc. v. Gateway, Inc.*, 580 F.3d 1301, 1317 (Fed. Cir. 2009).

[38] *See* Sections IX.C and X.C.

[39] *See also Limelight Networks, Inc. v. Akamai Techs,. Inc.*, 134 S. Ct. 2111, 2117 (2014).

The specific intent requirement for inducement necessitates a showing that the alleged infringer was aware of the patent, induced direct infringement, and that he knew that his actions would induce actual direct infringement. *Commil USA, LLC v. Cisco Systems, Inc.*, 720 F.3d 1361, 1367 (Fed. Cir. 2013), *aff'd and vacated in part on other grounds*, 135 S. Ct. 1920, 1926-28 (2015); *Global-Tech Appliances, Inc. v. SEB S.A.*, 131 S. Ct. 2060, 2068-70 (2011). Specific intent can be shown by, for example: (1) changes in importation practices effectuated to shift infringement liability; (2) the infringer's copying of patented technology; and (3) the infringer's willful blindness of the underlying direct infringement. *Certain Network Devices, Related Software and Components Thereof (I)*, Inv. No. 337-TA-944, Initial Determination at 82; *see also Commil*, 135 S. Ct. at 1924-25 ("It was not only knowledge of the existence of [the asserted] patent that led the Court to affirm the liability finding but also it was the fact that [the accused infringer] copied 'all but the cosmetic features of the [patented product],' demonstrating [the accused infringer] know it would be causing customers to infringe [the asserted] patent.") (quoting *Global-Tech*, 131 S. Ct. at 2071).).

Willful blindness, which also constitutes "knowledge," has two basic requirements: "(1) the defendant must subjectively believe that there is a high probability that a fact exists"; and "(2) the defendant must take deliberate actions to avoid learning of that fact." *Global-Tech*, 131 S. Ct. at 2070. The intent to induce infringement may be proven with circumstantial or direct evidence and may be inferred from all the circumstances. *Commil*, 720 F.3d at 1366; *Global-Tech*, 131 S. Ct. 2071-72.

The Federal Circuit has upheld the Commission's authority to cover "goods that were used by an importer to directly infringe post-importation as a result of the seller's inducement." *Suprema Inc. v. Int'l Trade Comm'n*, 796 F.3d 1338, 1352-53 (Fed. Cir. 2015).

2. Contributory Infringement

35 U.S.C. § 271(c) sets forth the rules for contributory infringement:

> Whoever offers to sell or sells within the United States or imports into the United States a component of a patented machine, manufacture, combination, or composition, or a material or apparatus for use in practicing a patented process, constituting a material part of the invention, knowing the same to be especially made or especially adapted for use in an infringement of such patent, and not a staple article or commodity of commerce suitable for substantial noninfringing use, shall be liable as a contributory infringer.

35 U.S.C. § 271(c).

Specifically with respect to Section 337 investigations, the Federal Circuit has held that "to prevail on contributory infringement in a Section 337 case, the complainant must show inter alia: (1) there is an act of direct infringement in violation of Section 337; (2) the accused device has no substantial non-infringing uses; and (3) the accused infringer imported, sold for importation, or sold after importation within the United States, the accused components that contributed to another's direct infringement." *Spansion, Inc. v. Int'l Trade Comm'n*, 629 F.3d 1331, 1353 (Fed. Cir. 2010). "[N]on-infringing uses are substantial when they are not unusual, far-fetched, illusory, impractical, occasional, aberrant, or experimental." *Vita-Mix*, 581 F.3d at 1327. To determine whether a use is substantial, an Administrative Law Judge may evaluate "the use's frequency, . . . the use's practicality, the invention's intended purpose, and the intended market." *i4i Ltd. Partnership v. Microsoft Corp.*, 598 F.3d 831, 851 (Fed. Cir. 2010). Section 271(c) also requires knowledge of the existence of the patent that is infringed. *Global-Tech*, 131 S. Ct. at 2068.

To satisfy contributory infringement's knowledge requirement, it is necessary to establish that "the accused contributory infringer knows that its component is included in a combination that is patented and infringing." This requires knowledge of the patent. *Global-Tech*, 131 S. Ct.

at 2068. In addition, the Federal Circuit has held that it is not sufficient to know of the patent and the relevant acts, but must also know that "these acts constituted infringement." *Fujitsu Ltd. v. LG Elecs.*, 620 F.3d 1321, 1320 (Fed. Cir. 2010). For purposes of contributory infringement, knowledge is inferred when the article at issue has no substantial non-infringing uses. *See Certain Semiconductor Chips with Minimized Chip Package Size and Prods. Containing Same*, Inv. No. 337-TA-605, Comm'n Op., 2009 WL 8144934, at *28 (June 3, 2009).

Where infringement allegations address a "separate and distinct" feature of a product, the contributory infringement analysis (for example, with respect to the existence of non-infringing uses) may address the particular feature in question rather than the product as a whole. *See i4i Partnership v. Microsoft Corp.*, 598 F.3d 831, 849 (Fed. Cir. 2010); *Lucent Techs., Inc. v. Gateway, Inc.*, 580 F.3d 1301, 1320-21 (Fed. Cir. 2009); *Ricoh Co. Ltd. v. Quanta Comput. Inc.*, 550 F.3d 1325, 1338 (Fed. Cir. 2008).

B. The Use of the GEM Chips with the Chromium™ Controllers Indirectly Infringes the Asserted Claims of the '682 and '635 Patents

1. Respondent's GEM Chips and Chromium™ Controllers Directly Infringe the Asserted Claims of the '682 and 635 Patents

Complainants have proven that Respondent's customers use the Chromium™ Controllers and GEM Chips to generate droplets in a manner that directly infringe claims 14, 16 and 17 of the '682 patent, and claims 1, 13, 14, 16, and 21 of the '635 patent. (*See, e.g.*, Tr. (Schnall-Levin) at 1053:16-24 ("Q. Dr. Schnall-Levin, could you please provide an example of the use of 10X's single cell V(D)J product in research? A. Sure. So I think one good example is from a doctor called Dr. Aude Chapuis, who's a medical researcher. She is at the Fred Hutchinson Cancer Research Center in Seattle. And she's basically using both our single cell gene expression, but also our single cell V(D)J product, to profile the immune cells that infiltrate

tumors."), 1083:1-19 ("Q. . . . [W]hat is RX-523? A. [redacted]), 1084:2-9, 1085:1-19; RX-0523C; RX-1608; RX-1609; *see also* Sections IX.C and X.C, *supra*.).

The only issue in dispute with regard to the '682 and '635 patents is whether the GEM Chips have a droplet generation region. As discussed in Section VII.D.1(c), *supra*, that the singulation channel contains components in addition to the sample-containing dispersed phase fluid in the singulation channel does not mean the singulation channel is not a sample inlet channel. First, Respondent did not contest that the singulation channel has sample-containing dispersed phase fluid. (CX-0616C (Bharadwaj Dep. Tr.) at 173:1-14.). Second, the claim construction of "droplet generation region" did not limit the sample inlet channel to only sample containing dispersed phase fluid. Third, the well-settled law on the recitation of "comprising" as a transitional phrase has been construed consistently to mean that additional material beyond that claimed can be present. *See, e.g.*, *Vivid Techs.*, 200 F.3d at 811. Fourth, by limiting the sample inlet channel to one that contains only fluid received directly from the sample well, Respondent is improperly attempting to re-argue claim construction, which is prohibited by Order No. 20.

For these reasons, Complainants have proven with compelling evidence that the Chromium™ System directly infringes the '682 and '635 patents.

2. Respondent Had Knowledge of the '682 and '635 Patents

There is no dispute that Respondent has known of the '682 and '635 patents since at least the filing of the Complaint in this Investigation. (*See, e.g.*, Tr. (Hindson) at 987:24-988:1, 1036:4-18.). *See, e.g.*, *Certain Beverage Brewing Capsules, Components Thereof, and Prods. Containing the Same* ("*Certain Beverage Brewing Capsules*"), Inv. No. 337-TA-929, Comm'n

Op., 2016 WL 9751230, at *10 (Apr. 6, 2016) (finding knowledge requirement for induced and contributory infringement satisfied based on service of the complaint); *Certain Semiconductor Chips and Prods. Containing Same*, Inv. No. 337-TA-753, Initial Determination at 65 (Mar. 2, 2012) (unreviewed in relevant-part) ("Respondents' knowledge of the Asserted Patents cannot be disputed since they have had notice since at least December of 2010, when the Complaint in this Investigation was filed.").

In addition, the '682 and '635 patents, both of which issued from continuations of U.S. Patent Application Serial No. 13,287,120 filed on November 1, 2011, name, *inter alia*, as inventors, Benjamin J Hindson, Kevin D. Ness, and Donald A. Masquelier. (*See, e.g.*, JX-0004 at (63), (72); JX-0005 at (63), (72).). On February 22, 2012, Drs. Hindson, Masquelier, and Ness, together with the other named inventors, assigned U.S. Patent Application Serial Nos. 15/351,335 ("the '351 application") and 15/351,331 ("the '331 application"), which issued as the '682 and '635 patents, respectively, to Bio-Rad Laboratories, Inc. (*See* Compl. at Ex. 8 ('682 Assignment), Ex. 9 ('635 Assignment).). The '351 and '331 applications, both of which were both published on March 2, 2017, issued as the '682 and '635 patents on May 2, 2017 and May 16, 2017, respectively, before the Complaint was filed on July 31, 2017. (JX-0004 at (65), (45); JX-0005 at (65), (45).). Therefore, axiomatically, as co-owners and inventors of the '682 and '635 patents, Drs. Hindson, Masquelier, and Ness were aware of the two (2) patents' content before Complainants filed their Complaint.

Moreover, Drs. Hindson and Ness co-founded Respondent 10X. (Tr. (Hindson) at 906:11-14, 949:18-19.). Dr. Hindson, who has been and is Respondent 10 X's current President and Chief Scientific Officer, acknowledged he knew of the patents: "I was aware of the inventions and the disclosures that I'd made at Bio-Rad and at QuantaLife." (Tr. (Hindson) at

906:12-14, 988:1-2.). Dr. Ness also served as Respondent 10X's former Chief Technology Officer and Chief Operating Officer. (*Id.* at 1118:5-6; Motion Docket No. 1068-003, Ex. 3 (Resp. to Interrogs.) at No. 14.). Dr. Masquelier, formerly a director of engineering at 10X, was in charge of the design and manufacture of Respondent 10X's microfluidic chips. (Motion Docket No. 1068-003, Ex. 2 (Masquelier Dep. Tr.) at 62:11-25.).

Therefore, both direct and circumstantial evidence admitted in this Investigation proves irrefutably that Respondent had knowledge of the '682 and '635 patents by the filing of the Complaint on July 31, 2017, and most likely by at least early 2012, given that Drs. Hindson, Ness, and Masquelier are the named inventors on, and assignors of, the '682 and '635 patents.

3. Respondent Knew or Should Have Known that the GEM Chips and Chromium™ Controllers Infringe the Asserted Claims of the '682 and '635 Patents

Respondent relied primarily upon Dr. Hindson's testimony with respect to his state of mind and his subjective belief that the Chromium™ System does not infringe the asserted claims of the '682 and '635 patents. Dr. Hindson testified and claimed that the ddPCR technology that QuantaLife transferred to Bio-Rad "is completely different to what has become the 10X Genomics products." (Tr. (Hindson) at 988:23-989:9; RBr. at 60.). Pertinent and persuasive evidence dating back to 2011 does not support: Dr. Hindson's claim that the ddPCR technology was different that 10X's products; his description of the technology that QuantaLife transferred to BioRad; or that his subjective belief was valid.

As an initial matter, in late 2011, Dr. Hindson and others sold QuantaLife and all of its intellectual property to Bio-Rad. (Tr. (Hindson) at 1001:24-1003:6.). As discussed in Sections IV.D and IV.E, and as observed above, Dr. Hindson is a named inventor on the '682 and '635 patents. Dr. Hindson, with the other co-owners of the patents that 10X sold to Bio-Rad,

expressly assigned their rights to those inventions without reservation to Bio-Rad. (JX-0004 at (72); JX-0005 at (72); JX-0114.0116 to -0121.). Dr. Hindson knew, and has acknowledged in testimony in a number of different ways at different times, that the patents and inventions he and the co-owners sold to BioRad were directed to the use of microfluidic chips to generate droplets. (Tr. (Hindson) at 993:19-25.). With respect to the '160 patent, Dr. Hindson acknowledged that the claims, which were published in 2011 (JX-0001 at (65)), made no specific reference to PCR and were more generally directed to forming emulsions in parallel. (Tr. (Hindson) at 992:16-993:25; JX-0004.0036, -0037.).

In 2012, less than one year after Bio-Rad acquired QuantaLife, Dr. Hindson and other key QuantaLife employees began leaving Bio-Rad to start 10X. (Tr. (Hindson) at 1003:7-17.).

In 2013, Dr. Hindson and one of 10X's co-founders and CEO since its founding, Serge Saxonov,[40] [redacted]. (Tr. (Tumolo) at 100:15-22, 101:1-14.).

[redacted]

[40] Dr. Serge Saxonov was a co-founder of 10X, and as of September 2016, 10X's CEO. (RPBr. at 3; CX-0129C.). Dr. Saxonov was not called to testify during the Hearing. However, Respondent identified Dr. Saxonov as a potential fact witness for the Hearing to address "[m]atters relating to 10X, its history, and its products; QuantaLife, its history, and its products; and the prior proceedings between 10X and Bio-Rad." (RPSt. at 3.). Some of Dr. Saxonov's deposition transcript was designated and admitted into evidence.

[41] [redacted]

. (Tr. (Hindson) at 940:6-13, 1021:18-1022:3.). It does not appear that any of their discussions were committed to writing.

(Tr. (Tumolo) at 100:15-101:14, 133:13-134:4, 135:19-136:4, 139:11-18; *see also* RX-1673C.0001; Tr. (Hindson) at 941:15-942:20.).

(Tr. (Hindson) at 1024:9-18; CDX-0878C.0002.).

Additionally, Dr. Hindson corroborated some of Ms. Tumolo's most critical testimony that goes directly to the heart of whether Dr. Hindson knew that 10X was using BioRad droplet technology—the very same technology Dr. Hindson and other founders of 10X had sold to BioRad. In each meeting, Dr. Hindson responded to Ms. Tumolo, :

(Tr. (Hindson) at 948:1-6.).

); *see also id.* at 137:1-12, 137:23-139:10, 167:14-25; RX-1674C.).

. (Tr. (Hindson) at 1016:20-22 ("Q. And would you agree that a GEM is a gel bead in a droplet? A. Yes."), 1015:4-22, 1024:25-1025:2.). 10X's corporate designee, Rajiv Bharadwaj, also described GEMs, similarly to Dr. Hindson, as "***a droplet which contains a gel bead***." (CX-0199C (Bharadwaj Dep. Tr.) at 11:22-25 (emphasis added); *see also id.* at 11:25-12:6 ("So 'gel beads' is a term which we use for one of our reagents which we use for our assays. , and that is encapsulated into an aqueous ***droplet*** and the ***droplet*** is suspended in an immiscible fluid which is, in our case, oil."); CDX-0008.0007).

Dr. Hindson also testified that

[redacted]

Even taking an accommodating view to 10X's and Dr. Hindson's explanations, the solid evidence is that by October 2012, if not by sometime in 2011, Respondent knew or should have known its GEMs would infringe the '682 and '635 patents.

Dr. Hindson's justifications [redacted] are not persuasive. To begin with, his claim that he was not in a position to tell Ms. Tumolo what 10X was developing without a non-disclose agreement in place (*id.* at 1025:3-10), easily could have been handled with a simple explanation communicating the same, as Complainants noted. (CBr. at 51.).

[redacted]

(*Id.*).

Finally, Dr. Hindson's assertion that in his mind, "a gel bead in a droplet is not the same as just an empty droplet" directly contradicts his Hearing testimony that most GEMs are just "empty" droplets. (Tr. (Hindson) at 962:10-17 ("[T]he idea is to load the cells such that only a small fraction of the GEMs get an individual cell. So most of them are actually empty.").).

There is additional evidence that Dr. Hindson was aware that the intellectual property that he and others sold to Bio-Rad was not limited to "empty" droplets. For example, Ms. Tumolo explained that when QuantaLife was positioning the sale of its company to Bio-Rad, Dr. Hindson and his colleagues (Tr. (Tumolo) at 91:3-14, 123:18-124:7.). Moreover, slides in one of QuantaLife's PowerPoint presentations in Figure No. 33 below, show . (*Id.* at 91:3-14, 123:18-124:7; CX-0032C.0169 ( ); CX-0032C.0170 ( ).

(CX-0032C.0169, -0170.).

Ms. Tumolo's testimony and QuantaLife's presentation, shown in-part above in Figure No. 33, undermine Dr. Hindson's testimony that the work in which he and others at QuantaLife were engaged, and that the . (Tr. (Hindson) at 924:8–25.). Additionally, Dr. Hindson's testimony about the ***product*** that he sold to Bio-Rad, the QX100, is largely irrelevant to the issue of infringement. (CPBr. at 25 (citing RBr. at 60-61).). As Complainants pointed out, it is the scope of the ***asserted claims*** in the '682 and '635 patents that determine Respondent's infringement—not the scope of the QX100's capabilities.

Respondent's argument that 10X did not indirectly infringe relies at least in part on a 2016 arbitrator's decision from a lawsuit that Bio-Rad brought against Drs. Hindson, Ness, and Saxanov in which Bio-Rad claimed that 10X breached certain non-competition and non-solicitation agreements between Bio-Rad and 10X's founders, Drs. Hindson, Ness, and Saxonov

(RBr. at 61-63; RX-0604C.0001, -0002 (arbitration final award)).[42] That arbitration decision is not germane here for the following reasons.

The arbitration focused on [redacted] (RX-0604C.0027.). The portions of the final award to which Respondent pointed relate to the [redacted]. (RBr. at 62 (citing RX-0604C.0052, -0054 to -0056). [redacted]:

- RX-0604C.0052: [redacted] (emphasis added);
- RX-0604C.0054: [redacted] (emphasis added);
- RX-0604C.0055 to -0056: [redacted] (emphasis added);

As evidenced by the quoted language from the final arbitration reward above, the [redacted]. This appears to be confirmed by [redacted]

[42] *In the Matter of the Arbitration Between Bio-Rad Labs, Inc. and Bio-Rad QL, Inc. v. Benjamin Hindson, Kevin Ness and Serge Saxanov*, AAA Case No. 01-14-0001-5239 (Jan. 25, 2016).

. (Tr. (Tumolo) at 114:17-115:7 (emphasis added).).

The knowledge required for induced and contributory infringement may also be satisfied by a showing of willful blindness. *Warsaw Orthopedic, Inc. v. NuVasive, Inc.*, 824 F.3d 1344, 1347 (Fed. Cir. 2016) ("[W]illful blindness can satisfy the knowledge requirement for active inducement under § 271(b) (and for contributory infringement under § 271(c)), even in the absence of actual knowledge.") (citing *Global-Tech.*, 131 S. Ct. at 2070). Willful blindness is established where a respondent: (1) subjectively believes that there is a high probability of infringement; and (2) deliberately avoids learning of infringement. *Global-Tech*, 131 S. Ct. at 2070. Here, evidence base on the totality of the circumstances reflects' Respondent's willful blindness to its infringement.

For example, Dr. Schnall-Levin testified that "Bio-Rad had already been suing us, and going after us, and so we knew that they had a very aggressive stance towards us." (Tr. (Schnall-Levin) at 1073:4-6.).

Even after the Complaint was filed, Respondent continued to import the GEM Chips and engage in infringing activities.

Respondent's only defense was Dr. Hindson's ultimate, conclusory but unsupported testimony that 10X did not "intend" to infringe. Unfortunately, Respondent offered no evidence to support its claim; not even advice from counsel that might have aided Respondent in steering it legally away from the same technology that Drs. Hindson, Ness and Masquelier had sold to BioRad. (Tr. at 1147:9-19 ( ).). *See, e.g., Certain Silicon Microphone Packages & Prods. Containing Same* ("*Certain Silicon Microphone Packages*"),

Inv. No. 337-TA-888, Initial Determination at 42-44, 47-48 (Aug. 29, 2014) (finding that respondents had "willfully blinded themselves to the possibility that their activities" infringed because they failed to investigate accusations of infringement despite being aware of the asserted patent and being warned that their product development could result in patent infringement).

Here, Respondent also was willfully blind to the fact that its products induce and contribute to its customers' infringement of the '682 and '635 patents.

For the reasons discussed above, Complainants have proven that Respondent knew or should have known that the GEM Chips and Chromium™ Controllers infringe the asserted claims of the '682 and '635 patents.

4. Respondent's Waiver Argument with Respect to Indirect Infringement Is Rejected

Respondent claimed that in their Pre-Hearing Brief that Complainants waived any argument that Respondent knew its acts were infringing, or that Respondent possessed the specific intent to encourage another's infringement by failing to include these contentions in its Pre-Hearing Brief. (RBr. at 71.). Respondent's assertion fails for the following reasons.

As Complainants and Staff pointed out, these are not new arguments. (CRBr. at 22; SRBr. at 16.). Complainants' arguments were "sufficiently implicated" in their Pre-Hearing Brief. *See, e.g., Certain L-Lysine Feed Prods., Their Methods of Prod. & Genetic Constructs for Prod.* ("*Certain L-Lysine Feed Products*"), Initial Determination, Inv. No. 337-TA-571, 2008 WL 3872209, at *15 n.113 (July 31, 2008).

In their Pre-Hearing Brief, Complainants argued that Respondent had knowledge of the Asserted Patents and their scope. (CPBr. at 3-4.). There is no requirement that there be "verbatim identity between the arguments in the pre-hearing and post-hearing briefs," because

the purpose of "the rules that require timely disclosure of contentions is to avoid gamesmanship and litigation-by-surprise." *Certain L-Tryptophan, L-Tryptophan Prods., and Their Methods of Prod.*, Inv. No. 337-TA-1005 ("*Certain L-Tryptophan Products*"), Initial Determination, at 10 (Aug. 11, 2017); *see also Certain Integrated Circuit Chips & Prods. Containing the Same* ("*Certain Integrated Circuit Chips*"), Inv. No. 337-TA-859, Comm'n Op. at 18-19 (Aug. 22, 2014) (rejecting respondents' waiver argument because respondents were "on notice" of the allegedly new claim construction argument and complainant had "reiterated its position consistently throughout its pre-hearing brief and again in its post-hearing briefs").

Additionally, Complainants placed Respondent on notice by explaining that Dr. Hindson and others left Bio-Rad to start 10X and to create a droplet-based system that infringed the Asserted Patents shortly after Bio-Rad acquired QuantaLife. (*Id.*). Complainants also explained that: (i) Respondent induced and contributed to infringement of the Asserted Patents; (ii) Respondent met all the requirements for indirect infringement, including specific intent and knowledge of infringement; and (iii) Respondent had the requisite knowledge and intent for induced and contributory infringement. (*Id.* at 11, 34-35, 37-38, 50, 54, 64.).

In its Initial Post-Hearing Brief, Respondent acknowledged that Complainants argued in their Pre-Hearing Brief that Respondent's "instruction manuals and guides encourag[e] customers to use the GEM Chips to generate emulsions." (RBr. at 71 (quoting CPBr. at 50).). Respondent recognized the same in one of its MILs. (Doc. ID No. 641275 at 7 ("Complainants have placed at issue inventors' state of mind with respect to indirect infringement by alleging that they have knowledge and intent to cause direct infringement.") (Apr. 6, 2018) (citing CPBr. at 11, 34, 37, 50) (other citation omitted).). Staff also agreed in its Pre-Hearing Brief that, based on Complainants' Pre-Hearing Brief, "the evidence [was] expected to show that 10X indirectly

infringes" certain claims of the Asserted Patents. (SPBr. at 38 (citing CPBr. at 34-35), 49 (citing CPBr. at 50-58), 59-60 (citing CPBr. at 64-69).).

Given the pleadings, there is no question that Complainants' Pre-Hearing Brief placed Respondent on notice of Complainants' argument that Respondent had the specific intent and knowledge of infringement for both induced and contributory infringement. *See Certain L-Tryptophan Products*, Initial Determination at 10 (rejecting respondent's attempt to "elevate form above substance, and seek to require verbatim identity between the arguments in the pre-hearing and post-hearing briefs").

Respondent's argument is not supported for another reason. As Complainants observed, Respondent opened the door during the Hearing to the circumstances surrounding its knowledge of and intent to infringe. (CRBr. at 23.). During direct examination, Respondent asked Dr. Hindson, its own fact witness, questions about his subjective belief and intent to infringe Bio-Rad's patents. (Tr. (Hindson) at 988:3-4 ("Dr. Hindson, at any time have you intended to cause 10X to infringe any of those patents?"), 988:23-25.). Permitting testimony about a witness's state of mind is supported by the case law, which acknowledges that the requisite intent can be inferred from circumstantial evidence. *See, e.g., Certain Radio Frequency Identification (RFID) Prod. & Components Thereof*, Inv. No. 337-TA-979, Initial Determination, 2017 WL 3331737, at *160 (June 22, 2017); *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1290 (Fed. Cir. 2011).

Because Respondent opened the door during Dr. Hindson's direct examination, Complainants were able to cross-examine and explore the circumstances surrounding his and Respondent's knowledge of infringement and their and intent to infringe. *See, e.g., Certain L-Tryptophan Prods.*, Initial Determination at 8-10 (denying motion to strike because respondent

"itself opened the door to [the relevant] testimony during cross-examination," and holding that the relevant ground rule with respect to waiver "precludes a party from raising a completely new argument in post-hearing briefing "but that "[i]t does not, . . . provide a means to ***bury potentially unfavorable testimony elicited on cross-examination and re-direct during the evidentiary hearing***.") (emphasis added).).

Respondent cited only one case in support of its waiver argument, *Certain Automated Media Library Devices*, which does not apply. (RBr. at 71 (citing *Certain Automated Media Library Devices*, Inv. No. 337-TA-746, Comm'n Op. at 14-16 (Jan. 9, 2013).). There, the Commission found that arguments that the party failed to raise ***at all*** in ***both*** its pre-hearing and opening post-trial briefs were waived. *Certain Automated Media Library Devices*, Inv. No. 337-TA-746, Comm'n Op. at 14-16 (Jan. 9, 2013). That is not the case here.

In short, Complainants have not raised any new arguments with respect to Respondent's alleged indirect infringement, and have instead "maintained its pre-hearing positions with additional support from the evidence presented at trial." *Certain L-Tryptophan Products*, Initial Determination at 10. Accordingly, Respondent's waiver argument is rejected.

5. Respondent's Actions Have Not Met the Additional Requirements for Induced Infringement

a) Respondent Intends to Cause or Encourage the Directly Infringing Acts

Complainants asserted that Respondent induces its users to directly infringe claims 14, 16, and 17 of the '682 patent and claims 1, 13, 14, 16, and 21 of the '635 patent by providing instruction manuals and guides with the intent of encouraging customers to use the GEM Chips with the Chromium™ Controllers to generate emulsions in a manner that infringes the '682 and '635 patents. (CX-0354; CX-0355; CX-0616C (Bharadwaj Dep. Tr.) at 131-132.).

Respondent argued, without any evidentiary support, that it did not specifically intend to encourage infringement of the '682 and '635 patents. (RBr. at 72, 78.). However, Respondent did not dispute that it provides manuals and guides and that the Gem Chips are "meant to work with the chromium instruments." (RBr. at 71 (citing CX-0354; CX-0355; CX-0616C (Bharadwaj Dep. Tr.) at 131:15-19).).

Respondent's fact witness, Dr. Hindson, testified that the 10X Genome user guide "tell[s] people in writing how to use our products," and that these guides "come with all of the [10X] products." (Tr. (Hindson) at 970:4-14; CX-0355.). He provided similar testimony with respect to the 10X Single Cell user guide. (Tr. (Hindson) at 972:1-14; CX-0354; RX-1565.). Moreover, a technical document entitled "[redacted]. (CX-0375C.0009; *see also* Tr. (Gale) at 447:14-448:9; CX-0353; CDX-0005.0101.). In other words, there is no other possible, non-infringing use of Respondent's products.

Courts have found that the specific intent requirement of indirect or contributory infringement is satisfied where the respondent provides instruction manuals instructing others how to use the product in an infringing manner. *See, e.g.*, *i4i Ltd. P'ship v. Microsoft Corp.*, 598 F.3d 831, 852 (Fed. Cir. 2010), *aff'd on other grounds*, 564 U.S. 91 (2011); *Certain Semiconductor Chips and Prods. Containing Same,* Inv. No. 337-TA-753, Comm'n Op. at 41-42 (July 31, 2012) ("The ALJ found that the respondents had taken 'active steps demonstrating a specific intent to induce infringement' of the [asserted] patents, by reason of: 'advertising the infringing use and providing technical support, instructions, tutorials, software device drivers and other materials directing end users to operate the Accused Products in an infringing manner.' . . .

[T]he types of materials that the ALJ relied upon to demonstrate inducement are ordinary: user manuals for how to perform an action that infringes, and technical support to assist. This is precisely the sort of evidence used by the court of appeals . . . .") (internal citations omitted).). Respondent cited no case law to the contrary. (*See* RBr. at 72.).

For the foregoing reasons, Complainants have proven that Respondent intends end-users to operate the GEM Chips with the Chromium™ Controllers in an infringing manner.

6. Respondent Meets the Additional Requirements for Contributory Infringement

a) The GEM Chips Are Material Components of the '682 and '635 Patented Inventions

Based on evidence that the GEM Chips cannot be used without the Chromium™ Controllers, Complainants' expert, Dr. Gale, testified that the GEM Chips "are material components" and stated that "[i]f you don't have the chips, the system doesn't work." (Tr. (Gale) at 433:6-15; *see also id.* at 433:16-17 ("So those clearly are very important and the system doesn't work without it."); CX-0375C.0009; CX-0353.0003; CDX-0005.0099.). Dr. Anna corroborated Dr. Gale's testimony. (Tr. (Anna) at 645:23-646:2 ("Q. Would you say that the GEM chip is a material component of the overall system? A. My understanding is that the overall system doesn't work unless the chip is there, so therefore I would consider it to be a material component of the system.").).

Respondent did not dispute that the GEM Chips are material components of the inventions claimed in the '682 and '635 patents. (RPBr. at 71-72, 80, 85, 89; RBr. at 72-73, 78-80.). Respondent has waived argument on this issue under Ground Rules 7.2 and 10.1.

Given the evidence produced and confirmed by Complainants and Respondent in documents and testimony, it is a finding of this decision that Complainants have proven that the

GEM Chips are material components of the ’682 and ’635 patented inventions.

b) Respondent Knows the GEM Chips Are Especially Made for Use with the Chromium™ Controllers to Generate Droplets

Based on irrefutable and unrefuted technical documents admitted as evidence, Dr. Gale testified that the GEM Chips “only fit with this [10X] instrument and they’re designed to fit only in this instrument,” “are specifically designed to generate droplets,” and that “[t]here is essentially no other use for these chips.” (Tr. (Gale) at 433:18-25; *see also* Tr. (Anna) at 646:3-13, 647:8-648:1 (“the GEM chips are specifically designed to be used with the 10X instrument or the Chromium instrument, and that they do not have any substantial non-infringing uses”); CX-0375C.0009; CX-0353.0003.). Rajiv Bharadwaj, 10X’s own corporate designee, was a third witness who confirmed in his testimony that the [redacted] (CX-0375C.0009).

As Dr. Gale summarized, “the purpose of the entire [10X] system is to produce an emulsion. . . . [T]hey] [10X] know what the use of the instrument is, they know what’s happening in there, and it occurs.” (Tr. (Gale) at 434:15-435:5; *see also* Tr. (Anna) at 645:15-22; CDX-0005.0099; CDX-0006.0187.).

Respondent did not dispute that the GEM Chips are material components of the inventions claimed in the ’682 and ’635 patents. (RPBr. at 71-72, 80, 85, 89; RBr. at 72-73, 78-80.). Respondent has waived argument on this issue under Ground Rules 7.2 and 10.1.

For the foregoing reasons, based on undisputed evidence, it is a finding of this decision

that Complainants have proven that Respondent knows the GEM Chips are especially made for use with the Chromium™ Controllers to generate droplets/an emulsion and have no other material use.

c) The GEM Chips Are Not a Staple Article or Commodity of Commerce Suitable for Substantial Non-Infringing Use

As discussed above in Section XI.B.6(a), Complainants have proven that the only function of the GEM Chips is for use in the Chromium™ Controllers to produce GEMs, which Respondent did not dispute. (*See* Tr. (Gale) at 433:18-25, 434:15-23; Tr. (Anna) at 646:3-13, 645:1-22, 647:8-648:1; CX-0616C (Bharadwaj Dep. Tr.) at 131:1-132:1; CX-0375C.0009; CDX-0005C.0099; CDX-0006C.0187.). Respondent only argued that [redacted] that Complainants have alleged satisfies certain limitations of the '682 patent, constitutes a substantial non-infringing use of the GEM Chips. (RBr. at 73-76; RDX-0004C.0006; Tr. (Santiago) at 1155:25-1156:11).). Respondent's assertion is unavailing for following reasons.

To begin with, Respondent failed to provide any evidence that the System NH has been [redacted]. During the Hearing, Dr. Hindson acknowledged that the [redacted]. (Tr. Hindson) at 1035:10-16 [redacted] (emphasis added).). The Federal Circuit has held that "it

matters not that the device can be manipulated into a non-infringing configuration, because the instructions packaged with each device teach the infringing configuration and nothing in the record suggests that . . . any end-user ignored the instructions or assembled the [10X system] in a manner contrary to the instructions so as to form a non-infringing configuration." *Golden Blount*, 438 F.3d at 1363; *see also Fujitsu*, 620 F.3d at 1330-31; *Skyhook Wireless*, 159 F. Supp. 3d at 162.

Moreover, "[t]o determine whether a use is substantial, an ALJ may evaluate 'the use's frequency, . . . the use's practicality, the invention's intended purpose, and the intended market.'" *Certain Network Devices, Related Software & Components Thereof(II)*, Inv. No. 337-TA-945, Comm'n Op., 2017 WL 3614521, at *11 (June 1, 2017) (quoting *i4iLtd. Partnership*, 598 F.3d at 851).

Courts have held routinely that the mere capability of "turning off" an infringing feature does not constitute a non-infringing use, especially where there is no evidence that any end-user actually implemented the modification. *See, e.g., Fujitsu Ltd. v. Netgear Inc.*, 620 F.3d 1321, 1330-31 (Fed. Cir. 2010) (holding that simply because "a user can turn off the infringing features" does not establish substantial non-infringing uses where, "when [the feature] is activated, the product is infringing"); *Golden Blount, Inc. v. Robert H. Peterson Co.*, 438 F.3d 1354, 1363 (Fed. Cir. 2006) ("[I]t matters not that the assembled device can be manipulated into a non-infringing configuration, because the instructions packaged with each device teach the infringing configuration and nothing in the record suggests that . . . any end-user ignored the instructions or assembled the burners in a manner contrary to the instructions so as to form a non-infringing configuration."); *Skyhook Wireless, Inc. v. Google, Inc.*, 159 F. Supp. 3d 144, 162 (D. Mass. 2015) (rejecting substantial non-infringing use argument based on the fact that the

accused device "can provide position information to the user with the GPS function turned off" because "simply being able to turn off an infringing feature does not give that feature a non-infringing use").

Here, 10X manuals and guides clearly instruct users to use its chip holders with the Chromium™ Controllers in the infringing configuration. (CX-0354.0022 (10X Single Cell User Guide: "Place a Single Cell A Chip in a 10X™ Chip Holder."); RX-1565.0023; CX-0355.0028 (10X Genome User Guide: "Place a Genome Chip in a 10X™ Chip Holder."). Respondent did not present any evidence to support a possible finding that it instructs its customers to use the Chromium™ Controllers [redacted]. (Tr. (Anna) 637:17-638:19, 639:11-15, 640:6-9.). It is a finding of this decision, based on unrebutted evidence, that Respondent's GEM Chips do not have any substantial non-infringing uses.

XII. DOMESTIC INDUSTRY REQUIREMENT: TECHNICAL PRONG

A. Legal Standard

A complainant in a patent-based Section 337 investigation must demonstrate that it is practicing or exploiting the patents at issue. *See* 19 U.S.C. § 1337(a)(2) and (3); *Certain Microsphere Adhesives, Process for Making Same, and Prods. Containing Same, Including Self-Stick Repositionable Notes*, Inv. No. 337-TA-366, Comm'n Op. at 8, Pub. No. 2949 (U.S.I.T.C. Jan. 16, 1996) ("*Microsphere Adhesives*"). "In order to satisfy the technical prong of the domestic industry requirement, it is sufficient to show that the domestic industry practices any claim of that patent, not necessarily an asserted claim of that patent." *Certain Ammonium Octamolybdate Isomers* ("*Certain Isomers*"), Inv. No. 337-TA-477, Comm'n Op. at 55 (U.S.I.T.C. Jan. 5, 2004).

The test for claim coverage for the purposes of the technical prong of the domestic industry requirement is the same as that for infringement. *Certain Doxorubicin and Preparations Containing Same*, Inv. No. 337-TA-300, Initial Determination at 109, 1990 WL 710463 (U.S.I.T.C. May 21, 1990), *aff'd*, Views of the Commission at 22 (October 31, 1990) ("*Doxorubicin*"). "First, the claims of the patent are construed. Second, the complainant's article or process is examined to determine whether it falls within the scope of the claims." *Id.* The technical prong of the domestic industry can be satisfied either literally or under the doctrine of equivalents. *Certain Dynamic Sequential Gradient Devices and Component Parts Thereof*, Inv. No. 337-TA-335, Initial Determination at 44, Pub. No. 2575 (U.S.I.T.C. Nov. 1992).

B. Complainants Have Satisfied the Technical Prong of the Domestic Industry Requirement

The Private Parties stipulated that the technical prong of the domestic industry is satisfied. (CX-0838C (Stipulation Regarding the Technical Prong of DI) ("Technical Prong Stipulation").). The Parties have agreed as a matter of fact and law that the following DI Products practice at least claim 20 of the '160 patent, claims 1, 2, 14, and 15 of the '664 patent, claims 14, 16, and 17 of the '682 patent, and claims 1, 13, 14, 16, and 21 of the '635 patent: (i) Bio-Rad's QX100 droplet generator and the DG8 Chip ("QX100 System"); (ii) Bio-Rad's QX200 droplet generator and the DG8 Chip ("QX200 System"); and (iii) Bio-Rad's AutoDG droplet generator and the DG32 Chip ("AutoDG System"). (*Id.* at ¶ 1.).

In its Pre-Hearing Brief, Complainants contended that Bio-Rad's ddSEQ Single-Cell Isolator and the ddSEQ microfluidic chip ("ddSEQ System") also practice the asserted claims of the '160, '664, '682, and '635 patents. (CPBr. at 8-9, 22-28, 41-50, 58-63, 69-75.). The Private Parties did not stipulate to facts with respect to the ddSEQ System. (CX-0838C (Technical

Prong Stipulation) at ¶ 1.). In addition, Complainants' experts did not offer any testimony on this issue at the Hearing. Accordingly, Complainants have not satisfied their burden of proof with regard to the ddSEQ System.

Accordingly, Complainants have satisfied the technical prong of the domestic industry requirement only with respect to Bio-Rad's QX100 System, QX200 System, and AutoDG System.

XIII. DOMESTIC INDUSTRY REQUIREMENT: ECONOMIC PRONG

A. Legal Standard

The Commission may only find a violation of Section 337 "if an industry in the United States relating to the articles protected by the patent . . . exists or is in the process of being established." 19 U.S.C. § 1337(a)(2) (emphases added). Typically, a complainant must show that a domestic industry existed at the time a complaint was filed. *See Motiva LLC v. Int'l Trade Comm'n*, 716 F.3d 596, 601 n.6 (Fed. Cir. 2013).

The legislative history of 19 U.S.C. § 1337(a)(2) and Commission precedent provide that an industry is 'in the process of being established' if: (i) the patent owner "can demonstrate that he is taking the necessary *tangible steps* to establish such an industry in the United States"; and (ii) there is "a *significant likelihood* that the industry requirement will be satisfied in the future." H. Rep. 100-40 at 157; S. Rep. 100-71 at 130 (emphasis added); *see, e.g., Certain Stringed Musical Instruments and Components Thereof*, Inv. No. 337-TA-586, Comm'n Op. (Apr. 24, 2008) at 13 (quoting same) ("*Stringed Musical Instruments*").

19 U.S.C. § 1337(a)(3) sets forth the following economic criteria for determining the existence of a domestic industry in such investigations that a complainant must satisfy:

> (3) For purposes of paragraph (2), and industry in the United States

> shall be considered to exist if there is in the United States, with respect to the articles protected by the patent, copyright, trademark, mask work, or design concerned –
>
> (A) significant investment in plant and equipment;
> (B) significant employment of labor, or capital; or
> (C) substantial investment in its exploitation, including engineering, research and development, or licensing.

With respect only to the subsections of 19 U.S.C. § 1337(a)(3), because the criteria are listed in the disjunctive, satisfaction of any one of them will be sufficient to meet the economic prong of the domestic industry requirement. *Certain Integrated Circuits, Chipsets and Prods. Containing Same* ("*Certain Integrated Circuits*"), Inv. No. 337-TA-428, Order No. 10, Initial Determination (unreviewed) (May 4, 2000). However, under Section 337(a)(3), a complainant must substantiate the nature and the significance of its activities with respect to the articles protected by the patent at issue. *Certain Printing and Imaging Devices and Components Thereof*, Inv. No. 337-TA-690, Comm'n Op. at 30 (Feb. 17, 2011). In explaining this, the Commission has also interpreted Sections 337(a)(3)(A) and (B) to concern investments in plant and equipment and labor and capital "with respect to the products presented by the patent." *Certain Ground Faults Interrupters and Prods. Containing Same,* Inv. No. 337-TA-739, 2012 WL 2394435 at *50, Comm'n Op. at 78 (June 8, 2012) (quoting U.S.C. §§ 1337(a)(3)(7)). It is not sufficient for the "substantial investment" under paragraph (C) to merely relate to articles protected by the asserted patents. Rather, "the complainant must establish that there is a nexus between the claimed investment and asserted patent regardless of whether the domestic- industry showing is based on licensing, engineering, research and development." *Certain Integrated Circuit Chips & Prods. Containing* ("*Certain Integrated Circuit Chips*"), Inv. No. 337-TA-845, Final Initial Determination, 2013 WL 3463385 at *14 (June 7, 3013).

In other words, the domestic industry requirement consists of both an economic prong (concerning "the activities of or investment in a domestic industry") and a technical prong ("whether complainant (or its licensees) practices its own patents."). *Certain Elec. Devices, Including Wireless Commc'n Devices, Portable Music & Data Processing Devices, & Tablet Computers*, Inv. No. 337-TA-794, Order No. 88, 2012 WL 2484219, at *3 (June 6, 2012).

There is no mathematical threshold test or a "rigid formula" for determining whether a domestic industry exists. *Certain Male Prophylactic Devices, Inc.* ("*Certain Male Prophylactic Devices*"), Inv. No. 337-TA-292, Comm'n Op. at 39, USITC Pub. 2390 (June 1991). However, to determine whether investments are "significant" or "substantial," the actual amounts of a complainant's investments or a quantitative analysis must be performed. *Lelo Inc. v. Int'l Trade Comm'n*, 786 F.3d 879, 883-84 (Fed. Cir. 2015) ("*Lelo*"). Even after *Lelo*, *supra*, which requires some quantification of a complainant's investments, there is still no bright line as to a threshold amount that might satisfy an economic industry requirement. It is the complainant's burden to show by a preponderance of evidence that each prong of the domestic industry requirement is satisfied. *Certain Prods. Containing Interactive Program Guide and Parental Control Tech.*, Inv. No. 337-TA-845, Final Initial Determination, 2013 WL 3463385 at*14 (June 7, 2013.). Moreover, the Commission makes its determination by "an examination of the facts in each investigation, the article of commerce, and the realities of the marketplace." *Certain Male Prophylactic Devices*, Comm'n Op. at 39) (quoting *Certain Double Sided-Floppy Disk Drives and Components Thereof*, Inv. No. 337-TA-215, Comm'n Op. at 17, USITC Pub. 1859 (May 1986).).

B. Complainants Have Satisfied the Economic Prong of the Domestic Industry Requirement Under Section 337(a)(A), (B), and (C)

The Private Parties stipulated that Complainants have met their burden and established the economic prong of the domestic industry under each of Sections 337(a)(3)(A)-(C) as to the Asserted Patents with respect to Bio-Rad's QX100 System, QX200 System, and AutoDG System. (CX-0832C (Stipulation Regarding the Economic Prong of DI) ("Economic Prong Stipulation") at ¶ 1.). The Private Parties have agreed as a matter of fact and law that through Complainants' significant investment in plant and equipment, significant employment of labor and capital, and substantial investments in R&D associated with Bio-Rad's QX100 System, QX200 System, and AutoDG System,[43] Complainants have met the economic prong of the domestic industry requirement. (*Id.*).

It is undisputed that the DG32 Chip, which consists of four DG8 Chips in a holder, is used in Bio-Rad's AutoDG instrument. (CX-0383C.0116.). Respondent also did not dispute that Bio-Rad manufactures [redacted] of its AutoDG instrument and [redacted] of its DI reagent products in the United States. (*See* CX-0832C (Economic Prong Stipulation) at ¶¶ 10, 17; JX-0092C.).

Moreover, each of the Asserted Patents include system claims that can encompass the AutoDG System in use with a DG32 Chip and DI reagent products, and/or method claims that are performed by the AutoDG System when used with a DG32 Chip and DI reagent products to form emulsions. (*See* JX-0001 ('160 patent) at cl. 20; JX-0002 ('664 patent) at cl. 1; JX-0004 ('682 patent) at cl. 14; JX-0005 ('635 patent) at cls. 1, 16.).).

[43] As discussed in Section XII.B, Bio-Rad's QX100 System includes the QX100 droplet generator and the DG8 Chip, Bio-Rad's QX200 System includes the QX200 droplet generator and the DG8 Chip, and Bio-Rad's AutoDG System includes the AutoDG droplet generator and the DG32 Chip.

1. Complainants' Expenditures on Plant and Equipment Are Significant

Complainants contended that Bio-Rad has made substantial investments in plant and equipment attributable to its domestic industry. (CBr. at 77-78.). Bio-Rad manufactures its AutoDG systems at its Hercules facility in California. (CX-0832C (Economic Prong Stipulation) at ¶ 10.) BioRad manufactures its reagents at its 925 facility also located in Hercules, California. (*See* CX-0832C (Economic Prong Stipulation) at ¶¶ 17-20.). Finally, Bio-Rad maintains several large research facilities in Pleasanton, California where employees conduct research and development ("R&D") related to the Asserted Patents. (*Id.* at ¶¶ 24, 61-74; JX-0050C; JX-0090C; CX-0544C; CX-0546C.).

Respondent has stipulated to the facts underlying Complainants' economic prong contentions. (*See* CX-0832C (Economic Prong Stipulation).). Thus, the evidence is unrebutted that Bio-Rad has made significant investments in plant and equipment related to its DI Products. (*See id.* at ¶¶ 28-75; RX-0578C (Mark A. DiPanfilo Dep. Tr.)[44] at 43-54; JX-0050C; JX-0090C; CX-0544C; CX-0546C.). The book value of Bio-Rad assets used in the manufacture of the DI Products totaled [redacted] as of August 2017. (*See* CX-0832C (Economic Prong Stipulation) at ¶ 108; JX-0050C; JX-0090C; CX-0544C; CX-0546C.). Bio-Rad invested [redacted] in plant and equipment associated with manufacturing and R&D activities related to the DI Products. (*See* CX-0832C (Economic Prong Stipulation) at ¶ 2.).

For these reasons, Complainants have satisfied the economic prong of the domestic

[44] When he provided his deposition testimony, Mr. Mark A. DiPanfilo was the Life Science and Digital Biology Group Controller of Bio-Rad Laboratories. (RX-0578C (DiPanfilo Dep. Tr.) at 6:3-12.). As the Life Science and Digital Biology Group Controller, Mr. DiPanfilo was responsible for the profits and loss ("P&L") of the Life Science and Digital Biology Groups, which involves the accounting, financial planning analysis and business partner support for these groups. (*Id.* at 6:13-20.).

industry requirement based on Bio-Rad's significant investment in plant and equipment.

2. Complainants' Expenditures on Labor and Capital Are Significant

Complainants asserted that Bio-Rad has made substantial employment of labor and capital related to its domestic industry. (CBr. at 78-79.). Respondent stipulated to the facts underlying Complainants' economic prong contentions. (*See* CX-0832C (Economic Prong Stipulation).). The undisputed evidence reflects that Bio-Rad invested [redacted] in labor and capital associated with manufacturing and R&D activities related to its DI Products. (*See* CX-0832C (Economic Prong Stipulation) at ¶ 4; JX-0050C; JX-0090C; CX-0828C; CX-0544C; CX-0546C.). Complainants contended that Bio-Rad's DI investments are significant and substantial in the context of its overall operations and have contributed to Bio-Rad's commercial products both from a qualitative and a quantitative perspective. (*See* CX-0832C (Economic Prong Stipulation) at ¶ 5.).

Accordingly, Complainants have satisfied the economic prong of the domestic industry requirement based on Bio-Rad's significant employment of labor and capital.

3. Complainants' Expenditures on Research and Development Are Substantial

Complainants argued that Bio-Rad has made substantial investments in research and development activities associated with its DI Products. (CBr. at 79-80.). Based on the Private Parties' stipulation, the evidence shows that Bio-Rad maintains [redacted] where research is conducted related to the DI Products. (CX-0832C (Economic Prong Stipulation) at ¶ 62; JX-0050C; JX-0090C; CX-0544C; CX-0546C.). [redacted], Bio-Rad has invested [redacted] in plant and equipment and [redacted] in labor and capital expenditures related to the DI Products. (CX-0832C (Economic Prong Stipulation) at

¶ 102.). The Private Parties stipulated that these R&D investments relate to the DI Products and have a sufficient nexus to each of the Asserted Patents. (CX-0832C (Economic Prong Stipulation) at ¶ 106.).

For the foregoing reasons, Complainants have satisfied the economic prong of the domestic industry requirement based on Bio-Rad's R&D activities.

XIV. WAIVER OR WITHDRAWAL OF RESPONDENT'S DEFENSES

In its Response to the Complaint and NOI, Respondent identified four (4) affirmative defenses: (i) First Affirmative Defense of non-infringement; (ii) Second Affirmative Defense of invalidity; (iii) Third Affirmative Defense for failure to state a claim for relief; and (iv) Fourth Affirmative Defense of prosecution history estoppel and/or prosecution disclaimer. (Resp. at 19-20.).

Respondent did not address in its Pre-Hearing Brief or provide any evidence during the Hearing to support its Third Affirmative Defense or its Fourth Affirmative Defense. (*Id.*). Consequently, it is a finding of this decision that Respondent has withdrawn, waived and/or abandoned its Third and Fourth Affirmative Defenses consistent with Ground Rules 7.2 and 10.1. *Kinik Co. v. Int'l Trade Comm'n*, 362 F.3d 1359, 1367 (Fed. Cir. 2004).

XV. CONCLUSIONS OF FACT OR LAW: THIS INITIAL DETERMINATION FINDS A SECTION 337 VIOLATION BASED UPON INFRINGEMENT OF U.S. PATENT NO. 9,500,664; U.S. PATENT NO. 9,636,682; AND U.S. PATENT NO. 9,649,635

1. The Commission has subject matter, personal, and *in rem* jurisdiction in this Investigation.

2. The Accused Products have been imported into the United States.

3. Complainants have not proven by a preponderance of evidence that the Accused Products infringe asserted claim 20 of U.S. Patent No. 9,126,160.

4. Complainants have proven by a preponderance of evidence that certain of the

Accused Products infringe asserted claims 1, 2, 14, and 15 of U.S. Patent No. 9,500,664.

5. Complainants have proven by a preponderance of evidence that the Accused Products infringe asserted claims 14, 16, and 17 of U.S. Patent No. 9,636,682.

6. Complainants have proven by a preponderance of evidence that the Accused Products infringe asserted claims 1, 13, 14, 16, and 21 of U.S. Patent No. 9,649,635.

7. Complainants have proven that they satisfy the technical prong of the domestic industry requirement for U.S. Patent Nos. 9,126,160; 9,500,664; 9,636,682; and 9,649,635.

8. Complainants have proven that they satisfy the economic prong of the domestic industry requirement.

9. Complainants have proven that Respondent has violated Section 337 of the Tariff Act of 1930, as amended.

The lack of discussion of any matter raised by the Parties, or any portion of the record, does not indicate that it has not been considered. Rather, any such matter(s) or portion(s) of the record has/have been determined to be irrelevant, immaterial or meritless. Arguments made on briefs, which were otherwise unsupported by record evidence or legal precedent, have been accorded no weight.

XVI. CONCLUSION AND ORDER

Based upon the foregoing, it is my Initial Determination on Violation of Section 337 that Respondent has not violated Section 337 of the Tariff Act of 1930, as amended, by importing into the United States, selling for importation, or selling within the United States after importation of certain microfluidic devices, by reason of infringement of claim 20 of United States Patent No. 9,126,160.

I have found that Respondent has violated Section 337 of the Tariff Act of 1930, as amended, by importing into the United States, selling for importation, or selling within the

United States after importation of certain microfluidic devices, by reason of infringement of claims 1, 12, 14, and 15 of United States Patent No. 9,500,664; claims 14, 16, and 17 of United States Patent No. 9,636,682; and claims 1, 13, 14, 16, and 21 of United States Patent No. 9,649,635.

This Initial Determination on Violation of Section 337 of the Tariff Act of 1930 is certified to the Commission. All orders and documents, filed with the Secretary, including the exhibit lists enumerating the exhibits received into evidence in this Investigation, that are part of the record, as defined in 19 C.F.R. § 210.38(a), are not certified, since they are already in the Commission's possession in accordance with Commission Rules. *See* 19 C.F.R. § 210.38(a). In accordance with 19 C.F.R. § 210.39(c), all material found to be confidential under 19 C.F.R. § 210.5 is to be given *in camera* treatment.

After the Parties have provided proposed redactions of confidential business information ("CBI") that have been evaluated and accepted, the Secretary shall serve a public version of this ID upon all parties of record. The Secretary shall serve a confidential version upon counsel who are signatories to the Protective Order (Order No. 1) issued in this Investigation.

Pursuant to 19 C.F.R. § 210.42(h), this Initial Determination shall become the determination of the Commission unless a party files a petition for review pursuant to 19 C.F.R. § 210.43(a) or the Commission, pursuant to 19 C.F.R. § 210.44, orders on its own motion a review of the Initial Determination or certain issues therein.

Within fourteen (14) days of the date of this document, the Parties shall submit to the Office of Administrative Law Judges a joint statement regarding whether or not they seek to have any portion of this document deleted from the public version. The Parties' submission shall be made by hard copy and must include a copy of this ID with yellow highlighting, with or

without red brackets, indicating any portion asserted to contain CBI to be deleted from the public version. The Parties' submission shall also include a chart that: (i) contains the page number of each proposed redaction; and (ii) states (next to each page number) every sentence or phrase, listed separately, that the party proposes be redacted; and (iii) for each such sentence or phrase that the party proposes be redacted, a citation to case law with an explanation as to why each proposed redaction constitutes CBI consistent with case law. Any proposed redaction that is not explained may not be redacted after a review. The Parties' submission concerning the public version of this document need not be filed with the Commission Secretary.

SO ORDERED.

MaryJoan McNamara
Administrative Law Judge

APPENDIX A

Accused Products	Chromium™ Genome Chip
	Chromium™ Single Cell A Chip

APPENDIX B

DI Products	Bio-Rad DG8 Chip
	Bio-Rad DG32 Chip

PUBLIC CERTIFICATE OF SERVICE

I, Lisa R. Barton, hereby certify that the attached **INITIAL DETERMINATION** has been served by hand upon the Commission Investigative Attorney, **Whitney Winston, Esq.**, and the following parties as indicated, on **October 16, 2018**.

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

On Behalf of Complainants Bio-Rad Laboratories, Inc. and Lawrence Livermore National Security, LLC:

Jeffrey Gerchick, Esq.
QUINN EMANUEL URQUHART & SULLIVAN LLP
1300 I Street, NW, Suite 900
Washington, DC 20005

☐ Via Hand Delivery
☒ Via Express Delivery
☐ Via First Class Mail
☐ Other:_____

Respondent 10X Genomics, Inc.:

Nicholas Groombridge, Esq.
PAUL, WEISS, RIFKIND, WHARTON & GARRISON LLP
1285 Avenue of the Americas
New York, NY 10019

☐ 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 DEVICES	**Inv. No. 337-TA-1068**

ORDER NO. 20: **CONSTRUING CERTAIN TERMS OF THE ASSERTED CLAIMS OF THE PATENTS AT ISSUE (*MARKMAN* CLAIM CONSTRUCTION)**

(April 4, 2018)

I. BACKGROUND

The Commission instituted this Investigation pursuant to subsection (b) of Section 337 of the Tariff Act of 1930, as amended, to determine:

> whether there is a violation of subsection (a)(1)(B) 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 devices by reasons of infringement of one or more of claims 1-12 and 14-16 of the '664 patent; claims 1-15 of the '844 patent; claims 1-21 of the '682 patent; claims 1-27 of the '635 patent; and claims 1, 2, 4-8, and 14-21 of the '160 patent; and whether an industry in the United States exists as required by subsection (a)(2) of section 337[.][1]

82 Fed. Reg. 42116 (Sept. 6, 2017).

The Notice of Investigation ("NOI") names as complainants: Bio-Rad Laboratories, Inc. of Hercules, CA, and Lawrence Livermore National Security, LLC of Livermore, CA ("Complainants"). *Id.* The NOI names as respondent: 10X Genomics, Inc. of Pleasanton, CA ("Respondent," and with Complainants, "the Private Parties"). *Id.* Commission Investigative Staff of the Office of Unfair Import Investigations ("Staff," and with Complainants and Respondent, the "Parties") is also named as a party. *Id.*

On September 13, 2017, a Proposed Scheduling Order issued to guide the timing and conduct of this Investigation. (Order No. 3 (Sept. 13, 2017).). Also on September 13, 2017, an initial determination ("ID") issued setting January 21, 2019 as the target date in this Investigation. (Order No. 2 (Sept. 13, 2017).). On September 29, 2017, an initial procedural schedule ("Procedural Schedule)" issued (Order No. 4 (Sept. 29, 2017)), that adopted dates in the Parties' Joint Proposed Procedural Schedule (Doc. ID No. 624144 (Sept. 27, 2017)).

[1] Initially, the asserted patents were: U.S. Patent No. 9,500,664 ("the '664 patent"); U.S. Patent No. 9,089,844 ("the '844 patent"); U.S. Patent No. 9,636,682 ("the '682 patent"); U.S. Patent No. 9,649,635 ("the '635 patent"); and U.S. Patent No. 9,126,160 ("the '160 patent"). *See, e.g.*, 82 Fed. Reg. 42115.

On January 12, 2018, in response to the Private Parties' Unopposed Joint Motion to Extend Certain Dates in the Procedural Schedule (Motion Docket No. 1068-001 (Jan. 10, 2018)), a revised Procedural Schedule issued. (Order No. 6 (Jan. 12, 2018)). The revised Procedural Schedule extended certain deadlines in the Investigation by one week, including deadlines pertaining to claim construction. (*Id.*). On January 11, 2018, the Parties filed a Joint Motion to File Joint Claim Construction Statement Out of Time. (Motion Docket No. 1068-002 (Jan. 11, 2018)). That Motion was granted the same day, giving the Parties until January 12, 2018, to file their Joint Claim Construction Statement. (Order No. 5 (Jan. 11, 2018)).

On January 12, 2018, consistent with Order No. 5, the Parties filed a Joint Claim Construction Chart. (Doc. ID No. 633763 (Jan. 12, 2018).). On January 23, 2018, the Parties filed an Amended Joint Claim Construction Chart ("Joint CC Chart"). (Doc. ID No. 634525 (Jan. 23, 2018).). The Joint CC Chart lays out the claim terms for which the Parties agree on a meaning and the claim terms for which a meaning remains in dispute. (*Id.*).

On January 23, 2018, Staff and Respondent each filed an opening claim construction brief. (Staff's *Markman* Brief ("SMBr."), Doc. ID No. 634518 (Jan. 23, 2018); Respondent's Opening *Markman* Brief ("ROMBr."), Doc. ID No. 634530 (Jan. 23, 2018).). Complainants filed their opening claim construction brief one day late, on January 24, 2018 (Complainants' Opening *Markman* Brief ("COMBr."), Doc. ID No. 634532 (Jan. 24, 2018)), and shortly thereafter sought leave of court for approval of the late filing, which was granted on January 30, 2018 (Order No. 9 (Jan. 30, 2018)).

Also on January 24, 2018, the Private Parties jointly filed *Markman* Hearing Proposals requesting that a *Markman* hearing be held in conjunction with the evidentiary hearing. (Doc. ID No. 634538 (Jan. 24, 2018).). On January 25, 2018, an order issued that effectively denied the

Private Parties' proposal to delay claim construction until the evidentiary hearing. (Order No. 7 (Jan. 25, 2018).). Order No. 7 also advised the Parties that a *Markman* hearing would not take place, either before or during the evidentiary hearing. (*Id.*). However, the Private Parties were given an opportunity to file reply claim construction briefs. (*Id.*).

On February 2, 2018, the Private Parties filed reply claim construction briefs. (Complainants' Reply *Markman* Brief ("CRMBr."), Doc. ID No. 635547 (Feb. 2, 2018); Respondent's Reply *Markman* Brief ("RRMBr."), Doc. ID No. 635528 (Feb. 2, 2018).). Staff did not file a reply claim construction brief.

On March 12, 2018, the Parties filed pre-hearing briefs. (Complainants' Pre-Hearing Brief ("CPBr.") (Doc. ID No. 638751 (Mar. 12, 2018)); Respondent's Pre-Hearing Statement and Brief ("RPBr.") (Doc. ID No. 638755 (Mar. 12, 2018)).). Complainants' Pre-Hearing Brief clarifies the asserted patents and patent claims remaining in the Investigation. (CPBr. at 9-69.).

II. PATENTS AT ISSUE

The complaint ("Complaint") and NOI identify five (5) asserted patents: U.S. Patent No. 9,126,160 ("the '160 patent"); U.S. Patent No. 9,500,664 ("the '664 patent"); U.S. Patent No. 9,089,844 ("the '844 patent"); U.S. Patent No. 9,636,682 ("the '682 patent"); and U.S. Patent No. 9,649,635 ("the '635 patent"). (*See, e.g.*, Compl. ¶ 1 (July 31, 2018).).

Several asserted patent claims identified in the Complaint and NOI from this Investigation. On March 6, 2018, claims 14-17 of the '160 patent, claim 3 of the '664 patent, claims 2, 8, 11, and 14-15 of the '844 patent, claims 2-3 of the '682 patent, and claims 2-4, 9-10, 15, 22, and 27 of the '635 patent were terminated from this Investigation. (Notice of Commission Determination Not to Review an Initial Determination (Order No. 12) Partially Terminating the Investigation as to Certain Patent Claims (Mar. 6, 2018).). On March 26, 2018,

claims 1 and 18 of the '160 patent, claims 6, 7, 9, and 13 of the '844 patent, claims 4 and 13 of the '682 patent, and claims 5 and 17 of the '635 patent were terminated from this Investigation. (Notice of Commission Determination Not to Review an Initial Determination (Order No. 16) Partially Terminating the Investigation as to Certain Patent Claims (Mar. 26, 2018).).

On March 14, 2018, Complainants filed a motion seeking partial termination of the Investigation based on their withdrawal of allegations with respect to certain additional claims ("Motion to Withdraw"). (Motion Docket No. 1068-015; Mot. at 1). Complainants sought termination of claims 2, 6, 7, and 19 of the '160 patent, claims 5-7, 10, and 12 of the '664 patent, claims 1, 3-5, 10, and 12 of the '844 patent, claims 5, 6, 8, 10-12, 15, 20, and 21 of the '682 patent, and claims 6-8, 11, 12, 18-20, and 23-26 of the '635 patent ("Withdrawn Claims") based on their withdrawal of those claims. (*Id.*). On March 15, 2018, the Court issued an Initial Determination that Complainants' Motion to Withdraw be granted and that the Investigation be terminated with respect to the Withdrawn Claims. (Order No. 19 (Mar. 15, 2018).).

Based on Complainants' Pre-Hearing Brief, four (4) patents and twenty-seven (27) patent claims remain in this Investigation: the '160 patent (claims 4–5, 8, and 20–21); the '664 patent (claims 1, 2, 4, 8, 9, 11, 14, 15, and 16); the '682 patent (claims 1, 7, 9, 14, and 16-19); and the '635 patent (1, 13–14, 16, and 21). (CPBr at 9-69.). Complainants have withdrawn all asserted claims of the '844 patent. (*Id.*). Each remaining asserted patent ("Asserted Patent") contains claim terms construed in this Order.

A. U.S. Patent No. 9,126,160

The '160 patent, entitled "System for Forming an Array of Emulsions," was filed on December 8, 2010 as U.S. Patent Application Serial No. 12/963,523 ("the '523 application").

(JXM–0001 at 1.). The '523 application claims priority to U.S. Provisional Application No. 61/194,043, filed on September 23, 2008. (*Id.* at 1:7-20; CPBr. at 5.). The '523 application issued as the '160 patent on September 8, 2015 and names Kevin D. Ness, Benjamin J. Hindson, Billy W. Colston, Jr., and Donald A. Masquelier as inventors. (JXM–0001 at 1.). Complainant Bio-Rad Laboratories, Inc. is the assignee of the '160 patent. (*Id.*).

The '160 patent relates generally to a system, including method and apparatus, for forming an array of emulsions. (*Id.* at 1:46-47.). "The system may include a plate providing an array of emulsion production units each configured to produce a separate emulsion and each including a set of wells interconnected by channels that intersect to form a site of droplet generation." (*Id.* at 1:47-51.). "Each set of wells, in turn, may include (1) at least one first input well to receive a continuous phase, (2) a second input well to receive a dispersed phase, and (3) an output well configured to receive from the site of droplet generation an emulsion of droplets of the dispersed phase disposed in the continuous phase." (*Id.* at 1:52-57.).

B. U.S. Patent No. 9,500,664

The '664 patent, entitled "Droplet Generation For Droplet-Based Assay," was filed on December 30, 2011 as U.S. Patent Application Serial No. 13/341,669 ("the '669 application"). (JXM-0002 at 1.). The '669 application claims priority to U.S. Provisional Application No. 61/341,218, filed March 25, 2010. (*Id.* at 2; CPBr. at 5.). The '669 application issued as the '664 patent on November 22, 2016 and names Kevin D. Ness, Christopher F. Kelly, and Donald A. Masquelier. (JXM-0002 at 1.). Complainant Bio-Rad Laboratories, Inc. is the assignee of the '664 patent. (*Id.*).

The '664 patent relates generally to systems, including methods and apparatus, for generating droplets suitable for droplet-based assays. (*Id.* at 2:31-33.). "The disclosed systems

may include either one-piece or multi-piece droplet generation components configured to form sample-containing droplets by merging aqueous, sample-containing fluid with a background emulsion fluid such as oil, to form an emulsion of sample containing droplets suspended in the background fluid." (*Id.* at 2:33-38.). "In some cases, the disclosed systems may include channels or other suitable mechanisms configured to transport the sample-containing droplets to an outlet region, so that subsequent assay steps may be performed." (*Id.* at 2:38-42.).

C. U.S. Patent No. 9,636,682

The '682 patent, entitled "System for Generating Droplets—Instruments and Cassette," was filed on November 14, 2016 as U.S. Patent Application Serial No. 15/351,335 ("the '335 application"). (JXM-0004 at 1.). The '335 application claims priority to U.S. Provisional Application No. 61/409,106, filed on November 1, 2010, U.S. Provisional Application No. 61/409,473, filed on Nov 2, 2010, and U.S. Provisional Application No. 61/410,769, filed on November 5, 2010. (*Id.* at 1-2; CPBr. at 5.). The '335 application issued as the '682 patent on May 2, 2017 and names Amy L. Hiddessen, Kevin D. Ness, Benjamin J. Hindson, and Donald A. Masquelier as inventors. (JXM-0004 at 1.). Complainant Bio-Rad Laboratories, Inc. is the assignee of the '682 patent. (*Id.*).

The '682 patent relates generally to a system, including methods, apparatus, and kits, for forming emulsions. (*Id.* at 3:39-40.). "An exemplary system may comprise a device including a sample well configured to receive sample-containing fluid, a continuous phase well configured to receive continuous-phase fluid, and a droplet well." (*Id.* at 3:40-44.). "The device also may include a channel network having a first channel, a second channel, and a third channel that meet one another in a droplet-generation region." (*Id.* at 3:44-47.). "The system also may comprise a holder for the device." (*Id.* at 3:47.). "The system further may comprise an instrument

configured to operatively receive an assembly including the device and the holder and to drive sample-containing fluid from the sample well to the droplet-generation region via the first channel, continuous-phase fluid from the continuous-phase well to the droplet-generation region via the second channel, and sample-containing droplets from the droplet-generation region to the droplet well via the third channel." (*Id.* at 3:47-55.).

D. U.S. Patent No. 9,649,635

The '635 patent, entitled "System for Generating Droplets with Push-Back to Remove Oil," was filed on November 14, 2016 as U.S. Patent Application Serial No. 15/351,331 ("the '331 application"). (JXM-0005 at 1.). The '331 application claims priority to U.S. Provisional Application No. 61/409,106, filed on November 1, 2010, U.S. Provisional Application No. 61/409,473, filed on Nov 2, 2010, and U.S. Provisional Application No. 61/410,769, filed on November 5, 2010. (*Id.* at 1-2; CPBr. at 5.). The '331 application issued as the '635 patent on May 16, 2017 and names Amy L. Hiddessen, Kevin D. Ness, Benjamin J. Hindson, Donald A. Masquelier, and Erin R. Chia as inventors. (JXM-0005 at 1.). Complainant Bio-Rad Laboratories, Inc. is the assignee of the '635 patent. (*Id.*).

The '635 patent relates generally to a system, including methods, apparatus, and kits, for forming and concentrating emulsions. (*Id.* at 3:35-37.). "An exemplary system may comprise a device including a sample well configured to receive sample containing fluid, a continuous-phase well configured to receive continuous-phase fluid, a droplet well, and a channel network interconnecting the wells. (*Id.* at 3:37-41.). "The system also may comprise an instrument configured to operatively receive the device and to create (i) a first pressure differential to produce an emulsion collected in the droplet well and (ii) a second pressure differential to decrease a volume fraction of continuous-phase fluid in the emulsion, after the emulsion has

been collected in the droplet well, by selectively driving continuous-phase fluid, relative to sample-containing droplets, from the droplet well." (*Id.* at 3:41-49.).

III. TERMS ADOPTED AND CONSTRUED IN THIS ORDER

A. Claim Construction and Ground Rules

Claim terms are construed in this Order solely for the purposes of this Section 337 Investigation. Only claim terms in controversy need to be construed, and then only to the extent necessary to resolve the controversy. *Vanderlande Indus. Nederland BV v. Int'l Trade Comm.*, 366 F.3d 1311, 1323 (Fed. Cir. 2004); *Vivid Tech., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999).

Going forward, including during evidentiary hearing ("Hearing") scheduled from May 7-May 11, 2018, the Parties are limited to the claim-term constructions contained in the agreed-upon constructions set forth in the Joint CC Chart filed on January 23, 2018, and the Court's constructions of the disputed claim terms. Ground Rule 1.14 states that "[t]he parties will be bound by their claim construction positions set forth on the date they are required to submit a joint list showing each party's final proposed construction of the disputed claim terms and will not be permitted to alter these absent a timely showing of good cause."

The Parties' claim construction briefs appear to track with agreed-upon and disputed claim terms contained in the Joint CC Chart. (*See, generally*, COMBr., CRMBr.; ROMBr.; RRMBr.; SMBr.). Consequently, pursuant to Ground Rule 1.14, modified or new claim-term constructions set forth for the first time in post-hearing briefs will be considered to be waived if claim terms have not been previously identified as disputed.

For example, it is not appropriate at this stage of the Investigation for Respondent to seek constructions of terms such as "channel" (previously agreed-upon), "fluidically connected" (not

raised previously), and "configured to" (not raised previously). (RPBr. at 28, 34, 77-78, 81, 86.). Pursuant to Ground Rule 1.14, Respondent is bound by its constructions in the Joint CC Chart.

Similarly, it will not be appropriate for any party to seek additional claim construction during the evidentiary hearing or to merely state that a claim term that may be implicated in an expert report or expert testimony has either a "plain or ordinary" meaning, or that a claim term is "indefinite." (*See* Proposed Scheduling Order and Ground Rules (Order No. at 3 at 5; Attachment B, G.R. 1.14 at 9 (Sept. 13, 2017).).

B. Claim Charts in Appendix A

Chart No. 1 in Appendix A is labeled "Court's Constructions of Disputed Claim Terms That Remain Relevant in this Investigation" and is self-explanatory. [2] To make the constructions easier to read, Chart No. 1 replicates in-part the Joint CC Chart that the Parties filed on January 23, 2018. There are six (6) columns in Chart No. 1: (i) Patent/Claim(s); (ii) Term(s) to be Construed; (iii) Complainants' Proposed Construction; (iv) Respondent's Proposed Construction; (v) Staff's Proposed Construction; (vi) the Administrative Law Judge's ("ALJ") Adopted Construction; and (vii) and the Rationale/Support for the Adopted Construction.

Chart No 2 in Appendix A, labeled "Adopted Claim Constructions Based Upon the Parties' Agreed Upon Constructions That Remain Relevant in this Investigation," contains the claim terms that the Parties have agreed upon, as set forth in their Joint CC Chart. The Parties' agreed upon claim constructions were adopted without providing a rationale or explanation.

[2] The Parties' claim construction briefs in total consisted of approximately 145 pages of argument. All of the arguments provided in the Parties' briefs were considered. However, in the interest of space and brevity, the Rationale/Support for the Construction column of Chart No. 1 selectively re-states and addresses only some of those arguments.

IV. APPLICABLE LAW[3]

Claim construction begins with the language of the claims themselves. Claims should be given their ordinary and customary meaning as understood by a person of ordinary skill in the art, viewing the claim terms in the context of the entire patent. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312-13 (Fed. Cir. 2005). In some cases, the plain and ordinary meaning of claim language is readily apparent and claim construction will involve little more than "the application of the widely-accepted meaning of commonly understood words." *Id.* at 1314. In other cases, claim terms have a specialized meaning and it is necessary to determine what a person of ordinary skill in the art would have understood disputed claim language to mean by analyzing "the words of the claims themselves, the remainder of the specification, the prosecution history, and extrinsic evidence concerning relevant scientific principles, as well as the meaning of technical terms, and the state of the art." *Id.* (quoting *Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc.*, 381 F.3d 1111, 1116 (Fed. Cir. 2004)).

The claims themselves provide substantial guidance with regard to the meaning of disputed claim language. *Phillips*, 415 F.3d at 1314. "[T]he context in which a term is used in the asserted claim can be highly instructive." *Id.* Similarly, other claims of the patent at issue, regardless of whether they have been asserted against respondents, may show the scope and meaning of disputed claim language. *Id.*

In cases in which the meaning of a disputed claim term in the context of the patent's claims is uncertain, the specification is "single best guide to the meaning of a disputed term." *Id.* at 1321. Moreover, "[t]he construction that stays true to the claim language and most naturally

[3] The constructions of the disputed claim terms in Chart 1 of Appendix A generally follow and apply the law cited in this Order. To the extent possible, the case law that applies to a construction is either identified explicitly or implicitly in adopting a party's argument or construction.

aligns with the patent's description of the invention will be, in the end, the correct construction." *Id.* at 1316. As a general rule, however, the particular examples or embodiments discussed in the specification are not to be read into the claims as limitations. *Id.* at 1323.

The prosecution history may also explain the meaning of claim language, although "it often lacks the clarity of the specification and thus is less useful for claim construction purposes." *Id.* at 1317. The prosecution history consists of the complete record of the patent examination proceedings before the U.S. Patent and Trademark Office, including cited prior art. *Id.* The prosecution history may reveal "how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be." *Id.*

If the intrinsic evidence is insufficient to establish the clear meaning of a claim, a court may resort to an examination of the extrinsic evidence. *Zodiac Pool Care, Inc. v. Hoffinger Indus., Inc.*, 206 F.3d 1408, 1414 (Fed. Cir. 2000). Extrinsic evidence may shed light on the relevant art, and "consists of all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises." *Phillips*, 415 F.3d at 1317. In evaluating expert testimony, a court should disregard any expert testimony that is conclusory or "clearly at odds with the claim construction mandated by the claims themselves, the written description, and the prosecution history, in other words, with the written record of the patent." (*Id.* at 1318.). Moreover, expert testimony is only of assistance if, with respect to the disputed claim language, it identifies what the accepted meaning in the field would be to one skilled in the art. *Symantec Corp. v. Comput. Assocs. Int'l, Inc.*, 522 F.3d 1279, 1289 n.3., 1290-91 (Fed. Cir. 2008). Testimony that recites how each expert would construe the term should be accorded little or no weight. *Id.* Extrinsic evidence is inherently "less reliable" than intrinsic

evidence, and "is unlikely to result in a reliable interpretation of patent claim scope unless considered in the context of the intrinsic evidence." *Phillips*, 415 F.3d at 1318-19.

Extrinsic evidence is a last resort: "[i]n those cases where the public record unambiguously describes the scope of the patented invention, reliance on any extrinsic evidence is improper." *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1583 (Fed. Cir. 1996).

V. PERSON OF ORDINARY SKILL IN THE ART

This is a hypothetical person of ordinary skill and "ordinary creativity." *KSB Int'l Co. v. Teleflex, Inc.*, 550 U.S. 398, 420 (2007). "Factors that may be considered in determining [the] level of ordinary skill in the art include: (1) the educational level of the inventor[s]; (2) type of problems encountered in the art; (3) prior art solutions to the problems; (4) rapidity with which inventions are made; (5) sophistication of the technology; and (6) educational level of active workers in the field." *Envtl. Designs Ltd. v. Union Oil Co. of California*, 713 F.2d 693, 696-97 (Fed. Cir. 1983) ("*Envtl. Designs*") (citations omitted). "These factors are not exhaustive but merely a guide to determining the level of ordinary skill in the art." *Daiichi Sankyo Co. v. Apotex, Inc.*, 501 F3d 1254, 1256 (Fed. Cir. 2007).). The hypothetical person of skill is also separately presumed to have knowledge of all the relevant prior art in the field. *Custom Accessories, Inc. v. Jeffrey-Allan Indus., Inc.*, 807 F.2d 693, 697 (Fed. Cir. 1983).

The Parties disagreed over the qualifications of a person of ordinary skill in the art ("POSA") for the Asserted Patents. According to Complainants, a POSA "would have had at least the equivalent of a Bachelor's degree in engineering, physics, or chemistry and two years of academic, research, or industry experience related to fluid mechanics, fluid dynamics, or microfluidics." (CPBr. at 12.). According to Respondent and Staff, a POSA "would have had a Ph.D. in chemical engineering, mechanical engineering, biomedical engineering, fluid dynamics,

or a related discipline, with two years of work experience in the field of microfluidic devices." (RPBr. at 17; SPBr. at 21.). The Parties have not explored the reasons for this disagreement.

This Order does not resolve the POSA issue because it is not germane to the claim construction requested by the Parties. In arguing for their proposed constructions of disputed terms, the Parties have appropriately focused on the intrinsic evidence. Neither of the Parties has indicated in any of their filed documents that the POSA definition is necessary or dispositive for construction of the disputed claim terms.

To the extent this issue could be necessary for testimony during the upcoming evidentiary hearing, the Parties should agree on a POSA definition. If the Parties have reserved their positions for the evidentiary hearing, their explanation must address each of the factors set forth in *Envtl. Designs*, *supra*.

VI. SUMMARY OF CONSTRUCTIONS REGARDING DISPUTED CLAIM TERMS

The Parties dispute the construction of "channel junction" and "droplet generation region." The Parties also dispute whether, in the context of the '664 patent, "droplet generation region" is adequately defined by the claim language and therefore does not require separate construction. The Parties agree that "channel junction" and "droplet generation region" have the same meaning. (ROMBr. at 1; COMBr at 1; SMBr. at 13.).

The meaning of "channel junction" and "droplet generation region" is "the intersection of (1) a sample-containing dispersed phase fluid inlet channel, (2) a continuous phase fluid inlet channel, and (3) a droplet outlet channel." To preserve consistency in the interpretation of claim terms across Asserted Patents and adhere to the intrinsic evidence, this construction of "droplet generation region" is incorporated into all asserted claims where that term appears, including claims of the '664 patent.

VII. PROCEEDINGS GOING FORWARD

A. Supplementation in Response to This Order

The Parties may not file supplemental expert reports in response to this Order. No additional discovery will be permitted because of this Order. No re-argument of the claims construed in this Order may occur.

As the Parties proceed in this Investigation, the Parties will be expected to notify Chambers of any issues that have become moot, or have been eliminated for any reason. The Parties' required outlines that must identify any issues, claims, defenses, prior art, theories, or any other content that was originally asserted or argued, should subsequently, in the final outline, identify all issues or contentions and patents that have been dropped or become moot for any reason.

The Parties should redact from expert reports and from any other documents upon which they intend to rely any issues, claims, defenses, prior art, theories, or any other content that has been rendered moot or disallowed as a result of this or other Orders, or termination from this Investigation of patent claims or allegations. The Parties must file on EDIS any expert reports or documents that have been redacted for the reasons stated above, and provide two (2) copies to Chambers.

B. Streamlining the Investigation

To the extent that this *Markman* Order will enable the Parties to streamline the Investigation, the Parties are encouraged to drop issues now in advance of the hearing scheduled for May 7-11, 2018.

For example, Respondent should be notified now which patents/claims will be eliminated so that it (and the Court) do not waste unnecessary resources preparing to address patents or

claims that will be dropped. Moreover, prompt identification of dropped patents/claims will give Respondent time to eliminate invalidity theories.

Complainants are ordered to identify additional eliminated claims and/or patents and to file a statement ("Statement") of its streamlined case (including redacted reports and pre-trial briefs) by April 13, 2018. Respondent is ordered to identify eliminated invalidity theories/prior art and to provide a streamlined Statement (and redacted expert reports and pre-trial briefs) by April 20, 2018. In the event that there are no eliminated claims, defenses, or issues, each of the Private Parties must still file a Statement indicating that there are no such eliminations. Moreover, the Private Parties are encouraged promptly to resolve each issue in this Investigation for which there is no reasonable dispute or little, or weak, evidentiary support.

C. Settlement

It is strongly recommended that the Parties take informal opportunities to engage in settlement.

VIII. CONCLUSION

Constructions of the disputed claim terms are adopted by this Order for the reasons discussed in Chart 1 in Appendix A. The constructions of the agreed-upon claim terms listed in Chart 2 in Appendix A are also adopted by this Order.

Within seven (7) business days of the date of this document, each party shall submit to the Office of the Administrative Law Judges a statement as to whether or not[4] it seeks to have any confidential portion of this document (including Charts 1 and 2) deleted from the public version. Any party seeking redactions to the public version must submit to this office two (2)

[4] This means that parties that do not seek to have any portion of this Order redacted are still required to submit a statement to this effect.

copies of a proposed public version of this document pursuant to Ground Rule 1.10 with red brackets clearly indicating any portion asserted to contain confidential business information.

The Parties' submissions may be made by facsimile and/or hard copy by the aforementioned date. In addition, an electronic courtesy copy is required pursuant to Ground Rule 1.3.2.

The Parties' submissions concerning the public version of this document need not be filed with the Commission Secretary.

SO ORDERED.

MaryJoan McNamara
Administrative Law Judge

Inv. No. 337-TA-1068
Appendix A to Order No. 20

Chart 1: Court's Constructions of Disputed Claim Terms That Remain Relevant in this Investigation[1]

Patent/ Claim(s)[2]	Term(s) to be Construed	Cs' Proposed Construction	R's Proposed Construction	Staff's Proposed Construction	Adopted Construction	Rationale/Support for the Adopted Construction
All Asserted Patents						
'160: **all**[3] '664: **all**[4] '682: **all**[5]	"channel junction" "droplet generation	the intersection of: a channel configured to carry or carrying a sample containing	the intersection of the sample input channel that receives the dispersed phase fluid	the intersection of a dispersed-phase or sample fluid inlet channel, a continuous-	the intersection of (1) a sample-containing dispersed phase fluid inlet channel,	The Parties agree that "channel junction" and "droplet generation region" have the same meaning and that the meaning includes the intersection of three channels. (ROMBr. at 1; COMBr at 1; SMBr. at 13.). The Parties disagree in terms of how to characterize

[1] Underlying means that the Parties have sought construction of that term, either as agreed upon or disputed.

[2] Dependent claims are listed in parentheses beside corresponding independent claims. "All" means all asserted claims.

[3] Heading into the hearing, Complainants accuse Respondent of infringing claims 4–5, 8, and **20**–21 of the '160 patent (independent claims in bold). (CPBr. at 12-21.).

[4] Heading into the hearing, Complainants accuse Respondent of infringing claims **1**, 2, 4, **8**, 9, 11, **14**, 15, and 16 of the '664 patent (independent claims in bold). (CPBr. at 29-41.).

Patent/ Claim(s)[2]	Term(s) to be Construed	Cs' Proposed Construction	R's Proposed Construction	Staff's Proposed Construction	Adopted Construction	Rationale/Support for the Adopted Construction
'635: **all**[6]	region"	aqueous or dispersed phase fluid (also referred to as discontinuous fluid), a channel configured to carry or carrying a continuous phase fluid (also referred to as oil or	from the sample well, the oil input channel that receives the continuous-phase or background fluid from the oil well, and the droplet outlet channel that outputs to the droplet well, at which	phase or background fluid inlet channel, and a droplet outlet channel, at which droplets are generated	(2) a continuous phase fluid inlet channel, and (3) a droplet outlet channel	the channels. Complainants' construction is too broad insofar as it includes "configured to carry or carrying" language. As Respondent rightly observes, Complainants' construction does not adequately differentiate between channels. (ROMBr. at 26.). This is because, while the aqueous or dispersed phase fluid inlet channel is configured to carry or carries "a sample containing aqueous or dispersed phase fluid," so does the outlet channel because droplets that move through the outlet

[5] Heading into the hearing, Complainants accuse Respondent of infringing claims **1**, 7, 9, **14**, and 16-19 of the '682 patent (independent claims in bold). (CPBr. at 50-58.).

[6] Heading into the hearing, Complainants accuse Respondent of infringing claims **1**, 13–14, **16**, and 21 of the '635 patent (independent claims in bold). (CPBr. at 64-69.).

Patent/ Claim(s)[2]	Term(s) to be Construed	Cs' Proposed Construction	R's Proposed Construction	Staff's Proposed Construction	Adopted Construction	Rationale/Support for the Adopted Construction
		background fluid) and a channel configured to carry or carrying droplets from the intersection.	droplets are generated[7]			channel include among their constituent parts aqueous or dispersed phase fluid. Similarly, while the continuous phase fluid inlet channel is configured to carry and carries "continuous phase fluid," so does the outlet channel because droplets that move through the outlet channel include among their constituent parts continuous phase fluid. In other words, Complainants' construction could cover the intersection of multiple mixed-use channels that each contain dispersed phase and continuous phase fluid. Such a broad claim scope is not consistent with the intrinsic evidence, which reveals that each inlet channel is characterized by the type of fluid it

[7] First, in its contention interrogatory responses on infringement, Respondent stated that the droplet generation region was "the intersection of (1) a first input channel with a dispersed phase or sample-containing fluid, (2) a second input channel with a continuous phase and (3) a third output channel with sample-containing droplets or emulsions." (CRMBr. at 1.). Next, in the Joint CC Chart, Respondent added the limitation that the sample input channel must "receive the dispersed phase fluid from the sample well." (*Id.*; Joint CC Chart at 3.). Then, in its claim construction brief, Respondent appeared to add the limitation that the sample channel must *extend from* the sample well to the droplet generation region. (ROMBr. at 24, 26, 40.).

Patent/ Claim(s)[2]	Term(s) to be Construed	Cs' Proposed Construction	R's Proposed Construction	Staff's Proposed Construction	Adopted Construction	Rationale/Support for the Adopted Construction
						carries (dispersed phase or continuous phase). (ROMBr. at 21 (citing JXM–0001 ('160 Patent) at 66:28-67:8; JXM–0002 ('664 Patent) at 16:60-17:28).). The construction of "channel junction" and "droplet generation region" that Respondent proposed in the Joint CC Chart is generally consistent with the intrinsic evidence and Respondent's interpretation of its extrinsic evidence.[8]

[8] Respondent offered the expert declaration of Dr. Juan Santiago ("Santiago Declaration"), a tenured professor in Stanford University's Mechanical Engineering Department, who has led teams of engineers in the design, construction, testing, and optimization of microfluidic devices. (RXM–015 (Santiago Declaration) ¶ 5-6, 8.). Dr. Santiago previously served as the chair of the Department's Thermosciences group, which studies fluid mechanics, among other things. (*Id.* ¶ 5.). According to Dr. Santiago, a POSA "would understand [droplet generation region and channel junction], in the context of the Asserted Patents, to require that: the sample input channel comes from the sample well and that this channel receives the fluid contained in the sample well; the oil input channel comes from the oil well and that this channel receives the fluid in the oil well; and the droplet outlet channel outputs an emulsion to the droplet well. The intersection of the sample channel, at least one oil channel, and the droplet (output) channel is where the droplets are formed." (*Id.* ¶ 20.). According to Respondent, Dr. Santiago is saying that "the sample input channel comes from the sample well *in that* the channel receives the fluid contained in the sample well; the oil input channel comes from the oil well *in that* the channel receives the fluid in the oil well; and the droplet outlet channel outputs to the droplet well." (ROMBr. at 26 (emphasis added).). To the extent that they assert that sample channels contain sample-containing fluid from sample-containing wells and oil channels

Patent/ Claim(s)[2]	Term(s) to be Construed	Cs' Proposed Construction	R's Proposed Construction	Staff's Proposed Construction	Adopted Construction	Rationale/Support for the Adopted Construction
						(Joint CC Chart at 3, 8, 10.). In the Asserted Patents, each inlet channel is characterized by the type of fluid it carries (dispersed phase or continuous phase). (ROMBr. at 21 (citing JXM–0001 ('160 Patent) at 66:28-67:8; JXM–0002 ('664 Patent) at 16:60-17:28).). Nevertheless, stating that a channel "receives the ___ fluid *from* the ___ well" does have a narrowing effect insofar as the language requires receipt of fluid in a channel from a well, as opposed to merely requiring that a channel be configured to receive such fluid. This narrowing inappropriately departs from the plain and ordinary meaning of the claim language, as

contain oil from oil wells, Respondent and Dr. Santiago generally enjoy the support of the intrinsic evidence. To the extent they argue that inlet channels must *extend from* particular wells to channel junctions or droplet generation regions, Respondent and Dr. Santiago improperly import limitations from the Asserted Patent specifications and impose a narrowing construction found only in the asserted claims of the '160 patent on all claims asserted by Complainants, as discussed below. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1318 (Fed. Cir. 2005) (In evaluating expert testimony, a court should disregard any expert testimony that is "clearly at odds with the claim construction mandated by the claims themselves, the written description, and the prosecution history, in other words, with the written record of the patent.").

Patent/ Claim(s)[2]	Term(s) to be Construed	Cs' Proposed Construction	R's Proposed Construction	Staff's Proposed Construction	Adopted Construction	Rationale/Support for the Adopted Construction
						informed by the intrinsic evidence. In a sudden departure from its position in the Joint CC Chart, Respondent used its Opening Claim Construction Brief to announce a new and overly narrow construction of "channel junction" and "droplet generation region." Specifically, Respondent argued that "to the extent that Bio-Rad suggests that a channel that does not *extend from the sample well on the one side to the channel junction on the other side of the channel* … is nevertheless a sample channel within the ambit of the asserted claims, this is inconsistent with the claims, specification, and also the prosecution history of the '160 Patent." (ROMBr. at 24 (emphasis added).).[9]

[9] For this argument, Respondent's reliance on RXM–001 (Jan. 8, 2015 Substitute Response to Office Action in U.S. Patent Application No.12/963,523) is misplaced. (ROMBr. at 25-26.). In that submission, which amended a particular set of claims in a patent application that issued as the '160 patent, the applicant did not clearly disclaim coverage of channels that do not extend all the way from wells to "channel junctions" and "droplet generation regions." (RXM–001 at 11-12.). This was because, among other reasons, the applicant argued that the amended claims were

Patent/ Claim(s)[2]	Term(s) to be Construed	Cs' Proposed Construction	R's Proposed Construction	Staff's Proposed Construction	Adopted Construction	Rationale/Support for the Adopted Construction
						Respondent characterizes Complainants as "reach[ing] for a broader construction … that untethers the channel from the sample well that it extends from." (*Id.* at 2-3.). Respondent is correct that asserted claims of the '160 patent contain the "extending … from" limitation. However, Respondent is wrong to import this limitation into the global construction of "channel junction" and, by association, "droplet generation region." (*Id.* at 31, 35, 44, 48.). The first problem with Respondent's new, "extending … from" construction

patentably distinct over the prior art Pollack reference because they disclosed not one but two things missing from Pollack—"each channel being bounded circumferentially" and "at least two input channels extending separately from the input wells to the channel junction." (*Id.*). Thus, the Substitute Response indicates that, from the applicant's perspective, the claims would have been patentably distinct without the "extend from" language, so long as the "bounded circumferentially" limitation remained. Consequently, this is not a clear cut case of an applicant disclaiming claim scope or narrowing an "invention." *See Phillips v. AWH Corp.*, 415 F.3d 1303, 1317 (Fed. Cir. 2005) (The prosecution history may also explain the meaning of claim language, although "it often lacks the clarity of the specification and thus is less useful for claim construction purposes.").

Patent/ Claim(s)[2]	Term(s) to be Construed	Cs' Proposed Construction	R's Proposed Construction	Staff's Proposed Construction	Adopted Construction	Rationale/Support for the Adopted Construction
						is that it deviates significantly from the construction it set forth in the Joint CC Chart. For this reason alone, pursuant to Ground Rule 1.14, Respondent's new construction is waived. (Order No. 3 (Proposed Scheduling Order and Notice of Ground Rules) at 5 ("Absent a showing of good cause, the parties will be bound by their proposed constructions for disputed claim terms on the date the joint submission of disputed claim terms is due.").). The second problem with Respondent's new construction is that the claims of the Asserted Patents vary in terms of the required connectivity of channels and wells (*Compare* JXM-0004 ('682 patent) at claim 1 ("an instrument configured . . . to drive sample-containing fluid *from the sample well to the droplet-generation region via the first channel*, continuous-phase fluid from the continuous-phase well to the

Patent/ Claim(s)[2]	Term(s) to be Construed	Cs' Proposed Construction	R's Proposed Construction	Staff's Proposed Construction	Adopted Construction	Rationale/Support for the Adopted Construction
						droplet-generation region via the second channel . . . ") *and* JXM-0002 ('664 patent) at claim 14 ("forming a droplet generation region defined by the intersection of a *first channel fluidically connected with the sample well*, a second channel fluidically connected with the background fluid well . . .") *with* JXM-0001 ('160 patent) at claim 20 ("wherein the set of channels includes at least two input channels *extending separately from the input wells to the channel junction*, at which droplets of the dispersed phase are generated in the continuous phase").). Put another way, in certain asserted claims, a first channel can still be fluidically connected to a sample well even if there are multiple channels in between the sample well and the first channel. (CRMBr. at 8.). The construction of "channel junction" and "droplet generation region" need to account for this variety in terms of how channels and wells connect.

Patent/ Claim(s)[2]	Term(s) to be Construed	Cs' Proposed Construction	R's Proposed Construction	Staff's Proposed Construction	Adopted Construction	Rationale/Support for the Adopted Construction
						Respondent's new proposed "extending from" construction would render superfluous certain claims that require connectedness between a channel and a well but not necessarily the channel extending all the way from the well to the "channel junction" or "droplet generation region." *See, e.g., Stumbo v. Eastman Outdoors, Inc.*, 508 F.3d 1358, 1362 (Fed. Cir. 2007) (rejecting a claim construction that renders other claim terms superfluous, and referring to the construction as "a methodology of claim construction that this court has denounced."); *Merck & Co. v. Teva Pharms. USA, Inc.*, 395 F.3d 1364, 1372 (Fed. Cir. 2005) ("A claim construction that gives meaning to all the terms of the claim is preferred over one that does not do so."). For example, Respondent's construction would render superfluous terms like "via" in claim 1 of the '682 patent ("from the sample well to the droplet-

Patent/ Claim(s)[2]	Term(s) to be Construed	Cs' Proposed Construction	R's Proposed Construction	Staff's Proposed Construction	Adopted Construction	Rationale/Support for the Adopted Construction
						generation region via the first channel") and "fluidically connected" in claim 14 of the '664 patent ("first channel fluidically connected with the sample well"). Also, Respondent's new global construction requiring that channels *extend from* a well to a "channel junction" or "droplet generation region," without any room for diversity in well and channel connectedness, is inconsistent with the intrinsic evidence on channels. For example, Asserted Patents disclose that a channel can have more than one inlet. (JXM-0001 ('160 patent) at 17:62; JXM-0002 ('664 patent) at 13:25.). Asserted Patents also state that a channel can be branched and nonlinear. (JXM-0001 ('160 patent) at 18:4-5; JXM-0002 ('664 patent) at 13:34-35.).

Patent/ Claim(s)[2]	Term(s) to be Construed	Cs' Proposed Construction	R's Proposed Construction	Staff's Proposed Construction	Adopted Construction	Rationale/Support for the Adopted Construction
						Staff's construction of "channel junction" and "droplet generation region" is closest to the plain and ordinary meaning of these terms as informed by the specifications of the Asserted Patents. This is because Staff characterizes the relevant channels only in terms of the fluid they carry. However, Staff's inclusion of the term "at which droplets are generated" in the construction is unnecessary and redundant, as that function of the "channel junction" and "droplet generation region" is either inherent in the term "droplet generation region" or separately specified in the asserted claims. (*See, e.g.*, JXM-0001 ('160 patent) at 164:6-8 (claim 20) ("wherein the set of channels includes at least two input channels extending separately from the input wells to the channel junction, *at which droplets of the dispersed phase are generated* in the continuous phase")(emphasis added)).

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Patent/ Claim(s)[2]	Term(s) to be Construed	Cs' Proposed Construction	R's Proposed Construction	Staff's Proposed Construction	Adopted Construction	Rationale/Support for the Adopted Construction
'664 Patent						
'664: 1 (2,4)	a droplet generation region defined by the network of channels and configured to generate sample-containing droplets suspended in the background fluid	a droplet generation region defined by the network of channels and configured to generate sample-containing droplets suspended in the background fluid [no underlining for droplet generation region]	a droplet generation region defined by the network of channels and configured to generate sample-containing droplets suspended in the background fluid		a droplet generation region defined by the network of channels and configured to generate sample-containing droplets suspended in the background fluid	Complainants argue that in the context of the '664 patent, "droplet genération region" does not require a separate construction. (COMBr. at 20.). Complainants contend, against opposition from Respondent and Staff, that, in these claims, "droplet generation region" is specified by the claims themselves and that this condition is signaled by the use of "defined" in the claim language. (*Id.*). Yet, Complainants' request is belied by its own claim construction arguments, which seek to harmonize "channel junction" and "droplet generation region" across Asserted Patents. (COMBr. at 13 ("The disclosure in the '664 patent is no different. The 'droplet generation region,' which the parties agree has the same meaning as channel junction and channel

Patent/ Claim(s)[2]	Term(s) to be Construed	Cs' Proposed Construction	R's Proposed Construction	Staff's Proposed Construction	Adopted Construction	Rationale/Support for the Adopted Construction
						intersection, is 'defined by a network of channels 530 and configured to generate sample containing droplets suspended in the background fluid.' Proposed JXM-0002, '664 patent at 25:62-64. The '664 patent describes the droplet generation region as 'the intersection of a sample channel 534, a pair of background fluid channels 536a, 536b, and droplet channel 538.' Proposed JXM-0002, '664 patent at 25:64-67.").). Moreover, Complainants appear to condition their opposition to the incorporation of the "droplet generation region" construction into the asserted claims of the '664 patent on the adoption of Respondent's construction of that term. (COMBr. at 22.). Complainants' stand against incorporation is now moot, as Respondent's construction of "droplet generation region" was rejected.

Patent/ Claim(s)[2]	Term(s) to be Construed	Cs' Proposed Construction	R's Proposed Construction	Staff's Proposed Construction	Adopted Construction	Rationale/Support for the Adopted Construction
						To preserve consistency in the interpretation of claim terms across Asserted Patents and remain true to the intrinsic evidence, the construction of "droplet generation region" set forth above is incorporated in asserted claims of the '664 patent.
'664: **14 (15,16)**	forming a droplet generation region defined by the intersection of a first channel fluidically connected with the sample well, a second channel fluidically connected with the	forming a droplet generation region defined by the intersection of a first channel fluidically connected with the sample well, a second channel fluidically connected with the background	forming a droplet generation region defined by the intersection of a first channel fluidically connected with the sample well, a second channel fluidically connected with the background fluid well, and a third channel fluidically connected with the droplet outlet region		forming a droplet generation region defined by the intersection of a first channel fluidically connected with the sample well, a second channel fluidically connected with the	To preserve consistency in the interpretation of claim terms across Asserted Patents and adhere to the intrinsic evidence, the construction of "droplet generation region" is incorporated in asserted claims of the '664 patent. See row immediately above for analysis.

Patent/ Claim(s)[2]	Term(s) to be Construed	Cs' Proposed Construction	R's Proposed Construction	Staff's Proposed Construction	Adopted Construction	Rationale/Support for the Adopted Construction
	fluidically connected with the background fluid well, and a third channel fluidically connected with the droplet outlet region	fluid well, and a third channel fluidically connected with the droplet outlet region [no underlining for droplet generation region]			background fluid well, and a third channel fluidically connected with the droplet outlet region	

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Chart 2: Adopted Claim Constructions Based Upon the Parties' Agreed Upon Constructions That Remain Relevant in this Investigation[1]

Patent/Claim(s)[2]	Term	Construction
'160 Patent[3]		
'160: **all**	channel	an elongate passage for fluid travel
'160: **all**	dispersed phase	an aqueous phase or other fluid that is immiscible with the continuous phase
'160: 1 **(4,5,8); 20 (21)**	at least two input channels extending separately from the input wells to the channel junction, at which droplets of the dispersed phase are generated in the continuous phase	at least two input channels extending separately from the input wells to the channel junction, at which droplets of the dispersed phase are generated in the continuous phase
'160: 1 **(4,5,8)**	a set of wells connected by channels that form a channel junction	a set of wells connected by channels that form a channel junction
'664 Patent[4]		
'664: **all**	channel	an elongate passage for fluid travel

[1] Underlying means that the Parties have sought construction of that term, either as agreed upon or disputed.

[2] Bolded claims are asserted, whereas un-bolded claims are not. Dependent claims are listed in parentheses beside corresponding independent claims. "All" means all asserted claims.

[3] Heading into the hearing, Complainants accuse Respondent of infringing claims 4–5, 8, and **20**–21 of the '160 patent (independent claims in bold). (CPBr. at 12-21.).

[4] Heading into the hearing, Complainants accuse Respondent of infringing claims **1**, 2, 4, **8**, 9, 11, **14**, 15, and 16 of the '664 patent (independent claims in bold). (CPBr. at 29-41.).

Patent/Claim(s)[2]	Term	Construction
'664: **all**	sample	a compound, composition, and/or mixture of interest, from any suitable source(s)
'664: **1 (2,4)**	a network of channels / a channel network	an interconnected arrangement of channels
'664: **1 (2,4)**	wherein the first channel is configured to transport sample-containing fluid from the sample well to the droplet generation region	wherein the first channel is configured to transport sample-containing fluid from the sample well to the droplet generation region
'664: **1 (2,4)**	a network of channels…fluidically interconnecting the sample well, the background fluid well, and the droplet well	a network of channels. . . fluidically interconnecting the sample well, the background fluid well, and the droplet well
'664: **8 (9,11)**	transporting sample-containing fluid through a first channel, from the sample well to a droplet generation region	transporting sample-containing fluid through a first channel, from the sample well to a droplet generation region
'682 Patent[5]		
'682: **all**	channel	an elongate passage for fluid travel
'682: **all**	sample	a compound, composition, and/or mixture of interest, from any suitable source(s)
'682: **1 (7,9); 14 (16-19)**	a network of channels / a channel network	an interconnected arrangement of channels

[5] Heading into the hearing, Complainants accuse Respondent of infringing claims **1**, 7, 9, **14**, and 16-19 of the '682 patent (independent claims in bold). (CPBr. at 50-58.).

Patent/Claim(s)[2]	Term	Construction
'682: **1 (7,9)**	a channel network having a first channel, a second channel, and a third channel that meet one another in a droplet-generation region	an interconnected group of channels having a first channel, a second channel, and a third channel that meet one another in a droplet-generation region
'682: **1 (7,9)**	an instrument configured . . . to drive sample containing fluid from the sample well to the droplet-generation region via the first channel	an instrument configured…to drive sample-containing fluid from the sample well to the droplet-generation region via the first channel
'682: **14 (16-19)**	a corresponding channel network for each sample well, the channel network including a droplet-generation region and fluidically connecting the sample well to one of the continuous-phase wells and one of the droplet wells	a corresponding channel network for each sample well, the channel network including a droplet-generation region and fluidically connecting the sample well to one of the continuous-phase wells and one of the droplet wells
'682: **14 (16-19)**	such that sample-containing fluid flows from each sample well to the corresponding droplet-generation region	such that sample-containing fluid flows from each sample well to the corresponding droplet-generation region
'635 Patent[6]		
'635: all	channel	an elongate passage for fluid travel
'635: all	sample	a compound, composition, and/or mixture of interest, from any suitable source(s)

[6] Heading into the hearing, Complainants accuse Respondent of infringing claims **1**, 13–14, **16**, and 21 of the '635 patent (independent claims in bold). (CPBr. at 64-69.).

Patent/Claim(s)[2]	Term	Construction
'635: **1 (13-14)**	a first pressure differential to drive sample-containing fluid from the sample well to the droplet-generation region via the first channel	a first pressure differential to drive sample-containing fluid from the sample well to the droplet generation region via the first channel
'635: **16 (21)**	a network of channels / a channel network	an interconnected arrangement of channels
'635: **16 (21)**	a plurality of separate channel networks, each sample well being fluidically connected to one of the continuous-phase wells and one of the droplet wells via one of the channel networks, each channel network having a first channel, a second channel, and a third channel that meet one another in a droplet-generation region	a plurality of separate channel networks, each sample well being fluidically connected to one of the continuous-phase wells and one of the droplet wells via one of the channel networks, each channel network having a first channel, a second channel, and a third channel that meet one another in a droplet-generation region
'635: **16 (21)**	a first pressure differential to drive sample-containing fluid from each sample well and continuous-phase fluid from each continuous-phase well, such that sample-containing droplets are formed in the droplet-generation region	a first pressure differential to drive sample-containing fluid from each sample well and continuous-phase fluid from each continuous-phase well, such that sample-containing droplets are formed in the droplet-generation region

PUBLIC CERTIFICATE OF SERVICE

I, Lisa R. Barton, hereby certify that the attached **ORDER** has been served by hand upon the Commission Investigative Attorney, **Whitney Winston, Esq.**, and the following parties as indicated, on **April 16, 2018**.

Lisa R. Barton, Secretary
U.S. International Trade Commission
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On Behalf of Complainants Bio-Rad Laboratories, Inc. and Lawrence Livermore National Security, LLC:

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