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.

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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

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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

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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).

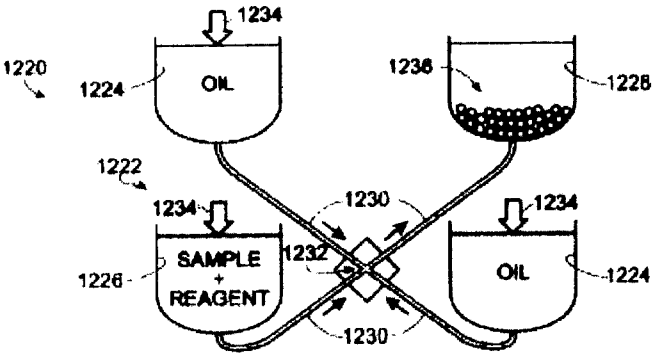
3. Respondent 10X Genomics, Inc.

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).

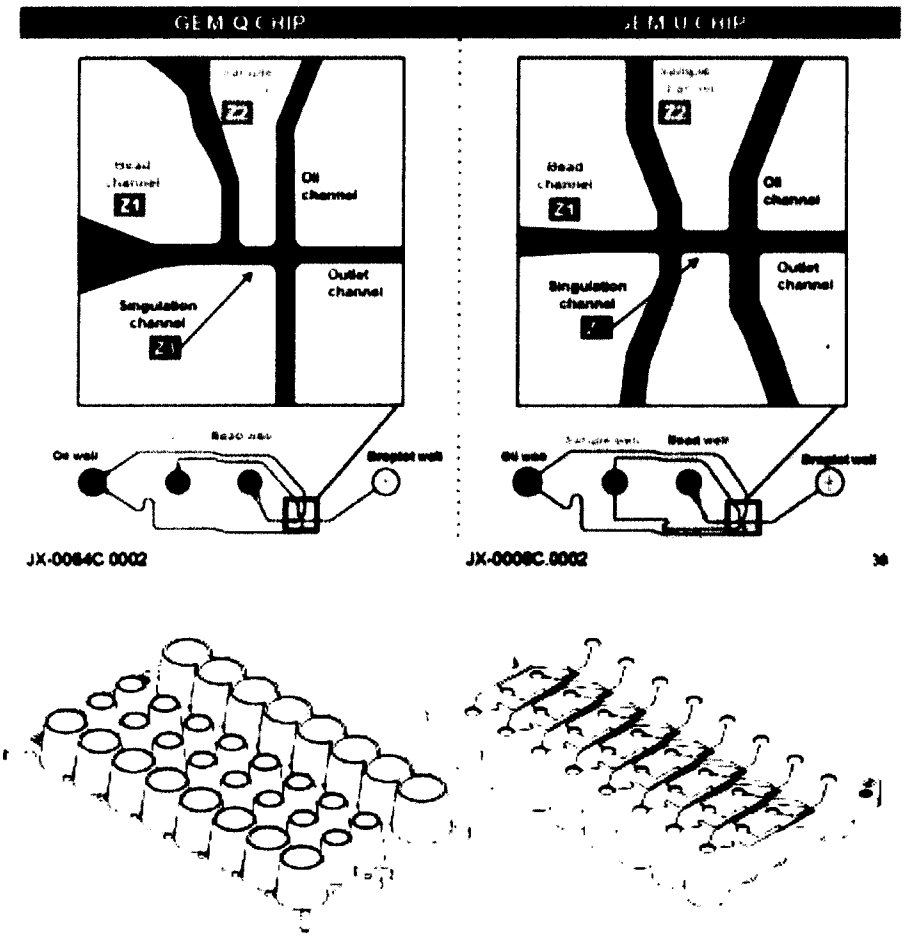
10X's "Single-Cell V(D)J Solution" (also called "Single Cell Immune Profiling") also uses either the Chromium or Chromium Single Cell Controller with 10X's GEM-U Chip and gel beads made using the Chip GB. Tr. at 1046:16–19, 1053:16–1054:19, 1028:1–5; CX-0568C at 34:13–21. "This solution allows mapping 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.

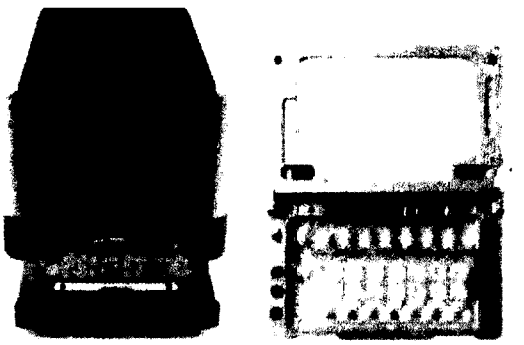
Schematics of the GEM Chips are reproduced below.



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

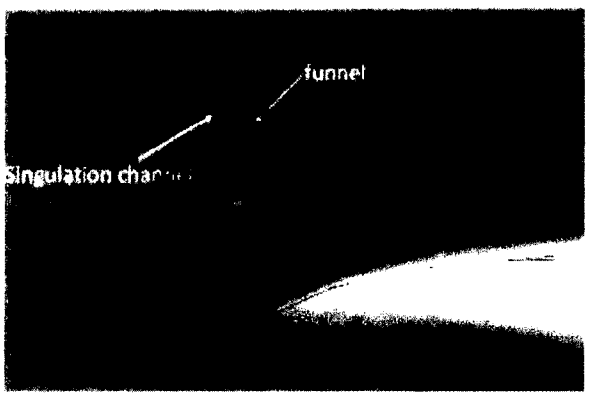
To function with the Chromium Controllers, the GEM Chips require what 10X calls a "backpack," which mounts onto a side of the chip. CX-0616C at 101:7–102:13. An

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.

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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

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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.

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> 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**.

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