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WRITER'S INTERNET ADDRESS  
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July 31, 2017

**VIA HAND DELIVERY**

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

Re: *Certain Microfluidic Devices*

Dear Secretary Barton:

Enclosed please find documents in support of a request by Bio-Rad Laboratories, Inc. and Lawrence Livermore National Security, LLC (“Complainants”) that the U.S. International Trade Commission institute an investigation pursuant to Section 337 of the Tariff Act of 1930, as amended, concerning certain microfluidic devices. Complainants’ submission includes the following documents:

1. One (1) original and eight (8) paper copies of Complainants’ Verified Complaint, pursuant to Commission Rule 210.8(a)(1)(i).
2. One (1) electronic copy of the public exhibits to the Verified Complaint on DVD, pursuant to Commission Rules 210.8(a)(1)(i) and 210.12(a)(9), including:
  - a. one (1) electronic certified copy of each of United States Patent Nos. 9,500,664 (“the 644 patent”); 9,089,844 (“the ’844 patent”); 9,636,682 (“the ’682 patent”); and 9,649,635 (“the ’635 patent”), and 9,126,160 (“the ’160 patent”) (collectively, the “Asserted Patents”), copies of which are included

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MUNICH | SYDNEY | HONG KONG | BRUSSELS

as Exhibits 1-5 to the Verified Complaint, respectively, pursuant to Commission Rule 210.12(a)(9)(i)<sup>1</sup>; and

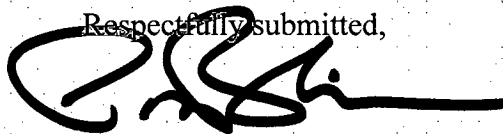
- b. one (1) electronic copy of the certified assignment records for all Asserted Patents, copies of which are included as Exhibits 6-10 to the Verified Complaint, pursuant to Commission Rule 210.12(a)(9)(ii).
3. One (1) electronic copy of the confidential exhibits to the Verified Complaint, pursuant to Commission Rules 201.6(c) and 210.8(a)(1)(ii).
4. One (1) additional copy of the Verified Complaint and accompanying electronic copies of the public exhibits, for service upon Proposed Respondent, pursuant to Commission Rules 201.6(c) and 210.8(a)(1)(iii); and one (1) additional copy of electronic copies of the confidential exhibits to the Verified Complaint for service upon Proposed Respondent's counsel after it has subscribed to the protective order.
5. Four (4) electronic copies each of the certified prosecution histories of the Asserted Patents as Appendices A, C, E, G and I, to the Verified Complaint, pursuant to Commission Rule 210.12(c)(1).
6. Four (4) electronic copies each of each patent and applicable pages of each technical reference mentioned in the prosecution histories of the Asserted Patents as Appendices B, D, F, H and J to the Verified Complaint, pursuant to Commission Rule 210.12(c)(2).
7. One (1) physical sample of a representative domestic article protected by the asserted patents, pursuant to Commission Rule 210.12(b). A representative imported article that is the subject of the complaint is not available.
8. A letter and certification requesting confidential treatment for the information contained in confidential exhibits 15 and 24-31 to the Verified Complaint, pursuant to Commission Rules 201.6(b) and 210.5(d).
9. A preliminary statement on the public interest regarding the remedial orders sought by Complainants in the Verified Complaint, pursuant to Commission Rule 210.8(b).

Please contact me with any questions regarding this filing.

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<sup>1</sup> Certified copies of the '682 and '635 patents have been ordered from the Patent Office but have not yet arrived. Complainants will submit the certified versions as soon as they arrive.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'P. Brinkman', written over the typed name.

Paul F. Brinkman  
*Counsel for Complainants Bio-Rad  
Laboratories, Inc. and Lawrence Livermore  
National Security, LLC*

Enclosures

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WRITER'S DIRECT DIAL NO.  
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WRITER'S INTERNET ADDRESS  
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**REQUEST FOR CONFIDENTIAL TREATMENT**

July 31, 2017

**VIA HAND DELIVERY**

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

Re: *Certain Microfluidic Devices*

Dear Secretary Barton:

Pursuant to Commission Rule 201.6, Complainants Bio-Rad Laboratories, Inc. (“Bio-Rad”) and Lawrence Livermore National Security, LLC respectfully request confidential treatment of certain confidential business information contained in confidential exhibits 15 and 24-31 to the Verified Complaint.

The information in the exhibits for which Complainants seeks confidential treatment consists of proprietary commercial information, including proprietary technical information regarding Bio-Rad’s products (exhibits 15, 25-29; confidential financial data regarding Bio-Rad’s products and confidential sourcing, manufacturing and employment details (exhibits 24, 30); confidential information regarding manufacturers and vendors of micro fluidic devices (exhibit 24); and confidential information regarding licensees under the involved U.S. Patents (exhibit 31).

The proprietary information described herein qualifies as confidential business information under Commission Rule 201.6 because substantially-identical information is not available to the public, because the disclosure of this information would cause substantial competitive harm to Complainants, and because the disclosure of this information would likely impede the Commission’s efforts and ability to obtain similar information in the future.

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Thank you for your attention. Please contact me with any questions regarding this request for confidential treatment.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'P. Brinkman', with a long horizontal flourish extending to the right.

Paul F. Brinkman  
*Counsel for Complainants Bio-Rad  
Laboratories, Inc. and Lawrence Livermore  
National Security, LLC*

Enclosure (Certification)

UNITED STATES INTERNATIONAL TRADE COMMISSION  
WASHINGTON, D.C.

**In the Matter of**

**CERTAIN MICROFLUIDIC DEVICES**

Inv. No. 337-TA-\_\_\_\_\_

**CERTIFICATION**

I, Paul F. Brinkman, counsel for Complainants Bio-Rad Laboratories, Inc. and Lawrence Livermore National Security, LLC declare:

1. I am duly authorized by Complainants to execute this certification.
2. I have reviewed confidential exhibits 15 and 24-30 to Complainants' Verified Complaint, for which Complainants seek confidential treatment.
3. To the best of my knowledge, information, and belief, founded after a reasonable inquiry, substantially-identical information to that contained in these exhibits is not available to the public.

I declare under penalty of perjury that the foregoing is true and correct.

Executed this 31st day of July, 2017 in Washington, DC.



Paul F. Brinkman

**UNITED STATES INTERNATIONAL TRADE COMMISSION  
WASHINGTON, D.C.**

**In the Matter of**

**CERTAIN MICROFLUIDIC DEVICES**

**Investigation No. 337-TA- \_\_\_\_\_**

**COMPLAINANTS' PRELIMINARY STATEMENT ON THE PUBLIC INTEREST**

Pursuant to Commission Rule 210.8(b), Complainants Bio-Rad Laboratories, Inc. and Lawrence Livermore National Security, LLC submit this preliminary statement on the public interest regarding the remedial orders Complainants seek against Proposed Respondent 10X Genomics, Inc.

Complainants seek a permanent limited exclusion order excluding from entry into the United States certain microfluidic devices (also known as chips or cartridges) that infringe one or more claims of United States Patent Nos. 9,500,664; 9,089,844; 9,636,682; 9,649,635; and 9,126,160 (collectively, the "Asserted Patents"). Complainants also seek a permanent cease and desist order prohibiting Proposed Respondent, its subsidiaries, related companies and agents from conducting any of the following activities in the United States: importing, selling, marketing, advertising, distributing, offering for sale, transferring (except for exportation), soliciting United States agents or distributors, or aiding and abetting other entities in the importation, sale for importation, sale after importation, transfer (except for exportation), or distribution of certain microfluidic devices that infringe one or more claims of the Asserted Patents. If the Commission grants these remedial orders as a result of this requested Investigation, there will be little or no negative impact on the public interest. In fact, the public interest is promoted by granting the requested remedial orders.

“[I]n assessing public interest factors when granting relief, the Commission relies on the strong public interest in enforcing intellectual property rights. *Certain Baseband Processor Chips and Chipsets et al.*, Inv. No. 337-TA-543, Commission Op. on Remedy, the Public Interest, and Bonding at 150 (June 19, 2007) (noting that the Commission had denied relief on public interest grounds only three times in the history of Section 337). In this proposed investigation, the requested remedial orders are in accord with the public interest at least for the following reasons: (1) the accused products are not necessary to the public health or welfare, as those issues are defined by the Commission; (2) Bio-Rad’s droplet partitioning technology, including the patent protected microfluidic cartridges and droplet generators used its ddSEQ systems, directly competes with Proposed Respondent 10X Genomics’ infringing products in the United States; (3) only a subset of the industry selling or offering for sale Next Generation Sequencing (“NGS”) preparation technology in the United States would be subject to exclusion; and (4) Bio-Rad and third parties will be in a position to fill any void in the market created by the requested remedial orders. As such, the strong public interest in protecting Complainants’ intellectual property rights outweighs any adverse impact on the public interest. *See id.* at 150 (“we must balance the negative impact [of exclusion on the public interest] against the important public interest of protecting intellectual property rights”).

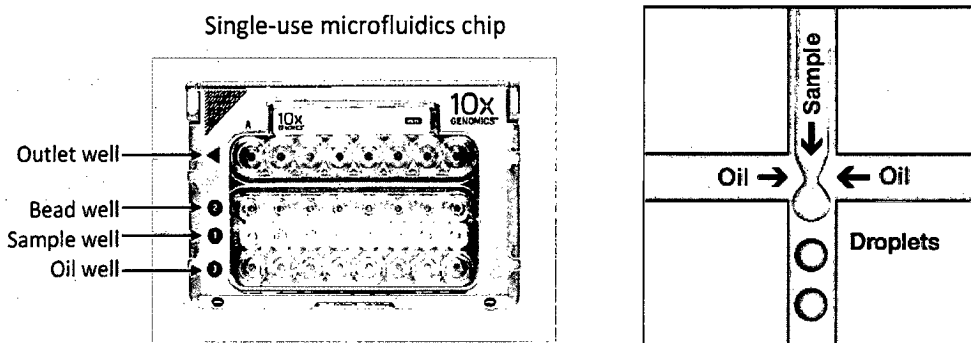
**I. Explanation of How the Articles Subject to the Requested Remedial Orders Are Used in the United States**

Proposed Respondent’s products potentially subject to remedial orders in the requested investigation are microfluidic devices known as chips or cartridges that are used for forming droplets that are then used for various forms of analysis such as genetic sequencing. This method of analysis can be a powerful research tool for those attempting to determine, for example, the function of a particular type of cell. However, Proposed Respondent’s accused products are not used at this time to perform



clinical diagnosis, to determine, for example, whether a particular virus or bacteria is present in a patient.

Proposed Respondent is currently offering the following accused products: 1) Single Cell 3' Solution, 2) Single Cell V(D)(J) Solution, 3) Genome Solution, 4) Exome Solution, and 5) DE Novo Assembly Solution. While used for slightly different applications, each of these products contain the same basic components that infringe the Asserted Patents. Those components are microfluidic devices, also commonly known as chips or cartridges, that contain a plurality of emulsion formation (*e.g.*, droplet) wells that are interconnected through a series of microfluidic channels. As is claimed in the Asserted Patents, the accused chips contain sample wells and oil wells. Once the sample and oil are loaded into their respective wells, pressure is applied and the oil and sample travel through microfluidic channels attached to the wells. The channels emanating from the sample and oil wells meet at an intersection point or junction where droplets containing a sample to be studied are formed. The droplets are then carried by an outlet channel to an outlet well where the droplets are collected. A picture of one of the accused chips is shown below along with a schematic representation of how the sample and oil flow through their respective microchannels to an intersection point where droplets are formed.



**II. Identification of Any Public Health, Safety, or Welfare Concerns Relating to the Requested Remedial Orders**

The issuance of the requested remedial relief would not adversely affect the public health, safety or welfare in the United States. While Proposed Respondent's products are used in ways that are related to the healthcare industry, its products are not directly used to diagnose or treat disease. In fact, such clinical uses are prohibited in the United States at this time. Moreover, they represent a small portion of the overall market. As discussed below, Bio-Rad and third parties are more than capable of supplying substitutes for Proposed Respondent's excluded products, thus obviating any concerns impacting whether the remedial orders would adversely affect the public health.

**III. Identification of Like or Directly Competitive Articles Made by Complainants, Licensees, and/or Third Parties That Could Replace the Excluded Subject Articles**

There are directly competitive products and substitutes that could replace the infringing devices if the accused products are excluded from the United States. These products include, but are not limited to, Bio-Rad's ddSEQ Single Cell Isolator system and associated kits. In addition, third parties such as Illumina and Pacific Biosciences offer products that can be used in performing sequencing that could replace the Proposed Respondent's accused products if an exclusion order is issued.

**IV. Identification of Whether Complainants, Licensees, and/or Third Parties Have the Capacity to Replace the Volume of Articles Subject to the Requested Remedial Orders in a Commercially Reasonable Time in the United States**

No public interest concerns exist when the market contains an adequate supply of competitive or substitute products for those subject to a remedial order. *See, e.g., Certain Lens-Fitted Film Packages*, Inv. No. 337-TA-406, Comm'n Op. at 18 (June 28, 1999). Bio-Rad is a large manufacturer of systems used to prepare samples for NGS and alone has the capacity to replace the majority of Proposed Respondent's future sales of accused products to the U.S. market without delay. Other third parties, such as those mentioned above, could also readily replace any applications that are prohibited by the exclusion of Proposed Respondent's accused products.

**V. Statement of How the Requested Remedial Orders Would Impact U.S. Consumers**

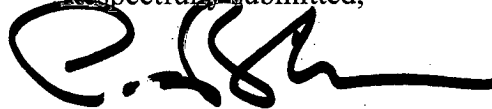
The issuance of exclusion and cease and desist orders in this investigation will not adversely impact consumers. Bio-Rad will be able to adequately supply and meet the demands of the United States market. In addition, as noted above, other third party competitors supply sequencing applications to support those lost if Proposed Respondent's accused products are excluded. Thus, research facilities in the United States will still be able to purchase systems to prepare samples for NGS or perform other forms of sequencing that provide results that are similar to 10X's infringing products.

**CONCLUSION**

The public interest in protecting Complainants' patent rights is strong, and protecting those rights would not harm any public interest because Bio-Rad and third parties can satisfy the market for products that practice its inventions or provide similar results. Accordingly, the Commission should issue a limited exclusion order and cease and desist orders if it determines that Proposed Respondent has violated Section 337.

Dated: July 31, 2017

Respectfully submitted,



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*Counsel for Complainants Bio-Rad Laboratories, Inc.  
and Lawrence Livermore National Security, LLC*

**UNITED STATES INTERNATIONAL TRADE COMMISSION  
WASHINGTON, D.C.**

**In the Matter of**

**CERTAIN MICROFLUIDIC DEVICES**

**Investigation No. 337-TA- \_\_\_\_\_**

**COMPLAINT UNDER SECTION 337 OF THE  
TARIFF ACT OF 1930, AS AMENDED**

**Complainants**

Bio-Rad Laboratories, Inc.  
1000 Alfred Nobel Drive  
Hercules, CA 94547  
Tel. (510) 724-7000

Lawrence Livermore National Security, LLC  
2300 First Street, Suite 204  
Livermore, CA 94550  
Tel. (925) 422-1100

**Counsel for Complainants**

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**Proposed Respondent**

10X Genomics, Inc.  
7068 Koll Center Parkway, Suite 401  
Pleasanton, CA 94566  
Tel. (925) 401-7300

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## EXHIBIT LIST

| <b>Exhibit</b> | <b>Description</b>  |
|----------------|---|
| 1              | Certified Copy of U.S. Patent No. 9,500,664   |
| 2              | Certified Copy of U.S. Patent No. 9,089,844   |
| 3              | Copy of U.S. Patent No. 9,636,682   |
| 4              | Copy of U.S. Patent No. 9,649,635   |
| 5              | Certified Copy of U.S. Patent No. 9,126,160   |
| 6              | Certified Assignment Records for U.S. Patent No. 9,500,664  |
| 7              | Certified Assignment Records for U.S. Patent No. 9,089,844  |
| 8              | Certified Assignment Records for U.S. Patent No. 9,636,682  |
| 9              | Certified Assignment Records for U.S. Patent No. 9,649,635  |
| 10A            | Certified Assignment Records for U.S. Patent No. 9,126,160 – Inventors to QuantaLife, Inc.  |
| 10B            | Certified Assignment Records for U.S. Patent No. 9,126,160 – QuantaLife, Inc. to Bio-Rad QL, Inc.   |
| 10C            | Certified Assignment Records for U.S. Patent No. 9,126,160 – Bio-Rad QL, Inc. to Bio-Rad Laboratories, Inc.   |
| 10D            | Certified Assignment Records for U.S. Patent No. 9,126,160 – Bio-Rad Laboratories, Inc. to Lawrence Livermore National Security, LLC                    |
| 11             | Foreign Counterparts of the Asserted Patents  |
| 12             | Bio-Rad Company Overview  |
| 13A            | <i>Laboratory Equipment</i> Readers' Choice Award for Bio-Rad's QX100™ Droplet Digital™ PCR System  |
| 13B            | <i>R&amp;D Magazine's</i> R&D 100 Award for Bio-Rad's QX100™ Droplet Digital™ PCR System  |
| 13C            | SelectScience Scientists' Choice Award for Best New Life Sciences Product of 2013 for Bio-Rad's QX200™ Droplet Digital™ PCR System                      |
| 13D            | Frost & Sullivan 2014 North American Frost & Sullivan Award for New Product Innovation for Bio-Rad's QX200™ Droplet Digital™ PCR System                 |
| 14A            | Bio-Rad Droplet Generation Procedure  |
| 14B            | Bio-Rad Droplet Digital™ PCR Applications Guide   |
| 14C            | Bio-Rad Droplet Generator Instruction Manual  |
| 14D            | Bio-Rad Product Brochure  |
| 15A            | Confidential Bio-Rad Technical Information – Full Technical Diagram of DG8 Chip   |
| 15B            | Confidential Bio-Rad Technical Information – Reduced Technical Diagram of DG8 Chip  |
| 16A            | <i>10x Genomics Announces New, Low-Cost Single cell Instrument</i> , 10X Press Releases and Company Information   |
| 16B            | <i>10x Genomics Closes \$55.5 Million Series B Round</i> , 10X Press Releases and Company Information   |
| 16C            | <i>10x Genomics Launches GemCode™ Platform, Provides Long Range Information with Short Read Sequencing</i> , 10X Press Releases and Company Information |



| <b>Exhibit</b> | <b>Description</b>   |
|----------------|--|
| 16D            | <i>10x Genomics New Chromium™ System Enables Full Access To Critical Molecular And Cellular Information</i> , 10X Press Releases and Company Information                                       |
| 17A            | <i>The Chromium™ de novo Assembly Solution</i> , Sale Offers from the 10X Website  |
| 17B            | <i>The Chromium™ Exome Solution</i> , Sale Offers from the 10X Website   |
| 17C            | <i>The Chromium™ Genome Solution</i> , Sale Offers from the 10X Website  |
| 17D            | <i>The Chromium™ Single Cell 3' Solution</i> , Sale Offers from the 10X Website  |
| 17E            | <i>The Chromium™ Single Cell V(D)J Solution</i> , Sale Offers from the 10X Website   |
| 17F            | <i>Products</i> , Sale Offers from the 10X Website   |
| 18A            | Chromium Brochure 2017 – 10X Technical Information   |
| 18B            | User Guide (Single Cell 3') – 10X Technical Information  |
| 18C            | Chromium Genome Reagents Kits – 10X Technical Information  |
| 18D            | Black Sales Presentation – 10X Technical Information   |
| 18E            | Chromium Single Cell Solution Presentation – 10X Technical Information   |
| 18F            | Chromium Controller Training Kit User Guide – 10X Technical Information  |
| 18G            | Mickael Ploquin Presentation – 10X Technical Information   |
| 18H            | Zheng, G. X. Y. <i>et al.</i> , Massively parallel digital transcriptional profiling of single cells. <i>Nat. Commun.</i> 8, 14049 doi: 10.1038/ncomms14049 (2017) – 10X Technical Information |
| 19             | '664 Patent Infringement Claim Chart   |
| 20             | '844 Patent Infringement Claim Chart   |
| 21             | '682 Patent Infringement Claim Chart   |
| 22             | '635 Patent Infringement Claim Chart   |
| 23             | '160 Patent Infringement Claim Chart   |
| 24             | Confidential Declaration Regarding Evidence of Importation   |
| 25             | Confidential '664 Patent Domestic Industry Claim Chart   |
| 26             | Confidential '844 Patent Domestic Industry Claim Chart   |
| 27             | Confidential '682 Patent Domestic Industry Claim Chart   |
| 28             | Confidential '635 Patent Domestic Industry Claim Chart   |
| 29             | Confidential '160 Patent Domestic Industry Claim Chart   |
| 30             | Confidential Declaration Regarding the Domestic Industry   |
| 31             | Confidential List of Licensees to the Asserted Patents   |
| P1             | Physical Exhibit: Domestic Industry Product  |

**APPENDIX LIST**

| <b>Appendix</b> | <b>Description</b>   |
|-----------------|--|
| A               | Prosecution History of U.S. Patent No. 9,500,664   |
| B               | Patents and Applicable Pages of Technical References Mentioned in the Prosecution History of U.S. Patent No. 9,500,664 |
| C               | Prosecution History of U.S. Patent No. 9,089,844   |
| D               | Patents and Applicable Pages of Technical References Mentioned in the Prosecution History of U.S. Patent No. 9,089,844 |
| E               | Prosecution History of U.S. Patent No. 9,636,682   |
| F               | Patents and Applicable Pages of Technical References Mentioned in the Prosecution History of U.S. Patent No. 9,636,682 |
| G               | Prosecution History of U.S. Patent No. 9,649,635   |
| H               | Patents and Applicable Pages of Technical References Mentioned in the Prosecution History of U.S. Patent No. 9,649,635 |
| I               | Prosecution History of U.S. Patent No. 9,126,160   |
| J               | Patents and Applicable Pages of Technical References Mentioned in the Prosecution History of U.S. Patent No. 9,126,160 |

## I. INTRODUCTION

1. Bio-Rad Laboratories, Inc. (“Bio-Rad”) and Lawrence Livermore National Security, LLC., (“LLNS,” collectively “Complainants”) files this complaint under Section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337, based on the unlawful importation into the United States, sale for importation into the United States, and/or sale within the United States after importation by proposed respondent 10X Genomics, Inc. (“10X” or “Proposed Respondent”) of certain microfluidic devices, commonly referred to as chips or cartridges (the “Accused Products”).<sup>1</sup> The Accused Products, either alone or in combination with other instruments specifically designed to use the microfluidic devices, infringe one or more claims of United States Patent Nos. 9,500,664 (“the ’644 patent”); 9,089,844 (“the ’844 patent”); 9,636,682 (“the ’682 patent”); 9,649,635 (“the ’635 patent”); and 9,126,160 (“the ’160 patent”) (collectively, the “Asserted Patents”), either literally or under the doctrine of equivalents.

2. Bio-Rad is a leading developer of equipment and assays used in the biotechnology field. It is the owner of all rights, title, and interest in and to the ’664 patent, the ’844 patent, the ’682 patent and the ’635 patent. Bio-Rad is the joint owner with LLNS of all rights, title, and interest in and to the ’160 patent. LLNS has given Bio-Rad its consent for Bio-Rad to enforce its rights in the ’160 patent.

3. LLNS operates Lawrence Livermore National Laboratory (“LLNL”), a leading research institution, recognized for its ground breaking advances in numerous scientific fields, under a U.S. Department of Energy Contract. Along with Bio-Rad, it co-owns the ’160 patent.

4. On information and belief, Proposed Respondent imports, sells for importation into the United States, and/or sells within the United States after importation Accused Products

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<sup>1</sup> Complainants use the terms microfluidic devices, chips and cartridges synonymously throughout the complaint.

that infringe the following claims of the Asserted Patents (independent claims in **bold with asterisk**):

| <b>Patent No.</b> | <b>Asserted Claims</b>   |
|-------------------|--|
| '664              | <b>1*</b> , 2, 3, 4, 5, 6, 7, <b>8*</b> , 9, 10, 11, 12, <b>14*</b> , 15, 16   |
| '844              | <b>1*</b> , 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, <b>15*</b>   |
| '682              | <b>1*</b> , 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, <b>14*</b> , 15, 16, 17, 18, 19, <b>20*</b> , 21                         |
| '635              | <b>1*</b> , 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, <b>16*</b> , 17, 18, 19, 20, 21, 22, <b>23*</b> , 24, 25, 26, 27 |
| '160              | <b>1*</b> , 2, 4, 5, 6, 7, 8, 14, 15, 16, 17, 18, 19, <b>20*</b> , 21  |

5. A domestic industry as required by 19 U.S.C. § 1337(a)(2) and (3) exists in the United States relating to articles protected by the Asserted Patents and in the exploitation of the Asserted Patents. Bio-Rad's domestic industry includes significant domestic investment in plant and equipment, significant domestic employment of labor and capital, and substantial domestic investment in the exploitation of the inventions claimed in the Asserted Patents.

6. Complainants seek as relief a permanent limited exclusion order under 19 U.S.C. § 1337(d) barring from entry into the United States infringing microfluidic devices that are manufactured abroad, sold for importation, imported, and/or sold in the United States after importation by or on behalf of the Proposed Respondent. Complainants further seek as relief permanent cease and desist orders under 19 U.S.C. § 1337(f) prohibiting the Proposed Respondent from importing, selling, marketing, advertising, distributing, offering for sale, transferring (except for exportation), soliciting United States agents or distributors, or aiding and abetting other entities in the importation, sale for importation, sale after importation, transfer (except for exportation), or distribution of microfluidic devices that infringe the Asserted Patents.

## II. COMPLAINANTS

### A. Bio-Rad Laboratories, Inc.

7. David and Alice Schwartz started Bio-Rad in 1952 in a 1,600 square foot Quonset hut in Berkeley, California as a research-focused company to deliver life science products and services to identify, separate, purify, and analyze chemical and biological materials. The company went public in 1966 and expanded into the clinical diagnostics market soon thereafter. Many of the products launched by Bio-Rad were firsts in their field and quickly established themselves as the gold standard. For example, in 1967 Bio-Rad launched the first commercially available test to accurately measure thyroid hormone T4.

8. By the early 1970's, Bio-Rad had launched tests for cardiovascular disease, lead poisoning, and anemia and formed a group dedicated to Clinical Diagnostics. In the 1980's, Bio-Rad established itself as a leader in the detection of hemoglobin A1c, a marker which is linked to diabetes, by introducing a number of tests and machines to automate those tests. In the 1980's, Bio-Rad also introduced the first commercially available gene pulser for transferring genes into cells and launched an electrophoresis system used to separate large fragments of DNA into clear patterns for analysis. In the 1990's, Bio-Rad tackled one of the biggest health problems of the time by introducing the first western blot test that could confirm the presence of HIV antibodies. During this time, Bio-Rad also expanded its offerings in hepatitis testing, as well as testing in other areas of microbiology and autoimmune diseases.

9. Through these and many more product offerings, Bio-Rad established itself as a leader in the fields of life sciences and clinical diagnostics, and today Bio-Rad's products and tools used in the biotechnology industry are recognized as the gold standard in numerous fields. One tool that Bio-Rad offered in 2000, which became revolutionary for those working in biotechnology, was its first thermocycler for performing Polymerase Chain Reaction.

10. Additional information about Bio-Rad and its product range can be found in Bio-Rad's Company Overview at Exhibit 12.

**B. Lawrence Livermore National Security, LLC**

11. LLNS, which operates LLNL, which is a United States government owned federal research facility that was established in 1952. The mission of the laboratory is to strengthen the United States' security by developing and applying world-class science, technology and engineering that enhances the nation's defense, reduces the global threat from terrorism and weapons of mass destruction, and responds with vision, quality, integrity and technical excellence to scientific issues of national importance. In its over 60 year history, it has been responsible for many key scientific and technological advancements including major contributions to the complete sequencing of the human genome through the Joint Genome Institute and the development of a type of polymerase chain reaction ("PCR") termed "rapid PCR."

**III. BIO-RAD'S DEVELOPMENT OF THE TECHNOLOGY AT ISSUE**

12. Polymerase Chain Reaction, or PCR, is a method of amplifying genetic material such as DNA to produce multiple copies of the starting DNA so that a sufficient amount of material will exist for analysis. To perform PCR, one must precisely cycle the temperature of the genetic material between hot and cold set points to break the double strands and allow new copies of the material to be formed. The inventor of PCR, Kary Mullis, won the Noble Prize in Chemistry for his discovery of PCR.

13. While a powerful tool, traditional PCR suffered from a number of analytical limitations. These limitations included the need for large sample sizes and obtaining only a single measurement from the sample that would indicate whether a target was present or not. Additionally, traditional forms of PCR were only semi-quantitative and required additional

samples (“standards”) to be analyzed each time PCR was performed in order to quantify the starting amount of the target molecule.

14. Subsequently, new approaches to PCR were developed, including “digital PCR.” Digital PCR is a technique that allows more precise quantification of the target sequences present in the original sample. Early forms of digital PCR required a user to separate the starting sample into multiple wells through a series of dilutions performed by repeatedly pipetting the sample to achieve very dilute samples that contained either a single molecule or no molecule. When this level of dilution was achieved, PCR was performed on the diluted sample. The resulting amplification products and “empty” wells are then evaluated using statistics to quantify the nucleic acid concentration of the target. Because digital PCR is an absolute measurement, no standards are needed to quantify starting amounts.

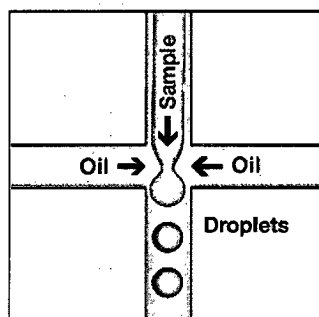
15. While an advance over prior forms of PCR, first generation digital PCR still suffered from a number of disadvantages. Performing serial dilutions is very laborious and prone to errors because of the need for multiple rounds of pipetting to sufficiently dilute the starting sample. Additionally, the sensitivity of the method was limited by the number of partitions practically available – *i.e.* the number of wells available on a tray. Last, first generation digital PCR was not particularly well suited to large scale applications because of the time it took to implement. As such, the industry was in need of a way to perform digital PCR that was scalable and fast, had an easy workflow, and provided precise results.

16. Recognizing the limitations with first generation digital PCR and the need for something better, Bio-Rad embarked on a way to improve it. Besides its own internal development efforts, Bio-Rad purchased transformative technology from QuantaLife, Inc. (“QuantaLife”). The centerpiece of QuantaLife’s solution and advancement of digital PCR was

partitioning the samples by placing them in individual microdroplets that were formed based on emulsion chemistry. The microfluidic process of forming these droplets took the place of the prior serial dilutions, with the droplets acting as the sample wells. Using the droplet method of partitioning a sample, one was now able to create a large number of partitions, each one effectively acting as a reaction well, with a minimum amount of sample handling.

17. Over 20 years after introducing its first PCR product, Bio-Rad began offering a next generation digital PCR solution in 2011, when it introduced the first commercially available droplet-based digital PCR platform, the QX100 Droplet Digital™ PCR (ddPCR™) System. With ddPCR™, droplets are formed containing the sample to be amplified and the droplets act as the reaction chamber for the PCR reaction. The droplets take the place of the prior serial dilutions.

18. The droplets are formed in innovative microfluidic devices commonly called chips or cartridges. These chips contain wells to load various liquids and the samples to be studied. They also contain microchannels connected to the wells. The microchannels cross or intersect at certain points and when the different liquids come into contact at these intersection points, droplets containing the samples are formed. This is illustrated in the figure below.



19. The droplet formation is driven by placing the chips in an instrument sometimes referred to as a “droplet generator” which applies pressure to the wells to drive liquids and samples through the microchannels. The pressure applied by the droplet generator also drives



the droplets that are formed into collection wells that are connected to the channel intersections through additional microchannels.

20. Bio-Rad's ddPCR™ platform, which was based on improvements Bio-Rad made to the technology it acquired from QuantaLife, was a breakthrough that greatly advanced the capabilities of PCR. Bio-Rad's new system offered unprecedented precision, sensitivity, and reproducibility that was not available with existing PCR products. Bio-Rad ddPCR™ products quickly became and remain the gold standard for droplet-based PCR systems. Shortly after its launch, Bio-Rad's first generation ddPCR™ product, the QX100 Droplet Digital PCR system, was widely acknowledged as an innovative design that contributed to the progression of PCR technology. The new product was an easy to use alternative to the existing technology, such as real-time or quantitative digital PCR ("qPCR"), for users looking for more precise and accurate methods of detecting rare mutations and small copy number variations.

21. The year after it introduced the QX100, Bio-Rad continued investing in ddPCR™ technology and formed its Digital Biology Center, and subsequently the Digital Biology Group, to develop products for the research and diagnostic markets based on the company's droplet partitioning technology.

22. Building on the success of its first generation ddPCR™ product, Bio-Rad's second generation ddPCR™ system, the QX200 Droplet Digital PCR system, was the first digital PCR system to include the use of both EvaGreen and TaqMan hydrolysis probe detection. At that time, no other digital PCR system provided this level of flexibility. Bio-Rad also launched a more automated version of its droplet generator called the Automated Droplet Generator ("ADG").

23. Bio-Rad's ddPCR™ products were rapidly adopted in the industry and led to an explosion of research. Just one year after the QX100 launch, the number of cancer research papers citing ddPCR™ nearly quintupled. In a short time after Bio-Rad's launch of its first generation ddPCR™ product, there were more than 250 peer-reviewed papers published in the fields of cancer, liquid biopsy, virology, and other diseases that cite to ddPCR™. With the help of ddPCR™, researchers were able to detect rare targets with a level of precision that was just not possible with previous technologies.

24. Bio-Rad's innovative ddPCR™ products have received repeated accolades for their contributions to the field. In 2012, just one year after its launch, the QX100 ddPCR™ product was awarded *R&D Magazine's* R&D 100 Award, which is given to the 100 most technologically significant products introduced into the marketplace over the past year. The QX100 ddPCR™ product was also awarded the *Laboratory Equipment Readers' Choice Award* in the biotech category, which is given to celebrate excellence in product design and performance for the tools and materials used by scientists and engineers in research laboratories. Similarly, the QX200 ddPCR™ product received the Scientists' Choice Award for Best New Life Sciences Product of 2013 from *SelectScience* because of its significant contribution in 2013. The following year, the QX200 ddPCR™ product received the 2014 Frost & Sullivan New Product Innovation Award for the Digital PCR Market in recognition of its innovation, value-added features/benefits, and the return on investment to customers. Copies of these awards can be found at Exhibits 13A-13D.

25. Bio-Rad also realized that its method for forming multiple partitions of a sample, e.g., generating droplets by using a microfluidic chip and particular surfactant chemistry, was not limited to performing ddPCR™, but could be used for other applications. Bio-Rad therefore

made further investments to develop new applications based on the foundational droplet formation technology. It formed a group of highly trained biologists, chemists, and engineers who worked on modifying the earlier generations of microfluidic chips to optimize them for use with various assays which could be used to study a variety of cells by various forms of genetic sequencing.

26. These further applications start with using the microfluidic chips to create partitions of various components. For example, it can include the patented preparatory steps of creating a first set of partitions (*e.g.*, droplets) containing adaptors that are uniquely barcoded and a second set of partitions (*e.g.*, droplets) comprising the sample to be studied. The barcoded adaptor partitions can be merged with the sample partitions, eventually resulting in the barcoded adaptors being attached to the sample in a droplet. With these preparatory steps performed, one can then use other reagents and tools to perform genetic sequencing or other forms of analysis. This patented preparatory method of highly scalable partitioning (*e.g.*, droplet formation) allows more individual cells to be analyzed and sequenced than was previously practical.

27. Bio-Rad's investment and development efforts led to a new generation of products to be used in the preparatory steps of creating thousands of microdroplets that are then evaluated in Next Generation Sequencing ("NGS") applications, such as in those provided by Illumina Corporation. Bio-Rad's next generation product that is used in NGS is called the ddSEQ™ system. It was launched in January 2017 and it consists of both a newly optimized microfluidic device (cartridge/chip) and a droplet generator instrument. As with its prior droplet products, the ddSEQ™ system is also receiving wide acclaim.

28. More information about Bio-Rad's ddPCR™ and ddSEQ™ products can be found in the product brochures and instruction manuals at Exhibits 14A-14D.

#### **IV. PROPOSED RESPONDENT**

29. 10X Genomics, Inc., formerly known as 10X Technologies, Inc. is a Delaware corporation founded in 2012 by former Bio-Rad employees and others.

30. In 2015, 10X introduced its GemCode sequencing platform. In 2016, 10X announced the launch of its Chromium sequencing platform. On information and belief, both platforms rely on infringing microfluidic chips and droplet generator instruments that partition samples into small droplets for sample preparation and analysis.

31. More information about 10X can be found in Exhibits 16A-16D.

#### **V. THE PRODUCTS AT ISSUE**

32. Pursuant to Commission Rule 210.12(a)(12), the Accused Products include certain microfluidic devices, including without limitation microfluidic chips designed for use in 10X's GemCode and Chromium sequencing platforms.<sup>2</sup>

#### **VI. THE ASSERTED PATENTS AND NONTECHNICAL DESCRIPTIONS OF THE INVENTIONS<sup>3</sup>**

##### **A. Non-Technical Overview of the Inventions in the Asserted Patents**

33. The inventions disclosed and claimed in the Asserted Patents relate to using a microfluidic chip to form partitions, which can be emulsions. The emulsion can be a small droplet in which the sample material is encased in an oil. In the case of using the technology to perform digital PCR, each droplet will contain on average one target molecule to be amplified, along with amplification reagents and, in the case of using the technology for NGS or single cell

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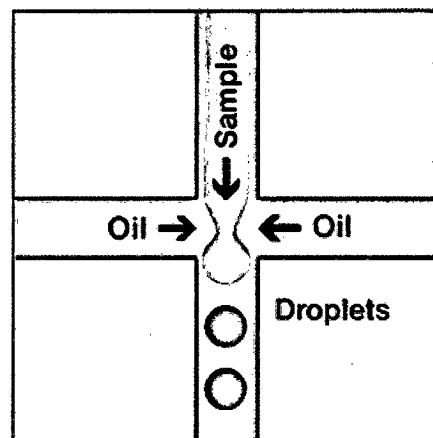
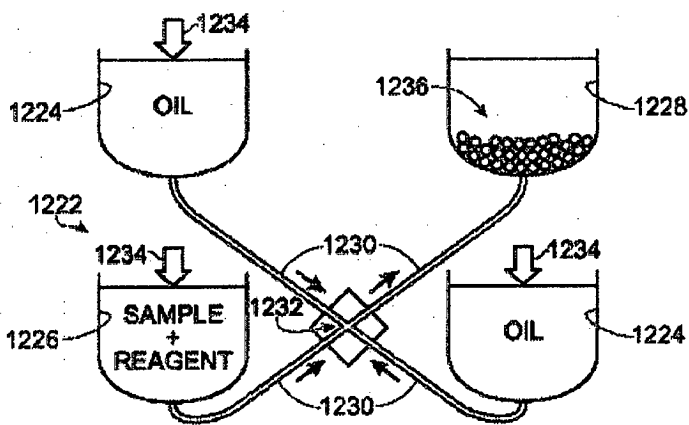
<sup>2</sup> A physical exhibit of the Accused Products is presently unavailable to Complainants. Information regarding the accused products can be found at Exhibit 18A-18H.

<sup>3</sup> All non-technical descriptions of the patents herein are presented to give a general background of those patents. These statements are not intended to be used nor should they be used for purposes of patent claim construction. Complainants present these statements subject to and without waiver of its right to argue that claim terms should be construed in a particular way under claim interpretation jurisprudence and the relevant evidence.

analysis, each droplet can contain one cell or strand of genetic material to be sequenced along with other necessary reagents, such as adaptors and barcodes and sequencing materials.

34. Each Asserted Patent claims a microfluidic device, typically referred to as a chip or cartridge, having multiple emulsion/droplet formation units. Each of the units comprise at least an inlet well for a sample, an inlet well for an oil phase, and an outlet well to collect the resulting emulsions/droplets. The wells in the emulsion formation units are interconnected by microfluidic channels within the chip. Each chip has multiple emulsion formation units, such that a single chip can be used to generate a plurality of emulsions from multiple samples at the same time.

35. The chips of this invention form emulsions by combining two different phases at an intersection inside the chip. These two phases, which are typically an aqueous and oil phase, are loaded to different input wells, and each flow through a separate channel extending from the input well to an intersection called a “channel junction.” As shown in the images below, the two different phases are combined at the channel junction to form emulsions – *i.e.*, water-in-oil emulsion. Similar to bubbles in a soda (*i.e.*, gas in a liquid), the two different phases (*i.e.*, water and oil) form an emulsion where the aqueous phase containing the sample to be studied is on the inside and is encapsulated by the oil phase.



36. Some of the Asserted Patents are directed to pressure being applied to a chip to drive the different phases through the microfluidic channels to form these emulsions. The pressure is applied with an instrument that receives the chips. The instrument is commonly referred to as a droplet generator. For these claims, the wells are subject to sufficient pressure such that the different phases are driven through the channels to the channel junction to form emulsions.

37. Using this design, the claimed microfluidic chips are capable of partitioning a single sample into tens of thousands of emulsions (droplets) per sample. These partitions are the equivalent of “droplet” test tubes and each droplet contains a very small number of nucleic acids or cells to be studied.

38. Unlike prior partitioning techniques, one does not need to do serial dilutions, which are tedious and prone to error, to determine starting copying numbers. Instead, the claimed technology relies on microfluidics to distribute the sample into individual droplet partitions, and relies on statistical methods (in the case of PCR) or informatics (in the case of NGS) to quantify or analyze the starting sample.

39. In addition to allowing for better and easier quantification of starting target numbers in PCR, the droplet techniques of the patents also allow for the detection of very low concentrations of mutations relative to the background of wild-type DNA in a given sample. For example, Bio-Rad’s QX200 System, which utilizes a microfluidic chip as claimed in the Asserted Patents, can easily scale to quantify target concentrations of a mutation in as low as one out of 1,000,000 (0.0001%) total copies in a given sample. Prior to the invention disclosed in the Asserted Patents, it was not practical to detect and quantify such low concentrations of a target sequence.

## **B. The '664 Patent**

### **1. Identification and Ownership of the '664 Patent**

40. Bio-Rad owns by assignment the right, title, and interest in United States Patent No. 9,500,664, titled "Droplet Generation For Droplet-Based Assay," which issued November 22, 2016, naming Kevin D. Ness, Christopher F. Kelly, and Donald A. Masquelier as inventors. A certified copy of the '664 patent is attached as Exhibit 1. A certified copy of the assignment from the named inventors to Bio-Rad Laboratories, Inc. is attached as Exhibit 6. A certified copy of the prosecution history of the '664 patent is attached as Appendix A. Copies of each patent and applicable pages of each technical reference mentioned in the prosecution history of the '664 patent, which were not included in the certified copy of the prosecution history, are attached as Appendix B.

### **2. Foreign Counterparts to the '664 Patent**

41. Exhibit 11 lists each foreign patent and each pending foreign patent application (not already issued as a patent), and each foreign patent application that has been denied, abandoned, or withdrawn, which contains a disclosure corresponding to the '664 patent, with an indication of the prosecution status of each such patent application. No other foreign patents or patent applications corresponding to the '664 patent have been filed, abandoned, withdrawn, or rejected.

### **3. Non-Technical Description of the '664 Patent**

42. The '664 patent relates generally to a system for forming a plurality of sample containing droplets suspended in a background fluid such as an oil. The system is comprised of a substrate having a bottom and top surface, and sample, background fluid (oil) and droplet wells all protruding from the upper surface of the substrate. Each of these wells are interconnected by a network of channels that are embedded in the bottom of the chip

(circumferentially bound) and intersect within the chip at channel junctions. A separate channel extends from each well in the chip to the channel junction, where the droplets are formed and pass down the outlet channel to an outlet well for collection. The substrate and the upper region of each well are injection molded as a single piece.

## **C. The '844 Patent**

### **1. Identification and Ownership of the '844 Patent**

43. Bio-Rad owns by assignment the right, title, and interest in United States Patent No. 9,089,844, titled "System For Forming Emulsions," which issued July 28, 2015, naming Amy L. Hiddessen, Donald A. Masquelier, Kevin D. Ness, Benjamin J. Hindson, Anthony J. Makarewicz, Jr., and Erin R. Chia as inventors. A certified copy of the '844 patent is attached as Exhibit 2. A certified copy of the assignment from the named inventors to Bio-Rad Laboratories, Inc. is attached as Exhibit 7. A certified copy of the prosecution history of the '844 patent is attached as Appendix C. Copies of each patent and applicable pages of each technical reference mentioned in the prosecution history of the '844 patent, which were not included in the certified copy of the prosecution history, are attached as Appendix D.

### **2. Foreign Counterparts to the '844 Patent**

44. Exhibit 11 lists each foreign patent and each pending foreign patent application (not already issued as a patent), and each foreign patent application that has been denied, abandoned, or withdrawn, which contains a disclosure corresponding to the '844 patent, with an indication of the prosecution status of each such patent application. No other foreign patents or patent applications corresponding to the '844 patent have been filed, abandoned, withdrawn, or rejected.



### **3. Non-Technical Description of the '844 Patent**

45. The '844 patent relates generally to a system for forming emulsions/droplets comprising a microfluidic device. The microfluidic device includes multiple emulsion/droplet formation units, wherein each unit comprises at least an input well for samples and an output/droplet well for collecting the emulsions. These wells are interconnected by a network of channels that are embedded in the chip and intersect within the chip at a channel intersection. A separate channel extends from each well in the microfluidic device to the channel junction, where the emulsions/droplets are formed and pass down the outlet channel to an outlet well for collection. The system includes an instrument to receive the microfluidic device and apply pressure to the emulsion formation units in parallel to drive formation of the droplets at the channel intersections. The instrument also includes a pressure sensor to monitor the pressure and to stop application of pressure when the sensor detects a change in pressure indicative of air entering the sample channels from the sample well.

#### **D. The '682 Patent**

##### **1. Identification and Ownership of the '682 Patent**

46. Bio-Rad owns by assignment the right, title, and interest in United States Patent No. 9,636,682, titled "System For Generating Droplets – Instruments And Cassette," which issued May 2, 2017, naming Amy L. Hiddessen, Kevin D. Ness, Benjamin J. Hindson, and Donald A. Masquelier as inventors. A copy of the '682 patent is attached as Exhibit 3.<sup>4</sup> A certified copy of the assignment from the named inventors to Bio-Rad Laboratories, Inc. is attached as Exhibit 8. A certified copy of the prosecution history of the '682 patent is attached as Appendix E. Copies of each patent and applicable pages of each technical reference

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<sup>4</sup> A certified copy of the '682 Patent has been ordered from the Patent Office. Complainants will submit the certified copy as soon as it arrives.

mentioned in the prosecution history of the '682 patent, which were not included in the certified copy of the prosecution history, are attached as Appendix F.

## **2. Foreign Counterparts to the '682 Patent**

47. Exhibit 11 lists each foreign patent and each pending foreign patent application (not already issued as a patent), and each foreign patent application that has been denied, abandoned, or withdrawn, which contains a disclosure corresponding to the '682 patent, with an indication of the prosecution status of each such patent application. No other foreign patents or patent applications corresponding to the '682 patent have been filed, abandoned, withdrawn, or rejected

## **3. Non-Technical Description of the '682 Patent**

48. The '682 patent relates generally to a system for forming an array of emulsions/droplets in parallel. The system includes a plate containing an array of emulsion/droplet production units, wherein each unit comprises an input well for continuous phase (oil), an input well for dispersed phase (aqueous or samples), and an output well for collecting the emulsions. These wells are interconnected by a network of channels that are embedded in the chip (circumferentially bound) and intersect within the chip at channel junctions where the droplets are formed. A separate channel extends from each well in the chip to the channel junction, where the emulsion/droplets that are formed then enter an outlet channel extending from the channel junction to an outlet well for collection of the emulsion/droplets. The system includes an instrument to receive the microfluidic device and drive formation of the droplets at the channel intersections, and then to a droplet well via an outlet channel.

## **E. The '635 Patent**

### **1. Identification and Ownership of the '635 Patent**

49. Bio-Rad owns by assignment the right, title, and interest in United States Patent No. 9,649,635, titled "System For Generating Droplets With Push-Back To Remove Oil," which issued May 2, 2017, naming Amy L. Hiddessen, Kevin D. Ness, Benjamin J. Hindson, Donald A. Masquelier, and Erin R. Chia as inventors. A copy of the '635 patent is attached as Exhibit 4.<sup>5</sup> A certified copy of the assignment from the named inventors to Bio-Rad Laboratories, Inc. is attached as Exhibit 9. A certified copy of the prosecution history of the '635 patent is attached as Appendix G. Copies of each patent and applicable pages of each technical reference mentioned in the prosecution history of the '635 patent, which were not included in the certified copy of the prosecution history, are attached as Appendix H.

### **2. Foreign Counterparts to the '635 Patent**

50. Exhibit 11 lists each foreign patent and each pending foreign patent application (not already issued as a patent), and each foreign patent application that has been denied, abandoned, or withdrawn, which contains a disclosure corresponding to the '635 patent, with an indication of the prosecution status of each such patent application. No other foreign patents or patent applications corresponding to the '635 patent have been filed, abandoned, withdrawn, or rejected.

### **3. Non-Technical Description of the '635 Patent**

51. The '635 patent relates generally to a system for forming an array of emulsions/droplets in parallel. The system includes a plate containing an array of emulsion/droplet production units, wherein each unit comprises an input well for continuous

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<sup>5</sup> A certified copy of the '635 Patent has been ordered from the Patent Office. Complainants will submit the certified copy as soon as it arrives.

phase (oil), an input well for dispersed phase (aqueous or samples), and an output well for collecting the emulsions. These wells are interconnected by a network of channels that are embedded in the chip (circumferentially bound) and intersect within the chip at channel junctions where droplets are formed. A separate channel extends from each well in the chip to the channel junction, where the emulsion/droplets that are formed then enter an outlet channel extending from the channel junction to an outlet well for collection of the emulsion/droplets. The system includes an instrument to receive the microfluidic device and drive formation of the droplets at the channel intersections, and then to the droplet outlet wells via outlet channels. After collecting the emulsions in the outlet wells, the instrument incorporates a “pushback” step of pushing the oil from the outlets well back into the outlet channels towards the inlet wells to remove excess oil from under the droplets – *i.e.*, concentrating the droplets.

## **F. The '160 Patent**

### **1. Identification and Ownership of the '160 Patent**

52. Bio-Rad owns by assignment a 50% joint interest with LLNS and has an exclusive license from LLNS, to the right, title and interest in United States Patent No. 9,126,160, titled “System For Forming An Array Of Emulsions,” which issued on September 8, 2015, naming Kevin D. Ness, Benjamin J. Hindson, Billy W. Colston, Jr., and Donald A. Masquelier as inventors. A certified copy of the '160 patent is attached as Exhibit 5. A certified copy of the assignment from the named inventors to QuantaLife is attached as Exhibit 10A, from QuantaLife to Bio-Rad QL, Inc., is attached as Exhibit 10B, from Bio-Rad QL, Inc. to Bio-Rad Laboratories, Inc., is attached as Exhibit 10C, and from Bio-Rad Laboratories, Inc. to Lawrence Livermore National Security, LLC., is attached as Exhibit 10D. A certified copy of the prosecution history of the '160 patent is attached as Appendix I. Copies of each patent and applicable pages of each technical reference mentioned in the prosecution history of the

'160 patent, which were not included in the certified copy of the prosecution history, are attached as Appendix J.

## **2. Foreign Counterparts to the '160 Patent**

53. Exhibit 11 lists each foreign patent and each pending foreign patent application (not already issued as a patent), and each foreign patent application that has been denied, abandoned or withdrawn, containing a disclosure corresponding to the '160 patent, with an indication of the prosecution status of each such patent application. No other foreign patents or patent applications corresponding to the '160 patent have been filed, abandoned, withdrawn, or rejected.

## **3. Non-Technical Description of the '160 Patent**

54. The '160 patent relates generally to system for forming an array of emulsions/droplets in parallel. The system includes a plate containing an array of emulsion/droplet production units, wherein each unit comprises an input well for continuous phase (oil), an input well for dispersed phase (aqueous or samples), and an output well for collecting the emulsions. These wells are interconnected by a network of channels that are embedded in the chip (circumferentially bound) and intersect within the chip at channel junctions. A separate channel extends from each well in the chip to the channel junction, where the emulsion/droplets and then to an outlet channel extending from the channel junction to an outlet well for collection of the emulsion/droplets.

## **G. Licensees Under the Asserted Patents**

55. A list of each licensee under each of the Asserted Patents is included in Confidential Exhibit 31.

## **VII. UNLAWFUL AND UNFAIR ACTS OF RESPONDENT – PATENT INFRINGEMENT**

56. On information and belief, Proposed Respondent imports, sells for importation, and/or sells in the United States after importation certain microfluidic chips that are specifically designed to be used in conjunction with instruments known as droplet generators to form microdroplets. The microfluidic chips either alone or in conjunction with the droplet generators infringe the Asserted Patents.

### **A. Infringement of the '664 Patent**

57. On information and belief, Proposed Respondent imports, sells for importation, and/or sells after importation into the United States Accused Products that infringe the '664 patent.

58. The Accused Products directly infringe, literally and/or under the doctrine of equivalents, at least claims 1-7 of the '664 patent under 35 U.S.C. § 271(a). Proposed Respondent directly infringe at least these claims by importing, selling for importation, and/or selling after importation into the United States the Accused Products. The Accused Products satisfy all claim limitations of claims 1-7 at the time of importation into the United States.

59. Proposed Respondent also induces the infringement of method claims 8 and 10-12 under 35 U.S.C. § 271(b) by providing to customers a microfluidic device and instrument for the device's use, along with directions for use that, when followed, Proposed Respondent knows infringes the preceding claims.

60. Proposed Respondent contributorily infringes under 35 U.S.C. § 271(c) claims 8 and 10-12. Proposed Respondent has designed the accused microfluidic devices specifically to be used in a manner as claimed in claims 8-12. As such, the accused microfluidic devices are a material component of the patented combination, specifically designed to be used with the

instrument claimed in the patent claims, and especially made and adapted for use in a manner that infringes the claims of the '664 patent. The Accused Products are not staple articles of commerce and they do not have substantial uses that do not infringe the patent claims. On information and belief, Proposed Respondent is aware of the '664 patent and is aware that the Accused Products are especially made to be used in a system which infringes the '664 patent.

61. Similarly, on information and belief, Proposed Respondent induces the infringement of method claims 14-16, under 35 U.S.C. § 271(b) and 35 U.S.C. § 271(g) by providing specifications for the manufacture of its microchip to a manufacturer outside the United States knowing that to meet those specifications, the foreign manufacturer will use a method of manufacture which practices the elements of claims 14-16. On information and belief, Proposed Respondent then induces the infringing devices manufactured in accordance with claims 14-16 to be imported into the United States pursuant to a contract.

62. A claim chart comparing the '664 patent's asserted independent claims 1, 8 and 14 to a representative Accused Product is attached as Exhibit 19.

#### **B. Infringement of the '844 Patent**

63. On information and belief, Proposed Respondent imports, sells for importation and/or sells after importation into the United States Accused Products that infringe the '844 patent.

64. The Accused Products, which are imported into the United States, indirectly infringe, literally and/or under the doctrine of equivalents, at least claims 1-14 of the '844 patent under 35 U.S.C. § 271(b) and/or 35 U.S.C. § 271(c). Proposed Respondent has designed the accused microfluidic devices specifically to be used with an instrument that applies pressure to the microfluidic device. As such, the accused microfluidic devices are a material component of the patented combination, specifically designed to be used with the instrument claimed in the

patent claims, and especially made and adapted for use in a manner that infringes the claims of the patent. The Accused Products are not staple articles of commerce and they do not have substantial uses that do not infringe the patent claims. On information and belief, Proposed Respondent is aware of the '844 patent and is aware that the Accused Products are especially made to be used in a system which infringes the '844 patent.

65. Proposed Respondent induces the infringement method claim 15 under 35 U.S.C. § 271(b) by supplying microfluidic devices and instruments to use the microfluidic devices to customers, along with instructions for their use, that Proposed Respondent knows will infringe claim 15 when used according to the instructions that it provides. Further, Proposed Respondent contributes to the infringement of method claim 15 under 35 U.S.C. § 271(c) by supplying customers with microfluidic devices that are specifically designed to be used as claimed in claim 15. As such, the accused microfluidic devices are a material component of the patented combination, specifically designed to be used in the manner claimed in claim 15, and especially made and adapted for use in a manner that infringes the claims of the '884 patent. The Accused Products are not staple articles of commerce and they do not have substantial uses that do not infringe the patent claims. On information and belief, Proposed Respondent is aware of the '844 patent and is aware that the Accused Products are especially made to be used in a system which infringes claim 15 of the '844 patent.

66. A claim chart comparing the '844 patent's asserted independent claims 1 and 15 to a representative Accused Product is attached as Exhibit 20.

**C. Infringement of the '682 Patent**

67. On information and belief, Proposed Respondent imports, sells for importation, and/or sells after importation into the United States Accused Products that infringe the '682 patent.



68. The Accused Products indirectly infringe, literally and/or under the doctrine of equivalents, at least claims 1-21 of the '682 patent under 35 U.S.C. § 271(b) and/or 35 U.S.C. § 271(c). Proposed Respondent imports the Accused Products and it has designed the accused microfluidic devices specifically to be used with an instrument that applies pressure to the microfluidic device. As such, the accused microfluidic devices are: a material component of the patented combination, specifically designed to be used with the instrument claimed in the patent claims, and especially made and adapted for use in a manner that infringes the claims of the patent. The Accused Products are not staple articles of commerce and they do not have substantial uses that do not infringe the patent claims. On information and belief, Proposed Respondent is aware of the '682 patent and is aware that the Accused Products are especially made to be used in a system which infringes the '682 patent, as it sells to customers both the imported microfluidic devices and the instrument to apply pressure to the microfluidic devices.

69. A claim chart comparing the '682 patent's asserted independent claims 1, 14 and 20 to a representative Accused Product is attached as Exhibit 21.

#### **D. Infringement of the '635 Patent**

70. Proposed Respondent imports, sells for importation, and/or sells after importation into the United States Accused Products that infringe the '635 patent.

71. The Accused Products indirectly infringe, literally and/or under the doctrine of equivalents, at least claims 1-22 of the '635 patent under 35 U.S.C. § 271(b) and/or 35 U.S.C. § 271(c). Proposed Respondent has designed the accused microfluidic devices specifically to be used with an instrument that applies pressure to the microfluidic device. As such, the accused microfluidic devices are: a material component of the patented combination, specifically designed to be used with the instrument claimed in the '635 patent claims, and especially made and adapted for use in a manner that infringes the claims of the patent. The Accused Products

are not staple articles of commerce and they do not have substantial uses that do not infringe the patent claims. On information and belief, Proposed Respondent is aware of the '635 patent and is aware that the Accused Products are especially made to be used in a system which infringes the '635 patent as Proposed Respondent sells both the microfluidic device and the instrument for creating pressure in the device to customers and knows that when these components are used together, they will infringe the claims of the '635 patent.

72. Proposed Respondent induces the infringement method claims 23-27 under 35 U.S.C. § 271(b) by supplying microfluidic devices and instruments to use the microfluidic devices to customers, along with instructions for their use, that Proposed Respondent knows will infringe claims 23-27 when used according to the instructions that it provides. Further, Proposed Respondent contributes to the infringement of method claims 23-27 under 35 U.S.C. § 271(c) by supplying customers with microfluidic devices that are specifically designed to be used as claimed in claims 23-27. As such, the accused microfluidic devices are a material component of the patented combination, specifically designed to be used in the manner claimed in claims 23-27, and especially made and adapted for use in a manner that infringes the claims of the '635 patent. The Accused Products are not staple articles of commerce and they do not have substantial uses that do not infringe the patent claims. On information and belief, Proposed Respondent is aware of the '635 patent and is aware that the Accused Products are especially made to be used in a system which infringes claims 23-27 of the '635 patent.

73. A claim chart comparing the '635 patent's asserted independent claims 1, 16, and 23 to a representative Accused Product is attached as Exhibit 22.

**E. Infringement of the '160 Patent**

74. Proposed Respondent imports, sells for importation, and/or sells after importation into the United States Accused Products that infringe the '160 patent.

75. The Accused Products, which are imported into the United States, directly infringe, literally and/or under the doctrine of equivalents, at least claims 1-2, 4-8, 14-15, and 20-21 of the '160 patent under 35 U.S.C. § 271(a). Proposed Respondent directly infringe at least these claims by importing, selling for importation, and/or selling after importation into the United States the Accused Products. The Accused Products satisfy all claim limitations of claims 1-2, 4-8, 14-15, and 20-21 at the time of importation into the United States.

76. Proposed Respondent also indirectly infringes, literally and/or under the doctrine of equivalents, at least claims 16-19 of the '160 patent under 35 U.S.C. § 271(b) and/or 35 U.S.C. § 271(c). Proposed Respondent has designed the accused microfluidic devices specifically to be used with an instrument that applies pressure to the microfluidic device. As such, the accused microfluidic devices are a material component of the patented combination, specifically designed to be used with the instrument claimed in the patent claims, and especially made and adapted for use in a manner that infringes the claims of the patent. The Accused Products are not staple articles of commerce and they do not have substantial uses that do not infringe the patent claims. On information and belief, Proposed Respondent is aware of the '160 patent and is aware that the Accused Products are especially made to be used in a system which infringes the '160 patent.

77. A claim chart comparing the '160 patent's asserted independent claims 1 and 20 to a representative Accused Product is attached as Exhibit 23.

### **VIII. IMPORTATION**

78. On information and belief, the Accused Products are manufactured to 10X's specifications in Germany and imported into the United States by or on behalf of 10X. Upon information and belief, 10X also sells the Accused Products in the United States after importation. Evidence regarding Proposed Respondent's importation and sale for importation

from Germany can be found in Confidential Exhibit 24. Evidence regarding Proposed Respondent's sales after importation in the United States can be found at Exhibits 17A-17F.

**IX. CLASSIFICATION OF THE INFRINGING PRODUCTS UNDER THE HARMONIZED TARIFF SCHEDULE**

79. On information and belief, the Accused Products may be classified under item number 9027.90.84 of the Harmonized Tariff Schedule of the United States. This classification is not intended to restrict the scope of any exclusion order or other remedy ordered by the Commission.

**X. RELATED LITIGATION**

80. Concurrently with the filing of this complaint, Bio-Rad and LLNS will be filing a complaint in the United States District Court for the Northern District of California, alleging infringement of the patents asserted herein along with others.

81. The unfair acts asserted here, or the subject matter thereof, have not been the subject of any other previous litigation in any domestic or foreign court or administrative agency.

**XI. THE DOMESTIC INDUSTRY RELATING TO THE ASSERTED PATENTS**

82. An industry as required by Section 337(a)(2) and defined by Section 337(a)(3) exists in the United States relating to the Asserted Patents and Bio-Rad's products protected by the Asserted Patents.

**A. Bio-Rad's Practice of the Asserted Patents**

83. As discussed above, Bio-Rad has designed several microfluidic chips, including models DG8, DG32, and ddSEQ that alone, or in combination with Bio-Rad's droplet generators, including models QX100, QX200, AutoDG and ddSEQ Single Cell Isolator, practice at least one claim of each of the Asserted Patents..

84. Claim charts demonstrating that representative Bio-Rad products practice at least one claim of each Asserted Patent are attached as Confidential Exhibits 25-29.<sup>6</sup> The underlying documents used in these claim charts are attached as Exhibits 14A-14D and Confidential Exhibits 15A-15B.

**B. United States Economic Activity Relating to the Domestic Industry Products and Asserted Patents**

85. Bio-Rad has made significant investments in plant and equipment, significant investments in the employment of labor and capital, and substantial investments in the exploitation of the Asserted Patents through product design, research, development, engineering, manufacturing, testing, distribution, marketing, sales, service, customer support and other activities relating to Bio-Rad's microfluidic chips and droplet generators that practice the Asserted Patents. Bio-Rad's domestic investments in these products has a strong nexus to the Asserted Patents.

86. In addition, Bio-Rad develops and manufactures dozens of assays that work in droplets created in its microfluidic chips, instruments that process those assays, and proprietary formulations of emulsions and reagents that are combined with biological samples in the microfluidic chips. All of these products rely heavily on Bio-Rad's patented technology used in its microfluidic chips and droplet generators.

87. Bio-Rad conducts these economic activities from its facilities in Hercules and Pleasanton, California, where it employs engineers, chemists, biologists, mathematicians,

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<sup>6</sup> Bio-Rad's products practice additional claims of the Asserted Patents, and Complainants may establish the technical prong of the domestic industry requirement through claims other than the representative claims, or through products other than or in addition to the exemplary products used in these exhibits.

technicians, sales and marketing teams, logistics personnel and administrative professionals to support its domestic industry.

88. A declaration discussing a portion of Bio-Rad's economic domestic industry through some of its applicable R&D and manufacturing activities can be found in Confidential Exhibit 30.<sup>7</sup>

## **XII. RELIEF REQUESTED**

89. Complainants respectfully request that the Commission:

(a) Institute an investigation pursuant to Section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337, with respect to Proposed Respondent's violations of that section arising from the importation into the United States, sale for importation, and/or the sale within the United States after importation of certain microfluidic devices that infringe one or more claims of the Asserted Patents;

(b) Schedule and conduct a hearing pursuant to Section 337(c) for the purposes of (i) receiving evidence and hearing argument concerning whether there has been a violation of Section 337, and (ii) following the hearing, determine that there has been a violation of Section 337;

(c) Issue a permanent limited exclusion order directed to products manufactured by or for Proposed Respondent, its subsidiaries, related companies and agents pursuant to 19 U.S.C. § 1337(d) excluding entry into the United States of certain microfluidic devices that infringe one or more claims of the Asserted Patents;

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<sup>7</sup> Bio-Rad's applicable domestic economic investments relating to its products that practice the Asserted Patents and the exploitation of the Asserted Patents are broader than those discussed in Exhibit 30, and Complainants may rely on additional investments to satisfy the economic prong of the domestic industry requirement.

(d) Issue a permanent cease and desist order pursuant to 19 U.S.C. § 1337(f) prohibiting Proposed Respondent, its subsidiaries, related companies and agents from conducting any of the following activities in the United States: importing, selling, marketing, advertising, distributing, offering for sale, transferring (except for exportation), soliciting United States agents or distributors, or aiding and abetting other entities in the importation, sale for importation, sale after importation, marketing, advertising, transfer (except for exportation), or distribution of certain microfluidic devices that infringe one or more claims of the Asserted Patents;

(e) Impose a bond upon importation of certain microfluidic devices that infringe one or more claims of the Asserted Patents sufficient to protect Complainants from any injury during the 60-day Presidential review period pursuant to 19 U.S.C. § 1337(j); and

(f) Issue such other and further relief as the Commission deems just and proper under the law, based on the facts determined by the investigation and the authority of the Commission.

Dated: July 31, 2017

Respectfully submitted,



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and Lawrence Livermore National Security, LLC*



UNITED STATES INTERNATIONAL TRADE COMMISSION  
WASHINGTON, D.C.

In the Matter of

CERTAIN MICROFLUIDIC DEVICES

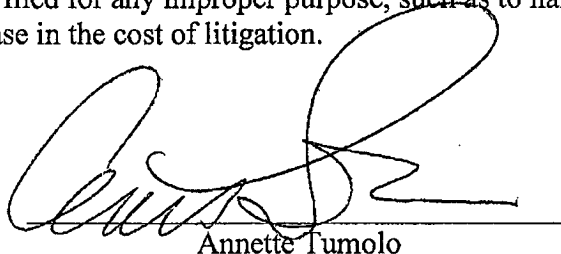
Investigation No. 337-TA- \_\_\_\_\_

VERIFICATION OF COMPLAINT

I, Annette Tumolo, am Executive Vice President of the Digital Biology Group of Bio-Rad Laboratories, Inc. and am authorized to execute this verification. I have read the Complaint and am aware of its contents. To the best of my knowledge, information, and belief and based upon a reasonable inquiry under the circumstances, I hereby certify that:

1. The allegations contained in the Complaint are well grounded in fact and have evidentiary support, or are likely to have evidentiary support after a reasonable opportunity for further investigation or discovery;
2. The claims and other legal contentions set forth in the Complaint are warranted by existing laws or by a good faith, non-frivolous argument for extension, modification, or reversal of existing law, or by the establishment of new law; and
3. The Complaint is not being filed for any improper purpose, such as to harass or to cause unnecessary delay or needless increase in the cost of litigation.

Dated: July 28, 2017



\_\_\_\_\_

Annette Tumolo

UNITED STATES INTERNATIONAL TRADE COMMISSION  
WASHINGTON, D.C.

In the Matter of

CERTAIN MICROFLUIDIC DEVICES


Investigation No. 337-TA- \_\_\_\_\_

VERIFICATION OF COMPLAINT

I, Mark Lough, am Deputy General Counsel of Lawrence Livermore National Laboratory and am authorized to execute this verification on behalf of Complainant Lawrence Livermore National Security, LLC ("LLNS"). LLNS is co-owner and licensor of U.S. Patent No. 9,126,160 (the '160 patent), and has provided its authority to Bio-Rad to assert the '160 patent herein. Other than attesting to the above, LLNS does not intend to take a position on the allegations in the complaint. I have read the complaint and am aware of its contents. To the best of my knowledge, information, and belief and based upon a reasonable inquiry under the circumstances, I hereby certify that:

1. The allegations contained in the Complaint relating to ownership and licensing of the '160 patent are well grounded in fact and have evidentiary support, or are likely to have evidentiary support after a reasonable opportunity for further investigation or discovery;
2. The claims and other legal contentions set forth in the Complaint relating to ownership and licensing of the '160 patent are warranted by existing laws or by a good faith, non-frivolous argument for extension, modification, or reversal of existing law, or by the establishment of new law; and
3. The allegations in the Complaint relating to ownership and licensing of the '160 patent are not being filed for any improper purpose, such as to harass or to cause unnecessary delay or needless increase in the cost of litigation.

Dated: July 28, 2017



Mark Lough