Public Version

UNITED STATES INTERNATIONAL TRADE COMMISSION

Washington, D.C.

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

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

Administrative Law Judge MaryJoan McNamara

(September 28, 2018)

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

I. PUBLIC INTEREST

A. Legal Standard

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

[1] On September 20, 2018, I issued the Final Initial Determination ("ID") in this Investigation, finding that Respondent 10X Genomics, Inc. has violated subsection (b) of Section 337 in the importation into the United States, the sale for importation, or the sale within the United States after importation of certain microfluidic devices.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

C. Respondent's Presence in the NGS Marketplace

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

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

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

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

1. Respondent's Accused Chips and Other Products

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

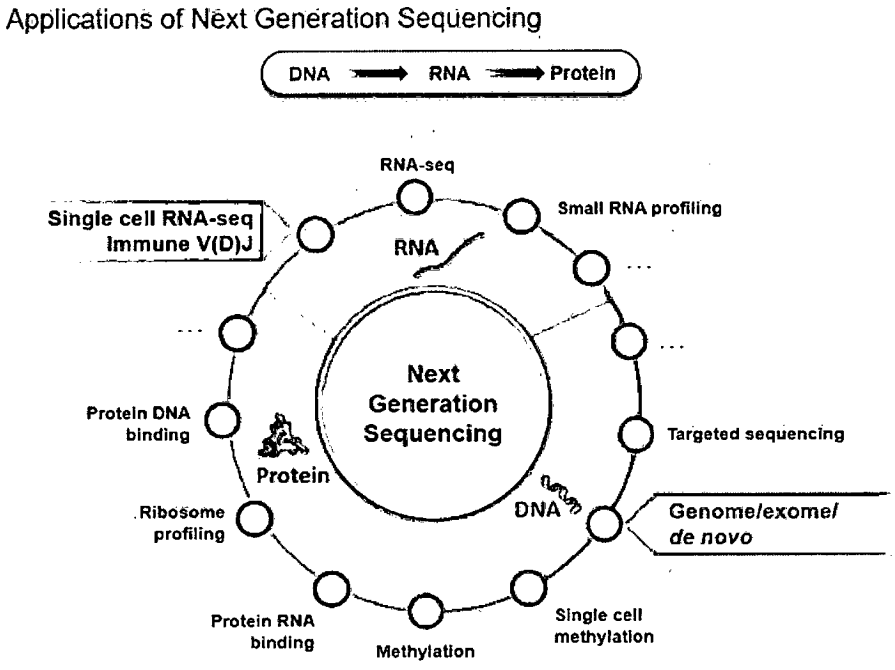
Respondent's "Single-Cell Gene Expression Solution" and "Single-Cell V(D)J Solution" appear to occupy the "single cell RNA-Seq transcriptome" market segment. (Tr. (Mulhern) at 300:10-301:7; JX-0149; CX-0568C (Schnall-Levin Dep. Tr.) at 56:3-57:10.). Respondent's penetration in this market segment is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

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

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

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

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



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

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

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

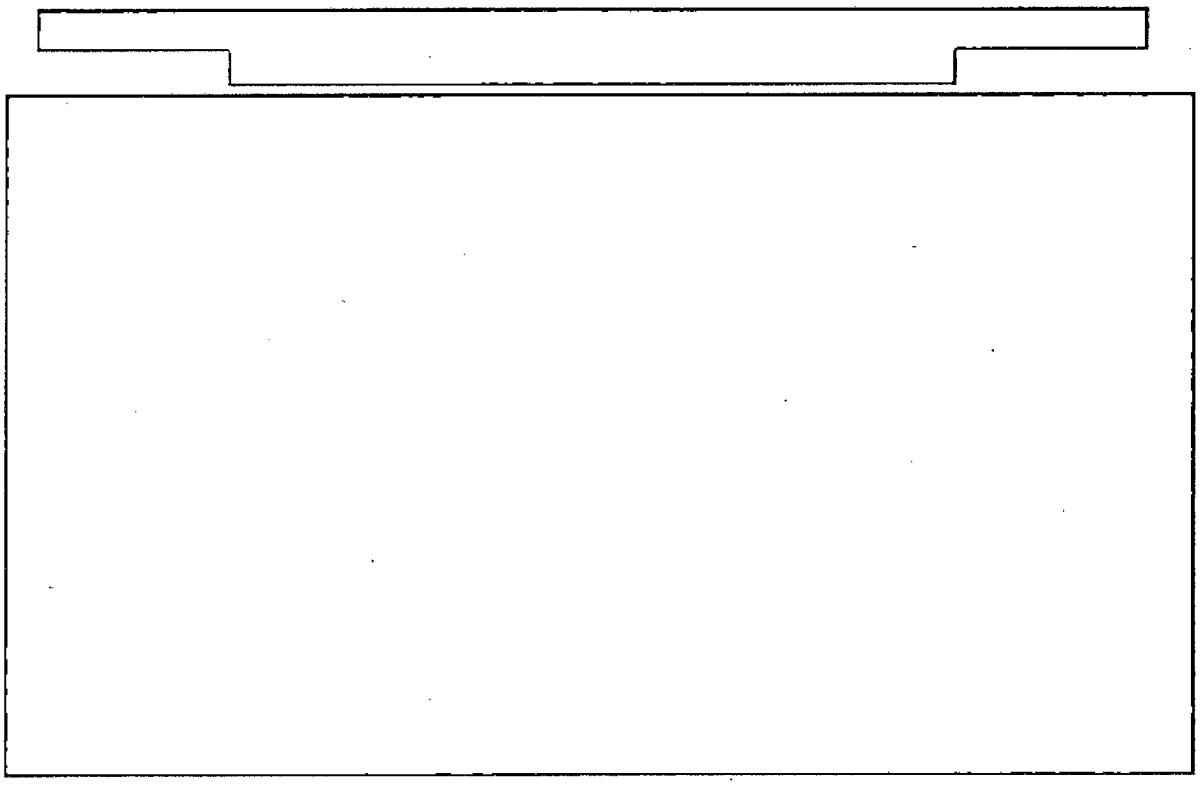
In rebuttal, Respondent critiqued Pacific Bioscience's and Oxford Nanopore's products as being less desirable than its own, or for having "higher error rates and lower cell throughput." (RBr. at 93 (citing Tr. (Schnall-Levin) at 1062:22-1063:25, 1131:21-1132:5; RX-0148C.0003, -0004; CX-0131.0055; CX-0568C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

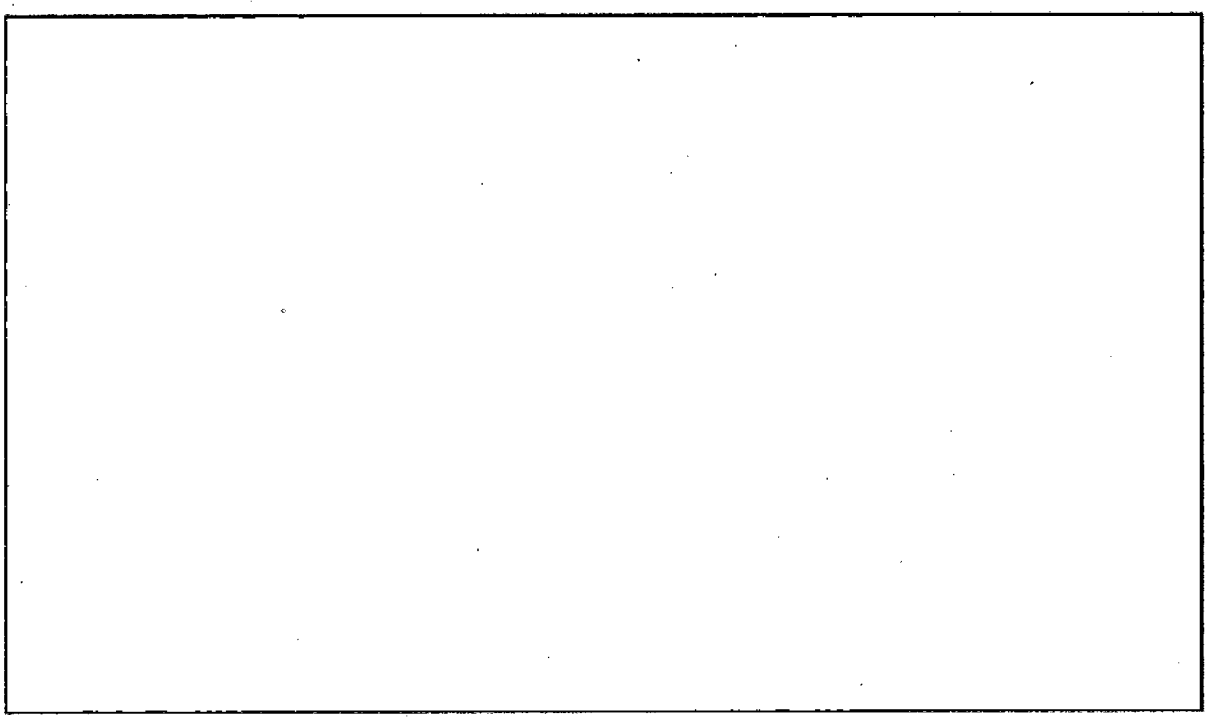
However, Respondent identified only one research application that was purportedly not possible without Respondent's "Linked Read Solution": Dr. Lo's non-invasive prenatal testing. (Tr. (Schnall-Levin) at 1045:12-1046:19, 1086:20-1088:9; RBr. at 88.). Yet, Dr. Schnall-Levin appeared to concede that one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

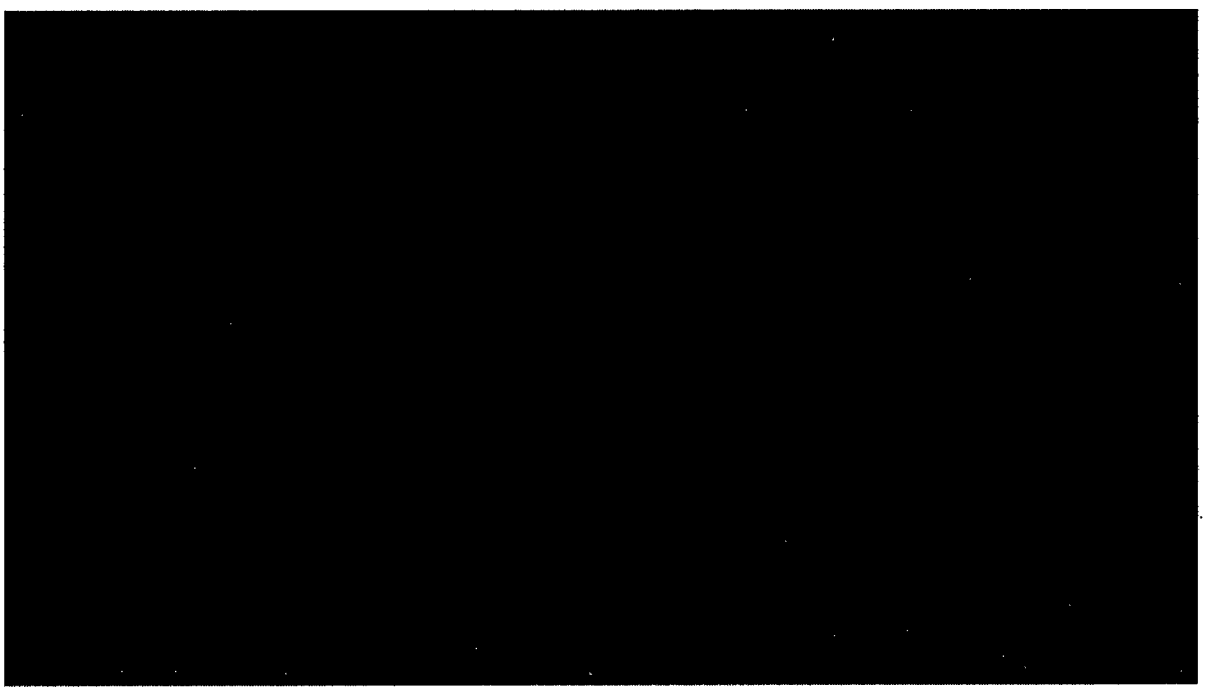
Figure No. 2: Complainants' Depiction of Competition in the "Long Range" Market Segment for Respondent's "Linked Read Solution"

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

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







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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

II. RECOMMENDATION ON REMEDY AND BOND

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

A. Legal Standard

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

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

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

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

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

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

81.).

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

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

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

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

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

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

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

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

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

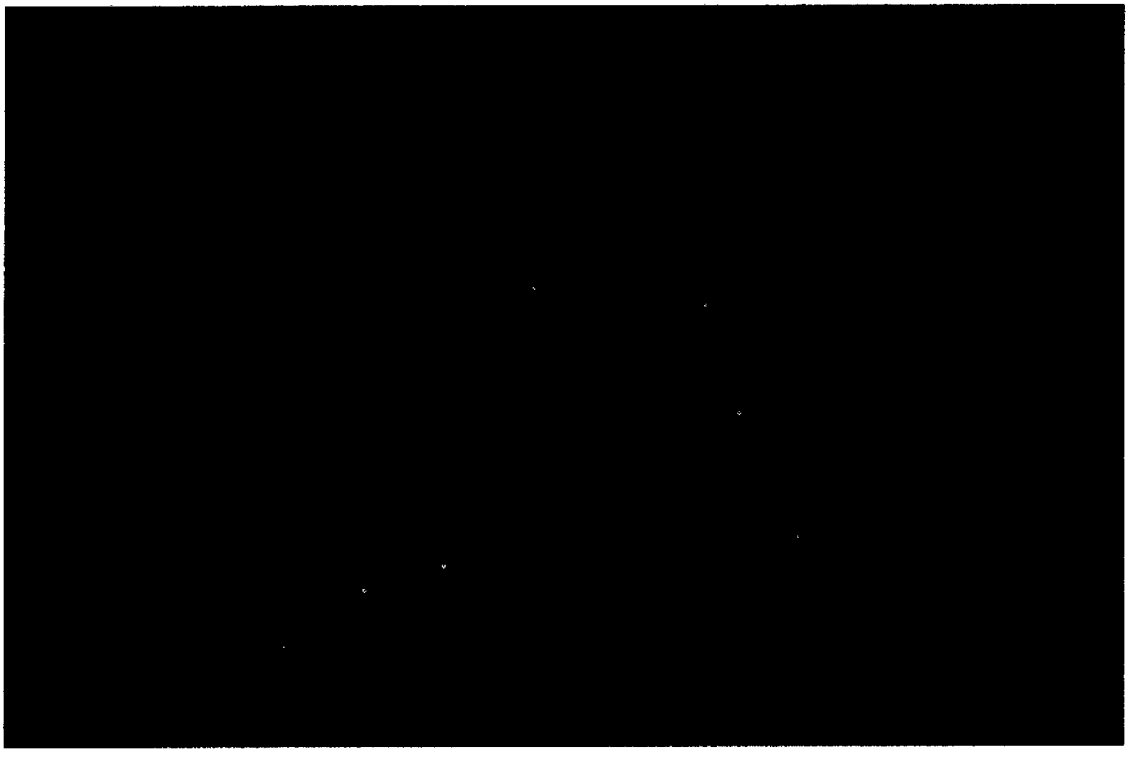
Complainants bear the burden of establishing the need for a bond, including the amount of bond. *See, e.g., Certain Rubber Antidegradants, Components Thereof & Prods. Containing Same*, USITC Pub. No. 3975, Inv. No. 337-TA-533, Comm'n Op. at 40 (April 2008); *Certain Coenzyme Q10 Prods. and Methods of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

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

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

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

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



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

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

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

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

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

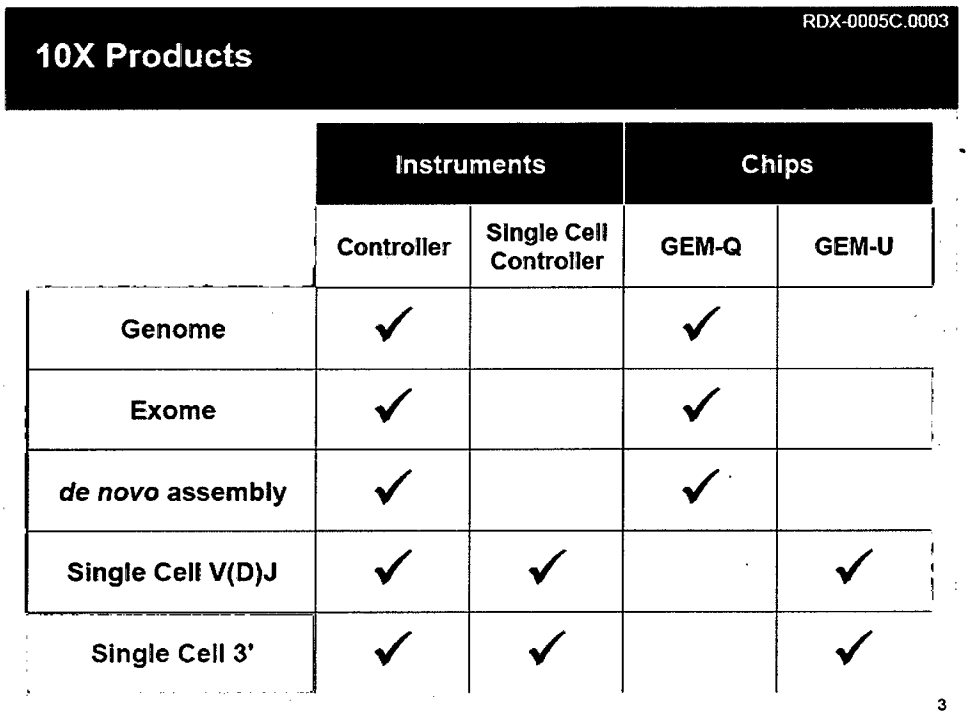
[21] Complainants cited two [redacted] (Tr. (Mulhern) at 307:17-308:18.).

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

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

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

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



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

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

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

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

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

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

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

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

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

D. A Cease and Desist Order Is Warranted

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

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

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

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

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

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

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

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

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

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

SO ORDERED.

MaryJoan McNamara
Administrative Law Judge

PUBLIC CERTIFICATE OF SERVICE

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

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U.S. International Trade Commission
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