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Office of the Secretary Int'l Trade Commission

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VIA HAND DELIVERY

February 23, 2016

Honorable Lisa R. Barton
Secretary
United States International Trade Commission
500 E Street, S.W.
Washington, D.C. 20436

Re: *In the Matter of Certain Nanopores and Products Containing Same*; Inv. No. 337-TA-_____

Dear Secretary Barton:

Enclosed for filing on behalf of Illumina, Inc., the University of Washington, and the UAB Research Foundation ("Complainants") are documents in support of Complainants' request that the Commission commence an investigation pursuant to Section 337 of the Tariff Act, as amended. Pursuant to the Commission's Rules of Practice and Procedure, a request for confidential treatment of Exhibits 3C, 4C, 34C, 65C, 71C-77C, 87C and 95C is submitted concurrently.

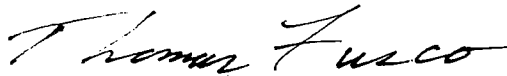
Accordingly, Complainants submit the following:

1. An original and eight (8) copies of the verified Complaint and one (1) CD of the Non-Confidential Exhibits pursuant to 19 C.F.R § 210.8(a)(1)(i);
2. One (1) CD of the Confidential Exhibits pursuant to 19 C.F.R § 210.8(a)(1)(ii);
3. Two (2) additional copies of the Complaint and two (2) sets of CDs containing the Confidential and Non-Confidential Exhibits for the proposed respondents pursuant to 19 C.F.R § 210.8(a)(1)(iii);
4. One (1) additional copy of the Non-Confidential Complaint for service upon the Embassy of the United Kingdom in Washington, D.C. pursuant to 19 C.F.R § 210.8(a)(1)(iv);
5. One (1) certified copy each of U.S. Patent Nos. 8,673,550 & 9,170,230, ("the '550 & '230 patents") included with the Complaint as Exhibits 1 and 92 respectively, pursuant to 19 C.F.R § 210.12(a)(9)(i);

February 23, 2016

6. One (1) certified copy each of the prosecution histories of the '550 & '230 patents, included with the Complaint as Appendices A and B respectively, plus three (3) additional copies thereof, pursuant to 19 C.F.R § 210.12(c)(1);
7. One (1) certified copy of the assignment records of the '550 & '230 patents, included with the Complaint as Exhibit 2, pursuant to 19 C.F.R § 210.12(a)(9)(ii);
8. Four (4) CDs of the technical references identified in the prosecution histories of the '550 & '230 patents, included with the Complaint as Appendices C and D respectively pursuant to 19 C.F.R § 210.12(c)(2);
9. A request for the confidential treatment of the accompanying Confidential Exhibits and Attachments pursuant to 19 C.F.R § 201.6(b); and
10. A statement regarding the public interest pursuant to 19 C.F.R § 210.8(b).

Respectfully submitted,



Thomas S. Fusco

Enclosures

UNITED STATES INTERNATIONAL TRADE COMMISSION
WASHINGTON, D.C.

In The Matter Of
CERTAIN NANOPORES AND
PRODUCTS CONTAINING SAME

Investigation No. 337-TA-____

**COMPLAINANTS' STATEMENT
ON THE PUBLIC INTEREST**

Pursuant to U.S. International Trade Commission Rule § 210.8(b), Complainants Illumina, Inc., the University of Washington, and the UAB Research Foundation submit this separate Statement on the Public Interest, filed concurrently with their Complaint. As discussed below, issuance of the relief requested will not adversely impact the public health, safety, or welfare conditions in the United States, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, or United States consumers. Thus, this Investigation does not present an instance where the Commission, the parties, and the public should be required to undergo the time and expense of discovery and trial for a Recommended Determination by the ALJ on the public interest.

I. THE REQUESTED REMEDIAL ORDERS ARE IN ACCORD WITH THE PUBLIC INTEREST

There is a strong public interest in protecting intellectual property rights. *Certain Baseband Processor Chips and Chipsets, Transmitter and Receiver (Radio) Chip, Power Control Chips*, Inv. No. 337-TA-543, USITC Pub. 4258 (Nov. 2011). In this case, the requested remedial orders are in accord with the public interest for at least the following reasons: (1) exclusion of the accused products will not have an adverse effect on the public health or welfare, as those issues are defined by the Commission; (2) only a small subset of the industry selling or offering for sale sequencing products in the United States would be barred; and (3)

Illumina and third parties will be in a position to fill any void in the market caused by the requested remedial orders. As such, the public interest in protecting Complainants' intellectual property rights outweighs any potentially adverse impact on the public.

A. How the articles potentially subject to the remedial orders are used in the United States

The accused products at issue in this Investigation are certain nanopores and products containing same. The accused products are used primarily for determining the sequence of nucleotide bases in DNA and other nucleic acids. Each of the accused products infringes Complainants' patent rights. The infringing products are imported into, sold for importation into, and/or sold after importation in the United States by or on behalf of the Proposed Respondents identified in the Complaint.

B. Identification of any public health, safety, or welfare concerns in the United States relating to the requested remedial orders

The issuance of the requested remedial orders would not adversely affect the public health, safety, or welfare in the United States. Proposed Respondents' products are not approved medical devices, pharmaceuticals, vaccines, or products otherwise used to treat or cure a disease or injury. Nor are these products otherwise implicated with the public health, safety, or welfare.

Although the Proposed Respondents' products are used by researchers in the United States for sequencing nucleic acids, their products represent a small portion of the DNA sequencing market. The number of researchers who would be affected by remedial orders directed to the Proposed Respondents' accused products is relatively small—only about 1% of the overall market according to one analyst report.¹ Moreover, as set forth in more detail in the following section, Illumina and other manufacturers of nucleic acid sequencing devices are more

¹ "Next Generation Sequencing Markets", Kalorama Information, February 2015. Because this report is approximately 400 pages long, Complainants are not able to attach it as an exhibit to this statement. However, counsel for Complainants will provide the Commission a copy of the report if so requested.

than capable of supplying substitutes for the Proposed Respondents' excluded products, thus overriding any concerns regarding whether the remedial orders would adversely affect the public health. Since the accused products represent a relatively small amount of the U.S. market, any remedial orders will not have a material effect on the market for such products because competing products are otherwise available from Illumina and other sources.

C. Identification of like or directly competitive articles that Illumina, its licensees, or third parties make which could replace the subject articles if they were excluded

The accused products in this Investigation are certain nanopores and products containing same used for sequencing strands of DNA. The United States market for genome sequencing devices is served by Illumina itself and several alternatives. For example, Illumina's own products in the DNA sequencing market could replace the accused products if the accused products were excluded from the United States, including, but not limited to, Illumina's MiSeq, MiniSeq, NextSeq, and other products that serve the full spectrum of the market. In addition, sequencers sold by Thermo Fisher Scientific Corporation (under the name "Life Technologies") (<https://www.thermofisher.com/us/en/home/brands/ion-torrent.html>) and Pacific Biosciences, Inc. (<http://www.pacb.com/products-and-services/pacbio-systems/>) could replace ONT's products if they were excluded. These other competitor products utilize alternatives to the technology claimed in the Asserted Patents, and thus their availability would not be affected by any remedial order issued by the Commission relating to the Asserted Patents.

D. Illumina and/or third parties will be in a position to replace the volume of articles subject to the requested remedial orders in a commercially reasonable time in the United States

Illumina and/or other manufacturers, including those listed in the previous section, have sold and continue to sell competitive sequencing systems in the United States that can produce similar results as the accused products. Further, as noted previously, ONT's products account

for a very small percentage of the United States market for sequencing devices, as little as 1 % according to one third party report. Therefore, Illumina and/or other manufacturers will be able to replace the infringing products subject to the requested remedial orders within a commercially reasonable time in the United States. There is thus no reason to hold an evidentiary hearing to establish that the exclusion of the Proposed Respondents' accused products would not result in any adverse impact to this already well-supplied market.

E. The requested remedial orders will not adversely impact U.S. consumers

The issuance of exclusion and cease and desist orders in this Investigation banning the accused products will not adversely impact consumers in the United States. Illumina will be able to adequately supply and meet the demand of the United States market. In addition, as noted above, there are third parties that supply competitive products to the United States market. Given that there would be no unfilled void because there are substitute products, including those made and sold by Illumina and other parties that could replace the volume of the excluded articles, any impact to the public interest by the exclusion of the Proposed Respondents' infringing products will be minimal.

In addition, the public interest favors the protection of intellectual property rights in this country. *Certain Two-Handle Centerset Faucets & Escutcheons*, Inv. No. 337-TA-422, Comm'n Op. at 9 (June 19, 2000). The exclusion of the accused products in this proposed investigation will therefore serve the public interest by protecting significant intellectual property rights developed by important research universities like the University of Washington and the University of Alabama at Birmingham.

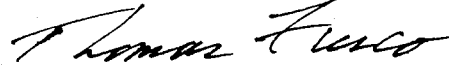
II. CONCLUSION

If the Commission grants the requested remedial orders, the public interest will be served. Exclusion of the accused products will not adversely affect the public health or welfare, and an

adequate supply of substitute devices will be available through at least Illumina and other parties. As such, the strong public interest in protecting Complainants' valid intellectual property rights outweighs any adverse impact on the public.

Respectfully submitted,

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*Counsel for Complainants
Illumina, Inc., University of Washington, and
UAB Research Foundation*

Dated: February 23, 2016

UNITED STATES INTERNATIONAL TRADE COMMISSION
WASHINGTON, D.C.

In The Matter Of
CERTAIN NANOPORES AND
PRODUCTS CONTAINING SAME

Investigation No. 337-TA-___

COMPLAINT OF ILLUMINA, INC., THE UNIVERSITY OF WASHINGTON, AND
THE UAB RESEARCH FOUNDATION UNDER SECTION 337 OF THE
TARIFF ACT OF 1930, AS AMENDED

COMPLAINANTS:

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San Diego, CA 92122

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LIST OF EXHIBITS

1. Certified copy of U.S. Patent No. 8,673,550 (“the ’550 Patent”)
2. Certified assignments of the ’550 and ’230 Patents-in-suit
3. **CONFIDENTIAL** License Agreement Between Illumina and the University of Washington
4. **CONFIDENTIAL** License Agreement Between Illumina and the UAB Research Foundation
5. Illumina webpage describing the history of its sequencing technology (<http://www.illumina.com/technology/next-generation-sequencing/solexa-technology.html>)
6. Illumina webpage providing an overview of its sequencing products (<http://systems.illumina.com/systems/sequencing.html>)
7. Illumina webpage describing its HiSeq X sequencing product (<http://www.illumina.com/systems/hiseq-x-sequencing-system/system.html>)
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9. ONT webpage describing locations of its offices (<https://nanoporetech.com/careers/working-for-oxford-nanopore>)
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13. ONT webpage describing its business and its MinION device (<https://nanoporetech.com/>)
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16. February 4, 2011 e-mail from Dr. Gordon Sanghera, CEO of ONT, to Dr. Jens Gundlach
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42. ONT's Petition for *Inter Partes* Review of U.S. Patent No. 8,637,550 in IPR2015-00057
43. ONT's October 17, 2013 Washington Public Records Act request to University of Washington
44. NHGRI's December 13, 2013 response to Baker Botts November 8, 2013 Freedom of Information Act request to National Human Genome Research Institute
45. ONT's June 5, 2014 Washington Public Records Act request to University of Washington
46. ONT's June 5, 2015 Washington Public Records Act request to University of Washington
47. ONT's July 21, 2014 Washington Public Records Act request to University of Washington
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50. MAP Guide, Equipment and Consumables
51. February 2014 Presentation Slides by ONT's Chief Technology Officer, Dr. Clive G. Brown
52. ONT webpage discussing the availability of MinION (<https://nanoporetech.com/technology-users>)
53. ONT webpage regarding the MinION Access Programme (<https://nanoporetech.com/community/the-minion-access-programme>)
54. ONT webpage regarding the MinION Access Programme (<https://nanoporetech.com/community/the-minion-community-philosophy>)
55. ONT webpage explaining how to pay for the MinION Access Programme (<https://nanoporetech.com/community/start-using-minion-what-you-need-to-know/how-to-pay-your-fee>)
56. September 14, 2014 Video Presentation by ONT's Chief Technology Officer, Dr. Clive G. Brown
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64. May 21, 2014 NY Genome Tweet About Using MinION
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66. October 19, 2014 Tweet showing pictures of PromethION and MinION products at the American Society of Human Genetics annual meeting in San Diego, CA
(<https://twitter.com/Scalene/status/523899454663843840/photo/1>)
67. October 17, 2014 Tweet from Oxford Nanopore advertising a MinION demonstration at the American Society of Human Genetics annual meeting in San Diego, CA
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71. **CONFIDENTIAL:** Declaration of Dr. Jeffrey Mandell Regarding Domestic Industry
72. **CONFIDENTIAL:** Claim Chart Demonstrating Illumina's Practice of the '550 patent
73. **CONFIDENTIAL:** Illumina Consulting Agreement
74. **CONFIDENTIAL:** Illumina Consulting Agreement
75. **CONFIDENTIAL:** Illumina Consulting Agreement
76. **CONFIDENTIAL:** Domestic Industry Payments to Contractors
77. **CONFIDENTIAL:** Spreadsheets Regarding Licensing Payments
78. ONT webpage describing its Accused Products
(<https://nanoporetech.com/applications/fields-of-use/fields-of-use>)
79. ONT webpage describing its Accused Products
(<https://nanoporetech.com/applications/analytes-applications-dna-rna-proteins>)

80. ONT webpage describing its Accused Products
(<https://nanoporetech.com/applications/dna-nanopore-sequencing>)
81. February 2014 Presentation of ONT's Chief Technology Officer, Clive Brown, describing the functionality of the accused products
82. ONT webpage describing its Accused Products
(<https://nanoporetech.com/science-technology/introduction-to-nanopore-sensing/introduction-to-nanopore-sensing>)
83. ONT webpage describing its Accused Products
(<https://nanoporetech.com/science-technology/introduction-to-nanopore-sensing/biological-nanopores>)
84. ONT webpage describing its PromethION device
(<https://nanoporetech.com/>)
85. ONT webpage describing its Accused Products
(<https://nanoporetech.com/science-technology/workflow-versatility-no-fixed-runtime/nanopore-sensing-informatics>)
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(<https://nanoporetech.com/science-technology/how-it-works>)
87. **CONFIDENTIAL:** Payments to Domestic Industry Contractors
88. Baker Botts July 24, 2014 FOIA Request to the National Institutes of Health
89. Baker Botts August 5, 2014 FOIA Request to the National Institutes of Health
90. ONT's PCT Appl. Publ. No. WO 2015/110813 A1
91. ONT's PCT Appl. Publ. No. WO 2015/110777 A1
92. Certified copy of U.S. Patent No. 9,170,230 ("the '230 Patent")
93. Exemplary Claim Chart Comparing the Independent Claims of the '230 Patent to the MinION
94. Exemplary Claim Chart Comparing the Independent Claims of the '230 Patent to the PromethION
95. **CONFIDENTIAL:** Claim Chart Demonstrating Illumina's Practice of the '230 Patent
96. Bo Lu et al., *Thermal Motion of DNA in an MspA Pore*, June 30, 2015, available at <http://biorxiv.org/content/biorxiv/early/2015/06/30/021766.full.pdf>

97. Nicholas J. Loman & Aaron R. Quinlan, *Poretools: A Toolkit for Analyzing Nanopore Sequence Data*, OXFORD UNIVERSITY PRESS (Aug. 20, 2014)
98. *Illumina, Inc. v. Oxford Nanopore Techs., Ltd., et al.*, No. 14-2-01553-4 SEA, Superior Court of the State of Washington, King County, Findings of Fact and Conclusions of Law
99. January 12, 2016 Tweet showing ONT's PromethION product at the Plant & Animal Genome XXVI Conference in San Diego, CA, <https://twitter.com/guamfr/status/687034883709915136>
100. Final Program for the Plant & Animal Genome XXVI Conference in San Diego, CA

LIST OF APPENDICES

- A. Prosecution History of the '550 Patent (four copies)
- B. Technical References Mentioned in the Prosecution History of the '550 Patent (four copies)
- C. Prosecution History of the '230 Patent (four copies)
- D. Technical References Mentioned in the Prosecution History of the '230 Patent (four copies)

I. INTRODUCTION

1. Complainants Illumina, Inc. (“Illumina”), the University of Washington, and the UAB Research Foundation (together “Complainants”) request that the United States International Trade Commission institute an investigation pursuant to Section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337, to remedy the unlawful importation into the United States, sale for importation into the United States, and/or sale within the United States after importation by the owner, importer, or consignee (or agents thereof), of certain nanopores and products containing the same (collectively “the Accused Products”) that infringe valid and enforceable United States patents that are owned by the University of Washington and the UAB Research Foundation and exclusively licensed to Illumina.

2. Proposed Respondents Oxford Nanopore Technologies Ltd. and Oxford Nanopore Technologies, Inc. (collectively, “ONT” or “Respondents”) have engaged in unfair acts in violation of Section 337, as amended, through and in connection with the unlicensed importation into the United States, sale for importation into the United States, and/or sale within the United States after importation of Accused Products that infringe, literally or under the doctrine of equivalents, at least one or more claims of United States Patent No. 8,673,550 (“the ’550 Patent”) and at least one or more claims of United States Patent No. 9,170,230 (“the ’230 Patent”). We refer to the ’550 and ’230 patents collectively as “the Patents-in-suit.” The Patents-in-suit are both valid and enforceable U.S. Patents.

3. Complainants assert that Respondents directly infringe, contributorily infringe, and/or induce the infringement of at least claims 2-4, 7-10, 13-15, 17-18, 20-22, 24, 26-28, 31-33, 35-36, and 38-40 of the ’550 Patent and claims 1-31 of the ’230 patent (collectively, “the Asserted Claims”). The table below identifies the independent claims and the claims that depend from them:

Patent	Independent Claim	Dependent Claims
'550 Patent	1 (not asserted)	2-4, 7-10, 13-15, 26, 35, 36
	17	18, 20-22, 27, 28, 31, 38, 39
	23 (not asserted)	24, 40
	32	N/A
	33	N/A
'230 Patent	1	2-9
	10	11-14
	15	16, 17
	18	19-30
	31	N/A

4. Certified copies of the Patents-in-suit accompany this Complaint as Exhibits 1 and 92. The University of Washington and the UAB Research Foundation co-own by assignment the entire right, title, and interest in and to the Patents-in-suit. Certified copies of the recorded assignments of the Patents-in-suit to the University of Washington and the UAB Research Foundation accompany this Complaint as Exhibit 2. The assignments are effective for both the '550 and '230 patents, because an assignment of the "invention" of the original application applies equally to any continuations. *See, e.g., WesternGeco LLC v. ION Geophysical Corp.*, 791 F.3d 1340, 1346-47 (Fed. Cir. 2015) (noting that an assignment of "the invention" in a patent application including assignments of the three patents-in-suit, which were all continuations of the original application); MPEP § 306 (8th ed. Rev. 7, Sept. 2008) ("In the case of a division or continuation application, a prior assignment recorded against the original application is applied (effective) to the division or continuation application because the assignment recorded against the original application gives the assignee rights to the subject matter common to both applications.").

5. Illumina is the exclusive licensee of the Patents-in-suit in the field of all methods of nucleic acid sequencing (including sequencing of RNA and DNA) and genotyping, without market restriction. A copy of the confidential license agreements between Illumina and the

University of Washington and between Illumina and the UAB Research Foundation accompany this Complaint as Confidential Exhibits 3 and 4.

6. As required by Sections 337(a)(2) and 337(a)(3), an industry exists in the United States relating to the Patents-in-suit at least by virtue of Illumina's significant investment in plant and equipment, significant employment of labor and capital, and/or substantial investment in the exploitation of the technologies covered by the Patents-in-suit through activities including engineering, research and development, and licensing. Further information is provided in the confidential Declaration of Dr. Jeffery Mandell Regarding Domestic Industry that is attached to this Complaint as Confidential Exhibit 71 and in Confidential Exhibits 34, 65, 73-77, and 87.

7. Complainants seek a permanent limited exclusion order, pursuant to Section 337(d), excluding from entry into the United States ONT's Accused Products that infringe one or more Asserted Claims of the Patents-in-suit. Complainants also seek a permanent cease and desist order, pursuant to Section 337(f), directed at activities including, but not limited to, importing, marketing, advertising, demonstrating, warehousing inventory for distribution, offering for sale, selling, distributing, or using such Accused Products in the United States.

II. COMPLAINANTS

8. Complainant Illumina is a publicly traded corporation organized under the laws of the State of Delaware and having its principal place of business in the city of San Diego, California.

9. Illumina, founded in 1998, is a leading developer, manufacturer, and marketer of life science tools and integrated systems for the analysis of genetic variation and function. Illumina was founded to commercialize technology developed in the laboratory of Professor David Walt at Tufts University, which could be used to build DNA microarrays that were useful for detecting genetic mutations. Illumina licensed the patents covering that technology from Tufts, and, after several years of hard work and after substantial investment in U.S.-based research and facilities,

Illumina brought embodying products to market in 2003. These initial products were a remarkable success. They could test over 100,000 traits simultaneously, had over \$100 million in sales, and generated over 70% of the data for the International HapMap Project—a large worldwide collaboration that extensively mapped genetic mutations associated with various diseases. Subsequent products practicing the Tufts patents have been even more successful, generating over \$1 billion in revenue to date. Illumina has invested hundreds of millions of dollars in U.S. plant, equipment, labor, capital, engineering, and research in bringing the patented Tufts technology to market.

10. Having developed significant expertise in creating tools for genetic analysis, Illumina next expanded its work to creating DNA sequencing products. Again, Illumina brought products to market based on an idea that originated in a university. Specifically, two University of Cambridge scientists had an idea in 1997 for a technique that later become known as “sequencing by synthesis.” They started a company called Solexa in 1998, and had launched their first sequencer—called the Genome Analyzer— by 2006. It could sequence 1 gigabase (Gb) of data in a single run. *See Exhibit 5.* Illumina acquired Solexa in 2007, and invested hundreds of millions of dollars in U.S. plant, equipment, labor, capital, engineering, and research. Thanks to this innovation and the sizable investments of resources, Illumina’s current sequencing products can sequence over a thousand times more data per run (1 terabase (Tb)), thus allowing researchers to move from ideas to data in a matter of hours or days.

11. Illumina is now the market leader in the genome sequencing business. Illumina offers a broad range of genome sequencing machines and components to meet the needs of scientists and researchers. *See Exhibit 6.* Illumina’s current sequencing products include a diverse set of offerings so that every scientist will have the right product for whatever type of sequencing

they wish to do. Illumina currently has 5 lines of sequencing products—the MiniSeq, MiSeq, NextSeq, HiSeq, and HiSeq X series—from which a user can select based on, among other things, the total numbers of samples they need to run and how quickly they need the results. The MiniSeq series is suitable for low-throughput, targeted DNA and RNA sequencing. The MiSeq series is suitable for smaller genomes or targeted sequencing. Illumina’s NextSeq series is suitable for everyday sequencing. Illumina’s HiSeq series is suitable for production-scale sequencing. Illumina’s HiSeq X series is suitable for population- and production-scale human whole-genome sequencing.

12. In 2014, Illumina’s sequencing products achieved a milestone that researchers had pursued for decades—scientists using Illumina’s HiSeq X series can now sequence the entire human genome for under \$1,000. *See* Exhibit 7.

13. Illumina continues to innovate and develop even better sequencing products. One of Illumina’s approaches involves sequencing using nanopores, which, in this context, are small pores formed using various proteins. The Patents-in-suit protect those nanopores and other important tools associated with this sequencing approach.

14. Complainant University of Washington is a public institution of higher education and an agency of the State of Washington having its principal place of business in the city of Seattle, Washington. UW CoMotion (formerly the UW Center for Commercialization) is the department of the University of Washington responsible for the licensing of university-owned intellectual properties, including patents.

15. Complainant UAB Research Foundation is a non-profit corporation organized under the laws of the State of Alabama having its principal place of business in Birmingham, Alabama. Although the UAB Research Foundation still retains its status as a separate corporate

entity and still holds ownership rights in the Patents-in-suit, it now also does business as part of the University of Alabama at Birmingham's Institute for Innovation and Entrepreneurship.

III. PROPOSED RESPONDENTS

16. Proposed Respondent Oxford Nanopore Technologies Ltd. is, based on information and belief, a corporation organized under the laws of England and Wales that has a principal place of business located at Edmund Cartwright House, 4 Robert Robinson Avenue, Oxford Science Park, Oxford, OX4 4GA, UK. *See* Exhibit 8. ONT also has offices in Cambridge, UK and in the United States in Boston, MA and New York, NY. *See* Exhibit 9.

17. Proposed Respondent Oxford Nanopore Technologies, Inc. is, based on information and belief, a corporation organized under the laws of Delaware with its principal place of business located at 1 Kendall Square, Bldg. 200, Cambridge, MA 02139. *See* Exhibits 10 & 11.

18. According to ONT's website, ONT was founded in 2005 "to develop a disruptive, electronic, single molecule sensing system based on nanopore science." *See* Exhibit 12. ONT's website further explains that it "is developing and commercialising a new generation of nanopore-based electronic systems for analysis of single molecules, including DNA, RNA and proteins." *See* Exhibit 13. ONT's website further states that "the handheld MinION™ device, the high-throughput/high sample number PromethION™ and GridION™ systems are designed to provide novel qualities in molecular sensing such as real-time data streaming, improved simplicity, efficiency and scalability of workflows and direct analysis of the molecule of interest." *Id.*

19. After the inventors of the Patents-in-suit first published their results, ONT recognized the value of the discovery in making nanopore sequencing a reality. ONT contacted the inventors in 2009-2011 about potentially commercializing the inventors' nanopore technology, as shown, for example, by these statements:

- “Having read and discussed your recent publications, we would be most interested in exploring ways in which we could work with you and hopefully help commercialise your technology.” *See* Exhibit 14 (4/10/09 e-mail from Dr. Spike Willcocks, Business Development Director for ONT, to inventor Dr. Jens Gundlach).
- “Many thanks for your time today, Gordon and I thoroughly enjoyed the meeting. We are both very impressed with your work thus far, many congratulations! Please let us know if you have any further queries and I hope we can continue discussions towards a fruitful partnership.” *See* Exhibit 15 (7/1/09 e-mail from Willcocks to Gundlach).
- “I am really excited about MSPA and would like to discuss what we need to do to get you on board.” *See* Exhibit 16 (2/4/11 e-mail from Gordon Sanghera, CEO of ONT, to Dr. Jens Gundlach).

Even ONT’s founder, Dr. Hagan Bayley, published a 2015 article that described the work of the inventors of the Patents-in-suit as a “significant discovery” in the “steps towards nanopore sequencing.” *See* Exhibit 17.

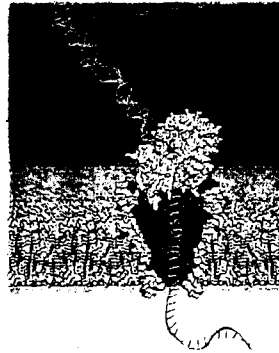
20. On information and belief, ONT designs, manufactures for import, imports into the United States, and/or sells for importation into the United States certain nanopores and products containing nanopores that infringe one or more Asserted Claims of the Patents-in-suit.

IV. THE TECHNOLOGIES AT ISSUE¹

21. The technology at issue covers proteins that can be incorporated into a membrane, like a lipid bilayer, to form microscopic pores called nanopores. Researchers have spent years attempting to use nanopores to analyze the structure of other molecules, such as the sequence of bases found in nucleic acids like DNA. The general idea is to apply an electrical potential to both sides of the nanopore, measure how the current varies as the molecule of interest (e.g., a single strand of DNA) enters and moves through the pore, and use those changes in current to determine

¹ This Complaint, including this section, does not, and is not intended to, construe or limit the scope or meaning of the Patents-in-suit or any of their claims.

the structure of the molecule (e.g., the sequence of the DNA strand). The image below shows an example of a strand of DNA (green) moving through a nanopore (yellow exterior, red interior) that is embedded within a membrane (blue):



See Exhibit 33. The image also shows a molecular motor (white) which separates double-stranded DNA into single-stranded DNA before it enters the nanopore and which slows the single-stranded DNA's movement, making it easier to detect current changes as the strand moves through the nanopore.

22. The Patents-in-suit addressed a difficult problem that had prevented nanopore sequencing from progressing—namely, scientists did not have a nanopore with the right characteristics to allow DNA to pass into the pore in a way that would generate current fluctuations that uniquely correlated with the identity of each individual base. At the time the inventors of the Patents-in-suit began their project, almost everyone else was investigating protein nanopores made from α -hemolysin (α -HL), a protein derived from the *Staphylococcus aureus* bacteria. The conventional wisdom that α -HL nanopores would be the key to sequencing was reflected in U.S. Patent No. 5,795,782, which was filed in 1995. For well over a decade after the '782 patent was filed, α -HL was considered the ideal nanopore to investigate. See, e.g., Exhibits 18, 19, 20.

23. Against this backdrop, the inventors of the Patents-in-suit took a wholly different approach and began investigating nanopores made from a protein derived from *Mycobacterium*

smegmatis. The inventors applied for a research grant in 2006 for projects where “the possible outcomes of the proposed feasibility study are unclear and it is not possible to propose sufficiently clear-cut and quantitative milestones for administrative evaluation.” See Exhibit 21 at 9. After many challenges, including skepticism from other scientists that *Mycobacterium smegmatis* porin (Msp) would actually work, the inventors eventually showed that Msp is a far more promising type of nanopore than anyone expected. See Exhibits 22 & 23. The inventors’ work has shown that Msp is far better than even α -HL because, for example, it generates a signal that is significantly better than that obtained with α -HL, e.g., it has a reduced number of DNA bases that contribute to the current blockade. See, e.g., Exhibit 24.

24. When the inventors published their remarkable results with Msp, others in the field immediately took notice and recognized the value of their work. For example, a 2010 article entitled “Proof-of-Principle Study Shows MspA Is Superior to Alpha-Hemolysin for Protein Nanopore Sequencing,” quoted several independent researchers who recognized that the inventors of the Patents-in-Suit discovered a superior nanopore that finally enabled nanopore sequencing:

Efforts to sequence DNA by threading it through protein-based nanopores have traditionally relied on one protein: alpha-hemolysin. But researchers from the University of Washington have diverged from that route, demonstrating in a recent proof-of-principle study that engineered *Mycobacterium smegmatis* porin A could yield a superior nanopore.

“It’s a proof of principle that nanopore sequencing is going to work. Now it’s just a matter of fine-tuning the method,” said David Deamer, a chemist at the University of California, Santa Cruz, who was not affiliated with the study but who also works with protein nanopores.

“This is very impressive work that has, for the first time, generated real experimental data that mirrors the idealized cartoon where the nanopore current flips between four steady current levels, one corresponding to each base,” said Ken Healy a physicist at the University College Cork in Ireland, and part of a University of Pennsylvania team that recently demonstrated DNA translocation through a graphene nanopore (IS 8/3/2010).

See Exhibit 25. Likewise, a scientist at Life Technologies, another company in the sequencing market, sent one of the inventors a glowing e-mail in 2012 about their results with Msp nanopores and expressed interest in licensing their technology:

Lost in the frenzy around Oxford, seems no one noticed that you are the first person to ever show any actual sequencing AT ALL with a protein nanopore, and also the first to show directing reading of sequence BY ANY means of more than a few contiguous bases . . . which is an historic achievement. Congratulations!

[I]s your technology still open for licensing and development? I do not know how you have proceeded with it, and whether you already have commitments to other parties. If there is still opportunity open, we should discuss.

See Exhibit 26 (capitalized words in original).

25. Illumina also recognized the enormous commercial potential of the inventors' work. In May 2013, Illumina took an exclusive license to the patent applications covering their technology. The '550 patent was the first to issue from the inventors' work, and it did so in March 2014. The '230 patent subsequently issued on October 27, 2015.

V. THE PRODUCTS AT ISSUE

26. Pursuant to 19 C.F.R. 210.12(a)(12), the category of the Accused Products may be described as nanopores and products containing these nanopores. Devices containing the patented nanopore technology allow researchers to more efficiently carry out procedures such as DNA sequencing. The Accused Products include, but are not limited to, ONT's MinION and PromethION devices. See Exhibits 27 & 28 (claim charts showing infringement).

VI. THE PATENTS-AT-ISSUE

A. Identification of the Patents, Ownership, and Licensing

27. The '550 Patent is entitled "Msp Nanopores and Related Methods" and issued on March 18, 2014. The '550 Patent issued from U.S. Patent Application Serial No. 13/069,187, filed on March 22, 2011. The '187 Application is a continuation of PCT Application Serial No.

PCT/US2009/057915, filed on September 22, 2009, and claims the benefit of Provisional Application No. 61/098,938, filed on September 22, 2008. The '550 Patent names as inventors Jens H. Gundlach, Michael Niederweis, Thomas Z. Butler, Mikhail Pavlenok, Mark A. Troll, Suja Sukumaran, and Bertil Hille. The '550 Patent is valid, enforceable, and is currently in full force and effect.

28. The '230 Patent is entitled "Msp Nanopores and Related Methods" and issued on October 27, 2015. The '230 Patent issued from U.S. Patent Application Serial No. 14/215,871, filed on March 17, 2014. The '871 Application is a continuation of the '550 patent, which is a continuation of PCT Application Serial No. PCT/US2009/057915, filed on September 22, 2009, that claims the benefit of Provisional Application No. 61/098,938, filed on September 22, 2008. The '230 Patent names as inventors Jens H. Gundlach, Michael Niederweis, Thomas Z. Butler, Mikhail Pavlenok, Mark A. Troll, and Suja Sukumaran. The '230 Patent is valid, enforceable, and is currently in full force and effect.

29. The University of Washington and the UAB Research Foundation are the owners, by valid assignment, of the entire right, title, and interest in the Patents-in-suit. *See* Exhibit 2.

30. Illumina is the exclusive licensee of the Patents-in-Suit in the field of nucleic acid sequencing. *See* Exhibits 3 & 4.

31. Pursuant to Rule 210.12(c), the Complaint is accompanied by Appendices A, B, C, and D. Appendix A contains a certified copy and three additional copies of the prosecution history of the '550 Patent, Appendix B contains four copies of each technical reference mentioned in that prosecution history of the '550 Patent, Appendix C contains a certified copy and three additional copies of the prosecution history of the '230 Patent, and Appendix D contains four copies of each technical reference mentioned in that prosecution history of the '230 Patent.

B. Non-Technical Description of the Patented Invention²

32. The Patents-in-suit describe *Mycobacterium smegmatis* porin (“Msp”) nanopores, nanopore systems, and methods of making and using such nanopores and systems. The *Mycobacterium smegmatis* porin is a nanometer-scale pore. See, e.g., Exhibit 1 at 20:1-42; Exhibit 92 at 20:21-62. The Patents-in-suit describe methods of making Msp nanopores having particular structures and properties. The Patents-in-suit describe numerous Msps, including various mutant Msps and single-chain Msps where one or more Msp monomers are connected or linked. The Patents-in-suit also describe systems that comprise these nanopores and methods of using these nanopores to detect and identify analytes.

C. Foreign Counterparts to the Patents-in-suit

33. The following foreign patents and patent applications correspond to the Patents-in-suit:

Patent/Application No.	Status
International PCT Application Publication No. WO2010034018A2	Published on March 25, 2010
European Patent Application Publication No. EP2344891A2	Published on July 20, 2011
European Patent Application No. EP15202190.3	Filed on June 20, 2014
Canadian Patent Application Publication No. CA2774710A1	Published on March 25, 2010
Chinese Patent No. CN102216783B	Issued on April 1, 2015
Chinese Patent Application Publication No. CN104710519A	Published on June 17, 2015

² This section, like the rest of the Complaint, does not, and is not intended to, construe or limit the scope or meaning of the Patents-in-suit or their claims.

German Patent No. DE202009019021 U1	Issued on September 24, 2015
German Patent Application No. DE202015000731.7	Filed on September 22, 2009
Hong Kong Patent Application No. HK15112202.2	Filed on December 10, 2015

No other foreign patents or patent applications corresponding to the patents in suit have been filed, abandoned, withdrawn, or rejected.

VII. UNLAWFUL AND UNFAIR ACTS OF PROPOSED RESPONDENTS

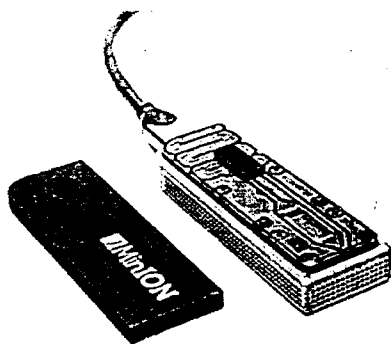
34. On information and belief, ONT's Accused Products directly infringe, contributorily infringe, and/or induce the infringement of at least the Asserted Claims, *i.e.*, claims 2-4, 7-10, 13-15, 17-18, 20-22, 24, 26-28, 31-33, 35-36, and 38-40 of the '550 Patent and claims 1-31 of the '230 patent. Upon information and belief, the use, sale, offer for sale, and importation of nanopores and products containing these nanopores directly infringes the Asserted Claims. Further, as discussed in the paragraphs below, ONT also contributorily infringes and/or induces infringement of the Asserted Claims, having had knowledge of the '550 patent since March 18, 2014, and knowledge of the '230 patent since October 27, 2015. Discovery may reveal that ONT infringes additional claims of the Patents-in-suit.

35. On information and belief, ONT manufactures, assembles, packages and tests, and/or purchases the Accused Products outside the United States, specifically, at least in the UK. ONT then imports into the United States, sells for importation, and/or sells within the United States after importation, the Accused Products.

36. On information and belief, and by way of example, ONT directly infringes, contributorily infringes, and/or induces infringement of one or more of the Asserted Claims by selling, selling for importation, and importing nanopores and products containing the same, such

as MinION and PromethION in the United States. The MinION and PromethION devices are representative of the larger group of ONT nanopores and products containing the same that constitute the Accused Products at issue in this investigation. Claim charts demonstrating how these representative Accused Products infringe claims 1, 2, 17, 23, 24, 32 and 33 of the '550 Patent and independent claims 1, 10, 15, 18 and 31 of the '230 Patent are attached to the Complaint as Exhibits 27, 28, 93, and 94, respectively.³ Further discovery may reveal additional infringing ONT products and/or models.

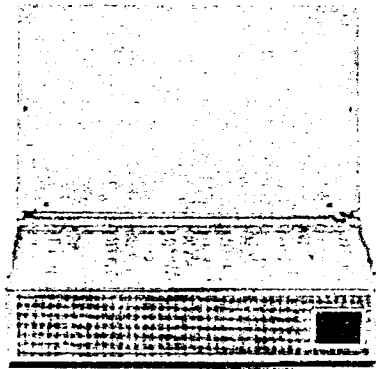
37. According to ONT's website, the MinION device is "a portable device for molecular analyses that is driven by nanopore technology." *See* Exhibit 13. The MinION device comprises a consumable flow cell integrating a sensor chip and an Application-Specific Integrated Circuit (ASIC) such that each of the nanopores contained in the sensor chip is connected to a channel of the ASIC. *See* Exhibit 29. An exemplary MinION device is shown below:



38. According to ONT's website, the PromethION device "is a high throughput, desktop instrument for molecular analyses driven by nanopore technology," *see* Exhibit 84, and

³ A chart for claims 1 and 23 of the '550 patent is provided because some of the asserted claims depend from either claim 1 or claim 23. Neither claim 1 nor claim 23 are themselves asserted. The claim charts also reflect how ONT infringes dependent claims that depend from claims 1 and 23.

can run up to “48 flow cells.” *See* Exhibit 30. On information and belief, the PromethION device uses the same core components as the current and/or planned MinION device, including the flow cell, sensor chip, ASIC, and software interface. *See* Exhibits 29 & 30. An exemplary PromethION device is shown below:



39. ONT has not publicly identified the type of nanopore used in the Accused Products, and an ONT spokesperson has indicated that ONT “does not plan to disclose the precise nanopore and enzyme that it will use in its system.” *See* Exhibit 39. Moreover, Complainants are unable to obtain and examine a physical specimen to identify the nanopore used in the Accused Products.⁴ Nevertheless, a large quantity of circumstantial evidence indicates that the Accused Products more likely than not contain Msp nanopores. That circumstantial evidence is discussed below and in the claim charts attached as Exhibits 27, 28, 93, and 94.

40. As an initial matter, ONT previously told the inventors of the Patents-in-suit that it wanted to “help commercialise your technology,” *see* Exhibit 14, and its CEO told the inventors

⁴ As addressed in Section VII. below, the MinION or PromethION devices are not available to members of the public through means other than the MinION Access Programme (“MAP”) or the PromethION Early Access Programme (“PEAP”). Because Complainants do not qualify to participate in ONT’s MAP or PEAP, they have been unable to obtain a sample of the MinION device or the PromethION device.

that “I am really excited about MSPA [a particular type of *Msp* nanopore] and would like to discuss what we need to do to get you on board.” *See* Exhibit 17. Those statements show that ONT has been very interested in putting *Msp* nanopores into commercial products, like the MinION and PromethION. And, from the other evidence below, it appears that ONT simply decided to take the inventors’ patented technology anyway, even though ONT did not secure a license.

41. ONT’s founder stated recently that ONT’s process for getting data “could be deduced in outline, at least, from presentations and *patent filings*.” Exhibit 17 at p. 5 (emphasis added). ONT’s pending patent applications tout the advantages of *Msp* nanopores for sequencing, disclose and claim *Msp* nanopores covered by the Patents-in-suit, and include working examples that use *Msp* nanopores covered by the Patents-in-suit. *See, e.g.*, Exhibits 35-37, 90-91. For example, one of ONT’s patent applications, which was filed well after the priority date of the Patents-in-suit, states that “[t]he inventors have surprisingly demonstrated that novel mutants of *Msp* display improved properties for estimating the characteristics, such as the sequence of nucleic acids.” *See* Exhibit 35 (U.S. Patent Appl. Publ. No. 2014/0186823) at ¶ 0007. All the *Msp* nanopores in that ONT patent application are derived from one of the mutant *Msp* nanopores disclosed in the Patents-in-suit. *Compare* Exhibit 92 at 45:56-59 (’230 patent, disclosing *MspA* nanopore with mutations at positions 90, 91, 93, 118, 134, and 139), *and* Exhibit 1 at 45:55-58 (’550 patent, disclosing same), *with* Exhibit 35 at ¶ 120 (ONT patent application starting from the same *MspA* nanopore with mutations at positions 90, 91, 93, 118, 134, and 139). Many of ONT’s other published applications include working examples that exclusively use *MspA* nanopores. *See, e.g.*, Exhibit 35 at 47, ¶ 0006, and ¶¶ 0111-0117; Exhibit 36 at ¶¶ 0193-94, and ¶ 217; Exhibit 37 at ¶¶ 197, 211, 216; Exhibit 90 at p. 78, lines 11-13 and p. 80, lines 19-20; Exhibit 91 at p. 69, lines 19-21, p. 72, lines 21-22, and p. 74, lines 16-17; *see also* Exhibits 27-28, 93-94 (claim charts).

Based on this evidence, ONT's Accused Products are more likely than not to include the Msp nanopores described and claimed in those pending patent applications.

42. ONT has distributed MspA nanopores to others in the United States. For example, one recent paper from Boston, MA posted on June 30, 2015, entitled "Thermal motion of DNA in an MspA pore," states that "[t]he MspA protein nanopore was provided by Oxford Nanopore Technologies, Inc., and is the G75S/G77S/L88N/D90N/D91N/D93N/D118R/Q126R/D134R/E139K mutant of wild-type MspA." Exhibit 96 at 5. ONT's distribution of these MspA nanopores is itself a separate act of infringement, because, as shown in the claims charts attached as Exhibits 27-28 and 93-94, many of the Asserted Claims cover the Msp nanopore mutants themselves. In addition, the fact that ONT has a supply of infringing Msp nanopores on-hand that it has made available to others in the United States, and that it is seeking to learn additional information about the properties of Msp nanopores, indicates that ONT is also using Msp nanopores in its accused MinION and PromethION products.

43. ONT has also taken aggressive steps to pre-emptively attack the validity of the '550 patent, which indicates that it knows its current MinION and PromethION products infringe the patent. For example, ONT filed two petitions for *inter partes* review of the '550 Patent on the same day that it issued, March 18, 2014. *See* Exhibits 40 & 41. When one of those petitions was denied, ONT subsequently filed a third petition for *inter partes* review of the '550 Patent. *See* Exhibit 42. There was little reason for ONT to challenge the '550 patent's validity so swiftly and so vigorously unless its current products were infringing the patent.

44. ONT has also sought to uncover the details of the exclusive license agreements between Illumina and the Universities, thus again indicating that ONT knows it is infringing the '550 and '230 patents. In mid-October 2013, the Universities issued press releases disclosing that

they had given Illumina exclusive rights to commercialize the technology covered by the '550 and '230 Patents for nucleic acid sequencing. Within days of this announcement, Mr. Matt Wood of Baker Botts, acting on behalf of ONT, submitted a request to the University of Washington under the Washington Public Records Act, seeking disclosure of all license agreements between the University and Illumina, all license agreements relating to DNA-sequencing technology (including but not limited to technology developed by Dr. Jens Gundlach, the first-named inventor of the Patents-in-suit), and other related documents. *See* Exhibit 43. On June 5 and July 21, 2014, Mr. Wood submitted three additional public records requests to the University of Washington seeking additional materials relating to the license between the University and Illumina, documents relating to consulting work performed by Drs. Jens Gundlach and Ian Derrington for Illumina, and documents relating to certain NIH grants used to support research relating to nanopore sequencing. *See* Exhibits 45, 46, and 47. Mr. Wood also submitted an open records request to the University of Alabama, Birmingham seeking licensing agreements between the University of Alabama and Illumina, and communications between the University of Alabama, Illumina and the University of Washington relating to the licensing of nanopore technology. *See* Exhibit 48. Baker Botts also submitted several requests under the Washington Public Records Act and FOIA for grant applications related to the inventors and Illumina's ongoing work. *See* Exhibits 44, 88, and 89. And, as discussed further below, ONT intervened in a Washington state court action and unsuccessfully sought disclosure of the confidential terms of Illumina's license with the University of Washington. *See* Exhibit 98. ONT's intense interest in the licensing terms further indicates it knows that it is infringing the '550 and '230 patents and wants to assess its potential liability for that infringement.

45. A member of ONT's technology advisory board, Dr. Mark Akeson, has publicly implied that ONT uses Msp nanopores through his comments on a paper published by one of the inventors of the Patents-in-suit, Dr. Gundlach, about Msp nanopores. *See* Exhibit 31. In particular, Dr. Akeson commented that Dr. Gundlach's paper is a "'very nice set of experiments and important *confirmation*' of the work being done at Oxford Nanopore." *See* Exhibit 31 (emphasis added). Dr. Gundlach's paper describes "recent progress with respect to nanopore resolution and DNA control to interpret the procession of ion current levels observed during the translocation of DNA through the pore *MspA*." *See* Exhibit 32 (abstract) (emphasis added). Dr. Akeson's comments indicate that ONT is also using MspA nanopores—otherwise, Dr. Gundlach's paper could not provide "confirmation" of anything happening at ONT.

46. All of the foregoing evidence shows that it is more likely than not that the Accused Products contain Msp nanopores, despite ONT's continuing efforts to hide the identity of the nanopore used in the Accused Products. Based on this evidence as well as the additional evidence presented in the claim charts attached as Exhibits 27, 28, 93, and 94, the Accused Products thus infringe at least the Asserted Claims.

47. On information and belief, ONT also actively induces others to infringe the Asserted Claims through its importation, sale, and offer to sell the Accused Products to customers in the United States along with directions, demonstrations, guides, manuals, training for use, and other materials that encourage the infringing use of the Accused Products. ONT also advertises on its website that customers are able to "ask questions of Oxford Nanopore support staff," thus providing an additional example of how ONT encourages them to use the products in an infringing manner. *See* Exhibit 49. Because it had knowledge of the '550 and '230 Patents as discussed in the preceding paragraphs, ONT induced such infringing acts and knew or should have known that

its actions would induce actual infringement of the Patents-in-suit. For example, on information and belief, in order to partake in ONT's MinION Access Programme ("MAP") or PromethION Early Access Programme ("PEAP"), each participant must agree to ONT's "Terms and Conditions," which require each participant to conduct certain "burn-in experiments" that use the MinION or PromethION to perform DNA sequencing in a manner covered by the '550 and '230 patents. *See* Exhibit 49; Exhibit 50 at 3-4; Exhibit 51 at 22. As part of these mandatory "burn-in experiments," when the performance of the MinION device is observed to be appropriate, MAP participants are required to "formally notify Oxford Nanopore that [they] have satisfied that the [burn-in experiment] outcome is suitable for [their] own experiments." *See* Exhibit 49. Based on its knowledge of the '550 and '230 Patents, ONT knows that these mandatory "burn-in experiments" infringe one or more of the Asserted Claims.

48. On information and belief, ONT also contributorily infringes certain of the Asserted Claims through its sale and offers to sell within the United States and/or imports into the United States of components of the Accused Products and/or Accused Products for use in practicing a process, constituting a material part of the Asserted Claims, knowing the same to be especially made or especially adapted for use in an infringement of the Patents-in-suit, and not a staple article or commodity of commerce suitable for substantial noninfringing use. For example, on information and belief, the ONT nanopores and products containing the same are specifically designed to sequence analytes such as DNA. Due to their specific design, the ONT nanopores and products containing the same do not have any substantial non-infringing uses.

VIII. SPECIFIC INSTANCES OF UNFAIR IMPORTATION AND SALE

49. On information and belief, ONT manufactures the Accused Products at least in UK, and then imports them into the United States, sells them for importation into the United States, and/or sells them within the United States after importation.

50. For example, ONT imports and distributes the MinION devices to users in the United States through its MinION Access Programme (“MAP”). According to ONT’s website, “MinION and consumables are now available to purchase by joining the MinION Access programme.” *See* Exhibit 52. The MAP is a “community-focused access project which started in Spring 2014,” *see* Exhibit 53, and designed to “allow[] scientists to develop sensing applications such as DNA sequencing” on the MinION device. *See* Exhibit 54. To join the MAP, a participant must “create an account by completing the registration form,” and then will be provided with “a login to the MAP secure website” if the “joining requirements” are met. *See* Exhibit 53. Finally, the participant must also pay an access fee of \$1,000 and agree to ONT’s terms and conditions to receive the MinION device. *Id.*

51. ONT’s website indicates that ONT has shipped its MinION devices to U.S.-based MAP participants. For example, ONT’s website provides a separate tab, titled “United States of America,” to tell U.S. customers how to pay the access fee. *See* Exhibit 55. As another example, ONT has offices in Boston and New York, and, on information and belief, these offices provide customer services to U.S.-based MAP participants. *See* Exhibit 9.

52. Various public statements by ONT and MAP participants show that ONT has been shipping MinION devices to users in the United States. For example, a September 14, 2014 video presentation by Dr. Clive Brown, Chief Technology Officer of ONT, included a world map showing the locations of MAP participants, including many sites in the United States. *See* Exhibit 56 at 54. This map is reproduced below:

Delivering around the Globe



- MAP Packages distributed globally
- Average delivery time 2.6 days
- MAP participants use 📄 as proof of delivery

 NANOPORE

53. MAP participants in the United States have published numerous articles describing or mentioning their experience using the MinION device. *See, e.g.*, Exhibits 57-64. These users are located throughout the United States, including in Santa Cruz and San Francisco, California; Cambridge, Massachusetts; Providence, Rhode Island; and Cold Spring Harbor and New York City, New York. *See id.*

54. On information and belief, ONT has imported and used the MinION and PromethION devices in the United States, including at the American Society of Human Genetics annual meeting held from October 18-22, 2014, in San Diego, California. *See* Exhibits 66, 67, and 68.

55. On information and belief, ONT imported and used the MinION and PromethION device in the United States, including at the Plant and Animal Genome XXIV conference in San Diego, California held from January 9-13, 2016. *See* Exhibits 38, 99, 100.

56. On information and belief, ONT also has established a program to import and distribute the PromethION devices to users in the United States called the PromethION Early Access Programme (“PEAP”), which is similar to the MAP. The PEAP allows participants to

purchase the PromethION device if they meet certain conditions and pay an access fee of \$24,000, and a \$75,000 deposit for the device. *See* Exhibit 69; Exhibit 70 (“Oxford Nanopore Technologies last week outlined the early-access program for its PromethION sequencer, including some pricing information.”).

57. On information and belief, ONT imported MspA nanopores and distributed them to a member of its technical advisory board who is located in Massachusetts. *See* Exhibit 96 at 5.

58. Accordingly, on information and belief, ONT has imported and continues to import the Accused Products into the United States.

IX. CLASSIFICATION UNDER THE HARMONIZED TARIFF SCHEDULE

59. The Accused Products are believed to fall within at least the following classifications of the Harmonized Tariff Schedule of the United States: 9027.50.40, 9027.90.54, 8479.89.98, 3507.90.70, 3822.00.50. These classifications are intended for illustration only and are not intended to be restrictive of the Accused Products.

X. LICENSEES

60. Illumina is the exclusive licensee of the Patents-in-suit in the field of nucleic acid sequencing. *See* Exhibits 3 & 4.

XI. ILLUMINA SATISFIES THE DOMESTIC INDUSTRY REQUIREMENT

61. As required by Section 337(a)(2) and defined by Section 337(a)(3), a domestic industry exists in the United States with respect to articles protected by the Patents-in-suit.

A. Illumina Satisfies the Technical Prong of the Domestic Industry Requirement

62. Illumina has invested and continues to invest in U.S. plant, equipment, labor, capital, research, and engineering for nanopores that are covered by the Patents-in-suit. Exemplary documents that show the Msp nanopores in which Illumina has made these investments are attached as Confidential Exhibits 34, 65, 71, 73-77, and 87. Claim charts demonstrating how

Illumina's Msp nanopores are covered by an exemplary claim of each of the Patents-in-suit are attached as Confidential Exhibits 72 and 95. Therefore, these Msp nanopores are articles protected by the Patents-in-suit, and a domestic industry for those protected articles exists.

63. In addition, Illumina's investments in U.S. plant, equipment, labor, capital, research, and engineering for Msp nanopores covered by the Patents-in-suit are being made to create commercial DNA sequencing products that use Illumina's Msp nanopores and are thus covered by the Patents-in-suit.

64. Illumina's activities are genuinely designed to exploit the patented technology within a reasonable period of time by making nanopore sequencing products that embody the Patents-in-suit available to the public. The Confidential Declaration of Jeffrey Mandell, attached as Confidential Exhibit 71, describes in detail Illumina's investments related to its Msp nanopores and products containing these nanopores.

B. Illumina Satisfies the Economic Prong of the Domestic Industry Requirement

65. A domestic industry, under subparts (A), (B), and/or (C) of Section 337(a)(3), exists by virtue of Illumina's significant U.S. investment in plant and equipment, significant employment of U.S. labor and capital, and substantial investment in U.S. exploitation of the Patents-in-suit, including through engineering and research and development. *See generally* Confidential Exhibits 34, 65, 71, 76, and 87.

66. Illumina's U.S. investments in the articles protected by the Patents-in-suit are discussed in more detail in the Confidential Declaration of Jeffrey Mandell, including financials showing the magnitude of Illumina's investments. *See generally id.*

67. Moreover, Illumina has a robust infrastructure of U.S. manufacturing, technical support, customer support, and service and repair personnel that supports its current sequencing

products, and that will perform functions related to the commercial sequencing products covered by the Patents-in-suit.

68. Illumina has made significant investments under subpart (A) of Section 337(a)(3), in, among other things, U.S. plant and equipment related to the domestic industry for the articles protected by the Patents-in-suit. The details of these investments and activities are set forth in the attached Confidential Declaration of Dr. Jeffrey Mandell, attached as Confidential Exhibit 71.

69. Illumina has made significant investments under subpart (B) of Section 337(a)(3), in, among other things, labor and capital related to the domestic industry for the articles protected by the Patents-in-suit. The details of these investments and activities are set forth in the attached Confidential Declaration of Jeffrey Mandell, attached as Confidential Exhibit 71.

70. Illumina has made significant investments under one or more subparts of Section 337(a)(3), in, among other things, contractors and consultants related to the domestic industry for the articles protected by the Patents-in-suit. The details of these investments are reflected in consulting agreements, which are attached as Confidential Exhibits 73, 74, and 75, and in spreadsheets showing payments to them, which are attached as Confidential Exhibits 34, 65, 76, and 87.

71. Illumina has made substantial investments under subpart (C) of Section 337(a)(3), in, among other things, research, engineering, and development of articles protected by the Patents-in-suit. The details of these investments and activities are set forth in the attached Confidential Declaration of Dr. Jeffrey Mandell.

XII. RELATED LITIGATION

A. State Court Litigation

72. On October 17, 2013, Mr. Matt Wood, acting on behalf of ONT, submitted a request to the University of Washington under the Washington Public Records Act, seeking disclosure of

materials relating to the '550 Patent license agreement with Illumina. On January 15, 2014, Illumina filed a complaint against the University of Washington and Matt Wood in the Superior Court for the State of Washington, King County, Case No. 14-2-01553-4SEA, seeking to enjoin disclosure of these materials. On May 14, 2014, ONT intervened as a defendant by stipulation of the parties. The Court found in Illumina's favor and entered judgment on November 20, 2015. *See* Exhibit 98.

B. District Court Litigation

73. Illumina, contemporaneously with or shortly after the filing of the instant Complaint with the United States International Trade Commission, is filing a complaint against Respondents in the U.S. District Court for the Southern District of California, alleging infringement of one or more claims of the Patents-in-suit.

C. *Inter Partes* Review of the '550 Patent

74. On March 18, 2014, ONT filed a petition for *inter partes* review of certain claims of the '550 Patent under 35 U.S.C. § 103(a). *See* Exhibit 40. The petition was assigned *Inter Partes* Review No. IPR2014-0512. On September 14, 2014, the Patent Trial and Appeal Board ("PTAB") denied the petition.

75. Also on March 18, 2014, ONT filed a separate petition for *inter partes* review of certain claims of the '550 Patent under 35 U.S.C. § 102(b). *See* Exhibit 41. The petition was assigned *Inter Partes* Review No. IPR2014-00513. On September 15, 2014, the PTAB granted the petition as to claims 1, 5, 6, 10–12, 16–19, 23, 25, 29, 30, 34, 37, and 41, and denied the petition as to claims 13, 24, 31, 35, 36, and 38–40. On December 11, 2014, the patent owners filed a motion to amend the '550 patent by cancelling claims 1, 5, 6, 11, 12, 16, 19, 23, 25, 29, 30, 34, 37, and 41. That motion remains pending. The parties are still litigating the patentability of the remaining claims—10, 17, and 18—and the hearing was held December 3, 2015.

76. On October 13, 2014, ONT filed a third petition for *inter partes* review of certain claims of the '550 Patent under 35 U.S.C. § 103(a). *See* Exhibit 42. The petition was assigned *Inter Partes* Review No. IPR2015-00057. On April 27, 2015, the PTAB instituted only as to claim 10 and also joined the two pending IPR proceedings. The hearing was held on December 3, 2015.

77. As of the date of this Complaint, the PTAB has denied any *inter partes* review of claims 2-4, 7-9, 13, 24, 26-28, 31, 35, 36, and 38-40. ONT has not sought an *inter partes* review of claims 14, 15, 20-22, 32, and 33 in any of its three petitions. Thus, asserted claims 2-4, 7-9, 13-15, 20-22, 24, 26-28; 31-33, 35-36, and 38-40 of the '550 patent will not be affected by the outcome of the pending IPRs.

XIII. REQUESTED RELIEF

78. WHEREFORE, by reason of the foregoing, Complainants request that the United States International Trade Commission:

(a) Institute an immediate investigation, pursuant to Section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337, with respect to Respondents' violations of Section 337 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 of certain nanopores and products containing the same that infringe one or more claims of United States Patent Nos. 8,673,550 and 9,170,230;

(b) Schedule and conduct a hearing on the unlawful acts and, following the hearing, determine whether there has been a violation of Section 337;

(c) Issue a permanent limited exclusion order, pursuant to Section 337(d) of the Tariff Act of 1930, as amended, excluding from entry into the United States all of Respondents' nanopores and products containing the same that infringe one or more claims of United States Patent Nos. 8,673,550 and 9,170,230;

(d) Issue permanent cease and desist orders, pursuant to Section 337(f) of the Tariff Act of 1930, as amended, directing each Respondent to cease and desist from the importation, marketing, advertising, demonstrating, installing, repairing, servicing, warehousing inventory for distribution, sale and use of certain nanopores and products containing same that infringe one or more claims of United States Patent Nos. 8,673,550 and 9,170,230; and

(e) Grant such other and further relief as the Commission deems just and proper based on the facts determined by the investigation and the authority of the Commission.

Respectfully submitted,

FISH & RICHARDSON P.C.



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Illumina, Inc., University of Washington, and
UAB Research Foundation*

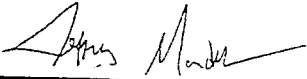
Dated: February 23, 2016

VERIFICATION

I, Jeffrey Mandell, declare in accordance with 19 C.F.R. §§ 210.4 and 210.12(a), under penalty of perjury; that the following statements are true:

1. I am a Senior Staff Scientist at Illumina, Inc. ("Illumina") and I am duly authorized to verify this Complaint of Illumina Under Section 337 of The Tariff Act of 1930, As Amended ("Complaint");
2. I have read Illumina's Complaint;
3. To the best of my knowledge, information, and belief, formed after an inquiry reasonable under the circumstances, (a) the claims and other legal contentions in the Complaint are warranted by existing law or by a non-frivolous argument for the extension, modification, or reversal of existing law or the establishment of new law, and (b) the allegations and other factual contentions in the Complaint have evidentiary support or, if specifically so identified, are likely to have evidentiary support after a reasonable opportunity for further investigation or discovery; and
4. The Complaint is not being presented for any improper purpose; such as to harass or to cause unnecessary delay or needless increase in the cost of the investigation or related proceeding.

I declare under penalty of perjury under the laws of the United States that the foregoing is true and correct. Executed on 2/22/16.



Jeffrey Mandell

General Information

Court	United States International Trade Commission; United States International Trade Commission
Docket Number	3123