UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, DC

In the Matter of	
CERTAIN SINGLE-MOLECULE NUCLEIC ACID SEQUENCING SYSTEMS AND REAGENTS, CONSUMABLES, AND SOFTWARE FOR USE WITH SAME	**Investigation No. 337-TA-1032**

NOTICE OF COMMISSION DETERMINATION TO REVIEW AN INITIAL DETERMINATION OF NONINFRINGEMENT; SCHEDULE FOR FILING WRITTEN SUBMISSIONS ON THE ISSUES UNDER REVIEW

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has determined to review an initial determination ("ID") (Order No. 12), granting summary determination of noninfringement of all asserted patent claims. The Commission requests certain briefing from the parties on the issues under review, as indicated in this notice.

FOR FURTHER INFORMATION CONTACT: Lucy Grace D. Noyola, Office of the General Counsel, U.S. International Trade Commission, 500 E Street, SW, Washington, DC 20436, telephone 202-205-3438. Copies of non-confidential documents filed in connection with this investigation are or will be available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street, SW, Washington, DC 20436, telephone 202-205-2000. General information concerning the Commission may also be obtained by accessing its Internet server (https://www.usitc.gov). The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at https://edis.usitc.gov. Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on 202-205-1810.

SUPPLEMENTARY INFORMATION: The Commission instituted this investigation on December 8, 2016, based on a complaint filed by Pacific Biosciences of California, Inc. of Menlo Park, California ("PacBio"). 81 *Fed. Reg.* 88703-04 (Dec. 8, 2016). The complaint, as amended, alleges violations of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337, in the importation into the United States, the sale for importation, and the sale within the United States after importation of certain single-molecule nucleic acid sequencing systems and reagents, consumables, and software for use with same by reason of infringement of certain claims of U.S. Patent Nos. 9,404,146 ("the '146 patent") and 9,542,527 ("the '527 patent"). *Id.*

at 88704; 82 *Fed. Reg.* 15236 (Mar. 27, 2017). The notice of investigation named as respondents Oxford Nanopore Technologies Ltd. of Oxford, United Kingdom; Oxford Nanopore Technologies, Inc. of Cambridge, Massachusetts; and Metrichor, Ltd. of Oxford, United Kingdom (collectively, "Oxford"). 81 *Fed. Reg.* at 88704. The Office of Unfair Import Investigations ("OUII") also was named as a party to the investigation. *Id.*

On May 23, 2017, the administrative law judge ("ALJ") issued Order No. 10 ("*Markman* Order"), construing the limitations "single-molecule sequencing process" recited in claims 1, 5-7, 14, and 16-17 of the '146 patent and claims 1 and 3-4 of the '527 patent and "single-molecule sequencing" recited in claims 20-21 of the '146 patent (collectively, "single-molecule sequencing" limitations).

On June 8, 2017, PacBio filed a motion for summary determination that the domestic industry requirement is satisfied. On June 9, 2017, Oxford filed a motion for summary determination of (1) noninfringement as to all accused products because they do not satisfy the "single-molecule sequencing" limitations; (2) noninfringement as to a subset of the accused products (directed solely to Oxford's 1D or $1D^2$ sequencing processes) because they do not satisfy the "linker" limitations; and (3) noninfringement as to a subset of the accused products (not directed solely to Oxford's 1D or $1D^2$ sequencing processes) because they are capable of substantial non-infringing uses.

On July 19, 2017, the ALJ issued an ID (Order No. 12), granting in part Oxford's summary determination motion. Specifically, the ID incorporated the *Markman* Order by reference and found no infringement of claims 1, 5-7, 10, 14, 16-21, and 23-25 of the '146 patent and claims 1 and 3-11 of the '527 patent based on the *Markman* Order's construction of the "single-molecule sequencing" limitations. The ID denied as moot Oxford's second and third requests for summary determination of noninfringement, as well as PacBio's motion for summary determination on the economic prong of the domestic industry requirement. The ID found no violation of section 337.

On July 31, 2017, PacBio filed a petition for review of the *Markman* Order's construction of "single-molecule sequencing" and the ID's finding of noninfringement. On August 7, 2017, Oxford and OUII filed responses to PacBio's petition. On August 16, 2017, PacBio filed a motion for leave to file a reply in support of its petition for review. On August 28, 2017, Oxford filed an opposition to PacBio's motion.

Having examined the record of this investigation, including the ID, the petition for review, and the responses thereto, the Commission has determined to review the ID in its entirety. The Commission has also determined to deny PacBio's motion for leave to file a reply.

In connection with its review, the Commission requests responses to the following questions:

1. For purposes of claim construction of the "single-molecule sequencing" limitations, what is the relevance of the patentee's statement defining the limitations at issue in the prosecution history of the asserted patents? Please discuss and apply any relevant Supreme Court and Federal Circuit precedent.

2. For purposes of claim construction of the "single-molecule sequencing" limitations, what is the relevance of the original and issued claims of parent application U.S. Patent Application No. 12/413,258 where those claims do not include the limitations at issue? Please discuss and apply any relevant Supreme Court and Federal Circuit precedent.

3. For purposes of claim construction of the "single-molecule sequencing" limitations, what is the relevance of developments in the pertinent art occurring after the effective filing date of the patent application? What is the relevance of such developments when they are referenced in the intrinsic record? Please discuss and apply any relevant Supreme Court and Federal Circuit precedent.

4. What is the basis for the different priority dates for the different claims in the asserted patents? For purposes of claim construction of the "single-molecule sequencing" limitations, what is the relevance of the different priority dates? Please discuss and apply any relevant Supreme Court and Federal Circuit precedent.

WRITTEN SUBMISSIONS: The parties to the investigation are requested to file written submissions on the issues identified in this notice. Initial written submissions must be filed no later than close of business on **Friday, September 15, 2017**. Initial written submissions by the parties shall be no more than 30 pages, excluding any attachments or exhibits. Reply submissions must be filed no later than the close of business on **Friday, September 22, 2017**. Reply submissions by the parties shall be no more than 20 pages, excluding any attachments or exhibits. No further submissions on these issues will be permitted unless otherwise ordered by the Commission. Persons filing written submissions must file the original document electronically on or before the deadlines stated above and submit 8 true paper copies to the Office of the Secretary by noon the next day pursuant to section 210.4(f) of the Commission's Rules of Practice and Procedure (19 C.F.R. § 210.4(f)). Submissions should refer to the investigation number ("Inv. No. 337-TA-1032") in a prominent place on the cover page and/or the first page. (*See* Handbook for Electronic Filing Procedures, https://www.usitc.gov/secretary/documents/handbook_on_filing_procedures.pdf.) Persons with questions regarding filing should contact the Secretary at (202) 205-2000.

Any person desiring to submit a document to the Commission in confidence must request confidential treatment. All such requests should be directed to the Secretary to the Commission and must include a full statement of the reasons why the Commission should grant such treatment. *See* 19 C.F.R. § 201.6. Documents for which confidential treatment by the Commission is properly sought will be treated accordingly. A redacted non-confidential version of the document must also be filed simultaneously with any confidential filing. All nonconfidential written submissions will be available for public inspection at the Office of the Secretary and on EDIS.

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

By order of the Commission.

Lisa R. Barton
Secretary to the Commission

Issued: September 5, 2017