UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

OXFORD NANOPORE TECHNOLOGIES, INC., Petitioner,

v.

PACIFIC BIOSCIENCES OF CALIFORNIA, INC., Patent Owner.

> Case IPR 2018-01792 Patent 9,738,929 B2

Before ULRIKE W. JENKS, ZHENYU YANG, and JAMES A. WORTH *Administrative Patent Judges*.

JENKS, Administrative Patent Judge.

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DECISION Denying Institution of *Inter Partes* Review 35 U.S.C. § 314(a)

I. INTRODUCTION

A. Background

Oxford Nanopore Technologies, Inc. ("Petitioner"), filed a Petition requesting an *inter partes* review of claims 1–17 ("the challenged claim") of U.S. Patent No. 9,738,929 B2 (Ex. 1001, "the '929 patent"). Paper 1 ("Pet."). Pacific Biosciences of California, Inc. ("Patent Owner") filed a Preliminary Response to the Petition. Paper 6 ("Prelim. Resp.").

We have authority under 35 U.S.C. § 314, which provides that an *inter partes* review may not be instituted "unless . . . there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." 35 U.S.C. § 314(a). Upon consideration of the arguments and evidence presented in the Petition and the Preliminary Response, we are not persuaded that Petitioner has established a reasonable likelihood that it would prevail in its challenges of any of the claims in the '929 patent. Accordingly, we decline to institute an *inter partes* review of claims 1–17.

B. Related Proceedings

Petitioner identifies district-court litigation involving the '929 patent in *Pacific Biosciences of California, Inc., v. Oxford Nanopore Technologies, Inc.*, which was consolidated into actions 1:17-cv-00275-LPS, 1:17-cv-01353-LPS (D. Del.). Pet. 2. Petitioner also identifies IPR2018-01785¹ as relating to the '929 patent. *Id.*

¹ The proceeding in IPR2018-01785 was terminated. *See* IPR 2018-01785 (Paper 8).

C. Real Party in Interest

Petitioner identifies itself, Oxford Nanopore Technologies, Inc. and "Oxford Nanopore Technologies, Ltd., the parent company of Oxford Nanopore Technologies, Inc., and Metrichor Ltd., a corporate affiliate of Oxford Nanopore Technologies, Inc., as the real parties in interest." Pet. 2. Patent Owner identifies itself, "Pacific Biosciences of California, Inc.," as the real party in interest. Paper 4, 2.

C. The '929 Patent (Ex. 1001)

The '929 patent is titled "Nucleic Acid Sequence Analysis." Ex. 1001, [54]. The '929 patent issued from Application No. 15/383,965 ("the '965 application"), filed Dec. 19, 2016, which ultimately claims benefit of U.S. Provisional Application No. 61/099,696, filed Sept. 24, 2008, and U.S. Provisional Application No. 61/139,402, filed Dec. 19, 2008 *Id.* at [60].

The '929 patent concerns obtaining sequence data from discontiguous portions of single nucleic acid templates. Ex. 1001, 3:7–10. The '929 patent teaches that "the sequencing reaction comprises passage of the single nucleic acid template through a nanopore." *Id.* at 4:40–42. The '929 patent teaches that the analytical reaction further "comprises at least one component comprising a detectable label, e.g., a fluorescently labeled nucleotide," and an optical detection system to collect the data. *Id.* at 4:59–61. The '929 patent describes numerous templates for use in the sequencing reactions.

[U]sing templates that allow repeated sequencing (e.g., circular templates, SMRTBELLTM templates, etc.) in a single reaction can increase the percent of a nucleic acid template for which nucleotide sequence data is generated and/or increase the fold-coverage of the sequence reads for one or more regions of

interest in the template, thereby providing more complete data for further analysis, e.g., construction of sequence scaffolds and/or consensus sequences for the nucleic acid template. For example, in certain preferred embodiments, templates sequenced by the methods described herein are templates comprising a double-stranded segment, e.g., greater than 75%, or even greater than 90% of the target segment will be double-stranded or otherwise internally complementary. Such templates may, for example, comprise a double stranded portion comprised of two complementary sequences and two single-stranded linking portions (e.g., oligos or "hairpins") joining the 3' end of each strand of the double-stranded region to the 5' end of the other strand (sometimes referred to as "SMRTBELLTM" templates).

Id. at 66:8–27.

The '929 patent describes sequencing a contiguous template in order

to obtain information about the sense and antisense strand of a double-

stranded template.

[A] sequencing process that begins, e.g., is primed, at the open end of the partially contiguous template, proceeds along the first or sense strand, providing the nucleotide sequence (A) of that strand, as represented in the schematic sequence readout provided. The process then proceeds around the linking oligonucleotide of the template, providing the nucleotide sequence (B) of that segment. The process then continues along the antisense strand to the A sequence, and provides the nucleotide sequence (A'), which provides consensus data for the sense strand as its antisense counterpart.

Id. at 38:1–11.

The '929 patent teaches that "template nucleic acids comprising the same nucleotide sequence are analyzed in a plurality of reactions sufficient to provide adequate redundant nucleotide sequence data to determine a consensus sequence for the template nucleic acids." *Id.* at 31:50–54. The '929 patent teaches a process for "transforming nucleotide sequence read

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data into consensus sequence data, wherein the nucleotide sequence read data is generated by sequencing a target region of a template nucleic acid multiple times, and the consensus sequence data is representative of a most likely actual sequence of the template nucleic acid." *Id.* at 12:7–12.

D. Illustrative Claim

Claims 1–17 of the '929 patent are challenged. Claim 1, the sole independent claim of the '929 patent is illustrative and reproduced below:

1. A method of determining a nucleotide sequence of a region of interest in a polynucleotide, the method comprising:

[a] introducing a polynucleotide comprising a region of interest to a sequence analysis system comprising a nanopore in a membrane, **[b]** wherein the polynucleotide comprises a double-stranded portion comprising complementary strands of the region of interest;

[c] applying a voltage across the membrane;

[d] monitoring variations in ionic current through the nanopore of the sequence analysis system **[e]** during enzyme chaperone-regulated passage of the polynucleotide through the nanopore;

[f] analyzing the monitored variations in ionic current to obtain nucleotide sequence information for the polynucleotide, **[g]** wherein the nucleotide sequence information comprises redundant sequence information for the region of interest, wherein the redundant sequence information comprises the nucleotide sequence of the complementary strands; and

[h] determining a consensus sequence for the region of interest based on the redundant sequence information.

Ex. 1001, 82:36–57 (labels [a]–[h] are added to distinguish the subparts for discussion purposes).

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