UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ILLUMINA, INC., Petitioner,

v.

CORNELL RESEARCH FOUNDATION, INC., Patent Owner.

Case IPR2016-00553 Patent 8,288,521 B2

Before TONI R. SCHEINER, JACQUELINE WRIGHT BONILLA, and SUSAN L. C. MITCHELL, *Administrative Patent Judges*.

MITCHELL, Administrative Patent Judge.

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DECISION Denying Institution of *Inter Partes* Review 37 C.F.R. § 42.108

I. INTRODUCTION

A. Background

Petitioner Illumina Inc. ("Petitioner") filed a Petition (Paper 1, "Pet.") requesting an *inter partes* review of claims 1–32 (the "challenged claims") of U.S. Patent No. 8,288,521 B2 (Exhibit 1001, "the '521 patent"). *See* 35 U.S.C. §§ 311–319. Patent Owner Cornell Research Foundation, Inc. ("Patent Owner") filed a Preliminary Response, which relies on testimonial evidence. Paper 7 ("Prelim. Resp."). Petitioner was granted the right to file a Reply to the Preliminary Response (Paper 12), and did so. Paper 13 ("Reply").

We have jurisdiction under 35 U.S.C. § 314. To institute an *inter partes* review, we must determine that the information presented in the Petition shows "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). For the reasons set forth below, we conclude that Petitioner has not established a reasonable likelihood that it would prevail in showing the unpatentability of at least one of the challenged claims of the '521 patent. Therefore, we deny institution of an *inter partes* review for claims 1–32 of the '521 patent.

B. Related Proceedings

Four patents, including the '521 patent, were asserted against Petitioner in *Cornell University v. Illumina, Inc.*, No. 10-433-LPS-MPT (D. Del.). Pet. 1; Paper 6, 3. On the same day it filed the Petition at issue in this case, Petitioner also filed Petitions for *inter partes* review of claims in the remaining three patents asserted against it. Pet. 1; Paper 6, 2 (IPR2016IPR2016-00553 Patent 8,288,521 B2

00559 (U.S. Patent No. 8,624,016), IPR2016-00557 (U.S. Patent No. 8,597,891), IPR2016-00549 (U.S. Patent No. 8,703,928)).

C. The '521 Patent (Ex. 1001)

The '521 patent involves the detection of nucleic acid sequence differences of one or more single base changes, insertions, deletions, or translocations in target nucleic acid sequences using a method including a ligation phase, a capture phase, and a detection phase. Ex. 1001, 1:23–25, 5:33–38. The claims of the '521 patent are drawn to kits for identifying one or more of a plurality of sequences differing by single-base changes, insertions, deletions, or translocations in a plurality of target nucleotide sequences that include capture oligonucleotides that differ in nucleotide sequence by at least 25% when aligned to another capture oligonucleotide. *See* Ex. 1001, 59:59–63, 62:9–14.

D. Illustrative Claims

Claims 1 and 18 are independent claims of the '521 patent. Claims 2– 17 depend directly or indirectly from claim 1, and claims 19–32 depend directly or indirectly from claim 18. Claim 1 and 18 are illustrative of the challenged claims and recite:

1. A kit for identifying one or more of a plurality of sequences differing by single-base changes, insertions, deletions or translocations in a plurality of target nucleotide sequences comprising:

a ligase;

a collection of oligonucleotide probe sets, each set characterized by (a) a first oligonucleotide probe comprising a target-specific portion and (b) a second oligonucleotide probe comprising a target-specific portion and a further portion, wherein the further portion IPR2016-00553 Patent 8,288,521 B2

> comprises a nucleic acid sequence of greater than sixteen nucleotides that differs for each different target-specific portion, and wherein the nucleic acid sequence of a complement to one further portion differs from the nucleic acid sequence of a complement to another further portion in the collection by at least 25%, when aligned to each other.

Ex. 1001, 59:58-63, 60:57-63.

18. A kit for identifying one or more of a plurality of target nucleotide sequences in a sample comprising:

a ligase;

- a plurality of oligonucleotide probe sets, each set characterized by (a) first oligonucleotide probe, having a target-specific portion and an address-specific portion and (b) a second oligonucleotide probe, having a target-specific portion; and
- a collection of capture oligonucleotides wherein each type of capture oligonucleotide in the collection comprises a nucleotide sequence complementary to an addressspecific portion, wherein the address-specific portion is comprised of a nucleotide sequence which is distinct from that of the target-specific portions, and wherein each type of capture oligonucleotide in the collection hybridizes to its complement under uniform hybridization conditions but differs by at least 25% in nucleotide sequence, when aligned to another type of capture oligonucleotide in the collection.

Id. at 61:57–61, 62:1–14.

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E. The Asserted Grounds of Unpatentability

Petitioner contends that the challenged claims are unpatentable based on the following grounds. Pet. 25. IPR2016-00553 Patent 8,288,521 B2

References	Basis	Claims Challenged
Landegren, ¹ Wallace, ² Davis, ³ and	§ 103	1–2, 7, 9–24, and 27–32
Wetmur ⁴		
Landegren, Wallace, Davis, Wetmur,	§ 103	3–6 and 25–26
and Van Ness ⁵		
Landegren, Wallace, Davis, Wetmur,	§ 103	8
and Fodor II ⁶		

Petitioner relies also on the Declaration of Ralph M. Sinibaldi, Ph.D. Pet. 2–60; *see* Ex. 1002.

II. ANALYSIS

A. Claim Interpretation

In an *inter partes* review, claim terms in an unexpired patent are given their broadest reasonable construction in light of the specification of the patent in which they appear. 37 C.F.R. § 42.100(b); *Cuozzo Speed Techs., LLC v. Lee*, 136 S.Ct. 2131, 2144–46 (2016). Under the broadest reasonable interpretation approach, claim terms are given their ordinary and customary meaning as would be understood by one of ordinary skill in the art in the

- ² PCT App. WO 93/25563, published Dec. 23, 1993 (Ex. 1006, "Wallace").
- ³ PCT App. WO 90/11372, published Oct. 4, 1990 (Ex. 1007, "Davis").
- ⁴ James G. Wetmur, *DNA Probes: Applications of the Principles of Nucleic Acid Hybridization*, 26 CRITICAL REVIEWS IN BIOCHEMISTRY AND MOLECULAR BIOLOGY 227–259 (1991) (Ex. 1008, "Wetmur").

¹ U.S. Patent No. 4,988,617, issued Jan. 29, 1991 (Ex. 1039, "Landegren").

⁵ European Pat. App. 0 455 905 A2, published Nov. 13, 1991 (Ex. 108, "Van Ness").

⁶ Stephen P. A. Fodor et al., *Multiplexed Biochemical Assays with Biological Chips*, 364 NATURE 555–556 (1993) (Ex. 1010, "Fodor II").

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