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Paper 65
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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ILLUMINA, INC.,
Petitioner,

v.

THE TRUSTEES OF COLUMBIA UNIVERSITY
IN THE CITY OF NEW YORK,
Patent Owner.

Case IPR2018-00797
Patent 9,868,985 B2

Before MICHELLE N. ANKENBRAND, *Acting Vice Chief Administrative Patent Judge*, JAMES A. WORTH and BRIAN D. RANGE, *Administrative Patent Judges.*

Opinion for the Board *per curiam.*
Opinion Dissenting filed by *Administrative Patent Judge*, WORTH.

Per curiam

FINAL WRITTEN DECISION
35 U.S.C. § 318(a) and 37 C.F.R. § 42.73

I. INTRODUCTION

This is a Final Written Decision addressing the *inter partes* review challenging each claim of U.S. Patent No. 9,868,985 B2 ("the '985 patent"). We have jurisdiction under 35 U.S.C. § 6. For the reasons that follow, we determine that Illumina, Inc. ("Petitioner" or "Illumina") demonstrates, by a preponderance of the evidence, that the challenged claims are unpatentable.

A. Procedural History

Petitioner filed a Petition (Paper 1, "Pet.") requesting an *inter partes* review of the '985 patent. We instituted trial on the following grounds:[1]

Patent	References	Basis	Claim Challenged
'985	Tsien,[2] Prober[3]	§ 103(a)	1
'985	Tsien, Prober, and Pallas[4]	§ 103(a)	2
'985	Dower,[5] Prober, Metzker[6]	§ 103(a)	1, 2

[1] *See* Paper 20.

[2] Tsien et al., WO 91/06678, May 16, 1991 ("Tsien") (Ex. 1013).

[3] James M. Prober et al., *A System for Rapid DNA Sequencing with Fluorescent Chain-Terminating Dideoxynucleotides*, 238 SCIENCE 336–41 (Oct. 16, 1987) ("Prober") (Ex. 1014).

[4] Pallas et al., WO 98/53300, pub. Nov. 26, 1998 ("Pallas") (Ex. 1080).

[5] Dower et al., U.S. 5,547,839, Aug. 20, 1996 ("Dower") (Ex. 1015).

[6] Michael L. Metzker et al., *Termination of DNA synthesis by novel 3'-modified-deoxyribonucleoside* 5'*-triphosphates*, 22(20) NUCLEIC ACIDS RESEARCH 4259–67 (1994) ("Metzker") (Ex. 1016).

After institution, the Trustees of Columbia University in the City of New York ("Patent Owner" or "Columbia") filed a Patent Owner Response. *See* Patent Owner's Response ("Resp."), Paper 29 (public version), Paper 32 (sealed version). Petitioner filed a Reply (Paper 43, "Reply"), and Patent Owner filed a Sur-Reply (Paper 47, "Sur-Reply"). Additionally, Petitioner filed a motion to exclude evidence (Paper 51, "Mot. Excl."), Patent Owner responded (Paper 54, "Opp. Mot. Excl."), and Petitioner provided a Reply brief (Paper 56).

We heard oral argument for this *inter partes* review (as well as for four other related *inter partes* reviews) on March 5, 2019, and a transcript of the hearing is part of the record of this proceeding. Paper 60 ("Tr."). After oral argument, we requested additional briefing regarding certain estoppel issues. Paper 59. The parties provided such briefing. Papers 61 (Patent Owner's Additional Brief ("PO Supp. Br.")), 62 (Illumina's Supplemental Brief Regarding Estoppel ("Pet. Supp. Br.")), 63 (Illumina's Supplemental Reply Regarding Estoppel ("Pet. Supp. Reply")), 64 (Patent Owner's Reply to Petitioner's Supplemental Brief ("PO Supp. Reply")).

B. Related Proceedings

The parties indicate that the '985 patent is the subject of the following district court proceeding involving Petitioner and Patent Owner: *Trustees of Columbia University v. Illumina, Inc.*, Case No. 17-cv-973-GMS (D. Del.). Pet. 78; Paper 3, 1.

Petitioner filed Petitions requesting an *inter partes* review of related U.S. Patent Nos. 9,718,852 B2 ("the '852 patent"), 9,719,139 B2 ("the '139 patent"), 9,708,358 B2 ("the '358 patent"), and 9,725,480 B2 ("the '480

patent"). We instituted trial in each matter. *See* IPR2018-00291, Paper 16 (June 25, 2018); IPR2018-00318, Paper 16 (July 3, 2018); IPR2018-00322, Paper 16 (July 3, 2018); IPR2018-00385, Paper 20 (July 27 2018). On June 21, 2019, we entered a Final Written Decision determining that Petitioner demonstrated, by a preponderance of the evidence, that each challenged claim of the four patents is unpatentable. *See, e.g.*, IPR2018-00291, Paper 67; *see also* IPR2018-00291 Paper 69 (providing minor errata).

The parties note that in IPR2012-00006, IPR2012-00007, and IPR2013-00011, the Board found unpatentable the challenged claims of Patent Owner's U.S. Patent Nos. 7,713,698; 7,790,869; and 8,088,575. Pet. 78–79; Paper 3, 1; *see* Ex. 1006; Ex. 1005; Ex. 1007; Ex. 1008 (Federal Circuit decision affirming these Board decisions). In IPR2013-00128 and IPR2013-00266, the Board found unpatentable the challenged claims of Petitioner's U.S. Patent Nos. 7,057,026 and 8,158,346. Pet. 79; *see* Ex. 1048; Ex. 1049; Ex. 1050 (Federal Circuit decision affirming these Board decisions). In IPR2013-00517, the Board held that Intelligent Bio-Systems, Inc. failed to demonstrate that the challenged claims of Petitioner's U.S. Patent No. 7,566,537 ("the '537 patent") were unpatentable.[7] Pet. 79–80; *see* Ex. 1044; Ex. 1045 (Federal Circuit decision affirming this Board decision).

[7] A third party also challenged the '537 patent in Cases IPR2017-02172 and IPR2017-02174, but the Board denied institution in each case. Pet. 80; Paper 10, 1.

C. *The '985 Patent*

The '985 patent is titled "Massive Parallel Method for Decoding DNA and RNA" and relates to a "system for DNA sequencing by the synthesis approach which employs a stable DNA template, which is able to self-prime for the polymerase reaction, covalently linked to a solid surface such as a chip, and 4 unique nucleotides analogues." Ex. 1075, 4:25–30.

The '985 patent discloses that electrophoresis was a bottleneck for high-throughput DNA sequencing and mutation detection projects. *Id.* at 2:16–19. It was known to perform sequencing without electrophoresis, using a chip format and laser-induced fluorescent detection for DNA sequencing. *Id.* at 2:20–27. The '985 patent discloses that "[l]ong stretches of the same bases cannot be identified unambiguously with [a] pyrosequencing method." *Id.* at 2:44–46. The '985 patent also describes limited success in the prior art for the incorporation of 3'-modified nucleotides by DNA polymerase. *Id.* at 2:52–53.

The approach disclosed in the '985 patent is

> to make nucleotide analogues by linking a unique label such as a fluorescent dye or a mass tag through a cleavable linker to the nucleotide base or an analogue of the nucleotide base, such as to the 5-position of the pyrimidines (T and C) and to the 7-position of the purines (G and A), to use a small cleavable chemical moiety to cap the 3'-OH group of the deoxyribose to make it nonreactive, and to incorporate the nucleotide analogues into the growing DNA strand as terminators. Detection of the unique label will yield the sequence identity of the nucleotide. Upon removing the label and the 3'-OH capping group, the polymerase reaction will proceed to incorporate the next nucleotide analogue and detect the next base.

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