

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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INTELLIGENT BIO-SYSTEMS, INC.,  
Petitioner,

v.

ILLUMINA CAMBRIDGE LTD,  
Patent Owner.

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Case IPR2013-00517  
Patent 7,566,537 B2

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Before LORA M. GREEN, FRANCISCO C. PRATS, and  
SCOTT E. KAMHOLZ, *Administrative Patent Judges*.

PRATS, *Administrative Patent Judge*.

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

Columbia Ex. 2012 Illumina, Inc. v. The Trustees of Columbia University in the City of New York IPR2020-01177
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## I. INTRODUCTION

### A. *Statement of the Case*

Intelligent Bio-Systems, Inc. (“Petitioner”) filed a revised Petition (Paper 7, “Pet.”) requesting *inter partes* review of claims 1–6 and 8 of U.S. Patent No. 7,566,537 B2 (Ex. 1001, “the ’537 patent”). Illumina Cambridge Ltd (“Patent Owner”) waived the filing of a preliminary response (Paper 10). We instituted trial on the following grounds of unpatentability:

References	Basis	Claims challenged
Ju, <sup>1</sup> Zavgorodny <sup>2</sup>	§ 103	1–6, 8
Tsien, <sup>3</sup> Zavgorodny	§ 103	1–6, 8
Tsien, Zavgorodny, Prober <sup>4</sup>	§ 103	3

Decision to Institute 15 (Paper 16, “Dec.”).

After trial was instituted, Patent Owner filed redacted and unredacted versions of its Patent Owner Response (Papers 32 and 33, “PO Resp.”), along with a Motion to Seal and proposed Protective Order (Paper 34).

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<sup>1</sup> U.S. Patent No. 6,664,079 B2 (filed Oct. 5, 2001) (Ex. 1002).

<sup>2</sup> Sergey Zavgorodny et al., *1-Alkylthioalkylation of Nucleoside Hydroxyl Functions and Its Synthetic Applications: A New Versatile Method in Nucleoside Chemistry*, 32 TETRAHEDRON LETTERS 7593–96 (1991) (Ex. 1004).

<sup>3</sup> Roger Y. Tsien, WO 91/06678 A1 (published May 16, 1991) (Ex. 1008).

<sup>4</sup> James M. Prober et al., *A System for Rapid DNA Sequencing with Fluorescent Chain-Terminating Dideoxynucleotides*, 238 SCIENCE 336–41 (1987) (Ex. 1009).

Petitioner filed unredacted and redacted versions of its Reply (Papers 54 and 55, “Pet. Reply”), along with its own Motion to Seal (Paper 52).

Both parties filed Motions to Exclude Evidence. Paper 61 (“Pet. Mot. to Exclude”) and Paper 62 (“PO Mot. to Exclude”). Patent Owner’s Motion to Exclude Evidence was accompanied by an additional Motion to Seal. Paper 63.

Both parties filed Oppositions to the Motions to Exclude Evidence. Paper 68 (“Pet. Opp.”); Papers 71, 72 (“PO Opp.”). Patent Owner’s Opposition was accompanied by a Motion to Seal (Paper 70); Paper 72 is the unredacted version of Paper 71. Both parties filed Replies to the Oppositions to the Motions to Exclude Evidence. Papers 74, 75.

Patent Owner filed a Motion for Observations on Cross Examination. Paper 64 (“PO Mot. Obs.”). Petitioner filed a Response to that Motion. Paper 67 (“Resp. to Mot. Obs.”).

Petitioner supports its Petition with a Declaration by Bruce P. Branchaud, Ph.D. Ex. 1011 (“Branchaud Pet. Decl.”). Petitioner supports its Reply with a second Declaration by Dr. Branchaud (“Branchaud Reply Decl.”), and a Declaration by Michael L. Metzker, Ph.D. (“Metzker Decl.”). Ex. 1031; Ex. 1046. Patent Owner relies on Declarations by Floyd Romesberg, Ph.D. (“Romesberg Decl.”) and Kevin Burgess, Ph.D. (“Burgess Decl.”). Ex. 2011; Ex. 2089.

Oral Hearing was held on October 10, 2014, and the Hearing Transcript (“Tr.”) has been entered in the record. Paper 84.

We have jurisdiction under 35 U.S.C. § 6(c). This Final Written Decision is entered pursuant to 35 U.S.C. § 318(a). We conclude that

Petitioner has not proved by a preponderance of the evidence that claims 1–6 and 8 of the '537 patent are unpatentable. Petitioner's Motion to Exclude Evidence is dismissed as moot. Patent Owner's Motion to Exclude Evidence is dismissed as moot also.

*B. Related Proceedings*

Petitioner states that the '537 patent is “the subject of the litigation captioned *The Trustees of Columbia University in the City of New York v. Illumina, Inc.*, 1:12-cv-00376-GMS, currently pending in the United States District Court for the District of Delaware (the ‘Delaware Action’)” in which Patent Owner alleges infringement by Petitioner of the '537 patent. Pet. 3.

Also, concurrently with the Petition in this proceeding, Petitioner filed a petition requesting cancellation of claims 7 and 11–14 of the '537 patent. Pet. 3; IPR2013-00518. That proceeding was terminated upon Patent Owner's request for adverse judgment. IPR2013-00518, Papers 28 and 29.

Petitioner states that it also filed three other petitions for *inter partes* review, IPR2013-00128, IPR2013-00266, and IPR2013-00324, challenging the patentability of claims of two related patents, U.S. Patent Nos. 7,057,026 B2 and 8,158,346 B2, which also are asserted in the Delaware Action, and which “share inventors, specifications, and a priority date with the '537 Patent.” Pet. 3.

Final Judgment was entered in IPR2013-00128 on July 25, 2014, and Patent Owner appealed that decision on September 24, 2014. IPR2013-00128, Papers 92 and 95. Final Judgment was entered in IPR2013-00266 on October 28, 2014, and Patent Owner appealed that decision on November

26, 2014. IPR2013-00266, Papers 73 and 75. The Board declined to institute trial in IPR2013-00324. IPR2013-00324, Paper 19.

*C. The '537 Patent (Ex. 1001)*

The '537 patent discloses a nucleotide or nucleoside molecule “having a base that is linked to a detectable label via a cleavable linker.” Ex. 1001, 2:23–24. The labeled nucleotide or nucleoside also has a protecting group removably attached to the 2' or 3' oxygen of the molecule's deoxyribose or ribose moiety. *Id.* at 2:26–27. “The protecting group can be removed to expose a 3'-OH.” *Id.* at 2:27–28. The '537 patent describes a method of labeling nucleic acids, in which a terminal transferase, a polymerase, or a reverse transcriptase is used to incorporate a labeled nucleotide into a nucleic acid molecule. *Id.* at 2:32–38.

The '537 patent also describes nucleic acid sequencing methods that are performed by synthesizing the complementary strand of a single-stranded polynucleotide of interest, using a polymerase to incorporate the labeled nucleotides into the complementary strand. *Id.* at 2:50–53; 8:50–57. The protecting group allows the polymerase to incorporate only one nucleotide at a time into the complementary strand. *See id.* at 7:51–54. The detectable label allows identification of the particular type of nucleotide incorporated into the complementary strand. *Id.* at 2:55–57. After removing the label and protecting group, subsequent nucleotides may be added one at a time, and their identities determined in sequential fashion, thereby determining the sequence of the nucleic acid of interest. *See id.* at 2:67–3:3.

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