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 IPR2018-00291
Patent 9,718,852 B2

Before JENNIFER MEYER CHAGNON, JAMES A. WORTH, and MICHELLE N. ANKENBRAND, *Administrative Patent Judges.*

WORTH, *Administrative Patent Judge*.

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

I. INTRODUCTION

On December 8, 2017, Illumina, Inc. ("Illumina" or "Petitioner") filed a Petition (Paper 1, "Pet.") requesting an *inter partes* review of claim 1 (the "challenged claim") of U.S. Patent No. 9,718,852 B2 (Ex. 1001, "'852 patent"). On March 27, 2018, The Trustees of Colu

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City of New York ("Columbia" or "Patent Owner") filed a Preliminary Response (Paper 8, "Prelim. Resp.").

Institution of an *inter partes* review is authorized by statute when "the information presented in the petition filed under [35 U.S.C. §] 311 and any response filed under [35 U.S.C. §] 313 shows that 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). For the reasons set forth below, we determine that Petitioner has demonstrated that there is a reasonable likelihood that claim 1 is unpatentable, and we institute an *inter partes* review of claim 1 based on the grounds set forth in the Petition.

A. Related Matters

The parties note as related IPR2012-00007 (Final Written Decision, Paper 140, Ex. 1005) with respect to U.S. Patent No. 7,790,869; IPR2012-00006 (Final Written Decision, Paper 128, Ex. 1006) with respect to U.S. Patent No. 7,713,698; and IPR2013-00011 (Final Written Decision, Paper 130, Ex. 1007) with respect to U.S. Patent No. 8,088,575. Pet. 1; Paper 4, 1. In these proceedings, the Board held all challenged claims unpatentable. *Id.* The Board decisions were affirmed *sub. nom. Trustees of Columbia Univ. v. Illumina, Inc.*, 620 Fed. Appx. 916, 927–28, 934 (Fed. Cir. 2015) (*see* Ex. 1008).

The parties state that Petitioner has filed petitions for *inter partes* review of U.S. Patents Nos. 9,719,139, 9,708,358, 9,725,480, 9,868,985 ("the '852, '139, '358, and '480 patents") alleged to be owned by Columbia, PTAB Case Nos. IPR2018-00291, -318, -322, -385, -797. Paper 4, 2; Paper 5, 1; Paper 9, 1. Patent Owner states that the '852, '139, '358, and '480 patents were asserted against Illumina in *Trustees of Columbia University v.*

Illumina, Inc., C.A. No. 17-cv-973-GMS (D. Del.). *Id.* Patent Owner further states that Columbia previously asserted related U.S. Patents Nos. 7,790,869, 7,713,698, and 8,088,575 ("the '869, '698, and '575 patents") against Illumina in *Trustees of Columbia University v. Illumina, Inc.*, C.A. No. 12-cv-376 (D. Del.). *Id.*

Patent Owner also points to other proceedings in which Illumina is involved that relate to patents owned by Illumina. *See* Paper 4, 2; Paper 13, 1.

B. The '852 Patent (Ex. 1001)

The '852 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. 1001, 4:25–31.

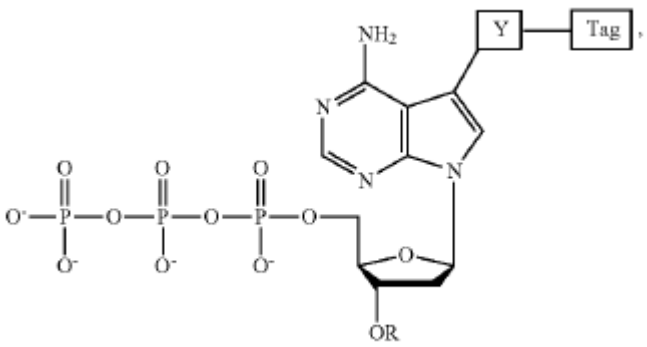
The '852 patent discloses that electrophoresis was a bottleneck for high-throughput DNA sequencing and mutation detection projects. *Id.* at 2:16–18. It was known to perform sequencing without electrophoresis, using a chip format and laser-induced fluorescent detection for DNA sequencing. *Id.* at 2:19–27. The '852 patent discloses that long stretches of the same bases cannot be identified unambiguously with a pyrosequencing method. *Id.* at 2:44–46. The '852 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 '852 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. *Id.* at 3:4–13; *see also id.* at 5:40–41. The approach disclosed in the '852 patent is further to incorporate nucleotide analogues, which are labeled with cleavable, unique labels, such as fluorescent dyes, to mass tags and where the 3'-OH is capped with a cleavable chemical moiety, such as either a MOM group ($-CH_2OCH_3$) or an allyl group ($-CH_2CH=CH_2$), into the growing strand DNA as terminators. *Id.* at 3:44–51; *see also id.* at 5:43–44.

C. Illustrative Claim

Claim 1, reproduced below, is the sole challenged claim and is illustrative of the subject matter:

> 1. An adenine deoxyribonucleotide analogue having the structure:
>
> 
>
>
> wherein R (a) represents a small, chemically cleavable, chemical group capping the oxygen at the 3' position of the deoxyribose of the deoxyribonucleotide analogue, (b) does not interfere with recognition of the analogue as a substrate by a DNA polymerase, (c) is stable during a DNA polymerase reaction, and (d) does not contain a ketone group;
>
> wherein OR is not a methoxy group or an ester group;

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