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Paper No. 20
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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

COMPLETE GENOMICS, INC.,
Petitioner,

v.

ILLUMINA CAMBRIDGE LTD.,
Patent Owner.

Case IPR2017-02174
Patent 7,566,537 B2

Before ERICA A. FRANKLIN, ZHENYU YANG, and TIMOTHY G. MAJORS, *Administrative Patent Judges*.

MAJORS, *Administrative Patent Judge*.

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

I. INTRODUCTION

Complete Genomics, Inc. ("CGI" or "Petitioner"), on October 5, 2017, filed a Petition to institute *inter partes* review of claims 1–6 and 8 of U.S. Patent No. 7,566,537 B2 ("the '537 patent"). Paper 1 ("Pet.").[1] Illumina Cambridge Ltd. ("Patent Owner"), on January 23, 2018, filed a Preliminary Response to the Petition. Paper 6 ("Prelim. Resp.").

Under 35 U.S.C. § 314(a), an *inter partes* review may not be instituted unless the Petition "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." For the reasons stated below, we determine that Petitioner has not established a reasonable likelihood that it would prevail in showing the unpatentability of claims 1–6 and 8 of the '537 patent.

II. BACKGROUND

A. *Related Matters*

Petitioner identifies other proceedings related to the '537 patent. Pet. 4–7. The identified proceedings include, *inter alia*, the following:

1) IPR2013-00517 (petition for *inter partes* review by Intelligent Bio-Systems, Inc. ("IBS"));
2) IPR2013-00518 (petition for *inter partes* review by IBS);
3) *Intelligent Bio-Systems, Inc. v. Illumina Cambridge Ltd.*, 821 F.3d 1359 (Fed. Cir. 2016) (appeal of IPR2013-00517);
4) *Illumina, Inc. v. Qiagen, N.V.*, 207 F.Supp.3d 1081 (N.D.

[1] Petitioner identifies BGI Shenzhen Co., Ltd. (and other BGI companies) as a real party-in-interest to these proceedings. Pet. 4.

Cal. 2016) (involving assertion of the '537 patent against Qiagen and its subsidiary, IBS);

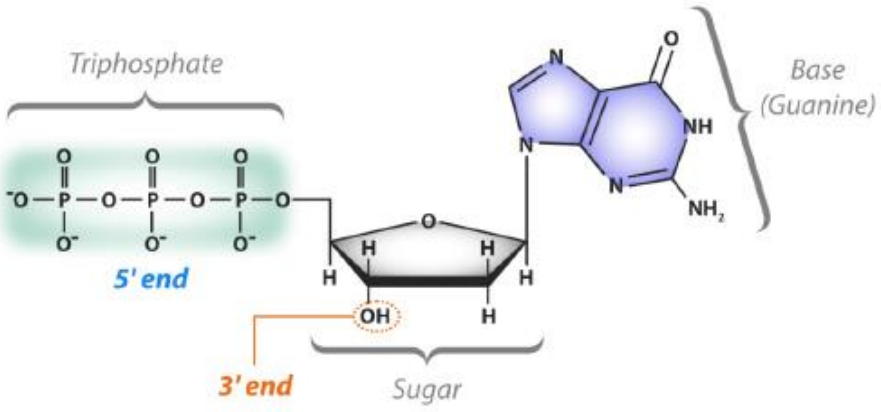
5) *The Trustees of Columbia University v. Illumina, Inc.*, 1:12-cv-00376-GMS (D. Del.) (involving assertion of patents against Illumina, and assertion of the '537 patent against IBS, Columbia's licensee of the accused technology); and
6) IPR2017-02172 (petition for *inter partes* review by CGI, filed concurrent with the present Petition).

Pet. 4–7. We describe these proceedings in more detail in Section II.E. below.

B. Background Technology and the '537 Patent

The '537 patent relates generally to labeled nucleotides and nucleosides, and to methods of using such molecules in, for example, nucleic acid sequencing reactions. Ex. 1501, 2:1–7.

A "nucleotide" consists of a nitrogenous base, a sugar, and one or more phosphate groups. *Id.* at 4:48–49. An illustrative depiction of a deoxyribonucleotide triphosphate is provided below.



Ex. 1601, ¶ 8. The depiction above shows, *inter alia*, the 3'-hydroxyl (3'-OH) group of the deoxyribose sugar; the sugar of a DNA nucleotide is a 2'

deoxyribose, meaning the 2' carbon lacks a bond to an oxygen atom. *Id.* ¶ 10 (depicting 2-deoxyribose and ribose); Ex. 1501, 4:49–51 ("In RNA, the sugar is a ribose, and in DNA is a deoxyribose, i.e., a sugar lacking a hydroxyl group that is present in ribose [at the 2' carbon]").

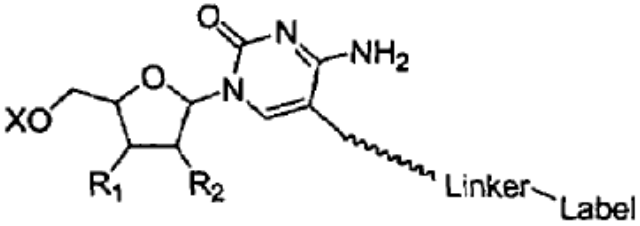
Nucleotides, such as depicted above, are building blocks of DNA and, through complementary base-pairing, form molecules of DNA that consist of two associated nucleic acid strands and a double-helical structure that resembles a twisting ladder. Ex. 1601, ¶¶ 8–9. Natural DNA contains four bases: the base may include a purine or pyrimidine, such as the purines adenosine (A) and guanidine (G), and the pyrimidines cytidine (C) and thymidine (T). Ex. 1501, 4:51–54. The sequence of these bases in DNA provides genetic information, and ultimately encodes the traits in living organisms. *Intelligent Bio-Systems*, 821 F.3d at 1362.

A base of one DNA strand bonds with the complementary base on the opposing strand in a known pattern: A pairs with T, and G pairs with C. Ex. 1601, ¶ 9. Because of this pattern of base pairing, if the sequence of one strand is known, the other strand's sequence can be deduced. *Id.* In addition, enzymes (e.g., DNA polymerase) may cause the strand to be extended with the phosphate group on the 5' carbon of each additional nucleotide attaching to the 3'-OH of the last nucleotide in the strand via a new phosphodiester bond. *Id.* ¶ 11. The added nucleotide is one that, as explained above, bonds with its complementary base of the nucleotide at a corresponding position on the opposing nucleic acid strand. *Id.* ¶ 9; Ex. 1501, 2:50–53.

As described in the '537 patent, "[t]he invention features a nucleotide or nucleoside molecule, having a base that is linked to a detectable label via a cleavable linker." Ex. 1501, 2:23–24. The label may be, for example, a

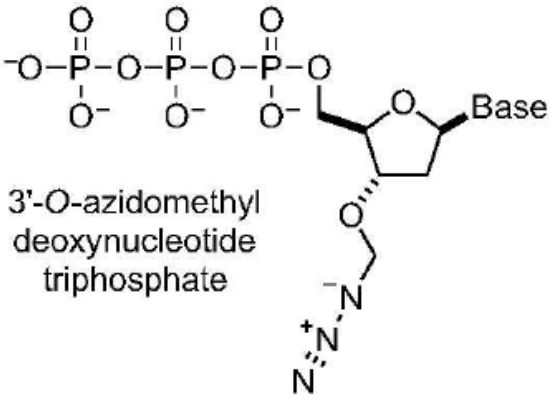
fluorophore that is detectable by fluorescence spectroscopy. *Id.* at 5:20–25. The nucleotide also includes a ribose or deoxyribose sugar, which "sugar can include a protecting group attached via the 2' or 3' oxygen atom," and the protecting group "can be removed to expose a 3'-OH." *Id.* at 2:25–28.

The '537 patent depicts several exemplary labeled nucleotide structures, such as shown below.



Cytidine C5-linker

Ex. 1501, Fig. 1 (partial). Figure 1 (partial) above shows a nucleotide having a base (here cytidine) attached to a label via a linker. *Id.* The '537 patent explains that "X" in this molecule can be, for example, a triphosphate, and that R_1 and R_2 may be selected from H, OH, or any group that can be transformed into an OH. *Id.* at 4:7–11. Among the "suitable hydroxyl protecting groups" that can be transformed into an OH, the '537 patent identifies azidomethyl (CH_2N_3). *Id.* at Fig. 3. A further representation of an azidomethyl protecting group is shown below.



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