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 LIMITED,
Patent Owner.

_____

Case IPR2013-00266
Patent 8,158,346 B2

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Before LORA M. GREEN, SCOTT E. KAMHOLZ, and
CHRISTOPHER L. CRUMBLEY, *Administrative Patent Judges*.

CRUMBLEY, *Administrative Patent Judge*.

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

I. BACKGROUND

A.   Introduction

Petitioner, Intelligent Bio-Systems, Inc. ("IBS"), filed a Petition
(Paper 1, "Pet.") for *inter partes* review of claims 1, 2, 4, 11, 12, 17, 18, and
19 of U.S. Patent No. 8,158,346 B2 (Ex. 1001, "the '346 patent") pursuant
to 35 U.S.C. §§ 311–319 and 37 C.F.R. §§ 42.1–42.123.

On October 28, 2013, the Board instituted *inter partes* review of
claims 1, 2, 4, 11, 12, 17, 18, and 19 of the '346 patent on the following
three grounds of unpatentability:

1. Whether claims 1, 2, 4, 11, 12, 17, 18, and 19 are unpatentable
under 35 U.S.C. § 102(a) or (e) as anticipated by Ju;[1]

2. Whether claims 1, 2, 4, 11, 12, 17, 18, and 19 are unpatentable
under 35 U.S.C. § 102(b) as anticipated by Tsien;[2] and

3. Whether claims 1, 2, 4, 11, and 12 are unpatentable under 35
U.S.C. § 102(b) as anticipated by Stemple.[3]
Paper 20 ("Dec."), 13.

Following institution of *inter partes* review, Patent Owner, Illumina
Cambridge Limited ("Illumina"), filed a Motion to Amend Claims (Paper
31, "Mot."), but did not file a response under 37 C.F.R. § 42.120 to the
Decision instituting *inter partes* review. IBS filed an opposition to
Illumina's Motion to Amend (Paper 37), and both parties filed Motions to
Exclude Evidence (Papers 46, 49).

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[1] As used in our Decision to Institute, "Ju" collectively referred to both Ju,
U.S. 6,664,079 B2 (Dec. 16, 2003) (Ex. 1002) and Ju, WO 02/29003 A2
(Apr. 11, 2002) (Ex. 1003).
[2] Tsien, WO 91/06678 A1 (May 16, 1991) (Ex. 1006).
[3] Stemple, WO 00/53805 A1 (Sept. 14, 2000) (Ex. 1007).

Pursuant to requests by both parties, an oral hearing was held on May 28, 2014, and the transcript of the hearing was entered into the record. Paper 69, "Tr."

The Board has jurisdiction under 35 U.S.C. § 6(c). This final written decision is issued pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73. For the reasons that follow, Illumina's Motion to Amend is *granted* to the extent it requests to cancel claims 1, 2, 4, 11, 12, 17, 18, and 19; Illumina's Motion to Amend is *denied* to the extent that it requests entry of substitute claims 20–26.

B.   The '346 Patent

The '346 patent relates to DNA sequencing using nucleotides that are labeled and blocked. Ex. 1001, 2:18–22. A detectable label is attached to the base of a nucleotide by a cleavable linker, and a polymerase-blocking group is removably attached at the 3′ (or 2′) position of the sugar moiety of the nucleotide. *Id.* at 2:38–44. A target DNA is sequenced by synthesizing its complement polynucleotide using the labeled and blocked nucleotides. *Id.* at 9:3–7. The blocking group prevents the polymerase from adding more than one nucleotide at a time. *Id.* at 8:13–20. The label then is detected, thereby identifying the newly-added nucleotide. *Id.* at 3:17–19. The label and the blocking group then are removed from the added base under identical conditions. *Id.* at 8:27–28. The process repeats with the next base. *Id.* at 3:20–22. The sequence of the target DNA then may be determined from the complementary sequence. *Id.* at 3:21–22.

C.   Related Proceedings

The '346 patent is asserted in the following copending district court case: *Trustees of Columbia University in the City of New York v. Illumina, Inc.*, 1:12-cv-00376-GMS (D. Del.). Pet. 5.

II. ORIGINAL CLAIMS

As noted above, Illumina did not file a Response following our Decision instituting *inter partes* review of claims 1, 2, 4, 11, 12, 17, 18, and 19. Instead, Illumina filed a Motion to Amend pursuant to 35 U.S.C. § 316(d)(1) ("During an inter partes review . . ., the patent owner may file 1 motion to amend the patent in 1 or more of the following ways: (A) Cancel any challenged patent claim. (B) For each challenged claim, propose a reasonable number of substitute claims."). In its Motion, Illumina requested cancellation of claims 1, 2, 4, 11, 12, 17, 18, and 19 and proposed substitute claims 20–26 to replace the cancelled claims, and asserted that each of the grounds upon which the *inter partes* review was instituted "is rendered moot in light of Illumina's proposed substitute claims." Mot. 1. We shall *grant* Illumina's Motion to Amend to the extent it requests to cancel claims 1, 2, 4, 11, 12, 17, 18, and 19.

III. PROPOSED SUBSTITUTE CLAIMS

In the Motion to Amend, Illumina proposed substitute claim 20 to replace claim 2. The claim, as annotated by Illumina to show the differences between original claim 2 and proposed substitute claim 20, is reproduced below:

> 20. A method ~~according to claim 1~~ <u>for determining the sequence of a target single-stranded polynucleotide, comprising</u>

monitoring the sequential incorporation of complementary nucleotides, the method ~~further~~ comprising the steps of

(a) providing said nucleotides, wherein the nucleotides each have a base that is linked to a detectable label via a cleavable linker, wherein the cleavable linker contains a disulfide linkage, wherein each of the nucleotides has a ribose or deoxyribose sugar moiety and the ribose or deoxyribose sugar moiety comprises a protecting group attached via the 3' oxygen atom; and wherein said monitoring comprises

(b) incorporating a nucleotide of (a) into the complement of the target single stranded polynucleotide;

(c) detecting the label linked to the base of the nucleotide of (b), thereby determining the identity ~~type~~ of the nucleotide incorporated;

(d) subsequently removing the label and the protecting group of the nucleotide of (b) under a single set of chemical cleavage conditions, wherein the chemical cleavage conditions cleave the disulfide linkage and permit further nucleotide incorporation into the complement of the target single stranded polynucleotide to occur; and

(e) ~~optionally~~ repeating steps (b)-(d) one or more times; thereby determining the sequence of a target single-stranded polynucleotide.

Mot. 2.

Proposed substitute claim 20 combines the limitations found in original claims 1 and 2, and also recites a newly added limitation that the cleavable linker "contains a disulfide linkage," which was not present in the original claims.

For illustrative purposes, an annotated generic nucleotide from Figure 1B of Stemple is reproduced below to show the main parts of a nucleotide used in sequencing-by-synthesis ("SBS") processes such as the one of proposed claim 20:

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