Paper 19 Date: November 21, 2013

# UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

INTELLIGENT BIO-SYSTEMS, INC., Petitioner,

v.

ILLUMINA CAMBRIDGE LIMITED, Patent Owner.

> Case IPR2013-00324 Patent No. 7,057,026

Before LORA M. GREEN, DEBORAH KATZ, and CHRISTOPHER L. CRUMBLEY, *Administrative Patent Judges*.

CRUMBLEY, Administrative Patent Judge.

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

### I. INTRODUCTION

On June 4, 2013, Intelligent Bio-Systems, Inc. ("IBS") filed a petition for *inter partes* review of claims 1-8 of U.S. Patent No. 7,057,026 (Ex. 1001, "the '026 patent"). Paper 1, "Pet." The owner of the '026 patent, Illumina Cambridge Limited ("Illumina"), waived filing of a preliminary response. Paper 14. We have jurisdiction under 35 U.S.C. § 314. For the reasons that follow, the Board does not institute an *inter partes* review.

### A. Related Matter: Case IPR2013-00128

Several months prior to filing the instant petition, IBS filed a petition on January 29, 2013, that requested an *inter partes* review of claims 1-8 of the '026 patent. IPR2013-00128, Paper 2 ("128 Petition"). On July 29, 2013, the Board granted the 128 Petition, and instituted *inter partes* review of claims 1-8. Illumina thereafter filed a non-contingent motion to amend pursuant to 37 C.F.R. § 42.121, requesting cancellation of original claims 1-8 of the '026 patent and entry of substitute claims 9-12. IPR2013-00128, Paper 45, 1. The Board has not yet ruled on Illumina's motion to amend.

#### B. The '026 Patent

The '026 patent is directed to labeled nucleotides and nucleosides used in "sequencing reactions, polynucleotide synthesis, nucleic acid amplification, nucleic acid hybridization assays, single nucleotide polymorphism studies, and other techniques using enzymes such as polymerases, reverse transcriptases, terminal transferases, or other DNA modifying enzymes." Ex. 1001 2:10-14. A detectable label is attached to the base of the nucleotide or nucleoside via a

cleavable linker group. *Id.* at 2:6-8. The label enables the nucleotide to be detected when it is incorporated into a strand of DNA. *Id.* at 2:56-64.

# C. Prior Art Relied Upon

IBS relies upon the following prior art references:

Dower	U.S. Patent 5,547,839	Aug. 20, 1996	(Ex. 1006)
Canard	U.S. Patent 5,798,210	Aug. 25, 1998	(Ex. 1007)
Odedra	U.S. Patent 7,078,499	Jul. 18, 2006	(Ex. 1002)

Meinwald, *An Approach To the Synthesis of Pederin*, 49 PURE AND APPL. CHEM. 1275 (1977) (Ex. 1004).

Takeshi Matsumoto *et al.*, A Revised Structure of Pederin, 60 TETRAHEDRON LETTERS 6297 (1968) (Ex. 1005).

Beckman Coulter CEQ<sup>TM</sup> 2000 DNA Analysis System User's Guide, June 2000 ("CEQ<sup>TM</sup> User's Guide") (Ex. 1008).

IBS asserts that Dower, Canard, and the CEQ<sup>™</sup> User's Guide are prior art under 35 U.S.C. § 102(b), whereas Odedra is prior art under 35 U.S.C. § 102(e).<sup>1</sup> Pet. 15-16, 27 n. 7, 30. Of the cited art, Dower, Canard, and the CEQ<sup>™</sup> User's Guide were submitted to the Board previously, accompanying IBS's 128 Petition.

<sup>&</sup>lt;sup>1</sup> IBS's petition contains no explanation why Meinwald and Matsumoto are prior art, but both references appear to qualify under 35 U.S.C. § 102(b).

### D. The Asserted Grounds

IBS asserts the following grounds of unpatentability (Pet. 6-7):

Claims	Basis	References
1-6	§ 102	Odedra
6	§ 103	Odedra in combination with Dower, further in view of Meinwald or Matsumoto
7-8	§ 103	Odedra alone, or Odedra in combination with Canard or $CEQ^{TM}$ User's Guide

### II. ANALYSIS

The standard for instituting an *inter partes* review is set forth in 35 U.S.C. § 314(a) which provides as follows:

THRESHOLD -- The Director may not authorize an inter partes review to be instituted unless the Director determines that the information presented in the petition filed under section 311 and any response filed under section 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.

Notably, Congress did not mandate that an *inter partes* review must be instituted under certain conditions. Rather, by stating that the Director—and by extension, the Board—*may not* institute review *unless* certain conditions are met, Congress made institution discretionary. In determining whether to institute an *inter partes* review, the Board may "deny some or all grounds for unpatentability for some or all of the challenged claims." 37 C.F.R. § 42.108(b); *see* 35 U.S.C. § 314(a).

Our discretion is further guided by 35 U.S.C. § 325(d), which reads as follows (emphasis added):

MULTIPLE PROCEEDINGS -- Notwithstanding sections 135(a), 251, and 252, and chapter 30, during the pendency of any post-grant review under this chapter, if another proceeding or matter involving the patent is before the Office, the Director may determine the manner in which the post-grant review or other proceeding or matter may proceed, including providing for the stay, transfer, consolidation, or termination of any such matter or proceeding. *In determining whether to institute or order a proceeding under this chapter, chapter 30, or chapter 31, the Director may take into account whether, and reject the petition or request because, the same or substantially the same prior art or arguments previously were presented to the Office.<sup>2</sup>* 

Several factors counsel against institution in the present case. As we noted above, in the 128 Petition, IBS requested *inter partes* review of claims 1-8 of the '026 patent, and we granted that petition on several grounds that mirror closely those presented in the instant petition. For example, in the 128 proceeding, we instituted trial on claims 1-6 as anticipated by either Tsien<sup>3</sup> or Ju,<sup>4</sup> whereas the first ground of the instant petition requests review of claims 1-6 as anticipated by Odedra. Similarly, in the 128 proceeding, we instituted trial on grounds alleging the obviousness of claims 7 and 8 over either Tsien or Ju in combination with the

<sup>&</sup>lt;sup>2</sup> Although this provision appears in Chapter 32 of the Patent Act, which is directed to post-grant reviews, by its terms it is applicable also to proceedings under Chapter 31, which covers *inter partes* review proceedings.

<sup>&</sup>lt;sup>3</sup> WO 91/06678 to Tsien et al., IPR2013-00128 Ex. 1012.

<sup>&</sup>lt;sup>4</sup> U.S. Patent No. 6,664,079 B2 to Ju et al., IPR2013-00128 Ex. 1008.

CEQ User's Guide, while the instant proceeding proposes a combination of Odedra with either Canard or the CEQ User's Guide.

Based on our review and the characterization of the references in IBS's petitions, the teachings of Odedra relied on in the instant petition are substantially the same as those found in Tsien and Ju. For example, the 128 Petition characterizes Ju as "generally disclos[ing] nucleic acid sequencing by synthesis methods that utilize 3'-OH capped, chain-terminating nucleotide analogs that include a fluorescent label attached to the nucleotide analogs through a cleavable linker." 128 Pet. 30. The instant petition describes Odedra using exactly the same language. Pet. 17. In addition, the claim charts presented in the petitions contain similar disclosures from each of Odedra, Ju, and Tsien. Compare Pet. 18 ("Odedra further teaches that the protecting group and the linker attaching the label to the base 'comprise the same enzyme-cleavable group thus facilitating *a single addition* or reaction causing cleavage of both blocking and reporter [label] groups in one reaction."" (emphasis in original)) with 128 Pet. 43 ("Tsien teaches that 'a fluorescent tag attached to the base moiety . . . may be chemically cleaved (either separately from or *simultaneously* with the deblocking step)."" (emphasis in original)).

Furthermore, we note that IBS has not provided any justification for filing the instant petition, other than its representation that it became aware of the relevance of Odedra after the filing of the 128 Petition. Pet. 2. IBS does not distinguish any teaching present in Odedra that is lacking from Ju, Tsien, or any of the other references cited in the 128 Petition. We, therefore, conclude that the 128

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Petition presented the same, or substantially the same, prior art and arguments to the Office as those in the instant petition. *See* 35 U.S.C. § 325(d).

Finally, we note that Illumina has filed a motion to amend the '026 patent in the 128 proceeding which requests cancellation of original claims 1-8. IPR2013-00128, Paper 45, 1. As part of its obligation to demonstrate how its proposed substitute claims are patentable over the known prior art, Illumina has filed Odedra as an exhibit to its motion to amend. *Id.* at 10-11; IPR2013-00128 Ex. 2013. IBS will, therefore, have the opportunity to address Odedra in the 128 proceeding, in the context of the patentability of the proposed substitute claims.

In light of the foregoing, and exercising our discretion under 35 U.S.C. §§ 314(a) and 325(d), and 37 C.F.R. § 42.108(b), we decline to institute an *inter partes* review in the instant proceeding.

#### III. ORDER

Accordingly, it is

ORDERED that the petition is *denied* as to all challenged claims of the '026 patent.

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