

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

NOTICE OF ENTRY OF JUDGMENT ACCOMPANIED BY OPINION

OPINION FILED AND JUDGMENT ENTERED: 05/09/2016

The attached opinion announcing the judgment of the court in your case was filed and judgment was entered on the date indicated above. The mandate will be issued in due course.

Information is also provided about petitions for rehearing and suggestions for rehearing en banc. The questions and answers are those frequently asked and answered by the Clerk's Office.

Costs are taxed against the appellant in favor of the appellee under Rule 39. The party entitled to costs is provided a bill of costs form and an instruction sheet with this notice.

The parties are encouraged to stipulate to the costs. A bill of costs will be presumed correct in the absence of a timely filed objection.

Costs are payable to the party awarded costs. If costs are awarded to the government, they should be paid to the Treasurer of the United States. Where costs are awarded against the government, payment should be made to the person(s) designated under the governing statutes, the court's orders, and the parties' written settlement agreements. In cases between private parties, payment should be made to counsel for the party awarded costs or, if the party is not represented by counsel, to the party pro se. Payment of costs should not be sent to the court. Costs should be paid promptly.

If the court also imposed monetary sanctions, they are payable to the opposing party unless the court's opinion provides otherwise. Sanctions should be paid in the same way as costs.

Regarding exhibits and visual aids: Your attention is directed Fed. R. App. P. 34(g) which states that the clerk may destroy or dispose of the exhibits if counsel does not reclaim them within a reasonable time after the clerk gives notice to remove them. (The clerk deems a reasonable time to be 15 days from the date the final mandate is issued.)

FOR THE COURT

/s/ Peter R. Marksteiner

Peter R. Marksteiner
Clerk of Court

15-1693 - Intelligent Bio-Systems, Inc. v. Illumina Cambridge Ltd.
United States Patent and Trademark Office, Case No. IPR2013-00517

Illumina Ex. 1069 IPR Decision USD 10,425,742

United States Court of Appeals for the Federal Circuit

INTELLIGENT BIO-SYSTEMS, INC.,
Appellant

v.

ILLUMINA CAMBRIDGE LTD.,
Appellee

2015-1693

Appeal from the United States Patent and Trademark
Office, Patent Trial and Appeal Board in No. IPR2013-
00517.

Decided: May 9, 2016

ROBERT R. BARON, JR., Ballard Spahr LLP, Philadel-
phia, PA, argued for appellant. Also represented by MARC
S. SEGAL; SCOTT DAVID MARTY, Atlanta, GA.

WILLIAM R. ZIMMERMAN, Knobbe, Martens, Olson &
Bear, LLP, Washington, DC, argued for appellee. Also
represented by JONATHAN EDWARD BACHAND; BRENTON R.
BABCOCK, JOSEPH S. CIANFRANI, SHEILA N. SWAROOP,
Irvine, CA; NATHANAEL LUMAN, KERRY S. TAYLOR, San
Diego, CA.

Before O'MALLEY, WALLACH, and HUGHES, *Circuit Judges*.
O'MALLEY, *Circuit Judge*.

Illumina Cambridge Ltd. (“Illumina”) owns U.S. Patent No. 7,566,537 (“the ’537 patent”), which is directed to a method of labeling nucleotides in a deoxyribonucleic acid (“DNA”) strand. Intelligent Bio-Systems, Inc. (“IBS”) filed a revised petition to the Patent Trial and Appeal Board (“Board”) requesting *inter partes* review of claims 1–6 and 8 of the ’537 patent on August 30, 2013. The Board instituted review of the challenged claims on the basis that they were invalid as obvious under 35 U.S.C. § 103 in view of certain prior art references. In its Final Written Decision, issued February 11, 2015, the Board found that IBS failed to satisfy its burden of demonstrating the obviousness of the challenged claims by a preponderance of the evidence. IBS appeals. Because we find that the Board’s judgment was supported by substantial evidence, we affirm.

BACKGROUND

A. Technology

By way of background, DNA is comprised of two strands of nucleotides, which bind to each other to form a double helix structure. “A nucleotide is made up of a sugar molecule, a phosphate, and a ‘base.’ It is the ‘base’—adenine (A), cytosine (C), guanine (G), or thymine (T)—that provides the code for the genetic information in DNA.” Appellant Br. 4. The bases of two nucleotide strands pair predictably: A with T, and G with C. In this way, if one knows the identity of a nucleotide in one strand, the identity of the corresponding nucleotide in the other strand is easily inferred. Identification of the sequence of nucleotides in DNA is important, as “the sequence of nucleotides in DNA determines the traits of living organisms.” *Id.*

INTELLIGENT BIO-SYSTEMS, INC. v.
ILLUMINA CAMBRIDGE LTD.

3

The invention of the '537 patent “relates to labelled nucleotides.” '537 patent, col. 1 l. 14. The labels, used to identify the nucleotides, are removable and are intended for “use in polynucleotide sequencing methods.” *Id.* at col. 1 ll. 14–16. The polynucleotide sequencing method at issue is the so-called sequencing by synthesis (“SBS”) method. SBS “is a process used to identify the sequence of nucleotides in DNA by synthesizing a single strand of DNA using nucleotides that are complementary to the nucleotides in a sample single strand of DNA.” Appellee Br. 3.

The claimed method in the '537 patent is directed to labelling nucleotide bases to determine their identity. The 3'-OH (“three prime hydroxyl”) position of the sugar components of the labeled nucleotides are further modified with a blocking group (also referred to as a protecting group). The blocking group (or protecting group) attached to the sugar molecule “prevent[s] the natural linking process between nucleotides.” Appellant Br. 4. By stopping the linking process, one can detect the label on the nucleotide base and determine its identity (A, C, G, or T). The blocking group is cleavable, which allows the linking process to continue after the label is detected.

The SBS method starts with a single strand of unknown nucleotides and adds complementary nucleotides one-by-one to form the complete, double-helix structure. “The protecting group allows the polymerase to incorporate only one nucleotide at a time into the complementary strand.” *Intelligent Bio-Sys., Inc. v. Illumina Cambridge Ltd.*, IPR2013-00517, 2015 WL 996355, at *3 (PTAB Feb. 11, 2015) (Final Written Decision of the Board). “By incorporating such modified nucleotides one-by-one into a growing DNA chain, researchers are able to first detect the label to determine the base of each nucleotide, before another nucleotide (with its own label attached to its own base) is added.” Appellant Br. 4–5. The identity of the attached label is determined “by any suitable method,

including fluorescence spectroscopy or by other optical means.” ’537 patent, col. 5 ll. 21–23.

The claims require that “the protecting group comprises an azido group.” *Id.* at col. 19 ll. 58–59 (claim 1). According to Illumina, “the inventors of the ’537 patent were the first to identify the azidomethyl group (CH₂N₃) as a protecting group that would meet the rigorous requirements of SBS.” Appellee Br. 9.

Claim 1, the only independent claim under review, is reproduced below:

1. *A method of labeling a nucleic acid molecule, the method comprising incorporating into the nucleic acid molecule a nucleotide or nucleoside molecule, wherein the nucleotide or nucleoside molecule has a base that is linked to a detectable label via a cleavable linker and the nucleotide or nucleoside molecule has a ribose or deoxyribose sugar moiety, wherein the ribose or deoxyribose sugar moiety comprises a protecting group attached via the 2' or 3' oxygen atom, and said protecting group can be modified or removed to expose a 3' OH group and the protecting group comprises an azido group.*

Id. at col. 19 ll. 49–59 (emphases added).

B. Prior Art

There are three articles of prior art at issue in this appeal: (1) Roger Tsien et al., WO 91/06678 (May 16, 1991) (“Tsien”); (2) Jingyue Ju et al., U.S. Patent No. 6,664,079 (Dec. 16, 2003) (“Ju”); and (3) Zavgorodny et al., *1-Alkylthioalkylation of Nucleoside Hydroxyl Functions and Its Synthetic Applications: A New Versatile Method in Nucleoside Chemistry*, 32 TETRAHEDRON LETTERS 7593 (1991) (“Zavgorodny”). IBS argued to the Board that Ju in combination with Zavgorodny or Tsien in combination with Zavgorodny render the patent invalid as obvious

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.