620 Fed.Appx. 916
This case was not selected for
publication in West's Federal Reporter.
See Fed. Rule of Appellate Procedure 32.1
generally governing citation of judicial
decisions issued on or after Jan. 1, 2007.
See also U.S.Ct. of App. Fed. Cir. Rule 32.1.
United States Court of Appeals,
Federal Circuit.

TRUSTEES OF COLUMBIA UNIVERSITY
IN THE CITY OF NEW YORK, Appellant
v.
ILLUMINA, INC., Appellee.
Trustees of Columbia University
in the City of New York, Appellant
v.
Illumina, Inc., Appellee.
Trustees of Columbia University
in the City of New York, Appellant
v.
Illumina, Inc., Appellee.

Nos. 2014–1547, 2014–1548, 2014–1550.
|
July 17, 2015.

Synopsis

Background: In inter partes reviews, the Patent and Trademark Office, Patent Trial and Appeal Board, 2014 WL 1252940, 2014 WL 1252946, and 2014 WL 1252992, cancelled patents in part that were generally directed to determining nucleotide sequence of deoxyribonucleic acid (DNA). Patentee appealed.

Holdings: The Court of Appeals, Wallach, Circuit Judge, held that:

[1] claims in patents would have been obvious to person having ordinary skill in the art who had higher level of knowledge and ability, where those claims were obvious to such a person not necessarily possessing those additional skills;

[2] Board was entitled to weigh credibility of witnesses in light of their qualifications and evaluate their assertions accordingly;

[3] substantial evidence supported finding by Board that person having ordinary skill in the art would have had reasonable expectation of success in achieving claimed invention, and thus patent was invalid for obviousness;

[4] secondary considerations did not weigh strongly in favor of nonobviousness; and

[5] patent claim on base-labeled, 3#–OH–capped nucleotide was anticipated.

Affirmed.

West Headnotes (7)

[1] Patents
Genes and genetic technology
291 Patents
291II Patentability and Validity
291II(E) Obviousness;Lack of Invention
291II(E)3 Particular Fields of Invention
291k736 Biological Subject Matter; Biotechnology
291k738 Genes and genetic technology
Claims in patents that were generally directed to determining nucleotide sequence of deoxyribonucleic acid (DNA) would have been obvious to person having ordinary skill in the art who had higher level of knowledge and ability, where those claims were obvious to such a person not necessarily possessing those additional skills. 35 U.S.C.A. § 103(a).

Cases that cite this headnote

[2] Patents
Inter partes review
291 Patents
291IV Patent Applications and Proceedings
291IV(G) Postissuance Proceedings
291IV(G)5 Other Postissuance Proceedings
291k1262 Inter partes review

Patent Trial and Appeal Board was entitled to weigh credibility of witnesses in light of their qualifications and evaluate their assertions accordingly, in inter partes review of patents that were generally directed to determining nucleotide sequence of deoxyribonucleic acid (DNA).

Cases that cite this headnote

[3] **Patents**

Inter partes review

291 Patents
291IV Patent Applications and Proceedings
291IV(G) Postissuance Proceedings
291IV(G)5 Other Postissuance Proceedings
291k1262 Inter partes review

Substantial evidence supported finding by Patent Trial and Appeal Board in inter partes review that person having ordinary skill in the art would have had reasonable expectation of success in achieving claimed invention, and thus patent that was generally directed to determining nucleotide sequence of deoxyribonucleic acid (DNA) was invalid for obviousness, through prior art disclosure of base labeling, cleavable linkers, and deazapurine, taken together. 35 U.S.C.A. § 103(a).

Cases that cite this headnote

[4] **Patents**

Genes and genetic technology

291 Patents
291II Patentability and Validity
291II(E) Obviousness;Lack of Invention
291II(E)3 Particular Fields of Invention
291k736 Biological Subject Matter; Biotechnology
291k738 Genes and genetic technology

Secondary considerations did not weigh strongly in favor of nonobviousness of patent that was generally directed to determining nucleotide sequence of deoxyribonucleic acid (DNA), since each feature claimed to be responsible for commercial success of invention was disclosed in single prior art reference, it was unclear whether any success in third party's sale of a patented invention was attributable to developments in the field that led to simultaneous invention or to copying, and evidence of unexpected results in comparison to technique that was not closest prior art was not probative of nonobviousness. 35 U.S.C.A. § 103.

Cases that cite this headnote

[5] **Patents**

Genes and genetic technology

291 Patents
291II Patentability and Validity
291II(C) Novelty;Anticipation
291II(C)2 Particular Fields of Invention
291k516 Biological Subject Matter; Biotechnology
291k518 Genes and genetic technology

Embodiment comprising 3#–OH–capped nucleotide, base-label, and cleavable linker could be envisaged clearly by one of ordinary skill in the art upon reading prior art disclosure of reversible chain-terminating nucleotide and label attached to base via cleavable tether, and therefore patent claim on base-labeled, 3#–OH–capped nucleotide was anticipated. 35 U.S.C.A. § 102.

Cases that cite this headnote

[6] **Patents**

In general;utility

291 Patents
291X Patents Enumerated
291k2091 In general;utility

US Patent 4,804,748, US Patent 5,547,839, US Patent 7,270,951. Cited as Prior Art.

Cases that cite this headnote

[7] **Patents**

In general;utility

291 Patents
291X Patents Enumerated
291k2091 In general;utility

US Patent 7,713,698, US Patent 7,790,869, US Patent 8,088,575. Cancelled in Part.

Cases that cite this headnote

***917** Appeal from the United States Patent and Trademark Office, Patent Trial and Appeal Board in Nos. IPR2012–00006, IPR2012–00007, IPR2013–00011.

Attorneys and Law Firms

Paul Reinherz Wolfson, Wilmer Cutler Pickering Hale and Dorr LLP, Washington, DC, argued for appellant. Also represented by Matthew Guarnieri; Donald J. Curry, Robert Seth Schwartz, Anthony M. Zupcic, Fitzpatrick, Celia, Harper & Scinto, New York, NY; John P. White, Cooper & Dunham, LLP, New York, NY.

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Before PROST, Chief Judge, SCHALL and WALLACH, Circuit Judges.

Opinion

WALLACH, Circuit Judge.

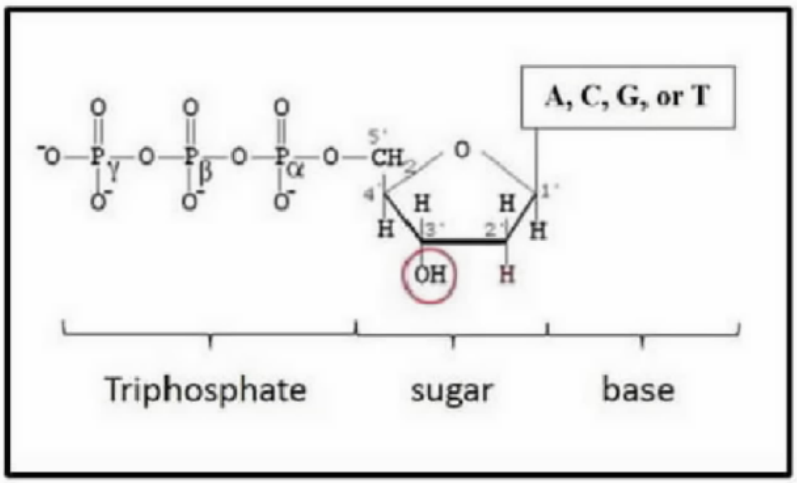
This opinion addresses companion appeals from the inter partes reviews of three patents before the Patent Trial and Appeal Board ("PTAB") of the United States Patent and Trademark Office, with Illumina, Inc. ("Illumina"), as petitioner and the Trustees of Columbia University in the City of New York ("Columbia University") as patent owner. The patents are generally directed to sequencing (i.e., determining the nucleotide sequence of) deoxyribonucleic acid ("DNA"), and include U.S. Patent Nos. 7,713,698 (the "#698 patent") (Appeal No. 2014–1547), 8,088,575 (the "#575 patent") (Appeal No. 2014–1548), and 7,790,869 (the "#869 patent") (Appeal No. 2014–1550). The PTAB found all challenged claims anticipated or obvious over the prior art. For the reasons set forth below, this court affirms.

BACKGROUND

I. The Science of DNA as It Relates to These Appeals

DNA is a double-stranded molecule that encodes the genetic information of living organisms. Each strand consists of a series of chemical structures called nucleotides, the particular order of which determines the heritable characteristics of living organisms. DNA sequencing is useful in a variety of fields, especially medicine, where it can help researchers uncover the genetic bases of diseases and in turn design targeted therapies.

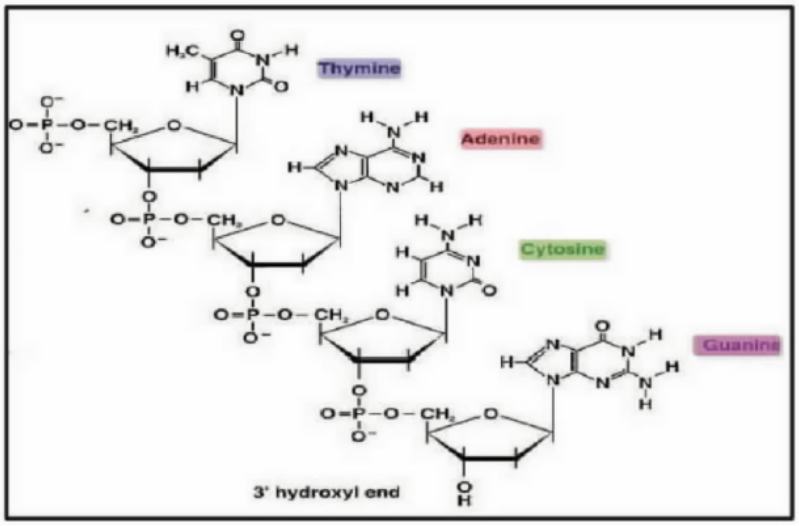
Each nucleotide within the DNA molecule consists of three distinct parts, including a sugar, a base, and one or more phosphate groups:



Appellant's Br. 4. [1]

[1] All references to the briefs and Joint Appendix ("J.A.") are to Appeal No. 2014–1547 unless otherwise indicated.

Four bases exist in naturally-occurring DNA, including adenine ("A"), guanine ***919** ("G"), cytosine ("C"), or thymine ("T"). A and G are known as "purines," while C and T are known as "pyrimidines." The sugar component of each nucleotide is comprised of five carbon atoms, conventionally numbered *V* ("one prime") through 5# ("five prime") and represented by the vertices of the pentagonal sugar structure, as illustrated. Nucleotides not incorporated into a DNA strand contain a hydroxyl group (oxygen bonded to hydrogen, or "OH") at the 3# position ("3#–OH group"). When nucleotides join together to form DNA, a single oxygen atom ("O") links the phosphate group with the sugar at the 3#–OH position:



Appellant's Br. 4.

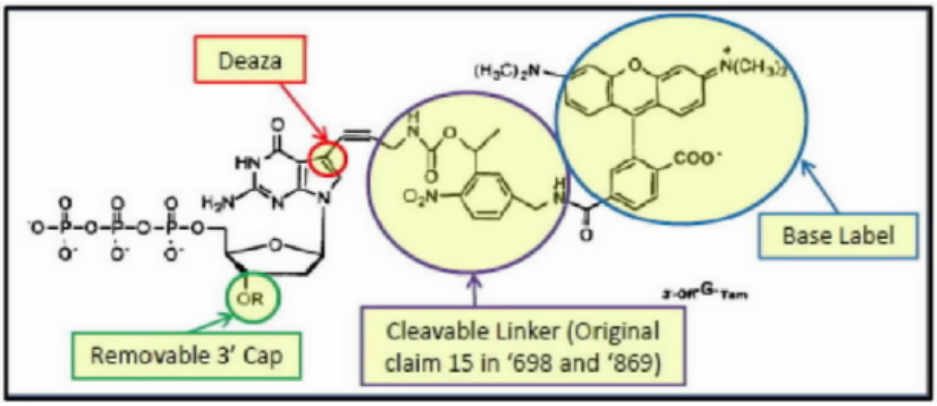
In living organisms, DNA exists as a double-stranded helical structure held together by hydrogen bonds between "complementary" base pairs. A and T are complementary, and thus pair with each other, and G and C are complementary, and thus pair with each other. During DNA replication (such as during sequencing), the two strands are separated and a short chain of nucleotides known as a "primer" binds to a portion of the single-stranded DNA where copying will begin. Polymerase, an enzyme, causes the primer to be extended in a manner complementary to the chain being copied (i.e., matching A to T, and G to C). Important to the present matter, the phosphate group of each new nucleotide added to the lengthening DNA strand bonds to the 3#–OH group of the last nucleotide already in the strand.

In the 1970s, British biochemist Frederick Sanger and Alan Coulson invented a sequencing method that relies on modified nucleotides called dideoxynucleotides ("ddNTPs"), which have a hydrogen atom ("H") rather than OH at the 3# position. *See* Frederick Sanger et al., *DNA Sequencing with Chain–Termination Inhibitors,* 74 Proc. Nat'l Acad. Scis. 5463 (1977). In the original version of Sanger sequencing, the DNA template molecule is mixed with polymerase, a primer, isolated nucleotides ("dNTPs"), and a small amount of ***920** ddNTPs. When a ddNTP is randomly incorporated into the nucleotide chain, elongation of the new strand cannot continue because there is no 3#–OH group to which the next nucleotide would otherwise bond. This chain termination cannot be reversed, and the result is an array of fragments of different lengths, each containing a single ddNTP.

Each ddNTP, and therefore each fragment, contains a radioactive label (or, in subsequently developed versions of Sanger sequencing, a fluorescent label) that can be detected. After the fragments are sorted by size using a process called electrophoresis, the length information can be combined with the label information to determine the sequence of the DNA. One challenge of Sanger sequencing is ensuring the fluorescent labels remain attached to the base. It was discovered that increased stability can be achieved if the label is attached to a carbon atom at the 7# position of a purine base (A or G) rather than to a nitrogen atom, which normally occupies the 7# position. Purines in which the nitrogen atom at the 7# position has been replaced by a carbon atom are known as "deazapurines."

Due to the electrophoresis step, Sanger sequencing was too slow to efficiently sequence entire genomes, which may contain bilhons of nucleotides. A new type of process called sequencing by synthesis ("SBS") avoided the need for electrophoresis by placing *removable,* label-bearing "caps" at the 3#–OH group, which would block synthesis long enough to detect the label (and thereby identify the nucleotide) but would then be removed to allow synthesis to continue. Unfortunately, this type of SBS worked poorly because the "caps" were located near the "active site" of the polymerase and thereby interfered with its operation.

According to Columbia University, Dr. Jingyue Ju and his colleagues avoided the problem caused by the bulky caps by placing an unlabeled removable cap on the 3#–OH group and attaching the label instead to a cleavable linker attached to the deazapurine base:



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