

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ILLUMINA, INC.,
Petitioner,

v.

TRUSTEES OF COLUMBIA UNIVERSITY
IN THE CITY OF NEW YORK,
Patent Owner.

IPR2020-00988
Patent 10,407,458 B2

Before SUSAN L. C. MITCHELL, JAMES A. WORTH, and
MICHELLE N. ANKENBRAND, *Administrative Patent Judges*.

MITCHELL, *Administrative Patent Judge*.

DECISION
Granting Institution of *Inter Partes* Review
35 U.S.C. § 314

I. INTRODUCTION

a. BACKGROUND

On May 29, 2020, Illumina, Inc., (“Petitioner”) filed a Petition (Paper 1, “Pet.”) requesting an *inter partes* review of claims 1 and 2 (the “challenged claims”) of U.S. Patent No. 10,407,458 B2 (Ex. 1001, “the ’458 patent”). See 35 U.S.C. §§ 311–319. On September 9, 2020, Trustees of Columbia University in the City of New York (“Patent Owner”) filed a Preliminary Response to the Petition. Paper 11 (“Prelim. Resp.”). On October 8, 2020, Petitioner filed an authorized Reply addressing discretion to institute under 35 U.S.C. §§ 314(a) and 325(d) and claim construction of the term “chemical linker.” Papers 13, 15 (“Reply”). On October 15, 2020, Patent Owner filed an authorized Sur-Reply responding to Petitioner’s statements concerning discretion to institute and claim construction. Papers 13, 17 (“Sur-Reply”).

We have the authority and discretion to determine whether to institute an *inter partes* review. 35 U.S.C. § 314; 37 C.F.R. § 42.4. We may not institute an *inter partes* review “unless . . . there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition.” 35 U.S.C. § 314(a). For the reasons provided below, we determine that the Petitioners have satisfied the threshold requirement set forth in 35 U.S.C. § 314(a). Therefore, we institute an *inter partes* review of the challenged claims.

b. REAL PARTIES IN INTEREST

Petitioner identifies itself as the real party-in-interest for Petitioner. Pet. 70. Patent Owner identifies itself as the real party-in-interest for Patent Owner. Paper 4, 1.

c. RELATED PROCEEDINGS

This Petition is part of a third set of petitions Illumina filed challenging claims of several of Patent Owner's patents. The remaining petitions in this set involve the following four patents: U.S. Patent Nos. 10,407,459; 10,457,984; 10,435,742; and 10,428,380. The petitions involving each of these patents are as follows: IPR2020-01065; IPR2020-01125; IPR2020-01177; and IPR2020-01323, respectively. Patent Owner asserted these patents in the parallel district court litigation, *The Trustees of Columbia Univ. in the City of New York v. Illumina, Inc.*, 19-1681-CFC (D. Del.) ("the Delaware litigation").

The first set of petitions between the parties involved three of Patent Owner's patents, U.S. Patent Nos. 7,790,869; 7,713,698; and 8,088,575 ("the '869, '698, and '575 patents", respectively). Pet. 72–73; Paper 4, 2. The Board held all challenged claims of these patents unpatentable, and the United States Court of Appeals for the Federal Circuit ("Federal Circuit") affirmed that judgment. *See Illumina, Inc. v. Trustees of the University of Columbia in the City of New York*, IPR2012-00007, Paper 140 (PTAB March 6, 2014) (Ex. 1021); *Illumina, Inc. v. Trustees of the University of Columbia in the City of New York*, IPR2012-00006, Paper 128 (PTAB March 6, 2014) (Ex. 1022); *Illumina, Inc. v. Trustees of the University of Columbia in the City of New York*, IPR2013-00011, Paper 130 (PTAB March 6, 2014) (Ex. 1023); *Trustees of Columbia Univ. in the City of New York v. Illumina, Inc.*, 620 F. App'x. 916 (Fed. Cir. 2015) (Ex. 1029); Pet. 72–73; Paper 4, 2.

Petitioner asserts that the challenged claims held unpatentable in the '869, '698, and '575 patents in the first set of petitions "were nearly identical to claim 1 of the '480 patent [U.S. Patent No. 9,725,480 (Ex. 1019)]." Pet.

72–73. The Board held claim 1 of the ’480 patent unpatentable over much of the same art asserted here in the second set of petitions Illumina filed against five patents including the ’480 patent. *See* Pet. 70–72; Ex. 1024, 76. Petitioner also asserts that claim 1 of the ’480 patent is “nearly identical to claims 1 and 2 of the ’458 patent” at issue here. Pet. 71. More specifically, Petitioner asserts that the only difference between the unpatentable claims of the ’480 patent and the ’458 patent “is that this latest set excludes an allyl capping group (which the Board determined was unpatentable in the last round of IPRs).” *Id.* at 72.

In addition to the ’480 patent, the remaining four patents of Patent Owner that Illumina challenged in this second set of petitions are as follows: U.S. Patent 9,718,852; 9,719,139; 9,708,358; and 9,868,985. Pet. 70–72; Paper 4, 1. Illumina challenged these patents in IPR2018-00291; IPR2018-00318; IPR2018-00322; IPR2018-00797, respectively; and IPR2018-00385 challenged the ’480 patent. The Board held all challenged claims of these patents unpatentable. *See* Exs. 1024, 1028. Patent Owner has appealed these judgments. *See* Pet. 72; Paper 4, 1.

Petitioner also identifies its own patents that it has asserted against Patent Owner and that Patent Owner has challenged before the Board. Pet. 73–74; Paper 4, 2. The Board upheld the patentability of the challenged claims of one of Petitioner’s patents, U.S. Patent No. 7,566,537. Pet. 74; Paper 4, 2; Ex. 1068 (IPR2013-00517); *Intelligent Bio-Sys., Inc. v. Illumina Cambridge Ltd.*, 821 F.3d 1359 (Fed. Cir. 2016).

d. THE ’458 PATENT (EX. 1001)

The ’458 patent issued from a series of continuation applications, two of which issued as the ’575 and ’869 patents that were challenged in the first set of petitions Illumina filed. Ex. 1001, code (60) (stating the only two

applications in the priority chain that were not continuations were the earliest application and the second earliest application, neither of which matured into patents at issue in the series of *inter partes* reviews between Petitioner and Patent Owner). The '458 patent issued September 10, 2019, subject to a terminal disclaimer, and is titled “Massive Parallel Method for Decoding DNA and RNA.” *Id.* (45), (54). The named inventors are Jingyue Ju, Zengmin Li, John Robert Edwards, and Yasuhiro Itagaki. *Id.* at code (72).

The subject matter of the '458 patent involves “methods for attaching a nucleic acid to a solid surface and for sequencing nucleic acid by detecting the identity of each nucleotide analog after the nucleotide analog is incorporated into a growing strand of DNA in a polymerase reaction.”

Ex. 1001, Abst. The nucleotide analogs described in the '458 patent are made by

linking a unique label such as a fluorescent dye or a mass tag through a cleavable linker to the nucleotide base or an analogue of the nucleotide base, such as to the 5-position of the pyrimidines (T and C) and to the 7-position of the purines (G and A), to use a small cleavable chemical moiety to cap the 3'-OH group of the deoxyribose to make it nonreactive, and to incorporate the nucleotide analogues into the growing DNA strand as terminators. Detection of the unique label will yield the sequence identity of the nucleotide. Upon removing the label and the 3'-OH capping group, the polymerase reaction will proceed to incorporate the next nucleotide analogue and detect the next base.

Id. at 3:4–17. This method is generally referred to as the “DNA sequencing by synthesis” approach or “SBS,” because the sequence of the DNA is determined by identifying the successive additions of labeled nucleotides to

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