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Paper No. 10
Entered: August 20, 2019

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

FOUNDATION MEDICINE, INC.,
Petitioner,

v.

GUARDANT HEALTH, INC.,
Patent Owner.

Case IPR2019-00636
Case IPR2019-00637
Patent 9,902,992 B2

Before TINA E. HULSE, JOHN E. SCHNEIDER, KRISTI L. R. SAWERT, Administrative Patent Judges.

HULSE, Administrative Patent Judge.

DECISION
Denying Institution of *Inter Partes* Review
35 U.S.C. § 314(a)

I. INTRODUCTION

Foundation Medicine, Inc. ("Petitioner") filed a Petition requesting an *inter partes* review of claims 1–11, 13, and 15–26 of U.S. Patent No. 9,902,992 B2 (Ex. 1001, "the '992 patent") in IPR2019-00636. IPR2019-00636, Paper 2 ("Pet."). Petitioner filed a second Petition requesting an *inter partes* review of claims 11, 12, 14, and 27–33 of the '992 patent in IPR2019-00637. IPR2019-00637, Paper 2 ("IPR637 Pet."). Guardant Health, Inc. ("Patent Owner") filed a corrected Preliminary Response to each Petition. IPR2019-00636, Paper 7 ("Prelim. Resp."); IPR2019-00637, Paper 7 ("IPR637 Prelim. Resp.").

We have authority under 35 U.S.C. § 314, which provides that an *inter partes* review may not be instituted "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). Upon considering the argument and evidence presented in each Petition, we determine that Petitioner has not established a reasonable likelihood that it would prevail in showing the unpatentability of at least one claim challenged in the Petitions. Accordingly, we decline to institute an *inter partes* review of any claim of the '992 patent on any ground.[1]

[1] The Petitions both challenge the '992 patent, in which claim 1 is the only independent claim. Because both Petitions turn on the same issue regarding claim 1, we exercise our discretion and issue a single decision to be entered in both proceedings. For the sake of convenience, and unless stated otherwise, paper and exhibit numbers refer to those filed in IPR2019-00636. Similar papers and exhibits were filed in IPR2019-00637.

A. Related Proceedings

The parties identify two district court cases where Patent Owner has asserted the '992 patent against Petitioner and Personal Genome Diagnostics, Inc. respectively: *Guardant Health, Inc. v. Foundation Medicine, Inc.*, Case No. 17-cv-1616 (D. Del.) and *Guardant Health, Inc. v. Personal Genome Diagnostics, Inc.*, Case No. 17-cv-1623 (D. Del.). Pet. 70; Paper 3, 2.

Petitioner filed two petitions for *inter partes* review of the '992 patent: IPR2019-00636 and IPR2019-00637. Petitioner has also filed other petitions for *inter partes* review of related patents: U.S. Patent No. 9,598,731 (IPR2019-00130), U.S. Patent No. 9,834,822 (IPR2019-00652 and IPR2019-00653), and U.S. Patent No. 9,840,743 (IPR2019-00634). Paper 3, 2–3.

Petitioner also identifies related patents and patent applications in the '992 patent family. Pet. 71.

B. The '992 Patent

Genetic testing is useful for a number of diagnostic methods. Ex. 1001, 1:35–36. Disorders that are caused by rare genetic mutations (e.g., sequence variations) or changes in epigenetic markers, such as cancer and partial or complete aneuploidy, may be detected or more accurately characterized with DNA sequence information. *Id.* at 1:36–40.

Early detection and monitoring of genetic diseases is often useful and needed in the successful treatment or management of a disease. *Id.* at 1:41–43. According to the '992 patent, one approach may include monitoring a sample derived from cell-free nucleic acids, which are polynucleotides that can be found in different types of bodily fluids. *Id.* at 1:43–46. Cell-free

DNA ("cfDNA") "has been known in the art for decades, and may contain genetic aberrations associated with a particular disease." *Id.* at 1:51–53.

The '992 patent states that "there is a need in the art for improved methods and systems for using cell free DNA to detect and monitor disease." *Id.* at 1:55–57. Accordingly, the '992 patent relates to a system and method for the detection of rare mutations (e.g., single or multiple nucleotide variations) and copy number variations in cell-free polynucleotides. Ex. 1001, 30:15–18.

C. Illustrative Claim

Petitioner challenges claims 1–11, 13, and 15–26 of the '992 patent in IPR2019-00636, and claims 11, 12, 14, and 27–33 of the '992 patent in IPR2019-00637. Claim 1, the only independent claim of the '992 patent, is illustrative and is reproduced below:

> 1. A method for detecting genetic aberrations in cell-free DNA ("cfDNA") molecules from a subject, comprising:
>
> a) providing cfDNA molecules obtained from a bodily sample of the subject;
>
> b) attaching tags comprising barcodes having a plurality of different barcode sequences to the cfDNA molecules to tag at least 20% of the cfDNA molecules, which attaching comprises ligating adaptors comprising the barcodes to both ends of the cfDNA molecules, wherein ligating comprises using more than 10x molar excess of the adaptors as compared to the cfDNA molecules, thereby generating tagged parent polynucleotides;
>
> c) amplifying the tagged parent polynucleotides to produce amplified tagged progeny polynucleotides;
>
> d) sequencing the amplified tagged progeny polynucleotides to produce a plurality of sequence reads from each of the tagged parent polynucleotides, wherein each sequence read of the plurality of sequence reads comprises a

barcode sequence and a sequence derived from a cfDNA molecule of the cfDNA molecules;

(e) mapping sequence reads of the plurality of sequence reads to one or more reference sequences from a human genome;

f) grouping the sequence reads mapped in e) into families based at least on barcode sequences of the sequence reads, each of the families comprising sequence reads comprising the same barcode sequence, whereby each of the families comprises sequence reads amplified from the same tagged parent polynucleotide;

g) at each of a plurality of genetic loci in the one or more reference sequences, collapsing sequence reads in each family to yield a base call for each family at the genetic locus; and

h) detecting, at one or more genetic loci, a plurality of genetic aberrations, wherein the plurality of genetic aberrations comprises two or more different members selected from the group of members consisting of a single base substitution, a copy number variation (CNV), an insertion or deletion (indel), and a gene fusion.

Ex. 1001, 64:2–41.

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