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Paper 47
Date: August 18, 2020

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

FOUNDATION MEDICINE, INC.,
Petitioner,

v.

GUARDANT HEALTH, INC.,
Patent Owner.

IPR2019-00652
Patent 9,834,822 B2

Before SUSAN L. C. MITCHELL, TINA E. HULSE, and KRISTI L. R. SAWERT, *Administrative Patent Judges.*

SAWERT, *Administrative Patent Judge*.

JUDGMENT
Final Written Decision
Determining Some Claims Unpatentable
Dismissing in Part and Denying in Part Petitioner's Motion to Exclude
Dismissing in Part and Denying in Part Patent Owner's Motion to Exclude
35 U.S.C. § 318(a)

I. INTRODUCTION

This is a Final Written Decision in an *inter partes* review challenging the patentability of claims 1–13 and 17–20 ("the challenged claims") of U.S. Patent No. 9,834,822 B2 (Ex. 1001, "the '822 patent"). We have jurisdiction under 35 U.S.C. § 6 and enter this Decision pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73. For the reasons set forth below, we determine that Petitioner has shown, by a preponderance of the evidence, that claims 1–11, 13, and 17–20 are unpatentable. We determine that Petitioner has not shown, by a preponderance of the evidence, that claim 12 is unpatentable. *See* 35 U.S.C. § 316(e) (2012).

A. Procedural History

Foundation Medicine, Inc. ("Petitioner") filed a Petition for an *inter partes* review under 35 U.S.C. § 311. Paper 2 ("Pet."). Petitioner supported its Petition with the Declaration of Stacey Gabriel, Ph.D. Ex. 1002. Guardant Health, Inc. ("Patent Owner") filed a Preliminary Response. Paper 6. On our authorization (Paper 9), Petitioner filed a Reply to Patent Owner's Preliminary Response (Paper 11).

On August 19, 2019, pursuant to 35 U.S.C. § 314(a), we instituted trial to determine whether any challenged claim of the '822 patent is unpatentable based on the grounds raised in the Petition:

Claims Challenged	35 U.S.C. §	Reference(s)/Basis
1–13, 17–20	103(a)[1]	Schmitt,[2] Schmitt 2012,[3] and Fan[4] or Forshew[5]

Paper 12, 7, 36 ("Institution Decision" or "Inst. Dec.").

Patent Owner filed a Response. Paper 26 ("PO Resp."). Patent Owner supported its Response with the Declaration of Jay Shendure, M.D., Ph.D., Ex. 2023, and the Declaration of John Quackenbush, Ph.D., Ex. 2025. Petitioner filed a Reply to Patent Owner's Response. Paper 32 ("Pet. Reply"). Petitioner supported its Reply with a Reply Declaration of Dr. Gabriel. Ex. 1104. Patent Owner filed a Sur-Reply. Paper 34 ("PO Sur-Reply"). Patent Owner supported its Sur-Reply with a Supplemental Declaration of Dr. Quackenbush. Ex. 2042.

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[1] The Leahy-Smith America Invents Act ("AIA"), Pub. L. No. 112-29, 125 Stat. 284, 287–88 (2011), amended 35 U.S.C. § 103, effective March 16, 2013. Because the challenged claims have an effective filing date before this date, the pre-AIA version of § 103 applies.

[2] Michael Schmitt et al., U.S. Patent No. 9,752,188 B2, issued Sept. 5, 2017 (Ex. 1011, "Schmitt").

[3] Michael W. Schmitt et al., *Detection of Ultra-rare Mutations by Next-generation Sequencing*, 109(36) PROC. NATL. ACAD. SCI. 14508–513 (2012) (Ex. 1047, "Schmitt 2012").

[4] Christina Fan et al., *Noninvasive diagnosis of fetal aneuploidy by shotgun sequencing DNA from maternal blood*, 105(42) PROC. NATL. ACAD. SCI. 16266–271 (2008) (Ex. 1048, "Fan")

[5] Tim Forshew et al., *Noninvasive Identification and Monitoring of Cancer Mutations by Targeted Deep Sequencing of Plasma DNA*, 4(136) SCI. TRANSL. MED. 1–34 (2012) (Ex. 1004, "Forshew").

Petitioner and Patent Owner each filed respective Motions to Exclude Evidence. *See* Paper 38 ("Pet. Mot."); Paper 39 ("PO Mot."). Petitioner filed an Opposition to Patent Owner's Motion, Paper 40 ("Pet. Opp."), to which Patent Owner filed a Reply, Paper 42 ("PO Reply"). Patent Owner filed an Opposition to Petitioner's Motion, Paper 41 ("PO Opp."), to which Petitioner filed a Reply, Paper 43 ("Pet. Reply Opp.").

An oral hearing was held on May 13, 2020. A transcript of the hearing is included in the record. Paper 46 ("Tr.").

B. Real Parties in Interest

Petitioner identifies Foundation Medicine, Inc., Roche Holdings, Inc., Roche Finance Ltd., and Roche Holding Ltd. as the real parties-in-interest. Pet. 73. Patent Owner identifies Guardant Health, Inc., as the real party-in-interest. Paper 4, 2.

C. Related Matters

Patent Owner has asserted the '822 patent against Petitioner in *Guardant Health, Inc. v. Foundation Medicine, Inc.*, Case No. 17-cv-1616 (D. Del.) ("the co-pending litigation"). Pet. 74; Paper 4, 2. Patent Owner has also asserted the '822 patent against Personal Genome Diagnostics, Inc. ("PGDx") in *Guardant Health, Inc. v. Personal Genome Diagnostics, Inc.*, Case No. 17-cv-1623 (D. Del.). Pet. 74; Paper 4, 2.

Petitioner filed a second petition seeking *inter partes* review of the '822 patent, designated IPR2019-00653. Paper 4, 2. A Decision denying institution in that case was issued on August 19, 2019 (Paper 12), and a Decision denying Petitioner's request for rehearing issued on January 22, 2020 (Paper 14).

Petitioner also filed several petitions seeking *inter partes* review of patents related to the '822 patent, including: IPR2017-01170, IPR2017-

01447, and IPR2017-01448 (challenging U.S. Patent No. 9,340,830); IPR2019-00130 (challenging U.S. Patent No. 9,598,731); IPR2019-00634 (challenging U.S. Patent No. 9,840,743); and IPR2019-00636 and IPR2019-00637 (challenging U.S. Patent No. 9,902,992). Of these cases, only IPR2019-00634 is pending.

PGDx also filed petitions seeking post-grant review of the '822 patent, designated PGR2018-00058, and of U.S. Patent No. 9,840,743, designated PGR2018-00057. *Id.* at 2. Both petitions were dismissed before a decision on institution.

D. Summary of the '822 Patent

The '822 patent relates to methods for detecting rare mutations and copy number variations in cell free polynucleotides. Ex. 1001, code (57). The '822 patent states that cell-free DNA ("cfDNA"), found in different types of bodily fluids, may be used to detect and monitor disease. *Id.* at 1:29–45. For instance, cfDNA may contain genetic aberrations—like a change in copy number variations and/or single or multiple sequence variations associated with a particular disease—that can be used to detect or monitor such disease. *Id*. at 1:29–41, 30:8–14. The '822 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 1:41–45.

The '822 patent states that the disclosed methods generally "comprise sample preparation, or the extraction and isolation of cell free polynucleotide sequence[s] from a bodily fluid; subsequent sequencing of cell free polynucleotides by techniques known in the art; and application of bioinformatics tools to detect rare mutations and copy number variations as compared to a reference." *Id*. at 30:4–14. The '822 patent states that "[s]ample preparation typically involves converting polynucleotides in a

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