

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

FORESIGHT DIAGNOSTICS, INC.,
Petitioner,

v.

PERSONALIS, INC.,
Patent Owner.

IPR2023-00317
Patent 11,408,033 B2

Before ULRIKE W. JENKS, ROBERT A. POLLOCK, and
TIMOTHY G. MAJORS, *Administrative Patent Judges*.

POLLOCK, *Administrative Patent Judge*.

JUDGMENT

Final Written Decision
Determining All Challenged Claims Unpatentable

35 U.S.C. § 318(a)

I. INTRODUCTION

This is a Final Written Decision in an *inter partes* review challenging the patentability of claims 1–23 of U.S. Patent No. 11,408,033 B2 (“the ’033 patent,” Ex. 1001). We have jurisdiction under 35 U.S.C. § 6.

Petitioner has the burden of proving unpatentability of the challenged claims by a preponderance of the evidence. 35 U.S.C. § 316(e) (2018). Having reviewed the parties’ arguments and cited evidence, for the reasons discussed below, we find that Petitioner has demonstrated by a preponderance of the evidence that claims 1–23 are unpatentable for the reasons set forth in the Petition.

A. Procedural History

Foresight Diagnostics Inc. (“Petitioner” or “Foresight”) filed a Petition for an *inter partes* review of claims 1–23 of the ’394 patent. Paper 1 (“Pet.”). Personalis, Inc. (“Patent Owner” or “Personalis”) timely filed a Preliminary Response. Paper 7. With our authorization (*see* Ex. 3001), Petitioner filed a Reply to the Preliminary Response (Paper 8); Patent Owner filed a corresponding Sur-reply (Paper 10). In view of the then-available preliminary record, we instituted an *inter partes* review. Paper 11 (“Institution Decision” or “DI”).

After institution, Patent Owner filed a Response. Paper 18 (“POR”). Petitioner filed a Reply. Paper 41 (“Reply”). Patent Owner filed a Sur-reply. Paper 38 (“Sur-reply”). With our authorization, Petitioner further filed a Response to Patent Owner’s Sur-reply. Paper 42 (“Resp.”).

On March 19, 2024, we held an oral hearing, the transcript of which is of record. Paper 46 (“Tr.”).

B. Real Parties-in-Interest

Petitioner identifies itself, Foresight Diagnostics Inc., as the real party-in-interest. Paper 32, 1. Patent Owner also identifies only itself, Personalis, Inc., as the real party-in-interest in this proceeding. Paper 6, 1.

C. Related Matters

In addition to the '033 patent at issue here, Petitioner concurrently challenges claims of related U.S. Patent No. 11, 384,394 B2 (“the '394 patent”) in IPR2023-00224. The '033 and '394 patents share substantially the same disclosure.

The parties further identify as “related proceedings,” Petitioner’s challenge of Personalis’s U.S. Patent Nos. 11,299,783 (“the '783 patent”) and 10,450,611 (“the '611 patent”) in IPR2023-00545 and IPR2023-00546, respectively. Paper 6, 1; Paper 33, 2. IPR2024-00170 involving U.S. Patent No. 11,584,968 (“the '968 patent”) is also before us. *See* Paper 33, 2

The '394, '033, '738, and '611 patents are at issue in *Personalis, Inc. v. Foresight Diagnostics, Inc.*, C.A. No. 1:22-cv-01913 (D. Colo.) (“the 01913 litigation”). *See* Pet. 3; Paper 6, 1; Ex. 1010, 1, 3–6; Exhibit 1010, 1 (First Amended Complaint adding '033 patent). Petitioner further identifies as a “related matter[,]” *Personalis, Inc. v. Foresight Inc.*, 1:23-cv-01623 (D. Colo.), which further involves the '968 patent. Paper 33, 2; Ex. 1010, 1; IPR2024-00170, Paper 1, 1, 3 (stating that Foresight has moved to consolidate the two district court proceedings).

D. Asserted Challenges to Patentability

Petitioner challenges the patentability of claims 1–23 on the following bases: (Pet. 16):

Ground	Claims Challenged	35 U.S.C. §	Reference(s)/Basis
1	1–7, 10–23	§ 102	ForsheW ¹
2	1–23	§ 103	ForsheW, Wagle ²
3	1–9, 11–23	§ 103	Wagle, Chan ³

In support of its patentability challenge, Petitioner relies on, *inter alia*, the First and Second Declarations of John Quackenbush, Ph.D., Exhibits 1020 and 1225, respectively. Patent Owner relies on, *inter alia*, the Declaration of Henry Morrice Furneaux, Ph.D., Exhibit 2031. Patent Owner further relies on the Declarations of Jonathan MacQuitty (Ex. 2033), Doug Zeman (Ex. 2034), Dan Norton (Ex. 2035), and John West (Ex. 2032).⁴

E. The '033 Patent and Related Background

1. Priority

The '033 patent, titled Methods and Systems for Genetic Analysis, issued to Bartha et al., from U.S. Application 17/078,857, filed October 23,

¹ Tim ForsheW, et al., “Noninvasive Identification and Monitoring of Cancer Mutations by Targeted Deep Sequencing of Plasma DNA,” 4 *Science Translational Medicine* 136ra68 (2012). Ex. 1030, Ex. 1032 (Supplementary Materials).

² Nikhil Wagle et al., “High-Throughput Detection of Actionable Genomic Alterations in Clinical Tumor Samples by Targeted, Massively Parallel Sequencing,” Jan. 2012 *Cancer Discovery* 83–93. Ex. 1033.

³ K.C. Allen Chan *et al.*, “Cancer Genome Scanning in Plasma: Detection of Tumor-Associated Copy Number Aberrations, Single-Nucleotide Variants, and Tumoral Heterogeneity by Massively Parallel Sequencing,” 59(1) *Clin. Chem.* 211–224 (2013). Ex. 1008.

⁴ Mr. West is a named inventor of the challenged patent. Ex. 1001, code (72). Mr. West co-founded Personalis and served as its Chief Executive Officer from August 2011 through December 2022. Ex. 2023 ¶ 3.

2020, via a series of continuation and divisional applications first filed on December 27, 2013, and further claims benefit of priority to U.S. Provisional Application No. 61/753,828, filed on January 17, 2013 (“the ’828 Provisional Application”). Ex. 1001, code (12), (21), (22), (54), and (60).⁵ The parties dispute whether the ’033 patent is entitled to the benefit of the provisional filing date. *See, e.g.*, Reply 12–13; POR 2, 6.

2. Abstract and Specification

The Abstract of the ’033 patent broadly describes “systems and methods for sample processing and data analysis,” which can include “nucleic acid sample processing and subsequent sequencing.” Ex. 1001, code (57). According to the Abstract, the resultant “sequence information may be analyzed with the aid of a computer processor, and the analyzed sequence information may be stored in an electronic storage location that may include a pool or collection of sequence information and analyzed sequence information generated from the nucleic acid sample.” *Id.*

The ’033 Specification more specifically discloses methods for “predicting, diagnosing, and/or prognosing a status or outcome of a disease or condition in a subject.” *Id.* at 55:38–50. In some embodiments, this involves the collection and analysis of sequence information derived from body fluid or tissue, including “from a subject suffering from a cancer.” *Id.* at 38:57–67, 55:51–57:8.

⁵ The ’394 patent likewise issued from a series of continuation and division applications first filed on December 27, 2013, and claims benefit of priority to the ’828 Provisional Application such that the ’033 and ’394 patents share the same disclosure. As such, the parties’ declarants generally cite only one of the two substantially identical disclosures. *See, e.g.*, Ex. 2031 ¶ 57 n.3; Ex. 1225 ¶ 39.

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