

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

FORESIGHT DIAGNOSTICS INC.,

Petitioner,

v.

PERSONALIS, INC.,

Patent Owner.

IPR2023-00545

U.S. Patent No. 11,299,783

**SUR-REPLY TO PETITION FOR *INTER PARTES* REVIEW OF U.S.
PATENT NO. 11,299,783**

PATENT OWNER'S EXHIBIT LIST

Exhibit No.	Description
2001	The Scientist Staff, “2022 Top 10 Innovations,” Dec. 12, 2022, available at https://www.the-scientist.com/features/2022-top-10-innovations-70792
2002	Swanton, C., “Plasma-Derived Tumor DNA Analysis at Whole-Genome Resolution,” <i>Clinical Chemistry</i> 59:1 6-8 (2013)
2003	Exemplary Embodying Product Claim Chart for U.S. Patent No. 11,299,783

I. “PERSONALIZED GENETIC TESTING”

Petitioner Foresight Diagnostic Inc.’s (“Petitioner”) does not dispute in its reply that the preamble “personalized genetic testing” is limiting, and instead contends that “the Petition establishes that the prior art’s methods are ‘personalized’ under any reasonable understanding of the term.” Pet. Reply at 1. For the reasons explained below and in Patent Owner’s preliminary patent owner response, neither prior art reference discloses a method for personalized genetic testing.

A. Ley

Ley does not disclose a method for *personalized* genetic *testing*. Rather, Ley discloses two distinct sets of experiments conducted for the purpose of *discovering* mutations that are responsible for initiation and pathogenesis of AML and other types of cancer across *entire patient populations*. See POPR 22-23 (collecting cites); *see also* Ex. 1012 at 66 (“Our study establishes whole-genome sequencing as an unbiased *method for discovering cancer-initiating mutations in previously unidentified genes that may respond to targeted therapies*”). First, Ley describes a series of experiments that resulted in the discovery of 8 new genes with mutations that the authors hypothesized are responsible for AML in the general patient population. Second, Ley describes a distinctly separate experiment used to validate these results. There is no indication in Ley that these distinct teachings should be or may be combined together as a method for personalized testing rather than just a

collection of separate experiments for *identifying* and validating new mutations responsible for a specific type of cancer. *See NetMoneyIN, Inc., v. Verisign, Inc.*, 545 F.3d 1359, 1371 (Fed. Cir. 2008) (“Thus, it is not enough that the prior art reference discloses part of the claimed invention, which an ordinary artisan might supplement to make the whole, *or that it includes multiple, distinct teachings that the artisan might somehow combine to achieve the claimed invention*”).

The fact that one step of Ley’s whole-genome sequencing protocol involved comparing a patient’s tumor genome to “its matched normal counterpart obtained from the same patient’s skin” does not make the protocol of Ley a method for personalized genetic testing. Ex. 1012 at 66. That is because this step is conducted to filter out the inherited mutations and identify only the somatic mutations; nothing in Ley’s tumor-normal whole-genome sequencing protocol is personalized or customized to the particular patient being sequenced. *See* POPR at 22-23.

Furthermore, this does not reflect an intent to *test* this individual’s personalized genetic profile, but rather to *discover* mutations that might correlate to a *typical* patient’s AML, and to also demonstrate the whole-genome sequencing protocol as broadly applicable to AML and other cancers. Ex. 1012 at 67. In contrast, the claimed invention describes “personalized genetic testing,” as using initial information gathered on an individual subject to design probes for *subsequent testing* that is “better focused on the *personal characteristics of the subject*” and

“can yield information *on the subject* which is either more insightful, or less expensive, or both.” Ex. 1001 at 31:19-29. Importantly, the whole-genome sequencing protocol *is* the focus in Ley and is not performed for the purpose of informing the design of the distinctly separate, targeted (amplicon) sequencing protocol Ley uses to validate the whole-genome sequencing results. Ley views the latter as ancillary to the whole-genome sequencing protocol. *See, e.g.*, Ex. 1012 at 70 (“Hence, these results justify the use of next-generation *whole-genome sequencing approaches* to reveal somatic mutations in cancer genomes.”).

Further, Petitioner posits the existence of other supposed motivations for Ley’s validation protocol. However, these alleged ulterior motives are neither mentioned nor alluded to within the four corners of the document; the only motivation articulated by Ley for the validation experiment was just that—to validate the results of the whole genome sequencing protocol. Finally, Petitioner’s bald-faced assertion that the use of probes tailored to a particular patient “even a single time...is sufficient to invalidate the claims” flies in the face of Federal Circuit precedent. *NetMoney IN*, 545 F.3d at 1269 (“This statement... does not tell the whole story. *Because the hallmark of anticipation is prior invention*, the prior art reference—in order to anticipate under 35 U.S.C. § 102—*must not only disclose all elements of the claim within the four corners of the document, but must also disclose those elements “arranged as in the claim.”*”).

A POSA therefore would not have understood Ley as advocating for personalized testing when its express purpose was to use non-personalized, whole-genome sequencing to identify new candidate genes responsible for AML in the general patient population.

Respectfully submitted,

WEIL, GOTSHAL AND MANGES LLP

Dated: June 16, 2023

By: /Derek C. Walter/
Derek C. Walter
Lead Counsel for Personalis, Inc.
Reg. No. 74,656
Weil, Gotshal & Manges LLP
201 Redwood Shores Parkway
Redwood Shores, CA 94065-1134
Telephone: 650-802-3000

CERTIFICATE OF COMPLIANCE

Pursuant to 37 C.F.R. § 42.24 et seq., the undersigned certifies that this document complies with the word count limitation of 37 C.F.R. § 42.24(c)(4) because the Petition contains 590 words, excluding the cover page, signature block, and the parts of the Petition exempted by 37 C.F.R. § 42.24(c)(4).

Respectfully submitted,

WEIL, GOTSHAL AND MANGES LLP

Dated: June 16, 2023

By: /Derek C. Walter/
Derek C. Walter
Lead Counsel for Personalis, Inc.
Reg. No. 74,656

CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of **PATENT OWNER'S SUR-
REPLY TO PETITION FOR INTER PARTES REVIEW OF U.S. PATENT
NO. 11,299,783** is being served on June 16, 2023, via email pursuant to 37 C.F.R. §
42.6(e) to counsel for Foresight Diagnostics, Inc., at the addresses below:

Andrew E. Krause
Reg. No. 76,276
IRELL & MANELLA LLP
1800 Avenue of the Stars, Ste. 900
Los Angeles, CA 90067
T: 310-277-1010
F: 310-203-7199
akrause@irell.com

Amir Naini
Reg. No. 45,770
NAINI P.C.
2632 Wilshire Blvd., Suite 268
Santa Monica, CA 90403
T: 310- 592-3030
F: 310-453-9008
amir@nainipc.com

Alan J. Heinrich (pro hac vice to be
requested)
IRELL & MANELLA LLP
1800 Avenue of the Stars, Suite 900
Los Angeles, California 90067
T: 310-277-1010
F: 310- 203-7199
aheinrich@irell.com

Jordan Nafekh (pro hac vice to be
requested)
IRELL & MANELLA LLP
1800 Avenue of the Stars, Suite 900
Los Angeles, California 90067
T: 310- 277-1010
F: 310- 203-7199
jnafekh@irell.com

Dated: June 16, 2023

By: /Derek C. Walter/
Derek C. Walter
Reg. No. 74,656