

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

FORESIGHT DIAGNOSTICS INC.,
Petitioner,

v.

PERSONALIS, INC.
Patent Owner.

Case IPR2024-00170
U.S. Patent No. 11,584,968

**PATENT OWNER'S SUR-REPLY TO PETITION FOR INTER PARTES
REVIEW OF U.S. PATENT NO. 11,584,968**

The construction of “whole genome sequencing” (WGS) has been—and remains—a central dispute between the parties dating back to Foresight’s first petition against Personalis in IPR2023-00224. Foresight violated 37 C.F.R. §42.104(b)(3)-(4) by failing to inform the Board and Personalis how it believes WGS should be construed in the present Petition. POPR 11-17.

Foresight’s Reply belatedly asserts that WGS should be given its “plain meaning,” Reply 2, but it still refuses to describe what it believes that means. It was incumbent on Foresight to explain what WGS means in this proceeding because: (1) Dr. Quackenbush testified that WGS has a variety of different definitions, EX2018 155:15-20, and (2) the parties submitted competing definitions of this term in IPR2023-00224, *see* POPR 11-12. In IPR2023-00224, Foresight even disputes the meaning of terms **within** Personalis’s construction of WGS. EX2190 2-5. Foresight bore the burden of defining WGS here because it is “a claim term in controversy as it relates to the grounds.” *See ams AG v. 511 Innovations, Inc.*, No. IPR2016-01792, Paper 15 at 13 (PTAB 2017). Its failure to do so warrants denial. *Id.*

Foresight grossly mischaracterizes Dr. Furneaux’s declaration to assert that there is no controversy regarding WGS. Reply 2. Dr. Furneaux’s declaration acknowledges that Newman (an article written by Foresight’s Founders) considers Chan to disclose a type of WGS. EX1127 ¶107. However, Dr. Furneaux unequivocally disagrees that Newman discloses the claimed WGS as follows:

Foresight and Dr. Quackenbush assert that Chan’s “shotgun sequencing of a plasma sample” constitutes the whole genome sequencing required by limitation 1(b). ***I disagree for reasons discussed below.***

Id. ¶166 (emphasis added). Dr. Furneaux provides several paragraphs analyzing Chan, *id.* ¶¶167-169, and then concludes “***none of Leary, Chan, or Liao teach or suggest the whole genome sequencing*** required by limitation 1(b),” *id.* ¶170 (emphasis added). Foresight’s assertion that it “could not have reasonably anticipated” the dispute regarding Chan and WGS is devoid of credibility. Reply 2.

Foresight seeks to bypass construction of WGS by alleging that this term is not disputed for Grounds 3-5. Reply 1. Foresight cannot avoid claim construction because the first step of a validity determination “involves the proper interpretation of the claims.” *TI Group Automotive Sys., Inc. v. VDO N.Am., LLC*, 375 F.3d 1126, 1139 (Fed. Cir. 2004). The meaning of WGS was foreseeably disputed for Grounds 1-2. POPR 11-17. If Foresight ever comes forward with the construction of WGS that it believes should be applied to Grounds 1-2, such a construction may raise disputes concerning the application of that construction to Grounds 3-5. That is precisely why the Trial Practice Guide requires a petition to “provide a claim construction for the challenged claims.” Consolidated Trial Practice Guide at 42 (Nov. 2019); *3Shape A/S v. Align Tech., Inc.*, IPR2019-00153, Paper 8 at 27-29 (PTAB 2019) (explaining the Trial Practice Guide requires petitioner to “provide a claim construction for the challenged claims” and denying institution because

petitioner failed to (i) provide an express construction for a broadly applied term and (ii) present arguments and evidence in support of the broad application).

Foresight’s reliance on the Federal Circuit’s *Axonics* decision does not save the Petition. Reply 2. *Axonics* confirms that 37 C.F.R. §42.104(b)(3) “requires a petitioner affirmatively to state how the challenged claim is to be construed.” *Axonics, Inc. v. Medtronic, Inc.*, 75 F.4th 1374, 1383 n.10 (Fed. Cir. 2023).

Foresight asserts that it “explains that Chan discloses WGS” in the Petition. Reply 2 (citing Petition 29). There is no such explanation. The Petition just wrongly equates MPS with WGS. Petition 29 (“MPS [i.e., WGS]”) (brackets in original). MPS and WGS do not refer to the same thing. POPR 17-22. Foresight’s attempt to equate MPS with WGS demonstrates why it “should have provided and explained its own construction of [this] critical term in the claims.” *Unified Patents, LLC v. Elecs. and Telecomms. Rsch. Inst.*, IPR2021-00827, Paper 14 at 10 (PTAB 2021).

Foresight tacitly admits it was aware of the claim construction dispute by burying a contingent claim construction theory of WGS in Dr. Quackenbush’s declaration. Reply 2-3 (EX1100 ¶120). Foresight refuses to adopt this construction. Foresight’s contingent claim construction theory does not absolve Foresight from affirmatively stating “how the challenged claim is to be construed.” *Axonics*, 75 F.4th at 1383 n.10; 37 C.F.R. §42.104(b)(3). The Petition should be denied for its failure to construe the critically disputed WGS claim term.

Respectfully submitted,

KNOBBE MARTENS OLSON & BEAR, LLP

Dated: March 29, 2024

/Nathanael R. Luman/

Nathanael R. Luman (Reg. No. 63,160)

Lead Counsel

Knobbe, Martens, Olson & Bear LLP

2040 Main St.

Irvine, CA 92614

Telephone: 949-760-0404

Derek C. Walter (Reg. No. 74,656)

Weil, Gotshal & Manges LLP

201 Redwood Shores Parkway

Redwood Shores, CA 94065-1134

Telephone: 650-802-3000

Counsel for Patent Owner Personalis, Inc.

CERTIFICATE OF SERVICE

I hereby certify that, pursuant to 37 C.F.R. § 42.6(e) and with the agreement of counsel for Petitioner, a true and correct copy of **PATENT OWNER'S SUR-REPLY TO PETITION FOR INTER PARTES REVIEW OF U.S. PATENT NO. 11,584,968** is being served electronically on March 29, 2024, to the e-mail addresses shown 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 ForesightIPRs@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 Jordan Nafekh IRELL & MANELLA LLP 1800 Avenue of the Stars, Suite 900 Los Angeles, California 90067 Telephone: (310) 277-1010 Facsimile: (310) 203-7199 jnafekh@irell.com aheinrich@irell.com
---	--

Dated: March 29, 2024

/Nathanael R. Luman/

Nathanael R. Luman (Reg. No. 63,160)
Lead Counsel for Personalis, Inc.