UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

NEOGENOMICS LABORATORIES, INC.
Petitioner,

v.

NATERA, INC.
Patent Owner.

Patent No. 11,530,454

Inter Partes Review No. IPR2024-00346

PETITIONER'S AUTHORIZED REPLY TO PATENT OWNER'S PRELIMINARY RESPONSE

Pursuant to the Board's email authorization on April 26, 2024, Petitioner ("Neo") files this reply to correct mischaracterizations in Patent Owner ("Natera")'s Preliminary Response ("POPR") (Paper 6).

I. Neo's Former Counsel's Statements Do Not Support Natera's Case

Natera submitted no expert testimony in support of its POPR. To fill that gap, Natera resorts to criticizing Neo's former counsel for making statements about Forshew (Ex.1003) in *Foresight Diagnostics v. Personalis*, IPR2023-00545, that purportedly conflict with the Petition. Every one of Natera's critiques is wrong.

Different Experiments. Natera attacks counsel for arguing in *Personalis* that "Forshew describes a series of experiments" but allegedly mixing and matching their disclosures here via "sleight-of-hand," "without comment," and by "cherry-pick[ing]." (*E.g.*, Paper 6, 3-4.) Natera fails to fully quote the *Personalis* briefing. Neo's counsel actually wrote, "Forshew describes a series of experiments *using the TAm-Seq method*…." (Ex. 2001, 15 (emphasis added).) Likewise, the Petition states Forshew teaches a "tagged-amplicon deep sequencing ('TAm-Seq') approach" and applying it in an "experiment." (Paper 1, 16-17.) There is no conflict and, more importantly, counsel's statement correctly framed Forshew. Forshew teaches TAm-Seq in Figure 1B, which the breast cancer experiment used. (Ex.1003, 3 ("**Fig. 1.** Overview of tagged amplicon sequencing") 9-10.)

The underlying premise of Natera's argument—that counsel's arguments

conflict *because* Forshew siloed its breast cancer disclosure—also is wrong. Dr. Lennon testified that Forshew teaches using TAm-Seq to detect multiple types of cancer and that Figure 1B shows how TAm-Seq works. (*E.g.*, Ex.1002, ¶¶137, 152, 159.) Natera provides no expert testimony in rebuttal. Moreover, when the Board summarized Forshew in *Personalis*, it first wrote that Forshew taught a "T[A]m-Seq approach," then used Forshew's Figure 1B to illustrate one of its steps, and finally explained that data from "the TAm-Seq studies" was used to track mutations relating to breast and other cancers. IPR2023-00545, Paper 13, 11-14 (Aug. 8, 2023). As both Dr. Lennon and the Board recognized, Forshew teaches one overarching protocol—TAm-Seq—and the experiments used to validate it.

As for Natera's critique of counsel for citing Tables S3, S6, and S7, those tables just confirm that TAm-Seq targets certain kinds of mutations. (Paper 6, 42; Ex.1003, 27-28, 31-33.) Because Forshew never carves up its disclosure as Natera claims, Natera is wrong that counsel's prior statements conflict.

Detection Limit. Natera next attacks counsel for arguing in *Personalis* that "Forshew was limited to detecting 'mutations occurring at a frequency higher than 2%'" while arguing here "that Forshew's Figure S3 'shows frequencies that could be detected' including mutation 'frequencies of 0.015% and below.'" (Paper 6, 4.) But counsel did not write that TAm-Seq is "*limited*" to the 2% sensitivity; they wrote it was "*able to*" detect mutations at that sensitivity. (Ex.2001, 17 (emphasis

added).) That Forshew validated TAm-Seq at a 2% sensitivity in no way conflicts with counsel's statement—much less Dr. Lennon's insight and Forshew's own teachings—that TAm-Seq also "could" work at even higher sensitivities. (*E.g.*, Paper 1, 43; Ex.1002, ¶251; Ex.1003, 11 (disclosing strategies "for enhanced mutation detection without change to protocols").) And regardless, Neo also explained why, in the alternative, increasing TAm-Seq's sensitivity would have been obvious based on a POSA's knowledge and disclosures from multiple references across multiple grounds. (Paper 1, 43-45, 54-56.)

Modifying Tam-Seq. Natera last attacks counsel for writing in *Personalis* "that one of skill would 'avoid attempting to redesign the TAm-Seq assay' in Forshew....'" (Paper 6, 40-41.) That statement critiqued replacing Forshew's PCR primers with hybrid capture probes; it did not denigrate every possible modification. (Ex.2002, 59-61.) Again, counsel's statements do not conflict.

II. Neo's Substitution Of Counsel Is Irrelevant

Natera implies that Neo's former counsel withdrew *after* Natera's POPR accused him of making inconsistent statements across two proceedings. (Paper 6, 3.) That implication is false. As Natera proved by filing counsel's email regarding withdrawal as an exhibit to its POPR, counsel sought withdrawal *before* that filing. (Ex.2027.) The February reply briefing in *Personalis* also did not lead to withdrawal. (Paper 6, 3 (citing Ex.2026).) Neo retained new counsel in *January*.

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Respectfully submitted,

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Certificate of Service (37 C.F.R. § 42.6(e)(4))

I hereby certify that the attached PETITIONER'S AUTHORIZED REPLY TO PATENT OWNER'S PRELIMINARY RESPONSE was served on the below date on the Patent Owner via e-mail (by agreement) to the following counsel of record:

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