Filed on behalf of Natera, Inc.
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UNITED STATES PATENT AND TRADEMARK OFFICE

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**BEFORE THE PATENT TRIAL AND APPEAL BOARD**

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NEOGENOMICS LABORATORIES, INC.,
Petitioner,

v.

NATERA, INC.,
Patent Owner.

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Case No. IPR2024-00346
U.S. Patent No. 11,530,454

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# PATENT OWNER'S SUR-REPLY

NeoGenomics requested a reply purportedly to "correct mischaracterizations" in Natera's brief. Paper 12 at 1. NeoGenomics instead seeks to correct its Petition, but merely replacing counsel does not excuse NeoGenomics' mistakes. *Link v. Wabash R.R.*, 370 U.S. 626, 633-34 (1962) (party "cannot now avoid the consequences of the acts or omissions" of its chosen attorney). The reply only confirms that NeoGenomics did not meet its burden here.

NeoGenomics' reply asserts Natera should submit expert testimony at this preliminary stage. Paper 12 at 1. It is black letter law that Natera does not bear the burden in this IPR, *In re Magnum Oil Tools*, 829 F.3d 1364, 1375 (Fed. Cir. 2016), and "no expert submissions are required" from Natera, *Fanduel v. Interactive Games*, 966 F.3d 1334, 1344 (Fed. Cir. 2020). This is particularly true here where an expert is not needed to show NeoGenomics' Petition is facially deficient.

As Natera pointed out, many of the Petition's statements are inconsistent with Forshew's disclosure. Paper 6 at 37-46. NeoGenomics doesn't dispute counsel's positions about (1) Forshew's two-step amplification process and criticisms of its approach, *id*. at 22-23, and (2) Forshew being several orders of magnitude less sensitive than modern ctDNA testing, *id*. at 60-61, all of which support Natera's position.

Natera pointed out that NeoGenomics fails to meet its burden to show a motivation to combine Forshew's different experiments without comment or

supporting evidence showing why a POSA would be motivated to do so with an expectation of success. *Id*. at 37-46. To show NeoGenomics failed to meet its burden, Natera accurately quoted counsel's admission of no motivation to combine Forshew's "series of experiments" and his subsequent discussion of Forshew's separate experiments in *Personalis*. *Id*. at 42 (citing EX2001 at 15-18). NeoGenomics' new argument that instead of separate experiments, "Forshew teaches one overarching protocol" and its efforts to harmonize Forshew's Tables S3, S6, and S7 are not in its Petition and only underscore that NeoGenomics failed to meet its burden. Paper 12 at 1-2; Pet. at 22, 42.

NeoGenomics also tries to backpedal counsel's statements about Forshew's 2% detection limit, Paper 12 at 2-3, despite his position ***here*** directly contradicting his factual representations to the Board in *Personalis*. *E.g.*, Paper 6 at 60-61 (collecting cites); 37 C.F.R. § 42.11. NeoGenomics never responds to counsel's admission that Forshew was criticized for "needing to achieve a more sensitive detection limit (<2% allele frequency) to identify mutations" in patients with early-stage cancers. EX2002 at 53 (quoted in Paper 6 at 60-61).

Natera correctly noted counsel's inconsistent material positions about Forshew's features in ***this*** IPR while warning the Board of "modifying Forshew's already-working assay" in ***Personalis***. Paper 6 at 40-41. Counsel's concerns about modifying Forshew apply equally here.

NeoGenomics concludes by claiming that "Natera implies that Neo's former counsel withdrew *after* Natera's POPR." Paper 12 at 3. That makes no sense because Natera mentioned the withdrawal in the POPR itself, implicitly indicating counsel sought withdrawal *before*. Paper 6 at 3. As Natera correctly pointed out, NeoGenomics' counsel was quite aware of his irreconcilable statements when requesting withdrawal because he'd already confronted them in *Personalis*. *Id*. (citing EX2026). NeoGenomics again shows no inaccuracy in Natera's briefing.

Institution should be denied because NeoGenomics raises no credible question of unpatentability here.

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Dated: May 8, 2024

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## CERTIFICATE OF SERVICE

The undersigned certifies that pursuant to 37 C.F.R. § 42.6(e), a true copy of the foregoing **PATENT OWNER'S SUR-REPLY** is being served electronically on May 8, 2024 to the following lead and backup counsel for Petitioner to the following email addresses:

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