



Jeffrey A. Lamken
MoloLamken LLP
The Watergate, Suite 500
600 New Hampshire Avenue, N.W.
Washington, D.C. 20037
T: 202.556.2000
F: 202.536.2010
jlamken@mololamken.com
www.mololamken.com

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VIA CM/ECF

Jarrett B. Perlow
Circuit Executive & Clerk of Court
U.S. Court of Appeals for the Federal Circuit
717 Madison Place, N.W.
Washington, D.C. 20439

Re: *Natera, Inc. v. NeoGenomics Laboratories, Inc.*, Nos. 24-1324, -1409
(argued March 29, 2024, before Moore, C.J., Taranto, Chen, JJ.)
Response to Letter Under Fed. R. App. Proc. 28(j)

Dear Mr. Perlow:

Natera hereby responds to NeoGenomics’ letter, ECF #49 (“Ltr.”), which states RaDaR® is now Medicare-reimbursable for HPV-negative head-and-neck squamous-cell cancer. The district court—not this Court—is the proper forum for raising that development. Because this Court “is limited to the evidence before the district court at the time of the preliminary injunction hearing,” later events are irrelevant to the issue here: “whether the district court abused its discretion in issuing the preliminary injunction.” *Verlo v. Martinez*, 820 F.3d 1113, 1125-26 (10th Cir. 2016); see *Porretti v. Dzurenda*, 11 F.4th 1037, 1047 (9th Cir. 2021) (review “restricted” to “record available to the district court when” injunction “granted”). Rule 28(j) is for “new *authorities*,” not for “bring[ing] new evidence through the back door.” *Manley v. Rowley*, 847 F.3d 705, 710 n.2 (9th Cir. 2017); see *Ferring B.V. v. Allergan*, 980 F.3d 841, 850 n.3 (Fed. Cir. 2020) (rejecting Rule 28(j) letter because appeal is “base[d] . . . on what was—and was not—presented” below).

The proper course for NeoGenomics is to seek *modification* of the injunction—*e.g.*, exemption for the particular cancer—from the district court. See Fed. R. App. P. 8(a)(1)(C); Fed. R. Civ. P. 62.1(a). District courts have broad authority to modify relief to protect patient welfare. *United States v. Oakland Cannabis Buyers’ Coop.*, 532 U.S. 483, 496-97 (2001). Tellingly, NeoGenomics

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sought no such relief. District-court proceedings would have permitted Natera to present evidence that Signatera™ has “pan-cancer” approval for patients taking immunotherapy drugs, rendering Signatera™ Medicare-reimbursable for those patients for *all* cancers, *including* the head-and-neck cancer NeoGenomics invokes. <https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleid=58434>.

The district court correctly found that Signatera™ was “clinically validated for use with”—and thus available for—“the same cancers as RaDaR,” including the head-and-neck cancer NeoGenomics now offers. Appx20; *see* Appx2446(¶44). And contrary to NeoGenomics’ suggestion, Ltr.2, *both* Natera and NeoGenomics have pending Medicare applications for lung cancer. Appx20367(214:12-21). Finally, NeoGenomics’ (wholly unrelated) assertion that RaDaR® is “more sensitive” than Signatera™ by examining up to 48 tumor-specific variants, Ltr.2, *remains* unpersuasive and unsupported. The record is clear, Appx7932, and Natera offers higher-variant versions of Signatera™ regardless, Appx7624.

Respectfully submitted,

/s/ Jeffrey A. Lamken

Jeffrey A. Lamken
MOLOLAMKEN LLP
The Watergate, Suite 500
600 New Hampshire Avenue, N.W.
Washington, D.C. 20037
(202) 556-2000
jlamken@mololamken.com

Counsel for Natera, Inc.

cc: Counsel of record
via CM/ECF