

NATERA, INC. v. NEOGENOMICS LABORATORIES, INC., Appeals Nos. 2024-1324, -1409 (Fed. Cir. July 12, 2024). Before Moore, Taranto and Chen. Appealed from M.D.N.C. (Judge Eagles).

### Background:

Natera and NeoGenomics are healthcare companies that manufacture products used for the early detection of cancer relapse. Relevant to this case, Natera owns a patent that claims methods for amplifying targeted genetic material (to facilitate detection of the genetic material).

Natera sued NeoGenomics, asserting that NeoGenomics's RaDaR product infringed Natera's patent by amplifying circulating tumor DNA (ctDNA) in patient samples. Natera moved for a preliminary injunction, and the district court granted it (with some exceptions for patients already using RaDaR and for finalized or in-process testing).

### Issue/Holding:

Did the district court err in granting the preliminary injunction? No, affirmed.

### Discussion:

In order to obtain a preliminary injunction, the moving party must establish (1) likelihood of success on the merits, (2) likelihood it will suffer irreparable harm absent preliminary relief, (3) the balance of equities tips in its favor, and (4) an injunction is in the public interest (citing *Metalcraft of Mayville, Inc. v. Toro Co.*, 848 F.3d 1358, 1363 (Fed. Cir. 2017)). The Federal Circuit concluded that the district court correctly decided on all four of these factors.

The Federal Circuit determined that Natera made a strong showing that NeoGenomics's RaDaR test likely infringed Natera's patent. Although the district court did not engage in any explicit claim construction, the Federal Circuit noted that "[a] district court has no obligation to definitely construe claims at the preliminary injunction stage" (citing *Sofamor Danek Group, Inc. v. DePuy-Motech, Inc.*, 74 F.3d 1216, 1221 (Fed. Cir. 1996)). In any case, the parties did not present any claim construction dispute. And NeoGenomics did not raise a substantial question of patent validity; it merely presented conclusory arguments with no supporting facts.

The Federal Circuit also determined that Natera would suffer irreparable harm in the absence of a preliminary injunction. Natera and NeoGenomics directly compete in a two-player market for "tumor-informed" testing products based on ctDNA detection; any market growth by NeoGenomics would result in lost sales for Natera. And although the Natera patent does not claim "tumor-informed" testing, Natera showed that RaDaR's tumor-informed testing would be impossible without practicing the particular amplification methods claimed in Natera's patent.

Finally, the Federal Circuit determined that no "critical public interest" would be harmed by the grant of injunctive relief in this case. Natera presented evidence that its own product is approved for all cancer indications for which RaDaR is approved, and thus any patients in need of a "tumor-informed" test could use Natera's product. And competition from infringing products is not itself enough to weight in favor of public interest (citing *Douglas Dynamics, LLC v. Buyers Products Co.*, 717 F.3d 1336, 1346 (Fed. Cir. 2013)).

The Federal Circuit concluded that the district court did not abuse its discretion in finding that the balance of equities tipped in favor of granting the preliminary injunction.