

# Understanding Preliminary Injunction: A Review of a Recent Federal Circuit Decision

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This Federal Circuit opinion addresses a district court's decision granting plaintiff's motion for a preliminary injunction.[1]

## **Background**

Plaintiff Natera, Inc. ("Natera") and defendant NeoGenomics Laboratories, Inc. ("NeoGenomics") are research focused healthcare companies operating in the oncology testing industry. Both companies manufacture products used for early detection of cancer relapse. Natera owns two relevant patents, U.S. Patent No. 11,519,035 ("the '035 patent") and U.S. Patent No. 11,530,454 ("the '454 patent"). Natera uses the methods claimed in the '035 and '454 patents in its "Signatera" product, while NeoGenomics offers a competing product under the brand name "RaDaR."

Natera sued NeoGenomics in the United States District Court for the Middle District of North Carolina, alleging RaDaR infringed the '035 and '454 patents and moved for a preliminary injunction. The district court granted the preliminary injunction because it determined that Natera satisfied the requirements for injunctive relief, including likelihood of success on the merits of its '035 patent infringement claim. The district court did not reach the likelihood of success of Natera's '454 patent infringement claim.

After the preliminary injunction issued, NeoGenomics timely moved for modification or clarification of the injunction. NeoGenomics presented evidence that several potential research contracts were finalized or nearly finalized such that enjoining performance under the contract would cancel or delay research. NeoGenomics requested the district court clarify whether the injunction applies to those potential research contracts and to testing of already-collected patient samples.

The district court issued multiple orders responding to NeoGenomics' motion to modify or clarify the injunction. The district court acknowledged three of NeoGenomics' clinical testing contracts under which testing of samples had not yet begun but for which third parties had designed experimentation and testing protocols around RaDaR. The district court clarified that the injunction does not bar RaDaR's use under these contracts because it is not in the public interest to delay potentially meaningful research and negatively impact third parties who had designed experimentation protocols

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around RaDaR's use.

The district court also clarified the injunction does not bar RaDaR's use on patient blood samples that were collected but not yet received by NeoGenomics when the injunction issued. One potential contract, about which NeoGenomics provided only a conclusory statement that the sponsoring organization had done significant work designing the study, remains barred by the injunction.

### **Issue(s)**

Whether there was abuse of discretion in the district court's decision to grant Natera's motion for a preliminary injunction.

### **Holding**

The Federal Circuit found that NeoGenomics had not shown abuse of discretion in the district court's decision to grant Natera's motion for a preliminary injunction. The district court's decision was affirmed.

### **Reasoning**

To obtain a preliminary injunction, a party must establish likelihood of success on the merits, likelihood it will suffer irreparable harm absent preliminary relief, the balance of equities tips in its favor, and an injunction is in the public interest. The Federal Circuit review the grant or denial of a preliminary injunction under the law of the regional circuit, here the Fourth Circuit. Both the Fourth Circuit and the Federal Circuit review the grant or denial of a preliminary injunction for abuse of discretion.

**Likelihood of Success.** To show likelihood of success on the merits, a patentee must show (1) it will likely prove infringement and (2) its infringement claim will likely withstand challenges to the validity and enforceability of the patents. NeoGenomics appealed the district court's conclusion that Natera demonstrated a likelihood of prevailing on its '035 patent infringement claim. NeoGenomics argued that the district court failed to resolve a key claim construction dispute and the district court's implied claim construction was erroneous. The Federal Circuit found that the district court did not err by not engaging in explicit claim construction before evaluating the likelihood of infringement, where NeoGenomics only raised its claim construction argument for the first time in its motion to stay the preliminary injunction pending appeal. NeoGenomics' newly raised claim construction dispute therefore does not establish that the district court abused its discretion. The Federal Circuit further held that the district court did not implicitly construe the claims incorrectly.

Regarding the substantial question of invalidity, NeoGenomics argued that the district court applied an incorrect legal standard in evaluating its obviousness challenge. NeoGenomics asserted that "mere vulnerability" of the patent to an invalidity challenge suffices to defeat a preliminary injunction. NeoGenomics argued that it met this burden and the district court, in determining NeoGenomics did not raise a substantial question of obviousness, demanded a greater showing than required at the preliminary injunction stage. The Federal Circuit disagreed, finding that the district court did not apply an incorrect legal standard in assessing NeoGenomics' obviousness challenge and that NeoGenomics has not shown clear error in the district court's findings on motivation to combine or reasonable expectation of success.

**Irreparable Harm.** A party seeking a preliminary injunction must show it is likely to suffer irreparable

harm if the injunction is not granted and establish a causal nexus between the alleged infringement and the alleged harm. The district court determined that Natera showed a likelihood of irreparable harm in the absence of a preliminary injunction based on its finding of direct competition between Natera and NeoGenomics. NeoGenomics argued the district court legally erred by misreading *Presidio Components, Inc. v. American Technical Ceramics Corp.*, 702 F.3d 1351 (Fed. Cir. 2012), to endorse a universal rule that irreparable harm is evident in any scenario of direct competition with an alleged infringer. The Federal Circuit disagreed, noting that the district court did not impose such a categorical rule and its analysis accords with the Federal Circuit precedent.

NeoGenomics next argued the district court legally erred in its causal nexus analysis by tying the alleged harm to an unclaimed feature. Specifically, NeoGenomics argued the district court erred by considering the tumor-informed testing market because tumor-informed testing is not claimed in the '035 patent. The Federal Circuit disagreed and found that the district court did not err by crediting Natera's argument that the allegedly infringing method is key to RaDaR's tumor-informed testing. The Court therefore saw no error in the district court's causal nexus analysis.

**Public Interest.** Before granting an injunction, a district court must balance the patentee's rights with any adverse effects on the public. In evaluating whether the public interest favors the grant of an injunction, the district court should focus on whether a critical public interest would be injured by the grant of injunctive relief. Here, the district court concluded the public interest weighs in favor of the preliminary injunction. Because Signatera is clinically validated for use with the same cancers as RaDaR, the district court reasoned, any patients in need of a tumor-informed MRD test will be able to access one through Natera. NeoGenomics argued the district court erred by overlooking harm to cancer patients absent access to RaDaR's MRD test. NeoGenomics asserted that no cancer test can substitute for RaDaR due to its high sensitivity and ability to detect small numbers of certain mutations, and therefore the public interest supports reversal of the injunction. The Federal Circuit disagreed, finding that the district court's public interest analysis did not overlook harm to cancer patients and that NeoGenomics has not shown that access to RaDaR will improve patient outcomes or that Natera is unable to satisfy the need for tests. The Federal Circuit affirmed the district court's decision, finding that NeoGenomics has not shown abuse of discretion in the district court's decision to grant Natera's motion for a preliminary injunction.

## FOOTNOTES

[1] [Natera, Inc. v. NeoGenomics Laboratories, Inc. 2024-1324, 2024-1409 \(Fed. Cir. July 12, 2024\)](#)

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National Law Review, Volume XIV, Number 260

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