

IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF NORTH CAROLINA

NATERA, INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	1:23-CV-629
	)	
NEOGENOMICS LABORATORIES,	)	
INC.,	)	
	)	
Defendant.	)	

ORDER

In this patent infringement case, NeoGenomics Laboratories, Inc. seeks to stay the preliminary injunction pending appeal. NeoGenomics contends that substantial questions exist concerning the validity and infringement of Natera Inc.’s ‘035 patent and the other requirements of a preliminary injunction. In its discretion and after considering the relevant factors, the Court finds and concludes that a stay is not appropriate.

I. Procedural History

In July 2023, Natera filed this lawsuit against NeoGenomics alleging NeoGenomics infringed the methods in Natera’s ‘454 and ‘035 patents through its tumor informed, molecular residual disease assay product, RaDaR. *See* Doc. 1. Natera asked the Court for a preliminary injunction. Doc. 5.

After briefing and oral argument, the Court found that (1) Natera had demonstrated a likelihood of success on its ‘035 patent infringement claim, (2) Natera was likely to suffer irreparable harm in the absence of an injunction, (3) the balance of equities weighed in Natera’s favor, and (4) a preliminary injunction was in the public

interest. Doc. 169 at 21. The Court issued a preliminary injunction on December 27, 2023, Doc. 171, and set the bond on January 10, 2024. Doc. 193 at p. 6 ¶ 1.

Natera posted the bond, *see* Doc. 197, and the preliminary injunction went into effect on January 12. *See* Doc. 193 at p. 6 ¶ 2. NeoGenomics asks the Court for a stay of the preliminary injunction pending NeoGenomics' appeal to the Federal Circuit. Doc. 173 (notice of appeal); Doc. 176 (motion to stay).

II. Legal Standard to Stay an Injunction

A court can stay a preliminary injunction while an appeal is pending. *See* FED. R. CIV. P. 62(d). When assessing a motion to stay, courts consider:

(1) whether the stay applicant has made a strong showing that he is likely to succeed on the merits; (2) whether the applicant will be irreparably injured absent a stay; (3) whether issuance of the stay will substantially injure the other parties interested in the proceeding; and (4) where the public interest lies.

Hilton v. Braunskill, 481 U.S. 770, 776 (1987); *see also Standard Havens Prods., Inc. v. Gencor Indus., Inc.*, 897 F.2d 511, 512 (Fed. Cir. 1990). The first two factors are often considered “the most critical.” *Nken v. Holder*, 556 U.S. 418, 434 (2009). But these factors “cannot be reduced to a set of rigid rules,” and courts must apply an individualized assessment in each case. *Hilton*, 481 U.S. at 777.

“Granting a stay is not a matter of right but an exercise of judicial discretion.” *See Casa de Md., Inc. v. Trump*, No. 19-CV-2715, 2019 WL 7565389, at *2 (D. Md. Nov. 14, 2019) (citing *Nken*, 556 U.S. at 433) (cleaned up). The moving party has “the burden of showing that the circumstances justify an exercise of that discretion.” *Nken*, 556 U.S. at

434. Because a stay is extraordinary relief, the moving party’s burden is heavy. *See Common Cause v. Rucho*, 284 F. Supp. 3d 780, 783 (M.D.N.C. 2018).

III. Discussion

NeoGenomics contends that a stay is necessary because there are substantial questions about the validity and infringement of the ‘035 patent and about irreparable harm to the parties. *See* Doc. 177 at 9–20. According to NeoGenomics, these substantial questions support a finding that NeoGenomics is likely to succeed on the merits of its appeal or at least has a substantial case on the merits. NeoGenomics also asserts that it will suffer irreparable harm and that a stay is in the public interest. *Id.* at 20–24.

A. NeoGenomics Has Not Shown Likely Success on the Merits

NeoGenomics again challenges the validity of the ‘035 patent, contending it is obvious and does not have an adequate written description. *Id.* at 10–13. NeoGenomics also contends that it has raised a substantial question as to whether RaDaR infringes the ‘035 patent, warranting a stay of the preliminary injunction. *See id.* at 14–17.

The Court already found that NeoGenomics did not raise a substantial question of patent validity based on obviousness. *See* Doc. 169 at 8–10. NeoGenomics points to statements made by Natera about cell free DNA to support obviousness, Doc. 177 at 10–11, but these statements were not discussing circulating tumor DNA or the ‘035 patent. *See* Doc. 97-12 at ¶ 115; Doc. 162-1 at 7. These statements were also available and considered by the Court when deciding Natera’s preliminary injunction motion.¹

¹ Natera contends that NeoGenomics’ motion is “effectively a motion for reconsideration.” *See* Doc. 190 at 8–9. Courts should only reconsider a preliminary injunction if there has been a

NeoGenomics contends that the Court erred by not considering arguments made at the preliminary injunction hearing in support of its challenge to the ‘035 patent’s written description. Doc. 177 at 13. The fact that the Court did not address an argument in detail in its written order, *see, e.g.*, Doc. 169 at 10–11, does not mean that the Court did not consider it. Moreover, the fact that the Court asked questions at the hearing about NeoGenomics’ cursory argument in a brief does not obligate the Court to respond to those oral arguments with an extended essay. The Court has no duty to set forth a detailed argument NeoGenomics chose not to make in briefing and then say why that argument is incorrect.

NeoGenomics again asserts that RaDaR is not infringing the ‘035 patent and takes issue with the Court’s interpretation of the patent claims. *See id.* at 14–17. This is nothing more than an argument for reconsideration. *See n.1 supra.* NeoGenomics has not shown likely success on appeal by reasserting the same arguments the Court has already considered and found unpersuasive. *See Casa de Md.*, 2019 WL 7565389, at *2.

B. Irreparable Injury

NeoGenomics contends that the Court legally erred in its analysis of Natera’s likely irreparable harm and that there are substantial questions concerning irreparable harm that support granting a stay. *See* Doc. 177 at 17–20. NeoGenomics also contends

change in law, there is additional evidence that was previously unavailable, or the prior decision was clear error or would work manifest injustice. *Turn and Bank Holdings, LLC v. Avco Corp.*, No. 19-CV-503, 2020 WL 733831, at *1 (M.D.N.C. Feb. 13, 2020) (citing *Akeva, LLC v. Adidas Am., Inc.*, 385 F. Supp. 2d 559, 566 (M.D.N.C. 2005)). To the extent the motion is more fairly viewed as a motion for reconsideration in disguise, NeoGenomics has not met this standard.

that it will be irreparably harmed and that any harm Natera might experience “cannot be reconciled with its delay in prosecuting this case” or Natera’s current “dominant market position.” *Id.* at 20–22.

The Court did not hold, as NeoGenomics contends, “that the existence of head-to-head competition is sufficient on its own to establish irreparable harm.” *Id.* at 17. Such competition is evidence of irreparable harm, Doc. 169 at 14, a point NeoGenomics does not dispute. In evaluating the evidence, the Court also covered the potential for lost customers, profits, business relationships, and clinical opportunities, as well as lost biopharmaceutical partnerships, all on the facts here. *Id.* at 15–16. NeoGenomics ignores these other findings.

NeoGenomics next says that the Court minimized the harm to NeoGenomics from the injunction. Doc. 177 at 20–21. It is true that the Court does not weigh the harm the same as NeoGenomics does, but that is different from “minimizing” the harm. To the extent NeoGenomics says that it is not appropriate to weigh its size, products, and revenue sources, it is mistaken; the case law says otherwise. *See, e.g., BioRad Lab’ys, Inc. v. 10X Genomics Inc.*, 967 F.3d 1353, 1378 (Fed. Cir. 2020) (holding that “[i]n considering the balance of hardships, courts may consider the ‘parties’ sizes, products, and revenue sources.”); *i4i Ltd. P’ship v. Microsoft Corp.*, 598 F.3d 831, 861–62 (Fed. Cir. 2010) (holding the same).

NeoGenomics otherwise does little more than repeat its argument that Natera unduly delayed in prosecuting this case. The Court already addressed and rejected this exact argument, *see* Doc. 169 at 16–17, and there is no need for the Court to repeat itself.

C. The Public Interest

NeoGenomics contends that the Court overlooked a critical public interest in granting a preliminary injunction because the “public interest favors broader availability of medical services and products.” Doc. 177 at 22. The fact that the Court weighed the factors differently than NeoGenomics, does not mean the Court overlooked a factor. The Court explicitly stated that “[b]efore granting an injunction, courts must balance ‘protecting the patentee’s rights’ with any adverse effects on the public.” Doc. 169 at 19 (citing *i4i*, 598 F.3d at 863). The Court then addressed the various public interests involved and tailored the injunction to ensure it would not disrupt clinical trials and research projects already in process as well as treatment for patients already using RaDaR. *Id.* at 19–21.

When NeoGenomics asked for clarification of the injunction, Doc. 178, the Court confirmed that the use of RaDaR is not enjoined in six clinical trials that either have signed contracts or approved procedures in place, or for testing patient samples that were collected before the injunction took effect as well as continued testing of those patients. Doc. 193 at 5–6; Doc. 206 at 2. Allowing these uses of RaDaR is in the public’s interest.² *See* Doc. 193 at p. 6–7 ¶ 3; Doc. 206 at 2.

NeoGenomics contends that RaDaR has a higher sensitivity than Natera’s product that “allows it to better detect cancer in early stages.” *see* Doc. 177 at 22–24. But that

² The Court addressed some components of NeoGenomics’ motion to modify in its order setting a bond amount, *see* Doc. 193, and others in its clarification order. Doc. 206. The rest of the motion to modify, Doc. 178, will be decided in an order issued concurrently with this one.

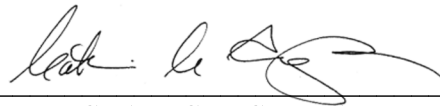
point is disputed, *see, e.g.*, Doc. 190 at 23–24, and it is not at all clear that this is so. Nor has NeoGenomics submitted satisfactory evidence that its RaDaR test is available for cancers for which Natera’s product is not available.

IV. Conclusion

NeoGenomics has not made a strong showing it is likely to succeed on the merits of its appeal. The other *Hilton* factors do not support staying the preliminary injunction.

In the Court’s discretion, it is **ORDERED** that the defendant’s motion to stay preliminary injunction, Doc. 176, is **DENIED**.

This the 14th day of February, 2024.



UNITED STATES DISTRICT JUDGE