IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

LABORATORY CORPORATION OF AMERICA HOLDINGS, Plaintiff, v. NATERA, INC., Defendant.	C.A. No. 21-669-GBW **UNSEALED ON 8/14/2025**
LABORATORY CORPORATION OF AMERICA HOLDINGS, Plaintiff, v. NATERA, INC., Defendant.	C.A. No. 21-1635-GBW **UNSEALED ON 8/14/2025**

Brian E. Farnan, Michael J. Farnan, FARNAN LLP, Wilmington, DE; Edward R. Reines, Derek C. Walter, WEIL, GOTSHAL & MANGES LLP, Redwood Shores, CA.

Counsel for Plaintiff

Karen Jacobs, Brian P. Egan, Derek J. Fahnestock, MORRIS, NICHOLS, ARSHT & TUNNELL LLP, Wilmington, DE; Eric Alan Stone, Daniel J. Klein, Eliza P. Strong, Ariella C. Barel, GROOMBRIDGE, WU, BAUGHMAN & STONE LLP; New York, NY.

Counsel for Defendant

MEMORANDUM OPINION

August 14, 2025
Wilmington, Delaware

GREGORY B. WILLIAMS
UNITED STATES DISTRICT JUDGE

Pending before the Court is Plaintiff Laboratory Corporation of America Holdings' ("Labcorp" or "Plaintiff") Motion for Summary Judgement ("Motion") (D.I. 186), which has been fully briefed (D.I. 187; D.I. 218; D.I. 237).[1] For the following reasons, the Court denies Plaintiff's Motion.

I. LEGAL STANDARD

"The court shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). "A genuine issue of material fact is one that could lead a reasonable jury to find in favor of the nonmoving party." *Bletz v. Corrie*, 974 F.3d 306, 308 (3d Cir. 2020). "The court must review the record as a whole, draw all reasonable inferences in favor of the nonmoving party, and must not 'weigh the evidence or make credibility determinations.'" *Id.* at 308 (quoting *Parkell v. Danberg*, 833 F.3d 313, 323 (3d Cir. 2016)).

II. DISCUSSION

Labcorp contends that the Court should grant summary judgment of no invalidity for lack of written description and enablement because Natera Inc.'s ("Natera" or "Defendant") experts, according to Labcorp, (1) present conclusory opinions without a scintilla of evidence and (2) rebut their own written description and enablement opinions. After a brief discussion on the law, the Court examines each contention. D.I. 187 at 28-32.

[1] References to docket cites refer to C.A. No. 21-1635, though, the rulings herein also apply to C.A. No. 21-669.

The written description and enablement requirements under the Patent Act are both found in 35 U.S.C. § 112(a). In particular, § 112(a) provides that the "specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor or joint inventor of carrying out the invention." 35 U.S.C. § 112(a).

The "written description requirement is satisfied if the specification conveys with reasonable clarity to those skilled in the art that the inventor was in possession of the claimed invention." *Pharmacyclics LLC v. Alvogen, Inc.*, No. 2021-2270, 2022 U.S. App. LEXIS 31479, at *18 (Fed. Cir. Nov. 15, 2022) (citing *Biogen Int'l GmbH v. Mylan Pharms., Inc.*, 18 F.4th 1333, 1341-42 (Fed. Cir. 2021)). A patent claim "need not provide *in haec verba* support for the claimed subject matter at issue" to satisfy the written description requirement. *Lampi Corp. v. American Power Prods., Inc.*, 228 F.3d 1365, 1378 (Fed. Cir. 2000). To satisfy the separate requirement of enablement, "the specification must enable the full scope of the invention *as defined by its claims*." *Amgen Inc. v. Sanofi*, 598 U.S. 594, 610 (2023) (emphasis added). Defendants bear the burden of demonstrating a lack of written description and enablement by clear and convincing evidence. *Invitrogen Corp. v. Clontech Labs., Inc.*, 429 F.3d 1052, 1072 (Fed. Cir. 2005).

A. In Contrast to Labcorp's Contention, Natera's Experts Present Sufficient Analyses and Opinion to Proceed Past Summary Judgment

In summary, Labcorp contends that Natera's experts, Dr. Metzker and Dr. Albert, fail to sufficiently set forth analyses supporting their opinions of no written description / no enablement, thereby necessitating summary judgment in Labcorp's favor. D.I. 187 at 29-31. Labcorp is incorrect.

In his report, Dr. Metzker opines that:

> It is my opinion that the term "mutations," and all claims reciting the term "mutations," in each of the Asserted Patents, are not enabled across their full scope or adequately described because the specification does not enable one of ordinary skill in the art to distinguish a mutation from a sequencing, assembly, or alignment error, nor does it demonstrate the alleged inventors were in possession of an invention that would accomplish this.
>
> To the extent that the claimed "mutations" detectable by methods of the invention, is interpreted to mean true sequence variants, rather than sequencing, assembly, or alignment errors, in my opinion the claims are not enabled or adequately described because the written description does not explain how to distinguish between a sequencing, assembly, or alignment error and a true variant using the claimed methods. In my opinion, the claimed method, to the extent it is enabled or adequately described at all, would output information about all differences between the reads and the reference sequence. But not all differences are actually indicative of mutations because some will be caused by sequencing, assembly, or alignment errors. In order to produce read:reference descriptions to map positional information of mutations, as required by Claim 1 of the '799 Patent, or to identify mutations(s), as required by Claims 8–12, one of ordinary skill in the art would not have necessarily known how to distinguish between insignificant differences in the reads relative to the reference genome from mutations that are actually present in the sample nucleic acid. The written description does not enable one of ordinary skill in the art to do this, nor does it demonstrate that the alleged inventors were in possession of a method of identifying mutations.

D.I. 188, Ex. 13 ¶¶ 1735-36.

The excerpted paragraphs above amount to a theory and analysis of no written description and no enablement that is sufficient in scope and rigor to proceed to resolution by the factfinder, of which the Court is not. *See Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (confirming that written description is a "question of fact"); *MagSil Corp. v. Hitachi Glob. Storage Techs., Inc.*, 687 F.3d 1377, 1380 (Fed. Cir. 2012) ("Enablement is a question of law based on underlying factual findings."). Dr. Albert's opinion, which is generally similar in scope (*see* D.I. 188, Ex. 12 ¶¶ 244-59), is likewise sufficient to proceed to resolution by the factfinder.

The Court briefly addresses some of Labcorp's quibbles. *First*, Labcorp asserts that "Dr. Metzker fails to analyze the then-current state of the art in distinguishing between errors and

mutations, as well as what a POSITA would have known to do to prevent and distinguish errors." D.I. 187 at 29. However, Labcorp does not provide any supporting case law and Labcorp itself does not explain the prior art that is purportedly missing from Dr. Metzker's analysis. Moreover, as explained above, Dr. Metzker's analysis is sufficient in scope and rigor to survive Labcorp's summary judgment contentions.

Second, Labcorp contends that, while "Dr. Metzker opines that the shared specification of the Asserted Patents does not *enable* a POSITA to distinguish errors," "the shared specification *describes* certain prior art methods for avoiding such errors." D.I. 187 at 29 (emphases added). However, aside from the point that it appears that Labcorp is conflating the standards for written description and enablement, the disagreement between the parties' experts on whether the shared specification sufficiently describes and enables the claimed inventions encompasses questions of fact that are not appropriate for resolution by summary judgment. Rather, those questions are appropriate for the jury, as the factfinder, to determine.

Third, Labcorp takes issue with Dr. Albert's opinion that "the specification of the Asserted Patents do 'not provide any guidance beyond the high-level algorithm as to which assembly and alignment algorithms, methods, or programs to use.'" D.I. 187 at 30 (citation omitted). Labcorp purportedly points to such guidance, including with respect to "exemplar assembly and alignment tools that may be used." D.I. 187 at 30. However, as above, the underlying questions of fact and merit of Labcorp's argument should be decided by the factfinder, the jury, and not by the Court via summary judgment.

For the foregoing reasons, the Court rejects Labcorp's contention that Dr. Metzker and Dr. Albert fail to sufficiently set forth analyses supporting their opinions of no written description / no enablement.

B. Labcorp's Contention that Natera's Experts Purportedly Rebut Their Own Written Description and Enablement Opinions in Other Sections of their Opinions Does Necessitate Summary Judgment

Labcorp also contends that the Court should grant summary judgment in its favor on the issues of no written description / no enablement because Natera's experts simultaneously opine that (1) the shared specification fails to describe and enable the claimed inventions and (2) the same claims at issue for written description and enablement are anticipated by the prior art. D.I. 187 at 31-32. However, as Natera correctly observes, claims can be simultaneously invalid because of anticipation and no written description / no enablement. *See, e.g.*, *Northpoint Tech., Ltd. v. MDS Am., Inc.*, 413 F.3d 1301, 1308, 1310 (Fed. Cir. 2005) (affirming invalidity on grounds of anticipation and lack of enablement for the same claims). Therefore, Labcorp's contention is flawed and there has been no showing made by Labcorp to warrant granting summary judgment in its favor.

III. CONCLUSION

For all of the foregoing reasons, the Court DENIES Plaintiff Labcorp's Motion for Summary Judgement (D.I. 186). An Order consistent with this Memorandum Opinion will be entered.