IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

COLD SPRING HARBOR LABORATORY, **Plaintiff,** **v.** **GUARDANT HEALTH, INC.,** **Defendant.**	**Court No. 1:25-cv-00263-JCG**

OPINION AND ORDER

[Denying Defendant's Partial Motion to Dismiss.]

Dated: October 10, 2025

Kelly E. Farnan and Sara M. Metzler, Richards, Layton & Finger, P.A., of Wilmington, DE; John M. Desmarais, Brian D. Matty, Kevin Goon, and Ashley DaBiere, Desmarais LLP, of New York, NY. Attorneys for Plaintiff Cold Spring Harbor Laboratory.

Brian E. Farnan and Michael J. Farnan, Farnan LLP, of Wilmington, DE; Edward R. Reines, Jones Day, of Palo Alto, CA; Derek C. Walter, Jones Day, of San Francisco, CA. Attorneys for Defendant Guardant Health, Inc.

Choe-Groves, Judge: Plaintiff Cold Spring Harbor Laboratory ("Plaintiff" or "Cold Spring Harbor") filed this case against Defendant Guardant Health, Inc. ("Defendant" or "Guardant") alleging infringement of U.S. Patent Numbers 10,947,589 ("'589 Patent") and 12,234,510 ("'510 Patent") (collectively, "Asserted Patents" or "Patents"). Pl.'s First Am. Compl. Patent Infringement ("Am.

Compl.") (D.I. 15); see U.S. Patent Number 10,947,589 ("'589 Patent") (D.I. 15-1); U.S. Patent Number 12,234,510 ("'510 Patent") (D.I. 15-17).

Defendant filed Guardant's Partial Motion to Dismiss. Def.'s Mot. Dismiss ("Defendant's Partial Motion to Dismiss" or "Def.'s MTD") (D.I. 24); Def.'s Opening Br. Supp. Partial Mot. Dismiss ("Def.'s Br.") (D.I. 25). Plaintiff opposed the motion, and Defendant filed a reply brief. Pl.'s Answering Br. Opp'n Guardant's Partial MTD Cold Spring Harbor's First Am. Compl. ("Pl.'s Resp. Br.") (D.I. 32); Def.'s Reply Br. Supp. MTD ("Def.'s Reply Br.") (D.I. 38).

For the reasons discussed below, Guardant's Partial Motion to Dismiss is denied.

BACKGROUND

Cold Spring Harbor is a not-for-profit education corporation headquartered in New York that conducts research and discovery, including in the areas of cancer, neuroscience, genomics, quantitative biology, and plant biology. Am. Compl. ¶¶ 2–4. This research has resulted in several applications, such as early cancer detection tests and liquid biopsies. Id. at ¶ 6. In addition, Cold Spring Harbor's research has led to the issuance of several patents, including the Asserted Patents. Id.

Cold Spring Harbor is the owner by assignment of all right, title, and interest in the Asserted Patents. Id. at ¶¶ 31, 37. The Asserted Patents are continuations of

the same application filed in 2011. ’510 Patent; ’589 Patent. The ’510 Patent was issued by the United States Patent and Trademark Office (“USPTO”) on February 25, 2025, and the ’589 Patent was issued by the USPTO on March 16, 2021. ’510 Patent; ’589 Patent. Both Patents are titled “Varietal Counting of Nucleic Acids for Obtaining Genomic Copy Number Information,” and are directed to a method of obtaining genomic copy number information from a sample of genomic material. ’510 Patent at Abstract; ’589 Patent at Abstract. Claim 1 of the ’510 Patent recites:

> A method comprising:
> a) obtaining segments of genomic nucleic acids from a sample containing the genomic nucleic acids:
> b) randomly tagging the segments of genomic nucleic acids with differing nucleic acid tags, thereby generating unique tagged nucleic acid molecules from the segments of genomic nucleic acids, such that each of the unique tagged nucleic acid molecules comprises a segment of the segments of the genomic nucleic acids from step (a) and a nucleic acid tag of the nucleic acid tags;
> c) subjecting the unique tagged nucleic acid molecules to a polymerase chain reaction (PCR), thereby generating copies of the unique tagged nucleic acid molecules;
> d) generating tag associated sequence reads by sequencing the copies of the unique tagged nucleic acid molecules of step (c);
> e) assigning each of the unique tagged nucleic acid molecules to a location on a genome by mapping each of the tag associated sequence reads of step (d) to a location in the genome; and
> f) in a plurality of locations in the genome, obtaining relative copy number information in the genomic nucleic acids from the sample based on the number of unique tagged nucleic acid molecules that have been assigned to each of the plurality of locations in the genome.

’510 Patent at 35:15–43.

Claim 1 of the ’589 Patent, which is substantially similar to Claim 1 of the ’510 Patent, recites:

> A method comprising:
> a) obtaining segments of genomic nucleic acids from a sample:
> b) tagging the segments with nucleic acid tags, thereby generating a plurality of unique tagged nucleic acid molecules, such that each of the unique tagged nucleic acid molecules comprises a segment of the segments of the genomic nucleic acids from step (a) and a nucleic acid tag of the nucleic acid tags;
> c) subjecting the plurality of the unique tagged nucleic acid molecules to a polymerase chain reaction (PCR), thereby generating amplified tagged nucleic acid molecules;
> d) generating tag associated sequence reads by sequencing the amplified tagged nucleic acid molecules of step (c);
> e) assigning each of the amplified tagged nucleic acid molecules to a location on a reference genome from the same species from which the sample has been obtained by mapping each of the tag associated sequence reads of step (d) to a location of the reference genome; and
> f) at a plurality of locations on the reference genome, counting the number of unique tagged nucleic acid molecules that have been assigned to the same location on the reference genome based on the mapping step to obtain a count for each location of the plurality of locations on the reference genome, thereby obtaining copy number information from genomic nucleic acids in the sample.

’589 Patent at 35:15–45.

The methods claimed in the Asserted Patents represent improvements in the field of early cancer detection and aim to overcome prior problems in DNA sequencing, such as amplification bias producing inaccurate copy number information. Am. Compl. ¶¶ 33–35, 39–41.

Guardant is a Delaware company that produces and markets blood tests that include “DNA library preparation, DNA sequencing, and DNA analysis steps to

provide genomic profiles, including genetic copy number information." Id. at ¶¶ 7–8. Cold Spring Harbor alleges that the Guardant360 blood test and the Guardant360 CDx blood test practice the methods of the Asserted Patents, such as obtaining segments of nucleic acids from a sample, tagging the segments with nucleic acid tags, subjecting unique tagged nucleic acid molecules to polymerase chain reaction, sequencing amplified copies of tagged nucleic acid molecules, assigning tag associated sequence reads to a location of a reference genome, and obtaining copy number information from the genomic nucleic acids in the sample. Id. at ¶¶ 44–57; Exs. 9–11, 13–14.

In January 2019, Guardant filed an opposition at the European Patent Office against Cold Spring Harbor's European Patent No. EP2630263 ("the European Patent"). Id. at ¶ 66. The European Patent shares the same title as the Asserted Patents, "Varietal Counting of Nucleic Acids for Obtaining Genomic Copy Number Information," and claims priority to the same provisional patent applications. Id. at ¶¶ 62–65; Ex. 16 ("E.P. 2630263") (D.I. 15-16). The European Patent contained similar disclosures as the Asserted Patents, with Claim 1 reciting:

> A method for obtaining from genomic material genomic copy number information unaffected by amplification distortion, comprising:
> a) obtaining segments of the genomic material;
> b) tagging the segments with nucleic acid tags, to generate unique tagged nucleic acid molecules, such that each of the unique tagged nucleic acid molecules comprises one segment of the genomic material from step (a) and a tag;

> c) subjecting the tagged nucleic acid molecules to amplification by polymerase chain reaction (PCR);
> d) generating tag associated sequence reads by sequencing the product of step (c);
> e) assigning each tagged nucleic acid molecule to a location on a genome associated with the genomic material by mapping the subsequence of each tag associated sequence read corresponding to a segment of the genomic material to a location on the genome; and
> f) counting the number of tagged nucleic acid molecules having a different tag that have been assigned to the same location on the genome, thereby obtaining genomic copy number information unaffected by amplification distortion.

E.P. 2630263 at 24:25–40.

Cold Spring Harbor filed its Complaint in March 2025, alleging infringement of the Asserted Patents and seeking monetary damages and injunctive relief. Compl. (D.I. 1). An Amended Complaint was filed on May 1, 2025. Am. Compl. Cold Spring Harbor alleges that Guardant became aware of the Asserted Patents when researching the patentability of its own patents, developing its blood tests, and due to its participation in the early cancer detection industry. Id. at ¶¶ 60–61. Cold Spring Harbor alleges further that Guardant's involvement in the European Patent opposition proceedings, which lasted through March 2021, resulted in Guardant's awareness of the Asserted Patents. Id. at ¶¶ 66–68.

Guardant filed a partial motion to dismiss Cold Spring Harbor's Amended Complaint, arguing that Cold Spring Harbor failed to allege sufficient facts to support its claims for enhanced damages based on willful infringement of the

Asserted Patents. Def.'s Mot. to Dismiss; Def.'s Br. The Parties did not request oral argument.

LEGAL STANDARD

The Court has jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338, which grant the Court jurisdiction over civil actions relating to patents, plant variety protection, copyrights, and trademarks. 28 U.S.C. §§ 1331, 1338. Federal Rule of Civil Procedure 8(a) requires that pleadings contain a short and plain statement of the claim showing that the pleader is entitled to relief. Fed. R. Civ. P. 8(a)(1). If pleadings fail to state a claim, in whole or in part, on which a court may grant relief, a defendant may seek to dismiss a complaint under Federal Rule of Civil Procedure 12(b)(6). Fed. R. Civ. P. 12(b)(6). "To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009) (quoting Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570 (2007)). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." Id. Plausibility requires "more than a sheer possibility that a defendant has acted unlawfully." Id. In considering a motion to dismiss, the Court must assume the factual allegations contained in the complaint to be true and draw all reasonable inferences in favor of the non-moving party. Twombly, 550 U.S. at

555–56. However, "[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice" to state a claim. Iqbal, 556 U.S. at 679.

In patent infringement cases, allegations of infringement are governed by the Iqbal/Twombly pleading standard. Golden v. Apple Inc., 819 F. App'x 930, 930–31 (Fed. Cir. 2020). There must be some factual allegations that, when taken as true, articulate why it is plausible that the accused product infringes the patent claim. Bot M8 LLC v. Sony Corp. ("Bot M8"), 4 F.4th 1342, 1353 (Fed. Cir. 2021).

DISCUSSION

Plaintiff pled both pre-suit and post-suit willful infringement claims for the Asserted Patents, alleging that Defendant had notice of its infringement "since at least the issue date" of the Asserted Patents, and willfully infringed and continues to infringe the Asserted Patents. Am. Compl. ¶¶ 60–78. Plaintiff seeks enhanced damages under 35 U.S.C. § 284 for willful infringement of the Asserted Patents. Id. at 28–29. Because this Court held previously that an amended complaint may allege post-suit willful infringement sufficiently by claiming that the initial complaint put the defendant on notice, Defendant moves to dismiss the Amended Complaint only to the extent that it alleges pre-suit willfulness. Def.'s Br. at 1, 8

n3; see Staton Techiya, LLC v. Harman Int'l Indus., Inc., 734 F. Supp. 3d. 354, 367 (D. Del. 2024).

Under 35 U.S.C. § 284, the Court may increase the amount of damages assessed by up to three times. 35 U.S.C. § 284. The U.S. Supreme Court has observed that enhanced damages:

> are not to be meted out in a typical infringement case, but are instead designed as a "punitive" or "vindictive" sanction for egregious infringement behavior. The sort of conduct warranting enhanced damages has been variously described in our cases as willful, wanton, malicious, bad-faith, deliberate, consciously wrongful, flagrant, or—indeed—characteristic of a pirate.

Halo Elecs., Inc. v. Pulse Elecs. Inc. ("Halo"), 579 U.S. 93, 103–04 (2016).

For willful infringement claims, "the patentee must allege facts in its pleading plausibly demonstrating that the accused infringer had committed subjective willful infringement as of the date of the filing of the willful infringement claim[.]" Välinge Innovation AB v. Halstead New England Corp., No. 16-cv-1082-LPS-CJB, 2018 WL 2411218, at *12 (D. Del. May 29, 2018), report and recommendation adopted, 2018 WL 11013901 (D. Del. Nov. 6, 2018). "The subjective willfulness of a patent infringer, intentional or knowing, may warrant enhanced damages, without regard to whether his infringement was objectively reckless." Halo, 579 U.S. at 105; see also WBIP, LLC v. Kohler Co., 829 F.3d 1317, 1341 (Fed. Cir. 2016) ("Knowledge of the patent alleged to be willfully infringed continues to be a prerequisite to enhanced damages.").

Subjective willfulness may be found when "the risk of infringement 'was either known or so obvious that it should have been known to the accused infringer.'" Halo, 579 U.S. at 101 (quoting In re Seagate Techs., LLC, 497 F.3d 1360, 1371 (Fed. Cir. 2007)).

At the pleading stage, this standard can be distilled into three elements, that the accused infringer: (1) was aware of the patent, (2) infringed the patent after becoming aware of its existence, and (3) knew or should have known that its conduct amounted to infringement. See Välinge Innovation AB, 2018 WL 2411218, at *13. The Court need not evaluate whether each allegation, taken alone, gives rise to a reasonable inference of pre-suit knowledge of the patent, but may consider the allegations as a whole. Elm 3DS Innovations, LLC v. Samsung Elecs. Co., No. 14-cv-1430, 2015 WL 5725768, at *3 (D. Del. Sept. 29, 2015), report and recommendation adopted, 2016 WL 1274812 (D. Del. Mar. 21, 2016); SoftView LLC v. Apple Inc., No. 10-389-LPS, 2012 WL 3061027, at *6 (D. Del. July 26, 2012).

Plaintiff alleges upon information and belief that Defendant had knowledge of the Asserted Patents "at least since the issue dates," because the Asserted Patents claim solutions in the early cancer detection industry that Defendant participates in, and Defendant would have become aware of the Asserted Patents while researching the patentability of its own patents and developing its blood

tests. Am. Compl. at ¶¶ 59–61. Plaintiff alleges upon further information and belief that Defendant acquired knowledge of the Asserted Patents through its participation in the opposition proceedings that it filed against the European Patent. Id. at ¶¶ 66–68. Plaintiff claims that if Defendant was unaware of the Asserted Patents during the European Patent opposition proceedings, then Defendant was willfully blind. Id. at ¶ 69.

Defendant argues that Plaintiff's allegations that Defendant gained pre-suit knowledge of the Asserted Patents through industry participation and research for its patents are too conclusory to support a claim of willful infringement. Def.'s Br. at 13–15. Defendant contends that its alleged participation in the European Patent opposition proceedings supports only knowledge of a related patent, which is insufficient to prove pre-suit willfulness. Id. at 8–10. Defendant avers that even if it gained knowledge of the Asserted Patents through the European Patent opposition proceedings, Plaintiff fails to plausibly allege that Defendant was on notice of possible infringement or took measures that amount to willful blindness. Id. at 10–13. Plaintiff responds that the factual allegations pled in the Amended Complaint, taken collectively, are sufficient to support Plaintiff's claim of pre-suit willful infringement. Pl.'s Resp. Br. at 1–2.

In general, mere knowledge of a related patent or the application underlying the patent in suit does not create a plausible inference that a defendant had

knowledge of the patent in suit. Cerebrum Sensor Tech., Inc. v. Revvo Tech., Inc., No. 24-245-JLH-SRF, 2025 WL 72110, at *2–3 (D. Del. Jan. 10, 2025), report and recommendation adopted, No. 24-245-JLH-SRF, 2025 WL 325547 (D. Del. Jan. 29, 2025); see also VLSI Tech. LLC v. Intel Corp., No. 18-0966-CFC, 2020 WL 3488584, at *5 (D. Del. June 26, 2020) ("allegations [. . .] about patents not asserted here do not plausibly establish that [Defendant] had knowledge of infringement of [the asserted patents]."); Novozymes North America, Inc. v. Danisco US Inc., No. 1:19-cv-01902-JDW, 2020 WL 12895027, at *3 (D. Del. Feb. 12, 2020) ("At the pleading stage, alleged knowledge of patent family members and related patents, along with other allegations, can be sufficient to overcome a motion to dismiss.").

Plaintiff's allegations claim that Defendant learned of the Asserted Patents in the following ways: (1) through researching the patentability of its own patents; (2) through monitoring the patent family after filing the European Patent opposition; (3) through participation in the early cancer detection industry that the Asserted Patents relate to; and (4) through the development and performance of Defendant's bloods tests, which practice the methods of the Asserted Patents and aim to produce their results. Am. Compl. at ¶¶ 59–61, 68. Plaintiff cites two cases to support its argument that an allegation regarding opposition proceedings for related patents can give rise to a reasonable inference of pre-suit knowledge when

taken together with such additional allegations. Pl.'s Resp. Br. at 9–11 (citing bioMérieux, S.A. v. Hologic, Inc., C.A. No. 18-21 (LPS), 2018 WL 4603267, at *5 (D. Del. Sept. 25, 2018); 3Shape A/S v. Align Tech., Inc., C.A. No. 18-886-LPS-CJB, 2019 WL 1416466 at *2, *4 (D. Del. Mar. 29, 2019)).

In bioMérieux, S.A., the district court held that the plaintiff alleged sufficiently that the defendant had knowledge of the patents in suit after considering the defendant's European opposition proceedings against the foreign counterparts to the patents in suit, together with evidence that the parties were competitors within the same small industry, and business relationships and practices that related to the accused products. 2018 WL 4693267, at *5. In 3Shape A/S v. Align Tech., Inc., the district court confirmed that patent opposition proceedings alone are insufficient to provide notice of possible infringement, but held that the plaintiff sufficiently pled willful infringement after considering the inter-partes review proceedings initiated by the defendant against the patent-in-suit, along with the parties' status as competitors in the same industry and the factual allegations that the defendant's accused products produced results similar to those of the claimed invention. 2019 WL 1416466 at *2, *4. Although the portions of bioMérieux, S.A. and 3Shape A/S cited by Plaintiff addressed claims of induced infringement, both courts reached their holdings with regard to the same prong in the induced infringement analysis that this Court considers in its willful

infringement analysis, which is whether Plaintiff has alleged facts demonstrating that Defendant had knowledge of the patent in suit in the relevant time frame. The courts in bioMérieux, S.A. and 3Shape A/S applied their findings for induced infringement to conclude that the plaintiffs in those cases also pled willful infringement adequately.

Defendant argues that even if Plaintiff's allegations are taken together as a whole, they are insufficient to create a reasonable inference of pre-suit knowledge and infringement. Def.'s Br. at 13–15.

When offered in isolation or without supporting facts, general allegations that a party has knowledge of another party's patents based on the simple fact that the parties are competitors or participants in the same industry have been considered too speculative to support a claim of willfulness. See VLSI Tech. LLC v. Intel Corp., No. 18-cv-00966-CFC, 2020 WL 3488584, at *5 (D. Del. June 26, 2020) (concluding that "allegations about monitoring competition generally" do not plausibly plead knowledge of infringement); Koninklijke Philips N.V. v. Lenovo (United States) Inc., No. 20-1242-CFC, 2024 WL 1050637, at *3 (D. Del. Mar. 11, 2024) (finding no pre-suit knowledge of infringement when the pleading alleged efforts to design around asserted patents); Novozymes North America, Inc., 2020 WL 12895027, at *3 (concluding that defendant had pre-suit knowledge but setting aside as "pure speculation" the allegation that defendant must have known

about the patent in suit because it performed experiments covered by the asserted patents seven years later). Although a party may plead "upon information and belief" when alleging actions that are non-public and known only to the defendant, a party must provide factual allegations to support their legal theory and cannot rely on "boilerplate and conclusory" allegations. McDermott v. Clonadalkin Gp., Inc., 649 F. App'x 263, 267–68 (3d Cir. 2016).

Plaintiff's remaining claims considered as a whole, including the European Patent opposition proceedings against a foreign patent with the same title and similar claims as the Asserted Patents, Plaintiff and Defendant's participation in the early cancer detection industry, and the detailed descriptions and exhibits provided by Plaintiff to support its allegations that Defendant's blood tests perform the methods of the Asserted Patents, are pled with sufficient detail to state a plausible claim for willful infringement. See Novozymes North America, Inc., 2020 WL 12895027, at *3. Although Plaintiff's allegations of pre-suit knowledge from the European Patent opposition proceedings were pled "on information and belief," these allegations were supported by sufficiently detailed factual allegations regarding the claims of the European Patent and Defendant's interest in the proceedings. Am. Compl. at ¶¶ 62–73, E.P. 2630263. Plaintiff's claims regarding Defendant's participation and activities in the early cancer detection industry would be insufficient to state a claim of willful infringement if offered alone and

unaccompanied by further factual allegations. See Novozymes North America, Inc., 2020 WL 12895027, at *3 ("as a general matter, the Court notes that the simple fact that [defendant] and [plaintiff] are competitors is insufficient to state a plausible claim based on pre-suit knowledge[.]"). However, Plaintiff's allegations are accompanied by exhibits and information regarding Defendant's patents, specialized knowledge in the field, and how the Guardant blood tests allegedly infringe the Asserted Patents. Am Compl. at ¶¶ 43–61, Ex. 6–9, 12–14; see also 3Shape A/S, 2019 WL 1416466 at *2 (concluding that plaintiff adequately alleged pre-suit knowledge and notice of infringement when plaintiff alleged participation in the same industry and explained how accused products produced the results of the patent in suit).

While each of these allegations would be insufficient if taken alone, together they create a plausible basis to infer that Defendant had knowledge of the Asserted Patents and notice of its potential infringement, and provide enough facts "'to raise a reasonable expectation that discovery will reveal evidence' to support plaintiff's allegations," which is all that the plausibility standard requires of Plaintiff at this stage. Nalco Co. v. Chem-Mod. LLC, 883 F.3d 1337, 1350 (Fed. Cir. 2018) (quoting Twombly, 550 U.S. at 556); see also SoftView LLC, 2012 WL 3061027, at *5–6.

Accordingly, the Court concludes that Plaintiff has sufficiently pled its claims of willful infringement for the pre-suit period and denies Defendant's motion to dismiss the pre-suit willful infringement claims.

CONCLUSION

Upon consideration of Defendant's Partial Motion to Dismiss (D.I. 24), and all other papers and proceedings in this action, it is hereby

ORDERED that Defendant's Partial Motion to Dismiss (D.I. 24) is denied.

IT IS SO ORDERED this 10th day of October, 2025.

/s/ Jennifer Choe-Groves
Jennifer Choe-Groves
U.S. District Court Judge*

*Judge Jennifer Choe-Groves, of the United States Court of International Trade, sitting by designation.