

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

COLD SPRING HARBOR LABORATORY,	)	
	)	
Plaintiff	)	
	)	
v.	)	C.A. No. 25-00263 (JCG)
	)	
GUARDANT HEALTH, INC.,	)	
	)	
Defendant.	)	
	)	

**DEFENDANT’S OPENING BRIEF IN SUPPORT OF PARTIAL MOTION TO DISMISS
FOR FAILURE TO STATE A CLAIM**

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TABLE OF CONTENTS

	Page
I. NATURE AND STAGE OF PROCEEDINGS	1
II. SUMMARY OF ARGUMENT	1
III. STATEMENT OF FACTS	3
A. CSHL’s Patents And Infringement Allegations.....	3
B. Overview Of The European Patent Opposition	6
IV. LEGAL STANDARD.....	7
V. ARGUMENT	8
A. The European Patent Opposition Proceedings Do Not Plausibly Support Willfulness	8
1. Knowledge Of A Mere Related Patent Is Insufficient To Support Willfulness	9
2. The European Patent Opposition Proceedings Do Not Plausibly Support Willfulness	10
B. Conclusory Allegations of Knowledge Do Not Plausibly Support Willful Infringement.....	13
VI. CONCLUSION.....	16

TABLE OF AUTHORITIES

	Page
CASES	
<i>Ashcroft v. Iqbal</i> , 556 U.S. 662 (2009).....	7
<i>Bayer Healthcare LLC v. Baxalta Inc.</i> , 989 F.3d 964 (Fed. Cir. 2021).....	11
<i>Bell Atl. Corp. v. Twombly</i> , 550 U.S. 544 (2007).....	7
<i>Bot M8 LLC v. Sony Corp.</i> , 4 F.4th 1342 (Fed. Cir. 2021)	7
<i>Cleveland Med. Devices Inc. v. ResMed Inc.</i> , 696 F. Supp. 3d 4 (D. Del. 2023).....	10, 12
<i>Cerebrum Sensor Technologies, Inc. v. Revvo Technologies, Inc.</i> , No. 24-245-JLH-SRF, 2025 WL 72110 (D. Del. Jan. 10, 2025)	9, 13
<i>Cerebrum Sensor Technologies, Inc. v. Revvo Technologies, Inc.</i> , No. 24-245-JLH-SRF, 2025 WL 326647 (D. Del. Jan. 29, 2025)	9, 13
<i>Halo Elecs., Inc. v. Pulse Elecs., Inc.</i> , 579 U.S. 93 (2016).....	8
<i>Hills Point Indus. LLC v. Just Fur Love LLC</i> , No. 22-1256-GBW, 2023 WL 8804046 (D. Del. Dec. 20, 2023).....	11
<i>Koninklijke Philips N.V. v. Lenovo (United States) Inc.</i> , No. CV 20-1242-CFC, 2024 WL 1050637 (D. Del. Mar. 11, 2024).....	10, 13, 14
<i>McDermott v. Clondalkin Gp., Inc.</i> , 649 F. App'x 263 (3d Cir. 2016).....	15
<i>Ravgen, Inc. v. Ariosa Diagnostics, Inc.</i> , No. 20-1646-RGA-JLH, 2021 WL 3526178 (D. Del. Aug. 11, 2021).....	15
<i>Staton Techiya, LLC v. Harman Int'l Indus., Inc.</i> , 734 F. Supp. 3d 354 (D. Del. 2024).....	8, 15

Technoprobe S.p.A. v. Formfactor, Inc.,
No. 1:23-cv-00842-JCG, 2024 WL 2271885 (D. Del. May 20, 2024).....14

Tonal Sys., Inc. v. ICON Health & Fitness, Inc.,
No. 20-1197-LPS, 2021 WL 1785072 (D. Del. May 5, 2021) 15

Tonal Sys., Inc. v. ICON Health & Fitness, Inc.,
No. 20-1197-LPS, 2021 WL 5860783 (D. Del. Aug. 12, 2021).....15

Välinge Innovation Ab v. Halstead New England Corp.,
No. 16-1082-LPS-CJB, 2018 WL 2411218 (D. Del. May 29, 2018) 8, 11

Välinge Innovation Ab v. Halstead New England Corp.,
No. 16-1082-LPS-CJB, 2018 WL 11013901 (D. Del. Nov 6, 2018) 8, 11

Vasudevan Software, Inc. v. TIBCO Software Inc.,
No. C 11-06638 RS, 2012 WL 1831543 (N.D. Cal. May 18, 2012) 10

VLSI Tech. LLC v. Intel Corp.,
No. 18-0966-CFC, 2020 WL 3488584 (D. Del. June 26, 2020).....9, 13

Wrinkl, Inc. v. Facebook, Inc.,
C.A. 20-cv-1345-RGA, 2021 WL 4477022 (D. Del. Sept. 30, 2021) 14

OTHER AUTHORITIES

Fed. R. Civ. P. 12(b)(6).....7

I. NATURE AND STAGE OF PROCEEDINGS

On March 6, 2025, Plaintiff Cold Spring Harbor Laboratory (“CSHL”) filed its initial complaint (“Original Complaint”) alleging that blood tests offered by Defendant Guardant Health, Inc. (“Guardant”) infringe U.S. Patent No. 10,947,589 (“the ’589 patent”). See D.I. 1. On May 1, 2025, CSHL amended its complaint (“Amended Complaint”) to further allege that Guardant also infringes U.S. Patent No. 12,234,510 (“the ’510 patent”) (collectively, with the ’589 patent, the “Asserted Patents”). D.I. 15. Guardant now moves to dismiss the Amended Complaint to the extent it alleges pre-suit willfulness.

II. SUMMARY OF ARGUMENT

CSHL’s willful infringement allegations are bereft of the typical grist of a willful infringement case. CSHL, for instance, never alleges that it gave Guardant advance notice of its patents, let alone an attempt to explain to Guardant why it believed there might be infringement. Nor does CSHL allege that Guardant copied its patents. The Amended Complaint likewise lacks any contention that there were *any* advance discussions between CSHL and Guardant. CSHL does not even allege that Guardant cited CSHL’s patents or applications in its own patent filings, which is the typical last-resort allegation by plaintiffs stretching to try to show that an accused infringer was aware of its patents.

Instead, the centerpiece of CSHL’s willful infringement theory is that Guardant was aware of the Asserted Patents by virtue of having participated nearly five years ago in European opposition proceeding wherein Guardant challenged a foreign patent that is merely *related* to the Asserted Patents. See D.I. 15 ¶¶ 59-78. Apparently, CSHL’s theory is that since Guardant knew about one of CSHL’s foreign patents, it must have also known all about the U.S. patents Guardant is now accused of infringing some five years later. Yet, the law is clear that mere knowledge of

related patents is insufficient to plead willfulness. On this basis alone, CSHL's willful infringement pleadings fail.

Moreover, even if Guardant could be plausibly charged with knowledge of the Asserted Patents, the Amended Complaint lacks any allegations to raise a plausible inference that Guardant should have further been aware that it was infringing, as is required. If anything, the allegations in the Amended Complaint would lead one to infer that Guardant cannot possibly be a willful infringer.

As shown in the documents attached to the Amended Complaint, CSHL's European patent issued in 2018 and originally included claims like those it now asserts here. Yet, what is mysteriously absent from the Amended Complaint are any allegations that CSHL ever sought to accuse Guardant of infringing its European patent in the nearly five years since the European opposition proceedings. The Amended Complaint is likewise conspicuously silent about the outcome of the European opposition proceedings. CSHL's omission of allegations on these points is more than just a fatal failure to plead facts suggesting that Guardant should have been aware of possible infringement, but rather an affirmative indicator that it is **implausible** that Guardant is a willful infringer.

Indeed, the reason CSHL says nothing about how the European opposition proceedings concluded and otherwise omits all relevant detail is that CSHL effectively **lost** the European opposition. While CSHL originally had claims little different from those it now asserts here, CSHL was forced to ditch those claims in response to Guardant's arguments in the opposition. In the end, CSHL was left with amended claims that are irrelevant to Guardant's products and that CSHL has never bothered to assert against Guardant.

The European Opposition proceedings that CSHL relies upon so heavily thus do not raise a plausible inference of willful infringement -- just the opposite. CSHL's willful infringement allegations are thus legally deficient and should be dismissed.

III. STATEMENT OF FACTS

A. CSHL's Patents And Infringement Allegations

The Asserted Patents are both continuations of the same 2011 application and are both entitled "Varietal Counting Of Nucleic Acids For Obtaining Genomic Copy Number Information." See D.I. 15 ¶¶ 30, 36, 38. As documented below, the lead inventor has long since confirmed that there is nothing special about these patents.

The Asserted Patents purport to address problems that arise when using DNA sequencing to count how many copies of particular types of DNA molecules are present in a diverse population of DNA molecules. For instance, one may have a population of DNA molecules that includes, among other molecules, a first type of molecule with the sequence AGGGTCATC and a second type of molecule with the sequence TTAGCTTGAA. Perhaps these molecules are associated with a gene of interest, and one may wish to determine precisely how many copies of each of them are present in the sample.

Such DNA molecules of interest, however, are often present in only small quantities, so researchers frequently need to first make copies of them to facilitate detection by sequencing. Without first doing this, one may miss them during the analysis. The copying is generally done by well-known methods, such as PCR.¹ The problem, however, is that PCR and other such methods may favor one molecule over another and create distortions in the relative numbers of

¹ PCR is the acronym for "polymerase chain reaction," and is a standard technique that has been used for decades to make copies of DNA molecules.

molecules that are present. As the Asserted Patents state, “obtaining accurate genomic copy number information by high-throughput sequencing of genomic DNA...is hampered by the copy number distortions introduced by non-uniform amplification of genomic DNA.” D.I. 15, Ex. 1 at 2:29-33, Ex. 17 at 2:29-33.

The Asserted Patents purport to overcome this problem by “tagging.” Briefly, each of the DNA molecules in the sample are augmented to include an additional DNA sequence, known as a “tag.” A large number of tags are used, and they are applied to the molecules randomly such that it is unlikely that two molecules will end up with the same tag sequence. As the Asserted Patents state, “[i]nput nucleic acid molecules...present in the sample, can be randomly tagged using a large choice of distinct tags. Every tagged molecule becomes essentially unique, the combination of the information in the tag and the information in the nucleic acid, which can later be read by sequencing.” D.I. 15, Ex. 1 at 19:36-42, Ex. 17 at 19:36-42.

After the sequencing is complete, to determine how many molecules of a given sequence were present in the original sample, one counts not the overall number of molecules, but the number of different tags that were detected. Even if the PCR amplification created distortion, such distortion is eliminated because one can be fairly certain that every instance of a particular tag arose from *the same* original parent molecule. As the Asserted Patents state, the “unique tagged nucleic acid molecules are amplified to facilitate detection, but no new species of tagged nucleic acid molecules are created. Thus, distorted counts are not created provided that the number of different tagged nucleic acid molecules is counted.” D.I. 15, Ex. 1 at 19:50-55, Ex. 17 at 19:50-55.

The claims of both Asserted Patents pertain to this general process of using tags and amplification to facilitate counting. D.I. 15 ¶¶ 32, 39. For example, claim 1 of the ’589 patent

recites (1) “tagging the segments with nucleic acid tags,” (2) “generating amplified tagged nucleic acid molecules,” and (3) “counting the number of unique tagged nucleic acid molecules.” D.I. 15, Ex. 1 at claim 1. Claim 1 of the ’510 patent includes virtually identical language. *See* D.I. 15, Ex. 17 at claim 1.

CSHL contends that this tagging process in its patents reflect “inventive concepts” that “represented a significant improvement in the early detection of cancer and addressed a need in the field.” D.I. 15 ¶¶ 35, 41. But named inventor Michael Wigler, who is the individual CSHL points to as having laid the groundwork for the Asserted Patents, *see* D.I. 15 ¶¶ 23-28, has said otherwise. In a 2014 scientific publication, he confirmed that the tagging process to facilitate counting is neither novel nor inventive, stating that the idea of “[m]odifying molecules to facilitate counting is not a new idea.” Ex. A at E4632.² To support his assertion that the tagging concept was “not a new idea,” Dr. Wigler cited to 10 different references as disclosing this concept, some of which predate the filing of the Asserted Patents by as much as six years. *See id.* at E4632, E4637 (citation 2 having a publication date of 2004).

In its Original Complaint, CSHL alleged that Guardant’s infringement of the ’589 patent was willful. D.I. 1 ¶ 67. To support these allegations, CSHL relied not on any direct correspondence or direct knowledge of the Asserted Patents, but rather on Guardant’s alleged participation in proceedings related to a patent that CSHL had acquired in Europe. *Id.* ¶¶ 60-62. As alleged in the Amended Complaint, on January 25, 2019, an opposition against CSHL’s European Patent No. EP2630263 (“the European Patent”) was filed at the European Patent Office. D.I. 15 ¶ 62. CSHL alleged that this European Patent has the same title as the Asserted Patents and contains similar disclosures to the Asserted Patents. *Id.* ¶¶ 63-64. CSHL further alleged, albeit

² “Ex.” refers to the exhibits attached to the Declaration of Derek C. Walter filed concurrently herewith.

solely “[o]n information and belief,” that (1) Guardant initiated the opposition against the European Patent, (2) evaluated not just the European Patent but also the Asserted Patents, and (3) continued to broadly monitor these patents following the opposition. *Id.* ¶¶ 66-68. To the extent CSHL alleges pre-suit willfulness, it relies exclusively on these European Opposition proceedings.

The relevant details of the European Opposition proceedings are summarized immediately below.

B. Overview Of The European Patent Opposition

Like the Asserted Patents, the patents at issue in the European Opposition proceedings pertain to the concept of tagging to facilitate counting of molecules. As originally published on April 25, 2018, step (b) of claim 1 of the European Patent recited “tagging the segments with nucleic acid tags to generate unique tagged nucleic acid molecules, such that each of the unique tagged molecules comprises one segment of the genomic material from step (a) and a tag.” Ex. B at sheets 1-2. The original claim language placed no requirements on the type or manner of tagging so long as the result was “unique tagged nucleic acid molecules.” *Id.* Importantly, claims of the Asserted Patents include similar tagging language. See D.I. 15, Ex. 1 at claim 1 (“tagging the segments with nucleic acid tags, thereby generating a plurality of unique tagged nucleic acid molecules”); D.I. 15, Ex. 17 at claim 1 (“randomly tagging the segments of genomic nucleic acids with different nucleic acid tags, thereby generating unique tagged nucleic acid molecules from the segments of genomic nucleic acids”).

According to CSHL’s Amended Complaint, oral proceedings in the European Opposition were held on March 17, 2021. D.I. 15 ¶ 70. There, Guardant argued that the specification failed to support the claims because the claim language was improperly overbroad. See Ex. B at sheets 2-3. The European Patent Office accepted this argument and, in response, CSHL amended the claims to recite “tagging the segments with **a sufficiently large number of distinct** nucleic acid

tags to generate unique tagged nucleic acid molecules, such that each of the unique tagged molecules comprises one segment of the genomic material from step (a) and a tag.” Ex. B at sheets 3-4. (emphasis added). Thus, by the amendment, CSHL introduced requirements as to the large number of tags that must be used. The updated language of Claim 1 of the European Patent became final on October 8, 2021. Ex. C.

Notably, since the close of the opposition proceedings nearly four years ago, Guardant has not been sued for patent infringement of the European Patent in any tribunal. Nor has CSHL even threatened Guardant with patent infringement litigation regarding the European Patent. Further, it was at roughly the time of the oral opposition proceedings in Europe that the ’589 patent issued in the United States on March 16, 2021. D.I. 15 ¶ 30. CSHL, however, never made any allegations of infringement by Guardant of the ’589 patent or any other patent. Just the opposite, CSHL stood silent and did not bring a patent infringement suit against Guardant until roughly four years later on March 6, 2025, when CSHL filed the Original Complaint. D.I. 1.

IV. LEGAL STANDARD

To survive a motion to dismiss pursuant to Fed. R. Civ. P. 12(b)(6), the plaintiff must allege “enough facts to state a claim to relief that is plausible on its face.” *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). The plaintiff’s factual allegations are presumed true provided that the plaintiff “pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.” *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). Yet, plausibility requires “more than a sheer possibility that a defendant has acted unlawfully.” *Id.* A plausible claim cannot “merely allege entitlement to relief; it must support the grounds for that entitlement with sufficient factual content.” *Bot M8 LLC v. Sony Corp.*, 4 F.4th 1342, 1352 (Fed. Cir. 2021).

As to willful infringement specifically, the patent owner “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. 16-1082-LPS-CJB, 2018 WL 2411218, at *12 (D. Del. May 29, 2018), *report and recommendation adopted*, No. 16-1082-LPS-CJB, 2018 WL 11013901 (D. Del. Nov. 6, 2018). The Federal Circuit has described the sort of conduct warranting enhanced damages “as willful, wanton, malicious, bad-faith, deliberate, consciously wrongful, flagrant, or—indeed—characteristic of a pirate.” *See also Halo Elecs., Inc. v. Pulse Elecs., Inc.*, 579 U.S. 93, 103-104 (2016). Accordingly, proving willful infringement requires demonstrating at least three elements: (1) the defendant was aware of the patent, (2) the defendant infringed the patent after becoming aware of its existence, and (3) the defendant knew or should have known that its conduct amounted to infringement. *Välinge Innovation AB*, 2018 WL 2411218, at *13.

As documented herein, CSHL has fallen far short of pleading sufficient facts to plausibly allege willful infringement.³

V. ARGUMENT

A. The European Patent Opposition Proceedings Do Not Plausibly Support Willfulness

To support its allegations of willful patent infringement, CSHL relies on Guardant’s participation in opposition proceedings against CSHL’s European Patent. D.I. 15, ¶¶ 62-73. The European opposition proceedings, however, cannot plausibly support a willful infringement

³ Guardant understands that this Court has previously held that an amended complaint may sufficiently allege post-suit willful infringement by alleging that the initial complaint put the defendant on notice. *See Staton Techiya, LLC v. Harman Int’l Indus., Inc.*, 734 F. Supp. 3d 354, 367 (D. Del. 2024). The instant motion is thus directed to dismissal of CSHL’s allegations of pre-suit willfulness.

theory. CSHL's European Patent is merely a related patent and is not one of the Asserted Patents. The law is clear that mere knowledge of related patents is insufficient to plead willful infringement. What's more, Guardant was **successful** in the European opposition. CSHL was forced to amend its European claims in the opposition, and in the four years since then has never sued Guardant under the European Patent. The claims CSHL now asserts in this Court have "tagging" language closely tracking the very language that CSHL was forced to throw out the window in the European opposition proceedings. If anything, the European Opposition proceedings undermine any contention that Guardant is a willful infringer.

1. Knowledge Of A Mere Related Patent Is Insufficient To Support Willfulness

Even assuming Guardant became aware of the European Patent in connection with the opposition proceedings, mere knowledge of a related patent is insufficient to plausibly allege knowledge of an asserted patent for willfulness. In *Cerebrum Sensor Technologies, Inc. v. Revvo Technologies, Inc.*, for instance, the Court considered willfulness allegations based on an accused infringer's awareness of a patent application relating to the asserted patent after a patent examiner identified the application in connection with the accused infringer's own patenting activities. *See*, 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 326647 (D. Del. Jan. 29, 2025). The court, however, found the connection between the plaintiff's patent application and the asserted patent to be too tenuous to support "a plausible inference of Defendant's knowledge of the [asserted patent] or its application." *Id.*

This and other courts have repeatedly held to similar effect. *See, e.g., 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 [Plaintiff] had knowledge of

infringement of [the asserted patents].”); *Koninklijke Philips N.V. v. Lenovo (United States) Inc.*, No. CV 20-1242-CFC, 2024 WL 1050637, at *2 (D. Del. Mar. 11, 2024) (rejecting willfulness allegation based on notice letter that did not mention the asserted patents but rather the “#809 patent and another patent not asserted in this case”); *Vasudevan Software, Inc. v. TIBCO Software Inc.*, No. C 11-06638 RS, 2012 WL 1831543, at *3 (N.D. Cal. May 18, 2012) (“The requisite knowledge of the patent allegedly infringed simply cannot be inferred from mere knowledge of *other* patents, even if somewhat similar.”) (emphasis in original), *Cleveland Med. Devices Inc. v. ResMed Inc.*, 696 F. Supp. 3d 4, 10–11 (D. Del. 2023) (finding insufficient pleading of pre-suit knowledge where the asserted patents issued two years after the parties’ last alleged communication).

Thus, CSHL’s allegations of pre-suit willfulness based merely on Guardant’s alleged knowledge of a related European patent fail. Indeed, CSHL’s allegations that Guardant was aware of the Asserted Patents are particularly attenuated because they are not even based on alleged awareness of domestic patents, but rather a *foreign* patent that is subject to different laws and procedures.

2. The European Patent Opposition Proceedings Do Not Plausibly Support Willfulness

Even assuming that one can impute Guardant with knowledge of the Asserted Patents based on its mere participation in the European opposition proceedings, the circumstances of these proceedings are the exact opposite of those that would plausibly support allegations of willfulness.

Under the European Patent Convention, an opposition to a European Patent may be filed by any member of the public. Ex. D. The court in *Hills Point Industries LLC v. Just Fur Love LLC* explained why such circumstances, which apply to U.S. reexaminations, are insufficient to alleged willfulness:

35 U.S.C. § 302 states that ‘any person at any time may file a request for reexamination ...’ Given that “any person” can file a request for reexamination, the mere fact that a person sought reexamination of a patent does not mean that person necessarily believed their conduct infringed the patent for which they sought reexamination. Therefore, the mere fact that [the counter-defendant] filed for reexamination of the [asserted] patent is not sufficient by itself to state a claim for willfulness.

Hills Point Indus. LLC v. Just Fur Love LLC, No. 22-1256-GBW, 2023 WL 8804046, at *3 (D. Del. Dec. 20, 2023). Simply put, even if CSHL’s European Patent were the exact patent that is now at issue here, the mere fact that Guardant previously challenged it does not plausibly suggest willful **infringement**.

CSHL’s Amended Complaint does not allege how the European opposition proceedings could have put Guardant on notice of **infringement**. There are no allegations regarding what transpired in the opposition proceedings, nor allegations regarding the outcome. As the Federal Circuit has explained, “[k]nowledge of the asserted patent and evidence of infringement is necessary, but not sufficient, for a finding of willfulness. Rather, willfulness requires deliberate or intentional infringement.” *Bayer Healthcare LLC v. Baxalta Inc.*, 989 F.3d 964, 988 (Fed. Cir. 2021).

Courts in this district thus regularly reject willfulness pleadings that focus solely on knowledge of the patent and that otherwise ignore how pre-suit events should have made an accused infringer aware of possible infringement. *See, e.g., Hills Point*, 2023 WL 880406 at *3 (“Commerce’s filing of its request for ex parte reexamination shows that Commerce had knowledge of the patent. However, Commerce’s filing does not show that Commerce knew or should have known that its conduct infringed the ’285 patent....”); *Välinge Innovation AB*, 2018 WL 2411218, at *13, report and recommendation adopted, 2018 WL 11013901 (D. Del. Nov. 6, 2018) (There “must be some other factual allegations...that plausibly demonstrate that the accused

infringer not only knew of the patent-in-suit, but also knew or should have known that what it was doing (and what it continued to do) amounted to infringement of that patent.”); *Cleveland Med. Devices Inc.*, 696 F. Supp. at 14 (reject the allegation that “CleveMed is informed and believes that, despite ResMed's notice and knowledge of the Asserted Patents and CleveMed's patented technology, ResMed made the deliberate decision to sell products and services that it knew infringes CleveMed's Asserted Patents” because it was “insufficient to plead knowledge of infringement”).

Here, the facts of the European opposition proceedings are such that it is particularly implausible to contend that they form the basis of a willful infringement theory. As documented above, the European Patent Office agreed with Guardant’s arguments that the European claims as originally drafted were invalid. Ex. B at sheet 2-3. These claims included “tagging” language little different from that of the Asserted Claims. There was no restriction on the type or manner of “tagging,” only that it ultimately yields “unique tagged nucleic acid molecules.” CSHL was forced to amend the claim language of its European Patent to eliminate such language.. *Id.* The language of the European Patent was finalized on October 8, 2021. Ex. C. In the nearly five years since, CSHL never alleged that Guardant infringed its European patent, nor did it file a lawsuit.

The only plausible inference from CSHL’s forced amendment of its European patent in the opposition and its subsequent four years of silence is that CSHL did not sue Guardant because it did not have a viable infringement case. Such facts hardly support a contention that Guardant is a willful infringer here, particularly given that CSHL is asserting claims that are little different from its cancelled European claims.

CSHL further alleges with respect to the European Opposition proceedings that on “information and belief, Guardant evaluated [the European Patent], and when doing so became

aware of the related patents in the same family,” and that on “information and belief, Guardant continued to monitor the patent family that included [the European Patent].” D.I. 15, ¶¶ 67-68. Yet, as documented above, the law is clear that “allegations about unasserted patents do not plausibly imply that [Defendant] had knowledge of infringement of the asserted patents.” *Koninklijke Philips N.V.*, 2024 WL 1050637, at *2; *see also VLSI Tech. LLC*, 2020 WL 3488584, at *5.

Finally, CSHL alleges that at a minimum, “Guardant was willfully blind to the existence” of the Asserted Patents. But a “defendant is willfully blind to patent infringement *only if* it ‘takes deliberate actions to avoid confirming a high probability of wrongdoing and...can almost be said to have actually known the critical facts.’” *Koninklijke Philips N.V.*, 2024 WL 1050637, at *2. CSHL’s Amended Complaint contains no allegations that point to deliberate acts by Guardant to avoid confirming even a possibility of infringement, let alone “a high probability of wrongdoing.” CSHL’s willful blindness allegations are not plausible. *See Cerebrum Sensor Techs.*, 2025 WL 72110, at *4, *report and recommendation adopted*, 2025 WL 326647 (recommending dismissal of willful blindness theory of willful infringement claims where “[n]o pleaded allegations point to deliberate acts Defendant took”).

B. Conclusory Allegations of Knowledge Do Not Plausibly Support Willful Infringement

CSHL’s remaining allegations are even more conclusory and attenuated and also do not plausibly support a willful infringement allegation.

CSHL alleges that Guardant participates in the same cancer detection industry as the Asserted Patents. D.I. 15 ¶ 59. In the same vein, CSHL alleges, “on information and belief,” that Guardant has been aware of the Asserted Patents since “at least the issue dates” of the Asserted Patents and, “on information and belief,” that “in researching that patentability of its own patents,

Guardant did become aware of the '589 patent and its related patents, including the published applications that led to the '589 patent, the '510 patent, and the earlier applications and patents... as early as May 2015.” *Id.* ¶¶ 60-61.

Courts in this district, however, have repeatedly rejected the notion that the public nature of patent proceedings, being in the same market as a competitor, or monitoring competition are sufficient to support a claim of willful infringement. Permitting such allegations to substantiate allegations of willfulness would prove too much and effectively gut any meaningful requirement to plausibly plead willfulness. *See, e.g., Wrinkl, Inc. v. Facebook, Inc.*, C.A. 20-cv-1345-RGA, 2021 WL 4477022, at *6 (D. Del. Sept. 30, 2021) (“The Complaint alleges pre-suit knowledge of the '192 Patent based on the fact that ‘its ongoing prosecution and eventual issuance were matters of public record.’ If such a pleading were sufficient it would effectively support a finding of pre-suit knowledge for every patent.”) (citations omitted); *Koninklijke Philips N.V.*, 2024 WL 1050637, at *2 (“But ‘allegations about monitoring competition generally’ do not plausibly plead knowledge of infringement.”); *Technoprobe S.p.A. v. Formfactor, Inc.*, No. 1:23-cv-00842-JCG, 2024 WL 2271885, at *4 (D. Del. May 20, 2024) (“Given the rapidly changing nature of

technology markets, the Court does not accept the position that participation in a specialized market is alone sufficient to establish knowledge of a particular patent.”⁴

The Third Circuit “has explained that pleading upon information and belief is permissible ‘[w]here it can be shown that the requisite factual information is peculiarly within the defendant’s knowledge or control’—so long as there are no ‘**boilerplate and conclusory allegations**’ and ‘**[p]laintiffs...accompany their legal theory with factual allegations that make their theoretically viable claim plausible.**’” *McDermott v. Clondalkin Gp., Inc.*, 649 F. App’x 263, 267-68 (3d Cir. 2016) (citations omitted). But the willful infringement allegations of the Amended Complaint described above are nothing more than the insufficient “boilerplate and conclusory.” *See, e.g.*, D.I. 15 ¶ 78 (“Despite its knowledge of the Patents-in-Suit and of its infringement of the Patents-in-Suit, Guardant has continued to willfully infringe the Patents-in-Suit”). Because CSHL fails to support its willful infringement allegations with plausible factual allegations, CSHL willful infringement claims must be dismissed.

⁴ Such generic allegations of the type relied upon by CSHL stand in contrast to the specific factual pleadings of knowledge of the asserted patents and knowledge of infringement that are sufficient. *See Tonal Sys., Inc. v. ICON Health & Fitness, Inc.*, No. 20-1197-LPS, 2021 WL 1785072, at *6 (D. Del. May 5, 2021), *report and recommendation adopted*, No. 20-1197-LPS, 2021 WL 5860783 (D. Del. Aug. 12, 2021) (finding willful infringement allegations plausible where the patent owner sent a notice letter to the alleged infringer, identified in detail why the accused product infringed the patent, and the alleged infringer continued to infringe.); *Staton Techiya*, 734 F. Supp. at 367 (finding willful infringement allegations plausible where the patent owner shared “studies, marketing materials, prototypes” and more with the defendant and where the defendant did a “detailed review” of the plaintiff’s patent portfolio); *Ravgen, Inc. v. Ariosa Diagnostics, Inc.*, No. 20-1646-RGA-JLH, 2021 WL 3526178, at *3 (D. Del. Aug. 11, 2021) (finding willful infringement where the defendants acknowledged pre-suit knowledge of the asserted patents and discussed their technology with the plaintiffs).

VI. CONCLUSION

For the foregoing reasons, Guardant respectfully requests the Court grant its motion and dismiss CSHL's allegations of pre-suit willfulness.

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Respectfully submitted,

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