

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

GUARDANT HEALTH, INC.,

Plaintiff and Counterclaim-Defendant,

v.

TEMPUS AI, INC.,

Defendant and Counterclaim-Plaintiff.

Civil Action No. 25-82-GBW

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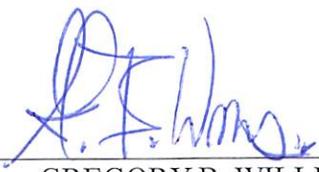
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**MEMORANDUM OPINION**

February 20, 2026  
Wilmington, Delaware

  
GREGORY B. WILLIAMS  
UNITED STATES DISTRICT JUDGE

Pending before the Court is Defendant and Counterclaim-Plaintiff Tempus AI, Inc.’s (“Tempus”) Motion for Preliminary Injunction against Plaintiff and Counterclaim-Defendant Guardant Health Inc. (“Guardant”) (D.I. 61), which is fully briefed (D.I. 62; D.I. 82; D.I. 98; D.I. 110). For the reasons stated below, the Court denies Tempus’s Motion for Preliminary Injunction (the “Motion”) (D.I. 61).

## **I. BACKGROUND**

Guardant and Tempus sell liquid and tissue biopsy tests that provide information about the molecular profile of a patient’s cancer. D.I. 64 ¶ 3. Doctors use these biopsy tests to create treatment plans. *Id.*<sup>1</sup> Liquid biopsy tests use a patient’s blood to analyze circulating tumor DNA (“ctDNA”) shed from a tumor that flows through the bloodstream. *Id.* ¶ 5. Tissue biopsy tests analyze tissue taken from a cancerous tumor. *Id.* Depending on various factors, physicians may choose to order one test, or both tests, to determine a patient’s appropriate course of treatment. *Id.* ¶ 6. For example, if a test identifies that certain mutations are present, the patient may qualify for certain treatments and may forgo other treatments, such as chemotherapy. *Id.* ¶ 4. Guardant offers Guardant360 Tissue, a tissue-based test, as well as Guardant360 Liquid and Guardant360 CDx, which are both liquid-based tests. *Id.* ¶ 7. Tempus offers tissue-based tests called xR and xT, along with liquid-based tests called xF and xF+. *Id.*

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<sup>1</sup> Jonathan Freaney (“Mr. Freaney”) is a Vice President of Research & Development Strategy & Operations at Tempus, who submitted his declaration in support of Tempus’s Motion for Preliminary Injunction. D.I. 64 ¶¶ 1-2.

In December 2024, Guardant distributed an advertisement<sup>2</sup> that compared Guardant360 Liquid to Tempus xF+. D.I. 62 at 6. The advertisement states that Guardant360 is “the most sensitive liquid biopsy available,” and compares various specifications between Guardant360 and Tempus xF+. D.I. 63-1, Exs. C–E. Tempus claims that, during the course of discovery, it became aware of additional advertisements making similar or identical claims. D.I. 62 at 6; *see also* D.I. 63-1, Exs. H–J (collectively, “Guardant’s Liquid Ads”).

Guardant also disseminated advertisements that compared Guardant’s tissue test, Guardant360 Tissue, to Tempus’s tissue tests, xT and xR (“Guardant’s Tissue Ads”). D.I. 62 at 8; *see also* D.I. 63-1, Exs. M–O. These advertisements claim that Guardant’s tests require physicians to submit “40% fewer slides” than Tempus’s tests (or the industry standard), and “[w]ith the lowest sample requirement, more patients get results.” D.I. 63-1, Ex. M at 512. One of Guardant’s Tissue Ads reports that Guardant can get answers when other competitors cannot, and that more samples can be evaluated. D.I. 62 at 9; *see also* D.I. 63-1, Ex. N.

In addition to Guardant’s Tissue Ads and Liquid Ads, Guardant sales representatives sent advertisements to customers in the form of newsletters and emails. D.I. 62 at 9. Specifically, one newsletter states that “another liquid biopsy missed . . . mutations in their advanced breast patients and . . . mutations in their metastatic lung patients.” D.I. 63-1, Ex. L. Additionally, the advertisement suggests that patients will have more “sunny days with their loved ones” when using Guardant360 Liquid. *Id.*

Guardant brought this lawsuit against Tempus seeking declaratory relief that (1) its advertising for Guardant360 is not false or misleading and (2) its advertising comparing

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<sup>2</sup> In its Motion, Tempus separates a single ad into separate categories to address the alleged false claims individually. D.I. 63-1, Exs. C–E.

Guardant360 with Tempus's xF+ is not false or misleading under § 43(a) of the Lanham Act, 15 U.S.C.A. § 1125(a). D.I. 1. Tempus filed counterclaims asserting that Guardant violated the Lanham Act, California Unfair Competition Law, and the Uniform Deceptive Trade Practices Act. D.I. 77. Tempus also seeks an injunction enjoining Guardant from publishing and disseminating various advertisements. *Id.* On November 10, 2025, Tempus filed this Motion seeking to “stop Guardant from disseminating false ads about Tempus’s cancer biopsy products.” D.I. 62 at 1.

## **II. LEGAL STANDARD**

“A preliminary injunction is an extraordinary remedy never awarded as of right.” *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 24 (2008). A party may be granted a preliminary injunction only “upon a clear showing that the plaintiff is entitled to such relief.” *Id.* at 22 (citation omitted). To determine whether to grant or deny a preliminary injunction, the court considers whether the moving party would likely succeed on the merits, whether the moving party would suffer irreparable harm without injunctive relief, whether granting the injunction will cause greater harm to the nonmoving party, and whether the injunction serves the public interest. *Holland v. Rosen*, 895 F. 3d 272, 285-86 (3d Cir. 2018). The moving party bears the burden of persuasion, and the court may not grant the motion unless the movant satisfies the first two gateway factors. *Id.* As applicable to this case, under the Lanham Act, “[a] plaintiff seeking any such injunction shall be entitled to a rebuttable presumption of irreparable harm . . . upon a finding of likelihood of success on the merits for a violation identified in this subsection.” 15 U.S.C. § 1116(a).

## **III. DISCUSSION**

Upon analyzing the factors that warrant preliminary injunctive relief, the Court finds that Tempus has failed to demonstrate the need for preliminary injunctive relief based on the reasons discussed below.

**A. Tempus Fails to Show a Likelihood of Success on the Merits**

The underlying claim to Guardant’s complaint for declaratory judgment is § 43(a) of the Lanham Act, which prohibits false advertising in interstate commerce. Section 43(a) provides, in pertinent part:

(1) Any person who, on or in connection with any goods or services, . . . uses in commerce any . . . false or misleading description of fact, or false or misleading representation of fact which . . . (B) in commercial advertising or promotion, misrepresents the nature, characteristics, qualities, or geographic origin of his or her or another person’s goods, services, or commercial activities, shall be liable in a civil action by any person who believes that he or she is likely to be damaged by such act.

15 U.S.C. § 1125(a). In other words, to establish a Lanham Act violation for false advertising, a plaintiff must show:

1) that the defendant has made false or misleading statements as to his own product or another’s; 2) that there is actual deception or at least a tendency to deceive a substantial portion of the intended audience; 3) that the deception is material in that it is likely to influence purchasing decisions; 4) that the advertised goods traveled in interstate commerce; and 5) that there is a likelihood of injury to the plaintiff in terms of declining sales, loss of good will, etc.

*Pernod Richard US v. Bacardi U.S.A.*, 653 F. 3d 241, 248 (3d Cir. 2011). “Liability arises if the commercial advertising is either (1) literally false or (2) literally true or ambiguous, but has the tendency to deceive consumers.” *Novartis Consumer Health, Inc. v. Johnson & Johnson-Merck Consumer Pharms. Co.*, 290 F.3d 578, 586 (3d Cir. 2002). To prevail on a claim for false advertising under Section 43(a), “a plaintiff must first prove by a preponderance of the evidence that the claims it challenges are false or deceptive.” *Toro Co. v. Textron, Inc.*, 499 F. Supp. 241, 251 (D. Del. 1980).

## 1. Standard for Literal Falsity

Tempus proceeds on a literal falsity theory. “The test for literal falsity is an objective one for the court’s determination.” *Benihana of Tokoyo, Inc. v. Benihana, Inc.*, 828 F. Supp. 2d 720, 729 (D. Del. 2011). “In deciding whether an advertising claim is literally false, a court must decide first whether the claim conveys an unambiguous message and second whether that unambiguous message is false.” *Groupe SEB USA, Inc. v. Euro-Pro Operating LLC*, 774 F. 3d 192, 198 (3d Cir. 2014). “A ‘literally false’ message may be either explicit or conveyed by necessary implication when, considering the advertisement in its entirety, the audience would recognize the claim as readily as if it had been explicitly stated. Regardless, only an *unambiguous* message can be false.” *Novartis Consumer Health, Inc.*, 290 F. 3d at 586-7 (cleaned up). “A claim is unambiguous when, read in the context of the entire claim, there is one available conclusion and only one plausible meaning.” *CareDx, Inc. v. Natera, Inc.*, No. 23-2427, 2025 WL 2480117, at \*5 (3d Cir. Aug. 28, 2025).

### a. Tempus Fails to Show a Likelihood of Success Against the Guardant Liquid Ads

Tempus contends that Guardant’s Liquid Ads<sup>3</sup> are literally false. D.I. 62 at 12. Specifically, Tempus claims that the advertisements conveying the general message that “[1] [Guardant’s] test is more sensitive and, [2] as a result, that doctors using Tempus’s test will miss treatment options for patients” are false because they lack support from scientific data. *Id.* at 12-13; *see* D.I. 63-1, Ex. J (“Don’t risk missing patients with a less sensitive test”); Ex. D (“Guardant360 evaluates more biomarkers with higher sensitivity than Tempus xF+”); Ex. H (“Don’t miss actionable biomarkers by compromising on sensitivity”); Ex. L (claiming “another

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<sup>3</sup> Guardant’s Liquid Ads consists of Exhibits C–E and H–J. *See* D.I. 63-1.

liquid biopsy” missed certain mutations); Ex. E (claiming doctors can “find more with Guardant” and identifying percentages of “[m]utations identified on Guardant360 below Tempus xF+’s limit of detection.”). Tempus contends that the claims are unsupported by scientific data because they rely on unreliable analytical validation<sup>4</sup> studies rather than “properly designed, head-to-head studies.” D.I. 62 at 13. Tempus states that analytical validation provides “only a baseline for how a specific test behaves in a specific lab,” and data from one laboratory cannot be compared to data from another laboratory’s separate test. *Id.* Therefore, Tempus contends that the claims are inadequately supported by “each test’s LOD based on separate validation,” which are “conducted in different labs, on different samples, using different testing protocols.” *Id.* To support its position that the advertised claims are false, Tempus also relies on *CareDx* which finds that comparative statements based on flawed and unreliable testing are viewed as literally false statements. *Id.*; *see also CareDx, Inc. v. Natera, Inc.*, No. 19-662, 2019 WL 7037799, at \*10 (D. Del. Dec. 20, 2019), *report and recommendation adopted*, 2020 WL 401773 (D. Del. Jan. 24, 2020).

In response, Guardant contends that Tempus offers no evidence demonstrating literal falsity of the claims that Guardant360 is more sensitive or that physicians using xF+ will miss treatment options. D.I. 82 at 9. Guardant maintains that its ads are supported by scientific data, which consists of both companies’ published performance specifications from their analytical validation and Guardant’s analysis of patient samples. *Id.* (arguing that its ad “accurately

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<sup>4</sup> Analytical validation is a laboratory-based process to evaluate the accuracy and reliability of results generated by liquid or tissue test. D.I. 62 at 5. The process also measures analytical sensitivity, “the rate at which a test can be expected to detect a concentration of a substance known to exist within a sample,” and limit of detection (“LOD” or “limit of detection”), “the lowest amount of a substance within a sample that can be detected with a stated probability.” *Id.*

compares the panel size and LODs of Guardant360 and Tempus xF+ from each company's own published specifications, as of September 2024"); *see also* D.I. 63-1, Ex. C. Guardant argues that its advertisement makes clear that it is based on Tempus's published analytical specification information. D.I. 82 at 9; *see also* D.I. 63-1, Ex. D. Guardant further argues that Tempus's reliance on *CareDx* is misplaced because in *CareDx* "the actual, meaningful differences in the pertinent studies rendered the comparison literally false," and Tempus has failed to explain actual differences in the analytical validation process or how any differences skewed results. *Id.*

Tempus also contends that the statistics found in several ads "are based solely on test results using [Guardant's] tests, while relying on inaccurate data for Tempus." D.I. 62 at 14; *see also* D.I. 63-1, Exs. E ("Comparison against over 400,000 patient samples tested by Guardant360 CDx or Guardant360 liquid biopsy"), J (similar), & L. Tempus argues that Guardant failed to (1) conduct a study demonstrating the amount of missed xF+ patients detected by Guardant360; (2) perform an analysis on the number of mutations xF+ detects, and (3) "analyze the actual rate at which the Tempus test reported breast and lung cancer mutations." D.I. 62 at 14. Tempus asserts that the proper method would require Guardant to perform "the same xF+ test against the same samples to determine whether both tests identified or missed the same mutations," and without scientific support, the claims are literally false. *Id.* Moreover, Tempus asserts that it published updated validation data relating to its xF+ test in April 2025 and that, because many of Guardant's Liquid Ads rely on outdated validation data, they are literally false. D.I. 62 at 15; *compare* D.I. 63-1, Ex. C (Tempus xF+'s limit of detection to 95% sensitivity is 0.5% indels), *with* Ex. F (Tempus xF+'s 95.5% sensitivity is less than or equal to 0.25% indels).

Guardant responds that its advertisements do not rely on one clinical study, but rather on xF+'s actual performance specifications derived from Tempus's published analytical validation,

which consists of “a process with the uniform purpose of ascertaining a test’s true performance under controlled laboratory conditions.” D.I. 82 at 11-12. Additionally, Guardant notes that Tempus’s new validation data became available months after the advertisement was released and therefore does not render the advertisement literally false. *Id.* Moreover, Guardant states that, in light of the new data, the advertisement was discontinued. *Id.*

Guardant also notes that several of Guardant’s Liquid Ads do not mention Tempus. *Id.* at 13; *see* D.I. 63-1 at Exs. H–J, L. For example, in Exhibit H, the challenged claim states: “[d]on’t miss actionable biomarkers by comprising on sensitivity.” However, Guardant contends that the statement makes no mention or direct comparison to Tempus. D.I. 82 at 13. Guardant further contends that Tempus fails to discuss or identify any false statements in Exhibit I. *Id.* at 14; *see also* D.I. 63-1, Ex. I. Lastly, Guardant contends that Exhibit L was not widely disseminated and Tempus fails to show that the advertisement was “part of an organized campaign to penetrate the relevant market.” D.I. 82 at 14.

Based on the present record, the Court cannot conclude that the claims are literally false. Several of the challenged statements convey establishment claims, which are claims that “explicitly or implicitly represent[] that tests or studies prove its product superior.” *CareDx, Inc.*, 2025 WL 2480117, at \*5 (citing *Castrol, Inc. v. Quaker State Corp.*, 977 F. 2d 57, 63 (2d Cir. 1992)). “A non-establishment claim represents that a product is superior, without reference to or reliance on studies or data.” *Id.* To satisfy its burden of showing that an establishment claim is false, Tempus must show that “the tests did not establish the proposition for which they were cited. This can be done by demonstrating (1) that the tests were not sufficiently reliable to permit a conclusion that the product is superior or (2) that even if reliable the tests do not establish the

proposition asserted by [Guardant].” *Id.* (internal quotations omitted). Below, the Court discusses each advertisement in turn.

**i. Exhibits C–E<sup>5</sup>**

Exhibit C compares key performance specifications – panel size and limit of detection at 95% sensitivity – of Guardant360 and Tempus xF+ based on information available as of September 2024. D.I. 62-1, Ex. C. Tempus’s argument is twofold: first, that analytical validation is not the appropriate test for comparisons; and second, that the advertisement relies on outdated data. D.I. 62 at 13-15.

Tempus fails to show that the analytical validation studies do not establish that Guardant360 performs better in limit of detection at 95% sensitivity. Both parties agree that analytical validation is a laboratory process to ascertain a test’s performance specifications, such as limit of detection. Beyond Tempus’s reliance on conclusory assertions concerning the necessity of head-to-head data, Tempus has not demonstrated that analytical validation studies lack sufficient reliability or that the results do not establish that Guardant360 has a lower limit of detection than Tempus’s xF+ at 95% sensitivity. *See* D.I. 64 ¶¶ 14-15. Based on the record evidence, it appears that analytical validation is a relevant test to show test sensitivity. *Cf. Castrol, Inc.*, 977 F. 2d at 63-64 (claims found to be literally false because the tests presented were irrelevant to party’s claim). Furthermore, Guardant represents that these results were derived from Tempus’s own studies (D.I. 84-1, Ex. B) and are routinely used by licensing agencies, regulatory submissions and evaluations for clinical trials because they provide “a common yardstick” for

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<sup>5</sup> As stated *supra* n.2, Tempus separated a single ad to address the alleged false claims individually. After considering the parties’ arguments, the Court will address the exhibits collectively.

comparing the performance of various tests. D.I. 82 at 5. At this time, Tempus has not demonstrated that the analytical validation studies fail to support Guardant’s position.<sup>6</sup> While ongoing discovery may reveal additional evidence bearing on a finding of literal falsity, the record as it now stands is insufficient to grant the extraordinary relief of a preliminary injunction. Therefore, Tempus has failed to meet its burden to show that the establishment claim is false<sup>7</sup>.

For Exhibit D, Tempus’s argument is directed to Guardant’s claim that “Guardant360 evaluates more biomarkers with higher sensitivity than Tempus xF+.” For Exhibit E, Tempus directs its argument towards the claims, “[f]ind more with Guardant,” the percentages of “[m]utations identified on Guardant360 below Tempus xF+’s limit of detection,” and “[c]omparison against over 400,000 patient samples tested by Guardant360 CDx or Guardant360 liquid biopsy.” D.I. 62 at 12-13. Similar to Exhibit C, Tempus contends that the claims about Exhibits D and E are outdated and unsupported by scientific data because they are derived from analytical validation studies rather than “properly designed, head-to-head studies.” D.I. 62 at 13. For the same reasons discussed above with respect to Exhibit C, Tempus has not presented sufficient evidence to demonstrate that the claims found in Exhibits D and E are literally false.

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<sup>6</sup> The Court further observes that an email from a Tempus representative to a medical personnel (D.I. 101-1), upon which Tempus relies on in its reply brief (D.I. 98), draws the same side-by-side comparison of Guardant 360 and Tempus xF+ performance specifications that Tempus contends is false, thereby further undermining Tempus’s claim.

<sup>7</sup> The Court is unpersuaded by Tempus’s argument that the advertisement relies on outdated analytical validation data because the new data was published in April 2025, which is after the advertisement’s publish date of December 2024. Tempus does not dispute that the advertisement contains its own published specifications. See D.I. 62-1, Ex. C (“based on publicly available information on tempus.com as of September 2024”). Additionally, Guardant avers that, in light of the new data, the ad was discontinued.

## ii. Exhibits H and J

With respect to Exhibit H, Tempus contends that the statement, “[d]on’t miss actionable biomarkers by compromising on sensitivity,” repeats the claim that Tempus xF+ is less sensitive and is literally false. However, neither the statement nor the advertisement mentions Tempus. The statement is not an affirmative statement that Tempus, or any particular competitor’s liquid biopsy test, is more or less sensitive. The Court notes that the parties appear to be largely in agreement on this point. *Compare* D.I. 62 at 4 (“a test with higher sensitivity reports fewer false negatives”), *with* D.I. 82 at 5 (“a test with lower sensitivity will miss more actionable biomarkers than a test with higher sensitivity”). Tempus fails to show that any statement contained in Exhibit H is false and, on its face, the Court finds there is nothing false about Guardant’s statement. *See Schering-Plough Healthcare Prods., Inc. v. Neutrogena Corp.*, 702 F. Supp. 2d 253, 263-64 (D. Del. 2010).

Moreover, Tempus’s complaints about the statements in Exhibit J - “[d]on’t risk missing patients with a less sensitive test” and “[f]rom over 400,000 patient samples tested with Guardant360 CDx or Guardant360 liquid biopsy” - fail for the same reasons discussed in the foregoing analysis of Exhibits H and C–E. Tempus makes no attempt to show any of the specific statements or figures in this advertisement are literally false.

## iii. Exhibit I

Although Tempus characterizes Exhibit I as an advertisement at issue and as a part of Guardant’s Liquid Ads, Tempus does not make any specific arguments that any statements therein are literally false. Therefore, Tempus has not met its burden to show literal falsity for Exhibit I. *See ECB USA, Inc. v. Savencia, S.A.*, No. 19-731, 2020 WL 5369076, at \*4 (D. Del. Sept. 8, 2020) (“As a general prudential rule, courts only decide issues that are fairly and fully presented. Therefore, cursory arguments not fully developed by the parties are waived.”); *Purewick Corp. v.*

*Sage Prods., LLC*, 666 F. Supp. 3d 419, 441 (D. Del. 2023) (“[A]rguments . . . not squarely argued[] are considered [forfeited].”) (some alterations in original).

#### iv. Exhibit L

Exhibit L is a newsletter discovered by a Tempus sales representative in a physician’s office. D.I. 62 at 9. Tempus claims that the newsletter falsely states that “Tempus did in fact miss mutations in lung and breast cancer patients.” *Id.* at 9; D.I. 63-1, Ex. L. Tempus also challenges as false the claim: “When it comes to giving your patients more SUNNY days with their loved ones, use Guardant360 Liquid to find more patients with targetable alterations!” *Id.* (emphasis in original). In addition to asserting the claims are not false, Guardant contends that the newsletter was not “widely disseminated,” as it was created and circulated by one Guardant sales representative to a limited audience of less than twenty potential customers. D.I. 82 at 14.

“The ‘touchstone’ of whether a defendant’s statements amount to the requisite commercial advertising or promotion is ‘that the contested representations are part of an organized campaign to penetrate the relevant market.’” *Shure Incorporated & Shure Acquisition Holdings, Inc. v. Clearone, Inc.*, No. 19-1343, 2020 WL 2839294, at \*6 (D. Del. June 1, 2020) (citing *Progressive Sterilization, LLC v. Turbett Surgical, LLC*, No. 19-627, 2020 WL 1849709, at \*10 (D. Del. April 13, 2020)). “Proof of widespread dissemination within the relevant industry is a normal concomitant of meeting this requirement.” *Progressive Sterilization, LLC*, 2020 WL 1849709, at \*10. At most, the newsletter was distributed to a limited group of potential customers. Tempus has not shown that this newsletter was widespread or part of an organized campaign to penetrate the market. Moreover, the statements referencing “another liquid biopsy” do not identify Tempus and are ambiguous, as they are susceptible to more than one plausible meaning. *See CareDx, Inc.*, 2025 WL 2480117, at \*5. Thus, Tempus has not demonstrated that the claims are literally false.

**b. Tempus Fails to Show a Likelihood of Success Against the Guardant Tissue Ads**

Tempus contends that Guardant's Tissue Ads are also literally false. D.I. 62 at 15. First, Tempus argues that Guardant's Tissue Ads contain "lower published requirements for tissue samples [that are] without head-to-head testing." *Id.* at 16. Also, Tempus contends that, the claim stating "lowest industry-wide sample requirements mean[] results for more patients," lacks scientific support because there is no head-to-head study. *Id.* Tempus further contends that substantiation of this claim would require Guardant to test the same or similar samples and compare the results, which Guardant has not done. *Id.* Tempus also contends that Guardant's advertisement claiming that the number of slides alone determines the ability to report a result is false because results depend on the quality of the tissue sample rather than the number of slides. *Id.* Lastly, Tempus contends there is no valid scientific basis for drawing conclusions regarding the number of patients who may receive test results from one company's test as compared to another. *Id.*

In response, Guardant addresses each alleged claim contained in Guardant's Tissue Ads. First, Guardant responds that Exhibit M, the only advertisement that mentions Tempus, "accurately states Guardant360 Tissue requires 6 slides whereas Tempus and other competitors require 10 slides." D.I. 82 at 14. Guardant further responds that the advertisement is supported by the Tomlins publication (D.I. 83-1, Ex. A) and Tempus's own marketing materials (D.I. 83-1, Ex. B). *Id.* Guardant also responds that the claim, "the lowest sample requirement, more patients get results," is also supported by the Tomlins publication and the accurate comparison of published tissue sample requirements. *Id.* Thus, Tempus fails to show that the claims are literally false.

Guardant further responds that Tempus's contention that the claims are misleading fails, because Tempus fails to identify any ambiguity or evidence of deception. *Id.* Guardant also responds that its claims regarding the number of slides accurately reflect Tempus's published requirements and are not misleading merely because Tempus claims it also processes orders with fewer slides. *Id.* Guardant notes that Tempus does not mention or demonstrate that Exhibits N–O and U–V are literally false in its Motion. *Id.*; 63-1 Exs. N–O and U–V. Guardant also responds that the advertisements do not mention Tempus and refer to an industry standard sample size requirement. *Id.* at 16.

After consideration of both parties' contentions and the record as it exists, the Court finds that Tempus has failed to show that Guardant's Tissue Ads are literally false. Tempus advances the same contentions regarding the lack of scientific support and the necessity of head-to-head testing, without providing sufficient evidence that such testing is, in fact, required. *See Schering-Plough Healthcare Prods., Inc.*, 702 F. Supp. 2d at 272 (stating that the movant has the burden of showing tests do not establish what is claimed). With respect to Exhibit M, the evidence presented shows that Guardant360 Tissue calls for six slides (D.I. 84-1, Ex. C) and there is a 40% reduction in slide usage relative to Tempus and other competitors' reported data of ten slides (D.I. 84-1, Exs. D–F). Tempus does not rebut its usage of ten slides, nor does it show that its test requires less than ten slides. Instead, Tempus contends that the claim is misleading because "Tempus reports a result whenever its quality control measures allow it to do so" and Tempus also receives samples fewer than Guardant's six slide threshold. D.I. 62 at 9, 17. However, Tempus has provided no evidence demonstrating that the claim is likely to mislead and confuse relevant consumers: physicians. *See Sandoz Pharms. Corp. v. Richardson-Vicks, Inc.*, 902 F.2d 222, 229-30 (3d Cir. 1990) ("[A] target audience's special knowledge of a class of products is highly relevant to any claim that it was

misled by an advertisement for such a product.”). Tempus fails to advance specific arguments related to Exhibits N–O and U–V. However, the advertisements’ claims are substantially similar to those in Exhibit M and fail for the same reason.

For these reasons, the Court finds that Tempus has failed to establish a likelihood of success on the merits of proving the literal falsity of Guardant’s advertisements.

### **B. Tempus Fails to Show Irreparable Harm**

Given Tempus’s failure to demonstrate a likelihood of success on the merits of literal falsity, Tempus is not entitled to a rebuttable presumption of irreparable harm, and the Court need not reach the issue of irreparable harm. *See* 15 U.S.C. § 1116(a); *see also Ferring Pharms., Inc. v. Watson Pharms., Inc.*, 765 F.3d 205, 210 (3d Cir. 2014) (“The failure to establish any element . . . renders a preliminary injunction inappropriate.”). However, to develop a more fulsome record, the Court will briefly address it.

“To establish irreparable harm, there must be a clear showing of immediate irreparable injury, or a presently existing actual threat.” *Golden Fortune Imp. & Emp. Corp. v. Mei-Xin Ltd.*, No. 22-1710, 2022 WL 3536494, at \*5 (3d Cir. Aug. 5, 2022); *ECRI v. McGraw-Hill, Inc.*, 809 F. 2d 223, 226 (3d Cir. 1987). Irreparable harm is harm that “cannot be redressed by a legal or equitable remedy following a trial.” *Instant Air Freight Co. v. C.F. Air Freight, Inc.*, 882 F. 2d 797, 801 (3d Cir. 1989). In other words, “[i]rreparable harm ‘must be of a peculiar nature, so that compensation in money alone cannot atone for it.’” *Opticians Ass’n of Am. V. Indep. Opticians of Am.*, 920 F. 2d 187, 195 (3d Cir. 1990) (citation omitted). The harm must be immediate and not speculative. *See Campbell Soup Co. v. ConAgra, Inc.*, 977 F. 2d 86, 91 (3d Cir. 1992); *Adams v. Freedom Forge Corp.*, 204 F. 3d 475, 488 (3d Cir. 2000). “Grounds for irreparable injury include loss of control of reputation, loss of trade, and loss of goodwill.” *Novartis Consumer Health, Inc.*,

290 F.3d at 596 (citing *Pappan Enters., Inc. v. Hardee's Food Sys., Inc.*, 143 F. 3d 800, 805 (3d Cir. 1998)).

Tempus contends that Guardant's false advertising has caused significant damage to its reputation and a loss of goodwill. D.I. 62 at 20. However, Tempus presents no evidence regarding harm to its reputation, loss of customers, loss of sales or market share. Guardant asserts that many of the advertisements at issue, such as Exhibits C–E, H, L, M and O, are no longer in circulation. D.I. 82 at 16. Therefore, the Court finds that any alleged harm would have already occurred, and the Court cannot grant relief for past injury. *Doe v. Delaware State Univ. Bd. of Trs.*, No. 20-1559, 2021 WL 2036670, at \*3 (D. Del. May 21, 2021) (“As these harms have already occurred, they cannot be *prevented* by injunctive relief. Even if the harms alleged can be *cured* by injunctive relief, they are amenable to such equitable relief whether ordered now or after Plaintiff potentially succeeds at trial.”)

To further demonstrate irreparable harm, Tempus contends that Guardant's advertisements concern medical misinformation implicating health and safety, which poses a “great threat” to Tempus's goodwill. D.I. 62 at 20. However, Tempus's evidence consists solely of two emails, which only show consumers seeking further information from Tempus about testing. D.I 63-1, Exs. Q & Y. Without more, this fails to establish loss of customers or goodwill. The irreparable harm asserted by Tempus rests on conclusory statements, which are insufficient and fail to meet the required showing. *Cnty. Legal Aid Soc'y, Inc. v. Adult & Prison Educ. Res. Workgroup*, No. 24-615, 2025 WL 1734992, at \*3 (D. Del. June 23, 2025) (“The party seeking injunctive relief bears the burden to provide clear evidence of irreparable harm, and arguments paired with conclusory allegations are insufficient to justify an injunction.”)

Lastly, Guardant highlights that Tempus admits to waiting almost a year after learning of the advertising campaign in December 2024 before filing this Motion. D.I. 82 at 17; D.I. 62 at 6. Tempus does not contest this fact. Rather than address the substance of Guardant's point, Tempus asserts that it advised Guardant of its intent to seek preliminary injunctive relief six weeks after Guardant's September 2025 production. D.I. 98 at 7. "[D]elay in seeking a remedy is an important factor bearing on the need for a preliminary injunction." *High Tech Med. Instrumentation, Inc. v. New Image Indus., Inc.*, 49 F. 3d 1551, 1557 (Fed. Cir. 1995). However, "a showing of delay does not preclude, *as a matter of law*, a determination of irreparable harm." *Hybritech Inc. v. Abbott Lab 'ys*, 849 F.2d 1446, 1457 (Fed. Cir. 1988). The Court finds that the unexplained delay between December 2024 and the filing of this Motion undermines any claim of urgency and further supports the Court's finding that Tempus has not established irreparable harm. *See Neology, Inc. v. Fed. Signal Corp.*, No. 11-672, 2012 WL 2308202, at \*16 (D. Del. June 18, 2012), *report and recommendation adopted*, No. 11-672, 2012 WL 3236718 (D. Del. Aug. 2, 2012).

For the reasons outlined above, the Court concludes that Tempus has failed to demonstrate irreparable harm.

#### **IV. CONCLUSION**

For the foregoing reasons, the Court denies Tempus's Motion for Preliminary Injunction (D.I. 61). The Court also denies-as-moot Tempus's Request for Oral Argument (D.I. 102).

An Order consistent with this Memorandum Opinion will be entered.

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

GUARDANT HEALTH, INC.,

Plaintiff and Counterclaim-Defendant,

v.

TEMPUS AI, INC.,

Defendant and Counterclaim-Plaintiff.

Civil Action No. 25-82-GBW

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David E. Moore, Bindu A. Palapura, POTTER ANDERSON & CORROON LLP, Wilmington, DE; Jennifer L. Keller, Chase Scolnick, Gregory Bernstein, Gregory M. Sergi, Akhil Sheth, KELLER ANDERLE SCOLNICK, Irvine, CA.

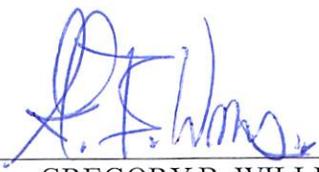
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**MEMORANDUM OPINION**

February 20, 2026  
Wilmington, Delaware

  
GREGORY B. WILLIAMS  
UNITED STATES DISTRICT JUDGE

Pending before the Court is Defendant and Counterclaim-Plaintiff Tempus AI, Inc.’s (“Tempus”) Motion for Preliminary Injunction against Plaintiff and Counterclaim-Defendant Guardant Health Inc. (“Guardant”) (D.I. 61), which is fully briefed (D.I. 62; D.I. 82; D.I. 98; D.I. 110). For the reasons stated below, the Court denies Tempus’s Motion for Preliminary Injunction (the “Motion”) (D.I. 61).

## I. BACKGROUND

Guardant and Tempus sell liquid and tissue biopsy tests that provide information about the molecular profile of a patient’s cancer. D.I. 64 ¶ 3. Doctors use these biopsy tests to create treatment plans. *Id.*<sup>1</sup> Liquid biopsy tests use a patient’s blood to analyze circulating tumor DNA (“ctDNA”) shed from a tumor that flows through the bloodstream. *Id.* ¶ 5. Tissue biopsy tests analyze tissue taken from a cancerous tumor. *Id.* Depending on various factors, physicians may choose to order one test, or both tests, to determine a patient’s appropriate course of treatment. *Id.* ¶ 6. For example, if a test identifies that certain mutations are present, the patient may qualify for certain treatments and may forgo other treatments, such as chemotherapy. *Id.* ¶ 4. Guardant offers Guardant360 Tissue, a tissue-based test, as well as Guardant360 Liquid and Guardant360 CDx, which are both liquid-based tests. *Id.* ¶ 7. Tempus offers tissue-based tests called xR and xT, along with liquid-based tests called xF and xF+. *Id.*

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<sup>1</sup> Jonathan Freaney (“Mr. Freaney”) is a Vice President of Research & Development Strategy & Operations at Tempus, who submitted his declaration in support of Tempus’s Motion for Preliminary Injunction. D.I. 64 ¶¶ 1-2.

In December 2024, Guardant distributed an advertisement<sup>2</sup> that compared Guardant360 Liquid to Tempus xF+. D.I. 62 at 6. The advertisement states that Guardant360 is “the most sensitive liquid biopsy available,” and compares various specifications between Guardant360 and Tempus xF+. D.I. 63-1, Exs. C–E. Tempus claims that, during the course of discovery, it became aware of additional advertisements making similar or identical claims. D.I. 62 at 6; *see also* D.I. 63-1, Exs. H–J (collectively, “Guardant’s Liquid Ads”).

Guardant also disseminated advertisements that compared Guardant’s tissue test, Guardant360 Tissue, to Tempus’s tissue tests, xT and xR (“Guardant’s Tissue Ads”). D.I. 62 at 8; *see also* D.I. 63-1, Exs. M–O. These advertisements claim that Guardant’s tests require physicians to submit “40% fewer slides” than Tempus’s tests (or the industry standard), and “[w]ith the lowest sample requirement, more patients get results.” D.I. 63-1, Ex. M at 512. One of Guardant’s Tissue Ads reports that Guardant can get answers when other competitors cannot, and that more samples can be evaluated. D.I. 62 at 9; *see also* D.I. 63-1, Ex. N.

In addition to Guardant’s Tissue Ads and Liquid Ads, Guardant sales representatives sent advertisements to customers in the form of newsletters and emails. D.I. 62 at 9. Specifically, one newsletter states that “another liquid biopsy missed . . . mutations in their advanced breast patients and . . . mutations in their metastatic lung patients.” D.I. 63-1, Ex. L. Additionally, the advertisement suggests that patients will have more “sunny days with their loved ones” when using Guardant360 Liquid. *Id.*

Guardant brought this lawsuit against Tempus seeking declaratory relief that (1) its advertising for Guardant360 is not false or misleading and (2) its advertising comparing

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<sup>2</sup> In its Motion, Tempus separates a single ad into separate categories to address the alleged false claims individually. D.I. 63-1, Exs. C–E.

Guardant360 with Tempus's xF+ is not false or misleading under § 43(a) of the Lanham Act, 15 U.S.C.A. § 1125(a). D.I. 1. Tempus filed counterclaims asserting that Guardant violated the Lanham Act, California Unfair Competition Law, and the Uniform Deceptive Trade Practices Act. D.I. 77. Tempus also seeks an injunction enjoining Guardant from publishing and disseminating various advertisements. *Id.* On November 10, 2025, Tempus filed this Motion seeking to “stop Guardant from disseminating false ads about Tempus’s cancer biopsy products.” D.I. 62 at 1.

## **II. LEGAL STANDARD**

“A preliminary injunction is an extraordinary remedy never awarded as of right.” *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 24 (2008). A party may be granted a preliminary injunction only “upon a clear showing that the plaintiff is entitled to such relief.” *Id.* at 22 (citation omitted). To determine whether to grant or deny a preliminary injunction, the court considers whether the moving party would likely succeed on the merits, whether the moving party would suffer irreparable harm without injunctive relief, whether granting the injunction will cause greater harm to the nonmoving party, and whether the injunction serves the public interest. *Holland v. Rosen*, 895 F. 3d 272, 285-86 (3d Cir. 2018). The moving party bears the burden of persuasion, and the court may not grant the motion unless the movant satisfies the first two gateway factors. *Id.* As applicable to this case, under the Lanham Act, “[a] plaintiff seeking any such injunction shall be entitled to a rebuttable presumption of irreparable harm . . . upon a finding of likelihood of success on the merits for a violation identified in this subsection.” 15 U.S.C. § 1116(a).

## **III. DISCUSSION**

Upon analyzing the factors that warrant preliminary injunctive relief, the Court finds that Tempus has failed to demonstrate the need for preliminary injunctive relief based on the reasons discussed below.

**A. Tempus Fails to Show a Likelihood of Success on the Merits**

The underlying claim to Guardant's complaint for declaratory judgment is § 43(a) of the Lanham Act, which prohibits false advertising in interstate commerce. Section 43(a) provides, in pertinent part:

(1) Any person who, on or in connection with any goods or services, . . . uses in commerce any . . . false or misleading description of fact, or false or misleading representation of fact which . . . (B) in commercial advertising or promotion, misrepresents the nature, characteristics, qualities, or geographic origin of his or her or another person's goods, services, or commercial activities, shall be liable in a civil action by any person who believes that he or she is likely to be damaged by such act.

15 U.S.C. § 1125(a). In other words, to establish a Lanham Act violation for false advertising, a plaintiff must show:

1) that the defendant has made false or misleading statements as to his own product or another's; 2) that there is actual deception or at least a tendency to deceive a substantial portion of the intended audience; 3) that the deception is material in that it is likely to influence purchasing decisions; 4) that the advertised goods traveled in interstate commerce; and 5) that there is a likelihood of injury to the plaintiff in terms of declining sales, loss of good will, etc.

*Pernod Richard US v. Bacardi U.S.A.*, 653 F. 3d 241, 248 (3d Cir. 2011). "Liability arises if the commercial advertising is either (1) literally false or (2) literally true or ambiguous, but has the tendency to deceive consumers." *Novartis Consumer Health, Inc. v. Johnson & Johnson-Merck Consumer Pharms. Co.*, 290 F.3d 578, 586 (3d Cir. 2002). To prevail on a claim for false advertising under Section 43(a), "a plaintiff must first prove by a preponderance of the evidence that the claims it challenges are false or deceptive." *Toro Co. v. Textron, Inc.*, 499 F. Supp. 241, 251 (D. Del. 1980).

## 1. Standard for Literal Falsity

Tempus proceeds on a literal falsity theory. “The test for literal falsity is an objective one for the court’s determination.” *Benihana of Tokoyo, Inc. v. Benihana, Inc.*, 828 F. Supp. 2d 720, 729 (D. Del. 2011). “In deciding whether an advertising claim is literally false, a court must decide first whether the claim conveys an unambiguous message and second whether that unambiguous message is false.” *Groupe SEB USA, Inc. v. Euro-Pro Operating LLC*, 774 F. 3d 192, 198 (3d Cir. 2014). “A ‘literally false’ message may be either explicit or conveyed by necessary implication when, considering the advertisement in its entirety, the audience would recognize the claim as readily as if it had been explicitly stated. Regardless, only an *unambiguous* message can be false.” *Novartis Consumer Health, Inc.*, 290 F. 3d at 586-7 (cleaned up). “A claim is unambiguous when, read in the context of the entire claim, there is one available conclusion and only one plausible meaning.” *CareDx, Inc. v. Natera, Inc.*, No. 23-2427, 2025 WL 2480117, at \*5 (3d Cir. Aug. 28, 2025).

### a. Tempus Fails to Show a Likelihood of Success Against the Guardant Liquid Ads

Tempus contends that Guardant’s Liquid Ads<sup>3</sup> are literally false. D.I. 62 at 12. Specifically, Tempus claims that the advertisements conveying the general message that “[1] [Guardant’s] test is more sensitive and, [2] as a result, that doctors using Tempus’s test will miss treatment options for patients” are false because they lack support from scientific data. *Id.* at 12-13; *see* D.I. 63-1, Ex. J (“Don’t risk missing patients with a less sensitive test”); Ex. D (“Guardant360 evaluates more biomarkers with higher sensitivity than Tempus xF+”); Ex. H (“Don’t miss actionable biomarkers by compromising on sensitivity”); Ex. L (claiming “another

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<sup>3</sup> Guardant’s Liquid Ads consists of Exhibits C–E and H–J. *See* D.I. 63-1.

liquid biopsy” missed certain mutations); Ex. E (claiming doctors can “find more with Guardant” and identifying percentages of “[m]utations identified on Guardant360 below Tempus xF+’s limit of detection.”). Tempus contends that the claims are unsupported by scientific data because they rely on unreliable analytical validation<sup>4</sup> studies rather than “properly designed, head-to-head studies.” D.I. 62 at 13. Tempus states that analytical validation provides “only a baseline for how a specific test behaves in a specific lab,” and data from one laboratory cannot be compared to data from another laboratory’s separate test. *Id.* Therefore, Tempus contends that the claims are inadequately supported by “each test’s LOD based on separate validation,” which are “conducted in different labs, on different samples, using different testing protocols.” *Id.* To support its position that the advertised claims are false, Tempus also relies on *CareDx* which finds that comparative statements based on flawed and unreliable testing are viewed as literally false statements. *Id.*; *see also CareDx, Inc. v. Natera, Inc.*, No. 19-662, 2019 WL 7037799, at \*10 (D. Del. Dec. 20, 2019), *report and recommendation adopted*, 2020 WL 401773 (D. Del. Jan. 24, 2020).

In response, Guardant contends that Tempus offers no evidence demonstrating literal falsity of the claims that Guardant360 is more sensitive or that physicians using xF+ will miss treatment options. D.I. 82 at 9. Guardant maintains that its ads are supported by scientific data, which consists of both companies’ published performance specifications from their analytical validation and Guardant’s analysis of patient samples. *Id.* (arguing that its ad “accurately

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<sup>4</sup> Analytical validation is a laboratory-based process to evaluate the accuracy and reliability of results generated by liquid or tissue test. D.I. 62 at 5. The process also measures analytical sensitivity, “the rate at which a test can be expected to detect a concentration of a substance known to exist within a sample,” and limit of detection (“LOD” or “limit of detection”), “the lowest amount of a substance within a sample that can be detected with a stated probability.” *Id.*

compares the panel size and LODs of Guardant360 and Tempus xF+ from each company's own published specifications, as of September 2024"); *see also* D.I. 63-1, Ex. C. Guardant argues that its advertisement makes clear that it is based on Tempus's published analytical specification information. D.I. 82 at 9; *see also* D.I. 63-1, Ex. D. Guardant further argues that Tempus's reliance on *CareDx* is misplaced because in *CareDx* "the actual, meaningful differences in the pertinent studies rendered the comparison literally false," and Tempus has failed to explain actual differences in the analytical validation process or how any differences skewed results. *Id.*

Tempus also contends that the statistics found in several ads "are based solely on test results using [Guardant's] tests, while relying on inaccurate data for Tempus." D.I. 62 at 14; *see also* D.I. 63-1, Exs. E ("Comparison against over 400,000 patient samples tested by Guardant360 CDx or Guardant360 liquid biopsy"), J (similar), & L. Tempus argues that Guardant failed to (1) conduct a study demonstrating the amount of missed xF+ patients detected by Guardant360; (2) perform an analysis on the number of mutations xF+ detects, and (3) "analyze the actual rate at which the Tempus test reported breast and lung cancer mutations." D.I. 62 at 14. Tempus asserts that the proper method would require Guardant to perform "the same xF+ test against the same samples to determine whether both tests identified or missed the same mutations," and without scientific support, the claims are literally false. *Id.* Moreover, Tempus asserts that it published updated validation data relating to its xF+ test in April 2025 and that, because many of Guardant's Liquid Ads rely on outdated validation data, they are literally false. D.I. 62 at 15; *compare* D.I. 63-1, Ex. C (Tempus xF+'s limit of detection to 95% sensitivity is 0.5% indels), *with* Ex. F (Tempus xF+'s 95.5% sensitivity is less than or equal to 0.25% indels).

Guardant responds that its advertisements do not rely on one clinical study, but rather on xF+'s actual performance specifications derived from Tempus's published analytical validation,

which consists of “a process with the uniform purpose of ascertaining a test’s true performance under controlled laboratory conditions.” D.I. 82 at 11-12. Additionally, Guardant notes that Tempus’s new validation data became available months after the advertisement was released and therefore does not render the advertisement literally false. *Id.* Moreover, Guardant states that, in light of the new data, the advertisement was discontinued. *Id.*

Guardant also notes that several of Guardant’s Liquid Ads do not mention Tempus. *Id.* at 13; *see* D.I. 63-1 at Exs. H–J, L. For example, in Exhibit H, the challenged claim states: “[d]on’t miss actionable biomarkers by comprising on sensitivity.” However, Guardant contends that the statement makes no mention or direct comparison to Tempus. D.I. 82 at 13. Guardant further contends that Tempus fails to discuss or identify any false statements in Exhibit I. *Id.* at 14; *see also* D.I. 63-1, Ex. I. Lastly, Guardant contends that Exhibit L was not widely disseminated and Tempus fails to show that the advertisement was “part of an organized campaign to penetrate the relevant market.” D.I. 82 at 14.

Based on the present record, the Court cannot conclude that the claims are literally false. Several of the challenged statements convey establishment claims, which are claims that “explicitly or implicitly represent[] that tests or studies prove its product superior.” *CareDx, Inc.*, 2025 WL 2480117, at \*5 (citing *Castrol, Inc. v. Quaker State Corp.*, 977 F. 2d 57, 63 (2d Cir. 1992)). “A non-establishment claim represents that a product is superior, without reference to or reliance on studies or data.” *Id.* To satisfy its burden of showing that an establishment claim is false, Tempus must show that “the tests did not establish the proposition for which they were cited. This can be done by demonstrating (1) that the tests were not sufficiently reliable to permit a conclusion that the product is superior or (2) that even if reliable the tests do not establish the

proposition asserted by [Guardant].” *Id.* (internal quotations omitted). Below, the Court discusses each advertisement in turn.

**i. Exhibits C–E<sup>5</sup>**

Exhibit C compares key performance specifications – panel size and limit of detection at 95% sensitivity – of Guardant360 and Tempus xF+ based on information available as of September 2024. D.I. 62-1, Ex. C. Tempus’s argument is twofold: first, that analytical validation is not the appropriate test for comparisons; and second, that the advertisement relies on outdated data. D.I. 62 at 13-15.

Tempus fails to show that the analytical validation studies do not establish that Guardant360 performs better in limit of detection at 95% sensitivity. Both parties agree that analytical validation is a laboratory process to ascertain a test’s performance specifications, such as limit of detection. Beyond Tempus’s reliance on conclusory assertions concerning the necessity of head-to-head data, Tempus has not demonstrated that analytical validation studies lack sufficient reliability or that the results do not establish that Guardant360 has a lower limit of detection than Tempus’s xF+ at 95% sensitivity. *See* D.I. 64 ¶¶ 14-15. Based on the record evidence, it appears that analytical validation is a relevant test to show test sensitivity. *Cf. Castrol, Inc.*, 977 F. 2d at 63-64 (claims found to be literally false because the tests presented were irrelevant to party’s claim). Furthermore, Guardant represents that these results were derived from Tempus’s own studies (D.I. 84-1, Ex. B) and are routinely used by licensing agencies, regulatory submissions and evaluations for clinical trials because they provide “a common yardstick” for

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<sup>5</sup> As stated *supra* n.2, Tempus separated a single ad to address the alleged false claims individually. After considering the parties’ arguments, the Court will address the exhibits collectively.

comparing the performance of various tests. D.I. 82 at 5. At this time, Tempus has not demonstrated that the analytical validation studies fail to support Guardant’s position.<sup>6</sup> While ongoing discovery may reveal additional evidence bearing on a finding of literal falsity, the record as it now stands is insufficient to grant the extraordinary relief of a preliminary injunction. Therefore, Tempus has failed to meet its burden to show that the establishment claim is false<sup>7</sup>.

For Exhibit D, Tempus’s argument is directed to Guardant’s claim that “Guardant360 evaluates more biomarkers with higher sensitivity than Tempus xF+.” For Exhibit E, Tempus directs its argument towards the claims, “[f]ind more with Guardant,” the percentages of “[m]utations identified on Guardant360 below Tempus xF+’s limit of detection,” and “[c]omparison against over 400,000 patient samples tested by Guardant360 CDx or Guardant360 liquid biopsy.” D.I. 62 at 12-13. Similar to Exhibit C, Tempus contends that the claims about Exhibits D and E are outdated and unsupported by scientific data because they are derived from analytical validation studies rather than “properly designed, head-to-head studies.” D.I. 62 at 13. For the same reasons discussed above with respect to Exhibit C, Tempus has not presented sufficient evidence to demonstrate that the claims found in Exhibits D and E are literally false.

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<sup>6</sup> The Court further observes that an email from a Tempus representative to a medical personnel (D.I. 101-1), upon which Tempus relies on in its reply brief (D.I. 98), draws the same side-by-side comparison of Guardant 360 and Tempus xF+ performance specifications that Tempus contends is false, thereby further undermining Tempus’s claim.

<sup>7</sup> The Court is unpersuaded by Tempus’s argument that the advertisement relies on outdated analytical validation data because the new data was published in April 2025, which is after the advertisement’s publish date of December 2024. Tempus does not dispute that the advertisement contains its own published specifications. See D.I. 62-1, Ex. C (“based on publicly available information on tempus.com as of September 2024”). Additionally, Guardant avers that, in light of the new data, the ad was discontinued.

## ii. Exhibits H and J

With respect to Exhibit H, Tempus contends that the statement, “[d]on’t miss actionable biomarkers by compromising on sensitivity,” repeats the claim that Tempus xF+ is less sensitive and is literally false. However, neither the statement nor the advertisement mentions Tempus. The statement is not an affirmative statement that Tempus, or any particular competitor’s liquid biopsy test, is more or less sensitive. The Court notes that the parties appear to be largely in agreement on this point. *Compare* D.I. 62 at 4 (“a test with higher sensitivity reports fewer false negatives”), *with* D.I. 82 at 5 (“a test with lower sensitivity will miss more actionable biomarkers than a test with higher sensitivity”). Tempus fails to show that any statement contained in Exhibit H is false and, on its face, the Court finds there is nothing false about Guardant’s statement. *See Schering-Plough Healthcare Prods., Inc. v. Neutrogena Corp.*, 702 F. Supp. 2d 253, 263-64 (D. Del. 2010).

Moreover, Tempus’s complaints about the statements in Exhibit J - “[d]on’t risk missing patients with a less sensitive test” and “[f]rom over 400,000 patient samples tested with Guardant360 CDx or Guardant360 liquid biopsy” - fail for the same reasons discussed in the foregoing analysis of Exhibits H and C–E. Tempus makes no attempt to show any of the specific statements or figures in this advertisement are literally false.

## iii. Exhibit I

Although Tempus characterizes Exhibit I as an advertisement at issue and as a part of Guardant’s Liquid Ads, Tempus does not make any specific arguments that any statements therein are literally false. Therefore, Tempus has not met its burden to show literal falsity for Exhibit I. *See ECB USA, Inc. v. Savencia, S.A.*, No. 19-731, 2020 WL 5369076, at \*4 (D. Del. Sept. 8, 2020) (“As a general prudential rule, courts only decide issues that are fairly and fully presented. Therefore, cursory arguments not fully developed by the parties are waived.”); *Purewick Corp. v.*

*Sage Prods., LLC*, 666 F. Supp. 3d 419, 441 (D. Del. 2023) (“[A]rguments . . . not squarely argued[] are considered [forfeited].”) (some alterations in original).

#### iv. Exhibit L

Exhibit L is a newsletter discovered by a Tempus sales representative in a physician’s office. D.I. 62 at 9. Tempus claims that the newsletter falsely states that “Tempus did in fact miss mutations in lung and breast cancer patients.” *Id.* at 9; D.I. 63-1, Ex. L. Tempus also challenges as false the claim: “When it comes to giving your patients more SUNNY days with their loved ones, use Guardant360 Liquid to find more patients with targetable alterations!” *Id.* (emphasis in original). In addition to asserting the claims are not false, Guardant contends that the newsletter was not “widely disseminated,” as it was created and circulated by one Guardant sales representative to a limited audience of less than twenty potential customers. D.I. 82 at 14.

“The ‘touchstone’ of whether a defendant’s statements amount to the requisite commercial advertising or promotion is ‘that the contested representations are part of an organized campaign to penetrate the relevant market.’” *Shure Incorporated & Shure Acquisition Holdings, Inc. v. Clearone, Inc.*, No. 19-1343, 2020 WL 2839294, at \*6 (D. Del. June 1, 2020) (citing *Progressive Sterilization, LLC v. Turbett Surgical, LLC*, No. 19-627, 2020 WL 1849709, at \*10 (D. Del. April 13, 2020)). “Proof of widespread dissemination within the relevant industry is a normal concomitant of meeting this requirement.” *Progressive Sterilization, LLC*, 2020 WL 1849709, at \*10. At most, the newsletter was distributed to a limited group of potential customers. Tempus has not shown that this newsletter was widespread or part of an organized campaign to penetrate the market. Moreover, the statements referencing “another liquid biopsy” do not identify Tempus and are ambiguous, as they are susceptible to more than one plausible meaning. *See CareDx, Inc.*, 2025 WL 2480117, at \*5. Thus, Tempus has not demonstrated that the claims are literally false.

**b. Tempus Fails to Show a Likelihood of Success Against the Guardant Tissue Ads**

Tempus contends that Guardant's Tissue Ads are also literally false. D.I. 62 at 15. First, Tempus argues that Guardant's Tissue Ads contain "lower published requirements for tissue samples [that are] without head-to-head testing." *Id.* at 16. Also, Tempus contends that, the claim stating "lowest industry-wide sample requirements mean[] results for more patients," lacks scientific support because there is no head-to-head study. *Id.* Tempus further contends that substantiation of this claim would require Guardant to test the same or similar samples and compare the results, which Guardant has not done. *Id.* Tempus also contends that Guardant's advertisement claiming that the number of slides alone determines the ability to report a result is false because results depend on the quality of the tissue sample rather than the number of slides. *Id.* Lastly, Tempus contends there is no valid scientific basis for drawing conclusions regarding the number of patients who may receive test results from one company's test as compared to another. *Id.*

In response, Guardant addresses each alleged claim contained in Guardant's Tissue Ads. First, Guardant responds that Exhibit M, the only advertisement that mentions Tempus, "accurately states Guardant360 Tissue requires 6 slides whereas Tempus and other competitors require 10 slides." D.I. 82 at 14. Guardant further responds that the advertisement is supported by the Tomlins publication (D.I. 83-1, Ex. A) and Tempus's own marketing materials (D.I. 83-1, Ex. B). *Id.* Guardant also responds that the claim, "the lowest sample requirement, more patients get results," is also supported by the Tomlins publication and the accurate comparison of published tissue sample requirements. *Id.* Thus, Tempus fails to show that the claims are literally false.

Guardant further responds that Tempus's contention that the claims are misleading fails, because Tempus fails to identify any ambiguity or evidence of deception. *Id.* Guardant also responds that its claims regarding the number of slides accurately reflect Tempus's published requirements and are not misleading merely because Tempus claims it also processes orders with fewer slides. *Id.* Guardant notes that Tempus does not mention or demonstrate that Exhibits N–O and U–V are literally false in its Motion. *Id.*; 63-1 Exs. N–O and U–V. Guardant also responds that the advertisements do not mention Tempus and refer to an industry standard sample size requirement. *Id.* at 16.

After consideration of both parties' contentions and the record as it exists, the Court finds that Tempus has failed to show that Guardant's Tissue Ads are literally false. Tempus advances the same contentions regarding the lack of scientific support and the necessity of head-to-head testing, without providing sufficient evidence that such testing is, in fact, required. *See Schering-Plough Healthcare Prods., Inc.*, 702 F. Supp. 2d at 272 (stating that the movant has the burden of showing tests do not establish what is claimed). With respect to Exhibit M, the evidence presented shows that Guardant360 Tissue calls for six slides (D.I. 84-1, Ex. C) and there is a 40% reduction in slide usage relative to Tempus and other competitors' reported data of ten slides (D.I. 84-1, Exs. D–F). Tempus does not rebut its usage of ten slides, nor does it show that its test requires less than ten slides. Instead, Tempus contends that the claim is misleading because "Tempus reports a result whenever its quality control measures allow it to do so" and Tempus also receives samples fewer than Guardant's six slide threshold. D.I. 62 at 9, 17. However, Tempus has provided no evidence demonstrating that the claim is likely to mislead and confuse relevant consumers: physicians. *See Sandoz Pharms. Corp. v. Richardson-Vicks, Inc.*, 902 F.2d 222, 229-30 (3d Cir. 1990) ("[A] target audience's special knowledge of a class of products is highly relevant to any claim that it was

misled by an advertisement for such a product.”). Tempus fails to advance specific arguments related to Exhibits N–O and U–V. However, the advertisements’ claims are substantially similar to those in Exhibit M and fail for the same reason.

For these reasons, the Court finds that Tempus has failed to establish a likelihood of success on the merits of proving the literal falsity of Guardant’s advertisements.

### **B. Tempus Fails to Show Irreparable Harm**

Given Tempus’s failure to demonstrate a likelihood of success on the merits of literal falsity, Tempus is not entitled to a rebuttable presumption of irreparable harm, and the Court need not reach the issue of irreparable harm. *See* 15 U.S.C. § 1116(a); *see also Ferring Pharms., Inc. v. Watson Pharms., Inc.*, 765 F.3d 205, 210 (3d Cir. 2014) (“The failure to establish any element . . . renders a preliminary injunction inappropriate.”). However, to develop a more fulsome record, the Court will briefly address it.

“To establish irreparable harm, there must be a clear showing of immediate irreparable injury, or a presently existing actual threat.” *Golden Fortune Imp. & Emp. Corp. v. Mei-Xin Ltd.*, No. 22-1710, 2022 WL 3536494, at \*5 (3d Cir. Aug. 5, 2022); *ECRI v. McGraw-Hill, Inc.*, 809 F. 2d 223, 226 (3d Cir. 1987). Irreparable harm is harm that “cannot be redressed by a legal or equitable remedy following a trial.” *Instant Air Freight Co. v. C.F. Air Freight, Inc.*, 882 F. 2d 797, 801 (3d Cir. 1989). In other words, “[i]rreparable harm ‘must be of a peculiar nature, so that compensation in money alone cannot atone for it.’” *Opticians Ass’n of Am. V. Indep. Opticians of Am.*, 920 F. 2d 187, 195 (3d Cir. 1990) (citation omitted). The harm must be immediate and not speculative. *See Campbell Soup Co. v. ConAgra, Inc.*, 977 F. 2d 86, 91 (3d Cir. 1992); *Adams v. Freedom Forge Corp.*, 204 F. 3d 475, 488 (3d Cir. 2000). “Grounds for irreparable injury include loss of control of reputation, loss of trade, and loss of goodwill.” *Novartis Consumer Health, Inc.*,

290 F.3d at 596 (citing *Pappan Enters., Inc. v. Hardee's Food Sys., Inc.*, 143 F. 3d 800, 805 (3d Cir. 1998)).

Tempus contends that Guardant's false advertising has caused significant damage to its reputation and a loss of goodwill. D.I. 62 at 20. However, Tempus presents no evidence regarding harm to its reputation, loss of customers, loss of sales or market share. Guardant asserts that many of the advertisements at issue, such as Exhibits C–E, H, L, M and O, are no longer in circulation. D.I. 82 at 16. Therefore, the Court finds that any alleged harm would have already occurred, and the Court cannot grant relief for past injury. *Doe v. Delaware State Univ. Bd. of Trs.*, No. 20-1559, 2021 WL 2036670, at \*3 (D. Del. May 21, 2021) (“As these harms have already occurred, they cannot be *prevented* by injunctive relief. Even if the harms alleged can be *cured* by injunctive relief, they are amenable to such equitable relief whether ordered now or after Plaintiff potentially succeeds at trial.”)

To further demonstrate irreparable harm, Tempus contends that Guardant's advertisements concern medical misinformation implicating health and safety, which poses a “great threat” to Tempus's goodwill. D.I. 62 at 20. However, Tempus's evidence consists solely of two emails, which only show consumers seeking further information from Tempus about testing. D.I 63-1, Exs. Q & Y. Without more, this fails to establish loss of customers or goodwill. The irreparable harm asserted by Tempus rests on conclusory statements, which are insufficient and fail to meet the required showing. *Cnty. Legal Aid Soc'y, Inc. v. Adult & Prison Educ. Res. Workgroup*, No. 24-615, 2025 WL 1734992, at \*3 (D. Del. June 23, 2025) (“The party seeking injunctive relief bears the burden to provide clear evidence of irreparable harm, and arguments paired with conclusory allegations are insufficient to justify an injunction.”)

Lastly, Guardant highlights that Tempus admits to waiting almost a year after learning of the advertising campaign in December 2024 before filing this Motion. D.I. 82 at 17; D.I. 62 at 6. Tempus does not contest this fact. Rather than address the substance of Guardant's point, Tempus asserts that it advised Guardant of its intent to seek preliminary injunctive relief six weeks after Guardant's September 2025 production. D.I. 98 at 7. "[D]elay in seeking a remedy is an important factor bearing on the need for a preliminary injunction." *High Tech Med. Instrumentation, Inc. v. New Image Indus., Inc.*, 49 F. 3d 1551, 1557 (Fed. Cir. 1995). However, "a showing of delay does not preclude, *as a matter of law*, a determination of irreparable harm." *Hybritech Inc. v. Abbott Lab 'ys*, 849 F.2d 1446, 1457 (Fed. Cir. 1988). The Court finds that the unexplained delay between December 2024 and the filing of this Motion undermines any claim of urgency and further supports the Court's finding that Tempus has not established irreparable harm. *See Neology, Inc. v. Fed. Signal Corp.*, No. 11-672, 2012 WL 2308202, at \*16 (D. Del. June 18, 2012), *report and recommendation adopted*, No. 11-672, 2012 WL 3236718 (D. Del. Aug. 2, 2012).

For the reasons outlined above, the Court concludes that Tempus has failed to demonstrate irreparable harm.

#### **IV. CONCLUSION**

For the foregoing reasons, the Court denies Tempus's Motion for Preliminary Injunction (D.I. 61). The Court also denies-as-moot Tempus's Request for Oral Argument (D.I. 102).

An Order consistent with this Memorandum Opinion will be entered.