

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

TEMPUS AI, INC.,
Petitioner,

v.

GUARDANT HEALTH INC.,
Patent Owner.

Case No. IPR2025-01434
Patent No. 11,149,306

**PATENT OWNER'S BRIEF IN SUPPORT OF
DISCRETIONARY DENIAL**

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I. INTRODUCTION

Pursuant to the Memorandum on Interim Processes for PTAB Workload Management, Patent Owner Guardant Health, Inc. (“Guardant”) requests the Director exercise discretion to deny institution of inter partes review of U.S. Patent 11,149,306 (“the ’306 patent”).

The validity of the ’306 patent has already been adjudicated—the present IPR is yet another challenge. The ’306 patent has now been asserted in district court in multiple different cases. The ’306 patent also was challenged in IPR2022-01400 (“the 1400IPR”) where the Board upheld all claims as patentable in view of the prior art in a Final Written Decision.

The present petition provides no compelling reason for yet another adjudication of the ’306 patent’s validity. Petitioner has known about the ’306 patent for years, has already challenged its validity in the parallel district court case, and waited to the last day of 1-year statutory period to file this IPR challenge. Worse yet, the present petition offers nothing beyond old and unconvincing art it scraped together from the face of the ’306 patent. The Office already considered the same art multiple times during prosecution and the prior IPR challenge. Asking the Board to take yet another look at the same claims in view of weak and recycled art is both prejudicial to Patent Owner and a poor use of Board resources. Taken as a whole, the circumstances here counsel for discretionary denial.

II. THE DIRECTOR SHOULD EXERCISE DISCRETION TO DENY THE PETITION

Guardant is a leading precision oncology company that provides to patients a suite of blood-based (“liquid biopsy”) tests including the FDA-approved Guardant360® tests (e.g., CDx, Response, Liquid). EX2016, 1-3; EX2017, 1-3; EX2018, 1-2. Guardant360® tests rapidly (e.g., 7-10 days) identify genetic alterations associated with cancer, which allows doctors to tailor treatment plans for individual cancer patients. EX2016, 2. As the FDA explained in 2020 when it approved Guardant360® CDx “In addition to benefitting from less invasive testing, patients are provided with a simultaneous mapping of multiple biomarkers of genomic alterations, rather than one biomarker at a time, which can translate to decreased wait times for starting treatment and provide insight into possible resistance mechanisms.” EX2018, 1.

The Guardant360® tests have been well-received in the industry, resulting in improved outcomes for patients. For example, a study published in 2024 demonstrated Guardant360® CDx test allows patients to “receive targeted treatment tailored to them based on comprehensive genomic profiling results.” EX2019, 2. The study further demonstrated that “patients who received targeted treatment guided by liquid biopsy results lived approximately twice as long as those who did not.” *Id.* The benefits Guardant360® tests provide to patients has resulted in widespread adoption and, to date, over 500,000 tests have been

performed by Guardant. EX2020, 2; *see Belden Inc. v. Commscope, Inc.*, IPR2025-00833, Paper 13 at 2 (finding commercialization of the invention supports settled expectations). For its innovations, the Office has awarded Guardant a portfolio of over 120 patents, including the '306 patent that embodies Guardant's highly successful Guardant360® tests.

Unfortunately, competitors took notice of Guardant's success and improperly copied Guardant's technology. In 2017, Guardant filed a complaint against Foundation Medicine, Inc. ("FMI") (Case No.: 1:17-cv-01616) for infringement of multiple patents. FMI filed six IPR petitions challenging four patents, all of which failed except with respect to a handful of claims in one patent. That litigation settled, with FMI taking a license to Guardant's '306 patent among others. EX2021, 1. Guardant patents were also subject to litigation with Illumina, Inc. in Case No.: 1:22-cv-00334.

In 2022, Guardant asserted several patents in Case No.: 1:21-cv-01126 against Twinstrand Biosciences, Inc. ("Twinstrand"). Twinstrand filed six IPR challenges against Guardant patents, including the '306 patent, all of which failed completely. Five of those challenges were denied at the institution stage. The 1400IPR against the '306 patent reached FWD, where the Board upheld the validity of all claims.

Several years later, in 2024, Guardant asserted several patents (including the '306 patent) in Case No.: 1:24-cv-00687 against Tempus, the present petitioner. *See* EX2022. Tempus has been aware of Guardant's patents for years. For example, the parent to the '306 patent was cited to the Office by Tempus in their own patent prosecution on June 28, 2021. EX2003, 6 (listing US9,920,366); EX2004, (56) (listing US9,920,366). Despite the validity of the '306 patent already having been adjudicated, Tempus has pursued parallel invalidity challenges both at district court and at the PTAB. At district court, Petitioner filed a motion to dismiss alleging the '306 patent is invalid under 35 U.S.C. §101. Petitioner also filed district court invalidity contentions indicating it will pursue prior art invalidity theories, including challenges asserting the same prior art it now raises in this IPR.

A. Prior Adjudication of the '306 Patent Validity Favors Discretionary Denial

All claims of the '306 patent were challenged with the closest prior art and upheld in the 1400IPR. Petitioner Tempus now asks the Board to reconsider validity in view of less relevant art scraped from the face of the patent. But where, as here, the Board has “entered a final written decision finding the challenged claims not unpatentable in” a prior proceeding, discretionary denial should be exercised because “[i]t is not an efficient use of Board resources to further consider petitions challenging patents that have already been subject to challenges before

the Office or patents that already have had validity adjudicated...at the Board.”

Samsung Electronics Co. Ltd. V. VB Assets, LLC, IPR2025-00869, Paper 13 at 2-3;

see also Advanced Micro Devices, Inc. v. Advanced Cluster Systems, Inc.,

IPR2025-00862 Paper 14 at 3 (“repeated prior challenges weigh against institution”).

The Board upheld the claims of the ’306 in the 1400IPR because the closest prior art (Schmitt¹) does not teach: (1) tagging with a small number of molecular barcodes relative to a number of duplicate molecules; and (2) distinguishing paired and unpaired reads as claimed. EX1027, 21-22, 30. The Board’s analysis in the 1400IPR was no cursory review. There, the ’306 patent was heavily litigated, and the Board heard from at least five different technical experts in the field.² At least 78 different prior art references were considered by both the various experts and

¹ The 1400IPR was based on the same Schmitt reference Tempus is asserting in IPR2025-01435.

² Testifying experts in the 1400IPR included Dr. John Quackenbush from Harvard, Dr. Ian Hagemann from Washington University, Dr. Paul Spellman from Oregon Health & Science University, Dr. Rahul Satija from New York University, and Dr. Aleksandar Rajkovic from University of California at San Francisco.

the Board, including many of the same references now asserted here. The only prior art reference not expressly at issue in the 1400IPR was Bielas, but as discussed further below, Bielas was considered on at least three occasions by the Office during prosecution. Thus, it is of no surprise Petitioner's current Bielas-based challenge suffers at least the same defects (and more) as those identified by the Board in the 1400IPR.

B. Petitioner's Rehash of Second Tier Art Previously Rejected During Prosecution is Improper

As outlined in the memorandum providing for interim processes for PTAB workload management, "all relevant considerations" will be evaluated in determining whether to exercise discretionary denial consistent with existing Board precedent. *See* Memorandum, Interim Processes for PTAB Workload Management, 2 (Mar. 26, 2025). *Advanced Bionics, LLC v. Med-El Elektromedizinische Geräte GMBH*, IPR2019-01469, Paper 6 at 8-9 (precedential); *see also TankLogix, LLC v. SitePro, Inc.*, Paper 10 at 2-3 (discretionary denial favored where "the same prior art was previously presented to the Office" and Petitioner failed to demonstrate Office error). The Office previously considered the same art now presented and it was rejected as deficient even before the substantial adjudication of validity in the 1400IPR. The petition should be denied accordingly.

The current petition challenges the claims with the Bielas, Vogelstein, Hendricks, Diehn, ForsheW, and Hicks references. Each of these references was submitted to the Office and expressly considered during prosecution of the '306 patent. *E.g.*, EX1002, 289, 294, 327, 338, 346, 670, 724. These facts are sufficient to satisfy Step 1 of *Advanced Bionics. Ecto World, LLC v. Rai Strategic Holdings, Inc.*, IPR2024-01280, Paper 13 at 4 (precedential) (“Challenging the claims using the same prior art that was previously presented on an IDS is sufficient to satisfy the first part of the *Advanced Bionics* framework.”).

Petitioner acknowledges (p. 19) that every ground reference was cited during prosecution yet argues *Advanced Bionics* Step 1 is not satisfied. Not only is this argument contrary to the Director’s guidance in *Ecto World*, but it is based on a mischaracterization of the file history and misapprehension of other Board precedential decisions.

Regarding the file history, Petitioner argues the grounds references were buried amongst 750 references. This is flatly false and an inexcusable mischaracterization of the record. Petitioner’s main reference—Bielas—was submitted to the Office no fewer than three times. In particular, Bielas was considered as US2021/0222243 in an IDS on August 19, 2021. EX1002, 774. In this IDS, Bielas was the *only reference* and was submitted along with a search report for a European counterpart of the '306 patent—EP Application No.

20183626.9 (“EP626”). EX1002, 725; *see also* EX2002, 5-7. Petitioner’s file history exhibit omits the EP626 search report even though it was submitted to the Office in its entirety. *See* EX2001, 1191-1202. The EP626 search report includes Bielas as WO2013123442 where even the EPO characterized the reference as “A” —i.e., not a reference that is relevant to the claims but one that provides “technological background.” EX2001, 1192. WO2013123442 was additionally submitted in an IDS amongst 50 other foreign patent documents on July 31, 2020. EX1002, 346. Bielas was submitted yet another time as US2015/0024950 in an IDS on July 31, 2020. EX1002, 338. Patent Owner did not bury any reference. Rather, Patent Owner specifically called attention to Bielas by submitting it in a single-reference IDS and by submitting the European search report in which it is mentioned, in addition to the *two other* times it was also submitted.

Petitioner argues there is “no evidence” that its grounds references were “substantively considered.” This too is false. The Examiner initialed each IDS stating: “all references considered except where lined through.” *E.g.*, EX1002, 289, 294, 327, 338, 346, 670, 724; *see also* *Rexnord Corp. v. Laitram Corp.*, 274 F.3d 1336, 1347 (Fed. Cir. 2001) (examiner presumed to follow rules prescribed by MPEP). None of the asserted references was lined through.

Petitioner argues with citation to *Oticon* that Step 1 of *Advanced Bionics* is not satisfied because the particular combinations of art asserted in the petition were

not considered by the Examiner. Petitioner's argument is in direct conflict with *Ecto World* and finds no support in *Oticon* either. *Oticon* is inapposite at least because it addresses a petition that asserted "new, noncumulative prior art." *Oticon Medical AB et al. v. Cochlear Limited*, IPR2019-00975, Paper 15 at 20 (precedential). Here, there is no new art asserted.

Petitioner alleges (p. 20) that the Office "overlook[ed] the teachings of the references cited in the Grounds herein." Petitioner's allegation lacks merit at least because the asserted combination does not describe each and every limitation of the claims. Nor does the petition argue it does—certain claim limitations are simply ignored in the petition. For example, in service of indefiniteness arguments in the parallel litigation, Petitioner has opted to forego identifying prior art disclosure of tagging cfDNA molecules with a small number of molecular barcodes relative to the number of duplicate molecules in a sample ("...cfDNA molecules are tagged with n different combinations of molecular barcodes, wherein n is at least 2 and no more than $100,000 * z$, wherein z is a mean of an expected number of duplicate molecules ..."). See Pet. 27-30 (claim 1), 37-38 (claim 7); EX1003, ¶¶145-150, 167-169; see also *infra* §III. Having made the decision to forego addressing the claims in their entirety, Petitioner cannot now demonstrate that the Office committed material error, much less obviousness.

Discretionary denial is appropriate here. The Office has considered Petitioner's prior art and rejected it. If anything, the petition materials confirm the propriety of the Office's conclusions in this regard.

C. The Current IPR is Even Weaker than the 1400IPR

As discussed above, the Board upheld the claims of the '306 in the 1400IPR finding the closest prior art did not teach: (1) tagging with a small number of molecular barcodes relative to a number of duplicate molecules; and (2) distinguishing paired and unpaired reads as claimed. EX1027, 21-22, 30. The current Bielas-based challenge is even worse.

Petitioner's challenge is weaker than 1400IPR at least because it fails to identify any prior art disclosure of tagging cfDNA molecules with a small number of molecular barcodes relative to the number of duplicate molecules in a sample. As discussed above in §II.B, the petition materials (pp. 28-30) point to disclosure of numbers of cyphers as meeting the number of molecular barcodes "n" but never address "z." *See also* Pet. 37-38 (mapping number of barcodes onto "z is between 2 and 8"). Having ignored part of the claim language, Petitioner cannot show the asserted obviousness combination teaches tagging as claimed. *See also infra* §III.

Bielas also does not describe distinguishing paired and unpaired reads as claimed. If anything, its disclosure is even more deficient in this regard than prior art asserted in the 1400IPR. Here, Petitioner relies solely on a phrase from the caption of Fig. 3B as meeting the paired reads

requirement. Pet. 33 (citing EX1005, 4:10-12). Bielas describes Fig. 3B at 4:10-12 as depicting “[a]ll sequencing reads having identical cypher pairs, along with their reverse complements, were grouped into families.” But this is not disclosure of paired

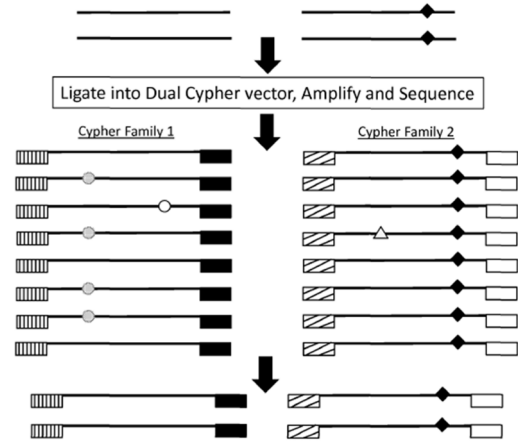


Fig. 3B

reads as claimed. The natural structure of DNA is a double-helix comprising complementary strands. That is, all DNA molecules, including PCR amplification products and even paired-end Illumina reads, comprise a reverse complement.

Identification of a generic read and its reverse complement is not disclosure of “a first tagged strand and a second tagged complementary strand derived from cfDNA molecules.” Nothing in the petition materials demonstrates otherwise.

Furthermore, Bielas reports using the same cypher on both reads and their reverse complements so they can be grouped together—not distinguished. For example, in Fig. 3B, all grouped reads are identical (other than sporadic errors). Petitioner annotates Fig. 3B to place boxes around “paired reads” but Bielas itself

does not make this distinction. *E.g.*, Pet. 34; *see also* EX1003 ¶158. This is pertinent here because Petitioner is asserting in the district court that the claims require determining distinct cfDNA molecules using information identifying sequence reads as paired reads or unpaired reads, i.e., the determination is not agnostic to whether the reads are paired or unpaired. EX2015; *see also infra* §III. Bielas does not do this; it is blind to whether its reads are paired or unpaired. *See, e.g.*, EX1005, Fig. 3B. The addition of Vogelstein changes nothing. If Bielas cannot see paired reads, it cannot see unpaired reads either.

In sum, Bielas does not cure any deficiencies the Board identified in Schmitt in relation to the claimed invention. Moreover, Petitioner provides no “persuasive reasoning”—and, indeed, no reasoning—why the Board should expend valuable resources to re-litigate the patentability of the *same* claims in view of less pertinent art. *Webgroup Czech Republic, A.S. v. Dish Techs. LLC*, IPR2025-00467, Paper 14 at 2-3; *see also* Prior Adjudication Memo (“if the Board reaches an initial or final decision on a finding of fact or conclusion of law that is different than the prior finding or conclusion of the Office, ..., the Board shall explain in the institution or final written decision why a different outcome is warranted.”).

III. PETITIONER’S IMPROPER AND INCONSISTENT CLAIM CONSTRUCTION ARGUMENTS FAVOR DISCRETIONARY DENIAL

Petitioner argues (pp.13-14) it “does not believe any terms require construction” and its expert does not purport to have any difficulty understanding the challenged claims under their plain and ordinary meaning. EX1003, ¶32 (“claim terms are presumed to take on the ordinary and customary meaning”).

At district court, however, Petitioner asserts that the scope of the claims of the ’306 are indeterminable and unpatentably indefinite based on multiple recited terms. For other terms, Petitioner has argued narrow interpretations, presumably in hopes of escaping infringement. None of these district court claim construction arguments or positions are disclosed in the petition materials, let alone accounted for in the prior art mapping allegations of the petition. In fact, it is not clear how Petitioner’s claim construction positions are reconcilable with their petition challenge.

Petitioner’s district court positions regarding claim terms recited in independent claims 1 and 17 are reproduced below. *See* EX2015, 2-3. Petitioner also alleges at district court that the term “unpaired reads corresponding to sequence reads generated from a first tagged strand having no second tagged complementary strand derived from cfDNA molecules from among the tagged parent polynucleotides” recited in independent claims 1 and 17 is indefinite.

<p>“cell-free DNA” (‘992 claim 1) / “cell-free deoxyribonucleic acid (cfDNA)” (‘306 claims 1 and 17) / “cfDNA” (‘693 claim 14)</p>	<p>DNA that exist(s) within a bodily fluid within the body outside of a cell and in solution, including in blood, plasma, serum, urine, saliva, mucosal excretions, sputum, stool or tears</p>
<p>“at least [20%/50%/80%] of the cfDNA molecules” (‘992 claims 1, 11, 12) / “at least 20% of the cfDNA molecules” (‘306 claim 4) / “at least 40% of the cfDNA molecules” (‘306 claim 6)</p>	<p>from [20%/40%/50%/80%] to 100% of the cfDNA molecules</p>
<p>“molecular barcode” (‘306 claims 1 and 17)</p>	<p>a nucleotide sequence that distinguishes one polynucleotide from another</p>
<p>“wherein the plurality of the cfDNA molecules are tagged with n different combinations of molecular barcodes, wherein n is at least 2 and no more than 100,000*z, wherein z is a mean of an expected number of duplicate molecules in the population of cfDNA molecules that map to identical start and stop positions on a reference sequence” (‘306 claim 1)</p>	<p>Indefinite</p>
<p>“the amplified progeny polynucleotides” (‘306 claims 1 and 17) / “the amplified tagged progeny polynucleotides” (‘916 claims 1, 13, 30)</p>	<p>the polynucleotides generated by amplification of the tagged parent polynucleotides</p>
<p>“distinct cfDNA molecules are determined based on (i) paired reads . . . or (ii) unpaired reads” (‘306 claim 1)</p>	<p>distinct cfDNA molecules are determined using information identifying sequence reads as paired reads or unpaired reads, i.e., the determination is not agnostic to whether the reads are paired or unpaired</p>
<p>“sequence information at the start and stop positions” (‘306 claims 13 and 24)</p>	<p>Indefinite</p>

Where Petitioner has proposed constructions at district court, those constructions are not presented in the petition materials and, in some instances, are irreconcilable with the claim mapping presented in the petition. For example, at

district court Petitioner argues the step e “wherein” clause of claim 1 requires determining cfDNA molecules in a manner that is not agnostic to whether the reads are paired or unpaired. Yet, the petition maps (pp. 33-35) this claim element to disclosure in Bielas and Vogelstein that makes no mention of distinguishing between paired or unpaired reads. *See supra* §II.A. The present petition does not explain this inconsistency—or address Petitioner’s different district court constructions and arguments at all—burdening Patent Owner and the Board with resolving the conflicting argument.

Asking the Board to sort through different constructions in a petition compared to those being advocated at district court for infringement purposes is not only improper, but a poor use of Office resources. Indeed, the Federal Circuit has explained that “claims must be interpreted and given the same meaning for purposes of both validity and infringement analyses.” *Amazon.com, Inc. v. Barnesandnoble.com, Inc.*, 239 F.3d 1343, 1351 (Fed. Cir. 2001). Petitioner’s inconsistent arguments and theories are best resolved at district court to better ensure the district court can properly address validity and infringement under the same construction. *Sun Pharms. Indust., Inc. v. Nivagen Pharms., Inc.*, IPR2025-00893, Paper 18 at 2-3 (granting discretionary denial where “Petitioner has taken different claim construction positions in this proceeding and the parallel district court proceeding”).

Regarding the various district court allegations of indefiniteness, Petitioner states (*e.g.*, p. 28 n.11) that it “expressly reserves the right to argue that this claim element is indefinite in the co-pending district court litigation.” *See also* EX1003, ¶146 (“Without taking a position on whether one of ordinary skill in the art would have understood the ‘z’ term ...”). But Petitioner simply cannot meet its burden of proving invalidity as alleged where it expressly “takes no position in this Petition as to whether the claims meet the requirements of Section 35 U.S.C § 112.” *See* Pet. 14. Indeed, Petitioner did clearly take the position at district court that the same claims are allegedly indefinite and of indeterminable scope. The petition offers no explanation how it could possibly meet its burden of showing the challenged claims encompass the prior art where it asserts the metes and bounds of those same claims is indeterminable. *Cambridge Mobile Telematics, Inc. v. Sfara, Inc.*, IPR2024-00952, Paper 12 at 8 (“At a minimum, the Petition should have explained...why the inconsistent positions are warranted...”). Instead, the petition offers no explanation at all and ignores entirely its inconsistent district court arguments that the metes and bounds of the challenged claims are unknown. As discussed above (*see supra* §II.B), Petitioner does not even bother to map allegedly indefinite terms to the prior art—it ignores those too. Having made its choice to pursue its indefiniteness theory, Petitioner presents improper and incomplete prior

art invalidity arguments in its petition that are nothing more than a waste of Board resources.

IV. CONCLUSION

For at least the reasons above, Patent Owner respectfully requests that the Director exercise discretion to deny institution of the petition.

Respectfully submitted,

Date: October 20, 2025

/ Michael T. Rosato /
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V. APPENDIX

Exhibit No.	Description
2001	Excerpts from File History of U.S. Patent Application No. 16/945,124 (issued as U.S. Patent No.11,149,306)
2002	Excerpts from File History of EP Application No. 20183626.9
2003	Information Disclosure Statement App. No. 17/179,279 which issued as U.S. Patent No. 11,221,144
2004	U.S. Patent No. 11,211,144 to Zhu
2005-2014	Intentionally left blank
2015	Tempus Proposed Claim Constructions, <i>Guardant Health, Inc., v. Tempus AI, Inc.</i> , Case 1:24-cv-00687
2016	Guardant Health Introduces Major Smart Liquid Biopsy Upgrade to Market – Leading Guardant 360 Test, Further Extending its Best-In-Class Performance. https://investors.guardanthealth.com/press-releases/press-releases/2024/Guardant-Health-Introduces-Major-Smart-Liquid-Biopsy-Upgrade-to-Market-Leading-Guardant360-Test-Further-Extending-Its-Best-in-Class-Performance/default.aspx (last viewed on October 20, 2024)
2017	Guardant Health to Showcase New Data at ESMO 2022 Demonstrating Utility of its Portfolio of Blood Tests for Advanced – Stage Cancer Patients. https://investors.guardanthealth.com/press-releases/press-releases/2022/Guardant-Health-to-showcase-new-data-at-ESMO-2022-demonstrating-utility-of-its-portfolio-of-blood-tests-for-advanced-stage-cancer-patients/default.aspx (last viewed on October 20, 2024)
2018	FDA Approves First Liquid Biopsy Next-Generation Sequencing Companion Diagnostic Test. News Provided by U.S. Food and Drug Administration https://www.prnewswire.com/news-releases/fda-approves-first-

	liquid-biopsy-next-generation-sequencing-companion-diagnostic-test-301108536.html (last viewed October 20, 2024)
2019	GOZILA Study Published in Nature Medicine Shows Patients with Advanced Cancer Who Receive Liquid Biopsy – Guided Treatment Using Guardant360 CDX Survive Twice as Long. https://investors.guardanthealth.com/press-releases/press-releases/2024/GOZILA-Study-Published-in-Nature-Medicine-Shows-Patients-With-Advanced-Cancer-Who-Receive-Liquid-Biopsy-Guided-Treatment-Using-Guardant360-CDx-Survive-Twice-as-Long/default.aspx (last viewed October 20, 2024)
2020	Guardant Health Named to TIME100 Most Influential Companies. https://investors.guardanthealth.com/press-releases/press-releases/2024/Guardant-Health-Named-to-TIME100-Most-Influential-Companies/default.aspx (last viewed October 20, 2024)
2021	Guardant Health and Foundation Medicine Reach Settlement in Digital Sequencing Technology Litigation. https://investors.guardanthealth.com/press-releases/press-releases/2022/Guardant-Health-and-Foundation-Medicine-Reach-Settlement-in-Digital-Sequencing-Technology-Litigation/default.aspx (last viewed October 20, 2024)
2022	Guardant Health, Inc.’s First Amended Complaint, <i>Guardant Health, Inc., v. Tempus AI, Inc.</i> , Case 1:24-cv-00687

CERTIFICATE OF SERVICE

The undersigned certifies that the foregoing Patent Owner's Brief In Support of Discretionary Denial and accompanying Exhibits 2001-2004 and 2015-2022 were served on October 20, 2025, on the Petitioner at the electronic correspondence address of the Petitioner as follows:

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Dated: October 20, 2025

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