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**UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF CALIFORNIA**

TEMPUS AI, INC.,

Plaintiff,

v.

GUARDANT HEALTH, INC.,

Defendant.

Civil Action No. '25CV0621 JO MMP

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**COMPLAINT FOR PATENT INFRINGEMENT**

Plaintiff Tempus AI, Inc. (“Tempus”) brings this Complaint against Defendant Guardant Health, Inc. (“Guardant”), and alleges as follows:

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**SUMMARY OF THE ACTION**

1. Tempus is a healthcare technology company advancing precision medicine through the practical application of artificial intelligence (“AI”). Tempus was founded in 2015 by Eric Lefkofsky after his wife was diagnosed with cancer. In the years since its founding, the company has helped to further medical care by combining real-world data from laboratory tests with other clinical datasets and AI to enhance the diagnosis and treatment of, and research into, multiple major diseases. Tempus’s AI-enabled precision medicine solutions bring to bear one of the world’s largest libraries of multi-modal data to enable personalized patient care while also facilitating discovery and development of new therapies, particularly in cancer.

2. Guardant was founded by Helmy Eltoukhy and AmirAli Talasaz in 2011. Guardant’s initial focus was on the development of liquid biopsy tests, including the original Guardant360, which was Guardant’s first, and to this day, most well-known product. Despite some early success, Guardant’s oncology business has stagnated. Unable to fairly compete in the marketplace with its own technology, Guardant has instead sought to emulate Tempus by introducing healthcare records platforms that leverage the power of AI and multi-source data. Guardant’s copy-cat platforms, which include GuardantINFORM, Guardant Galaxy, Guardant INFINITY, and the integrated

28  
GUARDANT - EXHIBIT 1034

1 Guardant360 TissueNext and Guardant360 CDx biopsy tests, infringe Tempus’s patented  
2 inventions.

3 3. Tempus brings this civil action under the patent laws of the United States, 35 U.S.C.  
4 §§ 1, *et seq.*, including 35 U.S.C. § 271, in response to Guardant’s past and ongoing infringement  
5 of U.S. Patent Nos. 12,112,839 (the “’839 Patent”), 11,640,859 (the “’859 Patent”), 10,957,041 (the  
6 “’041 Patent”), and 10,991,097 (the “’097 Patent”) (collectively, the “Patents-in-Suit”).

7 4. Through this case, Tempus seeks to put a stop to Guardant’s unlawful acts and to  
8 seek redress for the harm caused by Guardant’s infringement.

9 **THE PARTIES**

10 5. Tempus is a corporation organized and existing under Delaware law with a place of  
11 business at 600 West Chicago Avenue, Chicago, IL 60654.

12 6. Guardant is a corporation organized and existing under Delaware law with places of  
13 business at 10578 Science Center Drive, San Diego, CA, and 3100 Hanover Street, Palo Alto, CA  
14 94034.

15 **JURISDICTION AND VENUE**

16 7. This civil action arises under the patent laws of the United States, 35 U.S.C. § 1 *et*  
17 *seq.*, including 35 U.S.C. §§ 271, 281, 283, 284, and 285. The Court has subject matter jurisdiction  
18 over the claims asserted herein under 28 U.S.C. §§ 1331 and 1338(a).

19 8. The Court has personal jurisdiction over Guardant because Guardant is subject to  
20 general and specific jurisdiction in the state of California. Guardant is subject to personal  
21 jurisdiction at least because Guardant has regular and established places of business in California,  
22 has minimum contacts with California such that the maintenance of this suit does not offend  
23 traditional notions of fair play and substantial justice, and has committed acts of patent infringement  
24 in this District by offering, selling and using Guardant’s platforms of oncology testing related  
25 products, which include Guardant Galaxy, Guardant INFINITY, Guardant360 TissueNext,  
26 Guardant360 CDx, GuardantINFORM, and any other infringing method, product, device, or test  
27 developed by Guardant that applies Tempus’s patented systems and methods (together, the  
28 “Accused Products”).



1 things) molecular, clinical, and imaging data. These platforms, with their novel, multi-dimensional  
2 view of relevant data, enable physicians, academic medical centers, universities, pharmaceutical  
3 companies, biotechnology companies, and others to improve decision making across health  
4 research, drug development, product development, and patient treatment.

5 13. In the context of cancer treatment, for instance, Tempus’s proprietary analytical  
6 platform was designed to access and analyze patients’ clinical histories, including laboratory test  
7 results (such as from liquid and tissue biopsies), and imaging results (such as CT or other scans).  
8 Tempus’s approach merges these complex and enormous datasets, allowing physicians, researchers,  
9 and biopharmaceutical partners to uncover deeper insights about cancer diagnostics and treatment.

10 14. Through its innovative AI-driven platform, Tempus offers an array of laboratory  
11 tests, including liquid biopsy, solid tumor, hereditary cancer detection, minimal residual disease  
12 (MRD), and a suite of algorithmic tests designed to assist treating physicians across the timeline of  
13 cancer detection, treatment, and response monitoring. Tempus also maintains diverse product lines  
14 outside its laboratory testing business. Tempus licenses its de-identified data to third parties for a  
15 variety of purposes, including for advancement of precision-medicine research, in support of clinical  
16 trial matching, and for use in cutting-edge AI healthcare applications. Tempus products help  
17 physicians identify the right treatment at the right time for a particular patient based on the patient’s  
18 own unique genomic composition.

19 15. Tempus offers a series of AI-enabled applications, such as Tempus One, the first AI-  
20 enabled clinical assistant. With Tempus One, clinicians can obtain patients’ clinical and molecular  
21 profiles, along with an array of other datasets, to help inform clinical decision-making in real-time.

22 16. Tempus also offers a groundbreaking data and analytics cloud-based computing  
23 platform called Lens. Tempus Lens enables scientific discovery by providing researchers,  
24 clinicians, and other partners unprecedented access to over 35 petabytes of de-identified clinical and  
25 molecular datasets. The potential applications of the Lens platform are limited only by the creativity  
26 of its users. Tempus’s pharmaceutical partners can use the platform to validate drug targets as part  
27 of drug development and discovery. Researchers can use it to characterize genetic disease.  
28 Clinicians can use it to design customized clinical trials for particular patient populations.

1           17.     Tempus additionally offers Tempus Hub, an AI-enabled platform designed to make  
2 it easier and more efficient for clinicians to access their patients’ profiles to better inform care.

3           18.     As a result of Tempus’s extensive investments in research and development and its  
4 commitment to intellectual property, Tempus possesses a substantial patent portfolio. Over the  
5 years, the United States Patent and Trademark Office (“USPTO”) has granted Tempus a number of  
6 United States patents covering its inventions, including but not limited to those identified below and  
7 asserted against Guardant in this case.

8 **II.     The Tempus Patents-in-Suit**

9           **A.     U.S. Patent No. 11,640,859 and U.S. Patent No. 12,112,839**

10          19.     The ’859 Patent is titled “Data Based Cancer Research and Treatment Systems and  
11 Methods” and was duly and legally issued from the USPTO on May 2, 2023. Tempus owns the  
12 ’859 Patent, including the right to enforce it and seek damages for infringement. A true and correct  
13 copy of the ’859 Patent is attached as Exhibit 1.

14          20.     The ’839 Patent is titled “Data Based Cancer Research and Treatment Systems and  
15 Methods” and was duly and legally issued from the USPTO on October 8, 2024. Tempus owns the  
16 ’839 Patent, including the right to enforce it and seek damages for infringement. A true and correct  
17 copy of the ’839 Patent is attached as Exhibit 2.

18          21.     The ’839 Patent is a continuation of U.S. Application No. 16/657,804 (the ’804  
19 Application”), which issued as U.S. Patent No. 11,705,226.

20          22.     On January 6, 2023, the applicant of the ’804 Application filed a terminal disclaimer  
21 over U.S. Application No. 16/771,451, which issued as the ’859 Patent.

22          23.     The ’839 and ’859 Patents generally disclose and claim methods for storing and  
23 structuring clinical and genomic sequencing patient data for specific application programs. The  
24 methods involve “obtaining and employing data related to physical and genomic patient  
25 characteristics as well as diagnosis, treatments and treatment efficacy to provide a suite of tools to  
26 healthcare providers, researchers and other interested parties enabling those entities to develop new  
27 cancer state-treatment-results insights and/or improve overall patient healthcare and treatment plans  
28 for specific patients.” ’859 Patent at 1:30-37; ’839 Patent at 2:64-3:4.

1           24.     For example, independent claim 1 of the '859 Patent recites:

2           A method for conducting genomic sequencing, the method comprising the steps of:

3           storing a set of user application programs wherein each of the programs requires an  
4           application specific subset of data to perform application processes and generate user  
5           output;

6           for each of a plurality of patients that have cancerous cells and that receive cancer  
7           treatment:

8                   (a) obtaining clinical records data in original forms where the clinical records  
9                   data includes cancer state information, treatment types and treatment efficacy  
10                   information;

11                   (b) storing the clinical records data in a semi-structured first database;

12                   (c) for each patient, using a next generation genomic sequencer to generate  
13                   genomic sequencing data for the patient's cancerous cells and normal cells;

14                   (d) storing the sequencing data in the first database;

15                   (e) shaping at least a subset of the first database data to generate system  
16                   structured data including clinical record data and sequencing data wherein  
17                   the system structured data is optimized for searching;

18                   (f) storing the system structured data in a second database;

19                   (g) for each user application program:

20                           (i) selecting the application specific subset of data from the second  
21                           database; and

22                           (ii) storing the application specific subset of data in a structure  
23                           optimized for application program interfacing in a third database.

24           25.     Independent Claim 1 of the '839 Patent recites:

25           A method for conducting genomic sequencing, the method comprising the steps of:

26           storing a set of user application programs wherein each of the programs requires an  
27           application specific subset of data to perform application processes and generates a  
28           respective genomic variant characterization; and

          for each of a plurality of subjects that have cancerous cells and that receive cancer  
          treatment:

                 (a) obtaining clinical records data in original forms where the clinical records  
                 data includes cancer state information, treatment types and treatment efficacy  
                 information;

1 (b) for each subject, using a next generation genomic sequencer to generate  
2 genomic sequencing data for the subject's cancerous cells and normal cells;

3 (c) shaping at least a subset of the genomic sequencing data to generate  
4 system structured data;

5 (d) storing the system structured data in a first database; and

6 (e) for each user application program;

7 (i) selecting the application specific subset of data from the first  
8 database;

9 (ii) storing the application specific subset of data in a structure  
10 optimized for application program interfacing in a second database;  
11 and

12 (iii) receiving the respective genomic variant characterization from  
13 the user application program for each subject of the respective  
14 plurality of subjects; and

15 (iv) storing the respective genomic variant characterization received  
16 from the user application program for each subject of the respective  
17 plurality of subjects in a third database.

18 26. As explained in the patents' background section, prior to the claimed inventions  
19 "genetic testing in cancer cases [was] the rare exception, not the norm." '859 Patent at 4:32-33;  
20 '839 Patent at 6:8-9. At that time, "the lack of genetic and treatment efficacy data [made] it difficult  
21 to justify genetic testing for most cancer patients." '859 Patent at 4:50-52; '839 Patent at 6:26-28.  
22 Moreover, "the dearth of genomic data in most cancer cases impede[d] processes required to develop  
23 cause and effect insights between genetics and treatment efficacy in the first place." '859 Patent at  
24 4:52-55; '839 Patent at 6:28-31. "[W]ithout massive amounts of genetic data, there [was] . . . no  
25 easy way to build on and supplement many existing illness-treatment-results databases so that as  
26 more data is generated, the new data and associated results [could] be added to existing databases  
27 as evidence of treatment efficacy or to challenge efficacy." '859 Patent at 4:55-59, 5:49-53; '839  
28 Patent at 6:31-35, 7:26-30.

29 27. Even if patient health data and genome sequencing data were somehow aggregated  
30 from physicians, labs, researchers, and others, the '859 and '839 Patents further recognized that the  
31 collected data may be incomplete, inconsistent, or structured in different ways that made it difficult

1 to use. '859 Patent at 6:5-9; '839 Patent at 7:49-53 (“[I]n most cases there is no clear incentive for  
2 physicians to memorialize a complete set of treatment and results data and, in fact, the time required  
3 to memorialize such data can operate as an impediment to collecting that data in a useful and  
4 complete form[.]”), '859 Patent at 6:33-42; '839 Patent at 8:10-15 (“With no settled NGS standards,  
5 different NGS providers have different approaches for sequencing cancer patient genomics and,  
6 based on their sequencing approaches, generate different types and quantities of genomics data to  
7 share with physicians, researchers, and patients.”), '859 Patent at 6:43-47; '839 Patent at 8:20-24  
8 (“In addition to problems associated with collecting and memorializing treatment and results data  
9 sets, there are problems with digesting or consuming recorded data to generate useful conclusions.  
10 For instance, recorded cancer state, treatment and results data is often incomplete.”), '859 Patent at  
11 6:62-7:1; '839 Patent at 8:39-45 (“Another impediment to digesting collected data is that physicians  
12 often capture cancer state, treatment and results data in forms that make it difficult if not impossible  
13 to process the collected information so that the data can be normalized and used with other data  
14 from similar patient treatments to identify more nuanced insights and to draw more robust  
15 conclusions.”).

16         28. The '859 and '839 Patents also recognized that data segregation was an issue. For  
17 example, the patent teaches that “in most cases patient treatments and results [were] not published  
18 for general consumption and therefore [were] simply not accessible to be combined with other  
19 treatment and results data to provide a more fulsome overall data set.” '859 Patent at 5:35-38; '839  
20 Patent at 7:12-15.

21         29. In light of these and other problems of the prior art, the '859 and '839 Patents  
22 recognized the need for a new way of better capturing and organizing this highly important and  
23 meaningful health data:

24                 what is needed is a system that is capable of efficiently capturing all  
25 treatment relevant data including cancer state factors, treatment  
26 decisions, treatment efficacy and exploratory factors (e.g., factors  
27 that may have a causal relationship to treatment efficacy) and  
28 structuring that data to optimally drive different system activities  
including memorialization of data and treatment decisions, database  
analytics and user applications and interfaces. In addition, the system  
should be highly and rapidly adaptable so that it can be modified to

1 absorb new data types and new treatment and research insights as  
2 well as to enable development of new user applications and interfaces  
3 optimized to specific user activities.

4 '859 Patent at 9:43-55; '839 Patent at 11:34-46.

5 30. Rather than the performance of well-understood, routine, and conventional activities  
6 previously known in the art, the inventions claimed in the '859 and '839 Patents are directed to  
7 specific, innovative methods that improve the form, organization, and usability of health data  
8 (including genomic sequencing data) obtained using next generation genomic sequencers, and of  
9 the clinical records data from patients receiving cancer treatment. The claimed methods transform  
10 raw sequencing and clinical records data into specifically structured formats optimized for different  
11 analytical applications, thus facilitating the use of that data in treatment, research, and development.

12 31. The claimed inventions of the '859 and '839 Patents address these and other  
13 problems that existed in the prior art. For example, the '859 and '839 Patents disclose embodiments  
14 that include “an architecture where system processes are compartmentalized into loosely coupled  
15 and distinct micro-services that consume defined subsets of system data to generate new data  
16 products for consumption by other micro-services as well as other system resources enables  
17 maximum system adaptability so that new data types as well as treatment and research insights can  
18 be rapidly accommodated.” '859 Patent at 9:59-66; '839 Patent at 50:43-50. Employing such a  
19 distributed architecture as an embodiment “enables rapid changes to existing micro-services as well  
20 as development of new micro-services to meet any data handling and analytical needs.” '859 Patent  
21 at 10:7-9; '839 Patent at 50:58-60. In some embodiments, “system data may be represented in  
22 several differently structured databases that are optimally designed for different purposes,” which  
23 may demand “purpose specific data structures” to optimally enable physicians and researchers to  
24 make use of the varying kinds of data available. '859 Patent at 10:28-53; '839 Patent at 51:12-36.

25 32. In accordance with the above, the claims of the '859 Patent are directed to specific,  
26 nonconventional, non-routine methods for overcoming previously unresolved problems in this area,  
27 that impose specific requirements for arrangement and relationship on the stored data. For example,  
28 Claim 1 of the '859 Patent requires obtaining “clinical records data in original forms” that are

1 “stor[ed] . . . in a semi-structured first database,” “generat[ing] genomic sequencing data for [a]  
2 patient’s cancerous cells and normal cells” and “storing the sequencing data in [a] database,”  
3 “shaping at least a subset of [that] database data to generate system structured data including clinical  
4 record data and sequencing data wherein the system structured data is optimized for searching,”  
5 “storing the system structured data in a second database,” and then—for each application program—  
6 “selecting the application specific subset of data from the second database” and “storing the  
7 application specific subset of data in a structure optimized for application program interfacing in a  
8 third database.” *Id.* at Claim 1. These limitations, individually and as an ordered combination,  
9 describe an unconventional approach to address the aforementioned problems in the art.

10         33. Likewise, the claims of the ’839 Patent are directed to specific, nonconventional,  
11 non-routine methods for overcoming previously unresolved problems in this area, that impose  
12 specific requirements for arrangement and relationship on the stored data. For example, Claim 1  
13 requires obtaining “clinical records data in original forms” that are “stor[ed] . . . in a first database,”  
14 “generat[ing] genomic sequencing data for [a] subject’s cancerous cells and normal cells,” “shaping  
15 at least a subset of [that] genomic sequencing data to generate system structured data,” “storing the  
16 system structured data in the first database,” and then—for each application program—“selecting  
17 the application specific subset of data from the second database,” “storing the application specific  
18 subset of data in a structure optimized for application program interfacing in a third database,”  
19 receiving the respective genomic variant characterization from the user application program for each  
20 subject of the respective plurality of subjects,” and “storing the respective genomic variant  
21 characterization received from the user application program for each subject of the respective  
22 plurality of subjects in a third database.” *Id.* at Claim 1. These limitations, individually and as an  
23 ordered combination, describe an unconventional approach to address the aforementioned problems  
24 in the art.

25         34. As the ’859 and ’839 Patents describe, “system data is used for many different  
26 purposes such as memorialization of original records or documents, for data progression  
27 memorialization and auditing, for internal system resource consumption to generate interim data  
28 products, for driving research and analytics, and for supporting user application programs and

1 related interfaces, among others.” ’859 Patent at 10:32-38; ’839 Patent at 51:15-21. “[A] data  
2 structure that is optimal for one purpose often is sub-optimal for other purposes.” ’859 Patent at  
3 10:39-40; ’839 Patent at 51:22-23; *see also* ’859 Patent at 5:30-34 and ’839 Patent at 7:7-12 (a  
4 “plethora of treatment and customization options in many cases makes it difficult to accurately  
5 capture treatment and results data in a normalized fashion as there are no clear standardized  
6 guidelines for how to capture that type of information”).

7 35. To address these problems and others, the ’859 and ’839 Patents disclose that “[b]y  
8 shaping at least subsets of normalized system data, smaller sub-databases including application and  
9 research specific data sets can be generated and published for consumption by many different  
10 applications and research entities which ultimately speeds up the data access and manipulation  
11 processes.” ’859 Patent at 24:33-38; ’839 Patent at 106:32-37.

12 36. During prosecution of U.S. Application No. 16/771,451, the Examiner concluded  
13 that the claims of the ’859 Patent are patent eligible, not directed to any judicial exception, and not  
14 directed to an abstract idea:

15 **Claims 1-84 are patent eligible.** When considered as a whole using  
16 the 2-step framework outlined by the 2019 PEG and MPEP 2106,  
17 each of the claims satisfy Step 1 because they are directed to methods  
18 (i.e. processes). When examining these claims under Step 2A – Prong  
19 1, independent claims 1 and 20 are not found to recite any of the  
20 judicial exceptions enumerated in the 2019 PEG. For instance, none  
21 of the instant claims recite any mathematical relationships, formulas,  
22 or calculations. Further, none of these claims recite a mental process  
23 because they steps are not practically performable in the human  
24 mind. Finally, none of the claims recite certain methods of organizing  
25 human activity such as fundamental economic practices or managing  
26 interactions between people. Claim 1 is instead directed to methods  
27 for storing and structuring clinical and genomic sequencing patient  
28 data for specific application programs, while claim 20 is directed to  
method for obtaining and growing patient tumor samples and  
applying different treatments to determine and store treatment  
efficacies in a clinical database such that optimal treatments can be  
identified for specific cancer patients. Even if some of the steps could  
be construed as falling into one of the abstract idea groupings, the  
extensive combination of additional elements are meaningful to the  
claim and would provide integration into a practical application such  
that the claims would not be directed to an abstract idea. Thus,  
independent claims 1 and 20 are eligible because they do not recite

1 and are not directed to a judicial exception, as are claims 2-19 and  
2 21-84 depending therefrom.

3 Oct. 13, 2022 Non-Final Rejection at 7, U.S. Appl. No. 16/771,451 Prosecution History.

4 37. On January 25, 2023, the Patent Office issued a Notice of Allowance for the '839  
5 Patent, which stated:

6 5. The following is a statement of reasons for the indication of  
7 allowable subject matter: the applicant has brought to the attention of  
8 the examiner that the independent claims in U.S. application  
9 16/771,451 was allowed by the Office December 27, 2022. The  
10 Office had indicated in the '451 case the claims were eligible under  
11 35 U.S.C. 101. Exemplary claim 1 of the '451 case is substantially  
12 similar to claims 1, 84, 85 and 86 of the instant application. Not only  
13 are the independent claims between these two cases similar, but the  
14 claims in the instant application are more specific than what was  
15 found eligible by the Office. Accordingly, the examiner recognizes  
16 that claims 1-86 are eligible under 35 U.S.C. 101. In the Final Office  
17 action dated August 19, 2022, the only rejections made with regard  
18 to claims 1-86 were under 35 U.S.C 101.

19 Accordingly, claims 1-86 are in condition for allowance.

20 38. Several elements of at least Claim 1 of the '859 Patent are similar to elements of  
21 Claim 1 of the '839 Patent. For example, both claims recite a “method for conducting genomic  
22 sequencing,” comprising, among other limitations, “storing a set of user application programs  
23 wherein each of the programs requires an application specific subset of data to perform application  
24 processes,” “obtaining clinical records data in original forms where the clinical records data includes  
25 cancer state information, treatment types and treatment efficacy information,” “using a next  
26 generation genomic sequencer to generate genomic sequencing data for the patient's cancerous cells  
27 and normal cells,” “shaping at least a subset of the first database data to generate system structured  
28 data,” “storing the system structured data in a [] database,” and, “for each user application program,”  
“selecting the application specific subset of data from [a] database” and “storing the application  
specific subset of data in a structure optimized for application program interfacing in a [] database.”

39. The '859 Patent Examiner further acknowledged that the claimed inventions were  
novel and non-obvious improvements over the prior art.

Subject Matter Free from Prior Art

1 The following is a statement of reasons for the indication of  
2 allowable subject matter:

3 31. The prior art fails to expressly teach or suggest, either alone or in  
4 combination, each and every feature of claims 1 and 21. In particular,  
5 the prior art fails to teach shaping at least a subset of the first database  
6 data to generate system structured data including clinical record data  
7 and sequencing data wherein the system structured data is optimized  
8 for searching; storing the system structured data in a second database;  
9 for each user application program, selecting the application specific  
10 subset of data from the second database and storing the application  
11 specific subset of data in a structure optimized for application  
12 program interfacing in a third database; particularly in combination  
13 with performing genetic sequencing operations as in claim 1 and  
14 performing tumor growth and treatment efficacy testing as in claim  
15 21. . . .

16 32. Though many aspects of claims 1 and 21 are disclosed in the prior  
17 art, it would not have been obvious to one of ordinary skill in the art  
18 to combine the disparate features into the invention of the instant  
19 claims. Further, the prior art fails to provide teaching of the particular  
20 combination of limitations noted above. Accordingly, the prior art,  
21 either alone or in combination, does not disclose or render obvious  
22 all the features of claims 1 and 21 and they are found to recite subject  
23 matter that distinguishes over the prior art, as are claims 2-19, 23,  
24 and 25-84 depending therefrom.

25 Oct. 13, 2022 Non-Final Rejection at 10-11, U.S. Appl. No. 16/771,451 Prosecution History. Thus,  
26 at least the steps of “shaping at least a subset of the first database data to generate system structured  
27 data including clinical record data and sequencing data wherein the system structured data is  
28 optimized for searching,” “storing the system structured data in a second database,” and “for each  
user application program[,], selecting the application specific subset of data from the second  
database[] and [] storing the application specific subset of data in a structure optimized for  
application program interfacing in a third database” are not well-understood, routine, or  
conventional in the context of the claimed invention.

40. The dependent claims of the '859 Patent are directed to other embodiments of the  
claimed invention that further highlight the claimed invention's novelty and unconventionality in  
addressing the problems found in the prior art. For instance, Claims 11 and 12 depend from Claim  
1, and recite:

1 11. The method of claim 1 wherein the application programs include  
2 operational programs and wherein at least a subset of the operational  
3 programs comprise a physician suite of programs useable to consider  
4 cancer state treatment options.

4 12. The method of claim 11 wherein at least a subset of the  
5 operational programs comprise a suite of data shaping programs  
6 usable by a system user to shape data stored in the first database.

6 Claim 12 thus enables a system user to “shape data stored in the first database,” which is a “semi-  
7 structured database” that includes at least “clinical records data in original forms” and “genomic  
8 sequencing data for the patient’s cancerous cells and normal cells.” These limitations further  
9 support the ’859 Patent’s advantage of optimizing data access and functionality. *Id.* at 24:33-38  
10 (“By shaping at least subsets of normalized system data, smaller sub-databases including application  
11 and research specific data sets can be generated and published for consumption by many different  
12 applications and research entities which ultimately speeds up the data access and manipulation  
13 processes.”).

14 41. The dependent claims of the ’839 Patent are directed to other embodiments of the  
15 claimed invention that further highlight the claimed invention’s novelty and unconventionality in  
16 addressing the problems found in the prior art. For instance, Claim 2 depends from Claim 1, and  
17 recites:

18 2. The method of claim 1, wherein generating a respective genomic  
19 variant characterization comprises a model and training the model  
20 comprises fine tuning to improve the performance of the model,  
21 wherein the model is a machine learning algorithm or neural network.

21 42. Claim 2 is thus directed to an improvement to the process by which the claimed  
22 application(s) generate genomic variant characterizations.

23 43. Accordingly, the techniques employed by the claimed inventions of the ’859 Patent  
24 and the ’839 Patent are not routine or conventional, and serve not only to improve the operation and  
25 capability of the databases of clinical records data and genome sequencing data, but to provide  
26 specific methods of optimizing use of the data stored therein despite being incomplete or having  
27 inconsistent structure.

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1           44.       Thus, at least the additional elements of Claim 1 of the '859 Patent and Claim 1 of  
2 the '839 Patent identified above, along with the dependent claims, establish that the claims, as a  
3 whole, integrate an eligible practical invention.

4           **B.       U.S. Patent No. 10,957,041**

5           45.       The '041 Patent is titled “Determining biomarkers from histopathology slide images”  
6 and was duly and legally issued from the USPTO on March 23, 2021. Tempus owns the '041 Patent,  
7 including the right to enforce it and seek damages for infringement. A true and correct copy of the  
8 '041 Patent is attached as Exhibit 3.

9           46.       The '041 Patent generally discloses and claims methods for identifying biomarkers  
10 in a sample of target tissue. The methods involve “an imaging-based biomarker prediction system  
11 formed of a deep learning framework configured and trained to directly learn from histopathology  
12 slide images and predict the presence of biomarkers in medical images.” '041 Patent at 3:41-47.

13           47.       For example, independent Claim 1 of the '041 Patent recites:

14           A computer-implemented method of identifying biomarkers in a digital image of a  
15           hematoxylin and eosin (H&E) stained slide of target tissue, the method comprising:

16           receiving the digital image to an image-based biomarker prediction system having  
17           one or more processors;

18           separating, using the one or more processors, the digital image into a plurality of tile  
19           images, where each of the plurality of tile images contains a different portion of the  
20           digital image;

21           applying, using the one or more processors, the plurality of tile images to a deep  
22           learning framework comprising one or more trained biomarker classification models,  
23           each trained biomarker classification model being trained to classify a different  
24           biomarker, wherein the deep learning framework comprises a multiscale deep  
25           learning framework;

26           predicting, using the one or more processors, a biomarker classification for each of  
27           the plurality of tile images using the one or more trained biomarker classification  
28           models;

            from the predicted biomarker classifications of each of the tile images, determining  
            a predicted presence of one or more biomarkers in the target tissue; and

            generating a report containing the digital image and a digital overlay visualizing the  
            predicted presence of the one or more biomarkers,

1 wherein each of the applying the plurality of tile images to the deep learning  
2 framework and predicting the biomarker classification for each of the plurality of tile  
images comprises,

3 applying each of the tile images to one or more trained deep learning multiscale  
4 classifier models, each trained deep learning multiscale classifier models being  
5 trained to classify a different tissue classification for each tile image and determining  
6 a tissue classification for each of the plurality of tile images, using the multiscale  
deep learning framework,

7 identifying, using the one or more processors, cells within the digital image using a  
8 trained cell segmentation model, and

9 from the tissue classification determined for each tile image and from the identified  
10 cells within the digital image, predicting the biomarker classification for each tile  
image.

11 48. As explained in the '041 Patent's background section, tissue samples from patients  
12 with cancerous tumors were traditionally analyzed visually to "reveal growth patterns of the cancer  
13 cells in the tumor in relation to the healthy cells near them and the presence of immune cells within  
14 the tumor." '041 Patent at 1:41-43. That inspection was conventionally performed by pathologists  
15 or others by "visually analyz[ing] thin slices of tumor tissue mounted on glass microscope slides  
16 and identify[ing] each region of the tissue as corresponding to one of many tissue types that are  
17 present in a tumor sample." *Id.* at 1:45-49. Treatment decisions were informed based on that visual  
18 inspection and a determination of the tumor's characteristics (*id.* at 1:49-53), including  
19 characteristics such as "tumor grade, tumor purity, degree of invasiveness of the tumor, degree of  
20 immune infiltration into the tumor, cancer stage, and anatomic origin site of the tumor" (*id.* at 1:56-  
21 59), as well as "the presence of specific biomarkers or other cell types in or near the tumor, including  
22 immune cells" (*id.* at 1:65-67). For example, biomarkers of interest might include the presence of  
23 tumor-infiltrating lymphocytes (TILs) in elevated levels or specific molecules such as programmed  
24 death ligand 1 (PD-L1). *Id.* at 1:67-2:37.

25 49. Pathologists have traditionally used a process called "hematoxylin and eosin (H&E)  
26 staining" to aid with diagnosing cancer malignancy based on the morphology of the cancer tissue.  
27 *Id.* at 2:47-49. According to the '041 Patent, "[t]echnological advances have enabled the digitization  
28 of histopathology H&E and IHC slides into high resolution whole slide images (WSIs), providing

1 opportunities to develop computer vision tools for a wide range of clinical applications,” such as  
2 using “deep learning,” a subset of machine learning, to aid with cancer tissue classification. *Id.* at  
3 2:53-62.

4 50. Against this background, the '041 Patent teaches the need for new testing techniques:

5 There is a need for new easily accessible techniques of diagnostic  
6 testing for biomarkers, such as TILs, PD-L1, and others using H&E  
7 images, for identifying and characterizing such biomarkers in an  
8 efficient manner, across population groups, for producing better  
optimized drug treatment recommendations and protocols, and  
improved forecasting of disease progression.

9 *Id.* at 3:31-37.

10 51. The claimed inventions of the '041 Patent address these computer vision and other  
11 problems that existed in the prior art. For example, the '041 Patent discloses an “imaging-based  
12 biomarker prediction system formed of a deep learning framework configured and trained to directly  
13 learn from histopathology slide images and predict the presence of biomarkers in medical images.”

14 *Id.* at 3:41-45.

15 52. In particular, the '041 Patent inventions beneficially can “increase accuracy and/or  
16 to decrease processing time associated with a particular biomarker” including through the disclosed  
17 selection of “different pixel sizes and different pixel shapes.” *Id.* at 22:50-53. As the '041 Patent  
18 recognizes, “image classification to predict genotypes using the present techniques can be done in  
19 hours and with much larger training sets.” *Id.* at 66:58-61; *see also id.* at 66:42-61, 67:46-61. Such  
20 improvements in accuracy and efficiency for predicting the presence of treatment-relevant  
21 biomarkers leads to clinical benefits for patients.

22 53. The '041 Patent includes various examples of systems employing such techniques,  
23 including frameworks configured to include different trained biomarker classifiers, each configured  
24 to predict biomarkers associated with unlabeled histopathology images, which can then be used to  
25 identify potential immunotherapies for patients. *Id.* at 3:45-59. In some examples, the techniques  
26 taught by the '041 Patent “provide for machine learning assisted histopathology image review that  
27 includes automatically identifying and contouring a tumor region, and/or characteristics of regions  
28 or cell types within a region (for example, lymphocytes, PD-L1 positive cells, tumors having a high

1 degree of tumor budding, etc.), counting cells within that tumor region, and generating a decision  
2 score to improve the efficiency and the objectivity of pathology slide review.” *Id.* at 13:33-41. Such  
3 frameworks can identify biomarkers indicating the presence of a tumor, a tumor state or condition,  
4 or information about a tumor of the tissue sample, including for a variety of different cancer types.  
5 *Id.* at 3:55-4:24.

6         54. The inventions claimed in the ’041 Patent are generally directed to innovative  
7 methods of identifying biomarkers in a digital image of a sample of target tissue using deep learning  
8 techniques. The claims of the ’041 Patent are directed to specific, nonconventional, non-routine  
9 methods for overcoming previously unresolved problems in this area, that impose specific  
10 requirements for arrangement and relationship on the stored data.

11         55. For example, Claim 1 of the ’041 Patent requires “receiving the digital image to an  
12 image-based biomarker prediction system having one or more processors,” “separating . . . the  
13 digital image [of a slide] into a plurality of tile images, where each of the plurality of tile images  
14 contains a different portion of the digital image,” “applying . . . the plurality of tile images to a deep  
15 learning framework comprising one or more trained biomarker classification models, each trained  
16 biomarker classification model being trained to classify a different biomarker, wherein the deep  
17 learning framework comprises a multiscale deep learning framework,” “predicting . . . a biomarker  
18 classification for each of the plurality of tile images using the one or more trained biomarker  
19 classification models,” determining the presence of one or more biomarkers, and generating a report  
20 showing the “predicted presence of the one or more biomarkers,” wherein applying the tile images  
21 to the deep learning framework and predicting the biomarker classification(s) for the tile images  
22 comprises using one or more multiscale classifier models “trained to classify a different tissue  
23 classification for each tile image and determining a tissue classification for each of the plurality of  
24 tile images,” “identifying . . . cells within the digital image using a trained cell segmentation model,”  
25 and “predicting the biomarker classification for each tile image.” *Id.* at Claim 1. These limitations,  
26 individually and as an ordered combination, describe an unconventional approach to address the  
27 aforementioned problems in the art.

28

1           56.     Furthermore, during prosecution of U.S. Application No. 16/830,186, the Examiner  
2 issued a Notice of Allowance explaining that the claims of the '041 Patent were novel and non-  
3 obvious improvements over the prior art.

4           The following is an examiner's statement of reasons for allowance:  
5           The present invention comprises a generalizable and interpretable  
6           deep learning model for predicting biomarker status and biomarker  
7           metrics from histopathology slide images. The closest prior art,  
8           [Tunstall] . . . shows a similar system which also includes an image  
9           of a section of a tissue sample imaged from a microscope slide  
10          stained using Haemotoxylin and Eosin, using a learning method with  
11          classification data, obtaining a probability estimate based on  
12          comparing the feature vectors of tiles in tissue regions of the image,  
13          and displaying the resulting probability estimate as a color map.  
14          However, Tunstall fails to disclose wherein each of the applying the  
15          plurality of tile images to the deep learning framework and predicting  
16          the biomarker classification for each of the plurality of tile images  
17          comprises, applying each of the tile images to one or more trained  
18          deep learning multiscale classifier models, each trained deep learning  
19          multiscale classifier models being trained to classify a different tissue  
20          classification for each tile image and determining a tissue  
21          classification for each of the plurality of tile images, using the  
22          multiscale deep learning framework, identifying, using the one or  
23          more processors, cells within the digital image using a trained cell  
24          segmentation model, and from the tissue classification determined  
25          for each tile image and from the identified cells within the digital  
26          image, predicting the biomarker classification for each tile image, as  
27          claimed. The distinct features have been added to the independent  
28          claims 41, 56, 59, and 60; therefore, rendering them allowable.

19 Oct. 15, 2020 Notice of Allowance at 2, U.S. Appl. No. 16/830,186 Prosecution History.

20           57.     Thus, at least the steps of “wherein each of the applying the plurality of tile images  
21 to the deep learning framework and predicting the biomarker classification for each of the plurality  
22 of tile images comprises,” “applying each of the tile images to one or more trained deep learning  
23 multiscale classifier models,” “each trained deep learning multiscale classifier models being trained  
24 to classify a different tissue classification for each tile image and determining a tissue classification  
25 for each of the plurality of tile images,” “using the multiscale deep learning framework, identifying,  
26 using the one or more processors, cells within the digital image using a trained cell segmentation  
27 model,” and “from the tissue classification determined for each tile image and from the identified

1 cells within the digital image, predicting the biomarker classification for each tile image” are not  
2 well-understood, routine, or conventional.

3 58. Accordingly, the techniques employed by the claimed inventions of the '041 Patent  
4 are not routine or conventional, and serve not only to improve techniques for identifying biomarkers  
5 in a digital image of a stained slide of target tissue, but also to provide specific techniques for doing  
6 so including through the employment of novel deep learning techniques.

7 59. Thus, at least the additional elements of Claim 1 identified above, along with the  
8 dependent claims, establish that the claims, as a whole, integrate an eligible practical invention.

9 **C. U.S. Patent No. 10,991,097**

10 60. The '097 Patent is titled “Artificial intelligence segmentation of tissue images” and  
11 was duly and legally issued from the USPTO on April 27, 2021. Tempus owns the '097 Patent,  
12 including the right to enforce it and seek damages for infringement. A true and correct copy of the  
13 '097 Patent is attached as Exhibit 4.

14 61. The '097 Patent generally discloses and claims methods for generating an overlay  
15 map on a digital medical image of a slide. The methods involve receiving a medical image, such as  
16 an image of a tissue affixed to a slide, separating the image into tiles, and performing tile  
17 classifications and tissue classifications based on a multi-tile analysis.

18 62. For example, independent Claim 1 of the '097 Patent recites:

19 1. A method for creating an overlay map on a digital image of a slide, the method  
20 comprising:

21 receiving the digital image;

22 separating the digital image into a plurality of tiles, each tile of the plurality of tiles  
23 containing a respective portion of the digital image of the slide; and

24 for each tile of the plurality of tiles:

25 identifying features of the tile;

26 identifying structural tissue features of a second portion of the digital image of the  
27 slide including at least part of one or more other tiles of the plurality of tiles, wherein  
28 the second portion is larger than the respective portion of the digital image contained  
in the tile; and

1 identifying the majority class of tissue visible within the tile based at least in part on  
2 the features of the tile and the structural tissue features of the second portion of the  
digital image of the slide.

3 63. As explained in the '097 Patent's background section, inspection of tissue samples  
4 from a patient with cancerous tumors were traditionally visually analyzed to "reveal growth patterns  
5 of the cancer cells in the tumor in relation to the healthy cells near them and the presence of immune  
6 cells within the tumor." '097 Patent at 1:32-34. Such conventional inspection was performed by  
7 pathologists or others by "visually analyz[ing] thin slices of tumor tissue mounted on glass  
8 microscope slides to classify each region of the tissue as one of many tissue classes that are present  
9 in a tumor sample." *Id.* at 1:36-39. Treatment decisions were informed based on that visual  
10 inspection and a determination of the tumor's characteristics (*id.* at 1:39-43), including  
11 characteristics such as "tumor grade, tumor purity, degree of invasiveness of the tumor, degree of  
12 immune infiltration into the tumor, cancer stage, and anatomic origin site of the tumor" (*id.* at 1:47-  
13 50).

14 64. In the prior art, a pathologist's visual inspection of tumor samples resulted in  
15 "[n]umerical scores assigned during microscope slide analysis [that] include tumor purity, which is  
16 the percentage of the tissue that is formed by tumor cells." *Id.* at 1:42-46. But that traditional,  
17 manual technique had several drawbacks. Not only was it "time consuming and [did it] require[] a  
18 trained medical professional," but "because numerical scores [were] assigned by approximation,  
19 these scores [were] subjective, not quantitative." *Id.* at 1:56-59.

20 65. Against this background, the '097 Patent discusses the limitations of conventional  
21 AI techniques to "analyze the slides and classify the tissue components by tissue class." *Id.* at 1:60-  
22 62. For instance, using a conventional Convolutional Neural Network ("CNN") would require  
23 processing that results in "a high number of redundant calculations and is time consuming." *Id.* at  
24 1:63-2:9.

25 66. The '097 Patent discloses innovative methods of analyzing and classifying digital  
26 slide images, including receiving and separating a digital image into a plurality of tiles, each  
27 containing a portion of the digital image of the slide, and, for each tile, identifying features of the  
28 tile, "identifying structural tissue features of a second portion of the digital image of the slide

1 including at least part of one or more other tiles of the plurality of tiles, wherein the second portion  
2 is larger than the respective portion of the digital image contained in the tile,” and “determining a  
3 predicted class for each tile based at least in part on the features of the tile and the structural tissue  
4 features of the second portion of the digital image of the slide.” *Id.* at Claim 1.

5 67. The '097 Patent explains that its claimed inventions result in “reduce[d]  
6 computational redundancy” and “greater processing efficiency.” *Id.* at 6:54-56. In another example,  
7 the '097 Patent describes that the claimed inventions “can be used to assist medical professionals in  
8 more accurately estimating tumor purity, and in locating regions or diagnoses of interest.” *Id.* at  
9 8:7-11. Such improvements in accuracy and efficiency for identifying treatment-relevant features  
10 in patient tissue leads to clinical benefits for patients.

11 68. Furthermore, during prosecution of U.S. Application No. 16/732,242, the Examiner  
12 issued a Notice of Allowance explaining that the claims of the '097 Patent were novel and non-  
13 obvious improvements over the prior art:

14 The following is an examiner’s statement of reasons for allowance:  
15 The present invention comprises a generalizable and interpretable  
16 deep learning model for predicting biomarker status and biomarker  
17 metrics from histopathology slide images. The closest prior art,  
18 Tunstall[,] . . . shows a similar system which also includes an image  
19 of a section of a tissue sample imaged from a microscope slide  
20 stained using Haemotoxylin and Eosin, using a learning method with  
21 classification data, obtaining a probability estimate based on  
22 comparing the feature vectors of tiles in tissue regions of the image,  
23 and displaying the resulting probability estimate as a color map.  
24 However, Tunstall fails to disclose “each tile of the plurality of tiles  
25 containing a respective portion of the digital image of the slide; and  
26 for each tile of the plurality of tiles: identifying features of the tile;  
27 identifying structural tissue features of a second portion of the digital  
28 image of the slide including at least part of one or more other tiles of  
the plurality of tiles, wherein the second portion is larger than the  
respective portion of the digital image contained in the tile; and  
identifying the majority class of tissue visible within the tile based at  
least in part on the features of the tile and the structural tissue features  
of the second portion of the digital image of the slide,” as claimed.  
These distinct features have been added to the independent claims 1  
and 11; therefore, rendering them allowable.

27 Dec. 11, 2020 Notice of Allowance at 2, U.S. Appl. No. 16/732,242 Prosecution History.

1           69.     Thus, at least the steps of “each tile of the plurality of tiles containing a respective  
2 portion of the digital image of the slide; and for each tile of the plurality of tiles: identifying features  
3 of the tile; identifying structural tissue features of a second portion of the digital image of the slide  
4 including at least part of one or more other tiles of the plurality of tiles, wherein the second portion  
5 is larger than the respective portion of the digital image contained in the tile; and identifying the  
6 majority class of tissue visible within the tile based at least in part on the features of the tile and the  
7 structural tissue features of the second portion of the digital image of the slide” are not well-  
8 understood, routine, or conventional.

9           70.     Applying what the '097 Patent describes as a “multi-tile algorithm” allows for  
10 “achiev[ing] a multiscale, multiresolution analysis that captures both the contents of the individual  
11 tile and the context of the portion of the image that surrounds the tile.” '097 Patent at 5:46-49. The  
12 patent discloses that, “[b]ecause the portions of the image that surround two neighboring tiles  
13 overlap, analyzing many tiles and their surroundings concurrently instead of separately analyzing  
14 each tile with its surroundings reduces computational redundancy and results in greater processing  
15 efficiency.” *Id.* at 6:51-56. In this way, the unconventional and innovative approach described in  
16 Claim 1 of the '097 Patent addresses problems associated with prior art approaches.

17           71.     Accordingly, the techniques employed by the claimed inventions of the '097 Patent  
18 are not routine or conventional, and serve to improve methods for predicting biomarker status and  
19 biomarker metrics from histopathology slide images, including through the employment of novel  
20 deep learning techniques.

21           72.     Thus, at least the additional elements of Claim 1 identified above, along with the  
22 dependent claims, establish that the claims, as a whole integrate, eligible practical inventions.

### 23 **III.    Guardant’s Infringing Conduct**

24           73.     Guardant was founded by Helmy Eltoukhy and AmirAli Talasaz. Prior to founding  
25 Guardant, Dr. Eltoukhy and Dr. Talasaz worked together at Illumina, Inc. (“Illumina”), which  
26 manufactures genomic-sequencing machines and also competes with Guardant in the commercial  
27 liquid biopsy space. Dr. Eltoukhy and Dr. Talasaz founded Guardant while the former was still an  
28 Illumina employee, and shortly after the latter had left the company.

1           74.     Guardant was initially focused on the development of liquid biopsy tests, including  
2 its first test, Guardant360. After achieving some early success, however, Guardant increasingly  
3 struggled and suffered setbacks in its product development pipeline.<sup>2</sup>

4           75.     Unable to fairly make advances in the marketplace through its own technologies,  
5 Guardant has sought to emulate Tempus’s success by copying Tempus’s technology and unlawfully  
6 using Tempus’s patented inventions.

7           76.     Indeed, Guardant has a history of disrespecting intellectual property rights and  
8 willfully copying others’ technology. For example, in 2021, Twinstrand Biosciences filed a patent  
9 infringement lawsuit against Guardant, alleging that the technology underlying Guardant’s key  
10 Guardant360 liquid biopsy test infringed Twinstrand’s patents. The complaint alleged that “around  
11 the time Guardant launched the first of the [a]ccused [p]roducts, Guardant made several  
12 unsuccessful attempts to license the patent family that includes the [a]sserted [p]atents, and  
13 repeatedly faced patentability rejections . . . when Guardant was prosecuting its own patent  
14 applications directed to its infringing commercial sequencing method.” In November 2023, a jury  
15 concluded that Guardant had engaged in willful infringement and awarded Twinstrand \$83.4 million  
16 in damages.

17           77.     In 2022, Illumina, which is a manufacturer of the equipment Guardant uses to  
18 perform its liquid biopsy tests, alleged that Dr. Eltoukhy and Dr. Talasaz founded Guardant using  
19 trade secrets stolen from Illumina (their former employer). The complaint alleged, among other  
20 things, that upon leaving Illumina, Dr. Eltoukhy improperly and covertly transferred more than  
21 51,000 Illumina-owned emails, including more than 1,400 “Company Confidential” documents.  
22 The complaint further alleged that, despite Dr. Eltoukhy contributing to several inventions while at  
23 Illumina, Guardant removed Dr. Eltoukhy’s name as an inventor from its patent applications to  
24 prevent Illumina from claiming ownership.

25  
26 \_\_\_\_\_  
27 <sup>2</sup> Deena Beasley, *Guardant DNA blood test finds 83% of colorectal cancers in trial, shares fall*  
28 *35%*, REUTERS (Dec. 15, 2022), available at <https://www.reuters.com/business/healthcare-pharmaceuticals/guardant-heath-dna-blood-test-detects-83-colorectal-cancers-trial-2022-12-15/>.

1 78. Consistent with its history of copying the technology of others, Guardant has, in  
2 recent years, attempted to duplicate Tempus’s strategy. For example, after Guardant saw the success  
3 of Tempus in data analytics, Guardant released the “GuardantINFORM platform” in June 2020.  
4 GuardantINFORM is marketed as a tool to accelerate drug development by providing biopharma  
5 partners with access to a so-called “clinical-genomic” dataset collected through Guardant’s liquid  
6 biopsy testing. The GuardantINFORM data platform “operates as a text mining and natural  
7 language processing (NLP) precision oncology platform that extracts, transforms, and normalizes  
8 relevant information from clinical documents and genomic data.”<sup>3</sup>

9 79. The GuardantINFORM data platform integrates with the Guardant360 CDx liquid  
10 biopsy, which Guardant launched in August 2020.<sup>4</sup> As shown in the Guardant360 CDx  
11 Specification Sheet,<sup>5</sup> the Guardant360 CDx assay is a “qualitative next generation sequencing-based  
12 in vitro diagnostic device that uses targeted high throughput hybridization-based capture technology  
13 for detection of single nucleotide variants (SNVs), insertions and deletions (indels) in 55 genes,  
14 copy number amplifications (CNAs) in two (2) genes, and fusions in four (4) genes.”

15 80. In 2022, Guardant introduced Guardant INFINITY, a “smart liquid biopsy  
16 platform.”<sup>6</sup> According to Guardant’s website, Guardant INFINITY comprises a “single platform  
17 that powers [Guardant’s] entire portfolio, making epigenomic insights scalable from research to the  
18

19 <sup>3</sup> Brittany Wade, *Guardant and IQVIA Develop Precision Oncology Platform to Normalize*  
20 *Clinical Data*, BIO IT WORLD (June 2, 2022), available at [https://www.bio-  
21 itworld.com/news/2022/06/02/guardant-and-iqvia-develop-precision-oncology-platform-to-  
22 normalize-clinical-data](https://www.bio-itworld.com/news/2022/06/02/guardant-and-iqvia-develop-precision-oncology-platform-to-normalize-clinical-data).

22 <sup>4</sup> [https://investors.guardanthealth.com/press-releases/press-releases/2020/Guardant-Health-  
23 Guardant360-CDx-First-FDA-Approved-Liquid-Biopsy-for-Comprehensive-Tumor-Mutation-  
24 Profiling-Across-All-Solid-Cancers/default.aspx](https://investors.guardanthealth.com/press-releases/press-releases/2020/Guardant-Health-Guardant360-CDx-First-FDA-Approved-Liquid-Biopsy-for-Comprehensive-Tumor-Mutation-Profiling-Across-All-Solid-Cancers/default.aspx).

24 <sup>5</sup> Guardant360 CDx Specification Sheet, GUARDANT HEALTH, available at  
25 <https://www.guardantcomplete.com/assets/pdf/Guardant360-CDx-Technical-Information-US.pdf>.

26 <sup>6</sup> Press Release, *Guardant Health Introduces GuardantINFINITY™ Smart Liquid Biopsy for*  
27 *Research Use to Help Bring New Cancer Therapies to Patients Sooner*, GUARDANT HEALTH (Sept.  
28 9, 2022), available at [https://investors.guardanthealth.com/press-releases/press-  
releases/2022/Guardant-Health-Introduces-GuardantINFINITY-Smart-Liquid-Biopsy-for-  
Research-Use-to-Help-Bring-New-Cancer-Therapies-to-Patients-Sooner/default.aspx](https://investors.guardanthealth.com/press-releases/press-releases/2022/Guardant-Health-Introduces-GuardantINFINITY-Smart-Liquid-Biopsy-for-Research-Use-to-Help-Bring-New-Cancer-Therapies-to-Patients-Sooner/default.aspx).

1 clinic.”<sup>7</sup> The Guardant INFINITY platform “can both quantify and characterize cancer with  
2 genomic and epigenomic analysis, powering multiple applications in precision oncology.”

3 81. In 2023, Guardant introduced Guardant Galaxy, a “suite of advanced analytical  
4 technologies developed internally and through outside partnerships to enhance the performance and  
5 clinical utility of Guardant Health’s portfolio of cancer tests and to power the next generation of  
6 biomarker and drug discovery.”<sup>8</sup> Guardant’s press release discloses the use of “applications” in  
7 connection with Guardant Galaxy, which “include enhanced oncology drug and biomarker  
8 discovery and development capabilities based on mining the extensive genomic and epigenomic  
9 data produced by Guardant Health’s diagnostic tests,”—e.g., information obtained from the  
10 Guardant360 CDx and Guardant360 TissueNext assays—“cross-referenced to real-world outcomes  
11 data available through the GuardantINFORM data platform.”

12 82. The Guardant Galaxy suite includes an AI-backed digital pathology platform  
13 developed by Lunit, a South Korea-based company that develops AI solutions for diagnostics and  
14 therapeutics. Guardant Galaxy, including the Lunit SCOPE PD-L1, comprises a model and training  
15 that model includes fine tuning to improve the performance of the model, wherein the model is a  
16 machine learning algorithm or neural network. Guardant touted the enhancement of its TissueNext  
17 offering: “The AI-powered scoring algorithm for the enhanced Guardant360 TissueNext PD-L1 test,  
18 which is now commercially available, improved detection of the cancer biomarker by more than 20  
19 percent compared to manual pathologist interpretation in the most challenging non-small cell lung  
20 cancer (NSCLC) cases.”<sup>9</sup>

21  
22  
23 \_\_\_\_\_  
24 <sup>7</sup> GUARDANT COMPLETE, <https://www.guardantcomplete.com/biopharma/multiomic-solution>.

25 <sup>8</sup> Press Release, *Guardant Health introduces Guardant Galaxy™ suite of advanced AI analytics*  
26 *to enhance its portfolio of cancer tests and accelerate biomarker discovery*, GUARDANT HEALTH  
27 (Jan. 31, 2023), available at <https://investors.guardanthealth.com/press-releases/press-releases/2023/Guardant-Health-introduces-Guardant-GalaxyTM-suite-of-advanced-AI-analytics-to-enhance-its-portfolio-of-cancer-tests-and-accelerate-biomarker-discovery/default.aspx>.

28 <sup>9</sup> *Id.*

1           83.     In 2024, Guardant introduced the Guardant360 TissueNext tissue biopsy assay in the  
2 United States.<sup>10</sup> As shown in the Guardant360 TissueNext Specification Sheet, the Guardant360  
3 TissueNext assay is an “analytically validated comprehensive next-generation sequencing panel that  
4 includes clinically actionable biomarkers to enable informed treatment decisions for patients with  
5 advanced solid tumors.” The Guardant360 TissueNext tissue biopsy assay utilizes a sequencing  
6 approach identical or very similar to the Guardant360 CDx assay’s sequencing method (e.g.,  
7 Guardant Health’s proprietary Digital Sequencing technology).

8           84.     The Accused Products, which include Guardant Galaxy, Guardant INFINITY,  
9 Guardant360 TissueNext, Guardant360 CDx, GuardantINFORM, and any other infringing method,  
10 product, device, or test developed by Guardant that applies Tempus’s patented systems and methods,  
11 infringe the Patents-in-Suit.

12           85.     The Accused Products include technology platforms that integrate multiple oncology  
13 tests, such as the Guardant360 CDx and Guardant360 TissueNext assays, among others, with data  
14 associated with these tests and from patients. According to the Guardant Complete Website,<sup>11</sup> the  
15 Guardant Galaxy and Guardant Infinity platforms power Guardant’s liquid biopsy and tissue biopsy  
16 tests, and the GuardantINFORM data platform “integrates information from NGS [next-generation  
17 sequencing]”—e.g., information obtained from the Guardant360 CDx and Guardant360 TissueNext  
18 assays—“demographics, cancer diagnoses, treatment and procedures, and pharmacy prescription  
19 data across 60+ solid tumor cancer types.”

20           86.     Certain of the Accused Products are used by Guardant to conduct genomic  
21 sequencing. For example, the Guardant360 TissueNext assay is an “analytically validated  
22 comprehensive next-generation sequencing panel that interrogates 498 genes that includes clinically  
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25 <sup>10</sup> Press Release, *Guardant Health introduces new Guardant360 TissueNext test with nearly 500*  
26 *biomarkers to identify more treatment options for patients with advanced cancer*, GUARDANT  
27 *HEALTH* (June 4, 2024), available at <https://investors.guardanthealth.com/press-releases/press-releases/2024/Guardant-Health-introduces-new-Guardant360-TissueNext-test-with-nearly-500-biomarkers-to-identify-more-treatment-options-for-patients-with-advanced-cancer/default.aspx>.

28 <sup>11</sup> GUARDANT COMPLETE, <https://www.guardantcomplete.com/biopharma/multiomic-solution>.

1 actionable biomarkers to enable informed treatment decisions for patients with advanced solid  
2 tumors.”<sup>12</sup> Guardant360 TissueNext is “powered by Guardant Galaxy.”<sup>13</sup> Guardant Galaxy is “a  
3 suite of advanced analytical technologies developed internally and through outside partnerships to  
4 enhance the performance and clinical utility of Guardant Health’s portfolio of cancer tests and to  
5 power the next generation of biomarker and drug discovery.”<sup>14</sup>

6 87. The GuardantINFORM data platform “integrates information from NGS [next-  
7 generation sequencing]”—e.g., from Guardant360 CDx and Guardant360 TissueNext—  
8 “demographics, cancer diagnoses, treatment and procedures, and pharmacy prescription data across  
9 60+ solid tumor cancer types.”<sup>15</sup> “GuardantINFORM operates as a text mining and natural language  
10 processing (NLP) precision oncology platform that extracts, transforms, and normalizes relevant  
11 information from clinical documents and genomic data” and “integrates information from various  
12 sources, including Guardant360—the first FDA-approved liquid biopsy genomic profiling test for  
13 patients with advanced cancer. Guardant performs over 100,000 tests per year, and Guardant360  
14 sequences up to 500 genes”—e.g., by performing the Guardant360 CDx and Guardant360  
15 TissueNext assays.<sup>16</sup>

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<sup>12</sup> [https://www.guardanthealthmea.com/wp-content/uploads/Guardant360-TissueNext-  
19 Specification.pdf](https://www.guardanthealthmea.com/wp-content/uploads/Guardant360-TissueNext-Specification.pdf).

20 <sup>13</sup> *Guardant360 TissueNext*, GUARDANT COMPLETE, <https://www.guardantcomplete.com/products/guardant360-tissuenext>.

21  
22 <sup>14</sup> Press Release, *Guardant Health introduces Guardant Galaxy™ suite of advanced AI analytics to enhance its portfolio of cancer tests and accelerate biomarker discovery*, GUARDANT HEALTH  
23 (Jan. 31, 2023), available at [https://investors.guardanthealth.com/press-releases/press-  
24 releases/2023/Guardant-Health-introduces-Guardant-GalaxyTM-suite-of-advanced-AI-analytics-  
to-enhance-its-portfolio-of-cancer-tests-and-accelerate-biomarker-discovery/default.aspx](https://investors.guardanthealth.com/press-releases/press-releases/2023/Guardant-Health-introduces-Guardant-GalaxyTM-suite-of-advanced-AI-analytics-to-enhance-its-portfolio-of-cancer-tests-and-accelerate-biomarker-discovery/default.aspx).

25 <sup>15</sup> GUARDANT COMPLETE, <https://www.guardantcomplete.com/biopharma/multiomic-solution>.

26 <sup>16</sup> Brittany Wade, *Guardant and IQVIA Develop Precision Oncology Platform to Normalize*  
27 *Clinical Data*, BIO IT WORLD (June 2, 2022), available at [https://www.bio-  
28 itworld.com/news/2022/06/02/guardant-and-iqvia-develop-precision-oncology-platform-to-  
normalize-clinical-data](https://www.bio-itworld.com/news/2022/06/02/guardant-and-iqvia-develop-precision-oncology-platform-to-normalize-clinical-data).

1           88.     GuardantINFORM’s “NLP Methodology” “takes critical information extracted from  
2 medical records—such as tumor staging, biomarker profile, tumor histology, smoking history, and  
3 performance status—and normalizes it into structured data.”<sup>17</sup> The GuardantINFORM data platform  
4 is “an in-silico platform that combines de-identified longitudinal clinical information and genomic  
5 data” which “offers real-world insights into anti-cancer therapy use in the clinic, tumor evolution,  
6 and treatment resistance throughout each patient’s treatment journey for many advanced solid tumor  
7 cancers.”<sup>18</sup>

8           89.     According to Guardant, GuardantINFORM complements its “core diagnostic  
9 business with aggregated data obtained through real world genomic testing matched with clinically  
10 relevant information, which enables important insights into disease progression and treatment  
11 impact that can be fed back into drug discovery and development as well as clinical research and  
12 practice.”<sup>19</sup>

13           90.     Guardant “manage[s] and maintain[s] our applications and data utilizing a  
14 combination of on-site systems and cloud-based data centers” and “depend[s] on information  
15 technology systems for significant elements of our operations, including our laboratory information  
16 management system, our computational biology system, our knowledge management system, our  
17 customer reporting and our GuardantConnect software platform.”<sup>20</sup> Guardant’s information  
18 technology systems support “lab operations” and “store a wide variety of information critical to our  
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22 <sup>17</sup> *Id.*

23 <sup>18</sup> Press Release, *Guardant Health Launches Real-World Clinical-Genomic Platform to Accelerate*  
24 *Precision Oncology Drug Development*, GUARDANT HEALTH (June 23, 2020), available at  
25 [https://investors.guardanthealth.com/press-releases/press-releases/2020/Guardant-Health-  
Launches-Real-World-Clinical-Genomic-Platform-to-Accelerate-Precision-Oncology-Drug-  
Development/default.aspx](https://investors.guardanthealth.com/press-releases/press-releases/2020/Guardant-Health-Launches-Real-World-Clinical-Genomic-Platform-to-Accelerate-Precision-Oncology-Drug-Development/default.aspx).

26 <sup>19</sup> See Guardant Health Inc., Annual Report (Form 10-K) (Feb. 22, 2024), available at  
27 [https://s26.q4cdn.com/594050615/files/doc\\_financials/2023/ar/2023-Annual-Report.pdf](https://s26.q4cdn.com/594050615/files/doc_financials/2023/ar/2023-Annual-Report.pdf).

28 <sup>20</sup> *Id.*

1 business, including research and development information, patient data, commercial information  
2 and business and financial information.”<sup>21</sup>

3 91. On information and belief, Guardant makes, uses, sells, and offers for sale the  
4 Accused Products at facilities in the United States on a regular basis, including at Guardant’s  
5 facilities in San Diego.

6 92. On information and belief, Guardant designs, develops, makes, uses, and performs,  
7 or directs or controls the design, development, make, use, and performance of the Accused Products  
8 by purposefully directing the activities at its CAP/CLIA-certified laboratories in San Diego and  
9 Redwood City, California.<sup>22</sup>

10 93. Guardant has infringed and is infringing one or more claims of the ’859 Patent  
11 pursuant to 35 U.S.C. § 271(a), including at least Claim 1, literally or under the doctrine of  
12 equivalents, by its use of the Accused Products within the United States, without authority.

13 94. Guardant has infringed and is infringing one or more claims of the ’839 Patent  
14 pursuant to 35 U.S.C. § 271(a), including at least Claim 1, literally or under the doctrine of  
15 equivalents, by its use of the Accused Products within the United States, without authority.

16 95. Guardant has infringed and is infringing one or more claims of the ’041 Patent  
17 pursuant to 35 U.S.C. § 271(a), including at least Claim 1, literally or under the doctrine of  
18 equivalents, by its use of at least the Guardant360 TissueNext PD-L1 test on the Guardant Galaxy  
19 platform within the United States, without authority.

20 96. Guardant has infringed and is infringing one or more claims of the ’097 Patent  
21 pursuant to 35 U.S.C. § 271(a), including at least Claim 1, literally or under the doctrine of  
22 equivalents, by its use of at least the Guardant360 TissueNext PD-L1 test on the Guardant Galaxy  
23 platform within the United States, without authority.

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25 <sup>21</sup> *Id.*

26 <sup>22</sup> <https://www.guardantcomplete.com/>; Guardant360 CDx Specification Sheet, GUARDANT  
27 HEALTH, available at ; Guardant360 TissueNext Assay Specifications, GUARDANT HEALTH,  
28 [https://www.guardanthealthmea.com/wp-content/uploads/Guardant360-TissueNext-  
Specification.pdf](https://www.guardanthealthmea.com/wp-content/uploads/Guardant360-TissueNext-Specification.pdf).

1           97. Exhibits 5-8 are preliminary and exemplary claim charts illustrating Guardant's  
2 infringement of Claim 1 of the '859 Patent, Claim 1 of the '839 Patent, Claim 1 of the '041 Patent  
3 and Claim 1 of the '097 Patent. The claim charts are not intended to limit Tempus's right to modify  
4 the charts or allege that other products or activities of Guardant infringe the identified claims or any  
5 other claims of the Patents-in-Suit or any other patents.

6           98. Exhibits 5-8 are hereby incorporated by reference in their entirety. Each claim  
7 element in Exhibits 5-8 that is mapped to the Accused Products shall be considered an allegation  
8 within the meaning of the Federal Rules of Civil Procedure, and therefore a response to each claim  
9 element is required.

10                           **COUNT I: INFRINGEMENT OF U.S. PATENT NO. 11,640,859**

11           99. Tempus incorporates by reference and re-alleges all the foregoing paragraphs of this  
12 Complaint as if fully set forth herein.

13           100. In violation of 35 U.S.C. § 271, Guardant has infringed and is currently infringing at  
14 least Claim 1 of the '859 Patent by making, using, selling, offering for sale, and/or importing into  
15 the United States, without authority, one or more of the Accused Products. On information and  
16 belief, Guardant has practiced and is currently practicing each and every element of at least Claim  
17 1 literally or under the doctrine of equivalents.

18           101. At least as of the filing of the complaint, Guardant has knowledge of the '859 Patent  
19 and its infringement thereof.

20           102. Exhibit 5 is a preliminary and exemplary claim chart illustrating Guardant's  
21 infringement of Claim 1 of the '859 Patent pursuant to 35 U.S.C. § 271(a).

22           103. Guardant's infringement has damaged and will continue to damage Tempus, which  
23 is entitled to recover the damages resulting from Guardant's wrongful acts in an amount to be  
24 determined at trial, and in any event no less than a reasonable royalty.

25           104. Moreover, Guardant's infringement has caused, and will continue to cause,  
26 irreparable harm to Tempus, for which damages are an inadequate remedy, unless Guardant,  
27 including its corporate affiliates and subsidiaries, is enjoined from any and all activities that would  
28 infringe the claims of the '859 Patent.



1 113. At least as of the filing of the complaint, Guardant has knowledge of the '041 Patent  
2 and its infringement thereof.

3 114. Exhibit 7 is a preliminary and exemplary claim chart illustrating Guardant's  
4 infringement of Claim 1 of the '041 Patent pursuant to 35 U.S.C. § 271(a).

5 115. Guardant's infringement has damaged and will continue to damage Tempus, which  
6 is entitled to recover the damages resulting from Guardant's wrongful acts in an amount to be  
7 determined at trial, and in any event no less than a reasonable royalty.

8 116. Moreover, Guardant's infringement has caused, and will continue to cause,  
9 irreparable harm to Tempus, for which damages are an inadequate remedy, unless Guardant,  
10 including its corporate affiliates and subsidiaries, is enjoined from any and all activities that would  
11 infringe the claims of the '041 Patent.

12 **COUNT IV: INFRINGEMENT OF U.S. PATENT NO. 10,991,097**

13 117. Tempus incorporates by reference and re-alleges all the foregoing paragraphs of this  
14 Complaint as if fully set forth herein.

15 118. In violation of 35 U.S.C. § 271, Guardant has infringed and is currently infringing at  
16 least Claim 1 of the '097 Patent by making, using, selling, offering for sale, and/or importing into  
17 the United States, without authority, one or more of the Accused Products. On information and  
18 belief, Guardant has practiced and is currently practicing each and every element of at least Claim  
19 1 literally or under the doctrine of equivalents.

20 119. At least as of the filing of the complaint, Guardant has knowledge of the '097 Patent  
21 and its infringement thereof.

22 120. Exhibit 8 is a preliminary and exemplary claim chart illustrating Guardant's  
23 infringement of Claim 1 of the '097 Patent pursuant to 35 U.S.C. § 271(a).

24 121. Guardant's infringement has damaged and will continue to damage Tempus, which  
25 is entitled to recover the damages resulting from Guardant's wrongful acts in an amount to be  
26 determined at trial, and in any event no less than a reasonable royalty.

27 122. Moreover, Guardant's infringement has caused, and will continue to cause,  
28 irreparable harm to Tempus, for which damages are an inadequate remedy, unless Guardant,

1 including its corporate affiliates and subsidiaries, is enjoined from any and all activities that would  
2 infringe the claims of the '097 Patent.

3 **PRAYER FOR RELIEF**

4 WHEREFORE, Tempus respectfully requests the following relief:

5 1. A judgment that Guardant has infringed and is infringing the '839 Patent, the '859  
6 Patent, the '041 Patent, and the '097 Patent, literally or under the doctrine of equivalents;

7 2. An order enjoining Guardant and its respective officers, directors, agents, servants,  
8 affiliates, employees, divisions, branches, subsidiaries, parents, and all others acting on behalf of or  
9 in active concert or participation therewith, from further infringement of the '839 Patent, the '859  
10 Patent, the '041 Patent, and the '097 Patent;

11 3. An award of damages sufficient to compensate Tempus for Guardant's infringement  
12 under 35 U.S.C. § 284;

13 4. A determination that this is an exceptional case under 35 U.S.C. § 285 and that  
14 Tempus be awarded attorneys' fees;

15 5. Costs and expenses in this action;

16 6. An award of prejudgment and post-judgment interest; and

17 7. Such other and further relief as the Court may deem just and proper.

18 **DEMAND FOR JURY TRIAL**

19 Pursuant to Rule 38(b) of the Federal Rules of Civil Procedure, Tempus respectfully  
20 demands a trial by jury on all triable issues.

21  
22 Dated: March 14, 2025

Respectfully submitted,

23 /s/ Andrew J. Bramhall  
24 Andrew J. Bramhall

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