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

COMPLAINT FOR PATENT INFRINGEMENT

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

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

Guardant360 TissueNext and Guardant360 CDx biopsy tests, infringe Tempus's patented inventions.

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

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

THE PARTIES

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

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

JURISDICTION AND VENUE

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

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

9. The exercise of personal jurisdiction comports with Guardant's right to due process because, as described above, Guardant has purposefully availed itself of the privilege of doing business in California such that it should reasonably anticipate being haled into court here.

10. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391 and 1400(b) at least because Guardant has a regular and established place of business in this District, including at its CAP-accredited and CLIA-certified laboratory located at 10578 Science Center Drive, San Diego, California; Guardant has committed acts of infringement in this District by engaging in infringing conduct within, directed at, or directed from this District; and Guardant has purposely and voluntarily placed the Accused Products into the stream of commerce with the expectation that they will be used in this District. On information and belief, Guardant employs more than 100 employees in an approximately 37,000 square foot office located in San Diego, California, and Guardant designs, develops, makes, uses, performs, offers for sale, and/or sells the Accused Products within this District.[1]

FACTUAL BACKGROUND

I. Tempus's Groundbreaking Innovations

11. Eric Lefkofsky founded Tempus in 2015 after his wife was diagnosed with breast cancer. From his experience co-founding the global e-commerce company Groupon, Inc., Mr. Lefkofsky knew well the transformative value of data analytics. He founded Tempus to revolutionize healthcare by leveraging the power of AI and multi-modal data to enhance precision medicine, starting with the treatment of cancer.

12. One of the key insights behind Tempus's founding was that to enhance the diagnosis, treatment, and understanding of cancer and other major diseases it was necessary to combine robust, real-world datasets with a full spectrum of diagnostics technologies and the vast power of AI. From the beginning Tempus focused on building comprehensive platforms that integrated (among other

[1] *See, e.g.*, https://s26.q4cdn.com/594050615/files/doc_financials/2023/ar/2023-Annual-Report.pdf ("We currently perform our tests in our laboratories located in Redwood City, California, and San Diego, California. . . . Our San Diego laboratory is CAP-accredited, CLIA-certified and licensed in California.").

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

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

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

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

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

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

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

II. The Tempus Patents-in-Suit

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

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

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

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

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

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

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

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

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

for each of a plurality of patients 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;

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

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

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

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

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

(g) for each user application program:

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

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

25. Independent Claim 1 of the ’839 Patent recites:

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

storing a set of user application programs wherein each of the programs requires an application specific subset of data to perform application processes and generates a 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;

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

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

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

(e) for each user application program;

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

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

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

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

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

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

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

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

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

> what is needed is a system that is capable of efficiently capturing all treatment relevant data including cancer state factors, treatment decisions, treatment efficacy and exploratory factors (e.g., factors that may have a causal relationship to treatment efficacy) and 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

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

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

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

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

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

"stor[ed] . . . in a semi-structured first database," "generat[ing] genomic sequencing data for [a] patient's cancerous cells and normal cells" and "storing the sequencing data in [a] database," "shaping at least a subset of [that] database data to generate system structured data including clinical record data and sequencing data wherein the system structured data is optimized for searching," "storing the system structured data in a second database," and then—for each 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." *Id.* at Claim 1. These limitations, individually and as an ordered combination, describe an unconventional approach to address the aforementioned problems in the art.

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

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

related interfaces, among others." '859 Patent at 10:32-38; '839 Patent at 51:15-21. "[A] data structure that is optimal for one purpose often is sub-optimal for other purposes." '859 Patent at 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 "plethora of treatment and customization options in many cases makes it difficult to accurately capture treatment and results data in a normalized fashion as there are no clear standardized guidelines for how to capture that type of information").

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

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

> **Claims 1-84 are patent eligible.** When considered as a whole using the 2-step framework outlined by the 2019 PEG and MPEP 2106, each of the claims satisfy Step 1 because they are directed to methods (i.e. processes). When examining these claims under Step 2A – Prong 1, independent claims 1 and 20 are not found to recite any of the judicial exceptions enumerated in the 2019 PEG. For instance, none of the instant claims recite any mathematical relationships, formulas, or calculations. Further, none of these claims recite a mental process because they steps are not practically performable in the human mind. Finally, none of the claims recite certain methods of organizing human activity such as fundamental economic practices or managing interactions between people. Claim 1 is instead directed to methods for storing and structuring clinical and genomic sequencing patient 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

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

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

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

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

38. Several elements of at least Claim 1 of the '859 Patent are similar to elements of Claim 1 of the '839 Patent. For example, both claims recite a "method for conducting genomic sequencing," comprising, among other limitations, "storing a set of user application programs wherein each of the programs requires an application specific subset of data to perform application processes," "obtaining clinical records data in original forms where the clinical records data includes cancer state information, treatment types and treatment efficacy information," "using a next generation genomic sequencer to generate genomic sequencing data for the patient's cancerous cells and normal cells," "shaping at least a subset of the first database data to generate system structured 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

> The following is a statement of reasons for the indication of allowable subject matter:
>
> 31. The prior art fails to expressly teach or suggest, either alone or in combination, each and every feature of claims 1 and 21. In particular, the prior art fails to teach shaping at least a subset of the first database data to generate system structured data including clinical record data and sequencing data wherein the system structured data is optimized for searching; storing the system structured data in a second database; 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; particularly in combination with performing genetic sequencing operations as in claim 1 and performing tumor growth and treatment efficacy testing as in claim 21. . . .
>
> 32. Though many aspects of claims 1 and 21 are disclosed in the prior art, it would not have been obvious to one of ordinary skill in the art to combine the disparate features into the invention of the instant claims. Further, the prior art fails to provide teaching of the particular combination of limitations noted above. Accordingly, the prior art, either alone or in combination, does not disclose or render obvious all the features of claims 1 and 21 and they are found to recite subject matter that distinguishes over the prior art, as are claims 2-19, 23, and 25-84 depending therefrom.

Oct. 13, 2022 Non-Final Rejection at 10-11, U.S. Appl. No. 16/771,451 Prosecution History. Thus, at least the steps of "shaping at least a subset of the first database data to generate system structured data including clinical record data and sequencing data wherein the system structured data is 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:

> 11. The method of claim 1 wherein the application programs include operational programs and wherein at least a subset of the operational programs comprise a physician suite of programs useable to consider cancer state treatment options.
>
> 12. The method of claim 11 wherein at least a subset of the operational programs comprise a suite of data shaping programs usable by a system user to shape data stored in the first database.

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

41. The dependent claims of the '839 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, Claim 2 depends from Claim 1, and recites:

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

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

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

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

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

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

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

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

> A computer-implemented method of identifying biomarkers in a digital image of a hematoxylin and eosin (H&E) stained slide of target tissue, the method comprising:
>
> receiving the digital image to an image-based biomarker prediction system having one or more processors;
>
> separating, using the one or more processors, the digital image into a plurality of tile images, where each of the plurality of tile images contains a different portion of the digital image;
>
> applying, using the one or more processors, the plurality of tile images to a deep learning framework comprising one or more trained biomarker classification models, each trained biomarker classification model being trained to classify a different biomarker, wherein the deep learning framework comprises a multiscale deep learning framework;
>
> predicting, using the one or more processors, a biomarker classification for each of the plurality of tile images using the one or more trained biomarker classification 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,

> wherein each of the applying the plurality of tile images to the deep learning framework and predicting the biomarker classification for each of the plurality of tile images comprises,
>
> applying each of the tile images to one or more trained deep learning multiscale classifier models, each trained deep learning multiscale classifier models being trained to classify a different tissue classification for each tile image and determining a tissue classification for each of the plurality of tile images, using the multiscale deep learning framework,
>
> identifying, using the one or more processors, cells within the digital image using a trained cell segmentation model, and
>
> from the tissue classification determined for each tile image and from the identified cells within the digital image, predicting the biomarker classification for each tile image.

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

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

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

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

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

Id. at 3:31-37.

51. The claimed inventions of the '041 Patent address these computer vision and other problems that existed in the prior art. For example, the '041 Patent discloses an "imaging-based biomarker prediction system formed of a deep learning framework configured and trained to directly learn from histopathology slide images and predict the presence of biomarkers in medical images." *Id.* at 3:41-45.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

> 1. A method for creating an overlay map on a digital image of a slide, the method comprising:
>
> receiving the digital image;
>
> separating the digital image into a plurality of tiles, each tile of the plurality of tiles containing a respective portion of the digital image of the slide; and
>
> for each tile of the plurality of tiles:
>
> identifying features of the tile;
>
> identifying structural tissue features of a second portion of the digital 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.

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

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

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

66. The '097 Patent discloses innovative methods of analyzing and classifying digital slide images, including receiving and separating a digital image into a plurality of tiles, each containing a portion of the digital image of the slide, and, for each tile, identifying features of the tile, "identifying structural tissue features of a second portion of the digital 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 "determining a predicted class for each 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." *Id.* at Claim 1.

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

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

> The following is an examiner's statement of reasons for allowance: The present invention comprises a generalizable and interpretable deep learning model for predicting biomarker status and biomarker metrics from histopathology slide images. The closest prior art, Tunstall[,] . . . shows a similar system which also includes an image of a section of a tissue sample imaged from a microscope slide stained using Haemotoxylin and Eosin, using a learning method with classification data, obtaining a probability estimate based on comparing the feature vectors of tiles in tissue regions of the image, and displaying the resulting probability estimate as a color map. However, Tunstall fails to disclose "each tile of the plurality of tiles containing a respective portion of the digital image of the slide; and for each tile of the plurality of tiles: identifying features of the tile; identifying structural tissue features of a second portion of the digital 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.

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

69. Thus, at least the steps of "each tile of the plurality of tiles containing a respective portion of the digital image of the slide; and for each tile of the plurality of tiles: identifying features of the tile; identifying structural tissue features of a second portion of the digital 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" are not well-understood, routine, or conventional.

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

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

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

III. Guardant's Infringing Conduct

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

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

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

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

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

[2] Deena Beasley, *Guardant DNA blood test finds 83% of colorectal cancers in trial, shares fall 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/.

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

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

80. In 2022, Guardant introduced Guardant INFINITY, a "smart liquid biopsy platform."[6] According to Guardant's website, Guardant INFINITY comprises a "single platform that powers [Guardant's] entire portfolio, making epigenomic insights scalable from research to the

---

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

[4] 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.

[5] Guardant360 CDx Specification Sheet, GUARDANT HEALTH, *available at* https://www.guardantcomplete.com/assets/pdf/Guardant360-CDx-Technical-Information-US.pdf.

[6] Press Release, *Guardant Health Introduces GuardantINFINITY™ Smart Liquid Biopsy for Research Use to Help Bring New Cancer Therapies to Patients Sooner*, GUARDANT HEALTH (Sept. 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.

clinic."[7] The Guardant INFINITY platform "can both quantify and characterize cancer with genomic and epigenomic analysis, powering multiple applications in precision oncology."

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

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

---

[7] GUARDANT COMPLETE, https://www.guardantcomplete.com/biopharma/multiomic-solution.

[8] 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 (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.

[9] *Id.*

83. In 2024, Guardant introduced the Guardant360 TissueNext tissue biopsy assay in the United States.[10] As shown in the Guardant360 TissueNext Specification Sheet, the Guardant360 TissueNext assay is an "analytically validated comprehensive next-generation sequencing panel that includes clinically actionable biomarkers to enable informed treatment decisions for patients with advanced solid tumors." The Guardant360 TissueNext tissue biopsy assay utilizes a sequencing approach identical or very similar to the Guardant360 CDx assay's sequencing method (e.g., Guardant Health's proprietary Digital Sequencing technology).

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

85. The Accused Products include technology platforms that integrate multiple oncology tests, such as the Guardant360 CDx and Guardant360 TissueNext assays, among others, with data associated with these tests and from patients. According to the Guardant Complete Website,[11] the Guardant Galaxy and Guardant Infinity platforms power Guardant's liquid biopsy and tissue biopsy tests, and the GuardantINFORM data platform "integrates information from NGS [next-generation sequencing]"—*e.g.*, information obtained from the Guardant360 CDx and Guardant360 TissueNext assays—"demographics, cancer diagnoses, treatment and procedures, and pharmacy prescription data across 60+ solid tumor cancer types."

86. Certain of the Accused Products are used by Guardant to conduct genomic sequencing. For example, the Guardant360 TissueNext assay is an "analytically validated comprehensive next-generation sequencing panel that interrogates 498 genes that includes clinically

[10] Press Release, *Guardant Health introduces new Guardant360 TissueNext test with nearly 500 biomarkers to identify more treatment options for patients with advanced cancer*, GUARDANT 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.

[11] GUARDANT COMPLETE, https://www.guardantcomplete.com/biopharma/multiomic-solution.

actionable biomarkers to enable informed treatment decisions for patients with advanced solid tumors."[12] Guardant360 TissueNext is "powered by Guardant Galaxy."[13] Guardant Galaxy is "a suite of advanced analytical technologies developed internally and through outside partnerships to enhance the performance and clinical utility of Guardant Health's portfolio of cancer tests and to power the next generation of biomarker and drug discovery."[14]

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

---

[12] https://www.guardanthealthamea.com/wp-content/uploads/Guardant360-TissueNext-Specification.pdf.

[13] *Guardant360 TissueNext*, GUARDANT COMPLETE, https://www.guardantcomplete.com/products/guardant360-tissuenext.

[14] 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 (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.

[15] GUARDANT COMPLETE, https://www.guardantcomplete.com/biopharma/multiomic-solution.

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

88. GuardantINFORM's "NLP Methodology" "takes critical information extracted from medical records–such as tumor staging, biomarker profile, tumor histology, smoking history, and performance status–and normalizes it into structured data."[17] The GuardantINFORM data platform is "an in-silico platform that combines de-identified longitudinal clinical information and genomic data" which "offers real-world insights into anti-cancer therapy use in the clinic, tumor evolution, and treatment resistance throughout each patient's treatment journey for many advanced solid tumor cancers."[18]

89. According to Guardant, GuardantINFORM complements its "core diagnostic business with aggregated data obtained through real world genomic testing matched with clinically relevant information, which enables important insights into disease progression and treatment impact that can be fed back into drug discovery and development as well as clinical research and practice."[19]

90. Guardant "manage[s] and maintain[s] our applications and data utilizing a combination of on-site systems and cloud-based data centers" and "depend[s] on information technology systems for significant elements of our operations, including our laboratory information management system, our computational biology system, our knowledge management system, our customer reporting and our GuardantConnect software platform."[20] Guardant's information technology systems support "lab operations" and "store a wide variety of information critical to our

---

[17] *Id.*

[18] Press Release, *Guardant Health Launches Real-World Clinical-Genomic Platform to Accelerate Precision Oncology Drug Development*, GUARDANT HEALTH (June 23, 2020), *available at* 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.

[19] *See* Guardant Health Inc., Annual Report (Form 10-K) (Feb. 22, 2024), *available at* https://s26.q4cdn.com/594050615/files/doc_financials/2023/ar/2023-Annual-Report.pdf.

[20] *Id.*

business, including research and development information, patient data, commercial information and business and financial information."[21]

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

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

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

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

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

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

---

[21] *Id.*

[22] https://www.guardantcomplete.com/; Guardant360 CDx Specification Sheet, GUARDANT HEALTH, *available at* ; *Guardant360 TissueNext Assay Specifications*, GUARDANT HEALTH, https://www.guardanthealthamea.com/wp-content/uploads/Guardant360-TissueNext-Specification.pdf.

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

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

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

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

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

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

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

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

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

COUNT II: INFRINGEMENT OF U.S. PATENT NO. 12,112,839

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

106. In violation of 35 U.S.C. § 271, Guardant has infringed is currently infringing at least Claim 1 of the '839 Patent by making, using, selling, offering for sale, and/or importing into the United States, without authority, one or more of the Accused Products. On information and belief, Guardant has practiced and is currently practicing each and every element of at least Claim 1 literally or under the doctrine of equivalents.

107. At least as of the filing of the complaint, Guardant has knowledge of the '839 Patent and its infringement thereof.

108. Exhibit 6 is a preliminary and exemplary claim chart illustrating Guardant's infringement of Claim 1 of the '839 Patent pursuant to 35 U.S.C. § 271(a).

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

110. Moreover, Guardant's infringement has caused, and will continue to cause, irreparable harm to Tempus, for which damages are an inadequate remedy, unless Guardant, including its corporate affiliates and subsidiaries, is enjoined from any and all activities that would infringe the claims of the '839 Patent.

COUNT III: INFRINGEMENT OF U.S. PATENT NO. 10,957,041

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

112. In violation of 35 U.S.C. § 271, Guardant has infringed and is currently infringing at least Claim 1 of the '041 Patent by making, using, selling, offering for sale, and/or importing into the United States, without authority, one or more of the Accused Products. On information and belief, Guardant has practiced and is currently practicing each and every element of at least Claim 1 literally or under the doctrine of equivalents.

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

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

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

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

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

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

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

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

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

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

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

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

PRAYER FOR RELIEF

WHEREFORE, Tempus respectfully requests the following relief:

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

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

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

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

5. Costs and expenses in this action;

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

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

DEMAND FOR JURY TRIAL

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

Dated: March 14, 2025

Respectfully submitted,

/s/ Andrew J. Bramhall
Andrew J. Bramhall

OF COUNSEL:

Kevin P.B. Johnson
Andrew J. Bramhall
Margaret Shyr
QUINN EMANUEL URQUHART
& SULLIVAN, LLP
Tel: +1 650 801 5000
Fax: +1 650 801 5100
555 Twin Dolphin Dr., 5th Floor
Redwood Shores, California 94065
kevinjohnson@quinnemanuel.com
andrewbramhall@quinnemanuel.com
margaretshyr@quinnemanuel.com

Brian P. Biddinger
QUINN EMANUEL URQUHART
& SULLIVAN, LLP
295 5th Avenue, 9th Floor
New York, New York 10016
Tel: +1 212 849 7000
Fax: +1 212 849 7100
brianbiddinger@quinnemanuel.com

Attorneys for Plaintiff Tempus AI, Inc.