UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLORADO

Civil Action No. 1:23-cv-01623

PERSONALIS, INC.,

Plaintiff,

JURY TRIAL DEMANDED

v.

FORESIGHT DIAGNOSTICS INC.,

Defendant.

PLAINTIFF PERSONALIS, INC.'S FIRST AMENDED COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Personalis, Inc. ("Plaintiff" or "Personalis") hereby submits this First Amended Complaint against Defendant Foresight Diagnostics Inc. ("Defendant" or "Foresight Diagnostics") and states as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement arising under the patent laws of the United States, 35 U.S.C. § 271, *et seq.*, arising from Foresight Diagnostics' acts of infringement of United States Patent Nos. 11,584,968 (the "'968 Patent"), 11,649,507 (the "'507 Patent"), and 11,643,685 (the "'685 Patent").

THE PARTIES

2. Plaintiff Personalis is a Delaware corporation with its principal place of business located at 6600 Dumbarton Circle, Fremont, California 94555.

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3. Defendant Foresight Diagnostics is a Delaware corporation with its principal place of business located at 12705 E Montview Blvd Suite 360, Aurora, CO 80045-7111.

JURISDICTION AND VENUE

4. This Court has original subject matter jurisdiction over the asserted claims pursuant to 28 U.S.C. §§ 1331 and 1338(a) because this action arises under the laws of the United States, 35 U.S.C. §§ 271 *et seq*., for patent infringement.

5. This Court has personal jurisdiction over Foresight Diagnostics at least because Foresight Diagnostics has its principal place of business in the state of Colorado.

6. Venue over this action is proper in this Court pursuant to 28 U.S.C. §§ 1391(b), 1391(c) and 1400(b) at least because Foresight Diagnostics has its principal place of business in the state of Colorado.

BACKGROUND

7. Personalis was founded in 2011 as a Stanford University spin-out and its CLIA-certified, CAP-accredited laboratory is located in Menlo Park, California.

8. Personalis' mission is to transform the active management of cancer through breakthrough personalized testing. Personalis is committed to building a world where personalized testing provides greater confidence and exceptional outcomes for cancer patients.

9. Personalis' tests are routinely used by many of the largest oncology-focused pharmaceutical companies for analysis of patient samples from their clinical trials and, more recently, by a growing number of leading cancer centers.

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10. In December 2021, Personalis launched NeXT Personal®, a next-generation, tumor-informed liquid biopsy assay designed to detect and quantify minimal (or molecular) residual disease ("MRD") and recurrence in patients previously diagnosed with cancer.

11. NeXT Personal is designed to deliver industry-leading MRD sensitivity down to the 1 part-per-million range, which represents an approximately 10- to 100-fold improvement over other available technologies, through the use of whole genome sequencing of a patient's tumor to identify up to 1,800 specially-selected somatic variants that are used to create a personalized liquid biopsy panel for each patient.

12. NeXT Personal is unique in that it is also designed to simultaneously detect and quantify clinically known, targetable cancer mutations, drug resistance mutations, and new variants which can emerge over time and in response to therapeutic pressure.

THE PATENTS-IN-SUIT

13. On February 21, 2023, the United States Patent and Trademark Office issued United States Patent No. 11,584,968 (the "'968 Patent"), entitled "Methods For Using Mosaicism in Nucleic Acids Sampled Distal to Their Origin" naming John West as the inventor. A true and correct copy of the '968 Patent is attached to this First Amended Complaint as Exhibit A and incorporated herein by reference.

14. The '968 Patent is valid and enforceable.

15. Personalis owns by assignment all right, title and interest in, and has standing to sue for infringement of, the '968 Patent.

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16. Personalis has the right to assert all causes of action arising under the '968 Patent and the right to recover any remedies for infringement of it, including the right to sue for past infringement.

17. The '968 Patent relates to methods for improving detection and monitoring of human diseases. *See* Exhibit A, Abstract.

18. For example, claim 1 of the '968 Patent claims a method for analyzing a biological sample obtained from a subject being screened for a cancer by using whole genome sequencing (WGS) of the cancer patient's tumor DNA and matching normal samples to identify a set of single nucleotide polymorphisms (SNPs), multiple nucleotide polymorphisms, or other variants present only in the patient's tumor and then looking for those variants in cell-free DNA (cfDNA) from a subsequently obtained blood or other sample in order to predict, diagnose, and/or prognose a status or outcome of a cancer in that patient.

19. On May 16, 2023, the United States Patent and Trademark Office issued United States Patent No. 11,649,507 (the "'507 Patent"), entitled "Methods for Using Mosaicism in Nucleic Acids Sampled Distal to Their Origin" naming John West as the inventor. A true and correct copy of the '507 Patent is attached to this First Amended Complaint as Exhibit B and incorporated herein by reference.

20. The '507 Patent is valid and enforceable.

21. Personalis owns by assignment all right, title and interest in, and has standing to sue for infringement of, the '507 Patent.

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22. Personalis has the right to assert all causes of action arising under the '507 Patent and the right to recover any remedies for infringement of it, including the right to sue for past infringement.

23. The '507 Patent relates to methods for detection and monitoring of human disease by providing spatial or developmental localization of mutations within the body which is used in monitoring states of health in tissues of the body. *See* Exhibit B, Abstract.

24. For example, claim 1 of the '507 Patent claims a method for detecting, diagnosing, or monitoring a patient's cancer using WGS to identify somatic variants specific to the patient, by comparing to a reference sample, and tracking the presence or absence of those variants in one or more additional samples over the life of the patient.

25. On May 9, 2023, the United States Patent and Trademark Office issued United States Patent No. 11,643,685 (the "'685 Patent"), entitled "Methods and Systems For Genetic Analysis" naming John West, Christian Haudenschild, and Richard Chen as inventors. A true and correct copy of the '685 Patent is attached to this First Amended Complaint as Exhibit C and incorporated herein by reference.

26. The '685 Patent is valid and enforceable.

27. Personalis owns by assignment all right, title and interest in, and has standing to sue for infringement of, the '685 Patent.

28. Personalis has the right to assert all causes of action arising under the '685 Patent and the right to recover any remedies for infringement of it.

29. The '685 Patent relates to methods for sample processing and analysis to aid in the diagnosis, monitoring, treatment, and prevention of disease. *See* Exhibit C, Abstract.

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30. For example, claim 28 of the ’685 Patent claims a method for personalized genetic testing by generating a genetic signature for a patient, creating a personalized probe set based on the genetic signature, and using the personalized probe set to track cancer or other diseases across additional samples from the patient.

31. As testament to the strength of the ’968, ’507, and ’685 Patents, the United States Patent & Trademark Office (“USPTO”) granted the ’968, ’507, and ’685 patents over various prior art references that Foresight Diagnostics recently relied upon in four IPR filings directed to patents related to the ’968, ’507, and ’685 patents:

- The primary references relied upon in the first of the four IPRs were Leary, Liao, Ley, and Chan.
- The primary references relied upon in the second of the four IPRs were Forshew, Wagle, and Chan.
- The primary references relied upon in the third of the four IPRs were Ley, Forshew, and Dawson.
- The primary references relied upon in the fourth IPR were Ley and Newman.
- Additional secondary references relied upon across the four IPRs were Quake, Anderson, Gnirke, Mertes, Mamanova, Shendure, Ross, McBride, Kurtz, Oh, Lam, Untergasser, Forbes, Vale, Davies, Bentley, Haferlach, Sims, and Meyerson.

32. The examiner of the ’507 patent’s application considered each of the primary references listed above in paragraph 31 along with several of the secondary references,

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including Meyerson, Forbes, Untergasser, Ross, McBride, Oh, Lam, and Shendure. The Examiner allowed the '507 patent over these references.

33. The same examiner that examined the '507 patent also examined the '968 patent's application. During prosecution, the examiner considered all but two of the key references (Newman and Dawson) identified in paragraph 31 above, and also considered several of the secondary references, including Quake, Mertes, Mamanova, Anderson, and Gnirke. The Examiner allowed the '968 patent over these references.

34. During prosecution of the '685 patent, the examiner considered all but two of the key references (Newman and Dawson) identified in paragraph 31 above, and also considered several of the secondary references, including Quake, Mertes, Mamanova, Anderson, and Gnirke. The Examiner allowed the '685 patent over these references.

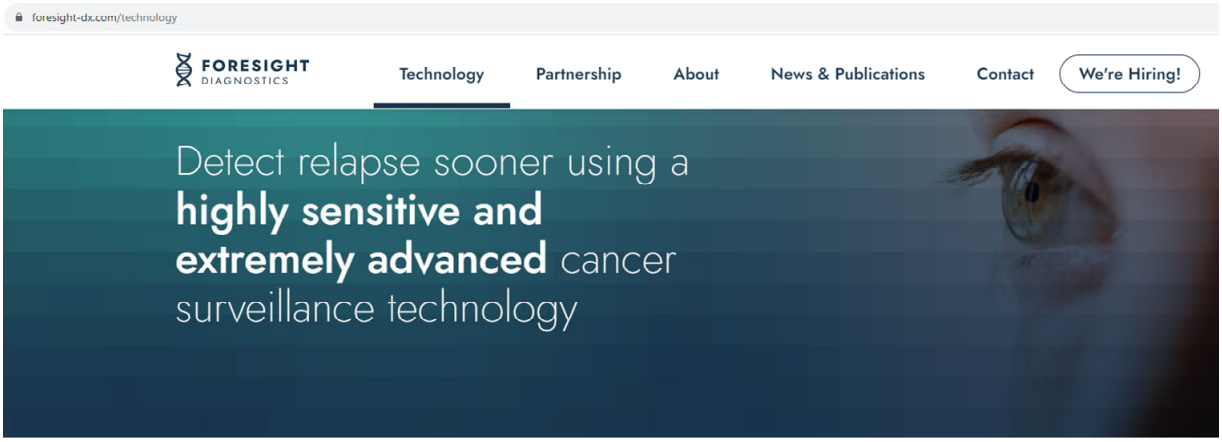
FORESIGHT DIAGNOSTICS' INFRINGEMENT OF THE PATENTS-IN-SUIT

35. Foresight Diagnostics offers a personalized assay for the detection of MRD for solid tumors referred to herein as the "Solid Tumor Recurrence Test" and that is described *inter alia* in the 2021 Nature Biotechnology publication listed on Foresight Diagnostics' website. *See* Foresight Diagnostics, *News & Publications*, FORESITE-DX.COM, https://foresight-dx.com/news (last visited June 9, 2023) (listing David M. Kurtz et. al., *Enhanced detection of minimal residual disease by targeted sequencing of phased variants in circulating tumor DNA*, 39 Nature Biotechnology 1537–1547 (July 22, 2021)) (hereinafter "Kurtz," attached hereto as Exhibit D).

36. The current Solid Tumor Recurrence Test as used by Foresight Diagnostics is described on the Foresight website at https://foresight-dx.com/technology. As confirmed

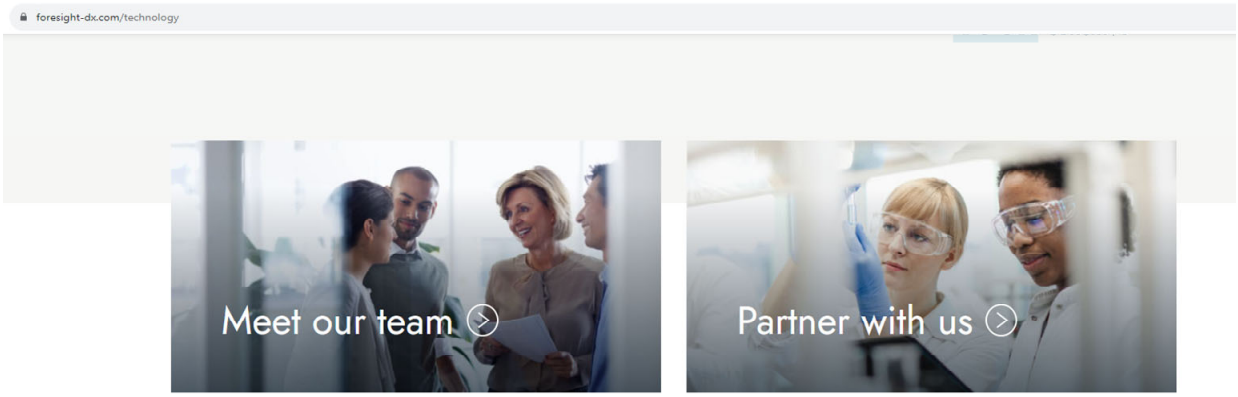
by this and other websites, the Solid Tumor Recurrence Test as used by Foresight Diagnostics implements the methods set forth in Kurtz and Isbell, J.M., Li, B.T., Eichholtz, J.E. et al. *Ultrasensitive ctDNA MRD Monitoring in early stage lung cancer with PhasED-Seq*. Poster, AACR 2023 Annual Meeting (hereinafter "Isbell." attached hereto as Exhibit J). Kurtz and Isbell both constitute reports of the same technology used in Foresight Diagnostics' minimal residual disease ("MRD") product that Foresight Diagnostics provides to customers by performing MRD testing in its CLIA laboratory in Aurora, Colorado.

37. For instance, the Foresight Diagnostics' technology website specifically points to Kurtz and Isbell as describing the technology utilized in its MRD platform. *See, e.g.*, https://foresight-dx.com/technology (last visited August 22, 2023) (attached hereto as Exhibit K) ("Foresight's peer-reviewed and proprietary minimal residual disease (MRD) technology has been validated in thousands of real-world samples from patients with B-cell malignancies, lung cancer, and breast cancer.[1,2,3] . . . [1] Kurtz, D.M., Soo, J., Co Ting Keh, L. et al. *Enhanced detection of minimal residual disease by targeted sequencing of phased variants in circulating tumor DNA*. Nat Biotechnol 39, 1537–1547 (2021) . . . [3] Isbell, J.M., Li, B.T., Eichholtz, J.E. et al. *Ultrasensitive ctDNA MRD Monitoring in early stage lung cancer with PhasED-Seq*. Poster, AACR 2023 Annual Meeting."). The relevant portions of the Foresight Diagnostics' technology website (attached hereto as Exhibit K) are shown below:



See relapses that others miss.

Foresight's peer-reviewed and proprietary minimal residual disease (MRD) technology has been validated in thousands of real-world samples from patients with B-cell malignancies, lung cancer, and breast cancer.[1,2,3]



[1] Kurtz, D.M., Soo, J., Co Ting Keh, L. et al. *Enhanced detection of minimal residual disease by targeted sequencing of phased variants in circulating tumor DNA.* Nat Biotechnol 39, 1537–1547 (2021)

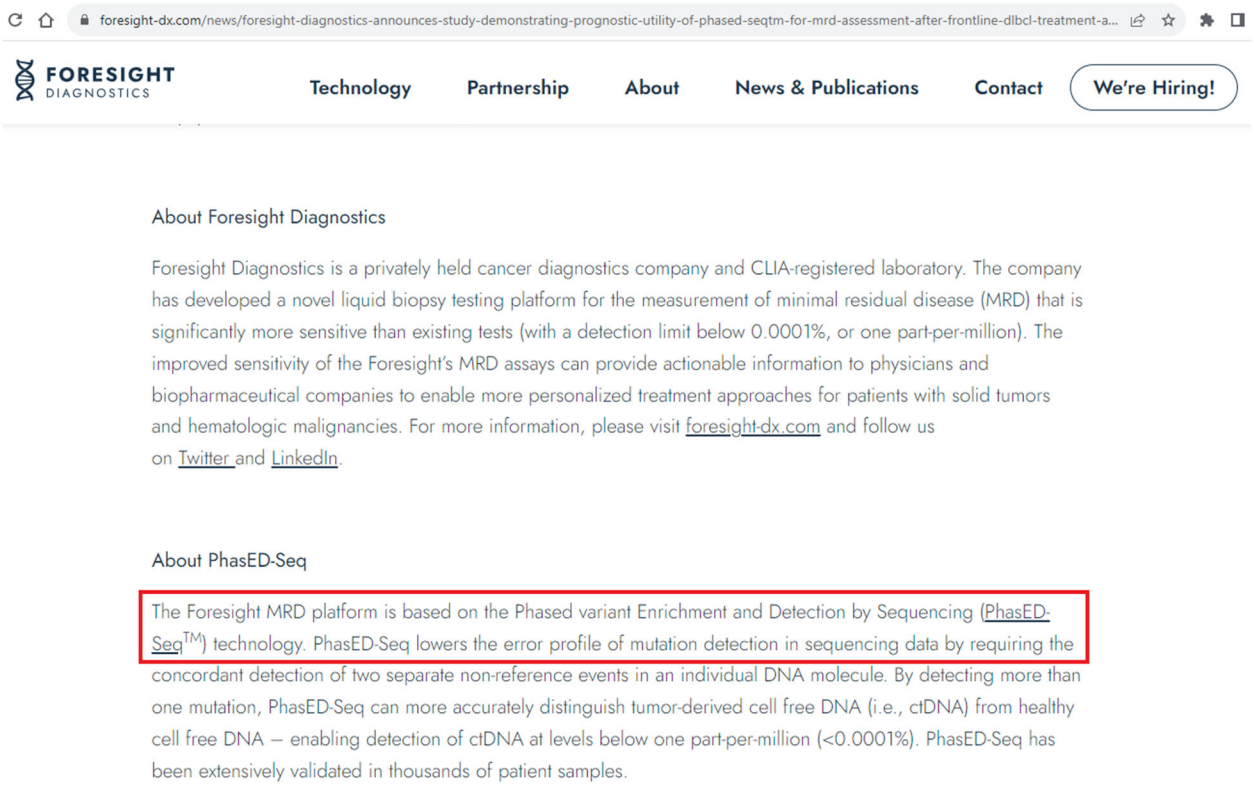
[2] Roschewski, M., Kurtz, D.M., Westin, J. et al. *MRD-Negativity As a Potential Surrogate Endpoint after Frontline DLBCL Therapy: Pooled Analysis of Trials & Implications for Clinical Trial Design.* Blood (2022) 140 (Supplement 1): 785–786.

[3] Isbell, J.M., Li, B.T., Eichholtz, J.E. et al. *Ultrasensitive ctDNA MRD Monitoring in early stage lung cancer with PhasED-Seq.* Poster, AACR 2023 Annual Meeting



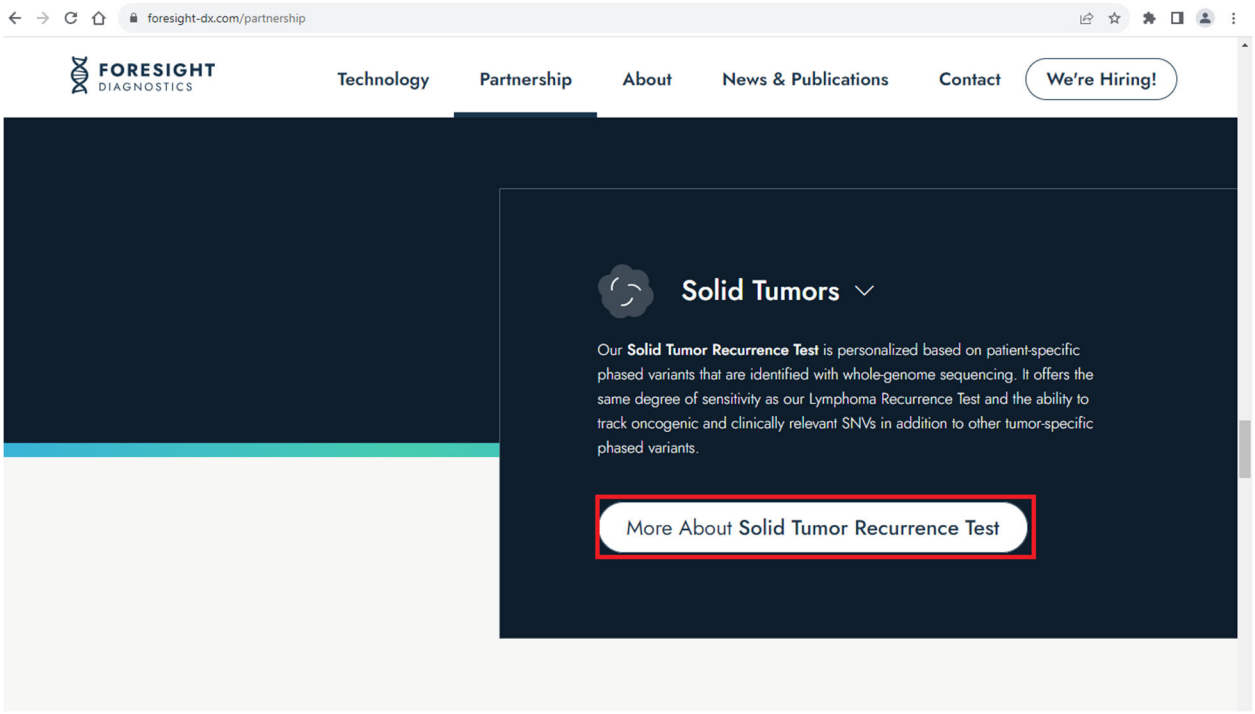
This confirms that the method set forth in Kurtz and Isbell reflects that which is utilized and provided to customers in Foresight Diagnostics' CLIA laboratory in Aurora, Colorado.

38. As another example, several recent studies from Foresight Diagnostics purportedly used so-called "PhasED-Seq" technology. The term "PhasED-Seq" is what Foresight Diagnostics uses to refer to the technology in its entire "MRD platform" and hence the Solid Tumor Recurrence Test. *See* https://www.foresight-dx.com/news/foresight-diagnostics-announces-study-demonstrating-prognostic-utility-of-phased-seqtm-for-mrd-assessment-after-frontline-dlbcl-treatment-at-the-17th-international-conference-on-malignant-lymphoma (attached hereto as Exhibit L) ("About PhasED-Seq - The Foresight MRD platform is based on the Phased variant Enrichment and Detection by Sequencing (*PhasED-SeqTM*) technology.") (italicized portion linking to https://foresight-dx.com/technology). The relevant portion of this website is shown below:



In the Isbell April 2023 poster presentation (attached hereto as Exhibit J), Foresight Diagnostics further cited Kurtz as disclosing the methodology used in the PhasED-Seq method that underlies its MRD platform. This further confirms that the methodology described in Kurtz reflects the approach that Foresight Diagnostics performs and provides to customers as part of its Solid Tumor Recurrence Test at its CLIA laboratory in Aurora, Colorado.

39. As yet another example, in the "Partnership" section of its website, Foresight Diagnostics offers to provide services related to its Solid Tumor Recurrence Test. *See* Foresight Diagnostics, *Partnership*, FORESITE-DX.COM, https://foresight-dx.com/partnership (last visited June 13, 2023) (attached hereto as Exhibit E). The relevant portion of this website is shown below:



40. These services would be provided by virtue of Foresight Diagnostics' performing its Solid Tumor Recurrence Test at its CLIA laboratory in Aurora, Colorado. Again, Foresight cites Kurtz and Isbell as setting forth the methodology used in its Solid Tumor Recurrence Test. *See id.* Indeed, a hyperlink labeled "More About Solid Tumor Recurrence Test" leads directly to an abstract by Kurtz. David M. Kurtz et al., *Abstract #8518: Leveraging phased variants for personalized minimal residual disease detection in localized non-small cell lung cancer*, https://foresight-dx.com/documents/KurtzDM_Lung_Poster_ASCO2021.pdf (May 20, 2021) (attached hereto as Exhibit M). The same methods were used in both reports and they were published the same year. This further confirms that the methodology described in Kurtz reflects the approach that Foresight Diagnostics performs and provides to customers as part of its Solid Tumor Recurrence Test at its CLIA laboratory in Aurora, Colorado.

41. Additionally, in the ongoing, related litigation, *Personalis, Inc. v. Foresight Diagnostics Inc.*, 1:22-cv-01913-NRN (D. Colo. 2022), Foresight did not move to dismiss the first amended complaint on the basis of Personalis' first amended complaint stating that Kurtz describes the Solid Tumor Recurrence Test. *See* 1:22-cv-01913-NRN, D.I. 9, First Amended Complaint ¶ 37 (attached hereto as Exhibit N); *see also* 1:22-cv-01913-NRN, D.I. 15, Answer to the First Amended Complaint ¶ 37 (attached hereto as Exhibit O). This prior acquiescence to Personalis' reliance on Kurtz further confirms that the methodology described in Kurtz reflects the approach that Foresight Diagnostics performs and provides to customers as part of its Solid Tumor Recurrence Test at its CLIA laboratory in Aurora, Colorado.

42. Foresight Diagnostic's Solid Tumor Recurrence Test involves a method for personalized genetic testing that includes (a) whole genome sequencing of a tumor sample, (b) the identification of genetic variants, (c) creating probes to selectively enrich for the genetic variants, (d) using the probes to selectively enrich for the genetic variants in a subsequent blood or plasma sample, and (e) sequencing the sample to identify the presence or absence of the genetic variants.

43. In connection with this approach, Foresight Diagnostics' Solid Tumor Recurrence Test identifies mosaic variants, as claimed in the '968 and '507 Patents. As those in the art understand, somatic cancer-causing variations are a type of mosaic variant. This is reflected, for instance, in a publication by Wilson et al.:

> ***The most well-studied example of somatic mosaicism is cancer***; all tumors represent a subset of cells within an individual that have accumulated mutations resulting in uncontrolled cell growth and survival advantage (16). Both benign and

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> malignant tumors constitute evidence of how common somatic mosaicism is in the human body. . . .
>
> Furthermore, NGS is also useful in identifying mutations underlying cancers (78). ***Cancer is a condition of mosaicism in two folds***: first, mosaicism is achieved by accumulation of mutations that confer survival advantage to the mutant cells and give rise to tumors (16); second, each mutant cell accumulates additional genetic alterations, due to lack of cell cycle checkpoints and DNA repair mechanisms, creating mosaicism within tumors (tumor heterogeneity) (79). Multiple NGS studies have successfully identified these two types of mosaicism, leading to a better understanding of different molecular subtypes of cancer and allowing for targeted therapy for each specific tumor and/or patient (80).

Cohen Wilson & Trinh Ye, *Detecting Somatic Mosaicism: Considerations and Clinical Implications*, 87 CLINICAL GENETICS 554, at 555, 558 (2015) (attached hereto as Exhibit P) (emphasis added).

44. The patents are consistent with this understanding and likewise make clear that somatic cancer-causing variations are a type of mosaic variant. For instance, the patents explain that somatic variants are commonly seen in cancer. *See* '968 Patent 18:6-35 ("In some cases, the specific genomic regions may comprise variants commonly seen somatically in cancer."); *see also* '507 Patent 18:6-35 (same). The dependent claims further confirm that "mosaic variants" constitute such cancer-causing somatic variants. *See, e.g.*, '507 Claim 21 ("The method of claim 1, ***wherein the mosaic variants identified in a cancer patient comprise somatic mosaicism***.") (emphasis added); '507 Claim 28 ("The method of claim 25, ***wherein the subset of the mosaic variants*** specific to the human cancer patient that are known to be associated with cancer ***comprises somatic variants***.") (emphasis added). As documented herein and in the infringement claim charts

accompanying this complaint, Foresight Diagnostic's Solid Tumor Recurrence Test detects such cancer-causing somatic variants that those in the art understand are mosaic variants.

45. Foresight Diagnostic's Solid Tumor Recurrence Test also compares the results from a "first assay" with the results from a "second assay," as required by, for instance, Claim 28, Step (f), of the '685 Patent. *See* Exhibit I at 8-9. The Solid Tumor Recurrence Test consists of a first assay and subsequent second assays. *See* Exhibit I at 2-3, 6-7. The first assay is whole genome sequencing ("WGS") of a patient's tumor biopsy, which is used to identify phased variants ("PVs") that appear in that tumor biopsy. *See* Exhibit I at 2-6, 8-9. The second assay is the sequencing of DNA a plasma sample, which is later collected from the same patient and from which cell free DNA ("cfDNA") is isolated. *See* Exhibit I at 6-7. This cfDNA is shed from cells into the bloodstream, and can be used in diagnostic tests. *See* Exhibit D at 1. In the Solid Tumor Recurrence Test, the sequence data from the second assay is compared to the identified PVs from the first sequencing assay to determine which cfDNA fragments include mutations corresponding to the previously identified PVs (and which do not) and to also determine which particular PV the cfDNA fragment corresponds to (if any). *See* Exhibit I at 8-9. In this regard, a comparison between the results of the first and second sequencing assays is a necessary part of the Solid Tumor Recurrence Test. Nevertheless, if such cfDNA is found that corresponds to one of the previously identified PVs, then the tumor has regrown and the patient has relapsed. *See* Exhibit D at 1.

> While PVs are concentrated in stereotyped genomic loci B cell malignancies, this is not the case in most other cancer types (Extended Data Fig. 3). Despite this, most cancer types considered in the Pan-Cancer Analysis of Whole Genomes (PCAWG)

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> dataset have a sufficient number of PVs in their genome to improve on the limit of detection for ctDNA from SNV-based or alternative approaches using a typical sequencing depth (Fig. 7a, Extended Data Fig. 10a–c and Methods). ***However, these PVs must first be identified and targeted on an individualized basis. To extend PhasED-seq beyond B cell cancers, a 'personalized' approach is therefore needed, including (1) up-front WGS from tumor–normal pairs to identify candidate PVs, (2) design of a personalized panel to select loci containing PVs and (3) targeted sequencing of cfDNA in these regions to monitor the previously defined PVs (Fig. 7b)***."

Kurtz, Exhibit D at 9.

COUNT 1

INFRINGEMENT OF U.S. PATENT NO. 11,584,968

46. Personalis re-alleges and incorporates by reference the allegations of paragraphs 1 to 45 above as if set forth fully herein.

47. Without license or authorization and in violation of 35 U.S.C. § 271, Foresight Diagnostics has infringed and continues to infringe the '968 Patent by using, offering for sale, and/or selling within this district and elsewhere in the United States, at least the Solid Tumor Recurrence Test ("the Accused Product").

48. Foresight Diagnostics directly infringes one or more claims of the '968 Patent, including but not limited to claim 1, either literally or under the doctrine of equivalents, by using, selling, or offering for sale the Accused Product that embodies each element of at least claim 1 of the '968 Patent.

49. The Accused Product meets each and every limitation of at least claim 1 of the '968 Patent. An infringement claim chart is attached to this First Amended Complaint for the Accused Product as Exhibit F and is incorporated herein by reference.

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50. Personalis has suffered and continues to suffer monetary damages and other injuries as a result of Foresight Diagnostics' past and continuing infringement under 35 U.S.C. § 271. Personalis has suffered damages in the form of lost profits, lost sales, and/or lost opportunities. Personalis is entitled to recover damages to compensate Personalis for Foresight Diagnostics' infringing activities in an amount to be determined at trial, but in no event less than a reasonable royalty.

51. Foresight Diagnostics had knowledge of the application that led to the '968 Patent at least as of May 17, 2022 and had knowledge of the '968 Patent at least as of February 21, 2023. Personalis' Patent Notice Letter to Foresight Diagnostics was sent on May 17, 2022, and a true and correct copy is attached as Exhibit G. As of the May 17 notice letter, Foresight Diagnostics was aware of and was monitoring Personalis' patent portfolio, including the impending issuance of Application No. 17/494513 (which issued as the '968 Patent) and was published as US2022/0056538 on February 24, 2022, then allowed on January 9, 2023, issuing on February 21, 2023. Foresight Diagnostics has thus had knowledge of the '968 Patent since at least February 21, 2023. Foresight Diagnostics' continuing infringement of the '968 Patent therefore is and continues to be willful, deliberate, and with knowledge of the '968 Patent, such that Personalis is entitled to recover enhanced damages pursuant to 35 U.S.C. § 284 and attorney's fees and other expenses of litigation pursuant to 35 U.S.C. § 285.

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COUNT 2

INFRINGEMENT OF U.S. PATENT NO. 11,649,507

52. Personalis re-alleges and incorporates by reference the allegations of paragraphs 1 to 51 above as if set forth fully herein.

53. Without license or authorization and in violation of 35 U.S.C. § 271, Foresight Diagnostics has infringed and continues to infringe the '507 Patent by using, offering for sale, and/or selling within this district and elsewhere in the United States, at least the Solid Tumor Recurrence Test.

54. Foresight Diagnostics directly infringes one or more claims of the '507 Patent, including but not limited to claim 1, either literally or under the doctrine of equivalents, by using, selling, or offering for sale the Accused Product that embodies each element of at least claim 1 of the '507 Patent.

55. The Accused Product meets each and every limitation of at least claim 1 of the '507 Patent. An infringement claim chart is attached to this First Amended Complaint for the Accused Product as Exhibit H and is incorporated herein by reference.

56. Personalis has suffered and continues to suffer monetary damages and other injuries as a result of Foresight Diagnostics' past and continuing infringement under 35 U.S.C. § 271. Personalis has suffered damages in the form of lost profits, lost sales, and/or lost opportunities. Personalis is entitled to recover damages to compensate Personalis for Foresight Diagnostics' infringing activities in an amount to be determined at trial, but in no event less than a reasonable royalty.

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57. Foresight Diagnostics had knowledge of the application that led to the '507 Patent at least as of May 17, 2022 and had knowledge of the '507 Patent at least as of May 16, 2023. Personalis' Patent Notice Letter to Foresight Diagnostics was sent on May 17, 2022, and a true and correct copy is attached as Exhibit G. As of the May 17 notice letter, Foresight Diagnostics was aware of and was monitoring Personalis' patent portfolio, including the impending issuance of Application No. 17/748,200 (which issued as the '507 Patent) and was published as US2022/0275462 on September 1, 2022, then allowed on April 5, 2023, issuing on May 16, 2023. Foresight Diagnostics thus had knowledge of the '507 Patent since at least May 16, 2023. Foresight Diagnostics' continuing infringement of the '507 Patent therefore is and continues to be willful, deliberate, and with knowledge of the '507 Patent, such that Personalis is entitled to recover enhanced damages pursuant to 35 U.S.C. § 284 and attorney's fees and other expenses of litigation pursuant to 35 U.S.C. § 285.

COUNT 3

INFRINGEMENT OF U.S. PATENT NO. 11,643,685

58. Personalis re-alleges and incorporates by reference the allegations of paragraphs 1 to 57 above as if set forth fully herein.

59. Without license or authorization and in violation of 35 U.S.C. § 271, Foresight Diagnostics has infringed and continues to infringe the '685 Patent by using, offering for sale, and/or selling within this district and elsewhere in the United States, at least the Solid Tumor Recurrence Test.

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60. Foresight Diagnostics directly infringes one or more claims of the ’685 Patent, including but not limited to claim 28, either literally or under the doctrine of equivalents, by using, selling, or offering for sale the Accused Product that embodies each element of at least claim 28 of the ’685 Patent.

61. The Accused Product meets each and every limitation of at least claim 28 of the ’685 Patent. An infringement claim chart is attached to this First Amended Complaint for the Accused Product as Exhibit I and is incorporated herein by reference.

62. Personalis has suffered and continues to suffer monetary damages and other injuries as a result of Foresight Diagnostics’ past and continuing infringement under 35 U.S.C. § 271. Personalis has suffered damages in the form of lost profits, lost sales, and/or lost opportunities. Personalis is entitled to recover damages to compensate Personalis for Foresight Diagnostics’ infringing activities in an amount to be determined at trial, but in no event less than a reasonable royalty.

63. Foresight Diagnostics had knowledge of the application that led to the ’685 Patent at least as of May 17, 2022 and had knowledge of the ’685 Patent at least as of May 9, 2023. Personalis’ Patent Notice Letter to Foresight Diagnostics was sent on May 17, 2022, containing patents in the same family as the ’685 Patent, and a true and correct copy is attached as Exhibit G. As of the May 17, 2022 notice letter, Foresight Diagnostics was aware of and was monitoring Personalis’ patent portfolio, including the impending issuance of Application No. 17/747,436 (which issued as the ’685 Patent) and was published as US2022/0275446 on September 1, 2022, and then allowed on January 31, 2023, issuing on May 9, 2023. Foresight Diagnostics thus had knowledge of the ’685

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Patent since at least May 9, 2023. Foresight Diagnostics' continuing infringement of the '685 Patent therefore is and continues to be willful, deliberate, and with knowledge of the '685 Patent, such that Personalis is entitled to recover enhanced damages pursuant to 35 U.S.C. § 284 and attorney's fees and other expenses of litigation pursuant to 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff Personalis respectfully requests that the Court find in its favor and against Defendant Foresight Diagnostics, and that the Court:

A. Enter judgment that Foresight Diagnostics has directly infringed at least one or more claims of the '968 Patent, literally and/or under the doctrine of equivalents;

B. Enter judgment that Foresight Diagnostics has directly infringed at least one or more claims of the '507 Patent, literally and/or under the doctrine of equivalents;

C. Enter judgment that Foresight Diagnostics has directly infringed at least one or more claims of the '685 Patent, literally and/or under the doctrine of equivalents;

D. Award Personalis its actual damages as a result of Foresight Diagnostics' infringing activities;

E. Award Personalis damages in an amount to be proven at trial because of the injury suffered by reason of Foresight Diagnostics' infringement of the '968 Patent;

F. Award Personalis damages in an amount to be proven at trial because of the injury suffered by reason of Foresight Diagnostics' infringement of the '507 Patent;

G. Award Personalis damages in an amount to be proven at trial because of the injury suffered by reason of Foresight Diagnostics' infringement of the '685 Patent;

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H. Increase the damages awarded to Personalis by three times the amount found to be Personalis' actual damages, as authorized by 35 U.S.C. § 284 as a result of Foresight Diagnostics' willful infringement of the '968 Patent;

I. Increase the damages awarded to Personalis by three times the amount found to be Personalis' actual damages, as authorized by 35 U.S.C. § 284 as a result of Foresight Diagnostics' willful infringement of the '507 Patent;

J. Increase the damages awarded to Personalis by three times the amount found to be Personalis' actual damages, as authorized by 35 U.S.C. § 284 as a result of Foresight Diagnostics' willful infringement of the '685 Patent;

K. Enter a permanent injunction prohibiting further infringement by Foresight Diagnostics, and each of its subsidiaries, successors, parents, affiliates, officers, directors, agents, servants, employees, and all persons in active concert or participation with it;

L. Award Personalis its expenses of litigation, including reasonable attorney's fees pursuant to 35 U.S.C. § 285;

M. Award Personalis prejudgment interest, post-judgment interest, and costs pursuant to 35 U.S.C. § 284; and

N. Award Personalis such other and further relief as the Court deems just and proper.

JURY DEMAND

Personalis hereby requests a trial by jury on all issues so triable, pursuant to Rule 38 of the Federal Rules of Civil Procedure, the United States Constitution, and other applicable laws.

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Dated: August 31, 2023

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on August 31 2023, I electronically filed the foregoing PLAINTIFF PERSONALIS, INC.'S FIRST AMENDED COMPLAINT FOR PATENT INFRINGEMENT with the Clerk of the Court using the CM/ECF system which will send notification of such filing to all counsel of record.

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