UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLORADO

PERSONALIS, INC. Plaintiff, v. FORESIGHT DIAGNOSTICS INC. Defendant.	Civil Action No. 1:22-cv-01913-NRN **JURY TRIAL DEMANDED**

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. 10,450,611 (the "'611 Patent"), 11,299,783 (the "'783 Patent"), 11,384,394 (the "'394 Patent"), and 11,408,033 (the "'033 Patent").

THE PARTIES

2. Plaintiff Personalis is a Delaware corporation with its principal place of business located at 1330 O'Brien Drive, Menlo Park, California 94025.

3. Defendant Foresight Diagnostics is a Delaware corporation with its principal place of business located at 12635 East Montview Boulevard, Aurora, Colorado 80045.

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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 development of next-generation therapies through the development of some of the world's most advanced genetic tests for cancer, thereby providing more comprehensive molecular data about each patient's cancer and immune response.

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.

10. In December 2021, Personalis launched NeXT Personal™, a next-generation, tumor-informed liquid biopsy assay designed to detect and quantify minimal

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(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 October 22, 2019, the United States Patent and Trademark Office issued United States Patent No. 10,450,611 (the "'611 Patent"), entitled "Personalized Genetic Testing" naming John West, Christian Haudenschild, and Richard Chen as inventors. A true and correct copy of the '611 Patent is attached to this Complaint as Exhibit A and incorporated herein by reference.

14. The '611 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 '611 Patent.

16. Personalis has the right to assert all causes of action arising under the '611 Patent and the right to recover any remedies for infringement of it, including the right to sue for past infringement.

17. The ’611 Patent relates to methods for personalized genetic testing by performance of sequencing assays on biological samples. *See* Exhibit A, Abstract.

18. For example, claim 1 of the ’611 Patent claims a method for personalized genetic testing comprising of sequencing nucleic acid molecules from a biological sample, identifying nucleic acid sequences having a set of genetic variants, obtaining a set of nucleic acid probe molecules configured to selectively enrich or amplify sequences with genetic variants, using the set of nucleic acid probe molecules to selectively enrich or amplify sequences with genetic variants in another biological sample to generate a sequencing library, and sequencing the sequencing library to identify presence or absence of at least some genetic variants.

19. On April 12, 2022, the United States Patent and Trademark Office issued United States Patent No. 11,299,783 (the “’783 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 ’783 Patent is attached to this Complaint as Exhibit B and incorporated herein by reference.

20. The ’783 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 ’783 Patent.

22. Personalis has the right to assert all causes of action arising under the ’783 Patent and the right to recover any remedies for infringement of it, including the right to sue for past infringement.

23. The ’783 Patent relates to methods for sample processing and data analysis by performance of sequencing assays on biological samples that can aid in the diagnosis, monitoring, treatment, and prevention of one or more diseases. *See* Exhibit B, Abstract.

24. For example, claim 1 of the ’783 Patent claims a method for personalized genetic testing comprising obtaining a personalized probe set that is designed to enrich or amplify genetic sequences in a biological sample that comprise at least one variable portion based on the results of a sequence assay and a fixed portion that is independent of the sequencing assay and using the probe sequence on an additional biological sample to identify the presence or absence of the genetic variants in the sample and generating a report that identifies the presence or absence of a disease as well as genetic variants that inform a therapy choice for the subject.

25. On July 12, 2022, the United States Patent and Trademark Office issued United States Patent No. 11,384,394 (the “’394 Patent”), entitled “Methods and Systems for Genetic Analysis” naming Gabor Bartha, Gemma Chandratillake, Richard Chen, Sarah Garcia, Hugo Yu Kor Lam, Shujun Luo, Mark Pratt, and John West as inventors. A true and correct copy of the ’394 Patent is attached to this Complaint as Exhibit C and incorporated herein by reference.

26. The ’394 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 ’394 Patent.

28. Personalis has the right to assert all causes of action arising under the '394 Patent and the right to recover any remedies for infringement of it, including the right to sue for past infringement.

29. The '394 Patent relates to methods for sample processing and analysis to aid in the diagnosis, monitoring, treatment, and prevention of disease. *See* Exhibit C, Abstract.

30. For example, claim 1 of the '394 Patent claims a method for analyzing nucleic acid samples isolated from an individual comprising whole genome sequencing nucleic acid molecules obtained from a first biological sample, contacting a second set of nucleic acid molecules with a set of capture probes that hybridize to polymorphisms that are based on or extracted from a database of polymorphisms or observed in a sample, or a combination thereof, sequencing the second set of nucleic acid molecules, repeating the capture probe hybridized sequencing on an additional sample from an additional time point, and generating a biomedical report that identifies the presence or absence of the polymorphisms.

31. On August 9, 2022, the United States Patent and Trademark Office issued United States Patent No. 11,408,033 (the "'033 Patent"), entitled "Methods and Systems For Genetic Analysis" naming Gabor Bartha, Gemma Chandratillake, Richard Chen, Sarah Garcia, Hugo Yu Kor Lam, Shujun Luo, Mark Pratt, and John West as inventors. A true and correct copy of the '033 Patent is attached to this Amended Complaint as Exhibit N and incorporated herein by reference.

32. The '033 Patent is valid and enforceable.

33. Personalis owns by assignment all right, title and interest in, and has standing to sue for infringement of the ’033 Patent.

34. Personalis has the right to assert all causes of action arising under the ’033 Patent and the right to recover any remedies for infringement of it.

35. The ’033 Patent relates to methods for sample processing and analysis to aid in the diagnosis, monitoring, treatment, and prevention of disease. *See* Exhibit N, Abstract.

36. For example, claim 1 of the ’033 Patent claims a method for analyzing nucleic acid samples isolated from an individual comprising producing a set of capture probes that hybridize to polymorphisms that are in sequences encoding genes with known biomedically interpretable variants, contacting the nucleic acid sample with the capture probes, sequencing the nucleic acid molecules, and repeating the capture probe hybridized sequencing on a subsequently obtained biological sample.

FORESIGHT DIAGNOSTICS’ INFRINGEMENT OF THE PATENTS-IN-SUIT

37. Foresight Diagnostics offers a personalized assay for the detection of MRD for solid tumors called the “Solid Tumor Recurrence Test” as described in the 2021 Nature Biotechnology publication listed on Foresight Diagnostics’ website. Foresight Diagnostics, *News & Publications*, FORESITE-DX.COM, https://foresight-dx.com/news (last visited May 16, 2022) (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 (2021)) (attached hereto as Exhibit J).

38. Foresight Diagnostics also describes its offer to provide services related to its Solid Tumor Recurrence Test MRD for solid tumors. *See* Foresight Diagnostics,

Partnership, FORESITE-DX.COM, https://foresight-dx.com/partnership (last visited July 26, 2022).

39. 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.

COUNT 1

INFRINGEMENT OF U.S. PATENT NO. 10,450,611

40. Personalis re-alleges and incorporates by reference the allegations of paragraphs 1 to 39 above as if set forth fully herein.

41. Without license or authorization and in violation of 35 U.S.C. § 271, Foresight Diagnostics has infringed and continues to infringe the '611 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").

42. Foresight Diagnostics directly infringes one or more claims of the '611 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 '611 Patent.

43. The Accused Product meets each and every limitation of at least claim 1 of the ’611 Patent. An infringement claim chart is attached to this Complaint for the Accused Product as Exhibit D and is incorporated herein by reference.

44. 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.

45. Foresight Diagnostics has knowledge of the ’611 Patent at least as of May 17, 2022. A true and correct copy of Personalis’ Patent Notice Letter to Foresight Diagnostics is attached as Exhibit E. Foresight Diagnostics’ continuing infringement of the ’611 Patent therefore is and continues to be willful, deliberate, and with knowledge of the ’611 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 2

INFRINGEMENT OF U.S. PATENT NO. 11,299,783

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 ’783 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 '783 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 '783 Patent.

49. The Accused Product meets each and every limitation of at least claim 1 of the '783 Patent. An infringement claim chart is attached to this Complaint for the Accused Product as Exhibit F and is incorporated herein by reference.

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 has knowledge of the '783 Patent at least as of July 12, 2022. A true and correct copy of Personalis' Patent Notice Letter to Foresight Diagnostics is attached as Exhibit G. A true and correct copy of the press release referenced in the letter is attached as Exhibit H. Foresight Diagnostics' continuing infringement of the '783 Patent therefore is and continues to be willful, deliberate, and with knowledge of the '783 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. 11,384,394

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 '394 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").

54. Foresight Diagnostics directly infringes one or more claims of the '394 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 '394 Patent.

55. The Accused Product meets each and every limitation of at least claim 1 of the '394 Patent. An infringement claim chart is attached to this Complaint for the Accused Product as Exhibit I 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.

57. Foresight Diagnostics has knowledge of the '394 Patent at least as of July 12, 2022. A true and correct copy of Personalis' Patent Notice Letter to Foresight Diagnostics is attached as Exhibit G. Foresight Diagnostics' continuing infringement of the '394 Patent therefore is and continues to be willful, deliberate, and with knowledge of the '394 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 4

INFRINGEMENT OF U.S. PATENT NO. 11,408,033

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 '033 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").

60. Foresight Diagnostics directly infringes one or more claims of the '033 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 '033 Patent.

61. The Accused Product meets each and every limitation of at least claim 1 of the ’033 Patent. An infringement claim chart is attached to this Complaint for the Accused Product as Exhibit O 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 has knowledge of the application that led to the ’033 Patent at least as of July 12, 2022. A true and correct copy of Personalis’ Patent Notice Letter to Foresight Diagnostics, regarding a continuation of the ’033 Patent application (17/078,857, which issued as the ’394 Patent), is attached as Exhibit G. As of the July 12 notice letter, Foresight Diagnostics was aware of and was monitoring Personalis’ patent portfolio, including the impending issuance of the ’033 patent, which was allowed on June 6, 2022 and issued on August 9, 2022. Foresight Diagnostics’ has thus had knowledge of the ’033 patent since at least August 9, 2022 and its continuing infringement of the ’033 Patent therefore is and continues to be willful, deliberate, and with knowledge of the ’033 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 ’611 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 ’783 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 ’394 Patent, literally and/or under the doctrine of equivalents;

D. Enter judgment that Foresight Diagnostics has directly infringed at least one or more claims of the ’033 Patent, literally and/or under the doctrine of equivalents;

E. Award Personalis its actual damages as a result of Foresight Diagnostics’ infringing activities;

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 ’611 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 ’783 Patent;

H. Award Personalis damages in an amount to be proven at trial because of the injury suffered by reason of Foresight Diagnostics’ infringement of the ’394 Patent;

I. Award Personalis damages in an amount to be proven at trial because of the injury suffered by reason of Foresight Diagnostics’ infringement of the ’033 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 '611 Patent;

K. 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 '783 Patent;

L. 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 '394 Patent;

M. 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 '033 Patent;

N. 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;

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

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

Q. 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.

Dated: August 17, 2022

Respectfully submitted,

Weil, Gotshal & Manges LLP

/s/ *Edward R. Reines*
Edward R. Reines

Attorney for Plaintiff Personalis, Inc.

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