EDWARD R. REINES (Bar No. 135960)
edward.reines@weil.com
DEREK C. WALTER (Bar No. 246322)
derek.walter@weil.com
WEIL, GOTSHAL & MANGES LLP
Silicon Valley Office
201 Redwood Shores Parkway
Redwood Shores, CA 94065
Telephone: (650) 802-3000
Facsimile: (650) 802-3100

Attorneys for Plaintiffs
VERINATA HEALTH, INC.

and

THE BOARD OF TRUSTEES
OF THE LELAND
STANFORD JUNIOR
UNIVERSITY

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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

VERINATA HEALTH, INC.,

and

THE BOARD OF TRUSTEES OF THE LELAND STANFORD JUNIOR UNIVERSITY,

Plaintiffs,

v.

SEQUENOM, INC.,

and

SEQUENOM CENTER FOR MOLECULAR MEDICINE, LLC,

Defendants.

Case No.

COMPLAINT FOR DECLARATORY JUDGMENT AND PATENT INFRINGEMENT

JURY TRIAL DEMANDED

Plaintiffs Verinata Health, Inc. ("Verinata") and The Board Of Trustees Of The Leland Stanford Junior University ("Stanford"), for their complaint against Defendants

Sequenom, Inc. ("Sequenom") and Sequenom Center for Molecular Medicine, LLC ("Sequenom CMM") (collectively "Defendants"), allege as follows:

NATURE OF THIS ACTION

1. This action arises under 28 U.S.C. §§ 1331, 2201 and 2202, and the United States Patent Act, 35 U.S.C. § 100 *et seq.*

2. Verinata by itself brings this action for a declaration that all claims of U.S. Patent No. 6,258,540 (the "'540 patent") are invalid and that no activities relating to Verinata's non-invasive pre-natal test using cell-free DNA circulating in the blood of a pregnant woman (the "Verinata Test") do or will directly or indirectly infringe that patent.

3. Verinata and Stanford bring this action to halt Defendants' willful infringement of Verinata's rights under the Patent Laws of the United States, 35 U.S.C. § 1, *et. seq.*, which rights arise under U.S. Patent Nos. 8,008,018 (the "'018 patent") and 7,888,017 (the "'017 patent").

PARTIES

4. Verinata is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 800 Saginaw Drive, Redwood City, California 94063. Verinata was formerly known as Artemis Health, Inc. ("Artemis"). Verinata's research and clinical facilities are located in Redwood City, California. Verinata is also an exclusive licensee of the '017 and '018 patents in the field of genetic analysis by nucleic acid sequencing.

5. Stanford is a trust possessing corporate powers that is organized under the laws of California, with a principal place of business at the Office of the President, Building 10 Main Quad, Stanford, California 94305. Stanford is the patent owner and licensor for the '017 and '018 patents and is joined in the infringement action for these patents because it is a necessary party.

6. On information and belief, Sequenom is a company organized and existing under the laws of Delaware, with its principal place of business at 3595 John Hopkins Court, San Diego, California 92121.

7. On information and belief, Sequenom CMM is a wholly-owned subsidiary

of Sequenom organized and existing under the law of Michigan, with its principal place of business at 350 E. Michigan Avenue Suite 300, Kalamazoo, Michigan 49007 and Sequenom and Sequenom CMM are agents and alter egos of each other.

8. On information and belief, Defendants have, and have had, continuous and systematic contacts with the State of California, including this District. On information and belief, Defendants have also purposefully directed a broad range of business activities at this District, including among other things research, sales, blood collection and processing, and related services. On information and belief, residents of this District have used services sold by or from Defendants.

JURISDICTION

9. This action arises under the Patent Laws of the United States of America, 35 U.S.C. § 1 *et seq*. This Court also has subject matter jurisdiction according to the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, because an immediate and substantial controversy exists between Verinata and Sequenom with respect to whether any activities relating to the Verinata Test infringe the '540 patent, and whether the patent is valid. This Court has federal question jurisdiction under 28 U.S.C. § 1331 and 28 U.S.C. § 1338(a) because this is a civil action arising under the Patent Act.

VENUE

10. Venue is proper in this District under 28 U.S.C. §§ 1391(b) and (c) because a substantial part of the events giving rise to Verinata's claim occurred in this District and because Defendants are subject to personal jurisdiction in this District.

INTRA-DISTRICT ASSIGNMENT

11. Pursuant to Civil Local Rules 3-5(b) and 3-2(c), because this action is an intellectual property action, it is properly assigned to any of the divisions in this District.

GENERAL ALLEGATIONS

Development of the Verinata Test

12. Since its founding, Verinata's activities have focused on developing and offering non-invasive tests for early identification of fetal chromosomal abnormalities using its

proprietary technologies.

13. The Verinata Test employs novel techniques to analyze cell-free DNA circulating in the blood of a pregnant woman by DNA sequencing in order to determine whether a fetus is at risk of having an abnormal number of chromosomes (sometimes referred to as "aneuploidy"). The Verinata Test is more accurate than currently available pre-natal screening techniques, including maternal serum screening techniques that measure alpha-fetoprotein. It also avoids the risk of the loss of a normal fetus associated with invasive tests that involve the extraction and analysis of cells obtained from amniotic fluid (amniocentesis) or the placenta (chorionic villus sampling) of a pregnant woman.

14. Verinata currently plans to start offering the Verinata Test on a commercial basis in early 2012. Verinata currently is, and has been, using the Verinata Test in this District to conduct clinical studies to validate the performance of the Test in the detection of fetal chromosomal abnormalities.

15. Verinata has made an extraordinary investment of resources to prepare for the commercial launch of the Verinata Test. In this regard, Verinata has recently moved to significantly larger facilities and has designed a new clinical laboratory with initial capacity of over 150,000 tests annually. In addition, Verinata has obtained certification of its laboratories under the Clinical Laboratory Improvement Amendments program (commonly referred to as "CLIA") and has signed multi-year supply agreements for DNA sequencing instruments and consumables for use in its commercialization efforts. Verinata has also acquired an exclusive patent license from Stanford for the field of genetic analysis by DNA sequencing in order to utilize the pioneering cell-free DNA sequencing analysis techniques claimed in the '018 patent and the '017 patent in its Verinata Test. Furthermore, Verinata has hired and trained sales and marketing employees who will alert healthcare providers to the availability and advantages of the Verinata Test. These are among the many concrete and substantial steps that Verinata has undertaken to prepare for commercial use and marketing of the Verinata Test.

16. Verinata has spent tens of millions of dollars in the research, evaluation, and development of the Verinata Test. Uncertainty as to the ability to market and offer the

Verinata Test in commerce puts at risk the substantial amounts of money, resources, and employee time that Verinata has invested in this project.

Sequenom's '540 patent

17. The '540 patent is entitled "Non-Invasive Prenatal Diagnosis." The '540 patent lists July 10, 2001, as its issuance date, and names Yuk-Ming Dennis Lo and James Stephen Wainscoat as inventors.

18. On information and belief, Sequenom is the exclusive licensee of all substantial rights in the '540 patent.

19. On August 10, 2010, patent litigation counsel for Sequenom sent a letter to Verinata's President, Richard Rava, with the purported purpose of calling Dr. Rava's attention to intellectual property allegedly relevant to Verinata's business. Specifically, the letter referenced information found in a press release and on the website of Verinata's predecessor, Artemis, regarding Artemis's development of non-invasive pre-natal diagnostic tests using cell-free fetal nucleic acids from a sample of maternal blood. The letter concluded by alleging that "the practice of non-invasive prenatal diagnostics, including diagnosis of the Down syndrome and other genetic disorders, using cell-free fetal nucleic acids in a sample of maternal blood infringes" the '540 patent, as well as the claims of a pending United States Patent Application.

20. On October 14, 2010, counsel for Artemis responded by letter to Sequenom. In its responsive letter, Artemis explained that the infringement position taken in Sequenom's August 20, 2010 letter was unsupported by the patent.

21. Since this initial exchange, Sequenom has repeatedly stated to the public that anyone who performs a non-invasive pre-natal test using cell-free DNA circulating in the blood of a pregnant woman would infringe the '540 patent. Indeed, many such statements have been specifically directed at Verinata. On information and belief, these statements, which misrepresent the scope of the '540 patent, are intended to broadly convey that, because Sequenom holds exclusive rights under the '540 patent, no one other than Sequenom has freedom to perform non-invasive pre-natal testing under the '540 patent—with the goal of deterring potential competitors from entering the market and deterring doctors and healthcare providers from using

anyone other than Sequenom for those services.

22. For example, on information and belief, during a May 5, 2011 earnings call, in response to a question about a validation study of Verinata's aneuploidy test published in *Clinical Chemistry*, Sequenom's CEO stated that "it's our opinion that they [Verinata] are infringing [*sic*: the Lo] 540 patent."

23. Similarly, in an article published on or about July 27, 2011, Sequenom is quoted as conveying to an investment analyst that "management believes the in-licensed '540 patent . . . will block all non-invasive cell-free DNA-based approaches."

24. In addition, on August 17, 2011, at the Wedbush Life Sciences Management Access Conference, Sequenom's Executive Vice President ("VP") of Research and Development ("R&D") reiterated Sequenom's belief that its "patent license from Dr. Lo is the large circle of IP in this whole field" of diagnostics using cell-free DNA in maternal plasma, "and anybody who is trying to develop a test around us we believe will be infringing upon this patent." This executive further explained that "[w]e believe they [Verinata] and [m]any other companies are infringing the core IP I mentioned earlier of Lo," and "[w]e've already warned Veranada [*sic*: Verinata] that we will prosecute that patent to the fullest extent."

25. Likewise, in an interview first published on the website GenomeWeb on or about September 7, 2011, Sequenom's Executive VP of R&D was quoted as saying: "We already warned them [Verinata] last year that when they launch [their test], this would be infringing." This executive further stated that Sequenom plans to enforce its patent.

26. During an earnings call on November 3, 2011, Sequenom's CEO stated that "we believe that they [Verinata] would be infringing our 540 patent . . . on the use of circulating cell-free fetal nucleic acids. And, in order to enter the market, they would be infringing that patent."

27. On November 14, 2011, Sequenom's Executive VP of R&D stated during an earnings call that "we believe this [the '540 patent] is the underpinnings of this whole field, and potentially believe anybody [who is] developing[] an approach that interrogates the circulating [*sic:* cell-free] DNA is infringing this key patent in the field."

28. Each of the above statements has been published on the Internet. On information and belief, Sequenom made these statements with the knowledge and intent that the statements would be widely disseminated to the public—and in particular, to Verinata. These statements, as well as the letter from Sequenom's patent litigation counsel, make it abundantly clear that Verinata is a target for enforcement of the '540 patent.

29. Sequenom, moreover, is currently involved in similar actions involving the '540 patent filed in this District filed by Aria Diagnostics, Inc. and Natera, Inc. who also seek to enter the market for non-invasive pre-natal testing using cell-free DNA. Sequenom in response filed infringement actions against these companies in the Southern District of California based on the '540 patent.

30. Sequenom's conduct creates a substantial and actual controversy between Verinata and Sequenom with respect to the Verinata Test of sufficient immediacy and reality to warrant the issuance of a declaratory judgment. There is a definite and concrete dispute between Sequenom and Verinata as to whether any activities relating to the Verinata Test infringe the '540 patent—and, in particular, claim 1 of the '540 patent, which is quoted in full in the letter from Sequenom's patent litigation counsel. Verinata therefore asks the Court to declare that no activities relating to the Verinata Test do or will directly infringe (whether literally or under the doctrine of equivalents), or contribute to or induce the infringement of, any claim of the '540 patent, or have done so in the past, which declaration is necessary and appropriate.

Defendants' MaterniT21™ Test

31. In or around October 2011, Sequenom and Sequenom CMM began offering a commercial non-invasive prenatal test for Down syndrome under the trade name MaterniT21. Specifically, as stated in a Sequenom press release dated October 17, 2011, Sequenom CMM "launched" the MaterniT21™ test. Moreover, on January 25, 2012, in a Motion to Dismiss or Transfer filed in this Court, Sequenom stated that it "market[ed]" the MaterniT21™ test.

32. Sequenom CMM has publicly stated in, among other things, literature made available on its website that the MaterniT21™ test involves the determination of the

presence or absence of Down syndrome through analysis of circulating cell-free fetal DNA extracted from maternal blood using massively parallel shotgun DNA sequencing.

33. On information and belief, Sequenom CMM has and continues to perform the MaterniT21™ test on samples of maternal blood provided by healthcare providers including, without limitation, those associated with Women & Infants Hospital of Rhode Island, Vanderbilt University Medical Center, and Florida Hospital in Orlando.

34. On information and belief, Sequenom has and continues to encourage Sequenom CMM to perform the MaterniT21™ test, intending that Sequenom CMM perform the test, and with knowledge of the '018 patent and the '017 patent, which are discussed in detail below.

35. On information and belief, Sequenom, knowing of the '018 and '017 patents, has and continues to supply to Sequenom CMM material components of the MaternitT21™ test having no substantial non-infringing use.

CLAIMS FOR RELIEF

COUNT I (By Verinata)

(Declaratory Judgment of Non-Infringement and Invalidity of U.S. Patent No. 6,258,540)

36. Verinata re-alleges and incorporates by this reference the allegations contained in paragraphs 1 through 35 above.

37. Verinata seeks a judicial declaration that the Verinata Test and activities related thereto do not and will not directly or indirectly infringe any claim of the '540 patent, and have not done so in the past, which declaration is necessary and appropriate.

38. Verinata seeks a judicial declaration that each claim of the '540 patent is invalid for failure to comply with the requirements of the Patent Laws of the United States as set forth in Title 35 of the United States Code, including without limitation the provisions of §§ 101, 102, 103, and/or 112, which declaration is necessary and appropriate. Indeed, the prior art invalidates the '540 patent establishing the claims are old and obvious. In addition, the overbroad scope of the claims, especially as Sequenom apparently construes the patent, renders them neither

enabled nor described adequately.

COUNT II (By Verinata and Stanford)

(Infringement of U.S. Patent No. 8,008,018)

39. Plaintiffs re-allege and incorporate by this reference the allegations contained in paragraphs 1 through 35 above as relevant to this count.

40. On August 30, 2011, the United States Patent and Trademark Office duly and legally issued U.S. Patent No. 8,008,018 (the "'018 patent"), entitled "Determination of Fetal Aneuploidies by Massively Parallel DNA Sequencing."

41. Stephen Quake, Ph.D., and Hei-Mun Christina Fan, Ph.D., are the sole and true inventors of the '018 patent. At the time of their invention, Drs. Quake and Fan were employed by Stanford. By operation of law and as a result of written assignment agreements, Stanford obtained the entire right, title, and interest to and in the '018 patent.

42. Pursuant to license agreements Verinata entered into with Stanford, Verinata obtained an exclusive license to the '018 patent in the field of genetic analysis by nucleic acid sequencing.

43. On information and belief, Defendants have and continue to directly infringe the '018 patent by practicing one or more claims of the '018 patent by, including without limitation, performing the MaterniT21™ test, and will continue to do so, unless and until enjoined by this Court.

44. On information and belief, Sequenom has and continues to induce others to infringe the '018 patent by, including without limitation, encouraging Sequenom CMM to perform the MaterniT21™ test, and will continue to do so, unless and until enjoined by this Court.

45. On information and belief, Sequenom has and continues to contributorily infringe the '018 patent by, including without limitation, supplying to Sequenom CMM material components of the MaterniT21™ test having no substantial non-infringing use, and will continue to do so, unless and until enjoined by this Court.

46. Defendants' infringement of the '018 patent has injured Plaintiffs in their

business and property rights. Plaintiffs are entitled to recovery monetary damages for such injuries pursuant to 35 U.S.C. § 284 in an amount to be determined at trial.

47. Defendants' infringement of the '018 patent has caused irreparable harm to Plaintiffs and will continue to cause such harm unless and until Sequenom's infringing activities are enjoined by this Court.

48. On information and belief, Defendants' infringement of the '018 patent has been and is deliberate and willful, warranting increased damages and attorneys' fees pursuant to 35 U.S.C. §§ 284 and 285.

COUNT III (By Verinata and Stanford)

(Infringement of U.S. Patent No. 7,888,017)

49. Plaintiffs re-allege and incorporate by this reference the allegations contained in paragraphs 1 through 35 above as relevant to this count.

50. On February 15, 2011, the United States Patent and Trademark Office duly and legally issued U.S. Patent No. 7,888,017 (the "'017 patent"), entitled "Non-invasive Fetal Genetic Screening by Digital Analysis."

51. Stephen Quake, Ph.D., and Hei-Mun Christina Fan, Ph.D., are the sole and true inventors of the '017 patent. At the time of their invention, Drs. Quake and Fan were employed by Stanford. By operation of law and as a result of written assignment agreements, Stanford obtained the entire right, title, and interest to and in the '017 patent.

52. Pursuant to license agreements with Stanford, Verinata obtained an exclusive license to the '017 patent in the field of genetic analysis by nucleic acid sequencing.

53. On information and belief, Defendants have and continue to directly infringe the '017 patent by practicing one or more claims of the '017 patent by, including without limitation, performing the MaterniT21™ test, and will continue to do so, unless and until enjoined by this Court.

54. On information and belief, Sequenom has and continues to induce others to infringe the '017 patent by, including without limitation, encouraging Sequenom CMM to perform the MaterniT21™ test, and will continue to do so, unless and until enjoined by this

Court.

55. On information and belief, Sequenom has and continues to contributorily infringe the '017 patent by, including without limitation, supplying to Sequenom CMM material components of the MaterniT21™ test having no substantial non-infringing use, and will continue to do so, unless and until enjoined by this Court.

56. Defendants' infringement of the '017 patent has injured Plaintiffs in their business and property rights. Plaintiffs are entitled to recovery monetary damages for such injuries pursuant to 35 U.S.C. § 284 in an amount to be determined at trial.

57. Defendants' infringement of the '017 patent has caused irreparable harm to Plaintiffs and will continue to cause such harm unless and until Sequenom's infringing activities are enjoined by this Court.

58. On information and belief, Defendants' infringement of the '017 patent has been and is deliberate and willful, warranting increased damages and attorneys' fees pursuant to 35 U.S.C. §§ 284 and 285.

PRAYER FOR RELIEF

WHEREFORE, Verinata and Stanford pray for relief as follows:

Verinata Only

A. Judgment in Verinata's favor on all claims for relief;

B. A declaration in favor of Verinata that no activities relating to the Verinata Test do or will directly infringe (whether literally or under the doctrine of equivalents), or contribute to or induce the infringement of, any claim of the '540 patent, and have not done so in the past;

C. A declaration in favor of Verinata that each claim of the '540 patent is invalid for failure to comply with the requirements of the Patent Laws of the United States as set forth in Title 35 of the United States Code, including without limitation the provisions of §§ 101, 102, 103, and/or 112;

Verinata and Stanford

D. Judgment that Defendants have infringed, induced others to infringe,

and/or contributorily infringed the '018 patent;

E. Judgment that Defendants have infringed, induced others to infringe, and/or contributorily infringed the '017 patent;

F. An order permanently enjoining Defendants from further infringement of the '017 and '018 patents;

G. An award of damages pursuant to 35 U.S.C. § 284;

H. An order for an accounting of damages from Defendants' infringement;

I. An award of enhanced damages, up to and including trebling of the damages awarded to Verinata and Stanford;

J. An award to Verinata and Stanford of their costs and reasonable expenses to the fullest extent permitted by law;

K. A declaration that this case is exceptional pursuant to 35 U.S.C. § 285, and an award of attorneys' fees and costs; and

L. An award of such other and further relief as the Court may deem just and proper.

DEMAND FOR JURY TRIAL

Pursuant to Federal Rule of Civil Procedure 38(b) and Civil Local Rule 3-6(a), Verinata and Stanford hereby demand a trial by jury on all issues so triable.

Dated: 2/22/12

Respectfully submitted,

WEIL, GOTSHAL & MANGES LLP
Edward R. Reines
Derek C. Walter

By: _____
Edward R. Reines
Attorneys for Plaintiffs
VERINATA HEALTH, INC.
and
THE BOARD OF TRUSTEES OF
THE LELAND STANFORD
JUNIOR UNIVERSITY