EDWARD R. REINES (Bar No. 135960)
edward.reines@weil.com
DEREK C. WALTER (Bar No. 246322)
derek.walter@weil.com
MICHELE A. GAUGER (Bar No. 281769)
michele.gauger@weil.com
ANANT PRADHAN (Bar No. 287227)
anant.pradhan@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

**UNITED STATES DISTRICT COURT**
**NORTHERN DISTRICT OF CALIFORNIA**

VERINATA HEALTH, INC., and THE BOARD OF TRUSTEES OF THE LELAND STANFORD JUNIOR UNIVERSITY,

Plaintiffs,

v.

CHINESE UNIVERSITY HONG KONG,

Defendant,

and

SEQUENOM, INC., and SEQUENOM CENTER FOR MOLECULAR MEDICINE, LLC,

Defendants/Counterclaim-Plaintiffs,

v.

VERINATA HEALTH, INC. and THE BOARD OF TRUSTEES OF THE LELAND STANFORD JUNIOR UNIVERSITY,

Counterclaim-Defendants,

and

ISIS INNOVATION LIMITED,

Nominal Counterclaim-Defendant.

Case No. 3:12-cv-00865-SI

**FIRST SUPPLEMENTAL COMPLAINT UNDER 35 U.S.C. § 146 TO APPEAL JUDGMENTS IN INTERFERENCES 105,920, 105,923, AND 105,924**

**JURY TRIAL DEMANDED**

Plaintiffs Verinata Health, Inc. ("Verinata") and The Board Of Trustees Of The Leland Stanford Junior University ("Stanford"), for their first supplemental complaint against Defendants Sequenom, Inc. ("Sequenom"), Sequenom Center for Molecular Medicine, LLC ("Sequenom CMM"), and Chinese University Hong Kong ("CUHK") (collectively "Defendants"), allege as follows:

## NATURE OF THIS SUPPLEMENTAL COMPLAINT

1. Verinata and Stanford supplement their Complaint pursuant to 35 U.S.C. §146 to review and correct the rulings of the United States Patent and Trademark Office Board of Patent Appeals and Interferences ("the Board") in: (1) the Decision (copy attached as Exhibit A) and Final Judgment (copy attached as Exhibit B) in Interference No. 105,920 ("the '920 Interference"), declared on March 12, 2013, redeclared on May 3, 2013, and titled Stephen Quake and Hei-Mun Christina Fan Junior Party ("Quake") v. Yuk-Ming Dennis Lo, Rossa Wai Kwun Chiu and Kwan Chee Chan Senior Party ("Lo"); (2) the Decision (copy attached as Exhibit C) and Final Judgment (copy attached as Exhibit D) in Interference No. 105,923 ("the '923 Interference"), declared on May 3, 2013, redeclared on June 14, 2013 and July 24, 3013, and titled Lo v. Quake; and (3) the Decision (copy attached as Exhibit E) and Final Judgment (copy attached as Exhibit F) in Interference No. 105,924 ("the '924 Interference"), declared on May 3, 2013, and titled Quake v. Lo, and to decide all issues that were decided by the Board in the '920, '923 and '924 Interferences.

2. The Board's rulings in the foregoing interferences were directed strictly to the issue of whether the '018 patent (and certain related patent applications) satisfied the written description requirement under 35 U.S.C. § 112. Because Sequenom and Sequenom CMM have raised written description of the '018 patent as a defense in this case, this Court will need to address written description in connection with the upcoming summary judgment and trial proceedings, currently set for August and November 2014, respectively. Accordingly, review of the Board's interference decisions (which focused strictly on written description) pursuant to 35 U.S.C. § 146 may be handled seamlessly as part of previously scheduled proceedings in this matter and will not necessitate any adjustment to the existing case schedule.

3. Verinata initiated this action in February 2012 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. On October 30, 2013, this Court invalidated Sequenom's '540 patent as not being directed to patent eligible subject matter. *See* Dkt. No. 254 in Case No. 11-06391. On November 20, 2013, this Court entered a Stipulation and Final Judgment under Federal Rule of Civil Procedure 54(b) dismissing Sequenom's counterclaims for infringement of the '540 patent and Verinata's claims for a declaratory judgment of non-infringement and invalidity of the '540 patent. *See* Dkt. No. 150.

4. Verinata and Stanford further brought this action in February 2012 to halt Sequenom and Sequenom CMM's 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"), 7,888,017 (the "'017 patent"), and 8,195,415 (the "'415 patent"). In their Answer, Sequenom and Sequenom CMM raised defenses of invalidity and declaratory judgment counterclaims under 35 U.S.C. § 112. *See* Dkt. No. 38. Subsequently, Sequenom and Sequenom CMM alleged that the '018 patent lacked written description in its Patent Local Rule invalidity contentions. As noted above, this issue was addressed by the Board in the '920, '923, and '924 interferences.

**PARTIES**

5. Verinata is a wholly owned subsidiary of Illumina, Inc., 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, '018, and '415 patents in the field of genetic analysis by nucleic acid sequencing.

6. 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,

'018 and '415 patents and is joined in the infringement action for these patents because it is a necessary party.

7. 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.

8. 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.

9. On information and belief, CUHK is a university in the Hong Kong Special Administrative Region whose registered office is at Shatin, New Territories, Hong Kong Special Administrative Region. On information and belief, CUHK has, and has had, continuous and systematic contacts with the State of California, including this District. On information and belief, CUHK have also purposefully directed a broad range of business activities at this District, including among other activities those set forth in Plaintiffs' reply brief in support of their motion to supplement the Complaint in this action. *See*, *e.g.*, Dkt. No. 177, Attachment 3. Most important, CUHK is the owner and licensor for U.S. Application Serial Nos. 13/070,275, filed on March 23, 2011 ("the Lo '275 application"), 12/178,181, filed on July 23, 2008 ("the Lo '181 application"), 13/070,240, filed March 23, 2011 ("the Lo '240 application"), 12/614,350, filed November 6, 2009 ("the Lo '350 application") 13/070,251, filed March 23, 2011 ("the Lo '251 application"), and U.S. Application Serial No. 13/417,119, filed on March 9, 2012 to Lo ("the Lo '119 application") to Sequenom.

10. On information and belief, Sequenom and Sequenom CMM have, and have had, continuous and systematic contacts with the State of California, including this District. On information and belief, Sequenom and Sequenom CMM 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 Sequenom and Sequenom CMM. On information and

belief, CUHK is the owner and licensor for U.S. Application Serial Nos. 13/070,275, filed on March 23, 2011 ("the Lo '275 application"), 12/178,181, filed on July 23, 2008 ("the Lo '181 application"), 13/070,240, filed March 23, 2011 ("the Lo '240 application"), 12/614,350, filed November 6, 2009 ("the Lo '350 application") 13/070,251, filed March 23, 2011 ("the Lo '251 application"), and U.S. Application Serial No. 13/417,119, filed on March 9, 2012 to Lo ("the Lo '119 application") to Sequenom.

## JURISDICTION

11. This action arises under the Patent Laws of the United States of America, 35 U.S.C. § 1 *et seq*. This Court has subject matter jurisdiction pursuant to 35 U.S.C. § 146. 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

12. Venue is proper in this District under 35 U.S.C. § 146 and 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.

## GENERAL ALLEGATIONS

### Development of the Verinata Test

13. 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.

14. 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.

15. Since early 2012, Verinata has offered the Verinata Test on a commercial basis. 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.

16. 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, '017, and '415 patents 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.

17. 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.

**Defendants' MateriT21™ and MateriT21™ *PLUS* Tests**

18. In or around October 2011, Sequenom and Sequenom CMM began offering a commercial non-invasive prenatal test for Down syndrome under the trade name MateriT21. Specifically, as stated in a Sequenom press release dated October 17, 2011, Sequenom CMM "launched" the MateriT21™ 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. Subsequently, in or around February 2012 Sequenom and Sequenom CMM introduced another commercial non-invasive prenatal test for Down syndrome, Edwards syndrome, and Patau syndrome under the trade name MaterniT21 *PLUS*. On information and belief, MaterniT21™ *PLUS* is an expanded and rebranded version of the MaterniT21™ test.

19. Sequenom CMM has publicly stated in, among other things, literature made available on its website that the MaterniT21™ and MaterniT21™ *PLUS* tests involve 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.

20. On information and belief, Sequenom CMM has and continues to perform the MaterniT21™ and MaterniT21™ *PLUS* tests 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.

21. On information and belief, Sequenom has and continues to encourage Sequenom CMM to perform the MaterniT21™ and MaterniT21™ *PLUS* tests, intending that Sequenom CMM perform the tests, and with knowledge of the '018, '017, and '415 patents, which are discussed in detail below.

22. On information and belief, Sequenom, knowing of the '018, '017, and '415 patents, has and continues to supply to Sequenom CMM material components of the MaternitT21™ and MaterniT21™ *PLUS* tests having no substantial non-infringing use.

**Interference 105,920**

23. The '920 Interference was declared between: (1) U.S. Patent No. 8,008,018, entitled "Determination of Fetal Aneuploidies by Massively Parallel DNA Sequencing," which issued on August 30, 2011 ("the Quake '018 patent") to Quake; and (2) the Lo '275 application to Lo.

24. The Quake '018 patent issued from U.S. Application Serial No. 12/393,803, filed February 26, 2009 ("the Quake '803 application"), which is a continuation of U.S. Application Serial No. 11/701,686, filed on February 2, 2007 ("the Quake '686

application"), now U.S. Patent No. 7,888,017, and claims benefit of U.S. Provisional Application Serial No. 60/764,420, filed February 2, 2006 ("the Quake '420 provisional").

25. The Quake '018 patent is assigned to Stanford, and Verinata is the exclusive licensee of all substantial rights therein.

26. The Lo '275 application is a continuation of the Lo '350 application, which is a continuation of the Lo '181 application, which claims benefit to U.S. Provisional Application Serial No. 60/951,438, filed July 23, 2007 ("the Lo '438 provisional").

27. The Lo '275 application is assigned to CUHK, and on information and belief, Sequenom is the exclusive licensee of all substantial rights therein.

28. The Count in the '920 Interference was as follows:

**Lo claim 24**

> A method for determining presence or absence of fetal aneuploidy in a maternal biological sample comprising fetal and maternal genomic DNA, wherein the method comprises:
> a. obtaining a mixture of fetal and maternal genomic DNA from said maternal biological sample;
> b. conducting massively parallel DNA sequencing of DNA fragments randomly selected from the mixture of fetal and maternal genomic DNA of step a) to determine the sequence of said DNA fragments;
> c. identifying chromosomes to which the sequences obtained in step b) belong;
> d. using data of step c) to compare an amount of at least one first chromosome in said mixture of maternal and fetal genomic DNA to an amount of at least one second chromosome in said mixture of maternal and fetal genomic DNA, wherein said at least one first chromosome is presumed to be euploid in the fetus, wherein said at least one second chromosome is suspected to be aneuploid in the fetus, thereby determining the presence or absence of said fetal aneuploidy.

29. During the '920 Interference, Quake filed a List of Proposed Motions requesting to file the following Motions:

a. Proposed Motion 1 to be accorded the benefit of the filing date of the '420 and '686 applications;

b. Proposed Motion 2 that all of the involved Lo claims are unpatentable under 35 U.S.C. § 102(a) as being anticipated or under 35 U.S.C. § 102(a)/§ 103(a) by U.S. Patent Publication 2007-0202525, which is the publication of the Quake '686 application;

c. Proposed Motion 3 that all of the involved Lo claims are unpatentable under 35 U.S.C. § 102(e) as being anticipated or under 35 U.S.C. § 102(a)/§ 103(a) over the Quake '420 provisional and/or the Quake '686 application;

d. Proposed Motion 4 for judgment on priority;

e. Proposed Motion 5 for judgment on derivation; and

f. Proposed Motion 6, contingent on a determination that Quake was not entitled to the benefit of the filing date of U.S. application 11/701,686, as requested in Quake Proposed Motion 1, (1) to substitute U.S. application 13/218,317 ("the '317 application") for the Quake patent currently involved, (2) to add one or more claims to the '317 application, which would correspond to the Count, (3) to substitute the current Count with a count that is one of the claims added to the '317 application, and (4) to be accorded the benefit of U.S. application 12/560,708 and provisional application 61/098,758, which are the parent and grandparent applications of the '317 application.

30. In an Order dated June 14, 2013, the Board authorized Quake's filing of Proposed Motion 1, deferred Quake's filing of Proposed Motions 2-5 until the priority phase, which did not occur as a result of the Decision on the Preliminary Motions, and did not authorize Proposed Motion 6.

31. During the '920 Interference, Lo filed a Motion 1 for judgment under 35 U.S.C. § 112, first paragraph, that the Quake specification did not provide written description for the Quake claims, and a Lo Motion 4 to exclude Quake evidence.

32. In its Decision dated April 7, 2014, the Board held that "the written description of the Quake '018 patent would [not] have indicated to one of ordinary skill in the art that the Quake inventors were in possession of the random massively parallel sequencing methods that they claim." (Exhibit A, p. 22, ll. 24-27)

33. The Board's findings are erroneous, at least because:

a. the patent disclosure is more than adequate to comply with the written description requirement and establishes that a person of ordinary skill in the art would recognize

that the Quake inventors were in full possession of the invention of the claim (Count) at issue;

b. the Board failed to consider the high level of skill in the art as set forth in the Declaration of Sequenom's expert, Dr. Stacy Gabriel;

c. despite stating repeatedly that references in the specification to "massively parallel sequencing" included "random massively parallel sequencing" the Board nevertheless found that the a person skilled in the art would not have recognized that the inventors were in possession of the claimed invention of the Count;

d. the Board held that references to massively parallel sequencing would have been understood by a person skilled in the art to be directed to targeted sequencing without pointing to any specific passage stating that the application was limited to the use of targeted sequencing;

e. the Board failed to consider testimony by Dr. Gabriel that the word "target" could refer to either a known or an unknown sequence (Exhibit A, p. 8, ll. 24-25); and

f. the Board decided there was insufficient written description despite expressly finding that Dr. Gabriel testified that the Balasubramanian reference, expressly incorporated into the Quake specification, "provides for random massively parallel sequencing." (Exhibit A, p. 12, ll. 1-3).

**Interference 105,923**

34. The '923 Interference was declared between: (1) U.S. Application Serial No. 12/393,833, filed on February 26, 2009 ("the Quake '833 application"), entitled "Non-invasive Fetal Genetic Screening by Digital Analysis," to Quake; and (2) the Lo '181 application. The Lo '240 application, the Lo '350 application, and the Lo '251 application were later added to the Interference.

35. The Quake '833 application is a continuation of the Quake '686 application and claims benefit of the Quake '420 provisional.

36. The Quake '833 application is assigned to Stanford, and Verinata is the exclusive licensee of all substantial rights therein.

37. The Lo ’251 application is a continuation of the Lo ’350 application, which is a continuation of the Lo ’181 application, which claims benefit to the Lo ’438 provisional.

38. The Lo ’181, ’240, ’350 and ’251 applications are assigned to CUHK, and on information and belief, Sequenom is the exclusive licensee of all substantial rights therein.

39. The Count in the ‘923 Interference is as follows:

**Quake ’833 application claim 25**

> A method for performing prenatal diagnosis of a fetal chromosomal aneuploidy from a plasma or serum sample of a female subject pregnant with at least one fetus, wherein the plasma or serum sample includes cell-free genomic DNA molecules from the female subject and from the at least one fetus, the method comprising:
>
> massively parallel sequencing cell-free genomic DNA molecules contained in the plasma or serum sample to obtain random nucleic acid sequences from the genomic DNA molecules of the female subject and of the at least one fetus;
>
> identifying at least a portion of the nucleic acid sequences as belonging to a first specific human chromosome and at least one second specific human chromosome;
>
> determining a first amount of the nucleic acid sequences identified as being uniquely present on the first specific human chromosome and
>
> determining a second amount of the nucleic acid sequences identified as being uniquely present on the at least one second specific human chromosome;
>
> determining a ratio based on the first amount and the second amount, thereby determining a ratio of the amount of the nucleic acid sequences identified as being uniquely present on the first specific human chromosome to the amount of the nucleic acids being uniquely present on the at least one second specific chromosome;
>
> determining whether the ratio is statistically significant; and
>
> correlating a statistically significant result with the presence of a fetal chromosomal aneuploidy on the first chromosome.

**Or Lo ’181 application claim 64**

> A method for performing prenatal diagnosis of a fetal chromosomal aneuploidy from a plasma or serum sample of a female subject pregnant with at least one fetus, wherein the plasma or serum sample includes cell-free genomic DNA molecules from the female subject and from the at least one fetus, the method comprising:

> random sequencing of cell-free genomic DNA molecules contained in the plasma or serum sample to obtain sequenced tags from the genomic DNA molecules of the female subject and of the at least one fetus;
>
> aligning at least a portion of the sequenced tags to a first human chromosome and at least one second human chromosome;
>
> determining a first amount of the sequenced tags identified as being uniquely aligned to the first human chromosome; and
>
> determining a second amount of the sequenced tags identified as being uniquely aligned to the at least one second human chromosome;
>
> determining a ratio based on the first amount and the second amount, thereby determining a ratio of the amount of the sequenced tags identified as being uniquely aligned to the first human chromosome to the amount of the sequenced tags being uniquely aligned to the at least one second human chromosome;
>
> determining whether the ratio is statistically significant; and
>
> correlating a statistically significant result with the presence of a fetal chromosomal aneuploidy on the first human chromosome.

40. During the ’923 Interference, Quake filed a List of Proposed Motions requesting to file the following Motions:

a. Proposed Motion 1 to be accorded the benefit of the filing date of the ’420 application;

b. Proposed Motion 2 that all of the involved Lo claims are unpatentable under 35 U.S.C. § 102(a) as being anticipated or under 35 U.S.C. § 102(a)/§ 103(a) by U.S. Patent Publication 2007-0202525, which is the publication of the Quake ’686 application;

c. Proposed Motion 3 that all of the involved Lo claims are unpatentable under 35 U.S.C. § 102(e) as being anticipated or under 35 U.S.C. § 102(a)/§ 103(a) over the Quake ’420 provisional or the Quake ’686 application;

d. Proposed Motion 4 for judgment on priority;

e. Proposed Motion 5 for judgment on derivation;

f. Proposed Motion 6 to designate as corresponding to the Count the allowed claims of the Lo '350 and Lo '240 applications; and

g. Proposed Motion 7 to designate as corresponding to the claims of the Lo '251 application if the claims were indicated to be allowable prior to the filing motions.

41. In an Order dated June 14, 2013, the Board authorized Quake's filing of Proposed Motions 1, and deferred Quake's filing of Proposed Motions 2-5 until the priority phase, which did not occur as a result of the Decision on the Preliminary Motions. Motions 6 and 7 were moot since the claims of all three applications were added to the Interference without motions being filed.

42. During the '923 Interference, Lo filed a Motion 1 for judgment under 35 U.S.C. § 112, first paragraph, that the Quake specification did not provide written description for the Quake claims, a Lo Motion 5 to deny Quake the benefit of the '686 application, and a Lo Motion 7 to exclude Quake evidence.

43. In its Decision dated April 7, 2014, the Board held that "the written description of the Quake '833 application would [not] have indicated to one of ordinary skill in the art that the Quake inventors were in possession of the random massively parallel sequencing methods that they claim." (Exhibit C, p. 25, ll. 1-4)

44. The Board's findings are erroneous, at least because:

a. the patent disclosure is more than adequate to comply with the written description requirement and establishes that a person of ordinary skill in the art would recognize that the Quake inventors were in full possession of the invention of the claim (Count) at issue;

b. the Board failed to consider the high level of skill in the art as set forth in the Declaration of Dr. Gabriel;

c. despite stating repeatedly that references in the specification to "massively parallel sequencing" included "random massively parallel sequencing" the Board nevertheless found that the a person skilled in the art would not have recognized that the inventors were in possession of the claimed invention of the Count;

d. the Board held that references to massively parallel sequencing would have been understood by a person skilled in the art to be directed to targeted sequencing without pointing to any specific passage stating that the application was limited to the use of targeted sequencing;

e. the Board failed to consider testimony by Dr. Gabriel that the word "target" could refer to either a known or an unknown sequence (Exhibit C, p. 9, l. 26- p. 10, l. 1); and

f. the Board decided there was insufficient written description despite expressly finding that Dr. Gabriel testified that the Balasubramanian reference, expressly incorporated into the Quake specification, "provides for random massively parallel sequencing." (Exhibit C, p. 13, ll. 8-9).

**Interference 105,924**

45. The ’924 Interference was declared between: (1) the Quake ’833 application; and (2) U.S. Application Serial No. 13/417,119, filed on March 9, 2012 to Lo (“the Lo ’119 application”).

46. The Lo ’119 application is a continuation of the Lo ‘350 application, which is a continuation of the Lo ’181 application, which claims benefit to the Lo ’438 provisional.

47. The Lo ’119 application is assigned to CUHK, and on information and belief, Sequenom is the exclusive licensee of all substantial rights therein.

48. The Count in the ’924 Interference was as follows:

**Quake ’833 application claim 25**

> A method for performing prenatal diagnosis of a fetal chromosomal aneuploidy from a plasma or serum sample of a female subject pregnant with at least one fetus, wherein the plasma or serum sample includes cell-free genomic DNA molecules from the female subject and from the at least one fetus, the method comprising:
>
> massively parallel sequencing cell-free genomic DNA molecules contained in the plasma or serum sample to obtain random nucleic acid sequences from the genomic DNA molecules of the female subject and of the at least one fetus;
>
> identifying at least a portion of the nucleic acid sequences as belonging to a first specific human chromosome and at least one second specific human chromosome;
>
> determining a first amount of the nucleic acid sequences identified as being uniquely present on the first specific human chromosome and
>
> determining a second amount of the nucleic acid sequences identified as being uniquely present on the at least one second specific human chromosome;

determining a ratio based on the first amount and the second amount, thereby determining a ratio of the amount of the nucleic acid sequences identified as being uniquely present on the first specific human chromosome to the amount of the nucleic acids being uniquely present on the at least one second specific chromosome;

determining whether the ratio is statistically significant; and

correlating a statistically significant result with the presence of a fetal chromosomal aneuploidy on the first chromosome.

**Or Lo '119 application claim 13**

A method for identifying a fetal aneuploidy in a maternal biological sample that includes cell-free fetal DNA from the genome of a fetus and maternal DNA from the genome of the mother of the fetus, the method comprising:

a. obtaining the maternal biological sample;

b. performing random sequencing of DNA fragments from the genome of the mother and from the genome of the fetus contained in the maternal biological sample to obtain a plurality of sequenced tags, wherein the obtained sequenced tags include sequenced tags corresponding to cell-free maternal DNA from the genome of the mother and sequenced tags corresponding to cell-free fetal DNA from the genome of the fetus;

c. identifying the chromosomes from which the sequenced tags obtained in step b) originate by aligning, with a computer system, the sequenced tags to a human genome;

d. using data of step c) to determine:

a first amount of sequenced tags identified as originating from at least one first chromosome in the maternal biological sample and not originating from a second chromosome of the human genome, and

a second amount of sequences sequenced tags identified as originating from a second chromosome in the maternal biological sample and not originating from the least one first chromosome, wherein the at least one first chromosome is presumed to be euploid in the fetus, wherein the second chromosome is potentially aneuploid in the fetus;

e. measuring a proportion of cell-free nucleic acid molecules in the biological sample that are from the second chromosome, the measuring including calculating a ratio of the first amount relative to the second amount; and

f. comparing the proportion to one or more cutoff values, thereby determining whether a fetal aneuploidy exists for the second chromosome, wherein the one or more cutoff values take

into account a size of the second chromosome relative to a size of the at least one first chromosome.

49. During the ’924 Interference, Quake filed a List of Proposed Motions requesting to file the following Motions:

a. Proposed Motion 1 to be accorded the benefit of the filing date of the ’420 application;

b. Proposed Motion 2 that all of the involved Lo claims are unpatentable under 35 U.S.C. § 102(a) as being anticipated or under 35 U.S.C. § 102(a)/§ 103(a) by U.S. Patent Publication 2007-0202525, which is the publication of the Quake ’686 application;

c. Proposed Motion 3 that all of the involved Lo claims are unpatentable under 35 U.S.C. § 102(e) as being anticipated or under 35 U.S.C. § 102(a)/§ 103(a) over the Quake ’420 provisional or the Quake ’686 application;

d. Proposed Motion 4 for judgment on priority;

e. Proposed Motion 5 for judgment on derivation; and

f. Proposed Motion 6 and 7 to add the same Lo applications to the Interference as had been requested in the '923 Interference.

50. In an Order dated June 14, 2013, the Board authorized Quake’s filing of Proposed Motions 1, deferred Quake’s filing of Proposed Motions 2-5 until the priority phase, which did not occur as a result of the Decision on the Preliminary Motions. The relief requested in Proposed Motions 6 and 7 was provided in the '923 Interference.

51. During the ’924 Interference, Lo filed a Motion 1 for judgment under 35 U.S.C. § 112, first paragraph, that the Quake specification did not provide written description for the Quake claims, a Lo Motion 5 to deny Quake the benefit of the ’686 application, and a Lo Motion 7 to exclude Quake evidence.

52. In its Decision dated April 7, 2014, the Board held that “the written description of the Quake ’833 application would [not] have indicated to one of ordinary skill in the art that the Quake inventors were in possession of the random massively parallel sequencing methods that they claim.” (Exhibit E, p. 25, ll. 3-6).

53. The Board’s findings are erroneous, at least because:

a. the patent disclosure is more than adequate to comply with the written description requirement and establishes that a person of ordinary skill in the art would recognize that the Quake inventors were in full possession of the invention of the claim (Count) at issue;

b. the Board failed to consider the high level of skill in the art as set forth in the Declaration of Dr. Gabriel;

c. despite stating repeatedly that references in the specification to "massively parallel sequencing" included "random massively parallel sequencing" the Board nevertheless found that the a person skilled in the art would not have recognized that the inventors were in possession of the claimed invention of the Count;

d. the Board held that references to massively parallel sequencing would have been understood by a person skilled in the art to be directed to targeted sequencing without pointing to any specific passage stating that the application was limited to the use of targeted sequencing;

e. the Board failed to consider testimony by Dr. Gabriel that the word "target" could refer to either a known or an unknown sequence (Exhibit E, p. 10, ll. 2-3); and

f. the Board decided there was insufficient written description despite expressly finding that Dr. Gabriel testified that the Balasubramanian reference, expressly incorporated into the Quake specification, "provides for random massively parallel sequencing." (Exhibit E, p. 13, ll. 10-11).

## CLAIMS FOR RELIEF

## COUNT II

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

54. Plaintiffs re-allege and incorporate by this reference the allegations contained in paragraphs 1 through 22 above as relevant to this count.

55. 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."

56. 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.

57. 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.

58. On information and belief, Sequenom and Sequenom CMM 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™ and MaterniT21™ *PLUS* tests, and will continue to do so, unless and until enjoined by this Court.

59. 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™ and MaterniT21™ *PLUS* tests, and will continue to do so, unless and until enjoined by this Court.

60. 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™ and MaterniT21™ *PLUS* tests having no substantial non-infringing use, and will continue to do so, unless and until enjoined by this Court.

61. Sequenom and Sequenom CMM's 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.

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

63. On information and belief, Sequenom and Sequenom CMM's 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**

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

64. Plaintiffs re-allege and incorporate by this reference the allegations contained in paragraphs 1 through 22 above as relevant to this count.

65. 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."

66. 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.

67. 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.

68. On information and belief, Sequenom and Sequenom CMM 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™ and MaterniT21™ *PLUS* tests, and will continue to do so, unless and until enjoined by this Court.

69. 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™ and MaterniT21™ *PLUS* tests, and will continue to do so, unless and until enjoined by this Court.

70. 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™ and MaterniT21™ *PLUS* tests having no substantial non-infringing use, and will continue to do so, unless and until enjoined by this Court.

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

72. Sequenom and Sequenom CMM's 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.

73. On information and belief, Sequenom and Sequenom CMM's 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.

## COUNT IV

**(Infringement of U.S. Patent No. 8,195,415)**

74. Plaintiffs re-allege and incorporate by this reference the allegations contained in paragraphs 1 through 22 above as relevant to this count.

75. On June 5, 2012, the United States Patent and Trademark Office duly and legally issued U.S. Patent No. 8,195,415 (the "'415 patent"), entitled "Noninvasive Diagnosis of Fetal Aneuploidy by Sequencing."

76. Stephen Quake, Ph.D., and Hei-Mun Christina Fan, Ph.D., are the sole and true inventors of the '415 patent. By operation of law and as a result of written assignment agreements, Stanford obtained the entire right, title, and interest to and in the '415 patent.

77. Pursuant to license agreements with Stanford, Verinata obtained an exclusive license to the '415 patent in the field of genetic analysis by nucleic acid sequencing.

78. On information and belief, Sequenom and Sequenom CMM have and continue to directly infringe the '415 patent by practicing one or more claims of the '415 patent by, including without limitation, performing the MaterniT21™ and MaterniT21™ *PLUS* tests, and will continue to do so, unless and until enjoined by this Court.

79. On information and belief, Sequenom has and continues to induce others to infringe the '415 patent by, including without limitation, encouraging Sequenom CMM to perform the MaterniT21™ and MaterniT21™ *PLUS* tests, and will continue to do so, unless and until enjoined by this Court.

80. On information and belief, Sequenom has and continues to contributorily infringe the '415 patent by, including without limitation, supplying to Sequenom CMM material components of the MaterniT21™ and MaterniT21™ *PLUS* tests having no substantial non-infringing use, and will continue to do so, unless and until enjoined by this Court.

81. Sequenom and Sequenom CMM's infringement of the '415 patent has injured Plaintiffs in their business and property rights. Plaintiffs are entitled to recover monetary damages for such injuries pursuant to 35 U.S.C. § 284 in an amount to be determined at trial.

82. Sequenom and Sequenom CMM's infringement of the '415 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.

83. On information and belief, Sequenom and Sequenom CMM's infringement of the '415 patent has been and is deliberate and willful, warranting increased damages and attorneys' fees pursuant to 35 U.S.C. §§ 284 and 285.

**COUNT V**

**(To review and reverse the Board's Decision and Judgment in Interference 105,920)**

84. Plaintiffs re-allege and incorporate by this reference the allegations contained in paragraphs 1 through 12 and 23 through 33 above as relevant to this count.

85. Pursuant to 35 U.S.C. §146, Stanford and Verinata have elected to file suit in this Court to review and reverse the Board's Decision and Judgment and to decide all issues decided by the Board. Stanford and Verinata have not sought review of the Board's Decision by the United States Court of Appeals for the Federal Circuit.

86. The Board's Decision and Judgment in the '920 Interference are erroneous, and, based on the record before the Board and any additional evidence Stanford and Verinata may introduce in this action, Stanford and Verinata are entitled to judgment correcting the erroneous Decision and Judgment of the Board.

87. The Board erred in finding that the Quake '018 patent specification does not provide written description for the Quake '018 claims.

88. The Board erred in not according Quake the benefit of the filing date of the '686 application and the '420 provisional for Count 1.

89. Quake should be awarded priority with respect to the subject matter of Count 1 of the '920 Interference.

**COUNT VI**

**(To review and reverse the Board's Decision and Judgment in Interference 105,923)**

90. Plaintiffs re-allege and incorporate by this reference the allegations contained in paragraphs 1 through 12 and 34 through 44above as relevant to this count.

91. Pursuant to 35 U.S.C. §146, Stanford and Verinata have elected to file suit in this Court to review and reverse the Board's Decision and Judgment and to decide all issues decided by the Board. Stanford and Verinata have not sought review of the Board's Decision by the United States Court of Appeals for the Federal Circuit.

92. The Board's Decision and Judgment in the '923 Interference are erroneous, and, based on the record before the Board and any additional evidence Stanford and Verinata may introduce in this action, Stanford and Verinata are entitled to judgment correcting the erroneous Decision and Judgment of the Board.

93. The Board erred in finding that the Quake '833 application specification does not provide written description for the Quake '833 claims.

94. The Board erred in not according Quake the benefit of the filing date of the '686 application and the '420 provisional for Count 1.

95. Quake should be awarded priority with respect to the subject matter of Count 1 of the '923 Interference.

**COUNT VII**

**(To review and reverse the Board's Decision and Judgment in Interference 105,924)**

96. Plaintiffs re-allege and incorporate by this reference the allegations contained in paragraphs 1 through 12 and 45 through 53 above as relevant to this count.

97. Pursuant to 35 U.S.C. §146, Stanford and Verinata have elected to file suit in this Court to review and reverse the Board's Decision and Judgment and to decide all issues

decided by the Board. Stanford and Verinata have not sought review of the Board's Decision by the United States Court of Appeals for the Federal Circuit.

98. The Board's Decision and Judgment in the '924 Interference are erroneous, and, based on the record before the Board and any additional evidence Stanford and Verinata may introduce in this action, Stanford and Verinata are entitled to judgment correcting the erroneous Decision and Judgment of the Board.

99. The Board erred in finding that the Quake '833 application specification does not provide written description for the Quake '833 claims.

100. The Board erred in not according Quake the benefit of the filing date of the '686 application and the '420 provisional for Count 1.

101. Quake should be awarded priority with respect to the subject matter of Count 1 of the '924 Interference.

**PRAYER FOR RELIEF**

WHEREFORE, Verinata and Stanford pray for relief as follows:

A. Judgment that Sequenom and Sequenom CMM have infringed, induced others to infringe, and/or contributorily infringed the '018 patent;

B. Judgment that Sequenom and Sequenom CMM have infringed, induced others to infringe, and/or contributorily infringed the '017 patent;

C. Judgment that Sequenom and Sequenom CMM have infringed, induced others to infringe, and/or contributorily infringed the '415 patent;

D. An order permanently enjoining Sequenom and Sequenom CMM from further infringement of the '017, '018, and '415 patents;

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

F. An order for an accounting of damages from Sequenom and Sequenom CMM's infringement;

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

H. Reversal of the Board's Decisions and Judgments in the '920, '923 and '924 Interferences;

I. Finding that the Quake '018 patent specification provides written description for the Quake '018 patent claims;

J. Finding that the Quake '833 application specification provides written description for the Quake '833 application claims;

K. According Quake the benefit of the filing date of the '686 application and the '420 provisional for Count 1 of the '920, '923 and '924 Interferences;

L. Awarding priority to Quake with respect to the subject matter of Count 1 of the '920, '923 and '924 Interferences; and

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

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

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

P. Plaintiffs reserve the right to bring prayers for relief based on 35 U.S.C. § 102(a), 102(e), or 103 and/or derivation of Counts 1 in the '920, '923 and '924 Interferences to the extent such issues are raised in any subsequent proceeding brought by Defendants.

**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: May 20, 2014

WEIL, GOTSHAL & MANGES LLP

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