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10 *Verinata Health, Inc.*

11 UNITED STATES DISTRICT COURT
12 NORTHERN DISTRICT OF CALIFORNIA

13 VERINATA HEALTH, INC.,

14 and

15 THE BOARD OF TRUSTEES OF THE
16 LELAND STANFORD JUNIOR
UNIVERSITY,

17 Plaintiffs,

18 v.

19 ARIOSIA DIAGNOSTICS, INC.,

20 and

21 LABORATORY CORPORATION OF
22 AMERICA HOLDINGS,

23 Defendants.
24
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Case No. 3:12-cv-05501-SI

**FOURTH AMENDED COMPLAINT
FOR PATENT INFRINGEMENT**

JURY TRIAL DEMANDED

1 Plaintiff Verinata Health, Inc. (“Verinata”) for its complaint against Defendant Ariosa
2 Diagnostics, Inc. (“Ariosa”) alleges as follows:

3 **NATURE OF THIS ACTION**

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

6 2. Verinata brings this action to halt Defendants’ infringement of Verinata’s rights
7 under the Patent Laws of the United States, 35 U.S.C. § 1, et seq.

8 **PARTIES**

9 3. Verinata is a corporation organized and existing under the laws of the State of
10 Delaware, with its principal place of business at 800 Saginaw Drive, Redwood City, California 94063.
11 Verinata was formerly known as Artemis Health, Inc. (“Artemis”). Verinata’s research and clinical
12 facilities are located in Redwood City, California. Verinata is the owner of U.S. Patent No. 8,318,430
13 (“the ’430 patent”). Verinata is also an exclusive licensee of U.S. Patent No. 8,296,076 (“the ’076
14 patent”) in the field of genetic analysis by nucleic acid sequencing.

15 4. On information and belief, Ariosa is a company organized and existing under
16 the laws of Delaware, with its principal place of business at 5945 Optical Court, San Jose, California
17 95138.

18 5. Defendant has, and has had, continuous and systematic contacts with the State of
19 California, including this District. For instance, Ariosa has acknowledged in *Ariosa Diagnostics, Inc.*
20 *v. Sequenom, Inc.*, Civil Action No. 11-03691 (N.D. Cal. Dec. 19, 2011) that it “currently is, and has
21 been, using the Aria Test in this District to conduct clinical studies in order to validate the performance
22 of the test in detection of fetal chromosome abnormalities.” On information and belief, Defendant has
23 purposefully directed a broad range of business activities at this District, including among other things
24 research, sales, blood collection and processing, and related services. On information and belief,
25 residents of this District have used services sold by or from Defendant.

JURISDICTION AND VENUE

6. This action arises under the Patent Laws of the United States of America, 35 U.S.C. § 1 et seq. 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.

7. 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 Defendant is subject to personal jurisdiction in this District.

INTRA-DISTRICT ASSIGNMENT

8. 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.

BACKGROUND

9. 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. In early 2012, Verinata began offering such a test, the verifi® prenatal test, on a commercial basis. The verifi® prenatal 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").

10. In or around May 2012, Ariosa began selling and offering to sell a commercial non-invasive prenatal test for Down syndrome, which it referred to by the trade name Harmony™ Prenatal Test. As Ariosa stated in a press release dated May 7, 2012, "[t]he Harmony Prenatal Test, which detects common fetal trisomies such as Trisomy 21 (associated with Down syndrome), will be offered through LabCorp and will be available at its 1,000+ patient service centers."

11. The press release goes on to explain that the Harmony™ Prenatal Test "is performed using a simple maternal blood draw taken at a doctor's office or patient service center." Technical literature describing the technology underlying the Harmony™ Prenatal Test (which Ariosa identifies in a section of its website entitled "ABOUT THE SCIENCE") explains that the method involves inter alia sequencing predefined subsequences of maternal and fetal DNA present in the

1 maternal blood draw. *See, e.g.*, Sparks, A.B., Struble, C.A., Wang, E.T., Song, K., Oliphant, A., Non-
 2 invasive Prenatal Detection and Selective Analysis of Cell-free DNA Obtained from Maternal Blood:
 3 Evaluation for Trisomy 21 and Trisomy 18, Am. J. Obstet. Gynecol. (2012). In view of this
 4 description, on information and belief Defendants' Harmony™ Prenatal Test infringes the '076 and
 5 '430 patents directly and indirectly.

6 12. On information and belief, Defendant has and continues to sell and offer to sell
 7 the Harmony™ Prenatal Test. Likewise, on information and belief, Defendant has and continues to use
 8 the Harmony™ Prenatal Test on samples of maternal blood.

9 **COUNT I**

10 **Infringement of U.S. Patent No. 8,318,430**

11 13. Plaintiff Verinata re-alleges and incorporates by this reference the allegations
 12 contained in paragraphs 1 through 12 above as relevant to this count.

13 14. On November 27, 2012, the United States Patent and Trademark Office duly and
 14 legally issued the '430 patent, entitled "Methods of Fetal Abnormality Detection."

15 15. Yue-Jen Chuu, Ph.D., and Richard P. Rava, Ph.D., are the sole and true
 16 inventors of the '430 patent. By operation of law and as a result of written assignment agreements,
 17 Verinata obtained the entire right, title, and interest to and in the '430 patent.

18 16. On information and belief, Defendant has and continues to directly infringe the
 19 '430 patent by practicing one or more claims of the '430 patent by, including without limitation,
 20 selling, offering to sell, and using the Harmony™ Prenatal Test, and will continue to do so, unless and
 21 until enjoined by this Court.

22 17. Defendant's infringement of the '430 patent has injured Plaintiffs in their
 23 business and property rights. Plaintiff Verinata is entitled to recovery monetary damages for such
 24 injuries pursuant to 35 U.S.C. § 284 in an amount to be determined at trial.

25 18. Defendant's infringement of the '430 patent has caused irreparable harm to
 26 Plaintiff Verinata and will continue to cause such harm unless and until their infringing activities are
 27 enjoined by this Court.

PRAYER FOR RELIEF

WHEREFORE, Verinata prays for relief as follows:

- A. Judgment that Defendants have infringed, induced others to infringe, and/or contributorily infringed the '430 patent;
- B. An order permanently enjoining Defendants from further infringement of the '430 patent;
- C. An award of damages pursuant to 35 U.S.C. § 284;
- D. An order for an accounting of damages from Defendants' infringement;
- E. An award to Verinata of its costs and reasonable expenses to the fullest extent permitted by law;
- F. A declaration that this case is exceptional pursuant to 35 U.S.C. § 285, and an award of attorneys' fees and costs; and
- G. 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 hereby demands a trial by jury on all issues so triable.

Dated: March 9, 2017

Respectfully submitted,

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By: /s/ Edward R. Reines
Edward R/ Reines
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