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6 Attorneys for Plaintiffs,

7 ILLUMINA, INC. and SEQUENOM, INC.

8
9 **UNITED STATES DISTRICT COURT**

10 **NORTHERN DISTRICT OF CALIFORNIA**

11 **SAN FRANCISCO DIVISION**

12
13 ILLUMINA, INC. and SEQUENOM, INC.,

14 Plaintiffs,

15 vs.

16 ARIOSIA DIAGNOSTICS, INC., ROCHE
17 SEQUENCING SOLUTIONS, INC. and
ROCHE MOLECULAR SYSTEMS, INC.

18 Defendant.

Case No. _____

COMPLAINT

1 Plaintiffs Illumina, Inc. (“Illumina”) and Sequenom, Inc. (“Sequenom”) (collectively
2 “Plaintiffs”) for their complaint against Defendant Ariosa Diagnostics, Inc. (“Ariosa”), Roche
3 Sequencing Solutions, Inc. (“RSS”) and Roche Molecular Systems, Inc. (“RMS”) (collectively
4 “Defendants”) allege as follows:

5 **NATURE OF THE ACTION**

6 1. This action arises under 28 U.S.C. §§ 1331 and the United States Patent Act, 35 U.S.C.
7 § 100 *et seq.*

8 2. Plaintiffs bring this action to halt Defendants infringement of their rights under the
9 Patent Laws of the United States, 35 U.S.C. § 1, *et seq.*

10 **PARTIES**

11 3. Illumina is a corporation organized and existing under the laws of the State of
12 Delaware, with its principal place of business at 5200 Illumina Way, San Diego, California, 92122.

13 4. Illumina is a leading developer, manufacturer, and marketer of life science tools and
14 integrated systems for large-scale analysis of genetic variation and function. Illumina’s products and
15 services serve customers in a wide range of markets, enabling the adoption of genomic solutions in
16 research and clinical settings. Illumina’s customers include leading genomic research centers,
17 academic institutions, government laboratories, and hospitals, as well as pharmaceutical,
18 biotechnology, commercial molecular diagnostic laboratories, and consumer genomics companies.
19 Illumina’s portfolio of integrated sequencing and microarray systems, consumables, and analysis tools
20 is designed to accelerate and simplify genetic analysis. Illumina is credited with achieving a
21 significant milestone in medical progress through the launch of sequencing technology capable of
22 pushing the cost of sequencing the human genome down to \$1000.

23 5. Sequenom is a corporation organized and existing under the laws of the State of
24 Delaware, with its principal place of business at 3595 John Hopkins Court, San Diego, California,
25 92121.

26 6. Sequenom develops enabling molecular technologies, and highly sensitive laboratory
27 genetic tests for *inter alia* non-invasive prenatal testing (“NIPT”), and was the first company to
28 commercially offer NIPT based on the use of cell-free fetal DNA. Sequenom is the owner of U.S.

1 Patent No. 9,580,751 (“the ’751 patent”) (attached hereto as Exhibit 1) and U.S. Patent No. 9,738,931
2 (“the ’931 patent”) (attached hereto as Exhibit 2).

3 7. Illumina is the exclusive licensee of the ’751 patent and the ’931 patent pursuant to an
4 amended 2014 Pooled Patents Agreement between Illumina and Sequenom.

5 8. On information and belief, Ariosa is a company organized and existing under the laws
6 of Delaware, with its principal place of business at 5945 Optical Court, San Jose, California 95138.
7 Ariosa is a wholly-owned subsidiary of RMS and provides a non-invasive prenatal test for the
8 determination of fetal chromosomal abnormalities that it markets under the tradename “Harmony™
9 Prenatal Test.” On information belief, Ariosa performs the Harmony™ Prenatal Test at its facility in
10 San Jose, California.

11 9. On information and belief, RSS is a company organized and existing under the laws of
12 Delaware, with its principal place of business at 4300 Hacienda Drive, Pleasanton, California 94588.
13 RSS is a corporate sister of Ariosa that provides nucleic acid products and solutions, including *inter*
14 *alia* for DNA extraction, library preparation, and target enrichment. RSS is the corporate entity
15 through which the activities of Ariosa are managed and controlled. On information and belief,
16 employees of Ariosa are effectively employees of RSS.

17 10. On information and belief, RMS is a company organized and existing under the laws of
18 Delaware, with its principal place of business at 4300 Hacienda Drive, Pleasanton, CA 94588. RMS is
19 the direct corporate parent of Ariosa and, on information and belief, further exercises control over
20 Ariosa.

21 **JURISDICTION AND VENUE**

22 11. This action arises under the Patent Laws of the United States of America, 35 U.S.C. § 1
23 *et seq.* This Court has federal question jurisdiction under 28 U.S.C. § 1331 and 28 U.S.C. § 1338(a)
24 because this is a civil action arising under the Patent Act.

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

13. Indeed, upon information and belief, Defendants' principal places of business are in this District. This Court also has jurisdiction over Defendants because, upon information and belief, they directly or indirectly, use, offer for sale, and/or sell the Harmony™ Prenatal Test throughout the United States and in this judicial district.

BACKGROUND

14. Plaintiffs repeat and re-allege the foregoing paragraphs as if set forth specifically herein.

Background Of The '751 And '931 Patents

15. The claimed methods of the '751 and '931 patents are directed to an improved technique for preparing and analyzing extracellular circulatory DNA. Representative claim 1 of the '751 patent is listed below:

1. A method for preparing a deoxyribonucleic acid (DNA) fraction from a pregnant human female useful for analyzing a genetic locus involved in a fetal chromosomal aberration, comprising:
 - a. extracting DNA from a substantially cell-free sample of blood plasma or blood serum of a pregnant human female to obtain extracellular circulatory fetal and maternal DNA fragments;
 - b. producing a fraction of the DNA extracted in (a) by:
 - i. size discrimination of extracellular circulatory DNA fragments, and
 - ii. selectively removing the DNA fragments greater than approximately 500 base pairs, wherein the DNA fraction after (b) comprises a plurality of genetic loci of the extracellular circulatory fetal and maternal DNA; and
 - c. analyzing a genetic locus in the fraction of DNA produced in (b).

16. The claimed methods apply knowledge regarding the relative size-distribution of fetal and maternal DNA in a specifically chosen combination of steps that was not routine or conventional. By way of background, the vast majority of DNA in blood plasma or serum from a pregnant human female is maternal DNA. As a result, maternal DNA can mask signal that arises from fetal DNA. The inventors, however, recognized that, in blood plasma or serum from a pregnant human female, fetal DNA fragments are on average smaller than maternal DNA fragments. By combining DNA extraction processes with techniques for size-discrimination and removal, the inventors created a technique that

1 enabled researchers to enrich samples for fetal DNA, thereby improving the low signal-to-noise ratio
 2 that had plagued researchers studying cell-free DNA from pregnant human females. The inventive
 3 concept of applying the combination of extraction, size discrimination, and selective removal of
 4 particular DNA fragments to a cell-free sample of blood plasma or blood serum of a pregnant human
 5 female represented a significant improvement in the preparation of samples used for non-invasive
 6 prenatal testing that helped to unmask previously undetectable fetal genetic traits.

7 **The Acquisition And Control Of Ariosa By Roche**

8 17. On December 2, 2014, Roche announced that it was acquiring Ariosa. Since Roche's
 9 acquisition of Ariosa, Ariosa has been controlled by RSS and RMS, are the agents of RSS and RMS,
 10 and/or are the alter egos of RSS and RMS. Defendants have repeatedly publicly confirmed this to be
 11 the case.

12 18. For instance, publicly available information regarding the Harmony™ Prenatal Test is
 13 housed within the website for RSS. Specifically, information regarding the Harmony™ Prenatal Test
 14 may be accessed via RSS's website at <http://sequencing.roche.com/en.html> via a link entitled "NIPT"
 15 or by clicking on the "Harmony Prenatal Test" image that periodically appears. This website is
 16 attached hereto as Exhibit 9. On information and belief, the activities of Ariosa are controlled and
 17 managed through the RSS corporate entity and employees of Ariosa are effectively employees of RSS.
 18 For instance, a press release regarding an update to the Harmony™ prenatal test identifies Roche as the
 19 responsible entity: "Roche expands Harmony® Prenatal Test to include 22q11.2 deletion testing." The
 20 point of contact for further information regarding the update is the Senior Director of Corporate
 21 Communications at RSS. This press release is attached hereto as Exhibit 10. These facts confirm that
 22 RSS exercises controls over Ariosa, that Ariosa is RSS's alter ego and/or RSS's agent, and that RSS
 23 holds out Ariosa as part of its own business.

24 19. Likewise, as to RMS, in April 2015, RMS filed a request for *inter partes* review with
 25 the Patent Office seeking to invalidate U.S. Patent No. 7,955,794 patent ("the '794 patent"). See
 26 *generally Roche Molecular Systems, Inc., v. Illumina, Inc.*, IPR2015-01091. , On information and
 27 belief, RMS's interest in attempting to invalidate the '794 patent, which Ariosa has been accused of
 28 infringing since April 2014, stems from the fact that Ariosa is RMS's alter ego and/or RMS's agent.

1 Consistent with this, RMS, which is the direct corporate parent of Ariosa, identified itself as a real
2 party in interest in the *inter partes* review proceeding alongside Ariosa. Likewise, RMS identified
3 itself as a real party in interest in *inter partes* review IPR2014-01093 alongside Ariosa. This *inter*
4 *partes* review proceeding was an earlier attempt by Ariosa to invalidate the '794 patent. *See generally*
5 *Ariosa Diagnostics, Inc., v. Illumina, Inc.*, IPR2014-01093

6 20. Numerous additional public statements regarding Ariosa further establish that Ariosa is
7 controlled by, is the agent of, and/or is the alter ego of one or more Roche entities. Upon information
8 and belief, these Roche entities are RSS and RMS.

9 21. For instance, Roche's press release regarding its acquisition of Ariosa states that the
10 acquisition will allow Roche to "enter the non-invasive prenatal test (NIPT) and cell-free DNA testing
11 service markets," thus making clear that Roche controls Ariosa, is one and the same as Ariosa, and
12 depends upon Ariosa to provide prenatal testing services. Likewise, shortly after the acquisition,
13 Ariosa's vice president of Market Access and Health Policy stated that "We believe that the Harmony
14 test will be a significant addition to the Roche portfolio, and we continue to make internal and external
15 investments in the development of noninvasive prenatal testing and Harmony test." In stating that the
16 Harmony™ Prenatal Test is part of the "Roche portfolio," Ariosa acknowledges that it is controlled by
17 Roche, that Ariosa is tightly integrated with Roche, and/or that Ariosa has accepted its role as Roche's
18 agent for the purpose of providing prenatal testing services. Documentation of these statements is
19 attached hereto as Exhibit 11.

20 22. As another example, Ariosa has made clear in a filing with the Federal Circuit that
21 Roche's (not Ariosa's) in-house attorneys are responsible for managing litigation matters involving
22 Ariosa, thus demonstrating that Roche controls Ariosa, that it communicates with Ariosa, that it
23 closely monitors Ariosa, that Roche and Ariosa are alter egos of one another, and/or that Ariosa is
24 Roche's agent. Specifically, Ariosa stated that the "acquisition and departure of Ariosa's in-house
25 attorney resulted in a reassignment of responsibilities for Ariosa's legal matters to attorneys at Roche."
26 Ariosa's filing with the Federal Circuit is attached hereto as Exhibit 12.

27 23. At a minimum, the foregoing facts demonstrate that RSS and RMS encourage and
28 support the ongoing infringement of the '751 and '931 patents as Ariosa performs the Harmony™

1 Prenatal Test for customers. In particular, RSS and RMS participate in marketing activity related to the
2 Harmony™ Prenatal Test, the creation of distribution channels for the Harmony™ Prenatal Test, and
3 the provision of infrastructure so that Ariosa may continue to perform the Harmony™ Prenatal Test.

4 **Defendants' Ongoing Infringement Of The '751 And '931 Patents**

5 24. In or around May 2012, Ariosa began selling and offering to sell its commercial non-
6 invasive prenatal test for fetal chromosomal abnormalities, including Down syndrome, which it refers
7 to by the trade name "Harmony™ Prenatal Test." Technical literature describing the technology
8 underlying the Harmony™ Prenatal Test explains that it involves *inter alia* analysis of cell-free DNA
9 present in maternal blood. *See, e.g.*, Sparks, A.B., Struble, C.A., Wang, E.T., Song, K., Oliphant, A.,
10 Non-invasive Prenatal Detection and Selective Analysis of Cell-free DNA Obtained from Maternal
11 Blood: Evaluation for Trisomy 21 and Trisomy 18, Am. J. Obstet. Gynecol. (2012) (attached hereto as
12 Exhibit 3). Following Roche's acquisition of Ariosa, Defendants have continued to perform the
13 Harmony™ Prenatal Test.

14 25. When Defendants perform the Harmony™ Prenatal Test, they infringe literally or under
15 the doctrine of equivalents at least claims 1, 2, 4, 5, and 9-10 of the '751 patent and claims 1-2 and 10-
16 14 of the '931 patent in the following exemplary way.

17 26. As set forth in the documentation for kits that Defendants distribute to allow others to
18 perform the Harmony™ Prenatal Test, Harmony includes a process called "Create UNA," in which
19 magnetic beads are mixed with cell-free DNA that has been extracted from blood plasma. *See, e.g.*,
20 Harmony Kit Instructions (attached hereto as Exhibit 4) at 14. This process is a size discrimination
21 process that prepares a fraction of cell-free DNA consisting of fragments that are less than
22 approximately 300 base pairs in length. Thousands of different genetic loci in the fraction of DNA
23 produced by this process are then analyzed to determine the presence or absence of fetal aneuploidy
24 and other fetal genetic traits. Upon information and belief, Defendants carry out this process when
25 they perform the Harmony™ Prenatal Test at their San Jose facility.

26 27. As examples, attached hereto as Exhibits 5 and 6 are preliminary and exemplary claim
27 charts detailing Defendant's infringement of at least claims 1, 2, 4, 5, and 9-10 of the '751 patent and
28 claims 1-2 and 10-14 of the '931 patent. These charts are not intended to limit Plaintiffs' right to

1 modify them or any other claim chart or allege that other activities of Defendants infringe the
 2 identified claims or any other claims of the '751 and '931 patents or any other patents. Exhibits 5 and
 3 6 are hereby incorporated by reference in their entirety. Each claim element in Exhibits 5 and 6 that is
 4 mapped to the Harmony™ Prenatal Test shall be considered an allegation within the meaning of the
 5 Federal Rules of Civil Procedure and therefore a response to each allegation is required.

6 **COUNT I**

7 **Infringement Of The '751 Patent By Ariosa**

8 28. Plaintiffs repeat and re-allege the foregoing paragraphs as if set forth specifically
 9 herein.

10 29. On February 28, 2017, the United States Patent and Trademark Office duly and legally
 11 issued the '751 patent, entitled "Non-Invasive Detection of Fetal Genetic Traits" which is solely
 12 assigned to Sequenom. Illumina is the exclusive licensee of the '751 patent and maintains the right to
 13 sue thereon.

14 30. On information and belief, Ariosa has infringed and continues to infringe at least claims
 15 1, 2, 4, 5, and 9-10 of the '751 patent pursuant to 35 U.S.C. § 271(a), literally or under the doctrine of
 16 equivalents, by performing within the United States without authority the Harmony™ Prenatal test. As
 17 an example, attached as Exhibit 5 is a preliminary and exemplary claim chart detailing Ariosa's
 18 infringement of these claims of the '751 patent. This chart is not intended to limit Plaintiffs' right to
 19 modify the chart or allege that other activities of Ariosa infringe the identified claims or any other
 20 claims of the '751 patent or any other patents.

21 31. Exhibit 5 is hereby incorporated by reference in its entirety. Each claim element in
 22 Exhibit 3 that is mapped to Ariosa's Harmony™ Prenatal Test shall be considered an allegation within
 23 the meaning of the Federal Rules of Civil Procedure and therefore a response to each allegation is
 24 required.

25 **COUNT II**

26 **Infringement Of The '931 Patent By Ariosa**

27 32. Plaintiffs repeat and re-alleges the foregoing paragraphs as if set forth specifically
 28 herein.

1 not intended to limit Plaintiffs' right to modify the chart or allege that other activities of RMS infringe
2 the identified claims or any other claims of the '751 patent or any other patents.

3 44. On information and belief, at a minimum RMS has and continues to induce others to
4 infringe the '751 patent by, including without limitation, encouraging Ariosa to perform the
5 Harmony™ Prenatal Test.

6 **COUNT VI**

7 **Infringement Of The '931 Patent By RMS**

8 45. Plaintiffs repeat and re-allege the foregoing paragraphs as if set forth specifically
9 herein.

10 46. On information and belief, RMS has and continues to directly infringe, literally or by
11 equivalence, at least claims 1-2 and 10-14 of the '931 patent by, including without limitation, selling,
12 offering to sell, and/or using the microarray-based version of the Harmony™ Prenatal Test either itself
13 and/or as Ariosa's alter ego and/or through Ariosa as its agent. As an example, attached as Exhibit 6 is
14 a preliminary and exemplary claim chart detailing RMS's infringement of these claims of the '931
15 patent. This chart is not intended to limit Plaintiffs' right to modify the chart or allege that other
16 activities of RSS infringe the identified claims or any other claims of the '931 patent or any other
17 patents.

18 47. On information and belief, at a minimum RMS has and continues to induce others to
19 infringe the '931 patent by, including without limitation, encouraging Ariosa to perform the
20 Harmony™ Prenatal Test.

21 **JURY DEMAND**

22 48. Plaintiffs demand a jury trial on all issues so triable.

23 **PRAYER FOR RELIEF**

24 A. A judgment that Defendants have infringed the '751 patent and the '931 patent
25 and that the '751 patent and the '931 patent are valid;

26 B. Damages or other monetary relief, including, but not limited to, costs and pre-
27 and post-judgment interest, to Plaintiffs;
28

1 C. An order enjoining Defendants and their officers, directors, agents, servants,
2 affiliates, employees, divisions, branches, subsidiaries, parents, and all others acting in active concert
3 therewith from further infringement of the '751 patent and the '931 patent;

4 D. Such further and other relief as this Court deems proper and just, including, but
5 not limited to, a determination that this is an exceptional case under 35 U.S.C. § 285 and an award of
6 attorneys' fees and costs to Plaintiffs in this action.
7

8
9 DATED: May 15, 2018

Respectfully submitted,

10 WEIL, GOTSHAL & MANGES LLP

11 By: /s/ Edward R. Reines

12 Edward R. Reines

13 Attorneys for Plaintiffs,
14 ILLUMINA, INC. and SEQUENOM, INC.
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