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
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 Plaintiff
ILLUMINA, INC.

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

ILLUMINA, INC., Plaintiff, v. ARIOSA DIAGNOSTICS, INC., and ROCHE MOLECULAR SYSTEMS, INC., Defendants.	Case No. 3:15-cv-02216-SI **FIRST AMENDED COMPLAINT FOR PATENT INFRINGEMENT** **JURY TRIAL DEMANDED**

Plaintiff Illumina, Inc. ("Illumina") for its first amended complaint against Defendants Ariosa Diagnostics, Inc. ("Ariosa") and Roche Molecular Systems, Inc. ("Roche"), alleges as follows:

NATURE OF THIS ACTION

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

2. Illumina brings this action to halt Defendant's infringement of Illumina's rights under the Patent Laws of the United States, 35 U.S.C. § 1, *et seq*.

PARTIES

3. Illumina is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 5200 Illumina Way, San Diego, California, 92122. Illumina is the owner of U.S. Patent No. 7,955,794 ("the '794 patent").

4. Illumina is a leading developer, manufacturer, and marketer of life science tools and integrated systems for large-scale analysis of genetic variation and function. Through its sequencing and array-based solutions, Illumina has revolutionized DNA analysis. Most recently, Illumina achieved a significant milestone in medical progress through the launch of sequencing technology capable of pushing the cost of sequencing the human genome down to $1000.

5. On information and belief, Roche is a company organized and existing under the laws of Delaware, with its principal place of business at 4300 Hacienda Drive, Pleasanton, CA 94588. Roche is the direct corporate parent of Ariosa and is the entity that controls Ariosa.

6. On information and belief, Ariosa is a company organized and existing under the laws of Delaware, with its principal place of business at 5945 Optical Court, San Jose, California 95138. Ariosa is a wholly-owned subsidiary of Roche.

7. Defendants have, and have had, continuous and systematic contacts with the State of California, including this District. On information and belief, residents of this District have used services sold by or from Defendants.

JURISDICTION AND VENUE

8. 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.

9. 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 Illumina's claim occurred in this District and because Defendants are subject to personal jurisdiction in this District.

INTRA-DISTRICT ASSIGNMENT

10. 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

The Harmony™ Prenatal Test

11. In or around May 2012, Ariosa began selling and offering to sell a commercial non-invasive prenatal test for Down syndrome, which it refers to by the trade name Harmony™ Prenatal Test.

12. Technical literature describing the technology underlying the Harmony™ Prenatal Test explained that the method involved *inter alia* a multiplexing method for detecting target sequences using massively parallel sequencing. *See, e.g.*, Sparks, A.B., Struble, C.A., Wang, E.T., Song, K., Oliphant, A., Non-invasive Prenatal Detection and Selective Analysis of Cell-free DNA Obtained from Maternal Blood: Evaluation for Trisomy 21 and Trisomy 18, *Am. J. Obstet. Gynecol.* (2012). Ariosa's publication referred to this multiplexing method as "DANSR™."

13. On April 25, 2014, Illumina filed a complaint in this district alleging that Ariosa's Harmony™ Prenatal test infringed the '794 patent. *See Illumina, Inc. v. Ariosa Diagnostics, Inc.*, No. 14-cv-14921 (N.D. Cal. filed April 25, 2014). This action is still pending in this district.

14. Sometime prior to September 2014, Ariosa began developing a new version of its Harmony™ Prenatal Test based on the use of microarrays rather than massively

parallel sequencing. In September 2014, an Ariosa publication appeared describing this test. *See* Juneau, et al., Microarray-Based Cell-Free DNA Analysis Improves Noninvasive Prenatal Testing, *Fetal Diagnosis and Therapy* (2014) (attached hereto as Exhibit A) ("Juneau et al.").

15. On November 27, 2014, a patent application assigned to Ariosa published a U.S. Patent Publication 2014/0349859 (attached hereto as Exhibit B) ("the 859 Pub").

16. Upon information and belief, the analysis described in paragraphs [0195] to [0198] of the '859 Pub is the same analysis that is described in the Juneau et al. paper.

17. Upon information and belief, the method described in the examples of the '859 Pub at paragraphs [0195] to [0198] is the same as the method described in Juneau et al.

18. Upon information and belief, the analyses at paragraphs [0195] to [0198] of the '859 Pub and Juneau et al. were performed on the same patient samples whose trisomy status had been determined before the analyses were conducted. Paragraph [0195] of the '859 Pub describes analyzing 878 maternal venous samples with a classification of trisomy where 691 were disomic, 18 were trisomy 13, 37 were trisomy 18, and 132 were trisomy 21. The Methods section of Juneau et al. at p. 2, col. 1 describes analyzing 878 maternal venous samples with a classification of trisomy where 691 were disomic, 18 were trisomy 13, 37 were trisomy 18, and 132 were trisomy 21.

19. The disclosure in paragraphs [0195] to [0198] of the '859 Pub was first included in a patent application assigned to Ariosa in U.S. Patent Application 14/450,144 filed Aug. 1, 2014. Juneau et al. describes that its manuscript was received on Aug. 4, 2014.

20. Paragraph [0196] of the '859 Pub describes using sets of fixed sequence oligonucleotides and bridging oligonucleotides corresponding to 864 genomic regions on chromosomes 13, 18, and 21. Paragraph [0196] of the '859 Pub also describes using sets of fixed sequence oligonucleotides and bridging oligonucleotides corresponding to 576 polymorphic sites on chromosomes 1-12 to evaluate the fraction of fetal cell-free DNA in each sample. A portion of ligation products from samples were amplified using universal primers, and the amplicons were cleaved prior to hybridization to an array.

21. Paragraph [0161] of the '859 Pub describes, among other techniques, cleaving an amplicon created by a universal amplification process, and introducing the portion of the cleavage product containing a capture region to the array for hybridization.

22. Paragraph [0013] of the '859 Pub describes using capture regions containing "engineered" sequences that serve as surrogates to identify specific target genomic regions.

23. Paragraph [0197] of the '859 Pub describes that custom DNA arrays were manufactured to quantify products of the DANSR assay, where each patient sample was assayed on a single custom DNA array.

24. Paragraph [0019] of the '859 Pub describes that quantification of the labels bound to capture probes on the array is the only type of readout used to estimate the levels or amounts of ligation products produced from each target genomic region.

25. Paragraph [0198] of the '859 Pub describes that the FORTE algorithm was used to assign risk scores. When analyzing data detected using a DNA array, the only readout used by the FORTE algorithm used in the example of paragraph [0198] of the '859 Pub is fluorescent intensity of the labels bound to capture probes on DNA arrays. Paragraph [0199] of the 859 Pub describes that, using the ligation assays and detection by hybridization, there was complete concordance between array-based risk scores and trisomy status.

26. Fig. 1 of Juneau et al. describes using sets of fixed sequence oligonucleotides and bridging oligonucleotides in the DANSR assay detected on a microarray. Juneau et al. describes on page 2, col. 1 that DANSR products were made from 864 assays on chromosomes 13, 18, and 21. Additionally, Juneau et al. describes on p. 2, col. 2 that 576 polymorphic assays were also used.

27. Fig. 1 of Juneau describes that a portion of the amplified DANSR products were quantified using a microarray. Juneau et al. describes on p. 2, col. 2 that custom DNA arrays were manufactured to quantify a portion of the DANSR product from each sample, where each patient sample was assayed on a single custom DNA array.

28. Juneau et al. describes at p. 2, col. 2 that the FORTE algorithm was used to assign risk scores. Juneau et al. describes on p. 3, col. 1 that, using the ligation assays and detection by hybridization, there was complete agreement between array-based risk scores and trisomy status.

29. The version of the Harmony™ test described in paragraphs [0195] to [0198] of the '859 Pub continues to utilize the infringing DANSR™ technique, albeit with a microarray rather than massively parallel sequencing. In fact, the description of DANSR™ in Juneau et al. cites to and relies upon the description of DANSR in Ariosa's earlier publications. Based on the description of the microarray-based version of Harmony™ test that appears in the '859 Pub and Juneau et al., it is clear that Ariosa's microarray-based test infringes the '794 patent.

30. In or around January 2015, the description of the Harmony™ test on Ariosa's website changed to describe only the microarray-based version of the Harmony™ test. *See, e.g.,* http://www.ariosadx.com/healthcare-professionals/technology/ ("Custom Microarray Quantifies DANSR Products with Speed and Accuracy") (attached hereto as Exhibit C). On information and belief, Defendants began offering the microarray-based version of the Harmony™ prenatal test to customers in or around January 2015.

Roche's Acquisition And Control Of Ariosa

31. On December 2, 2014, Roche announced that it was acquiring Ariosa. Roche's press release regarding this acquisition is attached hereto as Exhibit D. Roche first approached Ariosa in April 2014, and Roche and Ariosa were in full-fledged acquisition discussions no later than June 2014. Ariosa was represented in the negotiations by, among others, John Stuelpnagel, who is one of the named inventors on the '794 patent. These facts are confirmed in an Ariosa discovery response, which is attached hereto as Exhibit E. At the conclusion of the acquisition, a high-ranking Roche executive publicly stated that Roche would continue to defend Ariosa in Court and that it was acquiring Ariosa with its "eyes wide open" as to Ariosa's pending litigation with Illumina. Documentation of Roche's statements to this effect is attached hereto as Exhibit F. In view of Roche's negotiations with a named inventor on the '794 patent and its public statements confirming that it was well aware of the facts and

circumstances of Ariosa's litigation with Illumina, Roche has long since had knowledge of the '794 patent and the fact that it is infringed by the Harmony™ prenatal test.

32. Moreover, upon information belief, since Roche's acquisition of Ariosa, Ariosa has been controlled by Roche, is Roche's agent, and/or is Roche's alter ego. Ariosa and Roche have repeatedly publicly confirmed this to be the case.

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

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

35. As another example, in April 2015 Roche filed a request for *inter partes* review with the Patent Office seeking to invalidate the '794 patent. *See generally Roche Molecular Systems, Inc., v. Illumina, Inc.*, IPR2015-01091. On information and belief, Roche's interest in attempting to invalidate the '794 patent, which Ariosa has been accused of infringing

since April 2014, stems from the fact that Ariosa is Roche's alter ego and/or Roche's agent. Notably, on information and belief, attorneys at WilmerHale that are representing Roche in this action and in IPR2015-01091 now serve as Ariosa's primary counsel in an IPR proceeding that Ariosa filed before the completion of Roche's acquisition of Ariosa. *See generally Ariosa Diagnostics, Inc. v. Illumina, Inc.*, IPR2014-01093. A *pro hac* motion that Ariosa filed in its IPR (attached hereto as Exhibit Y) relies upon the fact that its attorney at WilmerHale has a "long-standing relationship with" Roche and has "represented Roche in numerous patent cases."

36. As another example, since the acquisition, press releases regarding Ariosa come not from Ariosa, but from Roche. For instance, an April 2, 2015 press release entitled "Ariosa's Harmony™ Prenatal Test shown to be superior to conventional pregnancy screening for Down syndrome (Trisomy 21) in largest clinical trial" is available on Ariosa's website, but was prepared by Roche and lists Roche Sequencing Media Relations personnel as the relevant point of contact. This press release is attached hereto as Exhibit I.

37. As another example, numerous Roche documents from Roche's website confirm that Roche controls Ariosa, that Ariosa is Roche's alter ego and/or Roche's agent, and that Roche holds out Ariosa as part of its own business. For instance, a March 2015 presentation by Roche's chief operating officer of diagnostics makes clear that the Harmony™ test is part of the Roche testing menu. This presentation is attached hereto as Exhibit J. Likewise, an April 2015 investor update asserts that Roche "also made a number of strategic acquisitions, including Ariosa Diagnostics to enter the non-invasive prenatal and cell-free DNA testing markets" and that the Harmony test was "added to Roche's portfolio" following the acquisition. This investor update is attached hereto as Exhibit K. Similarly, a January 2015 Roche media release explains that "Ariosa adds a highly targeted and accurate non-invasive prenatal testing service to Roche's portfolio." This media release is attached hereto as Exhibit L. Roche's statements that the Harmony™ test is part of its "portfolio" and testing menu demonstrate that Ariosa and Roche have an integrated operation for prenatal testing, that Roche views Ariosa as performing important services that Roche would have to perform itself were it not for Ariosa, and that Roche depends on Ariosa for prenatal testing services.

38. As another example, Roche has taken control of the hiring of Ariosa personnel, including managers and lower level positions. Roche's website includes job postings for numerous positions within Ariosa. The job postings for positions at Ariosa conclude with a header entitled "Who we are," which states that "At Roche, 88,500 people across 150 countries are pushing back the frontiers of healthcare." Roche's website includes postings for at least the following Ariosa positions that encompass the full range of Ariosa's business and technical activities: Associate Director of Oncology, Automation Engineer I, Client Services Representative, Data Scientist, Field Applications Scientist, Field Support Engineer, Global Business Development Manager, Reagent Manufacturing Quality Associate, Senior Instrument Technician, and Senior Systems Administrator. These job postings are attached hereto as Exhibits M through V. The fact that Roche controls the appointment of Ariosa's managers and lower level positions demonstrates that it closely monitors Ariosa, that it communicates closely with Ariosa, and/or that it views Ariosa as its agent.

39. At a minimum, the foregoing facts demonstrate that Roche encourages and supports the ongoing infringement of the '794 patent as Ariosa performs the Harmony™ prenatal test for customers. In particular, Roche participates in marketing activity related to the Harmony™ prenatal test, the creation of distribution channels for the Harmony™ prenatal test, and the provision of infrastructure so that Ariosa may continue to perform the Harmony™ prenatal test.

Defendants' Ongoing Infringement Of The '794 Patent

40. On September 1, 2009, the United States Patent and Trademark Office duly and legally issued the '794 patent, entitled "Multiplex Nucleic Acid Reactions."

41. Arnold Oliphant, John R. Steulpnagel, Mark S. Chee, Scott L. Butler, Jian-Bing Fan, Kenneth M. Kuhn, and Min-Jui Richard Shen, are the sole and true inventors of the '794 patent. By operation of law and as a result of written assignment agreements, Illumina obtained the entire right, title, and interest to and in the '794 patent. The '794 patent is attached hereto as Exhibit W.

42. On information and belief, Defendants have and continue to infringe the '794 patent by selling, offering to sell, and using the microarray-based version of the Harmony™ Prenatal Test.

43. As described in Juneau et al. and the '859 Pub, the microarray-based version of the Harmony™ prenatal test utilizes microarrays from Affymetrix, Inc. ("Affymetrix"). Consistent with this, on October 16, 2014 Ariosa "announced the signing of a multi-year supply agreement covering Affymetrix arrays and instruments to be utilized as part of Arisoa's Harmony™ Non-Invasive Prenatal Test (NIPT)." Ariosa's press release regarding its supply agreement with Affymetrix is attached hereto as Exhibit X.

44. Upon Information and belief, the microarray-based version of the Harmony™ prenatal test currently used by Defendants operates using the same operating principles as the microarray-based method described in paragraphs [0195] to [0198] of the '859 Pub.

45. Upon information and belief, the microarray-based version of the Harmony™ prenatal test currently used by Defendants operates as described in paragraph 18 of this Complaint.

46. Upon information and belief, the microarray-based version of the Harmony™ prenatal test currently used by Defendants operates as described in paragraph 20 of this Complaint.

47. Upon information and belief, the microarray-based version of the Harmony™ prenatal test currently used by Defendants operates as described in paragraph 21 of this Complaint.

48. Upon information and belief, the microarray-based version of the Harmony™ prenatal test currently used by Defendants operates as described in paragraph 22 of this Complaint.

49. Upon information and belief, the microarray-based version of the Harmony™ prenatal test currently used by Defendants operates as described in paragraph 23 of this Complaint.

50. Upon information and belief, the microarray-based version of the Harmony™ prenatal test currently used by Defendants operates as described in paragraph 24 of this Complaint.

51. Upon information and belief, the microarray-based version of the Harmony™ prenatal test currently used by Defendants operates as described in paragraph 25 of this Complaint.

52. Upon Information and belief, the microarray-based version of the Harmony™ prenatal test currently used by Defendants operates using the same operating principles as the microarray-based test described in Juneau et al.

53. Upon information and belief, the microarray-based version of the Harmony™ prenatal test currently used by Defendants operates as described in paragraph 26 of this Complaint.

54. Upon information and belief, the microarray-based version of the Harmony™ prenatal test currently used by Defendants operates as described in paragraph 27 of this Complaint.

55. Upon information and belief, the microarray-based version of the Harmony™ prenatal test currently used by Defendants operates as described in paragraph 28 of this Complaint.

56. The preamble of claim 1 of the ’794 patent recites “A multiplex method for determining whether a sample contains at least 100 different target sequences.” Upon information and belief, Ariosa’s Harmony™ prenatal test as described in the ’859 Pub utilizes blood samples obtained from pregnant women. ’859 Pub ¶ [195]; *see also id.* at Fig. 1 (“Provide a sample.”).

57. Step a) of claim 1 of the ’794 patent recites “providing a sample which may contain at least 100 different single-stranded target sequences attached to a first solid support.” Upon information and belief, Ariosa’s Harmony™ prenatal test as described in the ’859 Pub utilizes more than 100 target sequences, including, for instance, “864 genomic regions on each of chromosomes 13, 18, and 21” and “576 polymorphic sites on chromosomes 1 through

12." *Id.* ¶ [196]. As set forth in the '859 Pub, the "DNA sample was attached to a solid support." *Id.*

58. Step b) of claim 1 of the '794 patent recites "contacting said target sequences with a probe set comprising more than 100 different single-stranded probes, wherein each of said more than 100 different probes comprises: i) a first universal priming site, wherein each of said more than 100 different probes has identical universal priming sites, and ii) a target specific domain, such that different double-stranded hybridization complexes are formed, each of the different hybridization complexes comprising one of said more than 100 different single-stranded probes and one of the different single-stranded target sequences from the sample." Upon information and belief, Ariosa's Harmony™ prenatal test as described in the '859 Pub uses for each of the target sequences "sets of fixed sequence oligonucleotides and bridging oligonucleotides." *Id.* ¶ [196]; *see also id.* at Fig. 1 ("Introduce fixed sequence oligonucleotides comprising a label hybridization region to sample."); *see also id.* at Fig. 1 ("Hybridize fixed sequence oligonucleotides to target genomic regions."). The oligonucleotides include universal priming sites. *Id.* ¶ [196] ("A portion of the ligation assay product produced from each sample was amplified using universal primers…."); *id.* ¶ [161] ("In a multiplexed assay system, amplification preferably is done through universal amplification using universal primers that hybridize to universal primer regions on the first and second fixed sequence oligonucleotide of each set.").

59. Step c) of claim 1 of the '794 patent recites "removing unhybridized probes." Upon information and belief, Ariosa's Harmony™ prenatal test as described in the '859 Pub makes clear that "unhybridized oligonucleotides were removed prior to ligation." *Id.* ¶ [196].

60. Step d) of claim 1 of the '794 patent recites "contacting said probes of the hybridization complexes with a first enzyme and forming different modified probes." Upon information and belief, Ariosa's Harmony™ prenatal test as described in the '859 Pub introduces a ligase enzyme to form modified probes. *See, e.g., id.* ("DANSR™ (Digital Analysis of Selected Regions) assay products (*e.g.*, tandem ligation products) were made from loci…."); *id.*

at Fig. 1 ("Ligate the fixed sequence oligonucleotides to create ligation products.")

61. Step e) of claim 1 of the '794 patent recites "contacting said modified probes with: i) at least a first primer that hybridizes to said universal priming site; ii) NTPs; and iii) an extension enzyme; wherein said different modified probes are amplified and forming different amplicons." Upon information and belief, Ariosa's Harmony™ prenatal test as described in the '859 Pub utilizes primers, NTPs, and an extension enzyme to amplify the modified probes. *See, e.g.*, *id.* at Fig. 1 ("Amplify to create amplification products."); *id.* ¶ [161] ("In certain aspects of the invention, universal amplification is used to amplify the ligation products following hybridization and ligation of the fixed sequence oligonucleotides, either directly or following extension or the introduction of a bridging oligonucleotide."); Juneau et al. at Fig. 1 ("Selected and amplified DANSR products were divided and quantified using either microarray or sequencing methodologies.").

62. Step f) of claim 1 of the '794 patent recites "immobilizing said different amplicons to a second solid support." Upon information and belief, in Ariosa's Harmony™ prenatal test as described in the '859 Pub, the amplicons are "hybridized to a custom manufactured DNA array." '859 Pub ¶ [196]; *see also id.* at Fig. 1 ("Introduce amplicons to hybridization array and allow to competitively hybridize to universal capture probes.").

63. Step g) of claim 1 of the '794 patent recites "detecting said different amplicons immobilized to said second solid support, thereby determining whether the sample contains at least 100 different target sequences." Upon information and belief, Ariosa's Harmony™ prenatal test as described in the '859 Pub detects the target sequencing by detecting "labels from hybridized amplicons." *Id.* at Fig. 1; *see also id.* ¶ [197] ("Custom DNA arrays were manufactured by Affymetrix, Inc. (Santa Clara, Calif.) to specifically quantify products of the DANSR assay.")

64. Illumina now brings this suit to halt Defendants' ongoing infringement of the '794 patent by their microarray-based prenatal diagnostic test using the DANSR assay.

COUNT I

Infringement of U.S. Patent No. 7,955,794 by Ariosa

65. Illumina re-alleges and incorporates by this reference the allegations contained in paragraphs 1 through 63 above as relevant to this count.

66. On information and belief, Ariosa has and continues to directly infringe, literally or by equivalence, the '794 patent by practicing one or more claims of the '794 patent by, including without limitation, selling, offering to sell, and/or using the microarray-based version of the Harmony™ Prenatal Test.

67. On information and belief, Ariosa's infringement has been willful and deliberate since, at least, the date Ariosa employed or was affiliated with Arnold Oliphant and John R. Steulpgnagel, named inventors of the '794 patent.

68. Ariosa's infringement of the '794 patent has injured Illumina in its business and property rights. Illumina is entitled to recovery of monetary damages for such injuries pursuant to 35 U.S.C. § 284 in an amount to be determined at trial.

69. Ariosa's infringement of the '794 patent has caused irreparable harm to Illumina and will continue to cause such harm unless and until their infringing activities are enjoined by this Court.

COUNT II

Infringement of U.S. Patent No. 7,955,794 by Roche

70. Illumina re-alleges and incorporates by this reference the allegations contained in paragraphs 1 through 68 above as relevant to this count.

71. On information and belief, Roche has and continues to directly infringe, literally or by equivalence, the '794 patent by practicing one or more claims of the '794 patent by, including without limitation, selling, offering to sell, and/or using the microarray-based version of the Harmony™ Prenatal Test as Ariosa's alter ego and/or through Ariosa as its agent.

72. On information and belief, at a minimum Roche has and continues to induce others to infringe the '794 patent by, including without limitation, encouraging Ariosa to perform the microarray-based version of the Harmony™ Prenatal Test.

73. On information and belief, Roche's infringement has been willful and deliberate since, at least, the date it acquired Ariosa.

74. Roche's infringement of the '794 patent has injured Illumina in its business and property rights. Illumina is entitled to recovery of monetary damages for such injuries pursuant to 35 U.S.C. § 284 in an amount to be determined at trial.

75. Roche's infringement of the '794 patent has caused irreparable harm to Illumina and will continue to cause such harm unless and until their infringing activities are enjoined by this Court.

PRAYER FOR RELIEF

WHEREFORE, Illumina prays for relief as follows:

A. Judgment that Defendants have infringed the '794 patent;

B. An order permanently enjoining Defendants from further infringement of the'794 patent;

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

D. A declaration that Defendants' infringement was willful and deliberate, and an increase to the award of damages of three times the amount found or assessed by the Court, in accordance with 35 U.S.C. § 284.

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

F. An award to Illumina of their costs and reasonable expenses to the fullest extent permitted by law;

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

H. 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), Illumina hereby demands a trial by jury on all issues so triable.

Dated: June 10, 2015

Respectfully submitted,

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

By: */s/ Edward R. Reines*
Edward R. Reines
Attorneys for Plaintiff
ILLUMINA, INC.