IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

ILLUMINA, INC. and VERINATA HEALTH, INC. Plaintiffs, v. MOLECULAR LOOP BIOSCIENCES, INC., Defendant,	**COMPLAINT FOR DECLARATORY JUDGMENT OF NON-INFRINGEMENT AND UNENFORCEABILITY** Civil Action No. _____ JURY TRIAL DEMANDED

COMPLAINT FOR DECLARATORY JUDGMENT

Plaintiffs Illumina, Inc. ("Illumina") and Verinata Health, Inc. ("Verinata") (collectively, "Plaintiffs"), by and through their undersigned counsel, hereby bring this Complaint for declaratory judgment regarding non-infringement and/or unenforceability of U.S. Patent Nos. 9,163,281 ("the '281 Patent"), 11,041,851 ("the '851 Patent"), 11,041,852 ("the '852 Patent"), 11,768,200 ("the '200 Patent"), and 11,840,730 ("the '730 Patent") (collectively, "the Patents-in-Suit") against Defendant Molecular Loop Biosciences, Inc. ("Molecular Loop"). Plaintiffs allege for their complaint against Molecular Loop on personal knowledge as to their own activities and on information and belief as to the activities of others as follows:

NATURE OF THE ACTION

1. This is an action for a declaratory judgment of non-infringement and unenforceability arising under the Patent Laws of the United States, 35 U.S.C., §§ 101, *et seq.* and the Declaratory Judgment Act, 28 U.S.C. §§ 2201-2202. Plaintiffs seek relief because Molecular Loop's actions show that it intends to assert against Plaintiffs infringement of the '281 Patent (attached hereto as Exhibit A), the '851 Patent (attached hereto as Exhibit B), the '852

Patent (attached hereto as Exhibit C), the '200 Patent (attached hereto as Exhibit D), and the '730 Patent (attached hereto as Exhibit E) by certain of Illumina's and Verinata's products and/or services. Plaintiffs seek relief also because, on information and belief, Molecular Loop has baselessly alleged and continues to baselessly allege that certain of Illumina's and Verinata's customers infringe the Patents-in-Suit, at least in part, while using certain products or services they have purchased from Illumina or Verinata, thereby jeopardizing Plaintiffs' relationships with these customers, including Ambry Genetics ("Ambry"), ARUP Laboratories, Inc. ("ARUP"), Fulgent Genetics ("Fulgent"), Helix, Inc. ("Helix"), NeoGenomics Laboratories, Inc. ("NeoGenomics"), Personalis, Inc. ("Personalis"), and Tempus Labs, Inc. ("Tempus").

2. Molecular Loop's activities, including Molecular Loop's claims of infringement against Plaintiffs and their customers, and statements that Plaintiffs' products and/or services allegedly practice the Patents-in-Suit, have placed a cloud over Plaintiffs and their products and services and have created a substantial, definite, concrete, and immediate justiciable controversy between Plaintiffs and Molecular Loop over whether Plaintiffs' products and services infringe any of the Patents-in-Suit.

3. Plaintiffs have not infringed, and are not infringing, any claim of the Patents-in-Suit. Plaintiffs thus seek a declaratory judgment that, through their actions or through the normal, advertised and expected use of their products, services or technology, they have not infringed, induced others to infringe, or contributed to the infringement by others of any claim of the Patents-in-Suit.

4. Additionally, Plaintiffs have not infringed, and are not infringing, any claim of the '730 Patent because all claims of that patent are unenforceable due at least to the equitable doctrine of prosecution laches. As explained further below, Molecular Loop, as the applicant by

assignment of the ’730 Patent and its related applications, unreasonably and inexcusably delayed the prosecution of the applications that led to the ’730 Patent by over 12 years, including substantially amending the patent application’s claims and their scope to substantially change the alleged invention after nearly 10 years of prosecution of this patent family, in an effort to capture products brought to market by Illumina and others.

5. Compounding Molecular Loop’s unreasonably delayed prosecution of the ’730 Patent, representatives of Molecular Loop made multiple false representations regarding the filing status of related applications in order to prevent the Patent Office from publishing the applications that led to the ’730 Patent. These false representations kept the claimed contents of the applications that led to the ’730 Patent hidden for years, when those applications and associated prosecution history should have been publicly accessible. On information and belief, those misrepresentations were made intentionally to avoid the legal requirement of publication of the application, which otherwise may have alerted Plaintiffs and others to the Molecular Loop patent claims, and given them an opportunity to consider the impact of the claims on their existing and future products.

6. Plaintiffs have suffered prejudice attributable to the delays and improper concealment of the prosecution of the ’730 Patent, because, *inter alia*, Illumina’s accused TruSight Oncology 500 assay was developed and released years before the claims were amended, let alone issued.

7. Plaintiffs also have not infringed, and are not infringing, any claims of the ’730 Patent because all claims of that patent are also unenforceable due at least to the doctrine of inequitable conduct, based on the unmistakably false statements made by Molecular Loop’s lawyer to the Patent Office during prosecution of the ’730 Patent.

8. An actual and justiciable controversy therefore exists between Plaintiffs and Molecular Loop—concerning at least the enforceability of certain of the Patents-in-Suit and Molecular Loop's allegations of infringement regarding the Patents-in-Suit—that is sufficient to support the declaratory judgment relief sought by Plaintiffs.

PARTIES

9. Plaintiff Illumina is a Delaware corporation with its principal place of business at 5200 Illumina Way, San Diego, California 92122.

10. Plaintiff Verinata is a Delaware corporation with its principal place of business at 200 Lincoln Centre Dr., Foster City, CA 94404.

11. On information and belief, Defendant Molecular Loop is a corporation organized and existing under the laws of the State of Delaware, having a place of business at 300 Tradecenter, Suite 5400, Woburn, MA 01801. On information and belief, Molecular Loop is the owner by assignment of the Patents-in-Suit.

JURISDICTION AND VENUE

12. This action arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201-2202, and under the patent laws of the United States, 35 U.S.C. §§ 1, et seq.

13. This Court has subject matter jurisdiction over this action under 28 U.S.C. §§ 1331, 1338(a), and 2201(a).

14. This Court has personal jurisdiction over Molecular Loop because, on information and belief, Molecular Loop is headquartered in Massachusetts, which serves as its principal place of business.

15. Venue is proper in this District under 28 U.S.C. §§ 1391(b) and (c) at least because, on information and belief, Molecular Loop's principal place of business is located in

this District, such that Molecular Loop resides within this District, and because Molecular Loop is subject to personal jurisdiction here.

FACTUAL BACKGROUND

16. Plaintiffs re-allege and incorporate by reference each of paragraphs 1-15 above.

17. An actual controversy exists within the jurisdiction of this Court under 28 U.S.C. §§ 2201 and 2202.

The Patents-in-Suit

18. Molecular Loop purports to be the current owner of the ’281 Patent, entitled “Methods for Maintaining the Integrity and Identification of a Nucleic Acid Template in a Multiplex Sequencing Reaction.” The ’281 Patent lists Gregory Porreca, Mark Umbarger, and George Church as the inventors. A true and correct copy of the ’281 Patent is attached hereto as Exhibit A.

19. Molecular Loop purports to be the current owner of the ’851 Patent, entitled “Methods for Maintaining the Integrity and Identification of a Nucleic Acid Template in a Multiplex Sequencing Reaction.” The ’851 Patent lists Gregory Porreca, Mark Umbarger, and George Church as the inventors and Molecular Loop Biosciences, Inc. as the sole assignee. A true and correct copy of the ’851 Patent is attached hereto as Exhibit B.

20. Molecular Loop purports to be the current owner of the ’852 Patent, entitled “Methods for Maintaining the Integrity and Identification of a Nucleic Acid Template in a Multiplex Sequencing Reaction.” The ’852 Patent lists Gregory Porreca, Mark Umbarger, and George Church as the inventors and Molecular Loop Biosciences, Inc. as the sole assignee. A true and correct copy of the ’852 Patent is attached hereto as Exhibit C.

21. Molecular Loop purports to be the current owner of the ’200 Patent, entitled “Methods for Maintaining the Integrity and Identification of a Nucleic Acid Template in a

Multiplex Sequencing Reaction." The '200 Patent lists Gregory Porreca, Mark Umbarger, and George Church as the inventors and Molecular Loop Biosciences, Inc. as the sole assignee. A true and correct copy of the '200 Patent is attached hereto as Exhibit D.

22. Molecular Loop purports to be the current owner of the '730 Patent, entitled "Methods and Compositions for Evaluating Genetic Markers." The '730 Patent lists Gregory Porreca and Uri Laserson as the inventors and Molecular Loop Biosciences, Inc. as the sole assignee. A true and correct copy of the '730 Patent is attached hereto as Exhibit E

The Parties

23. Illumina is a global leader and pioneer in developing and manufacturing life science tools and systems for analyzing the building blocks of life: DNA that makes up the human genome. DNA is made up of a series of nucleic acids, the exact sequence of which determine the identity of each piece of DNA. Illumina's portfolio of DNA sequencing and analysis tools is designed to accelerate and simplify genetic DNA analysis, and has enabled studies that were not even imaginable just a few years ago. To that end, Illumina is credited with achieving a significant milestone in medical progress through the launch of sequencing technology capable of pushing the cost of sequencing the human genome from what was as high as six to seven figures down to just $600, and Illumina continues to drive down the cost of sequencing through its innovations. See, e.g., https://www.nature.com/articles/d42473-021-00030-9. Illumina's innovation has contributed substantially to advancing research of diseases and drug development and is moving the industry closer to realizing personalized medicine.

24. Illumina makes and sells world-leading genome sequencing instruments and chemistry, as well as various products used in sequencing workflows, such as library prep, bioinformatics, and assays such as TruSight Oncology 500 (TSO500) and Noninvasive Prenatal

Testing (NIPT) that run on Illumina's sequencing instruments. Illumina's next-generation sequencing systems offer high throughput sequencing, processing a given sample or samples in a massively parallel fashion to quickly determine their genetic sequence(s), i.e., the exact order of the nucleic acids that make up the genetic material of interest. This technology allows researchers to analyze genetic sequences, better understand the source of disease, and continues to facilitate pioneering advances in oncology, genetic and infectious diseases, and reproductive health. Illumina's customers include leading genomic research centers, academic institutions, government laboratories, and hospitals, as well as pharmaceutical, biotechnology, commercial molecular diagnostic laboratories, and consumer genomics companies.

25. Verinata is a wholly-owned subsidiary of Illumina, Inc. Verinata is a leading provider of non-invasive tests for early identification of fetal chromosomal abnormalities that supplies, among other things, noninvasive prenatal testing (NIPT) services.

26. According to its website, Molecular Loop was founded in 2018 by Dr. Greg Porreca and Dr. Eric Boyden and, upon information and belief, has benefited from the pioneering advancements in human genome sequencing developed by Illumina.

Existence of an Actual Controversy

27. The requested relief is appropriate because Defendant Molecular Loop has alleged that certain of Plaintiffs' products and/or services, such as TruSight Oncology 500 Circulating Tumor DNA (ctDNA), infringe at least one claim of the '281 Patent, at least one claim of the '851 Patent, at least one claim of the '852 Patent, at least one claim of the '200 Patent, and at least one claim of the '730 Patent.

28. On information and belief, Defendant Molecular Loop has alleged that certain of Plaintiffs' customers, such as ARUP, Fulgent, Helix, and NeoGenomics, have infringed the '281

Patent, the ’851 Patent, the ’852 Patent, the ’200 Patent, and the ’730 Patent, at least partially as a result of using certain kits containing Unique Molecular Identifiers (UMIs) and/or Unique Dual Indices (UDIs) they have purchased from Plaintiffs.

29. “Unique Dual Indexes,” or “UDIs,” and “Unique Molecular Identifiers,” or “UMIs,” are two types of tags that may be attached to nucleic acid sequences for use during sequencing analysis. They are often employed during certain next generation sequencing applications.

30. On June 26, 2023, Illumina was contacted by a representative of Molecular Loop regarding a “Possible IP Discussion” concerning Molecular Loop’s intellectual property. At that time, a representative of Molecular Loop asserted that Molecular Loop was not looking to enforce its intellectual property against Illumina.

31. On June 29, 2023, the representative of Molecular Loop again clarified to Illumina that Molecular Loop was “simply exploring a commercial opportunity with respect to its IP and is not looking at any enforcement activity toward [Illumina].” Molecular Loop’s representative also stated that “[Molecular Loop] believes that this IP is relevant to the [Illumina] workflows using UDIs and would be a nice compliment to [Illumina’s] products.” Molecular Loop provided Illumina with a presentation entitled “Corporate + IP Overview” that disclosed certain “UDI IP,” including the ’281 Patent, the ’851 Patent, the ’852 Patent, and U.S. Patent Application No. 17/339,527 (which later issued as the ’200 Patent), and provided claim 1 of the ’852 Patent as an “[e]xample issued claim.”

32. On November 21, 2023, Molecular Loop informed Illumina that it had retained outside counsel to assist in potential license negotiations concerning Molecular Loop’s IP portfolio.

33. On November 30, 2023, Molecular Loop's outside counsel sent Illumina a list of patent families it would like to discuss with Illumina, which included the Patents-in-Suit, including U.S. Application No. 16/952,764, which issued as the '730 Patent on December 12, 2023. Molecular Loop's email also listed "Illumina products [it] would like to discuss," including TruSight Oncology 500 ctDNA and VeriSeq NIPT Solution v2.

34. At the time of this correspondence, U.S. Application No. 16/952,764 and its corresponding prosecution history were not yet publicly available.

35. During a meeting between Illumina and Molecular Loop on December 1, 2023, in an abrupt change of tone from its June 2023 communications, Molecular Loop accused Illumina of infringing the Patents-in-Suit.

36. As discussions continued after the December 1, 2023 meeting, in another sign that Molecular Loop's goal was to sue Illumina if it did not acquiesce in taking a license to Molecular Loop's patents, Molecular Loop attempted to pressure Illumina by contacting Illumina's customers and threatening them by alleging infringement of Molecular Loop's UDI and UMI patent portfolios, including the Patents-in-Suit.

37. For example, Illumina's customer ARUP received a letter dated January 19, 2024 from counsel for Molecular Loop alleging that "ARUP requires a license to several of the patents in Molecular Loop's patent portfolio," expressly identifying the Patents-in-Suit. On information and belief, Molecular Loop accused ARUP of infringing the Patents-in-Suit by selling "non-invasive prenatal aneuploidy screening, solid tumor mutation panel sequencing, exome sequencing, familial targeted sequencing, and whole genome sequencing tests," at least partially as a result of using certain products or services ARUP had purchased from Plaintiffs.

38. On January 30, 2024, Illumina's customer Tempus received a letter from counsel for Molecular Loop identifying the Patents-in-Suit and alleging that "Tempus… infringes the UDI IP and the UMI IP." On information and belief, Molecular Loop accused Tempus of infringing the Patents-in-Suit through its use of "xF Liquid Biopsy Tests" at least partially as a result of using certain products or services Tempus had purchased from Plaintiffs.

39. On February 27, 2024, Illumina's customer Fulgent received a letter from counsel for Molecular Loop identifying the Patents-in-Suit and alleging that "Fulgent… infringes the UDI IP and the UMI IP," which were defined to include the Patents-in-Suit. On information and belief, Molecular Loop accused Fulgent of infringing the Patents-in-Suit through its use of certain of its Next Generation Sequencing products at least partially as a result of using certain products or services Fulgent had purchased from Plaintiffs.

40. Similarly, on or around March 6, 2024, Illumina's customer Helix was contacted by representatives of Molecular Loop requesting that Helix, Inc. take a license to Molecular Loop's patent portfolios concerning UDIs and UMIs. On information and belief, Molecular Loop expressly identified the Patents-in-Suit, and Molecular Loop accused Helix of infringing the Patents-in-Suit by selling services that use certain of its Next Generation Sequencing technology, including at least partially based on Helix's use of certain products or services that Helix had purchased from Plaintiffs.

41. As yet another example, on April 24, 2024, Illumina's customer NeoGenomics received a letter from counsel for Molecular Loop identifying the Patents-in-Suit and alleging that "NeoGenomics… infringes the UDI IP and the UMI IP." On information and belief, Molecular Loop accused NeoGenomics of infringing the Patents-in-Suit through its "Neo

Comprehensive tests" based at least partially on certain products or services NeoGenomics had purchased from Plaintiffs.

42. On information and belief, other customers of Plaintiffs have received similar correspondence from Molecular Loop alleging infringement of the Patents-in-Suit. These customers include Personalis and Ambry.

43. Plaintiffs reserve all rights to amend this Complaint to seek a declaratory judgment of non-infringement and/or unenforceability of any other U.S. Patents Molecular Loop contends are infringed by Plaintiffs and/or Plaintiffs' customers.

COUNT I
(Declaration of Non-Infringement of the '281 Patent)

44. Plaintiffs reallege and incorporates all of the foregoing paragraphs of this Complaint as though fully set forth herein.

45. Neither Plaintiffs nor their products, services or technology have infringed, directly or indirectly, any claim of the '281 Patent.

46. For example, Plaintiffs' VeriSeq NIPT Solution v2 assay products and TruSight Oncology 500 ctDNA v2 products accused by Molecular Loop do not practice at least the limitation of "incorporating at least two of the same sequence identifiers into the template," which is required by independent claim 1 of the '281 Patent and all claims that depend on it.

47. Similarly, Plaintiffs' VeriSeq NIPT Solution v2 assay products and TruSight Oncology 500 ctDNA v2 products accused by Molecular Loop do not practice at least the limitation of "attaching a pair of the same barcode sequences to the template," which is required by independent claim 16 of the '281 Patent and all claims that depend on it.

48. Similarly, Plaintiffs' VeriSeq NIPT Solution v2 assay products and TruSight Oncology 500 ctDNA v2 products accused by Molecular Loop do not practice at least the

limitation of "wherein the first and second barcode sequences are the same," which is required by claim 29 of the '281 Patent and all claims that depend on it.

49. Because Plaintiffs do not infringe any independent claim of the '281 Patent, they do not infringe any claim of the '281 Patent.

50. A substantial, definite, concrete, and immediate justiciable controversy exists between Plaintiffs and Molecular Loop with respect to whether Plaintiffs infringe any claim of the '281 Patent.

51. Plaintiffs seek a declaration that they do not infringe any claim of the '281 Patent.

COUNT II
(Declaration of Non-Infringement of the '851 Patent)

52. Plaintiffs reallege and incorporate all of the foregoing paragraphs of this Complaint as though fully set forth herein.

53. Neither Plaintiffs nor their products, services or technology have infringed, directly or indirectly, any claim of the '851 Patent.

54. For example, Plaintiffs' VeriSeq NIPT Solution v2 assay products and TruSight Oncology 500 ctDNA v2 products accused by Molecular Loop do not practice at least the limitation of "detecting the presence of two or more identifier sequences that are uniquely associated with an analyte of interest, wherein the two or more identifier sequences associated with each analyte of interest have four or more nucleotides and are the same," which is required by independent claim 1 of the '851 Patent and all claims that depend on it.

55. Because Plaintiffs do not infringe the only independent claim of the '851 Patent, they do not infringe any claim of the '851 Patent.

56. A substantial, definite, concrete, and immediate justiciable controversy exists between Plaintiffs and Molecular Loop with respect to whether Plaintiffs infringe any claim of the '851 Patent.

57. Plaintiffs seek a declaration that they do not infringe any claim of the '851 Patent.

COUNT III
(Declaration of Non-Infringement of the '852 Patent)

58. Plaintiffs reallege and incorporate all of the foregoing paragraphs of this Complaint as though fully set forth herein.

59. Neither Plaintiffs nor their products, services or technology have infringed, directly or indirectly, any claim of the '852 Patent.

60. For example, Plaintiffs' VeriSeq NIPT Solution v2 assay products accused by Molecular Loop do not practice at least the limitation of "discarding sequence reads obtained in said sequencing step that contain said combination of identifier sequences that are different than any of said distinct pairs, thereby to reduce cross-over error," which is required by independent claim 1 of the '852 Patent and all claims that depend on it.

61. Additionally, Plaintiffs' VeriSeq NIPT Solution v2 assay products and Illumina's TruSight Oncology 500 ctDNA v2 products accused by Molecular Loop do not practice at least the limitation of "incorporating at least two members of a plurality of identifier sequences into template nucleic acids obtained from at least two different samples, wherein said members constitute a distinct pair associated with said template," which is required by independent claim 1 of the '852 Patent and all claims that depend on it.

62. Because Plaintiffs do not infringe the only independent claim of the '852 Patent, they do not infringe any claim of the '852 Patent.

63. A substantial, definite, concrete, and immediate justiciable controversy exists between Plaintiffs and Molecular Loop with respect to whether Plaintiffs infringe any claim of the ’852 Patent.

64. Plaintiffs seek a declaration that they do not infringe any claim of the ’852 Patent.

COUNT IV
(Declaration of Non-Infringement of the ’200 Patent)

65. Plaintiffs reallege and incorporate all of the foregoing paragraphs of this Complaint as though fully set forth herein.

66. Neither Plaintiffs nor their products, services or technology have infringed, directly or indirectly, any claim of the ’200 Patent.

67. For example, Plaintiffs’ VeriSeq NIPT Solution v2 assay products accused by Molecular Loop do not practice at least the limitation of “validating the sequence of the nucleic acid analyte of interest by analyzing both identifiers and excluding the sequences of those nucleic acid analytes of interest containing only one identifier or an incorrect pair of identifiers from sequence analysis of the multiplex sequencing reaction,” which is required by independent claim 1 of the ’200 Patent and all claims that depend on it.

68. Additionally, Plaintiffs’ VeriSeq NIPT Solution v2 assay products and Illumina’s TruSight Oncology 500 ctDNA v2 products accused by Molecular Loop do not practice at least the limitation of “detecting the presence of two or more identifier sequences that are uniquely associated with the nucleic acid analyte of interest,” which is required by independent claim 1 of the ’200 Patent and all claims that depend on it.

69. Because Plaintiffs do not infringe the only independent claim of the ’200 Patent, they do not infringe any claim of the ’200 Patent.

70. A substantial, definite, concrete, and immediate justiciable controversy exists between Plaintiffs and Molecular Loop with respect to whether Plaintiffs infringe any claim of the ’200 Patent.

71. Plaintiffs seek a declaration that they do not infringe any claim of the ’200 Patent.

COUNT V
(Declaration of Non-Infringement of the ’730 Patent)

72. Plaintiffs reallege and incorporates all of the foregoing paragraphs of this Complaint as though fully set forth herein.

73. During prosecution of the applications that led to the ’730 Patent, one of the named inventors, Dr. Gregory Porreca, alleged in sworn declarations that “[a] distinguishing feature of the claims in my patent application is that each individual nucleic acid molecule is tagged with a unique differentiator tag prior to any amplification or sequencing steps.”

74. Dr. Porreca’s declarations elaborated that prior art identified by the patent examiner was allegedly distinguished because it did not disclose “tagging individual nucleic acid molecules each with a unique barcode sequence,” and that, in his invention, “[e]ach differentiator tag has its own unique sequence so that each individual nucleic acid molecule is tagged, and therefore associated, with its own unique differentiator tag.”

75. Dr. Porreca further represented to the Patent Office that the prior art did not describe “tagging each individual nucleic acid molecule with a unique barcode sequence as required by my pending claims,” and that “my claims require a unique barcode sequence per each individual target nucleic acid molecule.”

76. Neither Plaintiffs nor their products, services or technology have infringed, directly or indirectly, any claim of the ’730 Patent, as they do not operate as described by Dr. Porreca in his sworn declarations to the Patent Office.

77. For example, Illumina's TruSight Oncology 500 ctDNA and UMI plate products do not utilize a "set of differentiator tags, wherein members of said set of differentiator tags are associated with members of said plurality [of target nucleic acid molecules from more than one locus of origin]," which is required by claims 1-8 of the '730 Patent.

78. Likewise, for example, Illumina's TruSight Oncology 500 ctDNA and UMI plate products do not utilize a "set of unique differentiator tags, wherein members of said set of unique differentiator tags are randomly associated with members of said plurality of target nucleic acid molecules, such that any given tag is uniquely associated with said locus of origin," which is required by claim 9 of the '730 Patent.

79. As another example, Illumina's TruSight Oncology 500 ctDNA and UMI plate products also do not practice the limitation of "sequencing the amplicons obtained in said amplifying step to obtain sequence reads of each of the amplicons," which is required by independent claims 1 and 9 of the '730 Patent.

80. Because Plaintiffs do not infringe either of the independent claims of the '730 Patent, they do not infringe any claim of the '730 Patent.

81. A substantial, definite, concrete, and immediate justiciable controversy exists between Plaintiffs and Molecular Loop with respect to whether Plaintiffs infringe any claim of the '730 Patent.

82. Plaintiffs seek a declaration that they do not infringe any claim of the '730 Patent.

COUNT VI
(Declaration of Unenforceability of the '730 Patent Due to Prosecution Laches)

83. Plaintiffs reallege and incorporates all of the foregoing paragraphs and paragraphs 107 to 150 of this Complaint as though fully set forth herein.

84. Neither Plaintiffs nor their products, services or technology have infringed, directly or indirectly, any claim of the '730 Patent also because those claims are unenforceable due to, at least, the doctrine of prosecution laches.

85. Prosecution laches bars enforcement of the '730 Patent, which issued after an unreasonable and inexcusable delay in prosecution caused by Molecular Loop and its attorneys, and Illumina has suffered prejudice attributable to the delay. The equitable doctrine of prosecution laches is intended to avoid abuses of the patent system and unreasonable delays by a patent holder in claiming its alleged rights.

86. According to the public records of the United States Patent & Trademark Office ("Patent Office"), the '730 Patent is the first issued U.S. patent in its family, issuing on December 12, 2023. Ex. E (cover)

87. The first filed nonprovisional application in the family that led to the issued '730 Patent was filed as PCT/US2010/001293 on April 30, 2010, allegedly based on a series of provisional applications, the first of which was filed on April 30, 2009. Ex. E (cover).

88. On August 8, 2016, Molecular Loop filed U.S. Patent Application No. 15/231,687 ("the '687 Application"), which claimed priority to PCT/US2010/001293.

89. During prosecution of the '687 Application, Molecular Loop waited until October 2, 2020—over 4 years after filing of the '687 Application and nearly two years after the October 30, 2018 public release of Illumina's TSO 500 assay products—to amend the pending claims to "clarify[]" that the purported invention is directed to a "method for correcting for errors or biased introduced during nucleic acid analysis workflow" and entails "correcting for error or bias introduced during said workflow by collapsing target:differentiator tag combinations observed more than once into a single count."

90. An interview with the patent examiner was held on November 18, 2020. During that interview, representatives for Molecular Loop explained that the claims had been amended to "clarify the invention." The patent examiner objected, stating that "the amendments provide a new invention drawn to correcting errors or bias" and that it was "improper to switch inventions." The examiner explained that "the originally filed claims did not provide for [correction of errors or bias] and thus the instant claims were a distinct invention."

91. No further action was taken in the prosecution of the '687 Application, which was officially deemed abandoned by the Patent Office on July 28, 2021.

92. Instead, on November 19, 2020, Molecular Loop filed U.S. Patent Application No. 16/952,764 ("the '764 Application") as a continuation of the '687 Application. The '764 Application contained the same claims that had been rejected and abandoned during prosecution of the '687 Application.

93. The '764 Application did not issue as the '730 Patent until December 12, 2023, some 5 years after the public release of Illumina's TSO500 products, over 14 years after filing of the first provisional application in this patent family, over 13 years after the filing of Molecular Loop's 2010 PCT application, and over 7 years after the filing of the '687 Application.

94. Molecular Loop's claims directed to "correcting errors or bias" were not made available to the public, including Illumina, as a direct result of the misconduct of Molecular Loop and its representatives during prosecution of the underlying applications.

95. At the times of filing of the '687 Application and the '764 Application (August 8, 2016 and November 19, 2020, respectively), Molecular Loop filed a "Request Not to Publish," which represented that "the invention disclosed in the attached application **has not and will not**

be the subject of an application filed in another country, or under a multilateral international agreement, that requires publication at eighteen months after filing."

96. The representations made in the "Request Not to Publish" made in connection with the '687 Application and the '764 Application were false, as PCT/US2010/001293 had been filed in April 2010, many years earlier.

97. The Patent Cooperation Treaty is a multilateral international agreement that requires publication at 18 months after filing.

98. In the same filings that contained the "Request Not to Publish," Molecular Loop identified "PCT/US2010/001293" or "US2010/001293" as a related application, thus confirming Molecular Loop's knowledge of the PCT application.

99. The alleged invention had also been published previously in connection with at least the following related international applications: (1) IL 216054 A (published March 31, 2016); (2) JP 2016000046A (published January 7, 2016); (3) AU 2010242073 C1 (published December 24, 2015); (4) AU 20100242073 B2 (published September 3, 2015); (5) EP 2425240 A4 (published December 12, 2012); (6) JP 2012525147A (published October 22, 2012); (7) EP 2425240 A2 (published March 7, 2012); (7) AU 2010242073 A1 (published November 24, 2010); and (8) CA 2760439 A1 (published November 4, 2010).

100. On information and belief, the false representations in the "Request Not to Publish" were made in order to conceal the contents of the claims of the then-pending '687 Application and '764 Application, contrary to law.

101. The result of Molecular Loop's filing of the false "Request[s] Not to Publish" is that the '687 Application and '764 Application, and the documents filed during prosecution of

those applications, were not published or made available by the Patent Office for the public, including Illumina, to see.

102. Molecular Loop's conduct during the prosecution of the alleged invention of the '730 Patent, including (1) delaying approximately 10 years from the filing of PCT/US2010/001293 on April 30, 2010—waiting until Illumina's TSO 500 products were released in October 2018—and then changing the invention and amending the claims to direct them to "methods for correcting for errors or bias introduced during nucleic acid workflow," and (2) using false representations in order to conceal the prosecution of the alleged inventions, exemplifies unreasonable and inexcusable delays in prosecution.

103. Molecular Loop's unreasonable and inexcusable delays in prosecution have prejudiced Illumina. During Molecular Loop's concealed, 13 year prosecution of the applications that led to the '730 Patent, Illumina developed and released products (*e.g.*, TruSight Oncology 500 in October 2018) that Molecular Loop now alleges infringe the '730 Patent. Illumina's release of products that utilize its UMI technology occurred years before Molecular Loop had even amended its claims to direct them to the correction of errors or bias. As a result of Molecular Loop's false representations to the Patent Office and "Request Not to Publish," Illumina had no ability to access the pending prosecution of Molecular Loop's applications during the development of Illumina's accused products, including for purposes of assessing potential impact on its existing and future products.

104. Accordingly, the '730 Patent is unenforceable due to prosecution laches and cannot be infringed by Plaintiffs.

105. A substantial, definite, concrete, and immediate justiciable controversy exists between Plaintiffs and Molecular Loop with respect to whether the claims of the '730 Patent are not infringed due to unenforceability.

106. Plaintiffs seek a declaration that all claims of the '730 Patent are unenforceable.

COUNT VII
(Declaration of Unenforceability of the '730 Patent Due to Inequitable Conduct)

107. Plaintiffs reallege and incorporate all of the foregoing paragraphs of this Complaint as though fully set forth herein.

108. The '730 Patent is unenforceable due to inequitable conduct that occurred during prosecution of the '764 Application and the '687 Application to which the '730 Patent claims priority.

109. In particular, Molecular Loop and individuals having a duty of candor to the U.S. Patent and Trademark Office ("Patent Office") made multiple, unmistakably false statements regarding the filing status of other patent applications in order to conceal the scope of the claims and the prosecution record of the '764 Application and the '687 Application from the public, including Illumina.

110. Gregory Porreca and Uri Laserson are named as alleged inventors on the face of the '730 Patent.

111. Upon Information and belief, Gregory Porreca is the founder and Chief Executive Officer of Molecular Loop.

112. Thomas C. Meyers of the law firm Withers Bergman LLP (formerly of the law firm Brown Rudnick LLP), prosecuted the '764 Application and the '687 Application.

113. Mr. Meyers and Dr. Porreca had a duty of candor and good faith in dealing with the U.S. Patent Office in connection with the '764 and '687 Applications.

114. The first filed non-provisional application in the family that led to the issued '730 Patent was filed by Patrick R.H. Waller of Wolf, Greenfield & Sacks, P.C. on behalf of Good Start Genetics, Inc. as PCT/US2010/001293 on April 30, 2010, allegedly based on a series of provisional applications, the first of which was filed on April, 30, 2009. Dr. Porreca is a named inventor on PCT/US2010/001293.

115. On August 8, 2016, Mr. Meyers filed the '687 Application, which claimed priority to PCT/US2010/001293. At the time of filing of the '687 Application, Mr. Meyers submitted an Application Data Sheet that contained a "Request Not to Publish," in which he stated "I hereby request that the attached application not be published under 35 U.S.C. 122(b) and certify that the invention disclosed in the attached application **has not and will not** be the subject of an application filed in another country, or under a multilateral international agreement, that requires publication at eighteen months after filing." Mr. Meyers' representation was unmistakably false, as PCT/US2010/001293 had been filed on April 30, 2009 under the Patent Cooperation Treaty, a multilateral international agreement that requires publication at 18 months after filing.

116. PCT/US2010/001293 was in fact published on November 4, 2010 as WO/2010/126614.

117. At the time of the false "Request Not to Publish," the alleged invention disclosed in the '687 Application had also been published previously in connection with at least the following related international applications: (1) IL 216054 A (published March 31, 2016); (2) JP 2016000046A (published January 7, 2016); (3) AU 2010242073 C1 (published December 24, 2015); (4) AU 20100242073 B2 (published September 3, 2015); (5) EP 2425240 A4 (published December 12, 2012); (6) JP 2012525147A (published October 22, 2012); (7) EP 2425240 A2

(published March 7, 2012); (7) AU 2010242073 A1 (published November 24, 2010); and (8) CA 2760439 A1 (published November 4, 2010).

118. Mr. Meyers was involved in filing U.S. patent applications that claimed priority to PCT/US2010/001293 since at least October 28, 2011, when he filed U.S. Application No. 13/266,862, which claimed priority to PCT/US2010/001293. Therefore, Mr. Meyers was the attorney of record prosecuting patent applications in this patent family at the time of publication of at least 6 of the 8 international publications identified in the preceding paragraph. On information and belief, Mr. Meyers was aware of at least those 6 international publications when he submitted the false "Request Not to Publish."

119. Mr. Meyers was admitted to practice before the U.S. Patent Office on April 19, 1993 and, upon information and belief, was knowledgeable about the provisions of the Manual of Patent Examining Procedure ("MPEP") during prosecution of the '764 and '687 Applications.

120. Mr. Meyers' false representation in the "Request Not to Publish" violated at least Section 1122 of the MPEP.

121. In particular, Section 1122 of the MPEP required that before making the required certification in connection with a "Request Not to Publish," "the person who signs the certification must make an **actual inquiry** to determine whether the certification under 35 U.S.C. 122(b)(2)(B)(i) and 37 CFR 1.213(a)(3) can be appropriately made." https://www.uspto.gov/web/offices/pac/mpep/old/e9r07-2015_nov/mpep-1100.pdf. Mr. Meyers' false statement violated 37 CFR 11.18(b).

122. Section 1122 of the MPEP continues that "A nonpublication request is not appropriate unless the person who is signing the nonpublication request has made an actual inquiry consistent with the requirements of 37 CFR 11.18(b) to determine that: (A) The

application under 35 U.S.C. 111(a) **has not been** the subject of a foreign or international application filed in another country, or under a multilateral international agreement, that requires publication of applications at eighteen months after filing (*e.g.*, a counterpart PCT application); and (B) The applicant's intent at the time the nonpublication request is being filed is that the application under 35 U.S.C. 111(a) **will not be** the subject of a foreign or international application filed in another country, or under a multilateral international agreement, that requires publication of applications at eighteen months after filing." https://www.uspto.gov/web/offices/pac/mpep/old/e9r07-2015_nov/mpep-1100.pdf.

123. Section 1122 of the MPEP further states that "A nonpublication request is not appropriate if applicants have already filed a counterpart foreign or international application in another country, or under a multilateral international agreement, that requires publication of applications at eighteen months after filing. A nonpublication request is not proper even if the foreign or international application is abandoned before the foreign or international application is published." https://www.uspto.gov/web/offices/pac/mpep/old/e9r07-2015_nov/mpep-1100.pdf.

124. The MPEP also provides that "[a]ny applicant or applicant's representative who makes a false statement (e.g., an improper certification) may be in violation of 37 CFR 11.18(b). In addition, false statements by registered patent practitioners may also violate other Disciplinary Rules (see 37 CFR Part 11)." https://www.uspto.gov/web/offices/pac/mpep/old/e9r07-2015_nov/mpep-1100.pdf. Mr. Meyers' false statement violated 37 CFR 11.18(b).

125. "PCT/US2010/001293" was listed in the Application Data Sheet submitted and signed by Mr. Meyers on August 8, 2016 that contained the "Request Not to Publish," thus confirming Mr. Meyers' knowledge of the PCT application that had been filed and published years earlier on April 30, 2010 and November 4, 2010, respectively.

126. On information and belief, Mr. Meyers' false representation made in the "Request Not to Publish" the '687 Application was made in order to improperly conceal the contents of the claims and prosecution record of the then-pending '687 Application.

127. The result of Molecular Loop's filing of the "Request Not to Publish" is that the '687 Application and the prosecution record revealing, *inter alia*, the scope of the pending patent claims, were not published or made publicly available by the Patent Office.

128. Absent the "Request Not to Publish," the '687 Application would have been expected to publish no later than 18 months after the August 2016 filing of the '687 Application, and likely much sooner under § 1120 of the MPEP that was in force of at the time of the request. *See* https://www.uspto.gov/web/offices/pac/mpep/old/e9r07-2015_nov/mpep-1100.pdf. In addition to the publication of the '687 Application, the prosecution record of the '687 Application would also have been publicly available from the publication of the '687 Application via the Patent Office's website. MPEP, Section 1128.

129. By engaging in the foregoing actions, Mr. Meyers and Molecular Loop were able to covertly change the scope of Molecular Loop's pending claims in an attempt to capture the products of others that already been brought to market, including by Illumina, without the knowledge of Illumina and other concerned members of the public.

130. Specifically, during prosecution of the '687 Application, Molecular Loop (through Mr. Meyers) waited until October 2, 2020—over 4 years after filing, and nearly two years after the October 30, 2018 public release of Illumina's TSO 500 assay products—to substantially change the direction of the application by substantially amending the pending claims to "clarify" that the purported invention is directed to a "method for correcting for errors or bias introduced during nucleic acid analysis workflow" that entails "correcting for error or

bias introduced during said workflow by collapsing target:differentiator tag combinations observed more than once into a single count."

131. Because of Mr. Meyers' false "Request Not to Publish" the '687 Application, blocking the publication of the '687 Application, Molecular Loop's amended claims and statements "clarify[ing]" the invention were not made publicly available by the Patent Office.

132. An interview including the patent examiner, Mr. Meyers and Dr. Porreca, was held on November 18, 2020. During that interview, Mr. Meyers and Dr. Porreca, as representatives of Molecular Loop, explained that the new claim amendments had "clarif[ied] the invention." However, the patent examiner would not allow the amendments and "noted that the amendments provide a new invention drawn to correcting errors or bias" and that it was "improper to switch inventions." The examiner explained that "the originally filed claims did not provide for [correction of errors or bias] and thus the instant claims were a distinct invention."

133. No further action was taken by Mr. Meyers and Dr. Porreca in the prosecution of the '687 Application, which was officially deemed abandoned by the Patent Office on July 28, 2021.

134. Instead, on November 19, 2020, Molecular Loop again through Mr. Meyers filed U.S. Patent Application No. 16/952,764 ("the '764 Application") as a continuation of the '687 Application which contained the new claim amendments that the patent examiner would not allow in the '687 Application.

135. In connection with the new '764 Application filing, Mr. Meyers and Molecular Loop made a second unmistakably false representation in order to maintain their scheme to

conceal from the public, including Illumina, the amended scope of its patent claims and prosecution record of the '764 Application.

136. Specifically, in its November 19, 2020 filing, Mr. Meyers again submitted an Application Data Sheet that contained a "Request Not to Publish," in which he falsely stated "I hereby request that the attached application not be published under 35 U.S.C. 122(b) and certify that the invention disclosed in the attached application **has not and will not** be the subject of an application filed in another country, or under a multilateral international agreement, that requires publication at eighteen months after filing." This representation again was unmistakably false, as PCT/US2010/001293, to which the issued '730 Patent claims priority, had been filed on April 30, 2010 under the Patent Cooperation Treaty, a multilateral international agreement that requires publication at 18 months after filing, and in fact published on November 4, 2010.

137. At the time of the second false statement, the alleged invention disclosed in the '764 Application had also been published previously in connection with at least 8 international applications, 6 of which had published during the time Mr. Meyers was filing patent applications in this patent family on behalf of Molecular Loop or its predecessor.

138. As further evidence of an intent to conceal the amended claims and prosecution record, in the Application Data Sheet for the '764 Application filed November 19, 2020 that contained the "Request Not to Publish," Mr. Meyers identified "US2010/001293," as a priority application but omitted the crucial fact that this prior application had been filed under the Patent Cooperation Treaty. The Application Data Sheet expressly calls for the applicant to "indicate National Stage entry from a PCT application."

139. Mr. Meyers' unmistakably false representations in the "Request Not to Publish" violated at least Section 1122 of the MPEP, which, as of filing in November 2020, contained

substantially identical provisions to those discussed above, as well as 37 CFR 11.18(b). *See* https://www.uspto.gov/web/offices/pac/mpep/old/e9r10-2019/mpep-1100.pdf.

140. Upon information and belief, the inclusion of "US2010/001293" in the Application Data Sheet, and Mr. Meyers' omission of the critical fact that this submission had been made under the PCT as PCT/US2010/001293, demonstrates Mr. Meyers' knowledge that the PCT application had been filed and published years earlier, and reflects his decision to intentionally withhold that information from the Patent Office in connection with the filing of the '764 Application.

141. Upon information and belief, Mr. Meyers' knowingly false representation in the "Request Not to Publish" was made in order to conceal the prosecution record of the then-pending '764 Application, and any changes being made to the scope of the claims of the '764 Application.

142. The result of Molecular Loop's filing of the "Request Not to Publish" is that the '764 Application and the documents from its associated prosecution were not published or made publicly available by the Patent Office until after issuance of the '730 Patent.

143. Absent the "Request Not to Publish," the '764 Application and the contents of its prosecution would have been expected to publish within 14 weeks of filing of the '764 Application, or February 2021, prior to its issuance on December 12, 2023, under § 1120 of the MPEP that was in force of at the time of the filing. *See* https://www.uspto.gov/web/offices/pac/mpep/old/e9r10-2019/mpep-1100.pdf.

144. Dr. Porreca was one of the inventors and applicants named on the PCT/US2010/001293 application, and was also named as an inventor in the Application Data Sheets submitted for the '687 Application and the '764 Application.

145. On information and belief, Dr. Porreca was aware of the publication of the PCT/US2010/001293 application during the prosecution of the '687 and '764 Applications.

146. On information and belief, Dr. Porreca was aware of the decision to submit a "Request Not to Publish" the '687 Application and the '764 Application.

147. In recent discussions with Illumina (which Dr. Porreca attended), Molecular Loop represented that the priority date of the '730 Patent is based on the filing of PCT/US2010/001293, thus confirming that Molecular Loop, including at least Dr. Porreca and Mr. Meyers, were aware that the published PCT/US2010/001293 was a priority application for the alleged invention that issued as the '730 Patent.

148. On information and belief, the two unmistakably false statements to the Patent Office submitted and signed by Mr. Meyers were made with the full knowledge of Mr. Meyers and Dr. Porreca of their falsity.

149. On information and belief, these false statements were made to prevent publication of the U.S. applications that led to the '730 Patent and its prosecution record and constitute egregious misconduct, violated the applicant's duty of candor and good faith and fair dealing with the Patent Office, and constitute inequitable conduct that renders the '730 Patent unenforceable.

150. Plaintiffs are therefore entitled to a judgment that the '730 Patent is unenforceable due to inequitable conduct that occurred during the prosecution of the '730 Patent.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs ask this Court to enter judgment in Plaintiffs' favor and against Molecular Loop by granting the following relief:

a) Declaring that Plaintiffs have not infringed, and do not infringe, either directly or indirectly, any claim of the ’281 Patent, either literally or under the doctrine of equivalents;

b) Declaring that Plaintiffs have not infringed, and do not infringe, either directly or indirectly, any claim of the ’851 Patent, either literally or under the doctrine of equivalents;

c) Declaring that Plaintiffs have not infringed, and do not infringe, either directly or indirectly, any claim of the ’852 Patent, either literally or under the doctrine of equivalents;

d) Declaring that Plaintiffs have not infringed, and do not infringe, either directly or indirectly, any claim of the ’200 Patent, either literally or under the doctrine of equivalents;

e) Declaring that Plaintiffs have not infringed, and do not infringe, either directly or indirectly, any claim of the ’730 Patent, either literally or under the doctrine of equivalents;

f) Declaring that the ’730 Patent is unenforceable;

g) Finding that Plaintiffs are the prevailing party and that this is an exceptional case under 35 U.S.C. § 285;

h) Awarding Plaintiffs their costs, expenses, and reasonable attorneys’ fees in connection with this action; and

i) Granting such further and additional relief as the Court deems just and proper.

DEMAND FOR JURY TRIAL

Plaintiffs, under Rule 38 of the Federal Rules of Civil Procedure, request a jury trial for all issues deemed to be triable by a jury.

Date: June 10, 2024

Respectfully submitted,
SIDLEY AUSTIN LLP

By: */s/ Jack W. Pirozzolo*

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