

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

MOLECULAR LOOP BIOSCIENCES, INC.,	)	
	)	
Plaintiff,	)	
	)	C.A. No. 24-680-RGA
v.	)	
	)	JURY TRIAL DEMANDED
ILLUMINA, INC. and	)	
VERINATA HEALTH, INC.,	)	
	)	
Defendants.	)	

DEFENDANTS' ANSWER AND COUNTERCLAIMS TO THE COMPLAINT

Defendants Illumina, Inc. (“Illumina”) and Verinata Health, Inc. (“VHI”) (collectively, “Defendants”) by and through their counsel, hereby submit their Answer to the Complaint of Plaintiff Molecular Loop Biosciences, Inc. (“Molecular Loop” or “Plaintiff”), set forth their defenses to the Complaint, and set forth their Counterclaims. The Complaint’s section headings are carried over in this Answer for ease of reference only, and Defendants deny any allegations contained in the section headings.

By submitting this Answer and Counterclaims, Defendants expressly preserve and do not waive any applicable rights, defenses, or objections. Defendants also expressly reserve the right to amend this Answer, their defenses, and their Counterclaims based on, *inter alia*, discovery, factual developments, and Defendants’ ongoing investigation of Plaintiff’s claims. Unless expressly stated herein, nothing in this Answer should be construed as an admission by Defendants regarding the existence of any facts set forth in the Complaint.

ANSWER

Defendants hereby answer the Complaint as follows:

NATURE OF THE ACTION

ANSWER TO PARAGRAPH 1: To the extent this paragraph contains legal conclusions, no response is required. Defendants admit that Plaintiff purports to allege an action for patent infringement arising under the patent laws of the United States, 35 U.S.C. §§ 271 et seq., but deny that they have committed any acts of infringement of a valid and enforceable claim of any of the Patents-in-Suit, or caused any injury or damage to Plaintiff. Defendants admit that this Court has subject matter jurisdiction over actions arising under the patent laws of the United States. Except as so admitted, Defendants deny the allegations of this paragraph.

THE PARTIES

ANSWER TO PARAGRAPH 2: Defendants deny that Molecular Loop is a pioneering company or that its technology is a fundamental part of what makes NGS more scalable, efficient, and practical. Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations of this paragraph, and therefore deny them.

ANSWER TO PARAGRAPH 3: Defendants admit that Illumina is a company 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. Defendants admit that Illumina has appointed The Corporation Trust Company, Corporation Trust Center 1209 Orange Street, Wilmington, Delaware 19801, as its agent for service of process. Except as so admitted, Defendants deny the allegations of this paragraph.

ANSWER TO PARAGRAPH 4: Defendants admit that VHI is a company organized and existing under the laws of the state of Delaware. Defendants admit that VHI has appointed The Corporation Trust Company, Corporation Trust Center 1209 Orange Street, Wilmington,

Delaware 19801, as its agent for service of process. Defendants admit that VHI is a wholly owned subsidiary of Illumina. Except as so admitted, Defendants deny the allegations of this paragraph.

ANSWER TO PARAGRAPH 5: Defendants admit that Illumina and/or certain of its subsidiaries and affiliates make, use, and commercialize genetic tests marketed under the tradename “VeriSeq.” Defendants admit that the VeriSeq tests utilize NGS techniques and may include DNA library preparation kits that incorporate certain nucleic-acid-based adapters. Defendants admit that the VeriSeq tests may be used with certain data analysis methods to reduce certain errors that may arise after amplification and sequencing steps. Except as so admitted, Defendants deny the allegations of this paragraph.

ANSWER TO PARAGRAPH 6: Defendants admit that Illumina and/or certain of its subsidiaries and affiliates make, use, and commercialize non-invasive prenatal tests marketed under the tradename “Verifi.” Defendants admit that the Verifi tests utilize NGS techniques and may include DNA library preparation kits that incorporate certain nucleic-acid-based adapters. Defendants admit that the Verifi tests may be used with certain data analysis methods to reduce certain errors that may arise after certain amplification and sequencing steps. Except as so admitted, Defendants deny the allegations of this paragraph.

ANSWER TO PARAGRAPH 7: Defendants admit that Illumina and/or its certain of its subsidiaries and affiliates make, use, and commercialize oncology tests marketed under the tradename “TruSight.” Defendants admit that the TruSight tests utilize NGS techniques and may include DNA library preparation kits that incorporate certain nucleic-acid-based adapters. Defendants admit that the TruSight tests may be used with certain data analysis methods to reduce certain errors that may arise after certain amplification and sequencing steps. Except as so admitted, Defendants deny the allegations of this paragraph.

ANSWER TO PARAGRAPH 8: Defendants admit that Illumina and/or its subsidiaries and affiliates make, use, and commercialize sequencing products under the names “Illumina DNA/RNA UD Indexes,” “Illumina RNA UD Indexes,” “IDT for Illumina DNA/RNA UD Indexes,” “IDT for Illumina RNA UD Indexes,” “Nextera DNA Indexes,” and “AmpliSeq UD Indexes for Illumina.” Defendants admit that certain of these products may be used in NGS applications, including to reduce certain errors that may arise after amplification and sequencing steps when combined with data analysis methods. Except as so admitted, Defendants deny the allegations of this paragraph.

ANSWER TO PARAGRAPH 9: Defendants admit that Illumina and/or certain of its subsidiaries and affiliates offer services that utilize NGS techniques to its customers, and that these services may include DNA library preparation methods that include the use of certain nucleic-acid-based adapters. Defendants further admit that certain of its NGS-based services may include data analysis methods that reduce certain errors that occur after amplification and sequencing steps. Except as so admitted, Defendants deny the allegations of this paragraph.

ANSWER TO PARAGRAPH 10: Defendants admit that they offer and market products, including products under the tradenames Verifi; VeriSeq; TruSight; Illumina DNA/RNA UD Indexes, Tagmentation; IDT for Illumina DNA/RNA UD Indexes, Tagmentation; IDT for Illumina Nextera UD Indexes; and AmpliSeq UD Indexes for Illumina, in the United States via Illumina’s website. Except as so admitted, Defendants deny the allegations of this paragraph.

JURISDICTION AND VENUE

ANSWER TO PARAGRAPH 11: Defendants repeat and re-allege their responses to paragraphs 1-10 of the Complaint as if fully set forth herein.

ANSWER TO PARAGRAPH 12: This paragraph states legal conclusions to which no response is required. To the extent a response is required, Defendants admit that Plaintiff purports to allege an action for patent infringement, but deny that they have committed any acts of infringement of a valid and enforceable claim, or caused any injury or damage to Plaintiff. Defendants admit that this Court has subject matter jurisdiction over actions arising under the patent laws of the United States. Except as so admitted, Defendants deny the allegations of this paragraph.

ANSWER TO PARAGRAPH 13: This paragraph states legal conclusions to which no response is required. For purposes of this Action only, Defendants do not contest that venue is proper in this District. Defendants deny that they have committed any acts of infringement of a valid and enforceable claim, or caused any injury or damage to Plaintiff. Except as so admitted, Defendants deny the allegations of this paragraph.

ANSWER TO PARAGRAPH 14: This paragraph states legal conclusions to which no response is required. For purposes of this Action only, Defendants do not contest that this Court has personal jurisdiction over Defendants. Defendants deny that they have committed any acts of infringement of a valid and enforceable claim, or caused any injury or damage to Plaintiff. Except as so admitted, Defendants deny the allegations of this paragraph.

ANSWER TO PARAGRAPH 15: Paragraph 15 states legal conclusions to which no response is required. For purposes of this Action only, Defendants do not contest that this Court has personal jurisdiction over Defendants. Defendants admit that they are each entities organized under the laws of the state of Delaware. Except as so admitted, Defendants deny the allegations of this paragraph.

BACKGROUND OF THE “INVENTIONS”

ANSWER TO PARAGRAPH 16: Defendants deny that Molecular Loop has novel techniques in targeted sequencing or has demonstrated a basis to innovate the field of sequencing. Defendants

lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations of this paragraph, and therefore deny them.

ANSWER TO PARAGRAPH 17: Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore deny them.

ANSWER TO PARAGRAPH 18: Defendants admit that NGS applications are capable of processing multiple samples collected from different patients or sample types that are pooled together to be sequenced at the same time, and that such techniques may decrease costs and increase efficiency relative to prior methods of DNA analysis. Defendants admit that methods of processing multiple samples collected from different patients or sample types that are pooled together to be sequenced at the same time are generally known as multiplex sequencing. Except as so admitted, Defendants deny the allegations of this paragraph.

ANSWER TO PARAGRAPH 19: Defendants admit that errors are sometimes introduced during NGS (for example during amplification and sequencing) and may impact the ability to accurately analyze sequencing reads. Defendants deny that the Patents-in-Suit are inventive or the first to provide a solution to this issue. Defendants further deny that the Patents-in-Suit are valid and enforceable. Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations of this paragraph, and therefore deny them.

ANSWER TO PARAGRAPH 20: Defendants admit that there are various types of errors that may arise during sequencing or amplification. Defendants deny that the Patents-in-Suit are inventive or the first to provide a solution to this issue. Defendants further deny that the Patents-in-Suit are valid and enforceable. Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations of this paragraph, and therefore deny them.

ANSWER TO PARAGRAPH 21: Defendants admit that, in general, various types of errors that may arise during sequencing workflows may have effects on the accuracy of downstream data analysis. Except as so admitted, Defendants deny the allegations of this paragraph.

ANSWER TO PARAGRAPH 22: Denied.

ANSWER TO PARAGRAPH 23: Defendants deny that the Patents-in-Suit are inventive or the first to provide a solution to this issue. Defendants further deny that the Patents-in-Suit are valid and enforceable. Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations of this paragraph, and therefore deny them.

THE PATENTS-IN SUIT

ANSWER TO PARAGRAPH 24: Defendants repeat and re-allege their responses to paragraphs 1-23 of the Complaint as if fully set forth herein.

ANSWER TO PARAGRAPH 25: Denied.

A. The '852 Patent

ANSWER TO PARAGRAPH 26: Defendants admit that what purports to be a true and correct copy of U.S. Patent No. 11,041,852, entitled “Methods for Maintaining the Integrity and Identification of a Nucleic Acid Template in a Multiplex Sequencing Reaction” is attached to the Complaint as Exhibit 1. Defendants admit that the '852 Patent states on its face that its inventors are Gregory Porreca, Mark Umbarger, and George Church. Defendants admit that '852 Patent states on its face that Molecular Loop Biosciences, Inc. is the assignee. Except as so admitted, Defendants deny the allegations of this paragraph.

ANSWER TO PARAGRAPH 27: This paragraph states a legal conclusion to which no response is required. To the extent a response is required, Defendants lack knowledge or

information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore deny them.

ANSWER TO PARAGRAPH 28: Defendants admit that Paragraph 28 reproduces Claim 1 of the '852 Patent. Defendants deny that the '852 Patent is inventive or the first to provide a solution to errors that may arise during sequencing workflows. Defendants further deny that the '852 Patent is valid and enforceable. Except as so admitted, Defendants deny the allegations in this paragraph.

ANSWER TO PARAGRAPH 29: Denied. The specification and figures of the '852 Patent speak for themselves.

ANSWER TO PARAGRAPH 30: Denied. The specification and figures of the '852 Patent speak for themselves.

ANSWER TO PARAGRAPH 31: Denied. The specification and figures of the '852 Patent speak for themselves.

ANSWER TO PARAGRAPH 32: Denied. The “teaching” in the reproduced language was substantially taken from another company’s prior published patent application. Defendants further aver that the cited portion of the '852 Patent was copied substantially from, for example, pages 5-7 of PCT Patent Publication No. WO 2010/056728 to Steinman et al., which was assigned to Helicos Biosciences Corporation. Defendants therefore further deny that the quoted portions reflect any invention that could be attributed to the named inventors of the '852 Patent or Molecular Loop.

ANSWER TO PARAGRAPH 33: Denied. The “teaching” in the reproduced language was taken from Illumina’s prior published patent application. Defendants further aver that the cited portion of the '852 Patent was copied nearly verbatim from paragraphs 33 through 37 of U.S. Patent Publication No. 2009/0226975 A1 (Sabot), which was assigned to Illumina. Defendants

therefore further deny that the quoted portions reflect any invention that could be attributed to the named inventors of the '852 Patent or Molecular Loop.

B. The '200 Patent

ANSWER TO PARAGRAPH 34: Defendants admit that what purports to be a true and correct copy of U.S. Patent No. 11,768,200, entitled “Methods for Maintaining the Integrity and Identification of a Nucleic Acid Template in a Multiplex Sequencing Reaction” is attached to the Complaint as Exhibit 2. Defendants admit that the '200 Patent states on its face that its inventors are Gregory Porreca, Mark Umbarger, and George Church. Defendants admit that '200 Patent states on its face that Molecular Loop Biosciences, Inc. is the assignee. Except as otherwise admitted, Defendants deny the allegations in this paragraph.

ANSWER TO PARAGRAPH 35: This paragraph states a legal conclusion to which no response is required. To the extent a response is required, Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore deny them.

ANSWER TO PARAGRAPH 36: Defendants admit that the '200 Patent states on its face that it is a continuation of the '852 Patent. Defendants further admit that Paragraph 36 reproduces Claim 1 of the '200 patent. Defendants deny that the '200 Patent is inventive or the first to provide a solution nucleic acid sequences during multiplex sequencing reactions. Defendants further deny that the '200 Patent is valid and enforceable. Except as otherwise admitted, Defendants deny the allegations in this paragraph.

ANSWER TO PARAGRAPH 37: Denied. The “teaching” of the cited language was taken from Helicos’s and Illumina’s prior published patent applications. Defendants further aver that the cited portions of the '200 Patent were copied nearly verbatim from, for example, pages 5-7 of

PCT Patent Publication No. WO 2010/056728 to Steinman et al., which was assigned to Helicos Biosciences Corporation, and paragraphs 33 through 37 of U.S. Patent Publication No. 2009/0226975 A1 (Sabot), which was assigned to Illumina. Defendants therefore further deny that the quoted portions reflect any invention that could be attributed to the named inventors of the '200 Patent or Molecular Loop.

C. The '730 Patent

ANSWER TO PARAGRAPH 38: Defendants admit that what purports to be a true and correct copy of U.S. Patent No. 11,840,730 entitled “Methods and Compositions for Evaluating Genetic Markers” is attached to the Complaint as Exhibit 3. Defendants admit that the '730 Patent states on its face that its inventors are Gregory Porreca and Uri Laserson. Defendants admit that the '730 Patent states on its face that Molecular Loop Biosciences, Inc. is the assignee. Except as otherwise admitted, Defendants deny the allegations in this paragraph.

ANSWER TO PARAGRAPH 39: This paragraph states a legal conclusion to which no response is required. To the extent a response is required, Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore deny them.

ANSWER TO PARAGRAPH 40: Defendants admit that that Paragraph 40 reproduces Claim 1 of the '730 Patent. Defendants deny that the '730 Patent is inventive or the first to provide a solution to this issue. Defendants further deny that the '730 Patent is valid and enforceable. Except as otherwise admitted, Defendants deny the allegations in this paragraph.

ANSWER TO PARAGRAPH 41: Defendants admit that this paragraph contains what purports to be a quotation from the '730 Patent. Defendants deny that the '730 Patent is inventive or the

first to provide a solution to this issue. Defendants further deny that the '730 Patent is valid and enforceable. Except as otherwise admitted, Defendants deny the allegations in this paragraph.

ANSWER TO PARAGRAPH 42: Defendants admit that this paragraph contains what purports to be a quotation from the '730 Patent. Defendants deny that the '730 Patent is inventive or the first to provide a solution to this issue. Defendants further deny that the '730 Patent is valid and enforceable. Except as so admitted, Defendants deny the allegations in this paragraph.

ANSWER TO PARAGRAPH 43: Defendants admit that this paragraph contains what purports to be a quotation from the '730 Patent. Defendants deny that the '730 Patent is inventive or the first to provide a solution to this issue. Defendants further deny that the '730 Patent is valid and enforceable. Except as so admitted, Defendants deny the allegations in this paragraph.

ANSWER TO PARAGRAPH 44: Defendants admit that this paragraph contains what purports to be a quotation from the '730 Patent. Defendants deny that the '730 Patent is inventive or the first to provide a solution to this issue. Defendants further deny that the '730 Patent is valid and enforceable. Except as so admitted, Defendants deny the allegations in this paragraph.

DEFENDANTS' ACTIVITIES

ANSWER TO PARAGRAPH 45: Defendants repeat and re-allege their responses to paragraphs 1-44 of the Complaint as if fully set forth herein.

A. The Accused Verifi Prenatal Tests

ANSWER TO PARAGRAPH 46: Defendants admit that VHI announced the launch of a non-invasive prenatal test on March 15, 2012. Defendants admit that on January 7, 2013 Illumina announced that it had signed a definitive agreement to acquire VHI. Defendants admit that it began providing the Verifi Plus prenatal test in 2017. Defendants admit that the Verifi Plus prenatal test is marketed as containing “everything in the Verifi Prenatal Test and includes additional panels.”

Defendants admit that Verifi Prenatal Test and Verifi Prenatal Plus Test are both currently offered on Illumina's website. Except as so admitted, Defendants deny the allegations in this paragraph.

ANSWER TO PARAGRAPH 47: Defendants aver that the cited exhibits speak for themselves, and admit that this paragraph purports to quote from such exhibits. Except as so admitted, Defendants deny the allegations in this paragraph.

ANSWER TO PARAGRAPH 48: Defendants admit that performance of the Verifi Tests may entail incorporating nucleic acid adapters into segments of nucleic acids to be analyzed. Defendants aver that the cited exhibits speak for themselves, and admit that this paragraph purports to quote from such exhibits. Except as so admitted, Defendants deny the allegations in this paragraph.

ANSWER TO PARAGRAPH 49: Defendants admit that performance of the Verifi Tests may entail pooling multiple DNA samples. Defendants aver that the cited exhibits speak for themselves, and admit that this paragraph purports to quote from such exhibits. Except as so admitted, Defendants deny the allegations in this paragraph.

ANSWER TO PARAGRAPH 50: Defendants admit that performance of the Verifi Tests entails amplifying the DNA to be analyzed on the surface of a flow cell. Defendants aver that the cited exhibit speaks for itself, and admit that this paragraph purports to quote from such exhibit. Except as so admitted, Defendants deny the allegations in this paragraph.

ANSWER TO PARAGRAPH 51: Defendants admit that the Verifi Tests entail a sequencing step. Defendants aver that the cited exhibits speak for themselves, and admit that this paragraph purports to quote from such exhibits. Except as so admitted, Defendants deny the allegations in this paragraph.

ANSWER TO PARAGRAPH 52: Defendants aver that the cited exhibits speak for themselves, and admit that this paragraph purports to quote from such exhibits. Defendants admit that the Verifi Tests may entail a step of demultiplexing samples. Except as so admitted, Defendants deny the allegations in this paragraph.

B. The Accused VeriSeq Tests

ANSWER TO PARAGRAPH 53: Defendants admit that Illumina announced the launch of the VeriSeq NIPT solution in April 2017 and that Illumina announced the launch of the VeriSeq NIPT Solution v2 in June 2019. Defendants admit that they currently offer the VeriSeq Solution v2 for sale on their website, and that this product is sold and distributed in the United States. Defendants aver that the cited exhibits speak for themselves, and admit that this paragraph purports to quote from such exhibits. Except as so admitted, Defendants deny the allegations in this paragraph.

ANSWER TO PARAGRAPH 54: Defendants aver that the cited exhibit speaks for itself, and admit that this paragraph purports to quote from such exhibit. Except as so admitted, Defendants deny the allegations in this paragraph.

ANSWER TO PARAGRAPH 55: Defendants admit that performance of the VeriSeq Tests may entail incorporating nucleic acid adapters into segments of nucleic acids to be analyzed. Defendants aver that the cited exhibit speaks for itself, and admit that this paragraph purports to quote from such exhibit. Except as so admitted, Defendants deny the allegations in this paragraph.

ANSWER TO PARAGRAPH 56: Defendants admit that performance of the VeriSeq Tests may entail pooling multiple DNA samples. Defendants aver that the cited exhibits speak for themselves, and admit that this paragraph purports to quote from such exhibits. Except as so admitted, Defendants deny the allegations in this paragraph.

ANSWER TO PARAGRAPH 57: Defendants admit that performance of the VeriSeq Tests entails amplifying the DNA to be analyzed on the surface of a flow cell. Defendants aver that the cited exhibits speak for themselves, and admit that this paragraph purports to quote from such exhibits. Except as so admitted, Defendants deny the allegations in this paragraph.

ANSWER TO PARAGRAPH 58: Defendants admit that performance of the VeriSeq Tests entails sequencing nucleic acid segments. Defendants aver that the cited exhibits speak for themselves, and admit that this paragraph purports to quote from such exhibits. Except as so admitted, Defendants deny the allegations in this paragraph.

ANSWER TO PARAGRAPH 59: Defendants admit that the VeriSeq tests may entail demultiplexing sequencing data. Defendants aver that the cited exhibit speaks for itself, and admit that this paragraph purports to quote from such exhibit. Except as so admitted, Defendants deny the allegations in this paragraph.

ANSWER TO PARAGRAPH 60: Defendants admit that Illumina requests that users of its Web User Interface for the VeriSeq NIPT v2 product to accept an End User License Agreement. Defendants aver that the cited exhibit speaks for itself, and admit that this paragraph purports to quote from such exhibit. Except as so admitted, Defendants deny the allegations in this paragraph.

ANSWER TO PARAGRAPH 61: Defendants admit that Illumina offers product support, training solutions, and on-site service to at least certain of its customers that purchase VeriSeq tests. Defendants aver that the cited exhibit speaks for itself, and admit that this paragraph purports to quote from such exhibit. Defendants admit that they provide certain consumable materials to users of the VeriSeq Tests. Except as so admitted, Defendants deny the allegations in this paragraph.

ANSWER TO PARAGRAPH 62: Defendants admit that Illumina provides customers with installation instructions, product manuals, and other informational materials regarding the usage of the VeriSeq Tests. Except as so admitted, Defendants deny the allegations in this paragraph.

ANSWER TO PARAGRAPH 63: Defendants admit that they offer a software guide for VeriSeq NIPT Solution v2, which is attached to the Complaint as Exhibit 30. Except as so admitted, Defendants deny the allegations in this paragraph.

C. The Accused TruSight Tests

ANSWER TO PARAGRAPH 64: Defendants admit that on October 30, 2018 Illumina announced the launch of TruSight Oncology 500, a comprehensive pan-cancer assay designed to identify known and emerging tumor biomarkers. Defendants further admit that on November 5, 2019, Illumina announced the upcoming launch of TruSight Oncology 500 ctDNA and TruSight Oncology 500 High-Throughput. Defendants admit that TruSight Oncology ctDNA is a liquid biopsy solution for detecting cancer biomarkers. Except as so admitted, Defendants deny the allegations in this paragraph.

ANSWER TO PARAGRAPH 65: Defendants admit that Illumina currently offers for sale the TSO 500, TSO 500 ctDNA v2, and TSO500 HT (collectively the “TruSight Oncology 500 portfolio”) on its website. Defendants admit that this paragraph reproduces a quotation and diagram from Exhibit 34, the TruSight Oncology 500 portfolio brochure, which speaks for itself. Except as so admitted, Defendants deny the allegations in this paragraph.

ANSWER TO PARAGRAPH 66: Defendants admit that TSO 500 Tests entail obtaining one or more biological sample that contain one or more sequences of nucleic acids. Defendants aver that the cited exhibits speak for themselves, and admit that this paragraph purports to quote from such exhibits. Except as so admitted, Defendants deny the allegations in this paragraph.

ANSWER TO PARAGRAPH 67: Defendants admit that the TSO 500 Tests may entail the introduction of adapters that serve as molecular identifiers to a DNA sample during library preparation. Defendants aver that the cited exhibits speak for themselves, and admit that this paragraph purports to quote from such exhibits. Except as so admitted, Defendants deny the allegations in this paragraph.

ANSWER TO PARAGRAPH 68: Defendants admit that the TSO 500 Tests entail amplifying nucleic acid molecules on the surface of a flow cell before sequencing. Defendants admit that the TSO500 Tests generally entail sequencing on Illumina Sequencers. Defendants aver that the cited exhibits speak for themselves, and admit that this paragraph purports to quote from such exhibits. Except as so admitted, Defendants deny the allegations in this paragraph.

ANSWER TO PARAGRAPH 69: Defendants admit that the TSO 500 Tests entail software that performs error correction by collapsing certain sequences. Defendants aver that the cited exhibits speak for themselves, and admit that this paragraph purports to quote from such exhibits. Except as so admitted, Defendants deny the allegations in this paragraph.

ANSWER TO PARAGRAPH 70: Defendants admit that TSO 500 Tests may entail incorporating nucleic-acid-based adapters into nucleic acid sequences to be analyzed. Defendants aver that the cited exhibits speak for themselves, and admit that this paragraph purports to quote from such exhibits. Except as so admitted, Defendants deny the allegations in this paragraph.

ANSWER TO PARAGRAPH 71: Defendants admit that TSO 500 Tests may entail pooling multiple samples of nucleic acids to be sequenced together. Defendants aver that the cited exhibits speak for themselves, and admit that this paragraph purports to quote from such exhibits. Except as so admitted, Defendants deny the allegations in this paragraph.

ANSWER TO PARAGRAPH 72: Defendants admit that the TSO 500 Tests entail amplifying nucleic acid sequences on a surface of a flow cell. Defendants aver that the cited exhibits speak for themselves, and admit that this paragraph purports to quote from such exhibits. Except as so admitted, Defendants deny the allegations in this paragraph.

ANSWER TO PARAGRAPH 73: Defendants admit that the TSO 500 Tests entail the sequencing of nucleic acids that have been amplified. Defendants aver that the cited exhibits speak for themselves, and admit that this paragraph purports to quote from such exhibits. Except as so admitted, Defendants deny the allegations in this paragraph.

ANSWER TO PARAGRAPH 74: Defendants admit that the TSO 500 Tests entail identifying sequence reads that are determined to contain errors that arise from amplification, and that the TSO 500 Tests demultiplex DNA sequence reads. Defendants aver that the cited exhibits speak for themselves, and admit that this paragraph purports to quote from such exhibits. Except as so admitted, Defendants deny the allegations in this paragraph.

ANSWER TO PARAGRAPH 75: Defendants admit that Illumina provides an End-User Software License Agreement that users are requested to sign before utilizing its DRAGEN TruSight Oncology 500 Analysis Software. Except as so admitted, Defendants deny the allegations in this paragraph.

ANSWER TO PARAGRAPH 76: Defendants admit that Illumina offers product support, training solutions, and on-site service to its customers for the TSO 500 Tests. Defendants aver that the cited exhibits speak for themselves, and admit that this paragraph purports to quote from such exhibits. Except as so admitted, Defendants deny the allegations in this paragraph.

ANSWER TO PARAGRAPH 77: Defendants admit that Illumina provides installation instructions, product manuals, package inserts and other reference guides that describe the

operation of its products in the TruSight Oncology 500 portfolio. Except as so admitted, Defendants deny the allegations in this paragraph.

ANSWER TO PARAGRAPH 78: Defendants admit that Illumina’s materials describe the TruSight Oncology 500 portfolio as offering a “streamlined workflow using proven NGS technology that enables rapid, reliable CGP.” Defendants further admit that Illumina provides reference guides with instructions for use of the tests in the TruSight Oncology 500 portfolio. Except as so admitted, Defendants deny the allegations in this paragraph.

D. Defendants’ Knowledge of Molecular Loop’s Patents

ANSWER TO PARAGRAPH 79: Denied.

ANSWER TO PARAGRAPH 80: Defendants admit that they are the assignee of patents and patent applications that are related to the products accused in this case. Defendants admit that the ’730 Patent was identified to Illumina by Molecular Loop during discussions in December 2023. Except as so admitted, Defendants deny the allegations in this paragraph.

ANSWER TO PARAGRAPH 81: Denied.

ANSWER TO PARAGRAPH 82: Denied.

COUNT 1

(Infringement of the ’852 Patent)

ANSWER TO PARAGRAPH 83: Defendants repeat and re-allege their responses to paragraphs 1-82 of the Complaint as if fully set forth herein.

ANSWER TO PARAGRAPH 84: Defendants deny that the ’852 Patent is valid and enforceable.

ANSWER TO PARAGRAPH 85: Defendants deny that they have infringed or continue to infringe any valid and enforceable claim of the ’852 Patent.

ANSWER TO PARAGRAPH 86: Defendants deny that they have infringed or continue to infringe any valid and enforceable claim of the '852 Patent. Defendants aver that the cited exhibits speak for themselves, and admit that this paragraph purports to quote from such exhibits. Except as so admitted, Defendants deny the allegations in this paragraph.

ANSWER TO PARAGRAPH 87: Defendants deny that they have infringed or continue to infringe any valid and enforceable claim of the '852 Patent. Defendants admit that VHI is a wholly owned subsidiary of Illumina. Defendants admit that Verifi Tests are run in response to customer requests. Defendants aver that the cited exhibits speak for themselves, and admit that this paragraph purports to quote from such exhibits. Except as so admitted, Defendants deny the allegations of this paragraph.

ANSWER TO PARAGRAPH 88: Defendants deny that they have induced or continue to induce infringement of any valid and enforceable claim of the '852 Patent. Defendants also deny the remaining allegations of this paragraph.

ANSWER TO PARAGRAPH 89: Defendants deny that use of the Verifi Tests would infringe any valid and enforceable claim of the '852 Patent. Defendants aver that the cited exhibit speaks for itself, and admit that this paragraph purports to quote from such exhibit. Defendants admit that they sell and provide the Verifi Tests, and product manuals or other instructions therefor to their customers. Except as so admitted, Defendants deny the allegations in this paragraph.

ANSWER TO PARAGRAPH 90: Defendants deny that they contribute to any infringement by third parties of any valid and enforceable claim of the '852 Patent. Defendants also deny the remaining allegations of this paragraph.

ANSWER TO PARAGRAPH 91: Defendants deny that they infringe any valid and enforceable claim of the '852 Patent. Defendants aver that the cited exhibits speak for themselves, and admit

that this paragraph purports to quote from such exhibits. Except as so admitted, Defendants deny the allegations in this paragraph.

ANSWER TO PARAGRAPH 92: Defendants deny that they have infringed or continue to infringe any valid and enforceable claim of the '852 Patent. Defendants also deny the remaining allegations of this paragraph.

ANSWER TO PARAGRAPH 93: Defendants deny that they have induced or continue to induce infringement of any valid and enforceable claim of the '852 Patent. Defendants also deny the remaining allegations of this paragraph.

ANSWER TO PARAGRAPH 94: Defendants deny that use of the VeriSeq Tests and TSO 500 Tests would infringe any valid and enforceable claim of the '852 Patent. Defendants admit that they sell and provide the VeriSeq Tests and TSO 500 Tests, and product manuals or other instructions therefor to their customers. Except as so admitted, Defendants deny the allegations in this paragraph.

ANSWER TO PARAGRAPH 95: Defendants deny that they contribute to any infringement by third parties of any valid and enforceable claim of the '852 Patent. Defendants also deny the remaining allegations of this paragraph.

ANSWER TO PARAGRAPH 96: Defendants admit that the '852 Patent was identified by Molecular Loop to Illumina during discussions dated February 10, 2023. Except as so admitted, Defendants deny the allegations in this paragraph.

ANSWER TO PARAGRAPH 97: Denied.

ANSWER TO PARAGRAPH 98: Denied.

ANSWER TO PARAGRAPH 99: Denied.

COUNT 2

(Infringement of the '200 Patent)

ANSWER TO PARAGRAPH 100: Defendants repeat and re-allege their responses to paragraphs 1-99 of the Complaint as if fully set forth herein.

ANSWER TO PARAGRAPH 101: Defendants deny that the '200 Patent is valid and enforceable.

ANSWER TO PARAGRAPH 102: Defendants deny that they have infringed or continue to infringe any valid and enforceable claim of the '200 patent.

ANSWER TO PARAGRAPH 103: Defendants deny that they have infringed or continue to infringe any valid and enforceable claim of the '200 patent. Defendants aver that the cited exhibits speak for themselves, and admit that this paragraph purports to quote from such exhibits. Except as so admitted, Defendants deny the allegations in this paragraph.

ANSWER TO PARAGRAPH 104: Defendants deny that they have infringed or continue to infringe any valid and enforceable claims of the '200 Patent. Defendants aver that the cited exhibit speaks for itself, and admit that this paragraph purports to quote from such exhibit. Defendants admit that VHI is a wholly owned subsidiary of Illumina. Except as so admitted, Defendants deny the allegations in this paragraph.

ANSWER TO PARAGRAPH 105: Defendants deny that they have induced or continue to induce infringement of any valid and enforceable claim of the '200 Patent. Defendants also deny the remaining allegations of this paragraph.

ANSWER TO PARAGRAPH 106: Defendants deny that use of the Verifi Tests would infringe any valid and enforceable claim of the '200 Patent. Defendants aver that the cited exhibit speaks for itself, and admit that this paragraph purports to quote from such exhibit. Defendants admit that they provide product manuals and other instruction materials to their customers and partners

regarding the Verifi Tests. Except as so admitted, Defendants deny the allegations in this paragraph.

ANSWER TO PARAGRAPH 107: Defendants deny that they contribute to any infringement by third parties of any valid and enforceable claim of the '200 Patent. Defendants also deny the remaining allegations of this paragraph.

ANSWER TO PARAGRAPH 108: Defendants deny that they infringe any valid and enforceable claims of the '200 Patent. Defendants aver that the cited exhibits speak for themselves, and admit that this paragraph purports to quote from such exhibits. Except as so admitted, Defendants deny the allegations in this paragraph.

ANSWER TO PARAGRAPH 109: Defendants deny that they have infringed or continue to infringe any valid and enforceable claim of the '200 Patent. Defendants also deny the remaining allegations of this paragraph.

ANSWER TO PARAGRAPH 110: Defendants deny that they have induced or continue to induce infringement of any valid and enforceable claim of the '200 Patent. Defendants also deny the remaining allegations of this paragraph.

ANSWER TO PARAGRAPH 111: Defendants deny that use of the VeriSeq Tests and TSO 500 Tests would infringe any valid and enforceable claim of the '200 Patent. Defendants admit that they provide product manuals, guides, and other instruction materials related to the VeriSeq Tests and TSO 500 Tests. Except as so admitted, Defendants deny the allegations in this paragraph.

ANSWER TO PARAGRAPH 112: Defendants deny that they have infringed or continue to infringe, directly or indirectly, any valid and enforceable claims of the '200 Patent.

ANSWER TO PARAGRAPH 113: Denied.

ANSWER TO PARAGRAPH 114: Denied.

ANSWER TO PARAGRAPH 115: Denied.

ANSWER TO PARAGRAPH 116: Denied.

COUNT 3

(Infringement of the '730 Patent)

ANSWER TO PARAGRAPH 117: Defendants repeat and re-allege their responses to paragraphs 1-116 of the Complaint as if fully set forth herein.

ANSWER TO PARAGRAPH 118: Defendants deny that the '730 Patent is valid and enforceable.

ANSWER TO PARAGRAPH 119: Defendants deny that they have infringed or continue to infringe any valid and enforceable claim of the '730 Patent.

ANSWER TO PARAGRAPH 120: Defendants deny that they have infringed or continue to infringe any valid and enforceable claim of the '730 Patent. Defendants aver that the cited exhibits speak for themselves, and admit that this paragraph purports to quote from such exhibits. Except as so admitted, Defendants deny the allegations in this paragraph.

ANSWER TO PARAGRAPH 121: Defendants deny that they have infringed or continue to infringe any valid and enforceable claim of the '730 Patent. Defendants also deny the remaining allegations of this paragraph.

ANSWER TO PARAGRAPH 122: Defendants deny that they have induced or continue to induce infringement of any valid and enforceable claim of the '730 Patent. Defendants also deny the remaining allegations of this paragraph.

ANSWER TO PARAGRAPH 123: Defendants deny that use of the TSO 500 Tests would infringe any valid and enforceable claim of the '730 Patent. Defendants admit that they provide product manuals, guides, and other instructional materials to customers and partners regarding the

TSO 500 Tests. Except as so admitted, Defendants otherwise deny the allegations in this paragraph.

ANSWER TO PARAGRAPH 124: Defendants deny that they contribute to any infringement by third parties of any valid and enforceable claim of the '730 Patent. Defendants also deny the remaining allegations of this paragraph.

ANSWER TO PARAGRAPH 125: Defendants admit that the '730 Patent was identified to Illumina by Molecular Loop during discussions in December 2023. Except as so admitted, Defendants deny the allegations in this paragraph.

ANSWER TO PARAGRAPH 126: Denied.

ANSWER TO PARAGRAPH 127: Denied.

ANSWER TO PARAGRAPH 128: Denied.

RESPONSE TO PLAINTIFF'S PRAYER FOR RELIEF

Defendants deny that Plaintiff is entitled to any of the relief requested in its prayer for relief, or any relief whatsoever.

AFFIRMATIVE DEFENSES

Plaintiffs allege and assert the following defenses to the allegations in the Complaint.

First Affirmative Defense (Non-Infringement – U.S. Patent No. 11,041,852)

Defendants do not infringe and have not infringed (including directly, indirectly, contributorily, or by active inducement) any valid and enforceable claim of the '852 Patent.

Second Affirmative Defense (Non-Infringement – U.S. Patent No. 11,768,200)

Defendants do not infringe and have not infringed (including directly, indirectly, contributorily, or by active inducement) any valid and enforceable claim of the '200 Patent.

Third Affirmative Defense (Non-Infringement – U.S. Patent No. 11,840,730)

Defendants do not infringe and have not infringed (including directly, indirectly, contributorily, or by active inducement) any valid and enforceable claim of the '730 Patent.

Fourth Affirmative Defense (Invalidity – U.S. Patent No. 11,041,852)

Each asserted claim of the '852 Patent is invalid because it fails to comply with one or more requirements of 35 U.S.C. § 101, 102, 103, and 112.

Fifth Affirmative Defense (Invalidity – U.S. Patent No. 11,768,200)

Each asserted claim of the '200 Patent is invalid because it fails to comply with one or more requirements of 35 U.S.C. § 101, 102, 103, and 112.

Sixth Affirmative Defense (Invalidity – U.S. Patent No. 11,840,730)

Each asserted claim of the '730 Patent is invalid because it fails to comply with one or more requirements of 35 U.S.C. § 101, 102, 103, and 112.

Seventh Affirmative Defense (Prosecution Laches – U.S. Patent No. 11,041,852)

Defendants' infringement allegations with respect to the '852 Patent are barred under the doctrine of prosecution laches, as detailed in Count I of Defendants' Counterclaims, the allegations of which are incorporated by reference as if fully set forth herein.

Eighth Affirmative Defense (Inequitable Conduct – U.S. Patent No. 11,041,852)

The '852 Patent is unenforceable due to inequitable conduct in the prosecution of the applications leading to its issuance, as detailed in Count III of Defendants' Counterclaims, the allegations of which are incorporated by reference as if fully set forth herein.

Ninth Affirmative Defense (Prosecution Laches – U.S. Patent No. 11,768,200)

Defendants' infringement allegations with respect to the '200 Patent are barred under the doctrine of prosecution laches, as detailed in Count II of Defendants' Counterclaims, the allegations of which are incorporated by reference as if fully set forth herein.

Tenth Affirmative Defense (Inequitable Conduct – U.S. Patent No. 11,768,200)

The '200 Patent is unenforceable due to inequitable conduct in the prosecution of the applications leading to its issuance, as detailed in Count IV of Defendants' Counterclaims, the allegations of which are incorporated by reference as if fully set forth herein.

Eleventh Affirmative Defense (Prosecution Laches – U.S. Patent No. 11,840,730)

Defendants' infringement allegations with respect to the '730 Patent are barred under the doctrine of prosecution laches, as detailed in Count V of Defendants' Counterclaims, the allegations of which are incorporated by reference as if fully set forth herein.

Twelfth Affirmative Defense (Inequitable Conduct – U.S. Patent No. 11,840,730)

The '730 Patent is unenforceable due to inequitable conduct in the prosecution of the applications leading to its issuance, as detailed in Count VI of Defendants' Counterclaims, the allegations of which are incorporated by reference as if fully set forth herein.

COUNTERCLAIMS

For their Counterclaims against Plaintiff and Counterclaim Defendant Molecular Loop Biosciences, Inc. (“Molecular Loop”), Counterclaim Plaintiffs Illumina, Inc. (“Illumina”) and Verinata Health, Inc. (“VHI”, collectively with Illumina “Counterclaim Plaintiffs”) allege as follows:

PRELIMINARY STATEMENT

1. Each of the patents that Molecular Loop has asserted is unenforceable for two reasons. First, Molecular Loop¹ dragged out the prosecution of various patent applications for *more than a decade*—waiting until Illumina launched the products that Molecular Loop now accuses of infringement and then trying to gerrymander the patent claims to read on those products. The equitable doctrine of prosecution laches does not allow patent holders to benefit from their own extreme delay and deception in such a manner. Second, Molecular Loop deceived the Patent Office—multiple times—in order to overcome the Patent Office’s prior art rejections and to keep Molecular Loop’s applications hidden from the public and from Counterclaim Plaintiffs. The doctrine of inequitable conduct does not allow patent holders to enforce patents secured through such deceit.

2. The applications on which Molecular Loop has sued Illumina in 2024 got their start in 2010—nearly 15 years ago.

3. As for the ’730 Patent and its related applications, Molecular Loop unreasonably and inexcusably delayed prosecution for more than 12 years. In 2020, after a decade of procrastination, Molecular Loop asked the Patent Office to substantially amend the application’s

¹ When referring to activities during prosecution of the asserted patents, “Molecular Loop” is used to refer to the Plaintiff, its predecessors-in-interest to each of the asserted patents (including Good Start Genetics, Inc., another company founded by Gregory Porreca), and/or Gregory Porreca as inventor/applicant of each of the asserted patents.

claims to change the alleged invention. The proposed changes came two years *after* Illumina’s accused product had launched and were plainly made to try to capture those products. Although Molecular Loop disingenuously labeled this proposed overhaul as “clarify[ing] the invention,” the Patent Office saw through the ploy—recognizing that it was “improper to switch inventions” and requiring a new application for the new claims.

4. Along the way, Molecular Loop made repeated misrepresentations about the filing status of related applications. It filed a “Request Not to Publish” the applications and swore that the invention was not the subject of any patent application in another country or under an international agreement. That was unequivocally false, because there were numerous such applications filed and published. These falsehoods, in turn, kept the claimed contents of the applications hidden from the public—and from Counterclaim Plaintiffs—for years. And Molecular Loop surely knew exactly what it was doing when it kept its purported inventions under wraps and prevented companies, like Counterclaim Plaintiffs, from considering the impact of the claims on existing and future products.

5. Counterclaim Plaintiffs have suffered prejudice as a result of these delays and misconduct. Most glaringly, for example, Illumina’s accused TruSight Oncology 500 assay—the only product accused of infringement of the ’730 Patent—was developed and released years before the claims were amended or issued.

6. All claims of the ’730 Patent are therefore unenforceable under the doctrines of prosecution laches and of inequitable conduct.

7. The story for the ’852 and ’200 Patents follows the same patterns of unreasonable and inexcusable delay and deceit.

8. The provisional application that led to these patents was filed in December 23, 2010. During the next decade-plus, Molecular Loop prosecuted only two patent applications: (1) U.S. Patent Application No. 13/081,660, filed on April 7, 2011 and issued on October 20, 2015 as U.S. Patent No. 9,173,281 (“the ’281 Patent”); and (2) U.S. Patent Application No. 14/854,629, filed on September 15, 2015 and issued on June 22, 2021 as U.S. Patent No. 11,041,851 (“the ’851 Patent”). Molecular Loop does not contend that either of the ’281 or ’851 Patents covers any of Counterclaim Plaintiffs’ products or processes, and in fact has granted them a covenant not to sue under these patents.

9. Molecular Loop waited until 2021 to try to ensnare Counterclaim Plaintiffs’ products. More specifically, the application that led to the ’852 Patent was filed on January 14, 2021, and issued on June 22, 2021, while the application that led to the ’200 Patent was filed on June 4, 2021 and issued on September 26, 2023. By that time, Illumina’s accused TruSight Oncology 500 assay, Verifi Tests, and VeriSeq Tests—the products accused of infringement of these patents—had been developed and on the market for years. Indeed, as Molecular Loop acknowledges, the Verifi Tests were launched in 2012 (Compl., ¶ 46), the VeriSeq tests were launched in 2017 (Compl., ¶ 53), and the TruSight Oncology 500 assays were launched in 2018 (Compl., ¶ 64).

10. During prosecution, Molecular Loop’s lawyer and the inventors also made misrepresentations and false statements to the Patent Office. To start, the description of the alleged invention in the ’852 patent’s specification was not Molecular Loop’s work; it was substantially copied from *other* publications and *others’ work*—including Illumina’s. Of the 17 columns of Detailed Description in the patent, over 11 columns were copied almost entirely verbatim from others (mostly from Illumina). Molecular Loop never told the Patent Office that it had lifted these

disclosures from others. Not only that, but Molecular Loop's lawyer and the inventors explicitly misrepresented a prior art disclosure (Parameswaran) that rendered the proposed claims invalid. Molecular Loop told the Patent Office that Parameswaran was limited to a particular context and inapplicable to the field of the proposed invention, but, more than a year prior to Molecular Loop's earliest claimed patent filing date, *one of the named inventors of the '852 Patent had published a paper that cited to and described Parameswaran as saying the opposite*. Molecular Loop did not disclose this other publication to the Patent Office. The Patent Office then relied on Molecular Loop's misstatements about Parameswaran in allowing the patent. Particularly in light of the overlap in people involved, Molecular Loop's statements and its failure to disclose contradictory material prior art were all done with the intent to deceive.

11. Counterclaim Plaintiffs have suffered prejudice attributable to the delays and misconduct in prosecution of the '852 and '200 Patents. All of the accused products were developed and launched years before Molecular Loop had even *filed* the applications that led to the '852 and '200 Patents. And those patents never would have even issued but for Molecular Loop's deceptions about the prior art. That renders all claims of the '852 and '200 Patents unenforceable under the doctrines of prosecution laches and of inequitable conduct.

PARTIES

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

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

14. On information and belief, Counterclaim 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

15. This action arises under the patent laws of the United States, 35 U.S.C. §§ 1, et seq.

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

17. Molecular Loop is subject to personal jurisdiction in this District at least because it has availed itself of this Court by filing this action in this District.

18. Venue is proper in this District under 28 U.S.C. §§ 1391 and 1400. By filing its infringement action in this District, Molecular Loop has consented to the adjudication of its disputes with Illumina and VHI in this District.

COUNT I

(Unenforceability of the '852 Patent Due to Prosecution Laches)

19. Counterclaim Plaintiffs reallege and incorporate all of the foregoing paragraphs of these Counterclaims as though fully set forth herein.

20. The '852 Patent is unenforceable due to, at least, the doctrine of prosecution laches.

21. Prosecution laches bars enforcement of the '852 Patent, which issued after an unreasonable and inexcusable delay in prosecution caused by Molecular Loop, and Counterclaim Plaintiffs have 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.

22. On its face, the '852 Patent claims priority to Provisional Application No. 61/426,817 ("817 Provisional Application") filed on December 23, 2010. Compl. Ex. 1 ('852 Patent) (Face).

23. U.S. Patent Application No. 13/081,660 was filed on April 7, 2011 and issued on October 20, 2015 as U.S. Patent No. 9,173,281 (“the ’281 Patent”). U.S. Patent Application No. 13/081,660 was the first application filed based on the December 2010 provisional.

24. U.S. Patent Application No. 14/854,629 was filed on September 15, 2015 and issued on June 22, 2021 as U.S. Patent No. 11,041,851 (“the ’851 Patent”).

25. U.S. Patent Applications Nos. 13/081,660 and 14/854,629 were the only applications filed from the ’817 Provisional Application between December 2010 and the end of 2020.

26. Molecular Loop does not contend that either of the ’281 or ’851 Patents cover any of Counterclaim Plaintiffs’ products or processes, and in fact has granted them a covenant not to sue under these patents.

27. The application that led to the ’852 Patent was not filed until January 14, 2021, over 10 years after its earliest effective filing date based on the 2010 provisional application, and over 5 years after issuance of the first filed patent in its family.

28. Counterclaim Plaintiffs have suffered prejudice attributable to the delays in prosecution of the ’852 Patent, because, *inter alia*, Counterclaim Plaintiffs’ accused TruSight Oncology 500 assay, Verifi Tests, and VeriSeq Tests—the products accused by Molecular Loop of infringement of the ’852 Patent—were developed and released years before the 2021 filing and issuance of the ’852 Patent. In particular, as Molecular Loop acknowledges, the Verifi Tests were launched in 2012 (Compl., ¶ 46), the VeriSeq tests were launched in 2017 (Compl., ¶ 53), and the TruSight Oncology 500 assays were launched in 2018 (Compl., ¶ 64). Thus, all of these products were developed and launched by Counterclaim Plaintiffs years before Molecular Loop had even *filed* the application that led to the ’852 Patent. In the decade between the filing of the 2010

provision and the 2021 filing of the '852 Patent, Molecular Loop prosecuted claims that it acknowledges have no relevance to Counterclaim Plaintiffs' products and services.

29. Compounding this prejudice, Molecular Loop's '852 Patent seeks to take credit for advances in DNA sequencing technologies that were earlier taught and publicly disclosed by others, *including Illumina*.

30. On information and belief, when the '817 Provisional Application was written, at least those who prepared that application were aware of and/or had a copy of the text of the specification from PCT Patent Publication No. WO 2010/056728 and/or U.S. Patent Publication No. 2009/0226975 A1.

31. On information and belief, at least those who prepared the '817 Provisional Application and each of the named inventors on the '852 Patent knew that the content of the text was almost entirely copied from PCT Patent Publication No. WO 2010/056728 and/or U.S. Patent Publication No. 2009/0226975 A1 and was not obtained from the named inventors of the '852 patent or from Molecular Loop.

32. The "Detailed Description" portion of the specification of Molecular Loop's '852 Patent substantially copied from at least PCT Patent Publication No. WO 2010/056728 to Steinman et al., which has been assigned to Helicos Biosciences Corporation. *Compare* Compl. Ex. 1 ('852 Pat.) at 7:45-8:53 *with* Ex. A (WO 2010/056728 (Steinman)) at 9-11; *compare* Compl. Ex. 1 ('852 Pat.) at 9:5-28 *with* Ex. A (WO 2010/056728 (Steinman)) at 5; *compare* Compl. Ex. 1 ('852 Pat.) at 9:29-10:2 *with* Ex. A (WO 2010/056728 (Steinman)) at 6-7.

33. The portions of Helicos's patents that were substantially copied by Molecular Loop include Helicos's disclosures concerning the design of unique oligonucleotide barcode sequences,

including those with length of 4 nucleotides or greater, the preparation of nucleic templates, and the attachment of such unique oligonucleotide sequences to such template nucleic acid molecules.

34. For example, the specification of the '852 Patent copied almost entirely verbatim the following disclosure from page 5 of WO 2010/056728 (Steinman) regarding the nucleotide length of barcode sequences:

Methods of designing sets of unique oligonucleotide sequences is shown for example in Brenner et al. (U.S. patent number 6,235,475), the contents of which are incorporated by reference herein in their entirety. In certain embodiments, the unique portion of the oligonucleotide sequence ranges from about 5 nucleotides to about 15 nucleotides. In a particular embodiment, the unique portion of the oligonucleotide sequence ranges from about 4 nucleotides to about 7 nucleotides. Since the bar coded portion of the oligonucleotide is sequenced along with the template nucleic acid molecule, the oligonucleotide length should be of minimal length so as to permit the longest read from the template nucleic acid attached. Generally, the unique portion of the oligonucleotide sequence is spaced from the template nucleic acid molecule by at least one base (minimizes homopolymeric combinations).

35. The specification of Molecular Loop's '852 Patent also copied almost entirely verbatim from over 50 paragraphs of U.S. Patent Publication No. 2009/0226975 A1 (Sabot), which has been assigned to Illumina. *Compare* Compl. Ex. 1 ('852 Pat.) at 10:11-20:46 with Ex. B (U.S. Patent Publication No. 2009/0226975 A1 (Sabot)) at ¶¶ 20-78.

36. The portions of Illumina's patent application that were copied nearly verbatim by Molecular Loop include Illumina's disclosures concerning methods of amplifying segments of nucleic acid sequencing methods.

37. In total, over half of the specification of the '852 Patent, held out to the public as a detailed description of Molecular Loops' own invention, was actually copied from the descriptions of the inventions taught by the Helicos and Illumina patent publications.

38. During prosecution of the '852 Patent and its related applications, Molecular Loop did not inform the Patent Office that it had copied over half of its patent specification from patent publications filed by third parties.

39. In particular, Molecular Loop did not disclose WO 2010/056728 (Steinman) to the Patent Office during prosecution of the '852 Patent, or any other patent in its family, despite all of the patents in this family sharing a substantially identical specification.

40. Molecular Loop also did not disclose U.S. Patent Publication No. 2009/0226975 A1 (Sabot) to the Patent Office during prosecution of the first patent to issue in this family, the '281 Patent, again despite all of the patents in this family sharing a substantially identical specification.

41. Molecular Loop has relied on the portions of the specification that were copied from others (including Helicos) to argue its claimed inventions are differentiated from the prior art.

42. For example, during prosecution of the '281 Patent, Molecular Loop ultimately obtained allowance of the claims over the Examiner's prior art rejections by amending the claims to require that the "sequence identifiers" incorporated into the template nucleic acids "comprise four or more nucleotides."

43. Molecular Loop argued that the prior art identified by the Examiner, Parameswaran, was "silent on the element of incorporating two of the same barcodes into a template, wherein the barcodes comprise four nucleotides." Molecular Loop likewise argued the claims were allowable over a prior art combination of Kawashima, Parameswaran, and Kircher "because those references fail to disclose or suggest incorporating at least two of the same sequence identifiers into a nucleic acid template, wherein the sequence identifiers comprise four or more nucleotides."

44. After Molecular Loop made this amendment and corresponding arguments using the amended language, the Examiner withdrew its rejections and allowed the claims to issue as the '281 Patent. The Examiner specified the importance of the amendment, stating in the Notice of Allowability that "Applicant's amendments overcame the previously presented rejections."

45. The requirement that identifier sequences have four or more nucleotides is also a limitation of the claims of the '851 Patent and the '200 Patent.

46. The support for the four or more nucleotide limitation comes from the portion of the specification copied almost entirely verbatim from the Helicos patent publication, WO 2010/056728 (Steinman), which was not made known to the examiner when Molecular Loop made its arguments.

47. On information and belief, Molecular Loop knew that the concept of using sequence identifiers comprising four or more nucleotides had already been invented by others, including Helicos, and intentionally withheld that information from the Examiner.

48. Molecular Loop continues its practice of taking credit for the work of others in its Complaint, which cites to portions of the specification that are copied nearly verbatim from the Illumina and Helicos patents, but claims they reflect "benefit[s] of Molecular Loop's inventions." *See, e.g.,* Compl. ¶¶ 32, 33, 37.

49. In light of Molecular Loop's substantial and unreasonable delays in prosecution of the '852 Patent, and considering the substantial prejudice to Counterclaim Plaintiffs and the totality of Molecular Loop's bad faith conduct in prosecuting the '852 Patent, the '852 Patent is unenforceable due to prosecution laches.

50. Counterclaim Plaintiffs seek a declaration that all claims of the '852 Patent are unenforceable.

COUNT II

(Unenforceability of the '200 Patent Due to Prosecution Laches)

51. Counterclaim Plaintiffs reallege and incorporate all of the foregoing paragraphs of these Counterclaims as though fully set forth herein.

52. The '200 Patent is unenforceable due to, at least, the doctrine of prosecution laches.

53. Prosecution laches bars enforcement of the '200 Patent, which issued after an unreasonable and inexcusable delay in prosecution caused by Molecular Loop, and Counterclaim Plaintiffs have 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.

54. On its face, the '200 Patent claims priority to Provisional Application No. 61/426,817 filed on December 23, 2010. Compl., Ex. 2 ('200 Patent) (Face).

55. U.S. Patent Application No. 13/081,660, filed on April 7, 2011 and issued on October 20, 2015 as U.S. Patent No. 9,173,281 ("the '281 Patent"). U.S. Patent Application No. 13/081,660 was the first application filed based on the December 2010 provisional.

56. U.S. Patent Application No. 14/854,629 was filed on September 15, 2015 and issued on June 22, 2021 as U.S. Patent No. 11,041,851 ("the '851 Patent").

57. U.S. Patent Applications Nos. 13/081,660 and 14/854,629 were the only applications filed from the '817 Provisional Application between December 2010 and the end of 2020.

58. Molecular Loop does not contend that either of the '281 or '851 Patents covers any of Counterclaim Plaintiffs' products or processes, and in fact has granted them a covenant not to sue under these patents.

59. The application that led to the '200 Patent was not filed until June 4, 2021, and issued on September 26, 2023.

60. Counterclaim Plaintiffs have suffered prejudice attributable to the delays in prosecution of the '200 Patent, because, *inter alia*, Counterclaim Plaintiffs' accused TruSight Oncology 500 assay, Verifi Tests, and VeriSeq Tests—the products accused by Molecular Loop of infringement of the '200 Patent—were developed and released years before the 2021 filing and 2023 issuance of the '200 Patent. In particular, as Molecular Loop acknowledges, the Verifi Tests were launched in 2012 (Compl., ¶ 46), the VeriSeq tests were launched in 2017 (Compl., ¶ 53), and the TruSight Oncology 500 assays were launched in 2018 (Compl., ¶ 64). Thus, all of these products were developed and launched by Counterclaim Plaintiffs years before Molecular Loop had even filed the application that led to the '200 Patent. Thus, Molecular Loop's unreasonable delay in prosecuting the '200 Patents, combined with the prejudice to Illumina and other pertinent facts discussed below, give rise to prosecution laches rendering all claims of these patents unenforceable.

61. Compounding this prejudice, Molecular Loop's '200 Patent seeks to take credit for advances in DNA sequencing technologies that were earlier taught and publicly disclosed by others, *including Illumina*.

62. In particular, the '200 Patent shares a substantially identical specification with the '852 Patent, and thus includes the same copied material from the Helicos WO 2010/056728 (Steinman) and Illumina U.S. 2009/0226975 A1 (Sabot) patent publications as is discussed above with respect to the '852 Patent.

63. During prosecution of the '200 Patent and its related applications, Molecular Loop did not inform the Patent Office that it had copied over half of its patent specification, held out to

the public as a detailed description of Molecular Loops' own invention, from patent publications filed by third parties.

64. In particular, Molecular Loop did not disclose WO 2010/056728 (Steinman) to the Patent Office during prosecution of the '200 Patent, or any other patent in its family, despite all of the patents in this family sharing a substantially identical specification.

65. Molecular Loop also did not disclose U.S. Patent Publication No. 2009/0226975 A1 (Sabot) to the Patent Office during prosecution of the first patent to issue in this family, the '281 Patent, again despite all of the patents in this family sharing a substantially identical specification.

66. Molecular Loop has relied on the portions of the specification that were copied from others (including Helicos) to argue its claimed inventions are differentiated from the prior art.

67. As discussed above with respect to the '852 Patent, the requirement that identifier sequences have four or more nucleotides is a limitation of the '200 Patent, and the support for this limitation comes from the copied portions of the Helicos patent publication, WO 2010/056728 (Steinman).

68. On information and belief, Molecular Loop knew that the concept of using sequence identifiers comprising four or more nucleotides had already been invented by others, including Helicos, and intentionally withheld that information from the Examiner.

69. Further, Molecular Loop continues its practice of taking credit for the work of others in its Complaint, which cites to portions of the specification that are copied nearly verbatim from the Illumina and Helicos patents, but claims they reflect "benefit[s] of Molecular Loop's inventions." *See, e.g.*, Compl. ¶¶ 32, 33, 37.

70. In light of Molecular Loop’s substantial and unreasonable delays in prosecution of the ’200 Patent, and considering the substantial prejudice to Counterclaim Plaintiffs and the totality of Molecular Loop’s bad faith conduct in prosecuting the ’200 Patent, the ’200 Patent is unenforceable due to prosecution laches and cannot be infringed by Counterclaim Plaintiffs.

71. Counterclaim Plaintiffs seek a declaration that all claims of the ’200 Patent are unenforceable.

COUNT III

(Unenforceability of the ’852 Patent Due to Inequitable Conduct)

72. Counterclaim Plaintiffs reallege and incorporate all of the foregoing paragraphs of these Counterclaims as though fully set forth herein.

73. All claims of the ’852 Patent are unenforceable due to, at least, inequitable conduct during prosecution of the patent application.

74. The ’852 Patent was filed as U.S. Patent Application No. 17/149,504 (“the ’504 Application”) on January 14, 2021.

75. The named inventors of the ’852 Patent are Gregory Porreca, Mark Umbarger, and George Church.

76. Under 37 C.F.R. 1.56, each of the named inventors had “a duty of candor and good faith in dealing with the [Patent] Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability” of any pending claim. No patent shall be granted “on an application in connection with which fraud on the Office was practiced or attempted or the duty of disclosure was violated through bad faith or intentional misconduct.”

77. On information and belief, each of the named inventors were aware of the duty of candor and good faith and the duty of disclosure that they owed to the Patent Office.

78. During prosecution of the '504 Application, on February 26, 2021 the examiner rejected certain of the then-pending claims as anticipated under 35 U.S.C. 102(b) by Parameswaran et al., (Nucl. Acids Res., vol. 35, c130, pp. 1-9, 2007) ("Parameswaran").

79. On April 13, 2021, the applicants amended the claims to add the requirement of "amplifying said nucleic acid templates on a surface of a flow cell."

80. In arguing that the amendment overcame Parameswaran, the applicants argued that "[t]he Parameswaran paper is directed to overcoming a problem unique to pyrosequencing in which bead-bound DNA must be physically separated on a sequencing medium, thus limiting the number of output sequences," and that "Parameswaran reports a barcoding approach in which homopolymer length must be strictly limited due [to] limitations inherent in pyrosequencing."

81. The applicants continued that "Parameswaran does not mention forming clusters in a flow cell" and claimed this was "not at all surprising given that Parameswaran is all about pyrosequencing."

82. Applicants thus argued that Parameswaran was applicable only to pyrosequencing using bead-based amplification, and that Parameswaran was *not* applicable to other forms of sequencing that use a flow cell to form clusters of amplified nucleic acids.

83. The Applicant summarized an examiner interview dated April 13, 2021, which involved its representative, Thomas C. Meyers, Aditya Dean Ramanathan, and named inventor Gregory Porreca.

84. During that interview, the Applicant "pointed to the prior art reference Parameswaran as being limited to pyrosequencing, and therefore failing to disclose amplifying

nucleic acids to form clusters.” The examiner “understood the distinction pointed out by Applicant but requested that applicant distinguish in the claim from the bead-based amplification methods reported by Parameswaran.”

85. In a summary of the examiner interview dated April 13, 2021, the examiner likewise stated that Applicants’ representative, Mr. Meyers, “argued that the claims are not anticipated by Parameswaran et al., since the claims require amplification using clusters, which are used in Illumina sequencing machines,” and the “the claims should be amended to read on Illumina-type clusters to distinguish from Parameswaran et al.”

86. A Notice of Allowance issued on April 27, 2021. In the Notice of Allowance, the examiner stated that “Applicant’s claim amendments overcame the previously presented claim rejections.”

87. On information and belief, the statements made by Applicants (at least by prosecuting attorney Thomas C. Meyers on information and belief in consultation with Dr. Porreca and/or Dr. Church) distinguishing Parameswaran as limited to pyrosequencing and inapplicable to amplification using a flow cell (as in “Illumina sequencing machines”) were knowingly and unmistakably false, and made with intent to deceive the Patent Office.

88. In particular, in November 2009, named inventor George M. Church co-authored a paper entitled “The challenges of sequencing by synthesis” in Nature Biotechnology, vol. 27, no. 11, pp. 1013-1023, 2009 (“Fuller”). Ex. C.

89. Fuller has an online publication date of November 6, 2019, which is more than one year before the earliest effective filing date of the ’852 Patent, making Fuller prior art to the ’852 Patent and all other patents in its family.

90. In Fuller, Dr. Church and his co-authors described issues common to “ensemble sequencing methods,” which the authors described as including *both* Illumina flow cell-based amplification and sequencing and Roche/454 bead-based pyrosequencing. Ex. C at 1013-1015 (describing that “ensemble based” methods involve “sequencing of multiple identical copies of a DNA molecule, typically amplified together on isolated surfaces or beads” and identifying Illumina’s “Genome Analyzer” and Roche/454 Life Sciences’ “Genome Sequencer FLX”).

91. Dr. Church and his co-authors then went on to explain a problem common to all “ensemble-based” sequencing methods and offered a solution for overcoming that *common* problem (to *both* Illumina flow cell-based amplification and sequencing, *and* bead-based pyrosequencing). Namely, they discussed Parameswaran, explaining that “one option” to “reduce[] the inefficiencies of ensemble-based [sequencing-by-synthesis] architectures” “would be an effective technology to judiciously add sequence tags to the fragments of several different samples, then combine and process the DNA samples (encoding and binning) together, separating the resulting sequences by their tags in the computer analysis phase⁶⁰.” Ex. C at 1015.

92. The cited reference 60 in Fuller is Parameswaran, P. *et al.*, A pyrosequencing-tailored nucleotide barcode design unveils opportunities for large-scale multiplexing. *Nucleic Acids Res.* 35, e130 (2007). Ex. C at 1023.

93. The Parameswaran reference cited in Fuller is the same Parameswaran referenced cited in the examiner’s rejection during prosecution of the ’504 Application.

94. Dr. Church and his co-authors therefore acknowledged that Parameswaran’s disclosed technique of “add[ing] sequence tags to fragments of several different samples, [and] then combin[ing] and process[ing] the DNA samples... together, [and] separating the resulting sequences by their tags in the computer analysis phase,” was directly applicable to multiple

methods of sequencing, including those that utilize the formation of clusters on a flow cell (i.e., Illumina-type clusters).

95. The Applicants' statements to the Examiner distinguishing Parameswaran as limited to bead-based pyrosequencing and having no application to "Illumina-type clusters" are directly contradicted by Fuller.

96. On information and belief, the statement in Fuller citing Parameswaran demonstrates that at least George Church, a named inventor of the '852 Patent, and on information and belief at least Mr. Meyers and Dr. Porreca, understood that Parameswaran is *not* limited to bead-based pyrosequencing.

97. But-for the Applicants' false statements distinguishing Parameswaran, the claims of the '852 Patent would not have issued.

98. The Applicants also violated their duty of disclosure to the Patent Office by withholding disclosure of Fuller during prosecution of the '504 Application, and during prosecution of all of the related applications in the family of the '852 Patent.

99. Inventor George Church was a named author of the Fuller paper, and therefore, must have been aware of the reference at the time of prosecution of the '504 Application.

100. On information and belief, Gregory Porreca and/or Mark Umbarger were aware that Dr. Church had cited Parameswaran in a paper before the filing of the '817 Provisional Application, given their prior work together in the George Church laboratory at Harvard Medical School, and publications in which all three are named authors.

101. On information and belief, the Fuller reference was also known to inventors Gregory Porreca and/or Mark Umbarger, given their prior work together in the George Church laboratory at Harvard Medical School, and publications in which all three are named authors.

102. On information and belief, the inventors, including George Church, knew that Fuller was material to the patentability of the pending claims of the '504 Application, but intentionally withheld the reference from the Patent Office.

103. But-for the Applicants' withholding of Fuller from the Patent Office, the examiner would have understood that Parameswaran was not limited to pyrosequencing, and would not have allowed the claims of the '852 Patent to issue.

104. Counterclaim Plaintiffs seek a declaration that all claims of the '852 Patent are unenforceable.

COUNT IV

(Unenforceability of the '200 Patent Due to Inequitable Conduct)

105. Counterclaim Plaintiffs reallege and incorporate all of the foregoing paragraphs of these Counterclaims as though fully set forth herein.

106. All claims of the '200 Patent are unenforceable due to, at least, inequitable conduct during prosecution of the patent application.

107. The '200 Patent was filed as U.S. Patent Application No. 17/339,527 ("the '527 Application") on June 4, 2021.

108. The named inventors of the '200 Patent are Gregory Porreca, Mark Umbarger, and George Church.

109. On information and belief, each of the named inventors were aware of the duty of candor and good faith and the duty of disclosure that they owed to the Patent Office.

110. During prosecution of the '527 Application, on June 1, 2023 the examiner rejected certain of the then-pending claims as obvious in view of the '852 Patent and Parameswaran.

111. On June 14, 2023, the Applicants filed a terminal disclaimer over the '852 Patent in order to traverse the rejection.

112. A Notice of Allowance issued on July 27, 2023.

113. As explained above, the '852 Patent is unenforceable due to inequitable conduct. That discussion is incorporated and re-alleged herein by reference.

114. The '200 Patent is a continuation of the '852 Patent.

115. The inequitable conduct committed during prosecution of the '852 Patent also renders unenforceable the '200 Patent. The unmistakably false statements regarding Parameswaran and the failure to disclose material prior art (Fuller) during prosecution of the '852 Patent bears an immediate and necessary relation to the prosecution of the '200 Patent as confirmed, for example, by the similarity of the claims of the two patents, which both require at least two “identifier sequences,” that are “associated with” nucleic acids, and are sequenced and analyzed based on the presence of the identifier sequences. Additionally, the examiner rejected the claims of the '200 Patent as obvious in view of the '852 Patent and Parameswaran, and the Applicants filed a terminal disclaimer over the '852 Patent in order to obtain allowance of the claims.

116. Additionally, Fuller was not disclosed to the Patent Office during prosecution of the '527 Application.

117. The discussion of Fuller above with respect to the '852 Patent is incorporated and re-alleged herein.

118. The Applicants, including at least Dr. Church, Dr. Porreca, and Dr. Umbarger, violated their duty of disclosure to the Patent Office by withholding disclosure of Fuller during

prosecution of the '527 Application, and during prosecution of all of the related applications in the family of the '200 Patent.

119. Inventor George Church was a named author of the Fuller paper, and therefore must have been aware of the reference at the time of prosecution of the '527 Application.

120. On information and belief, the Fuller reference was also known to inventors Gregory Porreca and Mark Umbarger, given their prior work together in the George Church laboratory at Harvard Medical School, and publications in which all three are named authors.

121. On information and belief, the inventors, including George Church, knew that Fuller was material to the patentability of the pending claims of the '527 Application, but withheld the reference from the Patent Office intentionally and/or in bad faith.

122. But-for the Applicants' withholding of Fuller from the Patent Office, the examiner would have understood that Parameswaran was not limited to pyrosequencing, and would not have allowed the claims of the '200 Patent to issue.

123. Counterclaim Plaintiffs seek a declaration that all claims of the '200 Patent are unenforceable.

COUNT V

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

124. Counterclaim Plaintiffs reallege and incorporate all of the foregoing paragraphs of these Counterclaims as though fully set forth herein.

125. The '730 Patent is unenforceable due to, at least, the doctrine of prosecution laches.

126. 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 Counterclaim Plaintiffs have 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.

127. 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. Compl., Ex. 3 (Face)

128. 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. *Id.*

129. 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.

130. 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.”

131. 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.”

132. 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.

133. 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.

134. 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.

135. 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.

136. 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."

137. 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.

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

139. 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.

140. 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).

141. 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.

142. 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 Counterclaim Plaintiffs, to see.

143. 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.

144. 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.

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

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

COUNT VI

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

147. Counterclaim Plaintiffs reallege and incorporate all of the foregoing paragraphs of these Counterclaims as though fully set forth herein.

148. 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.

149. 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 Counterclaim Plaintiffs.

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

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

152. 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.

153. 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.

154. 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.

155. 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.

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

157. 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).

158. 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 six of the eight international publications identified in the preceding paragraph. On information and belief, Mr. Meyers was aware of at least those six international publications when he submitted the false “Request Not to Publish.”

159. 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.

160. Mr. Meyers’ false representation in the “Request Not to Publish” violated at least Section 1122 of the MPEP.

161. 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).

162. 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.

163. 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.

164. 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).

165. “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.

166. 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.

167. 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.

168. 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.

169. 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 a misguided 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.

170. Specifically, during prosecution of the '687 Application, Molecular Loop (through Mr. Meyers) waited until October 2, 2020—over four 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.”

171. 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.

172. 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.”

173. 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.

174. 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.

175. 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 Molecular Loop’s patent claims and prosecution record of the '764 Application.

176. Specifically, in Molecular Loop’s 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.

177. 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 eight international applications, six 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.

178. 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."

179. 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>.

180. 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.

181. 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.

182. 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.

183. 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>.

184. 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.

185. 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.

186. 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.

187. 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.

188. 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.

189. 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.

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

- a) Declaring that the '852 Patent is unenforceable;
- b) Declaring that the '200 Patent is unenforceable;
- c) Declaring that the '730 Patent is unenforceable;
- d) Finding that Counterclaim Plaintiffs are the prevailing party and that this is an exceptional case under 35 U.S.C. § 285;
- e) Awarding Counterclaim Plaintiffs their costs, expenses, and reasonable attorneys' fees in connection with this action; and
- f) Granting such further and additional relief as the Court deems just and proper.

DEMAND FOR JURY TRIAL

Counterclaim 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.

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