IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

TECAN GENOMICS, INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. _____
	)	
INVITAE CORPORATION,	)	**JURY TRIAL DEMANDED**
ARCHERDX, LLC, and	)	
INTEGRATED DNA TECHNOLOGIES,	)	
INC.,	)	
Defendants.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Tecan Genomics, Inc. ("Tecan Genomics"), by and through its attorneys, brings this action for patent infringement against Defendants Invitae Corporation ("Invitae"), ArcherDX, LLC ("Archer"), and Integrated DNA Technologies, Inc. ("IDT") (collectively "Defendants") and alleges as follows:

NATURE OF THE ACTION

1. Tecan Genomics brings this action to halt Defendants' infringement of, and seek damages for, Defendants' past, ongoing, and future acts of infringement of U.S. Patent Nos. 10,036,012 ("the '012 patent"), 10,876,108 ("the '108 patent"), 9,546,399 ("the '399 patent"), 11,098,357 ("the '357 patent"), and 11,725,241 ("the '241 patent") (collectively "the Asserted Patents") (attached hereto as Exhibits 1–5 respectively).

2. Tecan Genomics (formerly known as NuGEN Technologies, Inc. ("NuGEN")) is a leader in the delivery of Next Generation Sequencing ("NGS") library preparation kits and automation solutions.[1] Tecan Genomics' innovative technologies have revolutionized time-

[1] Tecan Genomics is a subsidiary of the Tecan Group, a market leader in the development, production, and commercialization of advanced automation and detection solutions within the life

consuming and error-prone procedures, streamlining complex processes for users. Since its founding as NuGEN in San Francisco, California, in 2000, Tecan Genomics has focused on the goal of improving processes for DNA sample preparation and genomic testing. Tecan Genomics focuses on the development of both automation tools and reagent kits, and now offers 20 different sample preparation kits, covering a wide range and variety of samples that can be enriched as well as a wide range of targets within those sample populations.

3. These products aid researchers in tackling challenging questions related to human, animal, and plant genomes as well as complex microbiomes and procaryotic samples, and also facilitate improvements to patient treatments and outcomes. For example, in oncology, these products allow for a better "understanding of the molecular changes that drive an individual tumor," which can lead "to clearer diagnosis, treatment, and even monitoring for recurrence."[2] These products also assist in the analysis of blood samples, "reducing the potential for the introduction of bias into" results that help inform patient treatments and drug development.[3] Tecan Genomics' innovations have aided scientists and clinicians by making their work easier and allowing for previously unrealizable testing and diagnostics objectives to be achieved. As a result, these innovations have also helped to improve the lives and well-being of many others.

4. Tecan Genomics, previously as NuGEN, was an early leader in the development and commercialization of new genetic sequencing techniques associated with NGS libraries. Tecan Genomics spent years developing proprietary and patented technologies for the use of NGS to identify specific target portions of DNA and RNA. The targeting of these fragments is important

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sciences. The Tecan Group acquired NuGEN in 2018 and has continued operating NuGEN and its products as Tecan Genomics.

[2] *Accelerating genomics with advanced sample preparation solutions*, NATURE BIOPHARM DEAL, accessible at https://www.nature.com/articles/d43747-020-00068-6.pdf.

[3] *Id.*

because it allows, for example, researchers to isolate individual genetic sequences and learn how those sequences may influence conditions, such as cancer and blood disorders. Prior to the development of Tecan Genomics' patented technologies, there were no simple, highly-efficient, and cost-effective technologies to target specific parts of nucleic acids. Instead, known methods required special instrumentation or platforms, were limited in their output, or required a large number of individual primer pairs when enriching for a multitude of regions of interest. These limitations made target enrichment costly and inefficient.

5. To address these issues, scientists at Tecan Genomics, then NuGEN, developed novel methods for selective target enrichment. These novel methods resulted in the development of NuGEN's target capture technologies, including NuGEN's selective target enrichment methods where the user captures desired transcripts and fragments and then amplifies them to create a library. Moreover, given the success of these enrichment methods in producing high volumes of enriched target genomic material, NuGEN's scientists also developed techniques to aid in the sequencing and use of these samples. One such patented innovation was the use of unique identifiers in a particular format to identify duplicate target samples. By creating a technology that could be used with high-throughput methods, this innovation reduced costs and eliminated errors associated with genetic sequencing.

6. Given the nature, and substantial benefits, of Tecan Genomics' patented technologies, others, including Defendants, have infringed and continue to infringe Tecan Genomics' patents. Invitae, Archer, and IDT have used and continue to use Tecan Genomics' patented NGS technology without authorization in violation of the U.S. Patent Laws. Specifically, Defendants provide both services and kits that use the enrichment and related technologies that Tecan Genomics developed years ago. Defendants tout that these products and services use their

"Anchored Multiplex PCR" (AMP) target enrichment technology. In reality, however, these products use technologies developed and patented by Tecan Genomics, including those claimed in the '012, '108, '399, '357, and '241 patents.

7. Defendants knowingly and willfully infringe the Asserted Patents. For example, a predecessor to Archer, ArcherDX, Inc., was aware of Tecan Genomics' technologies and patent filings in 2014. From that time forward, ArcherDX, Inc. and its successors-in-interest, both Archer and Invitae, have known of their infringement and nevertheless willfully infringed the Asserted Patents. Throughout this period of time, Tecan Genomics marked their commercial products with reference to the company webpage listing "Our Technologies" (meaning Tecan Genomics' proprietary technologies), and as competitors, Defendants would have been aware that Plaintiff's products embodying its innovative technologies were protected by patents.

8. On information and belief, IDT learned of Invitae's and Archer's infringement while conducting diligence on the limited asset sale that would occur between Defendants in 2022. Yet, IDT nonetheless decided to join Invitae and Archer in their ongoing infringement of Tecan Genomics' patented technologies.

9. In 2023, Tecan Genomics contacted Defendants notifying them of their ongoing infringement of the Asserted Patents. Defendants have continued to infringe Tecan Genomics' patents after receiving the notice letters.

10. Defendants' infringement is pervasive and willful. Through this action, Tecan Genomics seeks compensation for patent infringement and an injunction to prevent Defendants from further infringing Tecan Genomics' patented technology without permission.

THE PARTIES

11. Plaintiff Tecan Genomics, Inc., formerly known as NuGEN Technologies, Inc., is a Delaware corporation with its principal place of business at 900 Chesapeake Dr., Redwood City, CA 94063. In 2018, Tecan Group acquired NuGEN, which was renamed Tecan Genomics.

12. On information and belief, Defendant Invitae Corporation is a corporation incorporated under the laws of the State of Delaware with its principal place of business at 1400 16th St., San Francisco, CA 94103. Invitae can be served with process through its registered agent, The Corporation Trust Company located at Corporation Trust Center, 1209 Orange St., Wilmington, DE 19801.

13. On information and belief, Defendant ArcherDX, LLC is a limited liability company organized under the laws of the State of Delaware with its principal place of business at 2477 55th Street, Suite 202, Boulder, CO 80301. On information and belief, ArcherDX, LLC is a wholly-owned subsidiary of Invitae. On information and belief, Invitae acquired ArcherDX, LLC's predecessor, ArcherDX, Inc., in 2020. On information and belief, ArcherDX, Inc. merged with a Delaware limited liability company on October 2, 2020, and the surviving entity was named ArcherDX, LLC. ArcherDX, LLC is the successor-in-interest of ArcherDX, Inc. ArcherDX, LLC can be served with process through its registered agent, The Corporation Trust Company located at Corporation Trust Center, 1209 Orange St., Wilmington, DE 19801.

14. On information and belief, Defendant Integrated DNA Technologies, Inc. is a corporation incorporated under the laws of the State of Delaware with its principal place of business at 1710 Commercial Park, Coralville, IA 52241. IDT can be served with process through its registered agent, The Corporation Trust Company located at Corporation Trust Center, 1209 Orange St., Wilmington, DE 19801.

JURISDICTION AND VENUE

15. This is a civil action for patent infringement arising under the United States patent laws, 35 U.S.C. § 1 *et seq*., including 35 U.S.C. §§ 271 and 281.

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

17. This Court has personal jurisdiction over Invitae because Invitae is incorporated and exists under the laws of the State of Delaware and is a resident of the State of Delaware. Invitae has purposefully availed itself of the benefits and protections of Delaware state law by incorporating under Delaware law. Additionally, Invitae has designated The Corporation Trust Company as its registered agent for service of process in the State of Delaware.

18. This Court has personal jurisdiction over Archer because Archer is organized and exists under the laws of the State of Delaware and is a resident of the State of Delaware. Archer has purposefully availed itself of the benefits and protections of Delaware state law by organizing under Delaware law. Additionally, Archer has designated The Corporation Trust Company as its registered agent for service of process in the State of Delaware.

19. This Court has personal jurisdiction over IDT because IDT is incorporated and exists under the laws of the State of Delaware and is a resident of the State of Delaware. IDT has purposefully availed itself of the benefits and protections of Delaware state law by incorporating under Delaware law. Additionally, IDT has designated The Corporation Trust Company as its registered agent for service of process in the State of Delaware.

20. Defendants are also subject to personal jurisdiction in Delaware because, on information and belief, Defendants engage in infringing activities in Delaware by, for example, using, selling, and offering to sell the Accused Products, inducing others to use the Accused Products, and contributing to the use of the Accused Products by others throughout the United

States and in Delaware. Defendants have infringed and continue to infringe Tecan Genomics' patents in Delaware by, among other things, engaging in infringing conduct within and directed at or from Delaware and by purposely and voluntarily placing their infringing products and services, including at least ArcherDX VariantPlex AMP Panels, ArcherDX FusionPlex AMP Panels, ArcherDX LiquidPlex AMP Panels, Invitae Personalized Cancer Monitoring™ – Baseline Test, and Invitae Personized Cancer Monitoring™ – Monitoring Test, and any other products and services that use similar technologies, into the stream of commerce with the expectation that these products will be used in Delaware. For example, on information and belief, Defendants conduct activities related to the selling, marketing, advertising, promotion, support, and distribution of the Accused Products in Delaware.

21. Venue is proper in this District under 28 U.S.C. §§ 1391 and 1400 because Defendants are Delaware residents, and Delaware is a convenient forum for resolution of the parties' disputes set forth herein.

BACKGROUND

Tecan Genomics & NuGEN Innovations

22. Since its founding in 2000, NuGEN has been an innovator in the biogenetics space with its innovative NGS kits and genomic sample preparation solutions. NuGEN's mission has been to advance the life sciences through its innovative sample preparation solutions. Since NuGEN's renaming in 2018, Tecan Genomics has continued this legacy by leading the industry in the development, manufacture, and distribution of laboratory instruments, NGS technologies, and automation products for the biopharmaceutical, forensic, and diagnostic industries.

23. Tecan Genomics' innovations over the years have resulted in a growing portfolio of over 300 patents and patent applications, and wide praise across the genomics sequencing industry. Medical universities, research hospitals, and genomic informatics companies, among

others, have all praised Tecan Genomics' technologies as being "a critical component in addressing the challenges of extracting genomic information," enabling research projects that were once unthinkable.[4]

24. NuGEN recognized in the early 2000s that, although sequencing technologies had improved over the technologies available in the previous decades, there were still major deficiencies in the methods that were available.

25. These shortcomings of the technologies available at the time made it expensive and tedious to perform selective target enrichment. There was a need for improved methods for selective target enrichment that allowed for low-cost, high-throughput capture of genomic regions of interest without specialized instrumentation and for high efficiency nucleic acid library generation.

26. Scientists at NuGEN set out to develop novel methods for selective target enrichment. While investigating ways to reduce contaminating signals that were prevalent in known NGS enrichments and to increase the sensitivity and accuracy of these enrichments, the inventors of the Asserted Patents developed novel methods to select desired transcripts and fragments for further study. These novel methods resulted in the development of NuGEN's target capture technologies, including NuGEN's selective target enrichment methods where the user captures desired transcripts and fragments and then amplifies them to create a library.

[4] *See, e.g.*, *Ovation® FFPE WTA System*, Tecan Genomics, accessible at https://lifesciences.tecan.com/ovation-ffpe-wta-system#:~:text=Tecan Genomics'%20sample%20preparation%20technology%20is,small%2C%20fine%20needle%20aspirate%20biopsies.

The Amorese Enrichment Patents -- '012 and '108 patents

27. The '012 patent, issued on July 31, 2018, is entitled "Compositions and Methods for Targeted Nucleic Acid Sequence Enrichment and High Efficiency Library Generation." The '012 patent lists Doug Amorese, Chris Armour, and Nurith Kurn as named inventors. Tecan Genomics currently is the owner of the '012 patent with full rights to pursue recovery of royalties and damages for infringement of the patent, including past and future damages. A true and correct copy of the '012 patent is attached hereto as Exhibit 1.

28. The '108 patent, issued on December 29, 2020, is entitled "Compositions and Methods for Targeted Nucleic Acid Sequence Enrichment and High Efficiency Library Generation." The '108 patent lists Doug Amorese, Chris Armour, and Nurith Kurn as named inventors. Tecan Genomics currently is the owner of the '108 patent with full rights to pursue recovery of royalties and damages for infringement of the patent, including past and future damages. A true and correct copy of the '108 patent is attached hereto as Exhibit 2.

29. The inventions of the '012 and '108 patents are directed to "methods, compositions, and kits for targeted nucleic acid sequence enrichment in a nucleic acid sample and for high efficacy nucleic acid library generation for next generation sequencing (NGS)." Ex. 1 at Abstract.

30. As the '012 and '108 patents explain, techniques for sequencing nucleic acid fragments that were available by January 2012—namely PCR-based, hybrid capture, and molecular inversion probe—were insufficient. For example, the '012 patent describes the inadequacies of PCR-based methods at the time:

> PCR-based methods employ highly parallel PCR amplification, where each target sequence in the sample has a corresponding pair of unique, sequence-specific primers. The simultaneous use of numerous primer pairs makes multiplex PCR impractical due to high level of non-specific amplification and primer-primer interactions. Recently developed microdroplet PCR technology (Tewhey et al., 2009) in which each amplification reaction is physically separated into an individual droplet removes the constraints of multiplex PCR relating to non-

> specific amplification and primer-primer interactions. However, microdroplet PCR and other improved PCR-based methods require special instrumentation or platforms, are limited in their throughput, and, as with conventional multiplex PCR, require a large number of individual primer pairs when enriching for a multitude of regions on interest, thus making target enrichment costly.

Id. at 1:48–63.

31. The '012 patent explains why hybrid-capture methods at the time were also insufficient:

> Hybrid capture methods are based on the selective hybridization of the target genomic regions to user-designed oligonucleotides. The hybridization can be to oligonucleotides immobilized on high or low density microarrays (on-array capture), or solution-phase hybridization to oligonucleotides modified with a ligand (e.g. biotin) which can subsequently be immobilized to a solid surface, such as a bead (in-solution capture). The hybrid capture methods require complex pools of costly long oligonucleotides and long periods (typically 48 hours) of hybridization for efficient capture. For on-array hybrid capture, expensive instrumentation and hardware is also required. Because of the relatively low efficiency of the hybridization reaction, large quantities of input DNA are needed.

Id. at 1:64–2:10.

32. The '012 patent further describes the limitations of molecular inversion probe techniques:

> The molecular inversion probe (MIP) based method relies on construction of numerous single-stranded linear oligonucleotide probes, consisting of a common linker flanked by target-specific sequences. Upon annealing to a target sequence, the probe gap region is filled via polymerization and ligation, resulting in a circularized probe. The circularized probes are then released and amplified using primers directed at the common linker region. One of the main disadvantages of the MIP-based target enrichment is its relatively low capture uniformity, meaning there is large variability in sequence coverage across the target regions. As with PCR and hybrid capture, the MIP-based method requires a large number of target-specific oligonucleotides, which can be costly.

Id. at 2:11–24.

33. As described by the '012 and '108 patents, the inventors recognized a need "for improved methods for selective target enrichment that allow for low-cost, high-throughput capture of genomic regions of interest without specialized instrumentation" and "for high efficiency

nucleic acid library generation." *Id.* at 2:25–30. The inventions of the '012 and '108 patents fulfill those needs. *Id.*

34. As described by the '012 and '108 patents, "[a]ltogether, the methods of the present invention create a simple, low cost, high-throughput system for target enrichment and library preparation." *Id.* at 6:25–27.

35. To address these needs in the prior art, the '012 and '108 patents teach and claim new methods for improving selective target enrichment. Claim 1 of the '012 patent is representative of these novel methods:

> 1. A method for sequencing an enriched nucleic acid sequence of interest, the method comprising:
>
> a) obtaining a nucleic acid fragment ligated to a partial duplex adaptor, wherein the nucleic acid fragment comprises a nucleic acid sequence of interest, wherein the partial duplex adaptor comprises a first adaptor sequence, and wherein the partial duplex adaptor comprises a first strand and a second strand, wherein the first strand is longer than the second strand;
>
> b) annealing one or more oligonucleotides in solution to the nucleic acid sequence of interest in the nucleic acid fragment ligated to the partial duplex adaptor, wherein the one or more oligonucleotides comprise a 3′ portion with at least 10 bases designed to be complementary to the nucleic acid sequence of interest and a 5′ tail portion comprising a second adaptor sequence that is non-complementary to the nucleic acid sequence of interest;
>
> c) extending the one or more oligonucleotides annealed to the nucleic acid sequence of interest in the nucleic acid fragment ligated to the partial duplex adaptor with a polymerase, thereby generating one or more oligonucleotide extension products comprising sequence complementary to the first adaptor sequence at a first end, sequence complementary to the nucleic acid sequence of interest, and the second adaptor sequence at a second end;
>
> d) amplifying the one or more oligonucleotide extension products using a first primer that anneals to a complement of the first adaptor sequence and a second primer that anneals at its 3′ end to a complement of the second adaptor sequence to enrich for the nucleic acid sequence of interest, wherein products of the amplifying comprise a 3′ end with sequence complementary to a sequence on a surface;

> e) annealing a strand of the products of the amplifying to the sequence on the surface using the 3′ end with sequence complementary to the sequence on the surface; and
>
> f) sequencing the enriched nucleic acid sequence of interest on a massively parallel sequencing platform.

36. The claims of the ’012 patent are directed to novel methods for the sequencing of enriched nucleic acid sequences through the use of synthetic tools, such as synthetic adaptors. These novel methods provide innovative solutions to problems peculiar to the amplification and sequencing of enriched nucleic acid samples. The claims are not directed to a natural law or natural phenomenon.

37. As shown by claim 1 of the ’012 patent, the ’012 patent claims are directed to specific, unconventional, non-routine methods for overcoming previously unresolved problems in the art. For example, one novel aspect of the claimed methods of the ’012 patent is the use of a single adaptor to selectively target and enrich specific nucleic acid sequences. The use of a single adaptor to selectively target and enrich specific nucleic acid sequences was considered unconventional at the time due to limitations in the known technology, which would have made it impracticable to use just one adaptor to sequence large volumes of genetic materials without high levels of error. This approach reflected a novel advance for NGS methods and has been widely adopted in the industry to improve the efficiency and capabilities of sequencing.

38. The ’108 patent likewise teaches and claims new methods for improving selective target enrichment. Claim 1 of the ’108 patent is representative of these novel methods:

> 1. A method for sequencing an enriched nucleic acid sequence of interest, the method comprising:
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> a) annealing one or more oligonucleotides in solution in a reaction mixture to the nucleic acid sequence of interest in a nucleic acid fragment, wherein the reaction mixture comprises a plurality of nucleic acid fragments, wherein the nucleic acid fragment comprising the nucleic acid sequence of interest comprises a first adaptor sequence, wherein the one or more oligonucleotides comprise a 3′ portion with at least 10 bases designed to be

> complementary to the nucleic acid sequence of interest and a 5′ tail portion comprising a second adaptor sequence that is non-complementary to the nucleic acid sequence of interest;
>
> b) extending the one or more oligonucleotides annealed to the nucleic acid sequence of interest in the nucleic acid fragment comprising the first adaptor sequence with a polymerase, in the reaction mixture, thereby generating one or more oligonucleotide extension products comprising sequence complementary to the first adaptor sequence at a first end, sequence complementary to the nucleic acid sequence of interest, and the second adaptor sequence at a second end;
>
> c) amplifying the one or more oligonucleotide extension products, in the reaction mixture, using a first primer that anneals to the complement of the first adaptor sequence and a second primer that anneals at its 3′ end to a complement of the second adaptor sequence, thereby enriching the nucleic acid sequence of interest, by generating amplified products comprising the enriched nucleic acid sequence of interest; and
>
> d) sequencing the amplified products comprising the enriched nucleic acid sequence of interest on a massively parallel sequencing platform.

39. The claims of the ’108 patent are directed to novel methods for the sequencing of enriched nucleic acid sequences through the use of synthetic tools, such as synthetic adaptors. These novel methods provide innovative solutions to problems peculiar to the amplification and sequencing of enriched nucleic acid samples. The claims are not directed to a natural law or natural phenomenon.

40. As shown by claim 1 of the ’108 patent, the ’108 patent claims are directed to specific, unconventional, non-routine methods for overcoming previously unresolved problems in the art. For example, one novel aspect of the claimed methods of the ’108 patent is the use of a single adaptor to selectively target and enrich specific nucleic acid sequences. The use of a single adaptor to selectively target and enrich specific nucleic acid sequences was considered unconventional at the time due to limitations in the known technology, which would have made it impracticable to use just one adaptor to sequence large volumes of genetic materials without high

levels of error. This approach reflected a novel advance for NGS methods and has been widely adopted in the industry to improve the efficiency and capabilities of sequencing.

The Amorese UMI Patents –- '399, '357, and '241 patents

41. The '399 patent, issued on January 17, 2017, is entitled "Compositions and Methods for Identification of a Duplicate Sequencing Read." The '399 patent lists Doug Amorese, Jonathan Scolnick, and Ben Schroeder as named inventors. Tecan Genomics currently is the owner of the '399 patent with full rights to pursue recovery of royalties and damages for infringement of the patent, including past and future damages. A true and correct copy of the '399 patent is attached hereto as Exhibit 3.

42. The '357 patent, issued on August 24, 2021, is entitled "Compositions and Methods for Identification of a Duplicate Sequencing Read." The '357 patent lists Doug Amorese, Jonathan Scolnick, and Ben Schroeder as named inventors. Tecan Genomics currently is the owner of the '357 patent with full rights to pursue recovery of royalties and damages for infringement of the patent, including past and future damages. A true and correct copy of the '357 patent is attached hereto as Exhibit 4.

43. The '241 patent, issued on August 15, 2023, is entitled "Compositions and Methods for Identification of a Duplicate Sequencing Read." The '241 patent lists Doug Amorese, Jonathan Scolnick, and Ben Schroeder as named inventors. Tecan Genomics currently is the owner of the '241 patent with full rights to pursue recovery of royalties and damages for infringement of the patent, including past and future damages. A true and correct copy of the '241 patent is attached hereto as Exhibit 5.

44. The inventions of the '399, '357, and '241 patents are directed to "methods, compositions, and kits for detecting duplicate sequencing reads." Ex. 3 at Abstract. The '399,

'357, and '241 patents disclose that "[i]n some embodiments, the duplicate reads are removed." *Id.*

45. As the '399, '357, and '241 patents explain, an individual analyzing the results of PCR sequencing and amplification of nucleic acid fragments in November 2013 would have struggled to determine whether duplicate sequences were unique or artifacts of PCR amplification. For example, the '399 patent describes the problem as such:

> In RNA sequencing applications, accurate gene expression measurements may be hampered by PCR duplicate artifacts that occur during library amplification. When analyzing RNA sequencing data, when two or more identical sequences are found, it can be difficult to know if these represent unique cDNA molecules derived independently from different RNA molecules, or if they are PCR duplicates derived from a single RNA molecule. In genotyping by sequencing, duplicate reads can be considered non-informative and may be collapsed down to a single read, thus reducing the number of sequencing reads used in final analysis. Generally, sequencing reads may be determined to be duplicates if both forward and reverse reads have identical starting positions, even though two independently generated molecules can have identical starting positions by random chance. Single primer extension based targeted re-sequencing suffers from an issue in that only one end of a sequencing read is randomly generated, while the other (reverse read) end is generated by a specific probe. This may make it difficult to determine if two reads are duplicates because they have been duplicated by PCR or because by chance they happened to start at the same position.

Id. at 1:31–52.

46. The '399 patent goes on to explain one solution available at the time to resolve duplication analysis issues:

> In expression analysis studies there may be limited value in doing paired end sequencing since the goal of the experiment is to determine amounts of transcript present as opposed to studying exon usage. In these studies, paired end sequencing adds costs while the only value is in helping distinguish PCR duplicates. The probability of two reads starting in the same position on only one end is higher than the probability of two reads having the same starting position on two ends (forward and reverse read).

Id. at 1:53–61.

47. However, as the '399 patent explains, this solution was inadequate and left an unmet need to resolve issues arising from duplication:

> There is a need for improved methods that allow for low-cost, high throughput sequencing of regions of interest, genotyping or simple detection of RNA transcripts without inherent instrument inefficiencies that drive up sequencing costs due to the generation of unusable or non-desired data reads.

Id. at 1:61–66.

48. The inventions of the '399, '357, and '241 patents fulfill that need. As explained by the '399 patent, "[t]he invention described herein fulfills this need" through the use of "an adaptor approach that allows for the identification of true PCR duplicates and their removal." *Id.* at 1:66–2:02.

49. The '399 patent describes this invention in terms of its innovative approach to resolving this issue:

> [T]he present invention provides a method of detecting a duplicate sequencing read from a population of sample sequencing reads, the method comprising ligating an adaptor to a 5′ end of each nucleic acid fragment of a plurality of nucleic acid fragments from one or more samples, wherein the adaptor comprises an indexing primer binding site, an indexing site, an identifier site, and a target sequence primer binding site. The ligated adaptor-nucleic acid fragment products can be amplified, thus generating a population of sequencing reads from the amplified adaptor-nucleic acid ligation products. The sequencing reads with a duplicate identifier site and target sequence can then be detected from the population of sequencing reads. The methods can further include the removal of the sequencing reads with the duplicate identifier site and target sequence from the population of sequence reads.

Id. at 2:18–33.

50. To address this need in the prior art, the '399, '357, and '241 patents teach and claim new methods for detecting duplicate sequencing reads. Claim 1 of the '399 patent is representative of these novel methods:

> 1. A method for detecting a duplicate sequencing read from a population of sample sequencing reads comprising:

> a) ligating an adaptor to a 5′ end of each nucleic acid fragment of a plurality of nucleic acid fragments from one or more samples, wherein the adaptor comprises:
>
> (i) an indexing primer binding site;
>
> (ii) an indexing site;
>
> (iii) an identifier site consisting of between 1 and 8 nucleotides; and
>
> (iv) a target sequence primer binding site;
>
> b) amplifying the adaptor-nucleic acid fragment ligated products;
>
> c) generating a population of sequencing reads from amplified adaptor-nucleic acid fragment ligated products; and
>
> d) identifying a duplicate sequencing read as the sequencing read comprising the same identifier site and nucleic acid fragment as another sequencing read in the population of sequencing reads;
>
> e) wherein the indexing site is unique amongst a subset of the plurality of nucleic acid fragments and is an index for multiple polynucleotides; and wherein the sequence of the identifier site is variable in sequence content in a plurality of adaptors.

51. The claims of the ’399 patent are directed to novel methods for identifying true duplicate reads during sequencing. These novel methods provide innovative solutions to problems peculiar to the amplification and sequencing of enriched nucleic acid samples. The claims are not directed to a natural law or natural phenomenon.

52. As shown by claim 1 of the ’399 patent, the ’399 patent claims are directed to specific, unconventional, non-routine methods for overcoming previously unresolved problems in the art. For example, the ’399 patent describes that the “methods of the present invention provide novel methods for identifying true duplicate reads during sequencing, such as to improve data analysis of sequencing data, and other related advantages.” *Id.* at 2:03–06. These methods were unconventional at least because these methods used a single adaptor and allowed for the use of a small number of oligonucleotides to identify unique nucleic fragments, which was not otherwise

possible at the time. This approach reflected a novel advance for NGS methods and has been widely adopted in the industry to improve the efficiency and capabilities of sequencing.

53. The ’357 patent likewise teaches and claims new methods for identifying true duplicate reads during sequencing. Claim 1 of the ’357 patent is representative of these novel methods:

> 1. A method for detecting duplicate sequencing reads, the method comprising:
>
> a) ligating an adaptor to each of a plurality of nucleic acid fragments, wherein each adaptor comprises a unique identifier having from about 1 to about 8 nucleotides, an indexing site unique to a subset of the adaptors, and a primer binding site;
>
> b) amplifying the adaptor-ligated fragments into amplicons;
>
> c) sequencing the amplicons to produce sequence reads that include identifier and target sequences; and
>
> d) identifying sequence reads with identical identifier and target sequences as duplicates.

54. The claims of the ’357 patent are directed to novel methods for identifying true duplicate reads during sequencing. These novel methods provide innovative solutions to problems specific to the amplification and sequencing of enriched nucleic acid samples. The claims are not directed to a natural law or natural phenomenon.

55. As shown by claim 1 of the ’357 patent, the ’357 patent claims are directed to specific, unconventional, non-routine methods for overcoming previously unresolved problems in the art. For example, the ’357 patent describes that the “methods of the present invention provide novel methods for identifying true duplicate reads during sequencing, such as to improve data analysis of sequencing data, and other related advantages.” Ex. 4 at 2:07–10. These methods were unconventional at least because these methods used a single adaptor and allowed for the use of a small number of oligonucleotides to identify unique nucleic fragments, which was not otherwise

possible at the time. This approach reflected a novel advance for NGS methods and has been widely adopted in the industry to improve the efficiency and capabilities of sequencing.

56. The ’241 patent also teaches and claims new methods for identifying true duplicate reads during sequencing. Claim 1 of the ’241 patent is representative of these novel methods:

> 1. A method for detecting duplicate sequencing reads, the method comprising:
>
> a) obtaining amplicons each comprising an amplified fragment of a nucleic acid with an appended adaptor, wherein each adaptor comprises an identifier site comprising a plurality of nucleotides unique to the amplified fragment;
>
> b) sequencing the amplicons to generate sequence reads that include identifier and target sequences; and
>
> c) identifying sequence reads with identical identifier and target sequences as duplicates.

57. The claims of the ’241 patent are directed to novel methods for identifying true duplicate reads during sequencing. These novel methods provide innovative solutions to problems specific to the amplification and sequencing of enriched nucleic acid samples. The claims are not directed to a natural law or natural phenomenon.

58. As shown by claim 1 of the ’241 patent, the ’241 patent claims are directed to specific, unconventional, non-routine methods for overcoming previously unresolved problems in the art. For example, the ’241 patent describes that the “methods of the present invention provide novel methods for identifying true duplicate reads during sequencing, such as to improve data analysis of sequencing data, and other related advantages.” Ex. 5 at 2:06–09. These methods were unconventional at least because these methods used a single adaptor and allowed for the use of a small number of oligonucleotides to identify unique nucleic fragments, which was not otherwise possible at the time. This approach reflected a novel advance for NGS methods and has been widely adopted in the industry to improve the efficiency and capabilities of sequencing.

Defendants' Accused Products

59. Defendants have previously used and continue to use, manufacture, sell, offer to sell, and/or import testing kits that infringe Tecan Genomics' patents. Defendants also have previously provided and continue to provide services using kits and protocols that infringe Tecan Genomics' patents.

60. Specifically, Defendants have used and continue to use, manufacture, and/or commercialize products using infringing technology and methods including but not limited to technology that Defendants refer to as "Anchored Multiplex PCR" (AMP) target enrichment technology. These AMP products include at least ArcherDX VariantPlex AMP Panels, ArcherDX FusionPlex AMP Panels, and ArcherDX LiquidPlex AMP Panels.

61. Defendants also have offered and continue to offer services using these kits and the protocols.[5] For example, on information and belief, Invitae offered testing services that relied on the infringing methods as described in Defendants' AMP technology or similar technology and methods and continues to offer other infringing services, including at least the Invitae Personalized Cancer Monitoring™ – Baseline Test and the Invitae Personized Cancer Monitoring™ – Monitoring Test.[6] IDT continues to provide services involving those AMP products and supports

[5] *See* Archer Fusionplex Assays, https://web.archive.org/web/20161111212036/http://archerdx.com/fusionplex-assays/#documentation (Nov. 11 2016); Archer VariantPlex Assays https://web.archive.org/web/20180529114552/http://archerdx.com/variantplex/ (May 29 2018); Invitae Research Products https://web.archive.org/web/20210926002836/https://archerdx.com/research-products/ (Sept. 26 2021); Invitae Co-development Services https://web.archive.org/web/20201128190450/https://archerdx.com/services/co-development-services/ (Nov. 28 2020); "VariantPlex Anchored Multiplex PCR AMP," DNA Chemistry, https://archerdx.com/technology-platform/technology/; "FusionPlex Anchored Multiplex PCR AMP," RNA Chemistry, https://archerdx.com/technology-platform/technology/.

[6] *See* Invitae Test Catalog Invitae Personalized Cancer Monitoring™ - Baseline Test, https://www.invitae.com/en/providers/test-catalog/test-90002 (last visited Aug. 18, 2023); Invitae

Invitae's services.[7] On information and belief, Invitae and Archer continue to benefit financially from the infringing products that IDT sells or offers for sale.[8]

62. On information and belief, all of these products and services, as well as all other products made or sold or services offered or sold using AMP or making use of similar technology and methods infringe the Asserted Patents (collectively, the "Accused Products"). The Accused Products include at least the above sequencing kit products, as well as associated products including at least primer panels designed for use with the above sequencing kits and associated services including at least sequencing services including at least testing services. All references to the Accused Products shall incorporate any and all products and/or services that are associated with Defendants' infringing actions. Specific references to a product or service are meant to be illustrative of Defendants' infringing actions and are not limiting.

63. On information and belief, a number of these Accused Products were initially commercialized by Archer and/or its predecessor. Archer has been a technology competitor to

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Test Catalog Invitae Personalized Cancer Monitoring™ - Monitoring Test, https://www.invitae.com/en/providers/test-catalog/test-90003 (last visited Aug. 18, 2023); "Invitae Personalized Cancer Monitoring", https://nymacgenetics.org/wp-content/uploads/2022/03/Personalized-Cancer-Monitoring-PCM.PDF.pdf.

[7] Invitae Press releases, Invitae Completes Selected Assets Sale of its Next Generation Sequencing (NGS) research assays to Integrated DNA Technologies, Inc., (Dec. 20, 2022) https://ir.invitae.com/news-and-events/press-releases/press-release-details/2022/Invitae-Completes-Selected-Assets-Sale-of-its-Next-Generation-Sequencing-NGS-research-assays-to-Integrated-DNA-Technologies-Inc/default.aspx.

[8] Invitae Press releases, Invitae Completes Selected Assets Sale of its Next Generation Sequencing (NGS) research assays to Integrated DNA Technologies, Inc., (Dec. 20 2022) https://ir.invitae.com/news-and-events/press-releases/press-release-details/2022/Invitae-Completes-Selected-Assets-Sale-of-its-Next-Generation-Sequencing-NGS-research-assays-to-Integrated-DNA-Technologies-Inc/default.aspx; "VariantPlex Anchored Multiplex PCR AMP," DNA Chemistry, https://archerdx.com/technology-platform/technology/; "FusionPlex Anchored Multiplex PCR AMP," RNA Chemistry, https://archerdx.com/technology-platform/technology/.

NuGEN since Archer's founding in early 2013. Archer has unfairly profited over the years by copying NuGEN's innovative technologies.

64. Archer has been the subject of several different acquisitions, and on information and belief, Archer shared with each of these entities its knowledge of NuGEN's technologies and its Accused Products.

65. In August 2013, Enzymatics Inc. ("Enzymatics") acquired ArcherDX, Inc. After the acquisition, ArcherDX, Inc. operated as a business unit of Enzymatics.

66. On information and belief, in late 2014, QIAGEN N.V. ("QIAGEN") acquired Enzymatics (and with it ArcherDX, Inc.). As part of QIAGEN's acquisition of Enzymatics, Enzymatics became a wholly-owned subsidiary of QIAGEN, and ArcherDX, Inc. was spun out as a separate entity. As part of the acquisition of Enzymatics, QIAGEN entered into a strategic partnership with ArcherDX, Inc., providing QIAGEN with access and distribution rights for unique NGS products based on Archer's infringing AMP technology. Through this partnership, ArcherDX, Inc. instructed QIAGEN on its infringing methods and technology by sharing Archer's information with QIAGEN employees. The partnership also allowed for a QIAGEN employee to sit on ArcherDX, Inc.'s Board of Directors. As a result of this agreement to infringe NuGEN's patented technologies, QIAGEN began making, using, offering to sell, and selling products that also infringed NuGEN's patented technologies.

67. In 2020, Invitae acquired ArcherDX, Inc. ArcherDX, Inc. subsequently merged into a Delaware limited liability company, and the surviving company was renamed ArcherDX, LLC. ArcherDX, LLC is the successor-in-interest of ArcherDX, Inc. At the time, Invitae represented in regulatory filings and notices to shareholders that on completion of the merger, Invitae would assume ArcherDX, Inc.'s risks arising from legal proceedings.

68. After Invitae acquired ArcherDX, Inc. in 2020, Defendants continued to sell the Accused Products, including but not limited to ArcherDX VariantPlex AMP Panels, ArcherDX FusionPlex AMP Panels, and ArcherDX LiquidPlex AMP Panels.

69. Invitae also began commercializing its own products, services, and testing services that make use of the infringing AMP technology—for example, Invitae Personalized Cancer Monitoring™ – Baseline Test and Invitae Personized Cancer Monitoring™ – Monitoring Test.

70. On information and belief, these products and services make use of the same infringing AMP technology used and described in the ArcherDX VariantPlex, ArcherDX FusionPlex, and ArcherDX LiquidPlex kits and utilize the same methods described in the ArcherDX VariantPlex, ArcherDX FusionPlex, and ArcherDX LiquidPlex kits and protocol manuals, as described in detail below.[9]

71. On information and belief, IDT and Invitae entered into a limited asset purchase agreement in December 2022. As part of the purchase agreement, Invitae sold to IDT certain ArcherDX products and services, including ArcherDX VariantPlex AMP Panels, ArcherDX FusionPlex AMP Panels, and ArcherDX LiquidPlex AMP Panels.

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[9] *See* "Invitae Personalized Cancer Monitoring," https://nymacgenetics.org/wp-content/uploads/2022/03/Personalized-Cancer-Monitoring-PCM.PDF.pdf ("Invitae has developed a personalized cancer monitoring (PCM) assay to monitor MRD. PCM is a pan-cancer, tumor informed liquid biopsy assay that uses NGS powered by Anchored Multiplex PCR (AMP) chemistry to analyze ctDNA in a patient's plasma." at 3.); Zheng Z, Liebers M, Zhelyazkova B et al. Anchored multiplex PCR for targeted next-generation sequencing. Nat Med 2014; 20: 1479-1484; Archer VariantPlex-HS/HGC Protocol for Illumina, page 3 "Overview"; Archer FusionPlex Protocol for Illumina, page 4 "Overview"; Archer LiquidPlex Protocol for Illumina, page 4 "Overview"; "VariantPlex Anchored Multiplex PCR AMP," DNA Chemistry, https://archerdx.com/technology-platform/technology/; "FusionPlex Anchored Multiplex PCR AMP," RNA Chemistry, https://archerdx.com/technology-platform/technology/; Invitae VariantPlex Protocol for Illumina, page 4 "Overview"; Invitae FusionPlex Protocol for Illumina, page 4 "Overview"; Invitae LiquidPlex Protocol for Illumina, page 4 "Overview"; IDT VariantPlex Protocol for Illumina, page 3 "Overview"; IDT FusionPlex Protocol for Illumina, page 3 "Overview"; IDT LiquidPlex Protocol for Illumina, page 3 "Overview."

72. On information and belief, IDT also licensed the Archer® trademark from Invitae, as well as a license to the infringing AMP technology. On information and belief, ownership of this intellectual property was retained by Invitae. On further information and belief, this agreement is an ongoing partnership that allows IDT to offer to sell and sell the Accused Products in exchange for a royalty to Invitae and/or Archer while IDT also provides Invitae with support for services using AMP technology.[10]

73. On information and belief, the Accused Products now sold or offered for sale by IDT continue to be manufactured at the same Archer facility in Boulder, CO, at which the products were manufactured prior to the sale of the products from Invitae to IDT.[11]

74. On information and belief, the Accused Products now sold by IDT make use of the same infringing AMP technology as was used by the Accused Products before the limited asset sale.[12]

Defendants Have Known of their Infringement of the Asserted Patents

75. On information and belief, Defendants have been aware of Plaintiff's Asserted Patents well before the filing of this Complaint, and they have also known of the infringement of

[10] Invitae Press releases, Invitae Completes Selected Assets Sale of its Next Generation Sequencing (NGS) research assays to Integrated DNA Technologies, Inc., (Dec. 20, 2022) https://ir.invitae.com/news-and-events/press-releases/press-release-details/2022/Invitae-Completes-Selected-Assets-Sale-of-its-Next-Generation-Sequencing-NGS-research-assays-to-Integrated-DNA-Technologies-Inc/default.aspx.

[11] https://www.idtdna.com/pages/about/news/2022/12/20/integrated-dna-technologies-acquires-archerdx-next-generation-sequencing-research-assays-from-invitae-corporation.

[12] https://www.idtdna.com/pages/about/news/2022/12/20/integrated-dna-technologies-acquires-archerdx-next-generation-sequencing-research-assays-from-invitae-corporation.

the Asserted Patents. Specifically, on information and belief, Defendants have been aware of their infringement since they first began commercializing the Accused Products.

76. On information and belief, Archer has known of Tecan Genomics' enrichment technology since at least 2014. Moreover, on information and belief, as a result of Invitae and IDT subsequent diligence and acquisitions of Archer and collaborations with Archer (as well as other events and interactions listed below), Defendants have regularly monitored Tecan Genomics' patent filings and developments and have been aware of their infringement since the issuance of Tecan Genomics' patents. In addition, Defendants' own patent submissions confirm that they have been aware of the Asserted Patents and their patent families. Defendants have also been specifically notified of their infringement of the Asserted Patents before the filing of this complaint. Despite their knowledge of the infringement of the Asserted Patents, Defendants have and continue to infringe the Asserted Patents.

77. On information and belief, Archer has been aware of Tecan Genomics' proprietary enrichment technology and what would become the '012 and '108 patent family since at least 2014. At the 2013 Advances in Genome Biology and Technology ("AGBT") conference held on February 20–23, 2013, in Florida, NuGEN presented a poster and published a webcast to conference attendees on its innovative technologies.[13] On information and belief, Enzymatics agents, including one of the founders, were present at the event.

78. A year later, in February 2014, after Enzymatics had acquired and integrated ArcherDX, Inc. into its company as a business unit, Enzymatics was the gold sponsor of the AGBT conference, and NuGEN was a bronze sponsor for the same event. The two companies presented side-by-side in the same afternoon track of the conference on February 14, where NuGEN's

[13] *See* NuGEN's presentation at https://www.youtube.com/watch?v=Kqyy4zugqMk.

presentation had the title "Single Primer Enrichment Technology (SPET) Enables Fast and Reliable Detection of Cancer Associated Somatic Mutations." At the same event, an employee of the integrated Enzymatics/ArcherDX, Inc. approached an employee of NuGEN to tell him that Enzymatics/ArcherDX, Inc.'s management team had informed the employee that they planned to file a lawsuit against NuGEN related to the practice of NuGEN's enrichment technology. The NuGEN employee did not pursue the topic further with the Enzymatics/ArcherDX, Inc. employee. NuGEN subsequently provided Enzymatics/ArcherDX, Inc. with a copy of NuGEN's patent application, showing that NuGEN had in fact invented the technology. No lawsuit was ever filed.

79. On information and belief, from this time onward, Archer monitored and evaluated (and Defendants have continued to monitor and evaluate) NuGEN patent filings including the filing of U.S. Application Nos. 13/750,768, 14/540,917, 15/471,785, and 16/017,340 and the issuance of U.S. Patent Nos. 9,546,399, 9,650,628, 10,036,012, and 10,876,108. For example, on information and belief, Archer's monitoring of Tecan Genomics' patent portfolio since at least 2014 resulted in its learning of the '399 patent and its patent family by at least May 14, 2015, when the application for the '399 patent published. On information and belief, Archer continued to review Tecan Genomics' patent portfolio after becoming aware of at least one patent covering Archer's infringing products and services. On information and belief, this continued monitoring of NuGEN and Tecan Genomics patent submissions resulted in Archer citing to another of Tecan Genomics' patents in 2020.

80. On information and belief, Invitae became aware of Plaintiff's patented technologies no later than when Invitae acquired ArcherDX, Inc. in 2020. On information and belief, on or before October 2020, Invitae became aware of ArcherDX, Inc.'s prior awareness of the Asserted Patents as well as ArcherDX, Inc.'s assessments of Tecan Genomics' intellectual

property, including the Asserted Patents. On information and belief, as part of diligence for the acquisition of ArcherDX, Inc., Invitae was made aware of Tecan Genomics' patents and ArcherDX, Inc.'s infringement risks. For example, U.S. Patent No. 10,017,810, which issued years prior to the acquisition, and U.S. Patent Application No. 15/802,408, which ArcherDX, Inc. filed shortly before being acquired by Invitae both referenced NuGEN patent application publications.

81. On information and belief, high-level employees and executives at Enzymatics and ArcherDX, Inc. joined Invitae and shared their knowledge of NuGEN's patents and their infringement. For example, one of the leaders of ArcherDX, Inc., served in executive roles at ArcherDX, Inc., Enzymatics, and Invitae, including serving on Invitae's Board of Directors and as President of a business unit commercializing the AMP technology, where on information and belief, he would have been obligated to share his knowledge concerning ArcherDX, Inc.'s prior acts of infringement.

82. As another example, the General Counsel at Enzymatics during the entire period of time when Enzymatics owned ArcherDX, Inc., on information and belief, had access to information concerning Archer's infringing technologies. On information and belief, he was responsible for approving the launch and continued sales of the Accused Products and assessing risks of infringement. On information and belief, this included obtaining and assessing any Freedom-to-Operate assessments conducted by Enzymatics and ArcherDX, Inc. after its acquisition. On information and belief, he would have also had access to any prior Freedom-to-Operate assessments prepared by ArcherDX, Inc. before its acquisition. Additionally, as General Counsel, he would have been involved with any considerations or preparations to sue NuGEN in 2014. After Enzymatics was acquired by QIAGEN and ArcherDX, Inc. was spun off, he became

General Counsel for ArcherDX, Inc. where he would have continued to possess knowledge unique to both ArcherDX, Inc. and Enzymatics prior to the spin-off. He remained in Archer's legal department through Invitae's acquisition of the company. As part of Invitae's due diligence, he, among others, would have been obligated to share their knowledge of NuGEN's technologies and Archer's ongoing infringement.

83. Additionally, another senior Invitae executive started his career at ArcherDX, Inc. as a research scientist. After ArcherDX, Inc. was acquired by Enzymatics, he joined the newly merged company and spent nearly a year as the Director of NGS research and development. In these roles, he would have been familiar with NuGEN's technologies and Defendants' ongoing infringement of those technologies. After ArcherDX, Inc. was spun off, he became the senior executive for research and development at ArcherDX, Inc. Prior to Invitae acquiring ArcherDX, Inc., he was the Chief Operating Officer and Chief Scientific Officer at ArcherDX, Inc. After the acquisition, he joined Invitae as a senior executive leading their Oncology unit in the same city as the Archer manufacturing facilities. On information and belief, as part of his responsibilities, he was aware of competitor products and technologies, such as Tecan Genomics' products and technologies, as well as detailed comparisons of those technologies to the infringing AMP technologies. His senior leadership positions would have also obligated him to share the information he learned while at Enzymatics and then ArcherDX, Inc. with Invitae. On information and belief, other senior personnel with knowledge of the patented Tecan Genomics technology also remained at Invitae and shared this knowledge with Invitae (and later IDT).

84. On information and belief, IDT became aware of Plaintiff's patented technologies no later than when IDT entered into a limited asset sale with Invitae in 2022. On information and belief, on or before December 2022, IDT became aware of Invitae's and Archer's prior awareness

of the Asserted Patents as well as their assessments of Tecan Genomics' intellectual property, including the Asserted Patents.

85. On information and belief, as part of diligence for the acquisition of several of the Accused Products, IDT was made aware of Tecan Genomics' patents and Invitae/Archer's infringement risks. On information and belief, this included sharing Invitae/Archer's intellectual property, which explicitly references NuGEN's technology, as well as information on NuGEN's intellectual property and the Accused Products' infringement.

86. Defendants' own patent filings confirm their awareness of the patent families. Specifically, Archer U.S. Patent Application No. 15/269,448, filed on September 19, 2016, listed a NuGEN patent application publication (International Publication WO 2015/073711 A1, the international version of U.S. Patent Application No. 14/540,917, which later issued as U.S. Patent No. 9,546,399) in an Information Disclosure Statement (IDS). *See* 2/21/2018 Information Disclosure Statement (10,017,810 patent prosecution) at 4. The same Tecan Genomics patent application publication is listed on the face of U.S. Patent No. 10,017,810, which issued prior to Invitae acquiring ArcherDX, Inc.

87. Further, Archer's U.S. Patent Application No. 15/802,408, filed on July 14, 2020, listed another NuGEN patent application publication (U.S. Patent Application No. 2013/0231253, which later issued as U.S. Patent No. 9,650,628) in an IDS. *See* 7/14/2020 Information Disclosure Statement (10,947,582 patent prosecution) at 1. The same Tecan Genomics patent application publication is listed on the face of U.S. Patent No. 10,947,582, which issued after Invitae acquired ArcherDX, Inc.

88. On information and belief, IDT performed diligence on U.S. Patent Nos. 10,017,810 and 10,947,582, which both appear to purportedly be directed to the Accused

Products, in advance of licensing them from Invitae as part of its partnership with Invitae, again demonstrating IDT's awareness of Tecan Genomics patented technology.

89. Additionally, Swift Biosciences U.S. Patent Application No. 16/389,243, filed April 19, 2019, listed the same NuGEN patent application publication (U.S. Patent Application No. 2013/0231253, which later issued as U.S. Patent No. 9,650,628) in an IDS. *See* 4/19/2019 Information Disclosure Statement (11,162,135 patent prosecution) at 2. On information and belief, IDT conducted due diligence on the intellectual property portfolio of Swift Biosciences during acquisition and was aware of the prosecution reference made to the patent application publication related to the Asserted Patents. Moreover, the same Tecan Genomics patent application publication is listed on the face of U.S. Patent No. 11,162,135 which issued after IDT acquired Swift Biosciences.

90. These disclosures were made due to Defendants' continued awareness of NuGEN's technologies while pursuing their own patents. To the extent that Defendants claim ignorance of the Asserted Patents, any such ignorance comes from Defendants' willful blindness towards the Asserted Patents and the high probability that Defendants' actions infringed the Asserted Patents. In addition to Defendants operating in the same space as Tecan Genomics and knowing of Tecan Genomics, there are numerous other reasons why each Defendant knew or should have known of the Asserted Patents. Archer knew or should have known of the Asserted Patents given that its employee(s) were present at AGBT 2013 and AGBT 2014 where NuGEN presented the technology for the first time; subsequent to which Archer was an integrated unit of Enzymatics. Shortly thereafter, Enzymatics/ArcherDX, Inc. prepared to sue NuGEN for copying their technology. However, the lawsuit never materialized. Archer knew or should have also known of the Asserted Patents given that Archer has cited to the Asserted Patent families during the

prosecution of their own patents. Invitae knew or should have known of the Asserted Patents given that, on information and belief, it would have conducted a rigorous diligence review before acquiring ArcherDX, Inc. that would have requested all information about potential IP risks. Invitae knew or should have also known about the Asserted Patents given that high-level employees and executives of ArcherDX, Inc. and Enzymatics joined Invitae after its acquisition of ArcherDX, Inc. IDT knew or should have known of the Asserted Patents given that, on information and belief, it would have also conducted a rigorous diligence review before acquiring certain Accused Products and the Archer trademark associated with those Accused Products.

91. Each of the Defendants was also familiar with and had access to Tecan Genomics' products, which bore marking information informing users that the products were covered by the Asserted Patents. NuGEN and Tecan Genomics have marked their products as being covered by several issued U.S. and international patents and pending applications with reference to www.nugen.com, providing notice that their products are at least covered by the Asserted Patents.[14] For example, the '012 patent has been listed in connection with Tecan Genomics' own genetic enrichment protocols and kits.

92. Given that Defendants have long been aware of NuGEN and its technologies and have provided similar enrichment products, on information and belief, Defendants were also aware of the Asserted Patents and their infringement.

93. Defendants were again reminded of the '012, '108, '399, '357, and '241 patents and their infringement of those patents in advance of filing this Complaint. On September 29, 2023, Tecan Genomics sent Defendants notice letters concerning their continued infringement of Tecan Genomics' patents, which are attached as Exhibits 6 and 7. Additionally, copies of the

[14] *See, e.g.*, https://www.tecan.com/intellectual property/patent_portfolio.

September 29 notice letters were emailed to senior executives for Defendants on October 2. After not receiving a response from Defendants, Tecan Genomics followed up with a second set of emails to Defendants on October 3. That same day, IDT confirmed receipt of the notice letter.

94. As of the filing of this Complaint, no further responses or communications have been received from IDT, and Invitae/Archer have yet to provide any confirmation or response to the notice letter.

95. Despite having previously approached Tecan Genomics about their patented technology, citing Tecan Genomics' patents in their own patent applications, being aware of Tecan Genomics' marked products, and Tecan Genomics' September 29 letters, and despite having knowledge of the Asserted Patents, Defendants have continued their infringing acts. Aware of the Asserted Patents and their infringement of the Asserted Patents, Defendants nevertheless willfully disregarded Tecan Genomics' patent rights. On information and belief, Defendants continue to make, use, sell, and offer to sell the Accused Products that infringe the Asserted Patents.

DEFENDANTS' INFRINGEMENT OF THE ASSERTED PATENTS

96. On information and belief, Defendants' ArcherDX VariantPlex AMP Panels, ArcherDX FusionPlex AMP Panels, and ArcherDX LiquidPlex AMP Panels were manufactured, used, sold, and offered for sale originally by Archer. When Invitae acquired Archer, Invitae and Archer began to jointly and individually manufacture, use, sell, and offer to sell Defendants' ArcherDX VariantPlex AMP Panels, ArcherDX FusionPlex AMP Panels, and ArcherDX LiquidPlex AMP Panels. After IDT purchased Defendants' ArcherDX VariantPlex AMP Panels, ArcherDX FusionPlex AMP Panels, and ArcherDX LiquidPlex AMP Panels, IDT began to sell and offer to sell the Accused Products; however, on information and belief, Invitae and Archer continue to financially benefit from those sales made by IDT as part of a partnership between the parties. On information and belief, Defendants' ArcherDX VariantPlex AMP Panels, ArcherDX

FusionPlex AMP Panels, and ArcherDX LiquidPlex AMP Panels have historically utilized Defendants' infringing AMP technology, and the iteration of those products currently sold or offered for sale by Defendants continue to utilize the same or similar AMP technology. On further information and belief, Invitae's Personalized Cancer Monitoring™ – Baseline Test and Personized Cancer Monitoring™ – Monitoring Test testing services utilize the same infringing AMP technology. As a result, the disclosures below with respect to infringement of the Asserted Patents applies to all Accused Products, both those sold by Invitae and Archer, and those sold by IDT.

Defendants' Infringement of the '012 Patent

97. Defendants infringe at least claim 1 of the '012 patent under at least 35 U.S.C. §§ 271(a)-(c).

98. Defendants have used and continue to use the Accused Products in a manner that directly infringes literally or under the doctrine of equivalents at least claim 1 of the '012 patent. For example, when Defendants utilize the Accused Products, they infringe at least claim 1 of the '012 patent.[15] Moreover, Defendants conduct research, development, training, and/or testing

[15] *See* "VariantPlex Anchored Multiplex PCR AMP," DNA Chemistry, https://web.archive.org/web/20200811120340/https://archerdx.com/technology-platform/technology/; ArcherDX, LLC, VariantPlex™ Anchored Multiplex PCR AMP™, YouTube (Aug. 9, 2019), https://www.youtube.com/watch?v=Af2dSH5YMt4&t=4s; Anchored Multiplex PCR AMP," RNA Chemistry, https://web.archive.org/web/20200811120340/https://archerdx.com/technology-platform/technology/; ArcherDX, LLC, FusionPlex™ Anchored Multiplex PCR AMP™, YouTube (Aug. 9, 2019), https://www.youtube.com/watch?v=cHjKsgbmIsY; "VariantPlex Anchored Multiplex PCR AMP," DNA Chemistry, https://archerdx.com/technology-platform/technology/; "FusionPlex Anchored Multiplex PCR AMP," RNA Chemistry, https://archerdx.com/technology-platform/technology/; Archer VariantPlex-HS/HGC Protocol for Illumina; Archer FusionPlex Protocol for Illumina; Archer LiquidPlex Protocol for Illumina; Invitae VariantPlex Protocol for Illumina; Invitae FusionPlex Protocol for Illumina; Invitae LiquidPlex Protocol for Illumina; IDT VariantPlex Protocol for Illumina; IDT FusionPlex Protocol for Illumina; IDT LiquidPlex Protocol for Illumina.

activities relating to the launch, marketing, and sale of the Accused Products, which directly infringe at least claim 1 of the '012 patent.[16] Defendants also directly infringe at least claim 1 of the '012 patent by using the Accused Products in the United States when they instruct and train end-users on the use of the Accused Products at locations throughout the United States by demonstrating how to use the products, as well as when Defendants make, offer to sell, and sell the Accused Products.[17]

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[16] *See* BioSpace, Enzymatics Inc. Launches Archer Targeted Sequencing Technology To Dramatically Enhance Gene Mutation Identification And Discovery, https://www.biospace.com/article/releases/enzymatics-inc-launches-archer-and-0153-targeted-sequencing-technology-to-dramatically-enhance-gene-mutation-identification-and-discovery-/ (Feb. 14, 2014); Businesswire, ArcherDX Launches VariantPlex™ Product Line For DNA-based Targeted Sequencing, https://www.businesswire.com/news/home/20150529005043/en/ArcherDX-Launches-VariantPlex%E2%84%A2-Product-Line-For-DNA-based-Targeted-Sequencing (May 29, 2015); Cision, PR Newswire ArcherDX dives into liquid biopsy research with Reveal ctDNA™ 28 assay, https://www.prnewswire.com/news-releases/archerdx-dives-into-liquid-biopsy-research-with-reveal-ctdna-28-assay-300332446.html (Sept. 22, 2016); Archer, LiquidPlex ctDNR 28, https://web.archive.org/web/20200920070216/https://archerdx.com/research-products/solid-tumor-research/liquidplex/ (Sept. 20, 2020); Invitae Press Releases, Invitae Launches Full Access to its Liquid-Based Personalized Cancer Monitoring Platform to Help Detect Disease Earlier, https://ir.invitae.com/news-and-events/press-releases/press-release-details/2022/Invitae-Launches-Full-Access-to-its-Liquid-Based-Personalized-Cancer-Monitoring-Platform-to-Help-Detect-Disease-Earlier/default.aspx (Mar. 17, 2022); "VariantPlex Anchored Multiplex PCR AMP," DNA Chemistry, https://archerdx.com/technology-platform/technology/; "FusionPlex Anchored Multiplex PCR AMP," RNA Chemistry, https://archerdx.com/technology-platform/technology/.

[17] *See* "VariantPlex Anchored Multiplex PCR AMP," DNA Chemistry, https://web.archive.org/web/20200811120340/https://archerdx.com/technology-platform/technology/; ArcherDX, LLC., VariantPlex™ Anchored Multiplex PCR AMP™, YouTube (Aug. 9, 2019), https://www.youtube.com/watch?v=Af2dSH5YMt4&t=4s; Anchored Multiplex PCR AMP," RNA Chemistry, https://web.archive.org/web/20200811120340/https://archerdx.com/technology-platform/technology/; ArcherDX, LLC, FusionPlex™ Anchored Multiplex PCR AMP™, YouTube (Aug. 9, 2019), https://www.youtube.com/watch?v=cHjKsgbmIsY; Archer VariantPlex-HS/HGC Protocol for Illumina; Archer FusionPlex Protocol for Illumina; Archer LiquidPlex Protocol for Illumina; "VariantPlex Anchored Multiplex PCR AMP," DNA Chemistry, https://archerdx.com/technology-platform/technology/; "FusionPlex Anchored Multiplex PCR AMP," RNA Chemistry, https://archerdx.com/technology-platform/technology/; Invitae

99. To the extent the preamble of claim 1 is limiting, Defendants' Accused Products employ "a method for sequencing an enriched nucleic acid sequence of interest." For example, the Accused Products are used to generate target-enriched libraries for NGS by using a combination of gene-specific primers and partial duplex universal adaptors. The kit protocols of the Accused Products state their intended use is "to produce high-complexity libraries for use with . . . next-generation sequencing (NGS) instruments."[18] The kit protocols of the Accused Products also recite AMP technology as the "Test Principle" underlying their respective kits. AMP technology provides "a rapid target enrichment method for next-generation sequencing."[19]

100. Defendants' Accused Products "obtain[] a nucleic acid fragment ligated to a partial duplex adaptor, wherein the nucleic acid fragment comprises a nucleic acid sequence of interest, wherein the partial duplex adaptor comprises a first adaptor sequence, and wherein the partial duplex adaptor comprises a first strand and a second strand, wherein the first strand is longer than the second strand." For example, in the Accused Products, the protocol requires a nucleic acid

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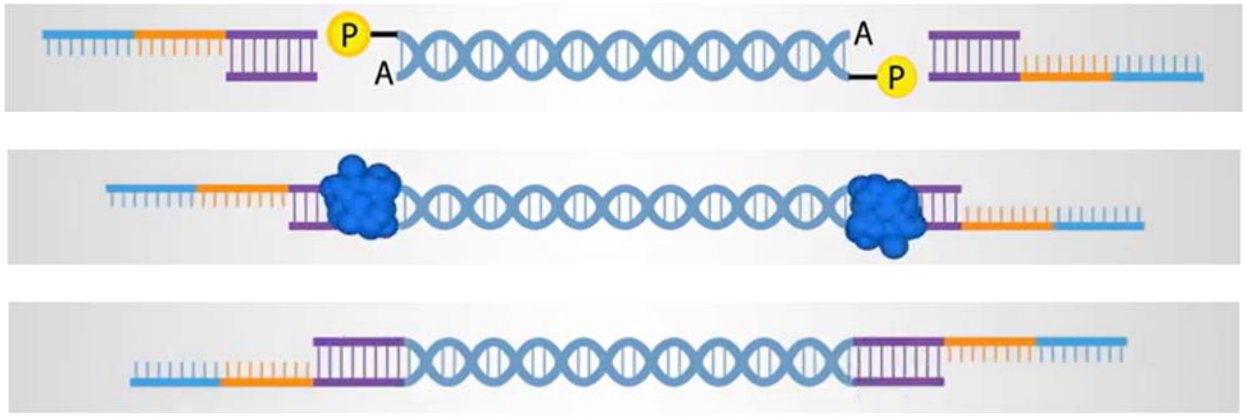
VariantPlex Protocol for Illumina; Invitae FusionPlex Protocol for Illumina; Invitae LiquidPlex Protocol for Illumina; IDT VariantPlex Protocol for Illumina; IDT FusionPlex Protocol for Illumina; IDT LiquidPlex Protocol for Illumina.

[18] *See* Archer VariantPlex-HS/HGC Protocol for Illumina, page 3 "Overview"; Archer FusionPlex Protocol for Illumina, page 4 "Overview"; Archer LiquidPlex Protocol for Illumina, page 4 "Overview"; "Invitae Personalized Cancer Monitoring", https://nymacgenetics.org/wp-content/uploads/2022/03/Personalized-Cancer-Monitoring-PCM.PDF.pdf; Zheng Z, Liebers M, Zhelyazkova B et al. Anchored multiplex PCR for targeted next-generation sequencing. Nat Med 2014; 20: 1479-1484; Invitae FusionPlex Protocol for Illumina, page 4 "Overview"; Invitae LiquidPlex Protocol for Illumina, page 4 "Overview"; IDT VariantPlex Protocol for Illumina, page 3 "Overview"; IDT FusionPlex Protocol for Illumina, page 3 "Overview"; IDT LiquidPlex Protocol for Illumina, page 3 "Overview."

[19] *See* Archer VariantPlex-HS/HGC Protocol for Illumina, page 3 "Overview"; Archer FusionPlex Protocol for Illumina, page 4 "Overview"; Archer LiquidPlex Protocol for Illumina, page 4 "Overview"; Invitae VariantPlex Protocol for Illumina, page 4 "Overview"; Invitae FusionPlex Protocol for Illumina, page 4 "Overview"; Invitae LiquidPlex Protocol for Illumina, page 4 "Overview"; IDT VariantPlex Protocol for Illumina, page 3 "Overview"; IDT FusionPlex Protocol for Illumina, page 3 "Overview"; IDT LiquidPlex Protocol for Illumina, page 3 "Overview."

fragment of interest to be ligated to a partial duplex adaptor.[20] Specifically, a first adaptor (below in blue, orange, and purple[21]) is ligated to the nucleic acid fragment of interest.



101. As shown in the below diagram (a blown-up version of the adaptor shown above[22]), the adaptors that are used are partial duplex adaptors: they are double stranded. In addition, one

[20] *See* Archer VariantPlex-HS/HGC Protocol for Illumina, pages 11-14 "Protocol Step 3-5"; *see also* Archer FusionPlex Protocol for Illumina, pages 16-19 "Protocol Step 6-8"; Archer LiquidPlex Protocol for Illumina, pages 13-16 "Protocol Step 2-4"; Invitae VariantPlex Protocol for Illumina, pages 13-17 "Protocol Step 3-5"; Invitae FusionPlex Protocol for Illumina, pages 16-19 "Protocol Step 6-8"; Invitae LiquidPlex Protocol for Illumina, pages 13-16 "Protocol Step 2-4"; IDT VariantPlex Protocol for Illumina, pages 13-14 "Protocol Step 2-3"; IDT FusionPlex Protocol for Illumina, pages 19-23 "Protocol Step 6-8"; IDT LiquidPlex Protocol for Illumina, pages 14-18 "Protocol Step 2-4."

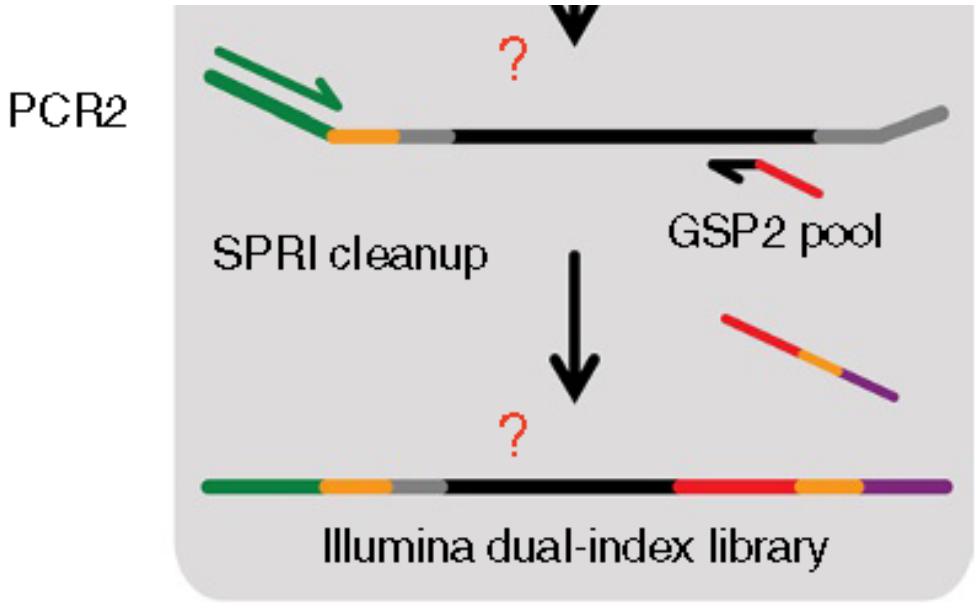
[21] *See* "VariantPlex Anchored Multiplex PCR AMP," DNA Chemistry, https://web.archive.org/web/20200811120340/https://archerdx.com/technology-platform/technology/; ArcherDX, LLC., *VariantPlex™ Anchored Multiplex PCR AMP™*, YouTube (Aug. 9, 2019), https://www.youtube.com/watch?v=Af2dSH5YMt4&t=4s; "VariantPlex Anchored Multiplex PCR AMP," DNA Chemistry, https://archerdx.com/technology-platform/technology/; "FusionPlex Anchored Multiplex PCR AMP," RNA Chemistry, https://archerdx.com/technology-platform/technology/.

[22] *See* "VariantPlex Anchored Multiplex PCR AMP," DNA Chemistry, https://web.archive.org/web/20200811120340/https://archerdx.com/technology-platform/technology/; ArcherDX, LLC., *VariantPlex™ Anchored Multiplex PCR AMP™*, YouTube (Aug. 9, 2019), https://www.youtube.com/watch?v=Af2dSH5YMt4&t=4s; "VariantPlex Anchored Multiplex PCR AMP," DNA Chemistry, https://archerdx.com/technology-platform/technology/; "FusionPlex Anchored Multiplex PCR AMP," RNA Chemistry, https://archerdx.com/technology-platform/technology/.

strand is longer than the other, creating a partial overhang shown in blue and orange in the below diagram.

102. Defendants' Accused Products further "anneal[] one or more oligonucleotides in solution to the nucleic acid sequence of interest in the nucleic acid fragment ligated to the partial duplex adaptor, wherein the one or more oligonucleotides comprise a 3′ portion with at least 10 bases designed to be complementary to the nucleic acid sequence of interest and a 5′ tail portion comprising a second adaptor sequence that is non-complementary to the nucleic acid sequence of interest." For example, the Accused Products obtain genetic fragments that are ligated to a partial duplex adaptor. Thereafter, the Accused Products anneal oligonucleotides to the sequence of interest in the nucleic acid fragment ligated to the partial duplex adaptor.[23]

[23] *See* Archer VariantPlex HGC v2 Protocol for Illumina, pages 14-15 "Steps 6-7"; Archer FusionPlex Protocol for Illumina, page 18-21 "Steps 9-10"; Archer LiquidPlex Protocol for Illumina, pages 16-18 "Steps 5-6"; Invitae VariantPlex Protocol for Illumina, pages 17-19 "Steps 6-7"; Invitae FusionPlex Protocol for Illumina, pages 21-23 "Steps 9-10"; Invitae LiquidPlex Protocol for Illumina, pages 16-18 "Steps 5-6"; IDT VariantPlex Protocol for Illumina, pages 15-18 "Steps 4-5"; IDT FusionPlex Protocol for Illumina, pages 23-26 "Steps 9-10: Second PCR"; IDT LiquidPlex Protocol for Illumina, pages 19-22 "Steps 5-6"; Invitae Personalized Cancer Monitoring"; https://nymacgenetics.org/wp-content/uploads/2022/03/Personalized-Cancer-Monitoring-PCM.PDF.pdf.



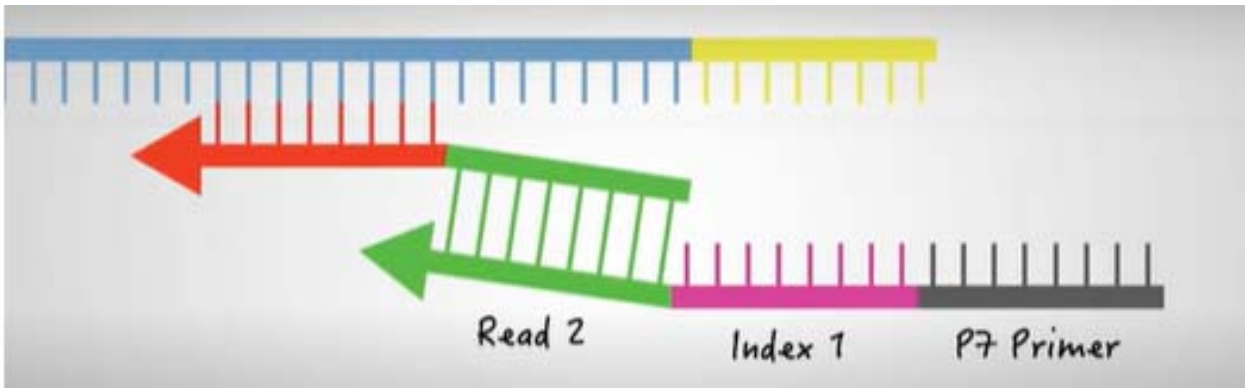
103. In the Accused Products, the annealed oligonucleotides (shown above as "GSP2"[24]) comprise a second adaptor sequence and a 3′ sequence that is complementary to the nucleic acid sequence of interest. As shown above, the black section is the portion complementary to the nucleic acid sequence of interest (in the figure below,[25] the complement is shown in red). This 3′ complement has at least 10 bases.[26] The annealed oligonucleotides also have a 5′ tail portion that

[24] *See* Zheng Z, Liebers M, Zhelyazkova B et al. Anchored multiplex PCR for targeted next-generation sequencing. Nat Med 2014; 20: 1479-1484.

[25] *See* "VariantPlex Anchored Multiplex PCR AMP," DNA Chemistry, https://web.archive.org/web/20200811120340/https://archerdx.com/technology-platform/technology/; ArcherDX, LLC., *VariantPlex™ Anchored Multiplex PCR AMP™*, YouTube (Aug. 9, 2019), https://www.youtube.com/watch?v=Af2dSH5YMt4&t=4s; "FusionPlex Anchored Multiplex PCR AMP," RNA Chemistry, https://web.archive.org/web/20200811120340/https://archerdx.com/technology-platform/technology/; ArcherDX, LLC., *FusionPlex™ Anchored Multiplex PCR AMP™*, YouTube (Aug. 9, 2019), https://www.youtube.com/watch?v=cHjKsgbmIsY; "VariantPlex Anchored Multiplex PCR AMP," DNA Chemistry, https://archerdx.com/technology-platform/technology/.

[26] *See* "VariantPlex Anchored Multiplex PCR AMP," DNA Chemistry, https://web.archive.org/web/20200811120340/https://archerdx.com/technology-platform/technology/; ArcherDX, LLC., *VariantPlex™ Anchored Multiplex PCR AMP™*, YouTube (Aug. 9, 2019), https://www.youtube.com/watch?v=Af2dSH5YMt4&t=4s; Zheng Z, Liebers M, Zhelyazkova B et al. Anchored multiplex PCR for targeted next-generation sequencing.

is non-complementary to the nucleic acid sequence of interest (see the red element after the black sequence in the figure above). This 5′ tail portion is again shown in the figure below (see the green element after the red sequence).



104. In the Accused Products, the 3′ portion comprises at least 10 bases complement to the target sequence of interest. For example, on information and belief, the base length of the complementary oligonucleotide is more than 10 bases given the temperature required at the annealing step of the process (68°C or 65°C).[27]

105. Defendants' Accused Products also "extend[] one or more oligonucleotides annealed to the nucleic acid sequence of interest in the nucleic acid fragment ligated to the partial duplex adaptor with a polymerase, thereby generating one or more oligonucleotide extension products comprising sequence complementary to the first adaptor sequence at a first end, sequence

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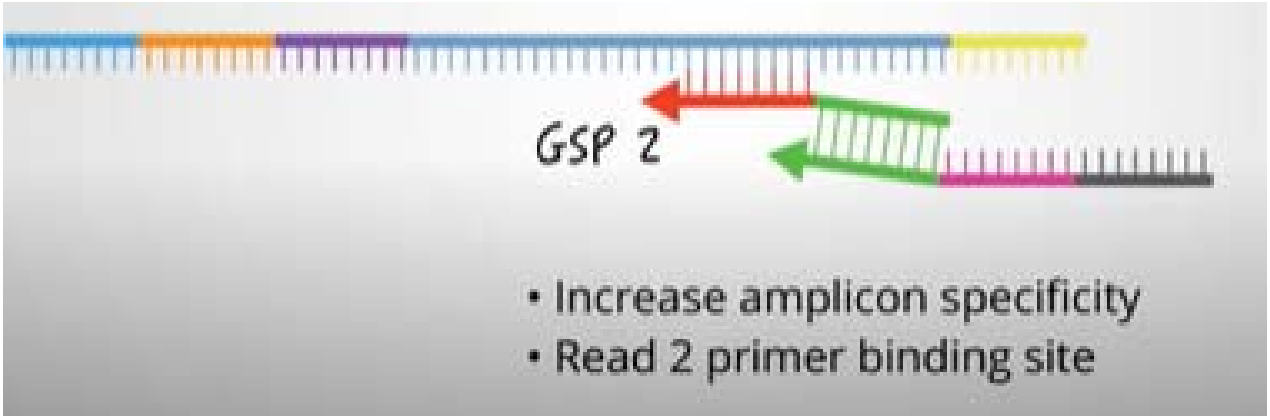
Nat Med 2014; 20: 1479-1484; "VariantPlex Anchored Multiplex PCR AMP," DNA Chemistry, https://archerdx.com/technology-platform/technology/; "FusionPlex Anchored Multiplex PCR AMP," RNA Chemistry, https://archerdx.com/technology-platform/technology/.

[27] The temperature in the annealing step is typically within 5°C of the melting temperature (Tm), the temperature at which half of the DNA is unbound from the other half of the DNA. In a PCR reaction, the Tm is based on the nucleotide content and length of the primer, as each nucleotide contributes additional hydrogen bonds which must be broken by heating to allow the primers to separate from the DNA. Each base adds ~2-4°C to the Tm. As a result, the number of nucleotides must be greater than 10 bases. *See* ThermoFischer Scientific "PCR Primer Design Tips," https://www.thermofisher.com/blog/behindthebench/pcr-primer-design-tips/; Sigma Aldrich "Oligonucleotide Melting Temperature," https://www.sigmaaldrich.com/US/en/technical-documents/protocol/genomics/pcr/oligos-melting-temp.

complementary to the nucleic acid sequence of interest, and the second adaptor sequence at a second end." For example, the Accused Products extend the one or more oligonucleotides annealed to the sequence of interest. As shown below,[28] the extension happens through the red arrow in the diagram. This extension is accomplished by using a polymerase found in the reaction mixture.[29]

[28] *See* "VariantPlex Anchored Multiplex PCR AMP," DNA Chemistry, https://web.archive.org/web/20200811120340/https://archerdx.com/technology-platform/technology/; ArcherDX, LLC., *VariantPlex™ Anchored Multiplex PCR AMP™*, YouTube (Aug. 9, 2019), https://www.youtube.com/watch?v=Af2dSH5YMt4&t=4s; "FusionPlex Anchored Multiplex PCR AMP," RNA Chemistry, https://web.archive.org/web/20200811120340/https://archerdx.com/technology-platform/technology/; ArcherDX, LLC., *FusionPlex™ Anchored Multiplex PCR AMP™*, YouTube (Aug. 9, 2019), https://www.youtube.com/watch?v=cHjKsgbmIsY; "VariantPlex Anchored Multiplex PCR AMP," DNA Chemistry, https://archerdx.com/technology-platform/technology/.

[29] *See* "VariantPlex Anchored Multiplex PCR AMP," DNA Chemistry, https://web.archive.org/web/20200811120340/https://archerdx.com/technology-platform/technology/; ArcherDX, LLC., *VariantPlex™ Anchored Multiplex PCR AMP™*, YouTube (Aug. 9, 2019), https://www.youtube.com/watch?v=Af2dSH5YMt4&t=4s; Archer VariantPlex HGC v2 Protocol for Illumina, page 15 "Step 7: Second PCR"; "FusionPlex Anchored Multiplex PCR AMP," RNA Chemistry, https://web.archive.org/web/20200811120340/https://archerdx.com/technology-platform/technology/; ArcherDX, LLC., *FusionPlex™ Anchored Multiplex PCR AMP™*, YouTube (Aug. 9, 2019), https://www.youtube.com/watch?v=cHjKsgbmIsY; "VariantPlex Anchored Multiplex PCR AMP," DNA Chemistry, https://archerdx.com/technology-platform/technology/; "FusionPlex Anchored Multiplex PCR AMP," RNA Chemistry, https://archerdx.com/technology-platform/technology/; Archer FusionPlex Protocol for Illumina, page 21 "Step 10: Second PCR"; Archer LiquidPlex Protocol for Illumina, pages 17-18 "Step 6: Second PCR"; "Invitae Personalized Cancer Monitoring", https://nymacgenetics.org/wp-content/uploads/2022/03/Personalized-Cancer-Monitoring-PCM.PDF.pdf; Zheng Z, Liebers M, Zhelyazkova B et al. Anchored multiplex PCR for targeted next-generation sequencing. Nat Med 2014; 20: 1479-1484; Invitae VariantPlex Protocol for Illumina, pages 18-19 "Step 7: Second PCR"; Invitae FusionPlex Protocol for Illumina, pages 21-23 "Step 10: Second PCR"; Invitae LiquidPlex Protocol for Illumina, pages 17-18 "Step 6: Second PCR"; IDT VariantPlex Protocol for Illumina, pages 16-18 "Step 5: Second PCR"; IDT FusionPlex Protocol for Illumina, pages 25-26 "Step 10: Second PCR"; IDT LiquidPlex Protocol for Illumina, pages 20-22 "Step 6: Second PCR."



106. The result of this extension is an oligonucleotide extension product comprising a sequence complementary to the first adaptor at one end (shown below,[30] annotated red box; image adapted from source image to crop out the amplification primer incorporated in the next step), a sequence complementary to the nucleic acid sequence of interest (annotated green box; image adapted from source image to crop out the amplification primer incorporated in the next step), and the second adaptor at the other end (annotated blue box; image adapted from source image to crop out the amplification primer incorporated in the next step).[31]

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[30] *See* "VariantPlex Anchored Multiplex PCR AMP," DNA Chemistry, https://web.archive.org/web/20200811120340/https://archerdx.com/technology-platform/technology/; ArcherDX, LLC., *VariantPlex™ Anchored Multiplex PCR AMP™*, YouTube (Aug. 9, 2019), https://www.youtube.com/watch?v=Af2dSH5YMt4&t=4s; "FusionPlex Anchored Multiplex PCR AMP," RNA Chemistry, https://web.archive.org/web/20200811120340/https://archerdx.com/technology-platform/technology/; ArcherDX, LLC., *FusionPlex™ Anchored Multiplex PCR AMP™*, YouTube (Aug. 9, 2019), https://www.youtube.com/watch?v=cHjKsgbmIsY.

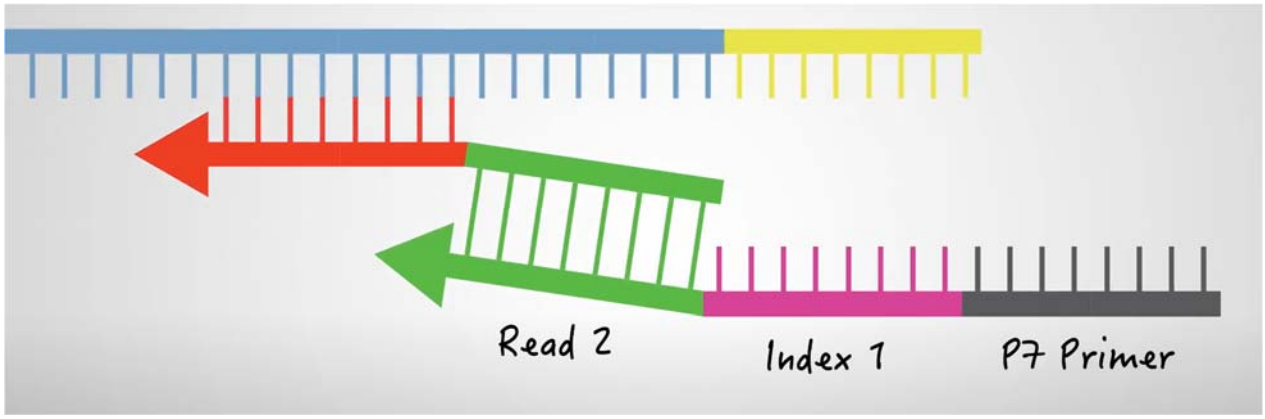
[31] *See* "VariantPlex Anchored Multiplex PCR AMP," DNA Chemistry, https://web.archive.org/web/20200811120340/https://archerdx.com/technology-platform/technology/; ArcherDX, LLC., *VariantPlex™ Anchored Multiplex PCR AMP™*, YouTube (Aug. 9, 2019), https://www.youtube.com/watch?v=Af2dSH5YMt4&t=4s; *see also* Archer VariantPlex HGC v2 Protocol for Illumina, page 15 "Step 7: Second PCR"; "FusionPlex Anchored Multiplex PCR AMP," RNA Chemistry, https://web.archive.org/web/20200811120340/https://archerdx.com/technology-platform/technology/; ArcherDX, LLC., *FusionPlex™ Anchored Multiplex PCR AMP™*, YouTube (Aug. 9, 2019), https://www.youtube.com/watch?v=cHjKsgbmIsY; Archer FusionPlex Protocol for Illumina, page 21 "Step 10: Second PCR"; Archer LiquidPlex Protocol for Illumina,

106. Defendants' Accused Products "amplify[] the one or more oligonucleotide extension products using a first primer that anneals to a complement of the first adaptor sequence and a second primer that anneals at its 3′ end to a complement of the second adaptor sequence to enrich for the nucleic acid sequence of interest, wherein products of the amplifying comprise a 3′ end with sequence complementary to a sequence on a surface." For example, the Accused Products are amplified by a primer (shown below in the first image,[32] where the primer is depicted in green, pink, and grey) that anneals at its 3′ end to the sequence complementary to the second

pages 17-18 "Step 6: Second PCR"; "VariantPlex Anchored Multiplex PCR AMP," DNA Chemistry, https://archerdx.com/technology-platform/technology/; "FusionPlex Anchored Multiplex PCR AMP," RNA Chemistry, https://archerdx.com/technology-platform/technology/; Invitae VariantPlex Protocol for Illumina, pages 18-19 "Step 7: Second PCR"; Invitae FusionPlex Protocol for Illumina, pages 21-23 "Step 10: Second PCR"; Invitae LiquidPlex Protocol for Illumina, pages 17-18 "Step 6: Second PCR"; IDT VariantPlex Protocol for Illumina, pages 16-18 "Step 5: Second PCR"; IDT FusionPlex Protocol for Illumina, pages 25-26 "Step 10: Second PCR"; IDT LiquidPlex Protocol for Illumina, pages 20-22 "Step 6: Second PCR."

[32] *See* "VariantPlex Anchored Multiplex PCR AMP," DNA Chemistry, https://web.archive.org/web/20200811120340/https://archerdx.com/technology-platform/technology/; ArcherDX, LLC., *VariantPlex™ Anchored Multiplex PCR AMP™*, YouTube (Aug. 9, 2019), https://www.youtube.com/watch?v=Af2dSH5YMt4&t=4s; "FusionPlex Anchored Multiplex PCR AMP," RNA Chemistry, https://web.archive.org/web/20200811120340/https://archerdx.com/technology-platform/technology/; ArcherDX, LLC., *FusionPlex™ Anchored Multiplex PCR AMP™*, YouTube (Aug. 9, 2019), https://www.youtube.com/watch?v=cHjKsgbmIsY; "VariantPlex Anchored Multiplex PCR AMP," DNA Chemistry, https://archerdx.com/technology-platform/technology/; "FusionPlex Anchored Multiplex PCR AMP," RNA Chemistry, https://archerdx.com/technology-platform/technology/.

adaptor sequence and a primer complementary to the first adaptor sequence (the second panel below,[33] the primer is shown in light blue).[34]



[33] *See* "VariantPlex Anchored Multiplex PCR AMP," DNA Chemistry, https://web.archive.org/web/20200811120340/https://archerdx.com/technology-platform/technology/; ArcherDX, LLC., *VariantPlex™ Anchored Multiplex PCR AMP™*, YouTube (Aug. 9, 2019), https://www.youtube.com/watch?v=Af2dSH5YMt4&t=4s; "FusionPlex Anchored Multiplex PCR AMP," RNA Chemistry, https://web.archive.org/web/20200811120340/https://archerdx.com/technology-platform/technology/; ArcherDX, LLC., *FusionPlex™ Anchored Multiplex PCR AMP™*, YouTube (Aug. 9, 2019), https://www.youtube.com/watch?v=cHjKsgbmIsY; "VariantPlex Anchored Multiplex PCR AMP," DNA Chemistry, https://archerdx.com/technology-platform/technology/; "FusionPlex Anchored Multiplex PCR AMP," RNA Chemistry, https://archerdx.com/technology-platform/technology/.

[34] *See* "VariantPlex Anchored Multiplex PCR AMP," DNA Chemistry, https://web.archive.org/web/20200811120340/https://archerdx.com/technology-platform/technology/; ArcherDX, LLC., *VariantPlex™ Anchored Multiplex PCR AMP™*, YouTube (Aug. 9, 2019), https://www.youtube.com/watch?v=Af2dSH5YMt4&t=4s; "FusionPlex Anchored Multiplex PCR AMP," RNA Chemistry, https://web.archive.org/web/20200811120340/https://archerdx.com/technology-platform/technology/; ArcherDX, LLC., *FusionPlex™ Anchored Multiplex PCR AMP™*, YouTube (Aug. 9, 2019), https://www.youtube.com/watch?v=cHjKsgbmIsY; "VariantPlex Anchored Multiplex PCR AMP," DNA Chemistry, https://archerdx.com/technology-platform/technology/; "FusionPlex Anchored Multiplex PCR AMP," RNA Chemistry, https://archerdx.com/technology-platform/technology/; Archer VariantPlex HGC v2 Protocol for Illumina, page 15 "Step 7: Second PCR"; Archer FusionPlex Protocol for Illumina, page 21 "Step 10: Second PCR"; Archer LiquidPlex Protocol for Illumina, pages 17-18 "Step 6: Second PCR"; Invitae VariantPlex Protocol for Illumina, pages 18-19 "Step 7: Second PCR"; Invitae FusionPlex Protocol for Illumina, pages 21-23 "Step 10: Second PCR"; Invitae LiquidPlex Protocol for Illumina, pages 17-18 "Step 6: Second PCR"; IDT VariantPlex Protocol for Illumina, pages 16-18 "Step 5: Second PCR"; IDT FusionPlex Protocol for Illumina, pages 25-26 "Step 10: Second PCR"; IDT LiquidPlex Protocol for Illumina, pages 20-22 "Step 6: Second PCR."

107. The result is an enriched population consisting of the oligonucleotide extension product comprising a sequence complementary to the first adaptor at one end (shown below,[35] annotated red box), a sequence complementary to the nucleic acid sequence of interest (annotated green box), and the second adaptor at the other end (annotated blue box).[36]

[35] *See* "VariantPlex Anchored Multiplex PCR AMP," DNA Chemistry, https://web.archive.org/web/20200811120340/https://archerdx.com/technology-platform/technology/; ArcherDX, LLC., *VariantPlex™ Anchored Multiplex PCR AMP™*, YouTube (Aug. 9, 2019), https://www.youtube.com/watch?v=Af2dSH5YMt4&t=4s; "FusionPlex Anchored Multiplex PCR AMP," RNA Chemistry, https://web.archive.org/web/20200811120340/https://archerdx.com/technology-platform/technology/; ArcherDX, LLC., *FusionPlex™ Anchored Multiplex PCR AMP™*, YouTube (Aug. 9, 2019), https://www.youtube.com/watch?v=cHjKsgbmIsY.

[36] *See* "VariantPlex Anchored Multiplex PCR AMP," DNA Chemistry, https://web.archive.org/web/20200811120340/https://archerdx.com/technology-platform/technology/; ArcherDX, LLC., *VariantPlex™ Anchored Multiplex PCR AMP™*, YouTube (Aug. 9, 2019), https://www.youtube.com/watch?v=Af2dSH5YMt4&t=4s; "FusionPlex Anchored Multiplex PCR AMP," RNA Chemistry, https://web.archive.org/web/20200811120340/https://archerdx.com/technology-platform/technology/; ArcherDX, LLC., *FusionPlex™ Anchored Multiplex PCR AMP™*, YouTube (Aug. 9, 2019), https://www.youtube.com/watch?v=cHjKsgbmIsY; "VariantPlex Anchored Multiplex PCR AMP," DNA Chemistry, https://archerdx.com/technology-platform/technology/; "FusionPlex Anchored Multiplex PCR AMP," RNA Chemistry, https://archerdx.com/technology-platform/technology/; Archer VariantPlex HGC v2 Protocol for Illumina, page 15 "Step 7: Second PCR"; Archer FusionPlex Protocol for Illumina, page 21 "Step 10: Second PCR"; Archer LiquidPlex Protocol for Illumina, pages 17-18 "Step 6: Second PCR"; Invitae VariantPlex Protocol for Illumina, pages 18-19 "Step 7: Second PCR"; Invitae FusionPlex Protocol for Illumina, pages 21-23 "Step 10: Second PCR"; Invitae LiquidPlex Protocol for Illumina, pages 17-18 "Step 6: Second PCR"; IDT VariantPlex Protocol for Illumina, pages 16-18

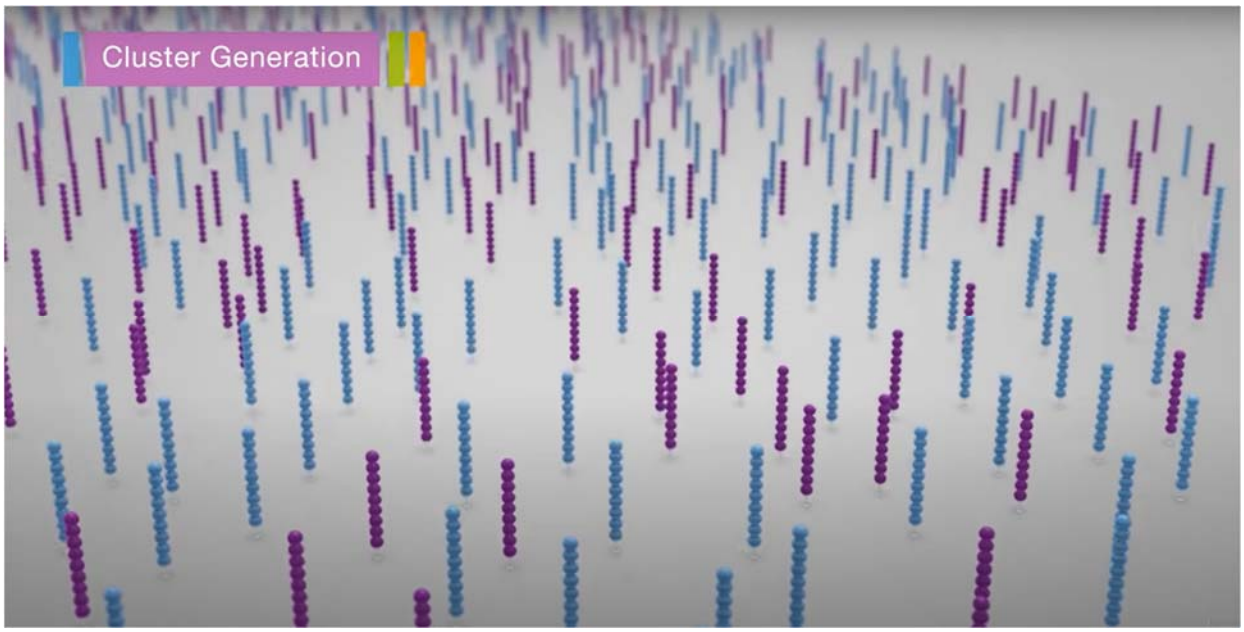
108. Defendants' Accused Products also "anneal[] a strand of the products of the amplifying to the sequence on the surface using the 3′ end with sequence complementary to the sequence on the surface." For example, the Accused Products then require use of next generation sequencing platforms. In connection with this, the kit protocols require that preparations are made to use the MiSeq or Ion Torrent platforms. These preparations are well-known and specifically mandated by the Accused Products. For example, the Accused Products instruct the user to load the sample into "the appropriate well of the MiSeq cartridge."[37]

109. Use of either sequencing platform requires "annealing a strand of the products of the amplifying to the sequence on the surface using the 3′ end with sequence complementary to the sequence on the surface." For example, the MiSeq platform employs a flow cell constituting a surface covered with short nucleotide fragments complementary to both adaptors that serve as

"Step 5: Second PCR"; IDT FusionPlex Protocol for Illumina, pages 25-26 "Step 10: Second PCR"; IDT LiquidPlex Protocol for Illumina, pages 20-22 "Step 6: Second PCR."

[37] *See* Archer VariantPlex-HS/HGC Protocol for Illumina, pages 17-18 "Quantify, Normalize and Sequence"; Archer FusionPlex Protocol for Illumina, pages 23-25 "Quantify, Normalize and Sequence"; Archer FusionPlex Protocol for Ion Torrent, page 21 "Quantify, Normalize and Sequence"; Archer LiquidPlex Protocol for Illumina, pages 19-21 "Quantify, Normalize and Sequence"; Invitae VariantPlex Protocol for Illumina, page 19 "Quantify, Normalize and Sequence"; Invitae FusionPlex Protocol for Illumina, page 23 "Quantify, Normalize and Sequence"; Invitae LiquidPlex Protocol for Illumina, page 18 "Quantify, Normalize and Sequence"; IDT VariantPlex Protocol for Illumina, page 19 "Quantify, Normalize and Sequence"; IDT FusionPlex Protocol for Illumina, page 27 "Quantify, Normalize and Sequence"; IDT LiquidPlex Protocol for Illumina, page 23 "Quantify, Normalize and Sequence"; IDT Protocol Quantify, Normalize, and Sequence for Illumina.

anchors (the blue and purple lines depicted below,[38] each color represents a different complementary adaptor sequence).

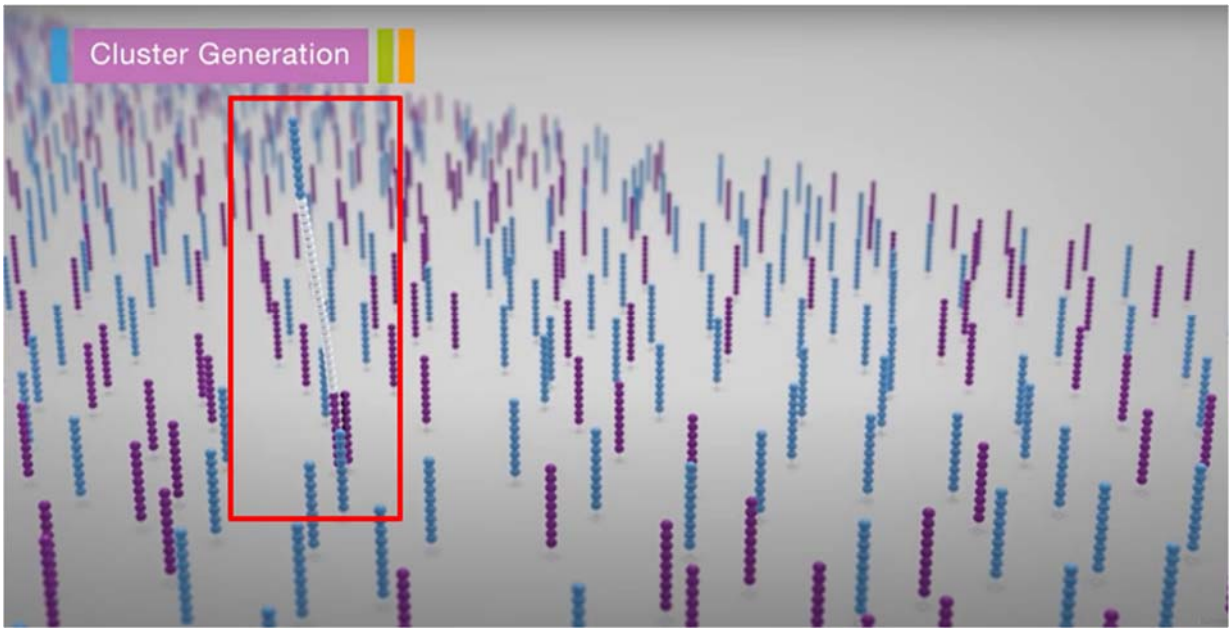


The target fragment molecule amplified in the prior step is first added to the flow cell, wherein the samples bind to the surface of the flow cell by annealing to the anchor complementary to the adaptor sequence (the single blue-white-purple line in the red box shown below,[39] see the purple region aligned with the purple primer). As PCR generates amplified products from both adaptors, a subset of the products of the amplification step will anneal to the sequence on the surface of the flow cell using a 3′ sequence complimentary to the sequence on the surface.[40]

[38] *See* "Sequencing by Synthesis (SBS) Chemistry," https://www.illumina.com/science/technology/next-generation-sequencing/sequencing-technology.html.

[39] *See* "Sequencing by Synthesis (SBS) Chemistry," https://www.illumina.com/science/technology/next-generation-sequencing/sequencing-technology.html.

[40] *See* "Sequencing by Synthesis (SBS) Chemistry," https://www.illumina.com/science/technology/next-generation-sequencing/sequencing-technology.html.



110. Defendants' Accused Products "sequenc[e] the amplified products comprising the enriched nucleic acid sequence of interest on a massively parallel sequencing platform." For example, the Accused Products direct the user to sequence samples on a massively parallel sequencing platform.[41,42]

111. As such, Defendants' Accused Products infringe at least claim 1 of the '012 patent.

[41] *See* Archer FusionPlex Protocol for Ion Torrent, page 21 "Quantify, Normalize, and Sequence"; Archer VariantPlex-HS/HGC Protocol for Illumina, pages 17-18 "Quantify, Normalize and Sequence"; Archer FusionPlex Protocol for Illumina, pages 23-25 "Quantify, Normalize and Sequence"; Archer LiquidPlex Protocol for Illumina, pages 17-18 "Step 6: Second PCR"; Illumina MiSeq System Guide; MiSeq System Specification Sheet; "; Invitae VariantPlex Protocol for Illumina, page 19 "Quantify, Normalize and Sequence"; Invitae FusionPlex Protocol for Illumina, page 23 "Quantify, Normalize and Sequence"; Invitae LiquidPlex Protocol for Illumina, page 18 "Quantify, Normalize and Sequence"; IDT VariantPlex Protocol for Illumina, page 19 "Quantify, Normalize and Sequence"; IDT FusionPlex Protocol for Illumina, page 27 "Quantify, Normalize and Sequence"; IDT LiquidPlex Protocol for Illumina, page 23 "Quantify, Normalize and Sequence"; IDT Protocol Quantify, Normalize, and Sequence for Illumina.

[42] The PCM kits use "NGS powered by Anchored Multiplex PCR (AMP) chemistry." NGS platforms are a type of massively parallel sequencing platform. *See* "Invitae Personalized Cancer Monitoring," https://nymacgenetics.org/wp-content/uploads/2022/03/Personalized-Cancer-Monitoring-PCM.PDF.pdf; "Introduction to NGS" What is NGS? https://www.illumina.com/science/technology/next-generation-sequencing.html.

112. Defendants further infringe at least claim 1 of the ’012 patent when the Accused Products are manufactured, used, or sold and implemented by Defendants’ customers and partners. Defendants do so by inducing and contributing to the direct infringement of the ’012 patent by Defendants’ customers and users. Customers and users of the Accused Products directly infringe the claimed methods of the ’012 patent, and at least claim 1, when they use and implement the enrichment methods and kits designed, produced, and marketed by Defendants. As set forth above, the steps of at least claim 1 are met by actions provided for and taken through the Accused Products.

113. Defendants have induced and continue to induce infringement of the ’012 patent. Defendants sell the Accused Products with instructions to end-users to perform the steps identified in the above workflows. Furthermore, Defendants distribute instruction materials, product manuals, and technical materials, and disseminate promotional/marketing materials, that describe the workflows and otherwise instruct users to use the Accused Products to infringe at least claim 1 of the ’012 patent. Defendants sell and offer for sale the Accused Products with the knowledge and specific intent that their instructions and workflows will cause users to use the kits to infringe at least claim 1 of the ’012 patent.

114. Defendants have also contributed to and continue to contribute to the infringement of at least claim 1 of the ’012 patent because they offer to sell or sell within the United States or import into the United States the Accused Products for use by users practicing the patented process of the ’012 patent. The Accused Products constitute a material part of the invention of the ’012 patent, and Defendants know the Accused Products to be especially made or especially adapted for use in infringing the ’012 patent. Furthermore, the Accused Products are not a staple article or commodity of commerce suitable for substantial noninfringing uses.

115. Defendants have committed and continue to commit acts of infringement in the United States and thereafter have sold and continue to sell the Accused Products or cause the Accused Products to be sold within and outside of the United States. Defendants' sales within and outside of the United States have resulted in harm to Tecan Genomics. Tecan Genomics brings this action to be made whole for damages that include both sales within and outside of the United States.

116. As set forth above, Defendants engaged in these activities with full knowledge that other parties' actions were infringing. This conduct makes Defendants liable for inducing and contributing to the infringement of at least claim 1 of the '012 patent.

Defendants' Infringement of the '108 Patent

117. Defendants infringe at least claim 1 of the '108 patent under at least 35 U.S.C. §§ 271(a)-(c).

118. Defendants have used and continue to use the Accused Products in a manner that directly infringes literally or under the doctrine of equivalents at least claim 1 of the '108 patent. For example, when Defendants utilize the Accused Products, they infringe at least claim 1 of the '108 patent.[43] Moreover, Defendants conduct research, development, training, and/or testing

[43] *See* "VariantPlex Anchored Multiplex PCR AMP," DNA Chemistry, https://web.archive.org/web/20200811120340/https://archerdx.com/technology-platform/technology/; ArcherDX, LLC., *VariantPlex™ Anchored Multiplex PCR AMP™*, YouTube (Aug. 9, 2019), https://www.youtube.com/watch?v=Af2dSH5YMt4&t=4s; Anchored Multiplex PCR AMP," RNA Chemistry, https://web.archive.org/web/20200811120340/https://archerdx.com/technology-platform/technology/; ArcherDX, LLC., *FusionPlex™ Anchored Multiplex PCR AMP™*, YouTube (Aug. 9, 2019), https://www.youtube.com/watch?v=cHjKsgbmIsY; "VariantPlex Anchored Multiplex PCR AMP," DNA Chemistry, https://archerdx.com/technology-platform/technology/; "FusionPlex Anchored Multiplex PCR AMP," RNA Chemistry, https://archerdx.com/technology-platform/technology/; Archer VariantPlex-HS/HGC Protocol for Illumina; Archer FusionPlex Protocol for Illumina; Archer LiquidPlex Protocol for Illumina; Invitae VariantPlex Protocol for Illumina; Invitae FusionPlex Protocol for Illumina; Invitae

activities relating to the launch, marketing, and sale of the Accused Products, which directly infringe at least claim 1 of the '108 patent.[44] Defendants also directly infringe at least claim 1 of the '108 patent by using the Accused Products in the United States when they instruct and train end-users on the use of the Accused Products at locations throughout the United States by demonstrating how to use the products, as well as when Defendants make, offer to sell, and sell the Accused Products.[45]

LiquidPlex Protocol for Illumina; IDT VariantPlex Protocol for Illumina; IDT FusionPlex Protocol for Illumina; IDT LiquidPlex Protocol for Illumina.

[44] *See* BioSpace, Enzymatics Inc. Launches Archer Targeted Sequencing Technology To Dramatically Enhance Gene Mutation Identification And Discovery, https://www.biospace.com/article/releases/enzymatics-inc-launches-archer-and-0153-targeted-sequencing-technology-to-dramatically-enhance-gene-mutation-identification-and-discovery-/ (Feb. 14, 2014); Businesswire, ArcherDX Launches VariantPlex™ Product Line For DNA-based Targeted Sequencing, https://www.businesswire.com/news/home/20150529005043/en/ArcherDX-Launches-VariantPlex%E2%84%A2-Product-Line-For-DNA-based-Targeted-Sequencing (May 29, 2015); Cision, PR Newswire ArcherDX dives into liquid biopsy research with Reveal ctDNA™ 28 assay, https://www.prnewswire.com/news-releases/archerdx-dives-into-liquid-biopsy-research-with-reveal-ctdna-28-assay-300332446.html (Sept. 22, 2016); Archer, LiquidPlex ctDNR 28, https://web.archive.org/web/20200920070216/https://archerdx.com/research-products/solid-tumor-research/liquidplex/ (Sept. 20, 2020); Invitae Press Releases, Invitae Launches Full Access to its Liquid-Based Personalized Cancer Monitoring Platform to Help Detect Disease Earlier, https://ir.invitae.com/news-and-events/press-releases/press-release-details/2022/Invitae-Launches-Full-Access-to-its-Liquid-Based-Personalized-Cancer-Monitoring-Platform-to-Help-Detect-Disease-Earlier/default.aspx (Mar. 17, 2022); "VariantPlex Anchored Multiplex PCR AMP," DNA Chemistry, https://archerdx.com/technology-platform/technology/; "FusionPlex Anchored Multiplex PCR AMP," RNA Chemistry, https://archerdx.com/technology-platform/technology/.

[45] *See* "VariantPlex Anchored Multiplex PCR AMP," DNA Chemistry, https://web.archive.org/web/20200811120340/https://archerdx.com/technology-platform/technology/; ArcherDX, LLC., *VariantPlex™ Anchored Multiplex PCR AMP™*, YouTube (Aug. 9, 2019), https://www.youtube.com/watch?v=Af2dSH5YMt4&t=4s; Anchored Multiplex PCR AMP," RNA Chemistry, https://web.archive.org/web/20200811120340/https://archerdx.com/technology-platform/technology/; ArcherDX, LLC., *FusionPlex™ Anchored Multiplex PCR AMP™*, YouTube (Aug. 9, 2019), https://www.youtube.com/watch?v=cHjKsgbmIsY; "VariantPlex Anchored Multiplex PCR AMP," DNA Chemistry, https://archerdx.com/technology-platform/technology/; "FusionPlex Anchored Multiplex PCR AMP," RNA Chemistry,

119. To the extent the preamble of claim 1 is limiting, Defendants' Accused Products employ "a method for sequencing an enriched nucleic acid sequence of interest." For example, the Accused Products are used to generate target-enriched libraries for NGS by using a combination of gene-specific primers and partial duplex universal adaptors. The kit protocols of the Accused Products state their intended use is "to produce high-complexity libraries for use with . . . next-generation sequencing (NGS) instruments."[46] The kit protocols of the Accused Products also recite AMP technology as the "Test Principle" underlying their respective kits. AMP technology provides "a rapid target enrichment method for next-generation sequencing."[47]

120. Defendants' Accused Products "anneal[] one or more oligonucleotides in solution in a reaction mixture to the nucleic acid sequence of interest in a nucleic acid fragment, wherein the reaction mixture comprises a plurality of nucleic acid fragments, wherein the nucleic acid

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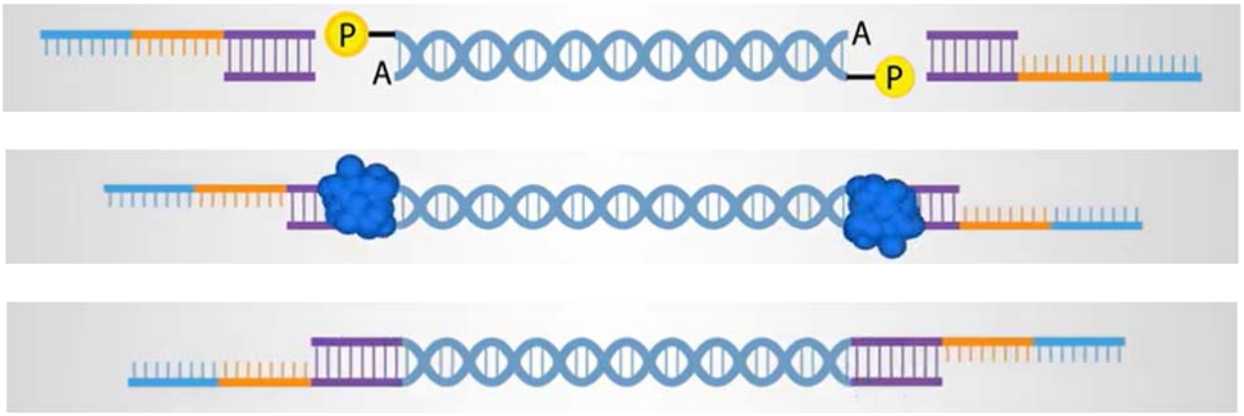
https://archerdx.com/technology-platform/technology/; Archer VariantPlex-HS/HGC Protocol for Illumina; Archer FusionPlex Protocol for Illumina; Archer LiquidPlex Protocol for Illumina; Invitae VariantPlex Protocol for Illumina; Invitae FusionPlex Protocol for Illumina; Invitae LiquidPlex Protocol for Illumina; IDT VariantPlex Protocol for Illumina; IDT FusionPlex Protocol for Illumina; IDT LiquidPlex Protocol for Illumina.

[46] *See* Archer VariantPlex-HS/HGC Protocol for Illumina, page 3 "Overview"; Archer FusionPlex Protocol for Illumina, page 4 "Overview"; Archer LiquidPlex Protocol for Illumina, page 4 "Overview"; "Invitae Personalized Cancer Monitoring", https://nymacgenetics.org/wp-content/uploads/2022/03/Personalized-Cancer-Monitoring-PCM.PDF.pdf; Zheng Z, Liebers M, Zhelyazkova B et al. Anchored multiplex PCR for targeted next-generation sequencing. Nat Med 2014; 20: 1479-1484; "VariantPlex Anchored Multiplex PCR AMP," DNA Chemistry, https://archerdx.com/technology-platform/technology/; "FusionPlex Anchored Multiplex PCR AMP," RNA Chemistry, https://archerdx.com/technology-platform/technology/; Invitae VariantPlex Protocol for Illumina, page 4 "Overview"; Invitae FusionPlex Protocol for Illumina, page 4 "Overview"; Invitae LiquidPlex Protocol for Illumina, page 4 "Overview"; IDT VariantPlex Protocol for Illumina, page 3 "Overview"; IDT FusionPlex Protocol for Illumina, page 3 "Overview"; IDT LiquidPlex Protocol for Illumina, page 3 "Overview."

[47] *See* Archer VariantPlex-HS/HGC Protocol for Illumina, page 3 "Overview"; Archer FusionPlex Protocol for Illumina, page 4 "Overview"; Archer LiquidPlex Protocol for Illumina, page 4 "Overview"; Invitae VariantPlex Protocol for Illumina, page 4 "Overview"; Invitae FusionPlex Protocol for Illumina, page 4 "Overview"; Invitae LiquidPlex Protocol for Illumina, page 4 "Overview"; IDT VariantPlex Protocol for Illumina, page 3 "Overview"; IDT FusionPlex Protocol for Illumina, page 3 "Overview"; IDT LiquidPlex Protocol for Illumina, page 3 "Overview."

fragment comprising the nucleic acid sequence of interest comprises a first adaptor sequence, wherein the one or more oligonucleotides comprise a 3′ portion with at least 10 bases designed to be complementary to the nucleic acid sequence of interest and a 5′ tail portion comprising a second adaptor sequence that is non-complementary to the nucleic acid sequence of interest."

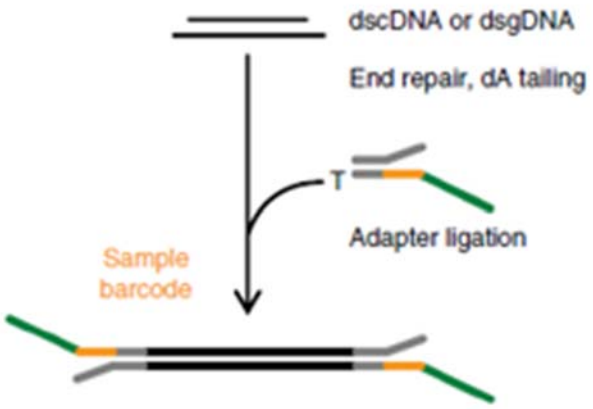
121. For example, in the Accused Products, a first adaptor is ligated to the target nucleic acid fragment.[48] As provided below,[49] a first adaptor (shown in blue, orange, and purple) is ligated to a target nucleic acid fragment.



[48] *See* Archer VariantPlex-HS/HGC Protocol for Illumina, pages 11-14 "Protocol Step 3-5"; Archer FusionPlex Protocol for Illumina, pages 16-19 "Protocol Step 6-8"; Archer LiquidPlex Protocol for Illumina, pages 13-16 "Protocol Step 2-4"; "Invitae Personalized Cancer Monitoring", https://nymacgenetics.org/wp-content/uploads/2022/03/Personalized-Cancer-Monitoring-PCM.PDF.pdf; Zheng Z, Liebers M, Zhelyazkova B et al. Anchored multiplex PCR for targeted next-generation sequencing. Nat Med 2014; 20: 1479-1484; Invitae VariantPlex Protocol for Illumina, pages 13-17 "Protocol Step 3-5"; Invitae FusionPlex Protocol for Illumina, pages 16-19 "Protocol Step 6-8"; Invitae LiquidPlex Protocol for Illumina, pages 13-16 "Protocol Step 2-4"; IDT VariantPlex Protocol for Illumina, pages 13-14 "Protocol Step 2-3"; IDT FusionPlex Protocol for Illumina, pages 19-23 "Protocol Step 6-8"; IDT LiquidPlex Protocol for Illumina, pages 14-18 "Protocol Step 2-4."

[49] *See* "VariantPlex Anchored Multiplex PCR AMP," DNA Chemistry, https://web.archive.org/web/20200811120340/https://archerdx.com/technology-platform/technology/; ArcherDX, LLC., *VariantPlex™ Anchored Multiplex PCR AMP™*, YouTube (Aug. 9, 2019), https://www.youtube.com/watch?v=Af2dSH5YMt4&t=4s; "VariantPlex Anchored Multiplex PCR AMP," DNA Chemistry, https://archerdx.com/technology-platform/technology/; "FusionPlex Anchored Multiplex PCR AMP," RNA Chemistry, https://archerdx.com/technology-platform/technology/.

122. The AMP ligation step underlying the Accused Products is shown below.[50]



123. The Accused Products anneal oligonucleotides to the sequence of interest in the nucleic acid fragment ligated to a first adaptor.[51]

[50] *See* Zheng Z, Liebers M, Zhelyazkova B et al. Anchored multiplex PCR for targeted next-generation sequencing. Nat Med 2014; 20: 1479-1484.

[51] *See* Archer VariantPlex HGC v2 Protocol for Illumina, pages 14-15 "Steps 6-7"; Archer FusionPlex Protocol for Illumina, page 18-21 "Steps 9-10"; Archer LiquidPlex Protocol for Illumina, pages 16-18 "Steps 5-6"; Invitae VariantPlex Protocol for Illumina, pages 17-19 "Steps 6-7"; Invitae FusionPlex Protocol for Illumina, pages 21-23 "Steps 9-10"; Invitae LiquidPlex Protocol for Illumina, pages 16-18 "Steps 5-6"; IDT VariantPlex Protocol for Illumina, pages 15-18 "Steps 4-5"; IDT FusionPlex Protocol for Illumina, pages 23-26 "Steps 9-10: Second PCR"; IDT LiquidPlex Protocol for Illumina, pages 19-22 "Steps 5-6"; Invitae Personalized Cancer Monitoring"; https://nymacgenetics.org/wp-content/uploads/2022/03/Personalized-Cancer-Monitoring-PCM.PDF.pdf.

124. The annealed oligonucleotides (shown above[52] as "GSP2") comprise a second adaptor sequence and a 3′ sequence that is complementary to the nucleic acid sequence of interest. As shown above,[53] the black section is the portion complementary to the nucleic acid sequence of interest (in the figure below,[54] the complement is shown in red). This 3′ complement has at least 10 bases. The annealed oligonucleotides also have a 5′ tail portion that is non-complementary to the nucleic acid sequence of interest (see the red element after the black sequence in the figure above[55]). This 5′ tail portion is again shown in the figure below[56] (see the green element after the red sequence).

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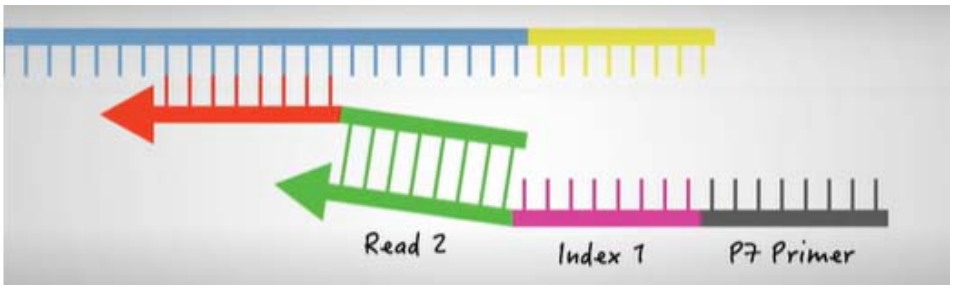
[52] *See* Zheng Z, Liebers M, Zhelyazkova B et al. Anchored multiplex PCR for targeted next-generation sequencing. Nat Med 2014; 20: 1479-1484.

[53] *See* Zheng Z, Liebers M, Zhelyazkova B et al. Anchored multiplex PCR for targeted next-generation sequencing. Nat Med 2014; 20: 1479-1484.

[54] *See* "VariantPlex Anchored Multiplex PCR AMP," DNA Chemistry, https://web.archive.org/web/20200811120340/https://archerdx.com/technology-platform/technology/; ArcherDX, LLC., *VariantPlex™ Anchored Multiplex PCR AMP™*, YouTube (Aug. 9, 2019), https://www.youtube.com/watch?v=Af2dSH5YMt4&t=4s; Zheng Z, Liebers M, Zhelyazkova B et al. Anchored multiplex PCR for targeted next-generation sequencing. Nat Med 2014; 20: 1479-1484; "FusionPlex Anchored Multiplex PCR AMP," RNA Chemistry, https://web.archive.org/web/20200811120340/https://archerdx.com/technology-platform/technology/; ArcherDX, LLC., *FusionPlex™ Anchored Multiplex PCR AMP™*, YouTube (Aug. 9, 2019), https://www.youtube.com/watch?v=cHjKsgbmIsY; "VariantPlex Anchored Multiplex PCR AMP," DNA Chemistry, https://archerdx.com/technology-platform/technology/; "FusionPlex Anchored Multiplex PCR AMP," RNA Chemistry, https://archerdx.com/technology-platform/technology/.

[55] *See* Zheng Z, Liebers M, Zhelyazkova B et al. Anchored multiplex PCR for targeted next-generation sequencing. Nat Med 2014; 20: 1479-1484.

[56] *See* "VariantPlex Anchored Multiplex PCR AMP," DNA Chemistry, https://web.archive.org/web/20200811120340/https://archerdx.com/technology-platform/technology/; ArcherDX, LLC., *VariantPlex™ Anchored Multiplex PCR AMP™*, YouTube (Aug. 9, 2019), https://www.youtube.com/watch?v=Af2dSH5YMt4&t=4s; "FusionPlex Anchored Multiplex PCR AMP," RNA Chemistry, https://web.archive.org/web/20200811120340/https://archerdx.com/technology-platform/technology/; ArcherDX, LLC., *FusionPlex™ Anchored Multiplex PCR AMP™*, YouTube (Aug. 9, 2019), https://www.youtube.com/watch?v=cHjKsgbmIsY; "VariantPlex Anchored Multiplex PCR AMP," DNA Chemistry, https://archerdx.com/technology-platform/technology/.



125. On information and belief, the base length of the complementary oligonucleotide is more than 10 bases given the temperature required at the annealing step of the process (68°C or 65°C).[57]

126. Defendants' Accused Products "extend[] one or more oligonucleotides annealed to the nucleic acid sequence of interest in the nucleic acid fragment comprising the first adaptor sequence with a polymerase, in the reaction mixture, thereby generating one or more oligonucleotide extension products comprising sequence complementary to the first adaptor sequence at a first end, sequence complementary to the nucleic acid sequence of interest, and the second adaptor sequence at a second end."

127. For example, the Accused Products extend the one or more oligonucleotides annealed to the sequence of interest. As shown below,[58] the extension happens through the red

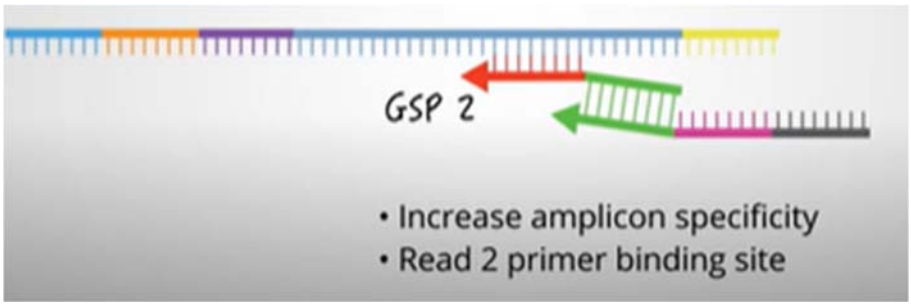
[57] The temperature in the annealing step is typically within 5°C of the melting temperature (Tm), the temperature at which half of the DNA is unbound from the other half of the DNA. In a PCR reaction, the Tm is based on the nucleotide content and length of the primer, as each nucleotide contributes additional hydrogen bonds which must be broken by heating to allow the primers to separate from the DNA. Each base adds ~2-4°C to the Tm. As a result, the number of nucleotides must be greater than 10 bases. *See* ThermoFischer Scientific "PCR Primer Design Tips" https://www.thermofisher.com/blog/behindthebench/pcr-primer-design-tips/; Sigma Aldrich "Oligonucleotide Melting Temperature" https://www.sigmaaldrich.com/US/en/technical-documents/protocol/genomics/pcr/oligos-melting-temp.

[58] *See* "VariantPlex Anchored Multiplex PCR AMP," DNA Chemistry, https://web.archive.org/web/20200811120340/https://archerdx.com/technology-platform/technology/; ArcherDX, LLC., *VariantPlex™ Anchored Multiplex PCR AMP™*, YouTube (Aug. 9, 2019), https://www.youtube.com/watch?v=Af2dSH5YMt4&t=4s; Archer VariantPlex HGC v2 Protocol for Illumina, page 15 "Step 7: Second PCR"; "FusionPlex Anchored

arrow in the below diagram. This extension is accomplished by using a polymerase found in the reaction mixture.[59]

Multiplex PCR AMP," RNA Chemistry, https://web.archive.org/web/20200811120340/https://archerdx.com/technology-platform/technology/; ArcherDX, LLC., *FusionPlex™ Anchored Multiplex PCR AMP™*, YouTube (Aug. 9, 2019), https://www.youtube.com/watch?v=cHjKsgbmIsY; "VariantPlex Anchored Multiplex PCR AMP," DNA Chemistry, https://archerdx.com/technology-platform/technology/; "FusionPlex Anchored Multiplex PCR AMP," RNA Chemistry, https://archerdx.com/technology-platform/technology/; Archer FusionPlex Protocol for Illumina, page 21 "Step 10: Second PCR"; Archer LiquidPlex Protocol for Illumina, pages 17-18 "Step 6: Second PCR"; "Invitae Personalized Cancer Monitoring", https://nymacgenetics.org/wp-content/uploads/2022/03/Personalized-Cancer-Monitoring-PCM.PDF.pdf; Zheng Z, Liebers M, Zhelyazkova B et al. Anchored multiplex PCR for targeted next-generation sequencing. Nat Med 2014; 20: 1479-1484; Invitae VariantPlex Protocol for Illumina, pages 18-19 "Step 7: Second PCR"; Invitae FusionPlex Protocol for Illumina, pages 21-23 "Step 10: Second PCR"; Invitae LiquidPlex Protocol for Illumina, pages 17-18 "Step 6: Second PCR"; IDT VariantPlex Protocol for Illumina, pages 16-18 "Step 5: Second PCR"; IDT FusionPlex Protocol for Illumina, pages 25-26 "Step 10: Second PCR"; IDT LiquidPlex Protocol for Illumina, pages 20-22 "Step 6: Second PCR."

[59] *See* "VariantPlex Anchored Multiplex PCR AMP," DNA Chemistry, https://web.archive.org/web/20200811120340/https://archerdx.com/technology-platform/technology/; ArcherDX, LLC., *VariantPlex™ Anchored Multiplex PCR AMP™*, YouTube (Aug. 9, 2019), https://www.youtube.com/watch?v=Af2dSH5YMt4&t=4s; Archer VariantPlex HGC v2 Protocol for Illumina, page 15 "Step 7: Second PCR"; "FusionPlex Anchored Multiplex PCR AMP," RNA Chemistry, https://web.archive.org/web/20200811120340/https://archerdx.com/technology-platform/technology/; ArcherDX, LLC., *FusionPlex™ Anchored Multiplex PCR AMP™*, YouTube (Aug. 9, 2019), https://www.youtube.com/watch?v=cHjKsgbmIsY; "VariantPlex Anchored Multiplex PCR AMP," DNA Chemistry, https://archerdx.com/technology-platform/technology/; "FusionPlex Anchored Multiplex PCR AMP," RNA Chemistry, https://archerdx.com/technology-platform/technology/; Archer FusionPlex Protocol for Illumina, page 21 "Step 10: Second PCR"; Archer LiquidPlex Protocol for Illumina, pages 17-18 "Step 6: Second PCR"; "Invitae Personalized Cancer Monitoring", https://nymacgenetics.org/wp-content/uploads/2022/03/Personalized-Cancer-Monitoring-PCM.PDF.pdf; Zheng Z, Liebers M, Zhelyazkova B et al. Anchored multiplex PCR for targeted next-generation sequencing. Nat Med 2014; 20: 1479-1484; Invitae VariantPlex Protocol for Illumina, pages 18-19 "Step 7: Second PCR"; Invitae FusionPlex Protocol for Illumina, pages 21-23 "Step 10: Second PCR"; Invitae LiquidPlex Protocol for Illumina, pages 17-18 "Step 6: Second PCR"; IDT VariantPlex Protocol for Illumina, pages 16-18 "Step 5: Second PCR"; IDT FusionPlex Protocol for Illumina, pages 25-26 "Step 10: Second PCR"; IDT LiquidPlex Protocol for Illumina, pages 20-22 "Step 6: Second PCR."



128. This extension anneals one or more oligonucleotides to the fragment with the first adaptor (represented above[60] by the blue-grey elements (the target fragment) and purple, orange, and blue elements (the first adaptor)).[61]

[60] *See* "VariantPlex Anchored Multiplex PCR AMP," DNA Chemistry, https://web.archive.org/web/20200811120340/https://archerdx.com/technology-platform/technology/; ArcherDX, LLC., *VariantPlex™ Anchored Multiplex PCR AMP™*, YouTube (Aug. 9, 2019), https://www.youtube.com/watch?v=Af2dSH5YMt4&t=4s.

[61] *See* "VariantPlex Anchored Multiplex PCR AMP," DNA Chemistry, https://web.archive.org/web/20200811120340/https://archerdx.com/technology-platform/technology/; ArcherDX, LLC., *VariantPlex™ Anchored Multiplex PCR AMP™*, YouTube (Aug. 9, 2019), https://www.youtube.com/watch?v=Af2dSH5YMt4&t=4s; Archer VariantPlex HGC v2 Protocol for Illumina, page 15 "Step 7: Second PCR"; "FusionPlex Anchored Multiplex PCR AMP," RNA Chemistry, https://web.archive.org/web/20200811120340/https://archerdx.com/technology-platform/technology/; ArcherDX, LLC., *FusionPlex™ Anchored Multiplex PCR AMP™*, YouTube (Aug. 9, 2019), https://www.youtube.com/watch?v=cHjKsgbmIsY; "VariantPlex Anchored Multiplex PCR AMP," DNA Chemistry, https://archerdx.com/technology-platform/technology/; "FusionPlex Anchored Multiplex PCR AMP," RNA Chemistry, https://archerdx.com/technology-platform/technology/; Archer FusionPlex Protocol for Illumina, page 21 "Step 10: Second PCR"; Archer LiquidPlex Protocol for Illumina, pages 17-18 "Step 6: Second PCR"; "Invitae Personalized Cancer Monitoring", https://nymacgenetics.org/wp-content/uploads/2022/03/Personalized-Cancer-Monitoring-PCM.PDF.pdf; Zheng Z, Liebers M, Zhelyazkova B et al. Anchored multiplex PCR for targeted next-generation sequencing. Nat Med 2014; 20: 1479-1484; Invitae VariantPlex Protocol for Illumina, pages 18-19 "Step 7: Second PCR"; Invitae FusionPlex Protocol for Illumina, pages 21-23 "Step 10: Second PCR"; Invitae LiquidPlex Protocol for Illumina, pages 17-18 "Step 6: Second PCR"; IDT VariantPlex Protocol for Illumina, pages 16-18 "Step 5: Second PCR"; IDT FusionPlex Protocol for Illumina, pages 25-26 "Step 10: Second PCR"; IDT LiquidPlex Protocol for Illumina, pages 20-22 "Step 6: Second PCR."

129. The result of this extension is an oligonucleotide extension product comprising a sequence complementary to the first adaptor at one end (shown below,[62] annotated red box; image adapted from source image to crop out the amplification primer incorporated in the next step), a sequence complementary to the nucleic acid sequence of interest (annotated green box; image adapted from source image to crop out the amplification primer incorporated in the next step), and the second adaptor at the other end (annotated blue box; image adapted from source image to crop out the amplification primer incorporated in the next step).[63]

[62] *See* "VariantPlex Anchored Multiplex PCR AMP," DNA Chemistry, https://web.archive.org/web/20200811120340/https://archerdx.com/technology-platform/technology/; ArcherDX, LLC., *VariantPlex™ Anchored Multiplex PCR AMP™*, YouTube (Aug. 9, 2019), https://www.youtube.com/watch?v=Af2dSH5YMt4&t=4s; "FusionPlex Anchored Multiplex PCR AMP," RNA Chemistry, https://web.archive.org/web/20200811120340/https://archerdx.com/technology-platform/technology/; ArcherDX, LLC., *FusionPlex™ Anchored Multiplex PCR AMP™*, YouTube (Aug. 9, 2019), https://www.youtube.com/watch?v=cHjKsgbmIsY.

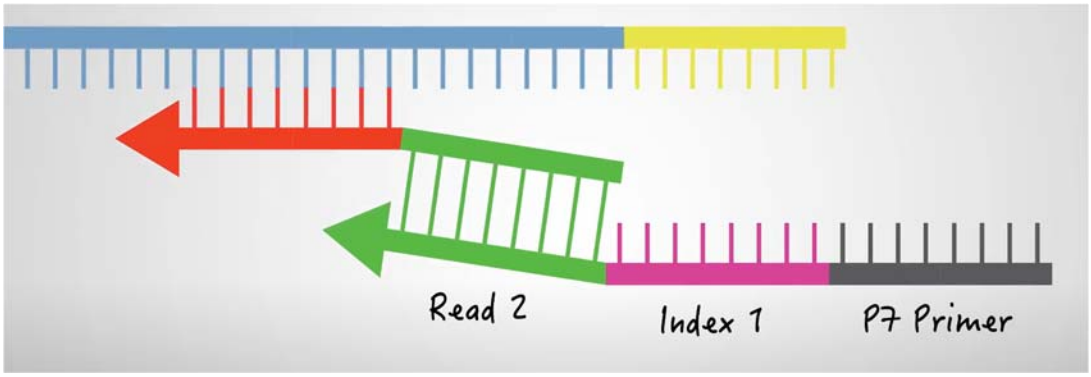
[63] *See* "VariantPlex Anchored Multiplex PCR AMP," DNA Chemistry, https://web.archive.org/web/20200811120340/https://archerdx.com/technology-platform/technology/; ArcherDX, LLC., *VariantPlex™ Anchored Multiplex PCR AMP™*, YouTube (Aug. 9, 2019), https://www.youtube.com/watch?v=Af2dSH5YMt4&t=4s; "FusionPlex Anchored Multiplex PCR AMP," RNA Chemistry, https://web.archive.org/web/20200811120340/https://archerdx.com/technology-platform/technology/; ArcherDX, LLC., *FusionPlex™ Anchored Multiplex PCR AMP™*, YouTube (Aug. 9, 2019), https://www.youtube.com/watch?v=cHjKsgbmIsY; "VariantPlex Anchored Multiplex PCR AMP," DNA Chemistry, https://archerdx.com/technology-platform/technology/; "FusionPlex Anchored Multiplex PCR AMP," RNA Chemistry, https://archerdx.com/technology-platform/technology/; Archer VariantPlex HGC v2 Protocol for Illumina, page 15 "Step 7: Second PCR"; Archer FusionPlex Protocol for Illumina, page 21 "Step 10: Second PCR"; Archer LiquidPlex Protocol for Illumina, pages 17-18 "Step 6: Second PCR"; Invitae VariantPlex Protocol for Illumina, pages 18-19 "Step 7: Second PCR"; Invitae FusionPlex Protocol for Illumina, pages 21-23 "Step 10: Second PCR"; Invitae LiquidPlex Protocol for Illumina, pages 17-18 "Step 6: Second PCR"; IDT VariantPlex Protocol for Illumina, pages 16-18 "Step 5: Second PCR"; IDT FusionPlex Protocol for Illumina, pages 25-26 "Step 10: Second PCR"; IDT LiquidPlex Protocol for Illumina, pages 20-22 "Step 6: Second PCR."

130. Defendants' Accused Products "amplify[] the one or more oligonucleotide extension products, in the reaction mixture, using a first primer that anneals to the complement of the first adaptor sequence and a second primer that anneals at its 3′ end to a complement of the second adaptor sequence, thereby enriching the nucleic acid sequence of interest, by generating amplified products comprising the enriched nucleic acid sequence of interest."

131. For example, the Accused Products are amplified by a second primer (first panel shown below,[64] the primer is depicted in green, pink, and grey) that anneals at its 3′ end to the

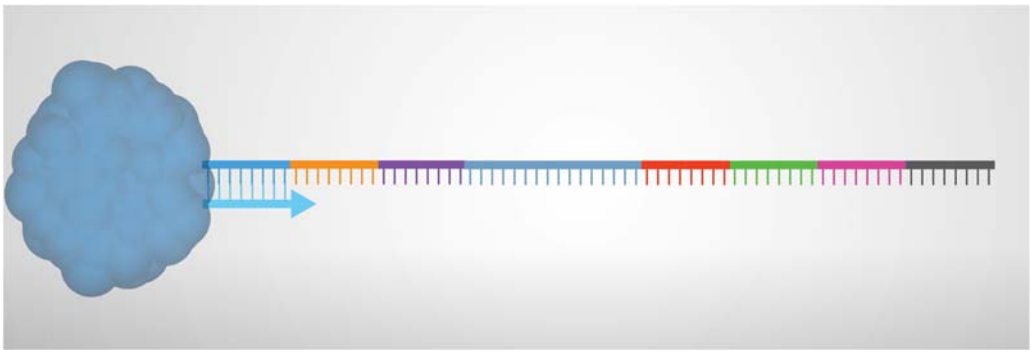
[64] *See* "VariantPlex Anchored Multiplex PCR AMP," DNA Chemistry, https://web.archive.org/web/20200811120340/https://archerdx.com/technology-platform/technology/; ArcherDX, LLC., *VariantPlex™ Anchored Multiplex PCR AMP™*, YouTube (Aug. 9, 2019), https://www.youtube.com/watch?v=Af2dSH5YMt4&t=4s; "FusionPlex Anchored Multiplex PCR AMP," RNA Chemistry, https://web.archive.org/web/20200811120340/https://archerdx.com/technology-platform/technology/; ArcherDX, LLC., *FusionPlex™ Anchored Multiplex PCR AMP™*, YouTube (Aug. 9, 2019), https://www.youtube.com/watch?v=cHjKsgbmIsY.

sequence complementary to the second adaptor sequence and a primer complementary to the first adaptor sequence (shown in the second panel,[65] the primer is depicted in light blue).[66]



[65] *See* "VariantPlex Anchored Multiplex PCR AMP," DNA Chemistry, https://web.archive.org/web/20200811120340/https://archerdx.com/technology-platform/technology/; ArcherDX, LLC., *VariantPlex™ Anchored Multiplex PCR AMP™*, YouTube (Aug. 9, 2019), https://www.youtube.com/watch?v=Af2dSH5YMt4&t=4s; "FusionPlex Anchored Multiplex PCR AMP," RNA Chemistry, https://web.archive.org/web/20200811120340/https://archerdx.com/technology-platform/technology/; ArcherDX, LLC., *FusionPlex™ Anchored Multiplex PCR AMP™*, YouTube (Aug. 9, 2019), https://www.youtube.com/watch?v=cHjKsgbmIsY.

[66] *See* "VariantPlex Anchored Multiplex PCR AMP," DNA Chemistry, https://web.archive.org/web/20200811120340/https://archerdx.com/technology-platform/technology/; ArcherDX, LLC., *VariantPlex™ Anchored Multiplex PCR AMP™*, YouTube (Aug. 9, 2019), https://www.youtube.com/watch?v=Af2dSH5YMt4&t=4s; "FusionPlex Anchored Multiplex PCR AMP," RNA Chemistry, https://web.archive.org/web/20200811120340/https://archerdx.com/technology-platform/technology/; ArcherDX, LLC., *FusionPlex™ Anchored Multiplex PCR AMP™*, YouTube (Aug. 9, 2019), https://www.youtube.com/watch?v=cHjKsgbmIsY; "VariantPlex Anchored Multiplex PCR AMP," DNA Chemistry, https://archerdx.com/technology-platform/technology/; "FusionPlex Anchored Multiplex PCR AMP," RNA Chemistry, https://archerdx.com/technology-platform/technology/; Archer VariantPlex HGC v2 Protocol for Illumina, page 15 "Step 7: Second PCR"; Archer FusionPlex Protocol for Illumina, page 21 "Step 10: Second PCR"; Archer LiquidPlex Protocol for Illumina, pages 17-18 "Step 6: Second PCR"; "Invitae Personalized Cancer Monitoring", https://nymacgenetics.org/wp-content/uploads/2022/03/Personalized-Cancer-Monitoring-PCM.PDF.pdf; Zheng Z, Liebers M, Zhelyazkova B et al. Anchored multiplex PCR for targeted next-generation sequencing. Nat Med 2014; 20: 1479-1484; Invitae VariantPlex Protocol for Illumina, pages 18-19 "Step 7: Second PCR"; Invitae FusionPlex Protocol for Illumina, pages 21-23 "Step 10: Second PCR"; Invitae LiquidPlex Protocol for Illumina, pages 17-18 "Step 6: Second PCR"; IDT VariantPlex Protocol for Illumina, pages 16-18 "Step 5: Second PCR"; IDT FusionPlex Protocol for Illumina, pages 25-26 "Step 10: Second PCR"; IDT LiquidPlex Protocol for Illumina, pages 20-22 "Step 6: Second PCR."



132. The result is an enriched population consisting of the oligonucleotide extension product comprising a sequence complementary to the first adaptor at one end (shown below,[67] annotated red box), a sequence complementary to the nucleic acid sequence of interest (annotated green box), and the second adaptor at the other end (annotated blue box).[68]

[67] *See* "VariantPlex Anchored Multiplex PCR AMP," DNA Chemistry, https://web.archive.org/web/20200811120340/https://archerdx.com/technology-platform/technology/; ArcherDX, LLC., *VariantPlex™ Anchored Multiplex PCR AMP™*, YouTube (Aug. 9, 2019), https://www.youtube.com/watch?v=Af2dSH5YMt4&t=4s; "FusionPlex Anchored Multiplex PCR AMP," RNA Chemistry, https://web.archive.org/web/20200811120340/https://archerdx.com/technology-platform/technology/; ArcherDX, LLC., *FusionPlex™ Anchored Multiplex PCR AMP™*, YouTube (Aug. 9, 2019), https://www.youtube.com/watch?v=cHjKsgbmIsY.

[68] *See* "VariantPlex Anchored Multiplex PCR AMP," DNA Chemistry, https://web.archive.org/web/20200811120340/https://archerdx.com/technology-platform/technology/; ArcherDX, LLC., *VariantPlex™ Anchored Multiplex PCR AMP™*, YouTube (Aug. 9, 2019), https://www.youtube.com/watch?v=Af2dSH5YMt4&t=4s; "FusionPlex Anchored Multiplex PCR AMP," RNA Chemistry, https://web.archive.org/web/20200811120340/https://archerdx.com/technology-platform/technology/; ArcherDX, LLC., *FusionPlex™ Anchored Multiplex PCR AMP™*, YouTube (Aug. 9, 2019), https://www.youtube.com/watch?v=cHjKsgbmIsY; "VariantPlex Anchored Multiplex PCR AMP," DNA Chemistry, https://archerdx.com/technology-platform/technology/; "FusionPlex Anchored Multiplex PCR AMP," RNA Chemistry, https://archerdx.com/technology-platform/technology/; Archer VariantPlex HGC v2 Protocol for Illumina, page 15 "Step 7: Second PCR"; Archer FusionPlex Protocol for Illumina, page 21 "Step 10: Second PCR"; Archer LiquidPlex Protocol for Illumina, pages 17-18 "Step 6: Second PCR"; Invitae VariantPlex Protocol for Illumina, pages 18-19 "Step 7: Second PCR"; Invitae FusionPlex Protocol for Illumina, pages 21-23 "Step 10: Second PCR"; Invitae LiquidPlex Protocol for Illumina, pages 17-18 "Step 6: Second PCR"; IDT VariantPlex Protocol for Illumina, pages 16-18 "Step 5: Second PCR"; IDT FusionPlex Protocol for Illumina, pages 25-26 "Step 10: Second PCR"; IDT LiquidPlex Protocol for Illumina, pages 20-22 "Step 6: Second PCR."

133. Defendants' Accused Products "sequenc[e] the amplified products comprising the enriched nucleic acid sequence of interest on a massively parallel sequencing platform."

134. For example, the Accused Products direct the user to sequence samples on a massively parallel sequencing platform.[69,70]

135. As such, Defendants' Accused Products infringe at least claim 1 of the '108 patent.

136. Defendants further infringe at least claim 1 of the '108 patent when the Accused Products are manufactured, used, or sold and implemented by Defendants' customers and partners. Defendants do so by inducing and contributing to the direct infringement of the '108 patent by Defendants' customers and users. Customers and users of the Accused Products directly infringe the claimed methods of the '108 patent, and at least claim 1, when they use and implement the enrichment methods and kits designed, produced, and marketed by Defendants. As set forth above,

[69] *See* Archer FusionPlex Protocol for Ion Torrent, page 21 "Quantify, Normalize, and Sequence"; Archer VariantPlex-HS/HGC Protocol for Illumina, pages 17-18 "Quantify, Normalize and Sequence"; Archer FusionPlex Protocol for Illumina, pages 23-25 "Quantify, Normalize and Sequence"; Archer LiquidPlex Protocol for Illumina, pages 17-18 "Step 6: Second PCR"; Illumina MiSeq System Guide; MiSeq System Specification Sheet; Invitae VariantPlex Protocol for Illumina, page 19 "Quantify, Normalize and Sequence"; Invitae FusionPlex Protocol for Illumina, page 23 "Quantify, Normalize and Sequence"; Invitae LiquidPlex Protocol for Illumina, page 18 "Quantify, Normalize and Sequence"; IDT VariantPlex Protocol for Illumina, page 19 "Quantify, Normalize and Sequence"; IDT FusionPlex Protocol for Illumina, page 27 "Quantify, Normalize and Sequence"; IDT LiquidPlex Protocol for Illumina, page 23 "Quantify, Normalize and Sequence"; IDT Protocol Quantify, Normalize, and Sequence for Illumina.

[70] The PCM kits use "NGS powered by Anchored Multiplex PCR (AMP) chemistry." NGS platforms are a type of massively parallel sequencing platform. *See* "Invitae Personalized Cancer Monitoring," https://nymacgenetics.org/wp-content/uploads/2022/03/Personalized-Cancer-Monitoring-PCM.PDF.pdf; "Introduction to NGS" What is NGS? https://www.illumina.com/science/technology/next-generation-sequencing.html.

the steps of at least claim 1 are met by actions provided for and taken through the Accused Products.

137. Defendants have induced and continue to induce infringement of the ’108 patent. Defendants sell the Accused Products with instructions to end-users to perform the steps identified in the above workflows. Furthermore, Defendants distribute instruction materials, product manuals, and technical materials, and disseminate promotional/marketing materials, that describe the workflows and otherwise instruct users to use the Accused Products to infringe at least claim 1 of the ’108 patent. Defendants sell and offer for sale the Accused Products with the knowledge and specific intent that their instructions and workflows will cause users to use the kits to infringe at least claim 1 of the ’108 patent.

138. Defendants have also contributed to and continue to contribute to the infringement of at least claim 1 of the ’108 patent because they offer to sell or sell within the United States or import into the United States the Accused Products for use by users practicing the patented process of the ’108 patent. The Accused Products constitute a material part of the invention of the ’108 patent, and Defendants know the Accused Products to be especially made or especially adapted for use in infringing the ’108 patent. Furthermore, the Accused Products are not a staple article or commodity of commerce suitable for substantial noninfringing uses.

139. Defendants have committed and continue to commit acts of infringement in the United States and thereafter have sold and continue to sell the Accused Products or cause the Accused Products to be sold within and outside of the United States. Defendants’ sales within and outside of the United States have resulted in harm to Tecan Genomics. Tecan Genomics brings this action to be made whole for damages that include both sales within and outside of the United States.

140. As set forth above, Defendants engaged in these activities with full knowledge that other parties' actions were infringing. This conduct makes Defendants liable for inducing and contributing to the infringement of at least claim 1 of the '108 patent.

Defendants' Infringement of the '399 Patent

141. Defendants infringe at least claim 1 of the '399 patent under at least 35 U.S.C. §§ 271(a)-(c).

142. Defendants have used and continue to use the Accused Products in a manner that directly infringes literally or under the doctrine of equivalents at least claim 1 of the '399 patent. For example, when Defendants perform tests with the Accused Products, they infringe at least claim 1 of the '399 patent.[71] Moreover, Defendants conduct research, development, training, and/or testing activities relating to the launch, marketing, and sale of the Accused Products, which directly infringe at least claim 1 of the '399 patent.[72] Defendants also directly infringe at least

[71] *See* "VariantPlex Anchored Multiplex PCR AMP," DNA Chemistry, https://web.archive.org/web/20200811120340/https://archerdx.com/technology-platform/technology/; ArcherDX, LLC., *VariantPlex™ Anchored Multiplex PCR AMP™*, YouTube (Aug. 9, 2019), https://www.youtube.com/watch?v=Af2dSH5YMt4&t=4s; Anchored Multiplex PCR AMP," RNA Chemistry, https://web.archive.org/web/20200811120340/https://archerdx.com/technology-platform/technology/; ArcherDX, LLC., *FusionPlex™ Anchored Multiplex PCR AMP™*, YouTube (Aug. 9, 2019), https://www.youtube.com/watch?v=cHjKsgbmIsY; Archer VariantPlex-HS/HGC Protocol for Illumina; Archer FusionPlex Protocol for Illumina; Archer LiquidPlex Protocol for Illumina; Invitae VariantPlex Protocol for Illumina; Invitae FusionPlex Protocol for Illumina; Invitae LiquidPlex Protocol for Illumina"; IDT VariantPlex Protocol for Illumina; IDT FusionPlex Protocol for Illumina; IDT LiquidPlex Protocol for Illumina.

[72] *See* BioSpace, Enzymatics Inc. Launches Archer Targeted Sequencing Technology To Dramatically Enhance Gene Mutation Identification And Discovery, https://www.biospace.com/article/releases/enzymatics-inc-launches-archer-and-0153-targeted-sequencing-technology-to-dramatically-enhance-gene-mutation-identification-and-discovery-/ (Feb. 14, 2014); Businesswire, ArcherDX Launches VariantPlex™ Product Line For DNA-based Targeted Sequencing, https://www.businesswire.com/news/home/20150529005043/en/ArcherDX-Launches-VariantPlex%E2%84%A2-Product-Line-For-DNA-based-Targeted-Sequencing (May 29, 2015); Cision, PR Newswire ArcherDX dives into liquid biopsy research with Reveal ctDNA™ 28 assay,

claim 1 of the '399 patent by using the Accused Products in the United States when they instruct and train end-users on the use of the Accused Products at locations throughout the United States by demonstrating how to use the products, as well as when Defendants make, offer to sell, and sell the Accused Products.[73]

143. To the extent the preamble of claim 1 is limiting, Defendants' Accused Products employ "a method for detecting a duplicate sequencing read from a population of sample sequencing reads." For example, the Accused Products are used to generate target-enriched libraries and directed toward sequencing libraries using NGS to generate a population of sample sequencing reads.[74] The Accused Products are used to detect duplicate sequencing reads within

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https://www.prnewswire.com/news-releases/archerdx-dives-into-liquid-biopsy-research-with-reveal-ctdna-28-assay-300332446.html (Sept. 22, 2016); Archer, LiquidPlex ctDNR 28, https://web.archive.org/web/20200920070216/https://archerdx.com/research-products/solid-tumor-research/liquidplex/ (Sept. 20, 2020); Invitae Press Releases, Invitae Launches Full Access to its Liquid-Based Personalized Cancer Monitoring Platform to Help Detect Disease Earlier, https://ir.invitae.com/news-and-events/press-releases/press-release-details/2022/Invitae-Launches-Full-Access-to-its-Liquid-Based-Personalized-Cancer-Monitoring-Platform-to-Help-Detect-Disease-Earlier/default.aspx (Mar. 17, 2022).

[73] *See* "VariantPlex Anchored Multiplex PCR AMP," DNA Chemistry, https://web.archive.org/web/20200811120340/https://archerdx.com/technology-platform/technology/; ArcherDX, LLC., *VariantPlex™ Anchored Multiplex PCR AMP™*, YouTube (Aug. 9, 2019), https://www.youtube.com/watch?v=Af2dSH5YMt4&t=4s; Anchored Multiplex PCR AMP," RNA Chemistry, https://web.archive.org/web/20200811120340/https://archerdx.com/technology-platform/technology/; ArcherDX, LLC., *FusionPlex™ Anchored Multiplex PCR AMP™*, YouTube (Aug. 9, 2019), https://www.youtube.com/watch?v=cHjKsgbmIsY; Archer VariantPlex-HS/HGC Protocol for Illumina; Archer FusionPlex Protocol for Illumina; Archer LiquidPlex Protocol for Illumina; Invitae VariantPlex Protocol for Illumina; Invitae FusionPlex Protocol for Illumina; Invitae LiquidPlex Protocol for Illumina"; IDT VariantPlex Protocol for Illumina; IDT FusionPlex Protocol for Illumina; IDT LiquidPlex Protocol for Illumina.

[74] *See* Archer VariantPlex-HS/HGC Protocol for Illumina, page 3 "Overview"; Archer FusionPlex Protocol for Illumina, page 4 "Overview"; Archer LiquidPlex Protocol for Illumina, page 4 "Overview"; Invitae VariantPlex Protocol for Illumina, page 4 "Overview"; Invitae FusionPlex Protocol for Illumina, page 4 "Overview"; Invitae LiquidPlex Protocol for Illumina, page 4 "Overview"; IDT VariantPlex Protocol for Illumina, page 3 "Overview"; IDT FusionPlex Protocol for Illumina, page 3 "Overview"; IDT LiquidPlex Protocol for Illumina, page 3 "Overview."

this population.[75] Further, on information and belief, methods for detecting duplicate sequencing reads are a standard feature of AMP technology, as exemplified by the Accused Products that recite AMP technology as the "Test Principle" underlying their respective kits. AMP technology provides "a rapid target enrichment method for next-generation sequencing."[76]

144. The Defendants' Accused Products are directed to "a method for detecting a duplicate sequencing read from a population of sample sequencing reads … wherein the indexing site is unique amongst a subset of the plurality of nucleic acid fragments and is an index for multiple polynucleotides; and wherein the sequence of the identifier site is variable in sequence content in a plurality of adaptors." For example, the Accused Products employ a method that utilizes indexing sites and identifier sites wherein the indexing site is unique among a subset of the plurality of nucleic acid fragments and is an index for multiple polynucleotides. The Accused Products are directed towards the use of indexing sites to distinguish between multiple pooled samples, wherein the adaptor-ligated nucleic acid fragments of each sample will contain an indexing site that is unique to that sample. The sample-specific indices are unique therefore among a subset of the plurality of nucleic acid fragments present in the pooled samples.[77]

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[75] *See* Archer VariantPlex-HS/HGC Protocol for Illumina, page 3 "Overview"; Archer FusionPlex Protocol for Illumina, page 4 "Overview"; Archer LiquidPlex Protocol for Illumina, page 4 "Overview"; Invitae VariantPlex Protocol for Illumina, page 4 "Overview"; Invitae FusionPlex Protocol for Illumina, page 4 "Overview"; Invitae LiquidPlex Protocol for Illumina, page 4 "Overview"; IDT VariantPlex Protocol for Illumina, page 3 "Overview"; IDT FusionPlex Protocol for Illumina, page 3 "Overview"; IDT LiquidPlex Protocol for Illumina, page 3 "Overview."

[76] *See* Archer VariantPlex-HS/HGC Protocol for Illumina, page 3 "Overview"; Archer FusionPlex Protocol for Illumina, page 4 "Overview"; Archer LiquidPlex Protocol for Illumina, page 4 "Overview"; Invitae VariantPlex Protocol for Illumina, page 4 "Overview"; Invitae FusionPlex Protocol for Illumina, page 4 "Overview"; Invitae LiquidPlex Protocol for Illumina, page 4 "Overview"; IDT VariantPlex Protocol for Illumina, page 3 "Overview"; IDT FusionPlex Protocol for Illumina, page 3 "Overview"; IDT LiquidPlex Protocol for Illumina, page 3 "Overview."

[77] *See* Archer VariantPlex-HS/HGC Protocol for Illumina, page 9 "Molecular Barcoding, Sample Indexing & Multiplexed Sequencing"; Archer FusionPlex Protocol for Illumina, page 11

145. The Defendants' Accused Products also employ a method that utilizes identifier sites wherein the sequence of the identifier site is variable in sequence content in a plurality of adaptors. The Accused Products utilize unique identifier sites present in the adaptors (Molecular Barcodes) to distinguish between fragments.[78] Further, each adaptor-ligated fragment has a unique identified site (Molecular Barcode) that is variable in sequence content with respect to other identifier sites present in the samples.[79]

146. The Accused Products "ligat[e] an adaptor to a 5′ end of each nucleic acid fragment of a plurality of nucleic acid fragments from one or more samples, wherein the adaptor comprises: (i) an indexing primer binding site; (ii) an indexing site; (iii) an identifier site consisting of between 1 and 8 nucleotides; and (iv) a target sequence primer binding site."

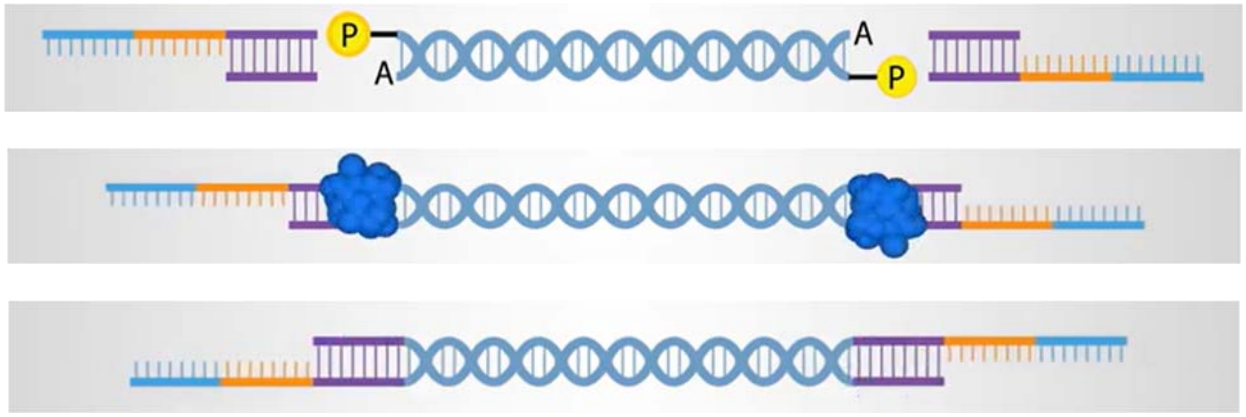
147. For example, the Accused Products ligate an adaptor comprising an indexing primer binding site, an indexing site, an identifier site consisting of between 1 and 8 nucleotides,

"Molecular Barcoding, Sample Indexing & Multiplexed Sequencing"; Archer LiquidPlex Protocol for Illumina, page 11 "Molecular Barcoding, Sample Indexing & Multiplexed Sequencing"; Invitae VariantPlex Protocol for Illumina; Invitae FusionPlex Protocol for Illumina; Invitae LiquidPlex Protocol for Illumina; IDT VariantPlex Protocol for Illumina; IDT FusionPlex Protocol for Illumina; IDT LiquidPlex Protocol for Illumina.

[78] *See* Archer VariantPlex-HS/HGC Protocol for Illumina, page 3 "Archer Library preparation reagents include"; Archer FusionPlex Protocol for Illumina, page 4 "Archer Library preparation reagents include"; Archer LiquidPlex Protocol for Illumina, page 4 "Archer Library preparation reagents include"; Invitae VariantPlex Protocol for Illumina; Invitae FusionPlex Protocol for Illumina; Invitae LiquidPlex Protocol for Illumina; IDT VariantPlex Protocol for Illumina; IDT FusionPlex Protocol for Illumina; IDT LiquidPlex Protocol for Illumina.

[79] *See* Archer VariantPlex-HS/HGC Protocol for Illumina, page 3 "Archer Library preparation reagents include"; Archer FusionPlex Protocol for Illumina, page 4 "Archer Library preparation reagents include"; Archer LiquidPlex Protocol for Illumina, page 4 "Archer Library preparation reagents include"; Invitae VariantPlex Protocol for Illumina; Invitae FusionPlex Protocol for Illumina; Invitae LiquidPlex Protocol for Illumina; IDT VariantPlex Protocol for Illumina; IDT FusionPlex Protocol for Illumina; IDT LiquidPlex Protocol for Illumina.

and a target sequence primer binding site to a plurality of nucleic acid fragments.[80] As shown below,[81] a first adaptor (shown in blue, orange, and purple) is ligated to a target nucleic acid fragment (middle blue-grey double strand).



148. As shown above,[82] the adaptor is ligated to the 5′ end of a nucleic acid fragment (represented by the yellow phosphate group denoted as "P"). The adaptor ligation is used in connection with NGS sequencing and as such, the target nucleic acid fragment is but one of "a plurality of nucleic acid fragments from one or more samples."[83]

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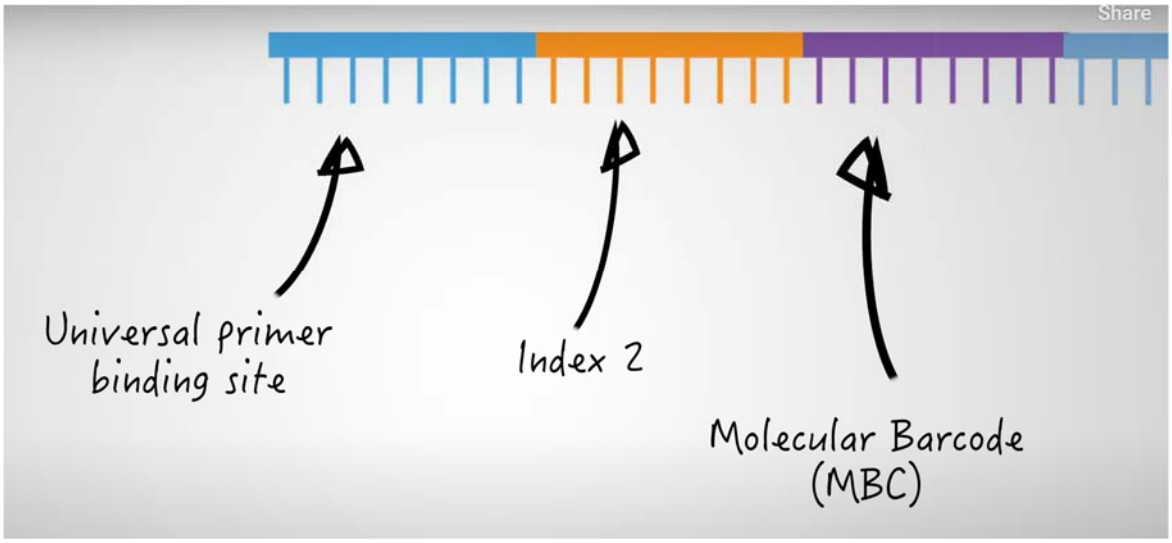
[80] *See* Archer VariantPlex-HS/HGC Protocol for Illumina, pages 11-14 "Protocol Step 3-5"; Archer FusionPlex Protocol for Illumina, pages 16-19 "Protocol Step 6-8"; Archer LiquidPlex Protocol for Illumina, pages 13-16 "Protocol Step 2-4"; Invitae VariantPlex Protocol for Illumina, pages 13-17 "Protocol Step 3-5"; Invitae FusionPlex Protocol for Illumina, pages 16-19 "Protocol Step 6-8"; Invitae LiquidPlex Protocol for Illumina, pages 13-16 "Protocol Step 2-4"; IDT VariantPlex Protocol for Illumina, pages 13-14 "Protocol Step 2-3"; IDT FusionPlex Protocol for Illumina, pages 19-23 "Protocol Step 6-8"; IDT LiquidPlex Protocol for Illumina, pages 14-18 "Protocol Step 2-4."

[81] *See* "VariantPlex Anchored Multiplex PCR AMP," DNA Chemistry, https://archerdx.com/technology-platform/technology/).

[82] *See* "VariantPlex Anchored Multiplex PCR AMP," DNA Chemistry, https://archerdx.com/technology-platform/technology/).

[83] *See* Archer VariantPlex-HS/HGC Protocol for Illumina, page 3 "Overview"; Archer FusionPlex Protocol for Illumina, page 4 "Overview"; Archer LiquidPlex Protocol for Illumina, page 4 "Overview"; Illumina | Archer Technical Note: The Use of Molecular Barcodes in Anchored Multiplex PCR, page 1 "Anchored Multiplex PCR (AMP)"; Invitae VariantPlex Protocol for Illumina, page 4 "Overview"; Invitae FusionPlex Protocol for Illumina, page 4 "Overview"; Invitae LiquidPlex Protocol for Illumina, page 4 "Overview"; IDT VariantPlex Protocol for

149. As shown in the below diagrams[84] (an expanded version of the adaptor shown above), the adaptor comprises an indexing primer binding site and indexing site (shown in orange), and an identifier site (shown in purple) consisting of between 1 and 8 nucleotides, and a target sequence primer binding site (shown in blue). The identifier site (the Molecular Barcode, shown in purple) consists of 8 nucleotides.[85]



150. The Index 2 region contains both an index primer binding site and an indexing site. With regard to the indexing site, Index 2 consists of a unique nucleotide sequence specific to all adaptors in a sample and allows for multiple samples to be pooled together and sequenced at the same time (the different colored tubes shown below).[86] After sequencing, the presence of sample-

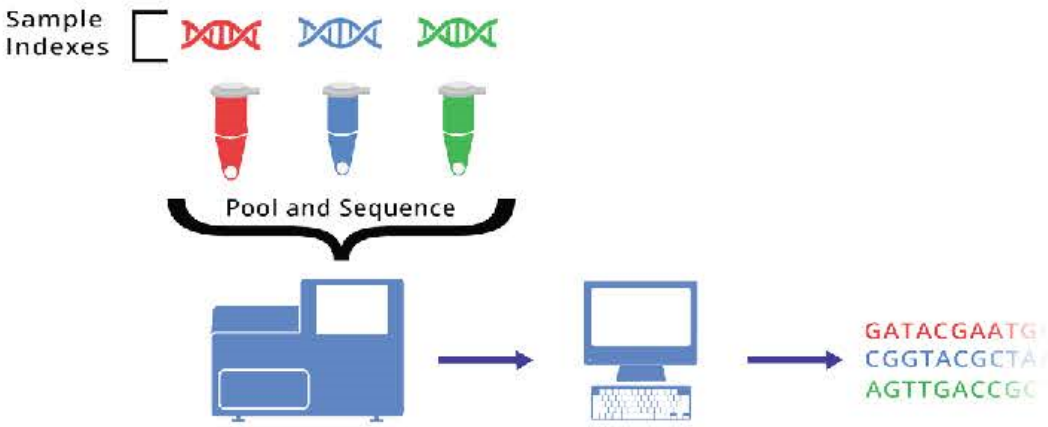
Illumina, page 3 "Overview"; IDT FusionPlex Protocol for Illumina, page 3 "Overview"; IDT LiquidPlex Protocol for Illumina, page 3 "Overview."

[84] *See* "VariantPlex Anchored Multiplex PCR AMP," DNA Chemistry, https://archerdx.com/technology-platform/technology/).

[85] *See* Illumina | Archer Technical Note: The Use of Molecular Barcodes in Anchored Multiplex PCR, page 1 "Anchored Multiplex PCR (AMP™)" "This adaptor contains a sample-specific index of pre-defined sequence and a random 8-mer molecular barcode."

[86] Illumina | Archer Technical Note: The Use of Molecular Barcodes in Anchored Multiplex PCR, page 1 "Figure 1 A"; "Sequencing by Synthesis (SBS) Chemistry," https://www.illumina.com/science/technology/next-generation-sequencing/sequencing-technology.html; Archer VariantPlex-HS/HGC Protocol for Illumina, page 9;

specific index sequences allows for matching of sequencing reads to their sample of origin (shown below,[87] the different colored text shown at right, each color corresponds to the individually colored tubes shown at left).[88]



151. With regard to the index primer binding site, Index 2 includes a known sequence complementary to the sequence of the index primer used during NGS. The indexing primer binding site allows for sequencing of the indices during NGS sequencing (shown below,[89] primer

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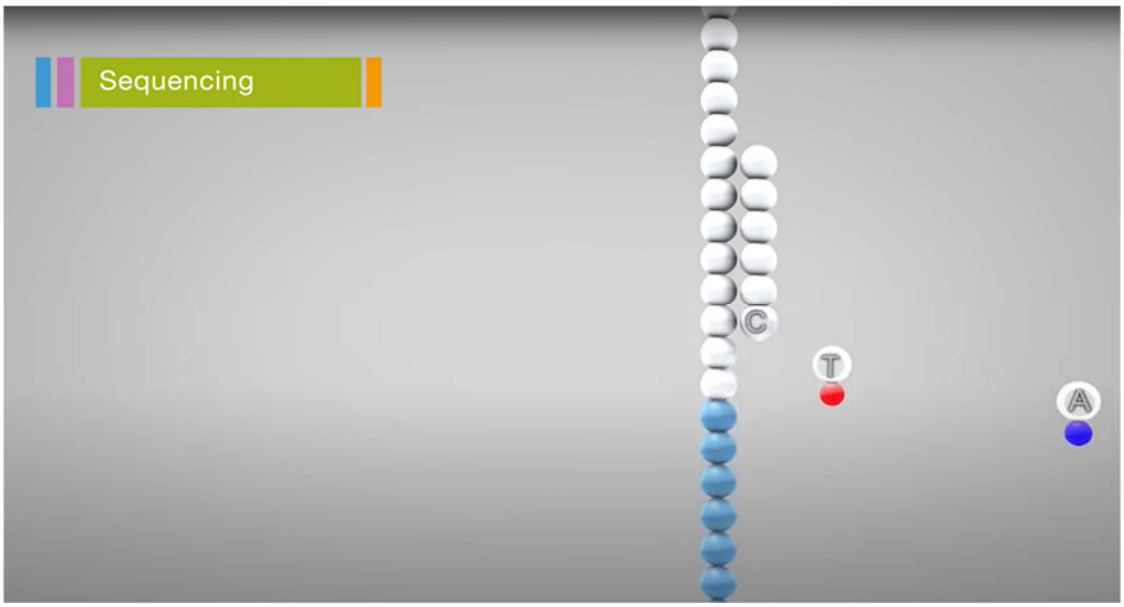
Archer FusionPlex Protocol for Illumina, page 11 "Sample Multiplexing";
Archer LiquidPlex Protocol for Illumina, page 11 "Sample Multiplexing"; Invitae VariantPlex Protocol for Illumina; Invitae FusionPlex Protocol for Illumina; Invitae LiquidPlex Protocol for Illumina; IDT VariantPlex Protocol for Illumina; IDT FusionPlex Protocol for Illumina; IDT LiquidPlex Protocol for Illumina.

[87] Illumina | Archer Technical Note: The Use of Molecular Barcodes in Anchored Multiplex PCR, page 1 "Figure 1 A."

[88] Illumina | Archer Technical Note: The Use of Molecular Barcodes in Anchored Multiplex PCR, page 1 "Figure 1 A"; "Sequencing by Synthesis (SBS) Chemistry," https://www.illumina.com/science/technology/next-generation-sequencing/sequencing-technology.html; Archer VariantPlex-HS/HGC Protocol for Illumina, page 9;
Archer FusionPlex Protocol for Illumina, page 11 "Sample Multiplexing"; Archer LiquidPlex Protocol for Illumina, page 11 "Sample Multiplexing"; Invitae VariantPlex Protocol for Illumina; Invitae FusionPlex Protocol for Illumina; Invitae LiquidPlex Protocol for Illumina; IDT VariantPlex Protocol for Illumina; IDT FusionPlex Protocol for Illumina; IDT LiquidPlex Protocol for Illumina.

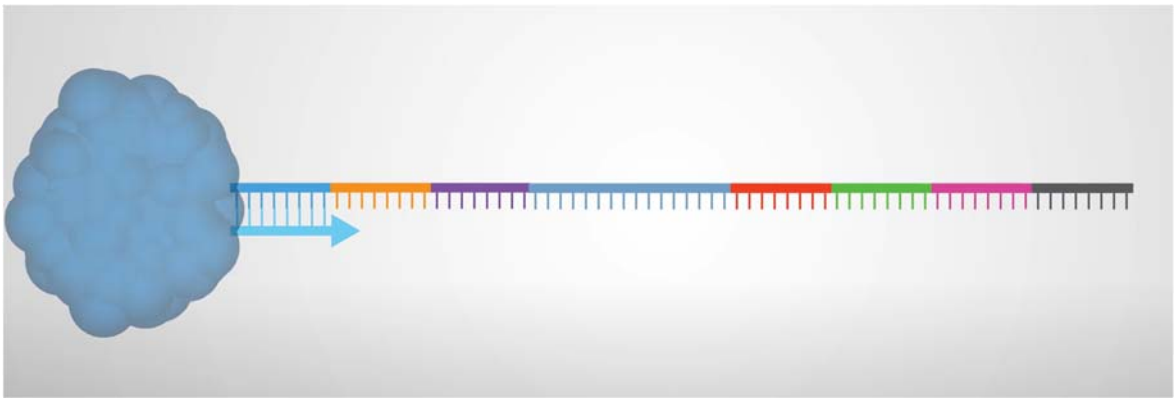
[89] *See* "Sequencing by Synthesis (SBS) Chemistry," https://www.illumina.com/science/technology/next-generation-sequencing/sequencing-technology.html.

represented by five unlabeled beads that the "C" is attached to), allowing sequencing reads to be matched to their sample of origin.

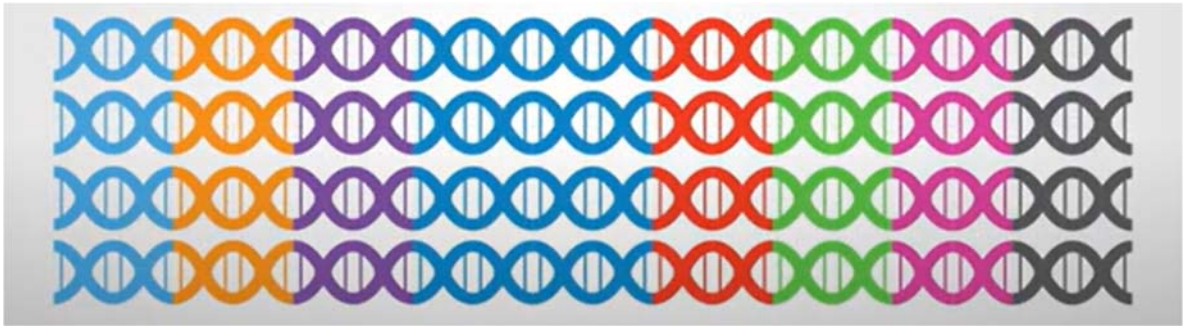


152. The Defendants' Accused Products "amplify[] the adaptor-nucleic acid fragment ligated products." For example, the Accused Products amplify the adaptor-nucleic acid fragment ligated products by PCR using at least a primer complementary to the target sequence primer binding site (representative image of amplification step shown below).[90]

[90] *See* "VariantPlex Anchored Multiplex PCR AMP," DNA Chemistry, https://archerdx.com/technology-platform/technology/; Archer VariantPlex HGC v2 Protocol for Illumina, page 15 "Step 7: Second PCR"; "FusionPlex Anchored Multiplex PCR AMP," RNA Chemistry, https://archerdx.com/technology-platform/technology/; Archer FusionPlex Protocol for Illumina, page 21 "Step 10: Second PCR"; Archer LiquidPlex Protocol for Illumina, pages 17-18 "Step 6: Second PCR"; Invitae VariantPlex Protocol for Illumina, pages 18-19 "Step 7: Second PCR"; Invitae FusionPlex Protocol for Illumina, pages 21-23 "Step 10: Second PCR"; Invitae LiquidPlex Protocol for Illumina, pages 17-18 "Step 6: Second PCR"; IDT VariantPlex Protocol for Illumina, pages 16-18 "Step 5: Second PCR"; IDT FusionPlex Protocol for Illumina, pages 25-26 "Step 10: Second PCR"; IDT LiquidPlex Protocol for Illumina, pages 20-22 "Step 6: Second PCR."



153. The result of PCR amplification is a number of adaptor-nucleic acid fragment ligated products shown below.[91]



154. The Accused Products also "generat[e] a population of sequencing reads from amplified adaptor-nucleic acid fragment ligated products." For example, the Accused Products direct the user to sequence samples on a massively parallel sequencing platform.[92]

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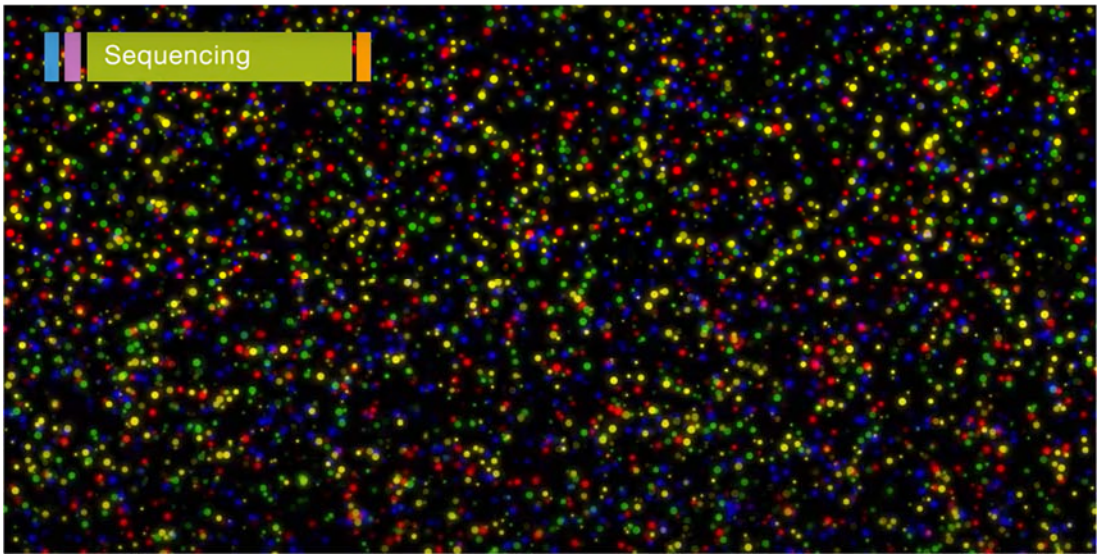
[91] *See* "VariantPlex Anchored Multiplex PCR AMP," DNA Chemistry, https://archerdx.com/technology-platform/technology/; Archer VariantPlex HGC v2 Protocol for Illumina, page 15 "Step 7: Second PCR"; "FusionPlex Anchored Multiplex PCR AMP," RNA Chemistry, https://archerdx.com/technology-platform/technology/; Archer FusionPlex Protocol for Illumina, page 21 "Step 10: Second PCR"; Archer LiquidPlex Protocol for Illumina, pages 17-18 "Step 6: Second PCR"; Invitae VariantPlex Protocol for Illumina, pages 18-19 "Step 7: Second PCR"; Invitae FusionPlex Protocol for Illumina, pages 21-23 "Step 10: Second PCR"; Invitae LiquidPlex Protocol for Illumina, pages 17-18 "Step 6: Second PCR"; IDT VariantPlex Protocol for Illumina, pages 16-18 "Step 5: Second PCR"; IDT FusionPlex Protocol for Illumina, pages 25-26 "Step 10: Second PCR"; IDT LiquidPlex Protocol for Illumina, pages 20-22 "Step 6: Second PCR."

[92] *See* Archer VariantPlex-HS/HGC Protocol for Illumina, page 3 "Overview"; Archer FusionPlex Protocol for Illumina, page 4 "Overview"; Archer LiquidPlex Protocol for Illumina, page 4

155. Sequencing on a massively parallel sequencing platform consists of sequencing the amplified adaptor-nucleic acid fragment ligated products generated in the amplification step. The fragments are attached to the platform and sequenced simultaneously (pictured below,[93] where each colored dot represents a single nucleotide sequencing event).



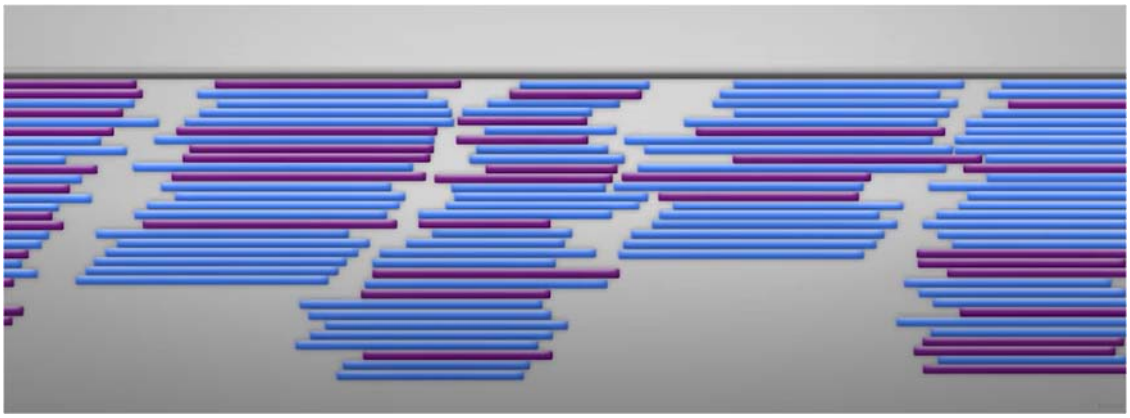
156. The result of sequencing the amplified adaptor-nucleic acid fragment ligated products is a population of sequencing reads generated from the amplified adaptor-nucleic acid fragment ligated products (pictured below in blue and purple,[94] aligned to a reference genomic sequence in grey).[95]

"Overview"; Invitae VariantPlex Protocol for Illumina, page 4 "Overview"; Invitae FusionPlex Protocol for Illumina, page 4 "Overview"; Invitae LiquidPlex Protocol for Illumina, page 4 "Overview"; IDT VariantPlex Protocol for Illumina, page 3 "Overview"; IDT FusionPlex Protocol for Illumina, page 3 "Overview"; IDT LiquidPlex Protocol for Illumina, page 3 "Overview."

[93] *See* "Sequencing by Synthesis (SBS) Chemistry," https://www.illumina.com/science/technology/next-generation-sequencing/sequencing-technology.html.

[94] *See* "Sequencing by Synthesis (SBS) Chemistry," https://www.illumina.com/science/technology/next-generation-sequencing/sequencing-technology.html.

[95] *See* "Sequencing by Synthesis (SBS) Chemistry," https://www.illumina.com/science/technology/next-generation-sequencing/sequencing-technology.html; Archer FusionPlex Protocol for Ion Torrent, page 21 "Quantify, Normalize, and



157. The Defendants' Accused Products "identify[] a duplicate sequencing read as the sequencing read comprising the same identifier site and nucleic acid fragment as another sequencing read in the population of sequencing reads." For example, the Accused Products provide for the identification of duplicative sequencing reads. Specifically, the instructions for the Accused Products recite that sequencing data produced by the recited method should be analyzed using dedicated analysis software designed to allow for read deduplication.[96] These duplicative sequence reads comprise the identifier sites (the Molecular Barcodes) and nucleic acid fragment.[97]

Sequence"; Archer VariantPlex-HS/HGC Protocol for Illumina, pages 17-18 "Quantify, Normalize and Sequence"; Archer FusionPlex Protocol for Illumina, pages 23-25 "Quantify, Normalize and Sequence"; Archer LiquidPlex Protocol for Illumina, pages 17-18 "Step 6: Second PCR"; Illumina MiSeq System Guide; MiSeq System Specification Sheet; Invitae VariantPlex Protocol for Illumina, page 19 "Quantify, Normalize and Sequence"; Invitae FusionPlex Protocol for Illumina, page 23 "Quantify, Normalize and Sequence"; Invitae LiquidPlex Protocol for Illumina, page 18 "Quantify, Normalize and Sequence"; IDT VariantPlex Protocol for Illumina, page 19 "Quantify, Normalize and Sequence"; IDT FusionPlex Protocol for Illumina, page 27 "Quantify, Normalize and Sequence"; IDT LiquidPlex Protocol for Illumina, page 23 "Quantify, Normalize and Sequence"; IDT Protocol Quantify, Normalize, and Sequence for Illumina.

[96] *See* Archer VariantPlex-HS/HGC Protocol for Illumina, page 3 "Test Principle"; Archer FusionPlex Protocol for Illumina, page 4 "Test Principle"; Archer LiquidPlex Protocol for Illumina, page 4 "Intended Use"; Archer Analysis 4.1 User Manual; Illumina | Archer Technical Note: The Use of Molecular Barcodes in Anchored Multiplex PCR; Invitae VariantPlex Protocol for Illumina; Invitae FusionPlex Protocol for Illumina; Invitae LiquidPlex Protocol for Illumina; IDT VariantPlex Protocol for Illumina; IDT FusionPlex Protocol for Illumina; IDT LiquidPlex Protocol for Illumina.

[97] *See* Archer VariantPlex-HS/HGC Protocol for Illumina, page 3 "Test Principle"; Archer FusionPlex Protocol for Illumina, page 4 "Test Principle"; Archer LiquidPlex Protocol for

158. As such, Defendants' Accused Products infringe at least claim 1 of the '399 patent.

159. Defendants further infringe at least claim 1 of the '399 patent when the Accused Products are manufactured, used, or sold and implemented by Defendants' customers and partners. Defendants do so by inducing and contributing to the direct infringement of the '399 patent by Defendants' customers and users. Customers and users of the Accused Products directly infringe the claimed methods of the '399 patent, and at least claim 1, when they use and implement the enrichment methods and kits designed, produced, and marketed by Defendants. As set forth above, the steps of at least claim 1 are met by actions provided for and taken through the Accused Products.

160. Defendants have induced and continue to induce infringement of the '399 patent. Defendants sell the Accused Products with instructions to end-users to perform the steps identified in the above workflows. Furthermore, Defendants distribute instruction materials, product manuals, and technical materials, and disseminate promotional/marketing materials, that describe the workflows and otherwise instruct users to use the Accused Products to infringe at least claim 1 of the '399 patent. Defendants sell and offer for sale the Accused Products with the knowledge and specific intent that their instructions and workflows will cause users to use the kits to infringe at least claim 1 of the '399 patent.

161. Defendants have also contributed to and continue to contribute to the infringement of at least claim 1 of the '399 patent because they offer to sell or sell within the United States or import into the United States the Accused Products for use by users practicing the patented process

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Illumina, page 4 "Intended Use"; Archer Analysis 4.1 User Manual; Illumina | Archer Technical Note: The Use of Molecular Barcodes in Anchored Multiplex PCR; Invitae VariantPlex Protocol for Illumina; Invitae FusionPlex Protocol for Illumina; Invitae LiquidPlex Protocol for Illumina; IDT VariantPlex Protocol for Illumina; IDT FusionPlex Protocol for Illumina; IDT LiquidPlex Protocol for Illumina.

of the '399 patent. The Accused Products constitute a material part of the invention of the '399 patent, and Defendants know the Accused Products to be especially made or especially adapted for use in infringing the '399 patent. Furthermore, the Accused Products are not a staple article or commodity of commerce suitable for substantial noninfringing uses.

162. Defendants have committed and continue to commit acts of infringement in the United States and thereafter have sold and continue to sell the Accused Products or cause the Accused Products to be sold within and outside of the United States. Defendants' sales within and outside of the United States have resulted in harm to Tecan Genomics. Tecan Genomics brings this action to be made whole for damages that include both sales within and outside of the United States.

163. As set forth above, Defendants engaged in these activities with full knowledge that other parties' actions were infringing. This conduct makes Defendants liable for inducing and contributing to the infringement of at least claim 1 of the '399 patent.

Defendants' Infringement of the '357 Patent

164. Defendants infringe at least claim 1 of the '357 patent under at least 35 U.S.C. §§ 271(a)-(c).

165. Defendants have used and continue to use the Accused Products in a manner that directly infringes literally or under the doctrine of equivalents at least claim 1 of the '357 patent. For example, when Defendants perform tests with the Accused Products, they infringe at least claim 1 of the '357 patent.[98] Moreover, Defendants conduct research, development, training,

[98] *See* "VariantPlex Anchored Multiplex PCR AMP," DNA Chemistry, https://web.archive.org/web/20200811120340/https://archerdx.com/technology-platform/technology/; ArcherDX, LLC., VariantPlex™ Anchored Multiplex PCR AMP™, YouTube (Aug. 9, 2019), https://www.youtube.com/watch?v=Af2dSH5YMt4&t=4s; Anchored Multiplex PCR AMP," RNA Chemistry,

and/or testing activities relating to the launch, marketing, and sale of the Accused Products, which directly infringe at least claim 1 of the '357 patent.[99] Defendants also directly infringe at least claim 1 of the '357 patent by using the Accused Products in the United States when they instruct and train end-users on the use of the Accused Products at locations throughout the United States by demonstrating how to use the products, as well as when Defendants make, offer to sell, and sell the Accused Products.[100]

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https://web.archive.org/web/20200811120340/https://archerdx.com/technology-platform/technology/; ArcherDX, LLC., FusionPlex™ Anchored Multiplex PCR AMP™, YouTube (Aug. 9, 2019), https://www.youtube.com/watch?v=cHjKsgbmIsY; Archer VariantPlex-HS/HGC Protocol for Illumina; Archer FusionPlex Protocol for Illumina; Archer LiquidPlex Protocol for Illumina; Invitae VariantPlex Protocol for Illumina; Invitae FusionPlex Protocol for Illumina; Invitae LiquidPlex Protocol for Illumina"; IDT VariantPlex Protocol for Illumina; IDT FusionPlex Protocol for Illumina; IDT LiquidPlex Protocol for Illumina.

[99] *See* BioSpace, Enzymatics Inc. Launches Archer Targeted Sequencing Technology To Dramatically Enhance Gene Mutation Identification And Discovery, https://www.biospace.com/article/releases/enzymatics-inc-launches-archer-and-0153-targeted-sequencing-technology-to-dramatically-enhance-gene-mutation-identification-and-discovery-/ (Feb. 14, 2014); Businesswire, ArcherDX Launches VariantPlex™ Product Line For DNA-based Targeted Sequencing, https://www.businesswire.com/news/home/20150529005043/en/ArcherDX-Launches-VariantPlex%E2%84%A2-Product-Line-For-DNA-based-Targeted-Sequencing (May 29, 2015); Cision, PR Newswire ArcherDX dives into liquid biopsy research with Reveal ctDNA™ 28 assay, https://www.prnewswire.com/news-releases/archerdx-dives-into-liquid-biopsy-research-with-reveal-ctdna-28-assay-300332446.html (Sept. 22, 2016); Archer, LiquidPlex ctDNR 28, https://web.archive.org/web/20200920070216/https://archerdx.com/research-products/solid-tumor-research/liquidplex/ (Sept. 20, 2020); Invitae Press Releases, Invitae Launches Full Access to its Liquid-Based Personalized Cancer Monitoring Platform to Help Detect Disease Earlier, https://ir.invitae.com/news-and-events/press-releases/press-release-details/2022/Invitae-Launches-Full-Access-to-its-Liquid-Based-Personalized-Cancer-Monitoring-Platform-to-Help-Detect-Disease-Earlier/default.aspx (Mar. 17, 2022).

[100] *See* "VariantPlex Anchored Multiplex PCR AMP," DNA Chemistry, https://web.archive.org/web/20200811120340/https://archerdx.com/technology-platform/technology/; ArcherDX, LLC., VariantPlex™ Anchored Multiplex PCR AMP™, YouTube (Aug. 9, 2019), https://www.youtube.com/watch?v=Af2dSH5YMt4&t=4s; Anchored Multiplex PCR AMP," RNA Chemistry, https://web.archive.org/web/20200811120340/https://archerdx.com/technology-platform/technology/; ArcherDX, LLC., FusionPlex™ Anchored Multiplex PCR AMP™, YouTube (Aug. 9, 2019), https://www.youtube.com/watch?v=cHjKsgbmIsY; Archer

166. To the extent the preamble of claim 1 is limiting, Defendants' Accused Products employ "a method for detecting duplicate sequencing reads." For example, the Accused Products are used to generate target-enriched libraries and directed toward sequencing libraries using NGS to generate a population of sample sequencing reads.[101] The Accused Products are also used to detect duplicate sequencing reads within this population.[102]

167. Further, on information and belief, methods for detecting duplicate sequencing reads are a standard feature of AMP technology, as exemplified by the Accused Products that recite AMP technology as the "Test Principle" underlying the respective kits. AMP technology provides "a rapid target enrichment method for next-generation sequencing."[103]

168. The Defendants' Accused Products "ligat[e] an adaptor to each of a plurality of nucleic acid fragments, wherein each adaptor comprises a unique identifier having from about 1

VariantPlex-HS/HGC Protocol for Illumina; Archer FusionPlex Protocol for Illumina; Archer LiquidPlex Protocol for Illumina; Invitae VariantPlex Protocol for Illumina; Invitae FusionPlex Protocol for Illumina; Invitae LiquidPlex Protocol for Illumina; IDT VariantPlex Protocol for Illumina; IDT FusionPlex Protocol for Illumina; IDT LiquidPlex Protocol for Illumina.

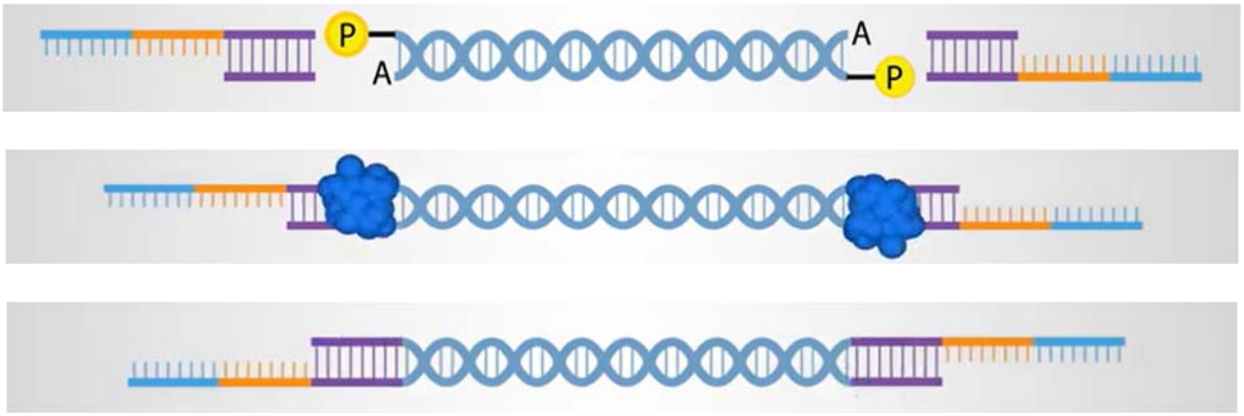
[101] *See* Archer VariantPlex-HS/HGC Protocol for Illumina, page 3 "Overview"; Archer FusionPlex Protocol for Illumina, page 4 "Overview"; Archer LiquidPlex Protocol for Illumina, page 4 "Overview"; Invitae VariantPlex Protocol for Illumina, page 4 "Overview"; Invitae FusionPlex Protocol for Illumina, page 4 "Overview"; Invitae LiquidPlex Protocol for Illumina, page 4 "Overview"; IDT VariantPlex Protocol for Illumina, page 3 "Overview"; IDT FusionPlex Protocol for Illumina, page 3 "Overview"; IDT LiquidPlex Protocol for Illumina, page 3 "Overview."

[102] *See* Archer VariantPlex-HS/HGC Protocol for Illumina, page 3 "Overview"; Archer FusionPlex Protocol for Illumina, page 4 "Overview"; Archer LiquidPlex Protocol for Illumina, page 4 "Overview"; Invitae VariantPlex Protocol for Illumina, page 4 "Overview"; Invitae FusionPlex Protocol for Illumina, page 4 "Overview"; Invitae LiquidPlex Protocol for Illumina, page 4 "Overview"; IDT VariantPlex Protocol for Illumina, page 3 "Overview"; IDT FusionPlex Protocol for Illumina, page 3 "Overview"; IDT LiquidPlex Protocol for Illumina, page 3 "Overview."

[103] *See* Archer VariantPlex-HS/HGC Protocol for Illumina, page 3 "Overview"; Archer FusionPlex Protocol for Illumina, page 4 "Overview"; Archer LiquidPlex Protocol for Illumina, page 4 "Overview."; Invitae VariantPlex Protocol for Illumina, page 4 "Overview"; Invitae FusionPlex Protocol for Illumina, page 4 "Overview"; Invitae LiquidPlex Protocol for Illumina, page 4 "Overview"; IDT VariantPlex Protocol for Illumina, page 3 "Overview"; IDT FusionPlex Protocol for Illumina, page 3 "Overview"; IDT LiquidPlex Protocol for Illumina, page 3 "Overview."

to about 8 nucleotides, an indexing site unique to a subset of the adaptors, and a primer binding site." For example, the Accused Products require ligating an adaptor comprising a unique identifier having from about 1 to about 8 nucleotides, an indexing site unique to a subset of the adaptors, and a primer binding site.[104]

169. The ligation step conducted in the Accused Products is shown below.[105] A first adaptor (shown in blue, orange, and purple) is ligated to a target nucleic acid fragment (middle blue-grey double strand).



[104] *See* Archer VariantPlex-HS/HGC Protocol for Illumina, pages 11-14 "Protocol Step 3-5"; Archer FusionPlex Protocol for Illumina, pages 16-19 "Protocol Step 6-8"; Archer LiquidPlex Protocol for Illumina, pages 13-16 "Protocol Step 2-4"; Invitae VariantPlex Protocol for Illumina, pages 13-17 "Protocol Step 3-5"; Invitae FusionPlex Protocol for Illumina, pages 16-19 "Protocol Step 6-8"; Invitae LiquidPlex Protocol for Illumina, pages 13-16 "Protocol Step 2-4"; IDT VariantPlex Protocol for Illumina, pages 13-14 "Protocol Step 2-3"; IDT FusionPlex Protocol for Illumina, pages 19-23 "Protocol Step 6-8"; IDT LiquidPlex Protocol for Illumina, pages 14-18 "Protocol Step 2-4."

[105] *See* "VariantPlex Anchored Multiplex PCR AMP," DNA Chemistry, https://web.archive.org/web/20200811120340/https://archerdx.com/technology-platform/technology/; ArcherDX, LLC., VariantPlex™ Anchored Multiplex PCR AMP™, YouTube (Aug. 9, 2019), https://www.youtube.com/watch?v=Af2dSH5YMt4&t=4s; Anchored Multiplex PCR AMP," RNA Chemistry, https://web.archive.org/web/20200811120340/https://archerdx.com/technology-platform/technology/; ArcherDX, LLC., FusionPlex™ Anchored Multiplex PCR AMP™, YouTube (Aug. 9, 2019), https://www.youtube.com/watch?v=cHjKsgbmIsY.

170. As shown above, the adaptor is ligated to a nucleic acid fragment (represented by the yellow phosphate group denoted as "P"). The adaptor ligation is used in connection with NGS sequencing and as such, the target nucleic acid fragment is but one of "a plurality of nucleic acid fragments from one or more samples."[106]

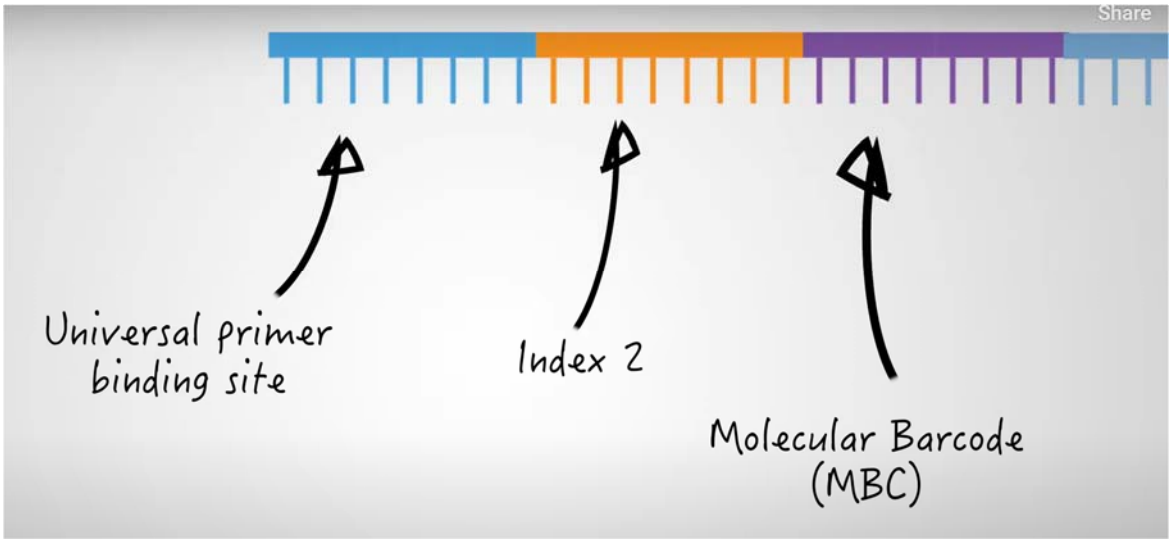
171. As shown in the below diagrams (an expanded version of the adaptor shown above),[107] the adaptor comprises a unique identifier (shown in purple) having from about 1 to about 8 nucleotides,[108] an indexing site unique to a subset of the adaptors (shown in orange), and a primer binding site (shown in blue). The adaptor contains a unique identifier (the Molecular Barcode, shown in purple) consisting of 8 nucleotides.[109]

[106] *See* Archer VariantPlex-HS/HGC Protocol for Illumina, page 3 "Overview"; Archer FusionPlex Protocol for Illumina, page 4 "Overview"; Archer LiquidPlex Protocol for Illumina, page 4 "Overview"; Illumina | Archer Technical Note: The Use of Molecular Barcodes in Anchored Multiplex PCR, page 1 "Anchored Multiplex PCR (AMP)"; Invitae VariantPlex Protocol for Illumina, page 4 "Overview"; Invitae FusionPlex Protocol for Illumina, page 4 "Overview"; Invitae LiquidPlex Protocol for Illumina, page 4 "Overview"; IDT VariantPlex Protocol for Illumina, page 3 "Overview"; IDT FusionPlex Protocol for Illumina, page 3 "Overview"; IDT LiquidPlex Protocol for Illumina, page 3 "Overview."

[107] *See* "VariantPlex Anchored Multiplex PCR AMP," DNA Chemistry, https://web.archive.org/web/20200811120340/https://archerdx.com/technology-platform/technology/; ArcherDX, LLC., VariantPlex™ Anchored Multiplex PCR AMP™, YouTube (Aug. 9, 2019), https://www.youtube.com/watch?v=Af2dSH5YMt4&t=4s; Anchored Multiplex PCR AMP," RNA Chemistry, https://web.archive.org/web/20200811120340/https://archerdx.com/technology-platform/technology/; ArcherDX, LLC., FusionPlex™ Anchored Multiplex PCR AMP™, YouTube (Aug. 9, 2019), https://www.youtube.com/watch?v=cHjKsgbmIsY.

[108] *See* Illumina | Archer Technical Note: The Use of Molecular Barcodes in Anchored Multiplex PCR, page 1 "Anchored Multiplex PCR (AMP™)" "This adaptor contains a sample-specific index of pre-defined sequence and a random 8-mer molecular barcode."

[109] *See* Illumina | Archer Technical Note: The Use of Molecular Barcodes in Anchored Multiplex PCR, page 1 "Anchored Multiplex PCR (AMP™)" "This adaptor contains a sample-specific index of pre-defined sequence and a random 8-mer molecular barcode."

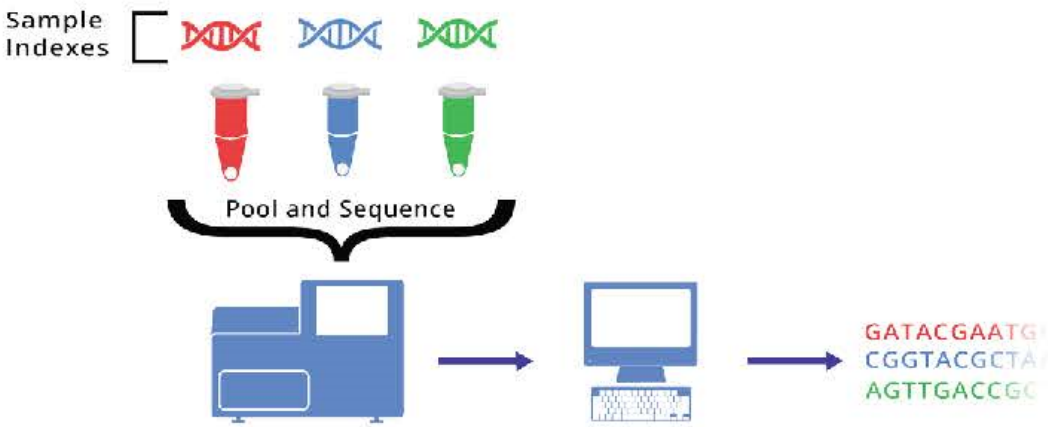


172. The Index 2 region contains an indexing site unique to a subset of the adaptors. The indexing site consists of a unique nucleotide sequence specific to all adaptors in a sample and allows for multiple samples to be pooled together and sequenced at the same time (the different colored tubes shown below).[110] After sequencing, the presence of sample-specific index sequences allows for matching of sequencing reads to their sample of origin (shown below;[111] with respect to the different colored text shown at right, each color corresponds to the individually colored tubes shown below at left).[112]

[110] Archer VariantPlex-HS/HGC Protocol for Illumina, page 9 "Sample Multiplexing"; Archer FusionPlex Protocol for Illumina, page 11 "Sample Multiplexing"; Archer LiquidPlex Protocol for Illumina, page 11 "Sample Multiplexing"; Illumina | Archer Technical Note: The Use of Molecular Barcodes in Anchored Multiplex PCR, page 1 "Figure 1 A"; "Sequencing by Synthesis (SBS) Chemistry," https://www.illumina.com/science/technology/next-generation-sequencing/sequencing-technology.html; Invitae VariantPlex Protocol for Illumina; Invitae FusionPlex Protocol for Illumina; Invitae LiquidPlex Protocol for Illumina; IDT VariantPlex Protocol for Illumina; IDT FusionPlex Protocol for Illumina; IDT LiquidPlex Protocol for Illumina.

[111] Archer VariantPlex-HS/HGC Protocol for Illumina, page 9 "Sample Multiplexing"; Archer FusionPlex Protocol for Illumina, page 11 "Sample Multiplexing."

[112] Archer VariantPlex-HS/HGC Protocol for Illumina, page 9 "Sample Multiplexing"; Archer FusionPlex Protocol for Illumina, page 11 "Sample Multiplexing"; Archer LiquidPlex Protocol for Illumina, page 11 "Sample Multiplexing"; Illumina | Archer Technical Note: The Use of Molecular Barcodes in Anchored Multiplex PCR, page 1 "Figure 1 A"; "Sequencing by Synthesis (SBS)



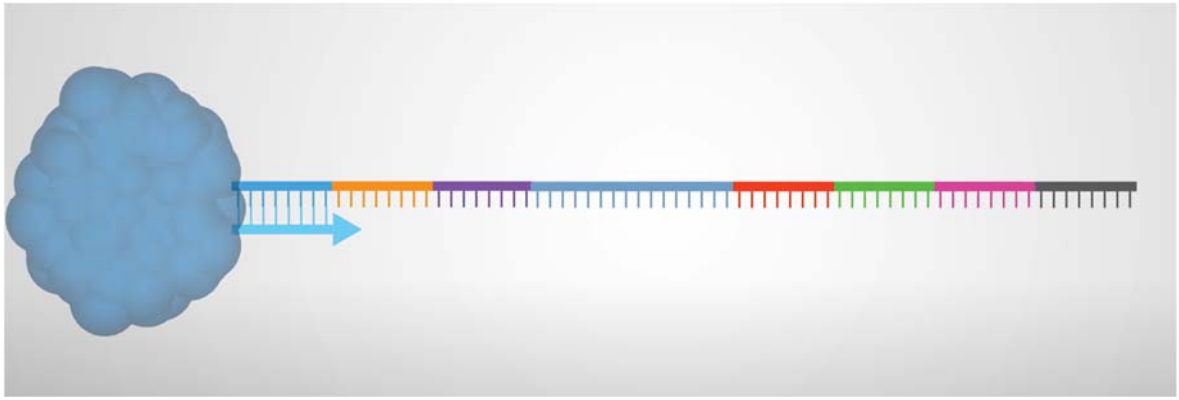
173. The Defendants' Accused Products employ a method that utilizes an indexing site unique to a subset of the adaptors. The Accused Products are directed towards the use of indexing sites to distinguish between multiple pooled samples, wherein the adaptor-ligated nucleic acid fragments of each sample will contain an indexing site that is unique to that sample.[113] The sample-specific indices are unique therefore among a subset of adaptors present in the pooled samples.[114]

Chemistry," https://www.illumina.com/science/technology/next-generation-sequencing/sequencing-technology.html; Invitae VariantPlex Protocol for Illumina; Invitae FusionPlex Protocol for Illumina; Invitae LiquidPlex Protocol for Illumina; IDT VariantPlex Protocol for Illumina; IDT FusionPlex Protocol for Illumina; IDT LiquidPlex Protocol for Illumina.

[113] *See* Archer VariantPlex-HS/HGC Protocol for Illumina, page 9 "Molecular Barcoding, Sample Indexing & Multiplexed Sequencing"; Archer FusionPlex Protocol for Illumina, page 11 "Molecular Barcoding, Sample Indexing & Multiplexed Sequencing"; Archer LiquidPlex Protocol for Illumina, page 11 "Molecular Barcoding, Sample Indexing & Multiplexed Sequencing"; Invitae VariantPlex Protocol for Illumina; Invitae FusionPlex Protocol for Illumina; Invitae LiquidPlex Protocol for Illumina; IDT VariantPlex Protocol for Illumina; IDT FusionPlex Protocol for Illumina; IDT LiquidPlex Protocol for Illumina.

[114] *See* Archer VariantPlex-HS/HGC Protocol for Illumina, page 9 "Molecular Barcoding, Sample Indexing & Multiplexed Sequencing"; Archer FusionPlex Protocol for Illumina, page 11 "Molecular Barcoding, Sample Indexing & Multiplexed Sequencing"; Archer LiquidPlex Protocol for Illumina, page 11 "Molecular Barcoding, Sample Indexing & Multiplexed Sequencing"; Invitae VariantPlex Protocol for Illumina; Invitae FusionPlex Protocol for Illumina; Invitae LiquidPlex Protocol for Illumina; IDT VariantPlex Protocol for Illumina; IDT FusionPlex Protocol for Illumina; IDT LiquidPlex Protocol for Illumina.

174. The Defendants' Accused Products "amplify[] the adaptor-ligated fragments into amplicons." For example, the Accused Products amplify the adaptor-ligated fragments by PCR using at least a primer complementary to the primer binding site (representative image of amplification step shown below).[115]



175. The result of PCR amplification is a number of adaptor-ligated fragment products, or amplicons shown below.[116]

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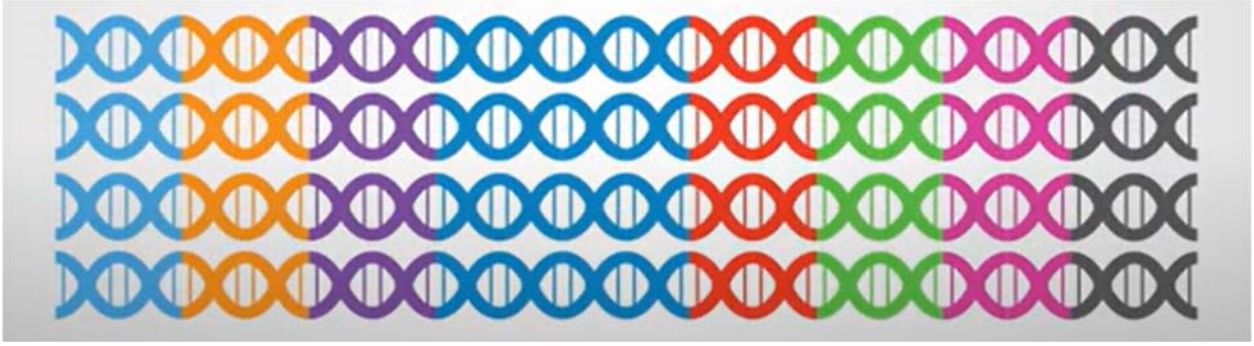
[115] *See* "VariantPlex Anchored Multiplex PCR AMP," DNA Chemistry, https://web.archive.org/web/20200811120340/https://archerdx.com/technology-platform/technology/; ArcherDX, LLC., VariantPlex™ Anchored Multiplex PCR AMP™, YouTube (Aug. 9, 2019), https://www.youtube.com/watch?v=Af2dSH5YMt4&t=4s; Anchored Multiplex PCR AMP," RNA Chemistry, https://web.archive.org/web/20200811120340/https://archerdx.com/technology-platform/technology/; ArcherDX, LLC., FusionPlex™ Anchored Multiplex PCR AMP™, YouTube (Aug. 9, 2019), https://www.youtube.com/watch?v=cHjKsgbmIsY; Archer VariantPlex HGC v2 Protocol for Illumina, page 15 "Step 7: Second PCR"; Archer FusionPlex Protocol for Illumina, page 21 "Step 10: Second PCR"; Archer LiquidPlex Protocol for Illumina, pages 17-18 "Step 6: Second PCR"; Invitae VariantPlex Protocol for Illumina, pages 18-19 "Step 7: Second PCR"; Invitae FusionPlex Protocol for Illumina, pages 21-23 "Step 10: Second PCR"; Invitae LiquidPlex Protocol for Illumina, pages 17-18 "Step 6: Second PCR"; IDT VariantPlex Protocol for Illumina, pages 16-18 "Step 5: Second PCR"; IDT FusionPlex Protocol for Illumina, pages 25-26 "Step 10: Second PCR"; IDT LiquidPlex Protocol for Illumina, pages 20-22 "Step 6: Second PCR."

[116] *See* "VariantPlex Anchored Multiplex PCR AMP," DNA Chemistry, https://web.archive.org/web/20200811120340/https://archerdx.com/technology-platform/technology/; ArcherDX, LLC., VariantPlex™ Anchored Multiplex PCR AMP™, YouTube (Aug. 9, 2019), https://www.youtube.com/watch?v=Af2dSH5YMt4&t=4s; Anchored Multiplex PCR AMP," RNA Chemistry,



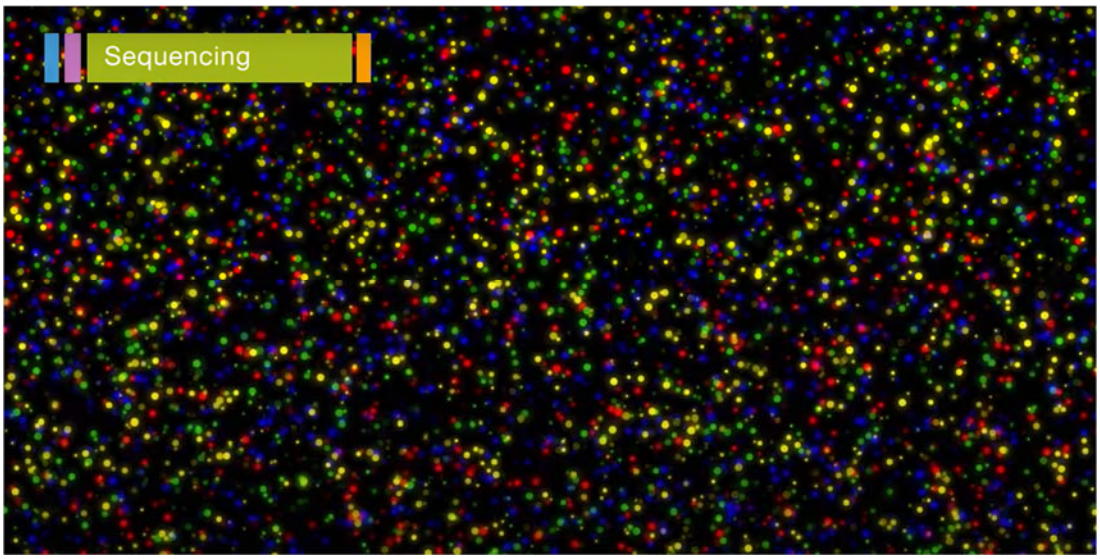
176. The Defendants' Accused Products "sequenc[e] the amplicons to produce sequence reads that include identifier and target sequences." For example, the Accused Products direct the user to sequence samples on a massively parallel sequencing platform.[117] Sequencing on a massively parallel sequencing platform consists of sequencing the adaptor-ligated fragment products, or amplicons, generated in the amplification step.[118] The fragments are attached to the

https://web.archive.org/web/20200811120340/https://archerdx.com/technology-platform/technology/; ArcherDX, LLC., FusionPlex™ Anchored Multiplex PCR AMP™, YouTube (Aug. 9, 2019), https://www.youtube.com/watch?v=cHjKsgbmIsY; Archer VariantPlex HGC v2 Protocol for Illumina, page 15 "Step 7: Second PCR"; Archer FusionPlex Protocol for Illumina, page 21 "Step 10: Second PCR"; Archer LiquidPlex Protocol for Illumina, pages 17-18 "Step 6: Second PCR"; Invitae VariantPlex Protocol for Illumina, pages 18-19 "Step 7: Second PCR"; Invitae FusionPlex Protocol for Illumina, pages 21-23 "Step 10: Second PCR"; Invitae LiquidPlex Protocol for Illumina, pages 17-18 "Step 6: Second PCR"; IDT VariantPlex Protocol for Illumina, pages 16-18 "Step 5: Second PCR"; IDT FusionPlex Protocol for Illumina, pages 25-26 "Step 10: Second PCR"; IDT LiquidPlex Protocol for Illumina, pages 20-22 "Step 6: Second PCR."

[117] *See* Archer VariantPlex-HS/HGC Protocol for Illumina, page 3 "Overview"; Archer FusionPlex Protocol for Illumina, page 4 "Overview"; Archer LiquidPlex Protocol for Illumina, page 4 "Overview"; Invitae VariantPlex Protocol for Illumina, page 4 "Overview"; Invitae FusionPlex Protocol for Illumina, page 4 "Overview"; Invitae LiquidPlex Protocol for Illumina, page 4 "Overview"; IDT VariantPlex Protocol for Illumina, page 3 "Overview"; IDT FusionPlex Protocol for Illumina, page 3 "Overview"; IDT LiquidPlex Protocol for Illumina, page 3 "Overview."

[118] *See* "Sequencing by Synthesis (SBS) Chemistry," https://www.illumina.com/science/technology/next-generation-sequencing/sequencing-technology.html.

platform and sequenced simultaneously (pictured below,[119] where each colored dot represents a single nucleotide sequencing event).



177. The result of sequencing the amplified adaptor-nucleic acid fragment ligated products is a population of sequencing reads generated from the amplified adaptor-nucleic acid fragment ligated products that include the identifier and target sequences (pictured below in blue and purple,[120] aligned to a reference genomic sequence in grey).[121]

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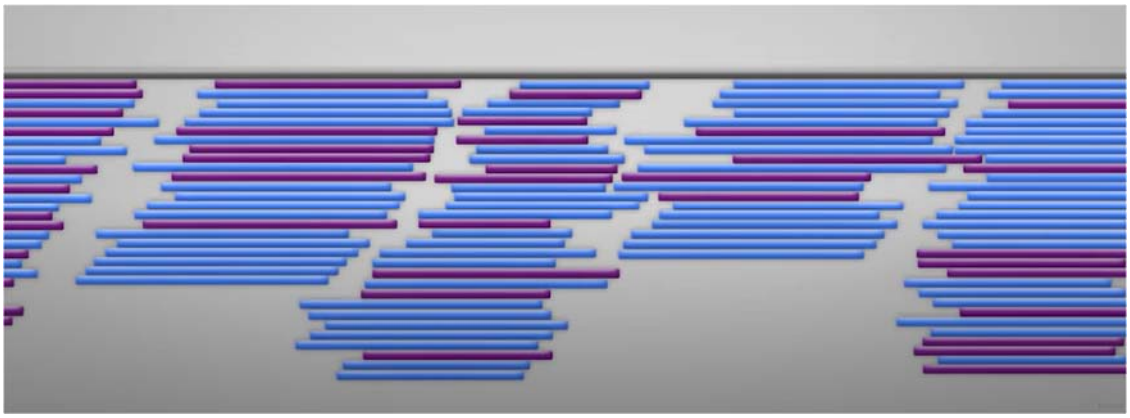
[119] *See* "Sequencing by Synthesis (SBS) Chemistry," https://www.illumina.com/science/technology/next-generation-sequencing/sequencing-technology.html.

[120] *See* "Sequencing by Synthesis (SBS) Chemistry," https://www.illumina.com/science/technology/next-generation-sequencing/sequencing-technology.html.

[121] *See* "Sequencing by Synthesis (SBS) Chemistry," https://www.illumina.com/science/technology/next-generation-sequencing/sequencing-technology.html; Archer FusionPlex Protocol for Ion Torrent, page 21 "Quantify, Normalize, and Sequence"; Archer VariantPlex-HS/HGC Protocol for Illumina, pages 17-18 "Quantify, Normalize and Sequence"; Archer FusionPlex Protocol for Illumina, pages 23-25 "Quantify, Normalize and Sequence"; Archer LiquidPlex Protocol for Illumina, pages 17-18 "Step 6: Second PCR"; Illumina MiSeq System Guide; MiSeq System Specification Sheet; Invitae VariantPlex Protocol for Illumina, page 19 "Quantify, Normalize and Sequence"; Invitae FusionPlex Protocol for Illumina, page 23 "Quantify, Normalize and Sequence"; Invitae LiquidPlex Protocol for Illumina, page 18 "Quantify, Normalize and Sequence"; IDT VariantPlex Protocol for Illumina, page 19 "Quantify, Normalize and Sequence"; IDT FusionPlex Protocol for Illumina, page 27



178. The Defendants' Accused Products "identify[] sequence reads with identical identifier and target sequences as duplicates." For example, the Accused Products provide for the identification of duplicative sequencing reads.[122] Specifically, the instructions for the Accused Products recite that sequencing data produced by the recited method should be analyzed using dedicated analysis software designed to allow for read deduplication.[123] These duplicative sequence reads consist of the identifier sites (the Molecular Barcodes) and target sequences.[124]

"Quantify, Normalize and Sequence"; IDT LiquidPlex Protocol for Illumina, page 23 "Quantify, Normalize and Sequence"; IDT Protocol Quantify, Normalize, and Sequence for Illumina.

[122] *See* Archer VariantPlex-HS/HGC Protocol for Illumina, page 3 "Test Principle"; Archer FusionPlex Protocol for Illumina, page 4 "Test Principle"; Archer LiquidPlex Protocol for Illumina, page 4 "Intended Use"; Archer Analysis 4.1 User Manual; Illumina | Archer Technical Note: The Use of Molecular Barcodes in Anchored Multiplex PCR; Invitae VariantPlex Protocol for Illumina; Invitae FusionPlex Protocol for Illumina; Invitae LiquidPlex Protocol for Illumina; IDT VariantPlex Protocol for Illumina; IDT FusionPlex Protocol for Illumina; IDT LiquidPlex Protocol for Illumina.

[123] *See* Archer VariantPlex-HS/HGC Protocol for Illumina, page 3 "Test Principle"; Archer FusionPlex Protocol for Illumina, page 4 "Test Principle"; Archer LiquidPlex Protocol for Illumina, page 4 "Intended Use"; Archer Analysis 4.1 User Manual; Illumina | Archer Technical Note: The Use of Molecular Barcodes in Anchored Multiplex PCR; Invitae VariantPlex Protocol for Illumina; Invitae FusionPlex Protocol for Illumina; Invitae LiquidPlex Protocol for Illumina; IDT VariantPlex Protocol for Illumina; IDT FusionPlex Protocol for Illumina; IDT LiquidPlex Protocol for Illumina.

[124] *See* Archer VariantPlex-HS/HGC Protocol for Illumina, page 3 "Test Principle"; Archer FusionPlex Protocol for Illumina, page 4 "Test Principle"; Archer LiquidPlex Protocol for Illumina, page 4 "Intended Use"; Archer Analysis 4.1 User Manual; Illumina | Archer Technical Note: The Use of Molecular Barcodes in Anchored Multiplex PCR; Invitae VariantPlex Protocol for Illumina; Invitae FusionPlex Protocol for Illumina; Invitae LiquidPlex Protocol for Illumina;

179. As such, Defendants' Accused Products infringe at least claim 1 of the '357 patent.

180. Defendants further infringe at least claim 1 of the '357 patent when the Accused Products are manufactured, used, or sold and implemented by Defendants' customers and partners. Defendants do so by inducing and contributing to the direct infringement of the '357 patent by Defendants' customers and users. Customers and users of the Accused Products directly infringe the claimed methods of the '357 patent, and at least claim 1, when they use and implement the enrichment methods and kits designed, produced, and marketed by Defendants. As set forth above, the steps of at least claim 1 are met by actions provided for and taken through the Accused Products.

181. Defendants have induced and continue to induce infringement of the '357 patent. Defendants sell the Accused Products with instructions to end-users to perform the steps identified in the above workflows. Furthermore, Defendants distribute instruction materials, product manuals, and technical materials, and disseminate promotional/marketing materials, that describe the workflows and otherwise instruct users to use the Accused Products to infringe at least claim 1 of the '357 patent. Defendants sell and offer for sale the Accused Products with the knowledge and specific intent that their instructions and workflows will cause users to use the kits to infringe at least claim 1 of the '357 patent.

182. Defendants have also contributed to and continue to contribute to the infringement of at least claim 1 of the '357 patent because they offer to sell or sell within the United States or import into the United States the Accused Products for use by users practicing the patented process of the '357 patent. The Accused Products constitute a material part of the invention of the '357

IDT VariantPlex Protocol for Illumina; IDT FusionPlex Protocol for Illumina; IDT LiquidPlex Protocol for Illumina.

patent, and Defendants know the Accused Products to be especially made or especially adapted for use in infringing the '357 patent. Furthermore, the Accused Products are not a staple article or commodity of commerce suitable for substantial noninfringing uses.

183. Defendants have committed and continue to commit acts of infringement in the United States and thereafter have sold and continue to sell the Accused Products or cause the Accused Products to be sold within and outside of the United States. Defendants' sales within and outside of the United States have resulted in harm to Tecan Genomics. Tecan Genomics brings this action to be made whole for damages that include both sales within and outside of the United States.

184. As set forth above, Defendants engaged in these activities with full knowledge that other parties' actions were infringing. This conduct makes Defendants liable for inducing and contributing to the infringement of at least claim 1 of the '357 patent.

Defendants' Infringement of the '241 Patent

185. Defendants infringe at least claim 1 of the '241 patent under at least 35 U.S.C. §§ 271(a)-(c).

186. Defendants have used and continue to use the Accused Products in a manner that directly infringes literally or under the doctrine of equivalents at least claim 1 of the '241 patent. For example, when Defendants perform tests with the Accused Products, they infringe at least claim 1 of the '241 patent.[125] Moreover, Defendants conduct research, development, training,

[125] *See* "VariantPlex Anchored Multiplex PCR AMP," DNA Chemistry, https://web.archive.org/web/20200811120340/https://archerdx.com/technology-platform/technology/; ArcherDX, LLC., VariantPlex™ Anchored Multiplex PCR AMP™, YouTube (Aug. 9, 2019), https://www.youtube.com/watch?v=Af2dSH5YMt4&t=4s; Anchored Multiplex PCR AMP," RNA Chemistry, https://web.archive.org/web/20200811120340/https://archerdx.com/technology-platform/technology/; ArcherDX, LLC., FusionPlex™ Anchored Multiplex PCR AMP™,

and/or testing activities relating to the launch, marketing, and sale of the Accused Products, which directly infringe at least claim 1 of the '241 patent.[126] Defendants also directly infringe at least claim 1 of the '241 patent by using the Accused Products in the United States when they instruct and train end-users on the use of the Accused Products at locations throughout the United States by demonstrating how to use the products, as well as when Defendants make, offer to sell, and sell the Accused Products.[127]

YouTube (Aug. 9, 2019), https://www.youtube.com/watch?v=cHjKsgbmIsY; Archer VariantPlex-HS/HGC Protocol for Illumina; Archer FusionPlex Protocol for Illumina; Archer LiquidPlex Protocol for Illumina; Invitae VariantPlex Protocol for Illumina; Invitae FusionPlex Protocol for Illumina; Invitae LiquidPlex Protocol for Illumina; IDT VariantPlex Protocol for Illumina; IDT FusionPlex Protocol for Illumina; IDT LiquidPlex Protocol for Illumina.

[126] *See* BioSpace, Enzymatics Inc. Launches Archer Targeted Sequencing Technology To Dramatically Enhance Gene Mutation Identification And Discovery, https://www.biospace.com/article/releases/enzymatics-inc-launches-archer-and-0153-targeted-sequencing-technology-to-dramatically-enhance-gene-mutation-identification-and-discovery-/ (Feb. 14, 2014); Businesswire, ArcherDX Launches VariantPlex™ Product Line For DNA-based Targeted Sequencing, https://www.businesswire.com/news/home/20150529005043/en/ArcherDX-Launches-VariantPlex%E2%84%A2-Product-Line-For-DNA-based-Targeted-Sequencing (May 29, 2015); Cision, PR Newswire ArcherDX dives into liquid biopsy research with Reveal ctDNA™ 28 assay, https://www.prnewswire.com/news-releases/archerdx-dives-into-liquid-biopsy-research-with-reveal-ctdna-28-assay-300332446.html (Sept. 22, 2016); Archer, LiquidPlex ctDNR 28, https://web.archive.org/web/20200920070216/https://archerdx.com/research-products/solid-tumor-research/liquidplex/ (Sept. 20, 2020); Invitae Press Releases, Invitae Launches Full Access to its Liquid-Based Personalized Cancer Monitoring Platform to Help Detect Disease Earlier, https://ir.invitae.com/news-and-events/press-releases/press-release-details/2022/Invitae-Launches-Full-Access-to-its-Liquid-Based-Personalized-Cancer-Monitoring-Platform-to-Help-Detect-Disease-Earlier/default.aspx (Mar. 17, 2022).

[127] *See* "VariantPlex Anchored Multiplex PCR AMP," DNA Chemistry, https://web.archive.org/web/20200811120340/https://archerdx.com/technology-platform/technology/; ArcherDX, LLC., VariantPlex™ Anchored Multiplex PCR AMP™, YouTube (Aug. 9, 2019), https://www.youtube.com/watch?v=Af2dSH5YMt4&t=4s; Anchored Multiplex PCR AMP," RNA Chemistry, https://web.archive.org/web/20200811120340/https://archerdx.com/technology-platform/technology/; ArcherDX, LLC., FusionPlex™ Anchored Multiplex PCR AMP™, YouTube (Aug. 9, 2019), https://www.youtube.com/watch?v=cHjKsgbmIsY; Archer VariantPlex-HS/HGC Protocol for Illumina; Archer FusionPlex Protocol for Illumina; Archer LiquidPlex Protocol for Illumina; Invitae VariantPlex Protocol for Illumina; Invitae FusionPlex

187. To the extent the preamble of claim 1 is limiting, Defendants' Accused Products employ "a method for detecting duplicate sequencing reads." For example, the Accused Products are used to generate target-enriched libraries and directed toward sequencing libraries using NGS to generate a population of sample sequencing reads.[128] The Accused Products are also used to detect duplicate sequencing reads within this population.[129]

188. Further, on information and belief, methods for detecting duplicate sequencing reads are a standard feature of AMP technology, as exemplified by the Accused Products that recite AMP technology as the "Test Principle" underlying the respective kits. AMP technology provides "a rapid target enrichment method for next-generation sequencing."[130]

189. The Defendants' Accused Products "obtain[] amplicons each comprising an amplified fragment of a nucleic acid with an appended adaptor, wherein each adaptor comprises an identifier site comprising a plurality of nucleotides unique to the amplified fragment." For

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Protocol for Illumina; Invitae LiquidPlex Protocol for Illumina; IDT VariantPlex Protocol for Illumina; IDT FusionPlex Protocol for Illumina; IDT LiquidPlex Protocol for Illumina.

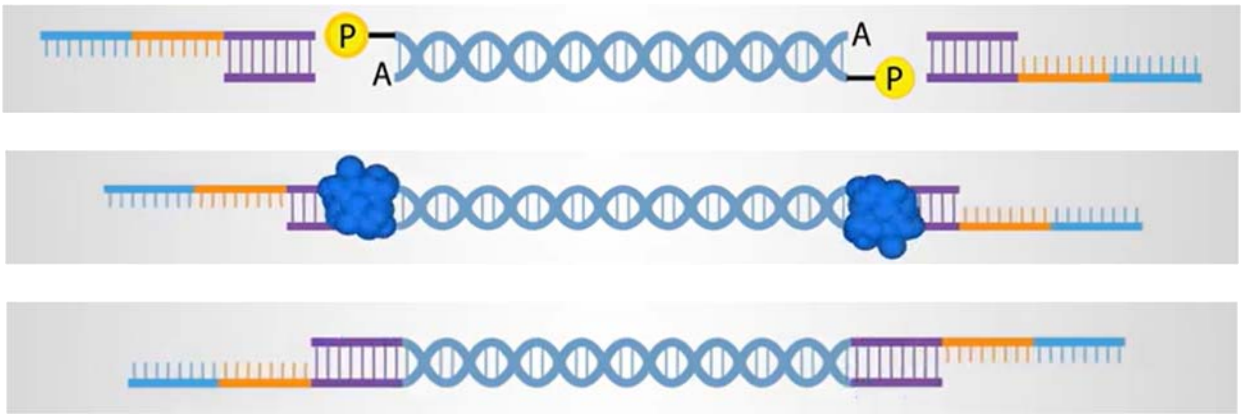
[128] *See* Archer VariantPlex-HS/HGC Protocol for Illumina, page 3 "Overview"; Archer FusionPlex Protocol for Illumina, page 4 "Overview"; Archer LiquidPlex Protocol for Illumina, page 4 "Overview"; Invitae VariantPlex Protocol for Illumina, page 4 "Overview"; Invitae FusionPlex Protocol for Illumina, page 4 "Overview"; Invitae LiquidPlex Protocol for Illumina, page 4 "Overview"; IDT VariantPlex Protocol for Illumina, page 3 "Overview"; IDT FusionPlex Protocol for Illumina, page 3 "Overview"; IDT LiquidPlex Protocol for Illumina, page 3 "Overview."

[129] *See* Archer VariantPlex-HS/HGC Protocol for Illumina, page 3 "Overview"; Archer FusionPlex Protocol for Illumina, page 4 "Overview"; Archer LiquidPlex Protocol for Illumina, page 4 "Overview"; Invitae VariantPlex Protocol for Illumina, page 4 "Overview"; Invitae FusionPlex Protocol for Illumina, page 4 "Overview"; Invitae LiquidPlex Protocol for Illumina, page 4 "Overview"; IDT VariantPlex Protocol for Illumina, page 3 "Overview"; IDT FusionPlex Protocol for Illumina, page 3 "Overview"; IDT LiquidPlex Protocol for Illumina, page 3 "Overview."

[130] *See* Archer VariantPlex-HS/HGC Protocol for Illumina, page 3 "Overview"; Archer FusionPlex Protocol for Illumina, page 4 "Overview"; Archer LiquidPlex Protocol for Illumina, page 4 "Overview"; Invitae VariantPlex Protocol for Illumina, page 4 "Overview"; Invitae FusionPlex Protocol for Illumina, page 4 "Overview"; Invitae LiquidPlex Protocol for Illumina, page 4 "Overview"; IDT VariantPlex Protocol for Illumina, page 3 "Overview"; IDT FusionPlex Protocol for Illumina, page 3 "Overview"; IDT LiquidPlex Protocol for Illumina, page 3 "Overview."

example, the Accused Products require appending, through ligation, an adaptor comprising an identifier site comprising a plurality of nucleotides unique to the amplified fragment.[131]

190. For example, the ligation step conducted in the Accused Products is shown below.[132] A first adaptor (shown in blue, orange, and purple) is ligated to a target nucleic acid fragment (middle blue-grey double strand).



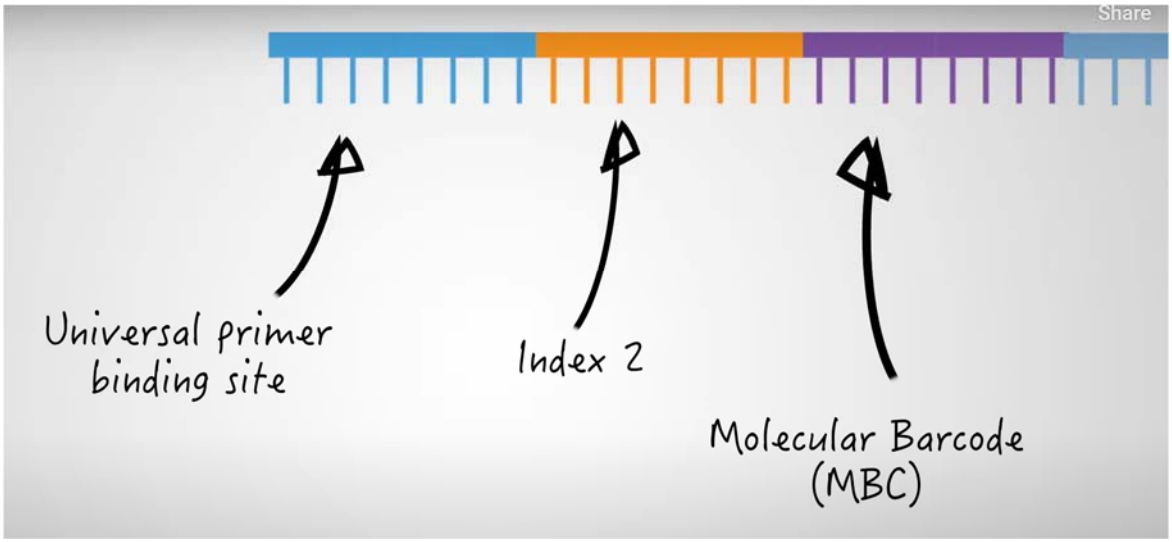
191. As shown above, the adaptor is ligated to a nucleic acid fragment (represented by the yellow phosphate group denoted as "P"). The ligation is used in connection with NGS

[131] *See* Archer VariantPlex-HS/HGC Protocol for Illumina, pages 11-14 "Protocol Step 3-5"; Archer FusionPlex Protocol for Illumina, pages 16-19 "Protocol Step 6-8"; Archer LiquidPlex Protocol for Illumina, pages 13-16 "Protocol Step 2-4"; Invitae VariantPlex Protocol for Illumina, pages 13-17 "Protocol Step 3-5"; Invitae FusionPlex Protocol for Illumina, pages 16-19 "Protocol Step 6-8"; Invitae LiquidPlex Protocol for Illumina, pages 13-16 "Protocol Step 2-4"; IDT VariantPlex Protocol for Illumina, pages 13-14 "Protocol Step 2-3"; IDT FusionPlex Protocol for Illumina, pages 19-23 "Protocol Step 6-8"; IDT LiquidPlex Protocol for Illumina, pages 14-18 "Protocol Step 2-4."

[132] *See* "VariantPlex Anchored Multiplex PCR AMP," DNA Chemistry, https://web.archive.org/web/20200811120340/https://archerdx.com/technology-platform/technology/; ArcherDX, LLC., VariantPlex™ Anchored Multiplex PCR AMP™, YouTube (Aug. 9, 2019), https://www.youtube.com/watch?v=Af2dSH5YMt4&t=4s; Anchored Multiplex PCR AMP," RNA Chemistry, https://web.archive.org/web/20200811120340/https://archerdx.com/technology-platform/technology/; ArcherDX, LLC., FusionPlex™ Anchored Multiplex PCR AMP™, YouTube (Aug. 9, 2019), https://www.youtube.com/watch?v=cHjKsgbmIsY.

sequencing and as such, the target nucleic acid fragment is but one of "a plurality of nucleic acid fragments from one or more samples."[133]

192. As shown in the below diagrams (an expanded version of the adaptor shown above),[134] the adaptor comprising an identifier site (shown in orange) comprising a plurality of nucleotides unique to the amplified fragment (shown only in part in blue grey).



193. The Defendants' Accused Products utilize unique identifier sites present in the adaptors (Molecular Barcodes) to distinguish between fragments. Each adaptor-ligated fragment

[133] *See* Archer VariantPlex-HS/HGC Protocol for Illumina, page 3 "Overview"; Archer FusionPlex Protocol for Illumina, page 4 "Overview"; Archer LiquidPlex Protocol for Illumina, page 4 "Overview"; Illumina | Archer Technical Note: The Use of Molecular Barcodes in Anchored Multiplex PCR, page 1 "Anchored Multiplex PCR (AMP); Invitae VariantPlex Protocol for Illumina, page 4 "Overview"; Invitae FusionPlex Protocol for Illumina, page 4 "Overview"; Invitae LiquidPlex Protocol for Illumina, page 4 "Overview"; IDT VariantPlex Protocol for Illumina, page 3 "Overview"; IDT FusionPlex Protocol for Illumina, page 3 "Overview"; IDT LiquidPlex Protocol for Illumina, page 3 "Overview."

[134] *See* "VariantPlex Anchored Multiplex PCR AMP," DNA Chemistry, https://web.archive.org/web/20200811120340/https://archerdx.com/technology-platform/technology/; ArcherDX, LLC., VariantPlex™ Anchored Multiplex PCR AMP™, YouTube (Aug. 9, 2019), https://www.youtube.com/watch?v=Af2dSH5YMt4&t=4s; Anchored Multiplex PCR AMP," RNA Chemistry, https://web.archive.org/web/20200811120340/https://archerdx.com/technology-platform/technology/; ArcherDX, LLC., FusionPlex™ Anchored Multiplex PCR AMP™, YouTube (Aug. 9, 2019), https://www.youtube.com/watch?v=cHjKsgbmIsY.

has a unique identified site (Molecular Barcode) that comprises a plurality of nucleotides unique to the fragment.[135] Specifically, each identifier site is unique in sequence content with respect to other identifier sites present in the samples.[136]

194. The Defendants' Accused Products amplify the adaptor-ligated fragments by PCR using at least a primer complementary to the primer binding site (representative image of amplification step shown below).[137]

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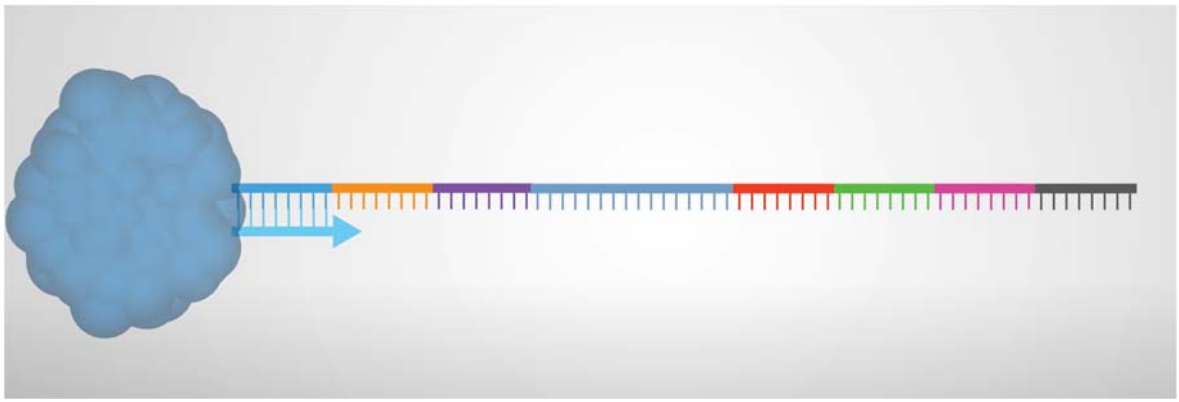
[135] *See* Archer VariantPlex-HS/HGC Protocol for Illumina, page 3 "Archer Library preparation reagents include"; Archer FusionPlex Protocol for Illumina, page 4 "Archer Library preparation reagents include"; Archer LiquidPlex Protocol for Illumina, page 4 "Archer Library preparation reagents include"; Illumina | Archer Technical Note: The Use of Molecular Barcodes in Anchored Multiplex PCR, page 1 "Anchored Multiplex PCR (AMP™)"; Archer VariantPlex-HS/HGC Protocol for Illumina, page 9 "Molecular Barcoding, Sample Indexing & Multiplexed Sequencing"; Archer FusionPlex Protocol for Illumina, page 11 "Molecular Barcoding, Sample Indexing & Multiplexed Sequencing"; Archer LiquidPlex Protocol for Illumina, page 11 "Molecular Barcoding, Sample Indexing & Multiplexed Sequencing"; Invitae VariantPlex Protocol for Illumina; Invitae FusionPlex Protocol for Illumina; Invitae LiquidPlex Protocol for Illumina; IDT VariantPlex Protocol for Illumina; IDT FusionPlex Protocol for Illumina; IDT LiquidPlex Protocol for Illumina.

[136] *See* Archer VariantPlex-HS/HGC Protocol for Illumina, page 3 "Archer Library preparation reagents include"; Archer FusionPlex Protocol for Illumina, page 4 "Archer Library preparation reagents include"; Archer LiquidPlex Protocol for Illumina, page 4 "Archer Library preparation reagents include"; Illumina | Archer Technical Note: The Use of Molecular Barcodes in Anchored Multiplex PCR, page 1 "Anchored Multiplex PCR (AMP™)"; Archer VariantPlex-HS/HGC Protocol for Illumina, page 9 "Molecular Barcoding, Sample Indexing & Multiplexed Sequencing"; Archer FusionPlex Protocol for Illumina, page 11 "Molecular Barcoding, Sample Indexing & Multiplexed Sequencing"; Archer LiquidPlex Protocol for Illumina, page 11 "Molecular Barcoding, Sample Indexing & Multiplexed Sequencing"; Invitae VariantPlex Protocol for Illumina; Invitae FusionPlex Protocol for Illumina; Invitae LiquidPlex Protocol for Illumina; IDT VariantPlex Protocol for Illumina; IDT FusionPlex Protocol for Illumina; IDT LiquidPlex Protocol for Illumina.

[137] *See* "VariantPlex Anchored Multiplex PCR AMP," DNA Chemistry, https://web.archive.org/web/20200811120340/https://archerdx.com/technology-platform/technology/; ArcherDX, LLC., VariantPlex™ Anchored Multiplex PCR AMP™, YouTube (Aug. 9, 2019), https://www.youtube.com/watch?v=Af2dSH5YMt4&t=4s; Anchored Multiplex PCR AMP," RNA Chemistry, https://web.archive.org/web/20200811120340/https://archerdx.com/technology-platform/technology/; ArcherDX, LLC., FusionPlex™ Anchored Multiplex PCR AMP™, YouTube (Aug. 9, 2019), https://www.youtube.com/watch?v=cHjKsgbmIsY; Archer VariantPlex

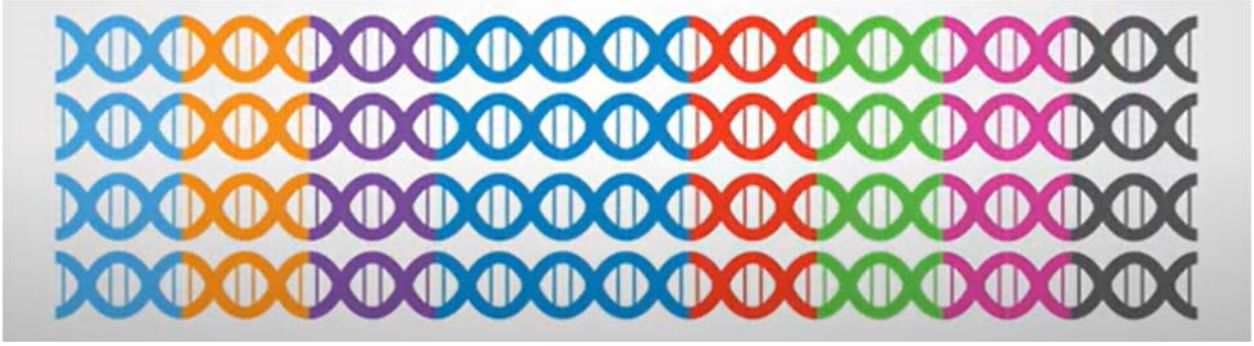


195. The result of PCR amplification is a number of amplified fragments, or amplicons, comprising nucleic acid fragments with appended adaptors containing an identifier site comprising a plurality of nucleotides unique to the amplified fragment (amplicons shown below,[138] with the identifier sites in orange).[139]

HGC v2 Protocol for Illumina, page 15 "Step 7: Second PCR"; Archer FusionPlex Protocol for Illumina, page 21 "Step 10: Second PCR"; Archer LiquidPlex Protocol for Illumina, pages 17-18 "Step 6: Second PCR"; Invitae VariantPlex Protocol for Illumina, pages 18-19 "Step 7: Second PCR"; Invitae FusionPlex Protocol for Illumina, pages 21-23 "Step 10: Second PCR"; Invitae LiquidPlex Protocol for Illumina, pages 17-18 "Step 6: Second PCR"; IDT VariantPlex Protocol for Illumina, pages 16-18 "Step 5: Second PCR"; IDT FusionPlex Protocol for Illumina, pages 25-26 "Step 10: Second PCR"; IDT LiquidPlex Protocol for Illumina, pages 20-22 "Step 6: Second PCR."

[138] *See* "VariantPlex Anchored Multiplex PCR AMP," DNA Chemistry, https://web.archive.org/web/20200811120340/https://archerdx.com/technology-platform/technology/; ArcherDX, LLC., VariantPlex™ Anchored Multiplex PCR AMP™, YouTube (Aug. 9, 2019), https://www.youtube.com/watch?v=Af2dSH5YMt4&t=4s; Anchored Multiplex PCR AMP," RNA Chemistry, https://web.archive.org/web/20200811120340/https://archerdx.com/technology-platform/technology/; ArcherDX, LLC., FusionPlex™ Anchored Multiplex PCR AMP™, YouTube (Aug. 9, 2019), https://www.youtube.com/watch?v=cHjKsgbmIsY.

[139] *See* "VariantPlex Anchored Multiplex PCR AMP," DNA Chemistry, https://web.archive.org/web/20200811120340/https://archerdx.com/technology-platform/technology/; ArcherDX, LLC., VariantPlex™ Anchored Multiplex PCR AMP™, YouTube (Aug. 9, 2019), https://www.youtube.com/watch?v=Af2dSH5YMt4&t=4s; Anchored Multiplex PCR AMP," RNA Chemistry, https://web.archive.org/web/20200811120340/https://archerdx.com/technology-platform/technology/; ArcherDX, LLC., FusionPlex™ Anchored Multiplex PCR AMP™, YouTube (Aug. 9, 2019), https://www.youtube.com/watch?v=cHjKsgbmIsY; Archer VariantPlex HGC v2 Protocol for Illumina, page 15 "Step 7: Second PCR"; Archer FusionPlex Protocol for

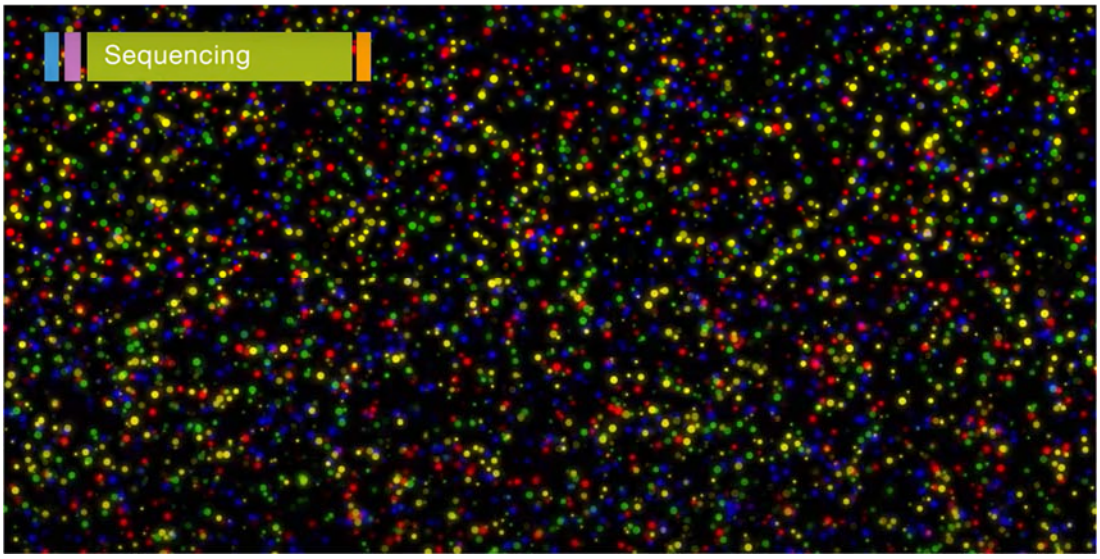


196. The Defendants' Accused Products "sequenc[e] the amplicons to produce sequence reads that include identifier and target sequences." For example, the Accused Products direct the user to sequence samples on a massively parallel sequencing platform.[140] Sequencing on a massively parallel sequencing platform consists of sequencing the adaptor-ligated fragment products, or amplicons, generated in the amplification step. The fragments are attached to the platform and sequenced simultaneously (pictured below,[141] where each colored dot represents a single nucleotide sequencing event).

Illumina, page 21 "Step 10: Second PCR"; Archer LiquidPlex Protocol for Illumina, pages 17-18 "Step 6: Second PCR"; Invitae VariantPlex Protocol for Illumina, pages 18-19 "Step 7: Second PCR"; Invitae FusionPlex Protocol for Illumina, pages 21-23 "Step 10: Second PCR"; Invitae LiquidPlex Protocol for Illumina, pages 17-18 "Step 6: Second PCR"; IDT VariantPlex Protocol for Illumina, pages 16-18 "Step 5: Second PCR"; IDT FusionPlex Protocol for Illumina, pages 25-26 "Step 10: Second PCR"; IDT LiquidPlex Protocol for Illumina, pages 20-22 "Step 6: Second PCR."

[140] *See* Archer VariantPlex-HS/HGC Protocol for Illumina, page 3 "Overview"; Archer FusionPlex Protocol for Illumina, page 4 "Overview"; Archer LiquidPlex Protocol for Illumina, page 4 "Overview"; Invitae VariantPlex Protocol for Illumina, page 4 "Overview"; Invitae FusionPlex Protocol for Illumina, page 4 "Overview"; Invitae LiquidPlex Protocol for Illumina, page 4 "Overview"; IDT VariantPlex Protocol for Illumina, page 3 "Overview"; IDT FusionPlex Protocol for Illumina, page 3 "Overview"; IDT LiquidPlex Protocol for Illumina, page 3 "Overview."

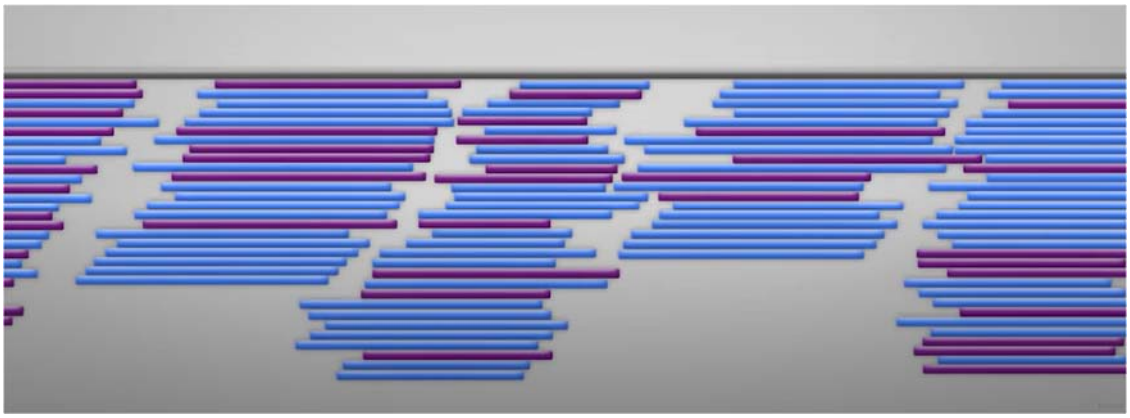
[141] *See* "Sequencing by Synthesis (SBS) Chemistry," https://www.illumina.com/science/technology/next-generation-sequencing/sequencing-technology.html;.



197. The result of sequencing the amplified adaptor-nucleic acid fragment ligated products is a population of sequencing reads generated from the amplified adaptor-nucleic acid fragment ligated products that include the identifier and target sequences (pictured below in blue and purple,[142] aligned to a reference genomic sequence in grey).[143]

[142] *See* "Sequencing by Synthesis (SBS) Chemistry," https://www.illumina.com/science/technology/next-generation-sequencing/sequencing-technology.html;.

[143] *See* "Sequencing by Synthesis (SBS) Chemistry," https://www.illumina.com/science/technology/next-generation-sequencing/sequencing-technology.html; Archer FusionPlex Protocol for Ion Torrent, page 21 "Quantify, Normalize, and Sequence"; Archer VariantPlex-HS/HGC Protocol for Illumina, pages 17-18 "Quantify, Normalize and Sequence"; Archer FusionPlex Protocol for Illumina, pages 23-25 "Quantify, Normalize and Sequence"; Archer LiquidPlex Protocol for Illumina, pages 17-18 "Step 6: Second PCR"; Illumina MiSeq System Guide; MiSeq System Specification Sheet; Invitae VariantPlex Protocol for Illumina, page 19 "Quantify, Normalize and Sequence"; Invitae FusionPlex Protocol for Illumina, page 23 "Quantify, Normalize and Sequence"; Invitae LiquidPlex Protocol for Illumina, page 18 "Quantify, Normalize and Sequence"; IDT VariantPlex Protocol for Illumina, page 19 "Quantify, Normalize and Sequence"; IDT FusionPlex Protocol for Illumina, page 27 "Quantify, Normalize and Sequence"; IDT LiquidPlex Protocol for Illumina, page 23 "Quantify, Normalize and Sequence"; IDT Protocol Quantify, Normalize, and Sequence for Illumina.



198. The Defendants' Accused Products "identify[]sequence reads with identical identifier and target sequences as duplicates." The Accused Products provide for the identification of duplicative sequencing reads.[144] Specifically, the instructions for the Accused Products recite that sequencing data produced by the recited method should be analyzed using dedicated analysis software designed to allow for read deduplication.[145] These duplicative sequence reads consist of the identifier sites (the Molecular Barcodes) and target sequences.[146]

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[144] *See* Archer VariantPlex-HS/HGC Protocol for Illumina, page 3 "Test Principle"; Archer FusionPlex Protocol for Illumina, page 4 "Test Principle"; Archer LiquidPlex Protocol for Illumina, page 4 "Intended Use"; Archer Analysis 4.1 User Manual; Illumina | Archer Technical Note: The Use of Molecular Barcodes in Anchored Multiplex PCR; Invitae VariantPlex Protocol for Illumina; Invitae FusionPlex Protocol for Illumina; Invitae LiquidPlex Protocol for Illumina; IDT VariantPlex Protocol for Illumina; IDT FusionPlex Protocol for Illumina; IDT LiquidPlex Protocol for Illumina.

[145] *See* Archer VariantPlex-HS/HGC Protocol for Illumina, page 3 "Test Principle"; Archer FusionPlex Protocol for Illumina, page 4 "Test Principle"; Archer LiquidPlex Protocol for Illumina, page 4 "Intended Use"; Archer Analysis 4.1 User Manual; Illumina | Archer Technical Note: The Use of Molecular Barcodes in Anchored Multiplex PCR; Invitae VariantPlex Protocol for Illumina; Invitae FusionPlex Protocol for Illumina; Invitae LiquidPlex Protocol for Illumina; IDT VariantPlex Protocol for Illumina; IDT FusionPlex Protocol for Illumina; IDT LiquidPlex Protocol for Illumina.

[146] *See* Archer VariantPlex-HS/HGC Protocol for Illumina, page 3 "Test Principle"; Archer FusionPlex Protocol for Illumina, page 4 "Test Principle"; Archer LiquidPlex Protocol for Illumina, page 4 "Intended Use"; Archer Analysis 4.1 User Manual; Illumina | Archer Technical Note: The Use of Molecular Barcodes in Anchored Multiplex PCR; Invitae VariantPlex Protocol for Illumina; Invitae FusionPlex Protocol for Illumina; Invitae LiquidPlex Protocol for Illumina; IDT VariantPlex Protocol for Illumina; IDT FusionPlex Protocol for Illumina; IDT LiquidPlex Protocol for Illumina.

199. As such, Defendants' Accused Products infringe at least claim 1 of the '241 patent.

200. Defendants further infringe at least claim 1 of the '241 patent when the Accused Products are manufactured, used, or sold and implemented by Defendants' customers and partners. Defendants do so by inducing and contributing to the direct infringement of the '241 patent by Defendants' customers and users. Customers and users of the Accused Products directly infringe the claimed methods of the '241 patent, and at least claim 1, when they use and implement the enrichment methods and kits designed, produced, and marketed by Defendants. As set forth above, the steps of at least claim 1 are met by actions provided for and taken through the Accused Products.

201. Defendants have induced and continue to induce infringement of the '241 patent. Defendants sell the Accused Products with instructions to end-users to perform the steps identified in the above workflows. Furthermore, Defendants distribute instruction materials, product manuals, and technical materials, and disseminate promotional/marketing materials, that describe the workflows and otherwise instruct users to use the Accused Products to infringe at least claim 1 of the '241 patent. Defendants sell and offer for sale the Accused Products with the knowledge and specific intent that their instructions and workflows will cause users to use the kits to infringe at least claim 1 of the '241 patent.

202. Defendants have also contributed to and continue to contribute to the infringement of at least claim 1 of the '241 patent because they offer to sell or sell within the United States or import into the United States the Accused Products for use by users practicing the patented process of the '241 patent. The Accused Products constitute a material part of the invention of the '241 patent, and Defendants know the Accused Products to be especially made or especially adapted

for use in infringing the '241 patent. Furthermore, the Accused Products are not a staple article or commodity of commerce suitable for substantial noninfringing uses.

203. Defendants have committed and continue to commit acts of infringement in the United States and thereafter have sold and continue to sell the Accused Products or cause the Accused Products to be sold within and outside of the United States. Defendants' sales within and outside of the United States have resulted in harm to Tecan Genomics. Tecan Genomics brings this action to be made whole for damages that include both sales within and outside of the United States.

204. As set forth above, Defendants engaged in these activities with full knowledge that other parties' actions were infringing. This conduct makes Defendants liable for inducing and contributing to the infringement of at least claim 1 of the '241 patent.

COUNT I
(Infringement of U.S. Patent 10,036,012 by INVITAE, ARCHER, and IDT)

205. Plaintiff repeats and re-alleges the allegations of paragraphs 1–204 as though fully set forth herein.

206. Plaintiff Tecan Genomics is the owner of all rights in the '012 patent.

207. Defendants have infringed and continue to infringe one or more claims of the '012 patent, including at least claim 1 of the '012 patent, in this District and elsewhere in the United States.

208. Defendants have infringed and continue to infringe one or more claims of the '012 patent, literally and under the doctrine of equivalents, in violation of 35 U.S.C. § 271(a), by making, using, offering to sell, or selling the Accused Products, without authorization from Plaintiff. For example, as alleged above, Defendants' Accused Products and the steps Defendants

or their agents perform in connection with the Accused Products infringe at least claim 1 of the '012 patent.

209. Defendants, by themselves and through their subsidiaries, agents, and business partners, have induced and continue to induce the direct infringement of the '012 patent by at least their distributors, customers, and users of the Accused Products pursuant to 35 U.S.C. § 271(b) in the United States and within this District. For example, as alleged above, Defendants have induced and continue to induce the direct infringement of the '012 patent by their distributors, customers, and users of the Accused Products that solely or jointly make, use, sell, and offer to sell the Accused Products that infringe or enable the infringement of at least claim 1 of the '012 patent, without license or permission from Plaintiff.

210. Defendants induce this infringement by, among other things, making and providing their distributors, customers, and users with the Accused Products, and conducting activities related to the selling, marketing, advertising, promotion, support, and distribution of the Accused Products. For example, as further alleged above, Defendants actively support and encourage the use of the Accused Products by their distributors, customers, and users.[147] Defendants also advertise and tout the benefits of the Accused Products to their distributors, customers, and users.[148]

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[147] *See, e.g.*, *Invitae Personalized Cancer Monitoring™ and MRD*, accessible at https://www.invitae.com/en/providers/test-catalog/personalized-cancer-monitoring?tab=tests; *Archer™ NGS assay innovations as a part of IDT*, accessible at https://www.idtdna.com/pages/landing/archer-now-part-of-idt?promo_name=Archer-Announcement&promo_id=1a1b&promo_creative=Run%20of%20Site%20Alert&promo_position=1&promo_item_name=23_NG_Archer-Landing-Page.

[148] *See, e.g.*, *Invitae Launches Full Access to its Liquid-Based Personalized Cancer Monitoring Platform to Help Detect Disease Earlier*, accessible at https://ir.invitae.com/news-and-events/press-releases/press-release-details/2022/Invitae-Launches-Full-Access-to-its-Liquid-Based-Personalized-Cancer-Monitoring-Platform-to-Help-Detect-Disease-Earlier/default.aspx;

211. As alleged above, Defendants had knowledge of the '012 patent at a date prior to the filing of this Complaint and knew, should have known, or were willfully blind to the fact of Defendants' infringement of the '012 patent at a date prior to the filing of this Complaint. Despite knowing that their actions constitute induced infringement of the '012 patent or that there was a high likelihood that their actions constitute induced infringement of the patent, Defendants nevertheless continue their infringing actions, and continue to make, use, sell, and/or offer for sale the Accused Products.

212. Defendants, by themselves and through their subsidiaries, agents, and business partners, also have contributed to and continue to contribute to the direct infringement of the '012 patent by at least their distributors, customers, and users of the Accused Products pursuant to 35 U.S.C. § 271(c) in the United States and within this District. For example, as alleged above, Defendants have contributed to and continue to contribute to the direct infringement of the '012 patent by their distributors, customers, and users of the Accused Products that solely or jointly make, use, sell, and offer to sell Accused Products that infringe at least claim 1 of the '012 patent, without license or permission from Plaintiff.

213. Defendants contribute to this infringement by, among other things, selling, offering to sell, and importing the Accused Products (or one or more components of the Accused Products) in the United States. Defendants do so with knowledge that the Accused Products and such components (a) constitute a material part of the invention claimed in the '012 patent, (b) have no

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Archer™ NGS assay innovations as a part of IDT, accessible at https://www.idtdna.com/pages/landing/archer-now-part-of-idt?promo_name=Archer-Announcement&promo_id=1a1b&promo_creative=Run%20of%20Site%20Alert&promo_position=1&promo_item_name=23_NG_Archer-Landing-Page.

substantial non-infringing uses, and (c) are especially made or adapted for use in infringing one or more claims of the ’012 patent.

214. As alleged above, Defendants had knowledge of the ’012 patent at a date prior to the filing of this Complaint and knew, should have known, or were willfully blind to the fact of Defendants’ infringement of the ’012 patent at a date prior to the filing of this Complaint. Despite knowing that their actions constitute contributory infringement of the ’012 patent or that there was a high likelihood that their actions constitute contributory infringement of the patent, Defendants nevertheless continue their infringing actions, and continue to make, use, sell, and/or offer for sale the Accused Products.

215. Defendants’ infringement of the ’012 patent has been and continues to be willful.

216. Despite knowing of the ’012 patent and their infringing activities, Defendants have continued their activities, including marketing and selling their infringing products, and they continue to do so to the present day. Since before the filing of this Complaint, Defendants have disregarded an objectively high likelihood that their actions infringe the ’012 patent. Defendants have known of the risk, or this risk is so obvious that Defendants should have known of it.

217. Plaintiff has been damaged by Defendants’ infringement of the ’012 patent and will suffer further substantial and irreparable harm if Defendants are not enjoined from continuing to infringe the ’012 patent. Plaintiff is entitled to recover damages pursuant to 35 U.S.C. § 284.

COUNT II
(Infringement of U.S. Patent 10,876,108 by INVITAE, ARCHER, and IDT)

218. Plaintiff repeats and re-alleges the allegations of paragraphs 1–217 as though fully set forth herein.

219. Plaintiff Tecan Genomics is the owner of all rights in the ’108 patent.

220. Defendants have infringed and continue to infringe one or more claims of the '108 patent, including at least claim 1 of the '108 patent, in this District and elsewhere in the United States.

221. Defendants have infringed and continue to infringe one or more claims of the '108 patent, literally and under the doctrine of equivalents, in violation of 35 U.S.C. § 271(a), by making, using, offering to sell, or selling the Accused Products, without authorization from Plaintiff. For example, as alleged above, Defendants' Accused Products and the steps Defendants or their agents perform in connection with the Accused Products infringe at least claim 1 of the '108 patent.

222. Defendants, by themselves and through their subsidiaries, agents, and business partners, have induced and continue to induce the direct infringement of the '108 patent by at least their distributors, customers, and users of the Accused Products pursuant to 35 U.S.C. § 271(b) in the United States and within this District. For example, as alleged above, Defendants have induced and continue to induce the direct infringement of the '108 patent by their distributors, customers, and users of the Accused Products that solely or jointly make, use, sell, and offer to sell the Accused Products that infringe or enable the infringement of at least claim 1 of the '108 patent, without license or permission from Plaintiff.

223. Defendants induce this infringement by, among other things, making and providing their distributors, customers, and users with the Accused Products, and conducting activities related to the selling, marketing, advertising, promotion, support, and distribution of the Accused Products. For example, as further alleged above, Defendants actively support and encourage the

use of the Accused Products by their distributors, customers, and users.[149] Defendants also advertise and tout the benefits of the Accused Products to their distributors, customers, and users.[150]

224. As alleged above, Defendants had knowledge of the '108 patent at a date prior to the filing of this Complaint and knew, should have known, or were willfully blind to the fact of Defendants' infringement of the '108 patent at a date prior to the filing of this Complaint. Despite knowing that their actions constitute induced infringement of the '108 patent and/or despite knowing that there was a high likelihood that their actions constitute induced infringement of the patent, Defendants nevertheless continue their infringing actions, and continue to make, use, sell, and/or offer for sale the Accused Products.

225. Defendants, by themselves and through their subsidiaries, agents, and business partners, also have contributed to and continue to contribute to the direct infringement of the '108 patent by at least their distributors, customers, and users of the Accused Products pursuant to 35 U.S.C. § 271(c) in the United States and within this District. For example, as alleged above, Defendants have contributed to and continue to contribute to the direct infringement of the '108

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[149] *See, e.g.*, *Invitae Personalized Cancer Monitoring™ and MRD*, accessible at https://www.invitae.com/en/providers/test-catalog/personalized-cancer-monitoring?tab=tests; *Archer™ NGS assay innovations as a part of IDT*, accessible at https://www.idtdna.com/pages/landing/archer-now-part-of-idt?promo_name=Archer-Announcement&promo_id=1a1b&promo_creative=Run%20of%20Site%20Alert&promo_position=1&promo_item_name=23_NG_Archer-Landing-Page.

[150] *See, e.g.*, *Invitae Launches Full Access to its Liquid-Based Personalized Cancer Monitoring Platform to Help Detect Disease Earlier*, accessible at https://ir.invitae.com/news-and-events/press-releases/press-release-details/2022/Invitae-Launches-Full-Access-to-its-Liquid-Based-Personalized-Cancer-Monitoring-Platform-to-Help-Detect-Disease-Earlier/default.aspx; *Archer™ NGS assay innovations as a part of IDT*, accessible at https://www.idtdna.com/pages/landing/archer-now-part-of-idt?promo_name=Archer-Announcement&promo_id=1a1b&promo_creative=Run%20of%20Site%20Alert&promo_position=1&promo_item_name=23_NG_Archer-Landing-Page.

patent by their distributors, customers, and users of the Accused Products that solely or jointly make, use, sell, and offer to sell Accused Products that infringe at least claim 1 of the '108 patent, without license or permission from Plaintiff.

226. Defendants contribute to this infringement by, among other things, selling, offering to sell, and importing the Accused Products (or one or more components of the Accused Products) in the United States. Defendants do so with knowledge that the Accused Products and such components (a) constitute a material part of the invention claimed in the '108 patent, (b) have no substantial non-infringing uses, and (c) are especially made or adapted for use in infringing one or more claims of the '108 patent.

227. As alleged above, Defendants had knowledge of the '108 patent at a date prior to the filing of this Complaint and knew, should have known, or were willfully blind to the fact of Defendants' infringement of the '108 patent at a date prior to the filing of this Complaint. Despite knowing that their actions constitute contributory infringement of the '108 patent or that there was a high likelihood that their actions constitute contributory infringement of the patent, Defendants nevertheless continue their infringing actions, and continue to make, use, sell, and/or offer for sale the Accused Products.

228. Defendants' infringement of the '108 patent has been and continues to be willful.

229. Despite knowing of the '108 patent and their infringing activities, Defendants have continued their activities, including marketing and selling their infringing products, and they continue to do so to the present day. Since before the filing of this Complaint, Defendants have disregarded an objectively high likelihood that their actions infringe the '108 patent. Defendants have known of the risk, or this risk is so obvious that Defendants should have known of it.

230. Plaintiff has been damaged by Defendants' infringement of the '108 patent and will suffer further substantial and irreparable harm if Defendants are not enjoined from continuing to infringe the '108 patent. Plaintiff is entitled to recover damages pursuant to 35 U.S.C. § 284.

COUNT III
(Infringement of U.S. Patent 9,546,399 by INVITAE, ARCHER, and IDT)

231. Plaintiff repeats and re-alleges the allegations of paragraphs 1–230 as though fully set forth herein.

232. Plaintiff Tecan Genomics is the owner of all rights in the '399 patent.

233. Defendants have infringed and continue to infringe one or more claims of the '399 patent, including at least claim 1 of the '399 patent, in this District and elsewhere in the United States.

234. Defendants have infringed and continue to infringe one or more claims of the '399 patent, literally and under the doctrine of equivalents, in violation of 35 U.S.C. § 271(a), by making, using, offering to sell, or selling the Accused Products, without authorization from Plaintiff. For example, as alleged above, Defendants' Accused Products and the steps Defendants or their agents perform in connection with the Accused Products infringe at least claim 1 of the '399 patent.

235. Defendants, by themselves and through their subsidiaries, agents, and business partners, have induced and continue to induce the direct infringement of the '399 patent by at least their distributors, customers, and users of the Accused Products pursuant to 35 U.S.C. § 271(b) in the United States and within this District. For example, as alleged above, Defendants have induced and continue to induce the direct infringement of the '399 patent by their distributors, customers, and users of the Accused Products that solely or jointly make, use, sell, and offer to sell the

Accused Products that infringe or enable the infringement of at least claim 1 of the '399 patent, without license or permission from Plaintiff.

236. Defendants induce this infringement by, among other things, making and providing their distributors, customers, and users with the Accused Products, and conducting activities related to the selling, marketing, advertising, promotion, support, and distribution of the Accused Products. For example, as further alleged above, Defendants actively support and encourage the use of the Accused Products by their distributors, customers, and users.[151] Defendants also advertise and tout the benefits of the Accused Products to their distributors, customers, and users.[152]

237. As alleged above, Defendants had knowledge of the '399 patent at a date prior to the filing of this Complaint and knew, should have known, or were willfully blind to the fact of Defendants' infringement of the '399 patent at a date prior to the filing of this Complaint. Despite knowing that their actions constitute induced infringement of the '399 patent or that there was a high likelihood that their actions constitute induced infringement of the patent, Defendants

[151] *See, e.g.*, *Invitae Personalized Cancer Monitoring™ and MRD*, accessible at https://www.invitae.com/en/providers/test-catalog/personalized-cancer-monitoring?tab=tests; *Archer™ NGS assay innovations as a part of IDT*, accessible at https://www.idtdna.com/pages/landing/archer-now-part-of-idt?promo_name=Archer-Announcement&promo_id=1a1b&promo_creative=Run%20of%20Site%20Alert&promo_position=1&promo_item_name=23_NG_Archer-Landing-Page.

[152] *See, e.g.*, *Invitae Launches Full Access to its Liquid-Based Personalized Cancer Monitoring Platform to Help Detect Disease Earlier*, accessible at https://ir.invitae.com/news-and-events/press-releases/press-release-details/2022/Invitae-Launches-Full-Access-to-its-Liquid-Based-Personalized-Cancer-Monitoring-Platform-to-Help-Detect-Disease-Earlier/default.aspx; *Archer™ NGS assay innovations as a part of IDT*, accessible at https://www.idtdna.com/pages/landing/archer-now-part-of-idt?promo_name=Archer-Announcement&promo_id=1a1b&promo_creative=Run%20of%20Site%20Alert&promo_position=1&promo_item_name=23_NG_Archer-Landing-Page.

nevertheless continue their infringing actions, and continue to make, use, sell, and/or offer for sale the Accused Products.

238. Defendants, by themselves and through their subsidiaries, agents, and business partners, also have contributed to and continue to contribute to the direct infringement of the '399 patent by at least their distributors, customers, and users of the Accused Products pursuant to 35 U.S.C. § 271(c) in the United States and within this District. For example, as alleged above, Defendants have contributed to and continue to contribute to the direct infringement of the '399 patent by their distributors, customers, and users of the Accused Products that solely or jointly make, use, sell, and offer to sell Accused Products that infringe at least claim 1 of the '399 patent, without license or permission from Plaintiff.

239. Defendants contribute to this infringement by, among other things, selling, offering to sell, and importing the Accused Products (or one or more components of the Accused Products) in the United States. Defendants do so with knowledge that the Accused Products and such components (a) constitute a material part of the invention claimed in the '399 patent, (b) have no substantial non-infringing uses, and (c) are especially made or adapted for use in infringing one or more claims of the '399 patent.

240. As alleged above, Defendants had knowledge of the '399 patent at a date prior to the filing of this Complaint and knew, should have known, or were willfully blind to the fact of Defendants' infringement of the '399 patent at a date prior to the filing of this Complaint. Despite knowing that their actions constitute contributory infringement of the '399 patent or that there was a high likelihood that their actions constitute contributory infringement of the patent, Defendants nevertheless continue their infringing actions, and continue to make, use, sell, and/or offer for sale the Accused Products.

241. Defendants' infringement of the '399 patent has been and continues to be willful.

242. Despite knowing of the '399 patent and their infringing activities, Defendants have continued their activities, including marketing and selling their infringing products, and they continue to do so to the present day. Since before the filing of this Complaint, Defendants have disregarded an objectively high likelihood that their actions infringe the '399 patent. Defendants have known of the risk, or this risk is so obvious that Defendants should have known of it.

243. Plaintiff has been damaged by Defendants' infringement of the '399 patent and will suffer further substantial and irreparable harm if Defendants are not enjoined from continuing to infringe the '399 patent. Plaintiff is entitled to recover damages pursuant to 35 U.S.C. § 284.

COUNT IV
(Infringement of U.S. Patent 11,098,357 by INVITAE, ARCHER, and IDT)

244. Plaintiff repeats and re-alleges the allegations of paragraphs 1–243 as though fully set forth herein.

245. Plaintiff Tecan Genomics is the owner of all rights in the '357 patent.

246. Defendants have infringed and continue to infringe one or more claims of the '357 patent, including at least claim 1 of the '357 patent, in this District and elsewhere in the United States.

247. Defendants have infringed and continue to infringe one or more claims of the '357 patent, literally and under the doctrine of equivalents, in violation of 35 U.S.C. § 271(a), by making, using, offering to sell, or selling the Accused Products, without authorization from Plaintiff. For example, as alleged above, Defendants' Accused Products and the steps Defendants or their agents perform in connection with the Accused Products infringe at least claim 1 of the '357 patent.

248. Defendants, by themselves and through their subsidiaries, agents, and business partners, have induced and continue to induce the direct infringement of the '357 patent by at least their distributors, customers, and users of the Accused Products pursuant to 35 U.S.C. § 271(b) in the United States and within this District. For example, as alleged above, Defendants have induced and continue to induce the direct infringement of the '357 patent by their distributors, customers, and users of the Accused Products that solely or jointly make, use, sell, and offer to sell the Accused Products that infringe or enable the infringement of at least claim 1 of the '357 patent, without license or permission from Plaintiff.

249. Defendants induce this infringement by, among other things, making and providing their distributors, customers, and users with the Accused Products, and conducting activities related to the selling, marketing, advertising, promotion, support, and distribution of the Accused Products. For example, as further alleged above, Defendants actively support and encourage the use of the Accused Products by their distributors, customers, and users.[153] Defendants also advertise and tout the benefits of the Accused Products to their distributors, customers, and users.[154]

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[153] *See, e.g.*, *Invitae Personalized Cancer Monitoring™ and MRD*, accessible at https://www.invitae.com/en/providers/test-catalog/personalized-cancer-monitoring?tab=tests; *Archer™ NGS assay innovations as a part of IDT*, accessible at https://www.idtdna.com/pages/landing/archer-now-part-of-idt?promo_name=Archer-Announcement&promo_id=1a1b&promo_creative=Run%20of%20Site%20Alert&promo_position=1&promo_item_name=23_NG_Archer-Landing-Page.

[154] *See, e.g.*, *Invitae Launches Full Access to its Liquid-Based Personalized Cancer Monitoring Platform to Help Detect Disease Earlier*, accessible at https://ir.invitae.com/news-and-events/press-releases/press-release-details/2022/Invitae-Launches-Full-Access-to-its-Liquid-Based-Personalized-Cancer-Monitoring-Platform-to-Help-Detect-Disease-Earlier/default.aspx; *Archer™ NGS assay innovations as a part of IDT*, accessible at https://www.idtdna.com/pages/landing/archer-now-part-of-idt?promo_name=Archer-Announcement&promo_id=1a1b&promo_creative=Run%20of%20Site%20Alert&promo_position=1&promo_item_name=23_NG_Archer-Landing-Page.

250. As alleged above, Defendants had knowledge of the '357 patent at a date prior to the filing of this Complaint and knew, should have known, or were willfully blind to the fact of Defendants' infringement of the '357 patent at a date prior to the filing of this Complaint. Despite knowing that their actions constitute induced infringement of the '357 patent or that there was a high likelihood that their actions constitute induced infringement of the patent, Defendants nevertheless continue their infringing actions, and continue to make, use, sell, and/or offer for sale the Accused Products.

251. Defendants, by themselves and through their subsidiaries, agents, and business partners, also have contributed to and continue to contribute to the direct infringement of the '357 patent by at least their distributors, customers, and users of the Accused Products pursuant to 35 U.S.C. § 271(c) in the United States and within this District. For example, as alleged above, Defendants have contributed to and continue to contribute to the direct infringement of the '357 patent by their distributors, customers, and users of the Accused Products that solely or jointly make, use, sell, and offer to sell Accused Products that infringe at least claim 1 of the '357 patent, without license or permission from Plaintiff.

252. Defendants contribute to this infringement by, among other things, selling, offering to sell, and importing the Accused Products (or one or more components of the Accused Products) in the United States. Defendants do so with knowledge that the Accused Products and such components (a) constitute a material part of the invention claimed in the '357 patent, (b) have no substantial non-infringing uses, and (c) are especially made or adapted for use in infringing one or more claims of the '357 patent.

253. As alleged above, Defendants had knowledge of the '357 patent at a date prior to the filing of this Complaint and knew, should have known, or were willfully blind to the fact of

Defendants' infringement of the '357 patent at a date prior to the filing of this Complaint. Despite knowing that their actions constitute contributory infringement of the '357 patent or that there was a high likelihood that their actions constitute contributory infringement of the patent, Defendants nevertheless continue their infringing actions, and continue to make, use, sell, and/or offer for sale the Accused Products.

254. Defendants' infringement of the '357 patent has been and continues to be willful.

255. Despite knowing of the '357 patent and their infringing activities, Defendants have continued their activities, including marketing and selling their infringing products, and they continue to do so to the present day. Since before the filing of this Complaint, Defendants have disregarded an objectively high likelihood that their actions infringe the '357 patent. Defendants have known of the risk, or this risk is so obvious that Defendants should have known of it.

256. Plaintiff has been damaged by Defendants' infringement of the '357 patent and will suffer further substantial and irreparable harm if Defendants are not enjoined from continuing to infringe the '357 patent. Plaintiff is entitled to recover damages pursuant to 35 U.S.C. § 284.

COUNT V
(Infringement of U.S. Patent 11,725,241 by INVITAE, ARCHER, and IDT)

257. Plaintiff repeats and re-alleges the allegations of paragraphs 1–256 as though fully set forth herein.

258. Plaintiff Tecan Genomics is the owner of all rights in the '241 patent.

259. Defendants have infringed and continue to infringe one or more claims of the '241 patent, including at least claim 1 of the '241 patent, in this District and elsewhere in the United States.

260. Defendants have infringed and continue to infringe one or more claims of the '241 patent, literally and under the doctrine of equivalents, in violation of 35 U.S.C. § 271(a), by

making, using, offering to sell, or selling the Accused Products, without authorization from Plaintiff. For example, as alleged above, Defendants' Accused Products and the steps Defendants or their agents perform in connection with the Accused Products infringe at least claim 1 of the '241 patent.

261. Defendants, by themselves and through their subsidiaries, agents, and business partners, have induced and continue to induce the direct infringement of the '241 patent by at least their distributors, customers, and users of the Accused Products pursuant to 35 U.S.C. § 271(b) in the United States and within this District. For example, as alleged above, Defendants have induced and continue to induce the direct infringement of the '241 patent by their distributors, customers, and users of the Accused Products that solely or jointly make, use, sell, and offer to sell the Accused Products that infringe or enable the infringement of at least claim 1 of the '241 patent, without license or permission from Plaintiff.

262. Defendants induce this infringement by, among other things, making and providing their distributors, customers, and users with the Accused Products, and conducting activities related to the selling, marketing, advertising, promotion, support, and distribution of the Accused Products. For example, as further alleged above, Defendants actively support and encourage the use of the Accused Products by their distributors, customers, and users.[155] Defendants also

[155] *See, e.g.*, *Invitae Personalized Cancer Monitoring™ and MRD*, accessible at https://www.invitae.com/en/providers/test-catalog/personalized-cancer-monitoring?tab=tests; *Archer™ NGS assay innovations as a part of IDT*, accessible at https://www.idtdna.com/pages/landing/archer-now-part-of-idt?promo_name=Archer-Announcement&promo_id=1a1b&promo_creative=Run%20of%20Site%20Alert&promo_position=1&promo_item_name=23_NG_Archer-Landing-Page.

advertise and tout the benefits of the Accused Products to their distributors, customers, and users.[156]

263. As alleged above, Defendants had knowledge of the '241 patent at a date prior to the filing of this Complaint and knew, should have known, or were willfully blind to the fact of Defendants' infringement of the '241 patent at a date prior to the filing of this Complaint. Despite knowing that their actions constitute induced infringement of the '241 patent or that there was a high likelihood that their actions constitute induced infringement of the patent, Defendants nevertheless continue their infringing actions, and continue to make, use, sell, and/or offer for sale the Accused Products.

264. Defendants, by themselves and through their subsidiaries, agents, and business partners, also have contributed to and continue to contribute to the direct infringement of the '241 patent by at least their distributors, customers, and users of the Accused Products pursuant to 35 U.S.C. § 271(c) in the United States and within this District. For example, as alleged above, Defendants have contributed to and continue to contribute to the direct infringement of the '241 patent by their distributors, customers, and users of the Accused Products that solely or jointly make, use, sell, and offer to sell Accused Products that infringe at least claim 1 of the '241 patent, without license or permission from Plaintiff.

[156] *See, e.g.*, *Invitae Launches Full Access to its Liquid-Based Personalized Cancer Monitoring Platform to Help Detect Disease Earlier*, accessible at https://ir.invitae.com/news-and-events/press-releases/press-release-details/2022/Invitae-Launches-Full-Access-to-its-Liquid-Based-Personalized-Cancer-Monitoring-Platform-to-Help-Detect-Disease-Earlier/default.aspx; *Archer™ NGS assay innovations as a part of IDT*, accessible at https://www.idtdna.com/pages/landing/archer-now-part-of-idt?promo_name=Archer-Announcement&promo_id=1a1b&promo_creative=Run%20of%20Site%20Alert&promo_position=1&promo_item_name=23_NG_Archer-Landing-Page.

265. Defendants contribute to this infringement by, among other things, selling, offering to sell, and importing the Accused Products (or one or more components of the Accused Products) in the United States. Defendants do so with knowledge that the Accused Products and such components (a) constitute a material part of the invention claimed in the '241 patent, (b) have no substantial non-infringing uses, and (c) are especially made or adapted for use in infringing one or more claims of the '241 patent.

266. As alleged above, Defendants had knowledge of the '241 patent at a date prior to the filing of this Complaint and knew, should have known, or were willfully blind to the fact of Defendants' infringement of the '241 patent at a date prior to the filing of this Complaint. Despite knowing that their actions constitute contributory infringement of the '241 patent or that there was a high likelihood that their actions constitute contributory infringement of the patent, Defendants nevertheless continue their infringing actions, and continue to make, use, sell, and/or offer for sale the Accused Products.

267. Defendants' infringement of the '241 patent has been and continues to be willful.

268. Despite knowing of the '241 patent and their infringing activities, Defendants have continued their activities, including marketing and selling their infringing products, and they continue to do so to the present day. Since before the filing of this Complaint, Defendants have disregarded an objectively high likelihood that their actions infringe the '241 patent. Defendants have known of the risk, or this risk is so obvious that Defendants should have known of it.

269. Plaintiff has been damaged by Defendants' infringement of the '241 patent and will suffer further substantial and irreparable harm if Defendants are not enjoined from continuing to infringe the '241 patent. Plaintiff is entitled to recover damages pursuant to 35 U.S.C. § 284.

DEMAND FOR JURY TRIAL

Pursuant to Federal Rule of Civil Procedure 38(b), Plaintiff demands a jury trial on all issues so triable.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for a judgment in its favor and against Defendants, as follows:

A. A judgment that Defendants have infringed and continue to infringe U.S. Patent Nos. 10,036,012, 10,876,108, 9,546,399, 11,098,357, and 11,725,241;

B. An award of damages adequate to compensate Plaintiff for Defendants' past, continuing, and any future infringement of the '012, '108, '399, '357, and '241 patents for all infringing products in no event less than a compulsory, ongoing reasonable royalty, in an amount according to proof and accounting for sales;

C. A finding that Defendants are liable for willful infringement and awarding Plaintiff trebled damages under 35 U.S.C. § 284;

D. Pre-judgment and post-judgment interest on Plaintiff's award, in an amount according to proof;

E. An order preliminarily and permanently enjoining Defendants, their officers, directors, agents, servants, affiliates, employees, divisions, branches, subsidiaries, parents, and all others acting in active concert with them, from further infringement of the patents;

F. An order requiring Defendants to pay supplemental damages to Plaintiff, including interest, with an accounting, as needed, of all infringement and damages not presented at trial;

G. A judgment declaring this to be an exceptional case, and an award to Plaintiff for their attorneys' fees, costs, and expenses incurred in this action pursuant to 35 U.S.C. § 285; and

H. Such other and further relief as the Court deems just and equitable.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

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